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The Effect of Lipid Absorption on the Mechanical Properties of Poly(Styrene-Block-Isobutylene-Block-Styrene) for Use in Biomedical Applications

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Abstract. The decrease in tensile strength and increase in specimen weight due to lipid diffusion in a biocompatible thermoplastic elastomer was studied and quantified. Mechanical and viscoelastic properties of poly(styrene-isobutylene-styrene) (SIBS) block copolymer are critical to determine feasibility of certain load bearing in vivo applications. Moreover, changes of these properties due to the presence of lipids must be well understood for long-term bio implantation. Dumbbell specimens were thermoformed via injection molding and weights were recorded. Lipid uptake in the body was simulated by specimen immersion in palm and castor oils at 25 °C and 37 °C. After only 96 hours of immersion at body temperature (37 °C), dumbbell weight increased by 6% and 0.3% for palm oil and castor oil, respectively. These values correspond to a reduction in ultimate tensile strength of approximately 30% and 10%, respectively. These results restrict the use of this biocompatible polymer in certain critical components due to the high concentration of lipids in vivo. Based on these significant and rapid reductions in tensile strength in the presence of lipids, it is of vital importance to fully understand the bio-durability and lipid uptake characteristics of SIBS for future design and performance prediction of implantable devices. Further, the results highlight the necessity of improving lipid resistance in order to fully exploit the biocompatibility of SIBS.

Keywords: SIBS, Lipid Absorption, Tensile Strength, Bio-degradation

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INTRODUCTION

Poly(Styrene-block-Isobutylene-block-Styrene) (SIBS), a thermoplastic elastomer, has become an increasingly important material in a variety of applications in the medical field due to its high degree of biocompatibility [1-5]. SIBS has been found to interact well with the human body: The Food and Drug Administration approved the material for ultra-long term vascular device applications and it is currently used in the TAXUS[®] drug-eluting coronary stent [1,4]. Despite favorable results in these applications, some in vivo studies have found SIBS to be susceptible to viscoelastic creep as well as surface cracking [4-9]. Among the more likely causes of these deficiencies is exposure of the material to lipids, which are an integral component of the in vivo environment. As such, careful study of the effects of lipids on the material's mechanical and viscoelastic properties is necessary. Although there is ample research detailing the effects of lipids on other elastomers, there has been no widely-published work that reports the effects of lipids on SIBS. The nature of these types of materials makes it a challenging issue that has yet to be adequately addressed in the open literature. Few of these studies have focused on thermoplastic elastomer block copolymers, though there are various reports of significant degradation in elastomers similar to SIBS after exposure to lipids. Lipid-induced degradation of SIBS is a significant impediment to the use of this extremely biocompatible polymer in vivo, particularly in lipid-rich areas of the body. It is extremely important to fully understand the mechanical properties of the material in order to take advantage of its excellent biocompatibility.

In order to efficiently assess the susceptibility of SIBS to lipid uptake and lipid-induced degradation, a suitable substitute fluid was chosen. Palm oil is an edible vegetable oil that is derived from the fruit of oil palms. This oil has multiple uses ranging from the manufacturing of soaps and lubricants to food and preservatives. Palm oil was chosen to represent in vivo conditions in this experiment as it contains both saturated and unsaturated fats, vitamin E, and beta-carotene, all commonly found in the human body. Palm oil is often used in this capacity. A study on the effect of palm oil on poly(urethane urea) polymer was performed on HFL9-PU1, HFL13-PU2, and HFL16-PU3

polymers. The results show that palm oil significantly decreases the ultimate tensile strength of the material while increasing specimen weight [10]. This significant change in mechanical properties was attributed to the absorption of the lipid, its plasticizing effect, the weakening of virtual cross links (VCL) and reformation and realignment of the molecular structure with VCLs of the material. Based on these results for materials with similar characteristics, it is important to understand how SIBS reacts when exposed to lipids, as there are high concentrations of lipids in certain areas of the body where this material might be implanted. It is of vital importance to fully understand the bio-durability and lipid uptake characteristics of SIBS for future design and performance prediction of implantable devices, as well as quantify tensile strength degradation and the expected onset of these effects.

The purpose of this study is to quantify the effects of palm oil absorption, and by extension *in vivo* lipids, on the mechanical and viscoelastic properties of the poly(styrene-isobutylene-styrene) (SIBS) block copolymer and to establish a preliminary relationship between lipid absorption and ultimate tensile strength.

