Framework for early manufacturability and technological process analysis for implants manufacturing

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***Abstract*— Patient specific implants, i.e. custom designed implants for an individual patient, are growing in popularity. This paper presents concept of a system, as well as the methodology of manufacturability analysis for custom designed implants manufacturing. System uses 3D model of implants with integrated implant knowledge. It also integrates a knowledge base and processes data base used for implants manufacturing. Set of rules gives recommendations for implants manufacturing and ranks them.**

I. Introduction

Contemporary approaches in integral development of a product implies methodology of simultaneous/concurrent engineering based on joint work of specialist experts in certain areas in the earliest phases of product inventing and designing. In the early phases of virtual product development, various experts' knowledge should be implemented in order to reduce development time and product price. Thus expert knowledge and experience is implemented in order to be able to completely observe, visualize and test it for work in simulated exploitation conditions [1, 2].

Through virtual product development various aspects of that product are considered, starting from conceptual design to its behavior in practice. One of the important phases in product creation is deciding on technologies and procedures for the most optimal product realization. It means that various methods and technologies should be considered and the most optimal one chosen. Thus, time of product realization and product price would be significantly reduced.

This paper presents concept of a system, as well as a methodology for manufacturability analysis for manufacturing implants used in medicine in surgical interventions. The paper is focused implants that are not typical and standard but are adjusted to patient specific needs (customized implants) [3]. Patient specific implants, i.e. custom designed implants for an individual patient, are growing in popularity.

The geometry and topology of those implants are adjusted to the anatomy and morphology of the selected bone of the specific patient. Their application has a positive effect on patients, but on the other hand requires more time for preoperative planning and manufacturing. Therefore, these are used in areas where the application of predefined fixators can lead to complications in the surgical interventions or in the process of recovery [4].

The second chapter of the paper describes reversible engineering customized implant design process [5]. Further on, the paper describes Knowledge Based (KB) implant manufacturability analysis, which gives a basis for manufacturability process analysis for manufacturing dynamic fixation on Tibia [6]. Decision on the optimal procedure choice is made by ranking criteria of the most important characteristics of a procedure (time, accuracy and cost).

II. Design of Customized Implants

An implant is a medical device manufactured to replace a missing biological structure, support a damaged biological structure, or fix an existing biological structure.

Conventional implant manufacturing methods provided that certain parts are manufactured in standard defined range. This way, certain implants couldn't adequately respond to patient specific needs, and the post-operative recovery was more difficult.

The creations of 3D models of customized implants are based on the 3D models of the patient specific bones. For this purpose, the first step is to create a 3D model of a selected bone [7]. Typical design loop is shown in Figure 1.

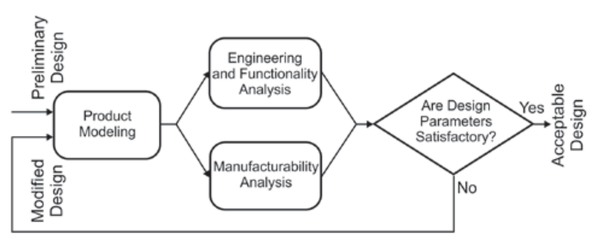

Figure 1. Typical design loop.

The creation of geometrically accurate 3D models of human bones utilizes number of different techniques and presents a unique challenge, because their geometry and form are very complex. These types of shapes can be modeled by using surface patches represented by Bezier or B-spline surfaces, or by using NURBS patches, which are commonly used in traditional CAD applications, e.g. CATIA [8].

The output of CATIA is presented in STL (Stereolithography) format, which allows it to be directly transferred into an RP (Rapid Prototyping) machine.

Reverse engineering of human bones implies the use of some kind of medical imaging device for the acquisition of medical data (Computed Tomography – CT, Magnetic

Resonance Imaging – MRI), then processing that data in medical or CAD software, and at the end, creating a valid geometrical model (surface, volume) [5].

The general reverse engineering techniques for design of customized implants, for selected bones, include several tasks (Figure 2).

- Importing and editing point cloud acquired from medical imaging device,
- Tessellation of point cloud and creation of polygonal model (mesh),
- Anatomical and morphological analyses of a selected bone,
- Identification of RGEs (Referential Geometrical Entities) which are based on the anatomical and morphological characteristics of a selected bone (points, directions, planes and views) [9],
- Creating and editing the curves on polygonal model of the selected bone, in accordance with the RGEs,
- Creating and editing the surface model of the selected bone's outer surface by sweeping, lifting, blending, and trimming the curves,
- Selection the places on the selected bone where the implant will be placed,
- Adjusting the geometry of the implant according to the requirements of the surgeon,
- Creation and modification of 3D models of implants,
- Simulation of implant placement to selected bones.

This methodology gives the opportunity to create a custom implant design adjusted to the patient's anatomy, improving structural, functional and aesthetic biocompatibility.

