Optimization of a Thermal Flow Meter for Failure Management of the Shunt in Pediatric Hydrocephalus Patients*

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Abstract—Hydrocephalus patients suffer from an abnormal buildup of cerebrospinal fluid (CSF) in their ventricles, and there is currently no known way to cure hydrocephalus. The most prevalent treatment for managing hydrocephalus is to implant a ventriculoperitoneal shunt, which diverts excess CSF out of the brain. However, shunts are prone to failure, resulting in vague symptoms. Our patient survey results found that the lack of specificity of symptoms complicates the management of hydrocephalus in the pediatric population. The consequences include persistent mental burden on caretakers and a significant amount of unnecessary utilization of emergency healthcare resources due to the false-positive judgement of shunt failure. In order to reliably monitor shunt failures for hydrocephalus patients and their caretakers, we propose an optimized design of the thermal flow meter for precise measurements of the CSF flow rate in the shunt. The design is an implantable device which slides onto the shunt and utilizes sinusoidal heating and temperature measurements to improve the signal-to-noise ratio of flow-rate measurements by orders of magnitude.

Clinical Relevance— An implantable flow meter would be transformative to allow hydrocephalus patients to monitor their shunt function at home, resulting in reduced hospital visits, reduced exposure to radiation typically required to rule out shunt failure, and reduced caretaker anxiety.

I. INTRODUCTION

Hydrocephalus develops due to an abnormal buildup of cerebrospinal fluid in the ventricles of the brain [1]. Currently, there is no cure for hydrocephalus [2]. The most common way to manage hydrocephalus is to insert a shunt, a flexible tube positioned to drain excess fluid from the ventricles to another part of the body. More than 125,000 shunts are implanted each year in the United States at a cost of US \$2 billion [3], [4].

Although shunt placement is the most common procedure performed by neurosurgeons, shunts remain among the most failure-prone life-sustaining medical devices implanted in modern medical practice. In pediatric patients, shunts have a 50% failure rate within the first two years of placement and will fail often throughout a patient's life due to blockage [5]. Nearly half of the cost associated with shunt implantation is associated with shunt revisions [3], [4]. Shunt failure can occur when there is an obstruction, infection, or if tubing gets disrupted, resulting in recurrence of symptoms. Most patients with shunt failure experience non-specific symptoms such as irritability, headache, nausea, vomiting and lethargy [6]. The high incidence of shunt failures and the potential for serious consequences as a result, combined with pediatric patients who may have difficulty communicating their symptoms, predicts mental burden on caretakers and frequent visits to emergency departments. Moreover, studies have shown nearly 75% of those diagnosed before the age of 18 months reported a history of depression and 45% had sought treatment for this diagnosis, further underscoring the lasting impact that childhood hydrocephalus and its associated treatment failures have on the overall well-being and quality of life of these patients [7].

To detect a shunt failure, a patient must get a series of radiological scans of the head, chest, and abdomen, while the size of the ventricles is assessed by computed tomography (CT) of the head or magnetic resonance imaging (MRI). This requires a visit to the emergency room or medical facility with the capability to manage shunts, which could mean a multihour commute for families. Additionally, the need to confirm shunt failure by X-ray radiograph or CT increases the longterm effects of ionizing radiation. Excessive exposure to ionizing radiation is of greater concern in children because rapidly dividing cells in children are more radiosensitive than those in adults. The effective doses for x-rays are 0.1 (skull), 0.1 (chest), and 0.7 (abdomen) mSv, respectively; and for CT of the head, it is 2.0 mSv [8]. In other words, a visit to the emergency department will result in nearly the same amount of radiation that any healthy individual gets from background radiation (estimated at 3 mSv) during a year [8]. Though MRI does not expose patients to radiation, machines are often only available at children's hospitals, or even inaccessible in developing countries.

To reduce hospital visits and exposure to radiation in hydrocephalus patients, an at-home, nonradioactive solution to detect shunt failures is preferred. This is especially relevant for pediatric patients, who, besides susceptibility to radiation, are less capable of communicating their symptoms. We conducted a survey among caretakers of pediatric patients to validate the need for a reliable, at-home approach to measuring CSF flow in shunts, and the thermal flow meter emerged as a promising solution.

