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Properties of crosslinked ultra-high-molecular-weight polyethylene

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Abstract

Substantially reducing the rate of generation of wear particles at the surfaces of ultra-high-molecular-weight polyethylene (UHMWPE) orthopedic implant bearing components, in vivo, is widely regarded as one of the most formidable challenges in modern arthroplasty. In the light of this, much research attention has been paid to the myriad of endogenous and exogenous factors that have been postulated to affect this wear rate, one such factor being the polymer itself. In recent years, there has been a resurgence of interest in crosslinking the polymer as a way of improving its properties that are considered relevant to its use for fabricating bearing components. Such properties include wear resistance, fatigue life, and fatigue crack propagation rate. Although a large volume of literature exists on the topic on the impact of crosslinking on the properties of UHMWPE, no critical appraisal of this literature has been published. This is one of the goals of the present article, which emphasizes three aspects. The first is the trade-off between improvement in wear resistance and depreciation in other mechanical and physical properties. The second aspect is the presentation of a method of estimating the optimal value of a crosslinking process variable (such as dose in radiation-induced crosslinking) that takes into account this trade-off. The third aspect is the description of a collection of under- and unexplored research areas in the field of crosslinked UHMWPE, such as the role of starting resin on the properties of the crosslinked polymer, and the in vitro evaluation of the wear rate of crosslinked tibial inserts and other bearing components that, in vivo, are subjected to nearly unidirectional motion.

Keywords: Ultra-high-molecular-weight polyethylene; Crosslinking; Wear

1. Introduction

Over the years, ultra-high-molecular-weight polyethylene (UHMWPE) has emerged as the material of choice for fabricating one of the bearing components in various arthroplasties, such as acetabular cups, tibial inserts, and glenoid sections [1]. For the most part, these components have performed admirably in vivo. The only major concern is wear and the effect of the wear particles on the in vivo longevity of the prosthesis [1]. A consensus has emerged that this effect takes the form of a macrophegic activation secondary to the phagocytosis of these particles [2]. For example, in hip implants, there is a general understanding that particulate debris generated by the wear of the UHMWPE acetabular cup or cup liner triggers osteoclast-mediated resorption of periprosthetic bone, culminating in loosening and, ultimately, revision of the prosthesis [2,3]. Loosening is the major failure mode and, hence, life-limiting factor in these arthroplasties. The significant impact of UHMWPE bearing component wear on the in vivo longevity of these implants may be garnered from a recent report by Sochart [3] on 235 Charnley low-friction hip joint replacements in a young population (mean patient age = 31.7 yr; range = 17–39 yr) [3]. The author pointed out: 'Twenty-year survivorship exceeded 90% for arthroplasties with a wear rate less than 0.1 mm per year, but the 20-year survivorship of acetabular components with a rate greater than 0.2 mm per year was below 30%, and none survived 25 years..... For every additional millimeter of wear observed, the risk of component revision or failure in any one year increased significantly ($p < 0.019$)' [3].

Given these observations, vast resources over the years have been invested in studying the UHMWPE wear phenomenon and developing strategies for reducing the in vivo wear of UHMWPE bearing components; specifically, acetabular cups, acetabular cup liners, and tibial inserts. As for the phenomenology, it has been postulated that the in vivo wear rate of an UHMWPE bearing component is affected by a large number of endogenous and exogenous variables [4–41]. Some of these variables,

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Table 1
Summary of some aspects of six categories of approaches for improvement of performance of UHMWPE components

Category	Salient feature of approach	Example of commercial product	In vivo performance of product	Reference
1	Variant of one of the six currently popular UHMWPE grades,[a] in terms of composition	PolyTwo,™,[b] which is a carbon fiber-reinforced UHMWPE	Poor	Wright et al. [44]
2	Variant of methods used to process the currently popular grades	(a) Hylamer®,[c] and Hylamer-M,™,[c] in which GUR 1150 resin is subjected to a proprietary crystallization process that converts the crystalline regions of the polymer from a short-folded-chain to a long-extended-chain crystalline morphology	Poor	Livingston et al. [30] Reis et al. [45]
		(b) A 'commercially available' UHMWPE was γ irradiated (typical dose: 1–3 Mrad) in vacuum at room temperature and then compressed between two metal platens at, typically, 180–208°C and then crystallized by cooling to room temperature over, typically, 10 h.	—[d]	Oka et al. [46]
3	Variant of methods used to sterilize products fabricated using currently popular UHMWPE grades	Duramer™,[e], which is made using GUR 1050 resin, and sterilized using ethylene oxide gas		Technical Bulletin [47]
4	Variant of packaging and post-sterilization conditions used with currently popular UHMWPE grades and γ irradiation	Duration™,[f] Stabilized, in which a GUR 1150 component is placed in an inert gas (N_2) medium within an O_2-free package, γ irradiated (typical dose: 2.5 Mrad), and then subjected to a proprietary post-irradiation stabilization process	—[g]	Technical Bulletin [48]
5	Various elements of approaches described in Categories #1–4 are combined	ArCom™,[h] in which the polymer component is compression molded in Ar; the resin contains no processing aids, such as calcium stearate	Good	Knutson et al. [49]
6	Extensive crosslinking of the polymer	—[i]	Good	Wroblewski et al. [43] Oonishi et al. [50–52] Grobbelaar [53] Oonishi et al. [54]

[a] These are: GUR 1020, GUR 1050, GUR 1120, and GUR 1150 (Ticona, Bayport, TX, USA); and 1900 and 1900H (Montell Polyolefins, Wilmington, DE, USA.
[b] Zimmer, Inc., Warsaw, IN, USA.
[c] DePuy, Inc., Warsaw, IN, USA.
[d] No reports of in vivo performance of the products have been reported, but Oka et al. [46] reported their low in vitro wear rates.
[e] Wright Medical Technology, Inc., Arlington, TN, USA.
[f] Stryker Howmedica, Osteonics, Inc., Rutherford, NJ, USA.
[g] No information on this aspect was given in the report [48].
[h] Biomet, Inc., Warsaw, IN, USA.
[i] No commercial products were identified in the literature reports [43,50–54].

such as counterface material [4–6], sterilization method [8,9], and type of crosslinking method [10–12], have been the subject of in vitro studies. Others, such as femoral head diameter [23–25], UHMWPE quality/resin grade [30,37,38], and patient age [25,41], have been the subject of clinical studies. Most of the variables, however, have not been investigated at all [42]. Furthermore, only a few reports have been published regarding a correlation between in vitro and in vivo wear rate results [43]. In terms of improvements of UHMWPE component performance, six main categories of approaches have been taken (Table 1).

Crosslinking of implant bearing components is not new, acetabular cups made of crosslinked UHMWPE having been first used clinically in 1971 [50]. However, interest in crosslinking has been rising in recent years, mainly, it is suggested, because of the favorable results of the three recent clinical studies [43,53,54]. With this interest, there has been an attendant burgeoning of the literature as far as UHMWPE is concerned. There are two key characteristics of this literature. First, it is dominated by in vitro studies of the wear of UHMWPE specimens and components that were crosslinked using a wide variety of methods, stabilized using a wide assortment

of conditions, and then sterilized using different methods. Second, only a few studies have been published on other mechanical and physical properties of crosslinked polymers, such as fatigue, fatigue crack propagation, and fracture toughness. The indications from these reports are that these fracture properties are degraded by crosslinking. These two features of the literature mean that, at the moment, there is lack of clarity regarding the following aspects: the best crosslinking process; the optimal values of the variables of that process; the best post-crosslinking stabilization and sterilization methods; and the optimal values of the variables of those methods. It is thus appropriate at this time to critically review the literature. The present work seeks to do this, with the focus being the crosslinking process.

The present article thus has three main objectives. First, to summarize and critically review trends in literature reports on the wear rate and other properties of crosslinked UHMWPE. Second, to present a methodology for estimating the optimal level of a crosslinking process variable. Third, to identify under- and unexplored areas that should be the subject of future research work in the field of crosslinked UHMWPE.

The article is organized along the following lines. The rationale for crosslinking, the principles of the three classes of crosslinking methods, and the details of these methods, as are given in literature studies and some recent patent applications, are the subject of Section 2. In Section 3, a compendium of literature results on the effect of crosslinking process variables on the wear rate and a plethora of other physical, thermal, and mechanical properties relevant to the use of a polymer for fabricating implant bearing components (for example, crosslink density, percentage crystallinity, and fatigue resistance), as obtained in vitro tests, is presented. Some salient features of literature clinical studies involving crosslinked UHMWPE acetabular cups are also covered in Section 3. A methodology for estimating the optimal level of a crosslinking process variable is presented in Section 4. The impetus for such estimation is the expectation that any improvement in a property of the polymer brought about by crosslinking (notably, decrease in wear rate) is likely to be accompanied by a depreciation of some other key material properties. Thus, for a specified crosslinking process variable, there is likely to exist an optimal level. Some details of currently commercially available crosslinked UHMWPEs are provided in Section 5. Areas for future research are discussed in Section 6, and the article ends (Section 7) with a summary of the main points and a recommendation.

2. Principles of crosslinking

Three classes of methods have been used in crosslinking polymers. One involves ionizing radiation ('radiation-induced crosslinking'). A second utilizes a suitable free-radical-generating chemical, FRGC ('chemical-induced crosslinking'). The third involves grafting a suitable silane compound onto the polymer ('silane compound-induced crosslinking').

2.1. Principles of radiation-induced crosslinking

When exposed to ionizing radiation, two structural changes occur in a polymer; for example, UHMWPE (Fig. 1). The first is chain scission (C–C breakage) of the 'taut' tie molecules (Fig. 1(a)). The second is the reaction of the free radicals (produced by the breakage of the C–H bonds) with each other to form crosslinks between adjacent molecule chains (Fig. 1(b)).

At the radiation dose that is usually employed in sterilizing UHMWPE implant bearing components (namely 2–4 Mrad), the first-mentioned structural change predominates; in other words, there is very little crosslinking although several free radicals are created. For UHMWPE, reduced crosslinking is attributed to the fact that carbon atoms in adjacent chains are too far apart (0.41 nm) to permit primary bonds between adjacent chains, and the lattice is too rigid at room temperature to form typical interchain C–C bonds (0.154 nm) [55]. The free radicals that are created remain trapped in the material, at a location that is a matter of debate. For UHMWPE, the core of the crystals, the surface of the surface, lamellae at the fold surfaces, and the interfacial zone have all been postulated to be this location [56].

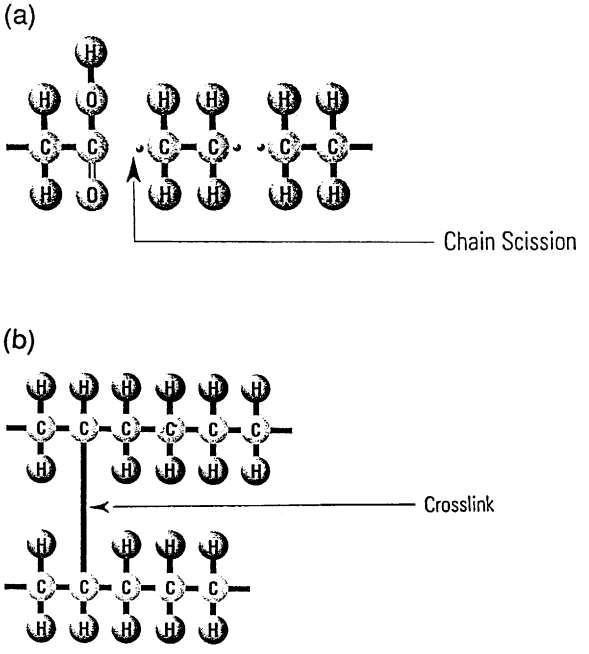

Fig. 1. (a) Chain scission in UHMWPE; (b) The crosslinking reaction, or formation of C–C covalent bonds between adjacent molecular chains in UHMWPE.

However, irrespective of where the free radicals are trapped, they are long-lived, and this means that they are available to diffuse into or be dissolved in the material during shelf storage and then interact with any available oxygen species (in the storage room atmosphere and/or in vivo [57]). This diffusion is controlled by the permeability characteristics of the polymer [57]. It is known that this oxidized material has poor properties.

