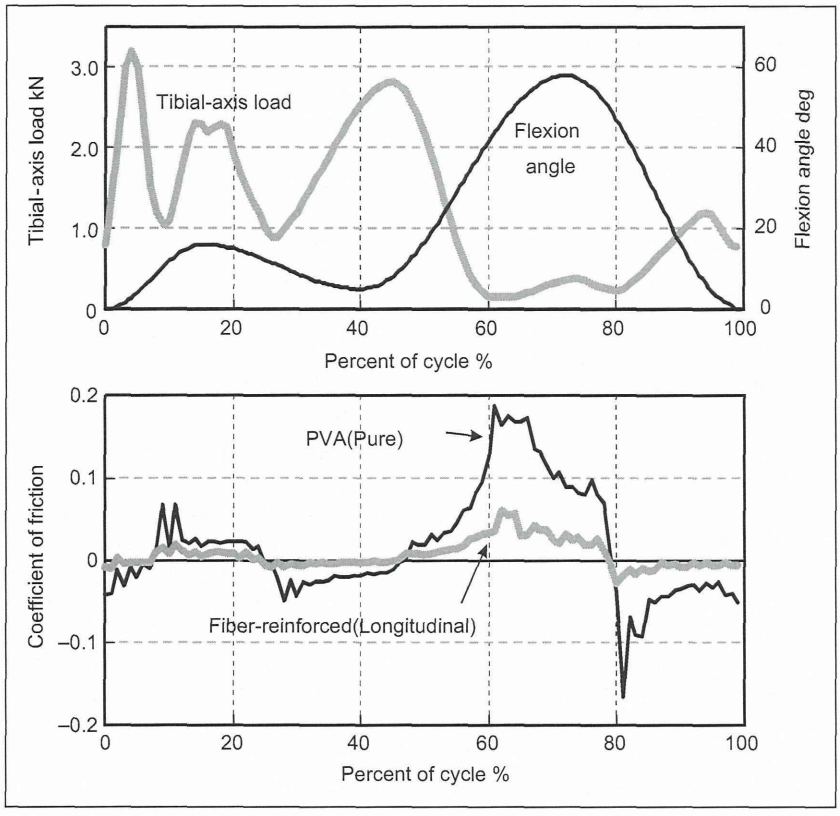

Figure 7. Frictional behaviours of simplified knee prostheses with PVA layer in the simulator. PVA: poly(vinyl alcohol).

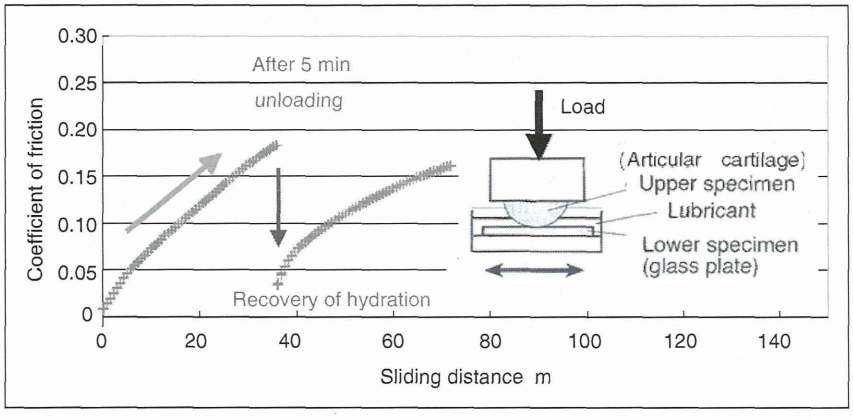

Figure 8. Frictional behaviour in repeated reciprocating test for ellipsoidal articular cartilage specimen against glass plate lubricated with saline.

appropriate lubricants and surface properties as discussed below.

Discussion

Biphasic FE analysis for articular cartilage during reciprocation motions

As shown in biphasic FE analysis (Figures 3 and 5), the high interstitial fluid pressure can be maintained accompanied with low Mises stress in the solid phase during repeated reciprocating motions at sufficiently long stroke of 8 mm under on–off loading to articular cartilage (migrating contact area), which enables the unloaded region in the cartilage to rehydrate. In contrast, after 127 cycles in the reciprocating test under continuous loading to the same region of cartilage, the interstitial fluid pressure was remarkably reduced, and Mises stress substantially increased and the deformation proceeded for larger load support by solid phase, as shown in Figures 4 and 5. For the latter condition under continuous loading, friction gradually increased to a high level (Figure 6). In this FE

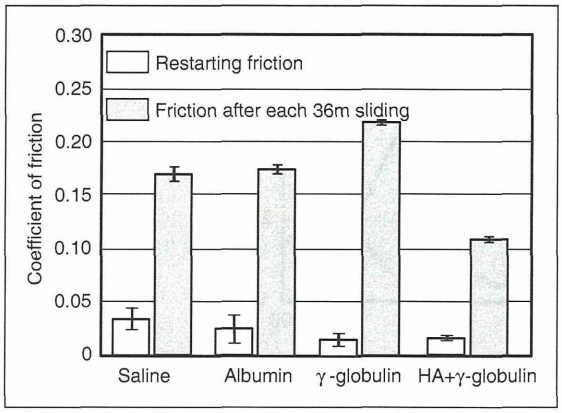

Figure 9. Influence of proteins and HA on changes in friction during repeated reciprocating test for articular cartilage.
HA: hyaluronate.
Error bars indicate standard deviation.

analysis, friction coefficient μ_{eq} for solid-on-solid contact is assumed as 0.2. In healthy synovial joints, the lubricating constituents in the synovial fluid and on uppermost superficial cartilage are likely to maintain μ_{eq} at a lower level than 0.01 and prevent the rising of friction as adsorbed film formation in a fail–safe system in case the interstitial fluid pressurization has subsided.

In repeated reciprocating tests of 36 m sliding with unloading for 5 min for an intact ellipsoidal cartilage specimen against a flat glass plate, time-dependent frictional behaviours were observed, as shown in Figure 8.[24,25] An intact ellipsoidal cartilage with a subchondral layer was carefully prepared from the femoral condyle in a porcine knee joint (6–7 months old), after it was brought with protective joint capsule and synovial fluid to the laboratory from the slaughterhouse. In saline, the gradual increase from an initial low friction was observed as suggested by a curve under continuous loading in Figure 6, but friction at 36 m sliding did not attain the equilibrium state. Furthermore, it is noticed in Figure 8 that the restarting friction immediately after reloading is reduced from the previous high friction before unloading. The level of restarting friction indicates the extent of recovery of biphasic and hydration lubrications after rehydration of the cartilage, and the state of adsorbed film formation appears to control this frictional behaviour. For example, the addition of a single protein such as albumin or γ-globulin improved the restarting friction but did show higher friction than saline at each 36 m sliding, as shown in Figure 9, where the restarting tests were carried out three times.[24,25] In contrast, a combination of HA as a viscous constituent and γ-globulin as a protein exhibited lower friction at restart and at 36 m sliding (Figure 9). This fact suggests the possibility of sustaining of low friction with appropriate lubricant composition even under continuous loading conditions. For example, Nakashima et al.[35] first found the good lubricating performance of this composition of proteins as 1.4 wt% albumin and 0.7% γ-globulin (A/G ratio = 2:1) or 0.7 wt% albumin and 1.4 wt% γ-globulin (A/G ratio = 1:2) in reciprocating tests of PVA hydrogel against itself. The elucidation of effect of lubricant compositions containing proteins, HA, phospholipids and other lubricating constituents on low friction and minimum wear for articular cartilage will be reported in future study.

Improvement of tribological performance of artificial cartilage

To improve the tribological performance of artificial hydrogel cartilage, the approaches of optimization for biphasic properties of hydrogel and lubricating properties of lubricant constituents are required. The effectiveness of fibre-reinforced structure in the PVA hydrogel in a simulator (Figure 7) is one successful example to mimic natural mechanism in articular cartilage. The lowering of friction during high-load stance phase at low sliding speed is a noticeable phenomenon.

