

Stress Urinary Incontinence Device

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Introduction

Enourein Dynamics' objective is to improve the quality of life for adult women struggling with stress incontinence. In addition to the inconvenience, urinary incontinence can be a source of a variety of physical and psychological health problems. We strive to overcome these symptoms by developing an efficient, safe and cost-effective device to manage urinary control. By making modifications and advancements in current technology, we will revolutionize the field of incontinence.

Background

Storage

- Bladder muscle relaxes
- Pelvic floor contracts
- Urethral Sphincter contracts (Voluntary Control)

Voiding

- Bladder muscle contracts
- Pelvic floor relaxes
- Urethral Sphincter relaxes (Voluntary Control)

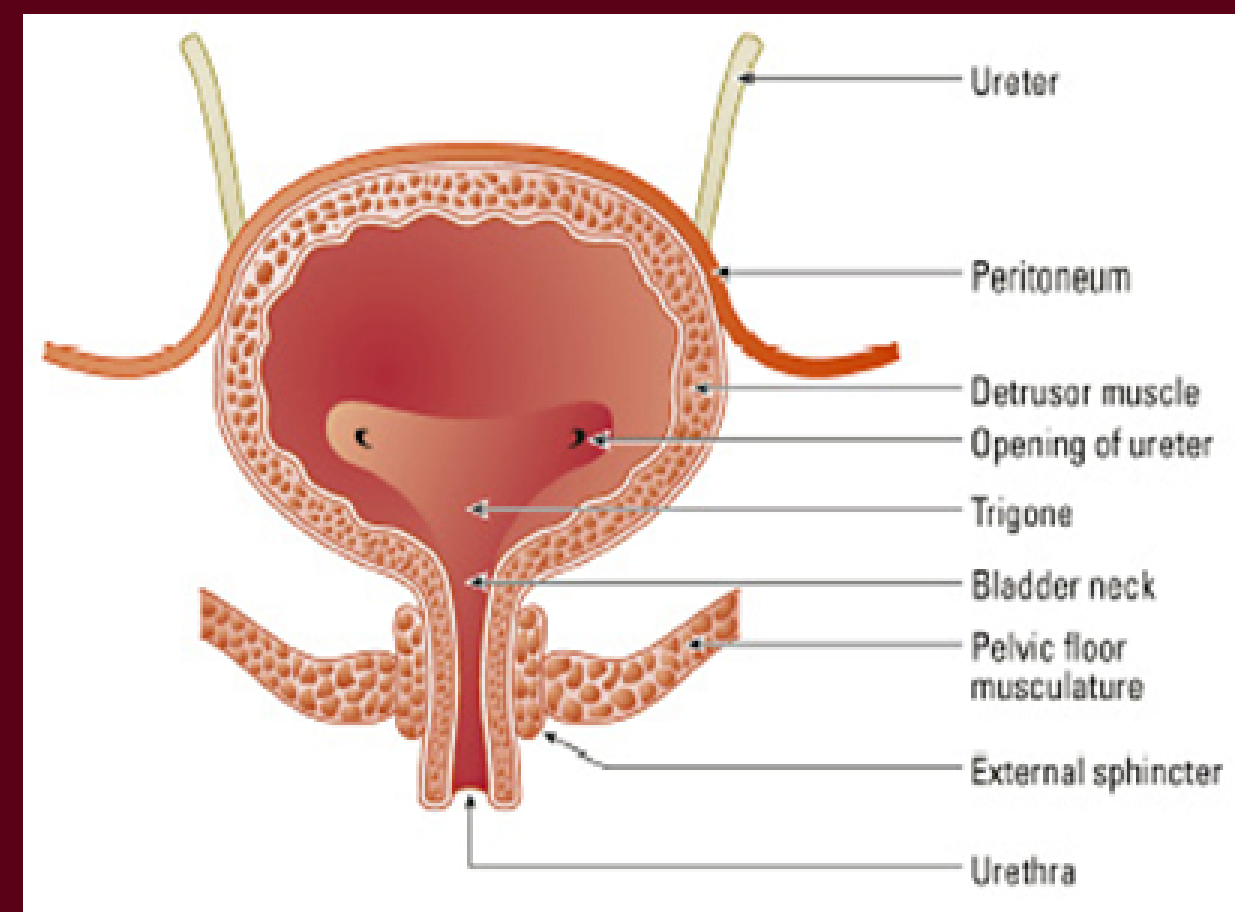


Figure 1. The Bladder Anatomy!