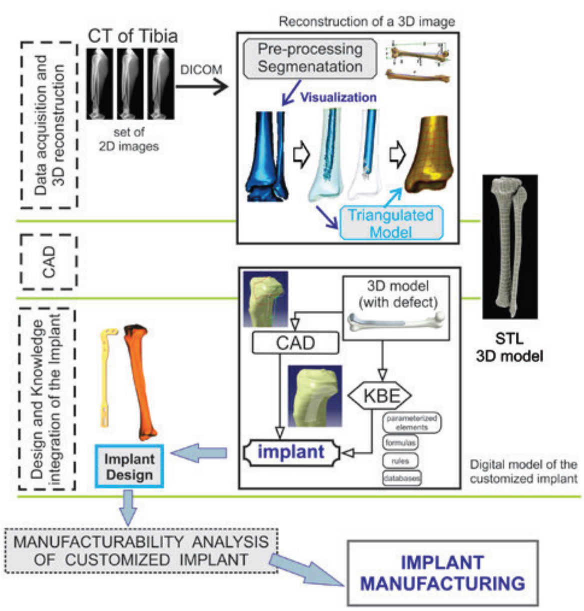

Figure 2. Automated design process phases and manufacture of customized implants

Implant modeling is performed in Computer-Aided development systems (CAPD), which, beside geometry and topology, enable integration of product knowledge, and manufacturing possibilities and applied technologies restrictions for some forms, in a virtual model of a product.

This knowledge is used for manufacturability analysis of suitable implant manufacture processes. In order to decide on the customized design for final user, some geometrical rules and restrictions can be included in 3D model, by means of databases, like "thickness" or „available tools for implant manufacturing".

Further on, the paper describes some of the existing methods and possible technological procedures and processes for manufacturing customized implants with their most important characteristics, advantages and disadvantages. Thus, a framework for manufacturability process analysis of specific implant is set.

III. Manufacturability analysis of costumized impalnt

Nowadays, in medicine a great number of different biocompatible materials for implants manufacturing are used. There are also a lot of manufacturing and material processing technologies, starting with conventional technologies, CNC technology to additive technologies. All of them have their own characteristics and influence the quality and price of the product. It is very important to choose an adequate technological procedure which gives implants satisfying exploitation characteristics, has optimal cost and short manufacturing lead time. This is very important for customized implants.

Even during the implant design phase it is important to consider and analyze possible technological procedures. That analysis is provided by using manufacturability analysis and analysis of systems and applications.

A product is manufacturable if it is suitable for manufacturing with planned technology. Therefore, when designing a product we try to find a solution that requires minimum use of manufacturing time and material with minimum necessary equipment for manufacturing a product suitable for a particular purpose and function. Product manufacturability as a production convenience measure is a very broad term and it is difficult to unilaterally define, because it depends on many influential factors, including process conditions. In the manufacturability analysis there is no absolute measure. What is manufacturable for one product may not be for the other [10].

According to the approach to considering manufacturability these systems could be divided into direct approach systems based on rules and checks; and indirect approach systems based on generating manufacturing plan and procedure, and then on modification of various procedures in order to reduce costs.

Measures of manufacturability for assessing the level of manufacturability:

- Binary measures (0 or 1/ yes or no/ manufacturable or non manufacturable/ …);
- Qualitative measures for descriptive manufacturability measures of virtual prototype (poor, average, good, excellent);
- Abstract-quantitative gives a manufacturability level by assigning numerical values to the abstract scale (e.g. assigning a manufacturability index range

between 0 and 1 and their combining in the final grade by using methods such as Fuzzy logic);

- Time and cost as a manufacturability measure are two most important parameters of a technological process easily combined in summative manufacturability rating, but they can not directly help designer in the assessment whether he really achieved satisfactory level of product manufacturability.

Depending on the moment of manufacturability analysis, we can define two approaches: analysis during the design process (on-line); and manufacturability analysis upon the design process completion (off-line).

Manufacturability analysis systems are actually Knowledge based systems (KB). Certain CAD programs integrate KB systems, thus CATIA has a "Knowledgeware" module, which is a kind of an expert system. In Knowledgeware, analysis is enabled by integrating information and data which are through certain relations (specified in VBScript) connected in model knowledge (e.g. parameterize elements, databases, create formulas or rules, check, etc.).

IV. IMPLANT MANUFACTURABILITY PROCESS ANALYSIS

Manufacturability process analysis actually assesses technology applicability by comparing techniques for creating certain designed implant and defines the techniques achieving maximum level of required quality with minimum costs and manufacturing lead time.

Generally, all the techniques, according to manufacturing processes, can be divided into three basic groups:

- *Formative Manufacturing are processes of material shaping by solidification- consolidation process;*
- *Substractive Manufacturing (Machining) is process where piece of raw material is cut into a desired final shape and size by a controlled material - removal process; and*
- *Additive Manufacturing are processes which are based on connecting points or material layers with the aim of achieving a desired shape- 3D printing process.*

In order to recognize a particular technological procedure and analyze a level of its applicability, Table 1 gives a review of certain procedures and some of their characteristics used to decide on the optimal process. Considering the fact that there is a great number of procedures, techniques and methods for manufacturing a particular implant, the table presents only processes related to customized implant manufacturing procedure on the example of dynamic tibia fixation.

