Intracranial Pressure Sensor

Mid-semester Report

Team:

Brad Lindevig (Leader)

Nick Shiley (BSAC)

Evan Flink (Communicator)

Luke Juckett (BWIG)

Client:

Dr. Joshua Medow, M.D.

Advisor:

Professor Bahr

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Table of Contents

Abstract

Hydrocephalus is a serious yet treatable disease that affects 1 in 500 births. It is characterized by an abnormal increase in pressure within the skull due to the accumulation of cerebrospinal fluid. The common treatment is a shunt system implanted in the brain that drains this fluid into other parts of the body. In order to detect whether the shunt system is functioning properly, a device that passively and accurately monitors intracranial pressure is wanted. This is achievable through the incorporation of a biocompatible capsule, tank circuit, interrogating device and user interface. A large prototype exists of the tank circuit and interrogating device. Our goal this semester is to minimize the tank circuit, incorporate it into the capsule and design a user interface system.

Background

Hydrocephalus is a condition that increases intracranial pressure (ICP) in the brain by the accumulation of cerebrospinal fluid (CSF) in the ventricles and subarachnoid spaces of the brain[3]. Hydrocephalus is primarily caused by problems with the body absorbing the CSF, blockage of the CSF flow inside the head, or the overproduction of the fluid [2]. The increase of ICP can lead to enlargement of the head, bulging fontanelle in infants, convulsions, mental disability and possibly death [2]. The condition can either be diagnosed during the third trimester of pregnancy, at the birth of the child, or it can be acquired later in life by bleeding inside the head, a severe head injury, an infection, or a tumor [2]. Hydrocephalus affects 1 in every 500 births making it one of the most common birth defects and the leading cause of brain surgery for children in the U.S [1].

The accepted treatment for hydrocephalus is the Ventriculoperitoneal shunt (cerebral

shunt), which has not changed much since it was developed in 1960 [1, 2]. The shunt is surgically placed in the ventricular space of the brain, located within the cerebrum. It consists of a small catheter that is threaded behind the ear with a one-way drainage valve that subdermally diverts CSF from the brain to the abdominal cavity where the fluid can be reabsorbed by the body [2].

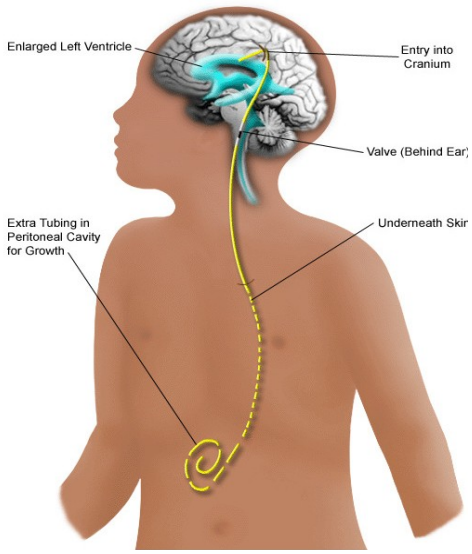

Figure 1. A diagram of a shunt system in a patient.

Ventriculoperitoneal shunt malfunctions are a serious problem for patients with hydrocephalus. 50% of all shunt systems fail within the first two years after implantation therefore requiring frequent medical checkups [1]. Further surgery is needed to replace or repair the failed components. However, the major problem with shunt malfunctions is that there are no reliable ways to diagnose whether it is failing from outside the skull. The reason being is that, the early symptoms of rising pressure in the brain vary widely: everything from headaches, to flu-like symptoms, to seizures [1, 2]. Because of the many symptoms, diagnoses are unreliable and potentially incorrect, neither of which bode well for the patient [1].

Therefore, the only way to correctly diagnose shunt malfunctions is exploratory surgery which poses a high risk for the patient [1].

ICP sensors are implantable devices that can measure the pressure inside the skull to determine shunt functionality. Current ICP sensors are quite flawed. They are all restricted to battery life and temporary implantation. Many ICP sensors have a wire that extends out of the skull which could lead to infection and other physical hazards.

Problem Statement

The main goal of this project is to minimize the number of invasive procedures for a patient suffering from hydrocephalous in order to determine shunt functionality. To obtain this goal our group will assemble a wireless ICP sensor that requires no battery. This sensor needs to transmit accurate ICP data over a long period of time. Additionally a user interface will be developed to relay the readings from the sensor and translate it into changes in ICP.

Design Specifications

The specifications given to us by Dr. Medow are divided into two categories: the ICP sensor and the user interface. First, the sensor must be small so that it does not cause damage to the patient's brain. It can be no larger than 3 mm in width and 15 mm long. Secondly, the sensor needs to be designed so that it can be implanted and removed easily. Thirdly, it needs to be more durable than the current ICP devices on the market. The ideal lifetime of our device is 10 to 20 years. Lastly, the device cannot drift more than 0.5 mmHg per year. With constant pressure, many materials begin to deform over time. The biocompatible material used has to be able to withstand the pressure being exerted on it by the brain while not deforming or drifting.

