CHAPTER 2

Ultra-High Molecular Weight Polyethylene in Total Knee Arthroplasty

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THE PROBLEM

The enduring success of the low-friction arthroplasty, advanced by Sir John Charnley as a solution for hip arthrosis, may be appreciated by the fact that in 2002 almost 700000 primary and revision hip and knee arthroplasties were performed in the United States, a number more than doubling on a global basis¹ (Table 2.1). The prevalence of aseptic loosening attributed to ultra-high molecular weight polyethylene (UHMWPE) wear debris-induced osteolysis is in the single digits in most contemporary knee series, with some reports describing prosthesis survival beyond 20 years.^{2–12} Despite this obvious success, UHMWPE wear is an inescapable consequence of total joint articulation and is of contemporary concern particularly as our population grays and lifestyle demands increase. 13-22 Appreciating both the causes and remedies of in vivo UHMWPE failure assists the goal of avoiding total knee arthroplasty revision as an endpoint.

THE MATERIAL

The UHMWPE used in joint arthroplasty components results from polymerization of ethylene gas into a fine resin powder of submicron and micron size distribution. A number of resin mixtures exist, but GUR 1050 is the prevalent polymer used in contemporary devices. They are consolidated with the use of ram extrusion or compression-molding techniques. Structurally, UHMWPE is made up of repeating carbon-hydrogen chains that are arranged in ordered (crystalline) and disordered (amorphous) regions.²³

Processing Shortcomings

Inadequate quality control during manufacture has resulted in fusion defects arising from incomplete polymerization, voids, and foreign body inclusions, which ultimately contribute to the in vivo degradation of the final part. 24-26 Previous attempts to improve UHMWPE performance have included carbon fiber reinforcement (Poly-2)²⁷ and polymer reprocessing by hot isostatic pressing (Hylamer).²⁸ The former was withdrawn from the market because of an unexpectedly high wear rate²⁹ (Figure 2-1), while the latter has been linked to debrisinduced osteolytic response, especially when sterilized by gamma irradiation in air³⁰ (Figure 2-2). Heat pressing was yet another attempt to improve the finish of the articular surface, but was associated with UHMWPE fatigue and early delamination³¹ (Figure 2-3). These material innovations describe checkered pasts as they moved from the laboratory to clinical application.

Sterilization Oversights

Gamma irradiation in air has, until recently, been the predominant method of UHMWPE component sterilization and, despite current concerns, represents the only gold standard against which contemporary material improvements will be measured over time. However, recent attention drawn to an increasing prevalence of tibial component failures associated with debris-induced osteolysis has raised concerns over the long-term durability of contemporary devices. ^{32,33} A clinical follow-up study reported by Bohl et al. suggests that this may be accounted for by the prolonged shelf storage prior to implantation of UHMWPE components gamma irradiated in air. ³⁴ A 12% to 20% reduction in *in vivo* survival is noted for shelf storage ranging from 4 to 11 years with a mean *in vivo* time to revision of 2.5 years (Figures 2-4 and 2-5).

TABLE 2.1. Hip and Knee Arthroplasty Procedures Performed in the United States in 2002.

	Primary	Revision	Total
Knees	321084	31 159	352243
Hips	300434	43 082	343816
Total	621518	74241	696059

Data from Orthopaedic Network News.1



FIGURE 2-1. Five-year retrieval of a failed Poly-2 tibial insert demonstrating a high component wear rate with infiltration of carbon fibers and polyethylene debris into surrounding tissue.



FIGURE 2-3. Six-year retrieval of a heat-pressed tibial component associated with polyethylene fatigue and early delamination.

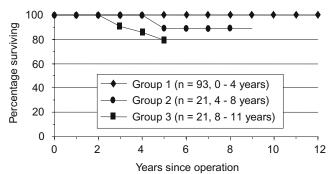
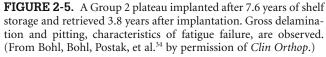


FIGURE 2-4. The influence of shelf storage on survival of a prosthetic knee plateau following gamma irradiation in air. (From Bohl, Bohl, Postak, et al. ³⁴ by permission of *Clin Orthop*.)



