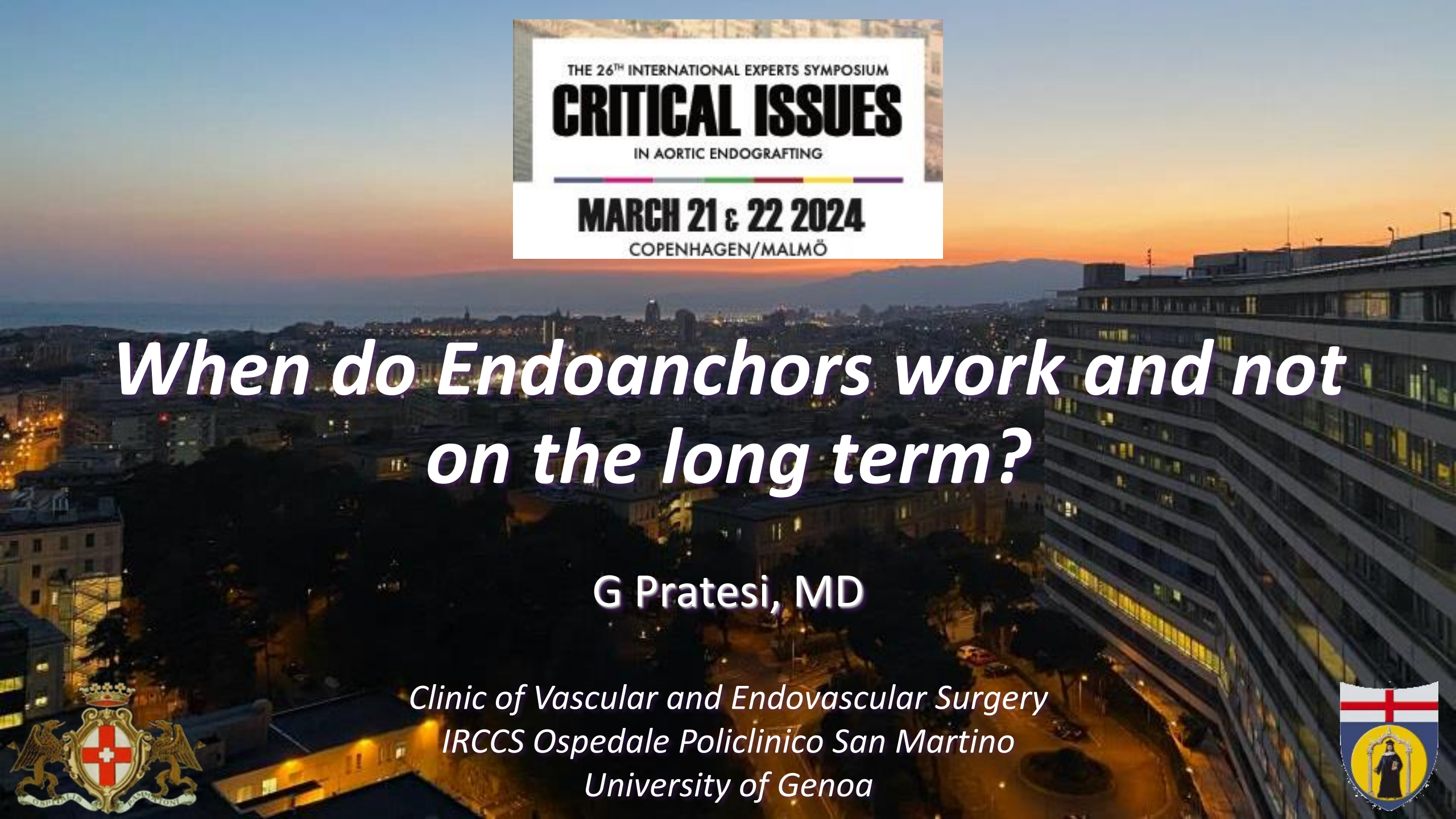

When do Endoanchors work and not on the long term?

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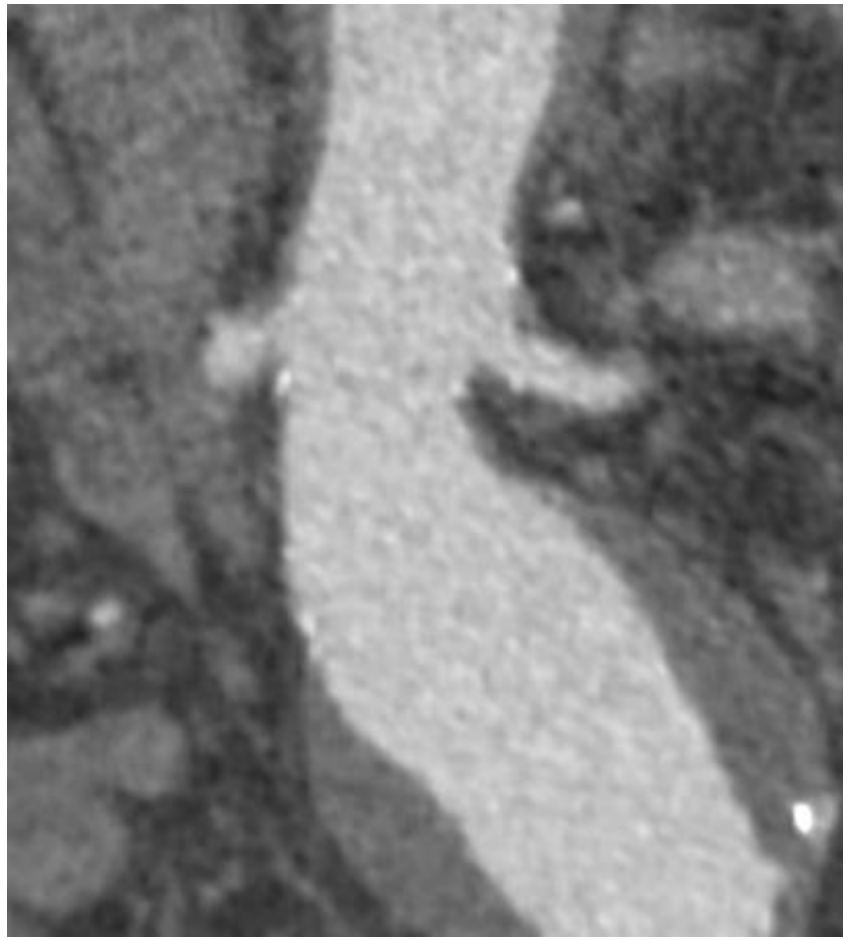
Disclosures

- Consulting/grants and research support/ honoraria and travel support: Abbott, Bentley, Cook Medical, Medtronic, Penumbra Inc., WL Gore & Associates, Terumo Aortic & Peripheral

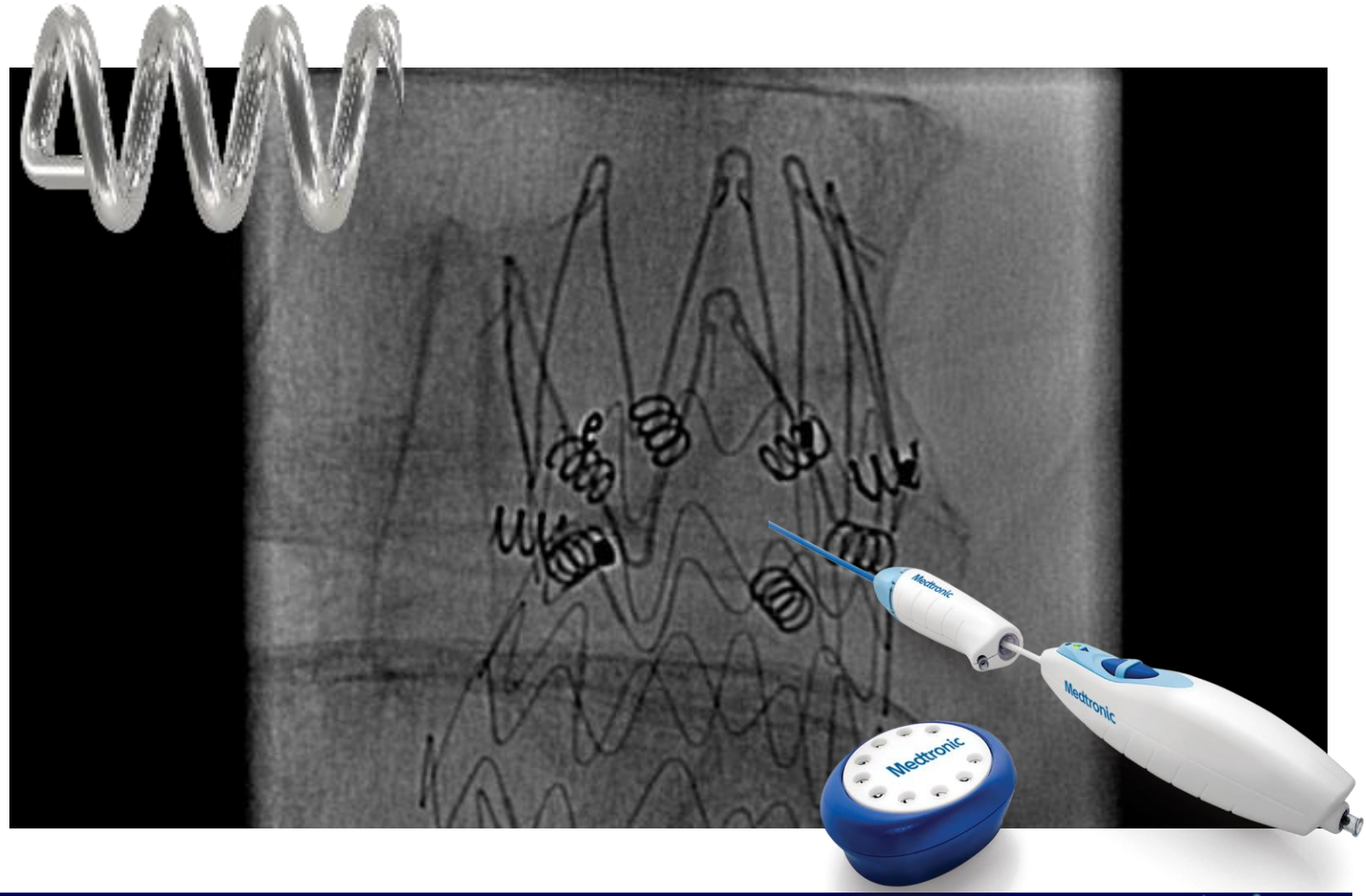
Hostile Neck: standard vs complex endo repair



