Development of a Novel Extra-Articular Device for Reducing the Weight-Bearing of the Hip Joint*

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Abstract
The morbidity associated with idiopathic osteonecrosis of the femoral head (ION) is increasing. The primary goal of treatment for ION is to prevent collapse of the femoral head. With the exception of hip arthroplasties, current joint-preserving surgeries for ION require long-term reduction of the load placed on the hip joint. To allow these patients to return quickly to their daily and social activities, we have developed a novel extra-articular device that reduces the weight-bearing of the hip joint. In this study, we evaluated the load-bearing function and the range of motion of a hip joint equipped with the extra-articular device. To demonstrate load reduction on the hip joint with this device, we measured the contact pressure on the femoral head surface and the principal strain on the coxal bone during static loading conditions, which simulated the various phases of human gait. The range of motion of the hip joint with the device was measured using an electro-goniometer. The extra-articular device remarkably reduced the contact pressure on the hip joint, with some restriction in hip flexion. Our novel extra-articular device appears to be a promising tool to secure reductions in the weight-bearing function of the hip joint, and will be applicable to new bone regeneration therapies.

Key words: Biomechanics, Hip Joint, Osteonecrosis, Collapse, Development, Device, Weight-bearing, Cell therapy

1. Introduction
The hip joint is one of the largest and most stable joints in the human body. Hip joint stability is provided by a ball-and-socket configuration that is composed of the femoral head and acetabulum of the pelvis, and this articulation has a joint capsule that is surrounded by large, strong muscles. This configuration facilitates the motion in three dimensions that is required for normal daily activities, such as walking, sitting, and squatting. It is well known that the hip joint has a weight-bearing function, and that deformity of the hip joint can alter the distribution of stress on the joint cartilage and bone, leading to osteoarthritis and dysfunction in daily life. The hip joint anatomy is shown in Figure 1.

Idiopathic osteonecrosis of the femoral head (ION) is one of the diseases that affect cancellous bone. In Japan, more than 7000 patients are suffering from ION annually.
Etiology of ION is still unknown, although it is clear that osteonecrosis occurs following deprivation of the blood supply to the femoral head. This bone ischemia leads to structural failure of cancellous bone, which results in the subsequent collapse of the femoral head (Fig. 2). After femoral head collapse, patients with ION have severe pain and the range of motion of their hip joints is restricted. Eventually, the femoral head deforms, which results in secondary osteoarthritis (1). Current bone- and joint-preserving surgeries, which include femoral osteotomy and bone grafting, require reduction of the load on the affected hip joint for a long period after these surgeries, and the success rates for these surgeries are not very high. Some patients, even young individuals, have to undergo total hip arthroplasty (THA) due to progressive collapse after these surgeries. THA should be avoided or delayed, especially in younger patients who will need several revision THAs (2). Recently, gene- or cell-mediated therapies have been developed to stimulate bone regeneration after ION (3). These treatments also require the reduction of weight loading on the hip joint after the surgeries. Therefore, the prevention of femoral head collapse and the elimination of weight loading on the hip joint are crucial to success these treatments for this ischemic bone disease.

To reduce the recovery time and prevent the collapse of the femoral head, we have developed a novel extra-articular device that reduces the load on the femoral head. With this device, patients with ION are able to enjoy their daily activities without physical support, such as crutches or wheelchairs.

In this study, we evaluated the load-bearing function and range of motion of hip joints equipped with the novel extra-articular device. To demonstrate load reduction on the hip joint with this device, we measured the contact pressure on the femoral head surface and the principal strain on the coxal bone during static loading conditions, which simulated the...
various phases of human gait. The range of motion of the hip joint with the device was measured with an electro-goniometer.

2. Design of a novel extra-articular device

To reduce the weight-bearing load transmitted from the pelvis to the femoral head, we developed a novel extra-articular device that connects directly to the coxal bone and femur. This device consists of an intra-medullary screw, a pelvic plate, and a distraction rod. All of the components are composed of a titanium alloy (Ti-6Al-4V) that features excellent biocompatibility and corrosion resistance. The intra-medullary screw and the pelvic plate are connected with two hinges, which allow internal-external rotation and flexion-extension of the hip joint, as shown in Figure 3.

