SYNTHETIC OSTEOCHONDRAL REPLACEMENT OF THE FEMORAL ARTICULAR SURFACE

MASANORI OKA, YONG-SHUN CHANG, TAKASHI NAKAMURA, KAZUYASU USHIO, JUNYA TOGUCHIDA, HAI-OU GU

From Kyoto University, Japan

We have studied damage to the tibial articular surface after replacement of the femoral surface in dogs. We inserted pairs of implants made of alumina, titanium and polyvinyl alcohol (PVA) hydrogel on titanium fibre mesh into the femoral condyles.

The two hard materials caused marked pathological changes in the articular cartilage and menisci, but the hydrogel composite replacement caused minimal damage. The composite osteochondral device became rapidly attached to host bone by ingrowth into the supporting mesh.

We discuss the clinical implications of the possible use of this material in articular resurfacing and joint replacement.

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Hemiarthroplasty using a metal prosthesis articulating with articular cartilage has been widely used for the hip, \(^1\,^2\) shoulder \(^3\) and other joints \(^4\,^5\) since the 1950s. The overall clinical results are usually satisfactory, but pathological changes in the opposing articular cartilage have often been observed. \(^6\,^7\) Erosion of the acetabular articular cartilage, with associated pain, is a recognised late complication of hemiarthroplasty. \(^10\,^11\)

Furthermore, the use of prosthetic replacements usually requires the removal of healthy cancellous bone which has an important shock-absorbing role. \(^12\) It is desirable therefore to develop new materials with mechanical properties which are more similar to those of normal articular cartilage.

We have developed an artificial replacement for articular cartilage which preserves healthy subchondral cancellous bone. This substance is polyvinyl alcohol (PVA) hydrogel and we have improved its mechanical properties using a new synthetic process. \(^13\,^15\)

In previous studies we characterised the mechanical properties of this material in relation to its use as an artificial articular cartilage including its lubricating and shock-absorbing functions. A series of in vivo tests showed that it had good biocompatibility. \(^17\) In addition, histological findings in synovial membranes and articular cartilage two months after the introduction of small particles (50 to 300 \(\mu m\)) of PVA hydrogel and ultra-high-molecular-weight polyethylene (UHMWPE) into contralateral knees of the same rats showed that the PVA hydrogel particles caused much less inflammation. They were not resorbed because of their bioinert properties. \(^17\)

A major problem, however, was the attachment of the material to the bone. To overcome this, we infiltrated PVA solution into the pores of one half of a block of titanium fibre mesh to obtain a composite material. The shear force between the PVA hydrogel and the titanium fibre mesh was approximately 2.2 MPa. \(^17\)

Our aim in this study was to determine the changes which occurred in menisci and articular cartilage in contact with various implants. We implanted alumina, titanium and our composite ‘osteochondral’ device (COD) into the load-bearing regions of the femoral condyles of dogs and examined the time-dependent changes in the tibial articular cartilage. We also determined the ingrowth of new bone into the pores of the titanium fibre mesh and the remodelling of the bone around the implants.

MATERIALS AND METHODS

Rectangular test pieces \((10 \times 6 \times 5 \, mm)\) were manufactured from pure titanium fibre mesh with a porosity of 60\% and a mean pore size of 170 \(\mu m\). The composite prostheses were made by infiltrating PVA (molecular weight 220000) solution into the pores of the distal half of the titanium fibre mesh, and binding it by gelling the PVA (Fig. 1). The joint surfaces were shaped using the mirror-finished PVA hydrogel which we have developed. Implants of the same shape, finish and size were manufactured from alumina and titanium.

M. Oka, MD, Professor
Y.-S. Chang, MD
T. Nakamura, MD
K. Ushio, MD
Department of Artificial Locomotive Systems, Research Centre for Bio-medical Engineering
T. Toguchida, MD, PhD
Department of Orthopaedic Surgery
Kyoto University, 53 Kawahara-cho, Shogoin, Sakyo-ku, Kyoto 606-01, Japan.
Correspondence should be sent to Professor M. Oka.
um. All the implants were produced by the Kyocera Corporation, Japan. The artificial CODs were sterilised using ethylene oxide gas and the titanium and alumina implants in an autoclave.

