Endovascular Grafting of the Aorta: Identification of the Endograft Candidate

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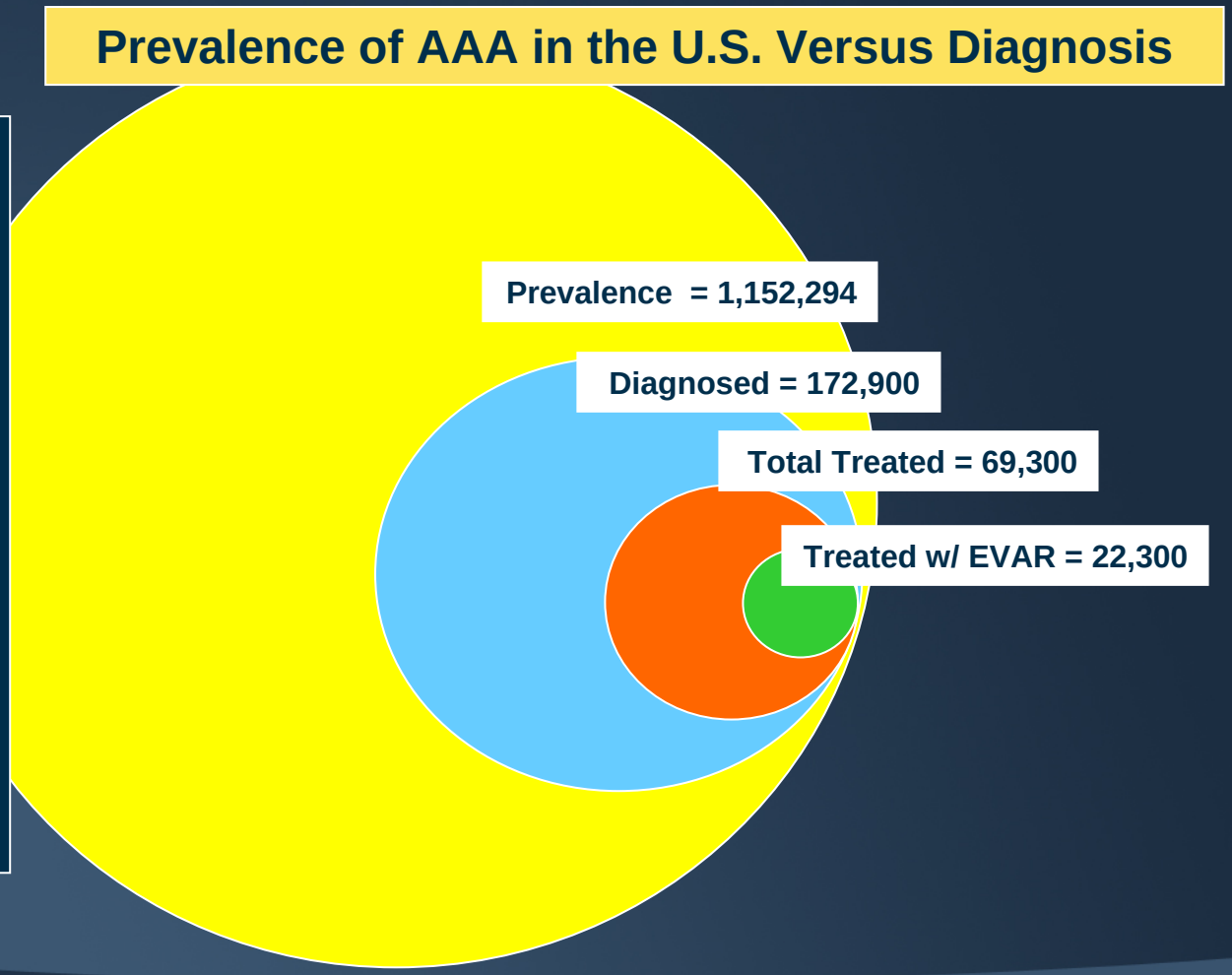
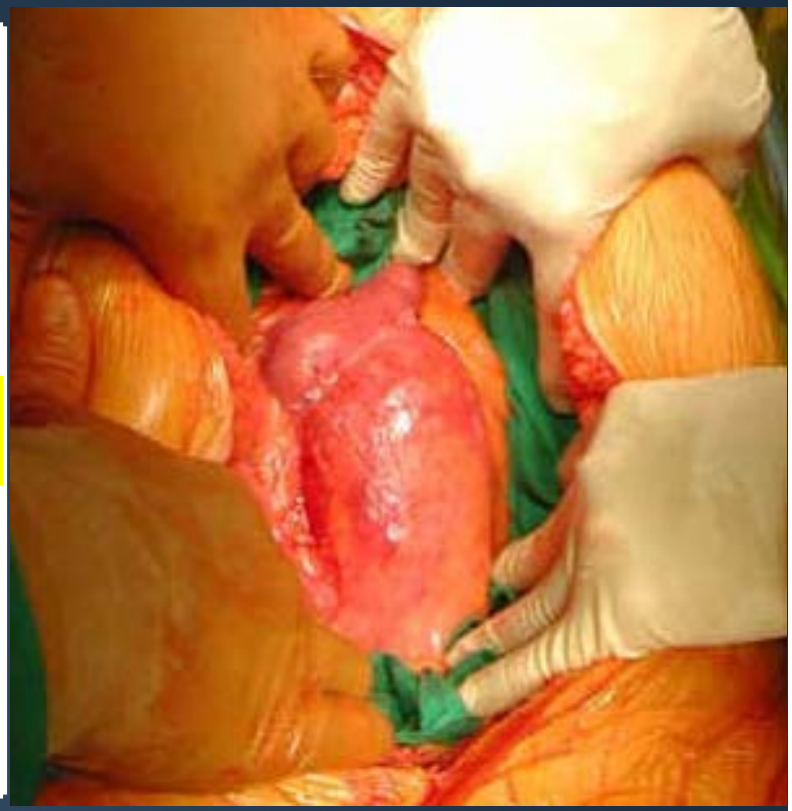
AAA is under diagnosed and under treated

- The prevalence of AAA in men is 4.5% and in women is 1.0% (data from SAVE screenings)
- 1,152,294 patients living with AAA
- 15% are diagnosed
- 6% are treated



Abdominal Aortic Aneurysm

Diameter	Annual Risk of Rupture
< 4 cm	0 %
4 - 5 cm	0.5 - 5 %
5 - 6 cm	3 - 15 %
6 - 7 cm	10 - 20 %
7 - 8 cm	20 - 40 %
> 8 cm	30 - 50 %



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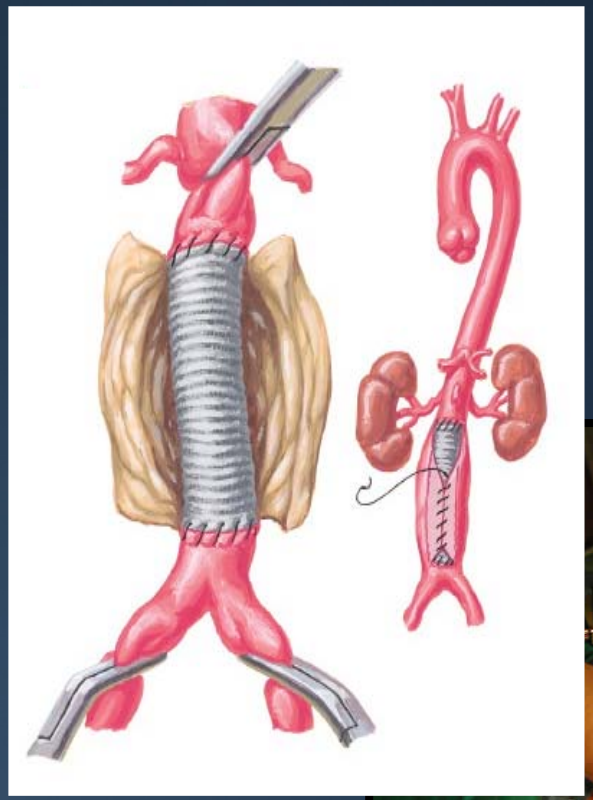
J Vasc Surg 2003;37:1106-17

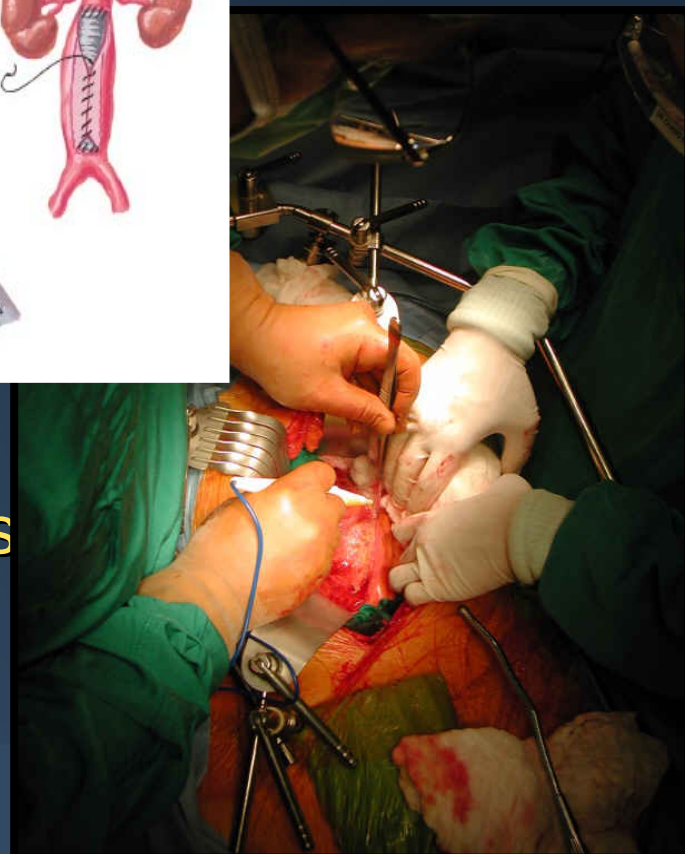
Threshold to intervention

- Prophylactic treatment decisions can be difficult (asymptomatic patients)
- Major considerations are operative mortality and life expectancy compared to risk of rupture
- In general, AAA's 5.0-5.5 cms in reasonable risk patients should be repaired
  - AAA's exceeding the expected rate of growth of 10% per year warrant repair
- EVAR may lower the threshold to treat

Elective open repair AAA

- Major surgical procedure
  - Mortality 2% to 5%
- Complications
  - Pseudoaneurysms
  - Erectile dysfunction
  - Aortoenteric fistula
  - Graft thrombosis
  - Graft infection
- Recovery period 6 weeks to 4 months





Functional Outcomes Following Open AAA Repair

- 154 consecutive elective AAA repairs
  - 1990-1997
- Operative mortality 4%
- Mean hospital stay 10.7 days
- Mean ICU stay 4.57 days
- 11% of pts transferred to skilled nursing facility
  - Mean stay 3.66 months
- Only 64% of patients experienced complete recovery
  - Mean time 3.9 mos
- 33% were not fully recovered at mean f/u of 34 mos
- 18% said they would not undergo AAA repair again knowing recovery process

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J Vasc Surg 2001;33:913-20

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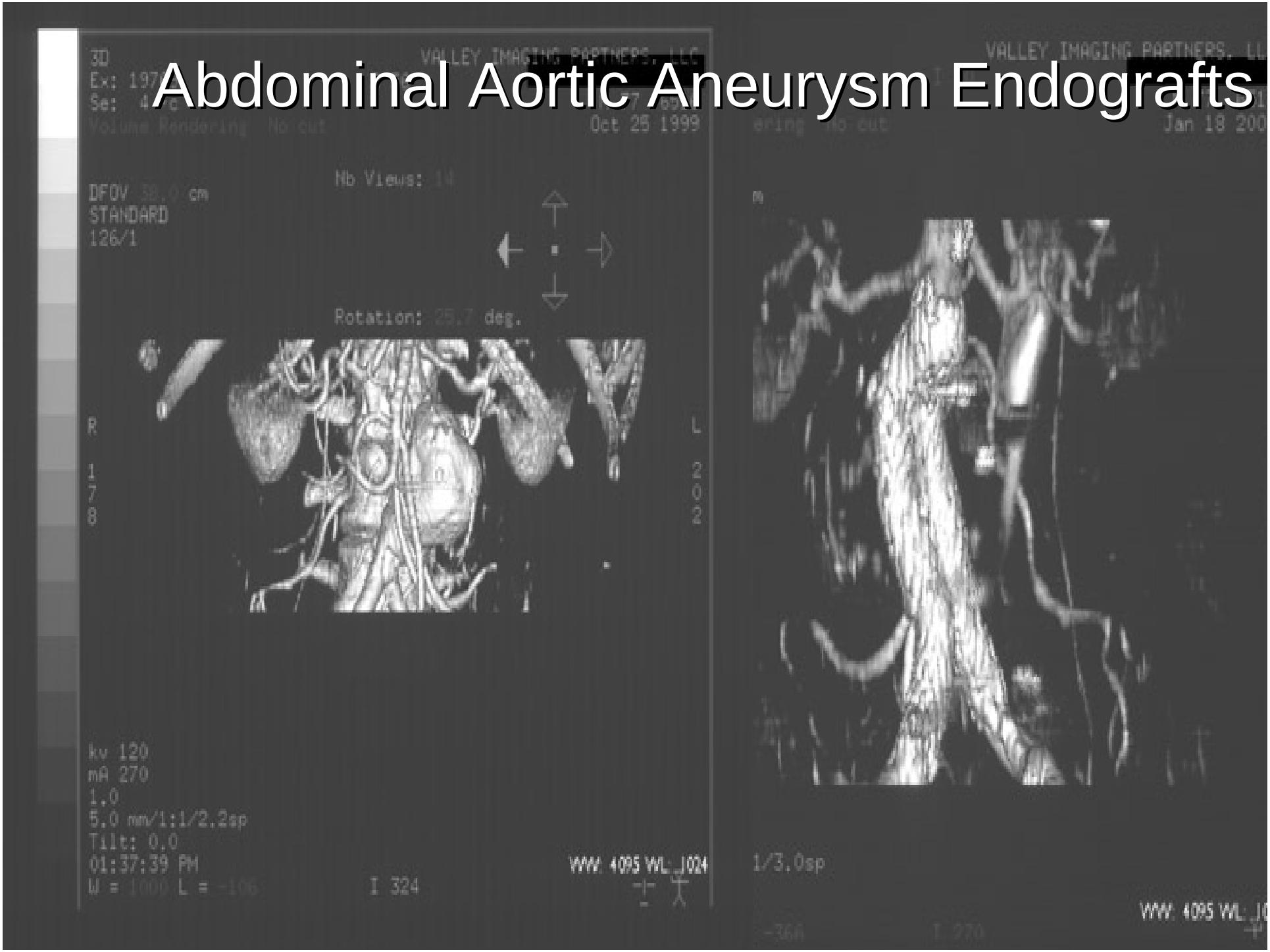
Endovascular Repair

- Proven benefits
  - Minimally invasive
  - Reduced morbidity
  - Reduced hospital stay
  - Early return to function
    - Typically 2 to 4 weeks for full recovery

Abdominal Aortic Aneurysm Endografts



Outcomes with EVAR: Lifeline Registry
Freedom from aneurysm-related issues

- 2664 EVAR vs. 334 open repairs
- K-M analysis at 6 years:
  - 99% freedom from rupture
  - 98% freedom from aneurysm-related death
  - 95% freedom from surgical conversion

EVAR 1: Trial descriptors

- Randomized controlled trial EVAR vs. open repair in patients referred for EVAR
- Enrollment period: 1999-2003
- Total randomized: 1082 (539 EVAR vs. 543 open)
- Inclusion criteria
  - Male or female
  - Aged at least 60
  - AAA diameter >5.5cm on CT scan
  - AAA anatomically suitable for EVAR
- Endpoints:
  - 30 day mortality
  - All cause and aneurysm-related death in follow-up

EVAR 1 : All-cause mortality

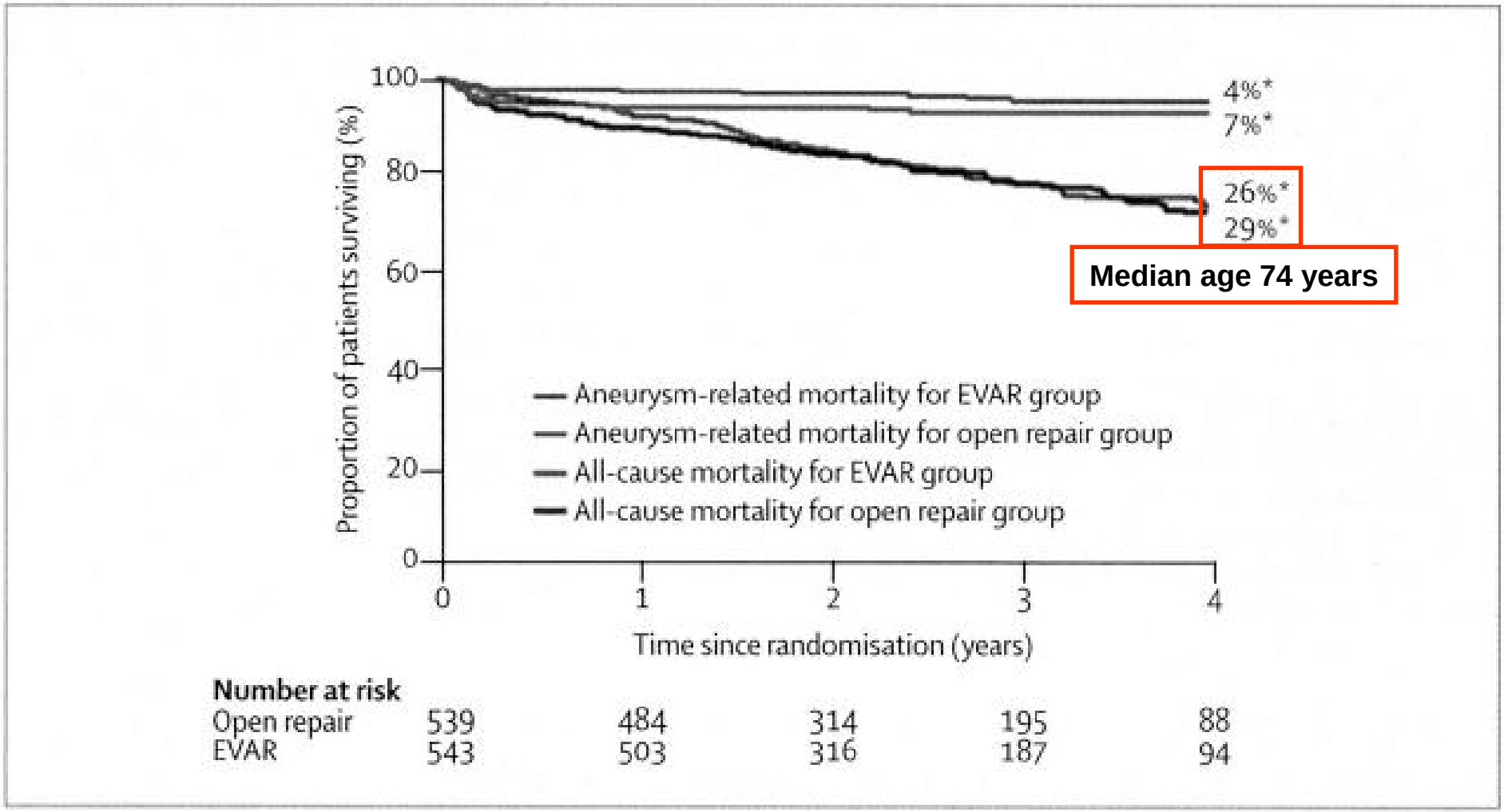
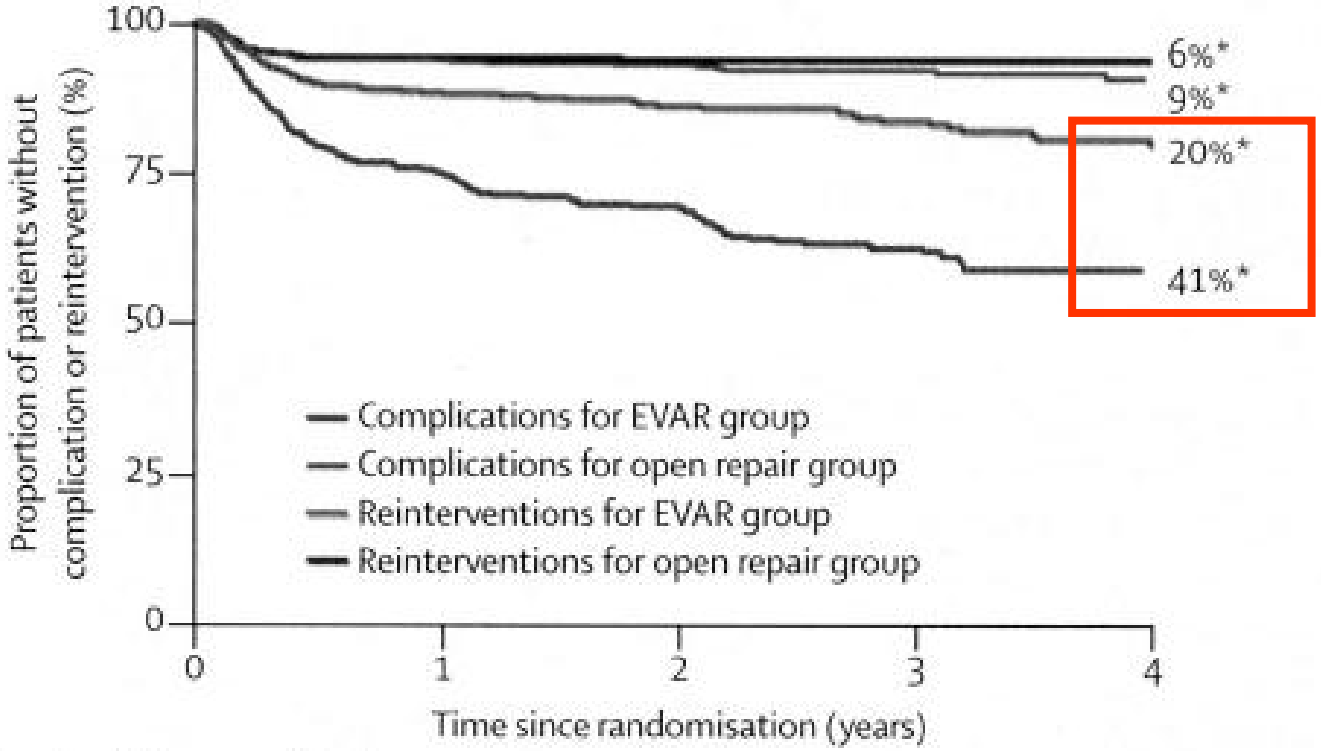


Figure 2: **Kaplan-Meier curve of survival and survival free from aneurysm-related death**

*Mortality 4-year point estimates.



