Intracranial Pressure Monitor

Department of Biomedical Engineering
University of Wisconsin-Madison
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Final Report

Josh White: Co-Team Leader
Erin Main: Co-Team Leader
Jess Hause: BSAC
Kenny Roggow: BWIG
Adam Goon: Communications

Client: Dr. Josh Medow
Advisor: Wally Block

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Abstract

Shunt malfunction can cause the build up of cerebrospinal fluid in the brain. Diagnosis of shunt malfunctions can be very expensive and is not always conclusive. Current intracranial pressure (ICP) monitors have finite life spans, exposure of power supply through the skin, and suffer from large drift characteristics over time. To address the concerns of a finite power supply and exposure through the skin, an external power supply was designed that can inductively power the internal component without penetration through the skin. To improve drift characteristics a capacitance pressure gauge was designed in conjunction with an LC circuit that allows for the measurement of intracranial pressure through changes in resonance frequency. Testing using an LC circuit with a variable capacitor validated this design as a mechanism to measure pressure through resonant frequency changes. Future work will involve the integration of all components for the ICP monitor.

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 when prolonged leads to progressive enlargement of the head, convulsion, and mental disability. Hydrocephalus is commonly caused by cerebrospinal fluid blockage in the ventricles, from an overproduction of cerebrospinal fluid, or from 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

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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 caught in time and it is properly treated.

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 a very serious problem for people with hydrocephalus. On a personal level, this group chose this project because one of our group members worked as a personal care assistant for a young girl with hydrocephalus caused by cerebral palsy. She was 5 years old and had a shunt implanted when she was born and as a result, lived a very normal, happy life. However, at the beginning of the school year her shunt failed and due to the fact that shunt failure symptoms are similar to those of normal sickness,

specifically: headache, nausea and dizziness, her teachers didn't think anything of it until she lost consciousness. She underwent two emergency brain surgeries in order to have it fixed and had a small amount of damage to a portion of her brain.

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 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 invasive and run the risk of brain damage during surgery.

Intracranial pressure monitors currently on the market include a wide variety of devices powered by battery or an external power supply that needs to be connected directly to the internal device. The downside of a battery powered device is its limited life. The battery of intracranial pressure monitors currently on the market are commonly located just beneath the collar bone on a patient's chest. Although surgery to replace this battery would not involve brain surgery, regular surgeries of any kind to replace the battery of the device is cumbersome to patients and thus, a battery-powered device is a less favored option. In addition, those devices that involve an external power supply that needs to be connected directly to the internal device must have a part of the device exposed through the skin in order to accept power. This type of device is also frowned

upon due to the fact that any kind of skin exposure is prone to infection and complications for patients.

Current Designs

Currently, there are a few intracranial pressure monitors that are being used and that have been used in the past. These monitors include the Telesensor made by Radionics and the Insite monitor made by Medtronic. Both are fairly accurate but are still not accurate enough to read a wide enough range of intracranial pressure. The Telesensor (*Figure 1*) is a non-invasive telemetric monitor that is implanted "in-line" with the shunt to measure pressure (Lee, 2004). It can either be connected to the Radionics Teleshunt system or can be spliced into an existing shunt system (Lee, 2004).
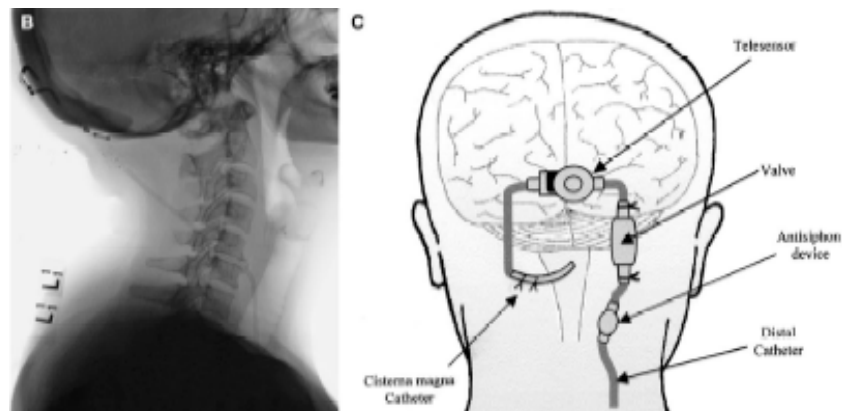

Figure 1. The Telesensor mounted in back of the head (Lee, 2004).

The Telesensor operates by radio frequency pressure balanced telemetry along with a moving solenoid. One of the biggest problems for these two monitors is their accuracy. The Telesensor can only indicate low versus high pressure, which means it cannot determine if an individual is building up pressure that could be dangerous until

the pressure is at a harmful level. The Insite monitor is more accurate and is capable of recording events and trends. However, the Insite monitor is much more expensive than the Telesensor and may not be affordable for many patients with hydrocephalus. The Insite monitor is powered by a large battery that is implanted in the chest. Since hydrocephalus and shunt implants usually take place in small children, it can often be very difficult to get this large battery in the child. Also, the strain gauge has to be tunneled to the skull making the surgery to implant the monitor even more difficult. Additionally, since the monitor is powered by a battery, there is a finite power supply. Therefore, the battery will have to be replaced at some point in time, which can become very expensive and difficult to undergo multiple surgeries for the patient.

A third monitor that is currently being used is the Camino 110-4B made by Integra. This monitor is a catheter that is designed for rapid placement with instantaneous monitoring (Camino, 2006). The monitor gives back an immediate ICP value or waveform. Camino is the most widely used ICP monitor in the world today. An ergonomic bolt is used for a rapid, simple placement so clinic inserting time can be decreased. The Camino (*Figure 2*) comes in a kit with a transducer-tipped catheter, the Camino bolt, and a 2.7 mm drill bit with safety stop (Camino, 2006). The major disadvantage of this device is that the bolt is put in the back of the head and protrudes from the skin. The bolt is then connected to the pressure monitor as seen in figure 2. Our design fixes this problem by having the transducer being completely external, which reduces the chance of infection for the patient.
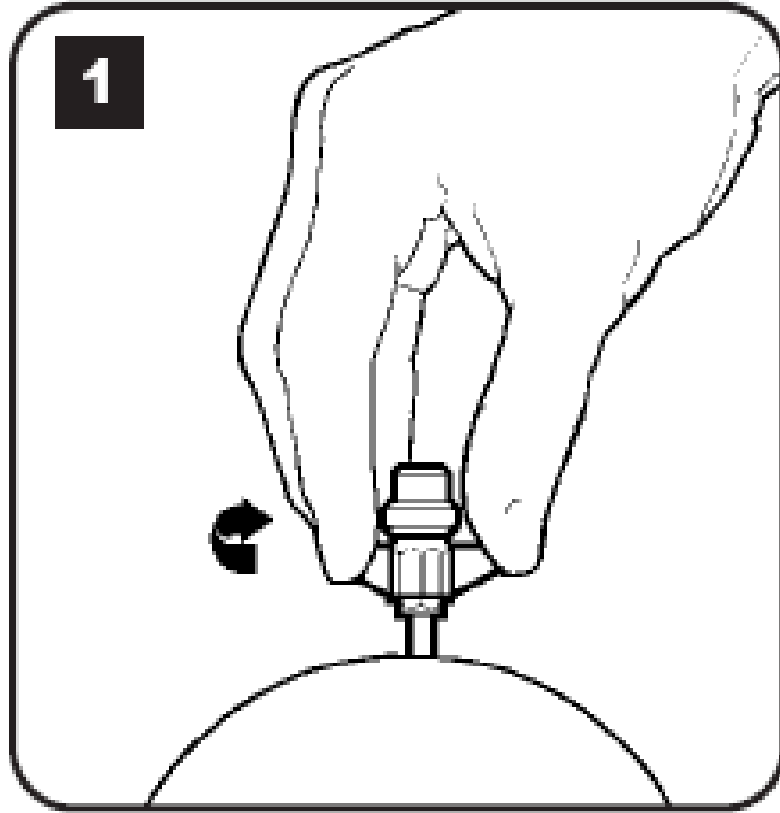
Figure 2. Camino 110-4B Inserted in head (Camino, 2006).

