Hydrocephalus Shunt Valve

BME 301

February 19, 2017

Team: Emma Alley (Leader), Andrew Miller (Communicator/BPAG), Karl Fetsch (BWIG), Catharine Flynn (BSAC)

Advisor: Beth Meyerand

dClient: John Webster

Abstract

Hydrocephalus is an incredibly common condition that affects three in every 2000 individuals at birth, and is the most common reason for brain surgery in children and infants [3]. A common treatment for the high intracranial pressures caused by hydrocephalus is the implantation of shunt valves. Shunt valve systems designed for the removal of cerebrospinal fluid (CSF) from the interior of the blood-brain barrier have been used in the treatment of hydrocephalus since the inception of spring-controlled valves in the 1960s[1]. Shunt valves have since been dynamically evolving with modern advancements in biomaterial diversity as well as micro-scale electronics. However, complications with overdrainage, underdrainage, and siphoning effects have continued to plague the designs, frustrating researchers and medical experts alike. Even with the development of highly advanced, programmable differential pressure systems, top of the line shunt valves display failure rates of 81% within 12 years of implantation [2]. The proposed device incorporates the use of localized ambient pressure in the brain as primary means of regulating fluid flow and control of the siphon effect. CSF removal is dictated *via* the incorporation of a Kelvin-Voight model of viscoelasticity to avoid commonly observed complications associated with overdrainage of fluid. We hypothesize that the model proposed below will serve as a more optimal system for control of intracranial CSF levels in comparison to market standard differential pressure-based systems.

Table of Contents

I. Introduction

I.A Motivation and Project Impact

Hydrocephalus is an incredibly common condition that affects three in every 2000 individuals at birth, and is the most common reason for brain surgery in children and infants. Total average medical expenditures on hydrocephalus exceed $1 billion per year, yet research pertaining to the condition is limited: the National Institutes of Health invests less than $1 million per year. Over 40,000 operations are conducted annually to attempt to correct the symptoms of hydrocephalus. Approximately 30% of these operations are the patient's first corrective surgery, which often includes the implantation of a valve to shunt CSF away from the cerebrospinal space when pressure becomes too high [3]. This suggests that the majority of operations are performed to correct shunt valve failures. Failure to properly treat individuals, such as when a shunt valve malfunctions, can result in brain damage, and roughly 30% of individuals with hydrocephalus will experience intellectual disability at some point in their life [4].

I.B Existing Devices/Competing Designs

There are currently a multitude of valve options offered to patients suffering from hydrocephalus. Unfortunately, there has yet to be a shunt valve brought to market that has the potential to serve as a 'universal' treatment option. Specific components that may aid in the functionality of the device in a particular individual can present as the cause of failure when the same device is implanted into a different individual. Patients generally consult with their neurologists in order to determine the type of valve that will function most optimally in their case. Additionally, small changes can be implemented by the neurosurgeon mid-operation to better fit the valve to the needs of the individual.

Shunt valves designed for hydrocephalic patients are designated to one of six subtypes based on the type of pressure by which the valve operates as well as the inclusion/exclusion of additional flow regulating components. These six valve subtypes are defined as: fixed differential pressure (DP), fixed DP with anti-siphon mechanisms, programmable DP, programmable DP with anti-siphoning mechanism, programmable anti-siphoning mechanism, and purely mechanical ambient pressure. Each of the first four valve subtypes listed function *via* reading changes in pressure across the valve, between outflow port and inflow port. A 'fixed' valve indicates the valve operates using an absolute pressure threshold, above which the valve opens and drainage can occur [5]. This requires surgeons and doctors to accurately anticipate the drainage needs of the individual pre-surgery to avoid the need of subsequent operations to adjust the pressure threshold of the valve. With modern advancements in micro-scale technology, programmable

pressure valves have been developed to eliminate the need for multiple operations by the integration of electrical components that allow doctors to adjust pressure thresholds from outside the body. A common mode of failure observed in these valves is the formation of a blockage at the junction of tubing and the valve itself, a phenomena commonly referred to as proximal occlusion. Proximal occlusion has been observed to be indirectly related to problems with valve overdrainage due to a siphoning effect [2]. To alleviate the extent that overdrainage occurs, newly presented shunt designs have begun to incorporate the use of flow regulating devices to control for the siphoning effect (anti-siphoning mechanisms) and gravity compensation devices to account for complications that occur from changes in altitude such as flying or standing up [6]. However, the use of flow regulating components have been associated with insufficient drainage in obese individuals.

New research efforts have begun to shift the focus of shunt valve designs away from using differential pressure as the mechanism that dictates opening and closing of the device [7,8]. Rather, research suggests ambient pressure in the brain can serve as a reliable alternative. It is hypothesized that the construction of a valve relying on a differential between ambient and inflow pressure (as opposed to inflow and outflow pressure) could assist in control of the siphoning effect while still draining sufficient amounts of fluid to avert potential trauma due to increased intracranial pressure.