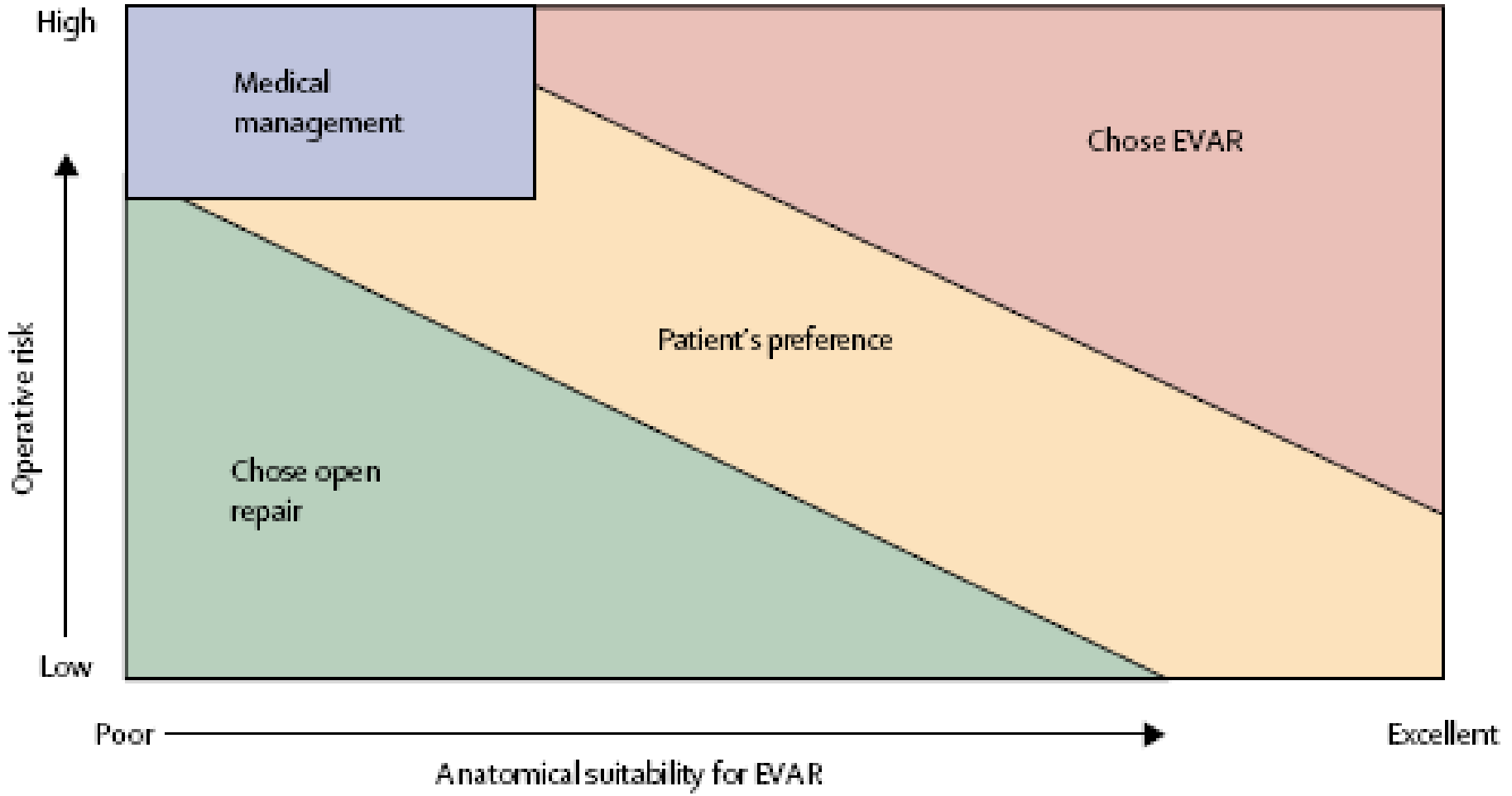
Number at risk for complications					
Open repair	539	466	301	182	82
EVAR	543	386	235	134	67

Number at risk for reinterventions					
No intervention	539	468	304	189	88
EVAR	543	450	278	168	80

***Figure 3*: Kaplan-Meier curve of postoperative complications and reinterventions**

*4-year point estimates for patients with complications or reinterventions.

EVAR vs Open surgery: strategy

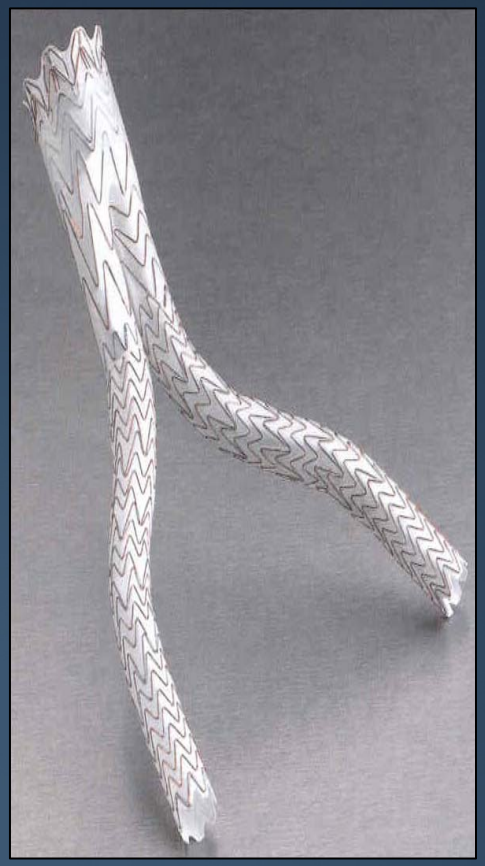


Jack L Cronenwett, Lancet Vol 365 June 25, 2005

Currently Available Devices (U.S.)

Medtronic AneuRx

US Trial Implants 1193



Gore Excluder

US Trial Implants 235

Cook Zenith

US Trial Implants 352

Endologix Powerlink

US Trial Implants 192

Medtronic Talent AAA Stent Graft System

- Flexible, independent stents
- Active, supra-renal fixation
- May suit challenging anatomies
- Low profile: 18, 21 F
- US Clinical trial launch: 2008

Device profiles

company	device	neck diameter	outer diameter	fixation location	graft material
cook	zenith	22,24,26, 28,30,32	20F,23F	suprarenal	woven polyester
endologix	power-link	25,28	21F,22F	infrarenal	ePTFE
wlgore	excluder	23,26, 28.5	18F	infrarenal	ePTFE
medtronic	aneuRx	20,22,24, 26,28	21F	infrarenal	woven polyester

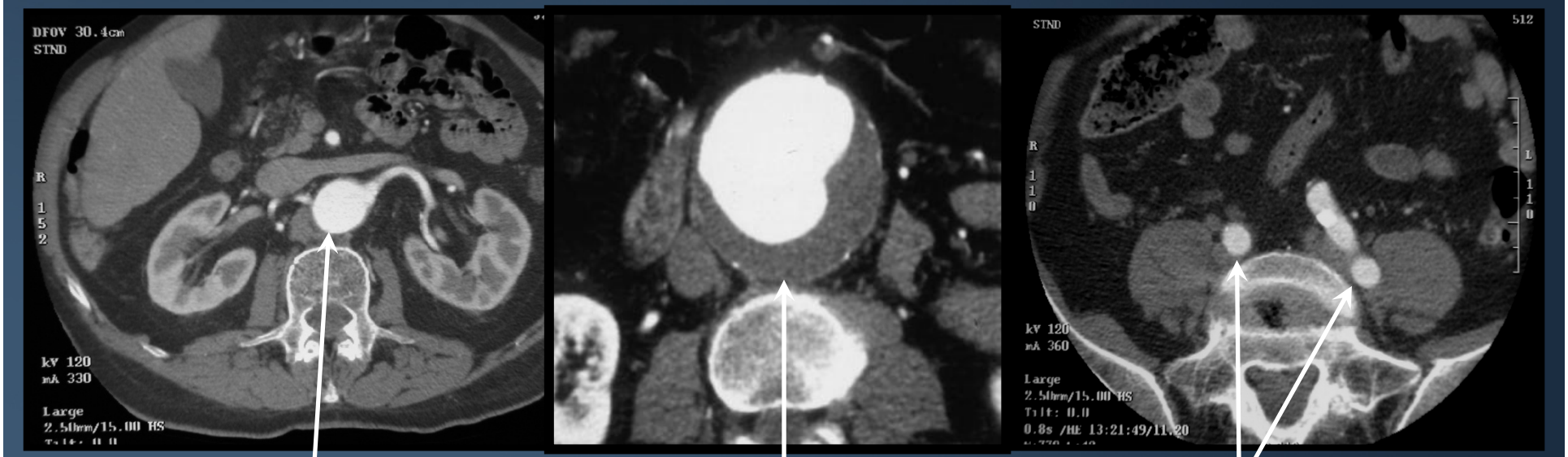
Anatomic considerations/limitations

Endovascular Stent Grafts

- Proximal aortic neck
  - Diameter of device oversized 10-20%
  - Length ≥ 1.0-1.5cm for all FDA approved devices
- Angulation/tortuosity
  - Short angulated necks, short wide necks, & severe AAA tortuosity can lead to suboptimal outcomes
- Iliac access
  - Large enough to accommodate 18F-21F delivery systems (~7mm for bifurcated devices)

Preoperative Imaging

CTA (3mm cuts)

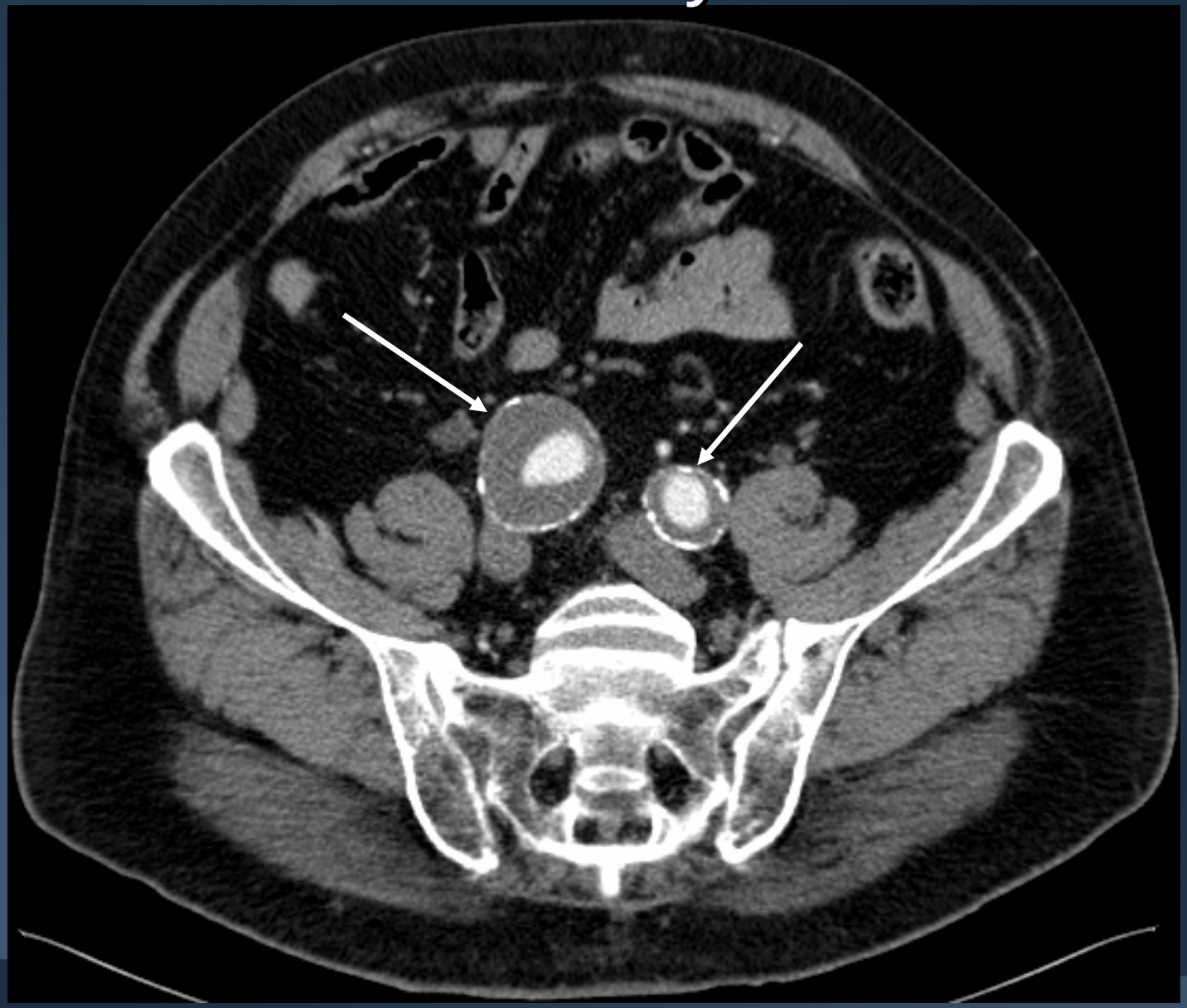


Infrarenal neck

Aneurysm with thrombus

Iliac access

Iliac aneurysms



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INTRAOPERATIVE ANGIOGRAM

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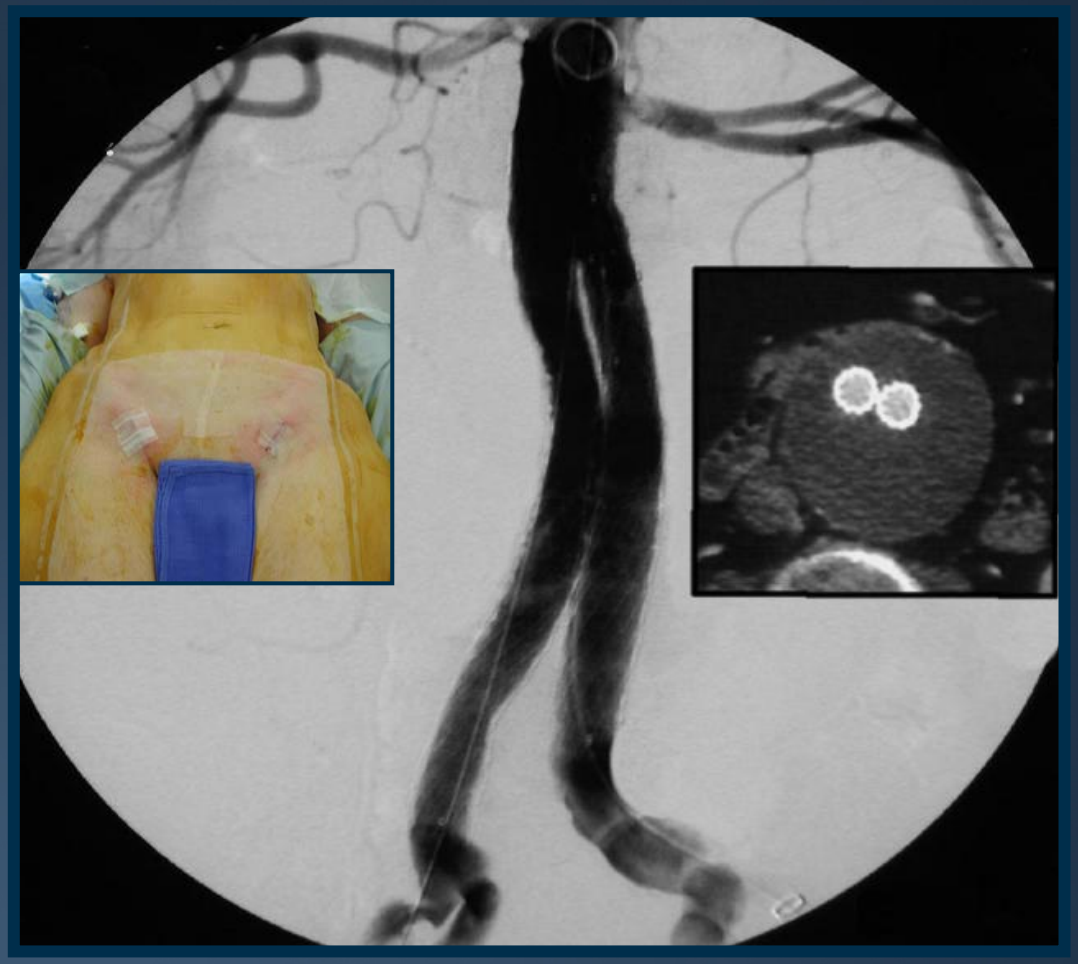
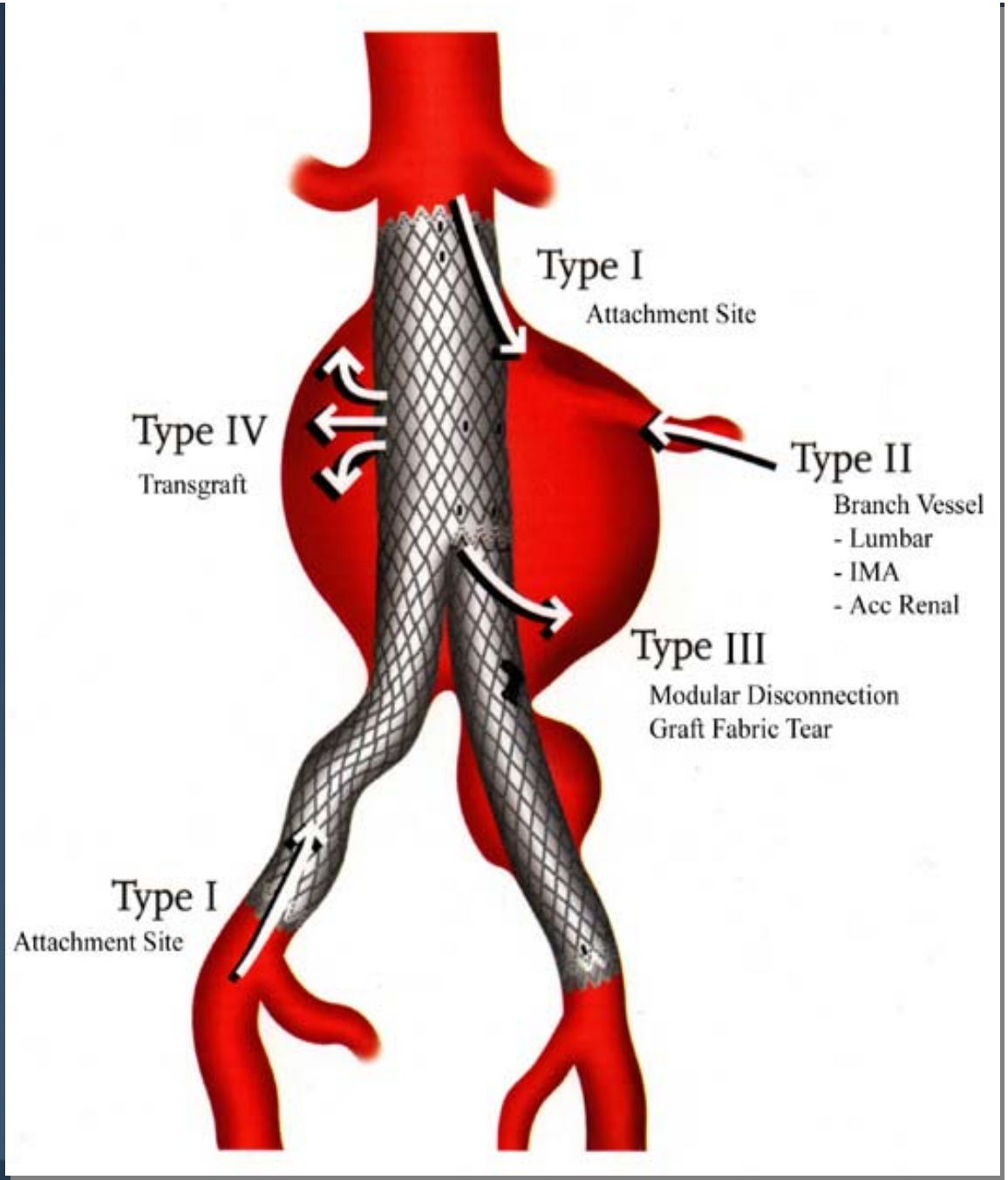


- Completion angiogram shows aneurysm exclusion
- Groins repaired
- Follow-up CTA reveals thrombosis of AAA sac

