**Ti-33.6Nb-4Sn Alloy Femoral Stem With Gradation of Young’s Modulus Reduces Stress Shielding After Total Hip Arthroplasty: A Biomechanical Study**

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**Introduction:** Stress shielding-related proximal femoral bone loss occurs after total hip arthroplasty (THA) because of the difference in the stiffness between the metal alloy stem and the host bone [1]. Although several types of femoral stems have been introduced, such as the anatomical, straight, wedge-taper, customized, and short stems, stress shielding still occurs in most cases, even with newer stem designs [2]. To overcome this biomechanical complication, we fabricated a low-modulus cementless hip stem from β-type Ti-33.6Nb-4Sn alloy (TNS) [3]. Local heat treatment applied at the femoral neck region of the TNS stem increased its tensile and fatigue strengths compared with those of the Ti-6Al-4V alloy and resulted in a gradual decrease in Young’s modulus of the TNS stem from the proximal to the distal regions. Young’s modulus for the stem’s distal region was <55 GPa, approximately half of that of the Ti-6Al-4V alloy and much closer to that of the bone. In this study, we compared stress shielding and initial stability between the TNS stem and a similar Ti-6Al-4V alloy stem.

**Methods:** We fabricated five TNS stems and compared them with five similarly shaped Ti-6Al-4V stems. An experienced surgeon implanted both stems into composite Sawbone femurs (Fig. 1). To evaluate stress shielding of the femur, we attached 13 triaxial strain-gauge rosettes (KFG-3-120-D17, Kyowa, Japan) to the femur and measured the cortical surface strain. Stress shielding was defined as the percentage of intact von Mises strain after stem insertion. Displacement transducers (GT2; KEYENCE, Japan) were attached to the greater trochanter with cortical screws to measure axial displacement and rotation of the stem relative to the femur. The intact (n = 5) and operated femurs (the TNS stem, n = 5; Ti-6Al-4V stem, n = 5) were tested on a material testing machine. Each femur was tilted laterally by 8° in the frontal plane and dorsally by 6° in the sagittal plane to simulate a single-leg stance. Compressive loads up to 2100 N were applied quasi-statically, and the load versus strain and displacement data were recorded. A maximal bending moment of 47 Nm was applied to avoid experimental errors caused by an altered head position after implantation [4]. Statistical analyses were performed using ANOVA. When an ANOVA indicated a significant difference among groups, the difference was evaluated using Fisher’s protected least significant difference test. A P-value of <0.05 was considered statistically significant.

**Results:** In the medial and lateral regions (A1, B1, B3, C1, C3, D1, and D3), the equivalent strains of each Ti-6Al-4V stem were significantly lower than those of the intact femur (all comparisons, P < 0.05), indicating stress shielding (Fig. 2). In particular, pronounced stress shielding was evident with the Ti-6Al-4V stem in both the proximal-medial and lateral regions (A1, B1, and B3). Conversely, significant differences in the equivalent strains between the TNS stem and the intact femur were evident at B1 (P = 0.003), B3 (P < 0.001), and B4 (P < 0.001). In the proximal-medial region (A1 and B1), the strains for the TNS stem were significantly greater than those for the Ti-6Al-4V stem (P = 0.01 at A1 and P = 0.006 at
B1). There were no significant differences in axial displacement ($P = 0.26$) or rotation ($P = 0.44$) between the TNS and Ti-6Al-4V stems (Table 1).

**Discussion:** Stress shielding mediated proximal bone loss and increased distal loading, and it is considered to influence implant fixation [5]. Thigh pain may also occur after THA, and its origin may be related to the relatively high bending stiffness of the femur implant [6]. The TNS stem was designed to decrease proximal bone loss and thigh pain by a decreased bending stiffness. We found that this low-modulus TNS stem decreased stress shielding in the proximal calcar region (relative equivalent strains at A1 and B1 were 83% and 85%, respectively) without affecting the proximal-lateral region (B3; 53%). Moreover, the initial stability of the TNS stem was comparable with that of the Ti-6Al-4V stem. Implantation of either stem changed the cortical strain pattern on the femur. A significant reduction in cortical strains in the proximal and middle regions occurred following implantation of the Ti-6Al-4V stem. In the proximal-medial region (A1 and B1), higher cortical strains with the TNS stem may have been caused by the lower bending stiffness of this stem relative to that of the Ti-6Al-4V stem. Gradation of Young's modulus of the TNS stem may have a positive influence on initial stability. Furthermore, decreasing the stem stiffness ameliorates stress shielding. However, such changes also cause interface debonding and relative motion. Using numerical design optimization methods, Kuiper and Huiskes proposed a nonhomogeneous distribution of Young's modulus in the femoral stem to decrease the relative motion [7]. Local heat treatment applied at the femoral neck region generated a temperature gradient in the stem through a low thermal conductivity, and Young's modulus was graded accordingly. We are currently conducting endurance tests of the TNS stem on the basis of ISO tests to prevent unfavorable clinical conditions before clinical introduction of the TNS stem.

**Significance:** This low-modulus TNS stem with a graded Young's modulus could minimize proximal femoral bone loss and improve biological fixation for long-term stability. The low-modulus TNS alloy may represent a candidate biomaterial for manufacturing cementless femoral stems to replace the conventional Ti-6Al-4V alloy.
Table 1. Relative axial displacement (μm) and rotation (*).  

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<tr>
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<th>TNS stem</th>
<th>Ti-6Al-4V stem</th>
<th>P-value</th>
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<tr>
<td>Axial displacement (μm)</td>
<td>73.0±12.7</td>
<td>67.1±15.5</td>
<td>0.262</td>
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Fig. 1. Photograph and X-ray images of a novel flexible cementless stem made of the β-type Ti-33.6Nb-4Sn alloy.

Fig. 2. Comparison of von Mises equivalent strain on the femoral surface between the intact femur and femurs implanted with the β-type Ti-33.6Nb-4Sn and Ti-6Al-4V stems. *P < 0.05.
| Axial rotation (deg.) | 0.298±0.083 | 0.291±0.006 | 0.444 |

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