Intracranial Pressure Sensor

Mid-Semester Report

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Abstract

Our client, Dr. Josh Medow, a neurosurgeon at UW-Hospital, works with many types of conditions in patients. One condition in particular is hydrocephalus, which is the buildup of cerebral spinal fluid in the ventricles of the brain. Currently a shunt system is implanted in the head of the patient to assist with the draining of fluid which reduces the pressure. These shunts can malfunction which leads to an abnormal amount of pressure in the skull. The onset of fluid pressure exerted on the brain can lead to multiple health complications and death.

Dr. Medow is working with Professor John Webster in developing a sensor that would monitor pressure inside the skull of hydrocephalus patients. Currently this project is in the initial stages. The goal of this semester is to design a large scale model of the sensor and a phantom tester. Our design focuses on the development of the phantom tester.

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 and delivering nutrients to the brain. The excessive accumulation of CSF results in an abnormal widening of spaces in the brain called ventricles. This widening creates potentially harmful pressure on the tissues of the brain [1]. Hydrocephalus can be caused by head injuries, but most commonly arises due to birth affects. Approximately 1 out of 500 children are born with this condition.
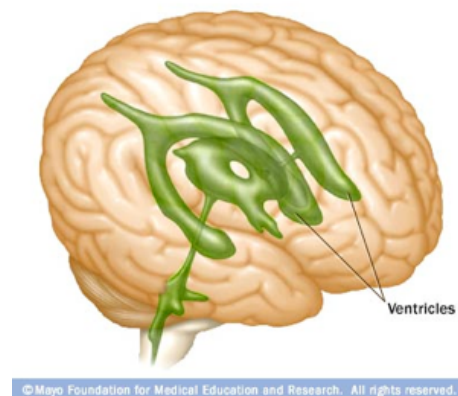
Figure 1: Ventricles of the human brain

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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.
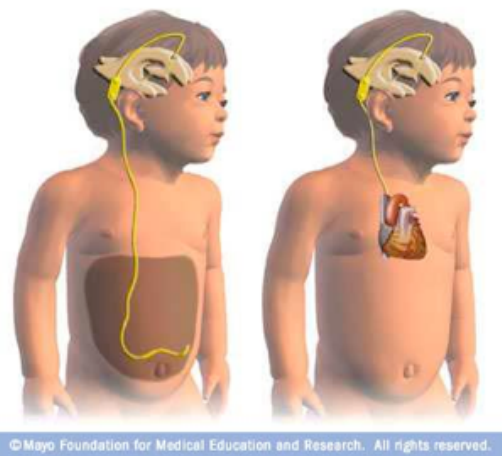
Shunt failure is common in children within the first two years of implantation [2]. Shunt systems malfunction in two ways: either they don't drain enough fluid or drain too much fluid (creating a vacuum). The symptoms of shunt failure include headaches, vomiting, irritability, and tiredness. Many times unnecessary hospital visits and

Figure 2: Layout of a common shunt system in a child

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, this device will 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. Due to the magnitude of this project, we will not be able to complete the final design in just one semester; therefore, the main focus of this semester will be to create and test a working prototype.

This is a highly invested in project spanning many levels of expertise. Our objective is to design a phantom tester that will measure whether or not the sensor has met the following 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

Sensor

The design of the sensor requires the following:

1) No recalibration
2) Drift stability: 2 mmHg to 3 mmHg

3) Reliability: within 0.1% error

4) Range: -30 mmHg to +100 mmHg

5) Telemetry data and power transmission

6) Small size: under 1 cm^3

7) Must not interfere with existing diagnostic instruments

Once implanted, the device needs to continuously output accurate measurements and transmit data without the need for invasive adjustment. The drift stability of the device is one of its most important features. For long-term use to be plausible, the measurements must not vary by more than 2 to 3 mmHg over a 20-year period.

The overall error of the device should be within 0.1% of the actual pressure. The required pressure range is -30 mmHg to 100 mmHg. The negative pressures on this range arise from the CSF being drained out of the brain too quickly, creating a vacuum. 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.

The physical requirements of the sensing device are restricted by size and environment. Our device will have no external battery source. Benefits of this feature include: no protruding wires, lighter weight, and allows the device to be more user-friendly. This will additionally allow the device to be built on a smaller scale. Eventually the sensor will need to be less than 0.5 cm^3.

