

## Why Balloon Expandable Bridging Stent-Grafts Are Best For F/B/EVAR: Which One Is Best And Why: A US Perspective On The Advantages Of The Gore VBX Stent Graft



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## Disclosures

	Cook Medical	WL Gore	Getinge	VITTA	Centerline Biomedical
Relationship	Research Support, Clinical Trials, Consulting	Clinical Trials, Consulting	Consulting	Clinical Trials, Consulting	Consulting
Received	Grants, Honoraria	Honoraria	Honoraria	Honoraria	Stock Options

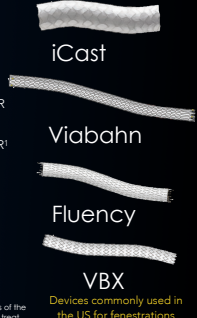
Images courtesy G. Oderich, MD 2

## Introduction

- Currently available stent-grafts used as bridging stents were designed for peripheral use. "Off-label" for F-BEVAR
- There are no consensus regarding the best bridging component for F/B/EVAR
- Self-expanding stent are not historically used in FEVAR
- Gore Viabahn Balloon-Expandable stent-graft designed for use during BEVAR!
- Limited experience with Bentley devices in the US
- Studies comparing different types of bridging stents are relatively scarce.

For BEVAR - UNC Preference is for VBX  
 For FEVAR - UNC Preference is for iCast

**WHY?**



Devices commonly used in the US for fenestrations and branches 3

1. Oderich GS, Farber MA, Silveira PG, Todor R, Martin M, Elfinger M, et al. Technical aspects and 30-day outcomes of the prospective early feasibility study of the GORE EXCLUDER Thoracoabdominal Branched Endoprosthesis (TAMBE) to treat para-aortic and extent IV thoracoabdominal aortic aneurysms. J Vasc Surg. 2019 Aug;70(2):358-368.e6.

## Decision: Branched versus Fenestrated Design

General Concepts

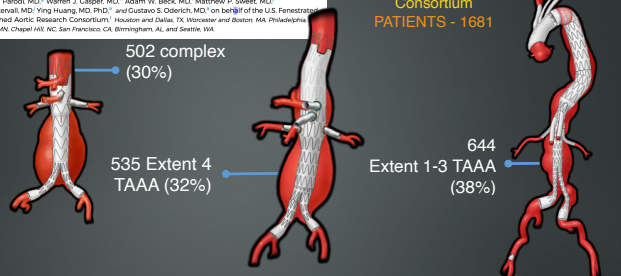
- Decision for design components is typically based upon aortic anatomy
  - Branches typically require
    - greater coverage length
    - improve flexibility in design
    - can be problematic in specific anatomies (cranially oriented target vessels)
  - Branches are preferred when
    - significant distance (> 5 mm) will be present between fenestration and target vessel origin then:
  - Fenestration considerations:
    - MAY provide better renal outcomes ???
    - Better suited for cranially oriented vessels
    - Typically used in narrow aortic lumens

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## Effect of bridging stent graft selection for directional branches on target artery outcomes of fenestrated-branched endovascular aortic repair in the United States Aortic Research Consortium

Emmanuel R. Tenorio, MD, PhD<sup>1</sup>, Andres Schenzer, MD<sup>2</sup>, Carlos H. Timoner, MD<sup>3</sup>, Darren B. Schneider, MD<sup>4</sup>, Bernardo C. Mendes, MD<sup>5</sup>, Matthew J. Eagleton, MD<sup>6</sup>, Mark A. Farber, MD<sup>7</sup>, F. Enriquez Parodi, MD<sup>8</sup>, Warren B. Cassier, MD<sup>9</sup>, Adam W. Beck, MD, Matthew P. Sweet, MD<sup>10</sup>, Sara L. Zafarani, MD, Ying Huang, MD, PhD<sup>11</sup>, and Gustav S. Oderich, MD<sup>12</sup> on behalf of the US Fenestrated and Branched Aortic Research Consortium<sup>1</sup> Houston and Dallas, TX, Worcester and Boston, MA, Philadelphia, Rochester, MN, Chapel Hill, NC, San Francisco, CA, Birmingham, AL, and Seattle, WA

US - Aortic Research Consortium PATIENTS - 1681



502 complex (30%)  
 535 Extent 4 TAAA (32%)  
 644 Extent 1-3 TAAA (38%)

Decision to use branches or fenestrations is on an individual patient basis directed by the treating physician 5

