Prosthetic Sanitizer and Deodorizer

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Silicone Degradation Test

I. INTRODUCTION

The following protocol was utilized in a research environment to analyze the affects of ultraviolet light exposure on silicone prosthetic liners. In correlation with the study of an ultraviolet disinfecting device, Dr. John Allen, inventor and client, questioned the integrity of the silicone prosthetic liners post-ultraviolet radiation.

The average life of a prosthetic liner is approximately six months and current disinfecting methods of soap, water, and rubbing alcohol do not pose a threat on the liner's integrity. If a transition to the disinfecting ultraviolet light were made, it would need to be guaranteed that the same integrity would remain. The approximate cost of a single prosthetic liner is $200-$400, so more frequent replacement would not be ideal.

Past research indicates that UV-irradiation exposure can cause similar degradation effects as that of heat exposure. Over time, the material loses its material strength and elasticity. With the comfort of the patient in mind, any lose of material properties is not acceptable. This protocol explains the testing incorporated with understanding the degradation of silicone liners to ultraviolet exposure, in hope of gaining insight on Dr. Allen's research question.

II. PROCEDURE

Two new silicone prosthetic leg liners were obtained with the help of Dr. Allen from two different companies ALPS Corporation and Freedom Innovations. Upon receiving the liners, the companies were contacted and questioned about the possibility of degradation of their liners with UV light exposure. Both companies claimed the liners would maintain their integrity if exposed to UV-irradiation for extended periods of time.

The prosthetic liner from ALPS Corporation had an outer tan fabric shell connected to 1/4" of silicone material (*Figure 1*). The liner received for Freedom Innovations was a white Parydonn liner approximately 1/8" thick (*Figure 2*). In comparison, both liners were made of silicone; however, each a slightly different kind.

Figure 1 and 2 respectively: ALPS (tan) liner and Freedom Innovations (white) liner.

UV-irradiation is harmful to both eyes and skin. In order to reduce the risk of physical damage, a wooden testing device was constructed to allow individual testing spaces to prevent light leakage into the environment. During initial construction, three separate enclosures were included in the design, representing the three wattages of ultraviolet light bulbs Dr. Allen provided, 9-watt, 5-watt, and 3-watt. However, due to an inconsistent luminosity and irregular socket requirements, the 3-watt bulb was pulled from the degradation testing. See *Figures 3* and *4* for experimental set-up and lights used.

Figure 3: Experimental set-up of degradation test.

Figure 4: 9-watt UV light (top) and 5-watt UV light (bottom) used for testing.

The two liners were cut into 5”x 1” strips and exposed to ultraviolet light for extended periods of time, 12 or 24 hours respectively. The average time to disinfect the liners is approximately one minute; therefore, the times used were quite an overestimate. See *Table 1* for a representation of the samples tested.

	Liner Type	**Total Number of Samples**	**Exposure Time (12 hrs)**	**Exposure Time (24hrs)**
Control	ALPS-Tan	2	N/A	N/A
Control	FI-White	2	N/A	N/A
9-Watt Exposure	Tan	4	2	2
5-Watt Exposure	Tan	4	2	2
9-Watt Exposure	White	4	2	2
5-Watt Exposure	White	4	2	2

Table 1: Sample distribution.

Once all liners were exposed for the given amount of time, the material properties of each liner needed to be tested in order to determine a potential loss in integrity. The Instron 1000, a tensile testing machine located in the mechanics lab at the University of Wisconsin-Madison, was used to test the liners to failure in order to calculate their relative force vs. displacement relationship (See *Figure 5* for tensile test set-up).

The analysis of the recorded force and displacement measurements provided quantitative data in which to compare and contrast. Because the material specimens were not all the same size and shape, dimensions were recorded and used in calculating the appropriate stress and strain. The stress-strain curves for each specimen were then graphed and compared directly. Note the equations in the text used for analysis.