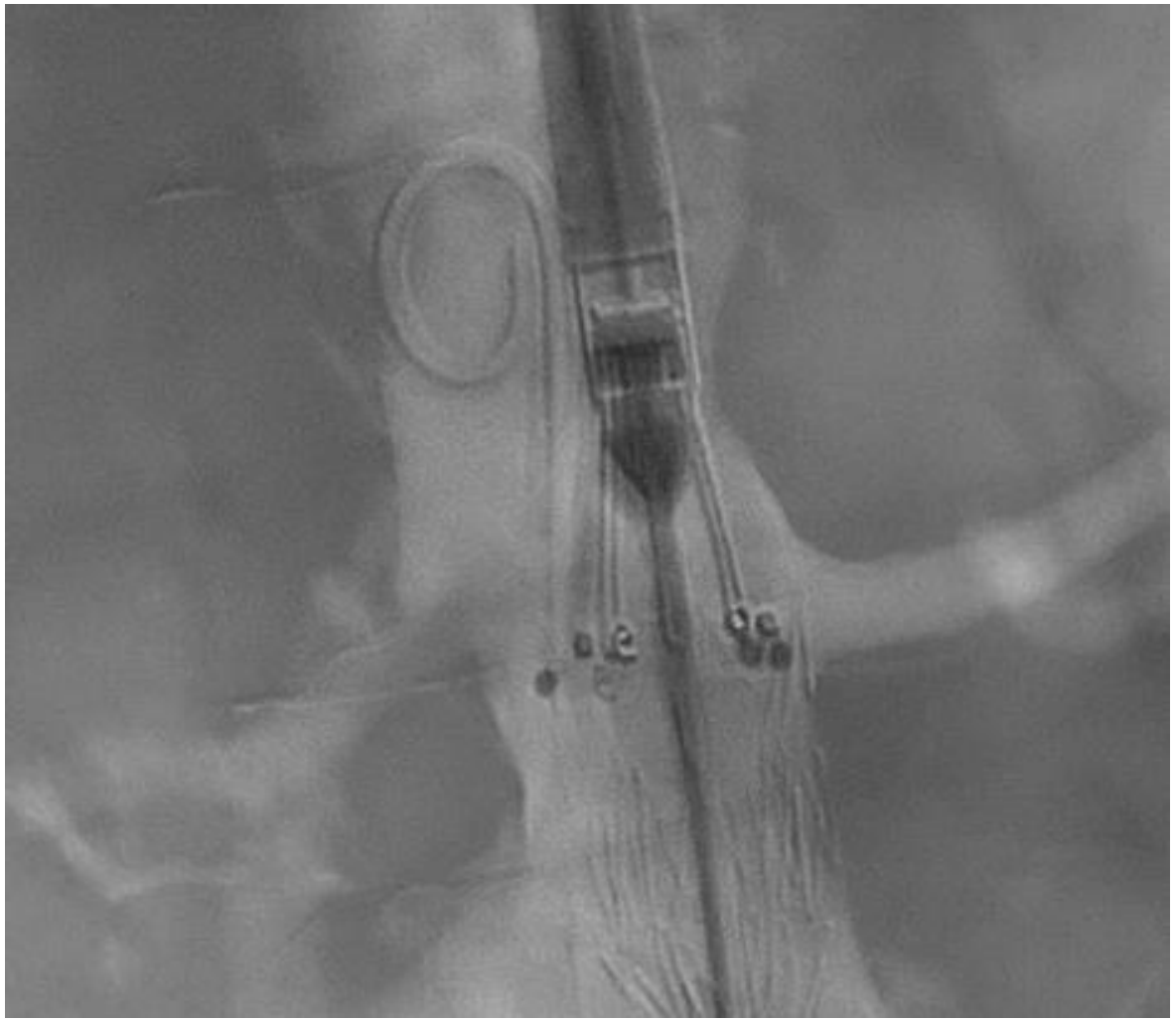
Use all the existing seal and maintain it over time

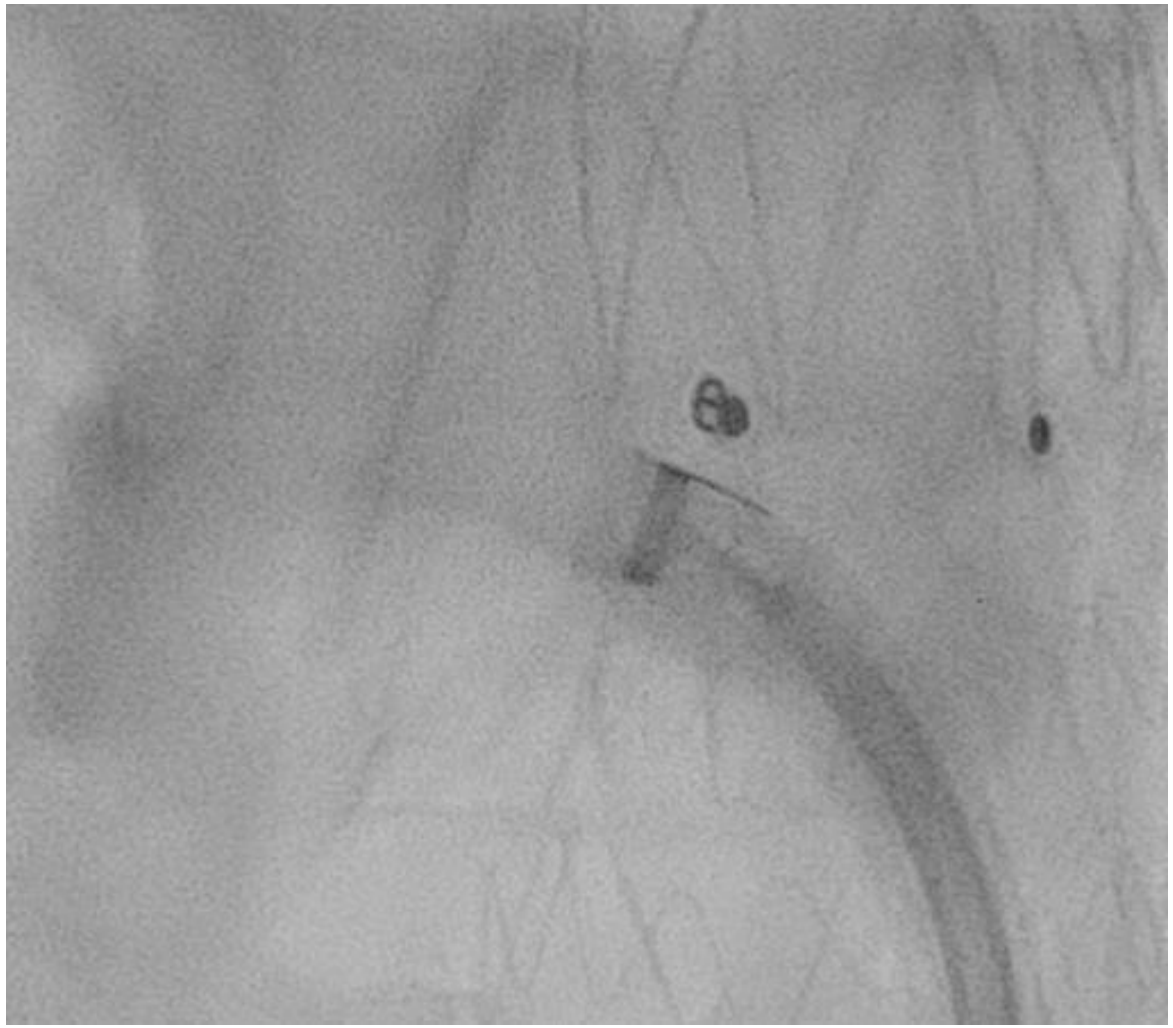
ESAR (EndoSuturing Aneurysm Repair) with the Heli-FX™ EndoAnchor™ System

- Endovascular suture of the endograft similar to a surgical anastomosis
- No additional access/techniques required
- Infrarenal sealing maintenance
- Visceral vessels are not involved
- Does not prevent any future option (Ch-EVAR, f-EVAR)

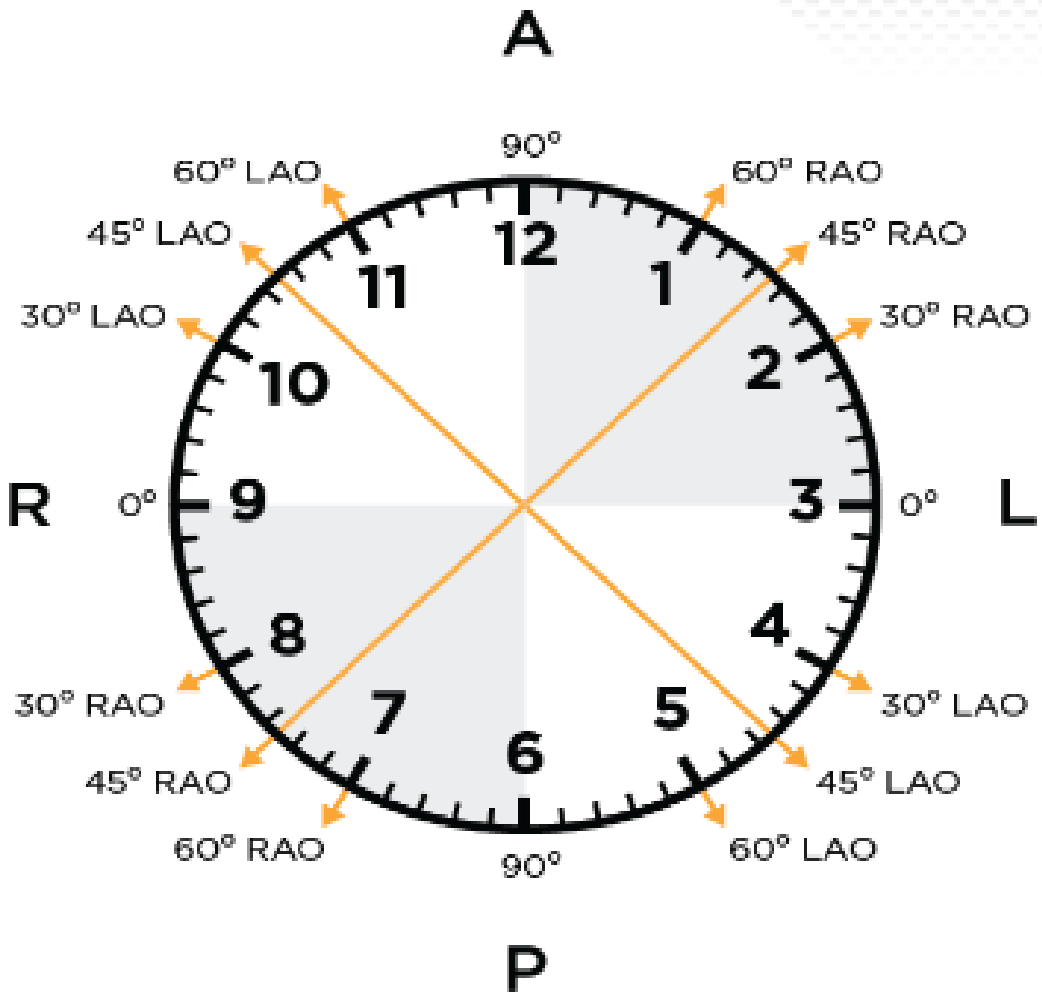


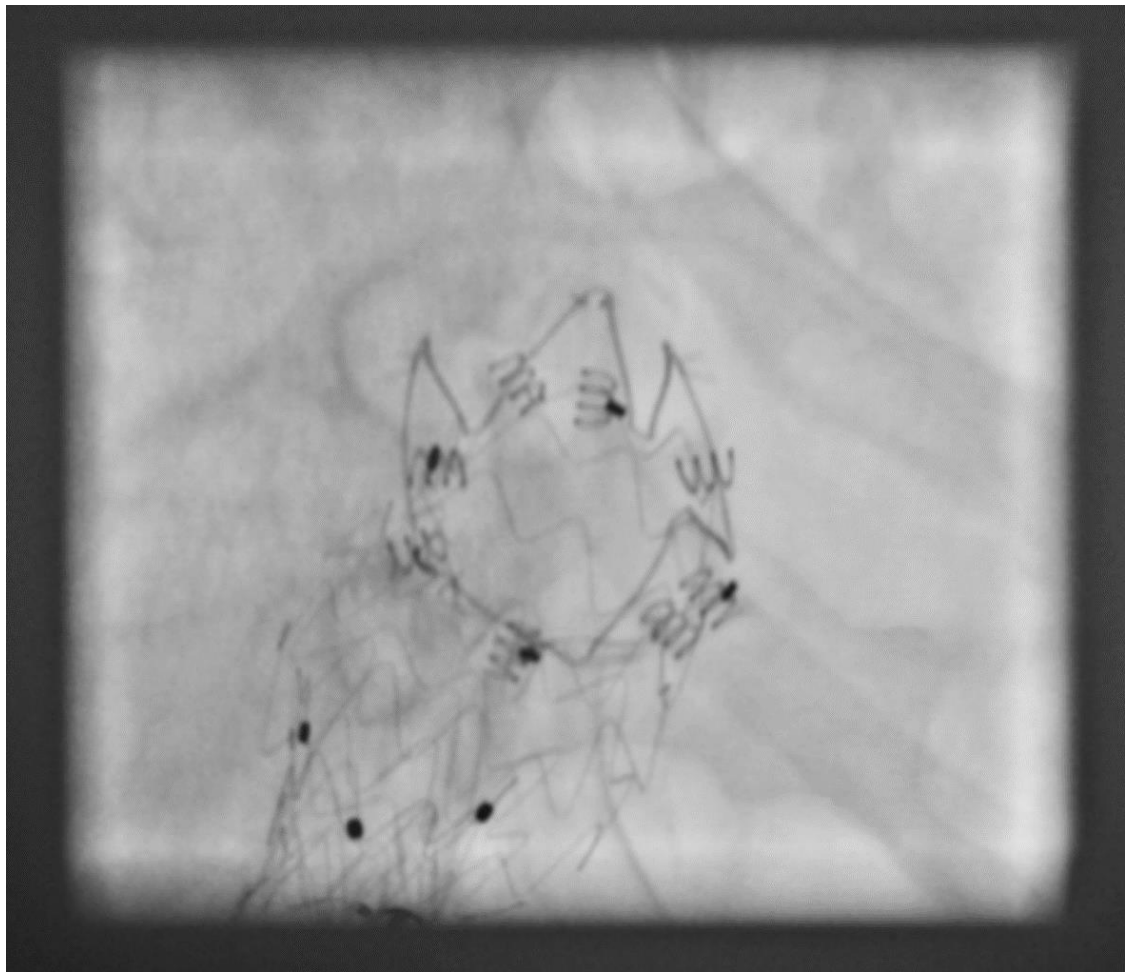
When do Endoanchors work?
Need for standardization





