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*J Bone Joint Surg Am.* 1986;68:606-609.

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The Journal of Bone and Joint Surgery  
20 Pickering Street, Needham, MA 02492-3157  
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## Excessive Metal Release due to Loosening and Fretting of Sintered Particles on Porous-Coated Hip Prostheses

REPORT OF TWO CASES\*

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The use of porous-surfaced metallic prostheses in total hip arthroplasty is attractive and is becoming increasingly popular<sup>2,12</sup>. The porous surface permits bone ingrowth and

of metal ions due to more corrosion associated with the large surface area of the porous metal<sup>18</sup>. The long-term effects of hyperphysiological concentrations of metallic ions

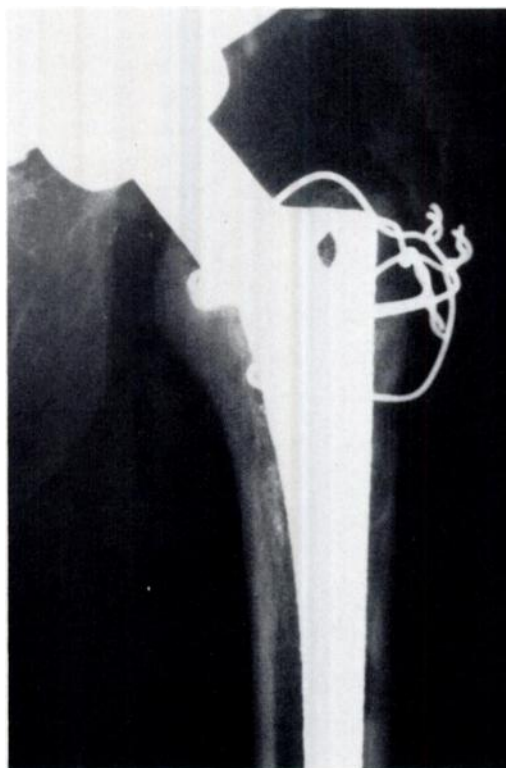


FIG. 1



FIG. 2

Fig. 1: Case 1. Four months postoperatively, the radiograph shows subsidence of the femoral component and loosening of metal particles.  
Fig. 2: Case 1. Photograph of the removed prosthesis, with a portion of the capsule blackened by metal debris.

direct mechanical bone-metal interlock without the use of acrylic cement. This new technology has several inherent problems, one of which is the potential for increased release

are largely unknown, but many studies have indicated that the potential for toxicity or even carcinogenicity exists<sup>10,15,18</sup>. In addition to simple corrosion, there is the release of metal debris due to wear or fretting and fretting-corrosion mechanisms. Experience with metal-on-metal articulations such as the McKee-Farrar prosthesis showed that the rate or quantity of release of metal due to wear can be far more significant than that due to corrosion<sup>4,6,9</sup>. Material released by wear or fretting is more susceptible to corrosion because the protective effect of the passive oxide film is reduced. Furthermore, corrosion is enhanced in the presence of fret-

\* No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article. No funds were received in support of this study.

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ting and by differences in electrochemical potential between passivated and non-passivated regions on the surface of the metal<sup>3</sup>.

The potential for porous metal systems to release metal by a wear or fretting mechanism due to loosening of the sintered porous surface has been largely ignored. The purpose of this paper is to draw attention to this problem by describing two similar cases of patients in whom metal debris was found when a loose femoral implant with a sintered porous coating was revised.

### Case Reports

**CASE 1.** In a twenty-nine-year-old woman who had had two previous cemented total hip arthroplasties, aseptic loosening of both components developed after the second procedure. A cobalt-chromium-alloy porous-coated straight femoral-stem device was inserted after a slurry of fresh-frozen allograft bone had been placed in the medullary canal. The porous coating was of the powder-made sintered type, which is applied to the implant after initial casting<sup>14</sup>. A threaded cementless cup was inserted in the acetabulum.

