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Crack growth in medical-grade silicone and polyurethane ether elastomers

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Abstract

One major problem with ball and socket artificial discs is the migration of wear particles to the surrounding tissues. This debris can cause inflammation that can lead to implant loosening. Encapsulating the artificial disc with an elastomer sheath, could prevent this problem by retaining the wear particles within the disc. The encapsulation sheath will face millions of tensile cycles during the implant life and, therefore, it must have the ability to withstand large strains without fracture. Using cyclic displacement, crack nucleation was applied on dumbbell specimens and crack growth was applied on rectangular specimens with an initial crack. Both tests were performed on Silex silicone and polyurethane ether elastomer specimens, both with a Shore durometer hardness of 40 shore A. No samples completely failed during the crack nucleation tests after five million cycles. The polyurethane ether elastomer showed a slower rate of crack growth life (421k cycles to reach 70 mm crack length) than silicone elastomer (221k cycles to reach the same crack length) in the control group. Accelerated ageing decreased the hardness and the crack growth rate of the polyurethane elastomer but had the opposite effect for the silicone elastomer. Gamma sterilization increased the crack growth rate and did not affect the

hardness of the polyurethane elastomer. The hardness and the crack growth rate of the silicone elastomer were increased after gamma sterilization.

KEYWORDS

Accelerated ageing; Crack growth; Crack nucleation; Gamma sterilization; Polyurethane ether and Silicone elastomers

1. Introduction

One of the major problems with artificial joint implants such as the hip is the generation of wear particles that result from the sliding of the ball against the socket [1-3]. The same problem occurs with ball and socket artificial disc replacements [4, 5]. When the wear debris reaches the nearby tissues it can lead to complications such as an inflammatory response, toxicity, osteolysis and, subsequently, loosening from the bone [6, 7]. The performance of the implant depends on the size and shape of the wear debris that are generated from the articulation between the ball and socket artificial disc, and these change throughout the implant life [8].

A polymeric sheath has been suggested for artificial joints to encapsulate the ball and socket articulation surfaces to prevent the migration of wear particles to tissues, thus preventing an inflammatory response [9, 10]. Such a capsule should be biocompatible, flexible to allow the required motion of the artificial disc and should withstand millions of loading cycles without failure. When the artificial disc is encapsulated, a formulated lubricant can be held inside the capsule to help reduce both friction and wear. Alnaimat, Shepherd and Dearn [11] tested a variety of formulated synthetic bio-lubricants as potential lubricants for an encapsulated artificial disc. For the encapsulating sheath, elastomers are ideal with the

ability to withstand large strains without fracture. Su, Hua and Zhang [12] used finite element analysis to investigate the effect of the capsule using silicone of thickness 0.5, 1, 1.5 and 2 mm. They found that stresses throughout the cross sectional area of the capsule decreased with thickness, with the 2 mm thick material showing the lowest stresses. Polyurethane and silicone elastomers have been shown to have improved biocompatible properties over other materials when they are implanted for long periods of time in the human body [13]. Silicone elastomers have been used and tested widely in finger joints, breast implants, electrodes and catheters [14-17]. Polyurethane can be used in similar applications, and offers improved mechanical properties such as higher tensile strength, tear and abrasion resistance over silicone elastomers [18, 19].

Boretos and Pierce [20] investigated the use of the polyurethane ether in a heart-assist pump and compared it with silicone. They found that the polyurethane performed better in flexural endurance, wear resistance and hemocompatibility than silicone. Polyurethane has found further use in tri-leaflet heart valves [21, 22]. In addition, it has also been used in the Bryan artificial disc as an outer flexible sheath [23]. Fan, Wu, Wu, Wang and Guo [24] reported a case of polyurethane sheath failure of the Bryan disc where a 5 mm transverse crack appeared on the sheath which led to revision surgery.

When selecting an elastomer for use as a sheath, long-term durability is a critical issue as a result of the strains that will be applied throughout the life of the joint. Fatigue, therefore, becomes a primary consideration for selecting an elastomer. A definition of fatigue life includes the propensity for crack nucleation (crack initiation), defined as the number of cycles required for a certain size crack to appear in the specimen. There is also a second

stage, after crack nucleation, as the crack grows (crack propagation) which is defined as the rate of propagation through the material with cyclic strain[25].

A requirement for *in-vivo* use would require the elastomer to be sterilized. Gamma radiation and electron beam are the most commonly used methods to sterilize medical devices [26]. Gamma radiation produced from cobalt isotope (60 Co) is ideal for medical products such as knee and hip replacements, syringes and bone implants. The most commonly used dose of this radiation to sterilize medical devices is 25 kGy [27]. This radiation energy can degrade elastomeric materials and affect mechanical properties, reducing the tensile strength, moduli and fatigue life of the material [28, 29].

Once sterilized, the implant should not undergo significant property changes in vivo [30]. To determine some of the likely changes in the materials, as a result of the ambient conditions within the body, a process of accelerated ageing can be used. This method is based on using elevated temperatures, for certain calculated time periods, to simulate the implantation time inside the human body [26]. The fatigue and elastic properties of polymers in general are affected by ageing and are likely to lead to faster crack growth [29].

The aim of this study was to compare the fatigue life of biomedical-grade silicone and polyurethane ether elastomers as a potential encapsulation sheath, including the effect of elastomer thickness, sterilization and accelerated ageing.

2. Materials and methods

2.1. Materials

Translucent silicone sheets 1.2 m wide x 1 m long with thicknesses of 1, 1.5 and 2 mm were bought from Silex Ltd (Bordon, UK). Yellow polyurethane ether sheets 0.5 m wide x 3 m long with thicknesses of 1.5 and 2 mm were bought from Bonaprene Products Ltd (Wrexham, UK). Rectangular specimens with dimensions 100 x 35 mm were cut using a ruler and scalpel (Swann-Morton, Sheffield, UK) from all the different thicknesses of the silicone and polyurethane sheets. An initial crack of length 20 mm was cut into the rectangular specimens, as shown in Figure 1.The rectangular specimens were used in the crack growth experiments. Dumbbell specimens were cut from all sheets by using a hand-operated cutter with a dumbbell cutting die (Wallace Instruments, Kingston, UK), with the dimensions shown in Figure 2, and these were used in the crack nucleation experiments [31]. Table 1 shows the mechanical properties of the silicone and polyurethane sheets.

