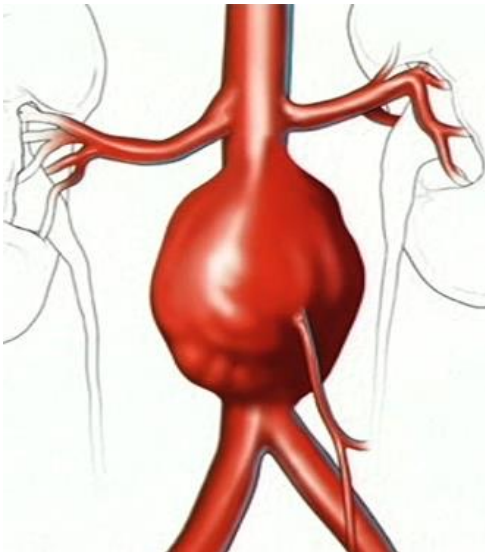




# **EVAR Technology Makes it the 1<sup>st</sup> Choice**

Dr. Dipankar Mukherjee, MD, FACS  
Chief of Vascular Surgery,  
Inova Fairfax Medical Campus

Inova Cardiovascular Symposium  
April 27<sup>th</sup>, 2019



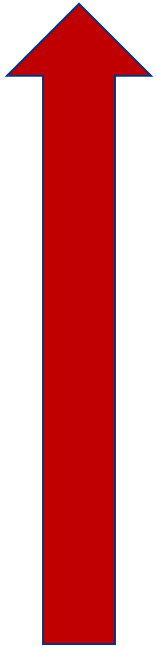
- On the speaker's panel for
- Silk Road Medical
- Endologix

# EVAR for 6cm AAA



# Levels of Evidence

**Strongest**



**Weakest**

<b>Level of Evidence A</b>	Data derived from multiple randomised clinical trials or meta-analyses.
<b>Level of Evidence B</b>	Data derived from a single randomized clinical trial or large non-randomized studies.
<b>Level of Evidence C</b>	Consensus of opinion of the experts and/or small studies, retrospective studies, registries.

# Classes of Recommendations

<b>Classes of Recommendations</b>	<b>Definition</b>
<b>Class I</b>	Evidence and/or general agreement that a given treatment or procedure is beneficial, useful, and effective.
<b>Class II</b>	Conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of the given treatment or procedure.
<b>Class IIa</b>	Weight of evidence/opinions in favor of usefulness/efficacy.
<b>Class IIb</b>	Usefulness/efficacy is less well-established by evidence/opinion.
<b>Class III</b>	Evidence or general agreement that the given treatment or procedure is not useful/effective, and in some cases may be harmful.

- Location: United Kingdom (UK)
- Years: 1999 to 2003
- Sample Size: 1,082
- Outcomes:
  - Better perioperative survival after EVAR (1.7% vs 4.7%)
  - Early survival benefit lost after 2 years, with similar long-term survival
  - Higher aneurysm related mortality for EVAR after 8 years
    - Mainly attributable to secondary aneurysm sac rupture
  - Higher reintervention rate after EVAR



- Locations: Netherlands and Belgium
- Years: 2000 to 2003
- Sample Size: 351
- Outcomes:
  - Better perioperative survival after EVAR (1.2% vs 4.6%)
  - Early survival benefit was lost by the end of the 1<sup>st</sup> year
  - Similar long-term survival
  - Higher reintervention rate after EVAR



- Location: United States
- Years: 2002 to 2008
- Sample Size: 881
- Outcomes:
  - Better perioperative survival after EVAR (0.5% vs. 3.0%)
  - Early survival benefit sustained to 3 years but not thereafter
  - **No difference in:**
    - Reintervention rate
    - Quality of life
    - Cost and cost-effectiveness

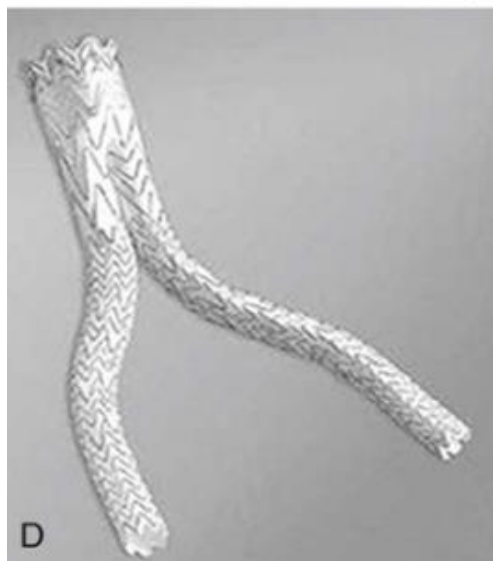
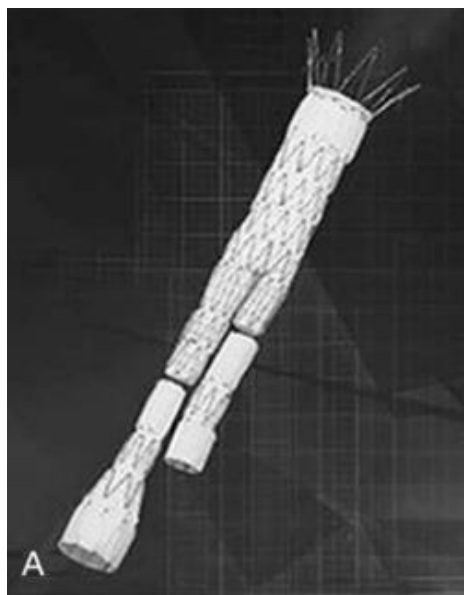




- Location: France
- Years: 2003 to 2008
- Sample Size: 316
- Outcomes:
  - No difference in perioperative survival (1.3% vs 0.6%)
  - No difference in long-term survival up until 3 years
  - Higher reintervention rate after EVAR



