

# Hydroxyapatite coating enhances fixation of porous coated implants

## A comparison in dogs between press fit and noninterference fit

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Intimate contact at the bone-porous surface interface is not always achievable in noncemented prosthetic implantation. We investigated the effect of hydroxyapatite (HA) coating on skeletal attachment in noninterference fit 4 weeks after implantation in 6 mature dogs. The push-out test of HA-coated implants surrounded by a 1-mm gap showed a twofold increased shear strength and fivefold increased shear stiffness compared with titanium alloy (Ti) coated implants. The fixation of Ti implants was reduced by two thirds when inserted in a gap as compared with press fit, whereas HA-coated implants in gap showed anchorage close to implants in press fit. Only minor differences were found between HA and Ti implants in press fit. Histomorphometric analysis showed a significant increase in bone in direct contact to HA-coated implant as compared with Ti implants inserted both in gap and press fit. The study indicates that tightness of surgical fit is an important factor for sufficient fixation of the implant. However, our results demonstrate that hydroxyapatite coating almost eliminates the negative influence of noninterference fit between bone and unloaded implant.

The quantity of bone ingrowth into porous-coated implants depends, among other factors, on the interference fit obtained with the surrounding bone (Albrektsson and Albrektsson 1987, Cameron et al. 1976, Carlsson et al. 1988a, Harris et al. 1983, Sandborn et al. 1988). In the clinical situation, however, direct apposition of implant to bone is not always achievable (Bobyn and Engh 1984, Engh et al. 1987,

Schimmel and Huiskes 1988). Lack of optimal flatness after bone cutting, implant design deficiencies, and anatomic variations may result in gaps between the implant surface and surrounding bone (Albrektsson and Albrektsson 1987, Larsen and Ryd 1990).

Calcium phosphates in the form of granules have been employed to fill in gaps between bone and implant with no demonstrable effect on bone ingrowth at early time periods (Eschenroeder et al. 1987, Rusotti et al. 1986). Recently, deposition of dense hydroxyapatite (HA) on titanium alloy (Ti) by plasma spraying technique has been shown to improve the HA-metal substrate interface shear strength (Geesink et al. 1988, de Groot et al. 1987, Thomas et al. 1987). HA coating provides earlier bone ingrowth compared with Ti (Geesink et al. 1988, de Groot et al. 1987, Søballe et al. 1989a, b, c, Thomas et al. 1987).

We examined the effect of HA coating on skeletal attachment of unloaded porous titanium implants inserted in noninterference fit compared with press fit insertion.

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## Material and methods

**Experimental design.** Six skeletally mature labrador dogs of both sexes weighing 28 (22-31) kg comprised the material. Ti- and HA-coated implants were inserted in press fit or in noninterference fit in the distal femoral condyles. The dogs were killed after 4 weeks and the results were evaluated by the mechanical push-out test and histomorphometric analysis.

**Bone-density measurements.** To investigate bone density at implantation site, CT scanning of the distal femora was performed 1 week before surgery as previously described (Søballe et al. 1989d) and recorded 10 mm proximal to the distal end of the femoral epiphysis at the site of later implantation. The CT scans were obtained with the EMI 7070 scanner and performed under general anesthesia (Immobilon vet., Pharmacia AS, DK-3400 Hillerød).

**Surgery.** The operations were performed under general anesthesia. The implantation sites were exposed by separate incisions through the lateral and medial capsule and defined immediately proximal to insertion of the lateral/medial collateral ligament on the femoral condyle. The periosteum was retracted only from the area to be perforated by the drill. Initially a 1.5-mm pilot hole was created and expanded by a drill with the final diameter. On the lateral side the holes were drilled 0.4 mm undersize to ensure a press fit of the implants that was hammered firmly in place. On the medial side the holes were drilled 2 mm larger in diameter than the diameter of the implant accounting for the thickness of the HA coating, permitting a 1-mm gap surrounding the implants, which were centralized by two titanium spacers fixed at each end of the implant. The implants were inserted perpendicular to the long axis of the femur. Soft tissues were closed in a routine manner, and prophylactic antibiotics were administered for 3 days starting 1 hour preoperatively.

