A PAPER ON RECOMMENDATIONS FOR THE REGULATION AND OVERSIGHT OF CNS SHUNT TECHNOLOGY

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Neurological CSF Shunts
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Section One: An Introduction

This paper is written in support of the Food and Drug Administration's "One-Day Conference on Neurological Shunts," which will address the present oversight and quality assurance practices in regards to the manufacture and distribution of central nervous system (CNS), or hydrocephalus shunts. The goal of the conference should be that of improving the free flow of information and technology with regard to CNS shunts.

Hydrocephalus, a condition often erroneously referred to as having water on the brain, is actually an accumulation of excess cerebrospinal fluid (CSF) in a central area of the brain known as the "ventricles." The accumulation of fluid, or ventricular enlargement as it is termed, can occur as a result of neurological injury, congenital malformation, and certain neurological pathology. The excess CSF fluid causes an increase in pressure within the brain, and a consequential decrease in blood flow to many of the brain's important anatomical structures.

The primary method of treatment involves the placement of a "shunt" and superficial drainage catheter between either the brain and abdomen (v-p shunt), the brain and heart (v-a shunt), or spinal canal and abdomen (l-p shunt). It was pioneered in the 1950's, and today still remains the most common method of treatment in hydrocephalus though more is known today with respect to shunt technology. The shunt is usually permanent and helps route the ongoing accumulation of fluid to a designated area of the body. In theory, shunting would seem to be rather simple, however, neuroscience has learned that precise CSF fluid pressures are needed to carry out many of the brain's higher level functions.

The Food & Drug Administration began regulating the manufacture and distribution of CNS shunts in 1976. Since that time, there have been minimal changes in guidelines and required practices. Most shunts still meet the same licensing, technological equivalency standards, and guidelines as were put in practice 22 years ago. These practices are now thought to create a hindrance to new technology, whereas in other cases, they are felt to be too lax. The true question for the conference should be, "Are we where we ought to be in 1999?"

Mr. Dolle, the author of this paper, comes from a technical and managerial background in medical imaging, and served in a consulting capacity in feasibility planning of new hospital products and services. He is shunted and has experienced field practices firsthand for six years now. He makes recommendations for a 4-way regulatory partnership, for new regulatory guidelines, quality assurance standards, testing, troubleshooting, and public affairs operations.

Any regulatory change will involve a dichotomy of issues, and must be well researched. These recommendations are based on review of published journal studies, field research, active correspondence with the FDA, the Hydrocephalus Association, the National Hydrocephalus Foundation, Southern California area support groups, detailed study with the internet group, "Hyceph-L," (University of Toronto), and communications with many shunted patients and family members over the past six years.

Section Two: Regulatory Philosophy and New Partnership

The Food & Drug Administration is empowered with the responsibility to regulate the manufacture and distribution of CNS shunts. In doing so, there exist an inherent partnership between shunt manufacturers, FDA divisions, attending neurosurgeons, and shunted patients and family members. The shunted patient and family is added on the premise that their input is valuable to maintaining the quality and effectiveness of the product and will further the free-flow of scientific information. This will act as an "invisible hand" over the marketplace where otherwise none exists, as patients do not directly pay for their medical care. This new relationship is also consistent with the trends toward education, self examination, and increased care in the home setting.

Present field philosophy and practice still maintains a number of old beliefs in such areas as a patient's need to know information, that shunts either work or they don't, that the shunt should never be touched or pumped by the patient or family, that shunts take over the patient's residual CSF reabsorption capability, and that when a shunt is suspected of malfunction, order a CT or MRI.

Below, are three widely held beliefs, or adages, used in the field. They are:

"All shunts are the same." (the practicing neurosurgeon)

"We only make them. The neurosurgeon puts them in." (the shunt manufacturer)

"We can only do what Congress tells us to do." (the Food & Drug Administration)

This author proposes these be amended to reflect the current knowledge of hydrocephalus, and should read, respectively:

"All patients are different."

"We can assist with information in their use."

"We hold the capacity to bring about change."

