Cementless total hip replacement

Bio-active glass ceramic coating studied in dogs

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We studied **2** types **of** a cementless total hip prosthesis in dogs. Both were coated with titanium plasma-spray. In both components, the pores in the deep layer of **1** group were further coated with apatite and wollastonite containing glass-ceramic (AW glass-ceramic). **50** dogs underwent unilateral total hip replacements, and were killed at **1,** 3, or **6** months postoperatively. We evaluated the femoral and the acetabular components mechanically and histologically. At **1** month, the detaching load and bone ingrowth of the AW glass-ceramic-coated femoral and acetabular components were higher than those of the control implants. At 3 and *6* months there were no differences between the **2** types **of** components. Thus, AW glass-ceramic enhanced the early phase of cementless implant fixation.

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AW glass-ceramic was developed at Kyoto University in 1982 (Kokubo et al. 1982, 1985). Experiments on rabbit tibiae demonstrated that blocks of **AW** glass-ceramic bonded directly to tibiae within 8 weeks under both non-weight (Nakamura et al. 1985) and load-bearing conditions (Kitsugi et al. 1989). Granules of **AW** glass-ceramic have good osteoconductivity (On0 et al. 1988) and low toxicity (Kawanabe et al. 1991). **AW** glass-ceramic coating **of** the deep portion of the porous layer of implants accelerated the bone-bonding process and implant fixation (Yamamuro and Takagi 1991).

In this study, 2 types of plasma-sprayed titanium porous, cementless, femoral and acetabular components were compared in dogs, with and without the porous layer coated with **AW** glass-ceramic in its deeper parts.

Material and methods

Total hip replacements on the left side were performed on 50 mature mongrel dogs weighing **15** (12–16) kg. The experiments were carried out according to the guidelines for animal experiments at Kyoto University.

Implants

The chemical composition of **AW** glass-ceramic by weight percent was MgO 4.6, CaO 44.7, Si02 34.0, **P2** *0 5* 16.0, and CaF2 0.5 (Kokubo et al. 1985).

Porous femoral and acetabular components were used (Figure l). The femoral head was made of zirco-

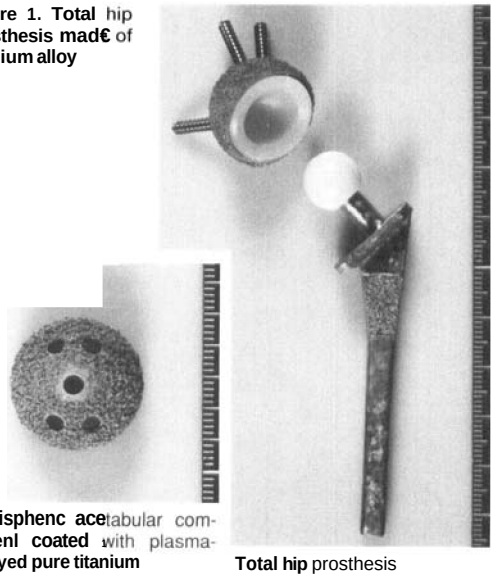
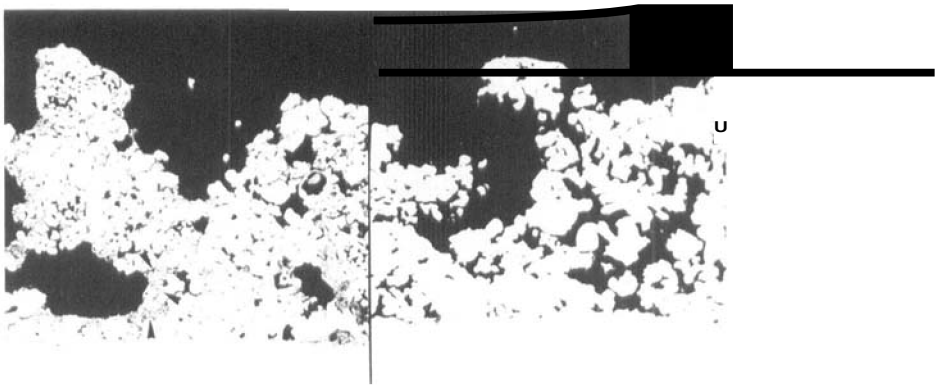


Figure 1. Total hip **prosthesis mad€** of **titanium alloy**

Hsmisphenc acetabular com-**ponenl coated** with plasma-**sprayed pure titanium**

