Medical Arts Prosthetics: Composite Prosthetic

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Abstract

Silicone is widely used in the aesthetic prosthetic industry due to its high levels of customizability, which allow for the reproduction of lifelike appendages. Silicone, however, has unsatisfactory mechanical properties which prevent silicone prostheses from providing patients with a cost effective life in service time. By coating the silicone with polyurethane (PU), the prosthetic can exhibit improved mechanical properties and an increased lifespan without affecting the aesthetic appeal. A series of mechanical tests were conducted on silicone, polyurethane, and silicone-coated polyurethane samples to assess and determine the peel strength, tear strength, coefficient of friction and wear rate. Preliminary testing showed that the bonded material had an increased tear strength ($p < 0.0001$) and bond strength. Mixed results were observed in the adhesive strength testing. Additionally, the calculated coefficient of friction for silicone was shown to be less than that of polyurethane, which is counterintuitive. Overall, additional testing and experimentation with fabrication need to be completed to allow further development of a prototype.

Background

Project Motivation

- Silicone aesthetic prostheses achieve high levels of realism and comfort, but have significant issues with their cost and life in service
- Prostheses experience significant wear and tear and discoloration from everyday use
- Coating silicone prostheses with another polymer could enhance durability and decrease the coefficient of friction, while maintaining aesthetics of prostheses

Figure 1: Silicone index finger prosthesis.

Figure 2: Attempted lining of silicone with PU sheath.

Figure 3: PU lining on the silicone prosthesis.

Materials

- Silicone - most commonly used material for aesthetic prostheses
  - Customizable, chemically inert, thermally and oxidatively stable
  - Porous and easily discolored [1,2]
- PU - increased strength and elasticity
  - Difficult to process, poor compatibility with adhesive systems, and UV sensitive [1,2]
- Methyl Methacrylates - increased strength and durability + compatible with adhesive systems
  - Rigid and destructive mold procedure [1, 2]
- Udagama Technique:
  - Polyurethane film vacuum formed onto a silicone prostheses
  - 5 year lifetime, prone to molding
  - Not compatible with finger prosthetics

Design Specifications

- The coated prosthesis must have a decrease in coefficient of friction by at least 10%
- The tear strength should also increase by at least 5% from the original model
- The material should not increase the difficulty of painting the prosthesis from the painting procedure of normal silicone
- Physical and Operational Characteristics: aesthetics, topography, performance, safety
- Production Characteristics: quality, competition, color, standards and specifications

Testing and Results

Tear Testing:

1. Prep sample and make cut ⅔ of the way across center
2. Separate samples at rate of 20mm/min in MTS machine
3. Obtain load, displacement, and time values from test
4. Plot in MATLAB. The peak is considered the tear strength

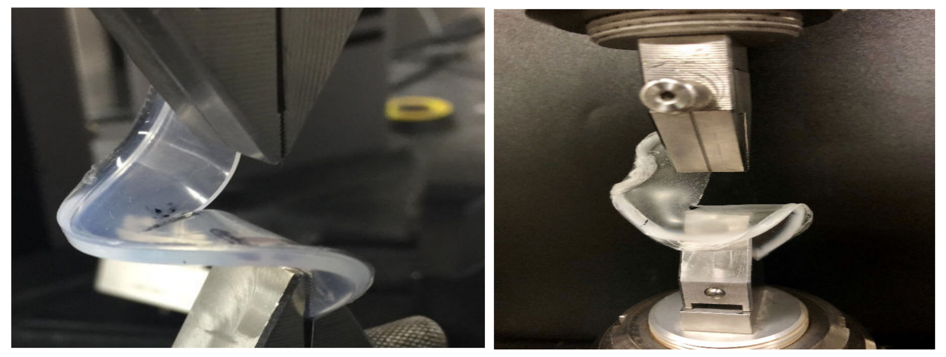

Figure 5: Silicone (left) and polyurethane (right) samples at the start of tear testing.

