Design of a CSF Shunt Valve for Hydrocephalus

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Erin Devine, BSAC
Lauren Eichaker, Team Leader
Brian Mogen, BWIG
Steve Wyche, Communicator

Clients
Dr. David Hsu
Dr. Bermans Iskandar
Department of Neurological Surgery, UW Hospital

Advisor
Dr. Naomi Chesler
Department of Biomedical Engineering

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Abstract

Hydrocephalus is a disease in which an over-accumulation of cerebral spinal fluid (CSF) results 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 work on the design of 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.

Background Information

Cerebrospinal fluid (CSF) has three main functions in the human body: to act as a cushion for brain tissue, to assist in the delivery of nutrients and waste removal from the brain, and to help compensate for changes in the blood volume of the brain[1]. CSF is produced by ependymal cells that make up the choroid plexus. The fluid fills the subarachnoid space and circulates through the interconnected ventricular system of the brainstem, allowing the brain and spinal cord to essentially "float" in a shock-absorbing cushion of CSF. With the assistance of respiratory, circulatory and postural pressure changes, the CSF eventually flows to the top of the outer surface of the brain where most of it enters to the veins through one-way valves in large veins[2]. Production and drainage of CSF in the brain is regulated to maintain intracranial pressure within the normal, healthy range of 8-15 cm H2O (784.5 Pa- 1471.0 Pa)[2]. Changes in the rate of production or the ability to drain the fluid can result in an over-accumulation of CSF, leading to

an increase in intracranial pressure. This increase in pressure is referred to as hydrocephalus and can lead to brain damage or even death. Approximately 1 out of every 500 children is affected by hydrocephalus[1].

Hydrocephalus ranges from purely absorptive (communicating) to purely obstructive[3]. Choosing the appropriate treatment depends on which type of hydrocephalus a patient presents with. Hydrocephalus can be classified into four groups based on the contributions of absorptive and obstruction factors. The groups are patients with purely communicating hydrocephalus, patients with an obstructive component along with a persistent communicating component, patients with obstruction and a temporary communicating component and patients with purely obstructive hydrocephalus. The latter two groups where obstruction is the primary cause generally only require an endoscopy procedure while the groups with primarily communicating components typically require the implantation of a CSF shunt to drain excess CSF to another cavity of the body and reduce intracranial pressure[3]. The shunt is place into a ventricle of the brain and in most cases, CSF drains into the peritoneal cavity, but alternative options include the right atrium and the pleural cavity[4]. Pressure sensitive valves, placed near the end of the catheter where CSF drains into a body cavity, are used to regulate the flow of CSF to maintain normal intracranial pressure.

Two complications that can occur in valves are over-siphoning and valve obstruction. Over-siphoning usually occurs due to positional changes or cardiac pulsations. Positional changes can sometimes create a pressure differential that causes the valve to open and drain fluid even when the intracranial pressure is not elevated[5]. Cardiac pulsations cause a transient increase in intracranial pressure that can cause the valve to open even though the mean intracranial pressure remains within the normal range. Chronic over-siphoning can cause a serious condition

called slit ventricle syndrome. Slit ventricle syndrome results from chronic over-siphoning of the CSF[6]. One of the most significant occurrences resulting from slit ventricle syndrome is when severe over-siphoning and negative pressure in the shunt cause brain tissue to enter the shunt, causing obstruction which allows intracranial pressure to rise quickly[5]. Since a change in position can correct the over-siphoning effect temporarily, obstruction and rises in intracranial pressure are often transient, making slit ventricle syndrome difficult to detect until the condition becomes very severe. This type of valve failure can be catastrophic since the pressure increases can cause brain damage and even result in death[2]. Patients with CSF shunts would greatly benefit from the development of a valve that can counteract the effects of both positional changes and cardiac pulsations since it would reduce the risk of over-siphoning and slit ventricle syndrome.

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.

Design Requirements

Current shunt designs are plagued by two problems; the siphon effect and a failure to respond to postural changes by the patient. When standing, forty centimeters of water pressure are added to the intra cranial pressure due to gravity. This can often cause valve systems to open and over-drain cerebrospinal fluid. The device must be designed to minimize the effects of cardiac pulsations which cause the CSF pressure to fluctuate, as well as controlling for postural changes.

