# Osteolysis and particle disease in hip replacement

## A review

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Much can be learned from a careful reassessment of the history of total hip replacement over the past 35 years. Such a review is revealing about certain aspects of the nature of medical science, and most importantly, about solving our current problems in total hip replacement, notably cementless surgery with the rapidly increasing incidence of major pelvic and femoral lysis, predominantly manifest after 5 years or so postoperatively.

It is fascinating that the problem of osteolysis around total joint implants antedated successful total hip replacement. The first major venture into total hip replacement on a large scale involved Charnley's polytetrafluorethylene (Teflon) prosthesis; in a short time span the failure rate was over 95 percent. The reason for that failure was osteolysis, the number one problem in total hip replacement between 1959 and 1962. In fact, periprosthetic osteolysis was seen but neither extensively studied nor recognized around the early Judet hemiarthroplasty femoral head made of acrylic.

This massive, nearly universal, osteolysis that doomed the Teflon hip was not called lysis, was not studied extensively or understood, and the role of the macrophage in this destructive process was not appreciated. It was, however, the same disease we are now recognizing in increasing numbers following certain cementless total hip replacements.

Thus, lysis was the first of a series of number one problems in total hip replacement, even before there was a successful artifical hip. But over the ensuing 35 years, the nature of the number one problem has been quite variable. The next one was deep sepsis with Charnley and Eftekar (1969) reporting 9 percent and Wilson et al. (1972) 13 percent. Once that problem had been markedly improved, the third number one problem became component loosening, both acetabular and femoral loosening. To the loosening problem was added the so-called new problem of lysis. Some called this lysis cement disease (Jones and Hungerford 1987).

It is interesting to note that Charnley, in his usual candor, reported lysis in his patients with ultra-high molecular-weight polyethylene. However, because his experience with sepsis was so high and particularly because he was seeing so much bone destruction from sepsis, he felt that this destructive process was infection, even though he was unable to grow bacteria from the lesions (Charnley et al. 1968).

Nor was McKee oblivious to the endosteal erosion associated with his metal-on-metal cemented total hip replacements. However, he interpreted the process to be mechanical in origin, secondary to motion (McKee and Watson-Farrar 1966).

It was not until the early seventies that Willert first focused attention on the particles and the macrophages in the tissue adjacent to the hip components (Willert and Semlich 1977). When we reported our first observations on the lytic aspects of the role of the macrophage (Harris et al. 1976), all 4 cases were cemented total hips. At that time, there was no recognition of the magnitude of the problem.

Subsequently came the report on a curious process in which small focal nonprogressive or slowly progressive areas of osteolysis occurred in the face of well-fixed cemented femoral components, called lysis without looseness (Jasty et al. 1986).

The next major step in understanding the lytic process was the detailed assessment of the histology of the fibrous membrane around some hip components. While confirming that the macrophage dominated the tissue, these studies established that the membrane could have a remarkable organization that was similar to that of synovium and that the tissue elaborated high levels of PGE2 and collagenase (Goldring et al 1983, 1986). These observations opened a new era in the study of periprosthetic osteolysis. As an aside, these

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observations were made before certain cytokines such as IL-1, IL-6, TGFß had been discovered.

Thus, this history is both important and educational. In short, periprosthetic osteolysis was denied, under-reported, and misunderstood. It is these errors of our past that have contributed to our current problems with lysis. Key among these errors was the the description of the lytic process as cement disease. The implication was that bone cement itself was the culprit, that cement caused the lysis. This error then led logically to the erroneous conclusion that getting rid of cement would get rid of lysis. Based on this premise, the major innovation of the 1980s was to use cementless components for the total hip replacement.

Extensive studies carried out during the past 4 years have done a great deal to reveal further the nature of periprosthetic osteolysis. It is now clear that it is not cement disease. There is no such thing as cement disease. In bulk form, bone cement is well tolerated by the body in service in total hips over decades (Maloney et al. 1989, Jasty et al. 1990, Malcolm 1991).

There is, however, particle disease. Periprosthetic osteolysis from particle disease can be produced from particles of bone cement, from particles of polyethylene, or from particles of metal. There is fragmented or particulate cement disease but the bulk material is not a stimulus to major macrophage accumulation and membrane formation.

