VIRTUAL ENVIRONMENT FOR COLLABORATIVE DESIGN ON HARD TISSUE IMPLANTS

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INTRODUCTION

As one of the most aging countries in the world, the number of plastic surgery operation in Japan is increasing at the annual rate of 8 ~ 10 %. Implant products used in those operations include artificial hip joint, artificial knee joint, and other artificial bone materials, and their market size reaches several billions of Japanese Yen, which is a very big market.

Figure 1: Example of ceramics implants

As shown in Figure 1, various shapes of prefabricated ceramics implants are available. Although a variety of product ranges is provided, available product range is limited as long as hard tissue implant is based on a non-custom-made production. Since the implant cannot be reshaped to fit the damaged portion of the bone at the time of operation, normal portion of the bone in operation must be reluctantly cut off to apply the products. Ideally, implant should be properly designed to apply to the portion, but actually not.

As for the material, porous ceramics are regarded as a suitable one for hard tissue implants which grow into the tissue to become compatible after a certain period of time, but their fragile features are not suitable for mechanical processing. We are proposing a new idea for mechanical processes on porous ceramics using an intrusion/extrusion wax method, and have obtained some significant results. This idea also enables us to perform mechanical processing on porous ceramics to obtain some desired shapes for hard tissue implants.

The study focuses on virtual manufacturing approach to collaborative design of hard tissue implants to enable custom-made design without preliminary operation, and to provide the appropriate shape of ceramics implants. The paper describes hard tissue implants in general, including hydroxyapatites used in our rapid prototyping system. Then, the paper covers the system overview, collaborative design procedure, and rapid prototyping. Concluding remarks will follow.

DESIGN ON HARD TISSUE IMPLANTS

Hard tissue implants of porous ceramics

As shown in Figure 1, a variety of shapes of various sizes are available. From several candidate products prepared beforehand, the most suitable one is selected at the time of surgery and used for the operation.

Although a variety of product ranges is provided by manufactures, the appropriate product range is limited as long as hard tissue implant is based on a non-custom-made production. Since those implants cannot be reshaped by mechanical processing to fit the damaged portion of the bone, normal portion of the bone in operation must be reluctantly reshaped to apply the products prepared. Ideally, implant should be properly designed to fit to the damaged portion, but actually it is not the case.

Several reasons can be considered. Hard tissue implant materials such as ceramics are very difficult to be processed, especially to make a very complicated shape. Imported implant products, of which design is based on the patients in the original country, are very

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often used, although several Japanese manufactures are on the market. Moreover, to design a custom-made implant, preliminary operation has to be made before the main operation, which must be a very much hard ordeal to the patient. Therefore, it is not easy to design and make a custom-made implant, which satisfy each patient's specific needs in a very timely manner. Therefore, one of our goal is to provide a custom-made hard tissue implant of porous ceramics, especially hydroxyapatite.

Basic idea of collaborative design

For competitive product development, it is essential to understand the market needs, to develop the products which satisfy the needs, and deliver them to the market in a timely manner. To do so, concurrent engineering techniques are regarded as an effective approach, and collaborative design by several participants from different area can be available with the techniques.

To design the shape of implant for each damaged portion, preliminary operation is required to obtain the physical data around the portion. However, it gives heavy burdens to the patient in terms of both mental and physical points of views. Our study focuses on collaborative design on hard tissue implants without preliminary operation. Using a 3D digital bone model created in a virtual environment, a custom-made shape of ceramics implants can be prepared in a timely manner.

As shown in Figure 2, medical doctor, design engineer, and process engineer collaboratively work on implant design in the virtual environment of the system, which can be accessed from ubiquitous network including PC, PDA, mobile, etc. Idea, proposal, feasibility, and judgement by medical doctor, design engineer, and process engineer work together based on the medical data to design the most suitable implant product to the patient.

VIRTUAL MANUFACTURING APPROACH OVERVIEW

To achieve the target two goals, or custom-made design and collaborative design on porous ceramics implants as described in the previous section, we propose a virtual manufacturing approach. Procedure of our approach is based on 5 stages, or modeling, designing, rapid prototyping, evaluation and production. Integrating these procedures, implementation of collaborative design system on hard tissue implants is under study.

Modeling stage

The first thing to do in the design procedure is to create a 3D model for hard tissue, or damaged bone to adopt implant operation. We are considering two approaches for this purpose. One is utilization of DICOM data from 3D CT scan, and the other one is data scanning. For data scanning, we have designed and developed a special jig which is shown in Figure 2.

