HYDROXYAPATITE COATING ON CARBON COMPOSITE HIP IMPLANTS IN DOGS

G. L. MAISTRELLI, N. MAHOMED, D. GARBUZ, V. FORNASIER, I. J. HARRINGTON, A. BINNINGTON

From Toronto East General and Orthopaedic Hospital and the University of Toronto

In 33 dogs we implanted femoral stems made either of carbon composite, some coated with hydroxyapatite, or of titanium alloy with a porous coating.

Osseo-integration was greater in the hydroxyapatite-coated than in the uncoated stems ($p < 0.001$). Push-out tests, at an average of 7.2 months after implantation, showed a six-fold increase in interface shear strength and a twelve-fold increase in shear stiffness in the hydroxyapatite-coated group compared with non-coated implants. The highest shear-strength values were found in the porous-coated titanium alloy stems, around which there was also the most resorptive bone remodelling.

Total hip replacements are being increasingly performed on younger and more active patients and therefore issues such as the effect of ion release (Bartolozzi and Black 1985; Black 1988), optimum load transfer to bone (Küsswetter et al 1984; Brown and Ring 1985; Engh and Bobyn 1988), fatigue performance (Stauffer 1982; Yue, Pilliar and Weatherly 1984; Hamblen and Paul 1988) and implant-bone bonding (Haddad, Cook and Thomas 1987; Collier et al 1988) are becoming more relevant. Several in vitro and in vivo studies have shown that a more physiological state can be restored in the proximal femoral bone if the modulus of elasticity of the implant material is reduced (Lewis et al 1984; Djerf and Gillquist 1987; Maistrelli et al 1991). Due to recent technological advances, carbon-fibre-reinforced composite materials now offer strength comparable to that of metals plus the ability to adapt their elastic characteristics (Harms, Mittelmeier and Mäusle 1984; Skinner 1988). Composite prostheses with greater strength and more flexibility than

metal ones can be produced. Nevertheless the reduction of the elastic modulus is not the sole answer to the problems of hip implantation. There is now clear evidence that most of the cementless prostheses currently in use fail to achieve direct anchorage with surrounding bone and depend for fixation upon the ingrowth of fibrous tissue (Ryd 1986; Haddad et al 1987; Collier et al 1988).

Recent investigations suggest that a 'chemical bond' may form between bone and calcium-phosphate coatings such as hydroxyapatite (HA), when they are applied to the surfaces of implants (Cook and Thomas 1988; Geesink, de Groot and Klein 1988; Lemons 1988; Søballe et al 1990). Most of the animal studies on HA bonding, however, have been on unloaded implants or have lacked quantitative measurements. Our aim was to compare quantitatively, in a loaded canine hip model, the interface of carbon composite stems, with and without HA coating, with that of a porous-coated titanium alloy stem. We also studied the intracortical porosity of the surrounding compact bone for evidence of stress shielding.

MATERIALS AND METHODS

Over a two-year period we implanted femoral stems into the right hips of 33 adult mongrel dogs weighing between 26 and 32 kg. In phase one, the histological study, 14 textured carbon composite (TCF) stems (Osteo, Selzach, Switzerland) were implanted; seven were coated with HA. Phase two was a mechanical study using 19 implanted stems; seven HA-coated TCF, six non-coated TCF and six porous-coated Ti-6Al-4V. All implants were of similar size and geometry (Fig. 1).

The TCF stems had a core of endless carbon fibre impregnated with a thermoset polymer based on triazin resin. The core was encased in an outer layer of pure

G. L. Maistrelli, MD, FRCS C, Assistant Professor
N. Mahomed, MD, Research Fellow
D. Garbuz, MD, Research Fellow
I. J. Harrington, MD, FRCS C, Assistant Professor
Department of Orthopaedic Surgery, Toronto East General and Orthopaedic Hospital, 825 Coxwell Avenue, Toronto, Ontario, Canada M4C 3E7.

