CONTROVERSIES & UPDATES IN VASCULAR SURGERY
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Are new generation devices realy better than the previous ones?

Marc RHM van Sambeek
Joep AW Teijink, Philippe W Cuypers
Department of Vascular Surgery
Catharina Hospital
Eindhoven

Disclosure

Marc RHM van Sambeek

I have the following potential conflicts of interest to report:

Consulting and speakersfee

WL Gore & Associates
Medtronic

Unrestricted research grants

Medtronic
Abbott Vascular

Results over time


Secondary interventions following endovascular abdominal aortic aneurysm repair using current endografts. A EUROSTAR report

Hobo R, et al.
J Vasc Surg 2006;43:896-902


Long-term Outcomes After Endovascular Abdominal Aortic Aneurysm Repair
The First Decade

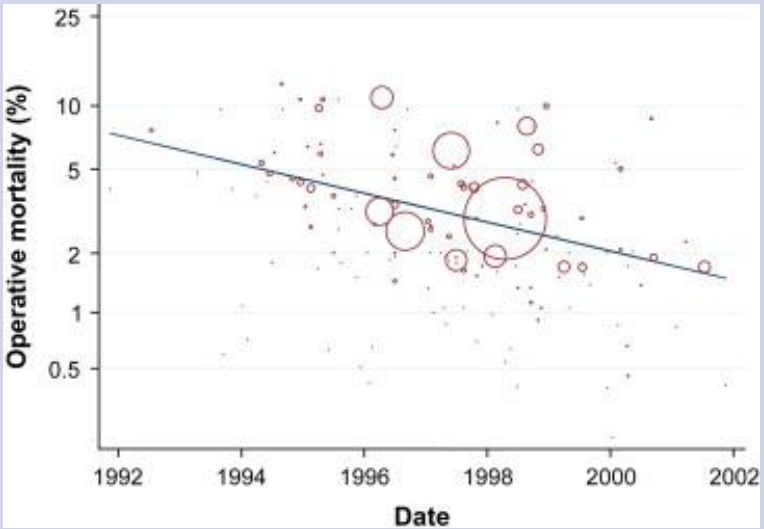
Brewster DC, et al.
Ann Surg 2006; 244:426-38

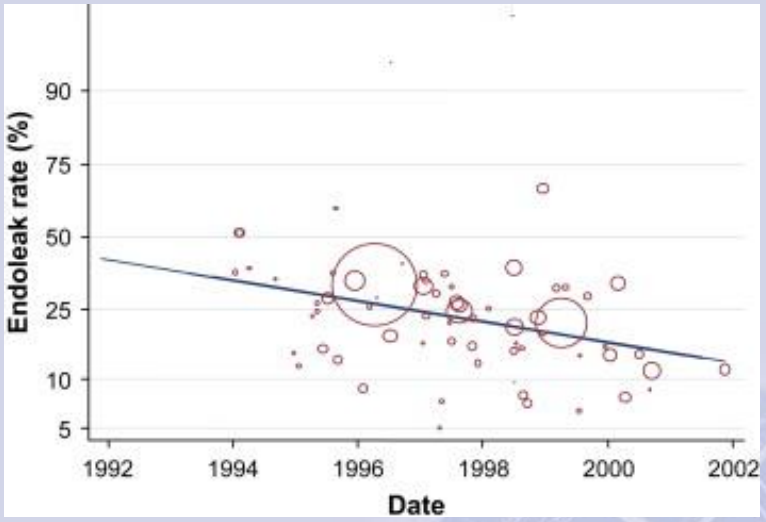

Risk-Adjusted Outcome Analysis of Endovascular Abdominal Aortic Aneurysm Repair in a Large Population: How Do Stent-Grafts Compare?