A fourth monitor also being used currently is The New ICP-Monitor made by Spiegelberg. It is powered by rechargeable batteries that can run independently for more than three hours. The monitor displays a variety of different measurements including ICP, systolic ICP, and diastolic ICP (New, 2004). When it is combined with the Compliance-Monitor, another Spiegelberg product, it can monitor both Cranio-Spinal Compliance and ICP (*Figure 3*). The features this monitor have include the patient being able to get in touch with a sterile probe only, which are very inexpensive (New, 2004). There is also no electrical connection to the patient, so the patient does not have to worry about anything going wrong with the electrical malfunctions. The device is also easy to use.
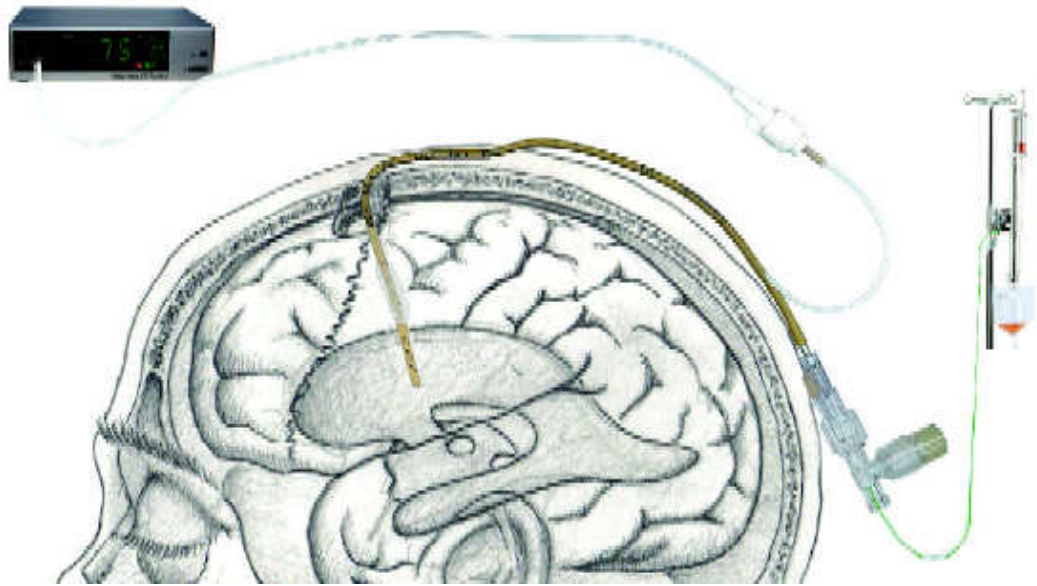
Figure 3. The New ICP Monitor, the monitor and probe inserted in the brain (New, 2004).

The disadvantage of the monitor made by Spiegelberg is similar to the Camino in that a probe is used that goes from the dura membrane through the skull and connects to the monitor outside the body. Our design solves this problem by making the transducer completely internal and the power supply completely external. This way there is nothing penetrating through the skin.

There is another transducer that was designed that is very similar to the transducer that we are creating. However, this device is used to measure intraocular pressure in the eye due to glaucoma. The device is a biomedical pressure sensor that is implantable and utilizes Microelectrical Mechanical Systems (MEMS) technology (Lloyd, 2003). The sensor is just one component of the whole system that is used to measure intraocular pressure on a continuous basis. The second component is a data acquisition and processing unit (DAP). The third component is a central database that is used for record

keeping purposes. The pressure sensor is placed in the eye and is small enough so that the patient's vision and functions of the eye will be unaffected. A signal is generated in the device that is transmitted using wireless telemetry to the sensor. The device then processes and temporarily stores the data that is returned from the sensor. This data is then uploaded to the central database so a time record of intraocular pressure measurements can be stored. This device has many advantages that include: fully implantable, wireless, and passive sensor designed and built sing MEMS technology; precision pressure measurement; continuous or scheduled measurement of IOP; variable data acquisition rate; alarm to alert patient of unsafe pressure levels; remote control of transmitter/receiver unit; portable transmitter/receiver unit with rechargeable batteries; and data storage for record keeping (Lloyd, 2003). The device is made of silicon or glass and is a variable capacitor with an on chip inductor. The sensor is an RLC circuit with the capacitor having a thin flexible diaphragm that is exposed to the pressure in the eye. The pressure in the eye deflects the diaphragm causing the capacitance of the circuit to change (Lloyd, 2003).. A change in resonant frequency will change in result of the capacitance change. Wireless telemetry of data to a DAP unit is then obtained using inductive coupling. Measuring the electrical characteristics of the DAP, a measure of resonant of frequency can be found which will create a measurement of the capacitance and pressure in the eye (Lloyd, 2003). We designed our device based on many different aspects of this design but we need to change it as it is not proven that this device can be used to measure intracranial pressure. Because ocular pressure uses totally passive transmission this may not be ideal for pressure measurements in the brain because of the

dynamic state of the intracranial pressure that fluctuates between 2-3 mmHg in every heart beat (Lloyd, 2003).

Current ICP monitors have finite life-spans, exposure of circuitry through the skin and suffer from large drift characteristic over time. To address these issues a non-invasive means to measure intracranial pressure through an inductively powered device will need to be designed. The power supply will need to transmit power across the scalp to an internal pressure gauge. The internal component will need to amplify a signal allowing it to be interpreted externally as a pressure measurement.

Design Specifications

To accurately check intracranial pressure without surgery, a prototype must be constructed which is an implantable device that can easily measure intracranial pressure in order to alert patients and doctors of shunt failure. The design has an internal component implanted under the scalp and contains a pressure gauge transducer which is further inserted through a hole in the skull and into the cerebrospinal fluid. This internal component measures and transmits the pressure, and an external part, on the outside of the body, receives and displays the pressure. The external part should also inductively power the internal circuitry.

Specific design constraints were given by the client to follow as design guidelines. The internal component, which houses the pressure gauge, needs to be completely internal to reduce the chance of infection and disease. It also needs to be 100% biocompatible, meaning it has no toxic or harmful effect on the human body. In

addition to this, the internal component needs to be MRI compatible. This means that it can contain only nonferrous materials; ferrous materials will blur an MRI image and hinder a doctor's interpretation of the image. The pressure gauge housed in the internal component also needs to have a broad range in its ability to measure pressure. A normal, healthy person has an absolute intracranial pressure between 10-15mmHg, but in a person with hydrocephalus can have a much broader range, especially if a shunt failure has occurred. Therefore, the pressure gauge needs to measure absolute pressure in the range of -3 to 30mmHg. Lastly the internal component needs to have a lifespan of no less than 20 years. Lifespan is important because the longer it lasts in the patient the less surgery is needed to repair or replace the device.

The external power supply also has design constraints. It needs to be completely external to reduce infection; this also eliminates the possibility of using an internal battery which has a finite lifespan. If it is completely external, the power supply can easily be repaired or replaced without the need of surgery. The power supply needs to induce 5 volts in the secondary coil because the average voltage required to power a PIC microcontroller is 3.5V. By providing 5 volts to the secondary coil, this ensures that the circuitry and pressure transducer will function correctly and an accurate pressure reading can be relayed back to the exterior of the skull. The 3.5 volts is a minimum that can be achieved by rectifying and regulating the signal but it is important to provide a greater power to ensure the circuitry functions.

The power supply also must supply no more than 100mA. Currents greater than 100mA can be potentially dangerous to an individual's health, therefore the power supply cannot create a current that exceeds this value. Ideally, the current induced in the

secondary coil will be on the order of 20mA or less, as this is a much safer level for the patient. Reference *Appendix A* for complete product design specifications.

