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Bone Ingrowth Through Porous Titanium Granulate Around a Femoral Stem

Histological assessment in a six-month canine hemiarthroplasty model

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Abstract

The procedure of using of porous titanium granules for cementless fixation of a hip replacement femoral stem was studied in a hemiarthroplasty model in 10 canines for 6 months. A vibrating instrument was used to facilitate both the delivery and distribution of the irregularly shaped porous titanium granules into the femoral canal as well as the subsequent insertion of a titanium alloy stem into the intramedullary bed of granules. Histological examination revealed lamellar bone formation through the mantle of porous titanium granules in continuity with the surrounding cortex resulting in the formation of an integrated mantle of bone and titanium granulate around the prosthesis.

Introduction

Porous titanium granules have been used successfully to stabilize total hip components in a small series of patients followed for up to 15 years (1). However, comprehensive histological assessment is lacking. The purpose of the present study was to histologically evaluate the use of porous titanium granules for cementless fixation of a hip replacement femoral stem in an established canine hemiarthroplasty model (2) after six-months implantation.

Materials and methods

Prosthesis design. The femoral prosthesis was based on a canine noncemented design which had previously been used successfully by the authors and which was slightly modified to the requirements of this experimental procedure (2). The prosthesis was made from Ti6Al4V alloy and had a tapered stem with a rectangular cross section. The anterior and posterior surfaces were macro-textured in a waffle pattern along the length of the stem. Additionally, the stem was grit-blasted using 1.2 mm aluminum oxide particles, giving the surface an R_a value of 5.5 µm. The neck of the prosthesis was machined to a Morse taper for mating with CoCrMo al-

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loy heads of various diameters. A series of five prosthetic heads ranging from 21 mm to 25 mm in diameter was manufactured to accommodate different acetabular sizes in the dogs.

Porous titanium granules. Highly porous, irregularly shaped, non-alloyed titanium granules (Tigran Technologies AB, Sweden) 1–2 mm in size were used. Nine to 10 grams of the porous granules were inserted into the medullary canal as described below.

Surgical procedure. Under a protocol approved by our Institutional Animal Care and Use Committee, hemiarthroplasty of the left hip joint was performed in ten skeletally mature male dogs. The animals were pre-medicated with acepromazine (0.05 mg/kg, s.q.) and morphine (0.5 mg/kg, s.q.). A fentanyl transdermal patch was applied one hour prior to anesthesia. Anesthesia induction was achieved with propofol (6-8 mg/kg, i.v.) or thiobarbiturate (8–16 mg/kg, i.v.). After intubation, anesthesia was maintained with isoflurane.

Through a posterior approach to the left hip, the head and neck were resected. The femoral canal was opened with a drill and then broached slightly greater in size than the stem to allow for a mantle of granules around the prosthesis. A cellulose-based hemostat dressing (Surgicel, Johnson & Johnson) was used as a medullary plug to prevent granule movement distally during insertion of the granules and stem. A modified pneumatic oscillating saw (Sultzer, Switzerland) was used as a vibrating tool. A funnel with a long delivery nozzle was inserted into the medullary canal. The granules were placed in the funnel, and the vibrating instrument was held against it. The resultant vibration activated movement of the granules into the canal. In this manner, the canal was filled from distal to proximal to within 1 cm of the osteotomy by withdrawing the nozzle during continuous vibration.

For insertion of the femoral prosthesis, the component was affixed to the vibrating instrument. The stem was inserted into the intramedullary bed of granules using mild pressure and continuous vibration. Care was taken to ensure that the stem maintained neutral alignment and neutral to 10 degrees of anteversion at insertion. The cellulose hemostat was wrapped around the proximal 5 millimeters of the stem just beneath the collar to serve as a proximal sealant for the granules during the initial healing phase. The prosthesis was finally seated by mallet impactions of the last 0.5 to 1 centimeter of stem.

