

ZFEN vs TREO Endografts As Platforms for PMEG F/EVARs: Which Is Best And When: Technical Considerations, Advantages and Disadvantages

Joshua D. Adams, M.D.
 Chief, Section of Aortic & Endovascular Surgery
 Director, Carilion Clinic Aortic Center
 Associate Professor, Department of Surgery
 Virginia Tech Carilion School of Medicine



Disclosures

- Cook Medical, Inc.
• Consultant & Proctor
- Integer, Inc. (Oscor, Inc.)
• Chief Medical Officer Vascular
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- Terumo Aortic (Bolton Medical, Inc.)
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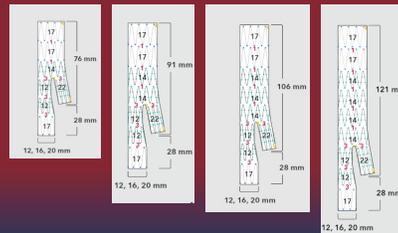
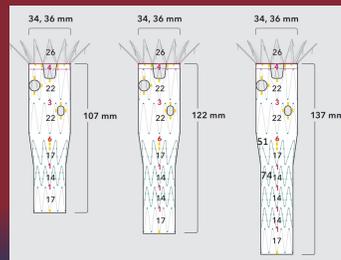
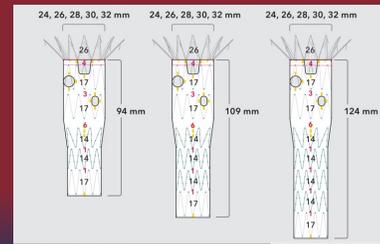
FEVAR in the United States

FDA APPROVED

Device	#1	#2
Surface Fenestration	Width	10 mm
	Height	10 mm
	Clock position	
Large Fenestration	Width	10 mm
	Height	10 mm
	Clock position	
Small Fenestration	Width	4 mm
	Height	4 mm
	Clock position	
	Distance from edge	

24 = lower fenestration boundary
 Note: Where PED=24-33, A*="35" Where PED=24-32, A*="33"
 Where PED=34-36, A*="46" Where PED=34-36, A*="21"

- Infrarenal neck ≥4 mm and <15 mm
- Max 3 fenestrations, 2 of same type



ZFEN PMEG Platform

- Advantages of ZFEN
 - Familiarity of Modular device design and procedure
 - Long Proximal Device with trigger wire fixation
 - Rapid taper from proximal diameter to 24 mm
 - Various length distal bifurcated devices
 - Cost over TEVAR Devices
 - Incorporate Commercially-produced Fenestrations
 - Posterior constraint already in place
 - Ease of repacking into original delivery sheath

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ZFEN PMEG Platform

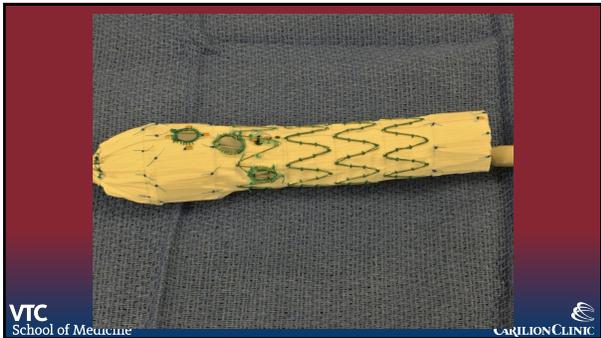
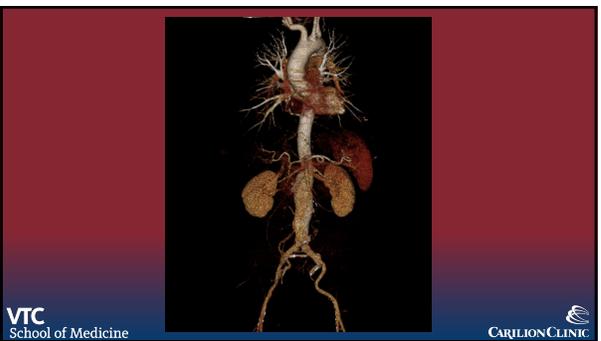
- Disadvantages of ZFEN Platform
 - Relatively larger delivery profile (20 or 22 FR sheath)
 - Less conformable device
 - Requires movement of stainless steel struts
 - 1:1 sizing of distal bifurcate to proximal device (24:24)

