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Spatial stress distribution analysis by thermoelastic stress measurement and evaluation of effect of stress concentration on durability of various orthopedic implant devices

Yoshimitsu Okazaki [a],*, Daisuke Ishii [b], Atsushi Ogawa [b]

[a] National Institute of Advanced Industrial Science and Technology, 1-1-1 Higashi, Tsukuba, Ibaraki 305-8566, Japan
[b] Implant Materials Evaluation Center, JFE Techno-Research Corporation, 1-1 Minamiwataridacho, Kawasaki, Kanagawa 210-0855, Japan

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ABSTRACT

Toward the development of highly durable devices, we investigated the effect of the thermoelastic constants of implantable raw metals and the surface stress distribution on the durability of various types of implant device by thermoelastic stress measurement and by evaluating the effect of the stress concentration. Surface stress was dynamically calculated from the bending moment, and the modulus of a section of a device was found to be consistent with the surface stress obtained by thermoelastic stress measurement. The durability limits of various types of bone plate and compression hip screw (CHS) calculated from maximum load vs number of cycles data (L–N data) were close to the notch fatigue strength of the raw material. The concentration factor of an artificial hip stem surface was estimated by comparing the L–N data of the stem and the S–N curve of the raw material. The dynamic analysis of durability by thermoelastic stress measurement is useful for selecting the worst case (a product deteriorating to the most severe state) in medical device design.

1. Introduction

The long-term clinical performance of products and the endurance of materials are important for implant devices. Therefore, metals such as Ti materials, stainless steel and Co-Cr-Mo alloys are widely used in orthopedic implant devices. Fatigue strength similar to that of a Ti alloy can be achieved by adding N to the above materials and treating with 20% cold working. For example, the fatigue strength of grade 4 commercially pure (C.P.) Ti approaches that of a Ti alloy upon 20% cold working. Ti alloys achieve higher corrosion resistance and biocompatibility than C.P. Ti through the addition of Mo, Zr, Nb, Ta and so forth [1]. In addition, the fatigue strength of materials can be substantially increased by changing the conditions of heat treatment and the hot forging process [2].

Fatigue crack initiation generally occurs in regions of stress concentration in implant devices. Surface stress mapping using a thermoelastic stress measurement method is useful for the analysis of stress concentration regions in implant devices. The purpose of this study is to investigate the effect of the thermoelastic constants of implantable raw metals and the spatial stress distribution on the durability of orthopedic implant devices using a thermoelastic stress measurement method. In addition, we examine the relationship between the fatigue characteristics of the raw material and the durability of implant devices. In other words, we examine the utility of an expression related to the bending moment for predicting the durability of implant devices from the raw material. Moreover, we estimated the effect of the surface stress concentration on the durability of implant devices. By applying a tensile or compressive force to an elastic material, heat absorption or heat generation occurs in proportion to the size of the material. The temperature changes owing to the change in the volume of the material, a phenomenon called the thermoelastic effect [3]. Thermoelastic stress measurement methods based on this thermoelastic effect have been established by ISO (International Organization for Standardization) TC (Technical Committee) 135/SC (Sub Committee) 8. The vocabulary and basic formula of thermoelastic stress measurement for use in nondestructive testing are standardized in ISO 10878 [4]. As a noncontact stress measurement technique, an infrared stress measurement method based on the thermoelastic effect is performed under the repeated application of a dynamic load to the specimen. When the load is added to the specimen, it is necessary to perform motion compensation by changing in the position of the specimen. The features of an infrared camera, namely, motion compensation software and a lock-in procedure using digital tracking technology, allow the measurement of such small changes in temperature. The temperature resolution when integrating approximately 200 images is 0.01 °C. To analyze the stress and strain in implant devices containing stress concentration regions, mechanical analysis with numerous strain gages is required. Therefore,

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* Corresponding author.
E-mail address: y-okazaki@aist.go.jp (Y. Okazaki).

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the measurement of a stress distribution with no leakage points is difficult. For the measurement of a spatial stress distribution, such as the stress concentration around the hole of an implant, the thermoelastic stress measurement method is advantageous. However, it cannot measure the stress distribution at internal positions, although it can be used to verify the validity of the results of finite element analysis for orthopedic implant devices.

