

Which ugly neck can be treated by standard EVAR (and Aptus), which one can't?

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Speaker name:

J.P.P.M de Vries

I have the following potential conflicts of interest to report:

X Consulting: Endologix Inc, **Medtronic**

X Educational grants: Bard, BTG, Cardionovum

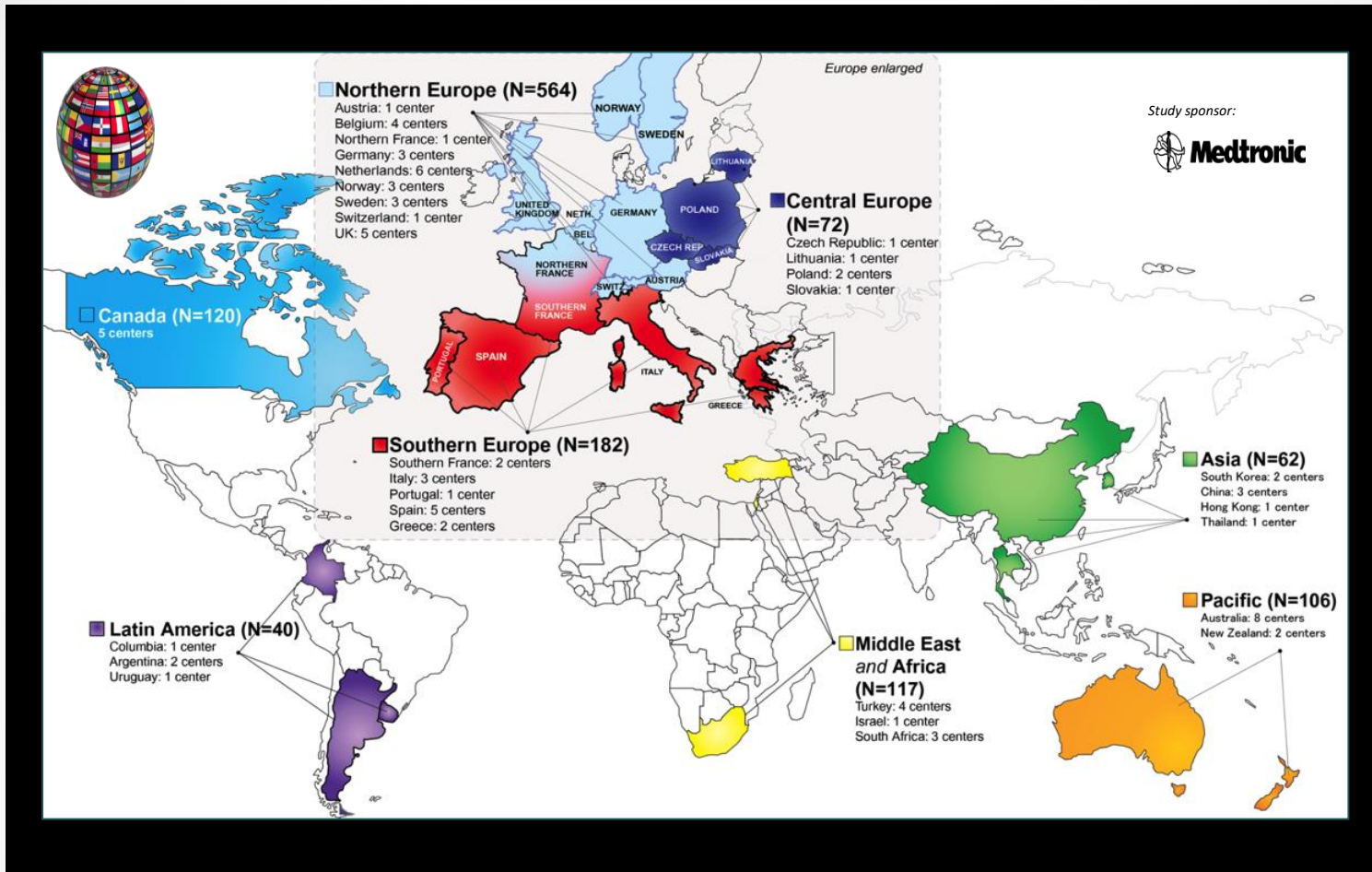
Well known ugly neck parameters

- Neck diameter >28 mm
- Neck length < 10 mm
- Suprarenal angulation > 60°
- Infrarenal angulation > 60 - 90°
- Neck thrombus > 50% of circumference
- Neck calcification > 50% of circumference
- Neck conicity (increase 10%/20% compared to baseline)

Well known ugly neck parameters

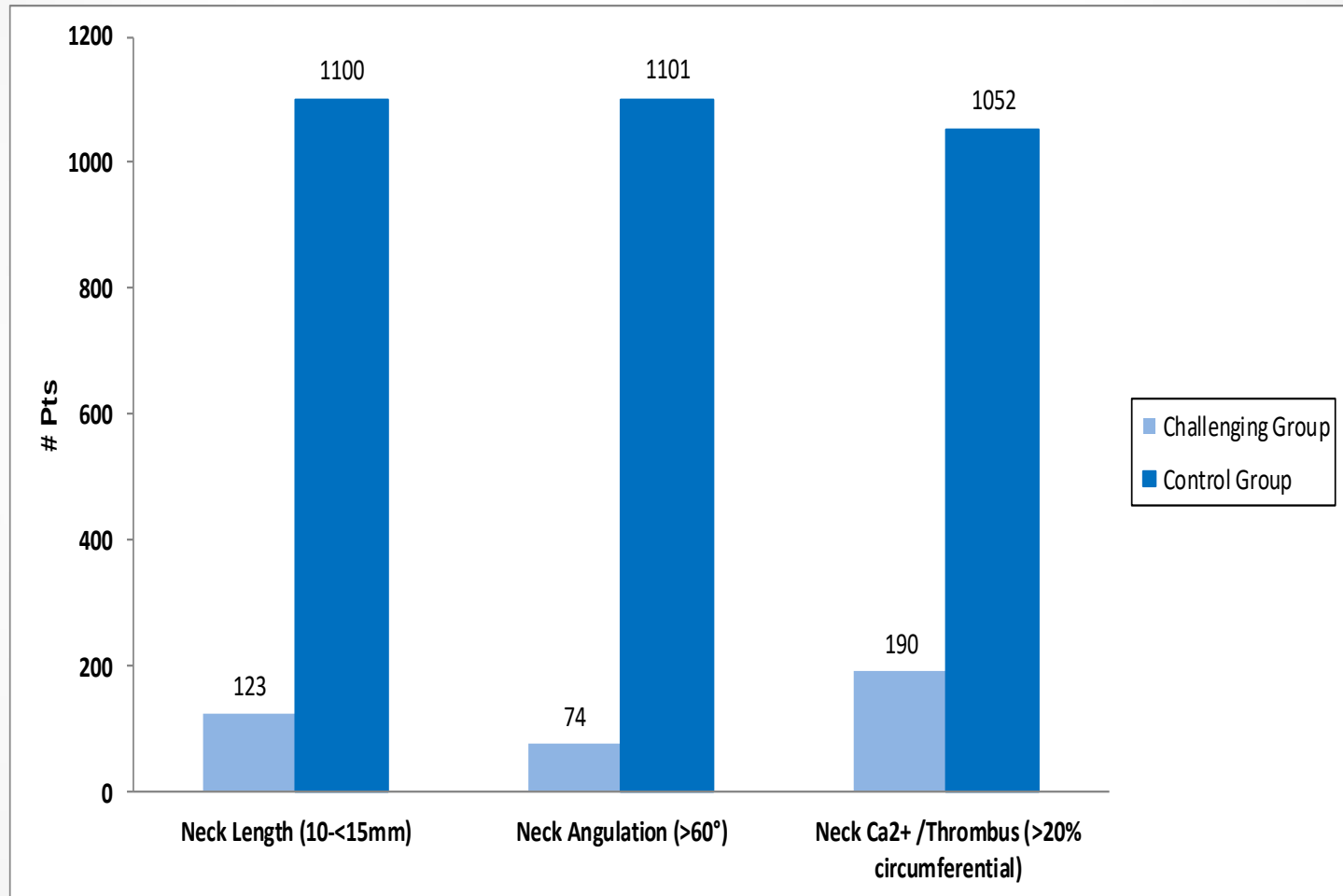
EVIDENCE??

