Hostile proximal neck : EndoAnchor

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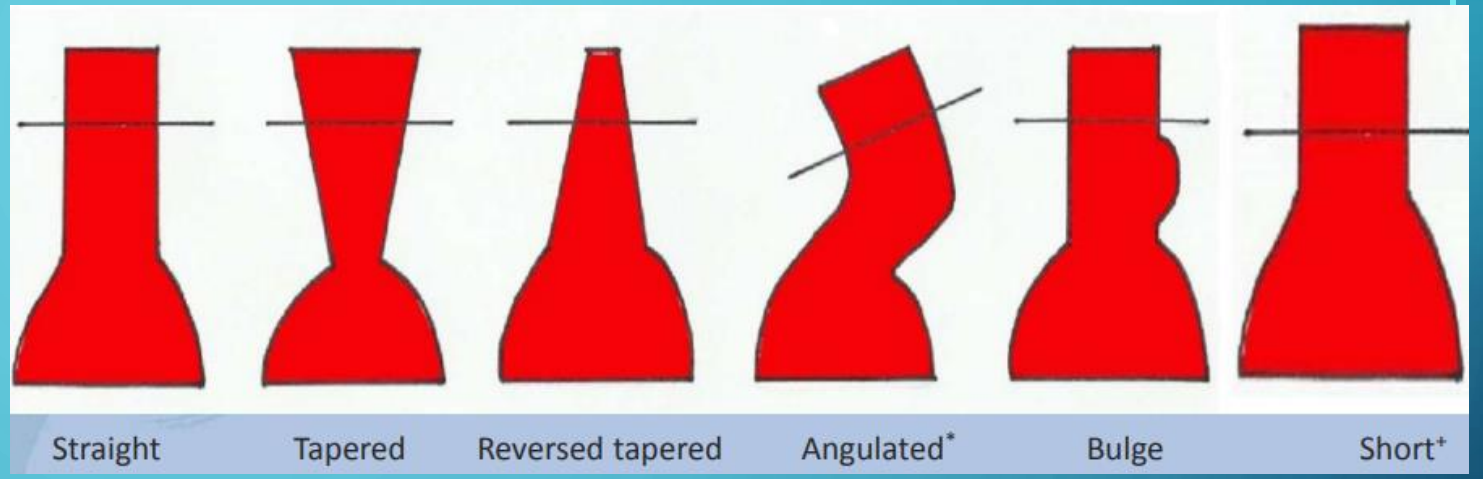
Hostile Neck

Definition of hostile neck anatomy varies from study to study

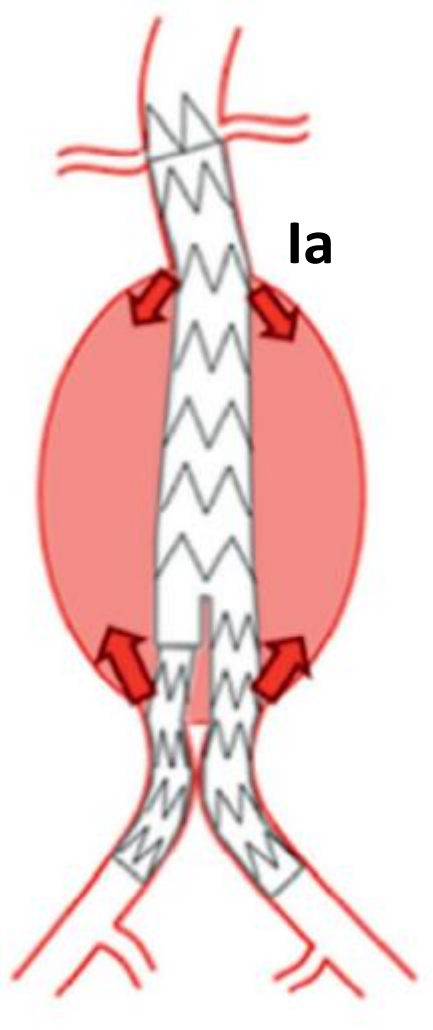


Not eligible for the manufacturer's regulatory criteria

Short
Wide
Angulated
Conical

Manufacturer	Model	Diameter (mm)	Min. neck length (mm)	Infrarenal angle	Suprarenal Angle	Other
Cook	Zenith	18-32	15	60	45	
Cordis	Incraft	17-31	10	60		
Endolc						
Endolc						
Endolc						
Gore	Anaconda	19-32	15	60		
Jotec	e-Tegra	24-36	15	75	60	
Medtronic	Endurant II	18-32	10 (15*)	60(75*)	45 (60*)	Calcification or thrombus >50% of perimeter
Vascutek-Terumo	Anaconda	17.5-31	15	90		

20-25% of cases do not fulfill the criteria !



Incidence of type Ia endoleak

Type Ia endoleak inevitably causes aneurysm sac growth and finally may be a reason of a *rupture*.

The overall rate of type Ia endoleaks varies between **3.6 and 5.4%.**
(Journal of Vascular Surgery. 2016;64(3):563-570, Journal of Vascular Surgery. 2017;65(6):1617-1624)

up to 12% incidence of proximal endoleaks in groups of patients with difficult anatomy and big aneurysm sac diameter.
(Journal of Vascular Surgery. 2017;66(4):1065-1072)

The data analysis from ANCHOR study revealed **9.2%** endoleak incidence in patients with hostile neck.
(Journal of Vascular Surgery. 2014;60(4):885-892.e2, J Vasc Surg. 2018 Jun;67(6):1699-1707)

Aneurysm sac expansion is independently associated with late mortality in patients treated with endovascular aneurysm repair

Sarah E. Deery, MD, MPH,[a] Emel A. Ergul, MS,[a] Marc L. Schermerhorn, MD,[b] Jeffrey J. Siracuse, MD,[c] Andres Schanzer, MD,[d] Philip P. Goodney, MD, MS,[e] Richard P. Cambria, MD,[a] *and* Virendra I. Patel, MD, MPH,[a] for the Vascular Study Group of New England, *Boston and Worcester, Mass; and Lebanon, NH*

J Vasc Surg. 2018 Jan;67(1):157-164.

