GREAT Insights:
5-Year Results for AAA repair with the Gore Excluder Stent Graft

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Background & Rationale

- EVAR is the more common means for AAA repair
  - Benefits in early survival, perioperative morbidity, and length of stay
  - Mid to long-term results → survival curves merge, but EVAR patients *exhibit a significantly elevated re-intervention rate at extended follow-up time points*.

- Questions remain to long-term durability and efficacy of EVAR.
  - Paucity of long-term outcomes in “real-world” use has created space for quality EVAR registry data to help answer these questions

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Objective & Methods

- Use the GREAT Registry to explore the 5-year outcomes of the Gore Excluder graft in “real-world” use
  - **Safety, Durability and Efficacy**

- The Global Registry for Endovascular Aortic Treatment (GREAT) Registry

  Loa J, Dubenec S, Cao P, Milner R, Silveira PG , Trimarchi S, Verhoeven E, Weaver F.
  The Gore Global Registry for Endovascular Aortic Treatment: Objectives and Design. *Ann Vasc Surg*. 2016 Feb;31:70-6.

  - Primary Endpoints
    - Endoleaks, Stent fracture or migration, aortic rupture, and endograft explantation.
  - Secondary Endpoints
    - Serious device events, aortic related mortality, Long term survival

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Cohort Characteristics & Follow-Up

Characteristics and Risk Factors	N=3226
Gender	
Male	2757 (85.5%)
Female	469 (14.5%)
Race	
White/Caucasian	2893 (89.7%)
Black/African American	108 (3.3%)
Asian	20 (0.6%)
Middle Eastern	7 (0.2%)
Native Hawaiian/Other Pacific Islander	11 (0.3%)
Other	44 (1.4%)
Unknown	136 (4.2%)
Medical Comorbidities	
Hypertension	2604 (81.3%)
Hypercholesterolemia	2077 (66.8%)
Tobacco Use	1756 (56.1%)
Coronary Artery Disease	1298 (41.2%)
COPD	821 (26.0%)
Cancer	722 (22.8%)
Peripheral Vascular Disease	613 (19.5%)
Diabetes Mellitus	601 (18.8%)
Renal Insufficiency	512 (16.0%)
Stroke	314 (9.9%)
Region	
Europe	1193 (37.0%)
United States	1669 (51.7%)
Brazil	233 (7.2%)
Australia/New Zealand	131 (4.1%)
Age (yrs)	
Mean (SD)	73.4 (8.3)
BMI	
Mean (SD)	27.5 (5.1)

Follow-Up Time Point	Actual follow-up /Eligible for follow-up (%)
1 Month	2313/3178 (72.8%)
6 Months	1828/3067 (59.6%)
1 Year	2158/2905 (74.3%)
2 Years	1933/2711 (71.3%)
3 Years	1152/1780 (64.7%)
4 Years	652/1071 (60.9%)
5 Years	306/477 (64.2%)

C3 cohort with 63.4% ASA III/IV

Verhoeven et al,. 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).*Eur J Vasc Endovasc Surg*. 2014 Aug;48(2):131-7

~64%
Follow-up though 5-Years

~52%
Cases done in U.S

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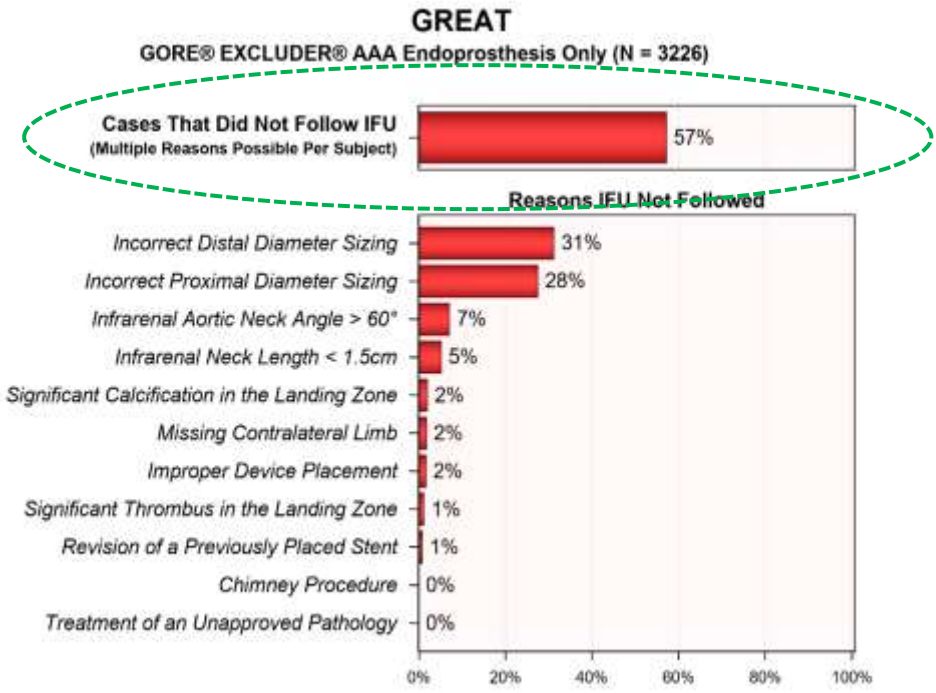
Index Procedural Characteristics

