



Stony Brook **Medicine**

Role of Endoanchors in Prevention and Management of Endograft Failures

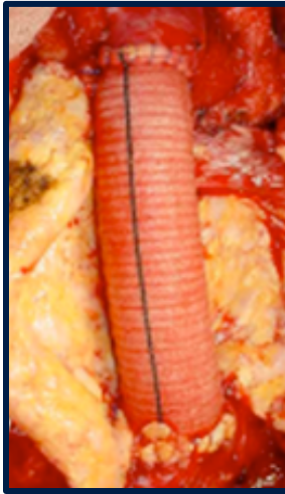
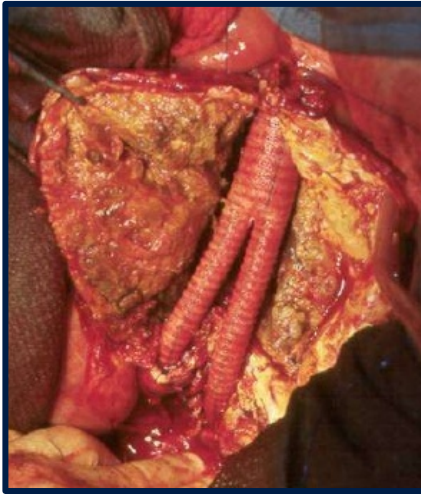
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PROFESSOR AND CHIEF

DIVISION OF VASCULAR SURGERY

INTERIM CHAIRMAN, DEPARTMENT OF S





Open AAA Surgery

- Proven long-term durability
- Competent suture lines; thrombus removal
- High perioperative/physiologic burden
- Extensive LOS and recovery

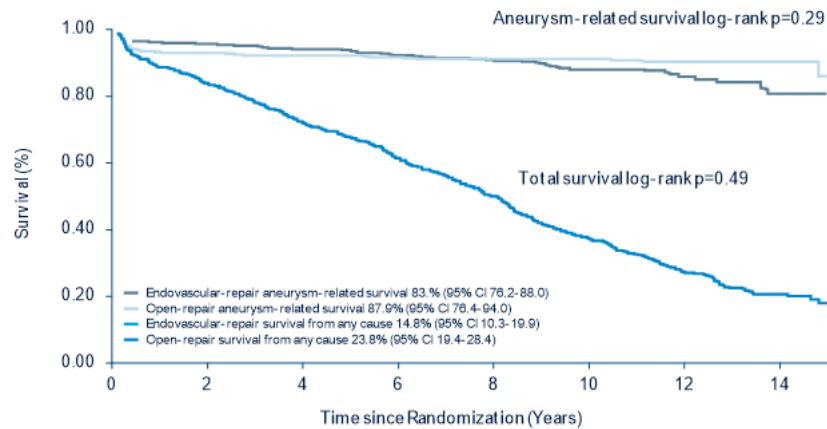
Goal of Contemporary AAA Therapy:

Long-Term Durability of OSR w/ Peri-op Benefi

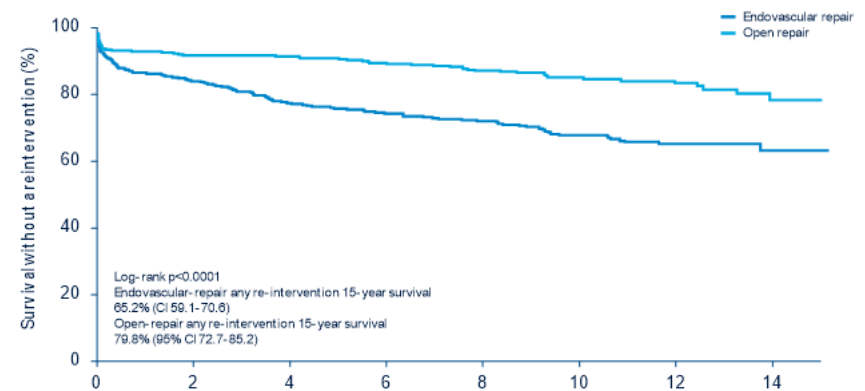




COMPARABLE SURVIVAL, GREATER REINTERVENTIONS VS OPEN REPAIR¹



No. at Risk								
Endovascular Repair	626	543	474	409	339	263	135	41
Open Repair	626	534	464	399	333	257	143	50



No. at Risk								
Endovascular Repair	626	469	381	323	264	192	90	28
Open Repair	626	506	436	357	282	214	112	35

EVAR 1: EVAR Durability at 15 years



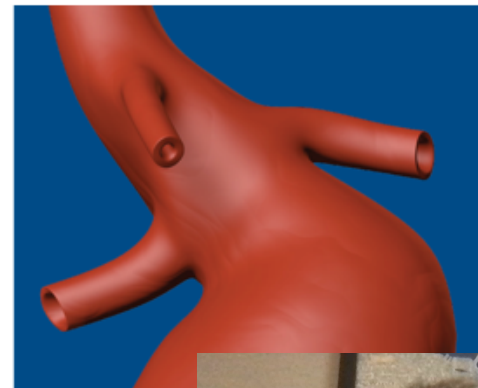
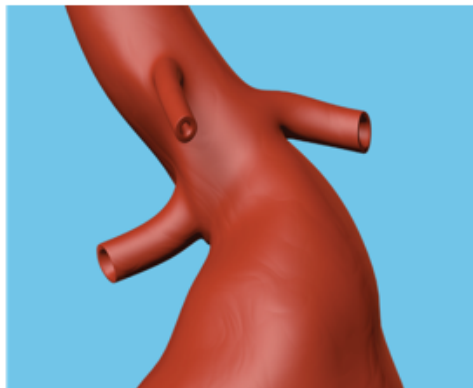
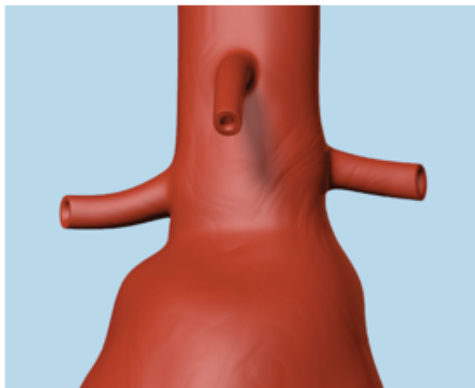


Seal zones are a distributed function:

- Dependent on length, angle, width, conical shape, Ca^{2+} , thrombus, device design, etc.

Adding hostile neck characteristics leads to:

- Higher risk of type Ia's, neck degeneration, secondary procedures, late failure¹



Antoniou, et al., J Vasc Surg 2013;57:527-38.





4.5x

Type I endoleaks 4.5x more likely at 1-year after endograft implantation in hostile proximal aortic neck anatomy (P = .010)

9x

Aneurysm-related mortality risk 9x greater in hostile neck anatomy at 1-year (P= .013)

Meta-Analysis of 7 major studies in EVAR by Antoniou et al¹ compared outcomes in hostile vs. friendly neck anatomies (total patients N = 1559)

Study	Sample Size	Endografts
Torsello et al, 2011	177	Endurant™
AbuRahma et al, 2010	238	AneuRx™, Excluder™*, Zenith™*, Talent™
Hoshina et al, 2010	129	Excluder™*, Zenith™*
Abbruzzese et al, 2008	565	AneuRx™, Excluder™*, Zenith™*
Choke et al, 2006	147	Talent™, Zenith™*, Excluder™*, Zenith™*
Fulton et al, 2006	84	AneuRx™
Fairman et al, 2004	219	Talent™

• ¹ Antoniou GA et al. JVS. 2013;57(2):527-38.





