Design of tailor-made hip-joint implants and the stress analysis[*]

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Abstract

To efficiently provide tailor-made hip joints, a system environment was developed. Our 3D-based pre-operative plan assistance system, we called JointVision, was used to subject the artificial hip joint to simulations for determining optimal placement and size. The position information after placement enabled stress simulation. The CAD model of the artificial hip joint implant after the design is used in implant placement simulation, stress analysis, and verifying the shape and arrangement. The head, socket, and stems are constructed by an electron-beam melting (EBM) device of Arcam Corporation.

Keywords: Pre-operative planning; Tailor-made implant; Total Hip Arthroplasty (THA); Electron-beam melting (EBM)

1. Introduction

One of the problems associated with population aging is the increased occurrence of hip joint diseases. As a result, the need for the total hip arthroplasty (THA) is increasing. THA is a surgical technique used for replacing hip joints with artificial components (an assortment of implants). Before starting the surgery, the doctor must carry out the pre-operative planning for the patient by using two-dimensional computed radiography (2DCR) images of the limb or/and three-dimensional computed tomography (CT) image. In the pre-operative planning, the doctor needs to decide the appropriate type and size of the total hip joint implant parts. However, since the hip joint implant parts are manufactured in advance, and they are not the tailor-made, it is difficult to fit the implants for each patient bone shape perfectly. The surgeon must select the most appropriate size and combination of hip joint implant parts from the brochure. In order to improve the problems, we propose the designing approach for tailor-made hip joint implants on a computer-aided design CAD) system in the treatment of hip joint diseases. In our approach, A CAD operator and doctors design the shape and size of hip joint implant on CAD system interactively. The model can be designed to match the bone surface since the stem shape follows the curvature of the surface of the exported triangulation mesh of bone. Furthermore, the bone shape and the designed stem are eventually converted into tetrahedral mesh for stress analysis, and evaluated in several ways. Finally, the most appropriately shaped stem for the hip joint diseases is manufactured by using an electron-beam melting (EBM) device. In this paper, we describe the details of interactive design for hip joint implant for each patient. We also describe our stress simulation method for a tailor-made hip-joint implant.

2. Overview of tailor-made implant design

2.1. Pre-operative planning of THA

In order to provide tailor-made hip-joint implant for each patient, pre-operative planning of total hip-joint replacement arthroplasty (THA) is first important step. In our approach, the doctor selects the pre-defined stem, and checks the pre-defined stem by using CT image, and adjusts the size and length if needed. After the parameters in the design table have been changed interactively, the CAD model of the implant has generated automatically. Therefore, a tailor-made hip implant design step needs trial and error by fitting to the shape of the patient's bones and joints. Figure 1 shows our concept from pre-operative planning to surgery in order to provide the optimal tailor-made hip-joint implant to the patient.
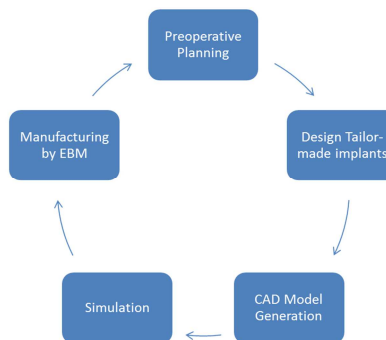

Figure 1 Concept of tailor-made implant design

2.2. A Pre-operative planning system

In order to provide tailor-made hip-joint implants efficiently, we have developed a pre-operative planning system, we called JointVision [1-3]. The system supports the acquisition of CT images of the entire length legs, and pre-operative planning for total hip arthroplasty. In the pre-operative planning, we have specified the shape and the position of tailor-made hip implant, and the generated triangulation model is recorded as a solid model by using a universal CAD system. The CAD/computer-aided manufacturing/CAE systems used in this study were CATIA Version 5 (e.g., for analyzing the stress between the designed plate and bone surface) by Dassault Systèmes [4]. We have designed tailor-made hip-joint implant by adjusting each parameter, such as length, angle for each part, which was defined as parameters on basic shapes (template). It is possible to parameterize each size after designing basic shapes in CATIA. We can change these parameters by using EXCEL of Microsoft Corporation, and after the adjustment of each parameter, the CAD model can be generated automatically. Figure 2 shows the basic hip implant shape (stem), and Figure 3 shows the design table. The modeling of tailor-made hip-joint implant has done by using the design table. For example, the specific hip implant shape (stem) is generated by changing the parameter values in the design table. We have designed cement type hip implant, which is to fix to the bone with bone cement. Therefore, the stem stiffness is very important. The material we used is Co-Cr-Mo alloy, we called COBARION. The material has the features that have high rigidity (stiffness), and is difficult to bend. Therefore, it is suitable for the cement type stems. In addition, using this support environment, we have designed and manufactured tailor-made hip-joint implant by using an electron-beam melting (EBM) device (Figure 4), and have verified its effectiveness.
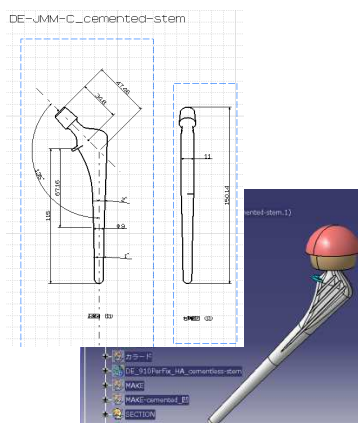

