Polymeric Trileaflet Heart Valve Development

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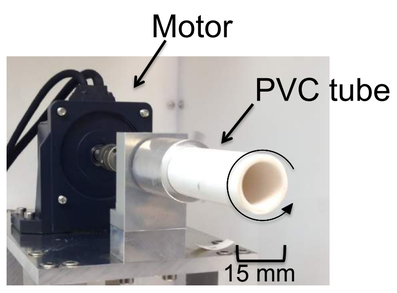
INTRODUCTION

In the past, both mechanical and biological heart valves have been used for heart valve replacements. However, these both show limitations with regards to long term physiological compatibility and durability. Attempts have been made to develop a new polymeric trileaflet heart valve made of a single polymer structure. Using medical grade silicone, this project explores the manufacturing processes needed to build such a valve and quantifies the valves performance.

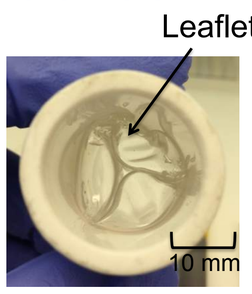
OBJECTIVES AND GOALS

1. Create a reliable and repeatable manufacturing process for silicone heart valves with consideration to thickness distribution
2. Perform pressure and flow rate analysis on newly manufactured valves

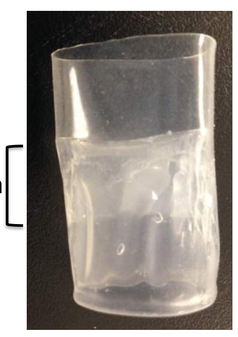
MANUFACTURING PROCESS



1. Silicone is introduced into a PVC tube and cured for 72 hours.

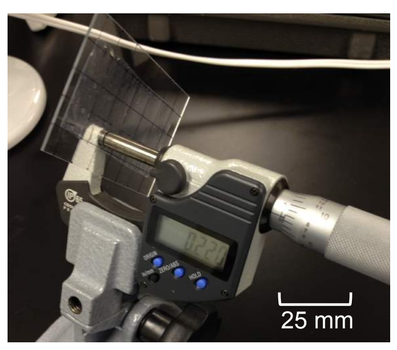


2. Leaflets are folded into place on inside of valve

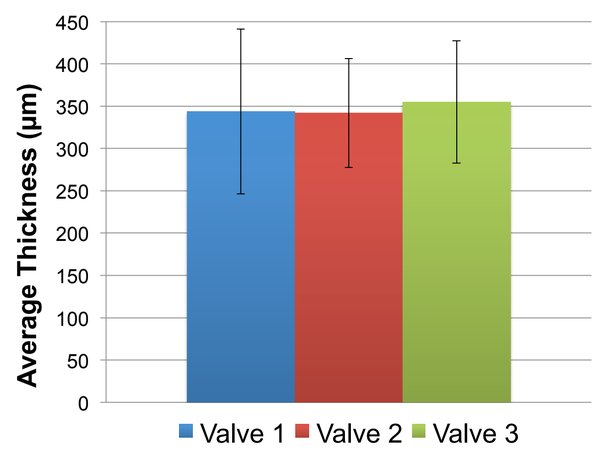


3. Silicone valve is removed from PVC tube

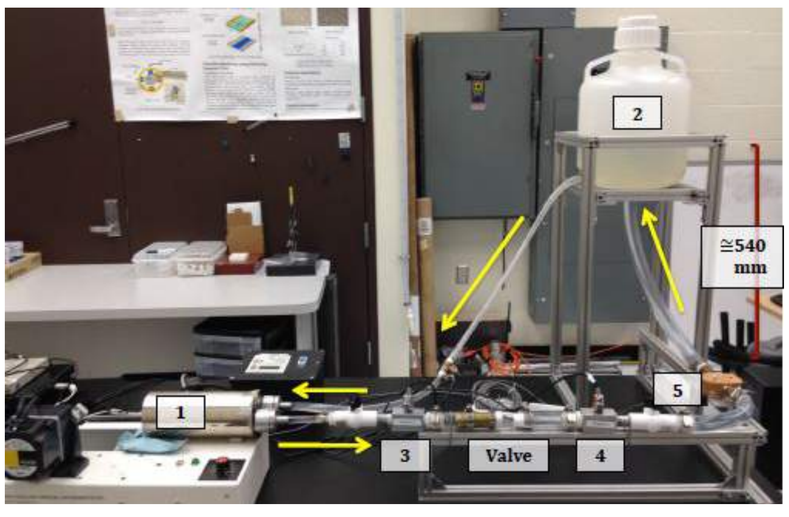
RESULTS – THICKNESS DISTRIBUTION



Micrometer silicone thickness measuring method



EXPERIMENTAL SETUP

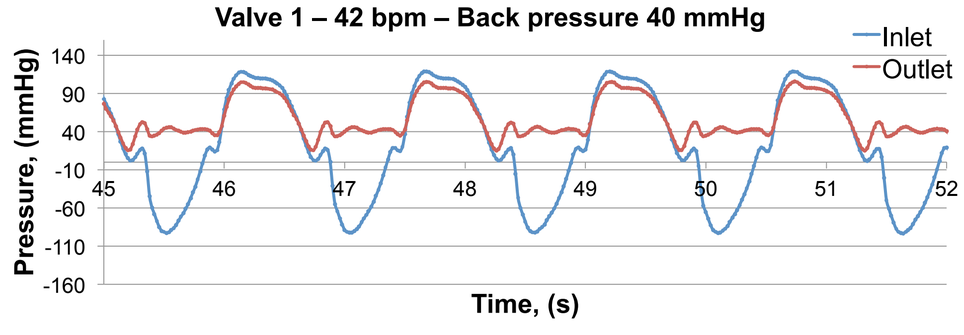


Water pump (1)
Back pressure tank (2)

Pressure transducers (3 & 4)
Flow meter (5)

RESULTS – DYNAMIC TESTING

	Pressure (mmHg)		Flow Rate (mL/s)
	Inlet	Outlet	Outlet
Maximum	199.23	105.10	48.00
Minimum	-94.14	14.63	0.00



CONCLUSION AND DISCUSSION

- A reliable silicone heart valve manufacturing process was designed and implemented.
  - Average error in thickness was found to be about 20%
- Dynamic testing showed that silicone heart valves under experimental conditions were durable over time.
  - Leaflets adjusted to pressure fluctuations, and no tearing occurred.

FUTURE WORK

- More attention will be placed on reducing the deviation of thickness along the valve. This is essential for balancing forces along the leaflets.
- FDA approved pressure and flow rate data will be acquired.
- Long term durability tests will be performed on manufactured valves.

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