The urinary tract is composed of the bladder and the urethra. Stress incontinence occurs when the sphincter muscle weakens due to trauma or failure of the pelvic floor muscle. So an increase in pressure due to coughing, laughing, and sneezing leads to urine leakage.

Analysis and Model of Bladder

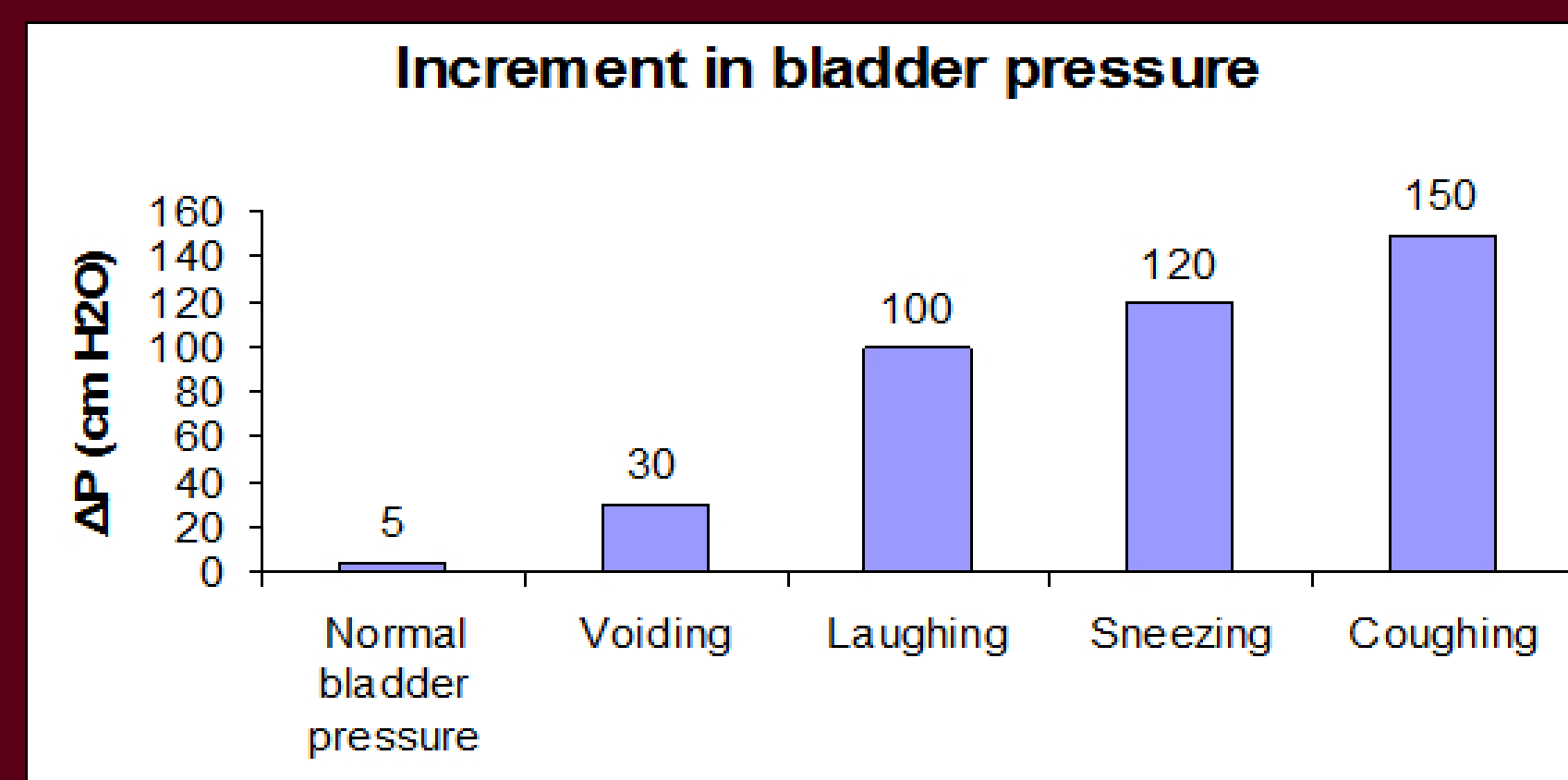


Figure 2. Pressures in the Bladder

A wide range of pressures occur in the bladder. The range of pressures in the bladder are caused by conditions which include normal voiding, laughing, sneezing and coughing.

