ANNALS of the ORADEA UNIVERSITY.
Fascicle of Management and Technological Engineering, Volume VII (XVII), 2008

Geometrical design of custom-made femoral stem prostheses

Mihai Ovidiu GHIBA, Lucian RUSU
POLITEHNICA University of Timisoara, Department of Mechanics and Vibration
e-mail: ovidiu@cmpicsu.upt.ro, luck@cmpicsu.upt.ro

Keywords: custom made femoral stem, Mimics, femur 3D modeling, CAD.

Abstract: Alloarthroplasty of the hip joint has been one of the most successful surgical procedures of the last century. Improved implant-bone fit appears to increase the longevity of cementless total joints. In this paper is described the design software that uses 3D bone models generated from X-ray computerized tomography to produce optimal-fit hip stems for individual femurs. The result is an implant designed to optimize load transfer and minimize stem motion within a given bone. This paper presents a general solution to the problem of constructing a surface over a set of points cloud [6] [7] [8].

1. INTRODUCTION

To optimize physiological load transfer and mechanical stability, a close geometric fit between cementless stems and the bone stock is essential [9].

Bone is a living tissue, which continuously rebuilds its structure according to the direction of loads exerted on it. After insertion of a metal prosthesis into the medullary canal, the load equilibrium in the bone is disturbed – the tissue remodels itself and, where there is a lack of stresses due to the stress-shielding activity of the implant, which is stiffer, the bone atrophies. Reduction of stresses in bone with respect to the natural state causes its adaptation to the new conditions manifested by mass changing (external remodeling) or bone density changing (internal remodeling). The latter is especially dangerous because, as already indicated, it can cause aseptic loosening of the implant. Taking the bone internal remodelling phenomenon into account during the process of hip prosthesis design can lead to a reduction in the number of such failures [4].

To solve the problem of a geometric mismatch between the anatomic shape of the femoral canal and conventional stems, and to achieve the best possible fit between vital bone tissue and stem surface, an individual stem was develop, custom-fitted to the patient's anatomy with preoperative computed tomography of the femur. [6] [9].

The main objective was to obtain contact all around the medial and lateral stem in the metaphysis and diaphysis of the femur and thus to allow broad stress distribution and contact surface. This should result in a very high initial stability [6].

In the paper the process of anatomical hip prosthesis design in a particular clinical case is presented. In the design process bone remodeling phenomenon has been taken into consideration. The process consists of three major steps:

1. acquisition of computer tomography (CT) data of the femur;
2. geometrical modelling of the femur and design of prosthesis stem in a computer-aided design (CAD) system;
3. verification of the designed stem prosthesis— stem prosthesis remodeling included.

The CT data acquired were used to model the anatomical shape of the medullary canal which determines the shape of the prosthesis stem. It is essential that the stem fill the medullary canal as completely as possible. Only then is continuous load transfer from the prosthesis to the bone ensured. In the next step the designed prosthesis is verify by studying sections of the implanted femur.

By including the remodeling phenomenon into this verification, the range of bone rejected that the designed prosthesis will cause can be determinate.

If the degree of bone rejected is too high the shape of the prosthesis stem is modified in step 3. The re-designed stem prosthesis is then verified in the same way, and the whole design process ends when the optimal shape of the stem has been found, thus completing the optimization process. It has to be strongly emphasized that during the design process continuous consultations with surgeons are carried out [4].

2. ACQUISITION AND PROCESSING OF CT DATA

CT measurements were performed on a 57 year old male patient who was suffering from a pathological change of the left hip joint. It was used the spiral scan method with a 1.5 mm distance between slices.

The pathological changes were so advanced that a standard prosthesis would not fulfill its role, so custom stem prosthesis was opted for [4].

