Introduction of Heli-FX EndoAnchor

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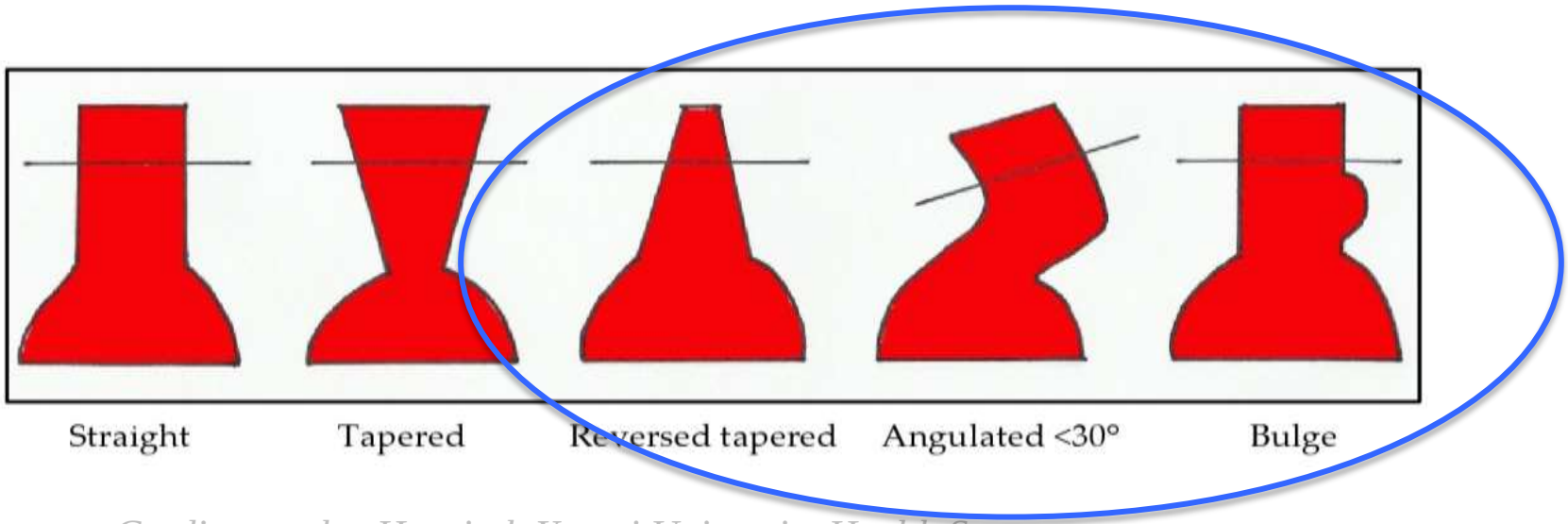
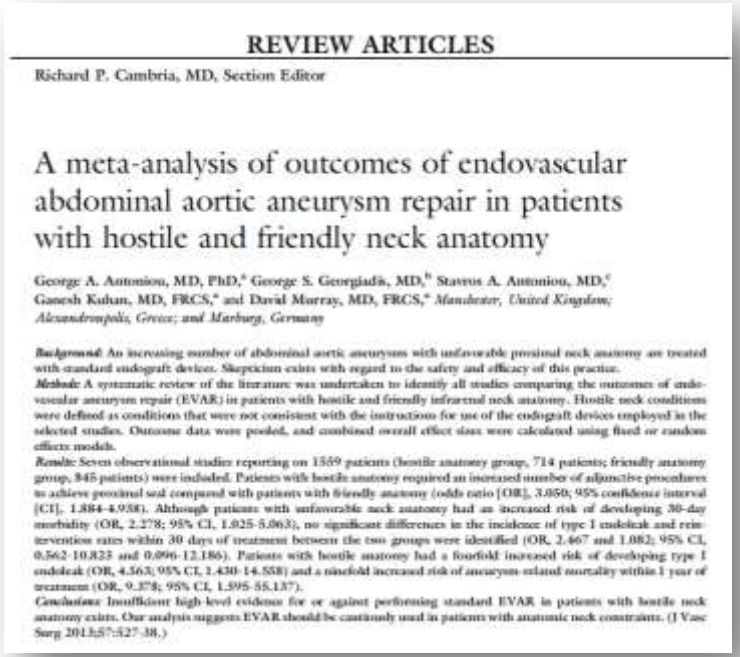
Hostile Aortic Neck

- Aortic neck length <15 mm
- Neck diameter > 28 mm
- Angulation >60°
- Thrombus
- Calcification



Hostile Neck: Increased Risk for Adverse Events after EVAR

Meta-analysis of 7 observational studies
N = 1559



REVIEW ARTICLES

Richard P. Cambria, MD, Section Editor

A meta-analysis of outcomes of endovascular abdominal aortic aneurysm repair in patients with hostile and friendly neck anatomy

George A. Antoniou, MD, PhD,[a] George S. Georgiadis, MD,[b] Stavros A. Antoniou, MD,[c] Ganesh Kuhan, MD, FRCS,[a] and David Murray, MD, FRCS,[a] *Manchester, United Kingdom; Alexandroupolis, Greece; and Marburg, Germany*

Background: An increasing number of abdominal aortic aneurysms with unfavorable proximal neck anatomy are treated with standard endograft devices. Skepticism exists with regard to the safety and efficacy of this practice.

Methods: A systematic review of the literature was undertaken to identify all studies comparing the outcomes of endovascular aneurysm repair (EVAR) in patients with hostile and friendly infrarenal neck anatomy. Hostile neck conditions were defined as conditions that were not consistent with the instructions for use of the endograft devices employed in the selected studies. Outcome data were pooled, and combined overall effect sizes were calculated using fixed or random effects models.

Results: Seven observational studies reporting on 1559 patients (hostile anatomy group, 714 patients; friendly anatomy group, 845 patients) were included. Patients with hostile anatomy required an increased number of adjunctive procedures to achieve proximal seal compared with patients with friendly anatomy (odds ratio [OR], 3.050; 95% confidence interval [CI], 1.884-4.938). Although patients with unfavorable neck anatomy had an increased risk of developing 30-day morbidity (OR, 2.278; 95% CI, 1.025-5.063), no significant differences in the incidence of type I endoleak and reintervention rates within 30 days of treatment between the two groups were identified (OR, 2.467 and 1.082; 95% CI, 0.562-10.823 and 0.096-12.186). Patients with hostile anatomy had a fourfold increased risk of developing type I endoleak (OR, 4.563; 95% CI, 1.430-14.558) and a ninefold increased risk of aneurysm-related mortality within 1 year of treatment (OR, 9.378; 95% CI, 1.595-55.137).

