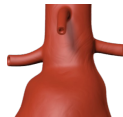



Mid-Term Results Of EVAR With Endoanchors In Patients With Hostile Neck Anatomy: Do They Work Better When Used Prophylactically Or Therapeutically? Do They Work Equally Well With All Endografts

Apostolos K. Tassiopoulos, MD,
FACS
on behalf of the ANCHOR Investigators
Professor and Chair
Chief, Division of Vascular and
Endovascular Surgery
Department of Surgery, Stony Brook Medicine

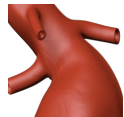
We know hostile neck anatomy challenges EVAR outcomes¹




Short



Wide



Angulated

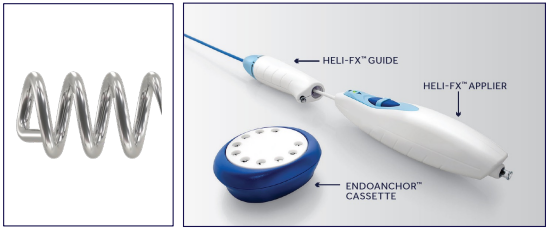


Conical

4.5x Increased risk of developing type Ia endoleak at 1 year (P = 0.01)¹

9x Increased risk of aneurysm-related mortality at 1 year (P = 0.01)¹

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




Labels in diagram: HELI-FX™ GUIDE, HELI-FX™ APPLIER, ENDOANCHOR™ CASSETTE

ESAR mechanism of action reinforces proximal seal and mimics surgical anastomosis^{1,2}


ESAR with the Heli-FX™ EndoAnchor™ System at the index procedure has been reported to:

- ① Attach adventitia to the graft
- ② Reinforce the proximal seal²
- ③ Protect against neck dilatation³
- ④ Promote greater sac regression⁴
- ⑤ Minimize Type Ia endoleaks⁵

Without EndoAnchor™ implants



With EndoAnchor™ implants



EndoAnchor™ implants have a protective effect on neck dilatation at their usual level of deployment³


ENDOANCHOR INDICATIONS FOR USE

The APTUS™ EndoAnchor™ implant and Heli-FX™ have been evaluated and determined to be compatible with the following endografts:


Medtronic	Cook	Gore	Jotec
Valiant™	Zenith™*	Excluder™*	Jotec E™*-vita
Endurant™	Zenith TX2™*	TAG™*	
AneuRx™ ¹			
Talent™ ¹			

ENDOANCHOR CONTRAINDICATIONS FOR USE

Treatment with the Aptus™ Heli-FX™ EndoAnchor™ system is contraindicated for use in the following circumstances:



- In patients with known allergies to the EndoAnchor™ implant material (MP35N-LT) (US & OUS IFU)


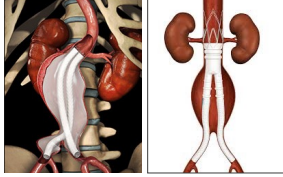


- In conjunction with the Endologix Powerlink™ and AFX endograft (US & OUS IFU)

- In patients with a condition that threatens to infect the endograft (OUS IFU)
- In patients with a bleeding diathesis (OUS IFU)

ENDOANCHOR CONTRAINDICATIONS FOR USE

Polymer-based technologies are also not indicated for EndoAnchor™ implants

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
Device	Heli-FX™ EndoAnchor™ System
Regions	US, EU, APAC

ANCHOR registry (N=1032 AAA subjects enrolled)

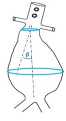
Primary arm (n=771) Revision arm (n=261)

1. Jordan W. Evidence that EndoAnchor can facilitate and maintain successful standard EVAR for AAA with challenging proximal necks: preliminary 5-year data from the Primary Arm of the ANCHOR Registry. First presented at Charing Cross International Symposium, April 15, 2021.

ANCHOR Registry: Primary Arm¹

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

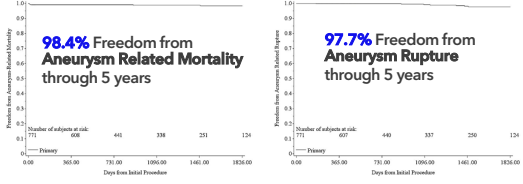
Presentation Status	Baseline Characteristics (Core Lab)
ASA Class III/IV: 87.8% (674/768)	Infrarenal Diameter: 23.9 mm (mean)
Urgent / Emergent Cases: 17.9% (119/664)	Conical Neck (>10%/10mm): 42.5% (276/649) (mean)
Female: 21.3%	Neck Length: 15.0 mm (median) 16.9 mm (mean)
Mean Age: 73.5 years (n=751)	Infrarenal Angulation: 36.6° (mean)
	Aneurysm Diameter: 59.3 mm (mean)
	Hostile Necks: 88.7% (572/645) <15mm, >28mm, >60°, Conical, Ca2+/Thrombus >50%



1. Jordan W. Evidence that EndoAnchor can facilitate and maintain successful standard EVAR for AAA with challenging proximal necks: preliminary 5-year data from the Primary Arm of the ANCHOR Registry. First presented at Charing Cross International Symposium, April 15, 2021.

