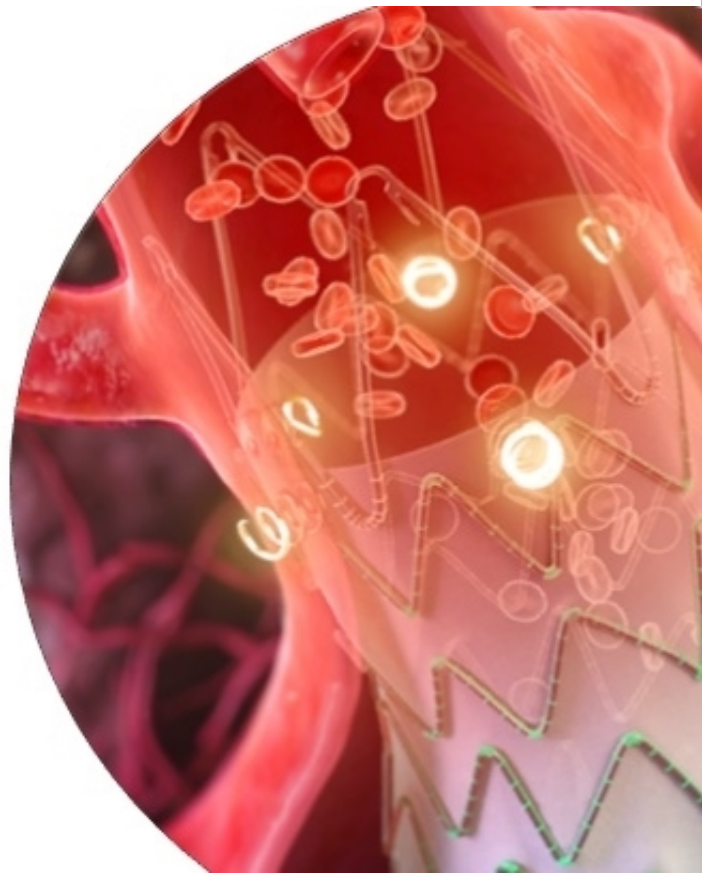


Addressing the unmet needs of challenging neck anatomy patients

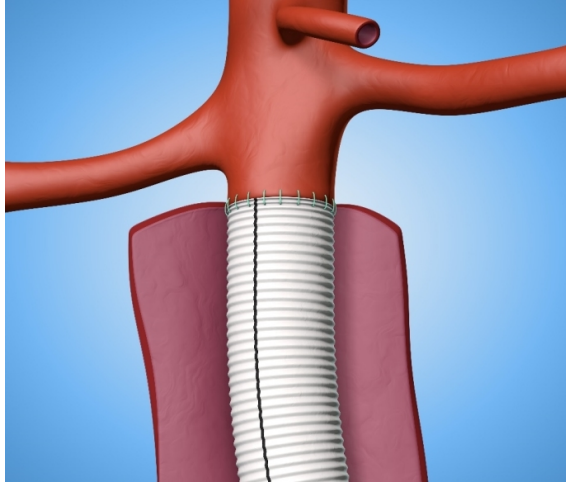
Preliminary 5-year data from the primary arm of the ANCHOR registry

3-year ANCHOR study results on Wide necks

Mr. Colin Bicknell, BM MD FRCS
Imperial College
London



Gold Standard for Aneurysm Repair



OPEN SURGERY¹⁻³

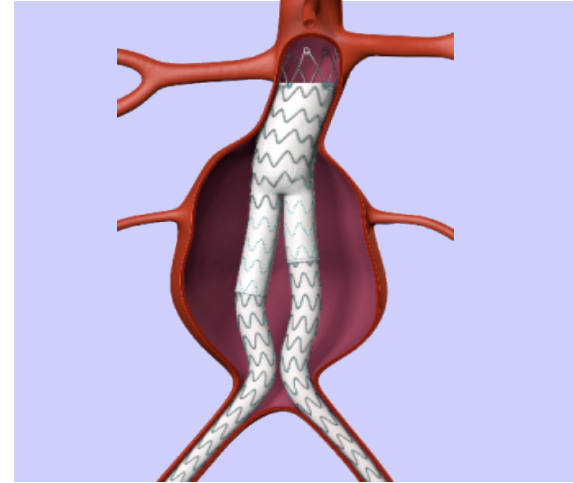
Open AAA Surgery

Proven long-term durability

Competent suture lines; thrombus removal

High perioperative/physiologic burden

Extensive LOS and recovery



Goal of Contemporary AAA Therapy:
Long-Term Durability of open repair w/ Peri-op Benefits of EVAR

