Original article



Stress distribution of cementless stems with unique flanges in a rectangular cross-section: thermoelastic stress imaging study

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Abstract

Objective: In this study, thermoelastic stress analysis was conducted to clarify the surface stress distribution of a femur in which a BiCONTACT E stem was inserted. The contact sites between the stem and femur were examined to investigate the association with the range of stress distribution.

Materials and Methods: BiCONTACT E was set up using two synthetic femurs that mimic the morphology and mechanical properties of living bone. Preoperative planning was performed using three-dimensional imaging software. The synthetic bone was placed in a sample holder. After the stem was implanted into the synthetic bone, computed tomography imaging was performed. The contact sites between the stem and the cortical part of the synthetic bone were examined using the imaging software. Subsequently, thermoelastic stress measurements were performed on the sample.

Results: The results of thermoelastic stress analysis indicated a minimum change in the sum of principal stresses $[\Delta (\sigma_1 + \sigma_2)]$ on the medial side and a maximum change in the sum of principal stresses on the lateral side. Thus, no minimum change was observed in the sum of the principal stresses at the maximum proximal part. It is reasonable to assume that the use of a cementless stem can inevitably lead to bone atrophy in the proximal part of the femur. The contact sites between the stem and femur were also investigated, and the results of the study clearly and quantitatively demonstrated the correlation of the contact sites with a range of stress distributions.

Conclusion: The surface stress distribution of a femur, in which a BiCONTACT E stem was inserted, was clarified. The contact sites between the stem and femur were also investigated. Furthermore, the correlation between these results and clinical bone response was investigated in this study.

Key words: thermoelastic stress analysis, femur stress distribution, total hip arthroplasty

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Introduction

Total hip arthroplasty (THA) is expected to improve pain, range of motion, and activities of daily living (ADL) in patients. The number of THAs is increasing in Japan every year, and approximately 70,000 operations are performed annually. Remarkable progress has been made in THA procedures in recent years, and patients exhibit excellent postoperative results¹). However, stress shielding often postoperatively leads to bone atrophy in the proximal femur around the stem. This leads to increased fragility in the proximal part of the femur, thereby causing fractures and loosening around the stem. This in turn raises concerns about the effect of stress shielding on the long-term performance of the stem.

Various stem designs have been examined and developed to devise a means of preventing bone atrophy due to stress shielding around the artificial hip joint stem. An important aspect of this process involves accurate evaluation of the effect of stem design on the surface stress distribution of a bone.

Conventionally, stress analysis²⁾ has been performed using a strain gauge. It has generally been used as an experimental mechanical method to measure the surface stress distribution of the femur. However, there is a limit to the number of gauges that can be attached, and it is impossible to perform measurements without missing points. Hence, we attempted to resolve these problems by using thermoelastic stress analysis to perform stress analysis on various implants³⁻⁶⁾. The thermoelastic stress analysis technique is the only experimental method that allows imaging of continuous surface stress (changes in principal stresses) on the surface as opposed to that at individual points. This technique enables visualization of the surface principal stress distribution $[\Delta (\sigma_1 + \sigma_2)]$ of the femur at the insertion of stem without missing any points. Furthermore, it allows for accurate evaluation of the effect of stem design on femur stress distribution during vertical loading by using an artificial femur to simulate the morphological and mechanical properties of living bone and controlling variations in mechanical properties due to differences in the shape of the femur.

There are various types of artificial hip joint stems with varying characteristics. Each type of artificial hip joint exhibits a stem design that is aimed at preserving bone and realizing physiological stress distribution. The BiCONTACT stem (B. Braun, Aesculap, Tuttlingen, Germany) exhibits a unique design with a rectangular cross-section and flanges on the front and back of the stem, thereby providing a stem shape that preserves the cancellous bone proximal to the femur to the maximum possible extent (Figure 1). Extant studies indicated that stress distribution can be expected through cancellous bone along with acquisition of high initial fixation. BiCONTACT was introduced in 1987 based on the philosophy of "bone preservation" with an aim of maximizing preservation of bone tissue which supports the implant. Good outcomes have been reported with a mean survival rate of 95.1% in 22.8 years, wherein stem revision surgery was set as the endpoint7). Furthermore, BiCON-TACT E, an implant system designed for bone preservation and proximal fixation to suit the femur morphology of Japanese patients, was launched in Japan in 2014. It is now becoming important to evaluate this implant system from a biomechanical point of view and to simultaneously accumulate clinical knowledge about it.