META-ANALYSIS OF 16 MAJOR STUDIES¹ 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
30-Day: All studies					
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
All studies					
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 p

¹ Stather PW, Wild JB, Sayers RD, Bown MJ, Choke E. Endovascular aortic aneurysm repair in patients with hostile neck anatomy. J Endovasc Ther. 2013 Oct;20(5):623-37. doi



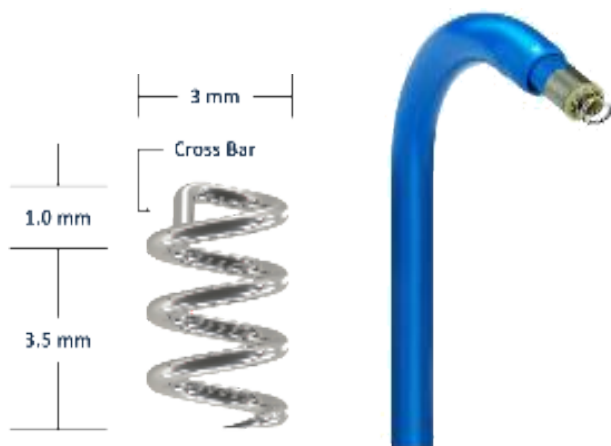


Unlike Open Repair, no endografts offer techniques for radial fixation

- Yet, AAA is a dilating disease

Heli-FX EndoAnchor System – *Facilitates EndoSuture Aneurysm Repair (ESAR)*

- Provides radial fixation^{1,2}
- Increases proximal seal competency³



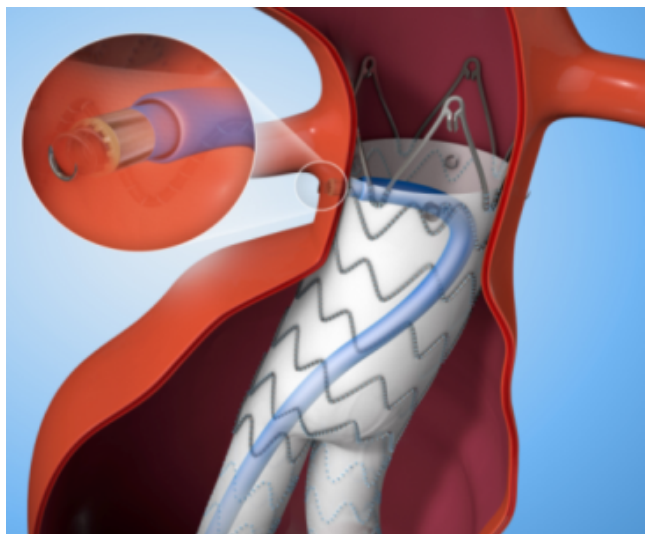
1: Melas et al. J Vasc Surg. 2012; 55(6):1726-33

2: Perdikides et al. J Endo Ther 2012; 19:707-715

3. Arko, et al., J Vasc Surg 2019;70:732-40



Transmural Fixation of EndoAnchors Has Unique Benefits



Establishes the strength of a sutured anastomosis:

EndoAnchor™ implants, which secure the aorta to the graft, have a *protective effect* against neck dilatation¹

Protects seal in a hostile neck: 100% freedom from type Ia endoleak (N=86) at 2-year follow-up after prophylactic implantation (median neck length: 11.5mm)² in ANCHOR

Promotes sac regression: Significantly greater regression with EndoAnchor™ fixation at 1-year post EVAR (29% vs. 20% without EndoAnchor™ fixation, $p=.02$)³



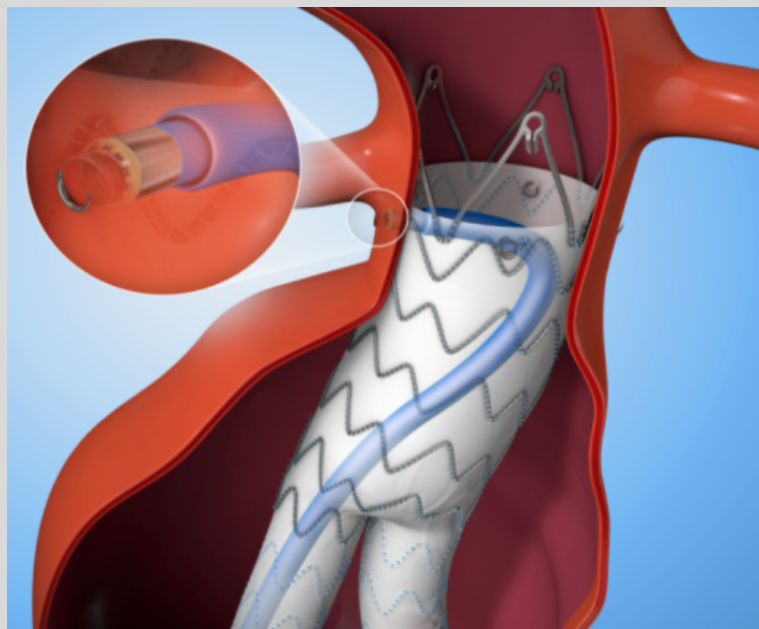
1. Tassiopoulos AK et al. J Vasc Med Biol.

2. Presentation by Dr. William

3. Presentation by Dr. Bart



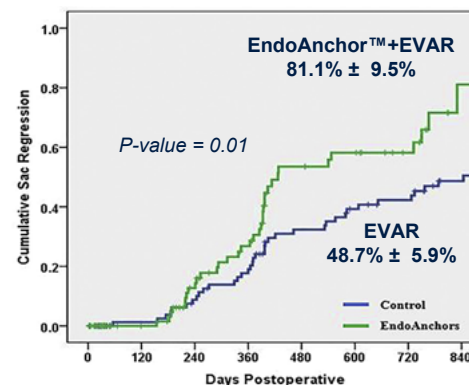
Endoanchors promote increased rate of AAA sac regression



In a propensity-matched study design, significantly greater AAA sac regression at 2 years post-EVAR

Methodology

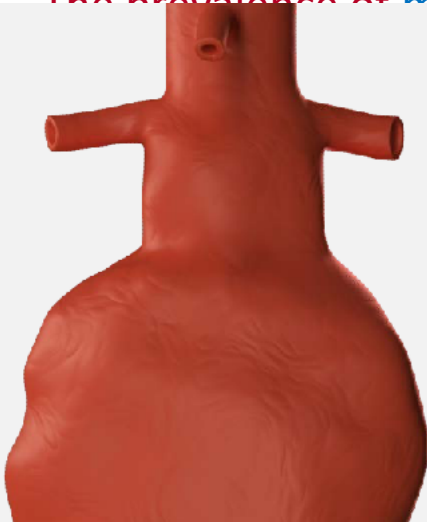
- Pre-EVAR CTs by core lab
- 2 cohorts:
 - 99pts EVAR
 - 99pts EVAR+EndoAnchor
- Propensity matching on 19 variables
- **Mean neck lengths > 20mm**





Metanalysis of 6 observational studies reporting on a total of 6602 patients (1616 with large and 4986 with small diameter neck)

- Patients with large proximal aortic neck were older ($P=0.001$).
- The prevalence of male gender (OR=1.62, 95% CI: 1.24-1.99; $P<0.001$), CAD (OR=1.20, 95%



6.7x more likely to have Type Ia endoleak	10x more likely to have sac expansion	5x more likely to have aneurysm rupture
n = 5922 patients P<0.001 95% CI: 4.39-10.20	n = 688 patients P=0.009 95% CI: 1.80-56.53	n = 1257 patients P=0.01 95% CI: 1.40-18.58

- sac expansion (HR=10.07, 95% CI: 1.80-56.53; $P=0.009$),
- aneurysm rupture (HR 5.10, 95% CI: 1.40-18.58; $P=0.01$), and
- survival (HR=1.55, 95% CI: 1.08-2.24; $P=0.02$).

