

The Aortyx Aortic Patch: A More Compliant Way Than TEVAR To Seal Aortic Defects With TBADs And Other Lesions: A New Endovascular Approach: How Does It Work: Improved Delivery System And Progress To Date.



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 November 21st, 2024

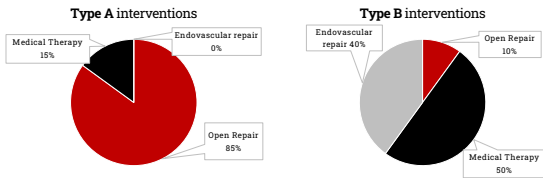
Disclosures



I have the following potential conflicts of interest to report:

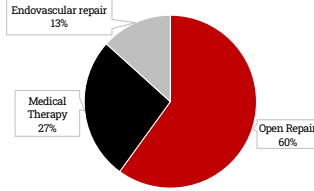
- Consulting: Terumo Aortic, Medtronic, Cook Medical, iVascular, W.L. Gore, VB Devices, Lifetech, Möller Medical, Aortyx, Balt Medical.
- Stockholder of a healthcare company: Aortyx, VB Devices

Current AD treatments present severe limitations



Evangelista et al., Rev Esp Cardiol., 2022

Only 13% of cases are treated via endovascular!

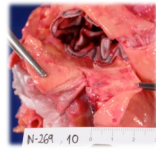
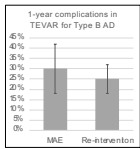


Evangelista et al., Rev Esp Cardiol., 2022

Current endovascular repair for AD



Main drawbacks



- Geometrical mismatch
- Mechanical mismatch
- Endograft Stiffness

J Vasc Surg. 2014;50:118F-5S
 J Vasc Surg. 2014;50:327-33.
 J Vasc Surg. 2020;71:1077-1087

Because TEVAR presents limitations and dangers



- Lack of landing zone

Table 3 Outcomes for Thoracic Endovascular Aortic Repair with Ultevasculatized and Revascularized left subclavian artery, Carotid-Subclavian Bypass, and F-FEVAR

Variables	Overall (N=291)	Unrevascularized (N=120)	Revascularized (n=171)	P-value	P ₁ value
30-day outcomes, n	171	28	102	42	
Mortality (%)	1.5(8)	1.3(6)	0.0(0)	0.0(0)	0.164
Stroke (%)	2.1(2)	0.0(0)	2.2(6)	0.2(6)	1
Left upper extremity ischemia (%)	2.1(2)	0.0(0)	2.2(6)	0.2(6)	1
Spinal cord ischemia (%)	5.2(9)	3.1(7)	1.1(3)	1.2(3)	0.032*
Median endoleak, n	167	26	100	41	
Mortality (%)	10.6(20)	2.7(7)	8.8(8)	0.0(0)	1
Stroke (%)	0.6(1)	3.1(1)	4.0(4)	2.4(4)	0.209
Left upper extremity ischemia (%)	12.7(2)	4.1(1)	6.0(6)	2.4(4)	0.177
Spinal cord ischemia (%)	0.0(0)	0.0(0)	0.0(0)	0.0(0)	-

P₁ value, unrevascularized versus revascularized
 P₂ value, CEB versus F-FEVAR
 *Statistically significant value

