Intracranial Pressure Sensor Testing Device

Detection of Shunt Malfunction in Hydrocephalus Patients

Final Design Report

Team Members:

Brad Lindevig- BSAC
Dan Miller- Team Leader
Jamon Opgenorth- Communicator
Sarah Sandock- BWIG

Advisor:

Prof. Willis Tompkins

Clients:

Dr. Josh Medow
Prof. John Webster
Elena Bezrukova

Table of Contents

Abstract

Currently, our client, Dr. Medow is working with Professor John Webster and Elena Bezrukova in developing a sensor that will monitor pressure inside the skull of hydrocephalus patients. This sensor will potentially notify medical personnel when a cerebral spinal fluid drainage shunt has failed.

Our team contributed to this project by designing a phantom testing device that will be used to calibrate and test sensor specifications (drift stability, accuracy, etc.)

The final design is an upright standing tank comprised of five sections of clear PVC tubing. During a testing procedure the sensor is placed at the base of the structure, and pressure is generated from loading water on top. The pressure can easily be altered by changing the amount of the water.

Following testing we concluded that our device can supply the appropriate consistent positive pressures, permits drift stability testing, and is physically stable.

Background

Excessive accumulation of cerebral spinal fluid (CSF) within the brain is referred to as a condition called hydrocephalus. CSF is a clear fluid that surrounds the brain and spinal cord cushioning them and delivering nutrients to the brain. The excessive accumulation of CSF results in an abnormal widening of spaces in the brain called ventricles. This increase in the volume of fluid creates potentially harmful pressure on the tissues of the brain [1]. Hydrocephalus can be caused by head injuries,

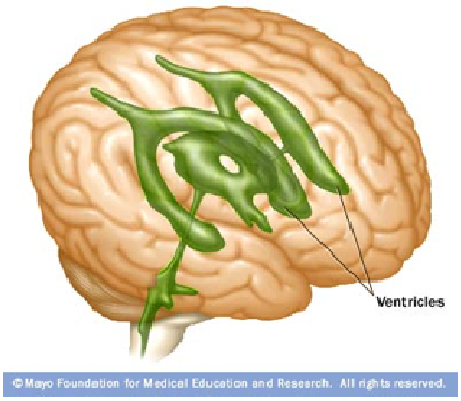

Figure 1: Ventricles of the human brain

but most commonly arises due to birth defects. Approximately 1 out of 500 children are born with this condition.

The ventricular system shown in Figure 1 is made up of four ventricles connected by narrow passages. Normally, CSF flows through the ventricles and exits into cisterns. Hydrocephalus impedes this process, creating an increase of pressure.

Hydrocephalus is most often treated by surgically inserting a shunt system that consists of the shunt, a catheter, and a valve [1].This system diverts excess flow of CSF to another area of the body, normally the stomach or the heart, where it can be reabsorbed into the circulatory system as seen in Figure 2.

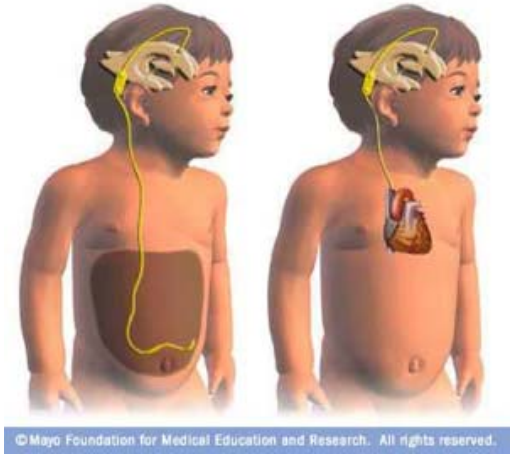

Figure 2: Shunt System

Shunt failure is common in children within the first two years of implantation [2]. Shunt systems malfunction in two ways: either they do not drain enough fluid or drain too much fluid (creating a vacuum). The symptoms of shunt failure include headaches, vomiting, irritability, and tiredness. Many times unnecessary hospital visits and operations occur due to shunt-failure symptoms mimicking flu-like symptoms. Failure of the shunt system arises from infections, obstructions, and simply being outgrown by the patient. Shunt systems require monitoring and regular medical follow ups.

