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THE ACCIDENTAL INVENTOR

His Device Could Help Him, Others Cope With Injury

By CHRIS BAIOCCHI

A car accident left medical consultant Stephen Dolle with a catheter permanently planted in his head. But now Dolle is putting his professional expertise and personal ordeal to work, designing a monitoring device that will make patients like himself able to live more comfortably.

Dolle was driving home alone from an awards banquet in Costa Mesa in July 1992 when a teenager ran a red light, ramming into the passenger side of Dolle's Ford Festiva.

Although Dolle's car was totaled, the teenager was unhurt and Dolle was initially diagnosed with only a mild concussion. He was given anti-vertigo medicine to combat dizziness and told to take it easy.

But in the ensuing weeks, Dolle found himself suffering mental lapses. "I was working one day when I couldn't remember what I was doing."

Then, on a Sunday, the simple act of driving home from a round of golf became a harrowing experience, as Dolle forgot what side of the road to drive on, and whether to stop or go at intersections.

Stephen Dolle

He managed to make it home. Tests soon disclosed that Dolle had suffered more than a concussion. The accident had left him with hydrocephalus, commonly called "water on the brain," a condition in which fluid in the brain is not properly absorbed, resulting in pressure that impairs blood flow and brain function.

After a few months of bed rest and medication, Dolle underwent shunting, a common treatment for hydrocephalus: A catheter is run from the brain into the abdomen, the heart or the spinal canal, where the fluid drains and is reabsorbed into the body.

This is where Dolle is now focusing his endeavors. He is developing the DiaCeph Monitoring System, a device that will monitor, record and diagnose the changes in intracranial pressure associated with central nervous system shunt failure.

Currently, Dolle has a patent pending on his device and is working to take the device from the drawing board to the clinical-trial phase, while he seeks financial and scientific assistance.

By allowing patients to track intracranial pressure and diagnose potential problems at home, Dolle hopes to avoid multiple trips to the doctor and surgeries to deal with shunt problems. Dolle has had five surgeries to correct problems with his shunt.

CNS shunts generally fail in one of two ways. They can either stop working, causing

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too much pressure to build up, or they can shunt too well, depriving the brain of fluid it needs to function. Either failure can affect a patient's brain functions.

Dr. Eldon Foltz of the UCI Medical Center's Department of Neurosurgery, who is helping Dolle develop his device, said that maintaining proper pressure is vital.

"The brain ... doesn't like to have higher pressure; it doesn't like to have lower pressure. It likes to have it right on the nose," Foltz said.

He said the problem of maintaining fluid pressure and watching for shunt failure is compounded by the unique nature of each patient's response to shunting, and to the "intermittence of shunt inadequacy."

In other words, a shunted patient may feel symptomatic (nausea, vomiting, headache, etc.) in the morning, yet those symptoms may be gone by the time the patient gets to a doctor. The patient then runs the risk of being sent away until symptoms reoccur.

"The only person really with that problem constantly is the patient himself," Foltz said. "The patient needs to be brought into the educational process."

Impetus for Design

These problems were the impetus for Dolle's idea. The DiaCeph system, once completed, will involve a hand-held computer unit and PC software. Patients input data into the hand-held device; quantifying the level of nausea, malaise, activity level and cognitive difficulty. The patient also inputs information such as shunt type and condition information. The idea, according to Dolle, is for the patient to take a number of measurements with the device — while sitting up, while lying down, when the patient feels symptomatic and when the patient feels good.

When problems with the shunt arise, the system has a "range" of pressures stored in memory. The patient inputs the new information and the computer compares it to the data on file. The system can then offer an initial diagnosis for the patient, indicating the nature of the shunt failure and possible treatment recommendations. The PC software component of the system allows the patient to chart and record pressure and shunt operations over a period of time on a home computer.

Dolle, who also has a background in medical imaging and nuclear medicine, is doing more than drawing up schematics, though.

In late 1996, he filed a citizen's petition with the FDA to draw attention to the problems with shunts and the relatively outdated regulations placed on them. Dolle saw shunt failure as a common and unreported malady.

"Neurosurgeons accepted that it was so common that they did not need to report it," he said.

His advocacy paid off. The FDA kicked off its Systematic Technology Assessment of Medical Products (STAMP) program, designed to increase product adoption and analysis, with a conference on CSF shunts. Dolle presented a paper on regulation and oversight of shunt technology.

Before that January conference, Dolle took a friend's advice and sought out Steven Nataupsky, an attorney at Newport Beach-based Knobbe, Martens, Olson & Bear, a firm that specializes in intellectual property law. In November, Nataupsky began guiding Dolle through the patent application process.

"His patent is now pending," Nataupsky said. While they have not been given an idea as to the Patent Office's timeline, Nataupsky predicts that "sometime in the next four months would be my guess. I am hopeful, but it is impossible to predict."

Assuming that the device can pass the patent requirements, Dolle plans to have further scientific evaluation done on his product, and then to move it out of the theoretical stages, since a prototype for the device has not yet been developed.

Clinical Trials to Come

Then, of course, there are still clinical trials to contend with after that. Biotech companies and device makers, after multimillion-dollar IPOs and financing, still find the clinical trial phase to be a significant financial burden. Needless to say, Dolle is a bit concerned about the trials.

"I will need funding and regulatory assistance," he said, adding that he feels the FDA has not made significant allowances for his status. "It is not fair to ask me to compete with these companies. It would be nice if I got some consideration for being a patient and was treated fairly."

Dolle also has to contend with a community of neurosurgeons, many of whom are opposed to the idea of patients diagnosing themselves.

"The concept is 98% completed," said Dolle. "Now I just need to get the neurosurgeon community to embrace and accept the product. I am trying to develop a device and I have to change the attitude of the FDA and the neurosurgeons."

Dolle said there is some similarity between the struggle he is facing —surgeons reluctant to arm patients with more information at home — and the conflict between physicians and direct-to-consumer advertising by pharmaceutical companies.

Industry observers say that the U.S. shunt market is an estimated $23 million annually, with prices ranging from $250 to $1,000. In 1995, 49,000 shunt operations were performed in the U.S., with 31,000 of those being first-time placements.

Hydrocephalus is a congenital disorder, often appearing in children. Other diseases and trauma also can trigger the condition. ■