# What Signs Indicate a Compromised Seal Zone?

How to achieve an adequate seal zone from the aortic arch to the iliac bifurcation.

BY NIKOLAOS TSILIMPARIS, MD, AND TILO KÖLBEL, MD, PHD

"You can compromise on a lot of things, but you cannot compromise on surgical exposure."

 Prof. Cambria, Past President of the Society for Vascular Surgery, Chair of Vascular Surgery at Massachusetts General Hospital

The respective dogma in endovascular surgery should read, "You can compromise on a lot of things, but you cannot compromise on seal zones!"

Placing any stent graft in a healthy, nondissected, thrombus-free, parallel aortic segment should be a nonnegotiable condition for endovascular aortic interventions. All of the currently available devices for endovascular aneurysm repair (EVAR) and thoracic endovascular aneurysm repair (TEVAR) have received CE Mark approval for use within the manufacturers' instructions for use (IFU). Deviation from this practice could lead to devastating results, as demonstrated in the article by Schanzer et al, reporting enlargement of the aortic sac

in 40% of overall patients at 5 years and a higher growth rate in patients treated outside the IFU for infrarenal abdominal aortic aneurysms (AAAs). Interestingly, of all patients who experienced sac enlargement, 30% manifested at 3 years or later after the index procedure, suggesting that late endoleaks are not that infrequent.

Currently, a number of publications suggest that technical success can be achieved by EVAR in patients with short-neck aneurysms,<sup>2-4</sup> but long-term results from these reports are lacking. A recent meta-analysis clearly demonstrated a higher risk of intraoperative type IA endoleaks requiring adjunctive procedures, as well as higher 30-day postoperative morbidity in patients with hostile neck anatomy that were not consistent with the IFU or at least meeting the criteria of neck length < 15 mm and neck angulation > 60°. Although EVAR can be performed in patients with short aortic necks, it is associated with a significantly higher rate of early and late type I endoleaks, resulting in an increased use of proximal aortic cuffs for endoleak sealing.

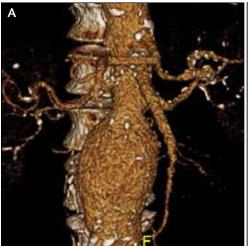






Figure 1. A patient with a short-neck aortic aneurysm that is unsuitable for treatment with a standard infrarenal stent graft (A) was successfully treated with a Zenith Fenestrated EVAR device (Cook Medical, Bloomington, IN) for the short aortic neck and a Zenith branch iliac device (Cook Medical) for a left common iliac artery aneurysm, as shown on intraoperative angiography (B) and the follow-up CT scan (C).



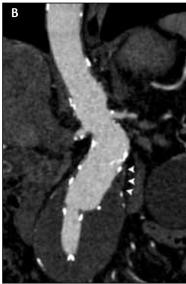


Figure 2. Follow-up CT scans at 6 months (A) and 2 years after EVAR (B) in a patient with a type II endoleak, demonstrating progression of the aortic neck diameter and shortening of the proximal seal zone. The double arrow demonstrates the initial length of the landing zone, and the multiple arrowheads demonstrate the lost sealing zone after aneurysm neck expansion.

Whether in the aortic arch, the visceral segment, or the iliac bifurcation, adequate preoperative imaging and careful preoperative planning are of paramount importance to identify potential failure modes in the sealing zones. CT scans with 1-mm slice thickness, as well as centerline measurements, are crucial in planning cases with challenging aortic anatomies. Knowing the particular anatomy of the patient cannot be overemphasized. We strongly advocate planning in workstations with three-dimensional reconstruction and centerline-of-flow measurements to reduce the risk of false measurements

of the aortic neck (eg, in elliptical or highly angulated necks). A number of obvious or masked signs may contraindicate a standard endovascular approach and require more advanced endovascular techniques or open surgery. Customized, as well as off-the-shelf devices, for complex aortic diseases are widely available, and the early advantages of fenestrated or branched EVAR compared to open repair are well documented.<sup>6-8</sup>

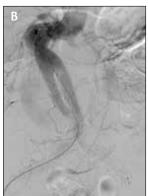
## PATTERNS OF SEAL FAILURE IN EVAR

Landing zones with at least 20 mm of straight, parallel, healthy aorta at the infrarenal level is the optimal condition for successful implantation of an aortic endograft, thus avoiding reinterventions. However, favorable proximal and distal neck anatomy are encountered in approximately only 50% of the elective<sup>9</sup> and 54% of the

emergent AAA cases.<sup>10</sup> In such cases, extension of the sealing zone proximal to the renal arteries with fenestrated or branched EVAR could substantially reduce the need for reintervention.<sup>11</sup>

