

Stroke Prevention During Endovascular Arch Repair

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Endovascular Therapy**

Department of Surgery

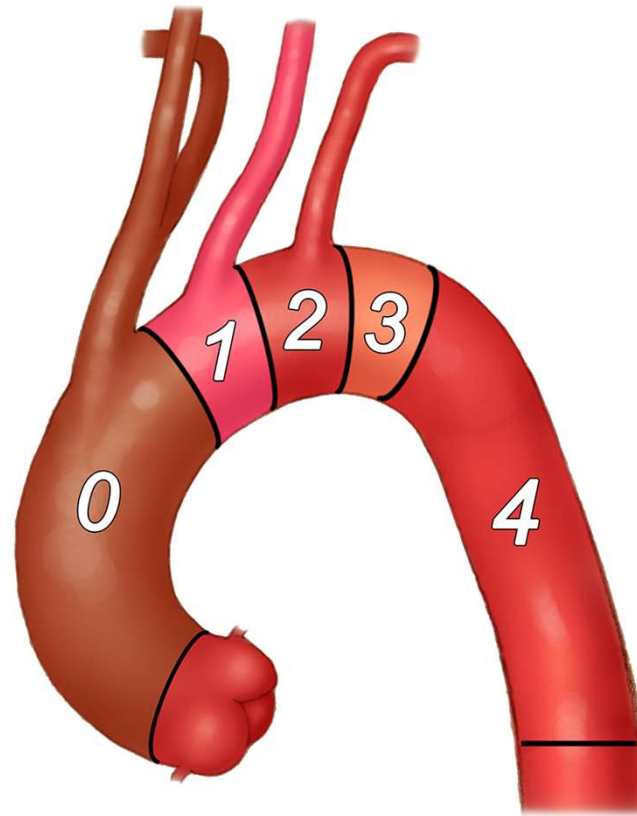


EMORY
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MEDICINE

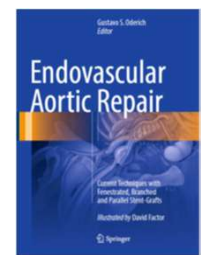
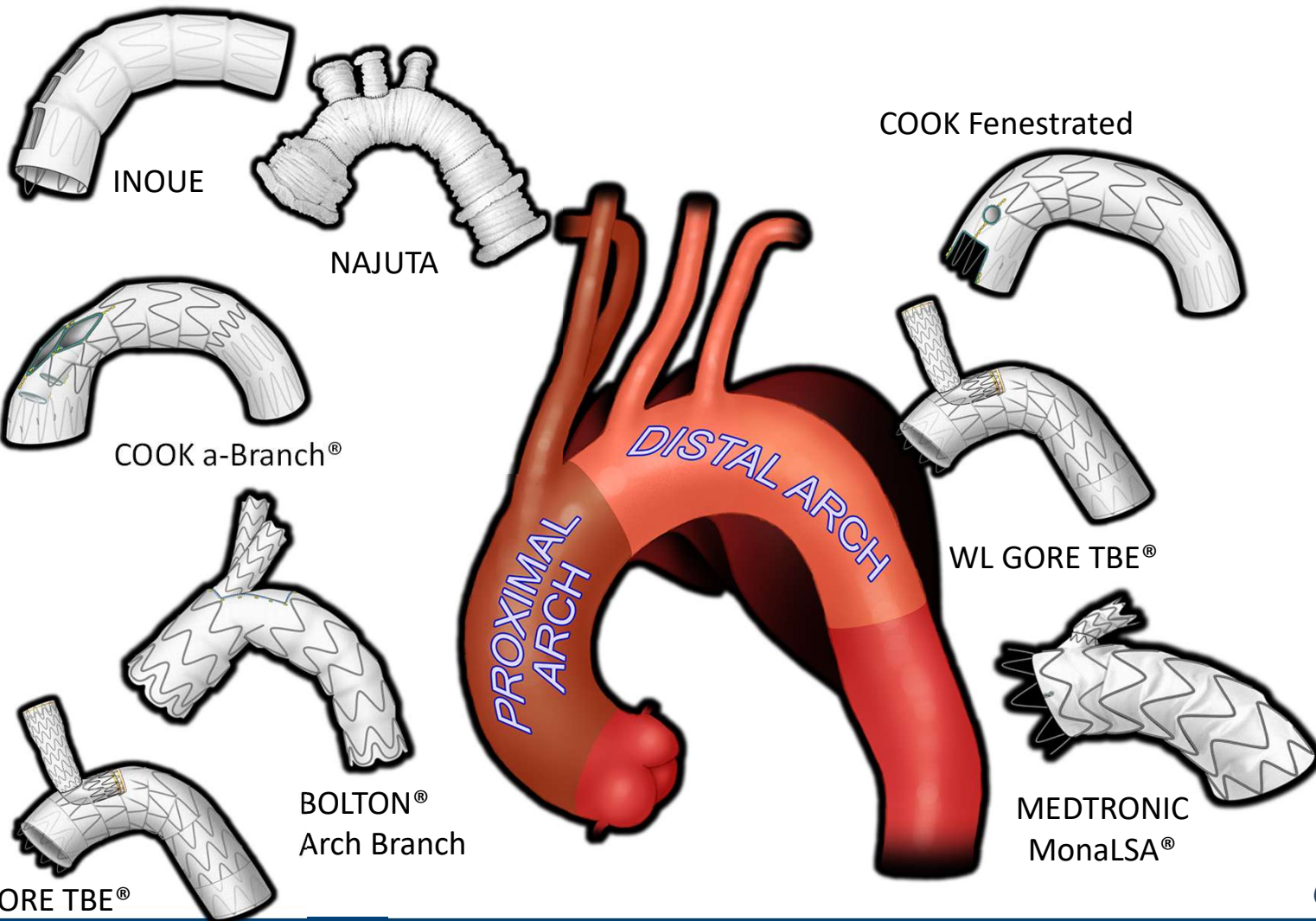
Disclosures

- Honoraria / Consultant / Research
 - Cook Medical Inc
 - W. L. Gore & Assoc
 - Philips Healthcare
- Some devices presented here are investigational and have not been approved by the FDA
- Acknowledgement
 - Gustavo Oderich, MD
Chief of Vascular Surgery & Professor of Surgery
Baylor College of Medicine, Houston, TX, USA

Aortic Arch Landing Zones

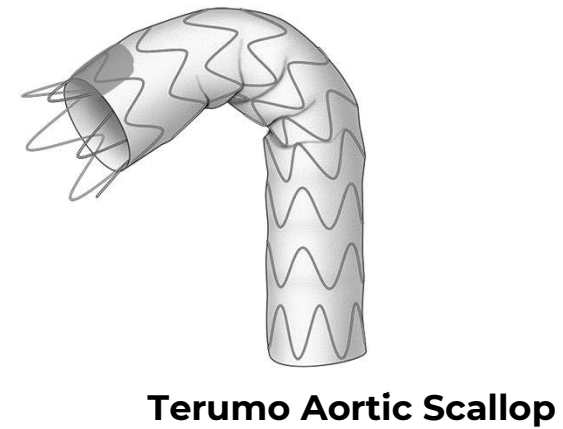
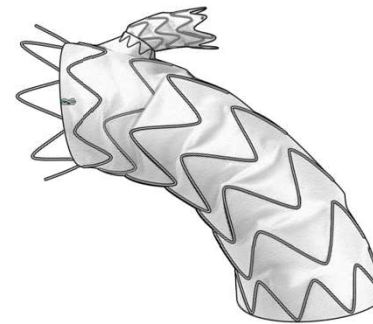
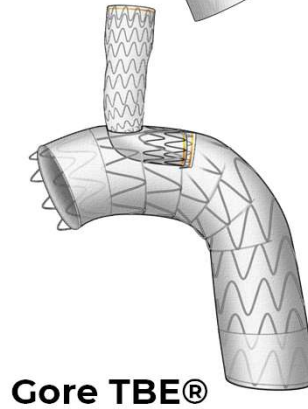
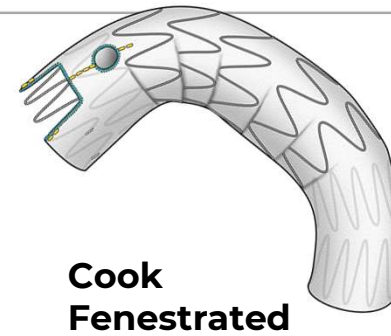


Arch repairs involve proximal landing in zones 0, 1 & 2

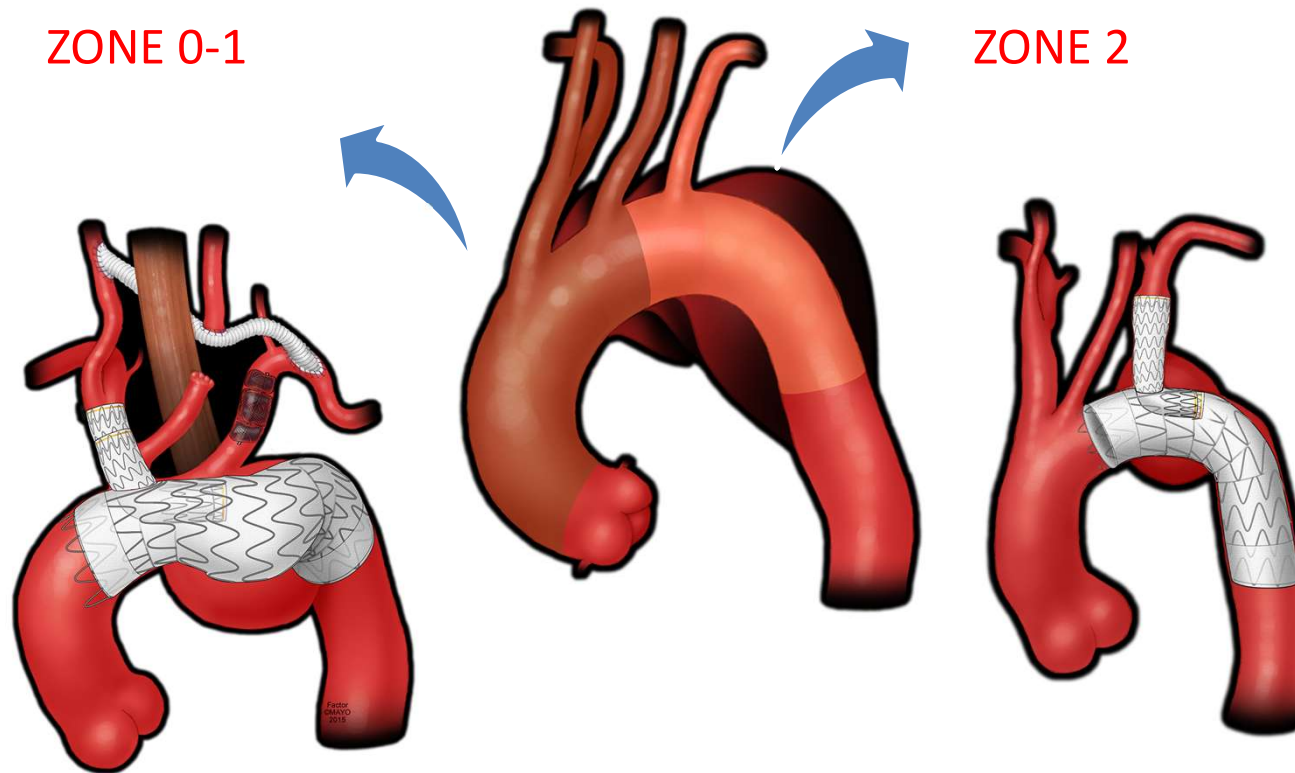


Oderich 2017

Distal arch branch options



Distal arch branch design for proximal arch



Left subclavian artery bypass

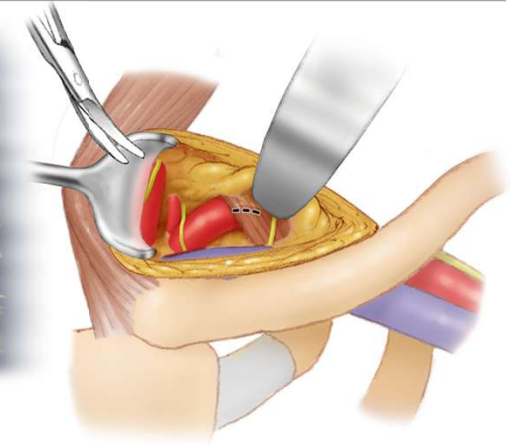
From the Southern Association for Vascular Surgery

Outcomes of carotid-subclavian bypass performed in the setting of thoracic endovascular aortic repair

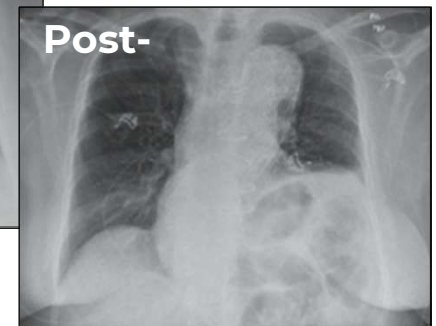
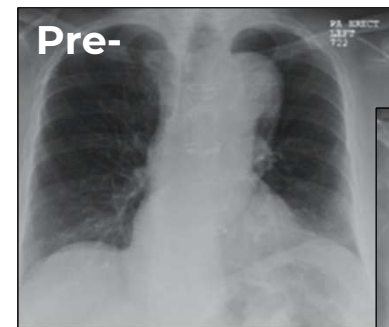


Soraya L. Voigt, MD,^a Muath Bishawi, MD,^a David Ranney, MD,^a Babatunde Yerokun, MD,^a
Richard L. McCann, MD,^b and G. Chad Hughes, MD,^a Durham, NC

J Vasc Surg. 2019 Mar;69(3):701-709



- 579 TEVAR patients → **19%** had LSA bypass
- Early complications, **29%**
 - **Phrenic nerve palsy, 25%**
 - Recurrent laryngeal nerve, 5%
 - Axillary nerve, 2%
 - Evacuation of neck hematoma, 1%
- Primary patency **97%** @ 5-years (3 occlusions)

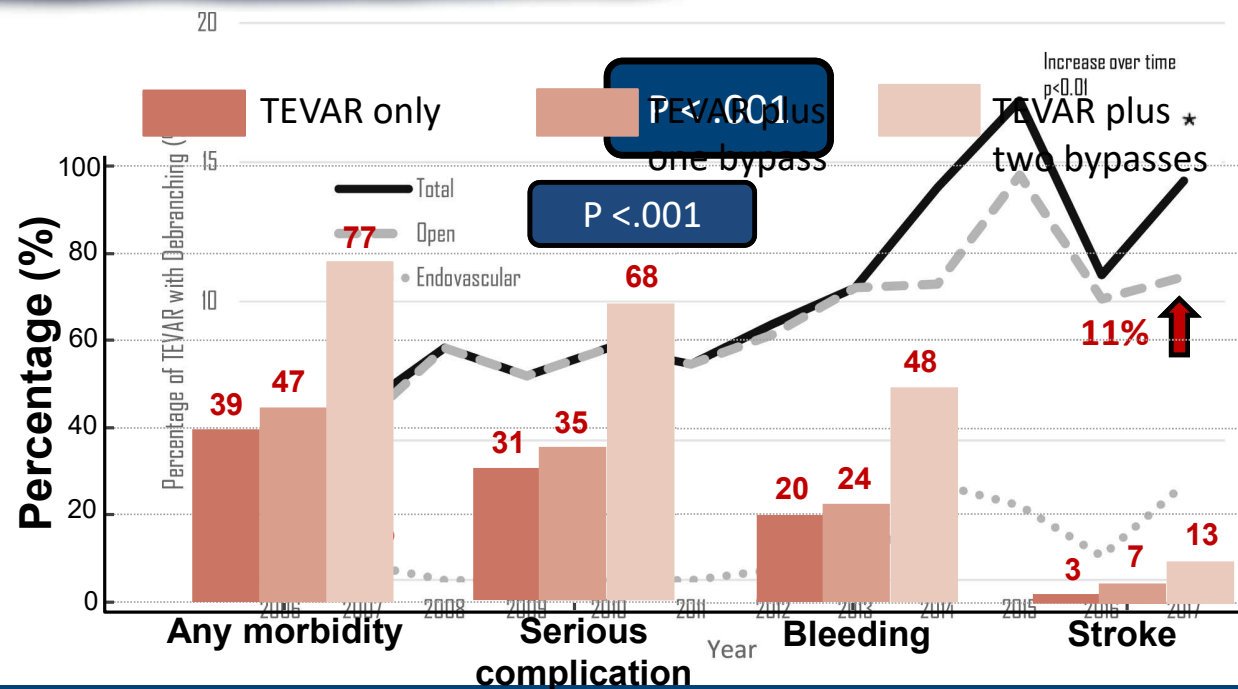


Trends and outcomes of thoracic endovascular aortic repair with open concomitant cervical debranching

Kirthi S. Bellamkonda, MSc,^a Sameh Yousef, MD,^b Naiem Nassiri, MD,^c Alan Dardik, MD, PhD,^c
 Raul J. Guzman, MD,^c Arnar Geirsson, MD,^b and Cassius I. Ochoa Char, MD, MS, FACS,^c *New Haven, Conn*

J Vasc Surg. 2021 Apr;73(4):1205-1212.e3.

