Acta Orthop Scand *57*, 25–29, 1986

Bone fixation of ceramic-coated and fiber titanium implants

A study in weight-bearing rats

We compared the fixation of glass ceramic-coated titanium and fiber titanium implants using a simple weight-bearing model in rats. The chemical composition of the glass ceramic was similar to 45S5F Bioglass®. One hundred and eight male Wistar rats were operated on. A segment of their right tibias was replaced by a disc-shaped implant with a central hole. A stable osteosynthesis was completed by means of an intramedullary nail and a tension band. Thirty-six rats received glass ceramic-coated and 36 fiber titanium implants. In 36 rats osteotomies were performed. All animals survived without complications until scheduled sacrifice at 3, 12 and 26 weeks, postoperatively. The ultimate bending moments of the fiber titanium-bone interfaces and the osteotomies increased with time, and approached the levels of the contralateral, intact tibias at the 12th and 26th week. Also, the ultimate bending stresses increased from the 3rd to 12th week. After 26 weeks the fiber titanium-bone interfaces had reached about 45 per cent, and the osteotomies about 75 per cent of the strength of the intact tibias. All the glass ceramic-coated implants were loose, and at 26 weeks there was no coating left.

Elin Barth
Helge Rønningen
Ludvig Fjeld Solheim

Institute for Surgical Research, National Hospital, University of Oslo, N-0027, Oslo 1, Norway

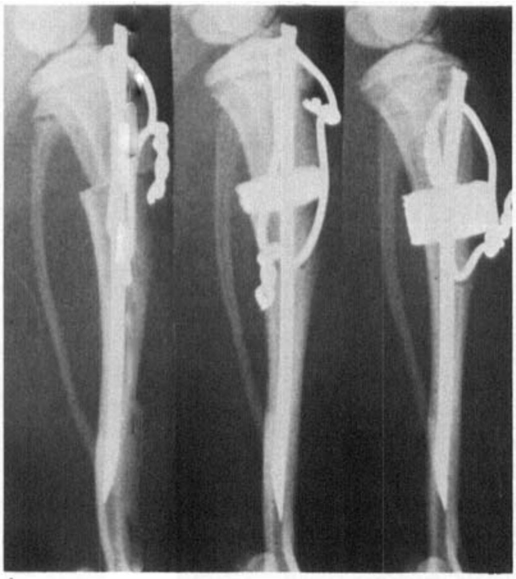
Bioactive glass ceramics and porous fiber titanium have emerged as two potential coating materials for prosthesis fixation (Galante & Rostoker 1973, Blencke et al. 1978). Both materials seem to be well tolerated by bone as well as soft tissue (Wilson et al. 1981, Brånemark & Albrektsson 1982). The former is claimed to react chemically with bone (Hench & Paschall 1973), while fixation of the latter seems to depend on bone ingrowth (Bobyn et al. 1980). Several experimental implantation studies have been performed with non-weight-bearing and static loading of implants (Ducheyne et al. 1977, Hulbert et al. 1979).

We introduce a simple, weight-bearing model for dynamic loading of implants in rats to compare the fixation of glass ceramic-coated titanium and porous fiber titanium to bone, and to investigate whether weight bearing would interfere with the bond strength.

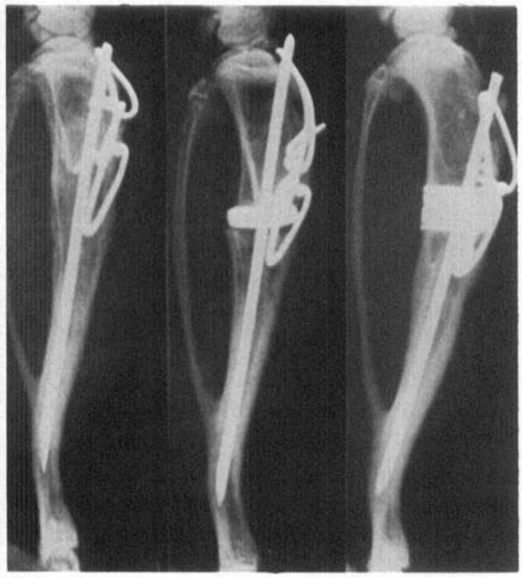
Material and methods

Thirty-six porous fiber titanium discs made from the Ti-6A1-4V alloy and 36 compact titanium discs coated with a glass ceramic similar to 45S5F Bioglass® were used (Piotrowski et al. 1975). The former had been manufactured by compressing 0.25-mm-thick wire stumps to a porous structure of 50 per cent void space. The latter had a 0.20-mm-thick plasma flame-sprayed glass ceramic coat (Barth & Herø 1986). All implants were 5.0 mm diameter by 3.0 mm height and had a central hole of 1.3 mm diameter. They were gas sterilized before implantation.

