Alternative Mechanical Evaluation Method for Ceramic Hip Joint Implants Utilizing Finite Element Analysis under *in vivo*-like Conditions*

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Abstract

This study proposes an alternative mechanical simulation protocol for ceramic femoral heads under *in vivo*-like conditions. A 3D pelvis model is obtained from CT images and the finite elements of the implanted models are validated based on Kwong's experimental results. The stress distribution of nine different femoral head models is then compared when using the conventional proof test (standard ISO 7206-10) and proposed test protocol (postoperative models). Both test methods show a decrease in the maximum stress when increasing the size of the femoral head and bore depth. However, for the stress distribution, the postoperative models reveal a concentration on the superior inner region of femoral head cranial, while the proof test shows an axisymmetric shape in the tangential direction. As a non-uniformed stress distribution increases the probability of fracture, the mechanical testing of ceramic femoral heads should be considered under *in vivo*-like conditions in order to improve the mechanical reliability of the joint. Thus, the current results show the necessity and viability of an alternative mechanical evaluation method for ceramic hip implants.

Key words: Total Hip Replacement, Ceramic Femoral Head, Finite Element Analysis, Mechanical Stability, *In vivo*-like Condition

1. Introduction

A total hip replacement (THR) is widely used as a successful treatment for several diseases, such as degenerative arthritis, rheumatoid arthritis, avascular necrosis, hip joint infections and congenital malformation⁽¹⁷⁾. It has been reported that THR surgery is performed on about 1.4 million people every year and the demand is rising rapidly⁽²⁵⁾. In general, an artificial hip joint consists of four major parts replicating a normal human hip. A stem is inserted into the bone-marrow cavity in the femur, a femoral head replaces the damaged original femoral head, a liner is placed between the femoral head and the acetabular cup, and the acetabular cup is directly fixed to the pelvis. The stem and cup are usually made of steel or titanium alloy, while the femoral head is made of metal or ceramic and the liner is made of polyethylene or ceramic. Such artificial joint components should

*Received 14 May, 2012 (No. 12-0213)
[DOI: 10.1299/jbse.7.336]

provide a high stability, good biocompatibility, and low wear rates.

Yet, various studies have reported the occurrence of *in vivo* fractures in artificial joint components^(23, 24), which could be due to trauma, impingement, demanding physical activity, obesity, improper surgical handling, implantation mistake, defective component manufacture and material flaws. When a fracture occurs, revision surgery is immediately required, which can be more invasive than the initial surgery, as the fragmented pieces must be completely removed from the neighboring tissues⁽⁷⁾.

Currently, ceramic is widely used due to their low coefficient of friction compared to metal or polyethylene in THR. Also, ceramic has a low foreign-body inflammatory response, making it a suitable biomaterial. Although the incidence of ceramic fracture continues to decrease, currently about 1/10,000⁽⁶⁾, this rate needs to be further reduced to avoid additional physical and psychological sufferings to patients^(7, 8).

Most causes of fractural failure of THR are difficult to eliminate, except the case of material flaws. One way to reduce the risk of defects or material flaws related to manufacturing process is to subject the ceramic femoral head to a proof test procedure. The proof test procedure for a ceramic femoral head is stated in ISO 7206-10 and is an established method for evaluating the mechanical stability of ceramic femoral heads. This test procedure specifies that the femoral head be mounted on a stem and statically loaded against a 100° metal cone⁽¹²⁾. The mechanical safety of the femoral head depends on their design characters and material properties. Insufficient mechanical strength of the femoral head induces most of the failures of femoral head. Through the proof test, the mechanical safety of the femoral head is confirmed and low-strength of femoral heads could be clearly eliminated⁽⁹⁾.