- 3,281 pts underwent TEVAR between 2005 and 2017 in ACS-NSQIP dataset (10% with debranching procedure)
 - One bypass (n=276;[9%])
 - Two bypasses (n=31;[1%])
- Increase in the frequency of the debranching procedures
- Increased number of complications in TEVAR with two bypasses



Trends and outcomes of thoracic endovascular aortic repair with open concomitant cervical debranching

Kirthi S. Bellamkonda, MSc,^a Sameh Yousef, MD,^b Naiem Nassiri, MD,^c Alan Dardik, MD, PhD,^c Raul J. Guzman, MD,^c Arnar Geirsson, MD,^b and Cassius I. Ochoa Charar, MD, MS, FACS,^c *New Haven, Conn*

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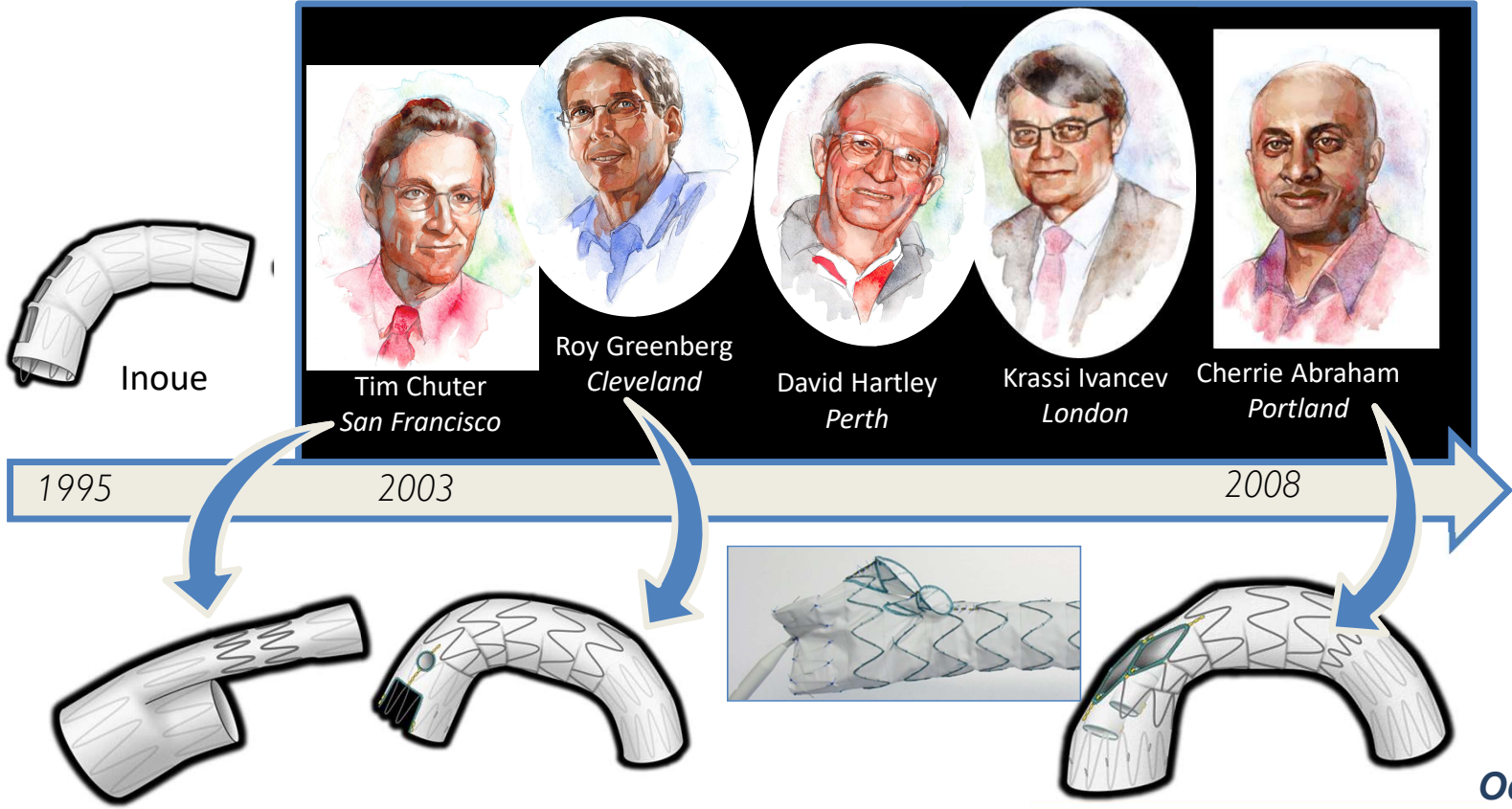
TEVAR with concomitant debranching has increasingly been used but is associated with worse outcomes than TEVAR alone

- Mortality was significantly higher for TEVAR plus two bypasses
- Independent predictors of mortality

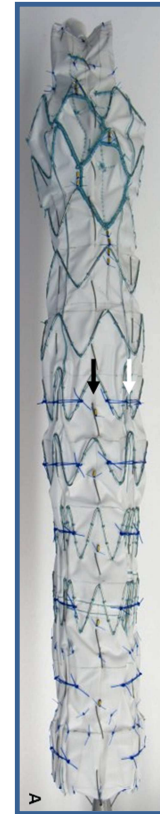
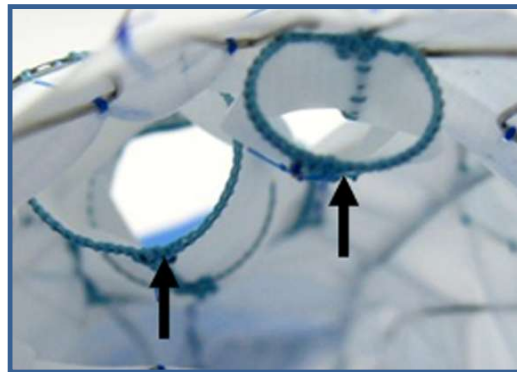
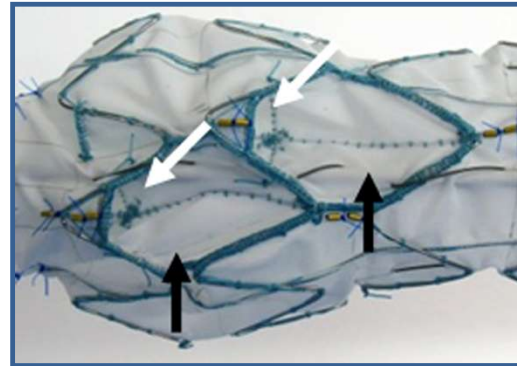
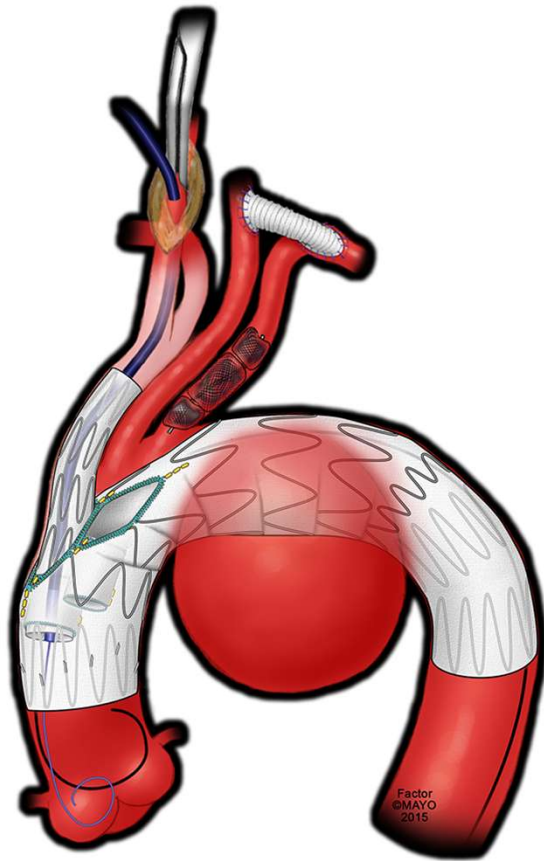
Table IV. Independent risk factors associated with mortality on multivariable analysis

Risk factor	OR (95% CI)
Two bypasses vs TEVAR only	4.33 (1.75-10.73)
Two bypasses vs 1 bypass	3.44 (1.24-9.51)
One bypass vs TEVAR only	1.26 (0.76-2.09)
Older age	1.74 (1.41-2.13)
Male sex	0.87 (0.66-1.15)
Functional dependent status	1.48 (1.00-2.19)
Smoking	1.21 (0.88-1.65)
Hypertension	0.68 (0.47-0.98)
Congestive heart failure	1.12 (0.53-2.39)
Dialysis dependency	2.61 (1.57-4.33)
Anesthesia	0.70 (0.34-1.45)
ASA class	2.24 (1.62-3.10)
Emergency case	3.66 (2.73-4.90)

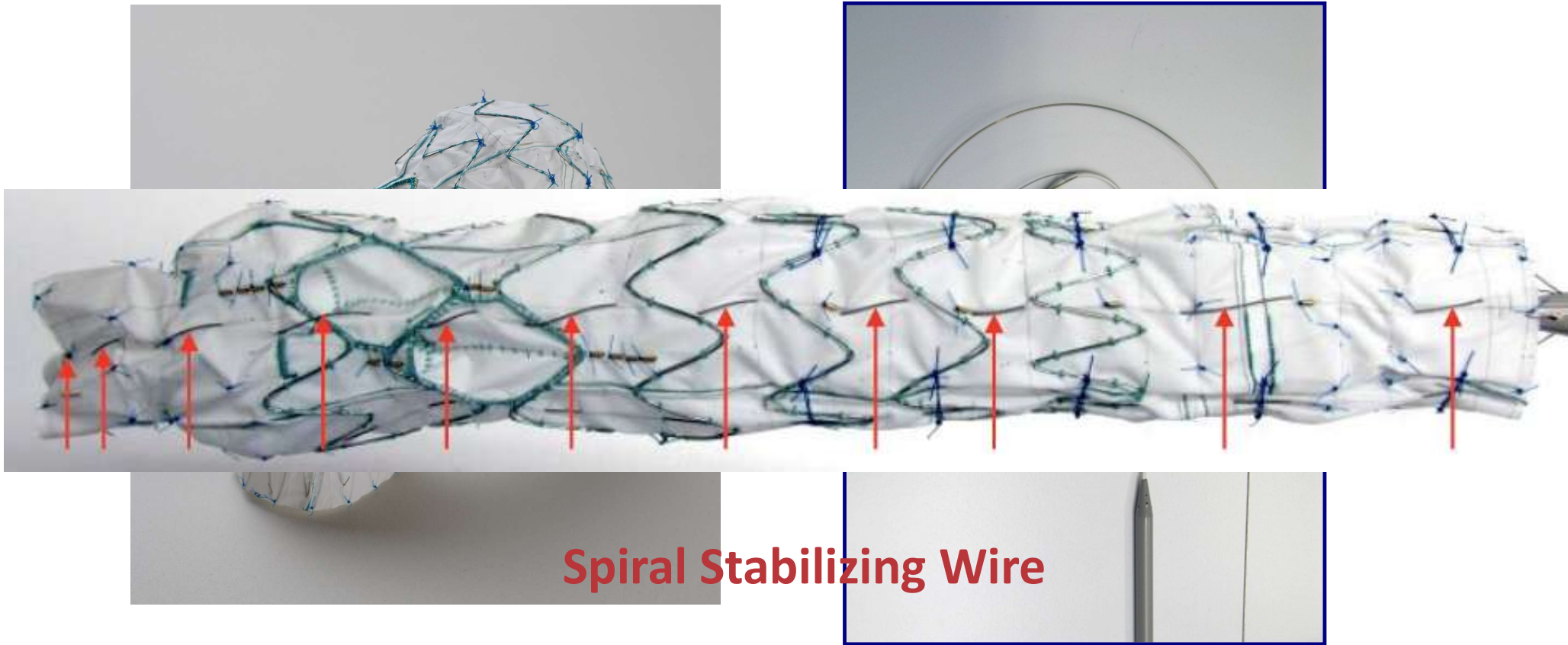
Arch Branch Evolution



2-Vessel arch branch design



2-3 Vessel arch branch design

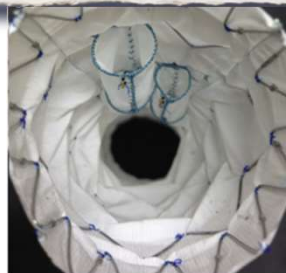


Early Experience - 2 vessel designs

Global experience with an inner branched arch endograft

Stéphan Haulon, MD. K. Greenberg, MD. Rafaëlle Spear, MD. Matt Eagleton, MD. Cherrie Abraham, MD. Christos Lioupis, MD. Eric Verhoeven, MD. Krassi Ivancev, MD. Tilo Kölbl, MD. Brendan Stanley, MD. Timothy Resch, MD. Pascal Desgranges, MD. Blandine Maurel, MD. Blayne Roeder, PhD. Timothy Chuter MD. Tara Mastracci, MD

J Thorac Cardiovasc Surg. 2014 Oct;148(4):1709-16.



38 patients with double inner branched arch endograft (Cook Medical, Bloomington, IN, USA)
- technical success 84.2%

Combined early mortality was 13.2% and neurologic complications were 15.8%

iTalian RegIstry of doUble inner branch stent graft for arch PatHology (the TRIUmPH Registry)

Ciro Ferrer, MD. Piergiorgio Cao, MD. Carlo Coscarella, MD. Michelangelo Ferri, MD. Luigi Lovato, MD. Stefano Camparini, MD. Luca di Marzo, MD. TRIUmPH Registry Investigators.

J Vasc Surg. 2019 Sep;70(3):672-682.e1.