Initial Treatment Data

Subject/Characteristic	Result
Max Aortic Dimeter (cm)	5.7 (1.2)
Aortic Neck Length (cm)	2.9 (1.5)
# (%) <1.5 cm Aortic Neck	169 (5.2%)
Aortic Neck Angulation ° (SD)	30.7 (21.5)
# (%) >60° Aortic Neck Angulation	229 (7.1%)
# (%) >75° Aortic Neck Angulation	98 (3.0%)
Hospital Duration (Days)	
Mean (SD)	4.0 (6.02)
Median	2.0
Technical Success (%)	3226 (100%)
Procedural Survival (%)	3226 (100%)
ICU Stay (%)	92 (2.9%)
Hospital Survival (%)	3218 (99.8%)

IFU Violations



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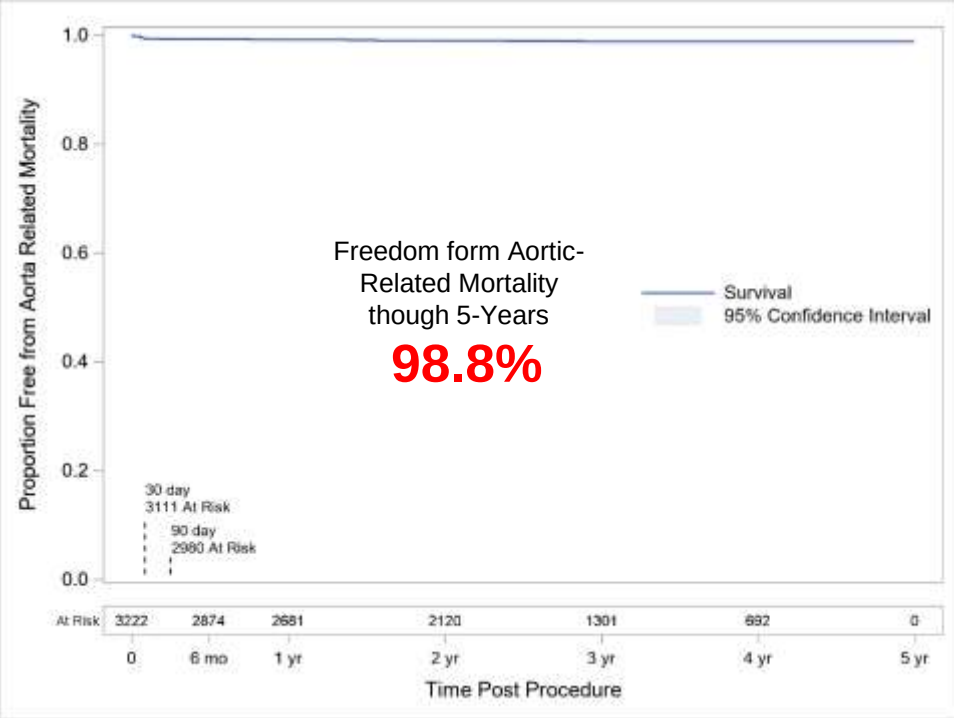
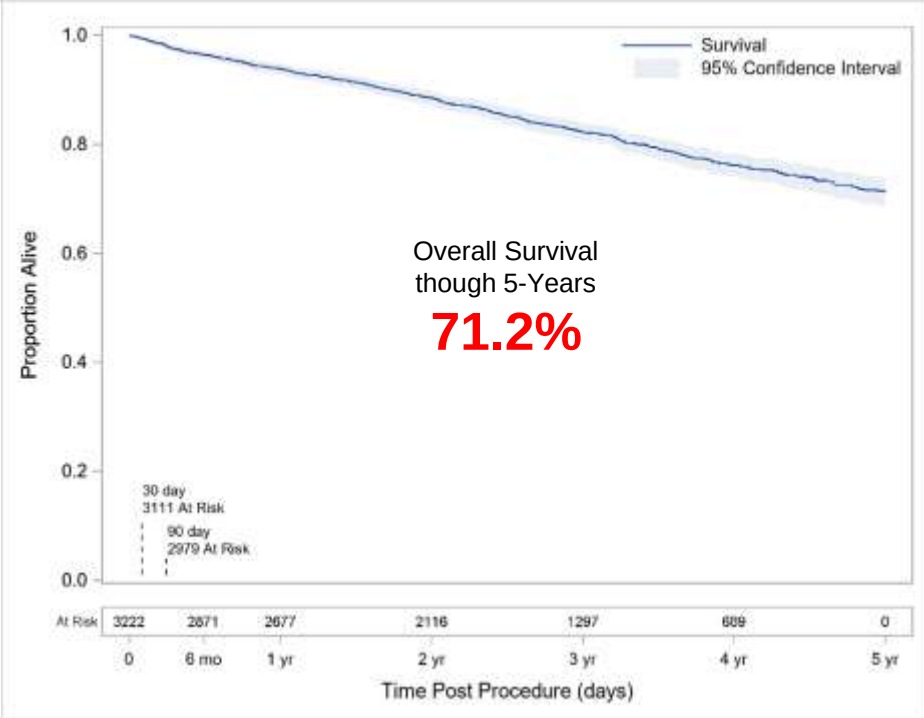
All-Cause & Aortic-Related Mortality

