Preliminary Design Report

Dan Frost, Rebecca Koszalinski, Justin Lundell, Michael Socie

University of Wisconsin-Madison

BME Design 201

Intracranial Pressure Monitor

Naomi Chesler

March 14, 2007

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Design Problem

We are to design a device to be implanted into the frontal section of a patient's brain to monitor the intracranial fluid pressure (ICP) in order to troubleshoot problems with failed shunts. Patients with headaches, nausea, and various other symptoms need to be able to use the device to test their own ICP. The device should also output data to be interpreted by a trained professional to diagnose shunt failure or abnormalities in the ICP. The design will use inductive power to eliminate the need for batteries or wires going into the head, and will thus be much safer, more efficient, and less costly.

Background Information

The monitoring of the ICP is critical for many patients of all ages. A common procedure for patients who experience elevations in the ICP involves the insertion of a shunt into the brain to drain excess cerebral spinal fluid (CSF). The shunts are straw-like and allow the CSF to drain, thus lowering the patient's ICP. However, shunts often become blocked or clogged, at a failure rate of 17% in the first year of use (Medow, 2007). When this occurs it may be hard to tell if the patient is undergoing symptoms from a different illness or just complications from a malfunctioning shunt. Our device will eliminate this confusion and be able to accurately diagnose increasing pressure.

Hydrocephalus, literally meaning "water brain," is a condition in which CSF collects in the brain in excess, leading to a raised ICP. It is generally caused by blockages in the arteries flowing to the brain. This is a serious condition that if left untreated can lead to life-threatening consequences, and is unfortunately hard to diagnose, especially in children. The symptoms for this condition, including headaches, vomiting, nausea, sleepiness, and even coma, are not unique, and obviously could be symptoms of a multitude of other conditions. Young children don't often report all of the symptoms they are experiencing, and this coupled with the fact that the symptoms are not unique can lead to misdiagnosis.

There are current methods being used to monitor the ICP, however, these are costly and inaccurate, and some can be dangerous. One method is to produce an image of the brain of which to study, and this can be done by using either CT scanning or ultrasound scanning (Medow, 2007). However, frequent CT scanning means frequently sending x-rays through the brain, and this radiation can prove dangerous. The use of an ultrasound provides a rough image of the brain, but this can be very unclear. Both of these methods provide only images of the brain, and data on actual pressure is induced by professionals, which is less efficient than a direct measurement and data. Another method being used is invasive and requires surgery. Two examples of this are: open exploratory surgery and a shunt tap operation to measure the pressure or drain fluid from a previously inserted shunt. Eliminating the need for multiple surgeries will greatly reduce expenses and also be much safer for the patient.

We hope to improve the efficiency, safety, and ease of use with our new design. Improving on current methods is a main goal of our project, and would provide benefits to a great range of patients. By permanently implanting a device in the skull which

inductively outputs measurements to an external device, we will allow patients to test their ICP anywhere, reducing hospital visits. This means that whenever a symptom is felt, the patient can test the ICP and get measurements quickly, lowering the chance of a large increase in pressure. Another key component of our new technology is that it will chart the change in pressure over time, and does not just provide a snapshot of pressure at one moment in time. And finally, the elimination of painful surgery and potentially dangerous radiation from CT scanning greatly increases the safety of the process.

In order to provide the best possible product, with the most efficient technology, cost effectiveness, and safety, our design includes some constraints. Because our product will be implanted in the skull long periods of time, we need it to be small and durable. When not in use, the inside component should be nothing more than a small bump under the skin. Durability is a key issue because we don't want any pieces of the product to damage, and avoiding surgery to replace the product is important. Another key constraint is the fact that this device must be made out of suitable materials. We do not want any materials that may cause complications with an MRI machine, meaning no iron, and also nothing that could lead to infection. Low power is also crucial, because we do not want to have to send a lot of current into the brain to power the device. As far as the performance of the device is concerned, it must be accurate and reliable over time. The readings should provide precision within one mmHg unit. The device will measure between -10 to 50 mmHg, so this precision will provide accurate measurements. Also the accuracy must drift less than 1% annually, so that even after extended use the device will still provide be reliable. The complete product design specifications can be found in the appendix.