Dr. Medow also would like our group to develop a user interface that will show the changes in ICP from the sensor. When taking a reading from the sensor, the interface must display a graph of the ICP in real time and should be able to store past test results. The interface needs to be able to display positive pressure as well as negative pressure, ranging from -30 mmHg to 100 mmHg. Also, this interface must be user friendly, meaning anyone from a physician at a hospital to a parent in a home should be able to take a reading of the ICP and be able to interpret the information.

Capsule Design

The capsule containing the ICP sensor is in the shape of two cylinders stacked on each other, one being 3mm in diameter and the other being 5mm in diameter. The capsule will be screwed directly into the skull which will penetrate the dura of the brain. Only biocompatible materials can be used to create the capsule to avoid infection or rejection of the device. It can contain no metal because it will interfere with the signal produced by the sensor and other medical machines.

The ICP sensor is made from two coils of wire which forms a tank circuit (Figure 2). A tank circuit consists of an inductor and a capacitor. The coils form the inductor and they are positioned to form a parallel plate capacitor. As the pressure inside the skull fluctuates, the distance between the two coils changes which affects the capacitance. This will then alter the resonant frequency of the tank circuit that is read by the interrogating device and displayed on the user interface.

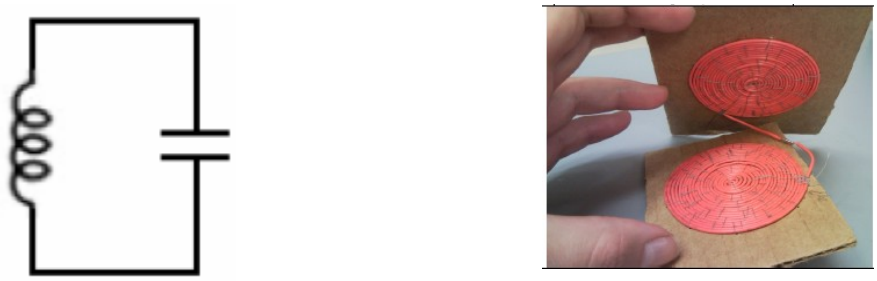

Figure 2. A diagram of the tank circuit on the left and the large scale model on the right.

In order to fabricate the coils, there are two methods that can be used in our sensor: photolithography and hand winding the coils. Photolithography uses a chemical reaction between acid and a silicon wafer to create grooves in the silicon, which are then hit with gold molecules. Then any excess gold is removed and a gold coil remains in the grooves. Using this method is reliable, repeatable, and mass producible because it can be done using machines. However, it is difficult to obtain an electrical connection between the coils. The other method of creating these coils is hand winding very thin wire. This method is simpler, but it is not mass producible and it is unreliable due to human error.

User Interface

The implantable sensor will be powered through inductive effects made possible through the magnetic coupling of the external and internal coils. When an AC current is passed through the external coil, it will produce a magnetic field which induces a current in the implantable sensor. This current resonates at a certain frequency that is dependent on the distance between the two parallel plates.

The external coil, or interrogating device, will sweep through frequencies, powering the internal tank circuit at the different frequencies. When the interrogating device reaches the

resonant frequency of the internal sensor maximum power will be drawn from the interrogating device. This can be seen as a sharp valley on the oscilloscope (Figure 3).

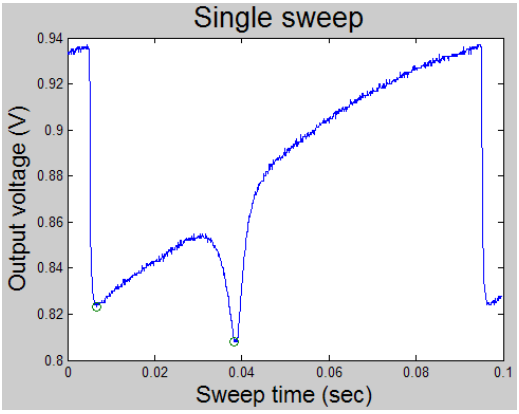

Figure 3. A dip in output voltage at .4 sec due to the resonant frequency of the sensor

When ICP increases, the two coils of the tank circuit will be pushed closer together thus, decreasing the distance of the capacitor. This changes the resonant frequency as seen by a shift to the right of the resonant frequency valley. A decrease in ICP will result in a shift to the left of the resonant frequency valley.