Obtaining durability data for implant devices is important for the development of reliable devices. Regarding fatigue and durability testing methods, several standards have been established under the Japanese Industrial Standards (JIS). JIS T 0309 [5] provides testing methods for investigating the fatigue of metallic implant materials. JIS T 0310 [6] standardizes a fatigue testing method for notch sensitivity. JIS T 0312 [7] and JIS T 0313 [8] specify methods for investigating the durability of osteosynthesis devices. ISO 7206-4 [9] specifies a method for investigating the durability of artificial hip stems. There have been few reports on durability tests of implants useful for commercially approving medical devices. The basic principle of selecting the worst case (the most severe state to which the product is degraded) in the mechanical evaluation of medical devices is important for application to the commercial approval of medical devices. The application of thermoelastic stress measurement to the mechanical evaluation of implants is expected to be used as a basis for selecting the worst case in medical device design.

In this study, we examined the effect of the thermoelastic constants of implantable raw metals and the surface stress distribution generated by applying a bending moment to various implants by thermoelastic stress measurement. Fatigue tests on stainless steel, Co-Cr-Mo and Ti materials were conducted to verify the accuracy of the thermoelastic constants. Four-point bending durability tests were carried out on bone plates and compression bending durability tests were carried out on compression hip screws (CHSs), short femoral nails and artificial hip stems to measure the surface stress distribution. The surface stress produced by a bending moment was compared with that obtained by thermoelastic measurement. Moreover, to compare the durability limit of metallic bone plates and CHSs and the notch fatigue strength of the raw materials, we carried out fatigue tests on V-notched specimens. A Ti-15Zr-4Nb-4Ta alloy [10–13] was used to determine the extent to which the thermoelastic stress is affected by the alloying element.

2. Materials and methods

2.1. Alloy specimens

Stainless steel meeting the specifications in ISO 5832-1 [14] was melted by vacuum-induction melting. After soaking at 1200 °C for 3 h, an ingot was forged to billet. The billet was soaked at 1200 °C for 1 h then hot-worked. After maintaining the resulting rod-shaped specimen at 1050 °C for 30 min, it was quenched in water. Finally, the stainless steel rod was cold-worked with a 20% reduction in area. A Co-Cr-Mo alloy, which meets the specifications of the ISO 5832-12 [15] standard for implants, was prepared by vacuum-induction melting. The Co-Cr-Mo alloy ingot was first homogenized at 1250 °C for 5 h. The homogenized ingot was then maintained at 1200 °C for 1 h and then hot-forged into rod specimens of 20 mm diameter by repeated hot forging under the same conditions. Vacuum-arc melting was conducted on $(\alpha + \beta)$-type Ti-15Zr-4Nb-4Ta and Ti-15Zr-4Nb-1Ta (JIS T 7401-4) [16], grade 4 α-type C.P. Ti (ISO 5832-2) [17] and $(\alpha + \beta)$-type Ti-6Al-4V (ISO 5832-3) [18] alloys used for medical implants. All the fabricated ingots were soaked for 5 h at 1200 °C and β-forged into rods. The rods were then α-β-forged (starting temperatures: 760 °C for Ti-15Zr-4Nb-1Ta and Ti-15Zr-4Nb-4Ta, 850 °C for C.P. Ti and 1000 °C for Ti-6Al-4V). After α-β forging, all the Ti rods were annealed at 700 °C for 2 h. The C.P. Ti rod was cold-worked with a 20% reduction in area after annealing.

