FATIGUE FAILURE OF NONCEMENTED POROUS-COATED IMPLANTS

A RETRIEVAL STUDY

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The causes of mechanical failure of five noncemented porous-coated components were studied. There were two cobalt-chromium alloy and three titanium alloy implants which fractured after 12 to 48 months. The implants included one acetabular component, and one femoral condylar, one patellar and two tibial components. Examination of the fractured surfaces revealed fatigue to be the mechanism of failure in all cases.

The porous coating and the processes required for its fabrication had resulted in weakening and reduction of substrate thickness. Additional factors were stress concentration due to limited, localised bone ingrowth, and some features of the design of the implants.

Mechanical failure of the metal components of polymethylmethacrylate (PMMA) cemented hip and knee implants has been widely reported. Charnley (1975) reported an incidence of fracture of the femoral component of 0.23% in his first 6500 total hip replacements. Others have reported an incidence of femoral stem breakage as high as 11% (Martens et al 1974; Carlsson, Gentz and Stenport 1977; Callaghan et al 1988). A number of clinical and radiographic findings have been related to the occurrence of implant fractures (Galante 1980; Callaghan et al 1988). Patient height and weight are important variables; in Charnley's series, the incidence of mechanical failure was approximately 6% in patients weighing more than 88 kg (194 lb). Vigorous activity has also been related to an increased likelihood of mechanical failure and radiographic evidence of loosening and loss of proximal support is present in the majority of femoral stem breakages (Galante 1980).

Mechanical failure of modern designs of cemented hip and knee implants is extremely rare due partly to advances in implant design and cement technique, and partly to the use of wrought and forged titanium and

cobalt-chromium alloys (Miller, Shastri and Shih 1982). These materials have superior mechanical properties compared to the annealed stainless steel and cast cobalt-chromium alloys used in earlier designs (Miller et al 1982; Callaghan et al 1988). There are only a few isolated case reports of mechanical failure of modern devices (Miller et al 1982; Mendes et al 1984; Gonzalez, Glass and Mallory 1988).

In recent years, the use of porous-coated hip and knee implants without cement has increased. The mechanical properties of cobalt-chromium and titanium alloy substrate materials are significantly compromised by the presence of the porous coating and the processes required for its fabrication. Such implants often demonstrate mechanical properties inferior even to the earlier cast materials (Pilliar 1983, 1987; Cook et al 1984; Yue, Pilliar and Weatherly 1984; Cook et al 1988c). The loss of mechanical strength is due both to the changes in the material's microstructure and to the notch effect occurring at the junction of the solid substrate and the porous layer.

Noncemented porous-coated implants are often employed in young active patients who may be expected to apply large loads to their prostheses for a long time. There are isolated case reports of failures of cemented and noncemented porous-coated tibial components (Moreland 1988; Morrey and Chao 1988) and uncemented porous-coated patellar components (Rosenberg et al 1988). We report the retrieval of five broken noncemented porous-coated components which have been studied in the light of the clinical and radiographic

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circumstances, the implant material and design and the pattern of tissue ingrowth observed.

MATERIALS AND METHODS

There were two broken porous-coated cobalt-chromium-molybdenum (Co-Cr-Mo) alloy components from among 137 such retrievals (90 patients) and three broken porous-coated titanium alloy (Ti-6Al-4V) components from 22 such retrievals (16 patients). The fracture surfaces were examined with a light stereomicroscope and a scanning electron microscope. In all cases the patients had been walking, symptom-free with a good range of motion, until the implant failed. The fractures occurred 12 to 24 months after implantation. In all cases breakage was the reason for the removal of the component. Radiographically the implants appeared to be well fixed prior to failure and all were well positioned and aligned.

