ICP Monitor

BME 301
3/12/08
Midsemester Report
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Abstract

Hydrocephalus is a condition characterized by increased intracranial pressure due to an abnormal accumulation of cerebrospinal fluid in the brain. The most common cure for hydrocephalus is a cerebral shunt that drains excess fluid from the brain. The two existing devices for monitoring shunt failure involve either an implantable battery or an electrical connection exposed through the skin. The proposed project involves an entirely internal pressure sensor to be inductively powered by an external power source, and that will transmit the average pressure and waveform to a receiver. This semester focuses on the housing for the internal pressure sensor, which will incorporate a capacitor-based MEMS circuit. Due to the sensitivity of a MEMS device, the housing will incorporate a sterile fluid-filled chamber to transfer any pressure changes to the lower capacitor plate of the device without risking damage to the circuit components. Two designs were considered for the housing configuration. Future testing is needed to determine an ideal method for adhering a polymer-based membrane over holes cut into the side of the housing. These membranes will transfer pressure from the intracranial fluid to the interior of the casing.

Background

About 1% of all people are born with hydrocephalus, a birth defect in which they have an abnormal accumulation of cerebrospinal fluid on the brain. Excess cerebrospinal fluid causes increased intracranial pressure inside the skull, which can lead to progressive enlargement of the head, convulsion, and mental disability. Hydrocephalus is commonly caused by cerebrospinal fluid blockage in the ventricles, an overproduction of cerebrospinal fluid, or head injuries. In a healthy person, cerebrospinal fluid circulates through the ventricles and spinal cord until it is eventually drained away from the brain and into the circulatory system. People born with hydrocephalus have the inability to release cerebrospinal fluid into the circulatory system and as a result, it accumulates in the ventricles of the brain and causes increased intracranial pressure against the skull and

brain. If untreated, this pressure continues to grow until it eventually causes serious damage to the brain. However, hydrocephalus can usually be treated if diagnosed early.

The most common cure for hydrocephalus is a cerebral shunt that is installed in the head to drain excess cerebrospinal fluid from the brain and carry it to other parts of the body. The shunt starts with a proximal catheter located inside the brain that takes the excess cerebrospinal fluid and empties it into a one-way valve located outside the skull but underneath the skin. The valve is one-way in order to prevent excess fluid from re-entering the brain. Lastly, a tube that connects to the valve carries the cerebrospinal fluid from the head and down into the abdominal cavity or atrium of the heart. The entire shunt is positioned underneath the skin with no external exposure. The shunt normally works very well to prevent intracranial pressure build-up. However, it is prone to failure due to blockage or the shunt simply being outgrown.

Shunt Failure

Shunt failure is fairly common in young people with shunts, 50% fail within the first two years due to it being outgrown or blocked. When there is suspicion that a shunt fails, doctors can choose either a non-invasive or invasive method to check the shunt. The non-invasive methods consist of checking the shunt by doing an MRI or CT scan which both render images of the inside of the brain without surgery. Although the non-invasive method would clearly be the more desired choice, both methods are very subjective and thus, prone to error. The only sure way for doctors to check for shunt failure is by doing brain surgery or a shunt tap, in which a gauged needle is inserted

through the skull and into the cerebrospinal fluid to produce a direct output of the intracranial pressure. Both methods are very invasive and involve risk during surgery.

Existing Designs

The two main designs for monitoring shunt failure that exist on the market today are a battery powered design and a direct electrical connection design. The battery powered design uses a permanently implanted ICP monitor connected to a large battery in the chest of the patient. This method has decent accuracy but in smaller patients the battery is very large. In addition, this method is very expensive, and the battery has a finite life. As a result, the mechanism needs to be replaced regularly through surgery. The direct electrical connection design also uses a permanently implanted ICP monitor but has an electrical contact exposure through the skin that is temporarily powered with an external power supply. The major drawback of this device is that it is very prone to infection due to the exposure through the skin and cannot monitor ICP on an ongoing basis.

Design Requirements

There are three major aspects to the intracranial pressure monitor of this project. The power supply for the device must be external. This will be accomplished via an iron core solenoid that will inductively power the internal circuit components by inducing a magnetic field. The internal circuit will encompass a MEMS capacitor-based sensor and two coupled inductors. Finally, the implanted circuit must transmit both a pressure waveform and average intracranial pressure reading to a receiver that will be able to

display this data. It is preferable to incorporate the receiver into the same housing as the power supply so there is only one external device for operators to handle.