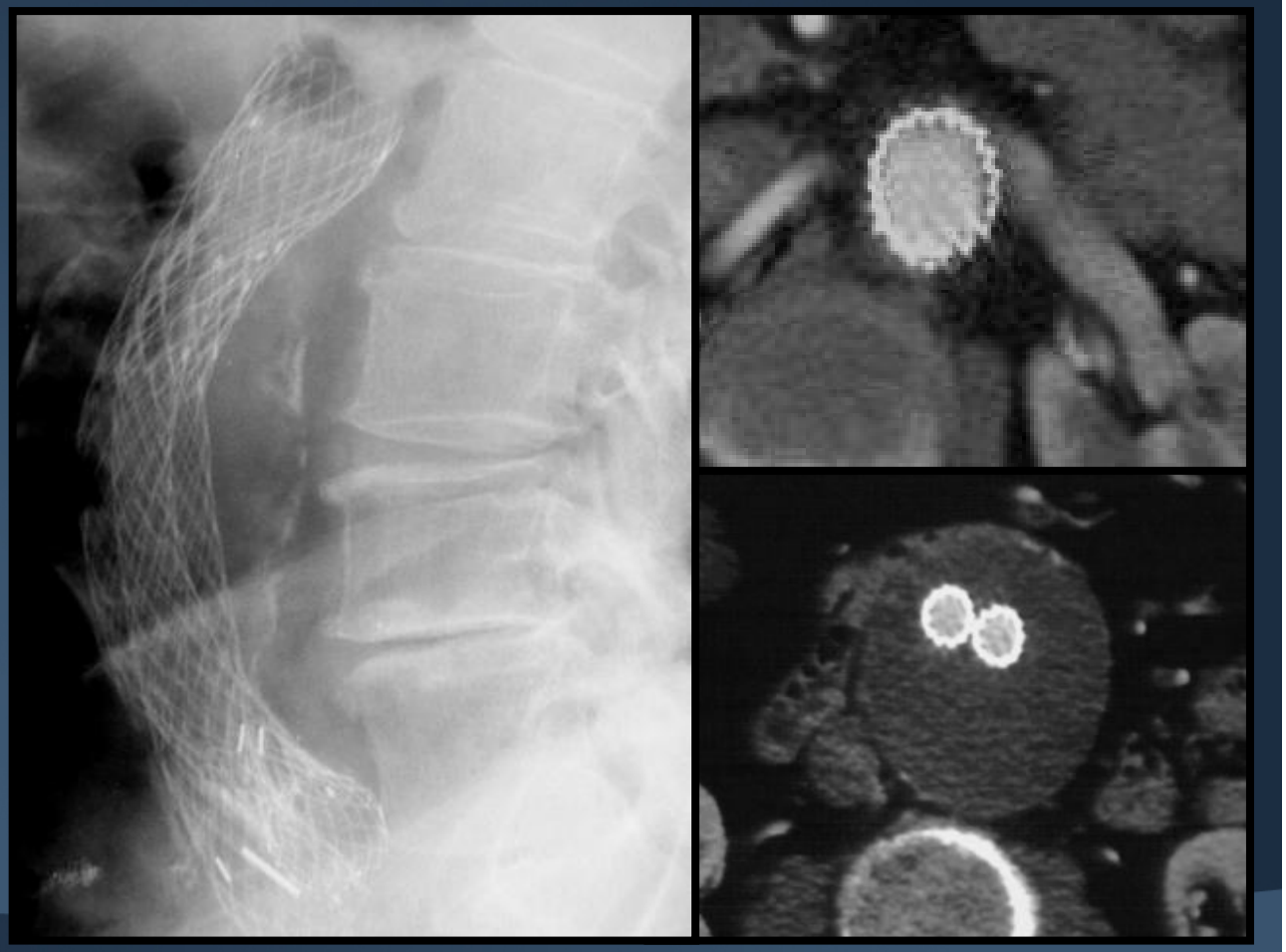
Endoleaks


Type I
Attachment Site
Type IV
Transgraft
Type II
Branch Vessel
- Lumbar
- IMA
- Acc Renal
Type III
Modular Disconnection
Graft Fabric Tear
Type I
Attachment Site

Follow-Up Imaging

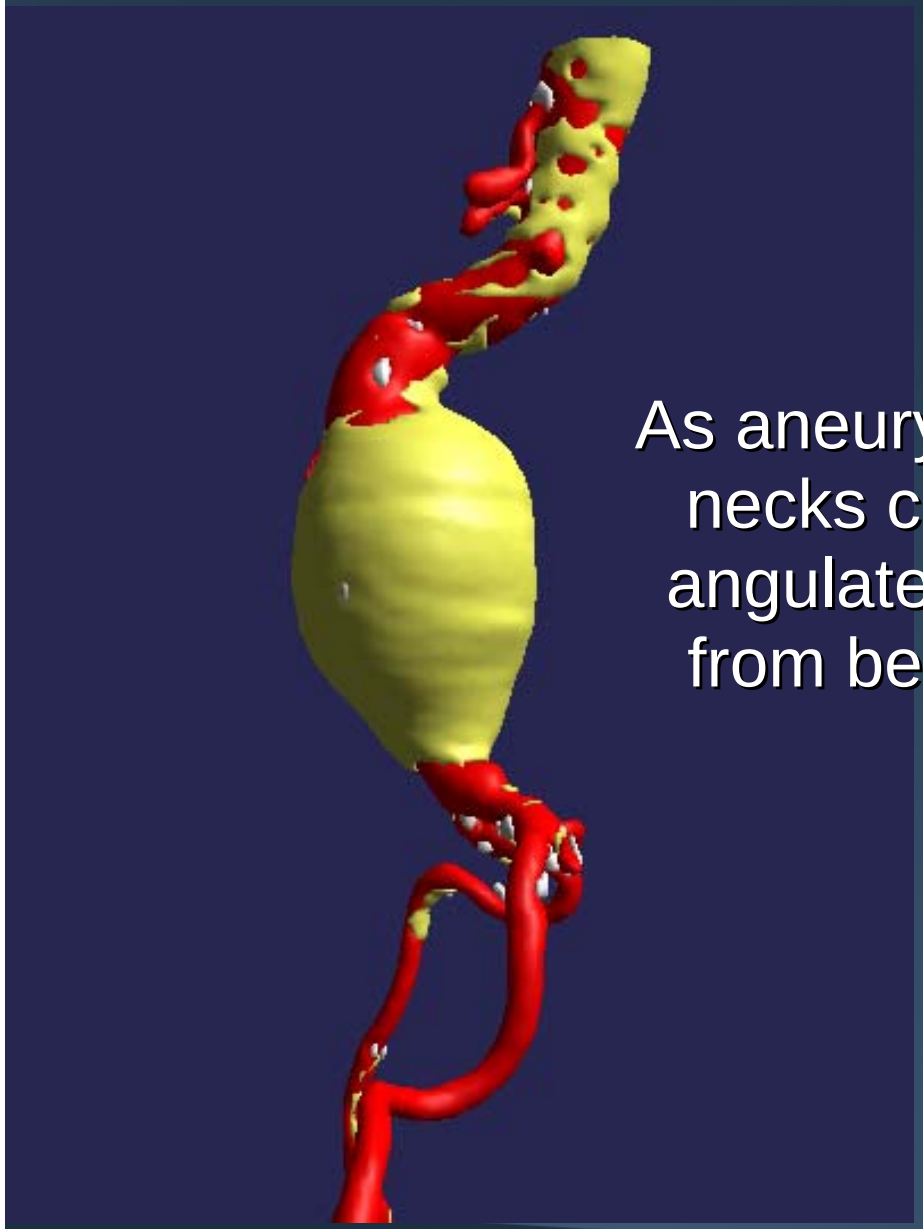
CTA to assess endoleak and size

- 1 month
- 6 months
- 12 months
- Annually



Alternatives to CT scanning

- Ultrasound with or without contrast agent
- Cardiomems device to assess endotension
  - May be more sensitive than other methods
  - Allows for direct measurement of pressure within the excluded sac
  - Need data to support endotension as a predictor of delayed rupture
  - Requires specialized monitoring equipment



As aneurysms grow in size, proximal necks can become shorter and more angulated which may preclude patient from being good anatomic candidate for stent graft

Small vs. large AAA

2 year clinical outcomes following EVAR

	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
J Vasc Surg 2003;37:1206-12

PIVOTAL Trial

- Positive Impact of endovascular options for treating aneurysms
- Randomization of close to 1700 patients with 4-5cm AAA's to EVAR or continued follow up
- AAA's must exceed double the diameter of the reference aorta and meet inclusion criteria for the AneuRX device
- Patients who become symptomatic, exceed 5.0 cms or experience rapid growth will be offered repair

What is on the horizon for EVAR?

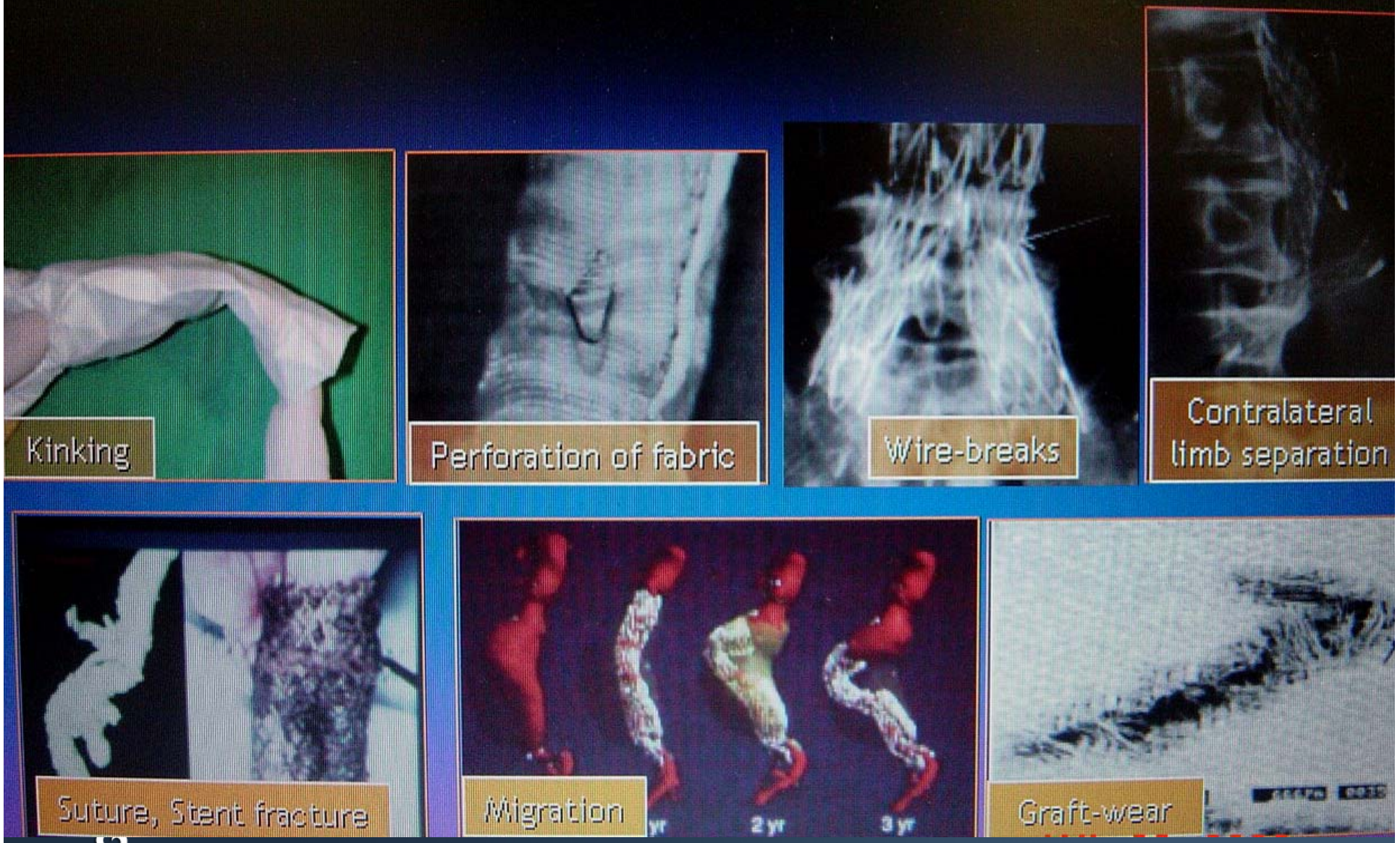
Next generation endografts: goals

Improved durability

Improved deliverability

Improved applicability

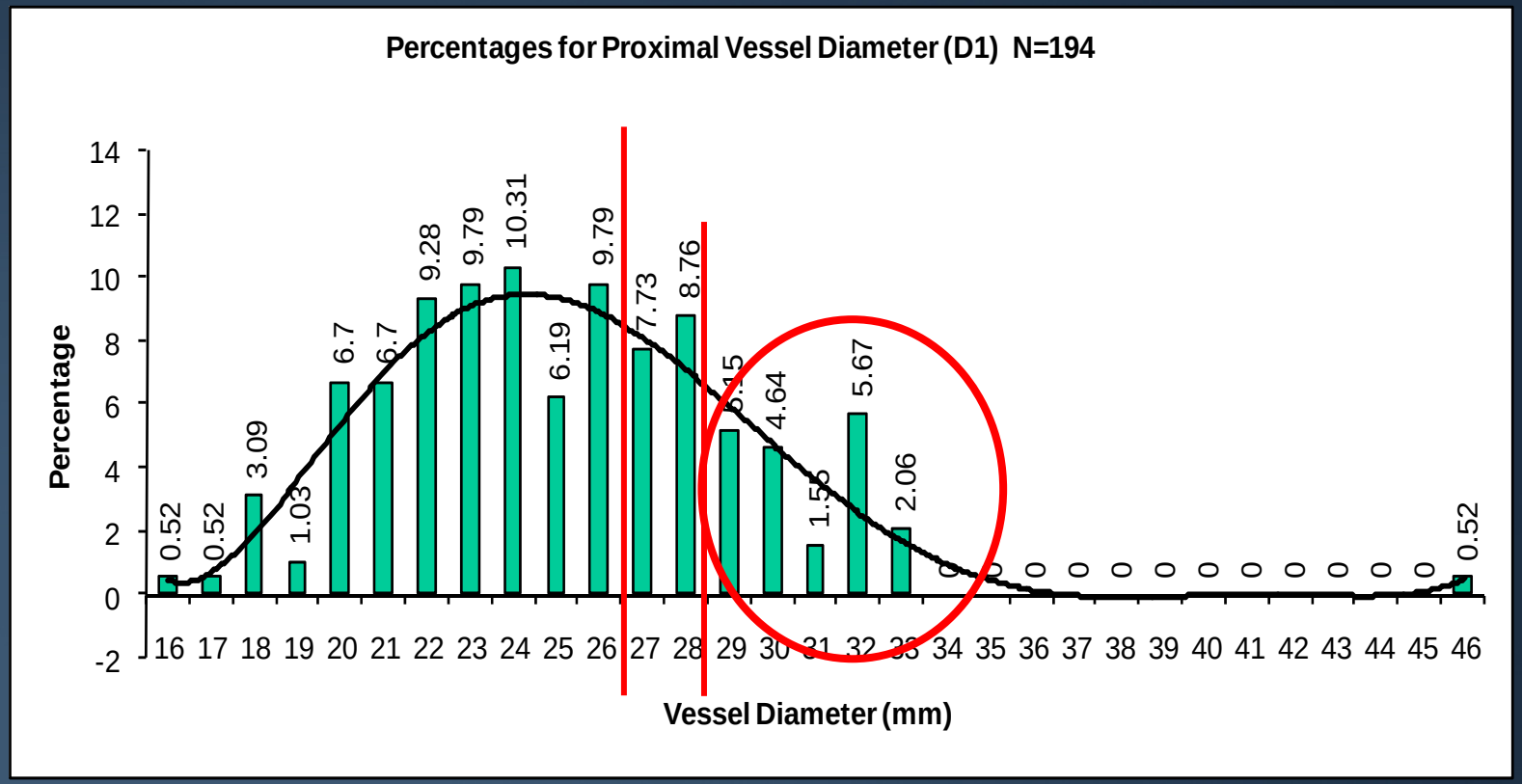
Specific stent-graft durability issues



Limits of AAA endograft application

Medtronic Talent US Clinical Trial

Proximal neck diameter: 47% ≥ 26mm



Frank Criado, Presented at ISET 2002

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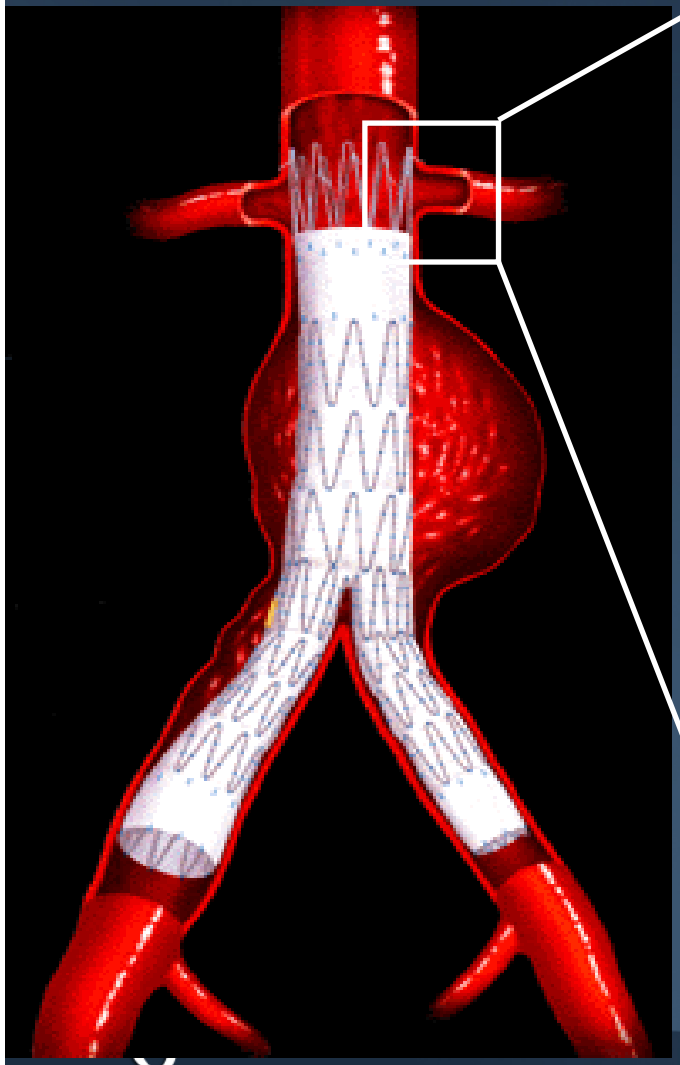
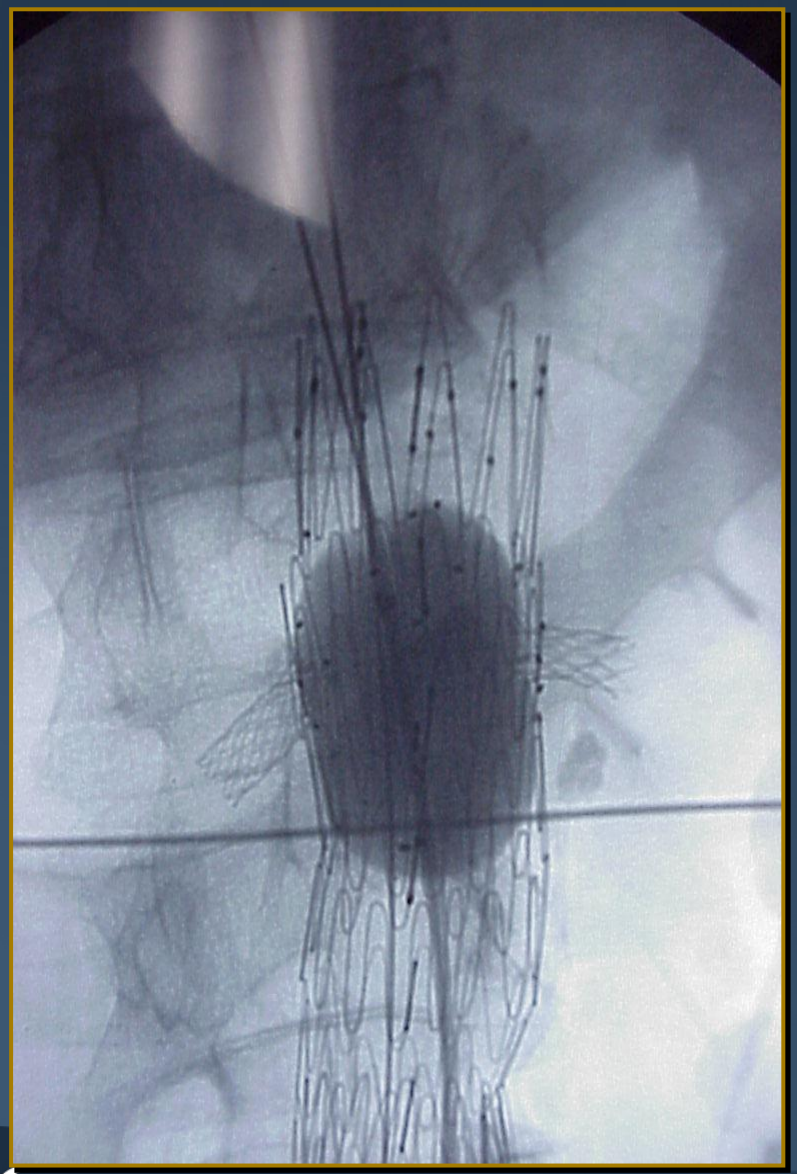
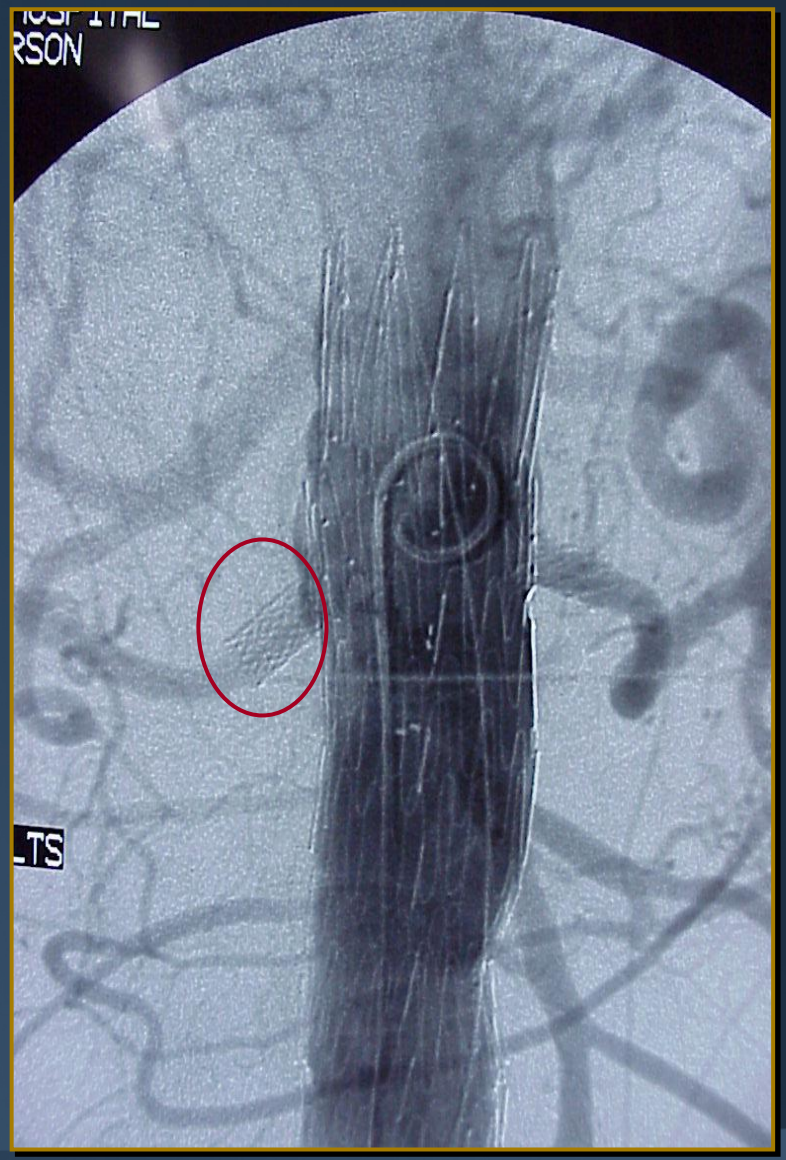
Extending applicability: Cook fenestrated







