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Connecting The Vascular Community

The EndoPatch: A Promising Solution For Endovascular Repair Of Aortic Dissections



Wei Guo, MD
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Disclosure

Speaker name: Wei Guo

I have the following potential conflicts of interest to report:

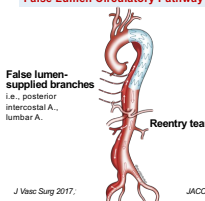
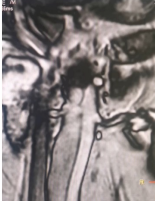
- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)
- I do not have any potential conflict of interest

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Risk Factors for Unfavorable Remodeling

Aortic dilatation is the most common complication after TEVAR.
Five-year incidence of 62.7% reported by IRAD.

False Lumen Circulatory Pathway

False lumen-supplied branches
i.e., posterior intercostal A., lumbar A.

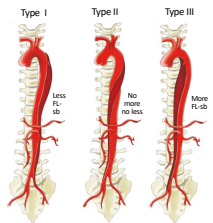
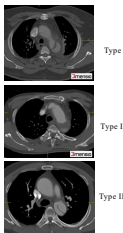
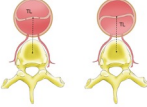
Reentry tears

J Vasc Surg 2017; JACC Cardio Interv 2013; Mayo Clin Proc. 2020; J Thorac Cardiovasc Surg 2018;

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"301 Classification" for TBAD

Mayo Clin Proc 2020.


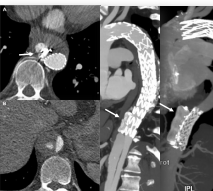
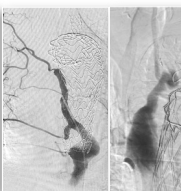
ROBUST study: ChCTR-POC-17011726

The 301 Classification: Old School Meets New School

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Current Techniques

Reentry tears as inflow tracts False lumen False lumen-supplied branches as outflow tracts

Stent-graft (Tube & Multibranches) FL Embolization (coil, candy-plug, glue) FL Branch Embolization (coil, glue)

EndoPatch™ for Sealing Intimal Tears

Top View

PTFE

Steerable sheath

knob

slider

knob

Locked discs

Procedure Key Points

- 1 Catheterize entry tear
- 2 Advance steerable sheath
- 3 Release the first disc
- 4 Release the second disc
- 5 Tighten the discs
- 6 Rotate the knob
- 7 Unlock the cable

Preliminary oversizing rule

- Max diameter and area measurement

- Requires 3-6 mm anchoring margin beyond the target tear.
- EndoPatch diameter type specification : 6-40mm

Entry Tear

Ø 26mm EndoPatch

Ø 13.6mm

Ø 16mm Entry Tear

CTA FU 3rd day after operation

First-in-man study

ClinicalTrials.gov ID: NCT04745039

- Prospective, single-arm study
- Start date: October, 2021
- Recruitment status: Enrolling
- A total of 29 patients with chronic aortic dissection were included up to April 2024
- Indications:
 - Rapid aortic enlargement (5mm in the past 6months)
 - Maximum diameter of aneurysm > 55mm;
 - Symptomatic dissection (thoracic, back, or abdominal pain excluding other causes),

True to false passage

False to true pas

First-in-man study

The first case treated by EndoPatch.

M/73yrs, TEVAR history 7 years ago, Ømax 56mm; HT; COPD

Eur Heart J. 2020

EndoPatch Ø10, 12mm

1 year FU

First-in-man study

F/62yrs; TEVAR history 5 years ago; abdominal aortic dissection aneurysm; right renal artery from false lumen.