The original design for the internal circuit involved strain gauges arranged in a Wheatstone bridge configuration. This setup was susceptible to both temperature changes and electronic drift. Because these devices will be inaccessible for recalibration after implantation, the electronic drift of the circuit was a significant flaw. More recently, an LC circuit was considered due to inductors and capacitors being minimally sensitive to electronic drift and temperature effects.

The biocompatibility of the internal components of this device is essential. Due to the location of the implant within the skull, no ferrous materials may be used. This is because they would prevent the patient from having a possibly necessary MRI scan.

Although the average pressure values measured will range from 10-15 mmHg, the pressure range of the gauge must span from -30 to 100 mmHg. This is to allow for the reading of extreme pressure changes due to shunt malfunction.

Specifications

This semester the project is focused on the internal portion of the device, more specifically the casing that will enclose the pressure sensor (**Figure 1**). The upper portion that will rest on top of the skull just below the skin will be approximately 2.5 cm in diameter and no more then 5 mm thick, allowing it to remain discrete. The long cylindrical portion will penetrate through the skull and into the intracranial fluid. This will need to be 3 cm long in order to reach the correct portion of the brain to measure

pressure accurately. The diameter of this portion will be 2 mm to allow it to fit through a hole drilled by a typical neurosurgical drill.

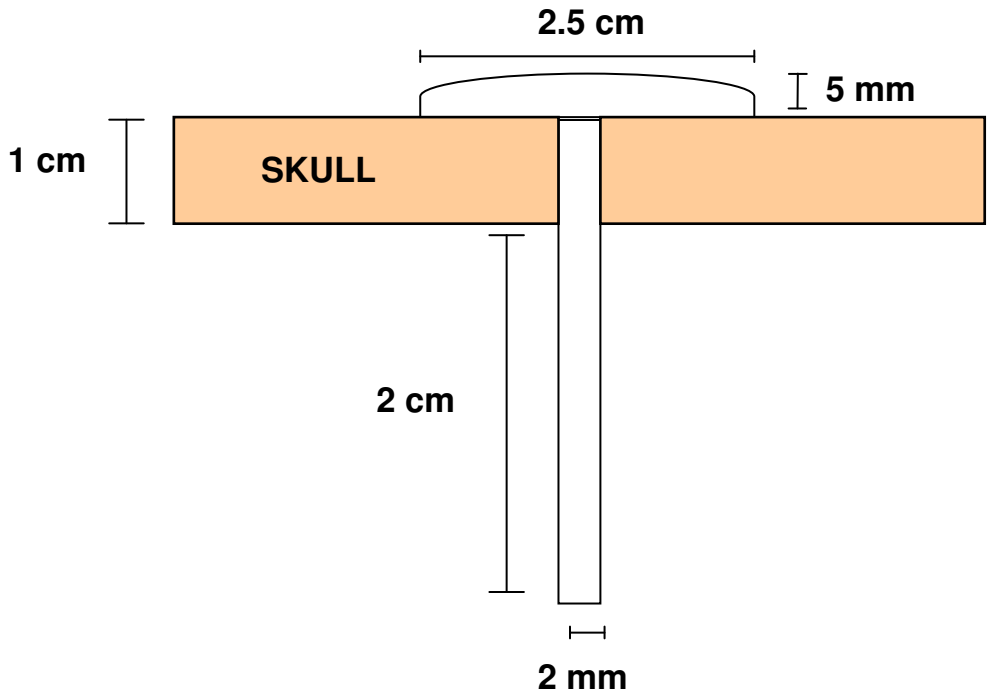

Figure 1. Internal Casing Specifications

More specifically the upper portion of the device will house the circuitry that will consist of two inductors coupled together and a MEMS chip (**Figure 2**). MEMS stands for microelectromechanical systems, which are extremely small circuits that are made on silicon wafers. Our MEMS device will consist of a variable capacitor that is able to achieve different values of capacitance by changing the distance between its plates. This is true because capacitance is inversely proportional to the distance between the plates through the formula $C = (E_oA)/d$. Because the MEMS device is extremely fragile and can be easily damage when touched, it cannot be in direct contact with the intracranial fluid. Therefore, the long cylindrical tube will be filled with sterile water, and a

membrane will be placed on the lower portion that will flex with changes in the intracranial pressure. This will cause the pressure inside the tube and on the MEMS plate at the top of the fluid column to change as well.

