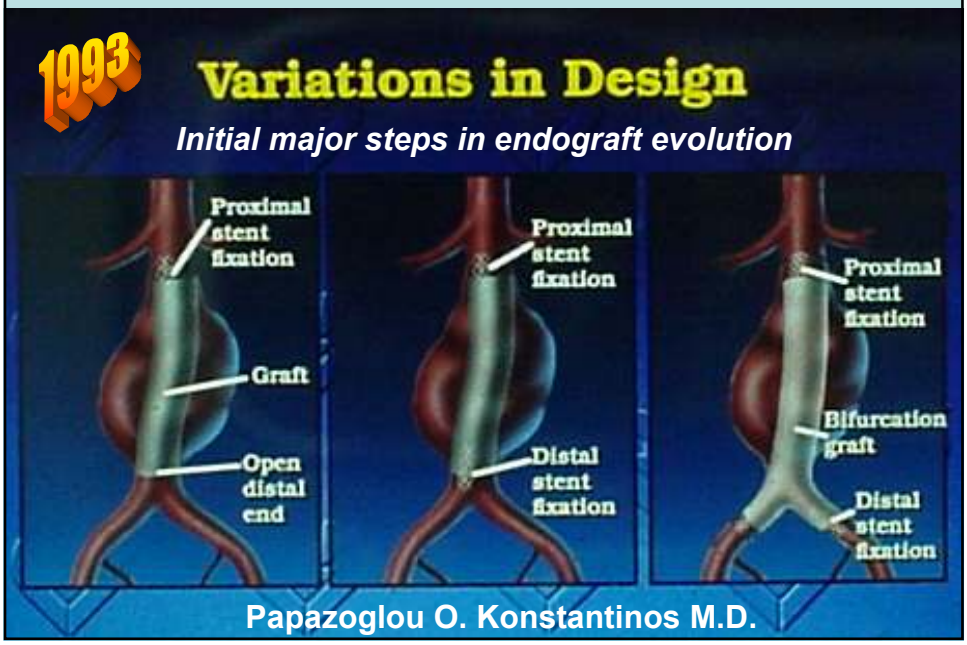
EVAR replaced standard repair in most cases. Why?



The story of a major breakthrough in vascular surgery

1991 Parodi introduces the concept of EVAR.

Feasibility was proven with the first custom grafts.

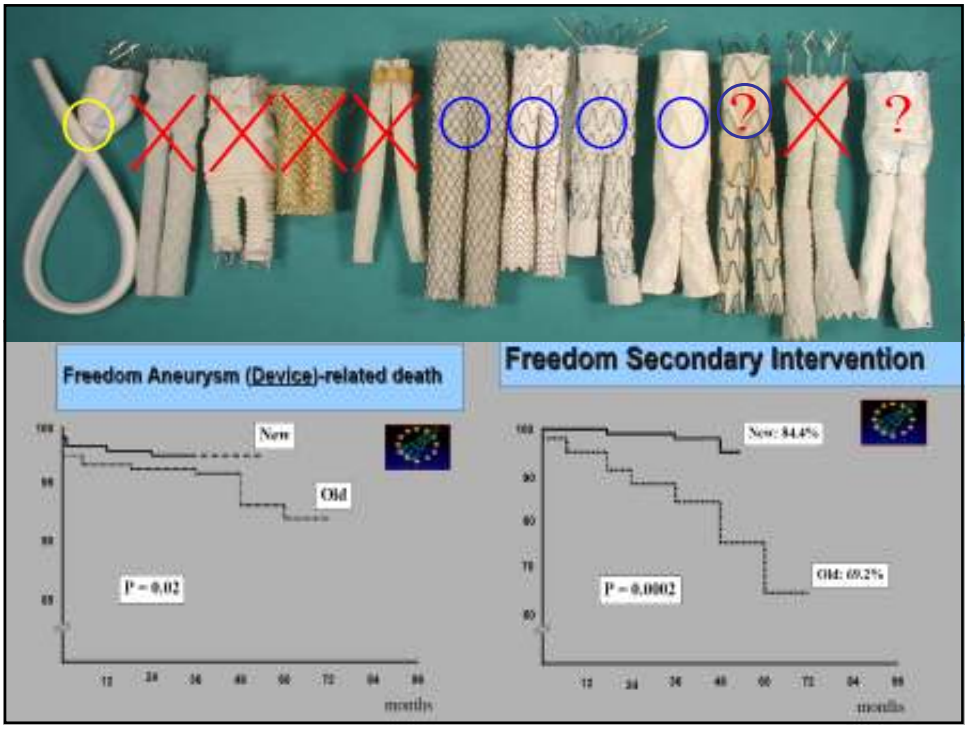
Purpose: Treatment of high risk patients with decreased mortality and less invasiveness.

During the next ten years criticism and evolution of several devices provide information about advantages and disadvantages of the new treatment.

Increasing doctors experience and device development with correction of the weak points of the 1st and 2nd generation devices improve short term clinical results.