ICP Monitor Design

The overall design of the ICP monitor will consist of three components; an external power supply, an internal component and an exterior pressure reading device. The external power supply will inductively power an internal component when held next to the head.   This portion of the device will be run on AC power. The internal component will have a flat circular portion that will rest on top of the skull below the skin. This portion will be 1cm in radius and house the inductor coil, the majority of the circuitry and the signal amplification mechanism (*Figure 4*).
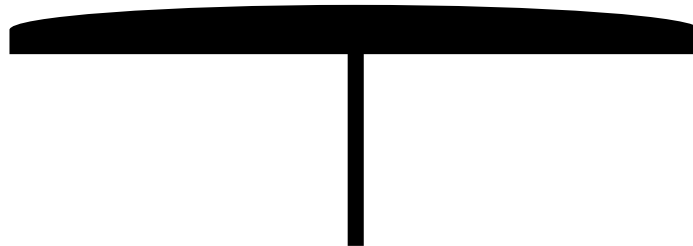

Figure 4. ICP monitor internal component.

The internal portion will also have a long cylindrical part that will extend through the skull and penetrate into the intracranial fluid. This portion will be 5 mm in length and 2 mm in diameter. The pressure gauge that will monitor the intracranial pressure will be located in the tip of this piece. The final component is the external pressure reading device. This portion will receive a signal from the internal component and generate a pressure reading externally. Ideally, this part will be able to be integrated into the external power supply in future work. This semester was dedicated to working on the

external power supply, as well as, the circuitry and mechanical design of the pressure measuring device.

Design Alternatives – External Power Supply

To avoid any issues regarding exposure of circuit components through the head and a finite battery supply, the internal circuitry will be powered via electromagnetic induction. Electromagnetic induction utilizes a changing magnetic flux to induce a voltage and current in a nearby wire. Any time a wire experiences a current it will produce a magnetic field that is perpendicular to the direction of the flow of the current. The direction of the magnetic field created by the wire can be determined by a "right-hand rule." To determine the direction of the magnetic field, one wraps the right hand as if clasping the wire and with the thumb pointing in the direction of the current as shown in *Figure 5* (Anderson). The closed fingers point in the direction of the magnetic field
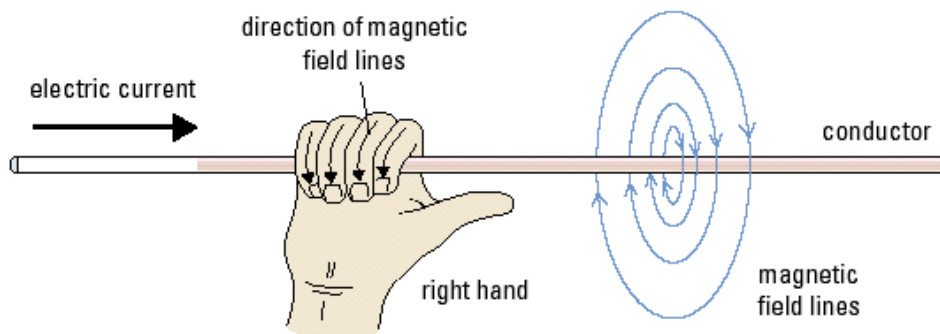

Figure 5. Production of a magnetic field by a current-carrying wire

that surrounds the current-carrying wire. This field is continuous and forms a closed loop at the same distance from the wire; however, as the distance from the wire increases the strength of the magnetic field decreases.

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Electromagnetic induction must utilize a changing magnetic flux in order to correctly operate; therefore it can operate in several manners. The first option is to drive the primary power source with AC frequency, thereby inducing a changing current and subsequently a changing magnetic flux. Otherwise, a constant magnetic field can be produced and the flux through the second loop can be changed by altering the area of the second loop or the amount of magnetic field lines that pass through the loop. According to Faraday's Law, an electromotive force can be created in a secondary loop because the magnetic flux through the loop will change (*Figure 6*).
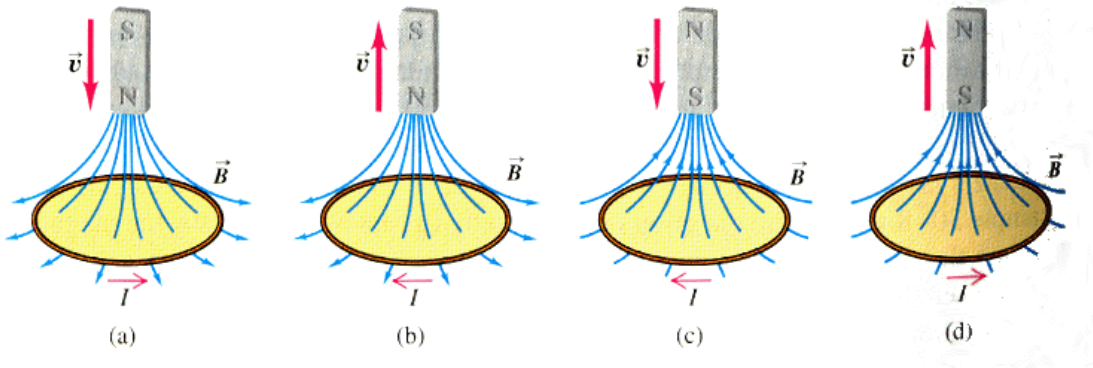

Figure 6. EMF created by a changing magnetic flux (Wohlgenannt).

As can be seen in *Figure 6*, the magnetic flux is increased and decreased by moving the bar magnet closer and further from the loop. This is similar to the changing magnetic flux produced by the primary wire; as the power source changes voltage polarity and magnitude, it changes direction and magnitude of the magnetic field, thereby changing the flux experienced by the loop and inducing a changing voltage in the secondary loop.

Transformer

The transformer utilizes a primary winding driven at a high voltage and current to induce a voltage in the secondary winding through mutual inductance. The primary winding would be composed of several step-up transformers to increase the voltage of the power source. The final winding of the primary coil would be held closely to the head in order to induce a voltage in the secondary coil implanted onto the skull. A diagram of a general transformer is shown in the figure below (***Figure 7***).
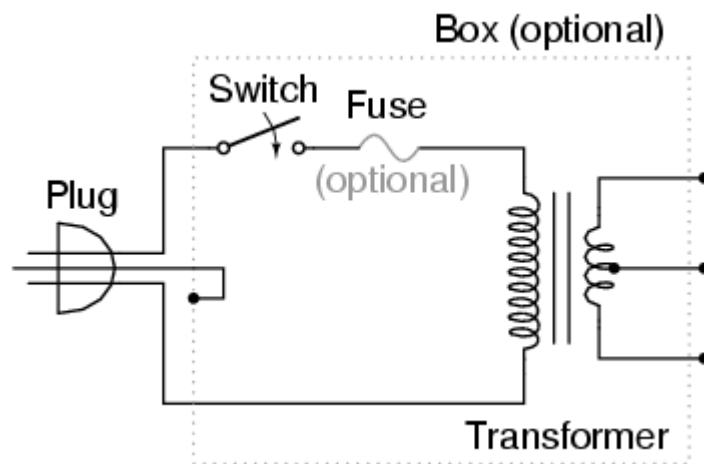

Figure 7. Transformer schematic
(http://web.ncf.ca/ch865/graphics/Solenoid.jpeg).

By driving the primary winding with an AC voltage, it will create a self inductance in which a magnetic field is present in the core of the winding; however, it will also create a magnetic field that encircles the winding. By bringing the primary winding in close proximity to the secondary winding, the secondary will experience a voltage according to the following equation.

$$V = M\frac{di_1}{dt} \qquad\qquad [1]$$

This equation shows that the voltage induced in the secondary coil depends on the changing current in the primary coil as well as the mutual inductance (M) between the two coils which can be determined using equation 2.

$$M = k\sqrt{L_1 L_2}$$ [2]

L_1 and L_2 are the inductances of coil 1 and 2, respectively and k is the coefficient of coupling; k can vary between 0 and 1 where 0 represents no mutual inductance and 1 represents an ideal transformer.

AC Solenoid

The solenoid design inductively powers the circuitry attached to the head by creating an axial magnetic field that is strongly focused in the center of the solenoid. This is accomplished by winding wire in a helical manner as shown in *Figure 8.*
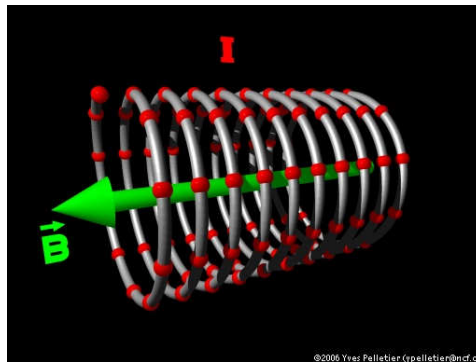

Figure 8. Magnetic field created by a solenoid.

