Update On Total And Partial Aortic Arch Lesion Repairs With The Gore TAG Single Branch Endograft: An Off-The-Shelf (OTS) Device For Revascularizing Arch Branches: Experience To Date, Advantages And Limitations

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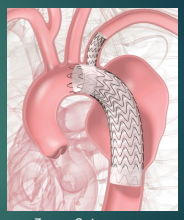
Disclosures - Michael Dake, MD

Within the past 12 months, the presenter or their spouse/partner have had a financial interest/arrangement or affiliation with the organization listed below.

- **Research/Research Grants, Clinical Trial Support**
  - W. L. Gore
  - Cook Medical
- **Consulting Fees/Honoraria**
  - W. L. Gore
  - Cook Medical
  - Boston Scientific
  - REVA Medical
- **Equity Interests/Stock Options**
  - REVA Medical
  - FluidX Medical
- **Officer, Director, Board Member or other Fiduciary Role**
  - FluidX Medical
- **Speaker's Bureau**
  - None

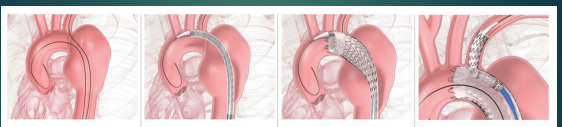
GORE® TAG® Thoracic Branched Endoprosthesis (TBE)

- Aortic Component (AC)
  - Diameter range 21-45mm
- Side Branch (SB) Component
  - Zone 2: 8- and 12-mm portals
  - Diameter range 8mm – 20mm
- Aortic Extender (Optional)
  - Diameter range 21-45mm
  - Length range 3.6 – 4.6cm



Zone 2 Aneurysm

TBE Procedure in Zone 2



1 Insert guidewires in aorta and branch vessel.

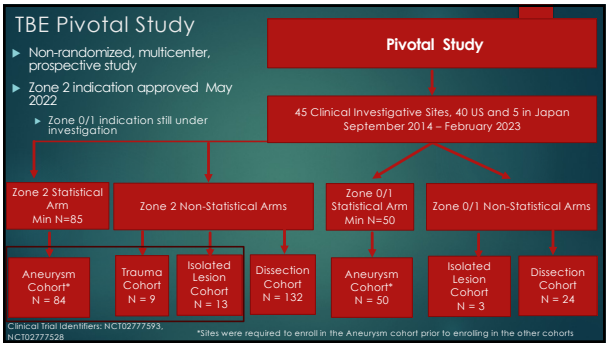
2 Introduce Aortic Component over both guidewires into position within the arch.

3 Deploy Aortic Component and withdraw catheter.

4 Advance and deploy Side Branch Component.

TBE Pivotal Study

- Non-randomized, multicenter, prospective study
- Zone 2 indication approved May 2022
  - Zone 0/1 indication still under investigation



Clinical Trial Identifiers: NCT02777593, NCT02777528

*Sites were required to enroll in the Aneurysm cohort prior to enrolling in the other cohorts

Baseline demographics for non-dissected zone 2 cohorts

	Aneurysm N=84	Trauma N=9	Other Isolated Lesions N=13
Age, years (SD)	70.3 (11.11)	42.4 (18.95)	64.8 (13.28)
Male gender, n (%)	53 (63.1%)	8 (88.9%)	6 (46.2%)
BMI, kg/m², median (STD)	28.8 (6.30)	29.5 (5.03)	25.8 (5.33)
Comorbidities, n (%)			
Hypertension	72/84 (85.7%)	4/9 (44.4%)	11/13 (84.6%)
Diabetes mellitus	14/84 (16.7%)	1/9 (11.1%)	2/13 (15.4%)
Hypercholesterolemia	44/84 (52.4%)	1/9 (11.1%)	6/13 (46.2%)
Coronary artery disease	27/83 (32.5%)	1/9 (11.1%)	3/13 (23.1%)
Coronary artery bypass grafting	12/83 (14.5%)	0/9 (0%)	0/13 (0%)
Peripheral vascular disease	11/83 (13.3%)	1/9 (11.1%)	1/13 (7.7%)
Previous stroke	12/84 (14.3%)	1/9 (11.1%)	1/13 (7.7%)
Nicotine use	30/84 (35.7%)	2/9 (22.2%)	7/13 (53.8%)
Chronic obstructive pulmonary disease	16/84 (19.0%)	0/9 (0%)	3/13 (23.1%)
Previous aortic repair	32/84 (38.1%)	0/9 (0%)	7/13 (53.8%)

