

# Evaluation of the ShuntCheck Noninvasive Thermal Technique for Shunt Flow Detection in Hydrocephalic Patients

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**Received,** January 5, 2010.  
**Accepted,** June 10, 2010.

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 Congress of Neurological Surgeons

**BACKGROUND:** ShuntCheck (Neuro Diagnostic Devices, Inc., Trevose, Pennsylvania) is a new device designed to detect cerebrospinal fluid (CSF) flow in a shunt by sensing skin temperature downstream from a region of CSF cooled by an ice cube.

**OBJECTIVE:** To understand its accuracy and utility, we evaluated the use of this device during routine office visits as well as during workup for suspected shunt malfunction.

**METHODS:** One hundred shunted patients were tested, including 48 evaluated during possible shunt malfunction, of whom 24 went on to surgical exploration. Digitally recorded data were blindly analyzed and compared with surgical findings and clinical follow-up.

**RESULTS:** Findings in the 20 malfunctioning shunts with unambiguous flow or absence of flow at surgery were strongly correlated with ShuntCheck results (sensitivity and specificity to flow of 80% and 100%, respectively,  $P = .0007$ , Fisher's exact test, measure of agreement  $\kappa = 0.8$ ). However, the thermal determination did not distinguish patients in the suspected malfunction group who received surgery from those who were discharged without surgery ( $P = .248$  by Fisher's exact test,  $\kappa = 0.20$ ). Half of the patients seen in routine office visits did not have detectable flow, although none required shunt revision on clinical grounds. Intermittent flow was specifically demonstrated in one subject who had multiple flow determinations.

**CONCLUSION:** Operative findings show that the technique is sensitive and specific for detecting flow, but failure to detect flow does not statistically predict the need for surgery. A better understanding of the normal dynamics of flow in individual patients, which this device may yield, will be necessary before the true clinical utility of non-invasive flow measurement can be assessed.

**KEY WORDS:** Flow detection, Hydrocephalus, Noninvasive, Shunt

*Neurosurgery* 68:198–205, 2011

DOI: 10.1227/NEU.0b013e3181fe2db6

www.neurosurgery-online.com

Hydrocephalus has an incidence of 0.2 to 0.8/1000 live births in the United States, with an overall mortality rate of 0.71 per 100 000 person-years.<sup>1</sup> CSF shunts, introduced in the late 1950s, remain the mainstay of treatment for hydrocephalus.<sup>2-6</sup> However, approximately 39% of shunts fail within the first year, 53% fail within the first two years, and about 80% fail at some point after insertion.<sup>7-9</sup> Shunt malfunction is a critical cause of mortality

in patients with shunted hydrocephalus, although little is known about normal physiological shunt flow.<sup>10-13</sup> Despite a reported decrease of 8.8% in the incidence of pediatric hydrocephalus in the last 20 years,<sup>14</sup> the diagnosis and repair of failed ventriculoperitoneal (VP) shunts for hydrocephalus is one of the most common neurosurgical procedures, with over 27 000 surgeries performed each year in the United States.<sup>15</sup> A noninvasive technique for assessing shunt flow would aid understanding of the working shunt and potentially improve proper diagnosis of shunt malfunction.

Standard methods for investigating shunt status rely either on interpretations of static

**ABBREVIATIONS:** **FD**, flow detected; **FNC**, flow not confirmed; **SSM**, suspected shunt malfunction; **VP**, ventriculoperitoneal.

imaging of the brain (ie, MRI, CT scans, and shunt x-rays<sup>16-18</sup>), or invasive measures of flow (eg, shunt tap, radionuclide studies<sup>19-21</sup>). A noninvasive technique of measuring CSF flow using ultrasonically excited bubbles has lacked the technical consistency needed for clinical settings.<sup>22</sup> MRI imaging can detect CSF flow within a shunt; however, further research is needed on the practical application and clinical use of this technique.<sup>23,24</sup> To date, reliable noninvasive techniques for detecting or quantifying flow in a shunt to distinguish normal shunt function from shunt failure in an individual patient are lacking.

Thermal techniques based on transcutaneous thermal convection are among the most promising and established noninvasive techniques to evaluate the patency of shunts. The first successful experiments to use noninvasive thermal techniques were done in the Netherlands in 1968,<sup>25,26</sup> followed by similar experiments in VP shunts in Japan.<sup>27,28</sup> Further investigation in the United States of transcutaneous thermal convection to evaluate CSF flow in CSF shunts led to the development of a portable device, tested and cleared for clinical use.<sup>29,30</sup>

ShuntCheck (Neuro Diagnostic Devices, Inc., Treviso, Pennsylvania) is a new, FDA-approved device using a thermal technique to detect and potentially quantify shunt CSF flow. We evaluated the ShuntCheck device and the transcutaneous thermal technique in patients having routine shunt follow-up, as well as in patients having suspected shunt malfunction. We sought to compare results of the test with actual observed flow in those patients who underwent shunt exploration and to determine whether the flow detection by this device would predict which patients—in both the malfunction suspect group and the group of all patients tested—required surgery.