The thermal flow meter measures the fluid flow rate in a duct by heating or cooling the fluid with a temperature actuator, and monitoring the consequent spatial and temporal temperature profile to infer the flow rate within the duct [9]–

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[11]. For applications of the thermal flow meter in hydrocephalus shunt monitoring, [9] shows the viability in principle, but the in-line thermistor interferes with the CSF flow, and thus increases the risk of obtrusion. The ShuntCheck system cools down a large area on the neck with an ice pack and measures the temperature drop downstream. However, the system is limited to exclusive use in clinics due to the cooling mechanism and the bulky temperature sensing system, and yields an inadequate sensitivity of 80% [10]. The solution in [11] is also placed on the neck, but uses a miniature actuator to generate a constant heating power above the skin surface, and detects the temperature changes upstream and downstream of the heater. Despite the reduced form factor and improved thermal efficiency compared with [10], the amplitude of the detected temperature change is attenuated by heat transfer through the skin between the device and the shunt. Such small temperature signals compromise the reliability of measurements due to the variation of ambient temperature. Although higher heating power may increase the signal amplitude, it would also increase the temperature of the body tissue, causing discomfort and potentially thermal damage to the patient.

We addressed these limitations by designing an implantable thermal flow meter which wraps around the shunt tubing to reduce the heat attenuation between the device and the CSF flow. By designing the material profile to direct heat transfer toward the CSF flow, and by using sinusoidal modulation to differentiate signals from ambient temperature variation, we obtained accurate flow rate measurements while minimizing size and maximizing efficiency, with an improvement on the signal-to-noise ratio (SNR) by orders of magnitude.

II. NEED VALIDATION THROUGH PATIENT SURVEY

In our study, we conducted a large-scale patient survey to quantify the need for the solution we propose in this work. The survey responses described in this paper were collected anonymously, as part of classroom activities, and the Institutional Review Board determined these activities were exempt from review. We validated the need by (1) quantifying the cost of the emergency room (ER) visit experience for pediatric hydrocephalus patients, and (2) measuring the mental stress of patients' caretakers using validated psychometric scales [12]. We also obtained feedback on the conceptual solution to guide the engineering design.

Our study sample comprises of caretakers of pediatric hydrocephalus patients with shunts (n=203), recruited via social-media posts by the Hydrocephalus Association (Bethesda, MD). The average age of patients in the survey was 7 years. Based on the survey, we learned that on average, a pediatric hydrocephalus patient will undergo 4 shunt revision surgeries over their lifetime. Most shunt revision surgeries occur before the age of 10. (Fig. 1).

In the last five years, 46% of patients have visited the ER for at least 5 times due to a suspected shunt failure and/or exhibiting symptoms of shunt failure. More importantly, the self-diagnosis of the patients has a false positive rate of 60% (60% of the times a patient visits the ER are due to mistaken suspicion of shunt failure).



Figure 1. Distribution of the number of shunt revision surgeries over lifetime by patients' age.

Additionally, the survey measured the psychological burden on parents. We learned that caretakers of pediatric hydrocephalus patients were under considerable mental stress, specifically:

- 45% of parents worry about their child's shunt not functioning properly once a week or more.
- 41% of parents are either very much or extremely worried about their child's radiation exposure due to current shunt malfunction detection methods.
- 47% of parents feel nervous, anxious, or on edge for a few days in the last two weeks.
- 34% feel afraid as if something awful might happen for a few days in the last two weeks.
- 14% feel afraid as if something awful might happen nearly every day in the last two weeks.

Taken together, our survey results reveal that a lack of an at-home shunt monitoring solution leads to unnecessary hospital visits, radiation exposure, and an increase in mental stress for caregivers.

III. SYSTEM MODEL (METHODS)

A. Benchtop prototype

As shown in Fig. 2, a Sophysa B905S distal catheter (Sophysa USA, Inc., IN) from a hydrocephalus shunt was placed in the groove of a polycarbonate breadboard with a height and width matching the diameter of the catheter. Four $2-k\Omega$ thermistors (NTCLE203E3202HB0, Vishav Intertechnology, Inc., Malvern, PA) and a 2-k Ω resistor were placed on the catheter, which are used as the temperature sensors and the heater, respectively. Components are spaced 5 mm apart, except for Sensor #0, which is placed distally from the catheter for sensing the ambient temperature. Thermal paste (XTM50, Corsair Gaming, Inc., Fremont, CA) was applied to improve the thermal coupling between the electronic components and the catheter. The structure is encapsulated in semi-cylindrically molded polyurethane foam (SOFF3, Smooth-On, Inc., Macungie, PA) with a diameter of 12 mm, to minimize heat dissipation into the ambient environment. Auxiliary resistors (R₀-R₃, R_h) were used to monitor the current through each component.