When do Endoanchors work?
Need for standardization





When do Endoanchors work and when not? Need for clinical evidences

CLINICAL PRACTICE GUIDELINE DOCUMENT

Editor's Choice – European Society for Vascular Surgery (ESVS) 2024 Clinical Practice Guidelines on the Management of Abdominal Aorto-Iliac Artery Aneurysms ☆

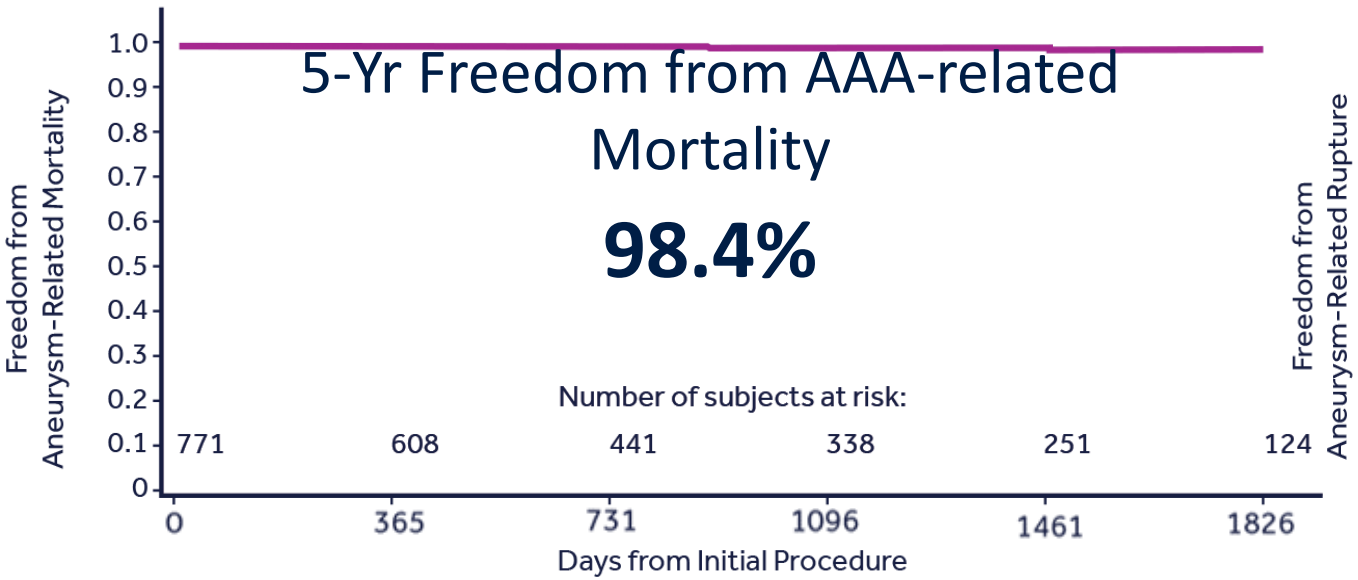
Recommendation 59		Unchanged
New techniques and concepts for abdominal aortic aneurysm treatment are not recommended to be used routinely in clinical practice but should only be used within the framework of studies approved by research ethics committees, until adequately evaluated.		
Class	**Level**	**References**
III	C	Consensus

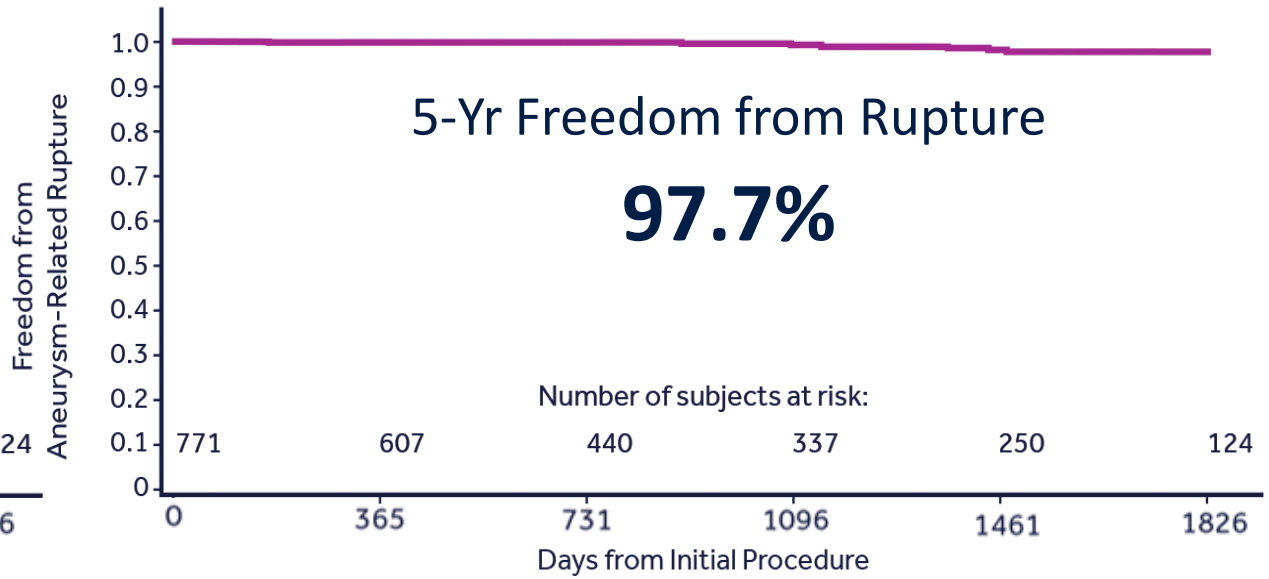
Wanhainen A et al., Eur J Vasc Endovasc Surg 2024

