Device uses telescoping system to achieve complete recanalization in stroke patients

Mechanical thrombectomy—an interventional procedure for removing a blood clot from a blood vessel using stents and suction catheters—helps restore blood flow and improve stroke symptoms. However, the procedure fails to completely reopen arteries in half of patients and multiple attempts may be required to achieve blood flow restoration.

The Solution

University of Michigan team Aditya S. Pandey, M.D., Luis Savastano, M.D. Ph.D., Albert Shih, Ph.D., and Yihao Zheng, Ph.D., have developed the Vortex Catheter Technology (V-CaTh). This new platform for minimally invasive treatment of stroke patients uses telescoping endovascular catheters that are navigated within the skull and activated to generate a whirlpool to completely remove obstructing clots with one pass while avoiding the release of small fragments.

V-CaTh has the potential to enable integrated, enhanced navigation into the target cerebral artery, which leads to complete recanalization (restoration of blood flow) regardless of the size, location, or firmness of the clots, and without clogging or releasing of clot fragments. This ultimately results in faster, easier, and more complete restoration of blood flow within stroke patients.
**V-CaTh, a self-deliverable device,** generates a powerful vortex suction mechanism that leads to complete recanalization in stroke

**Significant Need**
Current treatments fail to completely recanalize nearly 50% of stroke cases, which lead to major neurological deficits and high mortality. Recanalization failure modes include a clot in the same or adjacent vascular territory causing a new stroke; perforation of the artery, which can cause a hemorrhage; and artery dissection that leads to a delayed clot with blockage.

**Compelling Science**
The technology generates a powerful whirlpool by converting high rotational energy transmitted by a high-torque, fracture-resistant, and flexible shaft into a hydrodynamic vortex. This whirlpool can pull the clot into the catheter lumen more efficiently than stand-alone suction, and simultaneously drive the shaft through the catheter lumen in a translational swiping movement to soften the clot.

**Competitive Advantage**
V-CaTh provides stand-alone navigation and powerful whirlpool suction that allow for a one-pass thrombectomy of even large-dense clots. This reduces the time to recanalize, while minimizing downstream or adjacent embolization in other vessels.

**MTRAC Project Key Milestones**

- Identify partners for production supply chain: shaft, suction catheter, guide-wire, and device actuator
- Finalize design for manufacturability and build clinical prototype
- Hold a Pre-Submission meeting with the FDA
- Verify safety and efficacy of clinical device in benchtop testing and GLP animal studies
- Follow-On Funding
  - Seek SBIR funding for further technology development towards first-in-human studies.
  - Engage potential investors.

**Overall Commercialization**

- Commercialization Strategy
  - Develop technology through start-up formation, with the goal of acquisition by a partner when the technology is mature.
- Intellectual Property
  - Full utility international patent filed.
- Regulatory Pathway
  - FDA will classify V-CaTh as a Class II device; determine 510(k) vs. de novo pathway.