

# Evolution of EVAR Devices and Techniques to Deal with Complex Abdominal Aortic Aneurysm Morphologies

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# Disclosure Statement of Financial Interest

- Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

- Affiliation/Financial Relationship

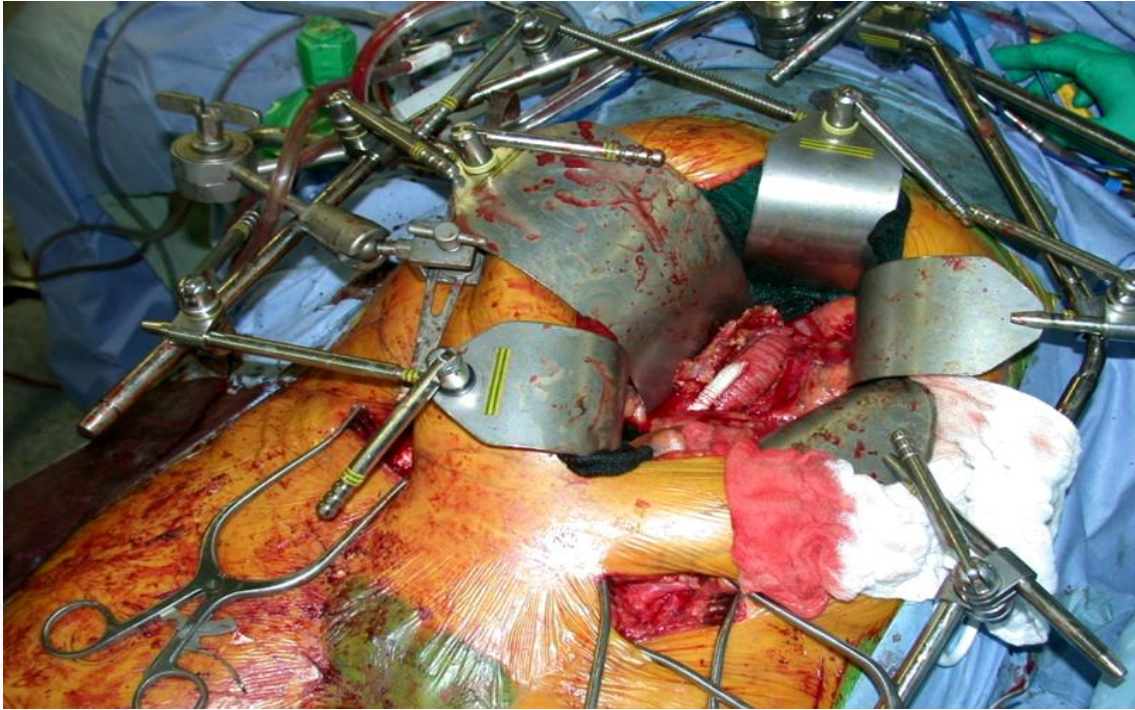
- Employee (Chief Medical Officer)
- Board Member, Stock Ownership

Company

Medtronic

Syntervention

# Open Surgery for AAA



Open surgery



4 days after

# The Typical EVAR Result



Home the following day

# Evolution of EVAR success

## **EVAR Advantages<sup>1-6</sup>**

- Shorter procedure time
- Shorter hospital stay
- Shorter recovery
- Lower perioperative mortality rate
- Lower morbidity rate
- Less blood loss
- Many unfit for open repair

## **EVAR Disadvantages<sup>1-6</sup>**

- Unproven durability
- Greater reinterventions
- Need for life-long surveillance

<sup>1</sup> Patel R, Sweeting M, Powel J, et al. Lancet 2016; 388: 2366–74.

<sup>2</sup> Antoniou GA, Antoniou SA, Torella F. Eur J Vasc Endovasc Surg. 2020 Mar;59(3):385-397.

<sup>3</sup> Stokmans RA, Teijink JA, Forbes TL, et al. Eur J Vasc Endovasc Surg. 2012 Oct;44(4):369-75.

<sup>4</sup> Schermerhorn ML, O'Malley AJ, Jhaveri A, et al. N Engl J Med. 2008 Jan 31;358(5):464-74.

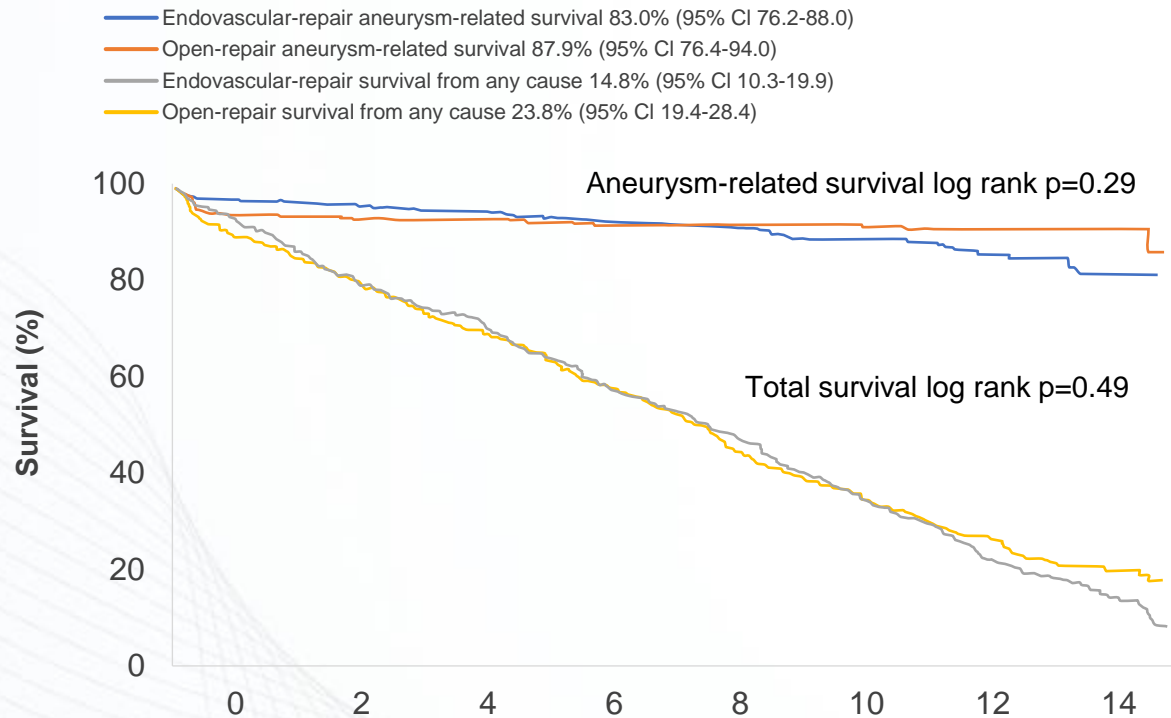
<sup>5</sup> Salata K, Hussain MA, de Mestral C, et al. JAMA Netw Open. 2019;2(7):e196578.

<sup>6</sup> Sweeting MJ, Patel R, Powell JT, et al. Ann Surg. 2017 Nov;266(5):713-719.

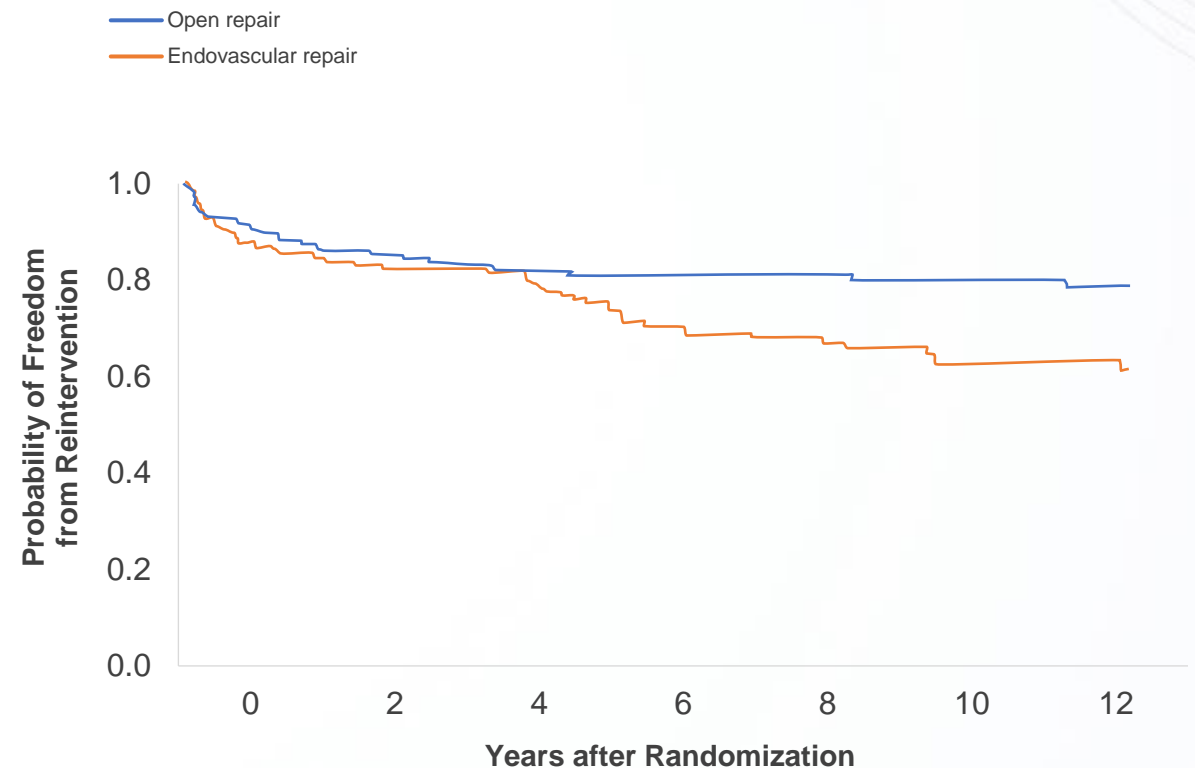
# EVAR Evolution

Original RCTs such as EVAR1 and DREAM raise concern for long term durability of first generation EVAR grafts

