


### Longer Term Outcomes with Gore Excluder (GORE®EXCLUDER® AAA Endoprosthesis featuring C3® Delivery System and GORE®EXCLUDER® Conformable AAA Endoprosthesis with Active Control System)



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### Disclosures

- Consultant & Speaker for Gore
- PI for Gore C3 Study in Europe

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### Introduction

- Evaluation of EVAR is about durability
- Correct endpoints are:
  - Longterm Aneurysm related mortality
  - Late rupture
  - Late complications requiring reintervention

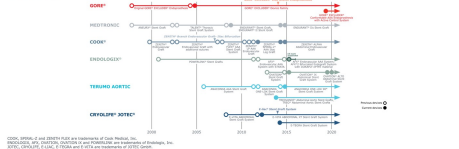
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### C3 Excluder Stent-graft (GORE®EXCLUDER® AAA Endoprosthesis featuring C3® Delivery System)

- Stent-graft design unchanged

#### Unique history

A low permeability film layer, added in 2004, is the only modification made to the GORE® EXCLUDER® AAA Device. Requiring so few regulatory changes, compared to currently available endografts, signals the enduring quality of the design.



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### European C3 Module (GRT 10-12)

### Global Registry for Endovascular Aortic Treatment

### GREAT

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### Real-world Performance of the New C3 Gore Excluder Stent-Graft: 1-year Results from the European C3 Module of the Global Registry for Endovascular Aortic Treatment (GREAT)

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European Journal of Vascular and Endovascular Surgery - Volume 48 - p. 1-7 Month/2014

- August 2010-December 2012
- 13 European Centers
- 400 patients

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### Early Results

- Technical Success: 99% (396/400)
  - 2 Conversions
  - 2 Unplanned renal chimneys
- 30-d Mortality: 0.5% (2/400)
- 30-d Reintervention: 0.5% (2/400)

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### Aortic Related Mortality @ 10 Yrs: 1.3%

At Risk	396	371	343	317	291	260	224	204	172	121	33
Events	0	3	3	5	5	5	5	5	5	5	5

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### Device related Reintervention @ 10 Yrs: 18%

At Risk	396	354	319	287	258	228	193	173	147	102	28
Events	4	19	28	38	44	55	55	56	56	59	60

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### Freedom from Aortic Rupture @ 10 Yrs: 99.2%

At Risk	396	371	343	316	289	259	223	204	172	121	33
Events	0	0	0	2	3	3	3	3	3	3	3

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### Sac Behaviour @ 10 Yrs

- Decreased: 65.8%
- Stable: 25.3%
- Increased: 8.9%

Characteristics	0 Months	1 Year	2 Years	3 Years	4 Years	5 Years	6 Years	7 Years	8 Years	9 Years	10 Years	Total (Procedure)
	Overall, N = 400	Overall, N = 392	Overall, N = 375	Overall, N = 359	Overall, N = 339	Overall, N = 319	Overall, N = 291	Overall, N = 260	Overall, N = 224	Overall, N = 204	Overall, N = 121	396
Mean (SD)	55.6 (10.46)	55.8 (10.60)	56.1 (10.80)	56.4 (11.00)	56.7 (11.20)	57.0 (11.40)	57.3 (11.60)	57.6 (11.80)	57.9 (12.00)	58.2 (12.20)	58.5 (12.40)	58.3 (14.37)
Median	55.5	55.5	55.5	55.5	55.5	55.5	55.5	55.5	55.5	55.5	55.5	55.5
Min, Max	36.5, 86.0	34.0, 90.0	36.0, 88.0	35.0, 95.0	34.0, 100.0	33.0, 105.0	32.0, 110.0	31.0, 115.0	30.0, 120.0	29.0, 125.0	28.0, 130.0	28.0, 130.0
Mean Change	-4.1 (2.50)	-4.2 (2.37)	-4.1 (2.41)	-4.0 (2.34)	-3.9 (2.27)	-3.8 (2.20)	-3.7 (2.13)	-3.6 (2.06)	-3.5 (1.99)	-3.4 (1.92)	-3.3 (1.85)	-3.3 (1.85)
Increased	20 (5.0%)	5 (2.3%)	10 (5.1%)	10 (5.6%)	10 (5.9%)	11 (6.3%)	12 (7.3%)	12 (7.6%)	13 (8.0%)	13 (8.4%)	14 (11.5%)	20 (5.1%)
Stable	146 (37.0%)	142 (36.3%)	138 (37.2%)	134 (37.3%)	130 (38.3%)	126 (37.2%)	122 (38.1%)	118 (37.7%)	114 (38.4%)	110 (39.2%)	106 (41.3%)	146 (37.1%)
Decreased	234 (58.9%)	245 (61.4%)	227 (60.7%)	215 (60.1%)	209 (61.8%)	202 (61.0%)	197 (64.3%)	191 (63.7%)	185 (62.6%)	174 (62.4%)	105 (47.2%)	230 (58.0%)