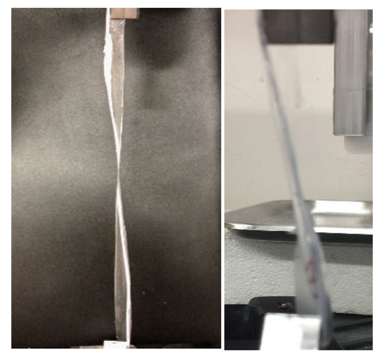

Figure 7: Silicone sample (left) after failure and PU (right) sample approaching failure.

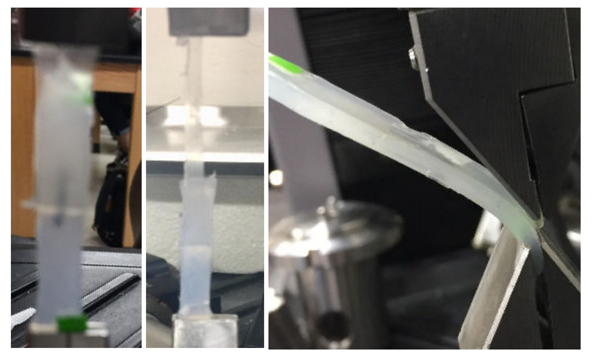

Figure 8: Shows samples mid-test with variable elongation during peel; sample shown at the beginning of T-peel test.

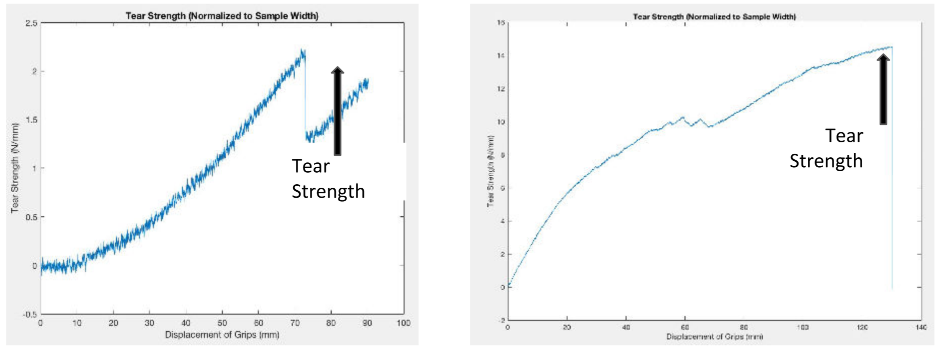

Figure 10: Representative loading profiles during tear test for silicone (left) and polyurethane (right).

UV Degradation Testing: ASTM D572

1. Sample placed under sun-lamp bulb contained in test chamber
2. Sample exposed to radiation from lamp for specified periods of times and imaged following exposure
3. Degree of discoloration is rated against reference standards and original sample

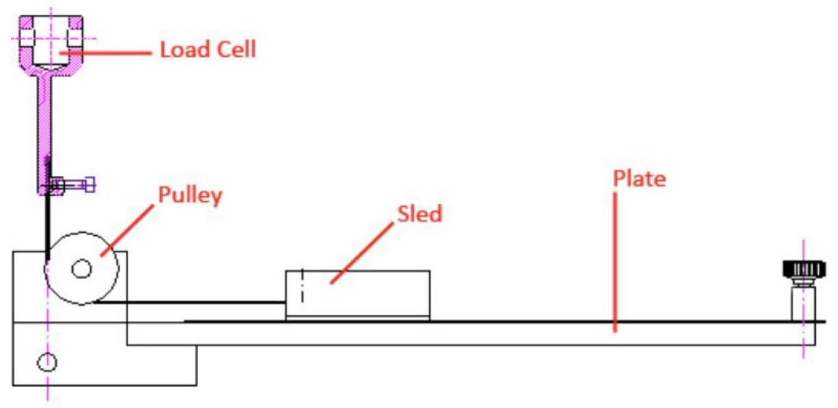

Figure 12: Testing setup for coefficient of friction quantification [3]