## Fenestrations v. Branches: Renal

5-year Kaplan-Meier Estimates (%)	All targets n = 3155	Fenestration n = 2166 (69%)	Branch n = 989 (31%)	P value
Primary patency	90±1	94±1	83±3	<.001
Secondary patency	94±1	97±1	89±2	<.001
Freedom from target vessel:				
Instability	85±1	88±2	80±2	.001
Type IC or IIIC Endoleak	94±1	94±1	95±1	.78
Secondary intervention	91±1	92±1	90±2	.051

3,155 renal vessels

Renal Fenestrations do better than Renal Branches (patency and instability)  
 Most likely related to high % of renal fenestrations in Type IV TAAA/ PRAA  
 \*Less variation in Mesenteric Vessel Outcomes\*

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## Stent selection for fenestrations

Incorporation aligned by stents	All targets n = 3717	Renal n = 2165	SMA n = 926	CA n = 628	P value
	n (%)				
Fenestrations*	3720	2166	926	626	
iCAST stent graft	3448 (93)	1993 (92)	869 (94)	586 (94)	<.001
VBX/iCast stent graft	116 (3)	93 (4)	15 (2)	8 (1)	
VBX stent graft	91 (2)	33 (2)	31 (3)	27 (4)	
Viabahn/iCast stent graft	35 (1)	31 (1)	2 (0.2)	2 (0.3)	
Other combinations	27 (1.2)	14 (1.2)	9 (1.2)	3 (0.5)	
More than 1 stent	530 (14)	398 (18)	91 (10)	41 (7)	<.001
Mixed stent	153 (4)	124 (6)	19 (2)	10 (8)	<.001
Adjunctive bare metal	727 (20)	365 (17)	310 (33)	52 (8)	<.001

\*Three vessels not stented (1 renal artery, 2 celiac axis)

92% of fenestration were treated with BESG (iCast) —> Not able to do direct stent type comparison

Renal target vessel are best treated with fenestrations using the iCast stent

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## Impact of Bridging Stent Selection in Reinforced Fenestrations During Fenestrated/Branching Endovascular Aortic Aneurysm Repair (FB-EVAR)

Jeremy Zack, BS, Kiera Zehner, BS, Andres Schanzer, MD, Adam W. Beck, MD, Matthew P. Sweet, MD, Gustavo Oderich, MD, Carlos H. Timaran, MD, Mark A. Farber, MD, Warren J. Gasper, MD, W. Anthony Lee, MD, Matthew J. Eagleton, Grace J. Wang, MD, MScE, and Darren B. Schneider, MD

U.S. Aortic Research Consortium (US-ARC)



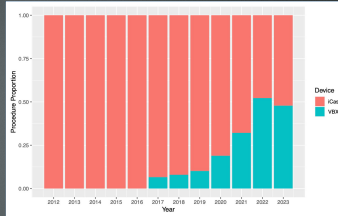
September 24, 2024

## Results: Demographics

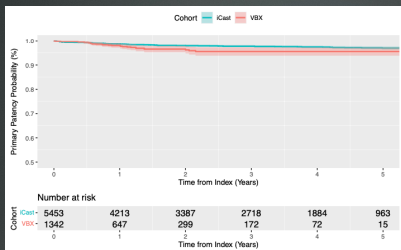
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- 1967 patients
- 6795 target arteries/fenestrations
  - 1342 (20%) VBX stents
  - 5453 (80%) iCAST stents
- Mean age was 74 (±8) years
- Median follow-up overall was 30 months (IQR, 11-54).

Proportion of BECS use over Time



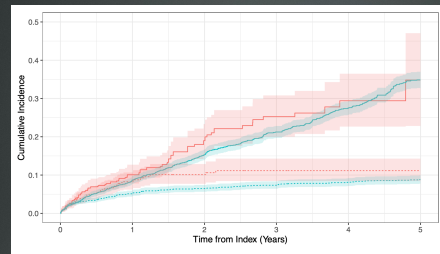
## Results: Primary Patency Renal-Mesenteric TAs



VBX stents had a lower primary patency compared to iCAST at 5 years: 95.5% versus 97%