The device must be designed to scale, up to 1.5 cm in diameter and 3 cm long. This will most likely keep the device in the realm of laminar flow, as well as making the device a physiologically feasible size for implantation in future iterations. As with all implantable materials, the device must be biocompatible, eliciting minimal response from the host immune system.

Design Alternatives

The current standard of care and most common procedure for draining CSF consists of implanting a single valve with a single pressure threshold. When excess pressure is detected by the valve, it drains a small volume of the fluid that causes this pressure into the peritoneal cavity. The volume of CSF that is drained depends on the amount of pressure, the size/age of the patient and the settings on the valve. Unfortunately, this design has a number of practical flaws; over-drainage and the siphon effect are often seen. These side effects often result in almost complete drainage of CSF from the brain. Also, the use of a single valve does not adjust for gravity, which is problematic since the pressure gradient in the shunt is affected by the position (sitting or standing) of the patient. In addition, it does not adjust for cardiac pulsations, another cause of excess flow.

A recent advancement in shunt technology is the placement of valves in series. The cascade of valves allows for the mediation of the effects of cardiac pulsations on the rate of CSF drainage. Each valve has a specific pressure threshold; when an individual threshold is reached, the valve opens to allow fluid to drain downstream. Incrementally increasing the thresholds of the valves down the tubing ensures drainage, but counteracts the effects of cardiac pulsations, which frequently cause over-drainage. Regrettably, this design fails to eliminate the issues with

over-siphoning. Our design thus needs to eliminate the adverse effects of cardiac pulsations and gravity to avoid both over-drainage and over-siphoning.

Due to the fact that both of the above configurations are not efficient methods of alleviating slit-ventricle syndrome, we did not consider any of these alternatives when deciding how to proceed this semester. We chose however to investigate the drawbacks of these models in order to better comprehend the task at hand. The only alternative configuration that the team found involved a programmable ball and spring system. This system employs a linear spring instead of a coiled spring along with the fact that its threshold can be altered and therefore is not considered a competing design[7].

Final Design

Our final design, seen in Figure 1, consists of a feedback loop utilizing a novel valve designed and modeled by the client. Pressure differential valves in the loop counteract the effects of cardiac pulsations.

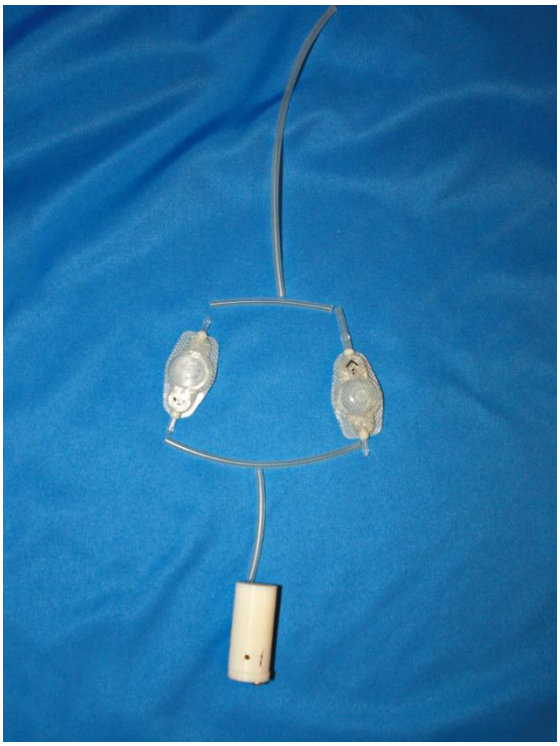

Figure 1. The setup of our system utilizing a feedback loop with a novel valve and two pressure differential valves.

The novel valve (designed and modeled by the client) at the bottom of the loop corrects for gravitational and positional over-siphoning (Figure 2). This uses a ball and spring system to balance the force of gravity as it pulls the CSF downwards when the patient is standing and then does not affect the CSF's drainage from the brain when the patient lies down. The spring holds the ball in place, blocking the flow of fluid downstream when the patient stands and returns it through the feedback loop. When the pressure reaches a sufficient level to displace the ball and spring, the valve opens and fluid drains downstream. This allows the optimal amount of excess fluid to flow; it should not result in over-siphoning. A number of components were considered for integration into our final design, all of which are reviewed in the design matrix sections. The final design utilizes a stainless steel spring, a Contoured, medium pressure valve (manufactured by Medtronic) and a silicon rubber ball, housed in ABS plastic.