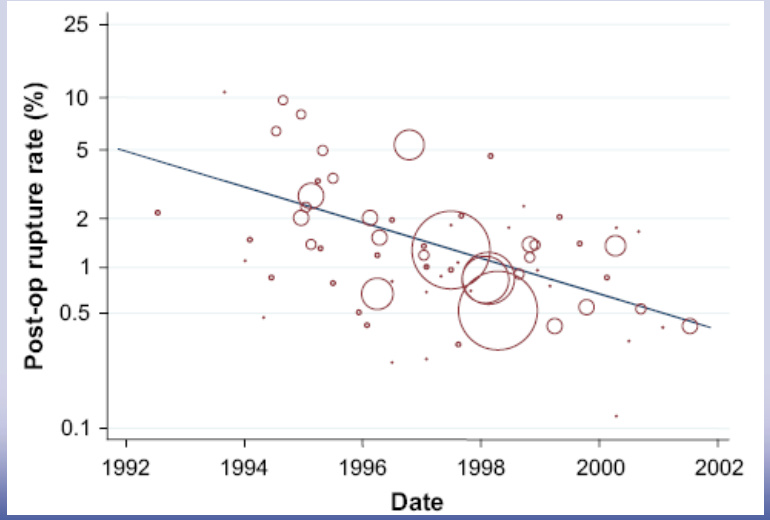
EUROSTAR Collaborators.
J Endovasc Ther 2005;12:417-429

Over time, the number of re-interventions is decreasing and endograft seems to perform better

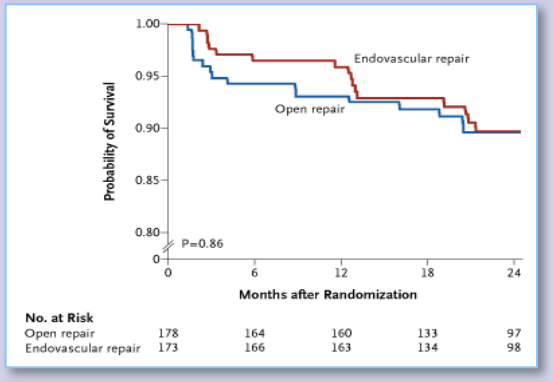
Results over time



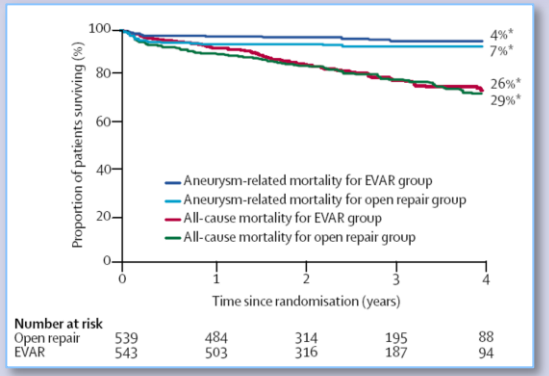




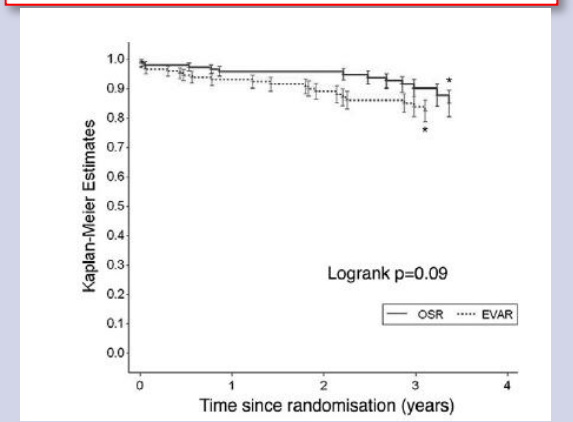
Franks SC, et al.
EJVES 2007; 33:154-171



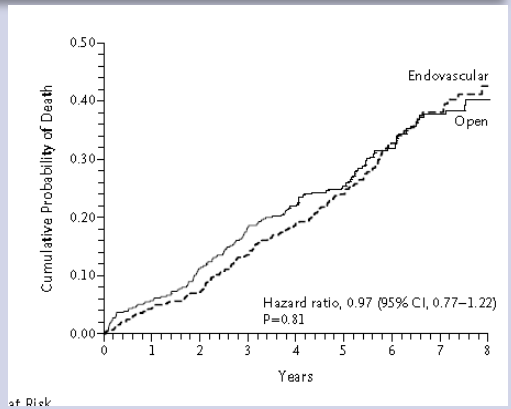
DREAM Trial
N Engl J Med. 2005;35:2398-405



