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Porous apatite-wollastonite glass-ceramic as an intramedullary plug

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We evaluated the efficacy and biocompatibility of porous apatite-wollastonite glass ceramic (AW-GC) as an intramedullary plug in total hip replacement (THR) for up to two years in 22 adult beagle dogs. Cylindrical porous AW-GC rods (70% porosity, mean pore size 200 μm) were prepared. Four dogs were killed at 1, 3, 6 and 12 months each and six at 24 months after implantation.

Radiological evaluation confirmed the efficacy of porous AW-CG as an intramedullary plug. Histological evaluation showed osteoconduction at one month and resorption of the porous AW-GC, which was replaced by newly-formed bone, at 24 months. Our findings indicate that porous AW-GC can be used clinically as an intramedullary plug in THR.

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Since its introduction by Charnley[1] in 1960, polymethylmethacrylate (PMMA) bone cement has generally been considered to be one of the most effective means of fixing hip prostheses. Aseptic loosening, however, has remained the most serious long-term disadvantage. There have been a number of advances in the methods of fixation of cement in the femoral component in total hip replacement (THR), including pulsatile lavage,[2] intramedullary plugging,[3,4] vacuum mixing,[5,6] retrograde insertion by cement gun, and compaction. These techniques have been shown to enhance the fixation of cement to bone, and better clinical results have been reported with their use.[7] An essential prerequisite is adequate plugging of the distal femoral canal and various methods for this have been described such as the use of doughy acrylic cement,[3] bone plugs,[8,9] polyethylene plugs,[10] biodegradable copolymer,[11,12] and hydroxyapatite.[13] Each has its advantages and disadvantages. In general, plugging converts the femoral canal into a closed space, facilitates preparation of bone surfaces, prevents the introduction of cement into the distal canal and may reduce the potential hazard of embolisation of the contents of the canal into the venous circulation.[14,15]

We have generally used cancellous bone chips obtained from resected femoral heads for primary THR. When it has been difficult to obtain bone chips as in revision, we have then employed porous apatite-wollastonite-containing glass ceramic (AW-GC) for intramedullary plugging.

Autografts have been used widely for repairing bone defects. This technique has been successful, but the amount of available bone is limited and harvesting it necessitates two operations. Implantation of allografts and xenografts does not require a second operation but does cause problems of antigenicity. Therefore the use of artificial bone substitutes, such as alumina, hydroxyapatite, tricalcium phosphate, Bioglass, and AW-GC[16] has been investigated.

Dense AW-GC has been reported to have high mechanical strength as well as the capacity to form strong chemical bonds with bone tissue.[17,18] Ijiri et al[19] studied the use of porous AW-GC, combined with bone morphogenetic protein (BMP) and collagen which induced ectopic bone formation.

Our aim was to evaluate in dogs the efficacy and biocompatibility of porous AW-GC as an intramedullary plug in THR for up to two years.

Materials and Methods

We used 22 adult beagle dogs weighing from 9.5 to 10.5 kg. Each had unilateral THR. Both the rearing of these animals and the investigations were carried out according to the guidelines for animal experiments at Kyoto University.

Porous AW-GC rods. These were prepared and provided by Nippon Electric Glass Co Ltd (Otsu, Japan) and had a porosity of 70% and a mean pore size of 200 μm (Fig. 1).

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The chemical composition of the porous AW-GC was 4.6% MgO, 44.7% CaO, 34.0% SiO_2, 16.2% P_2O_5, and 0.5% CaF_2, and the crystallised glass-ceramic consisted of 28% residual glass, 38% apatite [$Ca_{10}(PO_4)_6(O, F_2)$], and 34% β wollastonite (SiO_2•CaO), as described previously,[20] being the same as that of dense AW-GC. Its mean (SD) compressive strength was 17.54 ± 3.82 MPa[19] which is identical to that of cancellous bone.

AW-GC intramedullary plug. We prepared cylindrical AW-GC intramedullary plugs in sizes of 5 × 5, 6 × 5, and 7 × 5 mm (diameter × height).

Hip prosthesis. This consisted of an acetabular component, 18 mm in outer diameter, made of ultra-high-molecular-weight polyethylene (UHMWPE), a 12 mm modular femoral head made of stainless steel (SUS-316L), and a straight-stemmed, collared femoral component made of stainless steel (SUS-316L). On the outer surface of the acetabular component, circular and centrifugal V-shaped grooves of a depth of 0.8 mm were shaped. The femoral shaft was 4 mm in diameter and 50 mm in length. The surface of the femoral head was finished to a maximum roughness of 0.08 μm and a mean roughness of 0.04 μm. The prosthesis was sterilised by gamma irradiation before use. We used only one size of implant for all animals.