Core lab reported Device Events through 3 years

	Aneurysm N=84	Trauma N=9	Other Isolated Lesions N=13	Total Non-Dissected cohorts N=106
SB loss of patency	0/82 (0%)	1/9 (11.1%)	0/13 (0%)	1/104 (1.0%)
Aortic Rupture	0/83 (0%)	0/9 (0%)	0/13 (0%)	0/105 (0%)
Device Migration	0/84 (0%)	0/9 (0%)	0/13 (0%)	0/106 (0%)
Wire Fracture	0/84 (0%)	0/8 (0%)	0/13 (0%)	0/105 (0%)
Aortic Enlargement (>5mm)	4/66 (6.1%)	0/8 (0%)	0/10 (0%)	4/84 (4.8%)

*Denominator reflect subjects that had imaging quality that allowed for events to be identified, ** 3 years (1-1275 days)

Non-dissected zone 2 cohorts : Core Lab Endoleaks and Reinterventions

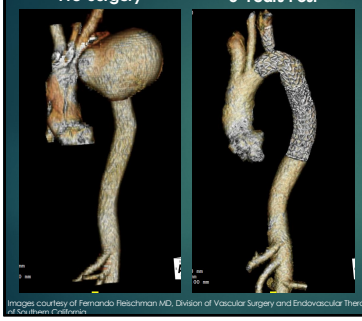
	Aneurysm N=84	Trauma N=9	Other Isolated Lesions N=13	Total Non-Dissected cohorts N=106
Any Endoleak	**36/82 (43.9%)**	**0/9 (0%)**	**1/13 (7.7%)**	**37/104 (35.6%)**
Type I	3/82 (3.7%)	-	0/13 (0%)	3/104 (2.9%)
Type II	21/82 (25.6%)	-	1/13 (7.7%)	22/104 (21.2%)
Type III	5/82 (6.1%)	-	0/13 (0%)	5/104 (4.8%)
Indeterminate	19/82 (23.2%)	-	0/13 (0%)	19/104 (18.3%)
CEC Adjudicated Reinterventions	**7/84 (8.3%)**	**1/9 (11.1%)**	**0/13 (0%)**	**8/106 (7.5%)**

35.6% of patient had any Endoleak, 7.6% of patients had type I and III endoleaks

Mortality and strokes in non-dissected zone 2 cohorts through 3 years

	Aneurysm N=84	Trauma N=9	Other Isolated Lesions N=13	Total Non-Dissected cohorts N=106
All-Cause Mortality	11/84 (13.1%)	0/9 (0.0%)	4/13 (30.7%)	15/106 (14.1%)
Lesion related mortality	0/84 (0.0%)	0/9 (0.0%)	1/13 (7.7%)	1/106 (0.9%)
Stroke	**8/84 (9.6%)**	**0/9 (0.0%)**	**1/13 (7.7%)**	**9/106 (8.4%)**
30 days	4/84 (4.8%)	0/9 (0.0%)	0/13 (0.0%)	4/106 (3.7%)
Outside 30 days	4/84 (4.8%)	0/9 (0.0%)	1/13 (7.7%)	5/106 (4.7%)

