# Outcomes following endovascular abdominal aortic aneurysm repair (EVAR): An anatomic and device-specific analysis

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***Objective:*** **We performed a device-specific comparison of long-term outcomes following endovascular abdominal aortic aneurysm repair (EVAR) to determine the effect(s) of device type on early and late clinical outcomes. In addition, the impact of performing EVAR both within and outside of specific instructions for use (IFU) for each device was examined.**
***Methods:*** **Between January 8, 1999 and December 31, 2005, 565 patients underwent EVAR utilizing one of three commercially available stent graft devices. Study outcomes included perioperative (≤30 days) mortality, intraoperative technical complications and need for adjunctive procedures, aneurysm rupture, aneurysm-related mortality, conversion to open repair, reintervention, development and/or resolution of endoleak, device related adverse events (migration, thrombosis, or kinking), and a combined endpoint of any graft-related adverse event (GRAE). Study outcomes were correlated by aneurysm morphology that was within or outside of the recommended device IFU. $\chi^2$ and Kaplan Meier methods were used for analysis.**
***Results:*** **Grafts implanted included 177 Cook Zenith (CZ, 31%), 111 Gore Excluder (GE, 20%), and 277 Medtronic AneuRx (MA, 49%); 39.3% of grafts were placed outside of at least one IFU parameter. Mean follow-up was 30 ± 21 months and was shorter for CZ (20 months CZ vs 35 and 31 months for GE and MA, respectively; $P < .001$). Overall actuarial 5-year freedom from aneurysm-related death, reintervention, and GRAE was similar among devices. CZ had a lower number of graft migration events (0 CZ vs 1 GE and 9 MA); however, there was no difference between devices on actuarial analysis. Combined GRAE was lowest for CZ (29% CZ, 35% GE, and 43% MA; $P = .01$). Graft placement outside of IFU was associated with similar 5-year freedom from aneurysm-related death, migration, and reintervention ($P > .05$), but a lower freedom from GRAE (74% outside IFU vs 86% within IFU; $P = .021$), likely related to a higher incidence of graft thrombosis (2.3% outside IFU vs 0.3% within IFU; $P = .026$). The differences in outcome for grafts placed within vs outside IFU were not device-specific.**
***Conclusion:*** **EVAR performed with three commercially available devices provided similar clinically relevant outcomes at 5 years, although no graft migration occurred with a suprarenal fixation device. As anticipated, application outside of anatomically specific IFU variables had an incremental negative effect on late results, indicating that adherence to such IFU guidelines is appropriate clinical practice. (J Vasc Surg 2008;48:19-28.)**

Since its first introduction by Parodi in 1991,[1] endovascular repair of abdominal aortic aneurysms (EVAR) has been validated in a number of large single center reports and randomized clinical trials.[2-9] There is no longer debate about the early benefits of EVAR, including shorter hospital stays, less blood loss, shorter operating times, and lower early morbidity and mortality.[4,5-8] Recent studies have focused on late outcomes, including the need for reinterventions.[2,10-12] Despite reports to the contrary from the EVAR 2 trial participants,[8] the intuitively logical application of EVAR in high-risk patients has been validated in multicenter reports.[13,14]

As experience with EVAR has increased, this modality has been offered to a wider population of patients, and our experience has confirmed favorable late outcomes;[2] accordingly, some 70% of abdominal aortic aneurysm repairs at our institution are currently performed with EVAR. Concomitant with the increased EVAR utilization has been the availability of a variety of graft designs and configurations. This technical evolution has allowed the endovascular surgeon to choose from several devices, without guidelines, or specific criteria as to which device may be preferred in any given clinical/anatomic situation. The only device-specific guidelines available relate to the suggested anatomic constraints and device-sizing table located in each device's instruction for use (IFU). Furthermore, few studies address the effect of device type and anatomic selection criteria on late outcomes.[15-21]

Accordingly, in this study, we performed an anatomically stratified (ie, within vs outside of device-specific IFU), device specific analysis, of our EVAR experience to deter-

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mine the effect(s) of device type on early and late clinical outcomes.

## METHODS

We performed a retrospective review of patients undergoing EVAR for elective, primary repair of infrarenal abdominal aortic aneurysm from January 8, 1999 to December 31, 2005 at the Massachusetts General Hospital (MGH). EVAR performed for repair of thoracic aortic aneurysms, isolated iliac artery aneurysms, subclavian artery aneurysms, vascular trauma, anastomotic pseudoaneurysms, or other vascular pathologies were excluded. The initial time interval was chosen to correspond with the first implantation of a currently commercially available endograft at our institution, and the later date was chosen to ensure that patients under consideration had at least 2 years of follow-up.

We limited this analysis of the MGH EVAR experience to endograft devices that remain commercially available and in active use. These devices are generally characterized by a bifurcated, modular, fully supported design with low-profile features, and many of them have undergone several iterations of graft construction and delivery system design features over the study interval. First generation devices, defined as those that were used early in our experience, which have subsequently been withdrawn from commercial use were excluded from consideration in this study. Furthermore, to ensure adequate numbers of patients in each stent graft group for comparison, we limited the current study to the three most frequently used stent graft devices at MGH, these included the Cook Zenith (Cook Incorporated, Bloomington, Ind), Gore Excluder (W. L. Gore & Associates, Incorporated, Flagstaff, Ariz) and Medtronic AnueRx (Medtronic Vascular, Santa Rosa, Calif) devices.

The primary operating surgeon was responsible for all decisions regarding treatment selection (EVAR vs open repair) and personally performing device planning measurements and selections. Patient and device selection, device deployment strategy, and procedure performance were as previously described.[2] All patients underwent follow-up by contrast-enhanced computed tomography (CT) scans either at discharge or within 1 month, 6 months, 12 months, and then yearly evaluations thereafter.

Aneurysm morphology (neck diameter, neck length, neck angle, aneurysm sac angle, and maximum sac diameter) was measured retrospectively by the primary author (TAA) for the purposes of the study using the original axial CT images and three-dimensional reconstructions. Neck angle was defined as the angle between the suprarenal aorta to neck of the aneurysm. Aneurysm sac angle was defined as the angle between the neck of the aneurysm and the aneurysm sac. Since the study was designed to compare device-specific outcomes after successful device deployment, we limited the analysis to successful EVAR procedures in which a device was successfully deployed. Preoperative iliac anatomy was not considered.

Study outcomes included perioperative (≤30 days) mortality, intraoperative technical factors and adjunctive procedures, aneurysm rupture, aneurysm-related mortality, conversion to open repair, reintervention, development and/or resolution of endoleak, device related adverse events (migration, thrombosis or kinking), and a combined endpoint of any graft-related adverse event (GRAE). Intraoperative technical factors included caudal migration during graft deployment (requiring placement of a proximal cuff for adequate fixation), development of a type 1 or 3 endoleak, or access site complications; all of which generally led to adjunctive corrective procedures. Intraoperative adjunctive procedures were procedures performed outside of the original device deployment strategy that were employed to address unexpected intraoperative technical issues. Aneurysm-related mortality (ARM) was defined as death from any cause within 30 days of the primary EVAR procedure, death within 30 days of any secondary reintervention or surgical complication, or any death due to aneurysm rupture or device-related complication. Significant device migration was defined as migration >5 mm compared with the initial position of the graft and device kinking was defined as a flow-limiting acute angulation of the graft or graft limb(s) that generally required a corrective intervention (eg, angioplasty and/or stenting of the graft body or limb). GRAE was defined as a combination of all aneurysm and EVAR-related events including perioperative mortality, aneurysm-related mortality, need for unplanned intraoperative adjunctive procedure, late graft problem (migration >5 mm, kinking, or thrombosis), conversion to open repair, aneurysm rupture, and the late development of a type 1, 3 or 4 endoleak.

