Design of Composite Hip Prostheses Considering the Long-Term Behavior of the Femur*

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A design method for the hip prosthesis is proposed which can alleviate problems associated with stress shielding, proximal loosening and the high stress of bone-implant interfaces after total hip replacement. The stress shielding which may lead to bone resorption, can cause a loosening of the stem and a fracture of femoral bone. Generally the composites were more suitable for hip prosthesis material in the long-term stability than metallic alloy because design cases of composite materials produced less stress shielding than titanium alloy. A bone remodeling algorithm was implemented in a nonlinear finite element program to predict the long-term performance of the hip prosthesis. The three neck shapes and three cross sections of composite hip were examined. It was found that the stress concentration in the distal region of the titanium stem which may cause the patient's thigh pains was reduced using composite material. The head neck shape was closely related with the cortical bone resorption and the cancellous bone apposition at proximal region whereas the cross-section was closely related with the relative micromotion between interfaces. The convex head neck type with the quadrangle cross-section produced less subsidence at proximal region on the medial side than the others. For all composite material cases, the cancellous bone apposition occurred at partial interfaces, which may result in a stable bio-fixation. The design performances of the convex neck head type with the hexagonal cross-section designed to insure the long-term stability were found to be more suitable than the others.

Key Words : Hip Prosthesis, Finite Element Analysis, Composite Materials, Bone Remodeling, Micromotion, Long-Term Stability

1. Introduction

After total hip replacement (THR) without cement, the loosening and the stress shielding effects on the femoral bone are major clinical problems^{(1),(2)}. They can lead to bone failures and cause clinical pains. Especially, the stress concentration between the prosthesis and bone is a common phenomenon at the proximal and distal edges⁽³⁾. Thus, the non-uniform stress distributions of cancellous bone have a bad influence upon the fixation stability that is caused by the micromotion and migration of the hip stem. The attempts to avoid the above problems have led to numerous implant design variations which include alteration with geometry and material properties of the hip prosthesis. Lately, the shape and stiffness optimization of the stem to reduce the bone resorption has been reported, and the cementless stem has been suggested to support the stability of the fixation⁽⁴⁾⁻⁽⁶⁾. The loosening and the stress shielding effects, which can be adjusted by the variable stiffness design and the conceptual shape-redesign, have been also investigated⁽⁷⁾. It is generally agreed that composite materials are better than metallic alloys because the stiffness of the composite stem can be altered even by changing the ply orientations without the geometry changes⁽⁸⁾.

The finite element analysis has been widely used to evaluate the design performance of the hip stem

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made of composite materials^{(9)–(12)}. In order to analyze the layered composite hip stem, it requires a layered brick element and the ply-drop-off along the element edges so that the complicated three-dimensional bone-structure can be modeled using CT data. A nonlinear finite element method which can analyze bone remodeling around cementless stem has been used to predict the behavior of the bone/stem interface^{(4),(5),(13)–(16)}. In this study, the behavior of the treated femur with the composite prosthesis or titanium alloys was analyzed using the developed nonlinear finite element program with a bone remodeling algorithm.

In order to ensure the high success rate of THR, the prediction of the long-term behavior of the treated stems using computer simulations is essential (*in vivo* simulation). Therefore, in order to evaluate design performances of composite stems designed to insure both the initial bio-fixation and the long-term stability, a study should be performed with various design parameters.

The cross sections and the neck shapes of composite stems are very important design parameters. In this study, we consider three cases of neck shapes, i.e., the convex, right angle and slope in the composite stems, and examine the stress shielding and loosening at the proximal region of the femur. The convex type was modeled similarly to the shape of intact femur, the right angle type similarly to the shape of commercial type. The slope type was modeled by referring other studies^{(1),(6),(13),(16)}. In addition, in order to predict the effects of bone remodeling and stem movements within the bone from proximal to isthmus region, the three cases of cross sections such as ellipse, hexagonal and quadrangle types were modeled after commercial product shapes⁽¹³⁾. The design performances for each case were evaluated, and the long-term stability of the treated femur was then analyzed.

