

EndoAnchors, a bailout option or an everyday tool?

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DISCLOSURES

ADVISORY BOARD MEMBER: MEDTRONIC

CONSULTANT: GETINGE, BENTLEY

CO-FOUNDER: ENDOVASCULAR DIAGNOSTICS

RESEARCH GRANTS: GORE, JSF FOUNDATION, FOUNDATION L & L.

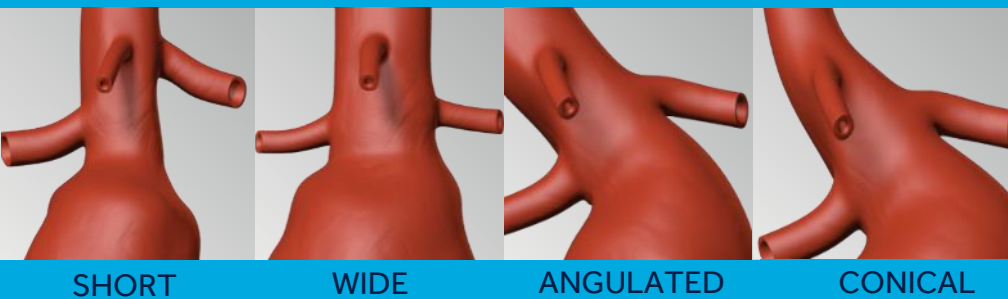
KEY FACTORS THAT PUT AN EVAR PATIENT AT RISK FOR SUBOPTIMAL OUTCOMES

MULTIPLE FACTORS = INCREASED RISK

HOSTILE NECKS

4.5x Increased risk of developing Type Ia endoleak at 1 year (P = 0.01)¹

9x Increased risk of aneurysm-related mortality at 1 year (P = 0.01)¹

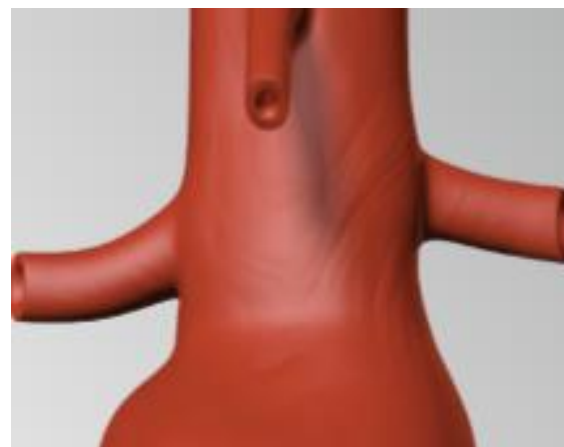


WIDE NECKS

Meta-analysis² of neck diameters ≥ 25 , ≥ 28 , & ≥ 30 mm

6.7x More likely to have Type Ia endoleak (P = 0.001)²

10x More likely to have sac expansion (P = 0.009)²



ADDITIONAL CONSIDERATIONS

LONG LIFE EXPECTANCY

AAA is a progressive dilating disease even after EVAR or open surgical repair³

AT RISK FOR NOT HAVING FOLLOW UP

22% of EVAR patients were lost to imaging f/u at 1yr⁴

Independent risk factors for not following up

- Urgent or emergent cases⁴
- Multiple comorbidities⁴
- Older patients⁴
- Travel time to hospital⁵

¹Antoniou GA, et al. *J Vasc Surg.* 2013;57:527-538

²Kouvelos GN, et al. *J Cardiovasc Surg.* 2019;60(2):167-174

³Oberhuber et al. *J Vasc Surg.* 2012;55(4):929-934

⁴Schanzer A, et al. *J Vasc Surg.* 2015;61:16-22

⁵Morris et al. *Am Surg.* 2017;83(8):339-341

SURGICAL STRENGTH, ENDOVASCULAR APPROACH

Radial support just as with sutures⁴

96.3% implants with adventitial penetration^{1†}

Stronger attachment over EVAR alone²

via secure transmural wall fixation³

Graft fixation strength with EndoAnchor™ implants exceeds inherent aortic integrity of cadaver²

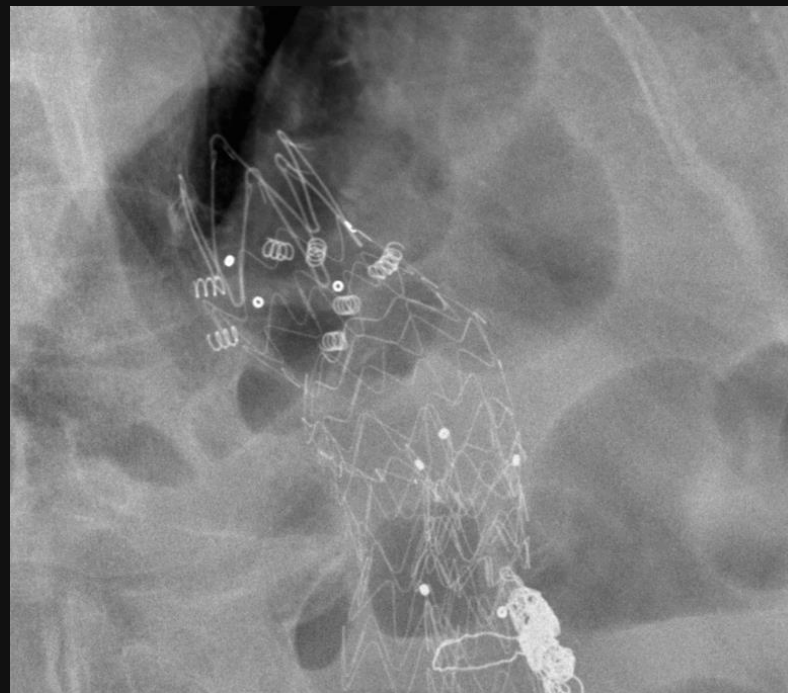
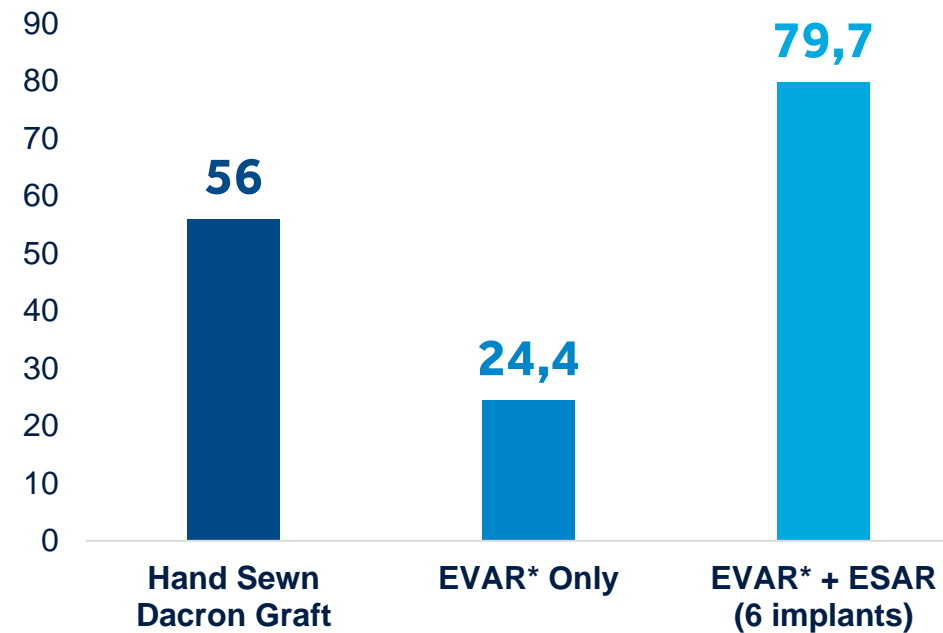


Image courtesy of Dr. K. Oikonomou

Mean Displacement Force (N)²



*Multiple endograft types were tested



Video courtesy of Dr. David Deaton

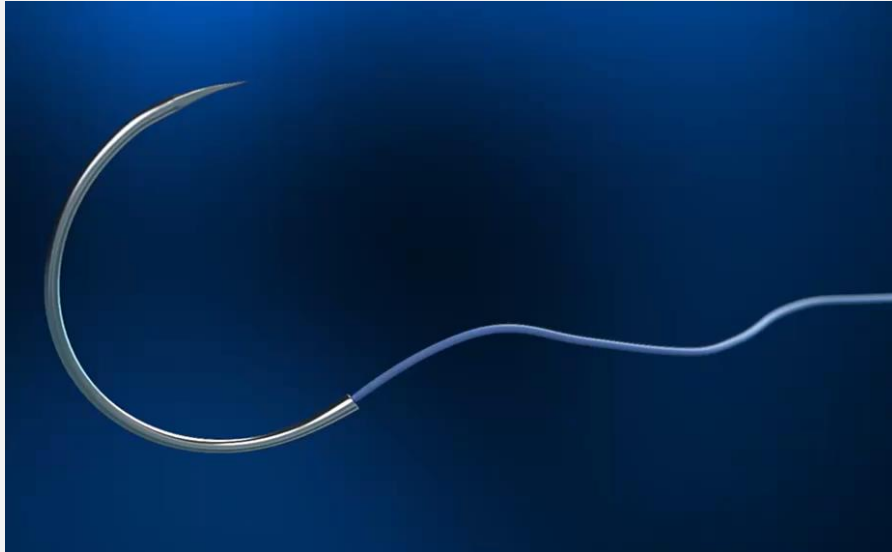
¹ Site Reported, ANCHOR Registry Primary AAA Arm, October 2020 data cut. Medtronic data on file.