This study aimed to clarify the surface stress distribution of femurs with the insertion of BiCONTACT E using



Figure 1 BICONTACT E stem and its characteristic Bilateral Flanges (←)

thermoelastic stress analysis. Furthermore, the contact sites between the stem and femur were examined to investigate the association based on the range of stress distribution.

Materials and Methods

Synthetic bone setting

BiCONTACT E was set up using two synthetic femurs (synthetic bone 1, synthetic bone 2). The stem size used was a #12 standard offset for all stems. The experiments were conducted with a 32-mm BIOLOX delta ceramic head fitted to the stem.

Synthetic femurs that mimic the morphology and mechanical properties of living bone were used as femur samples (Figure 2: composite femur #3403, grass-filled epoxy, 455-mm length medium size, Pacific Research Laboratories, Vashon, Washington, USA)^{8, 9}. The thermoelastic change associated with the change in the sum of principal stresses on the synthetic cortical bone is linear, and a temperature change of 1 K corresponds to a change in the sum of principal stresses of approximately 227 MPa (Figure 3). The thermoelastic coefficient was 1.47×10^{-11} Pa^{-1 5}).

In the experiment, the synthetic femur was scanned using computed tomography (CT) (Supria, HITACHI Medical Corporation) prior to checking for damage. Preoperative planning was performed with a 3-dimensional imaging software, ZedHip (LEXI, Tokyo, Japan), using the DICOM data obtained.



Figure 2 Synthetic femur used in the experiment



Figure 3 Thermoelastic stress characteristics of the synthetic femur (cortical bone)³⁾

The synthetic bone was cut through the distal shaft of femur to place the bone in the sample holder, and the bone was fixed in the sample holder using eight screws and acrylic bone cement. The bone was placed in a neutral position on the sagittal plane, and its front face was tilted by approximately 9° in the valgus position (Figure 4). The stems were fitted into the four synthetic bones as per the alignment in the ZedHip plan.



Figure 4 Alignment of synthetic femur⁹⁾

Contact sites

After the stem was implanted into the synthetic bone, CT imaging was performed to check for damage. Then, the contact sites between the stem and cortical part of the synthetic bone were examined via ZedHip. The boundary between the cancellous and cortical regions of the synthetic bone was defined with a CT value of 40 Hounsfield units, and contact analysis was performed by superimposing the actual implant position and CAD data with ZedHip (Figure 5).

The sample surface was coated with matte black paint to perform thermoelastic stress measurements, and the sample holder was fixed to a hydraulic servo type material testing machine (MTS 858 Minibionix, MTS, Eden Prairie, MN, USA). A vertical 5-Hz sinusoidal compression load (-1.0 ± 0.9 kN) was added to the caput femoris during the measurement (Figure 6).

Thermoelastic stress analysis

The thermoelastic stress measurement involves application of the relationship between the changes in stress and temperature in an object associated with adiabatic elastic deformation, as per the principles shown below. Specifically, this method uses infrared thermography to measure



Figure 5 Examination of contact sites with ZedHip



Figure 6 Thermoelastic stress measurement (a) Oscillator unit (hydraulic servo type material testing machine) (b) Infrared camera of thermoelastic stress analysis unit

small temperature changes (ΔT) due to the thermoelastic effect of the sample, which is generated because of the periodic loads added to the sample, and creates images of the changes in the sum of principal stresses [$\Delta (\sigma_1 + \sigma_2)$] on the sample surface^{4-6, 10}.

