A Programmable Point-of-Care Device for External CSF Drainage and Monitoring

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***Abstract*— This paper presents a prototype of a programmable cerebrospinal fluid (CSF) external drainage system that can accurately measure the dispensed fluid volume. It is based on using a miniature spectrophotometer to collect color data to inform drain rate and pressure monitoring. The prototype was machined with 1 µm dimensional accuracy. The current device can reliably monitor the total accumulated fluid volume, the drain rate, the programmed pressure, and the pressure read from the sensor. Device requirements, fabrication processes, and preliminary results with an experimental set-up are also presented.**

I. Introduction

External Ventricular Drainage (EVD) is a common clinical intervention for patients with severe head injury, subarachnoid hemorrhage, and other causes of elevated Intracranial Pressure (ICP) [1]. It is an established procedure in neurosurgical practice for continuous monitoring of ICP and therapeutic drainage of cerebrospinal fluid (CSF) [2]. Given that EVD involves invasive placement of catheters directly in the brain ventricles, there is a high risk of infection [3]. Several studies have investigated EVD infections and associated risk factors, but research on mechanical problems, which are equally critical, have been minimally studied [4]. Specifically, maintaining a balance between amount of CSF release and drainage amount is important in sustaining normal ICP levels. To this end, there is a need to develop effective ways to monitor and control the relative pressure [5]. This paper presents a programmable external CSF external drainage system that collects color data using a miniature spectrophotometer for management of EVD. This method of using a spectrophotometer allows multiple intervals of "hands-free" real-time data collection. The autonomous features of an integrated CSF monitoring system are the primary motivation of the work.

II. Device Requirements

A systematic design process and detailed requirements analysis are extremely important for medical devices, especially for devices that are targeted for a critical care setting. The following design requirements have been identified for developing the proposed research prototype.

- The device quantifies the volume of CSF discharged.
- The device can control the CSF fluid pressure.
- The total discharged volume and fluid pressure can be user programmable.
- The body of the device has the same working dimensions as a standard cuvette, including an optical path 10 mm in length and a scan height of 9mm from the bottom. This enables the use of cuvette spectrophotometers for calibration or comparison of collected data from POC spectrophotometer
- This device can initiate a color spectrophotometer for absorption spectroscopy analysis.

III. Device Design

An overall design of the device prototype is shown in Fig. 1. It consists of a catheter at one end with tubing connecting to a solenoid valve and the pressure sensor manifold, followed by a connection to a drip chamber, and a final tubing connecting the device to a collection bag. The pressure sensor, valve, source LED and spectrophotometer, electrodes, and buttons/display user interface are all peripheral components controlled by a 16-bit microcontroller.

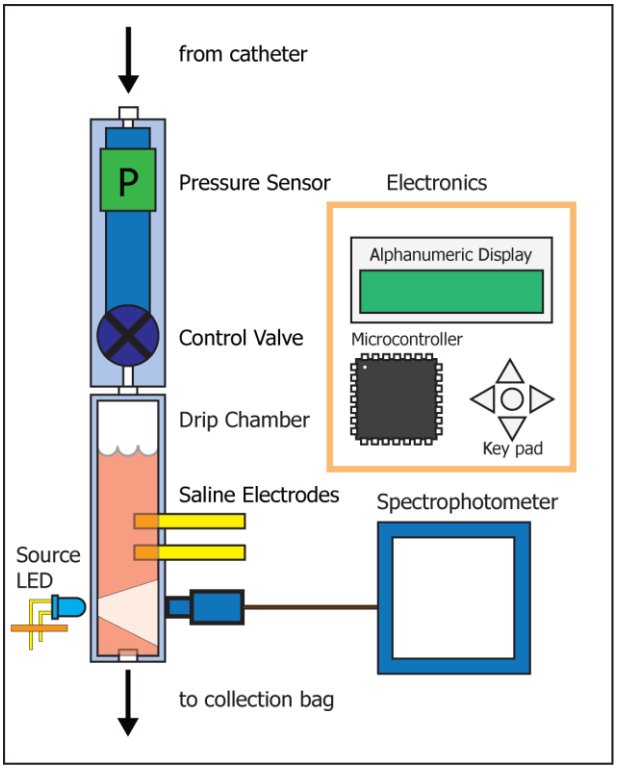

Figure 1. Overview of Device Design

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A. Material

The micromechanical body of device was machined from polymethyl methacrylate (PMMA) and assembled using a thermal bonding process. PMMA was selected for the following reasons: (1) ease of machinability, (2) the thermoplastic properties that allow assembly of complex structures without the need for chemicals or adhesives, and (3) the optical transmission properties that allow for reading the color of the CSF sample using a spectrophotometer.

