Rethinking the Concept of Aortic Neck Length

Will the concept of proximal aortic neck length become obsolete as aortic endograft designs incorporate new sealing technologies?

BY JENNIFER L. ASH, MD; NABEEL R. RANA, MD; RAVISHANKAR HASANADKA, MD; AND SYED M. HUSSAIN, MD

Juan Parodi placed the first endovascular stent graft for the purpose of treating abdominal aortic aneurysm (AAA) in 1990. The procedure employed an intraluminal, balloon-expandable, stent-anchored, Dacron prosthetic graft inserted via retrograde cannulation of the common femoral artery. The device created friction seals, which fixed the ends of the graft to the vessel wall. This excluded the aneurysm from circulation and allowed normal blood flow through the graft lumen.[1] In a follow-up article published in 1995,[2] Parodi described five limitations of the initial procedure, based on a population of 57 patients who were treated between 1990 and 1994: (1) preoperative measurements of the involved arteries and lesions, (2) arterial access challenges, (3) the absence of a distal aortic cuff or distal seal zone within the aorta, (4) stent migration (primarily due to incomplete stent deployment within the aneurysm neck), and (5) microembolization. The concept of progressive proximal neck dilatation was not described, and in fact, the authors stated that in their experience, the distal aortic cuff became shorter and tended to disappear, whereas the proximal aortic neck became shorter and elongated, thereby creating added tortuosity.[2]

In 2008, Rodway et al studied two groups of patients: those who had undergone open AAA repair and those who had undergone endovascular AAA repair. Their results demonstrated a statistically significant increase in proximal aortic neck diameter in the endovascular repair group versus the open repair group at 2 years.[3] Malas et al was the first group to describe the lack of aortic neck dilatation noted in those patients who underwent AAA repair employing a balloon-expandable stent graft design.[4] In 2007, Dalainas et al reported similar results when they assessed self-expanding versus balloon-expandable stents in the abdominal aorta. Two hundred forty-two patients were studied; 27.5% of the patients treated with self-expanding stent grafts demonstrated aortic neck dilatation versus 7.1% of the patients treated with balloon-expandable stent grafts.[5]

FIXATION AND SEAL

The aortic neck is generally defined in clinical studies as the longitudinal distance between the first transverse CT slice directly distal to the lowermost renal artery (D1) and the first transverse CT slice (D2) that shows at least a 10% larger outer aortic wall diameter versus the diameter measured directly below the lowermost renal artery (Figure 1). Hemodynamic forces tend to pull both ends of the stent graft into the aneurysm; however, the term "stent graft migration" typically refers to an unstable proximal attachment that results in caudal migration of the stent graft. The forces on the stent graft increase with the degree of angulation, the diameter of the trunk, and the pressure gradient across the walls of the stent graft.[6]

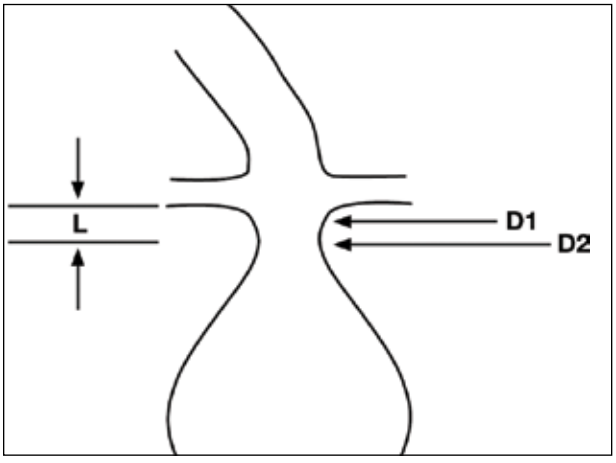

Figure 1. Neck length defined by L, where D1 is diameter at lowest renal and D2 is first diameter showing growth of 10% over D1.

