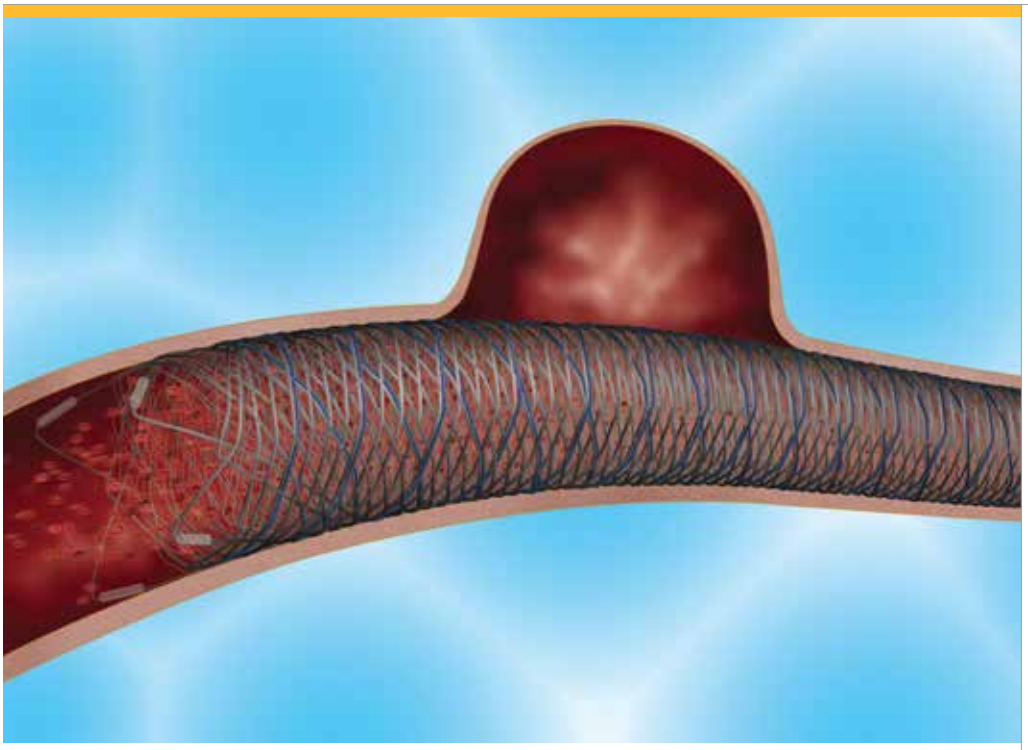
UCLA Health

Pivotal clinical trial investigates flow diversion device for brain aneurysm



Images of the FRED device are courtesy of MicroVention, Inc.

UCLA's Division of Interventional Neuroradiology is participating in a multi-center U.S. clinical trial to evaluate the safety and efficacy of the MicroVention, Inc. Flow Re-Direction Endoluminal Device Stent System (FRED™) for the treatment of intracranial aneurysms.

The prospective study aims to answer key questions on use of the FRED stenting system for wide-necked or large intracranial aneurysms. While treatment of these types of aneurysms has been particularly vexing, the new stenting system holds the promise of improved clinical outcomes and fewer procedure-related complications.

Intracranial aneurysms

Unruptured intracranial aneurysms occur in 3 to 6 percent of the general population. Larger aneurysms (10 millimeters in diameter) are more likely to rupture, as are those located in the posterior circulation. Ruptured intracranial aneurysms are associated with a high rate of permanent neurological disability and mortality. Aneurysms with significant risk of rupture should be evaluated by a neuroendovascular surgeon or neurosurgeon for possible treatment.

A less invasive treatment

The FRED stent system was designed to treat aneurysms that were previously thought to be untreatable, says Reza Jahan, MD, professor of radiology and director of the UCLA study site.

"These are very complex aneurysms that cannot be treated by any other method," Dr. Jahan explains. "The only way to treat them is to re-construct the area of involvement to direct and limit blood flow in the artery and exclude the aneurysm from the circulation, removing the chances of rupture. This device offers hope to these patients with complex aneurysms that have no other options for treatment."

The FRED system allows minimally invasive treatment of aneurysms that are not amenable to the coiling procedure.

UCLA has been a leader in the treatment of cerebrovascular disorders. The Guglielmi detachable coils were invented at UCLA and revolutionized the treatment of intracranial aneurysms.

Treatment options for intracranial aneurysms

The two options for treatment are open surgical clipping and endovascular therapy. Surgical clipping involves preventing the blood flow from entering the aneurysm by creating a barrier across the neck of the lesion. Endovascular therapy, or coiling, packs coils into the aneurysm to fill the space and prevent blood flow from entering the aneurysm.

The FRED stent system is a second-generation flow diversion device designed to block blood flow from entering the aneurysm. The system consists of an innovative, self-expanding stent-like design that is deployed through a micro-catheter into the blood vessel at the precise location of the aneurysm. The metallic mesh placed across the base of the aneurysm prevents blood from entering the aneurysm while allowing blood-flow to continue in the main blood vessel. It is specifically designed to treat large aneurysms that are not amenable to treatment with the coiling procedure.

Images of the FRED device are courtesy of MicroVention, Inc.

The FRED device is deployed via micro-catheter at the aneurysm site. It can be repositioned or redeployed as needed to ensure accurate placement.

Improved placement and outcomes

Unlike first-generation flow diversion devices, the FRED system can be partially deployed, retrieved and accurately repositioned or redeployed to ensure the most precise placement.

Study participants are asked to take blood thinning medications for up to seven days before being admitted to the hospital for the procedure and remain on these medications for six or more months afterward. Participants are evaluated upon discharge and at follow-up visits one month, six months and 12 months after surgery.

Study participants must be between the ages of 22 and 75 years old and have a single-target aneurysm located in the internal carotid artery. The aneurysm must have a neck greater than 4 mm or no discernible neck and a size (maximum fundus diameter) greater than 10 mm.

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