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Update

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INTRODUCTION

By Timothy McTighe
Editor

Recently there has been considerable discussion, debate, and controversy concerning the term fretting. What is fretting and what clinical/ surgical concern should there be as a result of fretting? Fretting is particulate debris generated by abrasion of two surfaces. However, is fretting the real issue of concern or is it osteolysis?

The most common cause of proximal, femoral bone loss is due to osteolysis. Although the specific cause of lysis is not known, it has been attributed to a variety of factors, including motion of the implant, foreign body reaction to particulate debris and hypersensitivity to metal. Femoral osteolysis is well documented with many loose and some well fixed cemented total hip arthroplasties. Particulate debris of polyethylene and/or polymethylmethacrylate seem to be responsible for causing this phenomenon. Osteolysis is now recognized to occur with cementless femoral components. It has occurred around loose as well as rigidly fixed femoral implants. Osteolysis is a potential problem common to all femoral components, independent of their metallurgy, design, or means of fixation whether cemented or cementless. The common underlying pathology in all cases is the host's response to the presence of particulate debris. Particulate prosthetic debris and its potential biological response is of growing interest to all total joint surgeons. In light of this concern, JISRF is publishing this report in an attempt to help clarify and understand this perplexing problem.

We look forward to your questions and concerns regarding this issue and will make every attempt possible to respond to your needs.

TORSIONAL RESISTANCE AND WEAR OF A MODULAR SLEEVE / STEM HIP SYSTEM

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Maximum metaphyseal fill with good contact of dense bone enhances mechanical fixation and bone ingrowth in porous coated hip replacement. In order to improve initial fit and fill, the S-ROM™ Total Hip System (Joint Medical Products Corporation, Stamford, CT) was developed with modular proximal sleeves and stems to allow the surgeon to "customize" the implant to the individual patient. However, concerns have arisen as to the torsional resistance of the sleeve/stem assembly and the potential for significant wear debris generation at this interface.

In total hip replacement considerable torque is generated against the femoral component in daily activities. Recently, using a

telemeterized femoral prosthesis implanted into an elderly 275 Kg (125 lb.) woman, in vivo torques were reported as high as 22 Nm (194.7 in-lb.) during activities such as stair climbing. In addition to having to withstand considerable torque, modular proximal sleeves and stem components introduce a metal/metal interface to the biological environment and the possibility of wear debris generation.

Fretting is the mechanical process whereby high contact stresses between two surfaces together with relative tangential, cyclic micromovements cause local removal of one or both surfaces. The fretting debris is usually trapped first, causing further surface destruction and particulate generation. For implant metals the passive oxide surface layer which protects subsurface metal is removed and corrosion in body fluids is greatly enhanced.

Implant wear debris can stimulate cells to elaborate agents capable of causing resorption of osseous tissue at the bone/implant interface. Investigations indicate that all of the orthopaedic biomaterials (metals, polymers and ceramics), when present in particulate size range small enough to be phagocytosed (less than about 10 microns), can elicit this biological response. Modular hip proximal sleeves and stems may result in the generation of interface metallic wear debris.

We have studied the torsional resistance of the bone/sleeve and sleeve/stem interfaces of the S-ROM™ Total Hip System and quantified the number and particle size distribution of wear debris generated during cyclic loading and physiological levels. The results indicate that the sleeve/stem interface of the S-ROM™ system is capable of withstanding a physiologic torque of 18-28 Nm under ideal conditions. Several samples underwent repeated disengagement and reimpaction of the stem into the sleeve as described in the surgical guide using appropriate instrumentation. This resulted in a decrease in maximum torque to interface slippage to 15-18 Nm. Contamination of the sleeve/stem interface with blood and fatty elements also resulted in a significant decline in the resistance to torsional slippage.