B. Computational modeling

COMSOL Multiphysics 5.3a (COMSOL, Inc., Stockholm, Sweden) was used for finite element modeling of the fluid and heat transfer dynamics of the thermal flow meter *in vivo*. A computer-aided design (CAD) geometry of the silicone shunt tubing, with a titanium enclosure, electrical surface mount components (microcontroller, battery, resistive heaters,



Figure 2. Top: circuit diagram of the benchtop prototype. Bottom: photograph of the benchtop prototype.

thermistors), thermal insulation, and thermal conductive paste, was created in COMSOL or SolidWorks (Dassault Systèmes, Vélizy-Villacoublay, France). Restive heaters and thermistors were modeled as homogenous silicon dioxide objects. The entire device was embedded within muscle tissue. Geometry dimensions were altered based on mechanical design optimization. Material properties, specifically, density (ρ) , thermal conductivity (k), and heat capacity at constant pressure (C_p) , were determined from published data sheets, COMSOL's built-in library, or vendor specifications [13], [14]. Fluid flow within the shunt tubing was modeled as laminar flow, with no outlet pressure and backflow suppressed. Fluid velocities tested were 0, 0.1, and 0.89 ml/min, representative of typical flow rates [15]. Heat transfer between all components was modeled through conduction. The entire configuration was set to 37°C at the simulation onset, with the outer boundary of the muscle tissue fixed at 37°C. Resistors were treated as heat sources with a constant or sinusoidal power output, and the average temperature of the modeled thermistors, or various points, were used for the temperature outputs.

IV. RESULTS

A. Engineering goals and approach

Our goal was to optimize the design of an implantable device that can be slid onto a shunt and clipped at an arbitrary location. We aimed to obtain accurate flow-rate measurements, with maximum efficiency, and minimum form-factor size. Our target size was similar to that of currently used shunt valves that are implanted with shunts, such as the Strata valve (Medtronic plc, Minneapolis, MN) or Codman Certas plus programmable valve (small: 82-8810PL, regular: 82-8800PL, Integra LifeSciences, Princeton, NJ). Using a combination of experimental results from a benchtop prototype, finite element modeling using COMSOL Multiphysics, and patient feedback, we optimized the algorithmic and mechanical design of such a device.

B. Position of heated region and temperature measurement

We first determined the ideal position of the temperature sensors along the axial position of the shunt, with respect to the heated region. Initial simulations were conducted with a constant 16 mW of uniform heating around the circumferential axis of the shunt tube. With no fluid flow, the temperature distribution along the axial direction of the shunt was symmetric with respect to the heated region. Increasing values of fluid flow transferred heat downstream, resulting in decreasing steady-state temperatures at the heated region, a non-monotonic trend downstream, and increasing temperatures further downstream (Fig. 3). Overall, measuring temperatures close to the heated region will maximize sensitivity, and result in a smaller form-factor, making this the ideal position for temperature measurement.



Figure 3. Left: simulated steady-state temperature distribution along shunt. Right: difference in temperature distribution from no-flow condition.

C. Directing heat transfer

One potential drawback of heaters and sensors being placed closely is direct thermal conduction from the heaters to the neighboring temperature sensors, without heat transfer through the shunt fluid, and consequently measurements not reflecting the flow rate. We simulated two heating resistors and two thermistors for temperature measurements, placed at the same axial position of the shunt and equidistant along the circumferential axis. By adding thermally conductive paste (k = 5 $^{W}/_{m\cdot K}$, $C_p = 1000 \frac{J}{kg\cdot K}$ between heaters or sensors and the shunt tube, and separating heaters and sensors with thermally insulative foam ($k = 0.0285 \text{ W}_{\text{m·K}}$, $C_p = 1450 \text{ J}_{\text{kg·K}}$), we directed the thermal conduction path from heaters, through the shunt fluid, and to the temperature sensors. Simulations confirmed that using thermally conductive paste increased heat flow into the fluid (Fig. 4). We observed a greater temperature difference between flow and no-flow conditions when using a combination of thermally insulative and conductive materials, compared with a thermally intermediate single material (k = 1 W_{mK} , $C_p = 1200 J_{kgK}$ (Fig. 4).



Figure 4. Simulated temperature of center fluid (left) and thermistors (right) during heating with a single material (mat.) and bi-material device.

