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Original Article

# A partial hemi-resurfacing preliminary study of a novel magnetic resonance imaging compatible polyetheretherketone mini-prosthesis for focal osteochondral defects

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## ARTICLE INFO

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## ABSTRACT

*Background:* The use of partial articular resurfacing surgery with a mini-implant has been gradually increasing; the implant is mainly made of cobalt–chromium metal material, and cartilage changes cannot be monitored after implantation. Thus, we aimed to develop a novel local articular resurfacing polyetheretherketone (PEEK) mini-implant and investigate its feasibility for postoperative magnetic resonance imaging (MRI) monitoring of implant location, bone changes, and cartilage degeneration without artefacts.

*Methods:* Nine skeletally mature female standardised goats were used and divided into the sham, PEEK, and cobalt–chromium–molybdenum alloy (Co–Cr–Mo) groups. The animals underwent local articular resurfacing operation with Co–Cr–Mo alloy (Co–Cr–Mo group) and PEEK (PEEK group) mini-implants. X-ray, computed tomography, and MRI examinations were performed at 12 weeks postoperatively. The sham group underwent a similar surgical procedure to expose the femoral head but without implantation. Gross necropsy and surface topography measurement of the articular cartilage of the acetabulum were performed after sacrificing the animals. Imaging artefacts and opposing cartilage degeneration in the acetabulum were also examined.

*Results:* Cartilage damage occurred in both the Co–Cr–Mo and PEEK groups, and the damaged cartilage area was markedly larger in the Co–Cr–Mo group than in the PEEK group, as assessed by gross necropsy and histological staining. The mean surface roughness of the opposing cartilage was approximately 65.3, 117.4, and 188.4 μm at 12 weeks in the sham, PEEK, and Co–Cr–Mo groups, respectively. The Co–Cr–Mo mini-implant was visualised on radiographs, but computed tomography and MR images were markedly affected by artefacts, whereas the opposing cartilage and surrounding tissue were clear on MR images in the PEEK group. Opposing cartilage damage and subchondral bone marrow oedema could be detected by MRI in the PEEK group.

*Conclusions:* The PEEK mini-implant can be a novel alternative to the Co–Cr–Mo mini-implant in articular resurfacing to treat focal osteochondral defects with less cartilage damage. It is feasible to postoperatively monitor the PEEK implant location, surrounding bone changes, and opposing cartilage degeneration by MRI without artefacts.

*The translational potential of this article:* The use of MRI to monitor changes in the opposing cartilage after prosthesis implantation has not been widely applied because MR images are generally affected by artefacts generated by the metal prosthesis. This study revealed that the PEEK mini-implant can be a novel alternative to the Co–Cr–Mo mini-implant in articular resurfacing to treat focal osteochondral defects, and it is feasible to monitor the PEEK implant location, surrounding bone changes, and opposing cartilage damage/degeneration by MRI without artefacts postoperatively.

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## Introduction

The articular cartilage provides a smooth sliding surface for joints during skeletal movement; thus, it is easily injured and prone to degeneration. Currently, the surgical options for the treatment of focal cartilage defects include arthroscopic debridement, subchondral microfractures, and autologous chondrocyte transplantation [1–3]. However, for the hip joint, the large cartilage defect of the femoral head is still difficult to treat because the main reason of cartilage damage with bone defect is femoral head necrosis [4]. Early femoral head necrosis can lead to local isolated cartilage destruction and bone defects in the femoral head, and the treatment of choice is always total hip arthroplasty (THA) and artificial femoral head replacement [5]. However, there is currently a renewed interest in articular resurfacing as an alternative resurfacing strategy for the treatment of damaged hip joint cartilage in patients who are too young for THA or not good candidates for regenerative procedures [4, 6–8]. Compared with THA and artificial femoral head replacement, previous authors have attempted to treat the local osteochondral defect of the femoral head with mini-resurfacing implants, for example, Hemicap®, to reestablish an articulating joint surface to maximise the retention of the femoral head and postpone THA. However, the failure rate after surgery is high, with a high incidence of hip arthritis; thus, the failure cases were finally converted to THA [4,6]. Therefore, it is very important to perform imaging monitoring to detect postoperative osteoarthritis (OA) progression, prosthesis loosening, and femoral head necrosis progression.