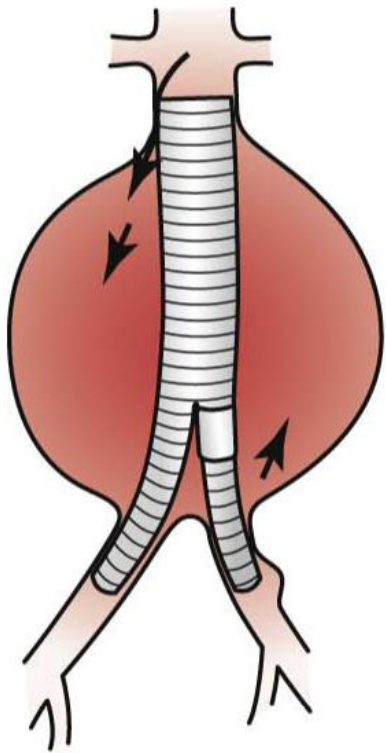
# Evolution of Endograft Technology



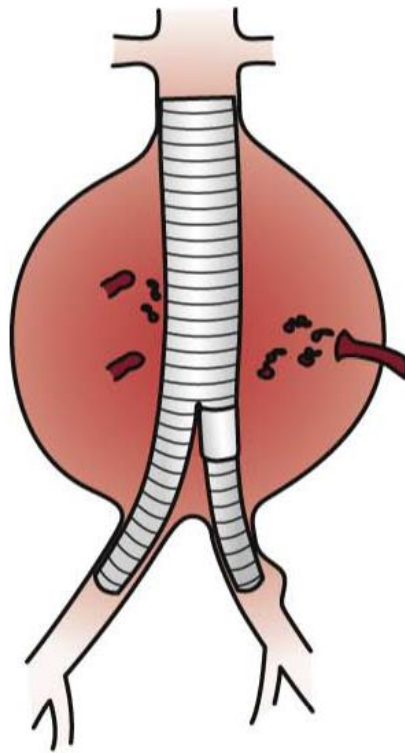
# Device Characteristics of Current Stent Grafts

Device Name	Company	Configuration	Min-Max Device Diameter	Fabric; Metal	Active Fixation	Anatomic Fixation
Zenith	Cook	Trimodular	22-36	Woven polyester; Stainless steel	Suprarenal stent w/ barbs	
Aorfix	Lombard Medical	Bimodular	24-31	Woven polyester; Nitinol	Hooks	
Endurant	Medtronic	Bimodular	23-36	Woven polyester; Nitinol	Suprarenal stent w/ barbs	
Excluder	Gore	Bimodular	23-31	ePTFE; Nitinol	Infrarenal barbs	
AFX	Endologix	Unibody	22-34(cuff)	ePTFE; Cobalt chromium	Suprarenal deployment at Aortic bifurcation	Deployment at Aortic bifurcation
Ovation	Trivascular	Trimodular	20-24	ePTFE; Nitinol	Suprarenal stent w/ barbs and infrarenal sealing rings	