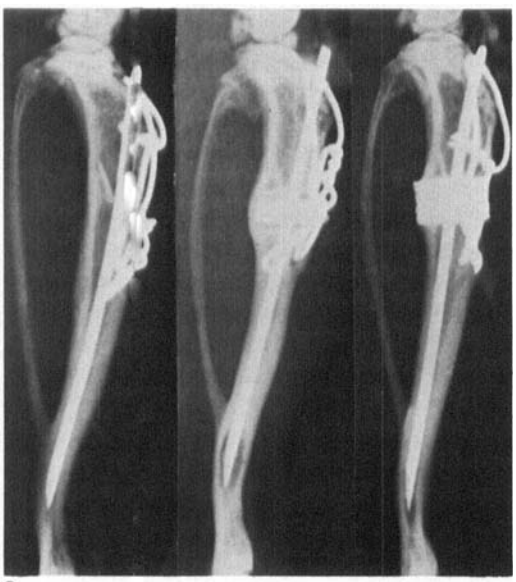
One hundred and eight juvenile, male Wistar rats with open physes (weight 310–335 g) were used. Thirty-six animals were scheduled for porous fiber titanium implants and 36 for glass ceramic-coated implants, while 36 had osteotomies. The healing of the osteotomies was used as a reference for the increase in strength during the study. The animals were anesthetized with fluanisone 0.5mg/100g subcutaneously (Hypnorm Vet.®, Mekos, Helsingborg, Sweden). The right tibia was exposed through an anteromedial incision and carefully dissected from muscles and periosteum. The patellar tendon was split longitudinally and a hole drilled into the marrow cavity with a dental burr (diameter 0.8 mm), 2 mm proximal to the tibial tuberosity. An osteotomy or a 3-mm resection of the tibia was performed 5 mm distal to the knee joint. The fibula was left intact. A horizontal hole was drilled through the anterior tibial ridge 2 mm distal to the osteotomy/resected bone. Implants were inserted in close contact with



A



B



C

Figure 1. Osteotomy (left), glass ceramic-coated implant (middle) and fiber titanium implant (right).
A. Postoperative. The physes are open. There is close contact between bone and implants.
B. After 3 weeks. The physes are now closed. The osteotomy site is still discernible. There is a radiolucency around the glass ceramic-coated implant. The fiber titanium implant is in close contact with bone.
C. After 12 weeks. Around the glass ceramic-coated implant there is a radiolucency. The adjacent bone is sclerotic. Bone bridges have formed across the implant site. The fiber titanium implant is in close contact with bone. The radiographs at 26 weeks were similar.

bone. A stable osteosynthesis was obtained by means of an intramedullary nail (diameter 0.8 mm) and a cerclage (diameter 0.5 mm), which was passed through the horizontal hole distal to the osteotomy or implant and then around the proximal tip of the marrow nail as a tension band (Figure 1). The tibias were radiographed postoperatively and at sacrifice. Twelve animals from each osteotomy/implant group were sacrificed at 3, 12 and 26 weeks postoperatively.

Before bending tests, the right and left (control) tibias were freed from soft tissue. In order to test the fixation between bone and implants, any bony bridges covering the implants were gently removed along with nails and cerclages. The bending tests were performed by ventral deflection of the proximal end of tibia. The bones and implant-bone interfaces were tested until failure by a constant deformation rate of 0.04 rad s-1 (Engesaeter et al. 1979), and the ultimate bending forces measured. The inner and outer diameters of the circular fracture areas of the right tibias and the inner and outer base lines and heights of the triangular fracture areas of the left (control) tibias were measured using a sliding caliper (accuracy ± 0.01 mm).

The ultimate bending moments were computed in

Nm (Engesaeter et al. 1979). The ultimate bending stresses (MN/m^2) were computed relating the bending moments to the areal moments of inertia. The area for a circular, hollow beam was used for the right operated tibias and a triangular hollow beam for the left, intact tibias (Popov 1978). Averages and dispersions were expressed as the arithmetic mean $\pm$ 1 SD. Analysis of variance was used to test for differences between multiple means. Where differences were found, means were contrasted using *a posteriori* tests (Sokal & Rohlf 1969).

