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Design of a biomimetic polymer-composite hip prosthesis

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Abstract: A new biomimetic composite hip prosthesis (stem) was designed to obtain properties similar to those of the contiguous bone, in particular stiffness, to allow normal loading of the surrounding femoral bone. This normal loading would reduce excessive stress shielding, known to result in bone loss, and micromotions at the bone-implant interface, leading to aseptic prosthetic loosening. The design proposed is based on a hollow substructure made of hydroxyapatite-coated, continuous carbon fiber (CF) reinforced polyamide 12 (PA12) composite with an internal soft polymer-based core. Different composite configurations were studied to match the properties of host tissue. Nonlinear three-dimensional analysis of the hip prosthesis was carried out using a three-dimensional finite element bone model based on the composite femur. The

INTRODUCTION

Most stems for total hip joint replacements are currently fabricated using Ti-6Al-4V alloy. This material has several properties that make it the material of choice for many orthopedic applications because of its high mechanical strength and corrosion resistance and excellent biocompatibility.¹ Like all other hip stems used in total hip prosthesis (THP), Ti-6Al-4Vbased stems have however two main drawbacks, namely, significant stress shielding and important migration. The first is the alteration of the stress pattern induced by the modulus of elasticity of the high modulus metallic prosthesis (100 GPa for Ti-based stems), which is much higher than that for the contiguous bone. Thus, the stiff implant will sustain the greater part of the load. The second is the conse-

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performance of composite-based hip and titanium alloybased (Ti-6Al-4V) stems embedded into femoral bone was compared. The effect of core stiffness and ply configuration was also analyzed. Results show that stresses in composite stem are lower than those in Ti stem, and that the femoral bone implanted with composite structure sustains more load than the one implanted with Ti stem. Micromotions in the composite stem are significantly smaller than those in Ti stem over the entire bone-implant surface because of the favorable interfacial stress distribution. © 2007 Wiley Periodicals, Inc. J Biomed Mater Res 82A: 27–40, 2007

Key words: total hip prosthesis; CF/PA12 composite; stress shielding; micromotions; FE analysis

quence of large micromotions at the bone-implant interface resulting from nonoptimal surface conditions. Both drawbacks lead to implant loosening and bone resorption in the surrounding femoral bone, limiting the *in vivo* longevity of the hip replacement.

Several attempts have been made to provide more suitable design/materials to overcome the problems associated with stress shielding and improve implant lifetime. One approach is the use of low-modulus Tibased alloys,^{2,3} with an elastic modulus ranging between 60 and 80 GPa. Among these materials, Ti-13Nb-13Zr and Ti-29Nb-13Ta-4.6Zr alloys provide sufficient strength and corrosion resistance and high biocompatibility.⁴ When compared with conventional biomedical Ti-6Al-4V, low modulus alloys are effective to reduce stress shielding and enhance bone remodeling, although their modulus is still four to five times higher than that of the contiguous bone. Other disadvantages of these materials are their high cost, inferior wear properties, and susceptibility to time-related phenomena-like corrosion effects.^{1,5}

Some investigations have suggested shape optimization of hip prosthesis⁶⁻¹² as an alternative to address the stress shielding and bone resorption problem. For this purpose, many numerical approaches

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Figure 1. 3D geometry of the cut femoral bone and coordinate system: (a) intact bone and (b) cut bone. [Color figure can be viewed in the online issue, which is available at www.interscience.wiley.com.]

have been developed to generate optimized designs. These shape optimization approaches for optimal design of prostheses have proved to be able to minimize either stress shielding or interfacial micromotion effects, but never simultaneously.

Other researches have focused on material optimization of femoral hip prosthesis. Aiming this objective, a numerical approach to three-dimensional material optimization of femoral prosthesis using fiberreinforced composite material was developed.¹³ This optimization procedure can be employed to minimize the concentration of stress at the bone-implant interface to reduce the risk of mechanical failure and interface debonding. Kuiper and Huiskes¹⁴ developed a numerical approach to minimize both calcar stress shielding and interfacial micromotion. Their results showed that the use of variable modulus prosthesis produces the desired load transfer distribution. The

TABLE I Mechanical Properties of Host Tissue

Meterial	Modules of Elasticity (GPa)	Shear Modulus (GPa)	Poisson's Ratio
Cortical bone	$E_x = 11.5$ $E_y = 11.5$ $E_x = 17.5$	$G_{xy} = 3.0$ $G_{xy} = 3.5$ $G_{yz} = 3.5$	$v_{xy} = 0.4$ $v_{xy} = 0.4$ $v_{xy} = 0.4$
Cancellous bone	E = 1.0	G = 3.0	v = 0.3



Figure 2. Design concept of the biomimetic hip stem. [Color figure can be viewed in the online issue, which is available at www.interscience.wiley.com.]



