Intracranial Pressure Monitor

Department of Biomedical Engineering
University of Wisconsin-Madison
BME 301

Final Report

Erin Main: Communicator
Jess Hause: Team Leader
Peter Strohm: BWIG
Lacey Halfen: BSAC

Client: Dr. Josh Medow
Advisor: Willis Tompkins

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Abstract

Hydrocephalus is a condition characterized by increased intracranial pressure (ICP) due to an abnormal accumulation of cerebrospinal fluid (CSF) in the brain. The most common cure for hydrocephalus is a cerebral shunt that drains excess fluid away from the brain. An ICP monitor is used to detect changes in CSF pressure caused by shunt malfunction. To address the concern of a finite lifespan, an ICP monitor that is inductively powered through the use of an external power supply was designed. An LC circuit with a MEMS variable capacitor detects changes in pressure and transmits the pressure reading externally through changes in resonance frequency. Due to the sensitivity of the MEMS device a biocompatible casing for the internal component was created using silicone (PDMS) and polyimide tubing. The casing involves housing for the MEMS and inductor coils, as well as a long fluid-filled cylindrical tube with end membrane for pressure transmission to MEMS device. Membrane in tubing demonstrated the ability to transmit pressure changes to the internal fluid filled chamber, and resistance to leaks and pressure force. Future work will involve the development of a relationship between pressure transmission to fluid filled chamber, MEMS capacitor plate distance and changes in resonance frequency to be interpreted as pressure changes externally.

Background

About 1% of all people are born with hydrocephalus, a birth defect in which they have an abnormal accumulation of CSF on the brain. Excess CSF causes increased ICP inside the skull, which can lead to progressive enlargement of the head, convulsion, and mental disability [4]. Hydrocephalus is commonly caused by CSF blockage in the ventricles, an overproduction of CSF, or head injuries. With healthy individuals, CSF 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 CSF into the circulatory system and as a result, it accumulates in the ventricles of the brain and causes increased ICP. If untreated, this pressure continues to grow until it eventually causes serious damage to the brain. However, a variety of treatments are available for those suffering from hydrocephalus if diagnosed early [12].

The most common cure for hydrocephalus is a cerebral shunt that is installed in the skull to drain excess CSF from the brain and carry it to other parts of the body. The shunt starts with a proximal catheter located inside the brain that drains the excess CSF 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 CSF 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 ICP build-up. However, it is prone to failure due to blockage or the shunt simply being outgrown [5].

Shunt Failure

Shunt failure is fairly common in young individuals, as 50% fail within the first two years [9]. When individuals present symptoms of shunt failure, doctors can choose either a non-invasive or invasive method to check the shunt and ICP. The non-invasive methods for checking the shunt include an MRI or CT scan, which both render images of the inside of the brain without surgery. Although the non-invasive method would be the more desired choice, both imaging methods are subjective and thus, prone to error. Surgery can give a more definitive answer regarding shunt failure by using a shunt tap. A gauged needle is inserted through the skull and into the CSF to produce a direct output of the ICP. However, this method is invasive and risky [10].

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 placed in the chest of the patient. This method has decent accuracy, but with smaller patients the battery is relatively large. In addition, this method is expensive and the battery has a finite life span resulting in the need for it to be replaced regularly through surgery [5]. 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. With the skin exposure this device is prone to infection and cannot monitor ICP on an ongoing basis [9].

Design Requirements

There are three major aspects to the ICP monitor; the external power supply, internal circuit and display. 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 a pressure waveform to a receiver for display. 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. Ferrous materials are prohibited, as they would prevent the patient from having an MRI scan. The biomaterials must maintain their durability and chemical stability over several years.

Although the average pressure values measured will range from 10-15 mmHg, the device must be able to detect pressures in the range of -30 - 100 mmHg. This range will encompass pressure values common with shunt malfunction. A pressure waveform must also be generated along with a numerical reading for the average pressure.

