Improved fixation of porous-coated versus grit-blasted surface texture of hydroxyapatite-coated implants in dogs

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We inserted, in 8 dogs, implants with either porous-coated or grit-blasted titanium surface and coated with hydroxyapatite (HA) into trabecular bone in the proximal humerus, using a 1 mm gap model. After 25 weeks, push-out tests showed that energy absorption for porous-coated implants was twice that of grit-blasted implants, whereas shear stiffness was reduced by one fifth, indicating a stronger fixation of porous-coated implants. Macroscopically, all grit-blasted implants had delamination of the HA coating, whereas porous implants failed mostly at the HA-tissue interface. Porous-coated implants had 47% bone ingrowth and grit-blasted implants 70% (p = 0.02), however, no difference in absolute surface area was found. Part of the HA coating was resorbed during the implantation period as regards volume and thickness. HA coverage was more reduced on porous-coated than on grit-blasted implants (p = 0.01). No foreign-body reaction or osteolysis was seen. An important finding was that one fifth of the surface with complete resorption of HA coating was replaced by newly formed bone.

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No consensus has been reached whether hydroxyapatite (HA) should be coated on a grit-blasted or a porous-coated substrate surface and questions about long-term performance have been raised (Søballe and Overgaard 1996). In this experimental study, we evaluated the effects of implants with porous-coated or grit-blasted titanium surface coated with HA on mechanical fixation, bone ingrowth, and resorption of HA coating.

Material and methods

Study design

Non-weight-bearing HA-coated implants were inserted bilaterally into 8 mongrel dogs, using a 1-mm gap model for a period of 25 weeks (Figure 1). The implants had either a porous-coated or a grit-blasted surface and were randomly allocated to the right or left proximal humerus (Figure 2). The dogs had an average age of 10 months, an average weight of 25 kg and were skeletally mature. 6 non-implanted porous-coated and 6 grit-blasted implants served as controls for evaluation of surface roughness and resorption of the HA coating.

Implants

The implants were made of titanium alloy (Ti-6Al-4V) and were manufactured by Biomet® Inc (Warsaw, IN, USA). The porous coating was plasma-sprayed and had a mean pore diameter of 480 µm and a porosity of 44%, as determined by the manufacturer. The grit-blasted implants were blasted with #30 grit aluminum oxide. All implants were cylindrical in shape and had a length of 10 mm and a final diameter of 6 mm (Figure 2).

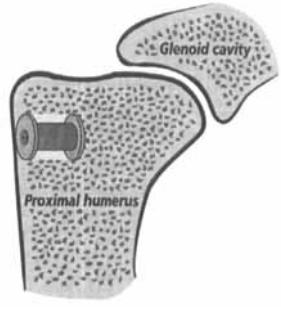
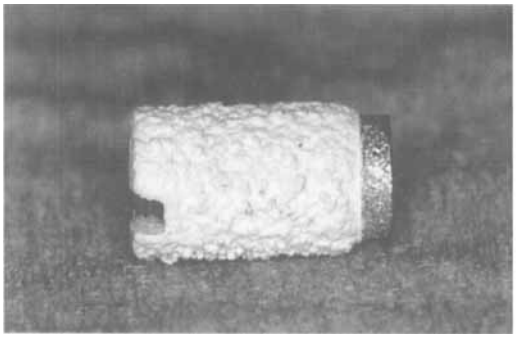
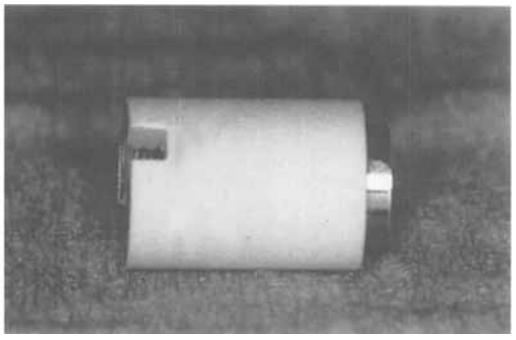


Figure 1. The gap model. The implant is inserted into trabecular bone of the proximal humerus in a stable position. Initially, the implant is surrounded by a 1-mm gap secured by two washers and a screw.