Magnetic resonance imaging (MRI) is a noninvasive and ideal technique with high sensitivity, and it can be used to detect bone changes, soft tissue inflammation, and neurovascular changes, thereby allowing the assessment of implant location, tissue hydration, water:fat ratio, and cartilage degeneration [9]. However, at present, the traditional replacement implants are made of metals (e.g., Hemicap®), and MR images are often affected by artefacts of the metallic material [4,6,10]. Therefore, acetabular joint degeneration can only be evaluated by X-ray, which does not accurately show osteonecrosis of the femoral head and cartilage tissue. Polyetheretherketone (PEEK) materials with excellent mechanical properties and biological inertness have been developed and applied clinically [11]. They are also radiologically transparent and do not present artefact interruptions on MRI [12]. Thus far, the use of MRI to monitor changes in the opposing cartilage after prosthesis implantation

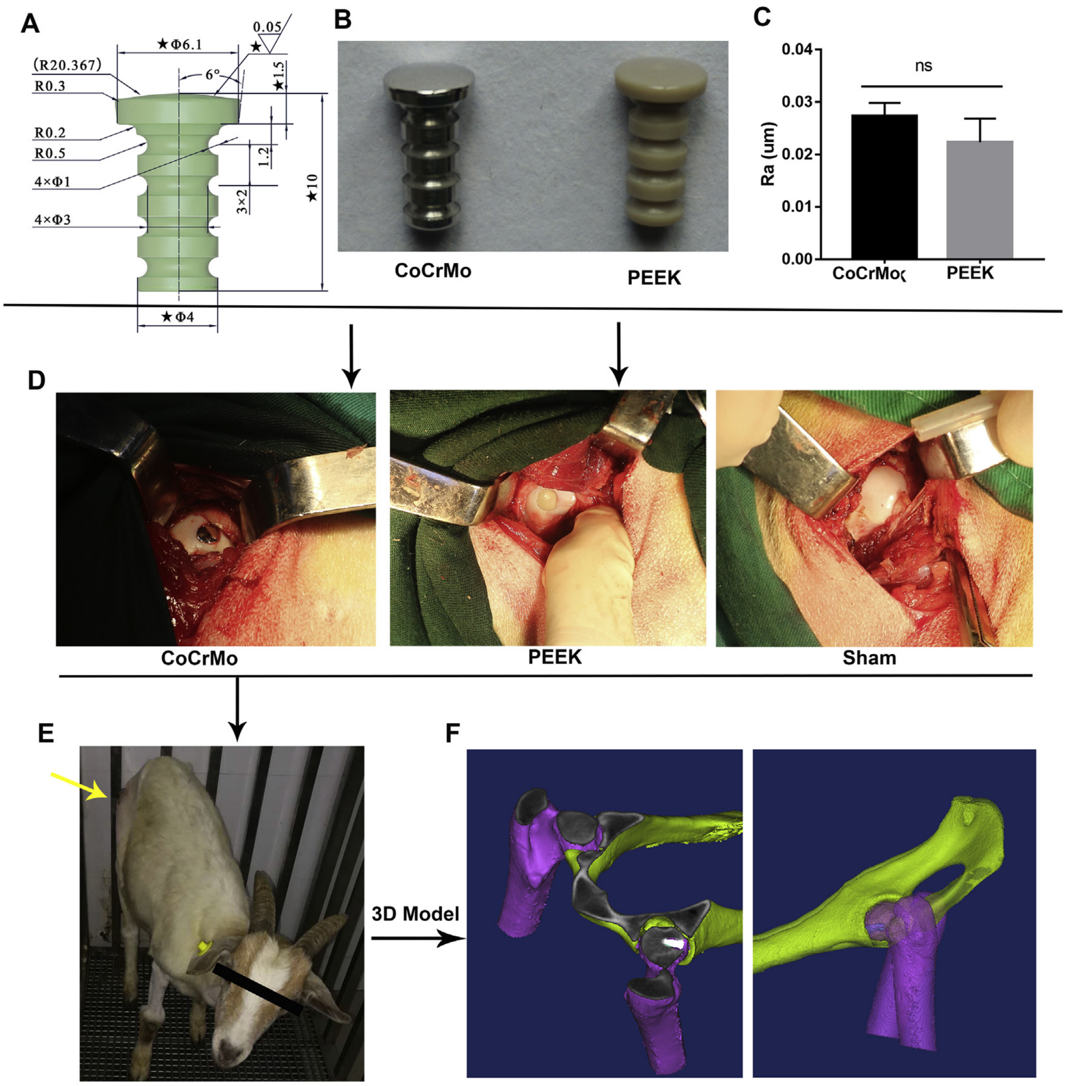

**Figure 1. Design, polishing, and implantation of the mini-prostheses**. (A) Design sketches of the PEEK and Co–Cr–Mo mini-prostheses. (B) Real images of the PEEK and Co–Cr–Mo mini-prostheses. (C) The articulating surfaces of both mini-implants were polished such that the Ra for both was <0.3 μm. (D) The implantation of the mini-implants in the right lamb femoral head. (E) The animal stood up at 4 h postoperatively. (F) The 3D model of the mini-prosthesis position. The yellow arrow indicates the position during surgery. 3D = three-dimensional; Co–Cr–Mo = cobalt–chromium–molybdenum; PEEK = polyetheretherketone; Ra = mean surface roughness

and determine the effect of technology and artefacts has rarely been reported. Reducing the effect of artefacts for the accurate diagnosis of cartilage degeneration is difficult.

In this study, the PEEK material was used as a mini-prosthesis for the first time to treat focal cartilage defects and evaluate the feasibility of using MRI to monitor complications of postoperative cartilage damage. This preliminary study aimed to develop a new animal model of the PEEK mini-prosthesis with focal surface replacement of the goat femoral head. The gross morphology of the acetabular cartilage and MR images were analysed to verify the feasibility of MRI monitoring for determining the process of cartilage damage/degeneration of the opposing cartilage.