Pre-Surgery / 5-Years Post

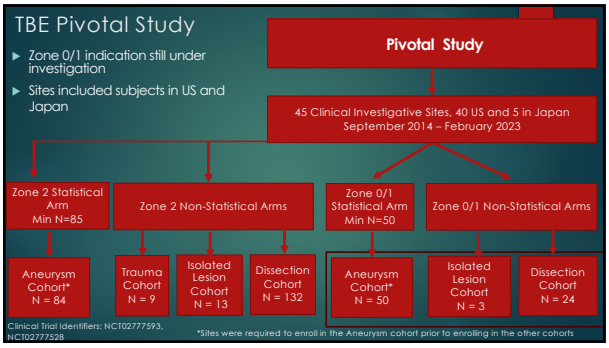


- 44-year-old Caucasian Female
- Saccular aneurysm:
  - 76.7 mm at pre-treatment
  - 30.3 mm at 5-year follow-up
- No reinterventions through 5 years
- No Device or aortic related adverse events

Images courtesy of Fernando Fleischman MD, Division of Vascular Surgery and Endovascular Therapy, Department of Surgery, Keck School of Medicine, University of Southern California

TBE Pivotal Study

- Zone 0/1 indication still under investigation
- Sites included subjects in US and Japan



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Baseline demographics for Zone 0/1 cohorts

	Aneurysm N=50	Dissection N=24	Other Isolated Lesions N=3
Age, years (SD)	74.3 (8.56)	63.0 (11.31)	73.7 (9.02)
Male gender, n (%)	32 (64.0%)	17 (70.8%)	2 (66.7%)
BMI, kg/m², median (STD)	27.3 (5.94)	29.9 (4.44)	23.4 (2.01)
Comorbidities, n (%)			
Hypertension	6/50 (12.0%)	3/24 (12.5%)	1/3 (33.3%)
Diabetes mellitus	5/50 (10.0%)	1/24 (4.2%)	0/3 (0%)
Hypercholesterolemia	32/49 (65.3%)	15/24 (62.5%)	2/3 (66.7%)
Coronary artery disease	19/50 (38.0%)	3/24 (12.5%)	1/3 (33.3%)
Coronary artery bypass grafting	7/50 (14.0%)	3/24 (12.5%)	1/3 (33.3%)
Peripheral vascular disease	6/49 (12.2%)	0/24 (0%)	1/3 (33.3%)
Previous stroke	6/50 (12.0%)	3/24 (12.5%)	1/3 (33.3%)
Nicotine use	46/50 (92.0%)	24/24 (100.0%)	3/3 (100.0%)
Chronic obstructive pulmonary disease	19/50 (38.0%)	4/24 (16.7%)	1/3 (33.3%)
Previous aortic repair	19/50 (38.0%)	21/24 (87.5%)	1/3 (33.3%)

Caution: Products listed are investigational and may not be available in all markets. Limited by United States law to investigational use only

Aneurysm Types in Zone 0/1

	Aneurysm N=50
Fusiform aneurysm (>55mm)	26/50 (52.0%)
Fusiform aneurysm (>2 times native aortic diameter)	2/50 (4.0%)
Saccular aneurysm	22/50 (44.0%)

Images Courtesy of Matthew Sweet, MD at University of Washington.

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Conclusions

- 3 year follow up in non-dissected Zone 2 cohorts shows low level of device events
  - Majority of strokes occurred early in follow up
  - Low rates of reinterventions in Zone 2
- Zone 2 post-market study through SVS-VQI has completed enrollment
  - N=350
- Zone 0-2 Feasibility 5-year data manuscript in development and will be presented in 2025
- Zone 0/1 indication expansion anticipated for 2025

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Thank you!

Midterm Outcomes of Endovascular Repair of Aortic Arch Aneurysms with the Gore Thoracic Branch Endoprosthesis

Evaluation of the Gore TAG thoracic branch endoprosthesis in the treatment of proximal descending thoracic aortic aneurysms

Outcomes of endovascular repair of aortic aneurysms with the GORE thoracic branch endoprosthesis for left subclavian artery preservation