Figure 3. Schematic dimensioned drawing of the hip stem (all dimensions are in mm).

application of optimization approaches for different problem formulations has resulted in a variety of interesting results for the constrained objective functions, for example, minimizing stress shielding or maximizing stiffness. These optimization studies give insights into femoral prosthesis as a mechanical structure. However, they did not consider the interactions between the prosthesis and the host tissue (biological structure). Moreover, it is very difficult to assemble all optimization criteria to create an ideal prosthesis model.

In the same thematic, long fiber composite materials for femoral hip prostheses were developed as alternatives to stiff metal alloys to overcome problems related to stress shielding and improve load transfer to bone. These composite biomaterials appear as very attractive solutions for orthopedic implants because of their potential benefits, such as tailored mechanical properties and anisotropy, mechanical reliability, environmental stability, and improved biocompatibility.¹⁵ Currently, most of the developed composite material prostheses have been fabricated from laminated fiber-reinforced composites.^{16–20} A preliminary study on composite hip prosthesis manufactured by resin transfer molding using vinyl ester resin reinforced by

a braided carbon fiber (CF) preform was conducted by Advani et al.²⁰ Two architectures with different fiber angles (15° and 20°) were used. The results of their investigation showed that direct braiding of the fibers onto insert could improve the quality of the prosthesis and resulting mechanical performance. Christel et al.¹⁶ developed hip prostheses made from carbon fiber-reinforced carbon (CF/CF). Early aseptic loosening was observed in these prostheses mainly because of the poorly designed shape and the low shear strength of materials at stem surface,²¹ which enhanced negative micromotions and migration. The implantation of these CF/CF prostheses has been stopped. Similar failures were reported for so-called isoelastic stems.²² Akay and Aslan¹⁷ performed a comparative stress analysis using carbon fiber-reinforced polyetheretherketone (CF/PEEK) manufactured by injection molding. A finite element code to







Figure 4. Ply configurations for the composite material used: (a) configuration I ($[(\pm 45^\circ)2]$ [(0°/90°)1] [($\pm 45^\circ$)3]) and (b) configuration II ([($\pm 45^\circ$)6]). [Color figure can be viewed in the online issue, which is available at www. interscience.wiley.com.]

Mechanical Hoperites of the composite Hosticesis			
Material	Modulus of Elasticity (GPa)	Shear Modulus (GPa)	Poissson Ratio (v)
Polymeric core	E = 0.1; 0.4; 1.0	G = 0.04; 0.17; 0.42	0.2
	$E_{x} = 3.5$	$G_{yz} = 2.5$	0.3
	$E_{\nu} = 16.4$	$G_{zx} = 3.0$	0.3
CF/PA12 composite	$E_{z} = 16.4$	$G_{rv} = 3.0$	0.3
$[(\pm 45^{\circ})_{2}][(0^{\circ}/90^{\circ})_{1}][(\pm 45^{\circ})_{3}]$	$E_x = 3.0$	$G_{vz} = 2.0$	0.3
	$E_{\nu} = 10.7$	$G_{77}^{5^{-}} = 2.5$	0.3
$[(\pm 45^{\circ})]_{6}$	$E_{z}^{y} = 10.7$	$G_{xy} = 2.5$	0.3

 TABLE II

 Mechanical Properties of the Composite Prosthesis³¹

analyze the response of a press-fit CF/PEEK implant was developed,^{18,19} which highlighted the effect of fiber orientation on the mechanical performance of the prosthesis. More recently a numerical method was developed to predict the progressive failure of a thick laminated composite femoral component for total hip arthroplasty²³ (THA). A hybrid concept design of the hip prosthesis based on a Co-Cr core with a flexible composite outer layer was developed by Simões et al.^{24–26} The prototypes of this design were manufactured using compression molding composite technology. Results showed that the combination of a stiff material with a more flexible one produced the desired load transfer distribution, potentially minimizing both calcar stresses without leading to large interface micromotion. They also showed that their hybrid concept resulted in a compromise between stress shielding and micromotions.

