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Design and optimization of the oriented groove on the hip implant surface to promote bone microstructure integrity

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ABSTRACT

We proposed a novel surface modification for an artificial hip joint stem from the viewpoint of maintenance and establishment of appropriate bone function and microstructure, represented by the preferred alignment of biological apatite (BAp) and collagen (Col). Oriented grooves were introduced into the proximal medial region of the femoral stem to control the principal stress applied to the bone inside the grooves, which is a dominant factor contributing to the promotion of Col/BAp alignment. The groove angle and the stem material were optimized based on the stress inside the grooves through a finite element analysis (FEA). Only the groove oriented proximally by 60° from the normal direction of the stem surface generated the healthy maximum principal stress distribution. The magnitude of the maximum principal stress inside the groove decreased with increasing the stem Young's modulus, while the direction of the stress did not largely changed. An *in vivo* implantation experiment showed that this groove was effective in inducing the new bone with preferential Col/BAp alignment along the groove depth direction which corresponded to the direction of maximum principal stress inside the groove. The anisotropic principal stress distribution and the oriented microstructure inside the groove are similar to those found in the femoral trabeculae; therefore, the creation of the oriented groove is a potent surface modification for optimizing implant design for a long-term fixation.

Introduction

The number of total hip replacements (THRs) has increases every year, and in the United States, nearly 231,000 THRs were reported in 2006 [1]. In recent years, THRs are increasingly performed on younger patients [2], and the ratio of the number of revision hip replacements to primary hip replacements is as high as 20% [3]. According to the results of a US epidemiological study that examined the factors contributing to revision hip replacements, Bozic et al. [4] reported that 24.7% of the revisions were due to mechanical loosening of the femoral component; 18.7% were due to periprosthetic fractures, both of which are thought to be induced by bone loss due to a stress shielding [5,6]. The stress shielding refers to inhibition of the transfer of physiological stress to bone tissues due to a difference between Young's modulus (YM) of the bone and that of the implant. Meanwhile, only 8.6% of the revisions were caused by implant failures [4], indicating high mechanical reliability of artificial hip joint implants themselves. The degradation of the bone tissues surrounding the femur and decrease in bone mechanical functions can lead to revision hip replacement. Prevention of such events requires an implant design that supports the microstructural and mechanical health of the bone surrounding the implant, rather than an improvement of the implant material itself.

Microstructure of bone materials, independent of bone mass and bone mineral density (BMD) [7,8], is an important factor in the assessment of bone health. The *c*-axis alignment of biological apatite (BAp) strongly contributes to bone mechanical functions, because BAp has a hexagonal-base crystal structure and shows marked mechanical anisotropy along the *a*- and *c*-axes. YM is significantly higher in the direction of the *c*-axis than in direction of the *a*-axis [9], and because the *c*-axis alignment of BAp in the bone is nearly identical to the direction of the extension of the Col fibril [10,11], the mechanical function of bone as a Col/BAp complex can display anisotropy depending on the degree of preferential alignment [12,13]. It is recently demonstrated that the degree of BAp *c*-axis alignment rather than BMD determines YM measured by nanoindentation along the direction parallel to the BAp alignment direction [14]. The maximum principal stress distribution loaded on the bone *in vivo* seems to be one of the vital contributory factors of the BAp alignment. As shown by Nakano et al. [8], along with the *in vivo* stress changes, the BAp alignment depends strongly on the bone site, such as the long bones, the skull bone, and the mandible bone. For example, in the cortical bone of a mature monkey mandible, the *c*-axis of BAp

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is uniaxially, mesiodistally aligned. However, the alignment direction near the teeth changes, becoming parallel to the biting direction. *In vivo* BAp alignment sensitively changes in response to the direction and magnitude of localized stress, such as mastication stress. Bone can improve its mechanical function by altering BAp alignment in the direction of the maximum principal stress, and such a phenomenon can be found not only in cortical bone, but also in the trabecular bone.

The trabecular bone is in direct contact with the implant, in cementless artificial hip joints. Therefore, trabecular bone is a site responsible for load transfer and bone-implant bonding. According to Wolff's law, trabecular bones exhibit a characteristic pattern along the principal stress direction, and the trabecular pattern is restructured as a result of changes in principal stress distribution due to trauma or changes in life pattern [15,16]. Furthermore, inside each individual trabecular bone, the BAp *c*-axis preferentially aligns along the direction of the trabeculae [17], which makes the trabecula mechanically anisotropic [18]. Thus, in the healthy trabecular bone, the principal stress direction corresponds to trabecular direction, which may be a goal to achieve the formation of appropriate Col/BAp alignment and resultant mechanical performance even after the implantation of a stem.

Since the Col/BAp alignment can be one of the indices of mechanical bone health, making it a focus may allow optimization of these implants [19], so that by vitalizing microstructure and mechanical function of the bone around the implant, new artificial hip joints can be designed to allow the implant to induce principal stress distribution suitable to the surrounding bone along with a BAp structure that is aligned similarly to that of normal bones. In this study, we propose an oriented groove structure in the medial part of the proximal region of the femoral stem. The trabecular bones in the proximal medial region of the femur are called a secondary compressive group consisting of trabeculae extending proximally toward the greater trochanter. Since this region contributes significantly to implant anchorage in cementless artificial hip joints [20], the induction of tissues with a healthy, aligned BAp structure is a pivotal strategy.

