Noninvasive Thermal Evaluation of Ventriculoperitoneal Shunt Patency and Cerebrospinal Fluid Flow Using a Flow Enhancing Device

**BACKGROUND:** While a noninvasive flow determination would be desirable in the diagnosis of cerebrospinal fluid shunt malfunction, existing studies have not yet defined a role for thermal flow detection.

**OBJECTIVE:** To evaluate a revised test protocol using a micropumper designed to transiently enhance flow during thermal testing to determine whether thermal detection of flow is associated with progression to shunt revision surgery.

**METHODS:** Eighty-two unique tests were performed in 71 shunts. The primary outcome, need for revision within 7 d of testing, was compared with results of micropumper-augmented thermal flow detection. Statistical analysis was based on blind interpretation of test results and raw temperature data recorded during testing.

**RESULTS:** The test was sensitive (73%) and specific (68%) in predicting need for revision, with 5.6-fold higher probability of revision when flow was not detected. Negative predictive value in our sample was 94.2%. The probability of not requiring revision increased with increasing total temperature drop. Analysis of various possible thresholds showed that the optimal temperature cutoff may be lower than suggested by the manufacturer (0.125°C vs 0.2°C).

**CONCLUSION:** This is the first study to report a strong association between thermal flow evaluation and a clinical impression that a shunt is not malfunctioning. The current recommended threshold may increase the false positive rate unnecessarily, and as clinicians gain experience with the method, they may find value in examining the temperature curves themselves. Multicenter studies are suggested to further define a role for this diagnostic test.

**KEY WORDS:** Cerebrospinal fluid, Hydrocephalus, Ventriculoperitoneal shunt, Ventriculoperitoneal shunt flow, Ventriculoperitoneal shunt malfunction

Even with increasing nonshunt options for hydrocephalus patients,1-4 the insertion of ventriculoperitoneal (VP) shunts and, consequently, the diagnosis and repair of shunt failure remain among the most common neurosurgical problems in the United States.5-11 Shunt malfunction is a critical cause of morbidity and mortality in patients with cerebrospinal fluid (CSF) shunts, and little is known about normal physiological shunt flow.12-17

The diagnosis of shunt malfunction is difficult to define by prospective diagnostic criteria. Standard methods for investigating shunt status rely either on interpretations of static imaging of the brain,18-22 or invasive procedures such as shunt taps, radionuclide studies, and lumbar punctures.23-27 However, it is well documented that true malfunctions occur without change in ventricular size on imaging,28-30 and asymptomatic ventriculomegaly can occur in the

**ABBREVIATIONS:** AUC, area under the curve; CSF, cerebrospinal fluid; FD, flow detected; FNC, flow not confirmed; NPV, negative predictive value; OR, odds ratio; ROC, receiver operating characteristic; SSM, suspected shunt malfunction; VP, ventriculoperitoneal
One of the patients enrolled in the study was a pediatric patient who had a shunt revision surgery based on the attending neurosurgeon’s clinical judgment, considering each patient’s individual history and current presentation, and the results of imaging and diagnostic studies (other than thermal flow detection) within 7 days. Patients who went on to surgery for reasons other than suspected occlusion were kept in the analysis, and their effect on the results will be noted.

Thermal Flow Detection

Micropumper

The micropumper (Figure 1A) is a hand-held, noninvasive CSF flow generating device made by the manufacturer of the ShuntCheck IIIR® system (NeuroDx Development) that “interrogates” VP shunts by delivering specific vibration pulses to the dome of the shunt valve.45 The device consists of a miniature electric motor with an eccentric counterweight, mounted on a plastic foot, and vibrates at 60 Hz for 60 s. The frequency, duration, and duty cycle of the vibration are controlled by an electronic circuit. The micropumper generates controlled, reproducible CSF flow through patent, but not occluded or partially occluded shunts. This temporary increase in flow can then be detected via thermal dilution, as in the test procedure below.