2. Material and Methods

A Total Hip Arthroplasty (THA) reconstruction composed of a cementless stem, a cortical bone, and a cancellous bone surrounding the stem are shown in Fig. 1, and a model for the three-dimensional finite element analysis (FEA) was generated. The geometry of the femur was obtained from CT-scan data of the femoral bone of a right human femur. The intact femur model consisted of 2,128 eight-node iso-parametric brick elements and 7,308 nodes, and the finite element model for the artificial hip prosthesis consisted of 1,936 elements and 6,588 nodes. The three-dimensional model was composed of ten segmental parts. In order to analyze the complicated geometry of a unidirectional composite stem, an eight node

Fig. 1 Three dimensional model of an artificial hip joint with the applied loadings used; the treated femur with a hip stem (left), a cancellous bone (center), a composite hip stem (right). The square boxes represent loading or viewing points.

layered brick element that has the multi-layered ply-drop-off along the element edges was used⁽¹⁰⁾.

The composite stem is fabricated by stacking layers, and each ply thickness is about 0.13 mm. The AS4/PEEK composite materials is used, and the material properties are as following⁽⁹⁾; Young's moduli E_1 and E_2 were given as 134 GPa and 8.9 GPa respectively, Poisson's ratio ν_{12} as 0.3, and shear moduli G_{12} and G_{23} as 5.1 GPa and 3.47 GPa. A titanium alloy was also considered, and its Young's modulus and Poisson's ratio are given as 117 GPa and 0.3, respectively. We selected the bend mold for the composite stems^{(10),(16)}, which involved a fabrication of a thick curved composite panel onto a mold, followed by cutting and machining the panel into a hip prosthesis.

The design cases and their dimensions are shown in Fig. 2. Three types of neck shapes, i.e., *slope*, *right-angle*, and *convex* types, and three types of cross-sections, i.e., *ellipse*, *hexagon*, and *quadrangle* types, are taken into consideration. Total of eight cases, each denoted by A – H, are analyzed which combine the different neck shapes, cross-sections and materials (see Table 1). The cases A – G use AS4/PEEK composite materials while the case H uses the titanium. The past investigators considered the femoral head offset (FHO) and the neck shaft angle (NSA) as design parameters⁽¹³⁾. However, for the simplicity of the design cases in this study, we used the average standard data for Koreans, i.e., 43 mm for the FHO and 132° for the NSA⁽¹⁷⁾. The cross-sections of the hip stems at the 160 mm height from the distal tip of the stem are presented in Fig. 3. The cross-sectional shapes of the distal region and the head-acetabulum connection region are circular, but in the middle and

Table 1 Materials, neck shapes, and cross sections for the cases A - H (see Fig. 2)

Cases	Material	Neck Shape	Cross-Section
A	AS4/PEEK	slope	ellipse
B		right-angle	
C		convex	
D		slope	hexagon
E		convex	
F		slope	quadrangle
G		convex	
H	Titanium	slope	ellipse

Fig. 2 Three different cross sections and three different neck head shapes for the hip prosthesis considered in this study

Fig. 3 Cross sectional view at 160 mm height from the distal end of the stem

proximal region (height range of 100 - 181 mm). Three cross-sections are modeled based on the same area. Only quadrangular cross-section has narrower width and longer length along medial-lateral direction than others.

In this paper, the collarless and cementless hip prostheses are considered. The interfaces between the prosthesis and cancellous bone are assumed to be perfect and full bonding, which means no gap and slippage are allowed at the interfaces. It is also assumed that the bonding condition is maintained

Table 2 Locations and magnitude of the hip contact and muscle forces

Force(N)	Component of location			-Fx (N)	-Fy (N)	-Fz (N)
	X (mm)	Y (mm)	Z (mm)			
Hip contact	41.6	0	204.9	-215	-91	-1234
Abductor	-24.4	-8.8	167.5	243	37	366
Tensor Fascia Proximal Part	-24.4	-8.8	167.5	5	10	10
Tensor Fascia Distal Part	-24.4	-8.8	167.5	0	0	-16
Vastus Laterals	-14.62	-5.6	119.5	0	32	-156

until the end of bone remodeling process. After THR, the joint and muscle forces taken from the data of Davy et al. and Duda et al.^{(18),(19)} These forces take into consideration the body weight of 55 kg with a single leg stand, acting around the joint of the proximal femur. We calculate the applied forces from data presented by Duda et al.⁽¹⁹⁾ The locations and magnitudes of them are presented in Table 2.

