Does Radial Force Enhance or Detract from Proximal Seal Zone in EVAR?
Disclosures

Speaker’s Bureau:
• Abbott
• Boston Scientific
• Cook
• Endologix

Stockholder:
• none

Medical/Scientific Boards:
• Boston Scientific
Enlargement of the infrarenal aortic neck has been noted in 20% to 33% of patients at 2 years, in 35% to 36% of patients at 3 years, and in 59% of patients at 4 years after implantation of a variety of devices.


SELF EXPANDING STENT GRAFT

Horizontal plane view:

Chronic outward force from stent, combined with blood pressure, can result in aortic neck dilatation.

Coronal plane view:

Seal created by chronic outward force with discontinuous points of wall apposition across a minimum 10-15 mm length.

Seal may be compromised over time, particularly in challenging anatomies.

Increased size of aorta
Blood pressure results in a bulge in aortic wall where tissue is weak.

Blood Pressure

Oversized wire and fabric graft allows transmission of blood pressure, and exerts pressure of its own.

Blood Pressure + Stent Outward Radial Force

Contributes to Neck Dilatation

Untreated Aneurysm

Self Expanding Stent Graft
The Evolution of EVAR

• “Wire & Fabric” Age
• the concept of OVER-SIZING

Long term follow-up extending to 10 years has shown neck enlargement up to the size of the implanted endograft in 100% of patients

Mohan et al found that the risk of type 1 endoleaks was significantly increased with oversizing of <10%.

Most endograft manufacturers recommend a device oversize of 10% to 20%.

Conners et al found an association of 20% device oversizing with late aortic neck dilation and subsequent endograft migration.
Influence of endograft oversizing on device migration, endoleak, aneurysm shrinkage, and aortic neck dilation: Results from the Zenith multicenter trial

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Background: Generous endograft oversizing has been associated with propensity for aortic neck dilation and subsequent device migration in endografts without suprarenal fixation. Effects of variable oversizing of endografts with suprarenal fixation have been poorly studied.

Methods: Three hundred fifty-one patients underwent endovascular AAA repair (EVAR) in a prospective multicenter trial using the Zenith AAA Endovascular Graft, a fully supported bifurcated 3-piece endograft with barb-enhanced suprarenal stent fixation. Blinded core-laboratory measurement of variables was prospectively recorded at predischarge and at 1, 6, 12, and 24 months after the procedure. Potential influence of endograft oversizing on subsequent aortic neck dilation (minor axis), aneurysm shrinkage (major axis), device migration, endoleak, rupture, open conversion, and death were retrospectively studied. Data are given as mean ± SEM.

Results: Risk of endograft migration (>5 mm) at 12 months was 2.3% (6/261). However, patients with endograft oversizing of >30% had a 14% (4/29) migration risk compared with those oversized ≤30% (0.9%, 2/232), P < .002. There was zero device migration by the SVS definition (>10 mm or clinical event). Device oversizing >30% was associated with decreased AAA sac shrinkage (48% vs 77%) and with increased sac enlargement (9.5% vs 6%) at 24 months when compared with oversizing of ≤30%, respectively (P = .001). Incidence rate of any endoleak at 12 and 24 months was 8.2% (21/256) and 7.1% (12/169), respectively. Oversizing of endografts by >30% was associated with an increased type II endoleak rate (11 vs 4.7%) that failed to reach statistical significance (P = .27). Aortic neck diameters increased significantly by 6 months (P < .001) but then stabilized through 24 months; the absolute changes at 1 (n = 298), 6 (n = 278), 12 (n = 264), and 24 months (n = 171) were 0.66 ± 0.10 mm (3.0%), 1.32 ± 0.11 mm (5.6%), 1.38 ± 0.12 mm (5.9%), and 1.44 ± 0.16 mm (6.1%), respectively. Linear regression analysis demonstrated no correlation between endograft oversizing and aortic neck dilation at 12 (P = .86) or 24 months (P = .64).

Conclusions: Device migration and endoleaks were very infrequent after treatment with the Zenith AAA Endovascular Graft. However, endograft oversizing of >30% was associated with an 14-fold increase in device migration (>5 mm) at 12 months and with a 16-fold increased risk of AAA expansion at 24 months. Although further follow-up will be essential to assess whether these early associations continue, avoidance of excessive endograft oversizing is recommended. (J Vasc Surg 2004;39:20-6.)

