ON A DESIGN METHOD OF COMPOSITE STEM BASED ON CT IMAGES

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ABSTRACT

Although Total Hip Replacement (THR) is an effective remedy for serious hip diseases, the lack of mechanical biocompatibility is a serious problem because its high rigidity causes stress-shielding to bone. Composites attract attentions as an alternate material to metal for stem. As the rigidity is treated as a design parameter, the tailor-made composites stem could be possible to reduce the stress shielding. In this paper, a design system for tailor-made composites stem has been described.

A design concept of composites stem has been proposed, and a tailor-made design system has been described based on the concept. Finite element analyses of 3 types of composites stems and a traditional metal stem which are same shapes have been carried out and the benefit of composites stem has been cleared. A composites stem has been fabricated and an *in-vitro* test has been also carried out with a femur specimen as a verification of the design system. As a result, it is revealed that the proposed design system is verified because the result of numerical analysis had good agreement with the result of *in-vitro* test.

1. INTRODUCTION

The number of patient of bone fracture is increasing year after year, e.g. there are 1.3 ~ 1.7 million hip fracture patients at 1990 in the world, and it is estimated that the number of patients will be 3 million until 2025 [1]. Total Hip Replacement (THR) is an effective remedy for serious hip-diseases. Although THR is a conventional treatment, the lack of mechanical biocompatibility of the stem is a serious problem. Figure 1 shows a typical example of X-ray images of healthy and operated femur, and b) in Fig.1 shows bone atrophy at proximal medial part of femur due to a high rigidity of stem causes 'stress-shielding' which suppresses bone remodeling [2, 3]. Figure 2 shows a comparison of elastic modulus of bone and typical materials for stem. This is the reason that conventional metal stem does not completely suite for hip-disease patients.

a) Intact femur b) Femur with THR

Fig1 Typical examples of X-ray image of hip disease patient.

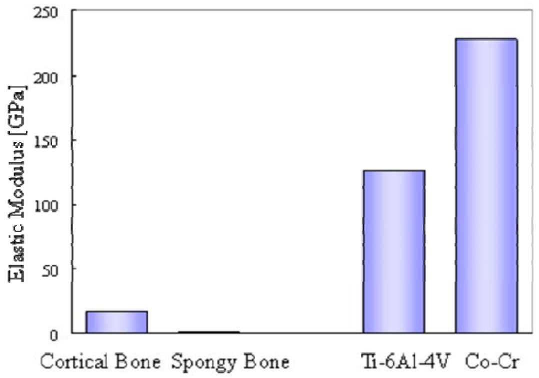


Fig 2 Comparison of elastic modulus of bone and typical materials for stem.

Composites attract many attentions as an alternate material to metal for stem. A tailor-made composites stem may be possible to reduce the stress-shielding because the rigidity of composites can be treated as a design parameter. However, it is necessary for tailored stem to get the shape and the mechanical property of femur, since there are variations among individuals in shape and mechanical property of femur. It is very important for the tailor-made composites stem with robustness to accumulate the design information on mechanical properties of many femurs.

The purpose of this study is to establish a design system for tailor-made composites stem. In this paper, a design system of composites stem using computed tomography (CT) images has been described. Finite element modeling procedure of femur and stem has been developed and the mechanical property of bone has been identified by using CT images. Numerical analyses have been carried out in composites stem and metal stem models, and the numerical results have been verified by *in-vitro* test using composites and metal stems.

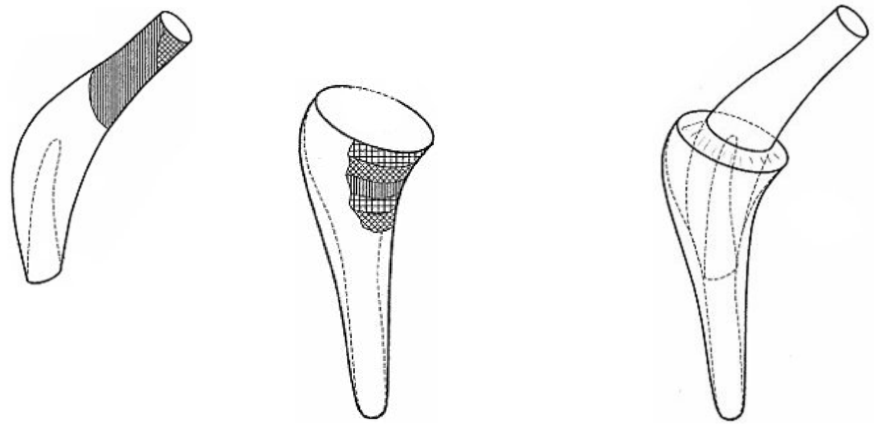
2. COMPOSITES STEM AND ITS DESIGN SYSTEM