Axial and torsional cyclic wet testing of the S-ROM™ sleeve/stem system resulted in the generation of significant wear debris. The wear debris generated during axial fatigue testing within the saline solution was relatively uniform in size with 99.8% of the particles in the range 0.255-1.915 microns. The war debris adherent to the sleeve and stem interface surfaces was slightly less uniform in size with 99.8% of the particles in the range 0.098-4.012 microns. Approximately 8.32 x 101 wear particles were generated and collected in the axial fatigue test specimen.

A significant amount of wear debris was also generated during torsional fatigue testing of the sleeve/stem system. Again, the wear debris was uniform in size with 99.0% of the particles in the range 0.6902.306 microns. The wear debris adherent to the sleeve and stem interfaces was slightly less uniform in size with 99.0% of the particles within the range 0.669-4.282 microns. There were fewer total wear particles generated during the torsional testing (3.5×10^6) which is most likely the result of significantly milder loading conditions.

Scanning electron and optical microscopy revealed significant wear and abrasion of the stem and sleeve surfaces. Wear and abrasion was observed primarily at the proximal and distal regions of sleeve/stem contact, and in areas of contact of the sleeve/stem components. Surface analysis also indicated minimal surface contact of the surfaces which may be the result of poor machining tolerances or distortion of the sleeve component due to the high temperature sintering processes used to apply the porous coating to the sleeve.

Our findings indicate that implants having modular proximal sleeves may be prone to slippage under physiologic loading conditions. Slippage of the sleeve/stem interface of the S-ROM™ system occurred in one half of our specimens under ideal conditions below torques reported for an elderly woman. Larger patients would most likely subject the

interface to higher torques because of both greater body weight and larger stem head offsets. The recommended feature of readjusting stem anteversion by repeated disengagement and impaction of the sleeve/stem interface should be discouraged because of the significant reduction in torsional resistance. Clinically, before assembly the stem/sleeve interface should be free of surface contaminants to provide maximum torsional resistance.

Our results also indicate that substantial wear debris are generated during both axial and torsional cyclic loading of the sleeve/stem interface. The majority of particles produced by the testing were much below 5 microns in diameter. Particles below this size are more likely to be ingested by macrophages and have been associated with osteolysis, joint pain, and implant loosening. Based upon the findings of our studies, the implantation of any type modular system must be carefully considered.

STRENGTH, STABILITY AND WEAR ANALYSIS OF A MODULAR TITANIUM FEMORAL HIP PROSTHESIS TESTED IN FATIGUE

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Materials and Methods The modular implant (S-ROM™, Joint Medical Products Corp., Stamford, Ct.) was fabricated from Ti-6A1-4V alloy and consisted of a sintered proximal sleeve that connected with a grit-blasted stem via a Morse taper. The in vitro experiments were performed with 30 implants under both dry and wet environments using a test setup that was designed to simulate proximal fixation of the device at the sleeve-bone interface only, with distal support against the lateral endosteal cortex. A porous coated sleeve was combined with an 11 mm stem size (36 mm neck length and a 150 mm body length) in all tests. To establish baseline mechanical properties two series of tests were performed in air at room temperature: one with direct vertical loading and one with a compound loading angle directed at 15 degrees out of plane (to simulate torsional physiological loads). Head loads ranging from 800 to 1400 lbs were delivered at 10 Hertz by an Instron apparatus to establish the stem endurance limit. The wet tests were conducted in a saline chamber with physiologic loading of 400 lbs applied 20 degrees out of plane for 20 million cycles. After each test, the sleeve was carefully sectioned and removed from the stem to allow examination of contact areas by optical stereomicroscopy and scanning electron microscopy (SEM). The same examination protocol was used with 5 stems retrieved from patients after 1 to 6 years of implantation. Saline samples obtained from the wet chambers were analyzed using a sophisticated particle counting technique based on impedance discharge technology (electrozone method). Rotational stability of the stem with respect to the sleeve was constantly monitored during testing with a linear voltage displacement transducer (LVDT).

