Partial hemiarthroplasty for the treatment of osteonecrosis of the femoral head

AN EXPERIMENTAL STUDY IN THE DOG

K. Ushio, M. Oka†, S.-H. Hyon, S. Yura, J. Toguchida, T. Nakamura

From Kyoto University and Kyoto City Rehabilitation Centre Hospital, Japan

The use of a composite osteochondral device for simulating partial hemiarthroplasty was examined. The device was composed of a polyvinyl alcohol hydrogel and a titanium fibre mesh, acting as artificial cartilage and as porous artificial bone, respectively. The titanium fibre mesh was designed to act as an interface material, allowing firm attachment to both the polyvinyl alcohol gel (through injection moulding) and the femoral joint surface (through bony ingrowth). We implanted 22 of these devices into canine femoral heads. Histological findings from the acetabular cartilage and synovial membrane, as well as the attachment of the prosthesis to bone, were examined up until one year after operation.

No marked pathological changes were found and firm attachment of the device to the underlying bone was confirmed. The main potential application for this device is for partial surface replacement of the femoral head after osteonecrosis. Other applications could include articular resurfacing and the replacement of intervertebral discs.

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Osteonecrosis of the femoral head (ONFH) is a disabling disease that can lead to destruction of the hip.¹⁻³ It occurs typically in young active patients who are in their second to

fifth decades. The appropriate treatment, depending on the stage of the disease, remains controversial, yet progression to collapse of the femoral head often necessitates total hip replacement (THR). Considering the young age of patients with ONFH and the poor prognosis associated with THR in younger patients, it is desirable to preserve as much of the joint as possible during treatment.^{1,4}

Some authors have used procedures to resurface only the femoral side of the hip joint.⁵⁻⁸ While the overall clinical results are usually satisfactory, pathological changes in the opposing articular cartilage have often been observed. Erosion of the acetabular articular cartilage, with associated pain, is a recognised late complication of hemiarthroplasty. Amstutz et al⁵ reported good clinical results using surface replacement to treat ONFH, but changes in the opposing articular surface indicated problems which may be related to the type of material used. It is therefore desirable to develop new materials with mechanical properties more similar to those of normal articular cartilage.

We have attempted to develop an artificial articular cartilage based on a rubber-like polyvinyl alcohol hydrogel (PVA-H). Previous studies have characterised the mechanical properties related to its use including lubricating and shock-absorbing functions.^{9,10} A series of tests in vivo showed that it had good biocompatibility.^{11,12}

The problem of attaining quick, firm attachment of this material to the underlying bone was addressed by creating a composite osteochondral device (COD) with a titanium fibre mesh (TFM) interface. The PVA solution was first impregnated into the pores of the TFM by injection moulding, followed by consolidation of the interfacial bond through a gelling process. The use of this design not only allows the formation of a strong bond at the PVA/TFM interface, but also the firm attachment of the device as a whole to the joint surface, by allowing bony ingrowth into the TFM pores.

This new composite has been implanted into the femoral condyles of rabbits, and the femoral condyles, femoral heads and intervertebral discs of dogs,^{13,14} and the implants achieved firm fixation to surrounding bone structure within four weeks after implantation.

In this study on canine hips, we observed the histological changes in the acetabular cartilage and synovial membrane

K. Ushio, MD, Orthopaedic Surgeon
S. Yura, MD, Orthopaedic Surgeon
T. Nakamura, MD, PhD, Professor and Chairman
Department of Orthopaedic Surgery, Faculty of Medicine, Kyoto University, 54 Kawahara-cho, Shogoin, Sakyo-ku, Kyoto, 606-8507 Japan.

S.-H. Hyon, PhD, Associate Professor
J. Toguchida, MD, PhD, Professor
Institute for Frontier Medical Sciences
Kyoto University, 54 Kawahara-cho, Shogoin, Sakyo-ku, Kyoto, 606-8507 Japan.

†M. Oka, MD, PhD, Professor Emeritus of Kyoto University (deceased)
Kyoto City Rehabilitation Centre Hospital, Mibu, Nakagyou-ku, Kyoto 604-8854 Japan.

Correspondence should be sent to Dr K. Ushio.

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Fig. 1

Photograph of a synthetic composite osteochondral device (COD) for partial replacement of the canine femoral head. The transparent portion is made of polyvinyl alcohol hydrogel (PVA-H).

and verified the attachment of the COD prosthesis to the underlying bone by bony ingrowth.