ANCHOR Primary AAA Arm 5-Year results

N= 771; Hostile Necks: 88.7%

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

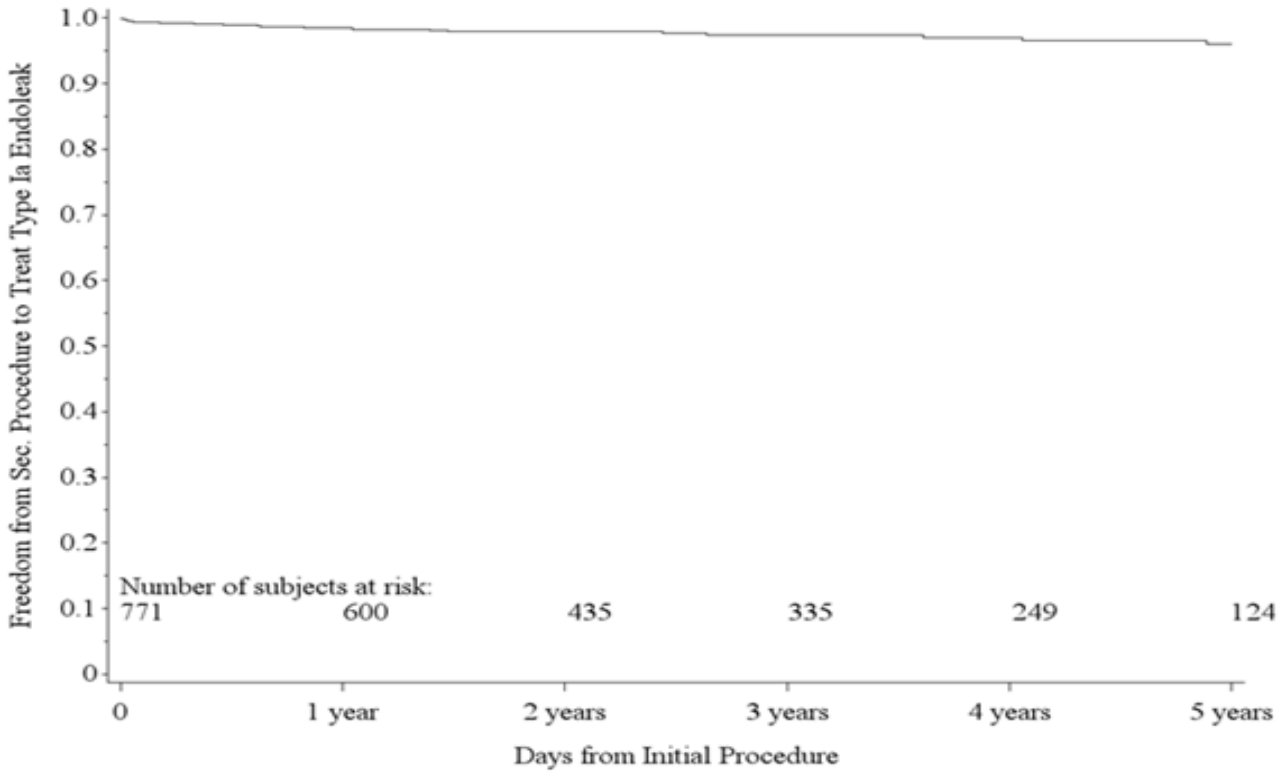




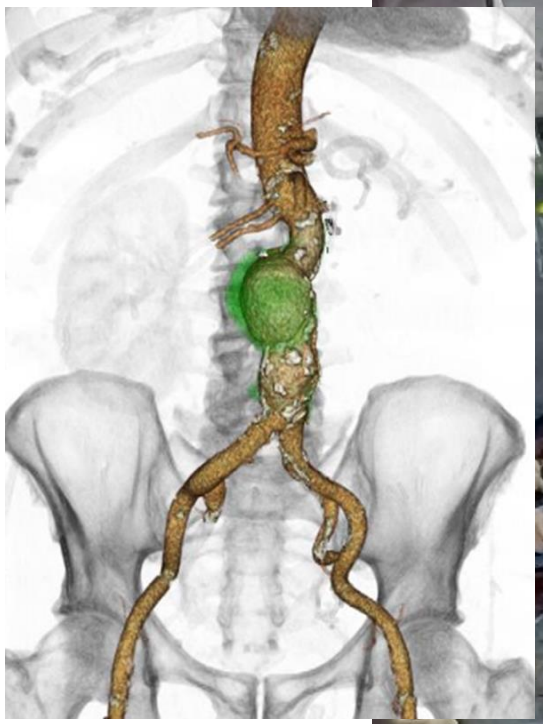
ANCHOR Primary AAA Arm 5-Year results

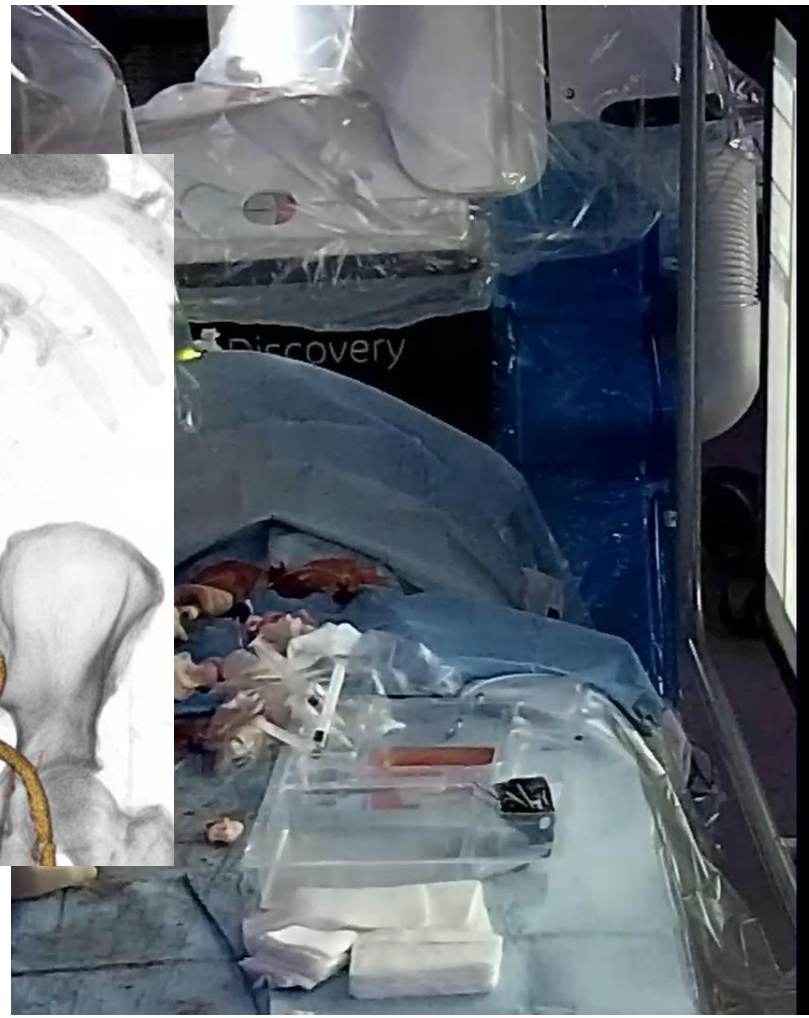
96% 5-Yr Freedom from Secondary Procedures to Treat Type Ia Endoleaks
No Migration

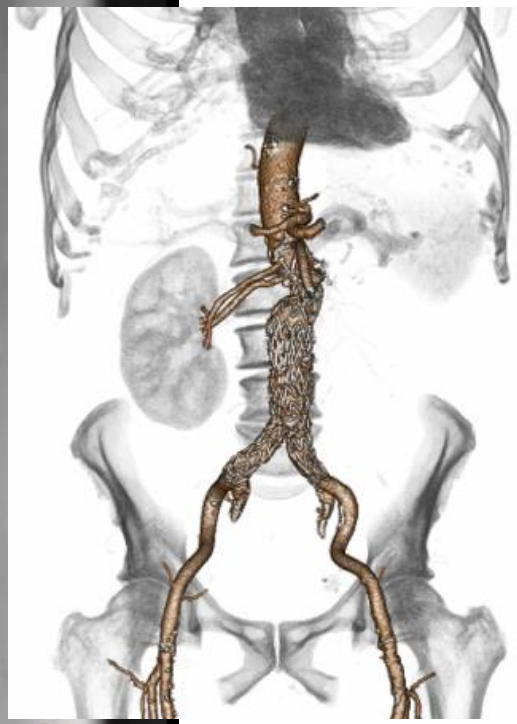
Type Ia Endoleaks
1 year: 2.5% (14/568)
2 year: 1.7% (6/346)
3 year: 2.9% (7/238)
4 year: 3.2% (5/154)
5 year: 4.8% (4/84)



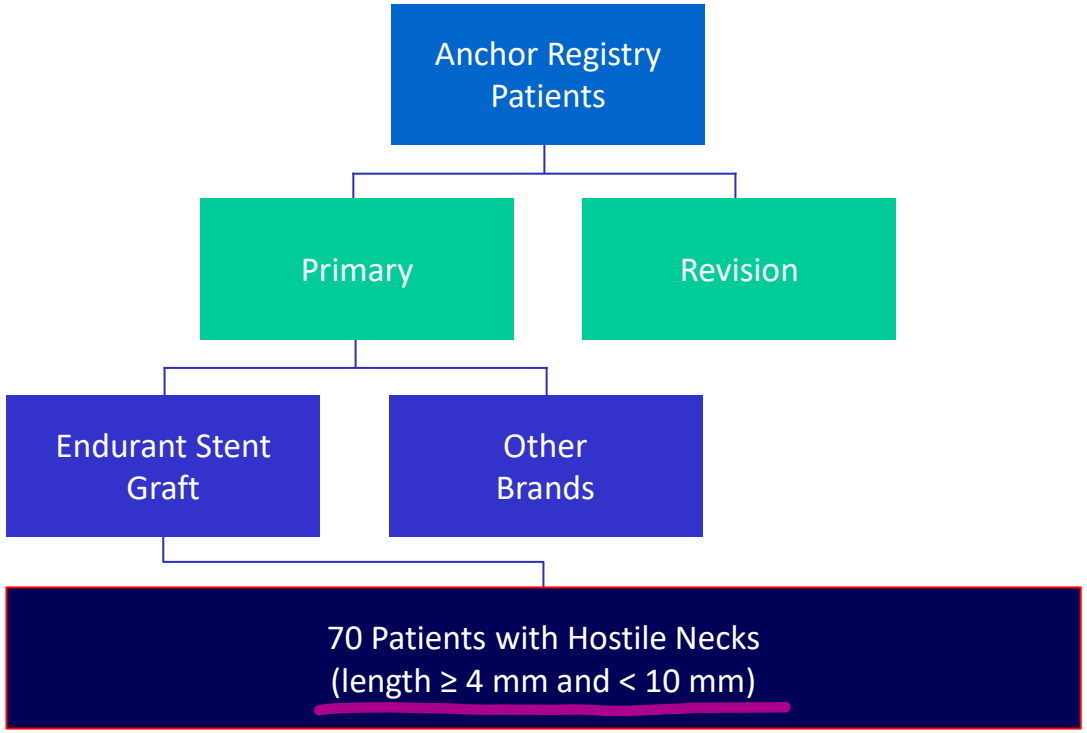
When do Endoanchors work?
Short/angulated neck







Endosuture aneurysm repair in patients treated with Endurant II/IIs in conjunction with Heli-FX EndoAnchor implants for short-neck abdominal aortic aneurysm



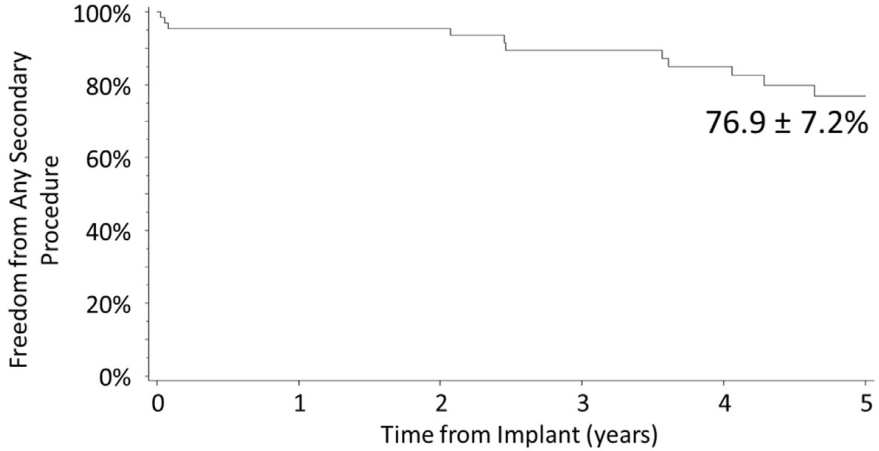
Arko F et al., J Vasc Surg 2019

Core Lab	1 month	12 months
Type 1a Endoleak	6.8% (4/59)	1.9% (1/53)
Endograft Migration	N/A	0.0% (0/41)

Core Lab	12 months
AAA sac decrease	42.6%
AAA sac stable	57.4%
AAA sac increase	**0.0%**

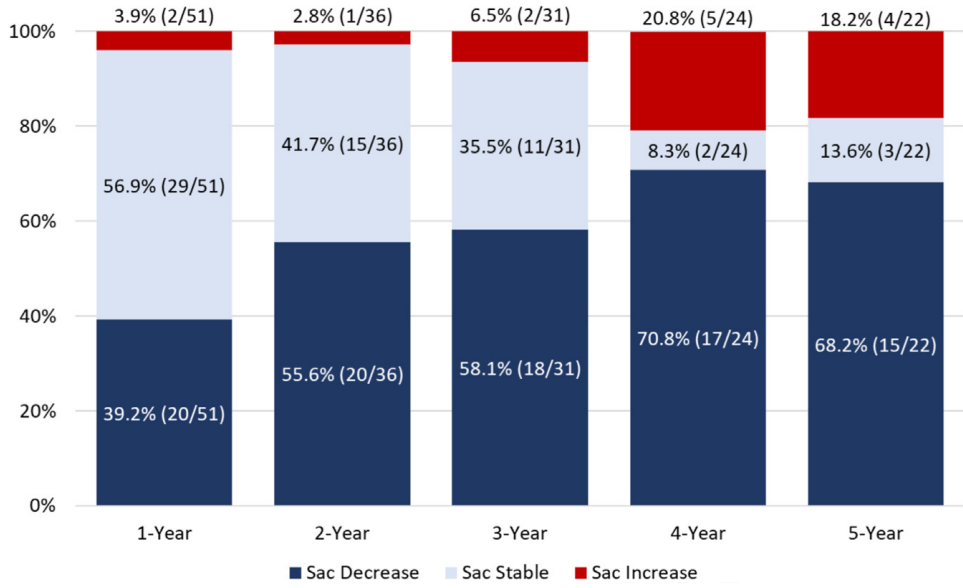
Five-year outcomes of endosuture aneurysm repair in patients with short neck abdominal aortic aneurysm from the ANCHOR registry

Frank R. Arko III, MD,[a] Benjamin J. Pearce, MD,[b] John P. Henretta, MD,[c] Mark W. Fugate, MD,[d] Giovanni Torsello, MD, PhD,[e] Jean M. Panneton, MD, FRCSC, FACS,[f] Yun Peng, MS,[g] *and* H. Edward Garrett Jr, MD,[h] *Charlotte and Asheville, NC; Birmingham, AL; Chattanooga and Memphis, TN; Münster, Germany; Norfolk, VA; and Santa Rosa, CA*



Time (days)	0-30	31-365	366-731	732-1096	1097-1461	1462-1826
No. at Risk[1]	70	63	59	53	43	36
No. of Events	3	0	0	3	2	3
KM Estimate[2]	95.5%	95.5%	95.5%	89.5%	84.9%	76.9%

