Non-Invasive, Non-Contact, Fiber-Optic Intracranial Pressure Monitor

Dan Kastl, Kim Kawatra, Travis Lindberg, Yuanzhen Liu, Anders Olmanson, Jenna Zimmerman

Team 5, Neurosurgery · Industry Advisor: Dr. Steven Saliterman · Clinical Advisor: Dr. Matthew Hunt

Department of Biomedical Engineering, University of Minnesota

Introduction

Raised intracranial pressure (ICP), defined as the pressure inside the lateral ventricles/lumbar subarachnoid space in supine position, is the most common cause of death in neurosurgical patients. Normal ICP values are between 10-15 mmHg in adults, but volume increases in brain tissue, cerebrospinal fluid, and intracranial blood can increase the pressure due the non-expanding nature of the skull, and if left untreated, may result in irreversible brain damage or death.

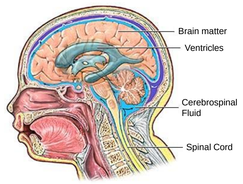
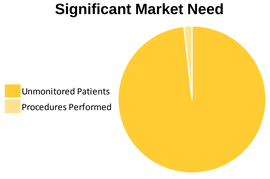


Figure 1. Simple anatomical illustration depicting physiological components relating to ICP

With almost 1.5 million incidents per year in the U.S. alone, patients with traumatic brain injuries (TBI) provide a large market for intracranial pressure monitoring. However, many TBI sufferers go unmonitored due to strict monitoring criteria. As a result, the severity of the injury is missed in up to 80% of patients with head trauma.

Elevated intracranial pressure may also be the result of strokes, or other various long-term neurological brain diseases such as brain tumors, hydrocephalus, and meningitis. As such, an additional 10 million patients, who currently are not monitored, may benefit from non-invasive ICP monitoring.

Significant Market Need



Despite the large market need for ICP monitoring, only 200,000 procedures are actually performed per year in the U.S. due to the highly invasive nature of the gold standard, and the inherent costs and risks of the procedure itself, as well as those associated with post-operative care.

Drawbacks of Current Methods

Intraventricular Catheter (Gold Standard)
In this highly invasive and costly method, an intraventricular catheter is inserted into the lateral ventricle of the brain by way of a burr hole drilled through the skull by a skilled neurosurgeon. While this monitoring method allows for accurate ICP measurements and draining of CSF, it holds a high risk of infection and brain trauma. Inaccurate placement of the catheter may result in less accurate pressure recordings or ventricular collapse.

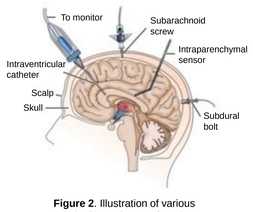


Figure 2. Illustration of various methods used to monitor ICP

Guiding Principles

Objective: To create a less invasive, cost-effective ICP monitoring method to help effectively diagnose and treat all patients at risk for elevated ICP

Subarachnoid cerebrospinal fluid (CSF) drains to the nasal mucosal lymphatics through olfactory nerve sheaths located in the easily accessible extracranial tissue lining the cribriform plate. Studies have shown that elevated CSF pressure, associated with elevated ICP, causes increased CSF drainage to the lymphatic system. Additionally, higher ICP levels are associated with increased drainage.

Increased CSF flow results in an increase in shear stress on the nerve sheath, which we hypothesize will alter the mechanical properties of the tissue surrounding the olfactory nerves.

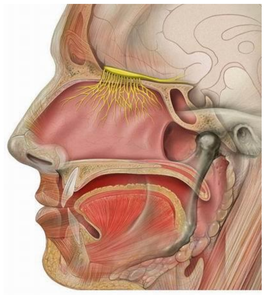


Figure 3. Anatomical cross section of head showing olfactory nerves (yellow root-like structures) in relation to the nasal cavity

Our proposed device utilizes the easily accessible olfactory epithelium in conjunction with significant advances over previous methodologies, such as ocular tonometry, used to characterize the mechanical properties of tissue, in order to determine ICP.

A fiber optic laser source will transmit light to the olfactory epithelium lining the cribriform plate, from which the intensity of the reflection will be detected by a direct-reading photodiode. The intensity received by the photosensor changes based on the location of the device and the curvature of the olfactory tissue, as shown in Figure 4 below. A proximity sensor will be used to ensure consistent placement of the device in respect to the tissue, eliminating the first degree of freedom. A known flow rate of air will be used to deflect the epithelium; the displacement of the tissue at a given flow rate is dependent on its mechanical properties.

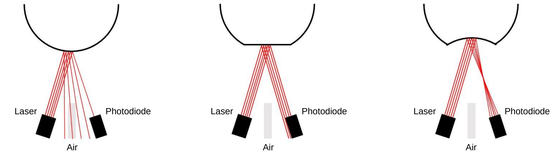


Figure 4. Intensity of reflected light detected by photodiode changes with concavity of incident surface

The pressure reading output by the device will be determined by matching the intensities recorded at several flow rates to one of several pre-existing data sets that corresponds to known ICP levels, as determined in future studies.

