Development of Implants Anatomically Adapted to Patient Specific Anatomy

Stanca COMSA, Adrian PACIOGA, Dan Nastase CIOBOTA
National Institute of Research and Development for Mechatronics and Measurement Technique
stanca_comsa@yahoo.com

***Abstract* — Personalized health care in general and personalized medical products in particular aim to provide the optimal diagnosis and treatment with the use of the right medicine, tools and devices to the right patient at the right time in order to meet well technical and clinical requirements as well as individual characteristics of each patient. This offer the increased effectiveness and better patient safety, and can obtain the best diagnosis and treatment quality. The design and development of personalized medical product is one of the most interesting areas for the last decades, especially from the time when Rapid Prototyping (RP) and Rapid Manufacturing (RM) were successfully applied for development of implants, surgical tools and medical devices for diagnosis and treatment. The main goal is to restore mobility and normal anatomic functionality of the joints affected by congenital and post-traumatic malformations, through the development of personalized implants based on 3D skeletal reconstruction from medical images.**

***Index Terms* — customized implants, medical device, rapid prototyping, skeletal reconstruction.**

I. INTRODUCTION

An important part of orthopedic surgery is the correct interpretation of the patient-specific anatomy. Joint replacement surgery, for instance, requires detailed knowledge and understanding of the morphology of the bone and anatomical and mechanical axes to restore the correct alignment of the joint. In today's clinical routine the choice of the appropriate endoprosthesis (size and design) and the implantation parameters (position and orientation) is largely based on the experience and training of the surgeon.

Automatic segmentation methods for segmentation of musculoskeletal structures of the human anatomy received much attention during the last decades. Especially the bone segmentation from CT data is a well studied topic. The methods for knee segmentation apply statistical shape models for the reconstruction of the knee bones. The semi-automatic segmentation of the pelvis uses a statistical shape model of the pelvic bones which is adapted to the image data in order to perform segmentation.

We try to develop specific customized implant for the orthopedically treatment and for infant medical casuistry with congenital malformations of the skeleton. In essence, bone reconstruction with anatomical-adaptive modeling of customized implants, made a reorientation of medical technology and procedures from general treatment of skeletal malformation to the patient treatment as individual with better results in terms of the degree of postoperative mobility and increasing the lifetime of the implant. In the case of infant malformations the increase of implant lifetime is of great importance because premature wear or failure leads to a revision surgery.

The novelty of the method consists in 3D reconstruction of the malformated areas based on data obtained by medical imaging (CT) in order to design and manufacture the custom implant.

The 3D reconstruction method will use a smaller number of CT images because allows digital interpolation of two consecutive images compensating the resulting errors and reducing the radiation dose absorbed by the patient and also the harmful effect.

Based on digital images, using specialized software [1], [2], [3], three-dimensional model of the area affected by malformation and also of the similar healthy area are obtained, these representing the necessary data for preparing the pre-operative plan and adaptive anatomical implant design.

II. SKELETAL RECONSTRUCTION

For skeletal reconstruction, CT images were imported into commercial software like 3D DOCTOR 2009 [3] and Solid Works and were made image segmentation.

In figure 1 is presented the selection of areas of interest and establishes threshold values for grayscale image segmentation and separation for bone area of interest from the rest of the skeleton and tissues.

Segmentation was done manually using the area of interest, plan to plan, and the corresponding contours obtained were then edited to correct errors.
This correction is necessary grayscale thanks very close, which makes it possible to attach external objects (artifacts) of tissue that is meant to be isolated for reconstruction [4].

The contour correction was used adjacent sections can view the edited and working tools such as moving contour deleting nodes or edges, smooth shape to reduce vertices
Three-dimensional surfaces that can be obtained are shown in Figure 2.

