Peri-implant cartilage and bone histological changes following treatment of focal osteochondral defects in the femoral head with polyether ether ketone implants versus cobalt chromium molybdenum alloy implants: assessment in a goat model

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Research article

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Abstract

Objective: This study aimed to quantitatively investigate the peri-implant histology of applying defect-size polyether ether ketone (PEEK) implant for the treatment of localized osteochondral defects in the femoral head and compared it with cobalt chromium molybdenum (CoCrMo) alloy implant.

Methods: A femoral head osteochondral defect model was created in the left hips of goats (n=12). Defects were randomly treated by immediate placement of a PEEK (n=6) or CoCrMo implant (n=6). The un-operated right hip joints served as a control. Goats were sacrificed at 12 weeks. Periprosthetic cartilage quality was semi-quantitatively analyzed macroscopically and microscopically. Implant osseointegration was measured by micro-CT and histomorphometry.

Results: The modified macroscopic articular evaluation score in the PEEK group was lower than that in the CoCrMo group ($p<0.05$), and the histological score of the periprosthetic and acetabular cartilage in the PEEK group was lower than that in the CoCrMo group ($P<0.05$). The mean bone-implant contact for PEEK implants was comparable with that for CoCrMo alloy implants at 12 weeks.

Conclusions: A PEEK implant for the treatment of local osteochondral defect in the femoral head demonstrated effective fixation and superior in vivo cartilage protection compared with an identical CoCrMo alloy implant.

Introduction

Localized osteochondral defects in the hip are primarily caused by steroid- or alcohol-induced osteonecrosis of the femoral head (ONFD), sports injury, and hip trauma[1; 2]. For example, ONFD at the subchondral region of the femoral head may show progressive marrow edema, bone resorption, cartilage surface fragmentation, and collapse, leading to a large focal osteochondral defect[3]; and obturator dislocations can result in a shearing type injury to the weight bearing portion of the femoral head causing compression of the posterosuperior and lateral portions of the femoral head against the anteroinferior margin of the acetabulum, which can cause damage to not only the articular cartilage, but also the subchondral bone producing femoral head fractures[4]. If not treated properly at this stage, the defect can also damage the surrounding and even opposing acetabular cartilages, deteriorating into hip osteoarthritis[5]. Many osteochondral repair or regenerative strategies used in the knee, such as microfracture, osteochondral autograft, and autologous chondrocyte implantation, are technically difficult to perform for the hip joint[6; 7]. As a result, patients with focal osteochondral injury or defects of the femoral head without severe hip osteoarthritis are often over-treated by total hip arthroplasty at a young age[8].

Commonly available brand for the partial resurfacing implant is limited, so with its clinical study. Although this treatment modality can be applied in patients after trauma of the knee, hip, toe, and shoulder, there is no experimental evidence suggesting its efficacy as an alternative to the more established surgical treatments. Moreover, in fact, several previous studies have shown that although the shape of implants closely matches the articular surface, the implant material properties may result in the degeneration of the opposing articular cartilage, mainly as its mismatch in the elastic modulus. Recently, Floerkemeier et al[9]. reported their study on the clinical outcome of partial resurfacing hip arthroplasty with HemiCap system consisting of a screw and a head resurfacing component made of metal alloy. The higher elastic modulus of a metal mini-implant also contributed to periprosthetic bone resorption due to stress shielding, followed by implant loosening[10].

Therefore, polyether ether ketone (PEEK) is a potential alternative to metal alloy used in orthopedics[11]. It offers good mechanical strength and resistance to wear, fatigue, and most chemicals and exhibits relatively lower Young's modulus, which is closer to that of the human bone as well[12]. Our previous study showed that PEEK on highly cross-link polyethylene (HXLPE) implant was generally safe and feasible in in vivo animal implantation study, in terms of the histology and functions of important body organs, their serological indicators, and periprosthetic bone and soft tissues [13]. The lower elastic modulus of PEEK implant tends theoretically to reduce bone loss due to stress shielding and to mitigate cartilage degeneration near the implant region due to mechanical property mismatch with normal native cartilage compared with the metal implant as partial resurfacing device of the femoral head, as a novel bearing surface, the actual in vivo behaviors of PEEK on native cartilage articulation are also proved in our previous study[14]. In this study, we want to quantitatively investigate the peri-implant cartilage and bone histology changes following treatment of focal osteochondral defects in the femoral head with PEEK implants versus CoCrMo alloy implants in a goat model, and further verify the feasibility of applying defect-size PEEK implant for the treatment of localized osteochondral defects.

