UHMWPE LONGEVITY:
INFLUENCES OF THE ORTHOPAEDIC TRIAD

AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
66th Annual Meeting
February 4 - 9, 1999
Anaheim, California

COMMITTEE ON BIOMEDICAL ENGINEERING
COMMITTEE ON HIP AND KNEE ARTHRITIS

Prepared by:
A. Seth Greenwald, D.Phil.(Oxon)
Christopher J. Lyons, M.D.
Jennifer R. Bohl, B.A.

The following individuals are acknowledged for their contributions:
Clive P. Duncan, M.D.
Herbert Kaufer, M.D.
Bernard N. Stulberg, M.D.
INTRODUCTION

Ultra-high molecular weight polyethylene (UHMWPE) wear is an inevitable consequence of in vivo articulation. Its manifestation is determined by device, patient, and surgical variables which together define an orthopaedic triad, influencing the clinical longevity of hip and knee arthroplasty.

Over the last three decades of arthroplasty use, patient profiles have substantially changed resulting in a greater service life demand for UHMWPE components. The following is an overview of some of the factors challenging this need for increased longevity.

MATERIAL AND DESIGN FACTORS

Bad Poly!

The UHMWPE used in hip and knee components results from polymerization of ethylene gas into a fine resin powder of sub-micron and micron size distribution. The polymer is then consolidated using ram extrusion or compression molding techniques. Inadequate processing control can result in fusion defects arising from incomplete polymerization, voids and foreign body inclusions such as calcium sterase which ultimately contribute to the in vivo degradation of the final part.

UHMWPE Sterilization

Gamma irradiation in air has been the standard method of UHMWPE sterilization for many years in the orthopaedics industry. This process is also ascribed to improve the strength and wear performance through recombination of free radicals generated from the irradiation. These free radicals, however, will preferentially combine with any oxygen that may be present in the environment resulting in oxidation of the polymer. This leads to embrittlement over time and subsequent polymer degradation. Figure 1 is a cross-section of a three-year, gamma irradiated UHMWPE tibial component retrieval demonstrating a circumferential white band indicative of polymer embrittlement. Numerous fusion defects are also appreciated. Contemporary methodologies seek to overcome this problem by gamma irradiating in a depleted oxygen environment or through the use of EtO or gas plasma techniques.

New Polys for Old?

Previous attempts to improve UHMWPE performance have included carbon fiber reinforcement of the polymer mass (Poly-2) and, more recently, the reprocessing of conventional ultra-high molecular weight material to enhance mechanical properties (Hylamer). The former was withdrawn due to excessive inflammatory responses attributed to carbon fiber release while the latter continues to demonstrate mixed results in early reports. Figure 2, a retrieved Poly-2 tibial plateau demonstrates surface abrasion and pitting.

Laboratory simulation demonstrates that UHMWPE resistance to wear is improved with increased cross-linking of the polymer chains. A number of thermal and chemical processing solutions have been advocated. One such approach involves storage of the components in an elevated temperature environment following gamma irradiation encouraging kinetic combination. Other techniques dramatically increase the radiation dose administered to the components followed by re-melting which changes the amorphous and crystalline regions of the polymer. These "new polys" must maintain a constancy of mechanical properties to ensure in vivo viability. Clearly, clinical experience will demonstrate the efficacy of these approaches.
Polymer Shelf Life

As demonstrated in Figure 3, progressive changes in peak surface stress distributions following gamma sterilization in air and shelf storage over time increase the prospect of UHMWPE material compromise early after surgery. Figure 4 illustrates a tibial retrieval with a 9 year, 7 month shelf life that was removed 13 months after implantation. Gross delamination and pitting are noted. Evidence suggests that shelf dating of components may be a qualifying index in assisting improvements in component longevity.

Component Design: Hip

Liner Thickness: Thicker liners accommodate the annual progression of UHMWPE wear, a benefit to the longevity of component integrity in the younger patient. It has been demonstrated that peak contact stress attenuation is a further derived benefit (Figure 5) and that increasing thickness may also serve to accommodate shock absorption during high demand functional activities.

Liner Conformity: Lack of conformity between a polyethylene liner and its acetabular shell as demonstrated in Figure 6 limits the surface area available for load transfer and concentrates surface and subsurface stresses in regions of contact increasing the prospect of permanent material deformation and backside wear contributing to component failure.
Component Design: Hip (cont.)