Table 1: Mechanical properties as provided from the manufacturers of Silex silicone and Bonathane polyurethane elastomer sheets.

	Silex silicone GP40	Bonathane ether polyurethane
Hardness (Shore A)	40	40
Tensile strength (MPa)	7	10.7
Elongation at break %	450	800
Tear strength (kN /m)	10.2	19.3

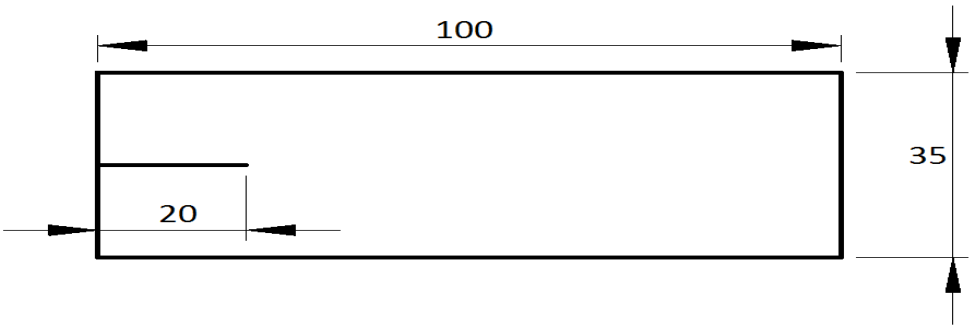


Figure 1: Rectangular specimen used for the crack growth experiments. All dimensions are in mm.

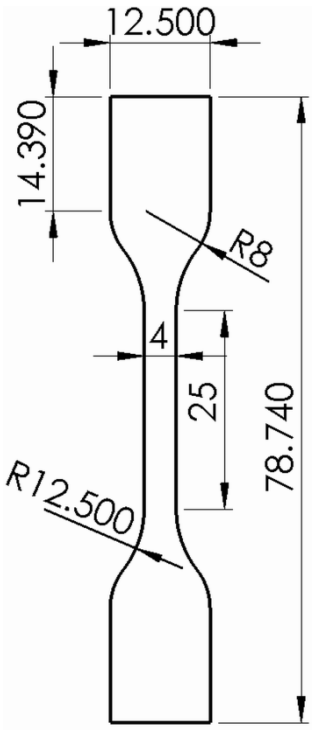


Figure 2: Dumbbell specimen used for the crack nucleation experiments. Dimensions satisfy the BS ISO 6943:2011 standard [31].

2.2. Methods

2.2.1. Specimen groups

The dumbbell and rectangular specimens were separated into four groups. The first group was the control group where specimens were not subjected to either sterilisation or ageing.

The second group was the aged group (A group) in which accelerated ageing was applied to the specimens. The third group was the sterilized group (S group) where the specimens were sterilised by gamma radiation. The last group was the sterilized/aged group (S+A group) where specimens were both sterilised and aged, as described in Tables 2 and 3. Before testing test sheets and test specimens were stored in the dark with a standard laboratory temperature. Each specimen was stored in different bag so there was no contact with any other material that could affect the fatigue life as described in the BS ISO 6943:2011 standard [31].

2.2.2. Ageing of the elastomers

For ageing, the specimens of silicone and polyurethane were placed in polypropylene sample jars and immersed in saline solution (9.5 g/L of sodium chloride in deionized water). The jars were then placed in a Carbolite laboratory oven (Carbolite, Hope Valley, UK) for 149 days at a temperature of 50 ^{o}C; this temperature equated to an ageing time, t_a, of 1 year according to the following equation, which will be a first approximation [26]:

$$t_a = \frac{t_e}{2^{(T_e - T_r)/10}}$$

where t_e is the real time equivalent (365 days), T_e is the elevated temperature (50^{o}C) and T_r is the reference temperature which was body temperature (37^{o}C).

2.2.3. Sterilization of elastomers

Twelve samples from each material, six dumbbells and six rectangular specimens, were sterilized using gamma radiation produced from cobalt isotope (60 Co). The radiation dose of the gamma was 25 kGy performed by Synergy Health Sterilisation UK Ltd (Swindon, UK).

2.2.4. Crack nucleation

Crack nucleation experiments were performed using a Bose ElectroForce 3300 testing machine (Bose Corporation, Minnesota, USA). The data were obtained using Wintest software (Bose Corporation, Minnesota, USA). The experiments were performed according to the standard BS ISO 6943:2011 [31]. The dumbbell specimens were attached to the Bose machine using two grips. The testing involved applying a sinusoidally varying displacement at 10 Hz. The testing was performed at room temperature. The applied strain was 50% which is more than the expected calculated strain of 18% resulting from the different motions of the artificial disc, measured from the length between the two grips, at 17 mm. The testing was continued until complete failure of the sample occurred or until five million cycles had been completed, which is the equivalent to five years implanted inside the human body [32]. The crack nucleation testing was undertaken for the control group and the sterilized/aged group (which represented the worst case). The detailed test conditions are described in Table 2.

Table 2: Crack nucleation testing conditions (S+A: Sterilized/Aged group).

Group	Materials	Thickness mm	Samples (n) from each material	Ageing	Sterilization
Control group	Silicone	1, 1.5, 2	1	No	No
	polyurethane	1.5, 2	1	No	No

S+A group	Silicone	1, 1.5, 2	1	yes	Yes
	polyurethane	1.5, 2	1	yes	Yes

2.2.5. Crack growth

The crack growth tests were completed in accordance with ASTM E647–15 [33]. Single edge crack tension growth experiments were undertaken using the same Bose testing machine detailed above, as described previously [34]. All tests were performed at room temperature. A sinusoidally varying tensile strain was applied in displacement control. The cyclic strain was cycled from 0% to 30% (in accordance with strain that the designed artificial disc is exposed to) from the distance of the sample between the two grips, which again was 17 mm. A 70% cyclic strain was used with the aged and sterilized/aged polyurethane samples because there was no crack growth at 30% strain due to change in hardness of the material from the ageing process. All crack growth tests were undertaken at 2 Hz. Slippage was monitored by force measurement, and none was noticed during all experiments. A starting crack of 20 mm length was produced in each sample. The test was stopped periodically to take crack growth readings; crack length was measured three times using digital callipers (Fisher Scientific, Leicestershire, UK). Testing was stopped when the crack had grown by 70 mm from the initial 20 mm length and before the failure of the sample. Linear interpolation was calculated for the data points before and after 70 mm to calculate the number of cycles required to reach 70 mm crack. The detailed test conditions are described in Table 3.

