A pre-operative plan assistance system of surgical instruments and metal plates for disease of bone

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Abstract: To efficiently provide surgical instruments and metal plates for treating disease of bone, such as fractures, a 3D-based pre-operative planning system was developed. Our system was used to manufacture tailor-made surgical instruments and metal plates for providing optimal surgery and care. The 3D information of human bone structure was generated by using CT scans. The CAD (Computer Aided Design) systems were used in designing the instruments and plates. In order to verify the shapes and application of them, we utilize computer analysis in the CAD system. The manufactured tailor-made bone plate was used to treat the fractures and the bone deformity of dogs, and observed the post-operative recovery.

Keywords: medical imaging, pre-operative plan assistance system, surgical instruments, bone fracture,

1. INTRODUCTION

In this study, a system was developed for fabrication of custom-fit plates from COBARION alloy and T-ALLOY TOUGH alloy for bone fracture fixation, and its effectiveness was evaluated in an on-site clinical application. COBARION is a value-added Co-Cr-Mo alloy (cobalt alloy) produced in AIWA Ltd. at Iwate prefecture, and the component is shown in Table 1. The metal was a composite material composed of biomedical cobalt-chromium-molybdenum (Co-Cr-Mo) alloy with zirconium (Zr); the alloy was developed at the Institute for Materials Research Laboratory, Tohoku University[1-2].

T-ALLOY TOUGH is a Ti-6AI-7Nb alloy(titanium alloy) produced in GC Corporation. It is manufactured by titanium medical bar, which is called “ASTMF1295”, and the component is shown in Table 2.

In the proposed system, custom-fit plates for repairing bone fractures are fabricated on the basis of pre-operative CT or X-ray (CR) images of the human body. The plates are designed to fixate the bone in a state near the original normal configuration. COBARION is a new value-added Co-Cr-Mo alloy (“cobalt alloy”) with properties that are potentially beneficial for bone plate therapy, but clinical studies (clinical trials) on its implantation for this purpose will be necessary under the Pharmaceutical Affairs Law in Japan. T-ALLOY TOUGH are commonly used for dental plates by the precision casting method. For large bone fracture plates, plates with complex shapes, and prosthetic joint implants, surgery support instruments (DIG), we can utilize several 3D metal printers, such as Arcam A2 3D metal printer, which is an Electron Beam Melting (EBM) machine that manufactured in Arcam Corporation.

The ultimate objective is to apply the system to human bone fracture repair, but it has not yet reached the stage required for clinical studies (clinical trials) under the Pharmaceutical Affairs Law in Japan. In the present study, an evaluation was therefore performed with regard to repair of bone fractures in small animals at the time of surgery, together with observation of the post-operative course.

Table 1. The Components of COBARION

	Co	Cr	Mo	Ni	Mn
COBALION	Bal.	26.3-30.0	5.0-7.0	0.1	<1.0

Table 2. The Components of T-ALLOY TOUGH

	Ti	Al	Nb	Else
ASTMF1295	86.5	6.0	7.0	0.5

2. SCOPE OF STUDY

The bone fracture plates used in orthopedic bone fracture therapy are often pre-fabricated products, and in some cases require bending before attachment by the surgeon. This places an added burden on the doctor and also poses a risk of plate damage and screw hole deformation during the bending process, with consequent problems.

Figure 1 shows the overall process flow for the integrated system for fabrication of custom-fit plates for small animals, which was adapted for use in the present study and is the subject of continuing research and development.[1)] The system utilizes three-dimensional CT images for computerized simulation of bone fracture and deformation repair, and for the design and fabrication of bone plate and prosthetic joint implants that match the bone shape in small animals. The plates are fabricated from

In the present study, the functions shown in Fig. 1 were extended to the design and fabrication of custom-fit plates for (human) bone fracture orthopedic surgery and rehabilitation therapy, and the system was evaluated to confirm its effectiveness. The members in the R&D project included specialists in the fields of orthopedics, veterinary medicine, software engineering, and design support. The outsourcing by the dental technician performed the precision casting on order. The overall effort envisions application of the system to patient specific instruments (PSIs) that can be used in intraoperative planning.

3. Designflow for Tailor-made Plates and Surgical instruments

We previously performed research[3-4] on a preoperative prosthetic joint planning support system (Fig. 1) and 3D image processing in support of preoperative bone extraction from small-animal CT images and planning of bone fracture surgery at Iwate Prefectural University, and the results of that research were applied in the present study.

For the plate design, as shown in Fig. 1, we first extracted the bone region from the patient's CT images and performed a precise triangular approximation of the surface of the bone region. The CT image prepared from the multi-slice images is divided into bone regions and other regions by using the image processing technique of binarization. The binarized bone region is converted into an iso-surface of the bone surface (triangular mesh) through iso-surface processing. These procedures are perfomed by using a comertial software, which is called "Volume Extractor 3.0" of i-Plants System Ltd. [5-6]. Volume Extractor 3.0 is an OpenGL [7] application for Windows OS. At this stage, the bone iso-surface is not defined as a solid model with a strict 3D geometry.