Biomaterials will be utilized to avoid interference with common diagnostic equipment such as MRI and CT scanning. Operation of the sensing device will ideally take place on the following channels: 402-405 MHz. These ten channels are FCC specified radio frequency bands designated for implanted medical devices [5]. A low transmitter power of below 25 μW for both sensor and transmitter will protect from interference will all other medical equipment found in a hospital setting.

Phantom Tester

The phantom tester, while it will not be implemented as part of the final design of the intracranial pressure sensor, is still a very important aspect of this project. It will determine whether or not the sensor that we've created meets the sensor's design specifications, and ultimately whether or not the sensor could be usable for real-world application.

The three main criteria the phantom tester must meet are: test the accuracy of the sensor, test the drift stability of the sensor, and be able to apply a pressure ranging from -30 to 100 mmHg. Also, the greater the ability the tester has on mimicking the environment within the skull, the more beneficial the results of the tester become.

Designing a tester to measure drift stability won't be complicated. For this test the sensor will sit inside the tester for a long period of time. Making sure the tester can apply the specified

range of data will require calculations/conversions to determine how much air, fluid, or any other type of pressure is needed in order to create the desired pressure range. The most important aspect of the tester is to design for will be in its ability to determine the accuracy of the sensor. If the pressure applied by the tester is unclear, then it will be impossible to determine the accuracy of the device. Therefore, extensive calculations will need to be done in order to determine what pressure is being applied, or another calibrated pressure sensor will have to be incorporated into the design to compare the two pressure readings.

Sensor Design

In order to create an intracranial pressure sensing device that doesn't contain a battery a passive circuit will be implemented. This circuit will be extremely simple as it contains only an inductor and a capacitor in series (Figure 3). Therefore, charge that is stored on the capacitor's plates will flow back and forth through the inductor. This oscillation of energy between the capacitor and inductor, much like the sloshing of water back and forth in a tank, is why this circuit is commonly referred to as a "tank" circuit.
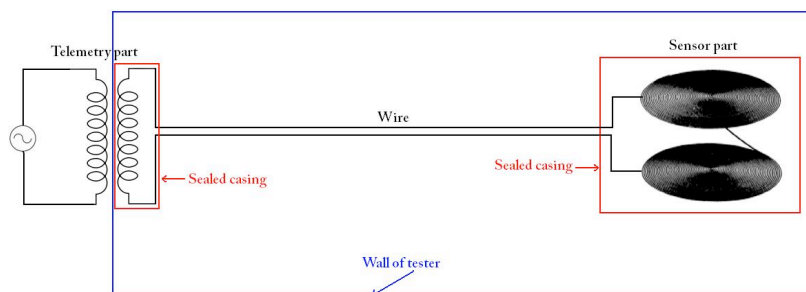
Figure 3: LC circuit design of sensor. (Elena Bezrukova)

The capac   asures the

pressure. The capa   n pressure is

applied to the circ   ;e in the

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capacitor's distance. The change in capacitance along with the constant inductor will yield a change in the resonant frequency of the circuit (resonant frequency is equal to the inverse of the square root of 2 multiplied by the inductance and capacitance of the circuit). Therefore, a specific resonant frequency of the circuit will correspond to a specific pressure applied to that circuit.

The ability of the tank circuit to measure pressure is important, but it is relatively useless unless that pressure can somehow be outputted to an external device. This is the main function the inductor provides. All that has to be done in order to read the pressure (translated from the resonant frequency) of the circuit is an external device containing an inductor must be swept across the sensor. As one inductor moves past another inductor a magnetic field is created. This allows for the current resonant frequency of the tank circuit to be induced onto the inductor of the external device. Therefore, the external device has the same resonant frequency as the tank circuit that would be implanted in a patient's head. This process of transferring/inducing power wirelessly from one circuit to another is known as telemetry.