There is a need for a device that can measure the intracranial pressure to determine whether or not the shunt system is working properly. If the shunt system has failed, such a device should output an abnormal pressure reading. The overall goal of this device is to minimize the amount of invasive procedures needed to measure the condition of the shunt system.

Our objective is to design a phantom tester that will measure whether or not the sensor meets its design specifications. Although we have helped with the sensor's construction, it is primarily being designed and built by Elena Bezrukova, a graduate student employed by our client.

Design Criteria

The design of the phantom tester requires the following:

1) Reliability: within 0.1% error
2) Able to test drift stability
3) Range: -30 mmHg to +100 mmHg
4) Not interfere with telemetry signal
5) Able to take readings at any pressure within range
6) User friendly
7) Accommodates water and vacuum conditions
8) Mimic intracranial environment for testing

The design criteria for the phantom tester are derived from the capabilities of the pressure sensor that will be tested in this device; the most important being reliability. Reducing the error in the calibration of the phantom tester will provide for more accurate final readings from the pressure sensor. During all stages of this design project, the lower the error observed, the safer the end product will be for the patient.

Once implanted, the pressure sensor needs to continuously provide accurate measurements and transmit data without the need for invasive adjustment. The drift stability of the device is one of its most important features. To test drift stability, the phantom tester must be able to stay at constant pressure for long periods of time giving a consistent reading.

The required pressure range is -30 to 100 mmHg. The positive range refers to the buildup of CSF in the ventricles creating excess pressure within the skull. The healthy range of CSF pressure for an adult human brain is 4 to 7 mmHg ±10 mmHg throughout any given day. The negative pressures on this range arise from the CSF being drained out of the brain too quickly, creating a vacuum. Negative pressures are only observed momentarily if ever due to actions such as sneezing and standing up quickly.

It is important for the testing device to be physically stable. To measure the required range of pressures, the phantom tester will need to accommodate both water and vacuum conditions; therefore, the device must be airtight.

Final Design

PVC Tubing

The phantom tester (Figure 3) consists of five clear PVC pipes that are .305 meters in height, and have an inner diameter of 15.31 centimeters. Four of the five tubes were made by cutting equal segments of a 1.22 meter long PVC pipe. Measuring the height of the water requires clear tubing so the user can easily observe the water level.

Figure 3: Testing Device

It was beneficial the column to have a large inner diameter in order to minimize the meniscus to provide more accurate readings. This keeps the height of the water more uniform than if a large meniscus were to form. The inner diameter also needed to be adequately large enough for pressure sensor to fit inside. An inner diameter of 15.31

cm accommodates the size of Elena's pressure sensor. In order to test drift stability the height of the water will need to remain constant over a long period of time. Evaporation of some water will occur over this period of time. With a large inner diameter, the change in the height of water will be insignificant; therefore, constant pressure will be achieved.

Multiple segments of tubing provide the user with more flexibility while testing the sensor. If the user is testing for low pressures only one or two segments will be needed; improving the ease of testing. A vacuum can be generated more efficiently by minimizing the volume of the space for the desired vacuum.

Rubber Connectors

Four black rubber pipe fittings were used to connect the tubes together. In order to prevent all water leakage, hose clamps were used to tightly seal the top and bottom portion of each rubber connector. Disadvantages arose from this setup. Water height cannot be accurately measured in these areas, which reduces the amount of data points that can be collected. Furthermore, tightening and loosening the hose clamps require a screwdriver. This decreases the tester's ease of use.

Base

The base is a 0.305 m by 0.305 m by 0.0254 m piece of polyproplyene plastic. A ring was milled out of the base, 0.12 centimeters deep, of the same thickness of the clear PVC pipe. The PVC pipe snuggly fit into the ring of the base. Since the PVC tubing sits into the base there is an extra level of stability of the prototype as well as the base is less prone to leaking. To ensure no leakage, epoxy was applied between the base and the bottom tube.