Long term problems are still under investigation for the different endografts.

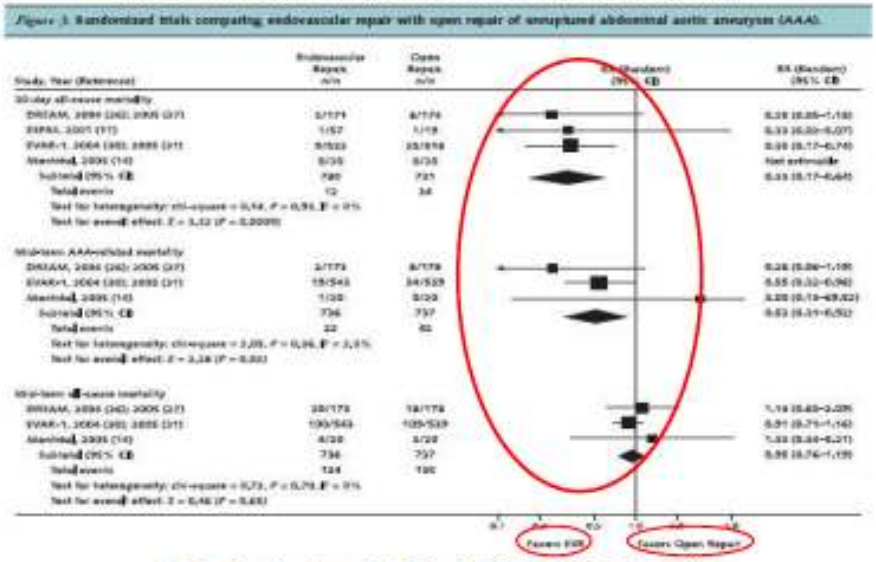
This is not a failed experiment !!! (2009)



2004 Randomized Trials
Level 1 Evidence!!

All-cause Mortality	30 days		2 years	
	OR	EVAR	OR	EVAR
dream	4.6%	1.2%	±10%	±10%
EVAR-1	4.7%	1.7%	±10%	±10%

Meta-analysis (EVAR vs Open Repair)



Lederle F, Ann Int Med 2007; 146: 735-741

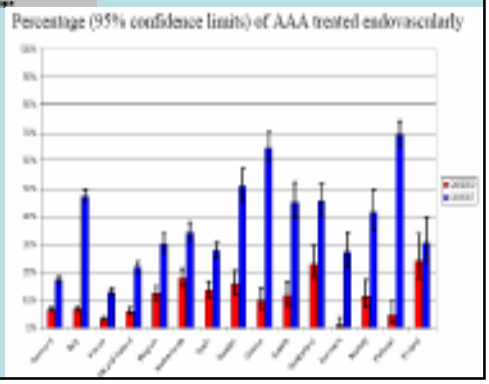
Evolution of Endovascular and Surgical Procedures Q3 2007/Q3 2008						
	Endovascular Procedures			Surgical Procedures		
	Q3 2007	Q3 2008	% +/-	Q3 2007	Q3 2008	% +/-
AAA	4,260	4,398	3.2%	11,642	11,374	-2.3%
TAA	1,253	1,338	6.8%	1,054	951	-9.8%
Aorto-Iliac	27,026	29,076	7.6%	8,416	8,868	5.4%
Carotid	5,682	6,415	12.9%	17,126	17,329	1.2%
Fem-Pop	33,507	35,973	10.7%	11,830	12,811	8.3%
Overall	71,728	77,200	7.6%	50,068	51,333	2.5%

The **real situation** in Vascular Surgery *Today!*

AAA (around 30 - 40%)

EVEM Panel report of Western Europe

USA more than 50% of AAA endovascular



Important decision factors *(change?)*

The patient

The anatomy

The device ***(change)***

The doctor, the team, the hospital ***(change)***

The technique ***(change)***

The results ***(change)***

The insurance policy ***(change?)***

The patient

Age

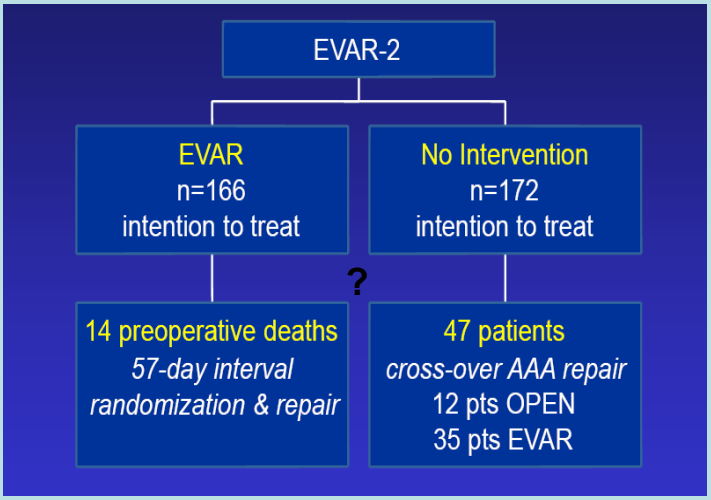
Sex

Co morbidities

Surgical risk !!