EXPERIMENTAL

The SIBS pellets used in this experiment have a composition by weight of 30% styrene and 70% isobutylene. The block copolymer, trade name SIBSTAR™ 103T, was used in the as-received condition from Kaneka Corporation. Pellets were injected using a bench top injection molder that was preheated to 450 °F to ensure adequate fusion and flow into the dumbbell mold, minimizing entrapped air bubbles. Injection speed is fully controllable via a linear actuator and variable speed controller built in to the injection molder. Before injecting the test samples, the injection molder was flushed to minimize specimen variability. The dumbbell mold used to create the samples is in compliance with Type V of ASTM D638 Standard Test Method for Tensile Properties of Plastics. The parameter levels used for this study were as follows: melt temperature of 450 °F, mold temperature of 50 °C, injection rate of 100 mm³/s, and packing time of 10 seconds. These levels were based on previous experience with this material and allowed a relatively consistent outcome for each specimen in terms of dimensions and strength. All specimens (128) were produced in one sitting to reduce the risk of any accidental variations in injection. Specimens that had visible imperfections or trapped air bubbles were replaced and discarded.

The specimens were numbered and weighed; 28 specimens were immersed in a distilled water control group at 25 °C and 36 in palm oil at 25 °C; 28 specimens were immersed in a distilled water control group at 37 °C and 36 in palm oil at 37 °C. All specimens were immersed between 0 and 550 hours prior to tensile testing. Lipid absorption was quantified via gravimetric analysis. Gravimetric data was obtained by removing the SIBS samples from palm oil immersion, followed by removal of surface oil with oil absorption towels. After most of the surface oil had been removed with the towels, each sample was washed in acetone to remove the remaining residue. After the acetone evaporated, each sample was weighed using a precision analytical balance, and then re-immersed after all samples had been recorded. The water-immersed specimens were dried and then weighed in a similar fashion, using water absorbent towels and brief exposure to ambient air to remove the liquid on the surface via evaporation. Testing of 120 specimens was performed using an Instron® 5966 Tensile Testing Machine at a rate of 500 mm/min. Four specimens were tested for each temperature and fluid immersion condition. All values represent the average of all four specimens tested for each immersion temperature, and all specimen groups are identified by the exposure temperature and fluid type.

RESULTS AND DISCUSSION

Table 1 shows the fluid content (by weight) after 550 hours of full immersion. Based on these results, it is clear that the specimens immersed in palm oil were much more susceptible to fluid uptake. Moreover, the specimens immersed in palm oil at 37 °C absorbed more fluid than equivalent samples exposed at 25 °C. This result is not unexpected, and conforms to the general behavior of fluid uptake in polymers at elevated temperatures.

TABLE 1. Fluid content by weight percentage after 550 hours immersed

Water 25 °C (%)	Palm Oil 25 °C (%)	Water 37 °C (%)	Palm Oil 37 °C (%)
0.1	8.3	0.2	13.8

Figure 1 shows the tensile strength as a function of the number of hours immersed in palm oil at 37 °C and 25 °C. The curve for the specimens at 37 °C is much steeper from the very first measurement, which is an indication of the sensitivity of tensile strength to the increase in temperature.

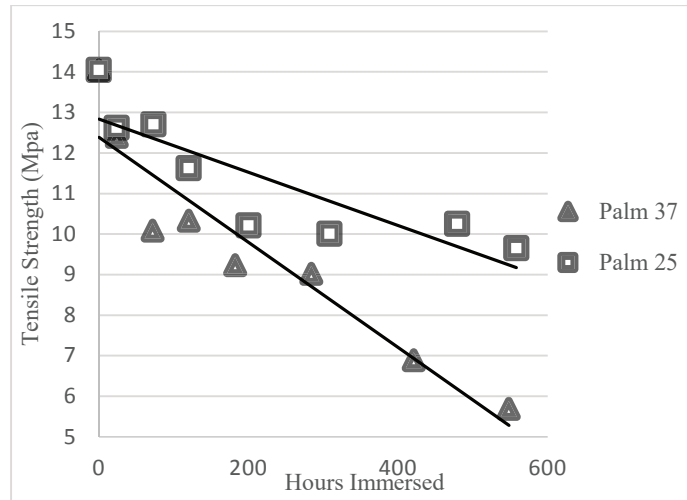


FIGURE 1. Tensile strength vs. immersion time in palm oil at 37 °C and 25 °C

Figure 2 shows that the behavior of SIBS in water is quite unlike that in palm oil. Serving as our control group, the water was expected to have minimal effect on the material. Despite the lack of water absorption, the specimens were still somewhat affected by the liquid.