The length of the proximal landing zone is often understood to be the primary factor in early type I endoleak and procedural success. Technical success in EVAR procedures can be assumed if the final intraoperative angiography is free of type IA endoleaks. However, this may not guarantee durable repair in the long-term.<sup>2-4,12</sup> A few groups have suggested that hostile neck







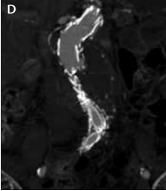


Figure 3. An 81-year-old woman was treated at another institution with aorto-bi-iliac EVAR for an inflammatory, 8-cm, infrare-nal AAA and severe neck angulation (> 90°). CT angiography before proximal cuff extension demonstrates a lack of adequate apposition (A), and intraoperative angiography shows a type IA endoleak (B). Final angiography after extending proximal with a proximal cuff (C) and the postoperative CT scan demonstrate successful exclusion of the endoleak (D).

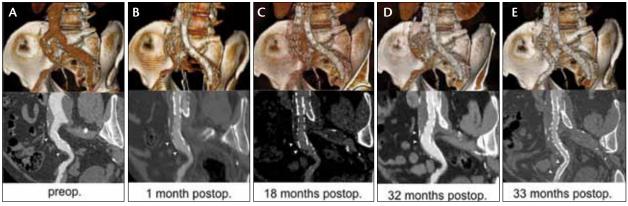


Figure 4. CT scans (three-dimensional and multiplanar reconstruction) of a patient with an aortoiliac aneurysm extending to the right iliac artery (A) who underwent EVAR extending to an aneurysmal common iliac artery (B). Progression of the diameter of the common iliac artery resulted in further reduction of the seal zone at 18 months (C) and a type IB endoleak at 32 months of follow-up (D). The patient was successfully treated with distal extension of the seal zone in the external iliac artery (E).

anatomy is related to stent migration, thus increasing the risk of late type IA endoleaks. <sup>13,14</sup> Furthermore, we have previously shown that aortic neck diameter significantly changes during a time frame of 24 to 36 months postoperatively. <sup>12</sup> Fenestrated or branched EVAR provides adequate proximal seal and achieves complete exclusion of short-neck aneurysms with a durable result (Figure 1). <sup>15</sup>

A tapered aortic neck should always warrant caution when planning an EVAR procedure. Reversed conical necks are also frequently associated with a relevant thrombus burden, thus reducing the actual seal zone to significantly less than the desired 20 mm. One group recently suggested that stent graft oversizing of 40% could reduce endoleak rates in patients with reverse-tapered aortic necks undergoing EVAR, but the data were retrospective and from a single center. <sup>16</sup>

Recommendations to accept hostile neck anatomy outside the IFU for elective EVAR cases are weak and should be handled with caution.

A shaggy aorta loaded with thrombus at the pararenal level is another potential indicator of severe disease in the landing zone area. Apart from the potential catastrophic embolic complications that may occur in both the mesenteric and renal branches, <sup>17,18</sup> the risk of further degeneration and aneurysmal dilatation is substantial.

Exclusion of a short-neck AAA with the absence of an intraoperative type IA endoleak but the presence of a type II endoleak should induce awareness of the possible effect of persistent aneurysm sac pressure causing disease progression and early expansion of the short aortic neck, which may subsequently result in type IA endoleaks or even stent graft migration (Figure 2).

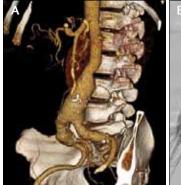
A dilated suprarenal or visceral segment, as well as a primary large aortic neck (30–36 mm), is known to be

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associated with a higher risk of migration on follow-up, potentially compromising the proximal seal, especially in patients with short necks.<sup>19</sup> Stather et al<sup>20</sup> demonstrated that an initial larger aortic diameter (> 28 mm) was independently associated with a higher risk for secondary intervention (P = .009), technical failure (P = .002), and late type I endoleaks (P = .002).

Penetrating aortic ulcers (PAUs) are also signs of a severely diseased aorta. In cases of AAA with a PAU in the landing zone, we recommend extending the seal zone 20 mm above the upper border of the PAU into the visceral segment using a fenestrated or branched stent graft. Management of such a PAU with adjunctive methods such as coils, liquid embolic agents (eg, Onyx, Covidien, Mansfield, MA), and deployment of the stent graft below the PAU have been reported<sup>21</sup> but obviously yield a high risk of reintervention and proximal seal failure.