I.C Problem Statement

A shunt valve controlling the expulsion of cerebrospinal fluid (CSF) from inside the blood-brain barrier to the abdomen in patients suffering from hydrocephalus is needed. The device will be of a minute enough size to avoid irritation in patients when implanted underneath the chin or behind the ear. Additionally, the device will avoid using electronic-based valve mechanisms, functioning on a purely mechanical basis. This is to avoid encountering circuitry problems as well as electronic failure. CSF is released from the skull of the patient by tubing, flowing through the tubing to the device. Flow is blocked by the valve until sufficient pressure opens the valve to drain the CSF into the abdomen where it is reabsorbed.

II. Background

II.A Biology and Physiology

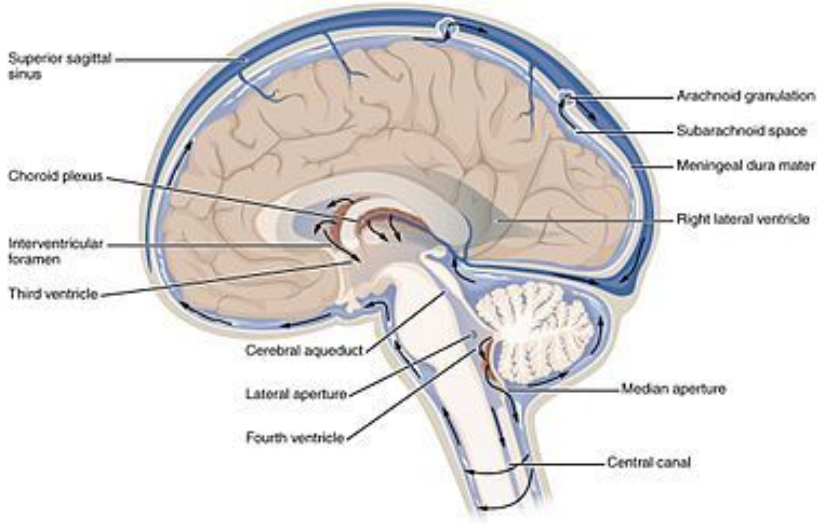

Figure 1: The image depicts the flow of CSF through the skull and spinal column. The section labeled "cerebral aqueduct" is equivalent to the aqueduct of sylvius.

The condition hydrocephalus is caused by the insufficient drainage of cerebrospinal fluid from the skull [9]. The CSF under normal intracranial pressures acts a delivery system for nutrients, a garbage disposal system for waste, and a protective coating against impact between the brain and the skull. The CSF is generated within the choroid plexuses (situated within the ventricles), which are the locations of diffusion across the blood-brain barrier. The flow of CSF starts in the lateral ventricles, moves into the third ventricle, then to the fourth via the aqueduct of sylvius and final out into circulation around the brain and spinal cord (Fig. 1). After the nutrients within the CSF have been consumed and replaced with waste, it is reabsorbed by the arachnoid granulations within the meninges to be recycled by the body [10]. CSF in a hydrocephalus patient generally accumulates within the ventricles, causing the intraventricular pressure to build, forcing the brain to expand into the skull, and crushing it if fluid cannot escape (Fig. 2) [11].

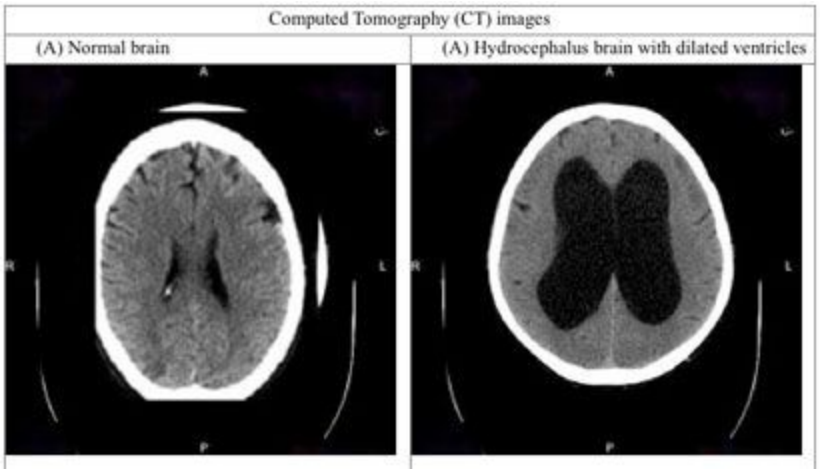

Figure 2: The two CT scans are depicting a normal brain (left) compared to one with hydrocephalus (right). The brain with hydrocephalus has severely dilated lateral ventricles.