Previous attempts to make the stem surface porous were performed to fixate implants at the proximal medial region of the femur [21–23]. However, the conformations of the pores introduced using conventional fabrication methods were three-dimensionally (3D) isotropic, and in most cases, their purpose was to simply achieve anchoring through formation of new bone tissue inside the pores [23]. Recently, it was reported that even though porous (Ti mesh)-coated cementless Ti–6Al–4V stem was applied into human femur, stress shielding occurred leading to bone loss and degradation of BAp alignment in the femur surrounding the stem [24]. This suggests that new strategy for designing implant is needed aiming at avoiding stress shielding and aggressively controlling the stress distribution around the implant. At present, we do not know of any other implant surface design that accounts for the control of the principal stress distribution and subsequent creation of healthy Col/BAp alignment.

In this study, we hypothesized that anisotropic pores (grooves) introduced onto the surface of an artificial hip joint stem would induce maximum principal stress along the groove depth, which would further stimulate formation of new bone with the suitable preferential alignment of Col/BAp. To test this hypothesis, finite element analysis (FEA) was conducted to examine the effects of anisotropic grooves on the maximum principal stress distribution generated in the grooves, followed by *in vivo* implantation experiment in beagles for exploring the creation of Col/BAp alignment in the newly formed bone inside the grooves. Finally, we proposed a guideline for designing optimized implants that allow control of the maximum principal stress by the groove and the resultant Col/BAp alignment.

Materials and methods

A beagle femur was used as a model for the optimized design of an artificial hip joint stem. An FEA was used for predicting principal stress generated in the anisotropic grooves. An animal implantation test was performed to examine establishment of the Col/BAp alignment in the bone formed inside the grooves. The predicted stress and the Col/BAp alignment were compared to derive an optimized surface design for an artificial hip joint stem.

Construction of the analytical model

For FEA analysis, 3D models of the beagle femur and the artificial hip joint stem were modeled separately. The intact right femur of a beagle (age: 2 years, weight: 13.0 kg) was extracted, and tomographic images with a resolution of 90 μm × 90 μm × 90 μm were obtained at 1-mm intervals along the femoral axis, using micro-focus X-ray computed tomography (μCT; SMX-100CT, Shimadzu, Japan), with a tube voltage of 65 kV, and a tube current of 27 μA.

To prepare an FEA model, the outline of the cortical bone was extracted after binarization of all tomographic images using CT image analysis software (Mimics 11, Materialise, Belgium). Procedures, such as spline interpolation, were performed from the stacked contours using a 3D surface modeling software (Imageware 10, Siemens, USA). Using these resources, a 3D model of the femur was constructed [25].

The stem was designed so that the cross-section from the femoral neck to the distal end was rectangular to preserve trabecular bone and marrow and minimize impairment of blood flow in the cortical bone [26,27]. The medial–lateral surface was tapered. While the features and dimensions needed for the design were measured based on a femur model, a femoral stem with an outer configuration similar to that shown in Fig. 1C was modeled using 3D CAD software (UGNX 4, Siemens, USA).

Introduction of the oriented groove on the stem surface

An oriented groove structure for controlling stress distribution was introduced to the proximal medial region of the femoral stem. To analyze the groove angle dependence on the principal stress distribution inside the groove, 5 groove angles were used, 60°, 30°, 0°, −30°, and −60°, with the proximal side as the positive direction compared to the normal direction of the stem surface (Fig. 1A). A pore diameter of several hundred microns is considered optimal for the migration of osteoblasts and the formation of mineralized tissue [28,29]. Therefore, for all cases, the groove width was set to 500 μm and the groove depth to 1 mm (Fig. 1B).

The artificial hip joint was inserted into the marrow cavity of the beagle femur model (Fig. 1C) using 3D imaging so that the groove that was introduced into the femoral stem surface was located approximately at the level of the lesser trochanter. The second compressive group that is dominantly subjected to compressive stress is present in this region.

Setting the FEA conditions

Three materials were defined on the bone-implant model: the femoral stem region, the cortical bone region, and the trabecular bone region or the interior of the groove cavity (Figs. 1A, C), and an analysis model was prepared using a finite element pre-processor (HyperMesh 9; Altair Engineering, USA). As shown in Fig. 1, the tetrahedral primary element with a dimension of 500 μm was used: the number of elements was 48,170, and the number of nodes was 592,088. To examine the effect of element dimension on the resultant principal stress distribution, we applied a small element (62.5 μm in dimension) to the 60° groove and calculated principal stress. As a result, slightly disordered principal stress direction was found near the stem surface, but there was little effect on the quantitative analysis. Therefore, the element 500 μm in dimension was used for all FEA calculation.

The loading conditions were based on the method described by Rietbergen et al. [30], as shown in Fig. 1C. The force applied on the