3. Bone Remodeling Theory

A bone remodeling theory is taken into consideration in the analysis of the long-term behavior of the femur. The apparent density of bone tissue in a remodeled state was approximated by the relation^{(15),(20)}:

$$\rho = K \left(\sum_{i=1}^{LC} n_i \bar{\sigma}_i^m \right)^{1/2m} \quad (1)$$

where LC denotes the daily number of the discrete loading conditions, the subscript i a specific loading condition, n a number of loading cycles, $\bar{\sigma}$ a continuum level effective stress, ρ a bone apparent density, and K, m the empirical constants. The daily bone tissue level stress stimulus is dependent on the intensity of the stress and the number of cycles for each loading case. The daily tissue level stress stimulus S_b is then defined as^{(14),(15)}:

$$S_b = \left[\sum_{day} n_i \bar{\sigma}_{bi}^m \right]^{1/m} \quad (2)$$

where $\bar{\sigma}_{bi}$ is a true bone tissue level effective stress. Equation (2) can be rewritten in terms of a daily stress stimulus measured at the continuum level, $S^{(14),(15)}$:

$$S = \left[\sum_{day} n_i \bar{\sigma}_i^m \right]^{1/m} \quad (3)$$

where $\bar{\sigma}_i$ is the continuum level effective stress:

$$\bar{\sigma}_i = \sqrt{2EU} \quad (4)$$

where E is the continuum average elastic modulus and U is the continuum model strain energy density.

Combining Eqs.(1), (2), (3) and (4) yields

$$S_b = (\rho_c / \rho)^2 S \quad (5)$$

where ρ_c is the saturated cortical bone density, and ρ the apparent density.

To determine the apparent bone density according to the time history, we use the formula suggested by Carter and Hayes⁽²¹⁾:

$$E = C\rho^\alpha \quad (6)$$

where α and C are experimental constants. An average elastic modulus is then calculated for each bone element in the femur. It is assumed that the bone is isotropic and has a uniform density. Those uniform density values are initially applied to cortical bone and cancellous bone, as shown in Table 3⁽¹⁴⁾. The amount of the stress shielding, called the tissue level bone remodeling error, is calculated by

$$e = S_b - S_{ref} \quad (7)$$

where S_{ref} is the reference stress signal. The reference stress signal can be obtained from an intact femur under the given force conditions, and the tissue level stress signal is calculated from the treated femur under the same force conditions^{(15),(22)}. The relation between the rate of the surface bone remodeling and stress stimulus for femoral bone is assumed to be piece-wise linear^{(20),(23)–(25)}.

A nonlinear three-dimensional finite element program has been developed which include the bone remodeling theory. The material nonlinearity resulting from the bone remodeling was considered using eight nodes brick element driven from strain-displacement relationship of bone^{(13),(16)}. In the present study, in order to calculate the bone surface area density, we use an approximate 3rd order polynomial function of a surface area density adapted from Martin because the internal and external bone remodeling takes place on the bone surfaces^{(24),(26)–(29)}. The bone remodeling procedure is iterated with a constant time step as shown in Fig. 4. The bone remodeling constants used

Table 3 Bone remodeling constants used in this paper

Material properties	value
Stress exponent	3
Experiment constant	3000
Minimum density	0.01g/cm ³
Maximum density	2.0 g/cm ³
Fully mineralized density	1.92g/cm ³
Width of dead zone	35%
Slope of rate remodeling curve	2x10 ⁻⁵ mm/MPa/day
Initial density of cortical bone	1.8 g/cm ³
Initial density of cancellous bone	0.5g/cm ³

in the simulation are summarized in Table 3^{(5),(14),(15),(21)}. This procedure is executed, in every time step, by using the finite element program with material nonlinear algorithm⁽¹³⁾.