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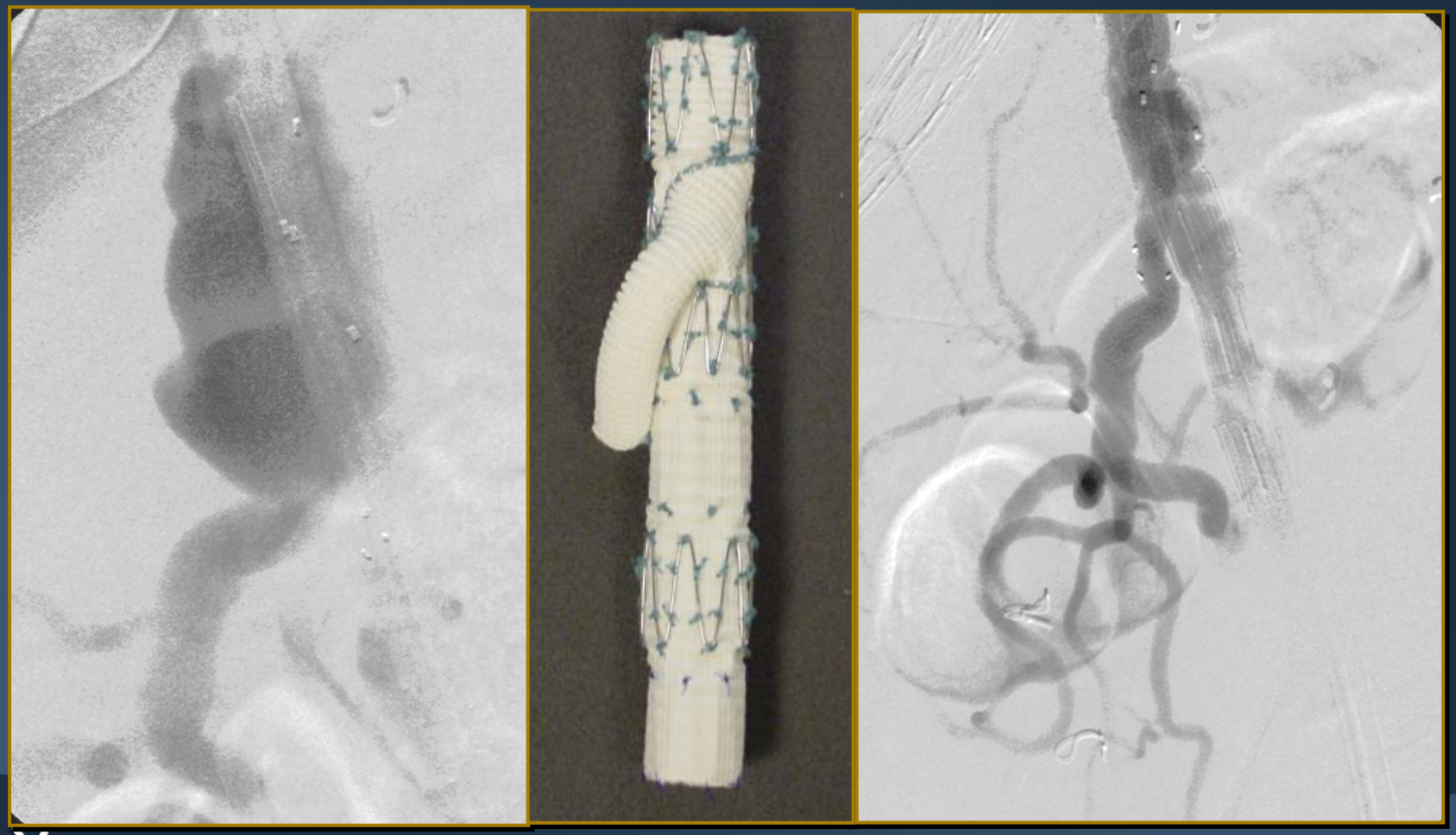
Extending applicability: branch grafts

Common Iliac Aneurysm



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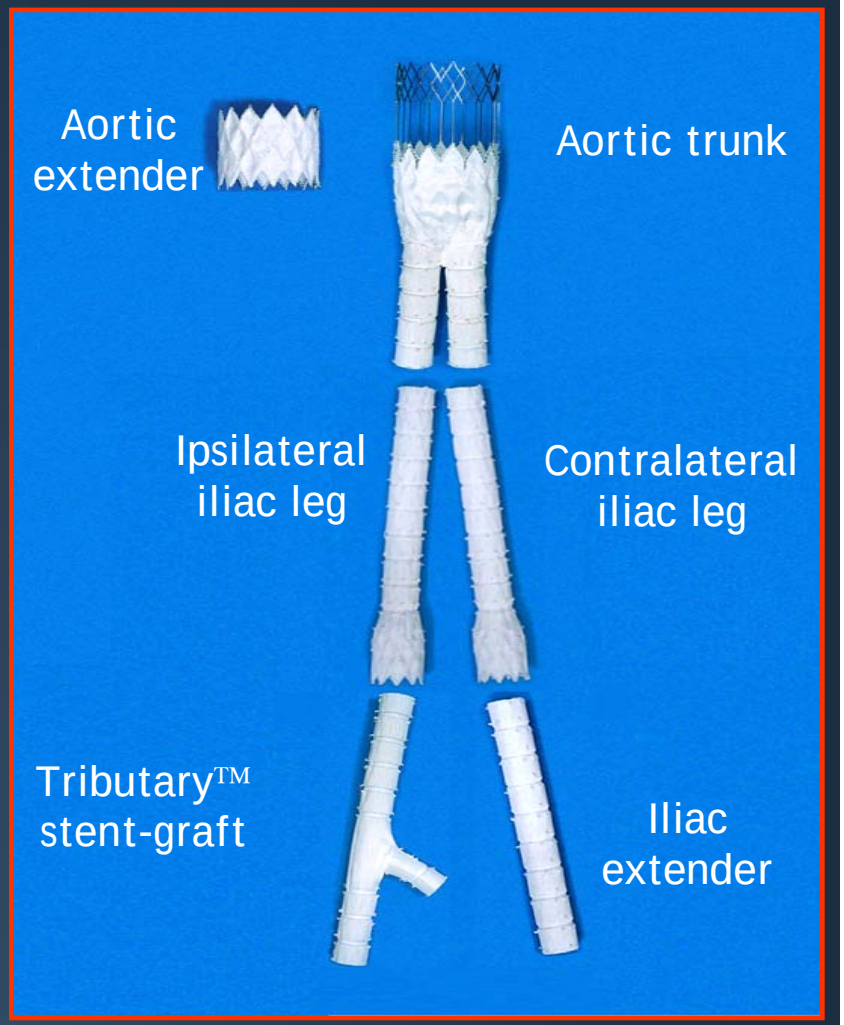
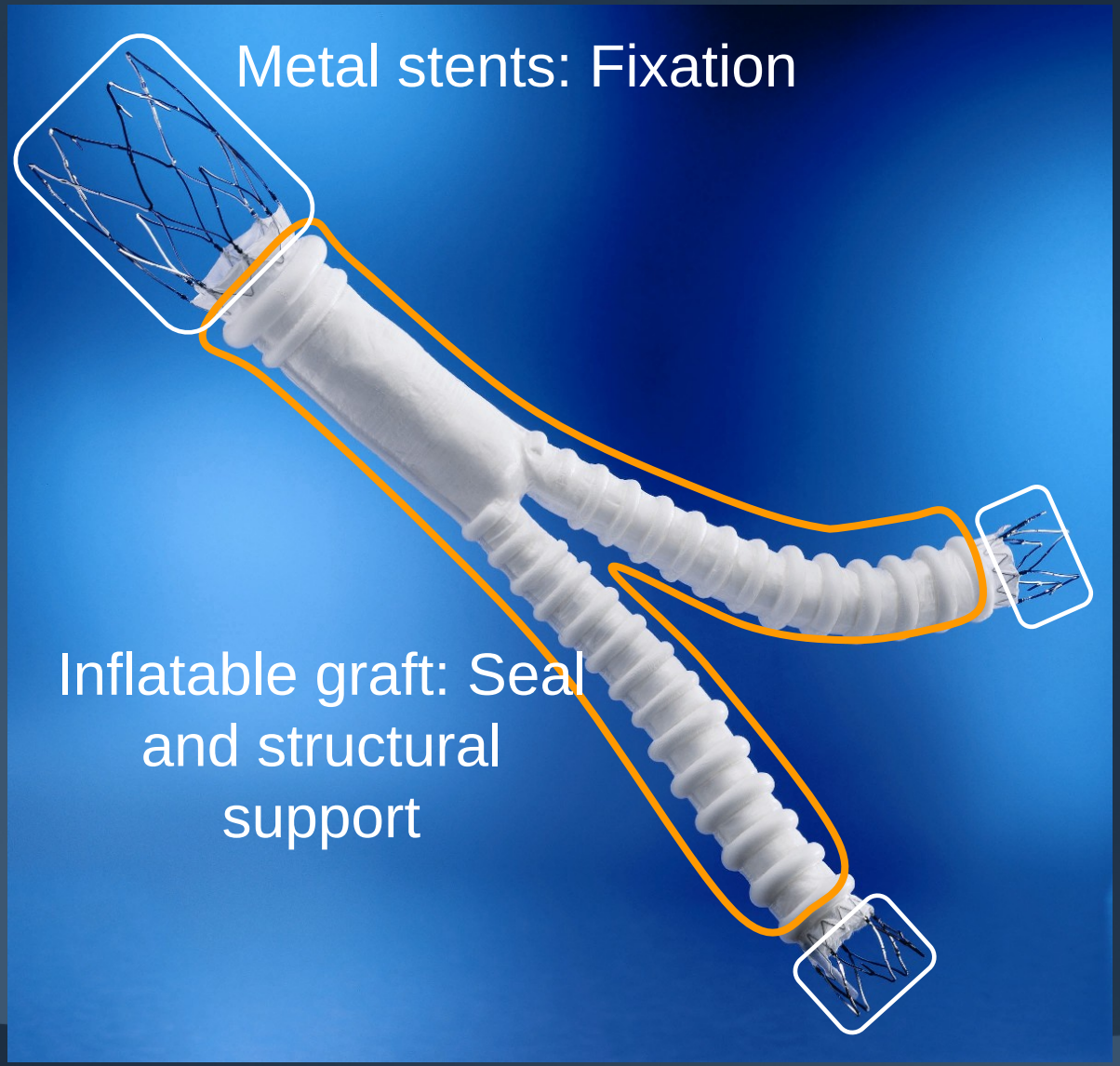
Cordis/J&J Fortron

- Pros
  - Supra-renal active fixation
  - Branch vessel option
  - Aorta up to 30 mm
- Cons
  - Difficulties with angulated neck
  - Several incidences of supra-renal stent fractures

- 3 delivery system failures encountered in Germany
- Voluntary product recalled in EU



Trivascular/BSC *E* NOVUS AAA Stent Graft
(14 Fr Percutaneous system)



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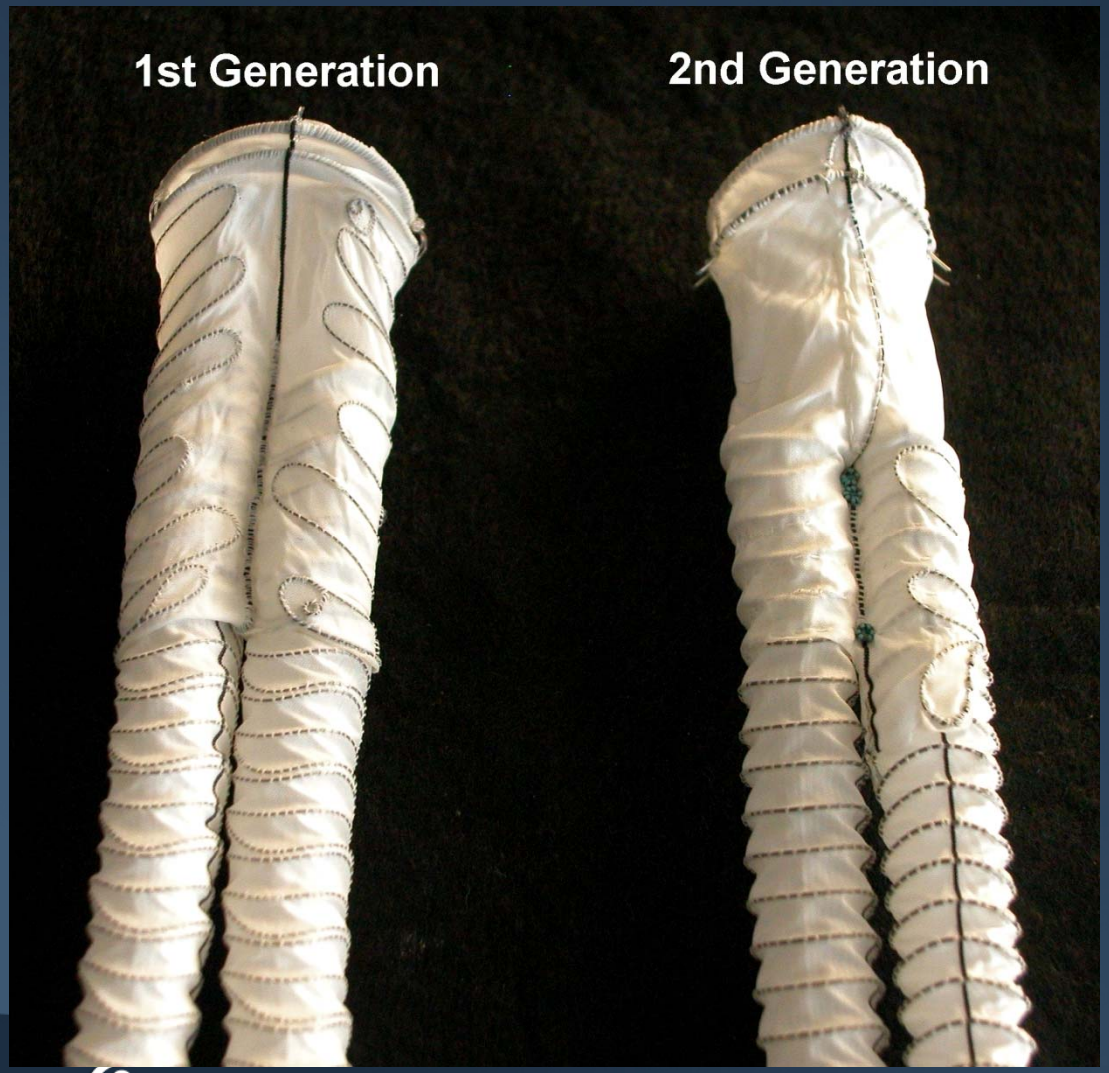
Trivascular/BSC Enovus

- Completed Phase 1 trial in 2Q 2004
- FDA approval for Phase 2, Feb 12, 2005
  - Started pivotal trial 4Q, 2005
- Nov 2005 up to 30% rate of stent-fabric separation noted
- Phase 2 trial halted
- Need for and degree of revision now being contemplated
- Company re-acquired by founders

Terumo Anaconda Vascutek



8 barbs added to prevent migration

More circular stent to evenly distribute stress

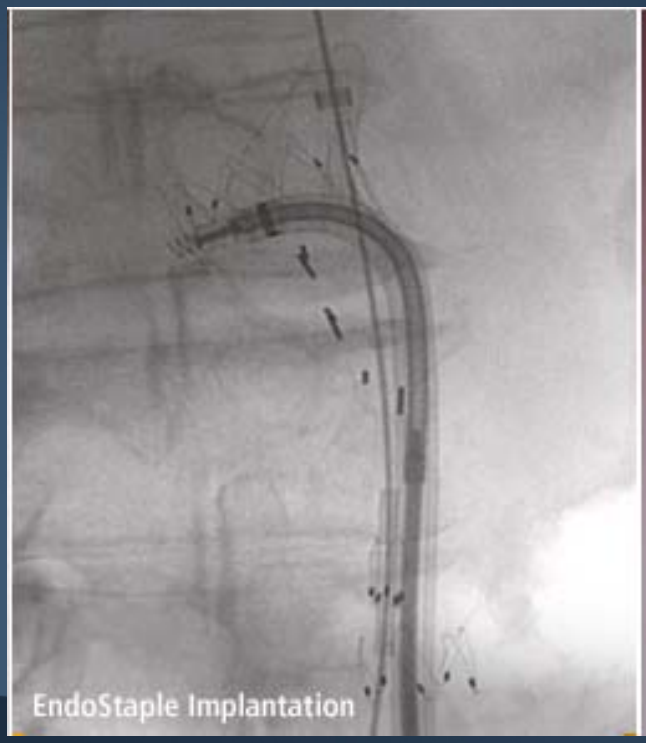
Flexible, kink-resistant, crush-resistant legs with nitinol support rings

Lombard Medical Aorfix

- Currently in US pivotal trial
- Specifically designed for highly angulated infra-renal necks

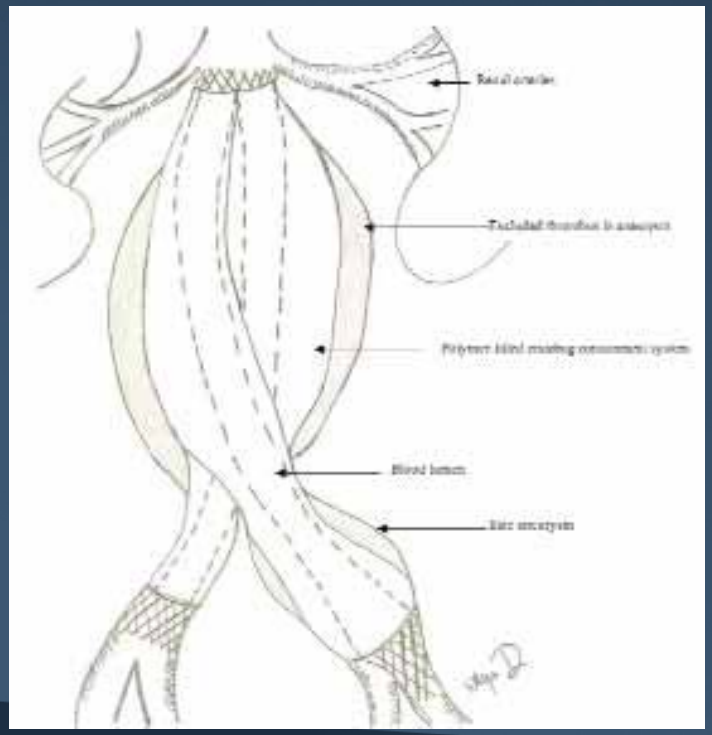
Aptus Endosysytems

- Proprietary endograft
- Adjunctive “Endostapling” system for greater fixation



Nellix Endovascular

- Designed to address the short neck and the late occurance of endoleak by filling the sac with filled bladders



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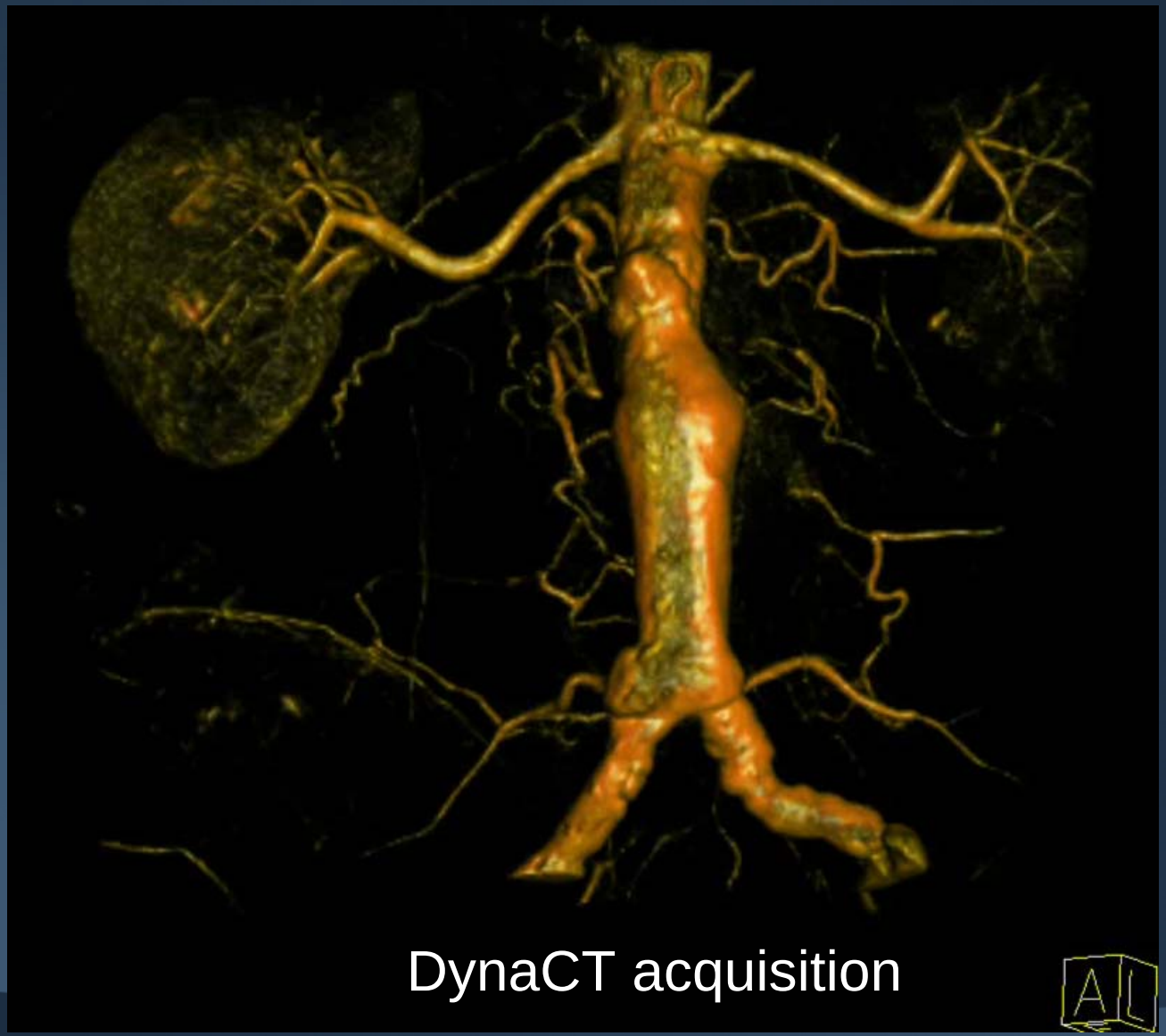
Improvements in Cath Lab imaging



