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Optimization of Patient-Specific Design of Medical Implants for Manufacturing

Matthew Chin Heng Chua, Chee-Kong Chui*

Department of Mechanical Engineering, National University of Singapore
9 Engineeirng Drive 1, Singapore 117575

* Corresponding author. Tel.: +65-65162137; fax: +65-67791459. *E-mail address:* mpecck@nus.edu.sg

Abstract

Medical implants are usually mass produced in fixed sizes, shapes and material properties. However, this process is not sustainable due to high levels of material wastage resulting from unused products because of the low demand of particular sizes. Furthermore, these modular implants are not optimized to specific patient's anatomy in terms of geometry, material composition and properties. This often leads to risk of injury, implant displacement, impairment of intended functions or even rejection by the host body, thus contributing to further healthcare costs, implants wastage and discomfort to patient. We have been investigating patient-specific design methods to tailor implant design and material composition to the patient's anatomy. With patient-specific implant modeled and simulated, rule-based methods, Genetic Algorithm (GA) and material knowledge bases are used to perform multi-objective optimization of the material composition for additive manufacturing. This method is investigated with reference to the design and fabrication of a patient-specific ENT implant.

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1. Introduction

There has been paradigm shift from the old mass production system of medical devices to customized-production systems that tailor each device to different individualized requirements [1]. In order for the customized manufacturing process to maintain the same level of output, the use of numerical-based patient-specific design models is important. As such, there has been much focus on the development of intelligent design systems that can integrate the use of rule-based algorithms [2] and multi-objective optimization, like genetic algorithm [3, 4] and particle swarm optimization [5], in tandem with existing knowledge bases.

Multi-objective optimization in medical implants involves finding the optimum design that will give the best performance in terms of stiffness, weight and many other factors. It is important to note that some material properties, like Young's Modulus in orthopedic implants, needs to be as close as possible to the native tissue (i.e. bone), in order to prevent stress shielding. Mechanical property mismatch between implants and soft tissues can also lead to severe foreign body response and eventual implant failure [6]. New materials are constantly being used to replace traditional engineering materials to improve the performances of implants. These multi-functional advanced biomaterials are usually composites comprising of a number of functionally graded materials [7, 8]. Hence, the large number of variables and constraints in these cases would require an intelligent design system to provide an optimized solution [9].

Although several works have been reported for the use of intelligent design in healthcare implants, most of them are based on hard tissues like orthopedic or dental implants [10, 11]. To the authors' best knowledge; there have not been any studies on the design optimization of soft tissue implants to date. Rungsiyakull et al.[2] implemented a rule-based and multi-objective optimization framework for coated bone implant design while Fernandes et al. [12] studied the use of

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multi-criterion optimization in the geometrical design of hip implants.

In this paper, we are proposing a rule-based classification method combined with genetic algorithm for the optimization of biomedical implant composition according to patient-specific requirements. A rule can be taken as a form to encode knowledge and experience, which are then used in decision making to predict results. The rule-based classification method will be initially used to form groups of biomaterials from the material knowledge base that are potential composite combinations for the designed implant. This also helps users to select or eliminate certain groups of materials from the material selection process. Genetic Algorithm (GA) is then applied on the selected groups to optimize each individual material composition to achieve optimal results for all mechanical criterions. We have been studying the use of carbon nanocomposites in Ear-Nose-Throat (ENT) implants for enhanced healthcare [13-16].

Section 2 describes the proposed intelligent design system for the material selection and optimization process in patient-specific implant design. Section 3 applies the process in the design and manufacturing of a patient-specific tracheal implant. Section 4 discusses our proposed intelligent design framework, its limitations and future work. The paper concludes in Section 5.

2. Intelligent-Design System

2.1. Overview

We propose a rule-based intelligent design system for the material selection and optimization of implant composition based on patient-specific data and virtual model. Figure 1 depicts the entire process flow that is built upon *MATLAB*, *SolidWorks* and *COMSOL Multiphysics* software. The biomaterials knowledge-base is the key source from which the algorithm derives all known quantitative material properties of existing biomaterials. The information is input into a rule-based classification algorithm that sorts materials into potential composite clusters based on user-defined rules. These design rules that include flexibility, strength, density and others, are determined from the intended application outcome. The human designer can then assess the suitability of each composite cluster based on their combined inherent biological properties and the non-quantitative biological requirements of the implant. Some examples of such biological factors may be bioactiveness, compatibility to host tissue and *in-vivo* degradability. Genetic algorithm is then used to optimize the compositions of the pool of accepted clusters according to the mechanical requirements of the application. Finally, these potential composites are evaluated with Finite Element Method (FEM) simulation using the patient's 3D reconstructed model to find the best solutions.

It is critical to link the design of the medical implant to the patient's anatomy and the manufacturing process. This ensures that the implants are optimized to each individual, which can vary greatly in anatomical dimensions. It provides a more sustainable form of implant manufacturing than the traditional mass production of fixed sizes and trial-and-error fitting that result in much wastages and lower quality of healthcare.

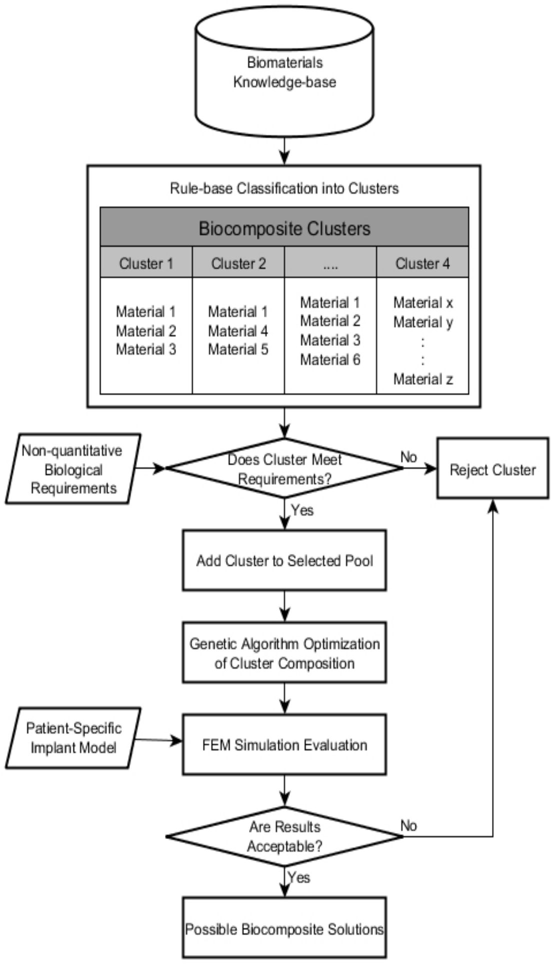

Fig. 1. Rule-based material selection and optimization process for medical implant design

2.2. Rule-Based Classification

The selection of candidate materials to form a new composite that will be most suitable for an implant design can be a daunting process due to the plethora of available materials and possible permutations. This requires a more systematic method utilizing rules to streamline down the possible combinations of materials according to the mechanical requirements of the medical application.

In an expert system, a rule is a conditional statement "if X condition is satisfied then the outcome is Y". According to the laws of mixture in composite [17], the final physical property of a composite falls within the range of the lowest value and highest value of the same property of constituents within, depending on the composition fraction. We can then craft the rule to select materials based on a property, for example Young's Modulus, as an *if-then* rule,