Alignment posts and bonding wells are an integral part of the bulk PMMA material.

- Alignment posts are used to pre-assemble the device for thermal bonding and hold the components in place as the bond process can cause a shift in the alignment
- Bonding wells are used to enhance the thermal bond process by increasing the force per unit area. They are also markers for the post thermal bond process machining, providing a stop value of 1.2 mm for the wall thickness at the optical path.

B. Drip Chamber

A custom-designed drip chamber is used to accumulate sufficient amount of CSF sample for a color reading with an optical path of 10 mm width and an overall depth of 5 mm. A design constraint was added that the device length and width be no more than 12.4 mm and that the height be no more than 44 mm. This allows for insertion of the device into standard cuvette color readers. The entrance to the chamber has a parabolic draft that makes collection activity easier to see. The exit from the chamber has a 45° slope from the left and right walls to direct all CSF towards the chamber exit, a 1.2 mm diameter hole in the channel cover that connects the drip chamber to the next component (siphon channel).

The chamber includes a vent at its highest point of the structure in order to eliminate the vacuum caused when CSF leaves the drip chamber. The vent diameter can affect the rate at which the fluid leaves the chamber. Also, the vent must be hydrophobic so that CSF does not leave the drip chamber through the vent.

C. Programmable Siphon Channel

A siphon channel is used to drain the drip chamber at regular intervals using the Bernoulli principle of hydrodynamics. The channel is programmable so that the channel dimensions can be designed to best fit the application. A channel cover is also required because the siphon channel is positioned over the face of the drip chamber; the drip chamber and the siphon channel cannot be placed side-by-side and still meet the dimensional constraint of 12.2 mm width.

D. Saline Switch Electrodes

Patterned metal is deposited on the siphon channel cover to create two 1 mm square planar electrodes inside the siphon channel. The electrodes are 1 mm wide and extend to the edge of the device for electrical connection. Each electrode has a 7.62 mm separation on center, which is also a standard pitch for SATA edge card connections. The remaining portion of the electrode dimension is controlled by the siphon channel width when it is encapsulated by the channel cover.

E. Pressure Sensor

The Amphenol NPC-100T pressure sensor was chosen for this application because it is made from biocompatible materials. A mechanically-held electric solenoid valve is used to open or close the line to the drip chamber. In treatment mode, the valve is left open. It is closed only if the collection bag needs to be changed or if the treatment is for a specific time interval.

F. Computing Platform

A 16-bit microcontroller (Microchip Inc.) is used for computation and management of all device peripherals such as the pressure sensor, saline electrodes, and solenoid valve. Other peripherals controlled by the microcontroller include (1) a spectrophotometer to collect color data from the drip chamber, (2) an LED to provide a light source for the spectrophotometer, and (3) a key pad and alpha-numeric LCD for purposes of user interface prototyping.

IV. Device Fabrication

Fig. 2 shows the various steps in the fabrication process of the device. Two designs of the device drip chamber were developed with a dimensional accuracy of 1 μm: (1) a planar single stage assembly and (2) a multi-level two stage assembly device.

- Planar design: The body, electrodes, and drain channel in the planar design are encapsulated and assembled from a single thermal bond of a PMMA plate with the patterned gold electrodes to the molded back plate that embodies the drip chamber and drain channel. The advantage of this design is the control of the drip chamber sample volume tolerances through a single thermal bond of the assembly. The thermal bond process will create some degree of deformation of the structure. This can be alleviated by using a thick cover plate and additional bond structures.
- Multi-level design: In this design, device encapsulates the drain channel and electrode pattern in the first thermal bond, followed by an overlay and encapsulation of the drip chamber in the second thermal bond. The advantage of the multi-level design when compared to the planar design is that the overall dimensions and optical path are comparable to that of a standard-sized cuvette. Also, color data is difficult to retrieve from the planar device.