Total hip prosthesis

Figure 2. Scanning electron micrograph of a cut section from the porous layers



AW Group. **Porous layer was coated with AW glass-ceramic in its deeper part.**

Control Group. **Porous layer was manufactured with plasma-sprayed pure titanium.**

nia ceramic, 12 mm in diameter. The straight-stemmed. collared femoral component, made of Ti-6AI-7Nb-ITa, had porous surfaces on the anterior and posterior proximal parts. The porous layer was manufactured with plasma-sprayed pure titanium. The porous layer of the femoral component was coated with **AW** glass-ceramic by the dipping method, with subsequent removal of the superficial **AW** glass-ceramic to open the pores in the porous surface **(AW** Group, Figure *2).* The Control Group had the same femoral components without **AW** coating. The average pore size was 3.50 **pi,** the porosity of 60 percent, and the thickness of 7' pi in the porous layer were identical in both groups.

The hemispheric acetabular component measured 20 mm in outer diameter, contained **4** holes in the central portion for the insertion of anchoring screws, and was coated with pkma-sprayed pure titanium on the outer surface. The **AW** and Control Group acetabular components were manufactured by the same method as the femoral component. *3* or 4 anchoring screws made of titanium alloy, **2.7** mm in diameter and **IS** mm in length, provided immediate fixation of the acetabular component. **A** 2-mm thick polyethylene liner provided the articulation with the femoral head.

The operation

The dogs were anesthetized by intramuscular injection of ketamine **HCI** (15 mg/kg body weight) and atropine sulphate (l.0 mg/dog). Under aseptic conditions, a direct lateral incision was made along the axis of the femoral shaft, and the greater trochanter was osteotoniized to expose the hip joint. The hip was then dislocated and a femoral osteotomy proximal to the lesser trochanter was performed. The femoral canal was serially reamed. and a femoral rasp, which had the same dimensions as the solid part of the femoral component. was used to prepare the proximal aspect of the femur. The femoral component was tapped into the femoral canal. The articular surface of the acetabuluni was curetted, and the acetabuluni was reamed with 3 reamers. The acetabular component was carefully positioned and securely fixed with 3 or 4 screws. The hip was reduced, checked for stability, and the wound was closed by layers. During the operation, piperacillin sodium (2 g) was administered intravenously, and the operation site was irrigated with physiological saline containing dibekacin sulphate. Radiographs were obtained immediately after the operation, and the dogs were allowed to move freely.

l dog in each group was excluded due **to** hip dislocation. **All** the other dogs were able to walk after about a week and appeared to be fully weight bearing, with it normal gait. The range of motion of the hip joint was close to normal after l month.

In each group, 9 dogs were killed at l month, 8 at 3 months, and **7** at 6 months by an intravenous overdose of pentobarbital. The entire femora and acetabula were harvested and radiographed.

Mechanical testing and histology

Femoral cornpotrent. In each group, all but 2 dogs were randomly selected for **a** pull-out test. Jigs **for** the pull-out test were set on each femoral component, and pull-out from the femur was performed at a cross-head speed of 2.0 mm/min using an Instron-type testing machine **(S-100,** Shimazu Co., Kyoto). Care was taken to ensure that the line of action of the loading force was parallel to the long axis of the femoral component. The detaching load of each femoral component was recorded. The other 2 samples in each group were examined histologically. The samples were fixcd in l 0

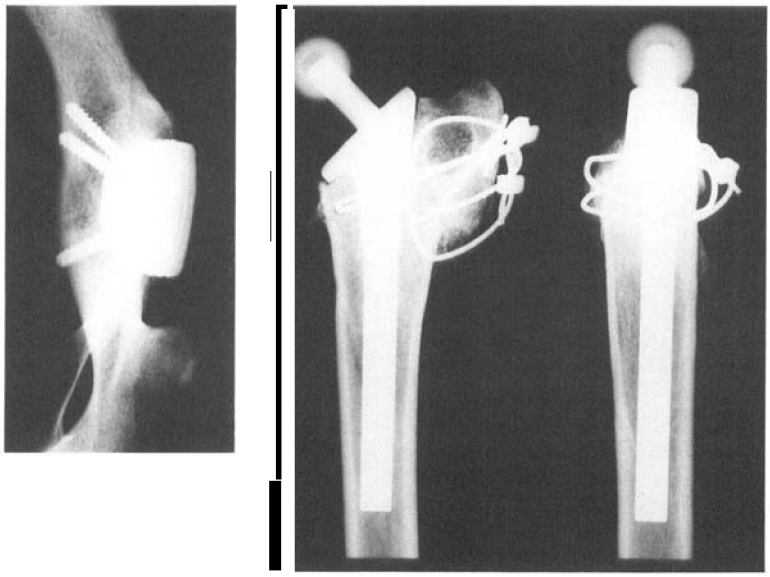


Figure 3. Soft radiograms of the AW glass-ceramic coated components 6 months after implantation.