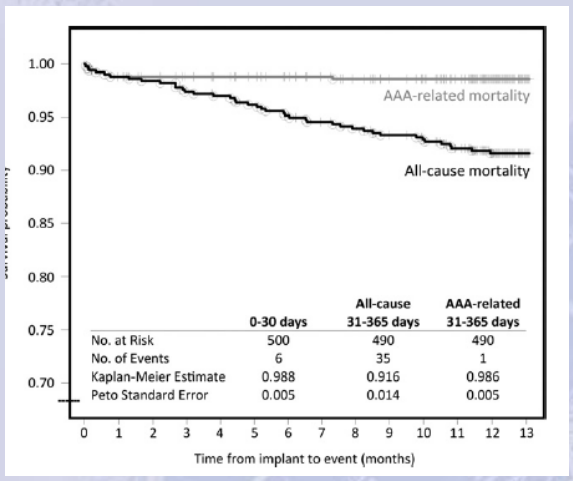
EVAR Trial
Lancet. 2005;365:2179-86



ACE Trial
J Vas 2011;53:1167-73-405



OVER Trial
N Engl J Med 2012;367:1988-97



ENGAGE Registry
Eur J Vasc Endovasc Surg 2012;44:369-75

Endograft specifics

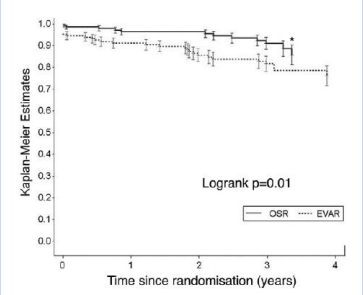
	Criteria	Endurant	Talent	Zenith Flex	Gore Excluder	Vascutek Anaconda
	Minimum Treatable Neck Length	10mm	10mm	15mm	15mm	15mm
	Maximum Treatable Infrarenal Angulation	75°	60°	60°	60°	60°
	Max Treatable Aortic Neck Diameter	32mm	32mm	32mm	28mm	31mm
	Max Treatable Iliac Diameter	25mm	22mm	20mm	18mm	21mm
	# of Main Body Configurations	3	2	2	1	1
	Min Access Profile (28mm graft)	20F	22F	23.5F	21F	22.5F

Remarkable at baseline

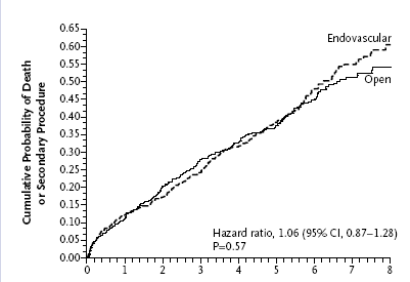
- 16.2% sAAA
- 10.6% ASA IV
- 17.8% outside IFU

→ **(Exclusion DREAM/EVAR1)**

Possibility to compare?



Survival or reintervention



Death or reintervention

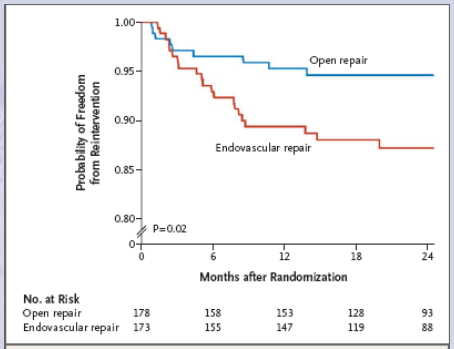
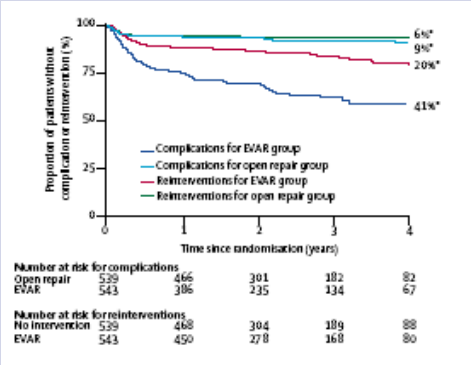


Figure 3. Kaplan–Meier Estimates of Freedom from Reintervention among Patients Assigned to Undergo Open or Endovascular Aneurysm Repair.