Typically, the inhibition of adequate flow of CSF that leads to hydrocephalus occurs before CSF is transported out of the fourth ventricle, with the aqueduct of sylvius being to most common site of blockage, however there are many causes for the condition. In the case of congenital hydrocephalus, which refers to those born with the condition, often times birth defects lead to stenosis of cerebral aqueducts, the spaces between ventricles. Infants can be born with naturally small aqueducts, however sometimes other defects can result in hydrocephalus [9]. Spina bifida, a birth defect that occurs when one or more of the vertebra do not properly form, results in an opening that the spinal cord can protrude from in the back. The displacement of the spinal cord can cause a herniation of the hindbrain through the foramen magnum (location where the skull and vertebrae join), and block the flow of CSF through the fourth ventricle resulting in hydrocephalus [9,12].

Acquired hydrocephalus refers to the acquisition of the condition after birth. The age range for individuals who can acquire hydrocephalus ranges from infancy to late adulthood, due to the various causes of the disease. Meningitis, multiple sclerosis, trauma, stenosis, sclerosis of aqueducts, and tumor growth are all potential causes of acquired hydrocephalus [9,13].

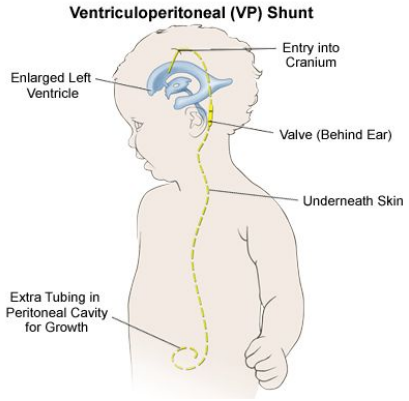

Figure 3: The image shows a child who has had a valve implanted. The ventricles are denoted in blue, and the catheter shunt system are yellow.

Generally, treatment for hydrocephalus requires brain surgery (Fig. 3). A catheter is placed into the lateral ventricles, and it exits via the back of the skull, remaining under the skin. The catheter is then snaked behind the ear, where the shunt valve is placed. The end of the valve is connected to another catheter, which drains the CSF to the abdomen.

II.B Design Specifications

All components must be biocompatible with their respective flexibility and rigidity as needed for function. Moving parts need to have resistance to repeated strain with the overall system having a long lifespan (more than 12 years). The system should not allow interaction between CSF and interstitial fluids. The client desires that the system should address increased pressure due to heartbeat and the valve responds to changes in ambient **and** intracranial pressures. It must safely remove CSF fluid when necessary without over draining. Any openings in the valve that regulates pressure should be less than or equal to 3μm in diameter to prevent tissue ingrowth. No electronic or magnetizable components should be included in the design. The valve should be smaller than a US half-dollar coin (~30 mm in diameter, ~2 mm in thickness).

II.C Client information

Prof. John G. Webster works in the Biomedical Engineering department at UW Madison, and works jointly with Prof. Joshua Medow from the Dept. of Neurological Surgery to develop instruments for patients with hydrocephalus. He is currently working on an instrument capable of externally reading intracranial pressure from an internal sensor implanted in the head. He is also working on a device capable of alleviating patients with sleep apnea.

III. Preliminary Designs

Discussed here are the most feasible designs brought up during the brainstorming process. Each design was evaluated using a design matrix.

III.A Dual Membrane Design

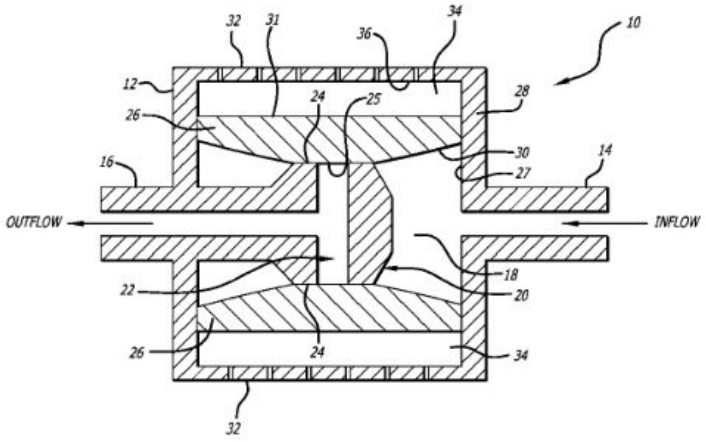

Figure 4: Differential pressure valve. Inflow pressure pushes against ambient pressure to open and close the valve.

