Implant Bearings in Total Knee Arthroplasty

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The Enduring Goal

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 2016 almost 1.4 million primary and revision hip and knee arthroplasty procedures were performed in the United States, a number more than doubling on a global basis [1] (Table 2.1). Improvements in surgical technique and implant design over the last four decades have resulted in total knee arthroplasty (TKA) being deemed one of the most successful, contemporary orthopaedic procedures to effectively relieve pain and allow patients to resume the activities of their daily lives. The prevalence of aseptic loosening attributed to ultra-high molecular weight polyethylene (UHMWPE) wear debris-induced osteolysis is in the single digits in most knee series, with some reports describing prosthesis survival beyond 20 years [2–25]. 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 [26–44]. Appreciating an orthopaedic triad where patient outcomes are not only dictated by the implant but are highly dependent on patient factors and technical proficiency assists the goal of avoiding total knee arthroplasty revision.

The Triad: The Implant

The Evolution of UHMWPE

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 1020 and GUR 1050 are the prevalent polymers utilized 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 [45]. While UHMWPE has remained the tibial insert and patellar component bearing material of choice over the last four decades, researchers are continually striving to increase its in-vivo longevity through alterations to processing and/or sterilization techniques.

Short- to mid-term clinical reports of UHMWPE damage in the 1990s led to a review

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Table 2.1 Hip and knee arthroplasty procedures performed in the United States in 2016

	Primary	Revision	Total
Knees	759,600	89,000	848,600
Hips	492,900	58,400	551,300
Total	1,252,500	147,400	1,399,900

Data from *Orthopaedic Network News* [1]

Fig. 2.1 A 5-year retrieval of a failed poly-II tibial insert demonstrating a high component wear rate with infiltration of carbon fibers and polyethylene debris into surrounding tissue

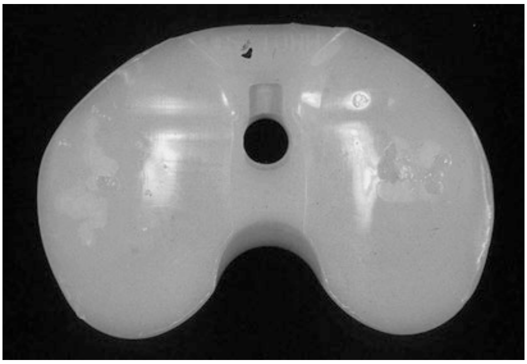


Fig. 2.2 A 3-year retrieval of a failed Hylamer-M tibial plateau demonstrating an unexpectedly high wear rate with corresponding wear and debris-induced inflammatory tissue response

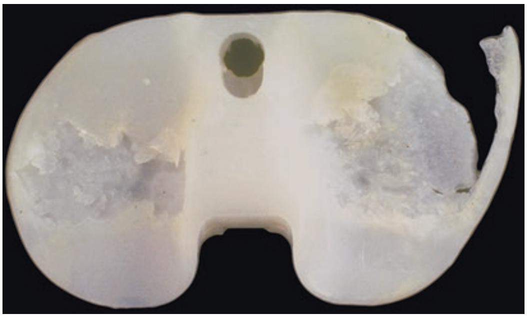


Fig. 2.3 A 6-year retrieval of a heat-pressed tibial component associated with polyethylene fatigue and early delamination

of manufacturing processes and determined that inadequate quality control resulted in fusion defects arising from incomplete polymerization, voids, and foreign body inclusions [46–48]. Recognizing the direct impact of these variables on the in-vivo degradation of the final parts, orthopaedic device manufacturers addressed the allowable tolerances for these components, and these issues have not reappeared in the peer-reviewed literature.

Previous attempts to improve UHMWPE performance have included carbon fiber reinforcement (Poly-II) [49] and polymer reprocessing by hot isostatic pressing (Hylamer) [50]. The former was withdrawn from the market because of an unexpectedly high wear rate [51] (Fig. 2.1), while the latter has been linked to debris-induced osteolytic response, especially when sterilized by gamma irradiation in air [52] (Fig. 2.2). Heat pressing was yet another attempt to improve the finish of the articular surface, but was associated with UHMWPE fatigue and early delamination [53] (Fig. 2.3). These material innovations had checkered pasts as they moved from the laboratory to clinical application.

Gamma irradiation in air was the predominant method of UHMWPE component sterilization, and, to this day, represents the long-term standard against which contemporary material improvements are measured. In the early 1990s, an increasing prevalence of tibial component failures associated with debris-induced osteolysis raised concerns over the long-term durability of contemporary devices [54, 55]. A clinical follow-up study reported by Bohl et al. suggested that this may be accounted for by the prolonged shelf storage prior to implantation of UHMWPE components gamma irradiated in air [56]. A 12–20% reduction in in-vivo survival was noted for shelf storage ranging from 4 to 11 years with a mean in-vivo time to revision of 2.5 years (Figs. 2.4 and 2.5).