Several studies have simulated the performance of ceramic femoral heads based on proof testing. Han et al.⁽¹⁵⁾ used three-dimensional (3D) finite element analysis to investigate the effect of the various sizes of femoral head on mechanical stability. Weisse et al.^(2, 6) and Affloter et al.⁽⁴⁾ suggested an optimized proof test through a comparison of the proof test using experiment and model simulation. Another study⁽⁵⁾ examined the influences of various diameter, material properties and taper design of the femoral head on the mechanical stability under trauma loading conditions. These studies showed that the stress distribution in the taper region was axisymmetric. However, the stress distribution in the taper region would be more likely to be non-axisymmetric under *in vivo* physiological circumstances^(3, 10).

The purpose of the current study is to suggest a new simulation model for femoral heads under *in vivo*-like conditions simulating the circumstances when the THR is implanted in the pelvis. To generate such *in vivo*-like conditions, FE models are developed from a computed tomography (CT)-based 3D pelvis. The reconstructed 3D pelvis model is then connected with 9 different femoral head models. These FE models are used to simulate the physiological conditions of a single-leg stance, plus a proof test is also performed following the ISO procedure to determine the mechanical stability of the femoral heads. Finally, the simulation results of the peak stress regions and stress distribution from the proof test and *in vivo*-like condition test are compared.

2. Methods

2.1 Finite element modeling of proof test

The finite element method (FEM) is widely used for resolving general structural analyses and the biomechanical evaluation in orthopedics. It includes the material characteristics of each component, such as Poisson's ratio, the friction factor, and Young's modulus. This numerical simulation is an effective way to predict the stress distribution in a

Diameter of femoral head (mm)	Bore depth (mm)		
	S (13.5)	M (17.0)	L (19.5)
28
32
36

Fig.1 Nine different femoral head designs; three different diameters: 28, 32 and 36 mm and three different bore depths: L (Long, 19.5 mm), M (Medium, 17 mm) and S (Short, 13.5 mm). Taper inside femoral head was designed based on 12/14 standard stem.

structure consisting of different components, and various studies have already proven that the results correspond with many actual experiments^(18, 19).

The 3D nonlinear FE model for the proof testing consists of the stem, femoral head, and cone. The femoral head was designed with three different diameters: 28 mm, 32 mm and 36 mm and three different depths for the bore: Long (L, 19.5 mm), Medium (M, 17 mm), and Short (S, 13.5 mm) (Fig. 1). The femoral head and stem were connected with a 12/14 taper.

Nine proof testing models were created as a solid model using 3D CAD software (SolidWorks 2009; Dassault System, Concord, MA) and exported into mesh generating software (Hypermesh ver. 8.0, Altair HyperWorks; Altair Engineering, Inc., Troy, MI) to generate a FE mesh. The FE analysis was conducted using commercially available software (ABAQUS 6.9, Hibbitt, Karlsson and Sorenson, Inc., Providence, RI). Figure 2 shows the complete FE model, consisting of an 8-node brick element, where the number of elements used in the stem, femoral head, and cone was about 22,000, 20,000~42,000, and 25,000, respectively. For the material properties, the stem was made of a titanium alloy (Ti6Al4V) the femoral heads were made of alumina (Al_2O_3) and the cone was made of steel. The material properties are given in Table 1 and the materials were assumed to be isotropic and homogeneous⁽⁶⁾.

2.2 Loading and boundary conditions of proof test

The loading condition for the static test of the ceramic hip implant was 46 kN, given by FDA Guidance (Guidance document for preparation of premarket notifications for ceramic ball hip systems)⁽¹³⁾, while the maximum load on the hip joint during physiological

Fig. 2 Static load and boundary conditions of proof test model. (a) ISO 7206-10 (Implants for surgery -- Partial and total hip joint prostheses -- Part 10: Determination of resistance to static load of modular femoral heads) (b) Finite element mesh of femoral components containing 3D 8-node brick elements. Axial load was applied to center of stem (46 kN), while bottom of cone was fixed.

activities was 2.5 kN⁽²⁶⁾. Note that the FDA Guidance is about 21 times greater than the physiological load. The proof test procedure fulfilled the ISO 7206-10 standard⁽¹²⁾, where the femoral head was mounted on the cone that acted as a support and connected to the stem that transferred the compression load to the femoral head. According to these references, an axial load was applied to the center of the stem and the femoral head was sustained against an axially retained 100° cone. The interfaces were modeled to have surface-to-surface contact. The coefficients of friction for the stem-head and head-cone were 0.35 and 0.3, respectively⁽⁶⁾.