Previous Work

The final circuit design created last semester consisted of an inductor and capacitor connected in parallel, or an LC circuit (**Figure 1**) powered by a

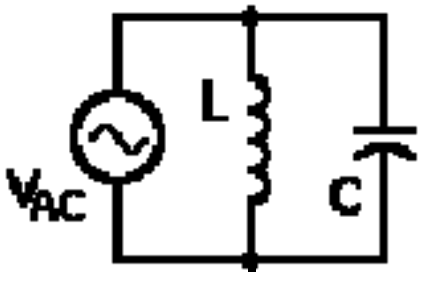

Figure 1. LC circuit configuration in parallel

variable AC source. For testing, a 238 mH inductor was placed in parallel with a variable 21 pF capacitor (**Figure 2**) to examine whether a change in capacitance could be associated with a change in resonance frequency.

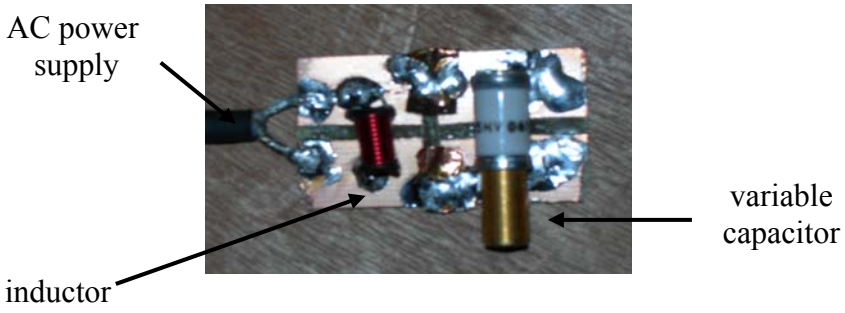

Figure 2. Variable capacitor and inductor used for testing.

Due to the relationship between capacitance and the distance between the capacitor plates,

$$C = \frac{\varepsilon_0 A}{d}$$

where C is the capacitance, A is the area of the plates and d is the distance between the plates, capacitance is inversely proportional to the distance between the plates. This varying value of capacitance, as well as the constant value of inductance, was used to calculate the equivalent impedance (ratio of voltage to current) of the circuit using the following equation

$$Z = \frac{1}{j\,\omega\,C - \frac{j}{\omega\,L}}$$

where Z is the equivalent impedance of the circuit, ω is the angular frequency, C is capacitance and L is inductance. Due to the fact that, at resonant frequency, the

denominator of the equivalent impedance equation is zero, we were able to calculate the angular frequency

$$\omega = \frac{1}{\sqrt{L\,C}}$$

of the circuit based on the inductance and capacitance values and, in turn, the resonant frequency of the circuit $2\,\pi\,f = \omega$ at any given capacitance.

We demonstrated that a change in capacitance resulted in a change in the resonant frequency of the circuit by attaching the capacitor circuit to an oscilloscope. The resonant frequency was indicated by a peak (due to division by zero in the equivalent impedance) in the graph with impedance on the y-axis and frequency on the x-axis. Upon changing

Figure 3. Resonant frequency peaks measured on oscilloscope.

the value of the capacitance, we observed the resonant frequency peak move along the x-axis indicating a direct relationship with capacitance (**Figure 3**). This resonant frequency can then be transmitted externally and interpreted as a change in intracranial pressure. This semester, the use of a MEMS device as our variable capacitor was proposed. MEMS stands for microelectromechanical systems, which are extremely small circuits that are made on silicon wafers. However, due to the sensitivity of a MEMS variable

capacitor, a specialized casing was designed to protect the MEMS device and allow it to indirectly measure intracranial pressure.

Specifications

The dimensions for the casing to enclose the MEMS device can be seen below (**Figure 4**). The upper portion that would rest on top of the skull just below the skin was designed to be approximately 2.5 cm in diameter and no more then 5 mm thick, allowing it to remain discrete. The long cylindrical portion would penetrate through the skull and into the intracranial fluid. This needed to be 3 cm long in order to reach the correct portion of the brain to measure pressure accurately. The diameter of this portion was 2 mm to allow it to fit through a hole drilled by a typical neurosurgical drill.