We next applied a CAD system to the approximated bone surface (triangular data) to produce a free-form surface that approximates the bone surface in the plate attachment region. The plate surface curvature was designed by modeling along this free-form surface. Plate design could be performed efficiently by parameterizing the plate length, width, curvature, screw-hole number, and location.

The CAD/computer-aided manufacturing/CAE system used in this study were SolidWorks 2012 and CATIA version 5 by Dassault Systems (e.g., for designing, analyzing the stress between the designed plate and bone surface).After designing the plate, the materials, and the methods for processing and manufacturing the actual plate and screws can be chosen from several options. Here we introduce samples manufactured by molding suitable materials, which include both COBARION and T-ALLOY TOUGH.

Plastic models of tailor-made plates are prepared with a 3D printer (uPrint SE, Stratasys Inc.), and the model material is acrylonitrile-butadiene-styrene resin, and the layer thickness is 0.254 mm (0.01 in).

We utilized a vacuum-pressure casting machine (Heracast iQ, Heraeus Ltd.). The metal plates were cast and fabricated from COBARION (Co-Cr-Mo alloy) and T-ARROY TOUGH, and then used in the surgical procedures, which resulted in successful bone fracture therapy. The postoperative course of rehabilitation for a dog with bone deformation due to rheumatism was also observed through recovery.

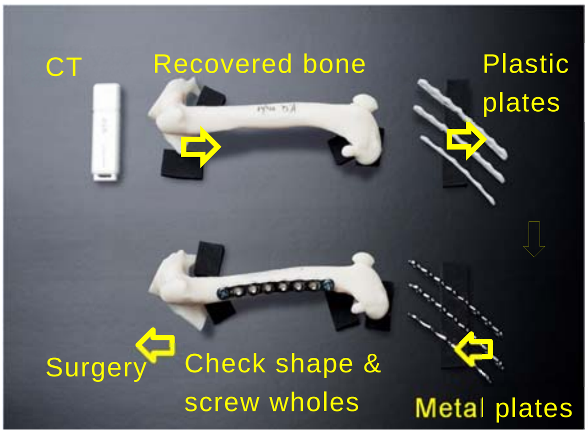

Fig. 1. Design and Manufacturing Flow

The method for production of the recovered bone model begins with extraction of the bone fracture region from CT images, and recovered the bone fractures by cut/past operations interactively. All operations are done by mouse, and in order to define the cutting plane in 3D space, we have utilized a directed line, we called "STROKE".

In order to manipulate 3D image components, we have developed a 3D-based pre-operative planning system, which is called "JOINTVISION" [8]. In this system, we use a texture-base volume rendering technique using OpenGL and GPU(Graphics Processing Unit). All volume images are displayed as 3D texture data on GPU memory. The recovered 3D images are approximated in the triangular polygons.

The SolidWorks 3D CAD system was used to read in the polygons and generate the bone surface (free-form surface) in the plate attachment region. Fig. 2 shows the surface regions on the repaired bone surface specified by the user through painting. It shows B-spline surface generation on the bone surface, where an optimized tailor-made plate is designed by adjusting the curvature of the plate on the bone iso-surface.

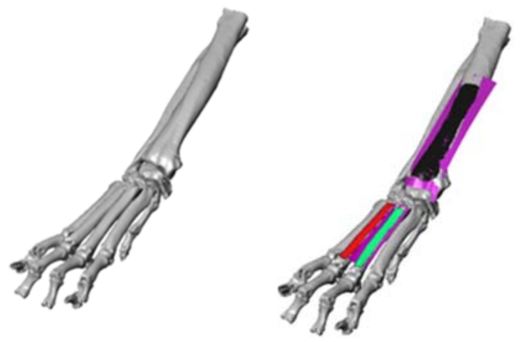

Fig. 2. An Example of Surface Functions

The bone fracture plate was designed to conform to this surface, together with the screw holes. Fig. 3 shows the feature of surface modeling at SolidWorks. The purple surface approximates bone polygons. This function is very useful to design a bone plate, since the surface is mathematical surface in comparison with polygons of bone surface.

