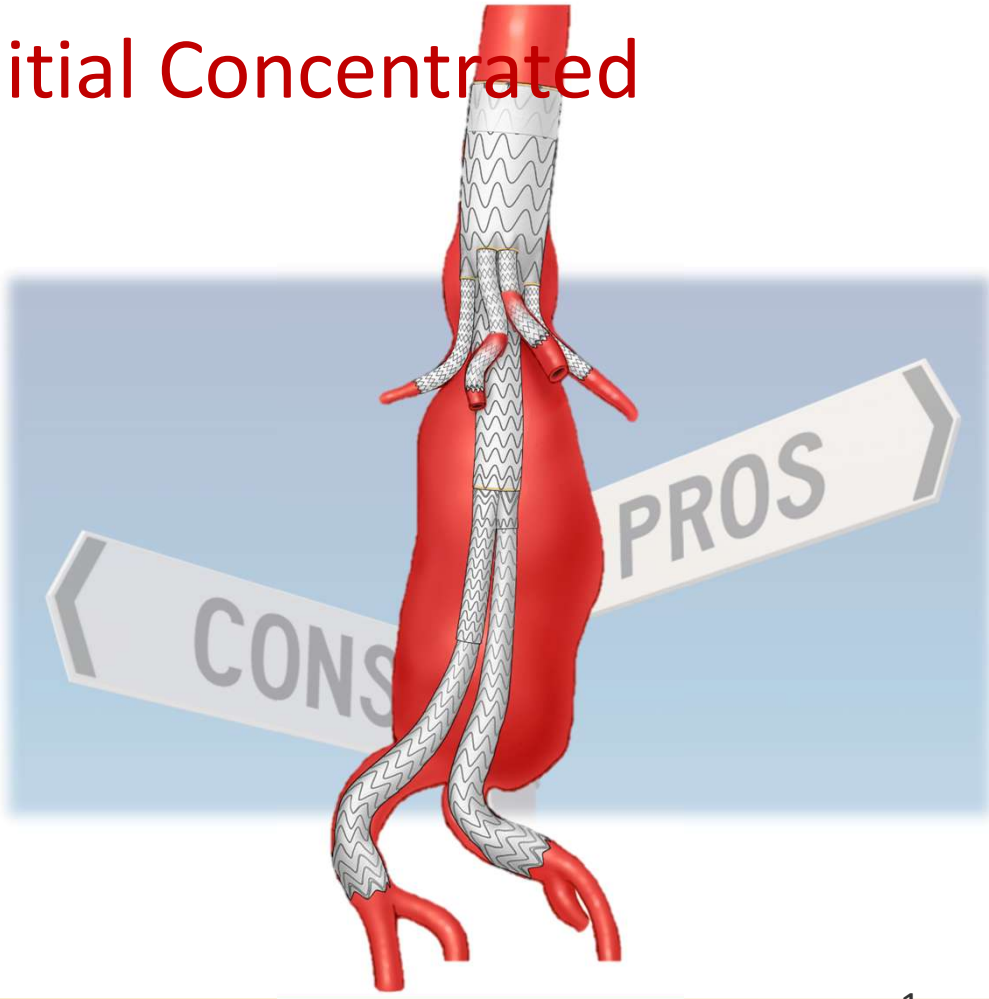
Lessons Learned from The Initial Concentrated Experience with TAMBE



Houston Aortic
March 6, 2026

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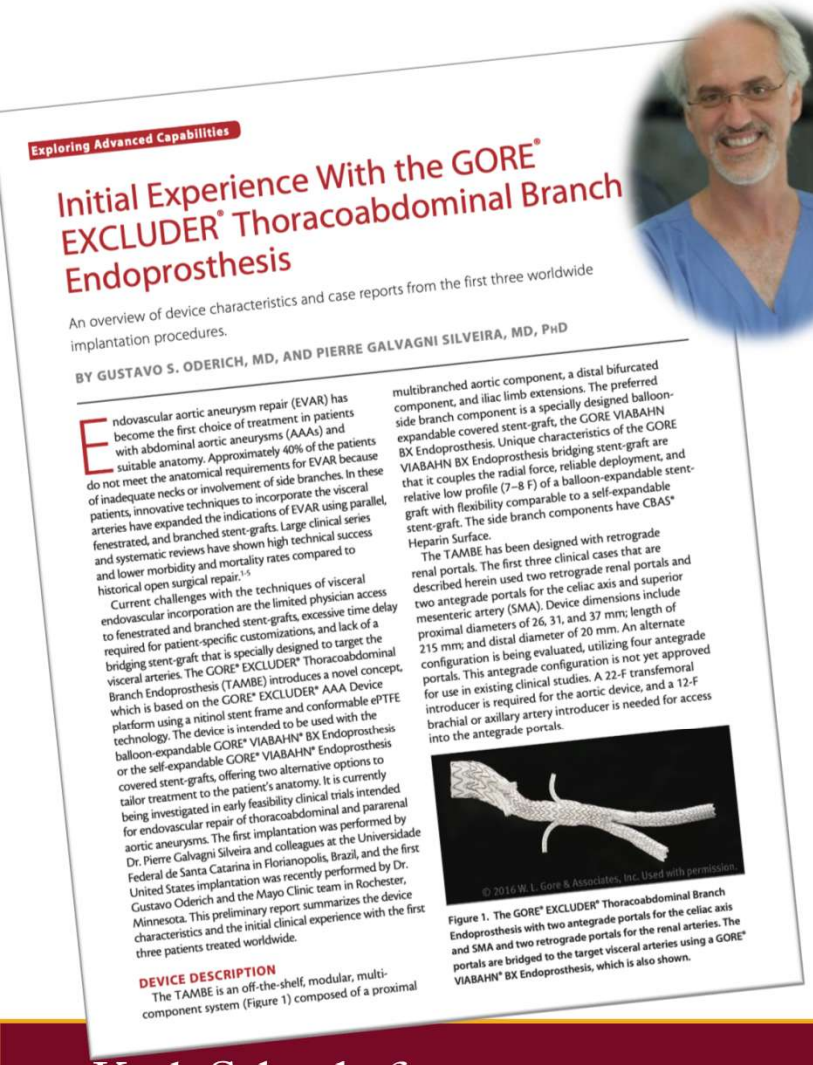
DISCLOSURES

- W.L. Gore & Associates: Scientific Advisory Board, Consultant, Research Support, Site PI for TAMBE, TBE, National PI for TOGETHER registry, OSMB for GREAT registry (No personal income, all paid to USC)
- Cook Medical: Scientific Advisory Board, Consultant, Site PI for ZFEN PLUS
- Terumo Aortic: Scientific Advisory Board, Consultant, Site PI for Relay Branch
- Medtronic: Consultant

Off-label applications of TAMBE



Exploring Advanced Capabilities

Initial Experience With the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis

An overview of device characteristics and case reports from the first three worldwide implantation procedures.

BY GUSTAVO S. ODERICH, MD, AND PIERRE GALVAGNI SILVEIRA, MD, PHD

Endovascular aortic aneurysm repair (EVAR) has become the first choice of treatment in patients with abdominal aortic aneurysms (AAAs) and suitable anatomy. Approximately 40% of the patients do not meet the anatomical requirements for EVAR because of inadequate necks or involvement of side branches. In these patients, innovative techniques to incorporate the visceral arteries have expanded the indications of EVAR using parallel, fenestrated, and branched stent-grafts. Large clinical series and systematic reviews have shown high technical success and lower morbidity and mortality rates compared to historical open surgical repair.[1-5]

Current challenges with the techniques of visceral endovascular incorporation are the limited physician access to fenestrated and branched stent-grafts, excessive time delay required for patient-specific customizations, and lack of a bridging stent-graft that is specially designed to target the visceral arteries. The GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE) introduces a novel concept, which is based on the GORE® EXCLUDER® AAA Device platform using a nitinol stent frame and conformable ePTFE technology. The device is intended to be used with the balloon-expandable GORE® VIABAHN® BX Endoprosthesis or the self-expandable GORE® VIABAHN® Endoprosthesis covered stent-grafts, offering two alternative options to tailor treatment to the patient's anatomy. It is currently being investigated in early feasibility clinical trials intended for endovascular repair of thoracoabdominal and pararenal aortic aneurysms. The first implantation was performed by Dr. Pierre Galvagni Silveira and colleagues at the Universidade Federal de Santa Catarina in Florianopolis, Brazil, and the first United States implantation was recently performed by Dr. Gustavo Oderich and the Mayo Clinic team in Rochester, Minnesota. This preliminary report summarizes the device characteristics and the initial clinical experience with the first three patients treated worldwide.