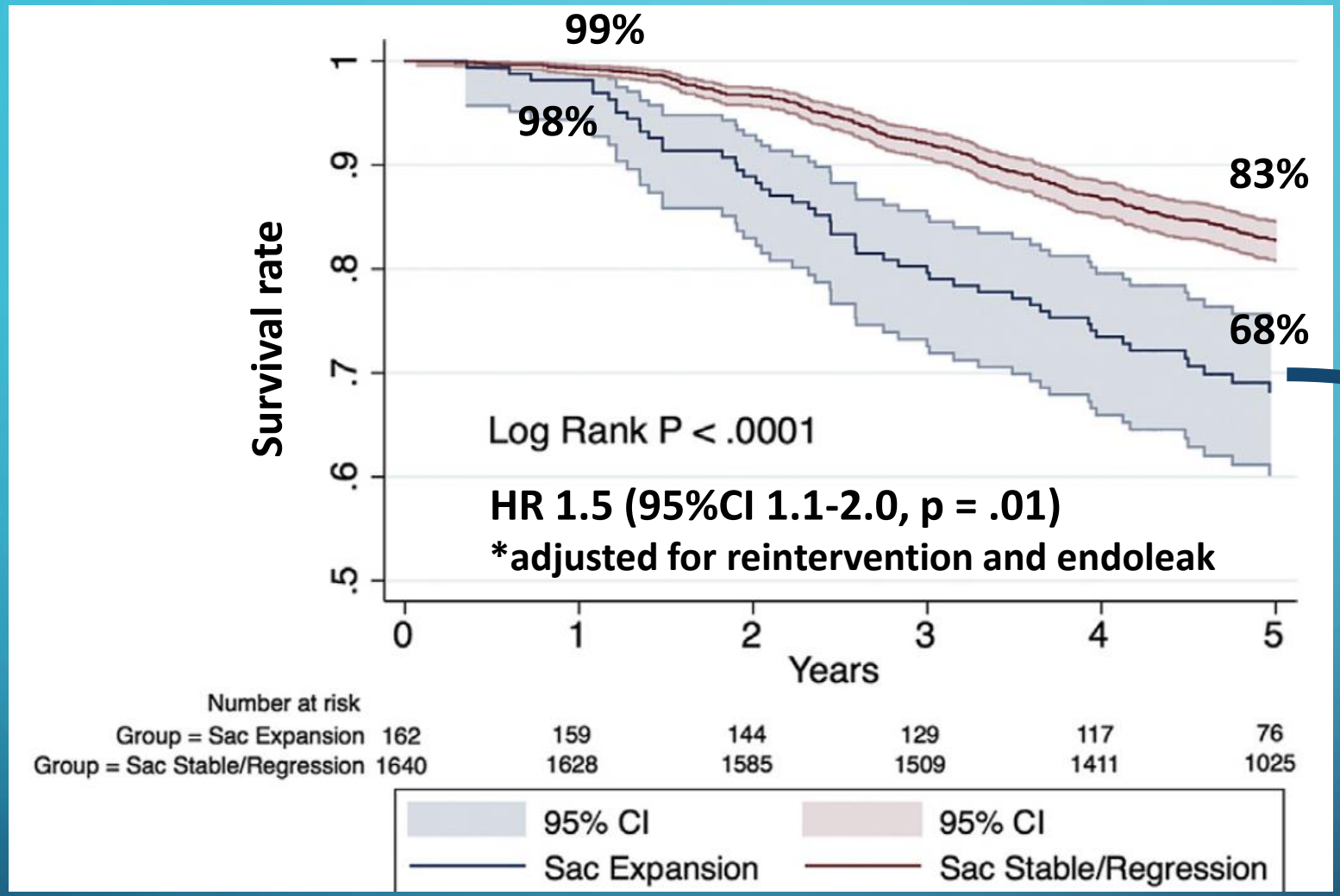
Vascular Study Group of New England (VSGNE) registry

31 academic and community hospitals in 6New England states

2003 – 2011

2437 patients who underwent EVAR

1802 (74%) had complete 1-year follow-up data



Risk factor

- CKD (OR 3.4)
- Urgent repair (OR 2.7)
- Hypogastric coverage (OR 1.7)
- **Type I/III endoleak (OR 16.8)**
- Type II endoleak (OR 2.9)

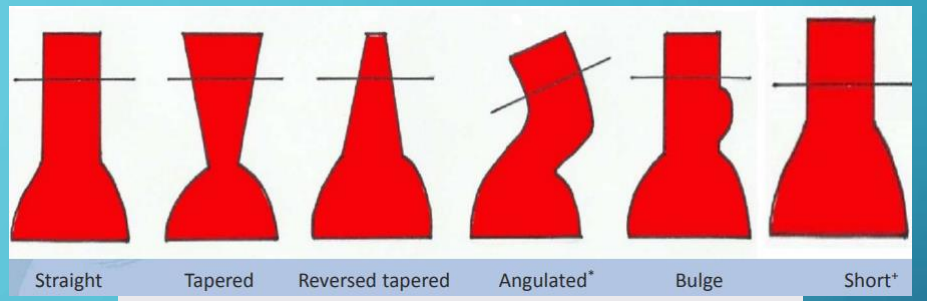
Sac expansion : aneurysmal sac enlargement > 5 mm - 9% (n = 162)

Sac regression : aneurysmal sac decrease > 5 mm - 52% (n = 931)

Clinical Impact of Hostile Proximal Neck for EVAR procedure

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

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



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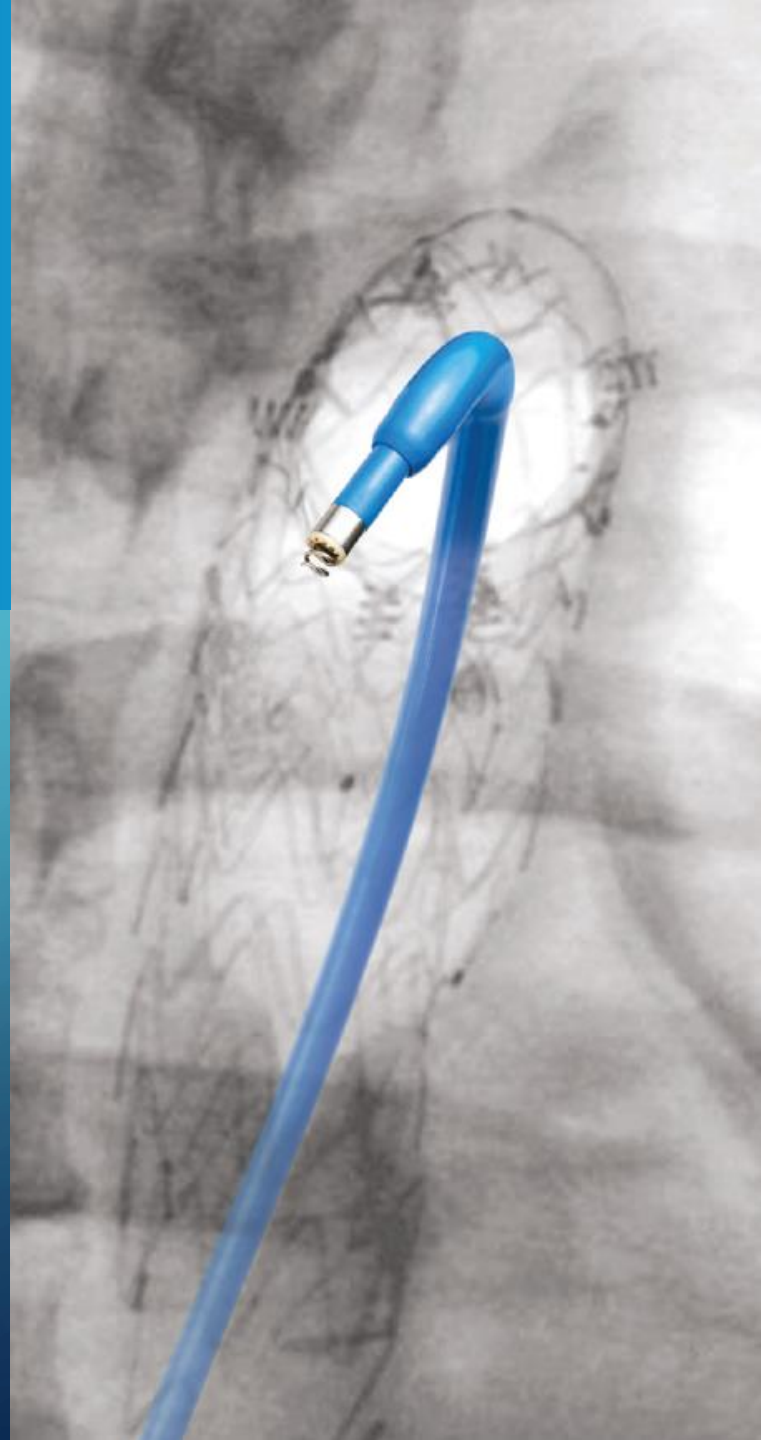
Greater than 1 hostile neck parameter substantially increases:

- Mortality
- MAEs
- Endoleaks
- Adjunctive procedures

Aptus™ Heli-FX™ EndoAnchor™ System



Aptus Endovascular AAA Repair System

Report of the 1-year follow-up in a first-in-man study.

BY TAKAO OHKI, MD; DAVID H. DEATON, MD; AND JOSÉ ANTONIO CONDADO, MD

Since 1991, when Parodi et al[1] described a minimally invasive alternative to open abdominal aortic aneurysm (AAA) repair via endovascular repair (EVAR), a variety of methods have been created to mimic principles of the traditional open AAA repair procedure. To date, all endovascular repair devices have a single method for delivery of an endograft into a diseased aorta. Additionally, each endograft relies primarily on the use of an oversized proximal stent, with or without a metallic barb, for fixation to the aortic wall. Experience has shown that these fixation methods can be prone to metal fatigue, as well as proximal stent migration. The Aptus Endovascular AAA Repair System (Aptus Endosystems, Inc., Sunnyvale, CA) divides the endovascular AAA repair procedure into two steps: (1) exclude the aneurysm with an endograft designed to provide radial support while maintaining longitudinal compliance and (2) secure the endograft to the vessel wall with an endovascular stapling system that provides transmural aortic fixation with a high pull-out force proportional to the number of EndoStaples (Aptus) deployed.