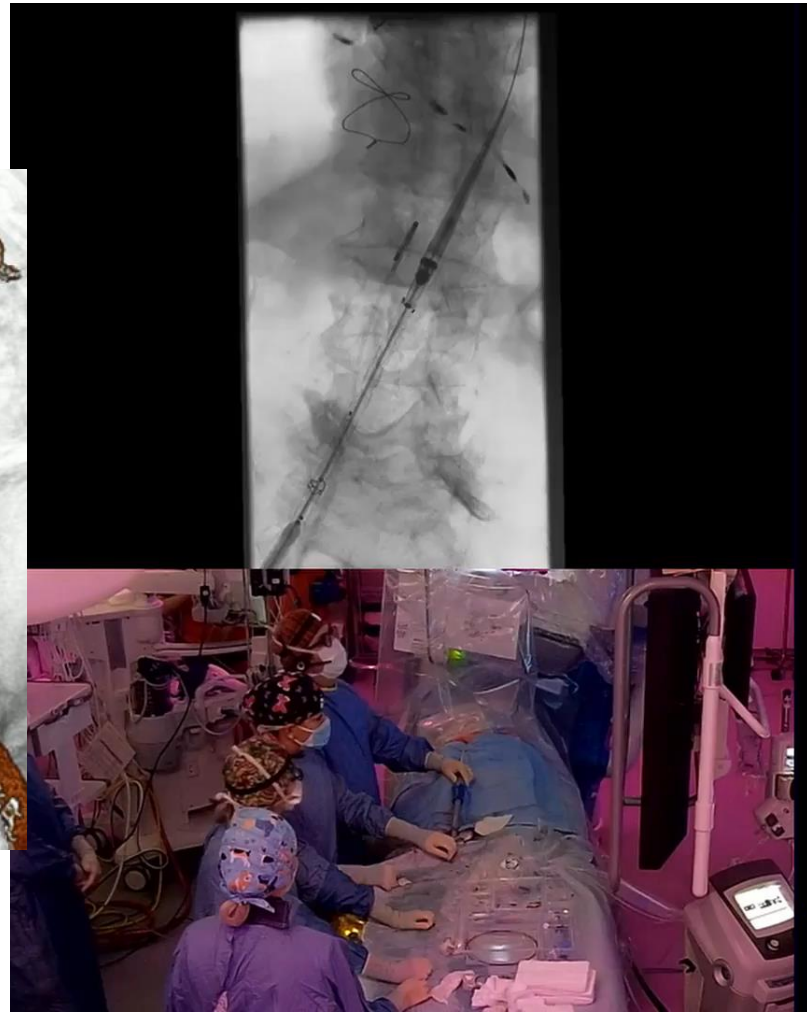
[1]Number of subjects at risk at the beginning of interval. [2]Estimate made at end of time interval.

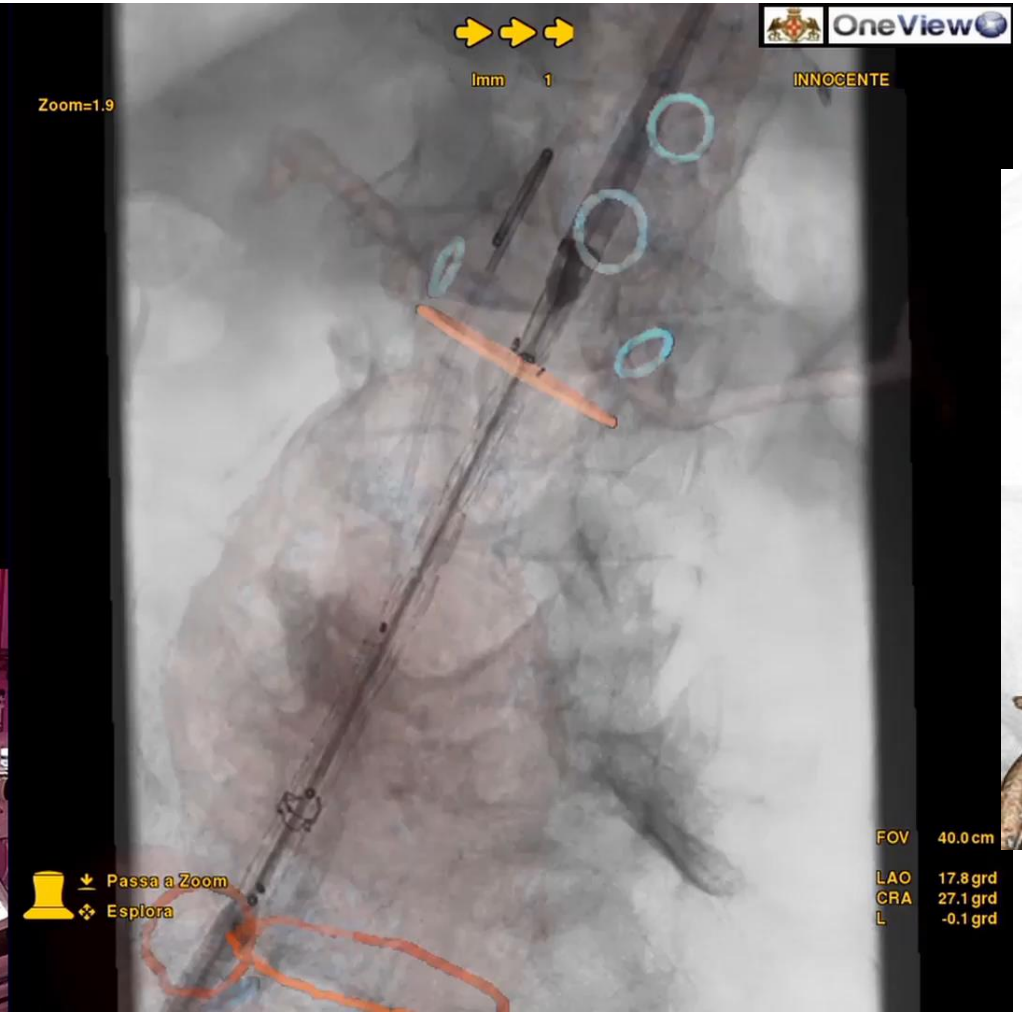


Conclusions: After ESAR treatment using Heli-FX EndoAnchors with Endurant, the 5-year outcomes of the short neck cohort from the ANCHOR registry had encouraging results with regards to proximal neck-related complications, secondary procedures, and sac regression. This review of ESAR in patients with short proximal necks showed positive outcomes through 5 years although follow-up of a larger cohort is necessary.

J Vasc Surg 2023

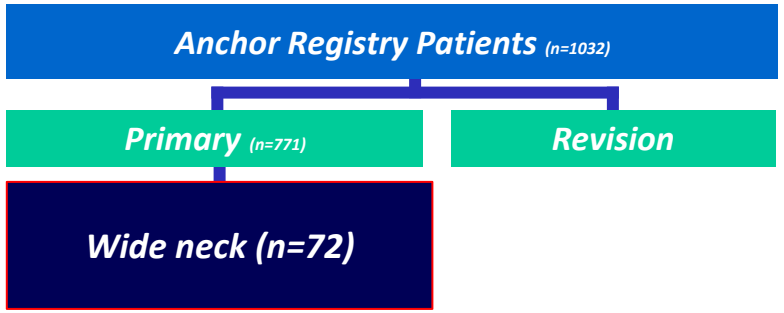
When do Endoanchors work?
Wide neck



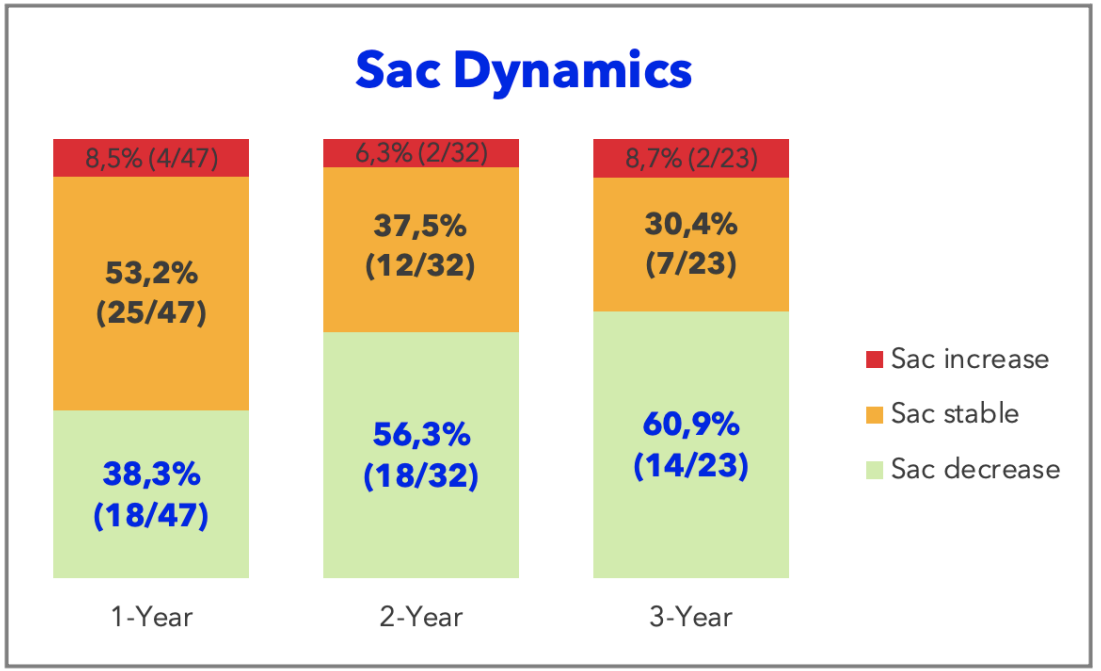


Wide Neck Patients in ANCHOR Registry

All Primary AAA Subjects with Proximal Neck Diameter ≥ 28mm but ≤ 32mm and Length ≥ 10mm

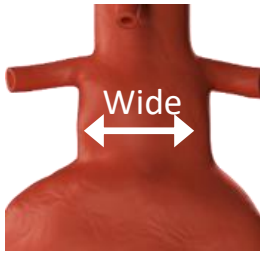


Freedom from Event through 3 years		No. at risk[3]			
		Yr 0	Yr 1	Yr 2	Yr 3
ACM	73.6 ± 6.7%	72	58	43	32
ARM	98.6 ± 1.4%	72	58	43	32
Conversion	100.0 ± 0.0%	72	58	43	32
Secondary procedures	87.4 ± 5.9%	72	56	39	26
Rupture	100.0 ± 0.0%	72	58	43	32
Migration	100.0 ± 0.0%	72	35	15	14
Type IA endoleaks	**98.5 ± 1.5%**	72	46	30	24
Reintervention for Type IA	**100.0 ± 0.0%**	72	58	43	32