Immediate postoperative mobilization and unrestricted weight bearing were allowed. The animals were killed 4 weeks after implantation. All the animals recovered well from surgery without infection. Bacterial cultures from the implantation site and synovial fluids, obtained immediately after the dogs were killed, were all negative. Ten and 3 days before killing, the dogs were tetracycline double labeled by i.v. administration of chlortetracycline (Dumocyclin®, Dumex, Copenhagen), 15 mg per kg (Frost 1983) for bone histomorphometry.

**Allocation.** Ti plasma spray coated cylinders were inserted into both condyles of the right femur, whereas HA-coated implants were inserted on the left side. CT scanning before surgery showed that

Table 1. CT values (HU) measured immediately prior to surgery centrally in the femoral condyles in 6 mature dogs. Mean SEM

Knee	Condyle	CT value	
Right	lateral	491	32
	medial	534	27
Left	lateral	453	31
	medial	511	32

Number of paired differences = 6.

bone density in the identical condyles in the right and the left knee was approximately equal, the density being higher medially than laterally (Table 1).

**Implants.** The two types of implant coatings used were HA and Ti (Biomet Inc. USA). The cylindrical Ti-coated plugs were 5.9 mm and the HA-coated implants 6.3 mm in diameter with an overall length of 10 mm. Ti implants consisted of a Ti-6Al-4V alloy core with a coating of Ti-6Al-4V deposited by plasma-spray technique resulting in a mean pore size of 300 (200-1000)  $\mu$ . The HA-coated implants consisted of analogous porous Ti-coated implants on which a 150-200- $\mu$  layer of spray-dried synthetic HA (Ca/P ratio 1.65) was deposited by the plasma-spray technique. The coating was identified as hydroxyapatite by x-ray diffraction analysis containing a small portion of tricalcium phosphate. The implants were sterilized with gamma irradiation.

**Preparation.** The distal femora were excised, radiographed in AP and lateral planes, and stored at -20 °C for 2 weeks. Sections orthogonal to the long axis of the implant were made on a water-cooled diamond band saw (EXAKT-Cutting Grinding System, EXAKT Apparatebau, 2000 Norderstedt, West Germany). The first cut was made 3 mm below the cortical surface. The first section was 3 mm thick, providing a specimen for mechanical testing. The second section was 150  $\mu$  thick and prepared for histologic evaluation. The third section was 3 mm thick and prepared for histomorphometric evaluation on ground-stained specimens. Specimens for histologic evaluation were preserved in 70 percent alcohol for approximate 6 weeks. Specimens for mechanical testing were stored at -20 °C for 1 week.

### Histologic evaluation

**Mineralizing surfaces.** On unstained and undemineralized 150- $\mu$ -thick sections, mineralizing bone in direct contact with the implant surface was recorded.

Table 2. Results from the push-out test. Mean SEM

	Ultimate shear strength (MPa)				Apparent shear stiffness (MPa/mm)				Energy absorption (J/m)			
	Nonint. fit		Press fit		Nonint. fit		Press fit		Nonint. fit		Press fit	
HA	5.73	0.8 *	6.57	0.4	65.6	17.6 *	62.3	9.3	18.3	3.0 *	20.0	1.6
Ti	2.60	0.7 **	7.04	0.7	12.5	4.2 **	52.2	8.5	7.8	1.7 **	24.0	3.0
Ratio HA/Ti	2.2	0.6	0.93	0.08	5.2	1.6	1.2	0.3	2.3	0.9	0.83	0.1

Number of paired differences = 6.

\* Hydroxyapatite coating significantly different from titanium ( $P < 0.05$ ).

\*\* Noninterference fit significantly different from press fit ( $P < 0.01$ ).