Conclusions: Insufficient high-level evidence for or against performing standard EVAR in patients with hostile neck anatomy exists. Our analysis suggests EVAR should be cautiously used in patients with anatomic neck constraints. (J Vasc Surg 2013;57:527-38.)

Outcome measure	*Meta-analysis model*	*OR (95% CI)*	P
Adjunctive procedures	Fixed effects	3.050 (1.884-4.938)	<.001
Technical success	Fixed effects	0.139 (0.015-1.275)	.081
30-day mortality	Fixed effects	1.022 (0.419-2.493)	.962
30-day morbidity	Fixed effects	2.278 (1.025-5.063)	.043
Reintervention within 30 days	Fixed effects	1.082 (0.096-12.186)	.949
Type I endoleak within 30 days	Fixed effects	2.467 (0.562-10.823)	.232
Type I endoleak at 1 year	Fixed effects	4.563 (1.430-14.558)	.010
Reinterventions at 1 year	Fixed effects	0.990 (0.547-1.792)	.974
Aneurysm-related mortality at 1 year	Fixed effects	9.378 (1.595-55.137)	.013

4 fold increase Type I endoleak at 1 year
9 fold increase aneurysm-related mortality at 1 year

J Vasc Surg 2013;57:527

Hostile Proximal Necks Further Challenge EVAR

Meta-analysis of 16 major studies confirms **higher risks in AAA with hostile necks**

Total sample size: N=11,959 patients

Outcome	N	Hostile Neck	Favorable Neck	Odds Ratio (95% CI)	p
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
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

Stather et al. JEVT. 2013;20:623–637

Multiple Hostile Neck Parameters Worsens Outcomes

Neck hostility	Intra-op adjunctive procedures	Intra-op endoleaks	All cause mortality
On label	9.9%	0.5%	1.1%
2 hostile neck parameters	26.7%	6.7%	13.3%
>2 hostile neck parameters	50%	16.7%	16.7%

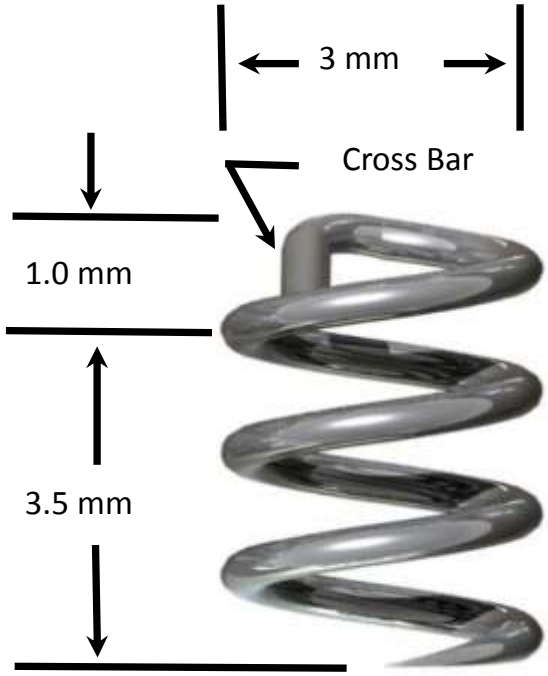
Greater than 1 hostile neck parameter *significantly* increases mortality, major adverse e vents, intra-op endoleaks and adjunctive procedures

Speziale F, Ann Vasc Surg 2014;06:57.

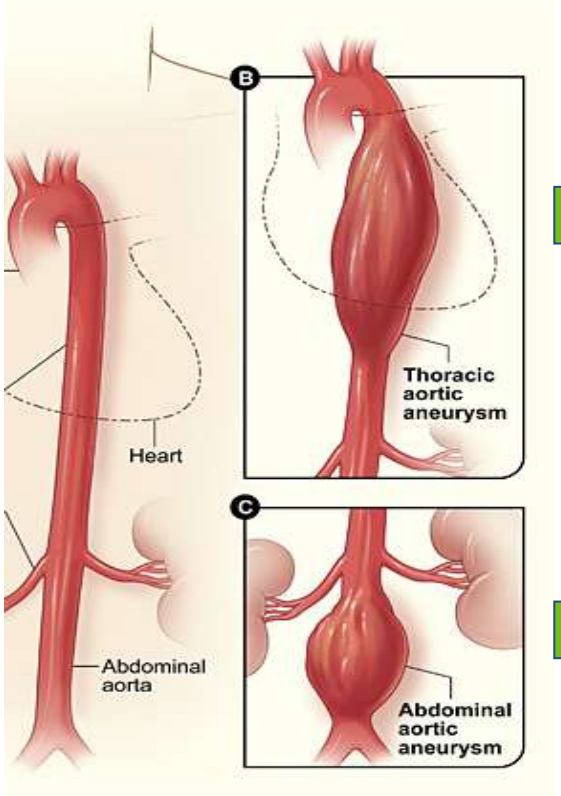
Management of Type I Endoleak

- Ballooning *(for immediate types)*
- Stenting (Bare metal stent)
- Aortic cuff with or without chimney graft
- Embolization using coils/glue
- Surgical conversion
- **EndoAnchor (Aptus/Medtronic)**