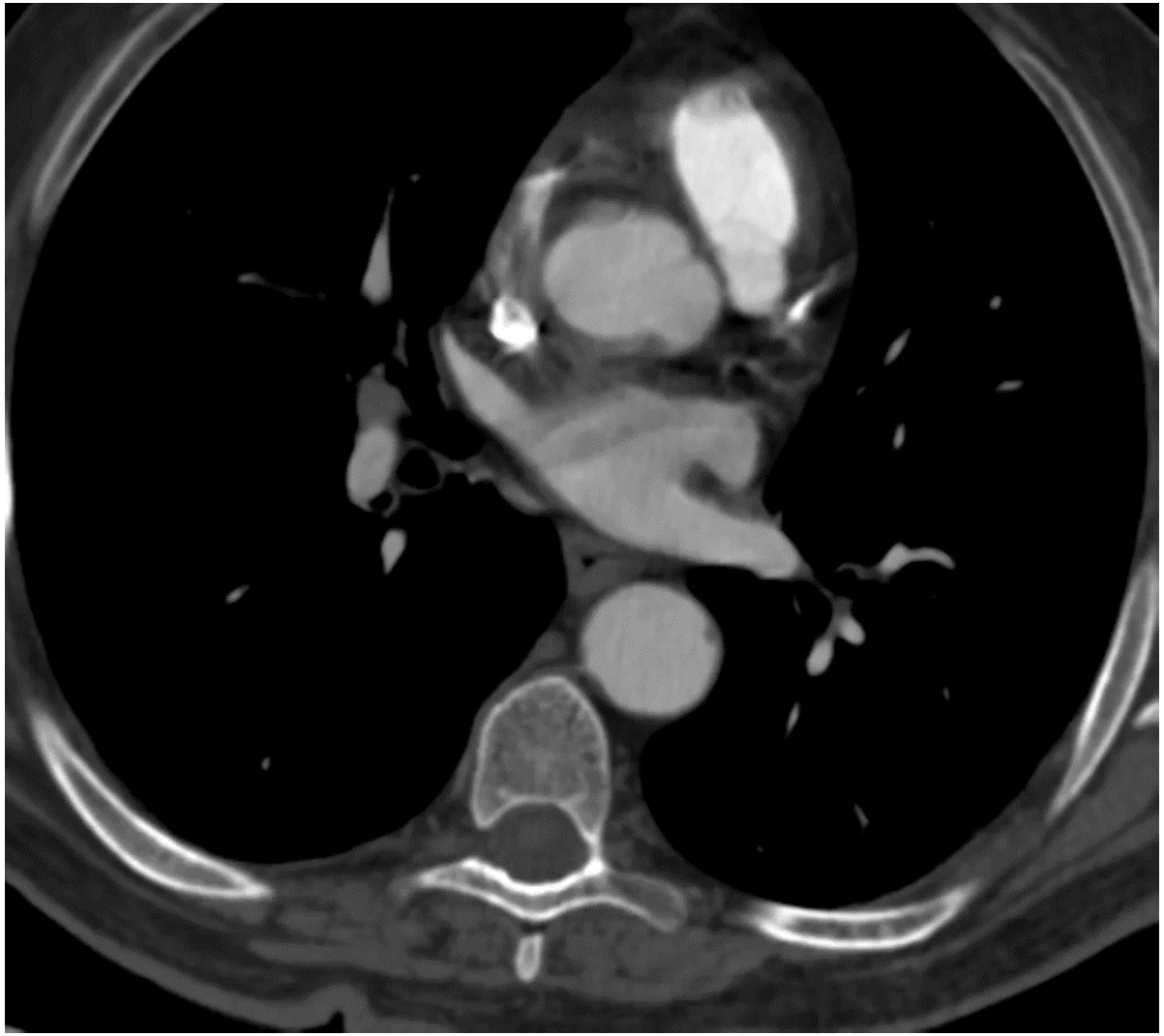


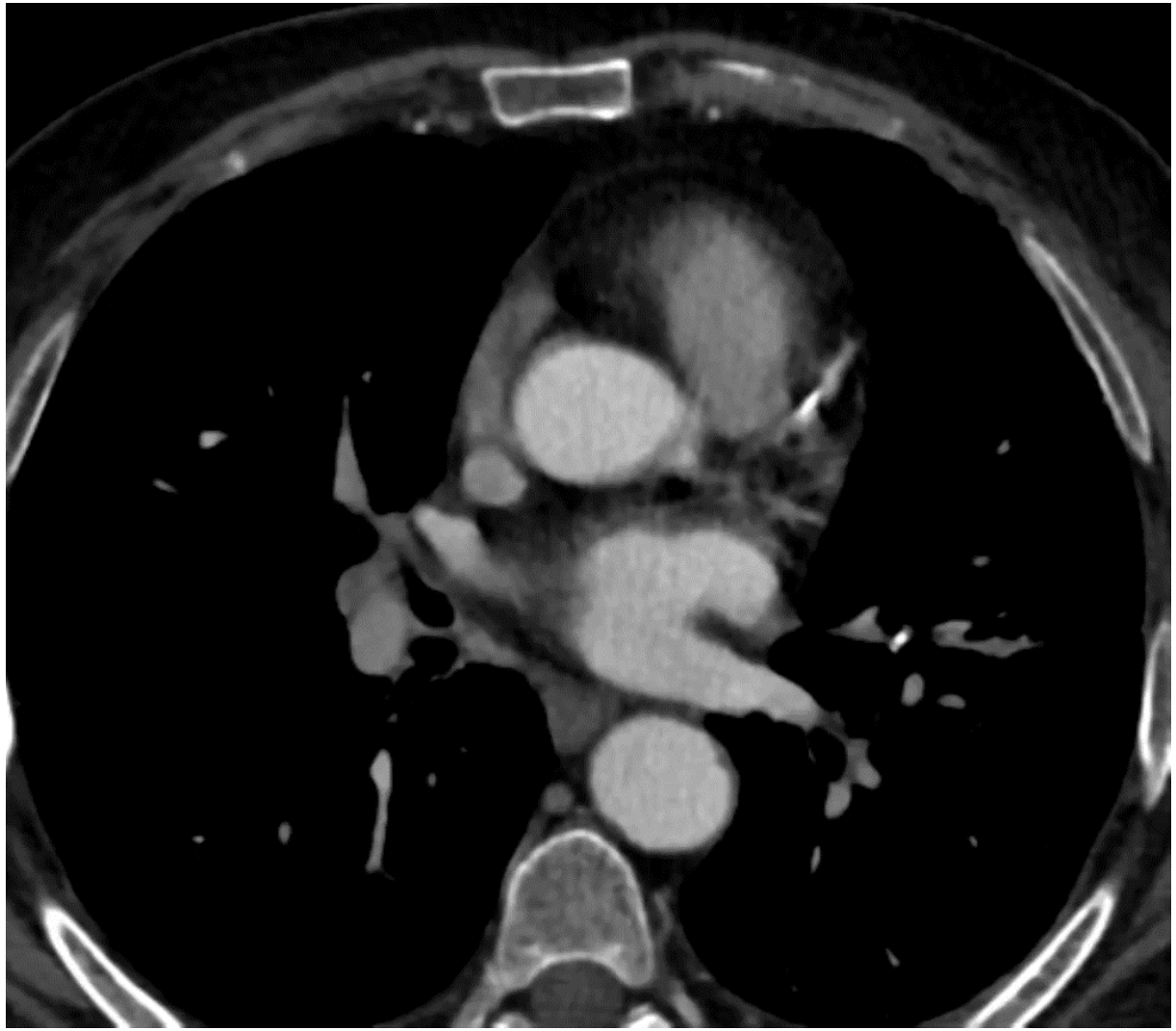
ESAR in wide neck: Hercules Study

Study Title	**Randomized controlled clinical trial on the application of Heli-FX EndoAnchors in conjunction with the Endurant II/IIs endograft in infrarenal aortic aneurysms with a wide infrarenal neck**
Purpose	To prospectively compare endosuture aneurysm repair (ESAR) to standard endovascular aneurysm repair (EVAR) clinical outcomes in treatment of infrarenal AAA in patients having wide proximal aortic neck diameters (≥ 28 mm and ≤ 32 mm)
Study design	Prospective, multicenter, randomized (1:1), two arm, superiority
Sample size/ Sites	• Up to 300 subjects • Up to 40 sites globally (EU and US)
Primary Endpoints	Composite based on core lab reported data from computed tomography (CT) with contrast imaging of freedom from: (1) Type IA endoleak AND (2) Migration of the proximal portion of the stent graft ≥5 mm (compared to 1-month imaging) AND (3) Aneurysm sac growth ≥ 5 mm (compared to 1-month imaging)
Follow-up	1 month and annually through 5 years CT scans with contrast required at each follow-up visit
Core Lab	Core lab will measure all baseline and follow-up visit imaging



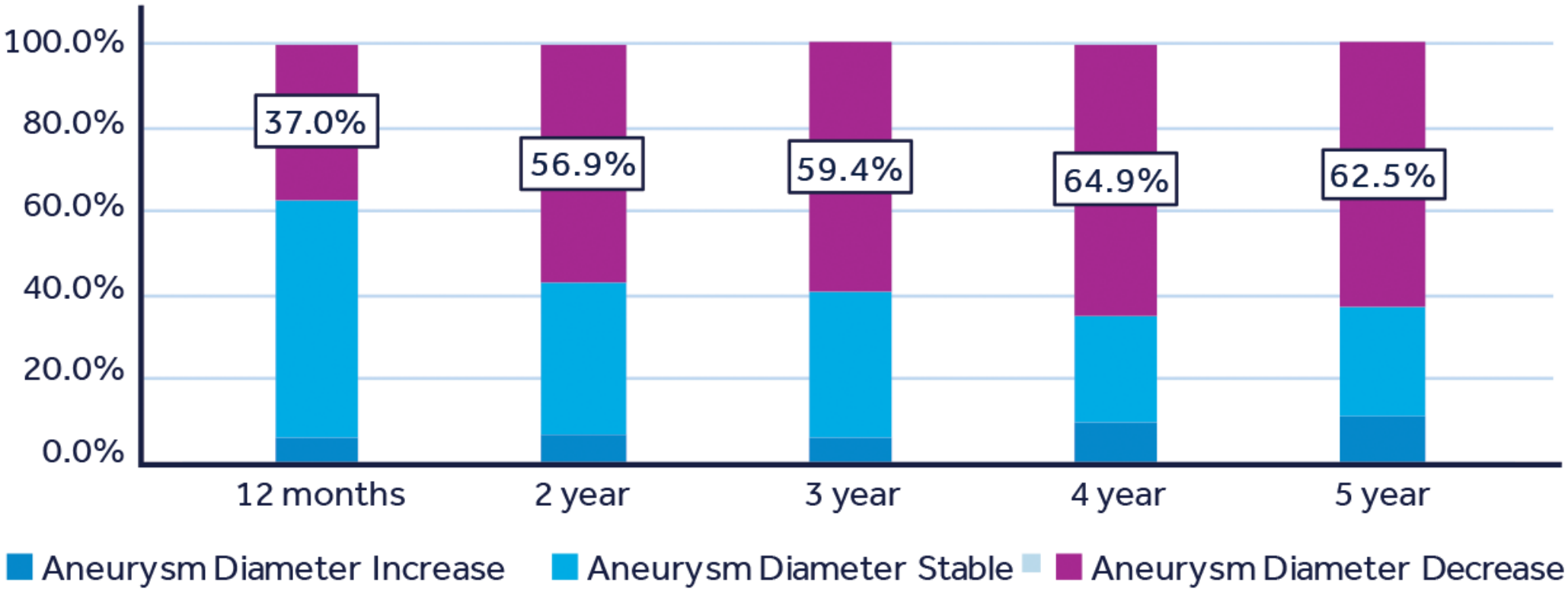
When do Endoanchors work on the long term? Aneurysm sac regression





ESAR and sac segression

ANCHOR Primary AAA Arm 5-Year results:
88.8% of sacs stable or decreasing at 5 years

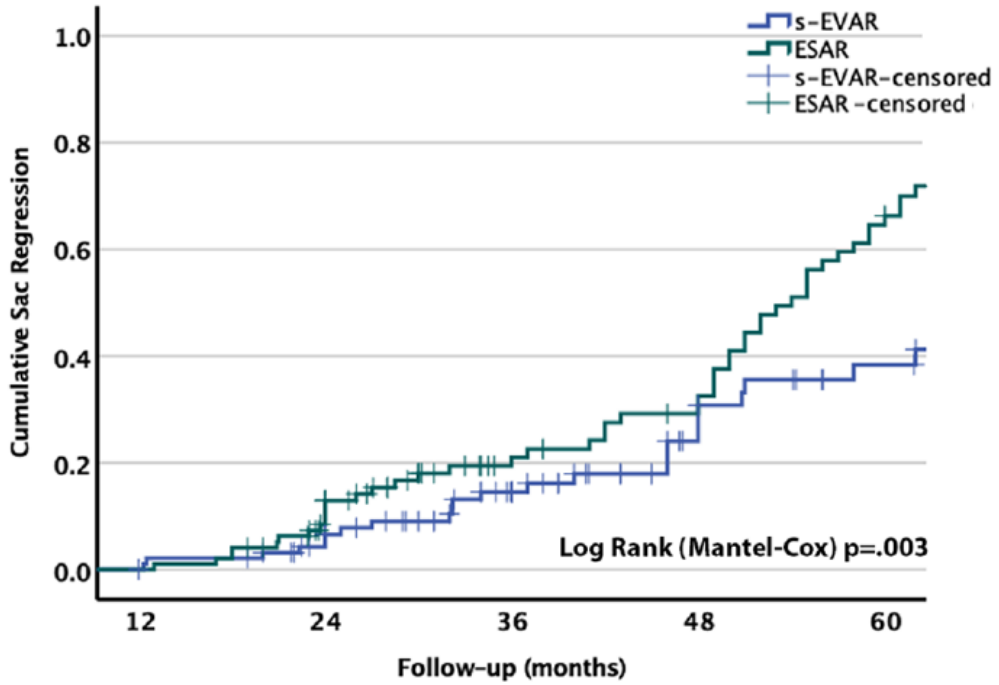


PERU Registry: EVAR versus ESAR
propensity matched patients with hostile neck anatomy