¹Schermerhorn et al. N Engl J Med 2008;358:464-74

²Prissen et al. NE J Med. 2004;351:1607-1618

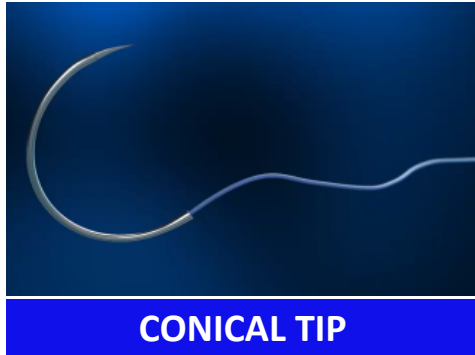
³Greenhalgh RM. Lancet 2004;364:843-8

⁴Morris et al. Am Surg. 2017;83(8):339-341

⁵Oberhuber et al. J Vasc Surg. 2012;55(4):929-934

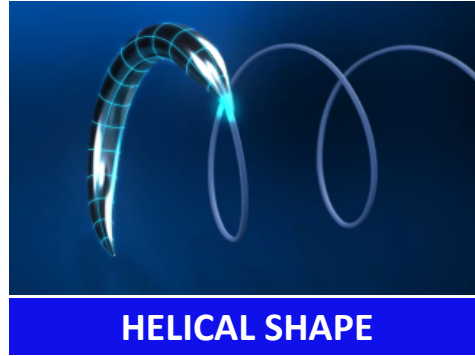
Endosuture aneurysm repair (ESAR) with the Heli-FX™ EndoAnchor™ System

ESAR delivers an endovascular “suture line” to provide radial fixation and increase proximal seal



CONICAL TIP

- Replicates SH-1 tip
- Transmural Penetration



HELICAL SHAPE

- Replicates suture loops
- Stability



REAR CROSSBAR

- Replicates suture knot
- Secure attachment

ESAR is the evolution of “standard” EVAR to align with the “gold standard” of open AAA surgery

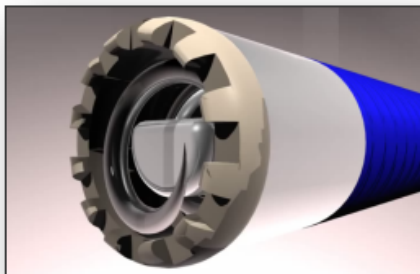
Heli-Fx™ EndoAnchor™ implant system



- Supersede strength of a hand-sewn anastomosis¹



Longitudinal
Fixation



- Mechanically prevent aorta-endograft separation²



Radial
Fixation

¹ Melas et al. JVS. 2012;55(6):1726-33

² Tassiopoulos AK et al. JVS. 2017;66(1):45-52

ANCHOR Registry: Capturing Real-World Usage

Registry Design	Prospective & Observational, International & Multi-Center with Core Lab Analysis	
Registry Principal Investigators	Europe:	Prof. dr. Jean-Paul de Vries University Medical Centre, Groningen, The Netherlands
	USA:	Dr William Jordan Emory University School of Medicine, Atlanta, Georgia
Enrollment & Duration	Initiated in 2012 and patients followed for 5 years	
Follow-up	Per Standard of Care at each center & discretion of Investigator	

771 patients in Primary Arm

ANCHOR Registry: Primary Arm

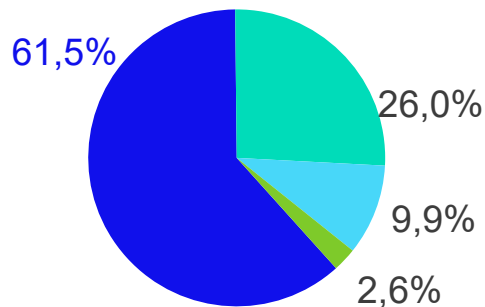
N=771 patients treated with EndoAnchor™ Implants at Index EVAR

Hostile Necks: 88.7% (572/645)

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

Endograft implanted

■ Endurant ■ Excluder ■ Zenith ■ Other



98.0% Endograft Delivered Successfully:

(734/749) (at intended location)

96.3% EndoAnchors Adequately Penetrated Aorta:

(739/767) (at intended location)