Table I shows the thermal bonding recipe with following 7 program steps.

1. Slow ramp to glass transition temperature of PMMA with enough closing force to keep the components in hard contact with the platens
2. Small bump to desired bonding temperature of 95 C
3. Heat soak at bonding temperature
4. Ramp to bonding pressure of 2.0 MPa [7]
5. Dwell at desired bonding temperature and pressure
6. Cool substrates while maintaining bond pressure
7. Heat soak at annealing temperature of PMMA [6]

TABLE I. THERMAL BONDING RECIEPE

Program Step #	**1**	**2**	**3**	**4**	**5**	**6**	**7**
Time (sec)	600	10	600	60	1200	60	600
Pressure (MPa)	0.2	0.2	0.2	2.0	2.0	2.0	2.0
Platen 1 Temperature (C)	90	95	95	95	95	50	50
Platen 2 Temperature (C)	90	95	95	95	95	50	50

V. PRELIMINARY RESULTS

A. Experimental Set-up

A test bed was developed from 63.5 mm square plate of PMMA that was machined with ten channels, each channel cross-section was 1 mm^2 with a length of 50 mm. At the center of each channel, a 0.57 mm diameter hole was drilled through the plate to insert a gold-plated machined male header pin. The pin enters the channel from the bottom with an approximate insertion height of 0.59 mm. A second header pin is added to each channel with an incremental separation distance of 2.54 mm on center, with channel 01 being the closest at 2.54 mm and channel 10 being the furthest away at 25.4 mm.

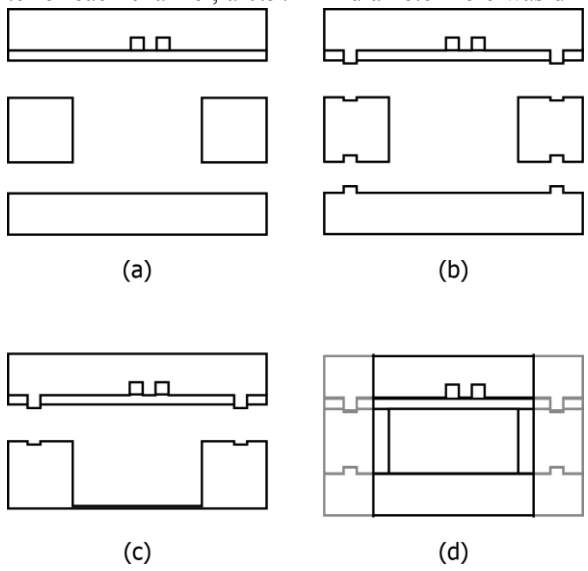

Figure 2. Device Fabrication (a) Simple model showing bottom bond layer, drip chamber (middle), and siphon channel (top) (b) Design with alignment posts (c) Current design with limitation of 5.2 mm thick plate of PMMA (d) Proposed new design with post process machining of sidewalls.

The test bed channels were encapsulated with Kapton adhesive tape, leaving an opening at each end of the channel for injection of 0.9% solution of sodium chloride and de-ionized water. The channel electrodes were connected to an HP 4155B Parametric Analyzer that was programmed for a voltage sweep from 0 V to 5.00 V in increments of 10 mV. Current measurements were recorded and a text file was generated for each run. The channels were first tested dry, and then tested again with the channel filled with saline solution. Fig. 3 shows a graph plotted for the voltage sweep vs. the measured current for all ten channels. The graph shows that the first three channels have the highest conductance. It also shows that the driving voltage at 5.00 V is too high causing the electrolyte to hydrolyze, lowering the conductance at higher potentials. Our target of interest was the conductivity at 0.6 V. Channel 03 showed the highest conductivity at this sweep potential, and therefore we chose this separation distance of 7.62 mm for our design.