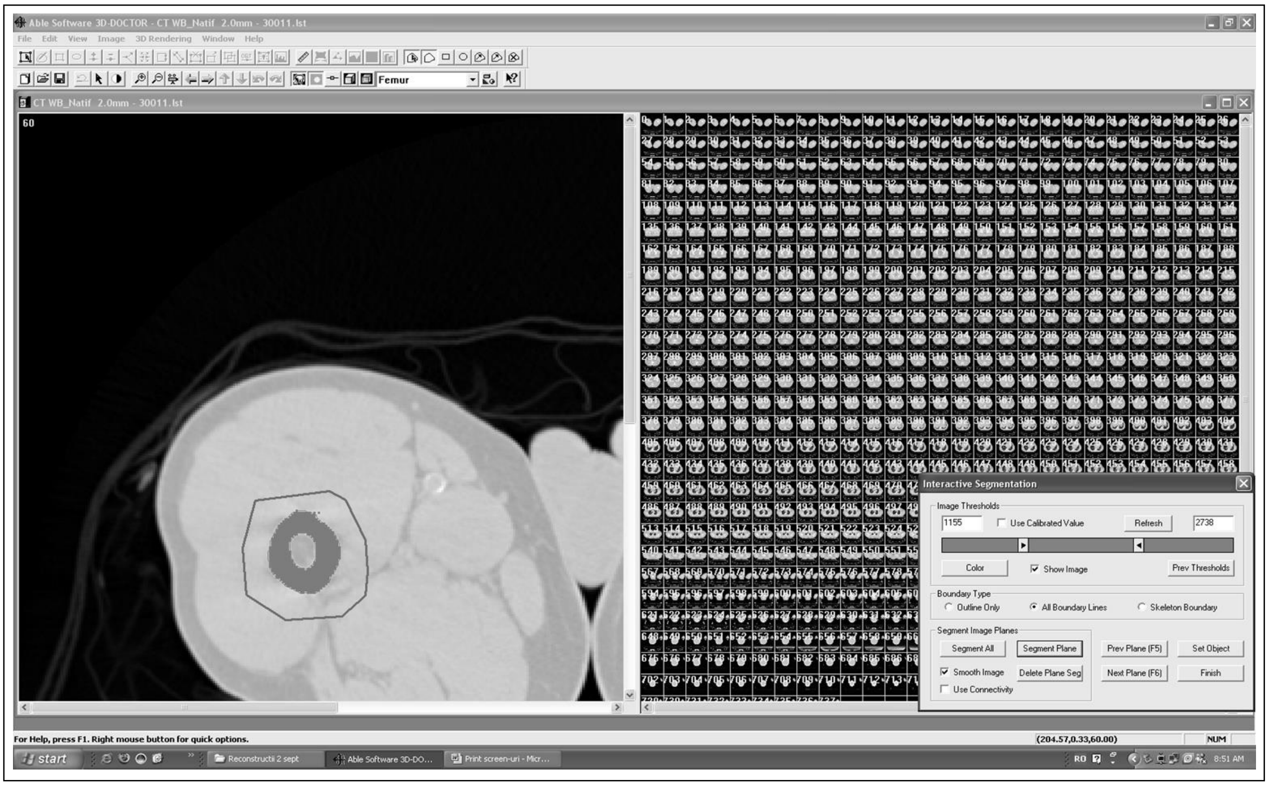
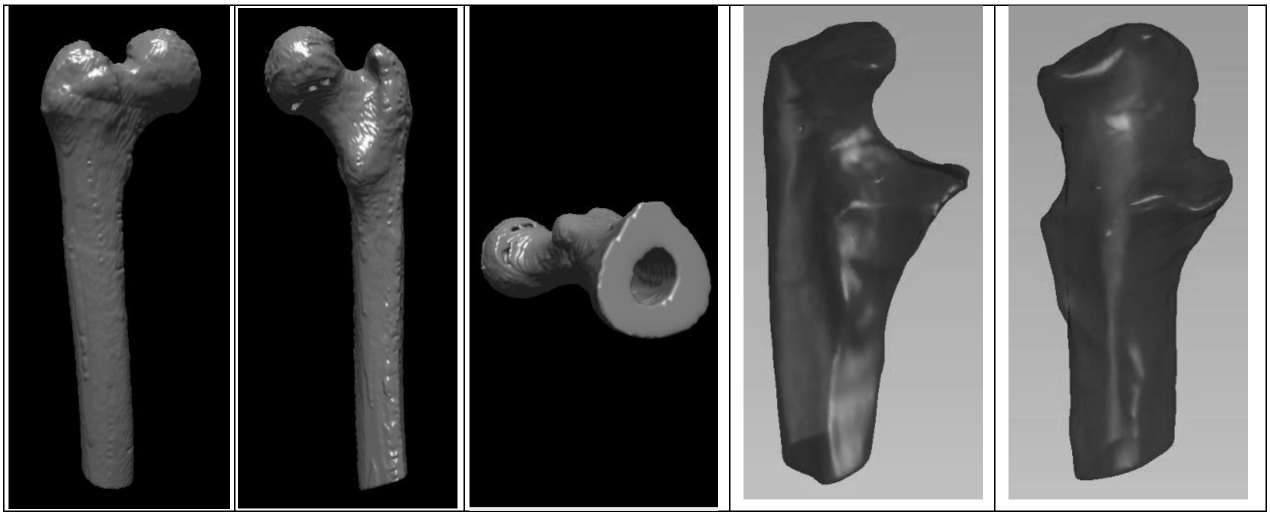


Fig.1: Defining the area of interest and image segmentation



a. Anteroposterior femur view	b. Posteroanterior femur view	c. Condylar direction femur view	d. Anteroposterior radius view	e. Lateral radius view

Fig. 2: Three-dimensional surface reconstruction of bone areas in the case of a femur and a radius.

