Acta orthop. scand. 52, 207–213, 1981

REPLACEMENT OF THE FEMORAL HEAD BY CERAMIC ENDOPROSTHESIS

An Experimental Study on Rabbits

ERIK B. RISKA & TEDDY HOLMSTRÖM

Department of Orthopaedics and Traumatology, and Department of Pathology, University of Helsinki, Helsinki, Finland.

In 31 rabbits the femoral head was replaced by a ceramic endoprosthesis. For 11 of the experimental animals the endoprostheses were made by the Arabia China Factory in Helsinki, and for 20 by Staatliche Porzellan Manufaktur in Berlin. The operation was performed under fully sterile conditions and the follow-up time was between 6 and 34 weeks. The hip joint was examined clinically, roentgenologically, macroscopically and histologically.

The bending tolerance of the ceramic endoprosthesis was not adequate. Mechanical loosening of the proximal part of the prosthesis occurred in 68 per cent and was combined with fracture of the prosthetic stem. This created a pseudarthrosis-like reaction in the acetabular area and limited the movement of the hip joint. The distal fragment of the stem was always surrounded by a thin layer of dense bone.

In the nonfractured cases (32 per cent), however, the reaction was only moderate and the movement of the hip joint was well preserved. The tissue reactions to the ceramic material were slight, but the great number of secondary reactions following stem fractures make the use of the ceramic endoprosthesis questionable in experiments with rabbits.

Key words: bone; bone reactions; ceramic endoprosthesis; femoral head replacement

Accepted 14.xi.80

The results of replacement of the hip joint in humans have improved with the use of better materials and a refined operative technique (Eftekhar 1978, Freeman 1978) but, nevertheless, there are many reports of complications associated with the various replacement procedures (Eftekhar 1978, Etienne et al. 1978, Maier et al. 1977, Ritter 1976). Mechanical loosening (Griss et al. 1974, Marmor 1976), metallosis years after operation (Deutman et al. 1977), fractures of the stem and wear of the socket are some of the difficult problems associated with hip joint replacement (Clarke et al. 1976). Therefore over the years new materials and prosthetic types have been introduced (Boutin 1972, 1974, Petersen et al. 1969, Riska 1971), and especially in Germany a great deal of experimental work has been done in the field of ceramics, because this material has proved to possess a good tissue tolerance (von Andrian-Werburg et al. 1973, Griss et al. 1973, 1974, 1975, 1976, Heimke et al. 1976).

In addition, reports have shown this material to be compatible within the human body in total hip replacement (Boutin 1972, 1974). After many experiments with various animals ceramic-metal composite hip endoprostheses were designed and their clinical testing commenced, and with good results (Heimke et al. 1976). But the ceramic material proved to possess disadvantages, e.g., the bending tolerance was not adequate. This indicated further experimental studies. The first ceramic endoprostheses for rabbits were made by

0001-6470/81/020207-07 $02.50/0

© 1981 Munksgaard, Copenhagen

Arabia China Factory in Helsinki and a preliminary report was given in 1971 by Riska. The next series of ceramic endoprostheses for rabbits were made of Prokorund® by Staatliche Porzellan Manufaktur in Berlin in order to improve the strength. The study was continued to further evaluate the behavior of ceramic hip joint endoprostheses in rabbits.

MATERIAL AND METHODS

Experimental animals

Replacement operations were performed on 31 rabbits with an average weight of 3 kg (range from 2 to 4 kg) and an average age of 1 year and 6 months (range from 8 months to 3 years). Two rabbits shared one cage after the operation. For the replacement operation, the right hip joint was always used. The follow-up time was between 6 and 34 weeks as shown in Figure 1.

