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# POROUS CERAMICS AS A BONE SUBSTITUTE IN THE MEDIAL CONDYLE OF THE TIBIA

*An Experimental Study in Sheep*

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A new porous ceramic material was tested for possible use as a bone substitute in regions exposed mainly to compressive forces. The porous ceramics were implanted into the medial condyle of the tibia of four sheep and left in position for 3 months. The operated tibia was then removed and sections were made of the implants. The sections were studied by transmitted light microscopy, microradiography and scanning electron microscopy. There was no apparent loss of function of the operated leg and the implants were found to be bound to the adjacent bone by ingrowth of bony tissue, in some regions to a depth of 2–3 mm. It is concluded that the properties of the porous ceramic implants justify a clinical trial, provided that the results of long-term animal experiments are equally satisfactory.

*Key words:* bone substitute; porous ceramics; tibial condyle fracture

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Bone substitutes are frequently required in orthopaedic surgery, both for the correction of acute traumatic lesions with bone loss or destruction, and as a substitute for chronically destroyed parts.

Various types of materials have been used, the most notable being metal alloys, devitalized animal bone (Kieler-Knochen-Span) and autogenous cancellous bone. None of these materials are ideal, however; either they are rigid, but fail to adhere permanently to the adjacent bone, or they are fragile and easily crushed. The search for new and more suitable bone substitutes therefore continues.

The possibility of employing ceramics has received increasing attention in recent years. These materials have a high degree of bio-compatibility, and it has been shown that small porous ceramic implants become anchored to the adjacent bone by invasion of bony tissue (Hulbert et al. 1971). The mechanical properties of the ceramics, especially their tendency to brittle fracture, limit their applicability as bone substitutes. But the compressive strength is high, and as the physical properties to a certain extent may be modified by varying the chemical composition, structure and density, they may be useful as implants in regions which are mainly exposed to compressive forces.

The purpose of the present study was

to determine whether porous ceramic implants were suitable as bone substitutes in weightbearing parts, exposed only to minor tensile and shearing forces. We have studied the fate of porous ceramics implanted into the medial condyle of the tibia of sheep.

## MATERIAL AND METHODS

*The implants* were made from porous ceramics produced as described by Lyng et al. (1973). The material consists of 99 per cent (by weight) of $Al_2O_3$ and 1 per cent CaO, MgO and SiO. The firing temperature was 1700° C and the soaking time 4 hours. Pore size was 100–1000 $\mu$ and the compressive strength of cylinders with diameter 10 mm, and height 10 mm, measured by standard methods, was 27 MN/m² (varying from 20–34 in 10 samples). In comparison it may be mentioned that the mean compressive strength of Kieler-Knochen-Span was found to be 5 MN/m² (varying from 2 to 10 in five samples).

Reports in the literature, Burke et al. (1971), Frakes et al. (1974) and Schnittgrund et al. (1973) indicate that the strength of alumina may deteriorate due to stress corrosion both *in vivo* and *in vitro*. However, according to Schnittgrund et al. the changes are less severe *in vivo* than in the *in vitro* tests.

Compact samples of the above-mentioned materials were therefore subjected to a dynamic fatigue test, and the tensile strength of the samples before and after cycling measured. The samples, submerged in Ringer solution at 37° C, were subjected to $10^7$ cycles with a load of 20–1600 N. (The dimensions of the samples were 10×10×60 mm; support distance in the test machine, 50 mm).

The tensile strength of these specimens was reduced approximately 40 per cent after cycling (from 305 to 180 MN/m²).

The height of the implants used in the present experiments was 10 mm; their shape can be seen in Figure 1.

### *Animals*

The animals used were four female sheep, weighing from 40 to 60 kg, and aged from 5 to 8 years. Epiphyseal fusion of the tibia had occurred in all animals prior to the operation.

### *Surgical procedure*

The operation was carried out under nembutal anaesthesia (Nembutal Veterinary® Abbott 0.5 mg/kg body weight intravenously in one initial dose with supplementary doses of 1–2 mg i.v. when required) under strictly sterile conditions. The proximal medial part of the left tibia was approached through an anteriorly curved incision running from the posterior part of the joint to the tibial tuberosity. The antero-medial surface of the tibial condyle was freed from muscular attachments by subperiostal elevation, and a 10 mm high bone segment was removed by means of a double-bladed electric saw and an osteotome. The resection was made parallel to the joint surface at a distance of approximately 1 cm. It extended from the tibial tuberosity to the medial crest of the tibia, and produced a defect which encompassed the major part of the medial condylar area (Figure 1 A).