The Aptus modular endograft is designed specifically for use with the Aptus Endovascular Stapling System, which in turn is designed to provide secure fixation of the proximal edge of the endograft to the infrarenal aortic wall.

The modular endograft is designed to accommodate changes in aneurysm and/or aorta morphology without compromising graft integrity, graft patency, or arterial attachment and sealing. In addition, this two-step approach to endovascular AAA repair allows for a significant reduction in the profile and increased flexibility of the delivery systems (endograft and EndoStaples). The modular endograft and the EndoStaple Applier are delivered through a 14-F sheath (16-F outer diameter). These attributes may allow a broader range of patients to be safely treated with an endovascular procedure.

The Aptus Endovascular Repair System provides active fixation via an endovascular stapling system that allows placement of EndoStaples along the proximal edge of the main body endograft. The EndoStaple is a 4-mm helical staple manufactured from medical-grade wire designed to engage the full thickness of the aortic wall in an active fashion (Figure 1).

STUDY OBJECTIVE

The primary objective of this study was to evaluate the feasibility of the Aptus Endovascular AAA Repair System in treating infrarenal abdominal aortic or aorto-iliac aneurysms. A series of intensive bench, animal, and cadaver tests were completed. This first-in-man experience was designed to evaluate the acute safety of the device.

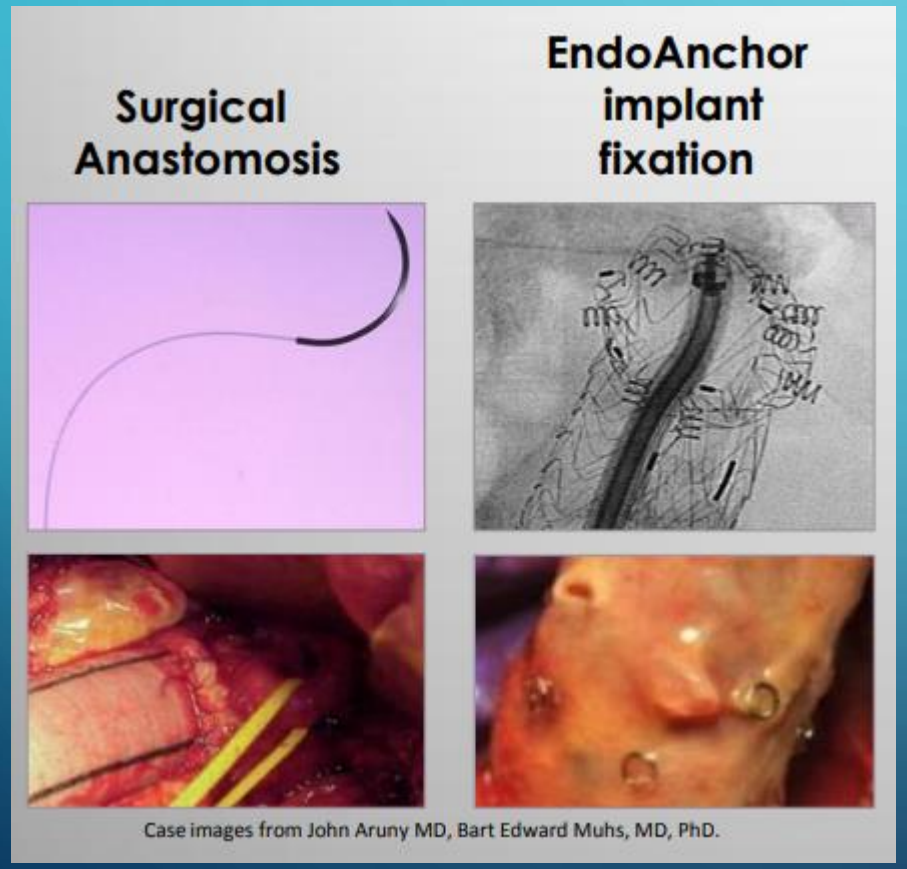
STUDY DESIGN

This study was a prospective, single-arm, ethics committee-approved study to evaluate the feasibility of the Aptus Endovascular AAA Repair System for treatment of infrarenal abdominal aortic or aorto-iliac aneurysms. No attempt was made to draw statistically valid conclusions regarding safety or performance from this small sample size. Postprocedure follow-up evaluations include 30 days, 6 months, 1 year, and 2 years.

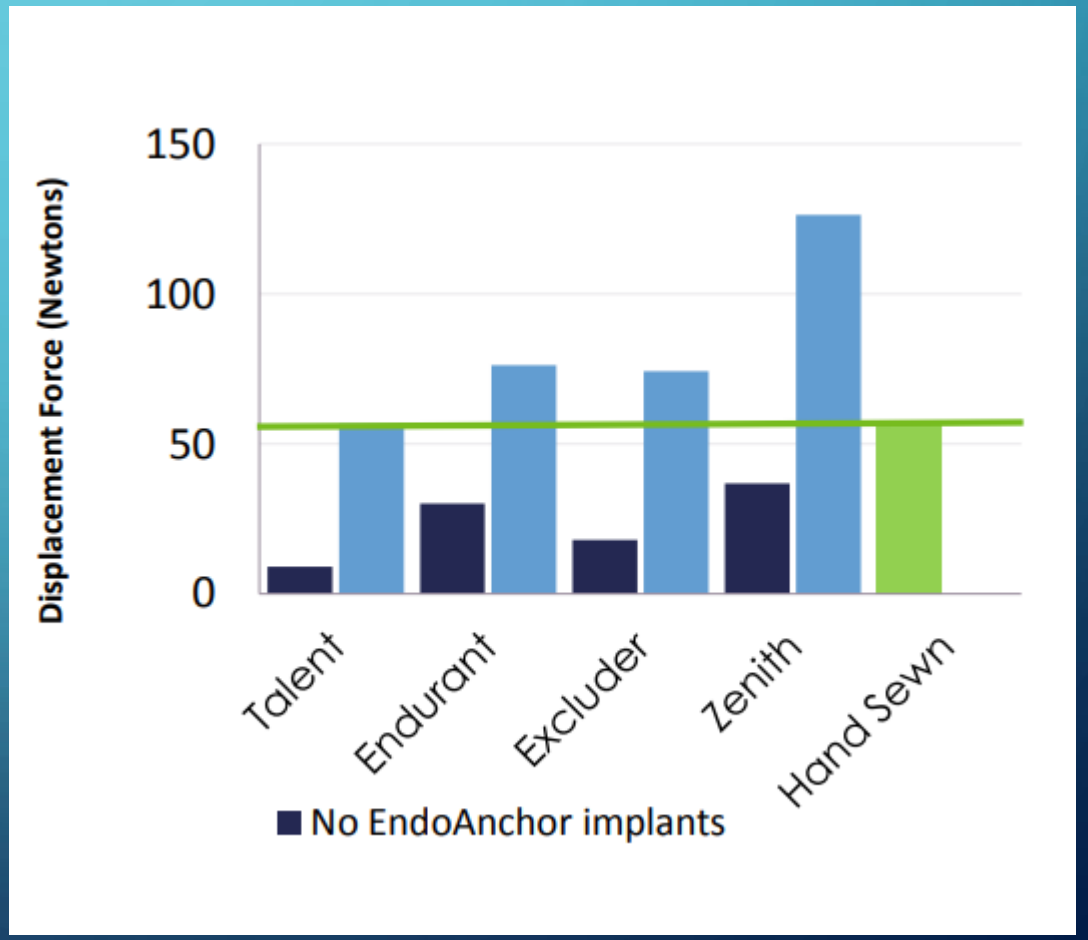
Figure 1. The relative scale of an EndoStaple.