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Case Presentation

- 68 year old male with 5.7 cm Juxtarenal AAA

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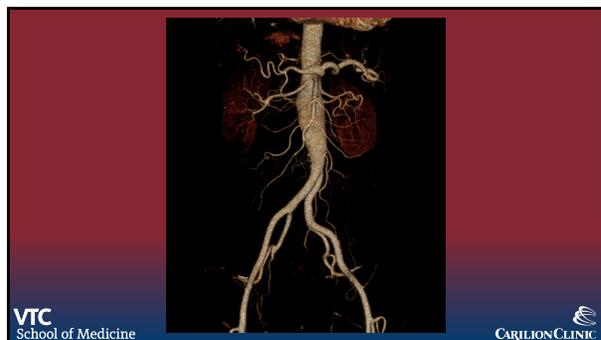


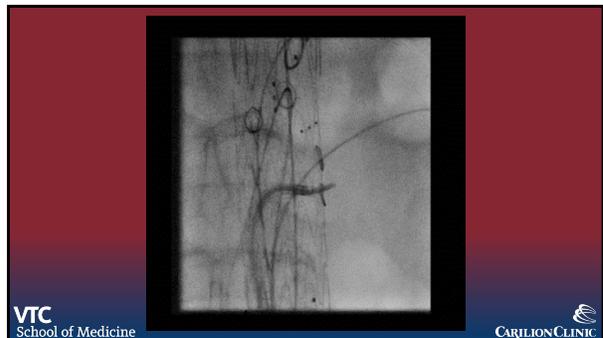
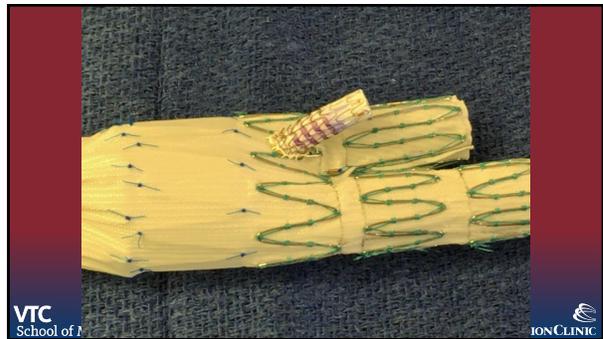