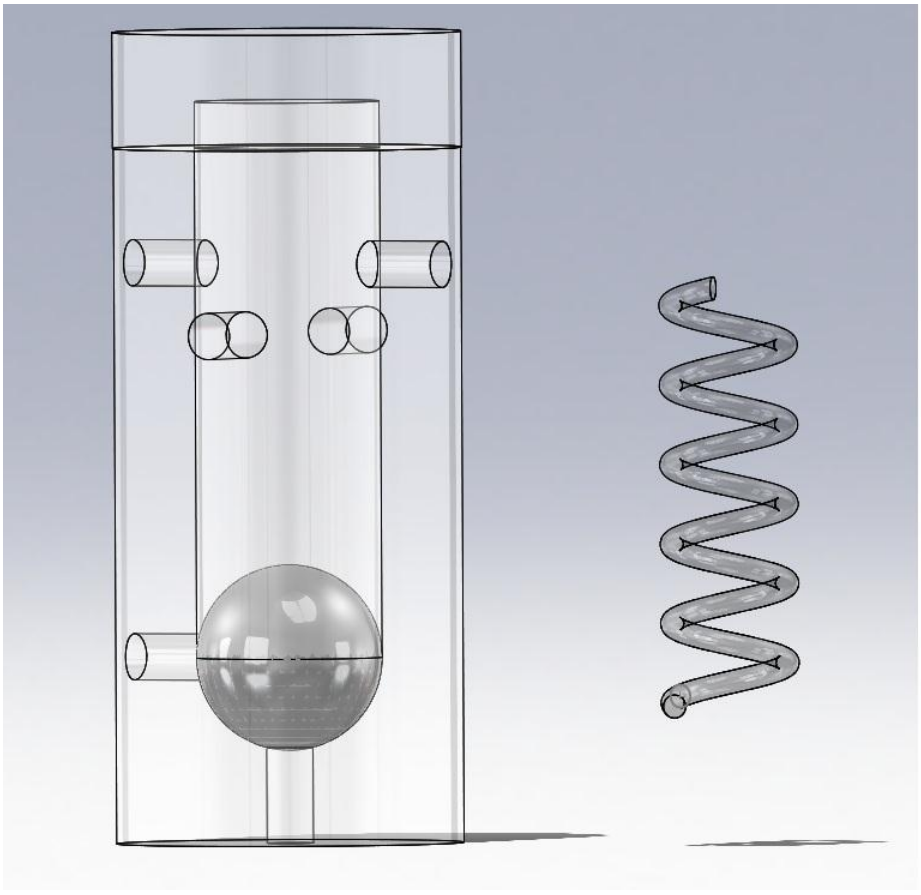

Figure 2. Solidworks design of the novel valve. A ball and spring allow flow at a certain pressure to open the valve and drain fluid downstream.

The non-programmable, off-the shelf valves were provided by our client (Figure 1, parallel valves). The literature confirms that there is no significant difference between brands of standard GAV valves[8], so the team plans to proceed with the valves given to us by the client. We may, however, employ valves of different pressure thresholds in future studies.

Ball and Spring Design

The ball specifications rely heavily on the biocompatibility and the ability to visualize the apparatus with an MRI. Both of these factors will help prevent unnecessary surgeries, a leading cause of complications in shunt patients. While all of the materials are quite biocompatible, it has been shown that silicone rubber materials are slightly more so. In terms of cost, all materials appear to be quite similar, especially in the low volume we are considering. Lifetime is a small factor because we have a limited timescale to design and prototype the valve, but most of these materials have been observed to fare well in the body, especially since the valve will be in the peritoneal cavity and not in contact with blood where foreign body reactions are more severe. If implanted, it can be expected that all materials will last for the patient's lifetime. Finally, MRI compatibility was assessed for each material. The silicone rubber is MRI transparent, giving it a neutral score, while the 316 L stainless steel produces and artifact approximately 150% of the sample's size in an MRI image. In high-strength MRI's of two or greater tesla, the paramagnetic properties of the steel ball may cause it to be pulled by the magnetic field, thus stressing the valve and patient in addition to the image artifact. The barium sulfate impregnated silicone rubber is MRI visible, but difficult to fabricate and thus scored the second highest. For our purposes this semester, we will use a Si-Rubber ball, but may utilize a Si-Rubber ball with Ba in the future.

