Intracranial Pressure Device

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Abstract

The problem proposed by our client is difficultly monitoring intracranial pressure non-invasively. Current methods require surgical operations that make them expensive and inefficient. The goal of our design project is to create a permanently implantable intracranial pressure monitor that can relay information about the pressure of the cerebrospinal fluid to an external meter. Our solution to this problem serves to minimize the electrical components inside the head. This makes the device less invasive to implant and makes the device cause less interference for MRI. The device measures the pressure in the head by measuring the deflection of a plastic diaphragm. Deflection of this diaphragm will be caused directly by pressure in the intracranial fluid. A sensor measures the distance between itself and the aluminum inside the implanted device using eddy currents. When the device is properly calibrated, each distance between the sensor and the aluminum in the device will correspond to a value for intracranial pressure.

Problem Statement

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 ICP or have a non-medical professional use the device on them, though this procedure may need to be done at a medical facility. The device should also output data to be interpreted by a trained professional to diagnose shunt failure or abnormalities in the ICP. If power is necessary for the device, it must be supplied to the inside of the head inductively, with no use of batteries or wires through the skull.

Background

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 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.

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 (Lundkvist, 2003). When this occurs it may be hard to tell if the patient has new 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.

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 using either CT scanning or ultrasound scanning (Moreno, 2000). However, frequent CT scanning means frequently sending x-rays through the brain, and this radiation can be dangerous. The use of an ultrasound provides a rough image of the brain, but can be unclear. Both of these methods provide only images of the brain, and professionals infer data on actual pressure, 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 that 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.

There are some existing devices that are used to measure either the ICP or the blood pressure, and these devices use similar technology that our device will use to measure the ICP. Radionics created a telesensor device that can give a rough reading of the pressure in the head. However, this device will only tell if a patient's ICP is relatively high or low, and our device needs to be much more accurate and give actual data of how high or how low the pressure is. There are two other devices, which measure blood pressure, the Medtronic Hemodynamic Monitor, which is implanted in the arteries, and the Duncan Graham-Rowe battery-less implant, which is implanted in the heart. The blood pressure is much higher than the average ICP, and because they are both connected to an external device, they are not permanently implantable into the head. Our device will use similar technology and address the need of measuring the ICP with only one surgery required.

Design Constraints

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 be damaged 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. The device will measure between -10 to 50 mmHg, so 1 mmHg is a reasonable acceptable error. 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.

Alternate Design Solutions

We have developed three distinct designs to successfully measure and report intracranial pressure within 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.

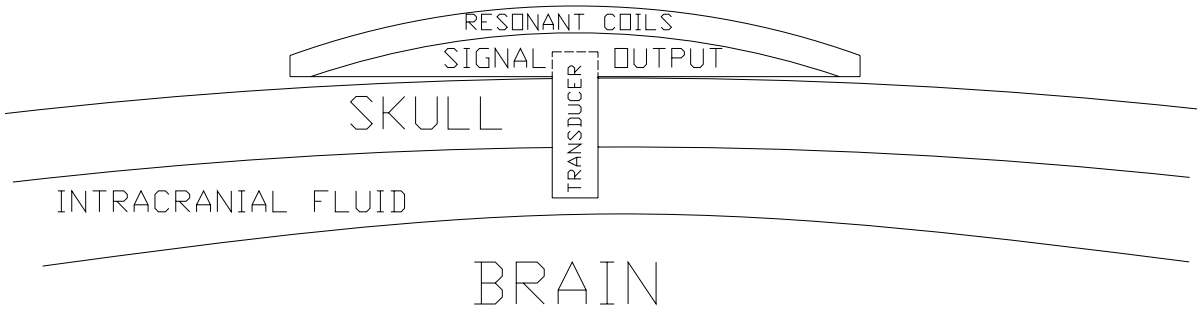

Figure 1. General shape and positioning of device.

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 cannot 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 cannot 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 (Medow, 2007).

Pressure transducers are one of the pieces that have multiple options. 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 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 responds 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 (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 will be used to send radio waves to that can be interpreted outside the head. 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 communicate the signal with radio waves. First, we could have a radio wave output device 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. Alternatively, a way to use radio waves to send signals is to use radio frequency identification (RFID) technology. A radio wave would be sent into the head at our device which would include an RFID tag that can pass signals by modifying a signal that is bounced off of it. 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 (Rao, 1999).