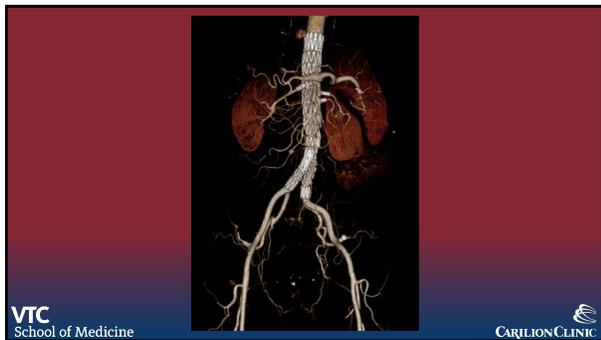
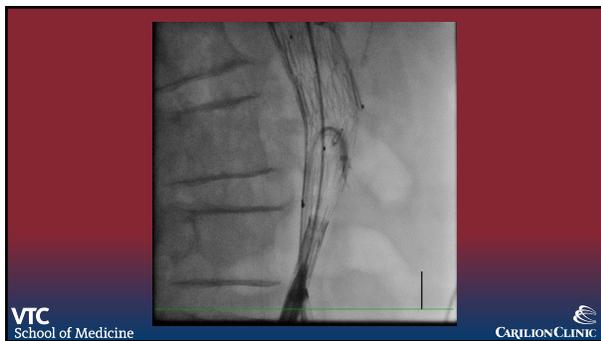
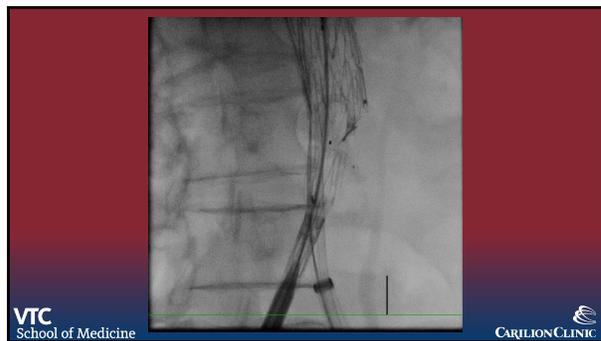
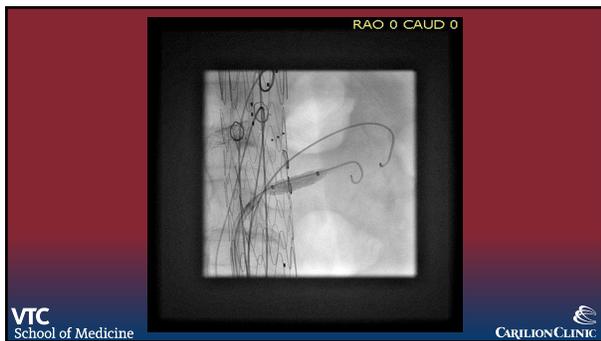
Can we do more than four?

- 76 year old male with 6.2 cm Suprarenal AAA and duplicated Left Renal Arteries

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ZFEN Outcomes

SOCIETY FOR CLINICAL VASCULAR BIOLOGY
BOCA RATON
47th ANNUAL SYMPOSIUM | MARCH 16 - 20, 2023

ZFEN Outcomes

Outcome	Value
Primary endpoint: ZFEN vs. ZFEN	...
...	...

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TREO PMEG Platform

May 5, 2020
FDA Approves Terumo Aortic's Treo EVAR System

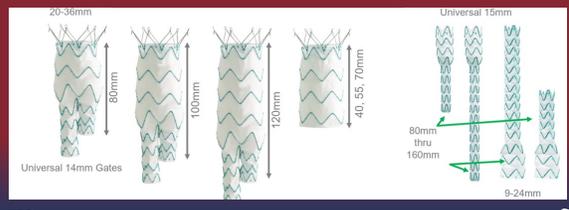
May 5, 2020—Terumo Aortic announced FDA approval of the Treo abdominal aortic stent graft system for endovascular aneurysm repair (EVAR) of abdominal aortic aneurysms (AAAs). The Treo device, which received European CE Mark approval in 2015, will now be commercially available in the United States.

According to the company, the Treo device provides dual proximal fixation and lock stent technology, and the three-piece design features in situ limb adjustability with a wide range of aortic device configurations to specifically address the anatomy of each patient. The system includes a proximal clamping mechanism and leave-behind sheath designed to simplify the procedure.



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TREO PMEG Platform



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TREO PMEG Platform

From the Southern Association for Vascular Surgery

Initial experience with the Terumo aortic Treo device for fenestrated endovascular aneurysm repair

Dale F. Isomberg, MD, Benjamin W. Gaines, MD, Brandon K. Kline, MD, and Brian Singh, MD, Seattle, Wash.