## EVAR1 Trial<sup>1</sup>



## DREAM Trial<sup>2</sup>



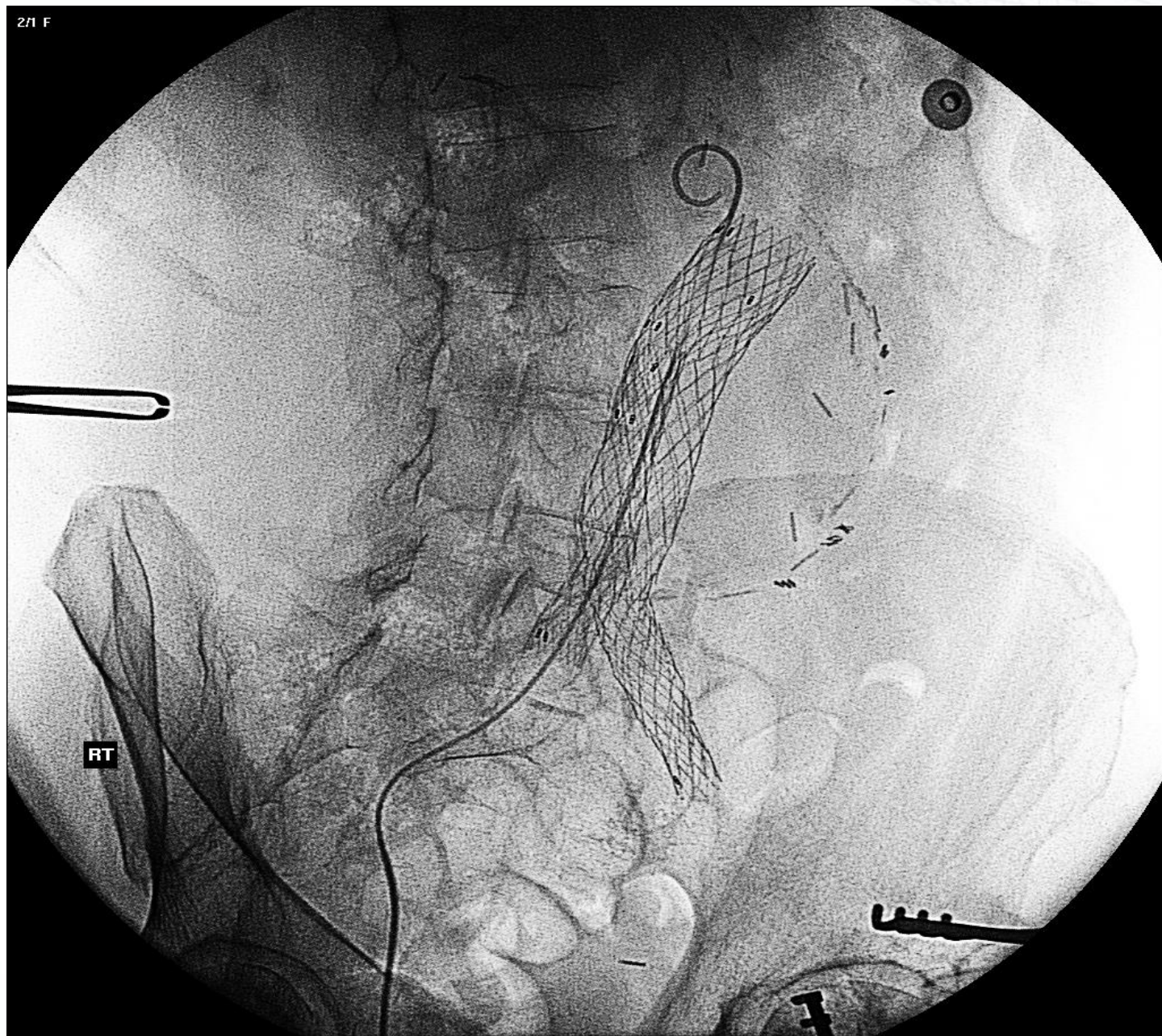
<sup>1</sup>Patel et al. Lancet. 2016;388(10058):2366-74. <sup>2</sup>van Schaik et al. J Vasc Surg. 2017;66(5):1379-89.

# First Generation EVAR Devices

- Rigidity of main body
- Lack of conformability to angulated neck
- Increased potential for distal migration
- Lack of suprarenal fixation
- Lack of sealing mechanism

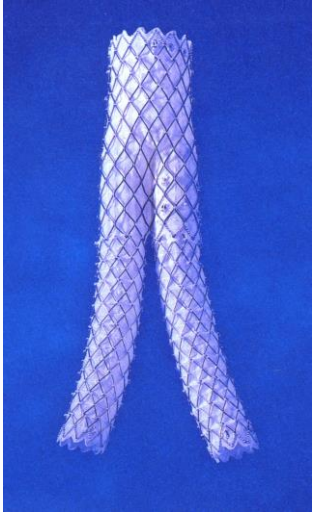


# Device Migration

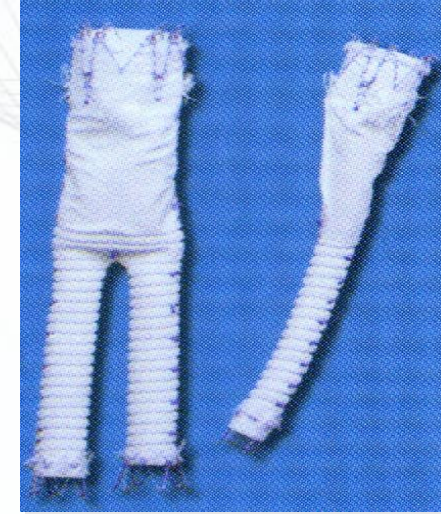




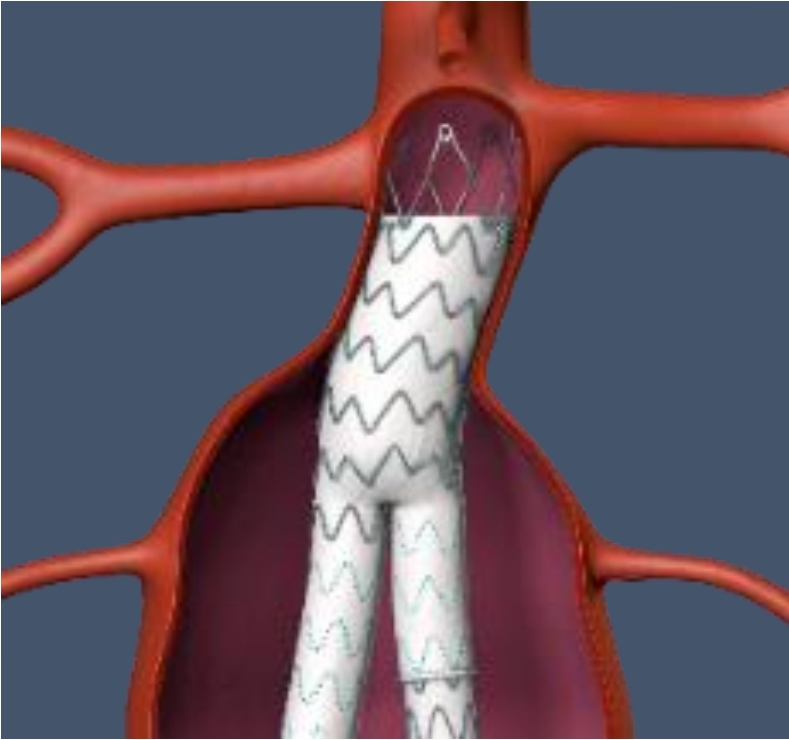
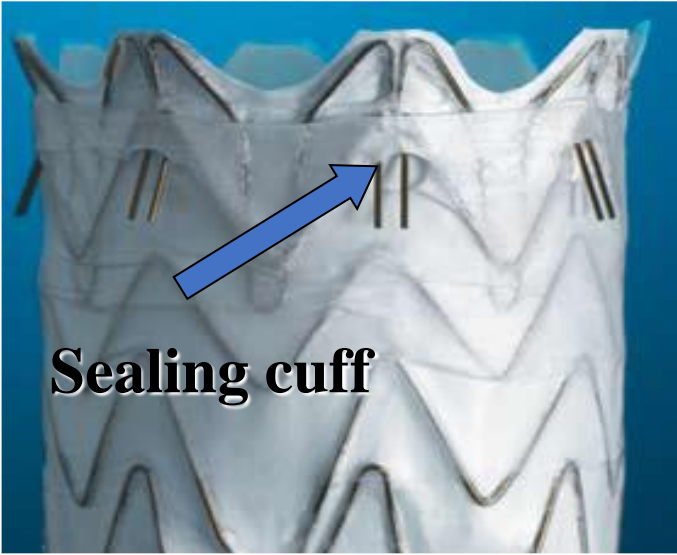
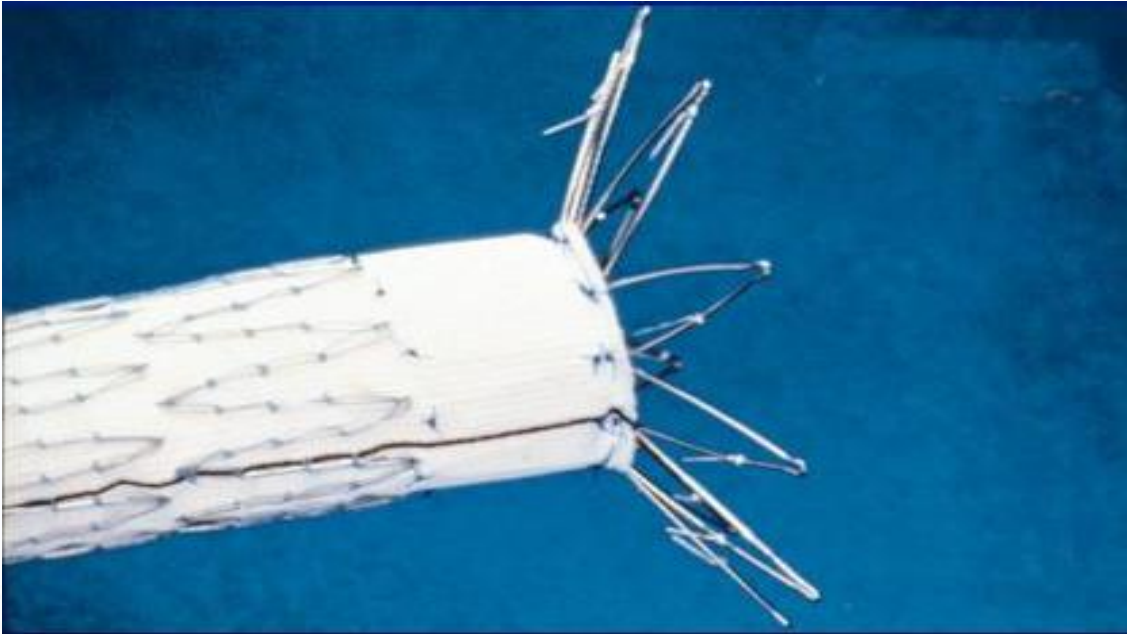
# Early EVAR Devices – FDA Approval