Bioactive bone cement. The composition of the bioactive bone cement (BABC) has been described in detail previously.[21] Briefly, it consists of AW glass-ceramic powder,[22] fused silica glass (SiO_2) powder,[23] and fumed silica powder as the filler in a ratio of 73:25:2 by weight, and bisphenol-A-glycidyl dimethacrylate-based resin as the organic matrix. The evaluation of BABC in canine THR has been previously reported.[24]

Operative technique. The dogs were anaesthetised by an intramuscular injection of ketamine HC1 (10 mg/kg body-weight) and atropine sulphate (1.0 mg/dog). A direct lateral incision was made along the long axis of the femoral shaft, and the greater trochanter was osteotomised to expose the hip which was then dislocated and a femoral osteotomy performed proximal to the lesser trochanter. After fixing the acetabular component, the femoral canal was reamed serially to remove the spongiosa. Using a special jig, the size of the medullary canal was measured to determine the largest diameter of plug which it was possible to insert. Two to four cylindrical intramedullary plugs of porous AW-GC were inserted into the femoral canal until a plug was 0.5 to 1.0 cm distal to the femoral component. Bone cement was injected into the femoral canal from the bottom to the top. The femoral component was then held securely by hand until polymerisation of the cement was complete. After the hip had been relocated, the greater trochanter was re-attached using two 20-gauge SUS-316 stainless-steel wires. The hip was then checked for stability and range of movement. During the operation, piperacillin sodium (2 g) was administered intravenously, and the site of the operation was irrigated several times with normal saline containing dibekacin sulphate. No postoperative antibiotics were used.

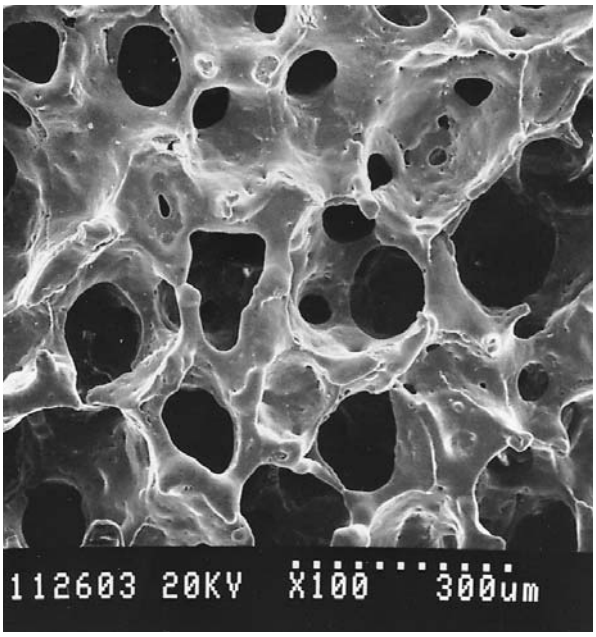

Fig. 1

SEM of the porous AW-GC (× 100; the dotted line indicates 300 μm).

Four dogs were killed at 1, 3, 6 and 12 months each, and six at 24 months after implantation, by an intravenous overdose of pentobarbital.

Radiological evaluation. The whole femur was removed and anteroposterior and lateral radiographs were taken.

Histological evaluation. The femur was cut into sections 5 mm in length along the line of the long axis, using a high-speed, water-cooled circular saw with a fine diamond coating (BS-3000; EXAKT, Norderstedt, Germany). These were fixed in 10% phosphate-buffered formalin solution. The specimens were dehydrated in serial concentrations of ethanol and then embedded in polyester resin. The section was attached to a polymer plate along the long axis of the femur, and cut using the circular saw into sections 500 to 600 μm thick, which were then ground to a thickness of 120 μm using a grinding machine (MG-4000; EXAKT). The surface was finished with number 4000 sandpaper. Specimens were examined by Giemsa surface staining and contact microradiography (CMR). Representative sections were further ground with alumina-coated sandpaper to remove the surface staining and then sputter-coated with a 10 nm layer of carbon. These were analysed by SEM (S-800; Hitachi, Tokyo, Japan) and energy-dispersive x-ray microanalysis (EMAX-3000; Horiba, Tokyo, Japan).