Recently, the authors' research group found that the network structure of PVA gels cross-linked by microcrystallites has important roles in time-dependent friction and deformation behaviours in reciprocating tests for two kinds of PVA hydrogel materials prepared by repeated freezing–thawing method and cast-drying method. It is worth noting that the cast-drying PVA hydrogel with uniform microstructure maintains superior low friction even under continuous loading condition.[49]

In the previous studies,[35–38] the effectiveness of optimum layered adsorbed film formation to minimize the wear of PVA hydrogel has already been reported. In this article, HA solution containing 1.4 wt% albumin and 0.7 wt% γ-globulin was used as an optimum lubricant. To evaluate the actual adsorbed film formation, the changes in conformation of proteins[50] should be considered in rubbing conditions. In further study, the mechanism for the optimum adsorbed film formation on PVA hydrogel should be elucidated in comparison with optimum adsorbed films on articular cartilage.

As discussed above, the superior lubrication mechanisms with a high load-carrying ability in natural synovial joints are expected to apply to the appropriate lubricating mechanism and biphasic structure with surface property providing the surface protection in cases of severe loading and little movement in hydrogel materials as artificial cartilage. In development of artificial hydrogel cartilage with superior lubricity, it is considered that the viewpoint of adaptive multimode lubrication becomes important.

The clinical application of PVA hydrogel as artificial cartilage for high-load joints is the final target, but at the present stage, the establishment for appropriate design for not only low friction but also zero wear is required. The conditions for zero wear will be

discussed on the basis of new experiment in future study.

Conclusions

From the viewpoint of adaptive multimode lubrication, the effectiveness of biphasic lubrication in natural synovial joints was examined by biphasic FE analyses under on–off loading and continuous loading to cartilage. The effectiveness of biphasic lubrication under on–off loading (migrating contact area) condition was clearly shown. For thin film condition for articular cartilage under continuous loading, the influence of adsorbed film formation was examined in experimental reciprocating test including restarting test after interruption and unloading, where the importance of rehydration and lubricant composition was indicated. Finally, the effectiveness of fibre reinforcement in PVA hydrogel was shown in the walking simulator test to be related to the biphasic mechanism.

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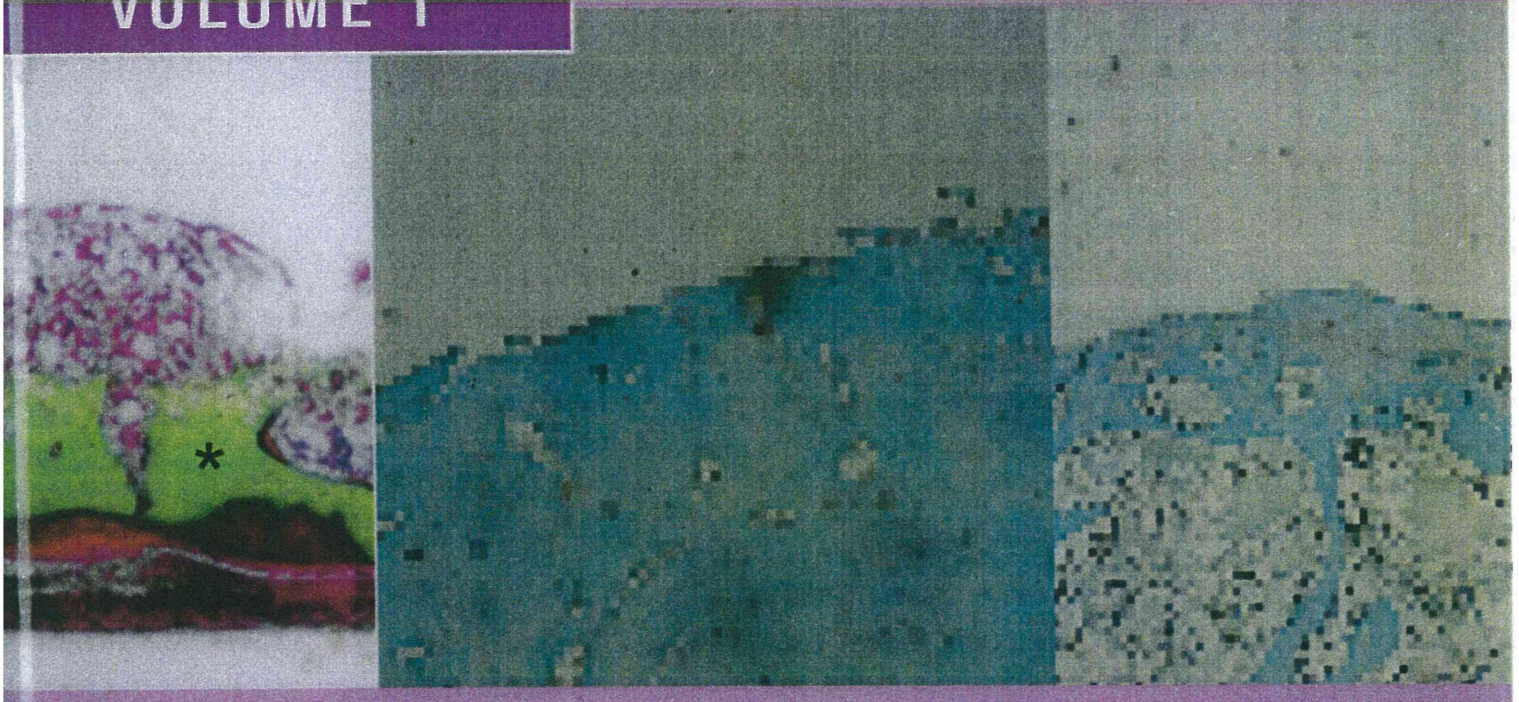

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25 Polymers for Artificial Joints

Masayuki Kyomoto, Toru Moro, and Kazuhiko Ishihara

CONTENTS

25.1 ARTIFICIAL JOINT REPLACEMENT

25.1.1 Hip Joint Replacement and Its Clinical Performance

A normal joint in our body is made up of bones that are lined by surface cartilage. The joint is surrounded by a capsule with a thin lining of synovial cells that produce a thin layer of lubrication film. The lubrication film (synovial fluid) together with the surface cartilage (articular cartilage) acts as a shock absorber and allows the joint to move smoothly; this protective action endures for many years (such as 50–60 years). If the surface cartilage is badly damaged or if the joint surfaces are misaligned (e.g., hip dysplasia), then the cartilage will wear out much quicker than in normal wear and tear, and as a result, the bone under the cartilage layer becomes exposed. The exposed bone starts to rub against the other and the process of osteoarthritis (wear and tear) is established. Osteoarthritis

is, therefore, the result of mechanical wear and tear on a joint. Its main feature is a loss of surface cartilage with bone rubbing on bone and this may include joint pain, tenderness, stiffness, creaking, and locking of joints. This process produces pain and local inflammation. In osteoarthritis, a variety of potential forces—hereditary, developmental, metabolic, and the mechanical—may initiate processes leading to loss of cartilage. As the body struggles to contain ongoing damage, immune and regrowth processes can accelerate damage. Sometimes the body tries to relieve this pain by increasing the amount of fluid in the joint. This is why joints are swollen. The formation of bone spurs and cysts around the joint is another hallmark of osteoarthritis.

The most common type of arthritis leading to total hip replacement is degenerative arthritis (e.g., osteoarthritis) of the hip joint. This type of arthritis is generally seen with aging, trauma, or congenital abnormality (dysplasia) of the hip joint. Other conditions leading to total hip replacement include bone fractures, rheumatoid arthritis, and bone death (aseptic necrosis) of the femoral head. Bone necrosis can be caused by fracture of the hip, alcohol and drugs (such as prednisone and prednisolone), diseases (such as systemic lupus erythematosus), and conditions (such as kidney transplantation).