Preference ?

EVAR 2 Trial (Pts. Unfit for Surgery)



No survival benefit at 4 years !!!

Lancet, August 25, 2004

Comparison EVAR-2 and U.S. IDE (Pt. high risk for Surg.)

	U.S. IDE	EVAR-2
30-day mortality	2.9%	9%
All cause 4yr mortality	44%	64%

J Vasc Surg 2006

Short-Term Survival Benefit Increases with Age.

45,660 Medicare patients (average age 76)
Open or endovascular repair of an AAA between 2001 and 2004.
Perioperative mortality **1.2% vs. 4.8%,** *P* <0.001
Reduction in mortality difference increased with age
Difference of 2.1% among 67-69 year olds and 8.5% seen in patients 85 years or older (*P* <0.001).

Open repair: higher per operative complication rate, longer hospital stay

During follow up

At 4 years rupture-rate 3 times higher in the endo group **1.8% vs. 0.5%,** *P* <0.001

Re-interventions targeting the aneurysm more common **9.0% vs. 1.7%,** *P* <0.001

Laparotomy-related complications more common after open **9.7% vs. 4.1%** *P* <0.001

Overall risk of complications equivalent for both treatments.

Interventions for both endovascular and open repair were minor in most cases.

Marc Schermerhorn, MD, January 31, 2008, The New England Journal of Medicine.

High risk patients EVAR or open repair? (Medicare data)

11,415 matched cohorts for each treatment
Overall mortality 1.8% EVAR vs. 5.3% open repair

Predictors of mortality

	OR (95% CI)	*P* VALUE
OPEN REPAIR	**3.2 (2.7-3.8)**	**<0.0001**
AGE		
71-75 YEARS	**1.2 (0.9-1.6)**	**0.34**
>80 YEARS	**3.1 (2.4-4.2)**	**<0.0001**
FEMALE	**1.5 (1.3-1.8)**	**<0.0001**
Chronic renal insuf.	**2.0 (1.6-2.6)**	**<0.0001**
Congestive hear failure	**1.7 (1.5-2.1)**	**<0.0001**
Vascular desease*	**1.3 (1.2-1.6)**	**<0.0001**

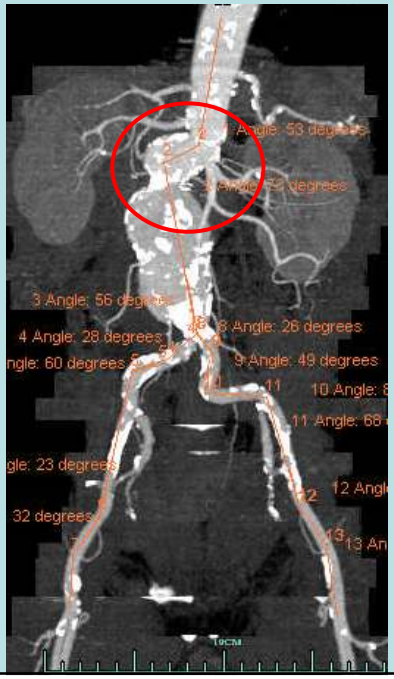
*Peripheral arterial or cerebrovascular.

K.A. Giles, M.L. Schermerhorn, at al. February 2009 Journal of vascular surgery

ANATOMY (Proximal neck, Size, Iliac arteries)

Suitability 50 – 80% increasing with graft evolution - experience

ANATOMY - *Proximal neck*



AAA neck at least 25% of non suitable cases (1)

Short neck (<15 mm)
Wide neck (diameter)
Angulated neck (>60o)
Calcification
Thrombus
Shape (barrel, inverted conical)

Combined problems >30% (2)
Large AAA
Iliac distortion

Higher complication rate (type I leak, Migration) (3)

Proper graft selection, graft evolution, proper technique

Experience expands indications and clinical success

(1) Carpenter JVS 2001
(2) Dillavou EUROSTAR Vasc. Endovasc. Surg. 2005
(3) Leurs JEVT 2006

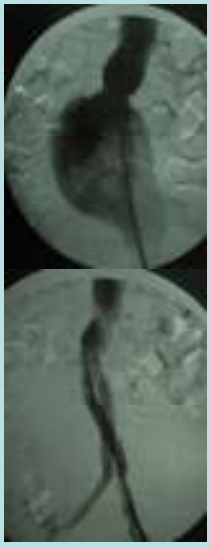
Small vs Large AAAs

EVAR results

	Small < 5.5 cm	Large > 5.5 cm
Type 1 Endoleak	1.4 %	6.4 %
Migration	4.4 %	13 %
Conversion	1.4 %	8.2 %
Aneurysm Related Death	1.5 %	6.1 %
Survival @ 24 months	86 %	71 %