## Materials and methods

### *Design and manufacturing of the mini-prosthesis*

The prosthesis was a weight-bearing cemented implant with an articulating surface fabricated from either PEEK (Zeniva PEEK ZA-500; Brussels, Belgium) or cobalt–chromium–molybdenum (Co–Cr–Mo) alloy and was designed for implantation in the femoral head of goats. The mini-prosthesis was designed based on the image shown in Fig. 1A and manufactured by Jiangsu Okani Medical Technology Co., Ltd. (Soochow, JS, China). The articulating surface of the mini-implant was polished during manufacturing in the company, and its mean surface roughness (Ra) was <0.05 μm. The Ra was obtained by averaging the Ra values of the three regions of the articulating surfaces using the laser scanning microscope Keyence VK-X200 (Keyence, Osaka, Japan) (Fig. S1).

### *Animals*

Nine skeletally mature female standardised goats were used in the study (weight, 30–33 kg; height, 66–70 cm). The animals were obtained from Jiagan Biotechnology Company (Shanghai, China). The study was undertaken after receiving approval from the Animal Ethical Committee of the Renji Hospital (Shanghai, China) for all animal care and procedures. All methods were performed in accordance with the relevant guidelines and regulations. All animals underwent X-ray (lateral), computed tomography (CT), and MRI examinations at 12 weeks postoperatively, and then were euthanised by overdose of pentobarbital. The animals were assigned to the following groups: sham ($n = 3$), Co–Cr–Mo ($n = 3$), and PEEK ($n = 3$) groups.

### *Surgical procedure*

The animals received intraperitoneal injections of pentobarbital sodium (Merck, Darmstadt, Germany) as general anaesthesia (50 mg/kg). The Co–Cr–Mo and PEEK groups underwent implantation of the mini-prosthesis in the right femoral head, whereas the sham group underwent the same surgical procedure to expose the femoral head, but implantation was not performed. The animals were placed on the left lateral position, and the skin of the right hip joint area was shaved and disinfected with povidone. The operation was performed via the anterior lateral approach to separate the muscles and to open the joint capsule. The right hip joint was subluxated to the front, and the femoral head was exposed. Drilled holes with a diameter of 4.2-mm drill bit were implanted with a mini-prosthesis and fixed with bone cement. The articulating surfaces of the mini-implants were smoothened to be on the same level as the surrounding cartilage surface. Antibiotics (penicillin, 60 mg/kg) were administered for 3 days after the surgery.

### *Postoperative radiographic evaluation*

Plain lateral radiographs and CT and MR images were obtained under general anaesthesia at 12 weeks postoperatively. The regions of interest, including the signal intensity changes in the cartilage and subchondral bones, were analysed by MRI. X-ray images were acquired using a digital radiography system (Definium 6000, Volume RAD, GE Healthcare), whereas CT and MR images were obtained using a 16-section multidetector row CT scanner (GE Medical Systems, Milwaukee, WI, USA) and a 3.0-T MRI scanner (Philips, Amsterdam, the Netherlands), respectively.