The patient's immediate postoperative course was uneventful. She was kept continuously on partial weight-bearing using axillary crutches. However, despite protected weight-bearing, she began to have progressive pain, and subsequent radiographs showed subsidence of the femoral component and absence of the bone hypertrophy and sclerosis that suggest the

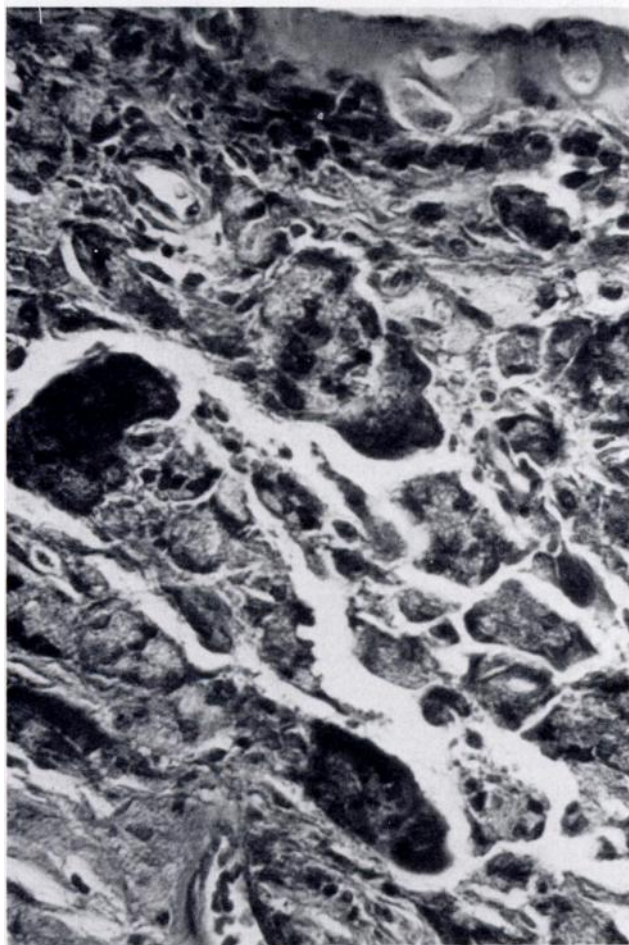


FIG. 3

Case 1. Photomicrograph of the capsule and synovial membrane, illustrating an aggressive inflammatory reaction with metal debris and foreign-body-type giant cells (hematoxylin and eosin,  $\times 100$ ).

presence of bone ingrowth (Fig. 1). In addition, loose particles from the porous surface were evident proximally, both medial and lateral to the stem.

Because of the patient's deteriorating course, four months after the third procedure a revision operation was performed. When the capsule of the hip was incised, exuberant black-stained tissue was encountered on the inner surface of the capsule, and the entire capsule was seen to be stained with metal debris (Fig. 2). When the femoral component was examined, it was noted to be freely movable within the femoral canal and was easily removed. Many of the sintered particles had been worn off the proximal part of the lateral surface of the stem. The femoral canal appeared darkly stained with metal debris throughout its proximal portion. The femoral medullary canal was thoroughly reamed with high-speed instruments, and a cemented femoral component was inserted. The acetabular component was firmly fixed and was left intact.

In the recovery room, after surgery, blood was drawn for analysis of metal-ion content. The patient's serum cobalt level was elevated at 12.1 micrograms per liter (normal range, one to seven micrograms per liter), while the levels of chrome were within normal limits at 7.6 micrograms per liter (normal range, zero to eleven micrograms per liter). Multiple histological sections of the capsule of the hip showed metal debris as well as a very aggressive inflammatory reaction characterized by multinucleated foreign-body-type giant cells (Fig. 3). The patient's postoperative course was uneventful, and one year after surgery she was free of pain; she could walk unlimited distances and used a cane only sparingly.

**CASE 2.** In a sixty-year-old man who had had a bilateral cemented total hip arthroplasty, symptomatic loosening of both components in the right hip developed four years after surgery (Fig. 4). The hip was revised using a cobalt-chromium-alloy porous-coated femoral component (with the same type of sintered coating as in Case 1) of the Mueller design in combination with a cemented acetabular component (Fig. 5). There was a tight fit of the stem within the intramedullary canal, and there was no evidence of loose metallic particles on the postoperative radiograph.

Over the next five months, the patient began to have increasing pain, even though he had always walked with protected weight-bearing and had pursued a sedentary lifestyle. Radiographs at that time showed subsidence of the femoral component and loose sintered particles along the lateral surface of the distal part of the stem (Fig. 6). Because of the patient's deteriorating course, revision was performed without further delay. At operation, the capsule was not noticeably stained with metal debris, but the femoral component was loose and was easily removed. Slightly stained granulation tissue was removed from within the intramedullary canal in the region where the radiographs showed accumulation of bone particles. A cemented stem was inserted and the acetabular component was left intact. At the time of writing, one year after revision, the patient's course had been uneventful.

