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Endovascular Cerebrospinal Fluid Diversion with the eShunt: Bridging Adult Trials to Pediatrics

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Neurointerventional surgeons are transforming medicine with minimally invasive treatments, especially in cerebrospinal diseases. Neurointerventional procedures offer safer, quicker recovery options for conditions like aneurysms and vascular malformations. While focus has traditionally been on arterial and venous diseases, growing interest surrounds the ability to directly influence cerebrospinal fluid (CSF) dynamics. CSF is vital for brain cushioning, waste removal via the glymphatic system, and maintaining CNS homeostasis—disruptions can lead to various disorders.

In the recent years there has been growing interest into developing strategies aimed at directly influencing CSF circulation which led to a shift of therapeutic efforts[1]; classically CSF diversion has been surgically influenced via ventriculoperitoneal (VP) shunts, ventriculoatrial shunts, lumboperitoneal shunts or endoscopic third ventriculostomies. Each of these surgical options has specific advantages and disadvantages depending on the underlying cause of the CSF dysregulation and the choice depends on factors such as patient's age, presence of prior infection and surgical history. Nonetheless, infections, malfunctions, and failures of these options are not uncommon.[2]

Recognizing the importance of better treatment options, Heilman and Malek[3,4] have recently developed an innovative medical device designed to redirect excess CSF into the venous system (**Figure 1**). This endovascular transvenous-transdural shunt, named eShunt System (CereVasc, Inc., Charlestown, MA), consists of a catheter with a distal tip (Malecot) and a proximal one-way valve that mimics the physiologic functions of arachnoid granulations and it is implanted via percutaneous access to the inferior petrosal sinus. In 2022, not long after the original description, Lylyk et al.[5] pioneered the successful therapeutic implantation of the first biomimetic eShunt System in an octogenarian patient presenting with communicating hydrocephalus and shunt dependance after subarachnoid hemorrhage from a ruptured middle cerebral artery aneurysm.

There are current three clinical trials (NCT05232838, NCT05250505, and NCT06498960) focusing on assessing the safety and efficacy of the eShunt System, for the treatment of Normal Pressure Hydrocephalus (NPH). NCT05232838 is[6] a U.S.-based, multi-center pilot study that includes 50 participants, aged 65 to 85, who are candidates for traditional CSF shunt implantation. This study evaluates the eShunt Implant over a 5-year period, aiming to demonstrate its safety and effectiveness in improving NPH symptoms. Similarly, NCT05250505 is[7] a pilot study conducted in Argentina with 30 participants, following the same methodology and objective of assessing the eShunt System's safety and efficacy over a five-year period. Both of these trials have shown that the eShunt System may offer a viable alternative to traditional CSF shunting methods, with encouraging outcomes for patients and no serious adverse events.

The STRIDE study (NCT06498960),[8] is a larger, multicenter, randomized trial that will involve approximately 230 participants across various sites in the United States. This pivotal trial is designed to compare the eShunt System with the traditional VP shunt, the current standard of care for NPH. Participants in this trial will be randomly assigned to receive either the eShunt Implant or the VP shunt, with a comprehensive follow-up plan over up to five years. The STRIDE study aims to provide robust data on the long-term safety, efficacy, and potential advantages of the eShunt System, with a focus on comparing it directly to the VP shunt in a larger, more diverse patient population.

While the focus of the eShunt clinical studies currently is on the treatment of adult hydrocephalus, expanding the indications to include pediatric patients could prove to be very impactful. In children, the underlying pathophysiological mechanisms that lead to hydrocephalus differ from those in adults, and children are at a much higher risk of shunt failure and infections. Moreover, the conventional VP shunt procedure carries other concerns such as pain associated with scar tissue formation along the shunt (known as shuntalgia), which can negatively impact a child's development and quality of life. In contrast, a minimally invasive endovascular alternative like the eShunt System may alleviate many of these concerns of infection and pain, while offering a less invasive procedure and a potentially better long-term outcome. Thus, the value proposition of a long-term indwelling device implanted via minimally invasive procedures in pediatric patients is high.

Our recently published manuscript[9] demonstrates that endovascular shunting is anatomically feasible in pediatric patients, opening up promising possibilities for treating hydrocephalus in children. Overall, we found that at least two thirds of patients (67%) between the age of 1 and 18 were deemed eligible for endovascular shunting using magnetic resonance imaging criteria developed for adult patients and currently utilized by the clinical trials (**Figure 1, A and B**). Interestingly age did not significantly affect eligibility and high-resolution postcontrast T1 sequences were consistently able to identify the inferior petrosal sinus in almost the entire cohort with only 2 patients (1 IPS each) not clearly seen on magnetic resonance imaging.

