AUTHOR CONTRIBUTIONS
Conception and design: MW, HM, KO
Analysis and interpretation: MW, HM, RJ, RK, AK, GM, FS, KO
Data collection: KO
Writing the article: MW, HM, KO
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REFERENCES

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DISCUSSION
Dr John F. Eidt (Greenville, SC). The authors have presented their early experience with the Endologix AFX (Irvine, Calif) with the so-called “Activescal” endovascular device in more than 100 patients with infrarenal aortic aneurysm—approximately 40% outside the instructions for use—with excellent midterm results; no ruptures, no limb occlusions, no stent fractures, and no
aneurysm-related deaths. In the words of Spence Taylor, “What’s not to like?”

As an aside, I would remind the audience that Tellon is slick. I used a 20-mm limb extension to cover an aortic pseudoaneurysm in a young patient after a thoracic gun shot wound a few years ago. I was dismayed to find on a follow-up computed tomography scan that the covered stent had migrated distally, covering the celiac trunk. It was just such migration with the ancestral version of this graft that led to the current strategy to build up from the aortic bifurcation. It was just such migration with the ancestral version of this graft that led to the current strategy to build up from the aortic bifurcation.

1. Neck dilation. The AFX device joins a family of new endovascular devices that includes most notably the Endologix Nellix and Trivascular Ovation that share unique design features that achieve aneurysm exclusion without applying constant outward force on the aortic neck. Virtually all of the traditional endovascular aortic aneurysm repair devices have reported varying degrees of “neck dilation” after long-term follow-up, and yet, the development of proximal endoleaks is distinctly uncommon if the device is implanted into a normal aortic neck. My first question is, does neck dilation matter and does its avoidance represent an important design goal in future devices?

2. There were two type Ia, one type Ib, and one type III endoleak in the 75% who were followed with computed tomography scan. As you have pointed out, the strata polytetrafluoroethylene material is located exterior to the metal scaffolding which allows the material to billow out. An imaging cohort showed extension of the anatomic neck related to this billowing. Interestingly, there were very few type II endoleaks which have been attributed to the ability of the fabric to cover the entire length of the infrarenal aorta. Are you aware of any data using either pressure wires or CardioMems pressure sensors regarding whether the design of the AFX device allows the excessive or ongoing transmission of pressure to the aneurysm wall? And, is there any consequence?

3. I notice that you have used an ipsilateral cut down despite the fact that the device has a percutaneous endovascular aneurysm repair (PEVAR) indication. Do you expect to adopt this practice in future, and if not, why not?

4. Finally, where do you fit this device into your current armamentarium? In what patients do you preferentially use this device? Thank you for presenting your data.

Dr M. Burress Welborn III. Thank you very much for the questions.

The first question regards neck dilatation. We oversize the aortic neck for the AFX graft more than other products. In patients with challenging necks we are more aggressive with oversizing. Often we end up oversizing >20%. The proximal stent has very little radial force. There is no indication from the original Powerlink device (Endologix) investigational device exemption studies that there was any neck dilatation. The AFX device is the second-generation of the Powerlink device so I expect no difference. I do not think that AFX stent component has much effect on neck dilatation. Clearly we will have to see what happens. The next issue is whether or not that constant pressure from unattached graft will result in neck dilatation. We certainly have not seen this but this needs to be considered. I think it is still too early to make any conclusions because our data represent only midterm results. Only longer-term data will tell us if either mechanism results in aortic neck dilatation.

The second question concerns intrasac pressure. There are some unpublished data from Cardiomems on intrasac pressure with the Powerlink device. The intrasac pressure when you initially put the graft in is quite high, but then after 45 to 60 days the intrasac pressure decreases to pressures that have been published for other devices. There are no data that I am aware of that suggests elevated intrasac pressures after placement of the AFX device.

The third question concerned PEVAR. I have been hesitant to get into PEVAR. My partner does PEVAR. I do not perform PEVAR because of personal reasons. I perform surgery on Friday and the last thing I want to do is get a call about an access site complication when I am spending time with my loved ones.

The final question is, in which patients to I chose to place an AFX device. The question is when do I use this device? My question is when don’t I use the device? The AFX device is great for saccular aneurysms. I think it is the ideal graft for saccular aneurysms. The AFX device is great for normal aortic bifurcations and the device is ideal for patients who have infringuinal disease that you are going to have to go back and intervene later. I think the one pitfall is patients who have very large iliac artery aneurysms in whom you do not have an aortic bifurcation on which you can reliably seat the graft. The real strength of the graft is that its fixation is at the aortic bifurcation. The issues of the neck sealing zone and neck coverage are important but the device uses the aortic bifurcation as the primary site of fixation. Patients with large iliac aneurysm and compromised aortic bifurcations are, in my opinion, not ideal candidates for the AFX device.