

Current State of Thoracic Branch Devices and Ongoing Clinical Trials

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Disclosure Statement of Financial Interest

I, Hiroo Takayama, DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.

Endovascular Therapy for Arch

Challenges of Arch TEVAR

- Angulation
- Limited seal zone
- Motion
- Limited work space
- Significant hemodynamic forces

Options

- Hybrid
- Chimney
- In-situ fenestration
- Fenestrated stent-graft
- Branched stent-graft

Hybrid Arch Repair: Needs 'Cracking Chest Open'



Systematic review:

n=956 from 26 studies

30d mortality 11.9%

Stroke 7.6%

Spinal cord injury 3.6%

Dialysis 5.7%

Pulmonary complication 19.7%

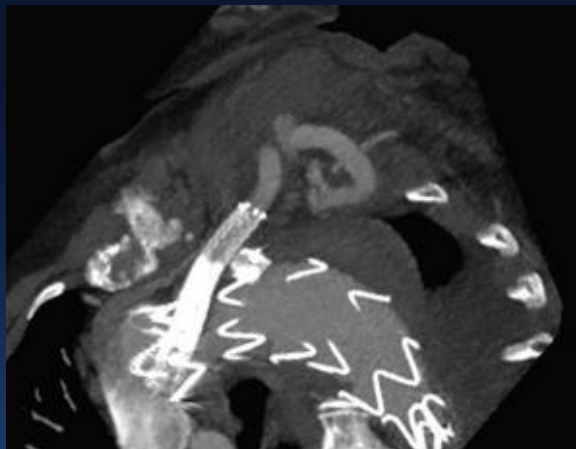
Aortic Center

Chimney Graft: Endoleak is the problem

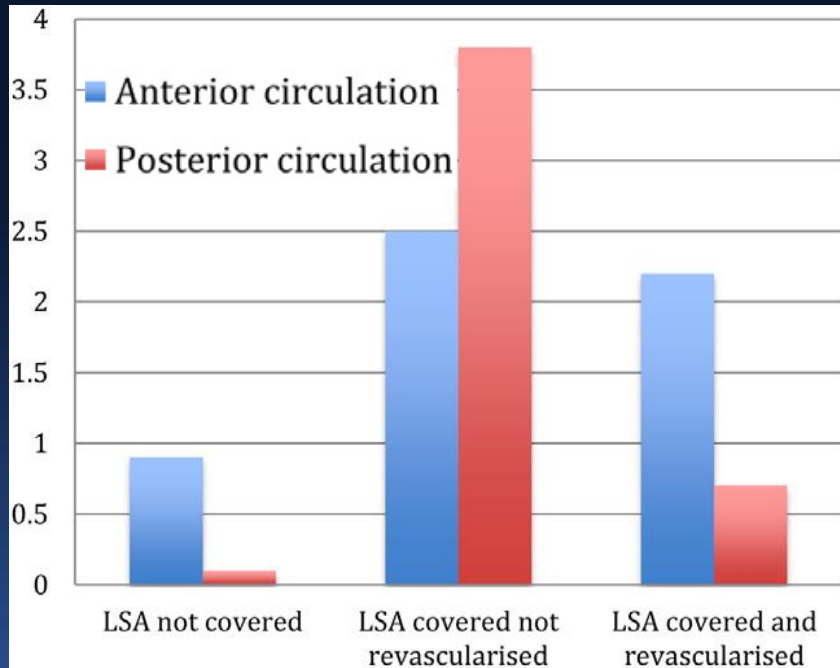
- **Meta analysis:**

11 publications (on 373 patients and 387 CGs)

technical success:	91.3%	(95%CI: 87.4%-94.0%)
30-day mortality rate	7.9%	(4.6%-13.2%)
early type Ia endoleak	9.4%	(6.5%-13.4%)
reintervention rate	10.6%	(5%-21%)
retrograde type A	1.8%	(0.8%-4.0%)
major stroke	2.6%	(1.3%-5.0%)
late patency	92.9%	(87.3%-96%)