Results In the dry fatigue tests, the stem endurance limit (load at 100 million cycles with fracture) was between 1000 and 1100 lbs for both load angles. Using high sensitivity displacement monitoring (detection limit = 100 μm), no relative motion was detected between the stem and sleeve for any tests. Upon inspection of the Morse taper surfaces, it was generally observed that contact areas between sleeve and stem were quite random and much less uniform than expected. The areas of high pressure contact between sleeve and stem were most evident at the proximal medial and distal lateral aspect of the sleeve.

Examination of the contact areas under SEM revealed surface modification (burnishing of the grit-blasted surface and oxidation) with occasional evidence of loose wear debris. The saline environment tests at 400 lbs also revealed random and surprisingly low contact areas between stem and sleeve. Retrieved human implants (up to 6 years after surgery) showed minimal stem and sleeve surface modification that was uniformly less

than observed in vitro. The particle analysis of the wet environment tests yielded particle counts in the saline chamber up to twenty million, but the technique was unable to discriminate between metal and non-metal particles (arising from background contamination).

Total particle volume was only on the order of $5xl0^{-3}$ mm^3, because of the small average particle size of about 1 μm. Assuming all the particles were titanium alloy (a worst case assumption since the background particle count for plain saline alone was several hundred thousand and contamination from the test setup was inevitable), an upper bound on the particles generated during the 20 million cycle fatigue tests was calculated to be 50- 100 g x 10^{-6}.

Discussion and Conclusions

• The S-ROM modular hip implant shows adequate fatigue strength and secure locking of stem and sleeve components.

• Fretting (defined as ≤ 25 μm of cyclic relative motion) scars develop at the small contact areas of the stem-sleeve interface in the presence of gross component stability.

• This results in surface modification and the generation of particulate debris. In vitro surface modification was greater than that observed with human retrievals.

• Particulate debris would probably be reduced by improving component surface finish and quality of fit.

• The particle levels generated in the wet tests are substantially less than the levels of polyethylene particles generated in the hip due to acetabular cup wear (based on a linear wear rate of 0.2 mm/yr and particle size range of 0.2 to 20 μm).

• Fretting and debris formation are inevitable at the hip prostheses modular junction. *There is a general lack of understanding about the level of metallic particulate debris that may be biologically active or inactive.

ISSUES IN COMMERCIALLY AVAILABLE UHMWPE

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UItra high molecular weight polyethylene (UHMWPe) has been the orthopaedic bearing material of choice for over 15 years. However, as it has become evident that debris from UHMWPe can lead to implant loosening', more attention has been paid to the mechanisms that lead to polymer damage in both acetabular and tibial components. There are ASTM guidelines for medical grade UHMWPe for use in implants but they only provide minimum values and do not address some properties important to observed damage mechanisms. It is worth noting that the guidelines for medical grade UHMWPe are not directly performance related. Important design material properties such as yield strength and modulus are not guidelines. It is probable that a portion of the differences seen in in vitro wear tests and in retrieval analysis are due to these material property and processing differences. With few exceptions[2,3] little attention has been paid to the nature of medical grade UHMWPe and the possible variations in material properties and quality that can occur in commercially available materials. This work addresses methods of characterizing UHMWPe and compares several commercial sources of material. These variations have direct implications on the performance of the polymer in total joint replacement applications.

Variations in Commercially Available UHMWPe

Several graded and lots of commercially available medical grade (implant quality) UHMWPe were obtained for testing along with the appropriate certifications from the suppliers. The materials included 415 GUR, 412 GUR (Hoechst/ Celanese), 1900cm (Himont) and Hylamer® (Du Pont)

Orthopaedic Bearing Polymer. The materials were characterized chemically (density, melting point, crystallinity, impurities) and physically (tensile modulus, yield strength, ultimate tensile strength, elongation to break and creep at 1000 psi) and then compared to certification values when possible. Further, optical evaluations were done to assess the quality of these materials. Materials were received in the form of 3" diameter cylindrical rods obtained from Poly He, Westlake Plastics and Du Pont. All materials were received with certification of physical and chemical properties. Tensile and flexural related tests were done in accordance with ASTM D638 guidelines with Type I tensile bars. Creep measurements were done in accordance with ASTM D621. Density measurements were conducted as described in ASTM D 1505. Sectioned slices for visual inspection were obtained using a Reichert-Jung 2040 microtome.