**Avg. time to
Implant EndoAnchors**

19.6 min

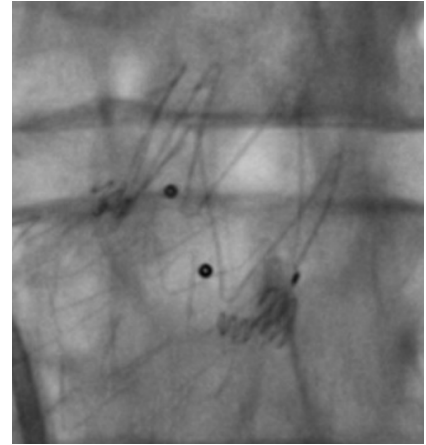
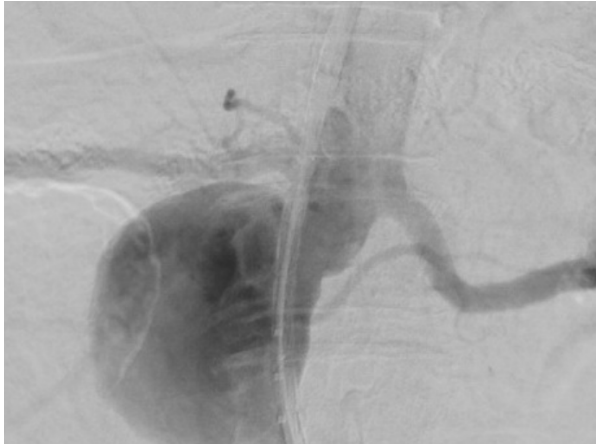
**Avg. number of
EndoAnchor implants**

6.0

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

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Example – EndoAnchors in short angulated neck

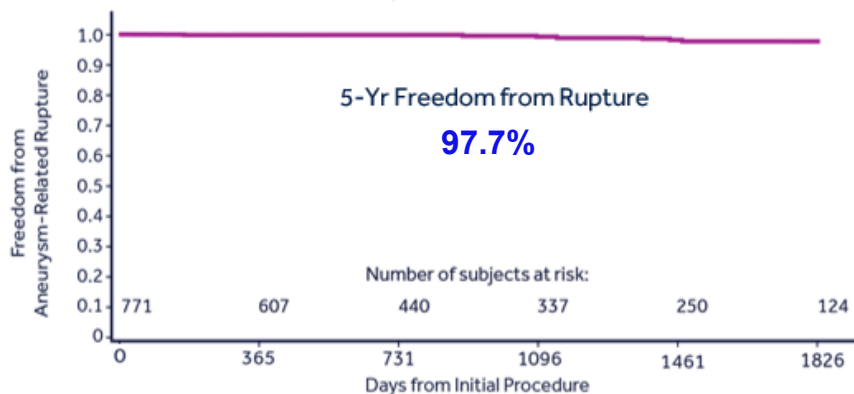
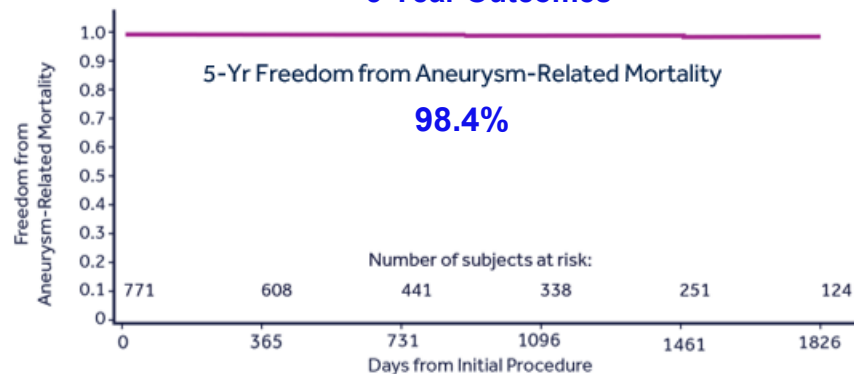


ANCHOR Registry: Primary Arm

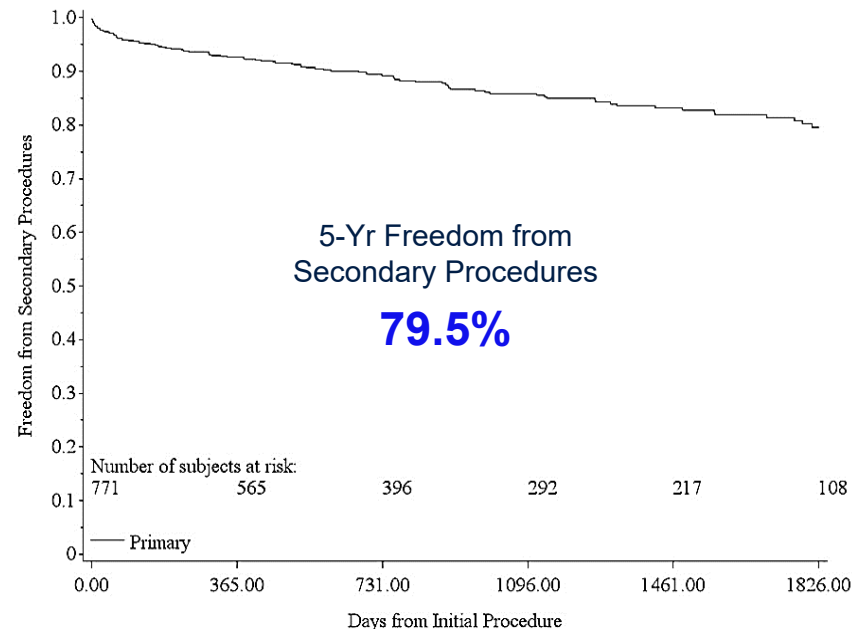
(N=771 pts)