FIGURE 2-2. Three-year retrieval of a failed Hylamer-M tibial plateau demonstrating an unexpectedly high wear rate with corresponding wear and debris-induced inflammatory tissue response.





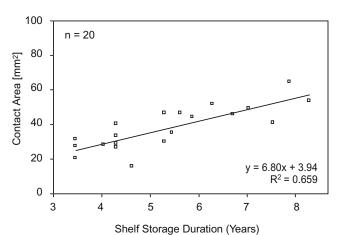


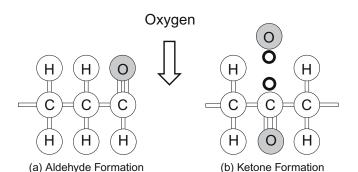
FIGURE 2-6. Tibial-femoral contact area for a 5.6-mm thick tibial plateau carrying >20 MPa stresses during articulation dramatically increases with lengthening shelf storage periods.

Further, laboratory studies indicate that as shelf storage increases, the amount of UHMWPE exposed to high surface stresses during articulation increases dramatically and is a contributing factor to early *in vivo* polymer failure^{35–37} (Figure 2-6).

The explanation for these observations lies in the mechanics of the sterilization process, which facilitates breakage of polymer chains by the incoming gamma radi-

FIGURE 2-7. Depicted polymer chain breakage following irradiation in air and combination with oxygen facilitating oxidative degradation of UHMWPE.

Gamma Irradiation H H H H H H H H C C C C O C C C H H H H H H (a) Chain Scission (b) Hydrogen Extraction



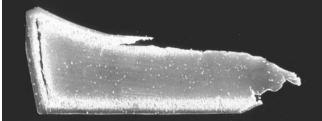


FIGURE 2-8. Three-year retrieval of a fully oxidized, gamma irradiated in air, UHMWPE tibial component demonstrating a circumferential white band indicative of polymer embrittlement after prolonged shelf life. Fusion defects from incomplete consolidation are noted.

ation, creating free radicals, which preferentially combine with available oxygen^{38,39} (Figure 2-7). The onset of mass UHMWPE component production and device modularity resulted in extended component shelf storage before use. This was not a previous consideration, but ongoing shelf life oxidation offers an explanation for mechanical compromise of the polymer *in situ*^{36,38,40,41} (Figure 2-8). It is also noted, in this regard, that *in vivo* component oxidation occurs, but to a lesser degree.⁴²

Component Manufacturing Deficiencies

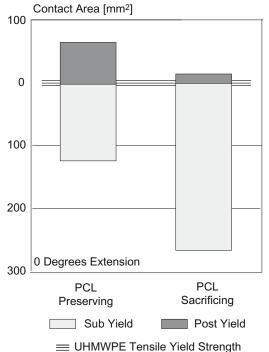
As knee designs have evolved, a growing appreciation of the avoidance of round-on-flat geometries through the ranges of knee flexion in favor of round-on-curved surfaces emerged.³² The ability of a given design to minimize contact stresses during walking gait contributes to UHMWPE tibial component longevity. The increased tibial-femoral conformity realized in posterior cruciate ligament (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 between PCL preserving and PCL sacrificing plateau geometries articulating against their respective, common femoral component (Figure 2-9).

The trend toward more conforming design geometries also has associated with it the expectation that femoral component tolerances be maintained during the manufacturing process. Failure to achieve this can dramatically decrease contact surfaces, elevate peak stresses, and, concurrent with articulation, is the harbinger of material damage⁴⁴ (Figure 2-10). This is of particular import with the current interest in mobile bearing knee designs, whose cited advantage is the maximization of contact surfaces during gait.⁴⁵

Third-Body Wear

The interaction of third-body particulate between articulation surfaces in knee replacement consistently demonstrates catalysis of UHMWPE damage. Surface scratching of the metallic counterface resulting from these interactions further contributes to the wear process. Foreign

FIGURE 2-9. Contact areas by surface stress range of PCL-preserving and PCL-sacrificing tibial-femoral conformities at 0 degrees extension. The overall bar height depicts the total contact area. (From Heim, Postak, Greenwald⁴³ by permission of AAOS.)



body inclusions may derive from acrylic bone cement, entrapped bone, and beads from an incomplete sintering process or hydroxyapatite (HA) particulate (Figure 2-11).



