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KNOWLEDGE-BASED ENGINEERING IN CRANIOPLASTY IMPLANT DESIGN

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ABSTRACT

The study is aimed at the development of a Knowledge Industry Technology (KIT) based tool that is easy to use for medical experts in cranioplasty. It should also allow for the intelligent design of cranial customized implants in an automated way. These implants will be created from medical images, with the intention of achieving both cost and time reductions during design and production stages.
The process begins with a cranial reconstruction, generating a 3D model with images from a Computed Tomography (CT) source. The program is capable of exploring the defect and finding its limits. In this way, it establishes the bases of the implant's design from which, through a defined system of rules and restrictions, the optimal design both the implant and its fixation system can be defined. The capturing and modelling of the necessary knowledge to carry out these functions is developed through Methodology and tools Oriented to Knowledge-based engineering Applications (MOKA). In order to make sure that the implant is capable of supporting stresses and tensile strengths from the environment, a Finite Element Method (FEM) module included in the CATIA software is used, thus assuring integration in the Knowledge-Based Engineering (KBE) system. The software tool yields a computer file in SLS format, which can be directly exported to a Rapid Prototyping (RP) machine, thus optimizing manufacturing times and raw material costs.
Therefore, the use of KBE provides an improvement in the surgical field with respect to healthcare, life quality and expenses.

Keywords: Knowledge Base Engineering, KBE, cranioplasty, implant, MOKA, finite element, PEEK, tissue engineering, Rapid Prototyping, CAD/CAM/CNC.

1 INTRODUCTION

The 2010 paradigm of medical industry will be surgical operations in which implants are fully adapted to the particular requirements of each patient. This vision will be fulfilled when new biomaterials are developed and new technologies for design and rapid manufacturing of such implants are implemented.
One of these new technologies is KBE, which has been successfully applied to many branches of medicine, thus originating all sorts of expert systems that nowadays work stealthily in many fields of the health industry [1, 2].
Initially, our research has been applied to the design and manufacturing of craniofacial implants. Traumatisms, diseases (such as cancer) and congenital malformations can lead to defects or large holes in the cranium, making these unprotected areas likely to be harmed by impacts. Whereas small defects often heal naturally, larger defects can only be treated with reconstructive surgery.
Cranium and brain defects require repairs that meet a number of particular reconstruction requisites. Dominant requisites include:

- Geometry: similarity to cranium thickness (3 to 5 millimetres) to avoid defects.
- Mechanical properties: implants must support normal compression and impact forces. A Young's modulus of 10-20 GPa and a resistance to compression stresses of 50-200 MPa are required.

The main target of our research consist in obtaining a KIT tool that is easy to use for medical experts in cranioplasty which allows for the intelligent design of cranial implants, taking into account the

anatomy and the properties of bone material, dimension and properties of implant material, interaction conditions in the implant-bone interface and the model's load conditions. This design will be obtained from a 3D model of the area where the implant is needed, that has been previously reconstructed from a 2D image from a tomography or a magnetic resonance.

Implant designs must fulfil the following specific requirements in cranial applications: low inner and outer profile, limited volume, minimal osseous destruction during its implant process, mechanical and elastic performance similar to the adjacent bone, fit into the different superficial profiles and the possibility of multiple removal and replacement. Implant design and manufacture must guarantee structural, functional and biological compatibility with the patient simultaneously optimizing the manufacturing process (reduction of manufacturing costs and times).

Design of the KIT tool will imply a significant advance in implant design and manufacturing. Although there are references to the use of CT, CAD/CAM and RP technologies in the literature [3-7], the fact is that nowadays these tools are not used extensively in the field of cranioplasty.

Two major benefits arise from our research, which are related to the medical-surgical supply chains: minimization of implant design/manufacturing lead times and use of knowledge generated by previous design/manufacturing experiences that is being disregarded nowadays.

The creation process of customized implants is based upon four different stages, which are detailed in the following sections (Figure 1):

- Reconstruction of the implant zone from medical images.
- Intelligent design of implants.
    - Knowledge capture and modelling (MOKA Methodology).
    - Optimal design of the implant and its fixation system.
- Implant simulation (FEM).
- Implant manufacturing.