## Improved cementing techniques

From the point of view of the contribution of cement to osteolysis, these observations now make it clear that the critical issue in the optimum use of cement, especially from the point of view of preventing lysis, is to make the cement stronger, use it better, and keep it from fragmenting. If that is done, the prevalence of lysis, particularly on the femoral side is low.

Still, the accumulated data on the incidence of loosening of cemented femoral components remains contradictory. However, if the confusing data on the durability of fixation in cemented total hip replacements are analyzed in a new way, in terms of generations, the data on the prevalence of loosening of cemented femoral total hip replacements become more rational, even though some series are excellent and some are poor. First generation femoral cementing techniques were those that involved finger-packing the cement without the use of a medullary plug or a cement gun. There was no pressurization. Generally a cast stem was used, not a superalloy, and often the stems had narrow medial borders with sharp corners. The excellent long term multicenter studies of the of first generation techniques in Sweden by Herberts and his colleagues have shown the difference in results based on implant design even in first generation techniques (Ahnfelt et al. 1990, Malchau et al. 1993).

About the mid 1970s, second generation femoral cementing techniques began to be widely used. They involved the use of medullary plug and the introduction of the cement with a cement gun. The femoral stems were made of superalloys and generally had a broad rounded medial border and usually a collar.

In the 1980s, additional factors were added and together constitute the third generation with pressurization, porosity reduction, precoating, a textured surface, and centralization.

The changes from first to second generation cementing for total hip replacements have made a dramatic difference in the incidence of femoral loosening. The results of second generation femoral cementing showed that among 105 hips with a minimum 10 year follow-up only 2 percent were loose and revised, 1 percent were loose but not revised, and thus 3 percent was the total percentage of femoral components that were loose (Mulroy and Harris 1990). This represents a major improvement compared with first generation femoral cementing which, in several series, had figures of from 20 to 30 percent of the femoral components loose but not revised, 10–15 percent revised, and thus 30–45 percent loose altogether (Stauffer 1982, Sutherland et al. 1982). Similar findings of marked improvement with second generation femoral cementing were reported from the Mayo Clinic at 10 years with 3 percent loose and revised and 4 percent loose and not revised, for a total incidence of loose femoral components of 7 percent (Stauffer 1991).

Using a different femoral stem, surgeons at the Brigham & Women's Hospital have reported a matched pair series with 29 hips in each cell with zero loosening at 8 years using second generation femoral cementing (Poss 1993), while the experience of the same 5 surgeons with the same prosthesis with first generation cementing showed 24 percent of the femoral components to be loose at just 4 years (Roberts et al. 1986).

Second generation femoral cementing has made a striking difference in the young patient as well. Chandler et al. (1981), Dorr et al. (1983, 1990) and Ranawat et al. (1984) have all reported poor results with cementing of femoral stems in young patients using first generation techniques. In contrast, Barrack et al. (1992) reported that in patients aged 50 years or under with the second generation femoral cementing in a group of 50 hips at minimum 10 years no stem had been revised, no stem had lysis and only 2 percent of the stems showed radiographic evidence of loosening.

A similar marked effect of second generation femoral cementing occurred in the revision of aseptic, loose cemented femoral components. At an average follow-up of nearly 12 years, Estok and Harris (1994) reported that among 38 hips followed for a minimum of 10 years after revision for treatment of a loose, aseptic cemented femoral component only 4 components were loose and revised, and 4 were loose but not revised.

These data demonstrate clearly the importance of how cement is used on the durability of fixation of the femoral component of the total hip.

## Mechanism of component loosening

In addition, a great deal of important information has been learned about the mechanism of loosening of total hip components. The true understanding of the mechanisms of component loosening has been a late development in total hip replacement because clinical routine techniques for study are basically of no value in this quest. One cannot determine the initiating event in loosening of a component of total hip replacement from clinical radiographs—by the time there has been an observable change, the initiating event of the loosening is long past. Secondary changes have confounded or obscured the initiating event.

That same is true of studies which attempt to assess the initiating event by observations made at revision surgery. By that time a large number of secondary events have already taken place which obscure an understanding of how the process began.

Even in the laboratory, the most common studies available are non-representative. These are studies done in cadaver bones. But in cadaver bones, no possibility exists for adaptive changes to take place over the long time history of the use of an artificial hip.

