

Infrarenal Fixation Is All That Is Necessary

Essential factors determining EVAR durability at the proximal sealing zone.

BY ROBERT Y. RHEE, MD

Endovascular therapy has revolutionized the treatment approach for patients with abdominal aortic aneurysm (AAA) disease. For those who meet specific anatomic criteria, endovascular repair of AAA (EVAR) is currently the preferred therapeutic approach. The main reason for this trend is that patients undergoing EVAR have significantly improved periprocedural outcomes compared to those who undergo direct open repair.¹⁻³ This advantage has been shown in multiple studies with respect to decreased 30-day mortality rates, shorter recovery times, and decreased lengths of hospital stay.³

Currently, the majority of patients with AAA disease have neck anatomy that is suitable for endovascular therapy. Since the inception of EVAR technology, the literature is relatively clear that when specific instructions for use (IFU) guidelines are followed, most endografts perform extremely well, as demonstrated by the excellent 5-year performance records of the currently available devices.^{4,5} Patients who have a proximal aortic neck length < 15 mm, neck diameter > 26 mm diameter, circumferential neck thrombus, reverse taper anatomy, and/or neck angulation > 60° have traditionally been considered to have a hostile neck, which was a contraindication for the currently available endografts.⁶

However, with the expansion of EVAR experience by most vascular specialists and with the significant improvement of devices during the last 15 years, the



Figure 1. EVAR candidate with hostile neck anatomy.

boundaries of the IFUs provided by the device manufacturers have been pushed to the limits by high-volume physicians to include patients exhibiting many of the so-called hostile neck properties (Figure 1). Numerous studies have shown reasonable results when these limits have been pushed with adjunctive stenting and other maneuvers to make neck fixation more secure.^{7,8} A recent review of the collected data from a nationally available EVAR imaging system revealed that 58% of the EVAR procedures being performed in the

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Figure 2. The fixation barbs of the Excluder device.

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United States are being done outside of the device-specific IFUs.⁹ The true long-term durability of results for these patients remains somewhat uncertain. However, based on 15 years of EVAR experience throughout the world, it is evident that if the endograft does not remain fixed in the proximal neck, adverse outcomes are expected, with inevitable rupture of the AAA.^{10,11}

THE ROLE OF FIXATION IN ENDOGRAFT STABILITY

The theoretical role of fixation in endograft technology is based on the fact that, if properly deployed, the mechanism prevents the device from distally migrating from the seal zone over time. Both the constant aortic blood flow and potentially tortuous anatomy make these devices susceptible to caudal migration. Endografts attempt to achieve fixation with multiple features, including active fixation (using barbs or hooks), columnar strength, outward radial force, and fibrotic reaction with prosthetic materials. Some devices may incorporate more than one of these features. The most common form used in modern endografts is active fixation into the aortic wall of the proximal aorta to maintain the endograft position. *Columnar strength* refers to the vertical stiffness of the graft to hold the superior aspect of the device. Endograft migration may be limited by the frictional forces induced by the outward radial strength of the device. However, numerous long-term reports have shown that this form of fixation is not durable in hostile necks.^{12,13}

There has been much controversy regarding the need and efficacy of fixation in the short- and long-term



Figure 3. Fixation mechanism of the Zenith device.

performance of endografts. Most physicians currently believe that some type of fixation is required for accurate placement and durability of endografts; most of the endograft systems have an integrated active fixation system incorporated into the proximal segment of the endograft. Some devices, such as the Ancure (formerly Guidant Corporation) and Excluder (Gore & Associates, Flagstaff, AZ) devices, have fixation systems that actively engage the proximal neck itself (Figure 2). Certain devices offer suprarenal fixation with the belief that the suprarenal aortic neck is less likely to dilate over time, thus providing more durable fixation (Figure 3). It is not yet clear if the bare-metal stents of these devices with transrenal stents, which span the orifices of the renal and mesenteric arteries, are associated with long-term renal dysfunction, but there have been reports of occlusive processes partially occluding the origins of the renal and mesenteric arteries after suprarenal stent graft implantation (Figure 4).¹⁴

EVAR IN HOSTILE NECKS: SUPRARENAL OR INFRARENAL?