Materials and Methods

Implants. The prostheses had a straight stem and spherical articular portion in order to replicate the sphericity of the canine femoral head. In addition to COD implants, prostheses made from ultra-high-molecular-weight polyethylene (UHMWPE) and alumina ceramics were also fashioned to act as a control group.

A COD prosthesis is shown in Figure 1. The mean total pore volume of the TFM was 60% and the mean pore size was approximately 180 μm . The transverse axial section of the stem portion was made square to minimise rotational micromovement around the long axis of the prosthesis. The PVA solution, with a viscosity-average degree of polymerisation of 8800 and molecular weight of 387200, was infil-

trated into the pores of the spherical portion of the TFM by high-pressure injection moulding.

A Nissei injection moulding machine (Model NS40-5A; Nissei, Nagano, Japan) was used, which infiltrated the viscous PVA solution at 150°C into the pores of the TFM placed in a mould under a pressure of 120 Mpa. In order to maintain the necessary space for bone ingrowth on implantation, PVA infiltration into the cubic stem portion of the device was prevented by temporary masking of the pores with cyanoacrylate. After infiltration, a gelling process was applied, and the cyanoacrylate was removed by dissolution in acetone.

The water content of the PVA-H was controlled by annealing in a silicone oil bath between 100°C and 150°C for 48 hours. The devices were then rehydrated for two days in excess water at 37°C yielding a final water content of approximately 30%. All prostheses were sterilised with gamma ray irradiation (5 megarad).

The UHMWPE and alumina ceramics control devices are shown in Figure 2. The articulating surfaces of both types were highly polished. All three types of implant were manufactured by Kyocera Co Ltd, Kyoto, Japan, and had the same radius of 8 mm in the articular portion and the same amount of spherical area for articulation. The size of the implant was decided from measurements obtained in a preliminary cadaver study.

Operative technique. Conic prostheses made of the COD were used to replace partially the surface of the canine femoral head for the purpose of simulating partial surface replacement hemiarthroplasty (Fig. 3) for the treatment of stage-III osteonecrosis of the femoral head according to Ficat and Arlet.¹⁵ We carried out the operations using a posterolateral approach to the hip, with the dog under general anaesthesia, using standard aseptic surgical technique. After making a T-shaped incision in the capsule of the joint, we severed the ligamentum teres and dislocated the hip. A hole for containing the stem portion of the prosthesis was prepared in the femoral head with an oscillating bone saw and drill bur (Microelectric System, Stryker Instruments,

Fig. 2

Photographs showing a) an implant made of ultra-high molecular weight polyethylene (UHMWPE) and b) an implant made of alumina ceramics.

Fig. 3

Diagrams showing partial surface replacement hemiarthroplasty for osteonecrosis of the femoral head.

Kalamazoo, Michigan). The prostheses made of COD were press-fitted while the other two types were inserted with a small amount of polymethylmethacrylate bone cement (CMW Laboratories, Blackpool, UK).

Specially designed instrumentation ensured the precise positioning of the implant with particular attention being paid to the alignment of the axis of the femoral neck. Irrigation of the joint with large volumes of saline removed any debris. When the hip was reduced and stable, the capsule and wound were closed. Prophylactic antibiotics were given intravenously during the operation.

We used 38 hips from 33 beagles (10.0 to 12.8 kg) with an intact femoral head. The surgeon chose the implant at the time of operation. COD implants were placed in 22 femoral heads of 22 beagles, UHMWPE implants in eight femoral heads of six beagles, and alumina ceramic implants in the other eight femoral heads of five beagles. Radiographs were taken after operation to check the congruency of the femoral head. The dogs were allowed unrestrained weight-bearing and normal activity in their living areas and exercised regularly. They were killed at time intervals of one, three, six and 12 months. In the COD group, five beagles were killed at one month, seven at three months, seven at six months and three at 12 months. In each of the UHMWPE and alumina ceramics groups, two hips were obtained at each of the time intervals. The study was carried out with full accordance to the guideline for animal experiments at Kyoto University.

Pathological examination. The joints were inspected for colour, integrity, contour, and smoothness of the acetabulum and femoral head and for the presence of any synovial reaction. Specimens were removed *en bloc* and fixed in a 10% formalin solution. Samples, cut from each acetabular dome, included the principal load-bearing region. After being decalcified and embedded in paraffin by routine methods, a section from the sample was cut into two 5 μ m slices. One was stained with haematoxylin and eosin and the other with Safranin O/Fast Green. The sections from the synovium were stained with haematoxylin and eosin.