Heli-FX System: Applier + Guide + 10 EndoAnchors



Aptus Heli-FX



Images courtesy of National Institute

Aptus® Heli-FX® Thoracic EndoAnchor® System

18F OD
90cm working length

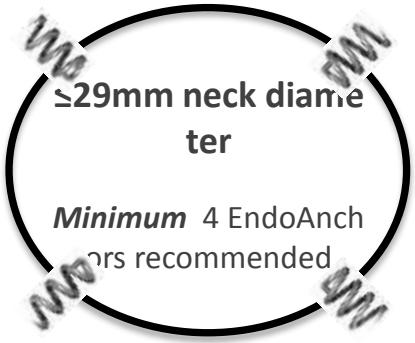
Aptus® Heli-FX® EndoAnchor® System

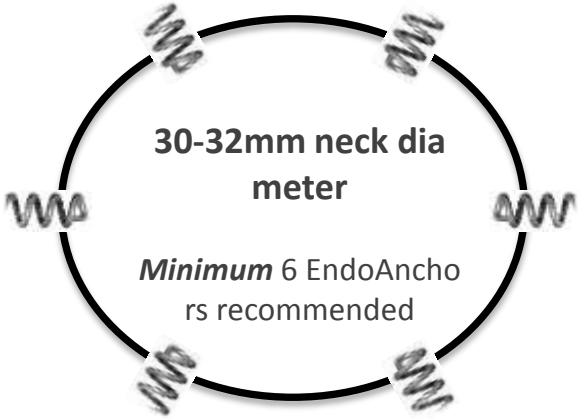
16F OD
62cm working length

Technical Specifications

Component	Specification	Aptus Heli-FX EndoAnchor System	Aptus Heli-FX Thoracic EndoAnchor System
Heli-FX Guide	French Size (OD)	16F	18F
	Working Length	62cm	90cm
	Deflecting Tip Length	2 options: 22mm 28mm	3 options: 22mm 32mm 42mm
	Recommended aortic neck	18-28mm 28-32mm	18-28mm 28-38mm 38-42mm
Heli-FX Applier	French Size (OD)	12F	
	Working Length	86cm	114cm
	Deployment Sequence	2 stage	
	EndoAnchor Size/Quantity	10 / Cassette 3 x 4.5mm (w x l)	
Ancillary EndoAnchor Cassette	EndoAnchor Size/Quantity	5 / Cassette 3 x 4.5mm (w x l)	

Recommended Number of EndoAnchors for Bifurcated SG

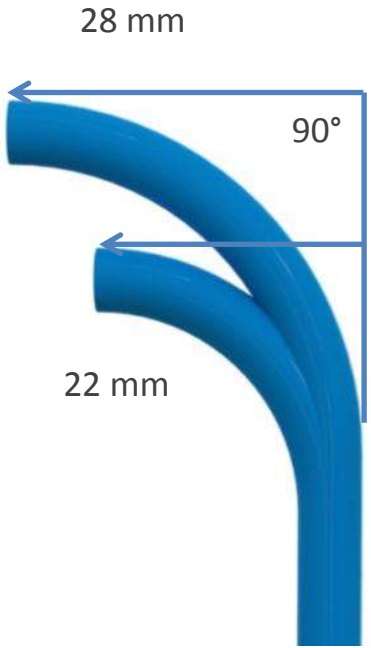




Where feasible, EndoAnchors should be placed uniformly around the circumference of the endograft and/or cuff

- To address a Type I endoleak, more EndoAnchors may be placed focally
- In a revision case, when possible, secure the main body to the aorta

Heli-FX Guide Selection



Heli-FX Guides
62 cm

Factors that affect selection:

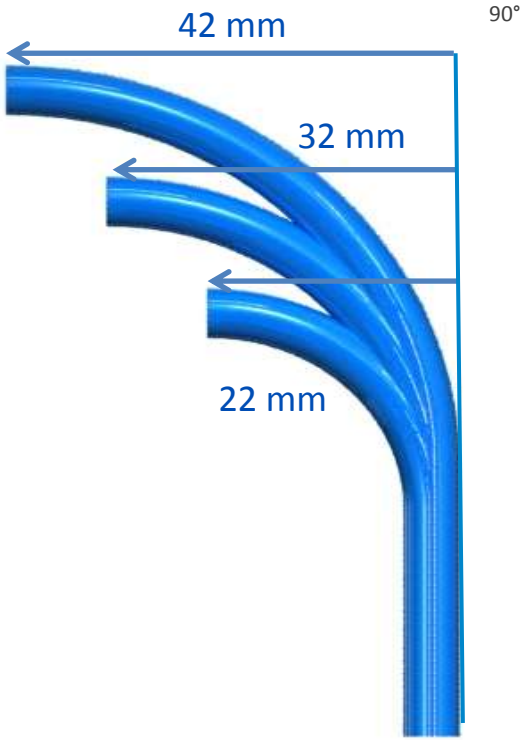
- Diameter
- Shape - Conical necks may need larger Guide
- Angulation of neck

Always have both sizes available during the procedure

Recommended Minimum Number of EndoAnchors for Thoracic SG

	Minimum Number of EndoAnchors		
	Graft Angulation		
Aortic Neck Diameter (Proximal or Distal)	≤ 60°	> 60° and < 75°	> 75° and < 90°
≤ 29mm	4	4	4
30 – 32mm	4	4	5
33 – 36mm	4	5	7
37 – 40mm	5	6	8
> 40mm	5	7	9

Heli-FX Thoracic Guide Selection



Heli-FX Thoracic Guides

Factors that affect selection:

- Diameter of aorta
- Shape – Conical necks may need longer tip reach
- Angulation of neck
- For Arch cases, two different sizes (tip reach) may be necessary

Always have different sizes available during the procedure

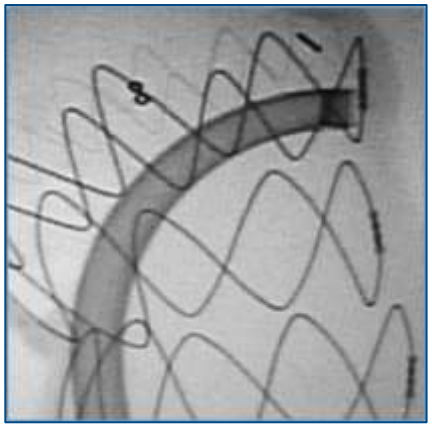
Sizing of the anatomy and EndoAnchoring decisions are the responsibility of the physician

Heli-FX Guide

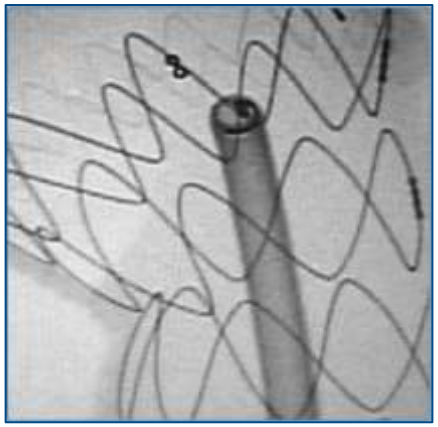
- C-Shaped Radiopaque Marker on the Distal Tip of the Guide provides visual r eference for lateral, anterior and posterior positioning
- Line Marker on outer radius of Guide assists with lateral orientation