- AnCure: '99 – '03
  - Removed from the market
  - Perioperative complications
- AneuRx: '99
- Excluder: '02
- Zenith: '03
- Powerlink: '04
- Talent: '08
- Ovation: '12
- Zenith Fenestrated; '12
- Aorfix: '13



# Evolution of EVAR Devices



# Next Generation Devices



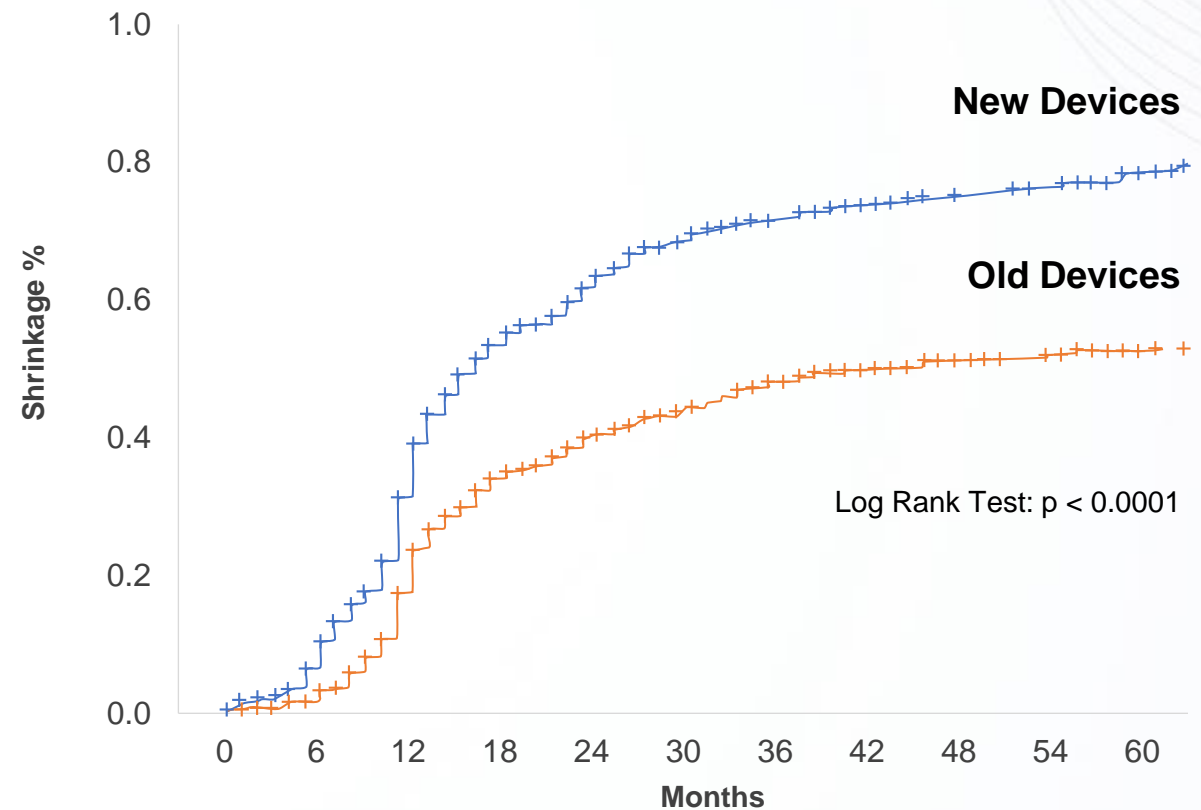
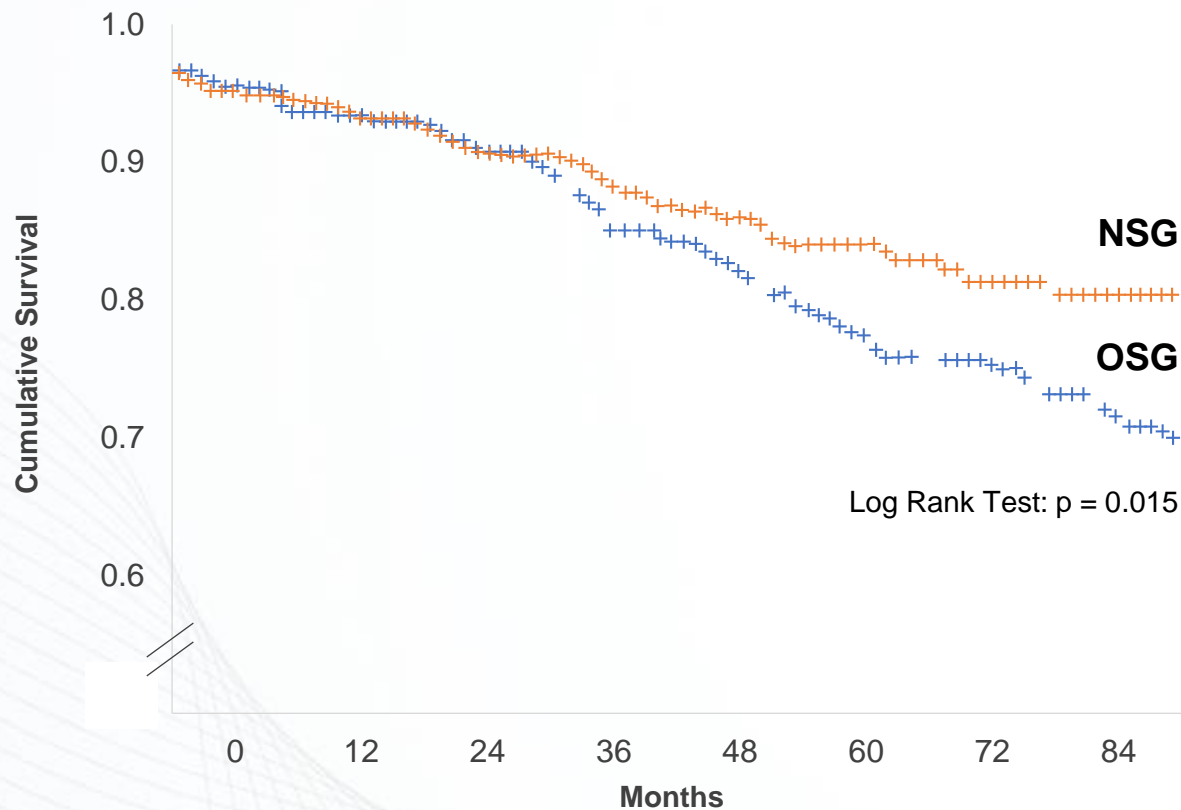
Conformable Excluder Endoprosthesis