ABSTRACT
 Objective: To report our initial experience with the Terumo Treo device for fenestrated endovascular aneurysm repair (EVAR) in a series of 10 patients. The Treo device is a bifurcated, fenestrated, endovascular stent graft system designed for the treatment of abdominal aortic aneurysms (AAAs). The device is composed of a main body and two limbs, which are joined at the proximal end by a proximal clamping mechanism. The device is designed to provide dual proximal fixation and lock stent technology, and the three-piece design features in situ limb adjustability with a wide range of aortic device configurations to specifically address the anatomy of each patient. The system includes a proximal clamping mechanism and leave-behind sheath designed to simplify the procedure.



Fig 1. Terumo aortic Treo device. The wide amplitude stent design, increased interstent distances, and low-profile design of the Treo device lend itself to physician modification.

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Advantages of TREO for PMEG

- Conformable device to aorta
- Space Between Stents for Fenestrations
- Range of Main Body Device Lengths
 - 80 mm, 100 mm, 120 mm
- Easy to Re-Sheath
- Low Profile Delivery System
- Bifurcated Device



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Disadvantages of TREO for PMEG

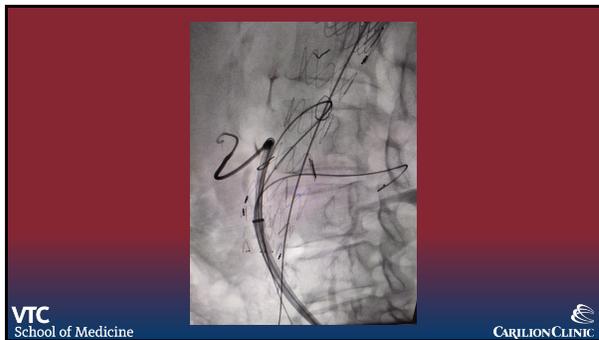
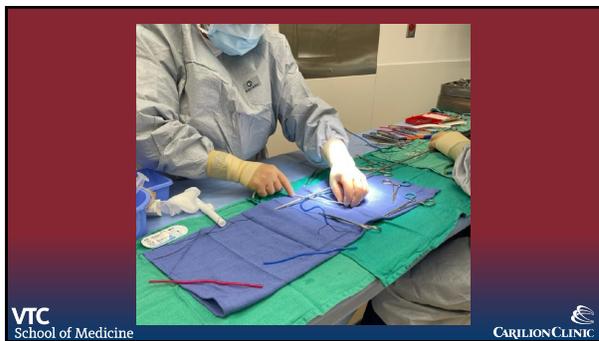
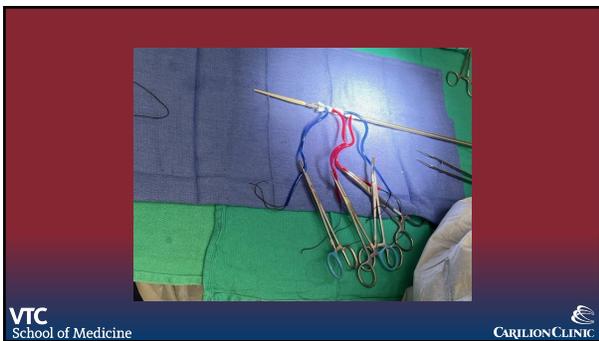
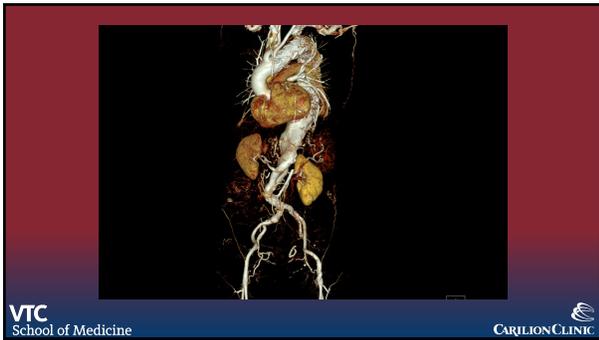
- Limited Length (120 mm long with contralateral gate)
- No Distal Control
- No Constraintment