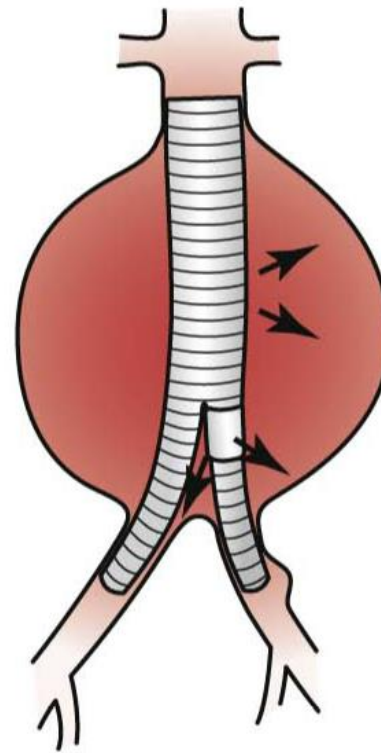
# Complications of EVAR



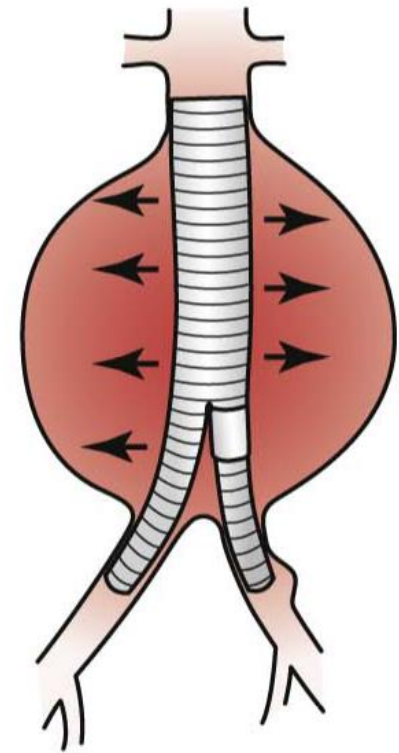
Type I



Type II



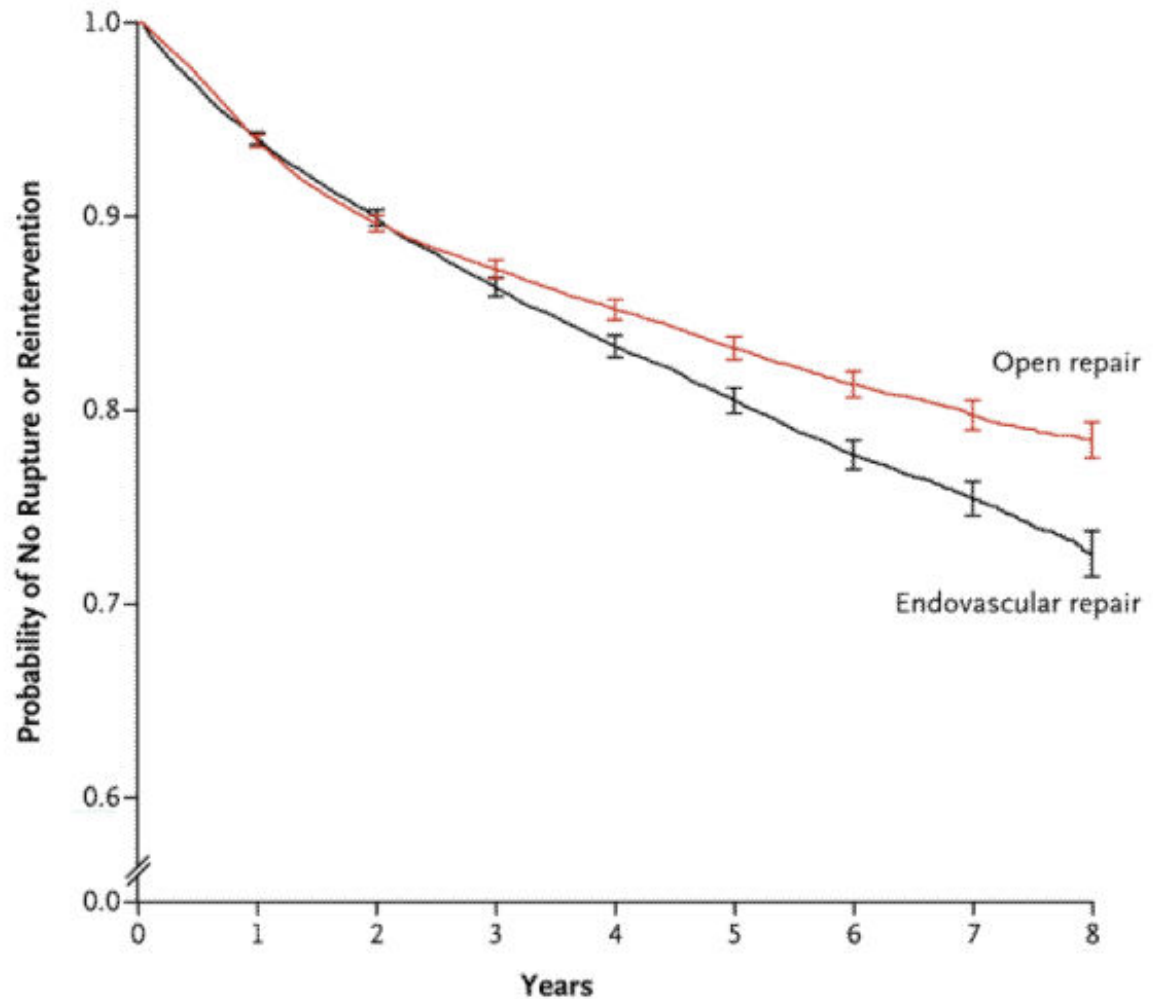
Type III



Type IV

# Durability Issue of EVAR

*Schermerhorn et al N Engl J Med. 2015 Jul 23;373(4):328-38.*

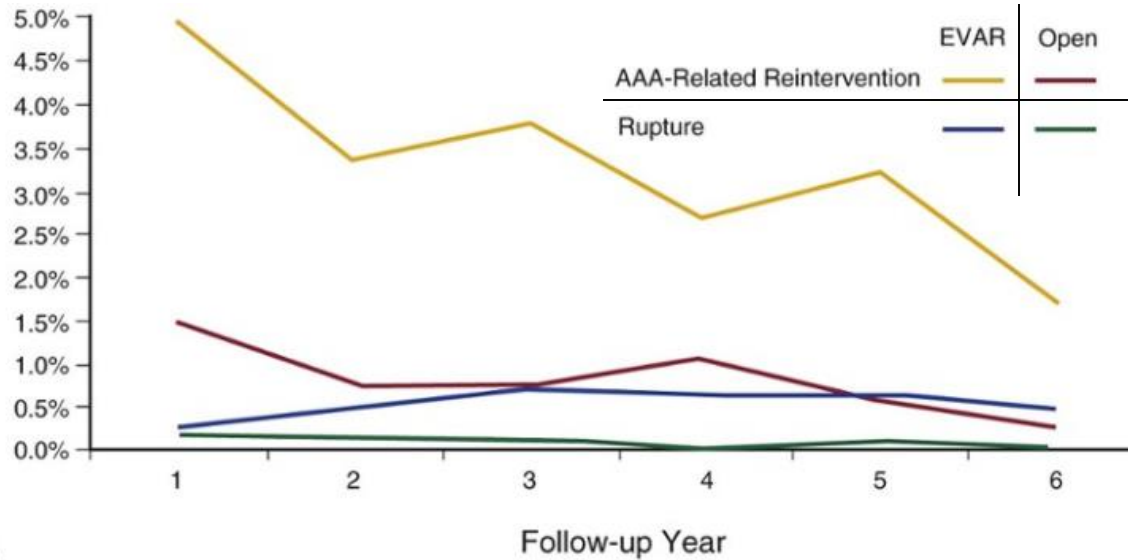


**No. at Risk**

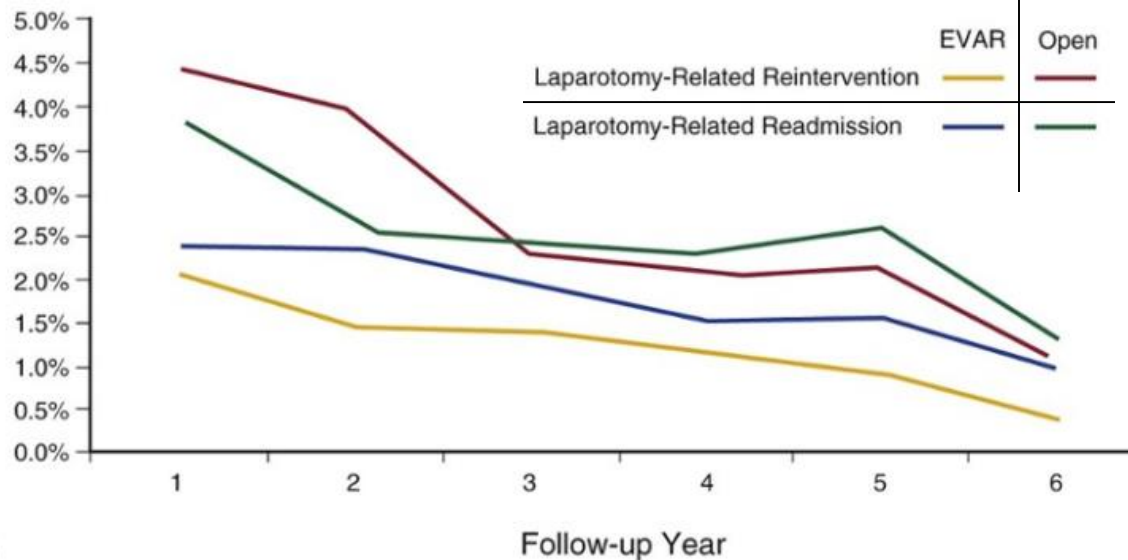
Endovascular repair  
Open repair

39,966	33,573	26,896	20,820	15,273	10,370	6353	3455	1286
39,966	32,495	26,386	20,970	15,772	10,869	6783	3768	1427

# Reinterventions for Medicare Beneficiaries – Long-Term Results: EVAR vs Open



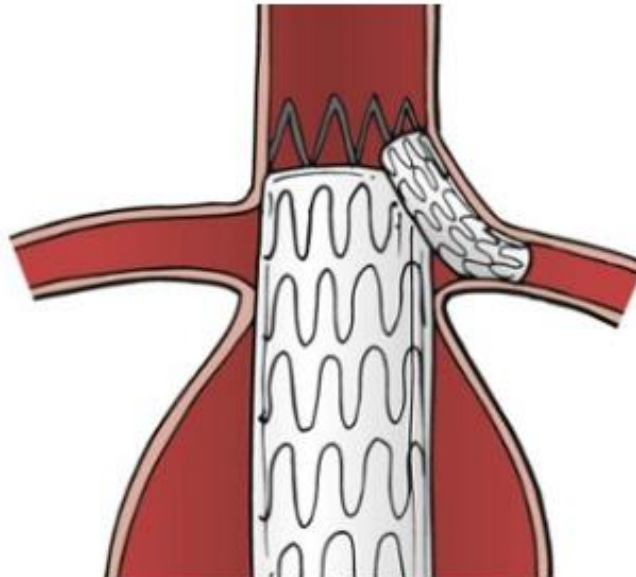
