Endovascular Solutions to Effectively Deal With Hostile Neck Anatomy of AAAs Other Than F/B/EVAR:
Why They Should Be Favored

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VEITH SYMPOSIUM Connecting The Vascular Community 51st

Speaker's Financial Disclosures

Gore, Medtronic, Hospital Line/Endologix

Delphi Consensus definitions of hostile neck anatomy (HNA) predict complications

Hostility characteristic	Complication(s)
Reverse taper (conical) neck	Proximal failure of standard EVAR
Aortic neck length <10 mm	Endoleak Stent-graft migration Intraoperative complications
Aortic neck length <15 mm	**Late graft-related complications** Intraoperative and postoperative complications Reinterventions Stent-graft migration

Marone, Ann Vasc Surg 2020

Delphi Consensus definitions of hostile neck anatomy (HNA) predict complications

Hostility characteristic	Complication(s)
Aortic neck angulation >60 ^{0}	**Late graft-related complications** Type Ia endoleak Reinterventions
Large neck diameter (from >26 mm to >32 mm)	Overall mortality Reintervention, technical failure, and late type IA endoleaks Endograft complications
Calcification (from >25 to >50%)	Intraoperative and postoperative complications Late prosthesis migration and type Ia endoleak

Marone, Ann Vasc Surg 2020

Criteria to compare success of dedicated endografts effectively dealing with HNAs compared with other solutions (FEVAR/BEVAR/open repair)


Aorta and Major Branches

Eur J Vasc Endovasc Surg (2024) 68, 294–302

EJVES Open Access

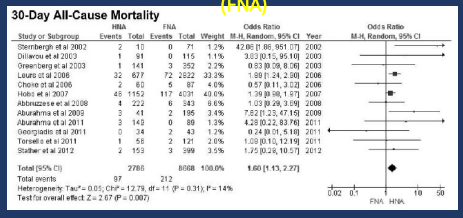
Editor's Choice – A Core Outcome Set for Intact Abdominal Aortic Aneurysm Repair

Matthew Machin [a,*], Anders Wanhainen [b,c], Mario D'Oria [d], Mark Koelemaij [e], Stavros Kakkos [f], Matthew Joe Grima [g], Janet T. Powell [h], and collaborators [†]

Ranking	Outcome	Time point
1	Death	30 days (or in hospital if longer)
2	Secondary rupture	Follow up
3	Quality of life	After recovery
4	Loss of cognitive function	After recovery
5	Longer term survival	5 years
6	Aneurym growth after repair	Follow-up, especially post-EVAR

Top ranking outcome

Hostile neck anatomy (HNA) is associated with a higher 30-day all-cause mortality after EVAR compared with favorable neck anatomy (FNA)



16 studies with 11,959 patients

Stather, J Endovasc Ther 2013

Hostile neck anatomy (HNA) is associated with a higher 30-day all-cause mortality after EVAR compared with favorable neck anatomy (FNA)

- OLD STUDIES
- DEVICES OUTSIDE OF IFU?
- BEFORE THE ADVENT OF DEDICATED DEVICES, DEALING WITH HOSTILE NECK ANATOMY!

16 studies with 11,959 patients

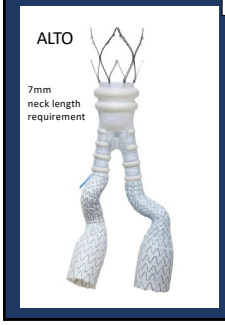
Stather, J Endovasc Ther 2013

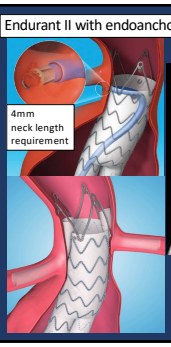
Approved endografts for hostile neck anatomy

HNA category	Conditions	Endografts	IFU
Angulated aortic neck	60°-90° angle of the aortic neck	Anaconda™*	≤ 90° aortic neck angle
		Aorfix™ *	≤ 90° aortic neck angle
		GORE® EXCLUDER® Conformable	≤ 90° aortic neck angle
		Treovance®	≤ 75° aortic neck angle if proximal neck length ≥ 15 mm
Reverse taper (conical) aortic neck	>2 mm reverse taper within 1 cm below the renal arteries	ALTO® Ovation iX™†	
Short aortic neck	<15 mm length of the aortic neck	ALTO®	≥ 7 mm aortic neck length
		GORE® EXCLUDER® Conformable	≥ 10 mm aortic neck length when aortic neck angulation ≤ 60°
		Endurant™ II	≥ 10 mm aortic neck length when aortic neck angulation ≤ 60°
		Endurant™ II w/EndoAnchors	≥ 4 mm aortic neck length
		Ovation iX™†	≥ 13 mm aortic neck length
		Treovance®	≥ 10 mm aortic neck length when aortic neck angulation ≤ 60°
Neck thrombus/ calcification	≥ 50% of the aortic neck circumference	N/A	N/A: Not available

* Not approved by the FDA

Pitros and Kakkos, Vasc Invest Ther, 2022





The only FDA approved device for short (10mm) neck length and aortic neck angulation ≤90^0

Dedicated devices for HNA have a high technical success and low 30-day mortality rate

