
ALTERNATIVE BEARING SURFACES: *THE GOOD, BAD & UGLY*



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INTRODUCTION

This exhibit discusses current bearing surface alternatives for long-term total hip articulation involving metal-polyethylene, ceramic-polyethylene, metal-metal and ceramic-ceramic couples.

METAL-POLYETHYLENE

The enduring success of the low friction arthroplasty advanced by Sir John Charnley as a solution for painful hip problems may be appreciated by the fact that in 1999, over 270,000 hip arthroplasties were performed in the United States.

Over the last three decades patient profiles have substantially changed resulting in a greater service life demand on UHMWPE hip components. Material failure often leading to osteolytic response is increasingly associated with younger, more active patients. In this context, the low friction solution has become a problem limiting *in vivo* system longevity, (Figures 1 & 2).



Figure 1: *Marked osteolytic response in a 50-year old patient.*

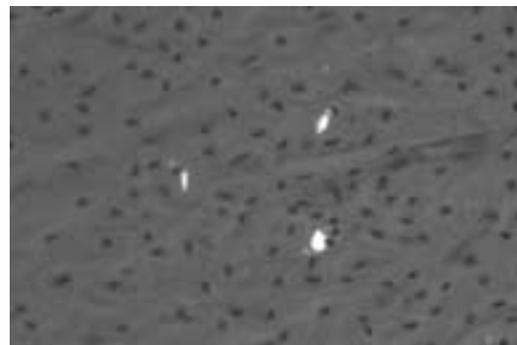


Figure 2: *Corresponding intracellular polyethylene debris viewed under polarized light.*

NEW POLYS FOR OLD?

Previous attempts to improve UHMWPE performance have included carbon fiber reinforcement (Poly-2) and, more recently polymer reprocessing to enhance mechanical properties (Hylamer). The former was withdrawn due to excessive inflammatory response while the latter has been linked to debris induced osteolytic response in early reports.

Laboratory simulation demonstrates that UHMWPE resistance to wear is improved with increased cross-linking of the carbon-hydrogen polymer chains. A number of thermal and chemical processing solutions have been described. One such approach involves component storage at elevated temperatures in an oxygen depleted environment. This is done following irradiation and encourages kinetic recombination of the carbon-hydrogen free radicals created by the radiation process.

Other techniques deliver increased radiation doses to the component material followed by re-melting to quench free radicals. While this results in dramatic wear reduction in laboratory simulation (Figure 3), it also changes the amorphous and crystalline regions of the polymer, affecting mechanical properties and potentially reducing fatigue strength. Clearly, clinical experience will demonstrate the *in vivo* viability of these "new polys."

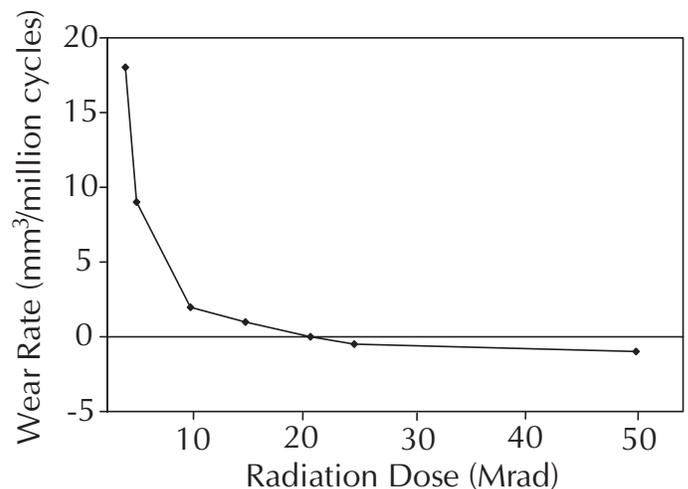


Figure 3: *Mean acetabular cup wear rates versus gamma dose level.*

From: McKellop et al., Trans ORS 23:98, 1998.

