

Abstract

Hydrocephalus 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 (ICP) caused by hydrocephalus is the implantation of shunt valves. The valve system removes cerebrospinal fluid (CSF) within the blood-brain barrier [1]. However, complications with over drainage, underdrainage, and siphoning effects have continued to plague current designs. 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 and the ICP to regulate fluid flow and prevent excess siphoning. CSF removal is dictated *via* the incorporation of a Kelvin-Voight model of viscoelasticity to avoid commonly observed complications associated with over drainage of fluid.

Background

Physiology

- Can be congenital or acquired
- Hydrocephalus causes increased intracranial pressure
 - Choroid plexuses create CSF in the Ventricles
 - Arachnoid granulations drain CSF
 - Ventricles can become blocked or damaged diminishing CSF removal
- CSF is responsible for nutrients and waste transport
- CSF protects brain from impact

Competing Designs

- Differential Pressure Valves
 - Complications: over and underdrainage
- Electronic Valves
 - Complications: proximal occlusion
 - Magnetic field interference
- Ambient Pressure Valves
 - Complications: largely unexplored

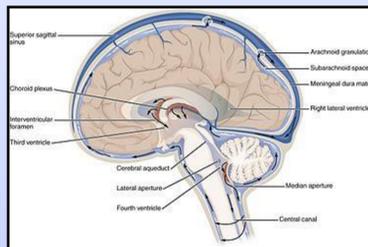


Figure 1: The above image is a cross-section of the brain. The image shows the flow of CSF within the skull.

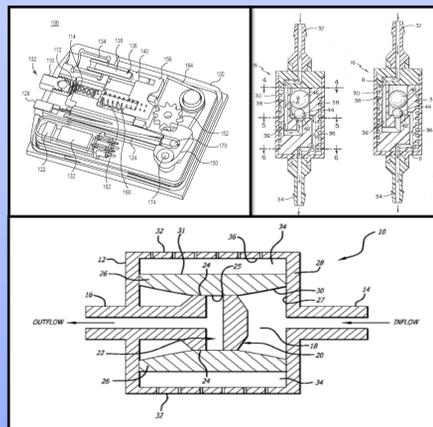


Figure 2: The images are an electrical valve (top right), differential pressure valve (bottom left), and an ambient pressure valve (bottom).

Design Criteria

- Biocompatibility
- Toughness/resistance to repeated strain
- Sealed system
- Use of ambient/intracranial pressure differential
- No over drainage
- No electronic or magnetic components
- Smaller than a US half-dollar coin (~30mm in diameter, ~2mm in thickness).

Final Design

Final Proposed Design

- Valve opens and closes with intracranial/spring+ambient pressure differential
- Kelvin-Voigt dashpot element “smooths” ICP
- Prevents sudden openings from pressure spikes
- No possibility of over drainage
- Increased lifetime

Modeling

- Model created using SolidWorks
- Preliminary valve was constructed
- Refinement
 - Scaled up due to fabrication constraints
 - Included O-rings to prevent fluid leakage

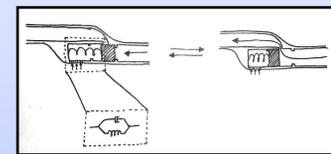


Figure 3: This is the preliminary final design. The key differences are noted in the permeable membrane located on the side and no O-rings.

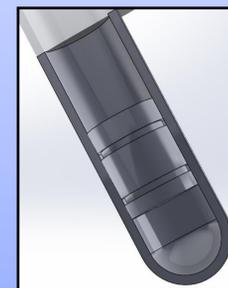


Figure 4: A cross-sectional view of the final design made in SolidWorks

Fabrication and Testing

Fabrication

- Off-the-shelf parts: PVC piping, PE dowel, spring, rubber O-rings
- Future designs should include biocompatible parts
- Modified UHMWPE rod to current piston design using a lathe
 - Outer diameter turned to 2.489 cm
 - O-ring groove diameter turned to 2.271 cm
 - 1.20cm diameter center hole drilled into bottom position
- 0.635 cm hole drilled into PVC housing 3.111cm from base
- Pieces were adhered together using an epoxy/amine resin putty



Figure 5: The above picture contains assembled and disassembled pieces of the shunt valve prototype.

Testing

- Compression testing
 - Goal: Assess force requirements of valve system
 - Max force without opening valve
 - Force to fully open valve
- Cyclic load testing
 - Goal: Determine viscoelasticity of system and assess % energy returned to system after valve fully opens and closes
 - 3x with water
 - 3x w/o water, lubricated



Figure 6: The prototype undergoing cyclic loading in the MTS machine.

Results

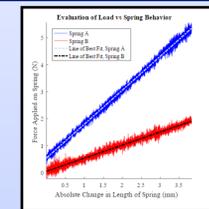


Figure 7: A force-displacement curve of the spring data was plotted from the MTS testing output using MATLAB. The slope of the line of best fit was used to approximate the spring constant of each selected spring. Spring A ($k=1.259$ N/mm) was selected over spring B ($k=0.487$ N/mm) due to its larger spring constant

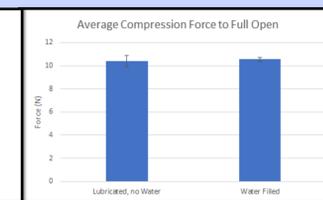
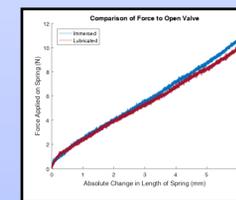


Figure 8: The lubricated group's (N=3) interior wall was wetted prior to testing, but contained no water in the lower reservoir while the water filled group (N=3) contained water in the lower reservoir along with wet walls. No significant difference was found between lubricated and water filled tests ($p=0.803$).

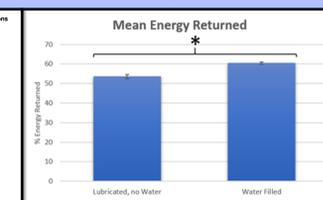
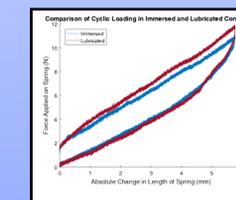


Figure 9: Energy returned was calculated by dividing the energy during unloading by the energy during loading. The water filled (N=3) valve returned significantly higher energy to the system than the lubricated (N=3) condition ($p=.004$).

Future Works

- Create a scaled down model
- Explore a wider range of springs
- Work to improve the seals created by the O-ring
- Develop an official prototype with appropriate materials

Acknowledgements

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