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THE EFFECT OF FLUID ENVIRONMENT AND CRACK CLOSURE ON THE FATIGUE CRACK PROPAGATION RESISTANCE OF CONVENTIONAL AND HIGHLY CROSSLINKED UHMW POLYETHYLENES FOR ORTHOPAEDIC IMPLANTS

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ABSTRACT

Fatigue related damage and fracture of ultra high molecular weight polyethylene (UHMWPE) components are two major causes for reduction in life of total joint replacements. Highly crosslinked UHMWPEs exhibit improved wear resistance but worse fracture resistance compared with conventional UHMWPE materials. Most fatigue fracture studies have been conducted under ambient air conditions. Little information is available on fatigue crack inception and propagation resistance of UHMWPE in a more physiologically relevant fluid body temperature environment. The objective of this study was to determine the effect of a 37°C phosphate buffered saline (PBS) environment on the fatigue crack propagation resistance of UHMWPE. Three UHMWPE materials, conventional (30kGy gamma sterilized in nitrogen), crosslinked/annealed (100kGy, 130°C), and crosslinked/remelted (100kGy, 150°C) were examined. Disk shaped compact tension specimens were tested in ambient air and in 37°C PBS at $R = 0.1$. To obtain a conservative estimate of fatigue crack inception resistance in the threshold regime, the presence of crack closure was also investigated. Crack closure was measured using a novel near crack tip opening displacement technique. It was found that in PBS at 37°C, the resistance to fatigue crack inception and propagation is reduced for conventional and highly crosslinked UHMWPEs. This study indicates that UHMWPE implants are likely to be less resistant to fatigue crack inception and propagation than might be expected from tests conducted in ambient air. This study also found that $\Delta K_{inception}$ obtained from fatigue tests conducted in PBS at 37°C is free from closure and therefore can be considered conservative for design purposes.

KEYWORDS
UHMWPE, fatigue crack propagation, fatigue crack inception, crosslinked polyethylene, crack closure

INTRODUCTION

Ultra high molecular weight polyethylene (UHMWPE) components frequently compose one-half of the articulating bearing couple in total joint replacements. UHMWPE has high impact strength, a low coefficient of friction, good abrasion wear resistance and biocompatibility in the bulk form; these characteristics have made it an excellent material for joint replacement bearing surfaces against metallic or ceramic counterfaces for more than forty years [1]. However, in-vivo damage of UHMWPE components can significantly reduce the life of a total joint replacement. Implant retrieval analysis indicates that the severity of damage increases with implantation time and patient weight [2]. Such studies are suggestive that certain forms of damage, namely pitting and delamination, are related to cyclic loading [3]. It is believed that cracks propagate due to cyclic tensile and compressive stresses acting on and below the bearing surface [4]. Thus, wear damage of UHMWPE is influenced by its fatigue fracture properties. Gross fracture due to fatigue crack growth is also a concern with UHMWPE joint replacement components [5]. Fatigue studies of one acetabular cup design that had fractured in-vivo indicated significantly increased risk for structural failure [6].

Because of favorable results from both simulator wear studies and clinical reports [7-10], highly crosslinked UHMWPE formulations have been introduced for use in total hip and total knee replacements [1]. However, crosslinking of UHMWPE, while beneficial for wear resistance, is detrimental to its static and cyclic fracture resistance [11-15]. Thus, the potential for gross fracture of highly crosslinked UHMWPE components has been a concern [16].

Except for a few studies [17-19], most static and fatigue fracture studies on UHMWPE have been performed in ambient air (room temperature) conditions. The mechanical properties, including fatigue resistance, of polymers are temperature dependent and environment dependent [20-22]. For UHMWPE, the monotonic compression behavior in air has been reported to be significantly different at room temperature compared with body temperature (37°C) [23]. In addition, fluid absorption studies of UHMWPE indicate that the steady-state rate of fluid absorption is lower in highly crosslinked compared with conventional (not crosslinked or lightly crosslinked from gamma radiation sterilization) UHMWPE; and, the absorption rate at 37°C is twice that at room temperature [24]. Therefore, the fatigue crack propagation behavior of UHMWPE at 37°C and in a fluid environment would be expected to be different from that under ambient conditions.