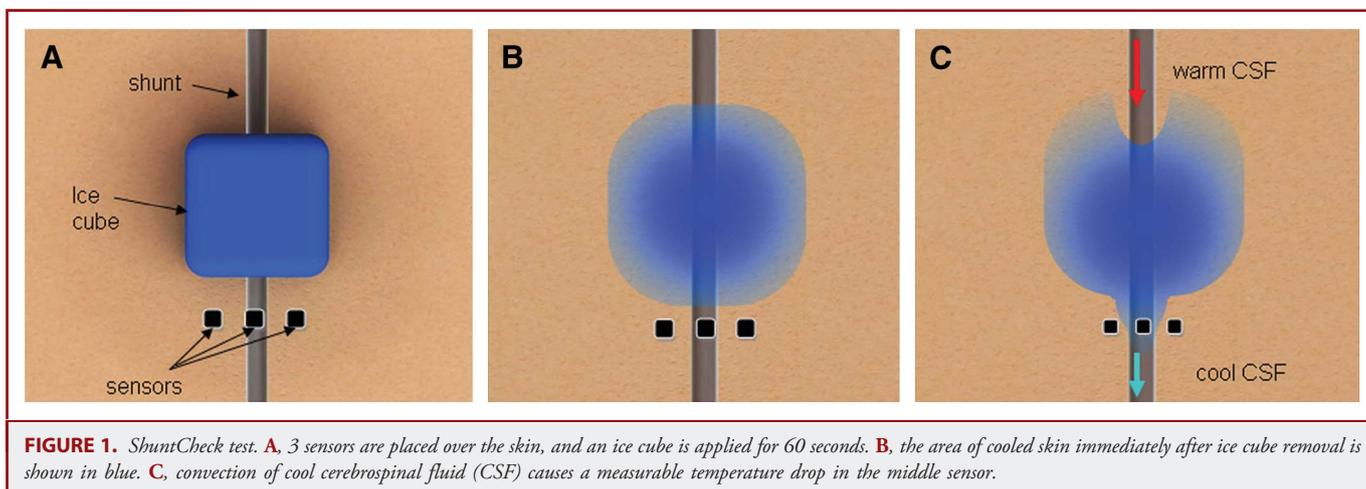
To evaluate utility and reliability of the device we tested 2 hypotheses: (1) the device accurately indicates whether CSF flow is present in CSF shunts; and (2) the absence of flow in the shunt as shown by ShuntCheck is a significant indicator that a shunt requires revision. We compared test results in outpatients who were asymptomatic, patients undergoing evaluation for suspected

shunt problems, and patients who had surgical exploration with direct observation of shunt status.

## PATIENT SELECTION AND METHODS

### Testing Technique

Informed consent was obtained prior to performing the ShuntCheck test, which included informing subjects that test results would not be made available to the clinical team, the patient, or family. ShuntCheck tests were done with the patient in two positions, supine first and then sitting. Following the device manufacturer's recommendations, an adhesive patch with 3 temperature sensors was placed on the skin, just below the clavicle, so that the middle sensor was over the shunt while the 2 remaining sensors, serving as controls, were positioned symmetrically on each side of the shunt (Figure 1A). The adhesive patch with the sensors contained an opening for the plastic-covered ice cube window (2.5 cm × 2.5 cm) overlying and just above the clavicle. The sticker was then connected to the ShuntCheck handheld device via electric cable. The ice cube was positioned on the skin within the window for 60 seconds (Figure 1B). When there is flow in the shunt, cooled CSF flows beneath the sensor, which results in a measurable temperature drop in the central ShuntCheck sensor as compared with the 2 control sensors (Figure 1C); absence of flow results in little difference in temperatures detected by all 3 sensors. The ShuntCheck device directs timing of application and removal of the ice cube and records temperature readings from all 3 sensors from 10 seconds before until 8 minutes after ice cube removal. In all cases, data were collected using the handheld device, and the electronically recorded thermal data were uploaded to the device manufacturer for interpretation blind to any clinical information. In the latest version of the device, this interpretation is made by an algorithm running on the handheld device. The algorithm first calculates a temperature curve  $T(t)$ , where  $t$  represents time, by computing for each time point the temperature difference between the middle sensor and the mean of the 2 controls. Next, a difference  $\Delta T$  between the maximal and minimal values of  $T(t)$  is calculated. Finally, a conclusion is made with regard to presence or absence of flow:  $\Delta T$  must be above a predetermined threshold as reported by the device for flow result to be established.

