

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

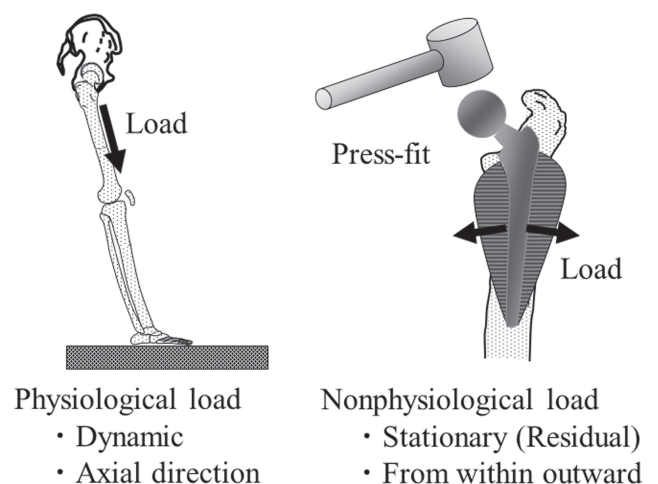


Figure 1. Load characteristics

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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

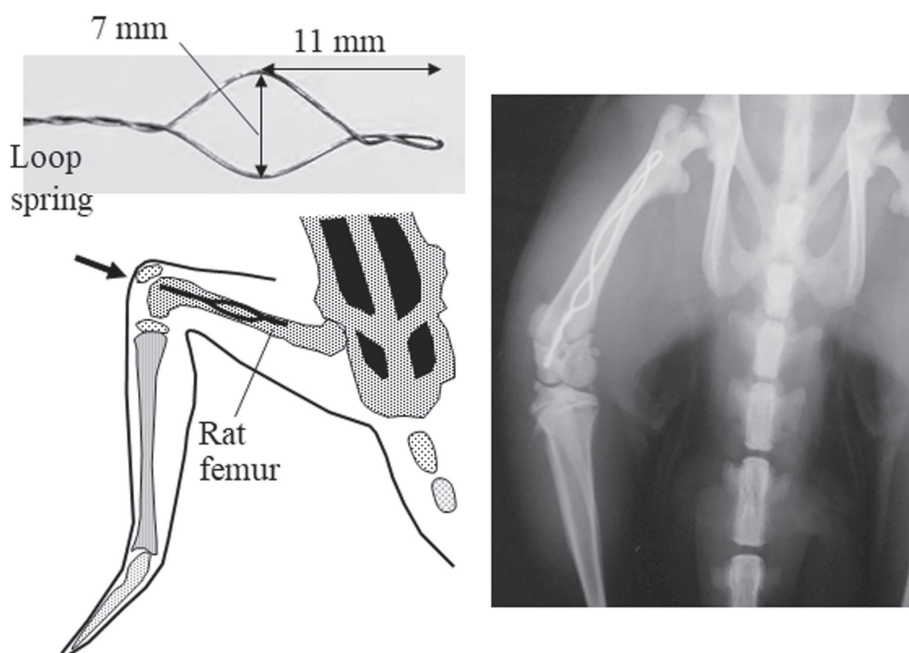


Figure 2. Loop spring made of a superelastic wire of Ni-Ti alloy inserted in a rat femur

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, $23 \pm 2^\circ\text{C}$; humidity, $55 \pm 10\%$; 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.