Non-Branched TEVAR Device with LCA-LSA bypass



***Device improvement:
flexibility, conformability
LCA-LSA bypass***

GORE Thoracic Branch Endoprosthesis



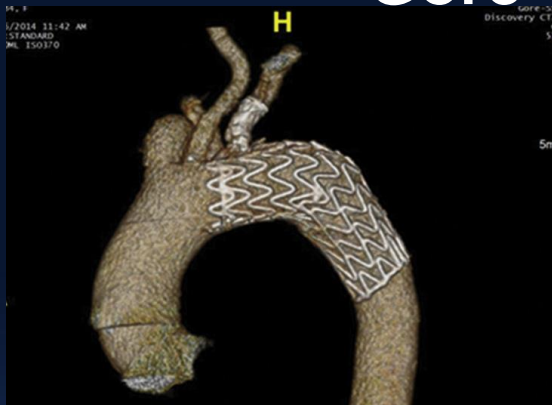
**First Human Implant
January 2014**

- **Zone 2 feasibility study in US**
- **Zone 0/1 early feasibility study**

- **Off-the-shelf components**
- **Inner lumen for anchoring and sealing branch component (retrograde orientation)**
- **Pre-cannulated side branch wire**



Gore TBE US Multicenter Trial



Endoleak Type	Procedure or Postprocedure	1 Month	6 Months
Number of Patients	22	20	15
Type I	4	0	0
Type II	2	2	2
Type III	1	0	0
Type IV or V	0	0	0

- Inclusion criteria
 - Fusiform (10) or saccular (12) DTA
 - Prox landing in zone 2
- N=22
- Additional distal TEVAR in 14
- Procedural success 100%
- Type I endoleak in 4 at completion angio, all resolved
- No major complications

Valiant Mona LSA



Main Stent Graft (MSG)

- Flexible, conical-shaped cuff for BSG
- Diameters: 30 – 46mm
- Nominal length: 15cm

Branch Stent Graft (BSG)

- Nitinol helical stent with high radial force
- PE material with proximal flare
- Diameters: 10, 12, 14mm
- Length: 40mm