Study outcomes were stratified by aneurysm morphology that was either within or outside of specific device instructions for use (IFU). The specific IFU parameters used for this study are listed in Table I.

Descriptive statistics are reported as mean ± standard deviation. Comparisons between groups were performed using a two-tailed *t* test for continuous variables and $\chi^2$ test for categorical data. Time-based clinical outcomes were evaluated using Kaplan-Meier life-table analysis. The log-rank test was used to compare Kaplan-Meier curves and logistic regression was used to identify variables potentially associated with study endpoints. In all analyses, a *P* value ≤ .05 was used to determine statistical significance.

## RESULTS

### Patient demographics, clinical characteristics, and aneurysm morphology

Over the study interval, 585 patients underwent EVAR at MGH. Of these, 565 patients met the study inclusion criteria and comprise the study group. These patients underwent primary EVAR for infrarenal AAA using 177 Cook Zenith (CZ, 31.3%), 111 Gore Excluder (GE, 19.6%) and 277 Medtronic AneuRx (MA, 49.0%) devices. Mean follow-up was 29.6 ± 20.8 months and was shorter for the CZ group than the other device groups (19.7 ± 14.5

**Table I.** Stent graft device instructions for use (IFU) anatomic and graft sizing parameters

| *Stent graft device IFU for aneurysm morphology* | | | |
|---|---|---|---|
| | *Graft brand* | | |
| *IFU parameter* | *Cook Zenith* | *Gore Excluder* | *Medtronic AneuRx* |
| Neck diameter | >18 mm or <28 mm | <26 mm | <26 mm |
| Neck length | >15 mm | >15 mm | >15 mm |
| Neck angulation (suprarenal aorta to neck) | <45 degrees | <60 degrees | <45 degrees |
| Aneurysm sac angulation (neck to aneurysm sac) | <60 degrees | Not specified | Not specified |
| Iliac fixation length | >10 mm | >10 mm | >25 mm |
| Aortic oversizing | >15% | >2 mm | >2 mm |
| Iliac oversizing | >1 mm | >1 mm | >1 mm |
| Iliac diameter | >7.5 mm or <20 mm | <18.5 mm | <18 mm |

Device-specific parameters of aneurysm morphology and graft sizing, included in each device's instructions for use. These parameters were used in the IFU analysis to determine IFU status and device-specific effects.

**Table II.** Patient demographics and clinical characteristics

| *Patient characteristic* | *Cook Zenith n = 177* | *Gore Excluder n = 111* | *Medtronic AneuRx n = 277* | *P* |
|---|---|---|---|---|
| Age (y) | 76.0 ± 7.8 | 75.7 ± 7.5 | 76.6 ± 7.2 | .50 |
| Gender | | | | |
| Male | 85.3% | 65.8% | 82.3% | **<.001** |
| Female | 14.7% | 34.2% | 17.7% | **<.001** |
| CVA | 9.6% | 10.9% | 12.3% | .67 |
| HTN | 71.8% | 69.4% | 73.3% | .74 |
| Hypercholesterolemia | 55.9% | 43.2% | 45.3% | **.04** |
| Diabetes mellitus | 11.9% | 11.7% | 13.0% | .91 |
| Coronary disease[a] | 54.2% | 45.0% | 50.9% | .31 |
| Renal insufficiency[b] | 14.1% | 6.4% | 14.1% | .09 |
| Dialysis-dependent | 3.4% | 0.9% | 0.7% | .07 |
| Smoking history | | | | |
| Previous smoker | 61.0% | 59.5% | 56.0% | .55 |
| Current smoker | 12.4% | 20.7% | 13.7% | .12 |
| COPD | 22.0% | 30.0% | 21.3% | .17 |
| Steroid-dependent | 4.0% | 5.5% | 7.6% | .27 |
| Home O2 | 1.1% | 0.9% | 2.2% | .56 |
| PVD | 7.3% | 14.5% | 11.3% | .14 |
| Preoperative aneurysm morphology | | | | |
| Sac diameter | 58.4 ± 11.1 mm | 54.3 ± 8.7 mm | 55.3 ± 12.1 mm | **.003** |
| Neck diameter | 24.1 ± 2.8 mm | 22.8 ± 2.5 mm | 23.2 ± 2.6 mm | **<0.001** |
| Neck length | 23.4 ± 11.5 mm | 25.2 ± 11.9 mm | 25.3 ± 12.2 mm | 0.25 |
| Neck angle | 24.2 ± 19.8° | 24.7 ± 22.1° | 21.0 ± 19.8° | 0.19 |
| Sac angle | 42.0 ± 19.5° | 42.6 ± 20.5° | 37.4 ± 21.6° | **0.04** |

*CVA*, Cerebrovascular accident; *HTN*, hypertension; *COPD*, chronic obstructive pulmonary disease; *PVD*, peripheral vascular disease.
[a]Coronary disease defined as having a history of any of the following: arrhythmia, myocardial infarction, congestive heart failure, previous coronary revascularization (percutaneous or surgical), angina, or cardiac valvular disease.
[b]Renal insufficiency defined as serum creatinine ≥2.0 g/dL.

months CZ vs 34.6 ± 26.1 and 31.3 ± 22.9 months for GE and MA, respectively; $P < .001$).

Patient demographics and clinical characteristics are summarized in Table II. Mean patient age was 76.2 ± 7.5 years with a range of 44 to 99 years and was not different between groups. Male patients comprised 80% of the study group. More female patients received a GE device compared with the other devices (34.2% GE vs 14.7% CZ and 17.7% MA, respectively; $P < .001$). Coronary disease was present in 50.8% of patients, including 10.3% with a history of previous myocardial infarction, 20.2% with angina, and 14.4% with atrial fibrillation. Significant chronic obstructive pulmonary disease was present in 23.2% of patients, 25% of whom were steroid-dependent. Similarly, chronic renal insufficiency (serum creatinine concentration ≥2.0 g/dL) was present in 12.6% of patients and 1.6% of patients were on hemodialysis. There was no difference in comorbidities between groups.