Kouvelos et





There is no clear threshold definition for wide proximal AAA neck diameter

Emerging trend in literature - wider necks have greater risks

- Type Ia endoleaks
- Secondary procedures
- Rupture
- Mortality

This trend is consistent across varying neck diameters, follow-up periods, and devices

Study characteristics¹

Study	Country	Single/ Multicenter	Study design	Recruitment period	Definition of large diameter
AbuRahma (2018)	USA	Single	Retrospective	2003-2015	>31 mm
Howard (2018) Oliveira (2018)	Australia The Netherlands	Multi Multi	Registry Registry	2011-2017 2009-2011	≥25 mm ≥30 mm
Oliveira (2017)	Portugal	Multi	Retrospective	2008-2012	≥30 mm
Kaladji (2015)	France	Multi	Retrospective	1998-2012	≥30 mm
Jim (2010)	USA	Multi	Registry	2002-2003	≥28 mm (stent graft ≥32 mm) ≥28 mm
McFarland (2019) ²	USA	Single	Retrospective	2000-2016	≥29 mm
Gargiulo (2017) ³	Italy / France	Multi	Retrospective	2009-2012	≥28 mm





NECK DILATATION LARGE DIAMETER NECKS

Data shows neck dilatation is common¹

24.6%

of all EVAR patients had neck dilatation¹

100%

of all wide necks ($\geq 28\text{mm}$) at 24m had neck dilatation²

- Meta analysis*
- 12 articles (1998-2015)
- 8,550 pts

* Data point from subset of full metanalysis

- 3 European centers
- 2009-2012
- 118 pts
- $\geq 24\text{m}$ follow-up

Large diameter necks have worse outcomes³

6x

More likely Type Ia endoleak ($p < 0.001$) in large diameter necks³

>10X

More likely sac expansion ($p = 0.009$) in large diameter necks³

- Large diameter necks have worse outcomes
- Meta analysis; 6 studies; 6,602 pts

- 5,922 pts
- 95% CI

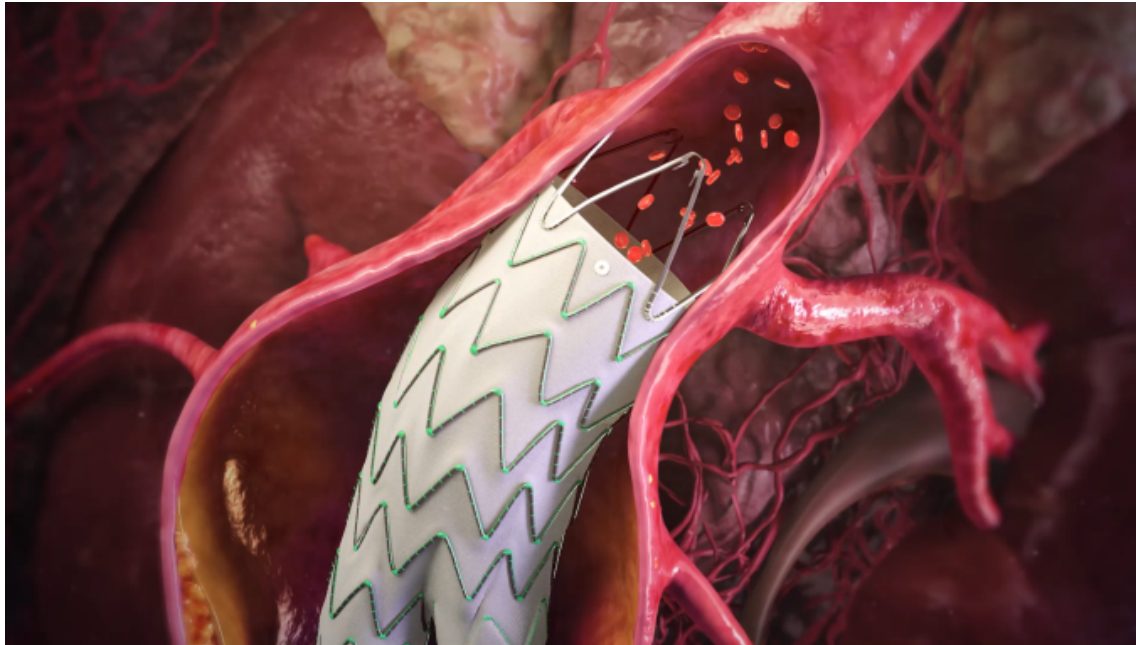
- 688 pts
- 95% CI

¹ Kouvelos. *J Endovasc Ther.* 2017;24(1):59-67

² Gargiulo M, et al. *J Vasc Surg.* 2017;66:1065-1072

³ Kouvelos, et al., *The Journal of Cardiovascular Surgery* 2019 April;60(2):167-174





**NECK
DILATATION**



Intermittent
Loss of Seal

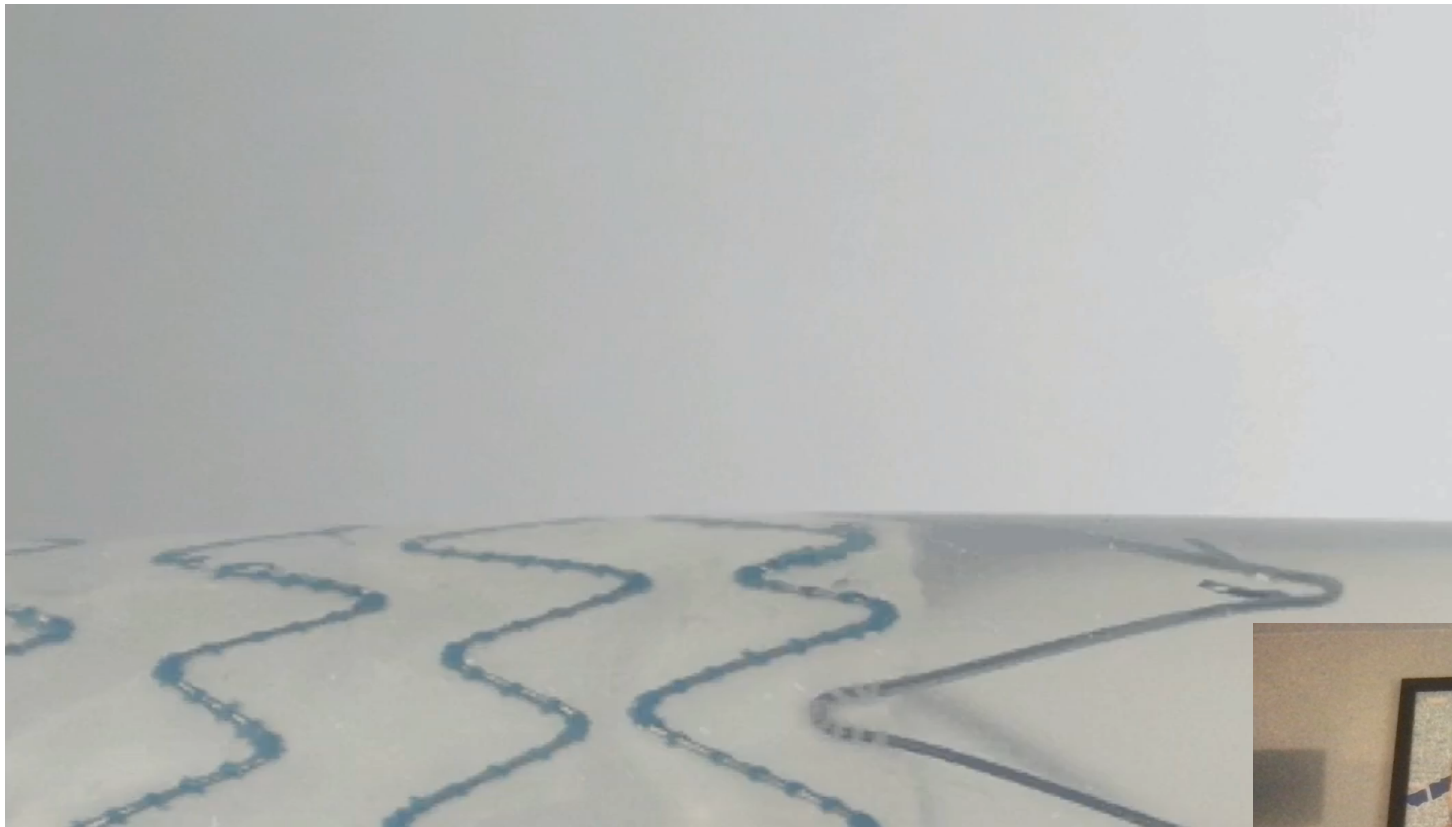


Transient
Type Ia endoleak





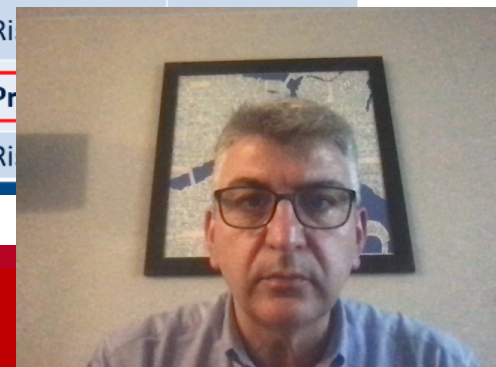
- Mechanism of endoanchor function





Predictors Of Aortic Neck Dilation Between The 1-month Post-operative And 12-month CT