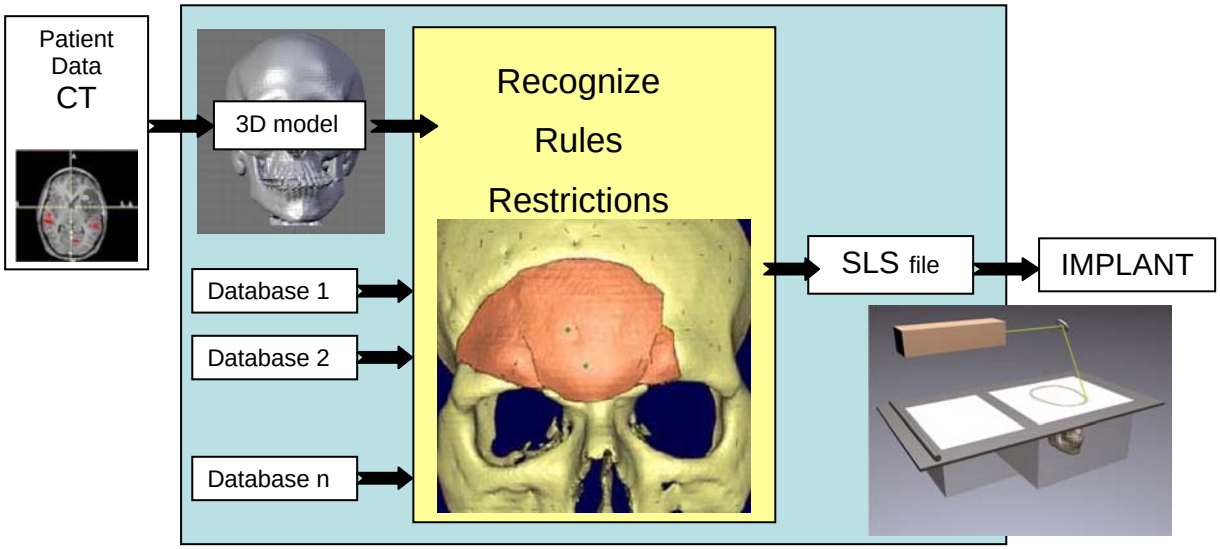

Figure 1. KIT tool for customized design of craniofacial implants

2 RECONSTRUCTION OF THE IMPLANT ZONE FROM MEDICAL IMAGES

The first stage is data acquisition. The two most frequently used systems for detailed anatomical data acquisition are CT and Magnetic Resonance Imaging (MRI). The most prominent feature of these technologies is their ability to provide detailed information about anatomical structure and abnormalities. CT and MRI allow for the finest resolution of all diagnosis systems. During the exploration process, data is generated for shear planes separated by 2 to 3 mm.

A standalone medical image has no meaning by itself. Thus, different images from the same patient must be related and also enclose a set of patient's data. Existing image formats (TIFF, JPEG, GIF) are not adequate for this purpose. For that reason, in 1983 a standard called Digital Imaging and Communications in Medicine (DICOM) was developed jointly by the American College of Radiology (ACR) and the National Electrical Manufacturers Association (NEMA).

One single DICOM file contains a header that stores the information about the patient's name, kind of exploration, kind of image, dimensions, etc., just as all image data that could contain the information in three dimensions. The generic format of the DICOM files is composed of two parts: Header, followed immediately by a DICOM Data Set. DICOM Data Set contains the image or images specified. The Header contains syntax of UID (Unique Identifier) transference that specifies the codification and compression of the Data Set.
Medical images must be reconstructed to be visualized in 3D and subsequently be converted to CAD format.
In order to reconstruct the 3D image, medical images must be treated. There are two main steps:

- Preprocessing: Attempts to improve the image as much as possible. The images from CT and MRI have a considerable quantity of "noise". Previous studies describe different algorithms to clean this noise [8].
- Segmentation: Transversal cuts (also named slices) are frequently performed in all organs and tissues within the exploration range [9]. A previous process is needed to select the objects of the organ or tissue considered whose transformation to 3D is desired. Tissues can usually be differentiated by the grey scale represented into the medical image.

