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Measurement of flow of cerebrospinal fluid in shunts by transcutaneous thermal convection

Technical note

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✓With the goal of developing a practical method of performing noninvasive measurements of flow in cerebrospinal fluid (CSF) shunts, transcutaneous thermal convection CSF shunt flow measurement was investigated using dimensional analysis, numerical modeling, and bench testing. Using appropriate manufacturing practices and controls, a microcontroller-based device was designed, constructed, and clinically tested. Flow was detected in functioning shunts nine times in 10 attempts. One test failed due to postoperative edema, and subsequent testing was limited to patients who had not undergone shunt surgery within the previous 2 weeks. On the basis of these data and previous reports, 510(k) clearance was granted by the Food and Drug Administration for detection of flow in CSF shunts. Flow in CSF shunts can be detected noninvasively and cost effectively by using a simple thermal convection system. The positive and negative predictive values of the test are equal to or greater than those of brain imaging and radionuclide shunt studies.

Key Words • **cerebrospinal fluid** • **shunt** • **thermal convection** • **pediatric neurosurgery**

Cerebrospinal fluid shunts are highly effective in the treatment of hydrocephalus, yet this efficacy is not achieved without significant effort: more than 80% of shunts fail at some point after insertion.[10] The failure mode of most shunts is clinical obstruction, with return of symptomatic hydrocephalus. A significant number of patients die every year of acute hydrocephalus due to shunt malfunction.[11]

The potential for sudden, catastrophic failure drives much of the follow-up care of patients with shunts, which includes low-yield, time-consuming neurosurgical office evaluations of asymptomatic patients, ophthalmological consultations, imaging studies, and invasive tests. From a public health standpoint, these interventions are both expensive and unproven. No protocol for monitoring shunt-treated patients has been shown to be cost effective in terms of years of potential life saved. Furthermore, from the viewpoint of the patient and family, these unproven screening strategies create a significant social burden. An additional loss is the value of the time lost from work, school, and other obligations created by the fear of shunt malfunction.

An inexpensive, reliable, and safe method of determining shunt function would significantly improve the care and lives of patients with CSF shunts, even if it required a physician to implement it. A test or procedure that could be done at home would be even better.

Soon after the introduction of modern shunts, Go and colleagues[3,4,8] showed that transcutaneous thermal convection could be used to detect flow in a working shunt. They used a thermistor placed over the shunt and applied an ice cube to the skin "upstream" of the thermistor. Stein and Apfel[12] then demonstrated in an in vivo porcine model that actual flow rate could be measured if two thermistors were used. Chiba and Yuda[2] performed tests in 21 patients prior to shunt surgery and confirmed that the results correlated with intraoperative findings.

Despite this initial success, the limitations of the temperature-measuring instruments and sensors of that time prevented commercialization of the technology (S Stein, personal communication, 2004). The concept has been discussed with at least one medical device manufacturer since then (J Pattisapu, personal communication, 2004), but again commercialization did not occur.

Assessing the results of the aforementioned investigators and evaluating the current state of thermometry, I hypothesized that with modern technology a medical device was feasible and practical.

Materials and Methods

I undertook a four-phase program to develop transcutaneous thermal convection as a clinical tool for the evalua-

Abbreviations used in this paper: CSF = cerebrospinal fluid; FDA = Food and Drug Administration; IRB = institutional review board.

tion of shunt function. First, using dimensional analysis, I assessed the theoretical basis for transcutaneous thermal convection measurement of CSF flow in shunts. This determined the physical constraints on the shunt tubing depths, detectable flow rates, and study times for a clinical device.

In the second phase, I developed a numerical model (finite difference) of transcutaneous thermal convection over a working shunt. This computer model allows the exploration of the effects of all parameters on the accuracy of the process, including tissue blood flow, shunt size, shunt depth, shunt flow rate, and air temperature. The model greatly speeds the search, in parameter space, for optimal operating protocols.

Third, I constructed a benchtop model of the human scalp with an embedded CSF shunt and simulated tissue blood flow. Thermistors were applied downstream of an applied ice cube (as in the actual clinical situation), and the temperature change over time was measured for a variety of fluid flow rates. These data were correlated with the numerical model.

Fourth, I developed and constructed (using appropriate design and manufacturing processes) a device and undertook a clinical investigation to measure CSF flow in asymptomatic patients with hydrocephalus who had shunts. I tested the device in nine patients with functioning CSF shunts and no symptoms of hydrocephalus and in one control patient with no shunt. The clinical protocols were approved as minimally risky, and investigational device exemptions were granted on this basis by the relevant IRBs (Graduate Hospital, Philadelphia, PA, and Our Lady of Lourdes Medical Center, Camden, NJ).