Each loop of the solenoid produces a magnetic field in the manner shown in *Figure 5*, in *Figure 8* the current is flowing through the solenoid starting at the front left and moving to the back right of the picture. Therefore, each loop acts to reinforce the magnetic field in the center of the solenoid while destructively interfering outside the solenoid and greatly decreasing the strength of the magnetic field. An ideal solenoid, one in which the

length of the solenoid is much greater than the radius, has a constant magnetic field within the solenoid and can be calculated using the following equation:

$$B = \frac{\mu_0 NI}{L} \qquad [3]$$

In the above equation, N is the number of turns in the solenoid, I is the current carried by the solenoid and L the length and μ_0 is a constant called the permeability of free space that relates mechanical and electromagnetic units of measurement (Hyperphysics). When a material is inserted into the core of the solenoid, the magnetic field changes according to the approximation:

$$B = \frac{\mu_0 (1 + \chi) NI}{L} \qquad [4]$$

The constant χ is the magnetic susceptibility of the material that is inserted into the core (Hyperphysics). By inserting a ferromagnetic material, or a material that can be permanently magnetized when subjected to an outside field, the strength of the overall magnetic field can be greatly increased because irons magnetic susceptibility is approximately 5000.

Further examination of the solenoid shows that the solenoid cannot be treated as ideal because its length will not be significantly larger than the radius and therefore will not produce a constant magnetic field within the core. The magnetic field produced by a non-ideal solenoid can be calculated along the central axis by using the following equation (Dennison):

$$B = \frac{\mu_0 (1+\chi) \cdot I \cdot N}{2L \cdot (r_2 - r_1)} \cdot \left[x_2 \cdot \ln \left(\frac{\sqrt{r_2^2 + x_2^2} + r_2}{\sqrt{r_1^2 + x_2^2} + r_1} \right) - x_1 \cdot \ln \left(\frac{\sqrt{r_2^2 + x_1^2} + r_2}{\sqrt{r_1^2 + x_1^2} + r_1} \right) \right] \qquad [5]$$
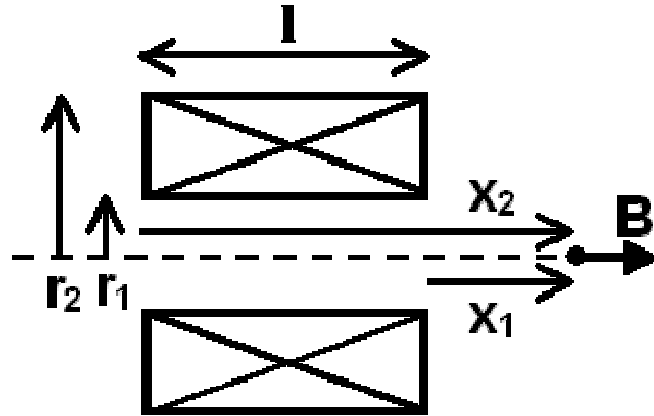
Figure 9. Magnetic field at a point along central axis (Dennison).

As can be seen in **Figure 9**, r_2 is the outer radius, r_1 is the inner radius, L is the length of the solenoid, x_2 is the distance from the far end of the solenoid to the point of interest, x_1 is the distance from the near end of the solenoid to the point of interest, μ_0 is the constant for permeability of free space, χ is the magnetic susceptibility of the core, I is the current through the wire, and N is the number of turns of the wire (Dennison). Additional experimentation was done by Chih-Ta Chia and Ya-Fan Wang to determine the magnetic field along the axial line of a solenoid. Their results are very similar to that shown above except in their test they related the strength of the magnetic field to the angle formed with the vertical by the point of interest and the end of the solenoid (Chia):

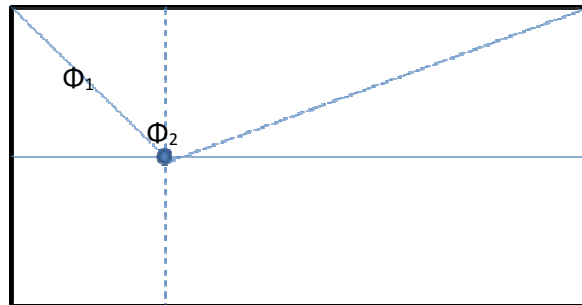$$B = \frac{1}{2}(\sin\varphi_1 - \sin\varphi_2)\mu_0 \frac{N}{L}I_0$$

[6]

Figure 10. Method for calculating the magnetic field at a point along central axis

Figure 10 shows the dimensions for equation 4: Φ_1 and Φ_2 are the angles formed by lines drawn from the point of interest to the ends of the solenoid and the vertical, μ_0 is the constant for permeability of free space, χ is the magnetic susceptibility of the core, I_0 is the current through the wire, and N is the number of turns of the wire. Chia and Wang also showed that the magnetic field reaches its maximum value at the exact center of the solenoid and decreases to half the relative field strength at the ends and continues to decrease drastically outside the solenoid.

To overcome the drastic decrease in magnetic field strength outside the solenoid, the iron core within the solenoid will be tailored such that it focuses that magnetic field to a more specific point or location. This can be seen in *Figure 11*, by narrowing the end of the ferromagnetic material to somewhat of a point, the magnetic field lines become concentrated at this point as they exit and therefore focus greatly at this location (Booske). In doing so, the secondary coil will experience a much greater flux and therefore experience a larger electromotive force.
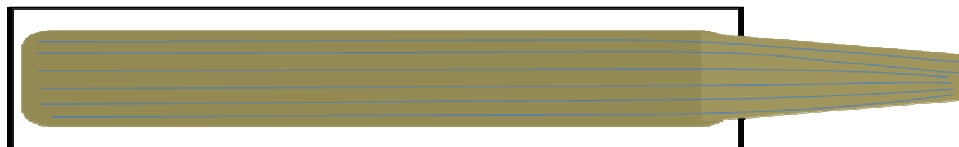
Figure 11. Focusing the Magnetic Field by Narrowing Ferromagnetic Core.

DC Solenoid

Much like the AC solenoid, the DC solenoid utilizes the fact that a current carrying wire produces a magnetic field. Instead of relying on an AC power source to create the changing magnetic field and thus the changing magnetic flux necessary to induce an EMF in the secondary coil, the DC solenoid will rely on a mechanical component to vibrate the solenoid component as shown in *Figure 12*.

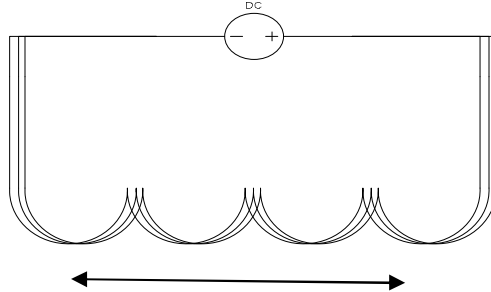*Figure 12.* DC solenoid.

In doing so, the solenoid will act very similar to the bar magnet in *Figure 6*. The DC
solenoid will have a consistent magnetic field because it is being driven by a DC voltage
source. By changing the distance between the solenoid and the secondary attached to the
head, the magnetic flux will change due to changes in the amount and strength of
magnetic field lines passing through the secondary coil. Therefore, the secondary loop
will experience an induced voltage and current.

Design Matrix

Design	Power (0.4)	Size (0.1)	Feasibility (0.2)	Safety (0.3)	Total
Transformer	3 (1.2)	6 (0.6)	5 (1)	2 (0.6)	3.4
AC Solenoid	*6 (2.4)*	*6 (0.6)*	*5 (1)*	*6 (1.8)*	*5.8*
DC Solenoid	5 (2.0)	6 (0.6)	6 (1.2)	3 (0.9)	4.9

Table 1. Design matrix for external power supply.

The power supply designs were compared by creating a design matrix (***Table 1***) that rated the designs on four different criteria. Each criterion was given a weight from 0-1 based on the importance of the criteria to the function of the final design. Then, each design alternative was rated on a numeric scale from 1-7 for performance for each of the factors with 7 being the best and 1 the worst.