It is clear that the loosening process of both acetabular and femoral components of either cemented or cementless types can involve a wide panorama of causes. At one extreme is the patient with well fixed components who, in a single severe event such as an automobile accident, has traumatically induced loosening. At the other end of the spectrum is the patient who develops the loosening of previously well fixed components by the very slow process of failure occurring in fatigue over 15 or 20 years. Also, there are components which were never stable from the time of insertion or those which, because of suboptimal techniques, were marginally fixed at insertion and rapidly failed. However, we will focus on the more central issue, the mechanism of failure of those cemented components inserted with adequate or good cementing in which loosening takes place over many years.

In order to determine the initiating event and the mechanism of loosening of such cemented components, the key approach is the detailed analysis, both mechanically and morphologically, of autopsy-retrieved successful total hip replacements. From such studies have come very important lessons. The first of these is that the previously held belief that loosening of acetabular and femoral components had a common mechanism is incorrect (Maloney et al. 1989, Jasty et al. 1990, Malcolm 1991). In fact, the mechanism of socket loosening is exactly the opposite of that of femoral loosening.

### *Femoral loosening*

The mechanism of femoral loosening is mechanical. It is not, as was widely thought, failure at the cement-bone interface. The initiating event in femoral loosening is dominated by debonding, separation of the stem from the cement at the cement-metal interface. Cracks in the cement through pores contribute also to failure but the critical issue is debonding. The cement-bone interface remains pristine. This is true regardless of whether or not the femoral component is bonded or debonded, polished or grit blasted. Debonding starts in two places, proximally and at the tip, and extends toward the mid stem. Debonding causes the single most common radiographic sign of loosening, a radiolucent zone at the cement-metal interface in Zone 1.

An additional form of failure can arise from defects in the cement mantle or very thin layers of cement, which lead to focal fragmentation of the cement and produce bone lysis without looseness.

### *Acetabular loosening*

In contrast the autopsy studies of successful cemented acetabular components show that in many instances the common pattern of late failure of such components is biological. It is caused by macrophage-induced resorption of bone at the cement-bone interface, secondary to the progressive ingress of particulate polyethylene debris (Schmalzried et al. 1992a). It is not related to overload or underload. It is not excess stress or disuse osteoporosis. It is not trabecular fracture or fragmentation of the cement. Obviously, with poor cementing, deficient bone stock, threaded ring cementless sockets et cetera, other mechanisms of loosening may be involved. The initiating event is the ingress of polyethylene particles into the interface between the cement and bone with progressive resorption of bone. Disruption of that interface marches from the periphery of the cup toward the dome. Once the process has reached the dome, the cup is loose.

The importance of such studies lies in the fresh insights that they provide on the important issues of enhancing the duration of fixation, and thus the prevention of cement fragmentation, and consequently the prevention of one of the causes of femoral lysis. Consequently, on the femoral side, the key factor not only in the durability of cemented femoral stems but also in the prevention of fragmentation of bone-cement and thus of its role in femoral osteolysis is the prevention of debonding.

In terms of the loosening of the acetabular components, two important observations grow out of the fact that it is caused by particle disease. The first is that efforts to enhance durability of fixation of acetabular components must hinge on the reduction of polyethylene particulate invasion and the macrophage-induced periprosthetic bone resorption. Secondly, it is critical to realize that both periprosthetic osteolysis and acetabular loosening represent the same disease process. The rates are different. The extents are different, but in fact, the mechanism is the same. The same is also true for cementless sockets in some cases (Santavirta et al. 1990).

With the increasing evidence that excellent long term fixation can be achieved for the femoral component with low levels of osteolysis with cemented techniques, the two remaining major problems in total hip replacement, namely osteolysis and socket loosening, suddenly must be viewed in a new perspective. They are not two separate problems, they are the same problem.

This leads to a single important observation. Fixation is no longer the dominant issue separating cement from cementless femoral total hip components. Lysis is.

The studies from the 1980s and early 1990s have produced two key observations concerning the femoral portion of the total hip. First, with improved cementing, there is virtually no loosening, virtually no lysis, there is no such thing as cement disease. Secondly, with cementless femoral components, lysis comes on earlier, is more extensive, is more common and is progressive.

Therefore, modern cementing on the femoral side is substantially better than first generation femoral cementing and is better than first generation femoral cementless components. Not only is this true in terms of loosening, thigh pain, subsidence and reoperation, it is, most importantly, true in terms of femoral lysis.