Recreating the stability of surgical anastomosis

EndoAnchor implants establish surgical anastomosis strength in EVAR & TEVAR



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



Aptus™ Heli-FX™ EndoAnchor™ System Indications

SELECT SUBSET OF ENDOVASCULAR PATIENTS

Secondary	Primary	Primary
EXISTING SEAL COMPLICATIONS	**HIGHLY CHALLENGING ANATOMIES**	**MITIGATING RISK FACTORS**
• Acute & late Type I endoleaks[1] • Type I endoleaks in urgent or ruptured EVAR • Augmenting stability in migrated grafts[2]	• Irregularly shaped necks (short, wide, highly angulated, conical)[1] • Difficult landing zones[2]	• Severe comorbidities • Patients potentially lost during F/U[3] • Long remaining life expectancy[3]

GUIDE

Deflectable tip

- Allows the user to position the EndoAnchor™ implant precisely to intended location in diverse and complex anatomies

16 F / 18 F profile

- Compatible with current EVAR and TEVAR procedures

Guide markers

- Ease orienting and positioning of Guide

Multiple deflection lengths

- Accommodate large range of aortic neck diameters

ENDOANCHOR™ IMPLANT[5]

Helical shape

- 3.0 mm diameter × 4.5 mm length
- MP35N-LT material: demonstrated durability, excellent radiopacity

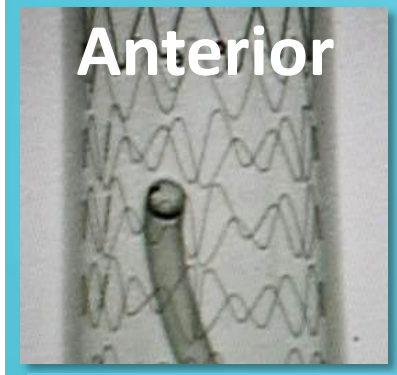
Conical tip

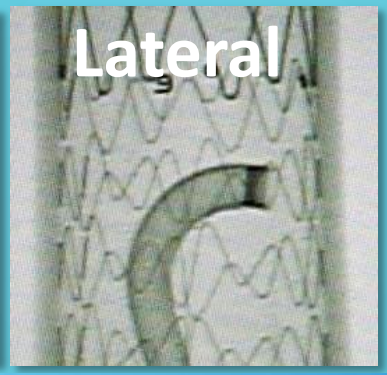
- Atraumatic and nondamaging to compatible stent grafts

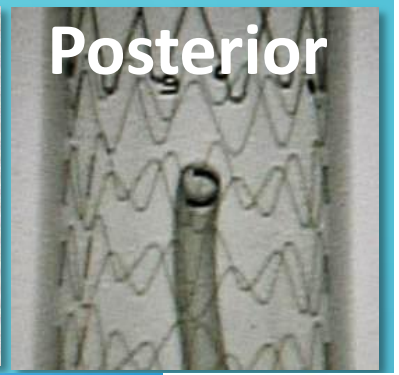
Crossbar

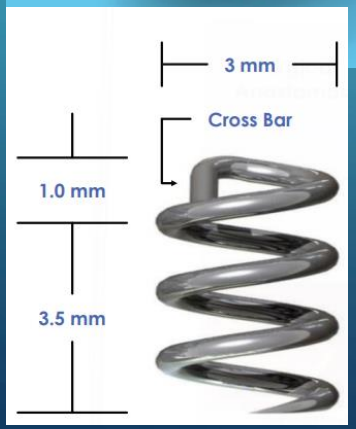
- Prevents over penetration

Orientation









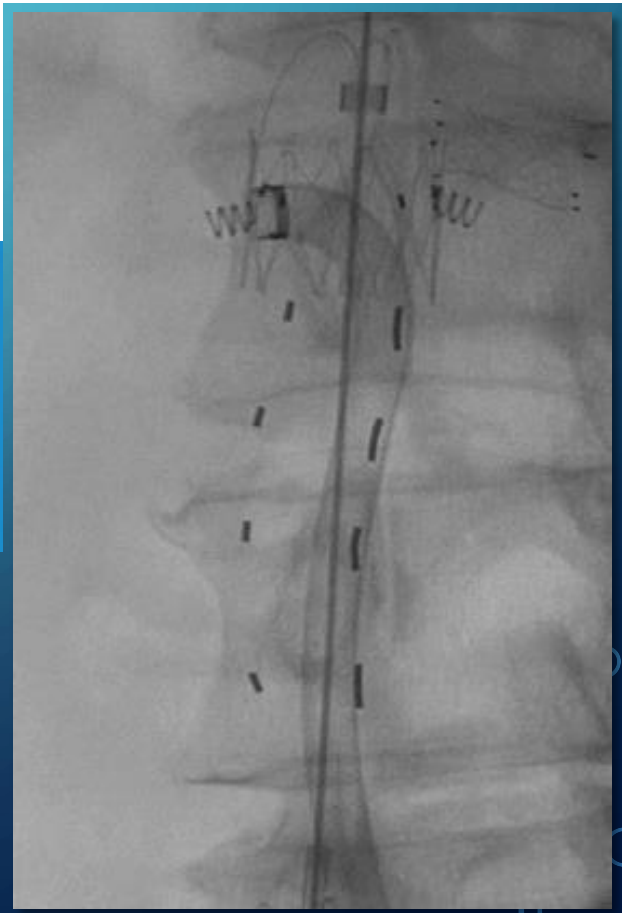
APPLIER

Two-stage EndoAnchor™ deployment

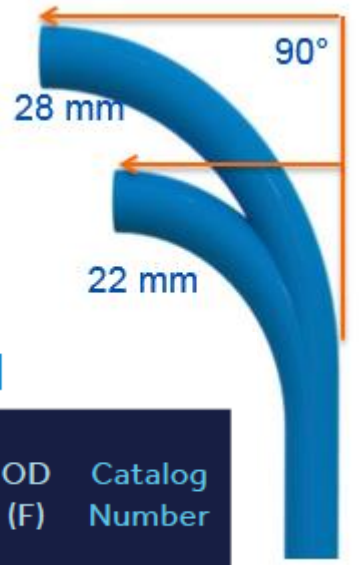
- Allows placement confirmation and repositioning

Motorized controls, light panel

- Ease of deployment, guides user through each step



Aptus™ Heli-FX™ EndoAnchor™ System



Product information

EVAR ORDERING INFORMATION

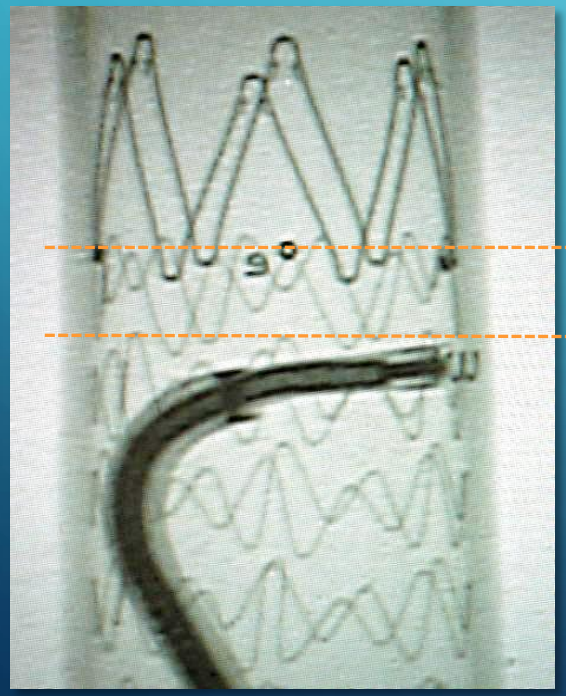
AAA Components (mm)	Deflected Tip Reach (mm)	Recommended Neck Diameter (mm)	Working Length (cm)	OD (F)	Catalog Number
Heli-FX™ Guide, 22	22	18-28	62	16	SG-64
Heli-FX™ Guide, 28	28	28-32	62	16	HG-16-62-28
Heli-FX™ Applier and EndoAnchor™ Cassette (w/10 EndoAnchor™ Implants)	NA	NA	86	12	SA-85

