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Implant fixation improved by close fit

Cylindrical implant – bone interface studied in rabbits

Lars Carlsson[1,2], Tord Röstlund[1,2], Björn Albrektsson[1,2] and Tomas Albrektsson[2,3]

Cylindric titanium implants of three different diameters were inserted and stabilized in a 3.7-mm burr hole in the rabbit tibia. The purpose of the study was to investigate the interfacial reaction to screw- and cylinder-shaped implants, and to determine if there is a critical gap at the insertion between bone and implant that prevents direct cortical bone apposition on the implant. The study indicated that this critical gap approached zero.

Most reports on bone ingrowth relate to fixation of porous implants (Clemow et al. 1981, Hedley et al. 1983, Rønningen et al. 1983), whereas there have only been a few attempts to evaluate variables that determine the interfacial response to screw-shaped implants (Carlsson et al. 1986, Johansson and Albrektsson 1987).

We have examined whether there is a critical gap between bone and solid implants in the case of external stabilization, which cannot be bridged by bone, but results instead in a soft-tissue interface. The interfacial response to screw-shaped implants was included in the study.

Material and methods

A test model was developed to evaluate the interfacial tissue response to each of three different initial gap widths between implants and host bone sites in 18 tibiae of 9 rabbits. An implant device was constructed of commercially pure (c.p.) titanium, designed to ensure primary rigid fixation and reliable centralization of transcortical cylinders inserted into burr holes in the proximal tibia (Figure 1). Each burr hole had a diameter of 3.7 mm. The implant consisted of a plate with two holes for fixating screws and one threaded hole for the implant to be studied. This central implant was screwed through the plate; the part of the implant transversing the cortical layer beneath the plate was machined to one of three different diameters: viz., size A: 3.7 mm, size B: 3.0 mm, and size C: 2.0 mm (Figure 1). All the implants were cleaned in butanol and ethanol in an ultrasonic bath and autoclaved before implantation.

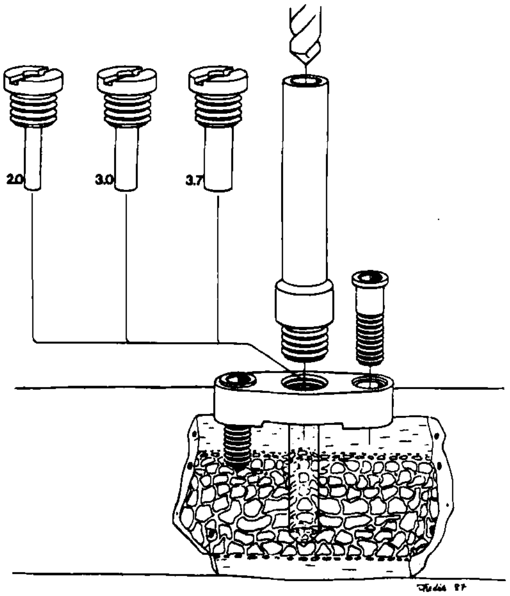


Figure 1. The surgical procedure. The plate was anchored firmly to the bone by two side screws. To ensure exact positioning of the central hole, a long drill guide was used. One of the three implant sizes A (3.7 mm), B (3.0 mm), or C (2.0 mm) was then inserted into the central hole.

[1]Department of Orthopedics, Mölndal Hospital, [2]Biomaterials Group of the Department of Handicap Research, and [3]Laboratory of Experimental Biology, Department of Anatomy, University of Gothenburg, Sweden

Correspondence: Dr. Lars Carlsson, Department of Handicap Research, Brunnsgatan 2, S-413 12 Gothenburg, Sweden

Each animal received one implant set in each tibia. The operations were performed under anesthesia under aseptic conditions, and no antibiotics were given. The proximal medial metaphysis was exposed through an anterior incision of skin and fascia. The periosteum was incised at the posterior border of the tibial metaphysis and lifted anteriorly, laying bare the flat proximal medial tibial metaphysis. The plate was anchored firmly to this flat surface of the tibia (parallel to the long axis of the bone) by two screws through the side holes. Thereafter, a drill guide was mounted in the central hole of the plate, and a 3.7-mm hole was drilled through the underlying cortex extending into the medulla (Figure 1). During drilling the bone was cooled by profuse saline irrigation. One of the cylinders (A, B, or C) was screwed into the central hole of the plate, the cylindric part of the implant passing through the hole in the cortex, centralized and firmly stabilized in the plate. Size-A cylinders had a perfect fit in the cortical defect, and had an initial bone-to-metal contact. With size-B cylinders, there was an initial gap between bone and metal of 0.35 mm; and with size-C cylinders, there was a gap of 0.85 mm. The fascia was sutured to the periosteal flap with Dexon®, and the skin was closed with interrupted Dexon®. No external bandage was used, and there were no restrictions of postoperative movements. Seven animals with 5 size-A, 4 B, and 5 C cylinders were killed after 6 weeks, and 2 animals with 4 size-B cylinders were killed after 12 weeks.

The proximal tibia with the implant in situ was removed en bloc. The specimens were dehydrated and embedded in hard methylmethacrylate plastic. The undecalcified specimens of bone and titanium were cut using a band saw with a diamond blade according to the procedure described by Donath and Breuner (1982). Cuts were made in the long axis of the plate through the center of the cylinders and side screws. The cut sections of 100 microns were then ground to a thickness of 10 microns or less (Struer's Scientific Instruments DPU-3, Copenhagen, Denmark). The specimens were stained with toluidine blue and gentiana. The interfacial tissue reaction was studied with a light microscope permitting photorecording with a video camera. Using a computer-based system, a morphometric assessment of the osteogenic response around the implants was performed. The surface area of lamellar bone appositioned to the metal of the cylinders and the screws was calculated.