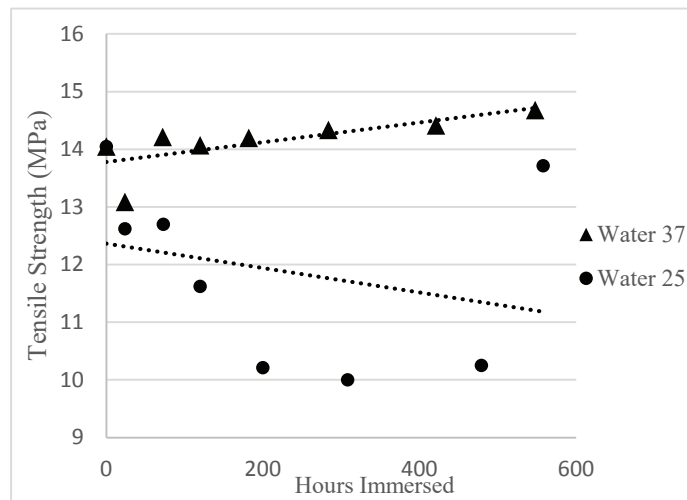


FIGURE 2. Tensile strength vs. immersion time in water at 37 °C and 25 °C

The percent weight increase of the specimens as a result of the immersion fluids at their respective temperatures in comparison to the percent decrease in tensile strength after 550 hours is shown in Table 2. A correlation can be seen between the two values, especially at a higher temperature. There is a direct correlation between the immersion temperature and degree of fluid absorption, which is itself directly related to the magnitude of the decrease in ultimate tensile strength. A predictive model based on these experimental results would enable estimations of the performance of SIBS-based implants.

TABLE 2. Percent weight increase and percent decrease in tensile strength of specimens after 550 hours immersion

Specimen Group	Weight Gain (%)	Decrease in Tensile Strength (%)
Water 25	0.1	-2.4
Water 37	0.2	-4.3
Palm 25	8.3	-31.3
Palm 37	13.8	-59.5

Figure 3 shows that the higher the percent weight palm oil content in the specimen, the lower its tensile strength. Despite this trend being slightly more pronounced at 37 °C, specimens at both temperatures exhibit the same behavior.

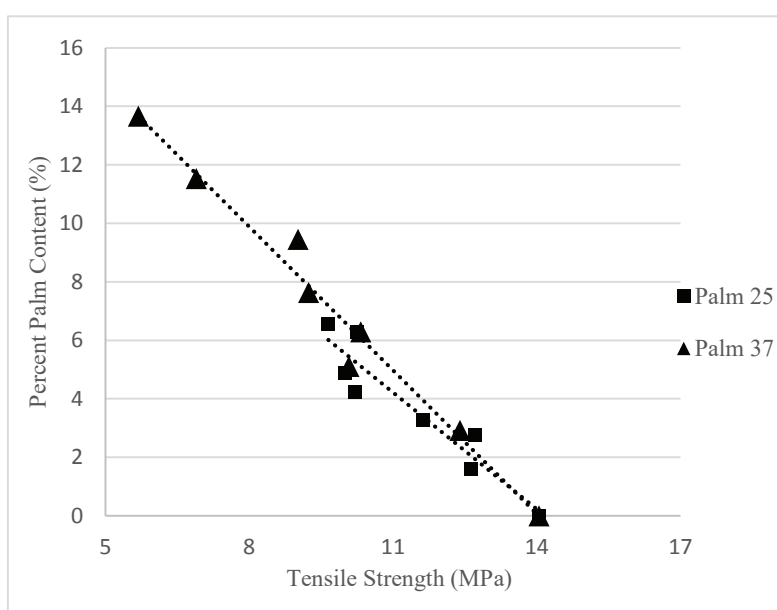


FIGURE 3. Percent palm oil content vs. tensile strength at 37 °C and 25 °C

CONCLUSION

In this study, the effects of immersion in palm oil and water at 25 °C and 37 °C on the ultimate tensile strength of a SIBS copolymer were analyzed and quantified. The total percent weight gain was approximately 8% and 14% for samples immersed in palm oil at 25 °C and 37 °C, respectively, after 550 hours. The percent decrease in tensile strength was about 31% and 60% for those same samples. A direct correlation was found between absorbed fluid and loss of ultimate tensile strength. These preliminary results bolster the feasibility and necessity of developing an accurate model of material property degradation based on both temperature and lipid concentration. Given the potential for the use of SIBS in implantable devices, these results suggest that careful consideration should be given to the long-term performance of these materials in the presence of elevated lipid concentrations.

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