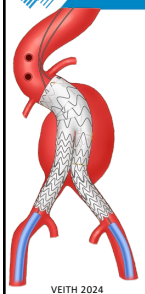

How To Optimize Infrarenal Aortic Neck Sealing With Short Or Angulated Necks (> 60-90 Degrees) Without Placing Branches In The Renals

The Unique Features Of The Gore Excluder Conformable AAA Endograft: >1 Year Results

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VEITH 2024

Disclosures

- WL Gore
  - National Principal Investigator of 13-03 IDE trial
  - Consultant, Speaker
- GE Healthcare
  - Consultant
- Cook
  - Research, Education grants
- Boston Scientific
  - Medical Advisory Board

2

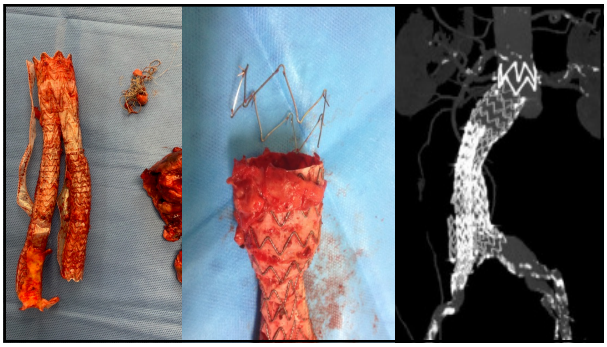
Why is this infrarenal EVAR device so significant?

INVITED COMMENTARY

The continued need for infrarenal sealing endovascular aneurysm repair devices

Why? 80%+ of all AAA's in USA

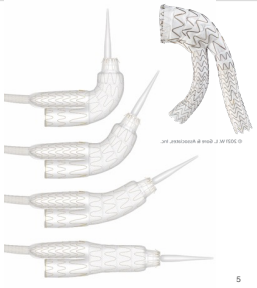
3



The Next Generation EVAR device "wish list" circa 2008

Control and Conformability

1. Entire use of landing zones
   "every mm of usable is neck used"
2. Stabilization and adjustability of device and delivery system during deployment
3. Conforming of the endovascular device to the native proximal aortic anatomy



5

Timeline of "new gen" Excluder (Conformable)

- 2008 Vascular surgeon input from US, EU, Asia (n=11)
- 2009 R&D concept and budget approved (100m +)
- 2012 National PI named, trial budget approved (15m +)
- 2014-15 FDA/PMA discussions
- 2017 Regulatory IDE clinical trial begins
- 2020 FDA approval *15mm-60 degree* indication
- 2024 FDA approval *10mm-90 degree* indication

6

U.S. Pivotal Trial overview

Study design

Prospective, non-randomized study with two arms.

- Short neck sub-study (≤ 60 degree)
  80 patients
- High neck angulation sub-study (> 60 < 90)
  95 patients

7

One-year results of the GORE EXCLUDER Conformable AAA Endoprosthesis system in the United States regulatory trial

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ABSTRACT

Objective: To report the 1-year clinical outcomes from the GORE EXCLUDER Conformable AAA Endoprosthesis system in the US regulatory trial.

Methods: The study is a prospective, multicenter, investigational device exemption clinical trial at 31 US sites with core laboratory assessment of imaging and independent event adjudication. The primary safety (incidence of major adverse events at 30 days) and effectiveness end points (successful aneurysm treatment at 1 year) were assessed in a cohort of

demonstrated with 98.5% freedom from primary effectiveness end point events at 1 year and 100% freedom from primary safety end point events assessed through 30 days. (J Vasc Surg 2022;76:951-9.)

respiratory failure, renal failure, procedural blood loss of more than 1000 mL, or thromboembolic events including limb occlusion or distal emboli. There were no type I or III endoleaks detected on the 1-, 6-, or 12-month follow-up computed tomography scans. There were no stent fractures, device migrations (≥10 mm), AAA ruptures, or conversions to open surgical repair observed. Two patients had AAA sac growth of more than 5 mm at 1 year owing to type II endoleaks. There were no aneurysm-related deaths within the 12-month follow-up, and freedom from aneurysm-related mortality was 100% through 1 year.