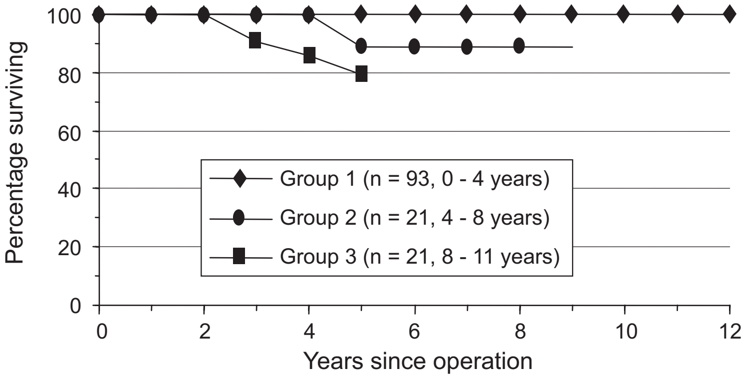


Fig. 2.4 The influence of shelf storage on survival of a prosthetic knee plateau following gamma irradiation in air (from Bohl JR, Bohl WR, Postak PD, et al. The effects of shelf life on clinical outcome for gamma sterilized polyethylene tibial components. Clin Orthop Relat Res. 1999;267:28–38, with permission)

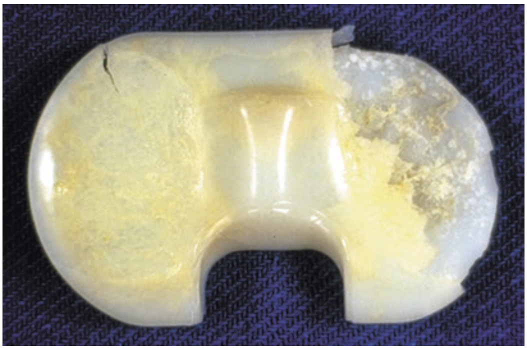


Fig. 2.5 A group 2 plateau implanted after 7.6 years of shelf storage and retrieved 3.8 years after implantation. Gross delamination and pitting, characteristics of fatigue failure, are observed (from Bohl JR, Bohl WR, Postak PD, et al. The effects of shelf life on clinical outcome for gamma sterilized polyethylene tibial components. Clin Orthop Relat Res. 1999;267:28–38, with permission)

Further, laboratory studies indicated that as shelf storage increased, the amount of UHMWPE exposed to high surface stresses during articulation increased dramatically and was a contributing factor to early in-vivo polymer failure [57–59] (Fig. 2.6).

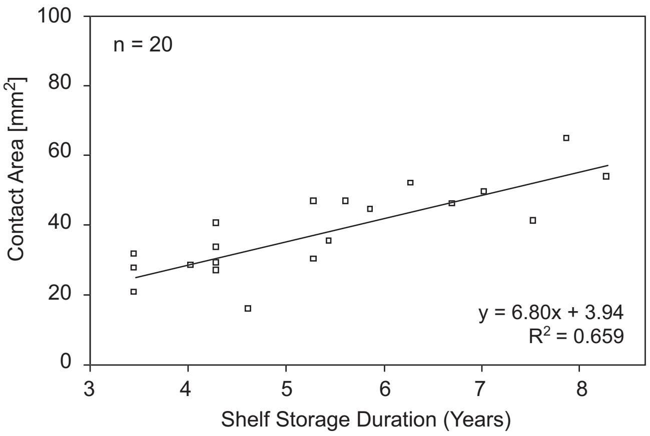
The explanation for these observations lies in the mechanics of the sterilization process, which facilitates breakage of polymer chains by the incoming gamma radiation, creating free radicals, which preferentially combine with available oxygen [60, 61] (Fig. 2.7). The onset of mass UHMWPE component production and device modularity resulted in extended component shelf storage before use. This was not a previous consideration, but ongoing shelf life oxidation offered an explanation for mechanical compromise of the polymer in-situ [58, 60, 62, 63] (Fig. 2.8). It was also noted that in-vivo component oxidation occurred, but to a lesser degree [64].

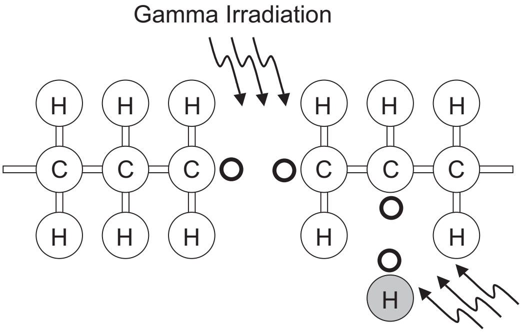
At this point, attempts to remove oxygen from the sterilization process included the use of inert gas and vacuum environments or by avoiding gamma irradiation altogether through the use of ethylene oxide (EtO) or gas plasmas [65–67]. Acetabular components sterilized by these techniques demonstrated a reduction in UHMWPE wear in hip simulation studies (Fig. 2.9). Today, orthopaedic device manufacturers avoid the use of an air environment when packaging UHMWPE components, and sterilization dates are standard on device package labeling.