### *Gross necropsy and surface topography measurement*

The hip joints were immediately harvested after sacrificing the animals and were grossly assessed to observe the articular surfaces and surrounding cartilage, as well as any degenerative changes in the opposing cartilage in the acetabulum. The degenerated cartilage area on the acetabular side was measured, and the contour and roughness of the degenerated cartilage surface were measured using the NPFLEX™ 3D Surface Metrology System ( Bruker Corporation, Germany).

### *Histological study*

The acetabulum specimens were fixed in 4% buffered formalin for 2 days and then decalcified for 2 months in 10% EDTA solution; the specimens were then dehydrated in ethanol, transferred to xylene, and embedded in paraffin. Six-micrometre paraffin sections were used for haematoxylin and eosin staining. The morphology of the cartilage was evaluated as per the OA cartilage degeneration scoring system. The sections underwent double-blinded examinations by at least two individuals independently.

### *Statistical analysis*

Data were analysed using one-way analysis of variance, and the Student t test was used for the parametric data. A $p$ value <0.05 was considered statistically significant.

## Results

### *Design and implantation of the mini-prosthesis*

The prosthesis was designed as a weight-bearing cemented implant with an articulating surface, as shown in Fig. 1A. The mini-prosthesis had an articulating surface with a 6.1-mm diameter and 20.367-mm radius of curvature. The stem was a 4-mm-diameter cylinder with a series of four grooves (Fig. 1B), and the total height of the mini-prosthesis was 10 mm. The articulating surfaces of the PEEK and Co–Cr–Mo mini-prosthesis were both polished to <0.3 μm (Fig. 1C). The mini-prosthesis was implanted to treat the local cartilage defects of the femoral head. The articulating surfaces of the mini-implants were smoothened to be on the same level as the surrounding cartilage surface (Fig. 1D). The animals were able to stand up at 4 h postoperatively (Fig. 1E), and the position of the mini-prosthesis was observed in the 3D model created using the CT data (Fig. 1F).

### *Imaging examinations verified the opposing acetabular cartilage, and the subchondral bone of the PEEK groups was monitored by MRI*

In the lateral X-ray images, the position of the Co–Cr–Mo mini-implant in the femoral head was observed (Fig. 2B), whereas the PEEK mini-implant was translucent (Fig. 2C), and no radiological signs of OA were observed on the acetabular side at 12 weeks postoperatively. In CT images of the three groups, artefacts were generated around the Co–Cr–Mo mini-implant, and the signals of the opposing cartilage and surrounding bone tissue were affected (Fig. 2E); in the PEEK group, there were no artefacts in the images. In the images of the PEEK mini-implant, the surrounding cement and bone tissue were clear (Fig. 2F). Furthermore, MR images of the opposing cartilage and surrounding tissue were more seriously affected by artefacts generated around the Co–Cr–Mo mini-implant (Fig. 2H); hence, these anamorphic images had no clinical diagnostic value. However, MR images of the PEEK mini-implant and