Material	Biocompatibility	Ease of Fabrication	Cost	MRI-Compatibility	Total
Weight	**3**	**2**	**2**	**3**	**10**
Si-Rubber	3[9]	2	2	1	**8**
Stainless Steel 316L	2[10]	2	2	0	6
Si- Rubber with Ba	3[9]	0	1	3	7

Table 1. Our design matrix evaluating the proper material for the ball in our ball-spring system generated the highest score for barium sulfate-impregnated silicone rubber.

The springs we analyzed were held to similar criteria. In terms of biocompatibility, all three samples are very similar, with stainless steel being slightly less biocompatible. The cost factor of each of them is also minimized since we are looking at a very low number of valves rather than mass production; however plastic springs are a newer technology and therefore are more expensive. Once again the lifetime is an issue that we will not have time to address in our limited prototyping window, but one can expect that with the low pressures and loads our system is seeing, the lifespan should be substantial. Finally the MRI compatibility of each option was addressed. The 316 L stainless steel has a 150% MRI artifact, and the carbon steel artifact is slightly smaller. The plastic composite will have a very minimal MRI artifact, depending on the materials used to dope the plastic to the correct spring constant, thus setting it apart as our top choice in the final design.

Material[11]	**Biocompatibility**	**Cost**	**Lifetime**	**MRI Compatibility**	**Total**
Weight	**4**	**1**	**2**	**3**	**10**
Stainless Steel 316 L	3	1	2	0	6
Carbon Valve ASTM A229	3	1	2	1	7
Plastic Composite	3	0	1	4	**8**

Table 2. Our design matrix evaluating the proper material for the spring in our ball-spring system generated the highest score for the plastic composite.

Valve Material

Many considerations must be taken into account when designing anything to be implanted into the human body, the most important of which is biocompatibility. A biocompatible material can be implanted into the body without an adverse host response. For our purposes, the implant will be placed in the CSF where it will interact mostly with water and proteins such as albumin. Second in importance to biocompatibility is durability. The material should have good wear properties so that corrosion does not weaken the implant and wear particles do not induce an inflammatory response. CSF shunts are most often placed in children and should be designed to last a lifetime without failure. After biocompatibility and durability have been established, important considerations to take into account are ease of manufacture and cost. Based on our design matrix, seen in Table 3, high-density polyethylene (HDPE) was chosen as the material to fabricate the casing for the novel valve in our design of a CSF shunt. It

has high biocompatibility, good durability and wear properties, is easy to process for manufacturing and is low cost. Based on our criteria, HDPE is the best choice for our design. Due to the opportunity to fabricate this part using ABS in a 3D printer, our initial prototype will be manufactured out of ABS. ABS is not generally considered for implantation into the body due to low biocompatibility. However, since our initial prototype will be tested ex vivo to prove the concept of the design, biocompatibility is not an issue at moment. Next semester, should we move to in vivo testing of the device, we will produce the valve out of HDPE as our design matrix indicates.

Material	Biocompatibility	Durability	Ease of Manufacture	Cost of manufacture	Total
Weight	**3**	**3**	**2**	**2**	**10**
High Density Polyethylene (HDPE)	3	2	2	2	**9**
Acrylonitrile-butadiene-styrene (ABS)	1	2	2	2	7
Polytetrafluoro-ethylene (PTFE)	3	1	1	2	7
Stainless Steel (361L, grade 2)	3	3	0	0	6

Table 3. Our design matrix evaluating the proper material for the valve generated the highest score for High Density Polyethylene (HDPE).