It is now also 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 cross-links between the molecules of adjacent chains, which is further enhanced in an oxygen-free environment [68–70]. Figure 2.10 from McKellop and coworkers [69] is descriptive of this phenomenon in a simulator comparison of acetabular cup components with the volumetric wear per million cycles dramatically reduced with increasing gamma radiation exposure.

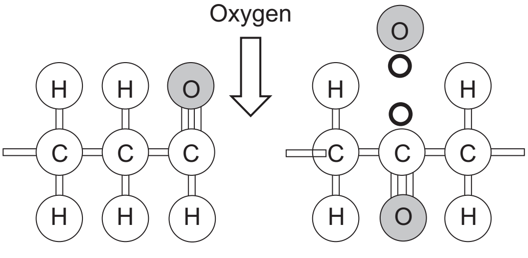
There are clinical reports attributed to Oonishi and Grobbelaar, which describe in-vivo UHMWPE wear reduction in acetabular components realized

Fig. 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





(a) Chain Scission (b) Hydrogen Extraction



(a) Aldehyde Formation (b) Ketone Formation

Fig. 2.7 Depicted polymer chain breakage following irradiation in air and combination with oxygen facilitating oxidative degradation of UHMWPE

through increased cross-linking [71–76]. However, these studies employed large doses of gamma radiation (>50 Mrad), which are known to cause polymer embrittlement 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 [77].

These isolated studies pointed the way to a new class of UHMWPEs, whose common denominator was an appreciation of the importance of increased cross-linking while minimizing oxidative degradation to reduce wear. Initial methods used to manufacture these moderately to highly cross-linked UHMWPEs included (1) heating above or below the melt temperature of the polyethylene, (2) the type of radiation employed, (3) the radiation dose level, (4) the sequence of stepwise application, and (5) the endpoint sterilization. The one common factor is that radiation was integrated into the manufacturing process. All received U.S. Food and Drug Administration 510[k] clearance, allowing commercial distribution for both hip and knee components (Table 2.2).

However, changes in the mechanical properties of these materials, particularly in their reduced resistance to fatigue crack propagation (fracture toughness), raised concerns about their long-term suitability in hip and knee components where locking mechanisms offered foci for stress risers [78–81] (Figs. 2.11, 2.12, and 2.13). Short-term clinical reports for total hip arthroplasty demonstrated a significant reduction in wear volume and rate for these polymers [82–87], which supported the impressive preclinical hip simulation laboratory data [88–92]. However, the negative impact of extreme component positioning on outcome was also demonstrated through case and retrieval reports at this time [80, 93, 94].

An appreciation of the differing modes of hip (abrasion and adhesion) and knee (pitting and delamination) failure, confirmed through

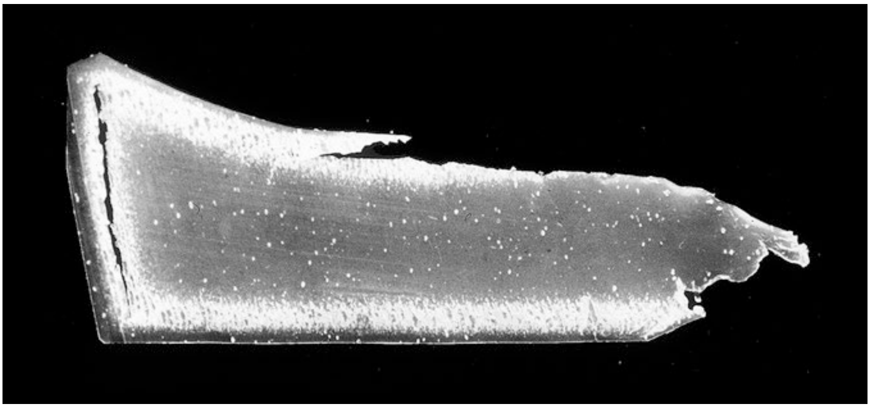


Fig. 2.8 A 3-year retrieval of a fully oxidized, gamma irradiated in air, UHMWPE tibial component demonstrating a circumferential white band indicative of polymer embrittlement after prolonged shelf life. Fusion defects from incomplete consolidation are noted

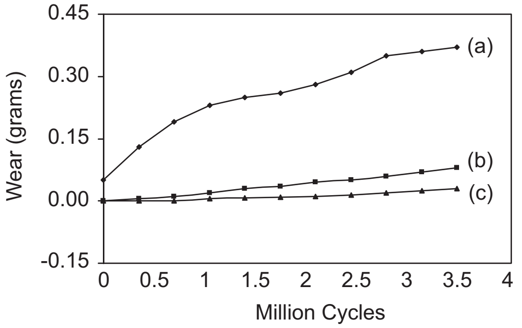


Fig. 2.9 Hip simulator weight-loss comparison for aged (25 days at 78 degrees Celsius in O_2) compression-molded cup components: (**a**) gamma irradiated in air; (**b**) sterilized with ethylene oxide; and (**c**) gamma irradiated in a vacuum environment and use of barrier packaging. (From Greer, Schmidt, Hamilton,[66] by permission of *Trans Orthop Res Soc.*)

