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Penn Clinical Briefing™

Enrolling Clinical Trials | Zenith® p-Branch® Endovascular Graft Pivotal Study

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CLINICAL BRIEFING™

Vascular Surgery and Endovascular Therapy

Enrolling Clinical Trials | Zenith® p-Branch® Endovascular Graft Pivotal Study

Endovascular surgeons with the Division of Vascular Surgery and Endovascular Therapy at Penn Medicine are participating in a clinical trial to assess the safety and effectiveness of the Zenith® p-Branch® endovascular graft for the treatment of pararenal or juxtarenal abdominal aortic aneurysms.

The conventional approach to abdominal aortic aneurysm (AAA) repair involves open surgery to place a graft at the dilated aorta. An alternative method developed in the 1990s, endovascular aneurysm repair (EVAR) involves stent grafts introduced into the aorta via a catheter and deployed at the aneurysm to bypass the dilation and reinforce the wall of the aorta. EVAR is particularly appropriate for individuals who are either unfit for open surgery, or who are at heightened risk for surgery as a result of concomitant cardiac, respiratory or renal disease.

In the early years of EVAR development, up to 40% of patients were deemed ineligible as a result of the anatomic features of their aneurysms, usually because there was insufficient length of normal aorta below the arteries going to the kidneys (the renal arteries) to seal the device. To overcome this limitation some newer and investigational stent devices now incorporate the renal and visceral vessels into the proximal seal zone by including holes in the fabric of the stent graft called fenestrations. Among these is the Zenith® p-Branch® endovascular graft (Cook Medical, Bloomington, IN) now being studied at Penn Medicine (further information provided below).

Currently, the only FDA-approved fenestrated device is a custom-made stent that can take up to six weeks to manufacture to fit an individual patient's anatomy.

The p-Branch device is novel in that it is not a custom-made device and so could potentially be used off-the-shelf in urgent and emergent circumstances. In addition, the p-Branch device affords a longer and more robust seal zone by incorporating 2 fenestrations and a scallop for the 4 renal-visceral vessels, more than any other FDA-approved device (Figure 1).

The p-Branch clinical trial is enrolling at the Division of Vascular Surgery and Endovascular Therapy at Penn Medicine, which has participated in virtually every stent graft clinical study in the United States since 1996. The principal investigator for this trial at Penn Medicine is Benjamin M. Jackson, MD, FACS.

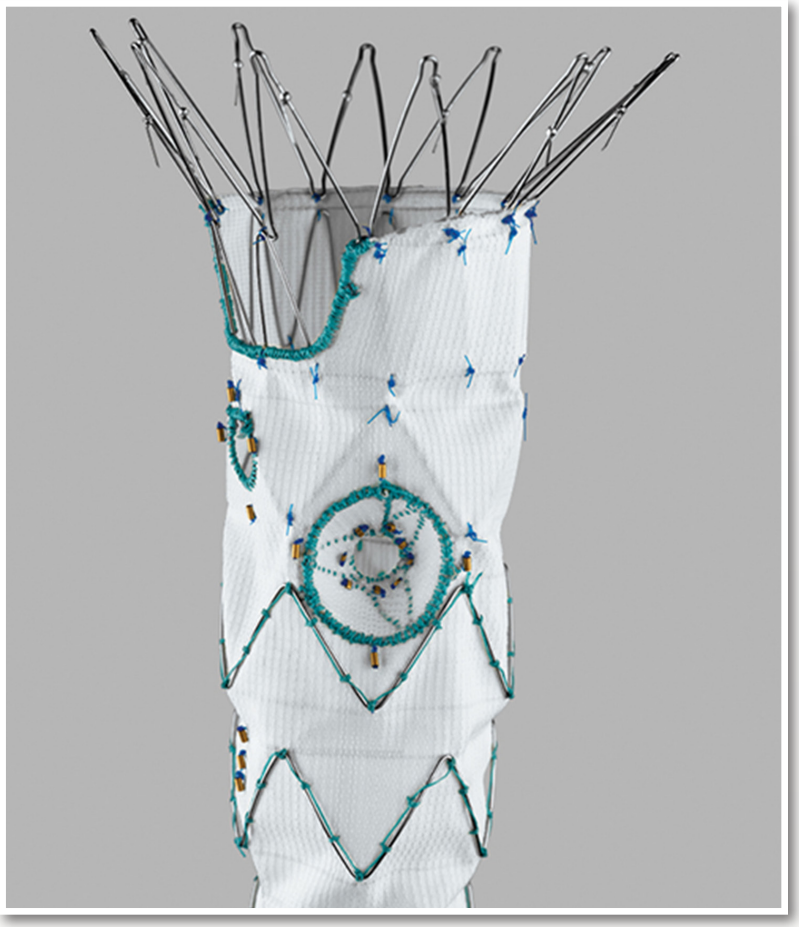

Figure 1: The p-Branch graft is composed of polyethylene terephthalate fabric, stainless steel and nitinol. The graft is appropriate only if there is a 4 mm or greater neck below the SMAs and the aorta in the proximal seal zone has a diameter of 32 mm or less.

ZENITH® p-BRANCH® ENDOVASCULAR GRAFT PIVOTAL STUDY [NCT02396199]

The Zenith® p-Branch® Pivotal Study is a clinical trial approved by FDA to study the safety and effectiveness of the Zenith® p-Branch® endovascular graft in combination with the Atrium iCAST™ covered stents in the treatment of pararenal or juxtarenal abdominal aortic aneurysms. The p-branch graft combines polyethylene fabric with a proximal stainless steel stent and nitinol z-stents, including a scallop for the celiac artery, a strut-free fenestration for the superior mesenteric arteries and two renal pivot fenestrations. The p-branch is made in two configurations for varying renal artery fenestration placement.

For information about enrolling in the Zenith studies and other endovascular clinical trials at Penn Medicine, please contact:

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FACULTY TEAM

The Division of Vascular Surgery and Endovascular Therapy at Penn Medicine has been at the forefront of clinical research in endovascular devices to treat abdominal aortic aneurysms (AAAs) for almost two decades and is currently among the handful of research centers nationwide involved in clinical trials to expand the indications for endovascular stent grafts..

In addition to a thriving research program, the Division performs more carotid, aortic, and peripheral arterial repair surgeries than any other medical center in the region.

Conducting Endovascular Clinical Trials at Penn Medicine

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