

Polyethylene wear in knee arthroplasty

A review

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In this issue of *Acta Orthopaedica Scandinavica* four articles (Blunn et al. 1992, Lindstrand et al. 1992, Lindstrand and Stenström 1992, Tulp 1992) focus on wear as a mechanism for unexpected prosthetic failure. The lifespan of knee prostheses has increased during two decades of improvements in choice of patients, implant design, surgical methods including guide instruments, soft tissue balancing, and better cementing techniques. These advances have led to 90–95 percent prosthetic survival at 10 years (Larsson et al. 1988, Scuderi et al 1989, Gill and Mills 1991, Scott et al 1991). The Swedish Knee Register has shown a steady decline in the number of complications after knee replacement (Lewold et al. 1991) and this trend has persisted, even without changes in prosthetic design (Lewold et al. 1991), and an increase in the patient's age at the time of operation over the years (Lidgren 1991). However, the comparative survival statistics used in many recent studies do not correct for age and improvements in surgical technique over time. In the survival study presented in this issue (Lindstrand et al. 1992), a time- and age-matched group has been selected for the comparison between a new knee implant and two older designs. After 6 years the cumulative revision rate of the PCA unicompartmental prosthesis was three times higher than that of two earlier designs, the Marmor and St Georg prostheses. It is clear that the new PCA prosthesis has a shorter longevity than the implants it was intended to replace. This study also showed the importance of a multicenter approach for the follow-up of implants, irrespective of preclinical laboratory tests and limited randomized studies.

The failure analysis of the PCA unicompartmental prosthesis showed that at least one fourth, probably up to half, of 65 revised knees had substantial wear of the heat-treated, high density polyethylene (HDPE) tibial component. Another failure pattern was loosening of the femoral component in one half of the revised knees.

The high failure rate of the PCA prosthesis in the Swedish Register Study has led to a more thorough radiographic analysis of a consecutive series of unicompartamental PCA prostheses performed in Lund (Lindstrand and Stenström 1992). From this study it is quite clear that the wear problem is not only confined to thin tibial polyethylene components, since weight bearing radiographs have also demonstrated potentially severe early wear in components thicker than 9 mm.

Causes of polyethylene wear

Tribology, the science of friction, is an important research area. However, few investigations of friction and wear of new implants have been carried out under laboratory conditions. Such studies should be performed for a new design or material using a test machine with a suitable lubricant and an authentic prosthetic set-up (Blunn et al. 1991) prior to the initiation of clinical studies. A set-up using bovine serum for the wear studies is not necessarily comparable to the clinical situation. The joint fluid viscosity in a prosthetic knee joint is probably lower without any boundary lubrication, especially late in the wear process (Radin et al. 1992). External wear between a prosthetic component and bone, as well as third body wear, should also be analyzed.

Wear patterns in the laboratory or in retrieved implants can be divided into abrasion, cracking, creep, and delamination (Wright and Bartel 1984, Landy and Walker 1988). The type and location of wear may be analyzed visually and by using more sophisticated techniques for surface and subsurface analyses. It is important to measure the amount of wear, crystallinity, molecular weight, and deformation of the polyethylene component. This may be done by using x-ray spectrophotometry, infrared spectrometry, gel permeation

chromatography, scanning electron microscopy, and light microscopy combined with polarized light (Blunn et al. 1991, 1992).

The wear of a polyethylene component depends on molecular weight (Rose et al. 1979), homogeneity (Schmotzer and Song 1991), thickness (Knutson et al. 1981, Bartel et al. 1986), geometry (Bartel et al. 1986, Buechel et al. 1991, Collier et al. 1991), and articular surface irregularities (Milliano and Whiteside 1991, Elbert et al. 1992). Intergranular defects and variations in the crystallinity of the superficial 1-2 mm of the surface increase in vivo and in vitro wear (Elbert et al. 1988, Blunn et al. 1991, Finlay et al. 1991, Werner et al. 1991, Blunn et al. 1992, Jensen et al. 1992, Li et al. 1992). The manufacturing process, for example, heat treatment of the articular surface, heat molding (Bartel et al. 1986), gamma irradiation (Rose et al. 1979), etc. may adversely affect the resistance to wear. One of the studies in this issue (Blunn et al. 1992) indicates that conventionally machined high density polyethylene (HDPE) components are substantially different in homogeneity and porosity because of inadequate pressing or molding techniques (Blunn et al. 1992). Inhomogeneity and porosity will inevitably result in increased wear and stress. Eccentric loading caused by a non-conforming design, antero-posterior sliding (Blunn et al. 1991), a small contact area within the normal prosthetic range of motion (Werner et al. 1991), and malalignment, will all increase wear (Finlay et al. 1991). The surface finish of the articulating component is of utmost importance. A cobalt-chromium alloy causes less wear than a titanium-alloy surface in tests simulating the clinical situation with third body wear or runaway wear (McKellop 1991, Milliano and Whiteside 1991).

