INNOVATIONS IN MEDICAL IMAGE PROCESSING FOR THE DESIGN OF CUSTOM MEDICAL DEVICES AND IMPLANTS

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ABSTRACT

In this article we will describe the use of 3D medical image information of individual patients as well as selected patient populations, combined with CAE tools and processes, in the rapid product development of custom and standard implantable devices. The combination of medical image information with CAE methods such as CAD, RP, FEA and CFD, allows the engineer to develop implantable devices faster and better, with optimized designs tailored to the anthropometry of the targeted patient (population), using virtual instead of mechanical prototype testing.

Case studies will be demonstrated for a variety of surgical fields such as orthopaedic, cranio-maxillofacial and cardiovascular surgery.

Keywords: CT/MRI, image processing, rapid product development, medical devices, custom design

1. INTRODUCTION

There is a growing trend towards the personalization of medical care, as evidenced by the latest developments in multi-slice CT imaging (Mather, 2005) and ultra-fast MR imaging, personalized treatment planning in a variety of surgical disciplines (Poukens, Haex & Riediger, 2003) and the development of more suitable implantable devices (Harrysson, Hosni & Nayfeh, 2007). To support this trend, the role of the biomedical engineer becomes increasingly important, as the operating theatre becomes more and more a technical environment. Hospitals need multidisciplinary teams for the development of diagnostic tools, implants and tissue engineered materials, computer assisted surgery and rapid product development and virtual process simulations.

In this paper we will describe the use of 3D medical image information of individual patients as well as selected patient populations, combined with computer aided engineering (CAE) tools and processes, in the rapid product development of custom and standard implantable devices.

Since geometrical complexity in anatomical structures is more rule than exception, most medical image processing softwares use the STL file format, initially developed for rapid prototyping (RP) applications, to describe the outer surfaces of anatomical models. The STL format is able to describe any shape and therefore provides much freedom compared to common computer aided design (CAD) formats. In order to use this medical image information as a basis for patient-specific implant or device design, the STL format is usually converted to a CAD format, a process known as 'reverse engineering', to be able to use the design tools available in CAD packages. This process is extremely time-consuming and requires a great degree of simplification of the surface structure, nullifying the attempt to extract accurate anatomical models from medical imaging datasets.

We propose a method of 'digital' CAD for the development process of medical implants or devices. The term 'digital' refers to the method of describing 3D structures with discrete elements (triangles), contrary to the 'analogous' way of describing these structures in traditional CAD packages using continuous surfaces, ruled by mathematical equations (NURBS).

Being able to use design tools directly on STL files eliminates the need for time-consuming reverse engineering and preserves the accurate geometry. This allows for faster and more accurate design of medical implants or devices.

Another rationale for working on STL files is the fact that finite element simulation packages, as the name suggests, also require 3D models described by discrete, or finite, elements. Finite element analysis (FEA) or computational fluid dynamics (CFD) can provide valuable insights in the performance of the design, before even producing (a prototype of) it. The design can be optimized, based on the outcome of the simulations. The combination of medical image information with CAE methods such as digital CAD, RP, FEA and CFD, allows the engineer to develop implantable devices faster and better, with optimized designs tailored to the anthropometry of the targeted patient (population), using virtual instead of mechanical (prototype) testing. Proof of principle for this innovative process is demonstrated by using several examples.

2. METHODS

2.1. Image processing

Medical imaging systems, like CT or MR scanners, typically generate stacks of gray scale images. These images are saved in DICOM format, the standard in medical imaging. To take full advantage of the 3D and density information that is included in these image stacks, Materialise's medical image software Mimics® is used (Materialise NV, Leuven, Belgium). Mimics® is a powerful, yet user friendly, software that generates 3D models of the tissues of interest. It contains intuitive segmentation tools and advanced interpolation algorithms, allowing the user to create accurate 3D models (Gelaude, Vander Sloten, Lauwers, 2008). The 3D models are generated in STL format, but can be converted to other formats, depending on the desired subsequent application.

2.2. Image-based design

For the design of patient-specific devices or implants, 3-matic® is used. 3-matic® is also developed by Materialise (Leuven, Belgium). This software allows the use of CAD-tools directly on STL files, the so-called digital CAD. It is also possible to combine both image-based STL data, with e.g. IGES files coming from typical CAD packages, a strategy adopted to improve the design of generic implants, which are usually designed in traditional CAD formats.

2.3. Finite element analysis preprocessing of image data

For finite element analysis, the surface mesh of the STL in Mimics® is first optimized before it is converted to a volumetric mesh. Common Finite Element packages, like Ansys (Ansys Inc., Canonsburg, PA, USA) or Abaqus (Simulia, Providence, RI, USA), for example, require volumetric meshes of the 3D to be analyzed. The optimization process of the surface mesh includes defeaturing the model, i.e. removing small dents and protrusions, reducing the number of triangles and converting the triangles to an equilateral shape. A volumetric mesh is generated inwards from the surface mesh. For these meshing operations Mimics® temporarily calls the 3-matic® software and uses its engine.