Total hip arthroplasty (THA) or hemi-arthroplasty is a surgical procedure whereby the diseased cartilage and the bone of the hip joint are surgically replaced with an artificial joint to restore joint movement (Figure 25.1). In general, total hip joint replacement consists of three (cement fixation) or four (cementless fixation) parts as follows:

- A plastic cup and metal shell that replaces the hip socket (acetabulum)
- A metal or ceramic ball that replaces the fractured femoral head
- A femoral metal stem that is attached to the shaft of the bone to add stability to the prosthesis

If a hemi-arthroplasty is performed, either the femoral head or the hip socket (acetabulum) will be replaced with a prosthetic device.

Upon inserting the prosthesis into the central core of the femur, it is fixed with a bone cement of poly(methyl methacrylate). Alternatively, a "cementless" prosthesis is used, which has microscopic

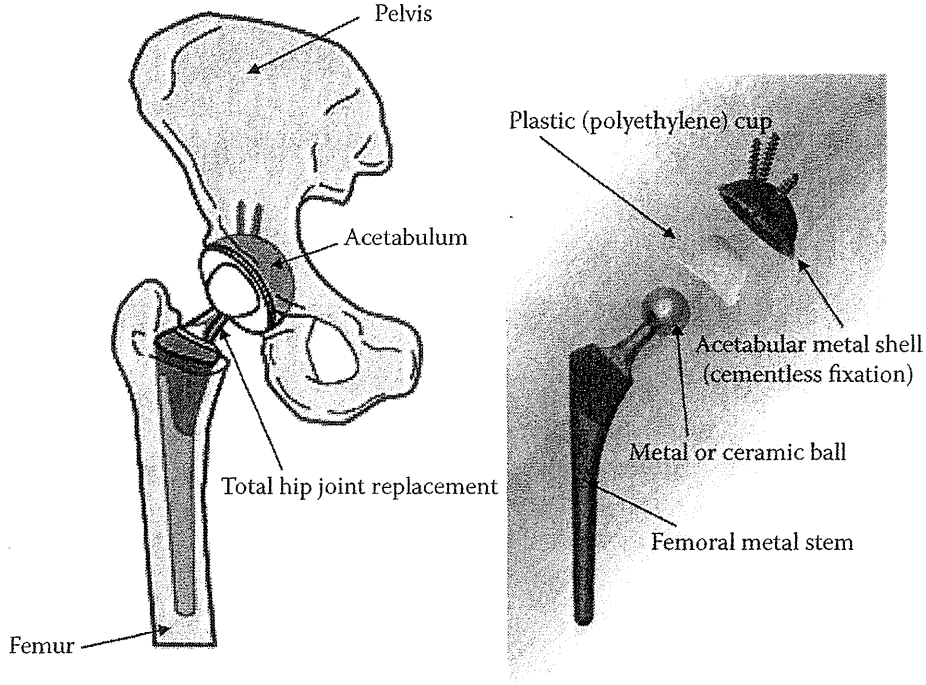

FIGURE 25.1 Schematic model of total hip joint replacement and typical product.

pores that allow bone ingrowth from the normal femur into the prosthesis stem. This "cementless" hip is considered to have a longer duration and will be chosen especially for younger patients.

THA is one of the most successful joint surgeries performed today. The operation relieves pain and stiffness symptoms, and most patients (over 80%) need no help in walking. In well-selected patients who are appropriate candidates for total hip replacements, the effects of the procedure last for at least 10 years in nearly 95% of patients [1,2]. However, with time, many problems have been observed due to the limited long-term fixation of the replacement. Hence, improvements with new devices and techniques are necessary. The future will provide newer devices that will further improve patient outcomes and lessen the potential for complications. Moreover, with improved devices and techniques, the operation could be recommended for younger individuals.

25.1.2 Knee Joint Replacement and Its Clinical Performance

The most common type of arthritis leading to knee replacement is also degenerative arthritis (i.e., osteoarthritis) of the knee joint. For patients with mild arthritis, which is confined to one of the condyles of the knee, the surgeon might decide to perform unicondylar knee arthroplasty (UKA). If the arthritis is more serious and both the condyles of the knee are diseased, the surgeon may perform a bicondylar total knee arthroplasty (TKA) (Figure 25.2). Finally, in the case of extreme circumstances, such as a revision operation or in the event of tumor resection, semi-constrained hinged knee design with metal or ceramic materials might be employed.
TKA includes a prosthesis consisting of three or four parts as follows:

1. A metal or ceramic femoral component
2. A plastic insert or all-plastic tibial component
3. A metal or ceramic tibial tray
4. A plastic patellar component

The plastic ultra high molecular weight polyethylene (UHMWPE) insert or all-plastic tibial component plays a primary role: articulating either against a metallic or ceramic femoral component; in several cases in patellar resurfacing, the UHMWPE may articulate against cartilage.

TKA continues to be a remarkably successful operation for pain relief. Cementless fixation of the artificial knee joint is much less common than cement fixation. Today, TKA yields beneficial and predictable results with a survival rate of over 90% at 10 years after surgery [3].

On the other hand, the number of primary TKA has continuously increased. Although the frequency of revision surgery has not changed, the failure mechanism that necessitates revision TKA appears to be increasingly related to UHMWPE wear and tear along with osteolysis. Rand et al.

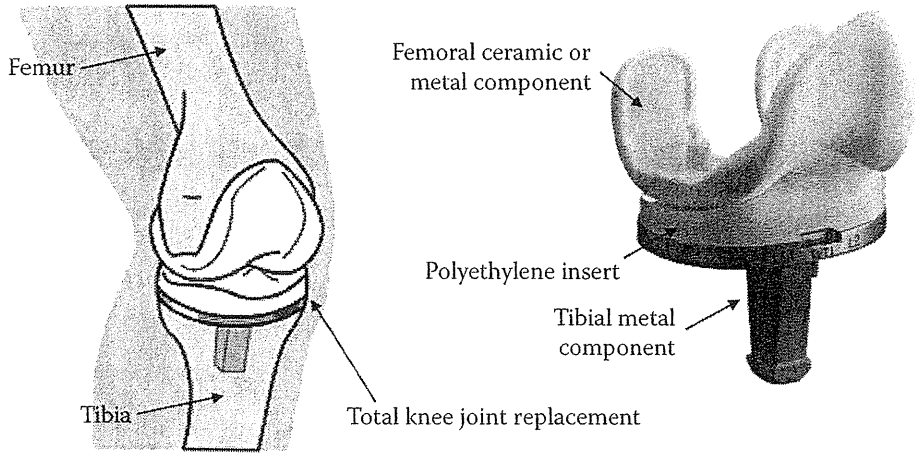

FIGURE 25.2 Schematic model of total knee joint replacement and typical product.

reported that implant loosening was the major mode of failure [4]. Aseptic loosening was the leading reason for revision arthroplasty, followed by osteolysis and polyethylene wear. However, the true wear and tear rate of polyethylene in TKA is not exactly known for a number of reasons as follows: no radiographic methods for measuring it have been established, the complex geometry of knee implants makes this task far more difficult than in THA, and the activity levels of the patient are largely unreported. In clinical outcome studies, the wear and tear of the tibial UHMWPE insert should be correlated with not only the period of clinical use but also the condition and type of use. The orthopedic community has also recognized that oxidative degradation can adversely affect the wear properties of UHMWPE. Oxidative degradation occurs due to prolonged shelf life and clinical use. An oxidatively degraded UHMWPE insert generally shows bad results with failure by wear and tear or osteolysis.

Wear and tear in TKA is far more dependent on alignment and ligament balancing techniques than wear and tear in THA is. The understanding of alterations in knee kinematics in TKA has markedly improved, but the surgical technique for TKA remains largely unchanged. Improvements in surgical technique with experience and teaching should reduce the frequency of component positioning that tends to accelerate wear and tear.