Materials And Methods

Implants

In this study, the implants were weight-bearing, cemented-type, single-component articular implants fabricated from either PEEK or CoCrMo alloy and designed for implantation in the femoral head of goats. The implants had a highly polished curved articulate surface with a 6.1 mm diameter and extended to a cylindrical stem with four grooves. The articulating surfaces of both the PEEK implant and CoCrMo implant were polished to less than 0.3 μm. (Fig. 1)

Animals

Twelve adult goats, aged 2.5 ± 0.31 years and weighing 60.4 ± 6.7 kg, were used for surgery. The animals were divided according to the choice of implants used, as follows: PEEK group (n=6) and CoCrMo group (n=6). The un-operated right hip joints of goats served as a control. The study was undertaken after receiving approval from the Animal Ethical Committee of the Renji Hospital, Shanghai Jiaotong University, School of Medicine (Shanghai, China).

Surgical Procedure

All animals assigned to the experimental groups underwent unilateral implantation of the device in the femoral head. Surgery was performed on the right hind limb under general anesthesia. Under sterile conditions, the limb was disinfected with iodine after shaving the wool and then draped. After the joint was dislocated, the femoral head was exposed, and a tapered defect representative of a grade IV osteochondral lesion was produced using a punch (a diameter of 6mm). The defect was matched with the implant, with a diameter of 6.1mm and a depth of 10mm, which were also homogenous to all the samples. The implant was then fixed into the surgically created osteochondral defect site with bone cement fixation, using custom insertion instruments to ensure device alignment and surface continuity of the implant and articular surface (Fig. 1).

General macroscopic articular evaluation

Two observers (Wangketao and Liuyuxin) inspected and evaluated the hip joint of goats according to the scoring system guidelines as described by O'Driscoll et al[15; 16]. The scoring system evaluates the joint through range of motion, intra-articular fibrosis, and cartilage appearance. (Table 1).

Histology of cartilage in the femoral head and observation of bone-implant interface

Cartilage tissue samples were obtained from predefined locations(the cartilage of the peri-implant in the femoral head and opposite to the implant in the acetabulum) and fixed in 10% buffered formalin for 48 h, embedded in paraffin, and then cut into 7-μm sections. The sections were stained with hematoxylin and eosin and Safranin-O for cartilage evaluation. Two independent and blinded reviewers examined the sections using light microscopy and evaluated the articular cartilage using the Mankin score[17]. We analyzed the histology of the peri-implant cartilage in the femoral head and the cartilage opposite to the implant in the acetabulum using the Mankin score for sections stained with HE and Safranin O.

The histology-assigned femoral head containing the implants were embedded in PMMA and sectioned along the anteroposterior axis (100 μm thick) in a longitudinal direction through the middle of the implant using an Exakt diamond blade saw. The center section of the implant was mounted on a plastic microscope slide using cyanoacrylate and polished to a final thickness of 50 μm. The sections were etched using 0.1% formic acid and subsequently stained with Van Gieson for bone-implant interface evaluation.

Micro-CT examination

The femoral head of goats' left hip joint of the hind limb and components were examined using a micro-CT system (SCANCO medical AG, Barsersdorf, Zurich, Switzerland) with 43-μm axial slices. CT data were examined in the transverse and sagittal planes. Three-dimensional images were reconstructed using Geomagic Studio 10.0 software program (Research Triangle Park, Chapel Hill, NC, USA). The cancellous bone was analyzed from the peri-implant zone (removal of bone cement and prosthesis), which was selected as the region of interest (ROI). We analyzed cancellous Bone Density(BD), Bone Volume/Tissue Volume (BV/CV), trabecular number (Tb.N), and trabecular thickness (Tb.Th) around the implant to assess peri-implant bone quality for evaluation of the stress shielding effect.