C - Shape
Anterior Orientation

| - Straight Line
Lateral Orientation



⊃ - Shape
Posterior Orientation

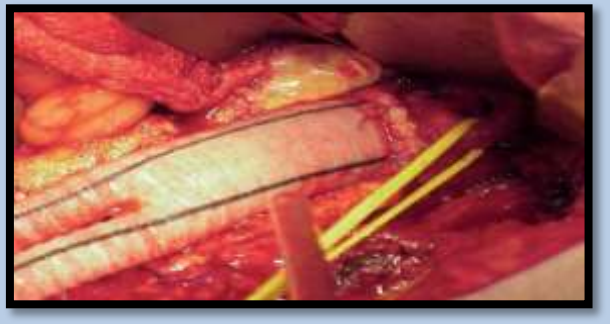


Note: Image intensifier in the anterior/posterior position

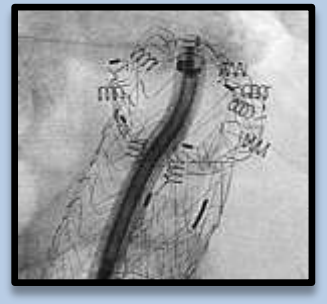
FIXATION OF ENDOANCHORS

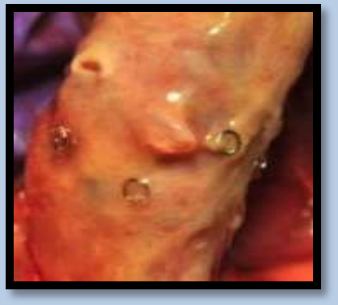
Create the stability of a surgical anastomosis in EVAR and TEVAR

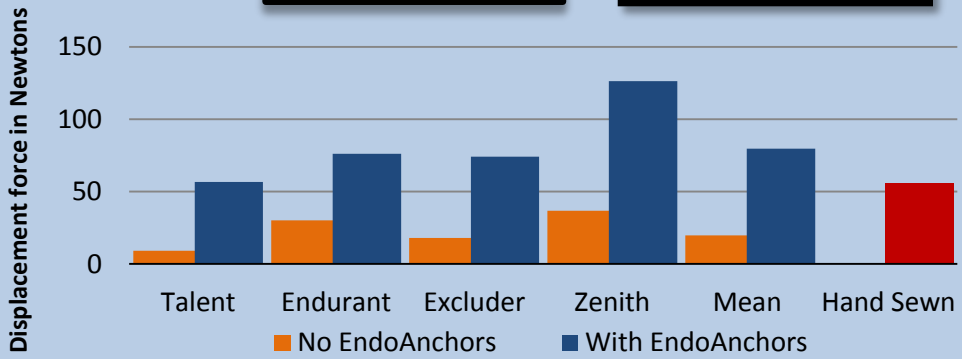
Surgical Anastomosis



EndoAnchoring







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

Case images from John Aruny MD, Bart Edward Muhs, MD, PhD.

Off Label Promotion Prohibited

- Off label promotion of any endograft is strictly prohibited by Medtronic

Infrarenal Neck Parameters for Various Commercially Available AAA Endografts[1]		
Stent Graft	**Neck Length**	**Neck Angle**
Endurant™	≥10mm	≤60°
Zenith™* Fenestrated	≥4mm	≤45°
Zenith™* Flex	≥15mm	≤60°
Excluder™*	≥15mm	≤60°
E™-vita	≥15mm	≤60°
Ovation™*	Not tested with EndoAnchor implants	
Aorfix™*	Not tested with EndoAnchor implants	
Endologix AFX™*	Contraindicated with EndoAnchor fixation[2]	

[1]Per manufacturers' IFU as of May 2016
[2]Other contraindication for EndoAnchor fixation is in patients with known allergies to the EndoAnchor implant material (MP35N-LT)

ANCHOR Prospective Registry

319 subjects enrolled at 43 sites in US & Europe
Primary arm: 242 patients (75.9%)
Revision arm: 77 patients

	Patients, No.	*Technical success,[a] No. (%)*	*Procedural success,[b] No. (%)*	*No evidence of type Ia leak at completion angiography, No. (%)*
All	319	303 (95.0)	279 (87.5)	290 (90.9)
Primary arm	242	233 (96.3)	217 (89.7)	223 (92.1)
Prophylaxis for hostile neck	186	180 (96.8)	172 (92.5)	177 (95.2)
Treatment of type Ia endoleak	52	51 (98.1)	43 (82.7)	43 (82.7)
Treatment of distal deployment	4	2 (50.0)	2 (50)	3 (75.0)
Revision arm	79	70 (90.9)	62 (80.5)	67 (87.0)
Treatment of type Ia endoleak	45	43 (95.6)	35 (77.8)	36 (80.0)
Treatment of migration	11	8 (72.7)	8 (72.7)	11 (100)
Treatment of endoleak and migration	21	19 (90.5)	19 (90.5)	20 (95.2)

[a]Technical success is defined as deployment of the desired number of EndoAnchors with adequate penetration of the vessel wall and without EndoAnchor fracture.
[b]Procedural success is defined as technical success without a type Ia endoleak at completion angiography.