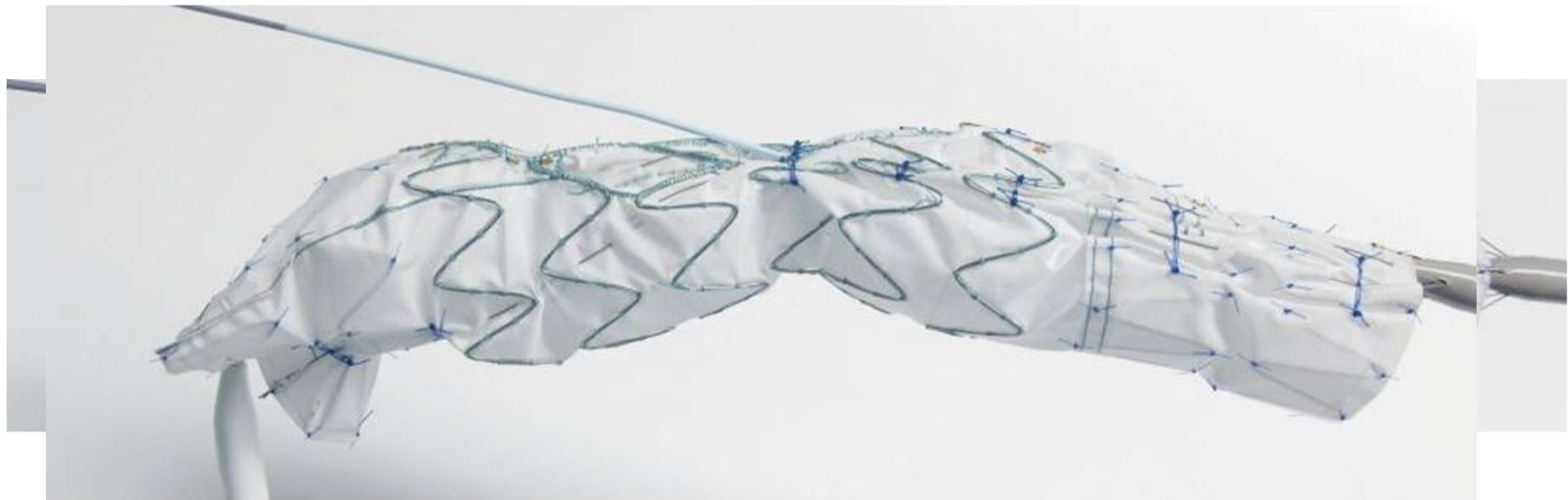
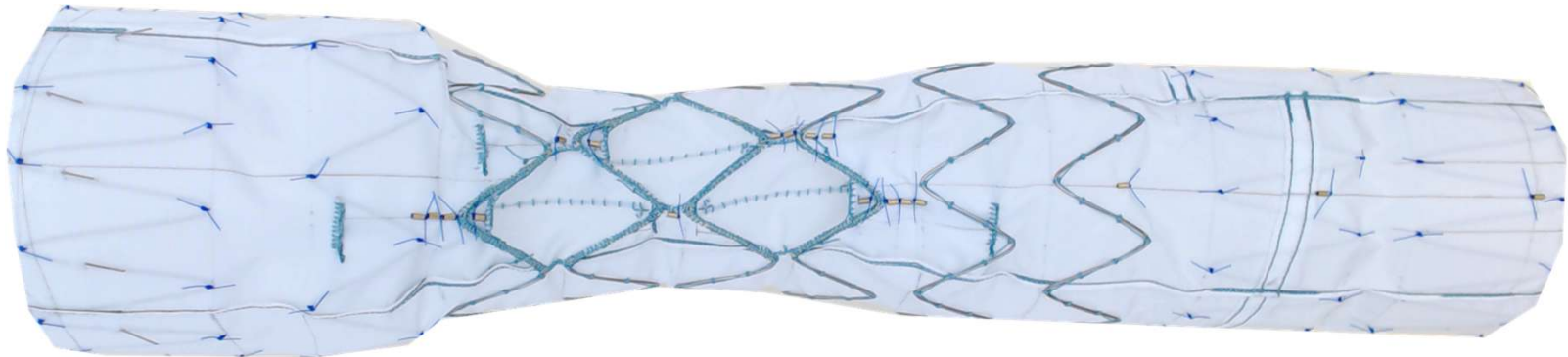


24 patients with Relay double inner branched stent-graft (Terumo Aortic, Glasgow, UK)
- technical success 95.8%

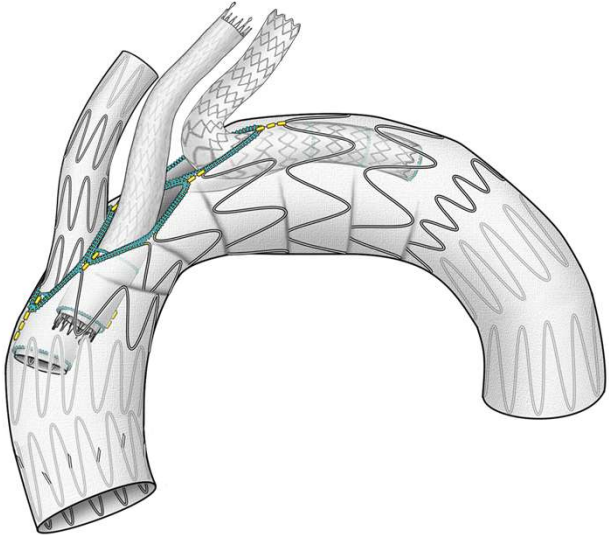
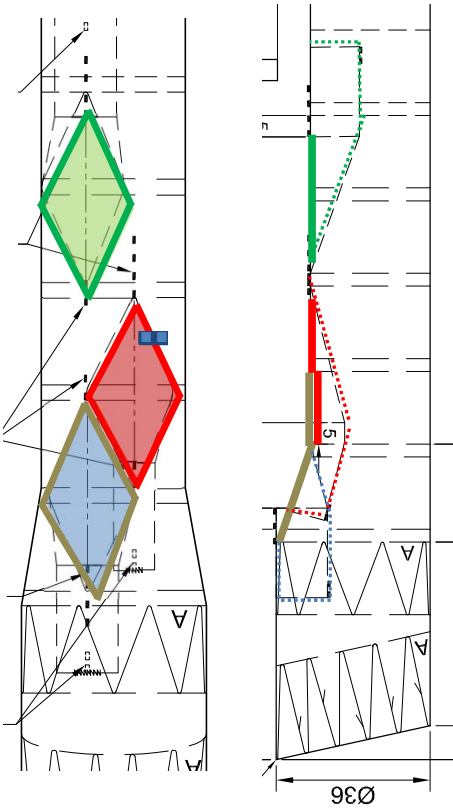
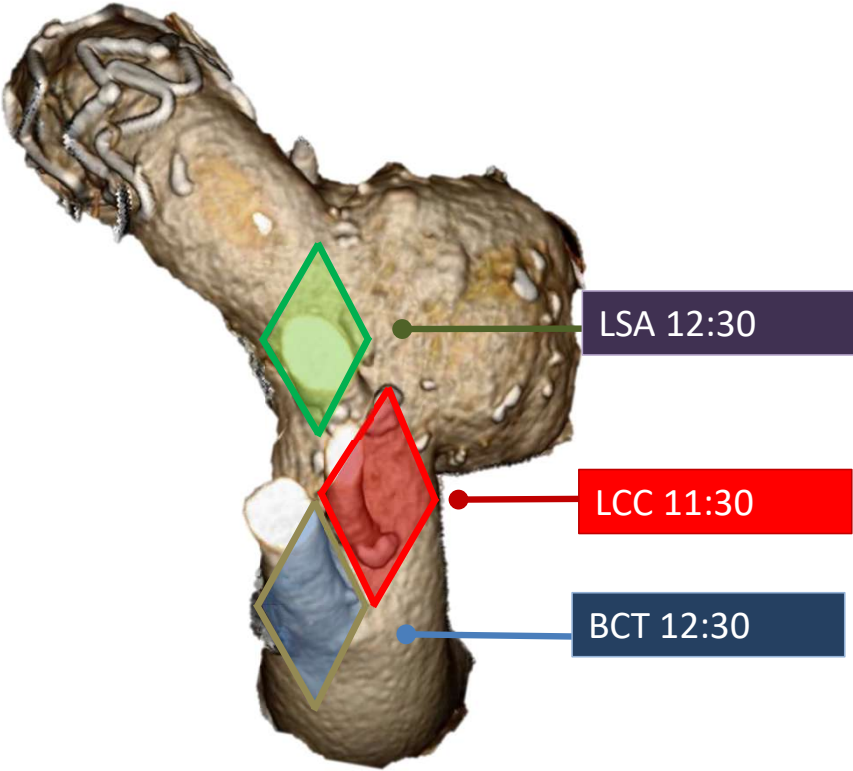
Early mortality was 16.7% and neurologic complications were 25%

Initial results were acceptable but not optimal

3-Vessel A-Branch Stent-Graft



3-Vessel A-Branch Stent-Graft



Multicenter global early feasibility study to evaluate total endovascular arch repair using three-vessel inner branch stent-grafts for aneurysms and dissections

Emanuel R. Tenorio, MD, PhD,^a Gustavo S. Oderich, MD,^a Tilo Kölbel, MD, PhD,^b Nuno V. Dias, MD, PhD,^c Björn Sonesson, MD, PhD,^c Angelos Karelis, MD,^c Mark A. Farber, MD,^d F. Ezequiel Parodi, MD,^d Carlos H. Timaran, MD,^e Carla K. Scott, MD,^e Nikolaos Tsilimparis, MD, PhD,^f Carlota Fernandez, MD,^f Tomasz Jakimowicz, MD, PhD,^g Katarzyna Jama, MD,^g Jarin Kratzberg, PhD,^h Justine Mouglin, MD,ⁱ and Stéphan Haulon, MD, PhD,ⁱ *Houston and Dallas, Tex; Hamburg and Munich, Germany; Malmö, Sweden; Chapel Hill, NC; Warszawa, Poland; Bloomington, Ind; and Gif-sur-Yvette, France*
J Vasc Surg. 2021 Oct;74(4):1055-1065.e4.

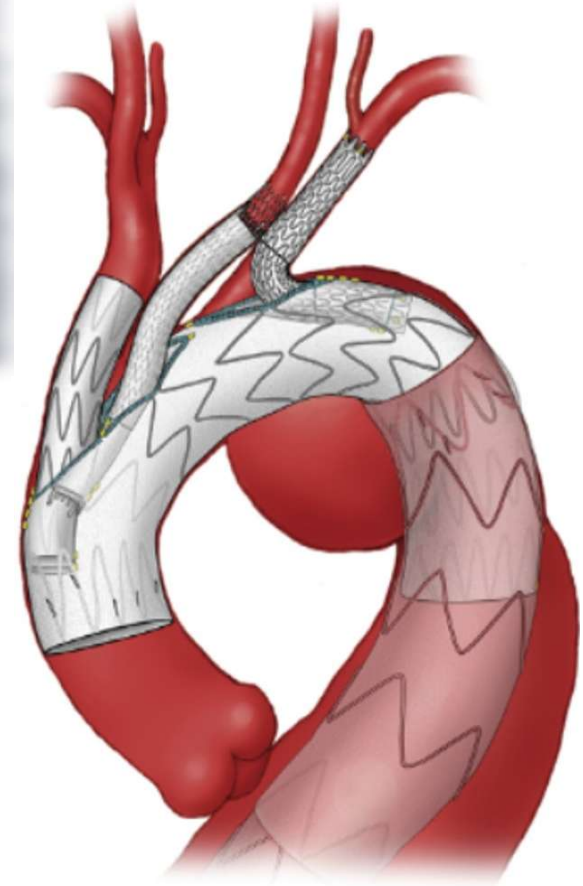
N=39

Mean follow-up 3.2 months

Technical success: 39 (100%)

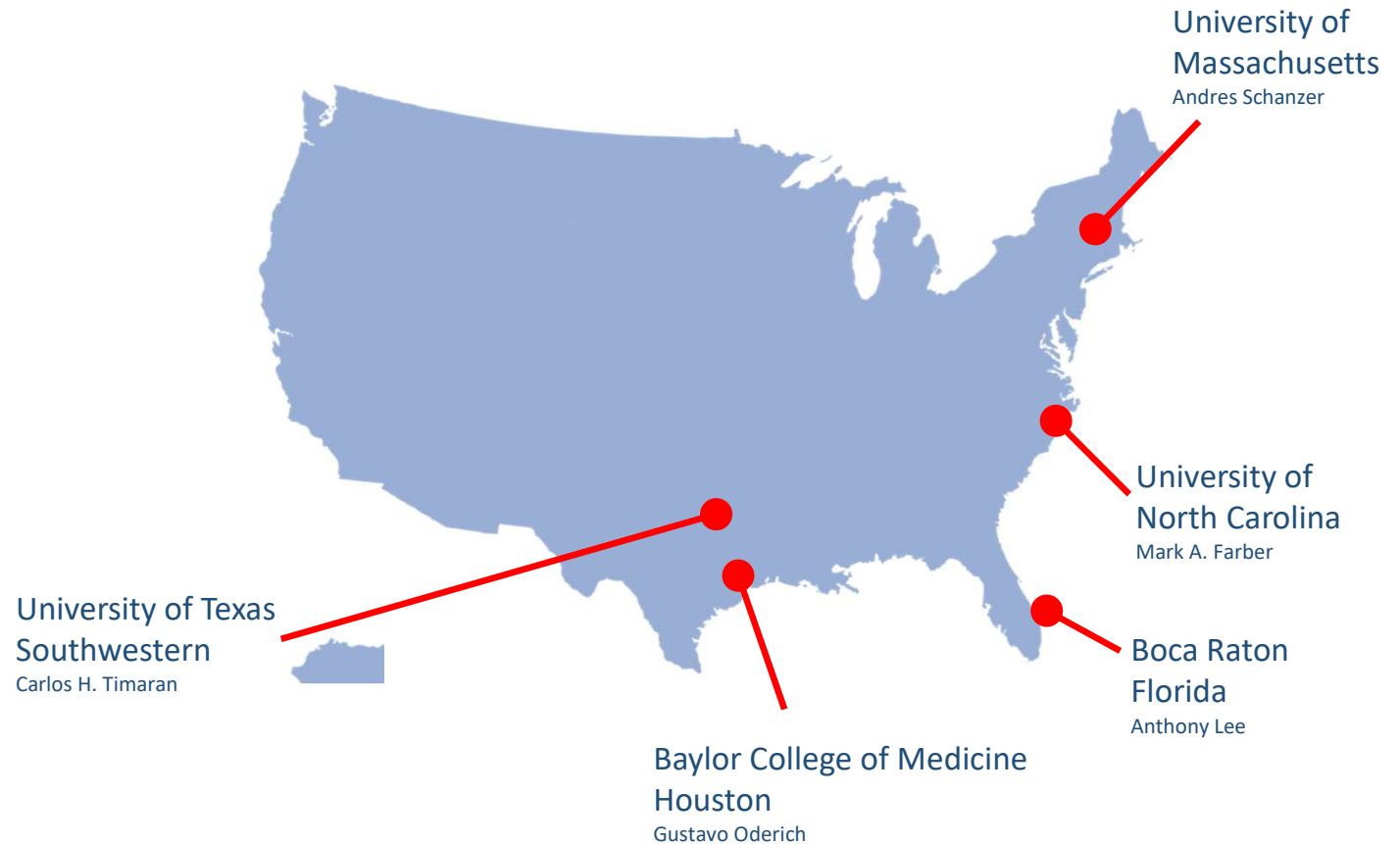
30-day mortality: 2 (5%)

Stroke: 2 (5%)