Despite the excellent long-term data from the EVT/Ancure endograft systems utilizing infrarenal fixation techniques,² many vascular specialists believe that suprarenal fixation is superior to infrarenal fixation for treating patients with short proximal aortic necks. In theory, the active fixation (barbs) would be in the healthy segment of normal aorta and should allow adequate apposition of graft material and aortic wall just below the renal arteries. In 2001, Stanley et al analyzed the Zenith Endovascular Graft Research Database on 238 patients treated with the Zenith (suprarenal fixation) device (Cook Medical, Bloomington, IN). They found a 56% type I endoleak rate in patients with short aortic necks (≤ 10 mm) and concluded that patients with short aortic necks should not be treated with the Zenith device.¹⁵

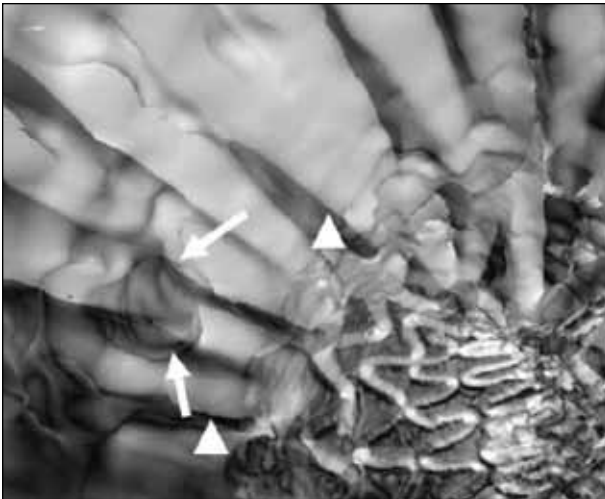


Figure 4. Virtual computed tomographic angiography of the suprarenal aorta after EVAR with a suprarenal device.

In 2006, an analysis of the 3,499 patients in the EUROSTAR registry was performed to help predict outcomes after EVAR based on the length of the proximal aortic neck. The patients were divided into three groups: group A had proximal aortic necks > 15 mm (reference group, n = 2,822), group B had necks of 11 to 15 mm (n = 485), and group C had proximal necks < 10 mm (n = 192). Univariate and multivariate analyses were performed and found a significantly higher number of type I endoleaks at 1 month in group C as compared to group A (10.9% vs 2.6%) and within 48 months (11.3% vs 3.4%).⁸

These outcomes were also demonstrated by AbuRahma and colleagues, who examined patients who underwent EVAR with short proximal aortic necks.¹⁶ Their study examined 238 patients and subdivided them into three groups: patients with proximal necks \geq 15 mm (L1, n = 195), patients who had necks of 10 to 14 mm (L2, n = 24), and patients with < 10 mm necks (L3, n = 17). They found that the rates of early type Ia endoleaks occurred in 12%, 42%, and 53% in groups L1, L2, and L3, respectively ($P < .001$). They also noted that the need for proximal aortic cuffs to achieve adequate seal was 10%, 38%, and 47%, respectively ($P < .0001$). There was no statistically significant difference in the rate of reintervention or sac regression. The investigators concluded that EVAR can be performed in patients with extremely short aortic necks, although the rate of proximal endoleaks is significantly higher and requires more frequent proximal extension cuffs to achieve adequate seal.

In a recent study that directly compared the midterm performance of two specific types of endograft systems utilizing two different fixation methods (tran-



Figure 5. The HeliFx EndoAnchor being applied to the infrarenal neck after application of a proximal stent graft in preparation for EVAR.

srenal and infrarenal), it was demonstrated that there were no differences in the rates of migration, AAA sac stability, and other associated complications such as aneurysm-related deaths. The study identified 84 of 1,379 patients with short proximal aortic necks over an 8-year period. Morphology inclusive of a short proximal neck was stratified into two groups: those who underwent EVAR with infrarenal fixation (Excluder device) or those who underwent EVAR with suprarenal fixation (Zenith device).