After obtaining the proper surface contours inside/ outside of the interest bone area, we start to smooth them to eliminate (if possible) the redundant vertices and obtain a surface as close as is possible to the real one.

A three-dimensional model of skeletal area of interest were constructed which is actually the form needed to have the customized implant and not a commercial one, with size suitable to local anatomy.

Following the procedures described above were obtained three-dimensional models consisting of inner and outer surfaces of the bone area of interest, 3D Doctor software allowing their export to many popular file types (in this case STL, DXF, IGS, PLY, WRL, RPT and TRI) which can be imported into other CAD / CAM software known and therefore can be the basis of a process reengineering. The best results were obtained with PLY file type. Import this file type leads to a mesh surface which is processed using the command Mesh Preparation and Surface preparation to obtain solid model of interest bone area and model for customized implant. Solid three-dimensional models of the outer and inside contour of the femur were obtained resulting 3D contour.

The final three-dimensional reconstruction for a hip implant was obtained by using a subtraction operation between the two solid models (inner from outer) using "Insert cavity" because meshing of both surfaces simultaneously, exceeds the possibilities of the Solid Works 2009 software and of used Workstations.

III. CUSTOM IMPLANT DESIGN

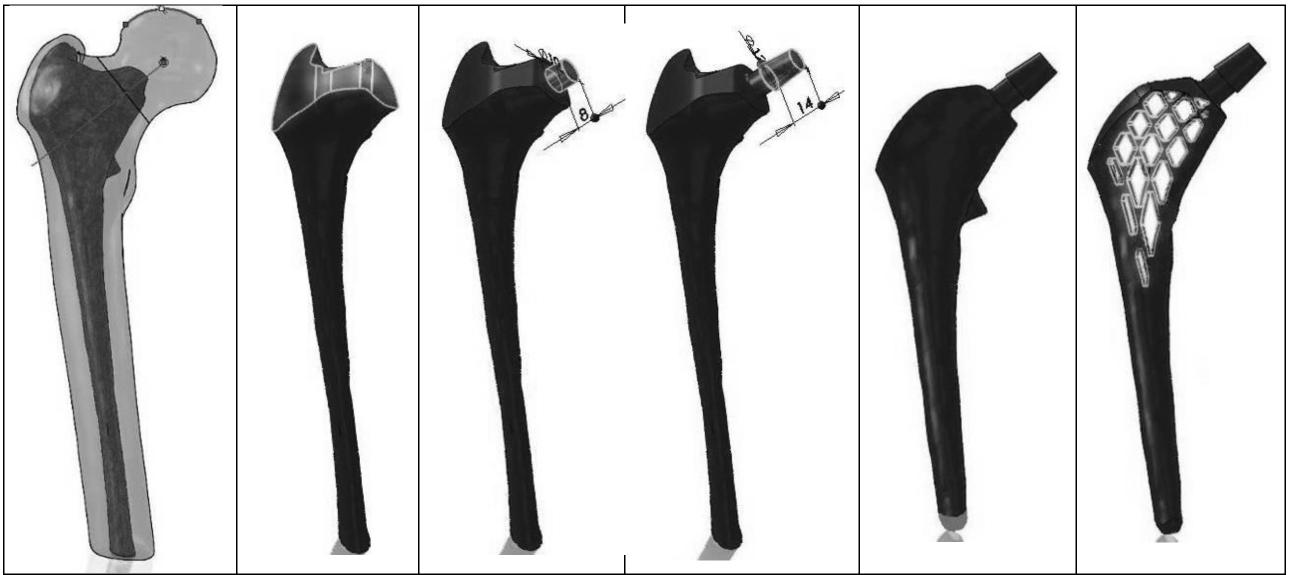
Multiple research and experimental studies have shown that a geometric adaptation of implant shape to the bone is essential to optimize the loading repartition and a better mechanical stability.

Based on the solid bone obtained by three-dimensional reconstruction and visualization software (based on tomographic images), they started to design custom implant. The starting point in hip implant design is, for example, inner contour of the femur, imported into SolidWorks 2009 as a network of points (PLY file) and transformed into 3D solid object. The basic model consists of conical head, cylindrical neck and shaft tail are designed sequentially, using basic functions of the 3D modeling program. The first step was the insertion of the inner contour inside the 3D femur and setting the direction and length needed to have for neck so that the prosthesis joint center to be in the center of the femoral head.

For this purpose the head center was determined by drawing multiple arcs that approximates the outer profile and marking joint center by interpolating drawn arcs centers and building the plane which passing through the axis of the femoral neck and joint center. In this plan was drawn the direction of prosthesis neck axis by uniting the rotation center previously determined with the middle of a segment which connecting the two opposite profiles of the outer contours of the femur (see Figure 3.a).

