



**November 15, 2005**  
**FOR IMMEDIATE RELEASE**

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## **Neuroscientists study extracranial-intracranial bypass as strategy for preventing recurrent stroke**

**“Patients with carotid occlusion may still have an option,”  
Says Mayfield Clinic neurosurgeon Mario Zuccarello, M.D.**

CINCINNATI, Ohio – A tricky neurosurgical procedure in which a healthy artery outside the skull is connected to a healthy artery inside the skull may be a life-saving option for certain stroke patients, neuroscientists believe.

And despite recruitment obstacles, neurosurgeons are continuing to test this method for preventing recurrent stroke in a federally funded study known as the Carotid Occlusion Surgical Study, or COSS.

The delicate surgical procedure, called “extracranial-intracranial bypass,” is used to bypass a carotid artery that has become completely blocked. The body’s two carotid arteries, one on the right side and one on the left, are the primary arteries in the neck. They play a critical role in supplying oxygen-rich blood to the brain.

Neuroscientists hypothesize that by bypassing an occluded (blocked) carotid artery, they can significantly reduce the risk of recurrent stroke during a two-year window following surgery. “Patients with complete carotid occlusion may still have an option,” said Mario Zuccarello, M.D., a neurosurgeon with the Mayfield Clinic and The Neuroscience Institute at the University of Cincinnati and University Hospital. Dr. Zuccarello is heading up the Cincinnati portion of the study.

Recruiting patients for the study, which began in 2003, has been difficult because only about 10 to 20 percent of candidates screened will qualify. Dr. Zuccarello’s team screened 56 patients and has six patients currently enrolled, about 10 percent of the national total. The study has involved an average of 20 centers around the United States at any given time.

In a bulletin posted in the spring of 2004 on the American Association of Neurological Surgeons’ Web site (AANS.org), the study’s principal investigators, including William J. Powers, M.D., and Robert L. Grubb, Jr., M.D., of Washington University in St. Louis, warned that “recruitment has been so slow that this important study is in danger of being closed down.” The investigators added that, despite recruitment obstacles, “there is good scientific, clinical, and economic evidence to proceed with the COSS as quickly as possible.”

“To achieve enrollment success under such difficult circumstances you need a well-organized system,” Dr. Zuccarello said. “The University of Cincinnati Academic Health Center, along with the referring physicians—including internal medicine physicians and neurologists—must be aware that patients with carotid occlusion still have this important option.”

The Neuroscience Institute, which has emerged as an important study site, is certified as a Primary Stroke Center by the Joint Commission on Accreditation of Healthcare Organizations. The Institute is affiliated with the Greater Cincinnati/Northern Kentucky Stroke Team, which treats stroke patients at all hospitals in Greater Cincinnati. The Stroke Team's clearly defined treatment protocols and excellent communications among the area's hospitals have ensured that stroke patients are referred for state-of-the-art treatment at University Hospital and/or enrollment in clinical trials when appropriate.

The COSS trial involves patients who: (1) have complete blockage of a carotid artery; (2) have already suffered a stroke or transient ischemic attack (TIA), sometimes referred to as a mini-stroke; and (3) have not developed natural bypass arteries of their own, a life-saving mechanism that enables some individuals with blocked carotid arteries to continue getting adequate blood flow to the brain. Patients who qualify for the COSS trial would face a 25 to 50 percent risk of suffering a stroke during the next two years if they were treated with medications alone.

The National Institute of Neurological Disorders and Stroke, which is funding COSS, seeks to enroll 372 patients through 2008. About 90 patients are expected to participate in the study at The Neuroscience Institute at UC and University Hospital.

The carotid bypass is considered experimental because it has not been generally performed for this condition. As yet there is no scientific proof that it will reduce the incidence of stroke in these patients.

Extracranial-intracranial bypass is not risk-free. The risk of stroke is 7.6 percent, and the risk of death is 1 percent, with most untoward incidents occurring during surgery or in the first month after surgery.

Most of the 700,000 strokes that strike Americans each year occur when a blood clot suddenly cuts off the flow of oxygen to the brain. Carotid occlusion is associated with an estimated 61,000 strokes in patients who had not previously experienced a stroke, and 19,000 TIAs. Stroke is the third leading cause of death and the leading cause of disability in the United States.

Major eligibility requirements for participation in COSS are: occlusion of one or both carotid arteries; hemispheric TIA or mild to moderate stroke in the territory of an occluded carotid artery within 120 days; reduced flow of blood to the brain and reduced oxygen use by the brain, as measured by PET (positron emission tomography) neuroimaging; arteries that can be surgically connected, as demonstrated by a cerebral arteriogram, a test that produces a map of arteries in the neck and brain.

Patients participating in COSS, a randomized, non-blinded study, are randomly assigned one of two treatment protocols. One group of patients undergoes extracranial-intracranial bypass surgery; the other group of patients remains on medications prescribed by their physicians. Participants remain in the study for two to six years.

The Mayfield Clinic is recognized as one of the nation's leading physician organizations for clinical care, education, and research of the spine and brain. The group includes 18 neurosurgeons and treats 20,000 patients from 35 states and a dozen countries in a typical year. Mayfield's neurosurgeons are active participants in important clinical trials and have pioneered surgical procedures and instrumentation that have revolutionized the medical art of neurosurgery for brain tumors and neurovascular diseases and disorders.

The Neuroscience Institute is a collaborative effort of the University Hospital, nine academic departments at the UC College of Medicine, and independent physician practice groups. The Institute is dedicated to patient care, research, education, and the development of new medical technologies.

For more information about the COSS study, including details about eligibility, visit: [www.mayfieldclinic.com/CT\\_COSS.htm](http://www.mayfieldclinic.com/CT_COSS.htm) or [www.cosstrial.org](http://www.cosstrial.org).

Patients or families wishing to enroll in COSS in Cincinnati can contact Suzanne Kempisty of the Mayfield Clinic at (513) 558-5387 or [suzanne.kempisty@uc.edu](mailto:suzanne.kempisty@uc.edu).