The device has received FDA 510(k) approval.46 Bench-top evaluation by the manufacturer has demonstrated that the use of the micropumper generates robust flow through commonly used commercial shunt valves while keeping the suction pressures generated at the ventricular tip 41% to 82% lower than those generated by manual shunt pumping, and does not adversely affect the valves themselves.

Test Procedure

All micropumper-augmented thermal flow detection tests were performed with patients in a sitting position. The distal shunt catheter was identified and marked as it passed subcutaneously over the clavicle. An adhesive skin patch with 3 temperature sensors was placed over the clavicle, with the middle (test) sensor directly over the shunt catheter and the 2 remaining (control) sensors positioned symmetrically on either side (Figure 1B). The shunt valve was located and marked for easy access during the latter part of the test. The sensors were then connected to a handheld device that directs the timing and application of subsequent test steps and records continuous temperature data from all 3 sensors, and the test was started.

After 10 s of baseline temperature recording, an instant gel ice pack was activated and placed on the skin over the shunt immediately above the adhesive patch for 60 s before being removed. When there is natural flow in the shunt, CSF passing underneath the adhesive patch results in a measurably lower temperature reading at the test sensor compared to the control sensors (Figure 1C). On the other hand, absence of flow does not cause any significant difference in temperatures detected by the 3 sensors. One hundred twenty seconds after removal of the ice pack, the same ice pack was reapplied for an additional 60 s. Immediately after removal of the second ice pack application, the activated micropumper was gently placed over the shunt valve and held in place for 60 s (Figure 1D). Temperature data collection continued for 240 s after removal of the massager. Total test duration was 550 s.

Thermal data were blindly interpreted by an algorithm that computes the difference in temperature between the test sensor and the mean of the control sensors for each time point, generating a curve of the locally adjusted temperature $T(t)$, where $t$ is time.
To understand the relative contributions of the 2 phases of the test, we identified the maximal temperature drop ($\Delta T$) prior to micropumper application (designated $\Delta T_{\text{natural}}$) and the additional maximal temperature drop after micropumper application ($\Delta T_{\text{induced}}$) and their sum ($\Delta T_{\text{total}}$; Figure 2A). Collected data are classified into categorical readings of “flow detected” (FD), which for this analysis we take as a testable prediction of “no malfunction,” or “flow not confirmed” (FNC; Figure 2B), taken as a testable prediction of malfunction. The manufactured devices include a preprogrammed $\Delta T_{\text{total}}$ threshold of 0.2°C, based on previous animal and pilot clinical tests. We further analyzed the consequences of varying this threshold parameter as will be described below.

**Statistical Analysis**

All statistical data analysis was conducted based on the blind interpretation of test results and raw temperature data made available by the manufacturer (NeuroDx Development). Power analysis indicated that the sample size was sufficient to provide 80% power ($\beta = 0.2$) for detecting a median difference of 0.1°C in total temperature drop between groups using the Mann–Whitney U-test with a 2-tailed alpha level of 0.05 (nQuery Advisor version 7.0, Statistical Solutions, Cork, Ireland).

Using a cutoff value for total temperature drop of <0.2°C, we calculated sensitivity and specificity and used logistic regression and Bayes’ theorem to estimate the odds of shunt revision and the negative predictive value (NPV) of thermal testing, respectively. Comparison of mean temperature drop in subjects that underwent shunt revision surgery and those who did not was performed using the nonparametric Mann–Whitney U-test and presented graphically using box-and-whisker plots, where the box is divided at the median and the length of the box represented the interquartile range (25th-75th percentile). The relationship between temperature drop and the probability of shunt revision was determined using maximum likelihood estimation in binary logistic regression with the likelihood ratio test to assess significance. Receiver operating characteristic (ROC) curve analysis was conducted to evaluate the diagnostic utility of the test with area under the curve (AUC) as a measure of accuracy. Two-tailed values of $P \leq 0.05$ were considered...
Figure 2. Temperature curves. A. Schematic representation of a thermal curve generated during a micropumper-augmented thermal flow detection test, showing $\Delta T_{\text{Natural}}$, $\Delta T_{\text{Induced}}$, and $\Delta T_{\text{Total}}$ parameters. The light gray bars represent first and second ice application, and the dark gray bar indicates micropumper placement. B. Representative thermal curves from 3 patients, showing no natural or induced flow (FNC), no natural flow but $>0.2^\circ\text{C}$ induced flow (FD 1), and $>0.2^\circ\text{C}$ natural flow as well as $>0.2^\circ\text{C}$ induced flow (FD 2). $\Delta T$, temperature drop; FD, flow detected; FNC, flow not confirmed.