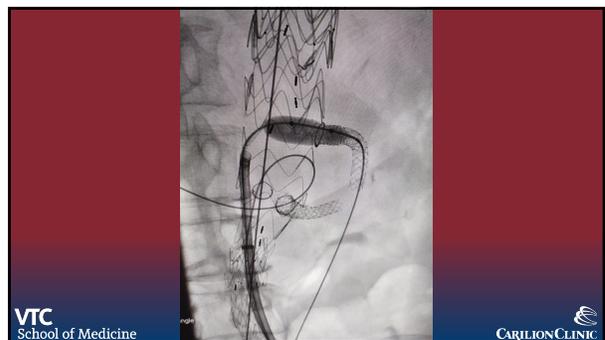
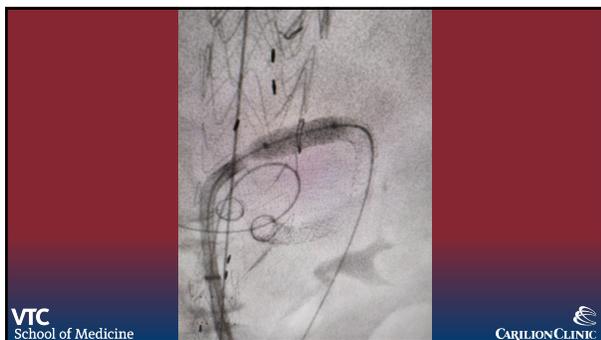
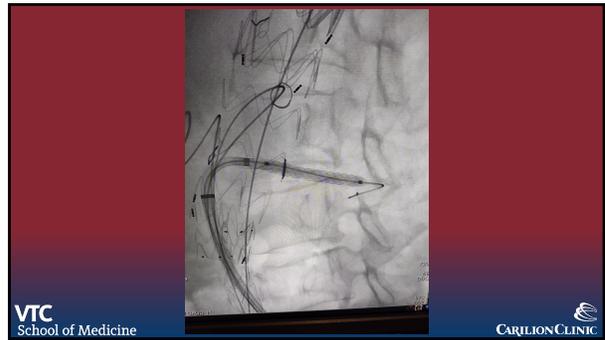
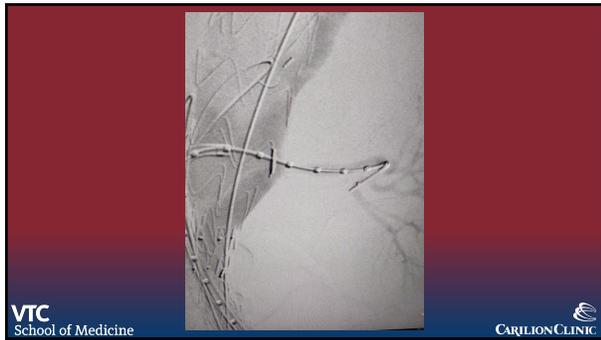
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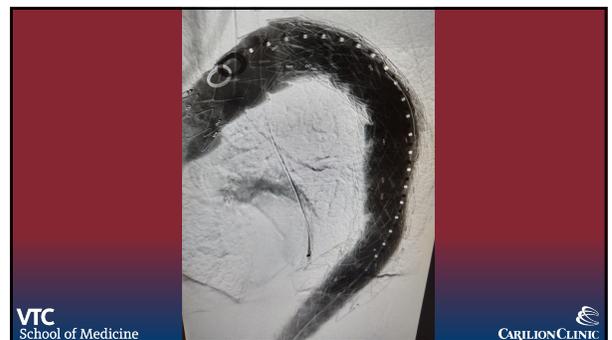
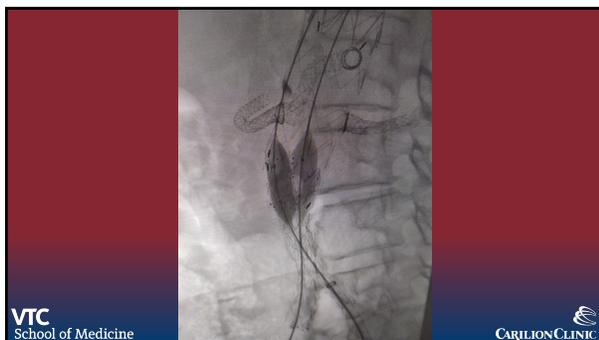
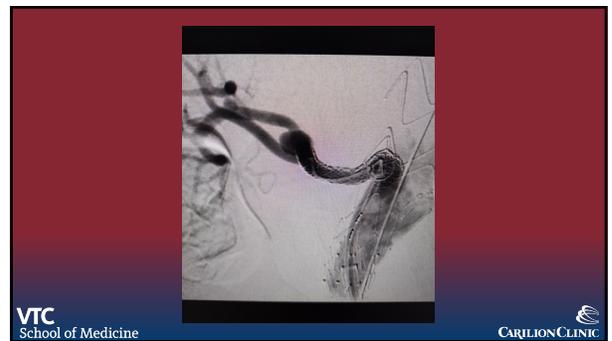
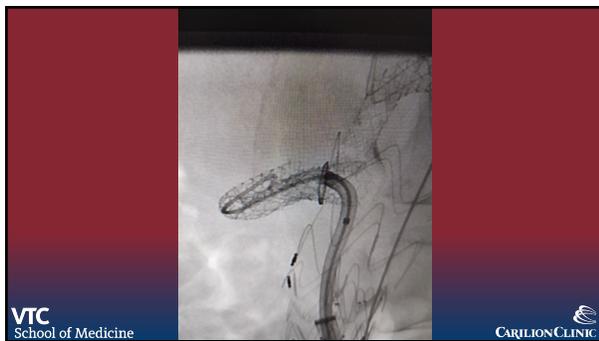
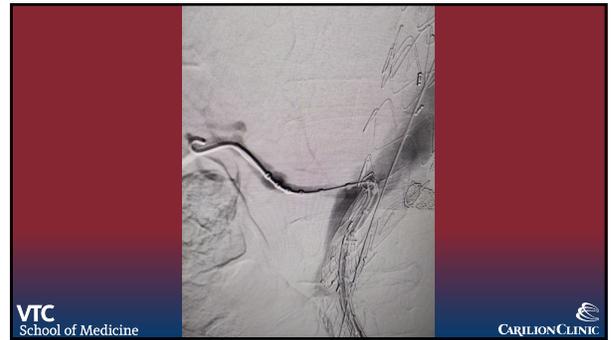
Case Example