The attachment procedure is as follows. The intra-medullary screw is inserted along the bone axis of the femur at the tip of the greater trochanter. The pelvic plate is fixed with a pin and two screws on the external table of the coxal bone. The distraction rod is connected with hinges to the intra-medullary screw and pelvic plate, which coincides with the femoral neck axis from the superior view. The distraction rod is extended, so that the femoral head surface is not in contact with the acetabulum surface, which reduces the load on the femoral head. Two rotation axes (A and B in Fig. 3), which are generated by the two hinges on the pelvic plate and the intra-medullary screw, respectively, intersect at the center of the femoral head (C in Fig. 3). This alignment makes it possible to preserve the internal-external rotation and flexion-extension of the hip joint. In terms of invasiveness, all of the components are designed to be as small as possible. Importantly, the use of this device requires neither resection of the joint capsule nor surgical manipulation of the femoral head. From this viewpoint, this novel device is minimally invasive compared to other joint-preserving procedures, such as osteotomy and bone grafting.

This device should be applied to the hip joint without severe deformities, and should be removed by 18 months. With the exception of strenuous exercise, such as jumping and running, this device guarantees the function of the femoral head during daily living activities.

![Fig. 3 Design of a novel extra-articular device for the hip joint.](image-url)
3. Materials and methods

3.1 Load-bearing function of the device

To evaluate the load-bearing function of the device, the contact pressures on the femoral head surface were measured in the hip joint with and without the device under various loading conditions that simulated gait. In addition, the principal strains on the coxal bone were measured, to evaluate the changes in the load transmission mechanism of the hip joint.

The experimental set-up is shown in Figure 4. Imitation femur and pelvis models (3B Scientific, Germany) were used in this study, due to the difficulties associated with obtaining human hip joints. The pelvis model was reversely fixed using dental stone in the metal box, so that the frontal plane corresponded to a plane composed of the three points, representing the pubic symphysis and both the anterior and superior iliac spines. A hinge was attached to the bottom surface of the metal box, which allowed fixation to the expected various angles of flexion and extension. Displacements of the pelvis in the anteroposterior and lateral-medial directions were not restricted by placing linear guides (NSR20TBA; THK, Japan) on the hinge, which enabled precise detection of changes in the contact characteristics between the femoral head surface and the acetabulum surface. The femur was fixed at the site of the femoral condyles in the metal box using dental stone, so that the functional axis of the femur, which was defined as a line that connected the center point of the femoral head and the middle point of the transverse axis of the femoral condyles, was perpendicular to the transverse plane. These alignments of the pelvis and femur were set as the neutral position (0°). The hip joint was assumed to have the ideal ball-and-socket configuration. Since the articular cartilage is not taken into account in the imitation hip joint, the contact surface had an incongruity. To generate a smooth contact surface, we replaced the femoral head by a 45-mm-diameter metal ball, and the acetabular surface was reamed to fit the metal ball on the femoral head, which allowed precise evaluation of the contact characteristics of the hip joint.

The hip-joint model was mounted on a mechanical testing machine (AG-25TD; Shimadzu, Japan) and loaded statically from the inferior femur under various angles of flexion and extension. This hip joint model could not mimic the material properties of the bone. It is made of polyvinylchloride (PVC) whose elastic modulus is approximately 0.4 GPa, which is about 1/40 times of the elastic modulus of human cortical bone. Considering the difference on the elastic modulus between the bone tissues and PVC, and assuming the

![Fig. 4 Experimental set-up to evaluate weight-bearing function.](image_url)
device to be a rigid body, we reproduced the physiological deformities on the hip joint. For duplicating the deformities of the hip joint when a 6.5 times body weight is loaded, a force of 100 N was applied to the imitate hip joint model at each joint angle. The applied load was determined from the assumption that the elastic modulus of the bone tissue and the body weight were 17 GPa and 650 N, respectively. It is well known that our hip joint always receives 3 to 5 times of body weight in daily lives. Therefore, our experimental condition seemed to reproduce physiological deformities on the hip joint.

