Intracranial Pressure Monitor

Department of Biomedical Engineering
University of Wisconsin-Madison
BME 200/300

Mid-Semester Report

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Abstract

At the beginning of the semester, an idea was proposed to create an intracranial pressure monitor. The motivation behind this project arose from the professional experiences of Dr. Josh Medow, a neurosurgeon that works at the UW Hospital. Through his line of work, he has seen a great deal of people that suffer from hydrocephalus, a condition in which they cannot regulate the pressure within the cranium. Extended lengths of exposure to this elevated pressure cause severe side effects and the only way to know if pressure levels are too high are to make trips to the emergency room where clinicians opinions are subjective and extremely costly. In order to more definitively determine if a patient needs to make a visit to the ER, Dr. Medow proposed an idea to permanently implant a transducer into the patient's skull to measure pressure. Using this in conjunction with other circuitry including a power supply, rectifiers, regulators, resistors and capacitors, the pressure could easily be related to a voltage output and this could give definitive information as to whether or not the patient needs to seek help. The following document gives a detailed outline about the background of this medical condition as well as the proposed ideas for designing the power supply and transducer.

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 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 very subjective and thus, prone to error. The only sure way for doctors to check for shunt failure is by doing brain surgery or a shunt tap, in which a gauged needle is inserted through the skull and into the cerebrospinal fluid to produce a direct output of the intracranial pressure. Both methods are very invasive and as any surgery, very risky.

Design Specifications

In order to accurately check intracranial pressure without surgery, a prototype must be constructed that is a noninvasive device that will easily measure intracranial pressure in order to alert patients and doctors of shunt failure. The device needs to have an internal component to be inserted under the skin with some kind of pressure gauge transducer inserted through the skull and into the cerebrospinal fluid. It also needs to include an external component that produces an output of the intracranial pressure and powers the internal component. The external component needs to transmit power over the 1.5 cm gap between the outer skin and the skull in order to effectively power the internal component.

Current Designs

Currently, there are a few intracranial pressure monitors that are being used and that have been used in the past. One of these monitors is the Telesensor, made by Radionics. The second is the Insite monitor, made by Medtronic. Both are fairly accurate but are still prone to error due to the sensitivity of the transducers and other circuitry used. The Telesensor 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).

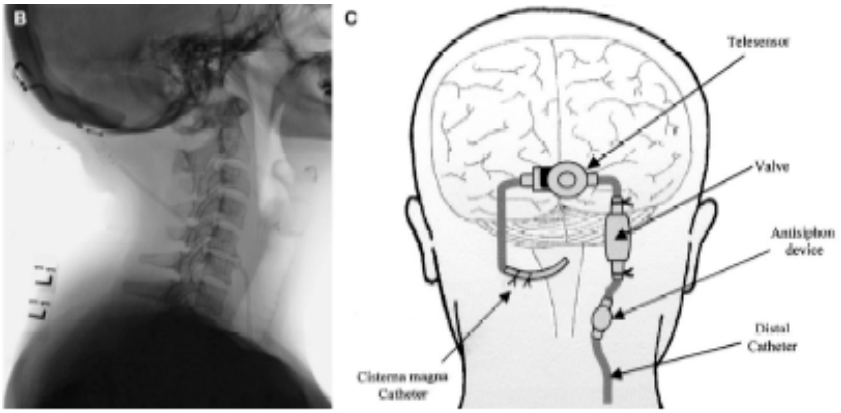


Figure 1- The Telesensor mounted in back of the head, (Lee, 2004)

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 time can be avoided. The Camino comes in a kit with a transducer-tipped catheter, the Camino bolt, and a 2.7 mm drill bit with safety stop (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. 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 2- The New ICP-Monitor made by Spiegelberg (New, 2004)

Design Alternatives – Power Supply

Direct Power Supply

For the power device, three different designs were considered that could be used to power the ICP monitor. One of the designs was a direct hook-up where the patient could connect and disconnect the power source wire from a socket, located behind the ear, at their convenience. This wire would connect to an external power supply located outside the body, which could be done at home. The design would contain small circuit components that would convert the incoming power to the required voltage and amperage for the pressure monitor inside the skull. There would also be a cap or removable cover to prevent the risk of infection.