DEVICE DESCRIPTION

The TAMBE is an off-the-shelf, modular, multi-component system (Figure 1) composed of a proximal multibranched aortic component, a distal bifurcated component, and iliac limb extensions. The preferred side branch component is a specially designed balloon-expandable covered stent-graft, the GORE VIABAHN BX Endoprosthesis. Unique characteristics of the GORE VIABAHN BX Endoprosthesis bridging stent-graft are that it couples the radial force, reliable deployment, and relative low profile (7–8 F) of a balloon-expandable stent-graft with flexibility comparable to a self-expandable stent-graft. The side branch components have CBAS® Heparin Surface.

The TAMBE has been designed with retrograde renal portals. The first three clinical cases that are described herein used two retrograde renal portals and two antegrade portals for the celiac axis and superior mesenteric artery (SMA). Device dimensions include proximal diameters of 26, 31, and 37 mm; length of 215 mm; and distal diameter of 20 mm. An alternate configuration is being evaluated, utilizing four antegrade portals. This antegrade configuration is not yet approved for use in existing clinical studies. A 22-F transfemoral introducer is required for the aortic device, and a 12-F brachial or axillary artery introducer is needed for access into the antegrade portals.

Figure 1. The GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis with two antegrade portals for the celiac axis and SMA and two retrograde portals for the renal arteries. The portals are bridged to the target visceral arteries using a GORE® VIABAHN® BX Endoprosthesis, which is also shown.

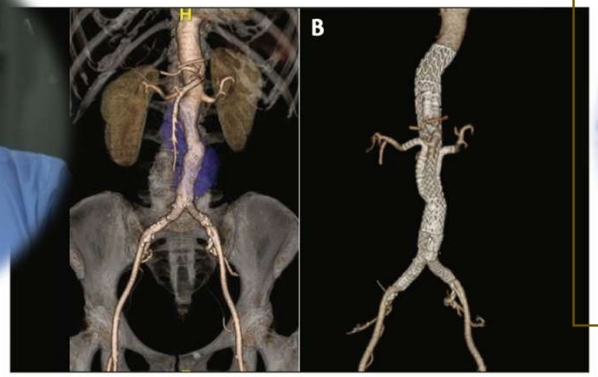


Figure 5. The first worldwide case performed in Florianopolis, Brazil, by Dr. Pierre Galvagni and colleagues at the Universidade Federal de Santa Catarina. Preoperative (A) and postoperative (B) CTA demonstrating widely patent stent-grafts and no endoleak at 1 year.

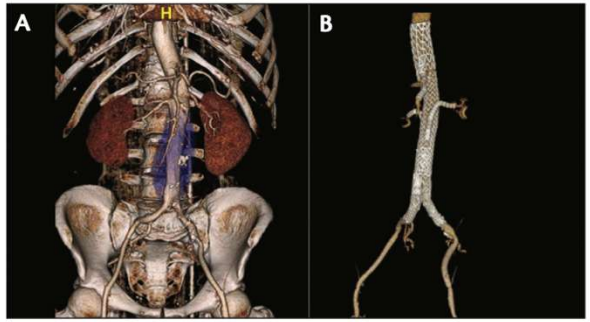
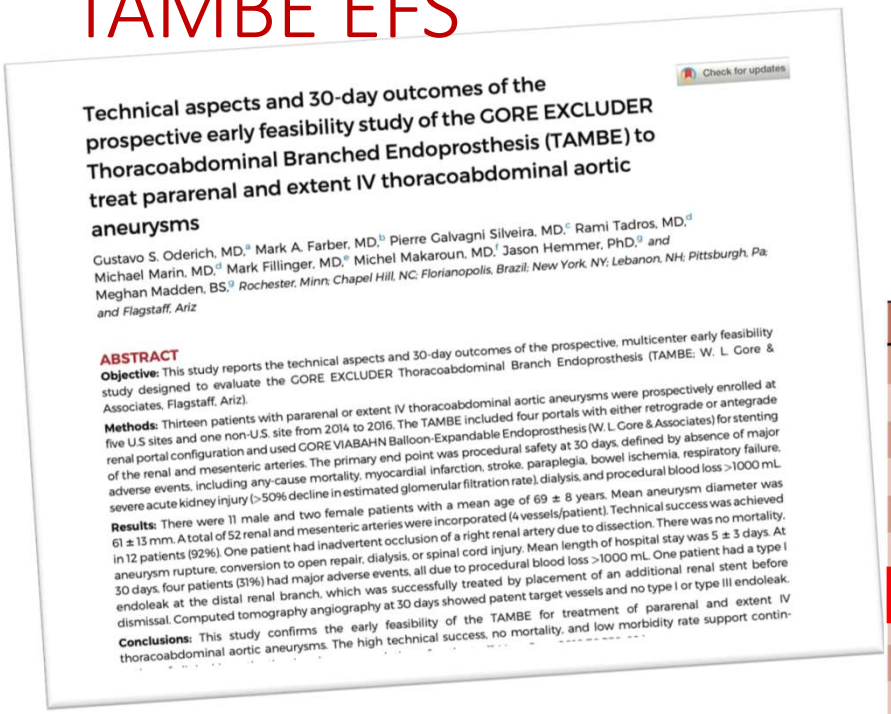


Figure 6. The second worldwide case performed in Florianopolis, Brazil, by Dr. Pierre Galvagni and colleagues at the Universidade Federal de Santa Catarina. Preoperative (A) and postoperative (B) CTA demonstrating widely patent stent-grafts and no endoleak at 1 year.

Figure 7. The third worldwide and first United States case performed at the Mayo Clinic in Rochester, Minnesota, by Dr. Gustavo Oderich and colleagues. Artist depiction shows the aneurysm (A) and preoperative (B) and postoperative (C) CTA. Artist depiction of the treated aneurysm (D) and the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (E).

TAMBE EFS



Technical aspects and 30-day outcomes of the prospective early feasibility study of the GORE EXCLUDER Thoracoabdominal Branched Endoprosthesis (TAMBE) to treat pararenal and extent IV thoracoabdominal aortic aneurysms

Check for updates

Gustavo S. Oderich, MD,[a] Mark A. Farber, MD,[b] Pierre Galvagni Silveira, MD,[c] Rami Tadros, MD,[d] Michael Marin, MD,[d] Mark Fillinger, MD,[e] Michel Makaroun, MD,[f] Jason Hemmer, PhD,[g] and Meghan Madden, BS,[g] *Rochester, Minn; Chapel Hill, NC; Florianopolis, Brazil; New York, NY; Lebanon, NH; Pittsburgh, Pa; and Flagstaff, Ariz*

ABSTRACT

Objective: This study reports the technical aspects and 30-day outcomes of the prospective, multicenter early feasibility study designed to evaluate the GORE EXCLUDER Thoracoabdominal Branch Endoprosthesis (TAMBE; W. L. Gore & Associates, Flagstaff, Ariz).

Methods: Thirteen patients with pararenal or extent IV thoracoabdominal aortic aneurysms were prospectively enrolled at five U.S sites and one non-U.S. site from 2014 to 2016. The TAMBE included four portals with either retrograde or antegrade renal portal configuration and used GORE VIABAHN Balloon-Expandable Endoprosthesis (W. L. Gore & Associates) for stenting of the renal and mesenteric arteries. The primary end point was procedural safety at 30 days, defined by absence of major adverse events, including any-cause mortality, myocardial infarction, stroke, paraplegia, bowel ischemia, respiratory failure, severe acute kidney injury (>50% decline in estimated glomerular filtration rate), dialysis, and procedural blood loss >1000 mL.

Results: There were 11 male and two female patients with a mean age of 69 ± 8 years. Mean aneurysm diameter was 61 ± 13 mm. A total of 52 renal and mesenteric arteries were incorporated (4 vessels/patient). Technical success was achieved in 12 patients (92%). One patient had inadvertent occlusion of a right renal artery due to dissection. There was no mortality, aneurysm rupture, conversion to open repair, dialysis, or spinal cord injury. Mean length of hospital stay was 5 ± 3 days. At 30 days, four patients (31%) had major adverse events, all due to procedural blood loss >1000 mL. One patient had a type I endoleak at the distal renal branch, which was successfully treated by placement of an additional renal stent before dismissal. Computed tomography angiography at 30 days showed patent target vessels and no type I or type III endoleak.