Preoperative CT data was available for measurement in 529 of 565 (93.6%) study patients. Mean maximum aneurysm sac diameter was 56.1 ± 11.3 mm with a range of 40 mm to 112 mm and was larger in the CZ group than the other groups (58.4 ± 11.1 mm CZ vs 54.3 ± 8.7 mm GE and 55.3 ± 12.1 mm MA, respectively; $P = .003$). Mean

**Table III.** IFU parameter violations in patients outside device-specific IFU (The incidence and distribution of IFU violations across the study cohort)

| *IFU parameter* | *Overall outside IFU (n = 565)* | *Cook Zenith (n = 177)* | *Gore Excluder (n = 111)* | *Medtronic AneuRx (n = 277)* | *P* |
|---|---|---|---|---|---|
| Neck diameter | 7.1% (40/565) | 6.2% (11/177) | 3.6% (4/111) | 9.0% (25/277) | .147 |
| Neck length | 15.4% (87/565) | 20.9% (37/177) | 12.6% (14/111) | 13.0% (36/277) | .051 |
| Neck angulation | 10.3% (58/565) | 13.0% (23/177) | 6.3% (7/111) | 10.1% (28/277) | .189 |
| Sac angulation | 14.7% (26/177)* | 14.7% (26/177) | N/A | N/A | N/A |
| Aortic oversizing | 17.0% (96/565) | 10.2% (18/177) | 17.1% (19/111) | 21.3% (59/277) | **.009** |
| *Number of IFU parameter violations per patient* | | | | | |
| 0 | 60.7% (343/565) | 51.4% (91/177) | 69.4% (77/111) | 63.2% (175/277) | **.043** |
| 1 | 27.4% (155/565) | 35.6% (63/177) | 23.4% (26/111) | 23.8% (66/277) | |
| 2 | 8.7% (49/565) | 9.6% (17/177) | 5.4% (6/111) | 9.4% (26/277) | |
| 3 or more | 3.2% (18/565) | 3.4% (6/177) | 1.8% (2/111) | 3.6% (10/277) | |

*IFU,* Instructions for use.
*Cook Zenith is the only device that includes aneurysm sac angulation as an IFU criteria.

neck diameter was 23.4 ± 2.7 mm with a range of 15 to 33 mm and was larger in the CZ group than the other groups (24.1 ± 2.8 mm CZ vs 22.8 ± 2.5 mm GE and 23.2 ± 2.6 mm MA, respectively; $P < .001$). Mean neck length was 24.6 ± 11.9 mm and was not different between groups ($P = .25$). Mean neck angulation was 22.7 ± 20.8° with a range of 0° to 88° and did not vary between groups ($P = .19$). Mean aneurysm sac angulation was 39.9 ± 20.8° and was less in the MA group than the other two groups (37.4 ± 21.6° MA vs 42.0 ± 19.5° CZ and 42.6 ± 20.5° GE, respectively; $P = .04$).

Overall, 222 of 565 (39.3%) endografts were performed outside of at least one device-specific IFU parameter as detailed in Table III. Endograft placement outside of IFU occurred more frequently in the CZ group than the other two groups (50.8% CZ grafts vs 39.4% GE and 39.7% MA grafts, respectively; $P < .001$).

## Operative and perioperative outcomes

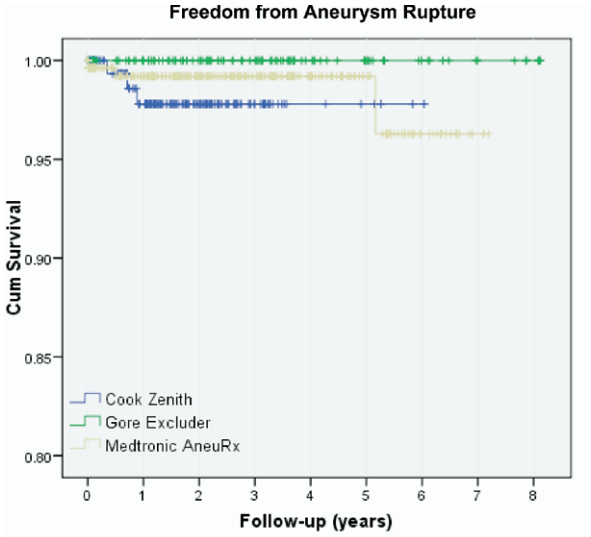
**Intraoperative technical factors and adjunctive procedures.** A variety of difficulties were encountered during the placement of endografts in this series. Intraoperative problems involved issues of proximal or distal fixation resulting in type 1 endoleak or caudal migration of the graft during deployment, limb kinking or thrombosis, and issues related to access vessels. Overall, we performed 180 adjunctive procedures in 145 of 565 (25.6%) patients. Intraoperative problems encountered included proximal type 1 endoleak in 72 (12.7%) patients, distal type 1 endoleak in 18 (3.2%) patients, type 3 endoleak in 8 (1.4%) patients, caudal migration of the graft during deployment in 13 (2.3%), graft limb kinking in 20 (3.5%) patients, acute graft limb thrombosis in 2 (0.4%) patients, incomplete opening of the contralateral gate in 4 (0.7%) patients, access vessel complications in 6 (1.1%) patients, and rupture in 2 (0.4%) patients. The incidence of intraoperative problems was not different between groups.

Intraoperative adjunctive procedures included 82 angioplasties, 40 proximal graft extensions, 13 bare metal stents placed at the proximal fixation point, 12 bare metal stents placed at a distal attachment point or the site of kinking, 5 aortouniiliac conversions with femoral-femoral bypass, 3 iliofemoral bypasses, 2 limb thrombectomies, 1 femoral-femoral bypass graft, and 2 renal artery stents. Notably, 31 patients required two or more procedures to address the intraoperative problem. Technical success, defined as successful endograft placement with resolution of the intraoperative issue, was achieved in 132 of 145 (91.0%) patients. The incidence of adjunctive procedures did not differ between device groups (20.5% CZ, 24.5% GE, and 25.4% MA, respectively; $P = .48$).

**Perioperative mortality.** Perioperative death, those within 30 days of the index operation, occurred in 10 of 565 patients (1.8%). They included 2 patients who experienced iliac artery avulsion during graft placement (one of whom died intraoperatively, and the other died in the postoperative period from a necrotizing soft tissue infection), 2 patients died from complications related to early graft limb thrombosis and acute leg ischemia, 1 patient died from complications of open conversion, 2 patients suffered hemispheric strokes, 1 patient had a myocardial infarction complicated by cardiogenic shock, and 2 patients died from sudden, unexplained cardiovascular collapse. Perioperative mortality did not differ between groups (1.1% CZ, 1.8% GE, and 2.2% MA, respectively; $P = .72$). Notably 4 of 10 deaths occurred in patients who were outside of IFU (1 patient outside IFU in both neck length and angulation, 1 patient outside IFU in neck and sac angulation, 1 patient outside IFU in neck length, and 1 patient outside IFU in neck angulation).