25.1.3 Increase in Hip Joint Arthroplasty Procedures

THA is widely recognized as a successful and effective treatment for degenerative hip joint disease. Worldwide, the number and rate of artificial hip joints used for primary and revised THA are substantially increasing every year. For example, the rate of primary THA per 100,000 persons increased by 46%, and the rates of revision THA increased by 60%, respectively, during 1990–2002 in the United States [1]. The number of primary THA increased from 119,000 in 1990 to 193,000 in 2002. Taking into account the population changes according to the United States Census Bureau, the overall rate of primary THA is 15 procedures per 100,000 persons per decade. On the other hand, in Japan, the number of primary THA and hemi-arthroplasties increased from 15,040 and 27,916 in 1994 to 35,793 and 49,315 in 2006, by 138% and 77%, respectively (Figure 25.3) [5]. Hip joint arthroplasties have important implications for health costs in Japan. For example, if the 85,108 hip joint arthroplasties performed in 2006 were to increase by 1%, the potential increase in cost could be 581 million (≈$5.81 million) based on recent procedural cost estimates of 0.7 million (≈$0.007 million) for each hip joint arthroplasty.

A general trend pointing to an increase in both the number and the rate of revision arthroplasties has also been observed. The number of revision THA increased from approximately 24,000 in 1990 to 43,000 in 2002 in the United States [1]. Further, the mean revision burden for THA was noted to be 17.5% (15.2%–20.5%). Taking into account the population changes according to the U.S. Census Bureau, the overall rate of revision THA was 3.7 procedures per 100,000 persons per decade.

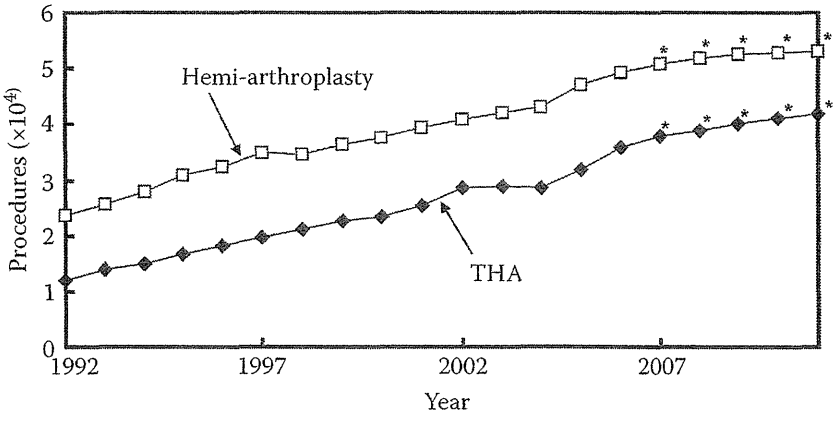

FIGURE 25.3 Procedures of primary THA and hemi-arthroplasty in Japan. *Forecast value.

TABLE 25.1
Revision Burdens for Hip Arthroplasty in Various Countries

Country	Period	Revision Burden (%)	Comments
Australia	1999–2002	18.2	—
Canada	2002–2003	13.1	—
Finland	1980–2001	15.7	—
Finland	1990–2001	18.3	—
Norway	1987–1998	15.0	—
Norway	1994–1998	16.4	—
Sweden	1979–2000	7.7	—
Sweden	1992–2000	11.0	—
Sweden	1992–2000	6.4	≥65 years old
United States	1990–2002	17.5	—
United States	1990–2002	16.9	≥65 years old

With the exception of THA performed in Sweden, the revision burden in the United States compared favorably with that in several countries with established total joint registries (Table 25.1) [1,2]. Overall, the THA revision burden of 17.5% in the United States from 1990 through 2002 fell within the range of revision burdens of 15.0%–18.3% observed in Norway, Finland, and Australia. In Canada, the revision burden for THA was lower (13.1% for 2002–2003). The overall revision burden for THA in the United States was substantially greater than the revision burden reported for Sweden (7%–11%).

25.1.4 Problems of Joint Replacement: Osteolysis

Table 25.2 illustrates the reasons for revision in the 14,081 first revisions for THA performed in the previous study [2]. The majority (75.3%) of the revision surgeries were performed because of aseptic loosening with or without focal osteolysis, 7.6% were performed to treat primary or secondary infection, and 8.8% were performed for technical reasons and dislocation that could have been mainly related to misalignment of the implants. Periprosthetic fractures (5.1%), implant fractures (1.5%), and a number of less prevalent reasons constituted the balance of the reasons.

TABLE 25.2
Reasons for Revision THA

Reason	Number	Share (%)
Aseptic loosening	10610	75.3
Primary deep infection	948	6.7
Dislocation	810	5.8
Fracture only	716	5.1
Technical error	425	3.0
Implant fracture	215	1.5
Secondary infection	128	0.9
Polyethylene wear	126	0.9
Pain	46	0.3
Miscellaneous	56	0.4
Missing	1	<0.1
Total	14081	100

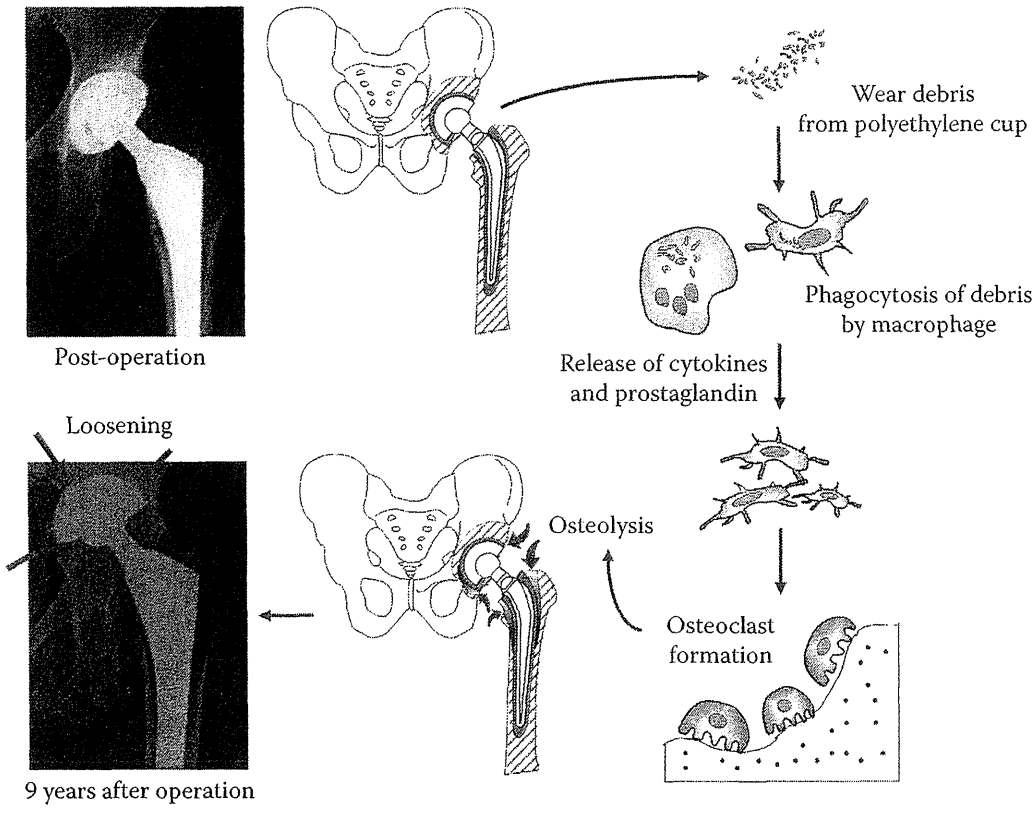

FIGURE 25.4 Schematic model of the mechanisms by which wear debris leads to osteolysis.

As shown in Table 25.2, a consensus statement on total hip joint replacement concluded that the major remaining issues of concern included long-term fixation of the acetabular component, osteolysis due to wear debris, the biological response to debris, and problems related to revision surgery. Although acetabular fixation is no longer a problem, wear and related complications continue to be the major issue affecting the longevity of total hip joint replacements. The bone loss associated with osteolysis can result in pelvic dissociation and instability and major segmental cortical defects in the femur. Young active patients are most at risk for wear and osteolysis.