Aortic Level	Predictors of Dilatation at Specified Level	Coefficient*	Effect	P Value
Lowest renal	Endograft type	0.62 (0.12, 1.04)	*	.006
	Aortic aneurysm sac diameter	-0.04 (-0.07, 0.00)	Protective	.020
	Aortic diameter at lowest renal	0.16 (0.08, 0.24)	Risk factor	<.001
	Aortic neck length	-0.02 (-.04, 0.00)	Protective	.021
	Infrarenal Angulation	0.02 (0.00, 0.04)	Risk factor	.016
	Endograft oversizing	5.37 (2.34, 8.39)	Risk factor	.001
5mm distally	Aortic diameter at lowest renal	0.17 (0.07, 0.26)	Risk factor	.001
	Endograft oversizing	6.00 (2.68, 9.31)	Risk factor	.001
10mm distally	Aortic diameter at lowest renal	0.17 (0.04, 0.29)	Risk factor	.003
	Endograft oversizing	4.86 (0.13, 9.58)	Ri	
	Number of EndoAnchors placed	-0.29 (-0.55, -0.04)	Pr	
Suprarenal level	Suprarenal aortic diameter	0.08 (0.01, 0.16)	Ri	

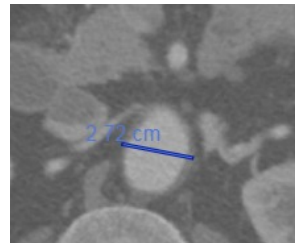




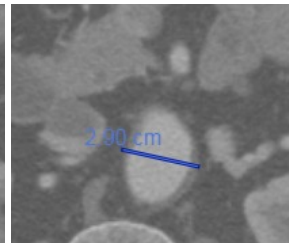
71 year old male with 7.3 cm AAA, short and conical neck and a concomitant malignancy



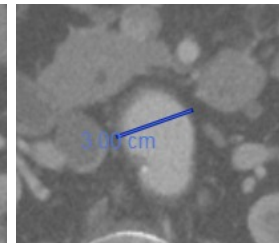
Pre Operative CTA



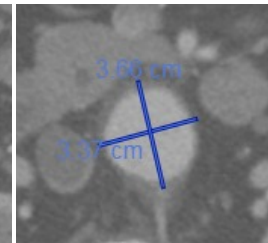
Diameter at lowest renal: **27mm**



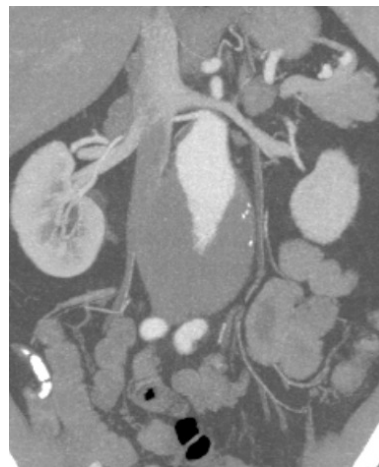
Diameter 3mm below renal: **29mm**



Diameter 9mm below renal: **30mm**



Diameter 15mm below renal: **36mm**



Short Conical Neck

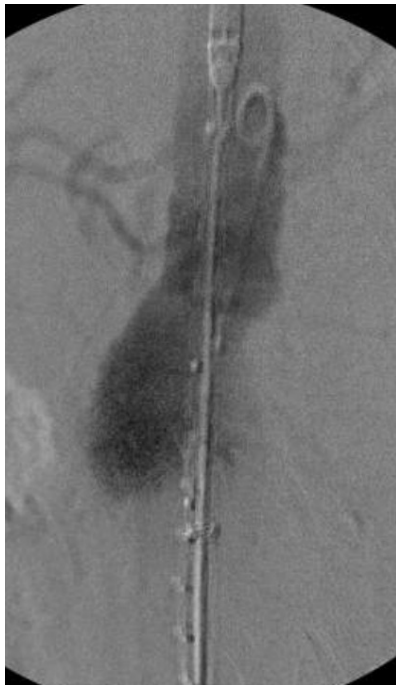


Bilateral Accessory Renals

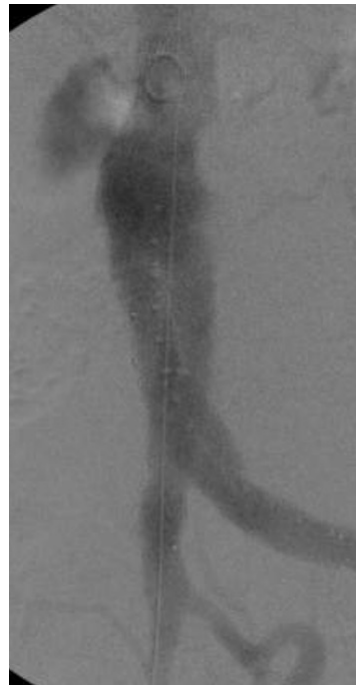




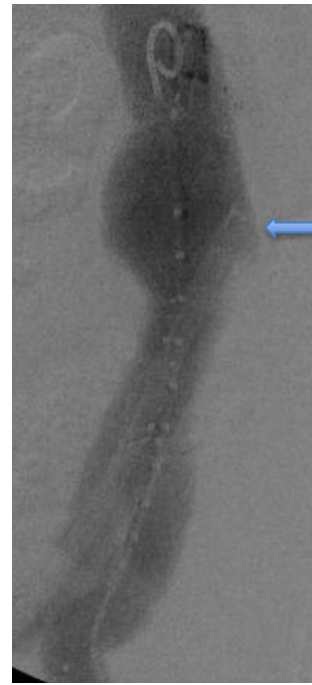
71 year old male with 7.3 cm AAA, short and conical neck and a concomitant malignancy



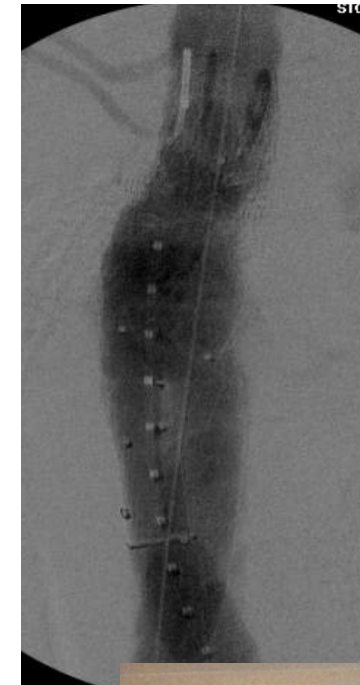
Initial



Post EVAR



Type IA endoleak



Post A

Intraoperative Images

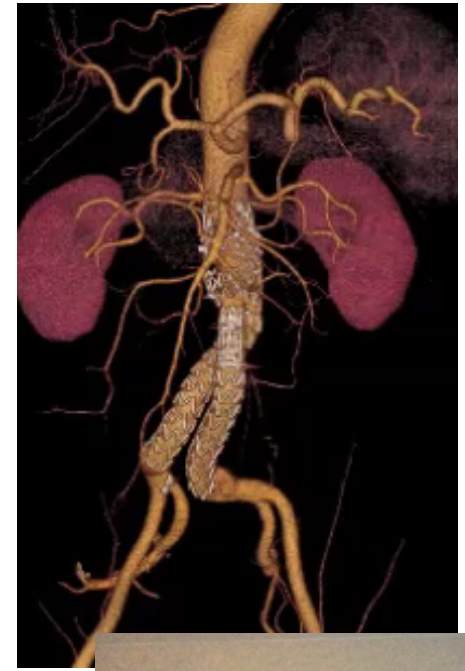
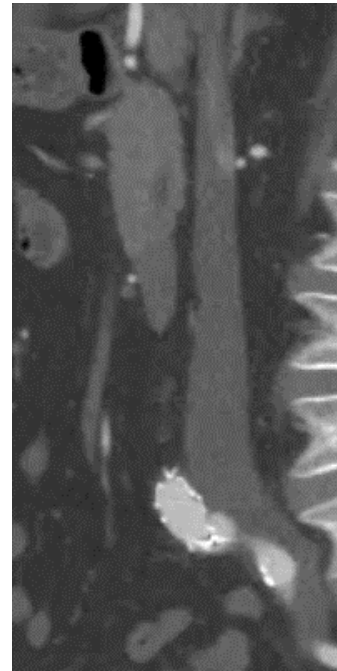