Statistical analysis

Statistical analysis was performed with one-way analysis of variance using PASW for Windows software (ver. 18.0; SPSS Inc., Chicago, IL, USA). All data were expressed as means ± standard deviation (SD), and overall significance was set at $p < 0.05$.

Results

General macroscopic evaluation of the hip joint and cartilage in the femoral head

Gross observation showed that the implants (both PEEK and CoCrMo implant) had good congruous alignment with the surrounding cartilage surface at 12 weeks after surgery (Fig. 2). Upon sacrifice, 12 weeks after inserting the implants, the scores of the modified macroscopic articular evaluation in the CoCrMo group had decreased significantly compared with that in the PEEK group. The mean of the modified macroscopic articular evaluation parameters was not significantly different between the PEEK group and the un-operated healthy hip joints (Fig. 3).

Histologic cartilage evaluation and osseointegration

The scores for the amount of cartilage of the peri-implant in the femoral head showed no significant differences between the PEEK group and CoCrMo group at 12 weeks after surgery, while the Mankin score of the cartilage opposite to the implant in the acetabulum for the PEEK group was significantly improved compared with that of the CoCrMo group ($p<0.05$) (Fig. 4).

Histologic sections (containing the implant) for Van Gieson staining at 12 weeks post-operation demonstrated excellent maintenance of the host cartilage-implant interface with minimal cellular and mechanical changes present for the PEEK implant. Histologic observations of the bone-implant interface for PEEK implants were comparable with those of CoCrMo alloy implants at 12 weeks, which maybe because both PEEK and CoCrMo implants were fixed by cement. (Fig. 5)

Micro-CT analysis

Moreover, 2D images of the femoral head and 3D images of new bones with peripheral implant (volume of interest, VOI) were reconstructed. Micro-CT analysis revealed the BD, BV/TV, Tb.N, and Tb.Th of the VOI. The BD of the femoral head in both groups decreased at 12 weeks compared with that in the control group, while no significant difference was found between the PEEK group and CoCrMo group. The BV/TV of the femoral head in the CoCrMo group decreased significantly compared with that of the control group ($p<0.05$), while no significant difference was found between the PEEK group and CoCrMo group. The Tb.N of the region of interest in both the PEEK group and CoCrMo group was decreased compared with that of controls, and the Tb.N of the CoCrMo group was lower than that of the PEEK group. The Tb.Th of the VOI in both the PEEK group and CoCrMo group was decreased compared with that in the control group, while no significant difference was found between the PEEK group and CoCrMo group (Fig. 6).

Discussion

This study demonstrated that a PEEK hemiarthroplasty implant material was superior to a CoCrMo alloy implant in respect of preventing peri-implant cartilage from degeneration. At 12 weeks after surgery, there were greater score of the modified Macroscopic Articular Evaluation Parameters and less Mankin score for the peri-implant cartilage in the PEEK group compared to those in CoCrMo group. Our previous study has also indicated that the PEEK hemiarthroplasty implant induced less cartilage degeneration in the opposing acetabular cartilage and that it was feasible to postoperatively monitor cartilage degeneration by MRI[14]. Though macroscopic joint and cartilage evaluation demonstrated increased joint and cartilage degenerations in both CoCrMo and PEEK groups, the degeneration caused by CoCrMo alloy implant was more severe than that by PEEK implants. This was also confirmed by the histology of cartilage explants from the peri-implant region in this study and the area opposite to the implant in the acetabulum in our previous study. The findings of this study implicated a decreased peri-implant cartilage degeneration found in PEEK group may benefit the protection of normal residual cartilage at both opposing bearing surface and peri-implant bearing surface.