Implantable Battery

The second design alternative was devised to run via an internal battery. The battery would be implanted inside the chest, near the heart, and a wire would be connected from the battery through the chest and up through the neck. It would connect to the pressure monitor in the back of the head. This design has been used before with the Insite monitor and should therefore be a valid power supply. Using a battery in this manner has also been used to power devices for the heart and should be able to do the same for devices in the brain. However, since it is a battery it will eventually die and need to be replaced. This can be very expensive for a patient since they would have to pay for the battery and the surgery each time the battery must be fixed or replaced. Also, batteries are not a dependable constant source of energy. They have a finite power supply that can vary with use. The size of the battery is also often times very cumbersome to have in the chest for a small child.

Solenoid: Electromagnetic Induction

After considering several power supply designs that focused on a direct supply of power, a new alternative was CONSIDERED that was based on inductive power. The central idea behind inductively powering the system is to use a solenoid in conjunction with an AC voltage source. In general, 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 (Figure 3). The direction of the magnetic field created by the wire can be determined by a "right-hand rule." In order 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 (Anderson). The closed fingers point in the direction of the magnetic field 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.

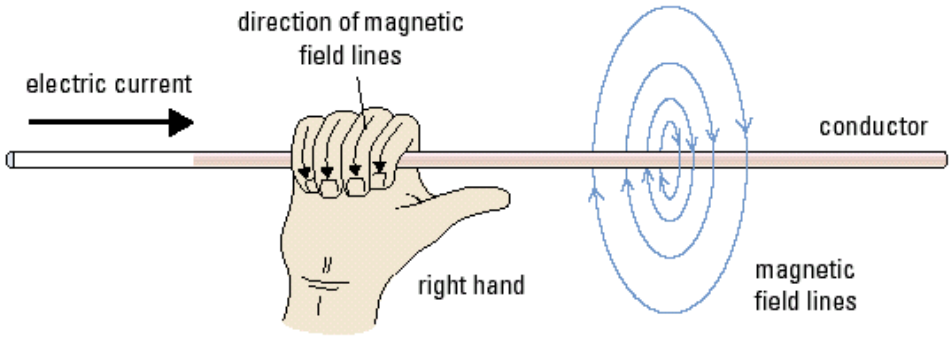


Figure 3: Magnetic Field Created by Current-Carrying Wire

When the wire is coiled into the shape of a solenoid, the magnetic fields created by each loop within the solenoid work to strengthen the overall field within the solenoid and also destructively interfere so the strength of the magnetic field outside the solenoid decreases drastically with distance. By powering the solenoid with an AC voltage source, the magnetic field that is produced within the solenoid will change direction and strength in time. This changing magnetic field is the important driving factor in powering the circuit attached to the skull through electromagnetic induction. According to Faraday's

Law, an electromotive force can be created in the secondary loop that is attached to the patient's head due to changing the magnetic flux through the loop (Figure 4).