The femoral heads implanted with COD prostheses were transected into halves vertically through the axis of the femoral neck before fixation in a 10% formalin solution. One of the two halves was cut into decalcified sections after

retrieval of the prosthesis and stained in a similar manner to the acetabulum. Using these decalcified specimens, photomicrographs were produced. After a serial alcohol dehydration process, the other half was made into an undecalcified specimen embedded in polyester resin (Maruto Instrument Co Ltd, Tokyo, Japan). It was cut and ground to 100 μ m-thick sections using a band saw and a grinding machine (BS-3000 and MG-4000; EXAKT, Norderstedt, Germany). These thin, undecalcified sections underwent histological examination using Giemsa surface staining. We used contact microradiography to estimate the extent of bone ingrowth into the pores of TFM, and the fixation of the device to the underlying bone.

Evaluation. Sections from the acetabulum were graded using the method reported by Mankin et al¹⁶ by comparison with normal acetabula. Using this system, total scores range from 0 (normal) to 14 (severely damaged). The synovial reaction was evaluated according to the grading scale of Noguchi et al¹² as follows: score 0 (normal), normal appearing synovial membrane, mostly monolayered intima; score 1 (slight inflammation), slight hypertrophy of the intima (two or three layers), some increase in subsynovial fibrous tissue; score 2 (mild inflammation), mild hypertrophy of the intima (four or five layers), increase in subsynovial fibrous tissue; score 3 (moderate inflammation), multilayered intima, increase in subsynovial inflammation, infiltration with inflammatory cells; and score 4 (severe inflammation), pronounced hyperplasia, increase in subsynovial fibrosis and in inflammatory cell infiltration.

Results

All the animals recovered from general anaesthesia without incident and were fully weight-bearing by two weeks after surgery. All had a full range of movement of the hip. Post-operative complications occurred in five hips in the COD group and two in each of the UHMWPE and alumina ceramics groups. These included four infections and five dislocations. All nine joints were withdrawn from the study leaving 29 hips for analysis, 17 in the COD group and six in each of the UHMWPE and alumina ceramics groups.

Radiological findings. Radiographs taken when the animals were killed showed that the reduction and position of

Fig. 4

Radiograph of a canine hip at 12 months after operation.

Fig. 5

Radiograph of the femoral head at three months after operation in the COD group.

Fig. 6

Photograph of a transected specimen of the femoral head at 12 months after operation in the COD group. The smooth contour of the femoral head was maintained, and the COD well integrated into the femoral head.

the femoral head were well maintained (Fig. 4). In the COD group there was a slight increase in bone density in and around the stem portion of the TFM and good fixation to the surrounding bone at three months and after (Fig. 5).

Macroscopic findings. There were no adverse responses, such as erosion or haemorrhage, in the articular cartilage of the acetabulum of the COD group, which were pearly-white, smooth, and firm. The smooth contours of the femoral heads were maintained with neither hyperaemia nor signs of inflammation. The transected specimens showed good congruity of the PVA-H with the adjacent natural articular cartilage (Fig. 6). The stem portion of the TFM was well incorporated into the surrounding bone without gaps between the prosthesis and articular cartilage or surrounding cancellous bone.

In the UHMWPE group, there was slight synovitis and discoloration of the acetabular cartilage three months after operation. Severe synovitis and erosion of the acetabular cartilage had developed by six months at the point of the most immediate contact between the implant and acetabulum.

These changes continued to become more severe, and focal subchondral bone was exposed by 12 months after operation.

In the alumina group, there was slight or moderate synovial thickening and discoloration of the acetabular cartilage throughout the experimental periods.

Histological findings. In the acetabular cartilage from the COD group, the structural integrity, cellularity, and the production of glycosamines in the matrix, as demonstrated by Safranin-O staining, were, except for slight surface irregularities, well maintained throughout the observation periods (Fig. 7). There was a slight hypertrophy of the intima in the synovium and some increase in subsynovial fibrous tissue.

Contact microradiographs of sections of the femoral heads showed excellent bone ingrowth into the pores of the TFM with slight or moderate remodelling around the TFM at three months. Continued ingrowth and maintenance within the porous structure were seen at 12 months (Fig. 8).

The decalcified and paraffin-embedded sections from which the COD prosthesis had been retrieved showed that the structural integrity, surface regularity, and thickness

Fig. 7

Contact microradiograph at 12 months after operation in the COD group ($\times 2.5$). The thin white shadow indicates the PVA-H portion.

