Design of a CSF Shunt Valve for Hydrocephalus

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Abstract

Hydrocephalus is a disease which causes an over-accumulation of cerebral spinal fluid (CSF), resulting in increased intracranial pressure. While treatment may vary with the cause of hydrocephalus, the most common treatment is surgical implantation of a shunt valve. Unfortunately, a number of failure inducing complications can arise with implanted shunts. The most prevalent complication is over-siphoning, which can lead to slit ventricle syndrome and possible valve obstruction. Failure of this device can be catastrophic and lead to brain damage or even death. Our clients, Dr. Bermans Iskandar and Dr. David Hsu, have asked us to design a valve system that corrects for the effects of gravity and cardiac pulsations, two contributing factors of CSF over-siphoning, to prevent slit ventricle syndrome and valve failure associated with this complication.

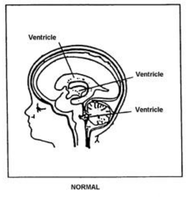
Introduction

Cerebrospinal fluid (CSF) has three main functions:

- Acts as a cushion for brain tissue
- Assists in the delivery of nutrients and waste removal
- Compensates for changes in blood volume in the brain[1].

Hydrocephalus is an abnormal over-accumulation of CSF in the ventricles of the brain.

- Raises intracranial pressure
- When inadequate absorption is the cause, surgical intervention is required
- A shunt is placed to drain excess CSF to the peritoneal cavity using a pressure differential valve[3][4].
- About 1 per every 500 children is affected by hydrocephalus[1]



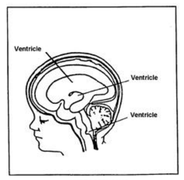


Figure 1: A diagram of how hydrocephalus affects ventricle size.

Chronic over drainage of CSF causes slit ventricle syndrome

- Brain tissue is sucked into the catheter intake[5]
- This causes an obstruction which can lead to catastrophic failure of the valve
- Gravity and cardiac pulsations are believed to contribute to the occurance of slit ventricle syndrome

The ability of a shunt to drain excess fluid to maintain appropriate intracranial pressures, while avoiding slit ventricle syndrome is one of the foremost issues in hydrocephalus research.

Problem Statement

We have been charged with designing, validating and testing a novel valve system for patients with hydrocephalus. The valve system must minimize cardiac pulsations and accommodate changes in gravity due to postural changes.

References

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Design Requirements

The overarching goal of the valve design is to reduce the risk of slit ventricle syndrome. The client asked us to address this by evaluating a design (Figures 1 and 2) that attempts to:

- Minimize the over-siphoning caused by positional changes (See Figure 1)
- Minimize the effects of cardiac pulsations (See Figure 2)

Additional requirements include that the device must:

- Be designed to scale with a maximum of 1.5 cm in diameter and 3.0 cm in length
- Have laminar fluid flow (Reynolds number of less than 2300)
- Be biocompatible and elicit minimal immune response from the patient.
- Not degrade during its lifespan in the patient

Modeling

We used Matlab to model the behavior of the shunt system using the dynamic equations governing the pulsatile flow of incompressible liquids in elastic tubes derived from blood flow theory. The factors affecting wave propagation include the tube radius, thickness and elastic modulus. The goal was to prove that the flow loop design would allow for backflow while minimizing cardiac pulsations.

Our results showed that the tubing radius is the most important factor with larger diameters providing more elastic energy storage and pulse minimization. Elastic modulus and tubing wall thickness both provided minimal differences in pulse minimization.

We found while modeling timing that if $\frac{C(r,h,E)}{L_{Loop}} = Heartrate$, the system would not allow backflow as the pressure wave propagating around the loop met the next incoming wave at the system entrance. This guided us to the final design where we used larger 2mm tubing, calibrated loop distance to shift phase for backflow and have a critical heart rate value above physiological levels (300 bpm).

Modeling Results: Tubing Properties

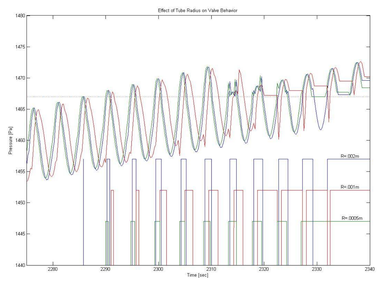


Figure 2: Modeling showed that cardiac pulsations were best minimized by tubing with a larger radius.

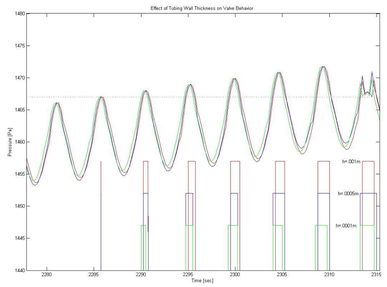


Figure 3: Modeling showed that wall thickness played a small role in minimizing cardiac pulsations with thicker tubing walls providing slightly more damping.