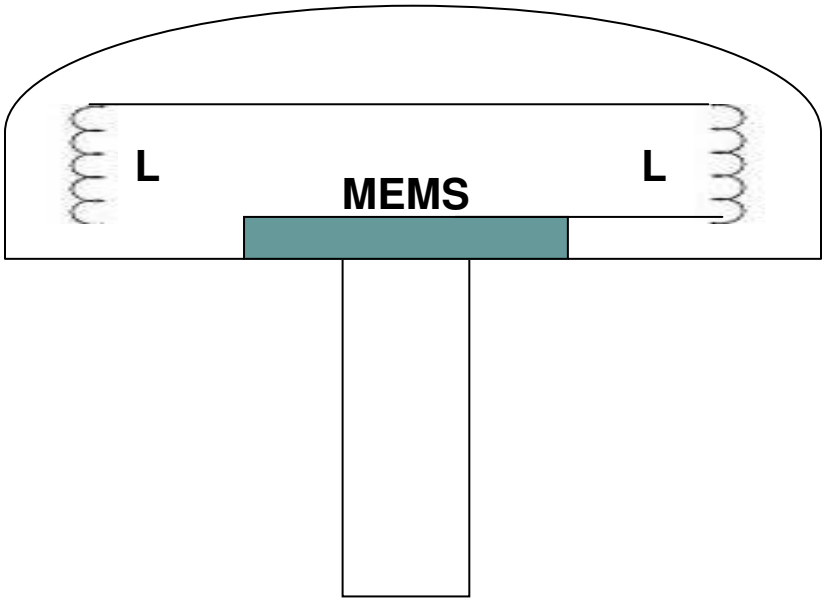

Figure 2. Circuitry in upper portion of internal casing.

A change in capacitance will allow the measurement of a change in pressure by detecting the changes in the resonance frequency of the circuit. The resonance frequency of the circuit is given by the equation $\omega = 1/\sqrt{(LC)}$ where L is the inductance and C is the capacitance. Based on the sampling rate that is used with frequency sweeps we will be able to obtain a pressure waveform as well as an average pressure reading.

Membrane Designs

In order to transfer pressure from the intracranial fluid to the interior of the casing, a flexible membrane, placed over a hole in the casing, will be used. The membrane will either be placed on the bottom or the side of the casing (**Figure 3**). A

bottom membrane design would be easier to construct (no hole drilling required) and would also be more sensitive to pressure changes. A larger bottom membrane would be more flexible than a smaller side membrane, which would allow a more effective transfer of pressure, but it would also result in a greater risk of hysteresis. A bottom membrane would also be much more susceptible to damage during insertion of the casing into the skull.

