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Implantation of the Femoral Stem into a Bed of Titanium Granules Using Vibration

A pilot study of a new method for prosthetic fixation in 5 patients followed for up to 15 years

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Abstract

This study describes a new method for the fixation of titanium hip stem prostheses based on interdigitation of irregularly shaped porous titanium granules onto bone tissue. The granules were distributed into the prepared femoral cavity using a vibrating tool, and the stem was vibrated and tapped into the bed of granules. In this pilot study, 5 patients were followed between 9 and 15 years. The clinical results were excellent and the prostheses remained stable. Autopsy (one specimen) and computer tomography (three patients) show that the granules become incorporated by bone ingrowth.

Introduction

The press-fit fixation of the femoral stem rely on a tight fit between the stem and the bone, which may be difficult to achieve in patients with hip deformities (as coxa valga, previous hip fracture, previous osteotomy), poor quality bone stock (osteoporosis) or previous prosthetic loosening. This problem has in our study been addressed by filling the interspace between the stem and the bone with irregular shaped porous titanium granules that interdigitate with each other and with the bone surface of the canal. The granules were first distributed into the prepared femoral cavity using a vibrating tool and the stem was then vibrated and tapped into the bed of granules. Our pilot study reports the clinical results as well as evaluation of one autopsy specimen and computerized tomography in three patients.

Patients and methods

Patients. Five patients (two men, three women; median age 54, range 47–68 years) underwent the procedure during the years 1987–88 because of osteoarthrosis in four hips and RA in one hip. No review panel was available in 1987 to evaluate the ethical aspects of the study. All patients, however, gave informed consent. Of the five patients, three are still alive. One woman (with RA) and one man died from unrelated causes; the prosthesis and adjacent tissues were retrieved post mortem from the latter.

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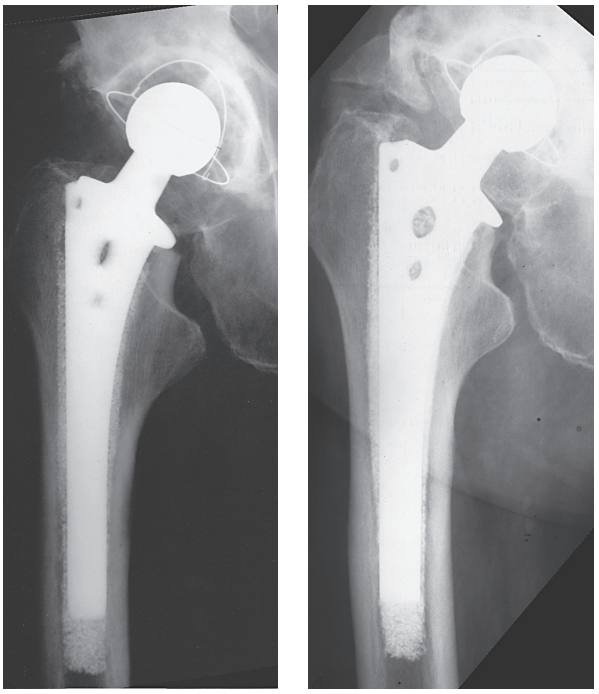
Prosthesis. The hip stems (Mecron Med. Produkte GmbH, Berlin, Germany) were made of titanium alloy (Ti6Al4V). To facilitate the introduction stems into the bed of granules the tip of the stems was shaped into a chisel by grinding prior to sterilization. The cemented acetabular cups were of ultra high-density polyethylene (Link, Hamburg, Germany). Sterile porous non-alloyed titanium granules, about 1.5 mm in diameter (Tigran Technologies AB) were used.