Thirty-two of each of the three types of implant (total 96) were inserted in pairs into the stifle joints of 24 mature adult mongrel dogs weighing approximately 15 to 20 kg. Each dog received two types of implant, one pair in each hind leg. Under general anaesthesia with intravenous ketamine HCl combined with intramuscular atropine sulphate, both hind legs of each dog were prepared and draped. A medial parapatellar approach was used to expose the femoral condyles and holes for the implants were made using a broach and a dental burr. After an undersize trial, the test prostheses were tapped into place. Routine anteroposterior and lateral radiographs were taken immediately after surgery to ensure that the implants were properly positioned (Fig. 2). No postoperative external fixation was used. Two identical implants were inserted into the medial and lateral femoral condyles of one joint, and a different pair into the opposite hind leg at the same operation. This ensured that the animal would be obliged to stand on the operated legs.

The animals were killed in two batches, 12 at eight weeks and 12 at 24 weeks using intravenous injections of 10% KC1. Immediately after death all the femoral and tibial joint surfaces, including the menisci, were removed. Colour macrophotographs of samples of the tibial articular cartilage were taken and graded using improved evaluation criteria (Table I) according to the classification of Cook, Thomas and Kester.16 These data were grouped by implant type and analysed using the Kruskal-Wallis non-parametric analysis of variance.

Each tibial plateau and its menisci, including the subchondral bone, was fixed with 10% neutral buffered formalin solution. The samples of tibial articular cartilage, including the subchondral bone, were decalcified using the Plank-Rychlo method.19 These, together with the menisci, were then dehydrated in a graded alcohol series and embedded in paraffin. Thin sections (5 μm) of each specimen were cut and stained with haematoxylin and eosin. Thio- nin was used to stain for proteoglycans.

To study new bone ingrowth into the titanium fibre mesh and bone remodelling around the implanted materials, each femoral condyle was fixed in 10% neutral buffered formalin solution. The samples were dehydrated in a graded alcohol series and embedded in polyester resin. Thin undecalcified sections of each femoral condyle and its implant were cut (EXAKT Cutting Machine, model BS-3000A, Norderstedt, Germany) and ground to a thickness of 100 to 150 μm using a bench-top polishing wheel (EXAKT Microgrinding Machine, Norderstedt, Germany) with graded levels of waterproof abrasive paper (Rikagaku Co Ltd, Sankyo, Japan). Each section was then subjected to Giemsa surface staining, contact microradiographic examination and studied by light microscopy.

RESULTS
Within one week of implantation all the animals were able to bear weight on their operated legs and were allowed to move freely outside their cages at two weeks after the operation. No animal died and there were no intra- or postoperative complications. All the knees had a nearly normal range of movement and all the alumina, titanium

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
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<tr>
<td>0</td>
<td>Normal cartilage</td>
</tr>
<tr>
<td>2</td>
<td>Minimal wear, no surface irregularities, slight colour change</td>
</tr>
<tr>
<td>4</td>
<td>Obvious cartilage thinning, limited regions of fibrillation, obvious colour change</td>
</tr>
<tr>
<td>6</td>
<td>Areas of eburnation, severe fibrillation, obvious colour change</td>
</tr>
<tr>
<td>8</td>
<td>Partial loss of cartilage, no exposed subchondral bone</td>
</tr>
<tr>
<td>10</td>
<td>Partial exposure of subchondral bone, pannus formation</td>
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and artificial COD surfaces remained intact. No effusion or inflammation was found and all of the test specimens were firmly fixed to the underlying bone.

Macroscopic examination of 24 joints at eight weeks and 24 at 24 weeks showed considerable changes in the menisci and tibial articular cartilage in those with alumina and titanium implants. Ulceration and cartilage loss were apparent in all specimens studied at eight weeks after implantation, and in some dogs the subchondral bone was exposed (Fig. 3). The surfaces of the menisci which had articulated with femoral condyles implanted with the two rigid materials were no longer glossy and bright. In joints with a COD, the menisci and tibial articular cartilages were still intact, even in the 24-week specimens (Fig. 4). Table II summarises the gross appearances of the tibial articular cartilage according to the criteria of evaluation (see Table I). There were no significant differences between the two rigid materials, but there were significant differences (p < 0.01) between the findings for the rigid implants and the COD at both eight and 24 weeks. At 24 weeks, we noted very slight colour changes in the cartilage in joints with a COD. There was much more severe cartilage damage and the formation of pannus on the surface of the cartilage in tibial specimens articulating with either of the rigid materials.

Thionin staining showed partial articular cartilage loss and exposed subchondral bone in the tibial plateau at eight weeks postoperatively in seven joints with three alumina and four titanium implants, respectively (Fig. 5). By contrast, in those with a COD, the tibial articular cartilage showed normal metachromatic staining, an intact surface, normal cells and a bright matrix (Fig. 6).