ANCHOR AAA Primary Arm 5-Year Results (N=771)

Hostile Necks: **88.7%** (572/645) <15mm, >28mm, >60°, Conical, Ca2+/Thrombus >50%



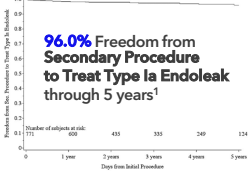
98.4% Freedom from Aneurysm Related Mortality through 5 years

97.7% Freedom from Aneurysm Rupture through 5 years

1. Jordan W. Evidence that EndoAnchor can facilitate and maintain successful standard EVAR for AAA with challenging proximal necks: preliminary 5-year data from the Primary Arm of the ANCHOR Registry. First presented at Charing Cross International Symposium, April 15, 2021.

ANCHOR AAA Primary Arm 5-Year Results¹

Hostile Necks: **88.7%** (572/645) <15mm, >28mm, >60°, Conical, Ca2+/Thrombus >50%



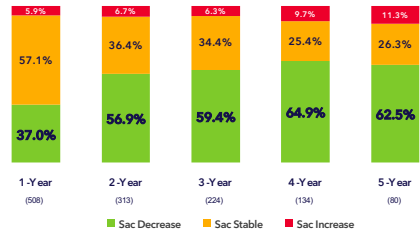
96.0% Freedom from Secondary Procedure to Treat Type Ia Endoleak through 5 years¹

Type Ia Endoleaks at ²
1 year: 2.5% (14/568)
2 year: 1.7% (10/546)
3 year: 2.9% (17/238)
4 year: 3.2% (5/154)
5 year: 4.8% (4/84)

No migration reported at any timepoint through 5yrs¹

1. Jordan W. Evidence that EndoAnchor can facilitate and maintain successful standard EVAR for AAA with challenging proximal necks: preliminary 5-year data from the Primary Arm of the ANCHOR Registry. First presented at Charing Cross International Symposium, April 15, 2021.
2. Borge Gudea. A Treatment Strategy of Endoleaks in Aortic Grafts. First presented at Leipzig International Course, June 2022.

ANCHOR Primary Arm: Sac Diameter



Year	Sac Decrease	Sac Stable	Sac Increase
1-Year (N=508)	37.0%	57.1%	5.9%
2-Year (N=313)	56.9%	36.4%	6.7%
3-Year (N=224)	59.4%	34.4%	6.3%
4-Year (N=134)	64.9%	25.4%	9.7%
5-Year (N=80)	62.5%	26.3%	11.3%

1. Jordan W. Evidence that EndoAnchor can facilitate and maintain successful standard EVAR for AAA with challenging proximal necks: preliminary 5-year data from the Primary Arm of the ANCHOR Registry. First presented at Charing Cross International Symposium, April 15, 2021.

Stony Brook ESAR Cohort

Aortic characteristics			Variables	Event/Total	Percentage, %
Aortic diameter 5mm above celiac, mm	35/37	27.4 (4.0)	Rupture at presentation	5/37	13.5
Aortic diameter 5mm above highest renal, mm	35/37	24.7 (3.7)	Length of AAA neck < 10mm	21/37	56.8
Aortic diameter at the level of lowest renal, mm	35/37	23.2 (3.4)	Infrarenal neck angulation > 60 degrees	15/37	40.5
Aortic diameter 5mm below lowest renal, mm	35/37	25.1 (4.2)	Diameter of AAA neck ≥ 28mm	5/37	13.5
Aortic diameter 10mm below lowest renal, mm	35/37	27.5 (5.2)	AAA neck with conical shape	28/37	75.7
Infrarenal neck angulation > 60 degrees	35/37	39.8 (22.7)	Circumferential mural thrombus > 50 %	10/37	27
Largest AAA mean diameter, mm	37/37	60.4 (12.6)	Circumferential calcification > 50 %	5/37	13.5
Volume of sac from lowest renal to bifurcation, cm ²	33/37	215.0 (178.9)	AAA characteristics ≥ 2	30/37	81.1

Tassiopoulos et al 2024.