Patients with severely angulated (≥ 60°) aortic necks (Figure 3) appear to have a 70% risk for adverse events despite an adequate length of proximal aortic neck.<sup>22</sup> Thus, great caution should be given to avoid early and





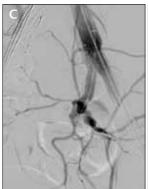




Figure 5. CT scan (A) and intraoperative angiography (B) of a AAA with aneurysmal dilatation of both common iliac arteries. The patient underwent repair with a Zenith bifurcated device and bilateral implantation of Zenith branch iliac devices, as demonstrated in the intraoperative angiography (C) and follow-up CT scan (D).

late complications in patients with such hostile neck anatomy.

Patients with aortoiliac aneurysms frequently have inadequate landing zones in the common iliac artery. Currently, iliac limb stents offer a range of diameters up to 28 mm. Although a 28-mm iliac limb can be a useful device in unusual situations, it is not recommended for treatment of standard elective AAAs. Assuming 20% oversizing, this would suggest anchoring the iliac limb in an aneurysmal 22-mm iliac artery.

The combined experience of a Dutch group and an American group with 154 endografts implanted at both centers demonstrated that, in addition to the risk of dis-

tal type IB endoleaks, patients with short seal zone lengths in the iliac arteries are at significantly higher risk of endograft main body migration.19 This is of great importance, especially because we know that at long-term followup, there is a trend toward dilatation of the aortic neck and iliac arteries, even in patients whose aneurysm sac has regressed. 12,23 In patients with aneurysmal iliac sealing zones, distal extension of the sealing area into the external iliac artery using occlusion techniques of the hypogastric artery (Figure 4) or using branched iliac stent grafts (Figure 5) is recommended to achieve durable long-term outcomes.

#### **SEAL ZONES IN THE THORACIC AORTA**

Although TEVAR is routinely performed with good technical success (93%–98%), the incidence of type I and II endoleaks is reported to occur in approximately 8% to 29% of treated patients.<sup>24-26</sup>

A critical point during TEVAR is to avoid deploying the stent graft in a segment of the thoracic aorta with extreme proximal angulation, which would result in "bird-beaking" and thereby a compromised proximal seal. Bird-beaking has become less of a problem over the years with the introduction of conformable stent grafts that offer staged proximal deployment.<sup>27</sup> In a comparison of the conformable Zenith TX2 with Pro-

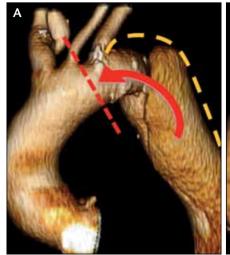




Figure 6. Determination of the proximal attachment site in TEVAR for type B aortic dissections: volume rendering of pre- and postoperative CT angiography in a patient with a type B aortic dissection. Preoperative: although contrast in the false lumen does not stretch to the ostium of the LSA, the aortic wall is dissected up to the LSA (dotted yellow line) so that the edge of the stent graft should land at the distal edge of the left common carotid artery (dotted red line) (A). Postoperative: the stent graft is placed as planned, covering the ostium of the LSA (dotted yellow line) (B).

Form thoracic delivery system (Cook Medical) with other non-conformable devices, Lee et al<sup>28</sup> demonstrated better apposition of the Zenith device in the landing zone of the thoracic aorta.

## SEAL ZONES IN AORTIC DISSECTIONS

A major issue in endograft repair of Stanford type B aortic dissections is overstenting of the left subclavian artery (LSA), with the stent graft landing in a dissected aortic segment. In our experience and as recently verified by the International Registry of Acute Aortic Dissection data presented at the European Society for Vascular Surgery 2013 annual meeting, a significant portion of type B aortic dissections (17%) extend in a retrograde fashion to involve the aortic arch. These patients are at high risk of developing a retrograde type A dissection when a stent graft

is deployed in the area of retrograde intramural hematoma. Manning et al<sup>29</sup> demonstrated that landing a stent graft distal to the LSA within a dissected segment of the aorta in a type B aortic dissection carries a high risk of subsequent dilatation and rupture due to the increased wall stress in the outer curvature. Therefore, our institution recommends intentional coverage of the LSA in all cases, with entry of the dissection close to the LSA (Figure 6).

#### **SEAL ZONES IN THE AORTIC ARCH**

Whether in type B aortic dissections with retrograde involvement of the aortic arch or in aneurysmal disease of the proximal descending thoracic aorta or even of the aortic arch, patients who are unfit for open repair could benefit from a totally endovascular repair. Fenestrated and branched stent grafts in the aortic arch could achieve better sealing zones in this very challenging vascular territory, thereby reducing endoleaks and reinterventions (Figure 7).