The new partnership would address more details in the use of shunts by neurosurgeons and patients. Manufacturers would provide more information and tools in meeting quality assurance standards. See section on quality assurance. Communications between the partners would be open-ended and streamlined with respect to the exchange of quality assurance information. The findings would be maintained in databases for scientific review and oversight.

Section Three: Food & Drug Administration Oversight and Guidelines

Hydrocephalus shunts are licensed by the Food & Drug Administration under the category of Class II, which carries with it certain requisite guidelines, most of which were established at the time of the Federal Food, Drug and Cosmetic Act of 1976. This designation permits manufacturers to claim "substantial equivalency" in scientific design to an earlier device and waive the exhaustive requirements of new clinical trials, the filing of an Investigational Device Exemption (IDE), new labeling, use, and warnings literature. There are vast differences in time and costs involved in meeting the burden of substantial equivalency verses the latter alternative. As such, all but two of the present shunts in use today were licensed in recent years under the more simplified substantial equivalency process. These original guidelines are arguably responsible for many of the present quality assurance problems relating to reporting, product labeling, testing, and literature.

The quagmire in the access to new and better technology seems to lie in the vastly disparate requirements of the two processes. The guidelines no doubt favor the redevelopment of old shunting technology and concepts for today's hydrocephalus treatment. From both a regulatory and scientific viewpoint, the more stringent requirements do not comport with Congress's language and granting of the 1993 Device Tracking exemption for CNS shunts. Here, they wrote, "that shunt malfunction is a common and readily treatable occurrence," and found that device tracking served no valid purpose and merely caused an unnecessary burden to the manufacture. If this is Congress's latest regulatory view, it would seem absurd to still continue to assign such stringent requirements to new shunt technology. It would seem the ideal licensing requirements exist somewhere between the two, and must reflect the status of shunting practices and the science of the times.

This author also recommends redrafting the FDA's labeling and licensing guidelines relating to labeling, literature, and warnings. This would include more extensive and specific information regarding surgical technique, use, warnings, post shunting considerations, and troubleshooting, plus separate information designed for patient use.

There should also be clear guidelines through which manufacturers must report adverse product information, and add labeling changes as they become known. Consideration is given here to past experience where the greater the amount of adverse information was reported, the larger the liability exposure. However, it appears the legal climate in regards to drugs and medical devices is changing, and it is now more advisable to be forthright of such information.

Section Four: Quality Assurance

The foremost recommendation in quality assurance is to secure a consensus of opinion as to the collective goals, values, and scientific practice of the industry. This author proposes that the goal in hydrocephalus shunting should be attainment of a full (100%) compensated, or asymptomatic state. Degree of compensation, shunt dependency, and shunt performance should become routine terms in measuring post shunting outcomes.

Hydrocephalus shunting is also in need of standardized in-vitro and in-vivo shunt performance test models, as well as more effective troubleshooting methods in evaluating malfunction. This author saw the need to develop a live type of monitoring system in evaluating shunt function and hydrocephalus complaints. This system is called the DiaCeph™ Test, and is intended for everyday use. It utilizes a computer program of measuring selected parameters which are specific to patient status, shunt performance, and types of malfunction. Shunt performance and outcome is then determined by evaluating timed serial data.

Detailed cognitive testing in the routine of the hydrocephalus patient is an excellent tool for measuring higher level functioning, which is sensitive to subtle changes in intracranial pressure (ICP) and thus is a good indicator of shunting outcomes and performance. The DiaCeph™ Monitoring System incorporates these cognitive tools within its program. Monitoring can then be carried out over the course of a day up to several weeks, which is often necessary in hydrocephalus care.