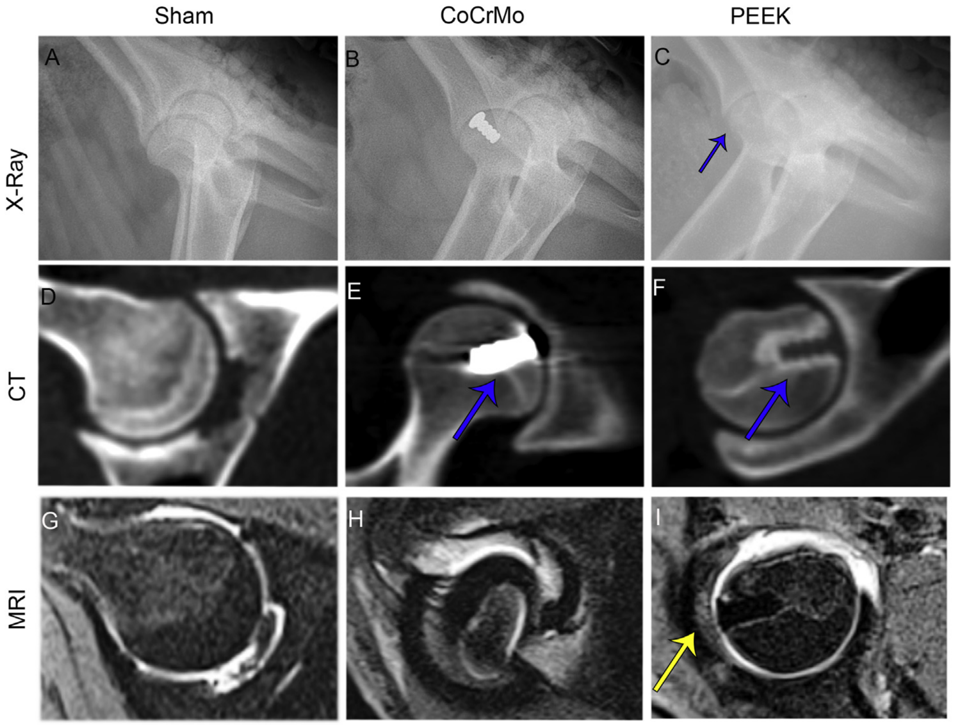

**Figure 2. X-ray, CT, and MR images of the opposing cartilage.** (A–C) The lateral X-ray images of the sham, Co–Cr–Mo, and PEEK groups. (D–F) CT images of the sham, Co–Cr–Mo, and PEEK groups. (G–I) MR images of the sham, Co–Cr–Mo, and PEEK groups. (E) There are artefacts generated around the Co–Cr–Mo mini-implant in the CT images. (H) There are artefacts generated around the Co–Cr–Mo mini-implant in the MR images. The opposing cartilage and surrounding tissue were affected. (F) In the PEEK mini-implant, no artefacts are noted in the CT images. (I) In the PEEK mini-implant, no artefacts are noted in the MR images. The signals of the surrounding tissue are clear. The opposing acetabular subchondral bone showed high signals (**yellow arrow**), suggesting bone marrow oedema and local cartilage damage. The blue arrows indicate the position of the mini-implant. The yellow arrow indicates a high-density area on the acetabulum. 3D = three-dimensional; Co–Cr–Mo = cobalt–chromium–molybdenum; CT = computed tomography; MRI = magnetic resonance imaging; PEEK, polyetheretherketone.

surrounding tissue were clear, and the prosthetic surface was highly consistent with the surrounding cartilage; the opposing acetabular subchondral bone showed high signals, suggesting bone marrow oedema and local cartilage damage on the surface (Fig. 2I).

### *The results of gross necropsy, surface contour scanning, and histological staining verified the slight degeneration of acetabular cartilage in the PEEK group and serious damage in the Co–Cr–Mo group*

The gross specimens at 12 weeks postoperatively showed that cartilage damage occurred in both the Co–Cr–Mo and PEEK groups, but the opposing cartilage in the Co–Cr–Mo group was more seriously damaged, whereas the cartilage in the PEEK group only showed slight damage (Fig. 3A, D, and G). The damaged cartilage area of the Co–Cr–Mo group was approximately 2.7 times larger than that of the PEEK group (Fig. 3J). Compared with that in the sham (Fig. 3B and C) and PEEK (Fig. 3E and F) groups, surface contour scanning of the opposing cartilage in the Co–Cr–Mo group showed more apparent unevenness and larger deep grooves, suggesting that cartilage damage was more serious (Fig. 3H and I). The Ra of the opposing cartilage was approximately 65.3, 117.4, and 188.4 μm at 12 weeks postoperatively in the sham, PEEK, and Co–Cr–Mo groups, respectively (Fig. 3K). The damage/degeneration of the cartilage in the Co–Cr–Mo groups was more serious than that in the sham and PEEK groups (Fig. 4).

## Discussion

This study indicated that the PEEK hemiarthroplasty mini-prosthesis material was superior to the identical Co–Cr–Mo alloy implants because less cartilage degeneration was observed in the opposing acetabular cartilage and that it is feasible to postoperatively monitor cartilage degeneration by MRI. This kind of novel mini-prosthesis material that does not affect MRI will be very beneficial for timely monitoring of changes in hip joints of young patients who have undergone partial articular resurfacing surgery.

Partial articular resurfacing surgery with a mini-implant for the treatment of focal osteochondral defects could reduce joint pain, increase joint mobility, and preserve more bone stock, allowing delayed total joint replacement in the future. The treatment modality, comparable with the concept of the Hemicap® made of Co–Cr alloy, has been applied in case of trauma to the knee, hip, and shoulder [7,8]; however, studies have indicated that this procedure can result in damage to the opposing cartilage [4,7,8]. The clinical outcome of the use of Hemicap® seems to be inferior to that of THA because of the associated high rate of conversion to THA (25%) [4]. The mostly negative results of the partial articular resurfacing surgery with Co–Cr–Mo implants make its wide clinical application uncertain [8,13,14].