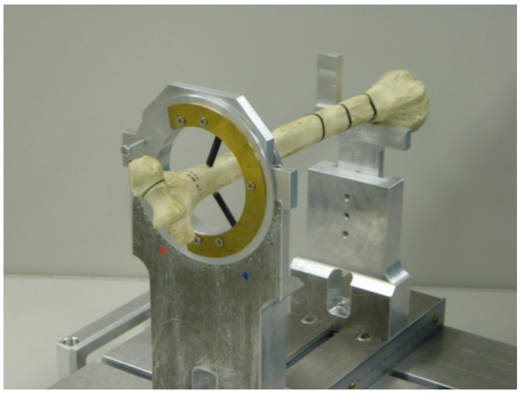

Figure 2: Data scanning using a special jig

Designing stage

Using the bone model including damaged part as shown in Figure 3, which are prepared in the modeling stage, an appropriate shape of implant is designed under the collaboration between medical doctor and engineer in the virtual environment.

Figure 3: An example of damaged part of bone

Rapid prototyping stage

Using the STL data generated from the designed model in the designing stage, rapid prototype is prepared using stereolithography and 3D printing methods. Both original bone and supplemental implant for the bone are prepared. The lower bone in Figure 4 shows the original bone and the upper bone shows the regenerated one.

Evaluation stage

The 3D model and its rapid prototype are further evaluated under the collaboration of the medical doctor and the engineer, and redesign procedure continues until the final design is fixed. These models as well as the virtual model are also used for presentation materials to the patient.

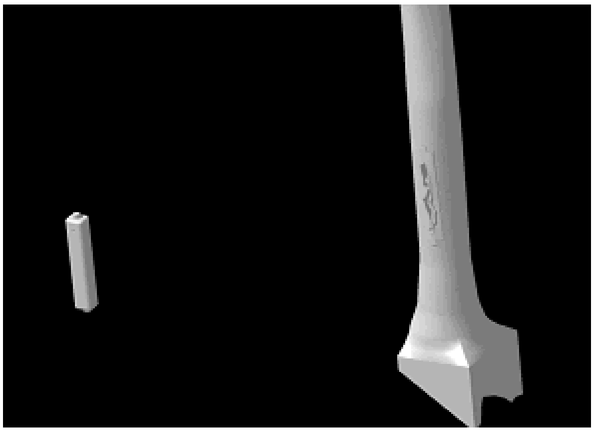

Figure 4: Example of virtual design

Production stage

After evaluation, the final STL data is used to produce the ceramics implant with the most appropriate shape.

KEY TECHNOLOGIES UNDER STUDY

Modeling techniques

As for the modeling procedure, two types of approaches are under study. One is utilization of DICOM data from 3D CT scan, and the other one is direct scanning.

Modeling with CT scan data enables us to create a precise model of hard tissue. However, it is not always available because of several reasons including economical, medical, or technical reason.

In addition to this typical approach, we also use direct scanning approach. As shown in Figure 2 a special jig for data scanning was invented for this purpose. Once a bone is set on the jig, it can be rotated precisely in a fixed angle with 2 degree of freedom, which allows the 3D laser scanner to collect data and combine them in a precise manner. For much more precise modeling, a direct contacting scanner is also used. Although actual bone of living human being cannot be processed in this way, we have a plan to expand the idea behind this approach to other applications. Also, we are conducting comparative study between these two approaches in terms of quality of the model created, of which results will be discussed in the future papers.

The bone model created using some of these techniques plays a critical role for hard tissue implants design.

Figure 5: Reproduced bone shape and its original

Precision process on porous ceramics

The virtual product also can be made available as a rapid prototype product, which may be easier for evaluation and understanding. When the design specification of hard tissue implant is prepared, precision process of the product can be available as long as the material is suitable for mechanical processing. However, it is not the case for porous ceramics such as hydroxyapatite.

The potential advantage offered by a porous ceramics implant is its inertness combined with the mechanical stability of the highly convoluted interface developed when bone grows into the pores of the ceramics. Mechanical requirements of the prostheses, however, severely restrict to the use of low-strength porous ceramics to low-load- or non-load- bearing applications. Studies show that, when load bearing is not a primary requirement, nearly inert porous ceramics can provide a functional implants. When pore sizes exceed 100micro m, bone will grow within the interconnecting pore channels near the surface and maintain its vascularity and long-term viability. In this manner, the implant serves as a structural bridge and model or scaffold of bone formation. The microstructure of certain corals make an almost ideal investment material for the casting of structure which highly controlled pore sizes.