FIGURE 2-10. Finite element analysis of tibial-femoral contact areas and surface stresses of a contemporary mobile bearing knee design at 0 degrees extension. Poor mating of the articulating surfaces is observed resulting in peripheral contact with damaging stress levels.

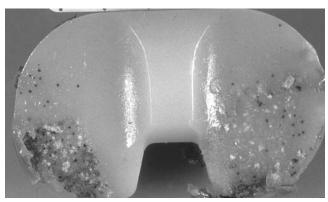


FIGURE 2-11. An early retrieval of a cementless, metal-backed tibial component demonstrating the effects of third-body entrapment. Bead embedment as well as delamination and pitting are observed in the posteromedial quadrant.

Component Design Influences

With the introduction of modularity, the interest in the all-poly tibia diminished, despite successful, long-term clinical reports. 46,47 Monoblock components were also introduced with the goal of optimizing stress transfer to the tibial bone surface. 48 Recently, attention has been drawn to the shortcomings of modular designs by the report of backside wear and an associated link to osteolysis and aseptic loosening. 49–58 Locking mechanism deficiency has been cited as a factor in allowing displacement between the insert and tibial tray to occur resulting in UHMWPE debris generation (Figure 2-12). Particulate transport to the intramedullary canal is facilitated through gaps at the locking mechanism interface as well as through screw holes when present.

Component Malalignment: A Surgical Prodrome

The forces and torques that occur during walking gait, particularly during toe-off, promote articulation in the posteromedial quadrant of tibial inserts. ^{59–63} Retrieved

FIGURE 2-12. Visualization of adhesive film transfer demonstrating UHMWPE insert rotatory micromotion in a modular tibial component.



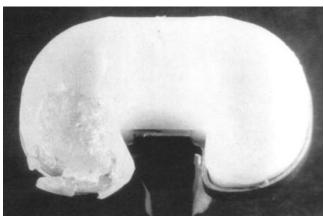


FIGURE 2-13. UHMWPE tibial component retrieval showing deformation and wear in the posteromedial portion of the insert. (From Swany, Scott, ⁶⁸ by permission of *J Arthroplasty*.)

components of failed knee arthroplasties demonstrate UHMWPE damage patterns in this area^{64–68} (Figure 2-13). Notwithstanding poor component design, causal factors include overloading the medial compartment, improper surgical correction or alignment of the bony structures, insufficient soft tissue balance and release, polyethylene cold flow near the edge of the tibial plateau, and surgical

malrotation of the components.^{64–68} In addition, the dynamic effects of lift-off and subsequent impact loading, and unusual patient kinematics further increase the potential for posteromedial failures.⁶⁹ The influence of surgical malrotation may be appreciated in Figure 2-14A, B, which demonstrate dramatic changes in location, contact area, and peak stresses for a PCL preserving knee in laboratory investigation.⁷⁰

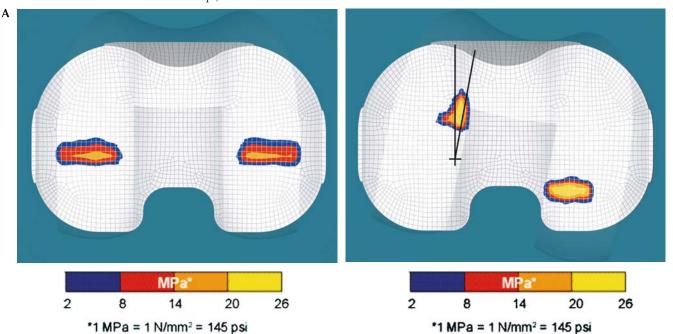
THE REMEDIES

UHMWPE Sterilization Techniques

Attempts to remove oxygen from the sterilization process include the use of inert gas and vacuum environments or by avoiding gamma irradiation altogether through the use of ethylene oxide (EtO) or gas plasmas.^{71–73} Acetabular components sterilized by these techniques demonstrate a reduction in UHMWPE wear in hip simulation studies (Figure 2-15).