71 year old male with 7.3 cm AAA, short and conical neck and a concomitant malignancy

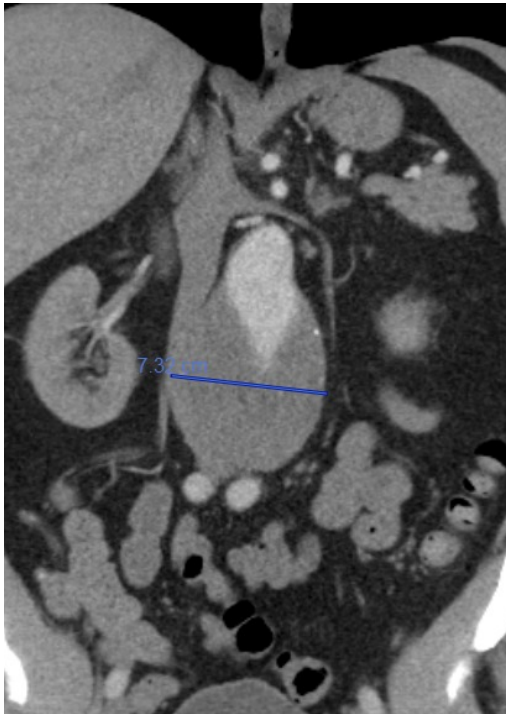


**3-year Post
Operative CTA :
No endoleak**

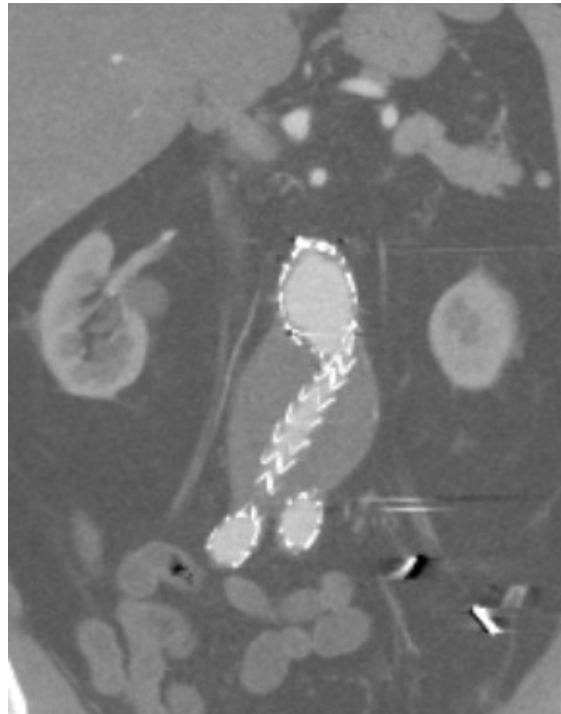




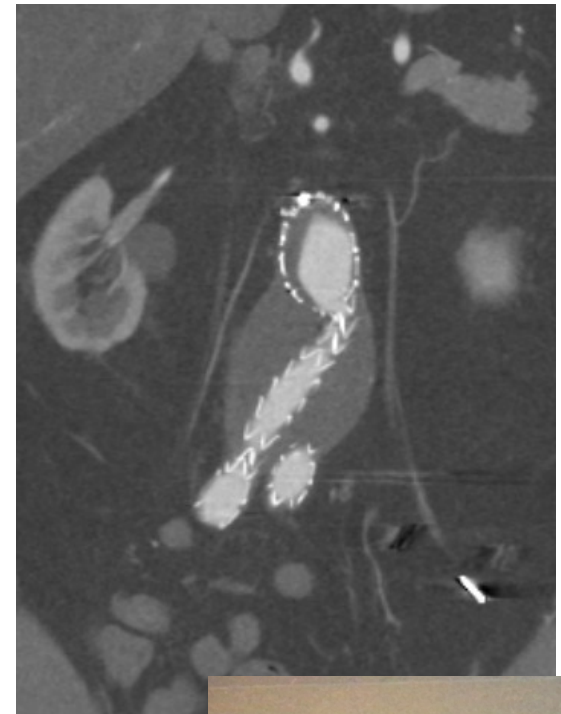
71 year old male with 7.3 cm AAA, short and conical neck and a concomitant malignancy



Pre-Op (73mm)



1-year Post Op (65mm)
Shrinking AAA sac

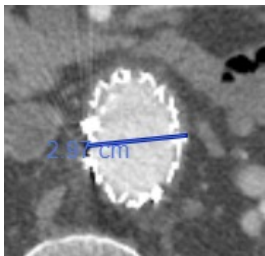
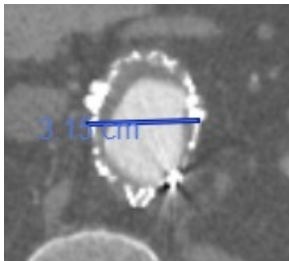
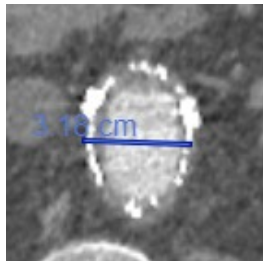

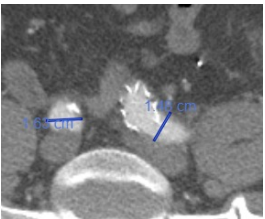
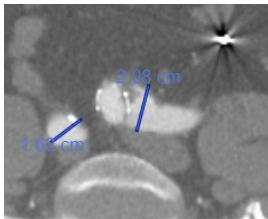
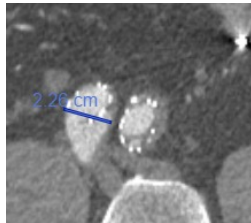
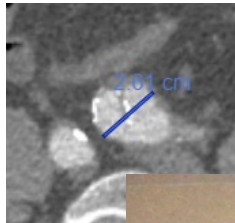


3-year





71 year old male with 7.3 cm AAA, short and conical neck and a concomitant malignancy

1 month	3 years	5 years	
			
29.7mm	31.5mm	31.8mm	
			
Rt Iliac: 15mm Lt Iliac: 14.5mm	Rt Iliac: 16.9mm Lt Iliac: 20.8mm	Rt Iliac: 22.6mm.	Lt Iliac: 2





2-Year Outcomes

Kaplan-Meier Estimates	1-YEAR	2-YEAR
Freedom from All-Cause Mortality	92.8%	86.7%
Freedom from Aneurysm-Related Mortality	94.3%	94.3%
Freedom from 2nd Endo Procedures	95.5%	95.5%
Freedom from AAA Rupture	100%	100%

Aneurysm-Related Mortality:

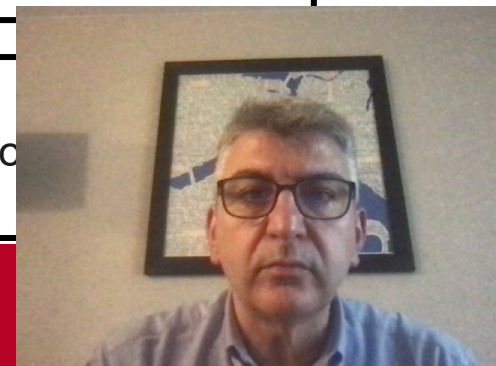
- Day 5: Cardiac arrest
- Day 6: Cardiac arrest, CHF
- Day 9: Cardiac and respiratory arrest
- Day 13: Acute alcoholic hepatitis, acute renal failure, acute pancreatitis

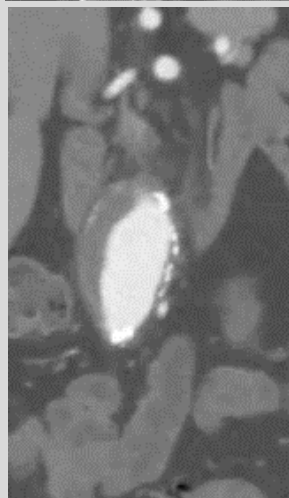
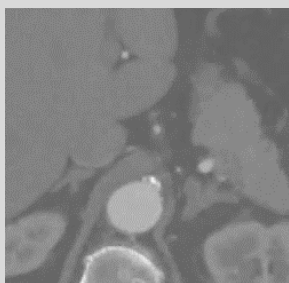
Aneurysm-Related Per Protocol Only

*(any death within 30-days is
considered Aneurysm-Related)*

2nd Endovascular Procedures for Proximal Neck:

- One patient, Day 9, additional graft extension and sac embolization to treat a type Ia endoleak. Resolved.