But, before presenting the data showing the high rates of femoral osteolysis around cementless femoral components, examine the recent information on the process of osteolysis.

## Mechanism of osteolysis

Valuable new data exist on the mechanism of osteolysis itself, specifically from three points of view: creation of particles, migration of particles, and cellular response to particles. Central to the understanding of particulate disease is the recognition that the periprosthetic osteolysis can be produced by metal particles alone, cement particles alone, or polyethylene particles alone. This concept is important to avoid the assumption that only one material is responsible for this process. It is also important, however, to appreciate that the bulk of the evidence supports the concept that it is the submicroscopic polyethylene particles that are the major culprit.

### *Creation of particles*

Polyethylene particles are produced in a variety of sizes, but those larger than 10 micra in diameter are not readily ingested by macrophages. In fact, it is probable that the submicron particles, which are produced by the billions, are most likely the most damaging.

The production of submicron particles of polyethylene in the hip is mainly secondary to abrasive wear (Jasty et al. 1993). Adhesive wear plays some role, but the response in hips is quite different from that in knees. The low congruence, high stress conditions of the knees produce different mechanisms of polyethylene wear than those that exist in the hip.

It has recently been shown that the abrasive wear stretches the crystalline form of the polyethylene from chain folded to a chain extended configuration. In the chain extended configuration, the stretched-out fibrils then rupture, leading to the submicron sized particles (Jasty et al. 1993).

### *Migration of particles*

To understand more accurately the migration of the particles, particular submicron polyethylene particles, the concept of the effective joint space is important (Schmalzried et al. 1992b). The effective joint space is not just the space within the hip capsule, but rather, it constitutes the entire region surrounding the joint into which particles can escape and still be in contact with bone. That is why lysis can occur at the tip of the prosthesis, or at the dome of the acetabulum.

### *Cellular response to particles*

The two key cellular populations associated with periprosthetic osteolysis are the macrophages and the fibroblasts. The particles are rarely ingested by the fibroblasts. Because the macrophages are unable to digest the particles they ingest, they synthesize and release a large number of cytokines and growth factors which initiate a complex chain of events. The cytokines, intracellular mediators which are non-antibody proteins, are released by specific cell populations in response to the stimulus of the particulate debris. These effects induce complex cellular responses, intercellular cross-talk, and ultimately result in bone resorption, primarily by osteoclasts but some by monocytes (Athanasou et al. 1992).

Recent in situ hybridization studies have identified the IL-1 ß messenger RNA in the stimulated macrophages but no IL-1 ß messenger RNA in fibroblasts or T lymphocytes (Jiranek et al. 1993). However, the accompanying immunolocalization studies show the IL-1 ß cytokine over both the macrophages and the fibroblasts. The interpretation of these data is that the macrophages made the IL-1 ß but that the IL-1 ß then migrated to and activated the fibroblasts. These studies also showed, in contrast, that both the macrophages and the fibroblasts were capable of making platelet-derived growth factor.

The bone lysis occurring in tissue culture secondary to the presence of the tissue membrane can be partially inhibited with indomethacin (Goldring et al. 1986). While this may suggest a role for nonsteroidal anti-inflammatory agents in delaying the progression of periprosthetic osteolysis, obviously, a far more desirable approach would be prevention of the lysis.

To address the issue of whether or not immune responses are essential for the development of granulomatous tissue by particulate debris, Jiranek et al. (1993) did a series of studies in nude mice. Different mice were used which had different specific cellular deficiencies, including absence of T cells, absence of B cells and absence of natural killer cells. In all of these animals particulate debris like that found around hip prostheses induced identical granulomas, identical within the experimental animals and identical to the granulomas that produce the lysis in man. Thus the granuloma formation can occur totally in the absence of T cells, totally in the absence of B cells, and totally in the absence of natural killer cells. This does not, per se, mean that none of these cells play a role in the generic human response nor a role in selected patients with this problem, but these studies do establish that these specific cells of the immune system are not essential for the creation of the granulomatous tissue.

## Lysis in cementless hips

Now, turning to the clinical picture, the critical question is whether going cementless has eliminated cement disease?