However, according to a previous research, partial articular resurfacing surgery has a certain positive significance for joint function and local cartilage [15]. The mini-prosthesis relieves shear and friction forces around cartilages, thereby avoiding further cartilage damage [15]. Some factors, including the hardness of the material, surface lubrication characteristics, biocompatibility of the material, and inflammatory properties of ions or small particles released by the material, have potential negative effects on cartilages and their microenvironment [15–18]. Materials with smooth surfaces, good biocompatibility, and lower inflammatory properties are less likely to damage the cartilage. Studies have shown that the higher the hardness, the greater the direct stress on the opposing cartilage, consequently leading to cartilage damage [18,19]. A previous study on the reconstruction of a cartilage defect in the knee with pyrolytic carbon and Co–Cr alloy prostheses reported that cartilage damage was more apparent in the identical Co–Cr alloy implant group [8]. The researcher demonstrated that the slight damage of the cartilage was related to the low elastic modulus of the pyrolytic carbon material [8]. In the present study, the PEEK and Co–Cr alloy as weight-bearing materials were used to treat focal cartilage defects of the femoral head. The results showed that the opposing cartilage damage was more serious in the Co–Cr–Mo alloy group, which indicates that the PEEK mini-implant is superior to the identical Co–Cr–Mo alloy implant in vivo. This was believed to be mostly due to the lower elastic modulus of PEEK implants (3.84–17.94 GPa) than Co–Cr–Mo alloy implants (200 GPa), which could cause less stress impact and cartilage damage [18,19]. In the present study, PEEK was designed to replace the focal cartilage defects as a weight-bearing implant with an articular surface, which is