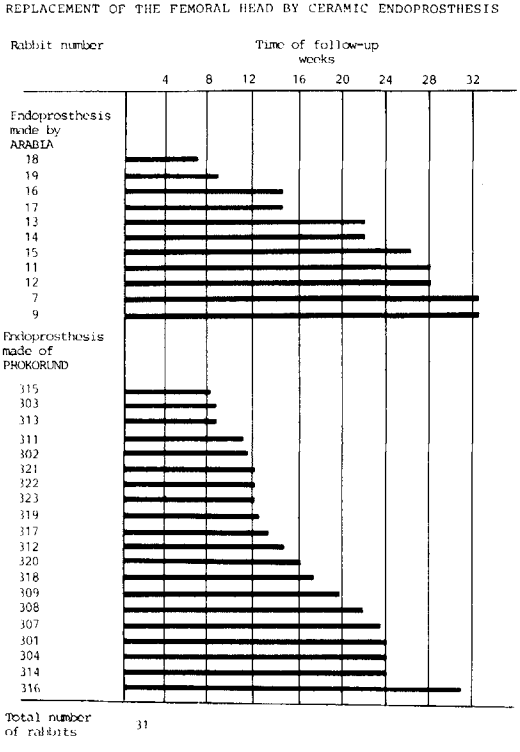


Figure 1. Follow-up times of the 31 experimental animals.

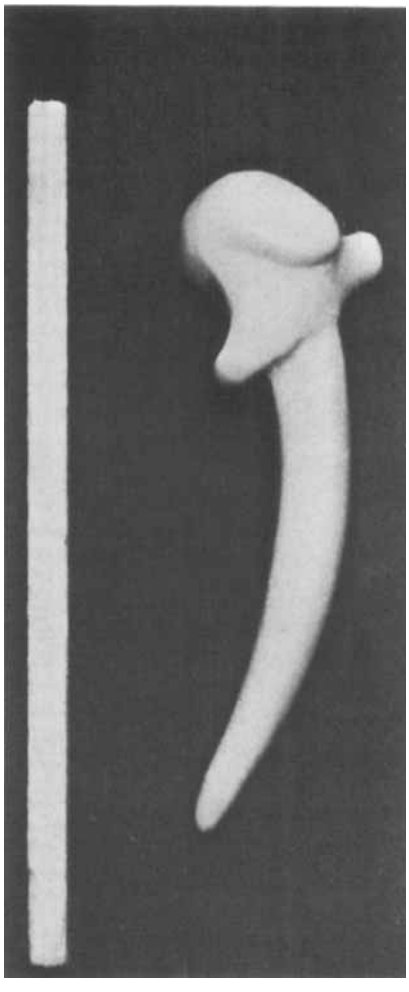


Figure 2. The ceramic endoprosthesis made by the Arabia China Factory in Helsinki. The match gives an idea of the size of the endoprosthesis.

Endoprosthesis

Eleven rabbits were fitted with polished ceramic endoprostheses made of kaolin, feldspar and sand (Arabia China Factory, Helsinki, Finland) (Figure 2), the chemical composition being alkaline aluminium silicate. The heat tolerance of the ceramic is over 1300°C, the compression tolerance 5000 kg/cm^2, and the bending tolerance 1000 kg/cm^2. The ceramic is resistant to alkalis and acids, electrostatically inactive and not subject to corrosion.

Twenty rabbits were fitted with polished ceramic endoprostheses made of "Prokorund®" (Staatliche Porzellan Manufaktur, Berlin, W. Germany). A chemical analysis of Prokorund showed: Al_2O_3 80.74 per cent and SiO_2 17.84 per cent. Prokorund has a heat toler-

ance of over 1500°C, a compression tolerance of 16700 kg/cm², and a bending tolerance of 2320 kg/cm². Prokorund is also resistant to alkalis and acids, and electrostatically inactive.

Operative procedure

The replacement operation was performed under fully sterile conditions. After premedication with 1 mg Atropin/kg and Pethidin 1 mg/kg the anesthesia was started intravenously with Nembutal 30 mg/kg (Abbott) and continued with ether inhalation. In addition 5 ml local anesthesia of 0.5 per cent Xylocain-Exadrin (Astra) was injected into the operative field. A posterolateral approach was used. The ligamentum teres was separated and the femoral neck was cut with a small chisel. The medullar cavity was reamed and the ceramic endoprosthesis was inserted. The hip joint was reduced and the capsule as well as the muscle, fascia and the skin closed with 3–0 mersilene® (Ethicon) sutures. Each experimental animal received Procain Penicillin 300.000 units prophylactically before the operation.