² Melas N, et al. J Vasc Surg. 2012;55:1726-1733

³ Schlosser et al. Eur J Vasc Surg. 2017;53:458-459

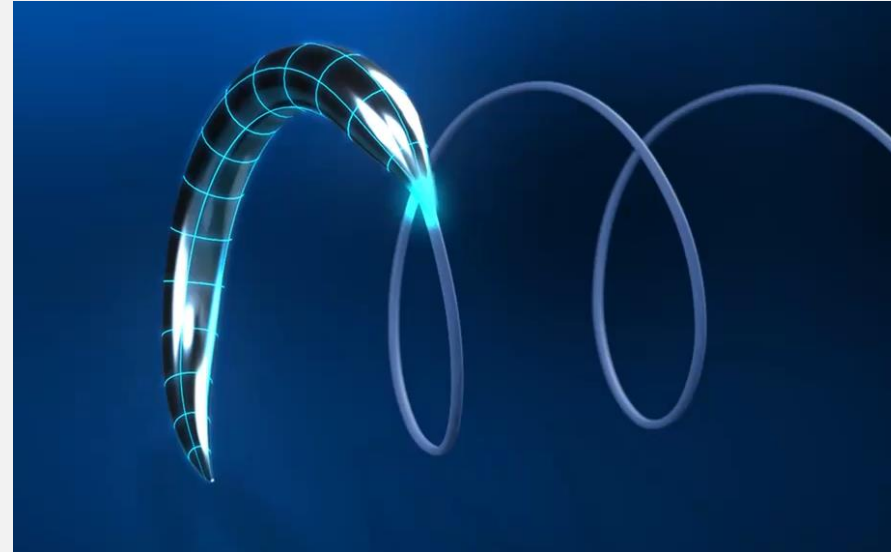
⁴ Foteh. EVToday. 2016. June:16-22

† ANCHOR 4-yr Primary AAA Arm, at intended location



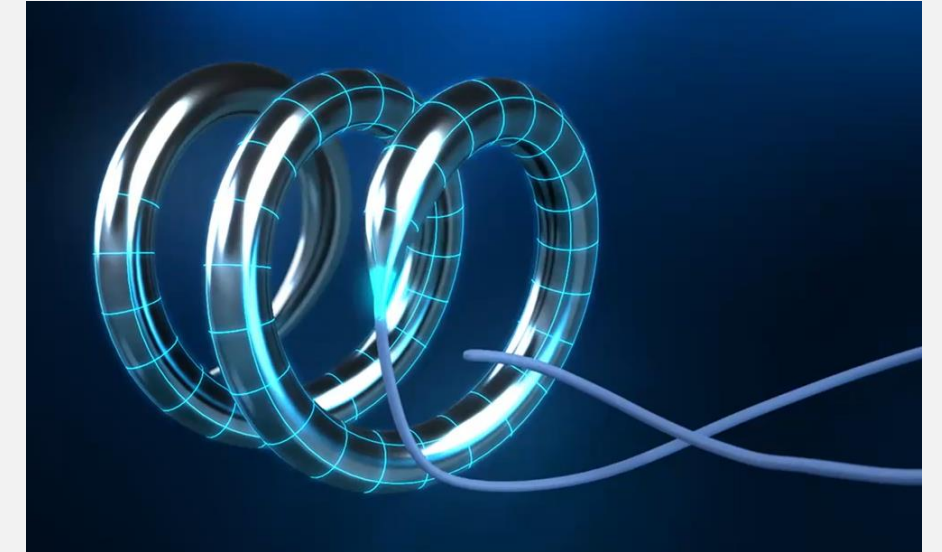
CONICAL TIP

- Replicates SH-1 tip
- Transmural Penetration



HELICAL SHAPE

- Replicates suture loops
- Stability

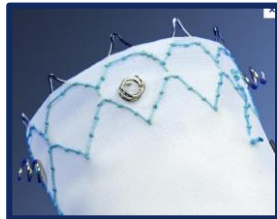


REAR CROSSBAR

- Replicates suture knot
- Secure attachment

LONG-TERM RESULTS

5-Year Safety and Efficacy Evidence by Core Lab

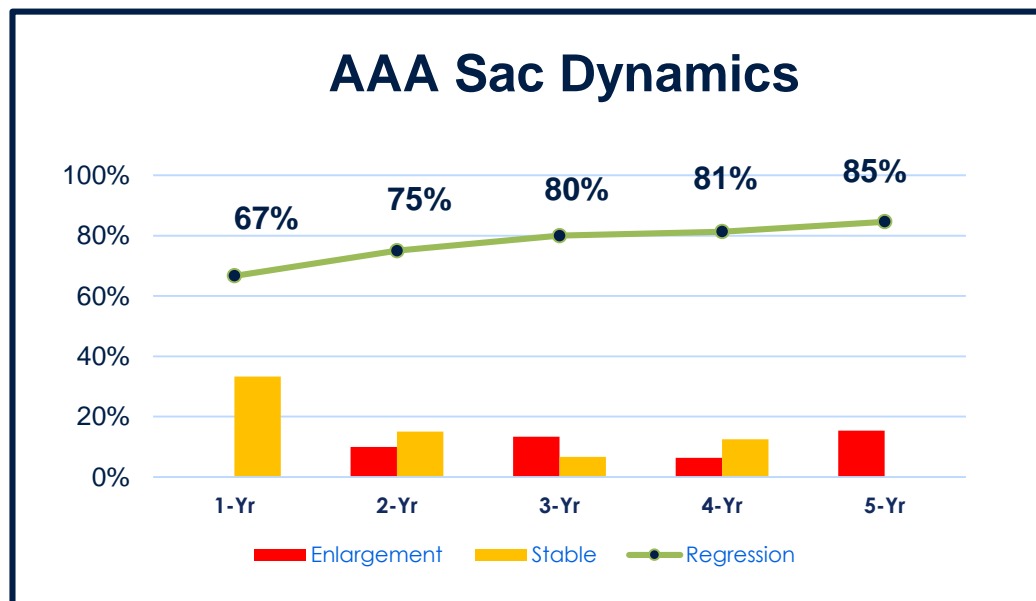


STAPLE-I Trial

Safety & Feasibility; 2006-2007

- 21 pts across 5 US sites

Endoleak	1-Yr	2-Yr	3-Yr	4-Yr	5-Yr
Type 1a	0%	0%	0%	0%	0%



No AAA ruptures

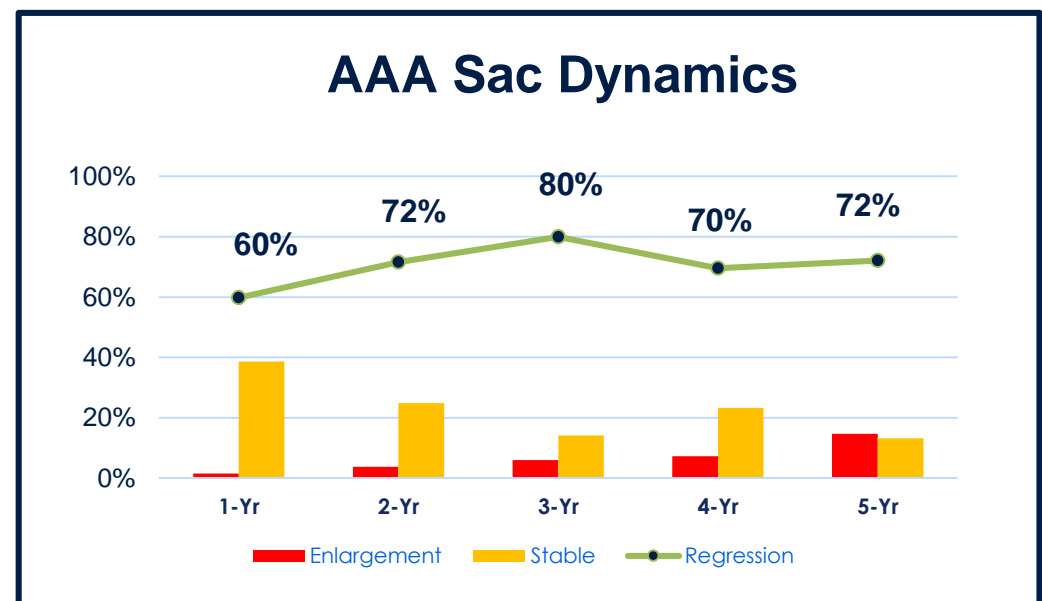


STAPLE-II Trial

Safety & Efficacy; 2007-2009

- 155 pts across 33 US sites

Endoleak	1-Yr	2-Yr	3-Yr	4-Yr	5-Yr
Type 1a	0%	0%	0%	0%	0%



No AAA ruptures

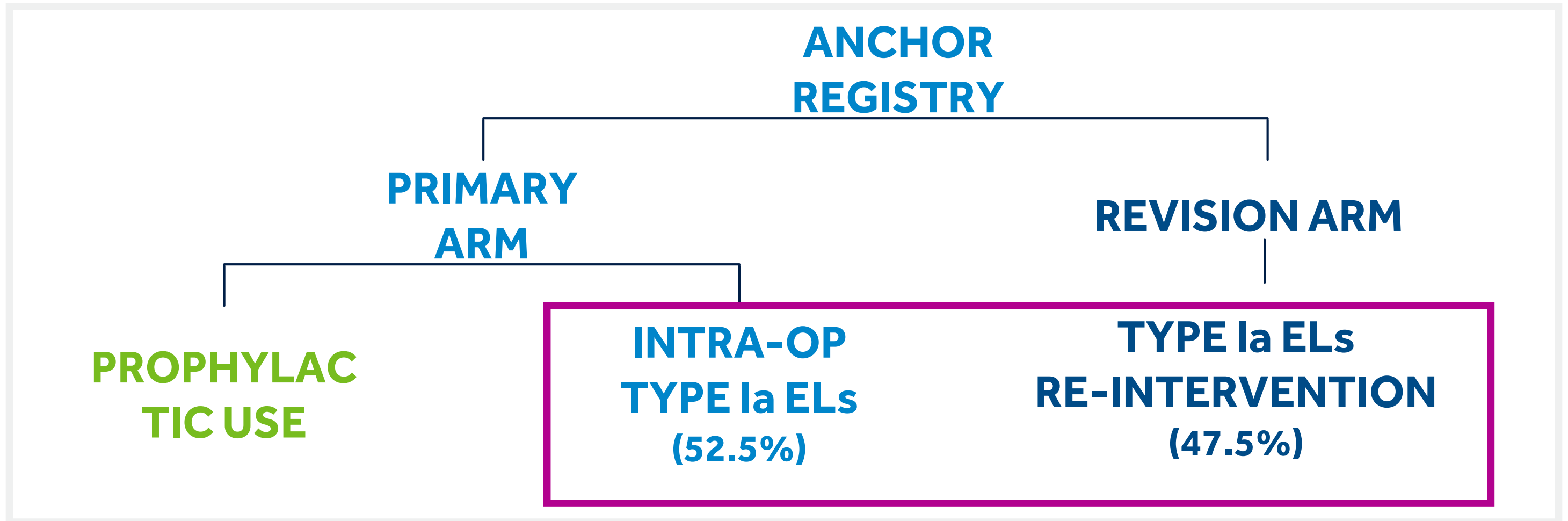
ANCHOR REGISTRY

Registry Design	Prospective & Observational International & Multi-Center Dual-arm Registry with Core Lab Analysis