The precise mechanisms by which wear debris leads to osteolysis will ultimately be determined by defining how specific types of particles combine with environmental factors to permit interactions with specific types of cells that then communicate with each other through the release of soluble mediators (Figure 25.4). Generation of wear debris occurs immediately after implant insertion and ultimately results in a profile of particles that includes all total hip joint replacement materials [6,7]. The extent of bone resorption at the implant–bone interface varies with the severity of the granulomatous tissue response to wear debris and determines the time lapsed before implant loosening occurs. Wear particle-induced macrophage activation plays a role in periprosthetic osteolysis. Essentially, this occurs by two biological mechanisms. First, wear particle-associated macrophages release proinflammatory factors (e.g., cytokines, growth factors, prostaglandins) that enhance the activity of osteoclasts, the cells that carry out bone resorption. Second, osteoclasts are formed from mononuclear precursors that are present in the wear particle-induced macrophage infiltrate. These processes are not mutually exclusive; other stromal and inflammatory cell elements found at the bone–implant interface likely influence both the extent of osteoclast formation and bone resorption.

The contribution of the cells present within the macrophage-rich inflammatory tissue to the induction of bone resorption and implant loosening involves multiple cellular mechanisms. The macrophages are activated by the particles and subsequently release proinflammatory cytokines and other agents that induce bone resorption. Macrophage products capable of inducing

bone resorption include interleukin (IL)-1α, IL-1β, IL-6, tumor necrosis factor (TNF)-α, arachidonic acid metabolites, and degradative enzymes. The existence of multiple factors at one site is likely to accelerate bone destruction. IL-1α, IL-1β, and TNF-α may also induce secondary effects on other cell types (such as osteoblasts) in the interfacial membrane, resulting in the release of matrix-degrading enzymes, including collagenase, stromelysin, gelatinases, and plasminogen activators. Granulocyte/macrophage colony-stimulating factor (GM-CSF) has also been implicated in cellular proliferation in the interfacial membrane around implants. Other cytokines that may exhibit immunomodulatory roles include IL-12, which is increased in the pseudosynovial fluid in patients with aseptic loosening of hip joint replacement. A primary response of macrophages to particulate debris is the increased release of TNF-α. TNF-α release results in part from the exposure of macrophages to particles, which activates the transcription factor NF-κB; this reaction is related to membrane receptor events. Alteration of the bone surface by these proteases may stimulate osteoclast bone-resorbing activity and may influence the recruitment and adhesion of mononuclear phagocyte osteoclast precursors at the bone–implant interface.

A second important mechanism relevant to the role of macrophages in implant loosening is revealed by data demonstrating that wear particle-associated macrophages are capable of differentiating into multinucleated cells that exhibit all the phenotypic features of osteoclasts. Osteoclasts are highly specialized multinucleated cells that are uniquely capable of carrying out lacunar resorption. Osteoclasts are formed by fusion of bone marrow-derived mononuclear precursors that circulate in the monocyte fraction. A number of cellular and humoral factors are known to influence RANKL and osteoprotegerin (OPG) expression. Osteoclast formation in periprosthetic tissues can effectively be viewed as a balance between the productions of these two factors. Various cytokines and growth factors (apart from macrophage CSF) abundant in periprosthetic tissues in aseptic loosening, such as IL-1 and TNF-α, increase the OPG mRNA expression by osteoblasts, suggesting that these factors that stimulate osteoclastic bone-resorbing activity appear to act conversely to downregulate osteoclast formation. Prostaglandins such as PGE2 have also been shown to increase RANKL production and to decrease OPG release, thus stimulating osteoclast formation and bone resorption. Inflammatory cells, such as T-cells, are present in the arthroplasty membrane and may influence osteoclast differentiation and periprosthetic osteolysis by modulating RANKL expression and OPG production. Recent studies have also highlighted the role of certain cytokines (e.g., TNF-α, IL-1β, and IL-1) in inducing osteoclast formation both in the presence and absence of RANKL.

25.2 BEARING MATERIALS FOR JOINT REPLACEMENTS

25.2.1 Polyethylene Bearing Material

Polyethylene is a polymer formed from ethylene (C_2H_4), which is a gas with a molecular weight of 28. The generic chemical formula for polyethylene is $-(C_2H_4)_n-$, where n is the degree of polymerization. For UHMWPE, the molecular chain can consist of as many as 0.2×10^6 ethylene repeat units, i.e., the molecular chain of UHMWPE contains up to 0.4×10^6 carbon atoms.

There are several kinds of polyethylene, which are synthesized with different molecular weights and chain architectures. Low-density polyethylene (LDPE) and linear low-density polyethylene (LLDPE) generally have branched and linear chain architectures, respectively, each with a molecular weight of typically less than 5×10^4 g/mol. High-density polyethylene (HDPE) is a linear polymer with a molecular weight of up to 0.2×10^6 g/mol. In comparison, UHMWPE has a molecular weight of up to 6×10^6 g/mol. In fact, the molecular weight is so ultra-high that it cannot be measured directly by conventional methods and must instead be inferred by its intrinsic viscosity. Table 25.3 summarizes the physical and chemical properties of LDPE, LLDPE, HDPE, and UHMWPE.

TABLE 25.3
Typical Physical and Chemical Properties of LDPE, LLDPE, HDPE, and UHMWPE

Property	LDPE	LLDPE	HDPE	UHMWPE
Molecular weight (10^6 g/mol)	—	—	0.05–0.25	2–6
Melting temperature (°C)	110–115	110–125	130–137	125–138
Poisson's ratio	—	—	0.40	0.46
Specific gravity	0.910–0.930	0.910–0.925	0.952–0.965	0.932–0.945
Tensile modulus of elasticity (GPa)	0.1–0.4	0.1–1.6	0.4–4.0	0.8–1.6
Tensile yield strength (MPa)	7–14	7–42	26–33	21–28
Tensile ultimate strength (MPa)	3–57	8–46	22–31	39–48
Elongation (%)	145–1000	460–1100	10–1200	350–525
Crystallinity (%)	<50	—	60–80	39–75

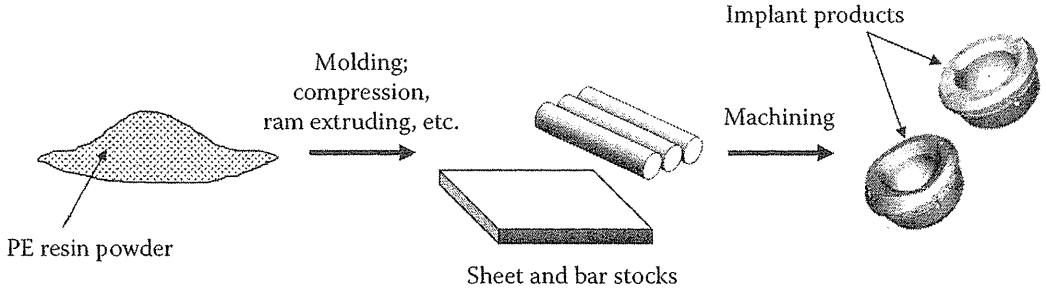

FIGURE 25.5 Typical processing steps in the manufacture of UHMWPE implants.

Three industrial steps are needed to manufacture orthopedic implants. First, UHMWPE must be polymerized from ethylene gas. Second, the polymerized UHMWPE, in the form of resin powder, needs to be consolidated into a sheet (i.e., compression molding), rod (i.e., ram extrusion), or near-net shaped implant (i.e., direct compression molding). Finally, in most instances, the UHMWPE implant needs to be machined into its final shape (Figure 25.5).

Since the 1950s, UHMWPE powders have been produced by Ruhrchemie (currently known as Ticona GmbH, Oberhausen, Germany) using the Ziegler process. The main ingredients for processing UHMWPE are reactive ethylene gas, hydrogen, and titanium tetrachloride catalyst. The polymerization takes place in a solvent used for mass and heat transfer. The requirements for medical-grade UHMWPE powder are specified in the American Society for Testing and Materials (ASTM) standard F648 and the International Organization for Standardization (ISO) standard 5834-1 [8,9].

