Novel Shunt System for Endovascular Management of Obstructive Hydrocephalus

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Biomedical Advances in Shunt Engineering

Background

Hydrocephalus: Buildup of cerebrospinal fluid (CSF) causes the brain's ventricles to enlarge and exert pressure on the brain tissue, restricting blood flow and causing damage.

Communicating: Buildup of CSF after leaving the ventricles

Obstructive: Buildup of CSF within the ventricles

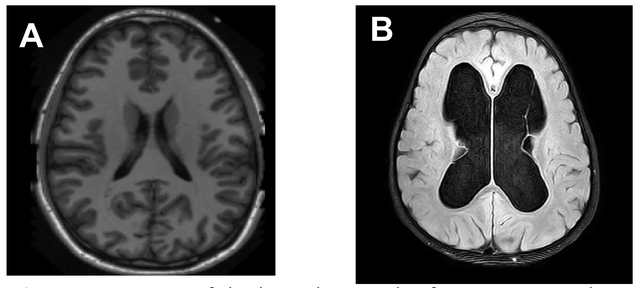

Fig 1. MRI images of the lateral ventricles for a patient without hydrocephalus (A) and with hydrocephalus (B).

Current solutions:

- Ventriculoperitoneal (VP) shunt
- Endoscopic third ventriculostomy (ETV)
- Choroid Plexus Cauterization

Mission statement:
Developing a shunt for obstructive hydrocephalus patients, with a **less invasive procedure**, **reduced infection risk**, and **shorter recovery time**.

Technical Models

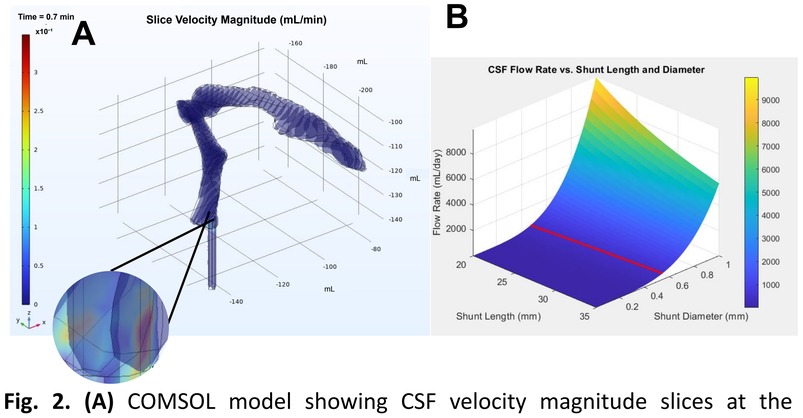

Fig. 2. (A) COMSOL model showing CSF velocity magnitude slices at the implant–ventricle intersection, with higher velocity observed exiting the implant. Simulated flow rate matched the target of 0.35 mL/min.
(B) Graph of flow rate versus shunt length and radius, with the target flow rate, 0.35 mL/min or 500 mL/day, indicated by the red line.

Product Architecture and Design

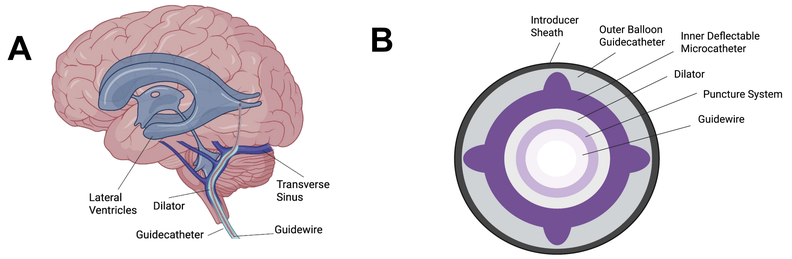

Fig 3. (A) Diagram showing the simplified implant delivery pathway.
(B) Diagram showing coaxial layers of the implant delivery system.