X-ray and macroscopical examination

The hip joints were X-rayed before and after the operation, and at the sacrifice of the animal. The rabbits were killed by an intravenous injection of air. All hip joints were opened, the joint was examined and the status of the endoprosthesis was determined. After decalcification in connection with the removal of the endoprosthesis, the final condition of the prosthesis was registered.

Histological examination

After approximately 10 days' fixation in formalin the femurs and the hip joints were decalcified in 10 per cent EDTA and embedded in paraffin by routine methods. The specimens were cut into 7 μ thick slices and stained with hematoxylin-eosin and alcian blue.

RESULTS

Examination of hip joint

The range of movement of the operated hip joint was normal in all rabbits immediately after the operation as well as in the properly healed cases at the final examination. In cases with broken stems, however, the motion was restricted.

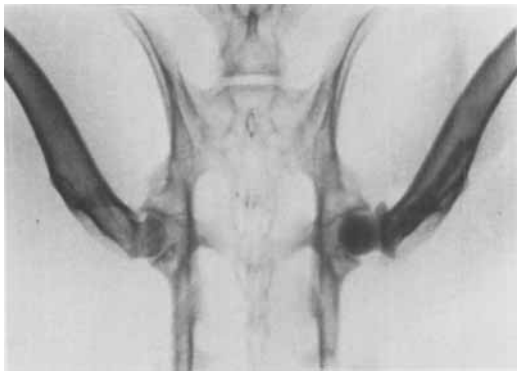


Figure 3. X-ray of the hip joints of a rabbit immediately after the operation. Ceramic endoprosthesis in the right femur.

X-ray examination

The X-ray examination immediately after the operation always showed a good position of the endoprosthesis (Figure 3). No differences were noted between the two types of prostheses. Broken prosthetic stems were encountered in 68 per cent, and were always combined with prosthetic loosening (Table 1). In these 21 cases pseudarthrotic bone formation developed around the proximal part of the stem while the distal part was situated in the femur without any visible surrounding reactions (Figure 4). In two cases the head of the endoprosthesis was dislocated in connection with fracture of the stem. The position remained good without endoprosthetic stem fracture in 10 cases only (32 per cent) (Figure 5). The cortical bone in the femoral shaft remained normal in all cases.

Table 1. X-ray and macroscopical examination of rabbit hip joints fitted with ceramic endoprostheses

Type of endoprosthesis	Number of cases	Number of broken endoprostheses	Number of dislocated endoprostheses	Number of properly healed cases
Made by Arabia China Factory	11	7	0	4
Made of "Prokorund"	20	14	2	6
Total	31	21	2	10

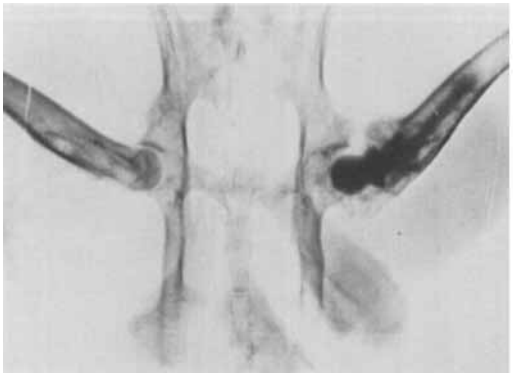


Figure 4. X-ray of the hip joint of a rabbit 12 weeks after the operation. Note the pseudarthrosis-like reaction in the acetabular area. No reaction was observed around the stem.

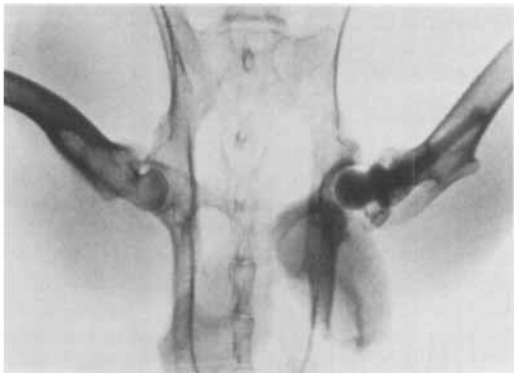


Figure 5. X-ray of the hip joints of a rabbit 21 weeks after the operation. Note the good alignment of the prosthesis and the very slight reaction in the acetabular area.