Historically, the UHMWPE powder has been converted by compression molding since the 1950s, because the industries in the area around Ruhrchemie already were experienced in this processing technique. Today, compression-molded sheets of the UHMWPE are produced commercially by two companies (Orthoplastics, Ltd., Lancashire, United Kingdom, and Meditech Poly Hi Solidur, Ltd., Fort Wayne, IN). One UHMWPE sheet is pressed between the upper and middle plates, and the second is produced between the middle and lower plates. The plates are oil heated and hydraulically actuated from below. The heating and loading systems are all computer controlled. Finally, the entire press is contained in a clean room, to reduce the contamination of extraneous matter into the sheet. In contrast, ram extrusion of UHMWPE was developed by converters in the United States during the 1970s. Today, only few converters supply medical-grade ram extrusion UHMWPE to the orthopedic industry. Medical-grade extrusion facilities are owned by Orthoplastics, Ltd., Meditech Poly Hi Solidur, Ltd., and Westlake Plastics Co. Ltd. (Lenni, PA). The process is as follows. UHMWPE powder is fed continuously into an extruder. The extruder itself consists essentially of a hopper that

allows powder to enter a heated receiving chamber, a horizontal reciprocating ram, a heated die, and an outlet. Within the extruder, the UHMWPE is maintained under pressure by the ram as well as by the backpressure of the molten UHMWPE. The backpressure is caused by frictional forces of the molten resin against the heated die wall surface as it is forced horizontally though the outlet. Beyond the outlet, the UHMWPE rod is slowly cooled in a series of electric heating mantles.

25.2.1.1 History of Polyethylene in the Orthopedic Field

The load-bearing articulating surface materials used in total joint arthroplasty comprise metallic alloys, ceramics, and polymers. The articulating couples of primary concern—those that generate considerable amounts of wear leading to osteolysis—include UHMWPE cups and inserts. Accordingly, in the past several decades, most research and development have been focused on improving the wear resistance of UHMWPE (Table 25.4).

Introduced clinically in November 1962 by Charnley, UHMWPE articulating against a metallic femoral ball remains the gold standard bearing surface combination in total hip joint replacement [11]. Considering how rapidly technology can change in the field of orthopedics, the long-term role that UHMWPE has played in hip joint replacement since the 1960s is fairly remarkable.

In the 1970s, the properties of UHMWPE were modified by including carbon fibers within the matrix of polyethylene, thereby creating a carbon fiber-reinforced UHMWPE, known as Poly II (Zimmer, Inc., Warsaw, IN) [13]. However, this UHMWPE composite was not found to exhibit consistent and improved clinical results relative to the conventional UHMWPE introduced by Charnley. The material was designed with orthopedic bearing applications in mind, under the assumption that increasing the modulus and ultimate tensile strength of the bearing as well as decreasing its creep properties would increase its longevity. This assumption was reasonable, since bearing surfaces are subject to high contact stresses, conditions under which conventional UHMWPE had often been observed to be pitted or delaminated. The inclusion of short chopped carbon fibers in a UHMWPE matrix resulted in a composite material with improved mechanical properties in vitro. Thus, the expectation was that Poly II would be more resistant to the pitting and delamination often seen in

TABLE 25.4
History of UHMWPE Development for Joint Replacement

Year	Comments
1958	Clinical use of polytetrafluoroethylene as bearing material of implants in hip arthroplasty by Charnley et al. [10]
1962	Charnley et al. adopts UHMWPE for use in hip arthroplasty [11]
1969	UHMWPE was gamma-ray sterilized in air with a minimum dose of 25 kGy [12]
1970	Commercial release of the Poly II-carbon fiber-reinforced UHMWPE for hip arthroplasty by Zimmer, Inc. [13]
1971	Clinical introduction of the 100 Mrad PE—extremely highly CLPE by more than 1000 kGy of gamma-ray irradiation in air by Oonishi et al. [16]
1982	Commercial release of alumina ceramic balls articulating against UHMWPE by Kyocera, Corp. [19]
1986	Clinical introduction of silane cross-linked HDPE by Wroblewski et al. [20]
1991	Commercial release of the Hylamer—highly crystalline UHMWPE for hip arthroplasty by DePuy Orthopedics, Inc. [21]
1997	Commercial release of highly CLPE with an energy-ray irradiation of 50–105 kGy by several orthopedic product manufacturers [13,24]
2006	Clinical use of the vitamin E-blended UHMWPE in knee arthroplasty produced by Nakashima Medical, Co. Ltd., as a trial [44]
2007	Clinical use of the PMPC-grafted CLPE in hip arthroplasty produced by Japan Medical Materials Corp. as a trial [42]

joint replacements. Further, wear testing of Poly II conducted by the manufacturer revealed it to have lower wear than conventional UHMWPE, suggesting that the strength benefits would result in longer lasting hip arthroplasties. However, unfortunately, the promise shown by Poly II in vitro was not borne out in the clinical setting, and within a short time after implantation, many patients presented with osteolysis and complete mechanical failure of their bearing surfaces [14]. One possible explanation for the mechanical failure was that the poor crack propagation resistance of Poly II was due to the carbon fibers not bonding with the UHMWPE matrix, instead serving as stress concentrators and crack nucleation sites [15].

In Japan, during the 1970s, an important technological advancement occurred: the clinical introduction of an extremely highly cross-linked polyethylene (CLPE) with more than 1000 kGy of gamma-ray irradiation in air by Oonishi et al., the so-called 100 Mrad PE [16,17]. A similar advancement in extremely highly CLPE also occurred in South Africa during the 1970s, where researchers in Pretoria clinically introduced a UHMWPE that was gamma-ray irradiated with up to 700 kGy in the presence of acetylene [18]. During the 1980s, two other noteworthy developments occurred relative to polyethylene in joint replacements. Chas F. Thackray-DePuy International Ltd. (Leeds, United Kingdom) began the development of an injection-molded HDPE that could be cross-linked by silane coupling. Only 22 of these implants were produced and implanted by Wroblewski et al. starting in 1986 [20]. After an initial wear period (initial bedding-in period), these cross-linked HDPE components have been found to exhibit very low clinical wear rates.

In 1991, a highly crystalline UHMWPE known as Hylamer was patented by Li et al. from E. I. Du Pont de Nemours and Company (Wilmington, DE) and marketed by the DePuy-DuPont Orthopedics joint venture (Newark, DE) [21]. Hylamer is a hot isostatically pressed UHMWPE, leading to the formation of an extended-chain crystallite morphology with thick (200–500 nm) lamellae and higher crystallinity (65%–71%) [13]. In contrast, conventional low-pressure sintered UHMWPE displays a folded-chain crystalline morphology with much thinner lamellae (10–50 nm in thickness) and a crystallinity of 50%–55%. By varying the postconversion heating, pressure, and cooling sequence, a family of materials was developed with varying crystalline morphologies and sizes. Hylamer has a higher density and crystallinity than conventional UHMWPE. Although the yield and ultimate strength of Hylamer are slightly higher, the most noticeable change occurs in the elastic modulus, which is nearly double for Hylamer as compared to conventional UHMWPE. The clinical results for the highly crystalline UHMWPE, which were clarified in the 1990s, have been mixed and are therefore controversial. Although several studies reported worse clinical performance using the Hylamer compared with conventional UHMWPE, other studies reported several satisfactory or even improved performances [13].

25.2.1.2 Cross-Linked Polyethylene

High-energy ray irradiation cross-linking and thermal treatment of UHMWPE has aroused intense scientific and commercial interest within the orthopedic field since the late 1990s (Figure 25.6). For decades, the cross-linking of polyethylene has been known to improve the abrasion resistance of the polymer for industrial applications. However, only a few applications of this technology have been reported in orthopedics literature [13,22,23]. All high-energy ray irradiation, including the standard 25- to 40-kGy dose of gamma-ray irradiation used for sterilization, leads to the formation of free radicals in polymeric materials through homolytic chain cleavage. In UHMWPE, some of these free radicals recombine with each other to form cross-links or trans-vinylene bonds, while others remain as highly reactive species in the structure for extended periods of time. Although the gel content of UHMWPE may be increased to 80% by an average gamma-ray radiation dose of 25 kGy, the polymer becomes highly cross-linked (corresponding to a gel content of 90%–100%) after an absorbed dose of 50 kGy [13,24]. Despite the plateau in gel content, the cross-linking density in UHMWPE did not reach an asymptotic value until a dose of 100–150 kGy had been absorbed. Therefore, several CLPEs, irradiated with 50–105 kGy, have been launched since 1998 and used extensively.