Figure 2. Test implants (6 x 10 mm).



Porous-coated implant.



Grit-blasted implant.

The HA coating was plasma-sprayed by BioInterfaces, Inc. (San Diego, CA, USA). Surface roughness (R_a) of the HA-coated implants was 30 (21–41) µm for porous-coated implants and 3.0 (2.9–3.8) µm for grit-blasted implants. Crystallinity, Ca/P ratio, and purity of the coating were determined by X-ray diffraction analysis, performed by the manufacturer. Crystallinity was found to be 68% and more than 97% of the coating was HA; the remainder was tricalcium phosphate. The Ca/P ratio was 1.67. Porosity of the HA coating itself was determined by scanning electron microscopy of control implants to be 15%. The mechanical properties of the HA-implant interface were determined in accordance with the ASTM standards by the manufacturer (ASTM 1988). The shear strength was 24 MPa and tensile strength 51 MPa. The implants were sterilized by gamma irradiation.

Surgery

The implants were inserted aseptically under general anesthesia. The proximal humerus was exposed from the lateral side. A guide-wire was inserted under fluoroscopic control perpendicular to the long axis of the humerus approximately 1.5 cm distal to the greater tubercle (Figure 1). Then a cavity, 8 mm in diameter and 15 mm in length was created, using a cannulated hand drill to avoid thermal injury. The cavity was cleaned with saline prior to insertion of the implant. 1 g ampicillin was administered preoperatively, and immediately postoperatively 0.3 mg Buprenorphine was administered intramuscularly twice a day, 2–3 days after the operation.

Preparation

The proximal humerus was harvested and stored at –80 °C pending preparation. Transverse bone-implant specimens were cut on a water-cooled diamond bandsaw. The first specimen of 3 mm was used for mechanical testing and stored at –80 °C pending testing. A second specimen of 3.5 mm was fixed in 70% ethanol for bone-implant sectioning.

Mechanical testing

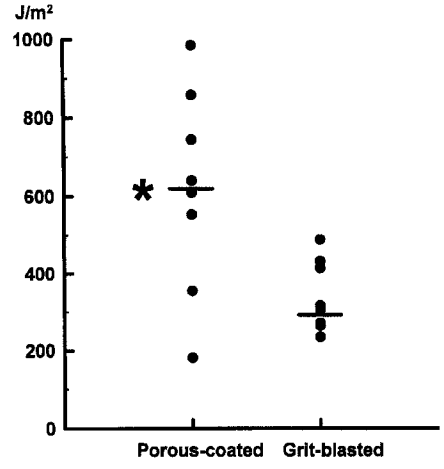
Implants were tested to failure by a push-out test on an Instron Universal test machine (Overgaard et al. 1997a). The specimens were placed on a metal support jig with a 7 mm circular opening. A preload of 2 N was applied, to define the contact position. The displacement rate was 5 mm/minute with a 1 KgN load cell. Ultimate shear strength (MPa), apparent shear stiffness (MPa/mm), and energy absorption (J/m^2) were determined from load-displacement curves, as described previously (Overgaard et al. 1997a). The implant surface was examined after the push-out test by use of stereomicroscopy (Wild M 32, Wild Heerbrugg Ltd., Heerbrugg, Switzerland) at a magnification of × 15–25.