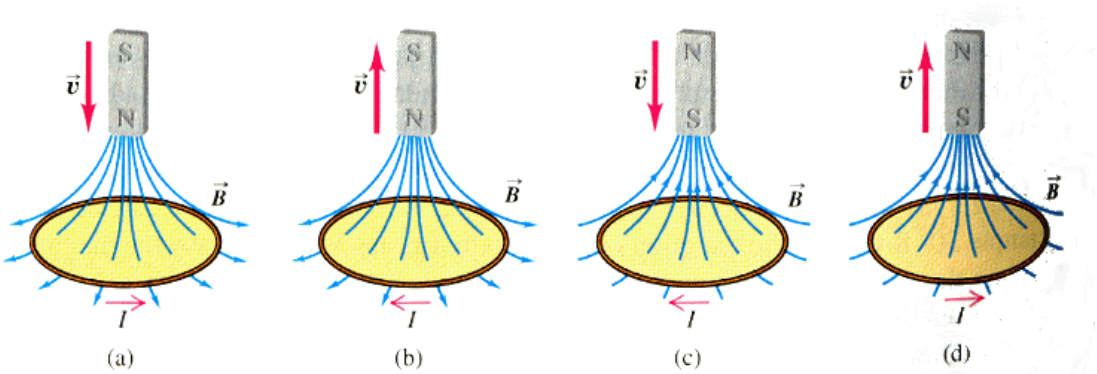


Figure 4: EMF Created by Changing Magnetic Flux

As can be seen in Figure 4 (Wohlgenannt), the magnetic flux is incrementally increased and decreased by moving the bar magnet closer and further from the loop. This is the same concept that will be utilized by combining a solenoid with an AC voltage source; the AC source will alter the direction and strength of the magnetic field in time, thereby inducing a current in the secondary loop. In order for the solenoid design to function, it is important to design the solenoid such that the magnitude of the magnetic field will be sufficient to induce a strong enough electromotive force to power all the circuitry attached to the skull.

The first important aspect in creating a sufficient power supply by using a solenoid is to make use of the geometry of the solenoid. For an ideal solenoid, the magnetic field that is produced within the solenoid is equivalent to the number of turns in the solenoid, current through the solenoid and length of the solenoid (Equation 1):

$$B = \frac{\mu_0 NI}{L}$$

In this case, N equals the number of turns, I the current, L the length and μ_0 the permeability of free space, which is a physical constant that relates mechanical and electromagnetic units of measurement (Hyperphysics). The above equation represents the magnetic field that is created when the core inside the

solenoid is air. When another material is inserted into the solenoid, the magnetic field changes according to the approximation (Equation 2):

$$B = \frac{\mu_0(1+\chi)NI}{L}$$

The constant χ is the magnetic susceptibility of the material that is inserted into the core (Hyperphysics). This value can vary from negative values to positive values of several thousand and depends on the type of material that is used. Diamagnetic materials are those that don't possess any appreciable magnetic properties and when used as a core will actually act to oppose the applied magnetic field and decrease the overall strength of the field. Paramagnetic materials don't emit magnetic fields by themselves, but when subjected to an external field will become slightly magnetized and work to strengthen the magnetic field. Finally, ferromagnetic materials can be permanently magnetized when subjected to an outside field and therefore work to greatly enhance the overall magnetic field. It should be noted that the above approximations are used to calculate the magnetic field within the interior of an ideal solenoid experiencing a direct current through it. An ideal solenoid occurs when the length of the solenoid is great enough to ignore fringe effects, or when the length is very long compared to the radius of the solenoid and the magnetic field is measured near the center of the solenoid.

While the above equations are good approximations for the magnetic field found within a solenoid, it is much more difficult to calculate the magnetic field outside the solenoid. As already stated, the magnetic field outside the solenoid drastically decreases as the distance from the central axis of the solenoid increases. Additionally, the solenoid that will be used as a power supply will not be an ideal solenoid because the length and radius of the solenoid must be such that it can be handheld by the operator. Therefore, it is important to derive calculations for the magnetic field outside a finite solenoid to determine the characteristics that are needed of the solenoid in order to produce a strong enough changing magnetic field to provide ample power supply to the circuit on the head. First, consideration

was given to calculating the magnetic field outside a finite solenoid along the central axis, this equation is given by (Dennison):

$$B = \frac{\mu_0 \cdot I \cdot N}{2L \cdot (r_2 - r_1)} \cdot \left[x_2 \cdot \ln\left(\frac{\sqrt{r_2^2 + x_2^2} + r_2}{\sqrt{r_1^2 + x_2^2} + r_1} \right) - x_1 \cdot \ln\left(\frac{\sqrt{r_2^2 + x_1^2} + r_2}{\sqrt{r_1^2 + x_1^2} + r_1} \right) \right]$$