Ouriel et al. JVS 2003;37:1206-1210

Eurostar Small vs Large (Excluder Endoprosthesis)



Large AAA

Older, higher operative risk, more difficult anatomy

More endoleaks (2 vs. 4%)
Higher migration (0% vs. 2%)
Higher 3 year mortality (4% vs. 14%)
Higher AAA related mortality (0.3% vs. 3%)

Satisfactory midterm outcome in both groups

Leurs LJ, Hobo R, Buth J, J Cardiovasc Surg. 2004 Aug;45(4):293-300

Iliac anatomy

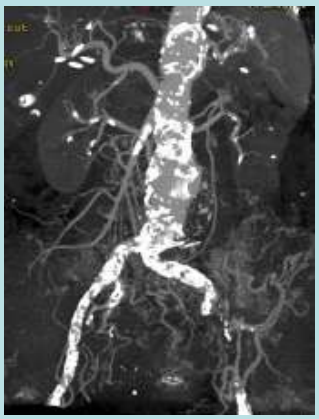
Aneurysm

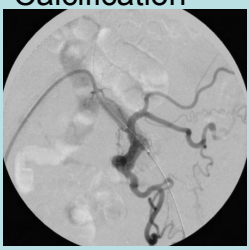
Occlusive disease

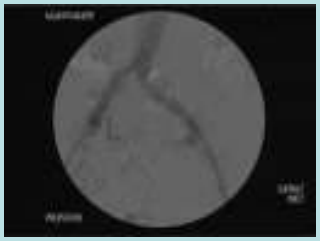
Occlusion

Tortuosity

Calcification

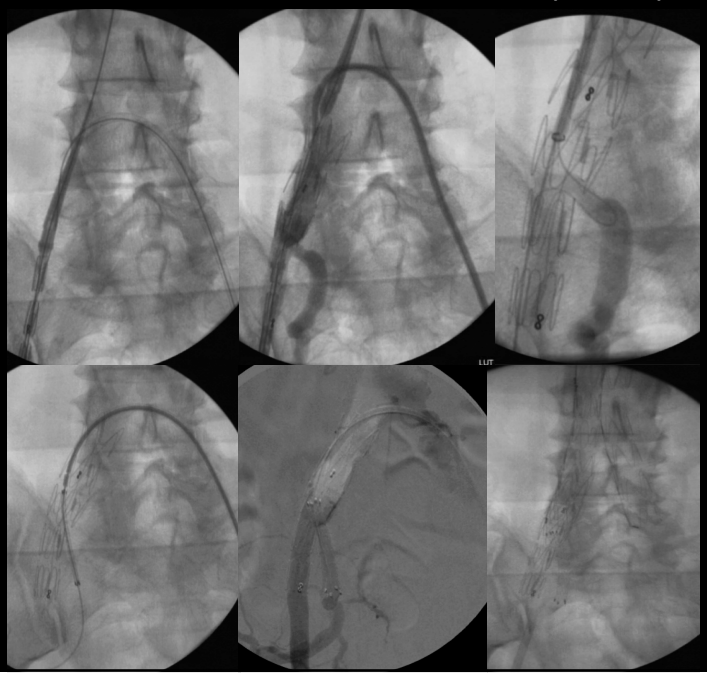






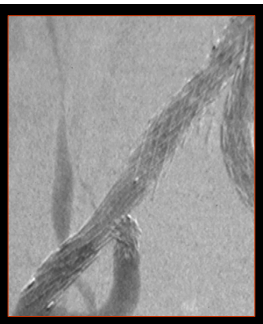
Iliac Bifurcation on the bench

Iliac Bifurcation – Limb Fenestration (feasible)



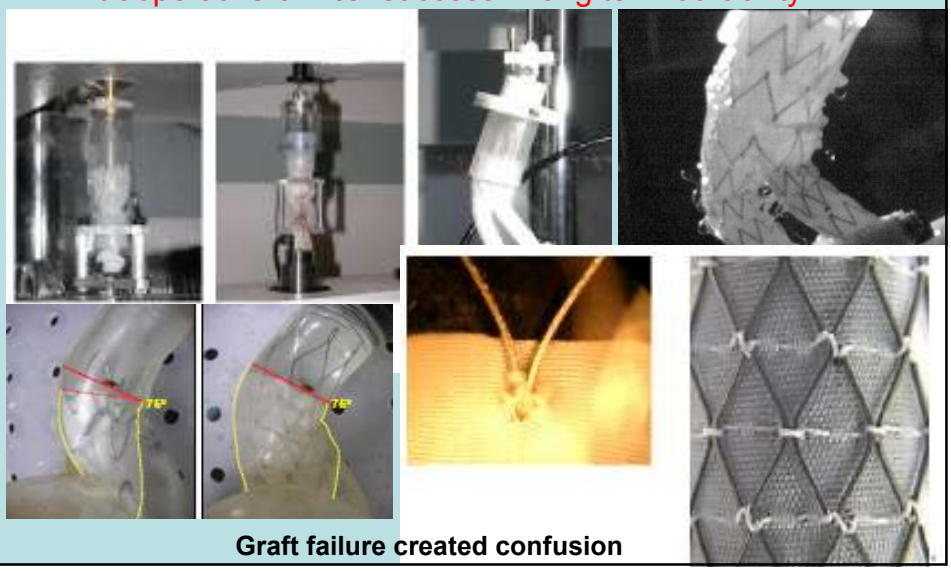
Iliac bifurcation ?