The defect needed minor extensions before the preformed porous implant would fit in snugly. The medullary cavity of the tibia extended to the lower resection level; the lateral part of the implant was therefore supported mainly by cortical bone, while the rest of the implant was in contact with trabecular bone (Figure 1 B).

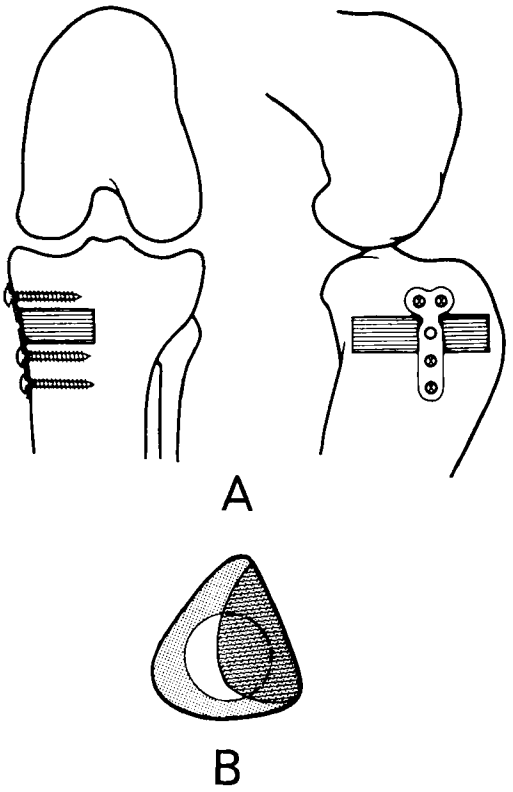



*Figure 1. A. Schematic illustration of the experimental model, frontal and medial view. B. Cross section showing the position of the implant (hatched) relative to the supporting surface of the tibia.*

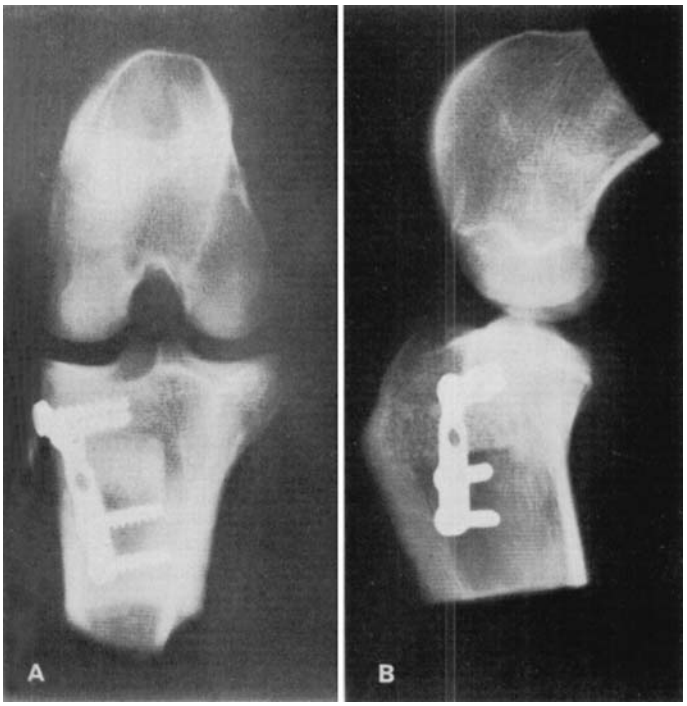



*Figure 2. Radiographs of an implant 3 months postoperatively. A. Frontal view. B. Lateral view. There is no sign of bone resorption around the implant and no collapse of the overlying joint surface.*

The implant was kept in position by a small A-O fingerplate placed across the bony defect as shown in Figure 1 A. The compressive load on the implant was measured by inserting a snugly-fitting pressure transducer into a corresponding defect in a sheep-cadaver tibia; it was found to be roughly one fifth of the applied load on the tibial plateau.

*Postoperative regimen*

No restrictions were put on the operated animals; they started weightbearing as soon as they recovered from the anaesthesia. The animals were transferred to their "home farm" after 7 days, and allowed to "roam the range" with the rest of the flock, until they were sacrificed 3 months later.