Results

Theoretical Model

The function of a transcutaneous thermal convection device is essentially that of measuring the temperature before, during, and after a thermal perturbation of the shunt–patient system. Because the major processes governing the transfer are thermal diffusion and convection, it is convenient to express heat flow in terms of local temperature. The effect of thermal diffusion on the local temperature is calculated using the following equation,

$$\left(\frac{\partial T}{\partial t}\right)_{diffusion} = -\frac{1}{\kappa}\nabla^2 T$$

which is the diffusion equation for temperature, where κ is the thermal diffusivity ($\kappa = k/C_p$, where k is the thermal conductivity and C_p is the specific heat). The tissue is perfused by blood at the core temperature of the body, which alters the local temperature according to the following equation,

$$\left(\frac{\partial T}{\partial t}\right)_{flow} = \frac{Cp(tissue)}{Cp(blood)}\, e(T_{blood} - T_{tissue})F$$

where e is the efficiency of heat exchange, and F the blood flow.

The flow in the shunt itself changes the local temperature by moving CSF of varying temperatures from place to place. This convection is described by the equation,

$$\left(\frac{\partial T}{\partial t}\right)_{convection} = \vec{v} \cdot \nabla T$$

where $\vec{v}$ is the velocity of the fluid (in the shunt tubing).

Putting these terms together,

$$\left(\frac{\partial T}{\partial t}\right) = -\frac{1}{\kappa}\nabla^2 T + F\,\frac{Cp(tissue)}{Cp(blood)}\, e(T_{blood} - T_{tissue}) + \vec{v} \cdot \nabla T$$

becomes the final equation.

To a reasonable approximation, over the aforementioned time scales, the values of Cp (tissue), Cp (blood), and e can be treated as constant. Conversely, $\vec{v}$ may be pulsatile on a time scale of $10^0 = 1$ second, but this time scale is so short compared with the time scales of interest (10^2 seconds) that $\vec{v}$ can also be treated as time invariant.

This partial differential equation can be solved analytically for $\vec{v} = 0$ and for special cases where it is not 0. In the case of a CSF shunt, with flow of 0.3 ml/minute in tubing with a length scale (diameter) of 1.2 mm, the flow will be at least strongly radius dependent (laminar), so that an analytic solution is not possible for meaningful physiological states. Furthermore, flow in patients may be pulsatile, so even a steady-state solution would be only an approximation.

Although we cannot express that solution analytically, significant information can be revealed by inspecting the scales of the equation. Table 1 gives generally accepted values for the various parameters in the equation. These values can be used to determine some general characteristics of the solutions to the equation.

The thermal diffusivity itself gives the relationship between the duration of events in the system and the length over which they occur. For example, the thermal diffusivity of human fat is reported to be 9.6×10^{-8} m^2/second.[7]

If we are interested in effects taking place over a length scale of 5 mm (the depth of a shunt below the skin), then we can determine a time scale for the event from the equation $\text{Time}_{\text{diffusion}} = \text{Length}_2/\pi$.

For a typical shunt, the length scale is on the order of 0.01 m, so the time scale is 103 seconds. This value leads one to suggest that thermal effects on the surface of the skin will diffuse to the shunt tubing on this time scale (1 minute).

Similarly, the velocity of the fluid in the shunt tubing, together with the time scale determined by the diffusion scale provided, can be used to set a practical distance criterion for the process—specifically, how far "downstream" the temperature change can be detected: $\text{Length} = \text{Time}_{\text{diffusion}}/\text{Velocity}_{\text{CSF}}$.

Using a velocity of 4 mm per second, we see that the CSF will flow 400 cm in 1000 seconds, well beyond the length of the patient. Therefore, CSF downstream flow will not be a limiting factor if a second thermistor is used.[12] On the other hand, CSF flow may limit the amount of cooling that occurs while the CSF is in the cooled part of the system. One way to increase this "dwell" time of the CSF in the cooled area is to slow the flow, which is most easily achieved by cooling a reservoir where the flow is already slow. A reservoir with a volume equal to 100 seconds of CSF production would be expected to significantly improve the sensitivity of the system. This aspect can be con-