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

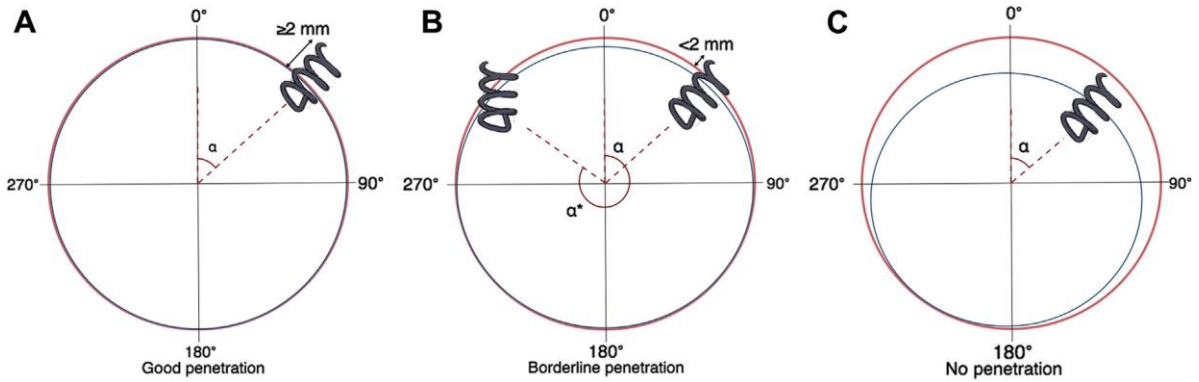


Reyes Valdivia A. et al, J Endovasc Ther 2022

When do Endoanchors not work?
Technical issues

Influence of aortic neck characteristics on successful aortic wall penetration of EndoAnchors in therapeutic use during endovascular aneurysm repair

Seline R. Goudeketting, MSc,[a,b] Kim van Noort, MSc,[a,b] Kenneth Ouriel, MD,[c] William D. Jordan Jr, MD,[d] Jean M. Panneton, MD,[e] Cornelis H. Slump, MSc, PhD,[b] *and* Jean-Paul P. M. de Vries, MD, PhD,[a] *Nieuwegein and Enschede, The Netherlands; New York, NY; Atlanta, Ga; and Norfolk, Va*



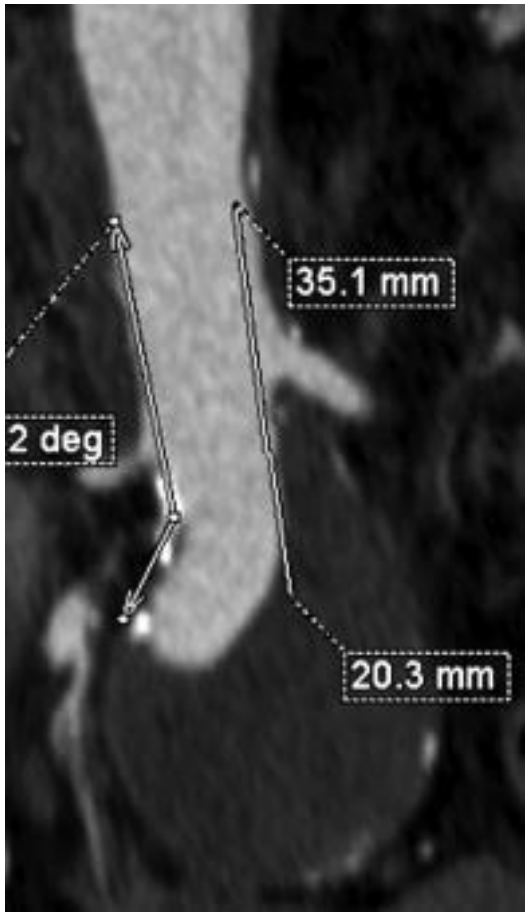
Variable[a]	Type IA endoleak group		No-endoleak group		Total	*P* value
EndoAnchors, No.	247 (42.6)	8 (4-10)	333 (57.4)	6 (4-8)	580 (100)	.060
Good penetration	98 (39.7)	3 (2-4)	235 (70.6)	4 (3-5)	333 (57.4)	.002
Borderline penetration	43 (17.4)	1 (0-2)	32 (9.6)	0 (0-1)	75 (12.9)	.003
No penetration	106 (42.9)	3 (1-5)	66 (19.8)	1 (0-2)	172 (29.7)	<.001
Distance from LRA, mm		9 (6-13)		8 (4-13)		.006
Fabric distance, mm[b]		7.5 (4.5-11.8)[b]		7.3 (4.3-10.3)[b]		.118
Clock face location, degrees		158 (90-278)		188 (98-285)		.273

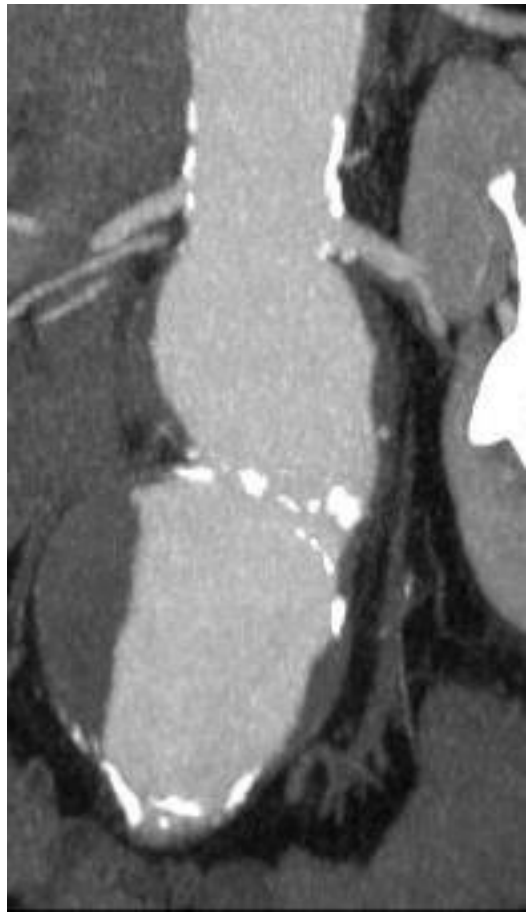
LRA, Lowest renal artery.
[a]Data are represented as number (%) and median (interquartile range).
[b]Seven EndoAnchors were deployed above the fabric, four in the persistent type IA endoleak group and three in the no-endoleak group.

Conclusions: Adequate EndoAnchor penetration into the aortic wall is less likely when the aortic neck diameter is large or when the neck contains significant mural calcium. No penetration of the EndoAnchor was the only factor predictive of postprocedural type IA endoleak. This study stresses the importance of careful selection of patients based on preoperative assessment of the infrarenal neck on CT angiography and emphasizes careful deployment of EndoAnchors into the aortic wall to improve successful treatment of type IA endoleaks.

J Vasc Surg 2018

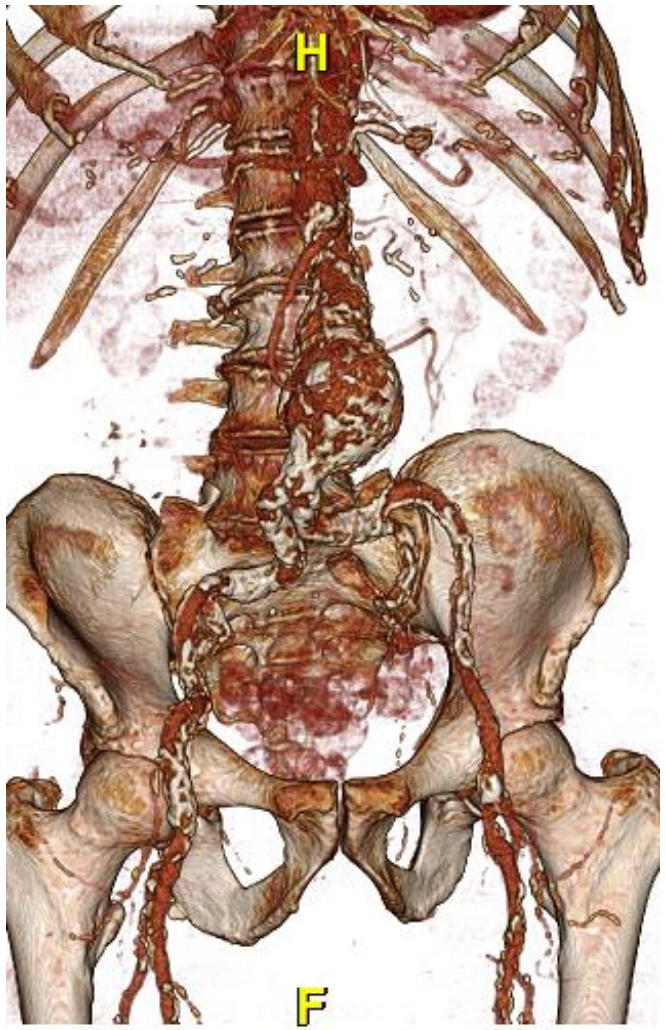
When do Endoanchors not work on the long term?
Wrong case selection