The main struggle with building such a "tank" circuit is trying to match/correlate each resonant frequency to a pressure. Resonant frequency depends on inductance and capacitance. Inductance and capacitance depend on several properties as well (distance of plates, number of turns, distance of turns, and size of coils). These properties create an infinite amount of tank circuits that could fit the pressure ranges needed for our sensor. Therefore, it will take some trial and error, along with proper analytical analysis via computer programming to properly create the desired sensor.
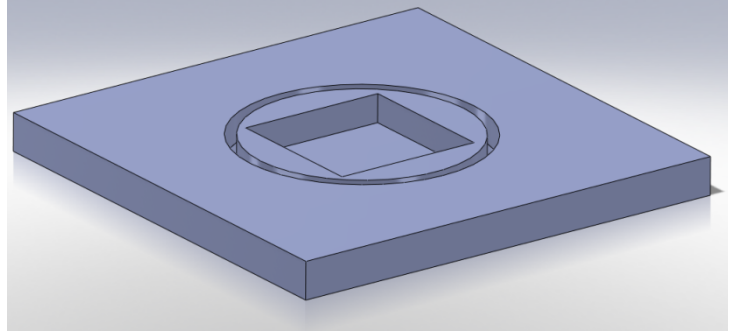
Phantom Tester: Design Alternatives

Design 1: Plastic Pipes

The first design uses a water column to generate pressure on the sensor. The variation in water height changes the amount of pressure acting on the sensor. During testing, the sensor is placed at the bottom of the water column. To meet the entire positive pressure range, the water column will need to be 1.37 meters tall.

The base (Figure 4) of this design is a rectangular (30.5 cm x 30.5 cm x 2.5 cm) polyurethane sheet. The sensor would rest in a bored out rectangular area (7.62 cm x 7.62 cm x 1.27 cm) inside the base. This would limit horizontal translation of the base during testing. There will be small hole through the base, which will allow wires from the sensor to connect to an external component.

Figure 4: Plastic Pipes Design Base: The sensor will sit inside the square area of the base. The first plastic PVC pipe will connect to the base by sitting inside the bored out ring.

The hole will then be surrounded by putty to inhibit leakage from the column. There will also be a bored out ring outside the sensor region on the base. This ring will have an inner diameter of 15.31 cm, an outer diameter of 16.82 cm, and a depth of 1.27 cm. The purpose of this ring is to hold the base plastic tube in place.

The water column container (Figure 5) will be constructed of clear PVC tubes. Each section has a length of 30.5 cm, an inner diameter of 15.31 cm, and an outer diameter of 16.82 cm. By using an inner diameter of 15.31 cm, the meniscus at the water level is minimized. This provides a more accurate height measurement, resulting in an accurate pressure calculation. The use of multiple sections of tubing allows lab personnel to adjust the height of the water column
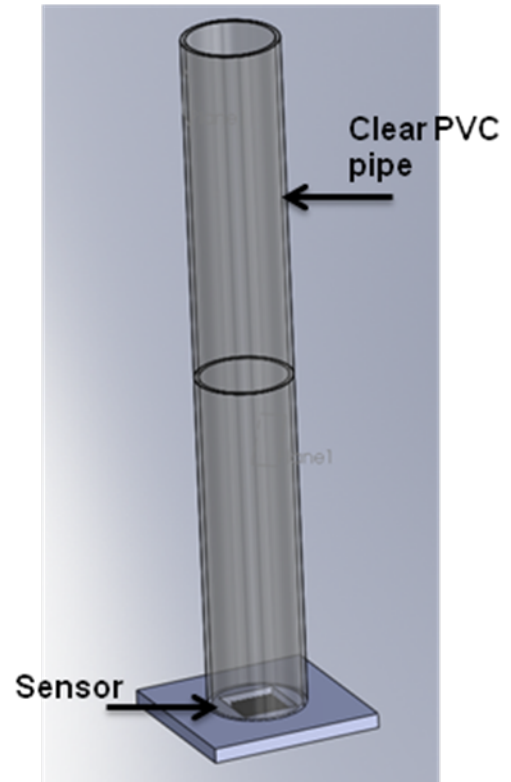
accordingly. Therefore the testing device can be reduced from a height of 1.37 meters to 30.5 cm when the lab staff is only investigating pressures within that range. To form the water column, tubes will be connected by clear pipe fittings. Lab staff will use a tape measure to quantify the height of the water. Having marks on the tubing would add complications adjusting the tubes when fit together.

Near the base of the bottom tube, a rubber stopper will be installed into the wall of the plastic tubing. A section of polyurethane tubing will run through this plug and into a drainage container. When the sensor is being tested, this drainage tube will be clamped closed, which prevents water from exiting the column. When the user wishes to drain the column after testing is completed, the clamp is removed and water can exit the column.

Figure 5: Plastic Pipe water column: The sensor will sit at the bottom of the column while tests are being performed. By using multiple sections of tubing, the user can adjust the height from 0.305 m to 1.37 m depending on the desired pressure.