The excised femoral heads were measured with a micrometer; a modular head was selected to within 1 mm of the naïve head; and the prosthetic head was impacted onto the neck taper of the femoral component. The acetabulum was inspected for debris and loose granules, and the hip was reduced. After closure of the joint capsule, the wound was closed in a routine manner in layers, and hip stability and range of motion was assured.

Postoperatively, in addition to the fentanyl transdermal patch, the dogs were given buprenophrene (10–30 μg/kg, i.m., b.i.d.) for three days, or longer if any signs of pain were evident. A cephalosporin antibiotic (22 mg/kg, p.o., t.i.d.) was

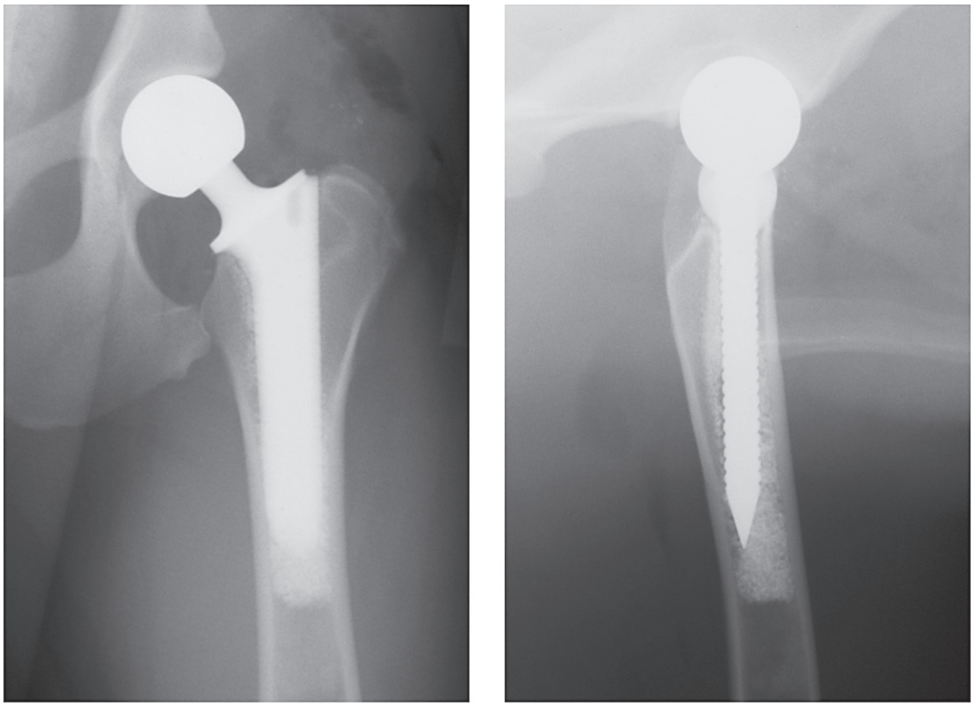


Figure 1 a–b. Radiographs (anterior-posterior and lateral views, respectively) demonstrating the placement of the femoral component within the mantle of granules surrounding the stem.

administered intraoperatively and for five postoperative days. A non-steroidal anti-inflammatory, carprofen (2.2 mg/kg, p.o., b.i.d.), was administered as needed.

Through the course of the study, the dogs were evaluated by periodic physical examination and from anterior-posterior and lateral radiographs of the hip joint obtained immediately postoperative (Figure 1) and at 1, 3 and 6 months. The animals were euthanized six months after surgery using a lethal intravenous dose of a supersaturated solution of sodium pentobarbital. The implanted femurs were stored frozen and processed further for histological evaluation.

Specimen preparation and histological evaluation. The femora were fixed in formalin and cut transversely at 1 cm intervals. The specimen blocks were embedded in plastic; and sections were cut and ground to approximately 100 µm in thickness. High-resolution contact radiographs were obtained; and the sections were stained with basic fuchsin and toluidine blue for examination in the light microscope. In selected specimens, additional sections were examined by scanning electron microscopy using backscattered electron imaging.