At high to very high radiation doses (5–1000 Mrad), the free radicals that are created recombine to form crosslinks (Fig. 1(b)).

Radiation-induced crosslinking has two drawbacks. First, when carried out in the solid state, a highly inhomogeneous polymer network results. This is because, during this process, the crosslinks are formed essentially in the amorphous regions in the polymer. Second, the crosslinking process is not 100% efficient; thus, free radicals may still exist in the polymer after the radiation treatment. Subjecting the radiated polymer to a suitable post-irradiation-induced crosslinking process eliminates these radicals.

2.2. Principles of chemical-induced crosslinking

Essentially, this process involves mixing a free-radical-generating chemical, FRGC, with the resin powder and then consolidating the mixture. The FRGC decomposes at elevated temperature, producing free radicals that abstract the hydrogen atoms in the polymer molecules. This process leaves reactive sites on the molecules and these reactive sites on neighboring polymer chains link to generate the network structure. Thus, crosslinking of the polymer occurs in its molten state.

The FRGC that is used should have two key desirable characteristics. First, it should slowly decompose at the polymer's melting temperature, T_M, to form highly reactive free radicals that react with the polymer, resulting in a crosslinked polymer network. Second, the chemical should have a long half-life at the temperature at which the polymeric part is to be molded, which is at or above T_M. This characteristic will ensure that as the FRGC decomposes slowly, the free radicals produced will diffuse in the polymer to form a homogeneous crosslinked polymer network. A high value of T_M also facilitates this process.

Examples of suitable FRGCs are organic peroxides, azo compounds, peresters, tetrazenes, and silanes. In the case of UHMWPE, current chemical-induced crosslinking practice involves using an organic peroxide, with three commercial formulations being the most preferred. These are: (1) 2,5-dimethyl-2,5-bis(*tert*-butylperoxy) 3-hexene (Lupersol 130; Atochem, Inc., Philadelphia, PA, USA); (2) dicumyl peroxide (Lupersol 101; Atochem, Inc.); and (3) 2,5-dimethyl-2,5-di(*t*-butylperoxy)-hexane (Varox 130).

Chemical-induced crosslinking has three drawbacks. First, imperfections of the crystal arise. Second, because crosslinking takes place in the molten state, there may be restricted FRGC diffusion, which leads to a tendency for crosslinks to agglomerate in areas adjacent to the polymer flake surface. Third, there are by-products (for example, undissociated peroxides) which, if not completely eliminated, can adversely affect the long-term stability of the crosslinked material.

2.3. Principles of silane compound-induced crosslinking

In this process, a silane compound that contains a vinyl group and hydrolyzable groups is grafted onto the polymer chain. Grafting is achieved using a suitable

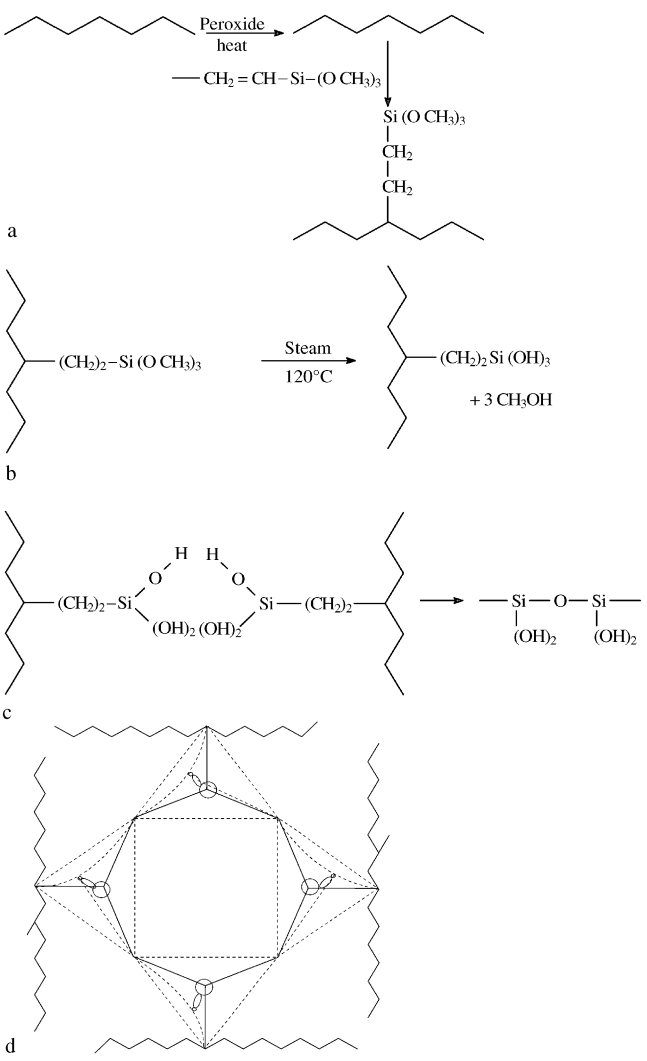

Fig. 2. Development of a silane-crosslinked high-density polyethylene structure (reprinted from Atkinson JR, Cicek RZ. Silane cross-linked polyethylene for prosthetic applications. Part I. Certain physical and mechanical properties related to the structure of the material. Biomaterials p. 1983;4:267–75, Copyright 1983, with permission from Elsevier Science).

peroxide. For example, in the case of high-density polyethylene, HDPE (a biopolymer that, in previous years, found use in bearing components of arthoplasties), one research group [58,59] has reported using vinyl trimethoxysilane as the silane compound and dicumyl peroxide as the grafting agent (Fig. 2(a)). In the crosslinking phase, the HDPE part is steam autoclaved at 120°C for at least 5 h. This allows the methoxy groups in the silane to be hydrolyzed to hydroxyl groups (Fig. 2(b)). The hydroxyl groups on neighboring chains then condense together to form the crosslinks (Fig. 2(c)). Because each silicon atom is connected to three hydroxyl groups, this single crosslinking site is capable of linking several chains together (Fig. 2(d)). Recently, Joyce et al. [60] presented results from wear tests on silane-crosslinked polyethylene specimens, although they provided no details on the crosslinking process used.

2.4. Radiation-induced crosslinking methods for UHMWPE

A number of variants of the method have been used in vitro studies. The main one are: (1) a process for which Muratoglu and coworkers [10,12,20,21,61–65] use the acronym CISM (Cold Irradiation and Subsequent Melt-annealing). This process involves maintaining the polymer at room temperature prior to and during electron beam radiation (typical dose of 15 Mrad) in air followed by subsequent melt annealing (typically at 150°C for at least 2 h) under vacuum and cooling to room temperature (typically at 10°C/min); (2) a process for which Muratoglu and coworkers [10,62,64,66–68] use the acronym WIAM (Warm Irradiation And Subsequent Melt annealing). This method involves maintaining the polymer at between 90 and 125°C prior to and during electron beam radiation (typical dose of 15 Mrad) in air followed by subsequent melt annealing (typically at 150°C for at least 2 h) under vacuum and cooling to room temperature (typically at 10°C/min); (3) a process for which Muratoglu and coworkers [10,69–71] use the acronym ISM (Irradiation in the Molten State). This method involves exposing the polymer to electron beam radiation (typical dose = 20 Mrad) while the polymer is molten; (4) exposing the polymer to electron beam radiation followed by annealing in the nonmelted state (that is, at, typically, 130°C); and (5) exposing the polymer to electron beam radiation followed by annealing in the melted state (that is, at, typically, 150°C).

An assortment of key process variables has been used in literature studies of radiation-induced crosslinking of UHMWPE [10–16,18–21,48,52,61–68,71–98], some of which are summarized in Table 2.

2.5. Chemical-induced crosslinking methods for UHMWPE

A plethora of process variables have been used in literature studies [11,12,21,22,80,88,89,97,99,100], a sample of which is presented in Table 3.

2.6. Silane-induced crosslinking methods for UHMWPE

The present reviewer is not aware of any report, in the open literature, on silane-induced crosslinking of UHMWPE.

2.7. Methods detailed in recent patent applications

Various methods for crosslinking UHMWPE specimens and acetabular cups are detailed in a number of patent applications that have been submitted in the past seven years. Three examples of these applications are those in which (a) it is claimed that the surface of a UHMWPE component is crosslinked through plasma treatment [101]; (b) Lupersol 130 is the crosslinking

Table 2
Radiation-induced crosslinking of UHMWPE: summary of key process variables

Radiation agent	Packaging medium	Radiation dosage (Mrad)	Post-crosslinking process details	Reference
γ	Air	4.50–100.00	Heated in air to 150°C, at 0.3°C/min, held at 150°C for 5 h, and slowly cooled to room temperature	McKellop et al. [16]
γ	Acetylene	2.50	Annealed at 100°C for 5 h	Marrs et al. [77]
γ	Air or vacuum	2.50–100.00	Heated at 150°C and held at that temperature for 5 h	Gillis et al. [81,82] Duus et al. [83]
γ	N_2	5.00	Remelted at 155°C for 24 h	McKellop et al. [85]
γ	Ar	20.00–1000.00	NS[a]	Shen and Dumbleton [92]
Electron beam	NS	2.50–20.00	Sheets placed in a vacuum oven, evacuated, and heated to 180°C for 0.5 h in an N_2 gas-filled environment and then slowly cooled to room temperature	Bajaria and Bellare [91]
Electron beam	Air	2.50–30.00	Melt annealed at 150°C under vacuum for 2 h and cooled to room temperature at 10°C/min	Muratoglu et al. [21]

[a]Details were not given in the report.

Table 3
Chemical (peroxide-induced) crosslinking of UHMWPE: values of key process variables

Peroxide agent	Concentration (wt%)	Mixture consolidation conditions			Reference
		Temperature (°C)	Pressure (MPa)	Time (h)	
Lupersol 130[a] + γ irradiation (upto 3.4 Mrad)	0.20–2.00	120–170	11.0–15.0	2	Shen et al. [99]
Lupersol 101[b]	0.25	216	6.9	1	Kurtz et al. [100]
Varox 130[c]	0.15–2.00	150	15.0	2	Muratoglu et al. [21]
NS[d]	1.00	170	6.9	2	McKellop et al. [11]

[a] 2,5-dimethyl-2,5-bis(*tert*-butylperoxy)-3-hexyne.
[b] Liquid dicumyl peroxide.
[c] 2,5-dimethyl-2,5-di(*tert*-butyl-peroxy)hexyne-3.
[d] Details were not given in the report.

agent [102]; (c) a method is used that, it is claimed, leads to crosslinking of a component's surface layer while leaving its interior uncrosslinked [103].

3. Literature results

3.1. In vitro studies

In these studies, a welter of properties of UHMWPE prior to and following crosslinking were determined. Selected results from these studies [10–19,20–22,43, 48,52,54,61–73,76–83,85–100,104] are summarized in Tables 4–10, from which one major observation is clear. This is that there are host of wear studies (involving both laboratory specimens as well as implant components worn in joint simulators) but only a few reports on fatigue, fatigue crack propagation rate, and fracture toughness [67,80–82,87]. This lack of attention to these latter properties is a serious matter for the following two reasons. First, normal contact between the articulating nonpolymeric and polymeric components (such as metallic femoral head versus UHMWPE acetabular cup or liner in a hip implant) leads to a large fluctuation in the stresses at and below the surface of the polymeric component. For example, in a condylar-type total knee replacement, it has been estimated that the maximum principal stress at a point near the surface of the UHMWPE tibial insert ranges from 10 MPa (tensile) to 30 MPa (compressive) [105]. Second, fatigue cracks can grow in the polymeric component under fully compressive cyclic loading conditions if stress riser(s) exist in the component. These subsurface cracks can then further propagate under tensile loading until they reach critical sizes, and this may culminate in local fracture, delamination, and/or pitting of the polymer component [106]. In other words, a polymer that displays low fatigue life, high fatigue crack propagation rate, and low fracture toughness is undesirable for use in fabricating implant bearing components.