	Successful EVARs completed (n=529)†		Open repairs completed (n=519)†	
	Number of patients with complication	Number of patients with reintervention	Number of patients with complication	Number of patients with reintervention
Graft rupture (9)	9	3	0	0
Graft infection (3)	1	1	2	0
Graft migration (EVAR specific 14)	12	7		
Endoleak type I (EVAR specific 26)‡	27	17		
Endoleak type II (EVAR specific 10)§	8	4		
Graft kinking (EVAR specific 2)	6	2		
Endotension (EVAR specific 6)¶	6	0	1 (confirmed after open repair)	0
Endoleak type V (EVAR specific 100)‖	79	17	1 (confirmed after open repair)	0
Technical deployment problems (EVAR specific 2)	2	2		
Unspecified endoleak (EVAR specific 4)	4	4		
Graft thrombosis (14)	12	10	1	1
Graft stenosis (4)	2	0	1	0
Distal embolisation from graft (2)	1	0	0	0
Renal infarction (3)	3	0	0	0
Anastomotic aneurysm (2)	0	0	1	1
Iliac dilatation (6)	1	1	5	2
Re-exploration of open repair (16)	-	-	16	16
Other surgery required (29)	13 (13)	13	16	16
Total (262 complications in 230 patients)	186 of 529 (35%; 95% CI 31–39)	81 of 529 (15%; 95% CI 12–18)	44 of 519 (8%; 95% CI 6–11)	36 of 519 (7%; 95% CI 5–9)

*In some cases patients have had more than one type of complication. In these cases most serious complication has been used for classification. Complications are listed in order of severity. Total numbers of complications are given in brackets in first column. †529 EVARs attempted: four conversions in theatre, two procedures abandoned. 525 open repairs attempted: four conversions from EVAR to open repair in theatre. ‡Type 1a=presence of blood leaking either from top or bottom of graft; type 2=other arteries backbleeding into aortic sac; type 3=structural fault of graft or its limbs. §Continued sac expansion after repair without observed endoleak.

Table 2: Postoperative complications* after leaving theatre by operation received (not intention to treat)

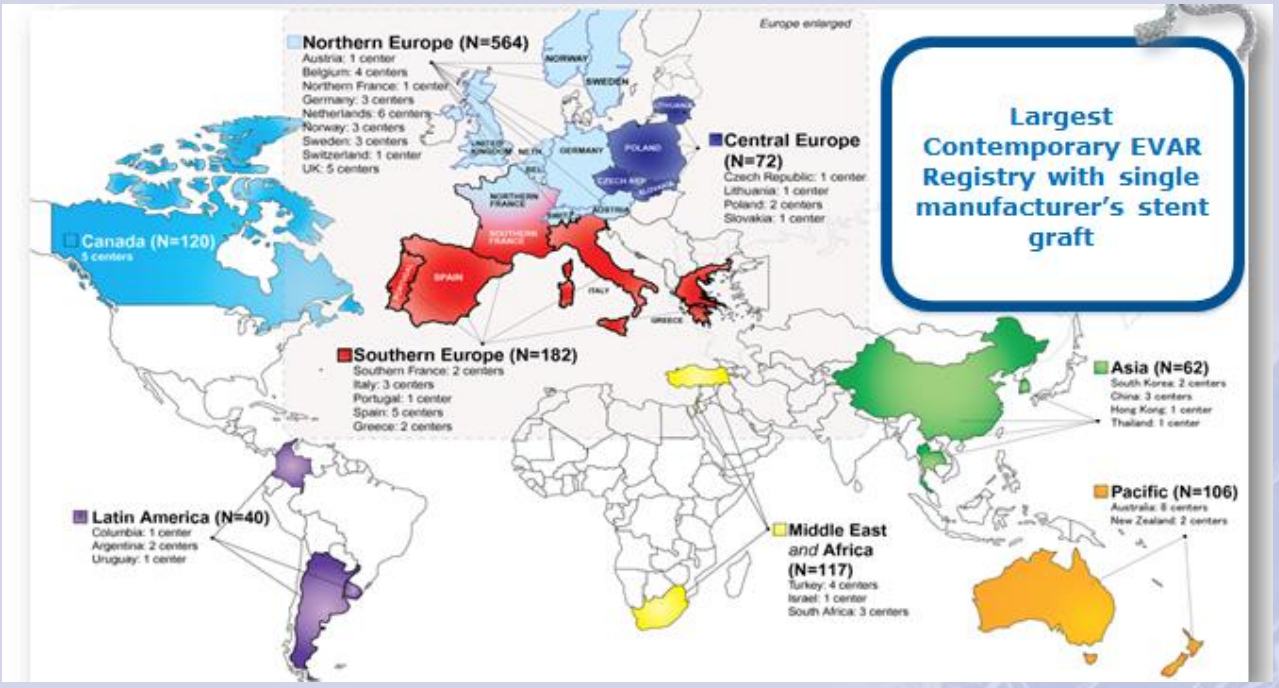
Table 2. Clinical Outcomes in the Two Treatment Groups.

