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FIXATION OF PERMANENT ORTHOPAEDIC PROSTHESIS USE OF CERAMICS IN THE TIBIAL-PLATEAU

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It would be of obvious importance if bone tissue ingrowth into porous materials as reported by Hulbert et al. (1971) for ceramics and Lueck et al. (1969) for titanium, could be used as a means of attaching load bearing devices to the skeletal system.

For the investigation of the possible use of ceramic materials such as Al_2O_3, implantation in the tibial-plateau is near ideal. The compressive forces acting here are not higher than the material can be expected to sustain and the implants are not exposed to tensile stresses and torsional forces which the brittle ceramics can not withstand. Furthermore the cancellous bone of the metaphysis should provide an adequate blood supply for the growth of mineralized tissue at the implantation site. Due to the chemical inertness of Al_2O_3, tissue reactions are not to be expected, as stated by Hulbert et al. (1972). However, initial attempts to insert ceramic pellets in the tibial plateau of pigs failed due to inadequate strength of the material used (Bhatti & Klawitter 1972). It was therefore necessary to carefully prepare the porous implants.

In this preliminary investigation on dogs, pellets of porous alumina were placed unilaterally in the medial tibial plateau of the right knee, and the tissue ingrowth was determined upon sacrifice after 6 and 8 weeks.

MATERIAL AND METHODS

Animals

Four adult mongrel dogs, 2 female and 2 male, were used. Their previous history was not known, but the animals were all young. The two female dogs both gave birth during the observation period. The mean weight of the four animals was 23.0 ± 4.7 kg.

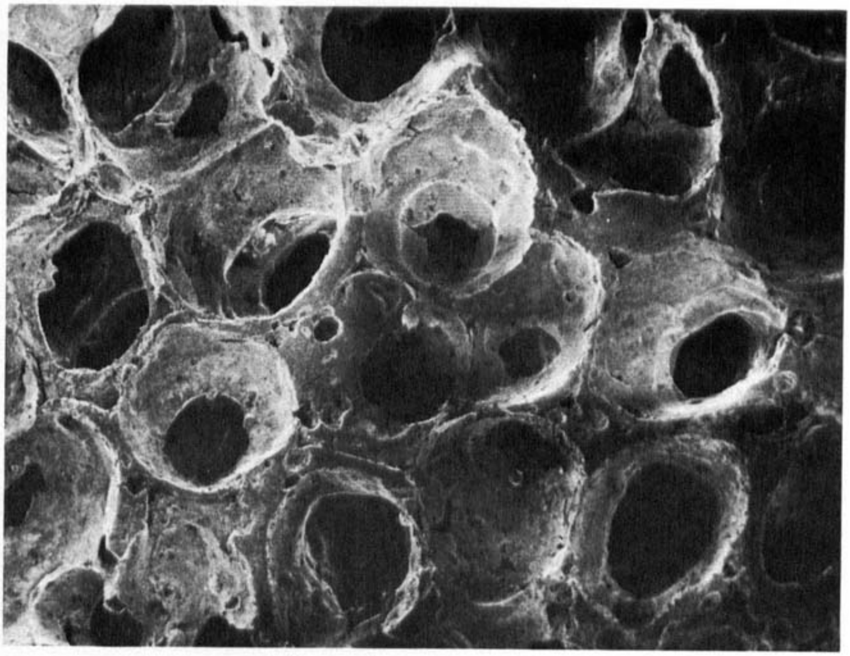

Figure 1. Scanning electron micrograph of the inner pore structure of the implant. (× 20).

Preparation of the implant material

A slurry made up of 100 g dry substance (α-Al_2O_3, kaolin, talc and $CaCO_3$) in 50 ml 3.5 weight per cent PVA-solution (Elvanol 71–30, Du Pont, Willmington, Del., USA) was ball milled overnight to homogenize the mixture. To induce the necessary porosity of the samples 3 ml H_2O_2 (30 per cent) was added to the slurry as well as a decomposition catalyst for H_2O_2. With the addition of the catalyst a fast decomposition was insured. This resulted in a more homogeneous structure of the as cast material.

The slurry was cast in plaster moulds where the decomposition was finished after approximately 10 minutes. The size of the mould was chosen so that it was filled completely with the slurry after the reaction had ended.