Iliac Branch Endoprosthesis

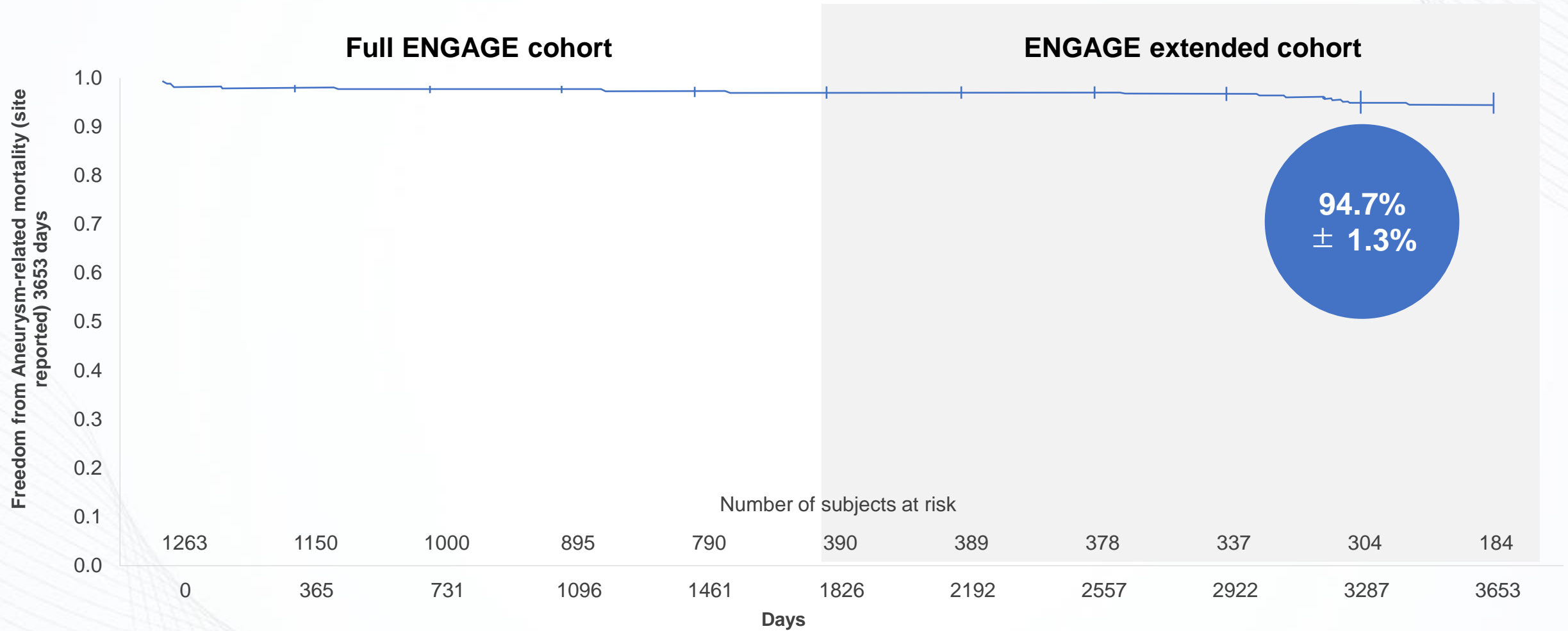
# EVAR Evolution

Contemporary grafts have demonstrated improvements in clinical outcomes compared to 1<sup>st</sup> generation grafts



<sup>1</sup>Verzini et al. J Endovasc Ther. 2014 Jun;21(3):439-47. <sup>2</sup>Cieri et al. Eur J Vasc Endovasc Surg. 2013 Aug;46(2):192-200.

# Freedom From Aneurysm-Related Mortality Through 10 years



Verhagen et al. Presented at: Charing Cross 2023 International Symposium; April 26, 2023; London, UK.  
 \*Number of subjects at risk are at the beginning of the interval and survival estimates are made at end of the interval. 1clinical events committee adjudicated

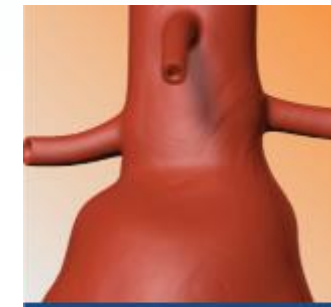
# Hostile neck anatomy challenges EVAR outcomes<sup>1</sup>

## Aortic seal zone is dependent on many factors:

- Length, angle, width, conicity, Ca<sup>2+</sup>, thrombus, device design, etc.

## Hostile neck characteristics leads to:

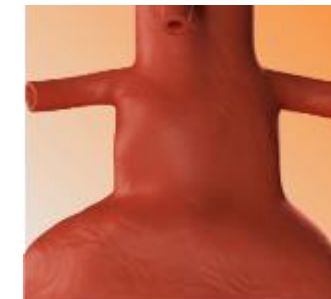
- Higher risk of type Ia's, neck degeneration, secondary procedures, late failure<sup>2</sup>



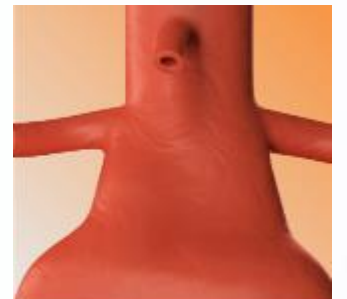
Short



Angulated



Wide



Conical

**4.5x**

Increased risk of developing Type Ia endoleak at 1 year (P = 0.01)<sup>1</sup>

**9x**

Increased risk of aneurysm-related mortality at 1 year (P = 0.01)<sup>1</sup>



<sup>1</sup> Antoniou, et al., J Vasc Surg 2013;57:527-38

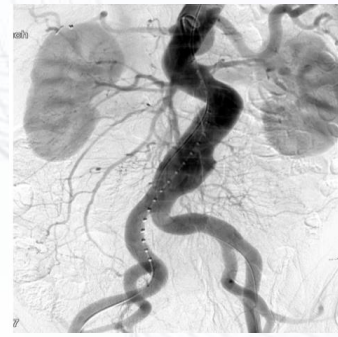
<sup>2</sup> Gargiulo M, et al. J Vasc Surg. 2017;66:1065-1072

# Meta-analysis of 16 major studies<sup>1</sup>

Higher risks in hostile necks

Total sample size: n=11,959 patients

- 8920 favorable neck
- 3039 hostile neck



Outcome	n	Hostile Neck	Favorable Neck	Odds Ratio (95% CI)	p-value
<b>30-Day: All studies</b>					
Primary Technical Success	6	1036 (96.8%)	3497 (98.3%)	0.45 (0.19, 1.06)	0.07
Intraoperative adjuncts	5	991 (15.4%)	3199 (8.8%)	1.88 (1.15, 3.07)	0.01
Stent-graft migration	4	1245 (1.6%)	4225 (0.9%)	2.08 (1.20, 3.62)	0.009

Outcome	n	Hostile Neck	Favorable Neck	Odds Ratio (95% CI)	p-value
<b>All studies</b>					
Early type I	8	1290 (6.5%)	3849 (4.0%)	2.92 (1.61, 5.30)	0.0004
Early type II	3	867 (8.5%)	3106 (10.8%)	0.74 (0.56, 0.97)	0.03
Late type I	8	2454 (7.1%)	7719 (3.8%)	1.71 (1.31, 2.23)	<0.0001
Late type II	6	1292 (9.1%)	3617 (10.5%)	0.74 (0.55, 0.99)	0.05

Further substantiation that **EVAR** in hostile necks faces significant challenges to proximal seal durability

<sup>1</sup> Stather PW, Wild JB, Sayers RD, Bown MJ, Choke E. J Endovasc Ther. 2013 Oct;20(5):623-37.

# Potential Solutions

- Alternative sealing solutions
- Recreate the surgical anastomosis
  - Endoanchor/Stapling device
- Move the fixation to visceral segment (more stable segment of the aorta)
  - Fenestrated/branched devices
- Parallel grafts





# Ovation Prime Stent Graft (ALTO)

Suprarenal nitinol stent with integral anchors for fixation

Low-viscosity, radiopaque, fill polymer

Neck Indication:  $\geq 7\text{mm}$

Inflatable rings for optimal seal and conformability



1°  
inch

LAO 18°  
CRAN 16°  
FD 14.4 inch

0:00  
4:00  
11:06:41

10  
1-13

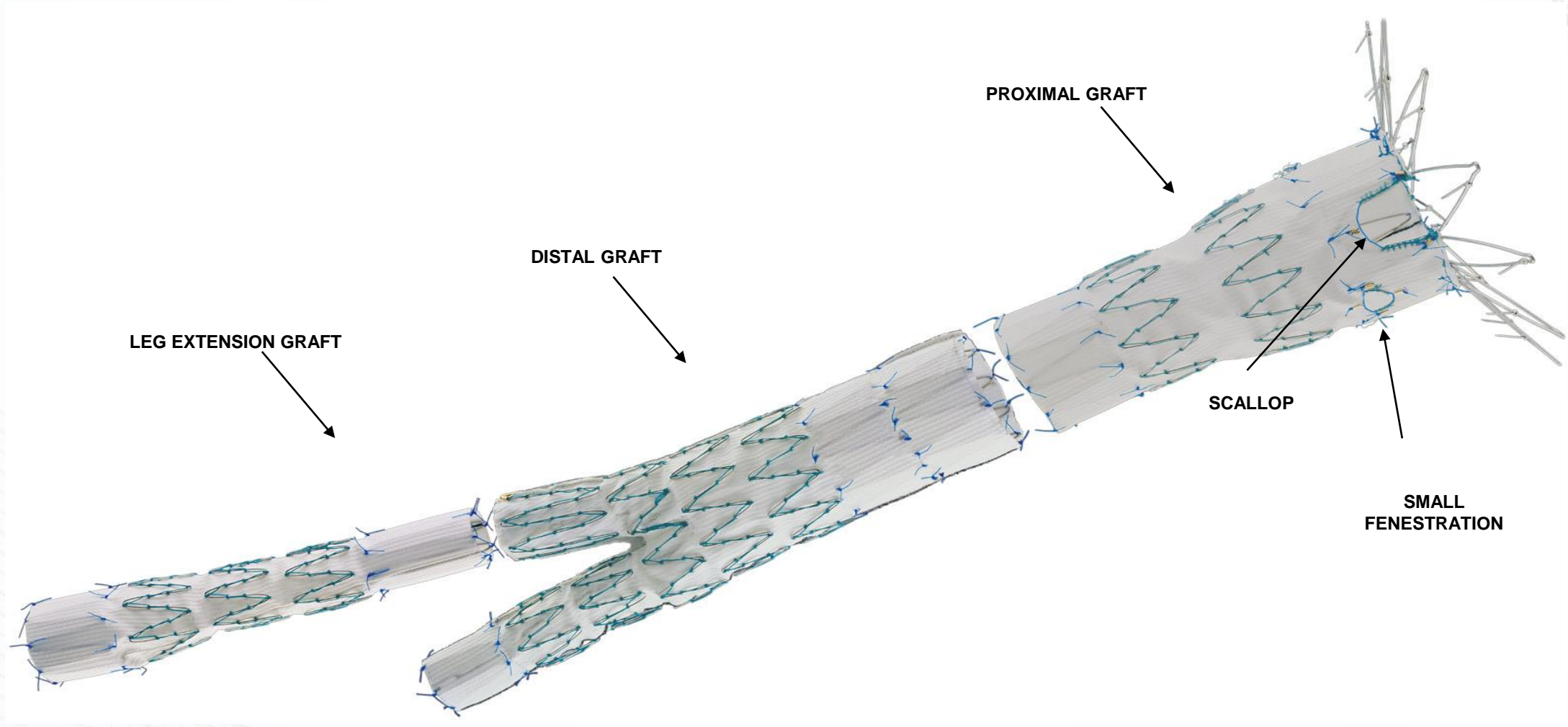
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# Baseline and One Year Follow-up CT