ENGAGE Registry



International multicenter registry: 1263 patients, 30 countries, 79 sites

ENGAGE Registry – Sub-Analysis



ENGAGE Registry – Sub-Analysis

Initial Implant

	Neck Length			Neck Angulation			Neck Ca ²⁺ /Thrombus		
	10-<15 mm	≥15 mm	P-value	>60 - ≤75°	≤60°	P-value	>20%	≤20%	P-value
Successful Delivery and Deployment	100% (123/123)	99.4% (1093/1100)	0.38	100% (0/74)	99.5% (1095/1101)	0.53	98.4% (187/190)	99.6% (1048/1052)	0.04
Type I Endoleak (uncorrected)	0% (0/123)	1.3% (14/1094)	0.21	1.4% (1/74)	1.0 % (11/1096)	0.77	2.1% (4/188)	1.0% (10/1048)	0.16

Early technical success impacted by Ca²⁺/thrombus, not impacted by neck length and angulation

ENGAGE Registry – Sub-Analysis

At 4-Year Follow-Up

	Neck Length			Neck Angulation			Neck Ca ²⁺ /Thrombus		
	10-<15 mm	≥15 mm	P- value	>60 - ≤75°	≤60°	P- value	>20%	≤20%	P- value
Type I Endoleak	3.6% (2/55)	1.6% (9/576)	0.26	0.0% (0/26)	1.9% (11/582)	0.48	2.3% (2/86)	1.8% (10/554)	0.74
Type IA Endoleak	1.8% (1/55)	0.5% (3/576)	0.25	0.0% (0/26)	0.7% (4/582)	0.67	0.0% (0/86)	0.9% (5/554)	0.38

Type 1 EL and Type 1A EL at 4 year not impacted by challenging neck anatomy

ENGAGE Registry – Sub-Analysis

Through 4-Year Follow-Up

	Neck Length			Neck Angulation			Neck Ca ²⁺ /Thrombus		
	10-<15 mm	≥15 mm	P- value	>60 - ≤75°	≤60°	P- value	>20%	≤20%	P- value
2 nd Endovascular Procedure	9.4% (11/117)	11.0% (118/1076)	0.61	8.3% (6/72)	10.6% (114/1074)	0.54	11.4% (21/185)	11.0% (113/1025)	0.90
2 nd Endovascular Procedure to Correct Type I/III Endoleak	4.3% (5/117)	3.3% (36/1076)	0.60	2.8% (2/72)	3.3% (35/1074)	0.82	4.3% (8/185)	3.6% (37/1025)	0.64

Secondary endovascular procedures overall and to correct Type I/III EL
are not impacted by challenging neck anatomy

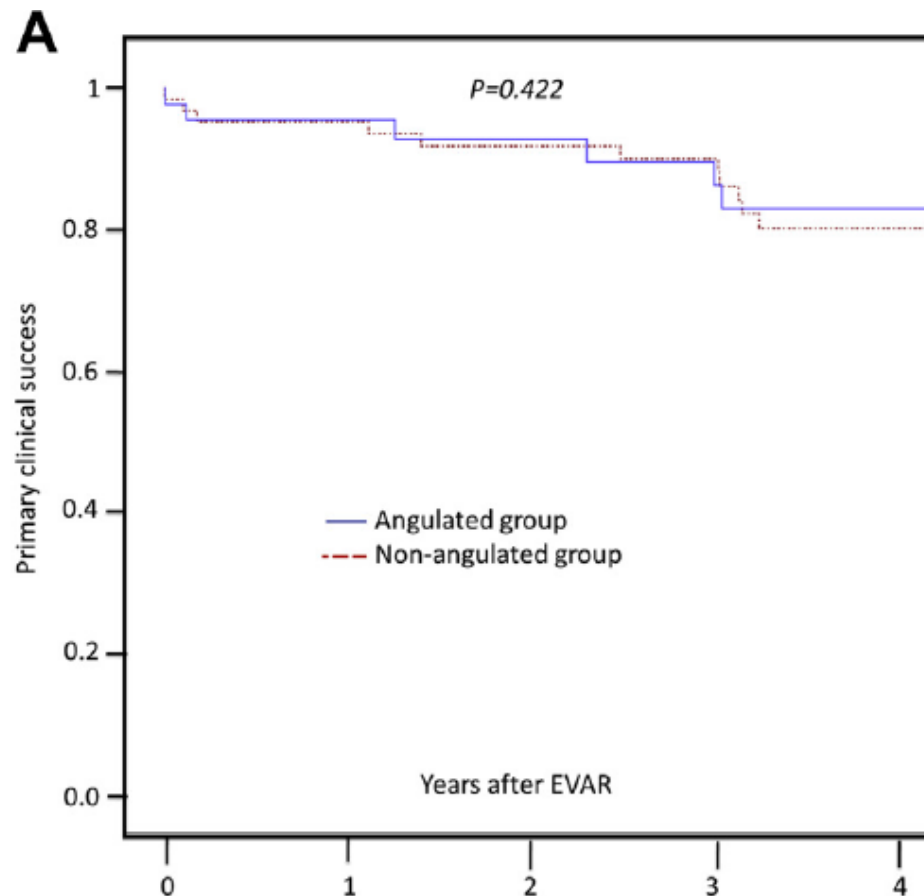
Mid-Term Results of EVAR in Severe Proximal Aneurysm Neck Angulation

N.F.G. Oliveira ^{a,b,*}, F.M. Bastos Gonçalves ^{a,c}, J.-P.P.M. de Vries ^d, K.H.J. Ultee ^a, D.A.B. Werson ^d, S.E. Hoeks ^a, F. Moll ^e, J.A. van Herwaarden ^e, H.J.M. Verhagen ^a

Characteristic	Angulated (<i>n</i> = 45)	Nonangulated (<i>n</i> = 65)	<i>p</i>
AAA Ø (mm), mean (SD)	68.6 (14.2)	58.8 (7.6)	<.01
AAA volume (cc), mean (SD)	309.5 (30.1)	187.4 (8.2)	<.01
Proximal neck Ø (mm), mean (SD)	25.2 (4.2)	25.5 (4.5)	.71
Proximal neck length (mm), mean (SD)	27.2 (14.8)	32.6 (13.1)	.05
Neck thrombus >25% of circumference	8 (17.8)	10 (15.4)	.74
Neck calcification >25% of circumference	3 (6.7)	1 (1.5)	.16
α Angle (degrees), mean (SD)	51.4 (21.1)	17.9 (17.0)	<.01
β Angle (degrees), mean (SD)	80.8 (15.6)	35.4 (20.0)	<.01