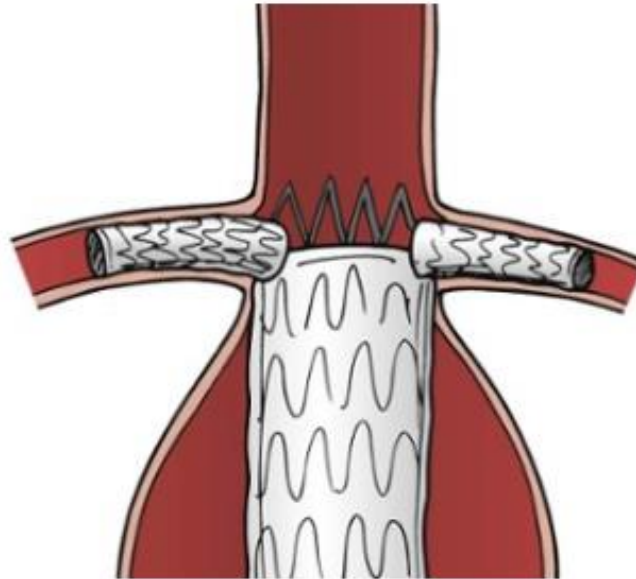
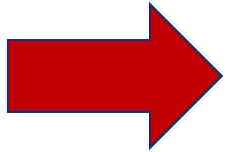
A



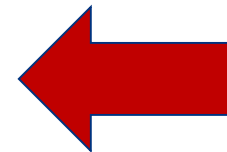
B

# EVAR for Short Neck AAA - Encroachment and Snorkel Techniques

Encroachment



Snorkel



- Most common failure mode of EVAR is loss of proximal seal
  - Most often seen in ‘wide neck’ AAA
- Poor or no seal in aneurysmal necks
- Seen with all endografts with outward expansile force from self-expanding metal stents
  - Similar results seen in the GREAT Trial (Excluder), ENGAGE Registry (Endurant), and meta analysis of EVAR for ‘wide neck’ AAA
- ***Favorable results with OVATION 34mm device in the ENCORE study...***