We found that there is a wide range of properties and quality of medical grade UHMWPe that can be obtained. There are extremely large physical property differences between the various grades of UHMWPe. The variations within a grade can also be significantly large. The magnitudes of the variations in important criteria such as the yield strength and creep of the materials are large enough to potentially influence the performance of the material in a joint replacement. In average overall types of conventional medical grade UHMWPe, yield strength varies 25%, modulus varies from 170 - 230 kpsi (35%) and creep varies over > 100%. We have also found that sheet stock material can be different from rod stock. These material variables have not been included in assessing the damage mechanisms of UHMWPe.

Optical examination of cross sections of materials shows there is often unconsolidated UHMWPe particles in the stock shape. These unconsolidated particles may lead to pitting, fracture or other observed types of damage.

To date, most of the attention has been focused on the physical properties of the material and little attention has been paid to the chemical degradation, in the form of oxidation, that is also occurring during use. Chemical degradation of UHMWPe may be an important factor in the damage rate of implants, especially at long implant times.[4] Earlier, we reported a Fourier Transform Infrared Microspectrometric (FT-IRM) Technique for assessing the level of type of oxidation found in UHMWPe.[3,6]

We report here detailed analysis of the oxidation state of commercial implants prior to implantation and analysis of retrieved knee and hip components at different implant durations. We also compare the relative chemical resistance of two UHMWPe samples of different crystallinity. The FT-IRM method allows us to assess the levels and locations of oxidation in both retrieved acetabular and tibial components. In general, we find that high levels of oxidation are almost always associated with high levels of damage in both acetabular and tibial components. The extent of oxidation also appears to increase with both increased stress and increased implant duration.

All microspectrometric measurements were obtained using a Digilab 60A FT-IR spectrometer with a UMA 300 IR microscope (Cambridge, MA). Spectra were obtained at a resolution of 4 cm^{1}, for 100 scans with a narrow range MCT detector. The microscope was equipped with a 4 x 4 motorized state, capable of accurately moving 10 micron steps. The adjustable sperture, was set to 50 µm x 200 µm. A Reichert-Jung 2040 microtome was used to make 250 µm cross-sectional slices of the samples. Spectra were obtained at depths from 0 µm to 2000 µm below the surface.

Studies on the degree of oxidation are done by examining the carbonyl bands between 1700 cm^{-1} and 1750 cm^{-1}) and the ester, ketone and acid bands occurring at 1738 cm^{-1}, 1720 cm^{-1} and 1697 cm^{-1} respectively. The overall peak area of the entire carbonyl band is determined between 1800 cm^{-1} and 1660 cm^{-1}. The data is normalized for sample thickness. This area is a measure of the extent of oxidation.

We find in studying commercially available implants prior to implantation, that the level of oxidation in some components is very high prior to use. This may be due to the type or quality of UHMWPe used, the sterilization methods and the thickness of the component.

We find the level of oxidation in retrieved acetabular and knee components is significantly higher than a corresponding new component. The extent of oxidation generally follows the extent of damage. The more severely damaged the component, the higher the level of oxidation. In acetabular components we find that the inside (articulating) surface is much more oxidized than the outside surface. In tibial components we find that the level of oxidation increases with time and is highest in areas of higher stress. Interestingly, we also find that the maximum level of oxidation in tibial components is found 1-2 mm below the surface the same area as predicted to have maximum stress.