Another factor that might be expected to alter the fatigue crack propagation behavior of UHMWPE is crack closure [25]. Crack closure refers to premature contact between crack faces during cyclic loading. Crack closure reduces the cyclic stress intensity ΔK at the crack tip; if not taken into account, the fatigue crack propagation behavior in the threshold regime can be overestimated [25]. Crack closure has been observed in some polymers and fiber reinforced plastics [26-30]. In test specimens like the compact tension specimen, crack closure may be more pronounced than in structures which experience more constrained conditions. Therefore, to obtain a conservative estimate of fatigue crack propagation in the threshold regime using laboratory specimens, the potential role of crack closure in UHMWPE materials during fatigue crack propagation should be investigated.

We hypothesized that in a physiologically relevant fluid environment at 37°C, the fatigue crack inception and propagation resistance of UHMWPE would be significantly reduced as compared to that in an ambient air environment. We also hypothesized that conventional and highly crosslinked UHMWPEs would be affected differently by a 37°C fluid environment, relative to ambient air. Accordingly, the objective of this study was to examine the fatigue crack inception and propagation behavior of conventional and highly crosslinked and thermally treated UHMWPEs in phosphate buffered saline at 37°C. The presence of crack closure and its influence on the fatigue properties was also investigated.

MATERIALS AND METHODS

Three treatment groups, one conventional (gamma radiation sterilized with 30kGy in nitrogen; “sterilized”) and two highly crosslinked (crosslinked with 100 kGy of gamma radiation) were tested. All three groups were made from ram extruded, orthopaedic grade, GUR 1050 UHMWPE (Perplas Medical, Lancashire, UK). The material was obtained in the form of cylindrical rods of diameter 55mm and length 510mm. One highly crosslinked group underwent post irradiation thermal processing below the melt temperature (130°C; “annealed”) and the other underwent thermal processing above the melt temperature (150°C; “remelted”). The material was stored at -20°C until machining.

Disk shaped compact tension specimens were machined from transverse cross-sections of the extruded rod such that the crack would propagate in the transverse plane of the rod. Specimen dimensions were selected as per ASTM E399 [31] and ASTM E647 [32]. Width (W) and thickness (B) of the specimen were 40 mm and 10mm respectively. The initial normalized crack length (a/W) was 0.35. For better visualization of the crack tip, the specimen surfaces were polished using a mechanical grinder/polisher (Ecomet 6, Buehler, Lake Bluff, IL). The polished specimens were precracked by pressing a razor blade into the notch using a controlled displacement rate (0.06 mm/min); this method has been found to minimize damage at the crack tip [33]. In this manner, a 2 mm long precrack was introduced. After razor sharpening, all the specimens fell in the ASTM E647 prescribed range of $0.35 < a/W < 0.55$. Specimens were stored at -20°C until testing.

Specimens were tested in a servo-hydraulic closed loop materials testing machine (Instron 8501, Canton, MA) in two environments: ambient air ($n = 3$/group) and a phosphate buffered saline (PBS) bath ($n = 2$/group) at 37°C. Dulbecco’s phosphate buffered saline with Ca and Mg (Mediatech, Inc, Herndon, VA) was used. This PBS solution provides an ionic strength similar to normal joint fluid (0.138 M NaCl and 0.0027 M KCl) [34]. Specimens tested in the PBS bath were first soaked in PBS at 37°C for 2 to 4 weeks. Specimens were kept submersed in a PBS bath maintained at 37°C throughout testing.