Today, orthopedic device manufacturers avoid the use of an air environment when packaging UHMWPE components sterilized through the gamma irradiation process. Further, sterilization dates are now standard on package labeling of UHMWPE components.

FIGURE 2-14. The distribution of contact stresses at the toe-off position of walking gait for a PCL preserving design at (A) neutral rotation and (B) after the application of a 16 N-m external torque, simulating deliberate component malalignment. A dramatic increase in peak contact stresses is observed, which is contributory to component damage. (From Morra, Postak, Plaxton, et al. ⁷⁰ by permission of *Clin Orthop.*)



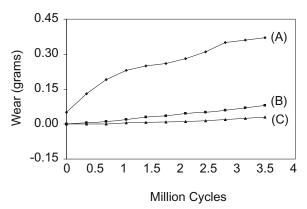


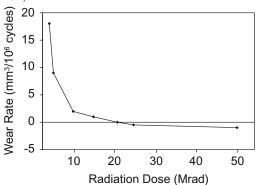
FIGURE 2-15. Hip simulator weight-loss comparison for aged (25 days at 78 degrees Celsius in O_2) compression-molded cup components: (A) gamma irradiated in air; (B) sterilized with ethylene oxide; and (C) gamma irradiated in a vacuum environment and use of barrier packaging. (From Greer, Schmidt, Hamilton, ⁷² by permission of *Trans Orthop Res Soc.*)

UHMWPE Processing Techniques

It is now quantitatively appreciated that increasing the gamma radiation dose above the 2.5 Mrad level used in conventional UHMWPE component sterilization, encourages free radicals to combine, creating crosslinks between the molecules of adjacent chains, which is further enhanced in an oxygen-free environment.^{74–76} This graph from McKellop and coworkers is descriptive of this phenomenon in a simulator comparison of acetabular cup components (Figure 2-16). The volumetric wear per million cycles is dramatically reduced with increasing gamma radiation exposure.

There are clinical reports attributed to Oonishi and Grobbelaar, which describe *in vivo* UHMWPE wear reduction in acetabular components realized through increased crosslinking.^{77–82} However, these studies employed large doses of gamma radiation (>50 Mrad), which are known to cause polymer embrittlement

FIGURE 2-16. Mean acetabular cup wear rates versus gamma dose level. (From McKellop, Shen, Lu, et al. 75 by permission of *J Orthop Res.*)



and yellowing. Wroblewski employing a chemically enhanced cross-linked polymer, achieved similar findings both *in vivo* and *in vitro*, when coupled with an Alumina articulation.⁸³

In some sense these isolated studies point the way to a new class of UHMWPEs, whose common denominator is an appreciation of the importance of increased crosslinking while minimizing oxidative degradation to reduce wear. Current methods used to manufacture these moderately to highly cross-linked UHMWPEs are shown (Figure 2-17). Process differences include (1) heating above or below the melt temperature of the polyethylene, (2) the type of radiation employed, (3) the radiation dose level, and (4) the endpoint sterilization.

All have received Food and Drug Administration 510[k] clearance, allowing commercial distribution for both hip and knee components. Currently, there is a minimum of short-term clinical reports supporting the advantage of these increased cross-linked UHMWPEs for the hip^{84–90} and knee.^{91,92} However, impressive laboratory data have been produced, predominantly with regard to hip simulation.^{93–97}

Manufacturing Optimization

The attainment of femoral component tolerances has markedly improved with the relatively recent use of computer-aided precision grinding as a standard finishing technique for metallic femoral knee components. This is particularly beneficial where small variations in surface contours have large effects on contact areas and surface stresses (Figure 2-18). The implications of this technique have potentially far-reaching consequences. As design specifications are produced with higher required tolerances, as in contemporary mobile bearing knee designs, the need for precision manufacturing is imperative (Figure 2-19).

