

## Penn IDE Study of Fenestrated and Branched Stent Grafts for Thoracoabdominal Aneurysms

Darren B. Schneider, MD, Chief, Vascular Surgery and Endovascular Therapy, is directing an endovascular stent graft investigational device exemption (IDE) trial at Penn Medicine.

The objective of the trial (ClinicalTrials.gov Identifier: NCT02323581) is to evaluate the feasibility, safety, and clinical outcomes of the endovascular repair of thoracoabdominal aortic aneurysms (TAAA) and aortic arch aneurysms using fenestrated and branched endovascular stent grafts in patients at high risk for open surgery.

The treatment of thoracoabdominal aortic aneurysms (TAAAs) can be complex and risky because they involve a long section of the aorta spanning from the chest into the abdomen and the part of the aorta where important branches originate to supply blood to the abdominal organs. Similarly, aneurysms of the aortic arch involve the part of the aorta in the chest where important branches originate to supply blood to the brain.

Open surgery remains the gold standard for TAAA and aortic arch aneurysm repair in the United States. However, open surgery is associated with substantial risks of death or major complications and a substantial population of patients are precluded from open surgery due to age, comorbidities, or other concerns.

**The current clinical trial** offers these patients access to potentially life-saving treatment using investigational stent grafts that have branches and fenestrations (reinforced holes) designed to be connected with the branches of the aorta to provide essential blood flow to the brain or abdominal organs. These investigational endovascular stent grafts are introduced into the aorta under radiographic guidance from femoral and brachial arteries using small skin punctures or incisions in the groins and arm.

Endovascular aneurysm repair (EVAR) of the aorta, which began with simple tubular stent grafts in the early 1990s, has evolved over 30 years and is now the most common approach in the U.S. to treat abdominal aortic aneurysms (AAAs) limited to the infrarenal aorta and thoracic aortic aneurysms limited to the descending thoracic aorta. More recent advances in stent graft technology include the addition of branches, or fenestrations, that can be connected to the aorta's branches using bridging covered stents. These next generation stent grafts allow treatment of more complex aneurysms of the thoracoabdominal aorta and aortic arch, but most are not yet commercially available and remain investigational in the U.S.

In the U.S., many fenestrated and branched endovascular stent graft studies are conducted as physician-sponsored IDE investigations. A status granted by the FDA, IDE clinical evaluations allow physicians to provide treatments using as-yet unapproved investigational devices and collect safety and effectiveness data. At this time, only about a dozen medical centers in the US have the FDA authorization and experience to conduct treatment studies of TAAAs and aortic arch aneurysms using endovascular stent grafts. Importantly, IDE studies include independent oversight and monitoring intended to ensure patient safety.

The IDE endovascular stent graft trial ongoing at Penn Heart and Vascular at the Hospital of the University of Pennsylvania is open to patients at high risk for open surgery who have aortic aneurysms involving either the aortic arch or the thoracoabdominal aorta. Specific trial inclusion and exclusion criteria are available at [ClinicalTrials.gov](https://ClinicalTrials.gov) (ClinicalTrials.gov Identifier: NCT02323581; <https://bit.ly/3ALuQCT>). Individuals desiring information about this trial may contact Darren Schneider at [Darren.Schneider@Pennmedicine.upenn.edu](mailto:Darren.Schneider@Pennmedicine.upenn.edu) or by calling 215.614.0243.

### CASE STUDY

Mr. K, a 72-year-old gentleman, was referred to Penn Heart and Vascular for evaluation when an asymptomatic extent IV TAAA was found during pre-surgical imaging for a planned hernia repair. A former smoker, Mr. K's medical history included symptomatic chronic heart failure (NYHC Class II), mild COPD, hypercholesterolemia and hypertension. His previous interventions as an adult included an angioplasty and a partial knee replacement, both in his late 60s.

Mr. K's age and comorbidities made him a poor candidate for open surgery, and he was enrolled into the IDE study at Penn to receive treatment using a custom-made fenestrated and branched stent graft.

CT angiography at Penn confirmed the presence of a TAAA that was greater than 6 cm in diameter. Based upon the CT scan image data a personalized branched stent graft was designed by the research team to treat Mr. K's aneurysm. A comprehensive evaluation of Mr. K's cardiac, pulmonary, and renal performance was also obtained as part of the pre-procedure evaluation.

At surgery several weeks later, the customized stent graft (packaged within a catheter) was introduced under fluoroscopic guidance via the femoral artery through a small puncture in the groin. Once inside the aorta, the stent graft was deployed and, via a second access site from the left axillary artery, bridging covered stents were introduced and deployed to connect each of the 4 stent graft branches to Mr. K's celiac, superior mesenteric and bilateral renal arteries. At the completion of these procedures, a CT angiogram showed that the aneurysm was successfully excluded from the circulation with no evidence of endoleak and with good blood flow to the branches of the abdominal aorta.

*Continued on back*

**CASE STUDY** *(Continued)*

One of the risks of both endovascular and open surgical procedures to treat TAAAs is compromise of spinal cord blood flow and paraplegia. Throughout surgery, neuromonitoring using motor and somatosensory evoked potentials as well as near-infrared spectroscopy were employed to gauge Mr. K's spinal cord perfusion and to guide management in order to optimize spinal cord blood flow. Following surgery, Mr. K was closely monitored in the ICU, and in his hospital room, where he spent four days before discharge.

Mr. K recovered without incident, and at his three-week follow-up reported that he was walking a mile every day.

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**ABOUT THE VASCULAR SURGERY AND ENDOVASCULAR  
THERAPY PROGRAM**

The Vascular Surgery and Endovascular Therapy Program at Penn Medicine is a high-volume, fully integrated and comprehensive center for vascular care, including surgery and repair. Comprised of vascular surgeons, vascular anesthesiologists and advanced practice providers, the Program focuses on complex aortic aneurysms, including open, endovascular and hybrid repair, lower extremity and limb preservation, and carotid artery disease treatment.

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