Crack length was monitored using a visual method both for the specimens tested in ambient air and in the PBS bath. Visual crack length measurements were obtained using a traveling microscope with a resolution of 0.01mm (Gaertner Scientific Corporation, Chicago, IL). The specimens were cyclically loaded under constant load range (ΔP), R-ratio (P_{min}/P_{max}) of 0.1, and a sinusoidal waveform at a frequency of 4 Hz. ΔP was chosen such that the threshold regime could be obtained. The crack tip was cooled by an air jet throughout the testing to minimize hysteretic heating in the ambient air specimens. All the ambient air specimens were tested at 23-24°C. The fatigue crack growth rate (da/dN, mm/cycle) was calculated using the secant method [32]. The cyclic stress intensity (ΔK) was calculated using $\Delta K = (\Delta P/B\sqrt{W})f(a/W)$ where ΔP is the load range, B is the specimen thickness, W is the specimen width, and $f(a/W)$ is a geometrical correction factor (a is the crack length) [32]. Linear regression analysis was performed in the Paris regime ($da/dN = C(\Delta K)^m$, $da/dN > 10^{-4}$mm/cycle) of the da/dN versus ΔK curve. The exponent (m) and the coefficient (C) of the Paris relationship were determined for each specimen. Statistical comparisons of exponent and coefficient between material groups and testing environment were performed using the linear test method ($p < 0.05$ taken as significant) [35]. Fatigue crack growth in the threshold regime was also evaluated, using $\Delta K_{inception}$, the ΔK required to produce a da/dN of 10^{-6} mm/cycle [17]. In this study, $\Delta K_{inception}$ was determined either at 10^{-6} mm/cycle when available or estimated from the da/dN versus ΔK data.

Crack closure was evaluated using a novel near crack tip displacement method. Crack closure was evaluated in the threshold regime for all three treatment groups (n=1/group). Specimen dimensions and preparation were the same as that described above. Specimens again were subjected to constant load range (ΔP) loading. Crack closure measurements were performed 3-5 times for each specimen intermittently by interrupting the cyclic loading. During the crack closure measurement the specimen was subjected to constant load range (ΔP) cyclic loading at a frequency of 0.05Hz and R ratio of 0.1. To prevent creep during the closure measurement, a triangular waveform was used. During cyclic loading, the crack tip was recorded at 45X magnification using a traveling microscope and a CCD camera connected through an adapter (Figure 1). Images were acquired at 30 frames per second. The recorded *.avi files were processed by a matlab routine to compute crack tip opening displacement (CTOD) at distances of 0.1 and 0.5mm behind the crack tip. A

CTOD resolution of 0.004 mm was achieved by this method. Normalized load versus CTOD curves were obtained during the unloading part of the closure measurement cycle. (normalized load = applied load / maximum load). A change of slope in the normalized load versus CTOD curve was considered to indicate the presence of crack closure [25].

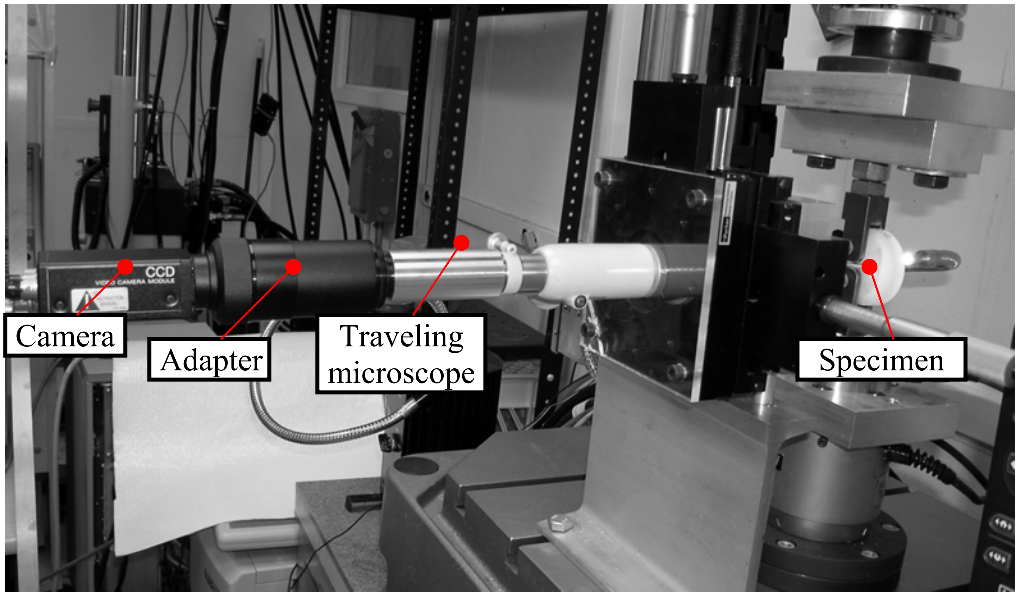


Figure 1: Experimental setup to measure crack closure.

