

ENGINEERING CHALLENGES IN DESIGNING CUSTOMIZED BONE IMPLANTS: A REVIEW

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Introduction

Conventional knee and hip implants have been in use for surgery for a long time and the techniques are well established. However for trauma cases such as war injuries, road accidents etc it is difficult to fit these standard implants due to excessive damage to bones and joints. For such cases it is necessary to design custom implants to match with each patient's situation. Making customized prostheses is a challenging engineering task as each and every design is unique. Advantage of making implant components to suit patient specific anatomy is to overcome the existing problems such as loosening of implants, problems with reaming and resurfacing to fix the implant, problems due to filler materials etc experienced with current standard designs (BIOMET, 2009). In this study, a review of engineering challenges faced in designing custom made implants is presented along with a case study.

Materials and methods

Evaluation of patient for deciding on the need for a custom-made implant: Diagnosis and decision has to be made by surgeons on what type of implant is needed. Whether it is possible to use an existing standard implant or it is necessary to make customized implants is to be decided because the cost involved in making a patient

specific implant is about 10 times that of a standard implant. Time restraint due to the patient's condition is also a challenge to the doctor and the design engineer as well as to the manufacturing engineer.

Extracting and modeling of patient's data: Necessary CT (Computerized Tomography) scans, MRI (Magnetic Resonance Imaging) scans and X-ray photographs taken from different angles should be obtained from initial examination of patients. Surgeon, design engineer and radiologist must work collaboratively for this purpose. Accurate digital reconstruction of the patient's data into a 3-D bone model using a 3-D modeler such as Solid Works is done at this stage (Jun and Choi, 2010). This is a crucial step as the final design depends on this model.

Preliminary design and final design: Considering surgeon's recommendations, a preliminary design is done to match the patient's anatomy using 3-D geometrical modeling. Tested design concepts which are applied in standard implants can be used whenever possible with necessary modifications in order to minimize time consumption in research needed to come up with new innovative design concepts. Those areas can be developed in a separate study with experience gained from making these custom made implants.

Materials selection based on economic, geometrical, strength and biocompatibility constraints is done at this stage. An approximate stress analysis for major stresses in the component is carried out to evaluate the feasibility of the design. A 3-D digital model of the implant is then shown to the surgeon and the manufacturing team for necessary modifications and additions. Final design is done after accommodating those and a detailed analysis is performed for stresses before sending working drawings to the manufacturing unit.

Difficulties faced by the medical team:

- a) During the surgery: The difficulties arise during the implanting process such as sequence of inserting and fixation, joining with screws, contact with skin, etc. are to be discussed in detail at this stage in order to avoid any complication during the surgery.
- b) Post surgery: The design team must have a good understanding of this aspect in order to avoid any post surgery complications such as loosening, stress shielding, pain and discomfort, lack of mobility, wear and tear. The continuous collaboration among design, medical and manufacturing teams is a must in this case. This itself is a great challenge as these professionals are otherwise working in different disciplines and very much indulged in their own professions.

Difficulties arise in manufacturing

Available material stock and the shape and sizes have to be considered with the design dimensions when purchasing materials. If much choice is not available on shape and size of the stock, manufacturer makes a request to

the designer to consider the available sizes and shapes of raw materials as well as the reamers in the process of selecting the basic dimensions and segments of the components. This can avoid manufacturing difficulties as well as the resulting material wastage. Acquiring special biomedical alloys is also a challenge to the manufacturer as it is not commercially available in small quantities. This increases the investment cost for custom made implant manufacturing, as each implant needs only a small quantity of material.

Acquiring necessary manufacturing technology is another challenge faced. The available methods of manufacturing and the degree of accuracy are also considered during the design process. A few different methods used in manufacturing are simple machining, machining using a 5-axis CN machine, forging and hot isostatic pressing for metallic materials. It should be also noted that machinability is high in stainless steel 316L but comparatively lower in cobalt-chromium and titanium alloys. For UHMWPE (Ultra High Molecular Weight Poly Ethylene) simple machining or compression molding is used (Anasane et al, 2007). Some implants are also manufactured using rapid prototyping, after the recent advances in this field along with the advances in the Reverse Engineering (RE) and image processing (Harrison, 2001).

Case study

An elbow joint was designed and manufactured by Biomedical Engineering Research Group at the University of Peradeniya in 2010 (Amarasinghe et al, 2010). Some of

the challenges the team faced during this research led the authors to make this review on custom designed implants. Some pictures depicting the design process are given in Figures 1 to 3.

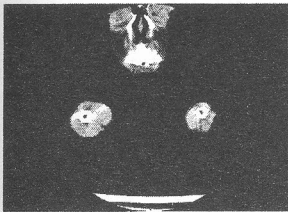


Fig. 1. CT scan data

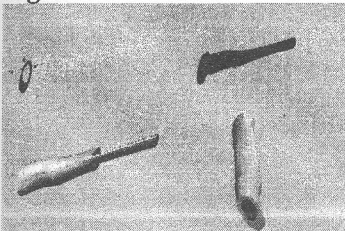


Fig. 2. 3-D Model of bone

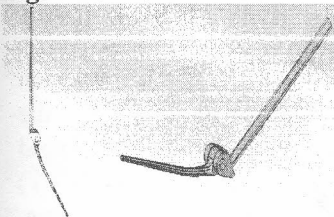


Fig. 3. 3-D model of implant

Conclusions

The design and manufacturing of biomedical implants are two undeveloped areas in Sri Lanka. It is certain that custom-made implants are the best form of orthopedic implants that patients can receive. The challenges that we have to face in making those are;

- a) The time constraint: the time available is limited depending on the patient's condition.
- b) Extraction of patient's data from CT and MRI scans in to a 3D digital model.

- c) Continuous coordination between different teams throughout the process.
- d) Difficulty in acquiring bio-compatible materials and cost compared to standard implants.

If it is possible to overcome the challenges faced in this field with available expertise and resources at the University of Peradeniya and Teaching Hospital, Peradeniya, then it will be beneficial to the patients as well as the country's economy. Currently, most of the trauma patients undergo amputations due to unavailability of custom made implants and a huge amount of foreign exchange is spent on importing standard implants.

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