The examination was performed blindly by fluorescence microscopy at 100 $\times$  magnification using linear-intercept technique (Revell 1986) with a Zeiss integrating plate with 10 grid lines. The number of intersections with tetracycline-labeled bone at the implant surface were counted. Recording was based on successive adjacent fields around the whole implant surface, i.e., 30 different locations, and an estimate of the percentage of the implant surface occupied by mineralizing surfaces was obtained.

**Bone ingrowth.** Specimens for grinding were dehydrated in graduated ethyl-alcohol solutions from 70 to 99 percent containing 0.4 percent basic fuchsin (Gofredsen et al. 1990). The sections were then embedded in methylmetacrylate and ground to approximately 50  $\mu$  using a microgrinding system (EXAKT-Micro Grinding System) and counterstained with 2 percent light green for 15 min to allow quantitative histologic evaluation of fibrous-tissue distribution and bone-to-implant apposition using transmitted light microscopy at 100 $\times$  magnification. The procedure was performed blindly and in random order using linear intercept technique (Revell 1986) with a Zeiss integrating plate with 10 grid lines mounted in the eyepiece of the microscope. The number of intersections with bone or fibrous connective tissue in direct contact with the implant surface were counted. Measurements were made on successive adjacent fields along the entire implant circumference. Approximately 300 test points were evaluated for each implant, and an estimate of the percentage of the implant surface in contact with bone or fibrous tissue was obtained.

### Mechanical testing

The push-out test was performed with a Instron test machine. The specimens were placed on a metal platform with a central circular opening supporting

the bone to within 500  $\mu$  of the interface. A metal rod was placed in the upper holding device for the axial push-out test of the implant from the surrounding trabecular bone. A displacement rate of 5 mm/min was used for all the tests, and load-deformation curves were obtained by an X-Y recorder. Ultimate shear strength, apparent shear stiffness, and energy absorption were estimated from the load-displacement curves as previously described (Søballe et al. 1990c).

**Statistics.** From all the parameters, the mean values and standard error of the mean (SEM) were calculated. Differences were considered statistically significant when the  $P$ -value (Student's paired  $t$ -test) was less than 0.05.

## Results

**Mechanical testing.** Titanium-implant fixation was reduced by 65 percent when inserted in a gap as compared with press fit, whereas only slight reduction was obtained using hydroxyapatite coating (Table 2). No difference in shear stiffness was found between HA implants inserted in press fit and gap, respectively. Surrounded by initial gap, the bone-implant interface shear strength of hydroxyapatite implants was increased by 120 percent as compared with titanium implants. The corresponding value for shear stiffness was 425 percent. Minor differences were found between HA and Ti implants inserted in press fit. Correcting for variation in bone density at implantation site did not influence the results.

The failure at testing occurred predominantly at the bone-implant interface, but small amounts of bone on both implant types were observed in the microscope following the push-out test. No failures were observed at the HA-Ti alloy substrate interface or in the HA coating.

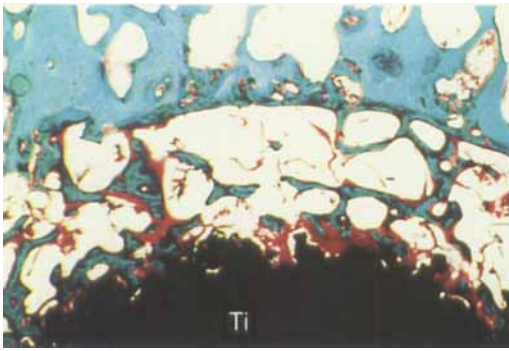


Figure 1. Microphotograph from a titanium alloy-coated implant initially surrounded by a 1-mm gap. Note the border of the drill hole and the limited amounts of bone (green) bridging the gap and fibrous tissue (red) separating the implant from the newly formed bone. Basic fuchsin and light green;  $\times 25$ . Ti = titanium.