*Investigative procedure*

Immediately after sacrifice the operated knee joint and proximal tibia was removed and inspected. The soft tissue was cut away and the specimen fixed in 4 per cent formaldehyde for 24 hours. The specimen was then X-rayed, dehydrated by successive soaking for 24 hours in 70, 80, 96 and 100 per cent alcohol, and embedded in methylmethacrylate.

After complete polymerization and cooling, sections 300 $\mu$ thick, were cut at 700 $\mu$ intervals with a diamond saw. The sections were cut vertically through the implant in three specimens, and horizontally (parallel to the joint surface) in the fourth.

Contact micro-radiographs were taken as described by Jowsey et al. (1965), the sections were then fixed with epoxy in well slides, ground down to a thickness of 40–50 $\mu$ and stained with Paragon 1301 ("Paragon PS 1301", Paragon C & Co. 1 nc., Bronx. N.Y., USA).

The slides were examined by light microscopy. Some unmounted and unstained sections were examined with scanning electron microscopy (SEM) to determine the distribution and semi-quantitative amounts of Al, P and Ca.

## RESULTS

### *Function and macroscopic appearance*

All the four animals appeared to recover normal function of the operated limb within a week, and no limping or other malfunction was observed on the range.

When inspected after sacrifice the operated parts exhibited no sign of infection or local reaction to the implants,

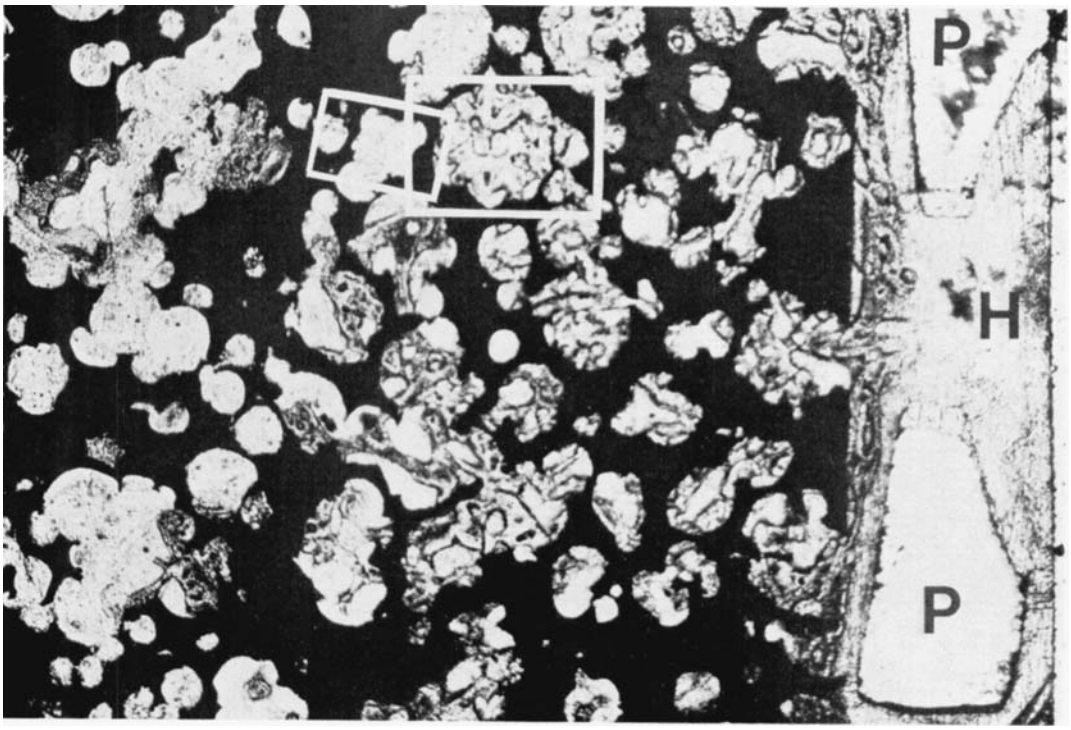



*Figure 3. Photomicrograph of a section cut horizontally through an implant. (Paragon, × 18). The picture demonstrates that the pores of the peripheral part of the implant (near the plate P) contain bony tissue (details in Figure 4) while the pores of the more central region (to the left) are filled with fibrous tissue (details in Figure 5). (The section has been cut at the level of the empty hole (H) in the plate—see Figure 1 A).*

and there were no signs of loosening of the implants or fracture of the condylar areas.