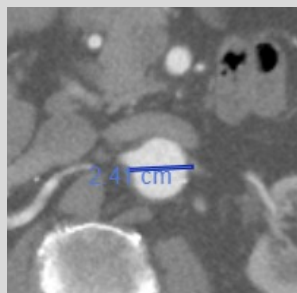


Anatomic Challenges

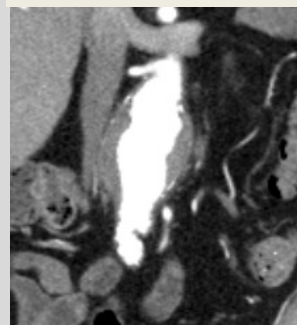
- Short neck: 7mm
- Accessory right renal
- Lateral angulation : 54°

Plan

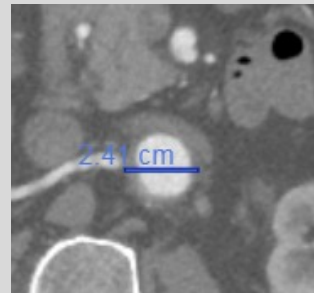
EVAR with coil embolization of the accessory right renal artery and endoanchors



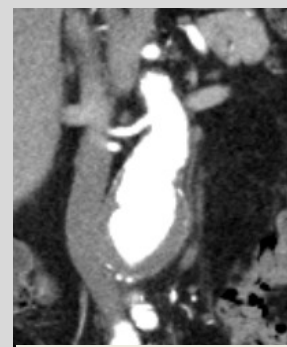
Rt renal artery
Aortic Diameter
24mm



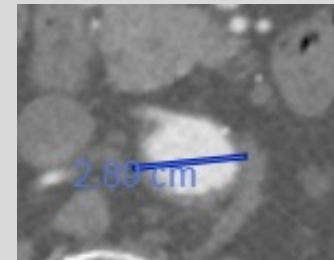
Accessory Rt renal
3.5mm
Proximal end of AAA



5mm below Rt renal
Aortic Diameter 24mm

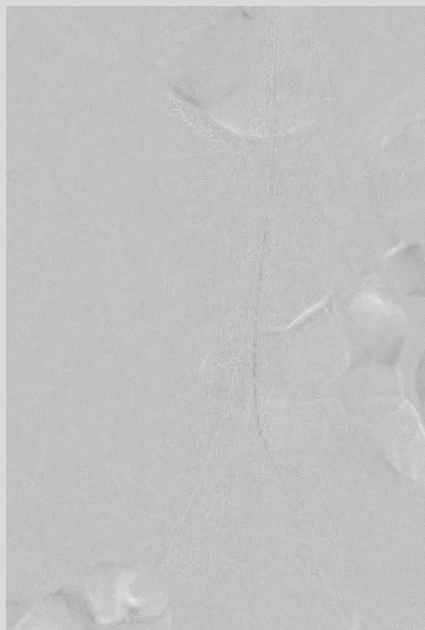


Main Rt renal
4.0 mm

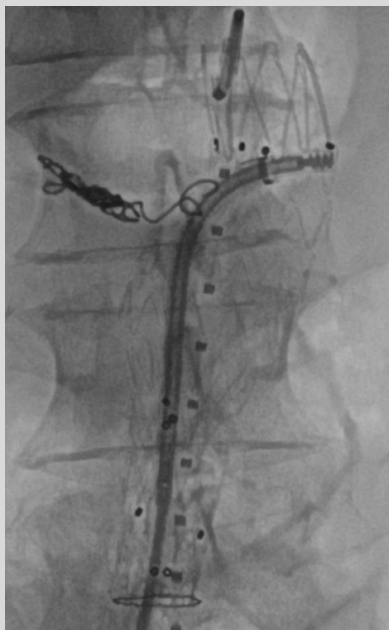


10mm below Rt renal
Aortic diameter 29mm
Accessory Lt renal



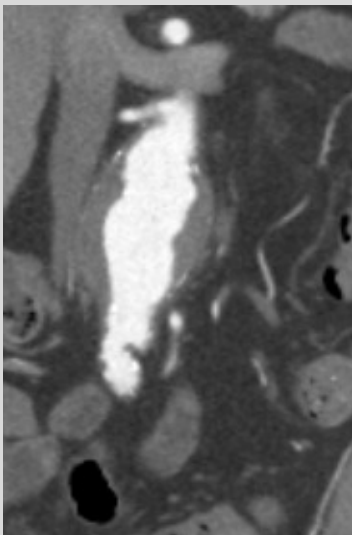


Post endograft deployment
(No endoleak)

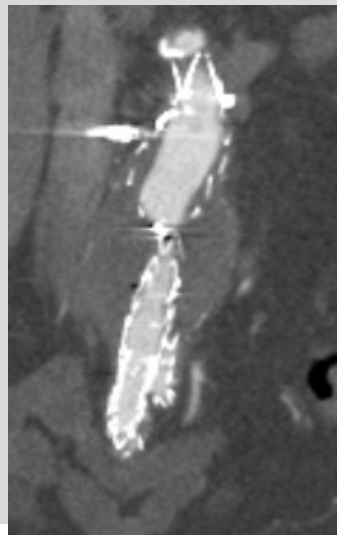


Proximal seal zone reinforced with 8 endoanchors
for short proximal neck

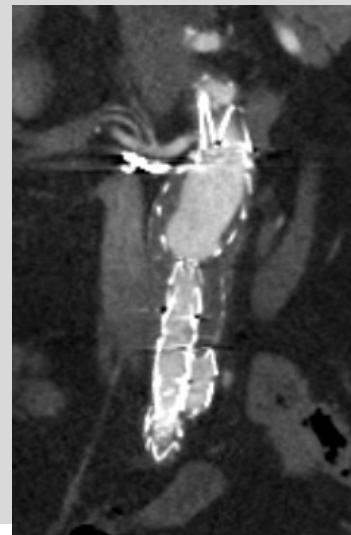




Pre-Op

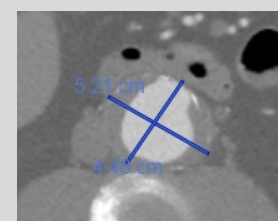


1-month post Op

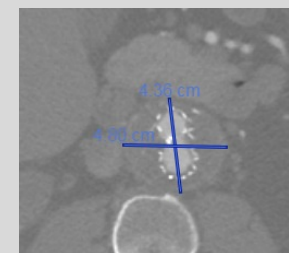
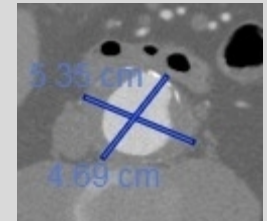