CT measurements of the diseased hip joint were performed in order to acquire coordinates of the points defining the femur shape. The CT images obtained were then processed to filter the required data and detect the femur shape. The first step in building a medical model is to extract an image file from medical data exchange formats. Mimics is a software suite that performs the segmentation of the anatomy through sophisticated three-dimensional selection and editing tools. [3] The Mimics software is an image-processing package with 3D visualization functions that interfaces with all common scanner formats. Mimics is a general-purpose segmentation program for gray value images. It can process any number of 2D image slices (rectangular images are allowed). The only restriction is the physical memory of your computer [5].The process of shape generation is carried out, with Mimics 10.01 software, as follows:

- selection of the CT images that represent the desired anatomical part of the body (Fig. 1);
- selection of the minim and maxim threshold density of the bone tissue in order to obtain a mask (Fig. 2);
- selection of the parameters for 3D model generate (Fig. 3);
- processing of the 3D model (cutting) in order to obtain the interested part of the femur(Fig. 4);
- remesh the 3D model with Magics software, in order to reduce triangles and to smoothing the model (Fig. 5);
- export the model from Mimics as a points cloud.

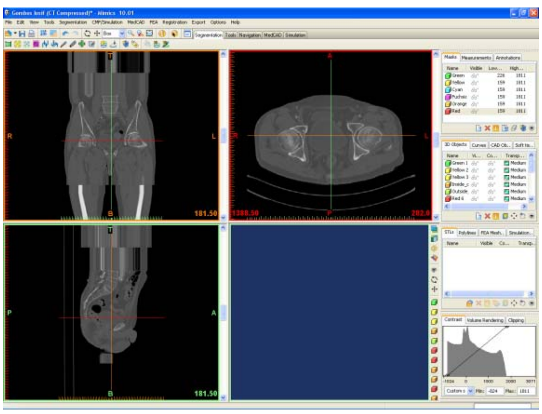

Fig. 1 Selection of the CT images

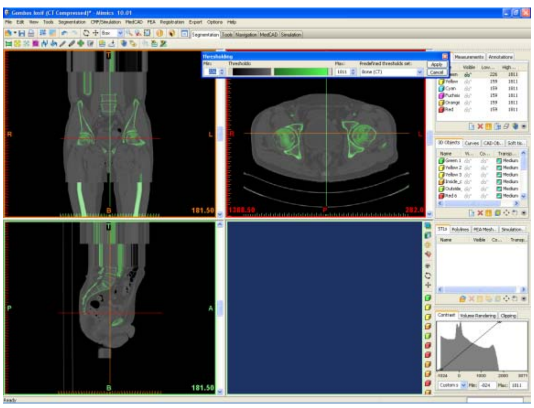

Fig. 2 Applied threshold

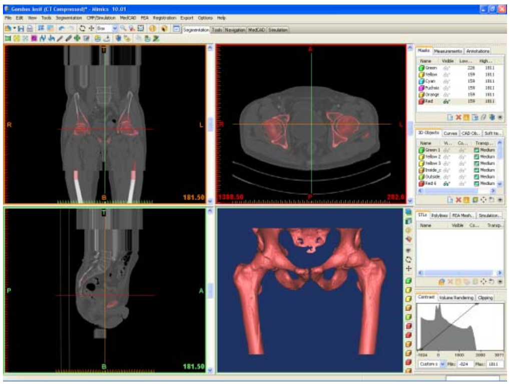

Fig. 3 The 3D generate model

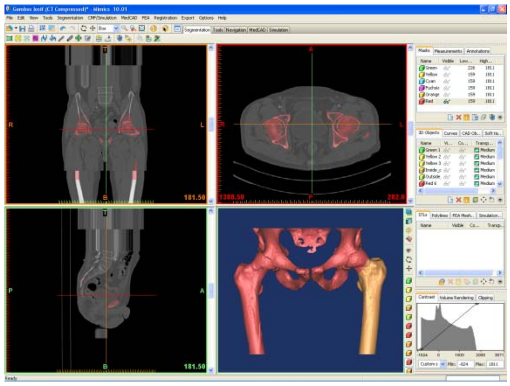

Fig. 4 Processing of the 3D model