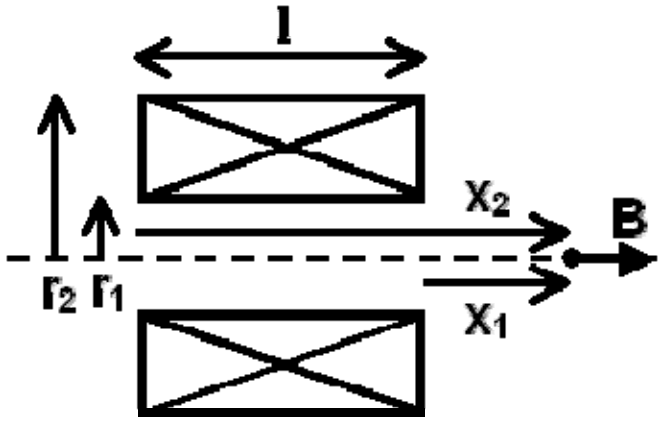


Figure 5: Magnetic Field at a Point Along Central Axis

Where, as can be seen from the figure, 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, I is the current through the wire, and N is the number of turns of the wire (Dennison). As can be seen, the degree of difficulty in calculating the magnetic field is much greater when dealing with a non-ideal solenoid outside the solenoid. 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).

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

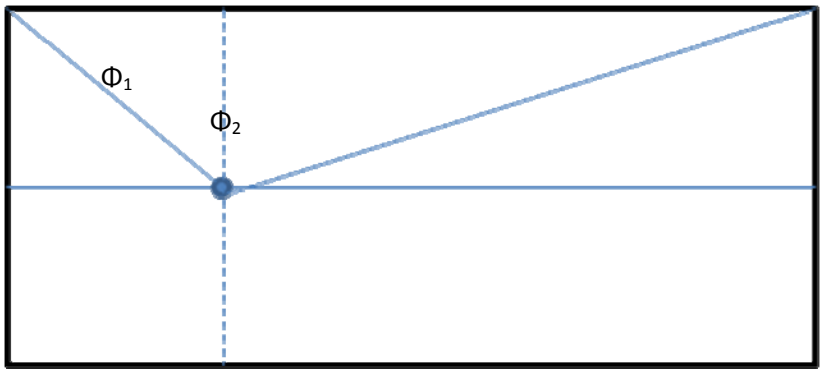


Figure 6: Alternative Method for Finding the Magnetic Field at a Point Along Central Axis

The constants remain the same in this equation as the one that was given. Additionally, Chia and Wang also showed that the magnetic field reaches its maximum value at the exact center of the solenoid and decreases as the point of interest approaches the ends of the solenoid. Once the solenoid is exited, the magnetic field decreases extremely drastically. In fact, they were able to plot the relative strength of an induced EMF with respect to the position at which it was placed with respect to the solenoid. They found that the relative strength of the magnetic field dropped to essentially zero when the secondary coil was placed at a distance of 150mm from one end of the solenoid. They did their testing by using a solenoid of copper wire with 472 turns, length of 15cm, diameter equal to 5.7cm, wound around an axial glass rod with diameter .8cm, and a secondary coil with 25 turns and a width of approximately .4cm (Chia).

As can be seen, the magnetic field decreases drastically once the core of the solenoid is exited. Therefore, in order to strengthen the magnetic field it is very likely that a ferromagnetic core will need to be used in conjunction with the solenoid to strengthen the magnetic field. Unfortunately, there is not a linear relationship between the applied field created by the current and the overall magnetic field that is the sum of the magnetic field within the ferromagnetic material and the applied field (Booske).