The first design discussed is a patent from 2016 intended to operate as a ambient pressure-controlled hydrocephalus shunt valve (Fig. 4). Fluid flows in from the brain in the inflow into the large chamber and exerts an outward pressure on the two flexible membranes. The membranes in turn are forced inwards by the surroundings. When inflow pressure is greater than ambient pressure, the two membranes flex outward and fluid flows into the T-shaped junction, and leaves as the outflow. The benefit of this design is that it prevents overdrainage: when the valve is already closed, sudden spikes in negative outflow pressure (e.g. from standing up) do not result in overdrainage since there is no way for fluid to be sucked in from the inflow [7]. Disadvantages of this design include concerns with tissue ingrowth into the spaces between the outer walls and flexible membranes and the fact that the design is already patented. This could obviously inhibit efforts to modify the design and adapt it for the team's requirements.

III.B Dashpot Design

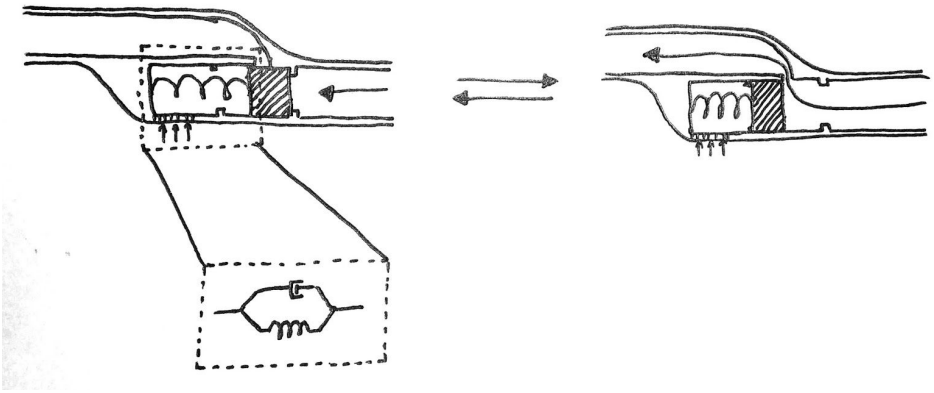

Figure 5: Spring-Dashpot operated valve. Valve is opened by inflow pressure, the movement of which is resisted by the dashpot element.

The second design discussed is intended to smooth out the pressure coming from the brain and consists of a valve that opens and closes with behavior resembling a dashpot and spring in parallel (Fig. 5). The valve blocks an opening and seals the CSF inflow from the brain. A spring opposes the force from the CSF. When the fluid pressure increases, the valve slowly moves backwards, with speed controlled by the dashpot element. This element in its current form consists of a membrane with several holes that allows incompressible fluid to **slowly** move through. This design would prevent sudden spikes in pressure from forcing the valve open, which could increase the lifetime of the design by preventing fatigue. Additionally, since the drainage opening is located to the side of the drainage valve, there is no possibility of overdrainage when the valve is closed, since the negative pressure would be exerted perpendicular to the valve's movement. Potential problems with this design include the possibility of fluid leakage around the valve element and unwanted biological effects of the dashpot membrane sucking in and extruding fluid from/into the interstitial space.

III.C Door-Flap Design

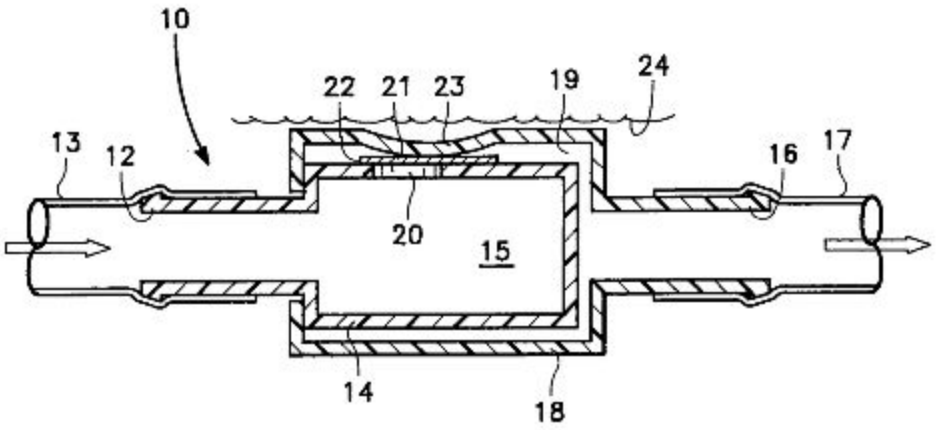

Figure 6: Ambient pressure operated valve. Inflow pressure acts against ambient pressure to operate the opening and closing of a small flap, which seals the drainage hole.

The third design examined was another patent for an ambient pressure valve (Fig. 6). This design operates similarly to the dual membrane design, but instead of using empty spaces between membranes and a flexible material to close the drainage opening, a flexible membrane directly exposed to the surroundings moves a small flap to seal and open the drainage hole. CSF would flow into the chamber and exert pressure on the flap, which would be opposed by ambient pressure. When inflow pressure surpasses ambient pressure, the flap opens and fluid flows out [8]. Like the first design, there is no chance for overdrainage since negative pressure has no way of affecting the system. However, expected problems with this design include the manufacturability of the small parts and the potential for fatigue on the small, delicate flap. It is also an already patented design, bringing into question the feasibility of the team working with it.