Tibial Tray Design Improvement

Improving the capture mechanisms of UHMWPE tibial inserts is an ongoing design challenge. Minimizing insert microdisplacement over time will contribute to reduced UHMWPE debris generation. This notwithstanding, careful attention must also be paid to the tibial tray material and its surface finish. Just as polished, titanium femoral heads fell from clinical popularity as their surfaces easily scratched and wore during articulation, 98–100 modular tibial tray components should be manufactured using cobalt-chrome alloys. If, because of modular mismatch, microdisplacement is inevitable, the articulation surfaces should be optimized to reduce the potential for wear debris generation. From a design perspective, circumferential capture and the capping or avoidance of screw holes should be considered, so as to avoid potential

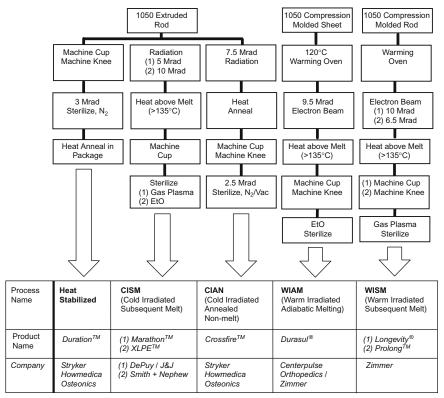


FIGURE 2-17. Current methods used to manufacture moderately to highly cross-linked UHWMPE.

FIGURE 2-18. A comparison of tibial-femoral contact areas by surface stress range for belt finishing and computer-aided precision grinding techniques of a single femoral component design at 0 degrees extension. The overall bar height depicts the total contact area. (From Helm, Postak, Greenwald⁴³ by permission of AAOS.)

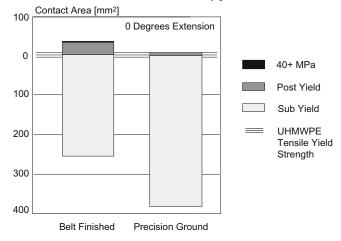
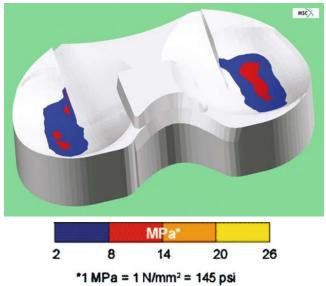


FIGURE 2-19. Finite element analysis demonstrating the optimization of tibial-femoral contact areas and surface stresses resulting from quality controlled finishing of the component demonstrated earlier in Figure 2-10. It is apparent that use of the conforming geometries has been achieved with the resulting diminishment of peak contact stresses.



pathways for debris transport. 101-105 A further consequence of modularity is the employment of highly cross-linked UHMWPE inserts whose fracture toughness is reduced. Locking points in tray design represent foci for stress concentrators, increasing the potential for crack initiation, the propagation of which occurs more rapidly in these materials than conventional polyethylene. 106

Surgical Optimization

The increasing emphasis on templating and the relatively recent introduction of computer-assisted navigation techniques offer the promise that component malalignment may ultimately be minimized. ^{107–109} Eliminating the outliers in component placement will contribute to diminishing UHMWPE material damage in knee arthroplasty. Continued improvements in instrument design go hand-in-hand with the achievement of this goal.

Patient Factors: Do They Really Matter?