The five mechanical failures were as follows:

- 1) The posterior medial condyle of the femoral component of a Co-Cr-Mo alloy knee replacement (Whiteside OrthoLoc: Dow Corning Wright, USA) fractured in a 69-year-old man after 20 months;
- 2) The fixation spikes of a Co-Cr-Mo alloy patellar component (AMK (Anatomic Modular Knee), DePuy, USA) fractured in a 74-year-old man after 12 months;
- 3) The metal backing of a Ti-6Al-4V alloy acetabular component (Harris/Galante: Zimmer, USA) fractured in a 52-year-old woman after approximately 48 months;
- 4) The medial part of a Ti-6Al-4V alloy tibial component

(PFC (Press-Fit Condylar), Johnson and Johnson, USA) fractured in a 62-year-old woman after 28 months;

- 5) The posteromedial part of a Ti-6Al-4V alloy tibial component (PFC (Press-Fit Condylar), Johnson and Johnson, USA) fractured in a 46-year-old man after 35 months.

After removal, the implants and attached tissues were immediately placed in 10% buffered formalin solution. The broken area was cut from the component with a water-cooled diamond saw for optical and scanning electron microscopy. Additional specimens were removed for chemical, metallurgical and microstructural analysis. The remainder of the component and attached tissues were dehydrated in graduated alcohol solutions from 70% to 100% and then embedded in methylmethacrylate. Serial histological sections were then prepared with the implant in place using diamond cutting and grinding techniques (Cook, Thomas and Haddad 1988a; Cook et al 1988b). After staining the sections with basic fuchsin and toluidine blue the type, amount, and anatomical distribution of tissue ingrowth was measured.

RESULTS

Scanning electron microscopy of the fracture surfaces revealed fatigue to be the mechanism of implant failure in all cases. All metallic structures if repeatedly loaded at sufficiently high stress and for a sufficient number of cycles will ultimately fail by this mechanism. Fatigue striations were evident on the fracture surfaces (Fig. 1)

Fig. 1a

Fig. 1b

Specimen from a 69-year-old male whose Co-Cr-Mo alloy total knee femoral component (Whiteside OrthoLoc) fractured after 24 months: (a) retrieved component, note the region of the posterior condyle which is not porous-coated; (b) scanning electronmicrograph of the fracture surface demonstrating fatigue striations and the area of crack initiation (arrow). Note the thin cross-section thickness (approximately 1.5 mm).

and in several components, secondary cracking was observed, oriented perpendicular to the primary fracture surface and often displaying a branched configuration (Fig. 2).

The fracture of the metal shell of the acetabular component initiated at a screw hole which had contained one of four screws used for fixation (Fig. 3). The knee femoral component failure initiated at the medial edge of the posterior condyle near the junction of porous-coated and uncoated regions (see Fig. 1). The patellar component failed at the junction of the pegs and the metal backing. Both tibial component failures initiated posteriorly, one at the medial end of the strut of the central stabilising stem and the other at the medial edge of the device, posterior to the central stabilising strut (see Fig. 2).

Metallurgical and chemical analyses revealed all implants to have microstructures typical of porous-coated Co-Cr-Mo and Ti-6Al-4V alloy substrate materials, and to be generally within accepted standards (Annual Book of ASTM Standards 1989). No metallurgical defects, nonmetallic inclusions, voids, porosities, or other irregularities were present in the areas of mechanical failure.

Histological sections showed that some bone ingrowth had occurred into the acetabular, the femoral condylar and into one of the tibial components (case 5). No bone ingrowth was present in the other tibial component (case 4) or in the patellar component. The amount of bone ingrowth was minimal, less than approximately 2% of the available pore volume in the tibial component (case 5) and approximately 2% to 5% of the available pore volume in the femoral condylar and acetabular components. Fibrous tissue was predominant in all components. This included areas of fibrous ingrowth, with fibre orientation perpendicular to the implant surface, and fibrous encapsulation with fibres parallel to the surface of the implant.

DISCUSSION

The fatigue strengths of porous-coated Co-Cr-Mo and Ti-6Al-4V alloys are approximately one-third those of the uncoated wrought or forged materials (Pilliar 1983, 1987; Cook et al 1984; Yue et al 1984; Cook et al 1988c). As a result, porous-coated bone ingrowth prostheses are generally much weaker than contemporary cemented devices, and similar in strength to the annealed stainless steel and cast Co-Cr-Mo devices used in the 1970s (Miller et al 1982; Callaghan et al 1988; Moreland 1988). Since mechanical failure of these earlier devices has been widely reported, breakages of current porous-coated devices are not unexpected.