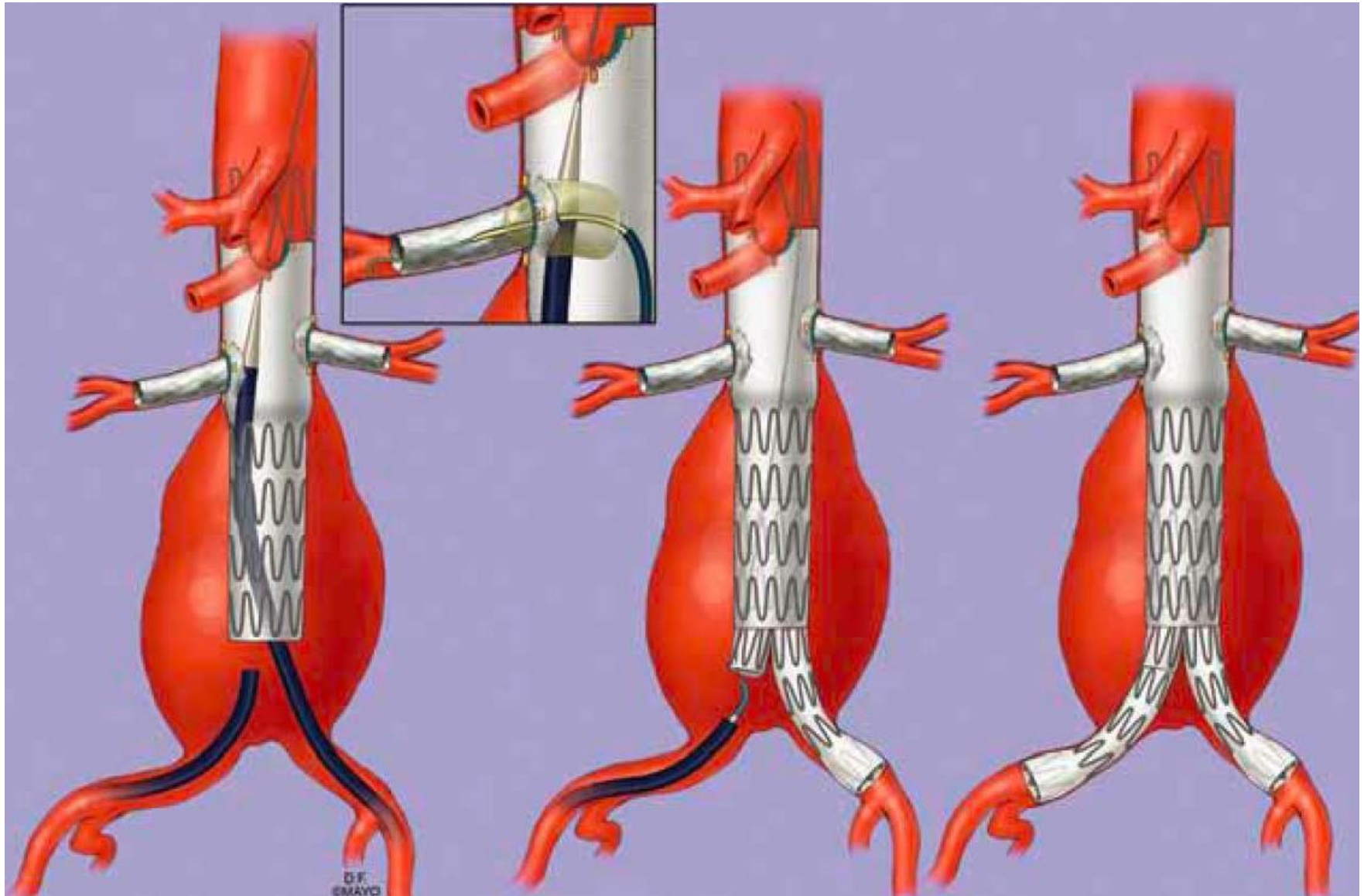
# OVATION for Short Wide Neck AAA



- **ENCORE:** *Addressing the ‘durability issue of EVAR’*
  - **E**ffectiveNess of **C**ustom seal with **O**vation: **R**evue of the **E**vidence
- OVATION device [34mm]; Largest current device
  - Objective: Determine impact of polymer sealing on neck-related adverse events looking at 5-year patient outcomes
- Retrospective analysis of 6 prospective studies
  - Sample Size: 1,296
    - 242 patients with OVATION device group
    - 1,054 patients = comparison group
  - Results:
    - 5-year results suggest EVAR w/ proximal polymer sealing does not appear to induce neck dilation compared to other devices
      - Suggests the **OVATION device is durable** w/ wide neck anatomy
    - Patients w/ OVATION at largest size had a comparable number of complications of other devices