This design also can accommodate vacuum conditions. Once the column is empty, it can be capped at the top. The drainage tube is then connected to a vacuum trap which forms a vacuum inside the sealed column.

Design 2: Graduated Cylinder

The graduated cylinder (Figure 6) acts similar to the first design alternative, as it uses varying water pressure. Instead of plastic, the column is made of glass and resembles a graduated cylinder. In order to meet our positive pressure range requirement, the column would

have a height of at least 1.37 meters. The same inner and outer diameters of the first design will be used for this device.

The sensor would rest at the base of the column while a test was performed. Water would enter and exit through the top of the cylinder. Heights would be permanently located on the side of the column, providing precise consistent measurements for every single test. This design could be set up for vacuum conditions, by capping the top and having running a tube from the inside to a vacuum trap.

There are user compatibility issues with this design. First, the column must remain at a constant height of 1.37 meters, which can be awkward to use in a typical lab setting. Placing and removing the sensor from the base of the column would also be challenging. The weight of the glass and water inside the column would make maneuverability difficult. These ergonomic dilemmas make this device seem irrelevant in terms of the design specifications.
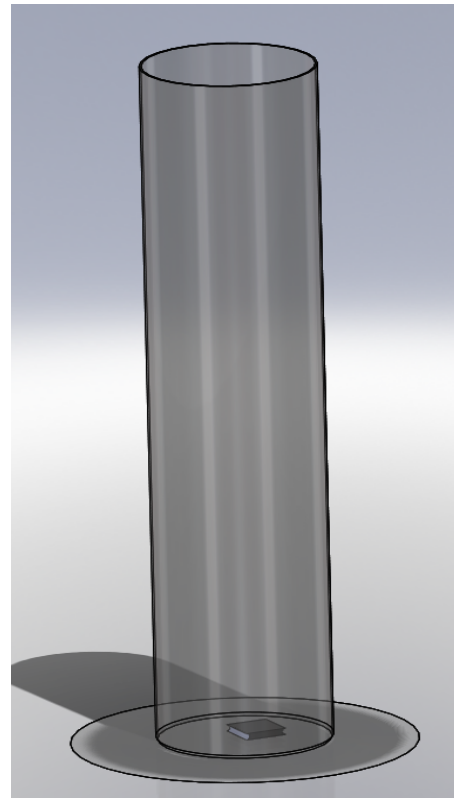
**Figure 6: Graduated Cylinder:** The sensor will sit at the bottom of the column while tests are being performed. The height of this design will be 1.37 m, with an inner diameter of .1537 m.

Design 3: Baseball Helmet

The helmet design for the phantom tester utilizes a baseball helmet, balloon, plastic sheet and a CO2 tank (Figure 4). The flaps baseball helmet will be removed to create a uniform

smooth circumference at the bottom. This will then sit flush with the plastic sheet in which a balloon will be pumped up by a CO2 tank. As the balloon is being pumped up, it will create pressure on the inside of the helmet. The capacitor will be placed inside the helmet through a hole pre-drilled through the top.
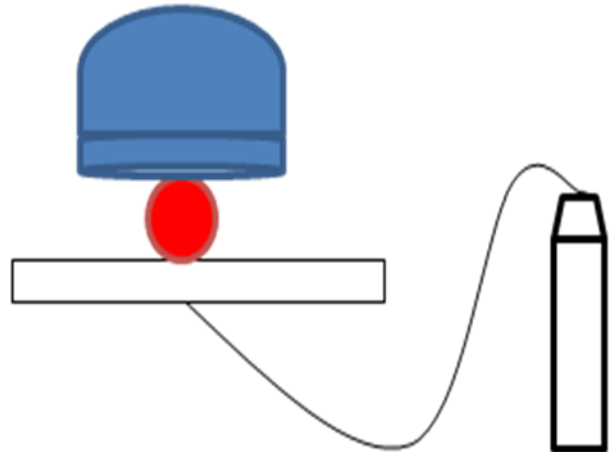
Figure 7: Baseball Helmet Design: is a replica of the helmet design for the phantom tester for the intracranial pressure sensor. The capacitor will sit inside the helmet (blue figure) and the balloon (red circle) fills up.

In order to measure the accuracy of the frequency the capacitor produces, one of two options could work. One would be to mathematically measure the pressure inside the helmet by determining the psi inside the balloon, then finding where the pressure is being distributed and finally converting that into fluid pressure. The second option would be to place a pressure transducer within the helmet with the capacitor and determine if they are giving off the same reading. The capacitor should be giving off the same frequency as the commercialized pressure sensor if it is accurate.

