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Material Properties

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 (421 k cycles to reach 70 mm crack length) than silicone elastomer (221 k 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.

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 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 biolubricants 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

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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 × 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 Fig. 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 Fig. 2, and these were used in the crack nucleation experiments [31]. Table 1 shows the mechanical properties of the silicone and polyurethane sheets.

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 sterilization 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 sterilized by gamma radiation. The last group was the sterilized/aged group (S + A group) where specimens were both sterilized and aged, as described in Tables 2 and 3. Before testing test sheets and test specimens were stored in the dark at 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].

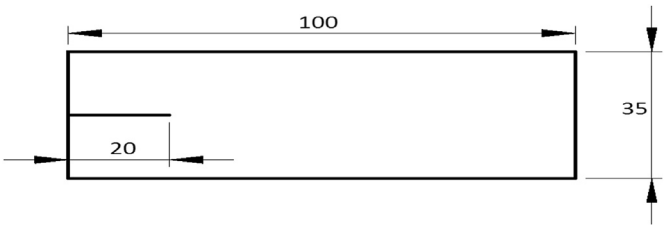

Fig. 1. Rectangular specimens used for the crack growth experiments. All dimensions are in mm.

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 °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 °C) and T_r is the reference temperature which was body temperature (37 °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 Sterilization UK

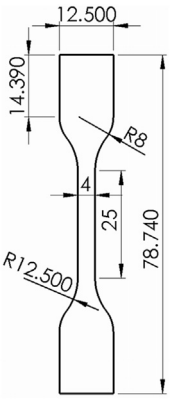

Fig. 2. Dumbbell specimen final used for the crack nucleation experiments. Dimensions satisfy the BS ISO 6943:2011 standard [31].