While these studies addressed specific weaknesses of existing implants and proposed individual solu-



Figure 5. FE models: (a) intact femoral bone, (b) femoral bone with Ti implant, and (c) femoral bone with CF/PA12 implant. [Color figure can be viewed in the online issue, which is available at www.interscience.wiley.com.]

3.270

14.979

TABLE III Details of the Finite Element Model Used			
Part	Element Type Used	Number of Nodes	Number of Elements
Cortical bone	Solid45-8 nodes	8,679	34,784
Cancellous bone	Solid45-8 nodes	10,265	46,790
CF/PA12 composite	Solid99-8 nodes	3.286	34,784

Solid45-8 nodes

Polymeric core

tions based on materials or implant design optimization, none considered an integrated biomimetic solution to stress shielding and aseptic loosening. Also, solutions based on lower modulus composite materials proposed to address stress shielding revealed to be inadequately designed with respect to micromotions and migration. Clinical studies^{27,28} showed that isoelastic prostheses (e.g., Butel's model and carbon fiber composite) did not fulfill its expected performance because of the dramatic implant migration related to high shear deformation at the bone-implant interface. It is worth mentioning however that results indicated reduced stress shielding effects with such lower modulus stem. Thus, there is a room for further work in this area.

In the present study, it is thus proposed to develop biomimetic total hip stem. The concept design of the prosthesis is inspired from the structure of the femoral bone itself. It is based on 3-mm thick substructure of a new polymer-composite (carbon fiber-reinforced polyamide 12, CF/PA12) with an internal soft basedpolymer core to mimic the natural bone. The proximal part of the prosthesis is plasma sprayed with a bioactive hydroxyapatite (HA) coating²⁹ to promote osteointegration. The innovation in the present approach lies in the biomimetic design of the composite stem and their HA coating.

The objectives of the work were twofold. The first was to compare the biomechanical performance of total hip stems made of Ti or HA-coated composite using a model developed of the proximal section of the femur. The second was to investigate the influence of architectural features of the composite stem architecture features on various biomechanical properties of a model that contains this stem. In all cases, the finite element analysis (FEA) method is used.

TABLE IV Values of the Components of the Applied Forces Used in the Finite Element Analysis

					-	
	Hip J Comj	Hip Joint Forces Component (N)		Abductor Forces Components (N)		
	F_x	F_y	F_z	F_x	F_y	F_z
Case 1 Case 2	$-1026 \\ -320$	$0 \\ -448$	2819 1820	0 430	0 0	0 -1160



Figure 6. Boundary conditions and applied loads (in Load case 2) acting on the prosthesis-femoral bone model.

[Color figure can be viewed in the online issue, which is available at www.interscience.wiley.com.]

MATERIALS AND METHODS

Femoral bone

In this investigation, a three-dimensional model of the proximal part of a right femoral bone was obtained from computerized tomography (CT) scan cross-sections of the composite femur.³⁰ Osteotomy of the upper end of the femoral bone was performed at the level of the greater trochanter as shown in Figure 1. The values used for the elastic properties of cortical and cancellous bone are given in Table I. For structural analysis, cortical and cancellous bone were both simplified as homogeneous linear-elastic materials with transversely isotropic and isotropic behavior, respectively.

THP design

The design concept and geometry of composite hip stem prosthesis are shown in Figures 2 and 3, respectively. The prosthesis is typical of modular designs that are implanted



Figure 7. Effect of ply configuration on micromotions expressed as sliding distance (in mm) and gap distance (in mm) using load case 2 and core stiffness of 1000 MPa: (a) configuration I ($[(\pm 45^{\circ})2]$ [$(0^{\circ}/90^{\circ})1]$ [$(\pm 45^{\circ})3$]) and (b) configuration II ($[(\pm 45^{\circ})6]$). MN and MX represent respectively, minimum and maximum values. [Color figure can be viewed in the online issue, which is available at www.interscience.wiley.com.]