Conclusions: This study confirms the early feasibility of the TAMBE for treatment of pararenal and extent IV thoracoabdominal aortic aneurysms. The high technical success, no mortality, and low morbidity rate support contin-

- N=13 (8 antegrade, 5 retrograde)
- 92% technical success (renal artery dissection)
- 31% MAE (all due to >1000cc EBL)

Variable	No. or mean ± standard deviation
General approach	
General endotracheal anesthesia	13
Cerebrospinal fluid drainage	7
Neuromonitoring (SSEP or MEP)	5
Cone beam CT assessment	7
Contrast material volume, mL	192 ± 121
Fluoroscopy time, minutes	103 ± 50
Estimated blood loss, mL	675 ± 577
Total operative time, minutes	308 ± 131
Transfusion of packed red blood cells	6
Right femoral artery access	
Open surgical exposure	10
Percutaneous technique	3
Left femoral artery access	
Open surgical exposure	4
Percutaneous technique	9

Editors' Choice

Check for updates

From the Society for Vascular Surgery

Early outcomes from the pivotal trial of a four-branch off-the shelf solution to treat complex abdominal and type IV thoracoabdominal aortic aneurysms

Mark A. Farber, MD,[a] Jon S. Matsumura, MD,[b] Sukgu Han, MD,[c] Michel S. Makaroun, MD,[d] Bjoern D. Suckow, MD,[e] Carlos H. Timaran, MD,[f] Bernardo C. Mendes, MD,[g] *and* Gustavo S. Oderich, MD,[h] *Chapel Hill, NC; Aurora, CO; Los Angeles, CA; Pittsburgh, PA; Dallas and Houston, TX; Rochester, MN; and Lebanon, NH*

ABSTRACT

Background: This study reports the 30-day outcomes of the primary arm of the GORE EXCLUDER Thoracoabdominal Branch Endoprosthesis (TAMBE) pivotal trial for complex abdominal aortic aneurysm repair.

Methods: This multicenter, nonrandomized, prospective study of the TAMBE device included patients enrolled in the primary study arm of extent IV thoracoabdominal aortic aneurysms and pararenal aneurysms. Technical success and major adverse events were analyzed per the Society for Vascular Surgery guidelines.

Results: The 102 patients of the primary arm who underwent endovascular repair using the TAMBE device were a mean age of 73 ± 6.4 years (range, 58–82 years) and 84 (84.2%) were male. The mean body mass index was 28.3 ± 5.0 kg/m^2. Fifty-nine patients (57.8%) were treated for extent IV and 43 (42.2%) pararenal aneurysms; the mean maximum diameter of the aneurysms was 59.4 ± 7.8 mm. A prophylactic cerebral spinal fluid drain was used in 10 patients (9.8%). Technical success was achieved in 99% of patients, with the single failure owing to unsuccessful cannulation of the left renal artery. Mean procedure time was 315 ± 103 minutes (range, 163-944 minutes), estimated blood loss was 300 ± 296 mL (range, 10-2000 mL), and contrast administration was 153.6 ± 73.5 mL (range, 16-420 mL). The intensive care unit length of stay was 58.7 ± 52.7 hours (range, 1-288 mL). In 28 patients (27.5%), a total of 32 additional endovascular components were deployed to manage procedural complications including aortic and target vessel dissections and injuries not related to access. Bridging stent grafts were deployed to incorporate 407 target vessels (mean 1.6/per vessel; range, 1-4). Postoperative transfusion was required in 14 patients (13.7%). Major adverse events occurred in seven patients (6.9%) through 30 days. Events included respiratory failure (n = 2), disabling stroke (n = 1), new-onset renal failure requiring dialysis (n = 2), and paraplegia (n = 2). At 30 days, there was one patient with intraoperative rupture; no severe bowel ischemia or lesion-related/all-cause mortality were reported. The Core lab-reported patency was 100% in the aortic component, superior mesenteric artery, and celiac artery, and 95.9% in the left renal and 99.0% in the right renal branch components through 30 days of follow-up. Reinterventions through 30 days were performed in 9 of 96 patients (9.4%) and were all minor.

Conclusions: Early TAMBE device outcomes demonstrate a high technical success rate, no 30-day lesion-related mortality, and a low rate of safety events within 30 days of the index procedure. (J Vasc Surg 2024;80:1326-35.)

Keywords: Aneurysm; Endovascular grafting; Endovascular interventions; Endovascular repair; Parasuprarenal; Thoracic/thoracoabdominal

FDA U.S. FOOD & DRUG ADMINISTRATION

January 12, 2024

W. L. Gore & Associates, Inc.
Edward Newton
Regulatory Affairs
3450 W. Kiltie Lane
Flagstaff, Arizona 86005

Re: P230023
Trade/Device Name: GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE)
Product Code: QZK
Filed: July 19, 2023

Dear Edward Newton:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the GORE EXCLUDER Thoracoabdominal Branch Endoprosthesis. This device is indicated for endovascular repair in patients with thoracoabdominal aortic aneurysms and high-surgical risk patients with pararenal aortic aneurysms who have appropriate anatomy as described below.

1. Adequate iliac / femoral access and brachial / axillary access
2. Proximal (supraceliac) aortic neck treatment diameter range over 2 cm seal zone of 22 - 34 mm for aneurysms extending up to 6.5 cm or less above the origin of the most proximal branch vessel
3. Aortic neck angle ≤ 60° at the Aortic Component proximal seal zone
4. Iliac artery treatment diameter range of 8 - 25 mm and iliac artery seal zone length of at least 10 mm
5. Renal artery seal zone diameters between 4.0 - 10.0 mm
6. Celiac and superior mesenteric artery seal zone diameters between 5.0 - 12.0 mm
7. ≥ 15 mm seal zone length in renal arteries, superior mesenteric artery, and celiac artery
8. Visceral segment of aorta (3 cm proximal through 9.5 cm distal to the most proximal visceral artery) must be ≥ 20 mm in diameter

Based upon the information submitted, the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions of approval described below. Although this letter refers to your product as a device, please be aware that some approved products may instead be combination products. The Premarket Approval Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm identifies combination product submissions.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Editors' Choice

From the Society for Vascular Surgery

Early outcomes from the pivotal trial of a four-branch off-the shelf solution to treat complex abdominal and type IV thoracoabdominal aortic aneurysms

Mark A. Farber, MD,[a] Jon S. Matsumura, MD,[b] Sukgu Han, MD,[c] Michel S. Makaroun, MD,[d] Bjoern D. Suckow, MD,[e] Carlos H. Timaran, MD,[f] Bernardo C. Mendes, MD,[g] and Gustavo S. Oderich, MD,[h] *Chapel Hill, NC; Aurora, CO; Los Angeles, CA; Pittsburgh, PA; Dallas and Houston, TX; Rochester, MN; and Lebanon, NH*

Device technical success/procedural safety co-primary end points	No. (%)
Device technical success (SVS reporting standards)[a,b]	101 (99.0)
Failure of delivery without need for reintervention	0
Failure of deployment	1 (1.0)
Type I or III endoleak at index procedure (Core lab determined)	0
Failure of uncomplicated technical success (protocol defined)[a]	19 (18.6)
Failure of successful access and delivery	0
Failure of successful and accurate deployment[c]	19 (18.6)

Clinical outcomes	Value
Protocol-defined procedural safety events at 30 days[b]	8 (7.8)
Stented segment aortic rupture	1 (1.0)
Lesion-related mortality	0
Permanent paraplegia	2 (2.0)
Permanent paraparesis	3 (2.9)
New onset renal failure requiring dialysis	2 (2.0)
Severe bowel ischemia	0
Disabling stroke	1 (1.0)
SVS reporting standards MAE at 30 days[b,c]	7 (6.9)
Respiratory failure	2 (2.0)
Myocardial infarction	0
Stroke	1 (1.0)
Paraplegia	2 (2.0)
Acute renal failure	2 (2.0)
Bowel ischemia	0
Death	0
Intraoperative aortic rupture[d]	1 (1.0)
Secondary end points	
Acute kidney injury, n/N, % (95% CI)	4/91 (4.4) [1.2-10.9]
Aneurysm-related mortality at 30 days	0/102 (0.0)
Endoleak[e]	
Type I	0/102 (0.0)
Type III	0/102 (0.0)
Reintervention through 30 days	9/96 (9.4)

From the Society for Vascular Surgery

One-year outcomes from the pivotal trial of a four-branch off-the-shelf solution to treat pararenal and extent IV thoracoabdominal aortic aneurysms

Mark A. Farber, MD,[a] Sukgu Han, MD,[b] Michel S. Makaroun, MD,[c] Jon S. Matsumura, MD,[d] Bernardo C. Mendes, MD,[e] Gustavo S. Oderich, MD,[f] Luis A. Sanchez, MD,[g] Bjoern D. Suckow, MD,[h] and Carlos H. Timaran, MD,[i] *Chapel Hill, NC; Los Angeles, CA; Pittsburgh, PA; Aurora, CO; Rochester, MN; Houston and Dallas, TX; St. Louis, Mo; and Lebanon, NH*

ABSTRACT

Objective: To report 1-year primary-arm outcomes of the GORE EXCLUDER Thoracoabdominal Branch Endoprosthesis pivotal trial.