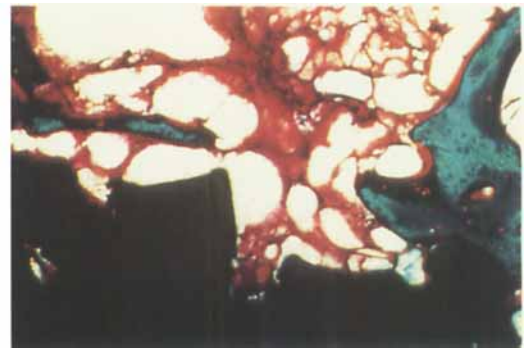


Figure 2. Close-up view of Figure 1 showing areas with fibrous tissue between bone and implant and other areas with bone-to-implant contact. Basic fuchsin and light green;  $\times 100$ .

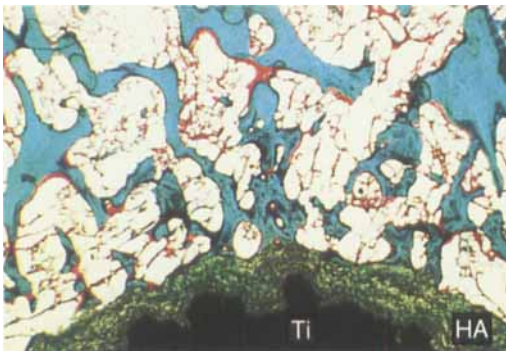


Figure 3. Microphotograph from hydroxyapatite-coated specimen initially surrounded by a 1-mm gap. Note the great amount of newly formed bone bridging the initial gap compared with the titanium-coated implant in Figure 1. Basic fuchsin and light green;  $\times 25$ . HA = hydroxyapatite, Ti = titanium.

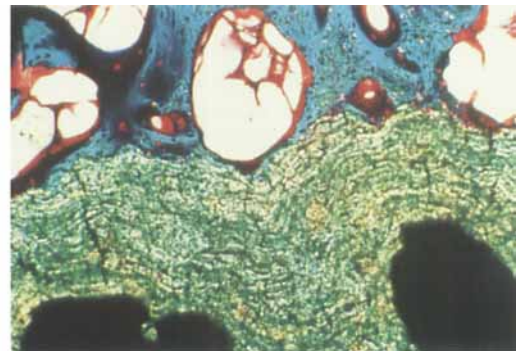


Figure 4. Close-up view of Figure 3 showing intimate contact between bone and hydroxyapatite surface without interposed fibrous-tissue layer present. Basic fuchsin and light green;  $\times 100$ .

Table 3. Percentage of mineralizing bone in direct contact with implant surface. Mean SEM

	Noninterference fit		Press fit	
Hydroxyapatite	31	1.2 <sup>***a</sup>	31	1.3 <sup>***a</sup>
Titanium	15	1.3 <sup>**b</sup>	21	1.3
Ratio HA/Ti	2.1	0.2	1.5	0.1

Number of paired differences = 6.

<sup>a</sup> Hydroxyapatite coating different from titanium.

<sup>b</sup> Noninterference fit different from press fit

\*\*  $P < 0.01$ , \*\*\*  $P < 0.001$ .

**Histologic analysis.** Mineralizing surfaces in direct contact with the HA coating were increased as compared with Ti when the implants were inserted in gap and press fit (Table 3). Ti implants inserted in gap had reduced mineralizing surfaces in direct con-

tact with the implant as compared with press fit, whereas HA-coated implants in gap obtained equivalent amounts of mineralizing bone as compared with press fit. These quantitative histologic data support the mechanical testing except for the increased mineralizing surfaces of HA-coated implants in press fit as compared with Ti-coated devices, where no significant difference in push-out test was found.

The gaps were bridged by very limited amounts of immature woven bone around Ti implants (Figures 1 and 2), whereas a great amount of newly formed bone filled the gap around HA-coated implants (Figures 3 and 4). Bone tissue was observed directly on the HA-implant surface with no interposed fibrous-tissue layer present. In some areas a thin fibrous layer separated the Ti implant surfaces from the ingrown bone, but in most areas direct apposition of bone was noted.