Once the signal is received on the outside of the head, a computer program could convert this radio wave to a pressure based on a calibration equation that would be formulated during product testing. Since the amplitude of the wave would change to reflect changing pressure in the head, it is possible to equate each value for amplitude with a specific pressure. The details of this calibration could not be determined until the testing phase. Once the radio wave is converted into a pressure reading, any screen could be used to display that information to the patient, patient's family, or physician in the room.

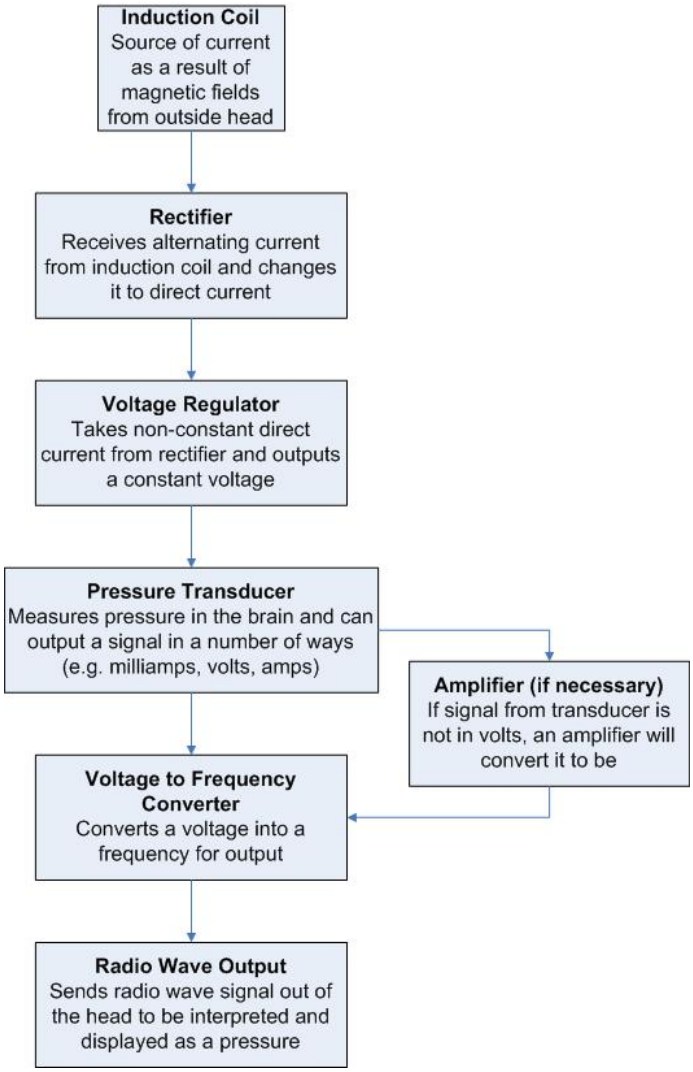

Figure 2. Schematic of interaction between different components of design.

Our second design alternative 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 corresponding pressure readout (Webster, 2007).

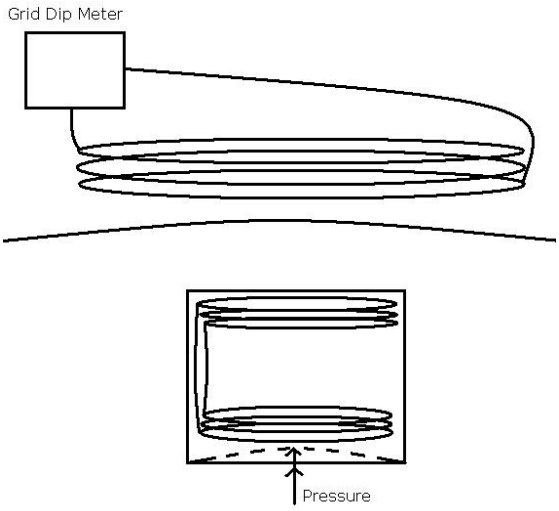

Figure 3. Resonant coil schematic.