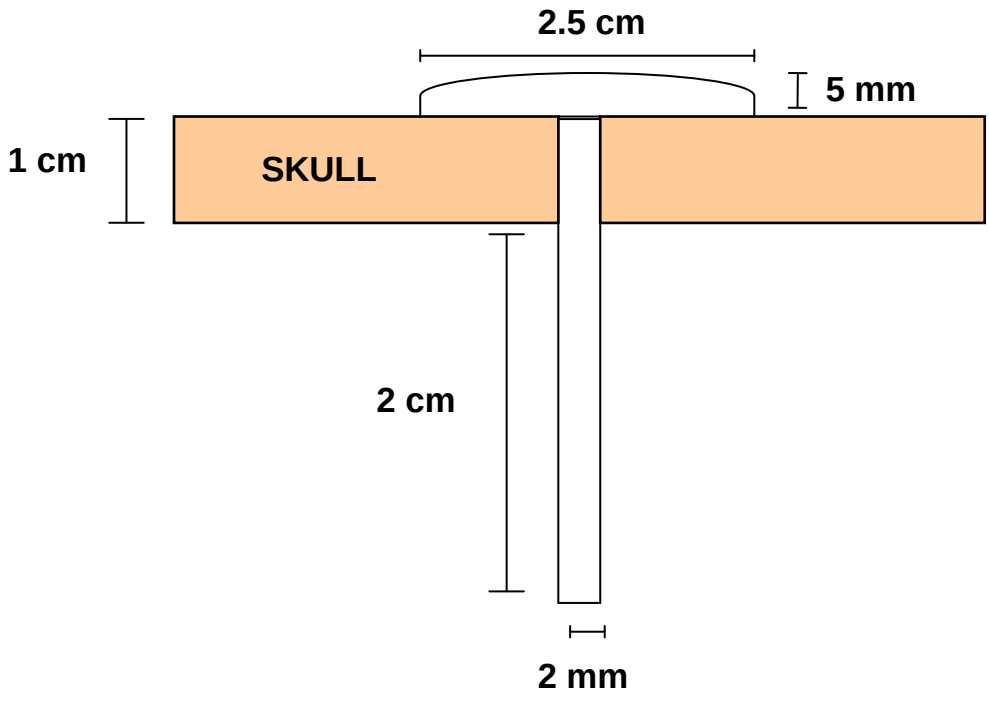

Figure 4. Internal Casing Specifications

The upper portion of the device was meant to house the circuitry that will consist of two inductors coupled together and a MEMS variable capacitor (**Figure 5**). Because the MEMS device is extremely fragile and can be easily damaged 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.

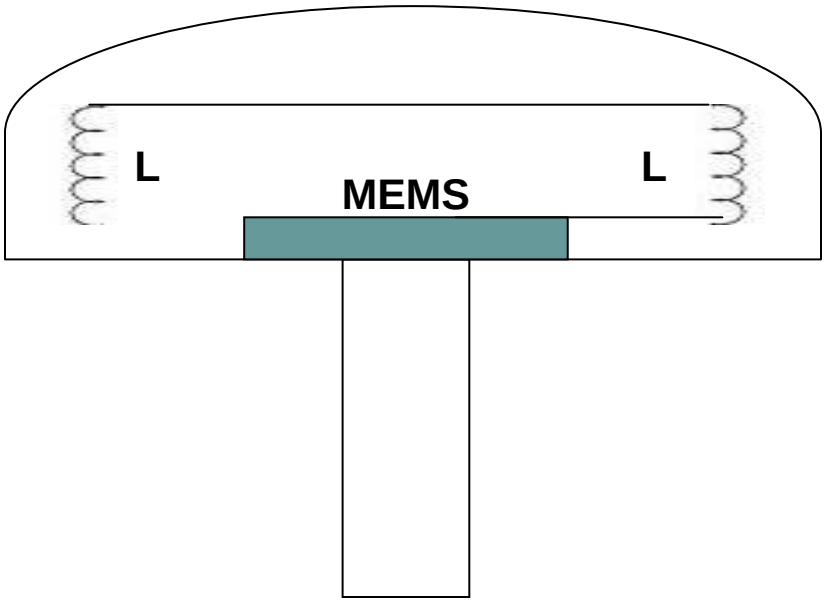

Figure 5. Circuitry in upper portion of internal casing.