Drainage System

Draining the water is an essential part of this design. When the water height inside the column reaches its maximum height with the five PVC tubes it is extremely heavy. Trying to dump this water out after testing is complete is not practical. Dumping water out in this manner could result in damage to surrounding equipment if the user lost control of the column. Therefore, a hole (2 cm OD) was drilled into the bottom-most PVC tube. In order to impede the flow of water out of this hole during testing, a small rubber stopper, polyurethane tube, and a clamp for the tube was implemented (Figure 4).

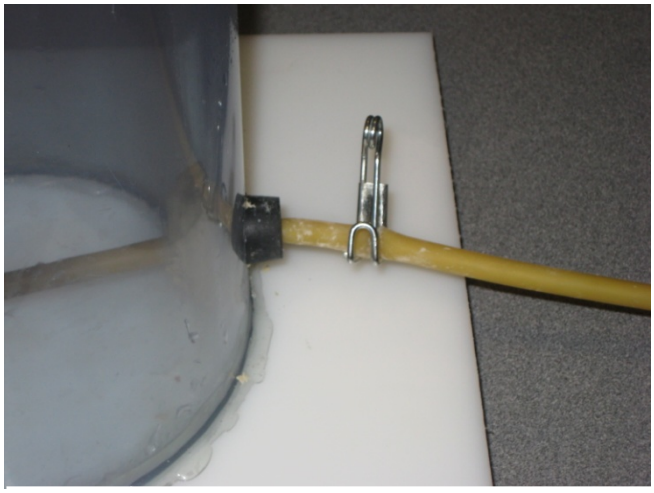

Figure 4: Drainage System

A hole was drilled into the rubber stopper and the polyurethane tube was fed though this hole. The stopper was then placed into the drilled hole of the PVC tube oriented is such a way that the thicker part lied on the inside of the column. This was done so that the water pressure won't be able to force the stopper out of the hole. This results in the water being able to flow uniformly out of the polyurethane tube. The polyurethane tube clamp is used to stop the flow of water out of the column.

Sensor Calibration

In order to test the accuracy of Elena's device, a differential pressure sensor (Figure 5) was borrowed from a graduate student, Juan Vivanco. The differential pressure sensor compares the pressure in one terminal to the pressure in the

Figure 5: A differential pressure sensor

opposite terminal. It outputs a change a differential voltage depending how large the pressure difference are. The differential pressure sensor was calibrated by recording this change in voltage and relating it to the actual pressure inside the column of water according to the equation: water density*height of water*gravity (p*h*g).

The differential sensor used was item code 29CAFA6D from Honeywell. The sensor has two ports that measure separate pressure. The difference of the pressure is read and a voltage is outputted. One port of the sensor was attached to the drainage tube and the other was left open to the air. The four prongs of the sensor were attached to a differential amplifier (Figure 6), and then further attached to an oscilloscope in order to record a voltage and a power source. The amplifier increased the voltage read by a magnitude of 150. This was done to obtain more valid data to properly calibrate the sensor.

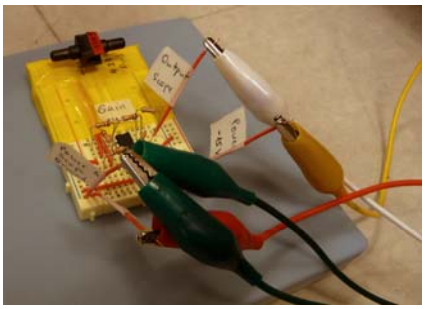

Figure 6: Circuit containing differential pressure sensor and voltage amplifier.

Calibration of the sensor included filling the tester with water and recording both the height of the water and the voltage read by the oscilloscope. This was repeated several times for various heights of water. The height of the sensor was subtracted from the total height of the water to determine the actual height of water that was above. The equation p*h*g was then used to determine the pressure that was applied to the sensor. This pressure (N/m^2) was then converted into mmHg through conversion factors. The pressure in mmHg was then correlated to the voltage outputted by graphing the data. The graph is extremely linear, showing that the pressure readings were consistent throughout the testing. The conversion factor between voltage and pressure was found to be 0.0828.