Precise sizing of aortic endografts increasingly has been recognized as an important element in attaining optimal early and late outcomes after endovascular abdominal aortic aneurysm repair (EVAR). In particular, the increased risk of type I endoleaks with inadequate oversizing has been emphasized. Mohan et al1 found that the risk of type I endoleaks was significantly increased with 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.1

Most endograft manufacturers indeed recommend a device oversize of 10% to 20% greater than the minor axis of the aortic neck. This degree of oversizing generally translates into use of an endograft that is 3 to 5 mm larger than the adventitia-to-adventitia measurement of the minor-axis aortic neck.
Late graft explants in endovascular aneurysm repair

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Objective: With more than a decade of use of endovascular aneurysm repair (EVAR), we expect to see a rise in the number of failing endografts. We review a single-center experience with EVAR explants to identify patterns of presentation and understand operative outcomes that may alter clinical management.

Methods: A retrospective analysis of EVARs requiring explants, >1 month after implant, was performed. Patient demographics, type of graft, duration of implant, reason for removal, operative technique, length of stay, complications, and in-hospital and late mortality were reviewed.

Results: During 1999 to 2012, 100 patients (91% men) required EVAR explant, of which 61 were placed at another institution. The average age was 75 years (range, 50-93 years). The median length of time since implantation was 41 months (range, 1-144 months). Explanted grafts included 23 Ancure (Medtronic, Minneapolis, Minn), 25 Excluder (WL Gore & Associates, Flagstaff, Ariz), 17 Zenith (Cook Medical, Bloomington, Ind), 15 Talent (Medtronic), 10 Ancure (Guidant, Indianapolis, Ind), 4 Powerlink (Endologix, Irvine, Calif), 1 Endurant (Medtronic), 1 Quantum LP (Cordis, Miami Lakes, Fla), 1 Aorta Unii Plus Rapture Graft (Cook Medical, Bloomington, Ind), and 1 homemade tube graft. Overall 30-day mortality was 17%, with elective case mortality of 9.9%, nonelective case mortality of 37%, and 56% mortality for repairs. Endoleak was the most common indication for explant, with one or more endoleaks present in 82% (type I, 40%; II, 30%; III, 22%; endotension, 6%; multiple, 16%). Other reasons for explant included infection (13%), acute thrombosis (4%), and classification (1%). In the first 12 months, 23 patients required explants, with type I endoleak (48%) and infection (38%) the most frequent indication. Conversely, 22 patients required explants after 5 years, with type I (36%) and type III (32%) endoleaks responsible for most indications.

Conclusions: The rate of EVAR late explants has increased during the past decade. Survival is higher when the explant is done electively compared with emergent repair. Difficulty in obtaining a seal at the initial EVAR often leads to failure >5 year, whereas progression of aneurysmal disease is the primary reason for failure >5 years.

Endovascular aneurysm repair (EVAR) has increased in use during the past decade and now has become the primary mode of treatment of infrarenal abdominal aortic aneurysms (AAA) in private and academic practices. In addition, clinicians have continued to push the limits of the application of the technology, attempting to address more challenging anatomical conditions outside the instructions for use (IFU). The long-term success of EVAR requires surveillance imaging to identify problems that develop, most of which can usually be solved with secondary endovascular interventions. With the increasing number of patients treated, the number presenting without further options for endovascular salvage will likely produce an increasing population needing open conversion. We reviewed our institution’s growing experience for late conversion of failed EVAR to better understand current results, predictors of outcome, and reasons for failure.

Methods

Patients were identified according to the Current Procedural Terminology codes (American Medical Association, Chicago, Ill) for open AAA repair, and International Classification of Diseases, 9th revision coding for AAA at the Cleveland Clinic Foundation between January 1, 1999, and December 31, 2012. We reviewed all operative reports to identify EVAR explants. After Institutional Review Board approval, a Research Electronic Data Capture database was generated. Patients were only included if the endograft was removed >30 days after implantation. We also included patients who underwent

- 1999-2012
- elective case mortality of 9%
- type 1a endoleak primary cause for failure at >5 years
- The type 1a endoleaks were typically from aneurysmal degeneration of the proximal sealing zone
- 77% of cases came from another institution
RADIAL FORCE DETRACTS FROM THE PROXIMAL SEALING ZONE
The Evolution of EVAR

• “POLYMER AGE”
• Nellix v Endurant II

• 5 year follow up

• EVAR using SES endografts resulted in progressive infrarenal aortic neck enlargement, whereas EVAR using BES endografts resulted in no neck enlargement over time.