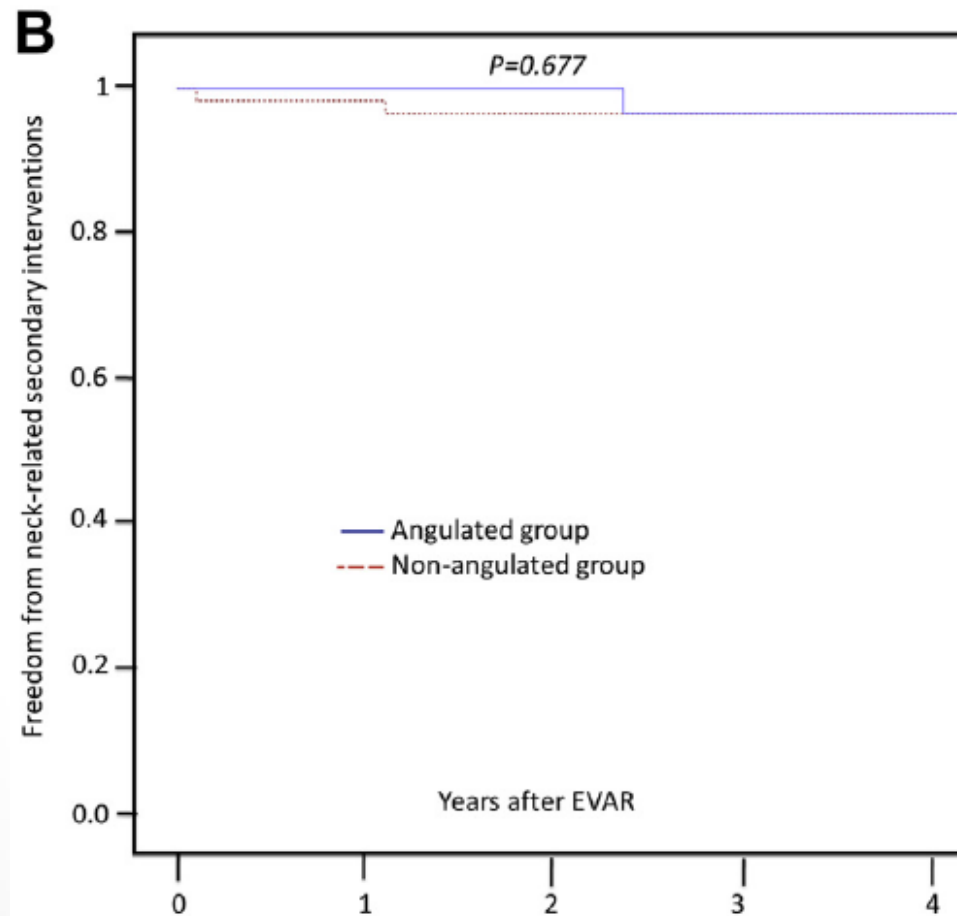
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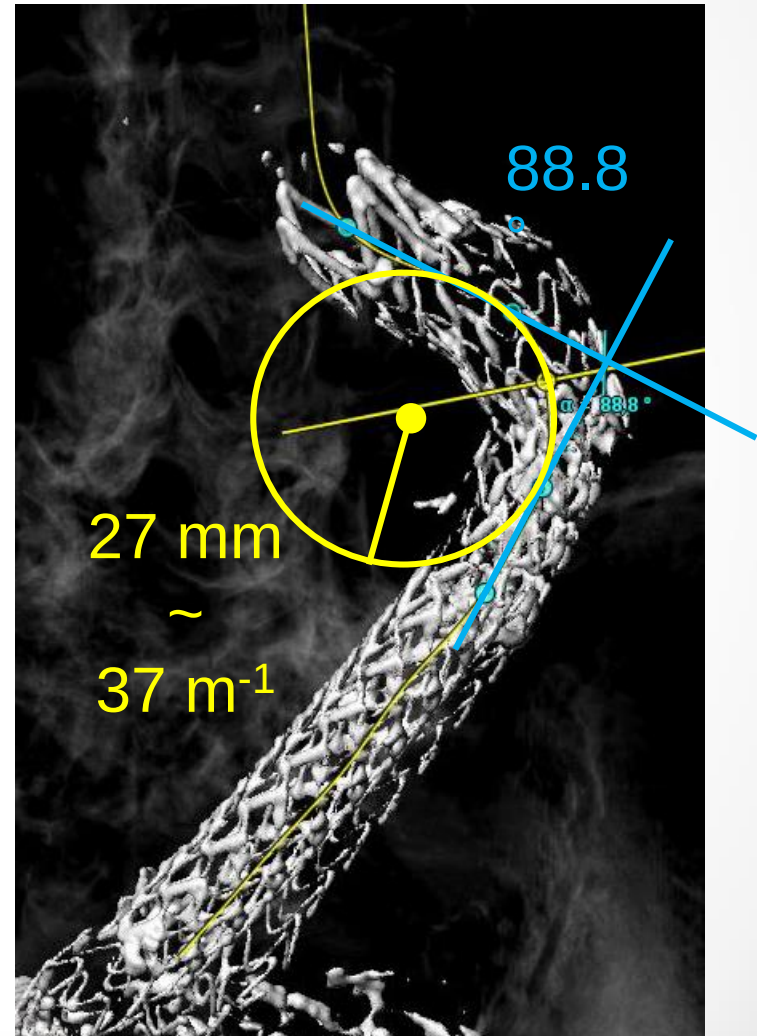
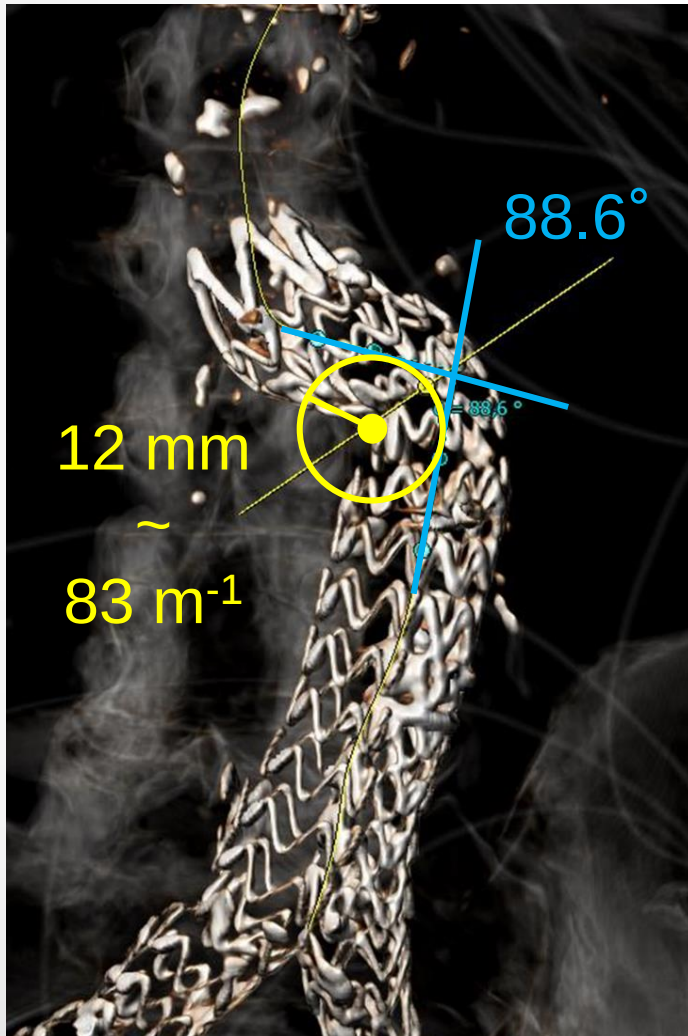


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Angulation vs curvature



Clinical proof



Journal of Vascular Surgery

2016;63:596-602



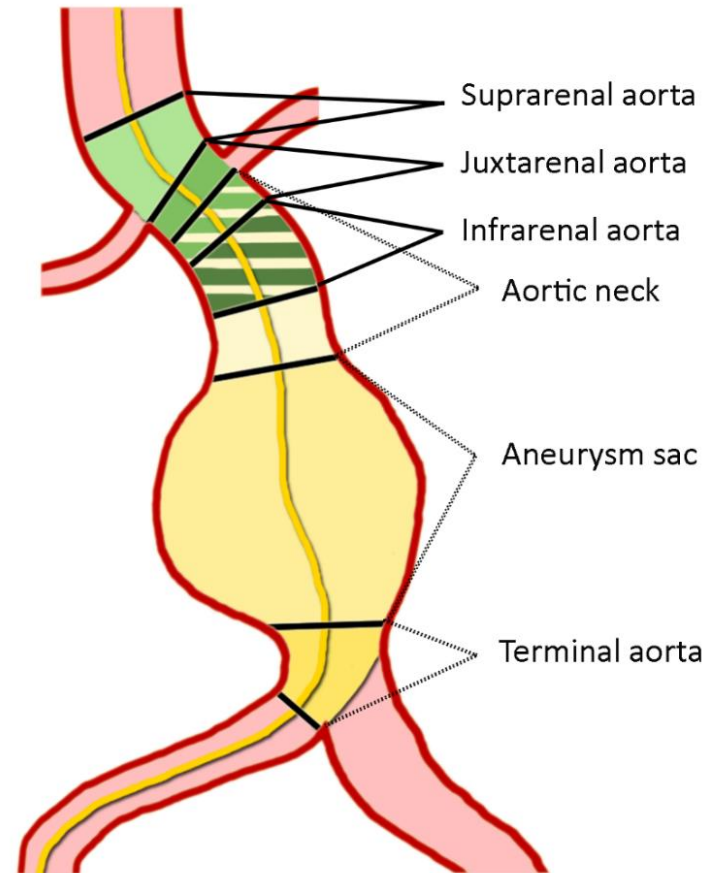
Aortic Curvature as a Predictor of Intraoperative Type IA Endoleak

Richte C.L. Schuurmann, MS^{a, b},  , Kenneth Ouriel, MD^c, Bart E. Mush, MD, PhD^d, William D. Jordan Jr., MD^a, Richard Ouriel, BS^c, Johannes T. Boersen, MS^{a, b}, Jean-Paul P.M. De Vries, MD, PhD^b

- Case-control study
- 143 elective EVAR patients
- 64 **Intraoperative** type IA endoleaks (ANCHOR) vs. 79 control patients
- Core lab analysis of preoperative CT-scans (Syntactx, New York)

Methods

- Curvature over 6 segments
- Other potential predictors:
 - Angulation
 - Tortuosity
 - Neck length
 - Neck diameter
 - Calcification
 - Thrombus
 - Max aneurysm diameter
- Logistic regression