Through this testing we were able to properly calibrate Juan's differential pressure sensor. This verified that our protocol is valid and complete. Furthermore, it proves that this tester can properly calibrate a pressure sensor. Juan's sensor can then be used to further verify the accuracy of the sensor built by Elena.

Testing Protocol

Positive Pressure

When testing the accuracy of the intracranial pressure sensor for positive pressures, the sensor is placed at the base of the structure, and pressure is generated from the height of the water inside the phantom tester. Before pouring the water into the phantom tester to make this positive pressure, it is important to make sure the differential pressure sensor and voltage amplifier are of the same height as the hole in the PVC tube. This will allow the differential pressure sensor to provide the most accurate change in voltage when comparing the two pressures of the air and the column. Positive pressures can then be easily generated by pouring water directly into the phantom tester once the differential pressure is connected to the correct ports, circuit and voltage amplifier. The average change in voltage can then be translated into pressure according to the graph (Figure 7) and then be compared to the intracranial pressure sensor's output. If these two readings are similar then a conclusion can be made that the intracranial pressure sensor is accurate at that instance of pressure.

In order to test for drift stability the top of the phantom tester can be capped to prevent water evaporation. After a period of time the pressure from the differential pressure sensor can be recorded and compared with the intracranial pressure sensor again.

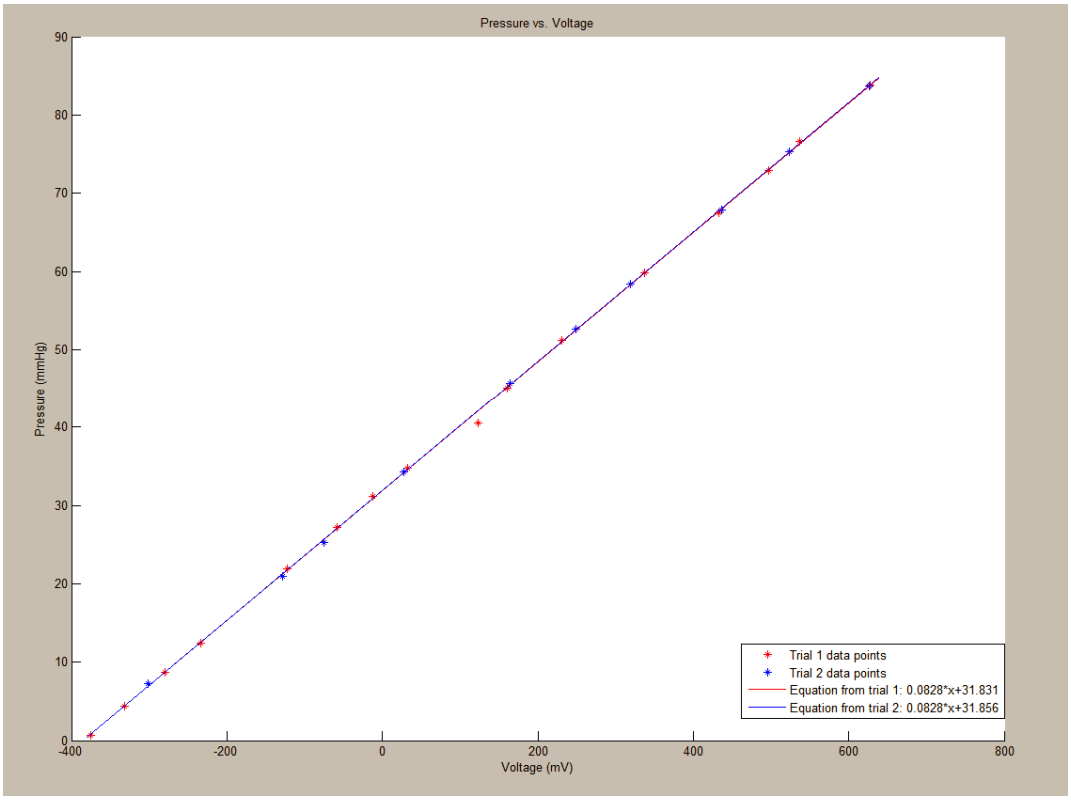

Figure 7: Final Curve (above) Data collected from testing during two separate sessions. The conversion factor from voltage to pressure was consistent in both trials (0.0828 mmHg/mV).