3.2. Clinical studies

To date, the only published clinical studies are from three research groups [43,50–54], with all of these studies being on acetabular cups. In vivo wear rates reported in these studies are presented in Table 11. One observation is common to all these reports [43,50–54]; this is that details on a number of important parameters are either not stated or are given in an unclear manner. Two sets of omissions are particularly glaring. First, the starting resin is, in some cases, not identified at all (Wroblewski et al. [43] stated: 'All acetabular cups were made of crosslinked polyethylene'), or, in other cases, is not clearly identified (thus, Oonishi et al. [52] stated: 'High density polyethylene (HDP) (Million followed by UHMWPE) irradiated with 10^8 rad of γ-radiation was used for the socket'). Furthermore, no information is given on either the crosslinking process (and associated post-crosslinking steps) or the method of fabrication of the cups. The second important omission is the collection of the in vivo wear rates for control cups (that is, those gamma irradiated with the usual dose of 2–3 Mrad).

4. Methodology for estimation of optimal value of a crosslinking process variable

Clearly, even if improvement of wear resistance of crosslinked UHMWPE is currently universally accepted, there is bound to be a concomitant depreciation in the values of some other key mechanical and physical properties. Thus, the goal should be to find the crosslinking process conditions that produce an optimal mix of the polymer's properties. This issue is well recognized, as evidenced by the remarks of Edidin et al. [107]: 'Therefore, from both a biomaterials and a biomechanics perspective, any modification of UHMWPE for total hip replacements must necessarily strike an optimal balance between wear performance, ductility, ultimate strength, fatigue endurance, and fracture resistance'.

Table 4
Indices of crosslinking [SR, swell ratio; X, gel content (in %); and v crosslink density (in mol/m^3)] of UHMWPE: results from selected literature reports

Resin and fabrication process	Crosslinking method details	Post-crosslinking treatment details	Method of determining SR, X, or v	Mean results	Reference
Ram extruded GUR 4150	Vacuum packed, sealed in pouches, and γ irradiated (5 Mrad)	Heated above the melt temperature of UHMWPE; slowly cooled; test rods machined, packaged and sterilized using gas plasma	ASTM D 2765 Method C	SR = 2.83 (unaged specimens) SR = 2.79 (accelerated aged specimens: in oxygen at 70°C and 0.51 MPa for 14 d)	DiMaio et al. [78]
GUR 4150HP	Packaged in N_2 and γ irradiated in N_2 with a dose of	NS[a]	Extraction in nearly boiling xylene		Edidin et al. [19]
	0.0 Mrad			$X = 6.5$	
	2.7 Mrad			$X = 80.6$	
	5.3 Mrad			$X = 85.3$	
	8.0 Mrad			$X = 87.1$	
	10.7 Mrad			$X = 88.4$	
	13.3 Mrad			$X = 88.4$	
Ram extruded GUR 4150	Electron beam radiated with a dose of	Melt annealed at 150°C for 2 h in vacuum	Measurement of expansion of the test specimen, immersed in xylene at 130°C, using a 'super LVDT'		Muratoglu et al. [63]
	2.5 Mrad			SR = 3.8; $v = 1100$	
	15.0 Mrad			SR = 2.7; $v = 2000$	
	30.0 Mrad			SR = 2.5; $v = 2200$	
GHR 8110	Lupersol 101	Not applicable	Per ASTM	$v = 2000$	Spiegelberg et al. [88]
GUR 1020	Lupersol 101	Not applicable	D2765, using xylene at 130°C	$v = 1600$	
GUR 1050	Lupersol 101	Not applicable		$v = 1900$	
GUR 1150	Electron beam radiated (15 Mrad) at room temperature	Melted		$v = 2000$	
Ram extruded GUR 1050	Electron beam radiation with a dosage of	Annealed in a vacuum oven at 100°C for 3 d	NS	X at the following positions below the surface (in mm) 0 1.5 2.0 3.0	McKellop et al. [11]
	5 Mrad			78 90 88 0	
	10 Mrad			90 72 0 0	
	15 Mrad			95 68 0 0	
RCH 1000C	γ irradiated (10 Mrad) in the presence of	NS	48 h Soxhlet extraction with decalin as solvent		du Plessis et al. [93]
	N_2			$X = 15.0$[b]; 55.0[c]	
	Acetylene			$X = 55.0$[b]; 35.0[c]	
	Chlorotrifluoroethylene + Acetylene			$X = 77.0$[b]; 50.0[c]	
	γ irradiated (30 Mrad) in the presence of	NS			
	N_2			$X = 30.0$[b]; 75.0[c]	
	Acetylene			$X = 75.0$[b]; 60.0[c]	
	Chlorotrifluoroethylene + Acetylene			$X = 80.0$[b]; 75.0[c]	
	γ irradiated (60 Mrad) in the presence of	NS			
	N_2			$X = 55.0$[b]; 75.0[c]	
	Acetylene			$X = 80.0$[b]; 75.0[c]	
	Chlorotrifluoroethylene + Acetylene			$X = 75.0$[b]; 75.0[c]	

Table 4 *continued*

Resin and fabrication process	Crosslinking method details	Post-crosslinking treatment details	Method of determining SR, X, or v	Mean results	Reference
	γ irradiated (80 Mrad) in the presence of	NS			
	N_2			$X = 55.0^b$; 75.0^c	
	Acetylene			$X = 80.0^b$; 75.0^c	
	Chlorotrifluoroethylene + Acetylene			$X = 75.0^b$; 75.0^c	
GUR 415	Lupersol 130	Not applicable	Extraction in stirred, boiling, *p*-xylene for 72 h		Shen et al. [99]
	0.2 wt%			$X = 100^d$; 78^e	
	1.0 wt%			$X = 99^d$; 98^e	
	2.0 wt%			$X = 99^d$; 99^e	
	0.2 wt%			SR = 3.6^d; 5.9^e	
	1.0 wt%			$X = 2.5^d$; 3.4^e	
	2.0 wt%			$X = 2.3^d$; 2.6^e	
Compression molded GUR 1020	Electron beam radiated with a dose of	Melt annealed at 150°C for 2 h	Measurement of expansion of the specimen, due to swelling (in xylene at 130°C)		Cook et al. [65]
	2.5 Mrad			$v = 90$	
	10.0 Mrad			$v = 170$	
	20.0 Mrad			$v = 220$	
Ram extruded GUR 4150	None: unirradiated	Not applicable		SR = 30	DiMaio et al. [98]
	Packaged in heat-sealed foil/plastic pouches and γ-irradiated with a dose of	Heat treated at 200°C for 48 h and cooled slowly to ambient temperature	ASTM D 2765 Method C		
	2.5 Mrad			SR = 4	
	5.0 Mrad			SR = 3	
	15.0 Mrad			SR = 2	
	25.0 Mrad			SR = 3	
GUR 1050	Peroxide	Not applicable			Muratoglu et al. [21]
	0.10 wt%			$v = 120.5$	
	0.20 wt%			$v = 139.4$	
	0.25 wt%			$v = 131.8$	
	0.30 wt%			$v = 162.8$	
	0.35 wt%			$v = 166.4$	
	0.40 wt%			$v = 180.2$	
	0.45 wt%			$v = 167.5$	
	0.50 wt%			$v = 165.8$	
	0.70 wt%			$v = 167.9$	
Ram extruded GUR 4150	γ irradiated in air with a dose of	None	Extraction of the sol-fraction by boiling in *p*-xylene for 72 h; following extraction, gel was transferred to fresh *p*-xylene and allowed to equilibrate at 120°C for 2 h		McKellop et al. [17]
	3.3 Mrad			$v = 17$; SR = 5.3	
	4.5 Mrad			$v = 40$; SR = 3.6	
	9.5 Mrad			$v = 74$; SR = 2.8	
	14.5 Mrad			$v = 127$; SR = 2.4	
	20.2 Mrad			$v = 140$; SR = 2.3	
	24.0 Mrad			$v = 156$; SR = 2.2	
	50.0 Mrad			$v = 233$; SR = 1.9	
	100.0 Mrad			$v = 350$; SR = 1.7	
	γ irradiated in air with a dose of	Heated in an oven in ambient air from room temperature to 150°C at 0.3°C/min, held at 150°C for 5 h, and then slowly cooled to room temperature in the oven for at least 5 h			

Table 4 *continued*

Resin and fabrication process	Crosslinking method details	Post-crosslinking treatment details	Method of determining SR, X, or v	Mean results	Reference
	3.3 Mrad			$v = 56$; SR = 3.2	
	4.5 Mrad			$v = 58$; SR = 3.1	
	9.5 Mrad			$v = 100$; SR = 2.5	
	14.5 Mrad			$v = 127$; SR = 2.4	
	20.2 Mrad			$v = 140$; SR = 2.3	
	24.0 Mrad			$v = 140$; SR = 2.2	
	50.0 Mrad			$v = 156$; SR = 2.2	
	100.0 Mrad			$v = 350$; SR = 1.7	

[a] Details were not given in the report.
[b] For samples taken from specimen surface.
[c] For samples taken from the inner section of the specimen.
[d] Before γ irradiation.
[e] After γ irradiation in air (up to 3.4 Mrad).

Table 5
Molecular weight between crosslinks (MW_c), lamellar thickness (t), and lamellar length (l) of crosslinked UHMWPE: mean results from selected literature reports

Resin and fabrication process	Crosslinking method details	Post-crosslinking treatment details	MW_c (g/mol)	t (nm)	l (μm)	Reference
Ram extruded GUR 4150	γ irradiated in air with a dose of					McKellop et al. [17]
	3.3 Mrad	None; remelted[a]	8400; 2500[a]			
	4.5 Mrad	None; remelted[a]	3500; 2400[a]			
	9.5 Mrad	None; remelted[a]	1900; 1400[a]			
	14.5 Mrad	None; remelted[a]	1100; 1100[a]			
	20.2 Mrad	None; remelted[a]	1000; 1000[a]			
	24.0 Mrad	None; remelted[a]	900; 1000[a]			
	50.0 Mrad	None; remelted[a]	600; 900[a]			
	100.0 Mrad	None; remelted[a]	400; 400[a]			
GUR 1050	Varox 130	Not applicable				Gul et al. [22]
	0.235 wt%		7300			
	0.375 wt%		5000			
	0.700 wt%		5000			
Ram extruded 4150	Electron beam radiated (15 Mrad)	Melt annealed		17.2		Muratoglu et al. [10,66]
Ram extruded GUR 1050	Preheated to 125°C and electron beam irradiated (15 Mrad)	Melt annealed		16.0		
GUR 1050	None: γ irradiated in air (2.5 Mrad)			24.0		
GUR 4150HP	γ irradiated in air with a dose of					Duus et al. [83]
	2.5 Mrad	None		86–124[b]	0.7–0.9[b]	
	2.5 Mrad	Stabilization; at 150°C for 5 h		53–96[b]	0.6–0.7[b]	
	10.0 Mrad	None		78–130[b]	0.7–0.9[b]	
	10.0 Mrad	Stabilization; at 150°C for 5 h		53–69[b]	0.6	
	50.0 Mrad	None		95–127[b]	0.7–0.9[b]	
	50.0 Mrad	Stabilization; at 150°C for 5 h		73–105[b]	0.7–1.0[b]	
	100.0 Mrad	None		104–126[b]	0.8–0.9[b]	
	100.0 Mrad	Stabilization; at 150°C for 5 h		83–109[b]	0.7–0.8[b]	
	Electron beam radiated with a dose of					
	2.5 Mrad	None		96–147[b]	0.8–0.9[b]	
	2.5 Mrad	Stabilization; at 150°C for 5 h		34–46[b]	0.5–0.6[b]	
	10.0 Mrad	None		58–101[b]	0.7–0.8[b]	

Table 5 *continued*

Resin and fabrication process	Crosslinking method details	Post-crosslinking treatment details	MW_c (g/mol)	t (nm)	l (μm)	Reference
	10.0 Mrad	Stabilization; at 150°C for 5 h		59–100[b]	0.7–0.8[b]	
	50.0 Mrad	None		81–121[b]	0.8–1.0[b]	
	50.0 Mrad	Stabilization; at 150°C for 5 h		70–114[b]	0.7–0.8[b]	
Ram extruded GUR 4150	Electron beam radiated with a dose of	Melt annealed at 150°C under vacuum for 2 h and cooled to room temperature at 10°C/min Melt annealed at 150°C under vacuum for 2 h and cooled to room temperature at 10°C/min				Muratoglu et al. [21]
	2.5 Mrad		9500			
	5.0 Mrad		6300			
	7.5 Mrad		5800			
	10.0 Mrad		5060			
	15.0 Mrad		4700			
	20.0 Mrad		4560			
	γ irradiation (4.0 Mrad)		7650			
GUR 1050	Peroxide	Not applicable	7160			Muratoglu et al. [21]
	0.10 wt%		6180			
	0.20 wt%		6540			
	0.25 wt%		5300			
	0.30 wt%		5180			
	0.35 wt%		4780			
	0.40 wt%		5150			
	0.45 wt%		5200			
	0.50 wt%		5130			
	0.70 wt%					

[a]Heated in an oven, in ambient air, from room temperature to 150°C at ~0.3°C/min, held at 150°C for 5 h, and then slowly cooled to room temperature in the oven for at least 5 h.
[b]Range of maximum values.