Predictors for acute type IA endoleak

Variable	Median (IQR)		P value
	Controls (n = 79)	Endoleak (n = 64)	
Diameter at lowest renal artery (mm)	25.6 (5.4)	26.3 (4.8)	.233
Neck length (mm)	23.2 (18.2)	26.3 (4.8)	.014^a
Maximum aneurysm sac diameter (mm)	54.3 (17.0)	55.7 (9.6)	.611
Suprarenal angulation (°)	14.0 (14.0)	15.0 (12.0)	.277
Infrarenal angulation (°)	25.0 (21.0)	26.0 (23.0)	.824
Infrarenal angulation to bifurcation (°)	35.0 (20.0)	35.5 (20.8)	.873
Neck tortuosity index (-)	1.05 (0.06)	1.05 (0.06)	.710
Neck thrombus thickness (mm)	0.0 (0.0)	0.0 (0.0)	.153
Neck thrombus circumference (°)	0.0 (0.0)	0.0 (0.0)	.346
Neck calcification thickness (mm)	0.0 (2.0)	1.6 (2.4)	.044^a
Neck calcification circumference (°)	0.0 (35.0)	14.9 (48.7)	.029^a
Curvature (m⁻¹)			
Suprarenal aortic neck	15.1 (8.8)	18.4 (13.7)	.115
Juxtarenal aortic neck	20.7 (14.4)	25.9 (16.8)	.001^a
Infrarenal aortic neck	27.6 (15.8)	27.4 (20.1)	.028^a
Aortic neck	24.2 (16.6)	27.3 (15.8)	.017^a
Aneurysm sac	21.6 (10.1)	26.2 (11.4)	.000^a
Terminal aorta	22.5 (19.2)	35.3 (21.9)	.000^a

No predictors for acute type IA endoleak

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Standard endovascular aneurysm repair in patients with wide infrarenal aneurysm necks is associated with increased risk of adverse events

J Vasc Surg

Nelson F. G. Oliveira, MD,^{a,b} Frederico M. Bastos Gonçalves, MD, PhD,^{a,c} Marie Josee Van Rijn, MD, PhD,^a Quirina de Ruiter, MSc,^d Sanne Hoeks, PhD,^e Jean-Paul P. M. de Vries, MD, PhD,^f Joost A. van Herwaarden, MD, PhD,^d and Hence J. M. Verhagen, MD, PhD,^a *Rotterdam, Nieuwegein, and Utrecht, The Netherlands; and Azores and Lisbon, Portugal*

Variables	Proximal neck Φ , ≥ 30 mm (n = 74)	Proximal neck Φ , < 30 mm (n = 353)	P value
Age, years	75.5 (69.5-80.1)	73.1 (67.4-78.8)	.06
Male sex	67 (90.5)	304 (86.1)	.31
Hypertension ^a	47 (65.3)	238 (67.8)	.68
Diabetes mellitus ^a	13 (17.8)	55 (15.6)	.64
eGFR < 60 ^b	18 (28.6)	84 (28.3)	.96
Previous history or continuous smoking at time of implantation ^c	55 (75.3)	251 (73.8)	.79
ASA class III/IV ^c	38 (53.5)	148 (44.7)	.18
SVS/AAVS cardiac status ≥ 2 ^c	17 (23.3)	82 (23.5)	.97
AAA Φ , mm	60 (55.8-69.0)	59.0 (54.0-68.0)	.39
Neck Φ at lowermost renal artery level, mm	30.0 (28.0-31.0)	24.0 (22.0-26.0)	$< .001$
Neck Φ 5 mm below lowermost renal artery, mm	31.0 (29.0- 32.1)	24.0 (22.4-26.0)	$< .001$
Neck Φ 10 mm below lowermost renal artery, mm	32.0 (29.0- 33.6)	25.0 (23.0-27.0)	$< .001$
Neck Φ 15 mm below lowermost renal artery, mm	32.0 (31.0- 34.0)	26.0 (23.0-28.0)	$< .001$
Proximal neck length, mm	27.0 (16.5-40.5)	28.0 (20.0-37.0)	.72
Reversed tapered neck configuration	31 (41.9)	88 (24.9)	.003
Neck thrombus $\geq 25\%$	51 (69.9)	190 (54.3)	.01
Neck calcification $\geq 25\%$	46 (63.0)	212 (60.6)	.70
α angle, $^{\circ}$	25.0 (13.5-39.0)	25.0 (13.5-39.0)	.76
β angle, $^{\circ}$	41.0 (29.0-58.0)	41.6 (30.0-62.0)	.99
Endograft diameter ^a	36 (36-36)	28 (28-32)	$< .001$
Oversizing, % ^a	12.5 (7.9-16.1)	16.6 (12.0-23.1)	$< .001$
Oversizing $\leq 10\%$	26 (35.6)	56 (16.0)	$< .001$
Endograft AUI configuration	4 (5.7)	30 (9.4)	.33
Proximal seal length at 30-day imaging, mm	19.5 (11.0-28.0)	28.0 (14.0-28.0)	.10

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Table II. Outcomes following endovascular aneurysm repair (EVAR)

	Univariate			Multivariable		
	Neck $\phi \geq 30$ mm	Neck $\phi < 30$ mm	<i>P</i> value	OR	95% CI	<i>P</i> value
Proximal neck-related adverse events	12 (16.2)	17 (4.9)	<.001	3.76	1.55-9.12	.003
Aneurysm-related adverse events	14 (18.9)	53 (15.1)	.42	1.71	0.83-3.51	.15
Any endoleak	18 (24.3)	80 (22.9)	.79	1.37	0.72-2.59	.34
Type Ia endoleak	7 (9.5)	10 (2.8)	.01	2.67	0.96-8.30	.05
Type I and III endoleaks	11 (14.9)	25 (7.1)	.03	3.06	1.30-7.19	.01
Type II endoleak	11 (14.9)	65 (18.6)	.45	0.91	0.44-1.91	.81
Migration >10 mm	0 (0.0)	4 (1.3)	.38			
Aneurysm sac growth	13 (20.6)	65 (20.2)	.95	1.85	0.93-3.69	.08
Aneurysm rupture	1 (1.4)	6 (1.7)	.82			
Aneurysm-related mortality	1 (1.4)	3 (0.9)	.69			
Open conversion	0 (0)	7 (2.0)	.22			
Neck-related secondary interventions	7 (9.5)	14 (4.0)	.04	3.19	1.11-9.17	.03
Secondary interventions	13 (17.6)	68 (19.5)	.7	1.20	0.58-2.46	.62
Primary clinical success	56 (75.7)	254 (72.6)	.58	0.92	0.49-1.73	.79
Secondary clinical success	61 (82.4)	289 (82.6)	.98	0.78	0.38-1.61	.51

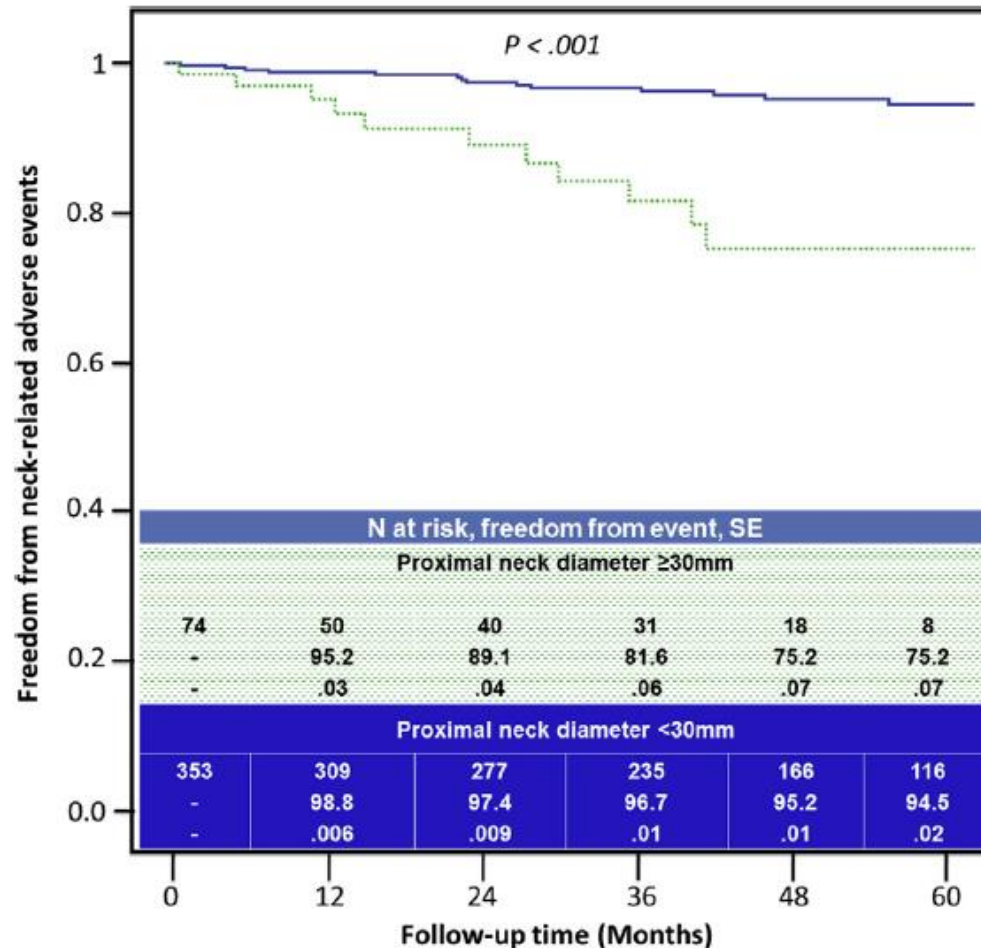
ϕ , Diameter; *CI*, confidence interval; *OR*, odds ratio.