Testing

Our testing involved two components: the validation of our design and the verification of our testing method. Our testing setup was as follows: a beaker with reagent grade water simulated the brain, which was then connected to a Harvard Apparatus Model 1407 Pulsatile Blood Pump for mice and rats. The pulsatile pump provided the simulation of cardiac pulsations

within the CSF. The luer lock fittings of the pump necessitated that we use larger diameter tubing for the initial pump connection (Tygon R3603, ID=2.4mm). After the pump we reduced tubing diameter to the medical standard 1mm ID tubing (Tygon S-54-HL Tubing ID=1.02mm). We then attached the 'Wisconsin Loop' consisting of two GAV valves connected with 1mm tubing and Harvard Apparatus polycarbonate T-connectors. At the distal end of the circuit we attached out valve. Initial testing was carried out to determine the minimum pressure output by the pump, as cardiac pulsations are much smaller than arterial pressure pulsations. Using 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 and converted to pressure values via MATLAB software (Mathworks).

Cardiac pulsations produced by the pump were measured upstream before the first valve series, with the system devoid of air bubbles, and checking to see that the upstream valves

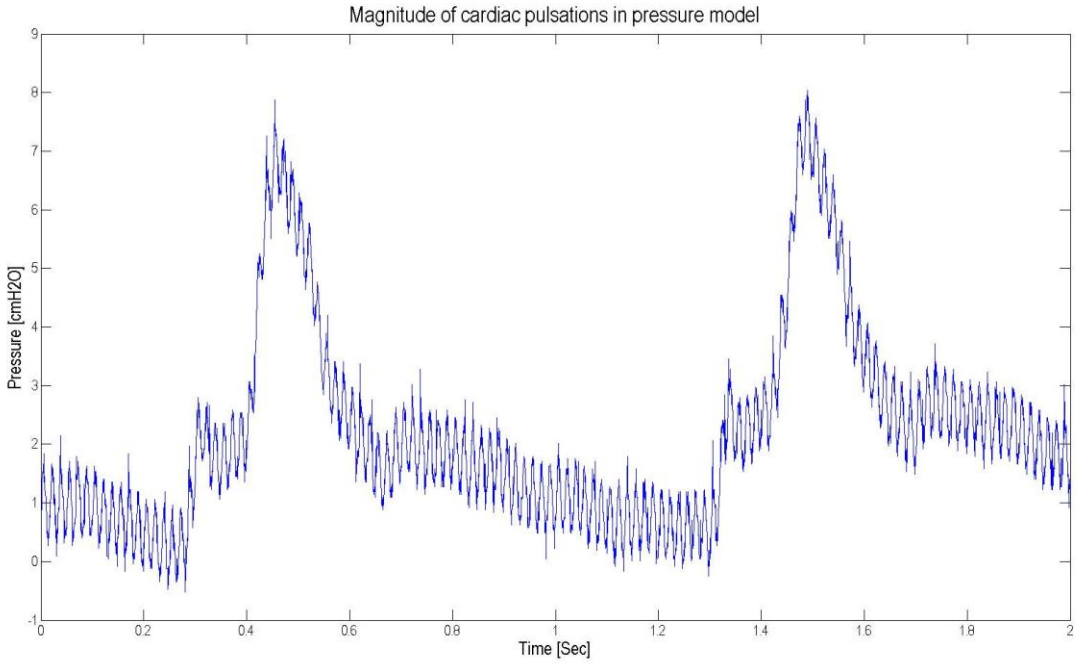

Figure 3. Input cardiac pulsation waveform. Baseline pressure was adjusted hydrostatically.

remained closed and no water left the system. The results seen in Figure 3 show that the magnitude of the pressure difference is approximately seven centimeters of water (686 Pa), or about four times the normal cardiac pulsation in an adult. While this difference is significant, it is still less than an order of magnitude larger, and will allow us to guarantee that our design can handle at 70 beats per minute to ensure a physiologic loading regiment, and that at least one data point is present in the short myDAQ oscilloscope acquisition window.