Hostile Necks: 88.7%

5-Year Outcomes



No migration through 5 years



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

ESAR at index procedure minimizes migration and Type Ia endoleaks

ANCHOR Primary AAA Arm 5-Year results (n=771)¹

Type Ia Endoleaks at

1 year: 2.5% (14/568)

2 year: 1.7% (6/346)

3 year: 2.9% (7/238)

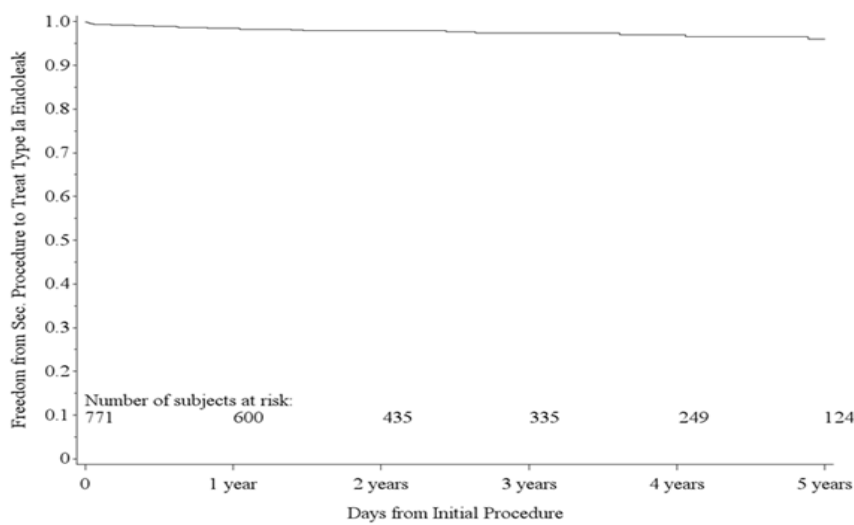
4 year: 3.2% (5/154)

5 year: 4.8% (4/84)

**No migration through
5 years**

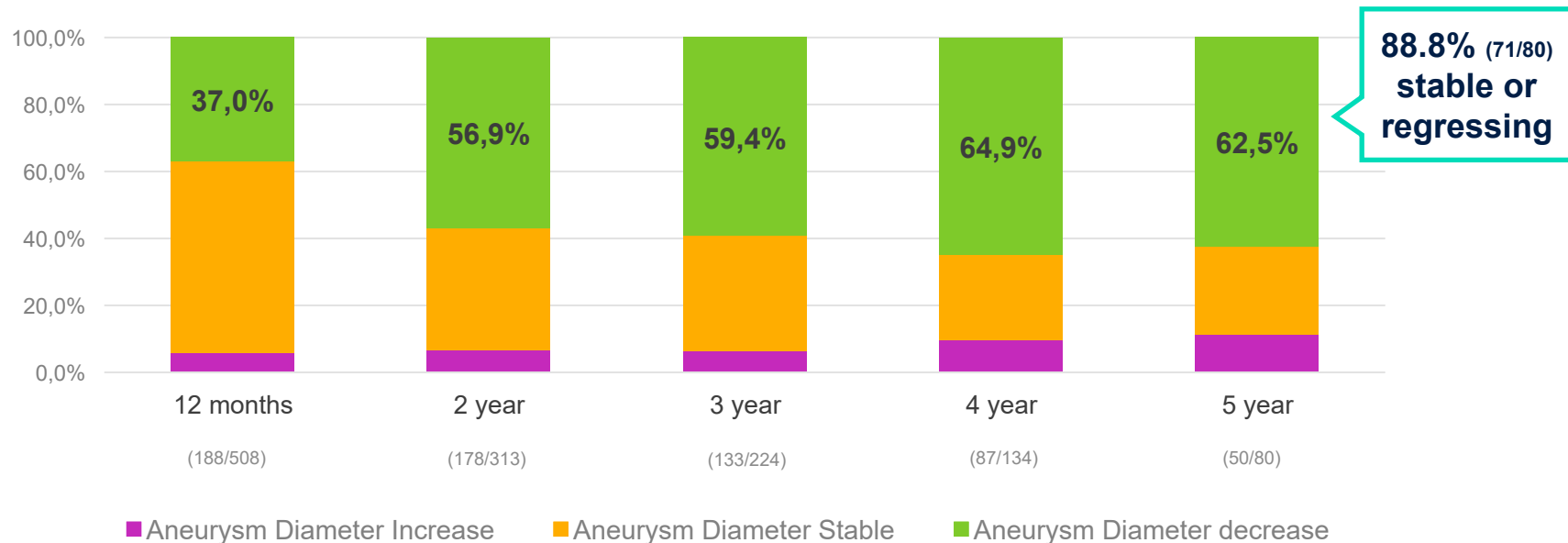
96.0%

5-Yr Freedom from Secondary Procedures to
Treat Type Ia Endoleaks



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

ANCHOR primary arm: sac diameter



Similar sac regression % compared with standard EVAR in non hostile necks (ENGAGE, others)