Data are presented as number (%). Multivariable regression analysis was performed correcting for follow-up time, oversizing, neck shape, neck thrombus, age, and sex. Significant *P* values are listed in bold.

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Conical neck is strongly associated with proximal failure in standard endovascular aneurysm repair



Georgios A. Pitoulas, MD, PhD,^a Andrés Reyes Valdivia, MD, FEBVS,^b Suteekhanit Hahtapornsawan, MD,^{c,d} Giovanni Torsello, MD, PhD,^c Apostolos G. Pitoulas, MD,^a Martin Austerlmann, MD,^c Claudio Gandarias, MD, PhD,^b and Konstantinos P. Donas, MD, PhD,^c *Thessaloniki, Greece; Madrid, Spain; Münster, Germany; and Bangkok, Thailand*

(J Vasc Surg 2017;66:1686-95.)

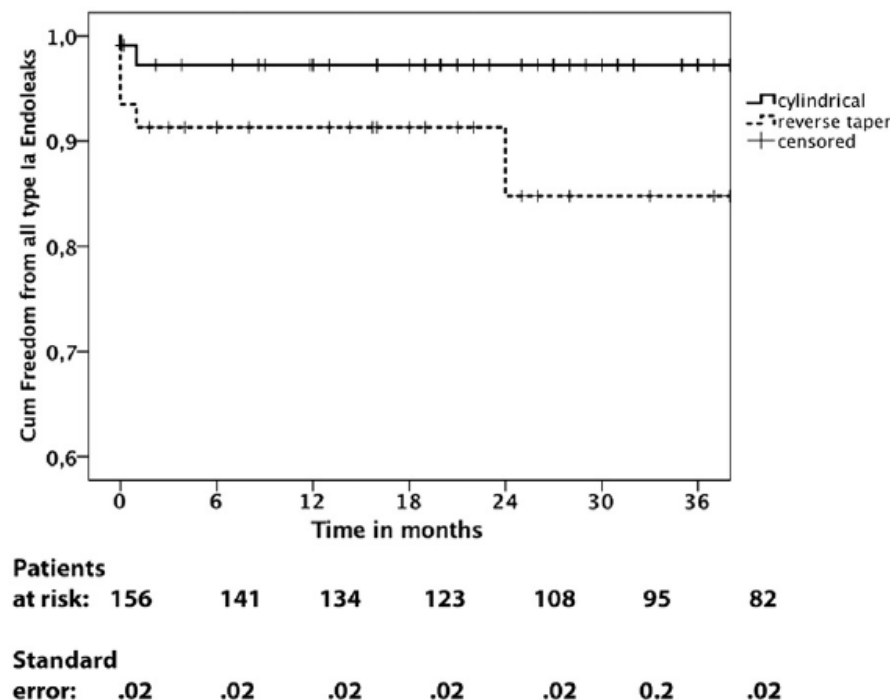


Fig 2. Freedom from all type Ia endoleaks in patients with cylindrical and reverse taper anatomy of the proximal neck.

Conical neck is strongly associated with proximal failure in standard endovascular aneurysm repair



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(J Vasc Surg 2017;66:1686-95.)

Methods: Data of 156 consecutive EVAR patients with short (<15 mm) HN, treated with the Endurant device (Medtronic Cardiovascular, Santa Rosa, Calif) at three European academic vascular centers between 2007 and 2015, were collected and retrospectively analyzed. All patients had at least one of the four well-known nonlength HN criteria (width >32 mm or bulge, angulation >60 degrees, reverse taper anatomy, and circumferential thrombus or calcification >50%) and underwent standard EVAR without additional techniques, such as use of chimney grafts or endoanchors. Primary end

Conclusions: A conical neck in hostile anatomies represents the single strongest factor associated with proximal failure of standard EVAR. This finding should be considered and highlighted apart from the length of the infrarenal neck to

Which hostile neck parameters may impair successful standard EVAR outcome

- Neck diameter >28 mm → **>30 mm**
- Neck length < 10 mm → **yes**
- Suprarenal angulation > 60°
- Infraarenal angulation > 60 - 90° → **only combined with length <10 mm**
- Thrombus > 50% circumference → **no**
- Calcium > 50% circumference → **no**
- Neck conicity → **yes**
- **Curvature**

ANCHOR REGISTRY: REAL-WORLD USE/ OUTCOMES OF THE HELI-FX ENDOANCHOR SYSTEM – 2012- CURRENT

US Principal Investigator	William Jordan, MD Emory University, Atlanta, GA, USA
EU Principal Investigator	Jean Paul de Vries, MD, PhD St. Antonius Hospital, The Netherlands
Registry Design	Prospective, observational, international, multi-center, dual-arm
Treatment Arm	“Primary” – Up to 1000 pts “Revision” – Up to 1000 pts
Duration	5 Years
Follow-up	Per Standard of Care at each center & discretion of Investigator
Current Enrollment	604 patients as of 15 June 2016, 40 US Sites, 17 European Sites



>680 patients enrolled

ANCHOR REGISTRY: 3 years data

Mean follow-up 599 ± 419 days

109 patients available for analysis at 3 years.

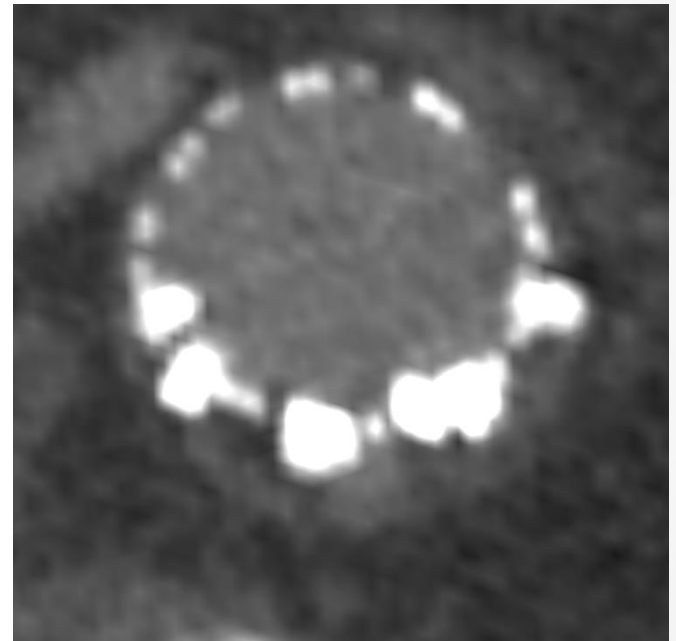
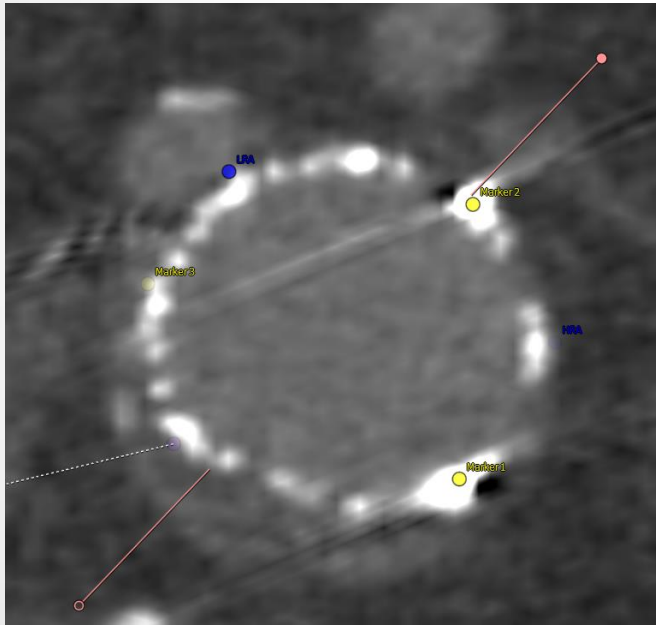
Patient survival 83.4%

Freedom from reintervention 73.7% (type II endoleak, PAD, type IA endoleak)

Freedom from neck-related reintervention 92.9%

Advantages of EndoAnchors?

