Design of a CSF Shunt Valve for Hydrocephalus

Team Members: Erin Devine, Lauren Eichaker, Brian Mogen, and Steve Wyche

Clients: Dr. Bermans Iskandar*† and Dr. David Hsu**†

Advisor: Dr. Naomi Chesler‡†

*Department of Neurological Surgery, **Department of Neurology, ‡Department of Biomedical Engineering, †University of Wisconsin, Madison

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 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.

Introduction

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 removal of waste from the brain and to help compensate for changes in the volume of blood in the brain[1].

An abnormal over-accumulation of CSF in the ventricles of the brain increases the intracranial pressure above the normal range of 10-15 cm H2O (980-1470 Pa)[2] in the horizontal position. This condition is known as hydrocephalus.

Hydrocephalus can be due to obstruction or inadequate absorption (communicating). Communicating hydrocephalus requires placement of a shunt to drain excess CSF and maintain ICP at normal healthy levels[3]. About 1 per every 500 children is affected by hydrocephalus[1].

In order to counteract the effects of hydrocephalus, a shunt is used to drain excess fluid from the brain into the peritoneal cavity, pleural cavity or right atrium via two catheters and a valve[4].

Chronic over drainage of CSF causes slit ventricle syndrome, which involves the physical suction of the brain tissue into the catheter's intake within the cerebrum[5]. This causes an obstruction which can lead to catastrophic failure of the valve.

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

[1] "Hydrocephalus Fact Sheet." National Institute of Neurological Disorders and Stroke. National Institutes of Health, 01 Nov 2010. <http://www.ninds.nih.gov/disorders/hydrocephalus/detail_hydrocephalus.htm>.
[2] Steiner LA, Andrews PJD. Monitoring the injured brain: ICP and CBF. Br J Anaesth. 2006; 97: 26–38.
[3] Beni-Adani A, Biani N, Ben-Sirah L. The occurrence of obstructive vs. absorptive hydrocephalus in newborns and infants: relevance to treatment choice. Childs Nerv syst. 2006;22:1543-1563.
[4] Zemack G, Romner B. Seven years of clinical experience with the programmable Codman Hakim valve: a retrospective study of 583 patients. J Neurosurg. 2000;92:941–948.
[5] Rekate HL. The Slit Ventricle Syndrome: Advances on Technology and Understanding. Pediatr Neurosurg. 2004;40:259-263.
[6] Ratner BD, Hoffman AS, Schoen FJ, Lemons JE. (2004). Biomaterials Science: An Introduction to Materials in Medicine. Academic Press. Maryland Height, MD.
[7] Osswald TA, Baur E, Brinkmann S, Oberbach K, Schmachtenberg E. (2006). *International Plastics Handbook: The Resource for Plastics Engineers*. Hanser Gardner Publications, Inc. Cincinnati, OH.
[8] Barrett SP, Howard K. Barium sulfate radio-opacity and bacterial adhesion to silicone catheter material. 1989. J Clin Path 42: 1226.
[9] Issel ALC. Biocompatibility of Stent Material. 2004. MURJ 11:33-37.
[10] Lee Spring Limited. Engineers Guide: Designing & Specifying Compression, Extension and Torsion Springs.

Design Requirements

The overarching goal of the valve design is reducer 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

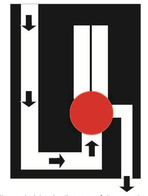

Figure 1: A basic diagram of the novel valve to correct for pressure changes due to position.

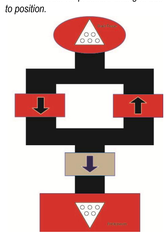

Figure 2: A basic diagram of the parallel valve system to correct for pressure changes due to cardiac pulsations.

Design Matrix 1

Valve Design

Table 1: A design matrix showing factors taken into account for the valve material selection. Weight assigned to each criteria indicates the relative importance of each factor.

Material	Biocompatibility[6]	Durability[6]	Ease of Manufacture[7]	MRI Compatibility[6]	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

Design Matrix 2

Ball Design

Table 2: A design matrix showing factors taken into account for the ball material selection. Weight assigned to each criteria indicates the relative importance of each factor.

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

Design Matrix 3

Spring Design

Table 3: A design matrix showing factors taken into account for the spring material selection. Weight assigned to each criteria indicates the relative importance of each factor.