J Vasc Surg 2014;60:885

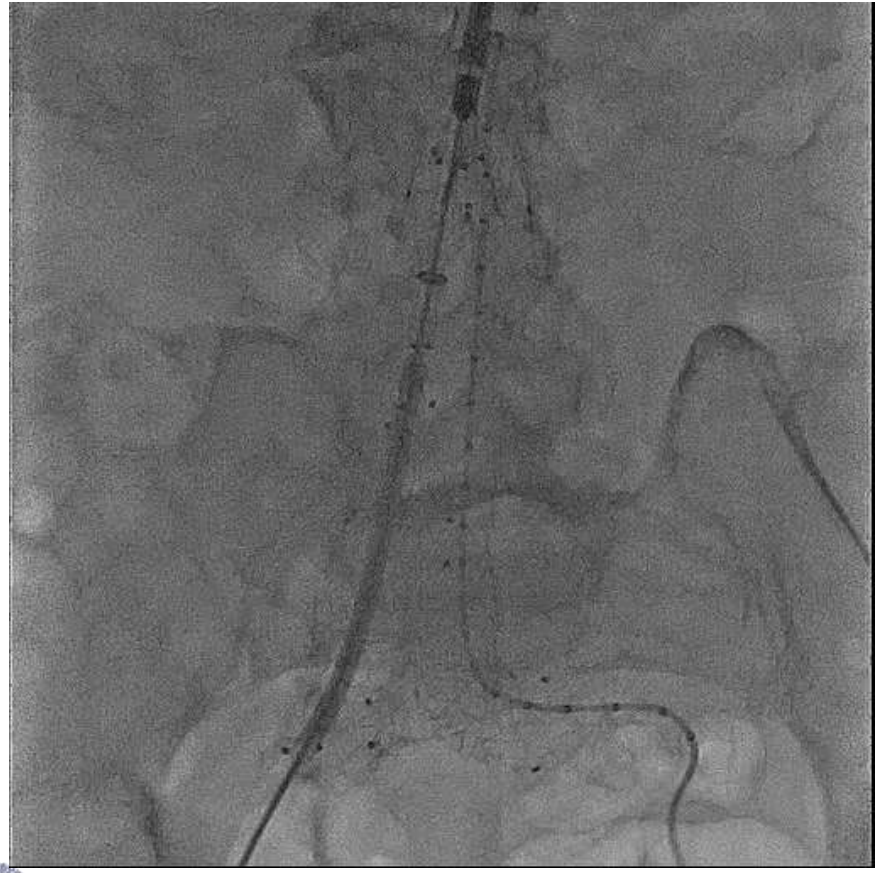
M/83, HSG#2113413

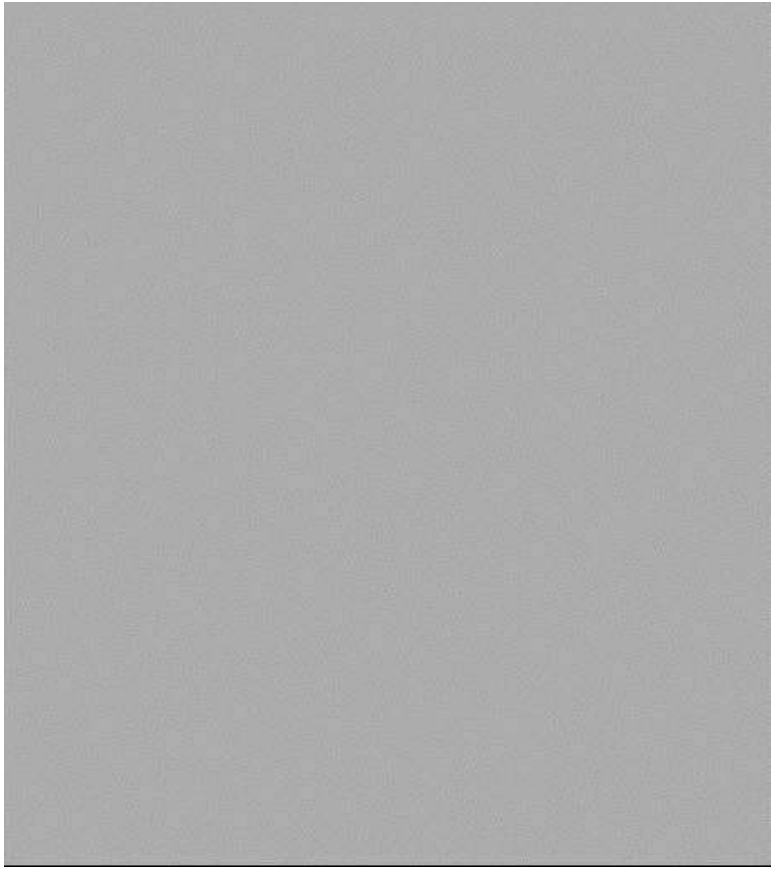
- Dx: Type Ia endoleak increasing aneurysm sac size (Max D. 108 mm)
- PHx:

  HTN, CKD (Cr 1.5 mg/dL), lung ca.
- Previous Tx

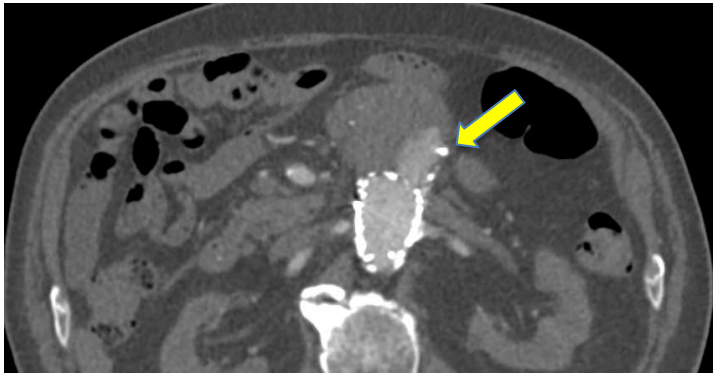
  - 1st EVAR, Endurant SG (2012/11/6) (AAA 87 mm)
  - 2nd EVAR using aortic cuff (2015/12/12)

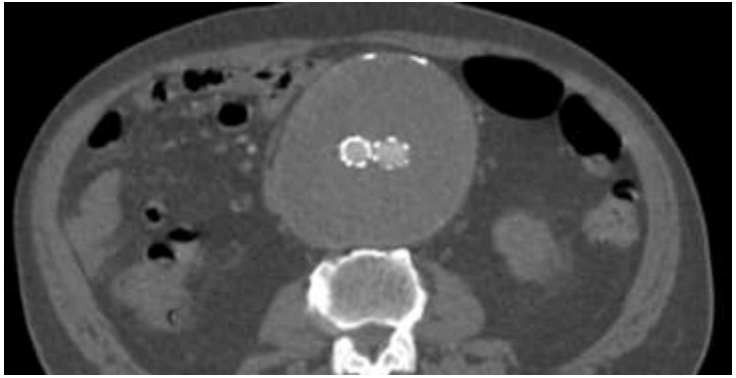
Reintervention with Aortic Cuff (36 mm)