## DISTAL SEALING ZONE ABOVE THE CELIAC TRUNK FOR TEVAR

Accurate deployment of thoracic stent grafts just above the origin of the celiac trunk is of paramount importance

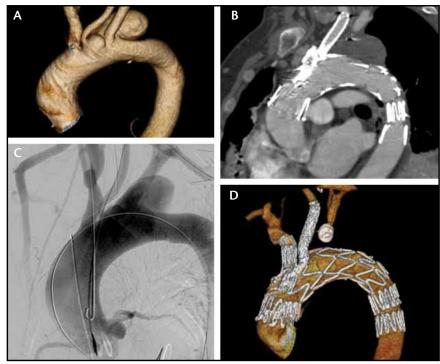


Figure 7. An aneurysm of the aortic arch in a patient who is unfit for open repair (A) was treated with a fenestrated branched endograft in the aortic arch with branches for the left carotid artery and the brachiocephalic trunk (B, C) to achieve an adequate proximal sealing zone and aneurysm exclusion, as seen in the postoperative CT scan (D).

to ensure an adequate distal seal zone and to avoid the possibly catastrophic complications of a celiac trunk occlusion. The distal component of the Zenith TX2 stent graft facilitates precise deployment without the risk of uncontrolled "jumping" of the stent graft during deployment. If distal thoracic sealing zones are compromised in length, diameter, thrombus load, or shape, extending the stent graft repair to the infrarenal aorta using fenestrated or branched devices should be considered. Distal landing in a thrombosed segment of a distal descending thoracic aortic aneurysm is not considered safe, as pressure is transferred through thrombus even in cases that do not show residual sac perfusion.

#### CONCLUSION

Endovascular surgery is beyond the "teenager phase" in which the role of adequate sealing zones has been unclear and indications have partly been liberalized. The fenestrated branched endografts now available for the entire thoracoabdominal aortic tree, including the aortic arch and hypogastric arteries, represent the future of interventional vascular medicine.

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- 1. Schanzer A, Greenberg RK, Hevelone N, et al. Predictors of abdominal aortic aneurysm sac enlargement after endovascular repair. Circulation. 2011;123:2848-2855.
- Torsello G, Troisi N, Tessarek J, et al. Endovascular aortic aneurysm repair with the Endurant stent-graft: early and 1-year results from a European multicenter experience. J Vasc Interv Radiol. 2010;21:73-80.
- 3. Smeds MR, Jacobs DL, Peterson GJ, Peterson BG. Short-term outcomes of the C3 excluder for patients with abdominal aortic aneurysms and unfavorable proximal aortic seal zones. Ann Vasc Surg. 2012;27:8-15.
- 4. Lee JT, Ullery BW, Zarins CK, et al. EVAR deployment in anatomically challenging necks outside the IFU. Eur J Vasc Endovasc Surg. 2013;46:65-73.
- $5.\ Antoniou\ \bar{G}A, Georgia dis\ GS, Antoniou\ SA, et\ al.\ A\ meta-analysis\ of\ outcomes\ of\ endovas cular\ abdominal\ a orticaneurysm repair\ in\ patients\ with\ hostile\ and\ friendly\ neck\ anatomy.\ J\ Vasc\ Surg.\ 2013;57:527-538.$
- Tsilimparis N, Perez S, Dayama A, Ricotta II JJ. Endovascular repair with fenestrated-branched stent grafts improves 30-day outcomes for complex aortic aneurysms compared to open repair. Ann Vasc Surg. 2012;27:267-273.
- 7. Donas KP, Eisenack M, Panuccio G, et al. The role of open and endovascular treatment with fenestrated and chimney endografts for patients with juxtarenal aortic aneurysms. J Vasc Surg. 2012;56:285-290.
- 8. Mastracci TM, Greenberg RK, Eagleton MJ, Hernandez AV. Durability of branches in branched and fenestrated endografts. J Vasc Surg. 2013;57:926-933; discussion 933.
- 9. Kristmundsson T, Sonesson B, Dias N, et al. Anatomic suitability for endovascular repair of abdominal aortic aneurysms and possible benefits of low profile delivery systems. Vascular. In press.
- Ten Bosch JA, Willigendael EM, van Sambeek MR, et al. EVAR suitability is not a predictor for early and midterm mortality after open ruptured AAA repair. Eur J Vasc Endovasc Surg. 2011;41:647-651.
- 11. Chisci E, Kristmundsson T, de Donato G, et al. The AAA with a challenging neck: outcome of open versus endovascular repair with standard and fenestrated stent-grafts. J Endovasc Ther. 2009;16:137–146.