RESULTS

For each material group, the exponent (m) and the coefficient (C) did not vary significantly between specimens; thus, the data from specimens for a given material were pooled (Table 1). In both environments, the two highly crosslinked materials demonstrated a significantly lower exponent (m) and coefficient (C) in the Paris regime compared to the sterilized material ($p=0$); the overall result was a reduced resistance to fatigue crack propagation of the two highly crosslinked materials compared with the sterilized material (Figure 2). The annealed and remelted materials had significantly different coefficient (C) ($p = 0.0$) in both environments (Table 2). With respect to the exponent (m), the annealed and remelted materials were significantly different ($p = 0.0$) in ambient air but not significantly different ($p = 0.5$) in the 37°C PBS bath (Table 2). The overall result was a reduced resistance to fatigue crack propagation of the remelted material compared to the annealed material. The sterilized material exhibited a significant increase (14%) in exponent (m) from the ambient air to the 37°C PBS bath (Tables 1, 3). In contrast, the exponent (m) was not significantly different between the two environments for the highly crosslinked materials (Table 3). In the 37°C PBS bath, all three materials showed a significant decrease in coefficient (C) compared to ambient air (Tables 1 and 3, Figure 2).

In both ambient air and the 37°C PBS bath, the highly crosslinked materials (annealed and remelted) had reduced fatigue crack inception ($\Delta K_{inception}$) when compared to the sterilized material (Table 1, Figure 2). $\Delta K_{inception}$ of the annealed and remelted highly crosslinked materials was 30% and 43% lower, respectively, compared to the sterilized material in ambient air and 35% and 46% lower, respectively, compared to the sterilized material in the 37°C PBS bath. In the 37°C PBS bath, $\Delta K_{inception}$ was reduced by 17%, 23% and 22% for the sterilized, annealed and remelted materials, respectively, compared to ambient air.

TABLE 1

Exponent (m), coefficient (C) for $da/dN = C(\Delta K)^m$ and $\Delta K_{inception}$ for the UHMWPE materials.

	Sterilized (30kGy in Nitrogen)		Annealed (100kGy, 130°C)		Remelted (100kGy, 150°C)	
	23°C air	37°C PBS	23°C air	37°C PBS	23°C air	37°C PBS
m	9.48	10.85	8.22	7.82	6.87	7.21
$C(\text{mm/cycle})/(\text{MPa}\sqrt{\text{m}})^m$	1.87×10^{-7}	6.02×10^{-7}	1.06×10^{-5}	5.47×10^{-5}	5.14×10^{-5}	3.22×10^{-4}
$\Delta K_{inception}(\text{MPa}\sqrt{\text{m}})$	1.59	1.32	1.12	0.86	0.91	0.71

TABLE 2

Effect of material type on exponent (m), and coefficient (C) for the UHMWPE materials.

		P-values			
Environment		Exponent (m)		Coefficient (C)	
		Annealed	Remelted	Annealed	Remelted
23°C air	Sterilized	0.0	0.0	0.0	0.0
	Annealed		0.0		0.0
37°C PBS	Sterilized	0.0	0.5	0.0	0.0
	Annealed		0.0		0.0

TABLE 3

Effect of testing environment on exponent (m), and coefficient (C) for the UHMWPE materials.

	P – values (23°C air vs 37°C PBS)	
	Exponent (m)	Coefficient (C)
Sterilized	0.0	0.0
Annealed	0.26	0.0
Remelted	0.25	0.0