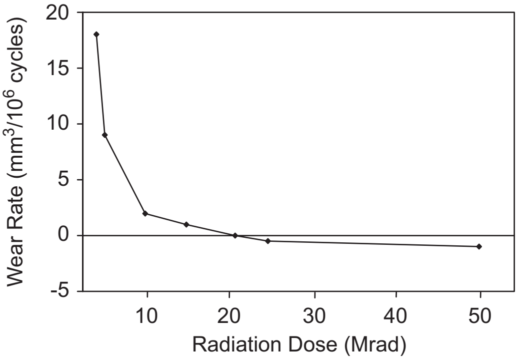


Fig. 2.10 Mean acetabular cup wear rates versus gamma dose level (from McKellop H, Shen FW, Lu B, et al. Development of an extremely wear-resistant ultra-high molecular weight polyethylene for total hip replacements. J Orthop Res. 1999;17(2):157–167, with permission)

Table 2.2 Moderately to highly cross-linked UHMWPEs

Manufacturer	UHMWPE trade name
Biomet	ArComXL
DePuy/J&J	Marathon AltrX
Smith + Nephew	XLPE
Stryker	Crossfire X3
Zimmer	Durasul Longevity Prolong

Fig. 2.11 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 S, Postak PD, Froimson AI, et al. A comparison of disassociation strength of modular acetabular components. Clin Orthop Relat Res. 1993;296:154–160, with permission)

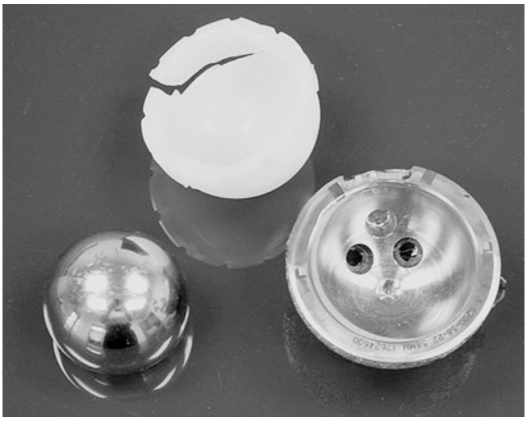


Fig. 2.12 A 10-month cross-linked UHMWPE, revision acetabular liner demonstrating crack initiation and propagation. The decision to retain the acetabular shell in an almost vertical and anteverted position contributed to this early failure, which was compounded by the decision to use a 40-mm femoral head and a correspondingly thin liner (from Halley D, Glassman A, Crowninshield RD. Recurrent dislocation after revision total hip replacement with a large prosthetic femoral head. J Bone Joint Surg Am. 2004;86(4):827–830, with permission)

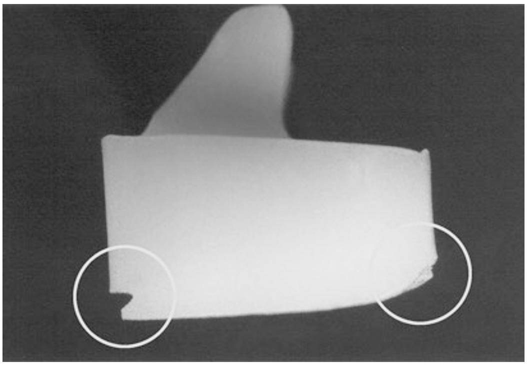


Fig. 2.13 A 3-year failure of a constrained condylar conventional UHMWPE tibial insert. Failure of the posterior locking mechanism resulted in posterior component lift-off (from Ries MD. Dissociation of an ultra-high molecular weight polyethylene insert from the tibial baseplate after total knee arthroplasty. J Bone Joint Surg Am. 2004;86(7):1522–24, with permission)

Table 2.3 Contemporary antioxidant-infused UHMWPEs

Manufacturer	UHMWPE trade name
Biomet	E1
Corin	ECIMA
DePuy Synthes	AOX
DJO global	E+
StelKast	EXp
Zimmer	Vivacit-E

conventional UHMWPE component retrieval [95–97], also suggested that a universal, moderately to highly cross-linked polymer may not be appropriate. To counter the reported degradation in material properties, “enhanced” UHMWPEs now have antioxidants, predominantly vitamin E, infused or blended into the resin powder during the manufacturing process (Table 2.3). Laboratory studies have confirmed the maintenance of UHMWPE mechanical properties and wear resistance in addition to prevention of oxidative degradation for these polymers [98–105].