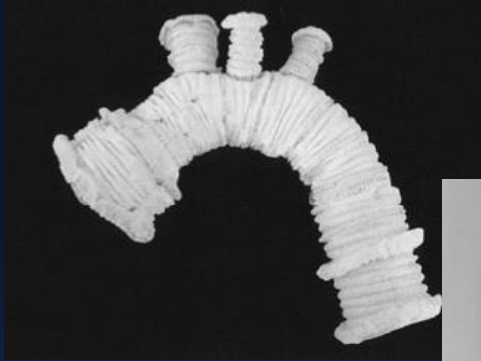
Courtesy of Medtronic

Medtronic Valiant Mona LSA Feasibility Study



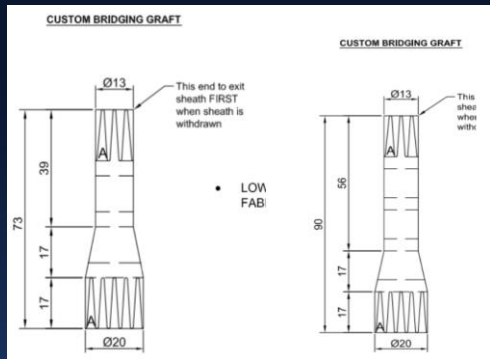
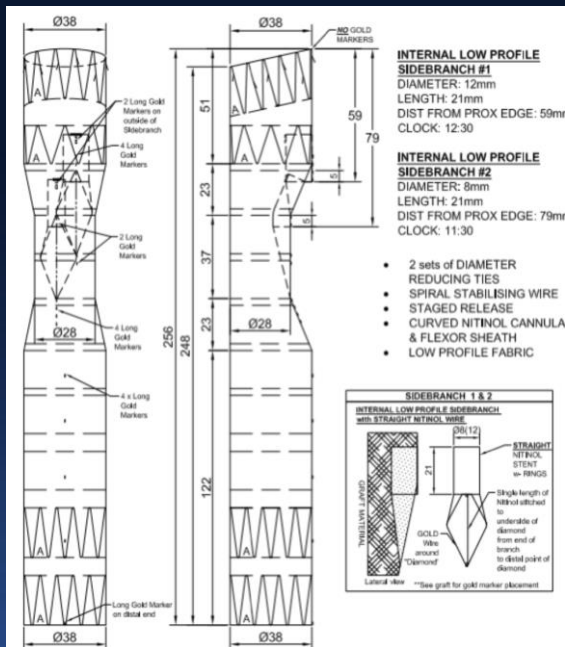
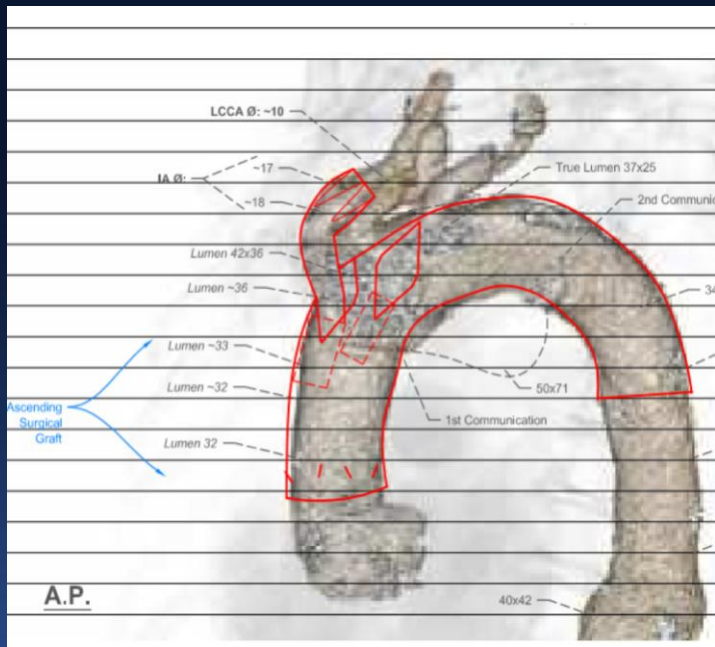
- Inclusion criteria
 - PAU or DTA, needing LSA coverage
 - >10mm between LCCA/LSA
- N=9
- 100% procedural success
- 7 distal extension
- 4 endoleaks (2 type II, 2 unknown)
- 4 nondisabling strokes

Future is here



- **Zone 0 landing**
 - **Multi-branch**
 - **Extra-anatomical bypass and one-branch**
- **From outer branch to inner branch**
- **Chronic arch/descending dissection**

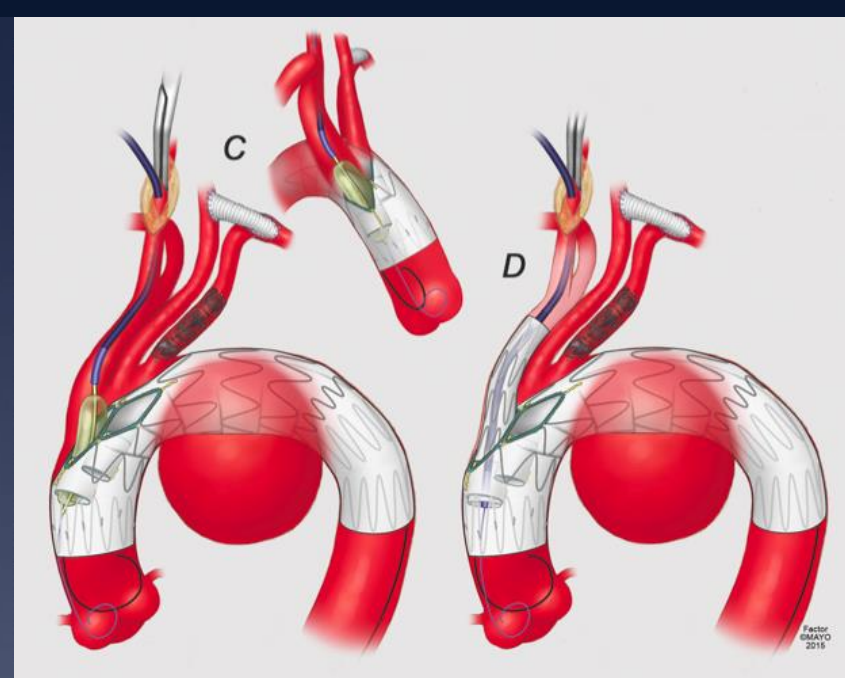
Cook Total Endovascular Arch Replacement