% Free from Aorta-Related Mortality



% Overall Survival



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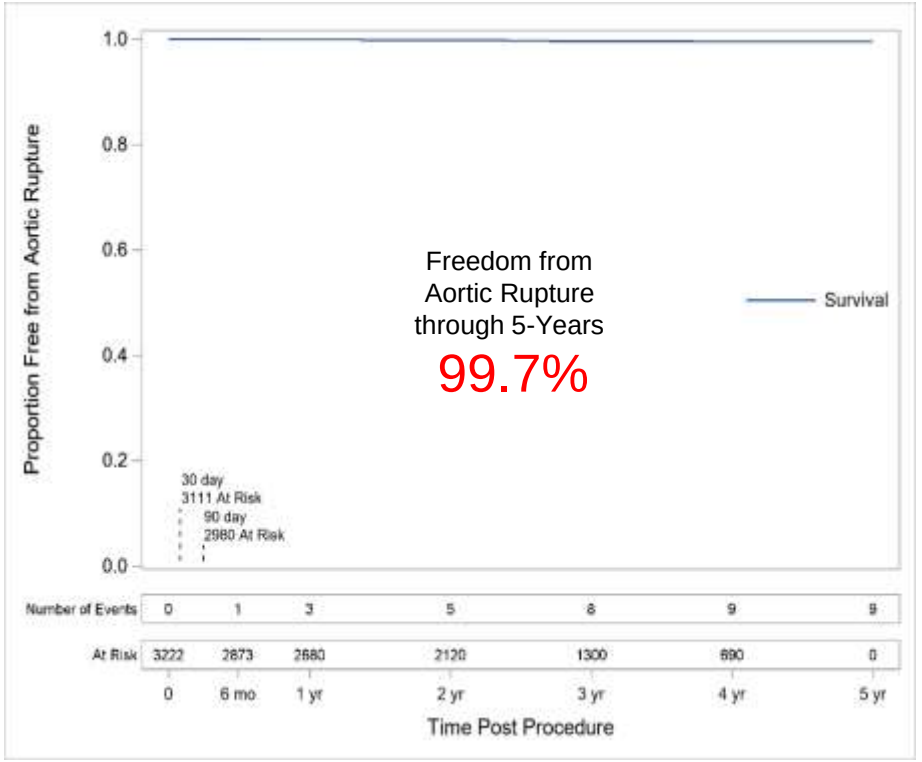
Key Outcomes Through 5-Years

Event Rates through 5-Years

Events	5 Years (N =3226)
Stroke/TIA	85 (2.6%)
Paraplegia/Paraparesis/Spinal Cord Ischemia	3 (<0.1%)
Device Related Reinterventions	164 (5.1%)
Conversion to Open/Explant	25 (0.8%)
Endoleak	177 (5.5%)
Type IA	26 (0.8%)
Type IB	21 (0.7%)
Type II	138 (4.3%)
Type III	7 (0.2%)
Type IV	0 (0%)
Stent Graft	
Migration	1 (<0.1%)
Fracture	0 (0.0%)
Compression	2 (<0.1%)
Aortic Rupture	9 (0.3%)