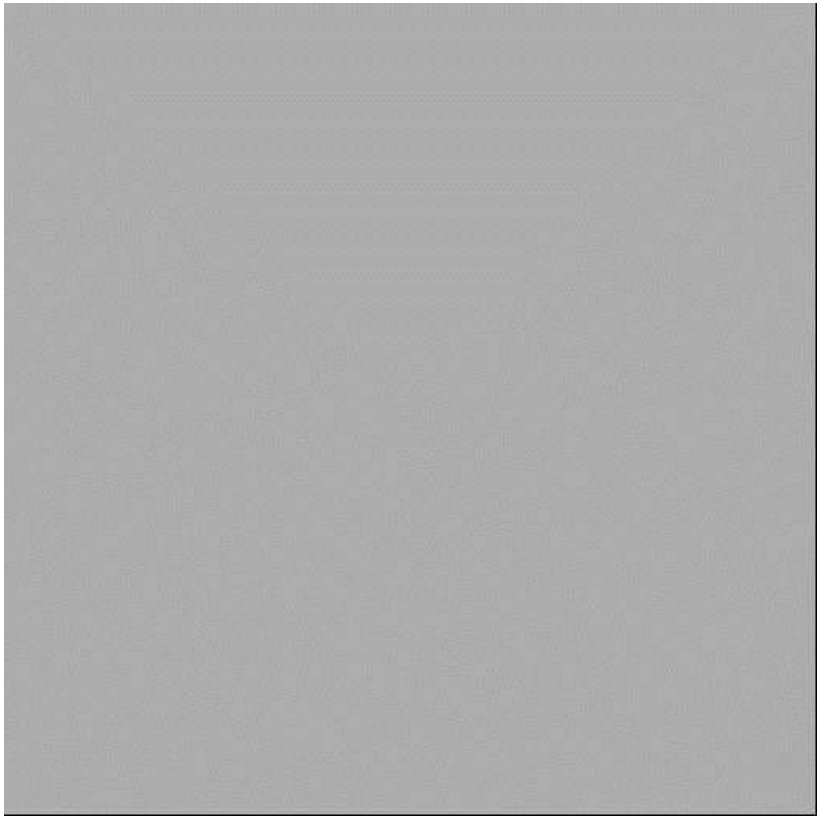
Type Ia Endoleak

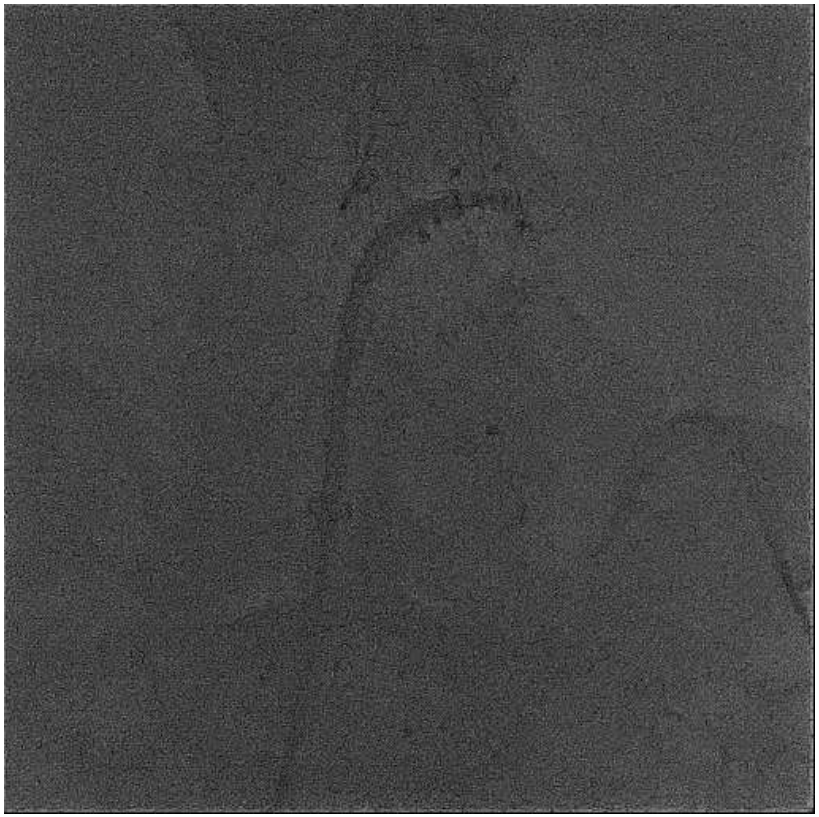




Aptus

RAO 90





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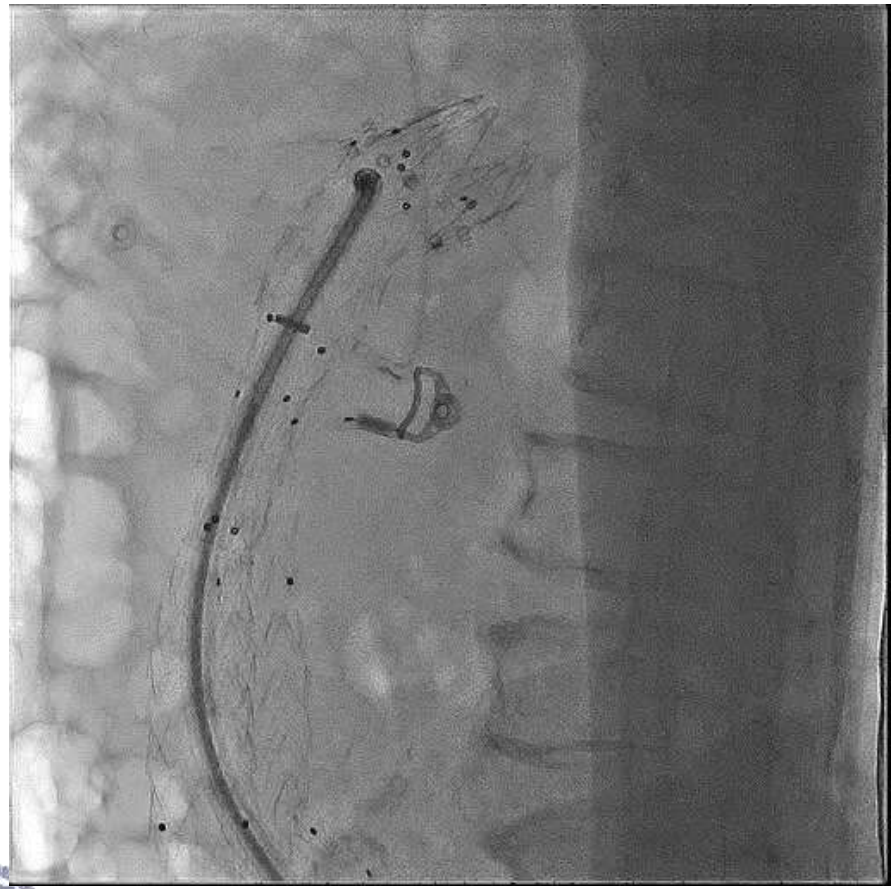