In recent retrieval and laboratory studies, catastrophic wear of polyethylene tibial inserts has been observed, especially for nonconforming, metal-backed implants with heat-treated HDPE (Kilgus et al. 1991, Engh et al. 1992). Bloebaum et al. (1991) found delamination in one third of 33 retrieved PCA tibial components an average of four years after implantation. In a comparable retrieval study by Hood et al. (1983) of 48 conventionally produced HDPE total condylar prostheses, only 5 showed delamination.

It is important to realize that the information about the actual thickness of an implant given to the surgeon often means the combined thickness of the metal backing and the polyethylene insert. On average, the thickness of plastic is 3 mm less than the total thickness indicated by the manufacturer (Chillag and Barth 1991).

Knutson et al. (1981) and Wright and Bartel (1986) advocated a minimum polyethylene thickness of 8 mm. Collier and co-workers (1991), using finite ele-

ment analysis, presented the maximum contact of von Mises stresses in bicompartamental knee prostheses. They found that with normal walking activity, a minimum thickness of 8 mm is preferable, and that tibial components with less than 5 mm of polyethylene (i.e., 8 mm combined polyethylene and metal) probably fail within the first 5 years, and possibly even earlier.

The contact stresses in the normal range of motion have been analyzed in two recent studies. Out of 4 modern bicompartamental knee designs, the PCA prosthesis had the highest contact stress within the normal range of motion (Werner et al. 1991). This was verified by a large clinical study in which the five-year revision rate for PCA prostheses was 5 percent or more (Kilgus et al. 1991). An additional 5 percent of the knees showed radiographic thinning of more than one third of the tibial polyethylene plateau (Kilgus et al. 1991). A failure rate of 19 percent for the PCA prosthesis was ascribed to problems with the tibial component (Moran et al. 1991). In some cases, polyethylene wear has resulted in severe granulomatous reactions (Nolan and Bucknill 1992, Tulp 1992).

Endosteal erosions around tibial screws, acting as stressrisers, increase tibial wear and may also cause wear between the tibial metal component and the plastic insert (Peters et al. 1991, Engh et al. 1992). Breakage of the tibial plateau or stem has been reported for both all-plastic and metal-backed components (Tjörnstrand et al. 1985, Flivik et al. 1990). Whether metal backing and the use of new polymers or designs will improve the wearing qualities is still debatable (Apel et al. 1991). The risk of third body, abrasive wear is present not only with PMMA but also with porous coating or enhancement coating, such as hydroxyapatite.

The measurement of early wear is made possible by roentgen stereo-photogrammetry (Ilchmann et al. 1992, Ryd 1992). If this method is not available with weight-bearing radiographs, the radiologist must measure joint space narrowing in the same way as for the arthrotic knee. The use of long-leg radiographs with measurement of the HKA angle will show a shift of the mechanical axis, probably before any measurable joint space narrowing. Synovitis is an early sign of wear (Mintz et al. 1991). By aspiration and the use of conventional and polarization microscopy of joint fluid, polyethylene and metal fragments can be identified. Arthroscopy may also be used to identify wear of knee components (Mintz et al. 1991).

Careful follow-up is advised for knees with a metal-backed component; when a reduction of more than 3/4 of the polyethylene space is noted, revision is recommended.

The higher failure rate for the PCA knee prosthesis is caused by a number of factors: a nonconforming

metal-backed tibial component with a small contact area, surface, heat-treated HDPE components, and porous coating with possible bead loosening and an increased risk for third body wear (Rosenqvist et al. 1987, McKellop 1991). The problem of wear is especially obvious in the unicompartamental knee prosthesis. In a metal-backed unicompartamental tibial component, the HDPE insert has to be thin in order to minimize bone resection and to prevent overcorrection. Revision from a unicompartamental prosthesis to a new unicompartamental prosthesis has been shown to give inferior results compared to a primary or revision bicompartmental prosthesis, probably as a result of the tissue reaction to wear debris and contracompartamental cartilage degeneration (Lewold et al. 1992).

