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

AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
69th Annual Meeting
February 13 - 17, 2002
Dallas, Texas

COMMITTEE ON BIOMEDICAL ENGINEERING
COMMITTEE ON HIP AND KNEE ARTHRITIS

Prepared by:
A. Seth Greenwald, D.Phil.(Oxon)
Jonathan P. Garino, M.D.

Acknowledgements:

David C. Ayers, M.D.
Joshua J. Jacobs, M.D.
Christine S. Heim, B.Sc.
Anastasia K. Skipor, M.S.

CeramTec AG
Sulzer Orthopedics, Ltd.
Wright Medical Technology, Inc.

Presented with the permission of The Journal of Bone and Joint Surgery.
This material was first published, in slightly different form, in J Bone Joint Surg Am 83(Suppl. 2):68-72, 2001.

INTRODUCTION

This exhibit discusses current bearing-surface alternatives for long-term total hip articulations 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 can be appreciated by the fact that in 2000, more than 270,000 hip arthroplasties were performed in the United States.

Over the last three decades, patient profiles have changed substantially, resulting in demands for a greater service life of ultra-high molecular weight polyethylene (UHMWPE) hip components. Material failure, often leading to an 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: *A marked osteolytic response in a 50-year-old patient.*

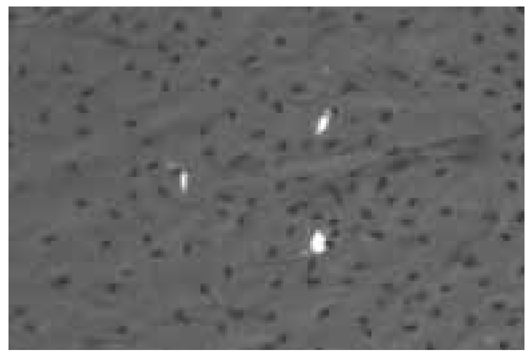


Figure 2: *Corresponding intracellular UHMWPE debris viewed under polarized light.*

NEW POLYS FOR OLD?

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 The former was withdrawn from the market because of excessive inflammatory response, whereas the latter has been linked to debris-induced osteolytic response in early reports.

Laboratory simulation has demonstrated that the resistance of UHMWPE 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 remelting to quench free radicals. While this results in dramatic wear reduction in laboratory simulations (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.”

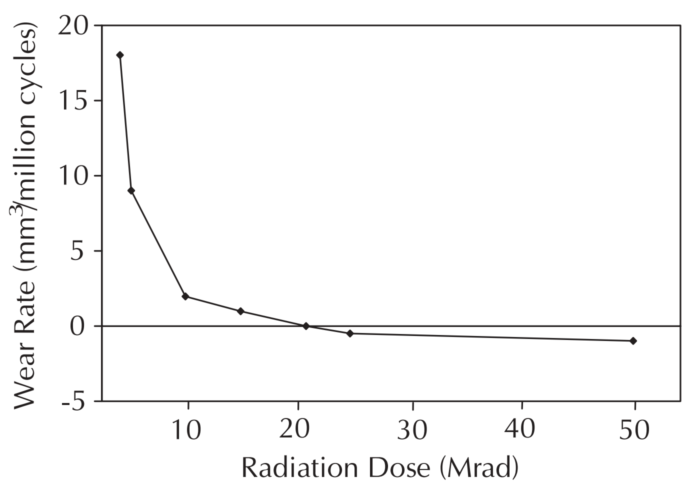


Figure 3: *Mean acetabular cup wear rates versus gamma dose level.*

From: McKellop et al., J Orthop Res 17:160, 1999.