Discussion Summary

ESAR AT THE INDEX PROCEDURE:

Attaches adventitia to the graft

Reinforces the proximal seal^{1,2}

Protects against neck dilatation³

Minimizes Type Ia endoleaks⁴

Promotes greater sac regression⁵

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
No migration

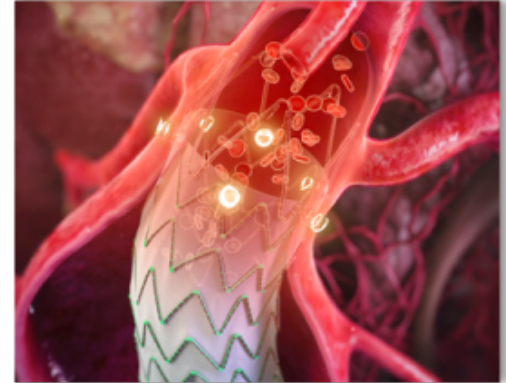
¹ Melas, et al., J Vasc Surg 2012;55:1726-33

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



ANCHOR registry 5-year results

Conclusions

1. Patients “at risk” for late-term endograft failure show acceptable outcomes when using EndoAnchor™ implants at both reducing Type-Ia EL as well as stabilizing the aneurysm
2. Patients with hostile necks may have acceptable durability when EndoAnchor fixation used, particularly at the index operation



ESAR is More than Reinforced Proximal Seal:

First Look at 3 Year ANCHOR Study Results on Wide Necks

on behalf of the ANCHOR Registry Investigators

Increased re-intervention rates in hostile neck anatomy

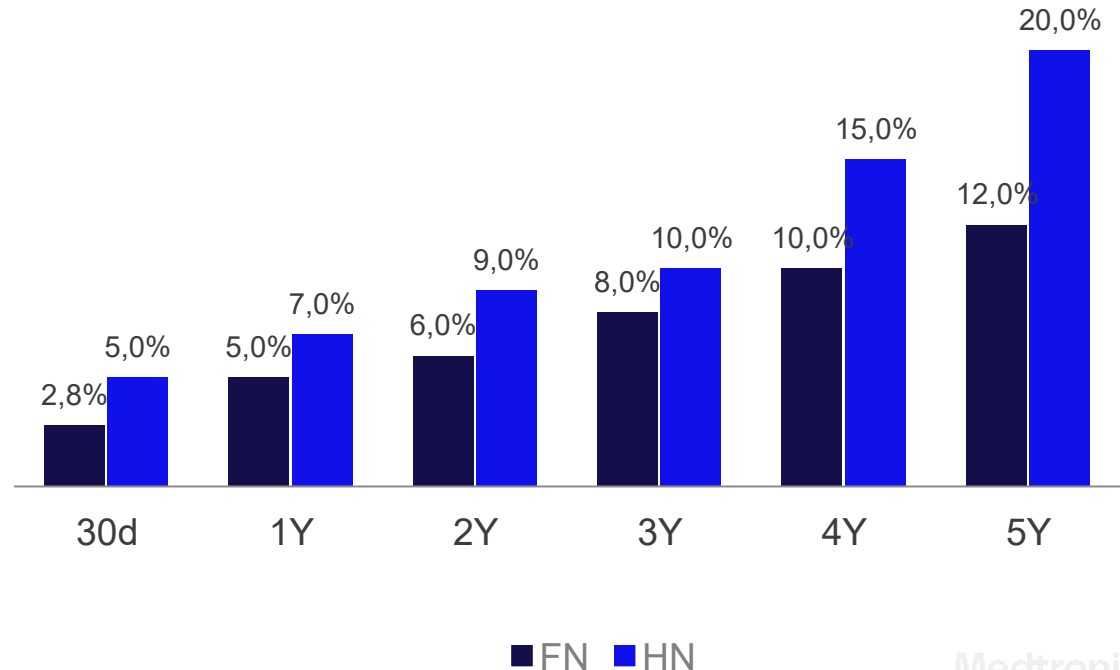
➤ Favorable Neck (353 pts, mean F/U: 49 m)

➤ Hostile Neck (199 pts, mean F/U: 49m)

➤ Hostile Neck defined as

- neck diameter >28 mm
- neck angulation >60°
- neck length <15 mm
- neck thrombus
- neck flare

Reintervention Rates
(Favorable vs. Hostile Neck Anatomy)



Wide necks associated with more complications

- > Definition of wide necks varies in literature: $\geq 25\text{mm}$ up to $\geq 30\text{mm}$
- > Systematic reviews conclude patients with wide necks have higher risk of various graft related complications

Endovascular aneurysm repair in patients with a wide proximal aortic neck: a systematic review and meta-analysis of comparative studies

Kouvelos GN, Antoniou G, Spanos K, Giannoukas A, Matsagkas M.
J Cardiovasc Surg. 2019 Apr;60(2):167-174.