Contemporary peer-reviewed literature for the moderately to highly cross-linked UHMWPEs in total hip arthroplasty is reporting dramatic reduction of wear rate when compared to conventional UHMWPE in mid- to long-term follow-up studies with metal femoral heads [106–121]. Total knee arthroplasty clinical reporting focuses on aseptic loosening and mechanical failures rather than wear rate, but again, in short- to mid-term studies, these UHMWPEs are demonstrating efficacy [122–126]. While short- to mid-term clinical studies supporting the further advantages of the antioxidant-infused UHMWPEs in total hip arthroplasty are increasing [127–131], reporting for total knee arthroplasty has just begun [132]. While the overall clinical gains of these enhancements have been questioned [133], the passage of in-vivo time will be, as has always been, the defining factor in the continued use of these moderately to highly cross-linked UHMWPEs with or without antioxidants.

The Femoral Side

While the predominant focus for increasing the in-vivo longevity of total knee arthroplasty is alteration of the UHMWPE tibial insert, there are alternative bearing options for the femoral component as well. As example, oxidized zirconium, marketed under the trade name Oxinium (Smith + Nephew, Memphis, TN) in the United States, has the strength of metallic cobalt-chromium

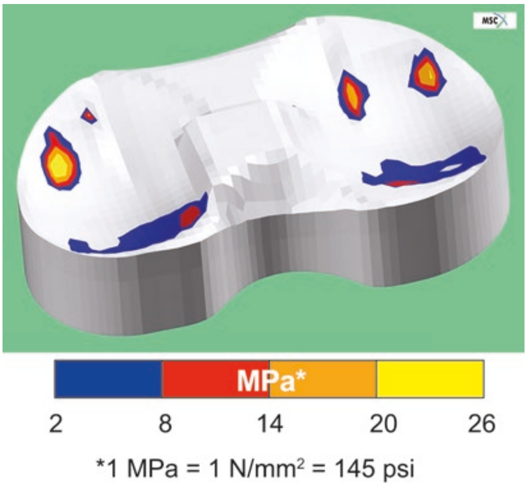


Fig. 2.14 Finite element analysis of tibial-femoral contact areas and surface stresses of a contemporary mobile bearing knee design at 0° extension. Poor mating of the articulating surfaces is observed resulting in peripheral contact with damaging stress levels

femoral components with the wear characteristics of ceramics [134], as has been shown in laboratory simulators for pairings with both conventional and highly cross-linked UHMWPE [135, 136]. The uniqueness of this material is that it offers patients with metal hypersensitivity, particularly to nickel, an implant option that has been shown to be clinically equivalent to cobalt-chromium femoral components [137–142].

The Tibial-Femoral Geometries

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 [54]. The ability of a given design to minimize contact stresses during walking gait contributes to UHMWPE tibial component longevity [143]. With this, 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 damage [144] (Fig. 2.14).

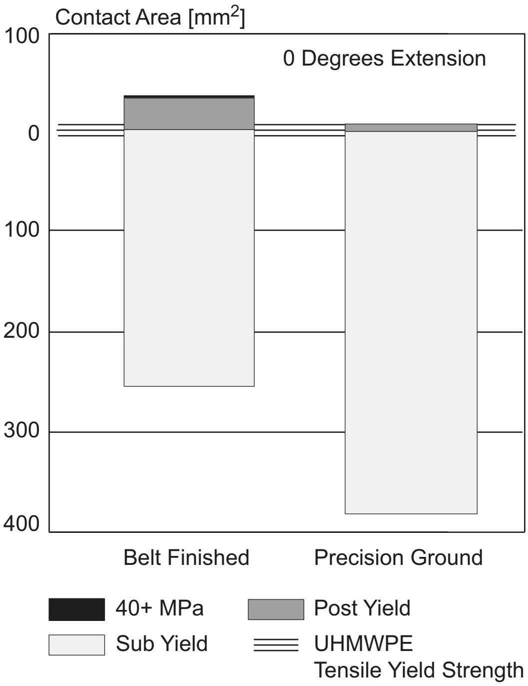


Fig. 2.15 A comparison of tibial-femoral contact areas by surface stress range for belt finishing and computer-aided precision grinding techniques of a single femoral component design at 0° extension. The overall bar height depicts the total contact area (from Heim CS, Postak PD, Greenwald AS. Factors Influencing the longevity of UHMWPE tibial components. In: Pritchard D, editor. Instructional Course Lectures, vol 45. Chicago, IL: American Academy of Orthopaedic Surgeons; 1996, with permission)

The attainment of femoral component tolerances has markedly improved with the 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 (Fig. 2.15). The implications of this technique have potentially far-reaching consequences. As design specifications are produced with tighter tolerances, the need for precision manufacturing is imperative (Fig. 2.16).