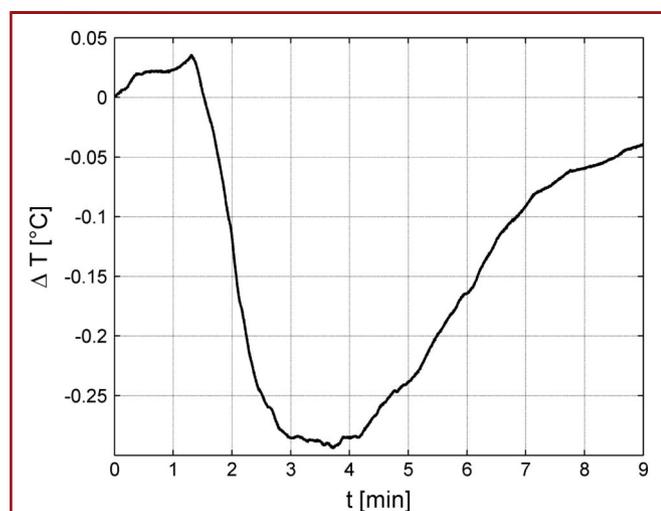


The algorithm used remotely to classify the collected data into categorical readings of “flow detected” (FD) or “flow not confirmed” (FNC), was based on previous animal and pilot clinical tests done with the same device.<sup>29</sup> The algorithm assumes that a concave U-shaped temperature curve with  $\Delta T$  of at least  $0.2^{\circ}\text{C}$  (Figure 2) is required for confirming flow; any other temperature curve will result in not confirming flow (Figure 3). All data analysis was conducted subsequent to the testing based on the blind interpretation reported by the manufacturer, Neuro Diagnostic Devices. If flow was detected in either the supine or sitting position, the test result was scored as FD. Digital data allowing inspection of the actual temperature curves, and differences between preoperative and postoperative curves in a single patient, also were made available by the manufacturer. Except in the comparisons of postoperative vs preoperative curves, and in the one subject with multiple repeat tests, all results discussed in the following sections are from the first set of tests of each patient.

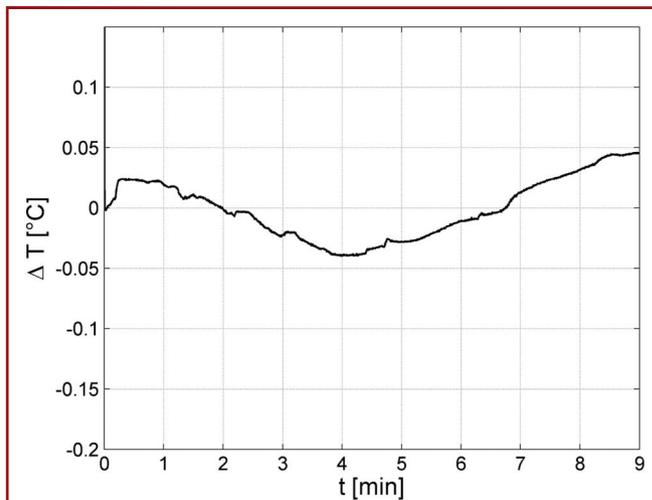
**Patient Selection**

Patients were recruited into the study under 1 of 2 circumstances: suspected shunt malfunction (SSM), or routine office visits. The SSM group (n = 48), which consisted of all subjects undergoing evaluation of a possible shunt-related problem, had 1 or more clinical signs of malfunction (eg, headaches, vomiting, nausea, irritability, seizures) requiring evaluation with an imaging study or other diagnostic procedure. These patients typically were tested with ShuntCheck in the emergency department, in the preoperative waiting area before emergency shunt surgery, or during emergency office visits. In this group with suspicion of shunt problem, 24 patients, or 50% of the group, went on to operative exploration. Thirteen of the operated patients were available for a postoperative flow determination, allowing preoperative and postoperative ShuntCheck tests to be compared (Table 1).

The second group included patients not suspected of having acute malfunction (n = 52), and ShuntCheck tests were performed during routine clinic visits.



**FIGURE 2.** Example of the temperature-vs-time graph of a ShuntCheck test with  $\Delta T > 0.2^{\circ}\text{C}$ , indicating that flow is detected (FD). The subject, an 8-year-old child, is asymptomatic.



**FIGURE 3.** Graph of a ShuntCheck test in sitting position with  $\Delta T < 0.2^{\circ}\text{C}$ , indicating flow not confirmed (FNC). The subject is an 8-year-old child with suspected shunt malfunction.

**Clinical Endpoints**

Subjects enrolled in this study were scored as to whether they required shunt revision surgery within 7 days of the ShuntCheck test (Tables 2 and 3). For patients who went to surgery, a determination of whether or not the shunt had observable CSF flow was made as follows: when the shunt was disconnected, complete lack of observable flow, or flow of less than 2 drops in 20 seconds, from above the disconnection, or obstruction of distal flow when checked with a manometer, was scored as “no flow.” Observed flow of at least 6 drops per minute with a patent system downstream by manometry was scored as “flow,” even if 1 or more components were revised for partial obstruction. Four cases were scored as “indeterminate” when distal flow could not be assessed because the distal end of a disconnected shunt was not available in the operative field.

**TABLE 1.** Comparison of ShuntCheck Results With Findings in Surgery in the SSM Group of Patients<sup>a,b</sup>

ShuntCheck Results	Findings in Surgery			Total
	Flow Detected	Flow Not Confirmed	Indeterminate	
Flow detected	8	0	1	9
Flow not confirmed	2	10	3	15
Total	10	10	4	24

<sup>a</sup>SSM, suspected shunt malfunction.

<sup>b</sup>With SSM patients having undergone operative exploration, correlation of ShuntCheck results with surgical findings is significant, with Fisher exact test of 0.0007 and the measure of agreement  $\kappa = 0.8$  when indeterminate cases are excluded. Even if all 4 of the indeterminate predictions are assumed incorrect, Fischer’s exact test is 0.013 and measure of agreement  $\kappa = 0.51$ .

**TABLE 2. ShuntCheck Prediction of Surgery in Patients With SSM<sup>ab</sup>**

ShuntCheck Results	Shunt Revision Surgery		Total
	No	Yes	
Flow detected	14	9	23
Flow not confirmed	10	15	25
Total	24	24	48

<sup>a</sup>SSM, suspected shunt malfunction.

<sup>b</sup>SSM group tested with ShuntCheck. Correlation of ShuntCheck results with shunt revision surgery within 7 days was insignificant. Fisher's exact test was 0.248 and  $\kappa = 0.208$ , showing at most slight predictive power.