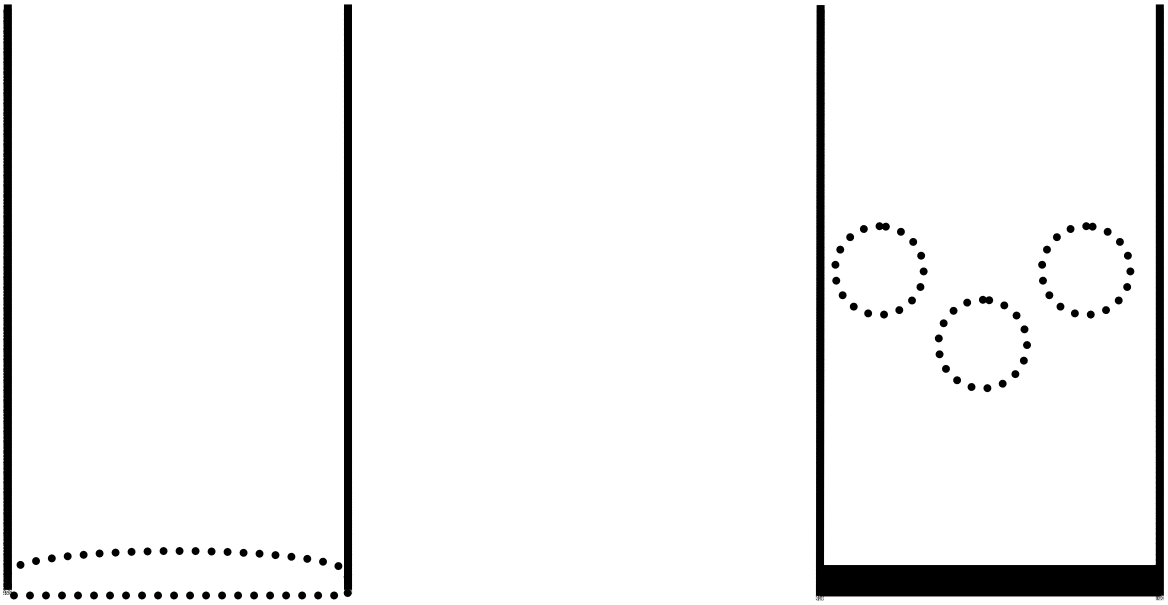

Figure 3. Bottom and side membrane configurations.

Both the bottom and side membrane designs would use the same materials. The casing will likely be made of a type of polyimide due to its excellent strength, biocompatibility, and chemical resistivity (Polyimide – Small Parts Inc.). We will use polyimide tubing from Small Parts Inc., with an inner diameter of 0.0720" and an outer diameter of 0.07345" (1.89 mm). The membrane will be made out of either silicone or Teflon due to their flexibility (when thin), biocompatibility, and chemical resistivity.

A design matrix is shown to compare the two designs (**Figure 4**). We assessed our designs on a 10 point scale with 10 being the highest and 1 beings the lowest and weighted each assessment category according to there importance in the final design. Although the bottom membrane design would be easier to build and would be more sensitive, the side membrane design was chosen for construction due to its low susceptibility to damage, which is critical considering the high cost of the device. It is also difficult to quantify the relative sensitivities of the two designs without direct testing. Future research or testing may reveal no significant difference.

	Biocompatibility (0.2)	Feasibility (0.3)	Damage Susceptibility (0.3)	Sensitivity (0.2)	Total (1.0)
Side Membrane	**10 (2.0)**	**5 (1.5)**	**8 (2.4)**	**6 (1.2)**	**7.1**
Bottom Membrane	10 (2.0)	7 (2.1)	4 (1.2)	8 (1.6)	6.9

Figure 4. Design matrix.

Attaching the membrane across the holes of the casing can be done in two separate ways. The casing could be dipped in a liquid polymer of either Teflon or silicone or a solid polymer form could be wrapped around the casing. Gluing the membrane to the casing may be difficult, as both silicone and Teflon are extremely slippery and do not adhere well to very many materials. Future testing in the lab is needed to determine the best adhesion method for the polymer membrane.

The Product Design Specifications (3/10/08)

ICP Monitor

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Function:

The overall function of the intracranial pressure monitor is to accurately measure the pressure in the skull and translate this measurement to a voltage or current reading that can be easily and accurately read. The two main components are the power supply and the transducer itself. The power supply is located outside the skull, not attached to the head and must be able to induce a current in the circuit attached to the skull. In order to do so, the power supply will be created using an alternating current in conjunction with a solenoid containing a ferromagnetic core. In doing so, the power supply will create a changing magnetic field that according to the principles of coupled inductors and Faraday's Law, will induce a current in the circuit located on the patients skull. The other primary component, the transducer, will have to have the ability to measure pressure via voltage or current measurements. The primary idea is to use a capacitor; the capacitance will change as the pressure varies the distance between the two plates.

Client Requirements:

- No ferromagnetic materials can be used in the circuit located on the skull (must be MRI compatible).
- The component located on the skull must be covered in biocompatible materials.
- Nothing located on the skull can be protruding from the skin (so as to eliminate the possibility of infections)
- Device on skull must have a constant current/voltage so as to achieve accurate results.
- The upper portion that will rest on top of the skull just below the skin will be approximately 2.5 cm in diameter and no more then 5 mm thick, allowing it to remain discrete.
- The long cylindrical portion will need to be 3 cm long in order to reach the correct portion of the brain to measure pressure accurately.
- The diameter of this portion will be 2 mm to allow it to fit through a hole drilled by a typical neurosurgical drill.