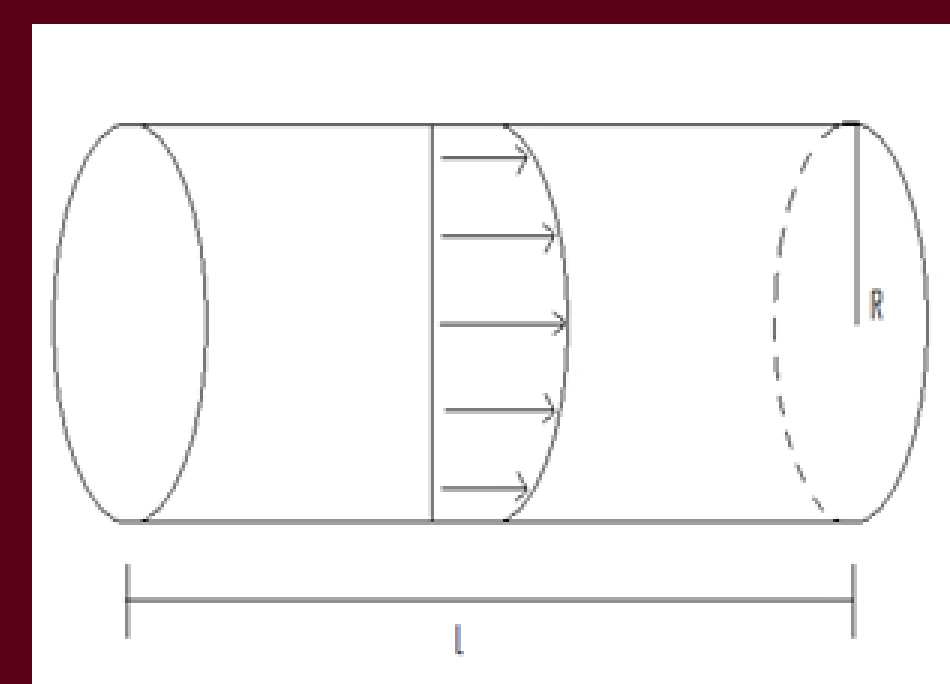


Figure 3. Cylindrical Fluid Model of Urethra

$$Q = \frac{\Delta p R^4}{8 \mu L}$$

The urethra is modeled as a cylindrical tube. It is assumed that flow density is constant and that flow is laminar and fully developed. Urine is modeled as a Newtonian fluid where Volumetric flow rate thru the cylinder can be calculated using the Hagen-Poiseuille equation.