A very open porous structure with interconnecting channels was obtained, probably due to the highly thixotropic nature of this slurry. This is in contrast to the materials with spherical, closed pores usually obtained with this method.

The samples were then allowed to dry overnight at room temperature, followed by 8 hours at 50° C before firing at 1600° C in an oxidizing atmosphere. The fired samples had a dense surface layer (the part nearest to the plaster walls) and a porous interior (Figure 1).

The chemical composition of the fired material was:

96.0 weight per cent α-Al_2O_3; 2.7 weight per cent SiO_2; 1.0 weight per cent MgO; 0.2 weight per cent CaO; 0.1 weight per cent Na_2O etc.

Pellets for implantations were drilled out of the fired samples with a diamond core bore (inner diameter 0.65 cm). The dense intra-articular facing surface of the pellet was given a high polish. The pellets were about 1 cm long.

Cleaning of the samples and the sterilizing procedure before implanting followed the procedure used by Hulbert et al. (1972).

The porous part of the ceramic showed the following structural and mechanical properties before implantation:

Pore volume:	60 volume per cent (Archimedes density measurements).
Compressive strength:	570 kp/cm^2
Channel diameter:	100–750 μm

Surgical procedure

The right knee joint was exposed through a medial, parapatellar, longitudinal incision. The patella was luxated laterally and the knee joint strongly flexed to provide maximum exposure of the tibial plateau. A 0.2 cm pilot hole was drilled perpendicular to the surface of the medial tibial plateau and then enlarged to 0.65 cm to receive the implant. All drilling was done under a stream of physiologic saline solution. The implant was driven into position using a mallet and nylon driver.

The joint cavity was flushed copiously with isotonic saline solution to remove debris before closure. The operation incision was closed in layers with non-resorbable sutures. A topical antibiotic ("Furacin", Eaton Laboratories Norwich, N.Y., U.S.A.) was dusted in the incision; no dressing was applied. Each animal received postoperative intramuscular injections of penicillin (500.000 units) and dihydrostrepthomycin (625 mg) ("Penstrep", Merck Chemical Division, Rahway, N.J., U.S.A.) twice a day for five days.

The position of the implant with respect to the surface of the articular cartilage varied somewhat in the four animals operated. In dog 1 the implant was slightly angulated in the anterior-posterior plane and projected above the surface of the articular cartilage. In dogs 2 and 3 the implants were positioned perpendicular to and flush with the articular cartilage. In dog 4 the implant was perpendicular to the articular cartilage but recessed 1–2 mm.

Radiographs were taken 2 days after operation and thereafter every two weeks. Early, during the beginning of the postoperative period a radiolucent seam was observed around the pellets. On the lateral and medial side this seam disappeared during the observation period, on the anterior and posterior side it could be seen throughout the experiment, mainly around the upper quarter of the pellets.

Histological techniques

At necropsy, about 2 cm of the tibial metaphysis including the pellet and the joint surface were retrieved. The specimens were immediately placed in buffered formalin and soaked for 24 hours. After fixation the samples were dehydrated by successive soaking in 75, 95 and 100 per cent ethyl alcohol, respectively. The specimens were then embedded in monomer methylmethacrylate and left to polymerize at room temperature. After complete polymerization excess embedding was trimmed off and 0.5 mm thick longitudinal sections were cut with a diamond precision saw.