AAA conclusions

- Endograft delivery systems becoming smaller/percutaneous
- Stent migration, stent fracture, are being addressed by technical improvements and better patient selection
- Endoleak remains a cause of repeat intervention, though less so
- Long-term “sac watch” may improve with alternative methods to CT angiography (CardioMEMS implantable pressure sensors)
- Applicability (currently ~50%-60%) and durability is improving with the development of larger neck devices with suprarenal fixation, bifurcated/fenestrated grafts, and the possibility of “endostapling”
- In the intermediate future, a greater number of endografts will be implanted, and likely in smaller aneurysms

Elective Open Repair AAA

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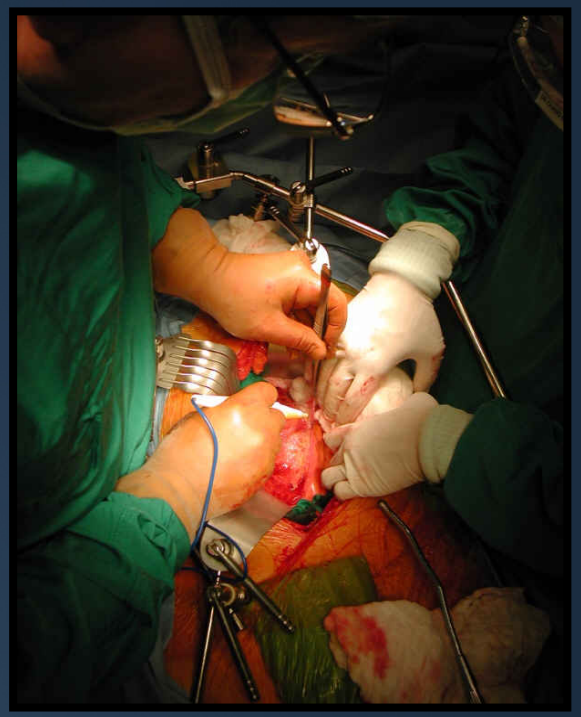

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- 18% said they would not undergo AAA repair again knowing recovery process

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Abdominal Aortic Aneurysm Endografts

Current guidelines for AAA treatment

- Indication for AAA repair: > 5.5 cm
- No current justification for treatment of small AAA (4.0-5.5 cm) without special circumstances
  - Although there is currently a Medtronic Small Aneurysm Trial ongoing

Brewster DC, et al J Vasc Surg. 2003 May;37(5):1106-17

EVAR 1: Operative mortality

	EVAR	Open repair	Odds ratio (95% CI)				p
			Crude	p	Adjusted*	p	
Outcome by intention to treat (number of patients)	531	516					
30-day mortality (number of deaths)	1·7% (9)	4·7% (24)	0·35 (0·16–0·77)	0·009	0·37 (0·17–0·83)	0·016	
In-hospital mortality (number of deaths)	2·1% (11)	6·2% (32)	0·32 (0·16–0·64)	0·001	0·30 (0·14–0·62)	0·001	
Median (IQR) length of hospital stay (days)†	7 (5–10)	12 (9–16)					<0·0001‡
Median (IQR) length of operation (min)†	180 (140–215)	200 (155–240)					<0·0001‡
Secondary interventions either during 30 days or during the primary admission							
Conversion to open repair	10	0					
Correction of endoleak	18	1					
Re-exploration of open repair	1	15					
Other surgery	21	14					
Unknown	2	0					
Total	52 (9·8%)	30 (5·8%)					0·02§
Outcome by per protocol (number of patients)	512	496					
30-day mortality (number of deaths)	1·6% (8)	4·6% (23)	0·33 (0·15–0·74)	0·007	0·34 (0·15–0·78)	0·011	
In-hospital mortality (number of deaths)	1·6% (8)	6·0% (30)	0·25 (0·11–0·54)	0·001	0·24 (0·11–0·54)	0·001	

*Adjusted for age, sex, FEV_1, AAA diameter, log[creatinine], statin use, and time from randomisation to surgery. †For primary procedure only. ‡Mann-Whitney test. §χ^2 test.

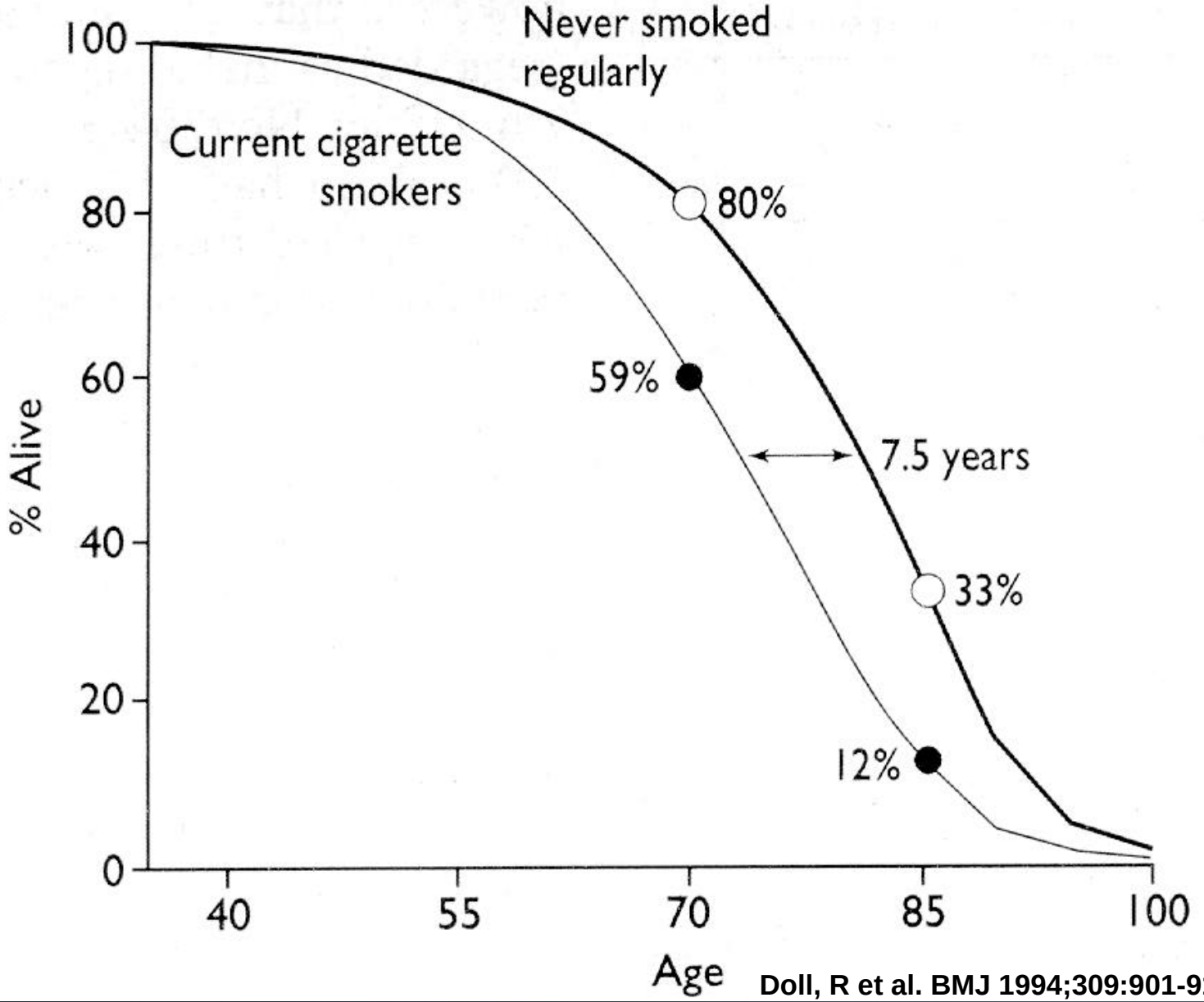
Table 2: **Outcome by intention-to-treat and per-protocol analysis**

	EVAR (n=543)	Open repair (n=539)
Age at randomisation (years)	74·2 (6·0)	74·0 (6·1)
Men	494 (91%)	489 (91%)
Body-mass index (kg/m²)	26·4 (4·6)	26·4 (4·4)
AAA diameter (cm)	6·5 (0·9)	6·5 (1·0)
Diabetes	49 (9%)	62 (12%)
Current smokers	115 (21%)	117 (22%)
Past smokers	367 (68%)	380 (70%)
Never smoked	61 (11%)	41 (8%)
Previous history of cardiac disease*	234 (44%)	229 (43%)
Aspirin use	292 (54%)	280 (52%)
Statin use	177 (33%)	181 (34%)
Systolic blood pressure (mm Hg)	148 (22)	147 (22)
Diastolic blood pressure (mm Hg)	82 (12)	82 (13)
Ankle-brachial pressure index (mean of both legs)	1·01 (0·18)	1·03 (0·18)
FEV$_1$ (L)	2·1 (0·7)	2·1 (0·7)
Serum creatinine (μmol/L)†	102 (91–118)	102 (90–119)
Serum cholesterol (mmol/L)	5·1 (1·2)	5·1 (1·1)

Data are mean (SD) or number of patients (%), unless otherwise indicated. Numbers do not always add up to totals in group because of occasional missing values. *Cardiac disease classified as history of any of the following: myocardial infarction, cardiac revascularisation, angina, cardiac valve disease, significant arrhythmia, and uncontrolled congestive cardiac failure. †Creatinine was positively skewed and data are presented as median (IQR).

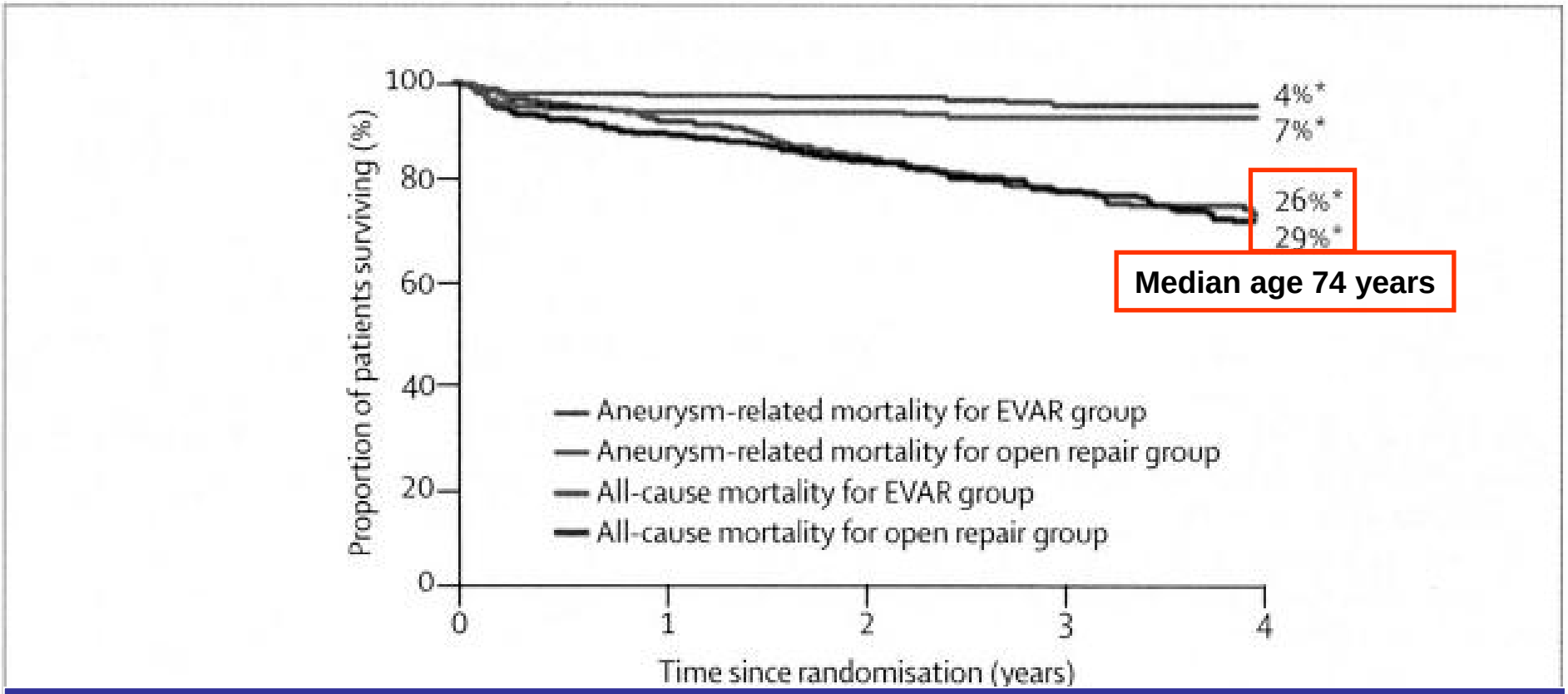
Table 1: Baseline characteristics

Overall survival after age 35 among smokers and non-smokers



Doll, R et al. BMJ 1994;309:901-911

EVAR 1 : All-cause mortality



Age 65-74:

2% death/year non-smokers **~13% expected 4 yr mortality in EVAR 1**

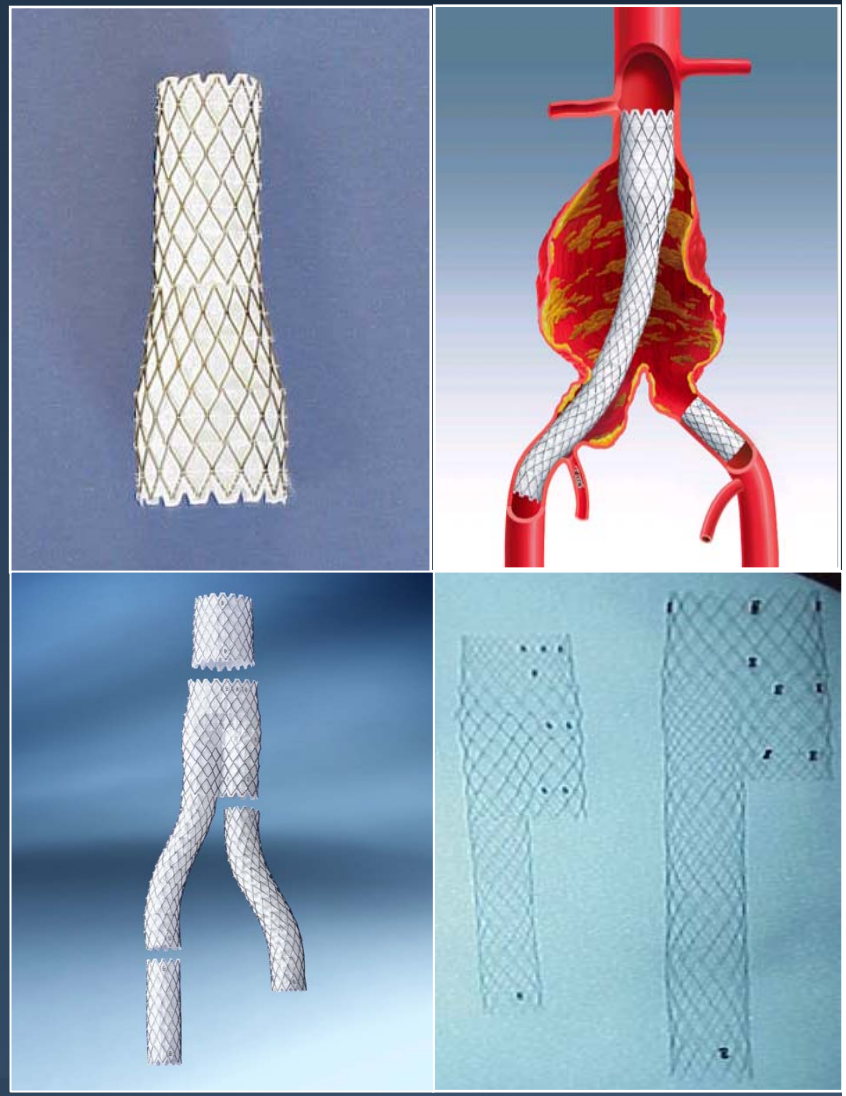
3%-6% death/year former-current smokers **~23% expected 4 yr mortality in EVAR 1**

Figure 2: **Kaplan-Meier curve of survival and survival free from aneurysm-related death**

*Mortality 4-year point estimates.

Medtronic AneuRx II Advantage: Enhancements

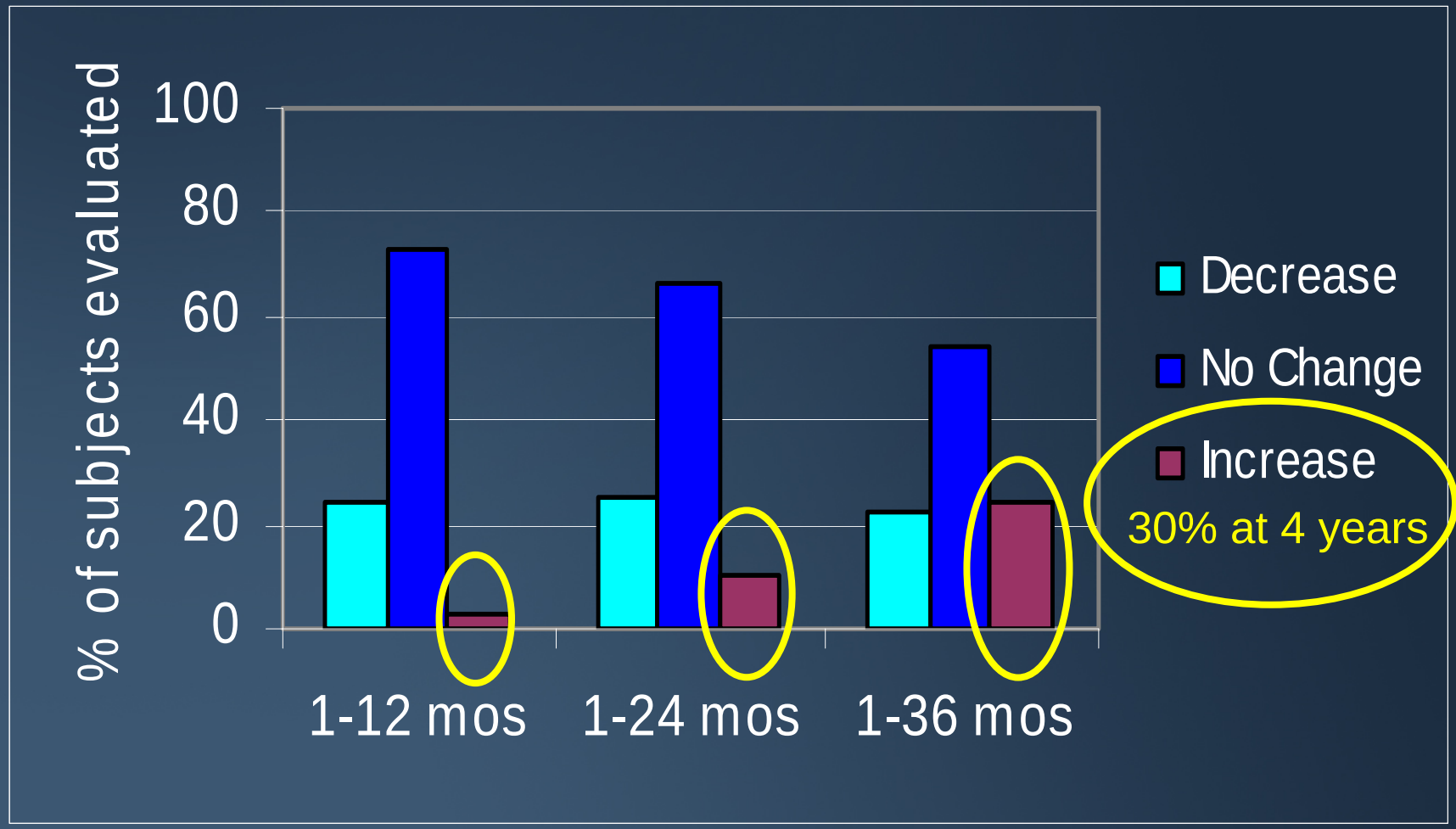
- Applicability:
  - Larger diameter bifurcations & aortic cuffs
  - Flared & tapered limbs
  - AUI (Aorto-Uni-Iliac)
- Deliverability:
  - Longer body & new markers
  - New delivery system
- Resilient graft material