## Statistical Analysis

Binary outcome event (FD vs FNC; surgery vs no surgery) comparison in a  $2 \times 2$  contingency analysis with a 2-tailed Fisher's exact test<sup>31</sup> and measurement of agreement (Cohen's kappa<sup>32</sup>) between the ShuntCheck results and observations in the operating room (OR) were computed using SPSS v16.0 software (SPSS Inc., Chicago, Illinois). Comparisons of differences within subjects pre- vs postoperatively were performed with statistical functions available in MATLAB R2007B (Mathworks Inc., Natick, Massachusetts), as described in the Results section.

This research study was done under the Institutional Review Board approved research protocol of Children's Hospital Boston.

## RESULTS

Findings in the SSM group were strongly correlated with the thermal flow results. Preoperative ShuntCheck test results showed "flow" in 8 of the 10 cases where flow was actually observed at surgery and "flow not detected" in all of the 10 surgical cases where this was observed in the OR (sensitivity to flow of 80%, specificity 100% in this group, Fisher's exact test, Table 1). The strength of agreement by Cohen's  $\kappa$  statistic<sup>32</sup> (actual agreement minus agreement expected by chance, divided by one, minus agreement expected by chance) is strong at 0.80 at  $P = .0002$ . This suggests that in the operative patients the device correctly describes the presence of flow. For the "indeterminate" subjects ( $n = 4$ ), no analysis is possible; however, even if we assume the ShuntCheck was incorrect in all 4 of these subjects (a worst-case scenario), the relationship between observed flow and predicted flow would still be highly significant ( $P = .013$ , Fisher's exact test).

**TABLE 3. ShuntCheck Prediction of Surgery in All Tested Patients<sup>a</sup>**

ShuntCheck Results	Shunt Revision Surgery		Total
	No	Yes	
Flow detected	41	9	50
Flow not confirmed	35	15	50
Total	76	24	100

<sup>a</sup>All patients were tested with the ShuntCheck device. Correlation of ShuntCheck results with shunt revision surgery within 7 days was insignificant. Fisher's exact test was 0.241 and  $\kappa = -0.120$ , showing lack of predictive value.

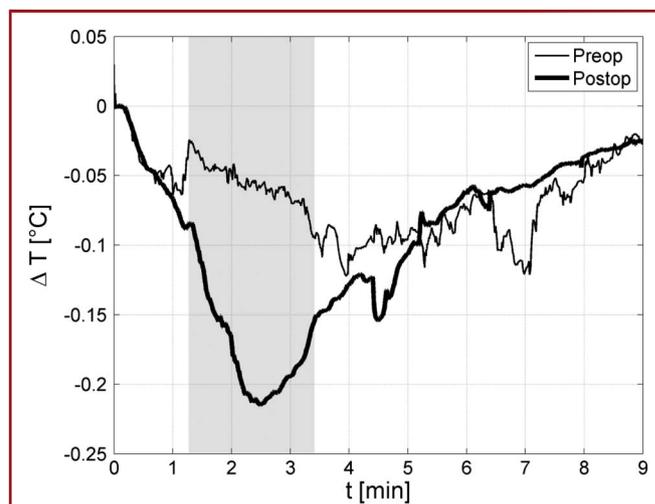
The test did not distinguish patients in the suspected malfunction group who underwent surgery from those who were discharged without surgery (Table 2, 3). Among the 48 patients evaluated for SSM, the result correctly identified patients who needed surgery 60.4% of the time (that is, showed FNC for those ultimately going to surgery, or FD in those not going to surgery). But because chance alone would have yielded a 50% agreement rate, the overall  $\kappa$  showed slight agreement ( $\kappa = 0.20$ ), while Fisher's exact test yields  $P = .248$ . If the entire group of 100 patients is considered, the test still is not significant:  $\kappa = 0.12$ ; Fisher's exact test = 0.241. Among the patients having routine follow-up, 25 of 52 also had readings of FNC, so that in the overall group of all patients (including surgical, nonsurgical, and routine outpatients) the absence of detectable flow proved *not* to be a predictive factor in determining the need for shunt revision.

## Post- vs Preoperative Flow Determination in Surgical Patients

Thirteen patients had both pre- and postoperative studies in both the supine and sitting positions. Blind interpretation indicated flow in 9 of the 13 patients (69.2% of cases). The pre- and postoperative graphs were averaged for a result of greater amplitude in the postoperative graphs, consistent with higher degrees of flow (Figure 4).

## Flow Status and Need for Surgery — Examples of Disparity

The disparity between the presence or absence of flow and need for revision is of interest, prompting consideration of



**FIGURE 4.** Comparison of the pre- and postoperative ShuntCheck test graphs, averaged over the 13 patients who had both pre- and postoperative ShuntCheck tests performed. Although this difference did not reach statistical significance at  $P < .05$ , for the shaded region it did reach  $P < .20$  in that the postoperative temperature drop was, on average, more than the preoperative temperature drop.

