

Aortic Neck Dilatation: Causes and Effects

A look at the mechanisms of aortic neck dilatation and how they can be overcome with new technology.

BY SEAN P. LYDEN, MD

When endovascular aneurysm repair (EVAR) began in the 1990s, very little was known about device design and durability. Physicians, engineers, and companies raced to create devices to mimic open surgical repair, simply replacing the aortic suture line with stents to achieve fixation. A minority of senior vascular surgeons embraced the technology, whereas most questioned the entire concept, believing that EVAR was destined for failure.

The biggest concern was the durability of the device to stay in place and seal off the aneurysm. Clinical experience with open repair noted an infrequent need for late surgical revisions.¹ Contrary to the belief that open repair was a forever fix, in 1997, Illig and colleagues reviewed the fate of the proximal cuff after open aortic repairs and noted that one-third of patients experience significant dilatation over time. They suggested that this dilatation could prove to be the Achilles' heel for EVAR.² The concern regarding neck dilatation was partially validated in a 2000 study. Wever and colleagues noted dilatation of the proximal neck by 15.5% at 12 months in patients undergoing EVAR.³ The reason for the dilatation could not be correlated with the graft diameter or amount of graft oversizing, and concern for late failure of EVAR remained.

Aortic growth leading to failure of the distal aortic seal zone was con-

firmed and publicized with the failure of the EVT/Ancure graft (formerly Guidant Corporation straight tube graft).⁴ This led to better understanding of what a seal zone should look like and abandoning the concept of sealing in the distal infrarenal aorta. After this point, seal zones for EVAR would always be proximal in the aorta next to the renal arteries and distal in a normal iliac artery. The midterm results from several different device trials for EVAR with bifurcated endografts eventually proved success with EVAR, with outcomes as good as open surgical repair.⁵⁻⁹ Multiple variations exist between devices to achieve fixation and sealing, with no one method proving superior.¹⁰ To date, reports for patients treated within the instructions for use (IFU) in the pivotal trials have not found loss of proximal fixation and migration to be a frequent problem. However, several devices did change the IFU to recommend treatment of longer and less-angulated necks.

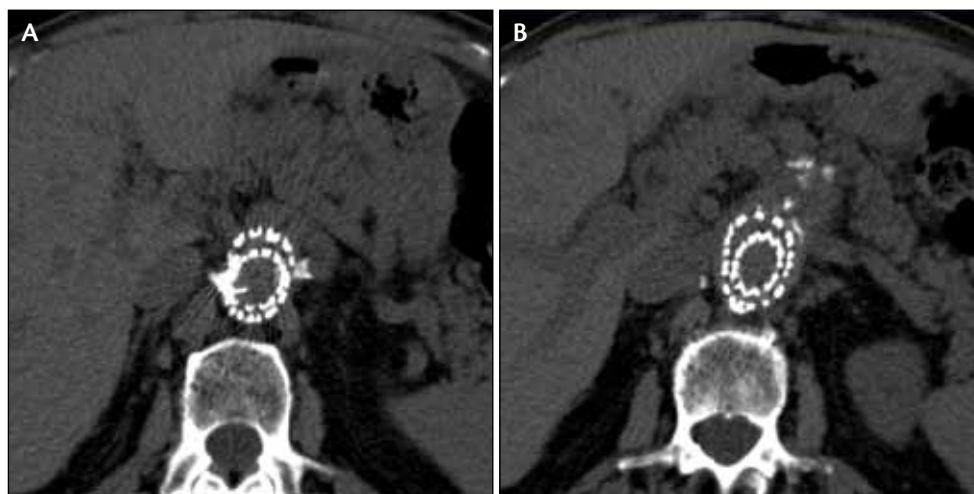


Figure 1. Dilatation in aortic neck diameter at the level of renal arteries (A) and 10 mm distal (B) at follow-up with a self-expanding stent graft, which was treated with a giant balloon-expandable stent to achieve sealing. The inner balloon-expandable stent stays at the same diameter while the self-expanding stent graft has enlarged the aortic neck seal zone.