Histomorphometry

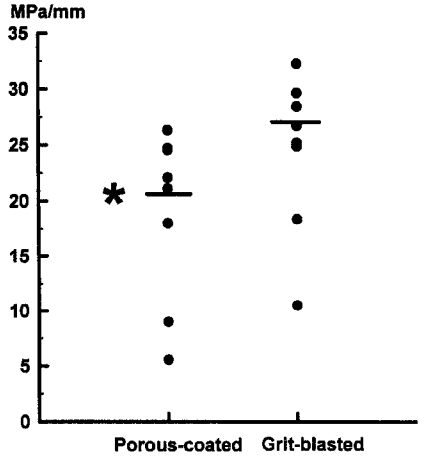
The bone-implant and control specimens were dehydrated in graded ethanols (70–100%) containing 0.4% basic fuchsin, and embedded in methylmethacrylate. To obtain unbiased estimates, the vertical section technique was applied and vertical sections parallel to the long axis of the implant were performed (Baddeley et al. 1986, Overgaard et al. 1997b). On average, 4 sections from each implant were used for histomorphometric evaluation at the light microscopic level. By mistake, 4 non-implanted control implants of each type were not cut vertically, but were randomly rotated in space before sectioning. However, the sections obtained were isotropic, uniform and random; unbiased estimates were made.

Each section was ground and polished to a thickness of approximately 50 µm, using a micro grinding system and counter-stained with 2% light green (Got-

Figure 3. Push-out test. Solid lines represent median values. *Significant difference between porous-coated and grit-blasted implants.



Energy absorption



Apparent shear stiffness.

fredsen et al. 1989). The field of vision from a light microscope was transferred to a monitor and a test system of lines and points was superimposed on the field of vision for histomorphometric evaluation, as described in detail previously (Overgaard et al. 1997b). The test systems were calibrated to have approximately 200 intercepts or points counted for each parameter per specimen (Gundersen and Jensen 1987). The surface area and volume were evaluated by the linear intercept technique and point counting, respectively (Kimmel and Webster 1983).

Parameters

Bone ingrowth was defined as bone in direct contact with the HA coating or the Ti surface without HA. Bone ingrowth is presented as a percentage of the total implant surface and as an absolute value per length of the evaluated bone-implant specimen. The surface area, volume and thickness of the HA coating were calculated as absolute values per implant length. In addition, HA coverage was calculated as a relative value in percentage of the total implant surface. Absolute values were normalized to control implants, and resorption of the HA coating was calculated. Gap-healing in the initial gap around the implant was defined as the bone volume fraction in a zone of 0–725 μm from the implant surface.

Stereological methods

Absolute surface area, volume and thickness of the HA coating were estimated using stereological methods, as described in detail previously (Overgaard et al. 1997b). Surface area per length of the implant for any surface was calculated as S_L:

$S_L = [2 \times \Sigma I \times t] / [[\, l/a] \times L(\text{implant})]$ (mm^2/mm),

where ΣI is the number of intersections with the surface, t is the distance between sections cut, l/a is test-line length per area on the monitor, and L is the implant length.

Volume of the HA coating per implant length was estimated as V_L:

$V_L(\text{coating}) = [\Sigma P(\text{coating}) \times [a/p] \times t] / L(\text{implant})$ (mm^3/mm),

where ΣP is the number of points that hit the coating, and a/p is the area per point of the test system corrected for magnification.

The mean thickness (T) of the coating was calculated as

$T = V_L/S_L$ (μm)

Statistics

Data are presented as medians and ranges in brackets. Significance was determined by Wilcoxon's signed rank test for paired data and by a Mann-Whitney test for independent data. P-values less than 0.05 (two-tailed) were considered significant.

Results

All dogs were fully weight-bearing within 3 days of surgery. One dog suffered a wound rupture and was resutured without further complications. At autopsy, no clinical signs of infection were present.