Infrarenal neck diameter >30 mm.



Not in undersized endograft

Advantage of EndoAnchors?

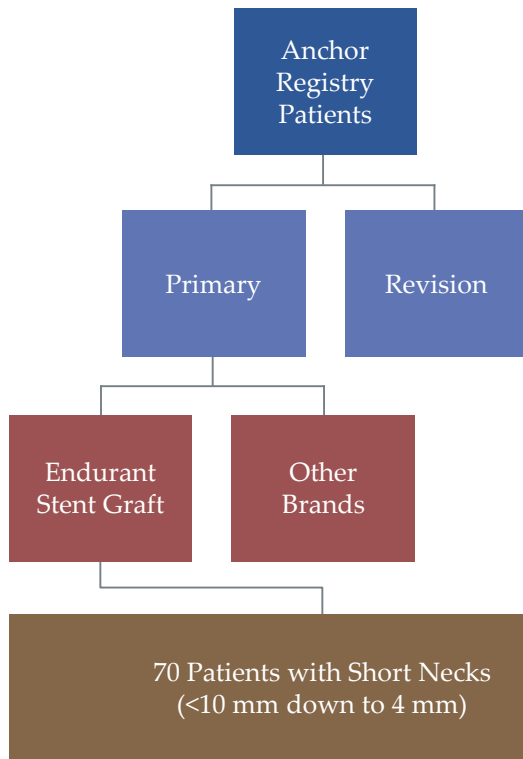
Infrarenal neck length 4-10 mm.

- Endurant endograft with additional EndoAnchors (CE-approved)

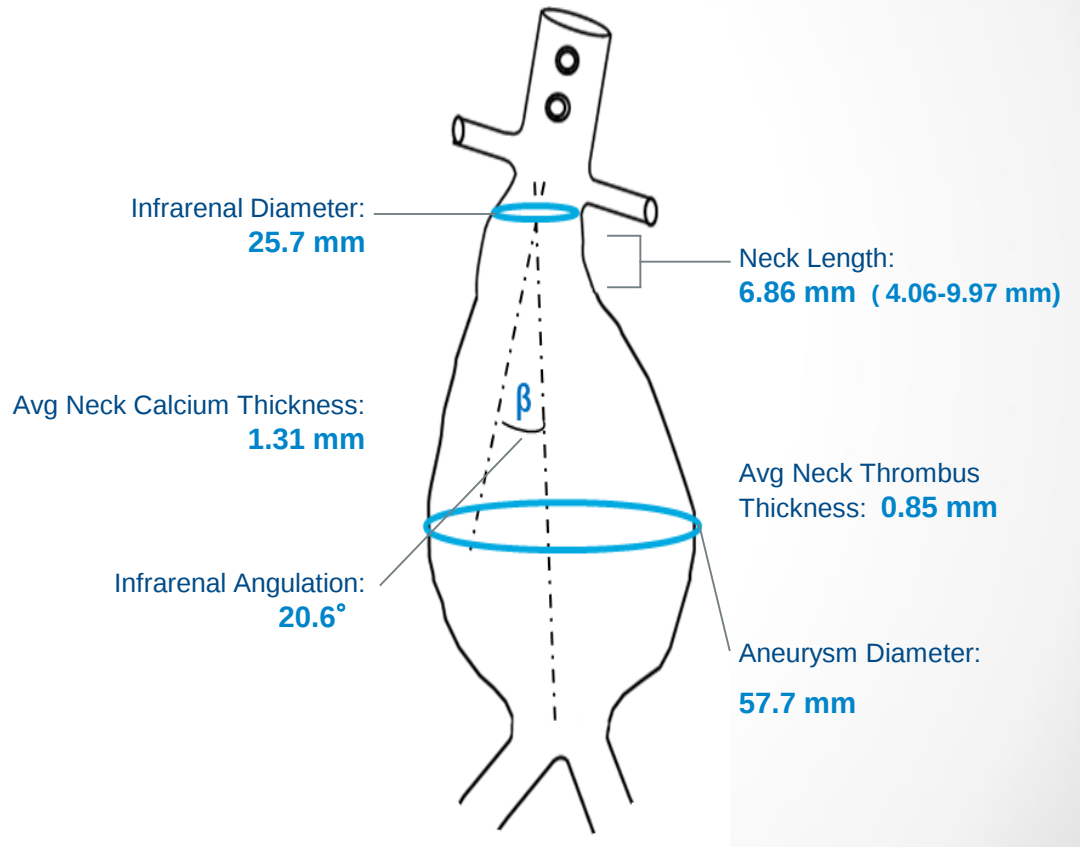
Endurant and EndoAnchors in short necks (4-10 mm).

Clinical Evaluation

ANCHOR Registry Short Neck Cohort

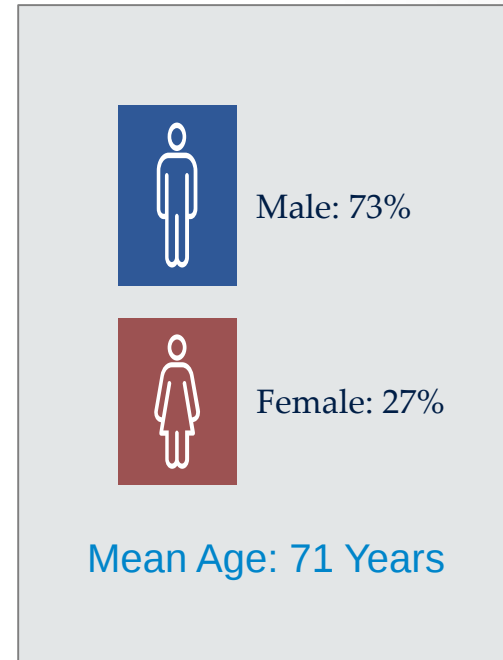
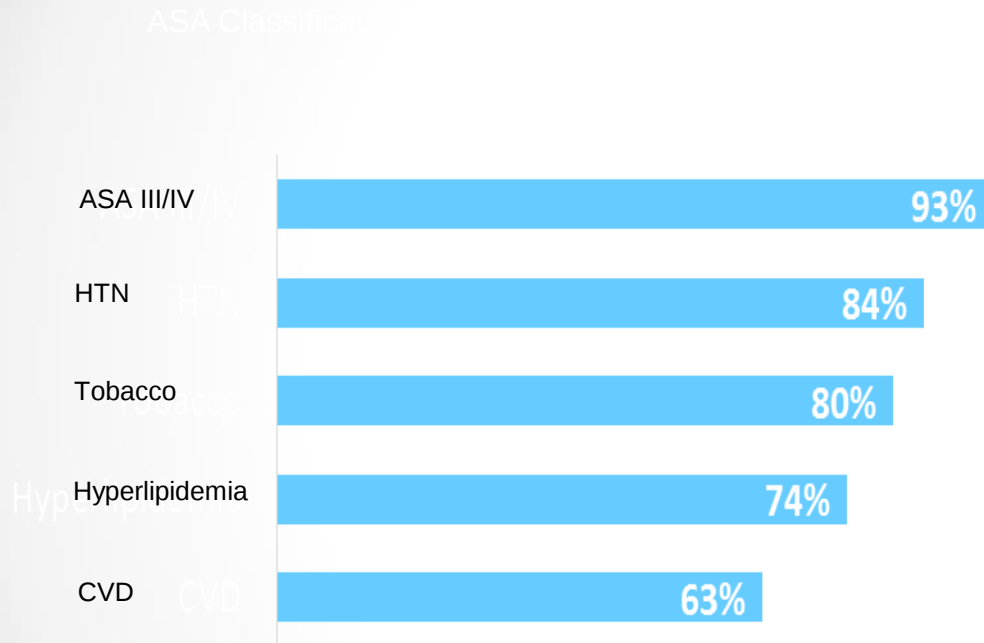


Baseline Anatomical Characteristics* – Core Lab



* Mean Core Lab measurements

Endurant and EndoAnchors in short necks (4-10 mm).



