Response of bone tissues to stationary and continuous loads simulating a femur

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Background: Residual stress remains in bone tissues after press-fit-fixation of a joint prosthesis recently implanted for joint arthroplasty. The response of bone tissues to the residual stress has been, however, unknown because that response was not known to be physiological.

Objective: We attempted to determine whether or not this unnatural stimulus may have adverse effects on bone tissues, including causing thigh pain and/or osteolysis.

Methods: An experimental method was designed to apply a stationary load from inside a rat femur by inserting a loop spring made of a superelastic wire made of a nickel titanium alloy.

Results: Twelve weeks after implantation, migration of the spring wire into the cortical bone was noted in 9 of 11 cases. The estimated contact stress between the spring wire surface and femoral bone was distributed from 56 to 85 MPa. Marked migration was noted in 3 cases in which the contact stress on the wire was over 80 MPa.

Conclusion: An excessive stationary load at the implant surface induces endosteal osteolysis together with the migration or protrusion of a prosthesis.

Key words: joint prosthesis, residual stress, tissue response, stationary load, superelasticity

Introduction

Since the 1990s, major cementless stems in total hip arthroplasty have undergone press-fit-fixation with firm hammering. Due to this procedure, marked stress remains for a long period. This residual mechanical stress is stationary, continuous, and directed from within pressing outward, unlike physiological conditions (Figure 1). This unnatural stimulus may have adverse effects on bone tissue, including causing thigh pain and/or osteolysis, which increases postoperative complications.

It is generally accepted that mechanical stimulation is feasible for bone tissues as the factor of bone formation or inhibition of osteolysis. Fukuda and Yasuda1 reported that the piezoelectric effect on bone had a role in the signal transfer of mechanical stimulations within bone tissues. Based on their findings, the piezoelectric effect must increase with the changing rate of mechanical stress. Therefore, the alteration of stress is necessary for osteogenesis. Huiskes, et al.2 theoretically formulated the response of bone tissues to mechanical stimulations. They showed that bone formation increases when the

Figure 1. Load characteristics
strain energy is appropriate, and too high or too low
strain energy induces osteolysis. Many investigators
supported this, as the mechanostat theory, and verified
that remodeling of the bone tissue occurs in an attempt to
reach a homogeneous state of stress when marked local
stress is generated on the mechanical stimulation of bone.3
This formula did not, however, clarify the response to
static stimulation.

In most studies,4 mechanical stimulation was applied
as fluctuating load. Few studies have discussed the effects
of stationary loads.4

In the present study, we designed an experimental
method to apply a stationary load from inside a rat femur
using a loop spring made of a nickel titanium (Ni-Ti)
alloy with superelasticity. The femoral response was
assessed based on the migration of the spring wire in the
bone 12 weeks after implantation. The results showed
wire migration in 9 of 11 cases. Marked migration was
noted in 3 cases, in which the contact stress on the spring
wire was estimated to be over 80 MPa.

Materials and Methods
All procedures involving the handling of animals were
in accordance with the guidelines of the animal ethics
committee of Kitasato University.

We developed a method using a loop spring made of
a superelastic Ni-Ti alloy that can maintain sufficient
stress in a rat femur for a prolonged period. This Ni-Ti
alloy, containing 43.94% titanium and 56.06% nickel,
was supplied as a wire (WDL1; Actment, Kasukabe).
The shape of the wire can be changed easily due to its
high-plasticity with a smooth surface. A subsequent
quenching process provides superelasticity so that the
wire can withstand a considerable amount of elastic
deformation. Additionally, this Ni-Ti alloy of this
constituency is generally known as an inert material in
animal bodies, showing marked corrosion resistance.5

The loop spring was fabricated with a twisting part
and a circular loop, as shown in Figure 2. An expansive
load can be generated with elastic deformation when the
loop spring is compressed with its insertion into the bone
marrow of a rat femur. Therefore, the natural diameter
of the loop must be sufficiently larger than that of the
bone marrow within the rat femur. We measured the
morphometric values of rat bone marrow on images of
micro-computed tomography (micro-CT) using an
InspeXio SMX-90CT system (Shimazu, Kyoto) to clarify
the size of the space within which the loop spring was to
be inserted. The average internal diameter was 1.4 mm
at the center of the diaphysis, which had a total average
length of 22 mm. The wire formed a loop of approximately
7 mm in diameter at the widest part, which is the center
of the spring (Figure 2).