Surgical procedure. The femoral canal was over-reamed about 2 mm in relation to the stem to give space for the porous titanium granules. The femoral canal was not cleaned from blood and debris before the granules were introduced. A bottom seal of Surgicel® (Johnson & Johnson, USA) or a bone plug was introduced into the femoral diaphysis just distal to the apical position of the prosthesis stem. About 25 ml of granules were poured into the femoral implant cavity using a 50 ml syringe barrel and a tube with a 4 mm inner diameter. A modified pneumatic oscillating saw (Sultzer, Switzerland), was used as a vibrating tool and was applied to the syringe and tube to facilitate the flow and even distribution of the particles. The femoral prosthesis was then inserted in the femoral canal by applying the same vibrating tool to the proximal part of the stem. The position of the implant was controlled and adjusted during the vibration until it was about 10 mm from its intended final position. A small rim of bone cement was then placed between the collar of the prosthesis and the cut surface of the femoral neck to ensure the initial retention of the granules. The prosthesis was seated in its final position before the cement was cured by tapping on an instrument attached to the taper of the prosthesis with a mallet. At this stage the prosthesis was clinically completely stable. All but the first patient were allowed full weight bearing the first day after the surgery and no other restrictions were imposed.

Clinical follow up. Regular clinical follow up was done every 2–3 years on all patients including clinical examination, scoring according to Charnley (1), and standard radiographs.

Analysis of the retrieved specimen. The autopsy specimen was fixed in formalin and then cut at 1-centimeter intervals along the length of the femur. From these pieces, both undecalcified plastic embedded and decalcified paraffin embedded slides were produced as previously described (2). The plastic sections were ground to approximately 100 micrometers thickness and high-resolution contact radiographs were produced. The sections were then stained with basic fuchsin and toluidine blue for examination in the light microscope or alternately carbon-coated for study using backscatter-electron scanning electron microscopy (840A, JEOL, Peabody, Massachusetts). The paraffin sections were prepared for examination by electron microprobe analysis (model JXA 8600A, JEOL) to identify minute particulate debris in the periprosthetic tissues. Selected membranes were studied using wavelength dispersive x-ray analysis for titanium.

Stained sections from six levels of the stem (2 proximal, 2 mid-level, and 2



a b

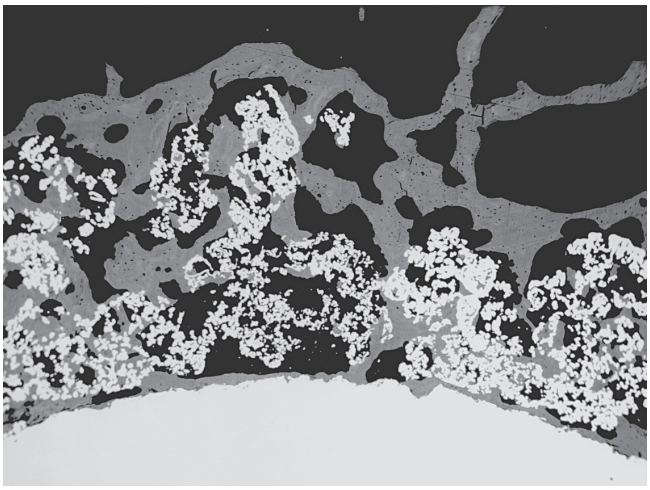
Figure 1. Radiographs of Subject 5 taken (a) postoperatively and (b) at 10 years follow up. Note the distribution of granules and the preservation of the interfaces between granules and stem as well as bone tissue.

distal) were used to quantify the extent of each type of tissue at the implant-host interface (2,3). The interface was divided into 1 mm fields using a grid in the microscope at 50 times magnification. Each field was classified either as bone, marrow, cartilage, or fibrous tissue. The extent of each tissue was expressed as a percentage of the total number of fields. This was performed at the three zones surrounding the prosthesis: the interface between the stem and the granules, the layer of granules, and the interface between the granules and the surrounding bone.

Results

Clinical observations and scoring. The mobilization of the patients was uneventful with minimal pain during the postoperative period. One patient had an aseptically loosened acetabular cup with associated pain that was successfully revised 14 years after surgery. All stems were asymptomatic for the whole follow up period.