Head Size: The use of 32mm femoral heads results in increased volumetric wear (Figure 7) in comparison to the increased linear wear observed when 22mm heads are employed (Figure 8). Enhanced articular performance lies midway in the selection of 26 or 28mm head sizes.

Locking Mechanism Integrity: Deficient mechanical capture of the shell/liner composite in modular designs has contributed to early UHMWPE failure. Figure 9 demonstrates galling of the metal cup, liner separation, and polyethylene fracture one year following index surgery due to a poorly designed locking mechanism.

Material Caveats: The use of titanium as an articulation counterface in hip and knee designs has resulted in accelerated wear of both the polymer and titanium surfaces contributing to early reports of lytic response and component loosening. The five-year retrieval shown in Figure 10 demonstrates an out of round geometry suggesting considerable loss of titanium substance.
Component Design: Knee

Conformity: The increased tibial-femoral conformity realized in PCL sacrificing knee plateaus serves to enhance UHMWPE service life by attenuation of peak contact stresses responsible for material damage. This is appreciated in the comparison shown in Figure 11 between PCL preserving and PCL sacrificing plateau geometries articulating against a common femoral component.

Plateau Thickness: Recent findings demonstrated in Figure 12 describe the relative insensitivity of peak surface stress distribution to thickness changes for a conformal knee design with tibial inserts greater than 6mm. Therefore, bone stock preservation, joint line restoration, PCL retention, patient weight and activity level should be the primary factors influencing component thickness selection.

Third-Body Wear: The interaction of third-body particulate between articulation surfaces in hip and knee replacements consistently demonstrates catalysis of UHMWPE damage. Surface scratching of the metallic counterface resulting from these interactions further contributes to the damage process. Figure 13 shows an early retrieval of a cementless metal-backed tibial component demonstrating the effects of third-body entrapment.

Locking Mechanism Integrity: Observed effects of UHMWPE insert micro-motion in retrieved modular tibial components suggest the presence of adhesive and abrasive wear which will influence component durability. This raises concerns regarding the effectiveness of current tray surface finish and capture mechanisms. The presence of adhesive film transfer is visualized in Figure 14 and is indicative of insert rotation.
Component Design: Knee (cont.)

Femoral Component Finishing: The use of precision ground components enhances articulation conformity and improves surface stress distribution reducing the prospect of polymer wear. This is appreciated in Figure 15 which demonstrates the advantage of precision ground components through maximized contact area and minimized peak surface stress distributions.

PATIENT FACTORS

An increasing under 65-year old patient population demonstrating more active lifestyles and longer life expectancy directly leads to greater in vivo service life demands on UHMWPE components. Quantitative assessments of walking suggest that cyclic activity in joint replacement patients varies from less than 1 million cycles per year in the elderly to greater than 3 million in younger populations.

Clinical observations between patient weight and damage in retrieved components point to the significant influence of this further variable. For every one pound of weight loss in the obese patient, three pounds are removed from the load acting on the patient’s hip. Other factors of patient habitus, including individual musculoskeletal assessment, will further influence UHMWPE integrity.

SURGICAL FACTORS

In 1997, over 550,000 hip and knee arthroplasty procedures were carried out in North America. Sixty percent of these were performed by orthopaedic surgeons who do twenty or fewer joint replacements annually. Clinical outcomes are directly influenced by physician experience. The following surgical factors effect the loading across UHMWPE articulating surfaces, influencing polymer durability over time.

**Hip Factors**
- maximization of femoral head coverage
- acetabular cup medialization
- restoration of femoral head offset
- avoidance of femoral neck impingement

**Knee Factors**
- accurate component placement
- ligamentous balance
- optimization of alignment

TAKE HOME MESSAGE

It is an irony that as the millenium is approached, the UHMWPE solution for achieving low-friction arthroplasty advanced three decades ago by Sir John Charnley has, in itself, become a significant problem challenging the longevity of hip and knee replacement procedures.

This exhibit describes a triad of device, patient, and surgical variables that influence the demanded longevity of UHMWPE. It is appreciated that polymer compromise is indeed a multi-factorial process.