Conclusions: The safety and effectiveness of the GORE EXCLUDER Conformable AAA Endoprosthesis system has been demonstrated with 98.5% freedom from primary effectiveness end point events at 1 year and 100% freedom from primary safety end point events assessed through 30 days. (J Vasc Surg 2022;76:951-9.)

Keywords: Abdominal aortic aneurysm; Endograft; Endovascular repair

8

Three-year outcomes of a US pivotal trial substudy for conformable endoprosthesis in ≥10 mm nonangulated neck anatomy

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ABSTRACT

Objective: To report the midterm clinical outcomes from the GORE® EXCLUDER® Conformable AAA Endoprosthesis system (EXCC) pivotal regulatory trial in the United States (U.S.).

Methods: This is a prospective, multicenter, investigational device exemption clinical trial at 31 U S. sites with Core Laboratory assessment of imaging and independent adjudication of safety. The study enrolled patients with abdominal aortic aneurysms (AAA) with a minimum proximal landing zone ≥10 mm and proximal neck angulation of ≤60 degrees between December 2017 and February 2019 as part of a larger study to gain indications of the EXCC device. Endpoints included patient survival, freedom from secondary interventions, and stent-graft related outcomes.

Results: There were 80 patients enrolled (88.8% male, mean 73.5 ± 8.14 years-old). Mean maximum aortic diameter was 57.7±8.0 mm (range, 42.5-82.7). There was 100% freedom from type I and III endoleak and aneurysm-related mortality at 36-months. Freedom from secondary intervention was 91.9 ± (0.83, 0.96, 95% C.I.) at 36-months. There were no device fractures, migrations (≥10 mm), or aneurysm ruptures. At 36 months, thirteen patients (26.5%) had type 2 endoleak, 32 patients (58.2%) had AAA sac regression, 17 (30.9%) had no change in diameter, and 6 (10.9%) had sac enlargement. Seven patients (8.8%) through 36 months underwent reintervention.

Conclusions: The 3-year outcomes have continued to show an adequate safety and efficacy profile of the EXCC device with no aneurysm related mortality or Type I/III endoleak. These results demonstrate durability for an EVAR device in US regulatory trials. (J Vasc Surg 2024;■:1-11.)

Midterm (3 year) Results 13-03 EXCC short neck IDE trial

Variable	1 month, N (%)	6 mo	12 mo	24 mo	36 mo	Total N (%)
Subjects	80	79	79	75	67	80
Subjects with CT scan	79	75	74	58	55	80
Endoleak	33/75 (44.0%)	25/70 (35.7%)	21/67 (31.3%)	16/53 (30.2%)	13/49 (26.5%)	36/78 (46.2%)
Type I	0/75	0/70	0/67	0/53	0/49	0/78
Type IA	0/75	0/70	0/67	0/53	0/49	0/78
Type IB	0/75	0/70	0/67	0/53	0/49	0/78
Type II	31/75 (41.3%)	24/70 (34.3%)	18/67 (26.9%)	16/53 (30.2%)	13/49 (26.5%)	35/78 (44.9%)
Type III	0/75	0/70	0/67	0/53	0/49	0/78
Type IV	0/75	0/70	0/67	0/53	0/49	0/78
Indeterminate	3/75 (4.0%)	1/70 (1.4%)	3/67 (4.5%)	1/53 (1.9%)	0/49	7/78 (9.0%)
Subjects with diameter change data (from baseline)	-	75	74	58	55	-
Change in maximum abdominal aortic diameter from baseline						
≥ 5 mm Decrease	-	26 (34.7%)	27 (36.5%)	30 (51.7%)	32 (58.2%)	-
No Change	-	48 (64.0%)	46 (62.2%)	24 (41.4%)	17 (30.9%)	-
≥ 5 mm Increase	-	1 (1.3%)	1 (1.4%)	4 (6.9%)	6 (10.9%)	-
AAA Rupture	0/77	0/72	0/69	0/53	0/49	0/80
Migration	0/79	0/75	0/73	0/58	0/55	0/80
Wire Fracture*	0/73	0/69	0/71	0/55	0/51	0/80
Extrusion/Erosion	0/79	0/75	0/73	0/58	0/55	0/80