Stress transfer is generally uniform in a cemented device and distributed over the entire bone-cement-implant interface. Mechanical failure normally occurs in the presence of loosening, the loss of support resulting in a cantilever loading of the prosthesis (Gruen, McNeice

and Amstutz 1979). In porous-coated prostheses, bone ingrowth is not uniform and generally occurs only in isolated areas (Collier et al 1988; Cook et al 1988a, b) creating regions of stress concentration due to enhanced stress transfer in the areas of bone ingrowth. Although three of the retrieved broken components contained some bone ingrowth, the majority of the implant surface was covered by fibrous tissue. The femoral condylar component, which had regions with and without porous coating, created obvious areas of enhanced fixation and it was at one of the sites of transition that the mechanical failure occurred (Fig. 1).

The location of the bone ingrowth also suggested that a cantilever loading effect may have been at work. This was particularly evident in the acetabular component where, at the primary operation, a bone graft had been placed superiorly. No bone ingrowth was present in this region and partial collapse of the graft had occurred. The problem was accentuated by the adjunct screws which had been used to fix the graft and the cup. The spikes on the patellar component, and the central keels on the tibial implants also imparted localised enhanced fixation through these design features.

Fatigue failure of the fixation pegs of titanium alloy porous-coated metal-backed patellar components has already been reported (Rosenberg et al 1988). Failure was attributed to the lack of bone ingrowth on the metal back of the implant and firm fixation of the pegs. No bone ingrowth was present in the Co-Cr-Mo alloy patellar component in the present study. The fixation pegs remained well-fixed in the bone and had to be forcibly removed at the revision operation.

Structural factors due to the presence of the 1 to 1.5 mm thick porous coating also contributed to the mechanical failures. The metal thickness in the region of failure of the femoral condylar, the tibial and the acetabular components was only about 1.5 mm. This is an extremely thin cross-section for a load-bearing structure, particularly in view of the reduced mechanical properties of the substrate material and the expected use in young and active individuals. In the acetabular component, the multiple screw holes reduced the overall component strength and served as stress concentrators. Reduced substrate thickness played a role in the failures of four of the six components and in a previously reported fracture of a porous-coated tibial component (Morrey and Chao 1988). Finite element stress analysis indicates that if any bone support is lost, many of the current metal-backed tibial components will have less load carrying capability than designs made of polyethylene alone (Koeneman et al 1986). Unfortunately, increasing the thickness of the substrate necessitates reduced polyethylene thickness or additional bone removal.

Fracture of a modern porous-coated device is a relatively rare event. The cases reported came not only from our institution but also from several other surgeons. Nevertheless, the designs of porous-coated components

Fig. 2a

Fig. 2b

Fig. 2c

Specimen from a 46-year-old man whose Ti-6Al-4V alloy tibial component (PFC) fractured after 35 months: (a) retrieved component, note the fracture and secondary cracking of the device; (b) microphotograph of the cracking shown in (a); (c) scanning electronmicrograph of the area of the failure initiation (arrow).

Fig. 3a

Fig. 3b

Fig. 3c

Specimen from a 52-year-old woman whose Ti-6Al-4V alloy acetabular component (Harris/Galante) fractured after 48 months: (a) radiograph showing a fracture in the component (arrows) and collapse of the superior bone graft; (b) the retrieved component; (c) scanning electronmicrograph of the region of failure initiation at a screw hole: F, fracture surface; C, interior cup surface; S, screw hole chamfer.

must be considered in the light of the weak material properties and the reduced cross-sections necessary to accommodate the porous coating. Methods should be employed in their fabrication to maximise the mechanical strength of the substrate, particularly those which have been shown to be effective in improving fatigue properties (Pilliar 1983, 1987; Georgette and Davidson 1986; Cook et al 1988c).

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