Pressure-sensitive conductive rubber sensors (PSCRSSs) were used to measure the contact pressures on the femoral head. PSCRSSs are so thin and flexible that they are ideal for measuring the contact pressures on articular joints, such as the wrist joint and knee. We used 13 round-type PSCRSSs, the thickness and diameter of which were 0.8 mm and 5 mm, respectively. They were placed on the femoral head, as shown in Figure 5. The principal strains on the coxal bone were also measured using three rosette gauges (KFG-1-120-D17-11; Kyowa, Japan) to evaluate changes in the load transmission mechanism through the hip joint. From the lateral view of the pelvis, three rosette gauges (A, anterior; B, superior; and C, posterior) were placed superior, anterior, and posterior to the pelvic plate on the coxal bone, as shown in Figure 5.

The contact pressures on the femoral head and the principal stresses on the coxal bone were measured for the hip joint with and without the device from 20° of flexion to 10° of extension at intervals of 5°. Data acquisition was performed 15 times, and the average values are presented.

3.2 Range of motion with the device

To evaluate the range of motion of the hip joint bearing the device, we used the 6 DOF instrumented spatial linkage (ISL). As shown in Figure 6, the ISL is composed of six potentiometers (FCP12AC; Sakae, Japan) and several linkages, and its accuracy is ± 0.25°. The ISL device is often used to measure the complete three-dimensional motion of anatomical joints and to obtain a better understanding of normal and pathological joints. The ISL was fixed to the imitation hip joint model together with the device, using pins to connect the components.

To measure the range of motion in the hip joint, hip joint alignment was performed as follows. In the pelvis, the frontal plane was defined as a plane composed of three points: the pubic symphysis and both the anterior and superior iliac spines. The functional axis of the femur, which was defined as a line that connected the center point of the femoral head and

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Fig. 5  Contact pressure sensor and rosette gauge locations.
the middle point of the transverse axis of the femoral condyles, was set perpendicular to the transverse plane, according to Pennock’s definition (8). This alignment of the hip joint was set as the neutral position (0°). In the experiment, the ranges of motion were measured by ISL while the femur was manually moved in two directions (flexion-extension and internal-external rotation). With this device, motion in the direction of abduction-adduction is restricted, as shown in Figure 3.

We also measured the range of motion during sitting down and getting up from a toilet, to assess the ability of the device to facilitate daily living activities. Three healthy volunteers (males, average age of 23 years) were subjected to the test. The ISL was placed non-invasively on the skin over the coxa and femur and secured with surgical tape. Data acquisition was performed 10 times for each volunteer, and the average values are presented.

4. Results

4.1 Load-bearing function of the device

Figure 7 shows the contact pressure distribution on the femoral head surface with and without the extra-articular device for each flexion-extension angle. The angles of joint flexion and extension are represented as positive and negative values, respectively. The maximum contact pressures on the femoral head without the device were approximately 2.00 MPa on the superior part at each angle. In contrast, for the hip joint with the device, the maximum contact pressure was 0.15 MPa. The contact pressure on the superior part was dramatically reduced in the hip joint with the device for all flexion-extension angles.

Figure 8 shows the mean contact pressures on the femoral head surface with and without the device. For the hip joint without the device, the mean contact pressure at each angle was approximately 0.4 MPa. In contrast, for the hip joint with the device, the mean contact pressure was approximately zero.