Motivation for this project stems from the fact that a more reliable, safe, and efficient method for measuring the ICP is something that will benefit many patients of any age group, and may eliminate misdiagnosis in terms of shunt failures. With induction powering we will reduce the amount of surgeries a patient will have to undergo and create a safe and accurate process that does not necessarily need to be run by a trained professional. Additional information that we will strive to attain includes exact size specifications of the device based on measurements of skull and brain size, accuracy, drift, and durability characteristics of materials and components, and more information on induction coils and powering.

Alternative Solutions

We have developed two distinct designs to successfully measure and report intracranial pressure as specified by our design constraints. Our first design is a component based design where the overall design layout and function is the same, but there are two key parts that have multiple options that would present different advantages if they were selected to be in the final design.

Generally, the way the component based design works is as follows: our device, shaped somewhat like a flat thumbtack, will be implanted in the frontal lobe of the head with most of the device superficial to the skull and only a small pin-like extrusion going through the skull and deeper into the intracranial fluid (*Fig. 1*). This pin-like extrusion would house a pressure transducer, which is the component that actually monitors

changes in fluid pressure. Pressure transducers require power to function, which would be provided in our design by induction.

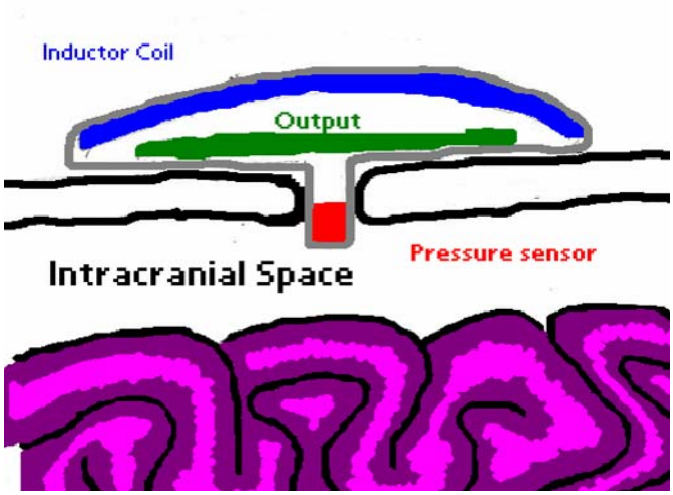

Figure 1. General shape and positioning of device.

Inductive power refers to creating an electric current using conductors and magnetic fields. It allows for current to be produced without any wired connection to a power source such as a battery. To successfully create inductive power requires two things: a source of changing magnetic field and a conducting coil that can be conducting wire coiled into circles several times. The voltage produced is related to the change in magnetic flux, which can be achieved either by a changing magnetic field, or a constant magnetic field that is being moved toward and away from the coil. The amount of voltage produced in the coil is controlled by the magnitude of the magnetic field, the area enclosed by the coil and the angle between the magnetic field and the central axis of the coil (Webster, 2007).

Inductive power is ideal for our device because of the hazards of other power sources inside the head (Medow, 2007). For instance, we can not wire our device to a battery outside the head because of the risk of infection that would arise from having wires going into the skull. Furthermore, we can not just put a small battery in our device because it would interfere with MRIs as well as introduce the issue of having to replace the battery at some point. Therefore, inductive power makes the most sense for our device because of the ability to send power into the skull without any physical wires or any issue of battery life.

Our component based design would include a receiving coil that would sit outside the skull in the outer portion of the tack. Current would flow in this coil when the inducting source is brought over the device on the outside of the head. However, this current would be coming in as alternating current (AC). To power the pressure transducer, we need to convert this alternating current to a constant direct current (DC). To accomplish this, we would include a rectifier and a voltage regulator in the circuit between the receiving coil and the pressure transducer. A rectifier is an electronic device that converts alternating current to direct current. This process can be carried out by a single diode, but more complicated circuits have been assembled to provide a more efficient rectification. While rectification suffices to give a form of DC output, it still maintains a cyclical nature. In order to create a constant DC output, the waveform needs

to be stabilized by a voltage regulator. The voltage can be regulated by a zener diode, which regulates the voltage across a circuit when connected in parallel. This is the simplest way to regulate the voltage across a load, but it is inefficient because it drops the excess current not needed by the load. There are more efficient ways to regulate the voltage, specifically linear regulators. Linear regulators create little output noise and have a fast response to input and output disturbance. They effectively act like a variable resistor, constantly adjusting a voltage divider to maintain a constant output. Unfortunately, they require an input voltage higher than the desired output, since our device is powered by induction and we're effectively using this rectified voltage to power our pressure transducer, it would be difficult to power an active voltage regulator.

