

Ultrasonic Sensor to Quantify Brain Pulsatility

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Abstract— Brain pulsatility is defined as the change of cerebral volume over the change in mean arterial pressure. During modern open-brain surgery, pulsatility is qualitatively monitored to determine the cerebral condition. However, related to the lack of quantitative measurements for pulsatility, numerous complications are associated with over/under anesthesiologic compensation. The CerebroSense device provides a tool for real-time, noninvasive, and quantitative measurements of brain functioning to reduce the risk for surgical complications. Utilizing an ultrasonic sensor and LabVIEW programming, the device can monitor a pulsating brain through a craniotomy within the operating room. Through extensive testing with various media within a proof of concept device, the team has made significant advancements with the CerebroSense device and looks to perform additional testing.

Keywords—Pulsatility, Open-Brain Surgery, LabVIEW, Ultrasonic Sensor, Craniotomy

I. INTRODUCTION

Open-brain surgeries are a common procedure necessary for a variety of medical ailments; tumors, embolisms, aneurysms, and trauma repairs are just a few examples of conditions in need of this type of surgery. Often, a surgeon can only gain access to the brain via a craniotomy, or removal of a portion of the skull. Once this is performed, the physician can not only visualize and perform the surgery through direct contact, but the pulsation and perfusion of the brain can be monitored, as well.

However, brain surgeons and anesthesiologists, in charge of monitoring brain perfusion, have no quantitative means of measuring blood flow and pulsatility. Pulsatility can be modeled in the following equation, Equation 1:

$$\text{pulsatility} = \frac{\text{volume of brain}}{\text{mean arterial blood pressure}}$$

Equation 1 – Pulsatility

Currently, a neurosurgeon must make a qualitative assessment of the brain's condition during surgery by

palpating the surface and determining rigidity or pliability. Without numerical means to monitor cerebral condition, these qualitative assessments can lead to mistaken evaluations that result in detrimental complications during and after surgery. Since the brain controls all bodily functions, complications due to brain tissue damage during neurosurgery can affect nearly every aspect of the patient's wellbeing. For example, the senses of hearing and sight are often altered, and sensation, motor functions, vestibular sense, bladder control, and homeostasis regulation have also been reported as complications after brain surgery.

Therefore, neurosurgeons are in need of a device that can produce real time, non-invasive, and quantitative readings of brain perfusion during open-brain surgery. CerebroSense provides such a solution, comprised of a system of sensors that can drastically reduce the risk of complications in the operating room. "With an approximate 160,000 open-brain surgeries performed in the US per year, and an average cost of \$60,000 per case due to complications, CerebroSense offers a way to reduce both costs and risks as the first device of its kind to gather quantitative data intraoperatively" [1].

CerebroSense is a research project initially taken on by a team of biomedical engineering students from the Class of 2017 as their capstone project. Several initial tests, experiments, and advancements were made by this group before it was passed on for continued research by a Stevens summer research team. Using the previous group's work, the summer team has made several adjustments and improvements to continue the development of such a revolutionary device.

II. DEVICE

The team constructed a proof of concept device that encompasses an ultrasonic sensor and camera module embedded in a Go Pro housing, which is attached to an IV pole. The camera provides visual feedback of the sensor's region of interest. The ultrasonic sensor used is the Baumer UNCK 09 sensor, ideal because of its high resolution and fast response time. The ultrasonic sensor measures distance from itself to an anterior surface; for the project, the sensor is

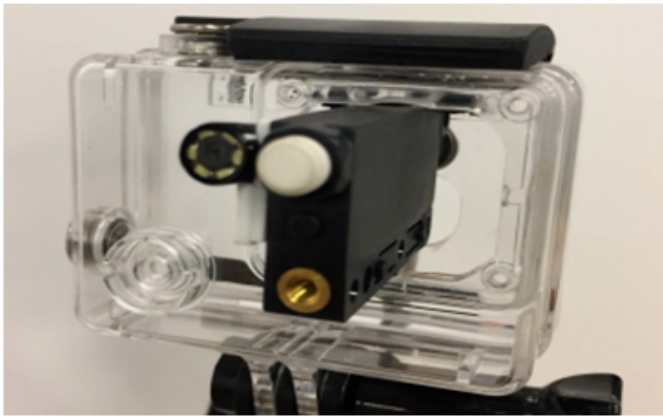


Fig. [1] – Go Pro Housing and Sensors

positioned to record a change in distance – or radius – of a pulsing brain through a craniotomy. The distance is reported as raw voltage to the National Instruments-DAQ, which is then displayed as voltage initially in the front panel of LabVIEW. In order to accurately convert the voltage output of the sensor into an actual distance in millimeters, extensive calibration testing was completed using the original code. The team then converted the linear estimation formula of the original code to a third degree polynomial function, allowing for more accurate data conversion along the range of the sensor. This system can be seen in Figure 1.