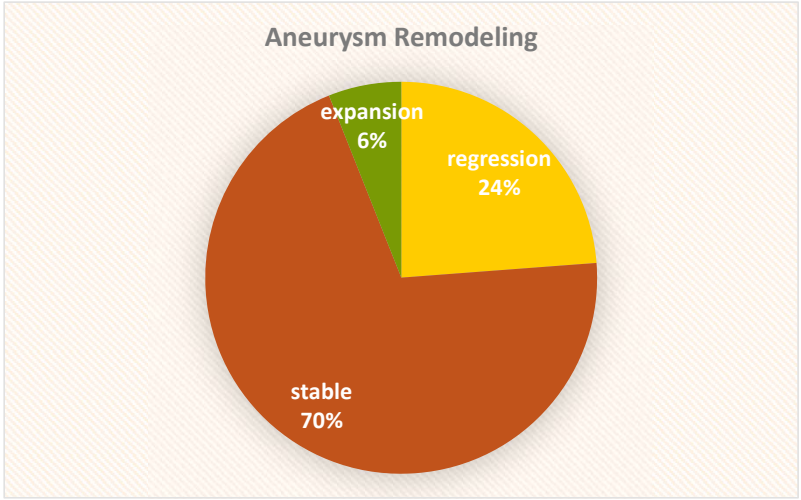
Methods: The multicenter, nonrandomized, prospective study included patients with extent IV thoracoabdominal aortic aneurysms (TAAAs) and pararenal aortic aneurysms (PRAAs). All-cause and adjudicated lesion-related mortality were assessed at 12 months. Core-lab-reported, imaging-dependent outcomes included aneurysm size, endoleaks assessed through 1-year follow-up window, and target vessel instability (defined as occlusion, stenosis, type Ic/IIIc endoleak, or reintervention) at 1 year.

Results: One hundred two patients were treated; 59 patients had an extent IV TAAA and 43 had a PRAA. The mean maximum aneurysm diameter was 59.4 ± 7.8 mm. At 1 year, eight patients were lost to follow-up and six patients died (1 device-related, 1 procedure-related, and 4 unrelated causes). No lesion-related mortality occurred. Freedom from all-cause mortality was 94.1% ± 2.3%. The 1-year combined freedom from "clinically significant reintervention" and lesion-related mortality was achieved in 78.7% and 60.5% of patients with extent IV TAAAs and PRAAs, respectively ($P = .09$). At least one target vessel branch occlusion occurred in 14.7% of patients through 1 year of follow-up. At the vessel level, freedom from target vessel instability at 1 year was 94.2% ± 1.2% (celiac 99.0% ± 1.0%, superior mesenteric 97.1% ± 1.7%, right renal 90.8% ± 2.9%, and left renal 89.8% ± 3.1%). Acute kidney injury requiring dialysis occurred in three patients (n = 2 permanent, n = 1 temporary) through 1 year. Renal artery occlusion occurred more often in arteries with diameters <5 mm (odds ratio = 3.04; 95% confidence interval: 1.08, 8.54) and in patients with pararenal aneurysms (odds ratio = 2.85; 95% confidence interval: 0.88, 9.25, statistically insignificant). Of the 22 reinterventions in 15 patients, 16 (73%) reinterventions were classified as minor: 13 (81%) for target vessel complications and 3 (19%) for type II endoleaks. Device- or procedure-related major reinterventions in six patients included thrombectomy or thrombolysis for target vessel occlusion (n = 5) and one exploratory laparotomy after procedural aortic rupture. No type I/III endoleaks were identified (Core Lab) through 1 year. Aortic enlargement (>5 mm) occurred in 5 patients (6.0%). Aneurysm shrinkage (>5 mm) occurred in 20 patients (23.8%). Aortic component fractures identified in 3 patients (3.6%) were clinically insignificant.

Conclusions: Although mortality remains low 1 year after treatment with the GORE EXCLUDER Thoracoabdominal Branch Endoprosthesis device for extent IV and pararenal aneurysms, renal artery occlusion was the predominant adverse event and was primarily associated with PRAAs and smaller renal vessel diameters. During extended follow-up, attention should be focused on renal branch assessment to identify patients at risk for occlusion. (J Vasc Surg 2025;■:1-10.)

Keywords: Aneurysm; Endovascular grafting; Endovascular interventions; Endovascular repair; Para-supra renal; Thoracic/thoracoabdominal; Target vessel instability

- N=102 with 96 patient data analyzed at 1 year follow-up
- 12 months
  - 0 aorta-related mortality
  - 94% overall survival
  - 29.4% clinically significant reintervention



1 YEAR TAMBE PIVOTAL DATA

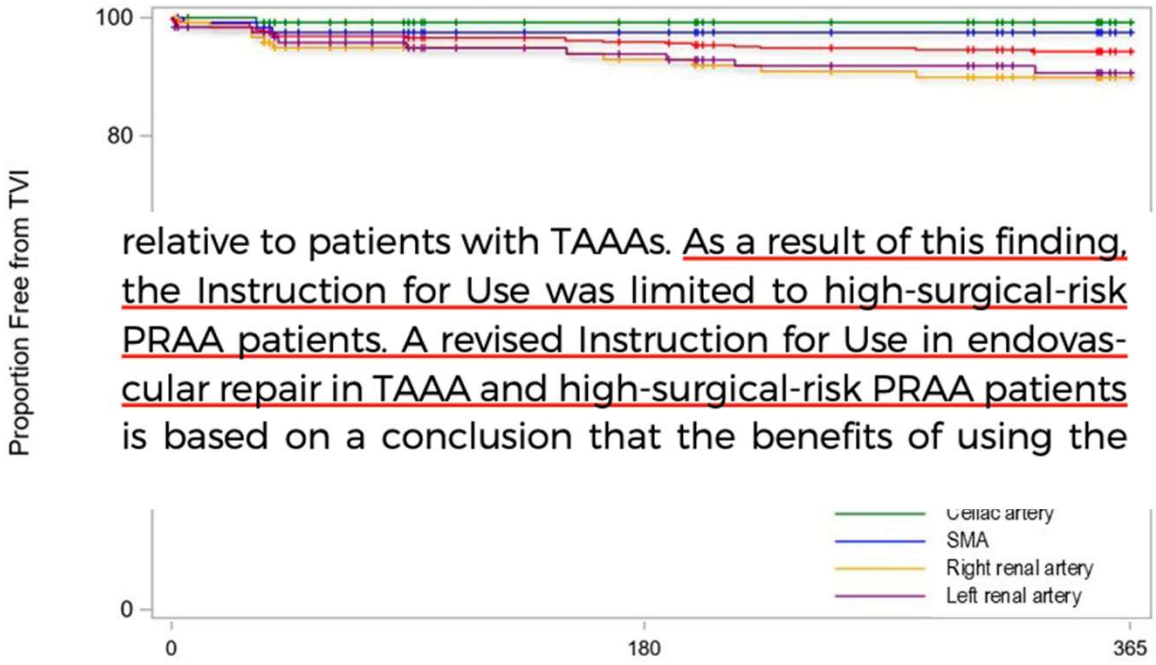
- 14.7% of patients experienced a branch vessel occlusion at 12 months

Vessel	N at risk[a]	N[b] events	N[b] censored	Survival, SE	Primary patency, %	95% CI
All						
0	408	1 (1)	0 (0)	0.002	99.8	98.3, 100
0-30 days	407	5 (6)	0 (0)	0.006	98.5	96.8, 99.3
90-180 days	382	3 (14)	8 (23)	0.009	96.5	94.2, 97.9
180-365 days	371	6 (20)	59 (82)	0.011	94.9	92.2, 96.7
Celiac						
0	102	0 (0)	0 (0)	0.000	100	100, 100
0-30 days	102	0 (0)	0 (0)	0.000	100	100, 100
90-180 days	97	0 (1)	2 (6)	0.010	99.0	93.2, 99.9
180-365 days	95	0 (1)	15 (21)	0.010	99.0	93.2, 99.9
SMA						
0	102	0 (0)	0 (0)	0.000	100	100, 100
0-30 days	102	1 (1)	0 (0)	0.010	99.0	93.2, 99.9
90-180 days	96	0 (3)	2 (5)	0.017	97.1	91.2, 99.0
180-365 days	94	0 (3)	15 (20)	0.017	97.1	91.2, 99.0
Right renal						
0	102	0 (0)	0 (0)	0.000	100	100, 100
0-30 days	102	2 (2)	0 (0)	0.014	98.0	92.4, 99.5
90-180 days	95	2 (5)	2 (6)	0.022	95.0	88.3, 97.9
180-365 days	91	3 (8)	15 (21)	0.028	91.8	84.2, 95.8
Left renal						
0	102	1 (1)	0 (0)	0.010	99.0	93.2, 99.9
0-30 days	101	2 (3)	0 (0)	0.017	97.1	91.2, 99.0
90-180 days	94	1 (5)	2 (6)	0.022	95.0	88.4, 97.9
180-365 days	91	3 (8)	14 (20)	0.028	91.7	84.2, 95.8

1 YEAR TAMBE PIVOTAL DATA

- Risk factors for renal artery occlusion
  - Arteries < 5mm diameter (OR: 3.04, 95%CI: 1.08~8.54)
  - Pararenal (vs extent IV TAAA) extent (OR: 2.85, 95% CI: 0.88~9.5).