### *The femur*

Consider first lysis in cementless femoral components with the requirement that a minimum four year follow-up be present. The figures are striking. In essence, for all first generation cementless femoral components, femoral osteolysis comes on earlier, has a higher prevalence, is progressive, and is more extensive than femoral osteolysis in association with modern femoral cementing over the same time period (Crutcher et al. 1991, Stulberg et al. 1992, Woolson and Maloney 1992, Beauchesne et al. 1992–1993a,b, Cox and Dorr 1992–1993, Kim et al. 1992–1993, Xenos et al. 1992–1993, Heekin et al. 1993, Kim and Kim 1993, Martell et al. 1993, Smith and Harris 1994). Representative figures for the prevalence of osteolysis around different cementless femoral components at 4–7 years are 22–56 percent for the AML, Anatomic Medullary Locking, DePuy Inc., Warsaw, IN, U.S.A. (Beauchesne et al. 1992–1993a,b, Kim et al. 1992–1993) the APR, Anatomic Porous Replacement, Intermedics, Inc., Austin, TX, U.S.A., 30 percent (Cox and Dorr 1992–1993), the HGP, Harris Galante Porous, Zimmer Inc., Warsaw, IN, U.S.A., 8–31 percent (Woolson et al. 1992, Martell et al. 1993, Smith and Harris 1994), and for the PCA, Porous Coated Anatomic, Howmedica Inc., Rutherford, NJ, U.S.A., 10–33 percent (Crutcher et al. 1991, Stulberg et al. 1992, Xenos et al. 1992–1993, Heekin et al. 1993, Kim et al. 1992–1993).

In our first report of femoral osteolysis with the HGP femoral component, the incidence was 3 percent (Maloney et al. 1990). The incidence in that series of HGP cases is now 31 percent (Smith and Harris 1994).

The incidence of femoral lysis in patients with PCA femoral components was initially 3 percent (Maloney et al. 1990) and has now increased to 18 percent (Heekin et al. 1993). Initially no lysis was reported with the AML. Subsequently, at 5–7 years, the figure was 22 percent (Beauchesne et al. 1992–1993a,b). At 8 years the figure has become 42 percent (Engh 1993). Comparable figures have been reported for APR (Cox and Dorr 1992–1993) and, although detailed numbers have not been published as yet, this process occurs with the Omniflex, Omnifit, TriLoc, Spotorno, Lord prostheses and others.

Another very meaningful insight that comes from these studies is the observation that 2-year follow-up data are of little value. Since the critical problem is lysis and since it rarely appears before 2 years, follow-up periods of 2 years do not address the critical issue. Equally unimpressive are 2-year studies that describe less thigh pain or 2 years, or even 5 years with better femoral cementless designs. While the observations may be correct, their importance is minimal because the issue of lysis, not the issue of thigh pain, dominates the scene.

Contrast those figures on femoral osteolysis with the lysis rate at 5–7 years with *second generation cementing*. The figures range from zero to 2 percent (Mulroy and Harris 1990, Barrack et al. 1992) in primary total hip replacements with an additional subgroup of patients who have the lysis without looseness, also at a low percentage. Similarly, at the same time duration, comparable figures (2 percent) exist for third generation femoral cementing (Schmalzried and Harris 1993).

Even at longer time durations, figures for femoral lysis among patients with cemented femoral components using good cementing techniques remain low. Among a group of 102 hips containing femoral components fixed by second generation cementing techniques surviving 14 years or more, only 3 femoral components had major proximal femoral lysis. All 3 were rigidly fixed. An additional three had lysis associated with a loose femoral component and an additional three had small focal lysis without looseness (Mulroy and Harris 1994). Johnston's group has recently reported a group of patients with an average follow-up of 18 years in which the incidence of femoral lysis in those 83 hips which were surviving and had not been revised was 3 percent (Schute et al. 1993). As noted above, in a series of 50 patients all 50 years or under undergoing second generation femoral cementing, the prevalence of femoral lysis was zero (Barrack et al. 1992). In a group of 38 hips in patients having second generation femoral cementing for revision of aseptically loose femoral components, the prevalence of lysis at 12 years in those not revised was 9 percent (Estok and Harris 1994).

The question often arises that cementing into a femur in a hip that has developed lysis must be hazardous because that individual patient must have a high prevalence of recurrent lysis. To investigate this issue we did a long term follow-up of 29 hips that had moderate to severe femoral lysis in which second generation femoral cementing was used for the femoral revision. At 9 years, lysis existed in only 2 of those hips. Fears about excessive recurrence of lysis with the second use of cement in the femur at the time of revision are unfounded (Pierson and Harris 1994).