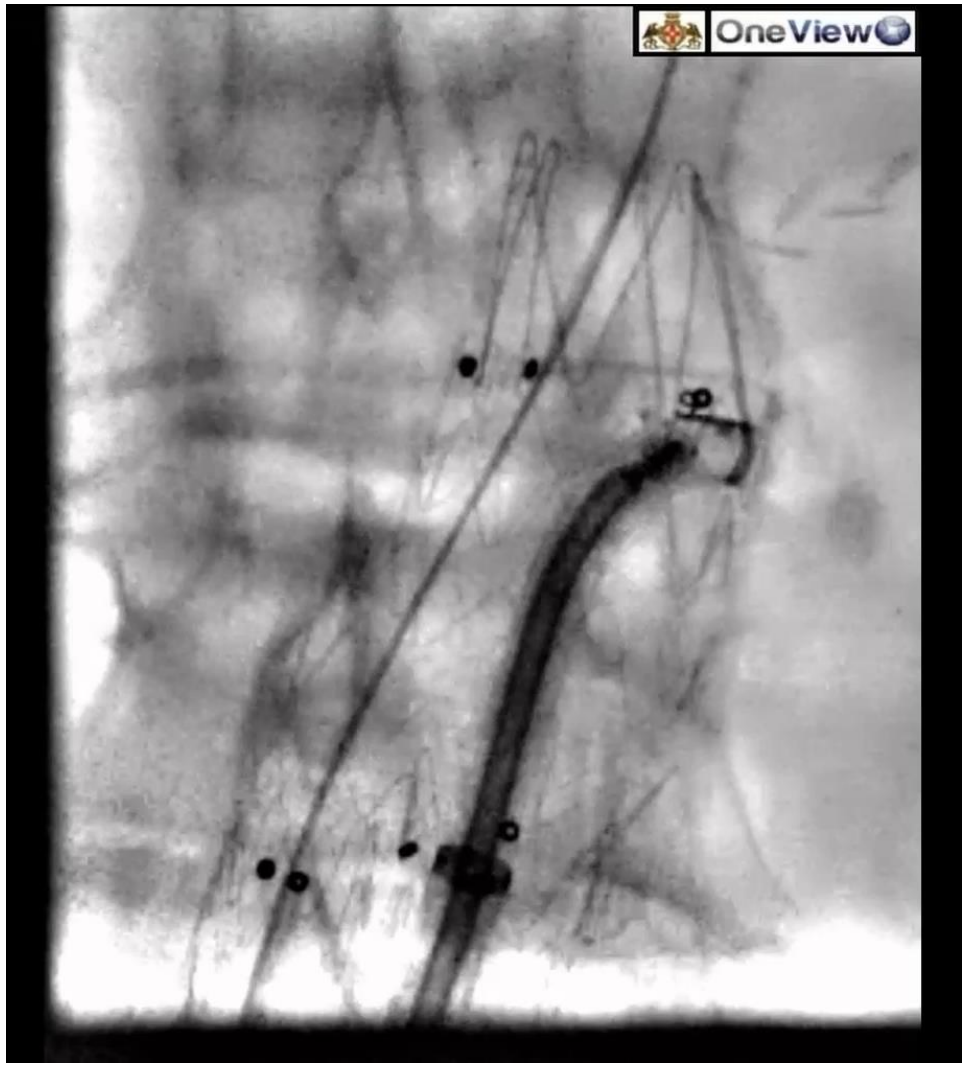


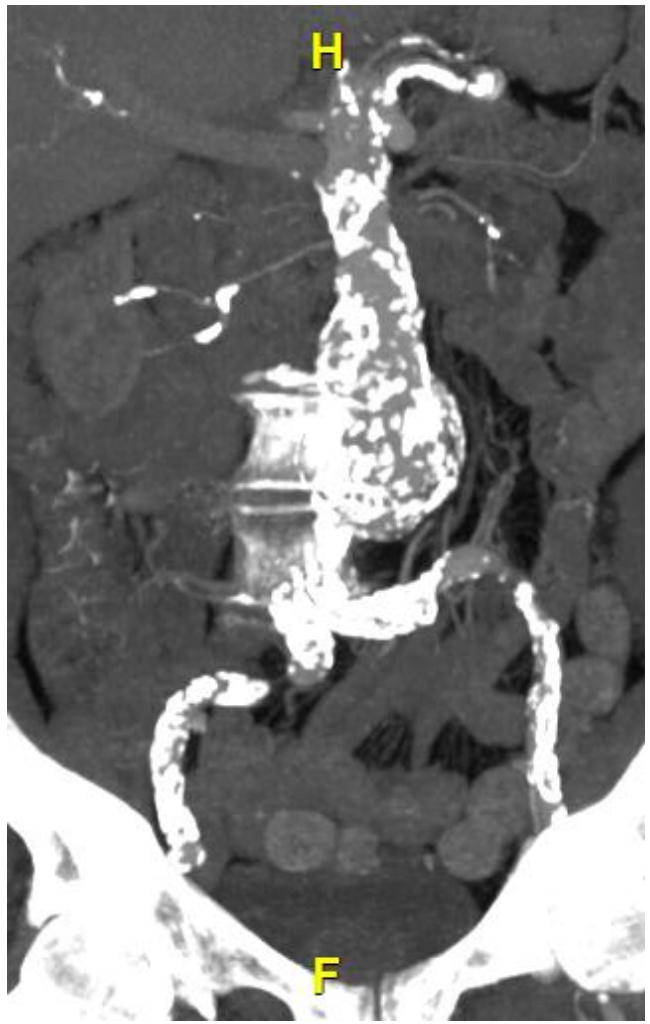


No neck, thick thrombus, Ca+++, large gap

When do Endoanchors not work?
ESAR in calcified neck



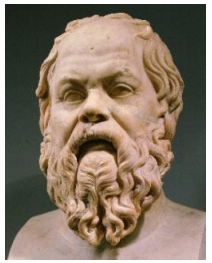


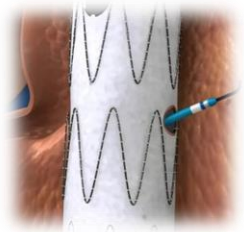


When do Endoanchors work and not on the long term

Socrates Trial

Study Title	**ShOrt neCK AAA RAndomized Trial - ESAR and FEVAR: SOCRATES** **Physician-Initiated Trial Investigating ESAR (EVAR plus Heli-FX EndoAnchors) and FEVAR for the treatment of aortic aneurysms with short infrarenal aortic neck**
Purpose	To prospectively evaluate and compare safety and performance of ESAR (Endurant & Heli-FX) and FEVAR (Cook Z-Fen and Terumo Anaconda) for treatment of aortic abdominal aneurysms with non-aneurysmal infrarenal aortic sealing zone, proximal to the aneurysm, that is sufficiently healthy for proximal neck length within 4mm and 15mm and has a circumferential minimum sealing zone length of 8 mm
Study design	Prospective, multicenter, randomized (1:1), two arm, non-inferiority
Sample size/ Sites	• ~204 (ESAR = ~102, FEVAR = ~102) subjects • 20 to 40 sites globally (EU and US; note: US expansion work approved/prioritized for FY22)
Primary Endpoints	Effectiveness: composite of technical success at index procedure, and freedom from type IA or type III endoleaks, freedom from aneurysm related mortality, freedom from secondary reinterventions through 12 months Safety: freedom from MAEs (ACM, bowel ischemia, MI, respiratory failure, disabling stroke, access related complications, procedural blood loss >1000cc, permanent paraplegia or paraparesis, renal complications) through 30 days Core lab and Clinical Event Committee will be installed to assess selected endpoints and datapoints (both managed by FCRE)
Follow-up	1M, 1YR, 2YR, and 3YR



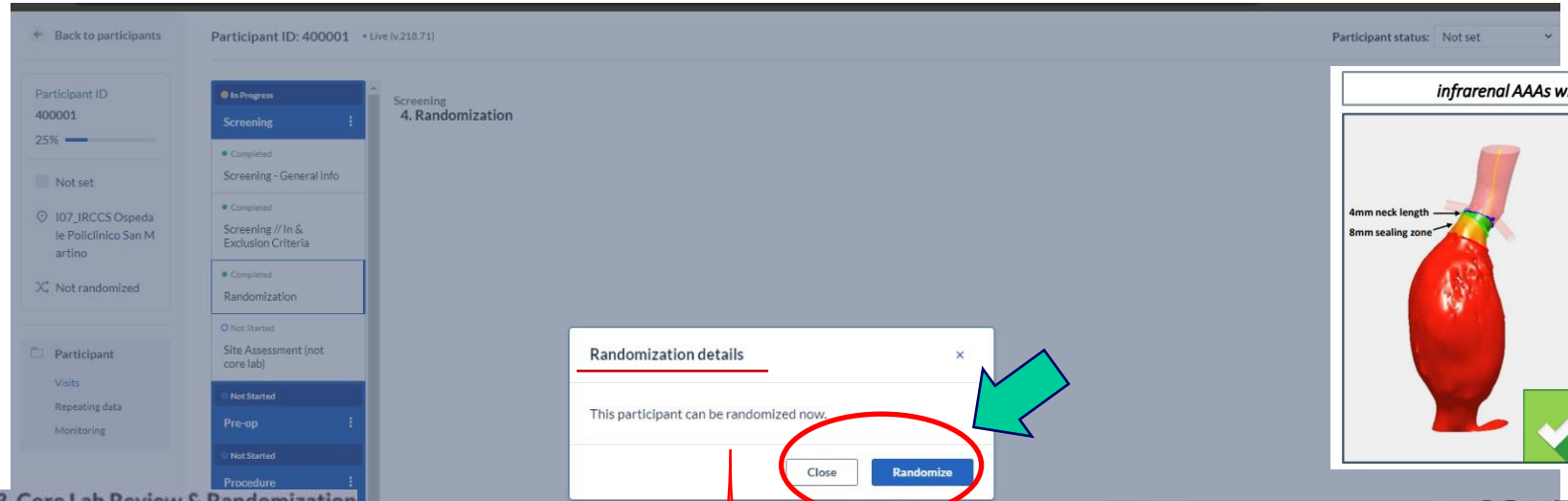


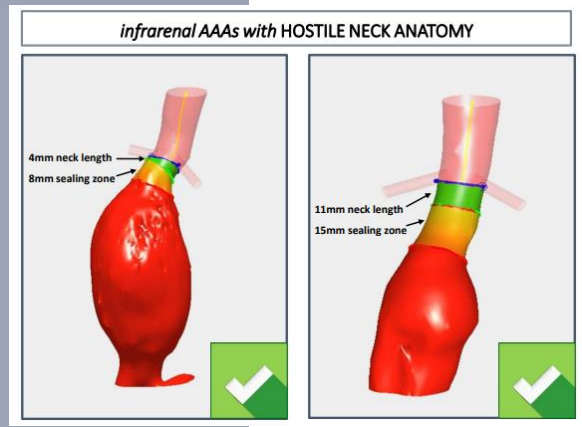
ShOrt neCK AAA RAndomized Trial - ESAR and FEVAR: SOCRATES

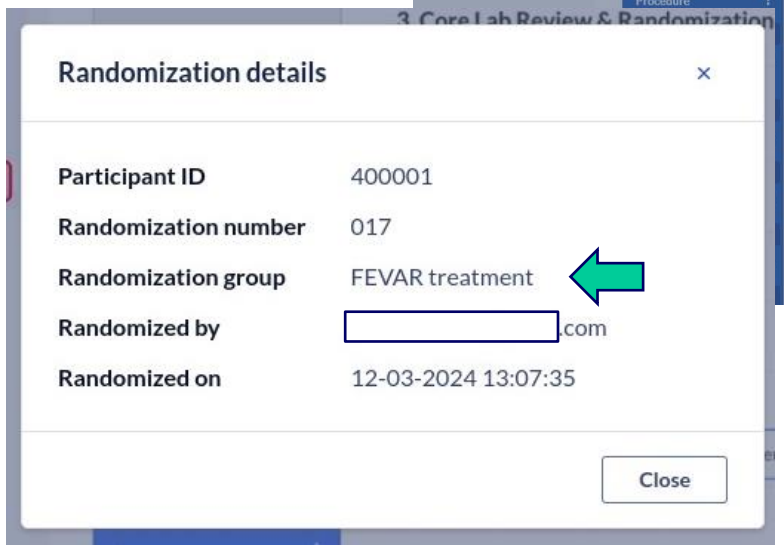
Inclusion Criteria
Neck length and sealing zone

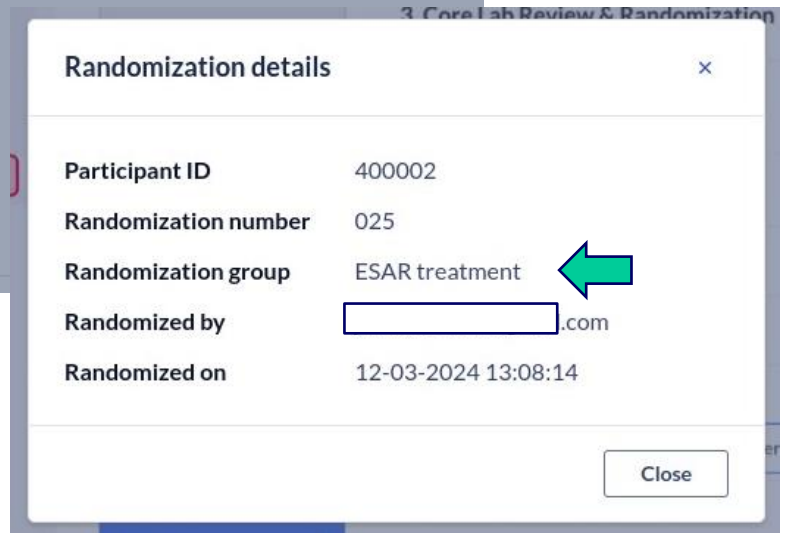
→ eligible *neck length 4-15 mm*

→ minimum circumferential *sealing zone* of *8 mm*









Randomization after Core Lab eligibility confirmation

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