Registry Principal Investigators	Europe: Dr Jean-Paul de Vries University Medical Centre, Groningen, The Netherlands
	US: Dr William Jordan Emory University School of Medicine, Atlanta, Georgia
Treatment Arms	“Primary”
	“Revision”
Enrollment & Duration	Enrollment began 2012 and patients will be followed for 5 years
Follow-up	Per Standard of Care at each center & discretion of Investigator

> 1000 Patients Enrolled

ANCHOR REGISTRY STRUCTURE

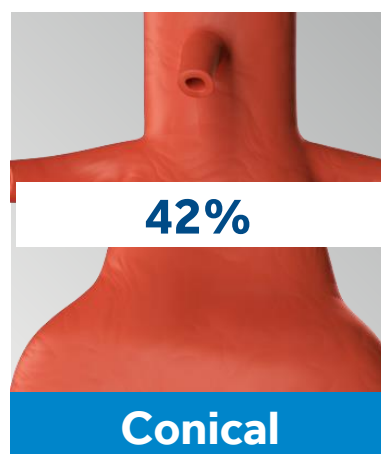
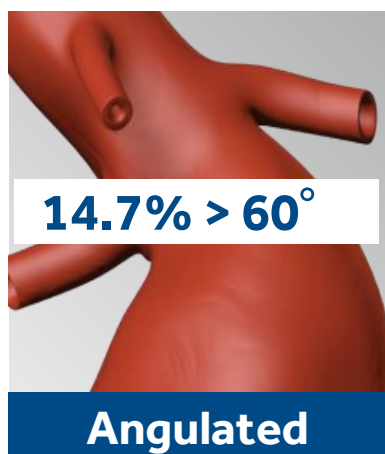
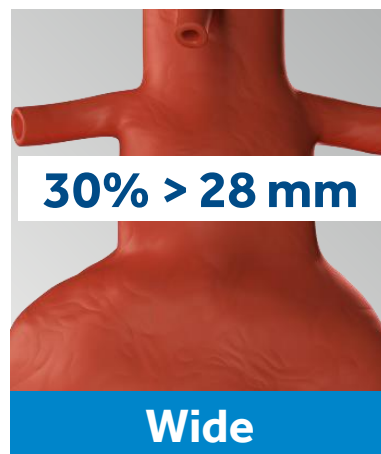
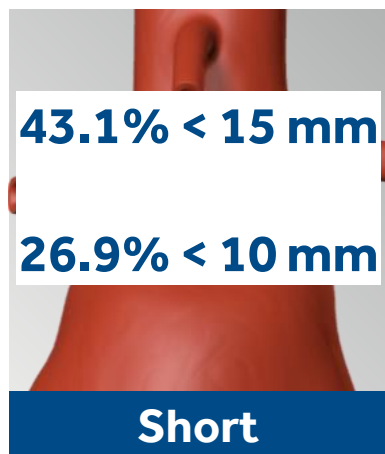
Therapeutic Use cohort consists of patients receiving EndoAnchor™ implants to treat Type 1a Endoleaks in the Primary and Revision Arms.



PATIENTS AT RISK FOR SUBOPTIMAL OUTCOMES MAY BENEFIT FROM ESAR

ANCHOR REGISTRY REVISION AAA ARM: 5-YEAR RESULTS

Hostile Necks



ANCHOR Registry: Revision Arm (N=260)

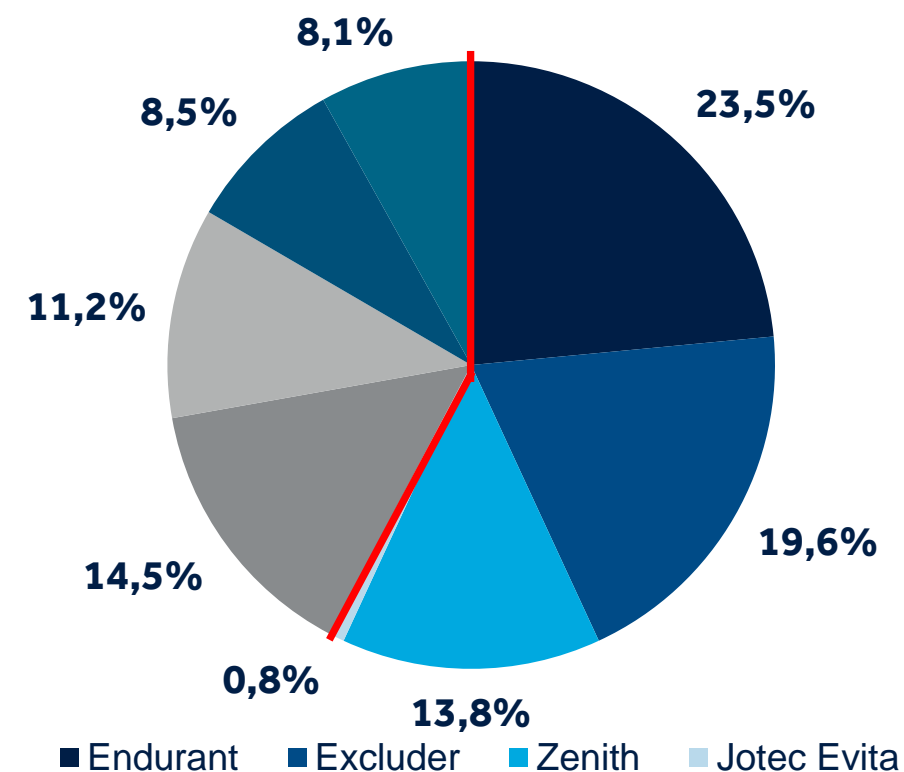
Hostile Necks: 86.1%

<15mm, >28mm, >60°, Conical, Ca2+/Thrombus >50%

- Male 85%; Mean age 78 yrs
- 87.9% ASA Class III/IV (674/768)
- 23% Urgent / Emergent Cases