One of goals this semester is to measure the exact point of which this resonant frequency valley occurs relative to the start of the frequency sweep of the interrogating device. Once an algorithm is developed with LabVIEW to determine this distance, a series of tests with a phantom tester and prototype will be conducted to create an equation that relates this distance and the ICP. We believe three different LabVIEW functions may provide the most readable and accurate data in order to accomplish this goal.

Peak Detection VI

The first design idea is to utilize the Peak Detection Function VI of LabVIEW to measure the exact point of the dip relative to the start of the frequency sweep. The Peak Detection VI

function will find all the peaks and valleys of a graph utilizing second order derivatives and given threshold values (Figure 4).

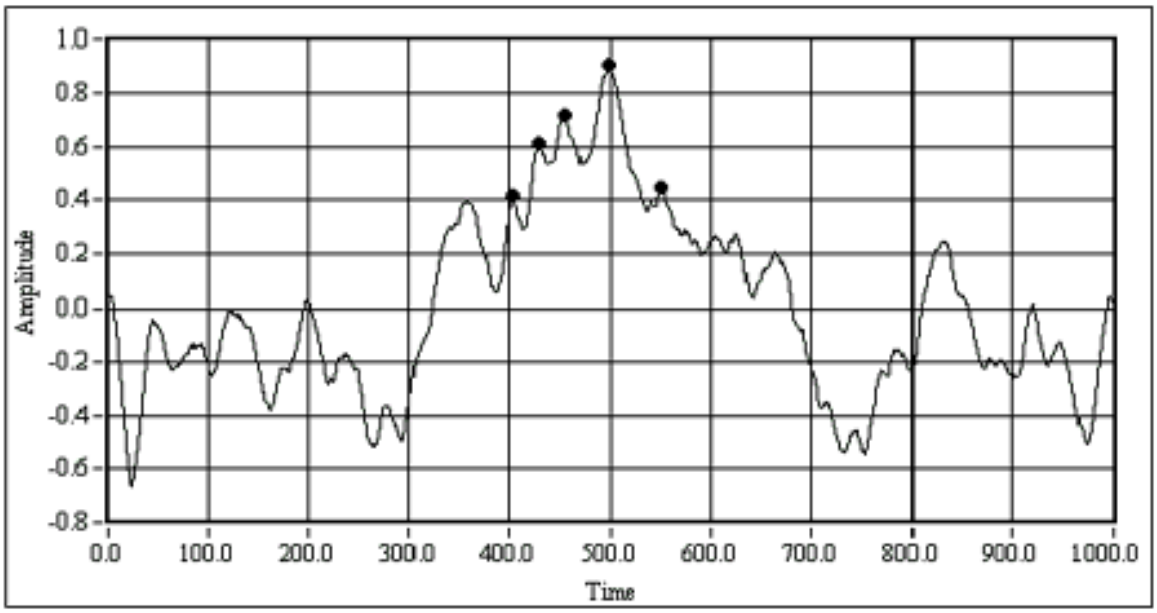

Figure 4: Peak Detection VI detects all peaks above a .4 threshold.

One problem with this function is that a threshold value is difficult to determine because the amplitude of the resonant frequency valley varies with time. With an inconsistent resonant frequency amplitude, a definite threshold may be difficult to determine. Another potential problem is the amount of background noise. The peak detection function may detect larger changes in noise; however filtering out the noise may be a solution to this problem.

Tone Measurement

A second design alternative is to use the Tone Measurement function to find the exact location of the resonant frequency valley relative to the start of the frequency sweep. The Tone measurement function will locate a single tone of a graph with the greatest amplitude. This function allows the user to define a section of the graph for the function to look for the greatest amplitude.

However, the Tone Measurement function works best with sine waves since these are considered to be tones. We believe the resonant frequency valley can be considered as a number of sine waves positioned closely together, so it is theoretically possible to determine the exact point of the valley. More research into how this function operates is needed to determine if this is possible.

Amplitude

The third design idea is a basic function that will take the average DC amplitude of the entire frequency sweep. A shift to the right of the graph will result in an increase of the average amplitude and shift to the left on the graph will result in a decrease. The average amplitude can then be correlated with a change in pressure. This is a simple and beneficial function since the user does not actually have to calculate the exact point on the graph of the resonant frequency valley.

However, this can prove to be unreliable over a long period of time since the amplitude of the resonant frequency valley may vary with time. This will require re-calibration and normalization of the resonant frequency before the average amplitude can be taken. To re-calibrate and normalize this point each time can result in inaccuracy of our user interface.