Early outcomes of the Conformable endograft in severe neck angulation from the Triveneto Conformable Registry

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ABSTRACT

Objective: The study reports retrospective evaluation of early outcomes from a multicentric experience with the Excluder conformable endograft with active control system (CEXC Device) in the treatment of abdominal aortic aneurysms. Its design allows more flexibility, given by proximal unconnected stent rows and a banding wire within the delivery catheter enables control of proximal angulation. This study specifically focuses on the severe neck angulation (SNA) subgroup (≥60°).

Methods: All patients treated with CEXC Device in nine vascular surgery centers of Triveneto area (Northeast Italy) between January 2019 and July 2022 were enrolled prospectively and analyzed retrospectively. Demographic and

respectively. Estimated freedom from reinterventions at 24 months was 92%. Aortic neck median postoperative angulation was 75° (range, 45°-139°).

and their data analyzed. The mean patient age was 78.9 ± 5.9 years and median abdominal aortic aneurysm diameter 59 mm (range, 45-94 mm). Median aortic infrarenal neck length, angulation and diameter were 22 mm (range, 13-58 mm), 77° (range, 60°-150°), and 22.0 ± 3.5 mm respectively. Analysis revealed a technical success rate of 100% and perioperative major complication rate of 1.7%. Intraoperative and perioperative morbidity and mortality rates were 3.5% (one buttock claudication and one inguinal surgical cutdown) and 0%, respectively. No perioperative type I endoleaks were observed. The median follow-up was 13 months (range, 1-40 months). Five patients died during follow-up from aneurysm-unrelated causes. Two reinterventions occurred (3.5%): one conversion for a type IA endoleak and one sac embolization for a type II endoleak. Aneurysm sac shrinkage was observed in 15 patients (26%) and aneurysm stability in 35 patients (62%), respectively. Estimated freedom from reinterventions at 24 months was 92%. Aortic neck median postoperative angulation was 75° (range, 45°-139°).

Conclusions: The Triveneto Conformable Registry shows good early results of the CEXC device in severely angulated aortic infrarenal necks. These data need confirmation on longer follow-up and a wider cohort of patients to further increase endovascular aneurysm repair eligibility in SNA. (J Vasc Surg 2023;78:954-62.)

11

From the Society for Vascular Surgery

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

High Neck Angle Substudy > 60 <90

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ABSTRACT

Objective: To report the investigational device exemption study 1-year clinical outcomes of the high neck angulation (HNA) substudy of the GORE EXCLUDER Conformable AAA Endoprosthesis (EXCC) for treatment of infrarenal abdominal aortic aneurysms (AAAs).

Methods: This study is a prospective, multicenter clinical trial conducted in the United States and included core laboratory assessment of imaging and independent event adjudication. Anatomical criteria for enrollment in the HNA substudy included infrarenal aortic neck angulation >60° and ≤90° with aortic neck length ≥10 mm. Primary safety end points included estimated blood loss of >1000 mL, death, stroke, myocardial infarction, bowel ischemia, paraplegia, respiratory failure, renal failure, and thromboembolic events. Primary effectiveness end points included technical success, absence from type I and III endoleaks, migration (≥10 mm), sac enlargement (≥5 mm), sac rupture, and conversion to open repair.

Results: Between January 2018 and February 2022, 95 patients were enrolled in the HNA substudy across 35 sites. Of the 95 patients, 71 (74.7%) were male and the cohort average age was 74.4 years. The mean infrarenal proximal aortic neck angle was 71.6° and the mean AAA size was 62.9 mm. Overall technical success was achieved in 93 patients (97.9%). Freedom from a primary safety end point through 30 days was 96.7%; 3 (3.3%) patients had an estimated blood loss of >1000 mL. Freedom from the primary effectiveness at 12 months was achieved in 94.8%. Four patients (4.3%) had a type IA endoleak; intervention after the procedure was not required and no subsequent interventions or sac enlargement were noted in these patients. At 12 months, 29 patients (39.7%) experienced a type II endoleak and 1 (1.3%) patient experienced AAA sac expansion of ≥5 mm. Through 12 months, 1 patient (1.3%) had a conversion to open surgical repair. There were no aneurysm-related deaths, ruptures, or migration through 12 months.