Xie et al., J Cardiothorac Surg., 2021

Because TEVAR presents limitations and dangers

- Lack of landing zone
- Increased cardiac load

NORMAL HEART A **WITH AORTIC STENT** B

SYSTOLE SYSTOLE

DIASTOLE DIASTOLE

Increased coronary flow

Aortic regurgitation

Sabatini et al., Front Surg, 2022
Krauss et al., 2022

Because TEVAR presents limitations and dangers

- Lack of landing zone
- Increased cardiac load
- Aorta growth

Supplementary Table 10 (online only): False lumen status by device region

Preoperative status	Percentage of patients (%)				
	1 year	2 years	3 years	4 years	5 years
False lumen region					
All patients					
Patent	18 (34)	0 (0)	0 (0)	0 (0)	0 (0)
Partially thrombosed	42 (78)	27 (50)	27 (50)	27 (50)	27 (50)
Completely thrombosed	87 (161)	84 (152)	81 (146)	82 (147)	78 (140)
No apparent false lumen	0 (0)	87 (156)	102 (183)	132 (238)	88 (158)
Patients with dissection aorta					
Patent	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Partially thrombosed	17 (32)	18 (33)	19 (34)	20 (36)	18 (32)
Completely thrombosed	33 (62)	34 (62)	35 (63)	36 (64)	35 (63)
No apparent false lumen	0 (0)	41 (75)	47 (85)	53 (95)	38 (68)
Patients without dissection aorta					
Patent	7 (13)	0 (0)	0 (0)	0 (0)	0 (0)
Partially thrombosed	42 (78)	35 (63)	35 (63)	35 (63)	43 (77)
Completely thrombosed	42 (78)	53 (95)	53 (95)	50 (90)	78 (140)
Dissection aorta region					
Patients with dissection aorta					
Patent	11 (20)	2 (4)	0 (0)	0 (0)	0 (0)
Partially thrombosed	43 (79)	33 (60)	33 (60)	34 (61)	33 (60)
Completely thrombosed	81 (148)	76 (137)	75 (136)	74 (135)	71 (128)
No apparent false lumen	0 (0)	24 (43)	30 (54)	38 (68)	44 (79)
Patients without dissection aorta NA					

Lombardi et al., J Vasc Surg, 2022

AX-GEN01 to minimize impact in the aorta

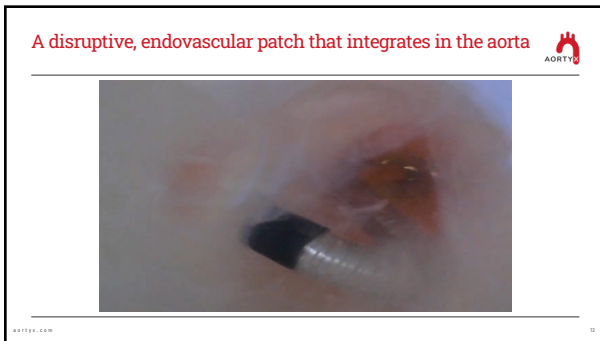
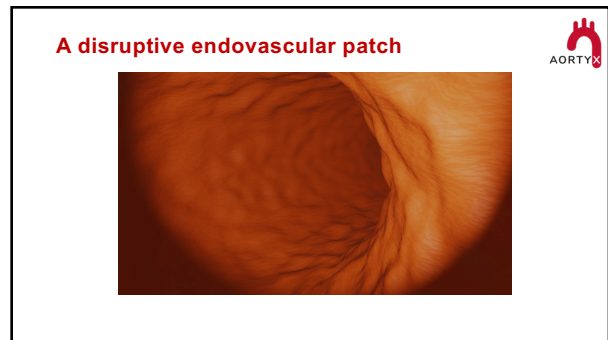
Aortic Dissection Tear

Tear sizes range from 7 to 26 mm (average 12 mm)

