

Endovascular TODAY

July 2015



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And why graft design matters in
treating Reverse Taper Necks



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Innovation that Empowers

Insights Into Treating a Reverse Taper Neck

Physician perspectives and experiences in addressing challenging aortic neck anatomy.

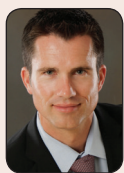
PARTICIPANTS



John S. Lane, MD, is a vascular surgeon at the University of California San Diego in San Diego, California. He has disclosed that he is a consultant and trainer for the Endologix AFX device and also a site primary investigator for the Endologix Nellix device. Dr. Lane may be reached at j1lane@ucsd.edu.



Mark F. Conrad, MD, MMSc, RPVI, FACS, is Director of Clinical Research at Massachusetts General Hospital Fireman Vascular Center in Boston, Massachusetts. He has disclosed that he is a consultant for Medtronic and Volcano Corporation and is part of a CEC committee for Bard. Dr. Conrad may be reached at mconrad@partners.org.



Zachary M. Arthurs, MD, is Chief of Vascular Surgery, San Antonio Military Medical Center in San Antonio, Texas. He has disclosed that he is a consultant for Endologix, Inc. Dr. Arthurs may be reached at zachary.arthurs@va.gov.

The cardiac output received by the abdominal aorta creates a challenging, dynamic environment for any endoprosthesis placed via endovascular aneurysm repair. In the presence of reverse taper neck anatomy, endograft placement is even more challenging. We spoke with Drs. Lane, Conrad, and Arthurs about what defines reverse taper neck anatomy, its prevalence in clinical practice, as well as their approaches to successful repair in this scenario.

How do you define reverse taper neck anatomy?

Dr. Lane: I define a reverse taper neck as an aortic diameter that increases by about 2- to 4-mm over the

course of 10-mm below the renal arteries. There is some controversy over the accepted definition, and there is no consensus on exactly what constitutes a reverse taper. An increase of 2- to 4-mm is a fairly standard definition in the literature, and it's one that I've adopted (Figure 1).

Dr. Conrad: To me, any change in neck diameter of > 4- to 5-mm over the 15-mm seal zone constitutes a reverse taper anatomy. I am not as worried about smaller changes in diameter because most devices can seal in that anatomy. However, when the change in diameter leads to excessive oversizing at the renal arteries, it can lead to pleating of the graft and compromise proximal seal.

Dr. Arthurs: Generally speaking, a reverse taper means more than 15% gradient over 15-mm of neck, using the perirenal aorta as the reference diameter.

In your practice, what is the prevalence of reverse taper neck anatomy?

Dr. Conrad: I see reverse taper anatomy in 5% to 10% of patients. This is dependent upon the location of the aneurysm, as patients with shorter necks are more likely to have a reverse taper.

Dr. Lane: By my definition, about one-third of patients have reverse taper anatomy. In my practice, it's probably a little bit more common than that because we have a referral practice. I would say our prevalence is closer to about 40%.

Dr. Arthurs: Using the definition I mentioned previously, somewhere between 20% and 30% of patients have reverse taper anatomy in my practice. I think this is probably pretty consistent with what's out there in routine practice. If anything, the number of people with reverse taper anatomy may be even a little bit higher in the general population. Generally, the anatomy is a little bit more ominous when it's evaluated by a third party, whether at a core lab or by a secondary reviewer. So if anything,

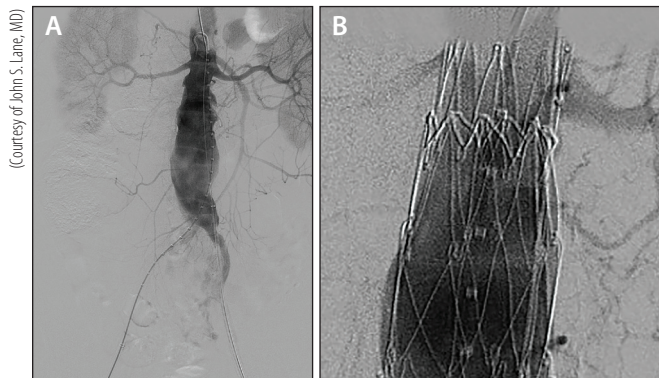


Figure 1. Example of reverse taper anatomy before (A) and after (B) placement of AFX® Endovascular AAA System.

I think the prevalence is probably higher in the general population than that reported in everyday practice.

At what point does this type of anatomy become clinically challenging?

Dr. Arthurs: A reverse taper is difficult to clinically manage at all points—whether it's acute or in the long term. As the gradient becomes increasingly steep, we're really just talking about a juxtarenal aneurysm cohort. Once the gradient reaches about 20% or 30%, these are the patients that we are challenged to treat.

Dr. Lane: It has been shown that there is a higher rate of complications with reverse taper necks, such as a higher prevalence of reintervention and a higher rate of neck complications, including Type I endoleaks. In any study of reverse taper anatomy, achieving a seal makes the case challenging. There are additional features that, in addition to having a reverse taper neck, make management even more challenging. For example, not only could you have a reverse taper, but also more extreme neck angulation or heavy calcification within the neck. In these cases, we're achieving a seal endovascularly, but it's very difficult.

Dr. Conrad: Once there is a difference of > 5-mm over the proximal seal zone, this may lead to more extensive oversizing of the graft, which will ultimately compromise the proximal seal.

What are the clinical challenges that you face with reverse taper anatomy?

Dr. Lane: When there is a reverse taper neck, the graft has to be oversized—either the main body of the graft or the cuff of the graft—in order to achieve an adequate seal. The graft has to be sized or oversized based on the largest portion of the reverse taper. The challenge is that many devices are limited for use in a very specific diameter range based on the indications for use (Figure 2). These

restrictions make it very difficult to adequately treat a reverse taper neck.

