The current status of hydroxyapatite coating of prostheses

The number of revisions for mechanical loosening after total hip replacement will probably continue to increase steadily from year to year due to the increasing number of arthroplasties; in addition, the results of revision are clearly inferior to those of primary arthroplasty (Overgaard et al 1992). In younger active patients, the conventional prostheses have not lived up to expectations and there is widespread concern about the significant risk of failure in this group (Malcuau and Herberts 1996). These considerations have led to an increased interest in cementless fixation, primarily by biological means whereby press-fit insertion is followed by bone ingrowth into a porous surface.

Many different types and designs of cementless prosthesis are now available, but so far there has been no evidence to suggest that cementless joint replacements perform better than cemented (Rorabeck et al 1994; Malcuaau and Herberts 1996), and radiological investigations have shown osteolysis around cementless implants in up to 40% of cases within ten years (Engh et al 1994). Retrieval studies of non-cemented, porous-coated hip and knee prostheses have revealed that many components are fixed to bone only by fibrous tissue, although some authors have reported greater amounts of bone ingrowth (Collier et al 1991; Sumner et al 1993; Engh et al 1995).

For these reasons there has been substantial research into methods of enhancing bone ingrowth into cementless prosthetic surfaces. Particular interest has been focused on hydroxyapatite (HA) which can be successfully coated on to metal surfaces by plasma-spraying techniques (de Groot et al 1987).

In recent years, there have been extensive animal studies on HA-coated implants. Some have failed to show enhanced fixation and others have demonstrated a positive but transient effect. A large group of weight-bearing and non-weight-bearing models with HA coating, however, has shown continued fixation for longer periods (Overgaard et al 1996a). One of the most striking effects of HA has been its ability to enhance bone growth across a gap around an implant in both stable and unstable mechanical conditions; it is even capable of converting a motion-induced fibrous membrane into a bony anchorage (Søballe et al 1992a, b, 1993a; Søballe 1993).

An important concern about HA coating is its degradability in the biological environment, which has been cited as a potential complication. Some resorption or dissolution is, of course, essential to trigger its basic osteoconductive effect. Calcium and phosphate ions are released from the coating, resulting in reprecipitation of crystals, and ion exchange with the surrounding tissue. This leads to the formation of a carbonated calcium phosphate layer of microcrystals and macrocrystals, with the incorporation of a collagenous matrix (LeGeros et al 1991). The rate of resorption is likely to have a great influence on implant fixation. Fast resorption could lead to disintegration of the coating, with rapid loss of the bonding strength between it and the prosthesis, resulting in delamination, the production of particles, and loss of mechanical fixation (Bloebaum et al 1994). By contrast, slow controlled resorption may give the surrounding bone the opportunity to replace resorbed coating. Experiments have shown that resorbed HA coating has been replaced by bone in 30% of the surface (Overgaard et al 1995, 1996a). This suggests that implant fixation will be maintained and that resorption is more of a theoretical concern.

HA coating has also been used as a carrier for growth factors. These can be successfully loaded on to the HA coating and later released after implantation into bone. A recent study from our laboratory has shown that transforming growth factor β further enhances the effect of HA on bone ingrowth (Lind et al, unpublished data).

At least 60 retrieval studies of HA-coated prosthetic components have been made during the last decade. Most have been of post-mortem specimens of femoral and acetabular components, but some are from revisions (Bauer et al 1991; Furlong and Osborn 1991; Hardy et al 1991; Søballe et al 1991; Bloebaum et al 1994). In most cases specimens have been obtained from six months to one year after implantation with a range from ten days to five years. Several components have shown bone ingrowth into the HA coating varying from 10% to 20% of the surface after 3 weeks, 48% after 12 weeks and 32% to 78% after 5 to 25 months. These clinical retrieval studies have confirmed the osteoconductive properties of HA found in animal studies and suggest that the retrieved prostheses have been mechanically stable, with stability obtained by bone ingrowth.
HA coating may also have a considerable sealing effect. The wear debris from polyethylene is a serious problem in arthroplasty; this may govern the long-term outcome of metal-polyethylene joint replacements (Schmalzried, Jasty and Harris 1992). Polyethylene particles have been demonstrated at the interface around cementless implants and have been associated with the formation of histiocytic granuloma and focal osteolysis around the components; these eventually cause failure of the prosthesis (Goldring et al 1983; Goodman, Fornasier and Kei 1988; Maloney et al 1990). A recent study from our laboratory has shown that HA coating is able to inhibit the migration of polyethylene particles along the bone-implant interface as compared with uncoated titanium implants (Rahbek et al 1996). In the long run, this effect of HA coating could be very important and may reduce the incidence of osteolytic lesions and the later failure of the implant.