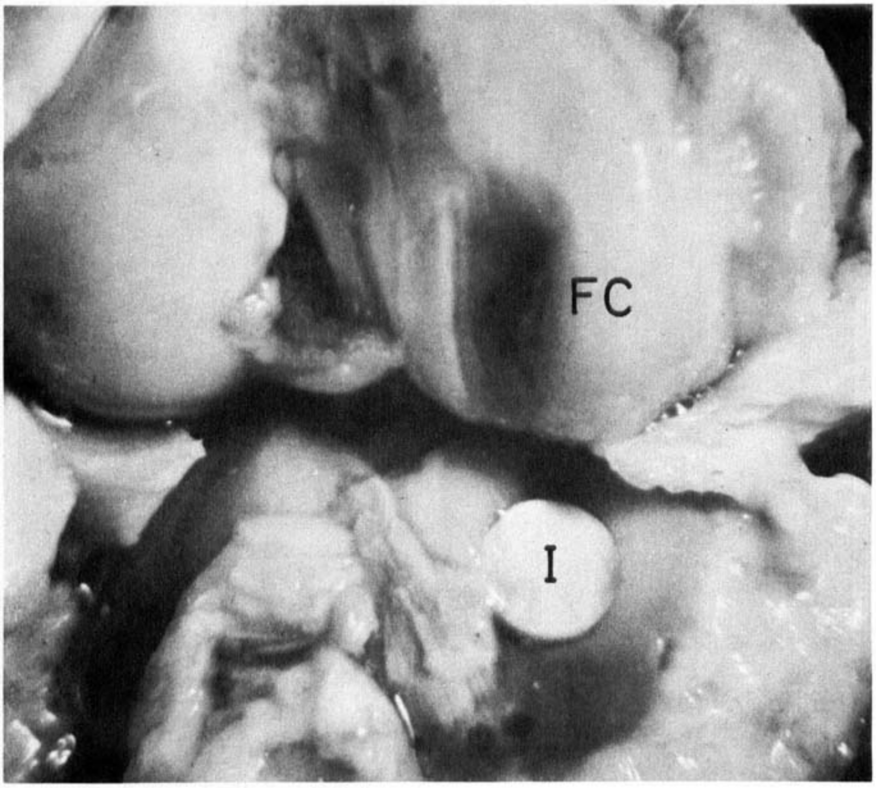

Figure 2. Wear of the femoral condyle (FC) opposite the ceramic implant (I). The implant is protruding slightly above the tibial plateau.

Contact microradiographs of the sections were taken according to a procedure outlined by Jowsey et al. (1965). For histological examinations the sections were fixed with epoxy in well-slides, ground down to a thickness of approximately 55 μm and stained with Paragon 1301. ("Paragon PS 1301", Paragon C & C Co. Inc. Bronx, N.Y., U.S.A.).

For evaluation of the bonding mechanism between new formed bone and implant, the distribution of the elements calcium, phosphorous and aluminium was determined in the transition layer bone/implant with an Electron-probe Microanalyzer Type EXM, SM (Applied Research Laboratories, Sunland/Ca., U.S.A.).

RESULTS AND EVALUATION

The dogs started walking a few days after surgery and apparently put weight on the operated limb. The gait appeared normal with brief periods of limping. No postoperative complications were observed.

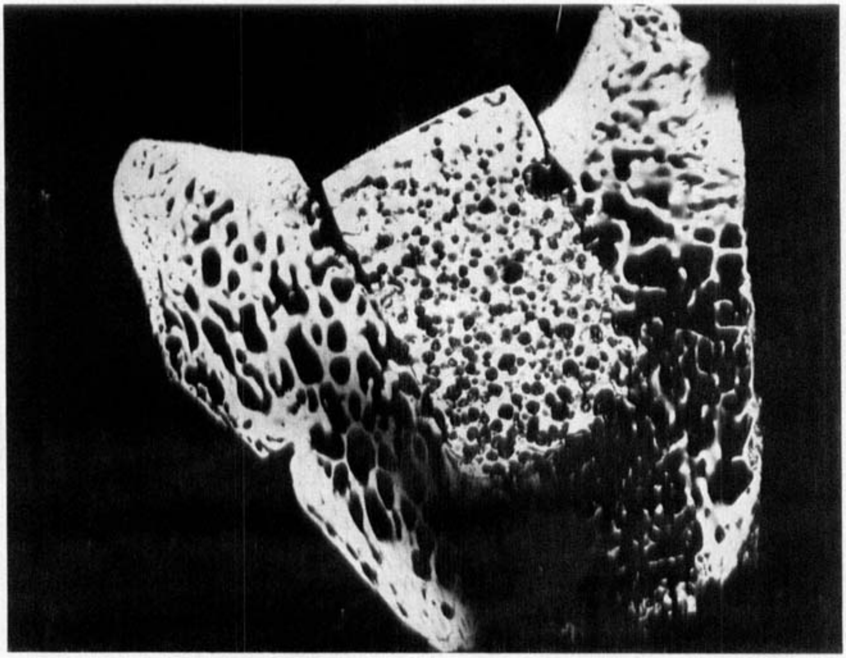

Figure 3. Microradiograph of the ceramic implant and the surrounding cancellous bone. The outer pores, especially in the lower part of the pellet are infiltrated with mineralized bone. (× 5).