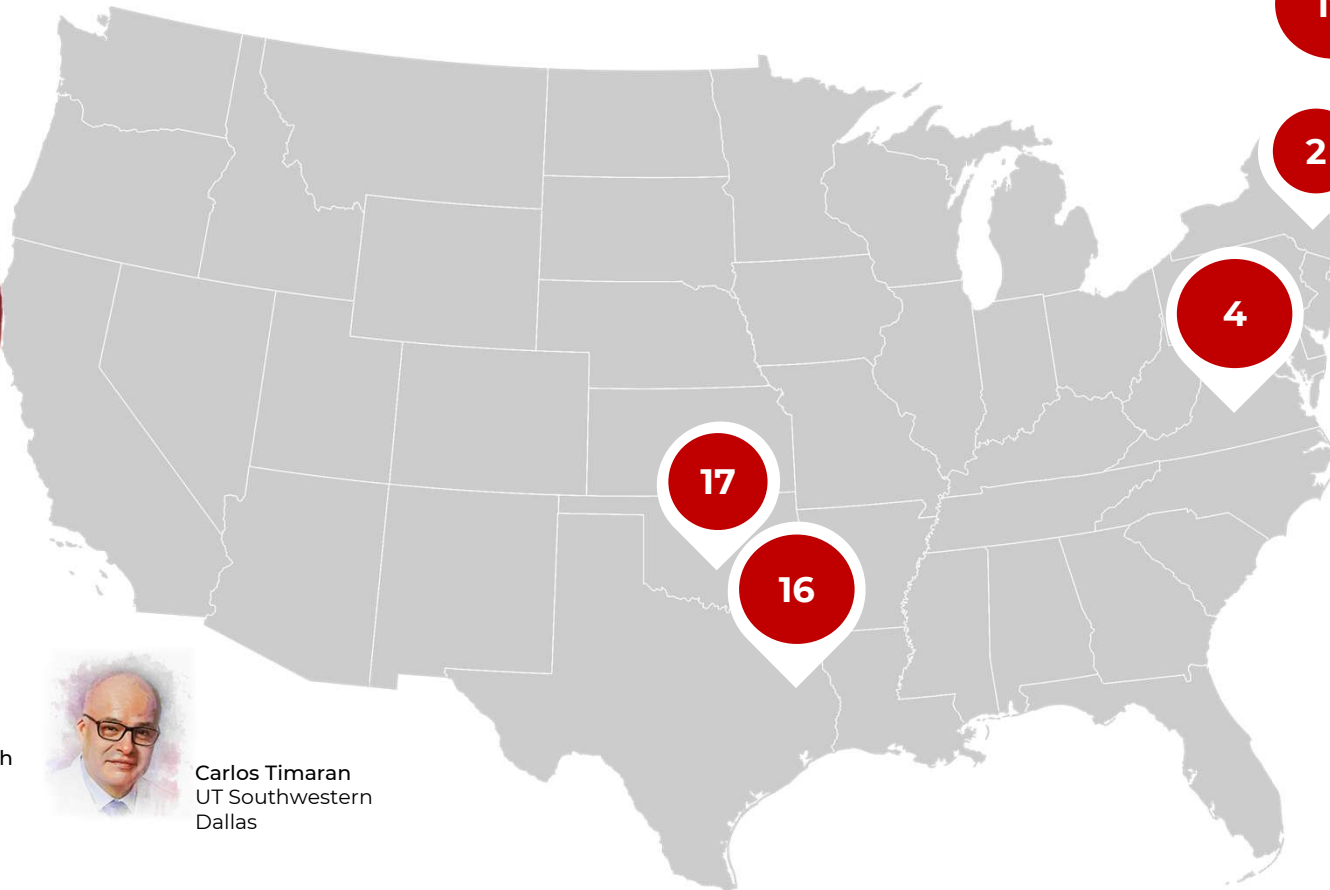


United States F/BEVAR Aortic Research Consortium (US-ARC)—Aortic Arch

- 6 US sites
- Prospective, physician-sponsored IDE studies
- Independent monitoring, FDA audited
- Cook 1, 2, 3 branch devices built custom on the A Branch platform



62 arch patients (157 targets)...



Gustavo Oderich
Baylor
Houston



Carlos Timaran
UT Southwestern
Dallas



Andres Schanzer
U of Massachusetts
Worcester



Matt Eagleton
Mass General
Boston



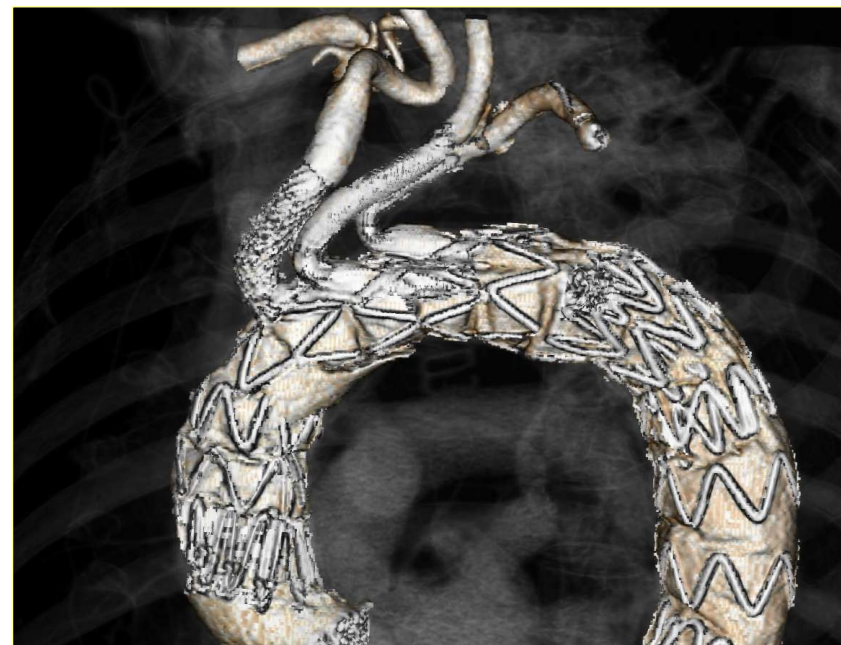
Darren Schneider
U of Pennsylvania
Philadelphia



Mark Farber
U of North Carolina
Chapel Hill

US ARC—Aortic Arch (n=62)

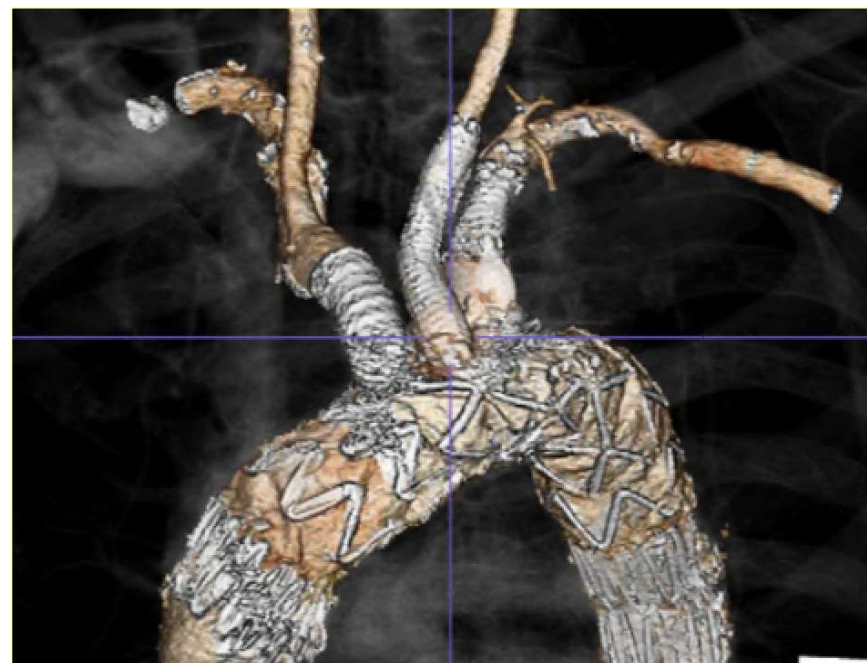
Device Type	Count
Arch Single Branch	4 (6.5%)
Arch Double Branch	21 (34%)
Arch Triple Branch	37 (60%)



US ARC—Aortic Arch (n=62)

Patient Characteristics

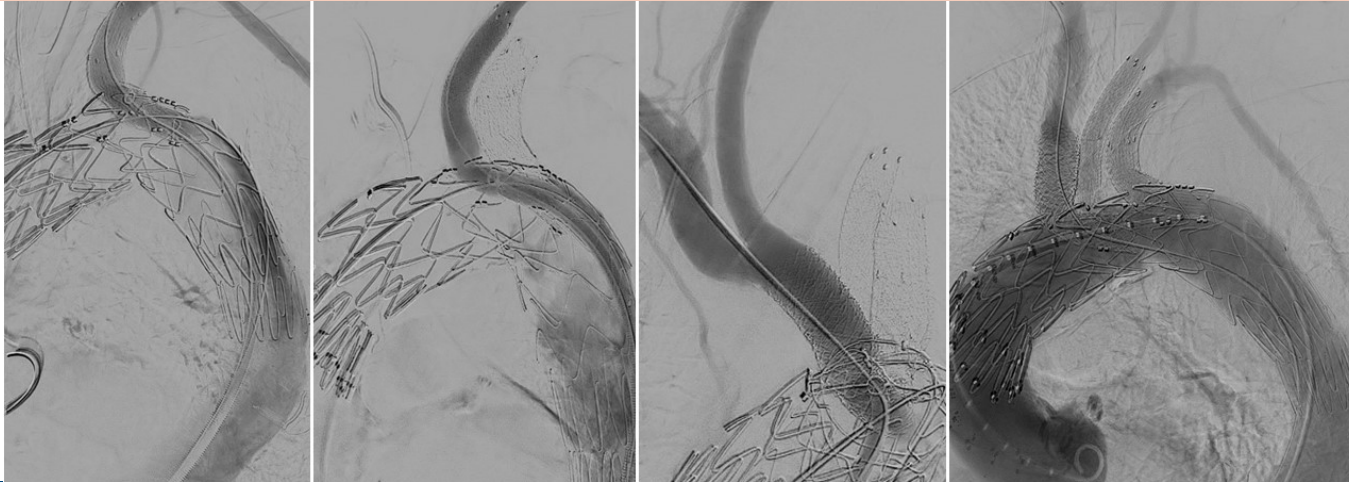
Prior Aortic Surgery	40 (65%)
Prior FEVAR	2 (3.2%)
Prior TEVAR without Type 1 Endoleak	2 (3.2%)
Prior TEVAR with Type 1 Endoleak	6 (9.7%)
Prior EVAR without Type 1a Endoleak	2 (3.2%)
Prior Open Infrarenal Aortic Repair	1 (1.6%)
Prior Open Thoracic Aortic Repair	4 (6.5%)
Prior Open Thoracoabdominal Aortic Repair	2 (3.2%)
Prior Open Arch Aortic Repair	5 (8.1%)
Prior Open Ascending Aortic Repair	28 (45%)
Prior Open Abdominal Surgery (not Laparoscopic)	9 (15%)
Prior Type A or B Dissection	34 (55%)



US ARC—Aortic Arch (n=62)

Technical Success

Technical Success (Overall)	59 (95%)
Patency of all required device components	61 (98%)
Absence of unintentional coverage of a target vessel	62 (100%)
Absence of Type 1 or Type 3 Endoleaks	59 (95%)
Absence of surgical conversion	62 (100%)
Absence of death on same day of procedure	61 (98%)



US ARC—Aortic Arch (n=62)

30-Day Stroke: 4/62

6.5%

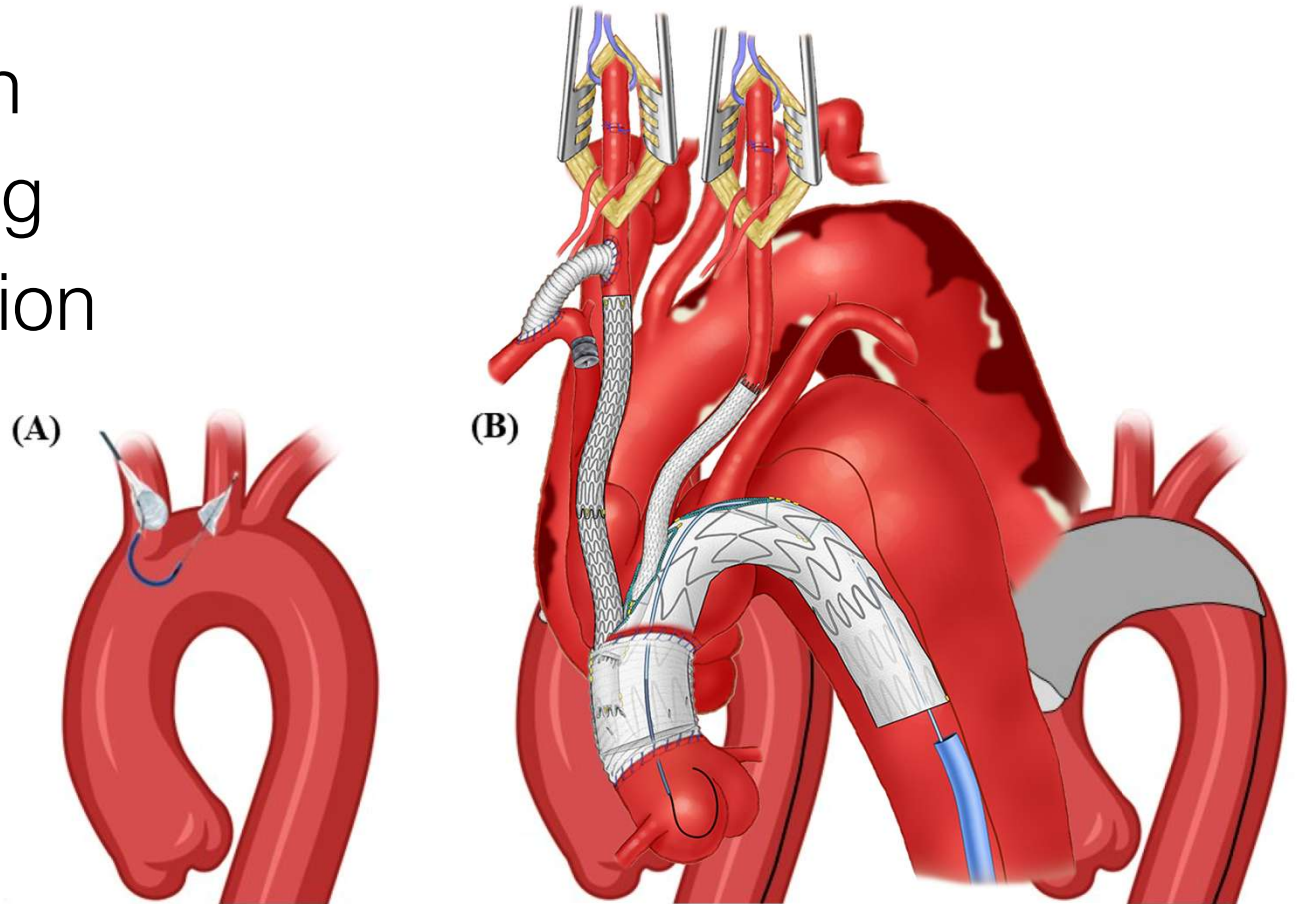
US ARC—Aortic Arch (n=62)

