


5-Year Results Of Endoanchors In The Global ANCHOR Registry To Treat Complications With Focus On Preventing And Treating Type IA Endoleaks: Can Virtual Techniques Predict The Need For Endoanchors

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on behalf of the ANCHOR Investigators

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Disclosures

I have the following potential conflicts of interest to report:

- Receipt of grants/research support
- Receipt of honoraria and travel support
- Participation in a company sponsored speakers' bureau (Medtronic Inc.)
- Employment in industry
- Shareholder in a healthcare company
- Owner of a healthcare company

I do not have any potential conflict of interest

Hostile neck anatomy challenges EVAR outcomes

Aortic seal zone is dependent on many factors:

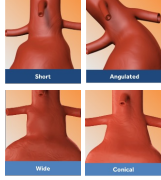
- Length, angle, width, conicity, Ca²⁺, thrombus, device design, deployment accuracy, etc.

Hostile neck characteristics leads to:

- Higher risk of type Ia's, neck degeneration, secondary procedures, late failure²

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



¹Arborelius, et al., J Vasc Surg 2015;57:527-38
²Gargallo, et al., J Vasc Surg 2017;64:1085-1092


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

ESAR delivers an endovascular "suture line" to provide radial fixation and increases proximal seal¹




CONICAL TIP

- Replicates SH-1 tip²
- Transmural penetration²



HELICAL SHAPE

- Replicates suture loops²
- Stability³



REAR CROSSBAR

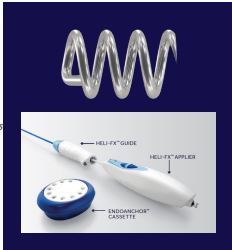
- Replicates suture knot²
- Secure attachment²

¹ Thull, C, Du Nighe, F, Meek, E, Poon, S, Tansig, A, Yoneda, Y. Endovascular under 20 navigation for type II endoleak after EVAR. Clin Case Rep 2019;6:6153-539-532.
² DeBorja, J, Hirsch, J, et al. Endovascular repair of type II endoleak with the Heli-FX EndoAnchor System. J Vasc Med Biol 2019;31:225-229.
³ DeBorja, J, Hirsch, J, et al. Endovascular repair of type II endoleak with the Heli-FX EndoAnchor System. J Vasc Med Biol 2019;31:225-229.

EndoSuture Aneurysm Repair (ESAR)

ESAR with Heli-FX™ EndoAnchor™ System reported to:

- Reinforce the proximal seal**
(Eur J Vasc Surg 2017;53:458-459)
- Minimize type Ia endoleaks**
(William D. Jordan, Jr., M.D. "New Developments From The ANCHOR Registry: Early 5 Year Prophylactic Results" presented at VEITH Symposium, November 18th 2022, Orlando, Florida, USA)
- Protect against neck dilatation**
(J Vasc Surg 2017;66:45-52)
- Promote greater sac regression**
(J Vasc Surg 2018;67:1699-1707)



ESAR elevates EVAR design elements to be more like OSR

Radial support just as with sutures
95.3% implants with adventitial penetration¹

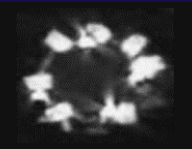
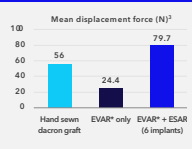


Image courtesy of Dr. Giovanni Pratesi


Stronger attachment over EVAR alone!
Via secure transmural wall fixation¹



Group	Mean displacement force (N) ¹
Hand sewn	56
EVAR only	24.4
EVAR + ESAR (6 implants)	79.7

¹Multiple endograft types were tested

Graft fixation strength with EndoAnchor™ implants exceeds inherent aortic integrity of cadaver²



Wides courtesy of Dr. David Dutton

¹ Finkel, M. J. et al. Endovascular repair of type II endoleak with the Heli-FX EndoAnchor System. J Vasc Med Biol 2019;31:225-229.
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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 neck: preliminary 5-year data from the Primary Arm of the ANCHOR Registry. First presented at Charing Cross Interventional Symposium, April 15, 2022.