by press-fitting into the contiguous bone without the use of an acrylic bone cement anchor. The stem is straight, follows the antecurvation of the shaft of the femoral bone, has an oval cross-section, and a shaft angle of 135°. It is composed of a 3-mm thick substructure made of several layers of a carbon fiber/polyamide 12 (CF/PA12) polymer composite laminate with predetermined fiber orientation, an internal polymeric core and a 100- μ m thick bioactive HA coating in the proximal section to enhance bone ingrowth and increase the fixation strength. Optimal sub-

	Ply Configuration		
	Configuration I $[(\pm 45^{\circ})_2][(0^{\circ}/90^{\circ})_1][(\pm 45^{\circ})_3]$	Configuration II $[(\pm 45^\circ)_6]$	
Maximum contact pressure (MPa)	24	33	
Maximum total contact pressure (MPa)	34	46	
Peak maximum stress in the prosthesis (MPa)	72	76	
Peak minimum stress in the prosthesis (MPa)	-96	-102	
Peak maximum stress in the femoral bone (MPa)	55	55	
Peak minimum stress in the femoral bone (MPa)	-94	-94	

 TABLE V

 Influence of the Ply Configuration of the Composite Material on Various Stresses in the Finite Element Model

structure thickness and different laminate fiber angle were determined experimentally by tensile and compression tests.³¹ CF volume fraction was 55%, as determined from thermal gravimetric analysis (TGA). Preliminary biocompatibility testing showed that this composite stem produced no adverse cytotoxic response in the peri-prosthetic tissues^{32,33} and, tests using simulated body fluid conditioning showed that the HA coating has excellent bioactivity.²⁹

Two fiber architectures were used in the present study. Configuration I had two plies oriented at $(\pm 45^{\circ})$, one at $(0^{\circ}/90^{\circ})$, and three others at $(\pm 45^{\circ})$ $([(\pm 45^{\circ})]_2[(0^{\circ}/90^{\circ})]1[(\pm 45^{\circ})]_3)$. Configuration II had all six plies oriented at $(\pm 45^{\circ})$ $[(\pm 45^{\circ})]_6$. A schematic of these two configurations is shown in Figure 4. The composite was manufactured by inflatable bladder compression molding.³¹ The values of the elastic properties used for the composite material are shown in Table II.

The solid model of the prosthesis was created using a commercially available software (CATIAV5R13; Dassault systèmes, Montreal, CA).

Details of FEA models

Three finite element analysis (FEA) models were meshed and analyzed using a commercially available software (ANSYS 9.0; Ansys, Montreal, CA). The first was a



Figure 8. Effect of core stiffness on micromotions, contact pressure and total stress at the bone-implant interface using load case 2 and ply configuration I.

model of the intact femoral bone [Fig. 5(a)], the second was one in which the implanted stem was made of a Tibase alloy (E = 110 GPa, V = 0.3), while, in the third, the biomimetic composite (CF/PA12) stem was used. Details of the meshes for all models are given in Table III. For the second and third models, frictional conditions were assumed to exist at the bone-implant interface, thereby allowing transfer of compressive and shear stresses. The interface condition between the proximal prosthesis surface (HA surface) and cancellous bone as well between distal prosthesis and cortical bone was modeled by contact elements (CONTAC174 - 8 nodes with dynamic friction capabilities). Two values of the friction coefficient were used: 1.0 at the bone-HA interface and 0.6 throughout the stem surface simulating stick/slip friction behavior. Fullybonded conditions were assumed at all other interfaces in view of interfacial adhesion measured from pull tests.²⁹ This resulted in a rigid link between the composite substructure (CF/PA12) and the internal core contact surfaces, allowing no relative sliding or gap opening.

The FE composite model was made of two types of elements: 3D structural solid elements (SOLID45-8 nodes having three degrees of freedom at each node with large strain capabilities) were used to simulate femoral bone and internal core and multilayer linear structural shell elements (Shell99-8 nodes having six degrees of freedom at each node) were used to simulate the composite substructure. The bone-implant interface was modeled using surface-tosurface contact elements (CONTA174 and TARGE170). The complete FE model involved 22,682 nodes, 114,613 elements, and 14,782 contact elements; additional details can be found in Table III.