Perhaps the two most remarkable observations about femoral osteolysis in association with cementless femoral components are these. First, the prevalence and extent of lysis for femoral osteolysis are worse than the original problems recognized in the mid-70s with cemented femoral components. The solution has turned out to be worse than the original problem. Secondly, periprosthetic femoral lysis is now the most common complication of cementless femoral total hip replacement. Osteolysis is higher in incidence than infection, dislocation, severe heterotopic ossification, nerve damage, deep vein thrombosis, and any other single complication of the operation.

Femoral lysis with cementless femoral components is thus more common than with cemented femoral components.

These comparative figures for lysis around cementless femoral components at 5–7 years versus those for second generation cementing suggest that the use of cement may *protect* these femurs from lysis in a way that cementless components do not. However, comparison across these studies may not take into account differences in age, sex, weight, diagnosis, activity levels, surgery, rehabilitation duration, radiographic criteria. To address this issue we did a study of 41 pairs of primary total hip replacements which were matched for age, sex, diagnosis, weight, duration, radiographic interpretation, approach and rehabilitation (Goetz et al. 1994). All patients had the same socket, same polyethylene, same surgeon, chrome-cobalt heads and similar polyethylene thickness. The only two differences in these cases were 1) the type of femoral component and 2) the fixation of the femoral component. We compared a precoated femoral stem made of forged chrome-cobalt with a chrome-cobalt – chrome-cobalt taper, Precoat total hip replacement, Zimmer, Inc., Warsaw, IN, U.S.A., against a cementless femoral component made of Tivanium with a Tivanium-chrome-cobalt taper, titanium fiber mesh proximally and a collar, HGP total hip replacement, Zimmer, Inc., Warsaw, IN, U.S.A. At 6 years' average follow-up (minimum 4) the incidence of lysis in the cemented series was zero, but the incidence of femoral lysis in the cementless series was 29 percent. Moreover, in the cementless series there was increased risk for revision among those that had femoral lysis ($P < 0.0002$). The explanation appears to be that cement seals off the femur, delaying the ingress of particulate polyethylene. In addition, there may be increased metallic debris associated with a cementless femoral stem.

Femoral osteolysis is the most common complication of cementless hip replacement in those cases followed 5 years or more. This one striking observation dominates the decision of the type of femoral component to be used. In the cement versus cementless debate of the 1980s, for the femur, cement won. Modern femoral cementing is preferable in terms of loosening, revision and lysis. Modern femoral cementing is the best fixation for the femur regardless of age, sex, weight, diagnosis and primary or revision.

Consider again the issue of the use of cement in younger patients. Sullivan et al. (1993) have reported on a series of 89 hips in patients aged 50 or under with an average age of 41 years at a duration of 18 years. In that group all but 5 had minimal or no pain and minimal or no limp. 2 stems were loose and revised and 4 were loose and not revised. Analysis of the quality of the femoral cementing techniques with the new cement mantle grading system (Barrack et al. 1992) revealed that 23 hips were graded A, 32 hips were graded B or a total of 55 hips being either A or B with 34 hips C and none D. These well formed cement mantles have functioned very well over nearly two decades in young patients.

Clearly some of the attitudes of the 1980's must change. It is necessary to forget about fit and fill, a concept inappropriate for cemented femoral components. It is optimum to have a cement mantle which is at least 2.5 mm thick surrounding the implant. The appropriate techniques for modern cementing have been well defined. Plugging the femoral canal is an advantage, as are the use of a cement gun, centrifugation or vacuum mixing of the cement, the use of a nozzle seal to reduce voids in the cement when withdrawing the nozzle, pressurization of the cement and centralization of the stem. The stem should be made of a superalloy and some would believe it should have a textured surface and precoating both proximally and distally (Schmalzried and Harris 1993) while others recommend a polished surface (Fowler et al. 1988).

### *Pelvic lysis*

In some current cementless systems pelvic lysis has an early onset, high prevalence, and can be extensive. Pelvic lysis around the PCA acetabular component reported by Stulberg et al. (1992) was 37 percent at 6 to 7 years and 41 percent at 7–8 years. Pelvic lysis led to revision surgery of the acetabular component in 8 percent of PCA cases at less than 10 years in the series by Lavernia et al. (1993). One report of lysis in the cementless AML at 7 years showed 36 percent acetabular and 35 percent femoral lysis alone for a total combined incidence of 72 percent (Kim 1993).