Radiographic evaluation. All stems appeared stable, i.e. no significant subsidence occurred during the observation period as estimated from standard radiographs (Figure 1). Some granules spilled at the time of surgery into the surrounding soft tissues, notably the muscle tissues. These granules remained stationary. Otherwise, granules were only found at the stem interface with no evidence of migration into



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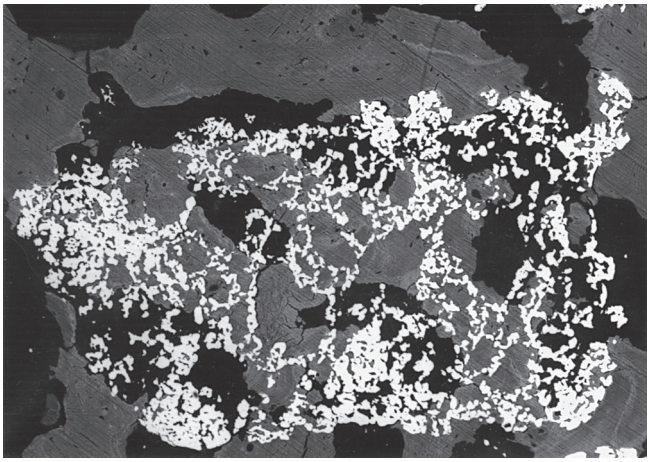

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Figure 2. Backscattered electron micrographs demonstrating (a) the interface between the stem, the granules and the surrounding trabecular bone (X25) and (b) the bone ingrowth into a single granule. Note the porosity of the granule and the close contact between bone and the metal of the granule (X65).

the joint space. Radiographs of the acetabular cups (excluding the revised one) showed no osteolysis and minimal wear.

Analysis of the retrieved specimen. The porous titanium granules were ingrown with bone resulting in the formation of an integrated mantle of bone and titanium granulate surrounding the stem (Figure 2). There was intimate contact between the granules and the surrounding medullary bone with the tissue extent 96 per cent bone and 4 per cent marrow. The extent of tissue within the granules was 97 per cent bone, 2 per cent fibrous tissue, and 1 per cent marrow. Bone contact with the stem varied by stem level: 33 per cent proximally, 27 per cent mid-stem, and 68 per cent distally. Where bone was not in direct contact with the stem surface, a thin membrane of intervening, well-organized connective tissue was present between the surrounding collar of bone and granules and the stem (Figure 3). These areas

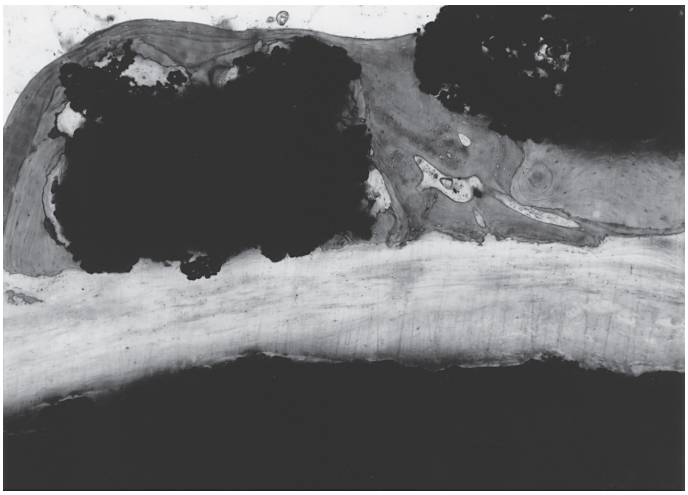

Figure 3. Microphotograph of stained, ground section from the retrieved specimen showing the thin undisturbed fibrous tissue seen occasionally in the proximal part of the stem between the stem and the granules with ingrown bone (X49).