Once the area to be treated is selected, the 3D model is built. Each transversal slice image is composed by a bidimensional matrix of pixels [10], each one having a (x, y) position. If individual images are overlaid, the pixels in every image for a given (x, y) coordinates will be aligned. Thus, pixels can be labelled with three dimensional coordinates. They maintain their original (x, y) coordinates and take a new z coordinate. Z coordinate is simply the slice number to which pixels are associated.
Visualization of 3D medical images was made possible with the application of the open source library Visualization Toolkit (VTK) [11]. This graphic library is most open-source medical image applications like 3D Slicer, MITK and OsiriX.
Treatment of DICOM images through VTK-based application generates geometries in VTK format (as for example with 3D Slicer). Subsequently, the VTK file is converted into a Standard Template Library (STL) file recognizable by all CAD programs.
The TKinter library for Python has been used for the development of the conversion interface from VTK files to STL files. This is an in open-source library for the development of user interfaces. Inside Two graphic windows for visualizing the VTK format and the triangulated STL format (Figure 2) are integrated into the interface. Transformation is basically done in two steps: first, triangulation the model surfaces and in the next step generation and saving of the STL file. This last file can be recovered with any CAD software.

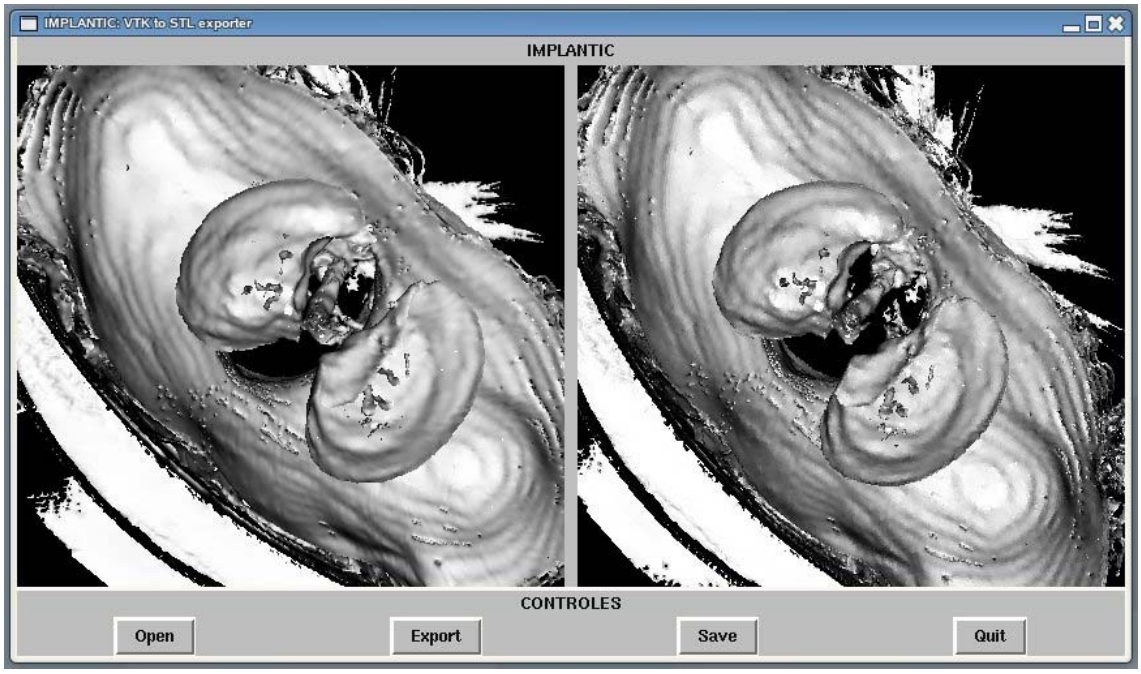

Figure 2. IMPLANTIC interface for VTK to STL file conversion

3 IMPLANT INTELLIGENT DESIGN

KBE is used to accomplish intelligent design of the implant. Knowledge is captured through the MOKA methodology, using the CAD and KBE modulus of CATIA software.

Development and maintenance of knowledge-intensive software applications is a complex and expensive activity. By employing a systematic approach, long-term risk can be reduced. The tool used to that avail is the MOKA methodology, which is intended to obtain reductions in development costs and KBE application times, as well as to have a consistent base available for the development and maintenance the aforementioned application [12].

Doctors and surgeons have worked together with engineers in the design process of the application in order to transfer their knowledge to the latter in order to transfer it by means of MOKA. This transcription is carried out in a first step in an informal model, using ICARE templates.

Knowledge is described in the informal model through the representation of five “concepts”:

- Entities. They are objects that describe the product.
- Illustrations. They are used to include historical cases and anecdotal knowledge.
- Physical restrictions, geometrical restrictions, etc. These are applicable to objects or their attributes.
- Activities. They refer to elements of the design process.
- Rules, knowledge which guides the decision making in activities.