Loads and boundary conditions

For each of FEA models, two load cases were used. Load case 1, consisting of a 3 kN load applied to the femoral head with an angle 20° was used to verify the FEA results obtained in the present study by comparing the stresses in the stem, in the Ti stem model, with those reported by previous workers.^{17,34} Load case 2 corresponded to the most critical load case of gait (a single limb stance phase) and consisted of a 1.9 kN load applied to the femoral head and a 1.24 kN abductor muscle load. Several authors reported that the physiological loading of the hip joint can be accurately represented by only applying joint and abducting forces, neglecting all other muscles.³⁵ For

E = 1000 MPa



E = 400 MPa

ues. [Color figure can be viewed in the online issue, which is available at www.interscience.wiley.com.]

each load case, the resultant load used, as well as the magnitudes and directions of these loads, resolved along each of the anatomic directions, were as given in the literature (Table IV). For each load case, the loads were distributed over several nodes to avoid stress concentration, and for all FEA work, the displacement of all nodes at the distal end of the femoral bone was rigidly constrained (Fig. 6).

RESULTS

Verification of the FEA results

For the load case 1 applied to the model with the implanted Ti alloy stem, the maximum tensile stress

E = 100 MPa



Figure 10. Effect of core stiffness on the maximum principal stress (MPa) in the femoral bone (cortical and cancellous) due to load case 2 and using ply configuration I. MN and MX represent respectively, minimum and maximum values. [Color figure can be viewed in the online issue, which is available at www.interscience.wiley.com.]

(79 MPa) and minimum compressive stresses (104 MPa) where within the range reported by Akay and Aslan.¹⁷ (100 and 137 MPa, respectively) and Prendergast et al.³⁴ (96 and 120 MPa, respectively) for the same combination of loading case and model. Keeping in mind in differences in the geometry of the stem used in these studies, the authors conclude that these results provide an adequate validation of the FEA model used.

Effect of ply configuration and core stiffness in the composite model on micromotion and stresses

Micromotions were defined as gap distance and sliding distance, that is, relative motions in the normal and tangential directions with respect to the stem. Results concerning ply configuration showed that peak micromotions were ~24% lower for ply configuration I compared with ply configuration II (Fig. 7). Results also showed that ply configuration only marginally affected the peak maximum principal stress in the cancellous bone, the peak minimum principal stress in the cancellous bone, the maximum principal stress in the prosthesis or the minimum principal stress in the prosthesis (Table V). However, results in Table V showed that ply configuration I led to maximum contact pressure and maximum contact stress at the bone-implant interface \sim 26% lower than those of ply configuration II. Results also showed that core stiffness had a very marginal influence on micromotions, maximum contact pressure or maximum total stress at the bone-implant interface (Fig. 8), on the principal stresses in the prosthesis (Fig. 9), and the maximum principal stress in the cancellous bone (Fig. 10).

Influence of stem material on stress

Compared with the case where the stem was made of the Ti alloy, the values of the principal stresses in the composite stem were lower and more uniformly distributed (Fig. 11). The maximum principal stress in the femoral bone implanted with the composite stem (Fig. 12) was also much closer to that obtained with the intact femoral bone, indicating that, with the composite stem, there is a higher potential for bone apposition³⁶ and hence a lower potential for stress shield-ing.³⁷ Micromotions at the bone-implant interface (Fig. 13) were also lower (sliding distance of between 0 and 20 µm, with a peak of 70 µm, and peak gap distance of between 0 and 33 µm, with peak minimum of 128 μ m), with the composite stem than with the Ti stem (sliding distance of between 0 and 50 µm and a peak gap minimum distance of 238 µm), indicating that the potential for migration is lower when the composite stem is used. These peak sliding distance and peak gap distance obtained with the composite stem are lower than a reported limit recorded in in vivo studies of 150 µm for porous-coated implants.^{38,39} However, there is no consensus on such a limit for micromotions as other limits have been proposed for surface-textured metallic implants (e.g., 40 µm for porous Ti wire surface) and are extensively discussed by Kienapfel et al.⁴⁰ It should be noted that no such limit currently exists for HA-coated implants.



Ti



Figure 11. Principal stress (MPa) in the prostheses due to load case 2, and using ply configuration I and core stiffness of 1000 MPa: (a) maximum stress and (b) minimum stress. MN and MX represent respectively, minimum and maximum values. [Color figure can be viewed in the online issue, which is available at www.interscience.wiley.com.]