Global experience with an inner branched arch endograft

Stéphan Haulon, MD, PhD,^a Roy K. Greenberg, MD,^b Rafaëlle Spear, MD,^a Matt Eagleton, MD,^b Cherrie Abraham, MD,^c Christos Lioupis, MD,^c Eric Verhoeven, MD, PhD,^d Krassi Ivancev, MD,^c Tilo Kölbel, MD, PhD,^f Brendan Stanley, MD,^g Timothy Resch, MD,^h Pascal Desgranges, MD, PhD,ⁱ Blandine Maurel, MD,^a Blayne Roeder, PhD,^j Timothy Chuter, MD,^k and Tara Mastracci, MD^b

- * Multicenter Study
- * n = 38
- * Technical success 32/38
- * Mortality 5/38 (13%)
- * Stroke/TIA 6/38



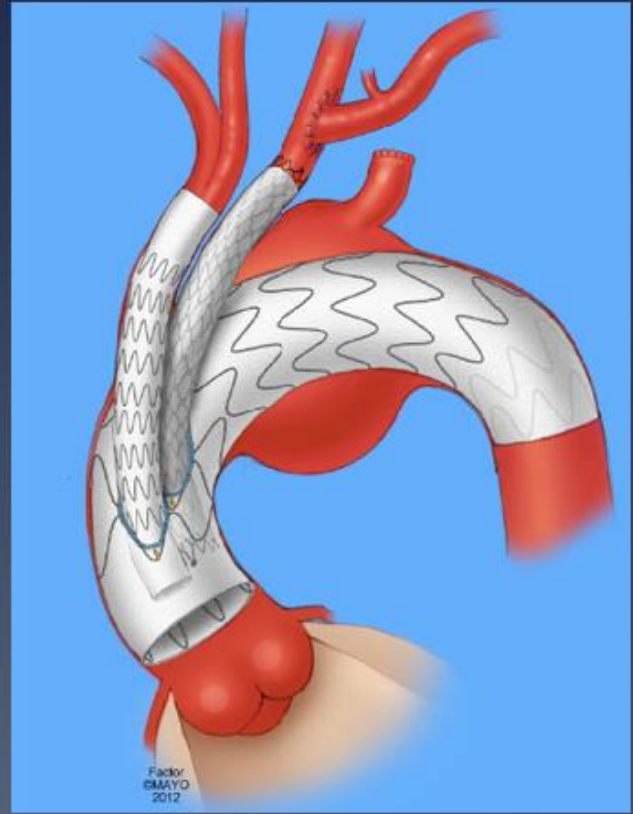
Haulon et al. 2013; J Thor Cardiovasc Surg 148:1709-16