A CATIA application has been developed directly from the informal model, leaving the formal model aside. To that avail, CATIA has a module assigned to knowledge management. This module allows us to link the knowledge with the design, in order to make the KBE application adopt the necessary decisions to automate the process.

In addition to knowledge captured and stored using the MOKA methodology and subsequently incorporated into the KBE application, the following inputs are required for the design of the customized implant:

- Patient Data. Includes anatomical dimensions and physical data of the patient. Anatomical dimensions come from the 3D model generated from the images taken of the patient, while patient physical data correspond to distinctive features such as weight, height, age, ethnic group, activity level, sex, build, osteoporosis, etc.
- Skull data base. The data base contains different skull models and skull parts dimensions and properties.
- Material data base. It contains physical and mechanical material properties, which will be used in the manufacturing of the final implant.
- Implant (microplates, plates, wire mesh) and fixation system data bases (clips, screws, clamps).

3D image in STL format is the starting point in KBE application. This image allows for location and calculation of the area where an implant is required. With this geometrical information, an implant is automatically generated through modelled knowledge. The implant design includes geometric shape, thickness, and number and layout of fixation points. If there is any doubt about resistance in the implant design, it can be simulated through FEM in an iterative process of design-simulation in order to get an optimal design. Figure 3 shows the automatized design process as viewed in CATIA interface.

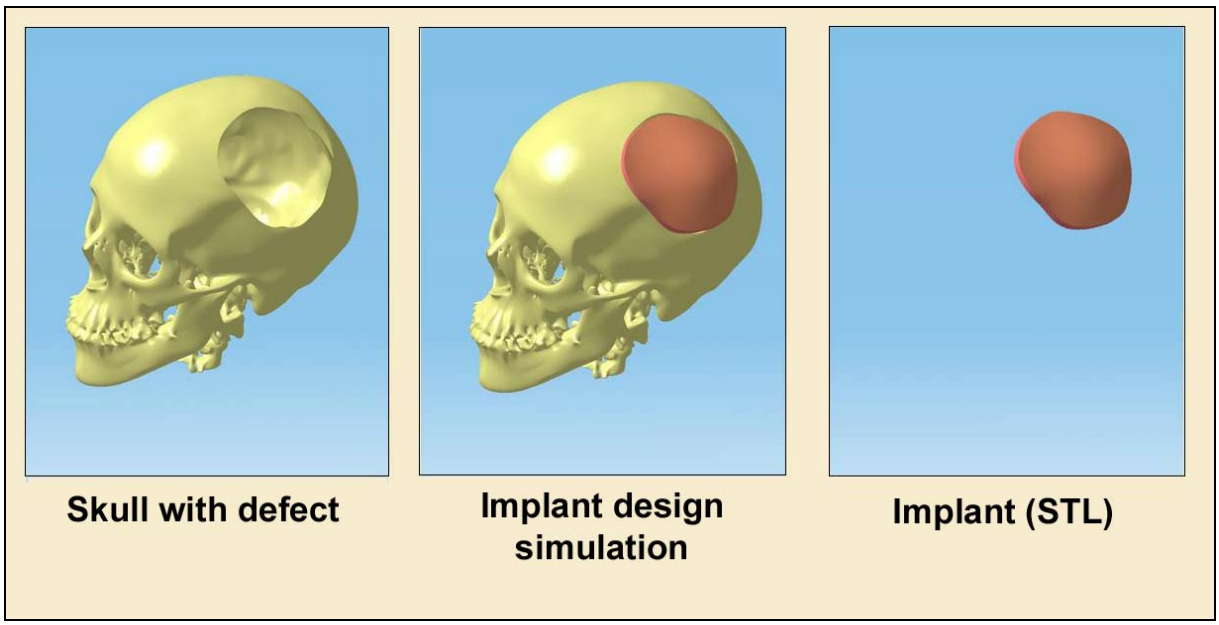

Figure 3.- Implant design process as showed in CATIA interface.

4 SIMULATION

FEM is broadly used to predict the operation of components or systems subject to external solicitations. In our research, the FEM module in CATIA software has been used to assure the integration with KBE system.

In cranioplasty, the implant must have certain mechanical properties in order to bear the stress and strain a skull is subject to on a daily basis. In a FEM calculation data is needed on the anatomy and bone material properties, dimension and material properties of the implant and its fixation system, interaction conditions in the implant-fixation-bone interface and load conditions of the model. Table 1 compiles the most significant properties from literature by different authors [13-20].