A comparison of two devices, AneuRx® (Medtronic, Inc., Minneapolis, MN) and Ancure® (formerly Guidant Corporation), both of which lack suprarenal stents, showed a higher incidence of migration with the unbarbed AneuRx device when compared to the barbed Ancure. Another comparison of two devices, Talent™ (Medtronic, Inc.) and Zenith® (Cook Medical, Bloomington, IN), both of which have suprarenal stents, showed a higher incidence of migration with the unbarbed Talent device when compared to the barbed Zenith device. A similar set of comparisons showed that the suprarenal stent also contributed to a reduced incidence of migration. Neither the stiffness (column strength) of the stent graft nor its incorporation into the wall of the aorta seemed to play much of a role in stabilizing the stent graft position. The result is a sixfold difference in migration rates between the AneuRx and Zenith stent grafts. Kaplan-Meier analysis of data from the AneuRx clinical trial showed migration in 19% of subjects at 3 years, although individual centers have reported much higher rates. Clearly, fixation with hooks or barbs improves the performance of aortic stent grafts in terms of migration.[7-14]

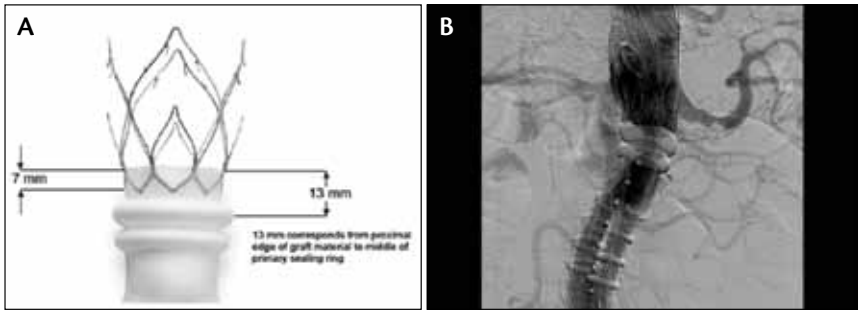

Figure 2. The Ovation Prime™ stent graft (TriVascular, Inc., Santa Rosa, CA) showing the middle of the sealing ring at 13 mm below the top of the fabric (A). The Ovation Prime stent graft under fluoroscopy with gasket-like seal achieved in the sealing ring and conventional wire and fabric seal above (B). The top of the graft material is identified by markers.

Mohan et al found that the risk of type I endoleaks was significantly increased with device oversizing of < 10%. Using a model derived from these clinical data, they predicted a reduced type I endoleak rate with 10% to 20% device oversizing.[15] Using this information, the anatomic seal zone can be defined as an aortic segment of sufficient infrarenal length that exhibits relatively parallel walls without significant calcification or mural thrombus in which a self-expanding stent graft can, by force, maintain contact between the endograft fabric and the aortic wall through interval points of contact.

However, Conners et al found an association of > 20% device oversizing with late aortic neck dilatation and subsequent endograft migration. In this study, there was a significant relationship between the degree of endograft oversizing and subsequent aortic neck dilatation.[16] The endograft's radial force is used to create wall friction, creating stability and seal of the endograft within the aorta. This radial force exerts a constant outward pressure on the aortic wall. Over time, this constant outward force may exhaust the elastic recoil of the degenerating aortic wall and result in enlargement of the aneurysm neck. As the aneurysm neck dilates, the endograft approaches its maximal diameter. This in turn translates into a reduction in outward force and, ultimately, a reduction in the friction that maintains the endograft's position and seal. Therefore, excessive oversizing (> 20%) may expose the aneurysm neck to a higher radial force generated by the large endograft. This may accelerate the phenomenon of aneurysm neck dilatation.[16]

IMPLICATION OF NEW SEALING METHODS

Limitations in current endograft design have spurred interest in new endograft designs and sealing methods. One such design (the Nellix® endovascular aneurysm sealing system, Endologix, Inc., Irvine, CA) consists of dual balloon-expandable endoframes surrounded by polymer-filled endobags, which obliterate the aneurysm sac and maintain endograft position. Nellix is designed to completely fill and seal the aortic aneurysm sac with the aim of preventing device migration and endoleak and therefore potentially reducing the need for secondary procedures. The following are among the anatomical requirements for patients to be enrolled in the clinical investigations: nonaneurysmal aortic neck length of ≥ 10 mm, nonaneurysmal aortic neck diameter of 18 to 32 mm, maximum aortic blood flow lumen diameter of ≤ 60 mm, and common iliac artery diameter of 8 to 35 mm.[17]

An additional novel design is the Ovation Prime abdominal stent graft system, which employs a sealing ring at the infrarenal aortic sealing zone. The Ovation Prime abdominal stent graft system is trimodular, consisting of a 14-F outer diameter aortic body and two iliac limbs—the smallest profile of any currently commercially available stent graft. The Ovation Prime system is designed to accommodate a broader range of anatomy by addressing the two most important issues in endovascular aneurysm repair: access and seal.