There is great variability in the quality of the HA coatings supplied by different companies and even in different batches. The quality of the coating has been shown to influence important variables for implant fixation such as bone ingrowth, mechanical fixation and the rate of resorption (Dalton and Cook 1995). We strongly recommend that surgeons who use HA-coated prostheses should request and receive a quality report for each batch of prostheses before they are inserted (Anderson et al 1990). At present there are several proposed standards for HA coatings and test methods, but few of these have been approved or accepted. The factors which are critical to the behaviour of plasma-sprayed HA coatings include chemical composition (purity), calcium to phosphorus (Ca/P) ratio, crystallinity, microstructure (porosity), and mechanical properties. The thickness of the coating is important. We believe that a 50 μm coating is preferable since it reduces the risk of HA fracture and can preserve the porous surface structure of a metal implant. Experimental data have shown that a thin coating of 50 μm gives a stronger fixation than a thick coating of 200 μm (Søballe et al 1993a).

There is general agreement that the purity of HA should be as high as possible (95% to 97%) with a Ca/P ratio of 1.67 (ASTM 1988). There is no agreement on crystallinity. We have used coatings with a crystallinity of approximately 70%, and are now studying the effect of different crystallinities. Mechanical properties are important for the long-term performance of the coating. The bond strength between HA and its substrate is related to the porosity and thickness of the coating and to the design of the prosthesis. According to proposed standards the shear strength should be 22 to 29 MPa, and the minimum tensile strength should be 51 MPa (FDA 1992; ISO 1996). The porosity of currently available HA coatings varies from 5% to 20%. High porosity results in a mechanically weaker coating and faster resorption as compared with low porosity. With regard to the metal substrate underneath the HA coating, a porous structure has been shown to be better than a grit-blasted surface (Overgaard et al 1996b).

There is increasing clinical experience with HA coating; several studies of HA-coated hip components have shown promising clinical and radiological results (D’Antonio et al 1992; Kroon and Freeman 1992; Søballe et al 1993b; Kärholm et al 1994b; Geesink and Hoefnagels 1995; Moilanen et al 1996; Önsten et al 1996). Geesink and Hoefnagels (1995) reported their six-year results for one design of HA-coated total hip replacement and found a survival rate of 100% for the stems and 99% for the threaded cups. Controlled studies using roentgen stereo-photogrammetric analysis (RSA) or similar radiological methods have shown that HA-coated femoral and acetabular components have significantly less early migration than non-HA-coated prostheses or even cemented prostheses (Kroon and Freeman 1992; Søballe et al 1993b; Karrholm et al 1994b; Moilanen et al 1996; Önsten et al 1996).

It is not yet clear whether the superior fixation of HA-coated prosthetic components will last longer than that of uncoated or cemented prostheses, but Kärholm et al (1994a) consider that mechanical loosening can be predicted on the basis of RSA during the first two years. There is therefore a strong indication that HA-coated prostheses will remain stable to a larger degree than non-HA-coated prostheses, and that this could result in a superior survival rate.

Several independent studies, both experimental and clinical, have repeatedly documented that HA coating can enhance the stability of cementless implants. The quality of the HA coating is of the utmost importance and is not identical for all coatings on the market. To avoid the use of coatings of poor quality, we consider that quality reports should be available for each batch of prostheses delivered.

The short-term clinical results have been encouraging, but longer follow-up and randomised controlled trials are needed before there can be a final conclusion on the efficacy of HA-coated prostheses. At present, close follow-up of the patients with such implants is still recommended.

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REFERENCES

THE JOURNAL OF BONE AND JOINT SURGERY
Evidence-based choice of hip prostheses

The prostheses in current use for hip replacement vary in cost by a factor of nearly ten (Murray, Carr and Bulstrode 1995). Since more than 40 000 hip arthroplasties are performed annually in the UK, it is clear that research is needed to establish whether the varying cost is related to long-term survival in patients and to the outcome as regards comfort and quality of life. In 1995, the National Health Service Research and Development Programme commissioned a systematic review which aimed at estimating the relative effectiveness of different prostheses.

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