Umbrella Valve

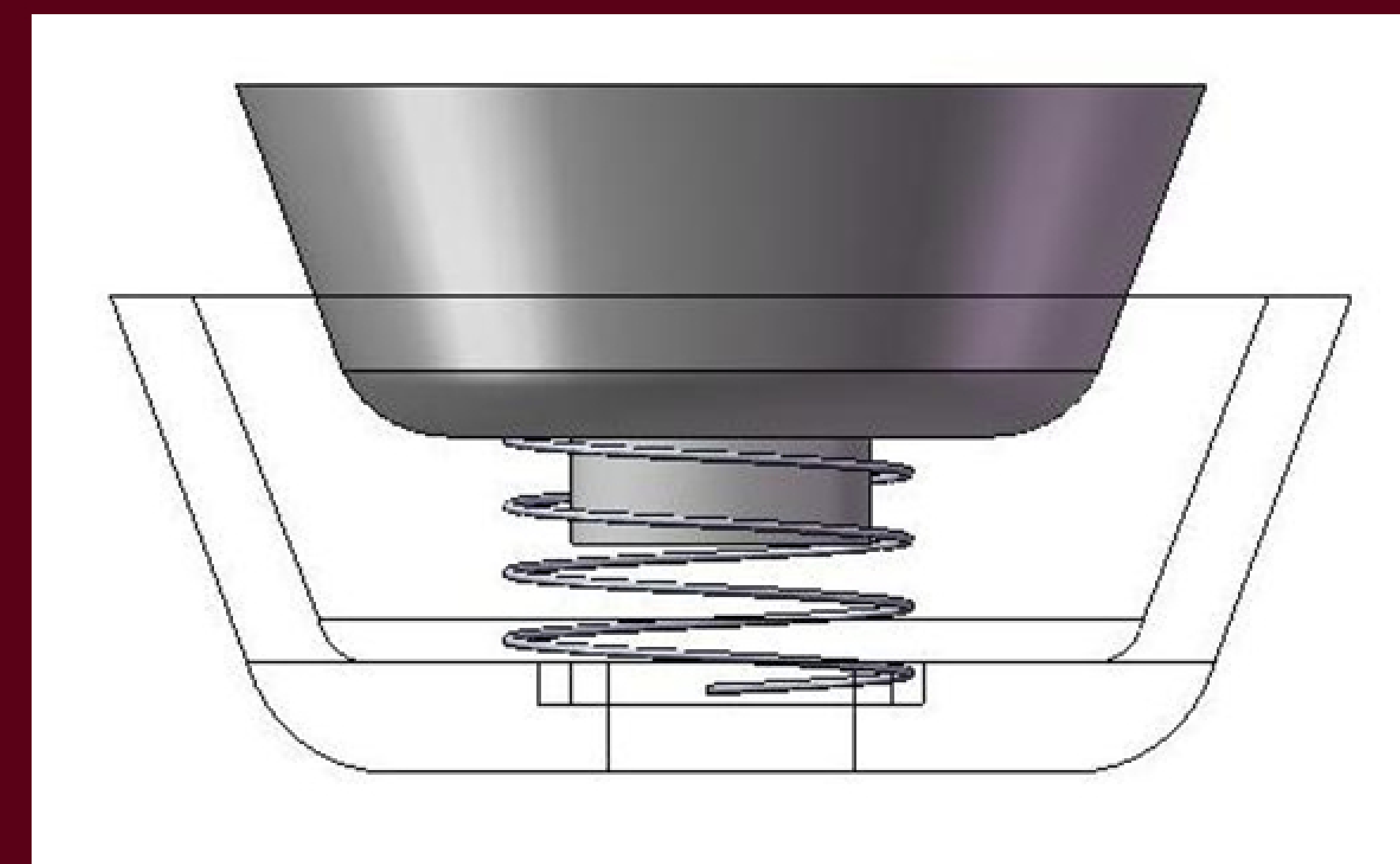


Figure 4. The Umbrella Valve

The valve consists of two separate chambers with a spring connecting the two together. The top chamber has one protrusion, which extends towards the lower chamber. In the lower chamber, a corresponding hole is positioned directly below the upper protrusion. The protrusion blocks the hole and the flow of urine is obstructed and allows the patient to retain urine.

The spring connects the chambers in order to maintain normal voiding and expulsion of urine. The spring is coiled around the protrusion of the top chamber and is connected around the corresponding hole of the bottom chamber. A hollow area is located where the spring is attached. Once the pressure in the bladder goes above normal voiding, such as pressure from a laugh or cough, the spring is compressed and the two chambers close, causing any urine flow to be obstructed. Once the pressure in the bladder is lowered, the spring decompresses and the valve opens, allowing urination to occur.

Fabrication

The working prototype was designed using Solidworks and constructed using a rapid prototyping machine. The spring was formed from galvanized stainless steel wires and heated in Materials Science oven at 315 °C.

The silicone valve was made using Dow Corning 3110 and the mold was designed using Solidworks and constructed in the rapid prototyping machine.