B. Drip Chamber Testing

The discharge rate of the device was tested using 50 mL of 0.9% saline solution for three different flow rates: 0.5, 1.0, and 1.5 mL/minute, with no rinsing or drying of the drip chamber between trials.. The theoretical volume of the drip chamber is 1.32 mL..A syringe pump (Legato 200 Series, KD Scientific Inc.) was programmed with one of the three different rates of infusion and the target volume of 50 mL. Prior to the run of tests, the dry weight of the drip chamber was measured (12.267 g).

As the chamber was filled with solution, the discharge cycle and the weight of the accumulated volume were recorded. When the syringe pump reached its target volume, the drip chamber and any remaining fluid were weighed

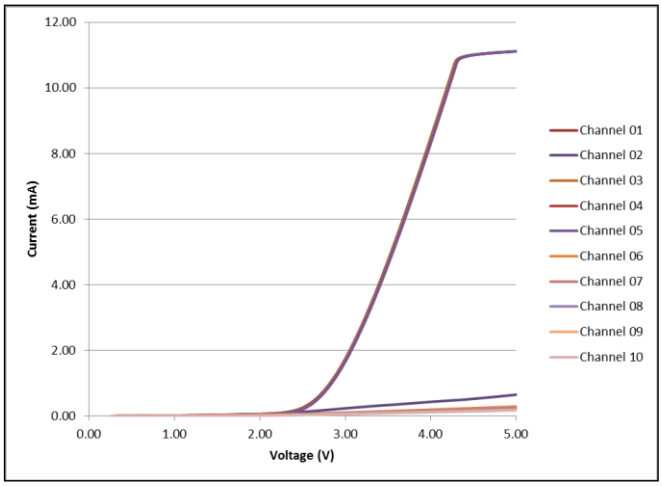

Figure 3. Saline Switch I-V Characteristic

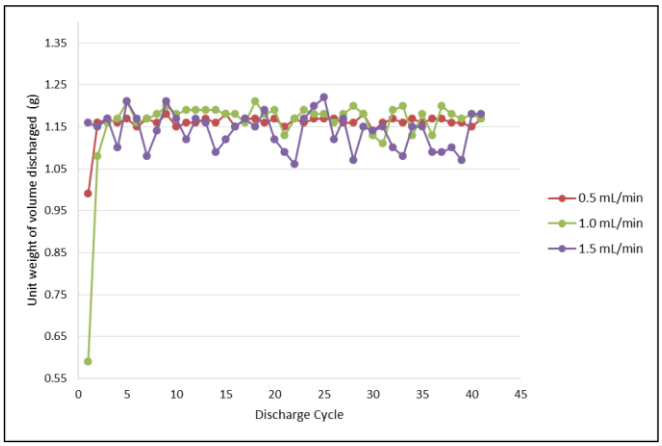

Figure 4. Plot of Drip Chamber Volume versus Flow Rate

together. For each flow rate (0.5, 1.0, 1.5 mL/min), the weight of the remaining fluid in the chamber was, 0.92 g, 0.46 g, and 0.08 g, respectively. The graph in Fig. 4 shows the calculated discharge volume derived from the measured accumulated weight of the fluid for 42 discharge cycles.

VI. Discussion

A research prototype for CSF drainage and monitoring has been presented. The device can monitor the total accumulated fluid volume, the drain rate, the programmed pressure, and the pressure read from the sensor. However, a potential pitfall of the current design is that blood and/or other proteins may attach to the surfaces of the device and skew both the color data from the spectrophotometer and the volume accumulated. An average discharge volume of 1.00 mL would be more convenient for programming target discharge volumes. An alternative strategy to cope with these limitations is needed. Also, there is no secondary means of verifying that the drip chamber is full before the siphon action empties the chamber. It is proposed that a second set of electrodes will be added to the channel cover to monitor the drip chamber.

Future work in improving machining and fabrication techniques includes (1) Ultrasonic bond process: This is faster than thermal compression bonding process and causes less deformation and (2) Injection molding: The drip chamber and supporting components take more than an hour to machine while injection molding takes only few minutes. The device has been tested with saline solution. Future laboratory tests will be done using actual CSF specimen.

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