Figure 2. The Ovation Prime™ device (TriVascular, Inc., Santa Rosa, CA) and polymer injection to fill the sealing rings.

RESEARCH FINDINGS AND CREATING BETTER TOOLS

Single-center studies have suggested that neck dilatation could be an issue and that excessive device oversizing could be the force leading to growth and eventual migration.^{11-14,15} Balloon-expandable stents have commonly been used to achieve sealing when treating neck anatomy outside of the IFU. We recently followed up the long-term results of usage of giant balloon-expandable stents to achieve sealing in proximal type IA endoleaks at the Cleveland Clinic, finding no late endoleaks or migration. An interesting side finding was the lack of diameter change in the balloon-expandable stent but progressive dilatation of the aortic neck to within 1 mm of the device diameter of the EVAR self-expanding stent grafts, suggesting a possible causal connection between oversizing with self-expanding stent grafts and neck dilatation in our series (Figure 1).¹⁶

Another study, which evaluated the long-term results of the Zenith® device (Cook Medical, Bloomington, IN), also noted that neck dilatation was associated with the device.¹⁷ The continued expansion in proximal neck diameter does raise concern for the risk of developing late migration and/or proximal endoleak. To date, all self-expanding stent grafts have

demonstrated neck enlargement and thus have this limitation.

Balloon-expandable stents do not place continued outward force on the aortic wall and may be an alternative for long-term fixation and sealing. The use of balloon-expandable stents for creating fixation and sealing in EVAR was used with the Lifepath device (Edwards Lifesciences Corporation, Irving, CA; note, this device did not progress to FDA approval) and the MEGS device (Montefiore Endovascular Graft System). Interestingly, experience with these devices noted no dilatation of the aortic neck with the MEGS device and significantly less dilatation with the Lifepath device compared to devices utilizing self-expanding stents.^{18,19} These data lead us to question the generally accepted notion that oversizing the EVAR device by a minimum of 10% to 15% with self-expanding devices is always the best option.

NEW OPTIONS

Clearly, devices that do not place chronic outward force on the aorta may have some merit. The Ovation Prime device was recently approved by the FDA and is the first FDA-approved device that does not use self-expanding stents to achieve proximal sealing.²⁰ This device uses a polymer to fill a sealing ring that, once



Figure 3. A proximal neck diameter of 19.8 mm in a small aneurysm in 2008 (A). An intimal neck diameter of 21.6 mm prior to EVAR in November 2011 (B). A proximal neck diameter 21.7 mm 18 months after EVAR in May 2013 (C).

cured, does not exert outward force on the aortic wall (Figure 2).

To date, 12-month data presented with the premarket approval application for the Ovation device have shown durability of the seal zone without migration or proximal endoleak in all patients. The aortic proximal neck diameters have been stable. This further suggests that an EVAR device that does not exert force against the wall may actually protect from growth of the aorta. The regression of aortic diameter when successful sealing is achieved supports this concept. Although late outcome data to prove this concept are still not available, in my own clinical experience with TriVascular EVAR devices, I have not seen aortic neck growth with either the first-generation unibody device or the current device iteration (Figure 3).

CONCLUSION

Aortic neck dilatation is seen with both open and endovascular repairs. Current concepts regarding the reason for this phenomenon remain poorly understood. Clearly, in some patients, this could be due to progression of the pathophysiologic changes in the vessel wall biology, leading to continued aneurysmal degeneration of the aorta. The influence of EVAR on this phenomenon is surely different for devices that exert continued outward force on the aortic wall versus those that do not. The amount of proximal device oversizing with self-expanding devices influences this phenomenon, and more is not always better. New innovative ways to achieve fixation and sealing may improve late outcomes with EVAR by protecting the aortic wall from pressure and growth. ■

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