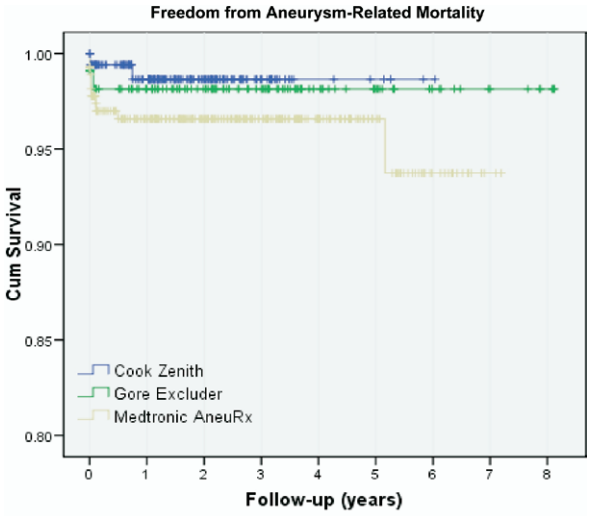
## Late outcomes

**Aneurysm rupture.** Aneurysm rupture occurred in six of 565 patients (1.1%) during the study interval. Rupture occurred at an average of 14.9 months postoperation with a range from 1.2 to 60.4 months. Five of the six patients (83%) died either of the rupture itself or subsequent complications thereof. One patient, who presented a new type 3 endoleak at the junction of the main body and contralateral limb that resulted in acute sac expansion and rupture, was successfully treated by percutaneous endovascular intervention consisting of bridging the contralateral limb/main




| Follow-up (years) | 1 | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|---|
| Cook Zenith | | | | | | |
| Number entering interval | 177 | 122 | 63 | 22 | 7 | 5 |
| Number of events | 3 | 0 | 0 | 0 | 0 | 0 |
| Cum. Proportion Surviving | 98.0% | 98.0% | 98.0% | 98.0% | 98.0% | 98.0% |
| Standard error | 1.0% | 1.0% | 1.0% | 1.0% | 1.0% | 1.0% |
| Gore Excluder | | | | | | |
| Number entering interval | 110 | 88 | 68 | 51 | 29 | 21 |
| Number of events | 0 | 0 | 0 | 0 | 0 | 0 |
| Cum. Proportion Surviving | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Standard error | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% |
| Medtronic AneuRx | | | | | | |
| Number entering interval | 277 | 212 | 155 | 113 | 70 | 37 |
| Number of events | 2 | 0 | 0 | 0 | 0 | 1 |
| Cum. Proportion Surviving | 99.0% | 99.0% | 99.0% | 99.0% | 99.0% | 95.0% |
| Standard error | 1.0% | 1.0% | 1.0% | 1.0% | 1.0% | 4.0% |

**Fig 1.** Kaplan-Meier freedom from aneurysm rupture; $P = .149$ CZ vs GE, $P = .377$ CZ vs MA, and $P = .252$ GE vs MA.




| Follow-up (years) | 1 | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|---|
| Cook Zenith | | | | | | |
| Number entering interval | 177 | 124 | 64 | 23 | 7 | 5 |
| Number of events | 2 | 0 | 0 | 0 | 0 | 0 |
| Cum. Proportion Surviving | 99.0% | 99.0% | 99.0% | 99.0% | 99.0% | 99.0% |
| Standard error | 1.0% | 1.0% | 1.0% | 1.0% | 1.0% | 1.0% |
| Gore Excluder | | | | | | |
| Number entering interval | 111 | 88 | 68 | 51 | 29 | 21 |
| Number of events | 2 | 0 | 0 | 0 | 0 | 0 |
| Cum. Proportion Surviving | 98.0% | 98.0% | 98.0% | 98.0% | 98.0% | 98.0% |
| Standard error | 1.0% | 1.0% | 1.0% | 1.0% | 1.0% | 1.0% |
| Medtronic AneuRx | | | | | | |
| Number entering interval | 277 | 212 | 156 | 113 | 70 | 37 |
| Number of events | 9 | 0 | 0 | 0 | 0 | 1 |
| Cum. Proportion Surviving | 96.0% | 96.0% | 96.0% | 96.0% | 96.0% | 96.0% |
| Standard error | 1.0% | 1.0% | 1.0% | 1.0% | 1.0% | 4.0% |

**Fig 2.** Kaplan-Meier freedom from aneurysm-related mortality; $P = .15$ CZ vs GE, $P = .66$ CZ vs MA, and $P = .35$ GE vs MA.

body junction with a limb extension graft. Two other patients ruptured from sac expansion with persistent type 2 endoleaks and were treated by open conversion during which the aneurysm sacs were opened, and bleeding lumbar arteries were suture ligated. One patient developed rupture in the perioperative period and underwent conversion to open repair, but ultimately died after a complicated, protracted hospital course. Two patients died prior to intervention, one of whom refused intervention. In all, four out of six rupture events (67%) occurred in patients with a known endoleak (one type 1 endoleak and three type 2 endoleaks). The incidence of post-EVAR rupture was not different between groups (1.7% CZ, 0.0% GE, and 1.1% MA, respectively; $P = .40$).

As depicted in Fig 1, by Kaplan-Meier analysis, freedom from aneurysm rupture at 1 and 5 years was 98% for CZ, 100% for GE, and 99% for MA. There was no difference in freedom from aneurysm rupture between device groups ($P = .149$ CZ vs GE, $P = .377$ CZ vs MA and $P = .252$ GE vs MA).

**All-cause mortality.** By Kaplan-Meier analysis, overall survival at 1 year and 5 years was 94% and 61%, respectively. At 1 year, survival was 95% for CZ, 95% for GE, and 93% for MA; and at 5 years, survival was 82% for CZ, 64% for GE, and 56% for MA. Mortality was higher in the MA group than the CZ group ($P = .049$), but was not different between CZ and GE ($P = .52$) or GE and MA ($P = .41$).

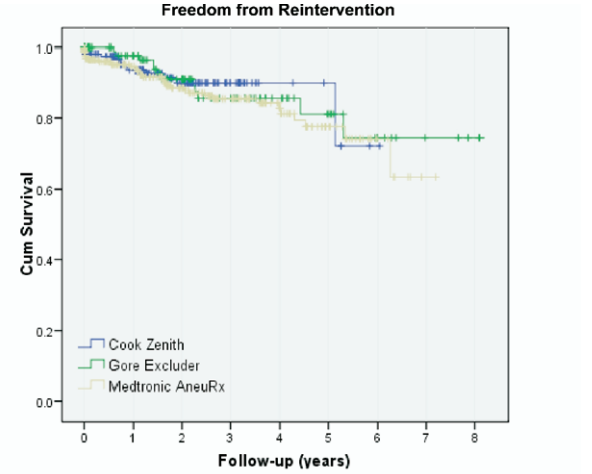
**Aneurysm-related mortality.** Aneurysm-related mortality (ARM) occurred in 14 of 565 patients (2.5%) and was not significantly different between device groups (1.1% CZ, 1.8% GE, and 3.6% MA, respectively; $P = .22$). Aneurysm rupture accounted for 3 of 14 deaths (21.4%), iliac artery avulsion/rupture during endograft placement resulted in 2 deaths (14.3%), graft limb thrombosis with limb ischemia for 2 deaths (14.3%), conversion to open aneurysm repair for 1 death, colon ischemia for 1 death (7.1%), stroke for 1 death (7.1%), myocardial infarction for 1 death (7.1%), acute renal failure for 1 death (7.1%), and unexplained cardiopulmonary arrest for 2 deaths (14.3%). Overall, eight of 14 deaths occurred in the perioperative period and two deaths occurred during the index hospital admission, but outside of the 30-day perioperative period. Thus, the majority of ARM (10 of 14 deaths, 71.4%) occurred during the index hospital admission. Aneurysm rupture accounted for the majority of late ARM.

By Kaplan-Meier analysis, freedom from aneurysm-related mortality was 97% at 1 year, 97% at 2 years, 97% at 3 years, 97% at 4 years, and 95% at five years. As depicted in Fig 2, freedom from aneurysm-related mortality was not device specific (99% CZ, 98% GE, and 96% MA, respectively; $P = .15$ CZ vs GE, $P = .66$ CZ vs MA, and $P = .35$ GE vs MA).