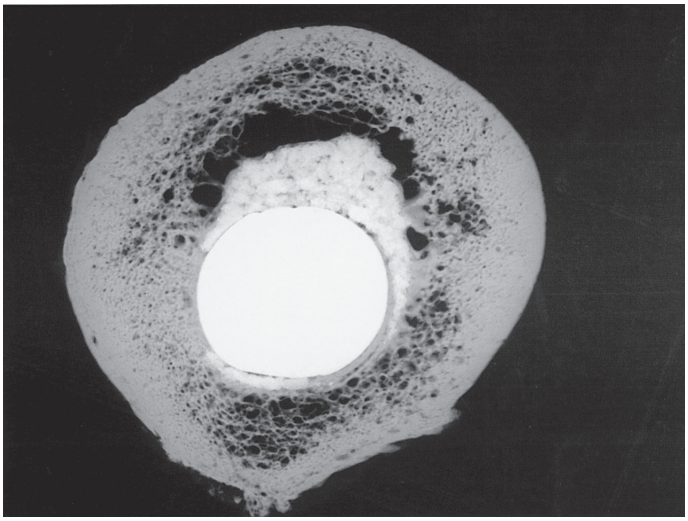

Figure 4. Contact radiograph of a cross section of the retrieved post-mortem specimen.

of fibrous tissue at the interface corresponded to a radiolucency in the contact radiographs (Figure 4). Within the fibrous membranes at the most proximal levels of the stem, adjacent to the joint, there were foci of macrophages containing fine, opaque particles and a lesser number of translucent birefringent particles consistent with polyethylene wear debris by polarized light microscopy. No particle-induced granulomas were present. Electron microprobe analysis of these membranes demonstrated focal aggregates of submicron metallic particles. The majority of the particles were identified as stainless steel alloy originating from the femoral head; and these were intermixed with occasional particles of zirconium oxide from the bone cement. Wavelength dispersive x-ray analysis detected only 2 to 3 submicron particles of titanium or titanium alloy in each of the examined membranes.

Discussion

The porous titanium granulate material used in this study promotes bone ingrowth and becomes fully embedded in the bone tissue. A technical problem associated with the use of a granulate material is how to distribute and retain it at the desired site until bone ingrowth has occurred. The insertion of the hip stem is another obstacle. In this study, vibration was used both to distribute the titanium granules and to facilitate the insertion of the hip stem. Vibration has theoretically been shown to optimize packing of objects (4) and has previously been used to achieve even distribution and packing of bulk materials, but has not found its way into orthopedic surgery.

The long-term stability of a cementless femoral stem is related to the nature of its interface contact with the surrounding bone. The amount of bone contact necessary to maintain stable, long-term implant fixation is unknown (2, 5). An extent of bone-stem contact of approximately 40 per cent (as indicated by the post mortem specimen) is apparently sufficient, since stem subsidence or thigh pain has not occurred in any of the patients up to 15 years following implantation.

Particles in conjunction with joint prostheses have in numerous studies been suggested to be causing bone resorption and prosthesis loosening. One of the intriguing findings of this study is that titanium granules can be used to anchor the stem of a hip prosthesis without generation of noxious particles and with no signs of bone resorption and prosthesis loosening. The analysis of the retrieved specimen showed, however, the presence of fine particles of stainless steel, zirconium oxide and polyethylene that were totally confined to a thin layer of connective tissue at the surface of the prosthesis. These particles were most probably generated from the level of the bearing surface; and their presence in periprosthetic membranes is similar to the findings with other fixation methods (2, 6). Particles less than a few micrometers in size have been associated with inflammation and prosthesis loosening. The relatively large metal granules (1.5 mm) employed in this procedure caused no tissue damage or inflammation. In addition to the size of the granules, the explanation may be, as discussed above, the good stability and absence of movements at the prosthesis interface and the use of non-alloyed titanium.

Removal of a granulate implant material, should it become necessary, must also be considered. The porous granules employed in this study were made of non-alloyed titanium, which is a relatively soft material. The granules are easy to drill through or saw with instruments intended for use in bone. Thus, removal of the titanium granules should be no more difficult than removal of acrylic cement.

The ingrowth of the bone may be due to the use of non-alloyed titanium as well as the porous topography of the granules. Both factors have been shown to be significant for bone ingrowth (7, 8). The initial mechanical stability is crucial to successful long term results for both dental (9) and orthopedic (10) implants and the initial stability that is achieved by using granules in combination with vibration is most likely the single most important factor in the success of the procedure.

Our clinical results show that initial and long-term stability is obtained where

the titanium granules provide the initial mechanical stability, and a scaffold for bone regeneration and ingrowth. This procedure may become useful, especially for patients with a lack of bone support, i.e. in revision surgery of the femoral stem (11).

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