Commercial devices now available



The device – The endograft ***1991-2009***

EVAR a story of continuous development and evolution.
Intraoperative clinical success – long term durability.



Graft failure created confusion

Custom made grafts 1995-1998

96 patients (31 tube – 45 bifurcated – 13 aortouni)

87 men – 9 women Mean age 72 years

Mean diameter 59 mm
Neck length 5-60 mm
Neck diam. 18 – 33 mm
Neck angulation > 60 : 27 patients
64 iliac aneurysms – 32 extensive iliac tortuosity

Graft diameter 20 – 33 mm. Graft length 100 – 225 mm
21 iliac extensions – 10 cuffs

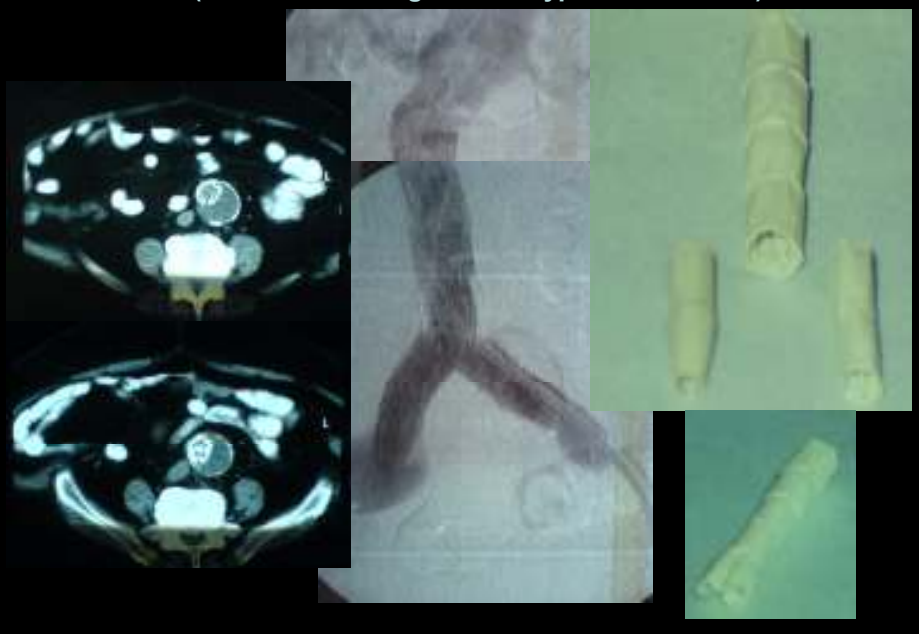
85 local – 11 epidural anesthesia
30 day mortality 3% - no conversions – 5.6 days mean hospital stay
30% endoleak rate mainly Type I

8 year follow up : 51 deaths (7 due to aneurysm)

6 conversions (2 deaths) – 34 reoperations (32 endovascular)

Papazoglou at. al.Eur Vasc Endovasc Surg 1999

Custom 3 tube bifurcated 12 years post
(Died 2 months ago due to type B dissection)



Approved in the USA (FDA)

Available in Europe (CE Mark)

Satisfactory 5 year results – *Longer ?*

AneuRx

Key Long-Term Clinical Results (1150 patients enrolled between June 1999 to September 1999)

Freedom from All Cause Mortality	85%	Through 5 years
Freedom from Aneurysm Related Mortality	98%	Through 5 years
Freedom from Aneurysm Rupture	97%	Through 5 years
Freedom from Conversion	95%	Through 5 years
Migration	4%	Through 5 years

Zenith

Key Long-Term Clinical Results (352 patients enrolled between January 2000 to July 2001)

Freedom from All Cause Mortality	74%	Through 5 years
Freedom from Aneurysm Related Mortality	97%	Through 5 years
Freedom from Aneurysm Rupture	99.7%	Through 5 years
Freedom from Conversion	98%	Through 5 years
Migration	3% 7% 8%	Through 5 years (STD Risk) Through 5 years (Poll-in) Through 5 years (High Risk)

Excluder

Key Long-Term Clinical Results (360 patients enrolled between December 1998 to November 2002)

Freedom from All Cause Mortality	79%	Through 5 years
Freedom from Aneurysm Related Mortality	98%	Through 5 years
Rupture	0.2%	Through 5 years
Conversion	3%	Through 5 years
Enlargement	17%	Through 5 years
Migration	6.5%	Through 5 years