**Conversion to open surgical repair.** Conversion to open surgical repair was required in 4 of 565 patients (0.7%) and was not different between groups (0.6% CZ, 1.8% GE, and 0.4% MA, respectively; P = .31). The indication for conversion to open surgical repair included aneurysm rupture in two patients and sac expansion in two patients. Notably, all conversion events occurred in patients with type 2 endoleaks emanating from patent lumbar branches. Aneurysm rupture was treated by endograft explantation and open aortic reconstruction in one patient and open ligation of back-bleeding lumbar branches and aneurysm sac closure without endograft explantation in the other. Sac expansion was treated with endograft explantation and open aortic reconstruction in both instances. Both patients who underwent graft explantation for sac enlargement and persistent type 2 endoleak had failed multiple percutaneous procedures intended to address the endoleak. Perioperative mortality after conversion to open repair was 25%.

**Reintervention.** Over the study interval, a total of 88 reinterventions were performed on 60 patients, resulting in an incidence of any reintervention of 10.6%. Indications for reintervention included type 1 endoleak in 7 patients, type 2 endoleak in 31 patients (2 of whom presented with aneurysm rupture), type 3 endoleak in 1 patient (who presented with aneurysm rupture), undefined endoleak in 5 patients, graft limb stenosis or thrombosis in 6 patients, and significant graft migration in 8 patients (7 of whom developed aneurysm sac enlargement and 1 who presented with aneurysm rupture). Overall, 73 of 88 (82.9%) reinterventions were performed percutaneously. Percutaneous procedures included placement of proximal and distal extension limbs, coil embolization of branch vessels to address endoleak, and angioplasty and stenting of graft limb kinks. Open procedures included open conversion to aneurysm repair, graft limb thrombectomy, repair of common femoral artery pseudoaneurysms, and extra-anatomic bypass for limb occlusion. By Kaplan-Meier analysis, freedom from reintervention (Fig 3) was 95% at 1 year and 80% at 5 years, and was not device-specific (94% CZ, 98% GE, and 95% MA, respectively at 1 year; and 91% CZ, 82% GE, and 77% MA, respectively at 5 years; $P = .45$ for CZ vs MA, $P = .99$ CZ vs GE, and $P = .46$ GE vs MA). The corrective procedure was clinically successful in resolving the problem 93% of cases.

**Late graft problems (migration, thrombosis, and kinking).** Graft migration, thrombosis and kinking occurred in 22 of 565 (3.9%) patients over the study interval. Graft migration events are detailed in Table IV. By Kaplan-Meier analysis, there was no difference in the freedom from graft migration at either 1 year (100% CZ, 100% GE, 100% MA) or 5 years (100% CZ, 99% GE, and 92% MA) between device groups (P = .332 CZ vs GE, $P = .12$ CZ vs MA, and $P = .13$ GE vs MA). There was no difference in either graft thrombosis (1.7% CZ, 0.0% GE, and 1.1% MA, respectively; $P = .39$) or graft kinking (1.1% CZ, 0.0% GE, and 1.5% MA, respectively; $P = .45$) between device groups.




| Follow-up (years) | 1 | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|---|
| Cook Zenith | | | | | | |
| Number entering interval | 177 | 117 | 58 | 21 | 7 | 5 |
| Number of events | 9 | 3 | 0 | 0 | 0 | 1 |
| Cum. Proportion Surviving | 94.0% | 91.0% | 91.0% | 91.0% | 91.0% | 65.0% |
| Standard error | 2.0% | 3.0% | 3.0% | 3.0% | 3.0% | 22.0% |
| Gore Excluder | | | | | | |
| Number entering interval | 110 | 83 | 59 | 41 | 24 | 17 |
| Number of events | 2 | 5 | 3 | 0 | 1 | 1 |
| Cum. Proportion Surviving | 98.0% | 91.0% | 86.0% | 86.0% | 82.0% | 76.0% |
| Standard error | 1.0% | 3.0% | 4.0% | 4.0% | 6.0% | 8.0% |
| Medtronic AneuRx | | | | | | |
| Number entering interval | 277 | 193 | 129 | 90 | 55 | 26 |
| Number of events | 13 | 11 | 4 | 2 | 3 | 1 |
| Cum. Proportion Surviving | 95.0% | 88.0% | 85.0% | 83.0% | 77.0% | 73.0% |
| Standard error | 1.0% | 2.0% | 3.0% | 3.0% | 4.0% | 6.0% |

**Fig 3.** Kaplan-Meier freedom from reintervention; $P = .45$ CZ vs GE, $P = .99$ CZ vs MA, and $P = .46$ GE vs MA.

**Graft-related adverse events.** By Kaplan-Meier analysis, there was no difference in the freedom from cumulative graft-related adverse events (GRAE) at either 1 year (93% CZ, 97% GE, and 93% MA) or 5 years (89% CZ, 82% GE, and 81% MA) between device groups ($P = 0.670$ for CZ vs GE, $P = 0.765$ for CZ vs MA, and $P = .435$ for GE vs MA).

IFU effects on early and late outcomes. A total of 222 of 565 (39.3%) EVAR procedures were performed outside of at least one device specific IFU parameter. In comparing the aneurysm morphology of EVAR performed within vs outside of IFU, we noted that outside of IFU aneurysms had larger maximum sac diameters (57.3 ± 11.9 mm outside IFU vs 54.5 ± 9.3 mm within IFU; P < .001), shorter neck lengths (22.2 ± 11.9 mm outside IFU vs 27.0 ± 10.7 mm within IFU; P < .001), larger neck diameters (23.7 ± 2.7 mm outside IFU vs 22.7 ± 2.3 mm within IFU; P <.001), greater neck angulation (29.2 ± 21.8° outside IFU vs 16.3 ± 15.3° within IFU; P < .001) and greater sac angulation (46.7 ± 20.7° outside IFU vs 34.6 ± 17.6° within IFU; P < .001). In consideration of gender and aneurysm morphology, women were outside IFU parameters more often than men with respect to neck length (7.1% of females vs 1.3% of males; P < .001) and neck angulation (3.5% females vs 0.7% males; P = .013). Operative time was greater for EVAR performed outside IFU (140.4 ± 49.6 minutes within IFU vs 152.2 ± 72.6 minutes outside IFU; P = .030).