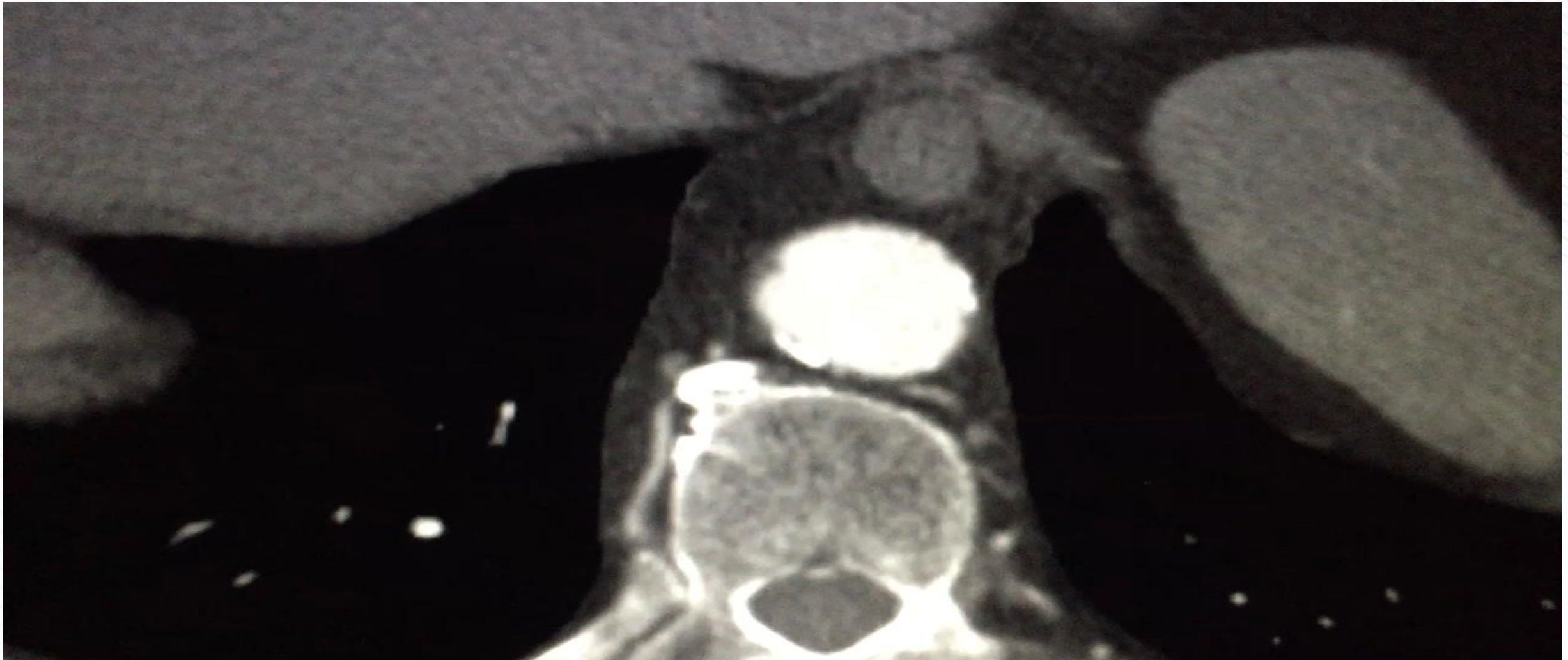




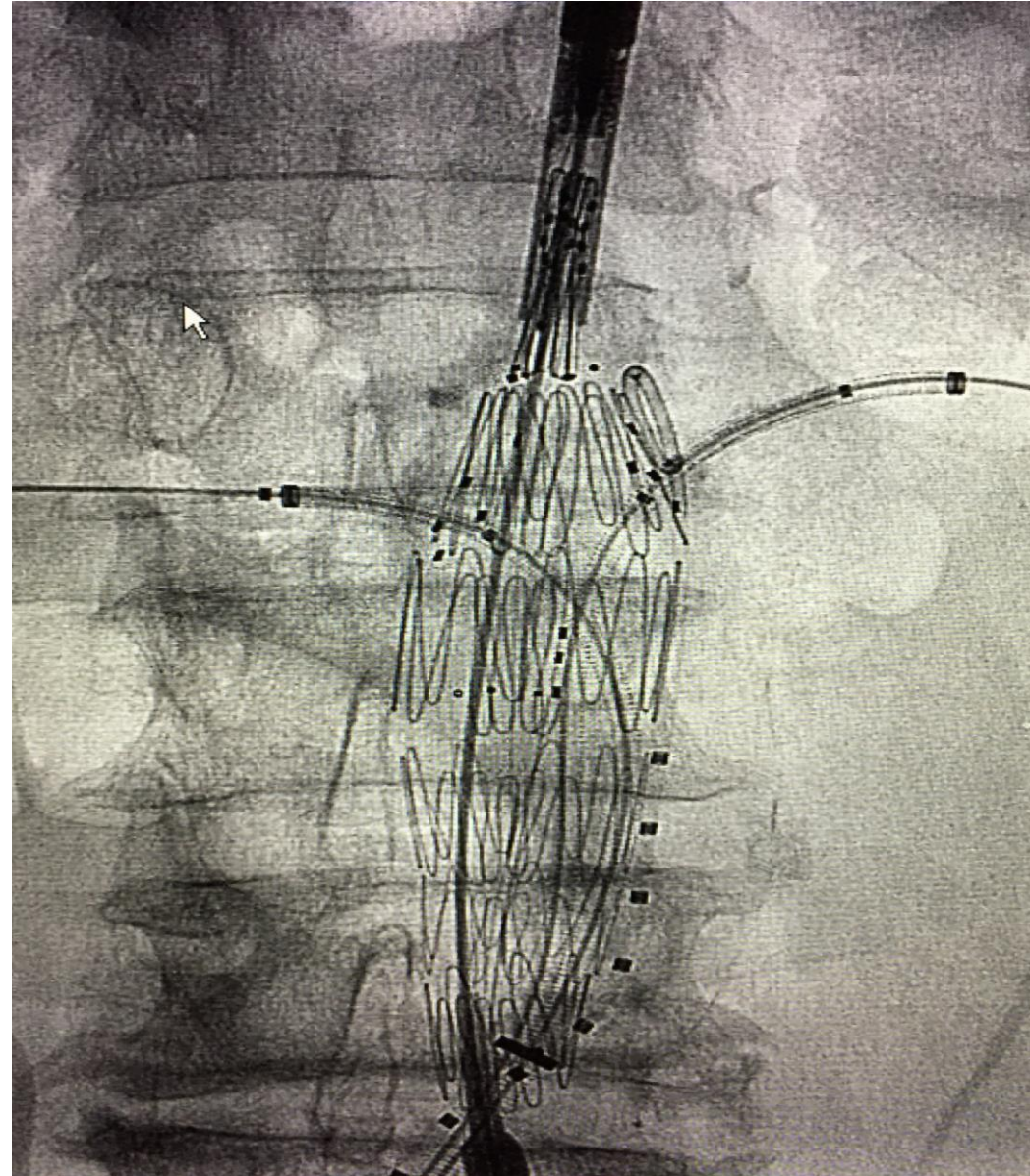
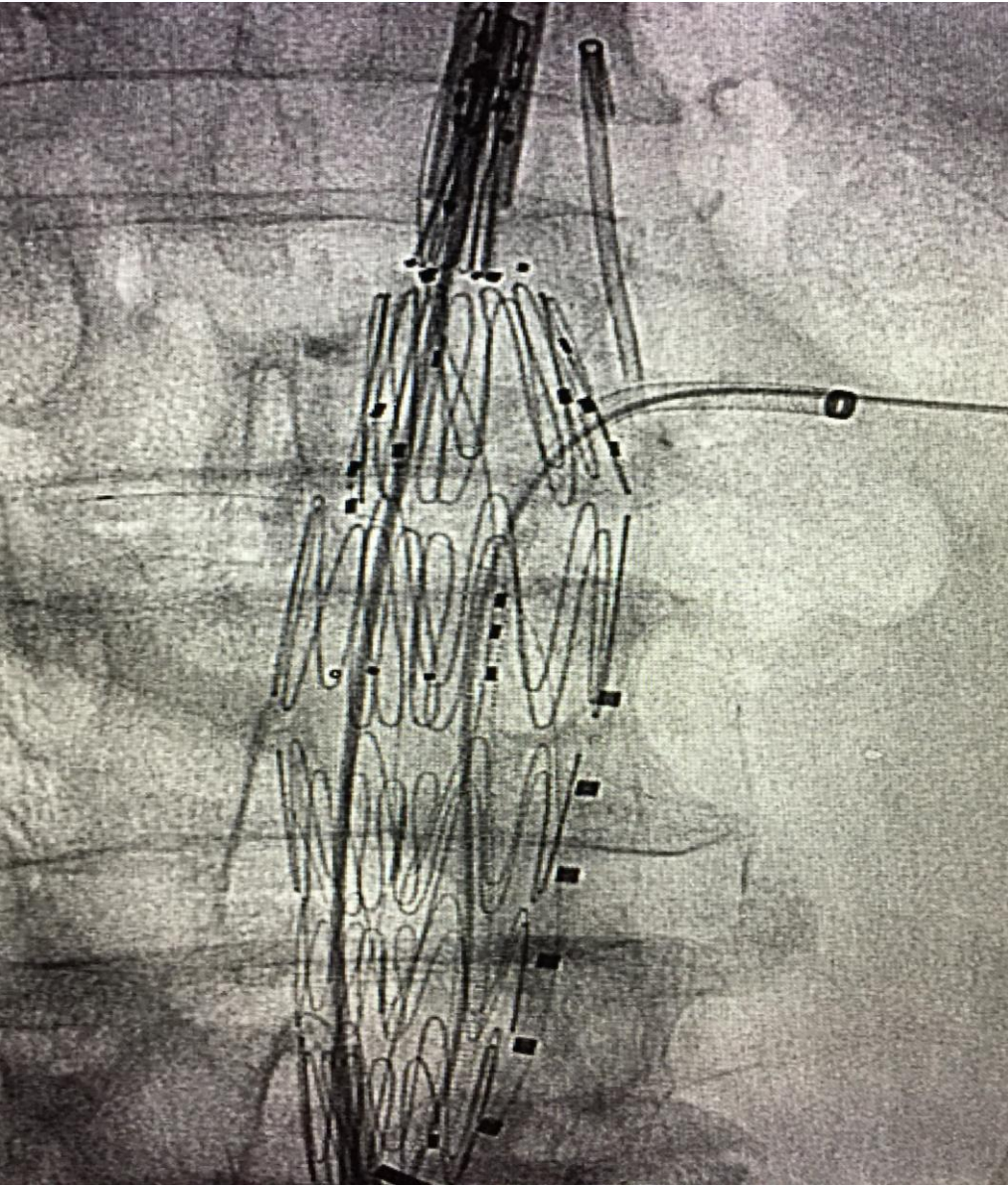
# Zenith Fenestrated AAA Endovascular Graft