Endologix

Key Long-Term Clinical Results (193 patients enrolled between July 2000 to March 2002)

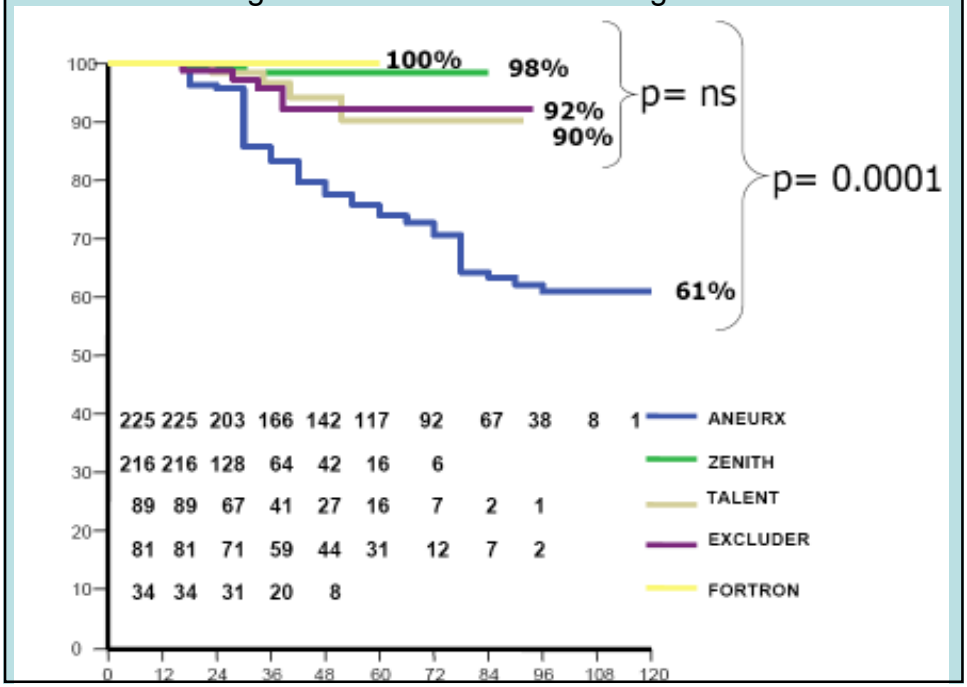
Freedom From All Cause Mortality	85%	Through 3 years
Freedom From Aneurysm Related Mortality	95%	At 18 months
Aneurysm Rupture	0%	At 72 months
Freedom From Secondary Procedures	83%	Through 5 years
Migration	4%	At 72 months

Talent

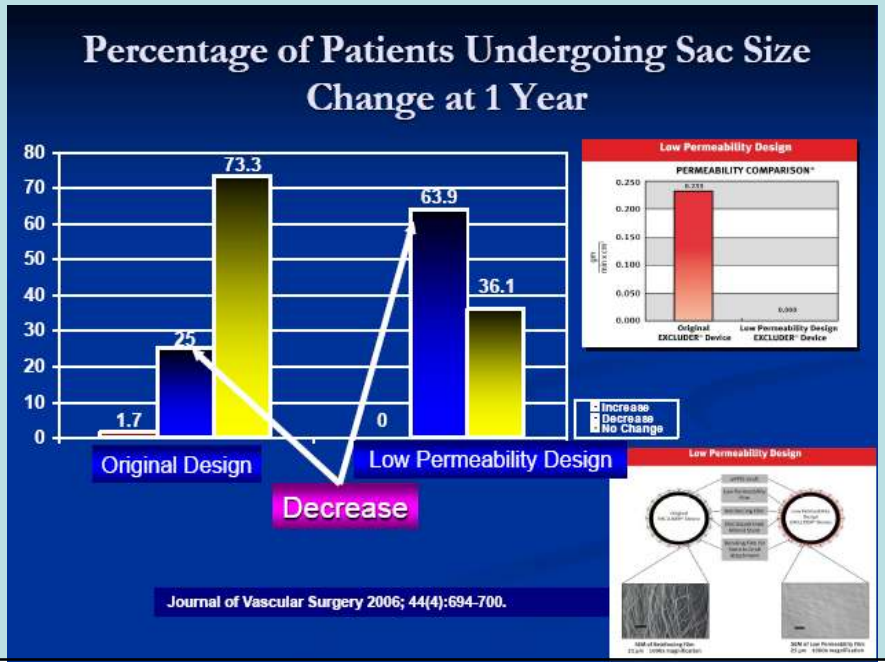
Key Long-Term Clinical Results (166 patients enrolled between February 2002 to April 2003)

Freedom from All Cause Mortality	71%	Through 6 years
Freedom from Aneurysm Related Mortality	97%	Through 6 years
Freedom from Aneurysm Rupture	98%	Through 6 years
Freedom from Secondary Procedures	90%	Through 6 years
Migration	1%	At 12 months

Migration rate of different endografts



Graft permeability change - Excluder



FDA notification 2007 (931 patients)

AneuRx device Medtronic *(FDA approved 1999)*

Worse results than previously estimated

Mortality rises from o.4% to 1.5% per year after the 4th year

5 year mortality related to this graft 5.3%

Reasons?