*Radiological examination*

There were no signs of collapse of the implants or of the over-lying joint surface; nor were there any osteolytic changes around the implants. To the contrary, there appeared to be continuity between the implants and the adjacent bone (Figure 2).

*Histological examination*

Some bone tissue was found in the peripheral parts of all implants, but the extent of bony invasion varied greatly. In some regions the bony tissue only extended into the surface irregularities of the implant, in others it infiltrated the superficial layer of pores, and in some regions bony tissue was found to a depth of 2–3 mm. As a rule bony tissue was found in all regions of the implant which were in contact with bone. The pores which did not contain bone were filled with connective tissue (Figures 3, 4 and 5).

The bony tissue seemed to be in intimate contact with the ceramics in some parts of the pores (Figure 4); in others a brim of unossified tissue was interposed. There were no histological changes indicating local tissue reaction to the implants.

The microscopy further showed that there was osteoid tissue in some pores,

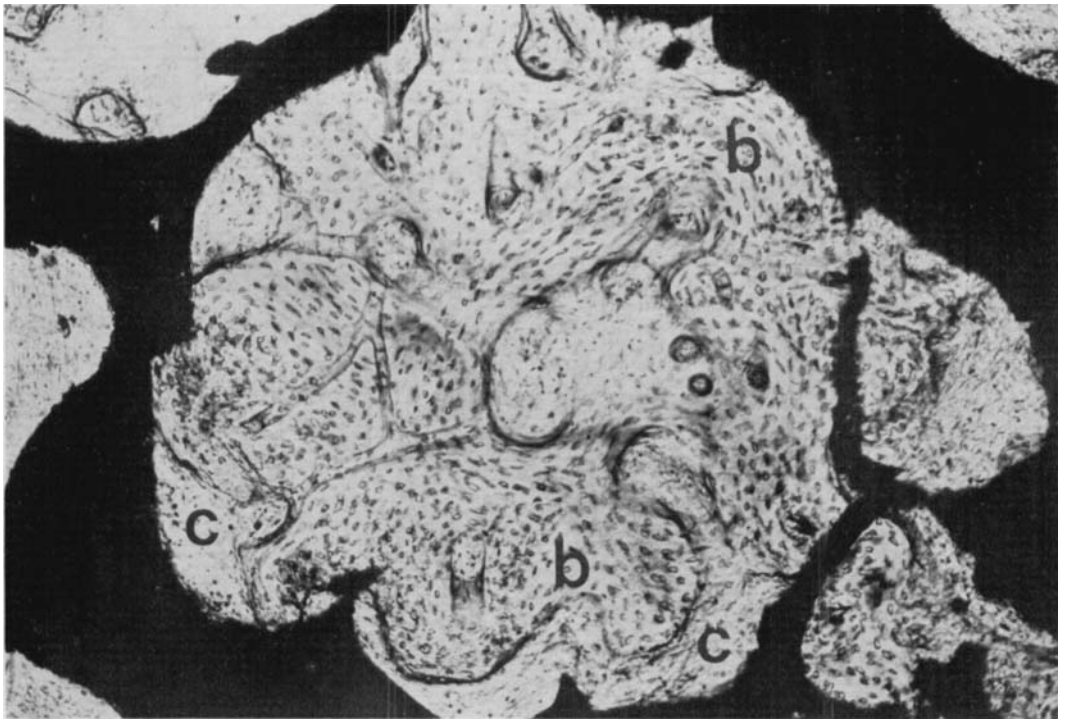



*Figure 4. Detail of the larger demarcated area in Figure 3. (× 110). The picture shows a pore almost completely filled with bone (b). In some regions fibrous connective tissue (c) is interposed between the bony tissue and the ceramics.*

with evidence of osteoblastic activity (Figure 6). In some of the widest pores the bony tissue appeared to be arranged in Haversian systems as judged by ordinary light microscopy.

*Microradiography*

The microradiographic findings corresponded closely to those of light microscopy; bony tissue was found at varying depths of the implants in different regions (compare Figure 7 with Figures 3–5).

*Scanning electron microscopy (SEM)*

The SEM-pictures indicated heavy concentrations of Ca and P in the regions which histologically contained new bone. Correspondingly "negative" images were obtained when the SEM was carried out to visualize Al. A few areas were blank on both types of SEM; these contained vessels, connective and osteoid tissue.

The quantities of Ca and P in the new bone inside the implants appeared to be nearly as large as those in the adjacent cancellous bone (Figure 8).

