# Impacts of Manufacturing Processes and Temperature on the Water Absorption of a Siloxane-Based Polyurethane

Genevieve Gallagher, Chris Jenney.
St. Jude Medical.

**Statement of Purpose:** Water absorption is an important property for implantable polymers, whose use conditions subject them to the largely aqueous environment of the human body. Water absorption affects the mechanical properties of polymers in a humid or fluid environment and is one factor that impacts a polymer's susceptibility to hydrolysis. In a previous work, Chaffin, et. al. used an assumption of constant water absorption with temperature to develop a temperature accelerated kinetic model of hydrolysis of siloxane-based polyurethanes. The purpose of the current work was to investigate the impact of manufacturing processes (compression molding vs. extrusion and not annealing vs. annealing) and temperature (room temperature – 85 °C) on the water absorption of Optim$^{TM}$ insulation, a siloxane-based polyurethane.

**Methods:** Optim$^{TM}$ insulation (AorTech International, Rogers, MN) is a thermoplastic siloxane-based polyurethane with a 90A Shore A hardness that is used as an insulation on cardiac leads. It consists of hard segments of 4,4'-methylenediphenyl diisocyanate chain extended with 1,4-butanediol and mixed soft segments of PDMS and PHMO in a ratio of 80:20. Pellets were dried and then either compression molded or extruded to produce 0.8-1.0 mm thick samples. ASTM D1704 dumb bells were punched out of the samples. Half of the samples were annealed for four hours at 85 °C, while the other half were left not annealed. Samples were thoroughly vacuum-dried at room temperature immediately prior to study initiation. Samples were exposed to deionized water at room temperature (~ 21 °C), 37 °C, 55 °C, 70 °C, and 85 °C. At 3, 7, 14, 21, and 35 days, samples were removed from the solutions, blotted dry with a low lint wipe, and weighed. Water absorption amounts were determined gravimetrically. The pH of the solutions was monitored and all solutions were changed weekly. After completion of the study, all samples were thoroughly vacuum-dried at room temperature and then immediately weighed one final time to determine whether or not any mass loss occurred in the samples during the study.

**Results:** At day 3, increased opacity was noted in samples aged at 55 °C, 70 °C, and 85 °C (**Figure 1**). Qualitatively, opacity increased with temperature and time. The opacity disappeared after the samples were vacuum-dried at the end of the study. For brevity, the following discussion focuses on the 14 day results (**Figure 2**). All samples had water absorption of less than 1%. Manufacturing method had a significant impact on water absorption with compression molded samples absorbing 14% more water than extruded samples. Annealing did not have a significant impact on water absorption. Temperature had a significant impact on water absorption with samples aged at 85 °C absorbing 44% more water than samples aged at room temperature. Water absorption did not increase over time for samples aged at room temperature, 37 °C, 55 °C, or 70 °C, however, it increased consistently over time for samples aged at 85 °C. This indicates that some change in the structure of the material is occurring at 85 °C that does not occur at lower temperatures and thus, test results obtained at 85 °C cannot be correlated to test results obtained at lower temperature through the use of temperature-accelerated models. No notable mass loss was observed in the samples at the conclusion of the study.

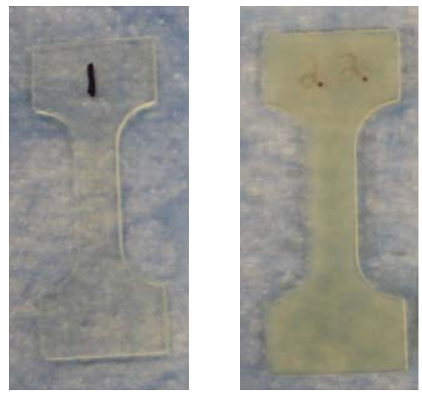

**Figure 1.** Representative images of wet compression molded annealed samples aged at room temperature (left) and 85 °C (right) after 35 days.

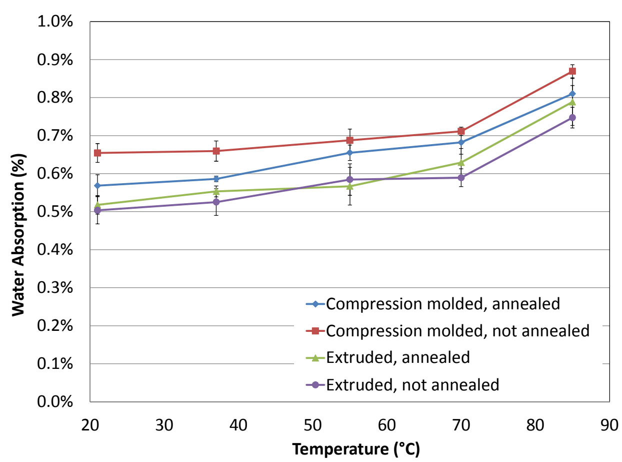


**Figure 2.** 14 day water absorption results.

**Conclusions:** Manufacturing method and temperature impacted the water absorption of Optim$^{TM}$ insulation, a siloxane-based polyurethane. Compression molded samples absorbed 14% more water than extruded samples. Samples aged at 85 °C absorbed 44% more water than samples aged at room temperature. Water absorption only increased over time for samples aged at 85 °C. This work indicates that an assumption of constant water absorption with temperature used in a previous work to develop a temperature accelerated kinetic model of hydrolysis of siloxane-based polyurethanes was invalid.

**References:** Chaffin KA. Macromolecules. 2012;45:9110-3120.