A change in capacitance will allow the measurement of a change in pressure by detecting the changes in the resonance frequency of the circuit, as discussed in the previous work section. 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. Refer to **Appendix A** for complete product design specifications.

Preliminary 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, was designed. The membrane would either be placed on the bottom or the side of the casing (**Figure 6**). 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.

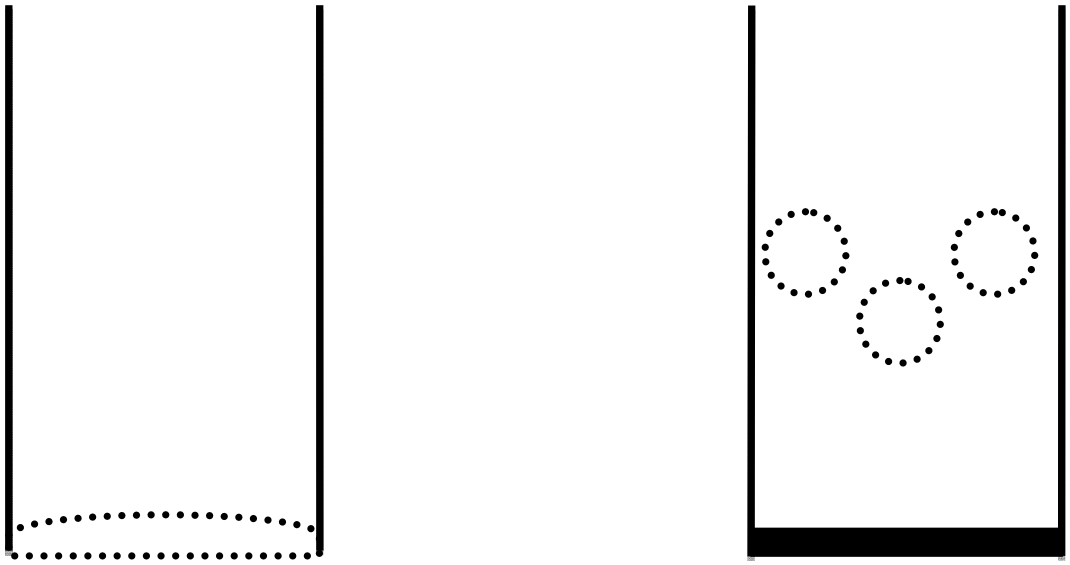

Figure 6. Bottom and side membrane configurations.

A design matrix is shown to compare the two designs (**Figure 7**). 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 their 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.

	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 7. Initial design matrix.

Upon ordering the materials and beginning work in the lab, the feasibility of each design possibility was reevaluated (**Figure 8**). With this reevaluation of the design matrix the final design pursued was the bottom membrane. To address any concerns about the damage susceptibility of the bottom membrane design, the strength of the membrane was tested after attachment to the tube.

	Biocompatibility (0.2)	Feasibility (0.3)	Damage Susceptibility (0.3)	Sensitivity (0.2)	Total (1.0)
Side Membrane	10 (2.0)	2 (0.6)	8 (2.4)	6 (1.2)	6.2
Bottom Membrane	**10 (2.0)**	**9 (2.7)**	**4 (1.2)**	**8 (1.6)**	**7.5**

Figure 8. Final design matrix.

Materials and Methods:

The final housing prototype was constructed from two separate materials. The design consisted of a silicone housing portion for the MEMS device, as well as a silicone membrane at the base of a connecting polyimide tube. The 1.87 mm diameter polyimide tube was ordered from Small Parts Inc. The silicone used was polydimethylsiloxane (PDMS), and was constructed in the lab by combining 10 parts silicone elastomer with 1 part silicone base curing agent. The gel product was then placed within a vacuum to remove air bubbles. Once the PDMS was fully prepared, it could be used to construct a membrane on the end of a section of polyimide tubing cut to approximately 2.5 cm. Using a SCS|G3-8 Spincoat: Specialty Coating System, a small portion of the prepared PDMS was spun into a thin, even layer. This was accomplished by placing a small drop in the center of a square transparency and spinning the PDMS at 800 RPM for 30 s. Once the gel was spun into a thin layer, several 2.5 cm pieces of polyimide tubing were placed vertically with one end flush against the PDMS. The sheet was then placed on a hot plate at 95 °C for 2-3 minutes. Once the PDMS had completely polymerized, it was removed from the hot plate, and the individual tubes were cut away from the larger mass of silicone. The result was a thin membrane fully attached to the end of the polyimide tube.