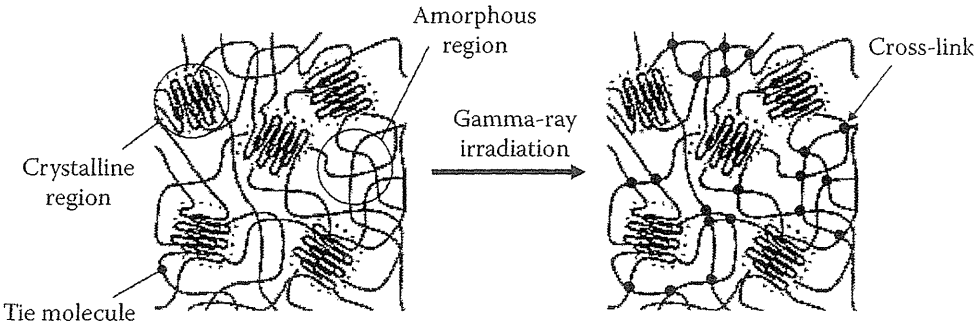

FIGURE 25.6 Schematic illustration of cross-linking induced by gamma-ray irradiation.

TABLE 25.5
Wear Reductions in Early- and Mid-Term Clinical Studies of CLPE Cups Compared with Conventional UHMWPE Cups

Manufacturing Process for CLPE	Mean Follow-Up Period (Years)	Wear Reduction (%)	Reference
Cold-irradiated and annealed	2.0	85	[27]
	2.3	42	[28]
	2.3	94	[23]
	4.0	58	[29]
	4.9	60	[30]
Cold-irradiated and remelted	2.8	72	[31]
	3.2	45	[32]
	5.3	73	[24]
	5.5	95	[33]
Warm-irradiated and remelted	2.0	54	[34]
	2.6	94	[35]
	2.9	44	[36]
	3.0	23	[37]
	3.8	83	[38]
	5.0	55	[39]

In several independent reviews of the literature, it was found that osteolysis is rare in patients in whom the UHMWPE cup is wearing at a rate of less than about 0.1 mm/year, but osteolysis becomes much more frequent and extensive as the wear rate increases substantially above this "threshold" value [25,26]. In several studies with a mean duration of follow-up of ~5 years or longer, the mean rates of wear of CLPE cups (Table 25.5) were all well below 0.1 mm/year [23,24,27–39].

On the other hand, the osteolysis threshold of 0.1 mm/year was established for hip joints with conventional UHMWPE cups—i.e., those that either were not cross-linked or were moderately cross-linked during gamma-ray sterilization. Some investigators have reported that the mean particle size is smaller with CLPE and that, in equivalent volumes, smaller particles tend to be more likely to cause osteolysis [40]. If that is correct, these factors could lead to the osteolysis threshold being somewhat lower for CLPE. We are aware of only one published case report of clinically relevant osteolysis in a hip with a CLPE cup [41]. However, the hip in question also had a forged-steel surface-grit-blasted femoral component that, at revision, was found to be loose at the stem–cement interface. Because the osteolysis in this hip joint occurred endosteally around the loosened stem, with no acetabular osteolysis, it is highly possible that the lesions were primarily due to debris produced at the stem–cement interface rather than from the CLPE cups. Continued close monitoring

of patients with CLPE cups is essential to determine if the improved wear resistance that has been observed in the mid-term, as summarized here, will translate into a substantial reduction in the prevalence and severity of osteolysis at long-term follow-up.

25.2.1.3 Antioxidants for Polyethylene

Recently, there has been an explosion of interest in the research and development of vitamin E as an antioxidant for UHMWPE in the orthopedic field. The primary role of vitamin E (α-tocopherol) is to stabilize the active free radicals resulting from oxidation. The antioxidant activity of vitamin E is due to hydrogen abstraction from the –OH group on the chroman ring by a peroxy free radical, which can combine with another free radical (Figure 25.7). In a gamma-ray irradiated UHMWPE with vitamin E, peroxy free radicals abstract a hydrogen from vitamin E, forming hydroperoxides. The oxidative degradation cascade in the gamma-ray irradiated UHMWPE is hindered in the presence of vitamin E.

The idea of vitamin E-blended UHMWPE is popular in the industrial field: the first widespread applications of the vitamin E-blending technology actually appeared in food packaging since the 1980s. In the orthopedic field, Tomita et al. demonstrated the use of vitamin E-blended UHMWPE in order to prevent delamination by reducing crack formation at the grain boundaries of UHMWPE in 1998 [43]. Then, they demonstrated that the vitamin E-blended UHMWPE with gamma-ray sterilization exhibited a higher resistance to oxidation and fatigue wear compared with conventional UHMWPE. In light of its acceptance as an effective antioxidant, the vitamin E-blended UHMWPE

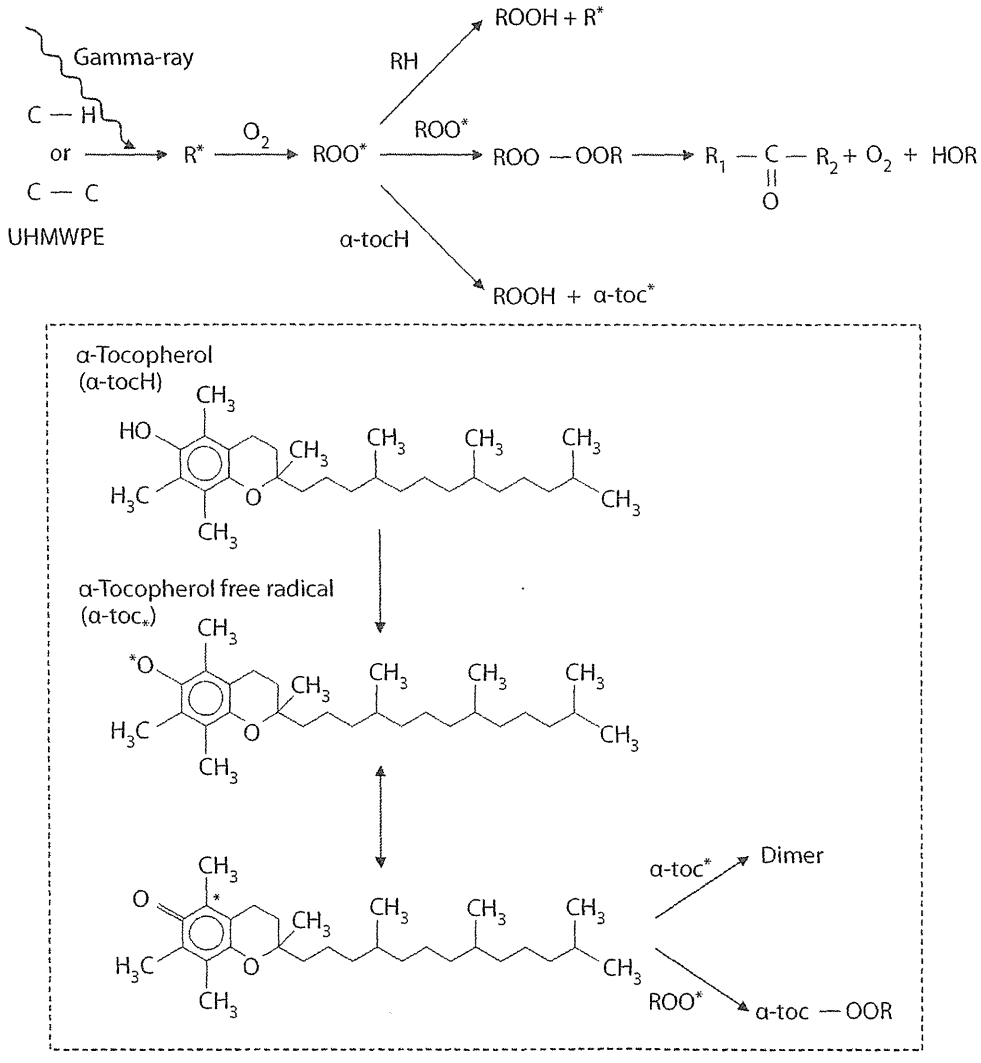

FIGURE 25.7 Schematic illustration of reaction of vitamin E (α-tocopherol).

insert in TKR was produced by Nakashima Medical Co. Ltd. (Okayama, Japan) and is being used in a clinical trial in Japan since 2006 [44]. Although this trial has taken place, the clinical results have not been published yet.

