Glass ceramic augmentation of the acetabulum

Total hip arthroplasties in 24 dogs

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Implants made of glass-ceramic containing apatite and wollastonite were used for reconstruction of large bone defects of the weight-bearing acetabulum in canine total hip arthroplasties. 24 dogs underwent replacements and were killed after 3, 6, and 12 months. The interface between the prosthesis and bone was examined radiographically, histologically, and mechanically. Bone bonding with the prosthesis occurred in all the implants.

Glass ceramic containing apatite and wollastonite implants seem promising for use in total hip arthroplasty as filling materials for large defects in weight-bearing bone.

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In 1982, glass ceramic containing apatite and wollastonite (AWGC) was developed at Kyoto University (Kokubo et al. 1986, 1987). Its compressive and bending strength, and elastic modulus are higher than those of human cortical bone (Yamamuro et al. 1990). Experiments on rabbit tibiae demonstrated that blocks of AWGC bonded directly to the bone within 8 weeks under non-weight-bearing conditions (Nakamura et al. 1985) and weight-bearing conditions (Kitsugi et al. 1989). Replacement of lumbar vertebrae of sheep with AWGC blocks resulted in bone bonding with the prosthesis in half of the implants (Yamamuro et al. 1990).

We report the use of AWGC blocks applied to total hip arthroplasty to substitute for large bone defects in the acetabulum of dogs.

Material and methods

The chemical composition of AWGC in weight percent is MgO 4.6, CaO 44.9, SiO_2 34.2, and CaF_2 0.5. It contains oxyfluorapatite($Ca_{10}(PO_4)_6(O,F_2)$) and ß-wollastonite($CaSiO_3$). The approximate weight percentages of the materials are apatite 35, wollastonite 40, and glass 25. The method of synthesis was reported by Kokubo et al. (1986). The bending strength is 0.21 GPa, and the compressive strength 1.05 GPa. The implant used was a 16 mm × 8 mm × 10 mm trapezoidal block. Each block had one 2.5 mm drill hole, and a difference of 1.0 mm in the level of each side wall to allow for fixation in the mechanical testing (Figure 1).

The hip prosthesis consisted of a metal-backed acetabular component, 20 mm in outer diameter, made of

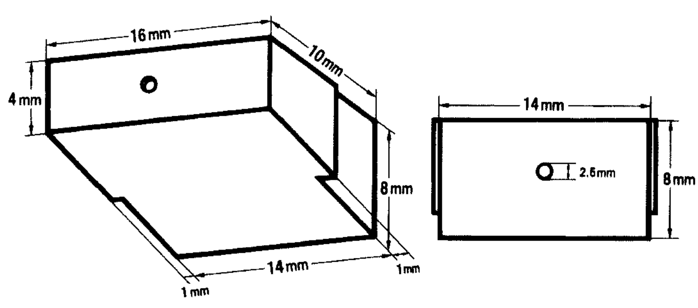


Figure 1. Drawing of the ceramic implant. On the right, the base of the implant.

titanium alloy and UHMWPE, a 12 mm femoral head made of zirconia ceramic, and a femoral component made of titanium alloy. The acetabular component was fixed to the bone and the AWGC block with PMMA bone cement (CMW 1, C.M.W. Laboratories Ltd., England). The collared straight-stemmed femoral component had porous surfaces overlying the anterior and posterior surfaces of the proximal part of the implant.

Animals

We used 24 adult mongrel dogs weighing 15 (14–17) kg. Rearing of these animals and the animal experiments were carried out according to the guidelines for animal experiments at Kyoto University.

Surgery

The dogs were anesthetized with an intramuscular injection of ketamine-HCL (15 mg/kg body weight) and atropine sulfate (1.0 mg/dog). Under standard aseptic conditions, a direct lateral incision was made along the axis of the femoral shaft. A femoral osteotomy was made proximal to the lesser trochanter and the articular surface of the acetabulum was reamed. Nearly all of the upper half of the acetabulum, which appeared to bear the body weight, was resected with a dental burr to create a large bone defect in the acetabulum. An AWGC block was inserted into the bone defect and fixed to the bone with a metal screw (OR-211, AO/ASIF, Switzerland), and the acetabular component was then fixed to the pelvis. The femoral component was then tapped into the femoral canal. The hip was reduced and checked for stability, and the wound was closed in layers. No postoperative external support was applied. Infection of the operation site did not occur. All the animals were able to bear weight within 1 week, and by 3 weeks they walked without a limp. During the procedure, 2 g piperacillin sodium was administered intravenously, and the surgical field was washed with physiological saline containing dibekacin sulfate.