  …?
  - NO association between aortic luminal diameter, renal angle, compression, branch length, tortuosity index, vessel position, orientation, antiplatelet use.



relative to patients with TAAAs. As a result of this finding, the Instruction for Use was limited to high-surgical-risk PRAA patients. A revised Instruction for Use in endovascular repair in TAAA and high-surgical-risk PRAA patients is based on a conclusion that the benefits of using the

1 YEAR TAMBE PIVOTAL DATA

Device effectiveness assessment by protocol definitions	Value, n/N[a] (%)
Endoleaks at 12 months[b]	
Type Ia, Ib, or Ic	0/81 (0)
Type II	64/91 (70.3)
Type III	0/81 (0)
Indeterminate	14/84 (16.7)
Migration[b]	0/87 (0)
Aneurysm enlargement[b]	5/93 (5.4)
Severe distal thromboembolic events[c]	2/95 (2.1)
Aortic rupture[c]	1/94 (1.1)
Device- or procedure-related laparotomy[d]	4/95 (4.2)
Conversion to open repair[d]	0/94 (0)
Aortoiliac device limb occlusion[b]	0/93 (0)
Loss of device integrity[b]	14/86 (16.3)
Wire fracture	3/83 (3.6)
Device compression	11/90 (12.2)
Kink	0/87 (0)
Reintervention in 12 months[a]	15/94 (16.0)
Renal function deterioration through 12 months[d,e]	14/74 (18.9)

- Branch compression was a major indication for reintervention (33%)
  - *No statistical association between compression and occlusion*
- More common in pararenal aneurysm vs extent IV TAAA

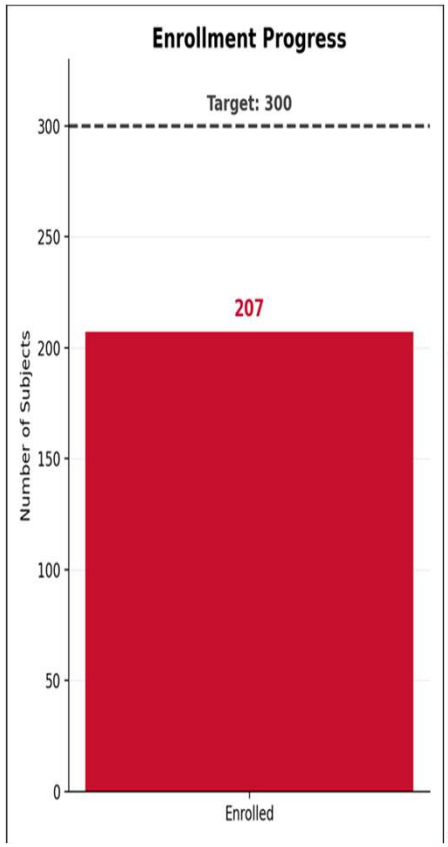
78% were patent at 1 year. Therefore, the need for intraoperative axial imaging assessment cannot be overemphasized. Angiography alone is not sensitive enough to detect compression that can be easily resolved during the index procedure. Cone-beam CT imaging is recommended during the treatment procedure after deployment to evaluate the TAMBE device orientation and integrity. None of the target vessel compression occluded after secondary intervention. This is an important finding and stresses the need for careful inspection

COMMERCIAL ROLL OUT since 5/2024

- Rapid adoption of TAMBE Certified and in-progress
- 450+ physicians attended training
- 2000+ cases
  - ~100 cases per month
- ANZ, Japan

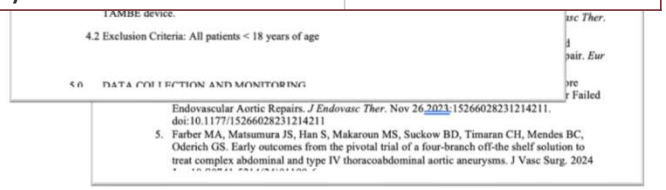
GORE POST-MARKET TAMBE STUDY

- National PI: Jason T Lee, MD, Stanford
- Enrollment: ***Prospective***
- Target Sample Size: 300
- Planned Follow Up: 10 years



PHYSICIAN-INITIATED POST-MARKET ”GAP” REGISTRY

Center	Patients Enrolled Currently
USC	92
Southern California Kaiser	27
Mayo Clinic	23
University of Missouri	22
Stanford	20
University of Texas, Dallas	17
University of North Carolina	13
Case Western	11
Honor Health	10
University of Utah	5
University of New Mexico	1


TAMBE device.

4.2 Exclusion Criteria: All patients < 18 years of age

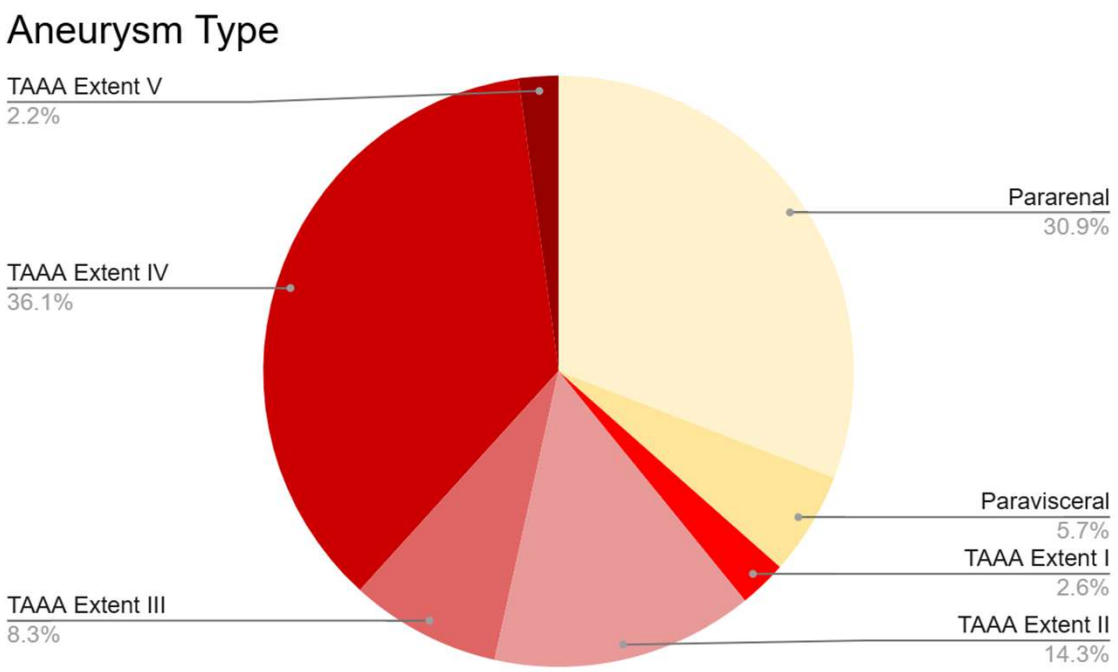
5.0 DATA COLLECTION AND MONITORING

Endovascular Aortic Repairs. *J Endovasc Ther*. Nov 26:2023:15266028231214211. doi:10.1177/15266028231214211.

5. Farber MA, Matsumura JS, Han S, Makaroun MS, Suckow BD, Timaran CH, Mendes BC, Oderich GS. Early outcomes from the pivotal trial of a four-branch off-the shelf solution to treat complex abdominal and type IV thoracoabdominal aortic aneurysms. J Vasc Surg. 2024

- Enrollment Status: N=241

Comorbidities	n	Percentage
Hypertension	209	89.3%
Hyperlipidemia	168	72.7%
Coronary Artery Disease	98	42.2%
COPD	59	25.5%
Diabetes	47	20.3%
MI	37	17.2%
Peripheral Arterial Disease	38	16.5%
Chronic Kidney Disease	37	16.2%
Congestive Heart Failure	37	15.9%
Stroke/TIA	37	15.9%
Atrial Fibrillation	28	14.1%
Prior Coronary Artery Bypass Surgery	22	12.5%
Arrhythmia	18	9.2%
Oxygen Dependent	3	1.4%
Smoking History		
Prior Use	115	46.9%
Current Use	52	21.2%
Genetic History		
Family History	12	4.9%
Marfan's	3	1.2%
Loeys-Dietz	1	0.4%
ACTA2 Mutation	1	0.4%
ASA		
2 - Mild Disease	23	3.4%
3 - Severe Disease Limiting Activity	121	49.4%
4 - Incapacitating Disease	67	27.3%
5 - Moribund, <24hr expected survival	3	1.2%



Operative Details	n	
Anesthesia Type		
General	186	98.4%
Regional	3	1.6%
CSF Drain Placed	61	31.3%
SES/MEP Monitoring	53	28.0%
	Mean	**Range**
OR Time	268	110-747
Procedure Time	185	66-637
Fluoroscopy Time	76.6	11-195
Contrast Volume	167	30-610
EBL	276	20-2000
Blood Products Transfused	**n**	**Percentage**
PRBC	52	27.1%
FFP	15	8.5%
Cell Saver	2	1.2%
Platelets	0	0%

Access Site Number		
1	11	4.9%
2	59	26.5%
3	153	68.6%
TAMBE Size		
31	77	31.4%
37	113	46.1%
Intraop Complication	18	7.3%
Technical Success	218	90.5%

Technical strategies and pitfalls for total transfemoral implantation of off-the-shelf four vessel thoracoabdominal multibranch endoprosthesis with or without utilization of preloaded wires

Sukgu M. Han, MD, MS,[a] Alyssa Pyun, MD,[a] and Gustavo S. Oderich, MD,[b] Los Angeles, California; and Houston, Texas

ABSTRACT
The thoracoabdominal multibranch endoprosthesis is a commercially available off-the-shelf four-vessel inner branched endograft for complex abdominal and thoracoabdominal aortic aneurysms. Although the device is intended to be used with upper extremity access per its instructions for use, total transfemoral approach may be needed in patients with unfavorable arch anatomy and may decrease the risk of cerebrovascular events. This article describes technical strategies and pitfalls of total transfemoral thoracoabdominal multibranch endoprosthesis implantation techniques with conventional co-axial steerable sheath, as well as variations of techniques utilizing preloaded wires in "up-and-over" configuration. (J Vasc Surg Cases Innov Tech 2024;10:101615.)