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) Urgent / Emergent Cases: 17.9% (119/664) Female: 21.3% Mean Age: 73.5 years (n=751)	Infrarenal Diameter: 23.9 mm (mean) Conical Neck (>10%/10mm): 42.5% (276/649) (mean) Neck Length: 15.0 mm (median) 16.9 mm (mean) Infrarenal Angulation: 36.6° (mean) Aneurysm Diameter: 59.3 mm (mean)

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

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

5-year data

Reinforced Proximal Seal

89.0% Freedom from Type Ia EL²

96.0% Freedom from Reinterventions for Type Ia EL¹

0% Migrations through 5 years¹

Clinical Durability

98.4% Freedom from Aneurysm Related Mortality¹

97.7% Freedom from Rupture¹

88.8% Stable or Regressing Sac¹

ANCHOR PRIMARY AAA ARM 5-YEAR RESULTS (N=771)
 AAA Maximum Diameter Sac Dynamics

1 year: 37.0% (184/500) Decrease, 56.9% (279/490) Stable, 6.1% (30/490) Increase
 2 year: 37.0% (218/590) Decrease, 59.4% (352/590) Stable, 3.6% (20/590) Increase
 3 year: 64.9% (307/473) Decrease, 32.5% (155/473) Stable, 2.6% (12/473) Increase
 4 year: 62.5% (210/336) Decrease, 37.5% (126/336) Stable, 0% Increase
 5 year: 88.8% (170/191) Stable or Regressing, 11.2% (21/191) Increase

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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 at²:

- 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 reported at any timepoint through 5yrs¹

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

88.7% (188/212) with Hostile Neck Characteristics

Male: 85% (221/261)
 Mean age: 78.7 yrs
 89.3% (233/261) ASA Class III/IV
 24% (58/244) Urgent / Emergent Cases

Reasons for EndoAnchor™ Therapy: 100% failed EVAR

- 13% Migration
- 53.3% Type Ia endoleak
- 19% Combined Type Ia and Migration

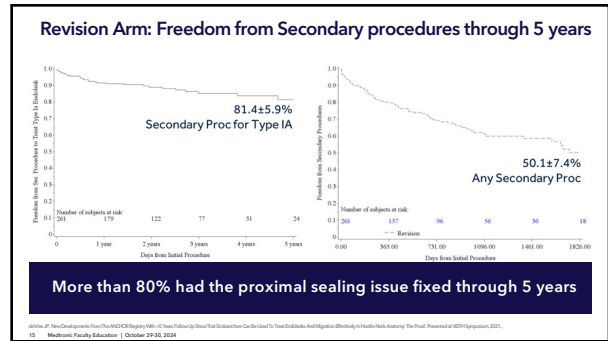
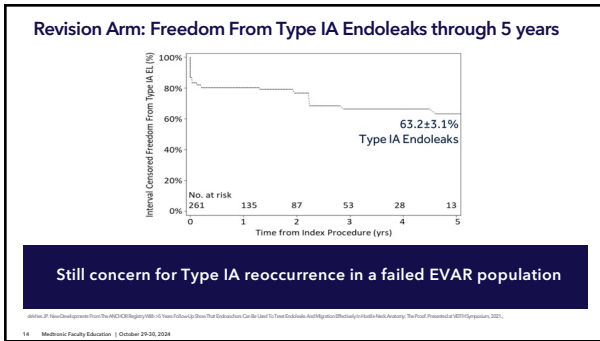
EndoAnchor™ Hostile Neck Characteristics:

- Short: 43.1% (81/257) <15 mm, 26.9% (53/257) >10 mm
- Wide: 30% (66/220) >28 mm
- Angulated: 14.7% (32/244) >60°
- Conical: 42% (89/212)

EndoAnchor™ Hostile Neck Characteristics (Pie Chart):

- EndoAnchor™: 23.1% (51/220)
- Zenith: 8.1% (18/220)
- Are UFX: 11.2% (25/220)
- Talent: 0.8% (2/244)
- Chlor: 12.8% (28/220)
- Unkown: 12.8% (28/220)

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Conclusions

Rescue of failed EVAR is a challenging scenario especially in hostile neck patients

Use of EndoAnchors can be successful in treatment of type Ia endoleaks and migration

In a 100% failed EVAR population, early 5-year ANCHOR revision results show positive outcomes

- >90% freedom from ARM, rupture, and conversion
- >80% freedom from secondary procedures for Type IA endoleaks

Based on ANCHOR primary arm results, consider use of EndoAnchors prophylactically especially in high risk patients such as wide or short necks

If the initial infrarenal aortic neck is too challenging choose another option (FEVAR, open, etc.)

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