Analytical Methods

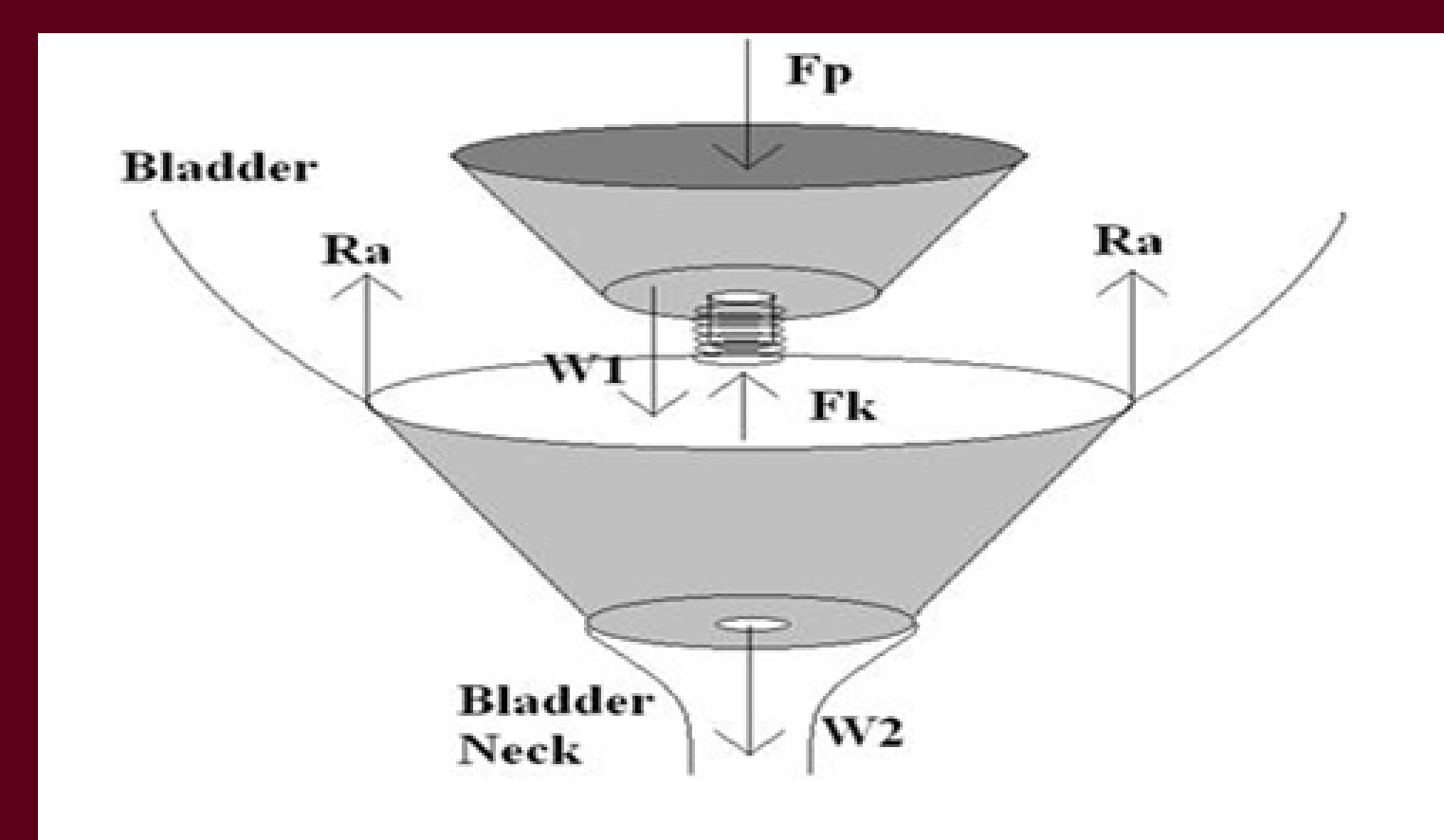


Figure 5. Free Body Diagram of the Device

$$Force = Pressure \times Area$$

$$F_k = -W_1 - F_p \quad F_k = -k \times \Delta x$$

Methods and Test Apparatus

A simulation of the bladder was created using a ball, jar, and gasket material. The pressure inside the simulation was measured using a manometer. Devices subjected to testing were attached to the gasket material and another piece of gasket material with a slit was inserted between the lid and the device. The second gasket material serves as the sphincter muscle. The change in pressure is proportional to the difference in height of the water column.

$$\Delta P = \rho gh$$

Pressures were induced by manually compressing the ball and the pressure was kept constant. A finger blocked water leakage until desired pressure could be reached. Five trials were conducted at 30 and 60 cmH20 for seven different prototypes. The volumes of water leakage were measured for ten seconds and the volumetric flow rates were then calculated.