	VBX	iCAST	P Value
TAI Cumulative Incidence			
Renal + Mesenteric	9.2±1.1	7.4±0.4	0.007
Renal	11.1±1.5	8.8±0.6	0.005
Mesenteric	6.7±1.5	5.2±0.6	0.268
All Target Arteries			
Secondary Intervention	93.3±1	95.8±0.3	<.001
Primary Patency	95.5±0.3	97±0.3	0.009
Secondary Patency	97.8±0.7	98.7±0.2	0.248
Endoleak	96.7±0.7	96±0.3	0.968
Renal Target Arteries			
Secondary Intervention	91.5±1.5	94.5±0.5	<.001
Primary Patency	95.3±1	95.7±0.5	0.109
Secondary Patency	97.8±0.7	97.5±0.4	0.801
Endoleak	95.9±1	95.8±0.4	0.503
Mesenteric Target Arteries			
Secondary Intervention	95.5±1.3	97.7±0.4	0.025
Primary Patency	96.1±1.4	98.9±0.3	0.002
Secondary Patency	97.2±1.2	99.2±0.2	0.018
Endoleak	97.8±0.9	96.3±0.6	0.405

## Results: Cumulative incidence of TAI, Renal Arteries



TAI was significantly higher for fenestrations using VBX stents compared to iCAST at 9.2% versus 7.4%.

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## Results: Multivariable and Matched Cohort Analyses

### Independent predictors of TAI

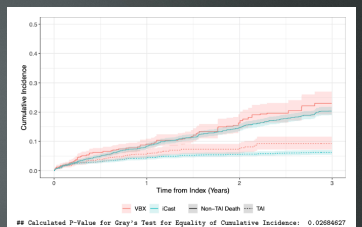
Variable	HR	95% CI Lower	95% CI Upper	P Value
Renal artery incorporation	2.21	1.56	3.12	<.001
Adjunctive self-expandable bare metal stent	0.99	0.76	1.30	0.96
TA diameter (≤1 mm)	1.08	0.98	1.19	0.11
Stent diameter (±1 mm)	1.01	0.87	1.17	0.91
Use of multiple vessels in one TA	2.00	1.56	2.56	<.001
Congestive heart failure	0.80	0.62	1.02	0.077
Current smoker	1.02	0.80	1.30	0.87
Prior aortic surgery	1.09	0.89	1.33	0.43
Creatinine (<1 mg/dL)	0.64	0.47	0.88	0.003

Independent predictors of TAI were:

- renal artery incorporation
- multiple stents within a single fenestration.

Matched cohort analysis also showed that TAI was higher for fenestrations using VBX stents compared to iCAST

### Cumulative incidence of TAI, matched analysis



# Calculated P-Value for Gray's Test for Equality of Cumulative Incidence: 0.02884627

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## Conclusion-Fenestrations

- The performance of both VBX and iCAST as bridging covered stents in reinforced fenestrations was excellent, with overall freedom from TAI exceeding 90% at 5 years
- Statistically, iCAST stents achieved slightly better overall outcomes in both the unmatched and matched analyses
- Renal artery incorporation and use of multiple stents within a single fenestration were independent predictors of TAI
- Limitations of the study include shorter follow-up for the VBX cohort, possible selection bias, and lack of granular data to detect target artery anatomy

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What about branch outcomes?



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## ARC - Directional Branch Results

5 year - KMs	Overall n = 2253	Viabahn stent graft n = 554	VBX stent graft n = 729	Fluency stent graft n=638	iCast stent graft n=332	P value
Primary patency	90±1.3	85±4.4	94±1.5	91±1.6	92±2.8	.089
Secondary patency	93±1.1	90±4.2	96±1.7	94±1.4	95±1.9	.720
Target artery instability	86±1.3	83±4.5	90±1.9	90±1.5	78±4.3	.004
Target artery endoleak I to III	95±0.7	97±1.0	95±1.3	98±0.7	86±3.6	<.001
Target artery secondary intervention	92±1.0	93±1.5	92±1.7	97±0.9	82±4.4	<.001
Follow up (months)	22±21	19±17	10±9	34±28	25±17	<.001

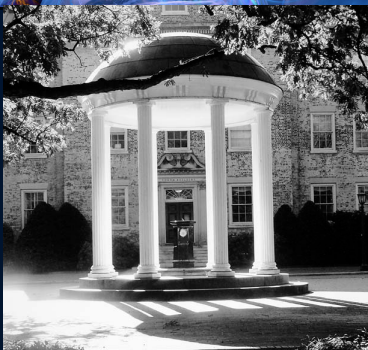
**VBX currently performing better overall however:  
Follow-up/experience is shorter compared to other stents**

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## Why?

- Shortcomings for all current bridging stents including VBX
  - SESG - more accurate deployment, but sacrifice delivery profile
    - Increased risk of stenosis/occlusion
  - BESG - foreshortening, lower profile, better trackability?
    - Increased risk of endoleaks
- Each stent has its inherent properties and deployment nuances which requires experience and particular techniques
- VBX does has some specific deployment step to ensure superb outcomes

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