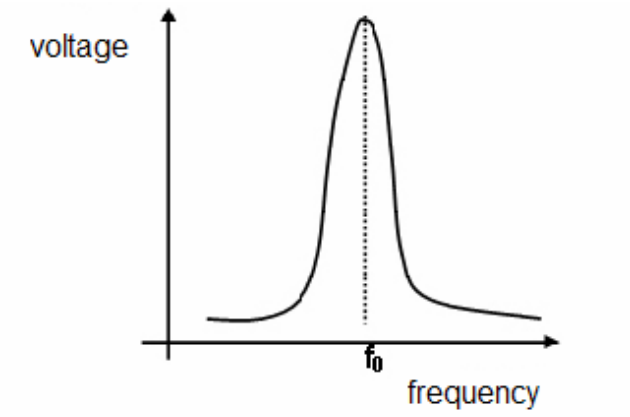

Figure 4. Graph of voltage vs. frequency for resonant coils.

Our third design alternative uses inductive technology and a pre-developed pressure transducer to measure displacement as it correlates with a pressure. The pressure transducer, which utilizes eddy current technology, would be ordered from an existing company, either Kaman or MicroEpsilon. This sensor would be completely external, and would have to be kept at a doctor's office, eliminating home use. The sensor would bounce a signal off of our implanted prototype and get a reading back in voltage. The necessary target material for this signal reflection is a non-ferrous metal disk. The sensor is then programmed to transform this signal into a displacement from the target disk. We could then create a calibration curve correlating each displacement to an intracranial pressure. Our prototype would be the internal component, consisting of an outer casing, a metal disk, and a flexible membrane (see figure 5). The membrane would be exposed to the intracranial fluid and react to changes in pressure. For example, as the pressure in the cavity increased, the membrane would deflect away from the brain, toward the outside of the head. This displacement would cause the metal disk to slide closer toward the sensor. The sensor could detect this change and report it in the form of a lower distance to target. Using calculations, an ICP could be derived. The advantages of this design are that it is simple to construct, inexpensive, contains few parts internally, and the electronic component is not complicated. This design choice could be disadvantageous in that it requires a durable but flexible membrane, the pressure transducer is quite expensive, and could be inaccurate.

Figure 5. Cut away of membrane design.

Evaluation of Preliminary Designs

	Weighting	Resonant Coils	Components: Resistance & RFID	Components: Resistance & V to F converter	Components: Capacitance & RFID	Components: Capacitance & V to F converter	Membrane Design
Power Consumption	1 / 6	5	3	2	4	3	5
Durability	1 / 6	3	4	3	3	3	5
Precision	1 / 6	4	3	3	4	4	1
Drift	1 / 6	1	2	2	4	4	4
Ease of Construction	2 / 6	4	2	2	2	2	5
Total:	1	**3.5**	**2.7**	**2.3**	**3.2**	**3.0**	**4.1**

For us, ease of construction was given a higher weighting because given the nature of this course and its time constraints, it was important for us to select a design with which we would be able to produce a prototype for the end of the semester. In this area, the membrane design outshines the others in its simplicity. The component we need to manufacture does not contain hand-spun coils like the other designs. It also contains limited internal electrical components. This boosts its durability, and prevents it from interfering with medical imaging.

Next to the membrane design, the resonant coil design is the best alternative. It is power efficient 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. It is made up of few parts, and compared to the component designs, easier 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.

The component-based designs have higher power consumption because they have more complicated internal circuitry. This circuitry also makes them much harder to

construct. Capacitive transducers are more precise and have less drift, but are more difficult to locate and may need to be manufactured manually.

