The Benefits of Utilizing a Low-Profile TAA Device

Factors that make the low-profile Zenith Alpha Thoracic aortic aneurysm device more useful than a standard abdominal aortic aneurysm device.

BY MICHAEL C. MOON, MD

Advances in stent graft technology have permitted the treatment of an increasing number of aortic pathologies, both with off-the-shelf devices and with custom devices (fenestrated and branched devices). The regions of the aorta that can currently be addressed in an endovascular manner extend proximally from the ascending aorta and the aortic arch (custom/special access devices), down through the thoracoabdominal aorta, to below the aortic bifurcation (custom/special access and off-the-shelf devices). Despite the availability of countless custom fenestrated and branched configurations, as well as the use of multiple separate stent graft pieces, the limiting factor in the ability to treat patients with aortic pathology is the size of their access vessels.

All manufacturers of endovascular technology are striving to reduce the external diameter of the delivery system, whether the aim is to treat peripheral arterial disease, aortic valve stenosis, or aortic pathology. The technological challenges of developing a low-profile system hinge on the ability to load a device into a small introducer while still yielding robust radial force for a durable seal and maintaining trackability and pushability at the same time.

BENEFITS OF A LOW-PROFILE TAA DEVICE

The aorta is largest proximally in the ascending segment and tapers as it approaches the aortic bifurcation. The inherent smaller size of the infrarenal abdominal aorta has required the delivery system of abdominal aortic aneurysm (AAA) devices to be small in diameter. The original Zenith infrarenal AAA stent graft (Cook Medical) had a delivery system between 18 to 22 F (outer diameters of 7.1–8.5 mm), and thus the minimal vessel size through which the standard Zenith stent graft could be delivered was 7.1 to 8.5 mm. Even with the smaller stent grafts used to treat infrarenal AAAs, there is a need to reduce the size of the delivery system. The resulting Zenith LP Abdominal device (Cook Medical), with a 16- or 17-F delivery system, can now treat patients with access vessels as small as 6 to 6.5 mm in diameter.

Stent grafts aimed at treating thoracic aortic aneurysms (TAAs) require larger-diameter devices because of the inherent larger proximal and distal landing zones. In many cases, this poses technical challenges due to the size of the access vessels by requiring iliac conduits or access to the distal abdominal aorta. Similar to the driving forces resulting in smaller infrarenal stent grafts, the design of the low-profile Zenith Alpha Thoracic device (Cook Medical) allows for treatment of TAAs in patients with smaller access vessels. The Zenith Alpha Thoracic device, with a 16- to 20-F delivery system, can be delivered through vessels as small as 6 to 7.7 mm while permitting treatment of aortas with diameters ranging from 15 to 42 mm.

The new low-profile Zenith Alpha Thoracic device has the ability to be delivered through access vessels as small as 6 mm, yet maintains the same pushability as the standard Zenith TX2 device (Cook Medical) and with superior trackability. As illustrated in the following three cases (Figures 1 through 3), the Zenith Alpha Thoracic device permits the treatment of aortic pathology that the standard Zenith TX2 could not easily treat.

THE CASE FOR A LOW-PROFILE TAA DEVICE OVER A AAA DEVICE

The benefit of a low-profile TAA device is greater than a low-profile AAA device because of the inherent larger diameters of the thoracic aorta than the abdominal aorta. The larger-diameter landing zones of the thoracic aorta require larger stent grafts, and thus the larger delivery systems and larger femoral and iliac artery

CASE STUDIES

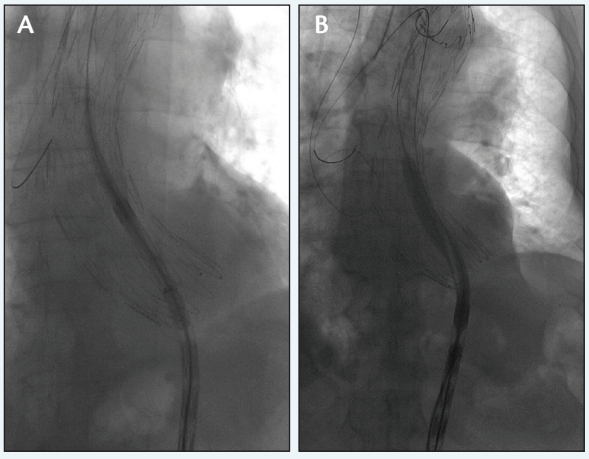

Figure 1. The Zenith Alpha Thoracic device (A) was able to negotiate a tortuous aorta that the Zenith TX2 (B) could not.

