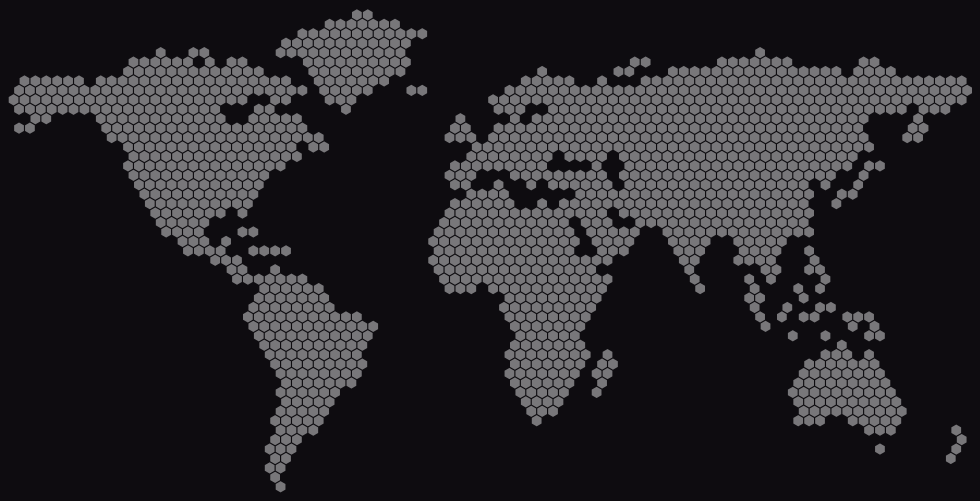
Real-world data



GREAT

GLOBAL REGISTRY FOR ENDOVASCULAR AORTIC TREATMENT

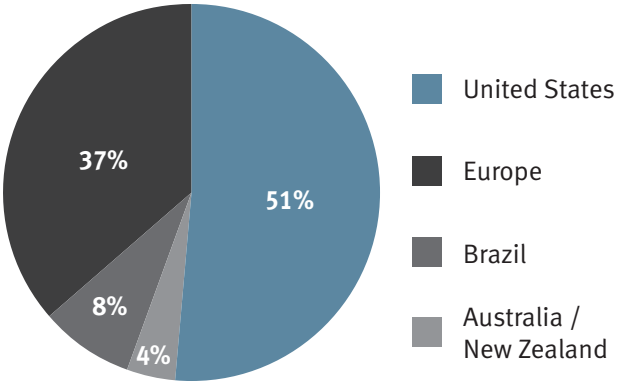
GREAT provided the opportunity to analyze outcomes on a subset of patients for TEVAR.

GREAT Objective: To improve clinical practice and patient outcomes through post-market surveillance and long-term device performance monitoring.

- Initiated in 2010 to evaluate Gore aortic devices in real-world cases
- Enrollment completed in October 2016
- Ten-year follow-up is planned for all enrolled patients
- 902 TEVAR patients treated
- 28 pathologies treated

Overall GREAT enrollment by region

5,013 patients,
14 countries, 114 centers



Type B aortic dissection (TBAD) patient subset

264
Patients treated

62
Mean age
(range: 52–69 years)

80%
of patients were male

75%
of patients were treated with a single device

- No statistically significant differences between chronic and acute TBAD groups in overall aortic event rate was found
- Aortic event rate was 20% in the first 30 days and 25% overall

> *Data from the GREAT, a large international multicenter registry, have demonstrated that TEVAR using the (GORE® TAG® Conformable Thoracic Stent Graft) device for TBAD can be performed with low perioperative complication rates.*[1]

Device and treatment details

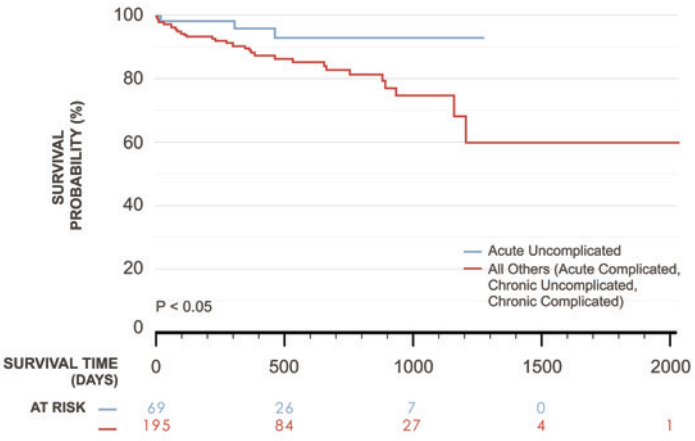
Variable	Total (n = 264; 100%)	Chronic (n = 94; 36%)	Acute (n = 170; 64%)
Conformable GORE® TAG® device number (%)	99	99	99
Median treatment length cm (range)	15–35	15–40	15–30
Left subclavian artery coverage number (%)	34	41	29