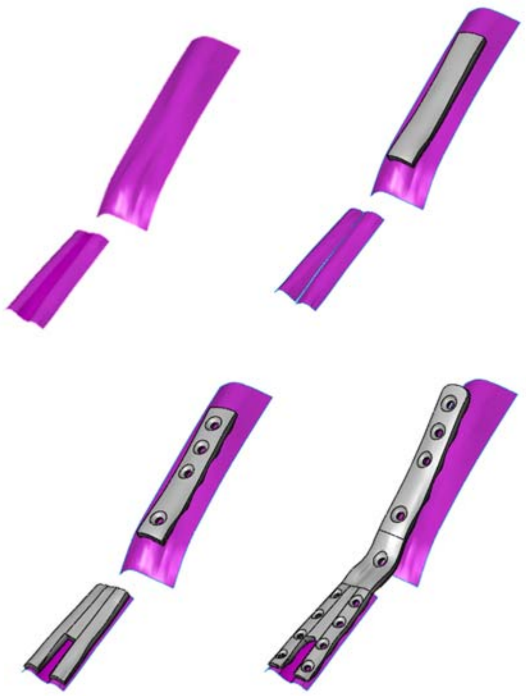

Fig. 3. Surface Function of SolidWorks

Fig. 6 shows the configuration of the bone fracture plate holes. The back side of the plate was given an irregular surface in order to maintain blood flow at the bone surface. Fig. 7 shows the opposite side of the bone plate.
Fig. 8 shows the difference between COBARION and T-ALLOY TOUGH. The base-model of 3D printer (ABS resin) is the same. Since T-ALLOY TOUGH is a titanium alloy, it is soft and difficult to cut, press-molding, and welding in comparison with COBALION.

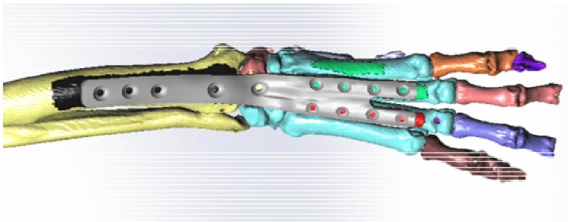

Fig. 4. Final Check for tailor-made bone plate

Fig. 5. Tailor-made metal bone plate (COBARION)

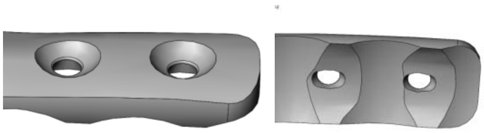

Fig. 6. An Example of the bone fracture plate holes

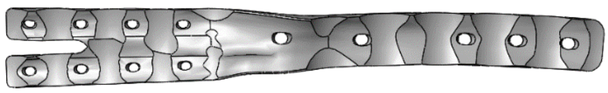

Fig. 7. An Example of the opposite side of bone plate

Fig. 8. Examples of tailor-made metal bone plates(COBARION, ABS resin, and T-ALLOY TOUGH(back, front side))

Fig. 9 and Fig. 10 shows the human bone model and tailor-made surgical instruments, respectively. The plastic guide was created by using 3D printer, and disinfected, and used in the surgery at the hospital. The human bone model was extracted by Volume Extractor 3.0. The surgical instruments is used to induce the screw in order to fix the bone of spine. The surgical instruments was designed by Geomagic Freeform software.

Fig. 9. An Example of human bone model

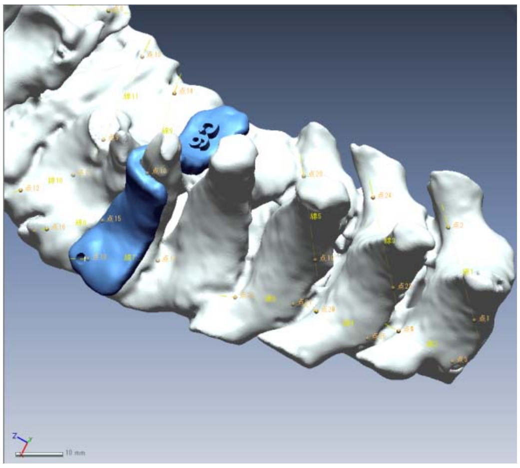

Fig. 10. An Example of tailor-made surgical instruments

4 Conclusion and Further Development

The research and development described here has established an integrated system for the production of 3D models from CT images, and the fabrication of actual COBARION and T-ALLOY TOUGH plates for bone fracture therapy. The ultimate objective is the application of the system to human bone therapy. The evaluation described here, however, was performed for animal bone fracture surgery since the system has not yet received approval for clinical studies (clinical trials) under the Pharmaceutical Affairs Law in Japan. In Europe and the U.S., in contrast, the application of custom-fit plates and custom surgery support instruments is relatively advanced [9]. Related system commercialization and legal revisions are therefore expected, and the prospects are clear for COBARION pharmaceutical approval and commercialization. It will also presumably be necessary to obtain approval for the software used in the proposed system. The dog in Fig. 5 has recovered to the healthy state that can be walking. The bone is fixed, and there is no shift in the tailor-made plate and the deformed bone.

At present, however, very few small animal hospitals are equipped with CT systems. For widespread adoption, it will therefore be necessary to develop technology for converting X-ray images to 3D data to allow modeling of bone shapes in human and animal fracture regions and fabrication of plates based on that information.

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