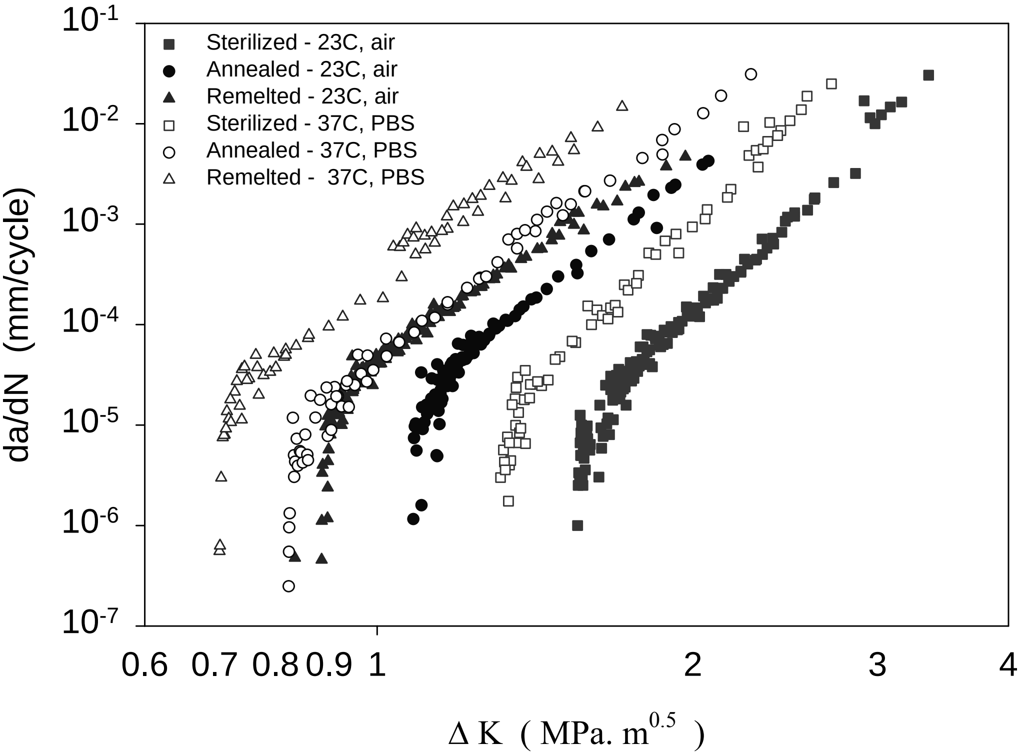
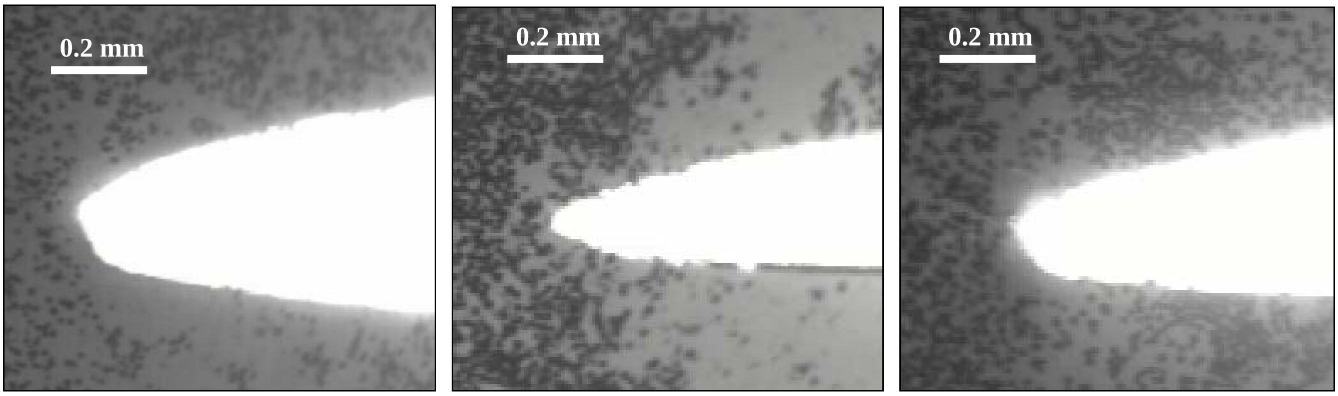


Figure 2: da/dN vs ΔK for sterilized and highly crosslinked (annealed and remelted) UHMWPE materials in ambient air (solid symbols) and in a 37°C PBS bath (open symbols).