2.1 Composites stem

We have lots of stems which are made from composites e.g. a stem cutting out from uni-directional (UD) laminate [4-7], a multilayer composites stem [8] etc., but these are not applicable because of lack of torsional rigidity and strength, and less of design variation. Although Adam et al. [9] have tried 51 clinical studies on anatomically shaped composites stem, aseptic loosening has been occurred in 47 cases in 6 years after operation due to lack of shape compatibility and surface property of the stem. From there cases, it became clear that the following points are important for composites stem.

1. Compatibility of the outer shape
2. Appropriate mechanical property in axial and torsional direction

Figure 3 shows a schematic drawing of CF/PEEK composites stem that have been proposed to grantee the above two points by authors. The stem is consisted of 2 components, which are *main-spar* and *outer-skin*, and joint together with injected resin. The main-spar is made of UD of CF/PEEK to carry loads from head. The outer-skin is made of carbon fabric PEEK composites and designed to fit the femoral medullary canal so that shear load can be transferred without high stress spot.



a) Main-spar b) Outer-skin c) Joint together with injected resin

Fig 3 Schematic diagrams of proposed composites stem.

The composites can solve various problems mentioned before. The composites stem is molded to each patient so that the compatibility of shape is achieved. Since the stem has a space inside of the stem and the section area decreases along to the longitudinal axis. The rigidity is able to be designed by changing the inner-structures. Additionally, the fiber direction of the outer-skin is $\pm 45^{o}$ along the longitudinal axis of the stem so that the torsional rigidity is able to be designed.

Consequently, the proposed composites stem can reduce stress-shielding. These things had been confirmed by numerical analysis [10].

2.2 Design system for composites stem

The shape and the mechanical property of individual femur are required in order to make the stem tailored. The X-ray CT image is available for these requirements, because it will take the image before a replacement surgery.

A stem which has compatible shape is able to be designed by using 3D geometry acquired from CT images [11]. Not only the shape of femur but also the mechanical property is able to acquire from CT images, because the pixel values of X-ray CT image (CT value) reflect the density. The bone density and the elastic modulus have been measured by X-ray CT and the mechanical test on femoral specimen, respectively. From these results, the relation between the bone density and the elastic modulus has been investigated [12].

Using above technical information, the design system for the individual femur has been developed. The stress-shielding on the femur and the strength for stem are evaluated by the results of numerical analyses [10, 13]. The flowchart of the design system is shown in Fig 4.

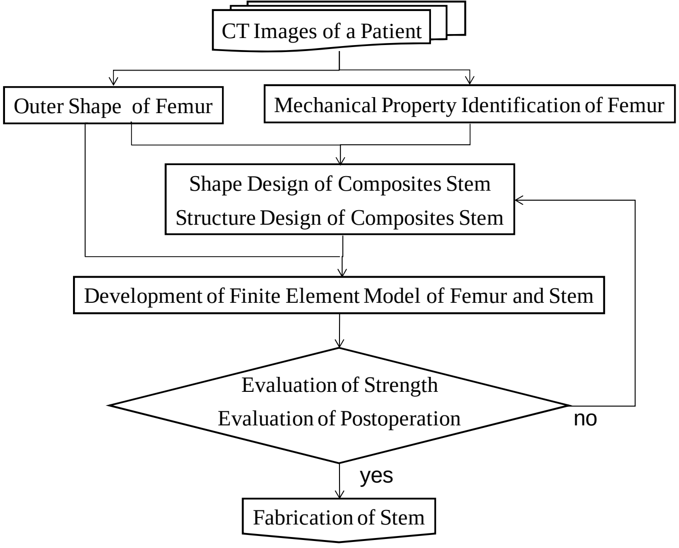


Fig 4 Flowchart of a design system for composites stem.