Reasons for EndoAnchor™ Therapy: 100% failed EVAR

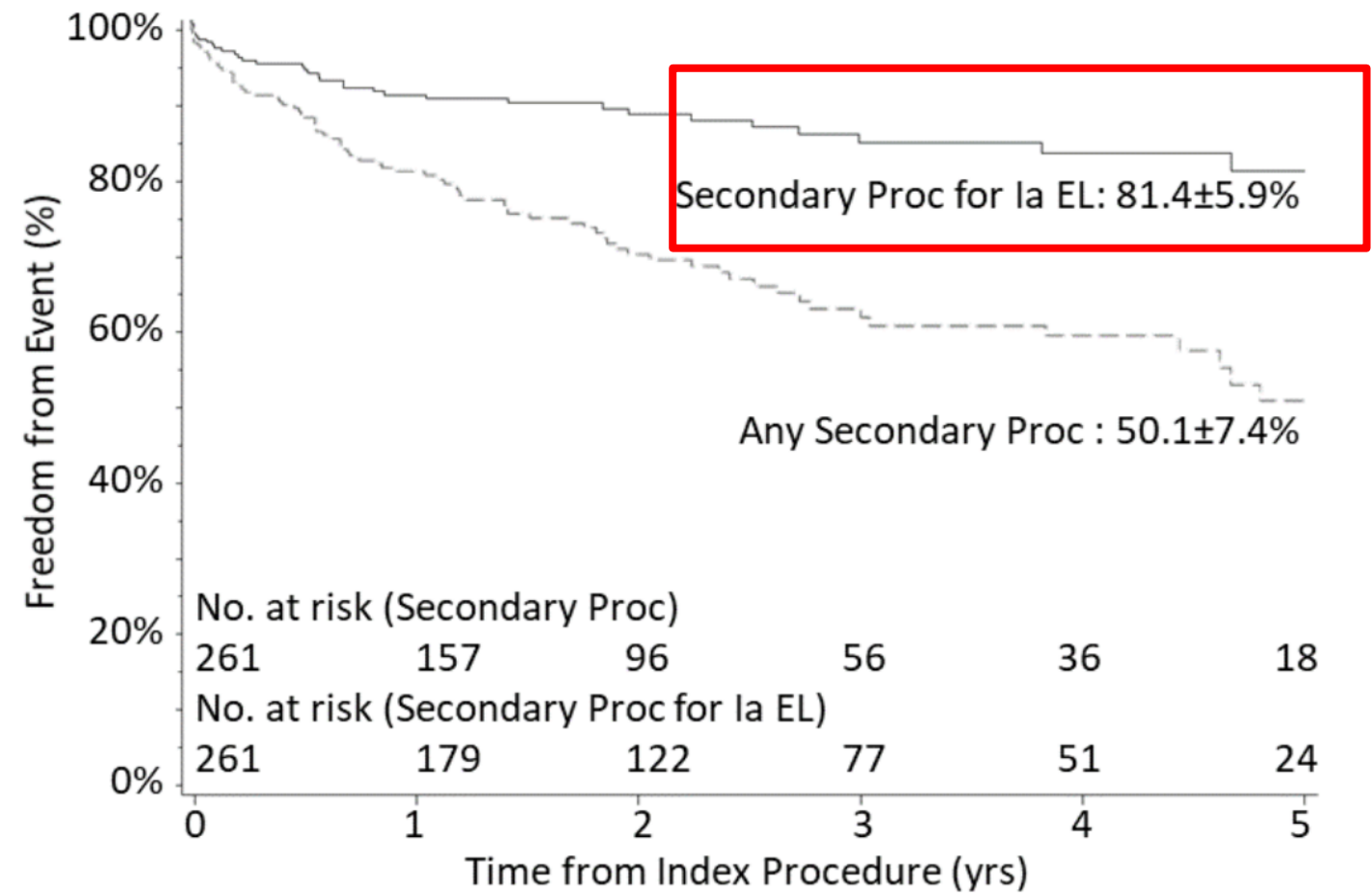
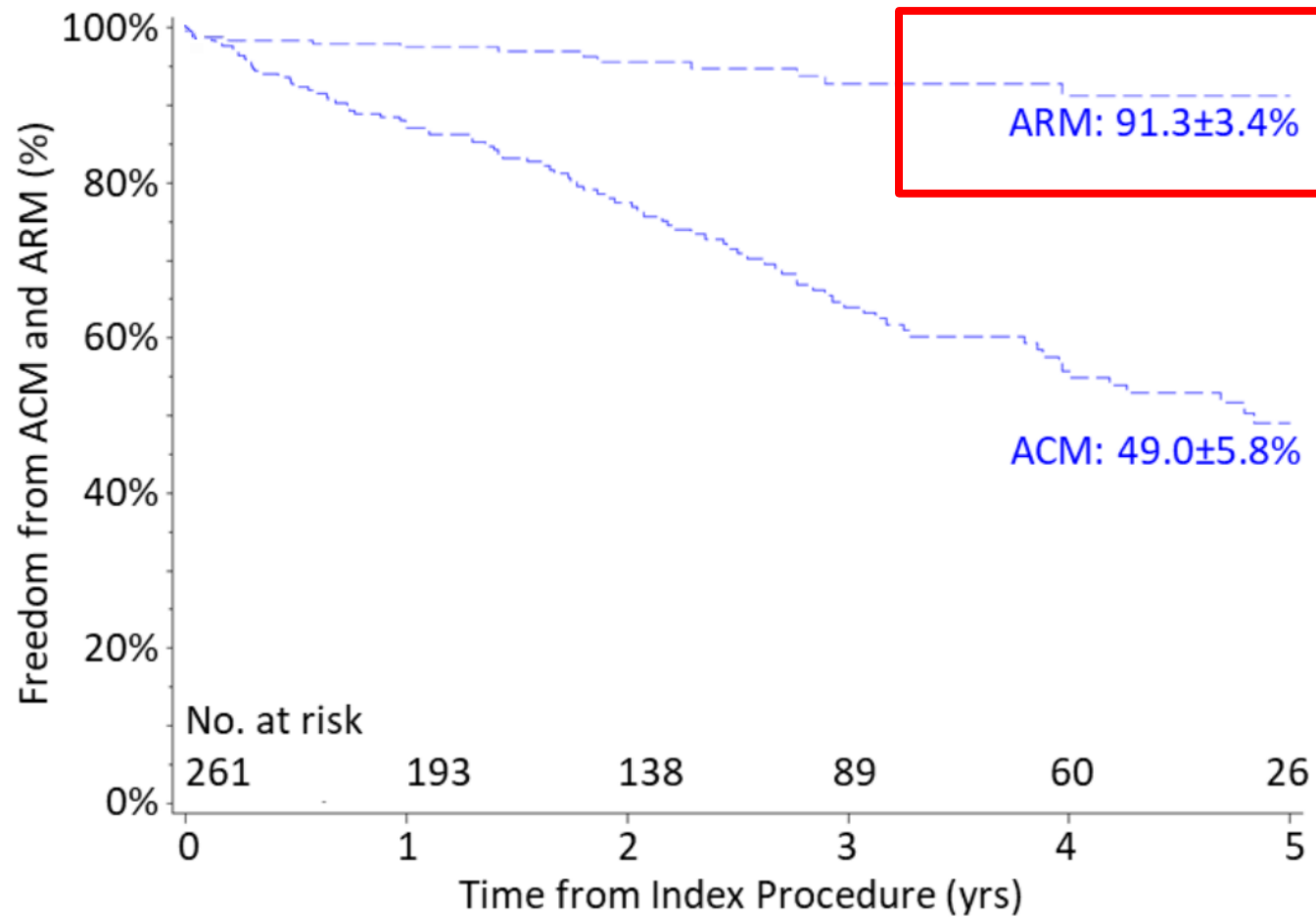
- 13%** Migration
- 53.3%** Type Ia endoleak
- 19%** Combination of type Ia and Migration