Results

A total of seven different prototypes were designed for testing, however prototypes #1 and #3 were not suitable for testing and results were not obtained. The different prototypes varied based on bump and hole sizes. As the prototypes progressed, new variations were made based on improvements upon the older ones.

Table 1. Variations in hole/bump sizes based on testing improvements

Prototype	Hole Size (mm)	Bump Diameter (mm)	Bump Depth (mm)
#1	6.5	6.5	4
#2	6.5	6.5	4
#3	5.5	5.5	4
#4	4.5	4.5	4
#5	6.5	7	4
#6	5.5	7	2.5
#7	5.5	7	4

Volumetric flow rates (VFR) at 30 cmH₂O and 60cmH₂O were compared.

In prototypes #1-4 the bump depths were constructed to protrude through the hole, however in prototype #5 we increased the bump diameter to only allow coverage of the hole. This adjustment in prototype #5 showed us an improvement in lowering the VFR at the higher pressure so prototypes #6 and #7 were both designed to cover the hole instead of protruding through it.

In all of the prototypes, the VFR decreased in the higher pressure compared with that of the lower. The lowest VFR, with a 8.34ml/s rate, appeared in prototype #6, where the bump diameter and depth were decreased. A control gasket material with no device attached was also tested and compared to prototype #6. At 60 cmH₂O the VFR of the control came out to be 77.77ml/s compared to the 8.34 ml/s obtained by prototype #6.

Results cont.