3. DESIGN AND NUMERICAL ANALYSIS

3.1 Design and modelling

As an application of the proposed system, a tailored composites stem for a femur (a desiccated dead femur) has been designed. An outer shape of stem has been designed by using CT images of a femur. 3 types of composites stem as shown in Fig.5, which have the same outer-shape and have different inner-structures have been designed. The short type has shorter main-spar, the middle type has longer main-spar, and the long type has no space in main-spar. Hence, the short type has the lowest rigidity and the long type has the highest rigidity in these 3 stems. According to FEM analyses for these stems, the effect of the rigidity of stem on the bone is able to make clear.


a) Short type b) Middle type c) Long type

Fig 5 Schematic diagrams of the designed composites stems

In order to evaluate differences of the stem’s design, strain energy density (SED) is utilized as an evaluation index for stress-shielding because it is reported that SED is an influential factor of bone remodeling phenomenon [14, 15]. Therefore, a high SED at the femur suppresses stress-shielding and promotes bone remodeling, while a small SED promotes stress-shielding and suppresses bone remodeling. SED $U(\varepsilon_l, \varepsilon_t, \ldots, \gamma_{lt})$ is calculated by following equation.

$$U(\varepsilon_l, \varepsilon_t, \cdots, \gamma_{lt}) = \frac{1}{2}\{\varepsilon_L\}^T[\mathrm{D}]\{\varepsilon_L\} = \frac{1}{2}\{\varepsilon_L\}^T\{\sigma_L\} \tag{1}$$

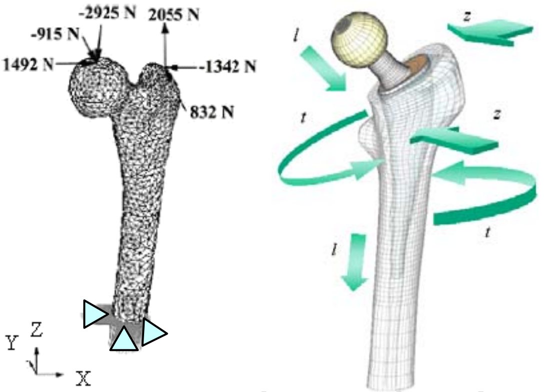
$$\{\varepsilon_L\}^T = \{\varepsilon_l \quad \varepsilon_t \quad \varepsilon_z \quad \gamma_{tz} \quad \gamma_{zl} \quad \gamma_{lt}\}$$

$$\{\sigma_L\}^T = \{\sigma_l \quad \sigma_t \quad \sigma_z \quad \tau_{tz} \quad \tau_{zl} \quad \tau_{lt}\}$$

where, $\{\varepsilon_L\}$ is strain vector, $\{\sigma_L\}$ is stress vector and [D] is stress-strain matrix, respectively. SED of cortical bone of the femur with the 3 composites stems and traditional metal stem which has the same outer-shape have been calculated. The mechanical properties in the numerical analysis are shown in Table 1, and the boundary condition and material coordinate system of orthotropic materials are shown in Fig 6. Fig 7 shows the FEM model which has been generated from CT image. The material property of bones has been obtained by using CT images as shown in Figs 8 and 9.

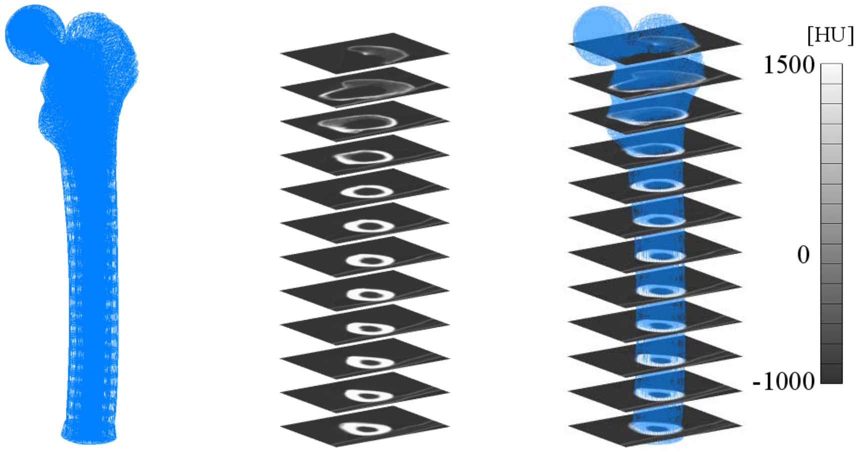
Table 1: Mechanical properties.