Biologic effects of polyethylene wear

Most conventional materials used in total joint replacement have excellent biocompatibility characteristics when in bulk form. However, particles of polymers and metals have been implicated in the etiology of loosening of joint prostheses. When the membrane surrounding loose components is examined microscopically, plastic and metallic debris are found associated with a foreign body reaction with histiocytes, giant cells and lymphocytes embedded in a fibrous tissue stroma (Heilmann et al. 1975, Vernon-Roberts and Freeman 1976, Willert and Semlitsch 1977, Mirra et al. 1982, Goldring et al. 1983, Linder et al. 1983, Goldring et al. 1986, Johanson et al. 1987, Maguire et al. 1987, Appel et al. 1988, Goodman et al. 1989, Schmalzried et al. 1992). The adverse biological effects of polymethylmethacrylate (PMMA) in particulate form have been intensively investigated both *in vitro* and *in vivo* (Goodman et al. 1988, Horowitz et al. 1988, Davis et al. 1989, Herman et al. 1989, Davis et al. 1990, Goodman and Chin 1990). Recently, the role of polyethylene debris in potentiating the process of prosthetic loosening has been emphasized (Goldring et al. 1986, Goodman et al. 1988, Howie et al. 1988, Campbell et al. 1990, Goodman et al. 1990, Willert et al. 1990, Fornasier et al. 1991, Santavirta et al. 1991, Schmalzried et al. 1992).

The early, disastrous experience with Teflon® emphasized the need to consider all the characteristics of a material carefully, prior to implantation in humans (Chamley 1979). Teflon® had extremely poor wearing properties when articulating with a metallic femoral head; voluminous amounts of debris evoked a severe foreign-body and chronic inflammatory response that quickly led to loosening of the components. A similar problem was seen with the Christiansen hip prosthesis

(Ahnfelt 1986, Ohlin and Persson 1989, Ohlin 1990) in which a trunion-bearing, large diameter metallic femoral head articulated with a socket made of polyoxymethylene (Delrin®, Dupont). The Weber (1970) hip prosthesis, employing an exchangeable polyester femoral head and a metallic socket also resulted in accelerated wear and plastic debris. These observations stimulated the use of HDPE as a bearing surface. Although adequate material was identified, further problems arose. Several hip prostheses incorrectly employed an HDPE femoral head and a metallic cup; the consequence of this arrangement was accelerated polyethylene wear and early prosthetic loosening. Similar mistakes were made in the knee: the Deane prosthesis had an HDPE femoral component. In the hip, some acetabular cup designs made solely of polyethylene (such as the Morscher cup) articulating against bone were also associated with severe bone resorption (Ahnfelt et al. 1990). In resurfacing arthroplasty of the hip, the large-diameter prosthetic femoral head articulated with a thin, deformable acetabular cup (Bell et al. 1985, Schatzker et al. 1987). The relatively high frictional torque at the different interfaces precipitated early loosening and a florid prosthetic synovitis secondary to polymer debris. In some cases, the destruction of bone associated with polymeric debris from loose conventional and resurfacing prostheses was so extensive that a neoplasm was suspected (Bell et al. 1983, Willert et al. 1990).

Examinations of the membrane surrounding loose joint prostheses have implicated polyethylene debris in the etiology of loosening (Bullough 1973, Vernon-Roberts and Freeman 1976, Willert and Semlitsch 1977, Mirra et al. 1982, Goldring et al. 1983, Bell et al. 1985, Johanson et al. 1987, Maguire et al. 1987, Campbell et al. 1990, Willert et al. 1990, Fornasier et al. 1991, Santavirta et al. 1991, Schmalzried 1992). Fragments of polyethylene, sometimes a millimeter or more in length, are universally identified in the thick, fibrous membrane surrounding loose, cemented components. These polyethylene particles are surrounded by histiocytes, giant cells, and lymphocytes, embedded in a fibrous tissue stroma. Particles smaller than about 10 µm are found within phagocytic cells. Submicron particles often cannot be detected by light microscopy; these particles might prove to be the most deleterious, as they are easily ingested by macrophages, and have been shown to stimulate the release of bone-resorbing factors (Williams et al. 1984, Murray and Rushton 1990).