Future Work

Our future work will largely be determined by the effectiveness of our tank circuit. At the moment, our tank circuit is designed to be located in the base of the probe in the brain where it is closest to the pressure. The coils of the tank circuit can only be a maximum of 3mm in diameter. Because it is so small, we need to test it by first hand coiling the 3mm coils in order to determine if they can generate a large enough signal so that our user interface can be applied to determine the resonant frequency valley. If the signal generated is large enough, then the

tank circuit will remain at the base of the probe. However, if the signal generated is not large enough, then the tank circuit will be moved higher up the capsule where the coils can have a 5mm diameter. The increased size of the coils will generate a larger signal allowing us to find the resonant frequency valleys. We then will have to develop an accurate way for the ICP to be detected by the two coils. Two prototypes exist for the capsule design which will help us visualize just how small our tank circuit needs to be.

We will also be deciding on a method to fabricate the coils. We have obtained a roll of 40 gauge wire and have begun winding it in tight coils, 3mm in diameter. Once the coils have been created, they will be tested by running the interrogating device over the coils it to see how effectively they perform. Another method to fabricate the coils we are pursuing is photolithography, as mentioned earlier. Once the coils have been fabricated, a method needs to be created to implant them into the capsule.

As for the user interface, we have decided on a method to determine the resonant frequency peaks. We will utilize LabVIEW to create our design and will be performing tests on signals given off by our prototype. An equation that relates the ICP and the frequency will be derived.

We have completed our mid-semester presentation and have presented it to our advisors. We are pleased with the progress that we have made so far and we hope to continue developing a useful prototype. Finally, as we move into the testing and fabrication stages of the design process, we hope to collect valuable data and information that will guide us towards the most viable and practical solution.

References

1. Medow, MD, Joshua E., Bezrukova, Elena, and Webster, John G. "NIH Grant." University of Wisconsin-Madison, 2010.
2. "Neurological Disorders - Hydrocephalus." *Schneider Children's Hospital Home Page*. Web. 09 Mar. 2010. <http://www.schneiderchildrenshospital.org/peds_html_fixed/peds/neuro/hydro.htm>.
3. "Hydrocephalus | Seattle Children's Hospital." *Seattle Children's Hospital - World Class Child Health Care | Seattle Children's Hospital*. Web. 09 Mar. 2010. <http://www.seattlechildrens.org/medical-conditions/chromosomal-genetic-conditions/hydrocephalus/>.

Appendix

Product Design Specifications:

Intracranial Pressure Sensor

Team Roles:

Team Leader: Brad Lindevig

Communications: Evan Flink

BWIG: Luke Juckett

BSAC: Nick Shiley

Last Update: February 04, 2010

Function: Shunt failure in hydrocephalus patients is difficult to detect. The current pressure sensor system is complex and bulky. Other detection methods can be inaccurate. Our client needs a more simple, inexpensive, and reliable implantable intracranial pressure monitor for patient care. The first step to developing this product is to design it on a large scale. A large prototype exists and our goal this semester is to design a user friendly interface to read the ICP pressure accurately.

Client Requirements:

• Must not interfere with sensor telemetry

• Must apply proper range of pressure (-30 to 100 mmHg)

• Must apply constant pressure over a long period of time

• Must be able to apply a known and accurate pressure

• Must be able to test drift-stability

• Testing protocol must be standardized and accurate

• 3mm max width, 15mm max depth

• Interface must show ICP pressure and the pulse rate

Design Requirements:

1. Physical and Operational Characteristics

a. Performance Requirements: The interface must be real-time and give accurate positive and negative ICP pressure readings. It also must give a pulse rate in real-time.

b. Safety: It must be accurate; otherwise false readings could lead to unnecessary surgery.

c. Accuracy and Reliability: The interface must be real-time that must be in close proximity to the actual pressure. The accuracy of the device will be improved continuously throughout the semester.

d. Life in Service: Components should have a life span of 20 years.

e. Shelf Life: Storing the product will have no effect on its ability to perform

f. Operating Environment: This device will be used in a traditional lab setting, but should be operable anywhere, including patients' homes.

g. Ergonomics: There should be a low learning curve, but interpretation should be done by licensed professionals.

h. Size: The sensing device should be a maximum of 3mm in diameter and 15mm in depth. The interface has no size requirement.

i. Weight: Not applicable

j. Materials: Not applicable

k. Aesthetics, Appearance, and Finish: The interface system should look professional, yet easy to interpret ICP pressure.

2. Product Characteristics

a. Quantity: Our team will be developing one computer program.

b. Production Cost: The cost should be reasonable in comparison with technologies and materials used. The interface should cost less than $500.

3. Miscellaneous

a. Standards and Specifications: Electrical components should be compatible with data scanner device and inductive power source.

b. Customer: The client would like an interface that can show the ICP pressure, the change in resonant frequency from the sensing device, and the pulse of the patient.

c. Patient-related concerns: The final product will require multiple patient related concerns, including: out-growing device, infection, replacement or recalibration of device, comfort, and interaction on daily use. However, this product has no interaction with the patient.

d. Competition: Currently there are other devices on the market that have the same relative use. However, these devices are inaccurate and prone to failure.