D. Drawbacks of constant heating

Thermal flow meters for hydrocephalus shunts typically apply a step function of heating. Portable devices powered by batteries rely on small steady-state temperature changes to measure flow rates. For example, the device in [11] heats at 30mW, and the difference in the steady-state temperature between adjacent flow rates is about 0.2°C at best. However, Fig. 5 shows that even in a relatively well-controlled laboratory environment, the temperature variation within 6 minutes, the typical time window of a measurement, can be as large as 0.3°C. Such variation of the ambient temperature affects the temperature of the inflow, and hence introduces a significant noise that compromises the precision of flow-rate measurements, regardless of the quality of the electronics. The susceptibility of the temperature reading to ambient variation is evidenced by the overlapping ranges of temperature change between adjacent flow rates in Fig. 6, in which constant 32mW of heating is applied. The average SNR of the temperature reading, defined as the sum of variance divided by the square of difference between two adjacent flow rates, is 5.9 dB. In a typical environment without strictly controlled ambient temperature, inference of flow rate from the temperature sensing using step-function heating is unreliable. Improvement of the SNR by increasing the heating power is possible, but it also reduces the battery life and raises the risk of thermal damage to the patient's body tissues.



Figure 5. Ambient temperature variation in a laboratory setting. Each red trace represents an independent measurement, and the blue line and shaded region represent the mean and range of one standard deviation, respectively.



Figure 6. Temperature readings with step-function heating. Left: temperature change as a function of time at different flow rates. The shaded areas represent the range of variation for each line. Right: steady-state temperature change probed at 6 minutes after the onset of heating. The error bars indicate the range of one standard deviation.

E. Sinusoidal heating improves signal-to-noise ratio

In order to achieve more reliable measurements of the flow rate with the same setup, we applied a sinusoidal modulation to the heating power to differentiate between the useful signal that reflects the flow rate, and the inevitable noise caused by the variation of ambient temperature. Because sinusoidal functions are the eigenfunctions of any linear time-invariant system, in principle, the temperature readings are also sinusoidal with no distortion. As shown in Fig. 7, with an average power of 16 mW and 10 mHz modulation, we are able to achieve an average SNR of 32.5 dB, better than the stepfunction heating by more than 2.5 orders of magnitude (300 times), with just half the heating power. Assume the signal amplitude linearly increases with the heating power, a SNR of 10 dB is achievable with 1.6mW of heating power.



Figure 7. Temperature readings with sinusoidal heating. Left: temperature change as a function of time at different sensors and flow rates. The shaded areas represent the range of variation for each line. Right: peak-to-peak modulation depths of the sine waves at steady state. Error bars indicate the range of one standard deviation.

F. Optimal heating parameters

The frequency of the sinusoidal modulation, the duration of each measurement and the heating power should be jointly optimized. With higher frequencies, a shorter duration of measurement is required to record the same number of cycles, but sensors would also yield a weaker signal (smaller peak-topeak amplitude) due to the diffusive nature of thermal conduction. The heating power should be chosen to render the desired precision of flow-rate measurements, but not much higher than that to avoid excessive heating and conserve battery power. Based on empirical optimization, we chose 10mHz, 6 min and 16 mW for the frequency, the duration of measurement and the heating power, respectively, which are comparable to existing solutions such as [11]. COMSOL simulations confirmed that these heating parameters provided enough difference in temperature reading to not only predict flow and no-flow states within the shunt, but also infer the flow rate (Table 1). We note these thermistor temperature measurements are taken at the same axial position as the heaters, and thus are greater than values obtained from the benchtop prototype, which measures temperature slightly downstream of the heater (Fig. 2). Temperatures outside the flow device increased by less than 1°C, well under the limit of thermal damage for biological tissues (Table 1) [16].

Table 1: Predicted temperatures measured at the thermistors located at the same axial position of the heater, and at the external boundary to the device.

Flow rate (ml/min)	Average peak-to-peak thermistor temperature (°C)	Max external temperature (°C)
0	2.4	37.35
0.1	1.6	37.17
0.89	0.84	37.08

G. Battery capacity

Next, we sought to determine the ideal battery capacity, which is the largest component of the flow meter device.

Based on our investigation of the ideal heating function, a single fluid-flow measurement would require ~6 Joules of energy. Given the intermittent nature of fluid flow, we anticipate up to three measurements need to be taken to accurately conclude a lack of fluid flow [15]. Most patients and caregivers surveyed were fine with a charging frequency of once per week or more (Fig. 8), and thus a 3.4 mAh battery size would be ideal. This would allow two independent fluidflow measurements for a single battery charge, consisting of six heating cycles. As mentioned above, in principle lower heat magnitudes could also be used, allowing more flow measurements per battery charge, or a smaller battery. The flow meter battery would be charged using inductive coupling using an external charging device. For example, the Qi standard is effective up to 4 cm [17]. We note that patients also expressed a preference for a continuous-monitoring solution over an on-demand solution (Fig. 8). However, this would drastically increase form-factor size due to a larger battery, and was not recommended by neurosurgeons.