Overenthusiastic patient use following total knee arthroplasty has been cited as a factor influencing failure. 110-112 Its occurrence, however, has generally been described in singular case reports in much the same way as failure attributed to obesity. Series reports do not support a relationship between increased body mass index and device failure following arthroplasty. 113-118 Surgical preference, however, weighs in favor of the lightweight patient as the ideal arthroplasty candidate. 119 However, it is known from both physical laboratory testing and finite element analysis that load magnitude in combination with displacement are factors influencing UHMWPE damage. 120-127 While a recommendation for patient weight loss before surgery may be justified from these laboratory investigations, the clinical reality of achieving this does not lie in the patient's or surgeon's favor. 128

THE CONCERNS

Highly Cross-Linked UHMWPE Use in TKA

The proclaimed advantage of highly cross-linked UHMWPEs lies in the reduction of wear debris generation through enhanced crosslinking of the polymer chains coincident with the elimination of oxidation. However, changes in the mechanical properties of these materials, particularly in their reduced resistance to fatigue crack propagation (fracture toughness) raises concerns about their long-term suitability in hip and knee components where locking mechanisms offer foci for stress risers (Figures 2-20, 2-21, and 2-22). An appreciation of the differing modes of hip (abrasion and adhesion) and knee (pitting and delamination) failure, confirmed through conventional UHMWPE component retrieval, 132-134 sug-



FIGURE 2-20. A 1-year conventional UHMWPE, primary acetabular liner demonstrating crack initiation and propagation. Failure initiated at a sharp edge of a locking point. (From Tradonsky, Postak, Froimson¹²⁹ by permission of *Clin Orthop*.)

gests that a universal, highly cross-linked polymer may not be appropriate.

Investigation into the means by which fracture toughness and ultimate tensile strength of these new polymers may be increased is and should be an ongoing quest, particularly if their rapid employment will lead to obsolescence of conventional UHMWPE. Its furthest hope in knee replacement application would be a reduction in the capacity for these materials to pit and delaminate or, in other words, when the knee behaves like a hip in terms of its wear process. This reality may be appreciated with designs of increasing conformity such as those found in mobile bearing knees.

FIGURE 2-21. A 10-month highly cross-linked UHMWPE, revision acetabular liner demonstrating crack initiation and propagation. The decision to retain the acetabular shell in an almost vertical and anteverted position contributed to this early failure, which was compounded by the decision to use a 40-mm femoral head and a correspondingly thin liner. (From Halley, Glassman, Crowninshield¹³⁰ by permission of *J Bone Joint Surg.*)



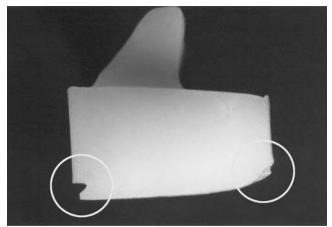


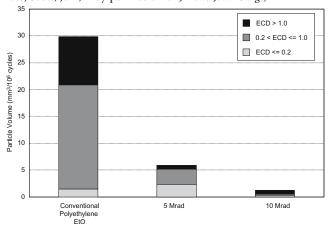
FIGURE 2-22. A 3-year failure of a constrained condylar conventional UHMWPE tibial insert. Failure of the posterior locking mechanism resulted in posterior component lift-off. (From Ries¹³¹ by permission of *J Bone Joint Surg.*)

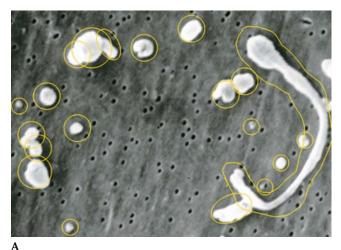
Particle Bioreactivity

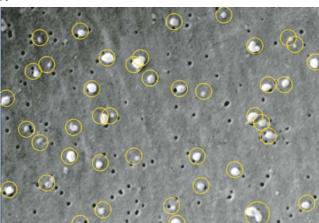
Conventional wisdom and our experience particular to hip arthroplasty suggest that osteolytic response is associated with both particle size and debris volume. Laboratory hip simulator experiments have shown that UHMWPE particle volumes in various size ranges are dependent on radiation dose¹³⁵ (Figures 2-23 and 2-24). The greatest potential for cytokine release, the first step in the sequelae leading to osteolysis, following macrophage debris encapsulation is at the <1 micron level. Ingram et al. have suggested that highly cross-linked UHMWPE debris obtained from scratched surface articulation is bioreactive when placed in culture medium and appears to be volume dependent. ¹³⁶