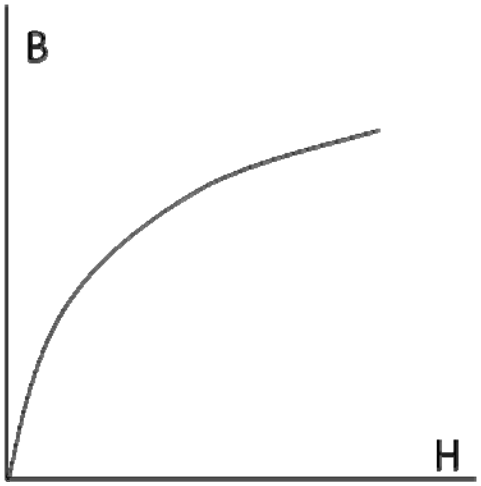


Figure 7: Overall Magnetic Field as a Function of Applied Magnetic Field with Ferromagnetic Core

As can be seen from the graph above, the overall strength of the magnetic field will increase greatly at first. But as the strength of the applied magnetic field increases, the overall strength of the magnetic field begins to increase to a smaller degree as it approaches somewhat of a limiting value. As can be seen, the ease of calculating the actual magnetic field when a ferromagnetic core is present is again more difficult and cannot be estimated by using the approximation that was found in Equation 2.

Although using a ferromagnetic core makes the calculations of the magnetic field much more difficult, it does present a very big advantage over air-core solenoids. When using a ferromagnetic material, the material can be tailored such that it focuses that magnetic field to a more specific point or location. This can be seen in Figure 8, 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).

Figure 8: Focusing the Magnetic Field by Narrowing Ferromagnetic Core

By using this idea, the magnetic field can both be strengthened and focused to a certain location, thereby greatly increasing the magnetic flux through the secondary coil on the head. By increasing this field in this manner, it can be guaranteed that there is sufficient magnetic field to power the circuitry.

Design Matrix – Power Supply

In order to evaluate each of the power supply designs, a design matrix was constructed with the important design characteristics weighted based on their importance to the prototype. As can be seen from the design matrix, the constraints that were assigned the most important were the power delivered to the secondary circuit, lifespan and the resulting patient safety of each design. Power is ranked as tied for the most important because it is vital that the supply provides enough power for the entire circuit attached to the head to function properly. If the power is lacking in any manner, the pressure readings that are obtained from the circuit may not be calculated correctly or the circuit may relay a smaller signal (smaller pressure reading) than should actually be produced. Therefore, it is absolutely essential that the power supply be capable of producing sufficient power to produce accurate readings and ensure the patient is not put at unnecessary risk due to equipment malfunction. In addition to adequate power supply, the patient safety was also taken into consideration and rated heavily. Patient safety plays a huge factor for several reasons. First, as already mentioned, it is essential that the power supply produce a sufficient electromotive force in the secondary circuit. If the EMF is not sufficient, it could put the patient at risk by not relaying an accurate pressure reading. Secondly, any components that are exposed to the environment put the patient at a very high risk for infection. Additionally, the more invasive techniques that are required to implant any of the power supply components also put the patient at a higher risk for infection and other complications that arise from surgery. Lifespan was also given a great deal of consideration because part of the motivation behind the project is to reduce the number of invasive surgeries performed on the patient. The components should be able to produce a consistent amount of power over an extended

duration of time to ensure that the circuitry always functions and also does not consistently require surgery to fix. In addition to these considerations, the cost and size were also taken into account because it is important that the power supply components can fit safely within the patient.