WL Gore Excluder Endograft

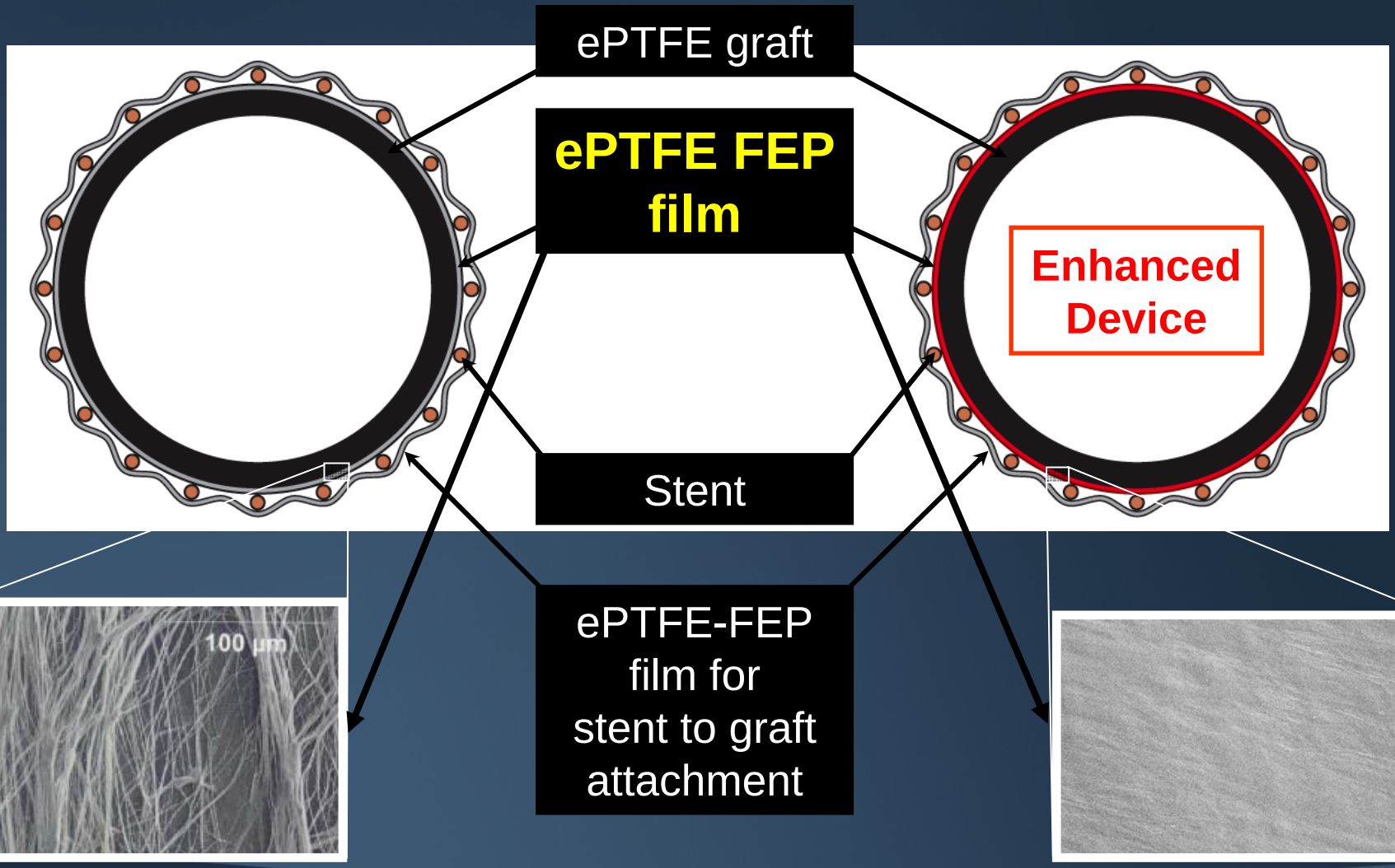
- Applicability:
  - Tapered limbs
- Durability
  - Active fixation
  - ePTFE with film
  - Independent stent struts
- Deliverability
  - Easy, modular delivery system
  - Percutaneous profiles (18F)

Gore Excluder:
3 year AAA size change (> 5 mm)



Expanding AAA the result of endotension

Gore Excluder: enhanced graft material

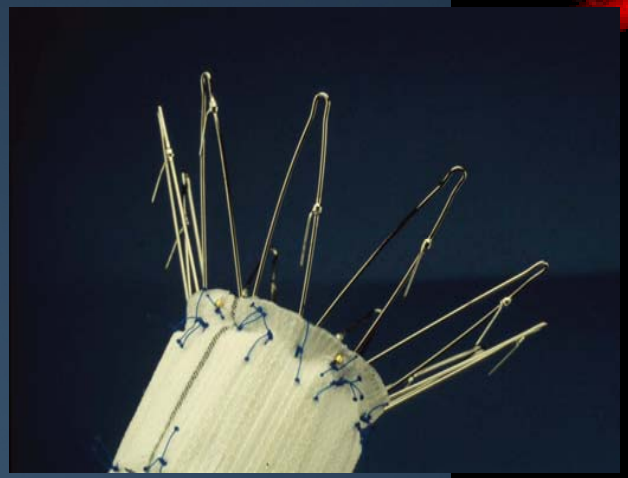


WL Gore Excluder Endograft

- Gaining market share
  - Ease of use
  - Resolution of endotension AAA expansion
  - Thoracic TAG device being leveraged
- Pipeline
  - Larger proximal stent
    - 31mm to be released sometime in 2006 (Currently 28.5mm)
  - Branch technology

Cook Zenith Endograft

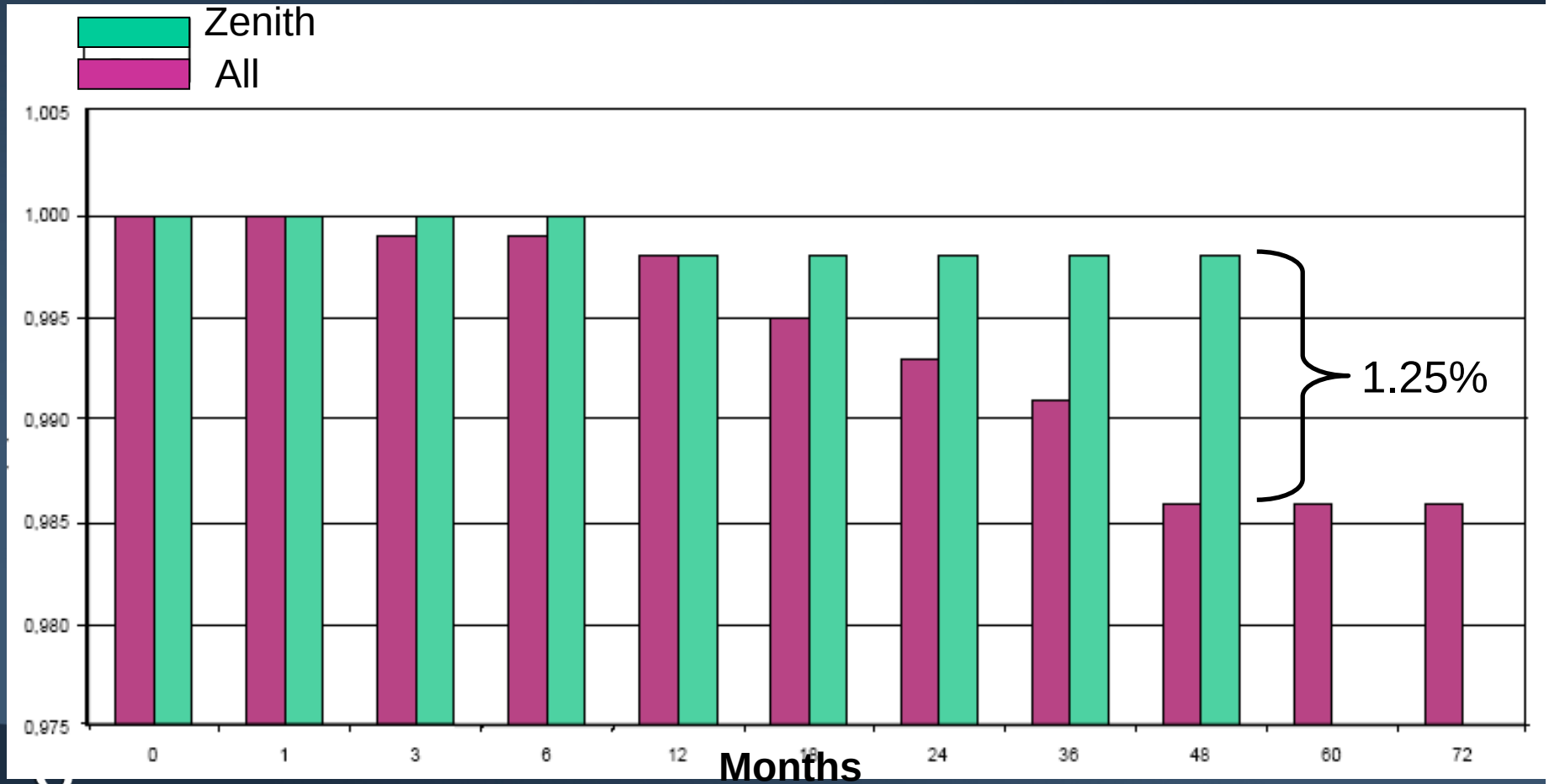
- Applicability
  - Suprarenal active fixation
  - Unibody system with variable limbs
- Durability:
  - Dacron cover
- Deliverability
  - Integrated sheath



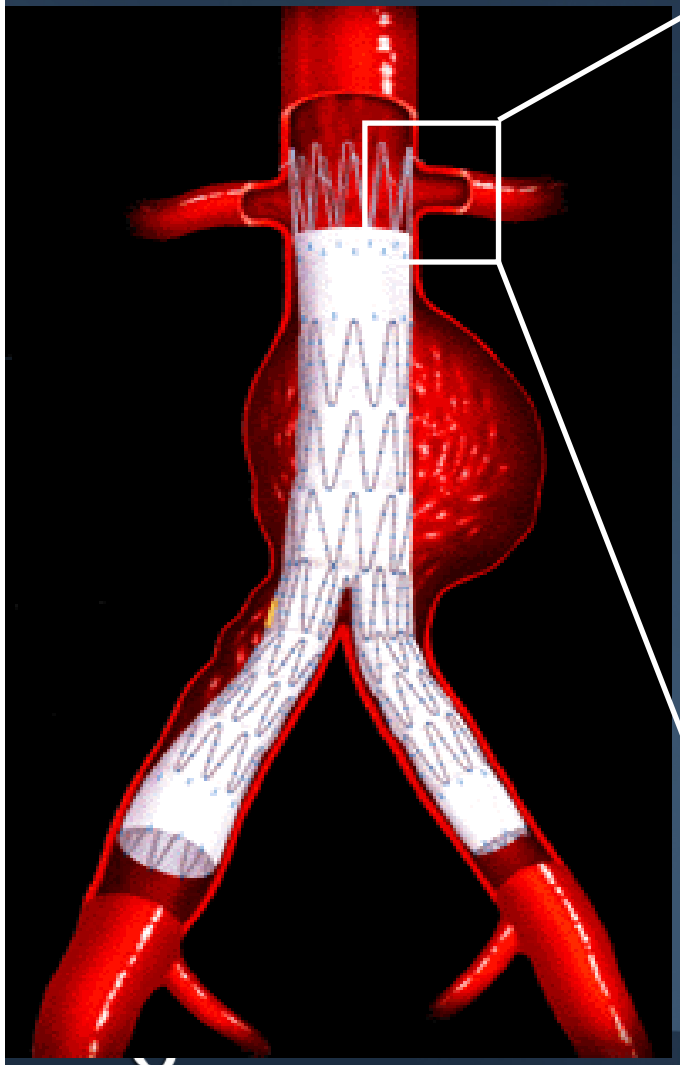
Cook Zenith: A durability advantage?

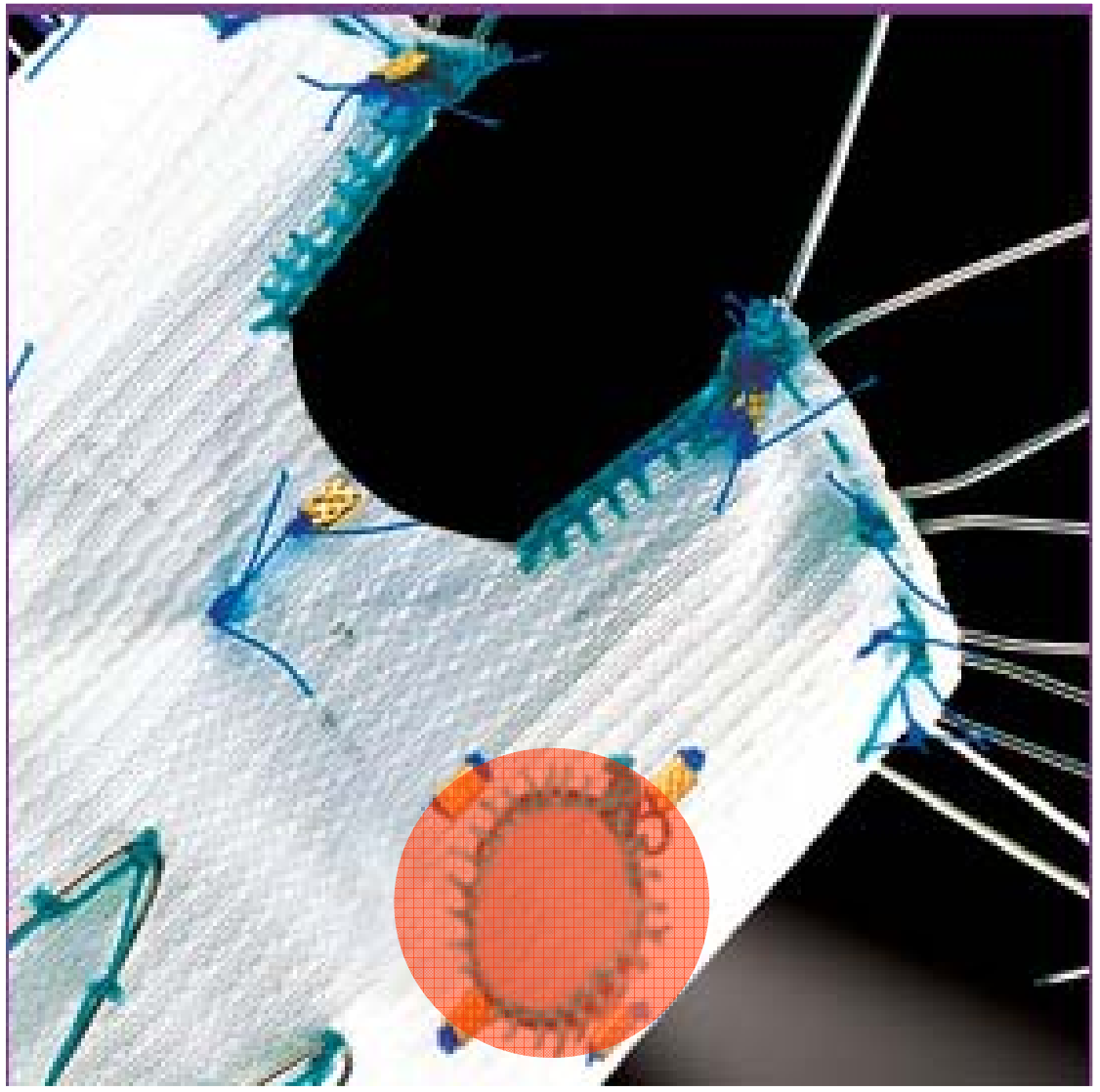
EUROSTAR

- 4242 patients total
- 1370 Zenith
- Similar rates of anatomic distortion, anesthetic risk, obesity, etc.



Cook fenestrated EVAR: the ultimate extension in applicability?





Current status of fenestrated technology

- WL Gore
  - Development
- Medtronic
  - Development
- Cordis
  - Programmatic pause
- Cook Zenith platform
  - +700 cases WW
  - In clinical trials
  - Awaiting longer term outcomes

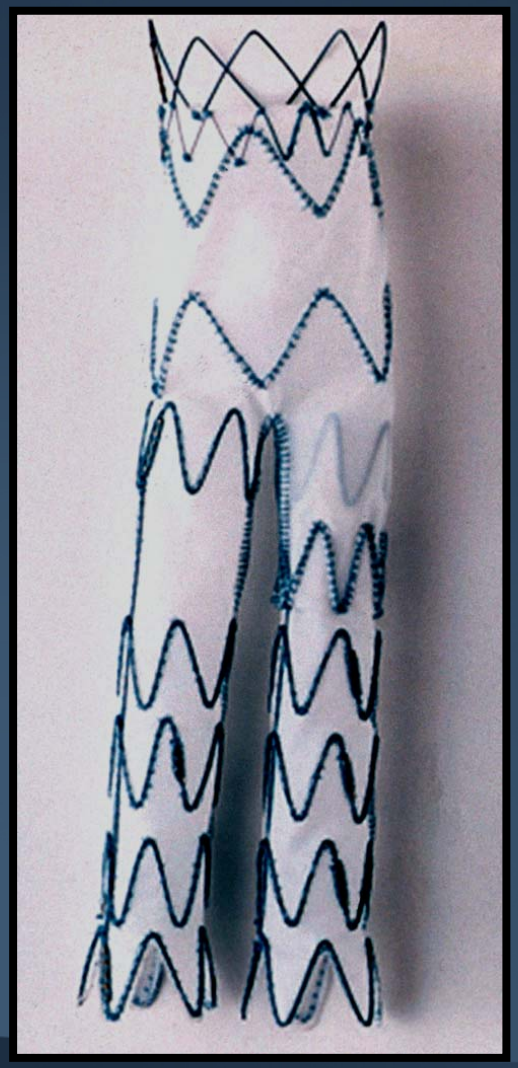
Endologix PowerLink

- Pros
  - Good result with US pivotal
    - Trial included small AAAs (mean 5.0cm) with good anatomy
  - Percutaneous on one side
- Cons
  - Possible stent migration
  - Uni-body lack of sizing versatility

US approval Dec 2004

Current market share <5%

Medtronic TALENT



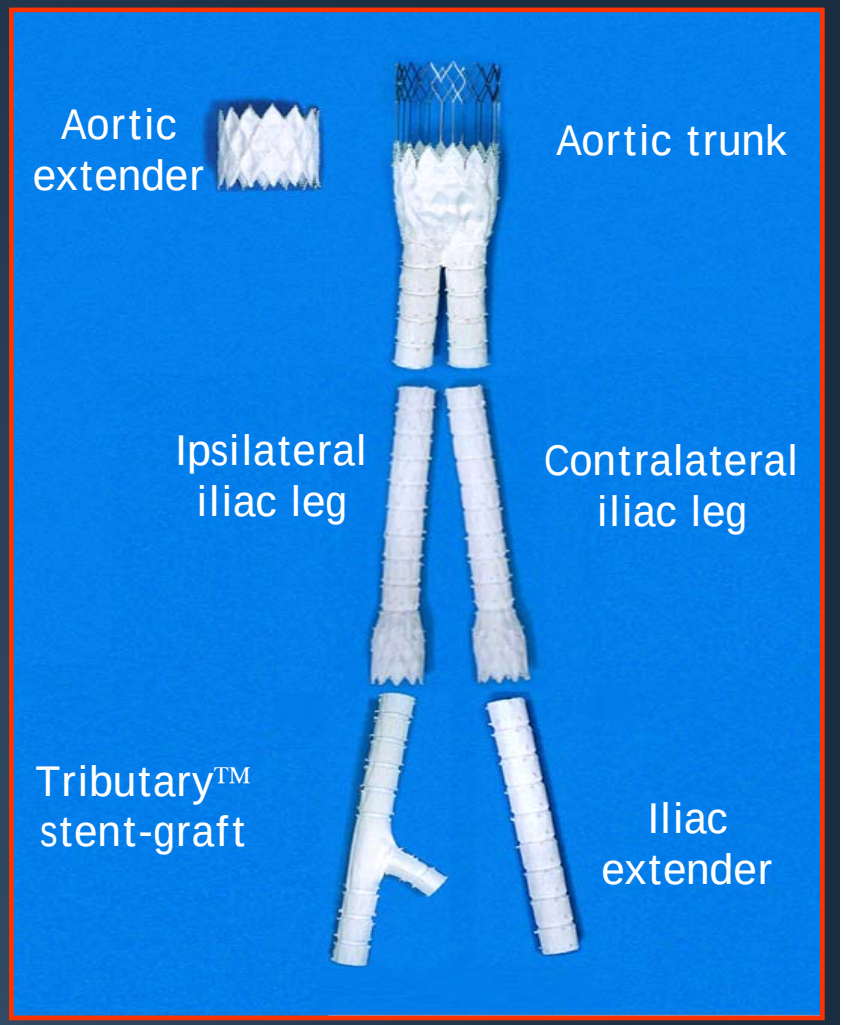
- Market leader in EU
- Large proximal stent
- Supra-renal stent

Medtronic/Talent Regulatory Status

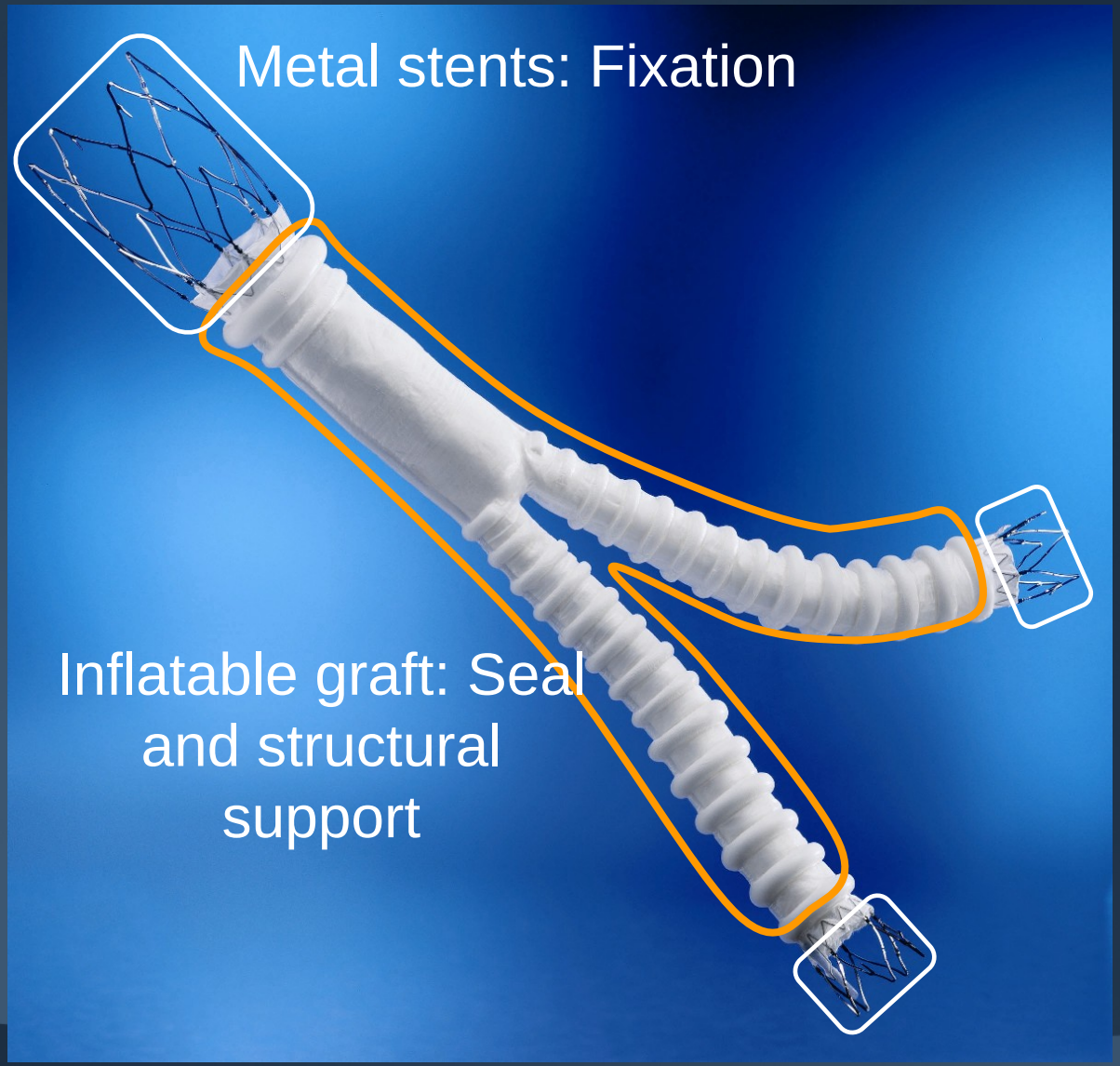
- 5 different clinical trials conducted under 3 different companies (World Medical, AVE, Medtronic)
- Over 1,300 implants in the US (vs 200 for other trials)
- Lack of robust follow-up data
- Accordingly, obtaining FDA approval delayed