percent phosphate-buffered formalin. They were subsequently dehydrated in serial ethanol concentrations, and embedded in polyester resin. Thin sections were made across the bone-implant interface axial to the long axis of the femoral component using a diamond-coated cutting band (BS-3000, EXAKT, Germany). 10 sections were obtained per sample. The sections were then ground to 150 pn thickness using a grinding machine (MG-4000, EXAKT, Germany). Following contact microradiography, all sections were examined with light microscopy.

Quantitative measurements of bone ingrowth into the porous layer were obtained using a high speed, computer-assisted, image-analysis system attached to a scanning electron microscope (SEM, X-6000, Hitachi, Tokyo) equipped with a back-scatter electron detector (BSE). The bone ingrowth within each field was expressed as a percentage of the area within the porous layer available for bone ingrowth, the area density of bone ingrowth (Jasty et al. 1989). These measurements were made along the entire length of the porous coating of the femoral component.

Acetabular component. In each group, all but 3 dogs were randomly selected for mechanical testing. After removing the surrounding soft tissue, the polyethylene liner and the screws, the segments containing the acetabular components were fixed on the table. A specially designed jig, used for detaching the acetabular component from the acetabulum, was set on each segment. Detachment was performed in the same way as in the femoral component. Care was taken to ensure that the line of detachment was vertical to the base of the acetabular component.

The other 3 samples in each group were sectioned serially in a sagittal orientation in the same way as in the femoral component. About 8 slices near the center of the acetabular component were made from each sample. Histological evaluation and the measurements of the area density of bone ingrowth were performed in the same way as in the femoral component.

Statistics

All the data, except the area density of bone ingrowth of the femoral component, were presented as the mean and the standard deviation. The data were assessed using ANOVA and the Newman-Keuls test. Differences were considered significant when the P-value was less than 0.05.

Results

At the time of killing the dogs, all of the implants appeared to be securely fixed to the skeletons, as determined by manual testing. On gross examination, neither adverse responses to the implant nor infections were noted. The radiographs showed intimate apposition of implants to bone, but a radiolucent area was seen near the center of the acetabular component in a few dogs at 1 month after the operation (Figure 3).

Table 1. Detaching load (N) of the femoral component. Mean *SD*

	1 month (n 7)	3 months (n 6)	6 months (n 5)
AW Group	1041 *28*	1514 *325*	1815 *28P*
ControlGroup	671 *159*	1410 *25$*	1691 *309*

a, b *P* c 0.05

Table 2. Detaching load (N) of the acetabular component. Mean *SD*

	1 month (n 6)	3 months (n 5)	6 months (n 4)
AW Group	299 *628*	583 *1078.'*	720 *8@*
ControlGroup	197 *75b*	274 *11@*	617 *7@cC*

a, *P* < 0.05

Mechanical tests

Fc~mordcomponent. Upon mechanical testing, the porous layer did not break, and fractures occurred at the interface between the porous surface and the bone in most of the l-month specimens. In most of the 3 and 6-months specimens, fractures occurred inside the bone. The detaching load increased with time in both groups (Table **1).** At 1 month, the average detaching load of the AW Group was 1041 N versus **671** N in the Control Group with the detaching load also higher than that of the Control Group. There was no difference between the **2** groups of 3 and 6 months, but the average detaching load was always higher in the AW Group.

Awruhular conipnnent. On mechanical testing, no separation of the coated layer occurred and all the separation occurred inside the bone. The detaching load increased with time in both groups (Table **2).** At 3 months, the average detaching load of the AW Group was 583 N versus **274** N in the Control Group. The detaching load of the AW Group at 3 months was higher than that of the Control Group. At l and 6 months, there were no differences between the **2** groups.