- 12. Tsilimparis N, Dayama A, Ricotta JJ. Remodeling of aortic aneunysm and aortic neck on mid- and long-term follow-up after endovascular repair with suprarenal fixation. J Vasc Surg. 2011;55(6S):965.
- 13. Cao P, Verzini F, Parlani G, et al. Predictive factors and clinical consequences of proximal aortic neck dilatation in 230 patients undergoing abdominal aorta aneurysm repair with self-expandable stent-grafts. J Vasc Surg. 2003;37:1200-1205.
  14. Litwinski RA, Donayre CE, Chow SL, et al. The role of aortic neck dilation and elongation in the etiology of stent graft migration after endovascular abdominal aortic aneurysm repair with a passive fixation device. J Vasc Surg. 2006;44:1176-1181.
  15. Verhoeven EL, Vourliotakis G, Bos WT, et al. Fenestrated stent grafting for short-necked and juxtarenal abdominal aortic aneurysm: an 8-year single-centre experience. Eur J Vasc Endovasc Surg. 2010;39:529-536.
- Mwipatayi BP, Picardo A, Wong J, et al. Endovascular repair of abdominal aortic aneurysms with reverse taper neck anatomy using the endurant stent-graft: analysis of stent-graft oversizing. J Endovasc Ther. 2013;20:514–522.
   Tabel SD. Genzalinia L. Havillon L. et al. Advances this receited with proceeding emberration in patients.
- Patel SD, Constantinou J, Hamilton H, et al. A shaggy aorta is associated with mesenteric embolisation in patients undergoing fenestrated endografts to treat paravisceral aortic aneurysms. Presented at ESVS 2013; Budapest, Hungary; September 18–21, 2013.
- 18. Shintani T, Mitsuoka H, Atsuta K, et al. Thromboembolic complications after endovascular repair of abdominal aortic aneurysm with neck thrombus. Vasc Endovascular Surg. 2013;47:172-178.
- 19. Waasdorp EJ, de Vries JP, Sterkenburg A, et al. The association between iliac fixation and proximal stent-graft migration during EVAR follow-up: mid-term results of 154 Talent devices. Eur J Vasc Endovasc Surg. 2009;37:681-687.
- 20. Stather PW, Sayers RD, Cheah A, et al. Outcomes of endovascular aneurysm repair in patients with hostile neck anatomy. Eur J Vasc Endovasc Surg. 2012;44:556-561.
- Sadeghi-Azandaryani M, Strube H, Heyn J, et al. Penetrating aortic ulcer in the infrarenal stent-graft landing zone: treatment with coils and the ethylene vinyl alcohol copolymer onyx. J Endovasc Ther. 2011;18:123–129.
- 22. Sternbergh WC 3rd, Carter G, York JW, et al. Aortic neck angulation predicts adverse outcome with endovascular abdominal aortic aneurysm repair. J Vasc Surg. 2002;35:482–486.
- 23. Kaladji A, Cardon A, Laviolle B, et al. Evolution of the upper and lower landing site after endovascular aortic aneurysm repair. J Vasc Surg. 2012;55:24–32.
- 24. Zahn R, Erbel R, Nienaber CA, et al. Endovascular aortic repair of thoracic aortic disease: early and 1-year results from a German multicenter registry. J Endovasc Ther. 2013;20:265–272.
- 25. Kotelis D, Geisbusch P, Hinz U, et al. Short and midterm results after left subclavian artery coverage during endovascular repair of the thoracic aorta. J Vasc Surg. 2009;50:1285–1292.
- 26. Fairman RM, Tuchek JM, Lee WA, et al. Pivotal results for the Medtronic Valiant Thoracic Stent Graft System in the VALOR II trial. J Vasc Surg. 2012;56:1222-1231; e1221.
- 27. Kölbel T, Resch TA, Dias N, et al. Staged proximal deployment of the Zenith TX2 thoracic stent-graft: a novel technique to improve conformance to the aortic arch. J Endovasc Ther. 2009;16:598-602.
- 28. Lee WA, Martin TD, Hess PJ Jr, et al. First United States experience of the TX2 Pro-Form thoracic delivery system. J Vasc Surg. 2010;52:1459-1463.
- Manning BJ, Dias N, Ohrlander T, et al. Endovascular treatment for chronic type B dissection: limitations of short stentgrafts revealed at midterm follow-up. J Endovasc Ther. 2009;16:590-597.