The load on the loop spring in the rat femur was
estimated from the spring wire deformation and
relationship between the load and deformation based on
the loading test. After the springs were prepared, the
load-deformation relationship of each loop spring was
obtained by the in vitro loading test. We incorporated a

Figure 2. Loop spring made of a superelastic wire of Ni-Ti alloy inserted in a rat femur
micrometer and a load transducer (TL-LF 1K; TEAC, Tokyo) into a device to measure the stiffness of the loop spring (Figure 3). Twelve springs were used in total. Eleven springs were inserted into rat femurs. The other spring remained under an *in vitro* load of approximately 2 N to verify the remaining load during the test period. The load decreased to approximately 85% of the original load (from 2.26 to 1.91 N) after 12 weeks (Figure 3). Therefore, the actual load in the rat femur was estimated by considering this reduction.

The average contact stress was approximately calculated by dividing the load by the contact area estimated from the curvatures of the spring wire within the bone marrow, elastic constants of the materials, and the load itself, following the elastic contact theory6-8 (see the Appendix). The longitudinal length of the contact area between the spring surface and femoral bone was estimated from the micro-CT image (Figure 4).

An specific-pathogen free colony of Wistar rats was maintained at Nippon Charles River Laboratories (Kanagawa). We used 10-week-old Wistar rats at the start of the experiment. A 10-week-old Wistar rat is equivalent to a human teenager. The rats were housed in a semi-barrier system with a controlled environment (temperature, 23 ± 2°C; humidity, 55 ± 10%; lighting: 12-hour light/dark cycle) throughout the study. All rats were fed a diet of standard rodent chow (CRF-1; Oriental Yeast, Tokyo).

The rats’ right knees were exposed through a medial parapatellar incision under nembutal anesthesia. The loop spring was subsequently inserted into the bone marrow cavity. The contralateral femur remained intact.

Figure 3. Force on the loop spring up to 12 weeks

Figure 4. Length of the contact area measured on a CT image
Appendix

The contact area can be estimated from the equivalent curvature, elastic constants, and vertical load. The width of the contact area $b$ [m] of two cylinder surfaces can be estimated by the elastic contact theory of Lundberg.6

$$b = \frac{4 f}{\pi E_q p l}$$

Here, $f$ [N] is the vertical load. $l$ [m] is the length of the contact area. $p$ [1/m] is the equivalent curvature. The equivalent curvature is calculated from the radii of the contact surfaces $R_1$ and $R_2$ [m].

$$p = \frac{1}{R_1} + \frac{1}{R_2}$$

The equivalent elastic modulus $E_q$ [Pa] is calculated from each elastic modulus $E$ [Pa] and Poisson's ratio $\nu$ of the contact surfaces.

$$\frac{1}{E_q} = \frac{1}{E_1} + \frac{1}{E_2}$$

The mean contact stress can be calculated with the following equation.

$$p_{\text{mean}} = \frac{f}{bl}$$

The characteristics used in this analysis, $R_1, R_2, E_1, E_2, \nu_1, \nu_2$, of the Ni-Ti alloy spring wire and bone marrow are shown Table 1. Elastic moduli of the spring wire and bone tissue were obtained from the literature.7-8

<table>
<thead>
<tr>
<th>Table 1. Characteristics of the wire and bone marrow6,7</th>
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<tbody>
<tr>
<td>Wire</td>
</tr>
<tr>
<td>------</td>
</tr>
<tr>
<td>Radius</td>
</tr>
<tr>
<td>Young's modulus</td>
</tr>
<tr>
<td>Poisson's ratio</td>
</tr>
</tbody>
</table>

*Negative number indicates concave

Figure 5. Soft X-ray image of the femur

A. Immediately after insertion of the loop spring
B. Twelve weeks after insertion
An X-ray image of the femur was taken immediately after the implantation and at 12 weeks after implantation using a soft X-ray system (TYPE HB-50; Hitex, Osaka) (Figure 5).

At 12 weeks, the rats were euthanized, femurs were collected, and cross-sectional images of the femur specimens were taken using an InspeXio SMX-90CT micro-CT system. The migration of the wire into the cortical bone tissues of the rat femur was assessed based on the image.

**Results**

Migration of the spring wire into the femoral bone was observed in 9 of the 11 specimens (Figure 6). To assess spring migration in cortical bone, we measured the distance from the endocortical surface to the tip of springs on micro-CT images (Figure 7). The line of the endocortical surface was extrapolated from the adjacent to the wire contact area.