Final Design

For the final prototype, we opted to go with the third alternative, the membrane design. We decided to use MicroEpsilon's EddyNCDT sensor. This sensor is $3600, including a digital readout. This is expensive, but only one of this component would be required, and it would stay in the hospital/doctor's office. We acquired an evaluation model in order to determine if the sensor would function with our prototype before an actual pressure transducer would be purchased. The outer casing of the prototype is cylindrically thermoformed polypropylene with a polypropylene cap on top, which will sit outside the skull and allow the device to be attached to the skull with medical screws. We chose to use polypropylene because it is a plastic that is cheap, easy to work with, and is bio-compatible. Polypropylene has been used in the past for artificial hips, which gives us confidence that the body will not form scar tissue around it and treat it like an outsider, which could interfere with our device. For prototype fabrication, we ordered 5 polypropylene sheets from McMaster.com for $1.60 per sheet. Each polypropylene sheet was 12'' x 12'' and 1/16'' thick. The cylindrical casing of our prototype is 8mm in diameter and 20mm in height (see figure 6). The cap is 3mm thick and extends 22mm in diameter. The walls of the cylinder are about 2mm thick. We stretched polypropylene to make a deflectable membrane that is only a few microns thick. Inside the casing, an aluminum rod will be resting on the membrane as the target material. The rod in our prototype is 4.76mm in diameter and 18mm long, to ensure the signal does not penetrate it without reflection. We chose aluminum because it is a non-ferrous metal that has good conductive properties, making it a good target source for the eddy current sensor. We ordered several aluminum rods for fabrication from McMaster.com for a total of $15.00. The total cost of materials for us to build our prototype was $25. However, we ordered more than the material we needed to allow for mistakes in fabrication. The actual cost of materials for one prototype would be less than $5.

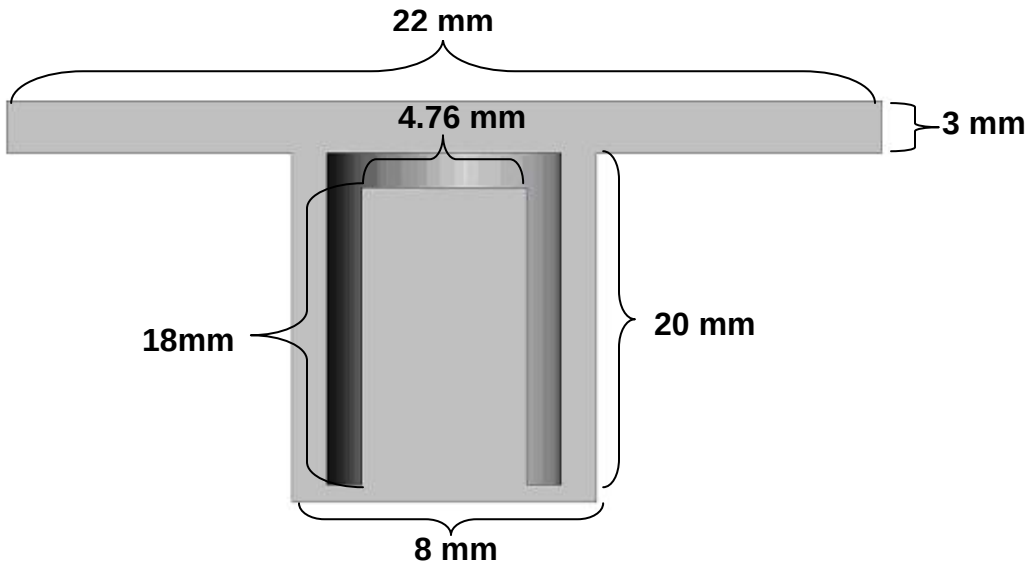

Figure 6. Final design with dimensions.

Prototype Construction

There are two methods to mold and make polymers that we examined to build our prototype. The first method is called thermoforming. In this process, a thin sheet of a polymer is placed on a flat surface. There is a male piece that pushes down on the heated polymer into a female piece that also has a vacuum sucking down on the polymer. The result can range from a cone to more intricate designs depending on the molds. It is a simple process that can be done at home with an oven. This is advantageous for our purposes because of its simplicity. However, if we were to mass-produce our device, this process would not be useable because it has low repeatability and is inefficient on a large scale. Another method of construction is injection molding. In injection molding, a stainless steel mold is created with runners on the sides. It is pressed against another steel plate with an injection tube and runners adjacent to those in the first. The polymer is melted down and injected through the tube and spread evenly through the mold. You can work with any number of substances at different points because the mold can spin and rotate to different angles. The most complex designs are molded this way, and the process has an extremely high repeatability rate. The steel molds are very expensive, so this method is generally only feasible for mass production. Based on these characteristics, we decided to use thermoforming to construct our prototype. We used a metal rod of larger diameter than the one that would actually go in the prototype as the male piece to create a cylinder of polypropylene. We then fused it to the polypropylene cap by melting. After inserting the proper size of aluminum rod for the prototype into the cylinder, we attached the membrane by stretching hot polypropylene until it was a few microns thick, then allowing it to harden across the open end of the cylinder, fusing the two. Due to a lack of precision with thermoforming as well as our own inexperience with the process, we were unable to make our prototype as small as we desired. The diameter of the bottom cylinder is supposed to be only 5 mm, the preferred size hole to drill in the skull. That dimension on our prototype turned out to be approximately 8mm. However, with more practice and better construction technique, our device could be rebuilt to fit that size before it would actually be put in someone's head.

