Aging study of silicone materials in simulated gastric fluid

BACKGROUND

Due to its unique properties, silicone is often the material of choice in the manufacture of medical devices. It is important to understand how the various environments of the human body affect the physical properties of the silicone used. For devices such as gastric feeding tubes, or other applications where silicone is exposed to the harshest environments of the human body, a firm understanding of how the silicone's physical properties will be affected is very beneficial because unexpected material changes in medical devices can have fatal consequences. Most importantly, product knowledge may help determine the longevity and performance characteristics of a device using silicone in these extreme environments. Accordingly, a study was performed to evaluate the properties of silicones in what is deemed to be the harshest environment of the human body: gastric acid. In this investigation, dimethyl, diphenyl, and trifluoropropyl silicones were tested and the changes in the product's physical properties such as elongation and tensile strength were recorded and evaluated.

MATERIALS

Simulated Gastric Fluid: Consisting of Hydrochloric Acid (21.8 mL, 37% solution), Sodium Chloride (6.2441g), and Pepsin from porcine mucosa (9.9866g, 800-2500 units/mg activity) dissolved into water (3129.28g, filtered via reverse osmosis).

Silicone Materials: The list below provides a summary of the silicones tested in this study. Slabs were cast according to each product's cure schedule. Tensile bars for tensile testing were cut using an ASTM D-412-C die and arbor press.

Product	Type of Silicone	Durometer
MED-6400	Diphenyl Dispersion	30
MED-6600	Diphenyl Dispersion	25
MED-6605	Dimethyl Dispersion	25
MED-6640	Dimethyl Dispersion	40
MED-6655	Trifluoropropyl Dispersion	35
FS-3775*	Trifluoropropyl Self-Leveling Adhesive	30
MED-4735	Dimethyl High Consistency Rubber	35

*FS-3775 is a non-healthcare silicone. It was included in this study for an additional data point on a fluorosilicone formulation. No biological testing support is currently available.

Testing Equipment: MTS Load Frame with Extensometer, ASTM D-412-C Die, Arbor Press

EXPERIMENTAL METHOD

Step 1: Stainless steel wire was bent into a stand with a central post protruding vertically. Each tensile bar was folded in half across the middle to form a loop and then the ends were skewered together on the stainless steel stand. Each successive tensile bar loop was turned so that it did not overlap with other loops on the stand. In this way, each tensile bar had its center section fully exposed to the acid solution with no overlapping sections to prevent complete exposure. The loops were arranged from the thinnest tensile bars at the top of the stand to the thickest tensile bars at the base of the stand. These stands were then placed in squat jars containing the simulated gastric fluid and maintained at 37°C. To verify the consistency of measurements and to account for any experimental error arising from slab preparation, a total of 5 tensile bars were analyzed for each sample rather than the standard 3 samples.

Step 2: A total of 5 tensile bars of each product were tested each week for Tensile (psi) and Elongation (%) for 6 consecutive weeks. The mean value was recorded and used to analyze trends in performance throughout the 6 week soak.

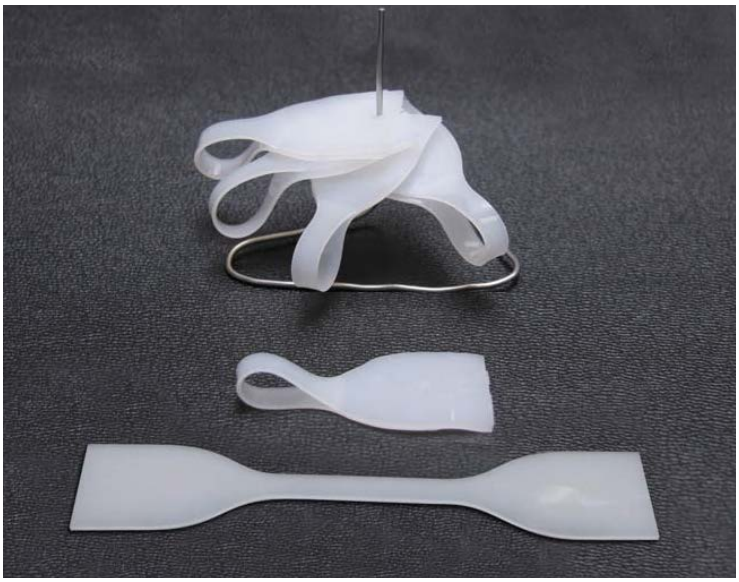

FIGURE 1: This image shows how tensile bars are shaped, folded and skewered onto the stainless steel wire.

RESULTS

The Tensile and Elongation values recorded for each product are graphed below to show any trends that may be present during the 6 weeks of testing.

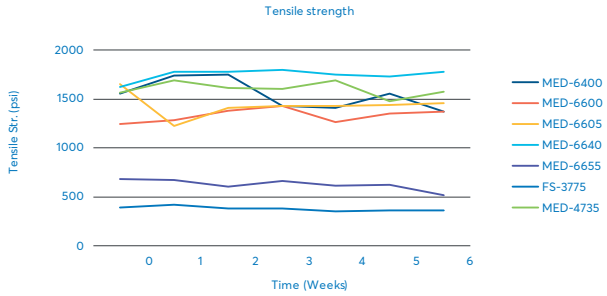

FIGURE 2: Tensile strength results over 6 weeks.

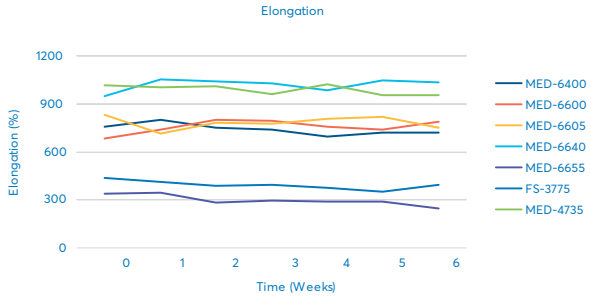

FIGURE 3: Elongation results over 6 weeks.

CONCLUSION

Over the course of 6 weeks at conditions similar to that of the gastro-intestinal tract, the two trifluoropropyl samples performed the least well out of the group and specifically, the MED-6655 was no longer conforming according to NuSil's certification testing due to its lowered tensile strength. While the other silicones showed slight degradation, they survived the acidic environment with only minor changes in physical properties that did not cause a significant impact on their performance. According to the test results in this study, the methyl and phenyl silicones proved to have better survivability when exposed to harsh conditions representing the stomach environment. To account for a wider variation in body chemistries among the population and for more permanent applications such as implantable devices in the gastro-intestinal tract, it may be necessary to further investigate similar studies using more concentrated acid solutions and allowing for longer than 6 weeks soaking time.

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