In the adiabatic elastic deformation of a homogeneous object, the changes in the sum of the principle stresses ($\Delta\sigma$) and temperature (ΔT) are proportional.

The relationship between the change in the sum of the principle stresses ($\Delta\sigma$) and the temperature change (Δ T) by the thermoelastic effect of linear elastic is proportional, and homogeneous objects under adiabatic conditions are described by the following equation (A).

 $(\mathbf{A})\,\Delta \mathbf{T} = -\,\mathbf{k}\cdot\mathbf{T}\cdot\Delta\sigma$

where T is the absolute temperature of the material (K), k is the thermoelastic constant of the material (Pa⁻¹), and σ is the

sum of the principle stresses (Pa).

The thermoelastic coefficient, k, is obtained by the following equation (B):

(B) $\mathbf{k} = \alpha / (\rho \cdot \mathbf{C} \mathbf{p})$

where α is the linear thermal expansion coefficient (K⁻¹), ρ is the density (kg/m³), and Cp is the specific heat at constant pressure of the material (J/kg-K).

The change in the sum of surface principal stresses [Δ ($\sigma_1 + \sigma_2$)] was visualized using infrared thermography units (Silver 450M, Cedip (FLIR), Täby, Sweden).

Results

Contact sites

The results are similar for synthetic bone 1 (Figure 7) and synthetic bone 2 (Figure 8). The stem and synthetic



Figure 7 Synthetic bone 1: Contact sites between stem and cortical bone: (from left to right; anterior, medial, posterior, lateral views)



Figure 8 Synthetic bone 2: Contact sites between stem and cortical bone: (from left to right; anterior, medial, posterior, lateral views)

bone are in close contact along the entire proximal medial region of the porous part of the bone (Figures 7, 8a). Furthermore, there is localized contact on the distal posterolateral side (Figures 7, 8b). There is no contact between the stem and cortex of the synthetic bone in areas other than the proximal part, including the distal part of the stem.

Thermoelastic stress analysis

Surface stress analysis was performed using thermoelastic stress measurements. The results indicate that the minimum change in the sum of the principal stresses [Δ ($\sigma_1+\sigma_2$)], namely the compression area, occurs on the medial side and gradually decreases distally (Figures 9, 10; A area). Additionally, no change in the sum of principal stresses is measured on the maximum proximal part of the medial side (Figures 9, 10; B area).

The maximum change in the sum of the principal stresses $[\Delta (\sigma_1 + \sigma_2)]$, namely the tensile area, is distributed laterally (Figures 9, 10; C area). This stress distribution is more localized than the medial minimum change in the sum of the principal stresses $[\Delta (\sigma_1 + \sigma_2)]$.

Investigation of the stem contact sites and thermoelastic stress analysis

Figure 11 shows a superimposed stress distribution map of the stem contact sites and thermoelastic stress analysis. There are stem contact sites on the medial side, and a minimum change in the sum of principal stresses $[\Delta (\sigma_1+\sigma_2)]$ is observed distally. Based on this figure, it is surmised that the load applied to the stem is transmitted to the femur via the contact sites with the cortex.

On the external side of the proximal region, there is an extremely small range of contact between the stem and femur in the distal region of the stem. In synthetic bone 1, there is an extremely small distribution of the maximum change in the sum of principal stresses $[\Delta (\sigma_1 + \sigma_2)]$.



Figure 9 Synthetic bone 1: Thermoelastic stress analysis: (from left to right; anterior, medial, posterior, lateral views)



Figure 10 Synthetic bone 2: Thermoelastic stress analysis (from left to right; anterior, medial, posterior, lateral views)

Discussion

The BiCONTACT E stem is a proximally fixed cementless stem based on the concept of bone preservation, which is similar to the conventional BiCONTACT stem. Morphologically, the stem is characterized by a proximal lateral fin and flanges on the front and back. These structures are expected to enhance early fixation. The stem length of Bi-CONTACT E is approximately 3 cm shorter than that of the conventional BiCONTACT, and the proximal medial curve is optimized to suit the bone morphology of Japanese patients, while the bilateral flanges are slightly elongated.