2.3 Finite element modeling of postoperative models

The postoperative models were combined with the pelvis and acetabular components. The pelvis was scanned by CT to obtain a set of slices. The CT image resolution was 512 by 512 pixels with a 1.5 mm interval. The CT data were imported to a software program (Mimics 10.0; Materialise Inc., Leuven, Belgium) and the pelvis contour was then

Fig. 3 3D Reconstruction of pelvis model from CT

Table 1 Material properties used in FE models

Part	Material	Elastic modulus (MPa)	Poisson's ratio, ν	References
Stem	Ti6Al4V	105,000	0.3	[6]
Femoral head	Al ₂ O ₃	380,000	0.245	[6]
Liner	Al ₂ O ₃	380,000	0.245	[6]
Cone	Steel	210,000	0.3	[6]
Acetabular cup	Ti6Al4V	105,000	0.3	[6]
Subchondral bone	Bone	500	0.3	[14]
Cortical bone	Bone	5600	0.3	[14]
Cancellous bone	Bone	100	0.3	[14]

extracted from each slice. A non-uniform rational B-spline (NURBS) is widely used in reverse engineering to represent free-form surfaces from a large number of discrete point data⁽²¹⁾. Thus, the pelvis contour was converted to point data and the 3D geometrical surface of the pelvis was reconstructed using SolidWorks which supports NURBS (Fig. 3). The THR model consisted of a ceramic femoral head and liner, a titanium stem and a cup. The cup was designed with an outer diameter of 52 mm and the femoral heads were the same size as in the proof testing. The exported pelvis model was combined with the acetabular components to make an exact fit. All the postoperative models were set up to 45 degrees abduction and 15 degrees anteversion. The elements representing the femoral head, liner and cup were created using 8-node brick elements, while the cortical bone, cancellous bone and subchondral bone consisted of 10-node tetrahedral elements. In the exact-fit, preserving the subchondral bone is recommended in the THR surgery since it provides similar stress distribution to that of the normal⁽²⁷⁾. Thus, the subchondral bone was considered to be remained after the reaming process (Kwong et al., 1994) and cortical bone was modeled with a constant thickness of 1 mm (Fig. 4). The number of elements in the stem, femoral head, liner, cup, subchondral bone, cortical bone and cancellous bone was approximately 7000, 2000~18000, 6600~12000, 8000, 600, 19000 and 13000, respectively. The material properties were assumed to be isotropic and homogeneous, as listed in Table 1^(6,14).

2.4 Loading and boundary conditions of postoperative models

The interfaces of the stem-head, head-liner and liner-cup were modeled based on surface-to-surface contact with coefficients of friction of 0.35, 0.02, 0.35 and 0.5, respectively^(6, 20). The methods of fixation for the cup are either an exact fit, where the cup has the exact dimensions of the reamed cavity, or a press fit, where the cup is oversized for the reamed cavity to ensure a good contact. However, in reality, the cavity diameters are

Fig. 4 Finite element implanted models showing loading and boundary conditions. (a) Implanted models consist of stem, femoral head, liner, cup, subchondral bone, cortical bone and cancellous bone. Cancellous bone was presented underneath cortical shell. (b) Load was applied to center of stem (2.13 kN), while sacroiliac and pubic symphysis were constrained.

generally larger than the diameter of the previously used reamer, and this error depends on the surgeon's technique and reamer type⁽¹⁴⁾. Yet, this error is difficult to generate in a simulation. In the present study, the interface of the cup and the pelvis was assumed to be exact fit. A loading of 1112 N was applied to the center of the stem to simulate a one-leg stance: 15 degrees of abduction and 10 degrees of forward flexion. The boundary regions in the sacroiliac and pubic symphysis were fixed for all degrees of freedom^(11, 14, 15).