The Ovation Prime stent graft's sealing ring is a doughnut- or torus-shaped O-ring. O-rings are typically used to prevent the passing of air or fluid between two surfaces. They provide a simple, precise, and reliable seal in a variety of applications and function by introducing a calculated mechanical stress between the O-ring itself and

the surface that the ring is in contact with. As long as the pressure of the fluid (in this case, blood) being "excluded" does not exceed the contact stress of the O-ring, leaking cannot occur. For this reason, an O-ring can easily seal at high pressures. As long as the infrarenal abdominal aortic diameter at 13-mm below the lowest renal artery (the site of the most proximal sealing ring) is measured as a treatable diameter, the O-ring design is designed to provide an adequate seal (Figure 2). This design application calls into question the current and most widely accepted definition of proximal aortic neck length that incorporates both length and diameter.

In the Ovation™ global pivotal study, short neck length was not a predictor of graft failure related to fixation or seal. The main inclusion criteria of the study were proximal aortic neck length ≥ 7 mm, inner-wall diameter between 16 to 30 mm, and iliac inner-wall diameter between 8 and 20 mm. Despite relatively broad inclusion criteria, results of the study were positive, as technical success was achieved in 100% of cases. The 30-day major adverse event rate, the primary safety endpoint of the study, was 2.5% (4/161). AAA-related and all-cause mortality rates were 0.6% and 2.5%, respectively, through 1 year. No migrations, AAA ruptures, or conversions to open surgery were reported.

Of the 161 patients enrolled, 39% (63 patients) presented with challenging anatomical characteristics, including a minimum access vessel of < 6 mm, aortic neck length < 10 mm, or both. No major adverse events were observed in this group at 30 days, and treatment success was achieved in all 63 patients at 1 year.

These new technologies call into question not only the definition of aortic neck, but also the concept of aneurysmal progression at the untreated aortic segment. If the argument holds true that aneurysmal progression is the result of self-expanding stent graft design along with oversizing, then perhaps a new design that alters the manner by which an endograft seals will address the dilemma of "aneurysmal disease progression" by altering the forces exerted at this aortic segment.

CONCLUSION

The treatment of AAAs changed dramatically with the introduction of the endovascular stent graft by Parodi in the early 1990s. Since that time, endograft design has continued to evolve and change, resulting in the most common and widely accepted aortic endograft design utilized today, that being a covered, self-expanding stent graft design. The endograft revolution has been accompanied by the use of currently available endografts in less than ideal circumstances. By pushing the limits of currently available technologies in challenging and hostile anatomies, the incidence of endoleak, aneurysm expansion, secondary intervention, and endograft failure has become a widely recognized downfall of the therapy as its limits are pushed.

New endograft designs are utilizing novel ways of achieving a proximal seal endeavor to overcome current anatomic limitations, thereby providing an endovascular treatment option for a broader patient population. These designs bring into question the definition of the aortic neck and also the concept of aneurysmal disease progression in the untreated abdominal aorta. Future trial results, long-term outcomes, and device applications will likely continue to push the limits of current indications and anatomies considered suitable for endovascular aortic aneurysm repair. ■

Jennifer L. Ash, MD, is a vascular and endovascular surgeon, HeartCare Midwest/OSF Healthcare, and Assistant Clinical Professor of Surgery, University of Illinois College of Medicine in Peoria, Illinois. She has disclosed that she is a consultant for TriVascular, Inc.

Nabeel R. Rana, MD, is a vascular and endovascular surgeon, HeartCare Midwest/OSF Healthcare, and Assistant Clinical Professor of Surgery, University of Illinois College of Medicine in Peoria, Illinois. He stated that he has no financial interests related to this article.