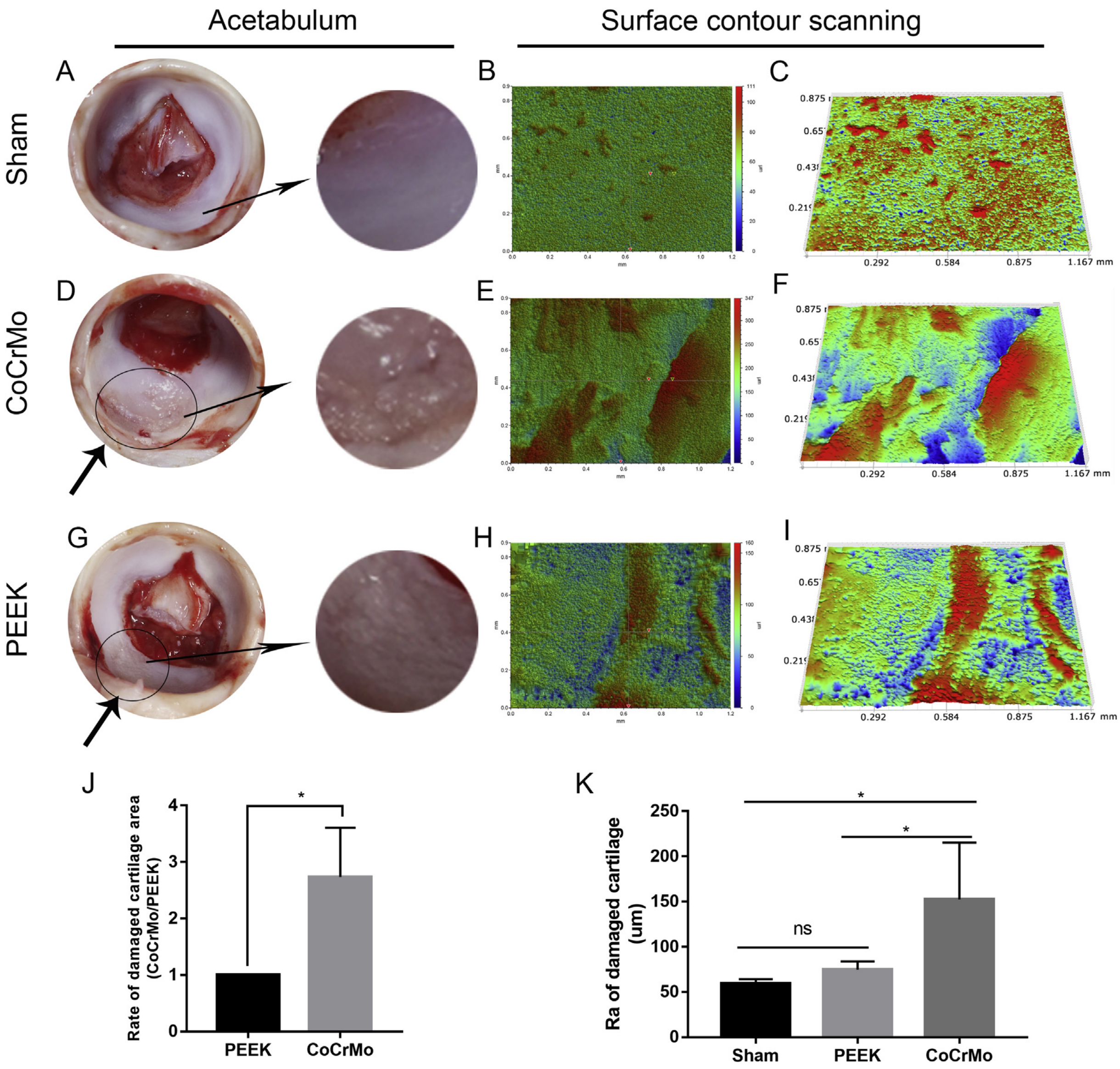

**Figure 3. Gross necropsy and surface contour scanning of the opposing cartilage in the three groups**. (A) Gross necropsy of the opposing cartilage in the sham group. (B and C) Surface contour scanning images of the opposing cartilage in the sham group. (D) Gross necropsy of the opposing cartilage in the Co–Cr–Mo group. (E and F) Surface contour scanning images of the opposing cartilage in the Co–Cr–Mo group. (G) Gross necropsy of the opposing cartilage in the PEEK group. (H and I) Surface contour scanning of the opposing cartilage in the PEEK group. (J) Rate of the damaged cartilage area in the Co–Cr–Mo and PEEK groups. (K) Ra of the opposing cartilage among the three groups. $*p < 0.05$, $N = 3$. Co–Cr–Mo = cobalt–chromium–molybdenum; PEEK = polyetheretherketone; Ra = mean surface roughness

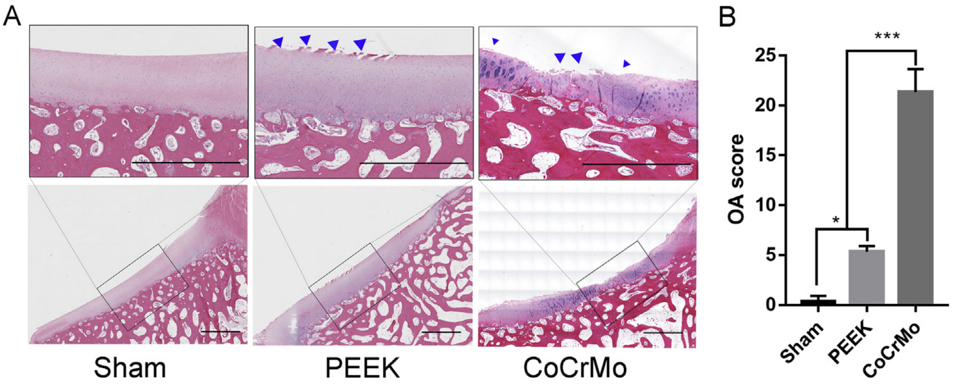

**Figure 4. H&E staining of the acetabular cartilage in the sham, PEEK, and Co–Cr–Mo groups**. (A) Representative images showing H&E staining of the acetabular cartilage in the sham, PEEK, and Co–Cr–Mo groups. (B) Summarised data showing the OA scores of the sham, PEEK, and Co–Cr–Mo groups. The blue triangle indicates the damaged cartilage of the acetabulum. * represents $p < 0.05$, *** represents $P < 0.001$. Magnification 20×; scale bars = 500 μm; $N = 3$. Co–Cr–Mo = cobalt–chromium–molybdenum; H&E = haematoxylin and eosin; OA = osteoarthritis; PEEK, polyetheretherketone.