TEVAR ORDERING INFORMATION

TAA Components (mm)	Deflected Tip Reach (mm)	Recommended Neck Diameter (mm)	Working Length (cm)	OD (F)	Catalog Number
Heli-FX™ Guide, 22	22	18-28	90	18	HG-18-90-22
Heli-FX™ Guide, 32	32	28-38	90	18	HG-18-90-32
Heli-FX™ Guide, 42	42	38-42	90	18	HG-18-90-42
Heli-FX™ Applier and EndoAnchor™ Cassette (w/10 EndoAnchor™ Implants)	NA	NA	114cm	12	HA-18-114

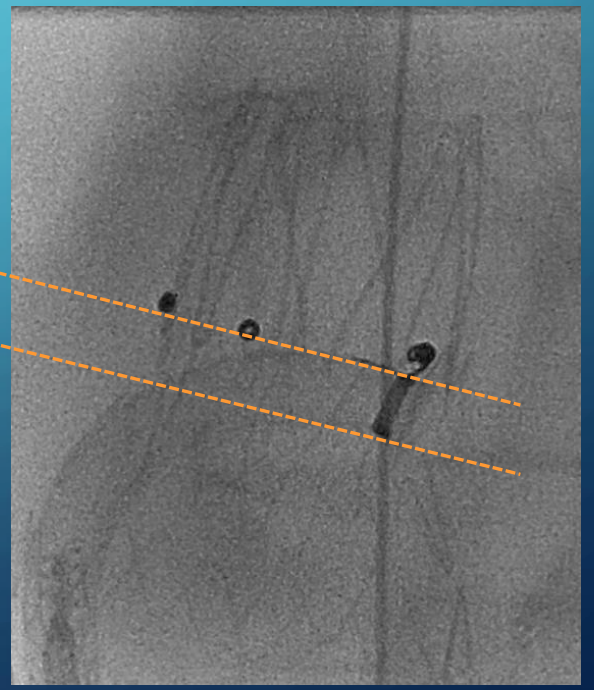
Recommended EndoAnchoring Zone

- EndoAnchor™ implantation should be performed in the proximal sealing zone of the endograft, typically within the ***most proximal*** sealing stent, in apposition to the native vessel wall.
- EndoAnchor™ implantation in areas of loose fabric or fabric not in apposition to the native vessel wall can result in **reduced fixation** and/or can lead to excessive catheter torque or potential EndoAnchor **disengagement** issues.



Marker Line – Edge of Graft

Bottom of Proximal Sealing Zone

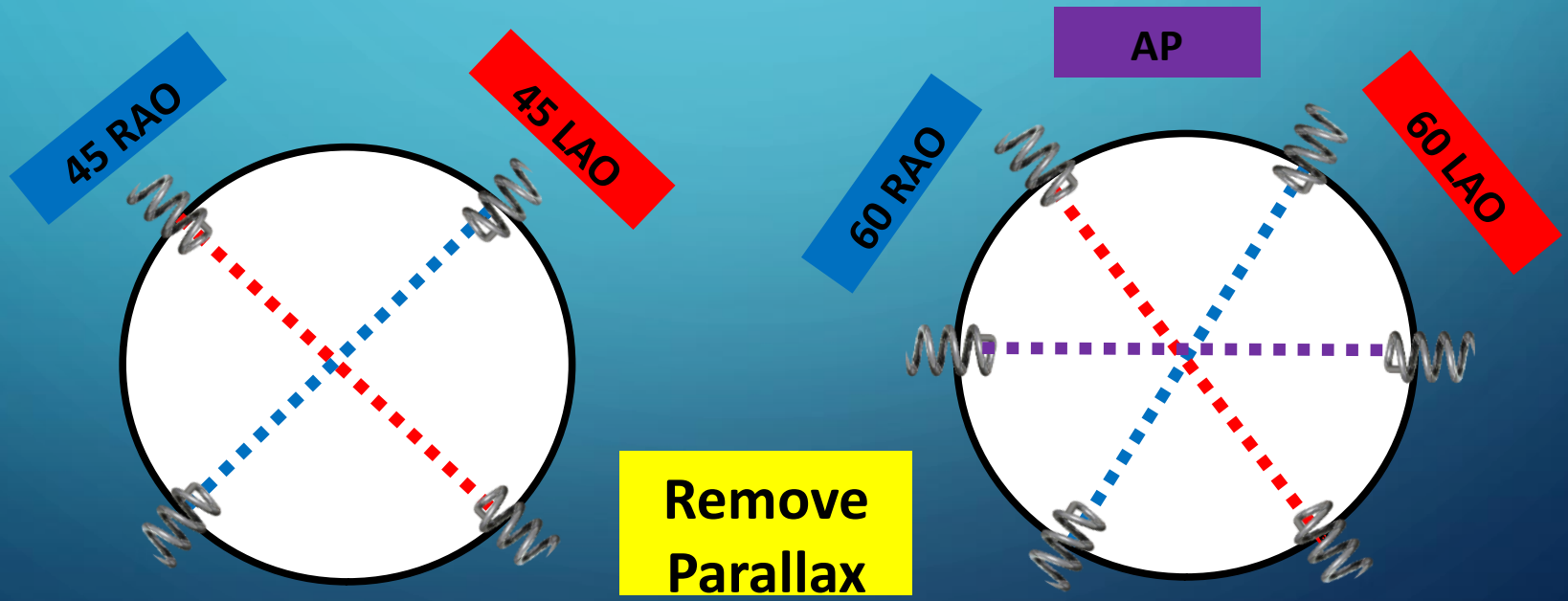


C-arm Positioning Guidelines For Best Visualization

Ensure Guide and Applier are perpendicular to the endograft before deploying the EndoAnchors