Current stents 200 mm

Aortyx patch 30 mm

Evangelista et al., Ann Cardiothorac Surg 2016

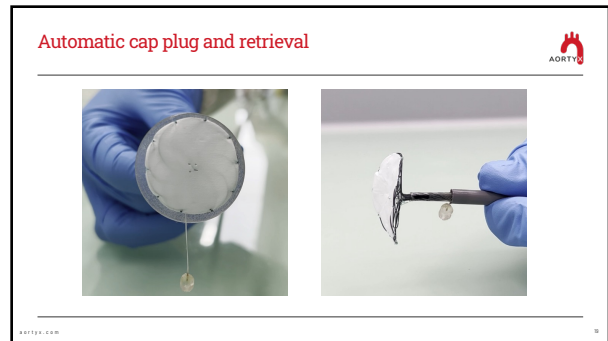
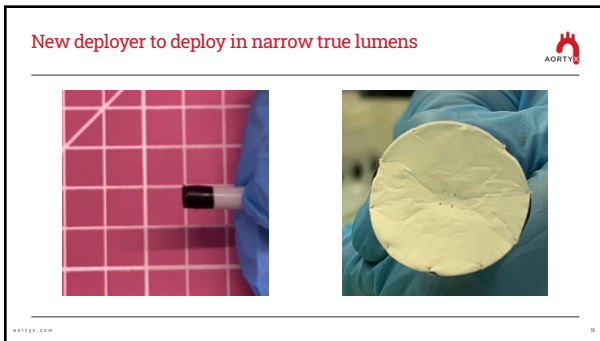
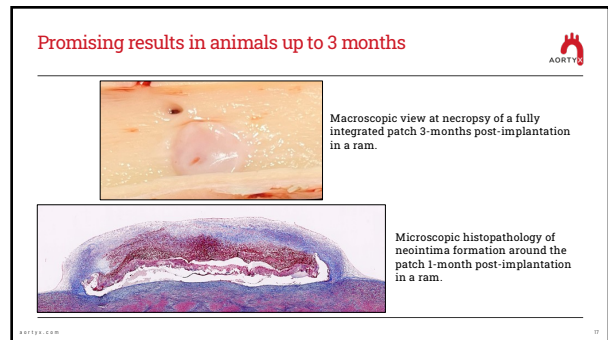
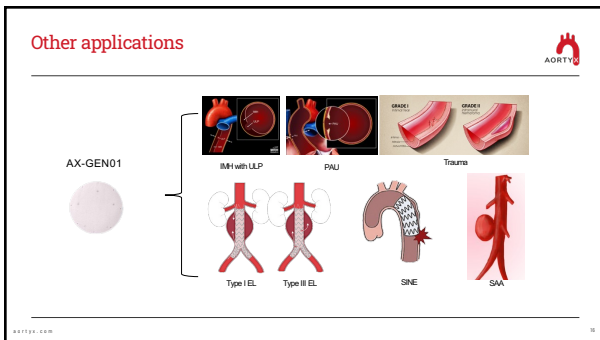
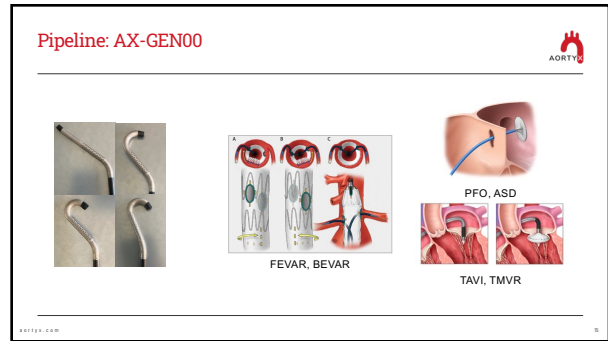
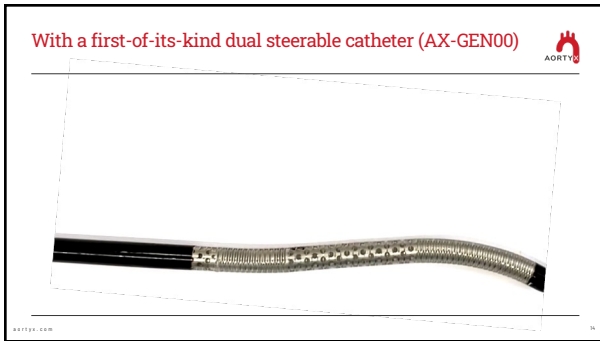



A patented proprietary system

Carrier Guider Deployer Patch + Adhesive

Patents

PCT/EP2024/054855 W02021058602 W02019175288
Steerable Catheters Patch Deployment Device Vascular Repair Patch



Conclusions and next steps 

AX-GEN01 is ready for verification and validation phase


- Series A closed to fund the project
- First in Human expected in 2026
- Negotiating with KOLs, hospitals and agencies

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