	Hazard ratio	p-value
Reintervention	2.06	0.006
Sac expansion	10.07	0.009
Type IA endoleak	6.69	<0.001
Rupture	5.10	0.01

Systematic review and meta-analysis of endovascular abdominal aortic repair in large diameter infrarenal necks

Laczynski DJ, Caputo FJ.
J Vasc Surg. 2021 Jul;74(1):309-315.e2.

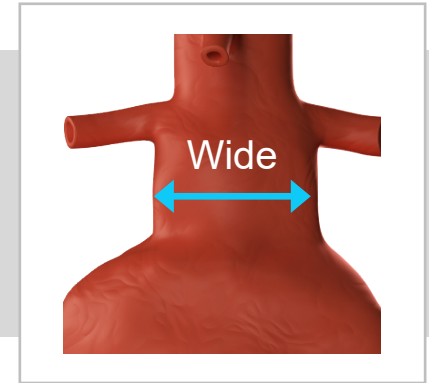
	Wide ratio	Normal Neck
Reintervention	17.4% (n=709)	12.3% (n=2295)
Sac regression	47.6% (n=412)	55.4% (n=841)
Type IA endoleak	11.3% (n=558)	3.1% (n=2251)
Migration	4.9% (n=450)	0.8% (n=2008)

Standard EVAR is insufficient in wide necks

Natural history of aortic neck
– dilatation and shortening

Loss of proximal
seal zone

Graft related complications



> Neck expansion common after EVAR ($\approx 25\%$)¹

> Neck expansion may lead to migration and type Ia endoleak

> The cause is likely multifactorial;

- Progression of disease
- Outward force of the endograft

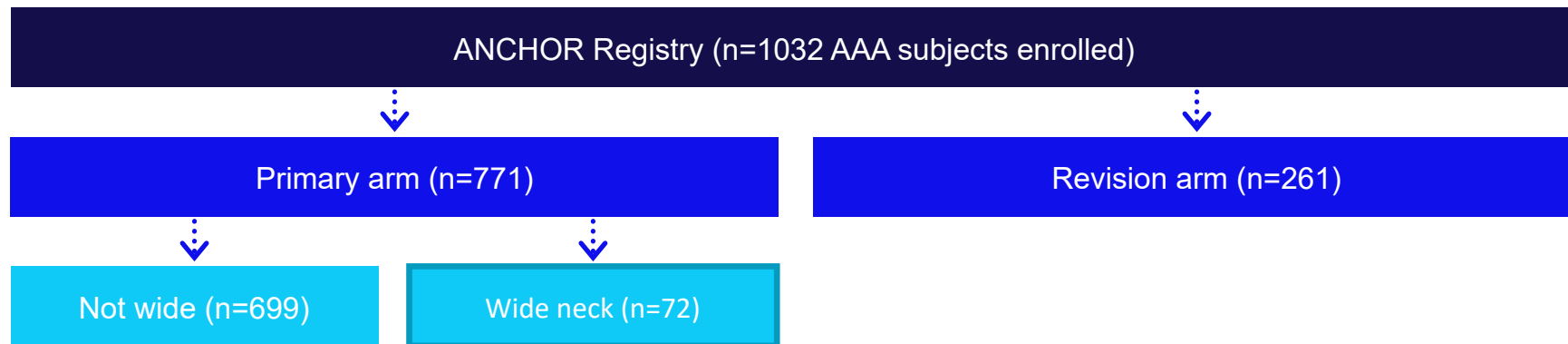
> Risk factors for neck expansion;

- Wide neck
- Extensive oversizing ($>25\%$)

¹Diehm et al. J Vasc Surg. 2008 Apr;47(4):886-92.