Results

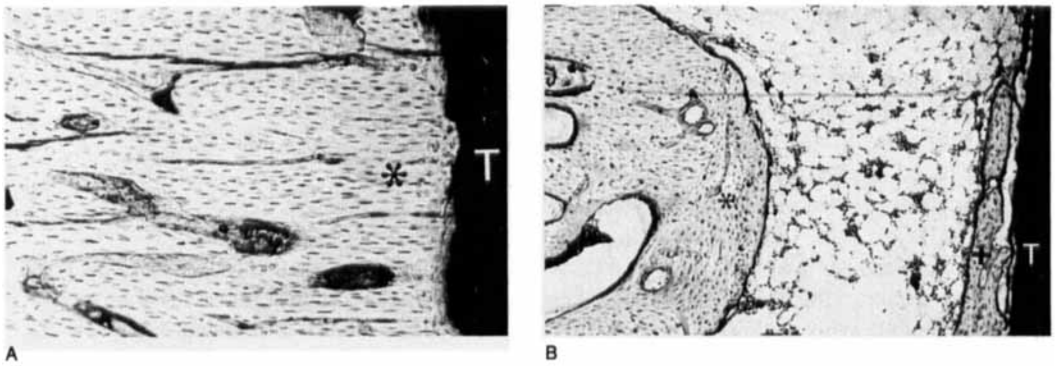
All the implants were clinically stable. No macroscopically observable adverse tissue reactions were seen around the implants, nor were there any microscopically identifiable inflammatory reactions.

All the size-A implants had a direct bone-to-implant contact without any intervening soft tissue at the level of the cortical passage (Figure 2).

One of the size-B 6-week implants displayed direct bone apposition at the cortical level, whereas the remaining three had a gap between the cortex and implant of 0.15 to 0.39 mm; the mean for all B implants was 0.22 mm. Some of the implants manifested small areas of trabecular bony contact, but there was no cortical bone bordering the titanium. The edges of the cortical bone without direct metal contact had rounded edges with no evidence of osteoblastic activity. After 12 weeks the situation was similar to the 6-week animals: Two size-B implants had a direct cortical bone-to-metal contact on one side of the cylinder and a gap on the other. The remaining two implants in this group had a gap between 0.23 and 0.51 mm. There were no signs of osteoblastic activity by the cortical bone approaching the interface gap.

There were no size-C implants that had direct bone-to-implant contact. There were some small areas with apparent trabecular implant attachment, but without any cortical connection. The mean gap between cortical bone and metal was 0.54 (0.17–0.80) mm. No osteoblastic activity could be seen at the rounded edges of the cortical bone.

All the titanium screws used to anchor the titanium plates, which in turn stabilized the central cylinders, had a direct bone-to-metal contact at the level of the cortical passage, with a ratio of apposition of cortical bone to the metal of 90 percent or more. The screw surface areas at the cortical passage were approximately 30 percent larger than that of the cylinder.



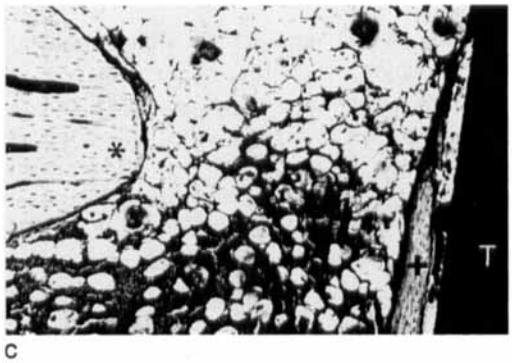


Figure 2. Histology of the cylindric central implants and adjacent tissue (X 220).
A. 3.7-mm implant with direct contact between the cortical bone (*) and titanium (T).
B. 3.0-mm implant with interposed soft tissue between the cortical bone and titanium. Trabecular bone (+) approaches the implant surface.
C. 2.0-mm implant, a wide gap with interposed soft tissue between the cortical bone and titanium, and trabecular bony contacts can be seen.

Discussion

Several variables influence implant fixation by bone growth. Among these, some are interrelated, such as the surgical fit, on the one hand, and the primary stabilization of the implant, on the other; an accurate surgical fit is thought essential. An attempt to evaluate the importance of the surgical fit necessitates a control of other factors influencing implant fixation. Our test model offers a possibility to evaluate the critical gap at insertion of a bone implant by providing control of relative motion between implant and host independently of the degree of surgical fit.

The occasional presence of bone trabeculae may in the two groups with gaps of 0.35 and 0.85 mm indicate that the lower of these values is close to the critical gap width for direct lamellar bone apposition to unloaded implants. Under physiologic loading conditions, such as those when a clinical implant is allowed to carry full weight bearing soon after its insertion, the critical gap for direct apposition of lamellar bone may well be even smaller (Cameron et al. 1973, Uhtoff 1973, Schatzker et al. 1975).

It seems reasonable to assume that a clinical bone implant with a good, but not exact surgical fit, may be fixed by partial bony ingrowth during the first 12 weeks after insertion, but that only a patchy direct contact between implant and bone is feasible. An exact surgical fit may, if stabilization is adequate, allow for fixation by appositional bone lamellae along the entire implant surface (Brånemark et al. 1969). Adequately inserted tightened threaded implants will be a better guarantee for an exact surgical fit than is the case with impacted implants, as indicated by the findings of Carlsson et al. (1986) and Johansson and Albrektsson (1987). Screws may therefore achieve a more complete bone-to-implant contact in comparison with other designs. The direct bone fixation of the screw is further enhanced by the larger surface area.

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