Proportion Free from Aortic Rupture



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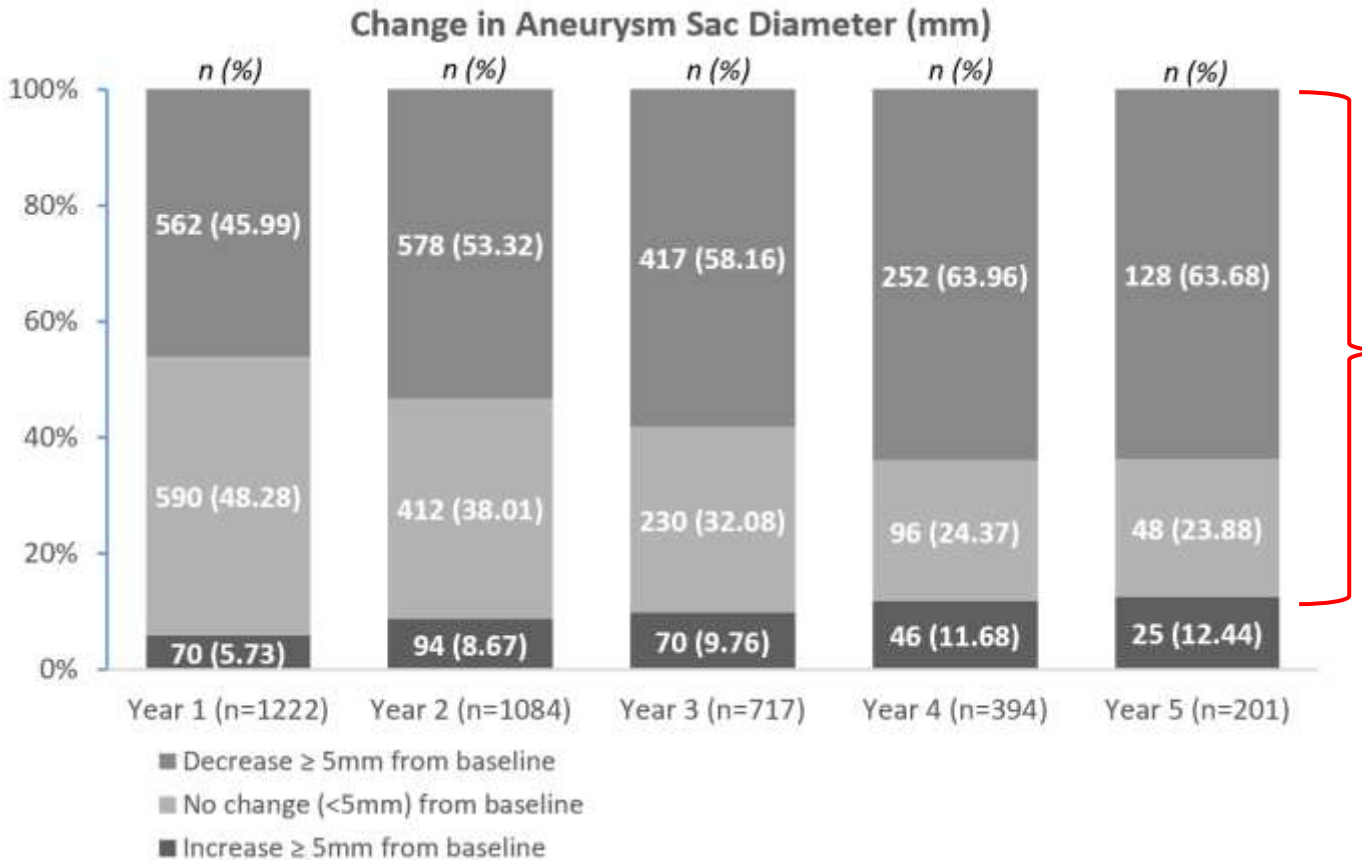
Aneurysm Sac Morphology



87.5%

Sac Regression/Stability

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Conclusion

- Limitations
  - Follow-up <80%→ Likely reflecting “real-world” circumstances
- Key Findings
  - **Safety** →Excellent technical success (*100%*), procedure survival (*100%*), hospital survival (*99.8%*), paraplegia rate (*0.1%*)
  - **Durability** → *No* stent fractures, *negligible* occurrence of stent compression and/or migration, and low aortic/device-related re-intervention rates
  - **Efficacy** → Extremely low aortic-related mortality and post EVAR aortic rupture rates, with ~ 88% sac regression/stability at 5 years

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Thank You

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