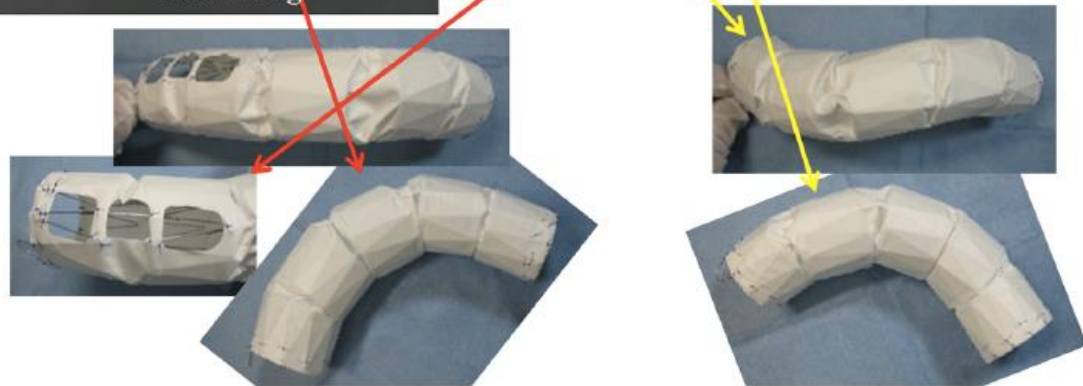
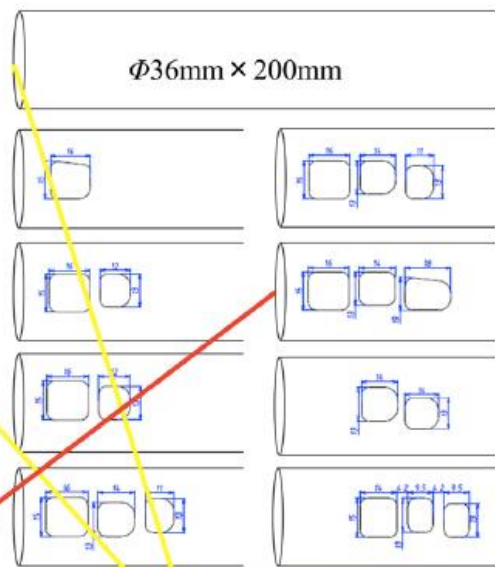
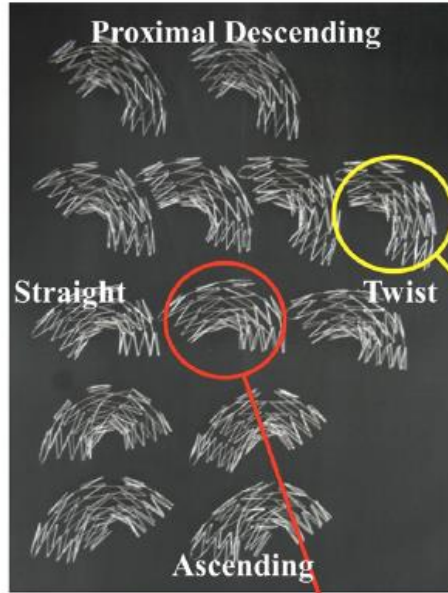


Improving Outcomes

Hamburg Experience 2012-2016:

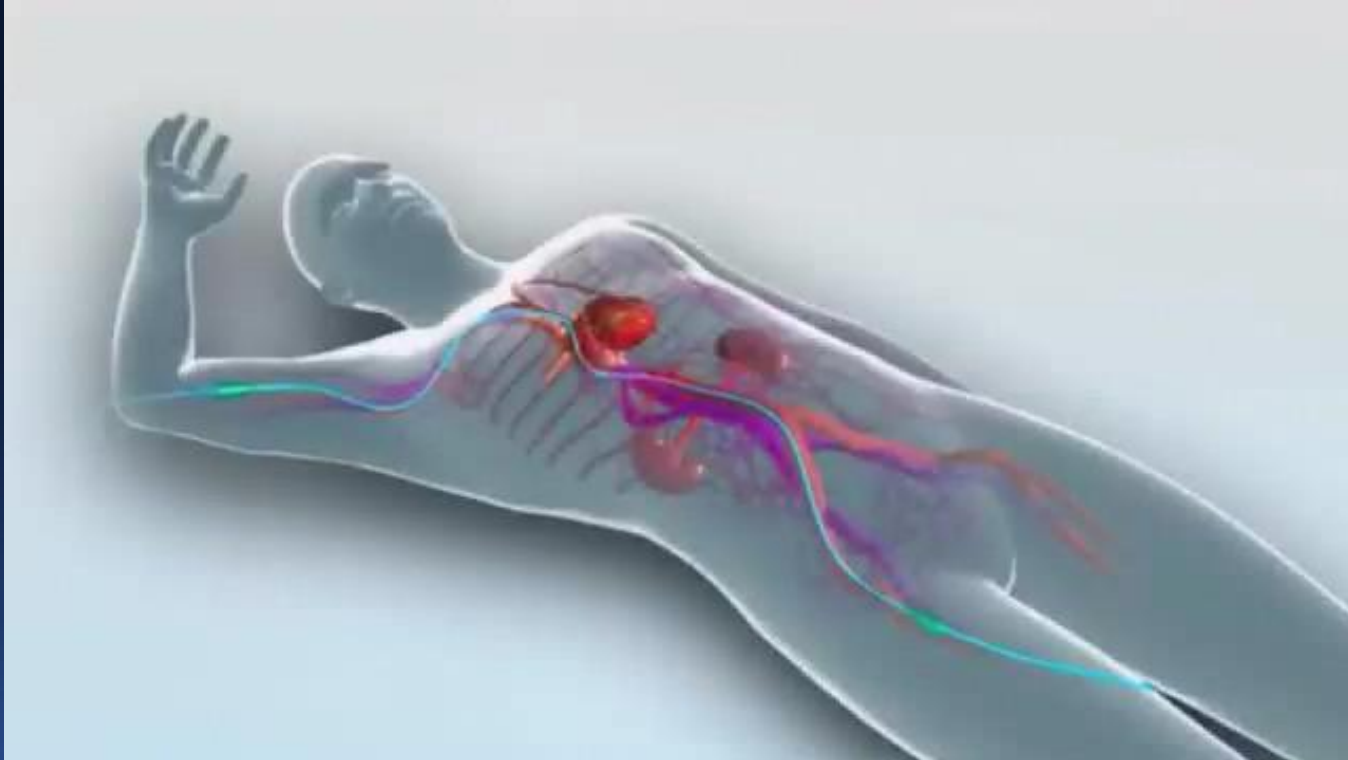
* Cases:	40
* Aneurysm:	18
* Residual dissection:	17
* Acute Type A:	2
* PAU:	3
* 30d-Mortality:	2 (5%)
* Stroke:	2 (5%)





- Japan, multicenter
- N=383
- Technical success: 99%
- 30d mortality: 1.6%
- Stroke: 1.8%

Endospan - NEXUS AORTIC ARCH SYSTEM;



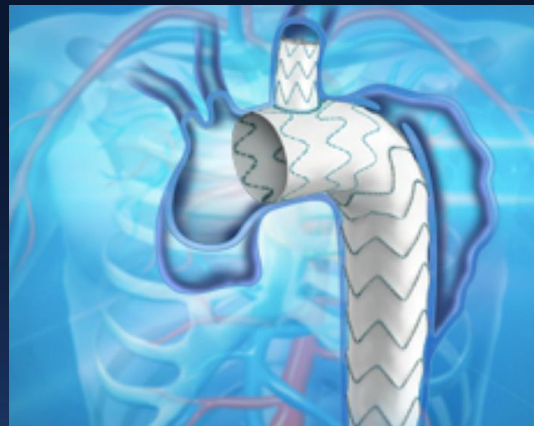
- The FIM study began in 2014 with planned 5-year followup and is taking place at centers in Switzerland, Czech Republic, and Italy.

