Acta Orthop Scand 57, 285–289, 1986

Osseointegration of titanium implants

Forty-eight screws, six double cylindrical implants and six T-plates were inserted into the tibia or femur of 6 dogs. Two titanium screws were inserted into the proximal tibia of 5 patients to anchor a titanium mould. The implants were removed *en bloc* with adjacent bone tissue after 3 to 14 months. They were sectioned using a technique that allowed analysis of the intact tissue-to-metal specimens. Osseointegration, defined as a direct bone-to-implant contact without interposed soft tissue, was confirmed in all screw-shaped implants while the cylindres had only partial bone contact as did the T-plates. We conclude that osseointegrated implants may be applicable in joint reconstruction for arthrosis or rheumatoid arthritis.

Correspondence: Dr. Tomas Albrektsson, Department of Anatomy, Box 33031, S-400 33, Göteborg, Sweden

Lars Carlsson[1,2]
Tord Röstlund[1,2]
Björn Albrektsson[2,3]
Tomas Albrektsson[1,3]
Per-Ingvar Brånemark[1,3]

From [1]the Laboratory of Experimental Biology, Depts of Anatomy and Handicap Research, University of Gothenburg, [2]the Orthopaedic Department of Mölndal Central Hospital and [3]the Institute for Applied Biotechnology, Gothenburg, Sweden

Introduction

Even if points of direct bone contact have been observed between clinical joint substitutes and skeletal beds (Draenert 1977, Linder & Hansson 1983), it is generally believed that the interface zone, irrespective of the mode of implant fixation, consists of a fibrous tissue layer which permits movements between bone and the foreign device (Charnley 1970, Lord et al. 1979, Ryd 1986). Why some implants fail while others, in spite of interfacial fretting, function well for years is not fully understood. The suggestion that the often reported gradually increasing failure rate with time may be associated with micromotion between the implant and host tissue appears reasonable.

Brånemark and associates (1969, 1977) have shown that load-bearing solid titanium implants in the jaw bone of man can become integrated with a direct contact between bone and titanium and remain so for 20 years or more (Brånemark & Albrektsson 1986). This osseointegrated interface has demonstrated a unique capacity: once established, osseointegration remains with hardly any implant losses with time (Zarb and Albrektsson 1985). Whether such a direct bone-to-titanium contact along the entire implant surface will also occur in the vicinity of the large joints is not known.

We analyzed the tissue reactions to three different types of titanium implants in skeletal sites adjacent to canine and human joints by means of a histological technique capable of producing a detailed overall image of the interface between bone and metallic implants.

Materials and methods

Implant manufacturing. The implants were machined from 99.75 per cent commercially pure titanium in a workshop and cleaned manually and ultrasonically. This controlled manufacturing process ensures the establishment of a defined implant surface geometry with an oxide layer of a thickness of 50–60 Å (Albrektsson 1985).

Experimental implants (Figure 1). Six adult beagle dogs were used for the experiments which were performed under general anaesthesia. Altogether sixty implants of three designs were inserted into the proximal tibial or distal femoral metaphysis, A *screw* (12 mm long, 3.75 mm in diameter) was inserted in a pre-tapped hole (n = 48). A *double cylinder* with an irregular surface (length 24 mm, 8 mm in diameter) was inserted into a preformed defect (n = 6), A *T-*