The migration mainly occurred on the anterior side, which is the left side in Figures 6 and 7. The depths of migration were 0.19 mm SD 0.13 mm on the anterior side and 0.06 mm SD 0.13 mm on the posterior side (Table 2). The actual deformation was estimated as the difference between the original position and that observed after migration on micro-CT images (Figure 6). The estimated load was distributed from 0.77 to 1.77 N. Each contact area was estimated as $0.014 - 2.08 \text{ mm}^2$. The contact stress was distributed from 56 to 85 MPa.

The migration depth on the anterior and posterior sides was associated with the estimated contact stress (Figure 8). Deep migration over 0.3 mm occurred when the contact stress exceeded 80 MPa.

**Discussion**

In the present study, we developed a method of generating a stationary stress field in a rat femur using a loop spring made from a Ni-Ti alloy with superelasticity. The load that originated from elastic deformation was large enough to apply mechanical stimulation to bone tissue. We
estimated the average contact stress to be 62–94 MPa, which is lower than the yield stress of 170 MPa for femoral bone tissue. Migration of the implanted loop spring in the femur was observed in 9 of the 11 cases. The migration depth apparently increased with the increase in contact stress (Figure 8).

Migration into the femur on the anterior side tended to be greater than that on the posterior side. This tendency can be explained by the difference in the thickness of cortical bone that had a decisive influence on the strain in the tissue. In femurs with a thin cortical bone, there is more strain, and migration tends to occur.

The period of implantation in the present experiment was 12 weeks. This period corresponds to approximately 6 years in humans because the lifespan of a rat is about 3 years, which is 1/20 of that in humans.

Table 2. Migration depth for the estimated contact stress on each spring

<table>
<thead>
<tr>
<th>No.</th>
<th>Load (N)</th>
<th>Contact area (mm²)</th>
<th>Contact stress (MPa)</th>
<th>Migration depth (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Anterior side</td>
</tr>
<tr>
<td>1</td>
<td>0.81</td>
<td>0.022</td>
<td>57.5</td>
<td>0.00</td>
</tr>
<tr>
<td>2</td>
<td>0.77</td>
<td>0.022</td>
<td>56.1</td>
<td>0.18</td>
</tr>
<tr>
<td>3</td>
<td>0.91</td>
<td>0.024</td>
<td>60.9</td>
<td>0.00</td>
</tr>
<tr>
<td>4</td>
<td>0.85</td>
<td>0.023</td>
<td>58.9</td>
<td>0.00</td>
</tr>
<tr>
<td>5</td>
<td>0.82</td>
<td>0.023</td>
<td>57.8</td>
<td>0.21</td>
</tr>
<tr>
<td>6</td>
<td>0.91</td>
<td>0.024</td>
<td>61.0</td>
<td>0.21</td>
</tr>
<tr>
<td>7</td>
<td>0.90</td>
<td>0.024</td>
<td>60.8</td>
<td>0.26</td>
</tr>
<tr>
<td>8</td>
<td>0.80</td>
<td>0.022</td>
<td>57.2</td>
<td>0.12</td>
</tr>
<tr>
<td>9</td>
<td>1.59</td>
<td>0.031</td>
<td>80.6</td>
<td>0.21</td>
</tr>
<tr>
<td>10</td>
<td>1.77</td>
<td>0.033</td>
<td>84.9</td>
<td>0.40</td>
</tr>
<tr>
<td>11</td>
<td>1.60</td>
<td>0.032</td>
<td>80.8</td>
<td>0.35</td>
</tr>
<tr>
<td></td>
<td>Average</td>
<td></td>
<td>65.1</td>
<td>0.19</td>
</tr>
</tbody>
</table>
To verify the present findings, we must assess the actual stress generated in a femur during the press-fit procedure of fixation of a prosthetic stem. In relation to this, the authors measured the impact force in a previous investigation during press-fit-fixation in a human femur. With the standard process, the maximum impact force was measured as 12 kN. Under this impact force, the maximum contact stress of 68 MPa was estimated by finite element analysis. Therefore, the contact stress of 60—90 MPa applied in the present experiments was comparable to the stress suggested in the fixation area of a human femur. The present findings suggest that residual stress at the implant surface may induce endosteal osteolysis.

As a limitation, this study cannot be applied to humans directly because it is an animal study.

We developed a method for configuring a stationary stress field in a rat femur using a loop spring manufactured from a Ni-Ti alloy with superelasticity. Migration of the wire in cortical bone was observed, which was accompanied by osteolysis on the surface of the wire toward the outside. The present findings suggest that an excessive stationary load at the implant surface induces endosteal osteolysis together with the migration or protrusion of a prosthesis. The response of bone tissues to the residual stress of a loop wire spring warrants further elucidation.

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**References**