Review

Mechanical Studies on Biomaterials for Reconstruction of Lower Limb Functions

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SYNOPSIS

In this paper, mechanical studies on biomaterials for reconstruction and regeneration of bone and joints of lower limb are summarized. Finite element analyses of knee and hip prostheses were performed to characterize the mechanical conditions of the artificial components and the mechanical interaction between bone and prosthesis. The computational results showed that for the knee prosthesis, the transitional behavior of stress concentration on ultra-high molecular weight polyethylene insert corresponded to actual damage formations, and for the hip prosthesis, the disturbed stress on the injured acetabulum was effectively reduced by the joint replacement, however, stress shielding effect in the femur was also induced by stem insertion. Strength enhancement of bioabsorbable porous poly(L-lactide) scaffold was also investigated using layered structurization. It was found that those properties were effectively improved by introducing layered structures.

KEY WORDS
biomaterial, biomechanics, finite element analysis, total arthroplasty, prosthesis, scaffold

1 Introduction

Population ageing has dramatically been growing in Japanese society and at the same time, elderly patients with severe joint diseases such as osteoarthritis and articular rheumatism have also been increasing. For severely injured knee and hip joints by osteoarthritis and articular rheumatism, total arthroplasty using knee or hip prostheses is known to be very effective to recover the function of joint movements as shown in Fig. 1. However, serious biomechanical problems such as bone resorption around such prostheses and wear and fracture of the joint components are arising as complications. For damaged bone tissues due to osteosarcoma and cyst, reconstructions using porous biomaterials are thought to be very effective. These biomaterials are required to possess mechanical properties compatible to the target tissues.

Based on these Japanese social conditions, my research group has mainly been working on mechanical studies on biomaterials used for reconstructions of lower limb joints. For example, from computational mechanical points of view, total knee and hip arthroplasties have been analyzed by using finite element analysis (FEA) technique\(^1\text{−}^5\). On the other hand, bioabsorbable polymer and organic/inorganic composite biomaterials have been developed and the relationship between microstructure and mechanical properties has been characterized\(^6\text{−}^{11}\).

In the present studies, finite element analyses of knee and hip prostheses were performed to characterize the mechanical conditions of the artificial components and the mechanical interaction between bone and prosthesis. In the knee joint study, a virtual knee simulator was developed to understand transitional behavior of stress concentration on the ultra-high molecular weight polyethylene (UHMWPE) insert. In the hip joint study, detailed hip joint models with

![Fig.1](image)

(a) OA knee  (b) TKA knee.

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and without hip prosthesis were constructed from computed tomography (CT) images and CAD data. Stress concentration and stress shielding effects were then examined by FEA.

Strength enhancement of bioabsorbable porous poly (L-lactide) (PLLA) scaffold was also investigated using layered structuration. Effects of porous and solid outer-layers on the compressive mechanical properties were examined and micromechanics of deformation was also characterized by scanning electron microscopy. Effect of bone tissue ingrowth into porous hydroxyapatite (HAp) material was also studied by both in vivo experiments and computational analysis. Computational models were developed from micro-CT images of rabbit femur with porous HAp. Effect of tissue ingrowth on the compressive strength was then analyzed by both experiment and computation.

2 Development of virtual knee simulator

Virtual knee simulator model constructed in this study is shown in Fig. 2. The simulator is understood to be a mechanical model imitating a lower limb consisting of a knee joint, hip joint and foot joint. This model possesses 6 degrees of freedom. The mechanical parts of the model were constructed based on an actual simulator and the bone parts and a soft tissue were made by using CT and magnetic resonance imaging (MRI) images, respectively. A muscle model of quadriceps femoris was also included as a cable-like structure with tension in this modeling. CAD model of an actual posterior stabilized (PS) type artificial knee joint, Stryker's NRG, was inserted into the knee joint model. Finite element meshing was conducted using 4-node tetrahedral elements and collateral ligament model was constructed using discrete elements. The total numbers of nodes and elements were 136,459 and 590,213, respectively. A FEM code LS-DYNA was used for analysis. The mechanical parts, bones, femoral and tibial components of the artificial joint were assumed to be rigid bodies. An elastic-plastic model expressed as a combination of three linear stress-strain relations was used for the UHMWPE tibial insert. The patella tendon and quadriceps femoris were assumed to be linear elastic. For the collateral ligament, Maxwell visco-elastic model was used to express a nonlinearity.

In this analysis, the obtained maximum flexion angle was 135 deg. Flexion motion naturally stopped at 135 deg due to mechanical equilibrium. Mises equivalent stress distribution on the tibial insert at 135 deg is shown in Fig. 3. The brighter regions correspond to higher stress concentration regions. At this flexion angle, the femoral component contacted only on the medial condylar surface of the tibial insert as a result of external rotation and therefore, stress significantly increased up to 39.7 MPa. It is noted that external rotation occurred in this flexional motion and increased up to 15 deg at 135 deg flexion. It should be also noted that these stress levels were comparable to the stress level previously obtained from a simplified FEA model of the same PS type knee joint model with use of analytical force data at the contact surface of a knee joint19.