CERAMIC-POLYETHYLENE

Alumina and subsequently Zirconia ceramic femoral head components were introduced as low friction metallic substitutes as a means of reducing polyethylene wear debris in hip replacement. They are highly biocompatible and significantly smoother, harder and more scratch resistant than their metallic counterparts. Laboratory studies document dramatic reductions in wear volume offering the prospect of increased polyethylene longevity and decreased potential for osteolytic response, (Figure 4).



Figure 5: *Fracture of an Alumina ceramic ball six years after implantation.*
From: Wagner, *Sem in Arthro* 9:143, 1998.

METAL-METAL

“Articulations ahead of their time” aptly describe the metal-metal experiences of the McKee-Farrar, Ring, Muller and Sivash prostheses. Short-term clinical failure in the face of a growing Charnley success led to their disuse by the early 1970’s.

Suboptimum design, component manufacture, poor fixation and high equatorial frictional torques have been cited as reasons explaining aseptic loosening of these designs often with little apparent wear of the bearing surfaces. Despite these early experiences many metal-metal implants have survived twenty years or longer and still exhibited highly polished surfaces, (Figures 6 & 7).



Figure 6: *McKee-Farrar metal-metal retrieval after 25 years in situ.*
From: Chan et al., *AAOS Scientific Exhibit*, 1997.

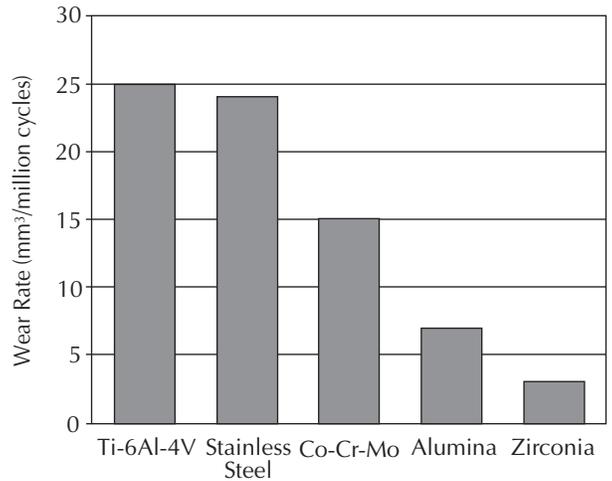


Figure 4: *Wear rate of polyethylene against orthopaedic materials.*

They enjoy ready application in younger populations with the concerns of added cost and a small reported incidence of brittle fracture, (4 in 100,000). The manufacture of precision tapers within the head and on the stem trunion as well as increasing ceramic quality and strength have reduced the latter, (Figure 5). In clinical application, care must be taken to use only stem and head assemblies from the same manufacturer with trunion inspection in revision situations where the stem is retained. It is also noted that a recent Food and Drug Administration advisory warns against autoclave resterilization of Zirconia heads as evidence suggests that their surface characteristics are degraded.



Figure 7: *Muller metal-metal retrieval after 20 years in situ.*
From: Wagner, *Sem in Arthro* 9:143, 1998.

METAL-METAL (Cont.)

Over the last decade, a resurgence of interest in metal-metal articulations has evolved. Currently, upwards of 100,000 Sulzer Metasul™ designs have been implanted in Europe and on 3 August 1999 this device received Food and Drug Administration 510K approval for commercial distribution. Other designs have recently been cleared by the FDA for clinical use in the United States and reclassification efforts should make them generally available in the near term.

In the Metasul™ design an UHMWPE sandwich is employed which theoretically dampens load transmission to periacetabular bone as a means of preventing component subsidence given the high rigidity of the metal-metal components, (Figure 8). This has also been adopted in some ceramic-ceramic applications where high rigidity as well as the low energy absorbing capacity of the ceramic is accommodated.



Figure 8: *Metasul™ acetabular component with Metasul™ insert in a UHMWPE bed. (Sulzer Orthopedics, Ltd.)*

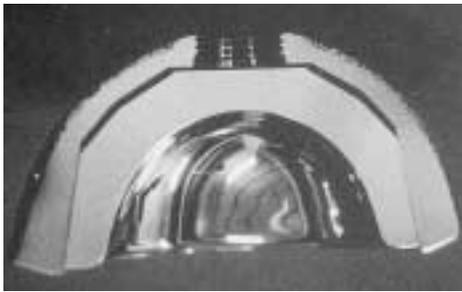


Figure 9: *Cross-section of the Transcend® Acetabular Cup with interchangeable metal insert. (Wright Medical Tech, Inc.)*

Other contemporary metal-metal designs maintain modularity by direct assembly of the cobalt chrome liner into its cementless shell, achieving stability usually by means of a Morse taper locking mechanism, (Figure 9).