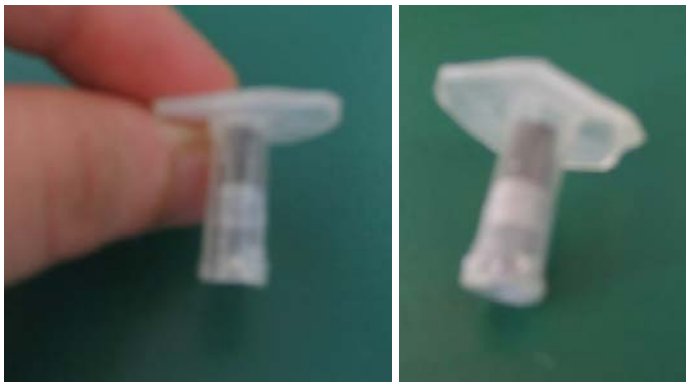

Figure 7. Completed prototype.

Testing

We tested our prototype using the EddyNCDT pressure transducer from MicroEpsilon. Before testing, the pressure transducer needed to be calibrated with the

aluminum rod to determine how actual distance correlated with the readout distance. This was done using ceramic tiles of known thickness (1mm, 2mm, etc) and the aluminum rod and sensor. After a linear graph was completed (see appendix), it was possible to test our prototype with the sensor. In order to compare the output displacement to a known pressure, we built a testing apparatus that exerted water pressure from a tube with inner diameter equal to the diameter of the prototype's membrane (see figure 8). At the P=0 line, the level of water on either sides of the tube are equal and no pressure is exerted on the sensor. We took our first reading at this point and every mL of water added could be directly correlated to a known pressure exerted on the membrane with 1mL = 0.6mmHg. Based on the known danger zones for ICP, we tested a range of pressures to determine the accuracy of the pressure readings.