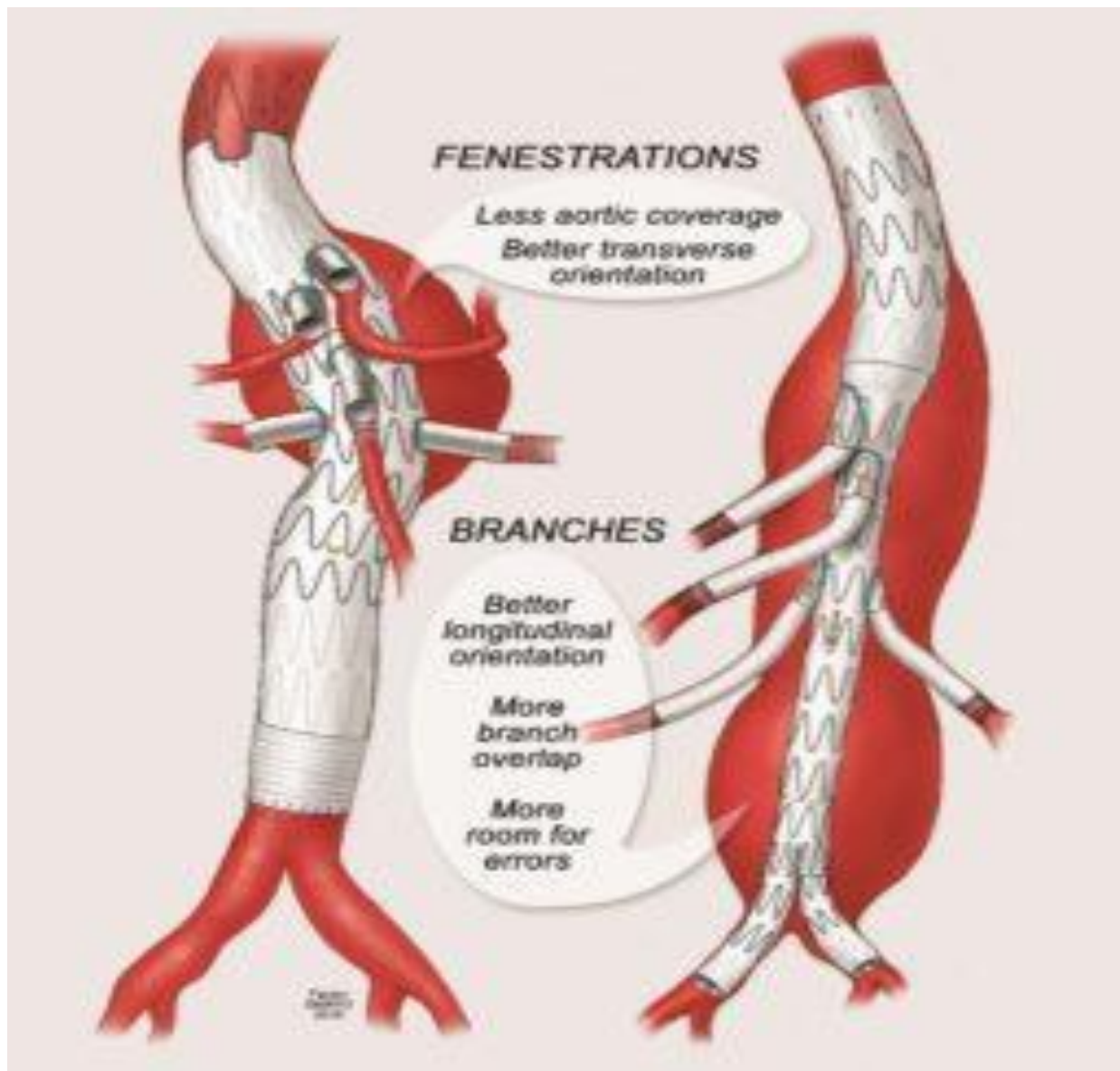
# FEVAR – “Building Up”



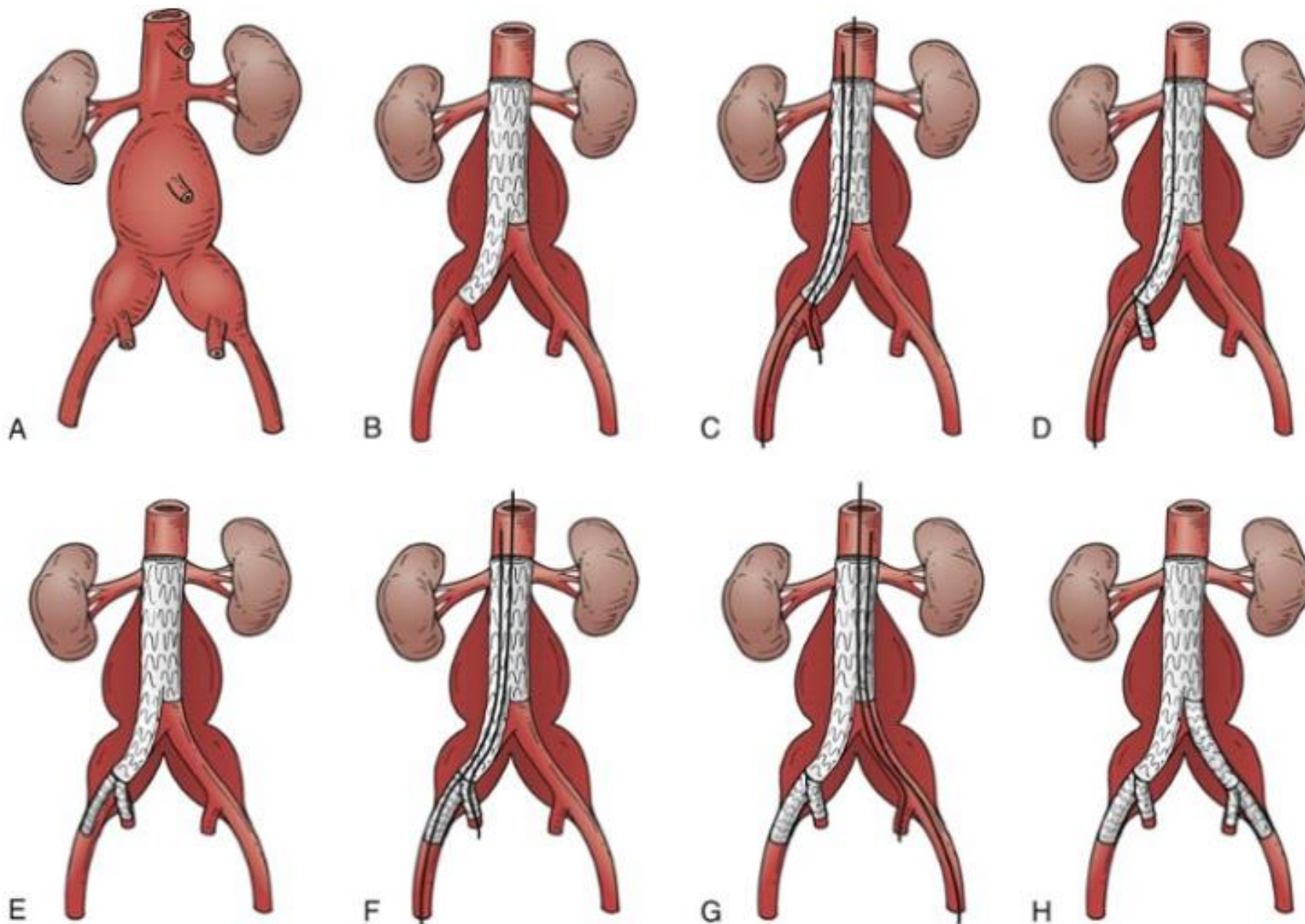
# 5-Year Outcomes of Fenestrated EVAR (FEVAR) Grafts