≤ 29mm Aorta:
4 Anchors

30-32mm Aorta:
6 Anchors



C-arm Positioning Guidelines For Best Visualization

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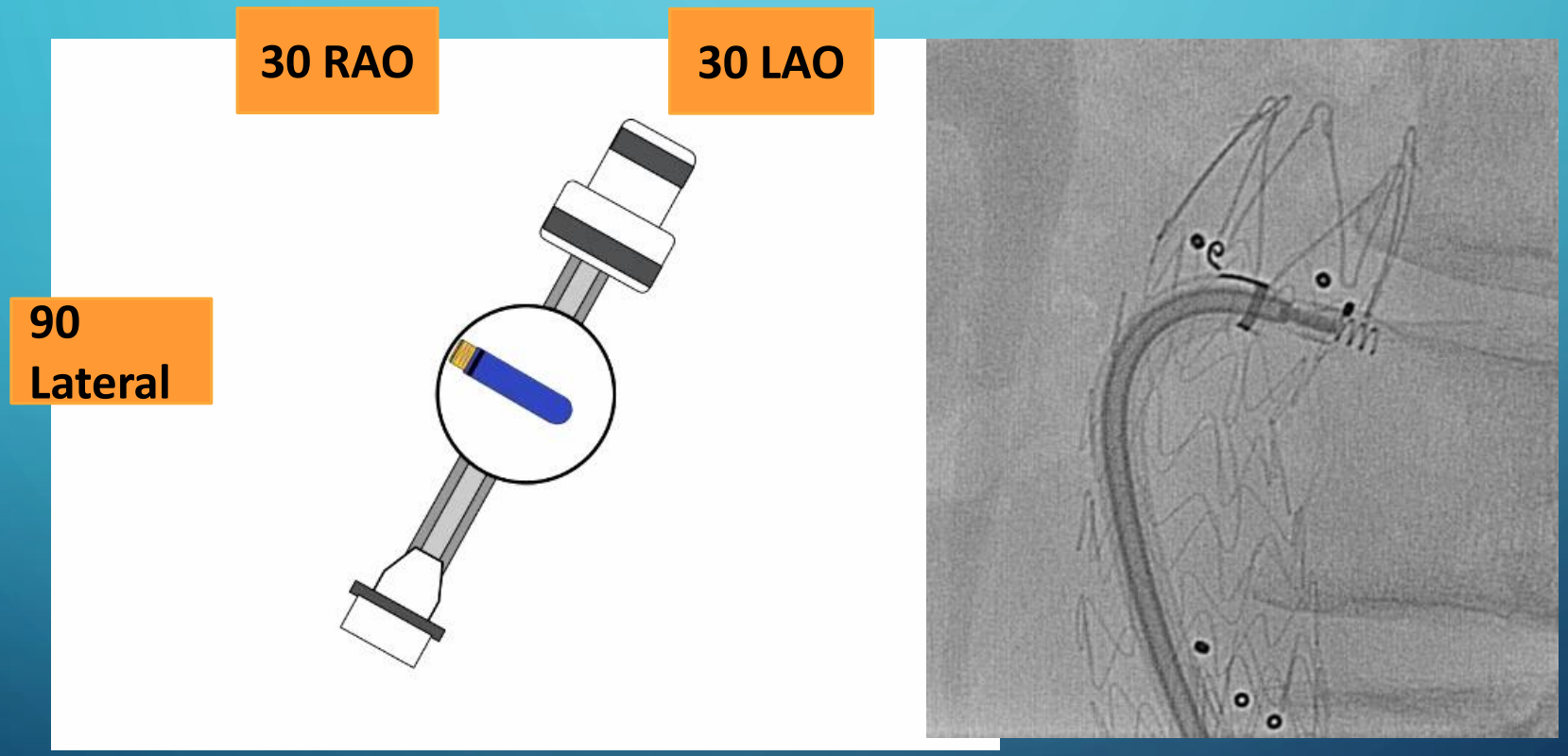


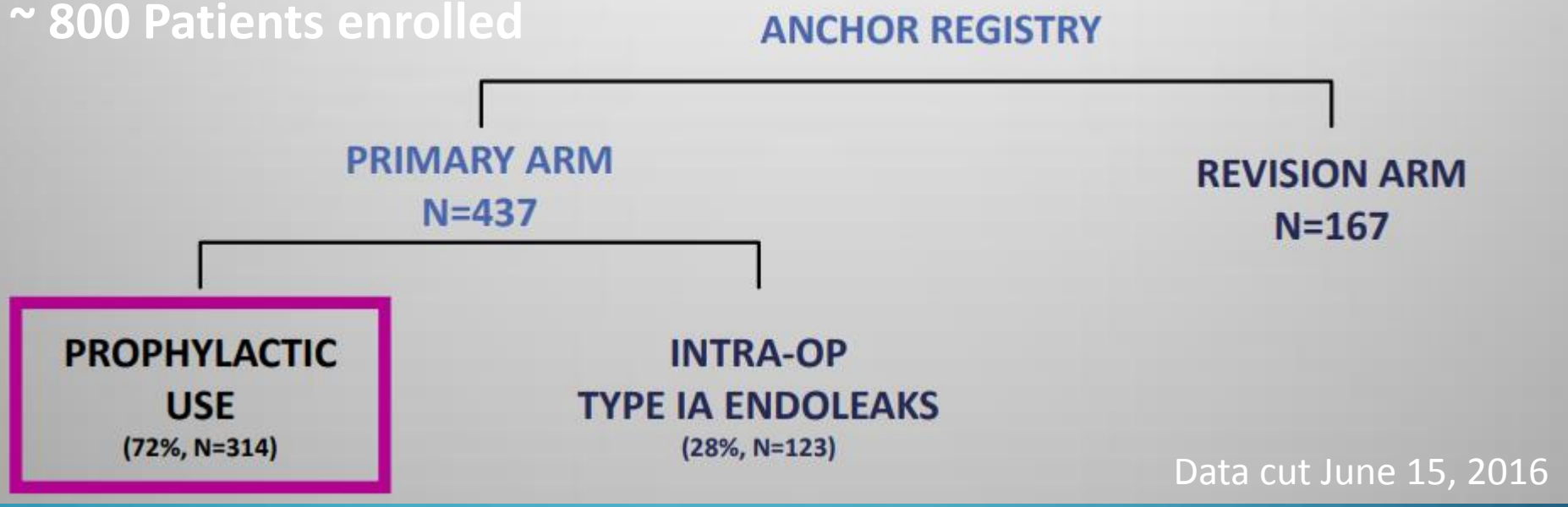
Remove Parallax

Note: Fixed C-Arm > 60 RAO / AP / 60 LAO

ANCHOR trial

prospective multinational trial, begun in 2012
includes 43 US and European centers

~ 800 Patients enrolled



Data cut June 15, 2016

Technical Success
Successful deployment of EndoAnchor implants with adequate penetration into aortic wall

Procedural Success
Technical success without type Ia endoleak at completion arteriography

Avg. duration of Procedure (min)	Avg. time to EndoAnchor implants (min)	Avg. number of EndoAnchor implants
141	15.8	5.5

*Market share :96%

1 year outcome of ANCHOR trial

Primary cohort (initial EVAR)
n = 73

Revision cohort
n = 27

Patient group	Medtronic Endurant	Medtronic Talent	Medtronic AneuRx	Cook Zenith	Gore Excluder	Other
All ($N = 100$)	36 (36%)	4 (4%)	11 (11%)	16 (16%)	31 (31%)	2 (2%)
Primary ($N = 73$)	33 (45%)	0	0	14 (19%)	26 (36%)	0
Revision ($N = 27$)	3 (11%)	4 (15%)	11 (41%)	2 (7%)	5 (19%)	2 (7%)

	All	Primary	Revision	*P*-value Primary vs. Revision
Patients with images available for core laboratory analysis	100	73	27	
Hostile neck[a]	83%	86%	76%	.325
Number of EndoAnchors deployed	5.3 ± 1.8	4.9 ± 1.5	6.1 ± 2.2	.021
Procedure duration (minutes)	132 ± 62	125 ± 53	151 ± 82	.147
Fluoroscopy use (minutes)	29 ± 14	29 ± 12	29 ± 18	.969
Technical success	93 (93%)	69 (95%)	24 (89%)	.384
Procedural success	89 (89%)	67 (92%)	22 (81%)	.161
Type Ia endoleak at end of procedure[a]	6 (6%)	3 (4%)	3 (11%)	.339
Intensive care unit (percent admitted)	32 (32%)	22 (30%)	10 (43%)	.630
Length of hospitalization (days)	3.0 ± 3.1	2.6 ± 2.3	3.9 ± 4.6	.176

*A hostile neck was defined for neck length <10 mm, neck diameter >28 mm, angulation >60, conical configuration or significant mural thrombus or calcium