DISCUSSION

The new concept design for hip replacement using a biomimetic composite was described. Three-dimensional finite element models were used to evaluate

the potential of the proposed design concept. Numerical study has shown that the performance of the composite prosthesis depends strongly upon ply configuration. The results of the simulation demonstrated that for the composite stem model, configuration I is



Figure 12. Maximum principal stress (MPa) in bone (cortical and cancellous) due to load case 2, using configuration I and core stiffness of 1000 MPa: (a) the intact femoral bone, (b) the femoral bone with composite prosthesis and (c) the femoral bone with Ti prosthesis. MN and MX represent respectively, minimum and maximum values. [Color figure can be viewed in the online issue, which is available at www.interscience.wiley.com.]

better in terms of micromotions than configuration II because of its resulting stiffness closer to that of cortical bone, while stress distribution was not as sensitive to ply configuration. However, several works^{24,41,42} have shown that it is desirable to have a stiff stem (i.e., metallic) to minimize cancellous bone stress and migration. Based on the latter, a compromise must thus be made between stress shielding and micromotions. On the contrary, the present study demonstrates that the current hip stem, based on HA-coated biomimetic composite, with its bone-matching stiffness and excellent bone-implant adhesion results in better load transfer and less micromotions.

The polymeric core stiffness, however, had less effect on micromotions and no significant effect on stress within the femoral bone. This is attributed to the low stiffness of the polymeric core, which is negligible with respect to that of the composite. Comparative study of composite and Ti prostheses revealed that the prosthesis stress was significantly reduced with the composite, which led to more load transfer to the surrounding bone than with Ti. In addition, the composite prosthesis reduced both total contact stress and pressure at the bone-implant interface.

The prototypes of THP stems were manufactured using an inflatable bladder compression molding process developed.³¹ This process allows manufacturing in a single molding step into a near-net shape. The process window and specific composite features are currently being determined. Preliminary work has also been undertaken and is under development to introduce the internal polymer core using a melt process. Once molded, the near-net shape stem is plasma-sprayed with HA to obtain a bioactive coating. A proprietary technique was developed to manage heat dissipation during the atmospheric plasma spraying process and obtain high adhesion for such HA coatings on heat-sensitive polymer-based substrates.²⁹ Finally, cytotoxicity and inflammatory response from *in vitro* cell culture as well as *in vivo* implantation for osteointegration and bone-implant bond strength (push–pull tests) on the biomimetic, HA-coated polymer composite stems are currently under investigation.

For the sake of simplicity, a number of assumptions were included in the finite element models, which may influence interpretation of results. First, the cancellous bone was treated as isotropic and homogenous, whereas it is known to be anisotropic and heterogeneous. As proposed elsewhere,³⁵ the physiological load used here in the models included only two forces (hip joint and abductors), all other muscle forces are neglected. Adding other muscle actions (e.g., iliotibial tract muscle) may impact load transfer, and therefore stress shielding. Moreover, the mechanical properties of the composite are dependent on the ply configuration (fiber orientation). The optimal ply configuration of the composite was obtained empirically from experimental testing. For more accurate analysis, theorical optimization of the ply configuration using classical laminate theory is required.

A possible extension of the present work would be to consider bone remodeling after total hip replacement surgery,⁴² for the purpose of predicting the CF/PA12

Ti





Figure 13. Distribution of micromotions on the proximal bone-implant interface using load case 2, configuration I and core stiffness of 1000 MPa: (a) contact gap distance (in mm) and (b) contact sliding distance (in mm). MN and MX represent respectively, minimum and maximum values. [Color figure can be viewed in the online issue, which is available at www.interscience.wiley.com.]

long-term response of host tissue to the insertion of the composite prosthesis.

CONCLUSIONS

The main conclusions of the study are:

1. When the biomimetic stem was used instead of a Ti stem, the stresses in the stem were lower

and more uniform, the stresses in the femoral bone were higher, very close to those modeled in an intact femoral bone, and micromotions were lower. This points to the possibility for reduced stress shielding and migration, hence lower bone resorption and implant loosening in total hip replacements with the compositebased biomimetic stem design. 2. When the biomimetic stem design is used, the ply configuration has an important influence on the various biomechanical parameters determined, whereas the stiffness of the polymeric core does not.

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