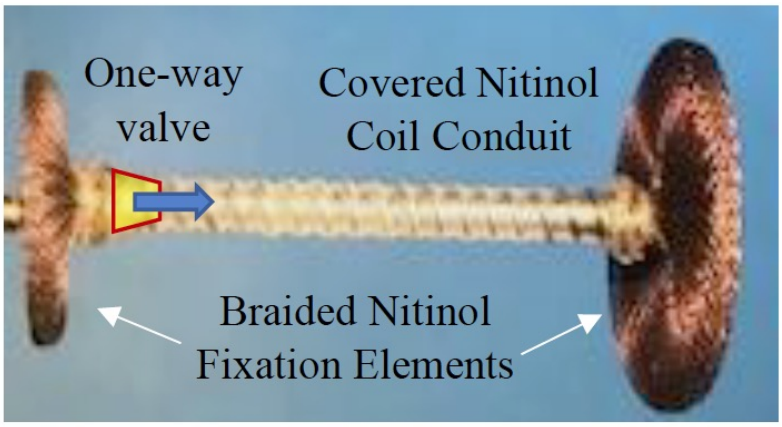
Docket #: S21-017

The Vortex Shunt – A Novel Prenatal Lower Urinary Tract Obstruction (LUTO) Vesico-Amniotic Shunt (VAS)

Physicians at Stanford Lucile Packard Children's Hospital (LPCH) have developed a novel Vesico-Amniotic Shunt (VAS) for treatment of Prenatal Lower Urinary Tract Obstruction (LUTO). LUTO is a birth defect in which the fetus has a blockage in the urethra, the tube that carries urine from the bladder to the amniotic sac. If left untreated, this condition renders a mortality rate of up to 80%. LUTO affects 1 in 5,000 -25,000 pregnancies and has limited treatment options available: (1) Fetal cystoscopy, a technically difficult procedure to remove the obstruction is associated with fetal injury and maternal morbidity (2) Placement of a VAS, a catheter connecting the fetal bladder to the amniotic sac facilitates decompression, however in 80% of cases kinking or dislodgment occurs (commonly multiple times in one pregnancy) requiring additional surgical intervention(s). While the two currently available shunts have potential for improved fetal survival, their double pigtailed design has high risks for intraoperative and postoperative shunt complications. To address current LUTO treatment limitations, inventors at LPCH have invented the vortex shunt consisting of a (1) Nitinol inner coil for dynamic adjustability/kink resistance (2) Nitinol braided fixation elements to provide robust fixation to the fetal bladder and amniotic sac (3) A one-way duckbill valve to allow bladder cycling (4) Echogenic visualization to aid ultrasound detection and (5) Controlled 6Fr delivery system that allows repositioning and recapture of shunt. The vortex shunt is an innovative product that aims to vastly improve outcomes for LUTO patients and has the potential to be applied to other conditions requiring a shunt such as in cases of hydrocephalus and pulmonary effusions.



Kink Resistant & Extendable

Applications

- LUTO VAS treatment
- Treatment of pleural effusions as alternative to chest tubes
- Hydrocephalus treatment
- Hemodialysis treatment

Advantages

- Improvement in shunt deployment by echogenic double braided fixation elements
- Decreased chance of dislodgment over time - Vortex dislodgement force was 21X greater than the Harrison shunt and 2.5 X greater than the Rocket shunt
- Less likely to kink as the fetus grows
- Novel shunt valve allows for bladder cycling preserving function
- Decreased need for multiple in-utero procedures leads to decreased preterm membrane rupture and decreased preterm birth

Patents

- Published Application: WO2022173865
- Published Application: 20250050075

Innovators

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