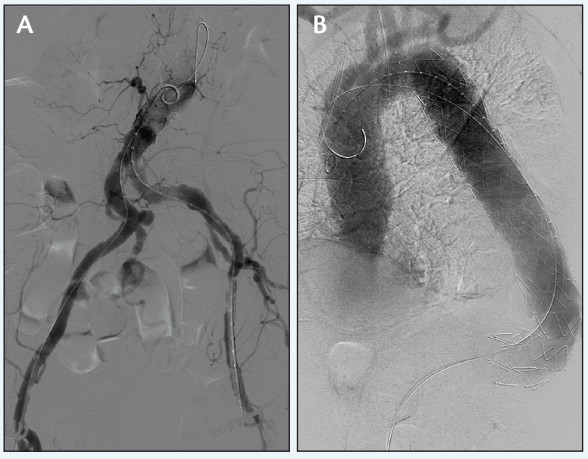

Figure 2. Vascular access (A) and deployment (B) of the Zenith Alpha Thoracic device in a patient who was unsuitable for a standard-profile device due to small access vessels.

CASE 1: TORTUOSITY

In a patient who had a TAA with significant tortuosity, a staged procedure was planned. The first Zenith Alpha Thoracic device was able to navigate the tortuous aorta easily, but we were unable to navigate the second standard-profile Zenith TX2 device around the angle (Figure 1). The second-stage procedure was to be completed at a later time.

CASE 2: SMALL ACCESS

In a patient who had small vascular access, the Zenith Alpha Thoracic device was able to negotiate easily and was successfully deployed (Figure 2).

CASE 3: TIGHT ARCH

In a patient who had a small-sized thoracic aorta with a tight arch, the Zenith Alpha Thoracic device was successfully deployed, with good conformance to the aorta (Figure 3).

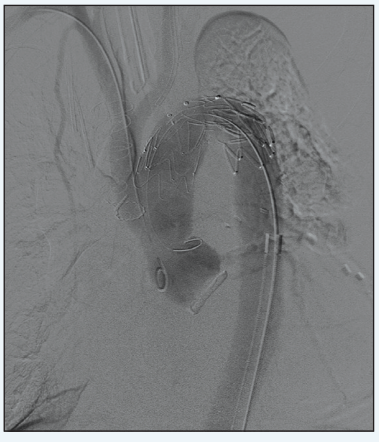

Figure 3. A Zenith Alpha Thoracic device was deployed in a small and tortuous thoracic aorta with good conformance.

diameters. In patients with small access vessels, this may mandate the need for an iliac artery conduit or access to the abdominal aorta in order to be able to deliver the stent graft. Additionally, in patients with adequate native iliac and femoral artery diameters but having atherosclerotic disease and/or calcification, the ability to deliver a standard-profile TAA device may not be possible.

The current smaller diameters of stent graft delivery systems meant for the treatment of AAA pathology can be used to navigate the femoral and iliac arteries in most patients, but the larger diameters of the delivery systems designed for TAA pathology will often preclude an endovascular option. In these cases, balloon angioplasty or vessel dilation with the use of dilators may permit the use of a standard-profile device, but this is not always possible. Thus, a low-profile TAA device, such as the Zenith Alpha Thoracic device, will allow patients with thoracic aortic pathology and femoral and iliac arteries of smaller diameters to still be appropriate candidates for an endovascular intervention.

DISCUSSION

As demonstrated in the previous cases, the Zenith Alpha Thoracic device has maintained the characteristics of the standard-profile Zenith TX2 while being packaged

in a smaller delivery system. The delivery system continues to have great pushability, and with a lower profile, offers unparalleled trackability. The redesigned mechanism to release the trigger wires has eliminated the need for the application of high deployment forces. In highly tortuous aortas, the release of the original trigger wires often required a coordinated effort from two operators and the application of high forces. The new Zenith Alpha Thoracic trigger wire release is now a single-operator job that is effortless and allows for precise maintenance of the stent graft position.

With the low-profile delivery system, excellent pushability and trackability, and an improved trigger wire release, the new Zenith Alpha Thoracic device is ideal for the treatment of TAA pathology, particularly in patients with smaller access vessels. These features make the Zenith Alpha Thoracic an excellent device to consider when treating women and patients of Asian descent, as both groups are noted to have difficulties with vascular access. ■

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Disclaimer: The Zenith Alpha Thoracic Endovascular Graft is an investigational device in the United States and is limited by United States law to investigational use. It is CE Mark approved only for the indication of endovascular treatment of patients with aneurysms and ulcers in the descending thoracic aorta having vascular morphology suitable for endovascular repair.