Table 2. Coefficients of Friction of Polyurethane and Silicone				
Material	Average Static Coefficient of Friction		Average Kinetic Coefficient of Friction	
600 grit Sandpaper	PU	0.2474	PU	0.2386
	Silicone	0.2345	Silicone	0.2186
Jean Pocket Fabric – 99% cotton, 1% spandex	PU	0.2397	PU	0.2250
	Silicone	0.2161	Silicone	0.2050

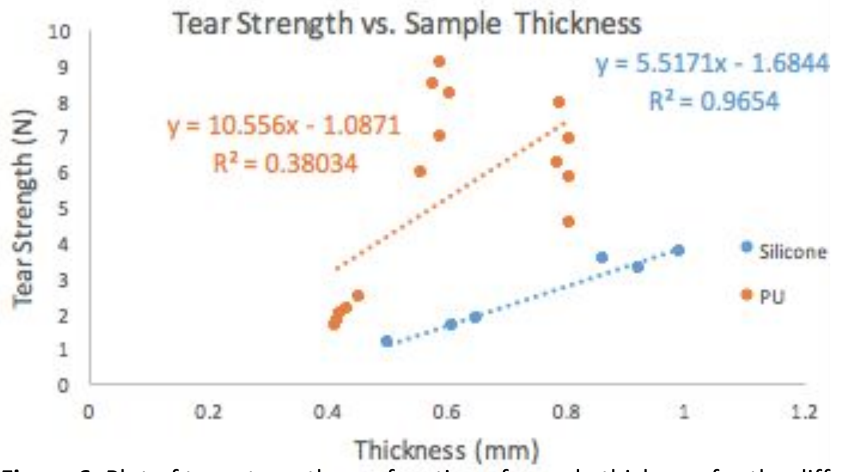

Figure 6: Plot of tear strength as a function of sample thickness for the different conditions.

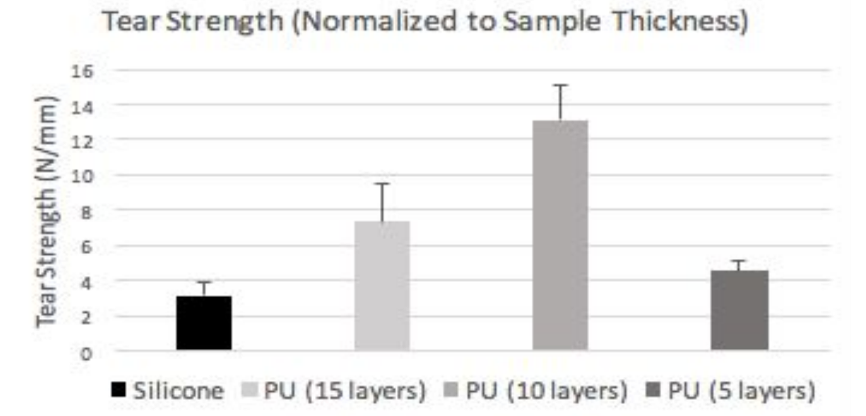

Figure 9: Comparison of tear strength between polyurethane (PU) and silicone.

Adhesive Strength Testing:

1. Fabricate a rectangular PU bound to silicone specimen with unbound ends
2. Separate ends of the sample at 25.4 mm/min
3. Obtain load, displacement, and time values
4. Plot in MATLAB to determine mean peel strength

Table 1. Adhesive Strength Testing Results	
Adhesive Strength Testing	**Results**
Peak Load	6.648 ± 4.928 N
Peak Peel Strength	0.960 ± 0.709 N
Mean Peel Strength	0.626 ± 0.502 N