To reduce the incidence of periprosthetic lysis, a number of steps are available immediately. The evidence is strong that titanium femoral heads should not be used. Similarly 32 mm heads appear to be a disadvantage. There are four reasons not to use the 32 mm head. The large head means that the polyethylene is thinner for the same outer diameter of the acetabular component (Livermore et al. 1990). The 32 mm head also leads to a greater linear wear than the mid size. It has a greater volumetric wear than any other, and finally it is associated with a higher revision rate for the acetabular component. Also, it is important to minimize modularity.

To avoid accelerated polyethylene wear, one should not use heat treated polyethylene, not use polyethylene liners that are less than 6 mm thick and be sure that the polyethylene is securely fixed if the acetabular component is metal backed.

The decisions on what acetabular components are best suited for different situations is less clear because of the lack of long term data. The quandary about the use of all-polyethylene acetabular components in primary total hip replacement operations lies in the disparity between the number that require revision versus the number that have radiographic signs of being loose. At 10 years or so in the patients above 60 years of age, 4–11 percent have required revision and 40–50 percent are loose by radiographic criteria (Stauffer 1982, Sutherland et al. 1982, Mulroy and Harris 1990). Both loosening and revision increase after 10 years (Charnley 1979, Schulte et al. 1993).

Shulte et al. (1993) and Wroblewski (1986, 1988) conclude that the all-polyethylene cemented acetabular component is the most challenging problem. Certainly it is in the young, even though the femoral results with modern cementing were excellent (Barrack et al. 1992).

The use of cementless acetabular components in primary total hip replacement is based on the hope that they will have a better record at 10 years than cemented, all-polyethylene acetabular components. However, no 10-year-data yet exist. Certainly some designs of cementless acetabular components have not been improvements. This includes some threaded ring cementless sockets as well as the AML, PCA and Dual Geometry acetabular components.

An interesting finding is that in the matched pair series of the comparative cemented versus cementless femoral components mentioned above in which 29 percent of the cementless femoral components had femoral lysis, none of the patients in either group had pelvic lysis. For whatever reasons, femoral lysis around the cementless femoral component with that design (HGP) was extensive while pelvic lysis was absent. This was not so with the AML or PCA in which both sides of the joint were heavily involved in lysis. Thus, for primary acetabular reconstruction some cementless acetabular components have done well regarding lysis at the 5–7 year duration but others have not. Only long term data will tell whether the results of cemented all-polyethylene sockets can be improved by selected cementless components.

For revisions of the socket, the short term studies favor cementless sockets fixed with screws. Over that duration, the cementless hemispherical titanium socket fixed with mesh and screws is superior to the use of cement in revision acetabular surgery. Of 140 consecutive acetabular revisions, only 2 have come loose at 4 years and both of these had pelvic discontinuity with Stage 4 bone loss (Tanzer et al. 1992). Galante et al. (1993) have a similar series of 129 hips followed 4 years in which, with the exception of 1 septic case and 1 case that had pelvic irradiation preoperatively, none were loose, none were revised, none had lysis. Combining the series from Rush-Presbyterian with that from the Massachusetts General Hospital, there are 269 HGP acetabular revisions at 4 years in which only 1 is loose and revised, 2 are loose and not revised, and none have pelvic lysis. Clearly, however, 4 years is much too short to provide a definitive indication of the longer term success of this approach.

## The hybrid hip

For a primary total hip replacement, I prefer a hybrid solution, using a cemented femoral stem of modern design and a cementless acetabular component of hemispherical design with a titanium mesh porous surface, press fit or fixed with screws as needed. Although the data on such sockets at 6 years is excellent, longer follow-up will be needed (Schmalzried and Harris 1993); there is some evidence that the acetabular component should be press fit without screws whenever possible (Schmalzried et al. 1992b, 1994).

In a report of 120 such hybrid total hips at 5 year average follow-up there have been no revisions, no reoperations and 2 acetabular migrations (1 associated with radiation necrosis and 1 with a bulk allograft). There were 2 loose femoral components, 1 in a patient who had a femoral fracture at operation and the other patient had renal osteodystrophy (Galante, personal communication 1993). For the acetabular decision in primary total hip replacements, however, 10-year-data and longer will be necessary for a more accurate assessment that this approach is appropriate.