2.2. Implant specimens

The bone plates were Synthes narrow LC-LCP (424-581S; 8 holes; width: 13.5 mm; length: 144 mm; thickness: 4.6 mm; type A), Synthes LC-LCP small (423-581S; 8 holes; width: 11 mm; length: 103 mm; thickness: 3.3 mm), Synthes LC-DCP (443–580; 8 holes; width: 5 mm; length: 42 mm; thickness: 1.7 mm) [20% cold-worked grade 4 C.P. Ti], Zimmer narrow compression (00-4945-008-00; 8 holes; width: 12 mm; length: 135 mm; thickness: 4 mm), Zimmer narrow compression small (00-4945-008-00; 8 holes; width: 8 mm; length: 68 mm; thickness: 2.7 mm) [both 20% cold-worked stainless steel] and Teijin Nakashima Medical wiring THA plates (9 holes; Ti-6Al-4V and Ti-15Zr-4Nb-4Ta; width: 13 mm; length: 200 mm; thickness: 3.5 mm), as well as Stryker compression plates (620208S; 8 holes; width: 13 mm; length: 146 mm; thickness: 4.5 mm; Ti-6Al-4V; type B). To examine the effect of the alloying element, bone plates with the same shape as the Synthes Narrow LC-LCP plates were made with Ti-15Zr-4Nb-4Ta alloy. The CHSs were Synthes DHS tube plates (481-160VS: Ti-6Al-4V and 281-160: stainless steel; neck shaft angle: 135°; 6 holes in side plate; width of side plate: 19 mm; length of side plate: 110 mm; thickness of side plate: 5.8 mm; lag screw length: 80 mm) and Stryker Omega Plus Ti compression plates (3368-1-105; Ti-6Al-4V; 5 holes in side plate; width of side plate: 16.3 mm; length of side plate: 117 mm; thickness of side plate: 5.5 mm; lag screw length: 80 mm). The short femoral nails were Stryker Gamma 3 Trochanteric (3130-0170S: Ti-6Al-4V; neck shaft angle: 130°; shaft diameter: 12 mm; nail length: 100 mm; lag screw length: 80 mm) and Zimmer ITST Asian short nails (00-2256-180-10; 20% cold-worked high-nitrogen stainless steel; neck shaft angle: 130°; shaft diameter: 12 mm; nail length: 100 mm; lag screw length: 80 mm). To examine the effect of the alloying element, short nails of the same shape as the Joyup proximal femoral nail system (neck shaft angle: 127°; distal diameter: 10 mm; nail length: 170 mm; lag screw length: 90 mm) were made with Ti-15Zr-4Nb-4Ta alloy. The cementless total hip prostheses were Zimmer VerSysHA/TCP Fiber Metal MidCoat colorless stems (65-7645-012-00; Ti-6Al-4V; stem length: 170 mm; proximal diameter: 12 mm; stem A), DePuy S-ROM (900533210; Ti-6Al-4V; stem length: 176 mm; proximal diameter: 12 mm; stem B), DePuy AML plus a femoral component (1345-23-000; bead-coated Co-Cr-Mo; stem length: 160 mm; distal diameter: 12 mm; stem C) and a Stryker Osteonics Super Secure-Fit HA stem (J6054-0812; Ti-6Al-4V; stem length: 170 mm; distal diameter 12 mm; stem D).

2.3. Thermoelastic stress analysis

The theoretical thermoelastic stress is expressed as follows [4]:

$$\Delta\sigma = -\Delta T/(\gamma \times T), \text{where } \gamma = \beta/(\rho \times C_p)$$

Here, $\Delta\sigma$ (thermoelastic stress) is the change in the total principal stress (Pa); tensile and compressive stresses are positive and negative values, respectively; ΔT is the temperature change (K) caused by cyclic loading; γ is the thermoelastic coefficient (1/Pa); T is the temperature of the specimen (K); β is the coefficient of linear expansion (1/K); ρ is the density (kg/m^3); C_p is the specific heat at constant pressure [J/(kg·K)]. While repeatedly applying a sinusoidal load in a fatigue test or a durability test, the temperature change ΔT of the specimen surface was measured using infrared thermography, from which the thermoelastic stress $\Delta\sigma$ was calculated, as shown in Fig. 1. The thermoelastic stress generated in implant devices having compression and tension sides, as shown later in Fig. 4(a)–(c), was independently measured while varying the amplitude of the sinusoidal load applied to each side. The absolute values of the tensile and compression stresses measured at the same amplitude were averaged for comparison with the surface stress generated by the bending moment of an artificial hip stem. A load ratio (minimum load/maximum load) of 0.1 and a wave frequency of