The dogs were killed at 3, 6, and 12 months with an intravenous overdose of pentobarbital, 8 dogs for each period, and the entire femora and acetabula were harvested and radiographed. For each period, 2 dogs were used for histological evaluation, and the other 6 dogs were used for mechanical testing.

Histological evaluation

The specimens were fixed in 10 percent phosphate-buffered formalin. They were progressively dehydrated in ethanol, soaked in styrene monomer, and embedded in polyester resin. From the undecalcified specimens, thin sections were made across the bone-implant interface with a diamond-coated cutting band (BS-3000, Cutting Machine, EXAKT, Germany). The sections were ground to 100 μm thickness using a grinding machine (MG-4000, EXAKT, Germany).

Following contact microradiography, all sections were stained with Giemsa surface stain and were evaluated by light microscopy. The length of bone directly opposed to the implant without any intervening connective tissue was measured with a digitizer (MUTO-ID20BL, Muto Industries, Tokyo) which was connected to a computer (Cannon AS-100M, Cannon, Tokyo). The affinity index of each section was calculated by dividing this length by the total length of the bone-implant interface, and multiplying by 100 (Hayashi et al. 1989). 3 indices were obtained per implant. The sections were then prepared for scanning electron microscopy with a back-scattered electron detector (X-650, Hitachi, Tokyo) and electron-probe microanalysis (EMAX-2200, Horiba, Tokyo). X-ray intensities for silicon, calcium, phosphorus, and magnesium were analyzed across the bone-implant interface.

Mechanical testing

The acetabular component and the PMMA bone cement were removed with a dental burr (Falcon, Morita Ltd., Osaka) and cleared of soft tissues. Any callus on the upper portion of the implant was removed using a dental burr, and the metal screw was then gently taken off. The innominate bone was mounted on a testing jig, and the implant was pulled at a cross-head speed of 2.0 mm/min, using an Instron-type autograph (S-100, Shimazu Co., Kyoto). Care was taken to ensure that the line of action of the loading force was exactly vertical to the interface between the implant and the bone.

Statistics

All data are given as the mean and the standard deviation. Data were assessed using one-way analysis of variance and the t-test. Differences were considered significant when the P-value was less than 0.05.

Results

Contact microradiography of the 6-month specimens demonstrated that there was direct bonding between the AWGC block and the host bone (Figure 2). Histologically, the gaps between the block and the host bone that had been observed at the time of surgery

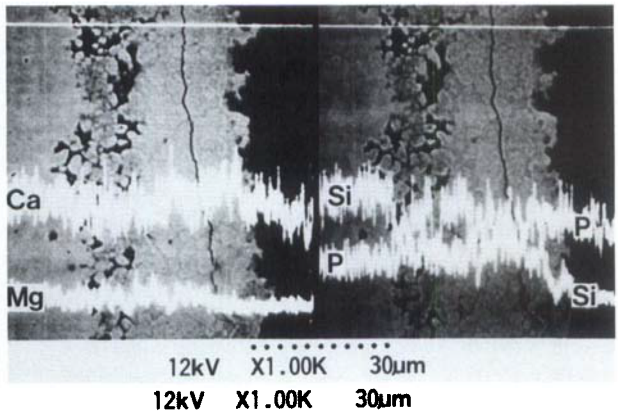


Figure 4. Scanning electron microscopy equipped with a back scattered electron detector and electron-probe analysis at 6 months. The area in which X-ray intensities changed is known as the reactive zone. The calcium-phosphorus layer is about 30 µm thick (×1000).

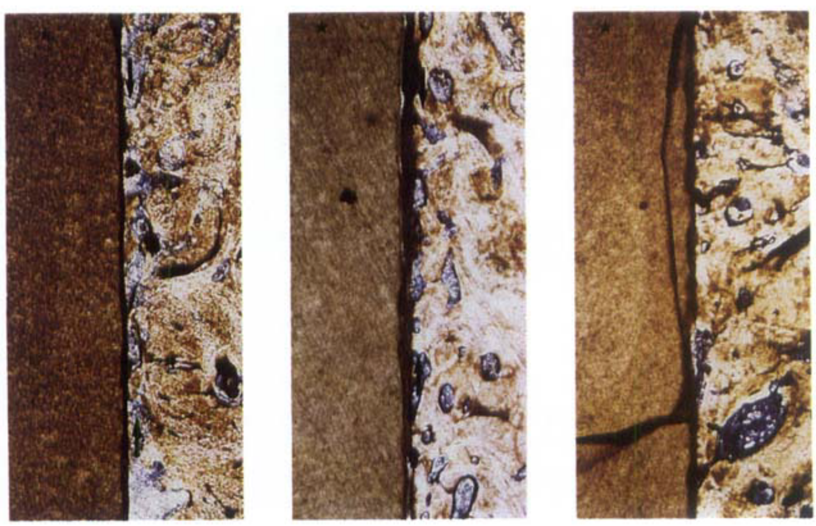
Figure 2. Contact microradiography of the 6-month specimens. Direct bonding between the implant and the bone is evident, and the arrow indicates reactive callus.