3 Computational analysis of total hip prosthesis

A patient with severe osteoarthritis was chosen to be modeled for FEA. Healthy right- hand hip joint of the patient was also modeled for comparison. For each of the hip joints, 3D-computational models of bone parts were constructed from CT images. For the healthy joint, cartilage cannot be discriminated on CT data, therefore,
cartilage model was constructed based on anatomical judgments by orthopedic surgeons. Total hip arthroplasty (THA) model was also constructed by inserting a hip prosthesis into the injured hip model. The THA and the preTHA models are shown in Fig. 4. CT values were translated into bone density distribution and furthermore, Young's modulus of each finite element was determined from corresponding bone density. The Young's modulus of the cartilage was assumed to be constant. Finite element analyses of the models were then performed under a midstance condition using Mechanical Finder as the solver.

Von Mises equivalent stress distribution was shown in Figs. 5 and 6. On the surfaces of pelvis, the distribution patterns were very similar, however, on the surfaces of femur, effect of inserted stem was clearly observed in Fig. 5 (b). Stress was dramatically reduced in the vicinity of the bone cutting area. Comparison of Figs. 6 (a) and (b) clearly illustrated stress shielding effect in which stress within the femur was significantly reduced because of constraint of deformation due to high stiffness of the stem placed in the bone marrow. It is well known that this kind of stress shielding likely causes bone absorption and therefore results in loosening behavior of stem.

4 Strength enhancement of PLLA Scaffold

PLLA pellets with an inherent density of 1.248 g/cm³ were dissolved in 1, 4 Dioxane to compose porous inner structure of the layered-structural scaffold and the monostructural scaffold. PLLA pellets and HAp powder were also used to fabricate PLLA and PLLA/HAp solid films by applying the thermal-press technique. The concentration of porous inner part was kept at 3 wt% PLLA solution for each scaffold, on the other hand, that of porous outer-layer was 10 wt%. Porous scaffold was fabricated by using the solid-liquid phase separation and freeze-drying methods. Each of the layered-structure scaffolds consisted of a surrounding solid or porous outer-layer with a porous inner structure. The scaffold specimens were tested under compression by using a conventional mechanical testing machine at a displacement rate of 1 mm/min. Compressive mechanical properties such as critical stress and initial elastic modulus were estimated from the experimental data. The initial elastic modulus was calculated from the slope of the initial liner region of the stress-strain curve. The critical stress was evaluated at a critical point that is defined.
as the end of the initial liner part of the compressive stress-strain relation. The morphology of the microstructure of each scaffold was observed by using the field emission scanning electron microscopy (FE-SEM) to characterize the porous structure and microdeformation mechanism under compression. MC3T3-E1 cells of $50 \times 10^4$ were seeded on the surfaces of the scaffolds for 12 days in order to check the adhesion behavior of the cells.

Microstructures of PLLA and PLLA/HAp outer layered scaffolds are shown in Fig. 7. It is seen that in these scaffolds, the outer layers are firmly connected to the porous inner structures and it is noted that the region in the inner structure close to the outer layer showed pore distribution with less porosity and smaller pores than the central region.

Compressive mechanical properties such as critical strength and initial elastic modulus were shown in Fig. 8. It is clearly seen that these properties were effectively improved by introduction of layered structure. It is also seen that the solid later resulted in higher properties than those of the porous outer layer. It should be noted that the layered PLLA/HAp scaffold exhibited higher properties than the layered PLLA scaffold. This suggests that the distribution of HAp particles increases the mechanical properties due to higher strength and modulus of HAp than PLLA.

Typical deformation behaviors at the critical stress points are shown in Fig. 9. In the layered-structural scaffolds, the microstructural deformation was characterized as buckling of the solid outer-layer. It is also seen that the porous inner structure could maintain the initial structure without local buckling of cell walls. It is thus considered that such initiation mechanisms of failure in the layered scaffolds require higher stress level than that in the monolithic scaffold, resulting in the effective improvement of the compressive properties as shown in Fig. 8.

![Graph](image1)

**Fig.8** Compressive mechanical properties of layered scaffolds.

![Image](image2)

**Fig.7** Microstructures of layered scaffolds. (a) PLLA layered (b) PLLA-HAp layered.

![Image](image3)

**Fig.9** Deformation behavior of layered scaffolds. (a) PLLA layered (b) PLLA-HAp layered.
Adhesion behavior of MC3T3-E1 cells on the surfaces of the scaffolds are shown in Fig. 10. This successful adhesion of MC3T3-E1 cells cultured for 12 days indicates that newly developed layered scaffolds might be applied to regenerate bone tissues with non-toxicity.

5 Conclusion

Mechanical studies on prostheses for lower limb joints and porous biomaterials were briefly reviewed in this paper. For knee and hip joints, computational analyses are thought to be very effective for risk-assessment of current products and development of next generation devices. In the field of tissue engineering, it is very important to develop new scaffolds having mechanical compatibility with objective tissue to be regenerated.

References