Other Branched TEVAR Grafts



Bolton Two-Branched Graft

- Used in Europe and Asia
- US trial coming soon



Castor™ Branched Aortic Stent-Graft System

- CFDA approval

Ascending (Zone 0) Landing

Ascending

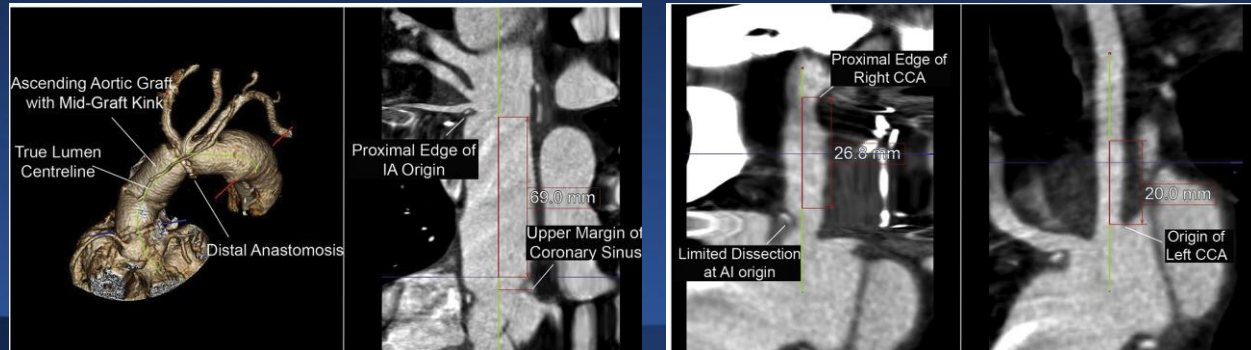
- ≤ 38 -mm diameter
- ≥ 40 -mm sealing zone length (by true lumen centerline analysis), or ≥ 24 -mm inner curvature, ≥ 45 -mm outer curvature

52 of 73 patients (71.2%) were anatomically fit for Cook branched device

Reasons for no-good:

Short ascending (71.4%)

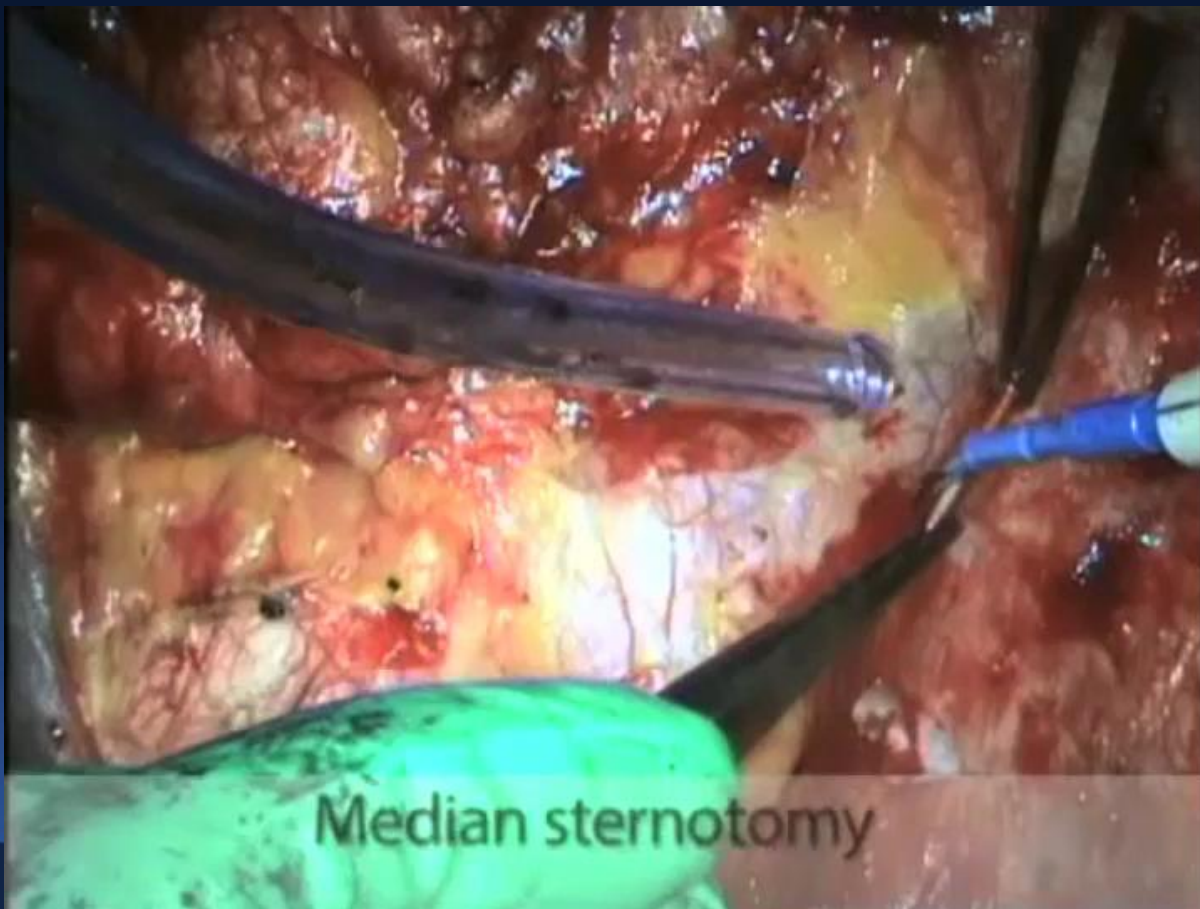
Ascending graft kink (23.8%)