Constants		*CFRP (UD)*	*CFRP (Fabric)*	*Ti-6Al-4V (Metal Stem)*	*PEEK*	*ZrO_2 (Head)*
E [GPa]	*l*	150	117	126	4	255
	t	9.81	117			
	z	9.81	9.8			
G [GPa]	*tz*	1.43	5.49	49.6	1.3	98.1
	zl	5.49	5.49			
	lt	5.49	6.08			
ν	*tz*	0.4	0.34	0.27	0.4	0.3
	zl	0.022	0.029			
	lt	0.34	0.05			



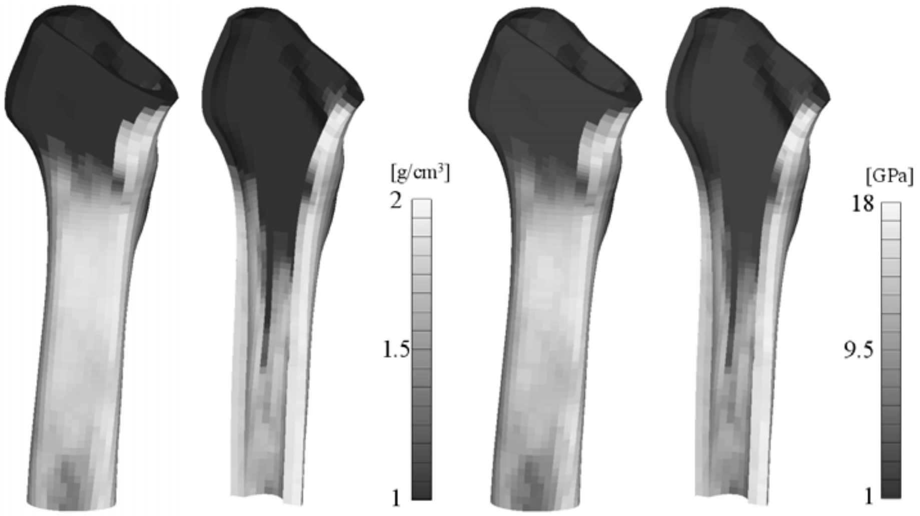
a) Boundary condition b) Material coordinate systems

Fig 6 Finite element model of stem and femur



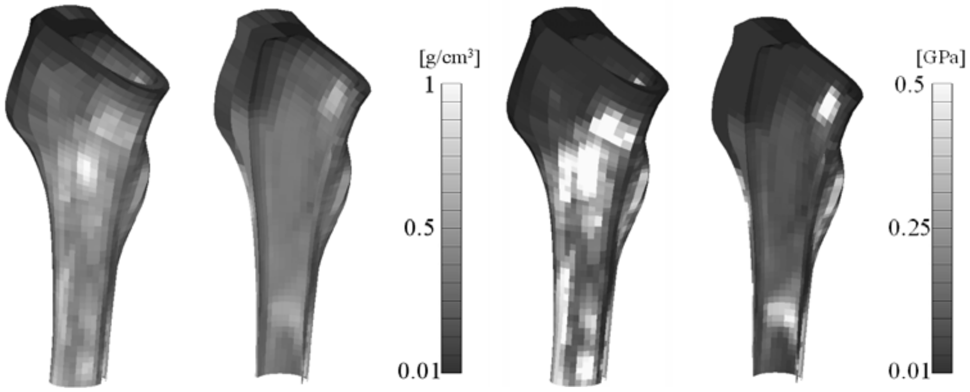
a) Finite element model b) CT image c) Superimposed diagram