Unlike the significant differences found in the histology of cartilage degeneration, the peri-implant bone mass or bone density for the PEEK implant was not better than that for the CoCrMo alloy implants, which maybe because the implants were fixed by cement. In this study, the BD of the region of interest in both groups decreased at 12 weeks compared with that in the control group, while no significant difference was found between the PEEK group and CoCrMo group, whereras the Tb.N of the region of interest in both the PEEK group and CoCrMo group was decreased compared with that of controls, and the Tb.N of the CoCrMo group was lower than that of the PEEK group, and we guess that the priority of the peri-implant bone preservation due to less stress shielding of low Young's modulus of the PEEK implants was compensated by the cement fixation effect. In our previous study, we also found that the BD of the peri-implant decreased in the cemented implant[18]. And in some cemented total knee arthroplasty, the density of bone peri cemented stem in the tibial metaphysis decreased[19; 20]. However, in an uncemented study, comparing the results of untreated critical-size cartilage defects in the medial femoral condyle of goats with defects treated with oxidized zirconium small hemiarthroplasty implants after 52 weeks, the implants showed good osseointegration [21; 22]. So we infer that the PEEK implant may have better osseointegration and higher bone-implant contact compare to metal implant in an uncemented condition, as its similar biomechanical property to bone, which means less stress shielding.

In this study, the implants in the femoral head was shown to have profound effects on the degeneration of the peri-implant cartilage in the femoral head, with flush placement of the PEEK implants causing less degeneration and better integration with surrounding cartilage compared with those caused by CoCrMo alloy implants. PEEK implants mediated less degeneration compared with CoCrMo alloy implants because of its lower elastic modulus, similar to the bone. This was also confirmed by Cook et al., who evaluated the degeneration of acetabular cartilage following implantation of proximal femoral hemiarthroplasties in dogs[23]. Results indicated that the native acetabulum in articulation with pyrolytic carbon implants experienced a lesser degree of joint degeneration, and there was significantly greater probability of cartilage survival with articulation against the pyrolytic carbon implant than the metal alloy implants. The less cartilage damage in the opposing acetabular cartilage might decrease in tune the peri-implant cartilage degeneration. Moreover, PEEK materials has been shown to have superior qualities for use in partial and total joint replacements, as its elastic modulus is similar to the bone, which reduces stress shielding[24]. In the present study, based on the direct comparison of PEEK implants with identical metal alloy implants, we hypothesized that the improved performance of PEEK devices results from the reduced material elastic modulus, as well as lower surface energy and the non-adhesive nature of the PEEK surface.

This study has some limitations. First, in the animal model, the implants were placed in a joint that was not truly arthritic. the implants were placed in a joint immediately after the defect was made. Second, this study did not include a control group with osteochondral defects that were left untreated. Third, the follow-up time was only 12 weeks, which may be not long enough. Finally, although the PEEK implant show significantly advantage in reducing degeneration of the cartilage compared to metal implant, the mechanical property of the PEEK material was still higher than the native cartilage.

Conclusions

A PEEK implant for the treatment of local osteochondral defect in the femoral head in a goat model demonstrated effective fixation and superior in vivo cartilage protection (less cartilage degeneration) at a 12-week follow up time compared with an identical CoCrMo alloy implant, while the osseointegration of the implant is not significantly different under the cemented fixation. Further optimization of sample-size, follow up time and the implants fixation are required to assess this therapy of choice for the treatment of local osteochondral defects.

Declarations

Ethics approval

This study received approval from the Animal Ethical Committee of the Renji Hospital, Shanghai Jiaotong University, School of Medicine for all animal care and procedures.

Consent for publication

Not applicable

Availability of data and materials

The datasets during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors’ contributions

All authors participated in the surgery, contributed to the manuscript preparation, and approved the final manuscript.

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Abbreviations

PEEK: polyether ether ketone; CoCrMo: cobalt chromium molybdenum；CT: computed tomography; MRI: magnetic resonance imaging；ONFD: osteonecrosis of the femoral head；HXLPE: highly cross-link polyethylene; VOI: volume of interest; Tb.N: trabecular number; Tb.Th: trabecular thickness; ROI: region of interest.