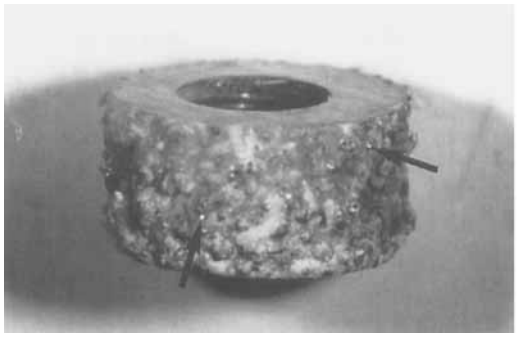
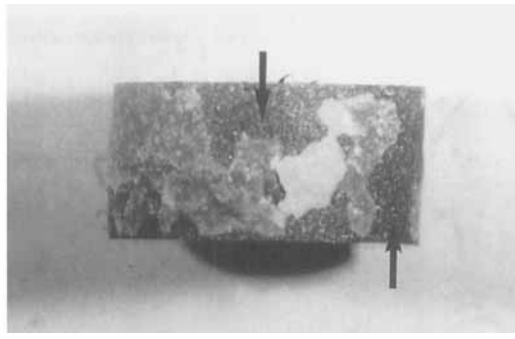


Figure 4. a) Porous-coated implant after push-out test. Failure occurred mainly in the hydroxyapatite (HA)-tissue interface. Delamination of the HA coating might have occurred on top of the titanium porous coating (arrows).



b) Grit-blasted implant after push-out test. Pronounced delamination of the HA coating is shown (arrows).

Mechanical testing

Push-out tests showed that energy absorption for porous-coated implants was 102% more than with grit-blasted ($p = 0.02$). Shear stiffness for porous-coated implants was reduced by 18% ($p = 0.03$) (Figure 3). Ultimate shear strength was 3.3 (0.9–4.6) and 3.5 (1.5–4.2) MPa for porous-coated and grit-blasted implants, respectively ($p = 0.6$). Macroscopically, porous-coated implants failed mostly at the HA-tissue interface. In contrast, grit-blasted implants had large areas of delamination of the HA coating at the edges of the implant and isolated areas elsewhere (Figure 4). More bone fragments were present on the porous-coated than on the grit-blasted implant surface after push-out testing.

Histology

Porous-coated and grit-blasted implants revealed bone ingrowth with bridges of bone in direct contact with the implant surface. The initial gap mainly contained lamellar bone, but small amounts of woven bone were also present. Fibrous tissue and marrow fibrosis but no fibrocartilage were found around both types of implants. A few HA particles were incorporated into the bone close to the implant surface, but no signs of foreign-body reaction or osteolysis were found.

Histomorphometry

The percentage of bone ingrowth on grit-blasted implants was 51% higher than on porous-coated implants (Table 1). However, the absolute surface area of bone ingrowth per implant length was 9.7 (4.9–12) mm^2/mm for porous-coated implants and 11 (6.0–13) mm^2/mm for grit-blasted implants ($p = 0.4$). Regarding gap-healing, the bone volume fraction was 13 (7.7–15)% for porous-coated implants and 15 (7.4–19)% for grit-blasted implants ($p = 0.16$).

Resorption of HA coating

Prior to implantation, grit-blasted implants were completely covered with HA, whereas porous-coated implants had a coverage of 98 (96.6–99.8)%. The HA coverage on porous-coated implants was reduced by 6.6 (2.1–11)% and by 0.2 (0–2.0)% on grit-blasted implants compared to non-inserted control implants (Table 2). The difference in relative surface area between porous-coated and grit-blasted implants was significant, but no differences between absolute surface area, volume and thickness of normalized values were found (Table 2). The thickness of the HA coating was reduced from 46 (36–50) µm to 30 (23–35) µm and from 66 (54–80) µm to 42 (38–76) µm on porous-coated and grit-blasted implants, respectively. The HA coating was mainly reduced in thickness when bone marrow was present on the HA surface, in contrast to areas with bone ingrowth (Figure 5). Resorbed HA on porous-coated implants was replaced by 23 (13–32)% bone ingrowth in direct contact with the titanium implant surface, by 58 (13–84)% bone marrow and by 18 (0–63)% fibrous tissue (Figure 6). Only 4 grit-blasted implants had a few very small areas with complete resorption of the HA coating, which did not justify statistical analysis.