Crack closure was measured intermittently in the da/dN range of 3.5×10^{-7} to 3.8×10^{-6} mm/cycle for the sterilized material. For the annealed and remelted materials, the closure measurement was performed in the da/dN range of 9.1×10^{-7} to 1.2×10^{-6} mm/cycle and 5.7×10^{-7} to 4.4×10^{-6} mm/cycle, respectively. CTOD measurements during unloading and loading showed similar trends at 0.1 and 0.5 mm behind the crack tip. Review of crack tip video revealed blunting of the crack tip for the sterilized and both highly crosslinked materials during loading. However, the crack tip of the sterilized material was qualitatively observed to blunt more than the highly crosslinked materials. No crack closure was observed visually in the da/dN range of observations (Figure 3). In addition to the visual observations, the normalized load versus CTOD curves did not show any indication of an opening load (Figure 4); the results support that the three UHMWPE materials do not exhibit crack closure behavior under the present testing conditions.

DISCUSSION

This study demonstrated that in a 37°C PBS bath, fatigue crack propagation resistance is decreased in sterilized and highly crosslinked (annealed and remelted) UHWMPEs compared to that in an ambient air environment. The results of this study therefore support our first hypothesis that, in a physiologically relevant fluid environment at 37°C, the fatigue crack propagation resistance of UHMWPE would be significantly reduced as compared to that in an ambient air environment. We also hypothesized that conventional and highly crosslinked UHMWPEs would be affected differently by a 37°C fluid environment, relative to ambient air. The results of this study also support this hypothesis: the sterilized material had a significantly higher exponent in the 37°C PBS bath compared to ambient air whereas the exponent was unaffected by environment for the two highly crosslinked materials. In addition, there was a greater decrease in $\Delta K_{inception}$ for the two highly crosslinked materials (> 20%) than for the sterilized material (< 20%) from ambient air to the 37°C PBS bath. Finally, we found that crack closure does not appear to occur in the threshold regime of these three materials, in either the ambient air or the 37°C PBS bath environments.



Sterilized
da/dN = 3.5 x 10^{-7} mm/cycle
$\Delta K = 1.52$ MPa√m

Annealed
da/dN = 9.1 x 10^{-7} mm/cycle
$\Delta K = 1.01$ MPa√m

Remelted
da/dN = 5.7 x 10^{-7} mm/cycle
$\Delta K = 0.87$ MPa√m

Figure 3: Crack tip images for each UHMWPE material showing evidence of crack tip blunting.

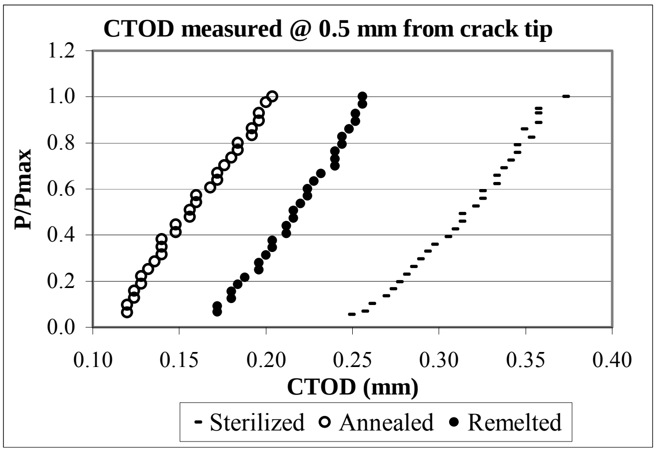


Figure 4: Normalized load vs CTOD for the unloading part of a closure measurement cycle. Test conditions as in Figure 3.

For the two environments that were evaluated, the exponent (m) of the Paris regime was not affected by temperature and/or environment for the highly crosslinked (annealed and remelted) UHMWPE materials in contrast to the conventional (sterilized) UHMWPE material. This indicates that, for the two environments that were evaluated, the crack propagated at a similar rate for a given ΔK increment in the highly crosslinked materials. However, the sterilized material was found to be sensitive to temperature and/or environment in the Paris regime. The higher exponent in the 37°C PBS bath as compared to ambient air indicates that in a 37°C PBS bath, the crack propagates at higher rate for a given ΔK increment compared to the ambient air environment. That is, once a crack has been initiated, the number of cycles to failure may be more limited in a 37°C PBS bath as compared to ambient air for the sterilized material. Overall, however, test temperature/environment had less of an effect on fatigue crack propagation (as indicated by the exponent of the Paris relationship) than on fatigue crack initiation (as indicated by the coefficient of the Paris relationship and by $\Delta K_{inception}$). This may be because the greater degree of mechanical damage and the higher fatigue crack growth rates associated with high ΔK levels in the Paris regime as compared to the threshold regime overshadows the influence of test temperature and environment.