Results

All the dogs were able to bear their body-weight within one week and walked without a limp by three weeks. No hips dislocated after operation. Deep infection was found on gross examination when one animal was killed after 24

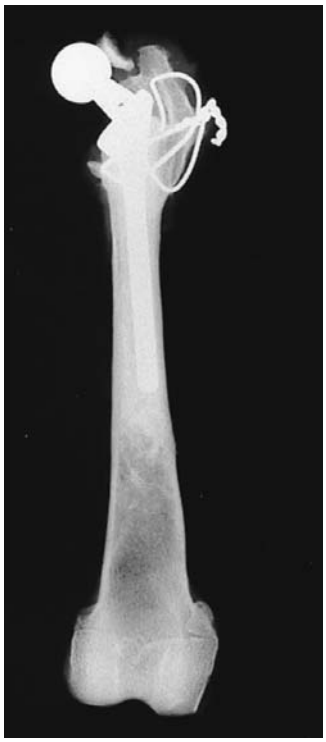

Fig. 2

Anteroposterior radiograph taken 24 months after implantation. There is no loosening of the hip prosthesis or abnormal bone resorption around the cement mantle.

months and it was excluded from the investigation. No infection or abnormal inflammatory reaction of the hip was found on gross examination in the other 21 dogs and all the implants appeared to be fixed securely.

Radiological evaluation. Over 24 months radiography showed neither loosening of the prosthesis nor abnormal bone resorption around the cement mantle. One month after implantation, the AW-GC plug showed radiopacity. There was no migration of the plug although small leaks of the cement were observed. At 12 months the radiopacity had decreased and at 24 months the plug became radiolucent although the cement remained at the same level and no subsidence was seen (Fig. 2).

Histological evaluation. Giemsa surface staining showed formation of new bone in the pores and around the plug at one month. Direct contact between the newly-formed bone and the AW-GC was also observed. At six months, abundant bone was apparent even in the centre of the pores, and there was direct contact between the plug and the inner surface of the endosteum. At 24 months, CMR showed that the walls of the pores had become thinner and were almost totally resorbed and replaced by newly-formed bone. SEM revealed newly-formed bone in the pores of the porous AW-GC at one month increasing until six months. At 12 months, the walls of the AW-GC pores had been partially resorbed and at 24 months they were almost fully replaced

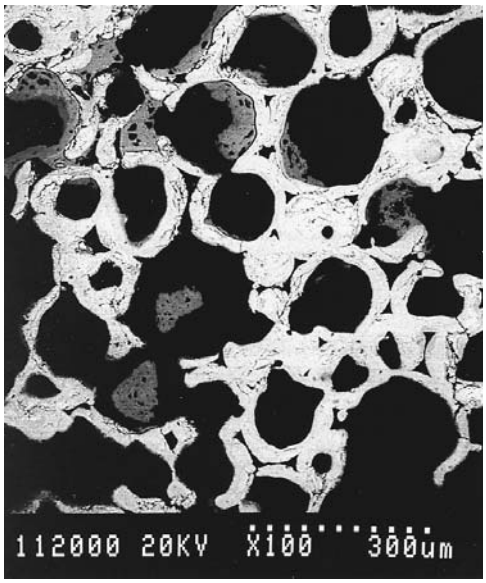

Fig. 3a

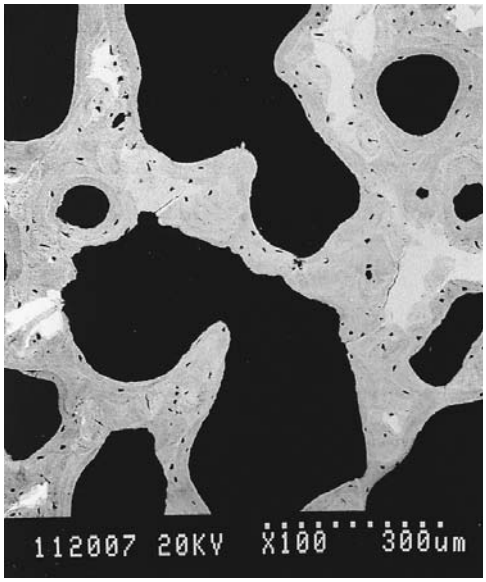

Fig. 3b

Back-scattered SEM of the femur at the bone-implant interface a) at one month showing newly-formed bone in the pores of the porous AW-GC and b) at 24 months. The walls of the AW-GC pores were almost totally resorbed and replaced by newly-formed bone ($\times$ 100; the dotted line indicates 300 μm).

by newly-formed bone (Fig. 3). In the 24-month specimens, back-scattered SEM of the interface between the bone and AW-GC showed a Ca-P-rich layer 10 μm thick. SEM and energy-dispersive x-ray microanalysis demonstrated that this layer had a higher phosphorus intensity, lower silicon and magnesium intensities, and almost the same calcium intensity as AW-GC; these are the characteristics of a Ca-P-rich layer (Fig. 4). The AW-GC was in direct contact with bone through this layer.