## Conclusion

The decade of the 1980s in total hip surgery was characterized by some as the decade of cement versus cementless. Now a number of the uncertainties underlying this debate have been resolved.

Using total hips consisting of an ultrahigh molecular weight polyethylene bearing surface, it is clear that modern femoral cementing does a superior job, in terms of both duration of fixation and femoral lysis, to first generation femoral cementless components. This appears true for primary total hip replacements regardless of the age of the patient. Improved cementing techniques have dramatically enhanced the results of cemented femoral revisions for aseptic loosening, as well as providing excellent results on into the second decade.

In acetabular revision surgery short term results of certain cementless acetabular components are substantially better than cemented results. Longer duration will be needed to assess if this improvement holds up.

For primary acetabular reconstructions cementless sockets are widely used in the young based on the poor results of cementing. Metal-backed acetabular components offer no advantage at any age. The decision favoring cemented or selected cementless acetabular components for the patient with a 15–20 year life span remains unresolved. Patients of any age who have a short life expectancy, say 10 years or less, are probably best treated with a cemented acetabular component.

To reduce the generation of particulate debris coming from the total hip replacement articulation several changes in past practice are now widely accepted:

1) Avoid the use of a titanium femoral head;
2) Avoid the use of a 32-mm head diameter femoral head;
3) Avoid thin layers of polyethylene, whether they occur concentrically or at the periphery of the acetabular component;
4) If a modular socket is used, the polyethylene must be rigidly fixed to the shell;
5) If a modular socket is used, the polyethylene must be fully supported by the shell;
6) Avoid third-body contamination of the articulation from all sources, be it cement particles, metal debris, or bone fragments.

Future developments will hinge a great deal on both radiographic and retrieval studies of wear of different types of total hip articulations, and the rapidly increasing focus on in vitro wear testing. Major improvements are being made in the sophistication of the wear testing machines (Saikko 1992, Saikko et al. 1992, 1993), the duration over which the studies are being carried out (Saikko 1993), and the effort to create in vitro testing circumstances which are closer to the in vivo status.

Major improvements in the reduction of third body wear in the articulation will come from the elimination of modularity on the femoral side of the reconstruction. It is probable that there will be a major shift back to monobloc type femoral components.

Major improvement could also come from one or more of the following advances in the future:

1) Improved ultrahigh molecular weight polyethylene. This could come with changes in composition, molecular organization, mode of sterilization and other techniques;

2) Improvement in the finishing of the articulating surface of the femoral head. This has already made a substantial difference, both in the finish possible on alumina heads and in the form of superfinishing of metallic heads;
3) Different head surfaces to articulate against polyethylene. Here various surface treatments of metallic heads such as ion implantation may play a role as well as the use of ceramic heads;
4) Entirely different combinations of articulating materials which eliminate polyethylene altogether, such as ceramic on ceramic (Nizard et al. 1992), the use of metal on metal (Weber 1993), or the development of entirely different substances which might be suitable for the articulation.

As has been pointed out in several recent editorials on joint replacement (Goodfellow 1992, Bauer 1992, Harris 1993) and is documented in this article, a high percentage of innovations proved to be change but not to be progress. It is clear that clinical information at 2 years is inadequte for a rigorous assessment of even the possibility that an innovation may prove to be equal to, let alone superior to, existing technologies which have 10–15 year track records. More rigorous and more specific data are required before the release of a new technology can be justified for wide use.

Faro and Huiskes (1992) and Huiskes (1993) have addressed this issue extensively and made detailed and thoughtful suggestions for the insightful use of systematic design evaluation, clinical testing and clinical trials in an algorithm which can provide a basis for self regulation and self control by the orthopedic community. These or similar programs should lead to substantial improvement in the process of evaluation of innovation and the wide distribution of only those changes which actually represent progress.

Since periprosthetic osteolysis is a dominant factor in the success and failure of contemporary total hip prostheses and since this appears to be primarily the response to particulate polyethylene, research is being aimed at improving or eliminating polyethylene or improving the polyethylene weight bearing couple. However, in the rush to get rid of polyethylene one must be cautioned by the experience related in this article which reflects on the unexpected outcome that followed the effort in the late seventies to get rid of cement. Metal on metal articulations, improved polyethylene and ceramic surfaces all hold promise.

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