After considering the design constraints that would guide the construction of the prototype, each design were ranked on a scale of 1-7. As can be seen, the solenoid consistently scored the highest in all categories. The solenoid received a 6 for power supply because it will be able to produce a strong enough magnetic field when used in conjunction with a ferromagnetic material to produce the EMF necessary to power the circuit. Additionally, it received a 6 for lifespan because the secondary coil within the skull will be safely implanted and will not experience unnecessary wear. Also, the solenoid on the exterior will be comprised of wire, a ferromagnetic core and an AC voltage source. As long as the solenoid is not dropped repeatedly (which destroys ferromagnetic properties), it will have a long duration because the AC voltage source can be recharged when needed. Finally, the patient safety also received high marks because the only danger would be the original implantation of the prototype and there would be no contact with the outside environment once implanted. The direct power supply also received high marks for power because it would definitely provide an ample supply. The lifespan of the direct supply received somewhat lower marks because the capsule attached to the head would be prone to damage due to it being exposed to the environment. Finally, it received a 1 for patient safety because the capsule exposes the patient to the exterior environment and puts the patient at a high risk for infection. Finally, the battery received lower marks for power supply because the power that is supplied will decrease over time and produce fluctuating and inaccurate pressure readings. This also comes into play when considering the lifespan; because the power decreases with time, it will have a much shorter lifespan and will require surgery to remove on a fairly consistent basis. Finally, it received somewhat lower marks for patient safety because the battery would be implanted into the patient's chest. The surgery increases the risk of infection to the patient; additionally, this device would be implanted into children with a great degree of frequency, so as the child grows the battery may shift after implantation and cause danger to the patient.

After ranking each design on the constraints, it became obvious that the solenoid was the most effective design and would be the safest to the patient and therefore would be the design that would be pursued.

Design	**Power (0.3)**	**Lifespan (0.25)**	**Cost (0.05)**	**Patient Safety (0.3)**	**Size (0.1)**	**Total**
Solenoid	*6 (1.8)*	*6 (1.6)*	*6 (0.3)*	*6 (1.8)*	*7 (0.7)*	*5.1*
Direct Power	7 (2.1)	5 (1.25)	6 (0.3)	1 (0.3)	6 (0.6)	4.55
Battery	4 (1.2)	2 (0.5)	2 (0.1)	5 (1.5)	4 (0.4)	3.6

Power Supply Design Matrix

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.

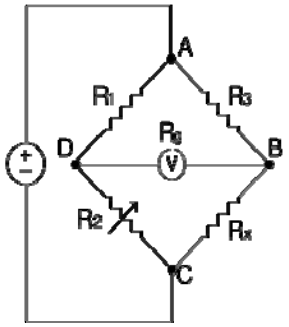


Figure 9: Wheatstone Bridge

(http://en.wikipedia.org/wiki/Wheatstone_bridge)

In the diagram above 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 below.

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

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, 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, where decreasing length causes a lower resistance in the strain gauge.

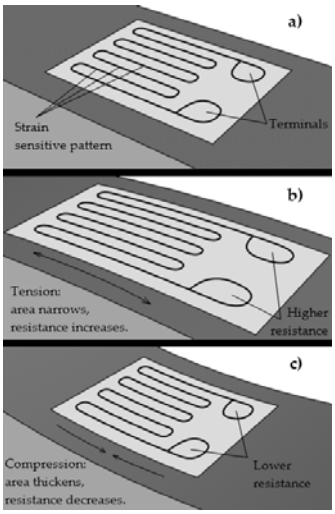


Figure 10: Strain Gauge

(http://www.answers.com/topic/straingaugevisualization-png)

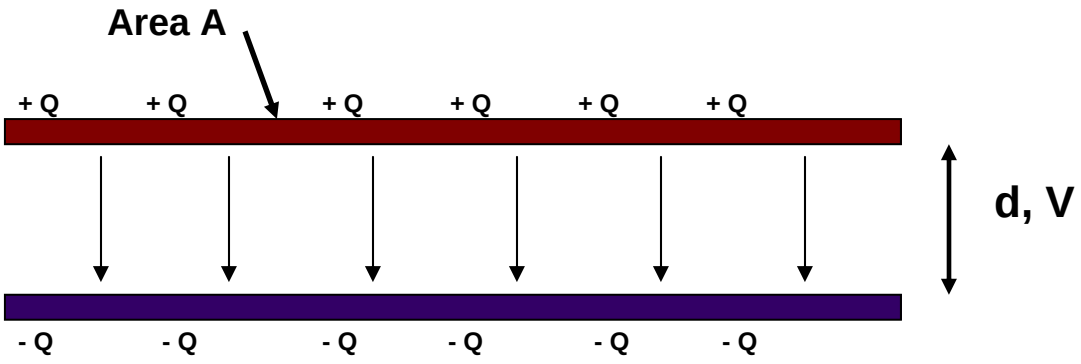
In this design the strain gauge will be placed on the durra membrane, the membrane that surrounds the brain. Therefore, with changes in the intracranial pressure it will cause fluctuations in the durra membrane which will cause deformations to the strain gauge. The resistance of the strain gauge will 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 11: Capacitor Basics