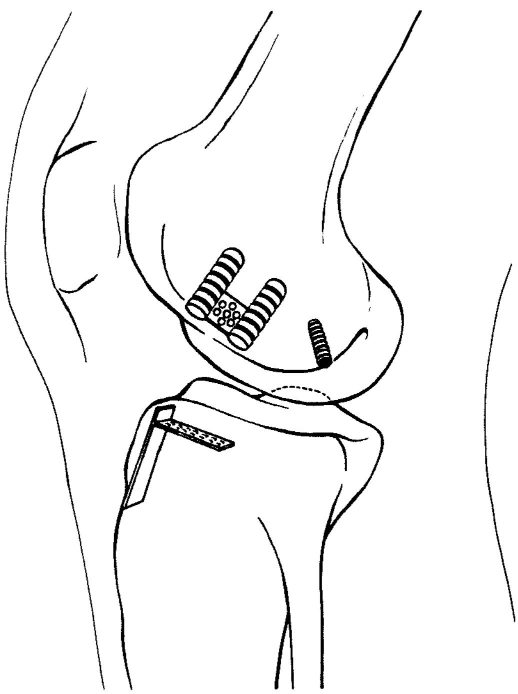

Figure 1. Three implants were used: screw, double cylinder and T-plate.

plate was placed with the transverse part of the T (length 18 mm) on the bone surface, and the 8 mm long shaft was inserted into a preformed slit in the cortical bone (n = 6).

The bone defects through the cortex and into the medullary cavity were prepared with a minimally traumatizing technique including profuse saline cooling and drilling and sawing at rotational speeds less than 100 rpm.

The implants were left in the bone site until the animals were killed, i.e. 15 screws for 3 months, another 15 screws for 14 months, and the remaining implants for 7 months. The animals were allowed full weight-bearing all the time. At the termination of the experiment all implants were removed *en bloc* with the adjacent bone tissue to enable later sectioning of the intact bone-to-metal interface.

Clinical implants. Two titanium screws (9 mm long, 3 mm in diameter) were inserted into the proximal tibial metaphysis of 2 men and 3 women, aged 24–40 years. The screws served to fix a titanium mould which was used for producing ossicular autografts for later transplantation to the middle ear (Tjellström et al. 1978). In the present study, only the interface zone around the fixation screws was examined. Five months after insertion into the human tibia, the screws were removed with a trephine that ensured an intact bone cover around them. All clinical and experimental implants were radiographed after insertion and at the time of removal from the bone.

Preparation of tissue specimens. The intact bone-to-metal specimens were dehydrated and embedded into hard methylmethacrylate plastic. Undecalcified sections of bone and titanium (Donath and Breuner 1982) were cut into a thickness of 100 μm or more with a band saw (Exact, Histolab, Gothenburg, Sweden) using a diamond blade. Thereafter, the sections were ground to 10 μm or less (Struers Scientific Instruments DPU-3, Copenhagen, Denmark). The specimens were stained with toluidine blue and with pyronine-G.

Results

Experimental implants. All implants were clinically stable. There was no discolouration or other tissue reactions surrounding the implants.

Microscopically, the titanium screws were well integrated into bone. At the cortical passage, bone with haversian systems filled the threads of the implants entirely (Figure 2). The threads were evenly surrounded by newly formed bone, with the exception of the tip of one or two threads in three of the implants, where slight bone resorption was noticed. At the level of the cortical passage, there were no signs of soft tissue between bone and titanium, and the screws were all firmly osseointegrated. There were no differences between the level of bone contact after three months and that after 14 months.

Double cylindrical implants showed patches with direct bone contact. However, fibrous tissue was interposed between bone and metal in many places, and the general image was that of a mixed bony-fibrous anchorage. The fibrous tissue coat was 170–250 μm thick (Figure 3).

T-plates likewise showed parts with a direct bone-to-implant contact without fibrous tissue inbetween. In other areas, however, there was soft tissue between bone and implant (Figure 4). The fibrous coat in such cases varied in thickness between 60 and 250 μm. Compared to the screws the bone integration of the plates was poor with fibrous tissue lining about 20 per cent of the plate surface.