Design Requirements:

1. **Physical and Operational Characteristics**

a. *Performance requirements:*

The internal component of the ICP monitor will have a portion that rests on top of the skull underneath the skin and a portion that penetrates through the skull and into the intracranial fluid. The device used to power the ICP monitor will be a hand-held device that when held up to the head with inductively power the internal component. The device will be used only when there is suspicion that the patient's shunt has failed.

b. *Safety:*

The portion of the device implanted inside the head will need to be completely biocompatible and cannot contain any ferrous materials that would disrupt MRI scans.

c. Accuracy and Reliability:

The internal pressure gauge will need to measure a pressure range of -30 mmHg to 100 mmHg. The accuracy of the pressure measurement needs to be within ± 1 mmHg. Drift in the pressure measurement should not exceed 1 mm Hg per 5 year period.

d. *Life in Service:*

Given that the device will be implanted inside of the body, it should work as long as the patient is alive with altering requirements at a maximum of once every 20 years.

e. Shelf Life:

Storage of the device will occur at approximately room temperature. The internal component should be able to last up to 20 years. The external portion should be rechargeable or replaceable.

f. *Operating Environment:*

The external component of this device should be able to be placed against an individual's skull as well as be stored at room temperature around the home and in hospitals. Part of the internal portion of the device will be located outside the skull and underneath the skin, while the other portion will have to penetrate through the skull and into the brain. Biocompatibility is therefore an important factor for the internal component and it will need to withstand average human body temperatures of approximately 98 °F. We will need to ensure that the device does not corrode or suffer from considerable drift when exposed to the body fluids. The device will also need to withstand a regular pressure change due to the heart rate of approximately 5 mmHg in both directions.

g. Ergonomics:

The external portion of the device should not exert an electric field that would cause any adverse effects on any other portion of the individuals head. The internal portion should be able to fit underneath the skin and outside of the skull. The portion that is inserted in the skull should be able to reach a depth within the brain to measure pressure accurately. The upper portion that will rest on top of the skull just below the skin will be approximately 2.5 cm in diameter and no more then 5 mm thick, allowing it to remain discrete. The long cylindrical portion will need to be 3 cm long in order to reach the correct portion of the brain to measure pressure accurately. The diameter of this portion will be 2 mm to allow it to fit through a hole drilled by a typical neurosurgical drill.

h. *Size:*

The size of the external portion of the device should be able to be held in an individual's hand. It should be less then 2.5 cm in diameter and no more than 3.5 cm in height. The internal portion that is placed on the exterior of the skull should be no more than 5 mm thick and no more than 2.5 cm in diameter. The cylindrical portion that penetrates through the skull and into the intracranial fluid should be 2 mm in diameter and 3 cm in length.

i. *Weight*:

The weight of the internal portion should be less than 0.25 lbs. The external portion should not weigh more than 5 lbs.

j. *Materials*:

Material restrictions: Any ferrous material, or metallic material. Patients need to be free of these materials for MRI scans. Since this is a permanent implant, we must make certain the product is composed of non-ferrous material, removing the implant for an MRI scan it not an option. The product should be enclosed in a biocompatible material, such that the body does not reject the implant. The external portion should be enclosed to cover all circuitry.

k. *Aesthetics*, *Appearance, and Finish*:

The internal transmitter of the device currently has no preferences of appearance of color. The external receiving device should be covered to enclose circuitry.

2. Production Characteristics

a. *Quantity*

One prototype. Hydrocephalus prevalence- 1-1.5% of population (6.46 per 10,000 births, approx 1 in 105,263 or 0.00% or 2,584 people in USA)

b. *Target Product Cost:*

The product should be under $3,000.00 market value and have a production cost of less then $1,000.00.

3. Miscellaneous

a. *Standards and Specifications:*
FDA approval is needed before the device can be used on patients.

b. *Customer*:
Used in conjunction with patients who have shunts.

c. Patient –related concerns:
The device needs to be sterile and completely inside the head so there is no risk for infection. The power supply must be stored in a safe place, most likely at home. The internal portion should be able to withstand forces that are applied to the head. The lifespan should be greater than 20 year in order to prevent additional surgeries.

d. Competition:
Radionics makes a device that has a solenoid that moves with pressure changes. Medtronic also makes an Insite Monitor that is more accurate and capable of recording trends but was very expensive. It also requires a large battery that has to be implanted to chest and has finite power supply