This constant, rectified voltage is then sent to the pressure transducer to allow it to read the intracranial fluid pressure. Pressure transducers are one of the pieces that have multiple options for ways we could go. The two options we looked at were resistance based pressure transducers and capacitance based pressure transducers.

Most implantable sensors are piezoresistive devices, where mechanical stress causes a change in electrical resistance (National Instruments, 2007). This is usually comprised of a silicon diaphragm with piezoresistive strain gauges inside it, attached to a silicon or glass back plate. Unfortunately theses sensors have a long term baseline drift (> 5mmHg/month) which is excessive for the range of pressures we're measuring (-10 to 50 mmHg). Also since strain gauges use a Wheatstone bridge configuration of resistors, they are somewhat inefficient in their use of power (Dwiarda, 2007). The Wheatstone bridge is design consisting of 4 resistors, two in series and two in parallel, in which 3 of the resistances are known. The fourth resistor operates over a gap, so that current through the resistor with respond differently depending on pressure. Pressure increases with voltage, so the unknown resistor can be determined based on the known initial voltage and the known return voltage (Wikipedia, 2007). The Wheatstone bridge does require power consumption and has unfavorable drift characteristics (Dwiarda, 2007). Alternatively, capacitive sensors measure the pressure by the changing position of a diaphragm which acts as one plate of the capacitor. They have high sensitivity, low power consumption, and are less prone to baseline drift.

When a voltage is outputted from the transducer, it can not directly convey a message out of the head. Therefore, we will use radio waves to transmit signals that can be interpreted outside the head and displayed on an oscilloscope or another type of monitor. To do this, we must have a voltage to frequency converter that takes the voltage output from the transducer and converts it to a frequency (in hertz) that can be conveyed with radio waves. There are two ways that we could go to communicate the signal with radio waves. First, we could have a radio wave outputter inside our device that will take the frequency from the converter and transmit a radio wave on a specific frequency that's amplitude will reflect the actual pressure. The other thing to do with radio waves it to use radio frequency identification (RFID) technology. A radio wave would actually be sent in at the device which would include an RFID tag that can pass signals by modifying the signal that is being sent in. These modifications are traceable on the sending end and make active RFID tags very effective at monitoring change. RFID technology is currently used in highway tolling such as the "I-Pass" that allows cars to be recognized as they go through toll booths and have the toll removed from an account rather than having

to stop and physically pay. Other applications of RFID technology include Smart-Keys for cars, as well as a number of logging processes for temperature, radiation, etc.

Once the signal is received again on the outside of the head, it will be calibrated and interpreted so that a pressure reading will appear on some sort of visual aid for the physician such as an oscilloscope. This will allow the physician to see exactly what the pressure is and to monitor its changes over time.