Manufacturability process analysis is seen in establishing the level of its applicability (if the process is applicable). And on the other hand which characteristics make is inapplicable (if the process is inapplicable).

Measures for establishing the level of technique applicability defined in Table I are: Accuracy, Cost and Manufacturing Lead Time. A value (weight) was assigned to each of these measures showing the importance of that value for establishing measures for manufacturability process analysis.

TABLE I.
Review of established manufacturing techniques used in medical field

	Accuracy	Cost	Manufacturing Lead Time
Stereolithography (SLA)	+++	$$	+++
Selective Laser Sintering (SLS)	++	$$$	+++
Fused Deposition Modeling (FDM)	++	$	+++
Direct Metal Laser Sintering (DMLS)	++	$$	+++
3DP	+	$	+++
Milling	++	$$$	+
Turning	+	$$$	+
Injection Molding	++	$$$$$	+
Sand Casting	++	$$$$$	+
Forging	+++	$$$$$	+

Conceptual scheme of a system for manufacturability process analysis is shown in the figure 3. System Input data on one hand are received from an implant model data base. System on the other hand involves Process Capability Database, in which available processes are presented with a set of rules and application restrictions related to constructive - technical features integrated in an implant model.

By applying rules system analyzes 3D implant model and gives recommendations for its manufacturing. It also ranks recommended procedures in accordance with knowledge stored in process knowledge base.

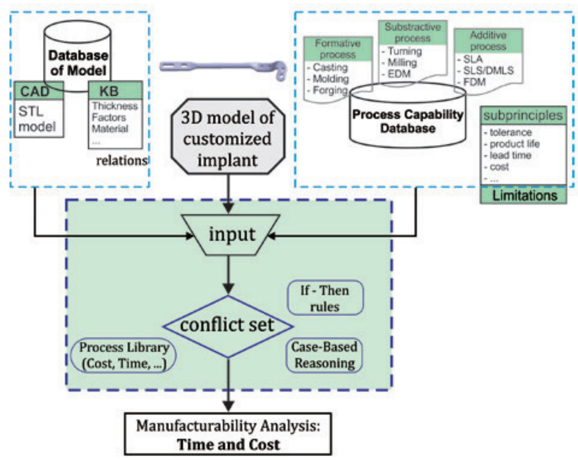

Figure 3. Concept of Manufacturability Process Analysis

The system is based on the use of If-Then rules. Beside If-Then rules, the system can use other available recommendations such as for example Case-Based decision making or similar known process libraries. Thus technological procedure knowledge about manufactured implant can be used for later comparisons of process criteria. This becomes particularly useful if a certain manufactured implant, primarily in its geometry and its position (on the bone itself), but also in other characteristics, is similar to customized implant model being manufactured. Existence of such data enables earliest design and process manufacturability analysis.

When analyzing, following criteria can be set: cost, manufacturing time and accuracy, or some other. These three criteria are used in manufacturability analysis of internal dynamic tibia fixation according to Mitkovic type TPL, (Figure 4) [5, 8, 11].

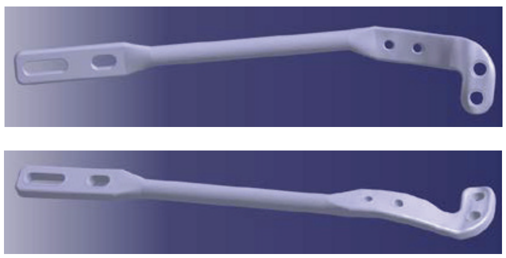

Figure 4. 3D Model of dynamic fixation according to Mitkovic

Analysis results can be reduced to the following conclusions, i.e. recommendation.

The shortest fixator manufacturing lead time and the most accurate shape are provided using additive manufacturing. But, the cost is by far the highest.

The cheapest fixator can be manufactured using classical manufacturing technologies (cutting and deformation), but this process is the longest and does not always give the same quality.

The most optimal procedure is the forging process which gives both good quality and reasonable price, but requires utilization of significant tool manufacturing resources, and it is the most optimal method for manufacturing large series of a product, which is rare in customized implant production.

V. Conclusion

This paper presents the concept of the system and the initial result for manufacturability analysis for customized implants. The system uses a parameterized 3D model of customized implants, which integrates general and expert knowledge about particular elements of implant construction. The knowledge is gathered from material manufacturers, production equipment manufacturers, orthopedists, implant manufacturers, and other experts involved in its realization. System is based on the use of knowledge base and rule base for implants, materials and manufacturing techniques. It is implemented in CATIA through Knowledgeware module.

Its application it the implant design phase gives recommendations and ranks potential technological procedures.

System is designed as an open system for upgrading knowledge base and rule base and gives a good basis for development of quality and applicable system for practical use.

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