Keywords: Complex abdominal aortic aneurysms; Fenestrated-branched endovascular aortic repair; Off-the-shelf multi-branched stent grafts; Thoracoabdominal aortic aneurysm; Thoracoabdominal multibranched endoprosthesis (TAMBE); Total transfemoral branched EVAR

The thoracoabdominal multibranch endoprosthesis (TAMBE, W.L. Gore & Associates) marks a significant advancement in this area as the first dedicated off-the-shelf four-vessel branched endograft to receive commercial approval from the United States Food and Drug Administration. The device is intended to be utilized with a preloaded guidewire system accessible from upper extremity (UE) approach. Although UE has several advantages for branch artery stenting, it has been associated with increased risk of cerebrovascular embolic events and possible risk of peripheral nerve and vascular injury.[1] Therefore, total transfemoral approach has been increasingly adopted during fenestrated branched endovascular aortic repairs (FBEVAR) using steerable sheaths.[1,2] We describe technical strategies and pitfalls for total transfemoral TAMBE implantation with or without utilization of preloaded wire system, and with or without utilization of staggered deployment system.

Institutional review board approval was waived for this case report. Patients provided institutional consent for participation with minimal risk research protocols.

TECHNIQUE 1: STANDARD TRANSFEMORAL TECHNIQUE WITHOUT PRELOADED WIRE SYSTEM

The technique was used in a 76-year-old female with symptomatic 5.5-cm extent III thoracoabdominal aortic aneurysm (TAAA). The patient's medical history was notable for coronary artery disease, congestive heart failure, atrial fibrillation, and chronic kidney disease. She had previous history of coronary artery bypass, ascending aortic replacement, and thoracic endovascular aortic repair with development of new focal dissection distally with 8-mm VBX stent grafts (W.L. Gore & Associates) for celiac and superior mesenteric artery (SMA), and 7-mm VBX stent-grafts for the renal arteries. Under general anesthesia, a temporary open right femoral conduit was placed after femoral endarterectomy, percutaneous left femoral access was achieved, and the left brachial artery was exposed per instructions for use. Following the micropuncture access of the left brachial artery, the left axillary and subclavian arteries were noted to be diseased and tortuous, leading to dissection. Attempts

ELSEVIER
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Available online 15 January 2025, 101737
In Press, Journal Pre-proof What's this?

Double Preloaded Internal Up-and-Over Technique for Total Transfemoral Four Vessel Thoracoabdominal Multibranch Endoprosthesis with Temporary Aortic Balloon Occlusion for Ruptured Complex Abdominal Aortic Aneurysm

Sukgu M. Han MD MS [1], Imani McElroy MD [1], Gustavo S. Oderich MD [2]

Sage Journals
EPUB Report

Techniques and Limitations of Gore Thoracoabdominal Multibranch Endoprosthesis (TAMBE) for Type 1A Endoleak After Failed Endovascular Aortic Repairs

Sukgu M. Han, MD, MS [1], Alexander D. DiBartolomeo, MD [1], Marin Chavez, MD [2], and Andrew J. Meltzer, MD, MBA [2]

Purpose: Endovascular aortic aneurysm repair (EVAR) is the dominant treatment modality over open repair for abdominal aortic aneurysms. However, a higher rate of reinterventions remains the Achilles heel of EVAR. Although type 1A endoleak from proximal seal zone failure of EVAR remains one of the leading causes for reintervention, fenestrated branched devices suitable for proximal extension of failed EVAR are not widely available in the United States. Gore Thoracoabdominal Multibranch Endoprosthesis (TAMBE) is an off-the-shelf investigational device that provides supraceliac seal by incorporating 4 visceral and renal arteries via preloaded inner branches.

Case Report: In this article, we describe 2 cases of type 1A endoleak from previous EVAR devices repaired using TAMBE. Both cases were performed under the Food and Drug Administration (FDA) compassionate use exemption. Considerations on the case planning and implantation techniques of TAMBE specific to previous EVAR devices are reviewed.

Conclusions: Gore TAMBE can be utilized to repair a type 1A endoleak of a previous infrarenal EVAR device. Greater supraceliac coverage necessary for TAMBE relative to the minimal seal zone should be considered when applying this device for a type 1A endoleak.

Clinical Impact This report demonstrates the feasibility of applying off-the-shelf TAMBE device to treat one of the most common failure modes of EVAR, type1A endoleak.

Keywords
Gore thoracoabdominal multibranch endoprosthesis, type1A endoleak, failed EVAR, complex endovascular aortic repair

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Application of off-the-shelf thoracoabdominal multibranch endoprosthesis for urgent repair of pararenal and thoracoabdominal aortic aneurysms with occluded target vessels

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ABSTRACT
The Thoracoabdominal Multibranch Endoprosthesis (TAMBE) is a commercially available off-the-shelf four-vessel inner branched endograft for thoracoabdominal aortic aneurysms (TAAA) and pararenal abdominal aortic aneurysms (AAA). However, there is paucity of data on the use of TAMBE in repair of pararenal AAA and TAAA with occluded target vessels. Here, we present two cases demonstrating the feasibility of TAMBE for repair of pararenal AAA and TAAA in patients with occluded target vessels. (J Vasc Surg Cases Innov Tech 2024;■:101689.)

Modified deployment technique of off-the-shelf Gore thoracoabdominal multibranch endoprosthesis for post-dissection thoracoabdominal aortic aneurysm repair

Kenneth Han, BA, Alyssa Pyun, MD, *and* Sukgu M. Han, MD, MS, *Los Angeles, CA*

ABSTRACT
The Thoracoabdominal Multibranch Endoprosthesis (TAMBE) is a commercially available off-the-shelf four-vessel inner branched endograft for complex abdominal and thoracoabdominal aortic aneurysms. As post-dissection thoracoabdominal aortic aneurysms (PD-TAAAs) were excluded from the pivotal trials, there is paucity of data on the use of TAMBE in PD-TAAAs. Here, we present a case demonstrating the feasibility of TAMBE in conjunction with iliac branch endoprosthesis to repair PD-TAAAs, with focus on the deployment technique specific to PD-TAAAs. (J Vasc Surg Cases Innov Tech 2024;10:101632.)

TRANSFEMORAL TAMBE (N=31)

Access Type	Transfemoral (n=31)	Standard Access (n=69)	p-Value
Coronary Artery Disease	32.3% (10)	33.3% (23)	1
Atrial Fibrillation	16.1% (5)	11.6% (8)	0.5343
Myocardial Infarction	6.5% (2)	13.0% (9)	0.4949
Congestive Heart Failure	19.4% (6)	10.3% (7)	0.335
CABG	12.9% (4)	11.8% (8)	1
Hypertension	93.5% (29)	84.1% (58)	0.3345
Hyperlipidemia	58.1% (18)	73.9% (51)	0.1601
Oxygen Dependent	3.2% (1)	2.9% (2)	1
Diabetes	19.4% (6)	24.6% (17)	0.6178
Stroke	22.6% (7)	18.8% (13)	0.7876
Chronic Kidney Disease	19.4% (6)	13.0% (9)	0.5454