V. Fornasier, MD, FRCP C, Senior Staff Pathologist
Princess Margaret Hospital, 500 Sherbourne Street, Toronto, Ontario, Canada M4X 1K9.

A. Binnington, DVM, MSc, ACVS, Associate Professor
University of Guelph Veterinary College, Guelph, Ontario, Canada N1G 2W1.

Correspondence should be sent to Dr G. L. Maistrelli.

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Fig. 1

Canine total hip implants. Left to right: non-coated TCF stem, HA-coated TCF stem, porous-coated titanium stem.

triazin resin. Half were coated with a calcium-phosphate layer using a low-temperature, dip-coating technique (Ro. Bosch GmbH, Stuttgart, Germany). This dense and relatively smooth layer was composed of 90% HA (Ca/P = 1.67) and 10% TCP (tricalcium phosphate) and was approximately 150 μ m thick. The metal implants were solid Ti-6Al-4V to which titanium beads had been sintered over the proximal half of the stem in a single layer, to provide a mean pore size of 150 μ m.

An anterolateral approach was used in all cases. Antibiotics were begun pre-operatively and continued for 48 hours postoperatively. The animals were allowed unrestricted weight-bearing and walked daily during the whole period of the study. We performed force-plate analysis before surgery and before they were killed; the animals were walked along a runway containing two force platforms (Advanced Medical Technology Incorporated, Newton, Massachusetts).

Phase one: histological study. The 14 animals were killed at an average of 6.4 months (2 to 8) after implantation and contact radiographs were made of the resected specimens.

Each specimen was fixed in formaldehyde for at least 48 hours and then placed in graduated concentrations of alcohol. Progressive concentrations of Spurr's low-viscosity medium were used for embedding. Sections, about 1 mm thick, were cut 1, 4 and 6 cm above the tip of the prosthesis and mounted on a plastic support with cyanoacrylate glue. The exposed surface was ground and polished with 4000 grit paper, etched, and then stained with toluidine blue (Schenk, Olah and Herrmann 1984).

The proportion of bone apposition along the interface between the implant and the surrounding tissue was measured, the porosity of the femoral cortex at each level quantified to estimate the degree of stress shielding, and

the character of the tissue immediately surrounding the prosthesis assessed.

Bone deposition around the implant was expressed as a percentage of the total surface area of the bone-implant interface, quantified by a Zeiss Video Plan Image Analyser. Femoral cortical porosity was expressed as that percentage of the total cortical area occupied by canals, and indicated the net result of the remodelling process. These measurements were undertaken with the Leco 2001 Image Analyser (Leco, St Joseph, Michigan). Each test femur was compared with its contralateral control.

The data were analysed for statistical significance using Student's *t*-test.

Phase two: biomechanical study. The 19 animals comprising the test and control groups were killed at an average of 7.2 months (4 to 8) after implantation. Their femora were kept in saline at a controlled temperature and, on the same day, underwent mechanical testing to determine micromotion, shear strength and stiffness at the interface.

Before testing, three holes were drilled through the medial cortex at fixed levels from the lesser trochanter. The distal femur was potted and mounted into the load train of the Materials Testing Machine (MTS Model 858, Biomix, Minneapolis, Minnesota). A linear variable differential transformer (LVDT) was fixed to the medial aspect of the proximal femur and the spring-loaded measuring probe inserted through the proximal drill hole so that its tip rested on the implant stem but was not in contact with the cortical bone. It therefore recorded stem movement relative to the femur. The femur was cyclically loaded at 100 N, 150 N, 200 N, 250 N and 300 N. The force-displacement measurements were digitised by a Data Translation DT 2801A A/D converter (Transduction, Mississauga, Ontario, Canada) and recorded on microcomputer diskette. The entire procedure was then repeated for each of the other two drill holes.