Negative Pressure

The phantom tester is capable of creating negative pressures when testing the accuracy of the intracranial sensor. When testing for negative pressures, the intracranial pressure sensor is placed inside phantom tester and the top is then sealed air-tight with a cap and a pressure gauge. The polyurethane tube is connected to a vacuum trap and an aspirator. Changing the water flow of the aspirator changes the negative pressures within the phantom tester. The pressure within the phantom tester can be measured directly from the pressure gauge. The pressure read from the pressure gauge is then compared to the pressure recorded from the intracranial pressure sensor to see if it is accurate. In order to test drift stability for negative pressures, the water flow from the aspirator can be left on for a certain time period.

Testing

At the beginning of this project we defined design specifications in order to meet the goals of our client. In order to properly test the sensor the testing device must be able to provide the complete range of pressures (-30 to 100 mmHg). Following the calibration of our differential pressure sensor, we filled the column to a known height of 140 cm. When the water level is at this height the pressure is 100.4 mmHg. At this mark, the pressure sensor gave a voltage reading of 801.8 mV which equals 100.8 mmHg, using our calibrated equation. The oscilloscope had approximately 2-3 mV of noise, which would contribute to the slight difference in measured pressure to the actual.

To test negative pressure, the bottom section of PVC tubing was used. This section was completely sealed and then connected to an aspirator and vacuum sensor. A vacuum was created by running water through the aspirator, which created a vacuum inside the section of tubing. Unfortunately our device could only supply a vacuum pressure of -12 mmHg. This specification shortfall can be attributed to the device not being completely airtight. As previously stated this specification is not a major concern, as it only occurs briefly in patients. Sealing the device prior to testing can improve the magnitude of vacuum pressure.

By testing the positive pressure protocol multiple times we were able to determine that the testing device will provide consistent pressures. If the tube is filled to the same height, and the water density remains constant, the pressure will be exactly the same. This was proven by filling the tube to a height of 117 cm two independent times. Each time the measured pressure matched the calculated pressure of 83.8 mmHg, proving that the tester provides the same pressure for the same height of water.

The tester must also be able to provide an acceptable environment for testing a pressure sensor's drift stability. To test drift stability, the sensor will be left in the tester for a prolonged

period of time. In order to record accurate data from this test, the amount of water inside the testing device must remain constant. The device was tested by filling the base tube with water to a height 30 cm. The tube was then sealed. After 12 hours, the 0 % evaporation had occurred proving that this device when sealed can provide an appropriate setting for testing drift stability.

The product was also required to be completely leak proof. It will be primarily used in an electronics lab, therefore the user must have complete control over the water inside the tester. After filling the device to its maximum water height of 152.4 cm, no leaking occurred. The base also provided sufficient stability when the column was completely full.

Ergonomics

The final design for the phantom tester is user friendly. The separate tubes allow for the column to be only as high as needed during testing. This creates a less cumbersome testing environment. Emptying the phantom tester of water after positive pressure testing requires the operator to only unclamp the polyurethane tube to allow the water to drain into a bucket. Although this may take a while if testing with 100mHg, it is safer compared to trying to tipping the entire phantom tester over in order to drain the water. In order to apply pressure with this sensor water is poured into the column. This is an extremely simple way to apply a known pressure to a sensor and therefore the phantom tester has a very low learning curve.

Ethical Considerations

Throughout the process of designing, manufacturing, and testing the phantom tester, ethical considerations were taken into account. Careful measurements of the water used in the calibration of the differential pressure sensor were done to ensure the calibration was valid. Many tests were performed when calculating the accuracy of the differential pressure sensor without any need to change our design because of ethical considerations. All purchases were

made with consent from Dr. Medow. Furthermore, all data recorded as well as flaws of the prototype were reported.

Future Work

While this product meets nearly all of our design specifications, there is still work that could be done to improve the prototype. First, a better sealing system is required to meet our complete negative pressure goal of -30 mmHg.

Another aspect that could be improved is the connections between PVC tubes. Currently the black rubber connectors prevent 7 cm of view for the user. In total these connectors prevent the user from accurately measuring the device over a distance of 28 cm. By using clear connectors the visibility would be improved in these locations and more data points could be observed.