### Discussion

These cases raise important questions as to the fixation of porous-coated hip prostheses and the mechanical integrity of the metallic porous coating. While it has been occasionally observed that a few sintered particles become loose from a femoral prosthesis as it is impacted into the intramedullary canal, in the vast majority of patients the implant has remained well fixed in the canal and no progressive loosening of particles has been observed<sup>8</sup>. If there is no motion at the bone-implant interface, constituents of the alloy are released primarily by corrosion (excluding wear debris from the ball-and-socket articulation). If, on the other hand, the implant is not fixed or it becomes loose, cyclic motion at the bone-implant interface during loading and unloading can cause increased loosening of particles, fretting wear of particles, fretting-corrosion, metallosis, and reactive changes in tissue. The metallic debris that is re-



FIG. 4



FIG. 5



FIG. 6

Figs. 4, 5, and 6: Case 2.

Fig. 4: Preoperative radiograph of the failed cemented femoral implant.

Fig. 5: Radiograph made immediately after revision using a porous-coated stem. There are no signs of metal-particle loosening.

Fig. 6: Five months postoperatively, the femoral component has subsided and loose particles have collected near the tip of the stem.

leased in this manner resembles that observed with metal-on-metal joint replacements. As discussed by Coleman et al., Dobbs and Minski, and Evans et al., high local (tissue) levels of metal can develop and there may be problems related to sensitivity, inflammatory response, or systemic toxicity.

More serious is the possibility that elevated levels of metallic debris might be carcinogenic. Experimental evidence from animal studies generally, although not uniformly, has supported this suggestion<sup>10,15,18</sup>. A direct association of metal implants and malignant change in humans is difficult to establish. However, there have been reports of tumors developing at the site of three stainless-steel plates<sup>5,7,11,17</sup>, in one patient with a cobalt-chromium-alloy plate<sup>13</sup>, and in four patients with a total hip replacement: one cemented stainless-steel implant<sup>10</sup>, two cemented cobalt-chromium-alloy implants<sup>1,16</sup>, and one cemented non-porous cobalt-chromium implant<sup>13</sup>. With the exception of two patients in whom a plate was involved, the times that the implants were *in situ* before tumor formation were relatively short (six years or less). Therefore, the role of the implant as the carcinogenic agent is uncertain. Nevertheless, any association of an implant or implant material with cancer is clearly worrisome, and precautions should be taken to minimize risk, however small or theoretical it may be.

When a non-cemented porous-coated femoral component is used, the stem is usually impacted with considerable force into a close-fitting channel. This may be the major cause of initial loosening of particles. The only published data on the incidence of loosening of particles<sup>3</sup> indicated that it occurs in about 2 per cent of patients. This figure includes patients in whom implants that were manufactured before 1978 were used. At that time, sintering techniques were not as reliable as they are currently<sup>8</sup>.

The cases of these patients emphasize the importance of quality control and proper fabrication techniques. Hopefully this problem will prove to be extremely rare, since current sintering techniques produce implants with well bonded porous surfaces. In addition, new methods for manufacturing textured or porous surfaces other than sintering are available. Thus, the porosity can be produced by direct casting of porous surfaces<sup>2,8</sup> or by texturing surfaces by ion-beam etching<sup>9</sup> — processes that should eliminate loosening of particles and delamination.

It seems reasonable to assume that loosening of particles would be most likely to develop after revision using a non-cemented porous-coated prosthesis. Under these circumstances, the bone stock is reduced and compromised, and the risk of loosening of the implant is greater than after a primary procedure. In our combined clinical experience,

a similar problem has not occurred after primary arthroplasty. In Case 1, by four months after revision enough debris had been produced by the constant abrasion of the loose prosthesis to cause metallosis and elevated levels of cobalt in serum. Hopefully the complete capsulectomy in combination with extensive reaming of the canal decreased the amount of long-term exposure to metal ions to a more acceptable level in this patient. In Case 2, the amounts of metal debris and reactive granulation tissue were not as

severe, but due to the combined effects of a loose prosthesis and a loose porous coating, the metallosis was becoming progressively worse.

In view of the findings in these patients, it is recommended that when any patient has a painful non-cemented prosthesis and radiographic evidence of motion at the bone-metal interface, the hip should be revised as soon as possible. This would minimize the risk of malignant degeneration and the poorly defined effects of metal-ion exchange.

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