A simplified formula for predicting shunting outcome is:

$$X + Y = Z$$

Where X = the patient's required CSF outflow and pressure requirements
(Note: required CSF outflow is directly related to degree of shunt dependance)

and Y = the specifications of the shunt

and Z = the resulting measured shunting outcome (% compensated)

It is possible, but not felt economical, to perform intracranial pressure monitoring in describing "X" for each shunt revision and placement. Using the above formula, once "X" is defined, and "Y" can be known regarding a particular shunt, it is possible to reasonably predict the outcome in "Z." This formula can be applied to DiaCeph™ monitoring data with good results. Here, DiaCeph™ data would describe the present shunting outcome in "Z." Providing that the shunt is shown to be functional, and using "Y" as specifications of that shunt, it would be possible to define "X," the patient's true CSF outflow and pressure requirements.

The next recommendation is for better manufacturer labeling and literature. Shunt manufacturers must provide more information to neurosurgeons regarding the effective use of their products. Such information is needed for shunt matching, surgical technique, in vivo use, and troubleshooting. Similarly, manufacturers should provide patients with information regarding the safe and effective use of their products, i.e. susceptibility and prevention of shunt trauma, other warnings, and information and tools for maintaining optimum shunt performance. These are frequently raised questions and issues among support groups.

This author reports from personal experience and interviews with patients and families that the present troubleshooting practices often fail to diagnose shunt malfunction and that these malfunctions are continuing unabated and intermittent at injurious levels, for periods up to and including several years, prior to being corrected. Certain makes of shunts have been shown to experience particular difficulties in these regards. Troubleshooting technology must improve in order to make any substantial gains in quality of life for hydrocephalus patients.

Difficulties are also seen in cases where there is a limited reduction in CSF flow in a highly shunt dependant individual, and again in cases where there is a more substantial compromise to flow, but in a minimally shunt dependant individual. New technology should also be more sensitive to subtle and more intermittent changes in shunt out flow, and perhaps include intervening measures. The proposed DiaCeph™ monitoring system could include such tools as cognitive compensation techniques, proven visualization tips, and specific shunt system manipulations to help offset these more subtle events.

Section Five: Public Affairs

Public affairs and public relations activities are key to the success of health care organizations in our free market system. There exist a multitude of possibilities that manufacturers, the Food & Drug Administration, National Institutes of Health, hospitals, and physicians could undertake. This author advocates that shunt manufacturers step up public affairs activities in tune with today's health trends. This will help support care by the neurosurgeon, and oversight by the FDA.

Public Affairs activities might include such things as focus groups, information on shunting technology, case management tools, and protective head gear, as well as the underwriting of a new concept in insurance where a separate policy would provide more detailed care in the event of a shunt malfunction.

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DIACEPH™ CNS SHUNT MONITORING SYSTEM

Nov. 1997 • S. Dolle • Patent Pending

Abstract

A method and instrument for measuring CNS shunt performance in an individual with hydrocephalus by sampling selected non-invasive parameters, or indicators of performance. The collected data is processed to produce a determination of probable shunt operation. Where the shunt may not be operating properly, the instrument processor enables a prediction of the likely nature of shunt malfunction(s), selected from a list of fourteen (14) possible malfunctions. The data can be used to monitor shunt performance over time, where patient profiles and time vs. data graphs are printed on plain paper and kept by the patient and treating physician as his/her clinical database. It is intended to be operated by patients and family members, skilled nurses, medical staff, physicians, and researchers. The results can be used to monitor patient progress, and manage daily activities. In the case of a suspected malfunction, it would assist in determining an effective diagnostic course.

Features of the Test System

- Portable, User Friendly Menu Prompts
- Results Available at Touch of a Button
- Up to Date Cognitive Assessment Tests
- Shunt Patency Test Warning Alert
- Accommodates a Variety of Patient Profiles and Shunt Systems
- Standard and Advanced DiaCeph™ Testing
- Single or Pre-set Serial Sampling
- Down-loadable to PC for Print/Display
- Prints Time vs. ICP/Parameter Graphs
- Also Maintains Personal Files
- Sold by Prescription Only

Uses

The application of this new hydrocephalus monitoring system is two-fold: 1) To serve as a standard tool in clinical office evaluations, by non-expert staff; and 2) To enable the hydrocephalus patient and family to have more involvement in care with an emphasis on increased stability and independence in the home, more in tune with today's trends.