Table 4. Bone ingrowth as the percentage of bone in direct contact with the implant surface. Mean SEM

	Noninterference fit		Press fit	
Hydroxyapatite	40	3.4 <sup>****a</sup> <sup>***b</sup>	60	2.4 <sup>****a</sup>
Titanium	7	2.5 <sup>**b</sup>	25	3.2
Ratio HA/Ti	5.7	0.9	2.4	0.35

Number of paired differences = 6.

<sup>a</sup> Hydroxyapatite coating different from titanium.

<sup>b</sup> Noninterference fit different from press fit

\*\*  $P < 0.01$ , \*\*\*  $P < 0.001$ .

The greatest amount of bone ingrowth was found at the HA-coated implants inserted in press fit, which was increased as compared with HA-coated implants surrounded by a gap which again was greater than Ti implants in press fit (Table 4). The smallest amount of bone ingrowth was found at Ti implants surrounded by initial gap.

## Discussion

The importance of surgical fit between implant and bone has been studied by Carlsson et al. (1988a), who found that even minor gaps (0.35 mm) around stable, smooth, commercial pure Ti cylinders were not bridged by bone and that the critical gap was close to zero. In contrast, our results showed that HA coating almost eliminated the negative influence of an initial gap between bone and implant. HA augmented the formation of hosting bone into the implant resulting in earlier and stronger skeletal fixation approximating that of implants with a tight initial press fit. A possible explanation for the increased speed of gap healing is that within a few weeks, a bone plate is formed on the HA surface. Further filling of the gap then proceeds from two ossification fronts, one from surrounding bone toward implant, the other from implant-covering bone plate toward surrounding bone. This phenomenon probably does not take place in the press-fit situation because of the initial intimate contact between bone and implant. Recently, Brown et al. (1989) showed that bone ingrowth occurs via direct bone formation in mechanically stable porous-coated implants inserted in press fit.

The equivalent shear strength of the press fit inserted Ti- and HA-coated implants indicate a relatively stronger bonding between bone and HA, because the surface area of the HA-coated implants

is much smaller than the porous-coated Ti implants. This might explain equal fixation of HA and Ti-coated implants in press fit despite the presence of relatively more bone on the HA-coated implant. Another explanation for the absence of increased mechanical strength by the relatively higher bone ingrowth and active mineralizing surfaces at HA-coated implants in press fit might be that maturation of bone was still incomplete. Recently, Barth et al. (1986) reported that strength of the interface depends on the maturation of the mineralized bone matrix of the ingrown trabeculae. In the present study the ingrown bone was still immature.

The amount of press fit differs in different studies on HA coating; it seems that this variable partly determines the effect obtained by hydroxyapatite. Geesink et al. (1987) studied the effect of HA in slightly oversized transcortical bone defects (drill hole 4.7 mm, implant diameter 4.5 mm) and obtained very strong fixation as compared with uncoated smooth titanium controls. Thomas et al. 1987 used a *slight press fit* (drill hole 5.95, implant diameter 6.0) of macrot textured transcortical implants and reported up to 95 percent increments in fixation of HA-coated implants after 5 weeks. Using similar *slight press fit* (0.05 undersized holes) for insertion, Cook et al. (1988) found no increased anchorage of HA-coated transcortical implants compared with porous-coated Ti-alloy implants. Rivero et al. (1988) used a *tight press fit* (drill hole 9 mm, implant 10 mm) and found only 24 percent increased fixation of intramedullary implants after 4 weeks and no effect after observation periods of 1, 2, and 6 weeks. Our findings correspond well with Rivero et al. (1988) in that no mechanical effect of HA was obtained in the implants in *tight press fit* (0.4-mm undersized holes), whereas a twofold increased fixation was attained in the gap situation. However, differences in purity of HA, Ca/P ratio, surface texture, surface on control implants, and the testing conditions might also be responsible for the differences in fixation.