Table 3: Crack growth testing conditions (S+A: Sterilized/aged group, A: Aged group, S: Sterilized group).

Group	Materials	Thickness mm	Samples (n) from each material	Ageing	Sterilization
Control group	Silicone	1, 1.5, 2	3,2,3	No	No
	polyurethane	1.5, 2	3,3	No	No
A group	Silicone	1, 1.5, 2	2,2,3	Yes	No
	polyurethane	1.5, 2	1,1	Yes	No
S group	Silicone	1, 1.5, 2	2,2,1	No	Yes
	polyurethane	1.5, 2	2,2	No	Yes
S+A group	Silicone	1, 1.5, 2	2,2,2	yes	Yes
	polyurethane	1.5, 2	1,1	yes	Yes

2.2.6. Surface imaging and roughness

Samples were scanned by using an Alicona G5 InfiniteFocus (Alicona, Raaba, Austria) using 10× magnification. Three samples of each material from each group were scanned nine times and the mean surface roughness and 95% confidence interval was calculated. The scanning was done on the outer undamaged surface to see the degradation that was potentially caused by sterilization, ageing and sterilization/ageing and to compare them with the control group (without aging or sterilization).

2.2.7. Hardness testing

Shore A hardness was measured for all the 2 mm thick samples according to the BS ISO 7619-1:2010 [35] using a shore A durometer (HUATEC Group Corporation, Beijing, China).

The Durometer was held for 20 seconds until the reading was stable. The test duration was 15 s or more for the thermoplastic rubber as described in BS ISO 7619-1:2010 [35]. Three samples from each group were measured 9 times and the mean and 95% confidence interval was calculated for the readings.

3. Results

3.1. Crack nucleation results

No silicone or polyurethane dumbbell specimens completely failed from the control group after five million cycles during the cyclic fatigue tests with 50% strain. In addition, there was no dumbbell specimens completely failed from the sterilized/aged group in the crack nucleation test after five million cycles. No noticeable damage or complete failure occurred for the dumbbell samples during all the nucleation tests.

3.2. Crack growth results

Crack growth was affected by the thickness of the sheath for all the materials, as shown in Figures 4 and 5. The rate of crack growth reduced with increasing thickness of the samples. Polyurethane ether samples showed higher resistance to crack growth than the silicone elastomer, as shown in Figures 4 and 6. The 2 mm thickness polyurethane from the control group reached 70 mm (without the initial crack) after approximately 421k cycles of the crack growth test, while the 2 mm thickness silicone from the control group reached 70 mm after 221k cycles.

Crack growth for the polyurethane samples for the thicknesses of 1.5 and 2 mm followed the same trend. The aged samples had the slowest crack growth rate between all the groups followed by the sterilized/aged samples. The aged and sterilized/aged group polyurethane samples were affected by the grips attachment area. Crack growth was not affected but there was evidence of deformation of the polyurethane, at the site of the grips and samples in the aged and sterilized/aged group, as shown in Figure 3.

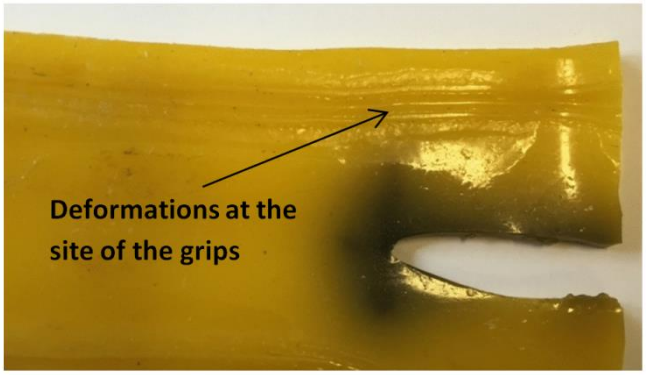


Figure 3: Deformations of the sterilized/aged crack growth sample at the site of the grips.

The control group had a higher crack growth rate than the sterilized/aged group and the sterilized group had the highest crack growth rate compared to the other groups, as shown in Figures 4 and 5.