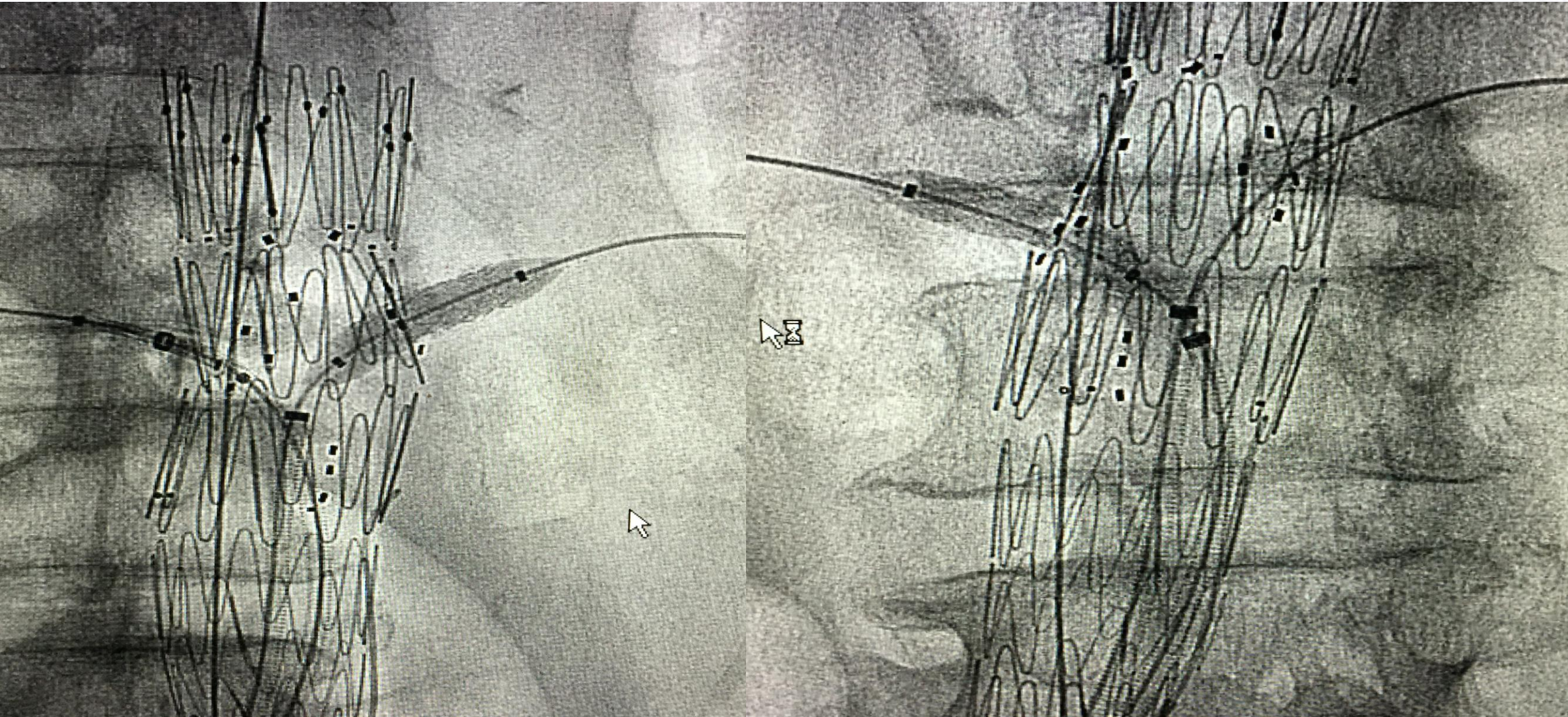


# No Infrarenal Aortic Neck



# FEVAR







# FEVAR



# EndoSuture Aneurysm Repair (ESAR)

ESAR with the Heli-FX™ EndoAnchor™ system has been reported to:

Reinforce the proximal seal<sup>1</sup>

*(Eur J Vasc Surg. 2017;53:458-459)*

Protect against neck dilatation<sup>2</sup>

*(J Vasc Surg. 2017;66:45-52)*

Promote greater sac regression<sup>3</sup>

*(J Vasc Surg. 2018;67:1699-1707)*

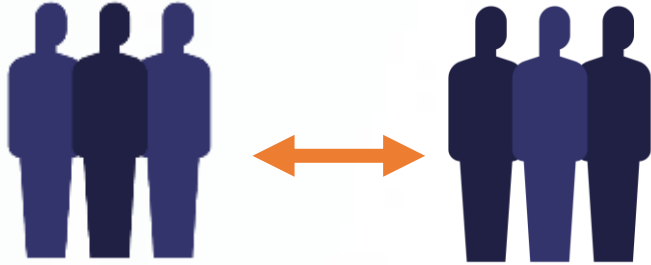


<sup>1</sup> Schlösser FJV, de Vries JPPM, Chaudhuri A., Eur J Vasc Endovasc Surg. 2017 Apr;53(4):458-459.

<sup>2</sup> Tassiopoulos AK, Monastiriotsis S, Jordan WD, et al., J Vasc Surg. 2017 Jul;66(1):45-52.

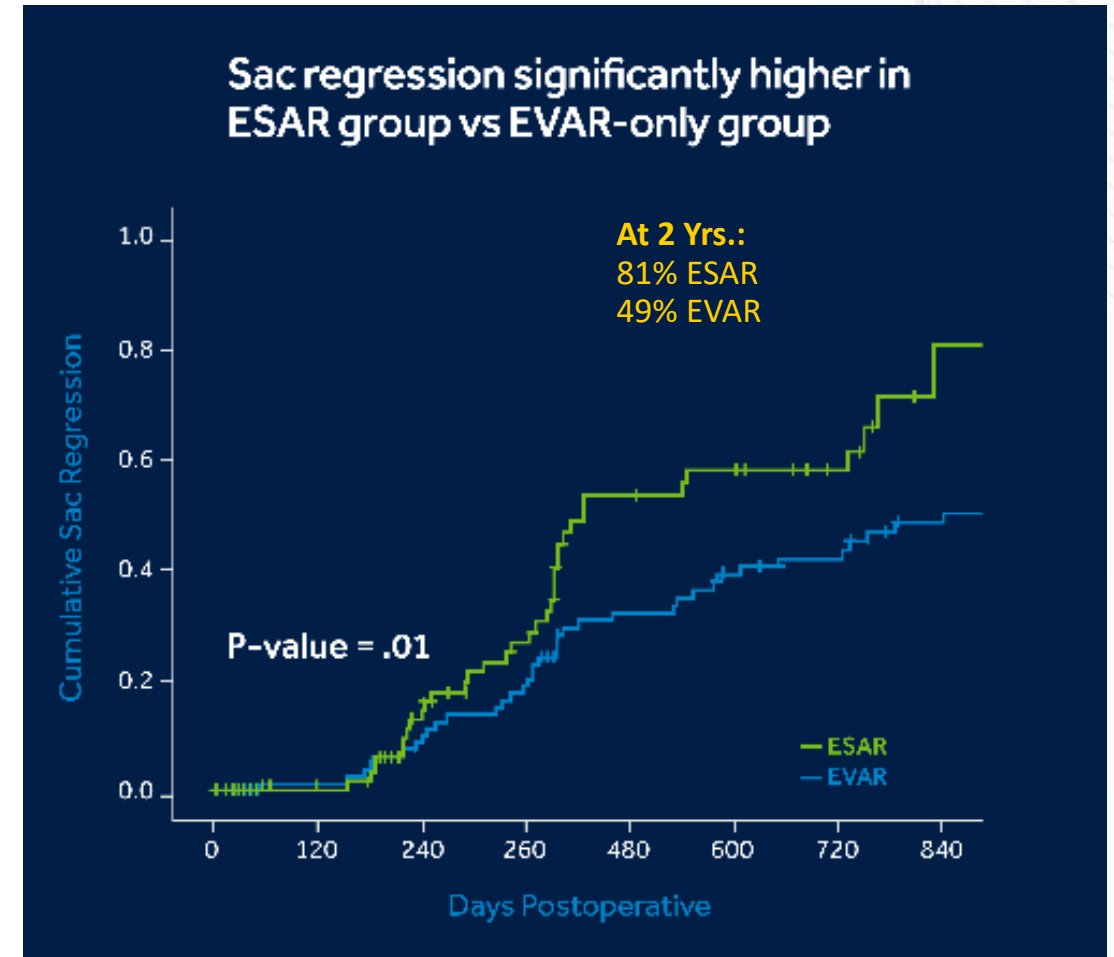
<sup>3</sup> Muhs BE, Jordan W, Ouriel K, et al., J Vasc Surg. 2018 Jun;67(6):1699-1707.