For all following tests, the pressure of the brain simulation was delivered using hydrostatic pressure calculated by a column of water a distance above the first valve. When the pressure transducer was moved downstream to our valve and a physiological ICP of 10 cm H20 (981 Pa) was applied our valve failed catastrophically. Failure first occurred at the input tubing location. Although the hole diameter of the input location appeared to be small enough for a press-fit, the length of the press-fit wasn't enough to seal the system even at low pressures. This may also have been an artifact of the 3-D printing process, as ridges in the tubing seal caused by layering ABS could have decreased the seal capabilities. When pressures we increased substantially (60-70 cm H2O (5890-6860Pa)) the spring/ball complex was pushed aside and water began leaking out of the outlet hold and holes around cap of the valve. The higher-than expected forces required to move the ball/spring complex are most likely attributable to fabrication technique of the silicon ball and ABS valve as well. Most likely the spherical aberrations present on the ball caused it to lose uniform pressure from the incoming fluid stream and attempt to roll in the valve. The ABS valve well contouring to the ball had ridges which could press into the deformable PDMS, thus increasing the friction present and effectively sealing the valve shut.

The next set of testing was done to validate the theory of the 'Wisconsin Loop' design. Since our fabricated valve failed, we added a third GAV valve in its place to simulate a closed system of valves. We tested the minimization of cardiac pulsations with the loop system at three levels: normal ICP (10 cm H2O (686Pa)), chronically elevated ICP (30 cm H2O (2940Pa)), and plateau waves (60 cm H2O (5890Pa)). We wanted to see how the system dealt with the physiological pressures presented, and evaluate how they reduced cardiac pulsations or flow. To test this we placed a pressure transducer in the middle of the flow loop and delivered the previously described standard cardiac pulsations on top of hydrostatic pressure levels.

At normal ICP, the system responded well to cardiac pulsations, reducing their magnitude to about one cm H2O inside the valve loop while not passing any fluid completely throughout the system. Figure 4 shows the general trend and small magnitude of the cardiac pulsations inside the closed valve loop.

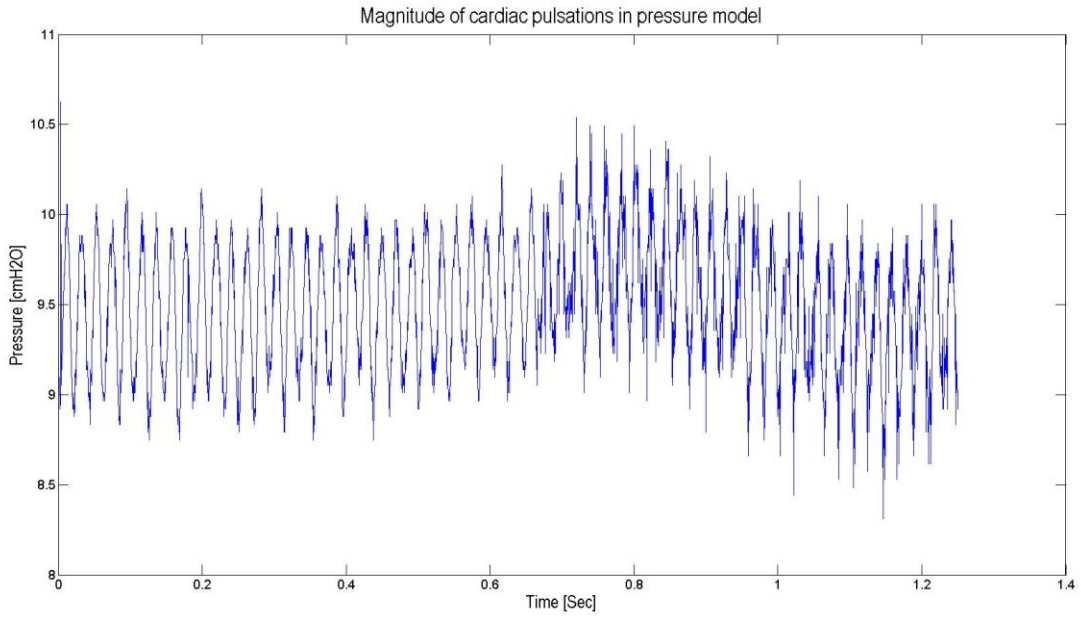

Figure 4. Minimization of Cardiac Pulsations at a normal ICP level.

At elevated ICP and plateau wave ICP, all draining valves in the system opened and while minimized or no cardiac pulsations were noted, absolute ICP was less than input, as the valve system was open and draining excessively. Figure 5 shows that the inner device pressure at elevated ICP was less than applied levels due to flow, and that the characteristic cardiac pulsation was lost in the flow. Similar to the elevated ICP, the plateau ICP levels exhibited identical behavior, just slightly shifted upward due to increased initial pressure and flow rate.