## DISCUSSION

The success of implants as substitutes for bone depends on several factors; the implant must be biologically compatible with the host tissue, it must have a surface or construction which allows it to be firmly anchored to the adjacent bone, and it must be strong enough to meet the physical demands in the implant situation.

The porous ceramic material used in the present study appears to fulfil the

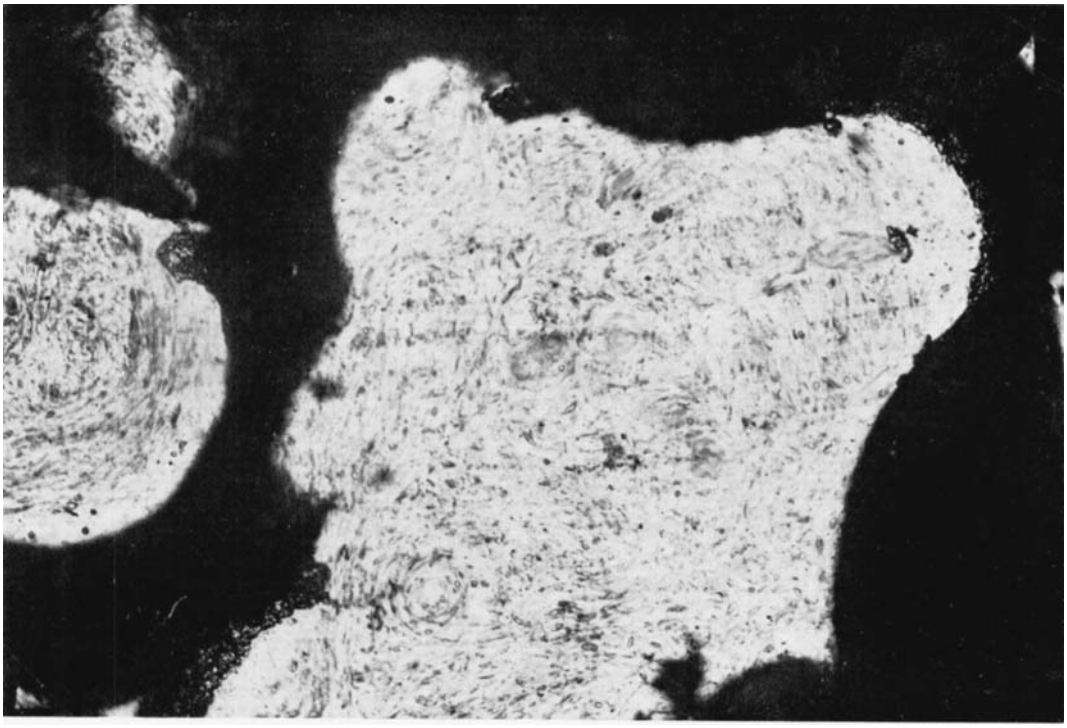


*Figure 5. Detail of the smaller demarcated area in Figure 3. (× 180). The picture shows a pore filled with connective tissue.*

first requirement; both the present study, and two previous studies (Lyng et al. 1973, Pedersen et al. 1974) show that it is biologically inert within the time intervals of the observations.

*In vitro* fatigue tests showed a deterioration of strength for compact samples, a deterioration which may be still more serious for porous samples, due to the much larger surface areas open to corrosive attacks. The effect of such effects *in vivo* for the actual samples is at present not known.

One also has to take the brittle nature of ceramics into account. The usual engineering principle of dimensioning the part according to the tensile stresses in the area has to be replaced by a statistical statement about the possibility of sustaining the actual tensile stresses for a defined period. Furthermore, according to the "weakest link theory", it is not possible to obtain higher strength of a ceramic construction detail by using larger dimensions, due to the possibility of critical stress concentrations at, for example, microcracks, leading to fracture.

In order to avoid these problems, we chose an implant site where the ceramics were mainly subjected to compressive forces, which are not thought to be critical.

Alumina has previously been used in the construction of total hip prostheses, as described for example by Heimke et al. (1974). Their results indicate that brittle fracture is not too critical a factor for such a use. However, the problems mentioned must be reviewed before clinical testing of ceramic materials.

