Medical Arts Prosthetics: Composite Prosthetic

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Abstract

Silicone is widely used in the aesthetic prosthesis industry due to its high levels of customizability, allowing for the reproduction of lifelike appendages. However, silicone has poor mechanical properties which prevents these prostheses from providing patients with a cost effective longevity. 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 and UV resistance tests were conducted on silicone, polyurethane, and silicone-coated PU samples to assess and determine the peel strength, tear strength, coefficient of friction, wear rate, and discoloration. PU increased tear strength over silicone ($p<0.0002$) and the coated samples demonstrated cohesive failure in the silicone matrix. Additionally, the calculated coefficient of friction (CoF) for PU is significantly lower than that for either either silicone ($p<0.05$) tested. Lower CoF values are expected to correlate to decreased wear from abrasion, although additional abrasion tests are required for optimal quantification of wear rate and thus longevity.

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

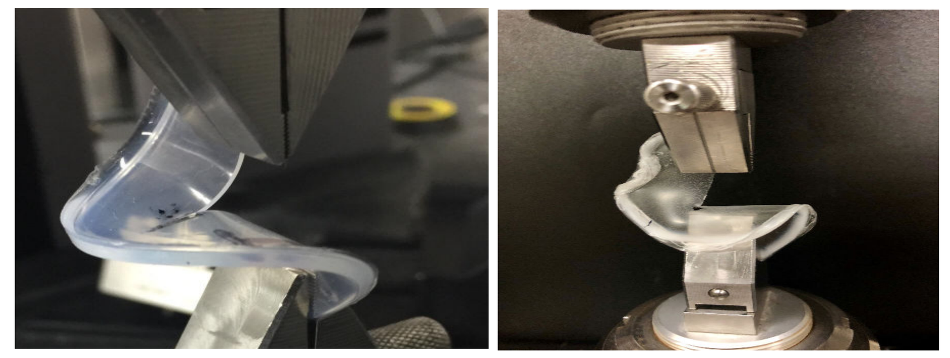


Figure 5: Silicone (left) and polyurethane (right) samples at the start of tear testing.

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

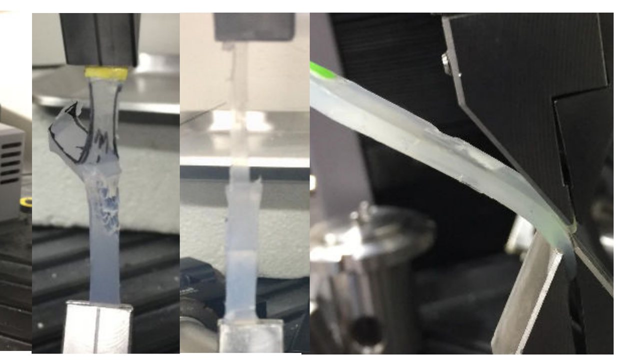


Figure 8: Shows samples mid-test with variable elongation during peel; sample shown at the beginning of T-peel test.

UV Degradation Testing: ASTM D572

1. Samples placed under RSM Type 275 W, 125 V sun-lamp bulb contained in metal housing test chamber
2. Samples exposed to radiation for lamp from 0 to 340 hours and imaged at 10 hour intervals
3. Degree of discoloration is rated against control group and original sample images, samples were analyzed qualitatively and quantitatively using a colorimeter

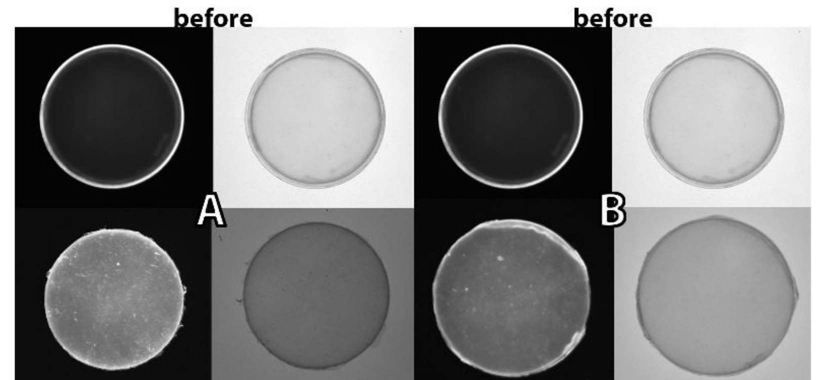
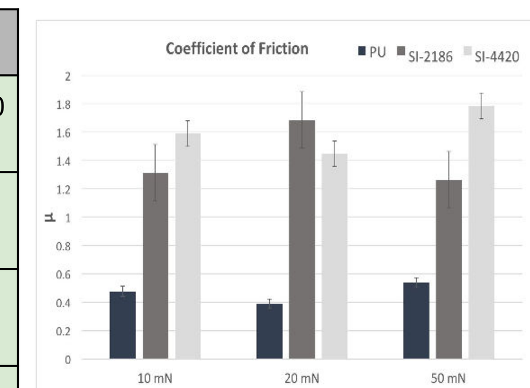


