

# A Practical Look at EVAR Fixation

Ross Milner, MD, discusses the properties of fixation for endovascular abdominal aortic stent grafts, including their strengths and weaknesses and how the technology has evolved.

## **What are the properties of fixation for endovascular aneurysm repair (EVAR) devices, and how do they relate to sealing?**

**Dr. Milner:** Fixation is designed to prevent distal migration of an endograft and can be accomplished by passive and active mechanisms. Generally speaking, passive fixation is provided via the radial force of the endograft, whereas active fixation is provided by such mechanisms as barbs and hooks, etc. The difference between fixation and sealing is commonly misunderstood. Fixation relates to migration but does not directly relate to sealing, which is accomplished via radial force in some approved devices. In the case of the EXCLUDER Device (W. L. Gore & Associates, Flagstaff, AZ), sealing is accomplished with both radial force and a sealant ring at the proximal end of the device, which is very useful in causing the device to stick to the inner wall of the aorta. The only correlation that exists between fixation and sealing is that poor fixation can result in migration of a device, which would then obviously affect sealing, but there is no direct correlation between the fixation properties of the various endografts and sealing.

## **How would you summarize the milestones in the evolution of fixation for EVAR devices from the first uses of the procedure through the current generations of devices?**

**Dr. Milner:** The first two devices approved by the US Food and Drug Administration, Ancure (Abbott Vascular, Santa Clara, CA, formerly Guidant Corporation) and AneuRx (Medtronic, Inc., Minneapolis, MN), accomplished fixation by different means. The Ancure had active fixation with hooks, whereas the AneuRx relied on passive fixation alone. Both devices encountered difficulties. The Ancure device had delivery system malfunctions<sup>1,2</sup> but excellent prevention of migration.<sup>3</sup> The AneuRx device struggled with distal migration.<sup>4</sup> This is especially true when treating challenging aortic neck anatomy.<sup>4</sup>

The next generation of devices included the Zenith device (Cook Medical, Bloomington, IN), which uses suprarenal fixation with barbs, the EXCLUDER Device, which uses infrarenal fixation with barbs, and the Powerlink device (Endologix, Inc., Irvine, CA) uses what they like to call “anatomical fixation” because the device is designed to sit on the iliac bifurcation. The Talent endograft (Medtronic, Inc.) is unique in that it uses passive suprarenal fixation.

There are currently no other endografts being marketed within the United States. One of the investigational devices, the Aptus endograft (Aptus Endosystems, Inc., Sunnyvale, CA), used staples to achieve fixation. The device had some issues regarding limb thrombosis, but that was not related to the staple fixation. I suspect that devices are evolving to incorporate the benefits of a combination of passive and active fixation mechanisms, but at present, the EXCLUDER Device is the only device that uses both passive and active fixation.

## **What are the possible risks associated with different types of fixation?**

**Dr. Milner:** Any device is subject to fatigue. All devices have shown some element of fracture or fabric issues, and fixation has not been exempt from fatigue problems. All active fixation materials (stainless steel, nitinol, and cobalt-chromium alloy) have all shown fracture events and are still prone to this type of problem. It is not clear that fractures lead to significant device issues, such as migration, but this concern exists.<sup>5</sup>

## **In your practice, have you seen examples of when a particular type of fixation created issues?**

**Dr. Milner:** I have seen a clinical trial device with suprarenal fixation develop a separation from the main body device. However, this did not lead to a migration event. When working in Europe, I did see an example in which oversizing of a passive fixation device led to aortic neck dilatation. I believe that we have seen less of that in recent years, and I don't know if that is because of device

improvements or if endovascular specialists have learned to do a better job of sizing devices for the anatomical measurements.

### How does the type of fixation used by a device affect the delivery/deployment of various EVAR devices?

**Dr. Milner:** I think it does not significantly change the delivery/deployment of the device. For some devices, it adds one or two additional steps during the main body deployment. In addition, I always take great care in removing the main body device delivery system when a suprarenal fixation system has been deployed.

### What are the proven benefits of different types of fixation? In short necks? In angulated necks?

**Dr. Milner:** I do not think there are data to support that different fixation means (ie, passive vs active, suprarenal vs infrarenal) allow for improved treatment in general or in short or angulated necks. This is based on the Instructions For Use (IFU) and my own clinical experience. Some specialists have assumed that devices with suprarenal fixation are better suited for treating shorter aortic necks, even though the devices' IFU were identical to that of other devices using infrarenal fixation. It may well be that those suprarenal devices are able to treat shorter necks but neither the clinical data nor the IFU have supported that conclusion. The Talent device differs slightly in that it is approved by the US Food and Drug Administration for a 10-mm aortic neck length.

I believe that the best option for treating challenging aortic necks is to use a debranching procedure, chimney/snorkel stent placement, or branched/fenestrated devices. All of these types of repair have been reported to be successful, but they have also had significant complications.<sup>6-8</sup>

Finally, open repair is still an appropriate option in physiologically suitable patients.

### Are there misconceptions about the different types of fixation?

**Dr. Milner:** I think the main misconception is that suprarenal fixation allows the user to treat a shorter aortic neck. The suprarenal fixation devices can be deployed successfully in challenging anatomies, but I am always concerned about the durability of this approach.

### What do you see as the short- and long-term future for fixation of EVAR devices?

**Dr. Milner:** In the short-term, the benefit of the new C3 Delivery System for the EXCLUDER Device (W. L. Gore & Associates) is that you can be exceptionally accurate in placing the device with active fixation because you will have the ability to deploy it and reposition it during the procedure. This device is available in Europe and recently FDA approved.

In the long-term, I think stent grafts will always need some amount of active fixation to prevent migration, and I do not think that improvements in fixation will change our ability to treat difficult anatomy. ■

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