	Transfemoral (n=31)	Standard Access (n=69)	p-Value
30-day Mortality	3.2% (1)	2.9% (2)	1
Technical Success	96.8% (30)	95.7% (66)	0.5348
Adverse Events	22.6% (7)	14.5% (10)	0.3899
Major Adverse Events	16% (5)	13% (9)	0.7579
Myocardial Infarction	3.2% (1)	0% (0)	0.289
Prolonged Ventilation	3.2% (1)	0% (0)	0.289
Reintubation	0% (0)	2.9% (2)	1
Acute Kidney Injury	0% (0)	2.9% (2)	1
New Hemodialysis	0% (0)	4.3% (3)	0.554
Bowel Ischemia	3.2% (1)	1.4% (1)	0.496
Stroke	0% (0)	0% (0)	
Spinal Cord Ischemia	16% (5)	7.2% (5)	0.146
Spinal Cord Ischemia Severity			1
Resolved with minimal sensory deficit	60.0% (3)	60.0% (3)	
Minor motor deficit	0% (0)	20.0% (1)	
Able to move against gravity	20.0% (1)	0% (0)	
Able to move the extremity laterally	0% (0)	20.0% (1)	
Minimal or no movement	20.0% (1)	0% (0)	

TYPE1A ENDOLEAK REPAIR (N=22)

	Rescue TAMBE (n=22)	De novo TAMBE (n=78)	p-Value
Coronary Artery Disease	40.9% (9)	30.8% (24)	0.443
Atrial Fibrillation	27.3% (6)	9.0% (7)	0.035
Myocardial Infarction	18.2% (4)	9.0% (7)	0.252
Congestive Heart Failure	13.6% (3)	13.0% (10)	1
CABG	18.2% (4)	10.4% (8)	0.457
Hypertension	90.9% (20)	85.9% (67)	0.727
Hyperlipidemia	68.2% (15)	69.2% (54)	1
Oxygen Dependent	4.5% (1)	2.6% (2)	0.53
Diabetes	13.6% (3)	25.6% (20)	0.389
Stroke	27.3% (6)	17.9% (14)	0.37
Chronic Kidney Disease	27.3% (6)	11.5% (9)	0.901

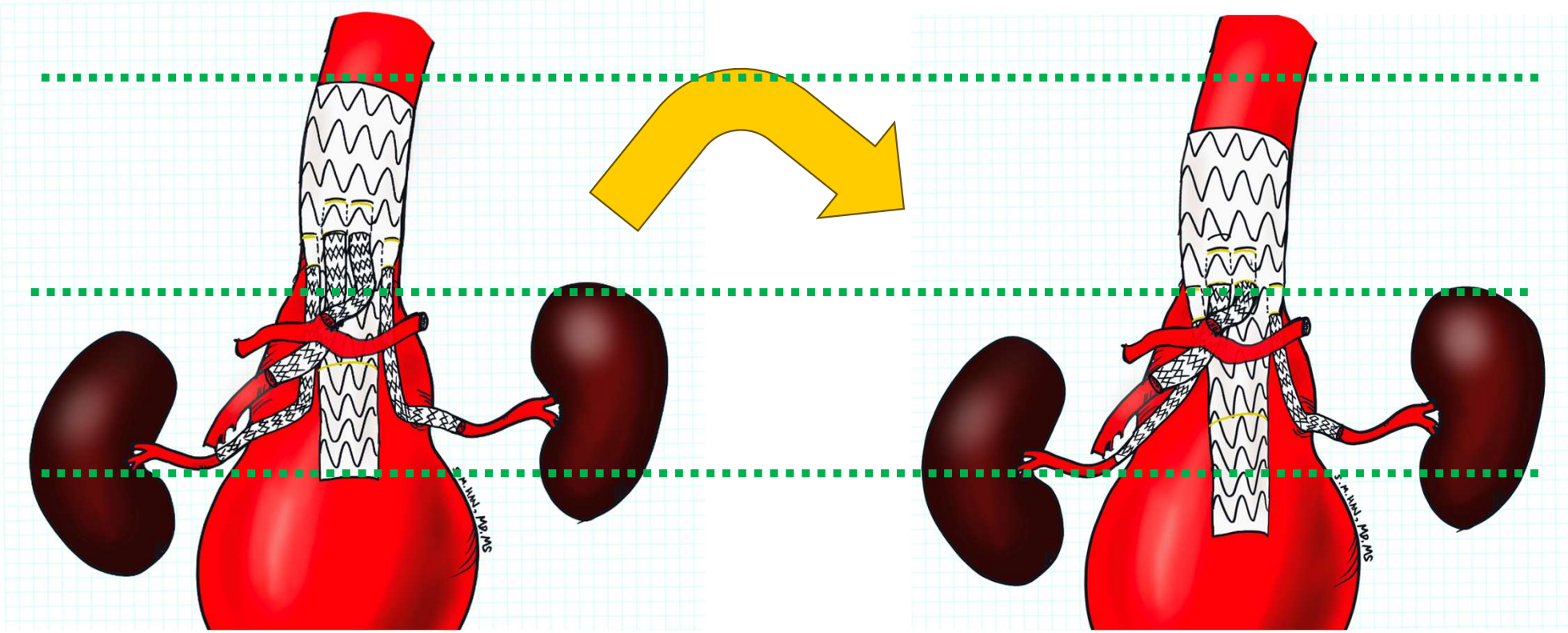
	Rescue EVAR (n=22)	De novo TAMBE (n=78)	p-Value
30-day Mortality	4.5% (1)	2.6% (2)	0.53
Technical Success	100% (22)	94.9% (74)	0.573
Adverse Events	27.3% (6)	14.1% (11)	0.197
Major Adverse Events	9.1% (2)	15.4% (12)	0.729
Myocardial Infarction	0% (0)	1.3% (1)	1
Prolonged Ventilation	0% (0)	1.3% (1)	1
Reintubation	4.5% (1)	1.3% (1)	0.404
Acute Kidney Injury	0% (0)	2.6% (2)	1
New Hemodialysis	4.5% (1)	2.6% (2)	0.542
Bowel Ischemia	0% (0)	2.6% (2)	1
Stroke	0% (0)	0% (0)	
Spinal Cord Ischemia	4.5% (1)	11.5% (9)	0.447

POST-DISSECTION ANEURYSMS (N=23)

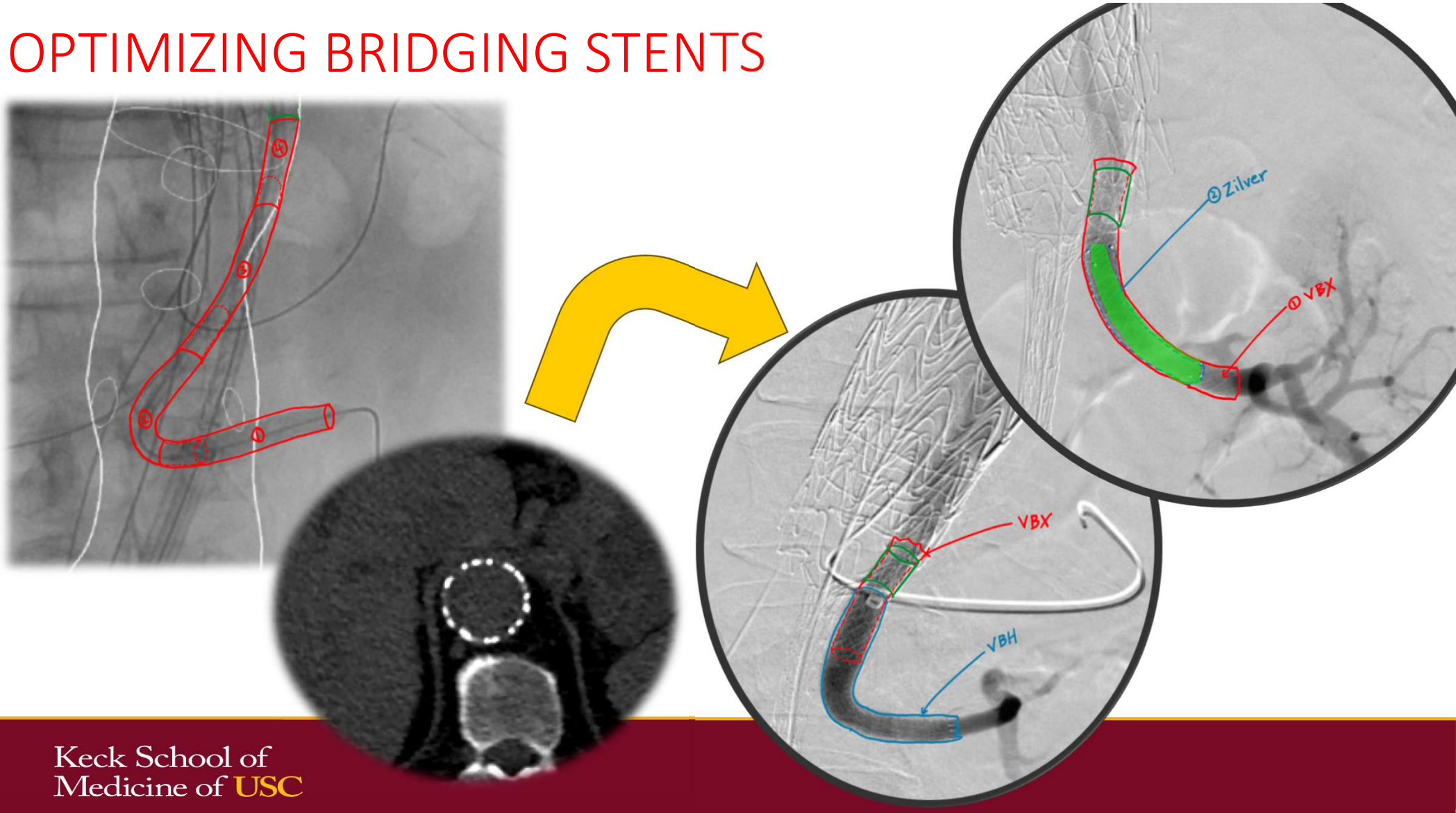
	Post Dissection (n=23)	Degenerative (n=77)	p-Value
Coronary Artery Disease	8.7% (2)	40.3% (31)	0.005
Atrial Fibrillation	13.0% (3)	13.0% (10)	1
Myocardial Infarction	0% (0)	14.3% (11)	0.064
Congestive Heart Failure	13.0% (3)	13.2% (10)	1
CABG	0% (0)	15.6% (12)	0.063
Hypertension	100% (23)	83.1% (64)	0.036
Hyperlipidemia	69.6% (16)	68.8% (53)	1
Oxygen Dependent	8.7% (2)	1.3% (1)	0.131
Diabetes	17.4% (4)	24.7% (19)	0.58
Stroke	30.4% (7)	16.9% (13)	0.232
Chronic Kidney Disease	8.7% (2)	16.9% (13)	0.51
Marfans	8.7% (2)	1.3% (1)	0.131
Family history	9.1% (2)	4.0% (3)	0.317