The Wear Particles Produced

Conventional wisdom and our experience particular to hip arthroplasty suggest that osteolytic response is associated with both particle size and

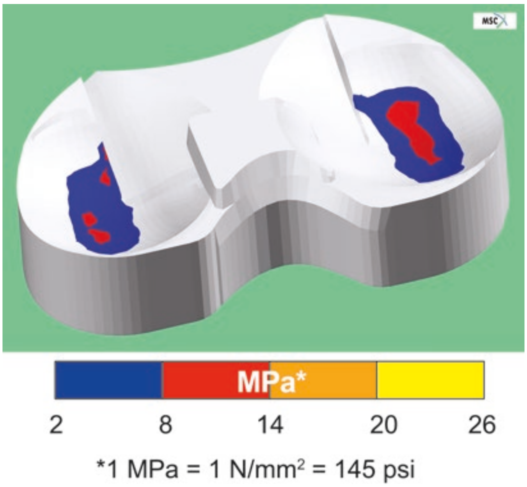


Fig. 2.16 Finite element analysis demonstrating the optimization of tibial-femoral contact areas and surface stresses resulting from quality controlled finishing of the component demonstrated earlier in Fig. 2.14. It is apparent that use of the conforming geometries has been achieved with the resulting diminishment of peak contact stresses

debris volume. Laboratory hip simulator experiments have shown that UHMWPE particle volumes in various size ranges are dependent on radiation dose [145] (Figs. 2.17 and 2.18). The greatest potential for cytokine release, the first step in the sequelae leading to osteolysis, following macrophage debris encapsulation is at the <1 μm level. Ingram et al. suggested that highly cross-linked UHMWPE debris obtained from scratched surface articulation was bioreactive when placed in culture medium and appeared to be volume dependent [146].

The influence of surface roughness was further investigated by Scott et al. in a hip simulator comparison between conventional, EtO, and 10 Mrad UHMWPE components [147]. As one appreciates from Fig. 2.19, roughened surfaces have a negative influence on particle production where highly cross-linked UHMWPEs are employed. This was challenged by Muratoglu et al. in a study in which retrieved femoral components were articulated in

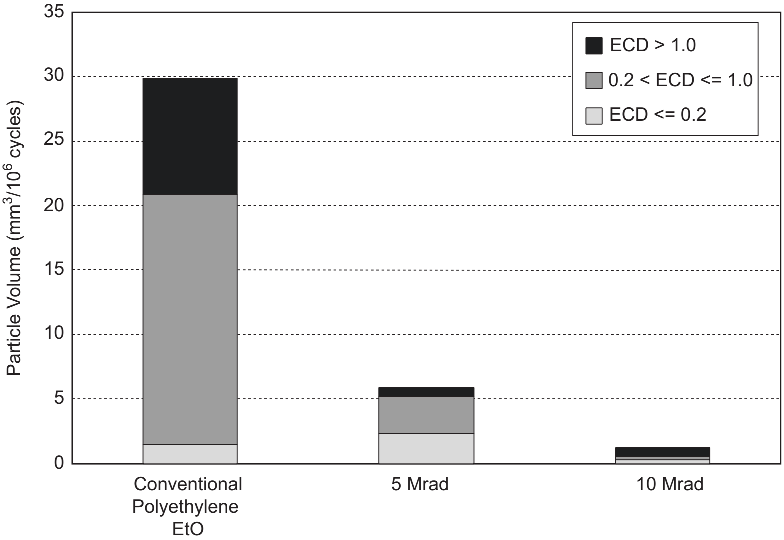


Fig. 2.17 Comparative volumes of acetabular particle generation for different size ranges per million cycles for conventional and highly cross-linked UHMWPEs at 5 and 10 Mrads resulting from hip simulation. ECD, equivalent circular diameter (from Ries MD, Scott ML, Jani S. Relationship between gravimetric wear and particle generation in hip simulator: conventional compared with cross-linked polyethylene. J Bone Joint Surg Am. 2001;83(Suppl 2, Pt 2):116–122, with permission)