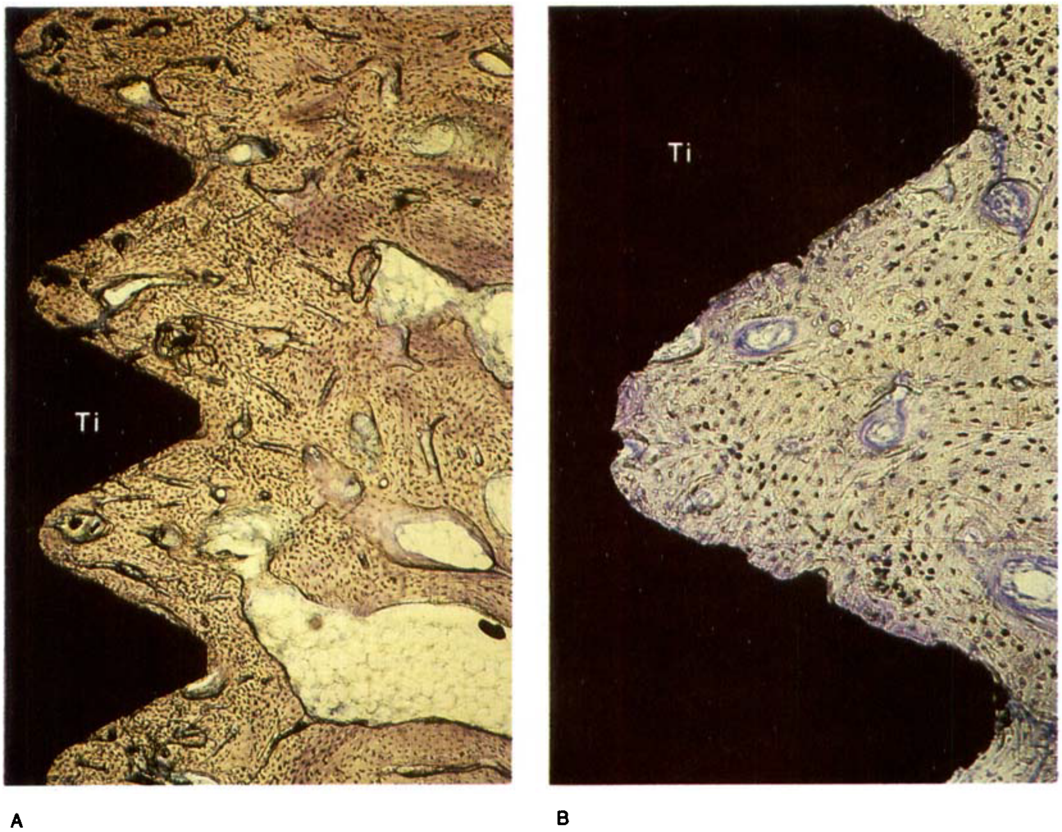

Figure 2. A. Direct contact between bone and Titanium(Ti) on all sides of the screw threads (×10). B. Small irregularities in the Titanium(Ti) surface are anchored in bone which means an improved stability over the interface (×25).

Clinical implants. All ten screws were macroscopically stable in the bone at the time of removal. Intact bone-to-titanium sections revealed direct bone contact without interposed soft tissue (Figure 5). Bone tissue was found anchoring the screws all around their circumference. There was no tendency to varying amounts of bone on any side of the screw thread. In some cases pre-existing bone was observed not yet totally remodelled. This old bone was always separated from the titanium surface by newly formed bone tissue.

Radiographs of clinical and experimental (Figure 6) implants at the time of removal indicated anchoring bone tissue without any radiolucent zone.

Figure 3. Double cylindrical implant with an interface of a mixed pattern with some places with a direct bone-to-implant contact and others with a fibrous tissue coat(*) separating the Titanium(Ti) from the bone (×25).