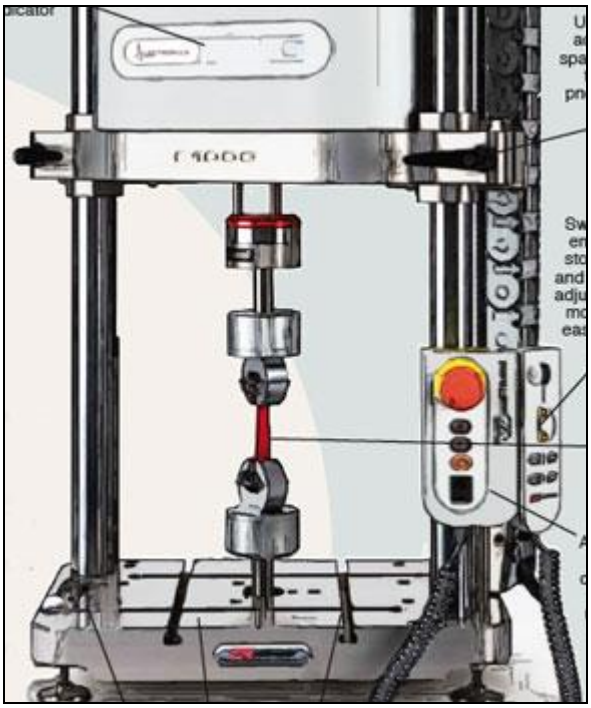

Figure 5: Experimental set-up of tensile test; example of similar Instron Model 1000 equipment with computer to retrieve data.

Equations used for calculating relative stress-strain:

$$Stress = \frac{Force}{Area}$$

$$Area = \frac{\pi \cdot D_1 \cdot D_2}{4}$$

$$Strain = \frac{Displacement}{L_0}$$

Where D_1 = liner thickness, D_2 = liner width across, and Lo = the length of the liner in the tensile testing machine. Force and displacement values were read from the tensile testing machine.

Due to time restrictions, the tests of the control liners and liners with the maximum exposure time and wattage (9-watt, 24 hours) were tested and compared for each liner type.

III. RESULTS AND DISCUSSION

The following stress-strain graphs were yielded with the aforementioned analysis. *Figure 6* represents the stress-strain curve for the ALPS Corporation (tan) liner, for both the control and 9-watt, 24-hour exposed liner. As the graph shows, there is variation between the maximum failure stress (last point on each data set) and the slope of each of the data sets. The exposed liners have a smaller maximum failure stress versus the control. Relative elasticity, or slope of each line, is inconclusive from these results.

During testing, the ALPS (tan) liner was able to stretch at least six times its original length and for all samples inevitably failed on the fabric portion. The variability in the stress-strain curve represents this occurrence. It is also apparent that the two liners exposed for the same amount of time are inconsistent with each other, questioning the consistency of the difference from the control.

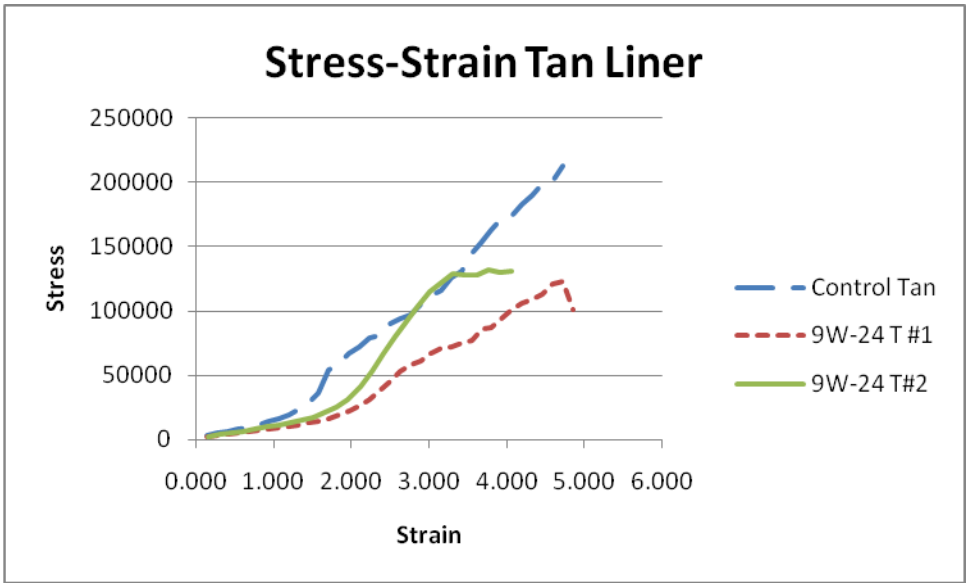

Figure 6: Stress-strain curve for the ALPS (tan) liner; Control versus 9-watt-24 hours.