After the membrane was constructed, the MEMS housing construction began. The top portion of the device required the initial construction of a metal mold for the PDMS to form around. A metal cylindrical ring and a thin metal disk were used to create the housing in two separate pieces. The construction of the first half involved centering the disk inside of metal ring and atop the hot plate. The mold was then filled until the

disk was completely covered with the silicone gel. The polymer was kept inside the mold while heated at 95 °C for 5-10 minutes. Once fully polymerized, the product was removed and allowed to cool. The second half of the housing was then constructed using only the metal ring for the mold. A polyimide tube with a functional membrane was centered within the ring while the PDMS was poured inside. This allowed for the creation of a flat layer of PDMS with a polyimide tube centered within it. Once both sides had cooled after heating, they were exposed to oxygen radicals to bind them together. The use of the metal disk successfully created an internal pocket where the MEMS device will be housed in the future, with the top end of the polyimide tube exposed through the bottom of the silicone housing.

Final Design

Pictured below is the final casing design (**Figure 9**). As previously discussed in the materials and methods section the housing and membrane are made of silicone (PDMS) and the tubing is made of polyimide. The silicone is an extremely flexible and durable material. The polyimide tubing is a sturdy material allowing it to withstand any damage that could result during implantation. The tubing will also be filled with a sterile water between the membrane and the housing allowing for the transmission of pressure from the intracranial fluid to the MEMS variable capacitor.

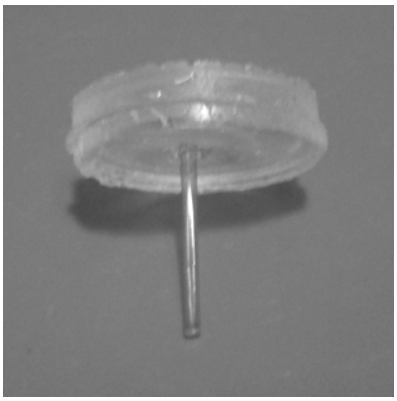

Figure 9. Final casing design.

Figure 10 gives the final dimension of the casing design. The housing has a final diameter of 2.86 cm and a height of 6.35 mm. The tubing is 2.22 cm in length and 1.87 mm in diameter.