Contemporary Outcomes of Open Arch Replacement

No. of patients	423	(%)
Hospital death		
Overall	19/423	4.5%
Elective cases	6/288	2.1%
Nonelective cases	13/135	9.6%
Acute type A aortic dissection	7/75	9.3%
Elective nondissection	5/231	2.2%
Complications		
Permanent Neurological Deficit		5.4%
Transient Neurological Deficit		8.7%
Renal failure		3.1%

Why is Branched TEVAR necessary?



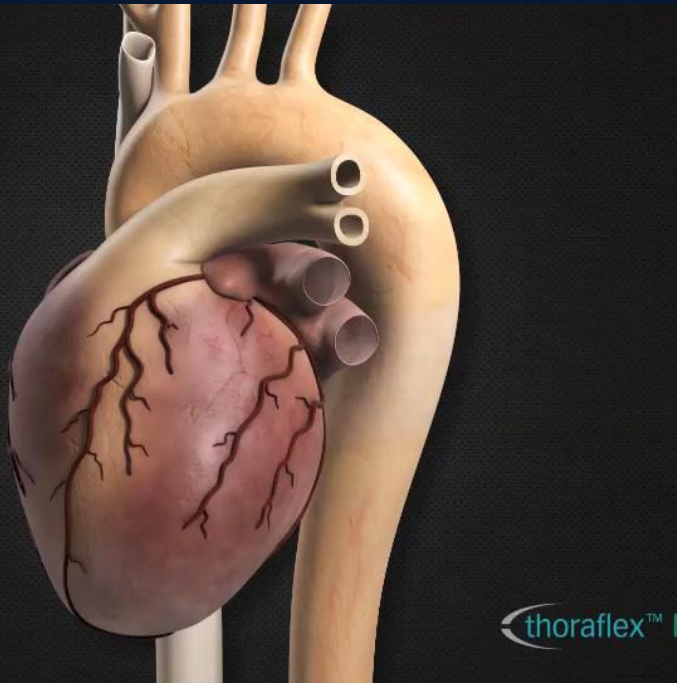
Frozen Elephant Trunk

- >2000 cases in Europe
- US Trial (n=40)

Single center series

Postoperative data

Ventilation, d	1.0 (0.6-3.7)
Prolonged ventilation	29 (29%)
Rethoracotomy for bleeding	10 (10%)
Stroke	9 (9%)
Paraparesis	7 (7%)
Recurrent nerve palsy	25 (25%)
Acute kidney injury	30 (30%)
Dialysis	14 (14%)
Dialysis at discharge	8 (8%)
Hospital stay, d	17 (12-27)
Perioperative mortality	7 (7%)



SCUTEK
TERUMO

thoraflex™

 ColumbiaDoctors
Aortic Center

 tct2017

Courtesy of Thoratec
Shrestha. *J Thorac Cardiovasc Surg* 2016;
152:148-59

Conclusions

- **(Multi-)branched TEVAR graft has been increasingly used with promising improvement in outcomes.**
- **Zone 0 landing will become more common but remain a challenge.**
- **Open arch surgery also shows improving outcomes (though it is very invasive).**