Fig. 8

Photomicrograph of an acetabular cartilage section at 12 months after operation in the COD group (Safranin O and Fast Green $\times 100$).

Fig. 9a

Fig. 9b

Figure 9a - Photomicrograph of an undecalcified section of the femoral head at 12 months after operation (Giemsa $\times 15$). The interface appeared to show a gap produced by shrinkage of the PVA-H during the processing for histological section. Figure 9b - Photomicrograph showing the unstained section of the femoral head at 12 months after operation ($\times 15$).

Fig. 10

Photomicrograph of acetabular cartilage at six months after operation in the UHMWPE group (Safranin O and Fast Green $\times 20$).

Fig. 11

Photomicrograph of a synovial section at 12 months after operation in the UHMWPE group (haematoxylin and eosin $\times 200$). Diffuse synovitis caused by polyethylene wear particles was visible.

Fig. 12

Mankin scores for the changes in acetabular cartilage in each group. Each point represents a single score for a joint (○, PVA-H, □, alumina ceramics, △, UHMWPE).

Fig. 13

Noguchi grading scales for each synovial reaction in each group. Each point represents a single score for a joint (O, PVA-H, □, alumina ceramics, Δ, UHMWPE).

were well maintained in the surrounding host articular cartilage throughout the experimental periods, although some hypocellularity or acellularity and reduction of Safranin-O staining were observed at the edges of the sections. The interface between the PVA-H and the articular cartilage or surrounding cancellous bone adjacent to the zone of implantation was filled with newly formed fibrocartilage-like tissue. The interface with the COD observed in the undecalcified, polyester-resin-embedded specimens appeared to show a gap, which was attributed to shrinkage of the PVA-H during the preparation of the specimen, and not to separation *in vivo* (Fig. 9).

In the UHMWPE group, surface irregularities, clefts, and slight to moderate reduction in staining with Safranin-O were seen in the acetabular cartilage at one month. Moderate focal synovial inflammation caused by UHMWPE wear particles was found at three months. Hypocellularity, erosion to the level of the radial zone or tidemark, and no staining with Safranin-O were noted in the acetabular cartilage at six months (Fig. 10). Erosion of the acetabular cartilage extended to the level of the calcified zone, and loss of Safranin-O staining was visible at 12 months. Diffuse synovitis became more severe with many inflammatory cells engulfing polyethylene wear particles (Fig. 11).

In the alumina ceramics group, a moderate deterioration in the structural integrity, surface regularity, and thickness were found in the acetabular cartilage at one month. Some chondrocyte clustering, mild hypercellularity and slight to moderate reduction in Safranin-O staining were also seen at one month and subsequent observation periods. Slight to moderate synovial inflammation was also visible throughout the experimental periods.

Mankin's scores for the acetabular cartilage in each group are summarised in Figure 12 and Noguchi's grading scale for synovial reaction in Figure 13. Some decrease in the transparency of the PVA-H was found in one hip one year after implantation.

Discussion

The common surgical approach for the treatment of advanced stage ONFH (Ficat and Arlet stage-III or early stage-IV) has been hemiarthroplasty using a unipolar or bipolar metal endoprosthesis. Although the overall clinical results are generally satisfactory, pathological changes occur in the opposing acetabular cartilage.¹⁷⁻¹⁹ Considering the young age of many patients with ONFH, a treatment which preserves the femoral head more effectively is desirable.

Some authors have reported favourable clinical results from surface replacement hemiarthroplasty in which the whole femoral head is covered with a metal cup for the treatment of patients with stage-III or early stage-IV osteonecrosis.⁵⁻⁷ Changes observed in the opposing acetabular articular surface, however, indicate problems which may be caused by the material used. Deterioration or complete absence of cartilage in the weight-bearing areas of the acetabulum is a major cause of failure in hips treated in this manner, and bone resorption induced by stress-shielding caused by the metal cup may also have contributed to failures. In the three-dimensional, finite-element stress analysis of the hip, femoral heads covered by a metal cup showed marked stress shielding, disrupting the even stress distribution and smooth transmission of force to the distal femur observed in the natural hip.²⁰ In this respect, it is desirable to replace the affected joint surface with a material which resembles articular cartilage.²¹

As the history of hip arthroplasty shows, it was not until the appearance of endoprosthetic replacements that large amounts of intact cancellous bone of the proximal femur were resected. Since the lesion is limited to the surface of the joint in most disorders, it is ideal to replace the affected surface with a new biomaterial, the mechanical properties of which are similar to those of natural articular cartilage.^{22,23}

Various materials, such as hydroxyapatite and a number of polymers, have been proposed for use as artificial cartilage. Recently, methods of repairing the articular surface have been reported using autografts, allografts, xenografts, periosteal autografts and cultured chondrocytes, all of which may be classified as biological resurfacing. The disadvantages, common to all of these materials, are insufficient mechanical strength, a limited size of the lesion which can be repaired and long-term durability.