DiaCeph™ could suit the cost conscious insurance industry by enabling a standardized evaluation in the family practice office. Test results would aid in the diagnostic course.

In the home, the DiaCeph™ system would permit patients and family members to monitor problematic complaints. It can enable continuity of care away from home, when out of town, and facilitate access to care in rural areas.

The test has four (4) home applications in the conscious and cooperative patient where results can be phoned in or taken to the physician's office: 1) Providing documentation of acute shunt malfunction; 2) Monitoring of intermittent shunt malfunction; 3) Post-op monitoring for proper shunt match-up and performance; and 4) Routine monitoring for assessing patient status, progress, activity scheduling, and dispensing of medication.

Benefits

- Provides Estimate of Relative ICP
- High Level of Sensitivity to Shunt Malfunction
- Helps Manage Daily Schedules
- Increases Access to Medical Care
- Reduces Needless Doctor/ER Visits
- Provides an Assessment of Shunt Patency

Rationale

The incentive for this new system stems from the fact that shunt malfunction is often an intermittent and costly diagnostic problem. It is ideal in cases where the patient is conscious, and not in immediate danger or in urgent need of surgical intervention. In the emergency room, CT scanning still remains the staple diagnostic tool in ruling out shunt

malfunction. Yet, a significant percentage of the shunted population will not demonstrate a measurable change in ventricular size during a malfunction. Thus, in any given patient, it is often not possible for an attending emergency room physician to make a reliable determination from CT, which renders CT scanning unreliable as a staple diagnostic test.

In the clinical office, the expert physician will rely heavily on evidence of papilledema and cranial nerve changes. However, again as in CT scanning, there must be a significant interruption in shunt CSF outflow (over a requisite period of time) in order to show findings. One must also take into account the patient's degree of shunt dependency. Many case histories demonstrate that shunt malfunction often occurs intermittently until a point at which CSF outflow is irreversibly compromised. Thus, both these assessment tools provide a relatively low level of sensitivity in determining shunt malfunction in the arbitrary patient. The resulting large numbers of indeterminate diagnoses are felt to create a burden on the affected patients and families, and restrict activities in their lives.

The portable DiaCeph™ monitoring system can offer a viable solution, and would be available only by prescription. It offers a high level of test sensitivity and specificity. Results are immediately displayed on the portable unit, and by downloading the data to the PC program the DiaCeph™ Test can display graphs of shunt patency vs. complaints, estimated ICP vs. time, and patency/complaints/ICP vs. post intervention, with the ability to compare to earlier results, and test standards.

The parameters are based on field study and corroborated in clinical trials by Stephen Dolle, a hydrocephalus patient and DiaCeph's™ inventor. DiaCeph™ was effective in describing anti-siphon shunt insufficiency, multiple shunt malfunctions, and in helping manage daily complaints. DiaCeph™'s sensitivity and specificity are in part dependant on the skill of the person administering the test, and the level of cooperation of the patient. Sensitivity and specificity will improve with increasing use. Comparison of subject test data over time will help to establish each patient's individual database.

Description of the Test Method and Instrument

The DiaCeph™ test method is a system of recording, processing, and providing diagnostic information regarding shunt performance. Its principal components include a portable (palm) computer with integral time, field, and barometric pressure measurement and processing, user instructions, a special DiaCeph™ PC software (output) program (requires a standard home personal computer) for display and printing.

The palm operating unit and program is set up in a "menu" language or format where the user is prompted by commands at each step to perform certain tasks or observations, and enter each result. Refer to the attached two-page flow chart of the DiaCeph™ Test System.

The user begins by selecting the patient's profile, shunt type, and preferred cognitive tests as "default" selections under set-up under the main menu. The user is prompted to enter the patient's personal and medical information. This also permits the user, upon the direction of his/her physician, to select the group of observation parameters that best match the patient. Next, the user is prompted to select the patient's shunt type from a list on the menu screen. Lastly, the user is asked to preview and select the preferred cognitive tests for later during the program testing. These default selections automatically modify the DiaCeph™ program.

