



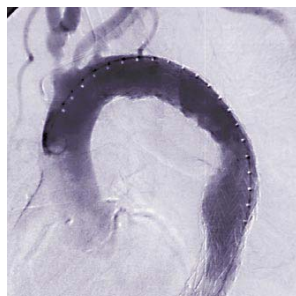
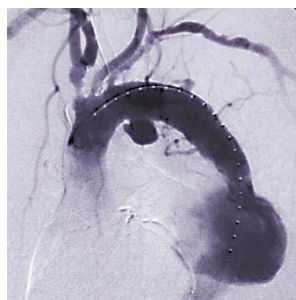
## Clinical Trial Spotlight : Thoracic Aortic Aneurysms

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**T**horacic aortic aneurysms (TAA) occur when an area in the body's largest blood vessel develops an area of weakness in its wall and balloons out. Larger aneurysms are more likely to rupture, and ruptured aneurysms are more likely to cause death. More than 21,000 Americans are diagnosed annually as having a TAA, which is traditionally treated with open chest surgery and replacement of the aorta's abnormal area. TAA patients at the University of Virginia Health System can benefit from access to leading-edge approved and investigational devices using minimally invasive techniques that will allow patients to avoid major open surgery and resume normal activities sooner.

The GORE TAG stent-graft – a metal wire (nitinol) tube covered with material impermeable to blood – received U.S. Food and Drug Administration approval in March 2005 to treat selected TAAs. The self-expanding stent-graft is inserted through a small incision in the groin and positioned at the site of the aneurysm, reducing the pressure on the aneurysm so that it will not burst, while allowing the blood to flow through the tubular stent-graft and the patient's aorta.

UVa physicians were the first in the U.S. to place the FDA-approved GORE TAG device in a TAA patient, says Michael Dake, M.D., the chair of UVa's radiology department and



A thoracic aorta with aneurysm before (top) and after (bottom) implantation of a GORE TAG stent-graft.

leader of a team of radiologists and surgeons who recently performed a live endovascular procedure on a thoracic aortic aneurysm patient as part of the Transcatheter Cardiovascular Therapeutics Conference. UVa has sig-

nificant experience with the procedure, having purchased more stent-grafts for insertion than any other hospital in Virginia, Maryland or Washington, D.C., Dake says.

The current FDA-approved stent-graft ranges in size up to 40 mm in diameter. A 45-mm diameter investigational version of the GORE TAG device is available at UVa as part of a multi-center clinical trial. If it is proven safe and effective, the larger device may expand the population that can be treated with stent-grafts by 10 to 15 percent, says principal investigator Alan Matsumoto, M.D.

A second clinical trial underway at UVa evaluates the Medtronic Valiant Thoracic Stent-graft. This self-expanding stent-graft is inserted similarly to the GORE TAG device, but it is available in a wider variety of configurations and sizes, is made differently and behaves slightly differently in the patient's body.

"Patients with TAAs who are able to be treated with a stent-graft do much better when compared to those treated with open surgical repair. They lose much less blood during the procedure, have a shorter hospital stay, have fewer major complications and return to normal activity two times faster. These trials will hopefully pave the way for physicians to have more tools in our bag, and more minimally invasive techniques with which to treat patients with TAA," Matsumoto says.

To refer a patient to the thoracic aneurysm clinical trials, contact Dr. Matsumoto by calling UVa Physician Direct at 800-552-3723.

# CASE STUDY

## THORACIC ANEURYSM

43-YEAR-OLD FEMALE PATIENT



(1) The patient has dense calcific stenosis of the paravisceral aorta. (2) The patient has a sacular aneurysm in the proximal descending aorta. (3) A CTA following the procedures demonstrates a widely patent paravisceral aorta and stent-graft repair of the aneurysm.

**PRESENTED WITH:** Worsening hypertension and claudication of her lower extremities

The patient has a history of Takayasu's arteritis with a right subclavian artery occlusion, a left common carotid artery occlusion and a left subclavian artery occlusion, determined Kenneth Cherry, M.D., UVa's chief of vascular surgery. She also has a history of atherosclerosis with complex lesions involving her great vessels, her proximal and her distal thoracic aorta as well as her upper abdominal aorta. She has also previously undergone a left nephrectomy and a great vessel reconstruction. Her chronically occluded left subclavian artery was not reconstructed.

**EVALUATED BY:** Multidisciplinary treatment team

**DIAGNOSIS:** A thoracic aortic aneurysm and stenosis of the aorta and celiac artery

Arteriography revealed that she had a sacular aneurysm of her proximal descending thoracic aorta as well as a very calcific stenosis of her distal thoracic and upper abdominal aorta extending to the level of the celiac and superior mesenteric arteries and a stenosis of her celiac artery. Dense calcium in this area of stenosis prevented either endovascular treatment of that stenosis or passage of an endovascular graft to treat the more proximal descending thoracic aortic aneurysm.

**TREATMENT:** Endarterectomy and insertion of a thoracic aortic stent graft

In December 2004, she underwent endarterectomy of her distal thoracic and paravisceral abdominal aorta as well as of her celiac artery through a thoraco-retroperitoneal approach.

In June 2005, she underwent placement of a thoracic aortic stent-graft to exclude the descending thoracic aortic sacular aneurysm. This device was inserted through her iliac and aortic systems, including the previously endarterectomized aortic segment, without difficulty. Her previous great vessel reconstruction and her occluded left subclavian artery together allowed more proximal and secure placement of her stent-graft.

**OUTCOME:** The patient was discharged from UVa, and subsequent studies have shown that the aneurysm remains thrombosed and excluded. The patient continues to do well.

"Overall, I had a very positive experience at UVa," the patient said. "Dr. Cherry is one of the doctors I thoroughly 100 percent trust. His staff is excellent and always willing to answer questions."

The UVa Health System treated more than 70 thoracic aortic aneurysm patients from mid-2005 through mid-2006.

UVa's multidisciplinary treatment team for thoracic aortic aneurysms includes vascular and cardiovascular surgeons, interventional radiologists and cardiologists.

UVa has leading-edge technology to help produce 3-D reconstructions of thoracic aneurysms that are vital in aiding stent-graft repairs.

Patients at UVa benefit from the full range of treatment options for thoracic aortic aneurysms, ranging from medical therapy to endovascular and open surgical procedures. UVa also offers hybrid procedures that combine endovascular and open procedures. UVa's length of stay, complication and mortality indices from mid-2005 through mid-2006 were lower than the state average, according to Solucient.