1-year post Op

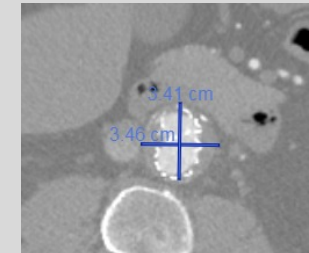
Aortic Sac regression 1-year post EVAR



Pre-Op CTA AAA max diameter 57mm



1-month Post-Op
Max diameter 57mm



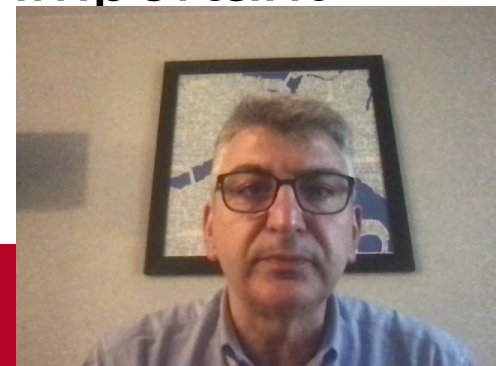
1-year Post-Op
Max diameter 57mm

AAA max d





- Hostile necks associated with worse outcomes after EVAR
- Higher need for expanding or enhancing proximal seal zone to decrease risk of Type 1 endoleaks
- Procedures should be tailored to individual patient characteristics and physician expertise
- Close long-term follow up particularly important



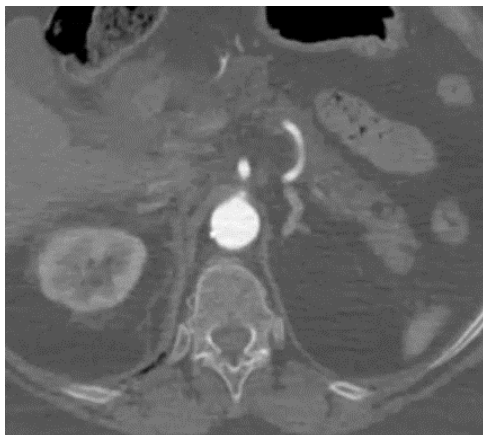


- Endoanchors in treatment of Intraoperative Type Ia endoleaks?

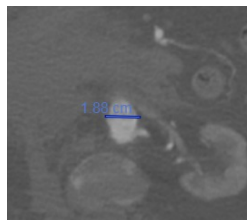




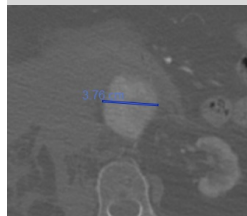
72 year old female with ruptured AAA and hostile neck anatomy



Pre-op CTA



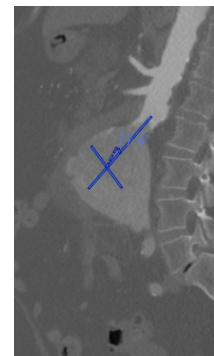
Aorta at lowest renal:
19mm



Aorta 15mm below
lowest renal: 38mm



Aortic neck length: 9 mm

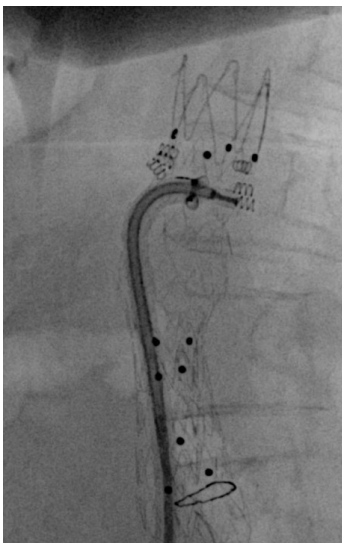


Neck: Severe
anterior angulation
77° and posterior
bulge





72 year old female with ruptured AAA and hostile neck anatomy: Intraoperative Angio



Proximal Seal zone reinforcement with 8 HeliFx endoanchors



Final Angio: No endoleak

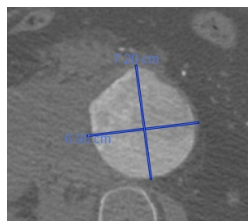




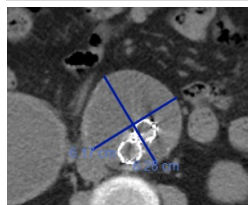
72 year old female with ruptured AAA and hostile neck anatomy
Postoperative CT scan 4 months after EVAR



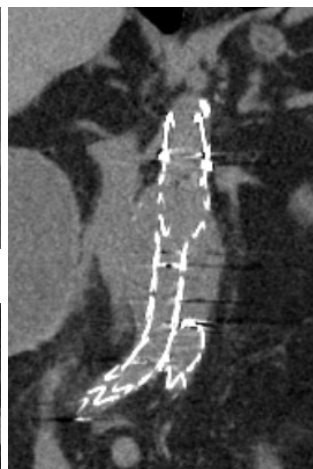
Non-contrast CT due to renal insufficiency



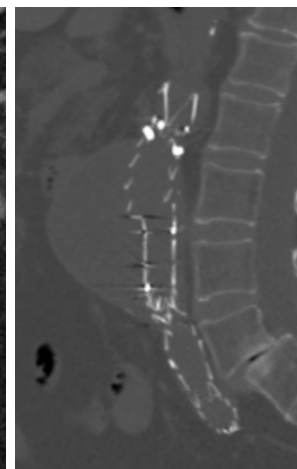
Pre-op CTA
Max diameter 70mm



Max diameter 62mm
4 months post-op



Decreasing aortic sac size 4 months post EVAR

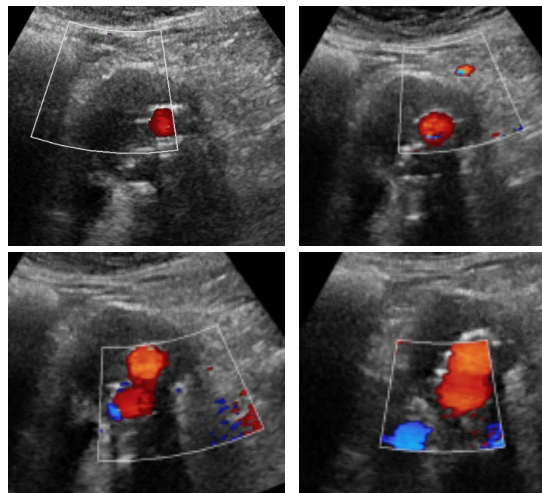




72 year old female with ruptured AAA and hostile neck anatomy



Decreasing aortic sac diameter on
duplex US 7 months post EVAR
Max diameter 46mm

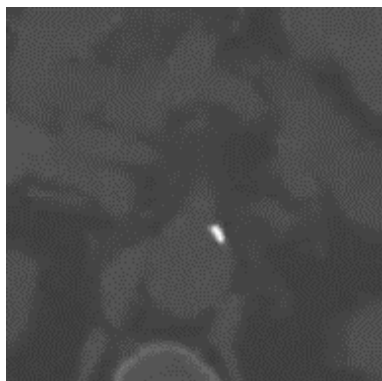


No endoleak 7 months post EVAR



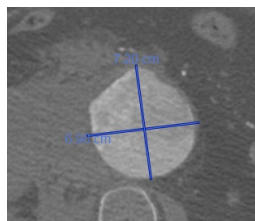


72 year old female with ruptured AAA and hostile neck anatomy
Postoperative CT scan 12 months after EVAR

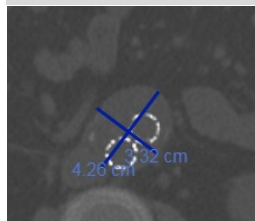


Non-contrast CT due to renal insufficiency

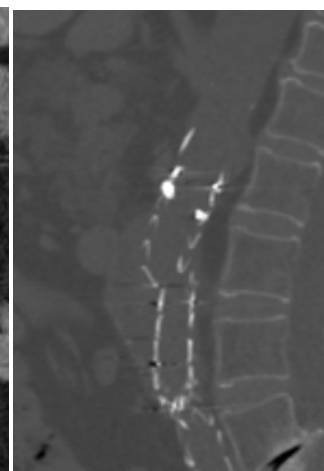
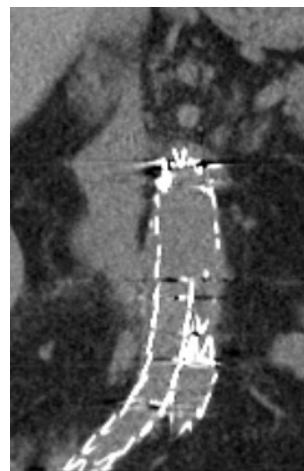
Further decrease in sac diameter at 12 months