Table 1. Material properties

	Young's Modulus (Mpa)	Poisson's ratio	Density (kg/m^3)
Skull	$6{,}0 \cdot 10^3$	0,21	2100
Facial bone	$5{,}0 \cdot 10^3$	0,21	3000
Cortical bone	$(15\text{-}13{,}7) \cdot 10^3$	0,33-0,3	1300
Cancellous bone	$(1{,}5\text{-}0{,}79) \cdot 10^3$	0,30	2000
PEEK	$(3{,}7\text{-}4) \cdot 10^3$	0,40	1444

The 3D implant model is designed with CAD and KBE modules in CATIA and simulated with FEM module. If the result is not satisfactory, a new design is automatically generated, processed again by FEM, following an iterative process until the best solution is reached. FEM simulation has many interesting properties for designing highly innovative implants. These innovations may consist of the use of new materials and integrated design of implant – fixation systems.

Once it has been stated that a certain material and fixation system are valid for a given implant, there is no need to perform FEM simulations on further customized designs of the same typology, for strain generated in the cranium is not generally significant [21].

Once the implant design is decided, soft tissue can be simulated getting an aesthetic reconstruction of the patient image [22, 23].

5 IMPLANT MANUFACTURING

Poli-ether-ether-ketone (PEEK) is the selected material for implant manufacture, which is considered to be a suitable material for that purpose given its similar-to-bone mechanical properties.

PEEK is a high performance thermoplastic with the characteristics common to this group - strong, stiff, hard, high temperature resistance, good chemical resistance and inherently low flammability and smoke emission. PEEK is pale amber in colour and usually semi-crystalline and opaque, also it has very good resistance to wear, dynamic fatigue and radiation, but it is difficult to process and very expensive.

Due to its high chemical resistance it is preferred to metals when it has to be sterilized or chemically cleaned. However, it has the disadvantage of its high economic cost compared to that of metals.

At the beginning of the research implants were machined from PEEK. This process has major drawbacks:

- High percentage of the material is wasted. That involves a significant raw material cost.
- High waiting times.
- Low optimized design, because it is not a customized design.

KBE system design adds the advantage of giving an output which can be transferred directly to a RP system. In that way an improvement is obtained in manufacturing time and material use.

RP has been introduced in medical field many times. There is previous work about bone implants development through this technology [3] or inside the implant field in general [24, 25]. Different RP techniques have been successfully applied in a similar way to PEEK processing and Tissue Engineering (TE) [26-30].

Stereolithography (SLA), Selective Laser Sintering (SLS), Fused Deposition Modelling (FDM), Single Jet Inkjet (SJI) and Three Dimensional Printing (3DP) are the most-often applied RP techniques for TE using PEEK. In the light of comparative studies [31] and tests [26] carried out about the different techniques applied to implant creation, current lines of investigation are focused on SLS technology, which is considered the preferred technique in the processing of ceramic materials for biomedical application [32], just like it is considered the best when is required to combine biomaterials with PEEK for the implant manufacture.

Hidroxyapatite (HA) is the chosen material as biodegradable polymer to be combined with PEEK [4, 33]. HA is a natural component of human bones that has been successfully combined with PEEK through TE using RP techniques [26, 27, 30] in order to improve osseointegration. Since a raise of HA percentage increases Young's Modulus of the composite [34], whereas a rise of porosity rate (achieved through TE) decreases Young's Modulus [35], an adequate combination of both parameters will allow the implant's necessary mechanical properties to be achieved.

6 CONCLUSIONS

Traumatisms, diseases –such as cancer- and congenital malformations can lead to defects or large holes in the cranium, making these unprotected areas likely to be harmed by impacts. Whereas small defects often heal naturally, larger defects can only be treated with reconstructive surgery.

Initially, this methodology has been applied to the design and manufacturing of craniofacial implants, and is expected to spread to vertebral disk and dental implants.

Two major benefits arise from our research, which are related to the medical-surgical supply chains: minimization of implant design/manufacturing lead times and use of knowledge generated by previous design/manufacturing experiences that is being disregarded nowadays.

In conclusion, the use of implants adapted to the needs of individual patients through the use of KBE will have the following advantages:

- Improvement of healthcare services provided to patients.
- Time and cost reductions.
- A greater degree of structural, functional and biological compatibility, allowing longer implant lifetimes.
- Improved implant aesthetics and functionality for better life quality of patients.
- Possibility of less invasive types of surgery.

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