At sacrifice the knee joint of dogs 1, 2 and 3 showed a more or less severe wear of the femoral condyle opposite the implant (Figure 2). The knee contained somewhat more synovial fluid than usual, 1–3 ml, and there was some discoloration of the fluid. Dog 4 showed only slight wear of the condyle and the pellet was covered with cartilage. The synovial fluid appeared normal.

Gross examination of the implants and the surrounding tissue at necropsy showed no signs of an adverse tissue reaction. None of the implants showed any visible displacement, and they were all solidly anchored to the metaphysis.

On all the examined sections the pores of the pellets were filled with tissue (Figures 3 and 4). Mineralized bone was found in the outer 500 μm of the pellets. The upper part, approximately 1/5 of the implants, was surrounded with cartilage and showed an ingrowth of fibrous tissue. Some bone resorption may have taken place here, possibly due to minor movements of the implant during the observation period.

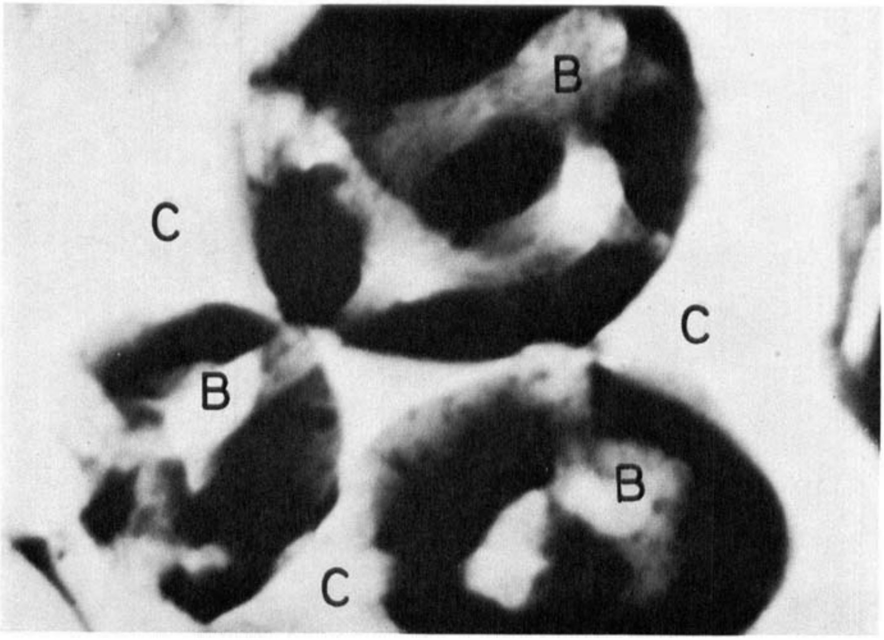

Figure 4. Microradiograph of bone growth (B) in the interior pore system of the ceramics (C). The bone inside the ceramic pores tends to form rings with an inner opening. (× 130).

Areas with a direct contact between ceramic implant and mineralized tissue could be found in the histological sections (Figure 5).

Electron-microprobe analysis of the distribution of the elements calcium, phosphorous and aluminium in these areas confirmed the assumptions of a close contact between new-formed bone and implant (Figure 6). The analysis further showed that the new bone inside the porous ceramic contained 80 relative weight per cent calcium and 90 relative weight per cent phosphorous as compared to cancellous bone in the metaphysis near the pellet.

However, as a rule the mineralized bone was separated from the ceramics with a seam of unmineralized tissue. This indicates that the implant material disturbs the crystallization of the mineral phase in bone, and that there usually is a lack of bonding forces across the interface. If that is the case, the mechanical strength of the composite material at the interface bone-implant will never be substantially higher than would be expected from the volume-fraction of bone present.