Figure 3. Giemsa surface staining at the interface (×40). Star indicates the ceramic implant, asterisk indicates the bone, and black arrows indicate the gaps.

A. Interface between the implant and the bone 3 months after implantation. The gaps between the implant and the bone, which had been observed at the time of the operation, are filled with regenerated osseous tissue.

B. 6 months after implantation, the interposed regenerated bone has become mature.

C. 12 months after implantation, direct bonding between the implant and the bone is apparent.



A B C

were filled with regenerated immature bone, as demonstrated by Giemsa surface staining of the 3-month specimens (Figure 3). In the 6-month specimens, direct bonding between the implant and the host bone was observed and the interposed regenerated bone was mature. The bonding appeared to be completed. In 12-month specimens, histological findings at the interface were essentially similar to those of 6-month specimens. The mean affinity index of the 3-month specimens was 31 ± 5 percent. It increased to 51 ± 10 percent 6 months after implantation, and it was maintained at 61 ± 15 percent 12 months after the operation. There was a substantial difference in the affinity index values between 3- and 6-month specimens (*P* 0.002).

Scanning electron microscopy revealed that the levels of silicon decreased, and of calcium and magnesium did not change, and of phosphorus increased across the interface between the implant and the bone 6 months after the operation. A calcium-phosphorus layer, 30 µm thick, was observed at the interface between the bone and the implant (Figure 4).

Most of the AWGC blocks had a callus on their upper portions (Figure 2), which was removed before mechanical testing. Upon mechanical testing, no breakage of the AWGC blocks occurred. In 3- and 6-month specimens, the fractures developed at the interface between the implant and the bone. In 12-month specimens, the fractures occurred inside the bone. 3 months after implantation, the mean tensile strength of bonding was 0.78 ± 0.5 MPa. It increased to 1.11 ± 2.8 MPa 6 months after implantation, and was maintained at 1.39 ± 3.0 MPa 12 months after the operation. The tensile strength values increased between 3 and 6 months (*P* 0.04). There was a close relationship between the results of the mechanical testing and those of the affinity indices with a regression coefficient of 0.93 (*P* 0001).

Discussion

For revision arthroplasty, allografts (Gross et al. 1985, Trancik et al. 1986, Oakeshott et al. 1987, Samuelson et al. 1988, Jasty et al. 1990) are generally considered the material of choice to reconstruct the deficient acetabulum. However, the use of allografts is still illegal in certain countries, including Japan. Cortico-cancellous allografts work well for a relatively short period (Trancik et al. 1986), but graft resorption (Jasty et al. 1990) would certainly limit their long-term usage, since they suffer from deterioration of the mechanical properties and may collapse. Morseled allografts have been used (Sommelet et al. 1989, Wilson et al. 1989, Brien et al. 1990) to reconstruct the acetabulum in revision arthroplasty with a bipolar prosthesis, but improved acetabular bone support was maintained in only a limited number of patients because of the high rate of resorption. Without good support and stability of the acetabular component, transplanted allografts and even autografts will be likely to suffer from mechanical failure.

We estimated the tensile strength values of cancellous bone at about 1.0 MPa from the data of human bone (Evans 1973) in the following way, as we could not find the tensile strength values of canine cancellous bone. We used the ratio of the tensile strength (65 MPa) to the compressive strength (86 MPa) of the cortical bone. The tensile strength of cancellous bone was estimated by multiplying the compressive strength of cancellous bone (0.74–2.09 MPa) by this ratio. At 12 months postoperatively, as the bonding strength between the implant and the bone appeared to be stronger than the tensile strength values of the cancellous bone, the fractures developed inside the bone.

AWGC appears to have good biocompatibility and its mechanical properties are superior to the human cortical bone. Several other features of AWGC are noteworthy. It shows no deterioration over extended periods in the fatigue and aging tests (Kitsugi et al. 1987) and it exhibits low toxicity (Kawanabe et al. 1991) even in the form of granules.

We conclude that the AWGC block could be a promising material for filling bone defects in the weight-bearing acetabulum in total hip arthroplasty.

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