# ESAR can almost double sac regression rates



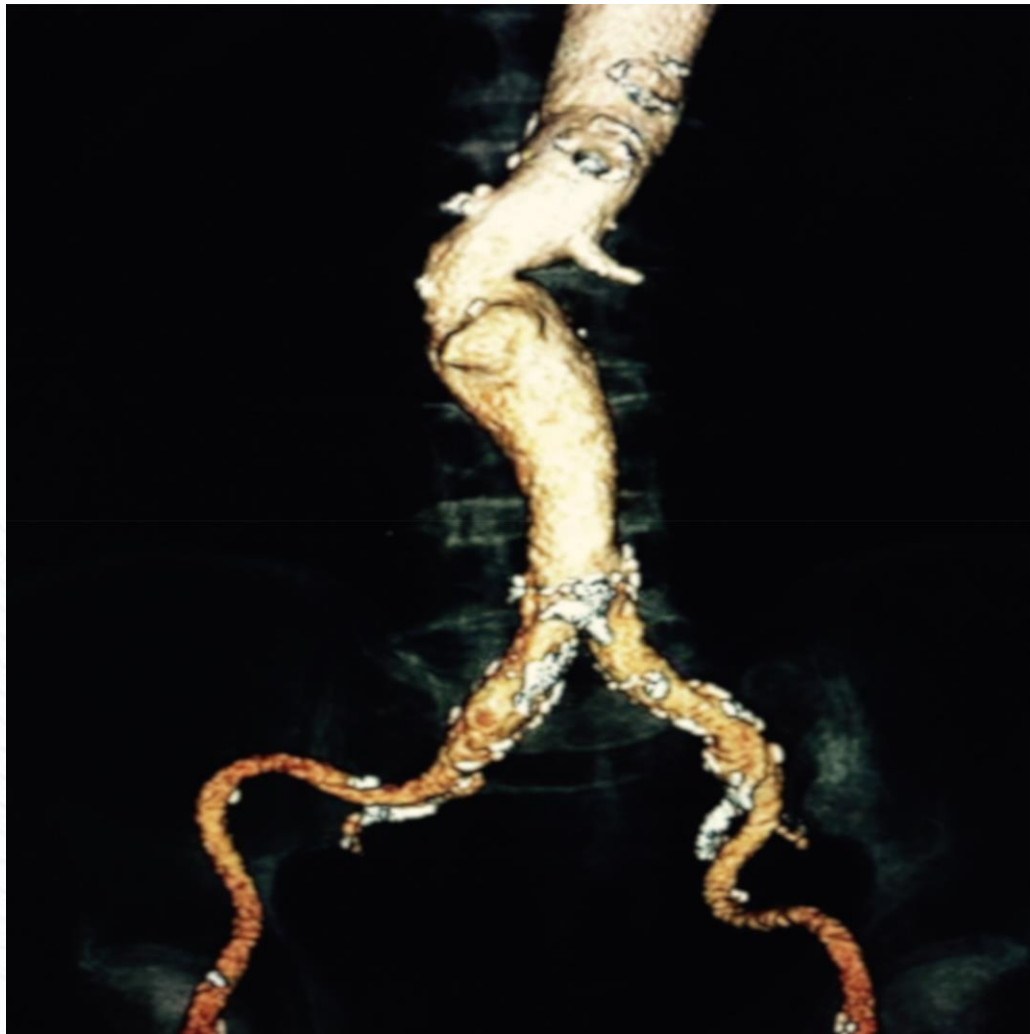
## Propensity matched baseline anatomies<sup>1</sup>

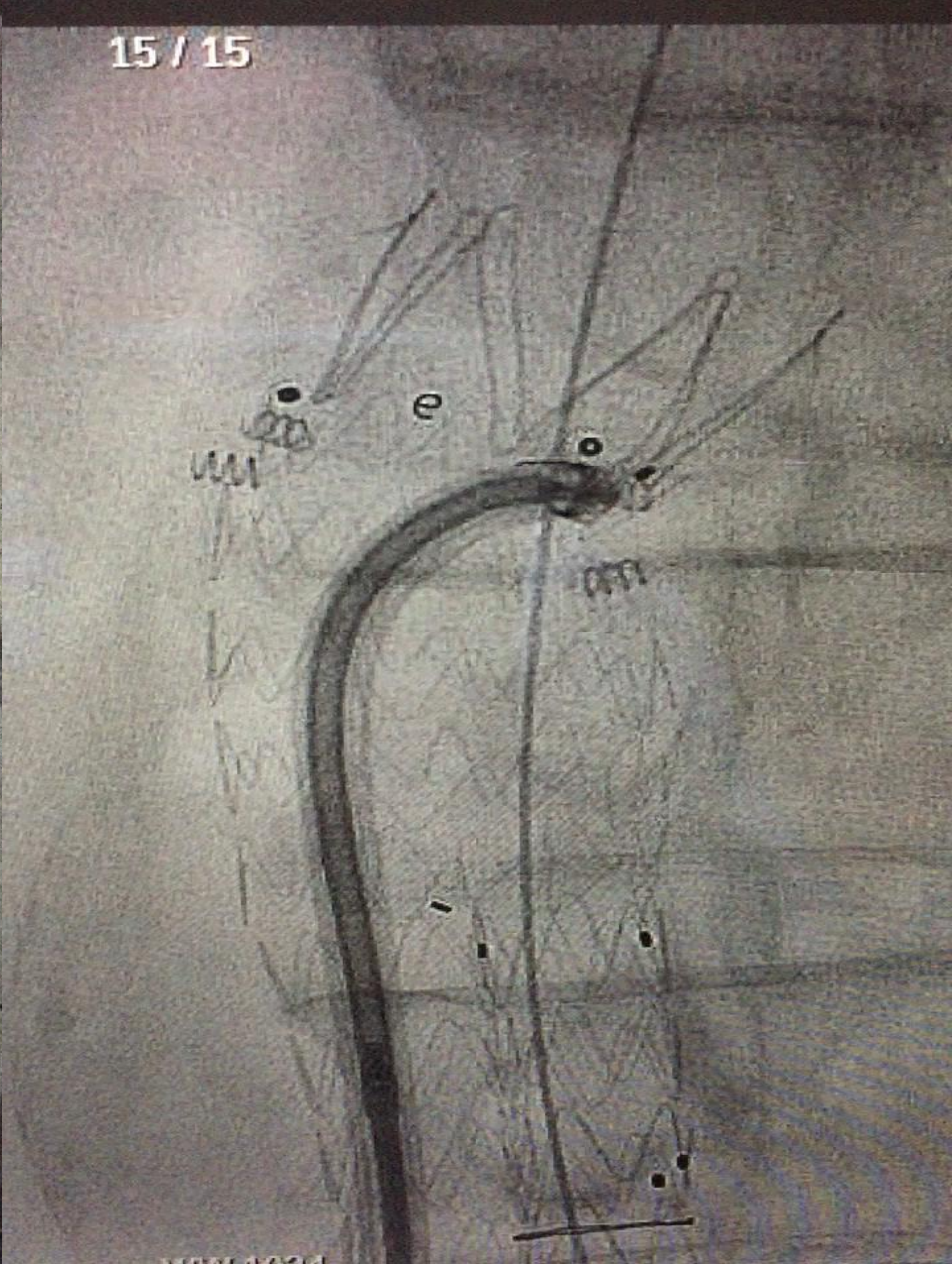
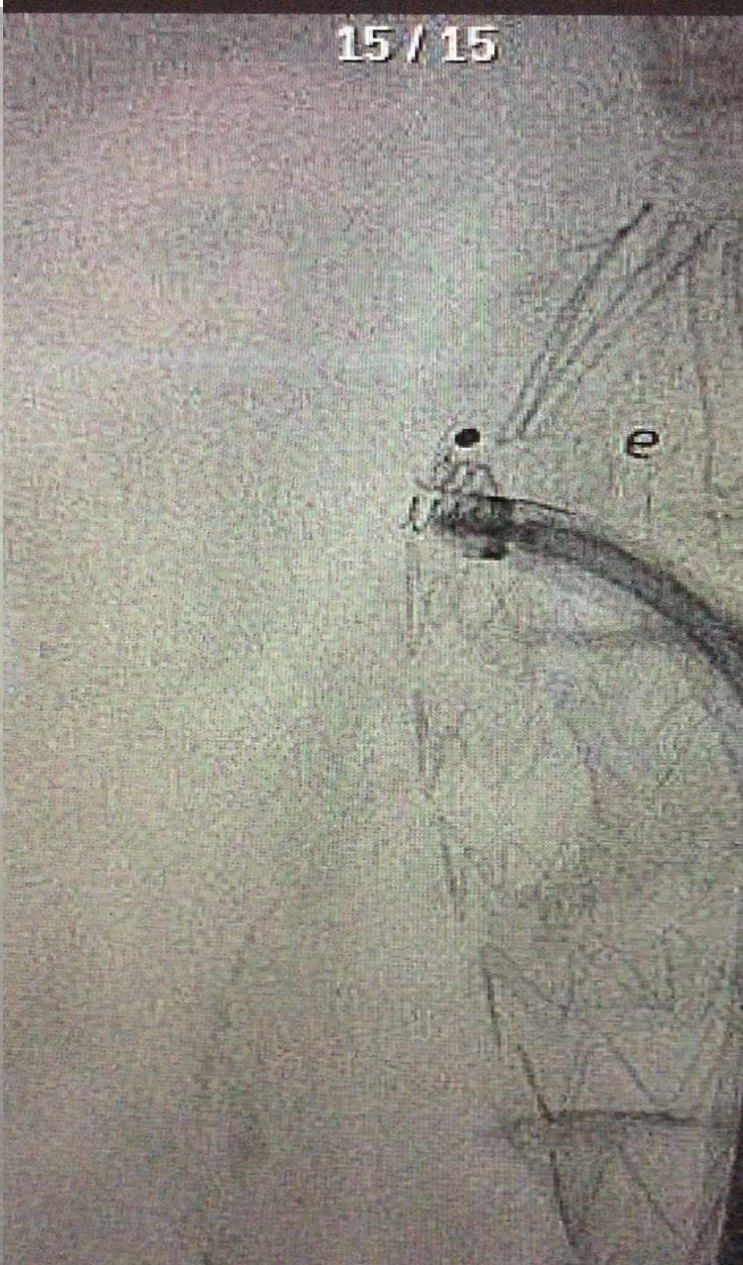
- 2 cohorts (99 pts EVAR + 99 pts ESAR)
- Various grafts (Endurant™, Excluder™\*, Zenith™\*)
- Average neck length >20mm
- No significant difference in detected type Ia endoleak rates between cohorts
- Core Lab reviewed images