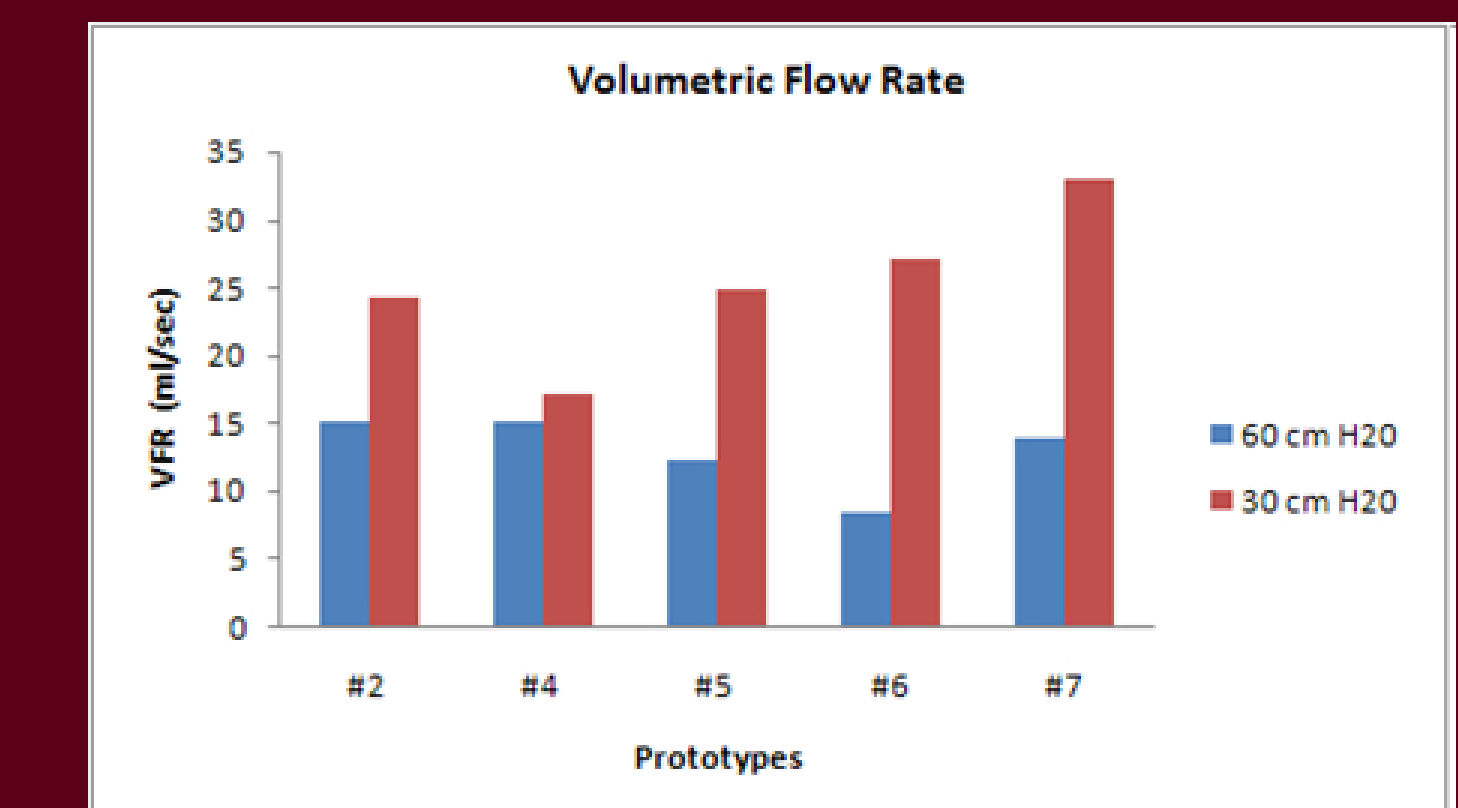


Figure 6. VFR of Prototypes Tested

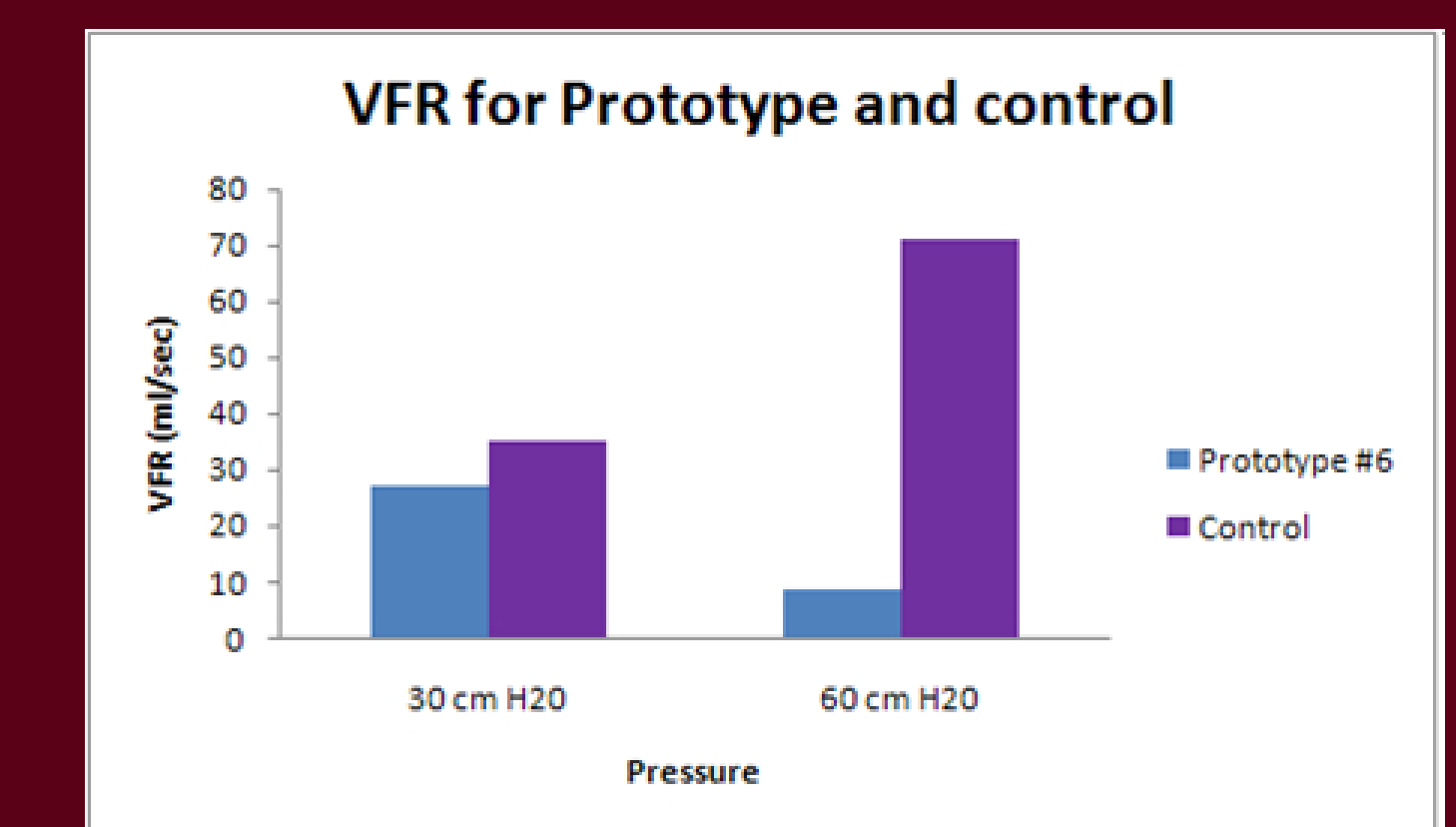


Figure 7. VFR of Prototype 6 vs. Control

Conclusions

From the results, prototype #6 proved to have the lowest VFR at 60cm/H₂O. At the normal voiding mark of 30 cmH₂O prototype #6 had a flow rate of 27ml/s, however the VFR for women during ideal voiding is measured at 14ml/s. As long as the VFR is greater than the 14ml/s the prototype is considered functional.

Although our device did not completely close and prevent fluid flow, the concept of the valve lowered the overall VFR at higher coughing, laughing, and sneezing pressures. The excess 8.34 ml/s that leaked during the 60 cm/H₂O pressure may be due to the slow reaction time of the spring.