RESULTS

Study Participants

Figure 3 shows the flow of recruited participants through study protocol. Thermal flow evaluation was completed in all enrolled patients, with no adverse events. Fifty-four unique tests (65.9%) were performed on asymptomatic patients presenting for routine follow-up assessment, and 28 tests (34.1%) were conducted in cases with SSM. In SSM cases, 11 tests (39.3%) progressed to shunt revision surgery. Eight patients were tested more than once (19 unique tests). Of these, 7 patients received a single repeat test during regular postoperative evaluation following shunt revision surgery. In addition, 4 tests were performed on a single patient, each spaced at least 1 mo apart while a fifth test was performed on this patient during a regular postrevision visit. Only 2 patients crossed over from FNC to FD on repeat testing; none changed from FD to FNC.

Thermal Flow Detection With Micropumper

Thermally Detectable Flow and Progression to Surgery

The observed prevalence of shunt revision surgery in our sample was 13.41%. Outcome (+malfunction/FNC or –malfunction/FD; +/- shunt revision surgery) comparison in a $2 \times 2$ contingency analysis indicated a sensitivity of 73% and a specificity of 68% when the manufacturer recommended test threshold was used (Table 1). The odds of shunt revision surgery following a +malfunction/FNC test result were 5.6 times higher compared to a –malfunction/FD result (odds ratio [OR]:

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TABLE 1. Thermal Prediction of Shunt Malfunction and Progression to Shunt Revision Surgery

<table>
<thead>
<tr>
<th>Predicted Malfunction</th>
<th>Shunt Revision</th>
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<tr>
<td></td>
<td>Yes</td>
<td>No</td>
<td>Total</td>
</tr>
<tr>
<td>+ (FNC)</td>
<td>8</td>
<td>23</td>
<td>31</td>
</tr>
<tr>
<td>– (FD)</td>
<td>3</td>
<td>48</td>
<td>51</td>
</tr>
<tr>
<td>Total</td>
<td>11</td>
<td>71</td>
<td>82</td>
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</table>

FD, flow detected; FNC, flow not confirmed

Outcome comparison shows a sensitivity of 73% and a specificity of 68%. The odds of shunt revision surgery following a predicted malfunction (FNC) on thermal testing were 5.57 times higher compared to a FD result (OR:5.57, $P = .01$). Probability of patients with FD not progressing to shunt revision surgery (NPV) was 94.1% in our sample, where prevalence of shunt revision surgery was 13.41%.

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5.57, \( P = .01 \). In addition, the probability of –malfunction/FD not progressing to shunt revision surgery (NPV) was 94.2% in our study sample.\(^5\) Since negative and positive predictive values actually depend on the true prevalence of the condition, these values were also estimated for different hypothetical patient populations with varying prevalence of shunt revision surgeries (Table 2, column A).

**Magnitude of Temperature Drop (\( \Delta T \)) is Significantly Lower in Patients who Require Shunt Revision Surgery**

The median values of all 3 thermally detected flow parameters, \( \Delta T_{\text{Total}} \) (0.07 vs 0.29, \( P = .004 \)), \( \Delta T_{\text{Natural}} \) (0.05 vs 0.17, \( P = .05 \)), and \( \Delta T_{\text{Induced}} \) (0.00 vs 0.11, \( P = .018 \)) were significantly lower in the shunts that subsequently underwent revision compared to those that did not (Figures 4A-4C).