The synthetic device, COD, described in our study was developed to replace joint surfaces. In a previous study in which the canine femoral condyles were replaced with the COD, the opposing joint surface showed no pathological changes.¹³ In this study, prostheses made of COD were implanted to replace the surface of canine femoral heads for the purpose of simulating partial hemiarthroplasty for ONFH.

As evaluated by Mankin's score, with the COD the changes in the acetabular cartilage were minimal throughout the 12-month experimental period. Although a slight increase of subsynovial fibrous tissue was observed, this change was minimal in comparison with those when UHMWPE was used. In the latter group, severe synovial inflammation with many macrophages phagocytosing UHMWPE wear particles was visible. These severe foreign-body reactions were evoked by the excessive number of wear particles of UHMWPE found histologically by polarised light microscopy.

The reason for this high volume of wear particles in the UHMWPE group may be explained by the presence of some instability after implantation caused by the resection of the ligamentum teres. In beagle dogs, resection of the ligamentum teres causes vertical instability of the femoral head, which is considered to accelerate the wear of UHMWPE. In addition, mismatches in the size and shape of the femoral component with those of the acetabulum (depending on the anatomy of each dog) may have played a role in promoting instability. Since no such apparent synovial changes were found in either the COD or alumina ceramics groups, in spite of the presence of equally unstable hips, this is evidence of the inferior wear-resistant and biocompatible properties of UHMWPE.

It may be anticipated that deterioration of intact natural articular cartilage will be more severe when it is articulated with stiffer materials. In our study, the results with the stiffest material, alumina, were much better than those with UHMWPE, but worse than those with PVA-H. The minimal changes found in the alumina ceramics group are in marked contrast to the results obtained in a previous study, in which time-dependent changes of tibial articular surfaces against three types of material implanted in canine femoral condyles under loading conditions were compared.¹³

Oka et al¹³ observed marked pathological changes in the tibial articular cartilage eight weeks after implantation of alumina and pure titanium, whereas the articular surface against the COD was still intact 24 weeks after operation.

Fig. 14

Histogram showing coefficients of friction for various combinations ($n = 3$ for each combination). The error bars show the SD.

The authors originally surmised that the marked pathological changes against alumina and metal prostheses were attributable to the rigid surface properties, and high coefficient of friction in these materials. Surface and interfacial mechanical properties, such as surface roughness, elastic modulus and contact pressure, are closely related to the wear and degeneration of cartilage which articulates with different material implants.²⁴ In an earlier study,²⁵ to determine the coefficient of friction of cartilage/cartilage, COD/cartilage, alumina ceramics/cartilage and UHMWPE/cartilage, there was a higher coefficient of friction for articular cartilage against alumina than against the PVA-H of the COD (Fig. 14). Our comparatively good results obtained with the alumina group may be attributed to better joint congruity of the canine ball-and-socket hip in comparison with that of the condylar canine knee. Regardless of any variations in results obtained with the other two materials, the consistently superior friction performance displayed by the COD suggests its superiority for use in joint replacement.

The first attempt to develop PVA-H as artificial cartilage is credited to Peppas.²⁶ Later attempts to improve the mechanical properties of the PVA-H included increasing its molecular weight (384000) and decreasing its water content. Using the improved PVA-H design as a basis, Oka, Ikeuchi and Tsutsumi²⁷ and Oka²⁸ have, over the past 12 years, been developing an artificial articular cartilage.