Materials & Testing Methods

Proof-of-concept testing required showing that laser intensity reflected off a membrane did in fact change with increasing force on the membrane, provided by a stream of air, and that the incremental changes in intensity differed with different, known pressures behind the membrane.

A known pressure was set behind the membrane, and the photodiode laser complex was squared to the membrane surface at its focal point, determined by a max voltage reading. Intensity of the reflected light, as measured by a photodiode, was recorded for several air flow rates and a curve was fitted. The previously described process was repeated for various membrane pressures.

A Newport model 505 laser diode driver delivered a 650 nm laser source, and a OPT101 monolithic photodiode with a single supply transimpedance amplifier was used to measure changes in reflected laser voltages

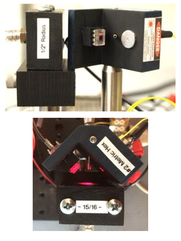


Figure 5. Photodiode, laser, air flow complex with test membrane

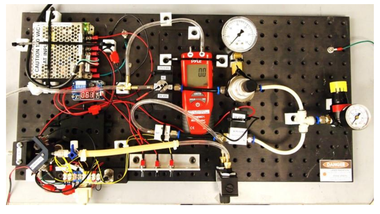
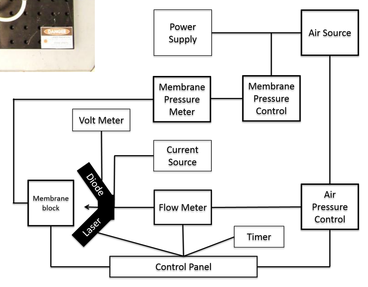


Figure 6. Left: Aerial view of testing apparatus (voltmeter and laser current source not shown); Bottom: Block diagram of components involved in testing apparatus

The testing apparatus provided a stable base that allowed for precise and accurate control of membrane pressure, air flow, and laser-diode distance to the membrane. The laser-diode block was designed such that transmitting and receiving angles remained at 45º.



Discussion

Figure 7 shows the results of our first proof of concept test and validates our hypothesis that the intensity of the reflected light detected by the photodiode increases as a non-linear function of airflow for a constant membrane pressure. This likely occurs because reflected light is focused onto the diode as the membrane increasingly deflects inward by the air flow, as depicted in Figure 3.

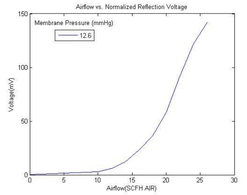


Figure 7. Normalized voltage curve for single membrane pressure

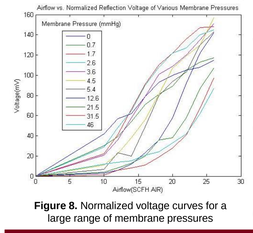


Figure 8. Normalized voltage curves for a large range of membrane pressures

Figure 8 verifies that the normalized voltage curves clearly differ for each membrane pressure over a range of air flows. The shape of each graph appears to resemble the beginning of a sigmoidal curve, with both elastic properties of the membrane and membrane pressure as parameters. These results lead us to believe that distinct voltage curves may exist for varying cranial pressures.

Next Steps

Our proof-of-concept testing method provides only a very simplistic representation of the actual anatomy in the region of interest. Next steps include testing the apparatus on a more complex and relevant membrane, including eventual *ex vivo* and *in vivo* tests. Final tests require comparison to a ventriculostomy, the gold standard in ICP monitoring.

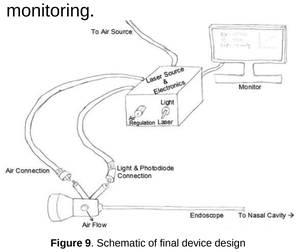


Figure 9. Schematic of final device design

We envision a final device design that incorporates a fiber optic laser light source, photodiode, proximity sensor, and air stream into a nasal endoscope-like introducer that will allow the user to navigate through the nasal cavity and correctly position the device. The device will be automated such that correct placement of the device, detected by the proximity sensor, will trigger rapid voltage readings at various flow rates, on a millisecond time frame. The measured voltage curve will be matched with a curve from a pre-programmed set of curves at known ICP levels, and will thus return a final ICP reading.

References & Acknowledgements

This project was supported by the Department of Biomedical Engineering and the Visible Heart Laboratory at the University of Minnesota. We would like to thank Dr. Steven Saliterman, Dr. Matthew Hunt, Shai Ashkenazi Ph.D., and Dr. Holly Boyer for their exceptional clinical and scientific expertise and for use of lab equipment. We would also like to thank ABC Electronics for their considerable help with electronic components.

[1] Boulton, M., et al. "Raised Intracranial Pressure Increases CSF Drainage through Arachnoid Villi and Extracranial Lymphatics." *American Journal of Physiology* 275 (1998): R889-896. [2] Caversaccio, M., et al. "The Drainage of Cerebrospinal Fluid into the Lymphatic System of the Neck in Humans." *ORL* 58.3 (1996): 164-66. [3] Umamaheswara Rao, G. S., Dr. "Neurological Monitoring." *Indian Journal of Anaesthesia* 46.4 (2012): 304-14.

UNIVERSITY OF MINNESOTA