Outcome	Endovascular Repair (N = 444)	Open Repair (N = 437)	P Value
All deaths — no. of patients (%)	146 (32.9)	146 (33.4)	0.81
Cause of death — no. of patients (%)			
Aneurysm-related cause	10 (2.3)	16 (3.7)	0.22
During hospitalization or within 30 days after repair	2 (0.5)	13 (3.0)	0.004
Cardiovascular cause not related to aneurysm	39 (8.8)	29 (6.6)	0.23
Cancer	39 (8.8)	48 (11.0)	0.27
Pneumonia or other infection	15 (3.4)	12 (2.8)	0.59
Chronic obstructive lung disease	5 (1.1)	13 (3.0)	0.05
Accident, homicide, or suicide	10 (2.3)	4 (0.9)	0.18
Other cause	15 (3.4)	9 (2.1)	0.23
Unknown cause	13 (2.9)	15 (3.4)	0.67
Aneurysm rupture	6 (1.4)	0	0.03
New or worsened claudication — no. of patients (%)	23 (5.2)	15 (3.4)	0.20
Secondary therapeutic procedures			
No. of patients (%)	98 (22.1)	78 (17.8)	0.12
No. of procedures	148	105	0.26
Hospitalizations after repair			
Total no. of hospitalizations	954	1040	0.08
Total no. of patients with one or more hospitalizations (%)	325 (73.2)	314 (71.9)	0.66
Hospitalizations related to aneurysm			
No. of hospitalizations	171	137	0.12
No. of patients (%)	95 (21.4)	78 (17.8)	0.19

Table 3. Causes of Death after Open and Endovascular Repair of Abdominal Aortic Aneurysm.

Cause of Death	Before Surgery*		In the Hospital†		After Discharge		Overall	
	Endovascular Repair (N=539)	Open Repair (N=543)	Endovascular Repair (N=539)	Open Repair (N=543)	Endovascular Repair (N=539)	Open Repair (N=543)	Endovascular Repair (N=539)	Open Repair (N=543)
	Number of patients							
All causes	1	1	8	5	9	12	18	30
Cardiovascular causes	0	0	3	1	3	6	2	7
Myocardial infarction	0	0	1	1	0	1	1	3
Cardiac arrest	0	0	1	0	3	3	3	3
Congestive heart failure	0	0	0	0	0	3	0	3
Stroke	0	0	0	0	1	1	1	1
Aneurysm-related, noncardiovascular causes	1	1	3‡	1§	1¶	1‖	8	3
Cancer	0	0	0	0	3	4	3	4
Other	0	1	0	0	1**	4††	1	2
Unknown	0	0	0	0	3‡‡	2§§	3	3

ENGAGE Registry



International Multicenter Registry:

1263 patients, 30 countries, 79 sites

ENGAGE Registry

Patients consecutively enrolled

Follow-up: 30-day, annual visits through 5 years

Extensive monitoring on-going

- 100% data management review
- Independent data monitoring (100% endpoints)
- Independent Clinical Event Committee