- 75 year old female with history of prior TEVAR presents to the ED with contained rupture of TAAA

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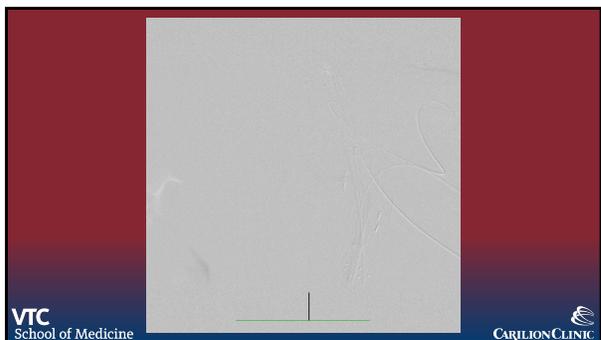
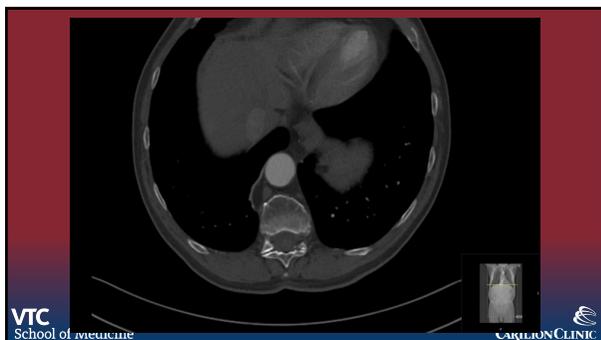