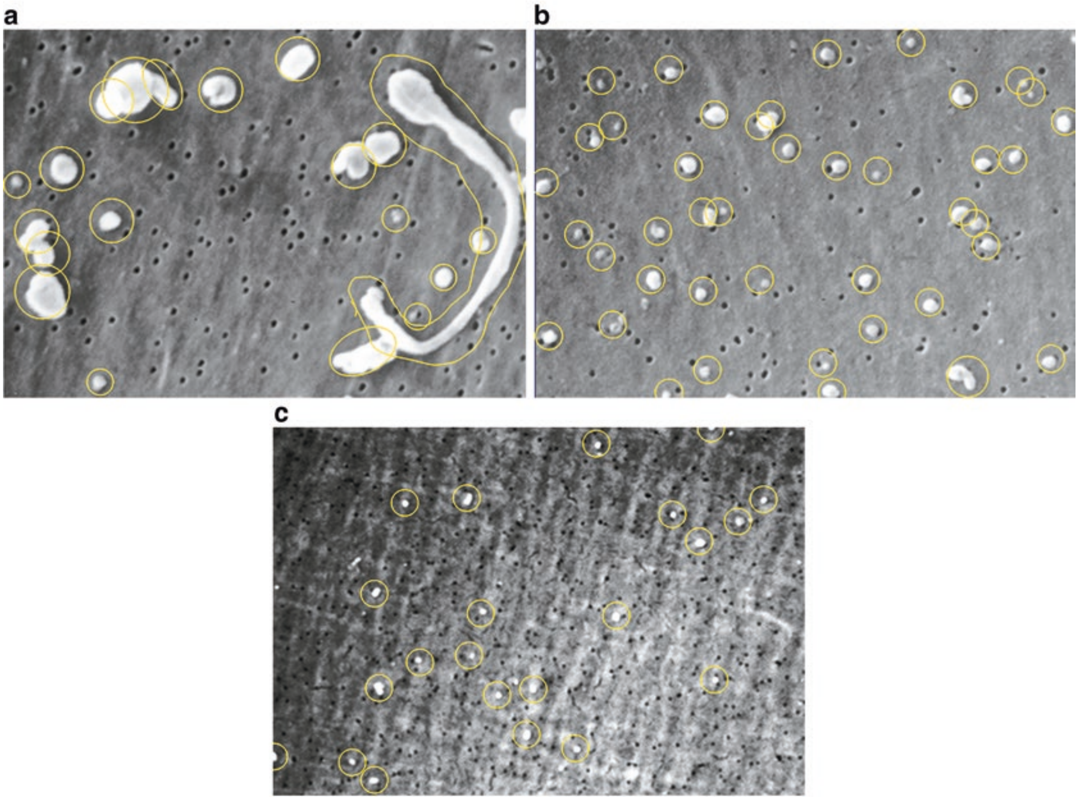
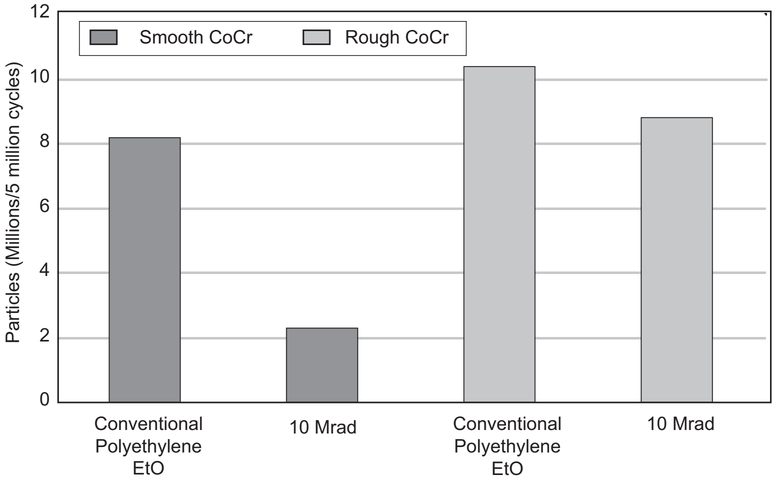


Fig. 2.18 Corresponding SEM visualization (10000×) of particle distribution for (**a**) conventional and (**b** and **c**) highly cross-linked UHMWPEs at 5 and 10 Mrads, respectively, employing a 0.05-μm filter. The particles are highlighted for appreciation (from Ries MD, Scott ML, Jani S. Relationship between gravimetric wear and particle generation in hip simulator: conventional compared with cross-linked polyethylene. J Bone Joint Surg Am. 2001;83(Suppl 2, Pt 2):116–122, with permission)

Fig. 2.19 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 V, Ries M, Barrack RL, et al. Reduced wear with oxidized zirconium femoral heads. J Bone Joint Surg Am. 2003;85(Suppl 4):105–110, with permission)



knee simulation against a highly cross-linked UHMWPE [148]. Further, retrieved oxidized zirconium femoral components have demonstrated decreased surface roughness with time in-vivo, suggesting another benefit of this cobalt-chromium alternative for improving the long-term viability of knee articulations [149–152].

The Triad: The Patient

Overenthusiastic patient use following total knee arthroplasty has been cited as a factor influencing failure [153–155]. 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 [156–161]. Surgical preference, however, weighs in favor of the lightweight patient as the ideal arthroplasty candidate [162]. It is also known from both physical laboratory testing and finite element analysis that load magnitude in combination with displacement are factors influencing UHMWPE damage [163–170]. 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 [171].

With the patient population pursuing total knee arthroplasty getting younger and living longer, it is imperative that contemporary implant bearing materials address these increasing demands [172]. Clinical studies are now focusing more on patient-reported outcomes and relating them to comorbidities in an effort to align expectations for both the patient and the surgeon [173–175].