It is expected that increasing the crystallinity of UHMWPe will improve the resistance to degradation. This has been demonstrated by exposing two samples of UHMWPe with different crystallinity and morphology to a strong oxidizing acid, chlorosulfonic acid. This acid turns UHMWPe black as it oxidizes. By measuring the depth of acid penetration with time, an oxidation rate can be obtained. UHMWPe of 50% crystallinity was 415 GUR The 75% crystalline material was enhanced UHMWPe, Hylamer@ Orthopaedic Bearing Polymer. The acid oxidized the more crystalline material at a slower rate.

Oxidation is a phenomenon that is strongly associated with the damage of UHMWPe. Oxidation of UHMWPe changes the chemistry of UHMWPe which may make it more susceptible to further damage. The rate and extent of oxidation may also be increased with increased stress. Oxidation may be a strong influence on the damage mechanisms of UHMWPe components, especially at long implant times.

It is evident from our studies that ASTM certified conventional UHMWPe can be highly variable in properties and quality. These variations are of a magnitude that may significantly influence the generation of polyethylene debris. Further, the oxidative state of UHMWPe in devices prior to implantation are also highly variable and may contribute to accelerated polyethylene damage.

In order to improve upon the conventional UHMWPe currently being used, a new material should provide improvements in creep resistance, chemical stability, quality, and strength without sacrificing other material properties. An offering that fits the criteria is Hylamer@ Orthopaedic Bearing Polymer made by DePuy - Du Pont Orthopaedics® which has been introduced into the marketplace as a bearing surface for acetabular liners. Hylamer® has improved creep resistance (50% improvement at 1000 psi load), increased yield strength (30%), increased tensile and flex modulus (ca 100%) over that of conventional UHMWPe. Further, its increased crystallinity has been shown to provide greater resistance to very strong oxidizing reagents and high doses of gamma irradiation. Hylamer® also has the highest known quality control standards of an orthopaedic bearing material.

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THE EFFECTS OF IMPLANT WEAR DEBRIS AND HUMAN BONE CELL PROLIFERATION: IN VITRO ANALYSIS

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Purpose This is the first study to use human bone cell cultures to investigate the biocompatibility of clinically relevant wear particulates, i.e., in terms of particle size and shape as demonstrated in vivo. Several investigators have reported significant levels of implant wear debris at revision surgery

implicating wear in osteolysis and loosening.

Methods

We used normal primary human bone cell cultures to characterize the metabolic response to various implant materials in particulate form. We feel the inhibition of cell growth as measured by [^{3}H] TdR incorporation during DNA synthesis, is a sensitive and valid way of determining the relative effects of implant materials on cell proliferation. In vitro models focus on the simulation of the in vivo environment. Since frictional heading during artificial hip joint articulation, as shown by Bergman, may potentially effect the response of the host-to-wear particulates, temperature was an additional variable.

Results

There was a definite inhibitory effect on the rate of bone cell proliferation with all the particles tested and with temperature elevations. Total cell counts reflected a 40% decrease in cell proliferation as compared to 37°C. This inhibitory effect was dose dependent and statistically significant when tested at specific concentrations. Elevated temperature appears to potentiate the metabolic response of bone cells to wear debris. Ti-6Al-4V particulates demonstrated the least inhibitory and the stainless steel particulates the most inhibitory effect. Inhibition was detected only with physical contact between cell and particulate. Conditioned media (pre-incubated with particulates) also did not affect proliferation. Although there was a reduction in the proliferation of cells as determined by DNA synthesis, the cells did not appear to be dying as judged both by microscopic examination and alkaline phosphatase level per cell. A decrease in enzyme activity with the addition of the particles was about the same ratio as with the decrease seen in DNA synthesis.