This design is a good anatomical representation of the skull and sensor interaction. However, this tester uses air pressure instead of liquid pressure, which makes it physiologically misrepresented. It would be difficult to test drift stability with this device, as the elasticity in balloons is compensated over a period of time. Testing for vacuum conditions would not be possible.

Design Matrix

In order to determine our final design as a group, a design matrix (Table 1) was made. A list of what makes a good design with a list of components of that design. According to the design criteria a weight was assigned to each design component. Each component was weighted accordingly, with the highest value being the most important in our final design.

Component	Weight	Plastic Pipes	Graduated Cylinder	Baseball Helmet
Accuracy	40	38	38	25
Ease of Use	25	24	15	18
Simplicity	20	10	10	5
Model of Existing System	15	18	18	14
Total	100	90	83	62

Table 1: Design Matrix: This is our design matrix, it aided in deciding on which design is to be pursued. The plastic pipes design ended up with the highest total, the graduated cylinder came in second, and the baseball helmet coming in third. Therefore the plastic pipes design will be pursued.

After these calculations, the plastic pipes design ended up with the highest total out of a hundred. The deciding factor between the plastic pipes design and graduated cylinder design was the user feasibility or ergonomics. The plastic pipes design allows the user to have easy access to the sensor at all times. The user can also change the height of tester in order to tailor the size to their specific need. Feasibility issues arise in the graduated cylinder model, because it would be incredibly cumbersome and heavy to use. The sensor would also be difficult to manipulate in that design. Therefore the plastic pipes design will be pursued as our final design.

Future Work

The next step in the design process is to completely define each detail of the final design. A preliminary testing protocol will also be established. Materials can then be ordered and fabrication. Fabrication of the design will include: making the base, connecting the plastic pipes with PVC connectors, and building the stopper/rubber tube component. Following the fabrication we will test the device for leakage, if any exists appropriate adjustments will be made. Once the sensor is completed, a conversion rate between pressure and resonance frequency will be developed through testing. Preliminary testing (drift, accuracy, and range) of the sensor can then occur.

References

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2. ¨Ghajar, J. (1995). Intracranial Pressure Monitoring Techniques. *New Horiz*, 3(3),395-399

3. ¨Kroin, J et al. (200) Long-term testing of an intracranial pressure monitoring device. *J. Neurosurg. Volume 93*

4. ¨Collins, C. (1967) Miniature Passive Pressure Transensor for Implanting in the Eye. IEEE Transactions Bio-Medical Engineering BME-14, NO. 2

5. Medtonic. (2006) Radio Frequency Considerations for the Use of Wireless Telemetry. Pamphlet.

Appendix:

Product Design Specifications:
Intracranial Pressure Sensor

Client:
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Professor John Webster
Elena Bezrukova

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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 tester and protocol for testing the device. Our secondary goal will be to develop a biologically friendly casing that incorporates all of the design requirements.

Client Requirements:

- Must not interfere with current imaging analysis
- No internal battery source
- Must maintain accuracy over a long period of time
- Data must be recorded via wireless transmission
- Case material must be durable and bio-friendly
- Testing protocol must be standardized and accurate

Design Requirements:

1. **Physical and Operational Characteristics**
   a. **Performance Requirements:** The intracranial pressure sensor must be powered by an inductive power source. Pressure data, change in capacitance, must be transmitted wirelessly and received as a wave signal. The resonance frequency must translate into a change in pressure. The outer casing must be made of bio-friendly material and prevent all leakage into the electrical components. The phantom testing system must accurately test the pressure sensing of the device.

b. Safety: All components should be water proof or able to interact with water. For future stages of this project, the outside must be made of bio-friendly materials.

c. Accuracy and Reliability: The device must be able to determine the pressure or an outside source within 0.1% of the actual value. It must be able to detect a range of 30mmHg to 100mmHg. The drift stability must be within 2mmHg to 3mmHg over 20 years.

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: The product should have the possibility to have "home-owned" data detection device. 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 base of the phantom tester will be (30.5 cm x 30.5 cm x 2.5 cm). The plastic cylinders placed onto of the base will each be 30.5 meters tall.

i. Weight: The sensing device should weigh less than 4 pounds. 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 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 $300.

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 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.