Results

The operated hind legs functioned normally within 2 days, and all animals survived without complications until scheduled sacrifice. The osteotomies were healed radiographically within 12 weeks. The fiber implants were in close contact with the bone during the whole observation period, whereas there was a radiolucent zone around the glass ceramic-coated implants 3 weeks after surgery. The fibulas were intact (Figure 1). The fiber titanium implants were macroscopically pervaded by bone at 12 and 26 weeks. The tibias with these implants failed at the *distal* implant-bone interface during bending. Removal of the bone bridges around the glass ceramic-coated implants revealed loose implants at all intervals. There was no extensive loss of the coating after 3 and 12 weeks, but at 26 weeks most of the coating had vanished. The fractured areas of the osteotomies and implant-bone interfaces were all circular. The left (control) metaphyses had triangular fracture areas. *The ultimate bending moments* of the fiber titanium-bone interfaces and the osteotomies increased with time after surgery and approached the bending moment levels of the contralateral, intact tibias at 26 weeks (Table 1). *The ultimate bending stresses* of the fiber titanium-bone interfaces and the osteotomies increased from the 3rd to the 12th week (Table 1). After 26 weeks the fiber titanium-bone interfaces had reached about 45 per cent and the osteotomies about 75 per cent of the strength of the intact tibias.

Discussion

In this model an intramedullary nail was used. The major difference in strength between the osteotomy group and the controls at 3 weeks may be explained by vascular damage caused by the introduction of this nail, a difference later compensated for through revascularization.

The intramedullary nails caused no stress shielding, as documented in a previous pilot study. The nails were removed 3 weeks after tibial osteotomy, and 3 weeks later there was no difference in bending strength compared to osteotomies which had healed with the nails *in situ*.

The porous and solid materials which we compared represent two different philosophies in implantology; one is fixation by ingrowth of bone and the other by bonding at the bone-implant interface. The porous fiber titanium implants were macroscopically pervaded by bone

Table 1. Ultimate bending moments (I) and stresses (II) of controls, osteotomies and the distal fiber titanium to bone interfaces (Mean ± SD).

		3 wk		12 wk		26 wk
	Control	0.50±0.10	*	0.7±0.2		0.7±0.1
		***				**
I	Osteotomy	0.20±0.05	***	0.6±0.1	***	0.8±0.1
		***		**		
	Fiber	0.10±0.04	***	0.4±0.2	***	0.7±0.2
	Control	105±54.6		140 ±45.9		114 ±45.4
		***		***		**
II	Osteotomy	8.4± 5.1	***	76.0±19.2		79.8±14.6
				***		
	Fiber	5.8± 0.8	***	35.0±13.6	*	48.3±14.9

Significantly different: *** $p<0.0005$, ** $p<0.005$, * $p<0.05$.

at 12 and 26 weeks. Porous ingrowth of bone is a process of fracture healing like the healing of osteotomies (Rønningen et al. 1983). Judged by the strength data the process was largely completed within 12 weeks, and this agrees with the data of other authors (Simmons 1980). The average pore size of these implants was 400 μm (Underwood et al. 1984). This is within the optimal range for bone ingrowth (Ducheyne et al. 1977, Bobyn et al. 1980). The fiber titanium has a low elastic modulus and very high compliance capabilities. This allows for a distributed load transfer from the implant material to the surrounding bone, avoiding stress concentrations at the bone-implant interface (Rostoker et al. 1974).

The fixation of the glass ceramic-coated implants failed in this model. The bone-bonding capacity of the coating has previously been documented under static loading (Barth et al. 1985), but under dynamic loading no bonding occurred even at 3 and 12 weeks when coating was still covering the implants. Thus there appears to be a discrepancy in bond formation in dynamic versus static loading. This agrees with Ducheyne (1985) who has hypothesized that the elastic discontinuity between the ductile bone and the brittle glass does not allow a distributed load transfer at the bone-implant interface. The resulting high stress concentration at the interface under dynamic loading will interrupt bond formation in cases where static loading does not interfere. In order to combine bioreactivity with ductility, Gheysen et al. (1983) have designed a metal-fiber reinforced glass ceramic.