TABLE 1

*Typical physical constants for thermal convection shunt**

Physical Constant	Thermal Conductivity (k) (W/m/K)	Density (g/cm^3)	Specific Heat (C_p) (J/g/K)	Thermal Diffusivity (K) (m^2/second)	Blood Flow (ml/100 g/min)
skin (human)	0.30	1	2.97	9.6×10^{-8}	0.04
air	0.02	1.293×10^{-3}	0.96	1.9×10^{-5}	NA
blood	0.49	NA	3.78	NA	NA
CSF	0.63	1	4.19	1.4×10^{-7}	NA
silastic	0.20	1.2	1.4	7.0×10^{-8}	NA
polyethylene	0.33	2.3	2.3	2.5×10^{-7}	NA

* NA = not applicable.

firmed easily in the numerical model, which shows one utility of the theoretical approach, even in the absence of a closed-form solution.

Numerical Model

The numerical model solves the differential equation by dividing the skin, shunt, CSF, and overlying air into small domains and then using a computer to keep track of the temperature changes in each compartment over time. Because the system boundaries are stationary and the flow is constant (on the time scales of interest), a finite difference method is convenient. This technique keeps track of the relevant variables (in this case temperature, CSF and blood flow, specific heat, and thermal diffusivity) at individual points or nodes. I use an alternating difference implicit technique for the integration. In addition, several runs were performed with doubling of the mesh density, and no significant differences were seen.

The simulations were run on an IBM RS6000 computer that used the IBM Parallel Engineering Scientific Subroutine Library software, and on an HP Alphaserver GS12801 that used a customized tridiagonal algorithm.

Figure 1 shows a schematic view of the simulated system. Figure 2 shows the simulated output of a pair of skin-temperature sensors applied 3 cm apart to the skin over the shunt tubing. This configuration is what would actually be seen by a clinical user of a transcutaneous thermal convection shunt analysis system.

In interpreting these data, the times of maximum temperature reduction at the proximal and distal thermistors can be discerned, and the difference between these two times is related to the CSF flow rate. Because the flow is laminar and the temperature change is modified by thermal diffusion, the relationship between flow and time is not linear. Figure 3 depicts the relationship between the distance the thermistor is placed (downstream) from the ice, the CSF flow, and the time to maximum temperature dip. At higher CSF flow rates and shorter interthermistor distances, this relationship is progressively more linear. This finding supports the in vivo observation of Stein and Apfel[12] of a linear flow–time relationship.[12]

Laboratory Model

Due to the practical limitations of a prolonged experiment in a living preparation, I constructed a tissue phantom to test the limits of the process and the predictions of the computer model. I used polyethylene, which has a thermal diffusivity of 2.5×10^{-7} m^2/second, comparable with human adipose tissue ($2.1–2.6 \times 10^{-7}$ m^2/second) for the tissue phantom. Into it was embedded a single piece of silastic shunt peritoneal tubing (Medtronic, Inc., Minneapolis, MN). Multiple holes (720) were drilled in the phantom (Fig. 4), and distilled water at a fixed temperature of 37°C was pumped through them at a rate of 160 ml per minute, to simulate blood flow in skin at 10 ml per 100 g of tissue per minute (Fig. 5).

Distilled water at a fixed temperature of 37°C was pumped through the embedded shunt tubing at a variety of flow rates. The system was allowed to reach thermal equilibrium prior to each experiment.

For each run, a 2-cm cube of ice was applied to the block of polyethylene at the "proximal" end for 5 minutes. This did not melt completely during the 5 minutes. Figure 6 provides an illustration of the simulated CSF flow results of 30 ml per hour.

Clinical Trial

Devices to measure function of CSF shunts are regulated by the FDA under Section 882.5550 as Class II medical de-

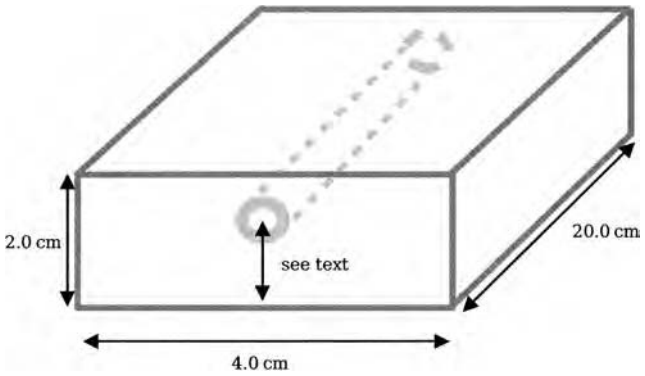

FIG. 1. Schematic illustration of the finite-difference computer simulation. The simulated block of tissue has a shunt running through it, with an inner diameter of 1.3 mm and an outer diameter of 2.5 mm. The tubing is given the thermal properties of silastic. Typical mesh sizes of $200 \times 200 \times 400$ were used. The depth of the shunt tubing below the simulated skin surface was varied between 5 and 7.5 mm to determine if this was a critical parameter. The boundary conditions were T = 27°C for air (top surface), 37°C for CSF, and 37°C for blood. After equilibration, a section of the top surface 2×2 cm and 5 cm from the front of the figure was cooled to 0°C and maintained at that temperature for 300 seconds.