**Table IV.** Late graft migration events

| | | *Aneurysm morphology* | | | | *Graft extent (from lowest renal or iliac bifurcation) and component oversizing* | | | *Iliac fixation length* | | *Clinical Summary* | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| *Patient* | *Graft brand* | *Maximum sac diameter (mm)* | *Neck length (mm)* | *Neck diameter (mm)* | *Neck angle (°)* | *Proximal (mm)* | *Right limb (mm)* | *Left limb (mm)* | *Right (mm)* | *Left (mm)* | *Within IFU* | *Presentation* | *Reintervention* |
| 1 | Excluder | 61 | 30 | 25 | 10 | IR (5)<br>OS (3.5) | CI (14)<br>OS (2.5) | CI (18)<br>OS (2.5) | 45 | 42 | Yes | 5 mm migration, no endoleak | None |
| 2 | AneuRx | 57 | 15 | 24 | 4 | IR (5)<br>OS (2) | CI (21)<br>OS (3) | CI (34)<br>OS (4) | 28 | 31 | Yes | Proximal type 1 endoleak | Proximal cuff |
| 3 | AneuRx | 74 | 17.5 | 26 | 21 | IR (2.5)<br>OS (2) | EI (n/a)<br>OS (1) | CI (37)<br>OS (4) | 62 | 28 | Yes | Proximal type 1 endoleak | Proximal cuff |
| 4 | AneuRx | 54 | 10 | 23 | 20 | IR (2.5)<br>OS (1) | CI (0)<br>OS (3) | CI (5)<br>OS (2) | 25 | 20 | No | Proximal type 1 endoleak | Proximal cuff |
| 5 | AneuRx | 46 | 17 | 22 | 22 | IR (0)<br>OS (6) | CI (27)<br>OS (5) | CI (20)<br>OS (3) | 40 | 37.5 | Yes | 7 mm migration, no endoleak | None |
| 6 | AneuRx | 72 | 22 | 27 | 47 | IR (0)<br>OS (1) | CI (50)<br>OS (2) | EI (n/a)<br>OS (2) | 42 | 55 | No | 5 mm migration with sac growth, no endoleak | Proximal cuff |
| 7 | AneuRx | 68 | 42 | 20 | 47 | IR (2.5)<br>OS (4) | CI (2.5)<br>OS (4) | CI (15)<br>OS (6) | 27.5 | 27.5 | No | Proximal type 1 endoleak, aneurysm rupture | Proximal and distal cuffs |
| 8 | AneuRx | 54 | 30 | 23 | 0 | IR (0)<br>OS (3) | CI (12)<br>OS (3) | CI (10)<br>OS (2) | 27 | 26 | Yes | Proximal type 1 endoleak with sac growth | Proximal cuff |
| 9 | AneuRx | 61 | 25 | 20 | 26 | IR (5)<br>OS (4) | CI (9)<br>OS (5) | CI (0)<br>OS (1) | 38 | 35 | Yes | Migration into sac, large proximal type 1 endoleak | AUI conversion with fem-fem bypass |
| 10 | AneuRx | 54 | 30 | 23 | 0 | IR (10)<br>OS (3) | CI (0)<br>OS (2) | CI (0)<br>OS (3) | 45 | 33 | Yes | 5 mm migration, no endoleak | None |

*IR*, Infrarenal aortic fixation (distance from lowest renal artery); *CI*, common iliac artery fixation (distance from iliac bifurcation); *EI*, external iliac artery fixation; *OS*, component oversizing (millimeters).

With respect to clinical outcomes, EVAR procedures performed outside of IFU had a similar perioperative mortality (1.7% within IFU, 1.8% outside IFU; $P = 1.00$), but a lower freedom from aneurysm-related mortality at 1 year (100% within IFU, 94% outside IFU) and 5 years (100% within IFU, 89% outside IFU) ($P < .001$). Freedom from reintervention was similar at 1 year (95% within IFU vs 96% outside IFU) and 5 years (85% within IFU vs 76% outside IFU) ($P = .39$). However, as the number of outside IFU parameters increased, there was an incremental decrease in the freedom from reintervention at both 1 year (95% within IFU vs 87% outside 3 IFU parameters) and 5 years (85% within IFU vs 21% outside 3 IFU parameters) ($P = .01$). There was no effect of IFU on the rate of aneurysm rupture (0.6% within IFU vs 1.8% outside IFU; $P = .19$), conversion to open surgical repair (0.3% within IFU vs 1.4% outside IFU; $P = .20$), graft migration (2.1% within IFU vs 1.4% outside IFU; $P = .44$), or graft kinking (0.6% within IFU vs 1.8% outside IFU; $P = .12$). There was a higher incidence of graft thrombosis outside IFU (2.3% outside IFU vs 0.3% within IFU; $P = .03$). By Kaplan-Meier analysis, there was a lower freedom from any GRAE at 1 year (94% within IFU vs 92% outside IFU) and 5 years (82% within IFU vs 67% outside IFU) for grafts placed outside IFU when compared with grafts placed within IFU ($P = .021$). When outcomes were correlated to both IFU status and device type, there were no device-dependent changes in outcome.

## DISCUSSION

Our results indicate that the three commercially available endograft devices evaluated in this study (Cook Zenith, Gore Excluder, and Medtronic AneuRx), provide similar clinical outcomes at 5 years. We found no device-specific differences in perioperative mortality, aneurysm rupture, aneurysm-related mortality, conversion to open repair, or reintervention rates. Endografts placed outside of at least one IFU parameter were associated with higher perioperative mortality, aneurysm-related mortality, reintervention, graft thrombosis, and combined graft-related adverse events.

In our series, more women received a GE device (opposed to a CZ or MA device), which relates to our preferential use of the GE device in patients with small iliac systems. Additionally, women were outside IFU parameters more often than men with respect to neck length and neck angulation. This gender discrepancy in aneurysm morphology and device type could bias results of the GE group in favor of the CZ and MA groups. The effects of gender on EVAR outcomes have previously been described in a number of reports. In a review of a prospective database of 118 MA grafts placed for aneurysm disease, Nordness et al found that that women had longer operative times, higher overall complication rates, and a higher 1-month mortality compared with men.[22] Although they demonstrated higher complication rates in women after EVAR, only 17 of the 118 procedures were performed in women, which limits the power of the study to identify predisposing factors relating female gender to unfavorable outcomes. Sampaio et al found that women undergoing EVAR tended to be older, and had smaller iliac arteries that were less tortuous, but more calcified than men.[23] Females had smaller aneurysms with shorter proximal necks than males, and EVAR in women was associated with greater need for additional access maneuvers such as angioplasty, creation of an iliac "chimney" conduit, and aortouniiliac conversion. However, despite more complicated anatomy and technically demanding EVAR procedures, women and men had similar clinical outcomes at 24 months. These findings were similar to Hugl et al who demonstrated a higher rate of conversion to open surgical repair in women at 24 months post-EVAR compared with men, but similar rates of survival, freedom from aneurysm rupture, and reintervention rates.[24] Biebl and colleagues also showed that women had shorter, more angulated aneurysm necks and smaller iliac arteries than men, but found similar rates of perioperative and late clinical outcomes with the exception of early wound dehiscence and open surgical conversion within the first year post-EVAR.[25] Our study results support the previous findings that women tend to have more hostile aneurysm neck anatomy than men, but given the evidence in the literature, we do not believe that gender discrepancies in device allocation significantly biased our results.