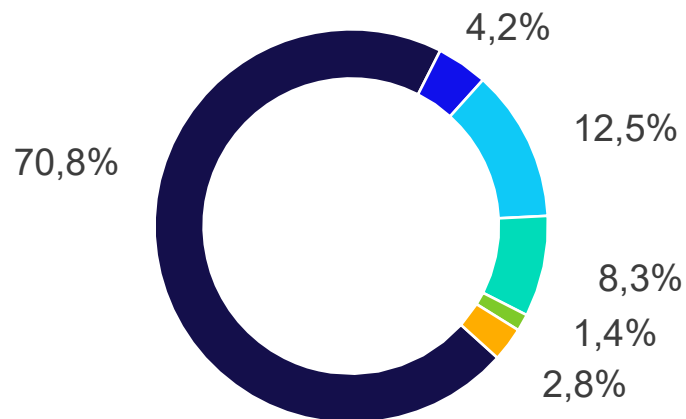
Wide neck patients in ANCHOR Registry

Registry design	Prospective, observational, international, multi-center
Principal investigators	Europe: Dr Jean-Paul de Vries, US: Dr William Jordan
Enrollment period	April 2012 to December 2019
Follow up duration	5 years
Wide neck definition	All primary AAA subjects with proximal neck diameter $\geq 28\text{mm}$ but $\leq 32\text{mm}$ and proximal neck lengths $\geq 10\text{mm}$



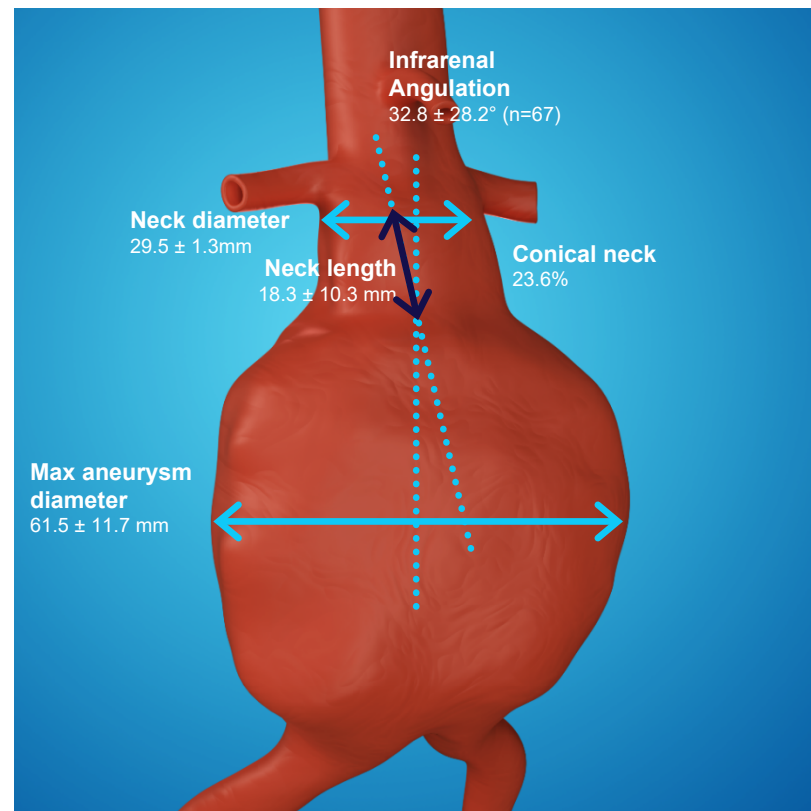
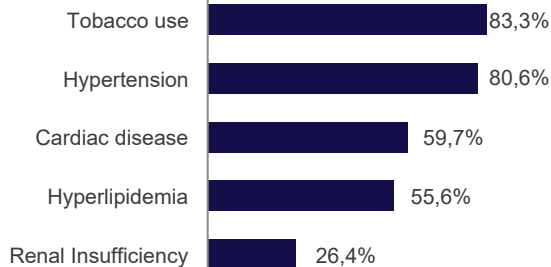
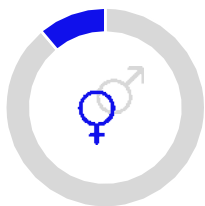
In this first look at 3 years outcomes
13 deaths, 3 withdrawals, 3 lost to FU, 10 not due yet for 3yr FU

Baseline characteristics of wide neck cohort (n=72)



■ Endurant ■ Jotec Evita ■ Excluder ■ Zenith ■ Not reported ■ Other

11.1% Female
73.0 ± 8.6 years (n=71)