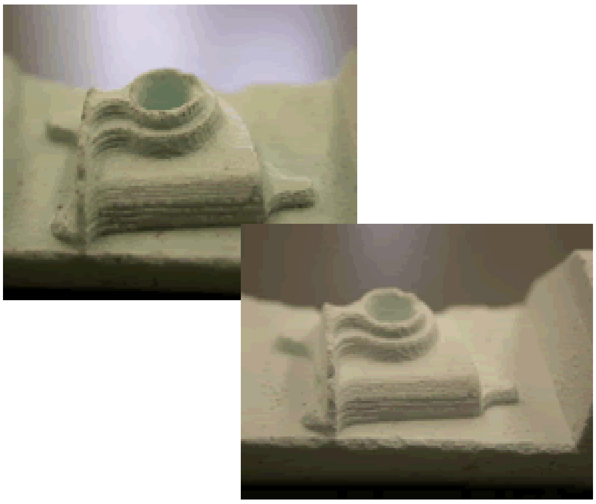

Figure 6: Porous ceramics processing

To prepare the hard tissue implants using the porous ceramics based on the STL data, we apply a new method using wax combination. Porous ceramics material comprising a special wax is thermally processed to stabilize in its physical shape, and prepared as a starting material for hard tissue implant. On the contrary to porous ceramics, which are too fragile to be processed, mechanical processing can be available on this waxed ceramics. After the processing, the unnecessary wax is to be removed by second thermal processing. Figure 6 shows two examples of sculptured ceramics, before and after the second thermal processing, which can hardly be processed by a normal method due to fragile features of the porous ceramics.

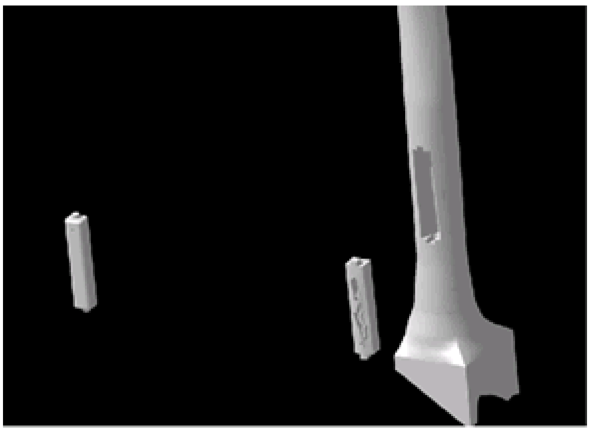

Figure 7: Example of virtual manipulation

Collaborative design in virtual environment

Based on the bone model, an appropriate shape of hard tissue implant is designed under the collaboration with medical doctor and engineer. Viewing 3D model of the bone on both sides via Intranet, appropriate shape is discussed and studied over the network. Specification from the doctor is directly given to the engineer, who manipulates the model and create what the doctor intends, then the doctor evaluates the results and gives further instruction to the engineer until the final design is made. Figure 7 shows a snapshot of virtual manipulation for implant design.

CONCLUDING REMARKS

Because of the increasing number of plastic surgery in Japan, hard tissue implants, especially, custom-made one, are required by the market. However, appropriate design for custom-made production needs preliminary operation, which is not easily accepted by the patients. Among several materials, porous ceramics are regarded as suitable material for hard tissue implants which grow into the tissue to become compatible, but their fragile features are not suitable for mechanical processing. We are proposing a new solution to this problem, and it enables us to mechanical processing on porous ceramics. The study focuses on a virtual manufacturing approach to hard tissue implants made of porous ceramics. The paper presents the overview of the idea behind the approach and shows some of the key technologies.

The paper described the current status of plastic surgery regarding hard tissue implants, and pointed out the critical issue for requirement on custom-made design and its difficulty in preparation for hard tissue implants. As a new approach to hard tissue implant design and production, we propose a collaborative design approach using virtual manufacturing environment. Our study focuses on precision process for porous ceramics for hard tissue, and development of a concurrent design system for hard tissue implants. The paper covered the basic idea and picked up some key technologies in the system.

In the final stage of the project, medical doctor collaborates with engineers to design the most appropriate shape of hard tissue implants, evaluates it on a virtual environment, and prepares it as a rapid prototyping product. After the evaluation, the implant design will be transferred to the manufacturing site through the network, produce the implant, and deliver it to the doctor in a very timely manner. During the preparation, the doctor can present the patient what sort of material is going to be used for the operation under the virtual environment, and even show the rapid prototype product.

Collaborative implant design using virtual manufacturing approach of our study provides a new approach to plastic surgery operation using implant products, and a solution to ease the pain of patients.

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