Early attempts to use non-cemented implants for joint replacement were dependent on producing a press-fit fixation between the implant and the prepared bony surface. The resultant interface often consisted of fibrous tissue, even when the surface of the implant was roughened or textured to provide a macro-interlock. True biological fixation by bony ingrowth has only been reliably achieved since the introduction of porous coatings for prostheses, permitting the so-called micro-interlock. A number of animal experiments have shown the importance of pore size to accommodate sufficient osteoblasts, capillaries and bone matrix to enter the surface. The coatings on most implants are approximately 500µm thick and have a pore size in the range 100 to 500µm. Initially all non-articular surfaces of the implant were coated, but in the case of the hip this resulted in undesirable stress shielding effects with the femoral component. Later designs have confined the porous coatings to the proximal portion of the femoral component, often as pads, covering 35 to 40% of the surface area. The performance of porous coated implants depends on the extent of the initial bony ingrowth, which in turn depends on the integrity of the porous coating. Orthopaedic surgeons may therefore feel concern at recent reports of beads loosening from the surfaces of these porous coated implants.

Cheng and Gross (1988), in the previous issue of this Journal, describe this finding in 23 of 40 arthritic knees treated with cementless chrome-cobalt porous coated anatomic (PCA) prosthetic replacements. Loose beads were present on both the femoral and tibial sides, but were more frequently associated with radiolucent lines at the tibial prosthetic–bone interface. The two findings were not necessarily correlated, since loosening of the tibial component is more common than the femoral with non-porous designs of knee replacement (Freeman, Samuelson and Bertin 1985). Progressive mechanical loosening with an increasing number of loose beads was present in three knees, but the follow-up was short (average 12.9 months) and others may develop later clinical failure. Of greater immediate concern was the presence of intra-articular beads in four knees since these will accelerate the production of wear particles from both the metal and polyethylene surfaces. These particles may become associated with the macrophage and foreign body giant cell response which characterises the membrane which forms between the implant and bone, and may itself result in further bone destruction (Goldring et al. 1983).

Similar radiological findings with the same design of knee prosthesis were reported by Rosenqvist et al. (1986). In their series of 34 knees, more than half showed loose beads after an average follow-up of 17 months and in one-third where bead loosening occurred later than three months, there were associated radiolucent zones. Separation of beads from two chrome-cobalt femoral prostheses with associated implant loosening was reported by Buchert et al. (1986). They comment on the potential for fretting corrosion with possible adverse effects from high levels of metallic contamination in the local soft tissues (a topic covered more fully in the editorial by Black in this issue of the Journal (p. 517)).

What is not clear is whether all the beads are loosened at the time of implant insertion, or if they become detached from the prosthesis as loosening develops, particularly on the tibial side. The extent of the micro-motion between prosthesis and bone on weight-bearing was investigated by Ryd (1986) using an in vivo radiographic stereophotogrammetric technique, which showed significant shear stress at the tibial implant–bone interface. This stress would need to be of sufficient amplitude to produce fatigue failure of bonds between beads and implant, unless there was an undetected fault in the manufacturing process.

Porous coatings can be applied to prostheses by three different techniques: sintering, diffusion bonding, or plasma spraying. The earlier porous implants, including those used in the reports mentioned earlier,
were manufactured by the gravity sintering technique. Spherical metal beads of appropriate size are first applied to the surface of the implant using a jelly-like binder to provide adhesion for a coating of controlled thickness at the appropriate sites. The entire component is then heated to a high temperature in a hydrogen or vacuum atmosphere allowing the binder to dissipate while fusing the beads to the substrate and to each other. The bond strength is controlled by the temperature and duration of the heating cycle, in the case of chrome-cobalt implants 1 300°C for three hours. This is reported to give a surface with an average pore size of 425μm, a porosity of 35% and a static shear strength greater than 21 MPa. Fatigue testing in shear loading showed the bond strength to be in excess of 7 MPa (Pilliar 1983).