While there remain many unanswered questions about the effectiveness of the eShunt device in children, the next critical step is to establish a pilot study with primary goals centered on safety. A

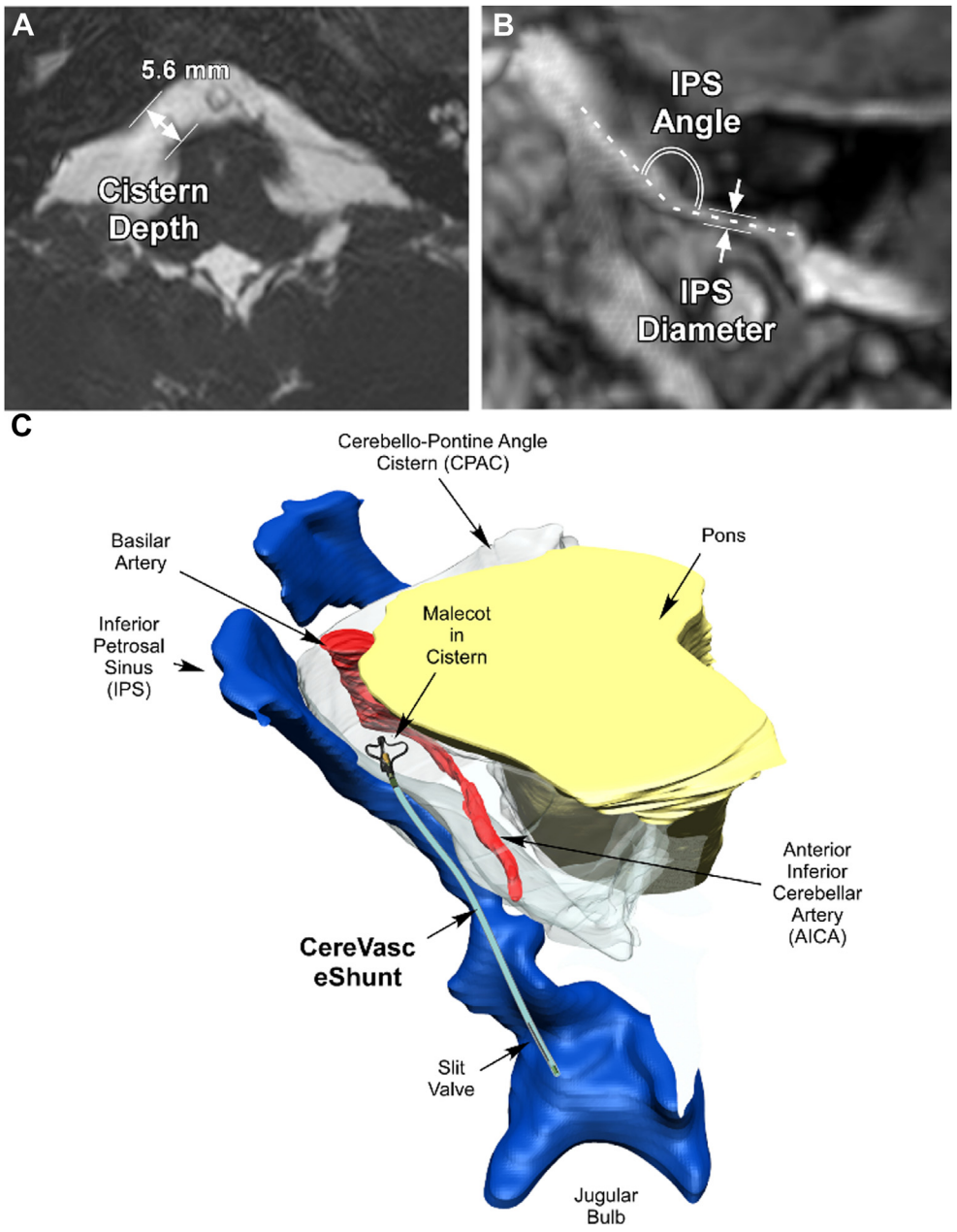


Figure 1. Illustration of the cistern depth in a 16-y-old patient using T2 high-resolution MRI (**A**) and multiplanar reconstruction of gadolinium-enhanced T1-weighted MRI the inferior petrosal sinus (IPS) showing diameter and angle (**B**). Corresponding 3-dimensional imaging of patient-based segmentation and schematic illustration of the minimally invasive CereVasc eShunt device as it would be deployed endovascularly through transfemoral venous route via the jugular vein/IPS pathway providing transdural access into the cerebello-pontine angle cistern with malecot expanded to prevent migration. The eShunt device enables unidirectional cerebrospinal fluid drainage from the cistern into the venous system at the jugular bulb with a one-way valve preventing blood reflux.

first pivotal step will be to identify the right patient population, minimizing procedural risk while at the same time providing the highest yield for effective treatment. We foresee that adolescent patients with shunt malfunctions and infections could be the ideal candidates. Additionally further insights into the device's long-term performance are also anticipated from the ongoing clinical trials.

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