Power is the most important consideration because the power supply must be able to deliver ample power to the secondary coil to power the pressure transducer and other circuitry. In this case, the secondary voltage should be 5 volts and current should be larger than 20mA but less than 100mA; therefore, the power delivered to the secondary coil should be in the range of 0.1W-0.5W. These values were determined because a PIC microcontroller requires an average of 3.5V to run properly (Microchip). Supplying 5V will allow enough power for the microcontroller to run properly and therefore transmit accurate pressure readings. Additionally, the 5V can be transformed to decrease the voltage to the required 3.5 volts with a rectifier and therefore will not damage the circuit.

Patient and user safety is an important criterion because the power supply will be used in close proximity to people. The voltage and current levels present in the primary power source should be less than 50V and 200mA because levels higher than this can severely harm the operator (Giovinazzo). As already mentioned, the current present in the secondary coil needs to be less than 100mA as well. Ideally, the current will be limited to a much smaller value of approximately 20mA in the secondary coil to completely avoid patient harm.

Feasibility of the design also plays an important role because the electrical and mechanical components of the design must be possible to fabricate. Therefore, feasibility in design and construction also play an important role in the selection of the final design.

Because an individual will need to manually operate the exterior power supply, it is important that the size and weight are small enough to be easily handled by a small adult. Therefore, the weight of the design will be limited to a maximum of ten pounds and must have dimensions that allow it to fit in a 15cm cube. By limiting the power supply to these sizes, it can easily be operated by a range of individuals with varying strength.

The AC solenoid design received the highest overall score and therefore is the design we chose to pursue for the semester. The AC solenoid scores highest in the two most important categories, more specifically it ranks highest in power delivery and patient and operator safety. The AC solenoid ranks highest in power delivery because driving the iron-core solenoid at 60 Hz allows the production of 5V and 100mA in the secondary coil. On the other hand, the transformer does not transmit enough power because the mutual inductance between the primary and secondary coils are too small (M=0.015) to produce the necessary voltage in the secondary coil. The AC solenoid also demonstrated the highest degree of patient safety because it is able to operate at reasonable voltages and frequencies, in fact, the AC solenoid will be driven at 12VAC and 200mA. On the other hand, the DC power supply and transformers would require a dangerous amount of current greater than 300mA to drive the supply and therefore pose threats to the operator. Taking these constraints into consideration, the AC solenoid was chosen as the most feasible and best design alternative to pursue.

Final Design – External Power Supply

The AC solenoid is used in conjunction with an AC power adapter (*Figure 13*) that is capable of stepping down the voltage from a wall socket to 12VAC with 200mA output (McMaster-Carr). Because the power adapter is connected to a wall socket, it will drive the solenoid at 60Hz.

Figure 13. AC power adapter
(http://www.mcmaster.com/)

This adapter has a six foot long cord that is used to connect the power adapter to the solenoid via the output connecter that has an outer diameter of 5.5mm and inner diameter of 2.1mm.

The solenoid itself will have an outer radius of 7cm and an inner radius of 2 cm and length of 5cm (*Figure 14*). Additionally, the solenoid will have 5000 turns/meter, or 250 turns of wire in the solenoid. The secondary coil will have 10 turns and a radius of 1cm. The solenoid will have a large outer radius in order to maximize the flux that is experienced by the secondary coil. Tests were conducted on an air core solenoid to determine the effect of moving the secondary coil away from the solenoid axially as well as transversely away from the solenoid with the results shown in *Figure 15*.
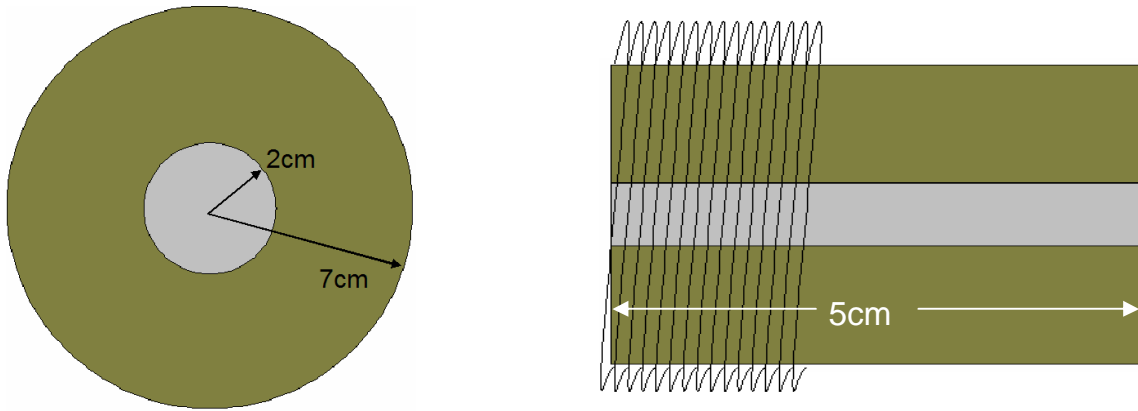
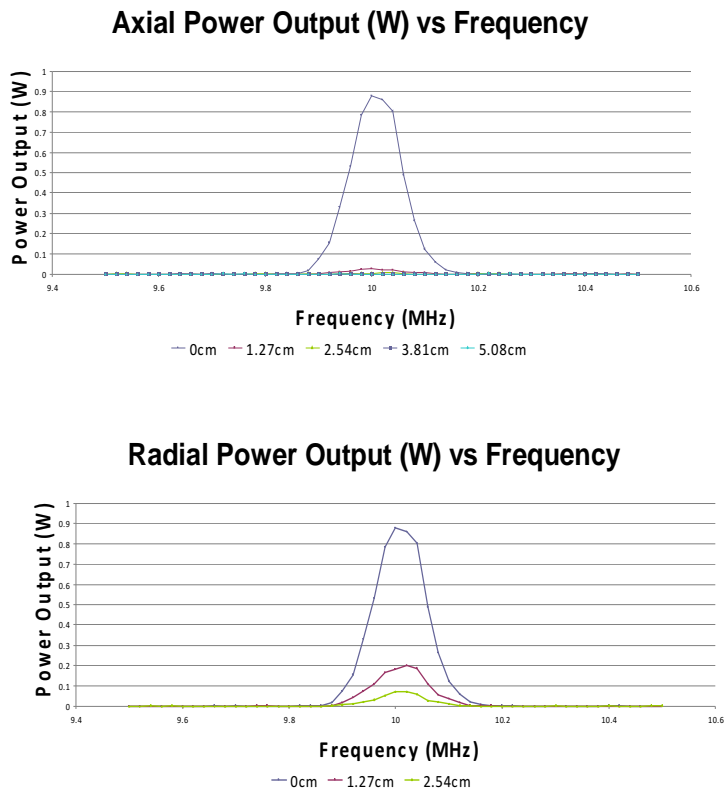***Figure 14***. Solenoid Dimensions.

Figure 15. Power output as a function of axial and radial distance.

This air core solenoid had a length of 2cm, outer radius of 3cm and inner radius of

7.5mm. As can be seen, the power output decreases extremely rapidly as the secondary

coil moves axially away from the solenoid. The power output decreases but to a lesser

degree when the secondary coil is moved away from the central axis of the solenoid transversely, but still remains within the outer radius.

Taking these results into consideration, we were able to derive the final solenoid design. The solenoid will have an outer radius of 7cm and inner radius of 2cm which allows greater transmission of power because greater magnetic flux is produced at all points within the outer radius of the solenoid. In order to further increase the power output, an iron core will be inserted into the core of the solenoid to reinforce the magnetic field produced by the solenoid. The iron core will be tailored so it comes to a tip just outside the solenoid as shown in *Figure 11*. By tailoring the iron core in such a manner, it will further focus the magnetic field lines to a point and will allow greater flux to pass through the secondary coil.