In stained sections from the proximal, middle and distal stem levels of each specimen, the medullary space surrounding the stem was divided into 1 mm wide fields using a reticule in the microscope eyepiece. The presence or absence of granules was recorded for each field. Fields in which granules were present were further categorized as containing predominately bone, marrow, or fibrous tissue (3, 4). The extent of each type of tissue within the granules was expressed as a percent of the total number of fields that contained granules. In this manner, both the fraction of the stem surrounded by granules and the extent of various tissues ingrown into the mantle of granules was determined.

Results

Delivery of granules and insertion of the femoral stem. Filling of the medullary canal with the titanium granules was accomplished easily and efficiently using the vibration instrument. Most of the femoral stems were inserted easily into the intramedullary bed of titanium granules. However, during the insertion process, the granules were once again activated by vibration of the stem; and as they moved around the stem, there was extraneous movement of a few granules out of the canal proximally onto the osteotomy site. The majority of these granules were removed intraoperatively with suction. A few granules remained within the soft tissues immediately adjacent to the collar and were visible on the postoperative radiographs. In one animal (Dog 10), the femoral prosthesis could not be fully advanced into the canal, and the stem had to be removed. Some granules were removed, and then the stem was successfully reinserted.

Clinical observations. No postoperative complications, dislocations, infections, wound healing abnormalities, or neurological deficits occurred throughout the study. All of the animals recovered uneventfully from the surgery. Seven dogs resumed normal weight bearing and function of the limb by two weeks, and another three dogs returned to normal weight bearing and function by six weeks. The dogs continued to exhibit normal clinical usage of the limb throughout the six-month study period and without any radiological signs of loosening. However, one animal (Dog 10) showed clinical signs of decreased weight bearing of the operated limb during the last month of the study.

Cross-section contact radiographs and scanning electron micrographs. High-resolution contact radiographs (Figure 2) and scanning electron micrographs (Figure 3) of the transverse sections showed that there was ingrowth of mineralized bone into the layer of granules in most sections with interdigitation between the granules and the surrounding bone trabeculae. In three of the 10 samples, there was extensive compaction of the granules at and immediately distal to the tip of the stem.

Histological analysis. The stained histological sections showed new haversian bone formation throughout the granules in continuity with the surrounding cortex forming a mantle of integrated bone and porous granules around the stem in all but one animal (Dog 10) in which granules had to be removed intraoperatively

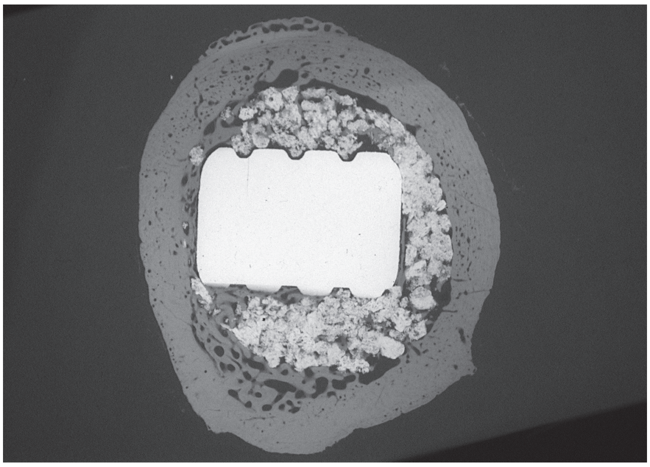
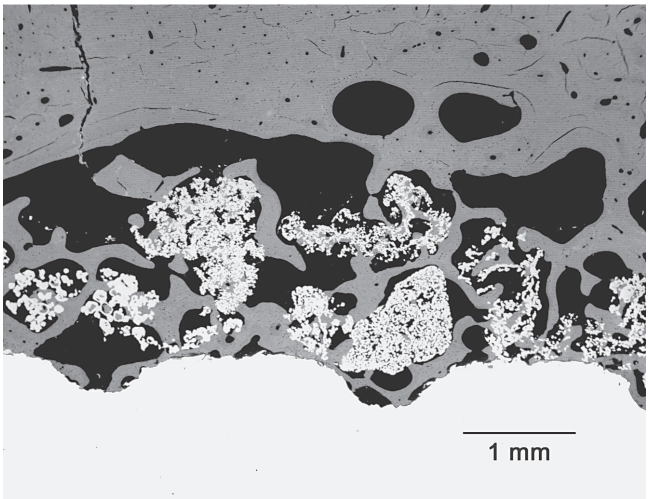