To run a simulation of forces or fluids further requires assigning material properties and boundary conditions. In Mimics® it is possible to assign material properties to the volumetric mesh, based on the gray values from the original image dataset. For easy boundary condition assignment, for example in/outlets for CFD, the ability to save distinct surface areas/zones exists.

3. RESULTS

3.1. Patient data preparation for FEA

Figure 1 shows the workflow to convert image data from a patient's femur to a suitable input file for a FE package. The DICOM data of a patient usually consists of transverse or axial (XY) slices. In Mimics® these data are also used to reconstruct coronal (XZ) and sagittal (YZ) views. Figure 1A shows such a reconstructed coronal view. Using semi-automatic segmentation tools like thresholding and region growing and also some manual editing options, a segmentation seen in Figure 1B is achieved. From the segmentation it is then possible to calculate a 3D model as seen in Figure 1C. This model consists of many small triangles to describe the outer surface as accurately as possible (these triangles are not shown in Figure 1C). However, for eventually running a simulation, it is advisable to reduce the number of triangles, since more triangles will mean longer simulation times. Also, all triangles need to be more or less equilateral. A strategy of defeaturing the model and reducing and optimizing the triangles of the surface mesh, called remeshing, is adopted. A very useful defeaturing tool is the 'wrap' feature, which virtually shrink-wraps the model, closing small holes and smoothing the surface. Then, a volumetric mesh is generated inwards from the surface mesh. This results in a model as shown in Figure 1D. As can be seen in Figure 1A, the images include not only geometrical information, but also information on the local density of the tissues (an inherent property of the Hounsfield scale in CT imaging). This information can be used to perform more realistic simulations; the local density is calculated for every volume element in the model and this density can be related to the Young's modulus of the tissue [Rho, Hobatho Asman, 1995]. In Figure 1E, a section is shown of the femur, revealing the internal volumetric elements with colour-coded densities: the low-density bone marrow inside the femur can be distinguished in blue/green, whereas the dense cortical bone is displayed in red along the outside of the stem.

Figure 1: Sequential steps to produce image-based volumetric meshes for FEA of a human femur; coronal CT slice (A), segmentation of the femur (B), the reconstructed 3D model (C), the optimized surface mesh (D) and a section through the volumetric mesh with colour-coded material properties (E).

3.2. Image-based custom implant design

For designing medical devices or implants, generating a volumetric mesh is not necessary. Using the digital CAD technique allows the user to start working on a model like the one displayed in Figure 1C. A nice example is shown in Figure 2. Here the design of a patient-specific cranioplate is demonstrated, a procedure that has been largely automated in 3-matic®. A CT scan of the patient is segmented from the image dataset using Mimics® (Figure 2A) and the 3D model is transferred to 3-matic®. Then an attached freeform curve is drawn to indicate the outline of the cranial defect (Figure 2B). The software will use this curve in the automated design process for a tangential connection to the skull. It is also possible to sketch one or more guiding curves (Figure 2B) that 'guide' the outline of the cranioplate, thus enabling the user to add concavity or convexity to the design. The next step is to assign a certain thickness to the designed cranioplate, a thickness that is dependent on the envisioned material and method of production. Using a certain clearance, a small distance between implant and skull, assures the easy fit of the cranioplate. The design of the custom implant is then nearly complete (Figure 1C). The user might still want to imprint a label and add fixtures to his design. Morphing tools are available for a final touch. To verify the accuracy of the design, it can be loaded into Mimics® in the original patient dataset and the contours can be visualized on all the views (axial, coronal and sagittal).

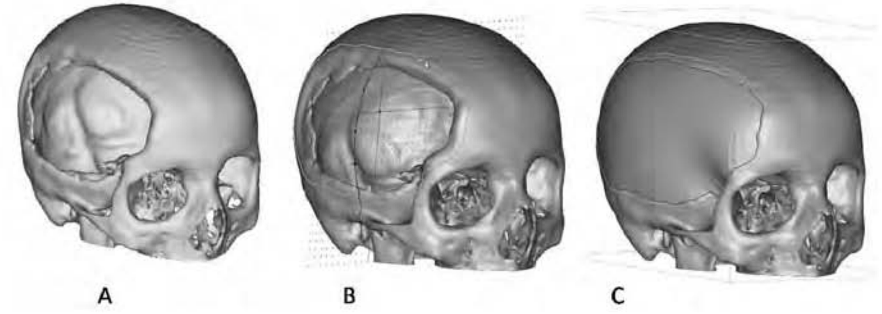

Figure 2: Steps to design a custom cranioplate, starting from an image-based model (A), drawing the outer contour of the defect and a guiding curve (B) to the final cranioplate design (C).