Table 6
Oxidation index (OI), degree of crystallinity (C) and melting temperature (T_M) of crosslinked UHMWPE: results from selected literature reports

Resin and fabrication process	Crosslinking method details	Post-crosslinking treatment details	OI	C (%)	T_M (°C)	Reference
Ram extruded GUR 4150	Vacuum packed, sealed in pouches, and γ irradiated (5 Mrad)	Heated above the melt temperature of UHMWPE; slowly cooled; test rods machined, packaged and sterilized using gas plasma	0.062; 0.067[a]	49; 50[a]	138; 138[a]	DiMaio et al. [78]
	None: γ irradiated in air (2.5 Mrad)		0.22; 0.51[a]			
Compression molded GUR 415	None: unirradiated	Not applicable		58.5		Bajaria and Bellare [91]
	Electron beam irradiated with a dose of	Sheets placed in vacuum oven; heated to 180°C for 30 min in N_2 gas-filled container; and slowly cooled to room temperature				
	2.5 Mrad			43.9		
	5.0 Mrad			43.8		
	10.0 Mrad			43.3		
	20.0 Mrad			42.4		

Table 6 *continued*

Resin and fabrication process	Crosslinking method details	Post-crosslinking treatment details	OI	C (%)	T_M (°C)	Reference
Compression molded GUR 1050	Electron beam radiated (18 ± 1.0 Mrad)	None Annealed at 130°C Annealed at 150°C		60; 59[b] 62; 60[b] 56; 55[b]	140; 140[b] 142; 140[b] 137; 137[b]	King et al. [90]
Ram extruded 4150	Electron beam radiated (20 Mrad)	None	0.03	38	126	Muratoglu et al. [10,66]
Ram extruded 4150	Electron beam radiated (15 Mrad)	Melt annealed	0.02	48	137	
Ram extruded GUR 1050	Preheated at 120°C, electron beam radiated (15 Mrad)	Melt annealed	0.03	45	137	
GUR 1050	Peroxide	Not applicable		40	126	
Himont 1900	Peroxide	Not applicable		46	127	
GUR 1050	None: γ irradiated in air (2.5 Mrad)		0.08	58	137	
Compression molded Hostalen	None: unirradiated	Not applicable		47.0		Birkinshaw et al. [94]
GUR	γ irradiated in air with a dose of	NS[c]				
	2.5 Mrad			45.1		
	5.0 Mrad			43.9		
	10.0 Mrad			41.5		
	20.0 Mrad			41.7		
	30.0 Mrad			40.7		
GUR 415	Lupersol 130	Not applicable				Shen et al. [99]
	0.2 wt%			43.4[d]; 49.0[e]	128.1[d]; 129.2[e]	
	1.0 wt%			42.0[d]; 42.6[e]	121.2[d]; 122.7[e]	
	2.0 wt%			37.5[d]; 38.0[e]	113.7[d]; 115.3[e]	
GUR 415	Lupersol 130 (1 wt%)	Not applicable	11[f]; 0[g] 2.5[h]; 0[i] 0.7[j]; 0[k]			McKellop et al. [17]
	γ irradiated in air (28 Mrad)	None				
	Surface		0.00			
	0.5 mm below surface		7.80			
	1.0 mm below surface		1.80			
	1.5 mm below surface		0.00			
	γ irradiated in air (28 Mrad)	Remelted in air at 150°C for 5 h and passively cooled to room temperature				
	Surface		0.00			
	1.0 mm below surface		0.00			
	1.5 mm below surface		0.00			
	4.0 mm below surface		0.00			
RCH 1000C	γ irradiated (10 Mrad) in the presence of	NS				du Plesiss et al. [93]
	N_2				134	
	Acetylene				138	
	Chlorotrifluoroethylene + acetylene				133	
	γ irradiated (30 Mrad) in the presence of	NS				
	N_2				136	
	Ethylene				142	
	Chlorotrifluoroethylene + acetylene				137	

Table 6 *continued*

Resin and fabrication process	Crosslinking method details	Post-crosslinking treatment details	OI	C (%)	T_M (°C)	Reference
	γ irradiated (60 Mrad) in the presence of	NS				
	N_2				136	
	Acetylene				141	
	Chlorotrifluoroethylene + acetylene				138	
	γ irradiated (80 Mrad) in the presence of	NS				
	N_2				135	
	Acetylene				141	
	Chlorotrifluoroethylene + acetylene				137	
NS	None	Not applicable	0	55		King et al. [97]
	Varox 130 (0.5 wt%)	Not applicable	0	46		
	Varox 130 (1.0 wt%)	Not applicable	0.07	43		
	Varox 130 (1.5 wt%)	Not applicable	0.006	46		
	γ irradiation (25 Mrad)	Heat stabilized for 3 h in air after onset of melting	0	55		
	γ irradiation (50 Mrad)		0	57		
	γ irradiation (100 Mrad)		0.098	58		
Ram extruded GUR 4150	None: unirradiated	Not applicable		55	134	McKellop et al. [17]
	γ irradiated in air with a dose of					
	3.3 Mrad	None; remelted[k]		60; 52[l]	135; 131[l]	
	4.5 Mrad	None; remelted[k]		66; 52[l]	136; 132[l]	
	9.5 Mrad	None; remelted[k]		67; 53[l]	137; 135[l]	
	14.5 Mrad	None; remelted[k]		70; 53[l]	138; 135[l]	
	20.2 Mrad	None; remelted[k]		71; 52[l]	137; 135[l]	
	24.0 Mrad	None; remelted[k]		68; 52[l]	138; 135[l]	
	50.0 Mrad	None; remelted[k]		67; 53[l]	139; 135[l]	
	100.0 Mrad	None; remelted[k]		63; 52[l]	140; 131[l]	

[a]After accelerated aging (heated in O_2 gas at 70°C and 0.51 MPa for 14 d).
[b]After accelerated aging (heated in O_2 gas at 37°C and 0.58 MPa for 70 d).
[c]Details were not given in the report.
[d]Before γ irradiation of the specimen.
[e]After γ irradiation of the specimen in air (up to 3.4 Mrad).
[f]At the surface after 30 d aging at 80°C.
[g]At the surface after 32 months on the shelf.
[h]At 1.5 mm below the surface after 30 d aging at 80°C.
[i]At 1.5 mm below the surface after 30 d months on the shelf.
[j]At 4.0 mm below the surface after 30 d aging at 80°C.
[k]At 4.0 mm below the surface after 32 months on the shelf.
[l]Heated in an oven, in ambient air, from room temperature to 150°C at ~0.3°C/min, held at 150°C for 5 h, and then slowly cooled to room temperature in the oven for least 5 h.

Table 7
Static mechanical properties[a] of crosslinked UHMWPE: mean results from selected literature reports

Resin and fabrication process	Crosslinking method details	Post-crosslinking treatment details	UTS (MPa)	YS (MPa)	E (MPa)	ε_f (%)	U (mJ)	Reference
Ram extruded GUR 4150	Vacuum packed, sealed in pouches, and γ irradiated (5 Mrad)	Heated above the melt temperature of UHMWPE; slowly cooled; test rods machined, packaged and sterilized using gas plasma	41.1 38.9[b]	22.8 23.2[b]	750 710[b]	270 257[b]		DiMaio et al. [78]

Table 7 *continued*

Resin and fabrication process	Crosslinking method details	Post-crosslinking treatment details	UTS (MPa)	YS (MPa)	E (MPa)	ε_f (%)	U (mJ)	Reference
GUR 4150HP	Packaged in N_2 and γ irradiated in N_2, with a dose of	NS[c]						Edidin et al. [19]
	0.0 Mrad						256	
	2.7 Mrad						228	
	5.3 Mrad						176	
	8.0 Mrad						165	
	10.7 Mrad						152	
	13.3 Mrad						142	
Ram extruded GUR 1050	Electron beam radiated (15 Mrad) at room temperature	Melt annealed at 150°C for a minimum of 2 h	27	19		173		Muratoglu et al. [64]
	Heated up to 125°C in air and then electron beam radiated (15 Mrad)	Melt annealed at 150°C for a minimum of 2 h	24	18		250		
Compression molded GUR 1050	Electron beam radiated (18 ± 1.0 Mrad)	None	35.8; 25.5[d]	22.0; 24.1[d]		23.1; 13.1[d]		King et al. [90]
		Annealed at 130°C	30.3; 26.2[d]	21.4; 22.7[d]		172; 159[d]		
		Annealed at 150°C	26.2; 28.2[d]	20.7; 19.3[d]		170; 173[d]		
GUR 4150HP	γ irradiated in air with a dose of							Gillis et al. [81,82]
	2.5 Mrad	None		23.5	939			
	2.5 Mrad	Stabilized (150°C for 5 h)		20.7	740			
	10.0 Mrad	None		23.4	975			
	10.0 Mrad	Stabilized (150°C for 5 h)		20.6	874			
	20.0 Mrad	None		23.7	1015			
	20.0 Mrad	Stabilized (150°C for 5 h)		19.6	749			
	50.0 Mrad	None		24.0	1219			
	50.0 Mrad	Stabilized (150°C for 5 h)		18.0	711			
	100.0 Mrad	None		24.6	1056			
	100.0 Mrad	Stabilized (150°C for 5 h)		17.6	663			
	Electron beam radiated with dose of							
	2.5 Mrad	None		23.2	952			
	2.5 Mrad	Stabilized (150°C for 5 h)		20.0	834			
	10.0 Mrad	None		23.8	986			
	10.0 Mrad	Stabilized (150°C for 5 h)		20.2	874			
	20.0 Mrad	None		24.1	1003			
	20.0 Mrad	Stabilized (150°C for 5 h)		19.3	713			
	50.0 Mrad	None		24.9	1087			
	50.0 Mrad	Stabilized (150°C for 5 h)		—[e]	—			
Ram extruded GUR 4150	None: unirradiated	Not applicable	52.0	23.0		350		McKellop et al. [17]
	γ irradiated in air with dose of	None						
	4.5 Mrad		47.0	25.0		310		
	9.5 Mrad		48.0	25.5		250		
	14.5 Mrad		47.0	26.0		210		
	20.0 Mrad		40.0	27.0		180		
	24.0 Mrad		40.0	27.5		160		