Fig. 5 Location of five screw holes in the acetabular cup. Four types of screw fixations were used : (1) single screw located at the A hole; (2) two screws located at the B and C holes; (3) three screws located at the A, B and C holes; (4) four screws located at the A, B, C and D holes.

Table 2 Micromotion compared with *in vitro* data (load applied = 1112 N)

Number of screws	Kwong et al.		Our study	
	Pole (μm)	Periphery (μm)	Pole (μm)	Periphery (μm)
1	82 $\pm$ 44.8	61.9 $\pm$ 51.3	21.35	12.72
2	32.9 $\pm$ 9.4	53.6 $\pm$ 52.2	21.14	12.46
3	32.3 $\pm$ 12.2	40.0 $\pm$ 41.6	19.28	11.36
4	28.1 $\pm$ 9.0	39.8 $\pm$ 35.1	18.51	10.30

2.5 Validation of finite element models

To validate its effectiveness, the FE model was compared with the *in vitro* model of Kwong et al.⁽¹⁵⁾ who studied the effect of screw fixation on the initial stability in a cementless acetabular cup. Four type of screw fixations were used according to the previous study of Hsu et al.⁽¹³⁾: (1) single screw located at the A hole; (2) two screws located at the B and C holes; (3) three screws located at the A,B and C holes; (4) four screws located A,B,C and D holes (Fig. 5). To reduce computation time, the screw threads were not modeled and the interfaces of screw-cup and screw-bone were assumed to be bonded. The initial stability index of acetabular cup was selected as the peak relative of micromotion between the cup and bone.

3. Results

3.1 Finite element model validation

For validation, the accuracy of the FE model was estimated based on the relative micro-motions in the dome pin site and lateral pin site of an acetabular cup. The result showed in table 2. The experimental results (Kwong et al., 1994) revealed the difficulty of repeating the same results for the same experiments due to large standard deviations. In particular, the mean and deviation for a single screw fixation were significantly larger than those for the other screw fixations. Hsu et al.⁽¹¹⁾ previously analyzed that a single screw fixation acts like a pivot point. Thus, the micro-motion of a single screw fixation can induce a large standard deviation in a cup. Also, Spears et al.⁽¹⁴⁾ showed that the micro-motions of dome pin site observed in the cadaver experiment were most likely due to surface penetration, while finite elements could not represent micro-motions in the surface of dome pin site. Thus, simulation results tend to underestimate surface micro-motions.

Our results were analyzed by one sampled T-test using statistical software (SPSS v12.0, Chicago, IL, USA) with $p < 0.05$ considered statistically significant. Statistically analysis showed no statistically significant difference in micro-motion for lateral pin sites, but the micro-motion for the dome pin sites was much smaller than those of the cadaver experiment (Kwong et al., 1994). Although the micro-motions of one and two screw fixations have statistically significant difference, those of three and four screw fixations show similar results as for the cadaver experiment. In addition, our overall data were slightly lower than those of Kwong et al.'s experiment and this tendency is similar to Spear et al.'s results.

The purpose of present study is comparing the stress distribution for the effect of design characteristics in the femoral heads. When considering the difference between the cadaver

Fig. 6 Representation of stress distribution (maximum principal stress) in femoral head for proof test under axial loading against 100° (28S). Stress was concentrated in conical bore and axisymmetrical distribution was shown in tangential direction as tensile hoop stress.

experiment and the FE analysis in terms of the geometry of the pelvis and cup, material properties, and location of the inserted screws, the proposed FE analysis method could be applicable to estimate the stress distribution in the femoral head after THR surgery. But, it is note that caution must be adopted when applying these results to other studies because our primary concern is to estimate the stress distribution.