Figure 8. Left: patient survey data on preferred maximum charging frequency. Right: patient preference for a continuous solution over an on-demand solution.

H. Form-factor and device location

A finalized computer-aided (CAD) model of the design was constructed based on sizes of internal electrical components, and a titanium enclosure (Fig. 9). This device has a comparable size to existing shunt valves, such as the Medtronic Strata valve ($4.7 \times 1.6 \times 0.28$ cm) or Codman Certas plus programmable valve (small: $3.19 \times 1.3 \times 0.7$ cm; regular: $3.4 \times 1.65 \times 0.7$ cm). A flow meter of this size could be placed on the distal end of the shunt in the peritoneal cavity, which is an ideal location due to several reasons: (1) surgeons often make an incision in the upper abdomen when installing the shunt, and thus could easily slip the device onto the shunt here; (2) the abundance of fatty tissue near the device would be more comfortable for the patient, as opposed to in the head or neck; (3) the device would be close enough to the skin surface to allow wireless charging.



Figure 9. 3D CAD model of finalized design (top) and 2D drawing indicating size (bottom).

V. DISCUSSION

Our design was able to accurately measure the CSF flow rate primarily due to two key improvements: optimized geometry to direct the heat transfer, and a sinusoidal heating scheme. As reported by [11], the amplitudes of temperature change at the sensors decrease due to the thickness of skin and other tissues between the device and the shunt. Therefore, minimal attenuation of the thermal signal requires the heater and sensors to be in direct contact with the shunt tube, necessitating an implantable design. The heater and the sensors are placed closely in space to maximize measured temperature changes and minimize form-factor size, and a material profile consisting of thermally conductive and insulative materials is used to avoid direct thermal conduction from the heater to the sensors. The temperature measurement reflects the CSF flow rate only when heat flows through the shunt into the CSF fluid.

The other key improvement, a sinusoidal heating scheme, is a feature independent of our physical design, and may readily be applied to other hardware, such as [11], to universally improve the SNR. The variation of the environment temperature is a fundamental source of noise which cannot be reduced by the device, but the sinusoidal modulation we proposed is robust to this ambient variation, because only signals at the specific heating frequency (10 mHz in our case) are measured, and spectral component of the noise at any specific frequency point is expected to be More generally, insignificant. assuming temperature fluctuations behave like white noise, the noise energy that affects the inference accuracy of the flow rate is proportional to the spectral bandwidth of the heating waveform. With the same time window of temperature measurement, sinusoidal heating clearly has a narrower bandwidth than step-function heating. The bandwidth is even narrower with higher sinusoidal frequencies because more cycles can be recorded in the same time window. However, due to the diffusive nature of thermal conduction, the amplitude of the temperature signal also decreases with sinusoidal frequency. The optimal frequency should be jointly determined by the time window available and the transfer function of the system.

Our survey shows a significant unmet need for caretakers of pediatric hydrocephalus patients to monitor the shunts on demand, upon which vital decisions could be made. Therefore, sensitivity in detecting shunt failure is critical, while high specificity is important as well to avoid false alarms. These requirements highlight the role of an extraordinarily reliable measurement approach. Note that participants took our survey voluntarily, following socialmedia posts by the Hydrocephalus Association, which could potentially constitute a selection bias if their children have more severe symptoms than the overall patient population. Additionally, participants might have a base level of stress due to being parents of newborn or young children.

Our design shall be paired with a wireless charger, and provides two modes of operation: (1) on-demand, in which the device is wirelessly powered and functions regardless of the battery status, and (2) battery-powered, in which the device measures independently up to a number of times limited by the battery life and the heating power. Before our design may be used in human patients, future work may include benchtop testing with *in vitro* models that mimic the human body tissue, as well as animal experiments with canine, porcine or primate models. The optimal parameters, such as heating power, measurement window and sinusoidal frequency, are to be finalized in experiments thereof.

Albeit the design we proposed is most valuable in pediatric patients, the same device can help adult patients monitor their shunt status as well. In addition, with the device providing reliable measurements of the CSF flow rate, the research community may find its relevance in the study of hydrocephalus - for example, prolonged study of the correlation between CSF production and behavioral patterns.

VI. CONCLUSION

The patient survey confirmed the need for a reliable method for pediatric hydrocephalus patients and their caretakers to monitor the shunt's function on-demand. We designed a thermal flow meter to conveniently measure the CSF flow rate in the shunt. The placement of heaters and temperature sensors, the material profile, and the sinusoidal heating modulation, together improved the SNR of the measurement by over 300 times.

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