The total loss of coating after 26 weeks agrees with a recent study where we found a leakage of silicon ions from glass ceramic into the tissues (Barth et al. 1985). Thus our results advocate against the use of this glass ceramic coating for fixation of highly stressed orthopedic implants because it is brittle, and because it is degraded by the tissues.

Acknowledgements

The authors express their gratitude to Mr. G. Farling and Mr. J. E. Parr, Zimmer Laboratories, Warsaw, Indiana, USA for the supply of specially designed porous fiber titanium implants.

References

Barth, E. & Herø, H. (1986) Bond strength of bioreactive glass ceramic on titanium substrate: The effect of molybdenum as bond coat. *Biomaterials*, **7**, in press.

Barth, E., Rønningen, H. & Solheim, L. F. (1985) Comparison of ceramic and titanium implants in cats. *Acta Orthop. Scand.* **56**, 491–495.

Blencke, B. A., Brømer, H. & Deutscher, K. (1978) Compatibility and long term stability of glass-ceramic implants. *J. Biomed. Mater. Res.* **12**, 307.

Bobyn, J. D., Pilliar, R. M., Cameron, H. V. & Weatherly, G. C. (1980) The optimium pore size for the fixation of porous-surfaced metal implants by the ingrowth of bone. *Clin. Orthop.* **150**, 263–270.

Brånemark, P-I. & Albrektsson, T. (1982) Titanium implants permanently penetrating human skin. *Scand. J. Plast. Reconstr. Surg.* **16**, 17–21.

Ducheyne, P., de Meester, P. & Aernoudt, E. (1977). Influence of a functional dynamic loading on bone ingrowth into surface pores of orthopaedic implants. *J. Biomed. Mater. Res.* **11**, 811–838.

Ducheyne, P. (1985) Bioglass coatings and bioglass composites as implant materials. *J. Biomed. Mater. Res.* **19**, 273–291.

Engesaeter, L. B., Ekeland, A. & Langeland, N. (1979) Methods for testing the mechanical properties of the rat femur. *Acta Orthop. Scand.* **49**, 512–518.

Galante, J. O. & Rostoker, W. (1973) Fiber metal composites in the fixation of skeletal prosthesis. *J. Biomed. Mater. Res.* (Symp.) **4**, 43–61.

Gheysen, G., Ducheyne, P., Hench, L. L. & de Meester, P. (1983) Bioglass composites; a potential material for dental application. *Biomaterials* **4**, 81–84.

Hench, L. L. & Paschall, H. A. (1973) Direct chemical bond of bioactive glass ceramic materials to bone and muscle. *J. Biomed. Mater. Res.* (Symp.) **4**, 25–42.

Hulbert, S. F., Young , F. A., Mathews, R. S., Klawitter, J. J., Talbert, C. D. & Stelling, F. H. (1979) Potential of ceramic materials as permanently implantable skeletal prostheses. *J. Biomed. Mater. Res.* **4**, 433.

Piotrowski, G., Hench, L. L. & Allen, W. C. (1975) Mechanical studies of the bone bioglass Interfacial bond. *J. Biomed. Mater. Res.* (Symp.) **6**, 47–61.

Popov, E. (1978) *Mechanics of Materials*. 2nd Ed. Prentice-Hall, New Jersey.

Rostoker, W., Galante, J. O. & Shen, G. (1974) Some mechanical properties of sintered fiber metal composites. *J. Test. Eval.* **2**, 107–112.

Rønningen, H., Lereim, P., Galante, J. O., Rostoker, W., Turner, T. & Urban, R. (1983) Total surface hip arthroplasty in dogs using a fiber metal composite as a fixation method. *J. Biomed. Mater. Res.* **17**, 2–11.

Simmons, D. J. (1980) Fracture healing. In: *Fundamental and clinical bone physiology* (Ed. Urist, M. R.), pp. 283–330. Lippincott, Philadelphia.

Sokal, R. R. & Rohlf, F. J. (1969) *Biometry*. W. H. Freeman and Co., San Francisco.

Underwood, E. E., Gilbertson, L. N., Hill, D. C. & Hamman, G. T. (1984) Stereological characterization of fiber metal for bone ingrowth. In: *Transactions of the 30th annual meeting of the Orthopaedic Research Society* (Ed. Woo, S. L-Y.) Vol. 9, p. 174. Adept Printing Inc., Chicago.

Wilson, J., Pigott, G. H. & Hench, L. L. (1981) Toxicology and biocompatibility of bioglasses. *J. Biomed. Mater. Res.* **15**, 805–817.