High quality registry data

ENGAGE outcomes

Endurant: low aneurysm-, device- and procedure-related mortality

	At 1 year N=1263	At 2 years N=1263	At 3 years N=1263	At 4 years N=500
All-Cause Mortality	**7.4 % (94)**	**13.8% (174)**	**19.4% (245)**	**24.0% (120)**
Device-related	**0.2% (2)**	**0.3% (4)**	**0.3% (4)**	**0.8% (4)**
Procedure-related	**0.7% (9)**	**0.8% (10)**	**0.8% (10)**	**1.2% (6)**
Both device- and procedure-related	**0.1% (1)**	**0.2% (2)**	**0.2% (2)**	**0.4% (2)**
Aneurysm-related mortality	**1.4% (18)**	**1.5% (19)**	**1.5% (19)**	**1.6% (8)**

ENGAGE outcomes

Low rates of conversion to open surgery and incidence of rupture

	At 1 year N=1263	At 2 years N=1263	At 3 years N=1263	At 4 years N=500
Conversion to open surgery	**0.6% (7)**	**0.8% (10)**	**0.9% (11)**	**0.8% (4)**
Rupture	**0.2% (2)**	**0.3% (4)**	**0.5% (6)**	**0.4% (2)**

ENGAGE outcomes

	At 1 month N=1163	At 1 year N=1079	At 2 year N=902	At 3 year N=729	At 4 year N=275
Endoleak (total)	**13.1% (152)**	**9.8% (106)**	**10.1% (91)**	**10.0% (73)**	**9.5% (26)**
Type I	**1.3% (15)**	**0.4% (4)**	**0.9% (8)**	**1.4% (10)**	**2.5% (7)**
Type IA	**0.8% (9/1163)**	**0.2% (2/1079)**	**0.3% (3/902)**	**0.7% (5/729)**	**0.4% (1/275)**
Type IB	**0.5% (6/1163)**	**0.2% (2/1079)**	**0.6% (5/902)**	**0.7% (5/729)**	**2.2% (6/275)**
Type III	**0.3% (3)**	**0.2% (2)**	**0.6% (6)**	**0.1% (1)**	**0%**
Type I and/or III	**1.5% (17)**	**0.6% (6)**	**1.6% (14)**	**1.5% (11)**	**2.5% (7)**

ENGAGE outcomes

	At 1 year N=1243	At 2 years N=1243	At 3 year N=1243	At 4 year N=490
Proximal migration *	**0%**	**0%**	**0%**	**0%**
Stent graft occlusion	**3.5% (44)**	**3.8% (47)**	**3.9% (49)**	**2.9% (14)**
Stent graft kinking	**2.3% (28)**	**2.4% (30)**	**2.4% (30)**	**2.9% (14)**
Stent fracture	**0%**	**0%**	**0%**	**0%**

* 0.6% (7) limb separation/limb migration reported within 3 years

ENGAGE outcomes

Endurant has proven a lower reintervention rate

	At 1 year N=1263	At 2 years N=1263	At 3 yearss N=1263	At 4 years N=500
Secondary endovascular procedure any type	**6.0% (76)**	**7.7% (97)**	**9.4% (119)**	**10.6% (53)**
Secondary endovascular procedure to correct type I or III endoleak	**1.4% (18)**	**2.1% (27)**	**3.0% (38)**	**3.4% (17)**

ENGAGE vs Landmark trials

Results at 2 years

	Enrollment	Primary Devices	Secondary Intervention	Conversion	Aneurysm-related Mortality
DREAM	2000-2003	Zenith Talent Excluder	12%	1.7%	2.1%
OVER *	2002-2008	Zenith Excluder AneuRx	13.7%	<1.5%	2.1%
Endurant U.S. IDE	2008-2009	Endurant	6.1 %	0%	0%
ENGAGE	2009-2011	Endurant	7.7%	0.8%	1.5%

Conclusion

EVAR is getting better

Endurant continues to show very good mid-term durability

4 year data from ENGAGE demonstrates:

- Low secondary endovascular intervention rate
- Low aneurysm related mortality
- Safety and effectiveness