Pivotal trial begins for repair of thoracoabdominal and pararenal aortic aneurysms

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Mark Farber, MD. Credit: UNC School of Medicine

The pivotal trial to determine the safety and effectiveness of a modular device designed to be the first completely off-the-shelf endovascular solution for aortic aneurysms involving the visceral branch vessels is successfully underway with its first surgery at UNC Hospitals in Chapel Hill, NC.

Mark Farber, MD, chief of vascular surgery at the UNC School of Medicine, is the national principal investigator of the study which is being conducted to obtain approval of the device from the U.S. Food and Drug Administration (FDA). The device—the GORE EXCLUDER Thoracoabdominal Branch Endoprosthesis (TAMBE) - is manufactured by W. L. Gore & Associates, Inc.

Farber performed the trial's first implant on July 8, 2019, using the endovascular device to repair a Crawford type IV thoracoabdominal aortic aneurysm which involved blood vessels supplying the kidneys, liver, stomach and intestines. The TAMBE device allows patients to avoid the traditional open surgical approach and utilizes a less invasive endovascular approach to repair the aneurysm. While thoracoabdominal aortic aneurysms constitute a low percentage of aortic aneurysms, the involvement of multiple vessels supplying the kidneys and visceral organs makes their repair one of the more challenging tasks in aortic surgery.

"Endovascular repair of thoracoabdominal aneurysms with appropriate devices is limited in the U.S. to a handful of centers," Farber said. "In most instances, the patients must wait several weeks for a custom manufactured device designed specifically for their individual anatomy. This makes it difficult to quickly treat these aneurysms, which are often life-threatening. New technology like the investigational Gore TAMBE device allows for expeditious repair while avoiding some of the risks associated with open surgical repair."

"Today marks important progress in our ability to provide patients with an advanced technological option for the treatment of thoracoabdominal and pararenal aortic aneurysms," said Eric Zacharias, a vascular business leader at Gore. "Results from this pivotal study could help in obtaining approval from the FDA for this innovative solution to better address challenging aortic anatomies and provide physicians with an even more

complete device portfolio for the treatment of aortic aneurysms."

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