Unfortunately the sintering process, when used with the new “super-alloy” forged implants, results in a dramatic loss of fatigue strength of the implants by up to 50%, from 850 to 300 MPa as they revert to cast material (Gibbons 1982). This adverse effect is even more marked with titanium alloy implants, from 625 to 200 MPa (Yue, Pilliar and Weatherly 1984). Work recently published by Cook et al. (1988) indicates that, although a porous structure strongly affects fatigue behaviour, the strength of the non-coated substrate can be significantly improved by 15.7% with the use of post-sintering heat treatment. Cook et al. also suggest that the discrepancy between the fatigue strengths of porous coated specimens reported by Cook et al. (1984) and Yue et al. (1984) is due to the different sizes of particles used, the smaller particle size used by Yue corresponding to a smaller reduction in the fatigue strength. This led to the development of the alternative process of diffusion bonding. In this, fibre metal pads of titanium wire are positioned in recesses on the implant and then subjected to heat and pressure to achieve bonding. Porosity is controlled by the wire configuration and the temperature, which is much lower than that required in sintering. The most versatile technique is the plasma spray process which can be used for both metallic and non-metallic coatings, such as polysulphone and hydroxyapatite. The coating is sprayed from a nozzle with a pressurised gas mixture in a high energy arc, so that only the powder and not the implant is heated. To date, little information is available for the fatigue characteristics of porous metal coatings produced by this technique.

In vivo testing of porous implants in animal models has concentrated on the strength of the bone implant interface following ingrowth and has not reported bead loosening. In vitro tests reported by Manley et al. (1987) study both chrome-cobalt alloy and titanium bead substrate interfaces of various designs. They found that the strength of bead welds on a smooth substrate was inadequate, with a preferential failure site between beads and substrate. However, implant surface contours or recesses protected the bead welds, which successfully withstood ten million dynamic loading cycles. Unfortunately the restricted number of test pieces used does not allow assessment of the scatter of the experimental data. Cyclic loading tests are noteworthy for the extent of scatter and the variability in the structure of the textured material would be expected to aggravate this. Unfortunately, as a consequence, assessment of fatigue data is unavoidably associated with the requirement for the use of at least 10 specimens for each fatigue limit determination.

Another problem associated with the application of coatings is that they induce high levels of stress locally in the same way as scratches or sharp corners. These stress concentrations reduce the strength of components in cyclic loading although for materials of reasonable deformability they have little effect on the static strength. Present generation proximal femoral components of arthroplasties have a cross-section of stem considerably greater than their predecessors and this, associated with higher strength metals, has largely eliminated the problem of stem fracture in cemented components. There must however be concern that the two factors of stress concentration and reduced fatigue strength of the base material due to the coating process will be associated with a recurrence of this problem in non-cemented prostheses (Yue et al. 1984). Fatigue of cemented stems is frequently associated, however, with resorption of the bone in the calcar and other regions. If the non-cemented technique can reduce the incidence of resorption then the problem may not be present in well seated prostheses. Fatigue fracture of femoral stems in cemented total hip replacements frequently occurs at a point approximately one-third of the stem length from its distal end. Various bodies such as the International Standards Organisation and the British Standards Institution are specifying that these components should be subjected to fatigue tests. In these tests the component is fixed by the distal third of its stem in a fixture clamped in a dynamic testing machine and cyclical load is applied through the centre of the prosthetic head. The orientation of the prosthesis and the direction of the line of application of the load are not agreed between the various standardising bodies.

Although these test systems have been defined to reproduce or simulate the conditions of a cemented prosthesis secured distally and loose proximally, they may be used to compare the strengths of coated implants for cementless fixation. It should be noted also that these tests may be more adverse than in vivo loading since they do not reproduce the effects of the forces developed in the muscles attached to the proximal femur, particularly the abductors. Standard tests should also reproduce the torsion of the stem of the prosthesis, which occurs during load bearing on a flexed thigh and is seen in walking with a long stride, negotiating stairs, or rising from the seated position.

The process of transmitting load from metal to bone is associated with a fundamental design problem. The
load transmitted by the hip joint, for instance, causes stress in the femoral component of the prosthesis which will have a high, if not maximum value in the calcar region. At the cut surface of the femoral neck the stress will be zero unless the prosthesis has a collar which is particularly well fitted. Thus there is inevitably a difference in deformation per unit length between the bone and the proximal end of the implant—whatever its material.

Although the same situation exists at the distal end of the prosthesis, it is not of the same severity since the cross-sectional dimensions of the prosthetic stem are much smaller relative to those of the enclosing bone at this level. Thus there will inevitably be a system of cyclic shear stress between the coating of the prosthesis and the surrounding bone during normal function. This might result in fatigue failure of the bond. This situation pertains at any junction between two load bearing materials and is consistent with the findings of Ryd (1986).

There is clearly a need for continued research into the ideal technique to produce a porous coating which will remain intact during implantation and subsequent normal patient loading. Fatigue tests of the type described by Manley et al. (1987) are therefore highly relevant to the assessment of the strength of the bond between coating and prosthesis. Standard fatigue tests can be utilised to assess the effect of the coatings on the overall strength of the stem. This may vary with the implant material chosen, but should be controlled by international technical standards if implant failure is to be avoided.

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REFERENCES