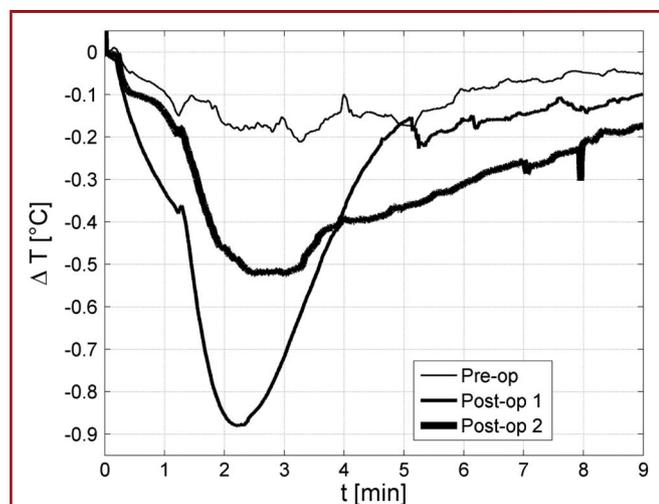
patients who had flow (both surgically observed and according to ShuntCheck), but needed surgery and those who had no flow (according to the test, since no additional flow data were collected), but did well without surgery. Reviews of clinical details in the first group explain how flow could be detectable even though revision was indicated.

**Example 1.** A 15-year-old girl with spina bifida, hydrocephalus, and VP shunt presented symptomatically in the clinic with significant neck pain but no headache for 1 week. X-rays showed the shunt to be intact, but MRI images indicated an increase in ventricular size compared to 12 months earlier. In the operating room, the neurosurgeon observed unequivocal flow, and a partially occluded proximal catheter that was replaced. This proved to correlate with the preoperative ShuntCheck result of FD. Two postoperative tests, at 5 and 14 days, showed flow, with higher amplitude, suggesting a greater flow postoperatively (Figure 5).

**Example 2.** A 9-year-old girl with VP shunted hydrocephalus presented in the emergency department with nausea, neck pain, and mild headache. Shunt series indicated a disconnected shunt, and CT showed enlarged ventricles (Figure 6A). The ShuntCheck results obtained preoperatively showed flow (Figure 6B). During revision, the abdominal incision was opened first and the shunt divided; brisk flow was observed, which implied flow through a fibrotic tract between the proximal and distal portions of the shunt. The preoperative ShuntCheck test showed flow (Figure 6B), and the 1 day postoperative test also showed flow (Figure 6C).

### Repeat Measures With ShuntCheck: Variability Within an Individual

The high FNC rate among asymptomatic patients suggests that, at least in some patients, this finding must be due to



**FIGURE 5.** Clinical example 1. The graph compares 1 preoperative with 2 postoperative ShuntCheck tests, before and after repair of a partially occluded ventricular catheter in a 15-year-old girl with suspected shunt malfunction.

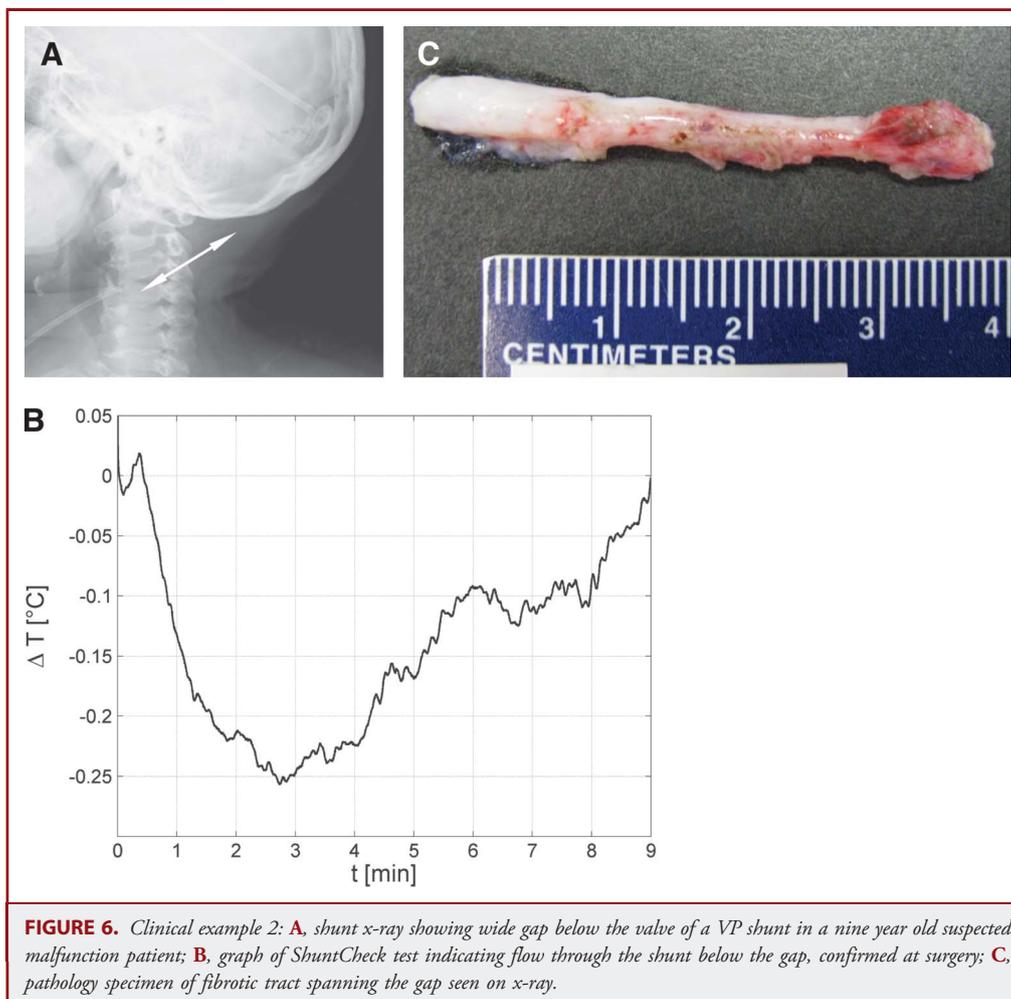
intermittency of flow. We addressed the question of flow intermittency by performing multiple ShuntCheck tests in a single asymptomatic 19-year-old subject who had never required revision since infancy, in various bodily postures and after performing various activities (including exercise, overnight sleep, and Trendelenburg position). A total of 38 ShuntCheck flow studies were performed over a 5-day interval. The sensors were left in place over the course of each day to minimize effects of replacement. The test results are summarized in Table 4. Surprisingly, 57.9% of the tests yielded results of FNC, while 42.1% read FD. No single activity consistently produced either FD or FNC results, but tests taken after sitting up yielded shunt flow most times. Five representative temperature curves interpreted as FD and FNC are shown in Figure 7.

