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/tumor 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 to the non-expanding nature of the skull, and if left untreated, may result in irreversible brain damage or death.

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, TBI suffers go untreated 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.

Materials & Testing Methods

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.

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 defocuses inward by the air flow, as depicted in Figure 3.

Figure 8 verifies that the normalized voltage curves clearly differ for each membrane pressure over a range of airflow. The shape of each graph appears to resemble the beginning of a sigmoidal curve, where both elastic and inherent 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.

We envision a final device design that incorporates a fiber optic laser light source, photodiode, pressure 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.

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.

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

A fiber optic laser source will transmit light to the olfactory epithelium lining the cribiform plate, from which the intensity of the reflection will be detected by a direct-reading photodiode. The intensity received by the photodiode 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.

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Subarachnoid cerebrospinal fluid (CSF) drains to the nasal mucosal lymphatics through olfactory nerve sheaths located in the easily accessible extracranial tissue lining the cribiform 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.

As such, the testing apparatus was inserted, allowing for the creation of an olfactory nerve sheath, which we hypothesize will alter the mechanical properties of the tissue surrounding the olfactory nerves.

The device design utilizes the easily accessible olfactory epithelium in conjuction with significant advances over previous methodologies, such as ocular tonometry, to utilize the mechanical properties of tissue, in order to determine ICP.

Materials & Testing Methods

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 45°.

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.

References & Acknowledgements

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