The difficulty of obtaining firm fixation of the implant to the adjacent bone depends not only on the surface and construction of the implant, but also on the

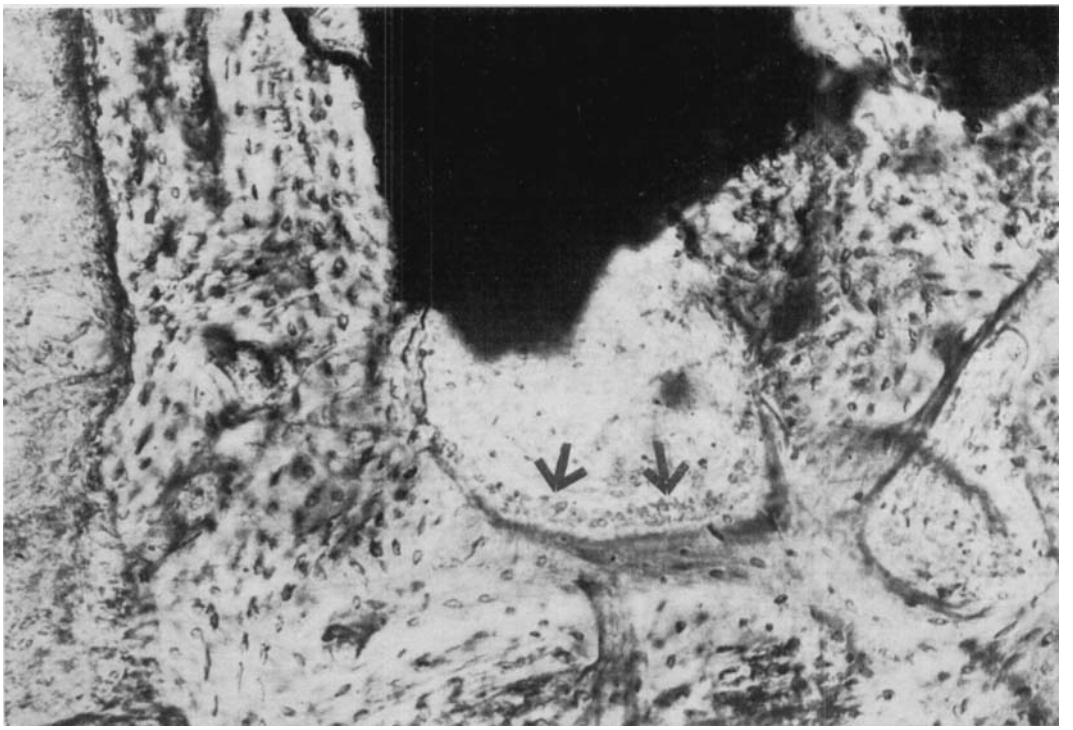


*Figure 6. Photomicrograph demonstrating a row of osteoblasts (indicated by arrows). (Paragon, × 180).*

possibility of relative movements between bone and implant. In cases where such movements are possible, the tissue seems to remain fibrous; ossification does not occur (Lyng et al. 1973). Compressive forces on the other hand give close contact between implant and bone and appear to promote the formation of new bone in the border area.

In the present study the implants were exposed mainly to compressive forces and all the investigation methods used show that ossification had occurred in the implants, in some regions to a depth of 2–3 mm. The trabeculae of the adjacent bone were directly continuous with those of the new bone in the pores of the implant, and microscopy gave evidence of osteogenic activity, indicating that ossification was still progressing. Further studies are required to determine how long this process continues, and at what depth the bony invasion finally stops.

The medial condyle of the tibia was chosen as the implantation site in the present series, as this is one of the most common sites for implantation of bone substitutes in clinical practice. Indeed implantation of Kieler-Knochen-Span or autogenous bone transplants is almost routinely required in the operative correction of compression fractures of the knee joint. Porous ceramics appear to present a favourable alternative to Kieler-Knochen-Span, and possibly also to autogenous bone grafts. The ceramics are more resistant to compression than dry Kieler-Knochen-Span, and the latter material is even weaker when moistened, as it usually is during implantation. Moreover, the ceramics probably retain adequate compressive strength, while that of Kieler-Knochen-Span and autogenous