## DISCUSSION

The most robust and compelling finding in this study was the prediction of surgical findings (flow or no flow) independently by the ShuntCheck technique (FD or FNC). We found no cases where flow was identified by the device when none was found at surgery and, when flow was detectable in the OR, the thermal technique detected this 80% of the time. These highly statistically significant results suggest ShuntCheck is a reliable determinant of CSF flow. As with all physical measurement devices, it is possible for flow to be below threshold for detection by the device, which could explain cases with surgically detected flow despite a reading of FNC by the device. In addition, noise resulting from patient movement could obscure a flow signal. Nevertheless, the device showed a good sensitivity to flow (80%) and excellent specificity of flow (100%) in the surgical cases that could be evaluated.

Given these results, if we make the apparently reasonable assumption that patients with no flow need surgery and those showing flow do not need surgery, then ShuntCheck should be able to predict which patients need surgery and which might be safely discharged. This proved, dramatically, not to be the case. Several subjects with documented flow according to the test did require surgery (including the 2 cases illustrated in the vignettes) and, more remarkably, many cases with no observable flow did not prompt immediate surgery or even surgery within 7 days. Even more dramatically, ShuntCheck registered absence of flow in half of our tested outpatients without suspected problems.

What explains the very high incidence of the finding of FNC in the routine group? Several possibilities should be considered. Perhaps shunt flow is intermittent, with variations after postural changes. Even shunts with high net flow over the day could allow periods of nondetectable flow. This pattern of intermittent flow was clearly seen in 1 subject studied in detail and is consistent with data in the literature suggesting the intermittent nature of CSF flow.<sup>2,33-35</sup> Perhaps some of the patients tested had shunts that simply never showed flow, with absence of symptoms resulting from shunt independence. These explanations are not mutually exclusive and may be resolved with longitudinal study and retesting of patients.



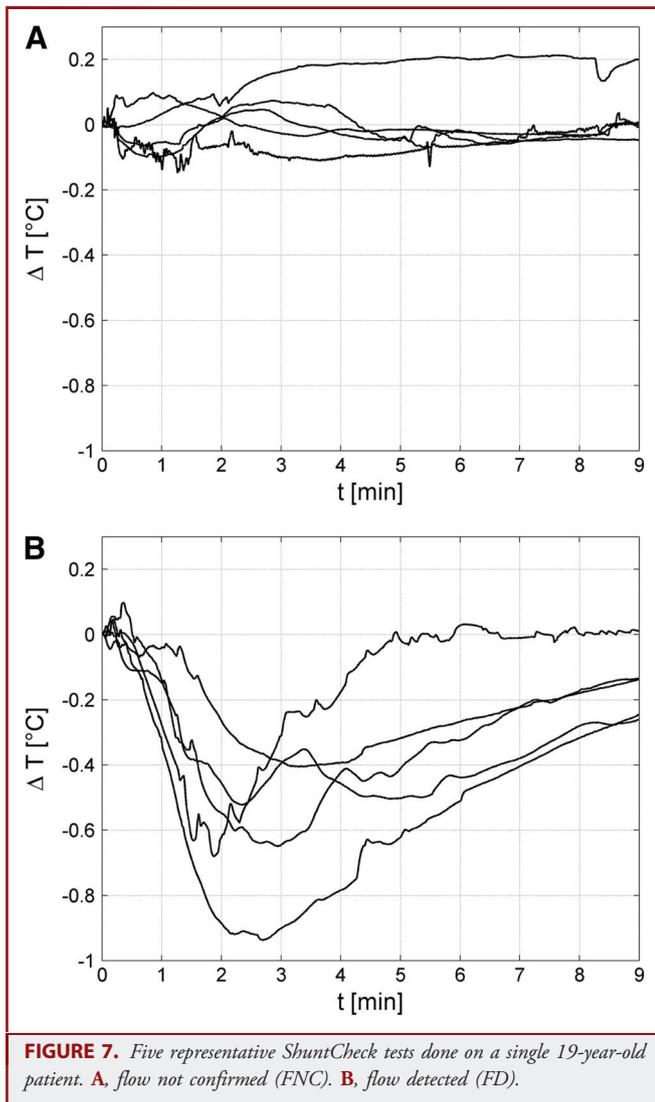
Further understanding of the quantitative aspects of flow could be acquired under those circumstances where an alternative method of quantitatively visualizing flow is possible. Shunts externalized below a subcutaneous region that might be tested by ShuntCheck would provide one such opportunity; patients undergoing radionuclide shunt scans would offer another.