Discussion

Since both cells are known to produce autocrine and/or paracine growth factors in vitro (e.g. TGF_{b}-IGF-I and -II) cell proliferation inhibition could be due to adsorption of these factors by particulates. Since physical contact was necessary for inhibition in our assay, adsorption did not appear to be the mechanism of inhibition. While the size of particulates has been shown to be in the range of 2-10 μm in vivo, the concentration at interfaces between bone and fibrous tissues, and fibrous tissues and implant is unknown. The cells in our assays appear to respond in a dose dependent manner, thus in vivo concentration becomes important. The fibrous membrane around prostheses in vivo may act as a physical barrier to mitigate the effects of particulates. The fact that hydroxyapatite significantly inhibited bone cell proliferation is not surprising since hydroxyapatite crystals in synovial joints induce intense inflammatory reaction (as in the Milwaukee Shoulder).

Conclusion

It is concluded that some characteristic unique to each biomaterial particulate has an inhibitory effect on bone cells. We are actively investigating the interesting effects of both temperature elevation and particulate characteristics focusing on the mechanisms of cellular inhibition.

CERAMIC IMPLANTS - BELATED ANSWER TO OSTEOLYSIS CONCERNS

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Why should we consider the more expensive ceramic femoral ball for total hips? Isn't there a real risk of catastrophic fracture, and is the added expense justified?

Some of this ceramic risk/benefit rationale ties into reduce polyethylene wear with associated osteolytic potential, and to the newly identified risk of metallic debris from the use of modular titanium and cobalt alloy femoral balls. There is a renewed awareness of the peri-implant destruction caused by debris-mediated osteolysis (Clarke and Campbell, 1989). With the advent of porous-coated titanium implants, the propensity for shedding of metallic debris with

3-body abrasive wear of both Ti-6AI-4V balls and accelerated UHMWPe wear has caused many concerns (Agins et al, 1988; Anthony et al, 1990; Nasser et al, 1990; Dorr et al, 199 1). As an obvious knee-jerk reaction, it has now become popular to advocate "improved coatings" for metallic balls (anodizing, ion-bombarding, nitriding, etc.).

However, in a further escalation of concerns over metallic debris, European authors have now described crevice corrosion with modular CoCr balls mounted on CoCr stems, with release of metal particulates into the joint space (Mathieson et al, 199 1). In the USA, several centers are now describing galvanic corrosion with the combination of Ti-6AI-4V stem and modular CoCr ball (McKellop et al, 199 1; Collier et al, 199 1). Concerns here relate to the two findings a) that it has 100% occurrence in implants with over 2 years implantation, and b) the corrosion phenomenon is progressive!

The first recorded use of the ceramic ball was in France as a non-modular stem design by P. Boutin in 1970. However, the modem history evolves from the modular, morse-taper designs popularized by Drs. P. Griss and H. Mittlemeier in Germany, circa 1973. These innovators visualize the alumina ceramic as a very inert, corrosion-free material with virtually a diamond-hard surface for good biocompatibility, low-friction and exceptional wear resistance. Early experiences combined with the use of ceramic acetabular cups (threaded-cup designs) were mixed, with some cases featuring component fractures and accelerated ceramic wear (Walter and Plitz, 1985; Cameron, 1991). However, modem designs of alumina ceramic ball combined with UHMWPe bearings have shown clinically 2-4 times Pe-wear reduction compared to metal balls (Clarke and Kabo, 199 1). In addition, there has been zero recorded incidence of corrosion problems at the morse-taper interfaces (L. Sedel, 1991: P. Bosch, 1991 - personal communications). Thus the ceramic ball appears to confer a clinically significant, increased protection from Pe-debris and eliminated the release of metallic corrosion products as demonstrated over an 18-year history.

Given the above comparisons between modular ceramic and CoCr balls, the surgeon may wonder why then has the ceramic ball not been more popular in North America? The answer predominantly lies in the fact that the FDA did not reclassify the alumina ceramic: UHMWPe total hip until January of 1989, and thus the approval processes occurred after this period. The alumina ceramic approvals were followed in 1990 by approval of zirconia ceramic balls.