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### Key Outcomes @ 10 Yrs

- Aortic Rupture: N=3 (0.8%)
- Migration: N=2 (0.5%)
- Endoleak Type 1A: N=11 (2.9%)
- Limb Occlusion: N=3 (0.4%)

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### Late Results Type Ia Endoleak

- N=11
  - Inside IFU: 0.6% (2/332)
  - Outside IFU: 13.2% (9/68)

$P < 0.001$

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### Limb Occlusion

- N=3/800 (0.4%)
  - Thrombectomy: N=2
  - Thrombolysis: N=1

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### Nuremberg C3 Experience

- August 2010 – November 2023
  - N= 450 (CXT 44)
  - (elective 412, symptomatic 16, rupture 22)
- Confounding Factors
  - EVAR with Cook Zenith: N = 385
  - FEVAR: N= 742

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### Follow-up Mean: 48 ± 32 months

- Type Ia Endoleak: N=6 (1.3%)
- Limb Occlusion: N=2 (0.4%)
- Typ IB Endoleak: N= 5 (1%, treated with Limb Extension)
- Aortic Related Death: N=1
  - aortoenteric fistula and conversion at 3 months  
(was most probably aortoenteric fistula to start with)

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### Follow-up

- Estimated freedom from reintervention
  - 94.7% ± 1.2% at 1 year
  - 91.4% ± 1.2% at 2 years
  - 88.7% ± 1.9% at 3 years
  - 81% ± 2.7% at 5 years
- Aneurysm Sac change during Follow-up
  - aneurysm sac shrinkage: (>5 mm): 47.1%
  - stable aneurysm diameter: (-5 to +5 mm): 46.8%
  - aneurysm sac growth: 6.1%

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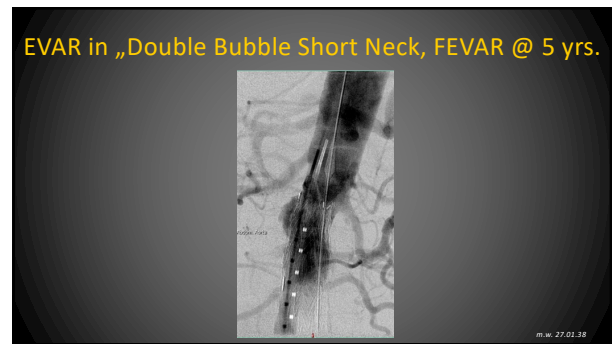
### Late Failures

- Ruptures: N=0
- Proximal Endoleak: N=6 (1.5%)
  - R/ FEVAR: N=3
  - R/ Conversion: N=2
  - R/ Endoanchoring: N=1

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Conclusions

Gore Excluder stent-graft is the leading global “Work Horse” for EVAR

- Excellent Long Term Outcomes
  - Very few Type Ia Endoleaks inside IFU
  - Late ruptures very rare.
  - Limb are second to none!

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