ANCHOR REVISION ARM 5 -YEAR RESULTS

Hostile Necks: 86.1%

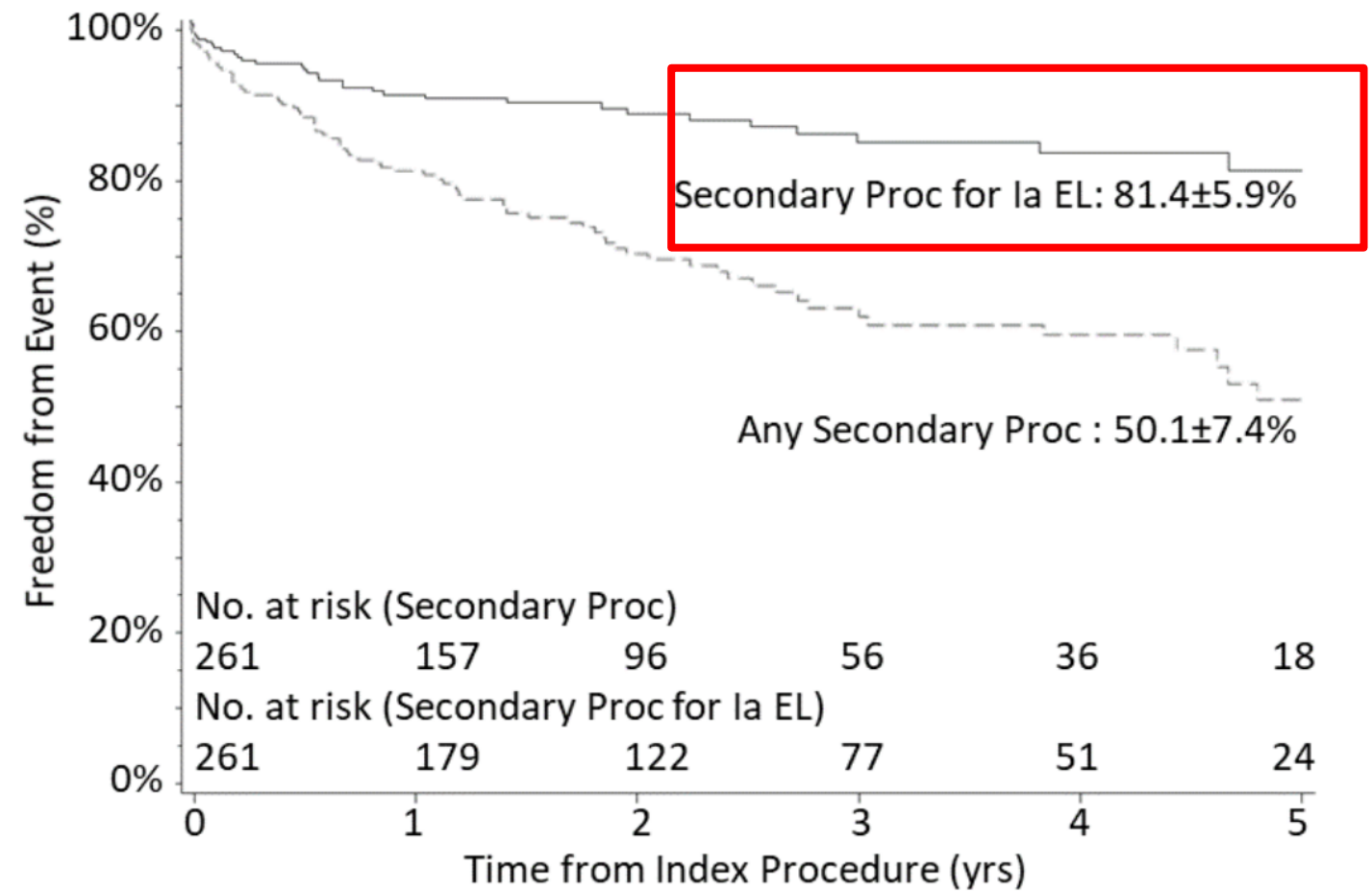
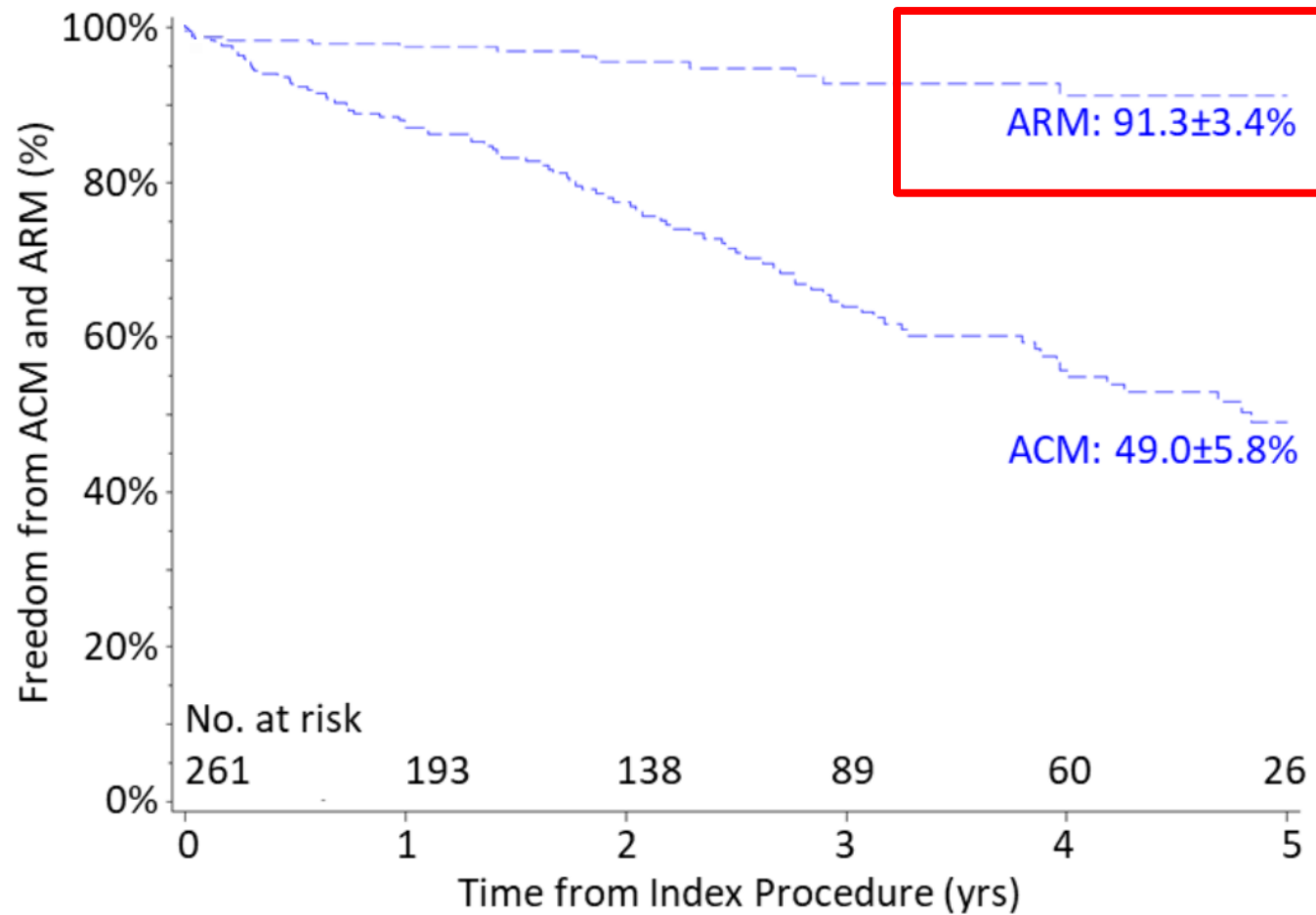
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ANCHOR REVISION ARM 5 -YEAR RESULTS

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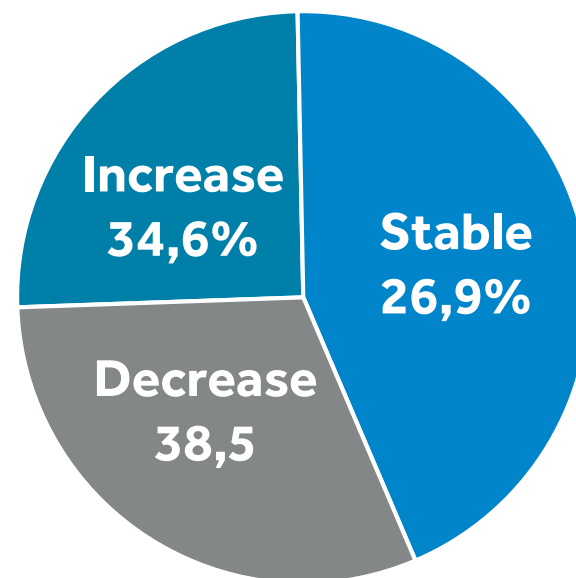
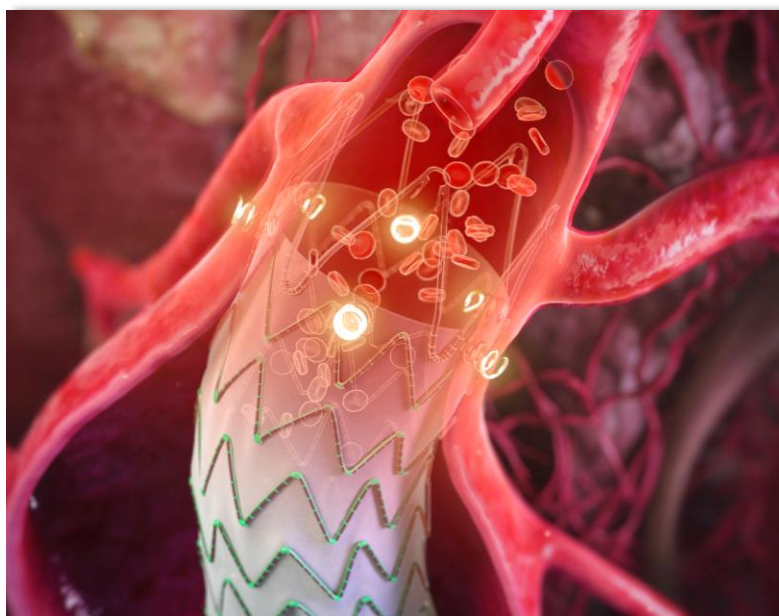
<15mm, >28mm, >60°, Conical, Ca²⁺/Thrombus >50%