Vascular. 2016 Apr;24(2):177-86

Original Article

Vascular

Vascular
2016, Vol. 24(2) 177–186

DOI: 10.1177/1708538115590727
vas.sagepub.com
SAGE

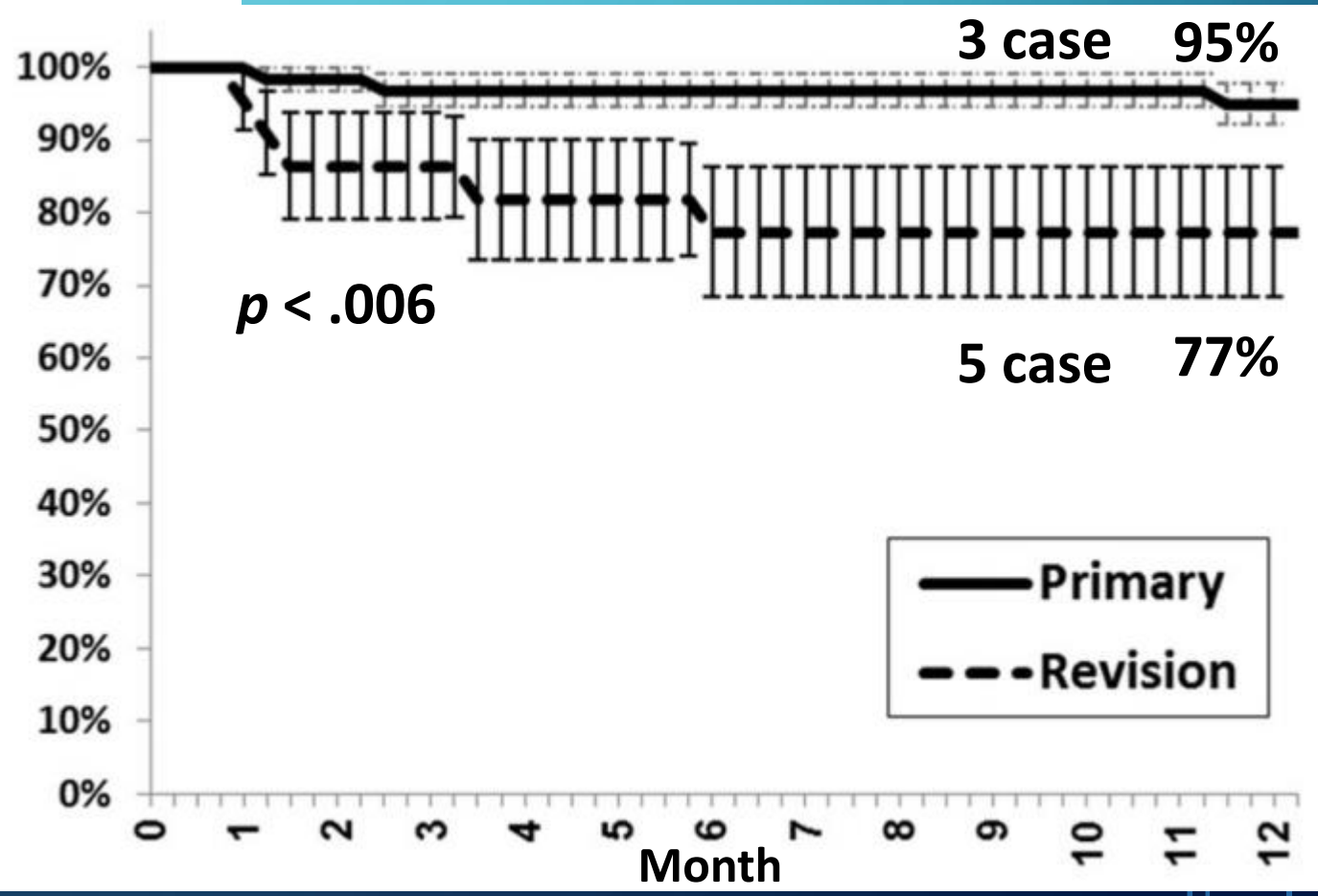
One-year results of the ANCHOR trial of EndoAnchors for the prevention and treatment of aortic neck complications after endovascular aneurysm repair

William D Jordan Jr[1], Manish Mehta[2], Kenneth Ouriel[3], Frank R Arko[4], David Varnagy[5], James Joye[6], William M Moore Jr[7] and Jean-Paul PM de Vries[8]

6 patients (6%) underwent aneurysm-related Reinterventions. (2/73 in primary patients, 4/27 in revision patients)

Aneurysm sacs regressed > 5 mm within one year in 45% (19/42) of the Primary cases and in 25% (3/12) of the Revisions. Aneurysm expansion > 5 mm occurred in one revision patient (1/12).