**The Probability of not Requiring Shunt Revision Surgery Increases with Oncreasing \( \Delta T_{\text{Total}} \)**

Binary logistic regression analysis using the likelihood ratio test indicates a significant relationship between greater temperature drop (reflecting more flow) and the probability of being discharged without a shunt revision (likelihood ratio test = 8.84, \( P = .003 \), Figure 5).

**Thermal Detection of VP Shunt Flow has Diagnostic Utility as a Means of Predicting that no Acute Intervention is Needed**

An ROC curve visually illustrates the performance of a dichotomous test as the criterion is varied, and is created by plotting the test’s sensitivity (true positive rate) against 1-specificity (false positive rate) at various threshold settings. A chance diagonal represents a useless test, and points above this line indicate better than random results with the curve of a “perfect” test running along the left and upper borders of the plot area.\(^5\)

Analysis of the curve for micropumper-augmented thermal flow detection shows that \( \Delta T_{\text{Total}} \) is a fair predictor of whether shunt revision surgery is needed (AUC: 0.773, 95% confidence interval: 0.612-0.934, \( P = .004 \)). Youden’s J statistic \((J_t = \text{Sensitivity} + \text{Specificity} - 1)\) for each threshold \( t \) was calculated, and the maximum \( J_t \) identified the cutoff \((\Delta T_{\text{Total}} \leq 0.125^\circ \text{C})\) at which the ROC curve is furthest away from the chance diagonal, representing the optimal balance between sensitivity (73%) and specificity (80.28%; Figure 6). Using this cutoff increases the NPV of the test in our sample to 95.1%, and similarly across the range of estimated prevalence of shunt revision (Table 2, column B).

### DISCUSSION

We report for the first time the diagnostic utility of thermally detected VP shunt flow in the management of chronically shunted patients presenting to a pediatric neurosurgical department, using a cross-sectional observational study design. One of the most robust and compelling findings in this study was the prediction of nonprogression to surgery by thermal flow detection with micropumper. The test correctly identified no flow (+-malfunction/FNC) in 8 out of 11 cases where the patient went on to shunt revision surgery (true positive, sensitivity 73%), and flow (-malfunction/FD) in 48 out of 71 shunts that did not subsequently require revision (true negative, specificity 63%). The odds of shunt revision surgery following FNC tests were 5.57 times higher compared to FD tests. Significantly lower natural, induced, and total temperature drops were seen in patients who progressed to surgery compared to those who did not (Figures 4A-4C). On the other hand, the NPV, which is the probability of not progressing to shunt revision surgery after a negative test (-malfunction/FD) result, was 94.2%. Additionally, the probability of not requiring revision surgery increased with increasing temperature drops (reflecting more flow) in our study population (Figure 5). In our opinion, the true utility of the test may lie in correctly identifying patients presenting with SSM who do not require immediate intervention—a “rule-out” test.

There were 3 cases where flow was identified by the device that nevertheless progressed to shunt revision surgery. However, none of these patients went to the operating room to replace obstructed shunts—one was a case of symptomatic over-drainage, another required valve replacement following mechanical failure of an adjustable shunt, and the third required surgery to repair a detached Rickham reservoir with subsequent subcutaneous collection of CSF. Post hoc exclusion of these patients would decrease the false negative rate to zero and increase both the sensitivity and NPV of the test to 100%. We had not stipulated exclusion of such patients in the study design, so they are included in our analyses, effectively making the statistical

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**TABLE 2. Estimated Positive and Negative Predictive Values of Thermal Flow Detection With Variations in Population Prevalence of Actual Revision**

<table>
<thead>
<tr>
<th>Prevalence (%)</th>
<th>( \Delta T_{\text{Total}} \leq 0.2 , ^\circ \text{C} )</th>
<th>( \Delta T_{\text{Total}} \leq 0.125 , ^\circ \text{C} )</th>
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<tr>
<td></td>
<td>PPV (%)</td>
<td>NPV (%)</td>
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<tr>
<td>5</td>
<td>11</td>
<td>98</td>
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<td>10</td>
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PPV, positive predictive value; NPV, negative predictive value; \( \Delta T_{\text{Total}} \), total temperature drop

Estimated positive and Negative Predictive Values using Bayes’ theorem for a range of possible shunt revision prevalence, using \( \Delta T_{\text{Total}} \) threshold of (A) <0.2°C and (B) <0.125°C. Values for the current study sample are in bold, and italicized.