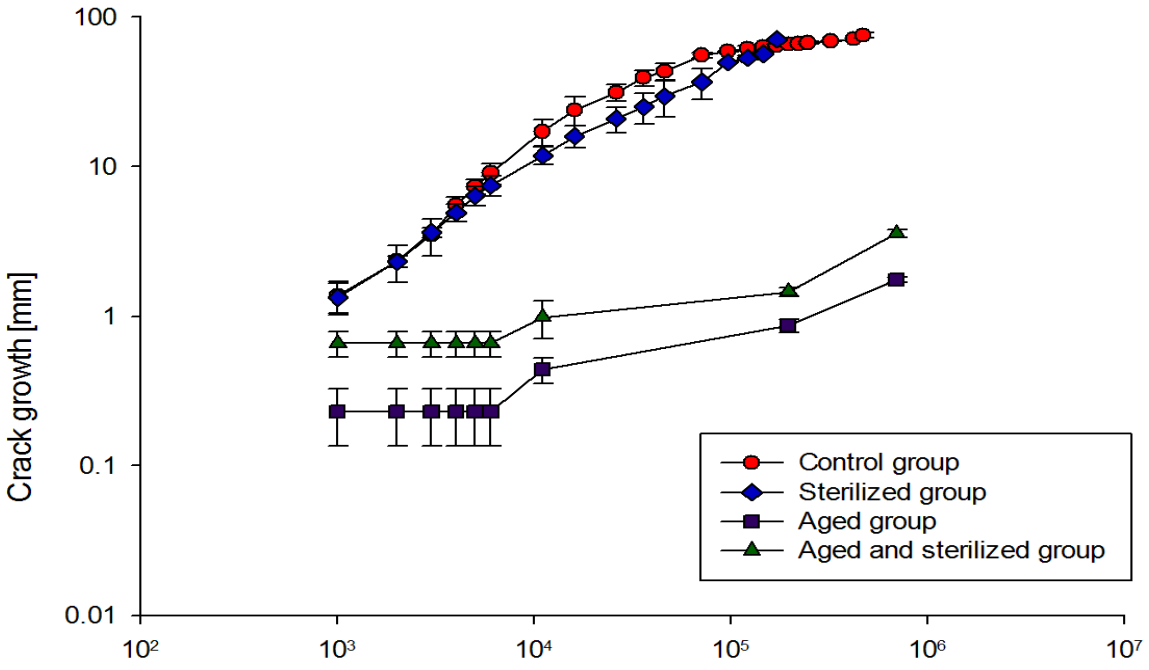


Figure 4: Crack growth for the 2 mm polyurethane ether samples; x and y-axis are on a logarithmic scale base 10. Error bars represent 95% confidence intervals.

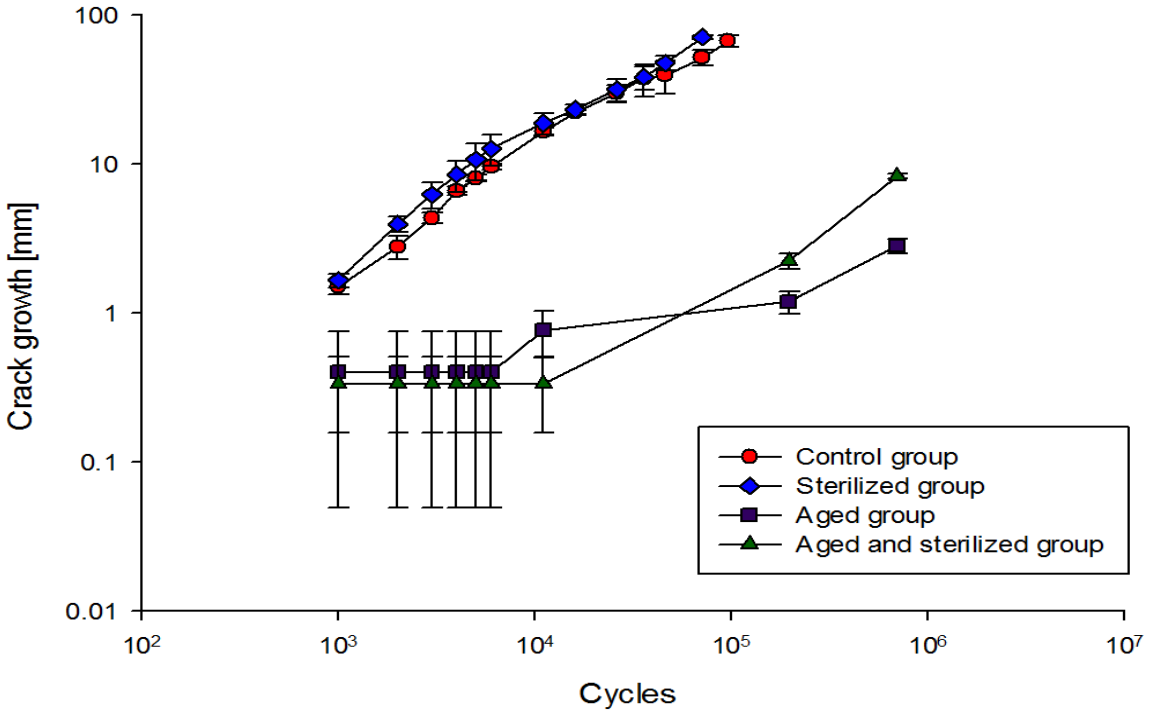


Figure 5: Crack growth for the 1.5 mm polyurethane ether samples; x and y-axis is on a logarithmic scale base 10. Error bars represent 95% confidence intervals.

The silicone samples with different thicknesses had the same crack growth trends. The control group for all the silicone samples had the slowest crack growth rate of all the groups followed by the sterilized group. Then, there was the aged samples followed by the sterilized/aged group, with the fastest rate of crack growth rate between all the groups, as shown in Figures 6, 7 and 8.

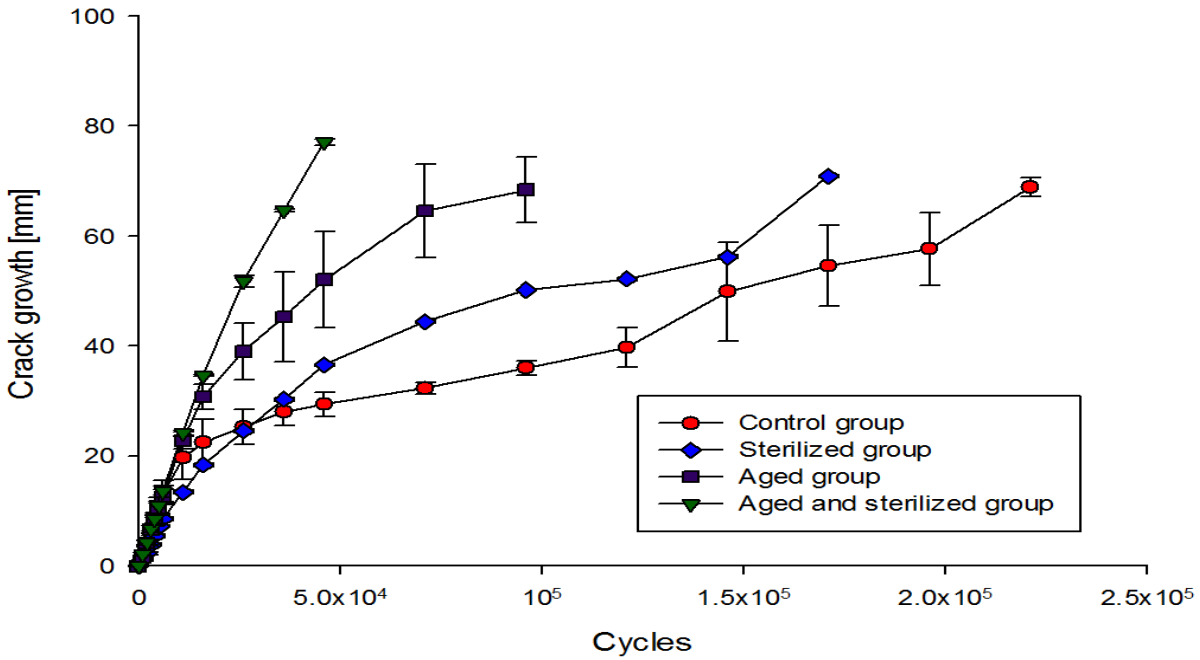


Figure 6: Crack growth for the 2 mm silicone samples. Error bars represent 95% confidence intervals.