The loosening membrane has been shown to produce high levels of prostaglandin E₂ and other substances that may stimulate bone resorption (Goldring et al. 1983, Linder et al. 1983, Goldring et al. 1986, Kim et al. 1988, Ayers et al. 1989, Goodman et al.

1989, Mather et al. 1989, Ohlin et al. 1990). Whether the polyethylene particles alone are the major stimulus for these events, or whether cement and metallic particles are of equal importance is unknown. Studies of failed, cementless components have shown that the presence of bone cement is not a prerequisite for the formation of a foreign body membrane and osteolysis; this has led to the recognition of a separate entity called cementless disease (Maloney et al. 1990). Recent immunological studies of the membrane from loose, cementless components have suggested an important role for polyethylene (and titanium) debris in the migration, adherence and phagocytosis of CD11b-positive, peroxidase-negative macrophages (Santavirta et al. 1991). However, more evidence is accumulating to suggest that metallosis may really be plasticosis (Campbell et al. 1992). Submicron particles of polyethylene were previously beyond the resolution of the light microscope. With stains such as Oil Red O (Peters et al. 1992), it has become apparent that particles of polyethylene less than 5 µm are more widely distributed than previously thought. These very small phagocytosable particles are probably more important in stimulating the release of osteolytic factors than are metallic particles. Indeed, histological analysis showed a much more florid foreign body reaction to polyethylene particles than did cobalt-chrome or titanium-alloy particles (Goodman et al. 1988, 1990).

Two recent studies have shed further light on the role of polyethylene particles in aseptic loosening. Fornasier et al. (1991) examined the interface surrounding 14 hip endoprostheses retrieved at autopsy 2 weeks to 14 years after implantation. All of these were stable, successful, cemented arthroplasties according to strict clinical, radiographic and gross pathologic criteria. Nevertheless, in each case, a fibrohistiocytic membrane, similar to that surrounding loose prostheses, was found at the bone cement interface. The density of histiocytes correlated with the thickness of the membrane, the density of polyethylene particles, and the time after implantation. Similar autopsy studies were done by Schmalzried et al. (1992) who concluded that loosening of cemented acetabular cups is the result of a macrophage-induced inflammatory response that is induced by HDPE particles. This response begins at the periphery of the cup and progresses proximally to undermine the bony support of the acetabular component.

Animal implantation experiments using single materials (rather than a complete arthroplasty) have shown that the physical form of implanted polyethylene determines the histological reaction of soft tissue and bone (Stinson 1964, Goldring et al. 1986, Goodman et al. 1988). Using different animal models,

bulk polyethylene rods were surrounded by a bland, encapsulating, connective-tissue layer. However, irregularly shaped polyethylene particles up to 1000 µm in diameter had evoked a fibrovascular connective tissue infiltrated by numerous histiocytes and giant cells. The latter reaction was similar histologically to the membrane surrounding retrieved loose components. The work of Schatzker et al. (1987) showed that shards of polyethylene were prominent at the bone-cement interface of stable, resurfacing components in dogs within 6 months of the arthroplasty. These particles appeared to be an important component of an ongoing process of loosening. In a classic study by Howie et al. (1988) HDPE particles 20-200 µm in diameter were repeatedly injected into rat knees which contained a non-weightbearing cement plug in the distal femur. At the end of the experiments, a foreign body membrane surrounded the cement implant and had eroded the underlying bone. Control limbs receiving sham injections did not have these findings. The authors concluded that a direct relationship existed between the accumulation of polyethylene debris and resorption of bone around a non-weightbearing cement implant.

Conclusions

Manufacturers of joint-replacement prostheses must produce a product that is biocompatible and has specific physical and chemical properties that meet national and international standards. Polyethylene, although not ideal, is currently the most frequently used bearing surface. Attempts to improve the properties of polyethylene, or substitute another material in its place, should be preceded by detailed theoretical, and in vitro and in vivo animal studies prior to the initiation of even limited clinical trials in humans. Continuous, well-monitored multicenter studies for truly long-term follow-up of implant function are imperative.

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