Theoretical values were used to determine the voltage produced by this iron core solenoid as axial distance varied shown in *Figure 16*. The driving voltage was assumed to be 12V, current of 200mA, a secondary coil with 10 turns and radius of 1cm and solenoid with outer radius of 7cm and inner radius of 2cm. These three curves represent solenoids with lengths of 10cm (blue), 7.5cm (red) and 5cm (purple). Clearly, the magnetic field produced by a longer solenoid is greater than shorter solenoids. However, the 5cm long solenoid is able to induce 5 volts in the secondary coil at a distance of 5cm from the solenoid and therefore increased length is excessive.
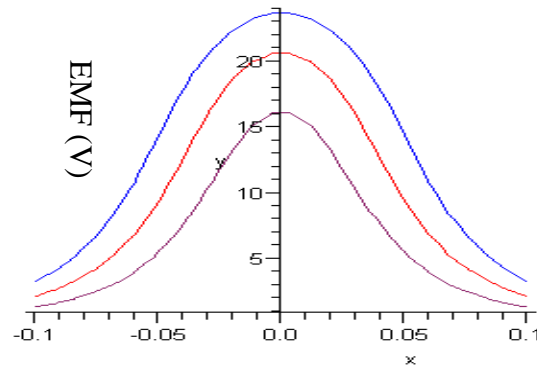
Figure 16. Voltage produced by solenoids at different axial distances

Design Alternatives – Internal Pressure Gauge

Strain Gauge

The strain gauge based design uses a strain gauge in conjunction with a

Wheatstone bridge. The Wheatstone bridge in the design will be composed of three

resistors and one strain gauge. In general, a Wheatstone Bridge contains four resistors,

three of known resistance and one of unknown resistance. A diagram of a typical

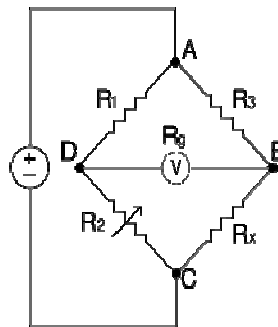Wheatstone bridge is show below (*Figure 17*).

Figure 17. Wheatstone Bridge.
(http://en.wikipedia.org/wiki/Wheatstone_bridge)

In the diagram above (*Figure 17*) the resistances R_1, R_2 and R_3 are know and R_x

is unknown. The value for the resistance of Rx can be determine by the proportion R_2 /

$R_1 = R_x / R_3$. When all the resistances are equal the voltage measured across the bridge

will be zero. When the resistances in the Wheatstone bridge are not all equal the voltage

measured across the bridge can be found using the equation 7 below.

$$V = \left(\frac{R_x}{R_3 + R_x} - \frac{R_2}{R_1 + R_2} \right) V_s \qquad [7]$$

For the strain gauge design, a strain gauge will be placed into the R_x position

shown above. A strain gauge is a measure of electrical resistance. When the length of

the strain gauge increases as shown in (b) of the figure below (***Figure 18***), tension is

created and the area narrows. As the area narrows a greater resistance is present in the

strain gauge. The opposite can be seen in (c) of the figure below (***Figure 18***), where

decreasing length causes a lower resistance in the strain gauge.

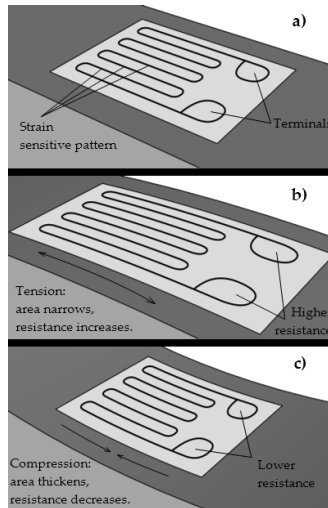***Figure 18***. Strain gauge.
(http://www.answers.com/topic/straingaugevisualization-png)

In this design the strain gauge will be placed on the durra membrane, the

membrane that surrounds the brain. Therefore, with changes in the intracranial pressure

it will cause the durra membrane to stretch which will cause deformations to the strain

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gauge. The resistance of the strain gauge will increase with increased length or decreased

cross-sectional area, caused by the expansion of the durra membrane as a result of

increased intracranial pressure. Based upon the above equation to obtain voltage across

the Wheatstone Bridge, an increase in resistance of the strain gauge will cause an

increase in voltage output. By having an increase voltage output, changes in pressure

will be able to be determined.

Capacitor

There are two capacitor based designs. A capacitor is used to store charge and

consists of two conducting plates separated by a non-conducting material or dielectric

(Brian). The conducting plates have area A and carry opposite charges +Q and –Q. The

plates are orientated parallel to each other and the electric field E moves from the plate

carrying the positive charge to the plate carrying the negative charge. There is a distance

d between the capacitors and a potential difference or voltage V. A diagram for this can
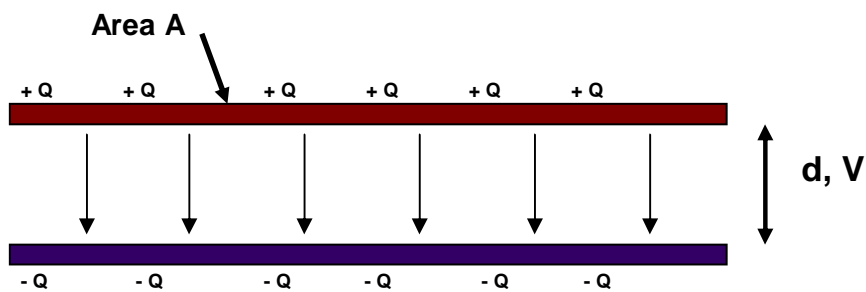
be seen below (**Figure 19**).

Figure 19. Parallel plate capacitor.

The capacitance of a capacitor varies with the distance between the plates and the

area of the plates themselves. The equation for this relationship is

$$C = \frac{\varepsilon_0 A}{d} \qquad\qquad \textbf{[8]}$$

The capacitance of a capacitor can also be related to the charge placed on the plates and

the voltage or potential difference across the plates. The equation for this relationship is

C = Q / V. Therefore, through changes in the distance between the plates of a capacitor

changes in voltage can be observed.

Capacitor-Cylindrical

The first capacitor design uses two circular parallel plates enclosed in a

biocompatible material. The top plate is fixed to the inside of the skull. The cylindrical

enclosure penetrates trough the durra membrane surrounding the brain and allows for the

direct exposure of the moveable plate to the intracranial fluid. A diagram showing the

location of the capacitor can be seen below (***Figure 20***).
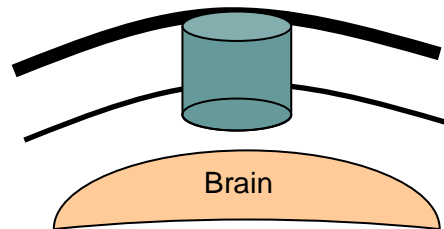
Figure 20. Cylindrical capacitor implantation.

This design uses the pressure exerted by intracranial fluid to change the distance

between the plates. The pressure from the fluid is exerted on the moveable plate. To

prevent the plates from coming together completely, a spring made of non-conducting

material will be placed between the two plates (***Figure 21***). Therefore to determine the

voltage drop across the capacitor we will need to not only take into consideration the

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change in distance between the plates, but we will also need to consider the force exerted

on the spring from the pressure and the necessary spring stiffness constant. The spring

stiffness constant will need to large enough so that the spring doesn't immediately

deform as a result of the internal pressure inside the durra membrane. However, the

constant will need to be sensitive enough to to detect small changes in pressure of

approximately 1-2 mmHg.
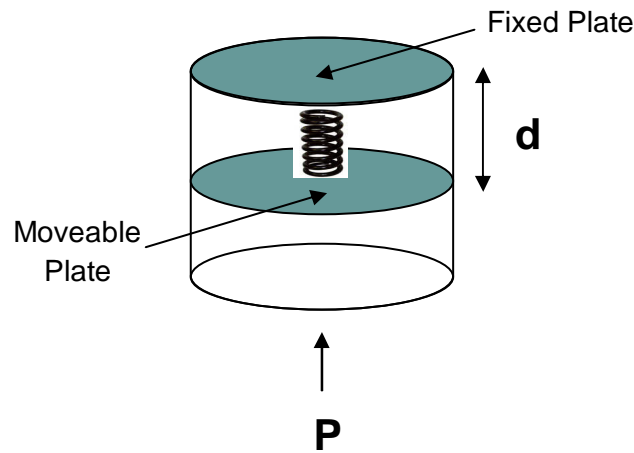
Figure 21. Cylindrical capacitor

Capacitor- Dome

The second capacitor design uses fluctuations in the durra membrane caused by

increased or decreased pressure to change the distance between the plates of the

capacitor. A flexible dome made from biocompatible material encloses two circular

plates. The dome is fixed to the exterior of the skull and touches the durra membrane.