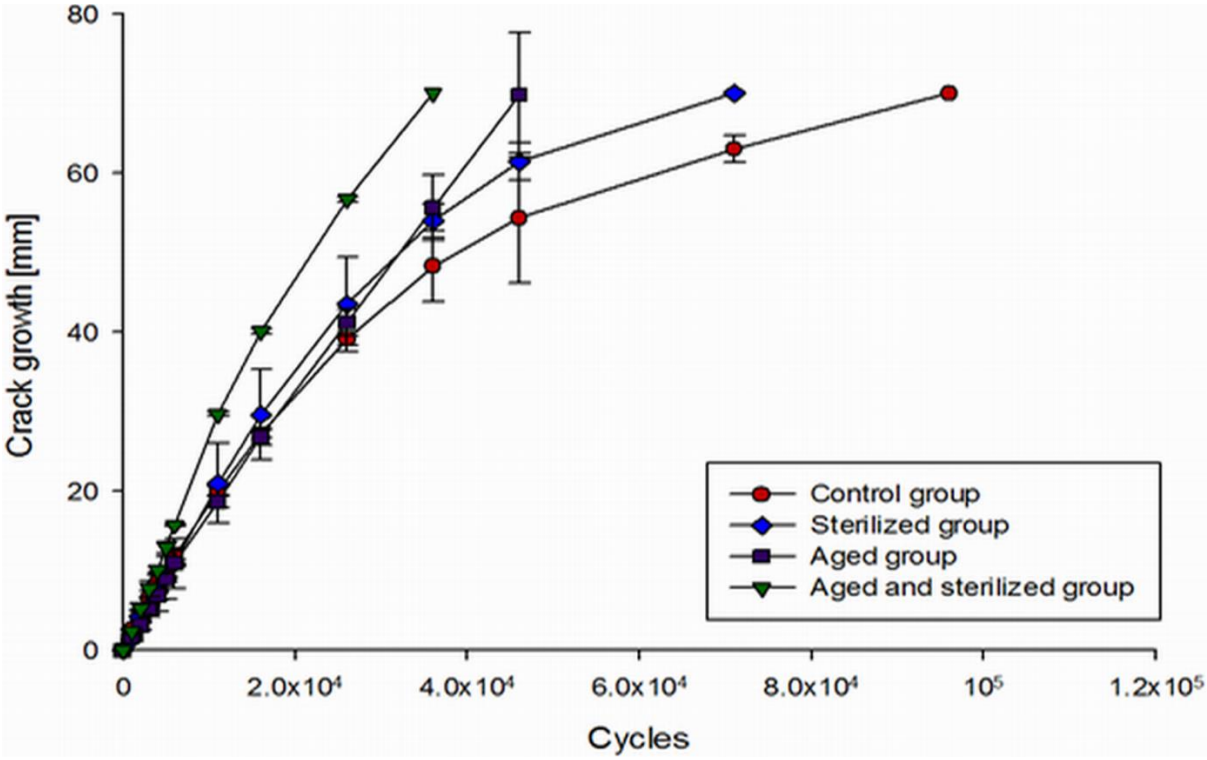


Figure 7: Crack growth for the 1.5 mm silicone samples. Error bars represent 95% confidence intervals.