The prototype of a brain within a skull was modeled by a latex balloon within a plastic skull. A craniotomy was mimicked through the removal of a 3.5-4.0 mm elliptical portion of the skull. A 60 mL syringe was attached to the balloon and used to inflate the balloon with either air or water. This prototype can be seen in Figure 2 below.

Due to the intricate shape of the brain, the team had to use a volumetric formula that would better represent the complexities of the brain. After consideration, it was decided that a spherical cap model has the ability to isolate the local change in volume [2]. After incorporating the formula, the CerebroSense device was able to take into account the size of the craniotomy during cerebral volume calculations, which is vital as the size of the craniotomy impacts the pressure felt on the brain by the skull during pulsations.

III. TEMPERATURE EFFECTS TESTING

Utilizing an ultrasonic sensor is a viable option for determining the radial change of the brain; however, an initial concern arose regarding if the sound waves emitted from the sensor would cause any harmful thermal effects. Currently, ultrasound imaging machines have shown to increase the temperature of the patient's tissue by one to two degrees Centigrade [3]. However, due to attenuation of the signal as it

moves through various media, ultrasonic sensors are less harmful than ultrasonic imaging.

The team conducted a test in order to prove that the ultrasonic sensor was indeed harmless. The passing criterion for the test was to have an increase, if any, of less than 0.5 °C, or 0.9 °F. The laser temperature gun was placed 14.25 in away from the skull opening and the balloon was marked with an "X" in order to ensure consistent temperature readings. The sensor ran continuously for 15 minutes and was positioned at the smallest operational distance. This was done to test an extreme scenario as the sensor would not be running for such an extended period of time in the operating room. Using the temperature gun the laser determined a temperature reading every 30 seconds for a total of 30 measurements.

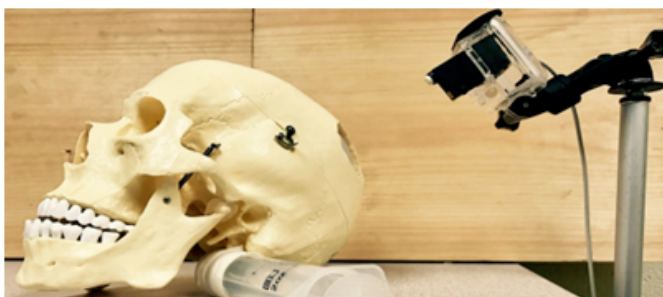
IV. ADDITIONAL TESTING

During the alteration of the LabVIEW code, the summer team sought to record data for more than 1 second, which was the extent of the previous code's capabilities. In order to record and report data for "N" minutes, the team added a "Write to measurement" function to the code. This allowed the team to obtain the required data in order to conduct the necessary testing.

Air and water testing were conducted to determine the effectiveness of the ultrasonic sensor in reporting the change in volume of a balloon. Air was the first media used in the balloon and was pumped via 60 mL syringe to simulate the brain perfusion. The test allowed the team to verify if the ultrasonic sensor was an accurate method of determining change in volume. The team chose to create the passing criteria based on noticeable change in volume. The protocol for the test is as follows:

1. Connect the sensor to the NI-DAQ and power it on
 - a. Ensure LabVIEW software is running successfully and the sensor is running properly and accurately outputting data
2. Inflate the balloon and place it inside the skull
 - a. Check to see if there are any leaks in the balloon by monitoring the volume readings
3. Stabilize the skull and inflated balloon
4. Properly align the Ultrasonic sensor and stabilize it for the duration of the experiment
5. Run the program and establish static reading of the balloon inflated 60mL and deflated 60mL
6. Continue testing and continuously inflate and deflate the balloon with the syringe. Perform 5-8 cycles and then stop the program.
7. Export the data to Excel

After conducting the air volume test, the team experimented with a medium more similar to the density of the brain, moving to a water-based balloon model. For the subsequent test, the balloon and 60 mL syringe were both filled with water, a Newtonian fluid. The same protocol from



air testing was used to run this test and obtain data. Three trials were performed with each media.