Modeling Results: Circular Flow

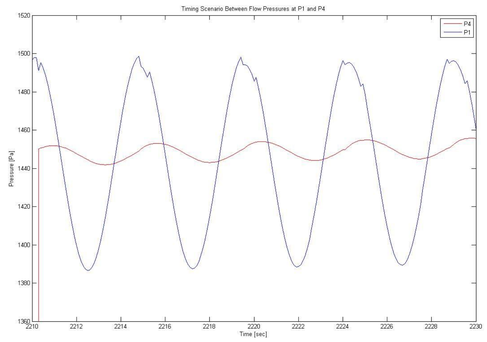


Figure 4: The model showed that by adjusting the length of the loop system we were able to phase shift the incoming and outgoing pressure waves to allow for backflow.

Final Design

The final design consists of a novel gravity assist valve in series with a parallel loop of standard pressure differential valves.

- The novel valve uses asymmetrical geometry to correct for gravity while still allowing backflow (see Figure 6)
- The novel valve was fabricated using Accura 60 plastic using the Viper SI2 #D printer at the Wisconsin Institutes for Discovery
- The parallel loop uses pressure differential valves (Medtronic) in parallel to dampen cardiac pulsations
- Length differences in the parallel loop offset the pressure wave to allow backflow (see Figure 7)

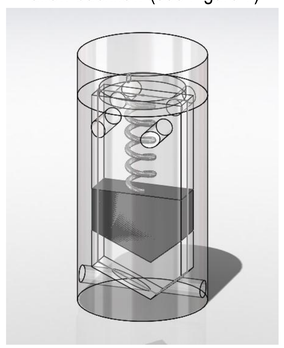


Figure 6: Solidworks representation of novel the valve.

Figure 7: The Medtronic valves are pictured in the testing loop above.

Future Work

Future investigations must be done to prove the functionality of the "Wisconsin Loop" setup and the novel valve. Research could begin with i*n vitro* assessments of thrombogenic and protein adhesion qualities. The ability of bacteria to adhere to and proliferate on the device in vitro could also be a next step in the development of this setup. Fatigue tests in vitro could also be executed whereby the device and loop could be monitored for hours to days should be done to investigate possible failure modes.

After in vitro assessments, a canine hydrocephalus model could be utilized to assess the in vivo functionality of the novel setup and device.

Testing

The goal of our testing regimen was two-fold. First to check the fabrication and pressure dynamics of our novel valve, and second to validate the concept of the 'Wisconsin Loop.' All testing was done on a Harvard Apparatus Model 1407 Pulsatile Blood Pump for mice and rats and hydrostatic pressure interfaced to a PC via BNC and a myDAQ hosting LabView software (National Instruments).

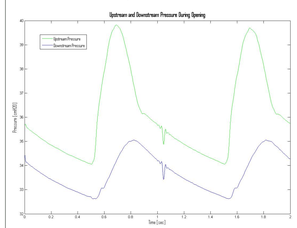
Valve Validation

The gravity valves were tested for opening gating pressures with an upstream pressure transducer and a syringe to apply pressure. Pressures were recorded as maximums seen before pressure drops indicating opening. The pressure required in the cylinder valve (16.8 mmHg) was significantly higher than that of the pentagonal prism valve (8.8 and 7.2 mmHg for forward and reverse directions, respectively). Although the same spring constant (547 Kg/s^2) was used for both designs it could be an increase due to the larger frictional contact area present in the cylinder design. Interestingly, the opening pressures for the forward and reverse directions of the pentagonal prism valve were not statistically different at the p=.05 level according to the Student's two-tailed T-Test (see Table 1.).

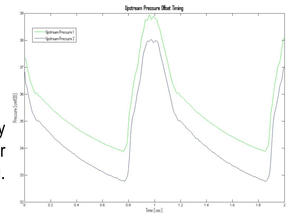
		Opening Pressure [mmHg]	
	Cylinder Valve	Prism Valve Forward	Prism Valve Reverse
Mean	16.8	8.8	7.2
Standard Deviation	2.387	1.483	1.304
n=5		Statistically Insignificant	P=0.108

Design Validation

All testing was done with a Harvard Apparatus Research Grade Blood Pressure Transducer interfaced with a myDAQ (National Instruments) to a PC via BNC connection, voltage data was collected directly from the pressure transducer, converted to pressure values via MATLAB and filtered below 50 Hz. A Harvard Apparatus Model 1407 Pulsatile Blood Pump was used to provide physiologic input pressures. Pressures were measured at the loop input and exit to quantify minimization of cardiac pulses and system timing. Pressures were also measured at the inlet and return portion of the ascending tubing to further verify timing. During testing circular flow was observed both visually and in the peak differences present in FIGURE XXX. The timing between the pressure pulse at the entrance and exit was 133 ms, while the circular flow pressure pulses were offset by 14 ms at the system entrance.



Test1: Cardiac pulsations were reduced by over 50% while pressure pulses were offset by 133 milliseconds.



Test2: Pressure peaks were offset by 14 milliseconds, thus allowing for backflow as observed during testing.

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