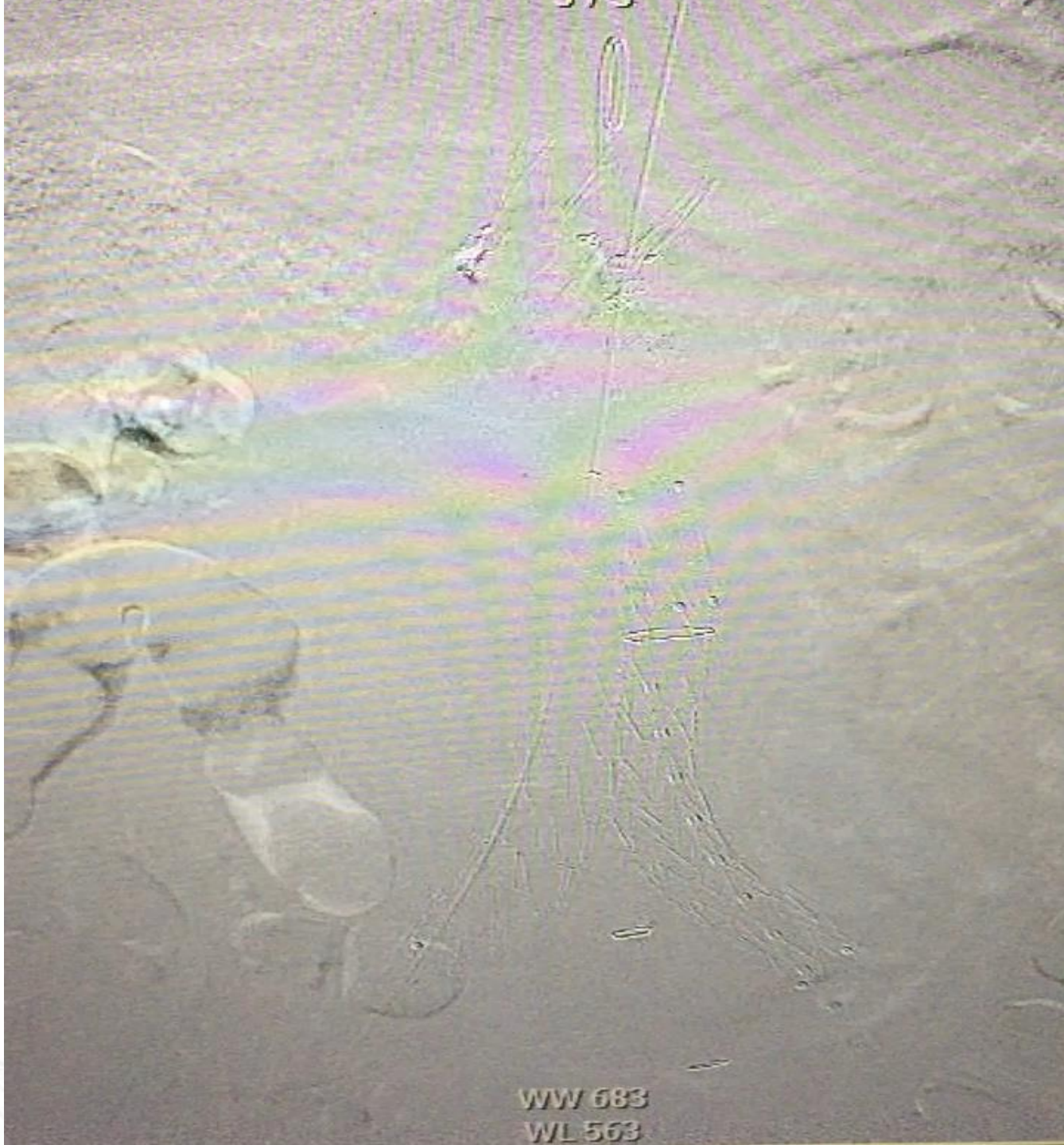


• ™\* Third party brands are trademarks of their respective owners. All other brands are trademarks of a Medtronic company.  
• <sup>1</sup> Muhs BE et al. J Vasc Surg. 2017

# Angulated Infrarenal Neck





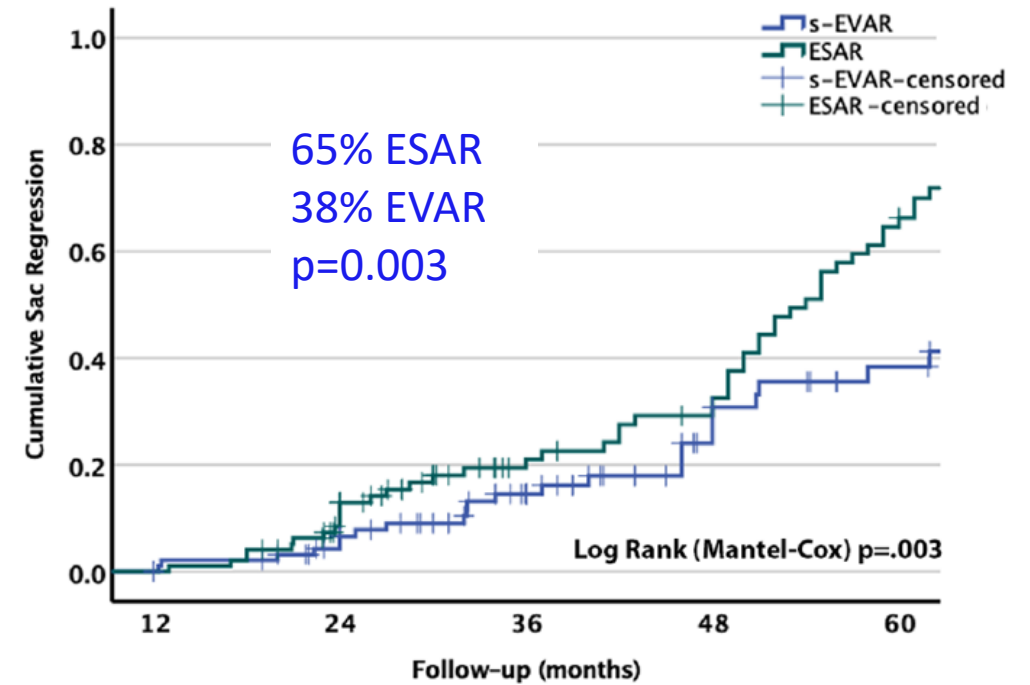


# PERU Registry: EVAR versus ESAR propensity matched patients with hostile neck anatomy

Independent study: PERU registry patients  
excluding patients that involved in the ANCHOR registry

- N = 96 EVAR; 96 ESAR
- Propensity Score Matching: Neck length, width, angulation, Fixation device type
- Excludes neck lengths > 15mm
- Multiple grafts: Endurant™, Cook Zenith™\*, Gore Excluder™\*

Cumulative sac regression at 5 years



Reyes Valdivia A, Oikonomou K, Milner R, Kasprzak P, Reijnen MMPJ, Pitoulias G, Torsello GB, Pfister K, de Vries JPM, Chaudhuri A. The Effect of EndoAnchors on Aneurysm Sac Regression for Patients Treated With Infrarenal Endovascular Repair With Hostile Neck Anatomies: A Propensity Score Analysis. J Endovasc Ther. 2022 Oct 10:15266028221127839.

# Meta-analysis of 8 studies and 17,096 patients

*Sac regression correlates with improved outcomes following EVAR<sup>1</sup>*

Aneurysm sac regression associated with<sup>1</sup>

1. Significantly **lower** hazard of **death**
2. Significantly **lower** odds of **rupture**
3. Significantly **lower** hazard of **secondary interventions and late complications**

<sup>1</sup> Antoniou GA, Alfahad A, Antoniou SA, et al, J Endovasc Ther. 2020 Oct;27(5):857-868.



# Conclusion

- Remarkable evolution of stent graft devices over the past 25+ years of EVAR
- Second and third generation devices have improved EVAR outcomes
- Hostile necks remain a challenge, but newer approaches and evolving equipment and techniques are leading to improved sac shrinkage and reduced aneurysm related mortality