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\( \text{PPV} = \frac{TP}{TP + FP} \), \( \text{NPV} = \frac{TN}{TN + FN} \), where \( TP \) is true positive, \( TN \) is true negative, \( FP \) is false positive, and \( FN \) is false negative.
bar more rigorous for this prospective study. Subsequent study designs, which exclude such patients, could yield higher sensitivity and NPVs. However, this does point to a qualification on the interpretation of the test: robust flow itself may be an indication for surgery in some cases of over-drainage, or persistent flow through a tenuous fibrous tract after shunt fracture. We believe it is likely that thermal flow detection will best be used in conjunction with clinical impressions or other tests, and not as a definition of shunt malfunction in isolation.

In our cohort, 23 shunts with FNC did not progress to surgery. There may be several plausible explanations for the seemingly high incidence of the finding of FNC in the nonsurgical group. For one, noise resulting from patient movement could obscure a flow signal. In addition, it is possible for flow to be below threshold for detection by the device, which is, of course, true for all measuring instruments. For principal binary outcome event comparison, we used the manufacturer recommended temperature threshold in classifying +malfunction/FNC vs –malfunction/FD results. This cutoff, as used in previous clinical studies, had been conservatively chosen to minimize the number of false negatives and avoid missing patients with potentially obstructed shunts. Indeed, the ROC curve analysis of our sample indicates that while thermal flow detection has diagnostic utility as a dichotomous test using the manufacturer recommended threshold (0.2°C), the algorithm could use a lower threshold (0.125°C) to increase specificity to 80% without sacrificing sensitivity (73%). Subsequent randomized multicenter trials with larger and more representative sample sizes could potentially identify even smaller thresholds that may further increase both the specificity and sensitivity of the test.

Alternatively, perhaps some of the patients tested were truly shunt independent, with VP shunts that no longer flowed. We have previously demonstrated the intermittency of shunt flow consistent with data in the literature suggesting the intermittent nature of CSF flow. These explanations are not mutually exclusive and may be resolved with serial retesting of chronically shunted patients.

Our data suggest that thermal flow measurement, along with a means to transiently and safely induce flow, may be useful as an additional, useful clinical data point when following chronically shunted patients in the clinic. Since clinical decision-making relies on the context of any given decision, neurosurgeons may also

FIGURE 4. Thermal flow parameters in surgical vs nonsurgical patients. Median temperature drops: A, \( \Delta T_{\text{total}} \) (0.07 vs 0.29, \( P = 0.004 \)); B, \( \Delta T_{\text{Natural}} \) (0.05 vs 0.17, \( P = 0.05 \)); and C, \( \Delta T_{\text{Induced}} \) (0.00 vs 0.11, \( P = 0.018 \)), were significantly lower in patients who subsequently underwent shunt revision surgery compared to those who did not. Boxes indicate median and 25th and 75th percentiles. Whiskers represent 2.5th and 97.5th percentiles. Outlier values are indicated by solid circles; \( \Delta T_{\text{total}} \), total temperature drop; \( \Delta T_{\text{Natural}} \), natural temperature drop; \( \Delta T_{\text{Induced}} \), induced temperature drop.
find value in viewing and comparing graphical temperature data from serial thermal testing in individual patients to form conclusions, rather than simply rely on the tests’ binary results. The skewness in the distribution of temperature measurements may indicate the possibility that trends or changes in flow dynamics within a patient may be more predictive of clinical trajectory than a single isolated value. Valuable insight into why some hydrocephalic patients need multiple shunt revisions while others may not require surgery for decades might be gained from serially testing shunt flow in individual patients using this relatively inexpensive and noninvasive technique, in future studies.