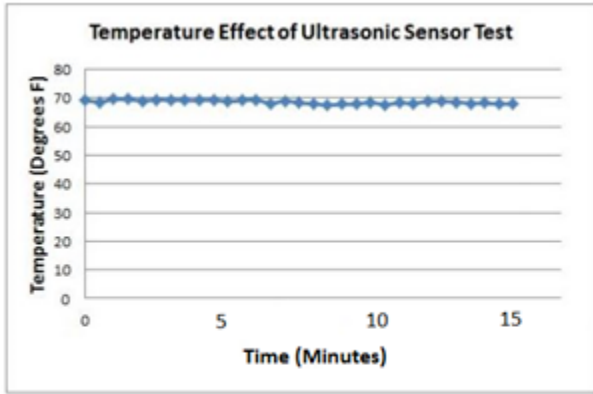


Fig. [3] – Temperature Test

After conducting the aforementioned test, the team desired to normalize the inflation and deflation of medium into the balloon. The team decided to implement a metronome to help keep the flow of medium consistent throughout the cycles. Since the water offered more resistance compared to air when inflating and deflating the balloon, the team was only able to simulate a rate of up to 10 cycles per minute, or a metronome pace of 20 beats per minute. For the this test, the protocol was the same as before, except that the balloon was inflated every 3 seconds and deflated every 3 seconds. It was important to inflate and deflate throughout the entire 3 seconds and not to finish early to ensure the consistency and maintain a constant slope throughout. This was repeated with 7.5 cycles per minute, or inflation every 4 seconds and deflation every 4 seconds with the metronome set to 15 beats per minute.

V. RESULTS

The results of the temperature testing show a value of 68.5 ± 1 °F. The maximum value recorded was 69.5°F and the minimum value was 67.5 °F, for a range of 2 °F. The results are shown in Figure 3.

Through supplemental testing performed in the summer of 2017, two additional tests produced quantitative data. The first compared the peak to peak values of the expansion of the balloon when pumped with 60 mL of air versus 60 mL of water. The results are displayed in Figure 4.

Additional testing was performed with the medium of water in which the pace of pulsation was varied. While producing sinusoidal data in accordance with the change of

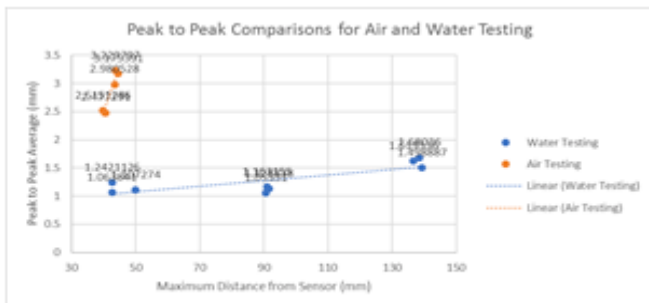


Fig. [4] – Peak to Peak of Air and Water Testing

radius, the team averaged the slopes of each wave’s minimum to maximum to compare linear increase. Figure 5 displays

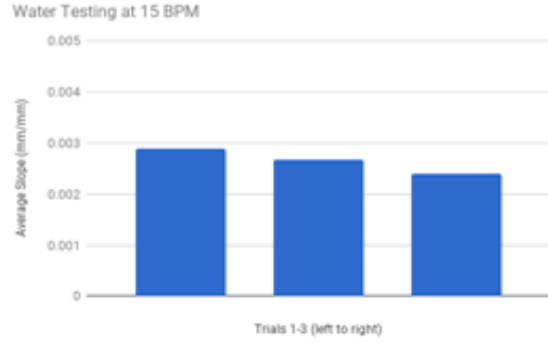


Fig. [5] – Water Testing at 15 BPM

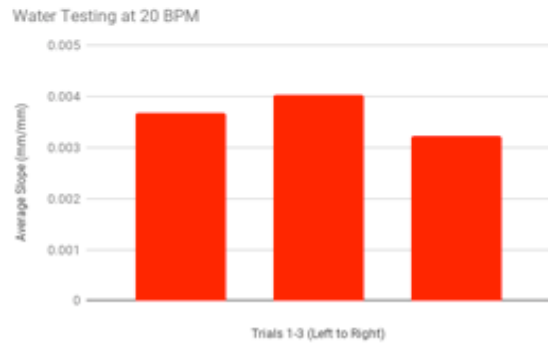


Fig. [6] – Water Testing at 20 BPM

trials from 15 BPM while Figure 6 displays trials from 20 BPM.

VI. DISCUSSION

The results of the thermal testing experiment support the claim that the thermal effects of the ultrasonic sensor on brain tissue are negligible. This test was necessary to rule out the possibility of tissue damage due to ultrasonic wave exposure. The mean temperature was 68.5 °F with a standard deviation of 0.596. With this concern quelled, subsequent tests could then take focus.

As seen in Figure 4, air testing was completed at the lower end of the range of the sensor, at a distance of 39.77 to 44.54 mm from the balloon. The peak to peak distance then ranged from 2.48 to 3.23 mm on average, with lower values of peak to peak correlating to closer distances to the balloon. This trend may be explained by the way in which the ultrasonic sensor functions. The sensor sends out a wave which rebounds off of the nearest surface; the rebound then returns to the sensor within a certain amount of time, which is then convert and displayed as voltage by the system. When the sensor is closer to the target surface, there is less room for interference from undesired surfaces, stray waves, and other factors that may skew the data. As the sensor gets farther, it is much more difficult to align the sensor with the small target area. Thus, at the upper end of the range, 200 mm, viable data could not be collect. Instead, the maximum distance used in these tests was 139 mm.