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Tables

Table I

Modified Macroscopic Articular Evaluation Parameters

Characteristics	Score
1. Range of motion	
a. Full	2
b. <20	1
c. >20	0
2. Intra-articular fibrosis	
a. None	2
b. Minor	1
c. Major	0
3. Appearance	
a. Translucent	2
b. Opaque	1
c. Discolored/irregular	0
Total	0-6

Figures

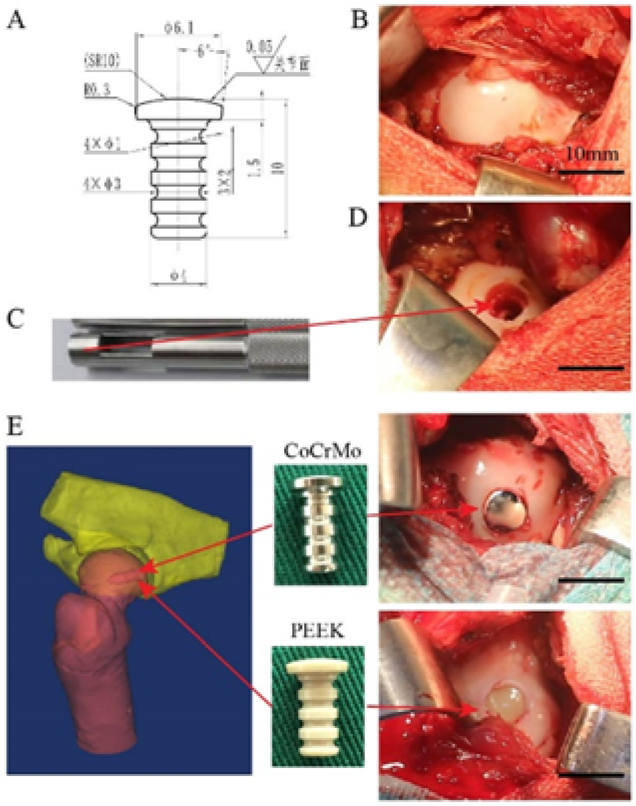

Figure 1. Characteristics and operation strategy of the implants. A. Technical drawing of the implants. B. Native femoral head of a goat. C. the punch used to create the defect. D. Osteochondral defect in the femoral head of a goat. E. Implantation of CoCrMo and PEEK implants in the femoral head of the goat.

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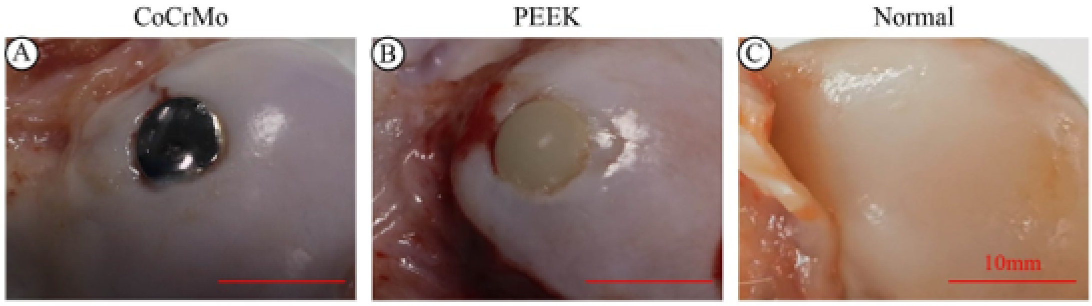

Figure 2. Examples of the femoral head after 12 weeks of follow-up. A. CoCrMo implant. The implant is surrounded by relatively healthy cartilage. B. PEEK implant. The implant is surrounded by relatively healthy cartilage. C. Native femoral head group.

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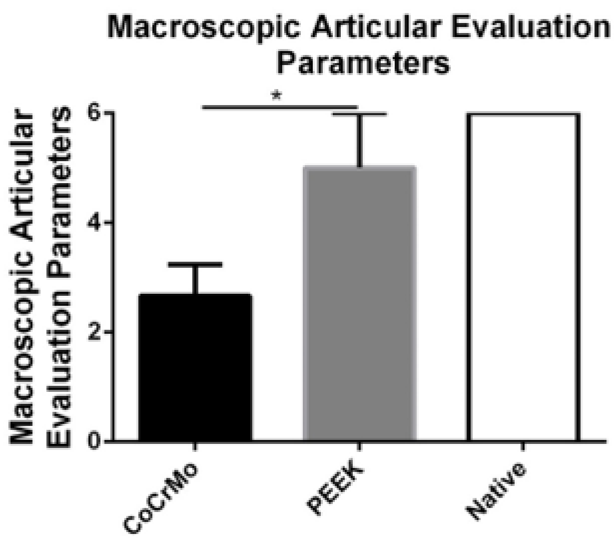