Formation of a preserved stem seating is expected to attain early biological fixation, and it is designed to ensure that any load applied to the stem is transmitted from the anterior and posterior flanges to the medial cortex via the cancellous bone (Figure 12). It has been reported that this design prevents sinking and mitigates future stress shielding.

The results of stress analysis using thermoelastic stress measurement indicate that there is a minimum change in the sum of the principal stresses $[\Delta (\sigma_1 + \sigma_2)]$ on the medial side and maximum change in the sum of principal stresses $[\Delta (\sigma_1 + \sigma_2)]$ on the lateral side. Thus, in this instance, no minimum change in the sum of principal stresses is observed at the proximal region. It is reasonable to assume that the use of a cementless stem can inevitably lead to bone atrophy in the proximal part of the femur; however, given that this stem exhibits stress distribution at least at and below the level of the lesser trochanter, it is essential to thoroughly investigate how this affects stress shielding using clinical evaluation. In synthetic bone 2 (Figure 13), the flange is not in contact with the cortical bone. However, there is a small amount of surface stress distribution in the area that corresponds to



Figure 11 Contact sites and stress distribution (Left: synthetic bone 1, Right: synthetic bone 2)



Figure 12 Load transmission by the flange



Figure 13 Contact sites in synthetic bone 2 and results of thermoelastic stress analysis



Figure 14 Stress distribution in synthetic bone 1 (Left: frontal view, Right: lateral view)

this site. This can be because of the effect of the flange that transmits the load via the cancellous bone.

As per extant studies, the incidence of cortical hypertrophy with the conventional BiCONTACT stem varies, ranging from 29.8% to 43.5%^{11–13}. The causes of cortical hypertrophy include stem size mismatch¹⁴ and non-physiological load transfer¹¹. Given that the BiCONTACT E stem exhibits a shorter stem length, it is expected to exhibit a lower incidence of cortical hypertrophy. However, in synthetic bone 1, the maximum change in the sum of principal stresses [Δ ($\sigma_1+\sigma_2$)] is observed at contact sites distal to the stem (Figure 14). It is necessary to further investigate the extent to which these results affect cortical hypertrophy. Notably, the concentration of stress can lead to cortical hypertrophy.

Previous studies have reported a correlation between stress distribution in thermoelastic stress analysis and clinical bone response^{8, 9}. Understanding stress distribution in the femur where the stem is inserted can serve as a clue for predicting future bone resorption and bone response. This implies that stress distribution in the femur is associated with a fixed load and reflects the differences in the material and morphology of the hip joint stems. In addition, it is potentially possible to evaluate mechanical biocompatibility at the design stage of hip joint stems based on the correlation between bone surface stress distribution and long-term bone response and clinical outcomes.

The study had some limitations. First, the edge effect can be seen on the margin of the femur in the stress measurement image. This is an unavoidable measurement error. However, by using two synthetic bones, we confirmed that there was no significant difference. By measuring the specimens from four different directions, we were able to measure even small amounts of the stress concentration without losing sight of it.

Second, the load in the experiment may not be able to completely reproduce the actual conditions of load during walking. During walking, it is necessary to consider not only the vertical load, but also the effect on the hip joint due to multiple directions of loading and muscle movement. These factors need to be combined with finite element analysis and motion analysis to analyze the stress in clinical cases for individual patients. However, these are only simulations, and the thermoelastic stress analysis is expected to continue as an experimental validation technique for such theoretical analysis.

Conclusion

In this study, thermoelastic stress analysis was conducted to clarify the surface stress distribution of a femur in which a BiCONTACT E stem was inserted. The contact sites between the stem and femur were also investigated, and the results of the study clearly and quantitatively demonstrated the correlation with a range of stress distributions. Furthermore, the correlation between these results and clinical bone response was investigated in this study.

Additionally, this research technique is applicable for evaluating the mechanical biocompatibility and conducting preclinical performance predictions for new artificial hip joint stem designs.

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