Immediately after the micromotion tests, transverse sections, 8 mm thick, were cut at three levels across the proximal part of the stem. Each specimen was positioned within the load train of the MTS for push-out tests. Normal force was applied to the surface to produce a shearing load between the implant and the bone. The servohydraulic actuator displaced the section at a rate of 2.08 mm/sec. Load-displacement curves were used to determine the ultimate shear strength. These data were normalised against the interface area for each specimen to facilitate uniform comparison. The maximum force attained during each trial was defined as the push-out strength.

RESULTS

Force-plate analysis. Force-plate analysis immediately before killing confirmed that all the dogs walked with adequate weight-bearing on the operated limb. The peak vertical force on the implanted limb was more than 90%

of the non-operated (control) limb in all animals. In the HA-coated TCF group it was 98%, in the non-coated TCF group 94.1%, and in the Ti-6Al-4V group 95.8%. The differences are not statistically significant.

Radiographic analysis. None of the TCF specimens showed evidence of proximal bone resorption. Remodelling changes were seen both proximally and distally in three titanium-implanted femurs (Fig. 2) and a radiolucent line was invariably present around the non-porous distal portion of the titanium stems.

An interesting feature of all the HA-coated TCF stems was an increase in the trabecular bone density in the metaphyseal region (Fig. 3a). This extended from the endosteal surface of the cortex to the surface of the prosthesis (Fig. 3b). No radiolucent areas were noted adjacent to the HA coating.

Histology. In both the TCF implant groups there was increased density of the trabecular bone proximally. In the HA-coated implants bone was in direct contact with the coating on the surface of the prosthesis indicating good osseointegration (Fig. 4).

The morphometric analysis showed osseointegration over an average of 29% of the HA-coated TCF stems and over 8.8% of the non-coated TCF stems ($p = 0.001$). Proximally, the HA-coated TCF stems had osseointegration of 41.9% while the non-coated stems showed only 5.9% ($p < 0.001$). The titanium implants showed direct bone bonding on only 5.8% of the porous surface with no bony apposition in the distal smooth sections of the implants.

Fig. 2a

Fig. 2b

Post-mortem contact radiographs of a titanium porous-coated stem with evidence of proximal and distal remodelling and a radiolucent line surrounding the distal smooth portion.

There was more bone porosity (4.1%) around the titanium implants ($p < 0.05$); the overall femoral bone porosity around the HA-coated TCF stems was 1.93% and around the non-coated TCF stems 2.25%. This latter

Fig. 3a

Fig. 3b

Figure 3a – Fine-detail radiograph of HA-coated TCF stem with increased density of the proximal trabecular bone surrounding the implant. Figure 3b – Fine-detail radiograph of a transverse section at the proximal level (6 cm above the tip of the implant) of an HA-coated TCF stem. There is almost complete restoration of the trabecular pattern so that the reamed defect produced at surgery for implantation is completely healed and trabecular structural integrity is restored. The trabecular structure extends up to the surface of the implant providing solid anchorage for the implant.

Fig. 4

Bone abutting directly onto the HA coating with no intervening connective tissue ($\times 125$).

Fig. 5

Loose beads embedded in fibrous tissue after push-out testing.

Table I. Micromotion of the implanted stem at three sites below the lesser trochanter

Stem type	Micromotion (μm)			
	Proximal	Middle	Distal	Mean
Non-coated TFC	17.5	17.5	12.5	15.8
HA-coated TFC	10.0	10.0	10.0	10.0
Titanium	18.3	11.7	11.7	13.9

Table II. Mean shear strength to push-out of the implanted stem at three sites below the lesser trochanter

Stem type	Mean shear strength (MPa)				p value compared with other 2 groups
	Proximal	Middle	Distal	Mean	
Non-coated TFC	0.14	0.17	0.78	0.32	<0.001
HA-coated TFC	2.72	1.84	1.43	2.03	<0.001
Titanium	3.29	3.52	3.80	3.54	<0.003

difference is not statistically significant. There was no inflammatory reaction at the interfaces in any group.