Figure 12: Images showing samples before and after 340 hours of UV degradation **A:** Silicone only; **B:** PU coated Silicone throughout process of testing

(CoF) of Polyurethane and Silicone

Normal Load	PU	SI-2186	SI-4420
10mN	0.478	1.312	1.590
20 mN	0.390	1.687	1.449
50 mN	0.540	1.263	1.787



Wear Rates of Polyurethane and Silicone ($1x10^{-6}$) [=] m^3/mN

Normal Load	PU	SI-2186	SI-4420
10mN	4	1.3	2.7
20 mN	2.9	3.3	1.3
50 mN	1.5	0.9	0.6

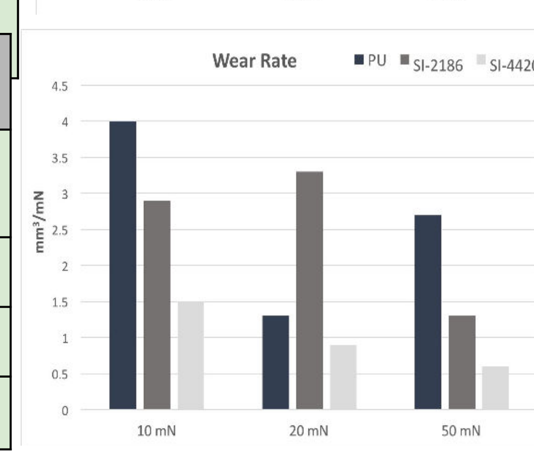


Figure 14: Table and chart of coefficients of friction (top) and wear rates (bottom) quantified at 10mN, 20mN, and 50mN normal loads

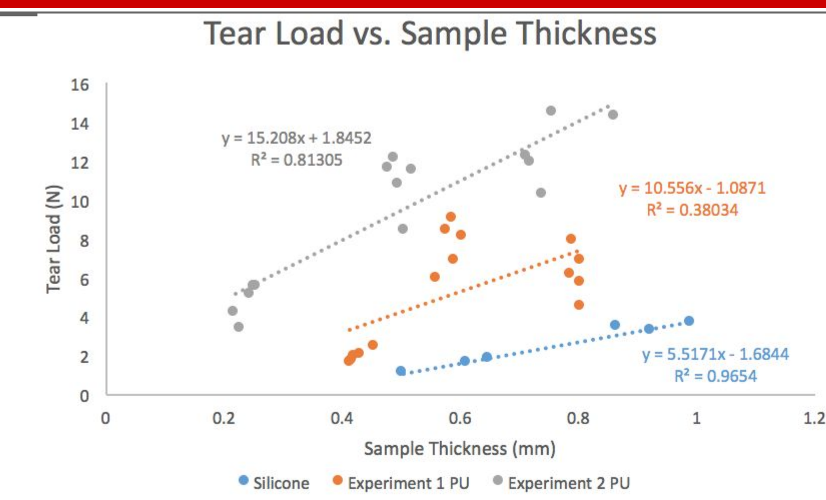


Figure 6: Plot of tear strength as a function of sample thickness for the different conditions.

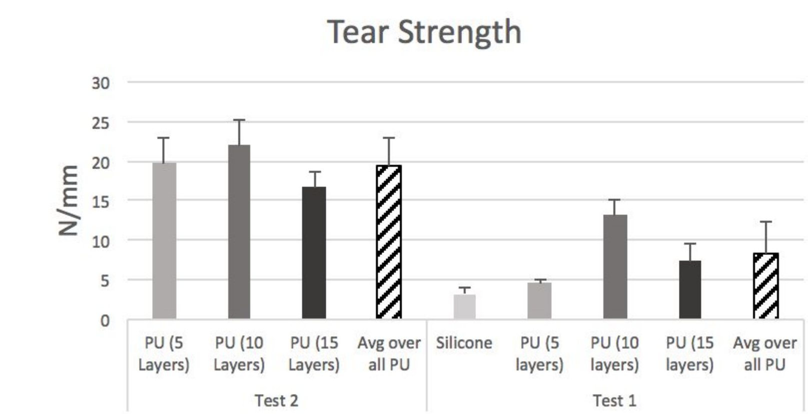


Figure 9: Comparison of tear strength between PU (2 experiments) and silicone.