III.D Punctured Dome Design

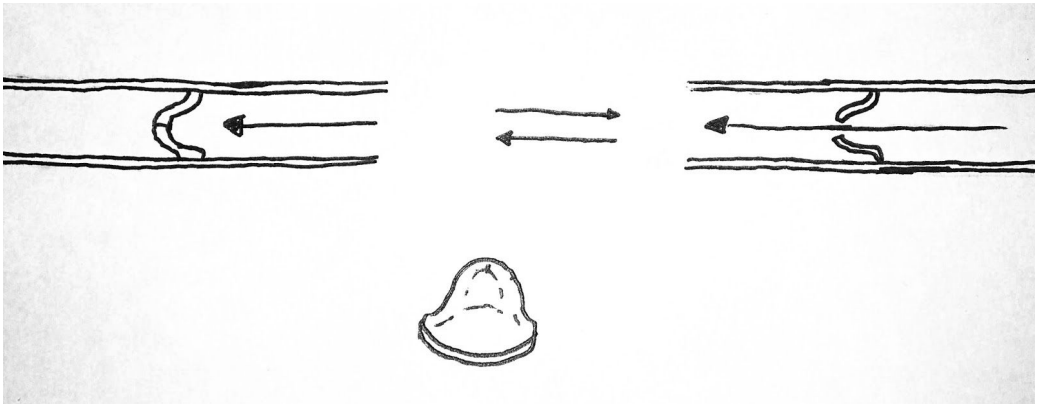

Figure 7: Differential pressure valve. Inflow pressure deforms the flexible material, expanding a small hole in the tip, allowing drainage.

The final design considered was a very simple differential pressure valve, consisting of a flexible dome-shaped piece with a small hole at the apex (fig. 7). When pressure behind the valve gets to a certain point, it is forced open and fluid drains. Problems expected included the possibility of overdrainage and fatigue from repetitive opening and closing.

IV. Preliminary Design Evaluation

The team evaluated the preliminary designs based on the design matrix, Table 1.

Table 1. Design Matrix

Properties (Weight)	Dual Membrane	Dashpot	Door-Flap	Dome
Cost (5)	4	3	4	5
Ease of Fabrication (20)	3	3	4	5
Safety (15)	4	4	3	2
Longevity (20)	4	5	3	2
Accuracy/ Precision (25)	4	4	3	2
Manufacturability (10)	3	4	3	5
Properties (Weight)	Dual Membrane	Dashpot	Door-Flap	Dome
Size (5)	3	3	4	5
Total (100)	73	78	65	64

IV.A Criteria for Evaluation

The chosen criteria and their respective weighting.

Cost (5/100): Criterion based on the cost of fabrication during the prototyping phase. The weight of this is low compared to the other criteria because the designs were thought to be under budget in fabrication and have a similar cost to produce on a large scale.

Ease of Fabrication (20/100): One of the second most heavily weighted criteria, this was based on the team's ability to create a large scale prototype with current knowledge of fabrication techniques.

Safety (15/100): This criterion considers the safety of the final product because the large scale prototypes would use water to gauge fluid control. Safety is a moderately weighted

criterion based on the required materials' interaction with the body at the implantation site.

Longevity (20/100): Tied for the second most heavily weighted criterion with Ease of Fabrication, it considers the perceived length of time the device can operate in the body without change in the mechanical properties.

Accuracy/Precision (25/100): The ability of the system to drain fluid in an accurate manner, only draining the CSF when the intracranial pressure is above the upper threshold and preventing drainage before the intracranial pressure is under the lower threshold.

Manufacturability (10/100): Manufacturability considers the perceived ease to manufacture the design in an industrial setting. This was weighted relatively low because this criterion is beyond the scope that the team can achieve within the allotted project time frame. The team still considered this criterion because the ultimate goal is to create a design that could be manufactured and sold on the market as an effective alternative to hydrocephalus valves currently in use.

Size (5/100): The criterion describes the overall size of the final design that would be implanted within the body. It was scored relatively low because the final designs should be similar in their sizes. The ultimate factor that was considered was the relative complexity of the designs, where more parts would result in a larger device.

IV.B Scoring

The reasoning behind the scores within the design matrix (Table 1).

Dual Membrane Design

The dual was investigated because of its fit to the client requirements: a mechanical, self-regulating valve that was activated based on differential pressure between the skull and the ambient pressure rather than differential pressure between the skull and the abdomen. This design scored well in most of the categories because of its overall simplicity in accomplishing the design requirements. However, the design fell short because the team was unsure as to how to fabricate the design, both in the prototype phase in a upscaled setting. The increased complexity also increased the hypothetical design size.