Are the ceramic balls safe to use? The initial testing regime used in various 5 1 OK applications to the FDA was to subject the ceramic balls to a high level of cyclic loading for 10 million cycles. Fatigue loads of over 40kN (almost 9,000 lbs.) were used initially as a stringent criterion, with the balls expected to pass 10 million cycles without failure. The represented a safety margin of over 50 times (patient weight = 180 lbs. avg.). Despite this, at least three ceramic ball fractures have occurred in North America, one a sterilization mishap, one a traffic accident, and one unexplained (Cameron et al, 199 1). Now that the ceramic 5 1 OK applications can get FDA approval with fatigue loads as low as the 3.5kN range (900 lbs.), there may well be an increased risk of fracture with certain designs in the future. The alumina ceramic ball has certainly fulfilled expectations with over 18 years of clinical history. However, the introduction of the new ceramic zirconia comes with very little history. Thus, with various claims that it has improved wear resistance, the surgeon needs to be fully aware the zirconia has little or no clinical history and also that it is labelled as "partially-stabilized zirconia," meaning that there has been concern that the material could degrade (Christel et al, 1990).

From the surgeon's point of view, there must also be total awareness of the uniqueness of ceramic design features. Given the specific features of taper-cone diameter, taper angle, specific contact-zones and tolerances, it is not possible to mix-n-match from one manufacturer's design to another. Even if the ceramic ball from one brand appears to fit nicely onto the femoral stem of another brand, do not take this risk.

So overall, it would appear that the approval and use of ceramic balls comes fortuitously at a time when the modular Ti-6A1-4V and CoCr balls have become increasingly suspect as one of the sources of the metallic debris implicated in the accelerated wear (3body abrasion) of the UHMWPe bearings. In addition, the ceramic balls have lower friction and much reduced Pe-wear which offers significant reduction of Pe-driven osteolysis. However, this technology comes at a price ($300-700 over CoCr ball price) and potentially could result in a small incidence of ceramic fractures. Thus the test standards must be maintained at a high level and the surgeons must respect the labelling requirements and resist the temptation to mix-n-match between brand names. Given these caveats, it would appear that the replacement of a metal femoral ball with ceramic will confer clinically significant improvements to the longevity of the total joint replacement.

SUMMARY

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The incidents of cementless osteolysis appears to be more than anticipated versus cemented stems compared to the same clinical time period. This perplexing problem must be addressed if we are to achieve 20 year plus survivorship of cementless implants.

There are many design features available on cementless total hips today however, we are still very limited in our selection of materials. We now know modularity is a site for generation of particulate debris. We must be careful in our selection of modularity to insure that we do not extend the risk benefit ratio beyond reasonable approaches. In a revision situation it is desirable to have many intraoperative options. However, routine primary surgery particularly in a patient with a life expectancy over 20 years may be a different situation. Do we really need to consider using excessive modular sites that can generate increased particulate debris for these routine cases or can we accomplish the reconstruction with a more conventional one piece stem? Can we modify, improve or strengthen all modular connections such that wear debris will not present itself as a clinical problem? Answers are not yet in.

It is becoming more and more obvious to many that we should do more to reduce the generation of particulate debris. This can be accomplished by the following actions:

- Use modularity only when needed.
- Do not use titanium as a bearing surface.
- C.C. or ceramic should be used. Consider ceramic in younger patients.
- Careful consideration on acetabular component design.
- Quality UHMWPe in all patients.
- Thick poly in younger patients.

These are actions that we, as surgeons, can initiate now. We also need to continue to encourage orthopaedic industry to spend money in research and development to design and develop new and improved materials.

Some have called the 90's the decade of poly wear or particulate debris. How fast can we alter that picture and prevent unexpected surprises? Remember, for our patients the best surprise is no surprise at all!

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