Material[10]	Biocompatibility	Cost	Life	MRI Compatilbility	Total
Weight	4	1	2	3	10
Stainless Steel 316 L	3	1	2	0	6
Carbon Valve ASTM A 229	3	1	2	1	7
Plastic Composite	3	0	1	4	8

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. Excess pressure results in the drainage of a small volume of fluid into the peritoneal cavity.

A recent advancement in shunt technology is the placement of valves in series. This allows for the mediation of the effects of cardiac pulsations on the rate of CSF drainage. Incrementally increasing the thresholds of the valves down the tubing ensures drainage, but counteracts the effects of cardiac pulsations.

With respect to the design of a novel valve, an example of a different configuration of ball and spring has been patented by Codman & Shurtleff, Inc. in 2009. It differs from our design in that our design utilizes a ball within a cylinder and a corkscrew spring; the patented design utilizes a linear spring and a rectangular chamber. The patented valve is also programmable, while our design is not.

Final Design

The final design consists of a feedback loop utilizing our designed novel valve in series with pressure differential valves placed in parallel as modeled by the client (see Figure 3) .

Figure 3: A photograph of the valve system. The two valves in parallel are commercial pressure differential valves while the bottom valve is the novel design.

Pressure differential valves (manufactured by Medtronic) are placed in parallel to counteract the effects of cardiac pulsations.

The novel valve (see Figures 4 and 5) corrects for gravitational over siphoning. It uses a ball and spring system to balance the force of gravity on the CSF in the system while the patient is standing and does not affect the CSF's drainage from the brain when the patient lies down.

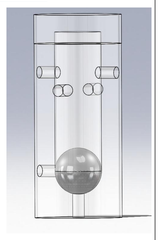

Figure 4: A SolidWorks model of the novel valve.

In the novel valve, a stainless steel spring and a PDMS ball are housed within an ABS plastic case (see Figures 4 and 5).

Figure 5: A photograph of the novel valve, manufactured out of ABS.

Future Work

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 during high rates of cardiac pulsations and elevated ICP . The team anticipates modifying the ball component of the valve and applying a sealant to the inlet of the valve to mollify this issue. Even when our model did not show any leaks, little to no fluid flowed through the feed-back loop.

Further investigations must be made into the testing setup in order to find the cause of this issue. Other geometries for our novel valve, such a cylindrical valve seal within a cylindrical chamber will be researched in the future.

Testing

The goal of our testing regimen was two-fold. First to check the fabrication and pressure dynamics of our fabricated 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 Failure

Initial testing of the loop design was done at 10 cm H_2O (686 Pa) created hydrostatically, with cardiac pulsations from the pump as seen in Figure 6.

Our valve failed almost immediately upon testing. 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.

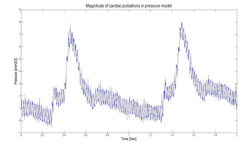

Figure 6: Input cardiac pulsation waveform. Baseline pressure was adjusted hydrostatically.

When pressures we increased substantially (60-70 cm H_2O (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.

The ABS valve wall contouring to the ball had ridges which could press into the deformable PDMS, thus increasing the friction present and effectively sealing the valve shut.

Design Validation

Validation of the valve system design was done by replacing our fabricated valve with a GAV valve. The system was tested under three conditions: normal ICP (10 cm H_2O (686Pa)), chronically elevated ICP (30 cm H_2O (2940Pa)), and plateau waves (60 cm H_2O (5890Pa)).
At normal ICP (Figure 7), the system responded well to cardiac pulsations, reducing their magnitude to about one cm H_2O inside the valve loop while not passing any fluid completely thought the system.

At elevated ICP and plateau wave ICP (Figure 8), 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.

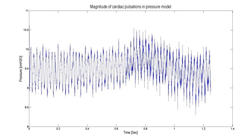

Figure 7: Minimization of Cardiac Pulsations at a normal ICP level.

It was also noted that no observable fluid passed through the flow loop, most likely because of the purely laminar flow behavior present in in the anterior T-junction.

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.

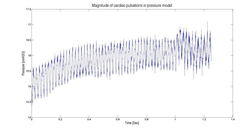

Figure 8: Pressure profile at elevated ICP and open flow conditions. Cardiac pulsations are absent and absolute pressure is less than applied.

Acknowledgements

Dr. Bermans Iskandar
Dr. David Hsu
Dr. Naomi Chesler

Dr. John Puccinelli
Rebecca Clayman