Comparing the present data with those of others, it must be emphasized that different types of surface coatings have been used as controls. Geesink et al. (1987) used uncoated smooth titanium implants as controls and Thomas et al. (1987) used macroscopic grooved-configuration implants without porous-coating. In contrast, the control implants used by Rivero et al. (1988) consisted of fiber-metal porous surfaces, which presumably may be considered similar to the porous plasma-sprayed controls used in the present study in terms of anchorage capacity. Using porous-surfaced controls instead of smooth-surfaced controls, skeletal fixation is increased,

which again increases the demands on the osteoconductive effect of the relatively smooth surfaced hydroxyapatite implant; the opposite is true for smooth-surfaced controls (Skalak 1983, Carlsson et al. 1988b, Thomas and Cook 1985).

Taking these facts into consideration, one would expect a reduced fixation of the relatively smooth HA-coated implants as compared with the porous-coated implants. However, the shear strength obtained by HA (5.7 MPa) in presence of a gap between bone and implant was stronger than Ti (2.6 MPa) and may be explained by chemical bonding between bone and HA (Jarcho 1981). The possible explanation of the chemical bonding between HA and bone is the presence of calcium and phosphate compounds, which participate in calcium phosphate solid-solution equilibria at their surfaces resulting in crystallization on the surface of the HA (Jarcho 1981). The HA will become coated with a microscopic layer of biologic apatite (bone-mineral coating) shortly after implantation in bone, which appears to coincide with the first appearance of acellular bone matrix from differentiating osteoblasts (Jarcho 1981).

The measurable effect of HA coating on bone implant fixation is temporary. Ducheyne et al. (1980) found a far greater amount of bony ingrowth after 2 and 4 weeks with the HA-impregnated samples. However, the amount of ingrown tissue equalized with values observed without hydroxyapatite coating by 12 weeks. This is in agreement with Thomas et al. (1987), who found an equivalent attachment strength for HA-coated implants in one half the time required for the uncoated implants, but the difference over time diminished after 10 weeks. After 3 weeks, they noted stiffness values three times that of uncoated implants which is in agreement with our findings after four weeks indicating an earlier, more rapid fixation using HA. The stimulatory effect is short term, but clinically important because, with an increased rate of bone ingrowth, weight bearing might be allowed much earlier. This reduces the recuperation period and the risk of developing fibrous connective tissue around the implant (Ducheyne et al. 1977, Heck et al. 1986) caused by micromovements (Cameron et al. 1973, Uthoff 1973, Schatzker et al. 1975, Søballe et al. 1990).

Attachment of plasma-sprayed apatite coating on smooth titanium implants has been reported to be 85 MPa in tensile strength (de Groot et al. 1987), which is equivalent to the strength of cortical bone (Carter and Sprengler 1978). However, information regarding the strength between HA and substrate after long-term implantation has not been reported.

Other investigators have reported experimental failures between HA and metal substrate 32 weeks after implantation (Thomas et al. 1987). The failures appeared at 12 MPa load which was less than the in vitro measured strength of HA-substrate bond (17 MPa) prior to implantation (Thomas et al. 1987) and might suggest a weakening of HA substrate bond strength in the physiologic environment. However, these failures only occurred on the crest of the grooves on the implant, which might indicate that implants should be designed to protect the HA coating to be pulled off the metal under applied loads (Thomas et al. 1987). This was the rationale for depositing HA on implants with a porous coating, which will increase the contact area between metal substrate and HA, and furthermore result in a rough surface on the HA-coated implant. An increased surface area increases the contact area with adjacent bone and thereby the mechanical fixation of the implant. However, a thinner coating is necessary to avoid obstruction of the pores in the Ti coating, which occurred in our implants. There is general acceptance that a 50-75  $\mu$  coating is preferable due to lesser risk of HA fracture and preservation of porous structure of the implant surface, but thicker coatings have also been recommended (Osborn 1987).

In conclusion, the tightness of "surgical fit" appears to be an important factor for fixation of the implant. However, hydroxyapatite coating apparently eliminates the negative influence of noninterference fit between bone and implant.

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