TABLE 4 Clinical outcomes of endografts for hostile neck anatomy

Device		Alto (46)	Anaconda * (40)	Aorfix (17) *	Conformable (21)	Endurant II (51)	Ovation iX (42, 43)	Treovance (52, 53)
Follow-up (months)		12	60	12–60	12	12–60	60	12
Technical success rate		100%	98.3%	96.3%	100%	99.3%	99.7%–100%	96%
Secondary intervention		2.7%	21.9%	1%–17%	2.5%	11%	7.6%–20.3%	3.5%–4.7%
Mortality rate	30-day	0%	1.7%	1.8% (median of groups)	0%	0%	0.3%–0.6%	0%
	AAA related	0%	2.3%	4% in 5 years follow-up	0%	0.8%	0.6%–0.7%	0%
	All causes	4%	34.1%	7%–31%	3.8%	17.7%	21.1%–21.7%	1.4%–6.4%

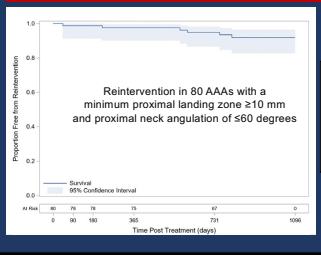
* Not approved by the FDA

Pitros, Mansi, Kakkos, Front Surg, 2022

Thirty-day mortality rate for standard EVAR is lower compared with FEVAR (or open repair)

- 6,058 AAA patients unfit for open repair in VQI (2003-2022): 4.5% for open repair vs 1.4% for PSM matched EVAR, P < .001. (Khoury, J Vasc Surg, 2024)
- Meta-analysis of 27 studies on 2974 patients with a short neck AAA or a complex AAA: 3.3% for FEVAR compared with 4.2% after open repair. (Jone, BJS Open 2019)
- UK COMPASS: Perioperative mortality with FEVAR: 2.2% and off label EVAR 1.2%.

Three-year outcomes of a US pivotal trial substudy for the Excluder Conformable endograft in ≥10 mm nonangulated neck anatomy



There was 100% freedom from type I and III endoleak and aneurysm-related mortality at 36-months

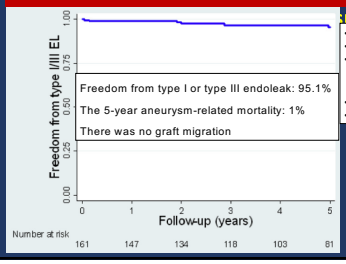
Yamanouchi, Oderich, et al, for the EXCC Investigators. J Vasc Surg 2024, in press

Early results from the pivotal trial substudy of the GORE EXCLUDER conformable endoprosthesis in angulated necks

- Overall technical success was achieved in 93/95 patients (97.9%).
- Primary effectiveness at 12 months (having device technical success and absence of type I and III endoleak, migration, sac enlargement or rupture, and conversion to open repair) was achieved in 94.8%.
- Four patients (4.3%) had a type IA endoleak, no intervention.
- No aneurysm-related deaths, ruptures, or migration through 12 months.

Rhee et al, J Vasc Surg 2024, in press

System investigational device exemption trial for endovascular

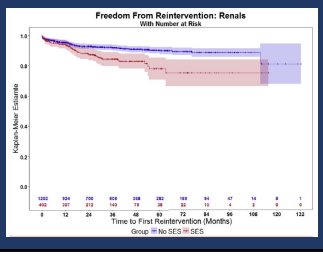


- AAA diameter ≥5 cm,
- proximal parallel neck length ≥7 mm,
- inner wall diameter of no less than 16 mm and no more than 30.5 mm at 13 mm below the inferior renal artery,
- neck angulation ≤60 degrees, and
- bilateral iliac fixation length ≥10 mm.

Barleben, et al, on behalf of the Ovation trial investigators, J Vasc Surg 2020

JAGUAR – ALTO – RCT TO BE PRESENTED TOMORROW

Standard – within the IFU – EVAR should be preferred, whenever possible, because it is simpler, safer and less expensive than FEVAR

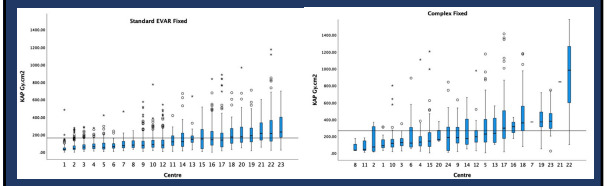


Risk of SMA/renal artery occlusion and re-intervention is negligible for standard and HNA-dedicated EVAR

Farivar, J Vasc Surg 2021

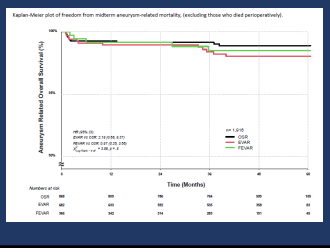
Reduced radiation dose with standard EVAR

75th percentile of the medians 162Gy*cm² vs 266Gy*cm² for BEVAR



RADEVAIR collaborator, Cardiovasc Intervent Radiol, 2024

Standard – within the IFU – EVAR should be preferred, whenever possible



Similar midterm aneurysm-related mortality with FEVAR and open repair of complex AAAs

UK-COMPASS
Vallabhaneni SR, EJVES, 2024

Conclusions

- **Recent – inside the IFU – innovations have accomplished a safe endovascular repair and mostly demonstrated excellent mid term effectiveness for AAAs with a "hostile" neck.**
- **These results challenge the concept of the hostile neck, which call for an individualized device selection approach, an already widespread practice across the globe.**
- **Long term (10 year) results are eagerly awaited.**


Thank you!