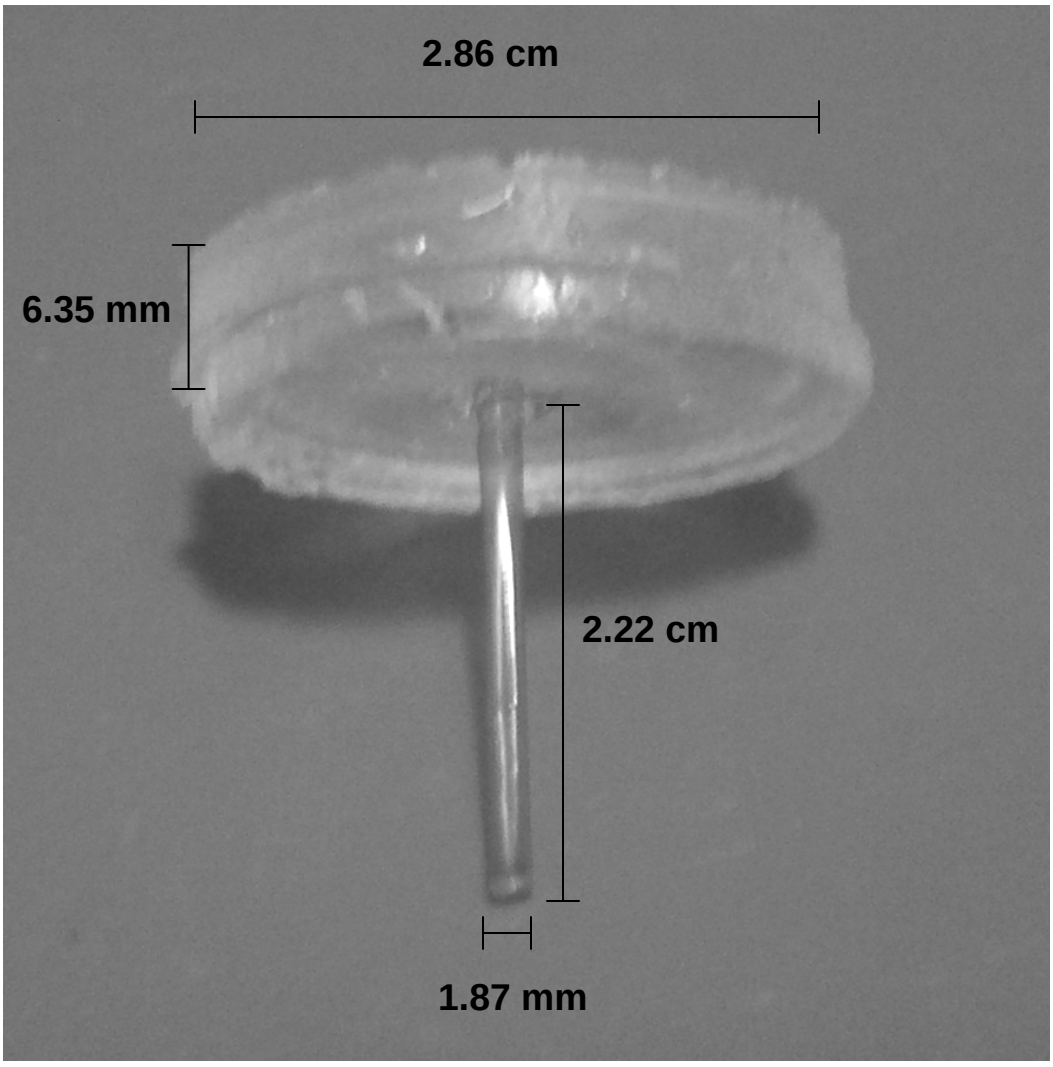

Figure 10. Final casing dimensions.

For the internal portion where the MEMS device and inductor coils will be located, the height is 2.4 mm and the diameter is 15.9 mm. This portion of the device can easily be visualized in the cross-section shown below (**Figure 11**).

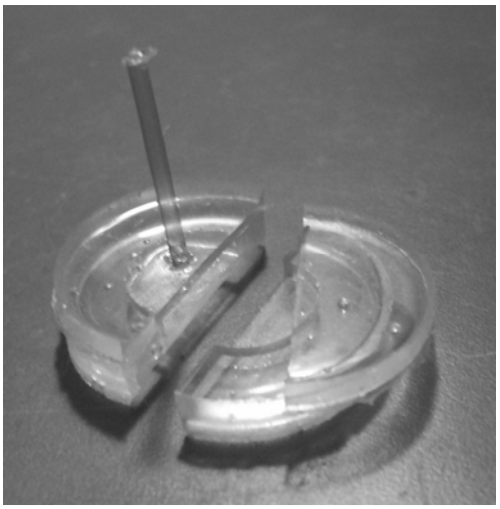

Figure 11. Cross-section of final casing design.

Testing

Once the membrane was constructed, testing was performed. The first test involved exposing the membrane to air pressure to ensure the stability and strength of the membrane. This test revealed that the membrane was securely positioned to the end of the tube and could sustain a great deal of pressure. After this exposure, a polyimide tube with a secure membrane was completely filled with dyed water. This test revealed no leaks in the membrane. The final test conducted involved exerting pressure against the external side of the membrane, and viewing the dyed water to make sure the membrane successfully transferred pressure differences to the internal fluid.