Aortic events during follow-up

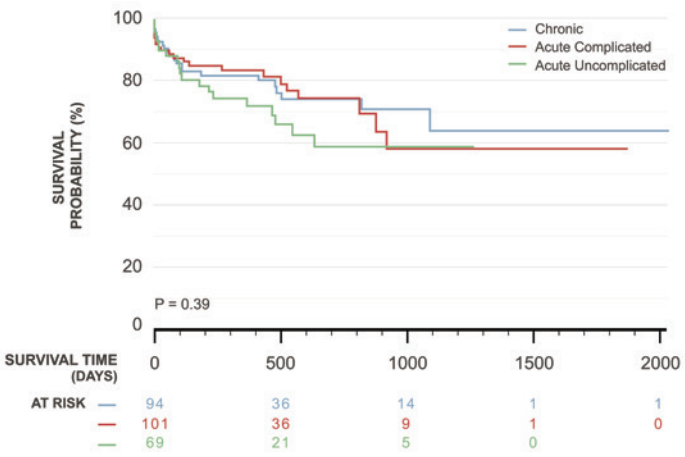
Aortic event (number, %)	Total (n = 264; 100%)	Chronic (n = 94; 36%)	Acute (n = 170; 64%)
Aortic rupture	4 (2)	0 (0)	4 (2)
Aneurysm formation / growth	3 (1)	1 (1)	2 (1)
Spinal cord ischemia	8 (3)	3 (3)	5 (3)
Stroke	3 (1)	0 (0)	3 (2)
Aortic branch vessel	5 (2)	4 (4)	1 (1)
New distal dissection	10 (4)	4 (4)	6 (4)
Retrograde dissection	6 (2)	3 (3)	3 (2)
Endoleak or false lumen flow	24 (9)	12 (13)	12 (7)
Endograft infection	3 (1)	1 (1)	2 (1)
Aortic death	7 (3)	2 (2)	5 (3)
Any aortic event (total)	65 (25)	21 (22)	44 (26)

Kaplan-Meier analysis

Freedom from all-cause mortality rate by dissection category



Freedom from adverse events by dissection category



INDICATIONS FOR USE IN THE US: The GORE® TAG® Thoracic Endoprosthesis is intended for endovascular repair of all lesions of the descending thoracic aorta, including: Isolated lesions in patients who have appropriate anatomy, including: adequate iliac / femoral access, aortic inner diameter in the range of 16–42 mm, ≥ 20 mm non-aneurysmal aorta proximal and distal to the lesion; Type B dissections in patients who have appropriate anatomy, including: adequate iliac / femoral access, ≥ 20 mm landing zone proximal to the primary entry tear; proximal extent of the landing zone must not be dissected, diameter at proximal extent of proximal landing zone in the range of 16–42 mm. **CONTRAINDICATIONS:** Patients with known sensitivities or allergies to the device materials; patients who have a condition that threatens to infect the graft. Refer to *Instructions for Use* at goremedical.com for a complete description of all warnings, precautions, and adverse events. **INDICATIONS FOR USE UNDER CE MARK:** The GORE® TAG® Thoracic Endoprosthesis is indicated for endovascular repair of the descending thoracic aorta. **CONTRAINDICATIONS:** Patients with known sensitivities or allergies to the device materials; patients with a systemic infection who may be at increased risk of endovascular graft infection. Refer to *Instructions for Use* at goremedical.com for a complete description of all warnings, precautions, and adverse events. ℞ Only

* Global enrollment as of October 2016

1. Tjaden BL, Sandhu H, Miller C, *et al*. Outcomes from the Gore Global Registry for Endovascular Aortic treatment in patients undergoing thoracic endovascular aortic repair for type B dissection. *Journal of Vascular Surgery*. 2018;68(5):1314-1323

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