ANCHOR REVISION AAA ARM 4-YEAR RESULTS

SAC DYNAMICS

AAA Maximum Diameter Sac Dynamics Outcomes 8-9 years after Index EVAR



65.4%
of sacs stable or
decreasing
at 5 years

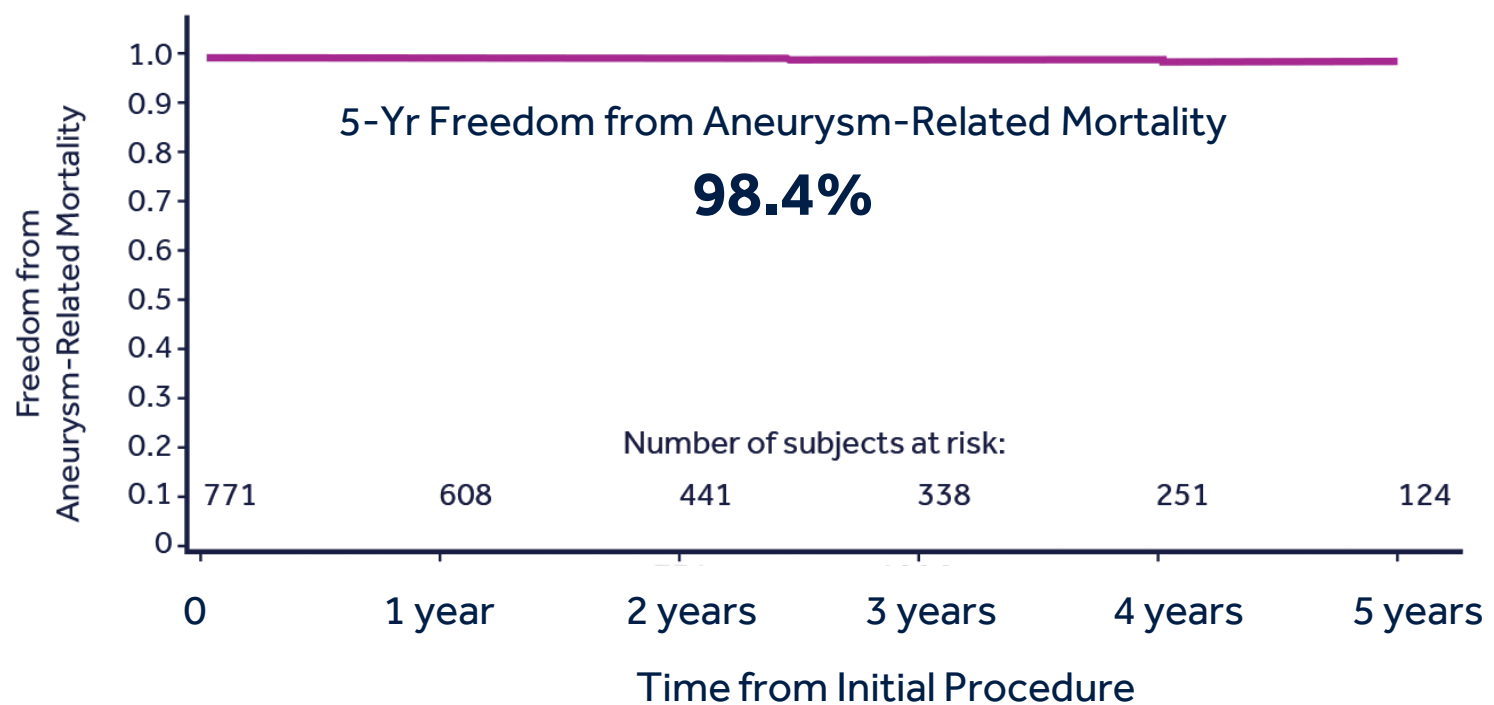
These sac dynamic data highlight the challenges of treating failed EVAR pts

“For those at high risk of disease progression, this revision cohort demonstrates the clinical value of treating these patients optimal at index instead of waiting for the EVAR to fail”

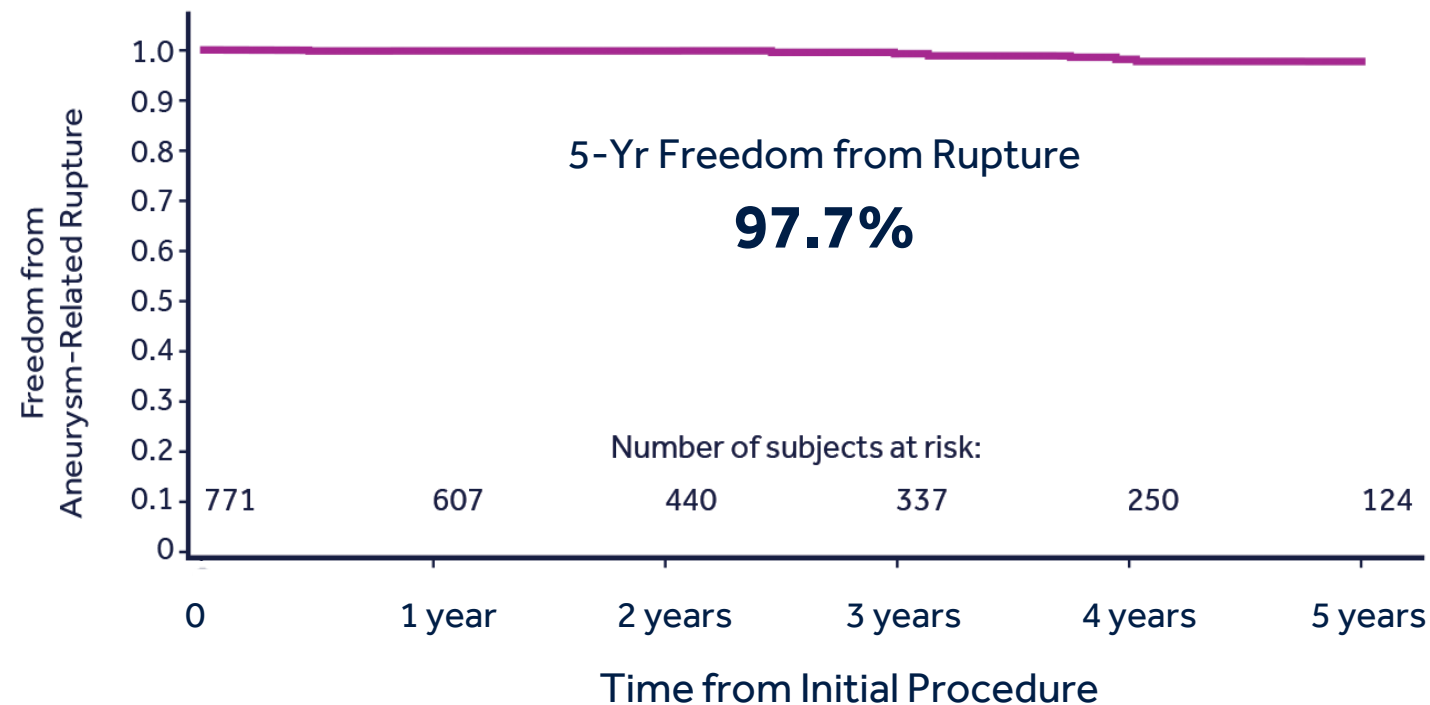
ANCHOR PRIMARY AAA ARM 5-YEAR RESULTS (N=771)¹

HOSTILE NECKS: 88.7% (572/645)