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 $C = \varepsilon A / d$. 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.

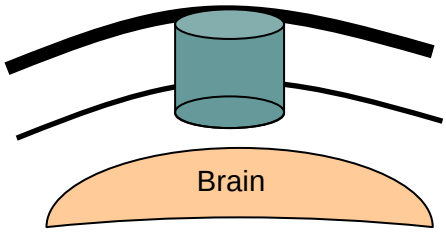


Figure 12: Cylindrical Capacitor Implantation

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. Therefore to determine the voltage drop across the capacitor we will need to not only take into consideration the 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 in order to detect small changes in pressure of approximately 1-2 mmHg.

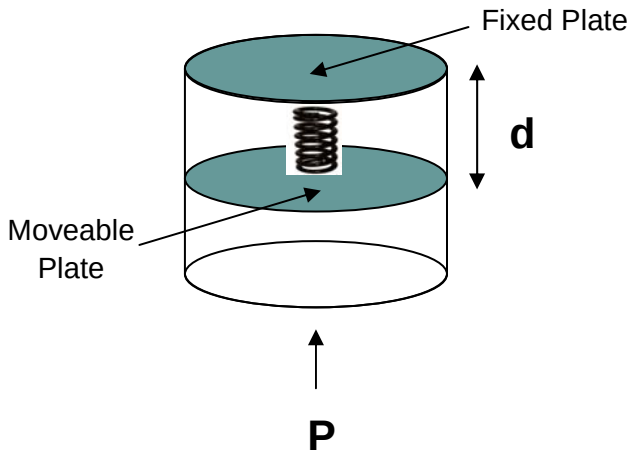


Figure 13: Cylindrical Capacitor

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.

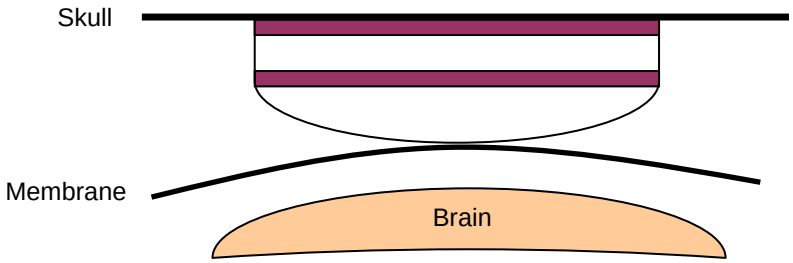
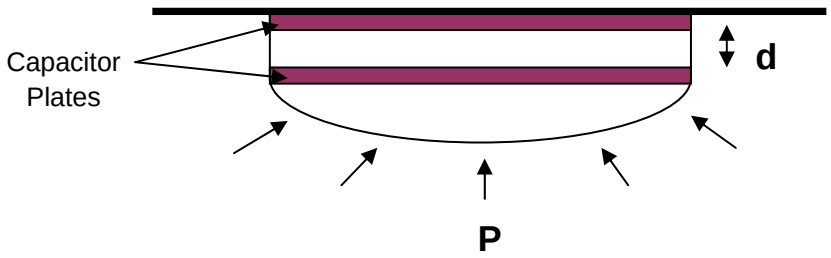


Figure 14: Flexible Dome Capacitor

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 15: 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

Pressure Gauge Design Matrix

The pressure monitor designs were compared by creating a matrix 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 something, namely the pressure inside the head, it should be extremely accurate and consistently give a true reading. The strain gauge was the more accurate of the two designs because it has a higher sensitivity to pressure changes.