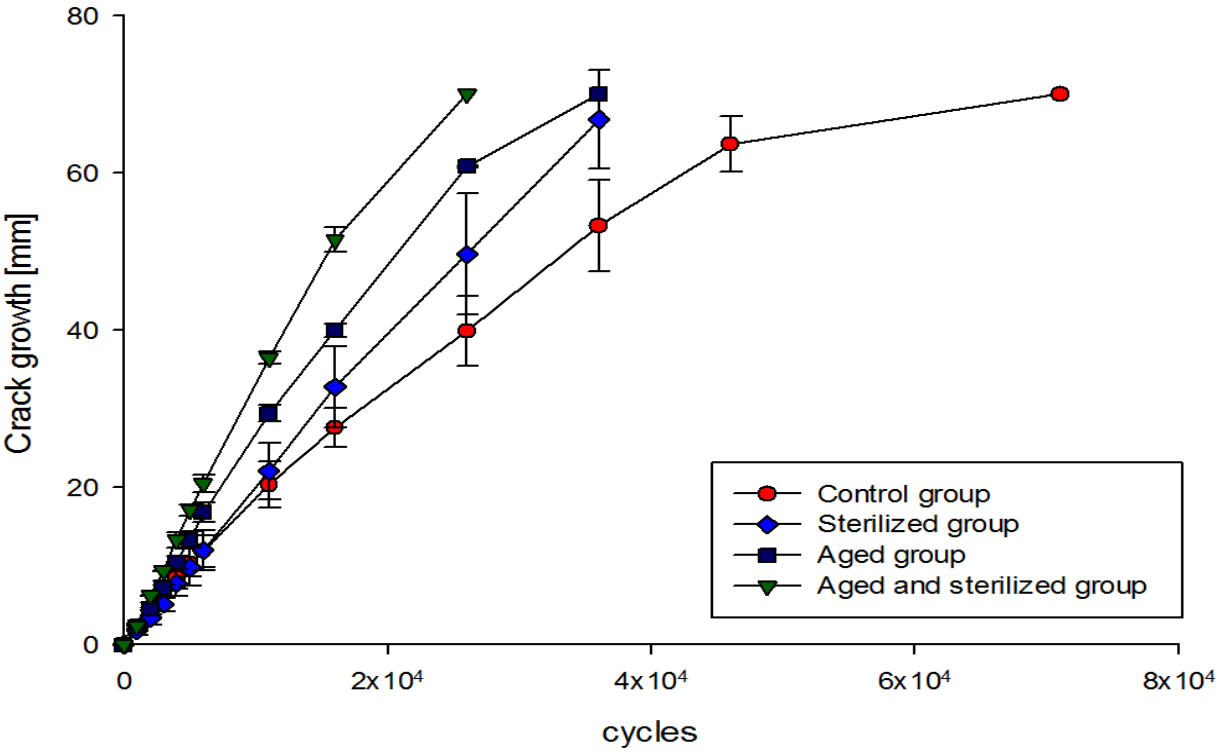


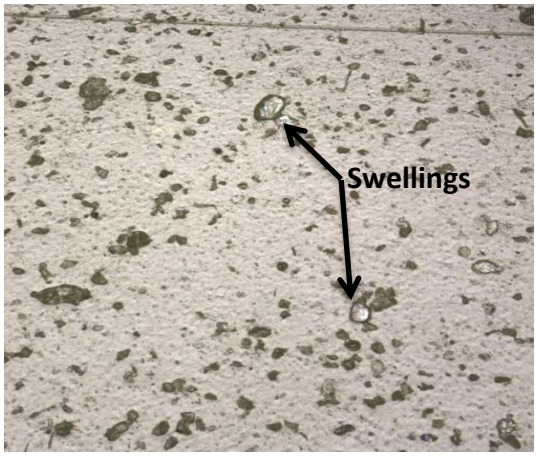
Figure 8: Crack growth for the 1 mm silicone samples. Error bars represent 95% confidence intervals.

3.3. Surface imaging and roughness results

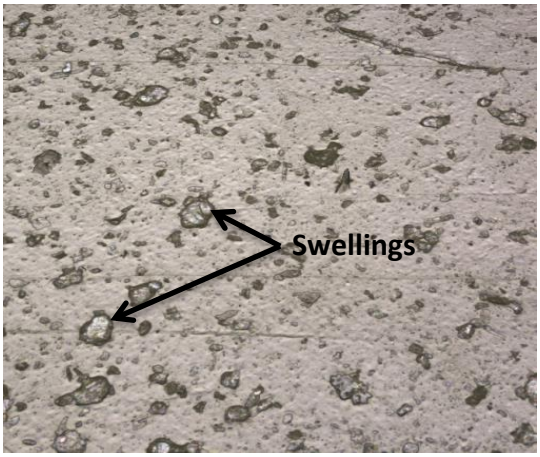
Figure 9 shows the surfaces of the elastomers from the different groups. Figure 9a is the polyurethane control group. There was no effect on the surface as a result of sterilizing the polyurethane, as shown in Figure 9b. However, the ageing process caused surface degradation and swelling of the surface, as shown in Figures 9c and 9d. There was no noticeable effect on the surfaces of the different groups of silicone, as shown in Figures 9e-h.

(a)

(b)



(c)



(d)