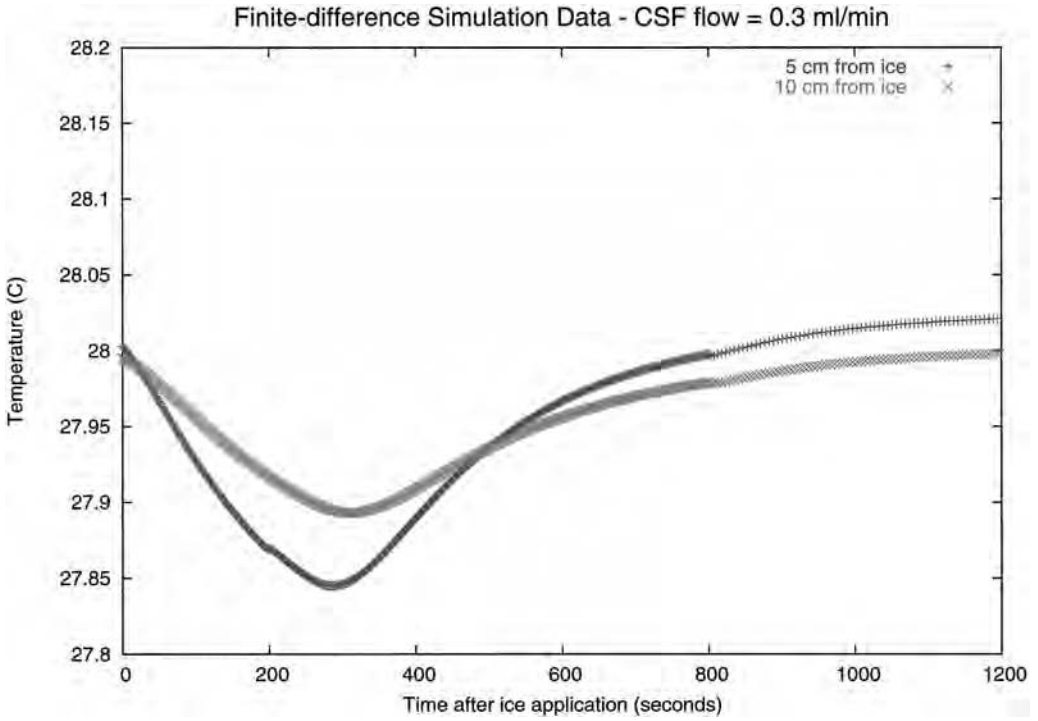

FIG. 2. A simulated temperature curve from thermistors placed 5 and 10 cm distal to ice, with shunt tubing 7.5 mm below the surface.

vices. After a discussion with the FDA, we created a medical device establishment and—using appropriate design controls, construction techniques, and testing—constructed a device to perform clinical measurement of skin temperature with the accuracy and stability necessary for transcutaneous thermal CSF shunt analysis. This device is functionally equivalent to that used by Stein and Apfel,[12] but takes full advantage of modern technology, using inexpensive

