GREAT

GLOBAL REGISTRY FOR
ENDOVASCULAR AORTIC TREATMENT

GREAT provided the opportunity to analyze outcomes on Type B aortic dissection (TBAD) patients, a subset of the study.

264 Patients treated	64% Acute 36% Chronic	62 Mean age (range: 52–69 years)	80% of patients were male

- 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]

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

Real-world data

GREAT was initiated in 2010 to evaluate how our family of aortic devices perform in real-world cases and to continue our commitment to advancing patient care in the treatment of aortic disease. Enrollment was completed in October 2016 and a 10-year follow-up is planned for all enrolled patients.

Enrollment resulted in a wide spectrum of treatments, reflecting real-world use:

5,013 Patients treated	18% TEVAR	3% Thoraco/ other	28 Pathologies treated

Together, improving life

GORE

Device and treatment details

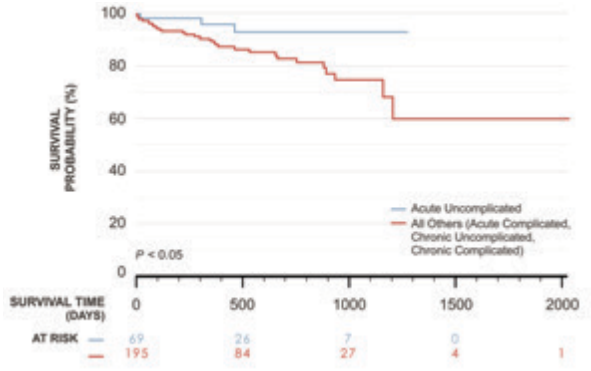
Variable	Total (n = 264; 100%)	Chronic (n = 94; 36%)	Acute (n = 170; 64%)
Conformable GORE® TAG® Device number (%)	99	99	99
Median treatment length cm (range)	15–35	15–40	15–30
Left subclavian artery coverage number (%)	34	41	29

Aortic events during follow-up

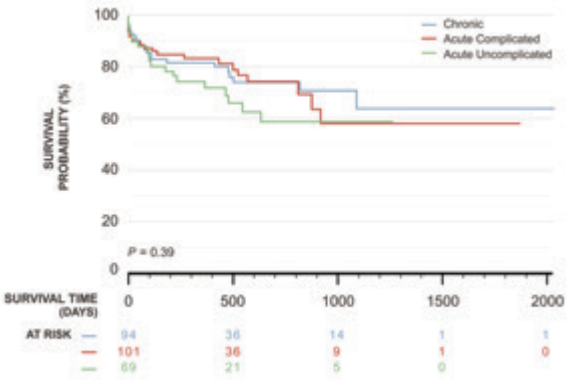
Aortic event (number, %)	Total (n = 264; 100%)	Chronic (n = 94; 36%)	Acute (n = 170; 64%)
Aortic rupture	4 (2)	0 (0)	4 (2)
Aneurysm formation/growth	3 (1)	1 (1)	2 (1)
Spinal cord ischemia	8 (3)	3 (3)	5 (3)
Stroke	3 (1)	0 (0)	3 (2)
Aortic branch vessel	5 (2)	4 (4)	1 (1)
New distal dissection	10 (4)	4 (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



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

Consult Instructions for Use
eifu.goremedical.com

INDICATIONS FOR USE IN THE U.S.: The GORE® TAG® Conformable Thoracic Stent Graft 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:** The GORE® TAG® Conformable Thoracic Stent Graft is contraindicated in: Patients with known sensitivities or allergies to the device materials (Table 1); Patients who have a condition that threatens to infect the graft. Refer to *Instructions for Use* at eifu.goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. ℞ Only **INDICATIONS FOR USE UNDER CE MARK:** The GORE® TAG® Conformable Thoracic Stent Graft is indicated for endovascular treatment of all lesions of the descending thoracic aorta including isolated lesions, such as aneurysms and traumatic transections and Type B dissections. **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 eifu.goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. ℞ Only

Products listed may not be available in all markets.

W. L. Gore & Associates, Inc.
goremedical.com

Asia Pacific +65 67332882 **Australia/New Zealand** 1800 680 424 **Europe** 00800 6334 4673
United States Flagstaff, AZ 86004 800 437 8181 928 779 2771