3.2 Calculation of stress distribution according to proof test

The major structural damage in the femoral head is caused by tensile hoop stress in the conical bore. From the proof testing results using ISO 7206-10, it was confirmed that the maximum principal stress in the conical bore occurred in circumferential direction. The stress distribution of the femoral head is given in Figure 6, and Table 3 shows the peak stress for the different sizes of femoral head and bore depths. As the diameter of the femoral head and the bore depth increased, the maximum stress decreased. When comparing only the maximum stress, the diameters of 32 mm and 36 mm showed about 18 % and 32 % lower stress, respectively, than the 28 mm diameter, while the M and L bore depths showed about 19 % and 34 % lower stress, respectively, than the S bore depth. The highest stress was found for the case of 28S (395 MPa), which was 38 % lower than the bending strength of third generation alumina (580 MPa).

Table 3 Maximum principal stress (MPa) with proof test models using ISO 7206-10

Bore depth (mm)	Femoral head diameter (mm)		
	28	32	36
S (13.5)	395.08	331.90	273.37
M (17.0)	330.73	265.71	211.97
L (19.5)	265.07	216.70	183.70

Fig. 7 Representation of stress distribution (maximum principal stress) in femoral head for postoperative model under physiological loading (28S). Stress distribution was shown non-axisymmetrically and high stress occurred in superior inner region of femoral head cranial. Maximum principal stress occurred in tangential direction in femoral head as tensile hoop stress.

3.3 Calculation of stress distribution according to postoperative models

From the results of FE simulation with the postoperative models, the peak maximum stress value decreased as the femoral head diameter and bore depth increased. Table 4 shows that the maximum principal stress value for the 32 mm and 36 mm femoral heads was about 21 % and 34 % lower, respectively, than that for the 28 mm femoral head, while the maximum principal stress value for the M and L depths was about 25 % and 45 % lower than that for S depth, respectively. However, while these results showed a similar tendency with the proof test simulation, the stress distribution was evidently different. Figure 7 represented pattern of stress distribution in 28S (diameter of 28 mm and bore depth of S) femoral head of postoperative model. The physiological conditions simulated by the postoperative model induced non-axisymmetric stress distributions concentrated in the superior inner region of femoral head cranial.

Table 4 Maximum principal stress (MPa) with postoperative models

Bore depth (mm)	Femoral head diameter (mm)		
	28	32	36
S (13.5)	22.81	17.35	15.46
M (17.0)	16.91	14.00	10.86
L (19.5)	12.75	9.89	8.12

4. Discussion

The cadaver experiments are appropriate to investigate the effects of hip implant in the body. However, a cadaver study for the purpose of biomechanical analysis has limitations such as cost, time and specimen preparation. Furthermore, the evaluation of femoral head stability after THR surgery cannot be performed in a cadaver model. FEM is useful for many academic and practical stress analyses and widely used in general. Therefore, we used a validated FE model to evaluate the femoral head stability.

Since their original introduction in 1970 by Boutin⁽¹⁾, ceramic femoral heads are now used worldwide for THR surgery. The advantages of ceramic include their excellent immunological bio-compatibility and low coefficient of friction when compared to other materials such as polyethylene and metal. However, ceramic suffers from a high risk of fracture due to its brittleness and low ductility. Thus, to enhance the reliability of ceramic femoral heads, manufacturers have implemented a proof test according to the procedure of ISO 7206-10 that eliminates products with a significantly low mechanical strength from the production line. Richter⁽⁹⁾ mentioned that the failure rate of the proof-tested ceramic femoral heads was more than 40 % below than that of the non-proof-tested heads. In addition, when comparing the fractured surface of the proof-tested heads with the case of an *in vivo* fracture, a high similarity was found in the microstructure of the fracture surfaces. Therefore, the proof test is considered to be a reliable method.