30-Day Mortality: 6/62

9.7%

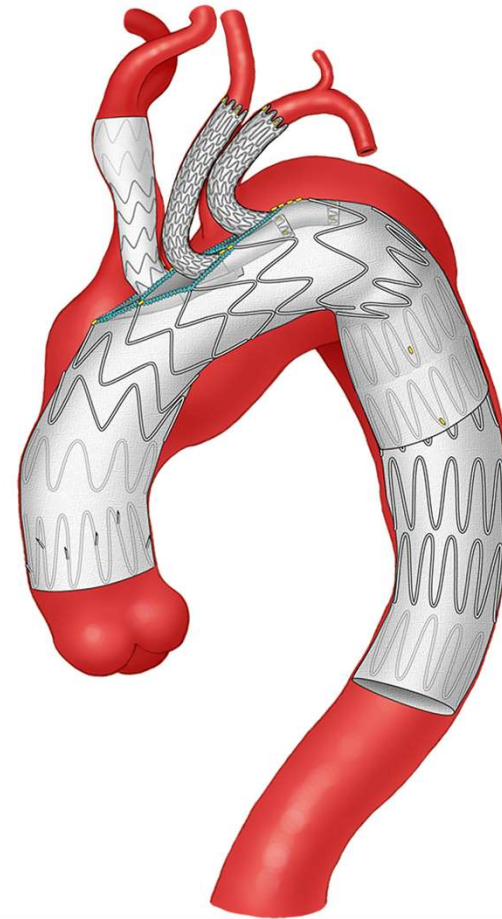
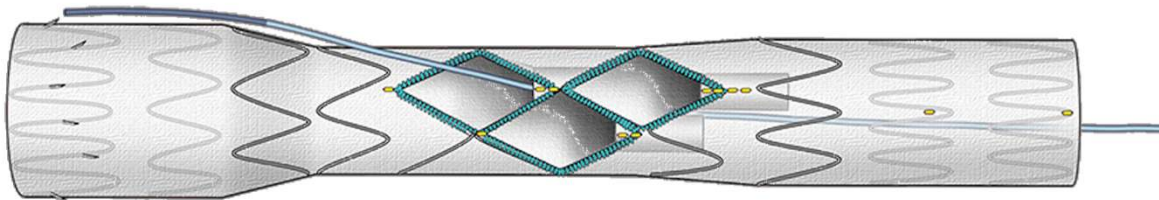
Strategies to minimize stroke

- Patient selection
- Carotid clamping
- Embolic protection devices
- Streamline the technique

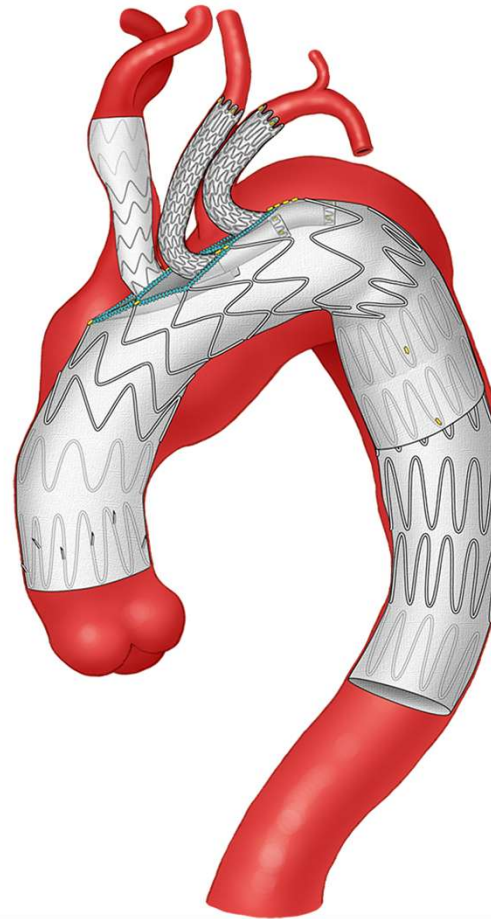
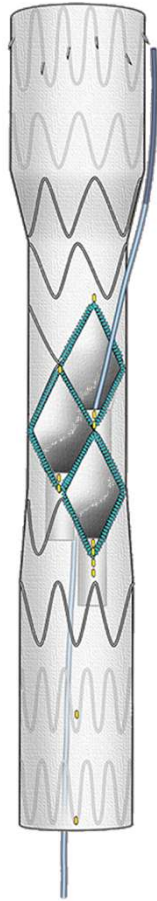


Current Strategy to minimize stroke

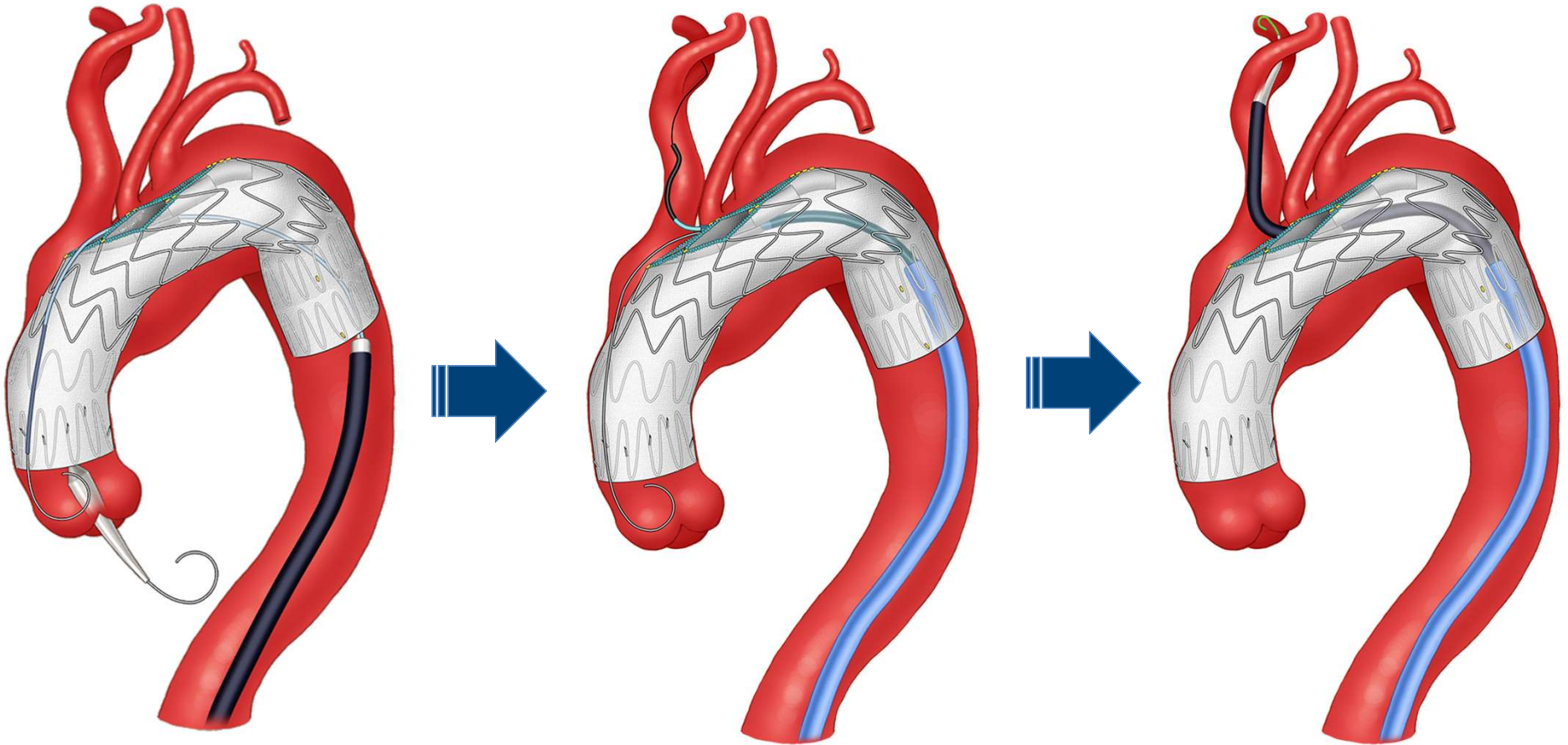
- Minimize arch manipulation
- Use 3-retrograde branches when possible
- Exclusive transfemoral access
- Exclusive use of self-expanding stents



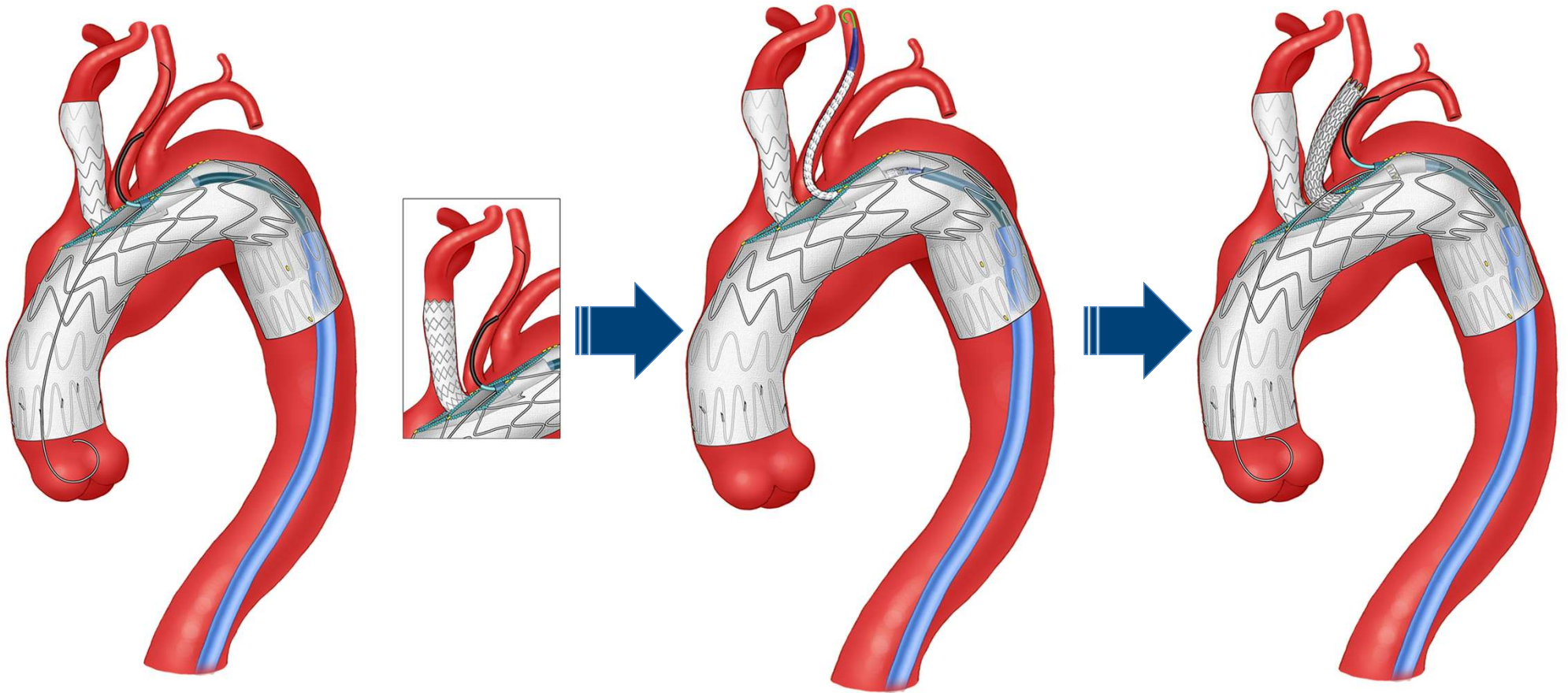
3-vessel arch branched device with retrograde branches



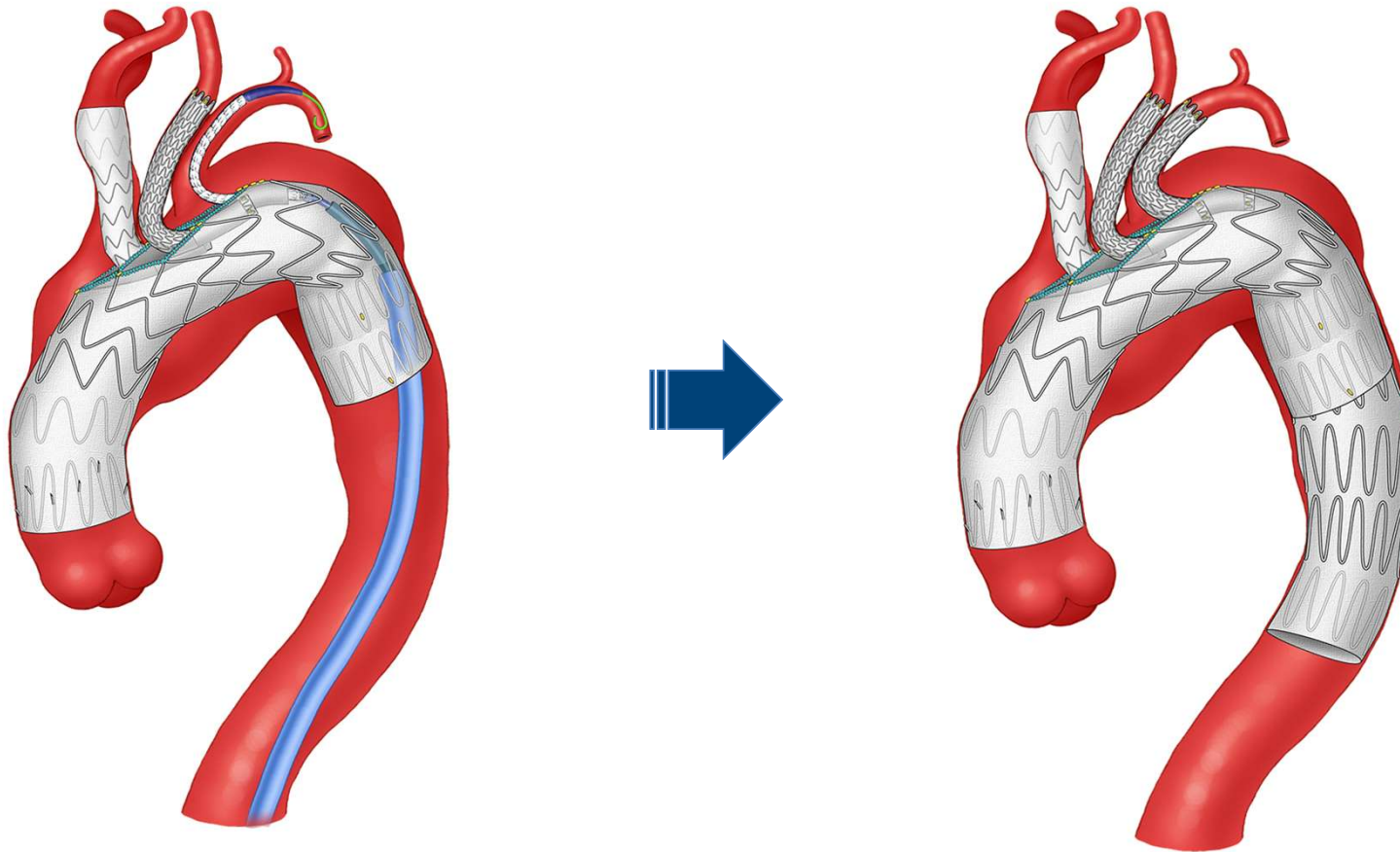
3-vessel arch branched device with retrograde branches