Figure 2. Contact radiograph of a cross section showing bone formation within the mantle of granules and direct contact between bone and prosthesis

and the stem reinserted. In the latter case there were some signs of osteolysis at the interface between the granules and the endosteal bone. Otherwise the granules were incorporated into the medullary bone, and the interface between the mantle of granules and the endosteal surface remained intact. Of the tissues present within the granules, in average 62 (26–95) per cent was bone, 37 (5–74) per cent fibrous tissue, and 1 (0–3) per cent was marrow. At the interface between the stem and the granules, there was intimate contact with the new bone and granules in the more distal levels of the stem, and some intervening fibrous membrane without apparent inflammation in the more proximal regions adjacent to the joint. Remnants of cellulose sponge were found in both the most proximal and most distal sections. Metal particle-induced granulomas were not observed.

Discussion

Despite minor technical limitations, this canine hip replacement model makes it possible to obtain histological data that cannot be obtained in clinical studies. The most notable difference between the clinical procedure and the current experiment is that, because only one size of canine stem was available, the dimensions of some canine femora did not always allow space for the granules as wide as is used for the human procedure. In addition, only a single broach, exactly the size of the prosthesis, was available. Therefore, extra broaching was required to increase the size of the cavity to allow for the mantle of granules. In some dogs with narrow femoral canals, these limitations resulted in a more variable layer of granules in terms of even distribution and thickness relative to what has been observed in human patients. In one of these animals (Dog 10), the stem had to be reinserted after some granules had been removed to make it possible to position the prosthesis correctly. Possibly, the thin irregular layer of granules might also have hampered the interdigitation of the granules and the stem, thereby diminishing the initial mechanical



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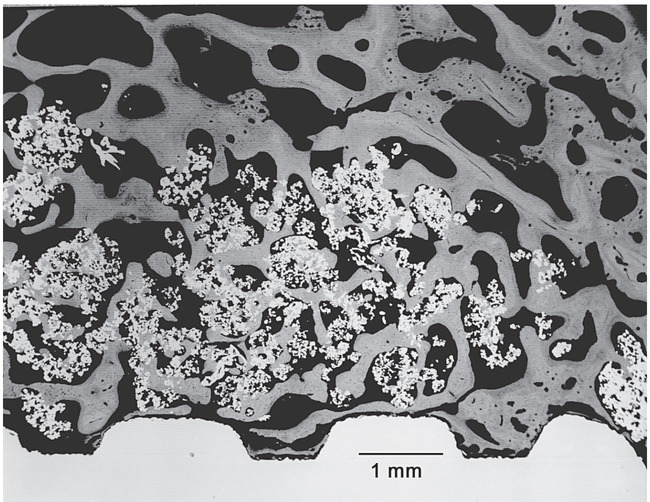

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Figure 3 a–b. Scanning electron micrographs of a cross section showing new bone formation within the mantle of granules, bone in direct contact with the prosthesis (bottom of micrographs), and bony connection with the surrounding endosteal bone (top of micrographs).

stability and the foundation for subsequent bone ingrowth up to the stem interface of this animal. These differences represent technical difficulties that could be resolved in future canine studies by the availability of more than one size stem and improved instrumentation for preparation of the medullary canal.

Our findings of lamellar bone formation through the mantle of porous titanium granules in continuity with the surrounding cortex resulting in the formation of an integrated mantle of bone and titanium granulate around the prosthesis means that the titanium granules did provide sufficient initial mechanical stability for bone ingrowth – and suggest thereby the possibility of obtaining the much desired permanent prosthetic fixation by direct contact (osseointegration) between bone and prosthesis.

Acknowledgement

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