Table 1. Ingrowth of bone, bone marrow, and fibrous tissue in percentage of the total implant surface (n 8). Median, range in brackets (paired data)

	Hydroxyapatite-coated implant		
Tissue ingrowth (%)	Porous-coated	Grit-blasted	P-value
Bone ingrowth	47 (39–612)	70 (41–75)	0.02
Bone marrow	39 (16—56)	26 (9.9–40)	0.2
Fibrous tissue	7.7 (0–45)	0 .0 (0–51)	0.09

Table 2. Resorption of hydroxyapatite (HA) coating on porous-coated and grit-blasted implants after a 25-week implantation period (paired data). Values were normalized to control implants. Median, ranges in brackets. P-values show statistical difference between test and non-inserted control implant of porous-coated and grit-blasted implants, respectively (independent data), and between porous-coated and grit-blasted implants (paired data)

Resorption parameters (normalized to control implants)	Porous-coated		Grit-blasted		Porous-coated vs Grit-blasted
Reduction in HA coverage (%)	6.6 (2.1–11)	p=0.002	0.2 (0–2.0)	p=0.2	p=0.01
Reduction in absolute surface area of HA (%)	13.3 (0–43)	p=0.52	9.3 (0–16)	p=0.9	p=0.5
Reduction in volume of HA (%)	41 (11–61)	p=0.005	35 (0–48)	p=0.0.02	p=0.2
Reduction in thickness of HA (%)	32 (21–49)	p=0.002	37 (0–44)	p=0.007	p=0.9

HA coverage was defined as the surface area of the implant covered by HA in percentage of the total implant surface area.

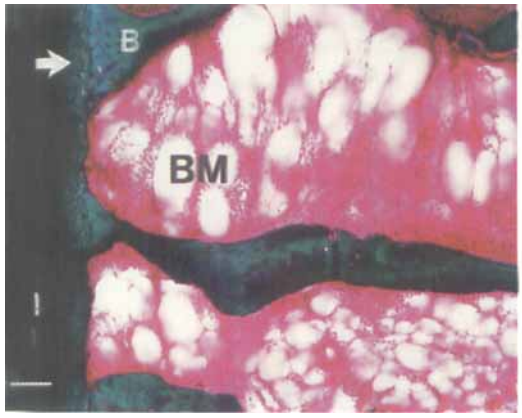


Figure 5. Vertical section of a grit-blasted implant (I). The thickness of the hydroxyapatite coating (arrow) is reduced where bone marrow (BM) is present in contrast to areas with ingrowth of lamellar bone (B). Light microscopy, section stained with light green and basic fuchsin. Bar 100 µm.

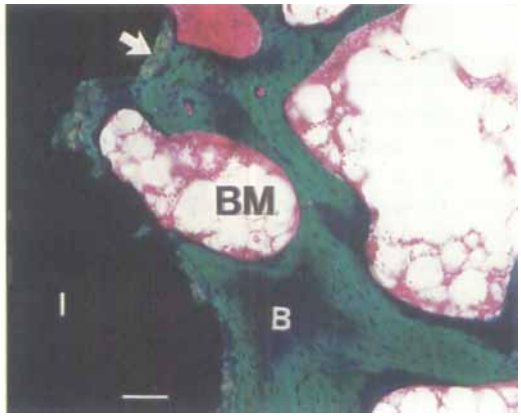


Figure 6. Vertical section of a porous-coated implant (I). The hydroxyapatite coating (arrow) is partly resorbed and replaced by bone (B) and bone marrow (BM) in direct contact with the titanium implant surface. Remaining coating is covered by bone of lamellar type. No signs of delamination or inflammation are seen. Light microscopy, section stained with light green and basic fuchsin. Bar = 100 µm.