Discussion

Our experiments demonstrate that direct bone-to-implant contact may be established along the entire circumference of a solid titanium implant in the vicinity of the knee joint in the dog and man. However, it must be observed that we have not tested the implants in a dynamic load situation. Plenk and associates (1984) have recently indicated the possibility of

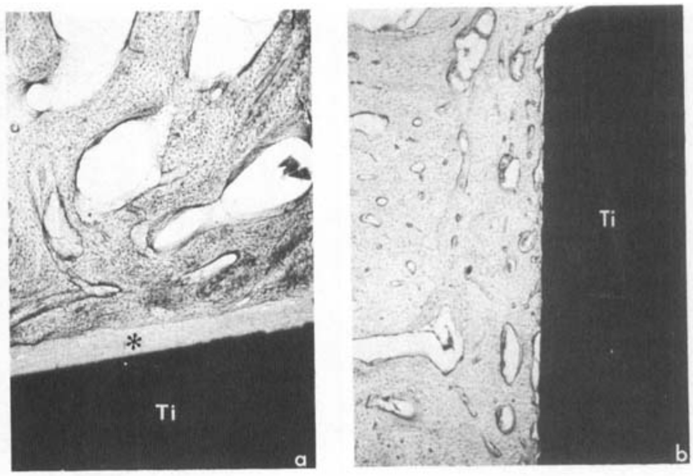

Figure 4. T-plates showing either interposed soft tissue (*) between Titanium(Ti) and bone (a) or evidence of a direct bone-to-metal contact (b). (×25).

establishing overall bone-to-implant contact in experimental hip joint reconstructions where the implants are dynamically loaded. Tantalum or niobium femoral stems were used to replace canine hips over an 18 month period, and there was osseointegration of the devices.

While our threaded implants became osseointegrated, the non-threaded ones showed a more varied picture with patches of bone-to-implant contact interrupted by areas with a fibrous tissue contact. This varied appearance was similar to that seen when bone invades porous fiber titanium composites (Chen et al. 1983, Hedley et al. 1983, Rønningen et al. 1983).

It remains to be determined whether the complete osseointegration of threaded, solid titanium implants in bone adjacent to large joints can resist dynamic loading when coupled to joint substitutes. It also seems mandatory to demonstrate whether direct bone-to-implant contact can be achieved in diseased bone adjacent to large joints. Experience from osseointegrated finger joint substitutes in arthrosis (Hagert et al. 1986) and from successful bone anchorage in the jaw bones of rheumatoid and

Figure 5. Screws inserted 5 months previously in the human tibia with a clear osseous integration and remnants of bone (*) from the time before implantation. (×25).

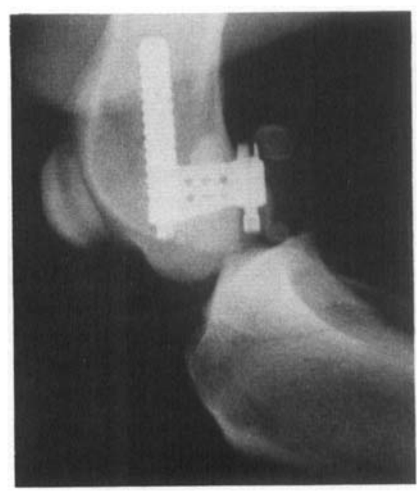

Figure 6. No radiolucent zones are seen around the implant in the knee region of a dog. However, the resolution level of the radiogram does not permit a conclusion whether osseointegration has occurred or not.

osteoporotic patients (Brånemark et al. 1977) indicate that there may be a potential for fixation of large joint substitutes via osseointegrated threaded, solid implants of commercially pure titanium.

Acknowledgements

The advice from Professor K. Donath, University of Hamburg, is gratefully acknowledged. This study has been supported by grants from the Swedish Medical Research Council, The Swedish Board of Technical Development (STU), the Trygg-Hansa Research Foundation, The King Gustaf V Foundation, Greta and Einar Askers Foundation, Å. Wiberg Foundation, the Gothenburg Medical Society and the University of Gothenburg, Sweden.

References

Albrektsson, T. (1985) The response of bone to titanium implants. *CRC Critical Reviews in Biocompatibility* **1**, 53–84.