Table 7 *continued*

Resin and fabrication process	Crosslinking method details	Post-crosslinking treatment details	UTS (MPa)	YS (MPa)	E (MPa)	ε_f (%)	U (mJ)	Reference
	γ irradiated in air with dose of							
	4.5 Mrad	Heated in an oven in	46.0	21.8		310		
	9.5 Mrad	temperature to 150°C	44.0	21.1		250		
	14.5 Mrad	at ~0.3°C/min held at	38.0	21.5		210		
	20.0 Mrad	150°C for 5 h; and then	35.0	21.5		185		
	24.0 Mrad	slowly cooled to room temperature in the oven for at least 5 h	33.0	21.3		160		
RCH 1000	None: unirradiated	Not applicable	31	26		460		Shen and Dumbleton [92]
	γ irradiated in Ar with a dose of	NS						
	20 Mrad		30	26		440		
	50 Mrad		26	26		150		
	100 Mrad		26	27		80		
	200 Mrad		27	28		40		
	500 Mrad		32	33		30		
	1000 Mrad		36	36		25		
NS	None: unirradiated	Not applicable	46.4	27.7	940.7	953.8		Premnath et al. [96]
	Heated to a temperature > melt temperature and held there for at least 0.5 h, and then electron beam radiated (20 Mrad)	NS	15.4	14.4	200.8	547.2		
GUR 4150	None	Not applicable			320	200		Muratoglu et al. [20]
	Electron beam radiated in air with a dose of	Heated at 150°C under vacuum and cooled to room temperature at a rate of 10°C/min						
	5 Mrad				250	180		
	10 Mrad				270	160		
	20 Mrad				260	130		
	30 Mrad				290	50		
GUR 415	None: unirradiated	Not applicable	49.0			400		Oonishi et al. [14]
	γ irradiated in air with dose of	NS						
	100 Mrad		24.0			25		
	250 Mrad		26.0			15		
	500 Mrad		29.0			0		
NS	None	Not applicable	46.9			370		King et al. [97]
	Varox 130 (0.5 wt%)	Not applicable	27.6			341		
	Varox 130 (1.0 wt%)	Not applicable	27.6			358		
	Varox 130 (1.5 wt%)	Not applicable	19.3			263		
	γ irradiation (25 Mrad)	Heat stabilized for 3 h	31.7			151		
	γ irradiation (50 Mrad)	in air after onset of	28.3			115		
	γ irradiation (100 Mrad)	melting	24.8			41		
Ram extruded GUR 4150	None: unirradiated	Not applicable				330		DiMaio et al. [98]
	Packaged in heat-sealed foil/plastic pouches and γ irradiated with a dose of	Heat treated at 200°C for 48 h and cooled slowly to ambient temperature						
	2.5 Mrad					310		

Table 7 *continued*

Resin and fabrication process	Crosslinking method details	Post-crosslinking treatment details	UTS (MPa)	YS (MPa)	E (MPa)	ε_f (%)	U (mJ)	Reference
	5.0 Mrad					280		
	15.0 Mrad					200		
	25.0 Mrad					150		
GUR 8110	Lupersol 101	Not applicable	109			226[f]	203	Kurtz et al. [100]
GUR 1020	Lupersol 101	Not applicable	69			120[f]	234	
GUR 1050	Lupersol 101	Not applicable	89			137[f]	258	
GUR 1150	None: unirradiated	Not applicable	79			171[f]	205	
	Electron beam radiated (15 Mrad)	'Subsequently melted'	39			80[f]	131	
Ram extruded GUR 1050	None	Not applicable	46	22.0				Muratoglu et al. [21]
	Electron beam radiated with a dose of	Melt annealed at 150°C under vacuum for 2 h and cooled to room temperature at 10°C/min						
	2.5 Mrad		37	19.6				
	5.0 Mrad		37	19.6				
	7.5 Mrad		37	19.9				
	10.0 Mrad		35	20.2				
	15.0 Mrad		28	19.6				
	20.0 Mrad		29	19.6				
	30.0 Mrad		27	20.0				
	γ irradiated (4.0 Mrad)		38	18.8				
GUR 1050	None	Not applicable	22.8	50.4				Muratoglu et al. [21]
	Peroxide	Not applicable						
	0.20 wt%		21.1	38.2				
	0.30 wt%		20.4	41.7				
	0.40 wt%		20.0	40.7				
	0.50 wt%		19.7	38.3				
	0.70 wt%		18.9	37.1				

[a] UTS: ultimate tensile strength; YS: yield strength; E: tensile modulus of elasticity; ε_f: tensile strain at failure; U: work to failure.
[b] After accelerated aging (heated in O_2 gas at 70°C and 0.51 MPa for 14 d).
[c] Details were not given in the report.
[d] After accelerated aging (heated in O_2 gas at 37°C and 0.59 MPa for 70 d).
[e] Result was not given in the report.
[f] Ultimate effective true strain.

Table 8
Wear rate (W) of crosslinked UHMWPE: mean results from selected literature reports

Resin and fabrication process	Crosslinking method details	Post-crosslinking details	Type of wear tester	W[a]	Reference
RCH 1000	None: unirradiated	Not applicable	Pin-on-disk	$\sim 0.1 \times 10^7$ mm^3/N m (uniaxial reciprocating on a smooth counterface) $\sim 0.9 \times 10^7$ mm^3/N m (biaxial motion on a smooth counterface) 2.3×10^7 mm^3/N m (uniaxial motion on a rough counterface)	Marrs et al. [77]
	γ irradiated (2.5 Mrad) in acetylene gas after O_2 was evacuated	Annealed at 100°C for 5 h		$\sim 0.1 \times 10^7$ mm^3/N m (uniaxial reciprocating motion on a smooth counterface) $\sim 0.1 \times 10^7$ mm^3/N m (biaxial motion on a smooth counterface) 3.5×10^7 mm^3/N m (uniaxial motion on rough counterface)	

Table 8 *continued*

Resin and fabrication process	Crosslinking method details	Post-crosslinking details	Type of wear tester	W[a]	Reference
Ram extruded GUR 4150	γ irradiated in air with dose of	Remelted by heating in air to 150°C at 0.3°C/min, holding at 150°C for 5 h; and slow cooling to room temperature. A final ethylene oxide sterilization step was applied	Hip joint simulator		McKellop et al. [16]
	3.3 Mrad			17.5 $mm^3/10^6$ cycles	
	4.5 Mrad			9.3 $mm^3/10^6$ cycles	
	9.5 Mrad			2.2 $mm^3/10^6$ cycles	
	14.5 Mrad			1.0 $mm^3/10^6$ cycles	
	20.2 Mrad			0 $mm^3/10^6$ cycles	
	24.0 Mrad			− 1.0 $mm^3/10^6$ cycles[b]	
	50.0 Mrad			− 1.2 $mm^3/10^6$ cycles[b]	
GUR 4150HP	Packaged in N_2 and γ irradiated in N_2, with a dose of	NS[c]	Hip joint simulator		Edidin et al. [19]
	0.0 Mrad			73.0	
	2.7 Mrad			45.2	
	5.3 Mrad			15.1	
	8.0 Mrad			11.1	
	10.7 Mrad			5.8	
	13.3 Mrad			5.4	
Ram extruded GUR 1050	Electron beam radiated with a dose of	Annealed in a vacuum oven at 100°C for 3 d and sterilized using ethylene oxide gas	Hip joint simulator		McKellop et al. [11]
	5 Mrad			25.6	
	10 Mrad			16.1	
	15 Mrad			8.5	
GUR 1050	Peroxide (1 wt%)			17.2	
Compression molded GUR 1120	None: unirradiated	Not applicable	Hip joint simulator	28[d]; 28[e]	Hamilton et al. [75]
	γ irradiated with a dose of	NS			
	1.0 Mrad			31[d]; 25[e]	
	2.5 Mrad			37[d]; 28[e]	
	4.0 Mrad			32[d]; 15[e]	
	5.0 Mrad			37[d]; 14[e]	
Ram extruded GUR 4150	γ irradiated (3.3 Mrad)	None	Hip joint simulator	21.4	McKellop et al. [17]
	γ irradiated (3.3 Mrad)	Melt annealed		19.2	
	γ irradiated (28 Mrad)	None		0.12	
	γ irradiated (28 Mrad)	Melt annealed		0.18	
Ram extruded GUR 4150HP	None: γ irradiated in air (2.5 Mrad)		Knee joint simulator	1.43; 3.50[f]	Hastings et al. [79]
	Vacuum packed, sealed in pouches, and γ irradiated (5 Mrad)	Heated above the melt temperature of UHMWPE; slowly cooled; test rods machined, packaged and sterilized using gas plasma		0.15; 0.50[f]	
GUR 415	None: unirradiated	Not applicable	Sphere-on-flat reciprocation type tribology tester	17.03×10^{-3} mm^3	Oonishi et al. [14]
	γ irradiated in air with a dose of	Heat treated in reduced pressure at 110°C for 2 h			
	50 Mrad			12.28×10^{-3} mm^3	
	75 Mrad			3.33×10^{-3} mm^3	
	100 Mrad			4.21×10^{-3} mm^3	
	125 Mrad			4.15×10^{-3} mm^3	
	150 Mrad			3.05×10^{-3} mm^3	
	200 Mrad			2.66×10^{-3} mm^3	

Table 8 *continued*

Resin and fabrication process	Crosslinking method details	Post-crosslinking details	Type of wear tester	W^a	Reference
GUR 415	None: unirradiated	Not applicable	Hip joint simulator	23.3	Shen et al. [99]
	Lupersol 130 (0.2–2.0 wt%)	Not applicable		1.1	
Ram extruded GUR 4150	γ irradiated in air (3.3 Mrad)	None	Hip joint simulator	20.7 $mm^3/10^6$ cycles	Shen et al. [18]
	γ irradiated in air (3.3 Mrad)	Remelted in air at 150°C for 5 h and passively cooled to room temperature		18.6 $mm^3/10^6$ cycles; 19.8 $mm^3/10^6$ cycles[g]	
	γ irradiated in air (28 Mrad)	None		~ 0.0	
	γ irradiated in air (28 Mrad)	Remelted in air at 250°C for 5 h and passively cooled to room temperature		~ 0.0	
Ram extruded GUR 4150	None	Not applicable	Bi-directional pin-on-disk	9.8	Muratoglu et al. [21]
	Electron beam radiated with a dose of	Melt annealed at 150°C under vacuum for 2 h and cooled to room temperature at 10°C/min			
	2.5 Mrad			9.1	
	5.0 Mrad			4.8	
	7.5 Mrad			2.5	
	10.0 Mrad			1.6	
	15.0 Mrad			0.5	
	20.0 Mrad			0.2	
	30.0 Mrad			0.1	
	γ irradiated (4.0 Mrad)			6.3	
GUR 1050	None	Not applicable	Bi-directional pin-on-disk	8.2	Muratoglu et al. [21]
	Peroxide				
	0.10 wt%	Not applicable		3.1	
	0.20 wt%			2.3	
	0.30 wt%			3.3	
	0.40 wt%			2.1	
	0.50 wt%			1.4	
	0.70 wt%			0.8	
Himont 1900	None	Not applicable	Bi-directional pin-on-disk	9.9	Muratoglu et al. [21]
	Peroxide	Not applicable			
	0.30 wt%			2.8	
	0.50 wt%			6.9	
RCH 1000	None: unirradiated	Not applicable	Thrush washer (pressure = 1.8 MPa)	207×10^{-8} m^3/h	Shen and Dumbleton [92]
	γ irradiated in Ar with a dose of	NS			
	100 Mrad			68×10^{-8} m^3/h	
	1000 Mrad			12×10^{-8} m^3/h	

[a] Units of $mg/10^6$ cycles except where otherwise stated.
[b] Weight gain.
[c] Details were not given in the report.
[d] Specimens were packaged in a polymer pouch with an air atmosphere.
[e] Specimens were in foil packages that were evacuated to a pressure of 1.8 kPa.
[f] After exposure to an accelerated aging regimen (70°C air at 0.51 MPa for 14 d).
[g] After aging (20 d at 80°C in air).

