New device may provide safer way to treat stroke

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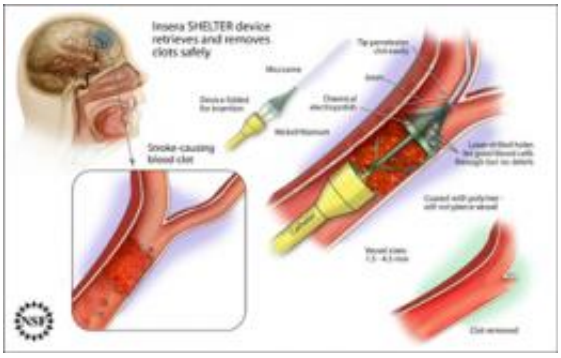

This medical illustration reveals how the SHELTER device traps and removes blood clots in the brain. Credit: Zina Deretsky, NSF

(PhysOrg.com) -- When someone suffers a stroke, time is critical -- more than a million brain cells die each minute, starved of nourishment due to critical damage in a cerebral blood vessel.

Now, researchers have developed a new tool for efficiently removing blood clots in the brain, the leading cause of strokes. The tool overcomes limitations in current emergency stroke treatments, potentially extending the time for a victim to get help.

Engineered with support from NSF's Small Business Innovation Research (SBIR) program, Insera Therapeutics, Inc. of Sacramento, Calif., developed the Stroke Help using an Endo-Luminal Transcatheter

Embolus Retrieval (SHELTER) device.

Created by two brothers--Vallabh Janardhan, an interventional neurologist, and Vikram Janardhan, an engineer and the company's CEO--SHELTER is built upon a lengthy catheter. The device contains two primary components: an outer sheath for containing captured clots and an inner filament that houses the collapsible, five-millimeter-diameter, nickel-titanium mesh that grabs and filters the clots. To prevent accidental puncturing of blood vessels, the inner component also contains a soft, spring-like tip and a polymer safety coating.

"At the end of the day, ischemic strokes are simply a clog in a pipe," said Vikram Janardhan. "But such strokes are the leading cause of long-term disability in the United States. We ought to be able to leverage innovative technology to successfully treat this medical emergency."

The technology recently completed rigorous testing in a unique, water-filled test bed that was modeled in silicone from human-cadaver brain vessels. Complete with aneurysms, atherosclerosis and "plaque", the new test-bed is more accurate than certain animal tests, and has helped speed the device's development. Potentially, the test-bed could present a new approach to late-stage evaluation of certain medical technologies.

SHELTERTM is the first platform to both filter and remove clots, the first to entrap the clot from both its near and far ends, and the first capable of accessing small vessels in the brain. Critically, the technology can be custom-fit for the specific length and diameter of a patient's clot, a personalized approach that may improve treatment success.

"Blood clots and blood vessels are not all the same size and shape, so a one-size-fits-all removal device is not the best solution," said Greg Baxter, the NSF program director who has overseen Insera's work.

"Personalized medicine is driving many new innovations, and Insera's approach follows this trend--they found a way to bring personalization to a potentially powerful treatment approach, and we're proud to have been a small part of this effort."

Strokes, or brain attacks, killed more than 130,000 Americans last year. In addition, strokes debilitate hundreds of people each day. An individual only has a few short hours to rush to the hospital, receive an accurate diagnosis, and then receive treatment to remove a debilitating blood clot before permanent brain damage occurs.

"Three hours allows an individual to get treatment from a stroke center as far as 65 miles away," said Vallabh Janardhan. "Extending the treatment window to eight hours extends the travel distance to 200 miles, a range that would enable 95 percent of the U.S. population to reach a certified stroke center. Potentially, hundreds of thousands of victims could be helped by the larger, eight-hour time window."

Current treatment for ischemic strokes (those involving a blood clot as opposed to a rupture) relies on a clot-dissolving drug that is effective up to three hours after onset of stroke symptoms; after three hours, the drug could cause systemic bleeding complications. As a result, even after 14 years of use, only three to four percent of all stroke patients benefit from the approach.

Medical devices, when used as an alternative to drug therapy, do not cause systemic bleeding complications and can extend the treatment time-window to as much as eight hours.

By using silicone copies of human cadaver blood vessels--further modified with aneurisms, atherosclerosis and "plaque"--Insera researchers are able to recreate a model environment for testing their blood-clot removal device. The cadaver model approach could potentially replace some animal testing experiments. Credit: Insera Therapeutics

Clot retrieval devices currently in use have only modest success rates because they have difficulty removing entire clots and reaching the smallest blood vessels in the brain. They are also prone to releasing blood debris, which can cause secondary strokes in smaller blood vessels "downstream".

In emergency use, a interventional neurologist would deploy SHELTER using an approach similar to other catheter-based treatments, guiding a catheter from a blood vessel in the leg to the site of the clot.

The catheter would travel through the blockage--unlike blood flow, the metal device has no trouble penetrating clots--to its far side, where the net deploys. The interventional neurologist then carefully pulls the debris into a cylindrical trap that caps the outer length of the catheter.

The Janardhans improved and evaluated their system using months of simulated extractions on their unique testing apparatus. To create the apparatus, Insera contracted a company to create a transparent silicone

replica from the brain vasculature of a plasticized human cadaver. Then, Insera added modifications (known in the trade as "severe disease burden") to accurately represent the arteries of a real stroke victim, an environment that is much more difficult to navigate than the arteries of a standard model or a laboratory animal.

"If widely adopted, the approach could significantly cut animal testing for some medical devices and reduce overall product development costs by as much as ten percent," said Vikram Janardhan. "The silicone replica of the human brain can also be used as a humane alternative to train hundreds of physicians in the use of SHELTER."

The developers hope to run clinical trials of SHELTER in the U.S. in 2012 or 2013 and seek regulatory approval shortly thereafter.

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