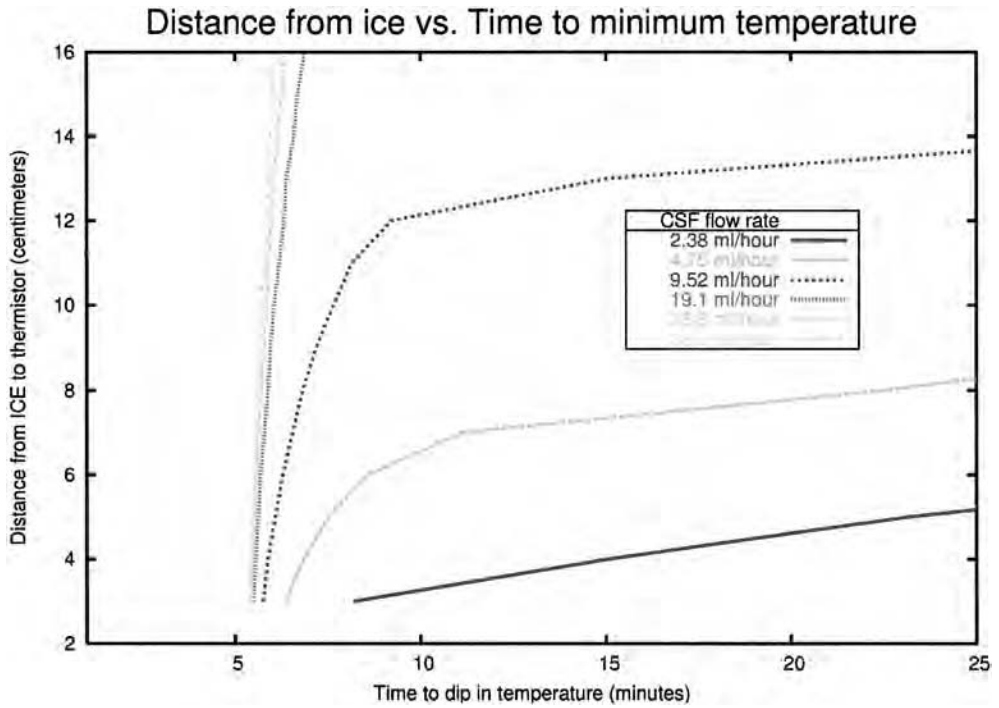

FIG. 3. Relationship between CSF flow velocity, thermistor distance (from ice), and time to maximum dip in temperature (300-second application of ice). Note that the curves do not overlap, so if the thermistor separation is known, the time to minimum temperature defines a unique flow.

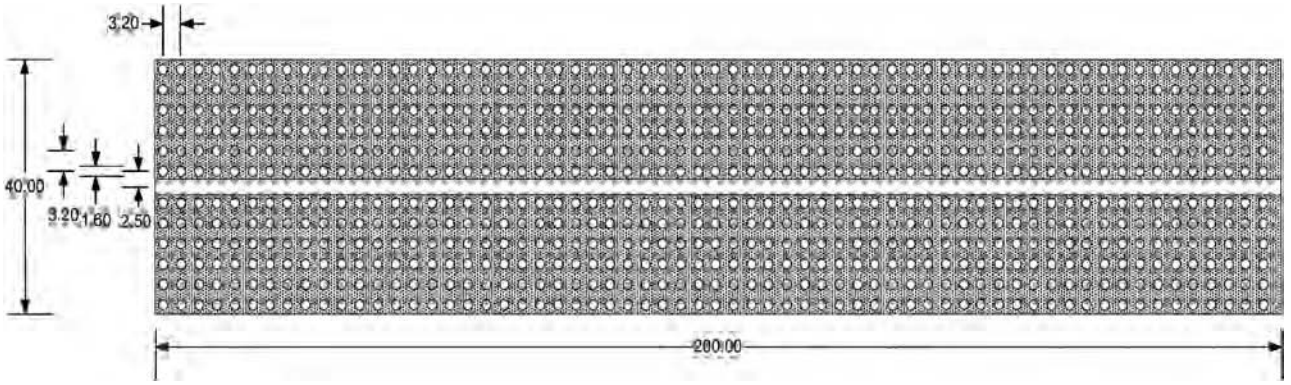

FIG. 4. Top computer-aided design view of polyethylene block. Its 720 vertical holes (seen en face) allow perfusion to be simulated. The horizontal path for the shunt tubing running parallel to the long axis is also shown.

disposable thermistors, a microcontroller, and a laptop computer. Control thermistors, applied to mirror the positions of the thermistors over the shunt, reduce the chance of false positives or negatives due to global skin temperature changes. I developed a clinical protocol and obtained IRB approval to test functioning shunts in patients. Under FDA regulations, the investigational device exemption to perform these trials is issued by the approving IRBs, based on their assessment of the trial's minimal risk.

A convenience sample of nine patients underwent 10 trials with the device. One trial yielded uninterpretable results. I believe this was due to postoperative edema and hyperemia of the skin over the shunt (the patient was tested 2 days after a revision and the incision over which the thermistors were was erythematous). This effect can be replicated in the numerical model. The other nine trials in eight patients yielded interpretable results, confirming flow of CSF in the shunts (Fig. 7).