Table 9
Dynamic properties of crosslinked UHMWPE: results from selected literature reports

Resin and fabrication process	Crosslinking method details	Post-crosslinking treatment details	Izod impact strength (kJ/m^2)	ΔK inception value[a] ($MPa\,m^{1/2}$)	J integral[b] (kJ/m^2)	Reference
Ram extruded GUR 4150	Vacuum packed, sealed in pouches, and γ irradiated (5 Mrad)	Heated above the melt temperature of UHMWPE; slowly cooled; test rods machined, packaged and sterilized using gas plasma	76; 76[c]			DiMaio et al. [78]
GUR 4150HP	None: unirradiated	Not applicable		2.01; 1.80[c]		Baker et al. [80]
	None: gas plasma sterilized	Not applicable		2.01; 1.81[c]		
	None: ethylene oxide sterilized	Not applicable		1.90; 1.71[c]		
	None: γ irradiated in air (2.5 Mrad)	Not applicable		1.51; 0.90[c]		
	None: γ irradiated in a vacuum medium after flushing with N_2 gas (2.5 Mrad)	Not applicable		1.51; 1.50[c]		
Ram extruded GUR 4150HP	Specimens vacuum packed, sealed in pouches and γ irradiated (3 Mrad)	Heated above UHMWPE melt temperature and cooled slowly		1.30; 1.30[c]		Baker et al. [80]
		As above + gas plasma sterilization		1.30; 1.30[c]		
Ram extruded GUR 1050	Lupersol 101	Not applicable				
	As-processed			1.27; 1.19[c]		
	Gas plasma sterilized			1.26; 1.20[c]		
	γ irradiated in air (2.5 Mrad)			1.13; 1.04[c]		
	γ irradiated in a vacuum medium after flushing with N_2 gas (2.5 Mrad)			1.12; 1.22[c]		
GUR 4150HP	None: unirradiated	Not applicable			77	Gillis et al. [81,82]
	γ irradiation in air with a dose of	Stabilized (150°C; for 5 h)				
	2.5 Mrad				57	
	5.0 Mrad				45	
	10.0 Mrad				25	
	20.0 Mrad				20	
	50.0 Mrad				10	
	100.0 Mrad				8	
Ram extruded GUR 4150	None: unirradiated	Not applicable	101.5			McKellop et al. [17]
	γ irradiated in air with a dose of					
	4.5 Mrad	Remelted	87.1[d]; 89.3[e]			
	9.5 Mrad		59.9[d]; 68.7[e]			
	14.5 Mrad		50.6[d]; 58.7[e]			
	100.0 Mrad		17.3[d]; —[f]			
Ram extruded GUR 1050	Preheated to 120°C, and then electron beam radiated (15 Mrad)	Melt annealed	62			Muratoglu et al. [10,66]
GUR 1050	None: γ irradiated in air (2.5 Mrad)	Not applicable	67			Muratoglu et al. [10,66]

Table 9 *continued*

Resin and fabrication process	Crosslinking method details	Post-crosslinking treatment details	Izod impact strength (kJ/m^2)	ΔK inception value[a] ($MPa\,m^{1/2}$)	J integral[b] (kJ/m^2)	Reference
Resin not specified; compression molded	None	Not applicable	75.6			King et al. [97]
	Varox 130 (0.5 wt%)	Not applicable	83.3			
	Varox 130 (1.0 wt%)	Not applicable	67.7			
	Varox 130 (1.5 wt%)	Not applicable	71.1			
	γ irradiated (25 Mrad)	Heat stabilized for 3 h	35.7			
	γ irradiated (50 Mrad)	in air after onset of	28.7			
	γ irradiated (100 Mrad)	melting	20.2			
Ram extruded GUR 4150	None	Not applicable	100			DiMaio et al. [98]
	Packaged in heat-sealed foil/plastic pouches and γ irradiated with a dose of	Heat treated at 200°C for 48 h and cooled to slowly ambient temperature				
	2.5 Mrad		90			
	5.0 Mrad		80			
	15.0 Mrad		50			
	20.0rad		40			

[a] Mode I stress intensity factor range corresponding to a crack growth rate of 1×10^{-6} mm/cycle (tension–tension loading; $R = 0.1$).
[b] Value for average crack growth of 1 mm.
[c] After exposure to an accelerated aging regimen (heated in 70°C oxygen; 0.51 MPa; for 14 d).
[d] No remelting of specimens.
[e] Specimens were remelted (by heating in an oven in ambient air from room temperature to 150°C at 0.3°C/min held at 150°C, and then slowly cooled to room temperature in the oven for at least 5 h).
[f] Result was not given in the report.

Notwithstanding this realization, the matter has not been addressed adequately in the literature. It is true that a number of studies have focused on the effect of radiation dose, D or peroxide concentration, C, on various properties of UHMWPE (Tables 4–10). Among these, there are nine reports that include wear results [11,14,16,17,19–21,75,92]. In all of these referenced studies, except two, no explicit recommendations were made or inferred regarding the optimal value of D or C. The exceptions are the reports by Oonishi et al. [14] and Muratoglu et al. [20]. Oonishi et al. [14] stated: 'From several kinds of tribological findings, mechanical tests, and studies of long-term clinical findings, it is concluded that approximately 200 Mrad is the optimum dose of gamma radiation for clinical use in total hip prostheses'. Muratoglu et al. [20] concluded: 'The interrelation of wear rate with absorbed radiation dose showed a sigmoidal dependence. The wear rate dropped significantly up to 100–150 kGy, above which it reached a plateau'. Although the Oonishi et al. [14] study considered wear volume as well other properties in arriving at the quoted optimum radiation dose, their recommendation must be treated with caution. This is because the other properties determined were static or quasi-static ones in which unnotched specimens were used (namely, tensile elongation at failure, ultimate tensile strength, and hardness). Furthermore, Oonishi et al. [14] did not present any radiation dose versus in vivo wear results. In the present review, the wear rate results from five literature studies [11,16,19,21,75] are plotted (Figs. 3 and 4), from which tentative estimates of the 'best' value of D (D_b) ranging from 4 to 26 Mrad are obtained. The estimate of 4 Mrad, obtained using the Hamilton et al. [75] results, is very low and is unlikely to effect any appreciable crosslinking. Thus, it appears that for radiation-crosslinked GUR 4150 UHMWPE, C_b is about 16 Mrad. For chemical-crosslinked UHMWPEs, the tentative 'best' value of $C(C_b)$ for both the GUR 1050-peroxide (Varox 130) and Himont 1900-peroxide (Varox 130) systems is estimated to be 1.3 wt% (Fig. 5). It needs to be pointed out that the aforementioned D_b or C_b estimates are of limited value. This is because they are based on wear rate results only and do not take into account the effect of D or C on other properties of the crosslinked polymer that are considered relevant to its use for fabricating implant bearing components, such as fatigue, fatigue crack propagation rate, and fracture toughness.

The inadequacy of this approach is illustrated by considering the effect of D on the wear rate, (WR) and the J integral (a measure of fracture toughness) of GUR 4150 UHMWPE gamma radiation crosslinked in air and melt stabilized. In this case, with an increase in D, there is a marked decrease in WR [16], which of course, is

Table 10
Friction coefficient, f, of crosslinked UHMWPE[a] mean results

Resin and fabrication process	Crosslinking method and details	Post-crosslinking treatment and details	f when applied load =			Reference
			22 N	64 N	169 N	
RCH 1000	None: unirradiated	Not applicable	0.185	0.136	0.058	Shen and Dumbleton [92]
	γ irradiated in Ar with a dose of	NS[b]				
	20 Mrad		0.305	0.153	0.075	
	50 Mrad		0.295	0.150	0.071	
	100 Mrad		0.270	0.136	0.068	
	200 Mrad		0.258	0.154	0.066	
	500 Mrad		0.246	0.153	0.065	
	1000 Mrad		0.209	0.136	0.065	

[a]Tests carried out on a thrust washer wear tester; counterface was 316 stainless steel, with a surface roughness of 0.13 μm; no lubricant was used; rotational speed was fixed at 7.8 m/min; f was measured using a torque cell.
[b]Details were not given in the report.

Table 11
In vivo wear rate of uncrosslinked and crosslinked polyethylene acetabular cups: summary of literature results

Crosslinking methods	Femoral head details	No. of implants	Length of follow-up period (yr)	Mean steady-state wear rate (mm/yr)	Reference
None	28 mm diameter; Co–Cr alloy	15	7.0	0.247	Oonishi et al. [52]
γ irradiated (100 Mrad)	28 mm diameter; stainless steel (20% Co)	19	7.0	0.076	
None	28 mm diameter; alumina	71	7.0	0.098	
γ irradiated (100 Mrad)	28 mm diameter; alumina	9	7.0	0.072	
'Crosslinked'[a]	22.225 mm diameter; alumina	19	0.9–8.3	0.057[b]	Wroblewski et al. [43]
None	28 mm diameter; Co–Cr alloy; 0.5 μm surface roughness	10	6.0–23.0	0.29	Oonishi et al. [54]
γ irradiated in evacuated bags (100 Mrad)	28 mm diameter; Co–Cr alloy; 0.5 μm surface roughness	28	6.0–23.0	0.06	

[a]No further details were provided in the report.
[b]Penetration rate of head into cup.

desirable. However, the decrease in J integral with increasing D is equally dramatic [81,82], an undesirable situation. Indeed, Gillis et al. [82] remarked, 'The significant (up to 25 × reduction) of fracture toughness is a major concern as it may lead to fracture related failures not currently experienced with non cross linked material.' A true 'optimal' radiation dose, D_{opt} is, thus, one that leads to the best compromise between the drops in WR and the J integral. For this example, a plot of the literature results for the variation of WR and the J integral with D is presented in Fig. 6. If a decrease of 88% in WR (relative to the 'projected' zero-dose case) and a concomitant 55% drop in the J integral (relative to the zero-dose case) is accepted as the best compromise, then it is seen that D_{opt} is 7.5 Mrad.

5. Current status of commercially available crosslinked materials and bearing components

Five fully crosslinked UHMWPEs have been approved or are being evaluated by the Food and Drug

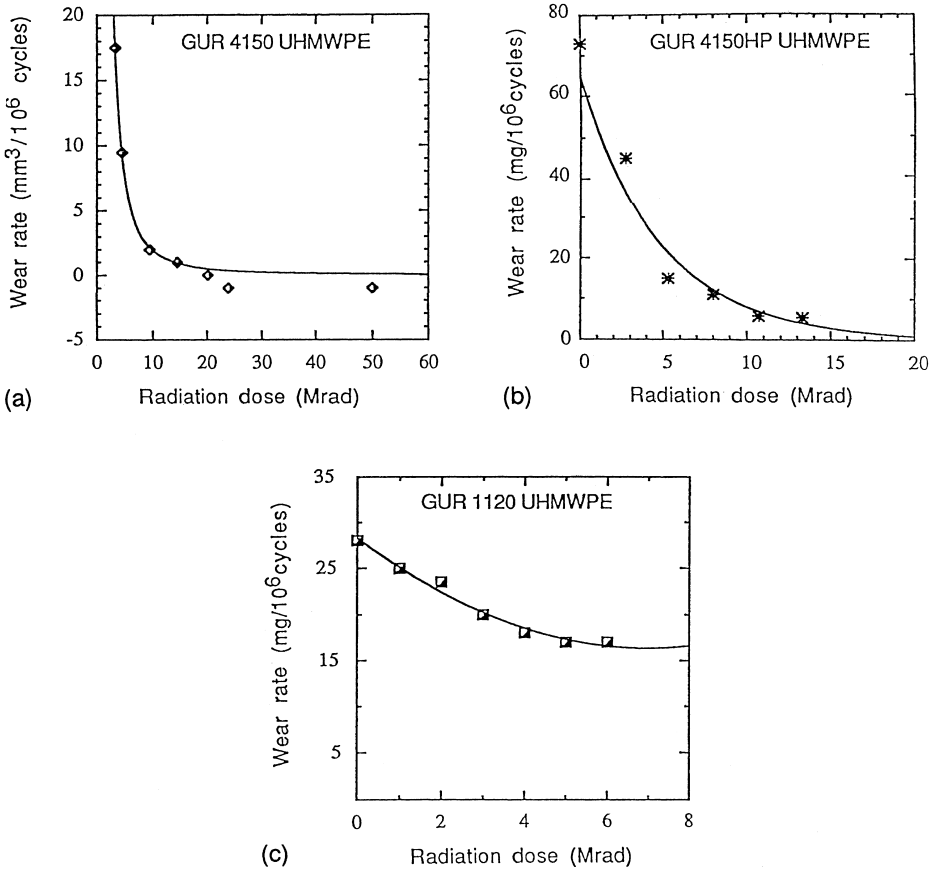

Fig. 3. The decrease in wear rate with increase in gamma radiation dose, as determined in a hip joint simulator, for (a) GUR 4150 UHMWPE acetabular cups, irradiated in air, and then remelted in air (data taken from results given in Ref. [16]); and (b) GUR 4150HP UHMWPE acetabular cups packaged in nitrogen and then irradiated (data taken from results given in Ref. [19]); (c) GUR 1120 UHMWPE acetabular cup liners packaged in evacuated laminates and then irradiated (data taken from results given in Ref. [75]).