3-vessel arch branched device with retrograde branches

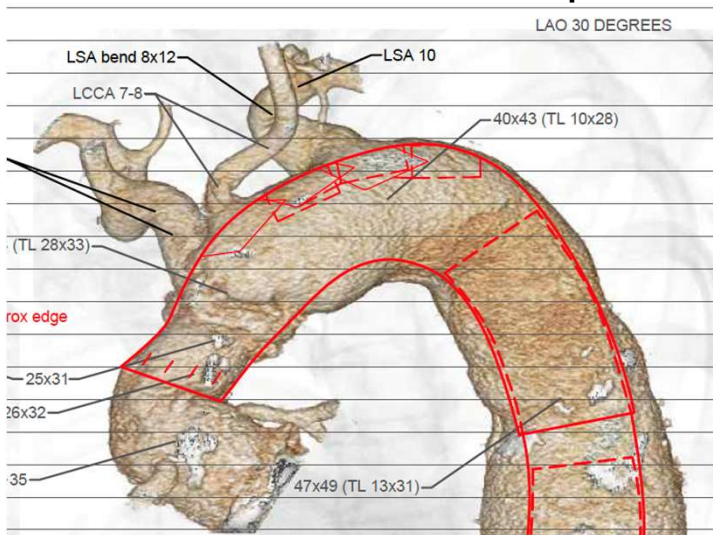


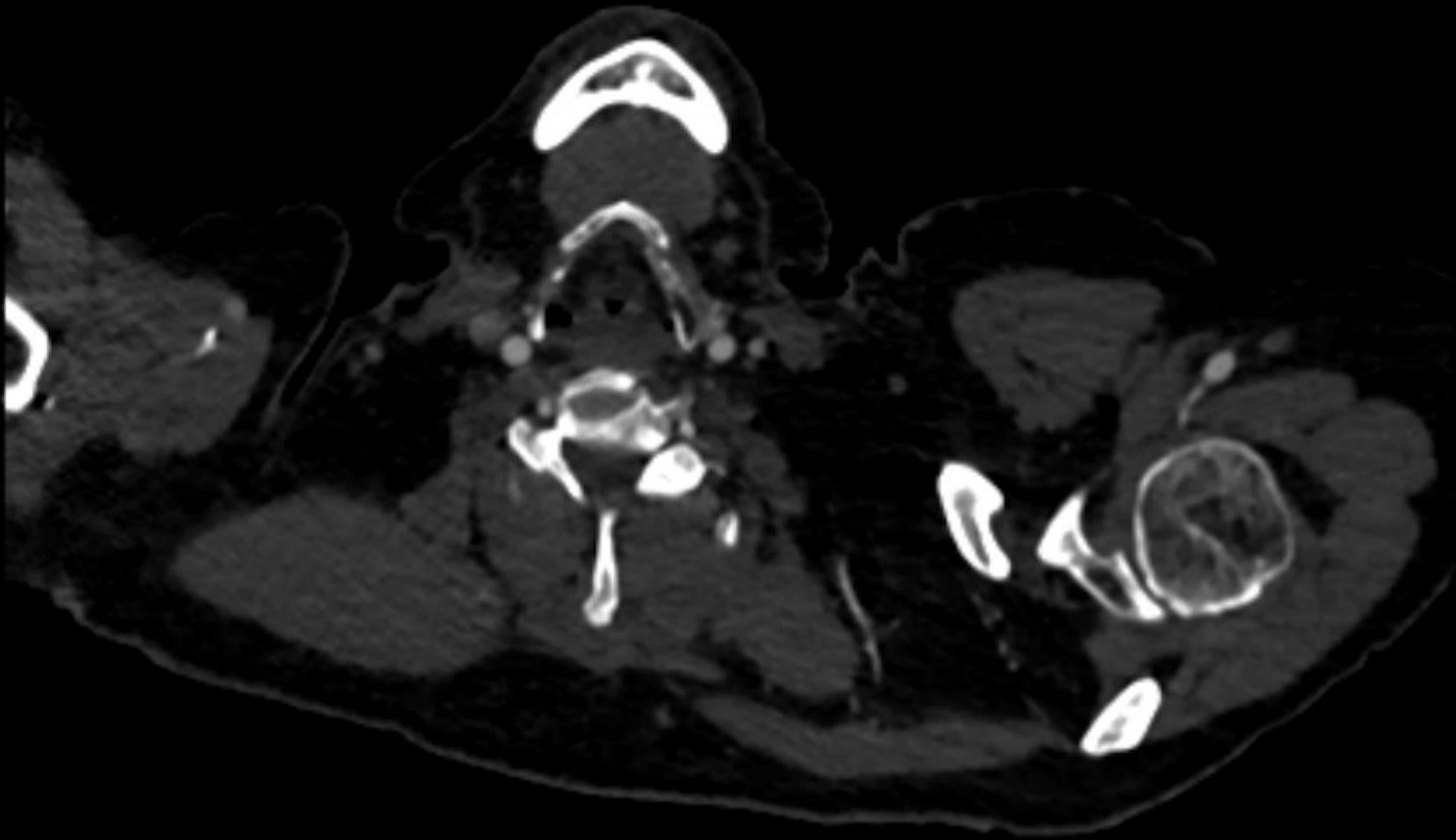
3-vessel arch branched device with retrograde branches



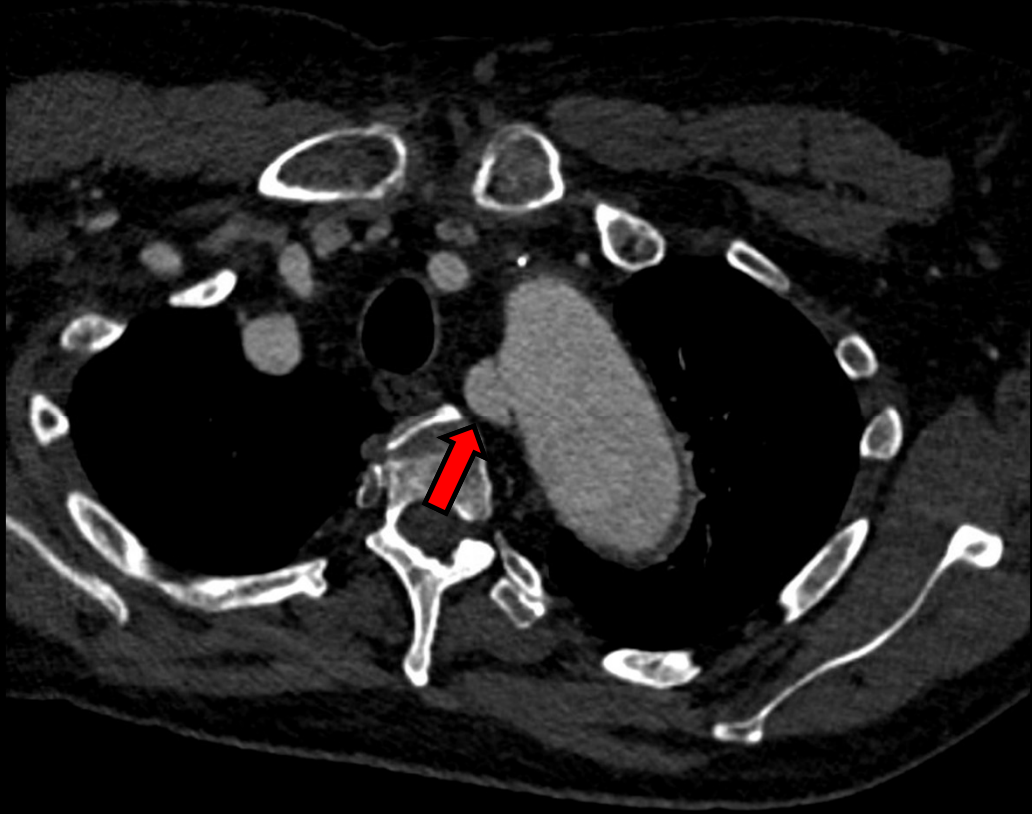
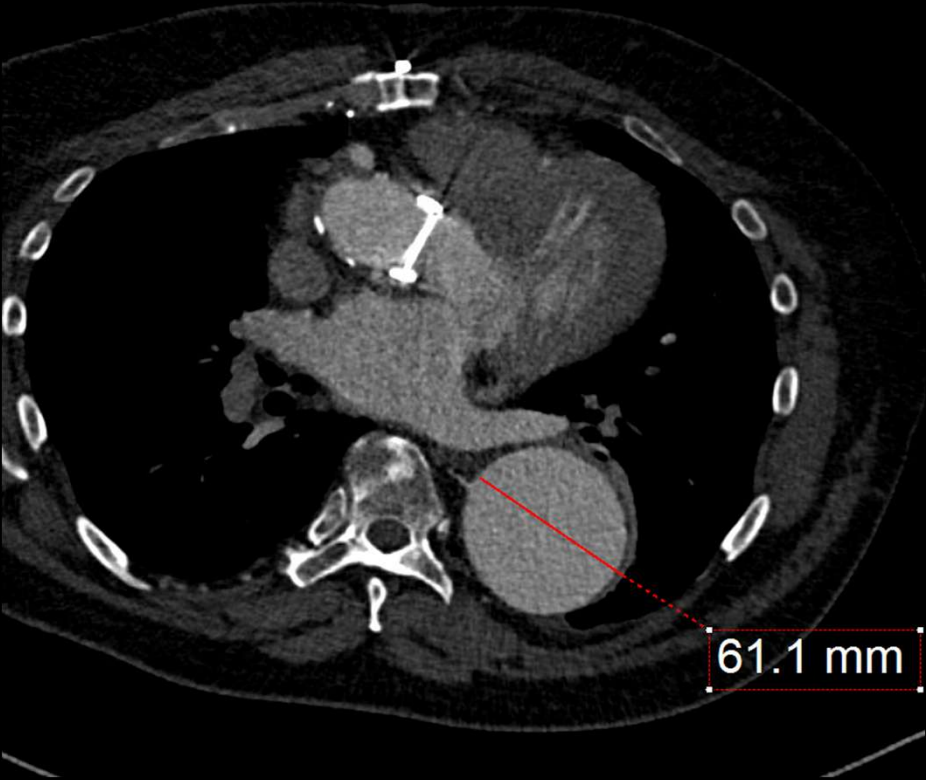
Case Example

- 55-year-old patient with prior type A repair
- Attempted redo open repair
- Excessive bleeding during sternotomy
- Referred for endovascular repair



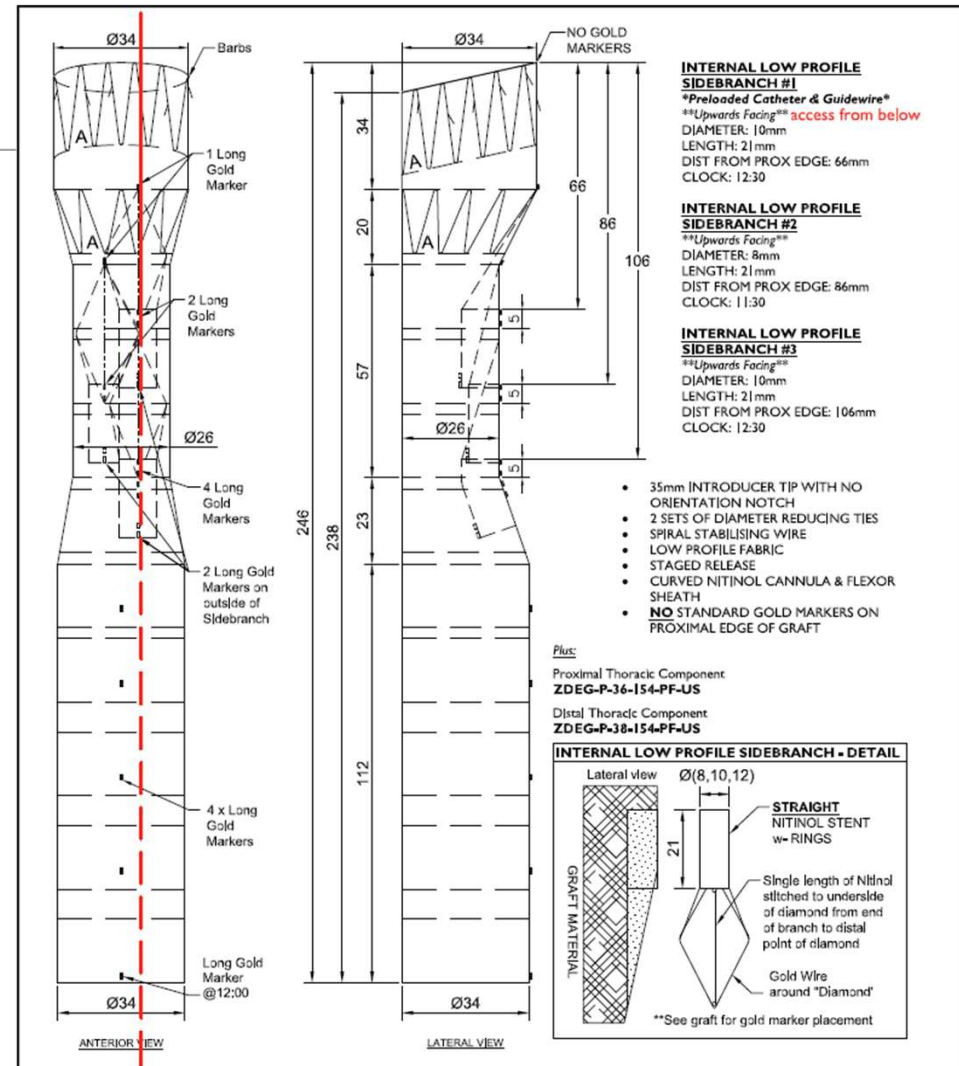


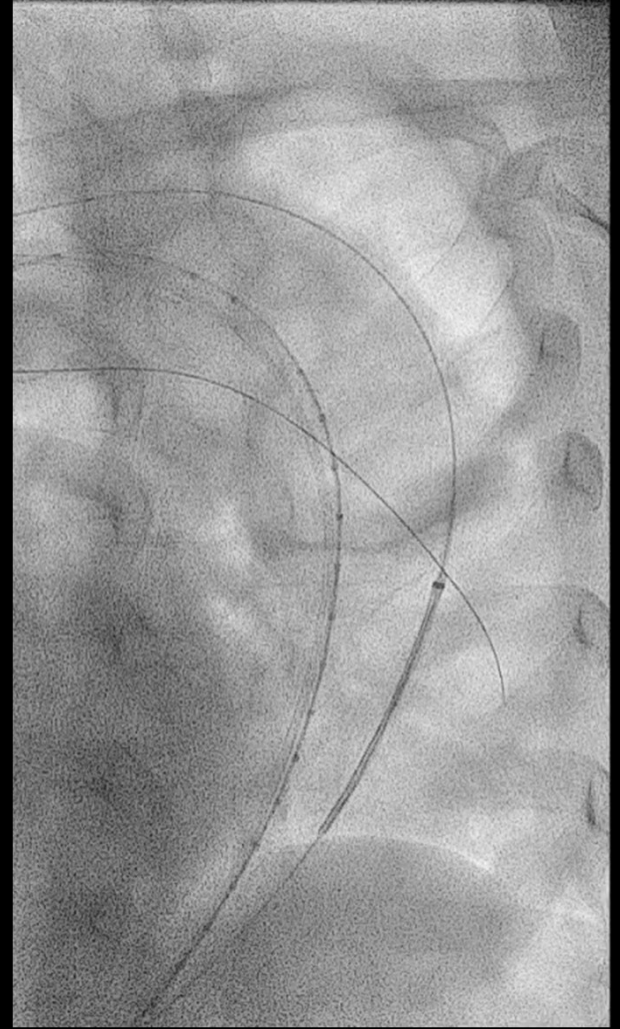
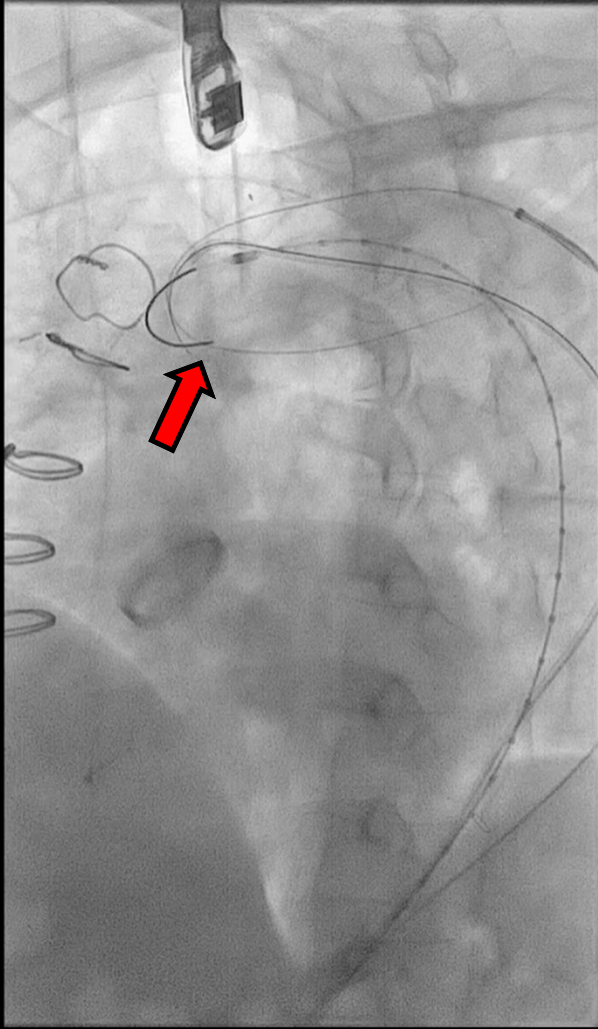
Preop CTA