**Study Limitations**

Clinicians could access the raw temperature curves generated by the test software if desired (although they did so infrequently) as allowed by the Institutional Review Board. However, they were instructed to disregard the thermal data during decision making, and all reported doing so. To avoid subconscious bias in surgical decisions, strict operator blinding could be achieved with specially designed (blinded) testing hardware, but such was not done in this study.

The major modification of this study procedure over that published earlier was the addition of a second thermal application with a flow-enhancing micropumper. While the sum of the baseline and micropumper enhanced flow succeed in clarifying the probability that a patient would go to surgery, it is not clear from these data whether this results from the micropumper activity per se, or the doubled time of cold exposure to increase the signal to noise ratio. Since the curves (Figure 2B) showed cases where there was no temperature drop with the first cold pack application, but presented temperature drops when the micropumper was added, there is likely to be an effect of both changes in the protocol.

While the current study implies a role for thermal detection of flow in the management of chronically shunted patients presenting to a pediatric neurosurgical department, rigorous clinical evaluation in a multicenter, prospective, double-blinded clinical trial with a large sample size and better stratification of pretest clinical status is required to provide a sharper estimation of the utility offered by this thermal approach to decision making in addition to clinical and imaging decision.

**CONCLUSION**

While prior studies suggested that flow in shunts can be detected by a thermal technique, this is the first study, utilizing 2 thermal exposures and a flow-enhancing micropumper, to show statistically significant results using the binary “FD” or “FNC” outputs of the device. The current temperature cutoff of 0.2°C, while intended to minimize false negatives, may increase the false positive rate unnecessarily, and experienced clinicians may also become increasingly skillful at interpreting the temperature curves themselves. It is likely that thermal flow detection will find one of its key values in the confirmation of clinical impressions or other tests suggesting that a shunt is not malfunctioning. Such questions of clinical utility should be tested in future studies. Further planned analyses include results of operator blinded studies and influences of a priori clinical impressions on the utility of the result.
Disclosures

Funding was received from NIH Phase I SBIR # 5R43HD065429 (PI: Marek Swoboda, PhD/NeuroDx Development, LLC; subcontract to Joseph R. Madsen, MD/Boston Children’s Hospital). Dr. Madsen and Dr Swoboda are coinventors of the micropump device (US patent # 9138568), with intellectual property assigned to Boston Children’s Hospital and NeuroDx Development, respectively.

REFERENCES


COMMENTS

This is an interesting paper as it begins to sketch a picture of how shunt-controlled hydrocephalus may be managed in the future. This work will not doubt inform strides to be taken by industry and perhaps in the medical domain by patients and families. As is happening in the type 1 diabetes world, patients are working with experts to define the technology evolution that we see today and will no doubt mature in the near future; continuous glucose monitoring integrated with insulin pumps that remove the limitations and the burden of the illness. For those fortunate individuals, current technology allows them to be less conscious of their disease as they live more normal lives.

If cerebrospinal fluid drainage remains a mainstay of hydrocephalus control, similar principles will likely be brought to bear; individualized monitoring and drainage control. Patients will no doubt play a greater role in the technology evolution and may do this in the public domain with lesser involvement of industry. Indeed, this is where valued shunting began with Holter and Dahl, and Till.

This study adds to our understanding of shunt behavior and what “flow” means and does not. As with diabetes, we will see technology evolve to support individualized management and once automated, hydrocephalus will have less impact on the lives of our patients. Until then, clinical judgement by patients, parents and surgeons supplemented by imaging and technologies as described will be the mainstays of management.

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The assessment of shunt function remains difficult. The most basic approach is to observe for change in ventricular size on a CT or MRI scan in the setting of appropriate symptoms (progressive headache, emesis, sleepiness/lethargy) but this simplistic and potentially dangerous approach misses a significant number of shunt failures.

This paper further develops the use of a previously reported commercial product called Shunt-CheckIII to utilize thermal variance to measure flow in a ventricular shunt. The tract of the shunt is identified and a cooling source applied over it. Changes in temperature downstream are detected and correlated with flow. Previously the existence or absence of flow (as reflected by detection of transcutaneous thermal variance) was detectable but did not accurately predict the need for ventricular shunt revision. In this study they augment the previous device with a micro pumping device which transcutaneously stimulates the valve with a pulsation frequency of 40 stimulations per second.