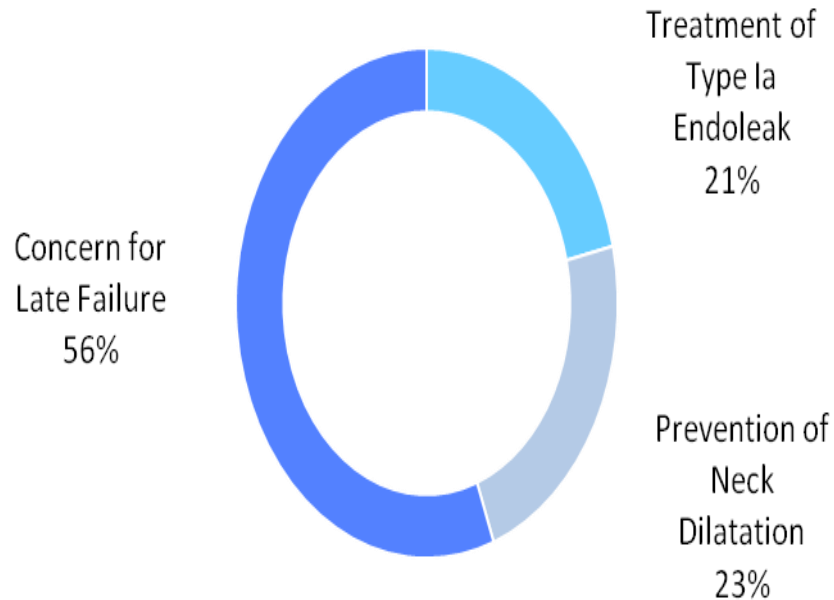
Median Core Lab measurements based on 70 pts with baseline CTs

1. PMA P100021/S063: IFU Clinical Summary
2. CSR

17.1% symptomatic
patients
2.9% ruptured cases

Endurant and EndoAnchors in short necks (4-10 mm).

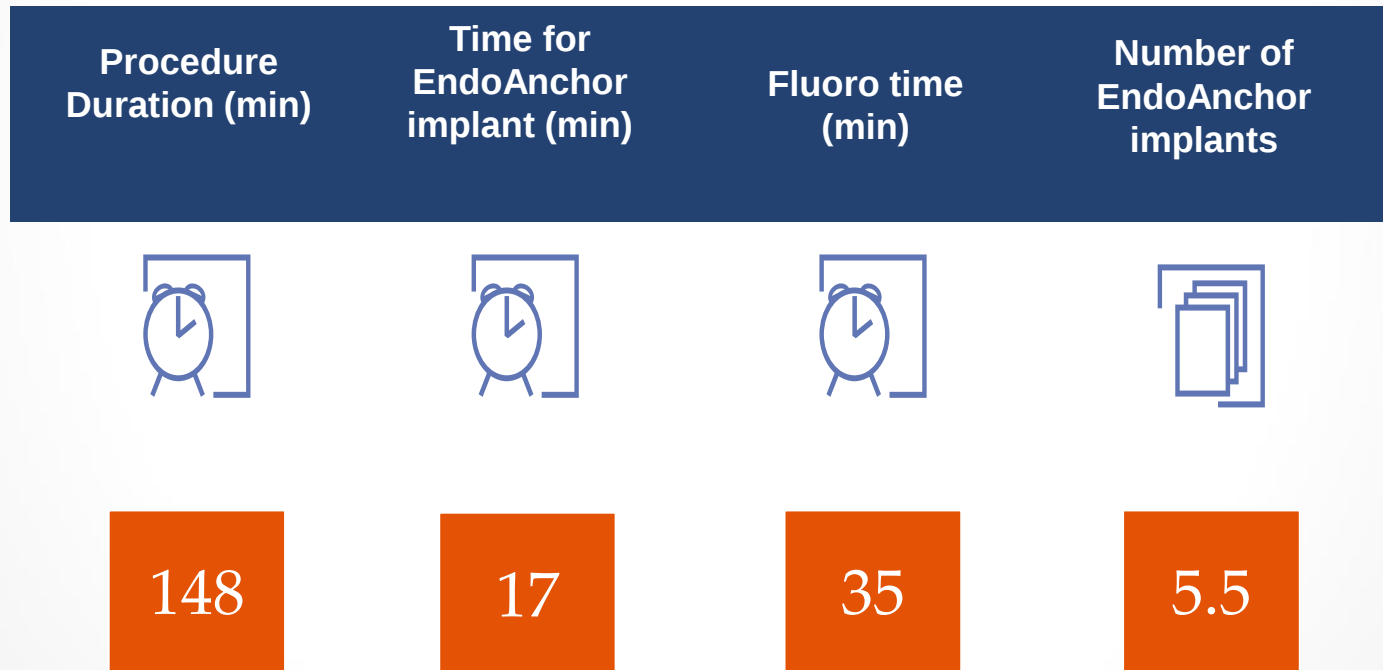
Reasons for EndoAnchor placement (site-reported)



SOURCE: Heli-FX CSR, 90 Day Update

Endurant and EndoAnchors in short necks (4-10 mm).

PROCEDURAL EFFICIENCY*



*Average figures

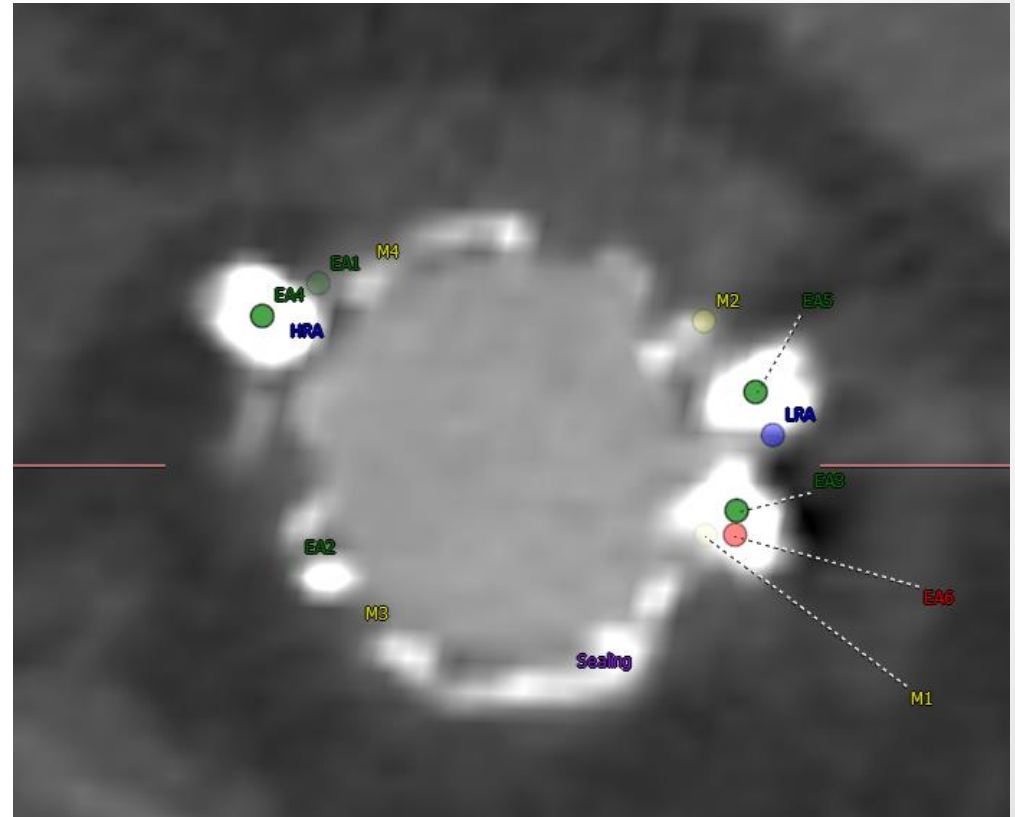
PMA P100021/S063: IFU Clinical Summary

Endurant and EndoAnchors in short necks (4-10 mm).