Migration, material fatigue, reoperations, rupture

Types of graft complications across both trials

EVAR 1,2

Type of complication (%)	Zenith N=427	Talent N=221
Graft rupture	5 (1.2%)	2 (0.9%)
Migration	2 (<1%)	5 (2.3%)
Type 1 leak	13 (3%)	10 (4.5%)
Type 3 leak	8 (1.2%)	1 (<1%)
Type 2 leak	12 (2.8%)	7 (3.2%)
Thrombosis	12 (2.8%)	3 (1.4%)
Other	25 (6%)	24 (11%)
Total	77 (18%)	52 (24%)

Proper Device selection *(Important!!)*

Graft – device size

Flexibility - adaptability

Fixation

Experience with the device deployment

Long term durability?

Especially if you do not follow IFU!!!

Team experience – Technique – Results

Team and Surgeons experience increases with training and increasing number of EVAR.

Technique improves with experience.

Results are getting better with increasing experience, Proper technique and device development.

The overall cost of the EVAR procedure drops.

(Short LOS, fewer postop. complications, more reasonable graft praises)

Team experience and outcome of EVAR (Eurostar)

	Team Experience (no. of procedures)			
	11 pts.	12-37 pts.	38-91 pts.	>92 pts.
Mortality	**12 %***	13 %	7 %	**5 %***
Sec. Interventions	**21 %****	18 %	11 %	**6 %****
Conversions	**6 %***	5 %	**2 %**	**2 %***
Ruptures	**0.8 %*****	0.7 %	0.6 %	**0.1 %*****

*p<0.02 , ** p=0.01, ***p<0.74

RJ Lahej et al. Eur Vasc Endovasc Surg 24; 2002

81000 patients – 2327 hospitals between 2001- 2003 Medicare USA

Table 1. Operative Mortality Rates by Hospital Volume and Type of Repair

Hospital Volume	Total AAA Repair Operative Mortality	Open AAA Repair Operative Mortality	Endovascular AAA Repair Operative Mortality	*P* Value[a]
Very High Volume	3.9%	5.2%	2.2%	<0.001
High Volume	4.7%	6.2%	2.3%	<0.001
Medium Volume	5.3%	6.6%	2.5%	<0.001
Low Volume	6.9%	7.8%	3.5%	<0.001

[a]*P* value for all comparisons.
During the 3-year study period, endovascular repair increased from 27% to 39% of total repairs ($P < 0.001$).

Personal experience with the Excluder graft

Between 4/2002 – 4/2009

Same medical team – 3 different hospitals

533 Patients with AAA
264 Excluder stent – graft *(low permeability)*
17 female – 247 male
Mean age 69.87years (46 – 92)

Patient characteristics

Age >80 years	23
CAD	178
Renal failure	27 (5 on dialysis)
Hypertension	192
Smoking	203
COPD	59
Diabetes mellitus	34
Obesity	29
Cancer	15
Cerebrovascular Infract	5

Anatomical data	Mean value	Range
Proximal neck **diameter** (mm)	24.8 mm	19-30
Proximal neck **length** (mm)	30.3 mm	5-75
Aneurysm max diameter (mm)	55.6 mm	36-130
Severe proximal neck angulation (>60°)	71 patients	
Tortuous iliac arteries	36patients	
Concomitant iliac aneurysms	59 patients	
Severe occlusive disease of the iliac arteries	48 patients	
Unilateral iliac artery occlusion	5 patients	

❑ Operative technique

•**Local anesthesia**

•Bilateral 3-4 cm transverse groin incision

•Needle puncture of proximal femoral art.

•Proximal neck angiogram through sheath

•Slow controlled if needed proximal graft deployment

•Iliac bifurcation angiogram before limb deployment

•Balloon dilatation of the graft (Reliant Medtronic)

•Completion angiogram and arterial closure with 5/0 prolene continuous suture

Operative results

- Mean operative time 64 min
- Mean fluoroscopy time 13 min
- Contrast media 250 (120 – 450 cc)

- 257 cases bifurcated (26 – 31 mm)
- 3 cases aortouniliac conversion and fem – fem
- 4 case aortouniliac without fem – fem

- 21 cuffs in 18 cases
- 62 iliac extensions
- 29 hypogastric occlusions
  (2 bilateral – 5 unintentional)
- 11 hypogastric embolizations
- 4 bell-bottom iliac limbs (26 mm)
- 1 double-barrel iliac bifurcation

- 7 renal angioplasties
- 1 carotid angioplasty
- 1 thoracic stent graft
- 3 iliac recanalisations
- 1 IMA transposition
- 1 cholecystectomy – 1 ERCP