<b>FEVAR Graft Outcomes - Varlevisser et al., February 2019</b>		
<b>Outcomes</b>	<b>Effect Values</b>	<b>P-value</b>
<b>Perioperative: ZFENS vs Open Complex AAA Repairs</b>		
Mortality (%)	1.8% vs 8.8%	0.001
*Mortality (OR)	4.9 [95% CI:1.4-18.0]	<0.05
Blood Transfusions (%)	22% vs 73%	<0.001
Length of Stay (median)	2 days vs 7 days	<0.001
<b>Postoperative: ZFENS vs Open Complex AAA Repairs</b>		
Renal Dysfunction (%)	1.4% vs 7.7%	0.002
*Renal Dysfunction (OR)	13.0 [95% CI:3.6-49.0]	<0.05
Overall Complications (%)	11% vs 33%	<0.001
*Overall Complications (OR)	4.2 [95% CI:4.2-7.5]	<0.05
<b>ZFENS vs EVAR (%)</b>		
Perioperative Mortality	1.8% vs 0.8%	0.084
Postoperative Renal Dysfunction	1.4% vs 0.7%	0.19
Postoperative Any Complication	11% vs 7.7%	0.09
<b>Notes:</b> for % values the % listed to the audience's left = ZFEN and right = Open Complex AAA Repair OR right = infrarenal EVAR. * = Adjusted multivariate logistic regression models (Odds Ratios). OR = Odds Ratios.		

# FEVAR and BEVAR



# Complex Repairs with IIA Preservation



# Vascular Recommendations - AAA Repair in Medical Centers

- AAA repair is not recommended in centers with a caseload of <30 repairs/year
  - Class IIa; Evidence Level C
- Centers, networks, and collaborators treating AAA patients are recommended to offer both endovascular and open aortic surgery at all times
  - Class I; Evidence Level B



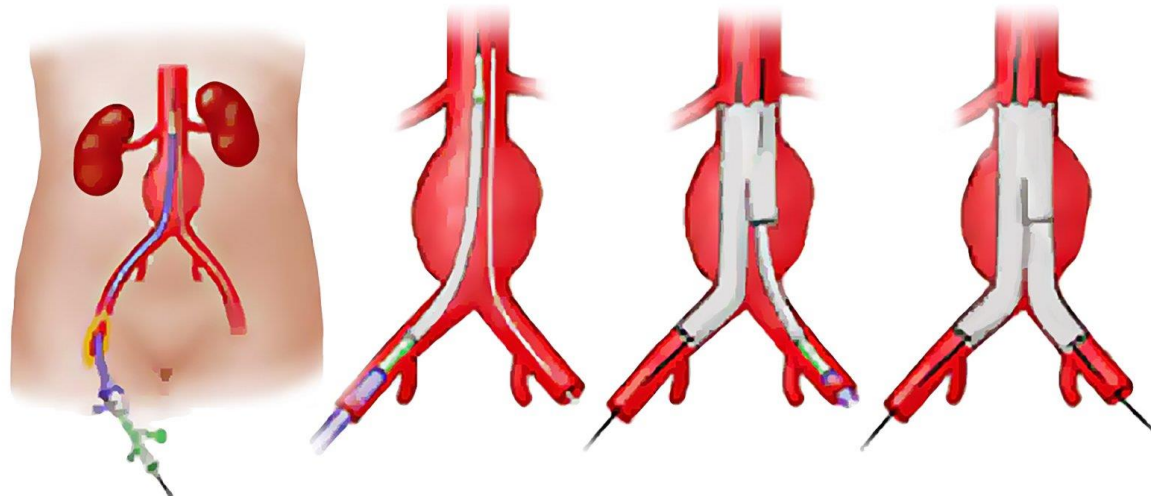
- Rupture Treatment - Endovascular AAA Repair:
  - In patients with known ruptured AAA and suitable anatomy EVAR is recommended as a 1<sup>st</sup> option
    - Class I; Evidence Level B
- Percutaneous Approach:
  - Ultrasound-guided percutaneous approach is recommended in endovascular AAA repair
    - Class IIa; Evidence Level B





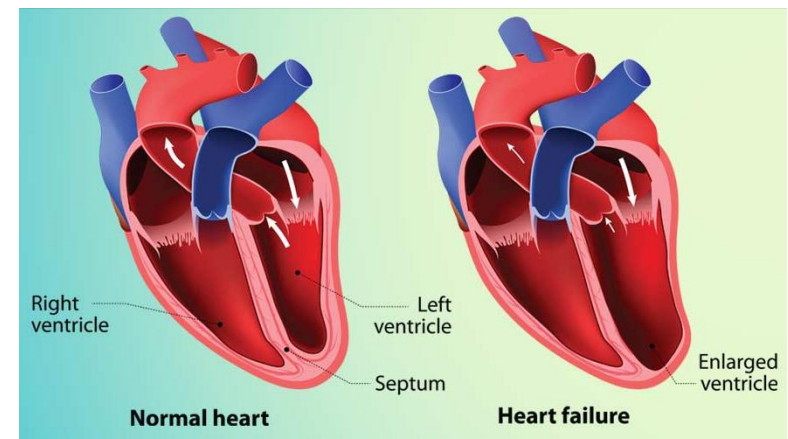
## Contraindications :

- Severely scarred groin
- High femoral bifurcation
- Need for frequent introducer sheath changes
- Significant proximal iliac occlusive disease
- Small iliofemoral arteries
- Anterior calcific femoral disease



# Summary of Recommendations

- Elective AAA Repair:
  - Normal survival is on average ~9 years
  - Not recommended in patients with limited life expectancy
    - Terminal cancer
    - Severe cardiac failure
  - A pragmatic definition of “limited life expectancy” is >2–3 years



