WALTER SCOTT, JR. COLLEGE OF ENGINEERING
COLORADO STATE UNIVERSITY

Mechanical Bladder: Controlled Fluid Outlet System

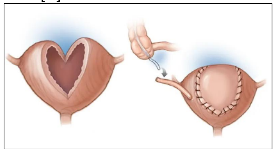
Teryn Degenhart[1,3], Emma Hurley[1,3], Anu Mathew[1,2], Jordan Schlitzer[1,3]

Advisors: Hiep T Nguyen MD[4], Shawn Smith PA[4], Katie Sikes[5]

School of Biomedical Engineering[1] | Department of Chemical and Biological Engineering[2] | Department of Mechanical Engineering[3] | Banner Health[4] | Department of Clinical Science[5]

Background Information

- Each year, there are about 1,600 babies born with spina bifida, 17,000 spinal cord injuries, and 68,000 bladder cancer patients with compromised bladder function [1]
- Treatments for spina bifida include an bladder augmentation procedure in which a piece of intestine or appendix is used to increase the bladder volume [2]

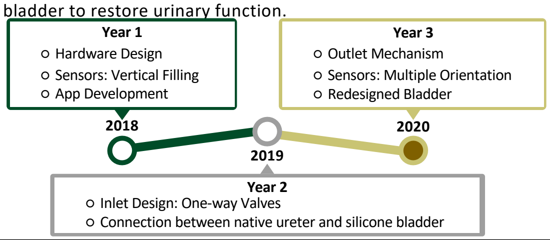


Bladder augmentation procedure [4]

- Treatment for bladder cancer patients and spinal cord injuries includes urostomy and orthotopic neobladder reconstruction [3]

Purpose

With no option currently existing for a total artificial bladder replacement, the Mechanical Bladder hopes to address the shortcomings with a monitored and user-controlled implantable bladder to restore urinary function.



Goals and Objectives

Safe and Complete Emptying	No leakage when closed
	Empties completely
	Minimize void time
Effective Filling and Emptying (Vent)	Air exits during bladder filling
	Air enters during bladder voiding

Constraints

Space	Bladder Volume	≈ 650 mL
Biological Urethra	Diameter	6 mm
	Length	200 mm (Male)
		40 mm (Female)
Properties of Urinary Flow	Emptying Time	<30s
	Flow Rate (Emptying)	9 – 21 mL/s
	Flow Rate (Filling)	1 -2 mL/s

References

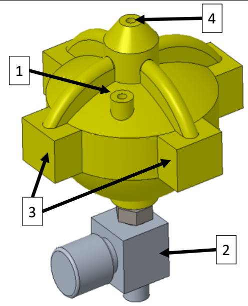
[1] CDC, "Spina Bifida Data and Statistics | CDC," Centers for Disease Control and Prevention, 23-Sep-2019. [Online].

[2] P. D. Metcalfe and R. C. Rink, "Bladder augmentation: Complications in the pediatric population," Curr. Urol. Rep., vol. 8, no. 2, pp. 152–156, Mar. 2007.

[3] D. T. S. Chang and N. Lawrentschuk, "Orthotopic neobladder reconstruction," Urol. Ann., vol. 7, no. 1, pp. 1–7, 2015.

[4]"Bladder augmentation,"http://mybladdermylife.com/inside-the-bladder/medical-procedures-for-a-sci-bladder/bladder-augmentation/

Design



Urine Pathway

(1)Inlet from kidney (designed year 2). Urine stored in 650mL reservoir

(2)Controlled outlet through solenoid valve

Air pathway

(1)Air pockets separated from urine by PTFE membrane filter (internal) with high air permeability and high water entry pressure

(2)Air travels through tubes that connect at top of bladder. Air outlet connected to continent channel out of body

Control and Measurement System

Mobile app allows user to:

- Control solenoid valve
- View current bladder volume using a system of conductive pins stuck into the silicone

Validation

1. Membranes

a. Calculation: under the pressure of a full bladder the membrane would remain impermeable to urine

$$P_{water\_entry} = 31.03 \text{ kPa} >> P_{bladder} = 1.12 \text{ kPa}$$

i. **Significance**: membranes will not leak

a. Calculation: Enough air must be able to move for the bladder to void at its highest flow rate $Q_{in} = Q_{out} = 1.388$ **mL/min**, between **14-24cm²** of membrane is required based on the permeability of the membranes.

i. The membrane area on the final bladder design is **44.3 cm²**

a. Physical Testing: a 50mL test tube was filled with water and sealed with the membrane over top.

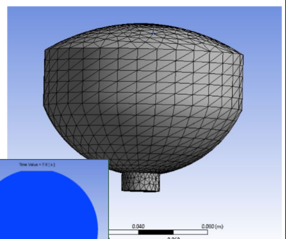
Result 1: Over 24 hour period no water leaked through the membrane

Result 2: A draining test was done to prove air could move through the membrane during voiding

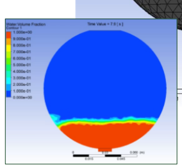
2. Outlet

a. Computational Fluid Dynamics Model

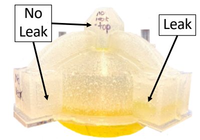
i. 3D ANSYS model showed that voiding by gravity of a full bladder (650mL) would be under set time constraint (30s)



Relevant Results	
Void Time	9.1 seconds
Average Volumetric Flow Rate	90.48 mL/s

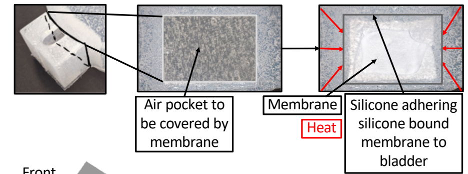


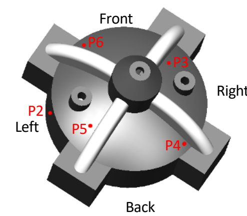
Experimental Results



Prototype Membrane Testing Results

- Initially, three-fifths of membranes were not completely sealed
- **New method sealed all membranes**





Electrical System Results

- Original Design Containing 13 pins, resulted in limitations
- **Redesign included 6 pins and is able to detect volume in 5 orientations at 50 and 80 percent capacity**

Prepared Methods

1. Join silicone bladder and electrical system
2. Physical pin/sensor placement and testing
3. Test flow rate for solenoid voiding mechanism

Conclusions And Future Work

Conclusions

1. The Sterlitech PTFE membranes did not leak when properly sealed onto the silicone bladder and allowed sufficient air flow for voiding purposes
2. The six pin electrical system worked and displayed expected volume on the App
3. The redesign of the bladder's geometry was required for implementation of a venting mechanism

Future Work

- Increase pins in electrical system for more specified bladder volume
- Add additional features to electrical system to comply with assessed failure modes and effects analysis
  - e.g. automatic emptying, additional alarms and alerts to user
- Redesign geometry of hard outer shell
- In vitro, in vivo, and biocompatibility testing
- Utilize smaller, custom solenoid valve for final product

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