# Addressing Challenging AAA Anatomies With Confidence

Hence J.M. Verhagen, MD, PhD, discusses how the Endurant II Stent Graft has performed well in challenging anatomy, enabling physicians to successfully treat a broader range of AAA patients.

### What are the biggest anatomical challenges that limit the practice of endovascular aneurysm repair (EVAR)?

Anatomical features that limit the practice of EVAR are traditionally a proximal aortic length < 15 mm, diameter > 26 mm, neck angulation > 60°, reverse taper, or thrombus burden. These characteristics comprise a "hostile neck." In particular, the anatomic characteristic that most limits the application of EVAR is an infrarenal neck < 15 mm. Short necks do not always allow for adequate seal of the device to healthy aorta, and of course, angulation makes delivery and placement more difficult than in standard anatomy (ie, > 15-mm anatomy).

### How does this affect abdominal aortic aneurysm (AAA) patient selection and long-term outcomes?

For standard EVAR, patients with necks 15 mm or greater have many options. Once you start treating patients with shorter necks, on-label treatment options are limited.

Short necks do not necessarily mean unfavorable angulation, and unfavorable angulation doesn't necessarily mean a short neck, so careful patient selection must always be considered. You must take each patient's unique anatomy into account when making a decision about AAA treatment and what type of endograft to use. Even in the short- and midterm, infrarenal neck length < 15 mm has been associated with an increased risk of complications such as endoleak or device migration. With the increased availability of devices such as Endurant® II Stent Graft (Medtronic, Inc., Minneapolis, MN), however, we are seeing improved clinical outcomes for this subgroup of patients (ie, short necks).

### What are some characteristics of Endurant II that enable the treatment of short necks?

The Endurant II Stent Graft was thoughtfully designed, with special consideration given to short-neck anatomy. It offers precise, millimeter-by-millimeter deployment, which is extremely useful when you only have a small amount of healthy vessel for landing. The device uses suprarenal fixation and anchor pins to enable secure active graft fixation even when placement is limited by a short neck. Correspondingly, we see that in clinical studies, Endurant II has 0% migration out to 3 years.

The enhanced tip-capture mechanism in Endurant® II allows for adjustment proximally or distally, even after deployment of up to three stent rings, so again, you are able to adjust the device even when the aortic neck is > 10 mm. As a result, the delivery and deployment success rates for Endurant II are > 99%.

### Could you summarize the data you presented at Charing Cross and SVS this year that analyzed Endurant performance?

The ENGAGE registry evaluated the global, real-world use of the Endurant II Stent Graft, consecutively enrolling more than 1,200 patients at 79 sites across six continents, with planned follow-up out to 5 years. The goal of ENGAGE is to gather real-world data on patients treated with the Endurant II Stent Graft, and thus, inclusion criteria were less strict than other registries. Because this trial enrolled such a large number of patients, we are able to analyze a cohort of patients with short necks. We found that Endurant II performs just as well in short necks in particular (10- to 15-mm anatomy) as it does in standard necks (15- to 20-mm anatomy). There was extensive monitoring and analysis of the data in ENGAGE—100% data managing review, independent data monitoring, and an independent clinical event committee—meaning that these are high-quality registry data.

When we looked at the current subanalysis of neck

length, we found the following: 123 patients had neck lengths of 10 to 15 mm, 227 were 15 to 20 mm, and 873 patients had neck lengths > 20 mm. We now have follow-up data at 30 days, 1 year, and 2 years, and we are seeing that there is no difference in performance related to neck length. Specifically, at the time of the initial implant procedure, there were no type I endoleaks in patients with 10- to 15-mm neck lengths compared to the 15- to 20-mm and > 20-mm neck groups, respectively. At 1 year, this difference remained insignificant, and we also observed a 0% rate of migration across all three groups. At 2 years, this was also sustained. The rates of secondary procedures to correct a type I or III endoleak were also quite low (0%, 1.3%, and 1.9% for the short, standard, and > 20-mm neck length groups, respectively).

Current analysis supports the use of Endurant II in necks that are at least 10 mm, which is consistent with its labeled indication. We can say with confidence that Endurant II performs equally well in standard EVAR neck lengths. Of course, the need for longer-term data remains, but overall, these results at 2 years are very encouraging.

### What strategies do you employ for overcoming the associated risks of treating necks shorter than < 10 mm?

One has to bear in mind that treating that sort of anatomy is outside the instructions for use for standard EVAR. It is important to realize that there's probably a good reason for that. In a very recent presentation from our group during ESVS 2013, we analyzed ENGAGE data for risk factors for proximal neck complications after EVAR with the Endurant Stent Graft. It showed that EVAR for AAAs with a neck length of 10 to 15 mm was associated with very few neck-related adverse events (type IA endoleak, conversion, unintentional renal artery coverage, deployment complications, or migration), resulting in the same results as can be expected when AAAs with longer necks are treated. It also showed that a neck length of < 10 mm increases the risk for intra- or postoperative neck-related adverse events by approximately ninefold. This highly significant finding should be taken into account when an endovascular option is considered for treating a < 10-mm-neck aneurysm. Personally, I'd select a fenestrated option in those cases. Of course, using a chimney technique has been advocated for this anatomy as well, but I still consider that concept a far less desirable method.

### What are some of the specific challenges of treatment in women, particularly in relation to anatomy?

The aortoiliac anatomy of women makes them a challenging population to treat via EVAR. Complications are somewhat more common in women versus men, often due to the increased age at the time of diagnosis and treatment and greater atherosclerotic risk factors present in women compared to men. We see more tortuous and occluded anatomy in older populations, which is especially true in women, and women generally have smaller vessels to begin with. These anatomic factors further impede the device delivery process, and shorter and more angulated aortic necks make acquiring an adequate landing zone and achieving a good seal more difficult. Thus, understanding the performance of a stent graft in this type of anatomy is a good indicator for its overall performance in challenging anatomy.

### What other features of Endurant II enable successful treatment specifically in women?

Endurant II's low profile and hydrophilic coating allow for easier access, which is key in overcoming the challenging aortoiliac anatomy common in women who, as previously mentioned, typically have smaller and more tortuous iliacs. The Endurant II delivery system is kink-resistant as well, which helps when you are navigating difficult anatomy.

### The sheer size of the ENGAGE registry allowed for close scrutiny of results in female anatomy. What is the significance of this, and what were the results?

Women have been shown to have worse outcomes after EVAR, including higher mortality, a higher rate of access complications, and a greater risk of endoleaks. However, results for Endurant II are promising. Based on what we see in ENGAGE, Endurant II has narrowed the outcome gap between sexes, despite the presence of more challenging aortoiliac anatomies and comorbidities in women.

Endurant II achieved equivalent outcomes regardless of sex. Early outcomes in the ENGAGE registry were similar in women and in men, with similar rates of technical success, similar freedom from type I and III endoleak, and no difference in presence of type I endoleak.

At 30 days, there was no statistically significant difference found between men and women in the rate of the occurrence of limb occlusion, type I endoleak, or the need for a secondary endovascular procedure. In addition, at 1 year, there was no difference between men and women in freedom from major adverse events or survival. Knowing this, we can again remain confident in the overall performance of the Endurant II Stent Graft. ■

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