different from its previous uses in spinal surgery, traumatology, dentistry, and other fields [11]. As a load-bearing articular surface, PEEK possesses both good mechanical strength and wear-resisting properties, which are critical for avoiding fracture or wear damage [11,20,21]. Our previous study showed that the PEEK-based implant was generally safe as a component of an artificial joint because of its good mechanical strength and biocompatibility [22]. As mentioned previously, some researchers found that pyrolytic carbon materials, used to replace focal cartilage defects on the knee, cause less damage to the opposing cartilage than the Co–Cr–Mo alloy [8]. Compared with pyrolytic carbon materials (20 GPa), the elasticity modulus of PEEK (3.84–17.94 GPa) was closer to that of the subchondral bone (3–7 GPa), which makes it more suitable as a replacement material in joint reconstruction [11,20,23]. Furthermore, the inflammatory responses induced by PEEK and highly cross-linked polyethylenes (*HXLPE*) particles were comparable, and PEEK particles did not induce CD4+ T-cell responses [24–26]. In addition, the Co–Cr–Mo particles in synovial membranes of mice have significantly increased interleukin 6 and tumor necrosis factor-α (*TNF-α*) levels compared with PEEK particles [25]. The apparent superiorities of PEEK to pyrolytic carbon materials indicate that PEEK-based implants may induce less mechanical damage to the opposing cartilage and less periprosthetic inflammation, possibly leading to further periprosthetic cartilage degeneration [27,28].

MRI is the preferred technique for assessing cartilage lesions because it has the advantages of direct visualisation of the articular cartilage, superior soft tissue contrast, absence of ionising radiation, and noninvasiveness [29,30]. For patients at a high risk of developing OA progression, timely and accurate MRI assessment of the disease postoperatively is needed. The accuracy of MRI is limited owing to the presence of metal artefacts. The feasibility of MRI monitoring of infection signs, healing process, and local recurrence of osteosarcoma without an artefact was proved in a previous in vivo animal study of PEEK knee prosthesis implantation [12]. For the novel MR-compatible PEEK mini-prosthesis material, it facilitates noninvasive and accurate detection of the opposing cartilage degeneration after surgery, which is beneficial for timely monitoring of the changes in the hip joints of young patients who have undergone partial articular resurfacing surgery. Some other metal resurfacing implants, such as HemiCap®, Episealer® Condyle Solo (Episurf Medical AB, Stockholm, Sweden), and BioPoly™, that are already commercially available and/or in the process of being tested in human trials also produce strong artefacts in MRI; thus, the use of MRI monitoring for these implants may not be suitable [31–33]. In the present study, PEEK materials were radiologically transparent and did not present with artefact interruption on MRI. The images of the surrounding bone and soft tissues around the PEEK mini-prosthesis were clear, and the prosthetic articular surface was highly consistent with the surrounding cartilage surface. The acetabular subchondral bone opposite to the PEEK prosthesis showed a high signal, suggesting bone marrow oedema and local cartilage damage on the surface, which was detected by gross necropsy and pathological tissue staining. These results indicated that slight damage in the opposing cartilage in the PEEK mini-implant group can be observed at an early stage through an MRI examination. Although cartilage damage was more serious in the Co–Cr–Mo alloy group, MRI could not clearly identify the signals of cartilage damage owing to the artefacts generated by the Co–Cr–Mo alloy.

This study also has some limitations. First, this study only included a small number of animals, which may skew the statistical elements. Second, the femoral head of the animals in the experiment is normal; thus, the cartilage recovered faster. There may be a difference in the results when animals with femoral head necrosis are used. More research studies are needed to assess the effect of the prosthesis in treating focal cartilage defects.

## Conclusion

The PEEK mini-implant may be a novel alternative to the Co–Cr–Mo mini-implant in articular resurfacing to treat focal osteochondral defects, and it is feasible to postoperatively monitor the PEEK implant location, surrounding bone changes, and opposing cartilage damage/degeneration by MRI without artefacts. Moreover, the changes in the material will also reduce the effect on the contralateral cartilage, may decrease the modulus of elasticity, and lessen the damage in the cartilage. The results of this preliminary study suggest that with the improvement of materials, it is possible to clearly monitor the joint soft tissues by MRI after surgery, which will contribute to the diagnosis and provision of corresponding treatment measures for postoperative cartilage destruction during the early stage. Finally, our data may be helpful in the diagnosis and treatment of postoperative complications in the future.

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## Conflict of Interest

The authors have no conflicts of interest to disclose in relation to this article.

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## Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jot.2020.02.010.

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