Mechanical analysis. The micromotion of the three types of implant was different (Table I); the HA-coated TCF stems moved only a mean $10\mu\text{m}$. Their shear strength was 6.4 times greater than the non-coated TCF implants ($p < 0.001$, Table II) whereas the mean shear strength of the porous-coated titanium implants was greatest at 3.54 MPa ($p < 0.003$). In the HA-coated group shear strength was greatest proximally and progressively decreased distally; the other two groups had the opposite trend. The mean interface stiffness was significantly higher in the HA-coated group than in the non-coated group, while the highest values were found in the titanium-implant group (Table III). Failure occurred predominantly at the bone-implant interface in the TCF stems, but small amounts of bone adhered to the HA-coated implants after push-out. In only one of the 21 HA-coated sections was there failure at the HA coating-substrate interface. Nine of the titanium sections, however, failed between the porous-coating and its base (Fig. 5), most of the loose beads being embedded in fibrous tissue only.

DISCUSSION

Several of our conclusions may be of clinical significance for the long-term survival of hip implants. Our radiographic and morphometric data suggest that composite low-modulus stems have a beneficial effect on adaptive remodelling changes in the surrounding bone. The better bone bonding observed in the HA-coated stems did not result in any increase in the stress-shielding effect.

Our study also indicates that direct bone anchorage can occur with HA-coated TCF prostheses under the in vivo condition of cyclical loading. We think that this is the first study in which direct bone bonding in these circumstances has been quantitatively analysed. Bone apposition and trabecular bone formation were greatest proximally and we regard this as an important factor in the prevention of cantilever and torsional loading with their potential for failure. This conclusion is supported by the absence of any increase in cortical porosity, indicating that stress shielding did not occur. The very small micromotion found in all three study groups confirmed the excellent stability of all the implanted stems. The least micromotion was found in the HA-coated stems.

The results of the push-out tests showed that the HA-

Table III. Interface stiffness of the implanted stem at three sites below the lesser trochanter

Stem type	Interface stiffness (N/mm)			
	Proximal	Middle	Distal	Mean
Non-coated TFC	98	100	464	220
HA-coated TFC	3182	2886	1880	2649
Titanium	3711	4595	4885	4397

coated implants engaged a sixfold increase in interface shear strength and a twelvefold increase in shear stiffness compared with the non-coated TCF group. The low shear-stiffness values in the non-coated samples were consistent with the interposition of fibrous tissue at their interfaces. We deduce that the interface shear strength and stiffness values of the 'press-fit' type of hip prostheses in clinical use today must be quite negligible. This observation, taken with the slightly higher micromotion detected in the uncoated stems, raises some doubts about the long-term performance of 'press-fit' implants, either metal or composite.

Evidence of failure at the implant-HA coating interface was detected in only one of 21 sections tested by push-out. The highest shear-strength values were obtained in the titanium group, no doubt because the large surface area of the porous coating increases the contact area with bone and fibrous tissue and provides mechanical fixation of the implant. It is therefore possible that the strength of the interface between the stem and its porous coat is similar or even less than that of the HA coat and the TCF stem. In 50% of the porous-coated stems there was push-

out failure at the bead-substrate level which raises further doubts about the long-term integrity of such surfaces (Buchert et al 1986; Cheng and Gross 1988). Contact radiographs and light-microscope analysis of the porous interface in both intact and failed beads showed evidence of inconsistent bone ingrowth and very little direct bone bonding.

The disadvantages of this form of fixation are numerous if one takes into account the increased risks of surface corrosion, notch sensitivity and toxic metal ion release as well as the potential for increased femoral bone resorption. Alternative materials and modes of fixation should continue to be investigated and the contribution of a composite low-modulus stem with a stable osteoconductive calcium-phosphate coating could well be a solution to these current problems.

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