Dashpot Design

The desired spring-dashpot of this design behavior would release CSF at a steady rate and then return to the original position at a steady rate once the maximum threshold pressure has been alleviated. It would likely suffer the least amount of wear because of the dashpot built into it that

resists sudden applications of force, giving the device a longer lifetime and allowing it to score the highest in the Longevity category. It was thought to be one of the more expensive designs because the components would need to be fabricated or ordered to perfectly match each other in order to prevent leakage. However, it is possible to create with the moderate complexity proposed. The overall size of the device was thought to be the largest of all the designs, scoring low in this category.

Door-Flap Design

This design scored just barely higher than the Punctured Dome design. It was thought to be fairly cheap to make due to its potential ease of fabrication in a larger scale with slight modifications. However, it scored lower in the three most weighted categories because of the method of function. The team thought there was a possibility that the membrane could get wedged between the door and the inner chamber to prevent proper closure and possibly puncturing the pliable membrane. Fabrication of this design was hypothesized to be complex because of the nested inner chamber and its accompanying covered opening. It was considered to be relatively small because of the singular opening within the valve.

Punctured Dome Design

This design was proposed as the simplest possible solution to function as a valve within the body. Because of its simplicity, the design scored the highest in the most categories due to the limited size and ability to be manufactured by the team and in a large scale setting. However, the three critical categories were scored low because of the combination of the flexible material and mode of function. Longevity was presumed to be low due to the valve's mode of function, which would likely cause the valve to fatigue over time. The valve would become less accurate as it fatigued with the possibility of it breaking up in time.

V. Proposed Design to Pursue Further

Although there are some possible issues with leakage and biological interactions, the spring-dashpot operated design was selected for further work. This selection was made based on its ability to smoothly regulate the intracranial pressure and to avoid problems with overdrainage commonly seen with standard differential-pressure shunt valves.

VI. Conclusions

Going forward, a large scale prototype of the spring-dashpot design will be fabricated. More research will be conducted on the spring-dashpot mechanism: the team will calculate the appropriate spring constant and damping constant needed based upon the comparison between

intracranial pressure and ambient pressure and investigate a combination of materials and structure that would have the same desired behavior of a spring and dashpot in parallel. The valve component will also be investigated further because previous prototype designs that used a spring-valve had problems with leakage.

VII. References

[1] H. Solomon, “Hydrocephalus Shunt with Spring Biased One-Way Valves.” U.S. Patent 3,288,142 A, issued November 29, 1996.

[2] Sainte-Rose C, Piatt J, H, Renier D, Pierre-Kahn A, Hirsch J, F, Hoffman H, J, Humphreys R, P, Hendrick E, B, Mechanical Complications in Shunts. Pediatr Neurosurg 1991/1992;17:2-9. 21 Jan. 2017.

[3]"Facts and Stats | Hydrocephalus Association", *Hydroassoc.org*, 2017. [Online]. Available: http://www.hydroassoc.org/about-us/newsroom/facts-and-stats-2/. [Accessed: 21- Feb- 2017].

[4]"Facts about Hydrocephalus | Hydrocephalus statistics | NHFOnline.org", *Nhfonline.org*, 2014. [Online]. Available: http://nhfonline.org/facts-about-hydrocephalus.htm. [Accessed: 21- Feb- 2017].

[5] Drake, James M., et al. "Randomized trial of cerebrospinal fluid shunt valve design in pediatric hydrocephalus." *Neurosurgery* 43.2 (1998): 294-303.

[6] Portnoy, Harold D., et al. "Anti-siphon and reversible occlusion valves for shunting in hydrocephalus and preventing post-shunt subdural hematomas." *Journal of neurosurgery* 38.6 (1973): 729-738.

[7]D. Watson, “Shunt Valve for Controlling Siphon Effect.” US Patent 9,526,879 B2, issued Dec. 27, 2016.

[8] E. D. Luttich, “Proportional Control Device for a Hydrocephalus Shunt.” U.S. Patent 20,040,082,900 A1, applied April 29, 2004.

[9]"Hydrocephalus Association", *Hydroassoc.org*, 2017. [Online]. Available: http://www.hydroassoc.org/. [Accessed: 16- Feb- 2017].

[10]"Cerebrospinal Fluid (CSF)", *National Multiple Sclerosis Society*, 2017. [Online]. Available: http://www.nationalmssociety.org/Symptoms-Diagnosis/Diagnosing-Tools/Cerebrospinal-Fluid-(CSF). [Accessed: 21- Feb- 2017].

[11]"Hydrocephalus - Mayo Clinic", *Mayo Clinic*, 2017. [Online]. Available: http://www.mayoclinic.org/diseases-conditions/hydrocephalus/basics/definition/con-20030706. [Accessed: 21- Feb- 2017].