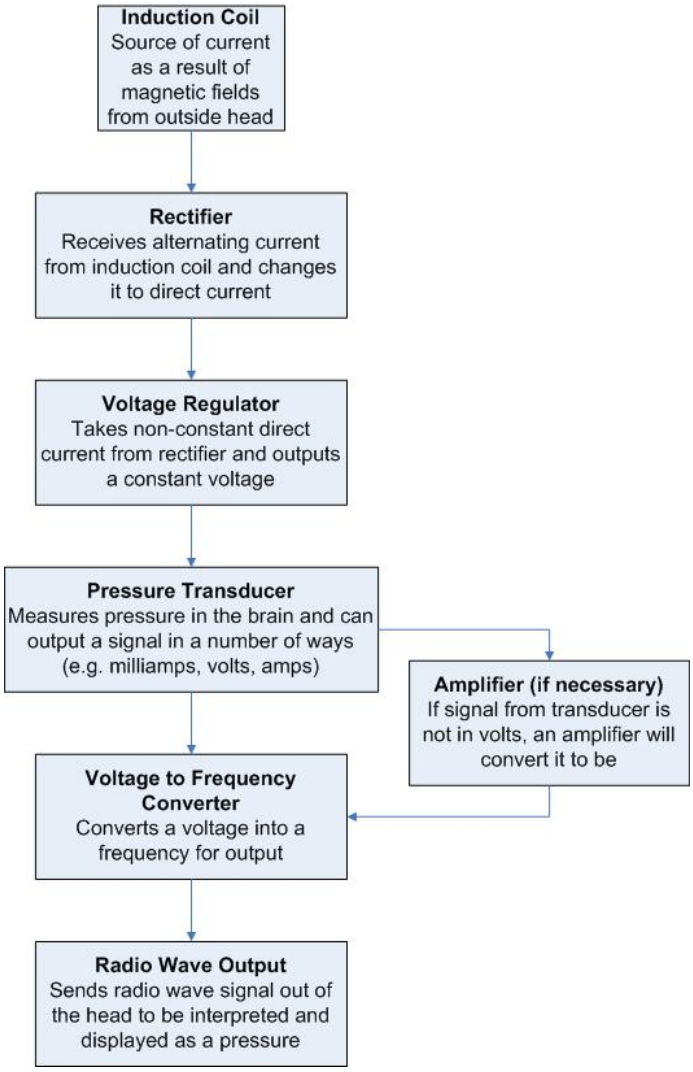

Figure 2. Schematic of interaction between different components of design.

Our second design alternative to solve our problem is what we call a resonant coils design. This design is based on a characteristic of a conjugated set of wire coils (Webster, 1978). The implantable device is a small sealed container, where one coil is fixed to the top, while the second coil is attached to a flexible silicon diaphragm (*Fig. 3*). A device called a "grid dip meter" is placed outside the head and scans a range of frequencies. The conjugated coil system will resonate at a certain frequency, much like a musical instrument (*Fig. 4*). This resonant frequency is dependent on the distance between the coils. As a result, the resonant frequency is directly related to the distance of

deflection of the silicon diaphragm. The inducted frequency can then be converted equivalently to give a corresponding pressure readout (Webster, 2007).

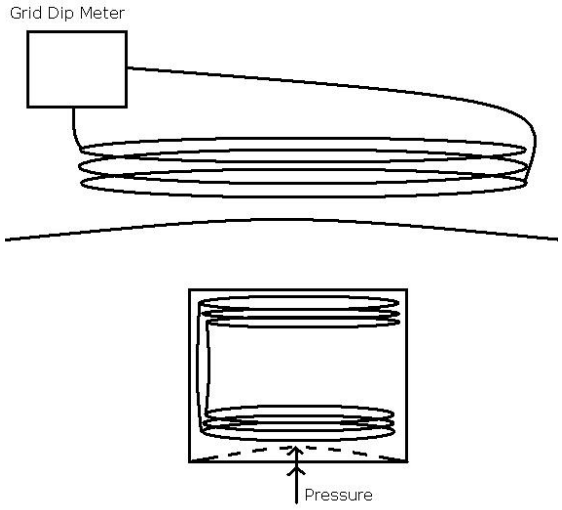

Figure 3. Resonant coil schematic.

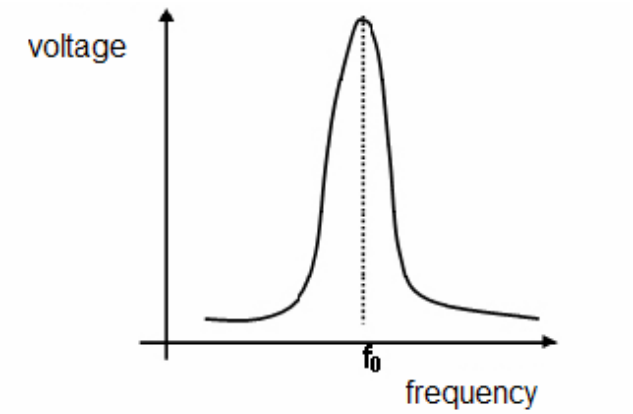

Figure 4. Graph of voltage vs. frequency for resonant coils.