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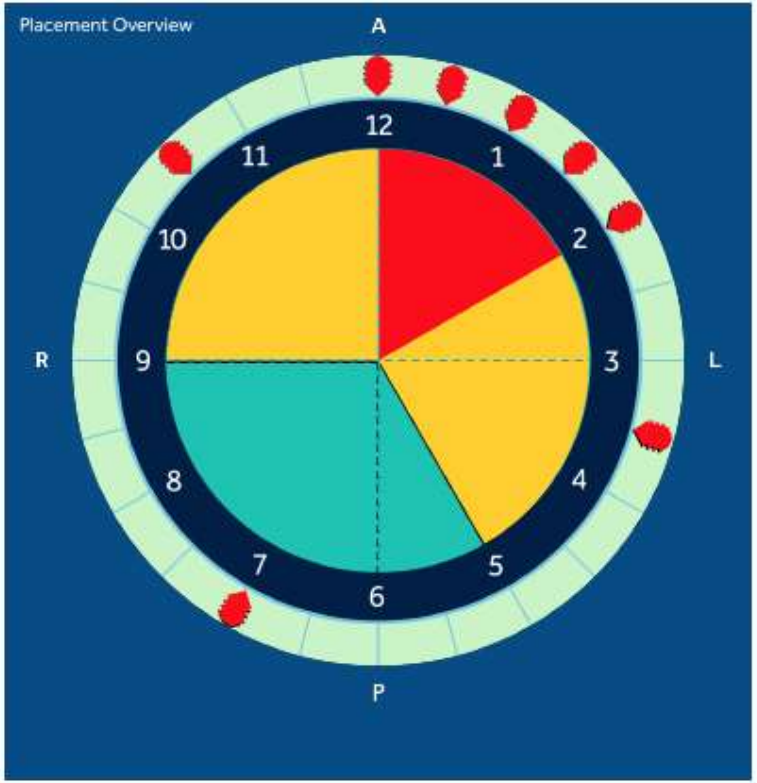
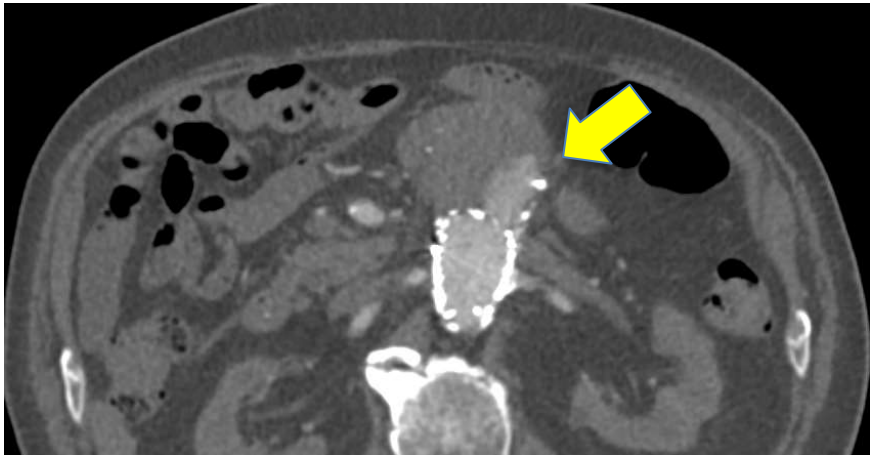


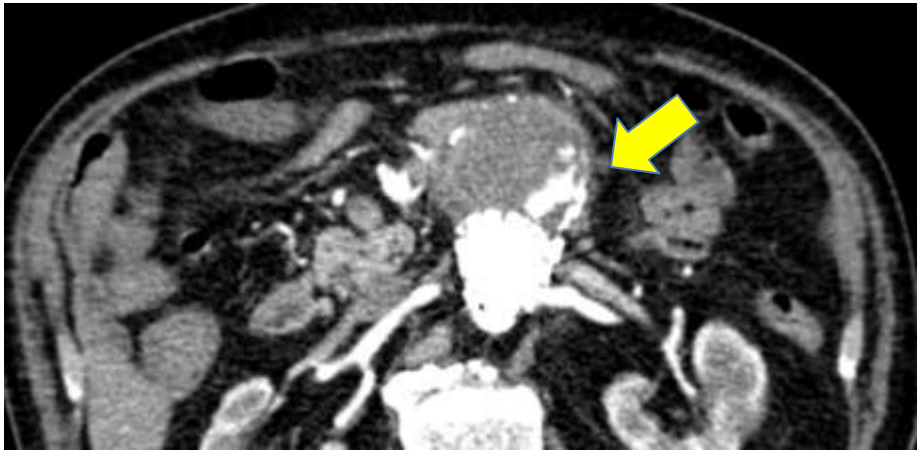
C-Arm Sequence	C-Arm Angle	Anchor Position	Anchor sequence	Level
1	90° RAO	12:00	1	Top
2	75° RAO	12:30	2	Top
3	60° RAO	01:00	3	Top
3	60° RAO	07:00	4	Top
4	45° RAO	01:30	5	Top
5	30° RAO	02:00	6	Top
6	15° LAO	03:30	7	Top
7	45° LAO	10:30	8	Top

CT Follow-up: 3 days later

Before



After



Influence of aortic neck characteristics on successful aortic wall penetration of EndoAnchors

J Vasc Surg. 2018 Apr 21. pii: S0741-5214(18)30384-7. doi: 10.1016/j.jvs.2018.01.039. [Epub ahead of print]

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

Goudeketting SR[1], van Noort K[2], Ouriel K[3], Jordan WD Jr[4], Panneton JM[5], Slump CH[6], de Vries JPM[7].

Author information

Abstract

OBJECTIVE: This study sought to quantify EndoAnchor (Medtronic Vascular, Santa Rosa, Calif) penetration into the aortic wall in patients undergoing endovascular abdominal aortic aneurysm repair and to assess predictors of successful penetration and its relationship to postprocedural type IA endoleak.