There was abundant new bone ingrowth into the pores of the titanium fibre mesh at eight weeks postoperatively (Fig. 7), and at 24 weeks lamellar bone remodelling had advanced further. Higher magnification showed mature bone ingrowth in the deep pore spaces. At 24 weeks, no demarcated or radiolucent zones were observed around the material and there was no interposing fibrous tissue sur-

| Table II. Changes of tibial articular cartilage of the three different biomaterials according to the criteria of evaluation (see Table I) |
|---------------------------------|----------|----------|----------|----------|----------|----------|----------|----------|
|                                | 8 weeks (n = 16) |                          | 24 weeks (n = 16) |                          |
|                                | Mean | Median | Maximum | Minimum | Mean | Median | Maximum | Minimum |
| Alumina                        | 8.38 | 8      | 10      | 8       | 9.38 | 10      | 10      | 8       |
| Titanium                       | 8.50 | 8      | 10      | 8       | 9.50 | 10      | 10      | 8       |
| PVA hydrogel                   | 0.25 | 0      | 2       | 0       | 0.25 | 0      | 2       | 0       |

Figure 3 – Photograph showing damage to the articular cartilage at eight weeks postoperatively in a knee with an alumina implant. Figure 4 – Photograph of articular surface in a knee with a PVA hydrogel implant showing that it was still intact at 24 weeks postoperatively.

Figure 5 – Photomicrograph eight weeks after implantation showing considerable erosion of the articular cartilage and exposure of subchondral bone in a joint with alumina implants (thionin ×70).
Figure 6 – Photomicrograph of the tibial articular surface in a knee with a COD at 24 weeks after implantation. There are no pathological changes (thionin ×140). Figure 7 – Photomicrograph of a COD at eight weeks after implantation. The dark, blunt area at the top of the titanium fibre mesh shows intact artificial cartilage PVA hydrogel (Giemsa surface staining ×8). Figure 8 – Photomicrograph of a COD at 24 weeks after implantation. The gap between the PVA hydrogel and the surrounding tissues is seen on both sides of the composite material (Giemsa surface staining ×8).
rrounding the titanium fibre mesh. Mature interstitial bone was seen in the pores of the titanium fibre mesh. The polished alumina and titanium implants were surrounded by a thin fibrous tissue layer at 24 weeks.

Figure 8 shows a typical gap between the surrounding normal articular cartilage and the PVA hydrogel. These gaps were not filled by fibrous repair tissues, and they persisted at 24 weeks after operation. The surface of the PVA hydrogel showed no signs of wear at 24 weeks after the operation.

DISCUSSION
Various methods of repairing articular surfaces have been proposed using autografts, allografts, xenografts, periostal autografts and cultured chondrocytes, all of which may be designated as ‘biological resurfacing’. Remarkable progress has recently been made in this field, particularly with the development of tissue engineering. In addition to these biological methods of resurfacing, different materials such as polymers, hydrogels and porous hydroxyapatite have been used. All these artificial materials suffer from the disadvantage of insufficient mechanical strength, which leads to degradation of the restored surface after only two or three months. A second problem is that the implant cannot be firmly attached to adjacent bone and is thus readily displaced. The scope of such repairs is therefore limited to small areas; larger areas require a new bio-material which has mechanical properties more similar to those of articular cartilage. The properties required for artificial articular cartilage include good lubrication, sufficient shock-absorbing ability, good biocompatibility, high wear resistance and the ability to be attached to the underlying bone.

Our findings have shown that our composite material has abundant new bone ingrowth into the pores of the titanium fibre mesh and can be firmly attached to the underlying bone. In regard to the response of the tibial articular surface, the two hard materials caused marked pathological changes but the COD produced minimal changes.

Cook et al investigated the low modulus and surface chemistry and energy characteristics of low-temperature isotropic (LTI) pyrolytic carbon. They reported that the COD implant cannot be firmly attached to adjacent bone and is thus readily displaced. The scope of such repairs is therefore limited to small areas; larger areas require a new bio-material which has mechanical properties more similar to those of articular cartilage. The properties required for artificial articular cartilage include good lubrication, sufficient shock-absorbing ability, good biocompatibility, high wear resistance and the ability to be attached to the underlying bone.

Since the most important problem of firm attachment of the material to the underlying bone has now been solved, clinical application of the COD becomes possible. The main potential application is in partial surface replacement of the femoral head after aseptic necrosis. Others could include articular resurfacing and the replacement of intervertebral discs.

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

REFERENCES