Nonetheless, the sensor should ideally output nearly identical peak to peak values regardless of distance from sensor, so long as the pulsation of medium into the balloon is performed identically. Peak to peak is merely a difference in the maximum and minimum values on a sinusoidal wave. Therefore, the peak to peak recorded at the lower end of the range should be the same as the peak to peak recorded at the higher end of the range. However, due to variation of accuracy along the range due to the estimation formula, a constant peak to peak could not be recorded by the system. These inconsistencies can be observed in Figure 4 for both air and water testing, which both display a slight increase in peak to peak as the sensor moves away from the balloon.

For water testing, peak to peak comparisons were performed at distances from the balloon of approximately 45 mm, 90 mm, and 140 mm. Once more, the upward trend of increasing peak to peak with increasing distance from sensor was observed. The significance of the peak to peak values of air testing compared to those of water testing was confirmed via t test ($p < 0.005$). Additional movement of water within the balloon may have caused some interference with readings. Overall, the peak to peak averages for water testing were lower than those of air testing. This may be due to uneven expansion as water is injected into the balloon, causing water to collect at the bottom of the balloon and less at the exposed portion monitored by the sensor.

In the pace testing, the team analyzed the differences in slope from minimum to maximum values during the sinusoidal outputs while the sensor was kept at the same distance from the balloon. For the three trials performed at 15 bpm, or 7.5 cycles per minute, the average of all the slopes was 0.002656 mm/mm with a standard deviation of 0.000249. At 20 beats per minute, 10 cycles were performed in one minute, with the slopes averaging at 0.003639 mm/mm with a standard deviation of 0.000497. Thus, with a faster pace, the expansion from minimum to maximum radius had to occur within a shorter amount of time, represented by a steeper slope. This type of testing may be helpful in the future to study the quality of brain pulsation during surgery, comparing its condition during more gradual pulsation versus quickened pulsation. In future testing, the pace can also be altered for testing with air inside the balloon.

Moving forward, many steps can be taken to further improve the project. The team considers a method to directly incorporate a blood pressure cuff to account for the variation of blood pressure during surgery. The current system design holds pressure as a constant input in order to focus on volume's effect on pulsatility. However, volatile pressure during surgery must be taken into account. The team is also considering the incorporation of a pressure sensor into the model to monitor pressure within the skull.

To eventually move the device to the market, it needs to gain a 510(k) Class II approval. This means that the device is subject to additional special controls as well as the general controls of Class I devices. The first step to get this device in the market would be to obtain a Premarket Notification

(PMN) or 510(k), stating it is substantially equivalent to a device that is currently on the market. Even though there are currently no brain pulsatility devices on the market, many other ultrasonic sensor technologies are capable of being declared as the substantial equivalent. The device would also be required to participate in a series of clinical trials. The team wishes to start with animal testing and eventually move to human trials.

While being the first device of its kind offers a competitive advantage on the market, there is currently no clinical evidence to declare a standard for pulsatility values. Through clinical testing and working alongside veteran neurosurgeons, the team aims to create a set of pulsatility standards, which will serve as a guide in the operating room when evaluating cerebral condition.

VII. CONCLUSION

Through the combined work of the capstone project along with intensive summer research, the CerebroSense device has evolved into a sophisticated proof of concept. A high resolution, real-time ultrasonic sensor can accurately report cerebral pulsation, with radial changes as small as 1.05 mm. Additionally, thermal effects from the ultrasonic waves were proved to have no detrimental effects on the brain tissue target area. Cycling of air and water within the balloon and syringe system provided a prototype for fluid pulsation within a brain. Changing the pace of pulsation provided information on the quality of pulsation and the subsequent effect on the monitoring system. Hence, CerebroSense will be the first device of its kind on the market; much progress has been made thus far, and many more tests must be conducted before the device can revolutionize the operating room and medical field as a whole.

VIII. Acknowledgements

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IX. References

- [1] Falcone, A., et al. "CerebroSense: Quantitatively Measuring Brain Pulsatility During Open-Brain Surgery to Reduce Intra- and Postoperative Complications." *NEBEC*, 2017.
- [2] "Spherical Cap." *Wolfram MathWorld*. Wolfram Research, Inc., n.d. Web. July 2017.
- [3] Helmy, Samir, Yvonne Bader, Marianne Koch, Denise Tiringier, and Christian Kollmann. "Measurement of Thermal Effects of Doppler Ultrasound: An In Vitro Study." *Plos One* 10.8 (2015): n. pag. Web.