Positive Long Term Outcomes with ESAR

AAA remodeling during follow-up and frequency of endoleaks

Variables	Event/Total	Percentage, %
Decrease in AAA maximum diameter	26/37	70.3
Stable AAA diameter	9/37	24.3
Increase in AAA diameter	2/37	5.4
Type Ia endoleak	1/37	2.7
Type Ib endoleak	2/37	5.4
Type II endoleak	6/37	16.2
Type III endoleak	1/37	2.7

AAA: abdominal aortic aneurysm

Mean follow up 65 months

1. Tassiopoulos et al 2024.

ANCHOR Registry

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ANCHOR registry (N=1032 AAA subjects enrolled)

Primary arm (n=771) Revision arm (n=261)

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Baseline Characteristics of ANCHOR Registry Revision arm (n=261)

88.7% (188/212) with Hostile Neck Characteristics

- Short: 43.1% (85/212) < 15mm
- Wide: 30% (66/220) > 28mm
- Angulated: 14.7% (89/212) > 60°
- Conical: 42% (89/212)

- Excluder: 23.5% (61/260)
- Zenith: 23.5% (61/260)
- J-Teve Evita: 19.6% (51/260)
- AneuRx: 11.2% (29/260)
- Talent: 8.5% (22/260)
- Other: 8.1% (21/260)
- Link-revo: 0.8% (2/260)

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ANCHOR Registry: Revision Arm¹

N=261 patients
ESAR for failed EVAR: 4.6 yrs after index EVAR (mean, N=246)²

Main Reasons for EndoAnchor™ Procedure		Baseline Characteristics (Core Lab)	
72.0% (188/261)	Type Ia endoleak with or without migration	Hostile Necks: 88.7% (188/212) <15mm, >28mm, >60°, Conical, Ca ²⁺ /Thrombus >50%	
13.0% (34/261)	Migration (without endoleak)	Short Neck (<15mm): 43.1% (85/197)	
7.3% (19/261)	Neck Dilatation	Short Neck (<10mm): 26.9% (53/197)	
Urgent / Emergent Cases: 23.8% (58/244)		Wide Neck (>28mm): 30.0% (66/220)	
		Angulated Neck (>60°): 14.7% (30/204)	
		Conical Neck: 42.0% (89/212)	

1. deVries JP, Vascular Symposium 2021
2. deVries JP, Vascular Symposium 2021

ANCHOR Revision Arm- 5yr Outcomes¹ (8-9yrs post index)

Freedom from Aneurysm Mortality through 5 yrs: 91.3 ± 3.4%

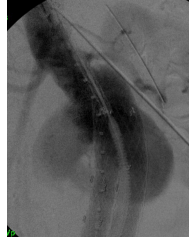
Freedom from Rupture through 5 yrs: 91.1 ± 4.2%

Freedom from Secondary Proc for Type IA through 5 yrs: 81.4 ± 5.9%

1. deVries JP, 48th Annual Vascular Symposium 2021

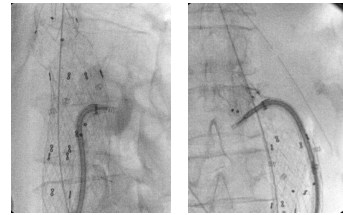
REMOTE TYPE IA ENDOLEAK

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



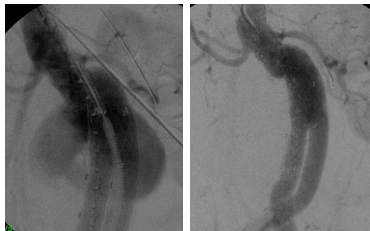
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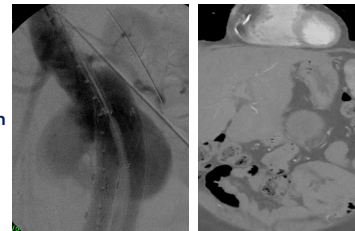
REMOTE TYPE IA ENDOLEAK

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



REMOTE TYPE IA ENDOLEAK

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



Summary

- ESAR therapy provides improved midterm outcomes when compared to standard EVAR in hostile neck anatomies¹
- Outcomes related to decreased proximal seal failures are linked to improved sac regression rates², although this needs further investigation
- Rescue of failed EVAR is challenging scenario especially in hostile neck patients³ and endoanchors use should be tailored to the individual revision strategy
- Based on ANCHOR primary arm results, consider use of EndoAnchors prophylactically

1. Mink MC, Jansen TG, Gombert S, et al. Midterm outcomes comparison of standard endovascular aortic aneurysm repair with endoanchors for hostile anatomy. J Vasc Med Biol. 2018;30(3):149-155.
2. Gray VA, et al. Outcomes of a novel endovascular aortic aneurysm repair (ESAR) in hostile neck anatomy: a retrospective analysis. J Vasc Med Biol. 2022;34(3):149-155.
3. Gray VA, et al. Outcomes of a novel endovascular aortic aneurysm repair (ESAR) in hostile neck anatomy: a retrospective analysis. J Vasc Med Biol. 2022;34(3):149-155.

Thank You!