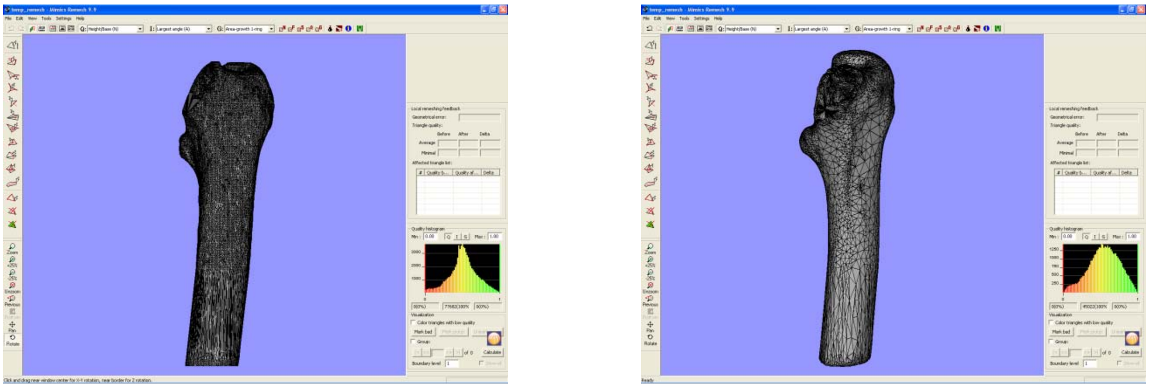

Fig. 5 The 3D model remesh with the Magics software

Using the technique shown above, a good segmentation could be obtained, with a good resolution of the studied structure [3]. After the bone model was established, it has to be translated into a CAD software, to be able to obtain the custom implant.

The data was then transferred into SolidWorks software in order to obtain a CAD model of the femur.

4. GEOMETRICAL MODELLING OF FEMUR AND PROSTHESIS

The opportunity to hold the model in the hand and view it from various angles in a natural fashion offers immediate ease of diagnosis and treatment in medicine [1].

The complex and irregular shape of the femur makes the process of prosthesis design very hard. Computer-aided modeling of the bone structure is related to:

- importation of data saved in txt (Points Cloud) format;
- generation of mesh model of the femur ;
- generation of surface model of the femur.

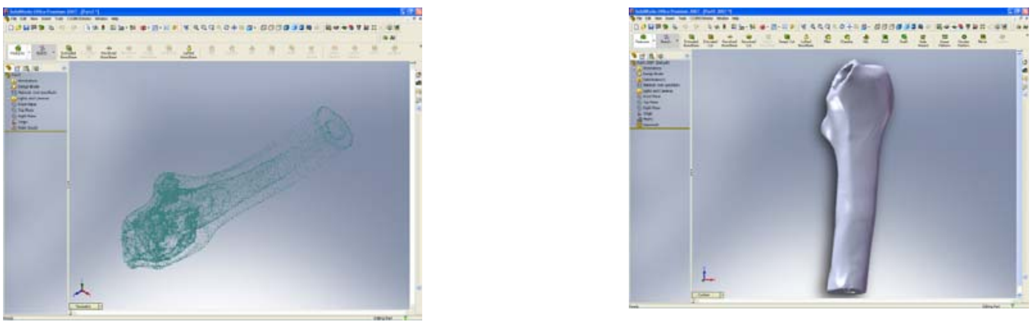

Fig.6. Computer-aided modelling of the bone structure

Using the internal surface of the femur, from surface model (Fig. 6), the stem will be design. The stem shape will follow the medullary canal for a better fixation of the prosthesis.

One of the most important characteristic of custom-made femoral stem prostheses is their degree of filling the medullary canal. That's why the planner must shape the prosthesis stem such that it would fit the medullary canal as much as possible.

Other important characteristic is that the stem must be designed such that insertion of the prosthesis into the femur will be possible after femur head resection.

For this stage of the project some femur measurements were made (Fig 7).