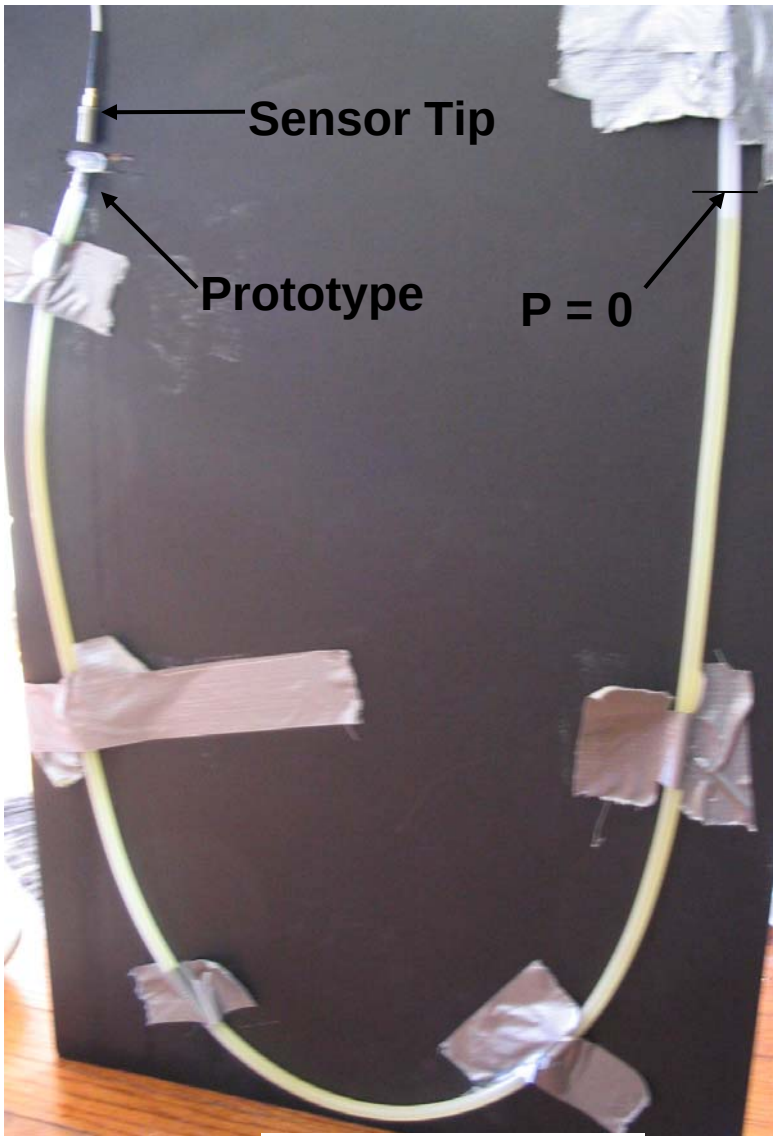

Figure 8. Testing apparatus.

Conclusion

Initially, the results of the tests appeared promising. The return resulted in good exponential curves representative of membrane displacement in the correct pressure range, with more displacement in the beginning and less toward the higher pressure (see appendix). Unfortunately, we soon found a problem with our results. Although the membrane and sensors were functional and precise, the initial starting values of the output based on location of the sensor head were too varied to draw any reliable conclusions from the data. We had hoped to consistent curves for each trial so that we could create a calibration curve between the displacement readout and the corresponding pressure.

There are a couple of factors that could play into the variation. The most probable factor is the size of the target material. In order to obtain a reading deep enough to reach the intracranial cavity, the sensor head must be at least 10mm in diameter. The recommended diameter of the target material for this product is two times the sensor, or 20mm. Our client did not want the design to extend beyond 5mm, for that is the largest he likes to drill a hole in someone's skull. Since our target is only 4.6mm, we fall well short of the 20mm distance. Unless perfectly centered, the sensor will read slight horizontal displacement in addition to vertical displacement, which could account for our variable starting values. A potential solution to this problem would be to develop a slightly different prototype that would require a more complicated surgical implantation. It would still have the cap and 5mm cylinder to go through the skull, but the bottom half of the cylinder and the membrane and aluminum rod could be much larger in diameter to give the sensor more target to pick up on, which would likely lead to much more accurate readings. To implant, the surgeon would have to cut back a part of the skull after drilling the hole and insert the bottom of the device, then replace the skull piece around the 5mm portion of the cylinder before screwing in place. Further research would need to be done regarding the feasibility of this sort of a design.

Another possible shortcoming could be our metal material selection. Ferrous materials are much better conductors for the sensor and would likely give us more accurate reading, but they are not MRI compatible, making them unusable for our device. A third factor that could account for inaccurate initial values is human error. We positioned the sensor by holding it above our prototype, which is difficult to keep consistent from trial to trial. A solution to this problem may be to design and incorporate an additional component to the external portion of the device that would hold the sensor in the same spot every time.

Future work to be done includes a variety of testing for factors such as membrane and casing durability over time, drift characteristics of the device, and absolute range of pressure that can be detected. Also, it may be necessary to incorporate a spring into the top of the design in order to return the aluminum rod to the same zero or low-pressure value instead of relying on gravity. This could also lead to more accurate starting values. One final issue in the development of this design is the ethical considerations. Since it is a device that will not only be used in healthcare, but will be used for such important life or death readings, accuracy is not only desired but also ethically necessary. It is impossible to claim our device's effectiveness and safety without extensive testing and extremely accurate recordings. It is also a matter of concern that only pure materials be

used to avoid toxicity. While there are many things to consider and further developments to be made, we are optimistic about the successful development of our membrane displacement apparatus as a valid means of measuring intracranial pressure in the future.