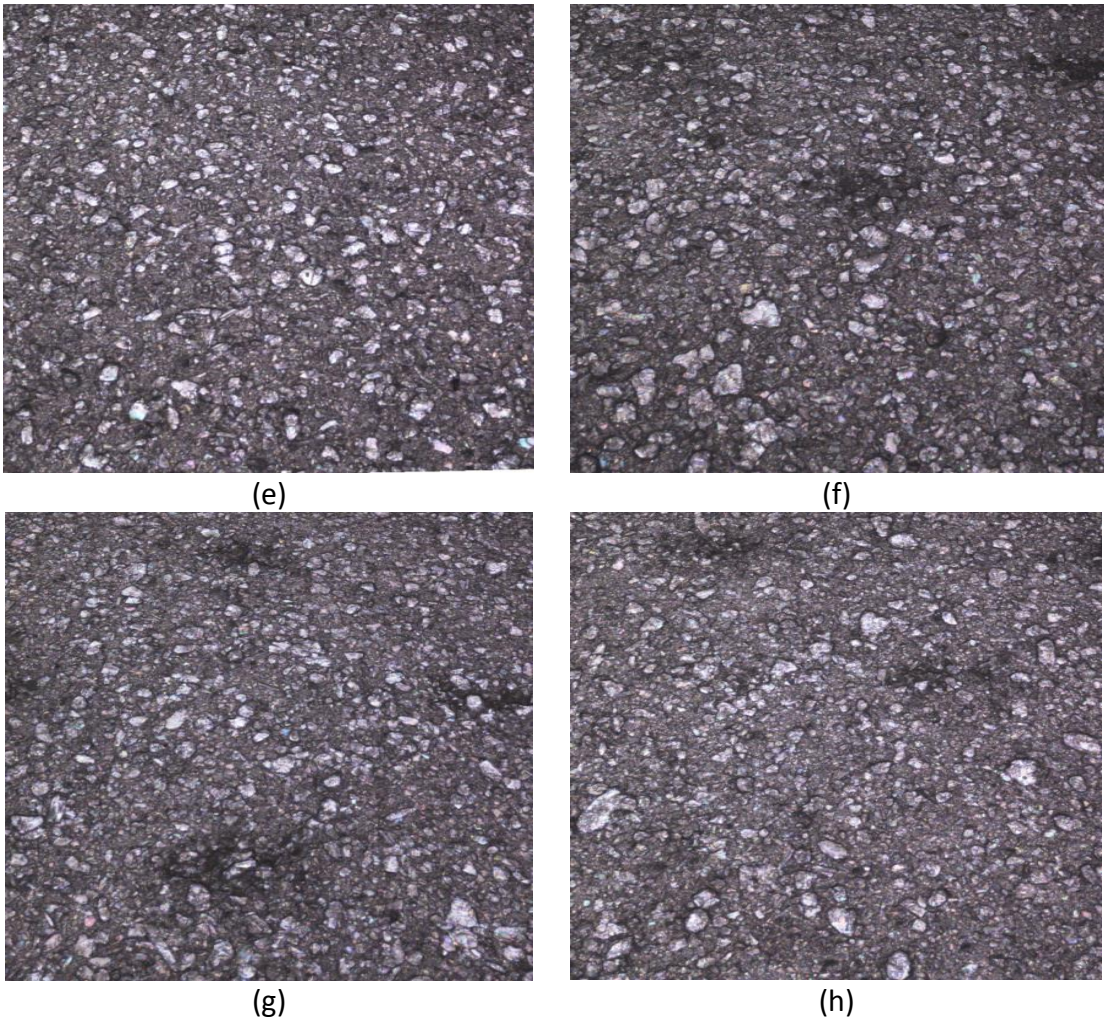


Figure 9: surface imaging by Alicona G5 InfiniteFocus for: a) Control polyurethane group. b) Sterilized polyurethane group. c) Aged polyurethane group. d) Sterilized/aged polyurethane group. e) Control silicone group. f) Sterilized silicone group. g) Aged silicone group. h) Sterilized/aged silicone group.

Figure 10 shows a polyurethane surface with topography plotted, from the red line, below. The peaks represent swellings and their heights are given on the chart. The peak values of the swellings reached 8 µm from the nominal surface.

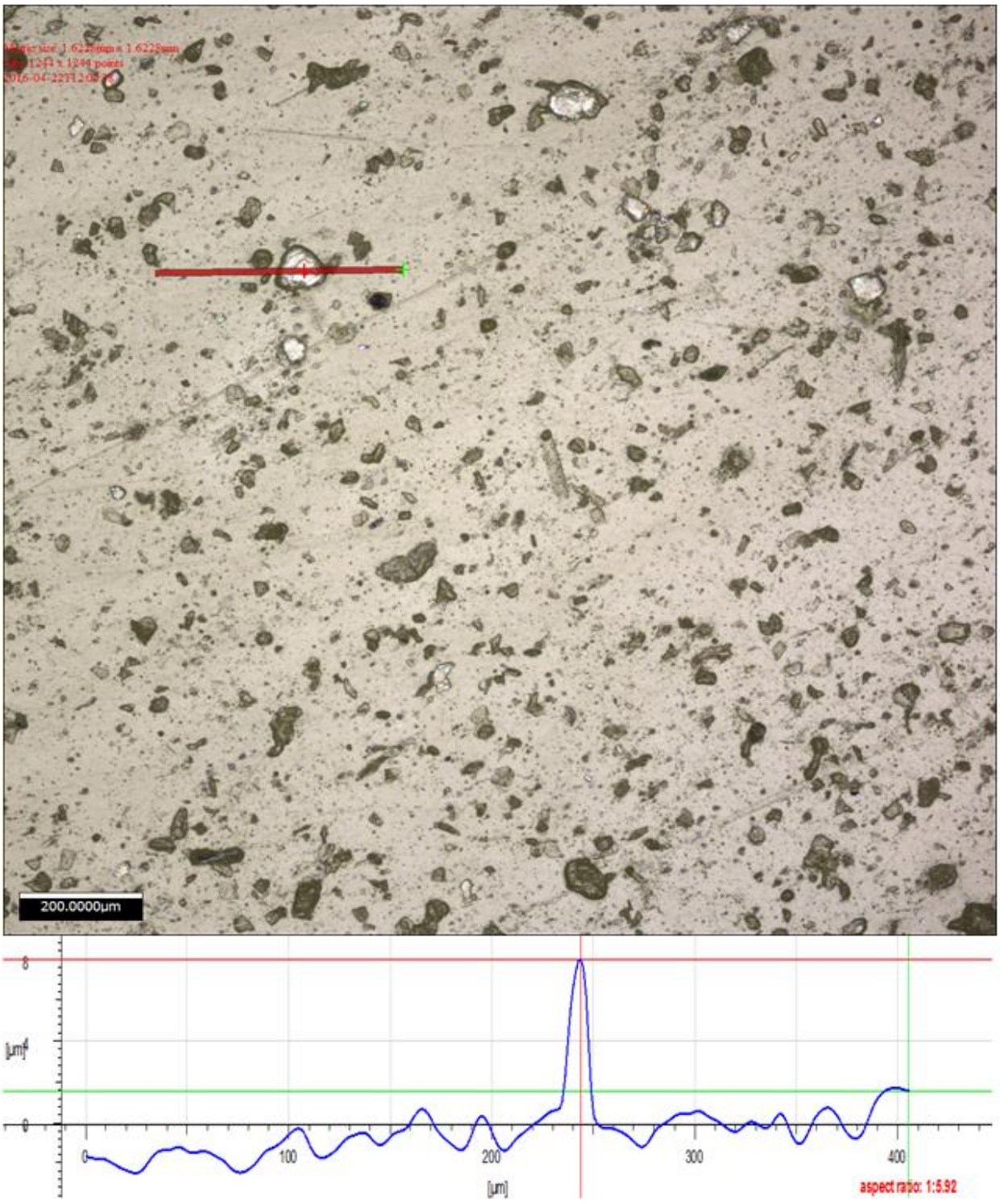


Figure 10: surface imaging by Alicona G5 InfiniteFocus for an aged polyurethane sample. The line chart represents the topography of the surface across the red line on the upper part of the Figure.

Table 4 lists the surface roughness measured from the tested samples. The mean values of R_a for aged and sterilized/aged polyurethane was lower than the sterilized and control group of the polyurethane. Also, the mean values of Ra for sterilized/aged silicone was lower than the control, sterilized and aged silicone samples.

Table 4: The mean surface roughness and 95% confidence interval for the test specimens.

Group	R_a mean [μm]	95% confidence interval [μm]
Control polyurethane	0.82	0.1
Sterilized polyurethane	0.89	0.34
Aged polyurethane	0.61	0.07
Sterilized/aged polyurethane	0.64	0.06
Control silicone	0.85	0.2
Sterilized silicone	0.79	0.25
Aged silicone	0.89	0.1
Sterilized/aged silicone	0.68	0.2

3.4. Hardness results

The hardness of the polyurethane was lower after the ageing process from 40 to 10 shore A; however, sterilization did not affect the hardness properties of the polyurethane samples. For the silicone samples, all combinations of sterilisation and ageing increased the hardness

to 50 from the control level of 45 shore A and increased by 10 shore A compared with the manufactured datasheet (Table 1). The results are listed in Table 5.