In the present study, the stress distribution in the proof test simulation was generated axisymmetrically in the conical bore (Fig. 8). This result has also been reported in previous studies^(2, 6, 9, 16). This stress distribution was generated by the compression load that caused radial stress that was then transformed into hoop stress. The radial stress can be calculated as:

$$F_L = \mu \sigma_r \quad (1)$$

Where F_L is the compression load, μ is the coefficient of friction and σ_r is the radial stress. The magnitude of the radial stress is affected by the coefficient of friction between the femoral head and the stem. When increasing the coefficient of friction, the radial stress decreased. The hoop stress can be calculated as:⁽²⁸⁾

$$\sigma_h = \frac{\sigma_r d}{2T} \quad (2)$$

Where d is the diameter of the head cranial, T is the thickness of the femoral head, and σ_h is the hoop stress. The hoop stress depends on the radial stress, diameter of the head cranial and thickness of the femoral head. To reduce the hoop stress, the radial stress and diameter of the head cranial should be decreased. Middleton et al.⁽²²⁾ reported that the stress magnitude depends on the coefficient of friction and the contact area between the femoral head and the stem. Thus, when increasing the coefficient of friction and contact area, the hoop stress around the conical bore decreased. Han et al.⁽¹⁶⁾ also reported that increasing the coefficient of friction reduced the stress in a femoral head. Another major factor affecting the stability of a femoral head is the structural stiffness. The stress magnitude in a femoral head changes according to the diameter of the head and large diameter could be expected to have a high structural stiffness. The present study showed that increasing the diameter of the femoral head increased the structural stiffness and reduced the maximum stress.

The proof test is considered as a standard method for confirming the mechanical stability of ceramic femoral head. However, a symmetric loading and boundary conditions induce a symmetric stress distribution on the conical bore. In the physiological conditions, loading and constraint act asymmetrically on the femoral head and the acetabular

Fig. 8 Tangential (hoop) stress generated by compression load in conical bore of femoral head. Hoop stress decreased when increasing coefficient of friction and contact area.

component is obliquely combined to the head. As these results are quite different to the proof test results, such conditions should also be considered in simulations or experiments when testing the reliability of ceramic femoral heads. The simulation using the proposed postoperative models was more comparable with *in vivo* conditions than the proof test using ISO 7206-10. Thus, the results were also more appropriate to the *in vivo* situation. The postoperative models showed an elevated stress magnitude in the superior inner region of femoral head cranial. As non-uniform stresses are apt to induce the incidence site of the stress concentrations, the stress concentrations enhance the probability of femoral head fracture. Therefore, knowing the region of stress concentration is important in order to reduce fracture. According to the study, the stress distribution and maximum stress of femoral heads could be predicted after THR surgery. If the stability of femoral heads is evaluated using each patient postoperative model, it could be possible to select more stable femoral head prior to THR surgery.

The limitation of the current study was that only one type of loading condition was considered based on a single-leg stance. Thus to optimize a further study, a variety of different physiological dynamic loading cases such as walking, climbing up/down stairs, standing up from a chair, and knee bending should also be considered. If the proposed proof test procedure fulfills all the conditions related to the physiological load cases, it can improve the reliability of ceramic femoral heads. Also, more patient-specific artificial hip implants are now being developed using each patient's biological and physiological characteristics instead of standardized conditions. This has special advantages such as a good alignment to the patient's morphology, less bone loss, and a long service life. The proposed proof test procedure with *in vivo*-like conditions will contribute to more stable designs of patient-specific femoral heads and reduced THR surgery failures due to ceramic head fractures.

Acknowledgements

This research was supported by the Public welfare & Safety research program through the National Research Foundation of Korea (NRF) funded by the Ministry of Education, Science and Technology (2011-0020976) and the KIST Institutional Program and Hansung University.

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