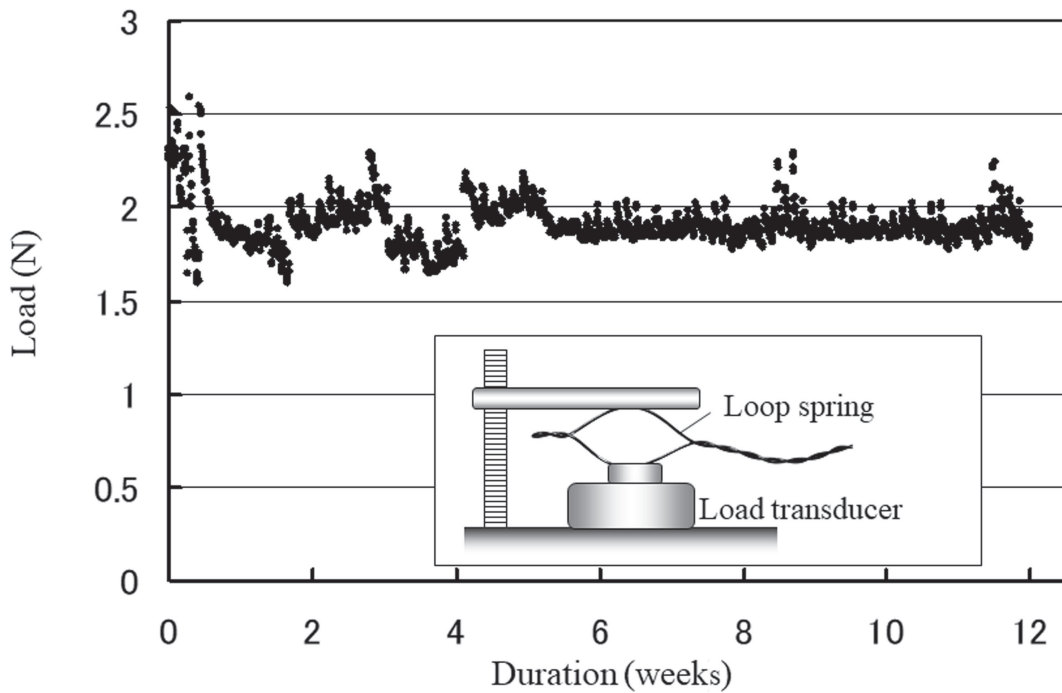


Figure 3. Force on the loop spring up to 12 weeks

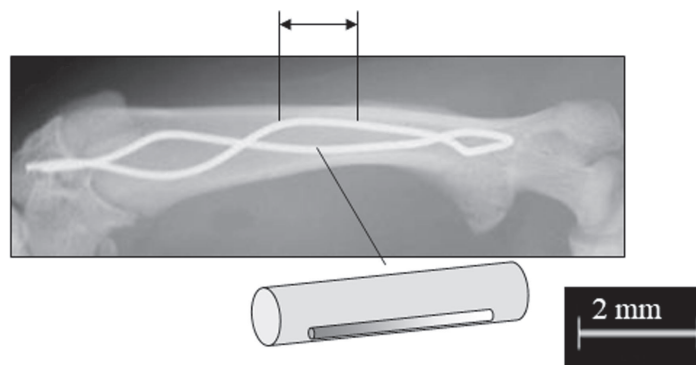


Figure 4. Length of the contact area measured on a CT image

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

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

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

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

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

$$\frac{1}{E_q} = \left(\frac{1-\nu_1^2}{E_1} + \frac{1-\nu_2^2}{E_2} \right)$$

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

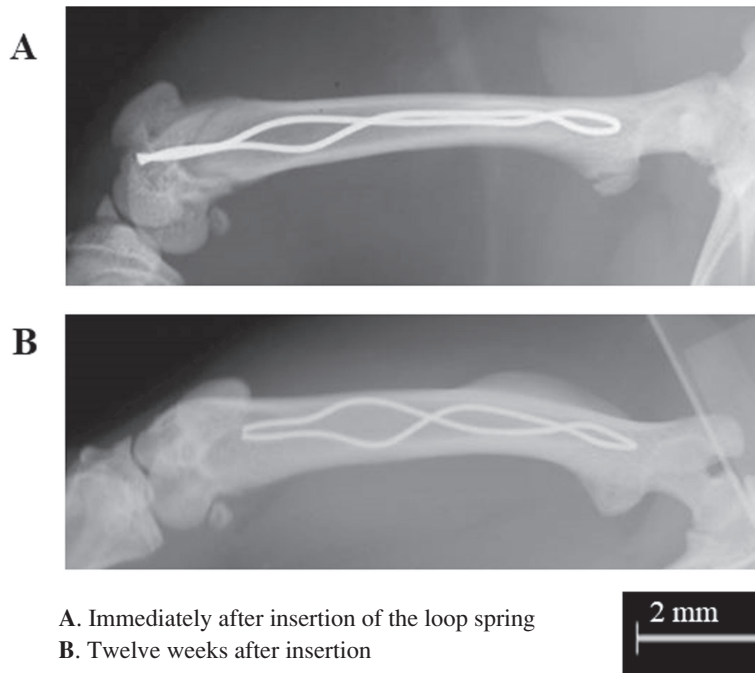
$$p_{mean} = \frac{f}{bl}$$

The characteristics used in this analysis, R_1 , R_2 , E_1 , E_2 , ν_1 , and ν_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 1. Characteristics of the wire and bone marrow^{6,7}