It does not appear that the thermal flow measurement could be used as a standalone diagnostic tool to triage patients, because in isolation the test results did not predict the subsequent surgical decisions made at our center. Further studies and clinical experience are needed to determine the optimal way in which the device can be used to assess patients. It is possible that trends or changes in flow dynamics within a patient may be more predictive of clinical trajectory than a single isolated value. Repeated tests on an individual patient to determine the impact, if any, of an intervention such as changing the opening pressure of an adjustable valve could prove useful. Provocative tests, to attempt

**TABLE 4. Summary of 38 ShuntCheck Tests in a Single Asymptomatic Subject, Performed Immediately After Various Activities<sup>a</sup>**

Activity	Test Results		
	Flow Detected	Flow Not Confirmed	Total
Sleeping	4	6	10
Sitting up	6	5	11
Trendelenburg	3	3	6
Walking	2	4	6
Exercise	1	4	5
Total	16	22	38

<sup>a</sup>Summary of 38 ShuntCheck tests in a single asymptomatic subject, performed immediately after various activities. Flow was detected in only 42% of tests. No single activity seemed to promote flow. The results confirm that cerebrospinal fluid flow is intermittent in at least some patients.



to define shunt patency as opposed to simply shunt flow at a particular time, might add to the clinical value of the technique. Clues to mysteries such as why some patients live for decades without shunt revision while others need many revisions may be elucidated from understanding the pattern of flow in individual patients' shunts and an inexpensive noninvasive technique may be key in uncovering these clues.

## CONCLUSIONS

Findings at shunt revision show that the thermal flow technique is sensitive and specific for detecting flow, but detection of flow does not statistically predict the clinical diagnosis of shunt failure. Additional device utility may become more obvious with broader prospective data collection.

## Disclosure

Partial funding for conducting the ShuntCheck research has been received from Neuro Diagnostic Devices. The authors have no personal financial or institutional interest in any of the drugs, materials, or devices described in this article.

## REFERENCES

- Chi JH, Fullerton HJ, Gupta N. Time trends and demographics of deaths from congenital hydrocephalus in children in the United States: National Center for Health Statistics data, 1979 to 1998. *J Neurosurg.* 2005;103(2 Suppl):113-118.
- Hidaka M, Matsumae M, Ito K, Tsugane R, Suzuki Y. Dynamic measurement of the flow rate in cerebrospinal fluid shunts in hydrocephalic patients. *Eur J Nucl Med.* 2001;28(7):888-893.
- Bergsneider M, Egnor MR, Johnston M, et al. What we don't (but should) know about hydrocephalus. *J Neurosurg.* Mar 2006;104(3 Suppl):157-159.
- Madsen JR, Egnor M, Zou R. Cerebrospinal fluid pulsatility and hydrocephalus: the fourth circulation. *Clin Neurosurg.* 2006;53:48-52.
- Scott RM, Madsen JR. Shunt technology: contemporary concepts and prospects. *Clin Neurosurg.* 2003;50:256-267.
- Williams MA, McAllister JP, Walker ML, et al. Priorities for hydrocephalus research: report from a National Institutes of Health-sponsored workshop. *J Neurosurg.* Nov 2007;107(5 Suppl):345-357.
- Garton HJ, Kestle JR, Drake JM. Predicting shunt failure on the basis of clinical symptoms and signs in children. *J Neurosurg.* 2001;94(2):202-210.
- Drake JM, Kestle JR, Milner R, et al. Randomized trial of cerebrospinal fluid shunt valve design in pediatric hydrocephalus. *Neurosurgery.* 1998;43(2):294-303; discussion 303-295.
- Kestle J, Drake J, Milner R, et al. Long-term follow-up data from the shunt design trial. *Pediatr Neurosurg.* 2000;33(5):230-236.
- Staal MJ, Meihuizen-de Regt MJ, Hess J. Sudden death in hydrocephalic spina bifida aperta patients. *Pediatr Neurosci.* 1987;13(1):13-18.
- Browd SR, Gottfried ON, Ragel BT, Kestle JR. Failure of cerebrospinal fluid shunts: part II: overdrainage, loculation, and abdominal complications. *Pediatr Neurol.* 2006;34(3):171-176.
- Browd SR, Ragel BT, Gottfried ON, Kestle JR. Failure of cerebrospinal fluid shunts: part I: obstruction and mechanical failure. *Pediatr Neurol.* 2006;34(2):83-92.
- Iskandar BJ, Tubbs S, Mapstone TB, Grabb PA, Bartolucci AA, Oakes WJ. Death in shunted hydrocephalic children in the 1990s. *Pediatr Neurosurg.* 1998;28(4):173-176.
- Massimi L, Paternoster G, Fasano T, Di Rocco C. On the changing epidemiology of hydrocephalus. *Childs Nerv Syst.* 2009;25(7):795-800.
- Patwardhan RV, Nanda A. Implanted ventricular shunts in the United States: the billion-dollar-a-year cost of hydrocephalus treatment. *Neurosurgery.* 2005;56(1):139-144; discussion 144-135.
- Pitetti R. Emergency department evaluation of ventricular shunt malfunction: is the shunt series really necessary? *Pediatr Emerg Care.* 2007;23(3):137-141.
- Zorc JJ, Krugman SD, Ogborn J, Benson J. Radiographic evaluation for suspected cerebrospinal fluid shunt obstruction. *Pediatr Emerg Care.* 2002;18(5):337-340.
- Iskandar BJ, McLaughlin C, Mapstone TB, Grabb PA, Oakes WJ. Pitfalls in the diagnosis of ventricular shunt dysfunction: radiology reports and ventricular size. *Pediatrics.* 1998;101(6):1031-1036.
- Howman-Giles R, McLaughlin A, Johnston I, Whittle I. A radionuclide method of evaluating shunt function and CSF circulation in hydrocephalus. Technical note. *J Neurosurg.* 1984;61(3):604-605.
- Chervu S, Chervu LR, Vallabhajosyula B, et al. Quantitative evaluation of cerebrospinal fluid shunt flow. *J Nucl Med.* 1984;25(1):91-95.
- Sood S, Canady AI, Ham SD. Evaluation of shunt malfunction using shunt site reservoir. *Pediatric Neurosurg.* 2000;32(4):180-186.
- Lam KW, Drake JM, Cobbold RS. Noninvasive cerebrospinal fluid shunt flow measurement by Doppler ultrasound using ultrasonically excited bubbles: a feasibility study. *Ultrasound Med Biol.* 1999;25(3):371-389.
- Frank E, Buonocore M, Hein L. Magnetic resonance imaging analysis of extremely slow flow in a model shunt system. *Childs Nerv Syst.* 1992;8(2):73-75.
- Martin AJ, Drake JM, Lemaire C, Henkelman RM. Cerebrospinal fluid shunts: flow measurements with MR imaging. *Radiology.* 1989;173(1):243-247.