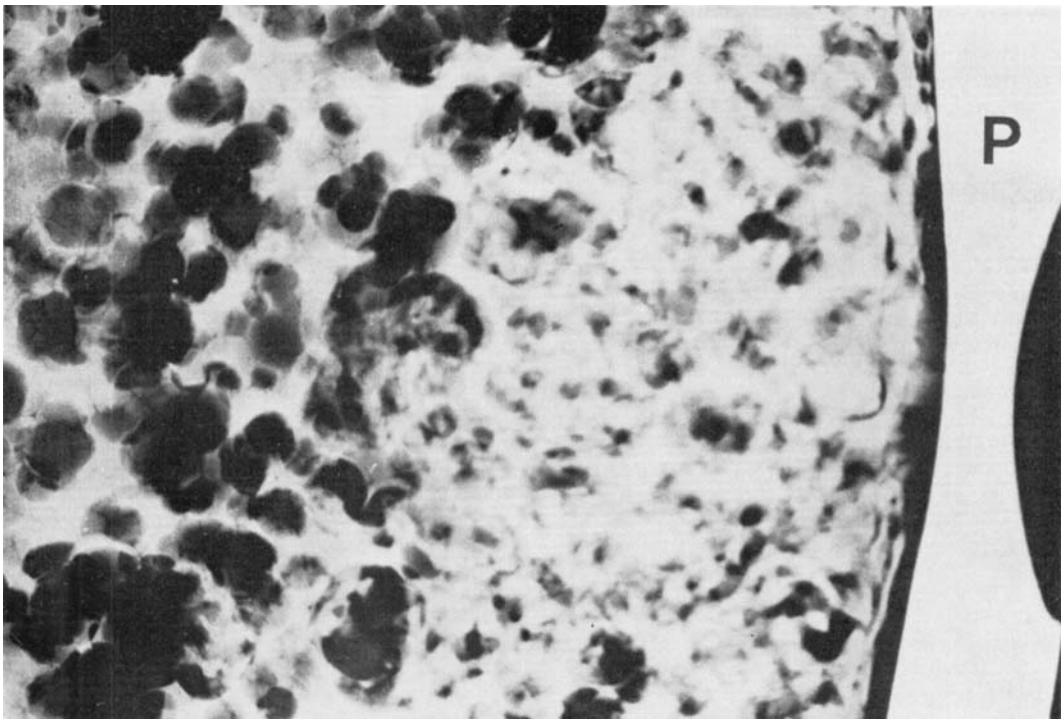
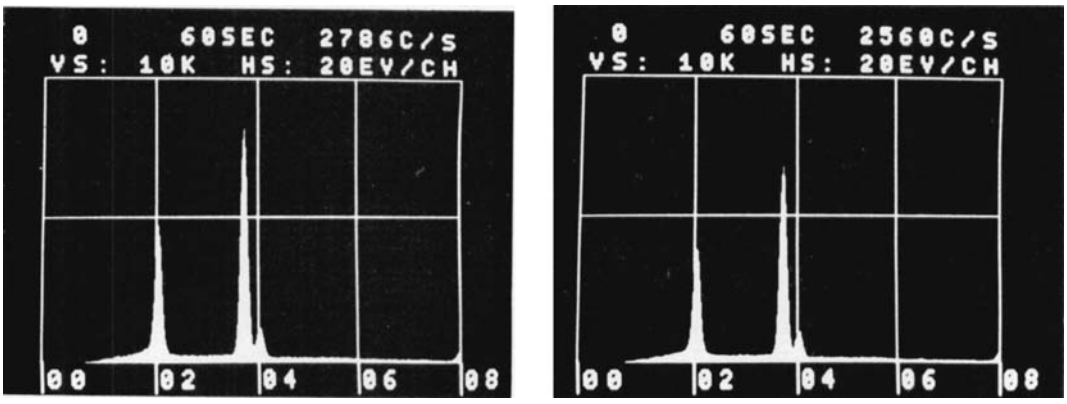



*Figure 7. Microradiograph of the section from which the slide shown in Figure 3 was prepared. (× 18). Most of the pores of the peripheral part of the implant (near the plate P) are filled with bony tissue.*




A. B.

*Figure 8. Energy dispersive X-ray analysis demonstrating the relative quantities of P (left) and Ca (right) in the bone outside an implant (A) and within a pore (B). The content of Ca and P of the bony tissue within the pore is only slightly lower than in the bone outside the implant.*

bone transplants may be gradually lost due to resorption. On the other hand the ceramics remain imbedded in bone as a foreign body, and it may therefore represent a possible focus of infection. This risk is shared by all foreign material implants, however, and the properties of the porous ceramic implants are such that

we feel that a clinical trial is warranted, providing the results are equally satisfactory after a supplementary study with a prolonged observation period.

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