The Triad: The Surgery

The forces and torques that occur during walking gait, particularly during toe-off, promote articulation in the posteromedial quadrant of tibial inserts [176–180]. Retrieved components of failed knee arthroplasties demonstrate UHMWPE damage patterns in this area [181–185] (Fig. 2.20). 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 [181–185]. In addition, the dynamic effects of lift-off and subsequent impact loading and unusual patient kinematics further increase the potential for posteromedial failures [186]. The influence of surgical malrotation may be appreciated in Fig. 2.21a, b, which demonstrate dramatic changes in location, contact area, and peak stresses for a PCL preserving knee in a laboratory investigation [187].

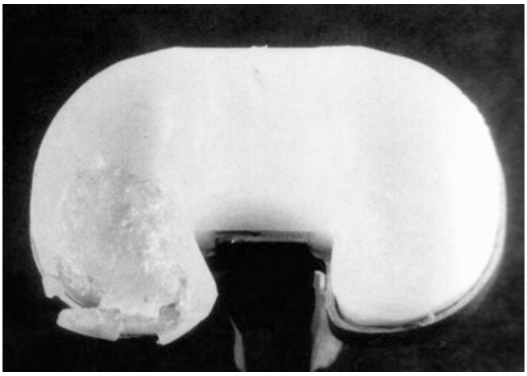


Fig. 2.20 UHMWPE tibial component retrieval showing deformation and wear in the posteromedial portion of the insert (from Swany MR, Scott RD. Posterior polyethylene wear in posterior cruciate ligament-retaining total knee arthroplasty: a case study. J Arthroplasty. 1993;8:439–846, with permission)

The continual emphasis on templating and the technological advances in computer-assisted and robotic navigation systems, intraoperative sensors as well as patient-specific instrumentation offer the promise that component malalignment may ultimately be minimized and patient satisfaction increased [188–194]. Eliminating the outliers in component placement will contribute to diminishing UHMWPE material damage in knee arthroplasty, however, the best technology to utilize in the achievement of this goal, is yet to be defined [195–197].

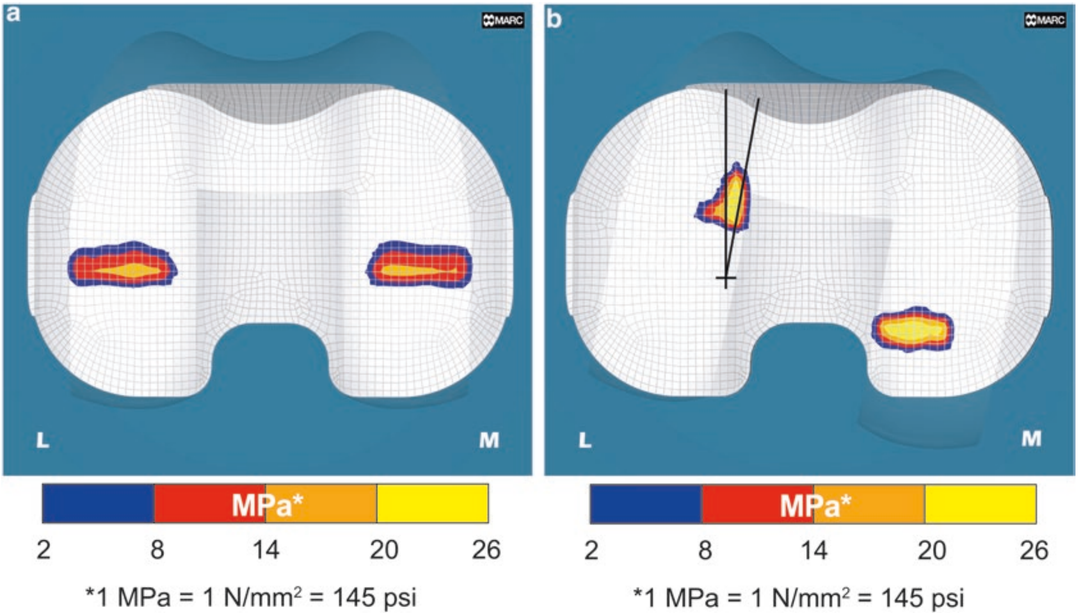


Fig. 2.21 The distribution of contact stresses at the toe-off position of walking gait for a left knee, PCL preserving design at (**a**) neutral rotation and (**b**) after the application of a 16 N-m external torque, simulating deliberate component malalignment. A dramatic increase in peak contact stresses is observed, which is contributory to component damage (from Morra EA, Postak PD, Plaxton NA, et al. The effects of external torque on polyethylene tibial insert damage patterns. Clin Orthop Relat Res. 2003;410:90–100, with permission)

The Enduring Promise

The previous remarks have attempted to define problems, solutions, and unknown performance factors of bearing materials currently utilized in total knee arthroplasty as they relate to the implant, the patient, and the surgery. What is important for the reader to appreciate is that this is a continually evolving experience, which will find advocacy or limitations, with the passage of in-vivo time.

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