Figure 7 represents the stress-strain curve of the Freedom Innovations (white) liner. The elasticity and relative strength of this silicone material stayed constant after 24 hours of ultraviolet light exposure. The relative strength of the material is also consistent up until very high strains. The Freedom Innovations liner was also able to stretch many times past its original length and tended to fail towards the top of the specimen. From the stress-strain curve it is apparent that the liner did not lose its integrity post-ultraviolet light exposure.

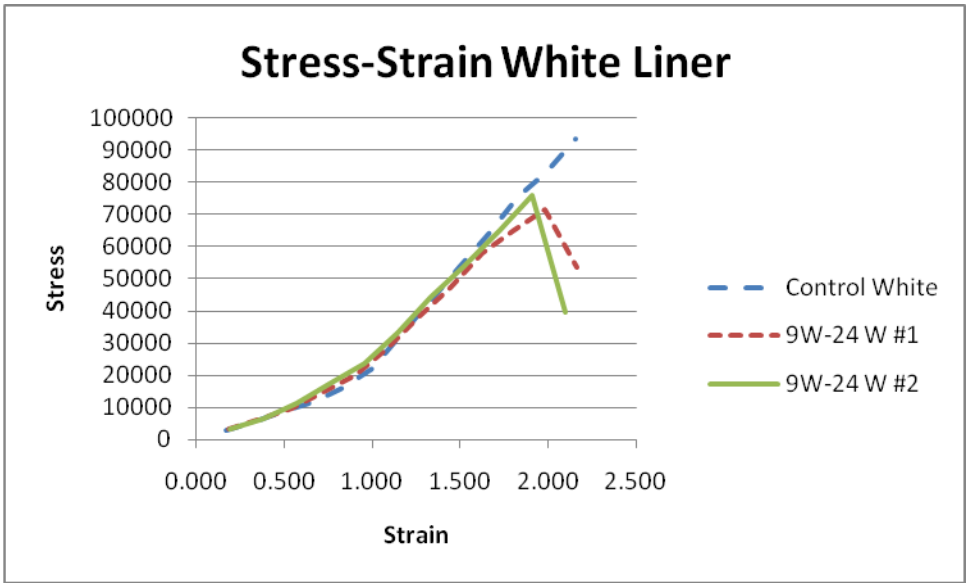

Figure 7: Stress-strain curve for the Freedom Innovations (white) liner; Control versus 9-watt-24 hours.

IV. CONCLUSIONS

The quantitative data represented in this protocol from the tensile testing machine was just one approach to understanding the effect of ultraviolet light on silicone liners. The overall test to consider is the comfort of the person wearing the liner; they would be the best judges of whether or not the liner has lost its integrity.

However, to answer the research question by looking at the raw data, there is NOT significant evidence within these tests to prove a considerable effect to the liner's integrity for both liners tested for the following reasons:

- The testing results shown use exposure of 24 hours; however, the typical user of this prosthetic disinfectant device will only be exposing their liner for approximately one minute each day. When summated to the 6-month life of a liner, the exposure time is approximately 3 hours total, or 1/8 of the tested time.
- The tested liners were exposed to the 24 hours of ultraviolet light within a few days. The gradual exposure of the liner will negate these affects.
- The stress-strain graph for the ALPS liner was affected by many variables, including fabric attachments and positioning of fabric seams.

Future work to understand the degradation test would be to have a clinical study with prosthetic liner wearers to more fully understand the comfort of a liner with possible integrity loss.