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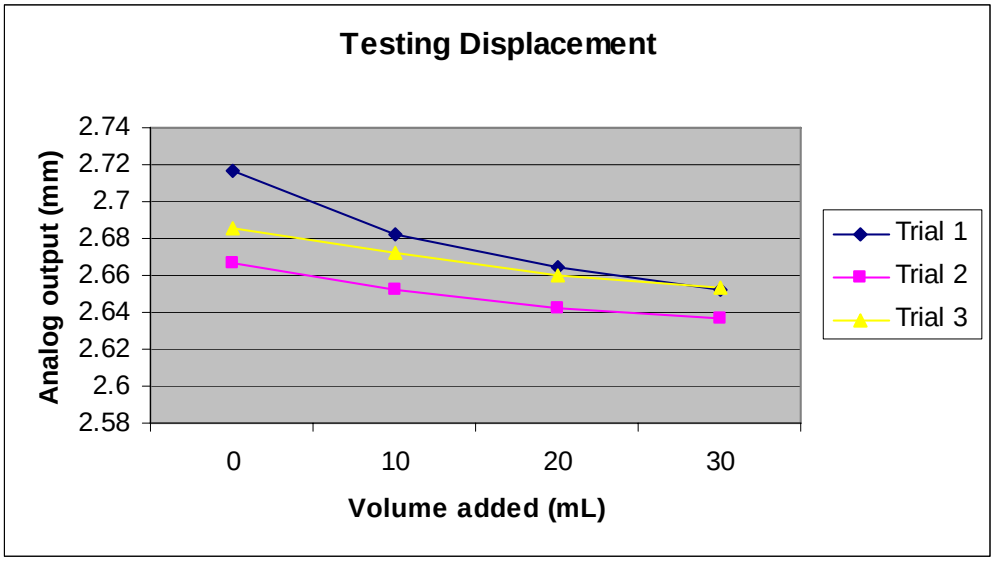
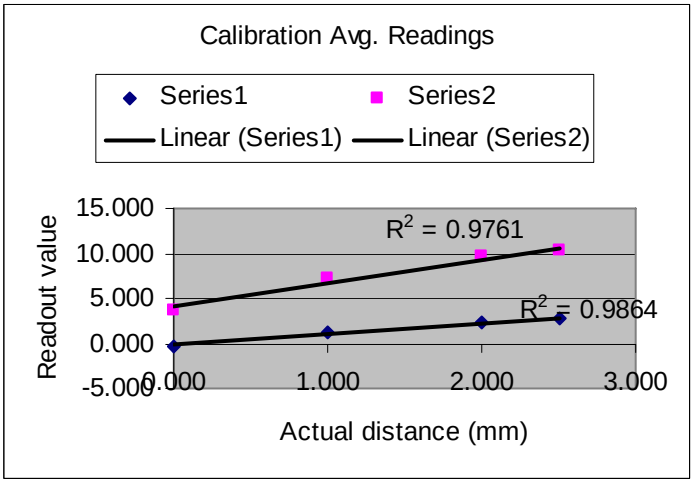
Appendix



Results of prototype testing



Calibration curve for EddyNCDT sensor

Testing Calculations

Volume = Mass/Density Density of water is 0.997g/mL
Mass water = (1mL)*(0.997g/mL)*(1kg/1000g) = $9.97*10^{-4}$kg
Pressure P = Force/Area
Area = $4\pi r^2 = 4\pi*(1/4*1/2in)^2*(2.54cm/1in)^2*(1m/100cm)^2 = 1.267*10^{-4}m^2$
Force = Mass*Acceleration = $(9.97*10^{-4}kg)*(9.81m/s^2) = 0.00978$ N
Pressure = $0.00978\ N/1.267*10^{-4}m^2 = 77.2\ N/m^2 = 0.579$mmHg

Conversion: 1mL water = 0.6mmHg pressure
Ranges of pressure: 10-15mmHg is normal, 25-35mmHg is dangerous
1mL/0.6mmHg = XmL/10mmHg ~ X = 17mL
1mL/0.6mmHg = XmL/25mmHg ~ X = 43mL

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.