Cordis/J&J Fortron

- Pros
  - Supra-renal active fixation
  - Branch vessel option
  - Aorta up to 30 mm
- Cons
  - Difficulties with angulated neck
  - Several incidences of supra-renal stent fractures
- Completed US clinical
  - Awaiting FDA submission
  - Cordis to decide on commercialization
- 3 delivery system failures encountered in Germany
- Voluntary product recalled in EU



Trivascular/BSC *E* NOVUS AAA Stent Graft
(14 Fr Percutaneous system)



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Trivascular/BSC Enovus

- Completed Phase 1 trial in 2Q 2004
- FDA approval for Phase 2, Feb 12, 2005
  - Started pivotal trial 4Q, 2005
- Nov 2005 up to 30% rate of stent-fabric separation noted
- Phase 2 trial halted
- Need for and degree of revision now being contemplated

Endurant AAA Stent Graft System

- Flexible, independent stents
- Active, supra-renal fixation
- May suit challenging anatomies
- Lower profile:16, 18, 21 F without compromising durability
- US Clinical trial launch: Q406-Q107

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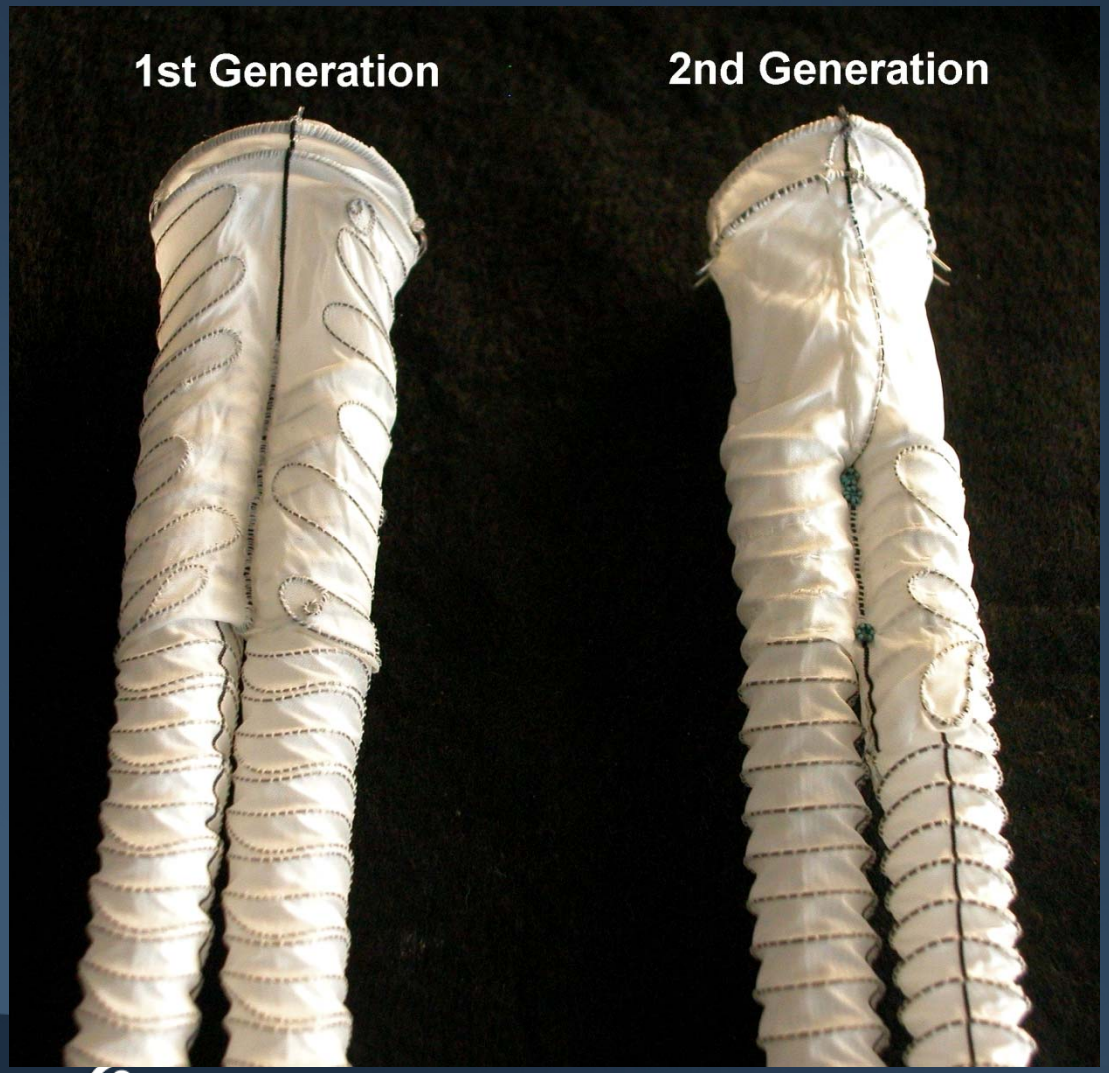
Terumo Anaconda Vascutek



8 barbs added to prevent migration

More circular stent to evenly distribute stress

Flexible, kink-resistant, crush-resistant legs with nitinol support rings

Endofit® Aorto-Uni-iliac Endoluminal Stent Graft

- Aorto-Uni-Iliac stent
- Proximal neck sizing 24mm-36mm
- Length 14cm-26cm
- Tapered proximal to distal to fit anatomy
- Can be used as straight tube graft or with Occluder kit
- Acquired by LeMaitre Vascular

AAA conclusions

- Endograft delivery systems becoming smaller/percutaneous
- Stent migration, stent fracture, are being addressed by technical improvements and better patient selection
- Endoleak remains a cause of repeat intervention, though less so
- Long-term “sac watch” may improve with alternative methods to CT angiography (CardioMEMS implantable pressure sensors)
- Applicability (currently ~50%-60%) and durability is improving with the development of larger neck devices with suprarenal fixation, bifurcated/fenestrated grafts, and the possibility of “endostapling”
- In the intermediate future, a greater number of endografts will be implanted, and likely in smaller aneurysms

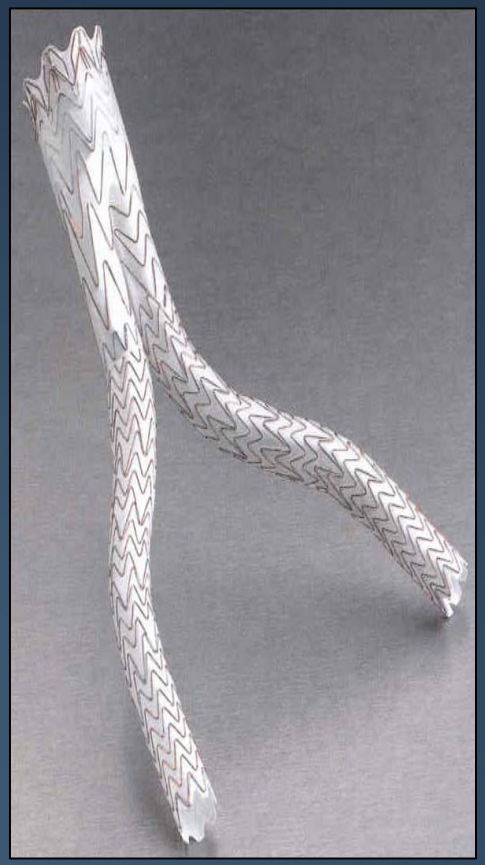
Endovascular AAA Repair

- Minimally invasive
- Reduced morbidity
- Reduced hospital stay
- Early return to function
  - Typically 2 to 4 weeks for full recovery

Currently Available Devices (U.S.)

Medtronic AneuRx

US Trial Implants 1193



Gore Excluder

US Trial Implants 235

Cook Zenith

US Trial Implants 352

Endologix Powerlink

US Trial Implants 192

Device profiles

company	device	neck diameter	outer diameter	fixation location	graft material
cook	zenith	22,24,26, 28,30,32	20F,23F	**suprarenal**	woven polyester
endologix	power-link	25,28	21F,22F	**infrarenal**	ePTFE
gore and associates	excluder	23,26, 28.5	18F	**infrarenal**	ePTFE
medtronic	aneuRx	20,22,24, 26,28	21F	**infrarenal**	woven polyester

Patient Inclusions*

- AAA > 5 cm
- AAA 4 to 5 cm with increase in size of > 5mm past 6 months
- AAA size twice the size of infrarenal neck
- Saccular

**** AneuRx U.S. Clinical Trial n=1192***

J Vasc Surg 2001;33:S135-45

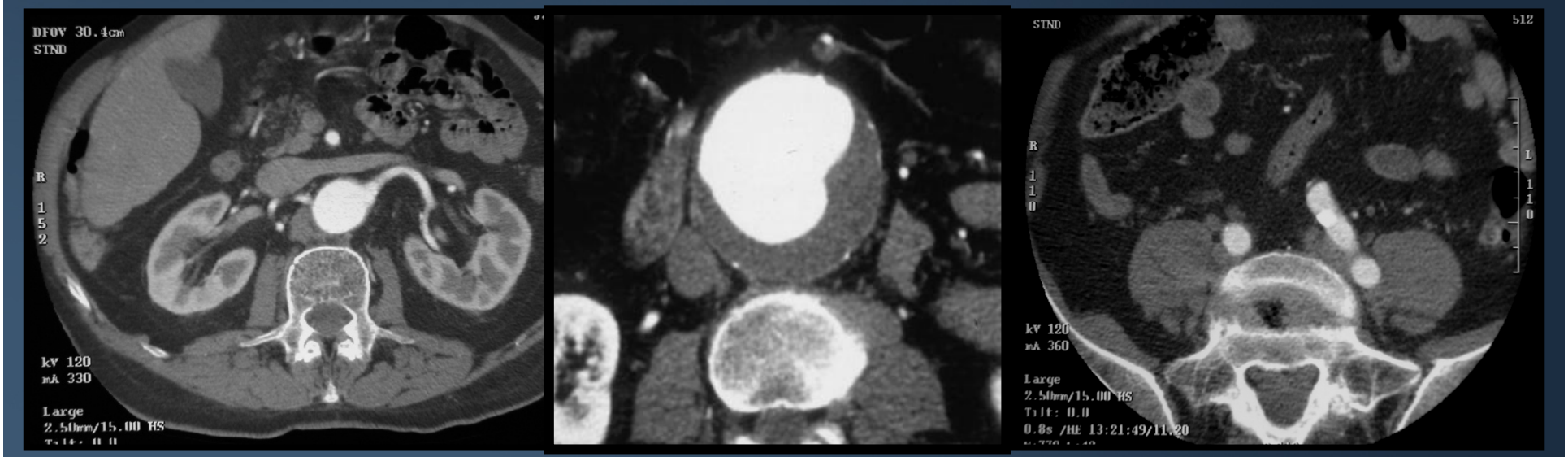
Anatomic Considerations

Endovascular Stent Grafts

- Proximal aortic neck
  - Diameter of device oversized 10-20%
  - Length ≥ 1.5cm for all FDA approved devices
- Angulation/tortuosity
  - Short angulated necks, short wide necks, & severe AAA tortuosity can lead to suboptimal outcomes
- Iliac access
  - Large enough to accommodate 18F-24F delivery systems (7-8mm for bifurcated devices)

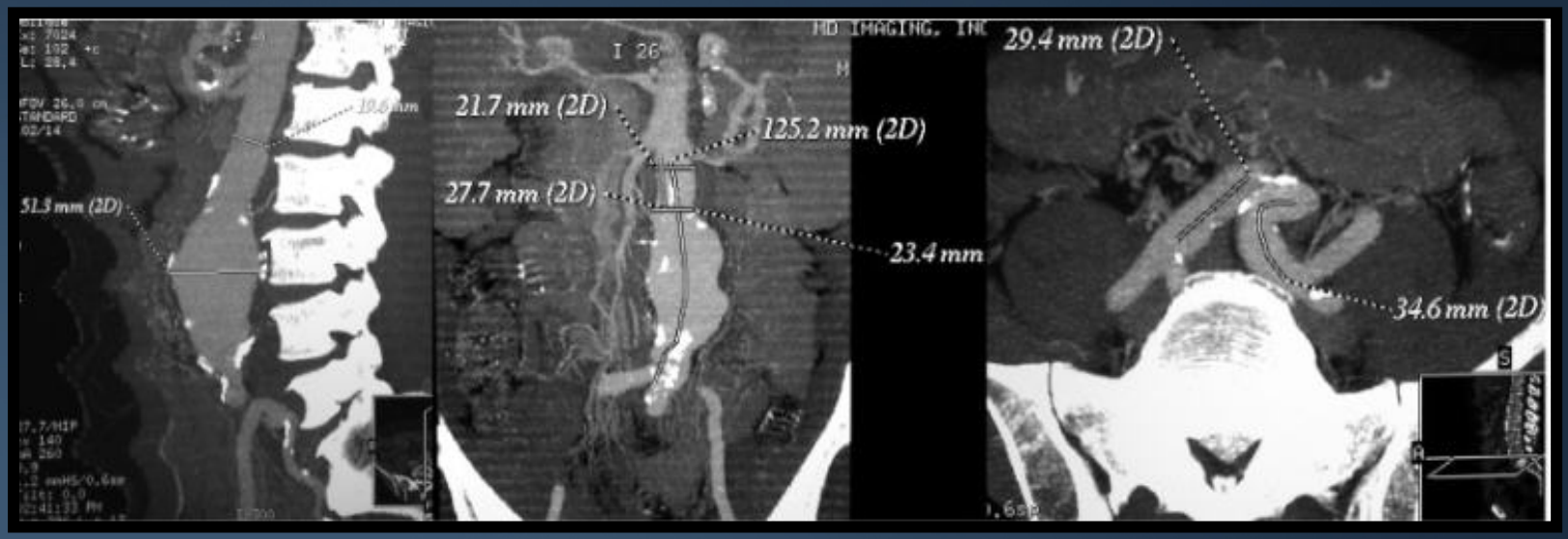
Preoperative Imaging

CTA (3mm cuts)



Preoperative Imaging

3D Reconstructions



INTRAOPERATIVE ANGIOGRAM

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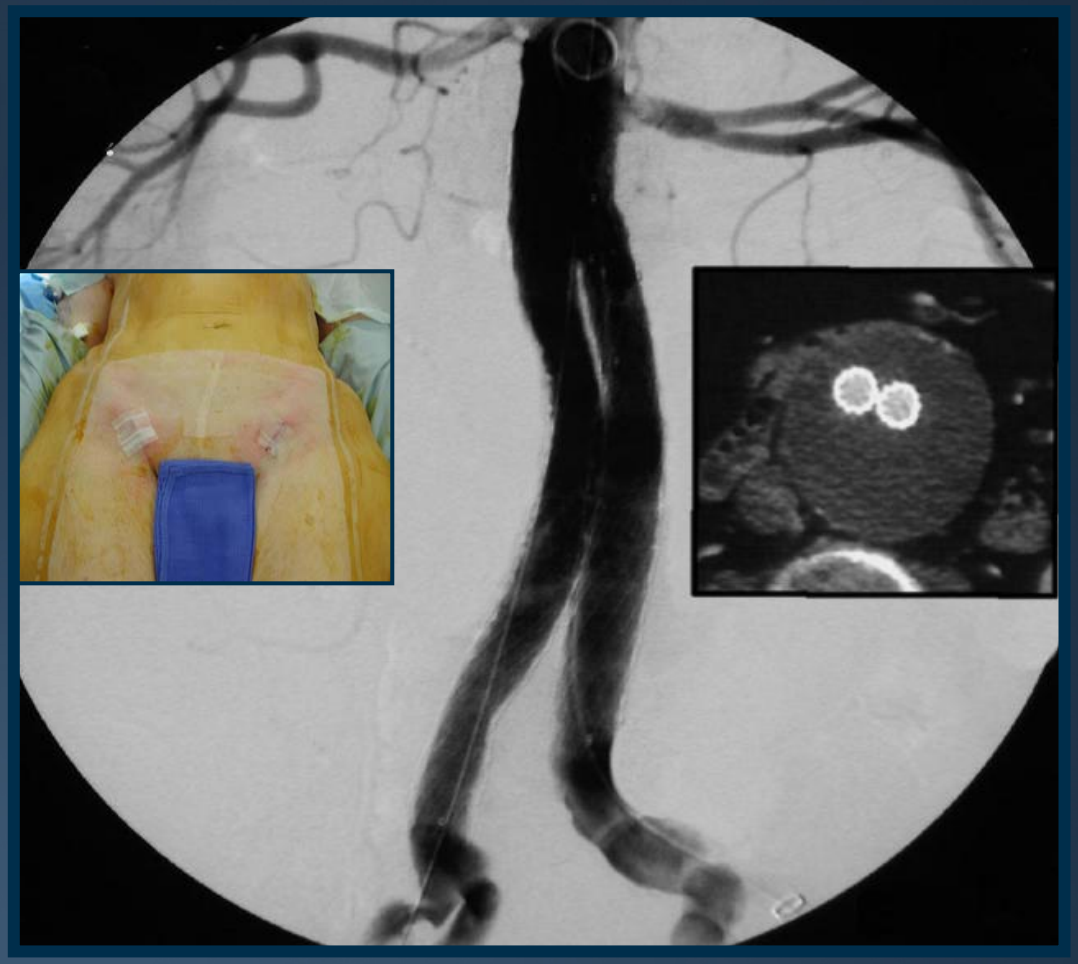


- Completion angiogram shows aneurysm exclusion
- Groins repaired
- Follow-up CTA reveals thrombosis of AAA sac

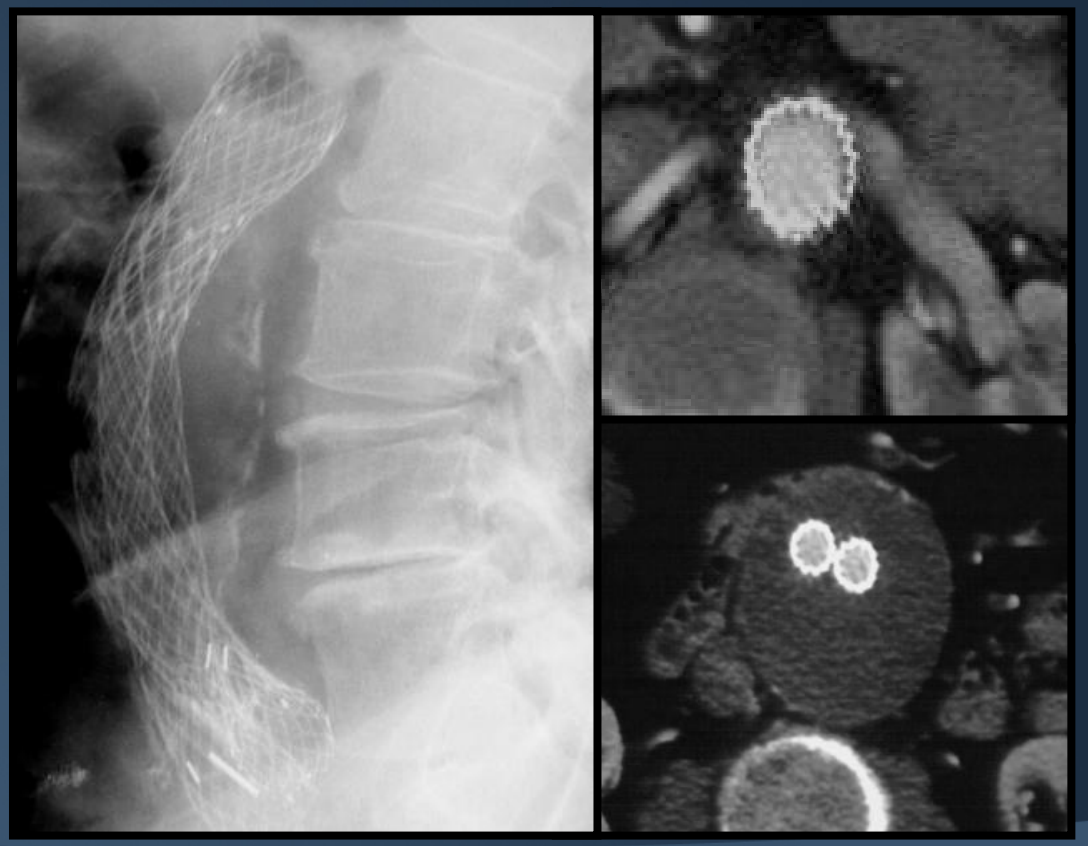
Keys to success

- Appropriate patient selection
- Precise device placement with focus on good fixation and seal in proximal aortic neck and distal iliac landing zones
- Appropriate and timely patient follow-up

Follow-Up Imaging

CT and Abdominal X-Rays (KUB)