• “infrarenal neck enlargement after EVAR with SES endografts is likely related to the force exerted by SES elements rather than disease progression in the infrarenal neck.”

change in infrarenal aortic neck diameter over time after treatment with balloon-expandable stent (BES) and self-expandable stent (SES) endografts
Aortic neck evolution after endovascular repair with TriVascular Ovation stent graft

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Objective: Aortic neck dilatation has been reported after endovascular aneurysm repair (EVAR) with self-expanding devices. With a core laboratory analysis of morphologic changes, this study evaluated midterm results of aortic neck evolution after EVAR by endograft with no chronic outward force.

Methods: This was a multicenter registry of all patients undergoing EVAR with the Ovation endograft (TriVascular, Santa Rosa, Calif). Inclusion criteria were at least 24 months of follow-up. Standard computed tomography (CT) scans were reviewed centrally using a dedicated software with multiaxis and volume reconstructions. Proximal aortic neck was segmented into zone A (suprarenal aorta/fixation area), zone B (infra-renal aorta, from lowest renal artery to the first polymer-filled ring), and zone C (infra-renal aorta, at level of the first polymer-filled ring/sealing zone). Images were analyzed for neck enlargement (≥2 mm), graft migration (≥3 mm), endoleak, barb detachment or neck bulging, and patency of the celiac trunk and superior mesenteric and renal arteries.

Results: Inclusion criteria were met in 161 patients (mean age, 75.2 years; 92% male). During a mean follow-up period of 37 months (range, 24-58), 17 patients died (no abdominal aortic aneurysm-related death). Primary clinical success at 2 years was 98.1% (defined as absence of aneurysm-related death, type I or type III endoleak, graft infection or thrombosis, aneurysm expansion >5 mm, aneurysm rupture, or conversion to open repair). Assisted primary clinical success was 100%. CT scan images at a minimum follow-up of 2 years were available in 89 cases. Patency of visceral arteries at the level of suprarenal fixation (zone A) was 100%. Neither graft migration nor barb detachment or neck bulging was observed. None of the patients had significant neck enlargement. The mean change in the diameter was 0.18 ± 0.22 mm at zone A, −0.32 ± 0.87 mm at zone B, and −0.06 ± 0.97 mm at zone C. Changes at zone B correlated significantly with changes at zone C (correlation coefficient, 0.183; P = .05), whereas no correlation was found with zone A (correlation coefficient, 0.006; P = 1.0).

Conclusions: No aortic neck dilatation occurred in this series at CT scan after a minimum 24-month follow-up. This may suggest that aortic neck evolution is not associated with EVAR at midterm follow-up when an endograft with no chronic outward radial force is implanted. (J Vasc Surg 2016;63:8-15.)

A continuous aortic enlargement at the level of the infrarenal aortic neck has been reported after endovascular aneurysm repair (EVAR) of abdominal aortic aneurysms (AAA).1,2 Current concepts about the reason for this phenomenon remain poorly understood, although it is known that the amount of proximal device oversizing with self-expanding stent grafts (SESGs) influences neck progression.3,4 Once deployed, SESGs continue to expand until the nominal diameter is reached,10 unless tissue resistance limits expansion. It has been reported that when aortic neck dilatation occurs, it is related to adverse midterm outcomes.5,9

A new stent graft has recently been introduced to the market, carrying a new sealing technology that is not based on chronic expanding force. The Ovation endograft (TriVascular, Santa Rosa, Calif), with its new concept of sealing by nonexpansive circumferential apposition of polymer-filled rings to aortic wall, creates no chronic outward force at the infrarenal aortic level. This sealing mechanism, which is completely different from that obtained by SESGs, promises to isolate the aortic neck from blood pressure, thus preventing aortic neck evolution over time.11,12

This study assessed midterm clinical outcomes after EVAR with the Ovation stent graft in a series of patients with a minimum follow-up of 24 months. With a core laboratory analysis of morphologic changes, this research evaluated aortic neck evolution at 2 years after EVAR by endograft with no chronic outward force.

- Multicenter registry
- 32 month mean follow up
- No aortic neck growth
0.18 mm at zone A

- 0.32 mm at zone B

- 0.06 mm at zone C
polymer sealing ring creates no chronic outward force and insulates the neck from blood pressure, resulting in stable neck diameters and no late Type 1 endoleaks at 4 years$^{3,4}$
CONCLUSION

• The clinical consequences of neck enlargement are not benign and may lead to type I endoleak and migration
• Radial force dependent EVAR platforms are known to detract from the proximal seal zone
• Polymer dependent EVAR platforms appear to stabilize the proximal seal zone
Does Radial Force Enhance or Detract from Proximal Seal Zone in EVAR?

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