	Wire		Bone marrow	
Radius	R_1	R_2	0.2 mm	-0.7 mm*
Young's modulus	E_1	E_2	60 GPa	17 GPa
Poisson's ratio	ν_1	ν_2	0.3	0.3

*Negative number indicates concave



A. Immediately after insertion of the loop spring
 B. Twelve weeks after insertion

Figure 5. Soft X-ray image of the femur

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 InspecXio 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 mm². 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

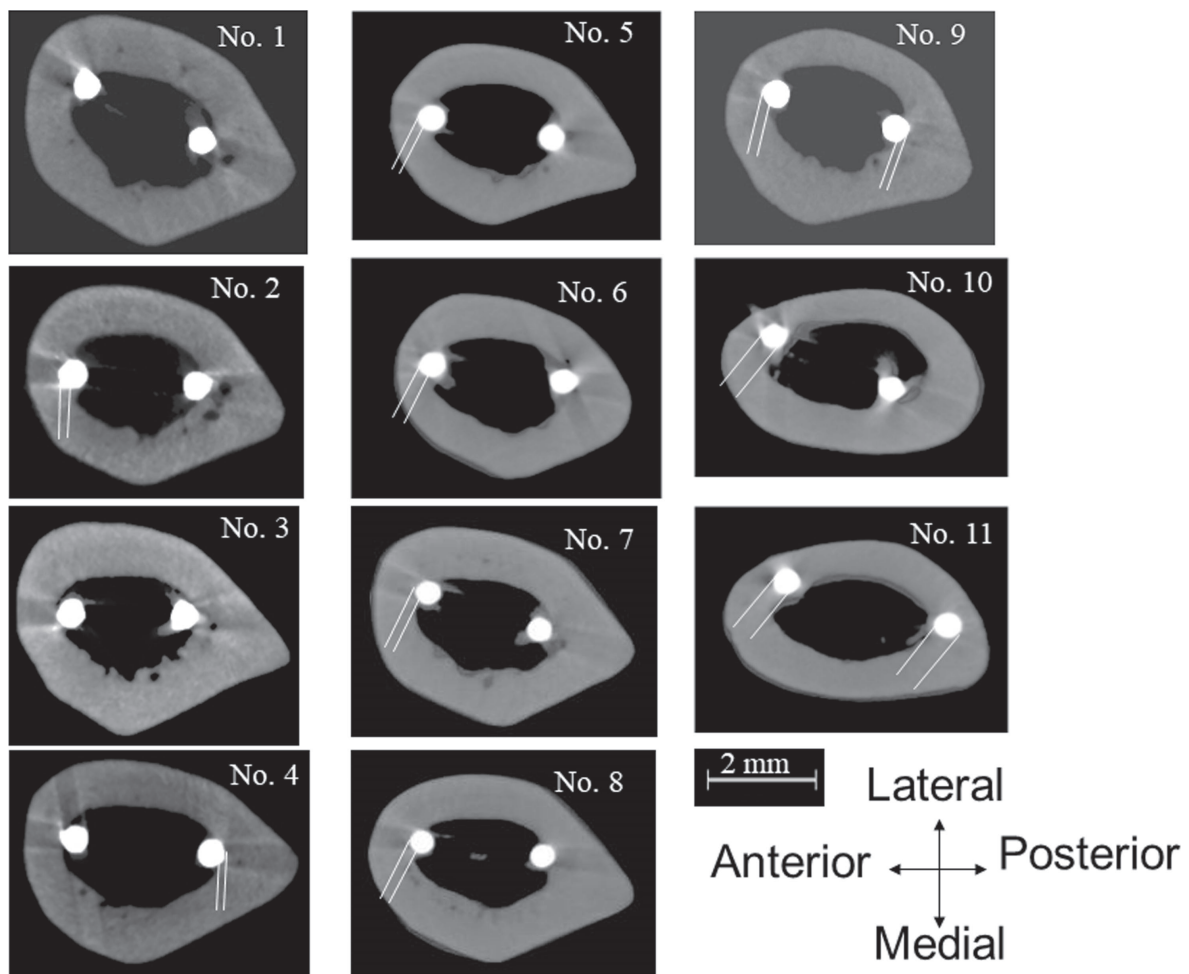


Figure 6. Micro-CT images of rat femurs 12 weeks after implantation

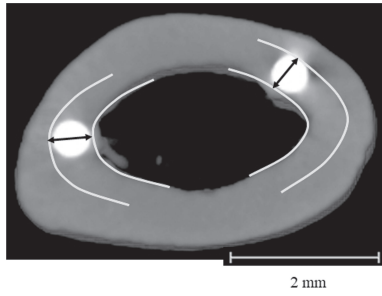


Figure 7. Measurement of wire migration in a micro-CT image of a rat femur

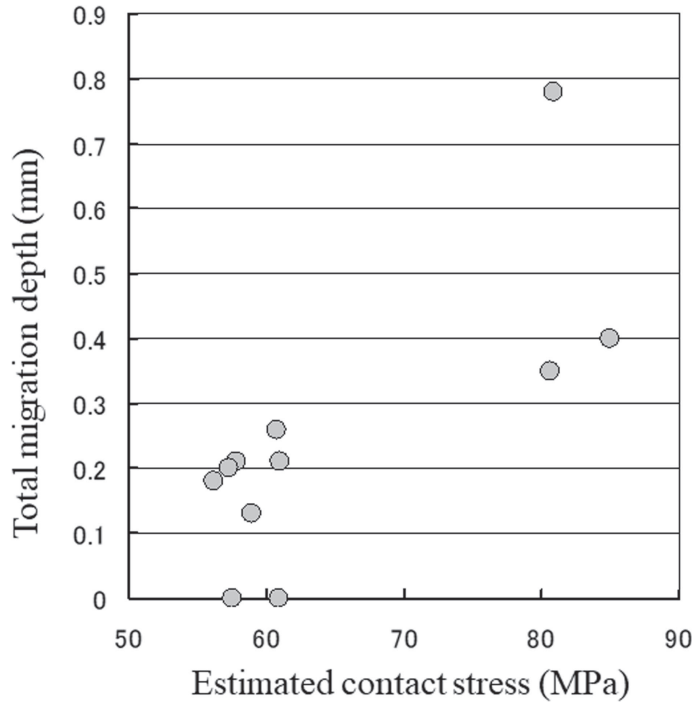


Figure 8. Migration depth of the spring wire observed in the femur sections 12 weeks after insertion for the estimated contact stress

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

No.	Load (N)	Contact area (mm ²)	Contact stress (MPa)	Migration depth (mm)		
				Anterior side	Posterior side	Total
1	0.81	0.022	57.5	0.00	0.00	0.00
2	0.77	0.022	56.1	0.18	0.00	0.18
3	0.91	0.024	60.9	0.00	0.00	0.00
4	0.85	0.023	58.9	0.00	0.13	0.13
5	0.82	0.023	57.8	0.21	0.00	0.21
6	0.91	0.024	61.0	0.21	0.00	0.21
7	0.90	0.024	60.8	0.26	0.00	0.26
8	0.80	0.022	57.2	0.12	0.08	0.20
9	1.59	0.031	80.6	0.21	0.14	0.35
10	1.77	0.033	84.9	0.40	0.00	0.40
11	1.60	0.032	80.8	0.35	0.43	0.78
Average	1.07	0.025	65.1	0.19	0.06	0.25

estimated the average contact stress to be 62–94 MPa, which is lower than the yield stress of 170 MPa for femoral bone tissue.⁷ 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.

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.⁹ Under this impact force, the maximum contact stress of 68 MPa was estimated by finite element analysis.⁹ 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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