4. Results

We analyzed the long-term behavior of the femur according to design cases. Mostly, we focused on reducing stress shielding and micromotion to maintain the long-term stability.

As shown in Fig. 5(a), for the hip prosthesis of composite materials, the amount of bone resorption on the surface of cortical bone at proximal region could be diminished after five years. Thus, the area of bone resorption for the case A with bend mold [0] n was smaller than titanium because the stiffness of the bend mold stem was more flexible than the titanium stem. It was shown that the contour of cortical bone resorption for the case A was not symmetrical, caused by the material flexibility with a stacking direction. For all design cases, the density changes in the cortical bone along the medial side after five years were presented in Fig. 5(b). The bone resorption for the case H at the proximal region was bigger than the others. The cases A, B and C with the ellipse section and the cases D and E with the hexagonal section showed less bone resorption than the cases F and G with the quadrangle section. Especially, it was noticed in the case F that the cortical bone resorption

Fig. 4 Flow chart for the bone remodeling in a finite element

(a) Bone resorption of the cortical surface at proximal region according to stem materials after 5 years

(b) Density changes in the cortical surface at proximal region along the medial side according to design cases after 5 years

Fig. 5 Density changes in the cortical surface according to design cases after 5 years

showed higher value (about 5%) than other composite stems. Thus, the head neck shapes except quadrangle section did not affect the cortical bone resorption. But the cortical bone resorption for five years produced little difference regardless of the composite design cases.

Figure 6 showed the comparison of the relative micromotion at the proximal end (point a) according to the design cases. This value was calculated from the difference of each directional displacement between a node of stem and a node within cancellous bone, located on a median point of the cancellous bone thickness at the proximal end. For the cases A, B and C (elliptic cross-section), the total relative micromotion gradually increased and completely converged into a range of about $10 \mu\text{m}$ even though they showed big variances in the early stage. Thus, the elliptic

Fig. 6 Changes of the relative micromotion at a proximal node "a" for five years

cross-section showed the poor long-term stability, and the larger relative micromotions may cause the subsidence and migration. For the case of titanium alloy stem, the micromotion showed little variances in the early stage, and converged to about $9 \mu\text{m}$ in five years. Thus, the initial stability was good, but the long-term stability was not suitable since movements were increased. In the case D, it increased from $4 \mu\text{m}$ to $7 \mu\text{m}$, and in the case E it converged to $4 \mu\text{m}$. For the case E, it was noticed that the variation of u_{total} was within only $1 \mu\text{m}$. For the cases F and G, it increased from $2 \mu\text{m}$ to $3 \mu\text{m}$ in the early period, and then a small variation was observed afterward. It was reported that the loosening could be happened in the interface after about 100 days because of the increased relative micromotion. Before 100 days, in the early period, the initial fixation was a very important issue for the long-term stability because of the probable loosening. Thus, the shape design for the cases E, F or G was suitable for the long term stability because the relative micromotion did not increase since little slip was observed.

Figure 7 showed the differences of relative micromotion for the case F and G in detail. The case F was initially more stable than the case G because of the less variance of the relative micromotion in the early stage. Especially, the change of subsidence, i.e., the z -directional displacement u_z must cause malfunctions in the treated femur because the variances of subsidence were larger than the migrations u_x and u_y . It is because F_x has the largest magnitude among the hip-contact loadings throughout gait cycles, and therefore subsidence has most important effects on the operated femur behavior. Although the initial micromotions of the cases F and G were different from each other, the subsidence rapidly reached the maximum of $2.3 \mu\text{m}$ after 6 months and gradually decreased to $1 \mu\text{m}$. But for both cases, the movements u_x and u_y showed almost identical values. It was observed that the case

G showed so profitable stability that it reduces the subsidence in the early stage (from insertion to 180 days) and after 3 years.