CERAMIC-POLYETHYLENE

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

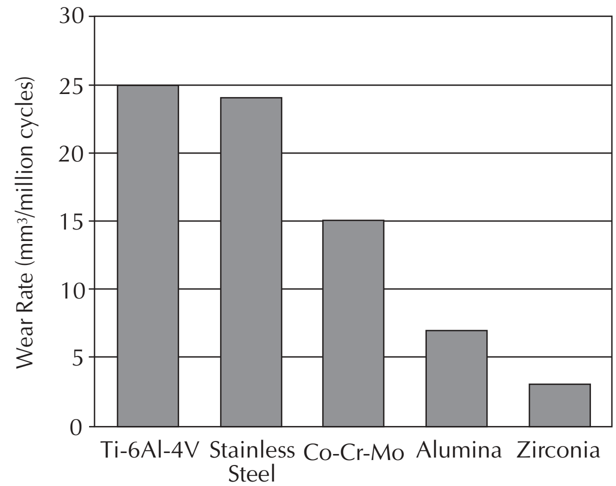


Figure 4: *Wear rates of UHMWPE against various orthopaedic materials.*

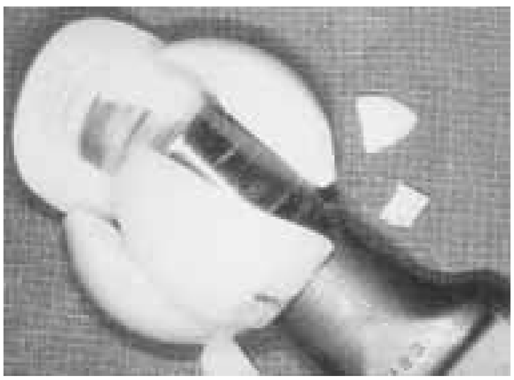


Figure 5: *Fracture of an Alumina ceramic ball 6 years after implantation.*
From: Wagner, Sem in Arthro 9:143, 1998.

Zirconia ball heads have proven to be safe and reliable for over 8 years in the United States. However, a recent manufacturing process change by a single producer has resulted in an elevated fracture rate leading to a recall of these components.

In clinical application, care must be taken to use only stem and head assemblies from the same manufacturer with inspection of the trunion in revision situations in which the stem is retained. It should also be noted that a recent Food and Drug Administration (FDA) advisory warns against autoclave resterilization of zirconia heads, as evidence suggests that their surface characteristics are degraded in this process.

METAL-METAL

"Articulations ahead of their time" aptly describes the metal-metal McKee-Farrar, Ring, Müller and Sivash prostheses. Short-term clinical failure in the face of growing success with Charnley prostheses led to their disuse by the early 1970s.

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

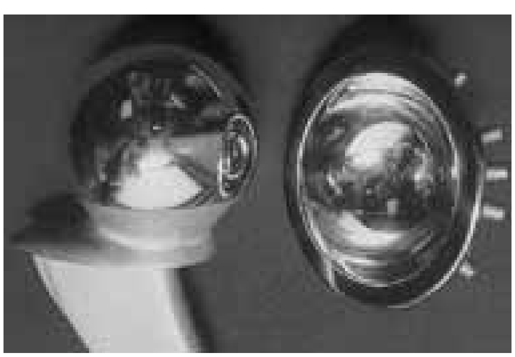


Figure 6: *McKee-Farrar metal-metal implant retrieved after 25 years in situ.*
From: Chan, et al., AAOS Scientific Exhibit, 1997.

Figure 7: *Müller metal-metal implant retrieved 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 FDA 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.

The Metasul™ design includes an UHMWPE sandwich that 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 approach has also been adopted in some ceramic-ceramic applications to accommodate high rigidity as well as the low energy-absorbing capacity of the ceramic.

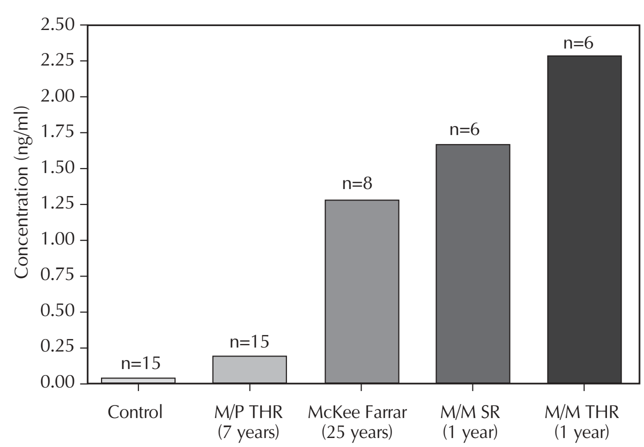
Figure 8: *Metasul™ acetabular component with Metasul™ insert in an UHMWPE bed. (Sulzer Orthopedics, Ltd.)*

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

With other contemporary metal-metal designs, modularity is maintained by direct assembly of the cobalt chromium liner into its cementless shell, with stability usually achieved 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 they add to manufacturing costs. Currently both cast and wrought Co-Cr-Mo alloys 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 have demonstrated a 20 to 100-fold reduction in the amount of particle generation in comparison with that demonstrated in similar evaluations of metal-UHMWPE articulations, suggesting their potential for longevity in *in vivo* use.