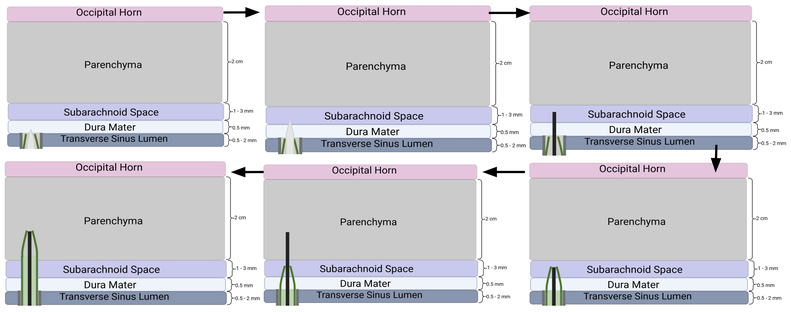

Fig 4. Schematic showing method of sequential inchworming of the guidewire and dilator through the parenchyma to improve targeting accuracy and guidewire stability en route to the occipital horn.

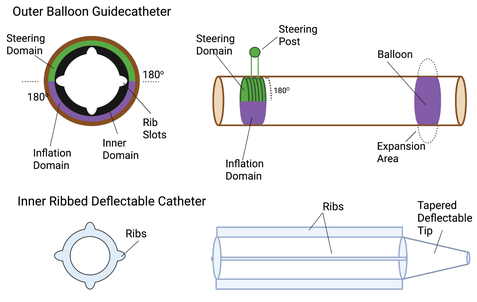

Fig 5. Diagram of interlocking outer and inner catheters allowing for 3D steering

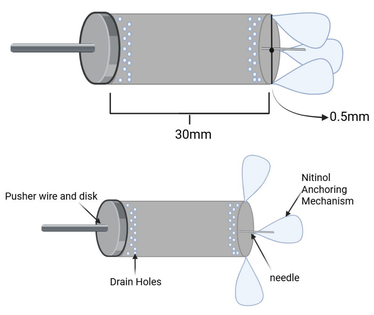

Fig 6. Diagram of shunt implant design for proper CSF drainage

Product Specifications

Specification	Target Value
Implant Diameter	0.5 mm
Implant Length	30 mm
Equilibrium Shunt Flow Rate	0.35 mL/min
Lateral Ventricle Pressure	5 - 15 mmHg

Table 1. Key requirements for our shunt implant in order to ensure steady and consistent drainage of CSF and maintain a stable intraventricular pressure.

Prototype

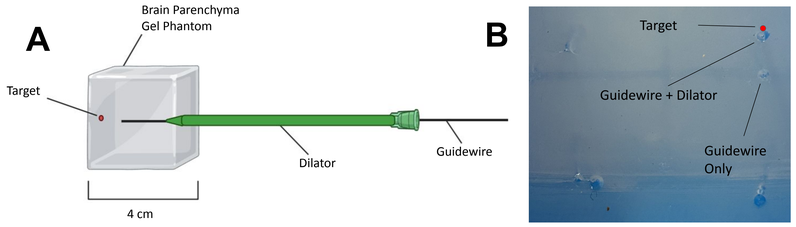

Fig 7. (A) Diagram of prototype setup **(B)** Image of physical gel showing puncture points further from the target using only the guidewire than when using the guidewire with the dilator.

Validation Results

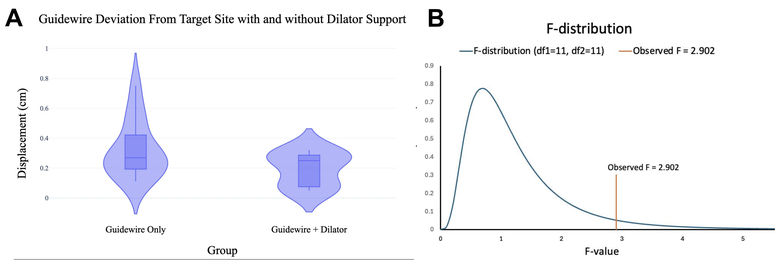

Fig 8. Violin plot comparing guidewire deviation through the brain tissue phantom with and without a supportive dilator (A). F-distribution curve showing F-test results for sample variance (B). Conclusions indicate no statistically significant difference between groups but suggest a need for further testing.

Future Work

Further Prototyping	FDA Regulation	Clinical Trials	Manufacturing
Refinements of the Comsol simulations. Developing more precise models to simulate our device's pathway and implantation through the endovascular system.	As a CSF shunt system, this product is a Class II device following the regulatory pathway of an Investigational Device Exemption (IDE) for a 510(k) clearance process.	Begin clinical trials to determine safety, effectiveness, and potential improvements, before obtaining FDA market approval.	After successful trials, a scalable manufacturing process will need to be developed in compliance with the FDA.

Acknowledgments and References

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