Administration (FDA) for fabricating acetabular cups or liners. FDA 510(k) clearance has been given for the products Durasul™ (Sulzer Orthopaedics, Austin, TX, USA), Longevity™ (Zimmer, Inc., Warsaw, IN, USA), Crossfire™ (Stryker Osteonics, Allendale, NJ, USA), and Marathon™ (DePuy, Inc., Warsaw, IN, USA). The product being evaluated is an as-yet-unnamed product from Implex Corp. (Allendale, NJ, USA). For Durasul™, the crosslinking is induced by electron beam radiation, at an elevated temperature, with a dose of 9.5 Mrad [108]. Sulzer received FDA approval for commercial release of this material in February 1999, although Durasul™ acetabular cups were first implanted in December 1998 in patients in Boston, MA, USA, and Goteborg, Sweden [109,110]. There are two ongoing clinical studies of Durasul™ acetabular components, which are planned to run for a minimum of 10 yr [109]. In Longevity™, electron beam radiation is utilized for the crosslinking [111]. In Crossfire™, crosslinking is 'achieved through elevated doses of gamma irradiation' [112]. In the case of Marathon™, gamma radiation of between 5 and 7 Mrad is used [113]. In the Implex material, GUR 1020 UHMWPE is gamma irradiated (6–9 Mrad) in a dual vacuum package [86,114].

To date, one report has been published on the comparative in vitro wear rates of commercial crosslinked materials [115]. Muratoglu et al. [115] found that when acceleratedly aged (in an air convection oven at 80°C for 21 d), the mean wear rate (obtained using a bi-directional pin-on-disk machine, versus implant-finish Co–Cr counterface disk) of solid circular pins made of UHMWPE crosslinked using electron beam radiation (namely, Longevity™ and Durasul™) was 5 and 31% that of Crossfire™ and Marathon™, respectively (materials that are crosslinked using gamma radiation). For two reasons, these results should be taken as tentative as far as the true comparative in vitro performance of these four materials is concerned. First, the materials should also be compared on properties other than the wear rate; for example, fracture toughness and fatigue crack propagation rate. Second, wear tests should be conducted in both hip and knee

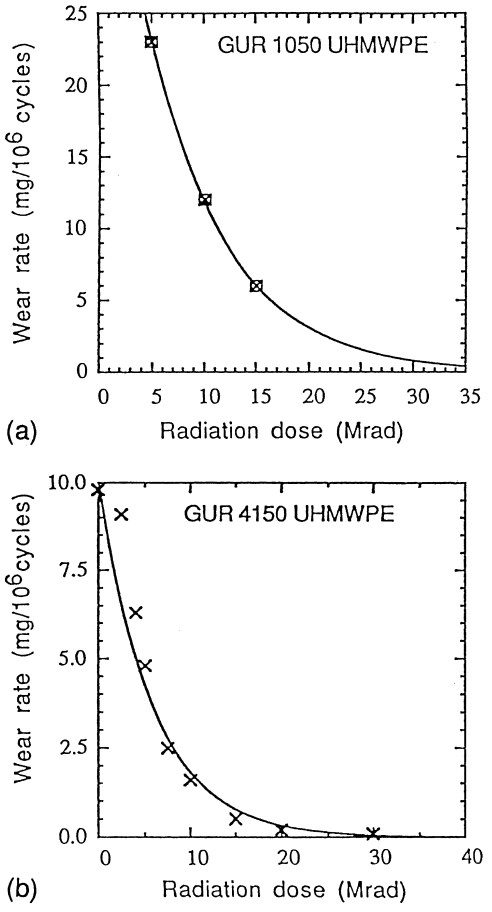

Fig. 4. The decrease in wear rate with increase in electron beam radiations dose for (a) GUR 1050 UHMWPE acetabular cups irradiated and then annealed in a vacuum oven (rate determined in a hip joint simulator) (data taken from results given in Ref. [11]); and (b) GUR 4150 specimens irradiated in air and then melt annealed (rate determined using a bi-directional pin-on-disk wear tester) (data taken from results given in Ref. [21]).

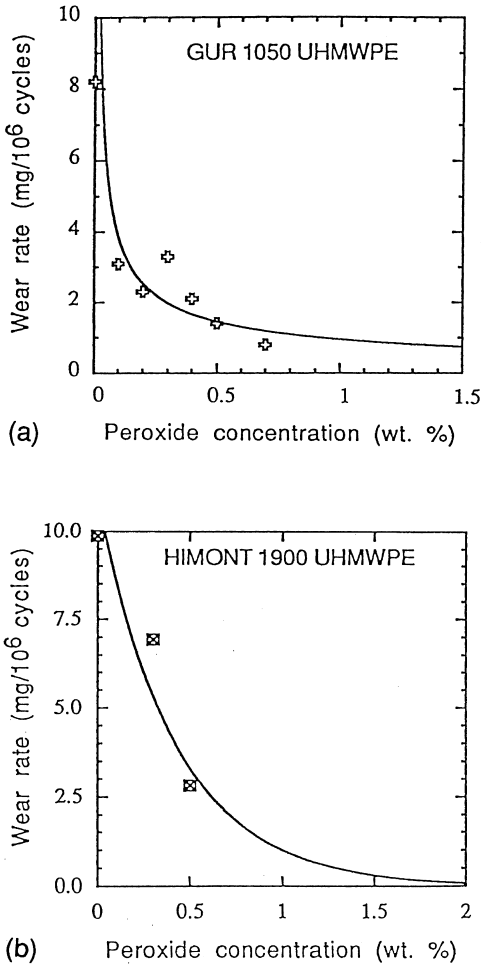

Fig. 5. The decrease in wear rate with increase in peroxide agent (Varox 130) concentration for specimens of (a) GUR 1050 UHMWPE and (b) Himont 1900 UHMWPE (data taken from results given in Ref. [21]).

simulators and include bearing components fabricated from sterilized but uncrosslinked UHMWPE as the controls.

Thus, at the present time, the relevant data are not available that would allow credible comments to be made on whether the anticipated benefits of using crosslinked UHMWPE being components have been achieved. Until such data become available, caution should be applied in recommending crosslinked components. As Rapp [116] has noted: 'The question concerning how crosslinked polyethylene will behave in the body with long-term uses has yet to be answered. It may reduce wear and lysis over time, or it may not. Therefore, crosslinked polyethylene should be viewed as any other material lacking long-term in vivo data. No one knows how these materials will perform in the long-term'.

6. Areas for future research

From the data in Tables 4–10, it is seen that the effectiveness of crosslinking (vis a vis its impact on polymer properties) is resin- and process-dependent. In addition, it is known that the in vivo wear rate of uncrosslinked UHMWPE implant bearing components is affected by fabrication method (that is, ram extrusion versus compression molding versus direct molding) [29,38]. Thus, strictly speaking, to ensure that excellent in vivo results are obtained with crosslinked polymeric bearing components (that is, ones that simultaneously have a very low wear rate and appropriate levels of other relevant properties), it would be necessary to identify an array of parameters. Four of these parameters are: the most influential polymer characteristic(s), the best component fabrication method, the best crosslinking process,

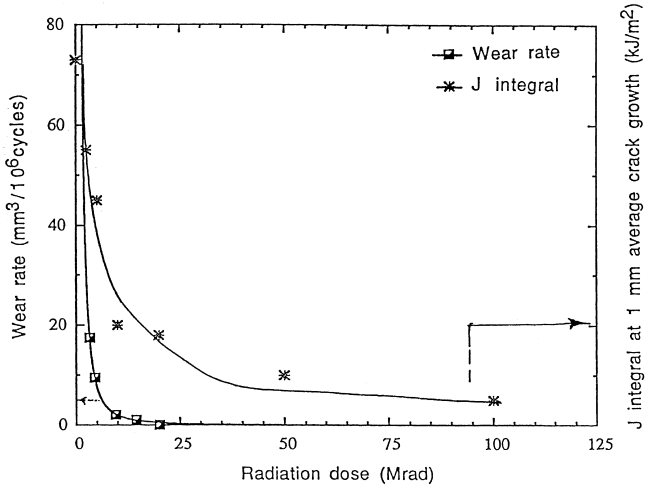

Fig. 6. The decrease in wear rate and fracture toughness (J integral) with increase in radiation dose for gamma-irradiated and melt-stabilized UHMWPE specimens [wear data are for GUR 4150 specimens, and are taken from McKellop et al. (data taken from results given in Ref. [16]); J integral data are for 4150HP specimens, and are taken from Gillis et al. (data taken from results given in Refs. [81] and [82]).

and the combination of optimal values of all the variables in this 'best' crosslinking process.

From the results of in vitro wear tests on crosslinked UHMWPE specimens, Spiegelberg et al. [88] have suggested that the most important polymer characteristic is its polydispersity index, PDI. These workers reported a statistically significant inverse relationship between the PDI and the crosslink density, v, of a crosslinked polymer ($r^2 = 0.91$; $p = 1 \times 10^{-4}$); that is, v of a crosslinked polymer increases as the polymer's PDI decreases (that is, the molecular weight distribution of the polymer narrows). For crosslinked UHMWPE, Muratoglu et al. [21] have shown that there is a positive linear correlation between molecular weight between the crosslinks (MW_c) of the polymer and the in vitro wear rate of specimens made from it. These relationships thus indicate that low in vitro wear rate of crosslinked UHMWPE specimens is associated with low values of the polymer's PDI and MW_c. To date, no work has been reported on the issue of the effect of fabrication method for a crosslinked component on its wear rate and other properties. To date, work on the effect of process variables on crosslinked polymer properties that may be important vis a vis the subsequent in vivo wear rate of polymer implant bearing components (hereafter referred to as 'germane crosslinked polymer properties') is inadequate. There are a myriad of these variables (Table 12), and only a few have been the subject of research, examples being the dose in radiation-induced crosslinking [11,16,19, 21,75,81,82] and the peroxide concentration in chemical-induced crosslinking [21]. In these studies, the issue of optimality, as explained in Section 4, has not been addressed.

Although many conditions have been used in literature hip simulator wear studies on crosslinked UHMWPE components (Table 13), the issue of the impact of joint simulator conditions on the wear resistance of crosslinked UHMWPE components has not been addressed. In this respect, there are four critical factors to consider.

The first is the use of simulator conditions that would be conducive to producing two-body abrasive wear on the UHMWPE component under test. Oblique scratches have been observed on retrieved femoral components of total knee arthroplasties (TKAs), with the maximum angles relative to the articulation direction being, typically, 30° [117]. It has been hypothesized that in TKAs, the scratched femoral component (two-body wear) contributes to wear of the UHMWPE tibial inserts [118]. Thus, if wear results obtained in a knee joint simulator are to have clinical relevance, the femoral component should be scratched in an oblique manner. This may be achieved by applying the proper motion cycles, which could be identified through, for example, fluoroscopic measurements on patients with TKAs.

The second aspect to consider is the use of simulator conditions that would be conducive to producing three-body abrasive wear on the UHMWPE component under test. Three-body wear results from the presence of particles other than those originating from either the UHMWPE or the surface of the counterface bearing member. Examples are bone cement particles (in the case of cemented arthroplasties), particles sheared off from porous-coated sections (in the case of cementless arthroplasties), and bone chips. In a hip joint simulator study, Polineni et al. [119] showed that the presence of Surgical Simplex® P acrylic bone cement particles (of size $162.3 \pm 127\,\mu m$) at the articulating junction between an uncrosslinked GUR 1020 UHMWPE cup and a 32-mm-diameter Vitallium® (a Co–Cr alloy) femoral head led to a 300% increase in the wear of the cup, relative to the case when no bone cement particles are present. The trend seen in the Polineni study [119] was consistent with that found in a clinical study by Minakawa et al. [120] on the in vivo wear of uncrosslinked polyethylene acetabular cups. In the case of radiation-induced crosslinked and re-melted UHMWPE cups, McKellop et al. [121] demonstrated the influence of Co–Cr alloy femoral head roughness on its wear rate (WR) in a hip joint simulator. They found, for example, that following exposure to an accelerated aging environment (oxygen gas; 70°C; 507 kPa pressure; 14 d), WR when the heads were extremely rough (mean roughness, $R_a = 0.9 \pm 0.02\,\mu m$) was, on average, 213% higher than when highly polished ($R_a = 0.05 \pm 0.01\mu m$) heads were used.