Pre-op CTA
Max diameter 70mm



Max diameter 42mm
12 months post-op



Decreasing aortic sac size 12 months post EVAR





CASE PRESENTATION

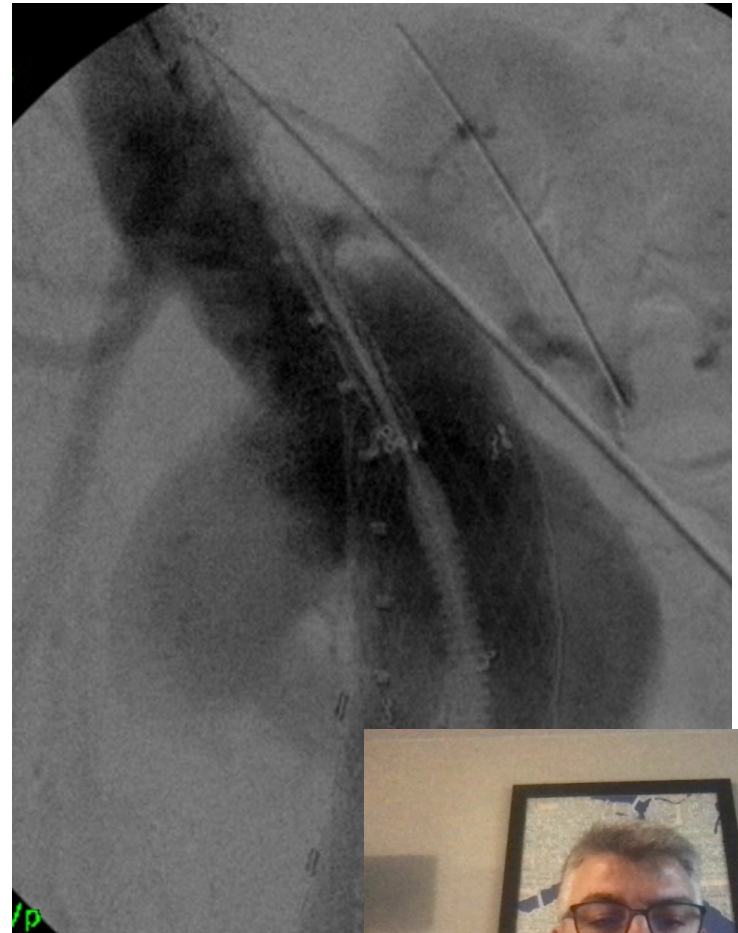
83 year old female 12 years after EVAR with AneuRx presented with abdominal pain and a pulsatile aneurysm





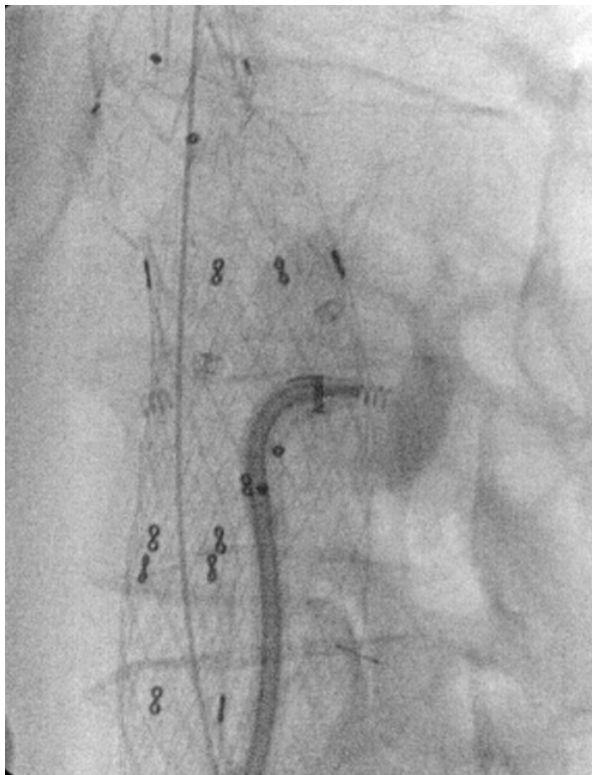
CASE PRESENTATION

83 year old female 12 years after EVAR with AneuRx presented with abdominal pain and a pulsatile aneurysm



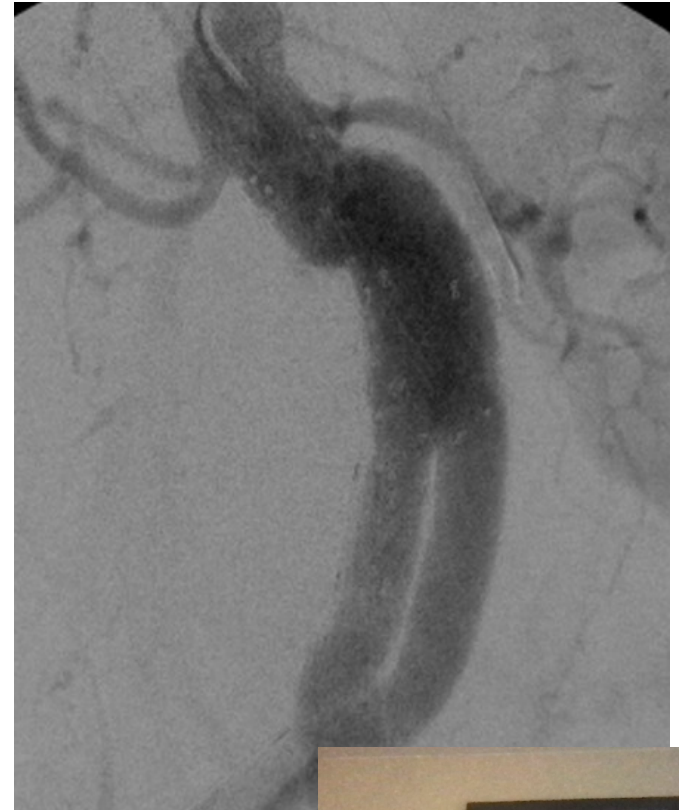


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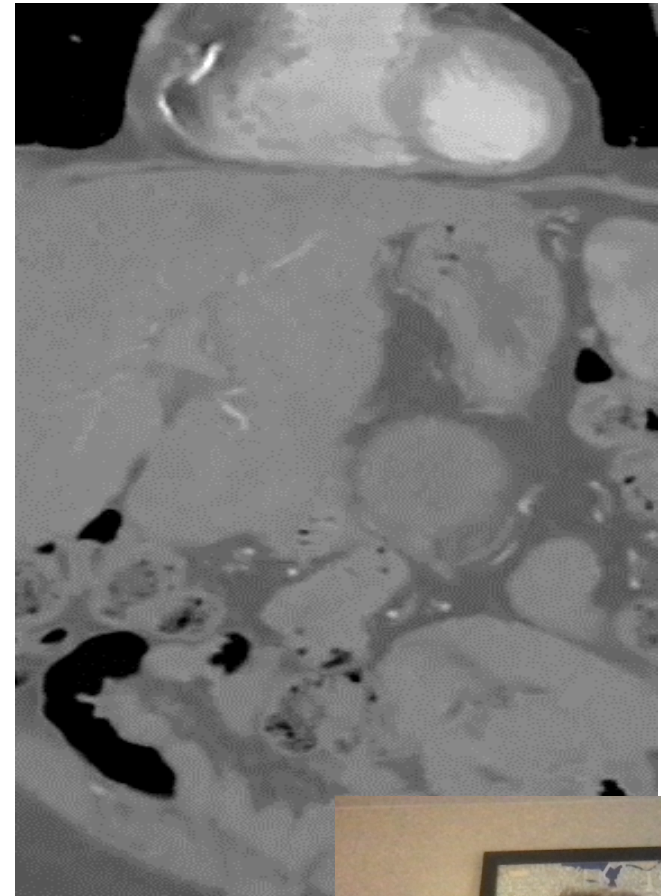


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Repair of Remote Type IA endoleak
1-month post repair





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THANK YOU