Table 5: The mean Shore A hardness for the test specimens.

Group	Mean Shore A
Control polyurethane	40
Sterilized polyurethane	41
Aged polyurethane	10
Sterilized/aged polyurethane	10
Control Silicone	45
Sterilized Silicone	50
Aged Silicone	50
Sterilized/aged Silicone	50

4. Discussion

All of the dumbbell samples from the control group exceeded 5 million cycles using 50% strain in the crack nucleation test, as did all the dumbbell specimens from the sterilized/aged group. There was no noticeable damage to the samples from the crack nucleation test for all the groups tested.

Polyurethane ether showed a greater crack growth resistance than the silicone elastomer with the same hardness for all the groups. There were also noticeable effects from the elastomer thickness on the crack growth rate, being higher for the thinner elastomers. The same effect of sample thickness was described previously [36, 37] in which the crack growth rate was higher for thinner samples.

For the crack growth tests, the control group for the silicone groups produced the lowest rate of crack growth compared to the sterilised, aged and sterilised/aged groups. The sterilized samples had a lower crack growth life than the control group due to the effects of gamma irradiation on the materials. Hutchinson, Savory and Bachus [38] observed the same negative effect of the gamma sterilization on polyurethane and silicone elastomers. In their experiments, there was a noticeable negative effect from gamma radiation on both materials and the polyurethane had slower crack growth rate more than the silicone elastomer. Gamma radiation has also been shown to increase crack growth rate for other polymers such as UHMWPE, as reported previously [39, 40]. This reduction in the fatigue life of the UHMWPE is caused by degrading of the mechanical and structural integrity of the UHMWPE [40, 41]. This might be the same case for the silicone and the polyurethane elastomers.

Accelerated ageing had a different effect on the two materials. For the silicone samples, ageing reduced fatigue life by increasing the rate of crack growth, compared to the control and sterilized samples. These results are similar to the effects described by Leslie, Jenkins, Shepherd and Kukureka [42] in which accelerated ageing reduced the mechanical properties of medical-grade silicone elastomers Med82-5010-80 and C6-180. The rate of crack growth in the aged polyurethane ether samples was much slower when compared with the control

group. The reduction of the crack growth rate in these samples was due to the reduction in strength and hardness due to the plasticization by water, as shown in Table 5. Davies and Evrard [43] described similar results in which they described a reduction of hardness and strength as a result of water driven plasticization. In this process the water molecules with the help of temperature can destroy the links between the polymer chains, as described by Boubakri, Elleuch, Guermazi and Ayedi [44].

The application of sterilization and ageing had a different effect on the two materials. For the silicone samples, the sterilization and ageing had the largest effect on the increase of speed of crack growth rate between all the groups. The sterilized/aged polyurethane ether samples showed a lower crack growth rate compared with silicone from the same group due to the plasticization by water, which occurred due to the ageing process. However, they showed a faster crack growth rate than the aged polyurethane ether samples. The sterilized/aged samples had the fastest crack growth rate. The aged samples of the silicone were slightly better but worse of all was the sterilised/aged silicone samples.

The polyurethane samples showed different results in which the aged samples had the lowest crack growth rate. The sterilized/aged polyurethane samples showed a slight increase in the crack growth rate. The reduction of the crack growth rate in these samples was due to the drop of the strength, due again to the plasticization by water. Water plasticization of the polyurethane was due to the water absorption during the accelerated ageing process as described previously [45]. There was a noticeable effect on the surface of the aged and sterilized/aged polyurethane groups with swellings on the surfaces of both groups; the peak height of the swelling reached 8 µm in some areas, as shown in Figure 10. These swellings might be caused by the penetration of water molecules into the material

structure. This phenomena was noticed by Boubakri, Elleuch, Guermazi and Ayedi [44] when the same swellings appeared after accelerated ageing and immersion of the polyurethane material in distilled water.

The sterilization and accelerated ageing had no measurable effect on the surface roughness of the silicone samples. The polyurethane, the aged and sterilized/aged samples showed a reduction in mean roughness, probably a result of water plasticization, as shown in Figure 9c and 9d.

The hardness of the polyurethane was same for the control and sterilized group, but this reduced as a result of ageing, as shown earlier in Table 5. The reduction in hardness will also have been a product of water plasticization in the polyurethane samples due to the ageing process. Davies and Evrard [43] noted a similar drop after ageing polyurethane in seawater for 1 month. The hardness of the silicone samples was increased to similar levels by both sterilization and ageing, this is again phenomenon similar to that described by Dootz, Koran and Craig [46] in which the hardness increased from 30.4 to 34.6 shore A after the accelerated ageing for 900 hours at 110 ^{o}F and distilled water spraying technique was used.

5. Conclusions

The following conclusions can be drawn from this study:

- For the crack nucleation tests no samples, of any thickness, from the control or the sterilized/aged group failed after the 5 million cycles.
- The rate of crack growth was slowest with the polyurethane ether elastomer. For example, the control group in the 2 mm polyurethane ether samples took 421k cycles to

reach 70 mm crack length whereas silicone elastomer from the same group and thickness took 221k cycles to reach the same crack length. The same trend was shown for all other groups.

- Crack growth life was dependant on the sample thickness in which the thicker elastomers took longer to crack.
- Accelerated ageing reduced the hardness of the polyurethane ether elastomer, created swellings on the surface of the material as a result of water plasticization and decreased the crack growth rate. For the silicone elastomer, there was no change in the surface of the elastomer but the hardness and the crack growth rate were increased.
- Gamma sterilization did not affect the hardness of the polyurethane ether elastomer; however, crack growth rate of the material was increased. The same sterilization process increased the hardness of the silicone elastomer and increased the crack growth rate.

Based on the results of this study the polyurethane ether elastomer exhibited superior performance over the silicone with a 2 mm thickness for use as a sheath for the development of an encapsulated artificial disc technology.

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