[12]"Spina bifida Symptoms - Mayo Clinic", *Mayo Clinic*, 2015. [Online]. Available: http://www.mayoclinic.org/diseases-conditions/spina-bifida/basics/symptoms/con-20035356. [Accessed: 21- Feb- 2017].

[13] Alfred Hospital, "Obstructive hydrocephalus caused by multiple sclerosis.", Prahran, 1989.

VIII. Appendix

A. Product Design Specifications: Hydrocephalus Shunt Valve

February 2, 2017

Team: Emma Alley (Leader), Andrew Miller (Communicator/BPAG), Karl Fetsch (BWIG), Catharine Flynn (BSAC)

Advisor: Beth Meyerand

Client: John Webster

Function

The device will function as a valve controlling the expulsion of cerebrospinal fluid (CSF) from inside the blood-brain barrier to the abdomen in patients suffering from hydrocephalus. The device will be of a minute enough size to avoid irritation in patients when implanted underneath the chin or behind the ear. Additionally, the device is anticipated to stray away from currently applied electronic-based valve mechanisms, functioning on a purely mechanical basis. This is to avoid encountering circuitry problems as well as electronic failure. CSF is released from the skull of the patient by tubing inserted through a surgical incision. CSF then flows through the

tubing to the device. Flow is blocked until sufficient pressure opens the valve to drain the CSF into the abdomen where it is reabsorbed.

Client requirements

- Prevent debris from entering system
- Self-regulating
    - Maintain a form of homeostasis with ambient pressure
        - Openings in shunt allow it to regulate with surrounding tissue
        - Openings in shunt to environment will be $\leq 3\mu m$
        - Placed under flaccid skin (either behind chin or ear)
    - No electronic components
- Address increased pressure due to heartbeat
- Increase longevity of device

Design requirements

- Biocompatibility (all components)
- Resistance to repeated strain (relevant components)
- Flexibility or rigidity (depending on component)
- Sealed (does not allow leakage outside the catheter system)
- Does not become clogged by tissue ingrowth
- Responds to changes in ambient **and** intracranial pressures--must safely remove CSF fluid when necessary without over draining
- Small size (described as about the size of a half dollar coin)

1. Physical and Operational Characteristics

a. Performance requirements: The device will need to last a lifetime, because ideally after implantation, it will never need to be removed. The shunt should also be able to remove excess fluid from the skull at approximately 1 ml/min, and should be designed so tissues do not clog the valve within the shunt. In order to properly displace excess pressure in the skull, the device should be designed to incorporate the use of ambient pressure as opposed to differential pressure. This will remove many complications patients suffer when standing up or changing elevations (such as in air travel).

b. Safety: The device poses two main safety concerns if it is improperly designed: over draining and under draining of cerebrospinal fluid from the skull. Over drainage can cause a significant drop in intracranial pressure, and in extreme cases, leading to the collapse of the ventricles in the brain due to insufficient support. In the reverse scenario, under drainage increases intracranial pressure, increased size of the ventricles push the

brain out, damaging the tissues [1]. Almost all of the ways that the device would fail, would cause one of these two scenarios to occur if untreated.

c. **Accuracy and Reliability:** Current devices have a failure rate of about 40%, so the proposed design needs to be more reliable than the standard for shunt valves. This lowered failure rate must be retained throughout the entire life of the product, corresponding with the patient's lifespan. The shunt should not need to be removed. Shunts will also need to be flexible in design, so that they may be customized for each patient's unique physiology.

d. **Life in Service:** Each shunt should be designed so that it may last the lifetime of the patient. In order to have the required longevity, the device needs to be designed to include ambient pressure as opposed to differential pressure. Differential pressure based shunts tend to cause complications with common actions, such as standing up too quickly or riding on airplanes.

e. **Shelf Life:** The device will be made out of polymers or biocompatible metals, so the storage life will be limited by the methods of sterilization. If the device can be re-sterilized before implantation, the shelf life should be indefinite.

f. **Operating Environment:** The device will function in standard human physiological conditions and fail to instigate an immune response. Such physiological conditions include a pH of 7.4 and temperature of approximately 37 degrees Celsius. The device will need to withstand pressure on all faces from the forces CSF will be exerting on the device's internal walls. Additionally, the final product must be resistant to failure as a result of tissue ingrowths. The device should prevent backflow through the valve and provide resistance to rapid opening and closing resulting from sudden pressure fluctuations such as heartbeats and changes due to standing or altitude.

g. **Ergonomics:** A common problem with competing shunt valves is the disconnection of tubing and migration of the valve from the original implantation site. To avoid this issue, the device must be completely immobilized within tissue. Further, the device must also not allow for tissue ingrowth to occur to an extent that function is lost. Since the device is idealized to remain in the patient for the remainder of his/her life, the device must be composed of materials resistant to biodegradation. Though infection is highly unlikely to occur with commonly used biomaterials, special caution may need to be taken with the implantation occurring in close proximity to the skull and brain.