In this study, patients were selected based on the presence of a proximal aortic neck < 15 mm (12 mm for the infrarenal fixation group and 11.4 mm for the suprarenal fixation group). All of these patients were considered to be high risk for direct open AAA repair. Patients were excluded if the neck angulation was > 60° and had a reverse taper > 5 mm. The primary endpoints for 1- and 2-year periods of the study were (1) the presence of type I endoleaks, (2) graft migration > 5 mm, and (3) change in sac size.¹⁷ The midterm results, even in these relatively high-risk EVAR patients, were excellent using both types of devices.

TECHNOLOGICAL ADVANCES

Recent advances in EVAR infrarenal fixation technology have focused on applying fixation after the endograft is already in place to ensure its stability. The HeliFX EndoAnchor system (Aptus Endosystems, Inc., Sunnyvale, CA) delivers anchors from the lumen of the endograft already in place to secure the proximal por-

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Figure 6. A suprarenal device with the fixation system disengaged off the aortic wall.

tion of the graft into the infrarenal neck (Figure 5).¹⁸ Some endograft systems employ “fish mouth” configurations with active fixation to the proximal portion to maximize the seal zone.¹⁹ The short- and midterm results of these infrarenal systems have also clearly demonstrated that excellent EVAR durability can be achieved with infrarenal fixation alone.

The evidence for durability of active infrarenal fixation is clear in the literature. Even in nonideal EVAR situations when hostile neck features are present, these endograft systems appear to have reasonable migration-free outcomes. The only real issue is whether there are adverse effects of suprarenal fixation. Oberhuber et al²⁰ studied the effects of infrarenal versus suprarenal fixation on aortic neck and proximal aortic stresses. They showed that patients who underwent EVAR with suprarenal devices had a significantly higher rate of neck expansion (31% vs 10%; neck expansion > 2 mm). These results may have been related to excessive oversizing in these suprarenal systems,²¹ but the influence of the suprarenal stent structure cannot be ignored.^{11,13,16} There are no biomechanical or clinical studies that have evaluated these metal structures across the suprarenal aorta. In some cases of extreme angulation, these fixation mechanisms may not even function in that capacity due to the lack of aortic apposition (Figure 6) and actually may cause direct trauma to the aortic wall when not apposed to the wall. The infrarenal fixation systems also allow for “reticulation” of the proximal fixation region to allow for increased flexibility (Figure 7).

CONCLUSION

Today, there are multiple infrarenal and suprarenal fixation endograft systems that perform extremely well



Figure 7. Reticulation of the proximal endograft to better conform to the curvature of the angled neck. Preoperative aortogram of an angulated neck patient (A). Intentional deployment of the device distal to extreme angulation (B). Proximal extension with aortic cuff to “reticulate” the proximal endograft (C).

under most conditions and even in situations of isolated hostile neck anatomy. The mid- and long-term data from these modern endograft systems do not demonstrate superiority of one type of system over another. Neck expansion appears to be higher in suprarenal systems, but this issue has not translated to higher migration rates in reports that have studied these patients. In severely angulated necks, caution must be taken with suprarenal devices due to disengagement of the fixation system in the suprarenal aorta.

The key to successful EVAR is good patient selection and accurate deployment of the device so that the fixation system can engage the aortic wall as intended. Both systems can lose their active fixation advantage when misdeployed (and not allowing the fixation to function properly). As endograft technology has progressed, there has been emphasis on refining deployment accuracy. This is evident by the introduction of the “repositionable” systems.^{22,23} When endografts are positioned accurately in appropriate patients, the long-term outlook for EVAR durability is extremely promising. ■

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