Each plate is enclosed in the biocompatible material, to prevent any drift within the dome

itself. A diagram showing the location of the capacitor can be seen below (*Figure 22*).
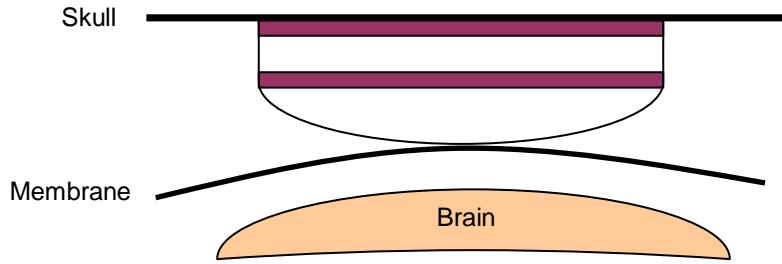
Figure 22. Flexible dome capacitor.

The inner portion of the dome membrane is filled with either a fluid or air allowing it to have an internal pressure of its own. Therefore, when a force is exerted on the dome by the durra membrane, compression of the fluid or air inside the dome will cause a force on the capacitor and allow for a change in distance. The distance that the dome capacitor will move will not only be dependent on the force that is exerted by the durra membrane, but the internal change in pressure associated with this force.

Also, consideration will have to be given to how the biocompatible material surrounding the plates of the capacitors will change the overall capacitance of the capacitor (*Figure 23*).

Figure 23. Flexible dome capacitor.

Design Matrix

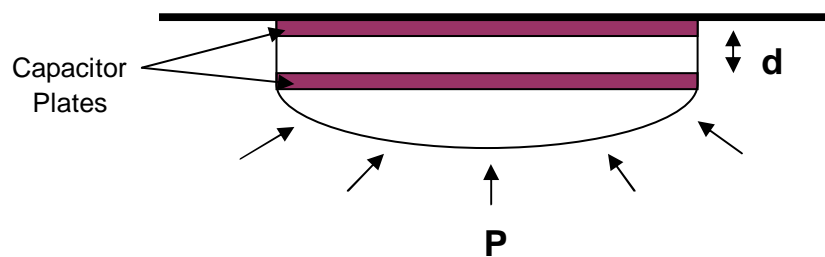| Design	Accuracy (0.35)	Lifespan (0.3)	Biocompatibility (0.2)	Size (0.1)	Cost (0.05)	Total
Strain Gauge	6 (2.1)	5 (1.5)	6 (1.2)	7 (0.7)	7 (0.35)	5.85
Cylindrical Capacitor	4 (1.4)	5 (1.5)	6 (1.2)	4 (0.4)	5 (0.25)	4.75
Flexible Dome	3 (1.05)	6 (1.8)	6 (1.2)	5 (0.5)	3 (0.15)	4.7

Table 2. Pressure gauge design matrix.

The pressure monitor designs were compared by creating a matrix (***Table 2***) that rated the designs in six different criteria. Weighing each criterion based on its importance to the clients constraints and design, each design alternative was rated on a numeric scale from 1-7. The grand total for the criteria was 1, and each design was given a value 1-7, with 7 being the best score and 1 being the worst.

Accuracy was given the highest weight because it is the most important characteristic for the final design. Since the device is going to be measuring the intracranial pressure, it should be relatively accurate and consistently give a true reading, because this reading will help a doctor decide if surgery is needed or not. It needs to have an accuracy of +/-1mmHg. The strain gauge was the more accurate of the two designs because it has a higher sensitivity to pressure changes.

Durability was also a highly weighted criterion for our design. The final design of the device should durable enough to last the entire lifespan of the implant because one

purpose of this project is to reduce the number of surgeries a patient must undergo. The lifespan and durability of the three designs were found to be equal so each received the same rating.

Next, the biocompatibility of the pressure gauges were compared and rated. The final design needed to be made of materials that would not be toxic or harmful to the patient. Again, all designs received the same rating in this criterion because each can be made of 100% biocompatible material and miniaturized to a safe size.

Finally, the two designs received a rating for their size and cost. Although these criteria were rated with low importance, they still have an impact on the final design. The size of the device needs to be reasonably small, so the technology needs to be able to be miniaturized, because it needs to be small enough not to cause harm to the patient's brain. The cost of the device must be comparatively cheaper than the surgical alternatives, because it must be cost effective for the patient. In both size and cost, the strain gauge received a higher rating. This gave the strain gauge design a final rating of 5.85 over the 4.57 capacitor design rating. The final design will therefore utilize a strain gauge in its pressure monitor system.

Based on further research, the strain gauge was found to have to great of an accuracy drift over time. Data found suggested that the strain gauge would lose accuracy within two weeks of implantation. A capacitor based model used by Medtronic was tested and demonstrated its ability to maintain an accuracy range of $\pm$ 1 mmHg over a four month period. Although this duration is still considerable less then the desired time period, with the evaluation of their design and further research a long term capacitance pressure gauge should be able to be designed.

Modified Design Alternatives – Internal Pressure Gauge

Longitudinal Capacitor

The longitudinal capacitor design will consist of two conducting plates and a thin flexible diaphragm. The diaphragm will be located at the very tip of the long cylindrical part of the internal component. Attached to a diaphragm will be a conducting plate. The plate and the diaphragm will move simultaneously when the intracranial pressure exerts a force on the external portion of the diaphragm (***Figure 24***). A fixed capacitor plate will be located further up the cylindrical shaft of the internal portion. With changes in
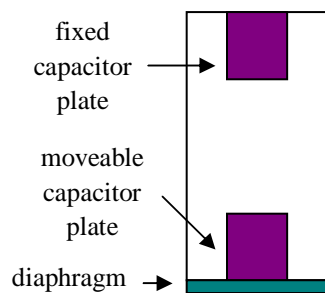

Figure 24. Longitudinal capacitor.

pressure the distance between the plates will be changed, therefore, changing the capacitance according to the equation $C = \varepsilon A / d$. In the equation A is equal to the area of the plates, d is the distance between the plates and ε is an electric constant. The dielectric in this capacitor will be air.

Axial Capacitor

The axial capacitor design will consist of a single conducting plate and a diaphragm. In this design the diaphragm will be oriented on the side of the long cylindrical portion of the internal component. This diaphragm will be made from a thin layer of silicon and doped with either boron or phosphorus. By doping the silicon it allows the diaphragm to become conducting and serve as a capacitor plate (***Figure 25***). A fixed capacitor plate will be placed opposite the diaphragm inside the long cylindrical

diaphragm with conducting
material

fixed capacitor
plate
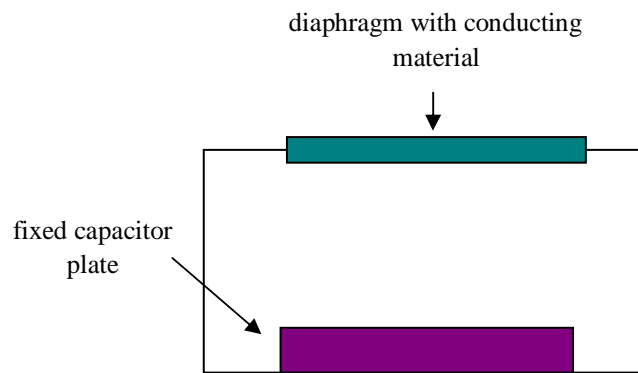
Figure 25. Axial capacitor.

component. When the intracranial pressure exerts a force on the external portion of the diaphragm it will cause a change in the capacitance because the conducting diaphragm and the fixed plate will have a smaller distance between them. The capacitor will have an air dielectric.