In this study, we observed a 17% decrease in $\Delta K_{inception}$ for the sterilized material (30kGy) tested in a 37°C PBS bath as compared with ambient air. A similar observation was noted by Baker et al [17] for non-sterile GUR4150HP UHMWPE tested in a 37°C de-ionized water bath. They observed a 9% decrease in $\Delta K_{inception}$ in specimens tested in the water bath as compared to specimens tested in ambient air [17]. The small difference between the findings of Baker et al [17] and this study may be due to differences in testing fluid, sterilization state of the material, specimen geometry, or testing protocols. We also found that there was a greater reduction in $\Delta K_{inception}$ for the crosslinked materials (23%, annealed) and (22%, remelted) when tested in a 37°C PBS bath compared to ambient air.

This study also demonstrated that gamma radiation crosslinking reduces fatigue crack inception resistance in both air and fluid environments (Table 1). In a study by Gencur et al [11] conducted in ambient air, gamma radiation crosslinking resulted in a 55% reduction in $\Delta K_{inception}$ compared to an unirradiated control material. Baker et al [12] demonstrated that $\Delta K_{inception}$ of a highly crosslinked (200kGy) material decreased approximately by 50% as compared to an unirradiated control group. A fatigue crack propagation study by Cole et al [13] showed a reduction in $\Delta K_{threshold}$ of approximately 30% for highly crosslinked annealed GUR1050 compared with an unirradiated annealed control group. Radiation induced crosslinking is believed to occur primarily in the amorphous regions of UHMWPE [12]. Crosslinking limits the molecular chain mobility. Chain mobility would be expected to affect the plastic deformation characteristics of the polymer and, thus, would be reflected in reduced energy associated with crack inception, regardless of environment.

In the highly crosslinked materials, it was found that fatigue crack propagation proceeds at a slower rate for a given ΔK increment (lower exponent, m) compared to the sterilized material. This finding suggests that, following crack initiation, the highly crosslinked materials may be better able to resist fatigue crack propagation than the sterilized material. This behavior was observed in both the ambient air and 37°C PBS bath. Similar findings have been reported by other investigators [11-13].

In this study, we observed a significant difference in coefficient (C) in both environments between the annealed and remelted materials, with the remelted material exhibiting reduced fatigue crack propagation resistance compared with the annealed material. Gencur et al [11] did not find a statistically significant difference between annealed (110°C) and remelted materials; however, there was a trend towards reduced resistance to fatigue crack propagation for the remelted material compared with the annealed material. The annealed and remelted materials used in this study, while similar to those used in the study of Gencur et al [11], were not identical. They were produced from different batch lots and the annealing temperature was not the same for the two studies (110°C for [11] versus 130°C in this study). It is possible that the somewhat different trends in fatigue crack propagation resistance behavior between annealed and remelted highly crosslinked UHMWPEs in these two studies can be attributed to the difference in annealing temperatures.

Crack closure was not observed either for the sterilized material or for the highly crosslinked materials under the testing conditions selected for this study. Because of the excessive crack tip blunting observed in all three UHMWPE materials, it is unlikely that crack closure will occur even with different specimen geometry and testing conditions. Therefore, the $\Delta K_{inception}$ obtained from fatigue tests conducted in a physiologically relevant fluid like PBS maintained at body temperature likely can be considered closure free and therefore conservative. However, further study may be needed to determine the extent to which these findings are generalizable to other UHMWPE formulations and test conditions.

CONCLUSIONS

The findings from this study indicate that in a more physiologically-relevant fluid environment at 37°C, the resistance to fatigue crack inception and propagation is reduced compared to ambient air for conventional and highly crosslinked UHMWPEs. Clinically, UHMWPE implants are more likely to be susceptible to fatigue crack inception and propagation than might be expected from tests conducted in ambient air. The findings also support that $\Delta K_{inception}$ obtained from fatigue tests conducted in a physiologically-relevant fluid like PBS maintained at body temperature are likely free from closure and therefore can be considered conservative for design purposes.

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