- Evidence for EVAR vs Open in AAA Repairs:
  - **Most in favor of EVAR:**
    - Significant short-term survival benefit
    - Similar long-term outcomes up to 15 years
  - **Possible negative EVAR outcomes:**
    - Increased rate of complications may occur after ~8–10 years
      - Earlier generation EVAR devices
    - Uncertain durability of current devices
      - Particularly low-profile devices

***Therefore: EVAR should be considered the preferred modality in most patients, but it's reasonable to suggest open first for younger, fit patients, with a life expectancy of at least >10–15 years***

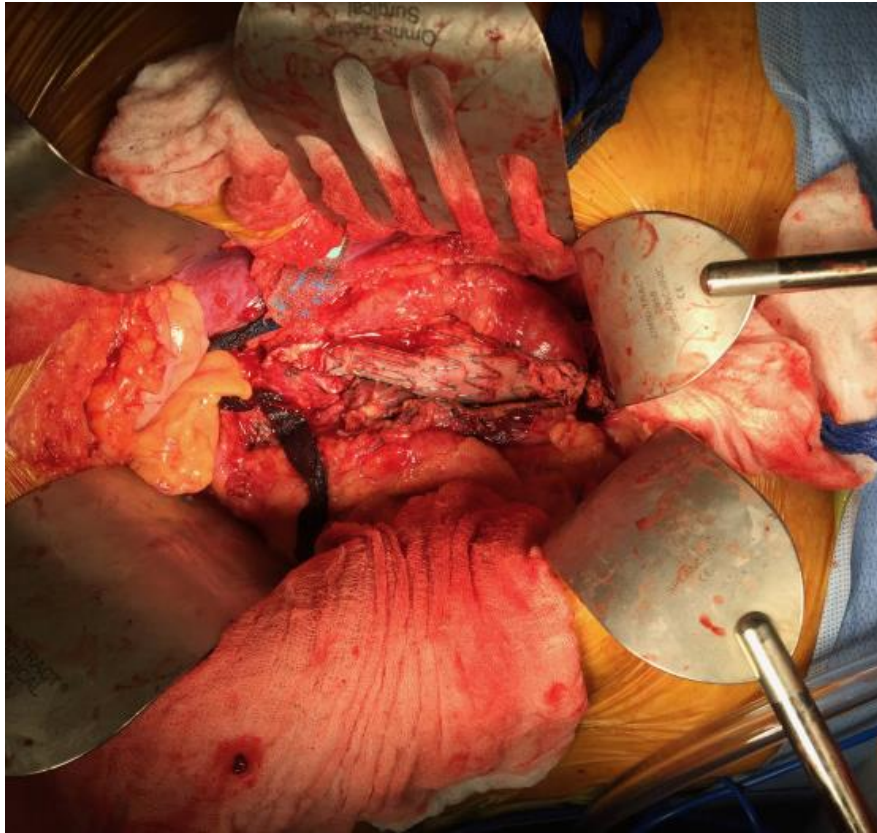


***Dua et al. “Progressive shortfall in open aneurysm experience for vascular surgery trainees with the impact of fenestrated and branched endovascular technology”. J Vasc Surg. 2017 Jan;65(1):257-261.***

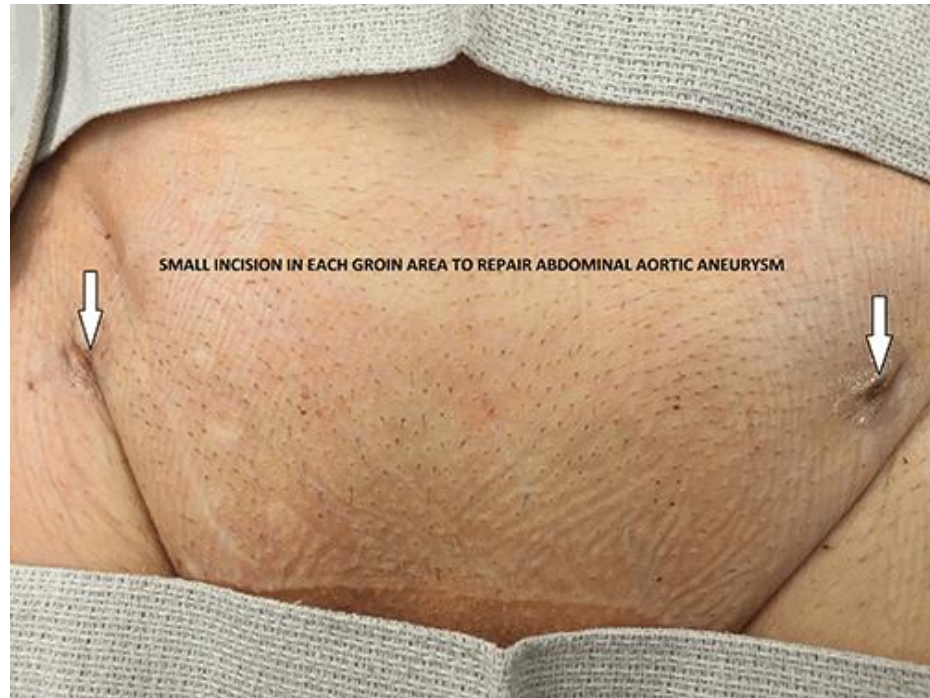
- Initial Prediction (2014):
  - Vascular trainees would complete ~5 open aortic repairs by 2020
- Updated Data:
  - BrEVAR and FEVAR:
    - Now appears vascular trainees will complete only 1 to 3 open aortic repairs during training
      - Therefore, ~1.2 open aortic repairs
      - Additionally, the accelerating pace of EVAR use from 2012-2014 contributes to this trend

# Which would you rather have?

## Open AAA Repair



## EVAR AAA Repair



# Thank You!