Figure 3. The modified Macroscopic Articular Evaluation Parameters. A score of 0 represents a severely degenerated, fibrillated, and fixated hip joint, whereas a score of 6 represents a healthy joint. (* p<0.05)

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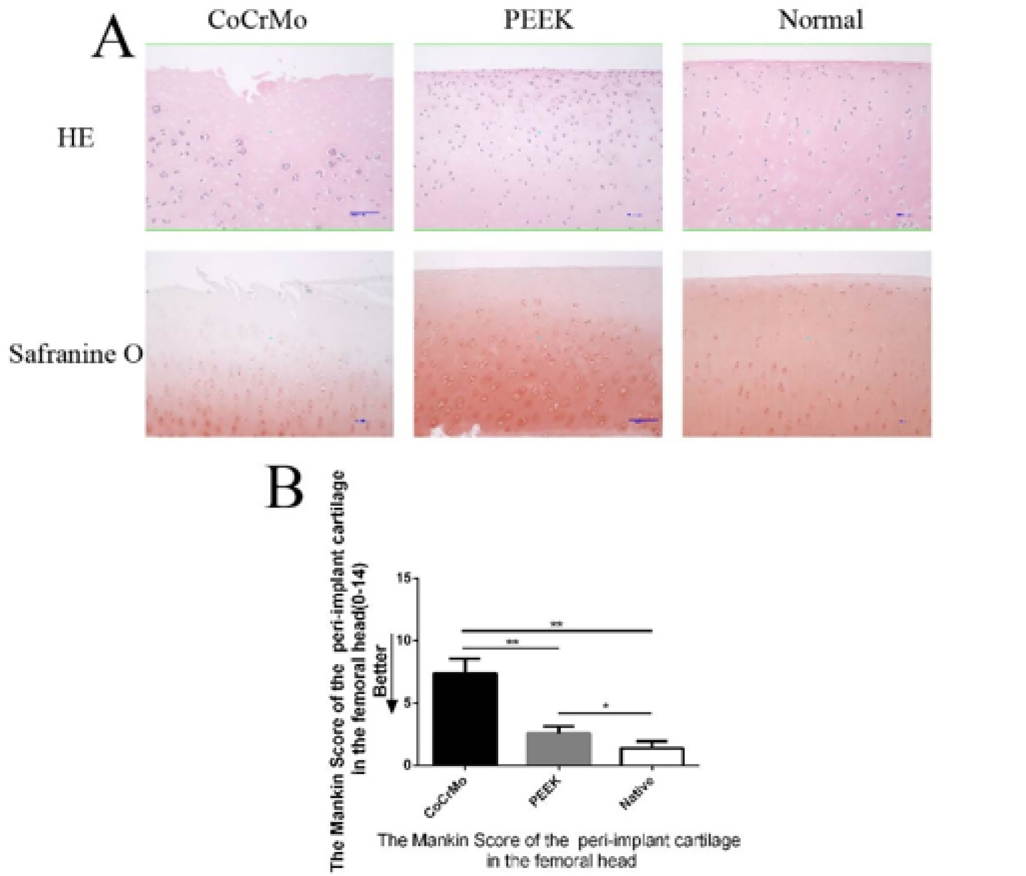

Figure 4. Histological analyses of the peri-implant cartilage in the femoral head at 12 weeks after surgery. A. The peri-implant cartilage stained with hematoxylin and eosin (H&E) and Safranin O. C. Mankin scores for the peri-implant cartilage in the femoral head. Data are expressed as mean ± standard deviation (n =5; *p < 0.05, **p < 0.01).

Figure 4

Histological analyses of the peri-implant cartilage in the femoral head at 12 weeks after surgery. A. The peri-implant cartilage stained with hematoxylin and eosin (H&E) and Safranin O. C. Mankin scores for the peri-implant cartilage in the femoral head. Data are expressed as mean ± standard deviation (n =5; *p < 0.05, **p < 0.01).