   With regard to device function, multiple factors must be considered with respect to ergonomics. The valve must be able to withstand the hydrostatic pressure of the CSF it contains, pressures from surrounding tissues, and other biological material on the outer

walls. Fracture is the most common source of failure in hydrocephalus shunt valves and a tough material is required to avoid this pitfall. The device will also need to operate with the pressure ranges from CSF in the human brain. The entire function of the shunt valve will be anticipated to rely on CSF reaching a certain pressure threshold, at which time the valve opens and pressure is relieved.

h. **Size:** The design is estimated to be comparable to a half dollar, circular with a diameter of approximately 32 mm. The thickness is speculative, but is likely to be less than 20 mm. The principal concern for reducing the size is the patient's comfort.

i. **Weight:** The weight will likely be under 10g. The principal concern for reducing the weight is for the patient's comfort.

j. **Materials**: All materials used should be biocompatible (i.e. not degrade or cause immune reactions in the body). Furthermore, the materials used should be able to withstand repetitive loading and unloading without changes to their physical properties or breaking. Finally, magnetic metals need to be avoided since hydrocephalus is a condition that often requires MRIs.

k. **Aesthetics, Appearance, and Finish:** Finish of material should be smooth to reduce patient discomfort and to allow for optimal flow of fluid through the device. Outward superficial aesthetics are not a concern as the device is an implant, however, the valve ought to be visibly labeled for implantation ease.

2. Production Characteristics

a. **Quantity:** Only one working prototype needs to be produced for demonstrative purposes.

b. **Target Product Cost:** The Cost should be around the $100 budget proposed by the client.

3. Miscellaneous

a. **Standards and Specifications:** The FDA has set forth requirements for Neurological devices under 21 CFR § 882.5550. Hydrocephalus Shunts are considered to be a Class II medical device (21 CFR § 860.3(c)), needing to demonstrate effectiveness and safety (21 CFR § 860.7). The FDA recognizes ISO 7192 (2006) and ASTM F647 (2014) relating to Hydrocephalus Shunts.

b. **Customer:** Customers will be considered to be the implanting surgeons and the patients who use the valve. The valve should not be noisy for the patient (no repetitive clicking

for example). The device should also be as small as possible to complete its function so that the patient can live a relatively normal life after implantation.

c. **Patient-related concerns:** As mentioned in the 'operating environment' section, there is serious risk of shunt valve failure in patients with hydrocephalus. Research studies have shown upwards to 81% of shunt valve implants fail within their twelve years of implantation. Additionally, failure of the first implant increases risk of failure in subsequent implants [2]. Patients receiving these valve implants must understand these associated risks of failure when being provided treatment options.

   Another important concern for patients is that no valve mechanisms proposed to date have shown to be a unanimous best option for all. Devices containing anti-siphoning mechanisms to prevent backflow and overdrainage are highly suggest for tall, slender individuals whereas these devices can result in underdrainage in obese individuals. Thus, there is no universal shunt valve design and patients should perform individual research and consult their health professional when considering implants.

d. **Competition:** The first designs for shunt valves appear to come from the 1960s in which one-way spring valves were used in an attempt to provide a novel drainage system to move collecting CSF in the brain into an absorbable area such as the abdomen [3]. Current hydrocephalus shunt valves operate using a variety of components. Some devices consist of fixed differential pressures valves that will open and close at predetermined values while others can be programmed from outside the body to different limits. In order to prevent a siphon effect, anti-siphoning devices such as the ball and cone mechanisms are often used. There are also new patent designs in which the valve operates purely mechanically with no need for electronics [4]. It appears these new biomaterial-inspired designs could overcome many of the shortcomings of current programmed shunt valves. The common theme amongst all researched shunt valves shows a device in which an upper and lower pressure limit is set, similar to a filter mechanism. When the upper threshold is reached in terms of differential pressure, the device opens and CSF is moved through the outflow pipe. When pressure falls back below the lower limit the valve closes and overdrainage is avoided.

References

[1] "Complications Of Shunt Systems | Hydrocephalus Association". *Hydroassoc.org*. N.p., 2017. Web. 2 Feb. 2017.

[2] Sainte-Rose C, Piatt J, H, Renier D, Pierre-Kahn A, Hirsch J, F, Hoffman H, J, Humphreys R, P, Hendrick E, B, Mechanical Complications in Shunts. Pediatr Neurosurg 1991/1992;17:2-9. 21 Jan. 2017.

[3] Salomon, Hakim. Hydrocephalus Shunt with Spring Biased One-way Valves. Salomon Hakim, assignee. Patent US3288142 A. 29 Nov. 1966.

[4] Watson A, David. Shunt Valve for Controlling Siphoning Effect. David Watson, assignee. Patent US9526879 B2. 27 Dec. 2016.