Macroscopical examination

The endoprosthetic stem was fractured in 21 cases out of 31 and accordingly unbroken in 10 cases (Table 1). In all cases there was clear colorless fluid in the hip joint. In the cases with stem-fracture and loosening of the proximal part of the endoprosthesis a pseudarthrosis-like reaction of the bone was noted and the prosthetic head was dislocated in 2 cases. The ceramic material was unchanged in all endoprostheses.

Histological examination

General. In 32 per cent of the cases the endoprosthesis remained in an ideal position in the femoral shaft, and the histological changes were moderate (Figure 6). In the remaining 68 per cent the prosthesis showed different degrees of mechanical loosening, regularly combined with fracture of the prosthetic shaft. The histological changes in all these cases were abundant, particularly in the acetabular area. No differences were noted between the two types of prostheses.

The main features of the histological changes were already present in the 6-week specimen; only in the acetabular cartilage did the picture vary during the follow-up time. There were no reactions of the foreign body type in any preparation, and the cortical bone of the femoral shaft was normal without any signs of resorptive changes.



Figure 6. Low power photomicrograph of the acetabular and upper femoral area in a rabbit at 24 weeks. Note the good position of the endoprosthesis and moderate changes in the capsular area (H & E. × 5).

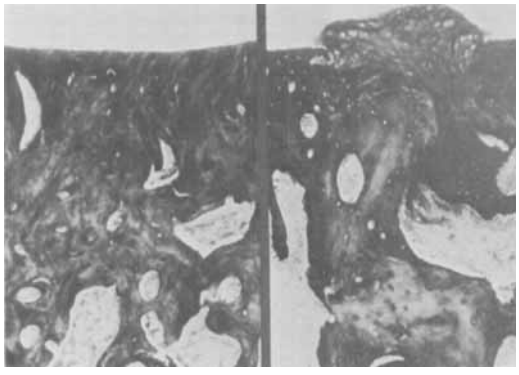


Figure 7. Photomicrographs of the acetabular surface in rabbits at 24 weeks (left) and at 15 weeks (right). Note absende of joint cartilage as late as 24 weeks and the incipient regeneration as early as 15 weeks. (Alcian blue × 150).

Acetabular area. The acetabular joint cartilage was well preserved in the 6-week specimen. Already at 10 weeks postoperatively the cartilage had disappeared and was still absent up to about 24 weeks postoperatively, but regeneration of the cartilage had started as early as 15 weeks in some cases (Figure 7). In the 28–34 week specimens the acetabular bone was covered with a cartilaginous layer (Figure 8).

In the properly healed cases (32 per cent) the joint capsule was thickened and fibrotic with chronic synovitis (Figure 6). In all the other cases there was a varying amount of cartilage and some new bone in the fibrotic capsule both on the femoral and the acetabular side, and the synovium was hypertrophied, with chronic inflammation. These processes made up a new joint, a kind of pseudarthrosis (Figure 9).

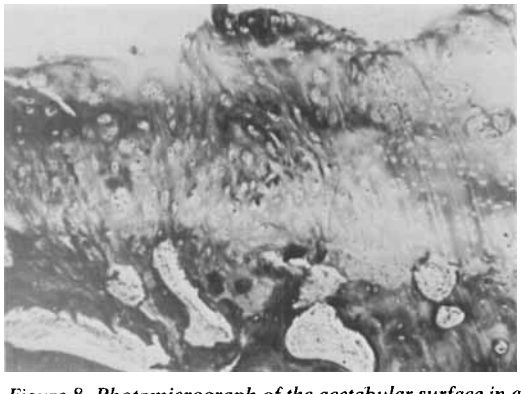


Figure 8. Photomicrograph of the acetabular surface in a rabbit at 28 weeks. Note irregularity in regenerating cartilage and fibrous appearance. (H & E. × 180).



Figure 9. Photomicrograph of the acetabular area in a rabbit at 21 weeks. Note pseudarthrotic cartilage (arrows). (Alcian blue × 9).

Prosthetic stem area. The prosthetic stem was in all cases surrounded by a layer of cells of osteoblast type of varying thickness. In half of the cases in the nonfractured group, this thin cell-layer was directly attached to a bony layer. In the other half there was a layer of fibrous tissue between the bone and the more prominent cell layer (Figure 10). The same picture was seen around the proximal part of the prosthesis in the group with mechanical loosening and stem fracture. The distal fragment of the stem was always surrounded by a thin layer of dense bone (Figure 11), without regular cell lining.