To collect a sample, choose either Standard/Adv. Sample, Pre-Set Timed Std./Adv. Sampling, or Advanced Test Sampling. In this discussion, we have chosen the "Standard/Adv. Sample," and the defaults "Pref. A," and "Delta shunt," and two popular "cognitive tests."

The test begins by prompting the user to select the patient's Activity that preceded the sample, by selecting it from a list of activities that appear on the screen. Now press

"enter." Next, it prompts the user to determine the patient's level of Nausea and select it from the display screen using a scoring system of N to 3, where "N" = normal, and "3" = most severe. Now press "enter." Next, identify the level of Headache in the same manner by identifying the respective level on the display screen, and press "enter." Continue in the same manner with Malaise. When prompted to perform the Cognitive Tests, follow the screen instructions and enter the resultant score at the prompt, from N to -3, where "N" = normal (for that patient) and "-3" = the worst score known to that patient.

Now follow the prompt instructions in performing the Positional Test. Select the resulting findings with the patient first placed in the Supine posture. Repeat the same observation in the Upright posture, and enter the findings. The program will now store these results in the patient's "Journal" file. Additionally, a Barometric Pressure differential result will be forwarded to the DiaCeph™ Diagnostic Processor (D-1). This data is used to evaluate an effect on the above parameters as a consequence of changes in atmospheric pressure.

Next, follow the prompt instructions in making a thorough observation of the patient's shunt and shunt tract, and select the resulting findings from the list on the display screen. Now perform an assessment of Proximal Patency as instructed by the treating physician. A demonstration is also provided in the user instructions. Match the findings to the possible selections on the display screen, from -2, -1, N, +1 and +2. Follow the prompt instructions and repeat the same for Proximal Refill, Distal Patency, and Distal Refill. These results are automatically stored in the "Journal" file for that sample, according to date and time.

In a few seconds, the screen will display what the test determined to be the diagnosis(s). It may include several possibilities from the list of fourteen (14) shunt malfunction diagnoses. These results are also stored in the "Journal" file. For the purpose of this discussion, let's say it identified three possible diagnoses for this sample. The program would prompt the user to either perform a Next Std. Sample, go to a Menu to download and print results, or go to the Advanced DiaCeph™ Test to further evaluate the findings. The use of Interventions should be done in communication with, and according to instructions, by the treating physician.

The Advanced DiaCeph™ Test utilizes a special Interventions Processor (D-2) that reviews the last sample data and selects the appropriate Interventions that can further describe the possible shunt malfunction. The display screen then prompts the user to perform the first Intervention, and select the resulting outcome from a list. Interventions are described in detail in the user instructions. A very common test Intervention is to lay down for a set period of time, and observe a change in one or more pre-defined parameters. Headache is a prime parameter. Another Intervention is to momentarily "pinch" off the distal catheter as it passes along the base of the skull. Yet another Intervention is to press on or manipulate some portion of the shunt system suspected of malfunctioning.

Continue with these Interventions until they are completed and the unit returns to the Menu. From here, a number of options are available. Several samples could be reviewed on the display screen, a single sample could be downloaded to a personal computer and printed, a series of samples could be plotted on a time vs. parameter (including ICP and Patency) graph, or the user could return to the Main Menu.

Timetable of Development

Limited clinical trials for the DiaCeph™ Monitoring System could be undertaken as early as mid-1999, following acceptance of a (FDA) pre-IDE, and once the DiaCeph™ software program is in finished form. The test system is felt to meet Food and Drug Administration guidelines as a Class 2 Accessory Device.

The clinical trials could utilize a standard PC computer, the DiaCeph™ software program, and perhaps a hand-held computer unit such as the Palm Pilot. A large number of

hydrocephalus patients wanting to participate is anticipated. All patients would be screened, cleared by their attending physician, and properly selected. The format of the trials, as well as the selected patients and institutions, is yet to be determined. Interested parties are asked to contact the person listed below.

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