A Noninvasive Retrograde Flushing System for Shunted Hydrocephalus: Initial Case Series of 25 Patients

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Hydrocephalus Background

• Hydrocephalus is associated with high morbidity and heavy resource utilization
• Nearly 400,000 new cases of pediatric hydrocephalus occur annually worldwide
• Healthcare systems carry a heavy burden:
  • 69,000 US hospital visits annually in 1995, half requiring placement of a new shunt
  • 27,870 US patients underwent shunt-related procedures in 2000, 42.8% were replacements
  • 35,816 US dollars was the average cost for these shunt revisions
  • 0.6% of all US pediatric hospital admissions but 3.1% of charges in 2003
• Shunting procedures are estimated to account for over 100 million US dollars of
  national health care expenditures annually
  • half of these costs are related to shunt revision
• Improving the rate of shunt failure has been identified as the factor with the greatest
  potential system-wide cost savings
Methods

• This is a multicenter case series review by four US pediatric hospitals:
  • Children’s Hospital of Orange County
  • Boston Children’s Hospital
  • Medical University of South Carolina
  • Cincinnati Children’s Hospital and Medical Center

• The first 25 consecutive patients implanted with the Reflow™ Ventricular System
  • Produced by Anuncia, Inc. (Lowell, MA, USA)
  • FDA approved for the treatment of hydrocephalus

• Reflow™ introduces two new components to a traditional shunt system:
  • A retrograde flushing device
  • A “relief-membrane” on the proximal catheter that can open in the setting of occlusion

• Operations were performed between May 2018 and November 2019

• Patients were chosen for clinical factors with high risk of shunt obstruction
  • recent infection, hemorrhage, high CSF protein counts, or multiple prior shunt failures
The Reflow™ Flusher

• Depressing the flushing dome obstructs normal anterograde flow and pressure builds until it is released toward the ventricle

• Once the dome is released, it refills with passive CSF flow from the proximal catheter and resumes normal function

• Creates controlled, limited bursts of proximally directed flow through a catheter and out its intraventricular openings

• Potential to clear obstructing debris
“Relief Membrane” on Proximal Catheter

• A membrane-bound side port on the catheter located just above the standard intraventricular inlet holes

• When the Reflow™ Flusher is pumped and proximal flow is directed against an occluded catheter, pressure builds and the membrane ruptures open, creating a new intraventricular opening
## Patient Demographics

<table>
<thead>
<tr>
<th>Age</th>
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<tbody>
<tr>
<td>Range (years)</td>
<td>2-34</td>
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<tr>
<td>Average</td>
<td>11.63 (SD 8.21)</td>
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<table>
<thead>
<tr>
<th>Sex</th>
<th></th>
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<tbody>
<tr>
<td>Female</td>
<td>11 (44%)</td>
</tr>
<tr>
<td>Male</td>
<td>14 (56%)</td>
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<table>
<thead>
<tr>
<th>Etiology of Hydrocephalus</th>
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<tbody>
<tr>
<td>Congenital hydrocephalus</td>
<td>10 (40%)</td>
</tr>
<tr>
<td>Spina bifida</td>
<td>4 (16%)</td>
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<tr>
<td>Neonatal hemorrhage</td>
<td>4 (16%)</td>
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<tr>
<td>Tumor</td>
<td>2 (8%)</td>
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<tr>
<td>Spontaneous hemorrhage</td>
<td>2 (8%)</td>
</tr>
<tr>
<td>Ruptured AVM</td>
<td>1 (4%)</td>
</tr>
<tr>
<td>Aqueductal stenosis</td>
<td>1 (4%)</td>
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Possible Rescues of Shunt Function

• Case 1: A 6-year-old with spina bifida presented with irritability 10 days after placement of a shunt with a Reflow™ system. Symptoms resolved hours after one pumping of the Reflow™ dome.

• Case 2: A 16-year-old with congenital hydrocephalus and frequent shunt failure who presented with symptoms of shunt malfunction that improved after being pumped once.

• Case 3: An 18-year-old with obstructive hydrocephalus presented with headache. Shunt Check initially showed 0.0° temperature drop, which persisted after one pumping of the Reflow™ System. After a second pumping, a 0.1° temperature drop was seen. The Strata shunt was dialed from 2.0 to 0.5, and a drop of greater than 0.2° was seen, confirming flow. The patient was discharged without operative intervention.
Shunt Failures

Five patients required operative revision for common reasons:

• Two presented with symptoms of shunt failure which did not resolve upon pumping of the Reflow™ System. On revision, the proximal catheters were noted to be obstructed with debris.

• One presented with a second which was ultimately attributed to high intra-abdominal pressure.

• One had distal tubing disconnection in the setting of trauma.

• There was one case of surgical wound infection.
Conclusions

• Hydrocephalus has a high medical and economic impact, and shunt failure is an important focus of neurosurgical research
• The Reflow™ Ventricular System by Anuncia, Inc. (Lowell, MA, USA) may have the potential to prolong shunt lifespan and decrease the rate of shunt revision
• This initial series demonstrates the use of this device in clinical practice
• We present preliminary evidence of the potential for the flushing mechanism to non-invasively salvage proximally obstructed shunts
• Ideal demonstration would be resolution of ventriculomegaly after flushing
• Long-term assessment and clinical studies of these patients is needed to show the potential impact of this new system
References