Figure 8 depicts the result of a control experiment on a volunteer without a shunt, undertaken to determine if reactive skin blood flow changes could create temperature variations that mimicked actual data. This test showed that even a thermistor placed 3 cm from the area of ice application to the scalp registered no change in temperature.

Regulatory Issues

Because the goal of this investigation was to develop a clinical tool that could be used by a neurosurgeon outside of the investigational setting, premarket notification (510[k]) was made to the FDA in January 2004 incorporating the clinical data gathered in this investigation. Additional information was provided in May 2004 and September 2004. On November 2, 2004, the device described here received FDA clearance for marketing in the US. Although the data shown in this article and in the references

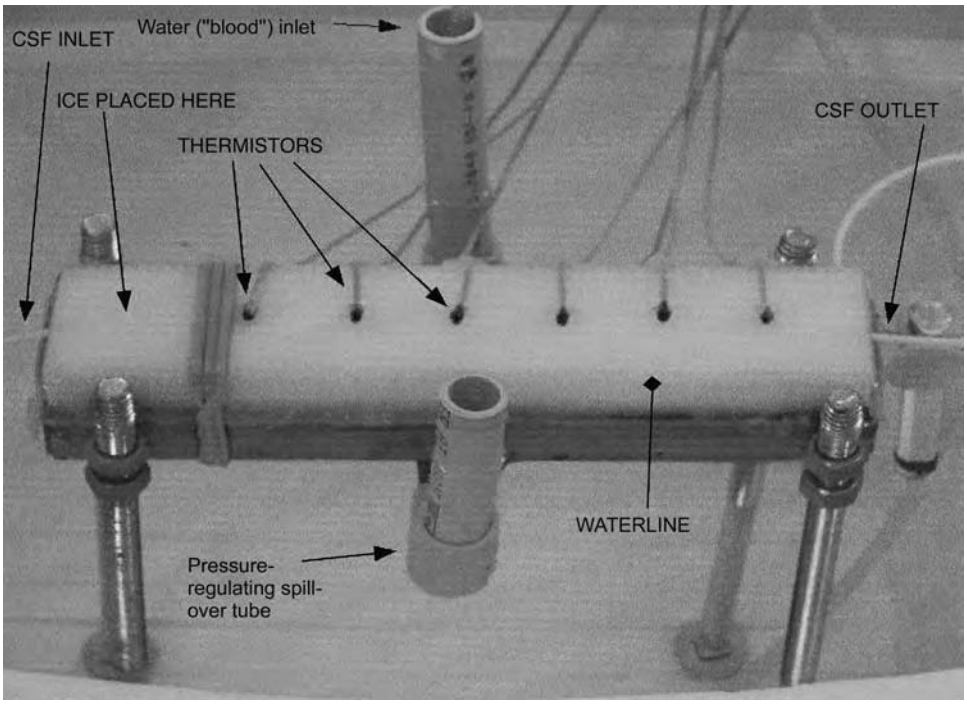

FIG. 5. Experimental setup for bench test of thermal convection flow detection.

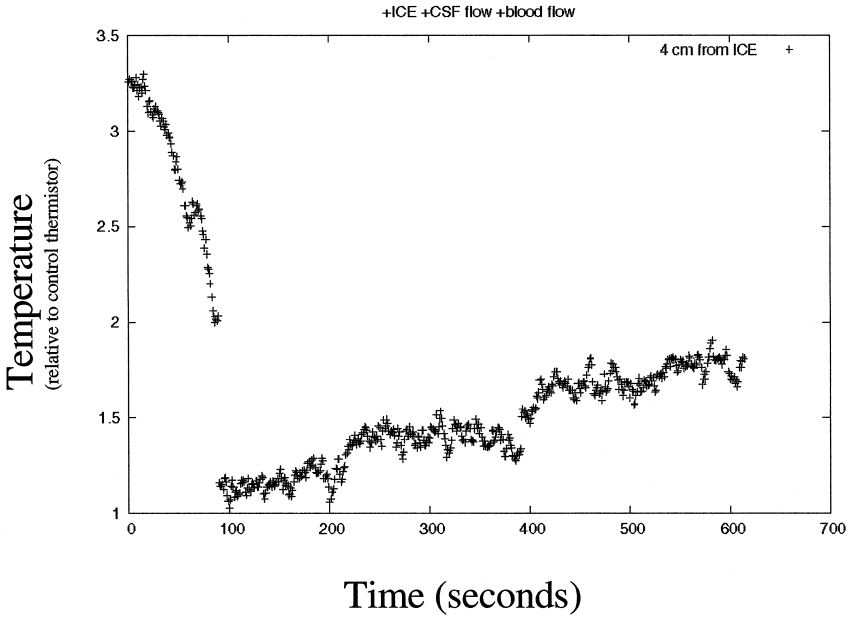

FIG. 6. Graph of illustrative results from bench test. The y axis gives the temperature (K) difference from a stable reference thermistor.

suggest that transcutaneous measurements can quantify flow, the current device labeling approved by the FDA specifies "detection" of flow. Figure 9 shows the completed device as used in clinical trials (the labeling is different on the production device).