The third aspect to consider is the protein concentration of the lubricant, L. Wang et al. [122] have shown

Table 12
Key process variables in radiation-induced and chemical-induced crosslinking methods and associated post-crosslinking methods

Variable	Gamma radiation-induced crosslinking method	Electron beam radiation-induced crosslinking method	Peroxide-induced crosslinking method
Specimen temperature prior to radiation exposure	✓	✓	—[a]
Specimen temperature during radiation exposure	✓	✓	—
Specimen package environment during radiation exposure	✓	✓	—
Radiation dose	✓	✓	—
Post-irradiation process conditions			
Environment	✓	✓	—
Temperature	✓	✓	—
Time	✓	✓	—
Free-radical-generating chemical	—	—	✓
Concentration of free-radical-generating chemical	—	—	✓

[a]Not applicable.

that, for the GUR 4150 UHMWPE acetabular cup versus 32-mm-diameter Co–Cr femoral head system, the UHMWPE wear rate peaks at $L = 10\,\text{mg/ml}$, with further increases in L leading to a gradual drop in the wear rate. These workers thus suggest that when bovine serum is used as part of the lubricant mixture in wear tests in joint simulators, it should be diluted to about 50%.

The fourth aspect to consider involves the details of the load applied to the UHMWPE component–counterface pair. In discussing the reason as to why in vivo results for Hylamer® acetabular cup liners, as reported by Livingston et al. [30], were so much higher than the hip simulator wear results with acetabular cups that were reported by McKellop et al. [123], Poss and Spector [124] pointed out that a question to pose is 'whether the in vitro testing adequately replicated all of the forces imposed on polyethylene during activities of daily living'.

Based on the findings in the present review, four key areas for future research are identified.

The first key area is the performance of more detailed systematic in vitro studies. Many studies are needed on the effect of starting resin (for a given set of specimen fabrication method and collection of process variables in a given crosslinking method) on the wear rate and germane crosslinked polymer properties. Second, more detailed systematic in vitro studies are needed on the effect of specimen fabrication method (for a given starting resin and collection of process variables in a given crosslinking method) on the wear rate and germane crosslinked polymer properties. Third, more detailed systematic in vitro studies are needed on the effect of the collection of process variables in a given crosslinking method (for a given starting resin and specimen fabrication method) on the wear rate and germane crosslinked polymer properties.

Three points must be borne in mind in designing and performing the aforementioned collection of detailed systematic in vitro tests. First, all wear testing should be performed in joint simulators whose regime includes aspects that take into account all the four points made above in discussing conditions in current literature joint simulator studies. Second, silane-crosslinked specimens must be included, as there is a dearth of current literature studies on these materials, on omission that is particularly troublesome in the light of two facts. One, recent tribological data point to their acceptable in vitro wear rate [60]. Two, it has recently been revealed [125] that the acetabular cups that were the subject of a clinical study that presented very favorable results [43] were fabricated from silane-crosslinked HDPE. The third point to note is that all the studies recommended here must include tests on the germane polymer properties; especially, fatigue, fatigue crack propagation (FCP), and fracture toughness. The rationale for this suggestion is the disastrous in vivo performance of PolyTwo™ (carbon fiber-reinforced UHMWPE) acetabular cups, which was presaged by poor in vitro FCP results [126].

A careful examination of the vast database that will be created from the results of these detailed systematic in vitro studies should lead to the identification of the optimal combination of starting resin, specimen fabrication method, crosslinking process, and crosslinking process variables.

The second key area for future research is the detailed systematic in vitro wear evaluation of crosslinked bearing components that, in vivo, are subjected to nearly unidirectional motion; an example is tibial inserts. This type of work is important in the light of results that show that radiation-induced crosslinked UHMWPE tibial inserts display poor wear resistance when subjected to

Table 13
Joint simulator wear test conditions: summary of selected literature reports

Femoral head diameter, material, and roughness	Lubricant details	Applied loading profile details	Maximum number of test cycles (million)	Reference
22.225 mm; alumina	Deionized water at 37°C	Paul-type loading; frequency of 1 Hz	7.3	Wroblewski et al. [43]
NS[a]	Calf serum at 37°C	'Physiologic' conditions of gait and associated loads; ± 23° of flexion/extension; ± 10° external/internal rotation; ± 8.5° abduction/adduction	2.8	Jasty et al. [69]
Co–Cr alloy	Bovine serum	Double-peaked physiological Paul-type hip load; P_{max}[b] = 2000 N; cup oscillated through a biaxial 46°C arc at ~ 1 Hz	NS	McKellop et al. [16,17]
Co–Cr alloy	Triple-filtered bovine calf serum + 0.1% sodium azide + 20 mM EDTA + 30% distilled water	Paul loading curve; P_{max} = 2500 N; 1 Hz	3	Edidin et al. [19]
NS	NS	'Physiologic conditions of gait' loading	12	Bragdon et al. [61]
22 and 32 mm Co–Cr alloy	Bovine serum at 37°C	'Simulated gait' loading; 2 Hz	5	Bragdon et al. [68]
28 mm; Co–Cr–Mo alloy; R_a[c] < 0.025 μm	Bovine calf serum + EDTA[d]	Paul loading curve; 1 Hz; P_{max} = 3000 N	NS	St. John et al. [86]
32 mm; Co–Cr–Mo alloy	Bovine serum	P_{max} = 3190 N; 1 Hz	NS	Bhambri et al. [117]
32 mm; Co–Cr; highly polished	Bovine serum + 0.2% sodium azide + 20 mM EDTA	Load applied at 1 Hz; P_{max} = 200 N; PE cup oscillated through a 46° biaxial arc at 1.13 Hz	NS	Shen et al. [99]
28 mm; alumina	Saline solution	Head ball was rotated around the longitudinal axis ± 10° at 0.44 Hz; socket was swung ± 20° at 0.44 Hz. Constant perpendicular load = 2452 N	NS	Oonishi et al. [13]
Alumina	30% bovine serum + additives of EDTA and sodium azide at 33–37°C	'Physiological' load profile; P_{max} = 2000 N; frequency = 1 Hz	NS	Clarke et al. [15]
32 mm; Co–Cr	Bovine serum	'Physiological' load profile	7	Shen et al. [18]
32 mm; Co–Cr; R_a = 0.02 or 0.20 μm	21 g/l bovine calf serum + 20 mM EDTA	Paul-type load; P_{min}[e] = 50 N; P_{max} = 2450 N; 1 Hz	NS	Essner et al. [104]
NS	Calf serum at 37°C	'Physiologic' load profile; ± 23° of flexion/extension; ± 10° external;/internal rotation; ± 8.5 abbuction/adduction	2.7	Jasty et al. [70]

[a] Details were not given in the report.
[b] Peak load.
[c] Mean surface roughness.
[d] Ethylene-diamine tetraacetic acid.
[e] Minimum load.

nearly unidirectional motion in a knee joint simulator [127].

Efforts in the third key future research area must focus on conducting many prospective, multi-center, randomized, and long-term clinical studies on various kinds of arthroplasties (for example, hip, knee, and shoulder total joint replacements) that include crosslinked polymer bearing components. A detailed characterization of these components, when retrieved at autopsy or revision, should contribute to a delineation of the role of starting resin, fabrication method, crosslinking process, and crosslinking process variables on bearing component in vivo wear rate. The significance of this aspect cannot be emphasized enough, especially in the light of the less-than-stellar in vivo performance of bearing components fabricated from UHMWPEs that were presented as being 'improved' (namely, Hylamer® and Hylamer-M™) [30,45].

As stated in Section 1, the issue of post-crosslinking stabilization and sterilization methods and their impact on the properties of crosslinked biopolymers is outside the ambit of the present review. It is to be noted, however, that these methods are likely to exert a significant influence on the subsequent in vivo performance of the crosslinked component. Furthermore, an assortment of such methods is used for the crosslinked UHMWPE bearing components that are currently being used or are planned to be used clinically. (For example, Durasul™ parts are 'subsequently heat-treated at 150°C' and cooled, and ethylene oxide is used for their sterilization [108]; Longevity™ parts are 'heated to a temperature above the polymer's crystalline melting point and… …then cooled', and gas plasma is used for their sterilization [111]; and Marathon™ parts are heated in a nitrogen gas-purged oven to 155°C for 24 h and then cooled slowly, and they are sterilized using gas plasma [113]). In the light of these points, the fourth key future research area should be performance of detailed systematic studies of the effect of post-crosslinking stabilization and sterilization methods and the associated variables on the in vitro wear rate, germane polymer properties, and in vivo were rate of crosslinked bearing components.

Table 14
'Mean of the means' and 'standard deviation of the means' of six properties of uncrosslinked[a] and crosslinked[b] UHMWPE

Property	Uncrosslinked UHMWPE	Crosslinked UHMWPE
% crystallinity[c]	53.6[d] ± 6.2[e]	45.3 ± 5.3
Melting temperature (°C)	139.0 ± 3.3	135.8 ± 5.6
Yield strength (MPa)	25.6 ± 3.3	21.1 ± 2.5
Ultimate tensile strength (MPa)	48.7 ± 7.5	29.3 ± 7.7
Tensile modulus of elasticity (MPa)	915 ± 423	860 ± 206
Tensile elongation at fracture (%)	317 ± 140	212 ± 61

[a]Averaged over a wide range of resins, specimen fabrication methods, and sterilization methods [128].
[b]Averaged over a wide range of resins, specimen fabrication methods, crosslinking methods, and post-crosslinking processes.
[c]At the surface of the specimen.
[d]'Mean of the means'.
[e]'Standard deviation of the means'.

7. Summary

The following is a summary of the main findings of this work:

(1) Many physical, thermal, and mechanical properties of radiation- and chemical-induced crosslinked UHMWPE have been determined in in vitro tests, from which it is clear that crosslinking leads to a decrease in this polymer's wear rate. For each of the other six key properties, a 'mean of the means' value for UHMWPE (based on the database presented in Tables 4–10) has been calculated and these values are presented in Table 14. Also included in this table, for comparison, are the corresponding values for sterilized but uncrosslinked UHMWPE. It is seen that crosslinking causes a depreciation in each of the properties examined, with the drop appearing to be dramatic for ultimate tensile strength and tensile elongation at fracture (30–40% drops are noted here).
(2) The literature on crosslinked UHMWPE contains many omissions. Thus, no reports have appeared on the properties of silane-crosslinked material, nor have third-body particles been included as part of the wear regimen in any reported in vitro wear tests. No systematic study of the effect of crosslinking on the in vivo performance of UHMWPE bearing component has been reported. Furthermore, very few reports have appeared on the effect of crosslinking on the polymer's in vitro fatigue, fatigue crack propagation rate, and fracture toughness properties.
(3) On the basis of the literature wear rate and fracture toughness results for gamma radiation-induced crosslinked and melt-stabilized GUR 4150 UHMWPE, the optimal dose for this polymer is estimated to be 7.5 Mrad. The gamma radiation dose used for Crossfire™ (which is a gamma radiation-induced crosslinked UHMWPE that has been approved by the US Food and Drug Administration, FDA) is proprietary information. Thus, no direct comparison can be made between that level and the optimal dose estimate reported here. The present estimate is however, within the value used in crosslinking Marathon™ (an FDA-approved UHMWPE) and the UHMWPE, produced by Implex Corp., that is currently under review by the FDA.
(4) Four areas for further research are identified, all of them designed to lead to recommendations regarding the mix of parameters to be used in the fabrication of crosslinked UHMWPE bearing components (namely, starting resin, fabrication method, crosslinking process, and optimal values for the crosslinking process variables) that may result in their excellent in vivo performance.

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