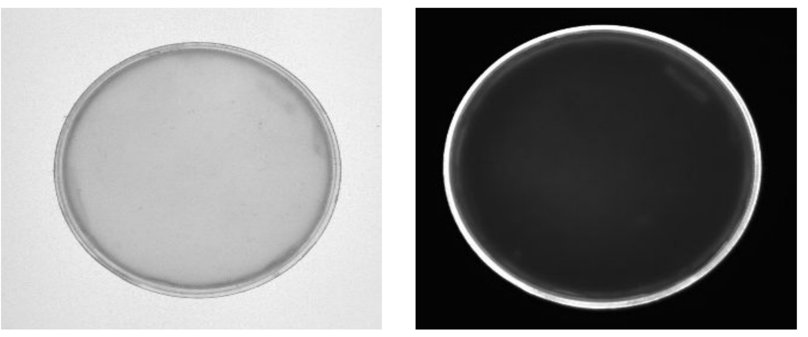

Figure 11: Representative testing images showing sample under light (left) and fluorescence (right) after UV exposure for 15 hours.

Coefficient of Friction Testing: ASTM D1894

1. Sample placed on sandpaper surface
2. Sample connected to load cell via fishing line and pulley
3. Load cell moving at 1 mm/s for 10-mm
4. Repeat to test on 99% cotton pocket fabric

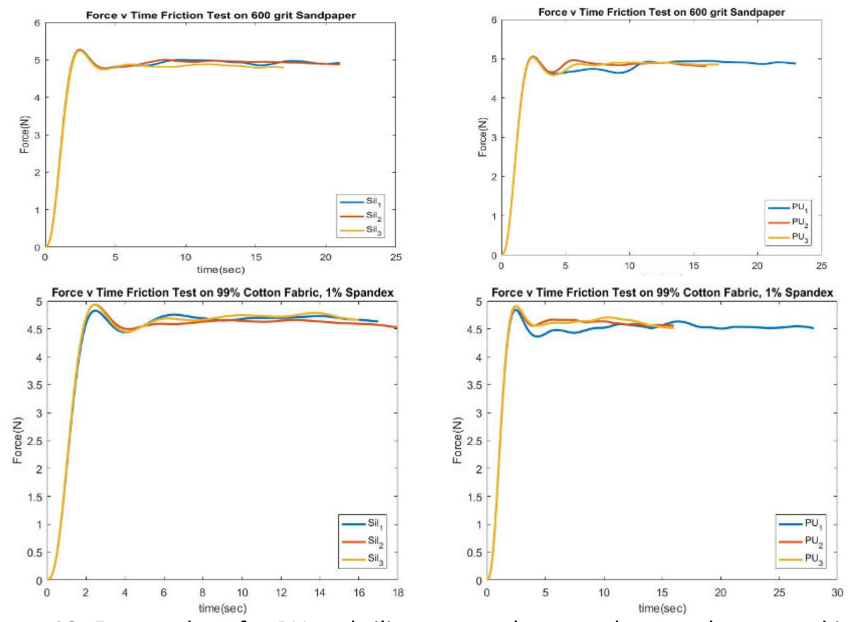

Figure 13: Force values for PU and silicone samples tested on sandpaper and jean pocket fabric

Methods

Materials:

- Silicone Elastomer A & B (RTV-4420)
- Polyurethane (SC-92)
- Sofreliner (T)
- Pasteur Micropipette
- Pressure Generator
- Hot Plate
- Vacuum Chamber

- PU diluted into 30:70 (v/v) water:PU
  - sprayed for 5 times into covers of petri dishes
  - allowed to cure via drying
  - 100 µL primer applied to each sample and spread with a paintbrush
  - 50 minute wait time and 50:50 (m/m) silicone A:B added onto primed PU