Discussion

Transcutaneous thermal measurements of CSF flow have been made since the introduction of modern shunts. In several published[1–5,8] and unpublished studies, independent investigators have found it a simple matter to detect CSF flow in shunts by using transcutaneous thermal convection.

Determining shunt function is a difficult process for which there is no ideal clinical procedure or diagnostic tool. Radionuclide studies are expensive, time-consuming, require specialized equipment, and have a 14% false-negative rate.[9] Imaging studies detect brain deformation caused by ventriculomegaly, but that is only an indirect (and late) measurement of shunt function, and up to one third of patients may have equivocal findings.[6,13] Both types of studies require the resources of a hospital or imaging center.

Go and colleagues[3,4,8] were the first to report transcutaneous measurement of CSF flow, with results of 21 patients tested. Chiba and Yuda[2] reported on 36 trials in 32 patients, with no false-negative or false-positive readings. Subse-

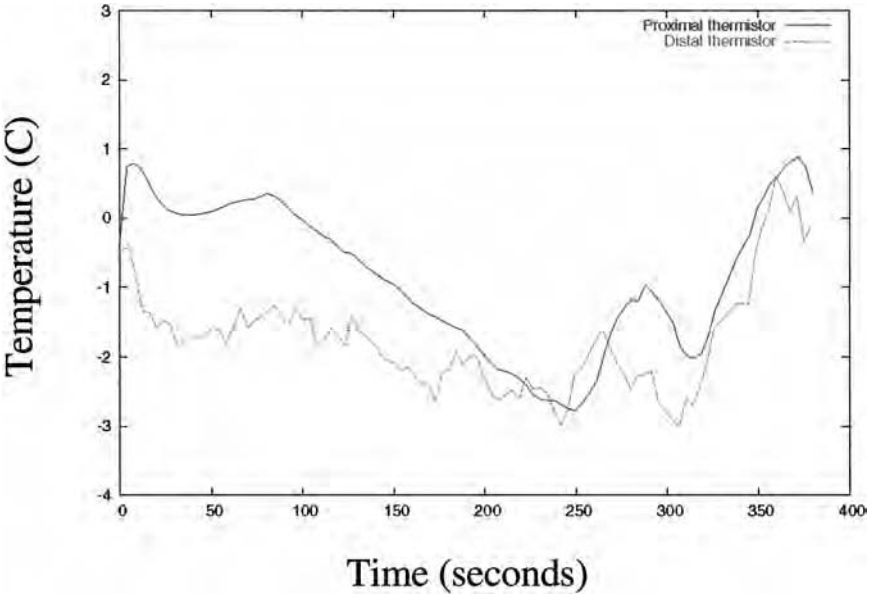

FIG. 7. Graph of typical results in a patient with a working CSF shunt.