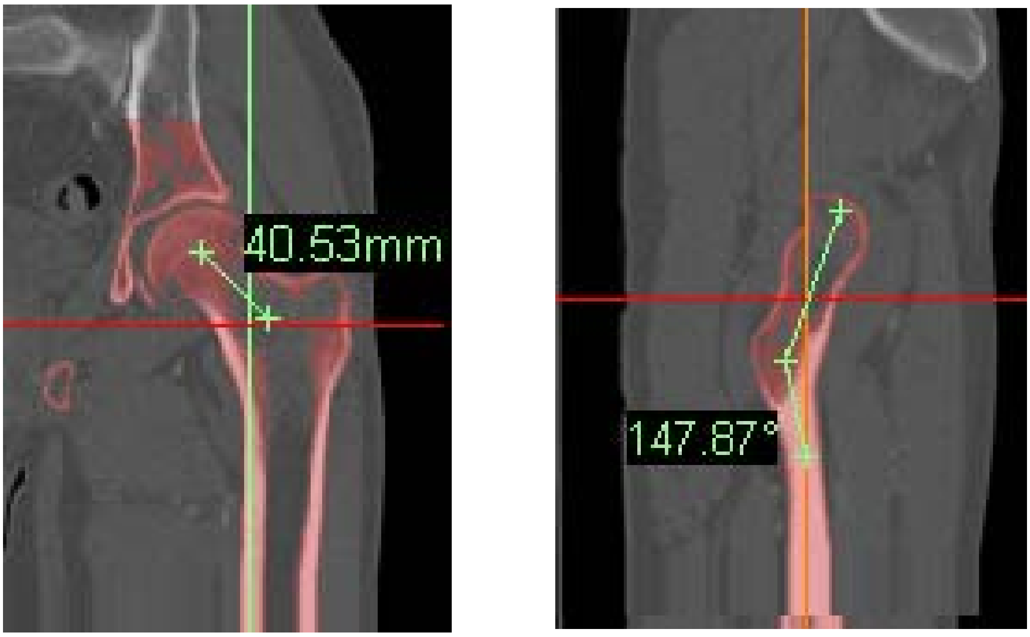

Fig.7. Femur measurements

These measurements were taken into account in the designing process of the prosthesis stem.

The design of the prosthesis stem consists in defining the contour of the, defining the caracteristic angular space orientation of the prosthesis neck follows, and then the final stage, which is that of building a solid model of the whole prosthesis by using the loft function of SolidWorks. The contour was defined on sections planes of the 3D femur.

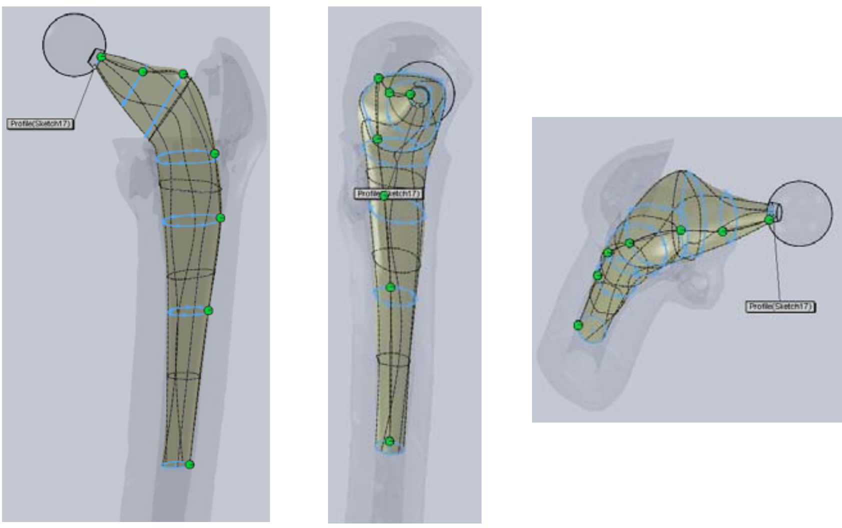

Fig.8. Contour of the stem

After the prosthesis was design a verification of the position of the prosthesis in the femur is needed, using section views like in pictures from fig.8.