Design Evaluation

The axial capacitor design will be pursued in the future over the longitudinal design. The orientation of the diaphragm of the axial capacitor has the ability to be recessed into the long cylindrical shaft, making it at less risk of being damaged during

placement in surgery. Also the axial capacitor design uses a conducting diaphragm as opposed to the diaphragm with a conducting plate attached in the longitudinal design. By eliminating the plate attached to the diaphragm it will allow the diaphragm to move more uniformly, making it a better gauge of pressure.

Final Design – Internal Pressure Gauge

The final design will be the axial capacitor, described above (**Figure 25**). The area of the diaphragm and the fixed capacitor plate will be equal and have dimensions of 2 mm x 1 mm, giving a total area of 2×10^{-6} m^2. The distance between the plates with no deflection will be 1.5 microns and at maximum deflection the distance will be 1 micron. Therefore, the maximum distance change for the device will be 0.5 microns. Given the plate areas and deflection values the values for the capacitance at no deflection and maximum deflection are approximately 7 pF and 11 pF respectively. Assuming that we use the same 238 mH inductor used in testing, we will see a resonance frequency range between 1.1 MHz and 0.9 MHz with changing capacitance. The resonance frequency value of 1.1 MHz would correspond to 0 mmHg intracranial pressure, while the 0.9 MHz value could be equated to 30 mmHg. Reference *Appendix B* for complete calculations and equations used.

The fixed capacitor plate would be made of gold with the area described above. Gold will provide a non-ferrous material that will not interact with MRI scans. Air will be used as the dielectric between the two plates. The diaphragm will be made of silicon and doped with either boron or phosphorus to make it conducting. Further research will be performed as to which material will have the highest conductance.

Internal Pressure Gauge Circuit

Circuit Design

The circuit design we came up with, to be placed on a pic microcontroller in our

future work, consists of a parallel inductor and capacitor, or LC, circuit (***Figure 26***)
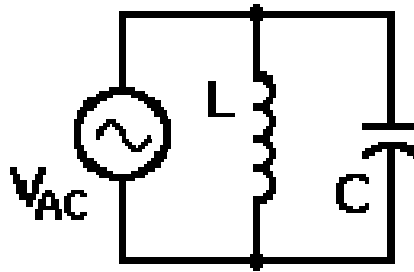
Figure 26. LC circuit configuration in parallel

powered by a variable AC source. We chose a 238 milliHenry inductor and a variable 21

picofarad capacitor for our circuit elements based off of the power constraints given to us

by our client and the required dimensions of the capacitor plates. The variable AC source

was used primarily for testing purposes and in our final design, will be replaced with the

inductor coil powered by an external solenoid. This circuit design (***Figure 27***) allowed us

to test our theory that with a change in capacitance, the resonant frequency of the circuit

would change by a constant amount.

Figure 27. Variable capacitor and inductor used for testing.

Testing

During testing, the distance between the plates of the capacitor was altered by turning a screw on the outside of the capacitor. In the actual 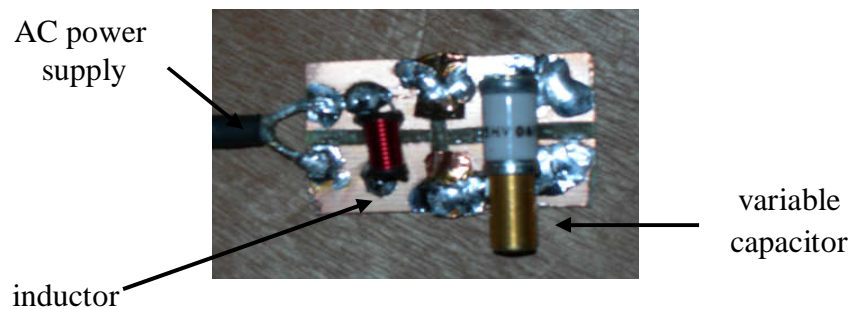device this distance will be changed with pressure as one plate of the capacitor will be pressure-sensitive. Due to the relationship between capacitance and the distance between the capacitor plates,

$$C = \frac{\varepsilon_0 A}{d} \qquad \text{[9]}$$

where C is the capacitance, A is the area of the plates and d is the distance between the plates, decreasing the distance between the plates increased the capacitance while increasing the distance between the plates decreased the capacitance. This varying value of capacitance as well as the constant value of inductance were used to calculate the equivalent impedance (ratio of voltage to current) of the circuit using this equation

$$Z = \frac{1}{j\,\omega\,C - \dfrac{j}{\omega\,L}} \qquad \text{[10]}$$

where Z is the equivalent impedance of the circuit, j is an imaginary number, omega is the angular frequency, C is capacitance and L is inductance. Using our knowledge of the fact that, at resonant frequency the denominator of our equivalent impedance equation is zero, we were able to calculate the angular frequency

$$\omega = \frac{1}{\sqrt{L\,C}} \qquad \text{[11]}$$

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

We demonstrated the fact that a change in capacitance changes 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 28. 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 between it and capacitance (*Figure 28*). This resonant frequency can than be used in conjunction with a PIC microcontroller and FM transmitter to transmit the resonant frequency back to the power supply to be interpreted as the intracranial pressure value that a patient is experiencing at the time of testing.

Future Work

Further configuration of the circuit is required so that it can be placed on to a PIC microcontroller. The PIC microcontroller can then be programmed to run our circuit and read the change in capacitance so that the change in resonant frequency can be interpreted. Putting the circuit on the PIC will help aid in the miniaturization of the circuit and transducer but more miniaturization of the circuit might be required. Further

research is needed on an FM transmitter and receiver to determine which configuration we will need to interpret the change in resonance frequency. Ideally, the FM transmitter will read the resonant frequency off the microcontroller then transmit it to a receiver outside the body that will be able to generate a pressure reading. This receiver could then interpret the frequency and display a numeric value for the intracranial pressure.

Regulations and Testing Protocols

At this point, our device is not at the state where testing can be conducted. However, as work progresses, the ICP monitor will have to comply with several regulations including the FDA 510K.

We must submit a FDA 510(k) pre-market notification because we are looking to design and ICP monitor that mimics some products that are already available on the market, including a Medtronic ICP monitor as well as a MEMS based device used to measure intraocular pressure. Therefore, a form must be submitted to the FDA with the product design specifications and mode of operation. Furthermore, the form must include a description of the intended use of the device. The design specifications and intended use ideas are vital to submission in order to prove to the FDA that our ICP monitor is substantially different from other products currently available.

Prior to performing animal testing we will need to consider whether the same analysis could be performed without the use of animals or on a "lower" class of animal species. If it is still deemed necessary after this investigation, we will work to minimize the number of research animals needed and any pain and suffering associated with the

testing. The ICP monitor must also comply with the Animal Welfare Act and the Public

Health Service Policy of Humane Care and Use of Laboratory Animals for testing

purposes. The Animal Welfare Act requires an Institutional Animal Care and Use

Committee (IACUC), procedures for self monitoring, adequate veterinary care, humane

facilities and occupational health and safety program (Responsible Conduct of Research,

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Appendix

Appendix A - PDS

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The Product Design Specifications (12/2/07)

ICP Monitor

</div>

Team Members: Erin Main, Josh White, Jessica Hause, Adam Goon, Kenny Roggow

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:

- Current in the circuit located on the skull should be no greater than 100mA and ideally around 20mA.

- Voltage required to power the circuit located on the skull should be approximately 5V.

- 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.

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. The inductive power supply will need to generate a minimum value of 3.5 V to the internal component, for the internal circuitry to function.

   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. The current in the circuit should no exceed 100 mA.

   c. *Accuracy and Reliability:*
   The internal pressure gauge will need to measure a pressure range of -3 mmHg to 30 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. The external power supply will need to generate a minimum of 3.5 V to power the internal component.

   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. We will need to ensure that the device does not corrode or suffer from considerable drift when exposed to the body fluids.

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.

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 20 cm in diameter and no more than 6 inches in height. The internal portion that is placed on the exterior of the skull should be no more than 1 cm thick and no more than 2 cm in diameter. The cylindrical portion that penetrates through the skull and into the intracranial fluid should be 2 mm in diameter and 5 mm 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 that 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 a 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 – Capacitor Calculations