Durability was another very important criterion in which the design was rated. The final design of the device should be very durable because one purpose of this project is to reduce the number of

surgeries a patient must undergo. Since this device is an implant, surgery would be needed replace or repair the device, so it is important that the device is durable enough to stay in the patients head as long as possible needed. The lifespan and durability of the three designs were about equal so each received the same rating.

Next, the biocompatibility of the transducers was compared and rated, that is, how safe the implant will be to a patient's body. It can't do any harm to a patient and must remain biocompatible for its lifespan. Again, both designs received the same rating in this criterion because both designs can be made 100% biocompatible.

Finally, the two designs received a rating for their size and cost. Although these two 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 will be going into a patients head. 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.

Future Research and Calculations

For the rest of this semester, more progress must be made on the design by accomplishing some important tasks. Further research will be conducted on the technology for strain gauge and inductive power supply until they are completely understood. For the power supply design, different frequencies and different core materials will ideally be tested to determine the effect of each on the magnetic field. This will also involve doing some in-depth calculations for magnetic flux. The pressure gauge of the design will need to be tested also; and one of the main tests will be to conduct deformation tests and durability tests. Additionally, it is vital to determine the kinds of pressures necessary to produce the

transformations of the strain gauge and determine what voltages are then produced. Piezo-resistive material is something that recently surfaced as another possible design alternative for the transducer and more information will be gathered to determine if it is viable as an alternative. It is a material which has pressure sensitive properties and it is hoped that this may be able to be used in conjunction or instead of the strain gauge design. From there, a final design will be completed using all the data and research that has been gathered and this design will be constructed into a prototype.

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Appendix: PDS

The Product Design Specifications (10/4/07)

ICP Monitor

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

1. **Physical and Operational Characteristics**

a. *Performance requirements:*

The main part of the ICP monitor, the pic microcontroller, will be implanted between the skin and the skull bone. The pressure gauge will then probe through the skull and into the brain. The device used to power the ICP monitor will be a hand-held device used on the outside of the head. The device will be used only when there is suspicion that the patient's shunt has failed. This number will vary from one patient to the next but, on average, will be no more than 10 in a person's lifetime. The device will be powered by electrical inductance from the power source to the PIC microcontroller and will require 15 volts in order to run effectively.

b. *Safety:*

Since this device will be implanted inside of the patient's body, it needs to be made with 100% bio-compatible materials. The inside portion of the device cannot employ any iron, as this would compromise the patient's safety in an MRI machine. The device cannot change temperature at all during powering and needs to run on a minimal amount of power (70-120mA).

c. *Accuracy and Reliability:*

In order to measure output of the device, a waveform output will be produced for positive and negative pressures. The transmitter frequency needs to be within 5 Hz. of the actual value of pressure being produced and the receiver needs to be within 0.01 V of the given transmitter frequency.

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 external power supply should have a life of 6 months, while the internal component should be able to last up to 20 years.

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. The portion of the device that is interior will need to either contain some kind of casing or be able to withstand the different fluids within the body. We will need to ensure that the device does not corrode or becomes altered as a result of these 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. The internal portion that is placed on the exterior of the skull should be no more that 1-2 cm thick and no more than 3-4 cm in length.

i. *Weight*:

The weight of the TIP monitor should be light, relative to the weight of a human head. There is no minimum weight. The patient should not have difficulties adjusting to the weight of the device, i.e. too heavy and the patients balance could be effected.

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 a preferred option. The product should be made of bio-? material, such that the body does not reject the implant.

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 (I don't know about this)

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)

3. Miscellaneous

a. *Standards and Specifications:*

FDA approval is needed before the device can be used on patients.

b. *Customer*:

Based more for kids who have headaches, nausea, and seizures caused from shunt malfunctions

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.

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