Subsequently, many orthopedic manufacturers have developed CLPE with vitamin E for joint replacements. However, several new problems have arisen, in particular for the procedures of introduction of vitamin E into the polyethylene as follows: (1) blending during compression molding or extrusion before the cross-linking and (2) diffusion after the cross-linking and machining [45]. The disadvantages of the former are that the cross-link density is suppressed to a low value during the cross-linking procedure with (e.g., gamma-ray) irradiation (Figure 25.8). On the other hand, those of the latter are that it is difficult to control the concentration and distribution of diffused vitamin E.

In both the cases, the hypothesized advantage of the vitamin E-blended/diffused CLPE is that the vitamin E protects the CLPE against oxidative degradation (Figure 25.9).

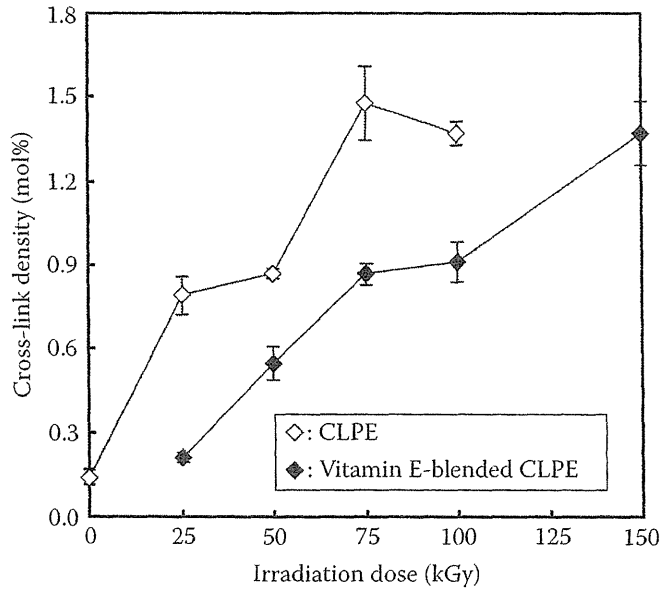

FIGURE 25.8 Cross-link density of vitamin E-blended CLPE as a function of the gamma-ray irradiation. Bar: Standard deviations.

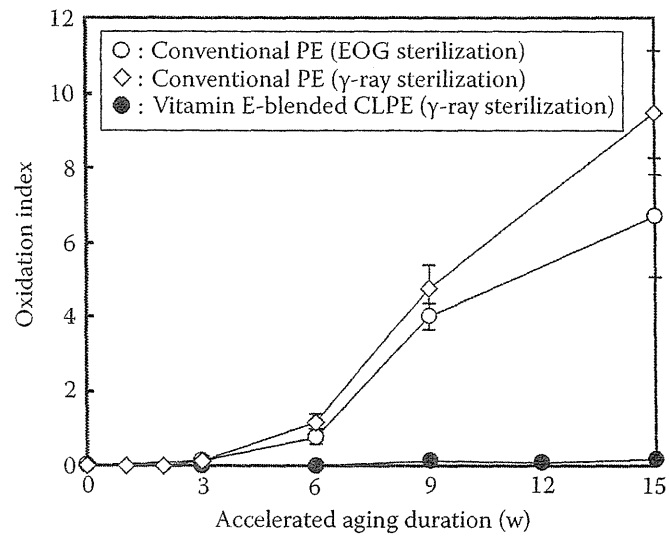

FIGURE 25.9 Oxidative degradation (oxidation index) of vitamin E-blended CLPE as a function of the accelerated aging duration in air at 80°C. Bar: Standard deviations.

25.2.2 Phospholipid Polymers for Mimicking Articular Cartilage

25.2.2.1 Hydration Lubrication

Water attracted by hydrophilic macromolecules in the surface layer plays an important role in lubrication. As macromolecules are flexible, they cannot support a load by themselves. The water in the surface layer would support most of the load because the water is attracted by the macromolecules. Frictional forces arise due to the adhesion of macromolecules to the counter surface. The time-dependent properties of friction forces can be interpreted as follows (Figure 25.10) [46]. Under a load, water exudes slowly from the surface layer with or without sliding. As the result of water loss, the thickness of the surface layer reduces and the water content of the surface layer decreases. Consequently, the degree of adhesion to the opposite bearing surface increases and the frictional force also increases. Therefore, it may be concluded that friction depends essentially on the water content of the surface layer. This hydration would lead to low friction and wear, by acting as "hydration lubrication."

25.2.2.2 Articular Cartilage and Material Design

Although the lubrication mechanism of human joints has been studied since the 1930s, it has not yet been understood clearly. However, it is well known that the composition elements of the articular cartilage surface consist of the collagen network, hyaluronic acid, and proteoglycan subunits. The proteoglycan subunits form a gel-like surface layer due to hydration along with the joint synovia. Although the binding between the proteoglycan subunits and hyaluronic acid can be visible [47], the binding between hyaluronic acid and the collagen network has not yet been confirmed. It was reported by Obara et al. [48] that the friction coefficient of joints increases when the gelled material on the cartilage surface is removed by gauze. After this, the joint surface is lubricated only by joint synovia or hyaluronic acid, i.e., following the loss of the gel comprising proteoglycan subunits, the friction coefficient of the joint cannot be lowered again. This fact indicates that the proteoglycan aggregates are not combined with the collagen network by physical adsorption and that the hydrophilic macromolecules on the joint surface play an important role in keeping the friction at low levels. A previous study reported that the hydrophilic macromolecules of the cartilage surface are assumed to have a brush-like structure: a part of the proteoglycan aggregate brush is bonded with the collagen network on the cartilage surface (Figure 25.11) [49]. The rest of the proteoglycan aggregate floats freely in joint synovia.

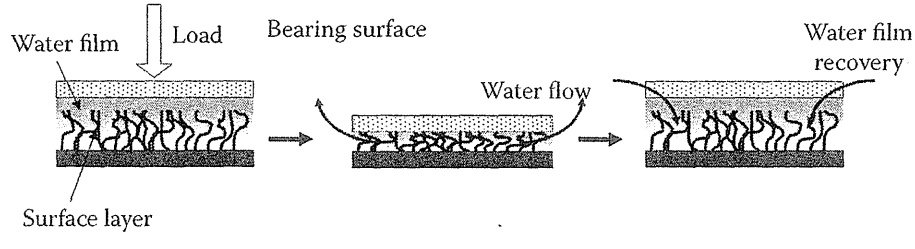

FIGURE 25.10 Schematic model of hydration lubrication.

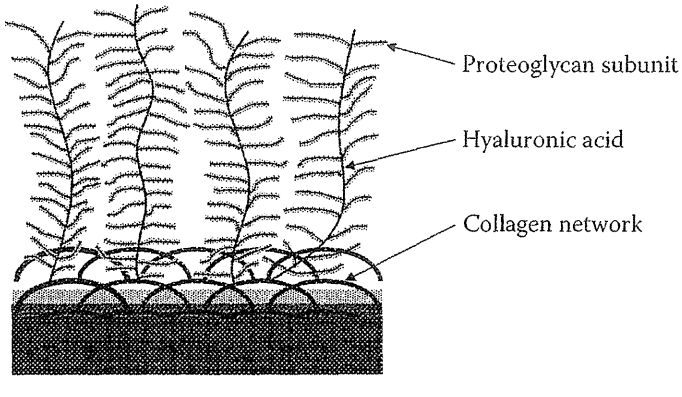

FIGURE 25.11 Schematic model of the brush-like structure of the cartilage surface.