It must also be noted that during the course of testing fluid was never observed circulating through the fluid loop at any point after initial filling of the valve system. This is most likely due to the laminar flow conditions present in the valve system. With a full laminar profile filling the small-diameter ventricular shunt tubing, there was no place for the outlet fluid to go. Unfortunately there was not enough time in the semester to full explore the phenomena.

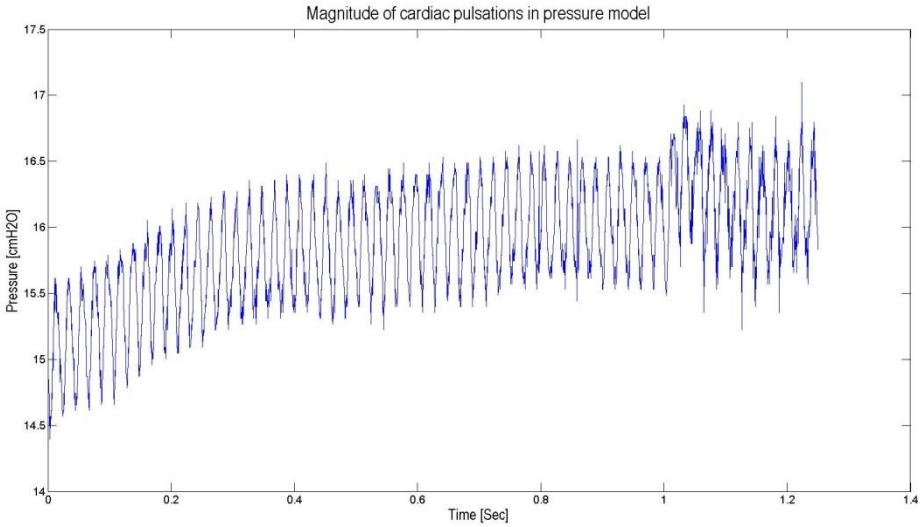

Figure 5. Pressure profile at elevated ICP and open flow conditions. Cardiac pulsations are absent and absolute pressure is less than applied.

Overall, the flow loop seemed to provide a minimal gain at normal ICP levels, but that gain broke down as ICP increased and the valve system opened up. The 'Wisconsin Loop' did not appear to effectively deal with cardiac pulsations in the disease state.

Future Work

Our current prototype has a few flaws that will need investigation in the future. During the testing procedure, despite the appearance of tight seals at the valve inlet and between the ball and the cylindrical chamber within the valve, leaks occurred. The fluid used during our initial investigations flowed out the sides of the tubing at the inlet and around the ball to flow out through the failsafe holes we drilled near the bottom of the valve (Figure 6). Even when our model did not show any leaks, little to no fluid flowed through the feedback loop, hinting that further investigations should be made to ensure the integrity of the set up. The team anticipates modifying the ball component of the valve and finding a method to secure the seal between the tubing and the valve inlet to alleviate these issues.

In the future, the team plans to carry out more design work. This semester's prototype is the embodiment of the clients' design, while other geometries could be utilized. For example, we could investigate the use of a cylindrical valve closure within a cylindrical chamber.

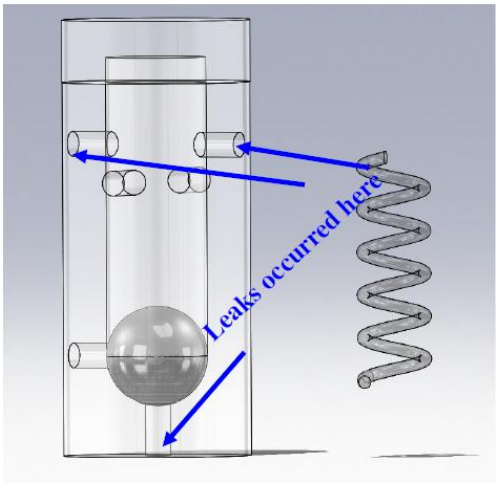

Figure 6. Fluid leaked out multiple holes during testing.

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