Discussion

To our knowledge, this is the first controlled study in trabecular bone comparing the effects of porous-coated with grit-blasted surface texture of HA-coated implants in a gap model. The study showed that energy absorption was higher and shear stiffness was lower for porous-coated implants, suggesting that the mechanical fixation of porous-coated implants was stronger than that of grit-blasted implants after 25 weeks' implantation during unloaded conditions. Although no difference in absolute bone ingrowth was found, the energy absorption was lower for grit-blasted implants. This can be explained by the interdigitated bone-implant interface, resulting in a variety of compression, tensile, and shear stresses at the porous surface during push-out testing (Fujiu and Ogino 1984, Hong et al. 1992). In contrast, shear stresses overshadow other stresses at the grit-blasted surface. The low degree of stiffness expresses a less brittle interface, allowing more motion without failure of the implant. The impact of surface texture and HA coating on mechanical fixation could not be distinguished separately, and control groups without HA coating were not included, as they would have resulted in fibrous implant anchorage (Søballe et al. 1991). Probably the mechanical result was due to a combination of the two factors.

The failure site during push-out testing is most likely influenced by a combination of several factors, including the surface texture and bonding between implant-HA and HA-bone and represents a balance between interface stress and strength (Huiskes and Weinans 1993). Pilliar and Bratina (1980) showed that lower strains and stresses appeared at a porous-coated surface than at an uncoated surface for a given applied load. This might explain why the grit-blasted implants had pronounced delamination of the HA coating at the same maximal load as porous-coated implants in the present study. Most probably, delami-

nation occurred on surfaces where bone ingrowth provided a stronger bonding to the HA coating than existed in the HA-implant interface. The HA coating delaminated at considerably lower shear strength than expected from the preoperative coating test, suggesting that the bonding strength between coating and substrate decreased during implantation. However, it is also important to note that different mechanical test conditions were used to test the coatings by the manufacturer and the bone-implants specimens in our laboratory (Wolke et al. 1992). Control coatings were tested by glueing a substrate to the HA coating surface (ASTM 1988).

The experimental finding that HA coatings can delaminate from a grit-blasted surface might have clinical importance because retrievals have shown delamination of the HA coating and loosening of prosthetic components with grit-blasted surfaces (Collier et al. 1993, Nilsson et al. 1994, David et al. 1995). However, the present study was performed in an unloaded model, which might affect findings from the mechanical test. Studies of loaded implants with the same two surface textures are currently in progress in our laboratory.

It has been suggested that resorption of the HA coating occurs during implantation and that this may weaken the bonding strength between coating and implant (Jarcho 1992, Bauer 1995, Overgaard et al. 1996, 1997b). Such weakening may lead to delamination of the coating resulting in third body wear debris, and ultimately failure of the implant (Campbell et al. 1993, Bloebaum et al. 1994). However, is it preferable that the HA coating should be retained on the substrate surface or should the HA coating be resorbed in the long-term? Ducheyne (1994) pointed out that it cannot reasonably be expected that the mechanical function of the HA coating can last for the patient's lifetime and he found it reasonable that resorption should occur. In this study, resorption of the HA coating on porous-coated and grit-blasted implants occurred in vivo, but did not lead to formation of a foreign body reaction or osteolysis. An interesting finding was that porous-coated implants had significant resorption of the HA coating leading to exposure of the titanium surface, which might be explained by a more uniform HA coating on grit-blasted implants. On porous-coated implants, one fifth of the area with completely resorbed HA coating was replaced by bone in direct contact with the titanium implant surface. This corresponds well to what was expected—namely, a coverage equal to that of the bone volume fraction in the surrounding bone—which suggests that resorption of the HA coating does not disturb bone remodeling.

Compared to previous reports, resorption was modest in this study. Recently we found that 18–75% of the HA coating was resorbed (Overgaard et al. 1996, 1997b). This might be explained by application of weight-loaded models and HA coatings from other batch numbers (Maxian et al. 1994, Dalton and Cook 1995). If the HA coating eventually is completely resorbed, the implant fixation would be solely provided by the metal surface. Whether one fifth bone ingrowth is sufficient to maintain implant fixation has not been investigated.

Acknowledgements

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