Hip simulator studies have demonstrated the importance of specific diametrical clearances to facilitate polar bearing and access for serum lubrication. Close control of component dimensions, sphericity and surface finish are also critical, but add to manufacturing costs. Currently both cast and wrought Co-Cr-Mo alloy of differing carbon content are used in this self-bearing application. These alloys possess high hardness and a capacity to “self heal” by polishing out third body scratches in contact areas. Simulator studies demonstrate a 20 to 100 fold reduction in the amount of particulate generation by comparison to similar evaluations of metal-UHMWPE articulations suggesting their longevity in *in vivo* use.

Despite their apparent advantage in younger patient populations there is a longer term concern about metal particulate and ion generation. Toxicity, hypersensitivity and carcinogenesis have all been cited as potential adverse events, but a relationship has not been established. Figure 10 depicts increased serum chromium concentrations in a long-term McKee-Farrar population.

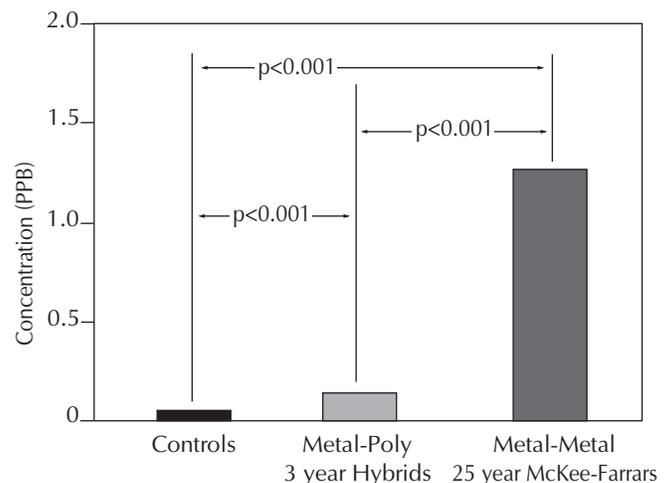


Figure 10: *Serum chromium levels for controls, 3 year hybrids & 25 year McKee-Farrars. From: Jacobs et al., J Bone Joint Surg 80A:1447, 1998 and Jacobs et al., Clin Orthop 329S:256, 1996.*

CERAMIC-CERAMIC

The clinical use of Alumina ceramic as a hard on hard articulation dates back to the early 1970's. Early failures attributed to poor implant design, acetabular component loosening and low quality ceramic resulting in fracture and debris generation dampened enthusiasm for their use. Only the Mittelmeier was marketed in the United States for a short time, (Figure 11).



Figure 11: *Early Mittelmeier, Autophor ceramic-ceramic cup. (Smith & Nephew, Inc.)*

The quality of today's Alumina ceramic is much improved with impurities, potential stress risers, held to a minimum. Reduction of grain boundaries has significantly increased material strength and toughness while better quality control through proof testing has significantly reduced the incidence of component fracture. Excellent tribology properties of wear, lubrication and friction are appreciated. Simulator studies demonstrate the lowest wear volumes of all currently available couples, (Figures 12 & 13).