PROMISING 1-YEAR OUTCOMES	
1.9% (1/53)	Type Ia Endoleak
1.6% (1/64)	Type Ia-Related Secondary Procedure
4.7% (3/64)	Secondary Procedure
0% (0/64)	Conversion to OSR
0% (0/64)	Rupture

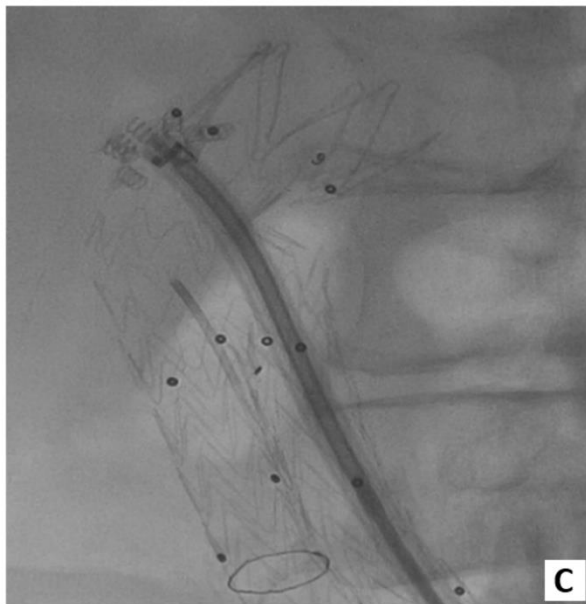
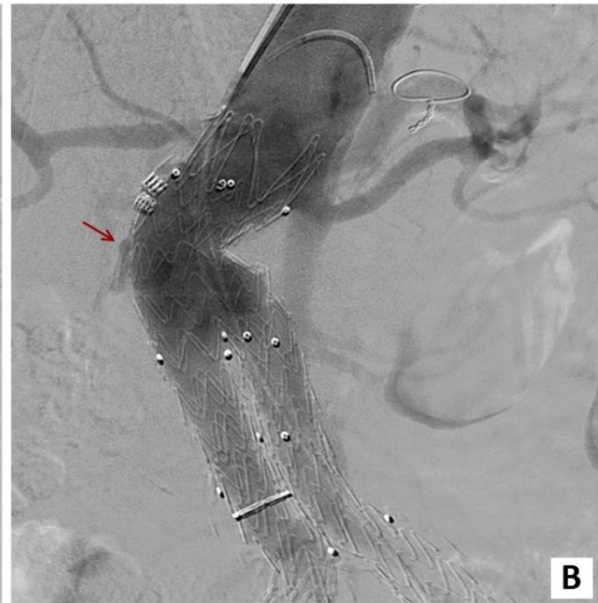
Advantage of EndoAnchors?

Neck conicity



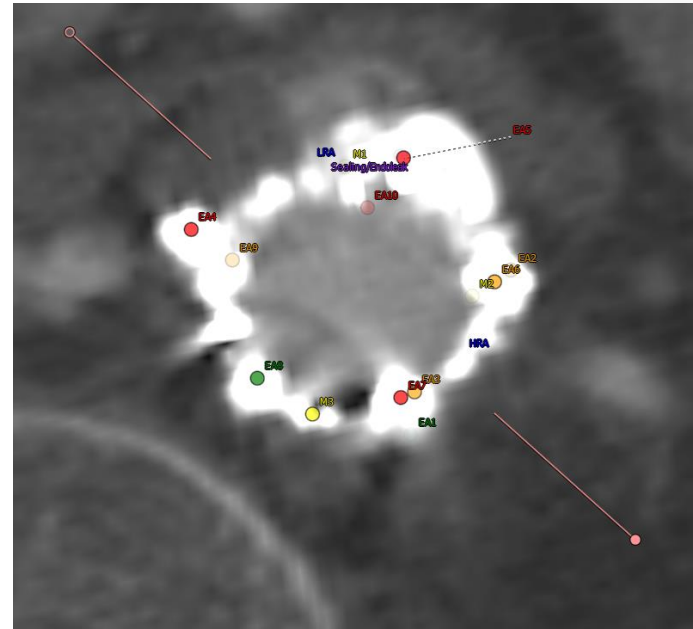
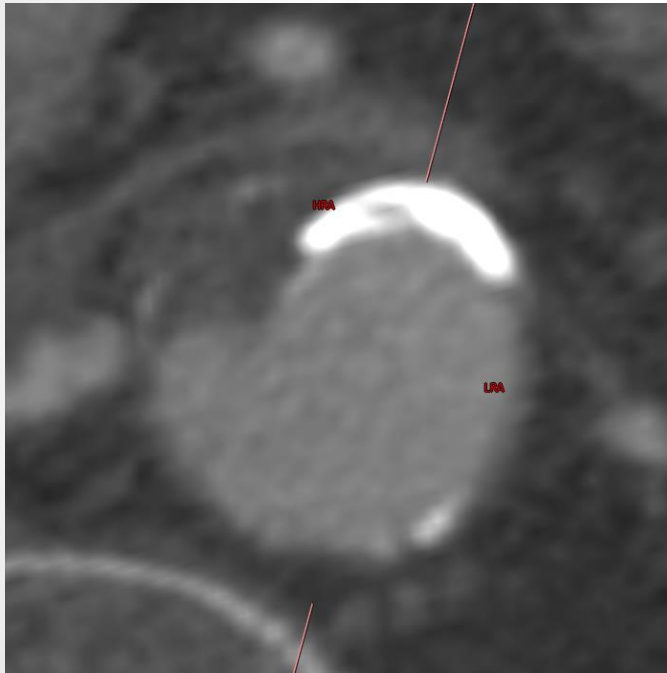
Advantage of EndoAnchors?

Angulation



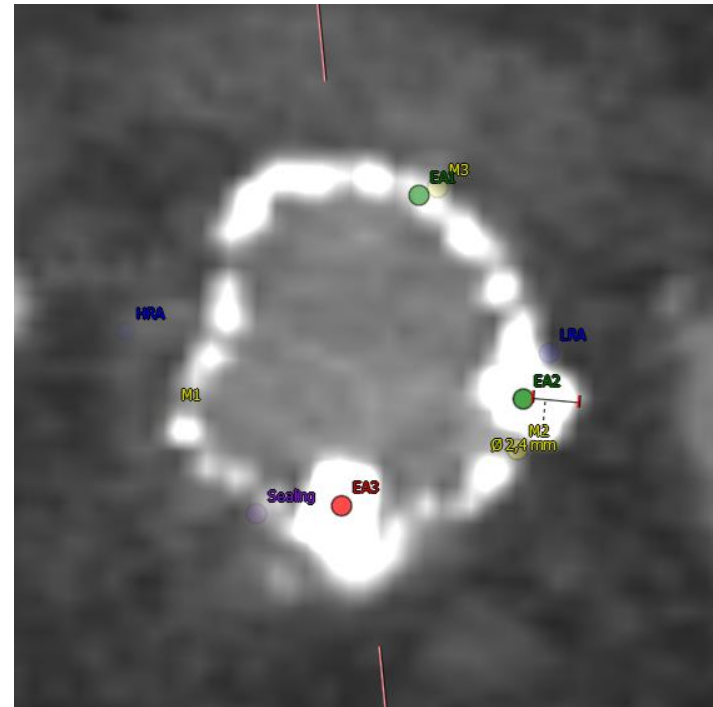
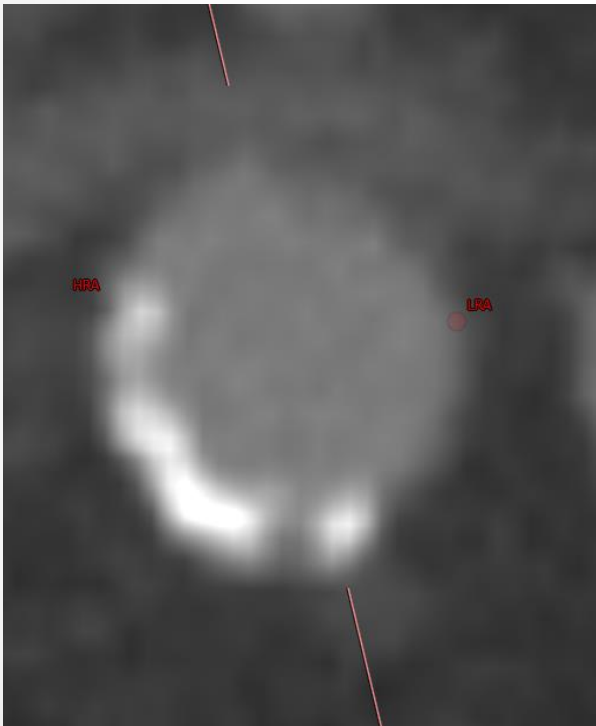
Advantage of EndoAnchors?

Thrombus and calcium



Advantage of EndoAnchors?

Thrombus and calcium



Wich ugly neck parameters impair successful EVAR outcome, can EndoAnchors increase success?

		Ugly necks	EndoAnchors
• Neck diameter >28 mm	→	>30 mm	No
• Neck length < 10 mm	→	yes	yes
• Suprarenal angulation > 60°			
• Infrarenal angulation > 60 - 90°	→	length <10 mm	yes
• Thrombus > 50% circumference	→	no	?
• Calcium > 50% circumference	→	no	?
• Neck conicity	→	yes	yes