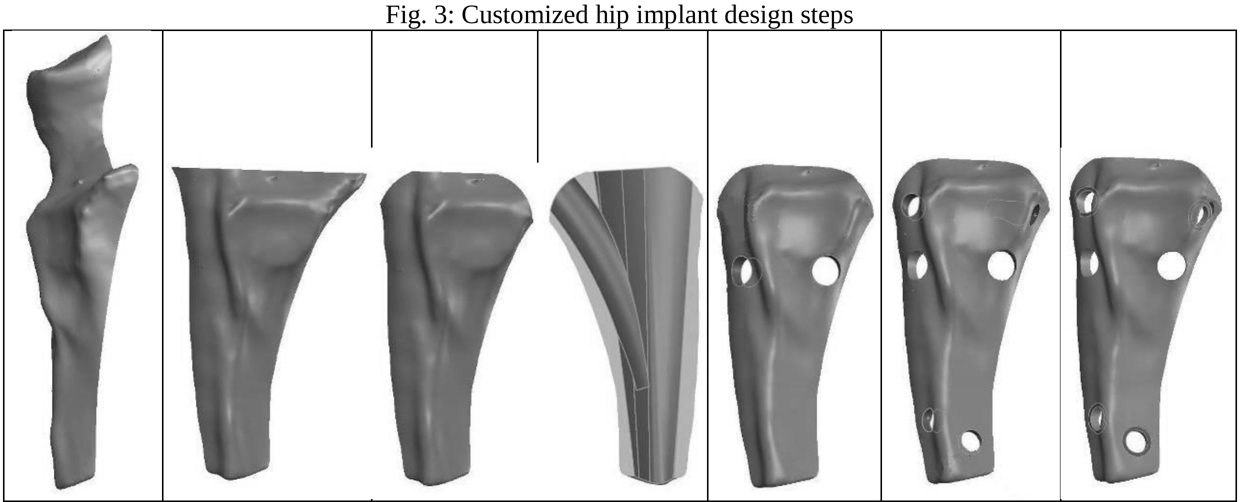
The design process followed with the establishment of femoral stem length that was done by studying the modular prosthesis length from several well-known companies and adoption of a medium length, in condition to not exceeding the femoral isthmus. Femoral isthmus is the narrowest portion of the spinal canal, 8-12cm below the small trochanter (see figure 3.b). The design continues to achieve cylindrical neck (see Figure 3.c), conical head (see Figure 3.d). Final length result by using the command "Revolved Cut", so in addition to the desired size to obtain a rounded tip which promotes the stem in the medullary canal (see Figure 3.e). The design continues with lateral thinning, and honeycomb structure for implant body (see Figure 3.f).

After all the operations described above was obtain the final contour of custom prosthesis dedicated to a specific patient anatomy.



a.	b.	c.	d.	e.	f.

Fig. 3: Customized hip implant design steps



a.	b.	c.	d.	e.	f.	g.

Fig. 4: Customized elbow implant design steps

Once made prosthetic models, it was performed the study of the contact surface size to the implant-bone interface and highlight areas of direct contact. For this analysis was used the command to detect collisions of the ensemble (Interference detection) with the option of recognizing direct contact as interference.

By using customize implant the contact surface growth, which leads to a decrease of micro movements and contact pressure and increase of final stability corresponding to increase lifetime of customized implant.

In figure 4 are presented the design steps for elbow customized implant which was carried out as follows: cut with a plan on fixing area to the bone (Fig. 4.a) and on the proximal side (Fig. 4.b), round the corners (fig. 4.c), achieve notch in the posterior side (Fig. 4.d), drill the holes for bioresorbable screws (fig. 4.e) and holes for implant fixation on ulna (fig. 4.f), execution of holes chamfer for screws head (fig. 4.g).

IV. EXEMPLE OF CUSTOMIZED IMPLANTS

The design implants was built on Laser sintering machine from Ti64 biocompatible metal powder (Figure 5).

Examples with the customized implants are presented in figure 6 and 7.

Fig. 5 Customized elbow implant manufacture

Fig.6. Two models of customized hip implant

Fig.7. Customized elbow implant for a patient with synostosis

The implant from figure 7 was designed for a patient with elbow dysfunction.

V. CONCLUSION

Utilization of CAD - CAM - CAE methods for computer aided design/manufacturing correlated with the use of the latest equipment, computers, advanced software, 3D scanner and laser sintering machine, allows the transition from virtual 3D model to finished parts and facilitates experimental testing in record time.

The development of treatment methods for malformations using customized prosthetic components, mechanically tested from the conception stage, will have a huge economic impact due to reduced medical care expenses for patients with malformations and realization of implants with long life cycle by appreciating the mechanical behavior before the manufacture of the final implant.

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