Subjects for the study were asymptomatic patients with ventricular shunts attending the Pediatric Neurosurgery clinic and symptomatic patients evaluated in Emergency Room. Absolute measurements of temperature and the degree of temperature change were made. The clinical endpoint was need for shunt revision within 5 days. This is an imperfect, non-objective endpoint but a single surgeon made operative decisions based on standardized criteria. Statistical evaluation occurred with blinded data. The authors found that thermal changes measured by the device predicted a need for shunt surgery with a 73% sensitivity and 68% specificity. The negative predictive value (ie, no need for intervention) was 94%. The magnitude of temperature change was found to correlate with need for shunt revision. Patients demonstrated a 5.6 times greater likelihood of requiring shunt revision when flow was not detected. As such the authors conclude that the device may have clinical utility in determining those patients who do not require intervention.

There is value in a clinical tool that corroborates a clinical impression that no intervention needs to be undertaken. In a difficult clinical setting of a shunt patient with conflicting clinical data a test that provides insight of function would be valuable. Most neurosurgeons with extensive experience with ventricular shunts have a low threshold for exploring shunts but significant variability and practice preferences exist between experienced centers. This device may be of value in further corroborating a clinical impression and may help prevent unnecessary interventions. As such the principal potential clinical benefit at present is likely to “rule out” obstruction rather than to rule it in.

There is potential utility of the device in providing more information about basic flow dynamics of shunt systems. Such information is badly needed to gain better insight into the natural history of flow dynamics of ventricular shunts and there is not a better available technique to my knowledge at present.

However, some significant challenges remain:

1) The fundamental premise that flow reflects function is challenging in that we simply do not know what degree of flow is necessary within a shunt for a child with a shunt. It is highly likely that the amount of flow through perfectly functional shunts varies considerably. There have never been normative flow curves published for shunts in humans or animal models. I suspect that the rate of flow through most functional shunts is small and symptomatic shunt failure results from a) subtle reductions in this drainage or b) stresses from other body system that cross a critical threshold thus prompting symptoms of shunt failure (such as are known to occur in select patients with other physiologic stresses like urinary tract infections, severe constipation etc).

2) The temperature differences observed are statistically significant but they remain very small absolute differences. As shown in the diagrams the absolute difference between values is 0.12° C. Even if the device works perfectly I can imagine significant confounders in the difficult real clinical domain of providing clinical care to frightened, hyperactive, developmentally delayed children that could seriously confound these results. The addition of the pumping device to augment flow results further challenges feasibility in the real life world of assessing children.

3) I would have valued more detailed information about surgical findings of shunt obstruction at surgery. Observations and correlations
of ventricular catheter obstruction would seem like important variables that are available without exposing the patient to any additional risk. I would strongly encourage the authors to keep detailed observations of the obstructed segment of shunt at the time of surgery for future studies.

In summary, this is a clever concept but challenges remain. The history of hydrocephalus is replete with a variety of different devices that were designed to contribute information about shunt function. None have persisted to remain widely used tools in the assessment of shunt function. There is potential in this device to corroborate a clinical impression of “no need for intervention” and to provide important natural history flow information on ventricular shunts. The authors are to be congratulated for tackling a difficult problem and pursuing a non-invasive tool for detecting shunt malfunction.

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The effort by this group shows a thoughtful attempt to add to the current methods of detecting shunt malfunction and selecting patients in need of surgical revision. The study design that allowed for a significant separation between the results of their augmented thermal flow test, and the decision for surgery, is a very positive aspect of the report. I also appreciate the inclusion of a group of patients with mechanical shunt problems which had to be revised, because their study design did not take that situation into account. The authors note, that if they had excluded those patients, the sensitivity would be 100%. This transparency in reporting is commendable and increases both the veracity and utility of their results.

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