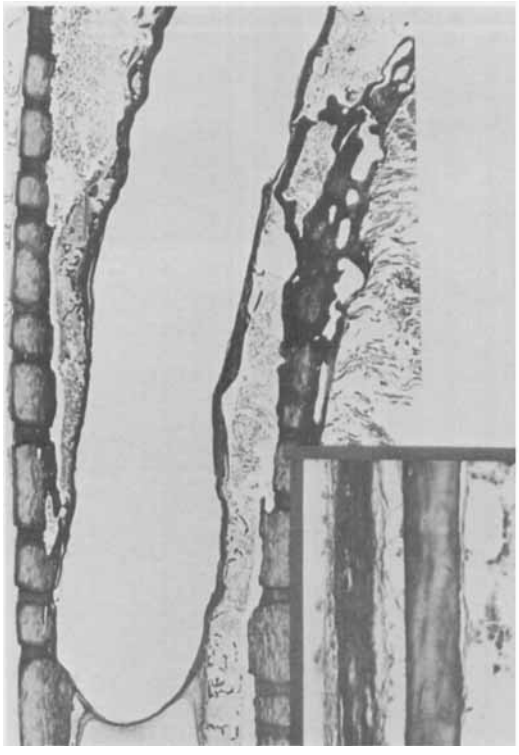


Figure 10. Photomicrograph of the prosthetic stem area in a rabbit at 24 weeks. Note around the stem the thin tissue layer with dense collagen between the stem and the bony layer (insert) (Alcian blue × 13, insert × 280).



Figure 11. Photomicrographs of the prosthetic stem area in a rabbit at 14 weeks. The prosthetic stem is broken. Note the bony layer directly attached to the prosthetic stem (insert) (H & E. × 13, insert × 220).

DISCUSSION

In the present material only 32 per cent of the cases showed proper healing with preserved range of movement in the operated hip joint and no mechanical loosening and fracture of the prosthesis. There was no difference between the two types of prosthesis used. In the light of this result it is obvious that the bending tolerance of the ceramic stem is not sufficient for a hip joint endoprosthesis in rabbits. The stem fracture, however, could be a result of the mechanical loosening of the prosthesis, but more likely the proportionally strong muscles of the lower extremities in the rabbits caused the stem to break at an early stage. This released the proximal part of the prosthesis, which then was able to sway and create the abundant pseudarthrosis-like reaction seen both on the X-ray pictures and in the histological preparations.

The destruction of the acetabular cartilage may be a result of pressure atrophy and the regenerated cartilaginous layer was more fibrous in type suggesting mechanical stress.

In X-ray pictures no adverse reactions to the ceramic material were seen and the cortical bone in the femoral shaft appeared normal. These findings were confirmed in the histological preparations. Tissue reactions were very slight as best seen around the firmly attached distal parts of the broken prostheses. This finding is in agreement with earlier reports (von Andrian-Werburg et al. 1973, Benum et al. 1976, 1977, Griss et al. 1973, 1974, Lyng et al. 1973, Peterson et al. 1969 and Riska 1971), indicating good tissue tolerance to the ceramic material.

The large number of prosthetic fractures and loosenings causing abundant secondary changes in the capsular area, and leading to impaired

movement in the hip joint, make the use of ceramic endoprostheses questionable at least in rabbits. The good tissue tolerance, however, renders the ceramic of interest as a prosthetic material in humans.

REFERENCES

Von Andrian-Werburg, H., Griss, P., Krempien, B. & Heimke, G. (1973) Experimentelle morfologische Befunde bei der Verwendung keramischer Werkstoffe in der Orthopädie und Unfallchirurgie. *Z. Orthop.* **111**, 577–579.

Benum, P., Lyng, S., Bø, O., Rafn, I. & Haffner, J. F. W. (1976) Porous ceramics as a bone substitute in the medial condyle of the tibia. *Acta Orthop. Scand.* **47**, 158–166.