There were device-specific differences in IFU status that may have affected results. The CZ group had more devices placed outside of IFU than the other devices, specifically related to placement in aneurysms with larger neck diameters. This difference is attributable to the CZ device being available with larger main body diameters than either the GE or MA devices, thus obviating placement in larger diameter aneurysm necks. The CZ device group also had a larger maximum aneurysm sac diameter than the other groups. Preoperative aneurysm sac diameter has been shown to be an important determinant of long-term outcome following EVAR,[12,26,27] and thus our results could have been skewed away from the CZ group in favor of the GE and MA groups; but, in fact, the opposite was observed. Peppelenbosch et al stratified EVAR outcomes based on initial maximum aneurysm sac diameter and found that patients with large aneurysms (6.5 cm or larger) were older and were at higher operative risk than patients with smaller aneurysms.[12] In their series, patients in the largest aneurysm diameter cohort had twice the perioperative mortality, a higher rate of early type 1 endoleak, a lower freedom from aneurysm rupture, and freedom from aneurysm-related death than patients in the smaller aneurysm cohorts. In a review of the nationwide EVAR database of Australia, Boult et al determined that large initial aneurysm size, neck angulation $\geq 45°$, and short infrarenal neck were all associated with increased perioperative complications and need for reintervention.[26] These findings were supported by a review of 923 patients who were treated in a multicenter prospective clinical trial by Zarins.[27] Patients were stratified by those who aneurysm was $\leq 5.5$ cm. He found that patients with large aneurysms were older, were at higher operative risk, and had a lower freedom from rupture,

freedom from aneurysm-related mortality, and freedom from conversion to open surgical repair than patients with smaller aneurysms. Although the results of our series could have been skewed in favor of the GE and MA groups, the difference in mean preoperative sac diameter between groups was small and unlikely to have had a significant effect on late outcomes.

Suprarenal fixation was associated with a lower cumulative incidence of graft migration. There were 10 significant graft migrations in our series, all of which occurred in devices without suprarenal fixation (GE and MA, respectively). Of the 10 graft migration events, seven occurred in patients who were within IFU and three occurred in patients outside IFU. Reinterventions were performed in seven patients. Although there were no graft migration events in endografts with suprarenal fixation, there was no significant difference in freedom from graft migration on Kaplan-Meier analysis. This discrepancy likely relates to a combination of a low graft migration event rate and differences in follow-up between device groups. Graft migration has been shown to occur with infrarenal fixation and is thought to relate to aneurysm neck length, aneurysm neck and device apposition zone length, and distal device support within the iliac system.[28-32] Our findings are consistent with those found in the literature, and indeed our graft migration rate is low at 2.5% over 5 years (for grafts with infrarenal fixation), which has been reported in the literature to range from 2-10%. Proximal and distal fixation are important variables in inhibiting graft migration, however, we found no consistent relationship between graft extent (either proximal or distal) or component oversizing and graft migration events.

It is intuitively logical that better anatomic results will be achieved and complications reduced when EVAR is performed within vs outside of device-specific IFU. In a series of articles from the EUROSTAR database, the investigators studied the effects of aneurysm sac and neck diameter[10], neck length[16], and neck angulation[18] on late outcomes, although they did not analyze outcomes by device-specific IFU parameters. Waasdorp et al showed a higher rates of aneurysm rupture, open conversion and mortality in patients with a sac diameter >6 cm or neck diameter >26 mm after 4 years of follow-up.[10] Leurs demonstrated that a neck length <15 mm was associated with significantly increased rates of early (<30 days) and late proximal type 1 endoleak.[16] Similarly, Hobo et al. found that EVAR in patients with severe aneurysm neck angulation (> 60°) had higher rates of early proximal type 1 endoleak and graft migration, and greater late proximal neck dilatation, type 1 endoleak, and reintervention rates.[18] In a review of their EVAR experience, Fulton and colleagues stratified patients by IFU status with respect to neck anatomy (length, angulation, and diameter) and found that patients outside IFU experienced higher rates of graft migration, device-related complications, and secondary interventions.[30] Our data support that placement of endografts outside of device specific IFU parameters is associated with higher perioperative and aneurysm-related mortality. In our series, we did not detect a difference in patient demographics or clinical characteristics based on IFU status, indicating that patients outside IFU simply had anatomically more complicated aneurysms than those within IFU and did not represent a higher medical risk group to account for the mortality differences. Presumably, the higher rates of reinterventions and graft-related adverse events that we observed in patients outside IFU contributed to a higher rate of perioperative and aneurysm-related mortality.

This retrospective study has important limitations and the results should be interpreted cautiously. First, the difference in follow-up intervals for the study groups could have had profound effects on determining outcome differences between device groups. The GE and MA groups had similar mean follow-up (31 and 34 months, respectively), and the CZ group had significantly shorter follow-up (20 months). In our series, the CZ group had a shorter follow-up because this device became commercially available later than either the GE or MA devices. However, limiting the analysis to a time interval based on CZ availability would have reduced the number of subjects in the GE and MA groups, which could have introduced a significant selection bias (ie, by comparing third and fourth generation GE and MA devices with early generation CZ devices and thereby unfairly favoring the GE and MA groups), and reduced the power of the study to detect device-specific differences in outcome.

IFU status was determined based on direct measurement from original CT scan data. The vessel diameter and length measurements were not based on centerline axial measurements, as the availability of CT three-dimensional reconstructions with postimaging processing that provided for centerline diameter and length measurements evolved over the study interval. M2S reconstructions were available for only 40% of the study cohort, thus, the measurements used for this study were performed directly from the digital CT image by the primary author without centerline reconstructions. Although the lack of centerline measurements may alter the IFU stratification to a degree, all study measurements were made by a single individual, which should limit measurement variability and thus minimize any effect on our conclusions.

The study was also limited to patients in whom a device had been successfully deployed, so by design, IFU status was heavily-weighted towards parameters relating to proximal fixation (aneurysm neck length, diameter, and angulation), and not on access issues. Therefore, we cannot analyze the effect(s) of access-related issues (iliac diameter, tortuosity and calcification) on clinical outcomes or detect any device-specific differences thereof.

## CONCLUSION

EVAR performed with three commercially available devices (Cook Zenith, Gore Excluder, and Medtronic AneuRx) provided similar clinically relevant outcomes at 5 years, although no graft migration occurred in our series with a suprarenal fixation device. As anticipated, EVAR

application outside of anatomically specific IFU parameters had an incrementally negative effect on late results. Although treatment outside IFU still yielded respectable results (1.8% perioperative mortality), EVAR under these circumstances should be performed cautiously, and perhaps not at all in patients who are otherwise candidates for open operation.

## AUTHOR CONTRIBUTIONS

Conception and design: TA, TC, RC
Analysis and interpretation: TA, TC, CK, DB, RC
Data collection: TA, JK
Writing the article: TA, CK, DB, TC, JK, GL, RC
Critical revision of the article: TA, CK, DB, TC, JK, GL, RC
Final approval of the article: TA, CK, DB, TC, RC
Statistical analysis: TC
Obtained funding: RC
Overall responsibility: TA