More complex reconstruction cases are not simply automated and might require the use of mirrored parts of the body, or even the use of medical data from third persons. To ensure a perfect fit of the implant on the patient in these cases, it is necessary to interpolate from the mirrored part or xenograft to the patient geometry.

3.3. Pre-operative diagnosis and device evaluation using CAE methods

CAE methods like FEA or CFD can be adapted to assist the surgeon and medical engineer in patient diagnosis and the pre-operative assessment of implants. In the case of an aneurysm (a localized dilation of a blood vessel caused by a weakening of the vessel wall), for instance, the decision for surgery depends on the diameter of the aneurysm, although it could better be based on wall stress analysis (Fillinger, 2007). Using patient image data as a basis for a CFD analysis allows for virtual, preoperative evaluation of, for example, stent placement. Placing a stent virtually and analyzing its effect on the blood flow, compared to the non-stented situation, assists the surgeon in choosing the best intervention, to the benefit of the patient. Figure 3 shows the results of a pre-operative CFD simulation on image-based patient data of an aneurysm without and with stent; the purpose of the stent is to prevent blood from entering the aneurysm, a goal that will be achieved according to the simulation outcome.

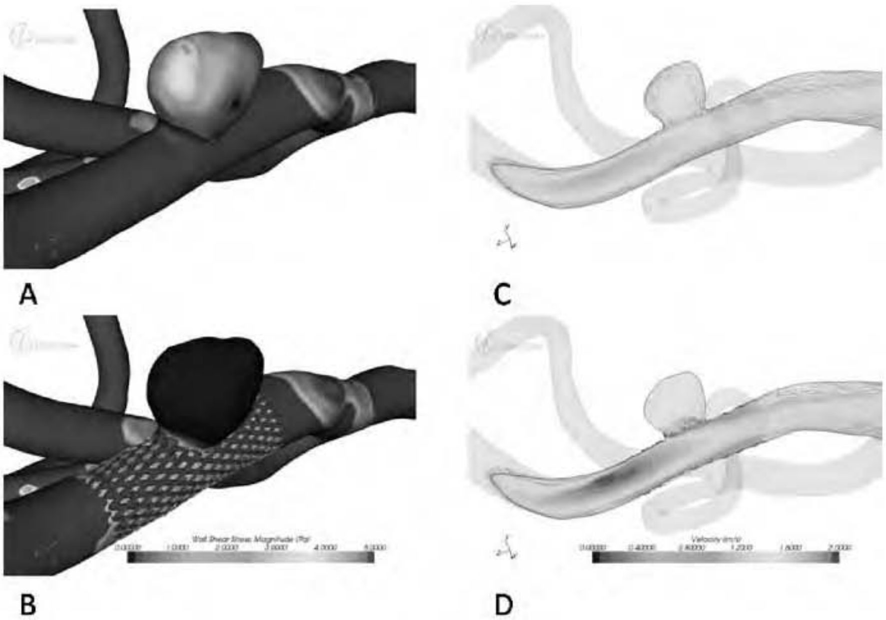

Figure 3: Results on wall shear stress (A and B) and flow velocity (C and D) from a CFD analysis on the blood flow for a patient with an aneurysm; high wall shear stress can be seen in the aneurysm (A), which is reduced when the stent is placed (B). Turbulent blood flow can be seen to enter the aneurysm (C), whereas the stent guides the main blood flow through the artery (D).

4. DISCUSSION AND CONCLUDING REMARKS

The approach to implant and device design, based on 3D medical image data proposed in this paper is different from the current design processes in the medical industry, which rely completely on traditional CAD methods. The digital CAD concept might not be commercially interesting for mass production of generic implants, but is undoubtedly beneficial when designing custom implants. Custom implants lead to more patient satisfaction, but come at a higher cost. However, since we have noticed an increase in the personalization of medical care over the last years, custom implants and custom devices might one day become the standard in medical care.

The most (commercially) valuable aspect in the proposed digital CAD method is the elimination of reverse engineering. This process is very time-consuming and for the moment there is no 'golden' solution to translate STL data to the common CAD format quickly and accurately. As indicated in this paper, there is no need for such a translation, since it is possible to design directly on STL data; it will only require a different mindset of the design engineers, who are trained to use 'analogous' CAD.

Virtual simulation techniques like FEA and CFD are not yet widely accepted in the medical field, in sharp contrast to the automotive industry, mainly because at the moment the complexity of human tissues (and our limited understanding thereof) prevents us from choosing the appropriate boundary conditions. This leads to many assumptions and in turn affects the accuracy of the simulation and its translation to reality. Still, the benefit of CAE simulations is that they have the potential to reduce the amount of in vitro tests with prototypes, animal tests, cadaveric tests, and perhaps even clinical trials. Here again, we noticed an increased interest over recent years on the part of both simulation software manufacturers and medical doctors in the application of finite element simulations in medicine. It will be the job of the biomedical engineer to unite these parties and accelerate the penetration of CAE technology in the medical field.

5. ACKNOWLEDGEMENT

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