Benum, P., Lyng, S., Alm, T. & Johannessen, N. (1977) Porous ceramics as a bone substitute in the medial condyle of the tibia. *Acta Orthop. Scand.* **48**, 150–157.

Boutin, P. (1972) Arthroplastie totale de la hanche par prothése en alumine frittée. *Rev. Chir. Orthop.* **58**, 229–246.

Boutin, P. (1974) Les prothéses totales de la hanche en alumine. *Rev. Chir. Orthop.* **60**, 233–245.

Clarke, I. C., Black, B. S., Rinnie, C. & Amstutz, H. C. (1976) Can wear in total hip arthroplasties be assessed from radiographs? *Clin. Orthop.* **121**, 126–142.

Deutman, R., Mulder, Th. J., Brian, R. & Nater, J. P. (1977) Metal sensitivity before and after total hip arthroplasty. *J. Bone Joint Surg.* **59**-A, 862–865.

Eftekhar, N. S. (1978) *Principles of total hip arthroplasty.* C. V. Mosby Co., Saint Louis.

Etienne, A., Cupic, Z. & Charnley, J. (1978) Postoperative dislocation after Charnley low-friction arthroplasty. *Clin. Orthop.* **132**, 19–23.

Freeman, M. A. R. (1978) Total surface replacement hip arthroplasty. *Clin. Orthop.* **134**, 2–4.

Griss, P., Krempien, B., von Andrian-Werburg, H., Heimke, G. & Fleiner, R. (1973) Experimentelle Untersuchung zur Gewebsverträglichkeit oxidkeramischer (Al_2O_3) Abriebteilchen. *Arch. Orthop. Unfallchir.* **76**, 270–279.

Griss, P., Krempien, B., von Andrian-Werburg, H., Heimke, G., Fleiner, R. & Diehm, T. (1974) Experimentelle analysis of ceramic-tissue interactions. A morphologic, fluorescenseoptic, and radiographic study on dense aluminia oxide ceramic in various animals. *J. Biomed. Mater. Res. Symp.* **5**, 39–48.

Griss, P., Krempien, B., von Andrian-Werburg, H., Heimke, G., Reipa, S., Lauterbach, H. J. & Hartung, H. (1975) Morphological and biomechanical aspects of Al_2O_3 ceramic joint replacement. Experimental results and design conservations for human endoprostheses. *J. Biomed. Mater. Res. Symp.* **6**, 177–188.

Griss, P., Greenspan, D. C., Heimke, G., Krempien, B., Buchinger, R., Hench, L. L. & Jentschura, G. (1976) Evaluation of bioglasscoated Al_2O_3 total hip prosthesis in sheep. *J. Biomed. Mater. Res. Symp.* **7**, 511–518.

Heimke, G., Griss, P. & Krempien, B. (1976) Ceramic endoprostheses. *Powder Metallurgy Internat.* **8**, 71–81.

Lyng, S., Sudmann, E., Hulbert, F. & Sauer, B. W. (1973) Fixation of permanent orthopaedic prosthesis. Use of ceramics in the tibial-plateau. *Acta Orthop. Scand.* **44**, 694–701.

Maier, S., Griss, P., Rahmfeld, T. & Dinkelacker, T. (1977) Nachuntersuchungsergebnisse der totalen Alloarthroplastik der Hüfte unter besonderer Berücksichtigung der Spätkomplikationen 4 bis 7 Jahre post operationem. *Z. Orthop.* **115**, 274–283.

Marmor, L. (1976) Femoral loosening in total hip replacement. *Clin. Orthop.* **121**, 116–119.

Petersen, C., Miles, J., Solomons, C., Predecki, P. & Stephen, J. (1969) Union between bone implants of open pore ceramic and stainless steel. A histologic study. *J. Bone Joint Surg.* **51**-A, 805.

Riska, E. B. (1971) Endoprosthesis made of ceramic. An experimental study on rabbits. *Acta Orthop. Scand.* **42**, 457–459.

Ritter, M. A. (1976) Dislocation and subluxation of the total hip replacement. *Clin. Orthop.* **121**, 92–94.

Correspondence to: Erik B. Riska, M.D., The Department of Orthopaedics and Traumatology, University of Helsinki, Topeliuksenkatu 5, 00260 Helsinki 26 Finland.