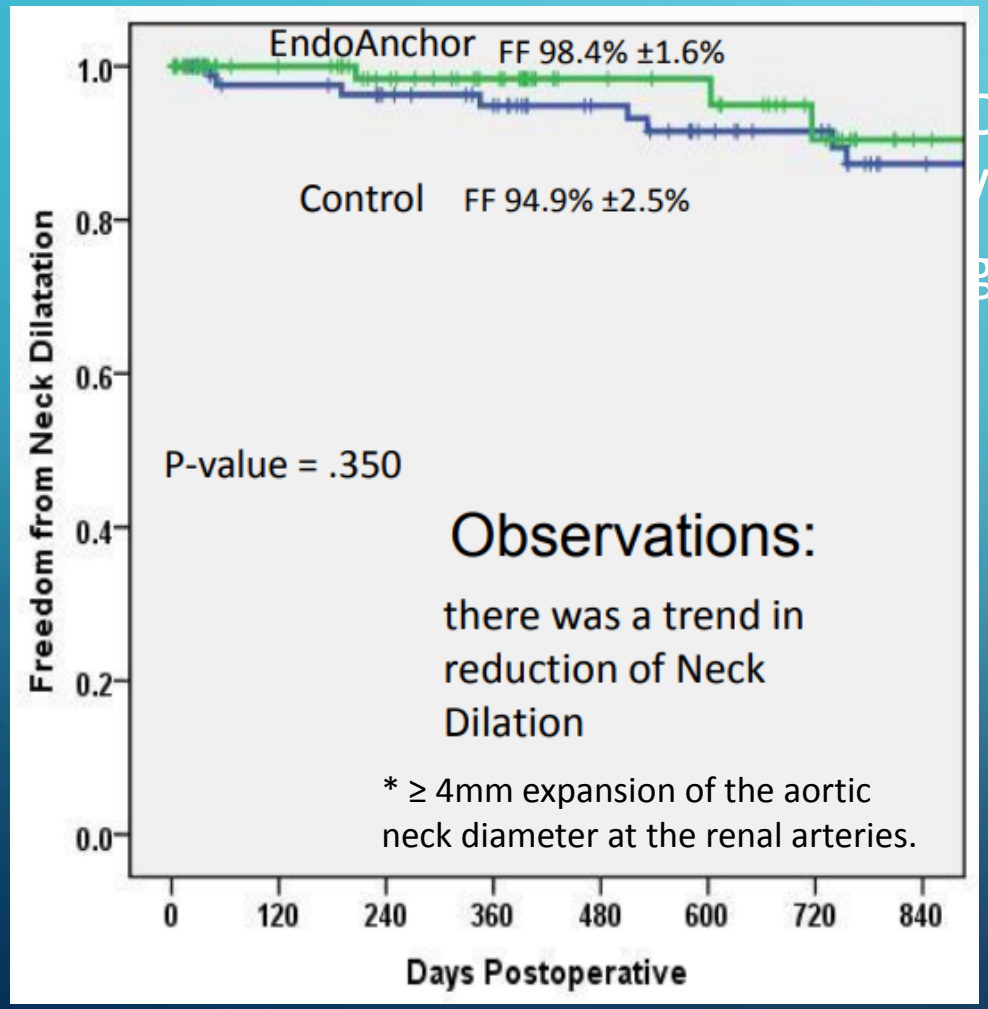
Freedom from type Ia endoleak

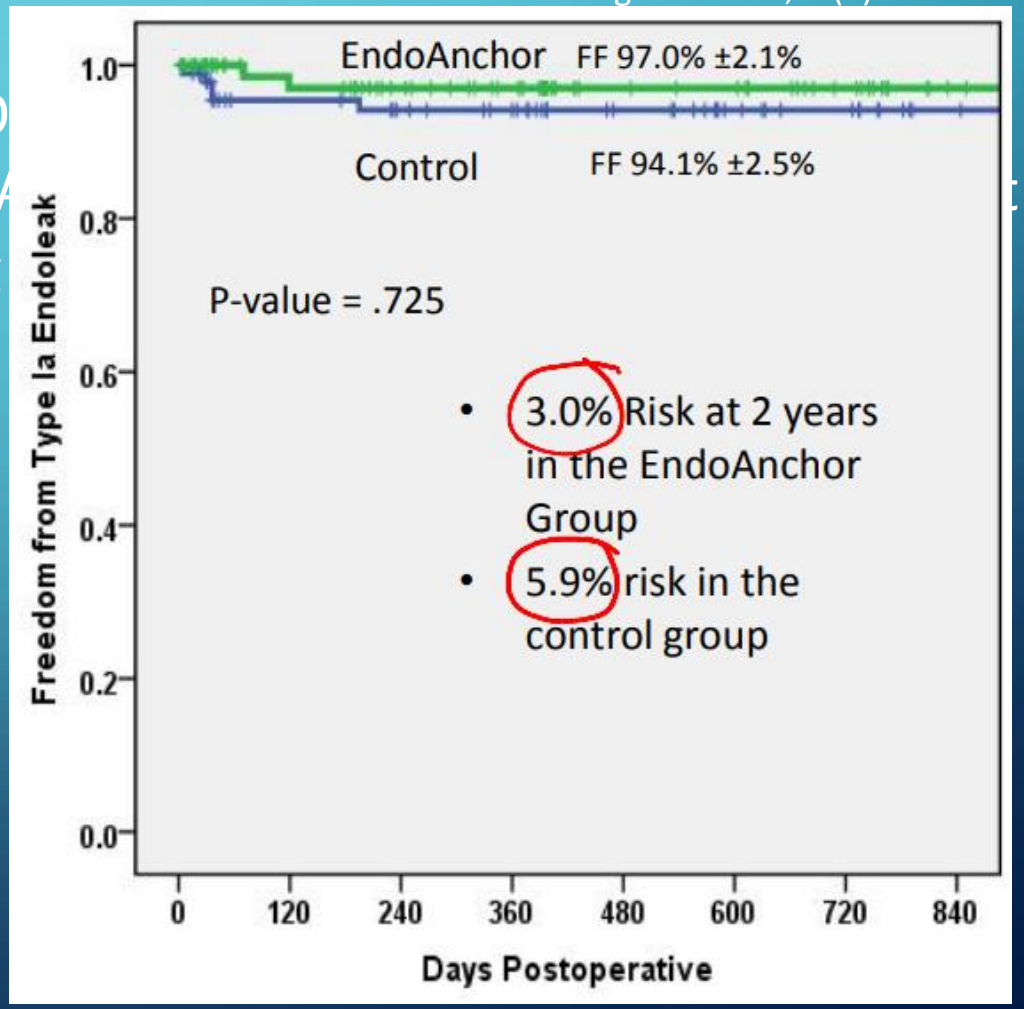


Matched cohort comparison of endovascular abdominal aortic aneurysm repair with and without EndoAnchors

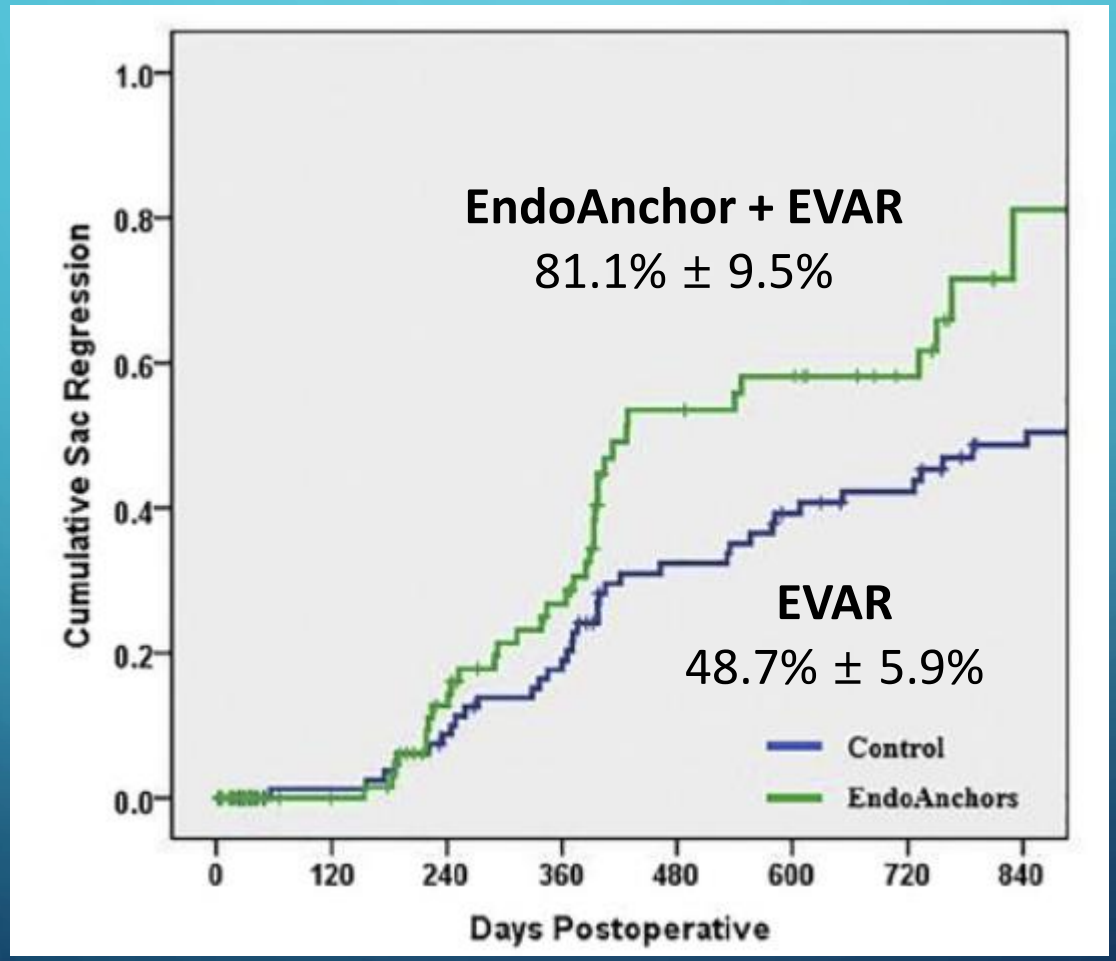
Bart E. Muhs, MD, PhD,[a] William Jordan, MD,[b] Kenneth Ouriel, MD,[c] Sareh Rajaee, MD,[d] and Jean-Paul de Vries, MD,[e] *Middletown and New Haven, Conn; Atlanta, Ga; New York, NY; and Nieuwegein, The Netherlands*

J Vasc Surg. 2018 Jun;67(6):1699-1707.





Cumulative sac regression 2 years after endovascular repair of AAA with or without EndoAnchors



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

Seline R. Goudeketting, MSc,[a,b] Kim van Noort, MSc,[a,b] Kenneth Ouriel, MD,[c] William D. Jordan Jr, MD,[d] Jean M. Panneton, MD,[e] Cornelis H. Slump, MSc, PhD,[b] *and* Jean-Paul P. M. de Vries, MD, PhD,[a] *Nieuwegein and Enschede, The Netherlands; New York, NY; Atlanta, Ga; and Norfolk, Va*

J Vasc Surg. 2018 Oct;68(4):1007-1016.

86 patients in ANCHOR registry were finally analyzed.

Good penetration = Medtronic Endurant endograft

Poor penetration = Large aortic neck diameter 10 mm below lowest renal artery
= Significant neck mural calcium

Postprocedural type IA endoleak = No penetration of the EndoAnchor

보험기준 및 국내 사용현황

Summary

1. Hostile neck is a significant risk factor for type Ia endoleak after EVAR. It substantially increase the incidence of re-intervention as well as mortality.

2. EndoAnchor is a helical endostaples designed to 'pin' the graft fabric to the aortic wall.

3. It can be considered when acute (intra-op.) or late type Ia endoleak and graft migration are developed as well as the prophylactic use for high risk hostile neck.

4. ANCHOR trial showed the promising results in cases of endoleak sealing and prophylatic use to prevent aneurysmal neck or sac dilatation.

5. Large aortic neck diameter and significant neck mural calcium could limit the technical success rate of EndoAnchor implantation. Therefore, careful patient selection and procedure would be important for better clinical outcome.

Thank you