5-Year Outcomes



No migration through 5 years

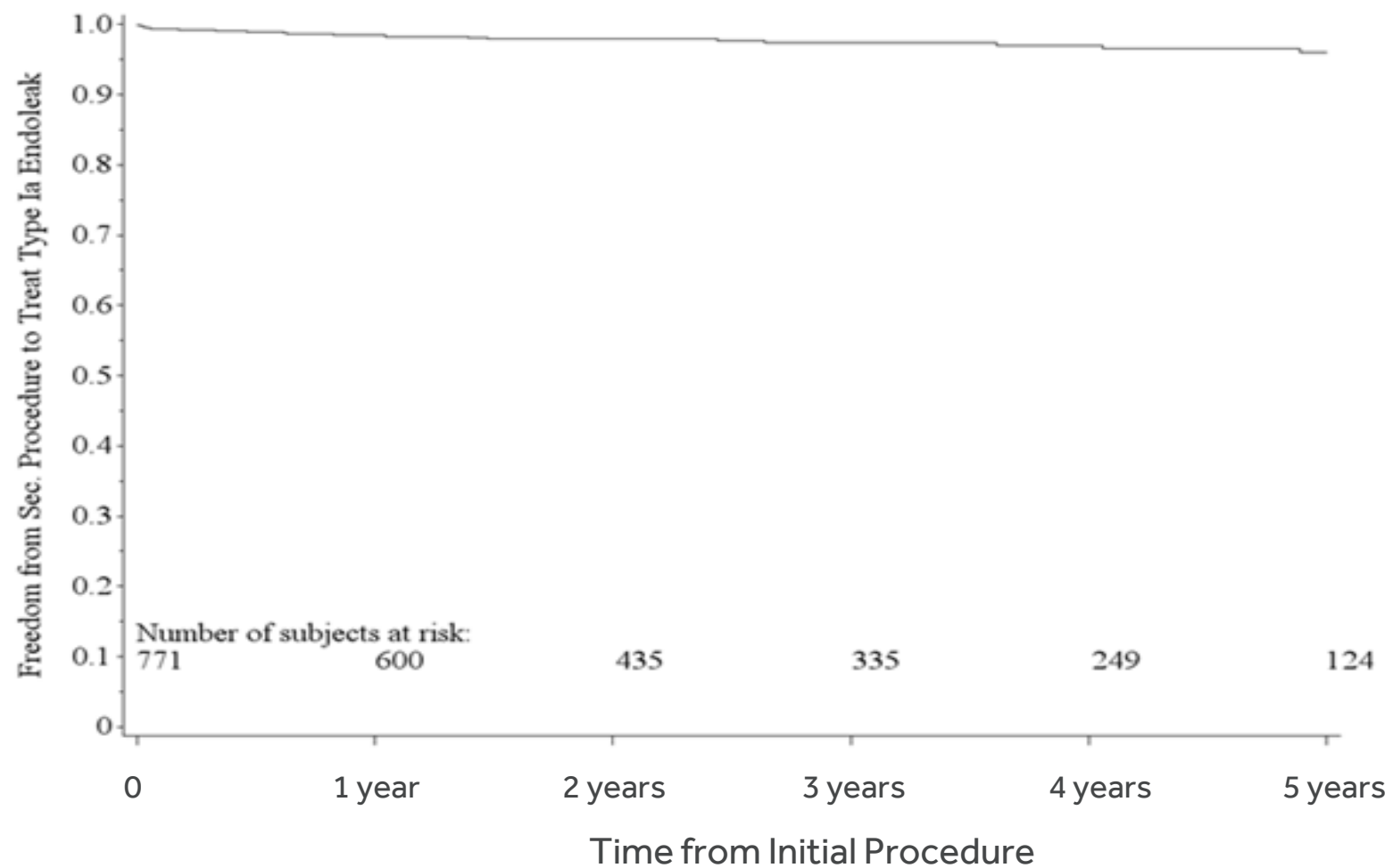


ANCHOR PRIMARY AAA ARM 5-YEAR RESULTS (N=771)¹

TYPE IA ENDOLEAKS

Type Ia Endoleaks at
1 year: 2.5% (14/568)
2 year: 1.7% (6/346)
3 year: 2.9% (7/238)
4 year: 3.2% (5/154)
5 year: 4.8% (4/84)

96.0% 5-Yr Freedom from Secondary Procedures to Treat Type Ia Endoleaks
No migration

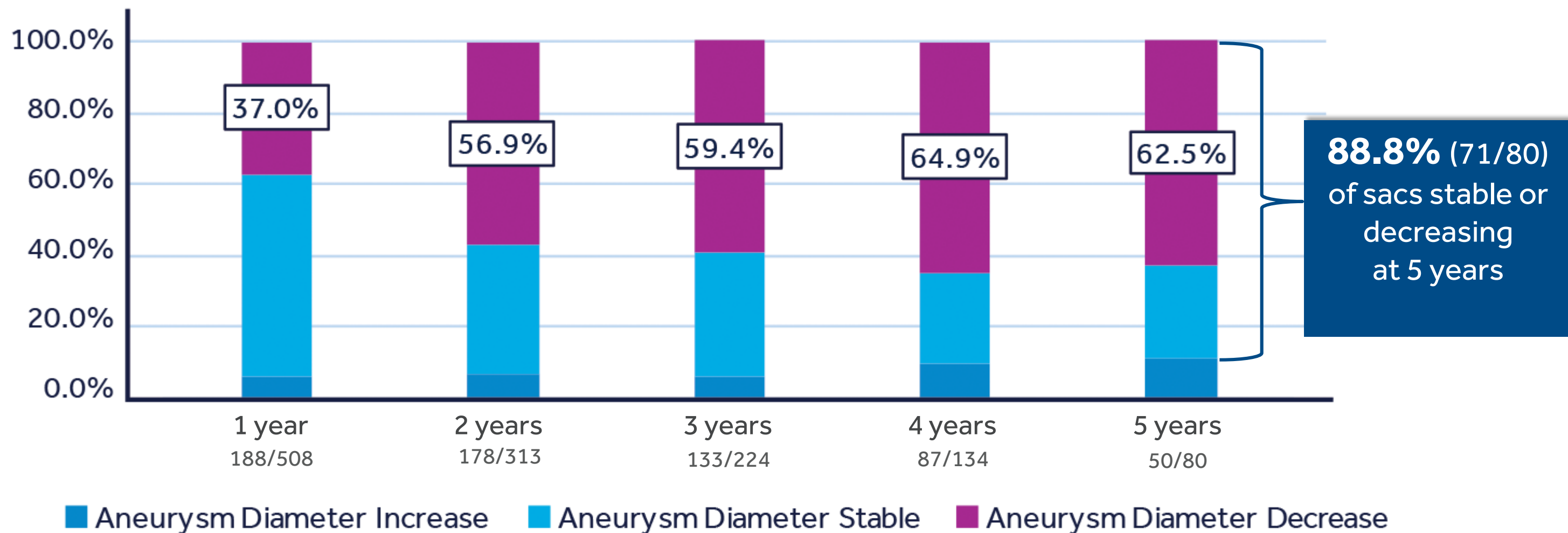


1. Data first presented by Dr William Jordan at Charing Cross Symposium 2021
Site Reported, ANCHOR Registry Primary AAA Arm, October 2020 data cut. Medtronic data on file

ANCHOR PRIMARY AAA ARM 5-YEAR RESULTS (N=771)¹

SAC DYNAMICS

AAA Maximum Diameter Sac Dynamics

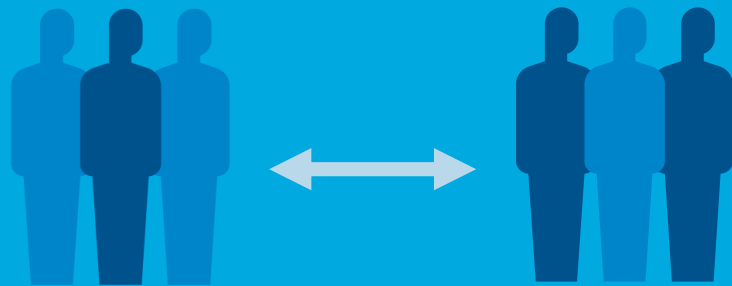


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BENEFITS OF TRANSMURAL RADIAL FIXATION IN PROXIMAL SEAL

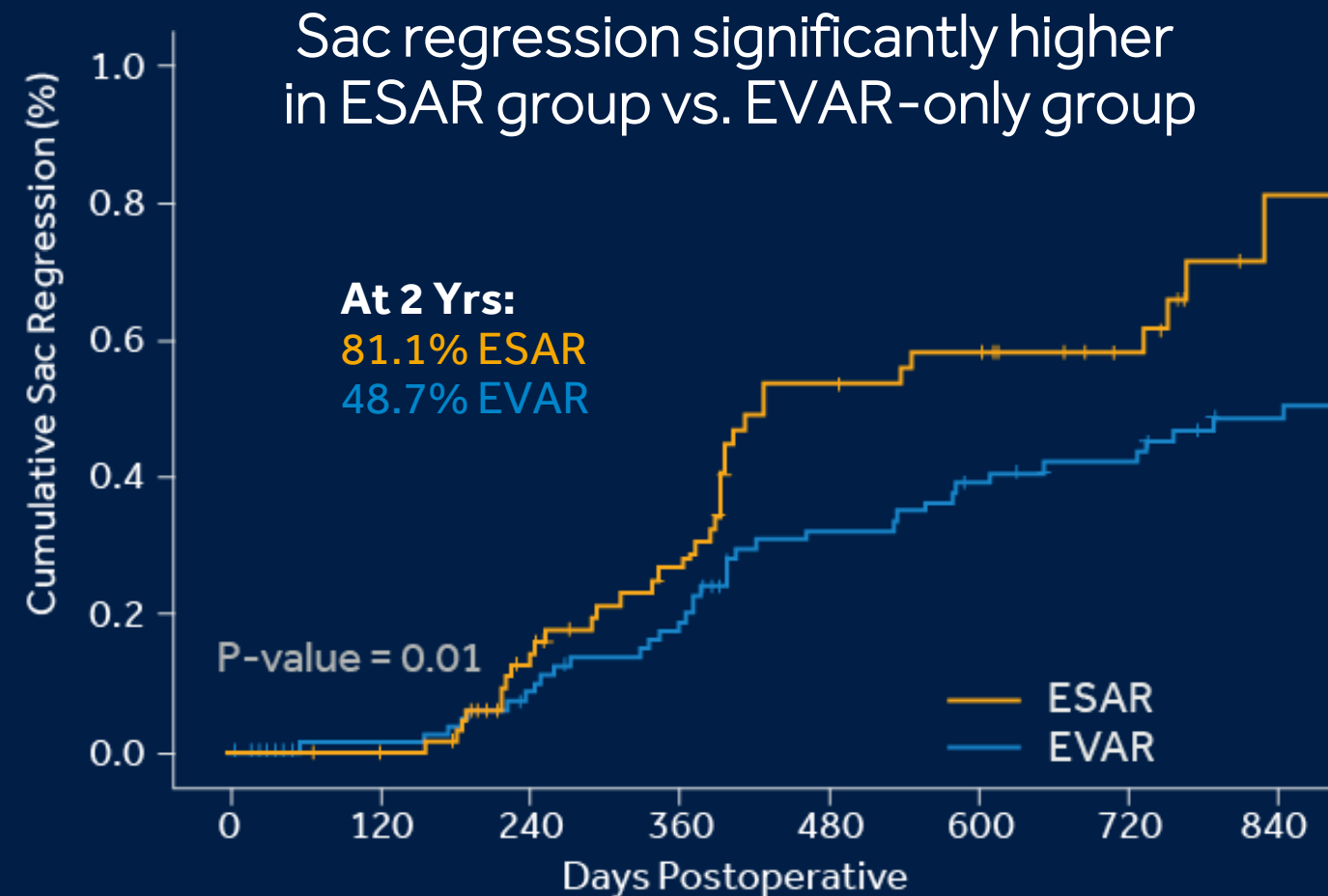
ESAR PROVIDES SIGNIFICANTLY GREATER SAC REGRESSION THAN EVAR ALONE