Fig 7 Schematic diagrams of finite element model on CT images



(a) Apparent density (b) Apparent density (cross section) (c) Ei (x=0) (d) Ei (x=0) (cross section)

Fig 8 Distributions of modulus of elasticity obtained from CT images for cortical bone



(a) Apparent density (b) Apparent density (cross section) (c) Ei (x=0) (d) Ei (x=0) (cross section)

Fig 9 Distributions of modulus of elasticity obtained from CT images for cancellous bone

3.2 Numerical results

SED distribution at medial femur along the longitudinal direction is shown in Fig 10. The horizontal axis indicates the position in the longitudinal direction of femur, i.e. left side represents the proximal part on femur and right side represents the distal part on femur, respectively. X=75mm represents the tip of the stems. SED in the cases of composite stems are higher than the metal stem. Therefore, it is recognized that a composites stem will reduce stress-shielding compared to a metal one. Comparing the 3 types of composites stems, it is observed that there are differences in SED distribution. A low rigidity stem can prevent stress-shielding and can promote bone remodelling. It indicates that the distributions of SED can control by the design parameters like the rigidity of stem.

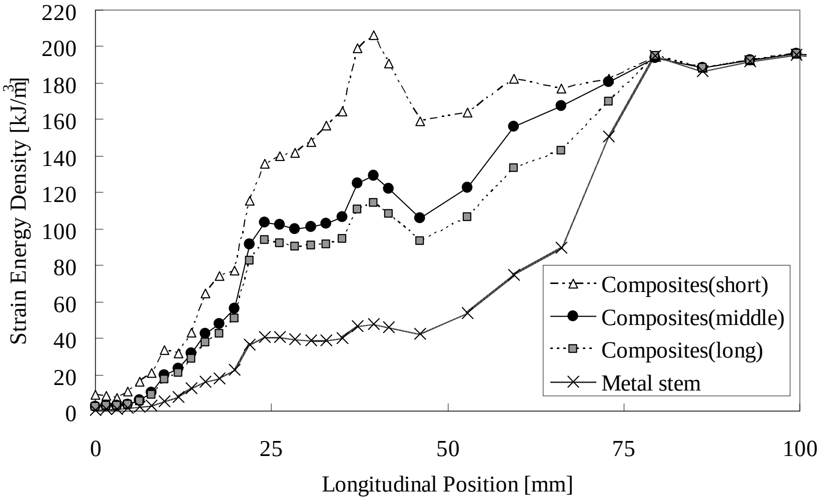


Fig 10 SED distribution for medial femur (cortical bone).