- 1 month
- 6 months
- 12 months
- Annually



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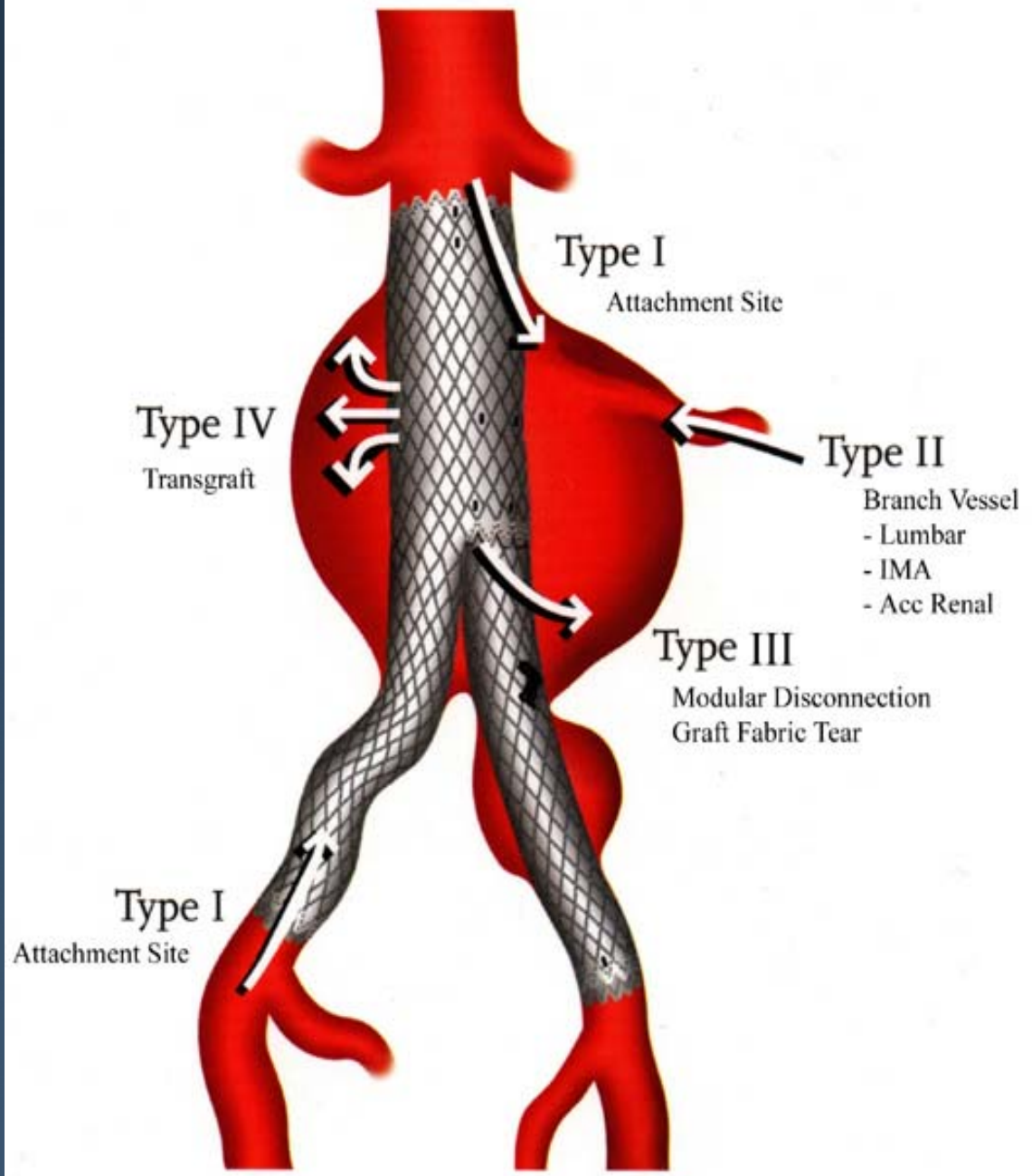
Alternatives to CT scanning

- Ultrasound with or without contrast agent
- Cardiomems device to assess endotension
  - May be more sensitive than other methods
  - Allows for direct measurement of pressure within the excluded sac
  - Need data to support endotension as a predictor of delayed rupture
  - Requires specialized monitoring equipment

Endoleak Classifications



How does endovascular repair compare to standard open surgery?

- EVAR trials surgical control groups inadequate
  - Patients only followed 1 year
  - No randomization
- The common assumption that there are no long term ruptures, graft complications or AAA related deaths following open repair is inaccurate

EVAR vs. Open repair of AAA

Level 1 evidence confirms early benefit of EVAR vs. OPEN

EVAR-1

DREAM

EVAR-1

	EVAR	OPEN
30 – Day Mortality	1.7 %	4.7 %
Secondary Interventions	9.8 %	5.8 %

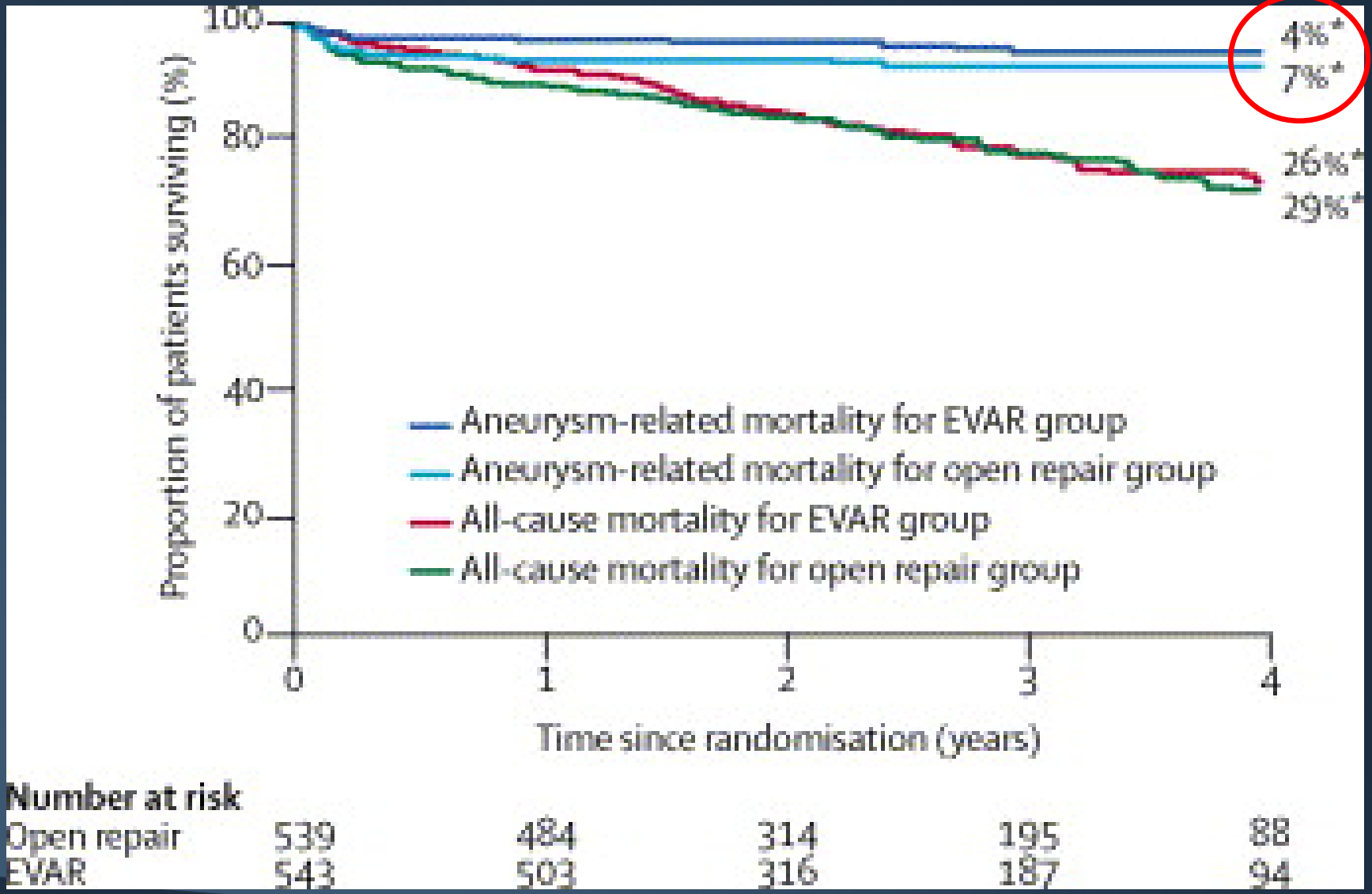
Lancet. 2004 Sep 4;364(9437):843-8

DREAM

	EVAR	OPEN
30 – Day Mortality	1.2 %	4.6 %
Combined Op Mortality & Complications	4.7 %	9.8 %

N Engl J Med 2004;351:1607-1618,1677-1679

Benefits of EVAR Sustained



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Recently released 5 year data

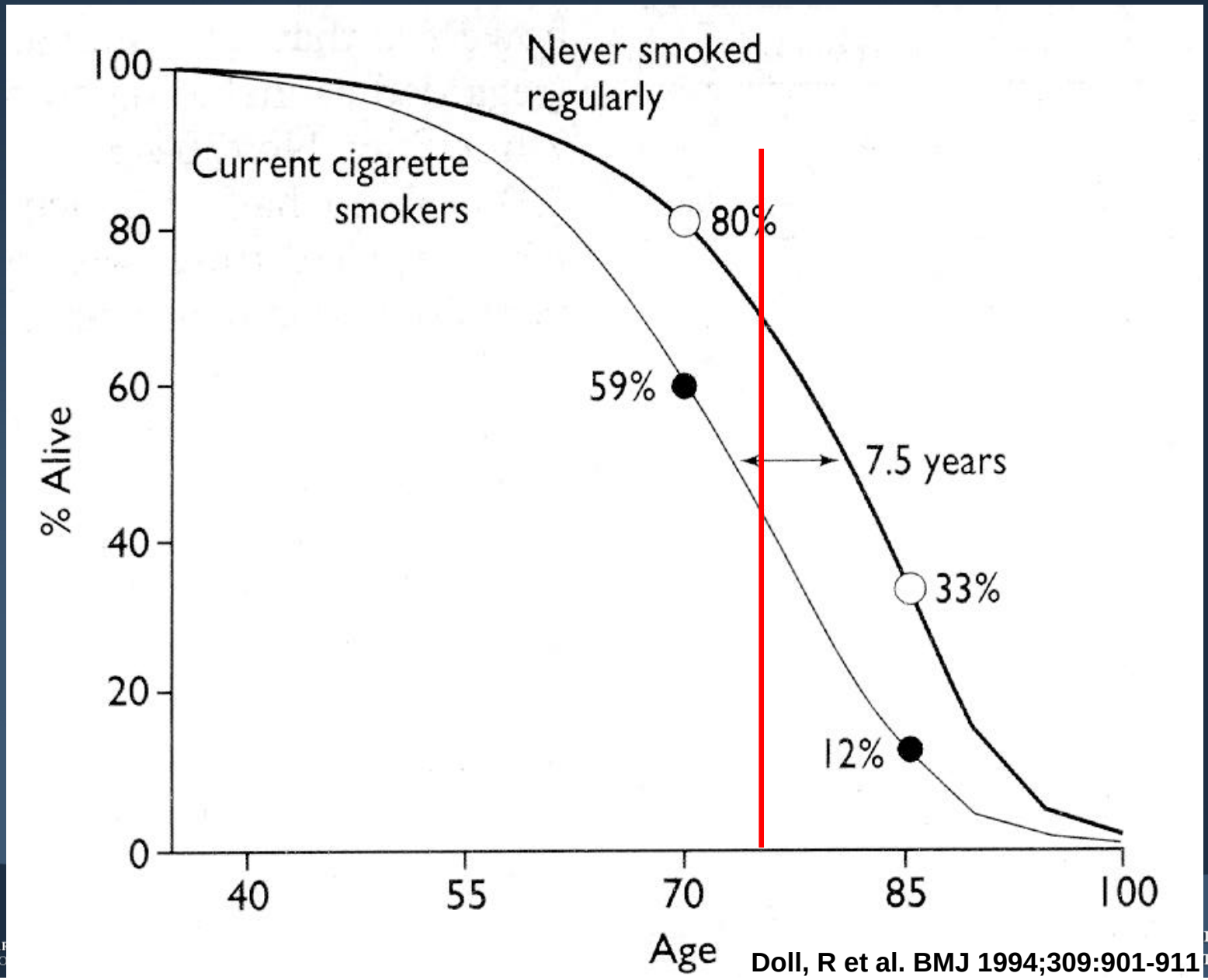
- Medtronic data
  - Device has the longest experience since FDA approval (1999)
  - Of the more than 600 patients in the trial at five years of follow-up, 96.0 percent were free from an aneurysm-related death at five years.

	EVAR (n=543)	Open repair (n=539)
Age at randomisation (years)	74·2 (6·0)	74·0 (6·1)
Men	494 (91%)	489 (91%)
Body-mass index (kg/m²)	26·4 (4·6)	26·4 (4·4)
AAA diameter (cm)	6·5 (0·9)	6·5 (1·0)
Diabetes	49 (9%)	62 (12%)
Current smokers	115 (21%)	117 (22%)
Past smokers	367 (68%)	380 (70%)
Never smoked	61 (11%)	41 (8%)
Previous history of cardiac disease*	234 (44%)	229 (43%)
Aspirin use	292 (54%)	280 (52%)
Statin use	177 (33%)	181 (34%)
Systolic blood pressure (mm Hg)	148 (22)	147 (22)
Diastolic blood pressure (mm Hg)	82 (12)	82 (13)
Ankle-brachial pressure index (mean of both legs)	1·01 (0·18)	1·03 (0·18)
FEV_1 (L)	2·1 (0·7)	2·1 (0·7)
Serum creatinine (μmol/L)†	102 (91–118)	102 (90–119)
Serum cholesterol (mmol/L)	5·1 (1·2)	5·1 (1·1)

Data are mean (SD) or number of patients (%), unless otherwise indicated. Numbers do not always add up to totals in group because of occasional missing values. *Cardiac disease classified as history of any of the following: myocardial infarction, cardiac revascularisation, angina, cardiac valve disease, significant arrhythmia, and uncontrolled congestive cardiac failure. †Creatinine was positively skewed and data are presented as median (IQR).

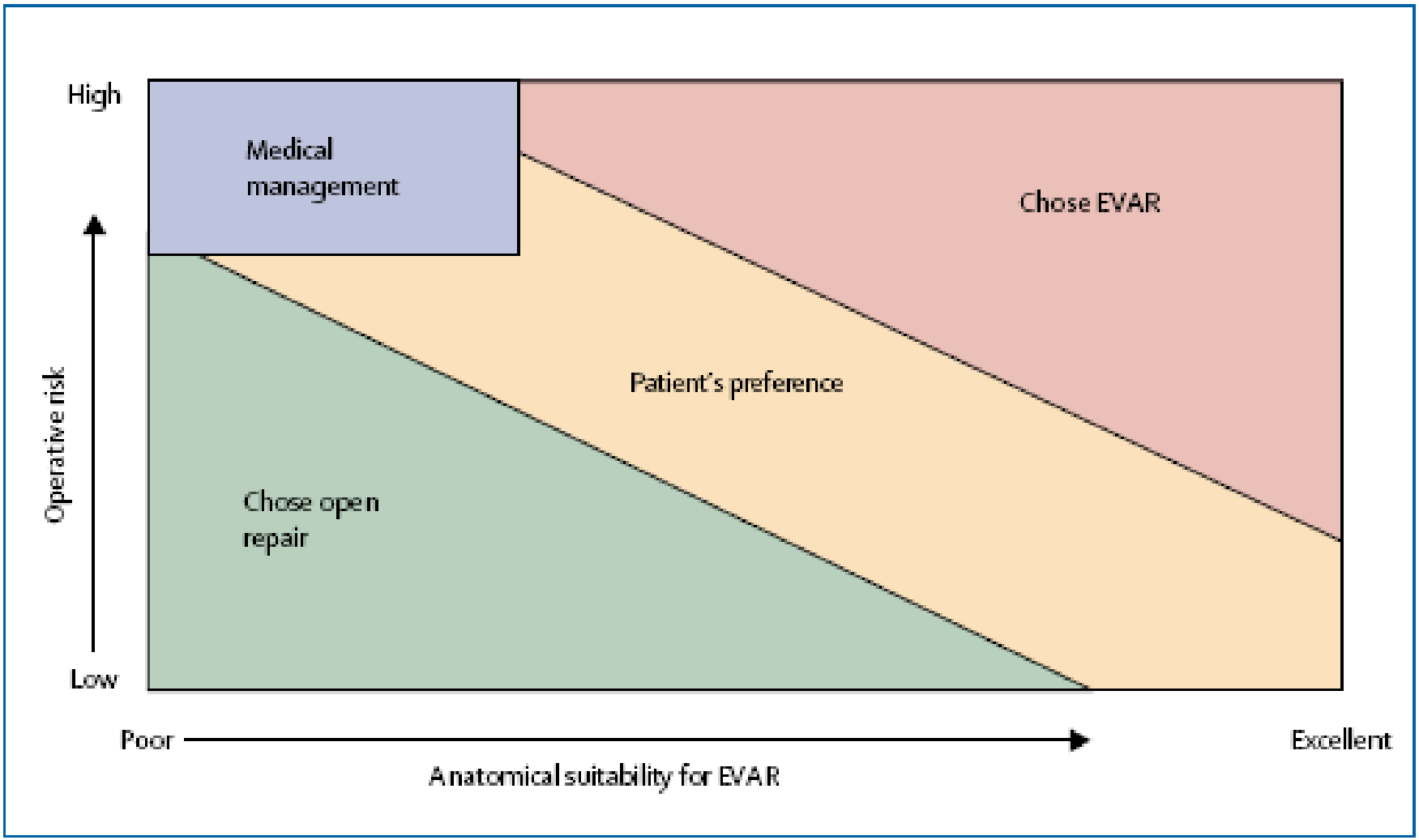
Table 1: Baseline characteristics

Overall survival after age 35 among smokers and non-smokers

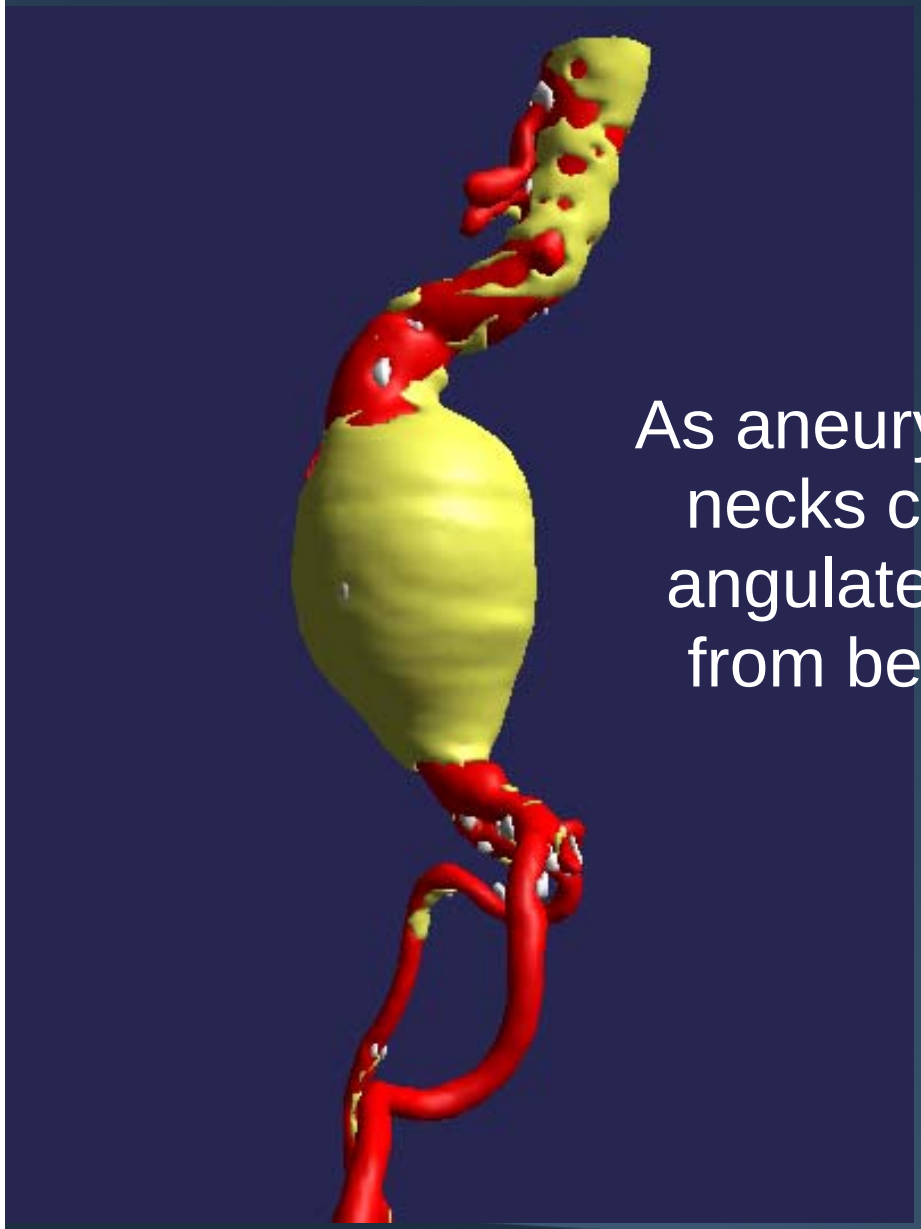


Doll, R et al. BMJ 1994;309:901-911

EVAR vs Open surgery: strategy has evolved



Jack L Cronenwett, Lancet Vol 365 June 25, 2005



As aneurysms grow in size, proximal necks can become shorter and more angulated which may preclude patient from being good anatomic candidate for stent graft

Small vs. Large AAA

Clinical Outcomes following EVAR

	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 %

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Ouriel et al
J Vasc Surg 2003;37:1206-12

Conclusions Regarding EVAR for Small vs. Large AAA

- Outcomes of EVAR influenced by AAA size
- Differences important in choosing observation or repair
- It is important to balance risk for rupture with size dependant outcome

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Ouriel et al
J Vasc Surg 2003;37:1206-12

PIVOTAL Trial

- Positive Impact of EndoVascular Options for Treating Aneurysms
- Randomization of close to 1700 patients with 4-5cm AAA's to EVAR or continued follow up
- AAA's must exceed double the diameter of the reference aorta and meet inclusion criteria for the AneuRX device
- Patients who become symptomatic, exceed 5.0 cms or experience rapid growth will be offered repair

EVAR
2007

- Patient selection and implant technique have improved
- Devices are better and easier to use
- Results are continuously improving
- Early detection and treatment of smaller aneurysms may lead to fewer aneurysm related deaths and better long term results