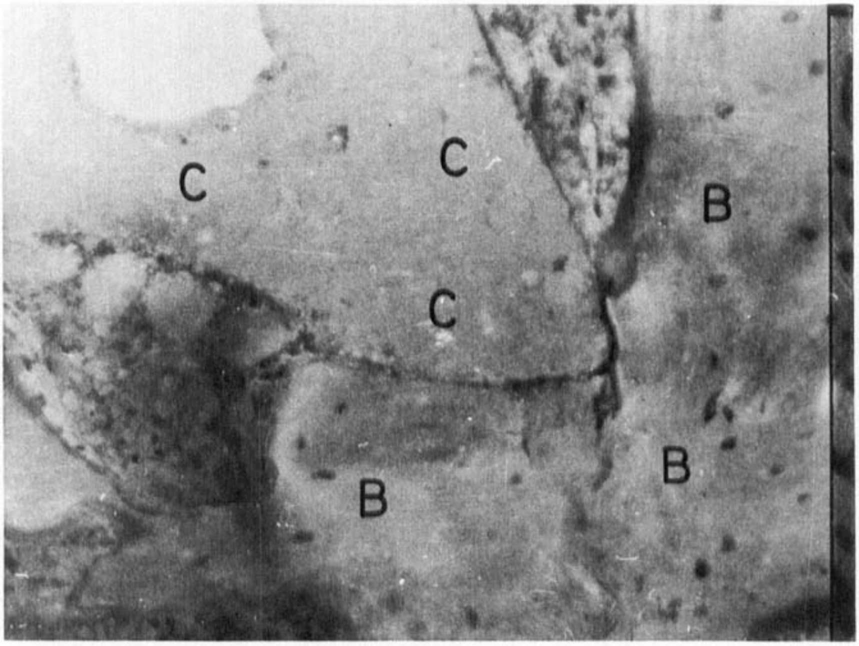

Figure 5. Fluorescence photomicrograph showing intimate contact between bone, B, and ceramics, C. (× 75, Reflected light, exciter filter BG 12, barrier filter 53).

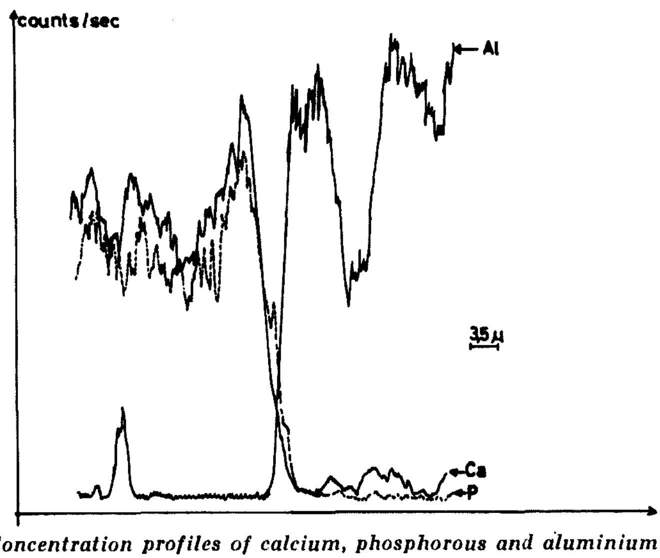

Figure 6. Concentration profiles of calcium, phosphorous and aluminium across the interface new-formed bone/implant. There is no visible transition layer of fibrous tissue between the two phases.

SUMMARY AND CONCLUSIONS

Pellets of a porous ceramic material were implanted unilaterally in the medial tibial plateaus of 4 mongrel dogs.

The ceramics contained open pores with a channel connection diameter of 100–750 μm. The compressive strength of a material with 60 per cent porosity was 570 kp/cm².

After implantation periods of 6 and 8 weeks respectively, the pellets were firmly anchored in the metaphysis due to ingrowth of bone and fibrous tissue. Such ingrowth may therefore be an alternative method for anchoring of functional devices to the musculo-skeletal system.

The lack of bone formation along parts of the implants might be due to shear forces acting in these areas. A slight movement of the implant may in such cases prevent mineralization. It can not, however, be ruled out that some bone resorption has taken place here. Bone resorption might lead to loosening of the pellets and long term investigations are therefore desirable.

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