Figure 8 showed the comparison of density changes in the cancellous bone on medial, lateral, anterior and posterior sides. As shown in Fig. 8(a), for the cases A, B, C and F, the density of cancellous bone at the proximal end on the medial side rapidly increased in the early stage to about 1.2 g/cm^3 .

Fig. 7 Changes of the relative micromotion components at a proximal node "a" for five years

(a) Medial side

(b) Lateral side

(c) Anterior side

(d) Posterior side

Fig. 8 Density changes at the point "c" in the cancellous bone on the four sides (medial, lateral, anterior and posterior) for five years

Although the cortical bone resorption occurred at the proximal region on the medial side, the increase of density in cancellous bone resulted from the transfer loading mechanism and the bone remodeling. For the case D, bone apposition occurred. For the case E, the density increased to 0.56 g/cm^3 for 2 years, and then converged to 0.9 g/cm^3 . Thus, in the beginning, the density apposition for the cases D and E showed the similar tendency as the cases A, B, C and F. For the case G, the cancellous bone density at point c on medial side decreased as time elapsed. As shown in Fig. 8(b), for the cases A, C, D and F, the density on the lateral side slowly increased to 0.54 g/cm^3 (increased by 6%), which implies bone apposition. For the case B, the density decreased after 2.5 years. For the cases C and G, the density of cancellous bone increased for three years, and then decreased up to five years. As shown in Fig. 8(c), for all the design cases, it was noted that the initial density of cancellous bone on the anterior side decreased to less than 0.5 g/cm^3 . It is because the stress on this point induced by the applied forces decreased as time elapsed. However, for the cases D and E, the phenomenon of bone apposition appeared after 720 days. As shown in

Fig. 8(d), the density on posterior side for all the design cases, except for the case H, increased to the wide range (0.52 to 0.65 g/cm³). Especially, for the case H, the density of the cancellous bone did not change on the medial and the lateral as well as the posterior sides, which implies no bone apposition. In addition, on the anterior side, bone density rapidly decreased to 0.4 g/cm³. We could not expect the stable bio-fixation between interfaces using the titanium alloy.

The density changes of the long bone at the middle side and the distal end were presented in Fig. 9. As shown in Fig. 9(a), the bone density increased for all the design cases. For the cases A, B, C and H, the density increased slowly at the initial stage and rapidly increased afterward. For the cases D, E, F and G, the bone density rapidly increased in the initial stage, and the density apposition slowly developed up to four years. As shown Fig. 9(b), the bone remodeling occurred for all the cases. For all the cases except the cases E and H, the density of cancellous bone converged to about 1.1 g/cm³. For the case E, it converged in 5 years to 0.8 g/cm³ that is less than 1.0 g/cm³.

(a) Middle level

(b) Distal level

Fig. 9 Density change in the cancellous bone at the middle and distal levels on medial side for five years

cm³. For the case H, the density approached over 1 g/cm³ even in one year. Generally, the density apposition can be regarded as new endosteal bone formation as long as bone remodeling occurred⁽³²⁾.

5. Conclusion and Discussion

The recent stem design is intended to minimize stress shielding and to reduce bone resorption and alleviate the loosening^{(6),(7),(30)}. In this study, the reduced bone resorption can be obtained using the bend mold stems made of composite materials such as AS4/PEEK. In order to reduce the probability of bone failure and the relative micromotion, we additionally considered the neck shapes and cross-sections of the composite hip prosthesis as the design cases.

The long-term performances of all the design cases were evaluated. The numerical results obtained from the nonlinear finite element program with bone remodeling algorithm could be analyzed and evaluated using the clinical observation such as radiographic inspection⁽³¹⁾. Although the designed composite stems have not been used in many clinical operations yet, those results and evaluations could be beneficial to the prediction of the long term stability of the operated femur as well as to the improvement of design performances of composite stem. For all the design cases using composite materials, the cancellous bone resorption at the proximal end on the anterior side and the cancellous bone apposition at the proximal, middle and distal regions on other three sides have occurred as presented in Figs. 8 and 9. However, the bone apposition did not occur in any interface, and some parts of the interfacial surface were showing more bone resorption and loosening as time elapsed, as shown in Fig. 8(a), (c) and Fig. 6.