Conclusions: The investigational device exemption study demonstrates safety and effectiveness of the GORE EXCLUDER Conformable AAA Endoprosthesis device in AAA with highly angulated necks (>60° and ≤90°) are preserved at the 12-month follow-up. (J Vasc Surg 2024;■:1-9.)

12

DEMOGRAPHICS & ANATOMIC CHARACTERISTICS

Characteristics of Enrolled Patients	
Demographics	**N=95**
Age, years, mean (SD)	74.4 (7.23)
Sex at birth, n (%)	
Male	71 (74.7)
Female	24 (25.3)
Ethnicity, n (%)	
Not Hispanic or Latino	88 (92.6)
Hispanic or Latino	3 (3.2)
Unknown	4 (4.2)
Race[a], n (%)	
White	87 (91.6)
Black or African American	3 (3.2)
American Indian or Alaska Native	1 (1.1)
Other	4 (4.2)
BMI, kg/m^2, mean (SD)	30.1 (7.93)
Range	16.9, 66.3
Median	28.5

Pretreatment measurements mean (SD)	N=95
Maximum aortic diameter, mm	62.9 (11.8) 42.7-103.1
Aortic neck length, mm	21.3 (10.1) 10.0-57.0
Infrarenal aortic neck angle	71.6 (9.2) 61.0-90.0

13

PRIMARY SAFETY OUTCOMES

Primary Safety Endpoint	
Patients eligible for safety endpoint analysis[a]	N=92
Freedom from safety event at 30 days, n (%)	89 (96.7)
Safety event at 30 days, n (%)	3 (3.3)
Procedural blood loss >1000 mL (at index procedure)	3 (3.3)
Death[c]	0
Stroke[c]	0
Myocardial infarction[c]	0
Bowel ischemia[c]	0
Paraplegia[c]	0
Respiratory failure[c]	0
Renal failure[c]	0
Thromboembolic events[c]	0

- Three patients with procedural blood loss >1000 ml
  - Access related complications
  - Received blood transfusions

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PRIMARY EFFECTIVENESS OUTCOMES

Primary Effectiveness Endpoint Through 12 months	
Patients eligible for primary effectiveness endpoint analysis[b]	N=77
Primary effectiveness endpoint success, n (%)	73 (94.8)
Technical Success, n (%)	75 (97.4)
Successful access, deployment, removal of delivery catheters, patent, and access site closure	77 (100.0)
Site-reported Type I and Type III endoleak[d]	2 (2.6)
Type I or Type III endoleak at 12 months[e], n (%)	0
Migration ≥10 mm[e], n (%)	0
AAA enlargement ≥5 mm[e], n (%)	1 (1.3)
AAA rupture[f], n (%)	0
Conversion to open repair[f], n (%)	1 (1.3)

15

12 month outcomes

AAA sac behavior

High Angulation Substudy	6 Months	12 Months
Substudy	76	75
High Neck Angulation Substudy (> 60° and ≤ 90°)		
Change in Maximum Abdominal Aortic Diameter from Baseline (Core Lab)		
≥ 5mm Decrease	22(28.9%)	26(34.7%)
No Change	53(69.7%)	48(64.0%)
≥ 5mm Increase	1(1.3%)	1(1.3%)

Endoleaks

	Procedure	Post-Procedure	1 Month	6 Months	12 Months
Number of Subjects	95	95	95	95	92
Endoleak	-	3/3(100.0 %)	43/81(53.1 %)	34/77(44.2 %)	31/73(42.5 %)
Type I	-	0/3	1/81(1.2%)	1/77(1.3%)	0/73
Type IA	-	0/3	1/81(1.2%)	1/77(1.3%)	0/73
Type IB	-	0/3	0/81	0/77	0/73
Type II	-	3/3(100.0 %)	35/81(43.2 %)	29/77(37.7 %)	29/73(39.7 %)
Type III	-	0/3	0/81	0/77	0/73
Type IV	-	0/3	0/81	0/77	0/73
Indeterminate	-	0/3	7/81(8.6%)	5/77(6.5%)	2/73(2.7%)
AAA Expansion ≥ 5mm	-	-	Baseline	1/76(1.3%)	1/75(1.3%)
Reintervention	0/95	0/95	2/95(2.1%)	2/95(2.1%)	3/92(3.3%)
Conversion to Open Repair	0/95	0/95	1/95(1.1%)	0/95	0/92