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



M/P = metal/polyethylene; M/M = metal/metal; SR = surface replacement; THR = total hip replacement

Figure 10: *Serum chromium levels for various hip articulations. Data compiled from: Jacobs, et al., ORS Presentation, 2002; Skipor, et al., AAOS Scientific Paper, 2002; Skipor, et al., AAOS Scientific Paper, 2001; Jacobs, et al., Clin Orthop 329S:256-263, 1996.*

CERAMIC-CERAMIC

The clinical use of alumina ceramic as a hard-on-hard articulation dates back to the early 1970s. Early failures attributed to poor implant design, acetabular component loosening and low-quality ceramic resulting in fracture and debris generation dampened enthusiasm for its use. Only the Mittelmeier implant 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 minimization of impurities, which are potential stress risers. Reduction of grain boundaries has substantially increased material strength and toughness, while better quality control through proof-testing has substantially reduced the prevalence of component fracture. Tribology properties of wear, lubrication and friction are excellent. Simulator studies have demonstrated that ceramic-ceramic articulations have lower wear volumes than all other currently available couples, (Figure 12).

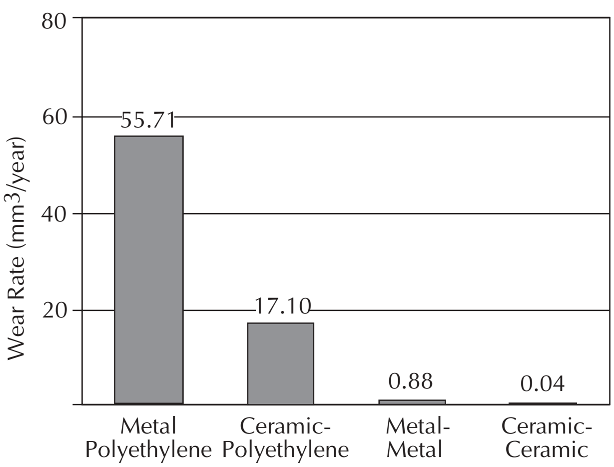


Figure 12: *Wear rates of bearing couples.*

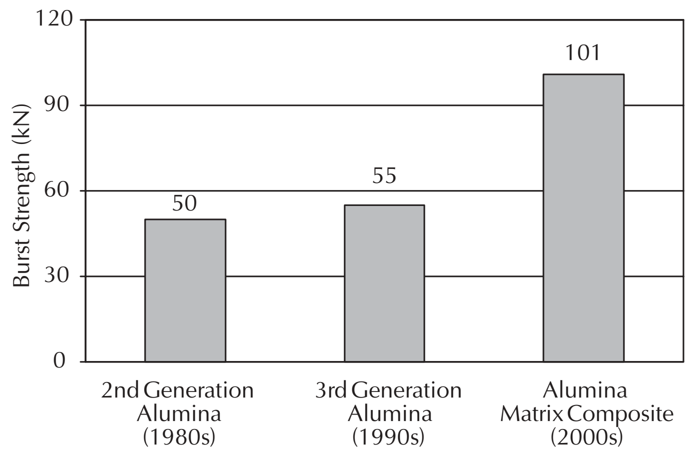


Figure 13: *Burst strength of alumina femoral heads.*

Although alumina is a superior bearing surface, efforts continue to make it stronger and more fracture resistant. As such, newer alumina composite ceramics with other additives such as zirconia, strontium and chromium have been developed and are undergoing clinical trials. These new composites are nearly twice as fracture resistant as the already safe and reliable alumina in use worldwide for the last 8 years, (Figure 13).

The goals of modern designs are to facilitate the articulation and to avoid ceramic-ceramic impingement while providing for durable acetabular fixation. These goals may be accomplished by employing a modular cup construction in which 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 very 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 metal-polyethylene 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 and with 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 that they were created with 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 substantially reduce UHMWPE wear volume but are highly taper tolerance sensitive. Their selection on the basis of patient age and activity level may well justify their added cost. They are currently available for clinical use in the United States with the noted caveat on the zirconia recall.

- Contemporary metal-metal 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. There is lingering concern about a causal relationship between malignancy and other systemic problems and elevated levels of trace metals, but no relationship has yet been established.

- Contemporary metal-metal hip articulations have been successfully used in Europe for more than a decade. On 3 August 1999 the Sulzer Metasul™ cup design received a 510K clearance for distribution in the United States; it has been followed by several other designs. Reclassification efforts should make these cups generally available in the near term. Ultimately, their increased cost will be weighed against patient benefit and will define which particular patients are candidates for their use.

- Like their metal-metal counterparts, ceramic-ceramic hip systems are widely used outside of the United States and 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 of 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 are not available for general clinical use in the United States. However, in July 2000, a first design gained a FDA Advisory Panel recommendation for approval. Ultimate general release will depend on the demonstration of their safety and effectiveness through ongoing clinical trials and laboratory evaluation as well as manufacturer compliance. Once this bearing-surface alternative becomes available, its increased cost will have to be carefully weighed against long-term patient benefit in the current reimbursement climate.