	Post Dissection (n=23)	Degenerative (n=77)	p-Value
30-day Mortality	0% (0)	3.9% (3)	1
Technical Success	100% (23)	94.8% (73)	1
Adverse Events	26.1% (6)	14.3% (11)	0.211
[illegible]	[illegible]	[illegible]	[illegible]
Myocardial Infarction	0% (0)	1.3% (1)	1
Prolonged Ventilation	0% (0)	1.3% (1)	1
Reintubation	0% (0)	2.7% (2)	1
Acute Kidney Injury	0% (0)	2.7% (2)	1
New Hemodialysis	0% (0)	4.0% (3)	1
Bowel Ischemia	0% (0)	2.7% (2)	1
Stroke	0% (0)	0% (0)	
Spinal Cord Ischemia	13.6% (3)	9.3% (7)	0.69

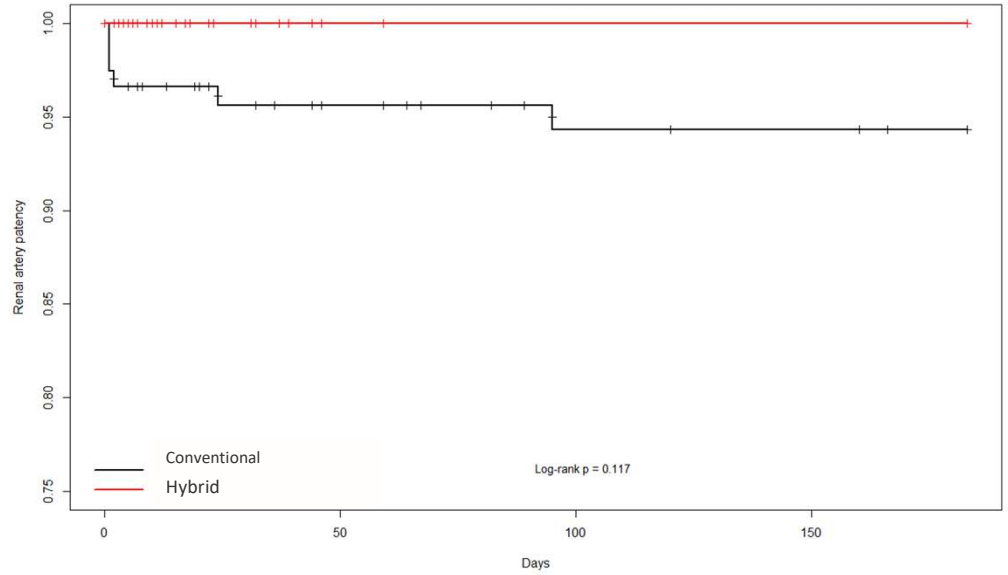
EVOLVING TAMBE CONFIGURATION



OPTIMIZING BRIDGING STENTS



VBX + Self Expanding Hybrid Bridging Stent Strategy



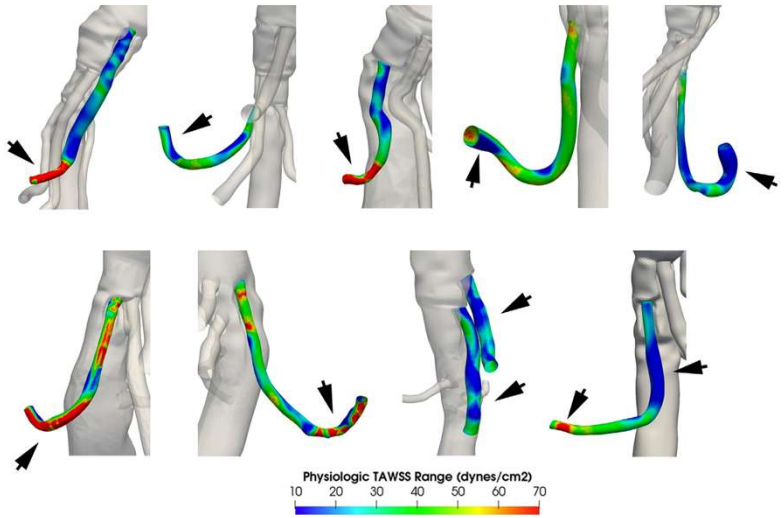
Primary Patency	Overall(n=200)	Hybrid (N=66)	Conventional (n=134)	p-Value
30-day	95.8% (115)	100% (20)	95.0% (95)	0.1733
6-month	92.2% (71)	100% (6)	91.5% (65)	0.1807

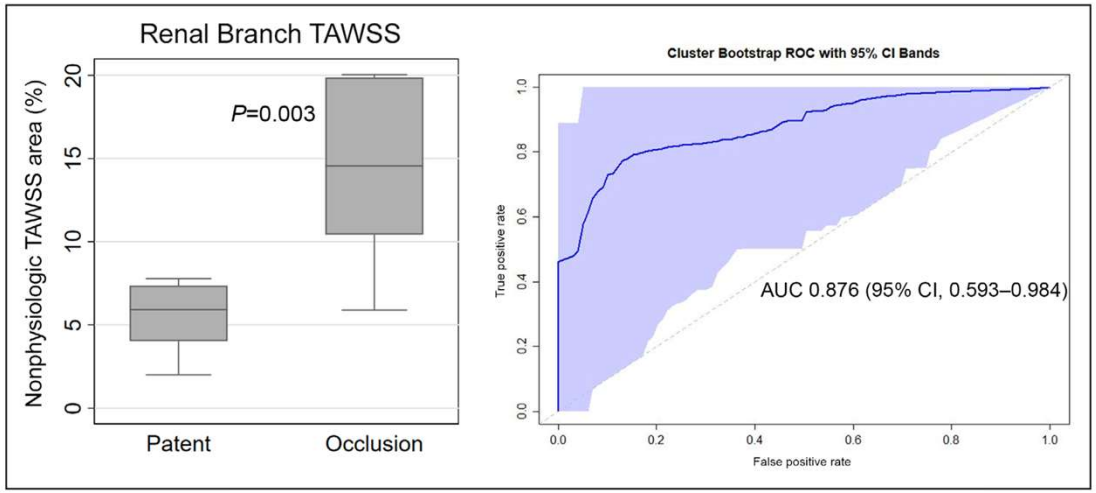
ORIGINAL RESEARCH

Patient-Specific Computational Flow Simulation Reveals Adverse Hemodynamic Factors Associated With Occlusion of Directional Branches After Fenestrated-Branched Endovascular Aneurysm Repair

Kenneth Tran, MD; Jesse Chait, DO; Emmanuel Tenorio, MD, PhD; Weiguang Yang, PhD; Alison Marsden, PhD; Bernardo Mendes, MD; Jason T. Lee, MD; Gustavo S. Oderich, MD

- Simulated abnormal wall shear stress associated with branch occlusion.
- Global assessment of branch geometry
- Localization of shear stress
- ***How do you avoid this?***





CONCLUSIONS

- TAMBE provides an off-the-shelf 4 vessel inner branch platform for cAAA and TAAA
- Rapid, organic adoption with regionalization of care with improved outcomes through institutional learning curve
- TAMBE application expanding beyond IFU (Dissection, Type 1A endoleak, Rupture, Total transfemoral approach)
- Opportunity for optimization and innovation through real-world data