The influence of surface roughness has been further investigated by Scott et al. in a hip simulator comparison

FIGURE 2-23. Comparative volumes of acetabular particle generation for different size ranges per million cycles for conventional and highly cross-linked UHMWPEs at 5 and 10 Mrads resulting from hip simulation. ECD, equivalent circular diameter. (From Ries, Scott, Jani, ¹³⁵ by permission of *J Bone Joint Surg.*)







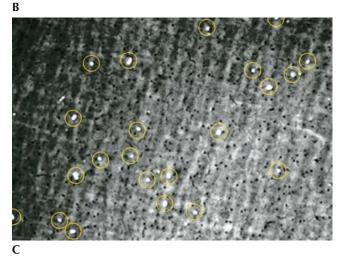


FIGURE 2-24. Corresponding SEM visualization (10000×) of particle distribution for (A) conventional and (B and C) highly cross-linked UHMWPEs at 5 and 10 Mrads, respectively, employing a 0.05-micron filter. The particles are highlighted for appreciation. (From Ries, Scott, Jani, ¹³⁵ by permission of *J Bone Joint Surg.*)

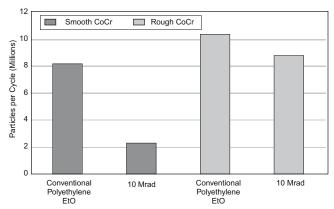


FIGURE 2-25. The influence of smooth and roughened femoral head surfaces on particle generation for conventional and highly cross-linked UHMWPE acetabular components resulting from hip simulation. (From Good, Ries, Barrack, et al. ¹³⁹ by permission of *J Bone Joint Surg Am.*)

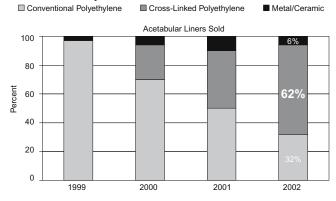
between conventional, EtO, and 10 Mrad polyethylene components.¹³⁷ As one appreciates from Figure 2-25, roughened surfaces have a negative influence on particle production where highly cross-linked polyethylenes are employed. This has been challenged most recently by Muratoglu et al. in a study in which retrieved femoral components were articulated in knee simulation against a highly cross-linked polyethylene.¹³⁸

Alternatives to reduce the influence of surface roughness on femoral component design have recently been reported using fully oxidized zirconium surfaces. This has relevance on the long-term viability of knee articulations with conventional UHMWPE tibial inserts, but its performance is unknown with highly cross-linked materials. ^{139,140}

Direct-to-Consumer Marketing

Further, it is no small coincidence that almost 62% of all polyethylene acetabular components sold in the United

FIGURE 2-26. Histogram illustrating the growth of highly cross-linked UHMWPE acetabular component sales in the United States. (Data from *Orthopaedic Network News.*¹)



States today are constituted of highly cross-linked polyethylenes in their various formulations¹ (Figure 2-26). Cost as well as patient selection and the unknown clinical realities of long-term series reporting are concerns with these materials that only *in vivo* time will elucidate. The march of progress toward increasing use of these materials—in the relative absence of mid- and long-term clinical reports—portrays a rapid direct-to-consumer marketing philosophy employed by orthopedic manufacturers for both the orthopedic surgeon and the patients they serve.

THE PROMISE

The previous remarks have attempted to define problems, solutions, and unknown performance factors of both conventional and emerging highly cross-linked UHMWPE materials currently used in knee arthroplasty. What is important for the reader to appreciate is that the description of employment of highly cross-linked polymers in knee arthroplasty is an evolving experience, which will find advocacy or limitation in what is now a tandem laboratory and clinical approach. The passage of *in vivo* time, as has always been, will be the defining factor in their use.

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