25. Go KG, Lakke JPWF, Beks JWF. A harmless method for the assessment of the patency of ventriculoatrial shunts in hydrocephalus. *Dev Med Child Neurol*. 1968;10(Suppl 16):100-106.
26. Go KG, Melchior HJ, Lakke JPWF. A thermosensitive device for the evaluation of the patency of ventriculo-atrial shunts in hydrocephalus. *Acta Neurochir (Wien)*. 1968;19(4):209-216.
27. Chiba Y, Ishiwata Y, Suzuki N, Muramoto M, Kunimi Y. Thermosensitive determination of obstructed sites in ventriculoperitoneal shunts. *J Neurosurg*. 1985;62(3):363-366.
28. Chiba Y, Yuda K. Thermosensitive determination of CSF shunt patency with a pair of small disc thermistors. *J Neurosurg*. 1980;52(5):700-704.
29. Neff S. Measurement of flow of cerebrospinal fluid in shunts by transcutaneous thermal convection. Technical note. *J Neurosurg*. 2005;103(4 Suppl):366-373.
30. Stein SC, Apfel S. A noninvasive approach to quantitative measurement of flow through CSF shunts. Technical note. *J Neurosurg*. 1981;54(4):556-558.
31. Fisher RA. On the interpretation of  $\chi^2$  from contingency tables, and the calculation of P. *J Royal Stat Soc*. 1922;85(1):87-94.
32. Cohen J. A coefficient of agreement for nominal scales. *Educ Psychol Meas*. 1960;20(1):37-46.
33. Drake JM, Sainte-Rose C, DaSilva M, Hirsch JF. Cerebrospinal fluid flow dynamics in children with external ventricular drains. *Neurosurgery*. 1991;28(2):242-250.
34. Kadowaki C, Hara M, Numoto M, Takeuchi K. Factors affecting cerebrospinal fluid flow in a shunt. *Br J Neurosurg*. 1987;1(4):467-475.
35. Kadowaki C, Hara M, Numoto M, Takeuchi K, Saito I. CSF shunt physics: factors influencing inshunt CSF flow. *Childs Nerv Syst*. 1995;11(4):203-206.

## Acknowledgments

Financial support for this project was received from Rotary International as an Ambassadorial Fellowship to Gani Abazi, MD, MPH, research grant support from NeuroDiagnostic

Devices, and the Webster Family. We gratefully acknowledge input from Matt Gregas, PhD, biostatistician in the clinical research program, Children's Hospital Boston and Harvard Medical School, as well as Paul Pikutis, publications editor, Department of Neurosurgery, Children's Hospital Boston.

## COMMENT

The concept of the ShuntCheck device was embraced enthusiastically by many whose practices include a large number of patients with shunts, given the vexing circumstances that these sometimes create. The idea of noninvasively assessing shunt function is very attractive, avoiding the time, expense, and the concern regarding long-term consequences of radiation exposure that our current methods have required. It is, therefore, disheartening to see that when subject to rigorous scrutiny, as was done so well in this article, the fundamental hope for the device was not borne out. One wonders whether technical modifications to detect flow at lower levels would allow it to be used more effectively to determine shunt function. There may be utility in using the instrument to try to understand the manner of function of a shunt in an individual patient over time, by establishing a baseline of data. The finding of periods of undetectable flow in patients with apparently well-functioning shunts could be a technical question of ongoing flow below the limit of device, or of intermittency of flow. But it also suggests that there remains much about the normal functioning of patent shunts which we still need to learn. The device may still shed light on this matter, when studied as carefully as was done in this investigation.

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