During an experiment, the most time consuming process is draining the water from the column. To improve this feature, a larger diameter rubber tube could be utilized to quicken drainage.

While the protocol we have developed should be adequate for calibrating and testing any pressure sensing device, this protocol may need to be adjusted as newer versions of the sensor are developed.

Appendix

Component	Unit Cost	Number of Units	Total Cost
4' Clear PVC Tubing	$ 92.62	1	$ 92.62
1' Clear PVC Tubing	$ 50.86	1	$ 50.86
Rubber Stopper	$ 0.75	2	$ 1.50
Polyeurethane tubing	$ 4.00	2	$ 8.00
Clamp	$ 0.98	1	$ 0.98
Rubber Connectors	$ 21.05	2	$ 42.10
Plumbing Putty	$ 7.00	1	$ 7.00
Hose Clamps	$ 13.88	1	$ 13.88
Polyethelene Base	$ 27.94	1	$ 27.94
Poster	$ 43.75	1	$ 43.75
		Total:	$ 388.63

Table 1: Bill of Materials

Product Design Specifications:
Intracranial Pressure Sensor

Team Roles:
Team Leader: Dan Miller
Communications: Jamon Opgenorth
BWIG: Sarah Sandock
BSAC: Brad Lindevig

Last Update: October 5, 2009

Function: Shunt failure in hydrocephalus patients is difficult to detect. The current pressure sensor system is complex and bulky. Other detection methods can be inaccurate. Our client needs a more simple, inexpensive, and reliable implantable intracranial pressure monitor for patient care. The first step to developing this product is to design it on a large scale. Our goal is to develop a phantom testing protocol in order to properly calibrate the sensor.

Client Requirements:

- Must not interfere with sensor telemetry
- Must apply proper range of pressure (-30 to 100 mmHg)
- Must apply constant pressure over a long period of time
- Must be able to apply a known and accurate pressure
- Must be able to test drift-stability
- Testing protocol must be standardized and accurate

Design Requirements:

1. **Physical and Operational Characteristics**
    a. **Performance Requirements:** The phantom tester must provide adequate conditions to test the newly developed intracranial pressure sensor. This includes supplying appropriate pressure (-30 to 100 mmHg), conditions to test drift stability, and a leak proof environment.

    b. Safety: All components should be water proof or able to interact with water. The device should not be to heavy or cumbersome for one person to handle.

    c. Accuracy and Reliability: The testing device must be able to apply many different pressures (over 100 points).

    d. Life in Service: Components should have a life span of 20 years.

    e. Shelf Life: Storing the product will have no effect on its ability to perform

f. Operating Environment: This device will be used in a traditional lab setting, but should be operable under the final product environment of the intracranial region.

g. Ergonomics: There should be a low learning curve, but interpretation should be done by licensed professionals. Final implanted product should cause no discomfort to the patient or disrupt daily activities.

h. Size: The sensing device should be a maximum of 12" x 6" x 4". The phantom tester has no size requirement, but should not unreasonably large, under 5'tall.

i. Weight: The phantom tester has no weight requirements, but a person should be able to transport by lifting. (Under 35 pounds)

j. Materials: All outer interface should be waterproof.

k. Aesthetics, Appearance, and Finish: The intracranial pressure sensor should appear safe and operable. The product should also look professional.

2. Product Characteristics

a. Quantity: Our team will be developing the one phantom tester used in calibrating the pressure sensor.

b. Production Cost: The cost should be reasonable in comparison with technologies and materials used. The phantom tester should cost less than $500.

3. Miscellaneous

a. Standards and Specifications: Electrical components should be compatible with data scanner device and inductive power source.

b. Customer: The client would like a sensing device that is operational on a large scale compared to the final product.

c. Patient-related concerns: The final product will require multiple patient related concerns, including: out-growing device, infection, replacement or recalibration of device, comfort, and interaction on daily use. However, this product has no interaction with the patient.

d. Competition: Currently there are other devices on the market that have the same relative use. However, these devices are inaccurate and prone to failure.