4. VERIFICATION OF NUMERICAL RESULTS

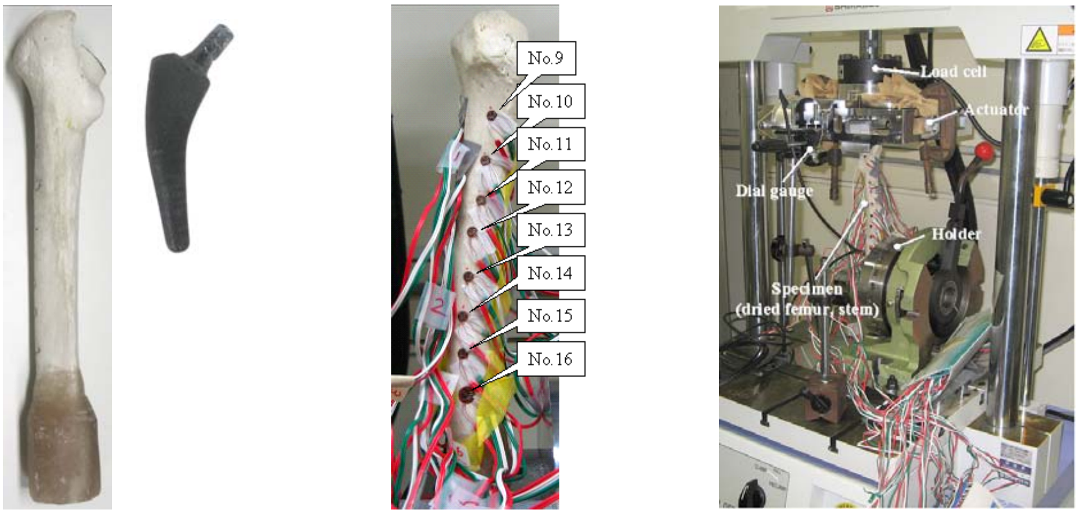
4.1 Fabrication and *in-vitro* test

A composites stem designed for a femur which has been taken from a human body (shown in Fig 5(a)) has been fabricated. The stem has been inserted to the real femur, and *in-vitro* compression test has been performed with a testing machine (Shimadzu Servopulser EHF-LB10kN-4LA). Rosette gauges are put on the femur. The specimen holder is designed to enable to set specimen at any angle in order to carry out tests under the different loading angles. The actuator has a moving unit to release horizontal loads to the load cell. Dial gauge is set at the side of the actuator to measure the horizontal displacement of moving unit. The fabricated stem, position of strain gauges and *in-vitro* testing apparatus is shown in Fig 11. The distal tip of the femur has been reinforced with GFRP sheet in order to prevent the fracture by grip as shown in Fig 11(a).

4.2 Experimental and numerical result

Compressive load has been applied to the head of stem by displacement control. Strains at 16 points have been measured by rosette gauges. However, the data of gauge No.1 has been removed due to the bad surface condition. Principal strains at 15 points have been calculated from strains in 3 directions measured by each gauges.

Finite element analysis of the *in-vitro* test has been performed in order to verify appropriateness of the proposed design system. The surface of the gripper of femur specimen model has been constrained. Applied axial displacement and measured horizontal displacement have been applied on the head of femur specimen model. Principal strains at 15 points correlate with the positions of strain have been calculated from the result of numerical analysis. Finite element model of the femur specimen and boundary conditions on the model are shown in Fig 12.



a) Femur specimen reinforced with GFRP and fabricated composites stem

b) Strain gauges on the specimen

c) *In-vitro* test apparatus

Fig 11 Test specimen and the testing apparatus:

A comparison of principal strain of the experimental and numerical results is shown in Fig 13. The horizontal and vertical axes indicate the experimental and numerical strains. As shown in Fig 13, the numerical results have good agreement with the experimental result.

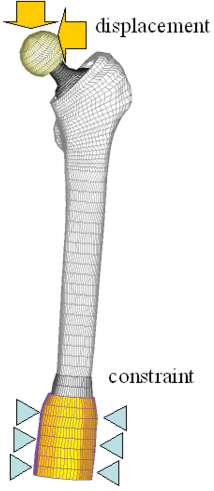


Fig 12 FEM model of the specimen.

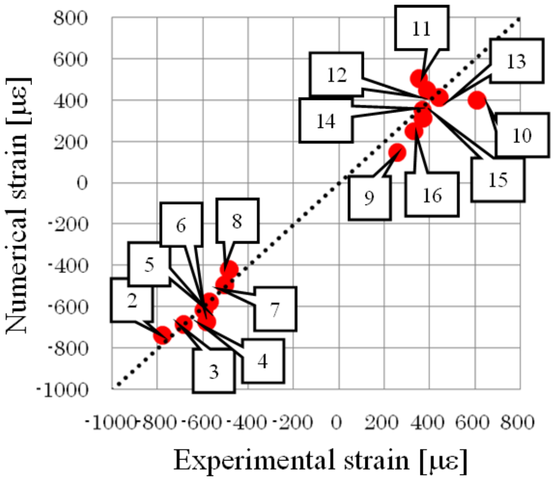


Fig 13 Comparison of the experimental and numerical principal strain.

5. CONCLUSIONS

A design system for tailor-made composites stem has been proposed and the advantage points have been described with the numerical results of FEM. A composites stem for a femur which has been taken from a human body has been designed and been fabricated. The stem has been inserted to the femur, and the *in-vitro* compression test has been performed with a testing machine. From the results of numerical analyses and experiment, it has become clear that the composites stem is able to reduce stress-shielding comparing to traditional metal stem. It has been recognized that the numerical result based on proposed deign system has verified by the *in-vitro* test because the numerical and the experimental results have agreed well.

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