***Bone** ingrowth*

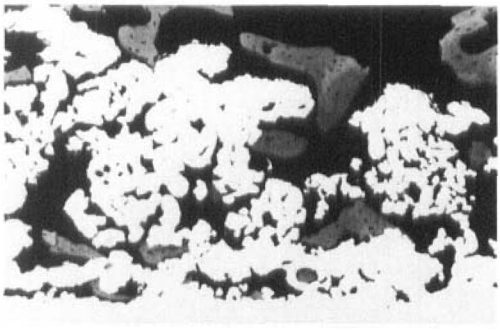
No great differences were noted between the femoral and the acetabular components. At l month, the AW glass-ceramic was no longer present, and bone had grown into the deepest part of the porous layer (Figure **4).** In the Control Group at l month, bone ingrowth was limited to the outer aspects of the porous layer. **In** the 3-month specimens, bone ingrowth into the porous layer was noted in both groups. However, the mass of bone that had reached the deepest part of the porous layer was larger in the AW Group. In the 6-month specimens, bone ingrowth was extensive in both groups (Figure 5).

The area density of bone ingrowth increased with time in both groups (Tables 3 and **4).**

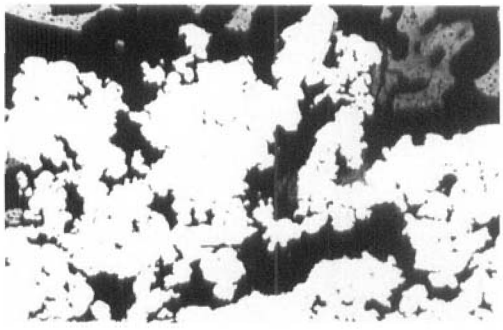
Discussion

Total hip prosthesis with a porous surface is thought to bear the body weight primarily via the porous layer. When hydroxyapatite is plasma-sprayed onto the porous layer of the prosthesis (Thomas et al. **1989,** Stephenson et al. 1991). the possibility exists that occlu-

Figure 4. BSE-SEM of the I-month specimens, x60



AW Group. **The AW glass-ceramic was** no **longer present and bone ingrowth into the deepest part of the porous layer was evident.**



Control Group. **Bone ingrowth** was **limited** to **the outer aspects of the porous layer.**

Table 3. The area density (percent) of bone ingrowth, femoral component

	1 month (n 2)	3 months (n 2)	6 months (n 2)
AW Group	17	25	29
Control Group	1.6	20	24

Table 4. The area density (percent) of bone ingrowth, acetabular component. Mean *SD*

	1 month (n 3)	3 months (n 3)	6 months (n 3)
AW Group	13 1.8	16 6.3	17 2.8
Control Group	7.7 2.2	13 3.1	16 5.7

sion of the surface pores and changing in the surface pore size, porosity, and thickness may occur. In cases where AW glass-ceramic was coated only into the deeper part of the pores, alterations in the surface pore size, porosity, and thickness do not occur. Recently, several investigators have reported that a hydroxyapatite coating on the smooth surface of implants (Bauer et al. 1991, Furlong et al. 1991, Hardy et al. 1991) promotes direct bonding between the hydroxyapatite and the bone. In such cases, the interface between the metal core and the ceramic, and degradation of the ceramic are critical, since the integrity of the component depends primarily on the strength of the ceramic.

Ceramic coating is a recommended means of enhancing bone tissue formation around and into the prosthetic surface, thereby helping to establish a mechanical anchoring (Ducheyne and Cuckler 1992). In our experiment, bone ingrowth into the deepest part of the porous layer was observed already at 1 month, even though AW glass-ceramic was no longer present. Thus, AW glass-ceramic enhanced bone ingrowth and implant fixation by mechanical anchoring was achieved without the degradation of the ceramic. AW glass-ceramic coating on the deeper part of the porous layer can lead to earlier implant fixation and thereby shorten the period of load-protection.

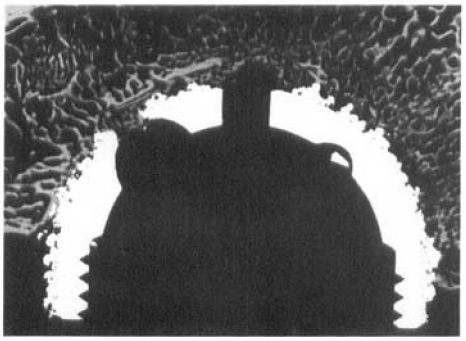


Figure 5. Contact microradiograph (x7) of AW glass-ceramic coated acetabular component 6 months after implantation. Bone ingrowth was extensive.

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