## REFERENCES

1. Parodi JC, Palmaz JC, Barone HD. Transfemoral intraluminal graft implantation for abdominal aortic aneurysms. Ann Vasc Surg 1991;5: 491-9.
2. Brewster DC, Jones JE, Chung TK, LaMuraglia GM, Kwolek CJ, Watkins MT, et al. Long-term outcomes after endovascular abdominal aortic aneurysm repair, the first decade. Ann Surg 2006;244:426-38.
3. Lifeline Registry of EVAR Publications Committee. Lifeline registry of endovascular aneurysm repair: long-term primary outcome measures. J Vasc Surg 2005;42:1-10.
4. Zarins CK, White RA, Schwarten D, Kinney E, Diethrich EB, Hodgson KJ, et al. AneuRx stent graft vs open surgical repair of abdominal aortic aneurysms: multicenter prospective clinical trial. J Vasc Surg 1999;29: 2929–308.
5. Greenberg RK, Chuter TAM, Sternberg WC III, Fearnot NE, for the Zenith Investigators. Zenith AAA endovascular graft: intermediate-term results of the US multicenter trial. J Vasc Surg 2004;39:1209-18.
6. Matsumura JS, Brewster DC, Makaroun MS, Naftel DC. A multicenter controlled clinical trial of open vs endovascular treatment of abdominal aortic aneurysm. J Vasc Surg 2003;37:262-71.
7. EVAR Trial Participants. Comparison of endovascular aneurysm repair with open repair in patients with abdominal aortic aneurysm (EVAR 1 Trial): randomized controlled trial. Lancet 2005;365:2179-86.
8. EVAR Trial Participants. Endovascular aneurysm repair and outcome in patients unfit for open repair of abdominal aortic aneurysm (EVAR 2): randomized controlled trial. Lancet 2005;365:2187-92.
9. Blankensteijn J, Sjors E, de Jong MD, van der Ham AC, Buth J, van Sterkenburg SM, et al. Two-year outcomes after conventional or endovascular repair of abdominal aortic aneurysms. N Eng J Med 2005;352: 2398-405.
10. Waasdorp EJ, de Vries JP, Hobo R, Leurs LJ, Buth J; EUROSTAR collaborators. Aneurysm diameter and proximal aortic neck diameter influence clinical outcome of endovascular abdominal aortic repair: a 4-year EUROSTAR experience. Ann Vasc Surg 2005;19:755-61.
11. Lange C, Leurs LJ, Buth J, Myhre HO; EUROSTAR Collaborators. Endovascular repair of abdominal aortic aneurysm in octogenarians: an analysis based on EUROSTAR data. J Vasc Surg 2005;42:624-30.
12. Peppelenbosch N, Buth J, Harris PL, van Marrewijk C, Fransen G; EUROSTAR Collaborators. Diameter of abdominal aortic aneurysm and outcome of endovascular aneurysm repair: does size matter? A report from EUROSTAR. J Vasc Surg 2004;39:288-97.
13. Hua HT, Cambria RP, Chuang SK, Stoner MC, Kwolek CJ, Rowell KS, et al. Early outcomes of endovascular vs open abdominal aortic aneurysm repair in the National Surgical Quality Improvement Program-Private Sector (NSQIP-PS). J Vasc Surg 2005;41:382-9.
14. Sicard GA, Zwolak RM, Sidawy AN, White RA, Siami FS; Society for Vascular Surgery Outcomes Committee. Endovascular abdominal aortic aneurysm repair: long-term outcome measures in patients at high-risk for open surgery. J Vasc Surg 2006;44:229-36.
15. Leurs LJ, Hobo R, Buth J; EUROSTAR Collaborators. The multicenter experience with a third-generation endovascular device for abdominal aortic aneurysm repair. A report from the EUROSTAR database. J Cardiovasc Surg (Torino) 2004;45:293-300.
16. Leurs LJ, Dievit J, Dagnelie PC, Nelemans PJ, Buth J; EUROSTAR Collaborators. Influence of infrarenal neck length on outcome of endovascular abdominal aortic aneurysm repair. J Endovasc Ther 2006;13: 640-8.
17. Sheehan MK, Ouriel K, Greenberg R, McCann R, Murphy M, Fillinger M, et al. Are type II endoleaks after endovascular aneurysm repair endograft dependent? J Vasc Surg 2006;43:657-61.
18. Hobo R, Kievit J, Leurs LJ, Buth J; EUROSTAR Collaboratorsz. Influence of severe infrarenal aortic neck angulation on complications at the proximal neck following endovascular AAA repair: a EUROSTAR study. J Endovasc Ther 2007;14:1-11.
19. Hobo R, Laheij RJ, Buth J; EUROSTAR Collaborators. The influence of aortic cuffs and iliac limb extensions on the outcome of endovascular abdominal aortic aneurysm repair. J Vasc Surg 2007;45:79-85.
20. Sternbergh WCz 3rd , Money SR, Greenberg RK, Chuter TA; Zenith Investigators. Influence of endograft oversizing on device migration, endoleak, aneurysm shrinkage, and aortic neck dilation: results from the Zenith Multicenter Trial. J Vasc Surg 2004;39:20-6.
21. Brown LC, Greenhalgh RM, Kwong GPS, Powell JT, Thompson SG, Wyatt MG for the EVAR Trial Participants. Secondary interventions and mortality following endovascular aortic aneurysm repair: device-specific results from the UK EVAR Trials. Eur J Vasc Endovasc Surg 2007;34:281-90.
22. Nordness PJ, Carter G, Tonnessen B, Sternbergh WC 3rd , Money SR. The effect of gender on early and intermediate results of endovascular aneurysm repair. Ann Vasc Surg 2003;17:615-21.
23. Sampaio SM, Panneton JM, Mozes GI, Andrews JC, Noel AA, Karla M, et al. Endovascular abdominal aortic aneurysm repair: does gender matter? Ann Vasc Surg 2004;18:653-60.
24. Hugl B, Hakaim AG, Biebl M, Oldenburg WA, McKinney JM, Nolte LA, et al. Impact of gender on the outcome of endovascular aortic aneurysm repair using the Zenith stent graft: midterm results. J Endovasc Ther 2007;14:115-21.
25. Biebl M, Hakaim AG, Hugl B, Oldenburg WA, Paz-Fumagalli R, McKinney JM, et al. Endovascular aortic aneurysm repair with the Zenith AAA endovascular graft: does gender affect procedural success, postoperative morbidity, or early survival? Am Surg 2005;71:1001-8.
26. Boult M, Babidge W, Maddern G, Barnes M, Fitridge R; Audit Reference Group. Predictors of success following endovascular aneurysm repair: mid-term results. Eur J Vasc Endovasc Surg 2006;31:123-9.
27. Zarins CK, Crabtree T, Bloch DA, Arko FR, Ouriel K, White RA. Endovascular aneurysm repair at 5 years: does aneurysm diameter predict outcome? J Vasc Surg 2006;44:920-9.
28. Sampaio SM, Panneton JM, Mozes G, Andrews JC, Noel AA, Kalra M, et al. AneuRx device migration: incidence, risk factors, and consequences. Ann Vasc Surg 2005;19:1-8.
29. Zarins CK, Bloch DA, Crabtree T, Matsumoto AH, White RA, Fogarty TJ. Stent graft migration after endovascular aneurysm repair: the importance of proximal fixation. J Vasc Surg 2003;38:1264-72.
30. Fulton JJ, Farber MA, Sanchez LA, Godshall CJ, Martson WA, Mendes R, et al. Effect of challenging neck anatomy on midterm migration rates in AneuRx endografts. J Vasc Surg 2006;44:932-7.
31. Tonnessen BH, Sternbergh WC 3rd , Money SR. Mid- and long-term device migration after endovascular abdominal aortic aneurysm repair: a comparison of AneuRx and Zenith endografts. J Vasc Surg 2005;42: 392-401.
32. Benharash P, Lee JT, Abilez OJ, Crabtree T, Bloch DA, Zarins CK. Iliac fixation inhibits migration of both suprarenal and infrarenal aortic endografts. J Vasc Surg 2007;45:250-7.

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