Proposed Design

We decided to pursue the resonant coils design. It is the most power efficient model we developed because the internal circuit does not need to be powered in a traditional sense. The power required to run the implantable device is transmitted with the scan of the resonant coils. We also feel this is a simple and elegant solution to our design problem. It is made up of few parts, and we feel it will be the least problematic design to construct. Also since it has very few components (a fixed coil and a coil attached to a flexible diaphragm) we will be able to minimize the size of implanted device in order to make the surgery less invasive. Also due to its reduced size, the size of the bump created by having this device set on top of the skull will be reduced, making the final result more cosmetically appealing to the patient. We also feel this is the most innovative and creative solution to the problem, and we feel it will be the most interesting to develop.

Future Work and Considerations

Going forward, we need to select and acquire all of the necessary parts that we will need for our prototype. This includes the implantable piece with the dual-linked coils as well as an inductive power source and a grid dip meter for the portion outside the head. From there, we need to fabricate our prototype and start testing for accuracy, drift, and durability. It is hard to predict how our product will react to the proposed environment, which is why testing will be an important part of our design phase. Another potential problem lies in the minute size of the device. For this reason, it would be very difficult for us to build the implantable piece of the device ourselves so we need to find a company to purchase a product from or seek extra assistance during prototype fabrication.

Appendix

Product Design Specifications

Function

The device should be implanted into the frontal section of a patient's brain to monitor the intracranial fluid pressure (ICP) in order to troubleshoot problems with failed shunts. Patients presenting with headache, nausea and various other symptoms need to be able to use the device to test their ICP. The device should also output data to be interpreted by trained professional to diagnose shunt failure or abnormalities in the ICP.

Client requirements

- transcutaneous pressure to be measured outside lumen
- non invasive
- produce logical output
- telemetry unit so data can be interpreted from their homes
- Small
- User friendly
- MRI compatible
- Low power need
- Use available technology

Design requirements

1. **Physical and Operational Characteristics**

a. *Performance requirements*: It needs to measure changes in pressure, it is going to measure those changes and the direct reading is going to be read in differences in voltage but it needs to be output in pressure (mmHg). The output should be displayed graphically to be interpreted by the physician. The pressure should be able to be measured continuously

b. *Safety*: Since it's implanted into the brain, it needs to be biocompatible. To be MRI compatible it needs to be durable to large voltages and currents (120V?) caused by the MRI it also needs to be made of non-ferrous materials. Our goal is to use 100 to 120 mA and 10 to 15 V to power the implantable device in order to not interfere with brain function. It should have encased electrical components to avoid electrical shock to the patient. It should not produce an excess of heat relative to internal body temperature 98.6 degrees.

c. *Accuracy and Reliability:* The normal ICP is about 15 mmHg so it needs to measure pressures in this range. It should be able to interpret measurements on the range of -10 to 50 mmHg. It should be accurate to 1 mmHg. Repeated measurements in quick succession (5 minutes) should produce consistent results.
d. *Life in Service*: Since it will require surgery to implant the pressure sensor, this part of the device should have a long life span (~2 years). The external device does not need to be as durable since external batteries are more easily replaced. It needs to have low drift (less than 1% degrading of accuracy per year).
e. *Shelf Life*: The external power source's batteries should last through at least 50 uses.
f. *Operating Environment:* The implantable device will be exposed to brain fluid and elements the brain is exposed to including magnetism and radiation. The external part will be used in a home environment and possible subject to patient abuse and household villains like dust and mold.
g. *Ergonomics:* Holding onto the device should be comfortable.
h. *Size:* The internal device should be minimized to be non-invasive (1 cc max). The external device needs to be small enough to hold in one hand (the size of a grapefruit.)
i. *Weight:* The external device should be light enough to hold over your head for a few minutes with one hand (1 lb or less).
j. *Materials:* It could be exposed to an MRI so no ferrous materials. Other than that, bio-friendly materials are required.
k. *Aesthetics, Appearance, and Finish*: The internal device needs to be finished in a way to avoid deterioration being exposed to the body's internal environment.

2. **Production Characteristics**

a. *Quantity:* Initially one working prototype, eventually enough to accommodate population of patients with cerebrospinal fluid shunts.
b. *Target Product Cost:* manufacturing cost under $300, eventual patient about $3000 or covered by insurance.

3. **Miscellaneous**

a. *Standards and Specifications*: FDA approval
b. *Patient-related concerns*: sterile, stored at home
c. *Competition*: Medtronic InSync Sentry CRT-D Device has similar application for intrathoracic fluid with OptiVol fluid status monitoring.

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