ANCHOR data shows **ESAR** (EndoSuture Aneurysm Repair) can significantly increase regression rates



Propensity matched baseline anatomies¹

- 2 cohorts (99 pts EVAR + 99 pts ESAR)
- Various stent grafts (Endurant™, Excluder™*, Zenith™*)
- Core lab reviewed images



¹Muhs BE, et al. *J Vasc Surg.* 2018;67:1699-1707

™* Third party brands are trademarks of their respective owners

GREATER SAC REGRESSION, GREATER SURVIVAL

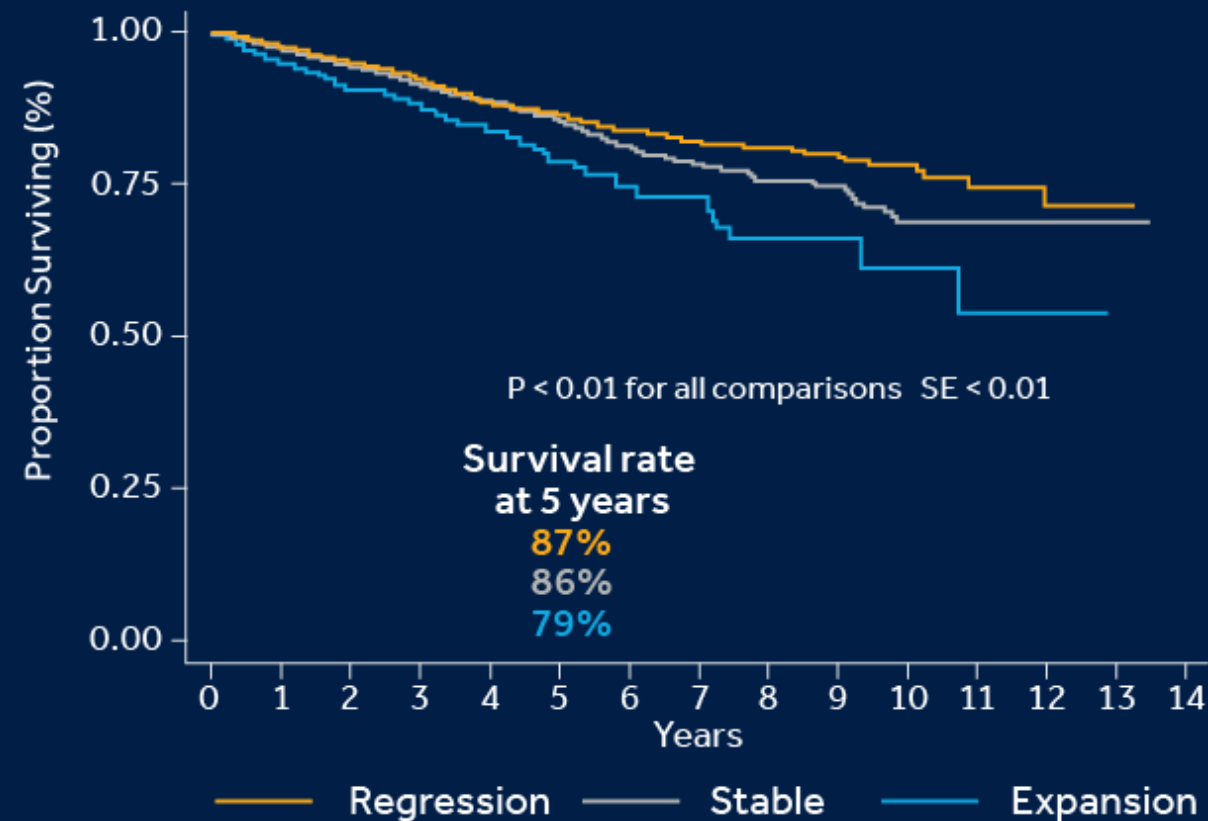
EVIDENCE LINKS SAC REGRESSION TO HIGHER RATE OF LONG-TERM SURVIVAL



14,817*

total subjects in VQI
(Vascular Quality Initiative)
treated with EVAR
between 2003–2017¹

Sac regression is linked to increased rate of long-term survival



Survival rate at
10 yrs:
Regressing: 78%
Stable: 69%
Expanding: 61%



*Total number of patients with 1-year imaging

¹O'Donnell TFX et al. JVS 2018

WHEN ENDOANCHORS WILL NOT SOLVE A TYPE IA ENDOLEAKS

- Endograft mis-deployment
- Insufficient apposition due to undersizing of stent graft
- Gaps >2 mm
- Excessive (circular) thrombus/calcium in seal zone
- Excessive oversizing creating gutters
- If extension of seal is necessary

CONCLUSION, PROPHYLACTIC USE

ESAR AT THE INDEX PROCEDURE:

Attaches adventitia to the graft

Minimizes Type Ia endoleaks⁴

Promotes greater sac regression⁵

No migration

5 YEAR CLINICAL OUTCOMES⁴

98.4% Freedom from Aneurysm-Related mortality

97.7% Freedom from Rupture

96.0% Freedom from Secondary Procedures to Treat Type Ia endoleaks



¹ Melas, et al., J Vasc Surg 2012;55:1726-33

² Schlosser et al. Eur J Vasc Surg. 2017;53:458-459

³ Tassiopoulos AK, et al. J Vasc Surg. 2017;66:45-52

⁴ Site Reported, ANCHOR Registry Primary AAA Arm, October 2020 data cut.
Medtronic data on file

⁵ Muhs BE, et al. J Vasc Surg. 2018;67:1699-1707

CONCLUSION, THERAPEUTIC USE

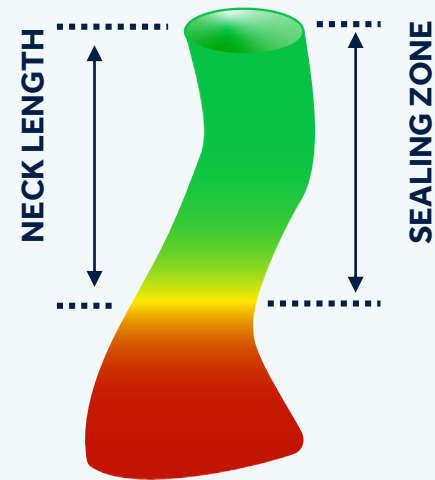
- Use of EndoAnchors in the revision setting can be successful in treating type Ia endoleaks if done for the right indications and technically correctly
- 5 years results from ANCHOR revision cohort demonstrate good results when treating failed EVARs:
 - Low percentage of aneurysm-related mortality, with
 - Relatively low need for 2nd procedures to treat type Ia's
 - ***However, the index procedure should be optimal, strive for at least 1 cm of circumferential apposition. If not with EVAR, perform other technique (FEVAR, open surgery)***

ESAR adds strength to seal

INFRARENAL SEALING ZONE



NEEDS

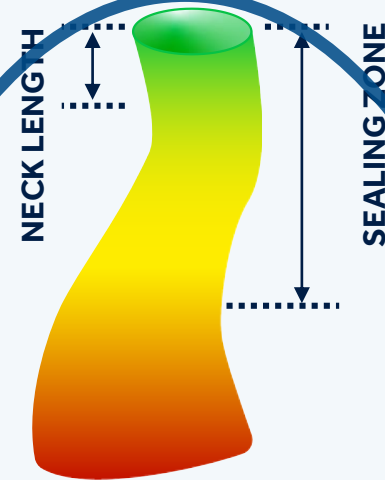


ADEQUATE



SEAL

**Standard
EVAR**



HOSTILE

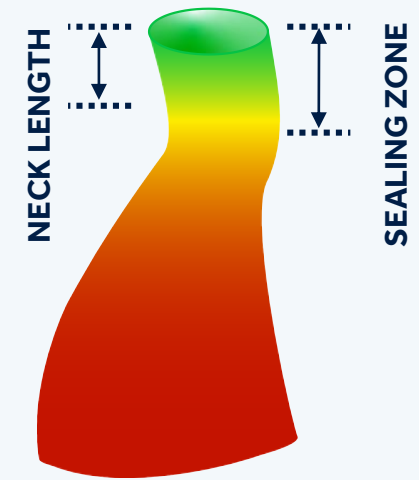


SEAL



STRENGTH

ESAR



INADEQUATE



SEAL



LENGTH

**FEVAR
Open surgery**