It was obtained that the cortical bone resorption was mainly influenced by the difference of material stiffness more than stem shapes. However, since only three head neck shapes of stem were considered in this study, the neck shapes except the quadrangle did not have a close relation to cortical bone loss induced by stress shielding. Only for the cases F and G with the same quad-section, the slope type showed less bone loss in the cancellous and cortical bone than the convex type, as shown Figs. 8 and 9. Thus, the slope type with the quad-section had lots of advantages in alleviating the loosening by bone resorption. But for the case E, although the convex type with the hexagonal cross section was modeled, the cancellous bone apposition showed more stable behavior than the others at proximal level on all four sides, as shown in Fig. 8.

For the cases A, B, C, and H with the elliptic shape, the long term stability could not be ensured

because the relative micromotion slightly increased as time elapsed. The cortical bone resorption and the cancellous bone resorption suddenly occurred in the adjacent areas. However, the design cases E, F and G did not cause progressive migrations, as shown in Figs. 6 and 7. For those cases, fixation by fibrous ingrowths or bony ingrowths could be predicted.

It was obtained that the cross-section had a close relation to the relative micromotion including the subsidence and migration. The effective movement which supported bone ingrowths into porous-surfaced implants was reported below $100\text{ }\mu\text{m}^{(32)}$. Thus, the maximum relative micromotion $10\text{ }\mu\text{m}$ on the medial side in this paper was sufficient for bone remodeling between the interfaces. In this model, the maximum relative micromotion occurred on the lateral height and its magnitude was approximately below $150\text{ }\mu\text{m}$ in five years. But they were in reasonable range which did not preclude the bio-fixation by bony ingrowths because the progressive movements as time elapsed were below $2 - 10\text{ }\mu\text{m}$ after the maximum movements almost occurred in the early stage⁽³³⁾. It was noticed that the convex type showed less $20 - 50\text{ }\mu\text{m}$ than the others. The attractiveness of biological fixation lies in its potential for direct attachment of the implant to bone without later interposed fibrous tissue. Therefore, for all the design cases, we could expect the biological fixation by bony ingrowths.

The high stress concentrations on the distal region of titanium stem, which may cause the severe pains, could be removed by using composite materials. The extremely new bone endosteal formation may prevent cancellous bone from normal function, and thickening of the cortical bone at the distal tip could be foreseen. In addition, the high density apposition could cause risky factors in thin layered bone such as crack initiation caused by stiffen bone or periosteal hypertrophy caused by lack of uniform stress distribution, even if bone remodeling was proceeding^{(31),(33)}. For all the cases except the case H, the long term stability could be confirmed by the fact that the density of the cancellous bone stably increased. It was observed in the case E that the density apposition induced by the stress concentration can be reduced below 1.0 g/cm^3 . In summary, the bend mold composite stem provided less stress shielding than metallic alloys such as titanium. The extreme stress concentration on cancellous bone at the distal region must be alleviated in stability by using the case E as shown in Fig. 9(b).

Finally, the observations are summarized as follows:

- The stress concentration in the distal region of the titanium stem which may cause the patient's

severe pains was reduced using composite material.

- The composite materials were more suitable in the long-term stability than metallic alloy because they showed less stress shielding.

- The head neck shape had a close relation to the cortical bone resorption and the cancellous bone apposition at proximal region while the cross-section was related with relative micromotion between interfaces.

- The convex head type with the quadrangle cross-section showed less subsidence at proximal region on the medial side than the others.

In conclusion, the current study on the designed composite and metallic stems with various design cases using computer simulation gave us the new design methodology and direction in spite of some limitations. We have no doubt that the designed composite stems showed many advantages to the long-term stability of artificial hip prostheses.

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