Membrane Bending

Beam bending analysis was used to model the deflection that would be observed on the silicone (PDMS) membrane with changes in intracranial pressure. Using a standard deflection diagram with a 2-D beam under a uniform pressure load and two supports on either side, a model for maximum deflection was determined (**Figure 12**).

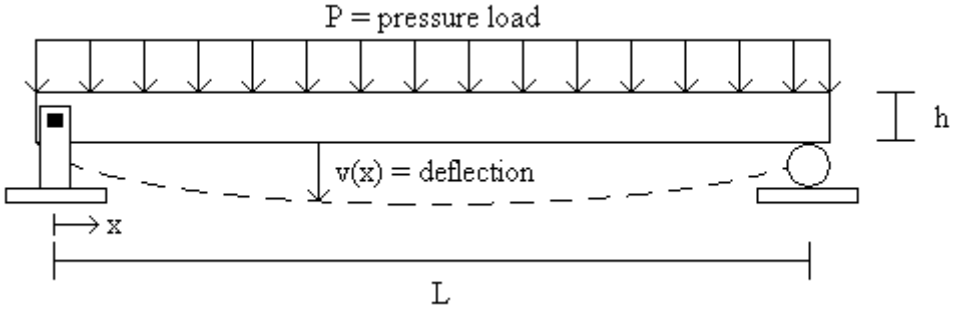

Figure 12. 2-D model of membrane bending. P is pressure load, h is membrane thickness, v(x) is vertical displacement from neutral axis, and L is membrane diameter.

The two supports are representative of the membrane attachments around the outside of the tube. This is merely a model of the maximum deflection that could be observed considering the beam is 2-D, while our design uses a 3-D circular surface. Maximum deflection, $v(x = L/2)$ was found to be approximately $(5/32) * (P/E) * (L^3/h^3)$. Thus the deflection of the membrane is very sensitive to changes in diameter (L) and thickness (h). If our final device was found to transfer pressure inadequately, we could simply increase membrane diameter or decrease membrane thickness to compensate. This is assuming a greater membrane deflection results in a more effective transfer of pressure.

Future Work

Although the membrane is capable of transmitting pressure from one side to the other, a quantitative relationship has not been determined. Further testing should include exposing one side of the membrane to various pressures (-15 to 100 mmHg) and measuring the pressure on the opposite side of the membrane. Ideally, the membrane would transmit pressure completely; a stiffer membrane would result in less pressure transmission. Also, linearity of pressure transmission must be considered over the entire pressure range. It may be the case that as pressure extremes are reached, the membrane stiffens and becomes unable to transmit further pressure. Because we are interested in generating a pressure waveform, the ability to transmit pressure quickly should also be considered. Slow pressure transmission times would essentially flatten the pressure signal.

The durability of the casing and membrane over an extended period of time should also be considered. Although both PDMS and polyimide are biocompatible, the membrane-casing attachment may weaken with exposure to CSF. Although the top of the casing will be counter sunk into the skull, the device may still be subject to shearing forces (e.g. from hair brushing, rubbing, hat wearing). Although the device was fairly durable as evidenced from preliminary tests, these forces may eventually weaken and damage the device. To assess durability, the device must be exposed to chronic physical and chemical stress.

Lastly, after incorporating the LC MEMS circuit into the casing, the relationship between changes in CSF pressure and resonant frequency must be examined. Assuming the capacitor plate distance is linearly related to pressure, it can be shown that pressure

can be expressed as $P = C_1 * f^2 + C_2$, where C_1, C_2 are constants and f is the resonant frequency. This is based on the fact that capacitance is inversely proportional to plate distance, and resonant frequency is inversely proportional to the square root of capacitance. This means that pressure is not linearly, but quadratically related to resonant frequency. Whether this relationship can be approximated as linear over the desired pressure range cannot be determined without knowing the capacitance value of the MEMS as well as how capacitor plate distance changes with pressure. However, estimating C = 1 pF and assuming an FM resonant frequency range, several frequency-pressure graphs can be generated (**Figure 13**). These graphs show that the frequency-pressure relationship can be approximately linearly or quadratically, depending on how the capacitor plate distance changes in response to pressure.