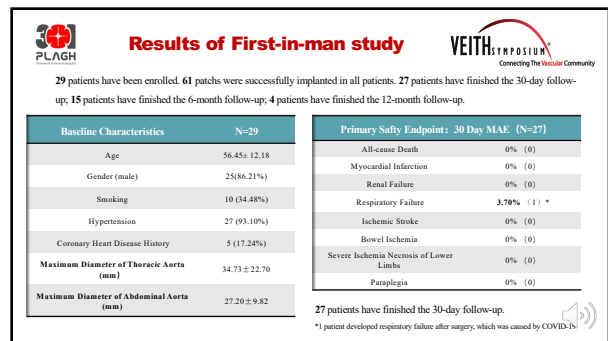
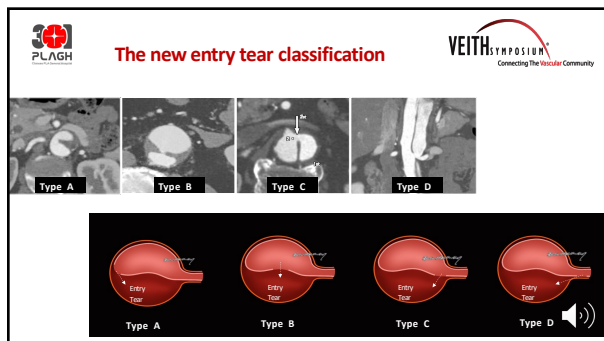
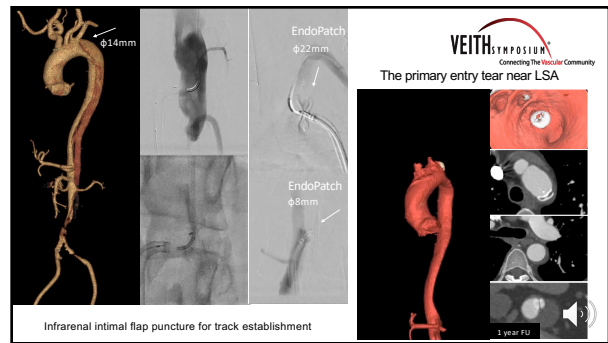
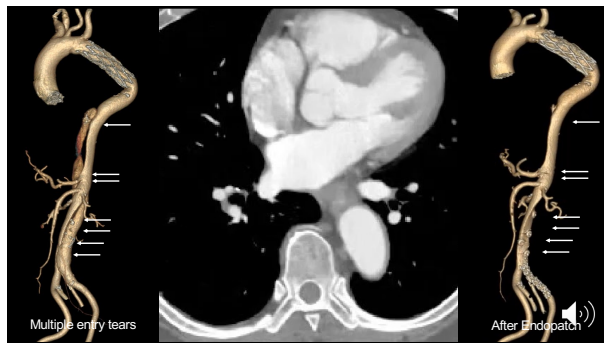
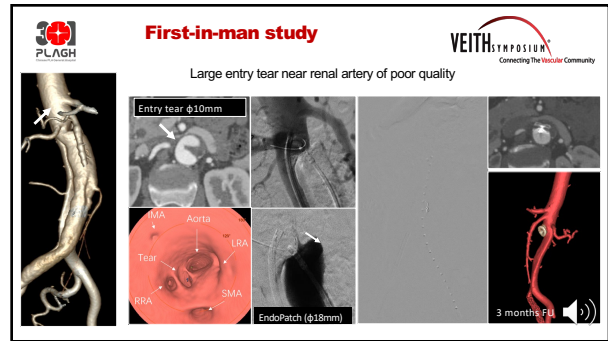
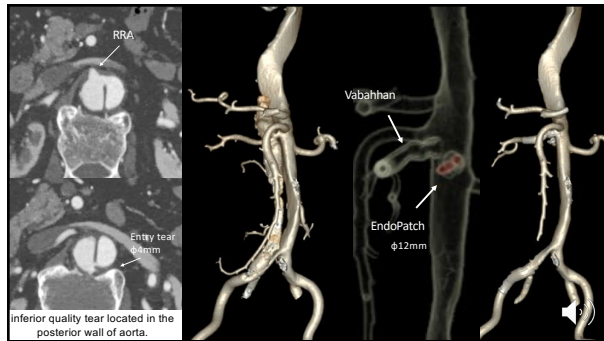
Infraarenal entry site with high quality tear


Ø5mm

EndoPatch Ø12mm

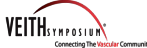
Post 1 month 3D

Post 6 months CTA





Results of First-in-man study




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- CTA showed a favorable extent of false lumen thrombosis: 80% complete FL thrombosis in thoracic aorta, as well as 46.7% complete FL thrombosis in abdominal aorta at 6 month.


Efficacy Endpoint Events	
Immediate Technical Success (%)	100%
The Clinical Success Rate (N=15)	
Year Leakage (%) *	27.59% (8/29)
Patch Migration (%) *	0% (0/29)
Secondary Intervention (%)	0% (0/15)

Efficacy Endpoint	Preoperative	6 Months
Maximum Diameter of Thoracic Aorta (mm)	33.61 ± 26.95	28.92 ± 24.22
Maximum Diameter of Abdominal Aorta (mm)	25.96 ± 7.27	22.07 ± 5.69

False Lumen Status			6 Month (n=15)	12 Month (n=4)
No thrombosis (%)			0% (0/15)	0 (0/4)
Thoracic Aorta	Partial thrombosis (%)		20% (3/15)	0 (0/4)
	Complete thrombosis (%)		80% (12/15)	100% (4/4)
No thrombosis (%)			0% (0/15)	0 (0/4)
Abdominal Aorta	Partial thrombosis (%)		53.3% (8/15)	25% (1/4)
	Complete thrombosis (%)		46.7% (7/15)	75% (3/4)



Existing Issues To Be Addressed




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- The feasibility in acute aortic dissections needs further assessment.
- Endopatch cannot be used to seal torn ostia of visceral arteries.
- Conventional vascular workstations makes it difficult to obtain precise tear dimensions.
- The current oversizing rule is based on preliminary empirical experience.


Take Home Message

- Preliminary results suggest that Endopatch has good feasibility and efficacy.
- Reduce coverage of health aorta means the low spinal cord ischemia risk.
- For non-visceral artery-originating tears in visceral region, eliminate VAs revascularization.
- More patient data is needed to verify its clinical effectiveness.
- EndoPatch could be a promising alternative for intimal tears.




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