Figure 2 Tailor-made hip implant basic models

	角度A` (deg)	直径A` (mm)	H0 (mm)	カップ直 径A` (mm)	カップ長 さA` (mm)	カップ角 度A` (deg)
	A	B	C	D	E	F
1						
2	30	8.5	2	14	14.5	4
3	30	9.5	2	14	14.5	4
4	30	10	2	14	14.5	4
5	30	11	2	14	14.5	4
6	30	11.5	2	14	14.5	4

Figure 3 Parameters of design table

Figure 4 An electric-beam melting (EBM) device

3. Tailor-made implant design

3.1. Worksheet based design approach

Though our method using this worksheet has been used to design in a conventional CAD modeling, more efficient design can be achieved in our approach. In order to increase the degree of freedom in shape design of tailor-made hip implant, we have added more parameters in the worksheet. Because, there are large individual differences for the shape of bones and muscles in human body. In addition, when we can't fit the shape model in human body in these parameters, it is also possible to design the shape model without the worksheet, and directly modify the shape model on CAD system. The CAD data after the design is used in implant placement simulation, stress analysis, and verifying the shape and arrangement.

Figure 5 shows the left head, socket, and stems that are constructed by an electron-beam melting (EBM) device of Arcam Corporation. The right white stem is constructed by 3D printer with ABS materials. It is advantageous in term of cost to use 3D printer. Figure 6 shows the comparison of before and after polishing. The geometry models of the stem, head, and socket (linar) are generated by using the parameter table of Figure 3.

Figure 5 Stem, cap, socket constructed by an EBM device

Figure 6 Stem, cap, socket of before and after polishing

3.2. An Electron-Beam Melting (EBM) device

An EBM device of Arcam Corporation consists of electric beam gun, chamber (3D printing room), metal powder tunk [5]. The electric beam projected from electric beam gun melt metal powder slice by slice, and metal products are generated finally. The EBM device makes it possible to manufacture a high-quality metal part. Since the laminated dissolution has been carried out in a vaccum, it has the merit that there is no contamination of impurities. Furthermore, since metal powder that was not dissolved in the chamber is re-used, a high recycling rate of the material has achieved. In EBM device, we can use several metal powders, such as stainless steel (Steel Use Stainless SUS), titanium alloy (titanium alloy), cobalt-chromium alloys (Co-Cr-Mo alloy), and so on. Therefore, it is possible to develop the products depending on the application, when necessary. In addition, the EBM manufacturing system is different from the pressing and casting, the mold and the heat treatment for removing strain after shaping parts are not required. The EBM approach is different with the conventional casting or the direct pressing for creating the metal parts. It is not necessary to remove heat treatment after the molding strain. It is not necessary the mold in order to create the metal parts directly. Currently, the EBM device, which is a very high price, has been introduced widely in the manufacture of the prosthesis in the medical fields, military industry, aviation, space industry, and so on.

3.3. Extraction of bone morphology

Three-dimensional (3D) images of bone morphology can be obtained easily with a computed tomography (CT) scanner. The implants are produced based on data obtained from the CT images and can thus be tailored to specific patients. Although there are individual differences in bone morphology, it is possible to accurately acquire the necessary parameters and elucidate the morphology by using a 3D image processing system to measure the CT images. For this work, we used Volume Extractor—a 3D visualization system researched and developed at Iwate Prefectural University [6, 7]. Volume Extractor can be used to perform the following tasks: 1) reads CT images, 2) edits CT images, 3) performs visualization by means of volume rendering, 4) measures lengths, angles, and volume, and 5) has a polygon conversion function (Figure 7).

Figure 7 3D visualization system of CT images

Basic shape templates and parameters are preset, so it is easy to generate a computer-aided design (CAD) model without requiring advanced CAD operation skills. For example, after selecting a row with a standard angle, length, and thickness, a CAD model can be produced with a single click. The CAD model is then output in a stereolithography polygon format, enabling placement simulations, stress analysis, and molding via a 3D printer or an electron-beam melting device.

