

Innovation Expected to Improve Brain Surgery Outcomes

Neurosurgeon at Children's Hospital Central California designs prototypes to treat hydrocephalus

By Shawna Marie Bryant

Writer

Children's Hospital Central California

Hydrocephalus, characterized by excess cerebrospinal fluid (CSF) on the brain, is a common side effect of brain surgery. While CSF diversion saves more lives than any other neurosurgical procedure, it has the highest complication rate. Improper drainage routinely causes life-threatening problems, with either too much or too little diversion of the fluid. Even with the many advances in CSF diversion technology, the complication rate remains high.

Dr. Gary Magram, medical director of neurosurgery at Children's Hospital Central California, hopes to change that. "While my primary focus has always been patient clinical care, I have also wanted to continue to pursue my interest in neurosurgical research," he said. A fund established by grateful parents opened the door for Dr. Magram's research, which has led to the design and development of prototypes that may lower the complication rate associated with current CSF diversion devices.

Automated External Ventricular Drainage

External CSF drainage problems can go undetected in the pediatric population because children may not effectively communicate the symptoms that signal trouble. Dr. Magram, an expert on shunt design who holds several device patents, developed a prototype of an automated external CSF drainage system designed to make CSF diversion safer and more effective. His controlled cerebrospinal fluid drainage device is designed to detect improper drainage and regulate accurate diversion.

Dr. Magram's groundbreaking device will automatically:

- measure the pressure in the drainage tubing,
- indicate the quantity of CSF drained,
- open or close a valve to regulate the drainage rate of CSF, and
- sound early-warning alarms when pressure or drainage levels

fall outside safe ranges.

"Multiple algorithms have been added to the controlled cerebrospinal fluid drainage device to accommodate a greater variety of clinical scenarios," said Dr. Magram. "Hopefully, in the near future this device will be ready for a clinical trial."

While presenting his automated device, Dr. Magram discovered a lack of data on the incidence of external drain problems attributed to human error and malfunctions stemming from other causes. With the help of the nursing staff in the neurosurgery practice at Children's, the function and management of the external ventricular drains will be tracked through the hospital's electronic medical records system. By making physician orders more explicit, increasing education for nurses and improving documentation, Dr. Magram hopes to discover the incidence of external ventricular drain malfunction and whether problems can be prevented by having nurses more frequently document the external ventricular drain parameters.

Before further testing on Dr. Magram's automated shunt can occur, the project must receive approval from the Food and Drug Administration and the hospital's Institutional Review Board. When approved, Dr. Magram plans to study outcomes of his device in 20 patients. In the meantime, he has been using the same computer-aided design (CAD) system that led to the prototype's development to design off-label products that will improve procedures and outcomes of pediatric brain surgery. He is currently working with manufacturers to develop both a CSF accumulator and a brain access system.

CSF Accumulator

Dr. Magram and Interface Catheter Solutions, a major manufacturer of vascular interventional catheters, are designing and producing prototypes of balloon reservoirs intended for insertion into shunt systems to improve long-term outcomes for children with hydrocephalus. The CSF accumulator device features a biocompatible plastic with specific physical characteristics and the potential for permanent

implantation. The balloon will allow the storage and return of CSF to better augment the perfusion of the brain in children with hydrocephalus. It is hoped this innovative device may help reduce the incidence of slit ventricle syndrome and its related symptoms of high intracranial pressure, headache, lethargy and nausea.

Brain Access System

Today's endoscopes provide a visual portal during minimally invasive surgery, but do not offer a peripheral view of the area. Looking straight down the channel of the instrument is not only counterintuitive, but the restricted line of sight does not allow the surgeon to see surrounding blood vessels that could easily be disrupted during a procedure. While breaking the tiny vessels does not cause damage during surgery, the bleeding obscures the already restricted view through the endoscope. Dr. Magram is using his CAD system to show the manufacturer exactly what he needs to improve his line of sight through the brain access system.

Vendors working with Dr. Magram have agreed to absorb the costs of

developing the off-label products he designed, and plan to one day market the balloon reservoirs and endoscopes to other customers.

Children's Hospital Central California together with Dr. Magram's intellect, creativity and vision are helping to advance science and improve outcomes.

Shawna Bryant is a staff writer in communications and marketing at Children's Hospital Central California, a nonprofit, pediatric regional medical center on a 50-acre campus near Fresno. The 348-bed facility has a medical staff of more than 550 physicians, making Children's Hospital Central California one of the 10 largest hospitals of its type in the nation and the second largest children's hospital in the state of California. Consistently ranking at the top of its peer group for quality patient outcomes, patient satisfaction and nursing care excellence, Children's has received repeated designations for high-quality nursing practice from the Magnet Recognition Program®.

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