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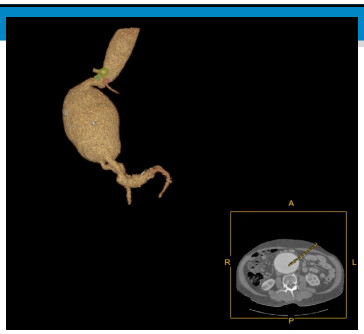
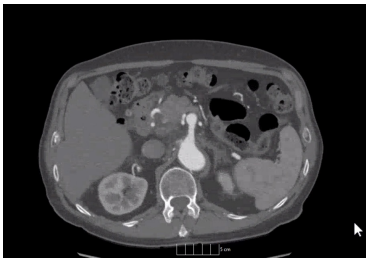


17

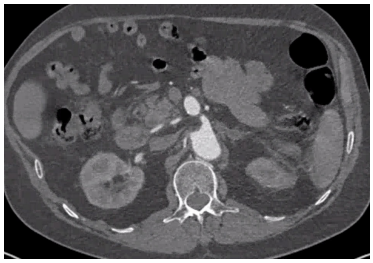
13-03 HAN subject November 2018 (6 months)



Neck 11mm
Sac 82mm

18

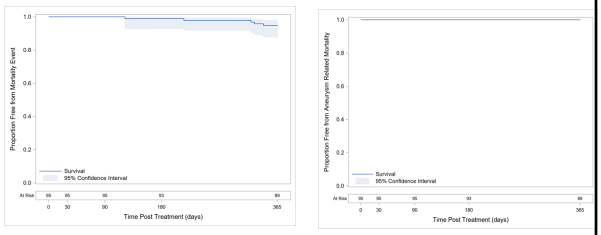
13-03 HAN subject December 2022 (5 year)



Sac 55mm

19

ALL CAUSE MORTALITY ANEURYSM RELATED MORTALITY



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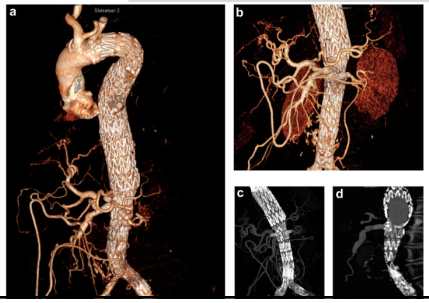
Comparison to Similar AAA Studies (Neck Length 10-15mm Enrolled)

		Endurant (2010)	Ovation (2012)	EXCC (Short Neck)	EXCC (High Neck)	EXCC (Both Substudies)
		Core Lab[1]	Core Lab	GIS	GIS	GIS
Proximal Neck Length (mm)	n	150	161	80	95	175
	N (<15mm)	**15[1]**	**25[3]**	**23**	**20**	**43**
	% (<15mm)	**10%**	**16%**	**29%**	**22%**	**25%**
	Follow Up Duration	12 month	12 month	60 months	60 months	60 months
	Indication	≥10mm	≥7mm	≥10mm	≥10mm	≥10mm

21

No Dorothy, not every aortic patients needs to die with a full metal



22

Conclusions

- USA IDE trial data (main cohort) at midterm (3 years) shows *unprecedented durability and clinical results*
- *High angle (≥10mm neck, ≤ 90-degree angulation)* IDE trial arm (95 patients) shows *same results* as standard subset.
- A new frontier for safely treating high risk aortic neck patients with an *infrarenal sealing AAA device*
- The EXCC is *being used* in 10/90 anatomic situations throughout the world with excellent results in the *ongoing registry out to 5 years*

23