A second problem is that some grafts achieve a seal by using a high degree of radial force at the aortic neck. When you are greatly oversizing the graft and also introducing a device that relies on high radial force, those devices are at a disadvantage, and I tend not to use them in this anatomy.

Dr. Conrad: If the aortic neck diameter changes from 22- to 28-mm over the proximal seal zone, a 31-mm graft would be required to obtain seal. However, the graft is then too large for the 22-mm portion of the aorta and will either pleat on itself, causing a gutter, or can slip down. Both will compromise the seal.

Dr. Arthurs: I think there's been a shift in how this anatomy is handled. Initially, the proximal fixation engineering concept to address a reverse taper was to oversize more aggressively so that the larger-diameter distal aorta is adequately treated. That may equate to 20% to 25% oversizing at the proximal portion of the seal, but only 10% oversizing distally. This allows for the possibility of infolding or Type IA endoleak. The endograft needs to be placed perfectly in order for that plan to succeed. Long-term sequelae relating to how the reverse taper neck handles a device that has a high radial force is also an issue. A device with high radial force is inclined to protrude itself or drive itself to the largest diameter, which is outside of the native seal zone.

From an engineering standpoint, some manufacturers have taken a new approach to seal that we haven't seen before, such as with the AFX® Endovascular AAA System (Endologix, Inc.). This device does not depend upon high radial force in the proximal neck and utilizes a pressure-activated sealing mechanism. The fabric can extend that seal zone irrespective of the shape of the neck (Figure 3).

Proximal Size (mm)	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32
25																	
28																	
34																	
23																	
25																	
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Figure 2. Recommended endograft oversizing for proximal components.



Maximize Seal Zone Length Without Infolding Consequences

- Graft apposition contributes to seal
- Ability to oversize without concern of infolding
- Controlled delivery and precision of VELA[™] Proximal Endograft

What have you done to overcome these challenges? Are there specific technologies you've utilized to surmount them?

Dr. Conrad: You have a few options depending on the health of the patient. Open repair remains a viable option and should be considered in this situation. There are also endovascular options. If the neck is too short, one option is to place a branched or fenestrated graft that will extend the proximal seal zone above the renal arteries. Many surgeons are leaning toward this approach, but it is currently not an option for everyone. There are obstacles to fenestrated grafts, including that it requires a more advanced endovascular skill and the only commercially available fenestrated graft in the United States currently takes about six weeks to build.

A second potential endovascular option, depending on the diameter of the neck and the presence of an adequate distance for seal, is to try a graft that is more pliable, such as the AFX. These grafts are more forgiving with oversizing and are less likely to plect.

Dr. Arthurs: There is a choice of an open repair, with the attendant complications. I have leaned on the AFX device in my practice in patients with suitable neck diameters and lengths, and I've had good sealing results and excellent sac regression.

Dr. Lane: I use the AFX system as my device of choice for treating reverse taper anatomy for two reasons. The first is that the device does not rely on high radial force proximally; therefore, it can be substantially oversized and remain within the instructions for use. For example, the 34-mm AFX device is indicated for aortic necks with a 23- to 32-mm diameter, which is the broadest diameter range for a single device among any of the commercially available endografts.

The other reason that the AFX device is ideal for reverse taper necks is its "ActiveSeal™" attribute. The graft (DuraPly™ ePTFE) is mounted on the outside of the stent and only attached at the proximal and distal ends. This construction allows the material to move away from the stent and conform to the aortic wall beyond the stent, which has been reported to extend the initial seal zone in some patients.

When treating this type of anatomy, what outcomes have you experienced, and what are the implications of these outcomes?

Dr. Lane: I've used the AFX device to treat patients with advanced disease and was able to achieve good results.



Figure 3. AFX® Endovascular AAA System illustrating extended seal zone characteristics.

For me, the device simplifies the procedure in these patients, and it provides a good outcome using a relatively standard technique.

With some proximally fixated devices, I have experienced Type IA endoleaks. There are a few options to address these, including usage of anchors (eg, Heli-FX EndoAnchor system, Aptus Endosystems, Inc.), in which helical tacks pull the device onto the aortic wall or fix the device on the aortic wall. I have had to use anchors to achieve seal and remedy a Type IA endoleak from a proximally fixated graft. The final remedy would be to convert to open surgery and explant the device.


Dr. Conrad: If the reverse taper is large (> 5-mm), the use of some devices will result in a Type I endoleak. In some of these patients, the seal zone is actually aneurysmal, so there will be degeneration loss of proximal seal over time. Endoleaks can lead to further interventions including explantation and open repair.

Dr. Arthurs: Prior to using AFX for certain reverse taper necks, I saw challenging Type IA endoleaks that required adjuvant procedures to achieve a seal, such as a balloon-expandable stent, an additional graft, or using increased radial force. In my experience using the AFX device with proper patient selection, I haven't seen a Type IA endoleak. I also believe that the rate of Type II endoleak has been reduced in my practice. We've done some analysis of core lab data, and it appears that the extent of endograft interaction with the aorta correlates with a reduced rate of Type II endoleak. It sounds fairly intuitive, but the other endografts simply do not interact with the same length of aorta that the AFX device does. This may lead to sealing of collateral flow due to high and low accessory lumbar and other vessels.

From what I've seen, perhaps the most remarkable feature of the AFX device is that the proximal neck does not appear to continue to degenerate as it does with a self-expanding stent. Does that have long-term advantages? I think it does. The implications overall are positive, as the rate of endoleak is low, the rate of Type II endoleak appears to be much lower, and sac regression is quite remarkable. All of those things may impact long-term outcomes. ■

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