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 peel strength

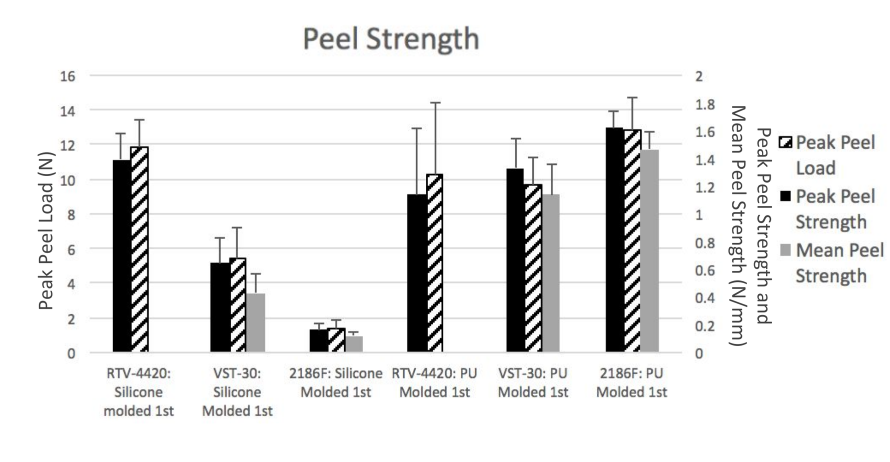


Figure 11: Comparison of peel strength between different silicones and fabrication methods

Coefficient of Friction Testing: Nano-Tribometer

1. Sample adhered to nano-tribometer holding plate
2. Cantilever slowly lowered close to sample surface
3. Set tribometer to oscillate linearly 250µm at 400hZ
4. Begin test, data recording begins once cantilever makes contact with sample surface

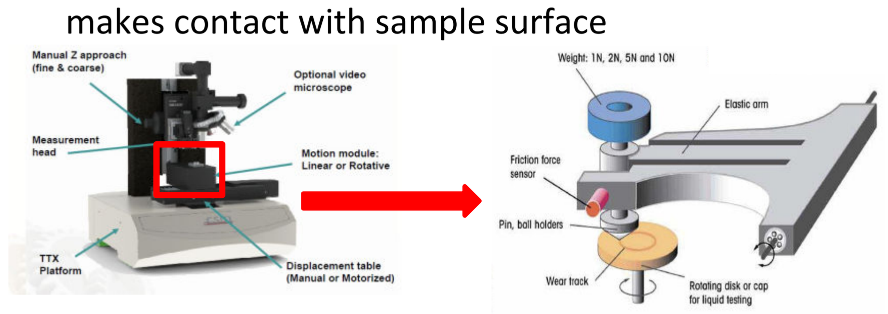


Figure 13: CSM Instruments Nano-tribometer system setup

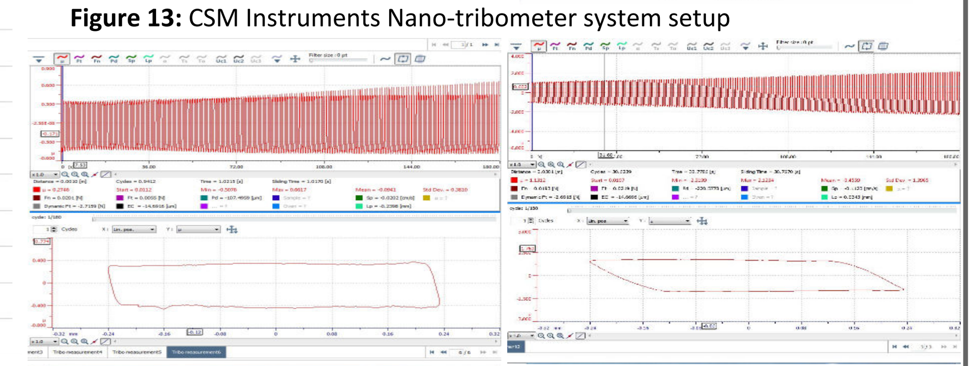


Figure 15: Hysteresis diagrams of CoF values throughout testing for PU (left) and Silicone (right) at 20mN loads

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 5, 10 or 15 times into petri dishes
  - allowed to cure via drying on hot plate (70°C)
- 100 µL primer applied to bonded samples, spread with paintbrush, left for 30 minutes
- Silicone made of 50:50 (m/m) A:B mixture added onto primed PU or into petri dish
  - Left to cure at least 24 hours