3.4. Process flow of implant placement

Step-1) Determining artificial hip joint shape

An artificial hip joint placement simulation can be performed in JointVision, and the appropriateness of the morphology can be verified. The suitability of the length, angles, and thickness of the produced artificial hip joint is confirmed visually. If there is a problem, the shape parameters are reset, and the artificial hip joint morphology is re-altered. In the stage resulting from this work, the artificial hip joint is a tailor-made device matching individual body type. In the following steps, detailed checks are performed at the pre-operative planning level.

Step-2) Orientation adjustment for volume image

JointVision can assess CT images from freely movable viewpoints, but the artificial hip joint placement simulation displays the patella from anteriorly, and in the subsequent steps, this is the baseline for the position and angle of the artificial hip joint (Figure 8).

Step-3) Implant selection

If there is a wide gap between the artificial hip joint and cortical bone, there is the possibility that the affixing will become defective. On the other hand, during actual surgery for artificial hip joints that are large compared with the medullary cavity of the sort that necessitates trimming of cortical bone, there is the risk of bone fracture and the possibility of postoperative femoral pain. Therefore, for a cementless stem, the selection of a size that is not too small, not too large, and fits in the medullary cavity is important. Moreover, cementless stems that are slightly too small are generally not problematic.

Step-4) Implant anteversion adjustment

The human femoral neck axis has a 10–30° anteversion angle with respect to the femur-malleolus axis, and the femur head faces anteriorly. For artificial hip replacement surgery, it is necessary to apply an appropriate anteversion angle to prevent dislocation (Figure 9 and Figure 10).

Step-5) Final determination of bone cutting line

The following precautions are necessary to determine the bone cutting line (Figure 11).
1) It is necessary to preserve enough bone stock in the greater trochanteric regions to which the hip abductor muscles attach.
2) The cutting position at the femoral neck is an important point that determines the postoperative leg length, so it is necessary to plan with consideration for the original neck length.

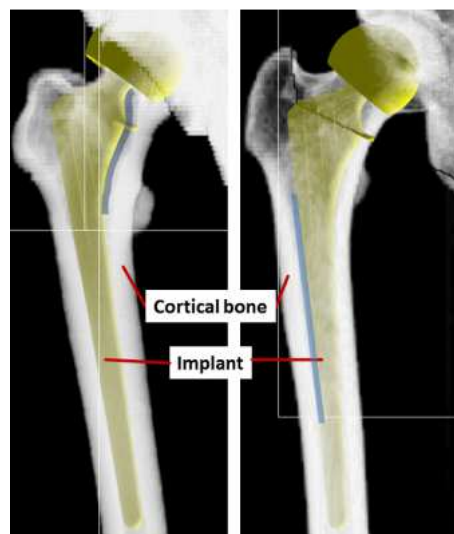**Figure 8 Adjust rotation to achieve the true AP view**

Figure 9 Implant size adjustment

Step-6) Head position and placement

The head is installed at the tip of the stem, but at this time it is necessary to adjust the length by changing the neck size (Figure 12).

Step-7) Socket position and placement

The socket is placed at the acetabular portion on the pelvis side. Socket size is determined in accordance with acetabular morphology, and the installation position is determined in a manner that ensures sufficient bony support of the socket. It is possible to select cement affixing and cementless affixing of surface-finished sockets.
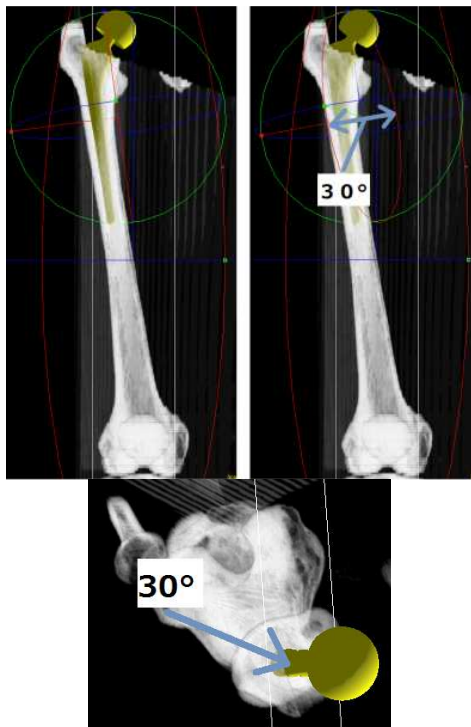
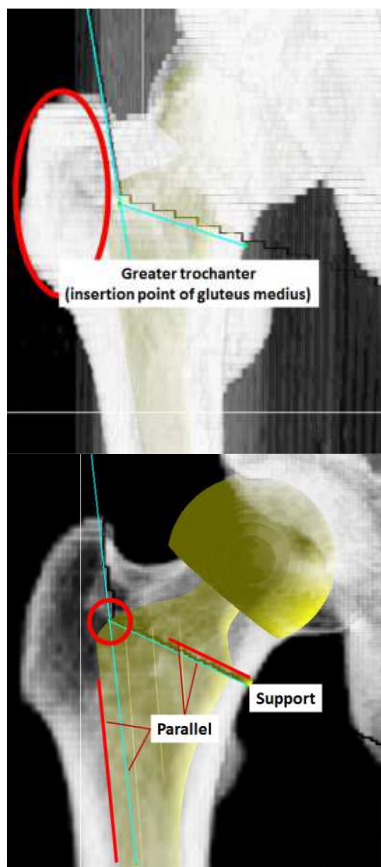**Figure 10 Setting an anteversion angle appropriate for the patient**