❑ Intra – Postoperative Complications

- 1 migration treated with a second graft
- 4 iliac dissections – iliac stenting
- 1 iliac rupture – limb extension to the femoral artery
- 2 iliac thrombectomies
- 5 femoral endarterectomies (1 post 6 hours)
- 1 renal occlusion
- 1 renal hematoma

- 38 cases creatinine elevation >2
- 28 cases postop. fever >37.5
- 5 cases 12 - 24 h ICU stay
- 1 minor MI

❑ Postoperative management

•Medication	antibiotics, statins
•Intraoperative	2 plasma units
•Alimentation	Immediate
•Mobilization	12 hours
•Mean Hospital stay	41 hours
•Blood transfusion	150 cc (0-600)

❑ Follow Up 3 – 70 months (76%)

No conversions
No migrations

Endoleaks	Immediate	Follow up
Type I	10 (9 closed)	2 (1 closed)
Type II	12 (8 closed)	23 (7 closed)
Type III	0	0
Type IV	0	0

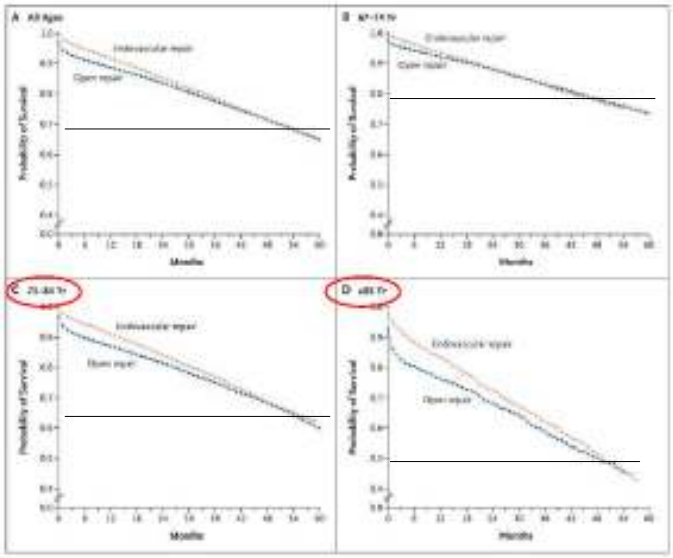
•**Reoperations 12 (4.5%)**
•5 iliac extensions – 1 proximal extension
•(3 type I distal endoleaks, 2 iliac aneurysm exclusions)
•2 limb thrombosis (1 thrombectomy – limb dilatation)
•1 celiac artery angioplasty
•1 renal angioplasty
•1 IMA ligation for type II endoleak
•1 hypogastric embolisation

•Diameter: Decreasing or stable except in 5 cases

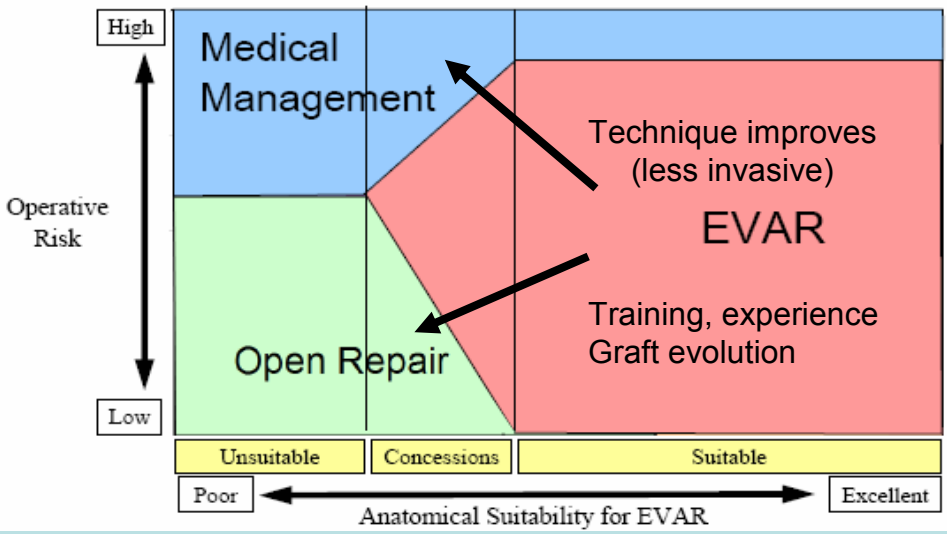
EVAR replaced standard repair in most cases. Why?

EVAR vs open repair of AAA in the Medicare population

Schermerhorn ML, NEJM, 358, January 2008



EVAR replaced standard repair in most cases. Why?



EVAR replaced standard repair in most cases. Why?

Physician experience grows

Endovascular grafts improve

Clinical results better

Long term results acceptable

Cost drops

Hospitals, health care adapt

Patients prefer !!!