The ratios of the minimum principal strains on the coxal bone of the hip joint with and without the device are shown in Figure 9. The ratio of the minimum principal strain was defined as the minimum principal strain on the hip joint with the device divided by the minimum principal strain on the hip joint without the device. At all measuring points, the minimum principal strain on the hip joint with the device was greater than that on the hip joint without the device, and this gradually increased with increases in the flexion angle. At >15° of flexion, the minimum principal strains on the hip joint with the device at positions A and B (anterior and superior location in relation to the pelvic plate) were almost 3-fold greater than those on the hip joint without the device.
4.2 Range of motion with the device

The ranges of motion of a normal hip joint (9), of a hip joint during sitting down upon and standing up from a toilet, and of a hip joint equipped with our device are shown in Figure 10. For the hip joint with the device, the degrees of flexion, extension, internal rotation, and external rotation were 56.2°, 24.7°, 27.2°, and 34.8°, respectively, which are comparable to those of a normal hip joint, although the motions of abduction and adduction were restricted. During sitting down upon and standing up from a toilet, the degrees of flexion, external rotation, and abduction were 119.3°, 16.5°, and 2.1°, respectively. It was generally observed for the action of sitting down upon the toilet that initially, both feet were opened widely, then the upper body was stooped, and finally, the knee was flexed to reach the toilet seat.
5. Discussion

Our novel extra-articular device remarkably reduced the contact pressure on the femoral head when the femur was loaded in the gait phase from 10° of extension to 20° of flexion. The load on the antero-superior part of the femoral head, in which the necrotic portion is always observed in patients with ION, was reduced completely by the device. For this reason, our device has excellent load-relieving functions and can be used to prevent the collapse of the femoral head after ION. This load-relieving mechanism for the femoral head is effective in that the femoral head surface is prevented from contacting the acetabulum surface and the load is transferred directly from the coxal bone to the greater trochanter of the femur and not through the femoral head. Therefore, the minimum principal strain at the location of the device was greater than that of the normal hip joint. It is thought that if the distraction rod were extended so as to prevent contact between the femoral head and acetabulum surfaces, the load transmitted to the femoral head would be reduced. However, in this situation, joint stability would be lost and dislocation of the hip joint would be more likely to occur.

The range of motion of the hip joint was preserved with our device, with the exception of motion in the direction of abduction-adduction. Bergman et al. have reported the joint motions and hip contact forces associated with various daily living activities, such as gait and sitting down, using instrumented implants (10). In the hip joint during gait, the average degrees of motion in the directions of flexion and extension were approximately 30° and 10°, respectively. Therefore, the range of motion conferred by our device appears to ensure the ability to walk easily with reduced loading on the hip joint. In the action of sitting down upon the toilet seat, healthy volunteers abducted their hip joints before flexion of the joints. They could also sit down upon the toilet seat by flexion before abduction of the hip joint. Our device restricts abduction and flexion of the hip joint. However, we believe that our device is applicable only to patients with unilateral ION. Therefore, if abduction and flexion of the hip joint are slightly restricted using the device, the patient can use other healthy joints, such as the knee, spine, ankle, and contralateral hip joint, to compensate the range of motion of the restricted joint, just like as the hip joints after arthrodesis. Thus, we believe that patients with our device can live their life and work actively after joint preserving surgeries.

The limitation of this study is the use of the imitation hip joint model. Since the mechanical properties of bone were not simulated, this hip joint model was subject to
deformation. For this reason, in order to reproduce the physiologically relevant deforming conditions of the hip joint, appropriate loads were applied in this study. Since the articular cartilage on the femoral head and acetabulum, as well as soft tissues, such as the labrum and transverse acetabular ligament, were not imitated, the hip joint was replaced by a ball-and-socket configuration, to improve joint congruity. Therefore, the contact pressure distribution values for the femoral heads differed from those reported in previous studies that used human hip joints (11)(12).

In conclusion, we have developed a novel extra-articular device that reduces the weight-bearing on the femoral head, and we have evaluated the load-bearing function and the range of motion of the hip joint. This study demonstrates that our device exerts a non-weight bearing function on the hip joint with some restricted ranges of motion. This device can prevent the collapse of the femoral head after ION. Recently, gene- or cell-mediated therapies have been developed to stimulate bone regeneration after ION (3). These therapies do not prevent the transient mechanical deterioration of bone during the regeneration phase. Combination of our extra-articular device with these regenerating therapies may allow the complete regeneration of necrotic bone without femoral head collapse, and we will be able to avoid hip arthroplasty for younger patients with ION.

References