Figure 11 Determining bone cutting lines

Figure 12 Checking cap position

4. Stress Analysis for THA

After confirming the installation position and shape by means of an implant installation simulation, it is possible to analyze stress by applying the finite element method in CAD/CAM/CAE software, such as CATIA, SolidWorks, MSC.Patran, and so on. This section indicates the data conversion procedure for reading JointVision format data in CAD/CAM/CAE software.

Step-1) Storing 3D image data
In JointVision, we store 3D image data in a format that retains image position information and cross-sectional image information (in JointVision, this is called the "jvd format"). For example, multiple segmented and moved 3D images are saved with an accurate relative position.

Step-2) Storing positions of the implants and bones
In JointVision, after implant placement, the polygon information for each implant and the affine transformation matrix thereof are output. The affine transformation matrix has the position and angle information for the placed implants.

Step-3) Generating analysis mesh from iso-surfaces
We generate iso-surfaces from 3D images by Volume Extractor, and output them in Step-1). Next, we reduce the number of polygons and padding for the generated iso-surfaces. The iso-surface coordinate system is in the image coordinate system.

Step-4) Placing the implants and 3D image in WC
We apply the affine transformation matrix outputted in Step-2) to the iso-surface data generated in Step-2) and the implant data. The data generated in this step can be used for stress analysis and the posture check.

Volume Extractor was used in Step-3) in order to approximate the 3D image bone portions with polygons and to correct data unconformities arising from noise or

error. The produced polygons are transformed into an analysis mesh by using FreeForm modeling system[8]. Figure 13 is an analysis example of the stem and femur morphology by SolidWorks2011. The element number is 297352, and the number of vertex is 413815. The right figure shows VonMises stress distribution of the cortical bone and the stem. Since our approach has perfect 3D information for bone and the implants, it is easy to simulate several cases before surgery.
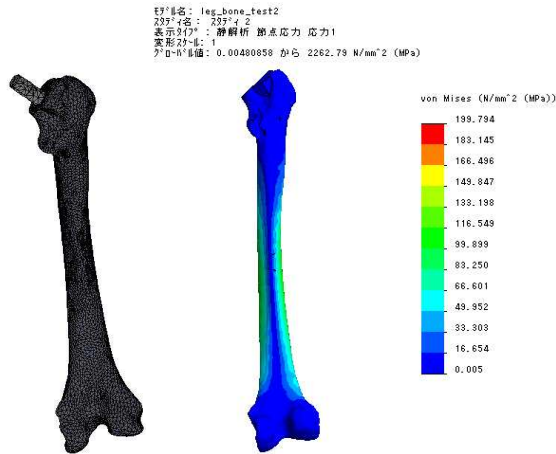

Figure 13 Analysis example

5. Conclusion

To efficiently provide tailor-made hip joints, a system environment was developed that assists the sequence of steps from acquiring CT images of the entire length of the lower limbs to the design, production, pre-operative plan creation, and appropriateness verification of an artificial hip joint shape.

Our 3D-based pre-operative plan assistance system, we called JointVision, was used to subject the artificial hip joint to simulations for determining optimal placement and size. The position information after placement enabled stress simulation. An artificial hip joint was designed and produced with this system by taking advantage of the properties of COBARION (Co-Cr-Mo alloy), an alloy developed by the Tohoku University Institute for Materials Research. COBARION has a higher rigidity than many other metals, and so a cement-type stem was adoped to demonstrate the superiority of the alloy. The Iwate artificial hip joint is tailor-made to match individual body types. In the future plan, we will evaluate the proposed techniques by using several CT images of actual patients.

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