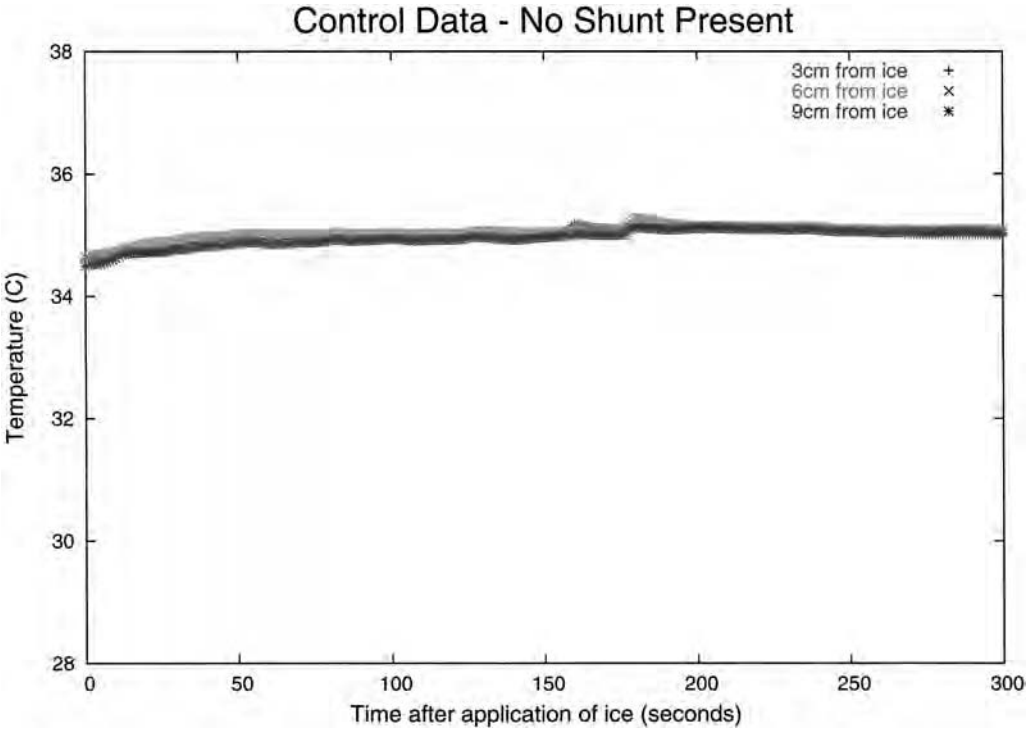

FIG. 8. Graph of control results in a volunteer with no shunt.

quently, the technique was also shown to be useful for lumboperitoneal shunts.[1,5] These data (for ventricular shunts only) are combined in Table 2.

Despite these reports, thermal convection shunt testing has not been available to neurosurgeons. The high cost of thermistors, the cumbersome nature of the strip chart recorders, the high barriers to entry for manufacturers, and the relatively small size of the potential market have all played a role in preventing commercialization of this technology.

FIG. 9. Photograph of experimental model used for clinical trial.

The device described in this report uses a laptop computer for the data recording and display function, replacing the cumbersome and expensive chart recorder used by previous investigators. Another improvement is the development of an inexpensive way to make identical low-noise measurements from four thermistors simultaneously. Four identical channels allow a control thermistor for each data thermistor, potentially reducing errors and eliminating any need for the operator to "zero" the device. The wide availability of disposable thermistors approved for clinical use further simplifies system design and device use.

Many scientific questions about CSF production and the operation of shunts in humans can be addressed now that it is possible to obtain noninvasive measurements outside of the laboratory setting. Some of these questions are as follows: 1) Can flow rates be accurately measured in humans? 2) Is there a postural dependence of CSF flow once equilibration has occurred? 3) How long does equilibration take with postural changes? 4) Is the CSF flow rate different in different patients? 5) Is the CSF flow rate different from day to day or week to week? 6) Do failing shunts occlude gradually, intermittently, or suddenly? 7) Which patients are already independent of their shunts? 8) Is the CSF flow rate different in specific diseases? 9) Do programmable valves alter flow? If so, which ones?

Conclusions

An inexpensive, portable device that uses thermal convection to detect the presence of flow in CSF shunts was developed, tested, and cleared for clinical use. In a noninvasive 20-minute test, CSF flow detection can be performed in the neurosurgeon's office or at the bedside. Additional studies are under way to determine if patients can

TABLE 2

Combined clinical data for thermal convection testing of ventricular shunts

Authors & Year	No. of Patients	Positive Tests	True Positives	Negative Tests	True Negatives
Lakke, et al., 1968	21	16	16	5	4 (confirmed at op, 1 not followed)
Chiba & Yuda, 1980	32	25	25	2	2 (confirmed at op)
present study	8	8	8	1	0

be taught to perform the study at home, with the neurosurgeon interpreting the transmitted data. This home-use capability, if proven, will further improve the lives of patients with CSF shunts.

Additional studies with transcutaneous thermal convection will improve our understanding of CSF shunt function in humans. Diurnal and postural variations in flow can be elucidated and studied in different patient populations. The effect on flow of different settings of programmable valves will be discernible. Finally, correlation of minor symptoms such as headache with CSF shunt flow will be possible.

Investment/Financial Disclosure

The author has a financial interest in NeuroDiagnostic Devices, Philadelphia, PA, which manufactures ShuntCheck, a device that implements the technique described in this study.

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The friends and colleagues of Dr. Samuel Neff are deeply saddened to announce his unexpected death on August 11, 2005. He was an energetic inventor and devoted surgeon.