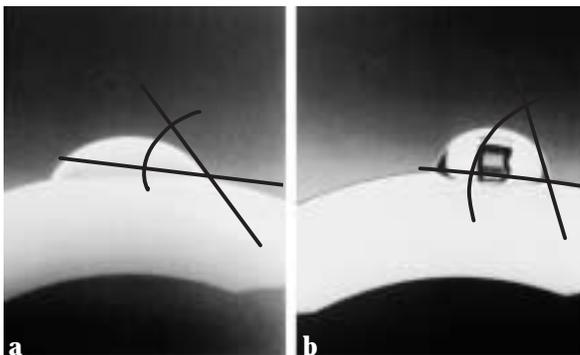


Figure 12: *Wetting of (a) Alumina ceramic and (b) metal ball heads. The smaller the wetting angle the better the lubrication.*

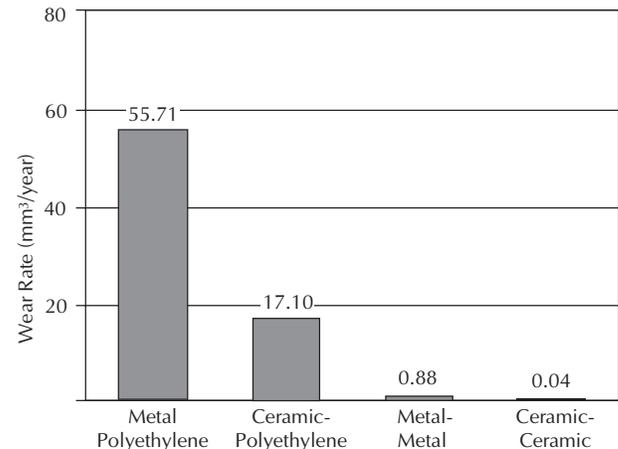


Figure 13: *Wear rates of bearing couples.*

Modern designs seek to facilitate the articulation and avoid ceramic-ceramic impingement while providing for durable acetabular fixation. These goals may be accomplished by employing a modular cup construction where the ceramic liner is secured to a cementless metal shell through a taper lock, (Figure 14). Closely matching tolerances of head-neck and cup-liner junctions to avoid fracture remain a most important factor for the successful use of these constructs.



Figure 14: *Cross section of the Transcend[®] acetabular cup with interchangeable ceramic insert. (Wright Medical Technology, Inc.)*

TAKE HOME MESSAGE

- The debris from standard polyethylene-metal bearings has been responsible for aseptic loosening and osteolysis in many patients. With the indications for hip replacement expanding into younger and more active patients as well as the increasing recreational activities and life expectancy of our senior population, the search for bearing alternatives has intensified.
 - Enhanced polyethylenes represent a class of emerging UHMWPE alternatives whose common denominator is an appreciation of the importance of increased cross-linking of the polymer chains and the elimination of free radicals to reduce component wear. A number have already gone through the FDA regulatory process and their *in vivo* performance should be closely followed.
 - Alumina and Zirconia ceramic femoral head components significantly reduce polyethylene wear volume but are highly taper tolerance sensitive. Their selection based on patient age and activity level may well justify their added cost. They are currently available for clinical use in the United States.
 - Both contemporary metal-metal and ceramic-ceramic hip replacement systems are widely used in Europe with clinical experience dating back 10 years and longer. The poor clinical performance of first generation metal-metal designs appear to have been overcome through improved metallurgy, design and manufacture. Lingering concern over a causal relationship between malignant and systemic problems and elevated trace metals continues, but has not been established.
 - Contemporary metal-metal hip articulations have been successfully used in Europe for over a decade. On 3 August 1999 the Sulzer Metasul™ cup design received a 510K clearance for its distribution in the United States and has been followed by several other designs. Reclassification efforts should make them generally available in the near term. Ultimately, their increased cost will be weighed against patient benefit and will define particular patient use.
 - Ceramic-ceramic hip systems have good biocompatibility with much improved material composition, designs and manufacturing. Matching taper tolerances of the head-neck and cup-liner junctions reduces the prospect for fracture. Precise technical placement of the hip components during surgery is essential to avoid ceramic-ceramic impingement and the potential for debris generation.
 - Currently ceramic-ceramic hip systems are investigational and not available for clinical use in the United States. However, in July 2000, a first design gained FDA Advisory Panel recommendation for approval. Ultimate FDA release will depend on the demonstration of their safety and effectiveness through ongoing clinical trials and laboratory evaluation. Once available the increased cost of this bearing surface alternative will have to be carefully weighed against long-term patient benefit in the current reimbursement climate.
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