Positive three-year outcomes with ESAR

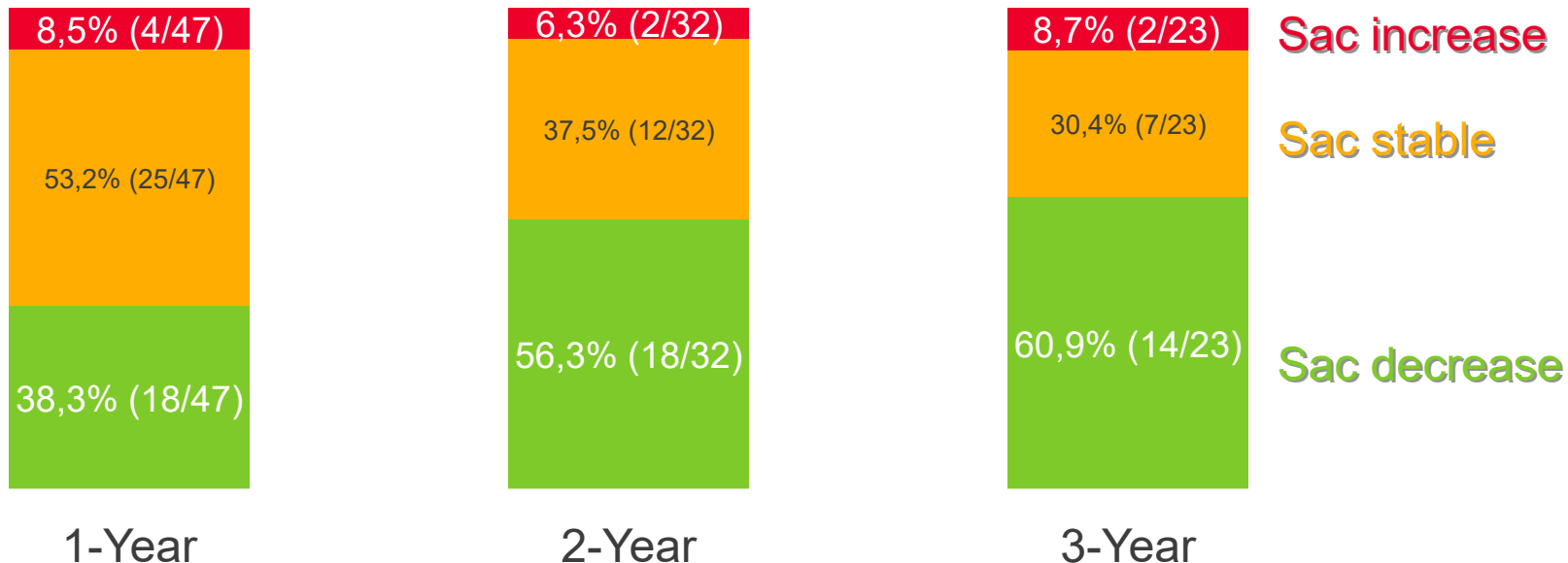
One Type IA endoleak detected within first 30 days.
Patient was monitored and subsequent imaging showed no endoleaks

Freedom from Event through 3 years ¹		No. at risk ²			
		Year 0	Year 1	Year 2	Year 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

¹Estimate made at end of time interval.

²Number of subjects at risk at the beginning of interval.

ESAR sac dynamics



➤ Positive association between sac regression and long term survival¹

➤ The wide neck ESAR cohort had consistent and good sac regression rates

¹O'Donnell et al. J Vasc Surg. 2019 Feb; 69(2):414-422.

Limitations

- Small patient cohort at 3 years
-

- Imaging protocol followed standard hospital procedure which likely means DUS instead of CTA at later FUs

HERCULES study – ESAR vs EVAR



Study Title	Randomized controlled clinical trial on the application of Heli-FX EndoAnchors in conjunction with the Endurant II/IIIs endograft in an infrarenal aortic aneurysms with a wide infrarenal neck
PIs (Collaborative Research)	Michel Reijnen, Rijnstate, Arnhem, the Netherlands Konstantinos Donas, Asklepios Clinic Langen, Langen, Germany
Purpose	To prospectively compare ESAR to standard EVAR clinical outcomes in treatment of infrarenal AAA in patients having wide proximal aortic neck diameters (≥ 28 mm and ≤ 32 mm)
Devices	Endurant II/IIIs (EVAR arm) and Endurant II/IIIs + Heli-FX EndoAnchors (ESAR arm)
Study design	Prospective, multicenter, randomized (1:1), non-inferiority study
Sample size/ Sites	Up to 300 subjects Up to 40 sites globally (US & EU)
Primary Endpoint	Composite endpoint at 1 year based on core lab reported data from CT with contrast imaging of freedom from: <ul style="list-style-type: none"> (1) Type IA endoleak or (2) Distal migration of proximal portion of stent graft ≥ 5 mm (compared to 1 month imaging) or (3) Aneurysm sac growth ≥ 5 mm (compared to 1 month imaging)
Follow-up	1M, 1YR and annually through 5YR
Vendors	Core lab will assess selected endpoints and data points

Conclusions

- ④ Literature demonstrates that patients with wide necks are at greater risk for Type Ia endoleaks, rupture, secondary procedures, and mortality
-

- ④ Wide neck ANCHOR patients treated with the Heli-FX™ EndoAnchor™ System demonstrate excellent outcomes through 3 years, comparable to standard EVAR in favorable anatomies¹
-

- ④ HERCULES study with a head-to-head comparison will help clarify the role of ESAR in wide neck patients

¹Laczynski et al., J Vasc Surg. 2021 Jul; 74(1):309-315

Thank you