Future Recommendations

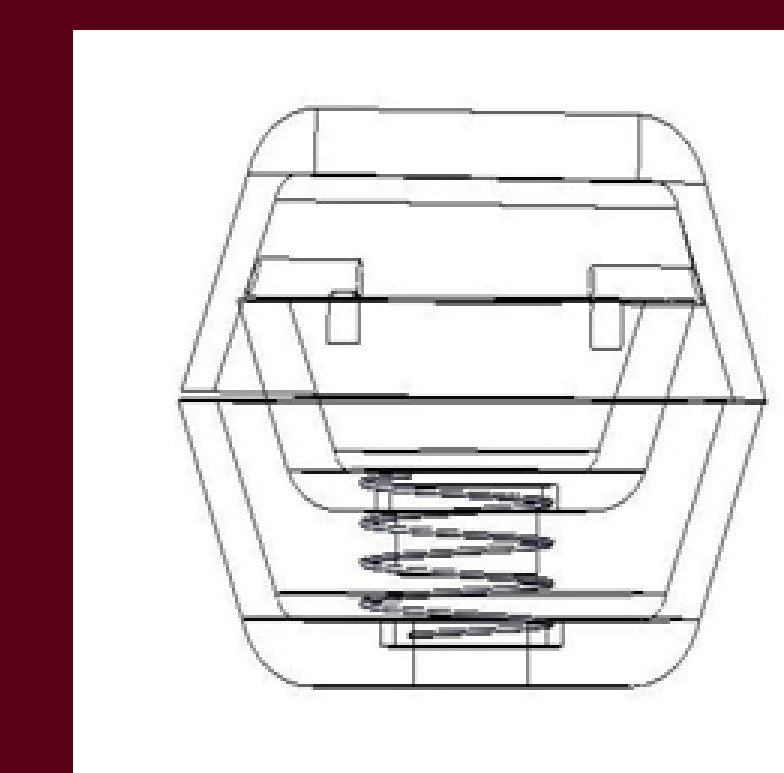


Figure 8: Valve with Cover

In the future we will look to add a chamber that will prevent the springs from migrating into the bladder if it were to ever detach from our device. We will also have to test the effects of the glue that adheres the valve to the bladder wall. To improve on spring functionality and faster reaction times we may also have to use different materials and create better spring constants.

References

www.thewomens.org.au/BladderTraining1

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