METHODS: A subset of patients from the Aneurysm Treatment Using the Heli-FX Aortic Securement System Global Registry (ANCHOR) were included if they met the following criteria: the indication for EndoAnchor use was to treat a type IA endoleak, and postprocedure contrast-enhanced computed tomography (CT) scans of sufficient quality were available for core laboratory review. Patients undergoing implantation of cuffs or stents during the EndoAnchor implantation procedure were excluded. Baseline anatomic characteristics were recorded. The cohort was divided into patients with and without persistent type IA endoleaks at the first postoperative CT scan. Penetration of each EndoAnchor measured on this CT scan was defined as good penetration when the EndoAnchor penetrated ≥2 mm into the aortic wall, borderline penetration when EndoAnchor penetration was <2 mm or a gap remained between the endograft and aortic wall, or no penetration when the EndoAnchor did not penetrate into the aortic wall. Differences between the groups were analyzed with the Mann-Whitney U test or Fisher exact test. Multivariate analyses were performed to identify independent predictors of EndoAnchor penetration, and procedural success was defined by absence of type IA endoleak.

RESULTS: Eighty-six patients of the primary (n = 61 [71%]) and revision (n = 25 [29%]) arms of the ANCHOR registry were included. There were 53 (62%) without and 33 (38%) with persistent type IA endoleaks on the first postprocedural CT scan. The median number of EndoAnchors with good penetration was significantly greater in the cohort without endoleaks, 4 (interquartile range, 3-5) vs 3 (interquartile range, 1.5-4), respectively (P = .002). A multivariate model for EndoAnchor penetration identified use of a Medtronic Endurant endograft as a factor associated with good penetration (P = .001), whereas poor penetration was associated with a larger aortic neck diameter 10 mm distal to the lowest renal artery (P < .001) and greater proximal neck calcium thickness (P = .004). EndoAnchor penetration was the only variable that attained significance (P < .001) in the multivariate model for successful treatment of a type IA endoleak.

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.

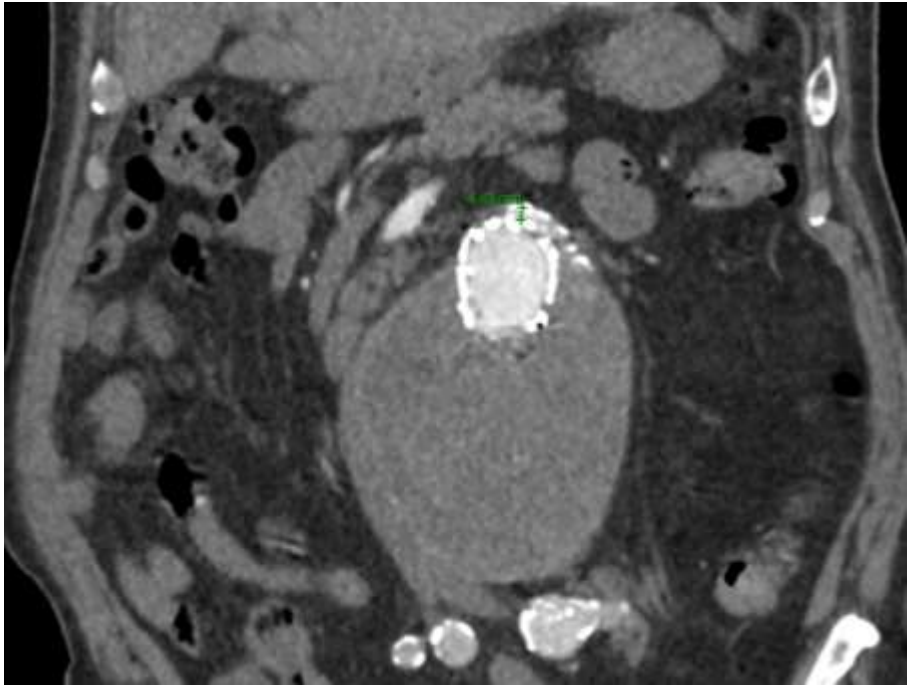
EndoAnchor penetration was the only variable that attained significance (P < .001) in the multivariate model for successful treatment of a type IA endoleak.

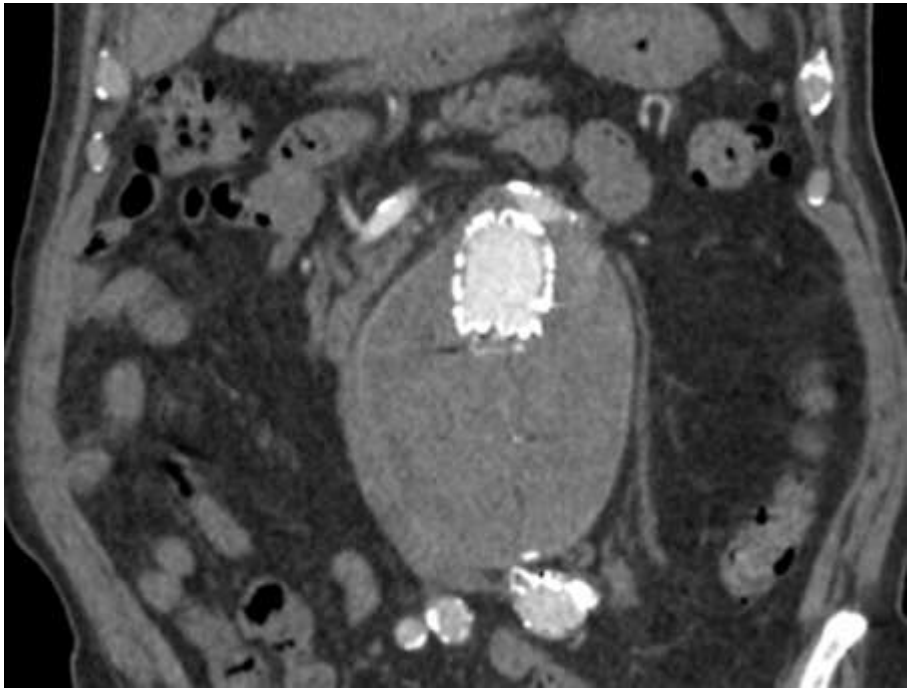
Poor penetration:

- a larger aortic neck diameter 10 mm distal to the lowest renal artery (P < .001)
- greater proximal neck calcium thickness (P = .004).

J vasc Surg 2018, in Press

CT prior to Aptus Implantation






Thank you
for your attention!