Ravishankar Hasanadka, MD, is a vascular and endovascular surgeon, HeartCare Midwest/OSF Healthcare, and Assistant Clinical Professor of Surgery, University of Illinois College of Medicine in Peoria, Illinois. He stated that he has no financial interests related to this article.

Syed M. Hussain, MD, is Senior Vascular & Endovascular Surgeon, HeartCare Midwest/OSF Healthcare, and Assistant Clinical Professor of Surgery, University of Illinois College of Medicine in Peoria, Illinois. He has disclosed that he is a consultant to TriVascular, Inc. and National Principal Investigator of the Ovation and Ovation Prime Post-Approval Study.

1. Parodi JC, Palmaz JC, Barone HD. Transfemoral intraluminal graft implantation for abdominal aortic aneurysms. Ann Vasc Surg. 1991;5:491-499.
2. Parodi JC. Endovascular repair of abdominal aortic aneurysms and other arterial lesions. J Vasc Surg. 1995;21:549-557.
3. Rodway AD, Powell JT, Brown LC, Greenhalgh RM. Do abdominal aortic aneurysm necks increase in size faster after endovascular than open repair? Eur J Vasc Endovasc Surg. 2008;35:685-693.
4. Malas MB, Ohki T, Veith FJ, et al. Absence of proximal neck dilatation and graft migration after endovascular aneurysm repair with balloon-expandable stent-based endografts. J Vasc Surg. 2005;42:639-644.
5. Dalainas I, Nano G, Bianchi P, et al. Aortic neck dilatation and endograft migration are correlated with self-expanding endografts. J Endovasc Ther. 2007;14:318-323.
6. Chuter TAM, Schneider D. Abdominal aortic aneurysms: endovascular treatment. In: Rutherford's Vascular Surgery, 7th ed. Philadelphia, PA: Saunders Elsevier; 2010;1984-1985.
7. Beebe HG, Cronenwett JL, Katzen BT, et al. Results of an aortic endograft trial: impact of device failure beyond 12 months. J Vasc Surg. 2001;33:55-63.
8. Guidoin R, Marois Y, Douville Y, et al. First-generation aortic endografts: analysis of explanted Stentor devices from the EUROSTAR registry. J Endovasc Ther. 2000;7:105-122.
9. Zarins CK; AneuRx Clinical Investigators. The US AneuRx clinical trial: 6-year clinical update 2002. J Vasc Surg, 2003;37:904-908.
10. Zarins CK, Bloch DA, Crabtree T, et al. Stent graft migration after endovascular aneurysm repair: importance of proximal fixation. J Vasc Surg. 2003;38:1264-1272.
11. Van Marrewijk CJ, Leurs LJ, Vallabhaneni SR, et al. Risk-adjusted outcome analysis of endovascular abdominal aortic aneurysm repair. J Endovasc Ther. 2005;12:417-429.
12. Resch T, Malina M, Lindblad B, et al. The impact of stent design on proximal stent-graft fixation in the abdominal aorta: an experimental study. Eur J Vasc Endovasc Surg. 2000;20:190-195.
13. Malina M, Brunkwall J, Ivancev K, et al. Endovascular healing is inadequate for fixation of Dacron stent-grafts in human aortoiliac vessels. Eur J Vasc Endovasc Surg. 2000;19:5-11.
14. Conners MS, Sternbergh WC, Carter G, et al. Endograft migration 1 to 4 years after endovascular abdominal aortic aneurysm repair with the AneuRx device: a cautionary note. J Vasc Surg. 2002;36:476-484.
15. Mohan IV, Laheij JP, Harris PL; on behalf of the EUROSTAR collaborators. Risk factors for endoleak and the evidence for stent-graft oversizing in patients undergoing endovascular aneurysm repair. Eur J Vasc Endovasc Surg. 2001;21:344--349.
16. Conners MS, Sternbergh WC, Carter G, et al. Endograft migration 1-4 years after endovascular AAA repair with the AneuRx device (a cautionary note). J Vasc Surg. 2002;36:476-484.
17. Endologix, Inc. website. Nellix endovascular aneurysm sealing system product features. http://www.endologix.com/investigational_devices/nellix/features.php. Accessed July 10, 2013.