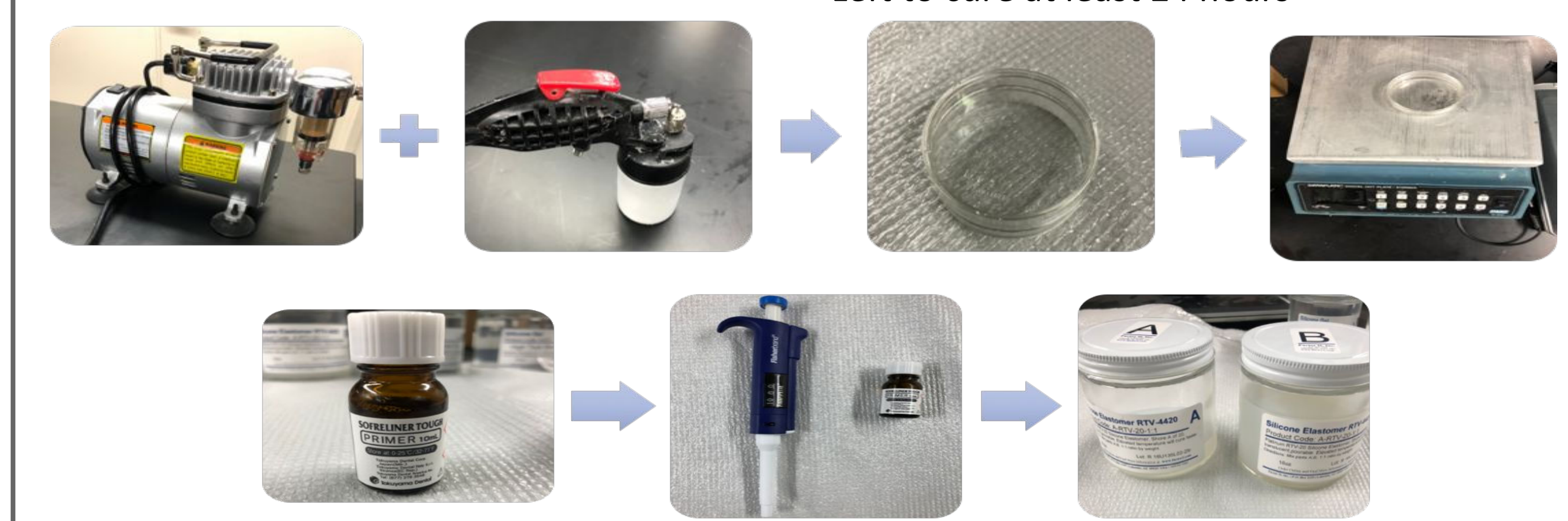


Figure 4: Sample fabrication schematic

Discussion

- Tear strength improvement from silicone to all PU samples was found to be statistically significant (unpaired t-test): silicone vs PU average (Trial 2), $p < 0.00014$
  - Trial 2 PU was markedly more resistant to tearing that Trial 1. This may be due to the 12 month shelf life of PU; Trial 1 used an already opened container while Trial 2 used new PU.
- Although highest peel load was observed with one of the 2186 trials, best results were observed with RT-V20, where the silicone tore before the bond separated
- Calculated CoF for PU was significantly lower ($p < 0.05$) than that of either silicone tested
  - Difference found to be statistically significant in all cases, n = 3
  - A minimum 57% decrease in CoF was found in the PU coated samples (max: 77% decrease)
- Wear rate test showed the elasticity of each material → PU was more elastic than either silicone

Conclusions & Future Work

Conclusions

- Use of a primer allows PU bound to silicone to not fail at the interface between the two materials
- PU coated silicone reduces the likelihood of failure at low thickness areas such as those that engage with the digit residuum
- PU coated silicone reduces the coefficient of friction decreasing the generation of friction forces during use of the prosthesis (less material volume loss expected from abrasion)

Future Work

- More complete UV testing and analysis using colored silicone
- Optimization of the fabrication method for use by an anaplastologist
- Perform aesthetic finger prosthetic clinical trial utilizing this method to assess performance over time during daily use
- Further testing with color retention after PU coating in addition to testing into the ease of coloring PU

Acknowledgements

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References

[1] V. S. Deepthi, "Maxillofacial Prosthetic Materials - An Update," *Journal of International Medicine and Dentistry*, vol. 3, no. 1, Feb. 2016.
[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]