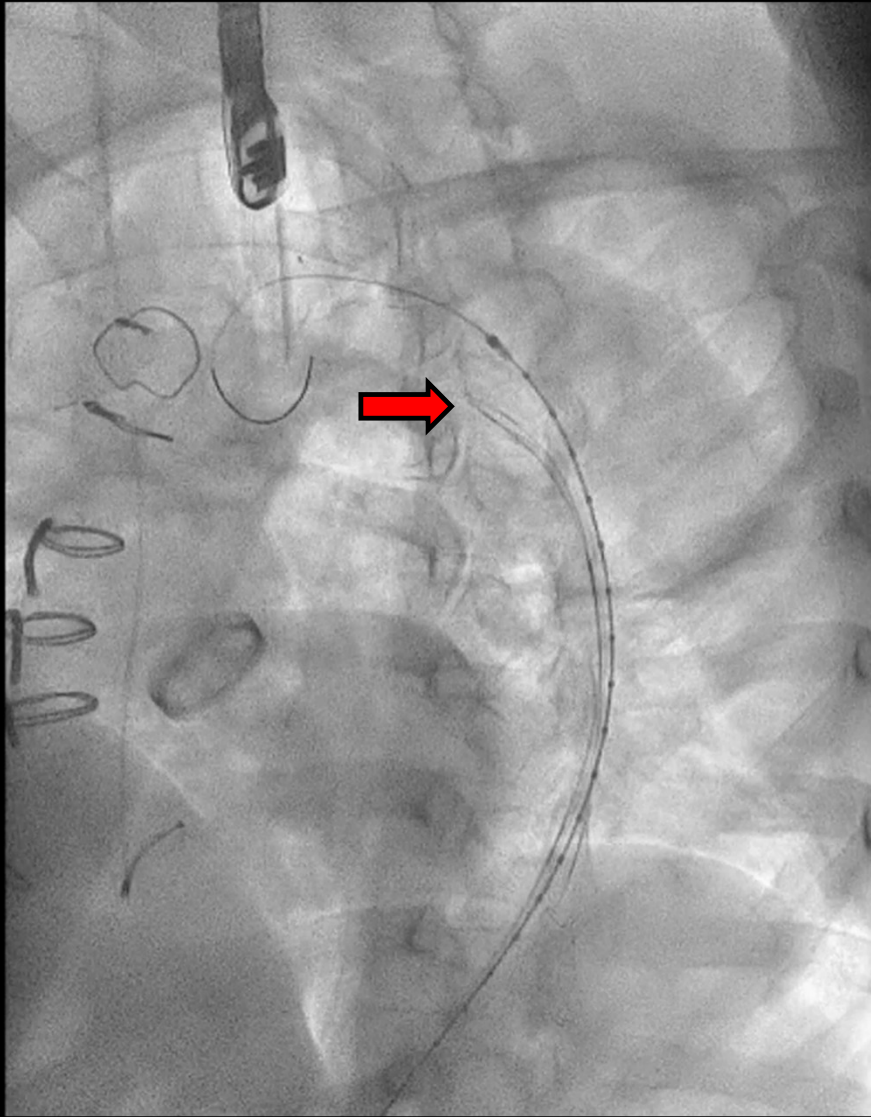


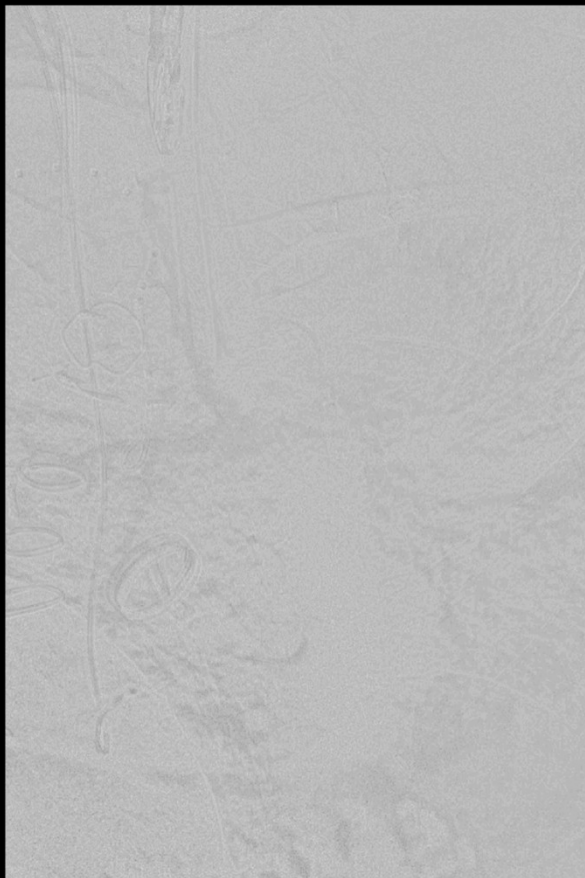
Treatment Plan

- Endovascular aneurysm arch repair using a patient-specific company-manufactured device (PS-CMD)
- Transcatheter electrosurgical aortic septotomy