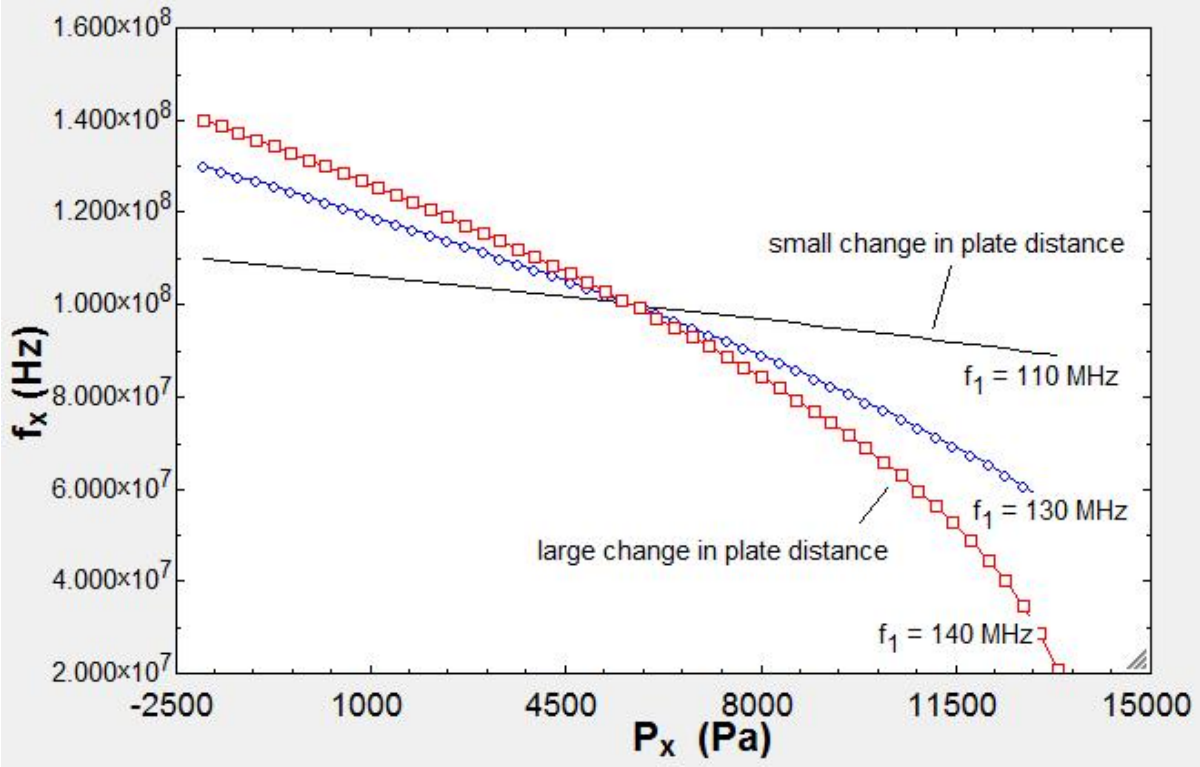

Figure 13. Resonant frequency (y-axis) vs. gage pressure (x-axis). f_1 is the resonant frequency value at the lower pressure value (-15 mmHg).

This information is helpful in approximating the relationship as linear equates to a simpler and less expensive device. Additionally, choosing a MEMS capacitor that changes plate distance little in response to pressure will yield a more linear relationship than one with large changes in plate distance. However, little distance change also means little frequency change; frequency change must be at high enough levels for detection.

Appendix A

The Product Design Specifications

Function:

The overall function of the intracranial pressure monitor is to accurately measure the pressure in the skull using an internal MEMS device and transmit it to an external power supply to be displayed as a pressure reading. This semester focused on designing a biocompatible casing for the internal portion of the intracranial pressure monitor. The casing would house the MEMS device and must incorporate a flexible membrane to transmit intracranial pressure changes to a fluid filled chamber which then alters the MEMS capacitor plate distance. Two inductor coils located on opposing sides of the MEMS circuit allow the device to be inductively powered, requiring no exposure through the skin.

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 6 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

Appendix B

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