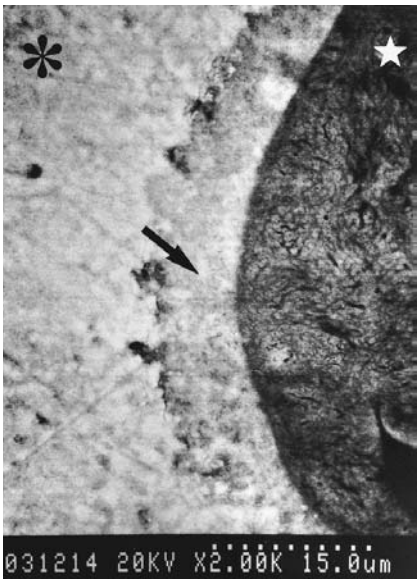

Fig. 4a

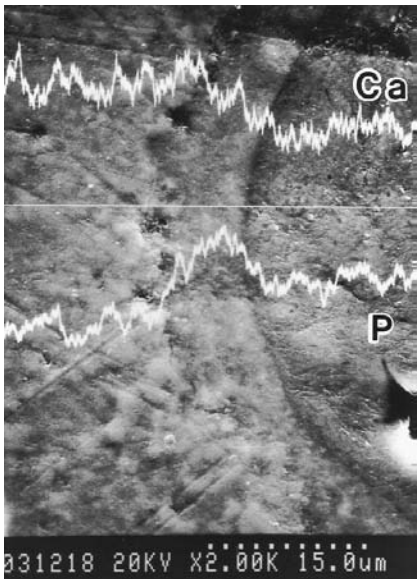

Fig. 4b

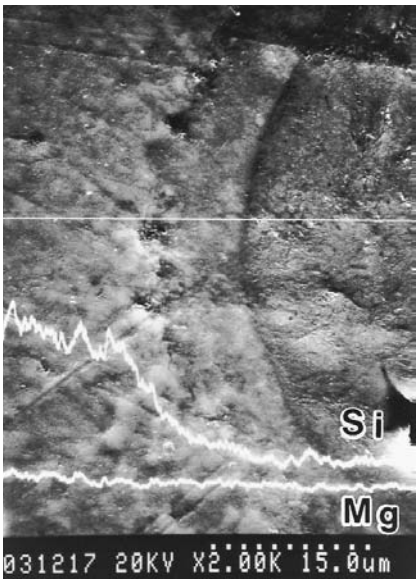

Fig. 4c

Back-scattered SEMs of the femur at the bone-implant interface 24 months after implantation. Figure 4a – The AW-GC shows direct bonding to bone without any intervening soft-tissue layer. The surface of the AW-GC is covered with a Ca-P-rich layer 10μm thick (black arrow) through which direct bonding between the AW-GC and bone was accomplished. The star indicates the bone and the asterisk the AW-GC. Figure 4b – The calcium (Ca) level did not change and the phosphorus (P) level increased across the bone-implant interface. Figure 4c – The levels of silicon (Si) and magnesium (Mg) decrease across the cement-bone interface (× 1400; the dotted line indicates 15 μm).

Discussion

There are various techniques for plugging the femoral canal, each with advantages and disadvantages. The use of PMMA plugs prolongs the operating time and requires handling of a large amount of cement and instruments.[4] Insertion of a cancellous bone plug taken from the excised femoral head requires experience and specialised instruments.[8,9] Polyethylene plugs are easier to use, but do not always achieve adequate and consistent occlusion of the femoral canal.[4,11] Although cylindrical porous AW-GC may be insufficient to occlude the elliptical shape of the femoral canal, the insertion of several spherical-shaped AW-GC plugs and their compaction are thought to achieve complete plugging of the femoral canal without any migration or leakage.

Raut, Siney and Wroblewski[25] reported excellent clinical results in one-stage revision of a discharging infected THR using antibiotic-soaked PMMA bone cement and Kawanabe et al[26] described the efficacy of antibiotic-soaked AW-GC blocks as a new drug delivery system for osteomyelitis in vitro and in vivo.

Neo et al[27] reported that particles of AW-GC of 100 to 220 μm implanted into rat tibiae were not resorbed completely, even after 96 weeks. The resorbed or replaced width of the surface of AW-GC was less than 50 μm per year. In our study, the thickness of the wall of porous AW-GC was 10 to 30 μm, and the AW-GC was subtotally resorbed within two years. It is often difficult to remove the plug through the medullary canal at revision operations. Giardino et al[12] found that intramedullary plugs made of poly D, L-lactic acid (PDLLA) completely disappeared in the femoral medullary cavity of rabbits 26 weeks after implantation. Although the rate of resorption of porous AW-GC is lower than that of bioresorbable materials including PDLLA, it is resorbed within two years.

We conclude that porous AW-GC is effective as an intramedullary plug and has good biocompatibility and resorption within two years.

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