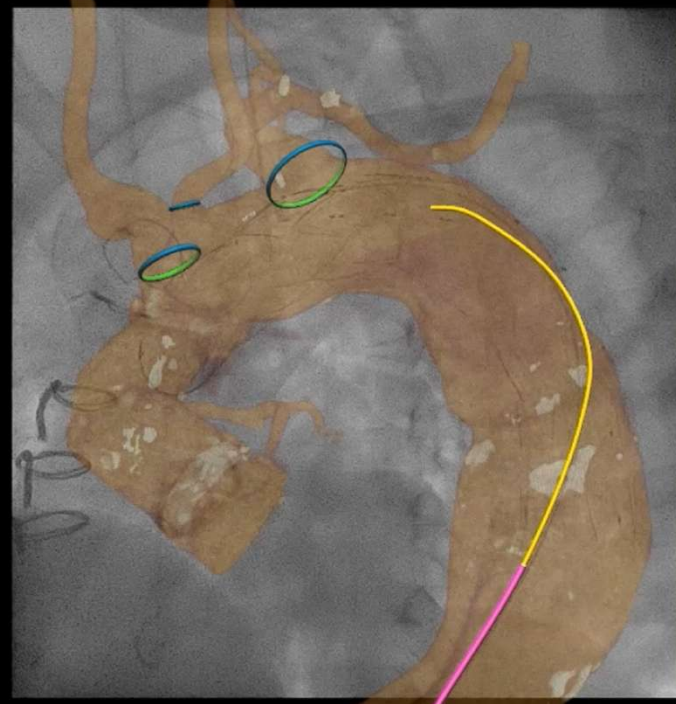




Innominate artery cannulation

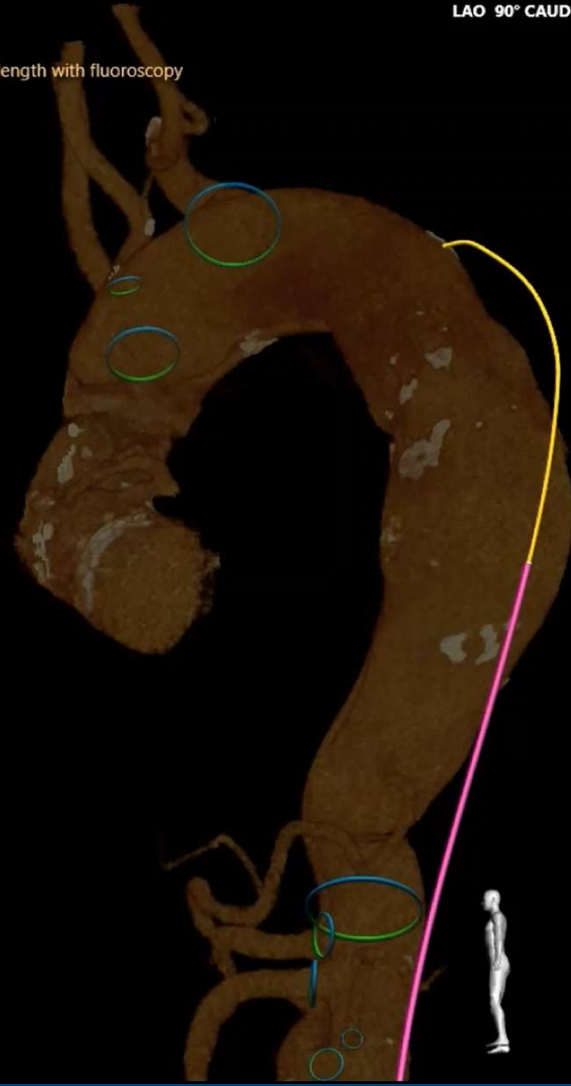
.AO 45° CAUD 2°

Catheter registration may be inaccurate. Check length with fluoroscopy



Replay 97/97

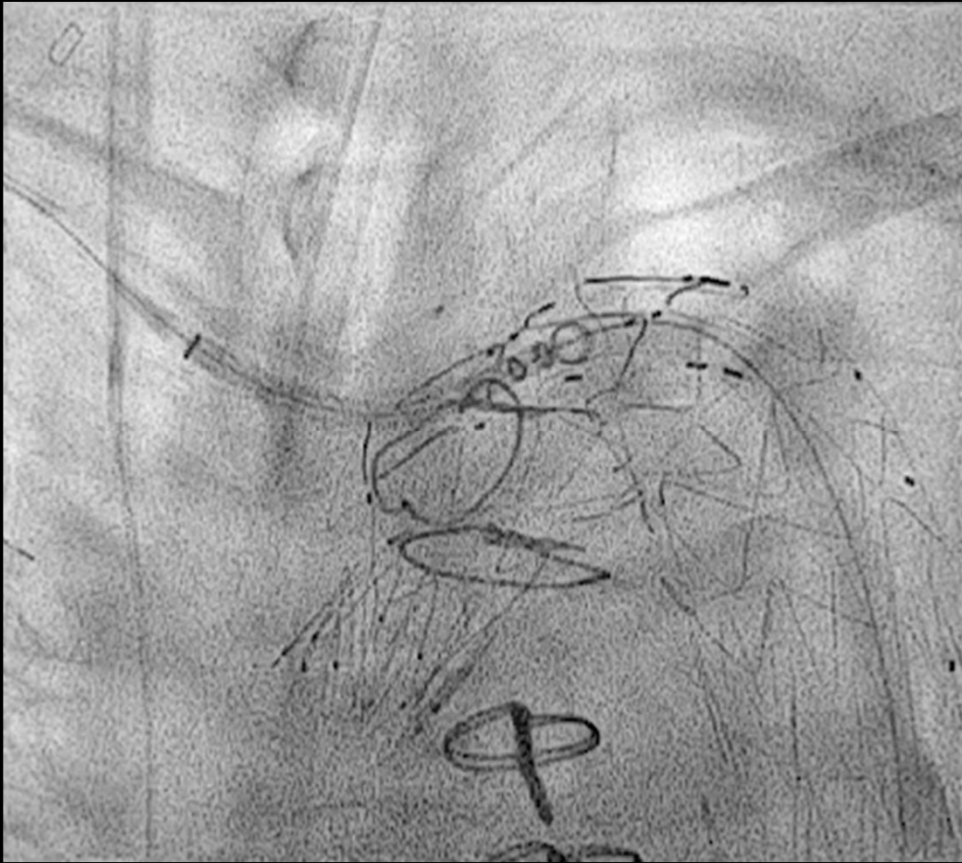
LAO 90° CAUD 13°



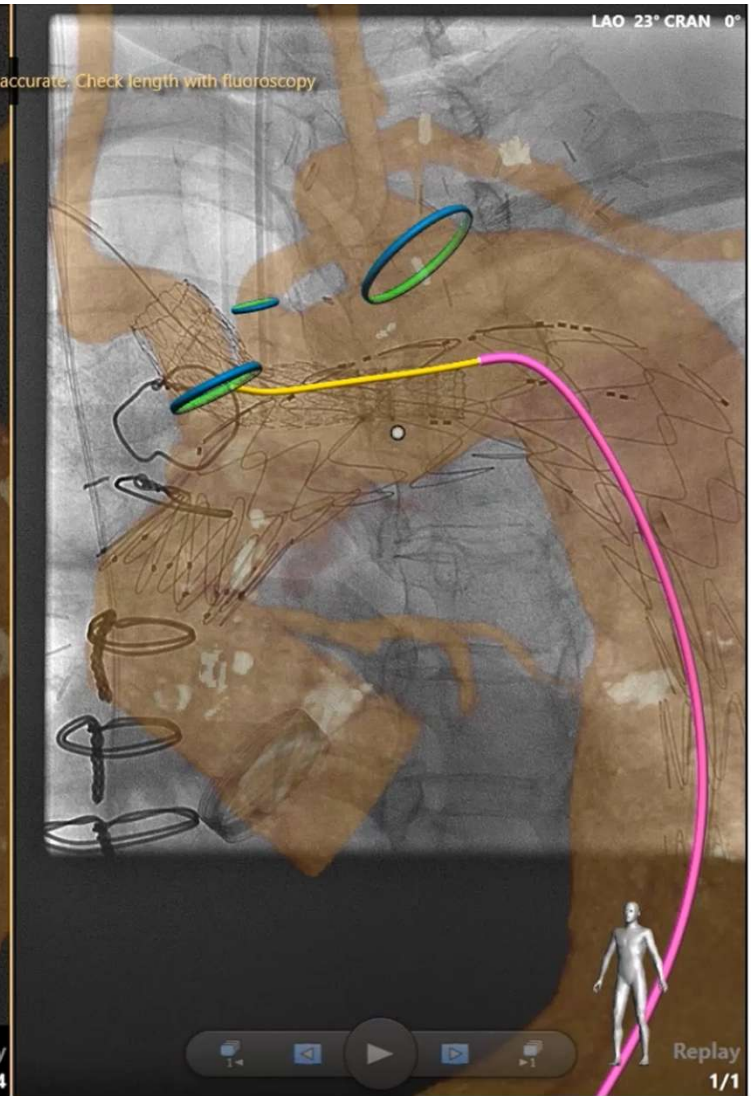
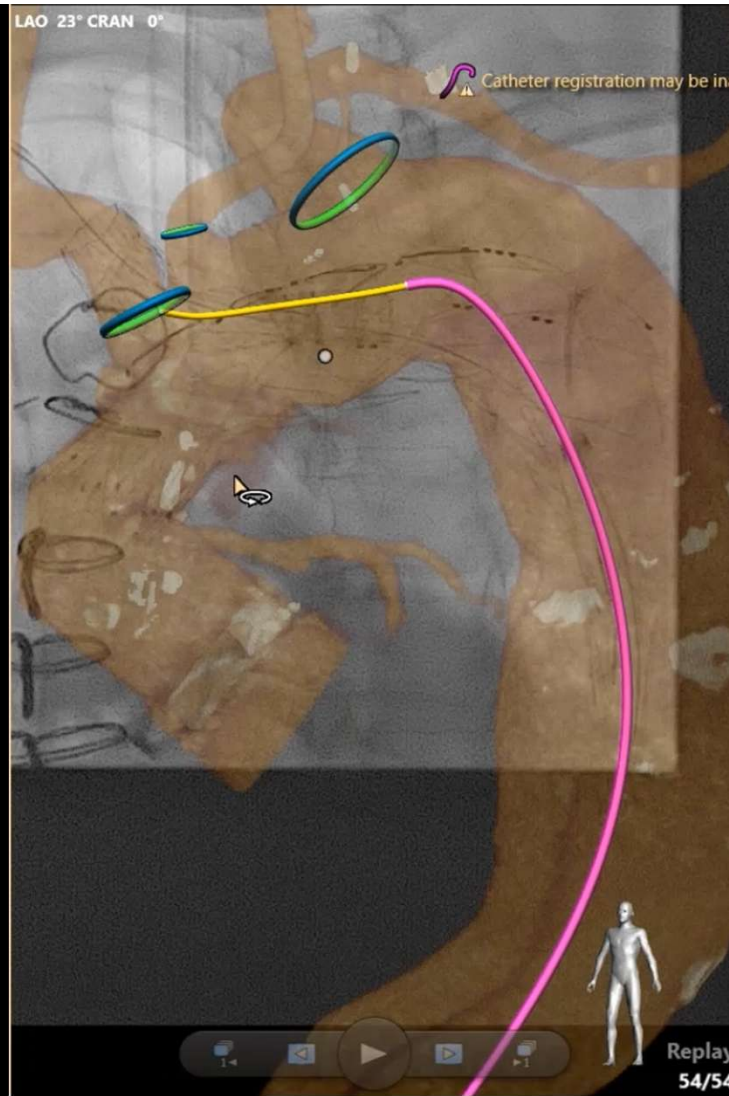
Innominate Artery Stenting



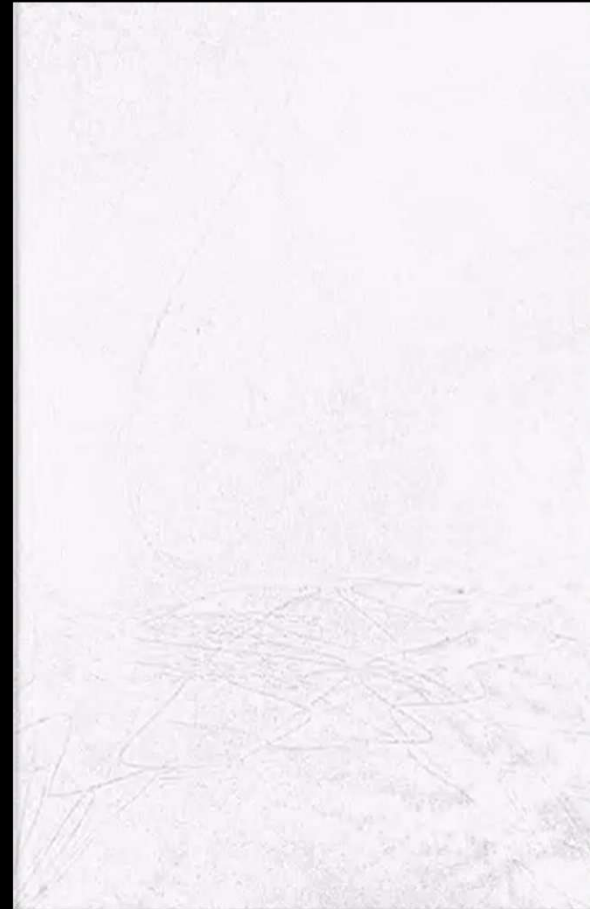
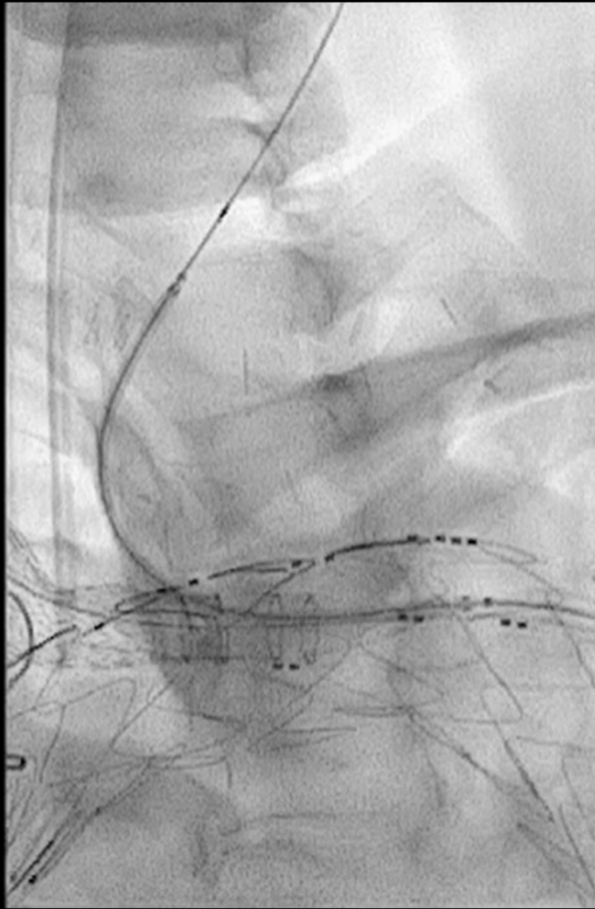
Innominate artery stenting



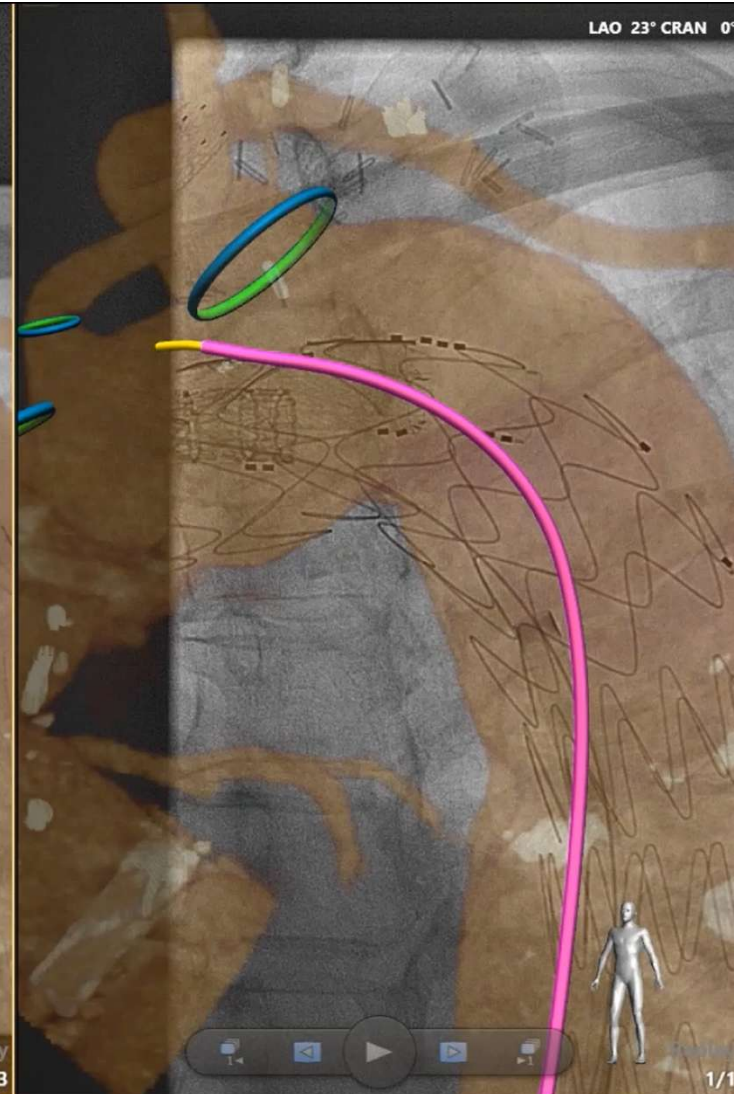
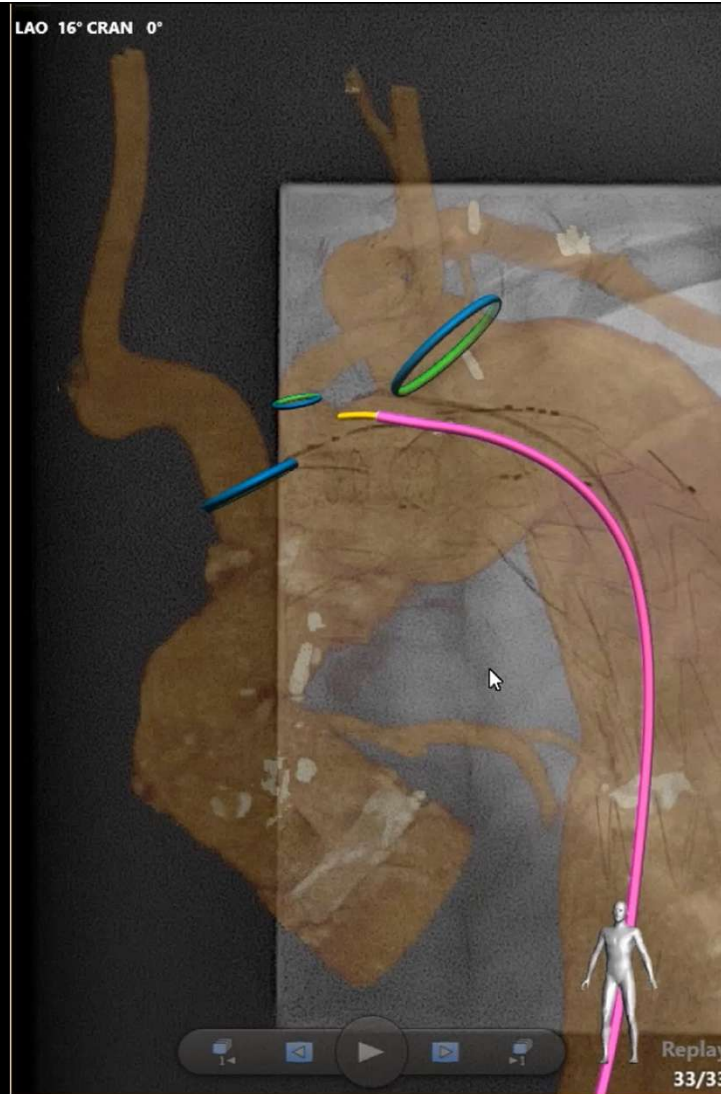
Left carotid artery cannulation



LCCA artery stenting

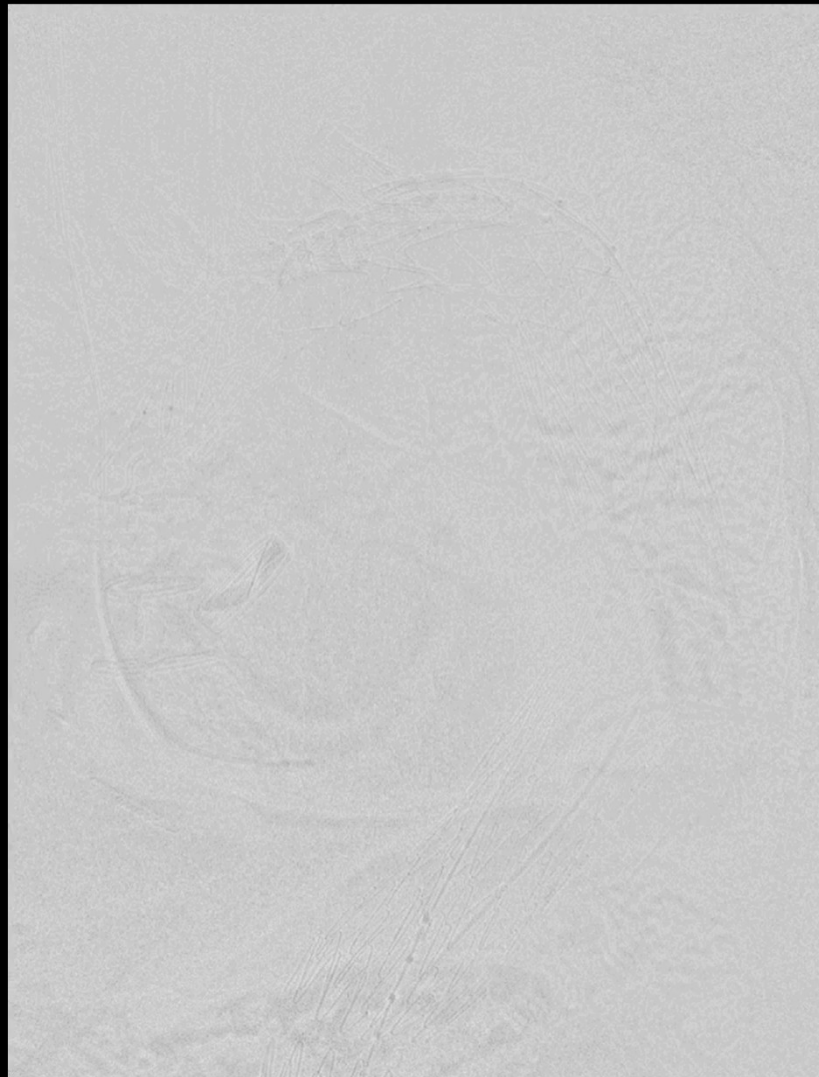


Left subclavian artery cannulation



LSCA artery stenting







United States Aortic Research Consortium

Aortic Arch

- Thoughts
 - Aortic Arch is the next frontier
 - We have built the infrastructure to rigorously evaluate this technology, now we must use it
 - High-quality adjudicated data that is harmonized across sites
 - Standardization of best practices
 - Potential to partner more closely with the FDA to act as a trial network in order to more rapidly bring new technologies to market (akin to oncology or HIV)

Conclusions

- Current evidence support the technical feasibility and safety of total endovascular aortic arch repair for aneurysms and chronic dissections using one, two and three-vessel inner branch stent-grafts
- Patient selection, minimizing arch device manipulation and streamlining the technique are key to reduce periprocedural stroke
- 3-vessel arch device designs allow total endovascular repair without the need for extra-anatomical revascularization and associated morbidity and mortality