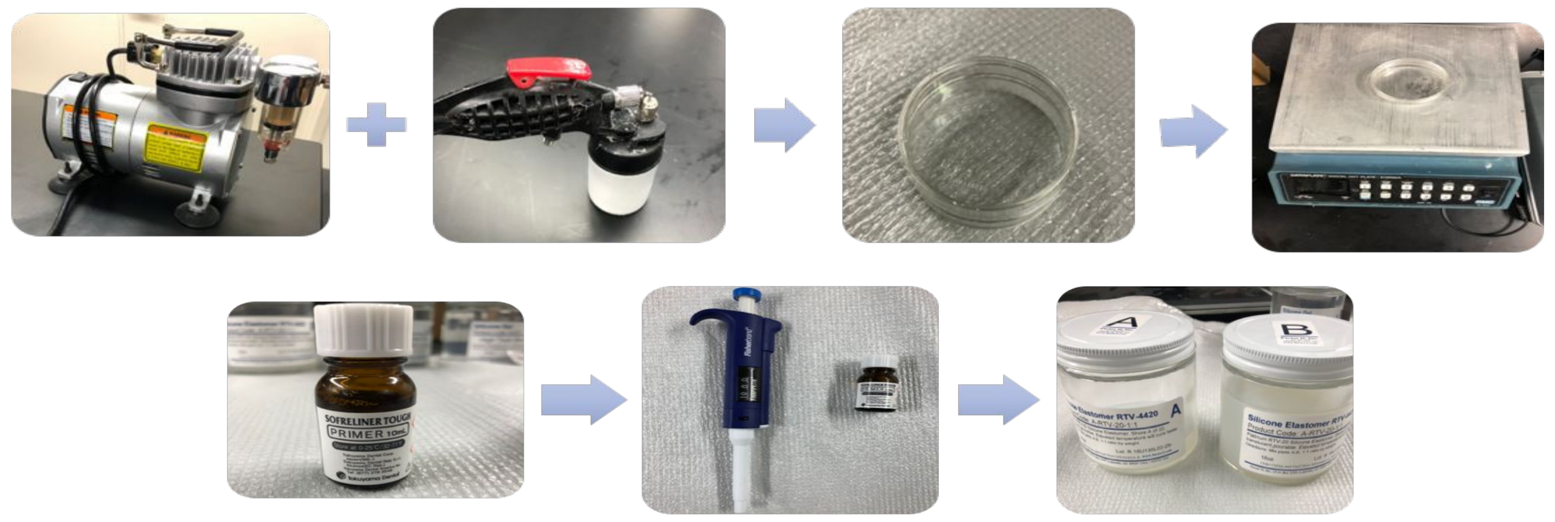

Figure 4: Sample fabrication schematic

Discussion

- Tear strength improvement from silicone to all PU samples was found to be statistically significant (unpaired t-test), but samples should be of similar thickness
  - For silicone vs 10-layer, $p < 0.0001$, $t = 11.6540$, $N = 5$
- Bond strength is promising given some mixed failure results in adhesive testing
  - Further consistency should be developed in adhesive process
- Calculated coefficient of friction for silicone is less than polyurethane
  - Results are counterintuitive
  - Testing equipment resolution not compatible with small sample masses used
  - Will need to test again with better equipment or larger samples
  - Difference found to be statistically significant in all cases, n = 3

Conclusions & Future Work

Conclusions

- Aesthetic prosthetics can indirectly improve function of hand and result in enhanced trauma rehabilitation through psychological and physical improvements
- There is a significant need for these prostheses to have an enhanced longevity given their high cost
- Composite prostheses that conjoin silicone with polyurethane can significantly enhance the mechanical properties and thereby improve the product longevity

Future Work

- Complete further testing and analysis on coefficient of friction and wear rate using a nano-tribometer and Hysitron Nano-Indenter, respectively
- Experiment with a polyurethane that is UV resistant and has higher toughness
- Repeat tear testing with larger sample sizes
- Experiment with vacuum forming techniques using the primer to adhere PU sheets onto silicone surfaces

Acknowledgements

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References

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[2] A. Mitra, S. Choudhary, H. Garg, and J. H.G, "Maxillofacial Prosthetic Materials- An Inclination Towards Silicones," *Journal Of Clinical And Diagnostic Research*, vol. 8, no. 12, Dec. 2014.
[3] "ASTM D1894 Coefficient of Friction Test on Plastic How to Guide", *ADMET - Materials Testing System Manufacturer*, 2017. [Online]