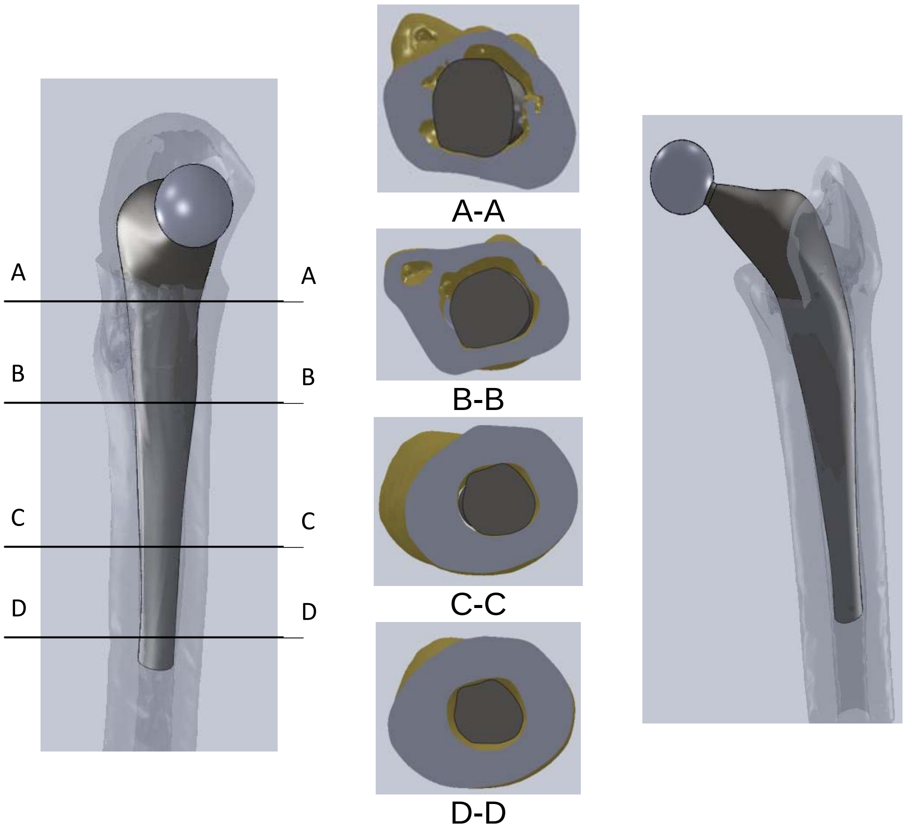

Fig.9. Position of the prosthesis

During the whole process of the prosthesis design in the CAD system consultations with the surgeon who was to perform the alloplasty operation were indispensable. The surgeon's advices and remarks on the shape of the prosthesis stem allowed us to create a good femoral stem.

Moreover, we could also simulate the artlloplasty operation by performing virtual femoral head resection and virtually inserting prosthesis into the bone (Fig.9).

Boundary conditions based on the contact points between the femur and the implant. The bone may be displaced or reshaped by the insertion of the implant, resulting in regions of contact through which stress would be distributed. Parts of the bone may need to be reamed out for the implant to be inserted [2].

6. CONCLUSIONS

In order to design an anatomical prosthesis of extended durability it is essential to conduct the design process of the prosthesis as it was shown in the paper, i.e. to begin with CT data acquisition, then to model the femur and design a custom-made prosthesis in a CAD system and finally to verify the position in the femur of the new-designed prosthesis. The factor of including bone remodelling phenomenon in the process is of significant importance. It is obvious that during the design process consultations with a surgeon must be carried out. Given that the bone-implant interface is customized, about 40% less bone must be removed.

The steps for generating the 3D model of custom made hip implant been established, is now necessary to prove that the custom implant is the suitable solution for total hip replacement. Future plans regarding custom made implant are: to realised a numerical analysis of the bone-implant assembly, to manufacture the implant using rapid prototyping.

The primary disadvantages are the time and cost required for the design and the possible need for a surgical robot to perform the bone resection. Some of these disadvantages may be eliminated by the use of rapid prototyping technologies, especially the use of Electron Beam Melting technology for quick and economical fabrication of custom implant components.

The prosthesis will be manufactured on RP machine, and will be coated with hydroxyapatite in the proximal part of the stem and implanted.

REFERENCES

[1] P. Berce, H. Chezan, N. Balc, *The application of Rapid Prototyping Technologies for manufacturing the custom implants*
[2] Chandrajit L. Bajaj Daniel R. Schikore *Custom Prosthesis Design, Visualization, and Prototyping*
[3] K. L. Chelule, Dr. T. Coole, D.G. Cheshire, *Fabrication of medical models from scan data via rapid prototyping techniques*
[4] M. Pawlikowski, K. Skalski, M. Haraburda *Process of hip joint prosthesis design including bone remodeling phenomenon*
[5] MIMICS 10.0 tutorial
[6] http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2267557.
[7] http://portal.acm.org/citation.cfm?id=22842.22845&coll=guide&dl=#CIT.
[8] http://portal.acm.org/citation.cfm?id=359846&dl=&coll=guide&CFID=64199799&CFTOKEN=65679988.
[9] http://linkinghub.elsevier.com/retrieve/pii/S0268003305001245.