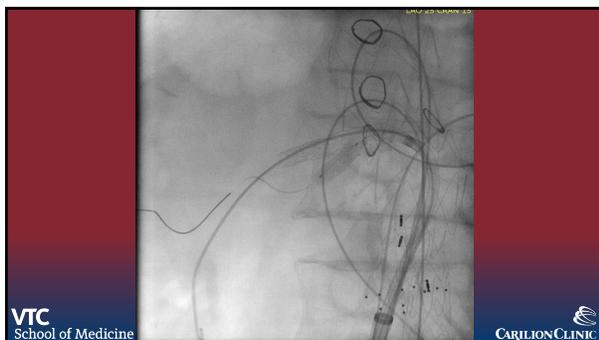
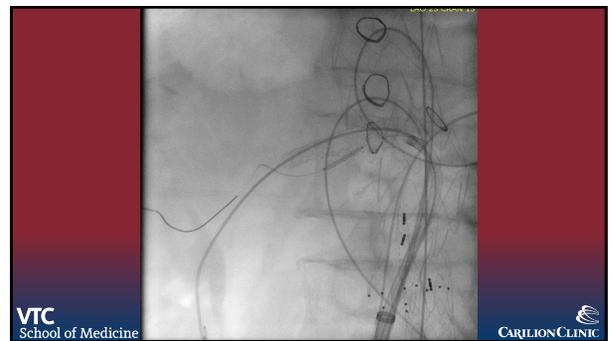
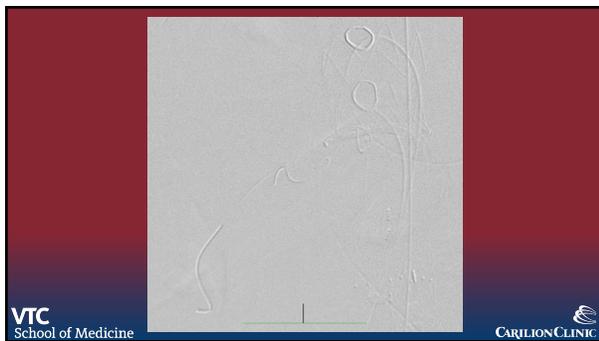
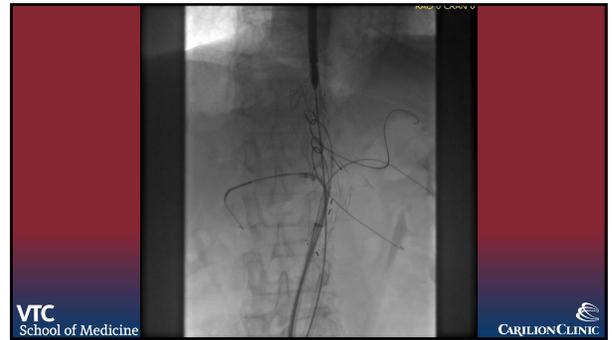
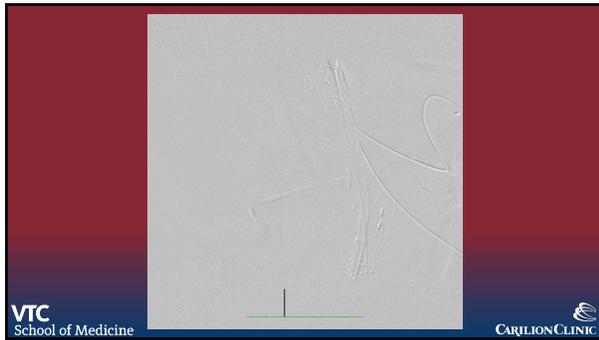