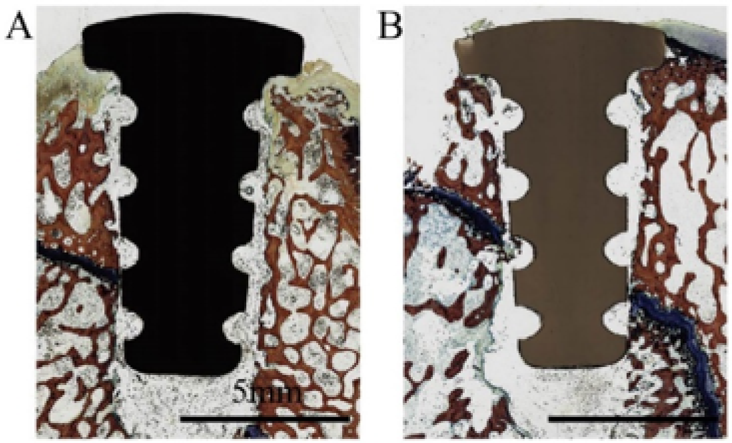

Figure 5. Van Gieson staining of the sections including an implant. A. Histological example of a CoCrMo implant 12 weeks after implantation. B. Histological example of a PEEK implant 12 weeks after implantation.

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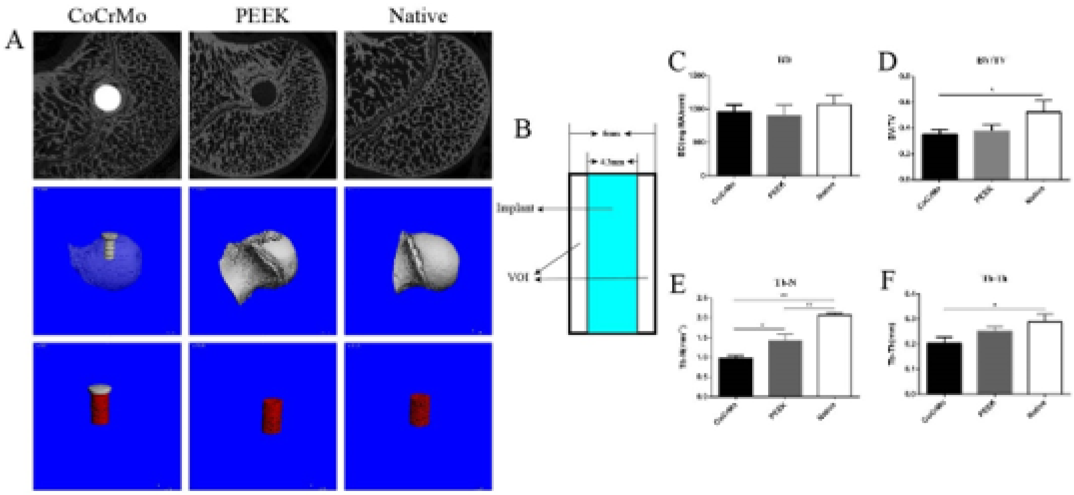

Figure6. Micro-CT of the femoral head with the implants. A. Radiological reconstruction images of the bone in the peripheral regions, 2D reconstructions of the femoral head are shown in the first row, 3D reconstructions of the femoral head are shown in the second row, and 3D reconstructions of the bone in the peripheral regions are shown in the third row. B. Diagrammatic sketch for volume of interests. C. Bone density (BD) in the peri-implant area. D. BV/CV of the peri-implant area. E. Trabecular number (Tb.N) in the peri-implant area. F. Trabecular thickness (Tb.Th) in the peri-implant area. The bars represent the mean, and the error bars represent the standard deviation. *p < 0.05, **p < 0.01

Figure 6

Micro-CT of the femoral head with the implants. A. Radiological reconstruction images of the bone in the peripheral regions, 2D reconstructions of the femoral head are shown in the first row, 3D reconstructions of the femoral head are shown in the second row, and 3D reconstructions of the bone in the peripheral regions are shown in the third row. B. Diagrammatic sketch for volume of interests. C. Bone density (BD) in the peri-implant area. D. BV/CV of the peri-implant area. E. Trabecular number (Tb.N) in the peri-implant area. F. Trabecular thickness (Tb.Th) in the peri-implant area. The bars represent the mean, and the error bars represent the standard deviation. *p < 0.05, **p < 0.01