A key problem pertaining to the development of materials for replacement of articular cartilage is the difficulty associated with obtaining their firm attachment to the underlying joint surface, and this may be the reason why many attempts to develop artificial cartilage have been abandoned. We have addressed this problem by adopting the COD design. While PVA-H is extremely difficult to attach directly to joint surfaces, use of the COD design allows the TFM component to act as an interface material bonded strongly to both the PVA-H through injection moulding/gel-ling and to the joint surface through bony ingrowth, thus

Fig. 15

Photomicrographs of thin sections of the two types of COD (Giemsa $\times 35$). The left column of the histogram indicates the shear strength of PVA-H with TFM (mean SD, $n = 4$ for old type, $n = 10$ for new type).

achieving the firm attachment unattainable with monotonic designs. Our contact microradiography findings confirmed firm attachment of the COD to the femoral head. Periodic observation showed that this attachment occurred very quickly by means of the anticipated mechanism of bony ingrowth into the pores of the TFM. No submergence of the implant in relation to the surrounding cartilage affected the opposing acetabular articular cartilage.

The PVA solutions, especially those of high molecular weight and concentration, are so viscous that adequate infiltration into the pores of TFM under negative pressure is extremely difficult. Previous COD implants, which were created using an old immersion infiltration method, were prone to failure brought on by displacement of the PVA-H from the TFM. During the past two years, the infiltration method has been improved by adopting high-pressure injection moulding and, as demonstrated by our study, no such displacement failures have been subsequently observed. In another previous experiment, thin sections of TFM into which PVA solution had been impregnated by the old immersion method generally showed very scant filling of the pores as shown on the upper-right figure in Figure 15. By contrast, sections from devices prepared using the injection moulding method showed markedly increased infiltration deep into the TFM. The shear strength of the PVA-H/TFM interface was four times stronger for injection-moulded CODs than for those prepared using the previous infiltration method (Fig. 15).

A series of tests *in vivo* has demonstrated the biocompatibility of PVA-H. One of these included a study¹¹ in which small particles (50 to 300 μm in diameter) of PVA-H and UHMWPE were introduced into the right and left contralateral knees of rats (respectively). Histological examination of the synovial membrane and articular cartilage after two

months showed that the PVA-H particles caused much less inflammation than UHMWPE.

There are concerns about a gap between the existing natural and implanted artificial cartilage discovered in the undecalcified Giemsa surface-stained specimens and the possibility of such a gap leading to degeneration of the adjacent cartilage. Observation of specimens before processing, however, clearly indicated that CODs were well integrated into the femoral head. The observed gap was produced by shrinkage of PVA-H during the processing for histology and not by an *in vivo* phenomenon, which could jeopardise the stability of the device. Shrinkage of the PVA-H during histological preparation was seen in a preliminary study *in vitro*. Although some fibrocartilage-like tissues were found in decalcified sections adjacent to this apparent gap, the COD was firmly attached to subchondral bone and had a solid foundation in the surrounding tissue.

Histological changes in the adjacent articular cartilage after implantation of PVA-H have been examined in a previous study, in which time-dependent histological changes in the articular cartilage in the patellar grooves of rabbit femora, into which cylindrical test specimens of PVA-H had been implanted, were observed.¹² This study compared the PVA-H results with those obtained by substituting UHMWPE for equal periods of 52 weeks after operation. While the articular cartilage adjacent to PVA-H showed slight inflammation until four weeks after implantation, these reactions completely subsided and no structural disturbances remained after 26 weeks.

The final concern pertaining to the COD relates to deterioration of the *in vivo* PVA-H in the long term. This issue was addressed in another preliminary study in which dumbbell form sheets of PVA-H were implanted into the subcutaneous tissue of four beagle dogs and changes in the elastic

modulus, molecular weight, and surface properties examined at time intervals of one, three, six and 12 months. The results showed no particular changes in any of the properties of PVA-H, and demonstrated the biologically stable nature of the PVA-H.

Our study, like any animal experiment, has limitations. Both hips of two of the beagles in the polyethylene group and three in the ceramic group were used, which may have biased the results. Selection bias, related to which beagle was used for which implant and killed at particular time intervals, may have influenced the results. One shortcoming is the small number of subjects. A trial involving a sample-size needed to detect a statistical difference between groups is certainly possible. The feasibility of such a trial is doubtful, however, since the polyethylene and ceramic groups have performed poorly in previous experiments, and there are ethical as well as economic grounds for killing fewer animals.

Despite the limitations of our study, we found important differences among the three groups. The results demonstrate the superior ability of the COD, in comparison with conventional UHMWPE and alumina ceramics implant materials, to preserve the opposing acetabular articular cartilage in partial hemiarthroplasty, and its capacity for quick, firm attachment to the joint surface.

We believe that these results, in combination with the results of numerous previous studies, indicate that COD implants prepared using the injection moulding/gelling process are appropriate for clinical application. Planning and preparation for clinical trials are currently underway.

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