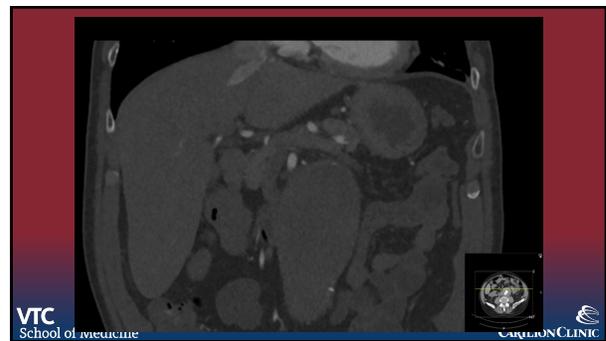
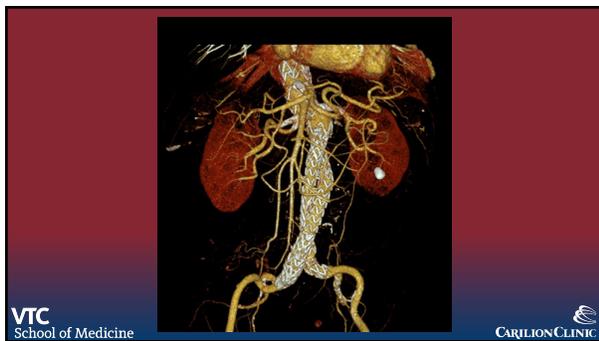
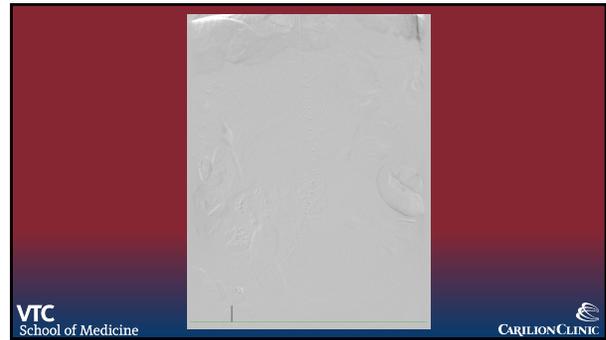
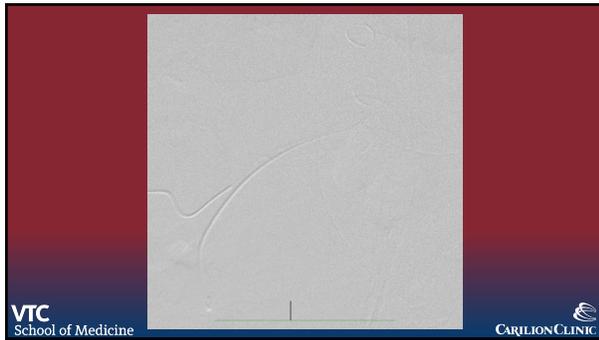
Case Presentation

- 76 year old with angulated juxtarenal AAA and short main right renal artery

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ZFEN vs Treo

	ZFEN	Treo	P-value
Device details (%)	203 (63.2%)	118 (36.8%)	
All cause mortality (%)	54 (29.0%)	15 (13.0%)	0.0012
Average Maximum Aortic Diameter (mm)	61.95	61.77	0.91
Total Modification Time (min)	80.61	71.24	0.01
Total Procedure Time (min)	260.46	207.54	0.00005
Average Number of Fenestrations	3.66	3.24	0.0003

- ### ZFEN vs Treo
- ZFEN
 - Long Visceral Segment (TAAA's)
 - Tapered Anatomy
 - Need for Rotation
 - Access not an Issue
 - Treo
 - Poor Access Vessels/Small Iliacs
 - Small Terminal Aorta
 - Angulated Anatomy
 - Type IA Endoleak Rescue