Brånemark, P-I. & Albrektsson, T. (1986) Osseointegrated dental implants in the treatment of the edentulous jaw. In *Reconstructive preprosthetic oral and maxillofacial surgery*. Ed. by H. Davis and R. Fonseca, W. B. Saunders, Philadelphia, pp. 210–224.

Brånemark, P-I., Breine, U., Lindström, J., Adell, R., Hansson, B-O. & Ohlsson, Å. (1969) Intraosseous anchorage of dental prostheses. I. Experimental studies. *Scand. J. Plast. Reconstr. Surg.* **3**, 81–100.

Brånemark, P-I., Hansson, B-O., Adell, R., Breine, U., Lindström, J., Hallén, O. & Öhman, A. (1977) Osseointegrated implants in the treatment of the edentulous jaw. Experience from a 10-year period. *Scand. J. Plast. Reconstr. Surg.* **11**, 1–132.

Charnley, J. (1970) The reaction of bone to self-curing acrylic cement. *J. Bone Jt. Surg.* **52**-B, 340–353.

Chen, P. O., Turner, T. M., Rönningen, H., Galante, J., Urban, R. & Rostoker, W. (1983) A canine cementless total hip prosthesis model *Clin. Orthop.* **176**, 24–33.

Donath, K. & Breuner, G. A. (1982) A method for the study of undecalcified bones and teeth with attached soft tissues. *J. Oral Pathol.* **11**, 318–326.

Draenert, K. (1977) Histomorphology of the boundary surfaces of bone and acrylic cement. In Scanning Electron Microscopy II. Proc. workshop on biomedical applications-SEM in Medical Prostheses, IIT Research institute, Chicago, IL, 229–238.

Hagert, C-G., Albrektsson, T., Strid, K-G., Irstam, L. and Brånemark, P-I. (1986) Osseointegrated implants for metacarpophalangeal joint prostheses. *Scand. J. Plast. Reconstr. Surg.*, in press.

Hedley, A., Kabo, M., Kim, W., Coster, I. and Amstutz, H. C. (1983) Bony ingrowth fixation of newly designed acetabular components in a canine model. *Clin. Orthop.* **176**, 12–23.

Linder, L. and Hansson, H-A. (1983) Ultrastructural aspects of the interface between bone and cement in man. Report of three cases. *J. Bone Jt. Surg.* **65**-B, 646–649.

Lord, A. G., Hardy, J. R. and Kummer, F. J. (1979) An uncemented total hip replacement. Experimental study and review of 300 Madreporique arthroplasties. *Clin. Orthop.* **141**, 2–16.

Plenk, H., Pflüger, G., Böhler, N., Gottsauner-Wolf, F., Grundschober F. and Schider, S. (1984) Long-term anchorage of cementless tantalum and niobium femoral stems in canine hip-joint replacement. In *Biomaterials and Biomechanics* (Ed. Ducheyne, P., van der Perre, G. & Aubert, A. E., pp. 61–66. Elsevier Science Publishers B.V., Amsterdam.

Ryd, L. (1986) Micromotion in knee arthroplasty. A roentgen stereophotogrammetric analysis of tibial component fixation. *Acta Orthop. Scand.* **57**, Suppl. 220.

Rønningen, H., Lerheim, P., Galante, J., Rostoker, W., Turner, T. & Urban, R. (1983) Total surface hip arthroplasty in dogs using a fiber-metal composite as a fixation method. *J. Biomed. Mat. Res.* **17**, 643–653.

Tjellström, A., Lindström, J., Albrektsson, T., Brånemark, P-I. & Hallén, O. (1978) A clinical pilot study on preformed autologous ossicles II. *Acta Otolaryngol. (Stockh)* **85**, 232–242.

Zarb, G. & Albrektsson, T. (1985) The nature of an attachment. In *Osseointegration in Clinical Dentistry*, Ed. Brånemark, P-I., Zarb, G. & Albrektsson, T., pp. 89–98. Quintessence, Chicago.