



A lifetime of specialist care

Failure modes for aortic arch endografts and solutions

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AMERICA

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WASHINGTON, D.C.

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CN: No relevant financial relationships to disclose.

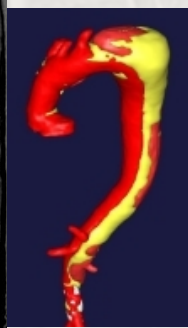
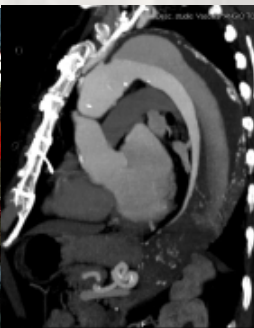
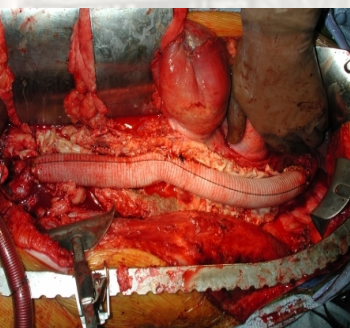
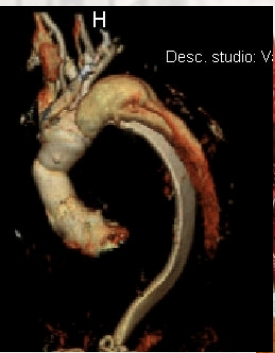
May Ellen Pittman

Floyd Banta

ONE DOLLAR

Management of the Aortic Arch during Type A Dissection

Do we have a Problem with the
Downstream Aorta??



Distal re-operation rate after Type A Dissection Repaired “Classically”

Senior Surgeon Series

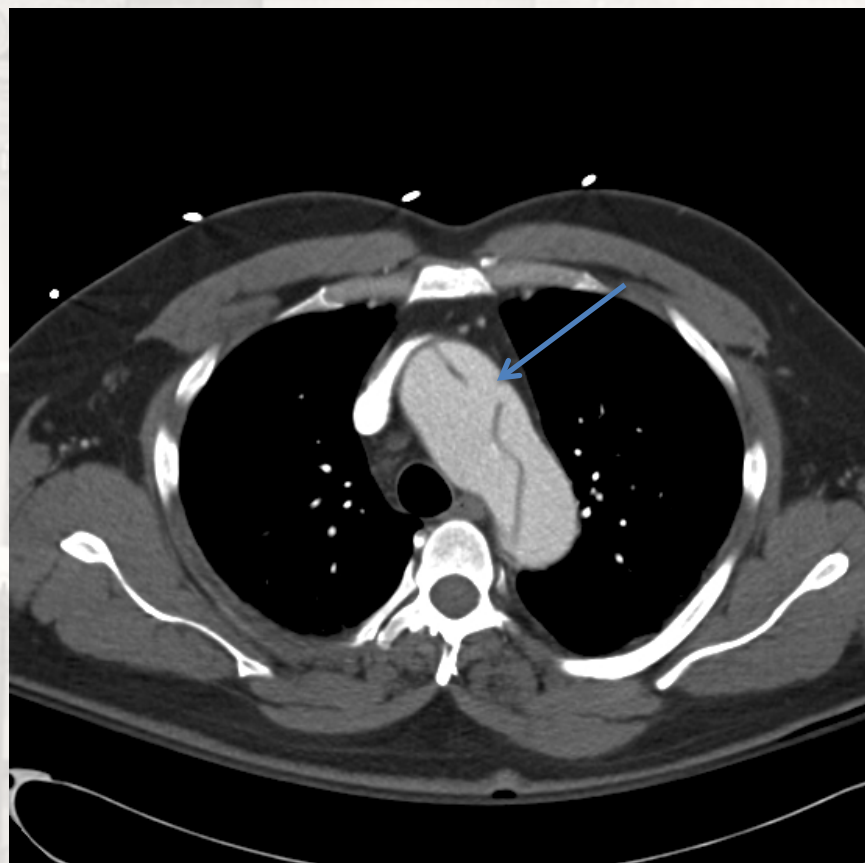
- Bavaria et al, 2007 (USA), 26% **Reoperation** at 12 years
– Included DeBakey II
- Ishihara et al, 2009 (Japan), 27% **Aortic Events** at 5 years
- DeBartolomeo et al, 2001 (Italy), 27% **Reoperation** at 7 years
- Griepp et al, (USA), 16% **reoperation** at 8 years
– Included DeBakey II
- Glauber and Murzi, 2010 (UK), 39% **reoperation** at 10 years (proximal and distal)

Example of late aneurysmal degeneration in a 68yo male 10 years post type A repair (7.3 cm)

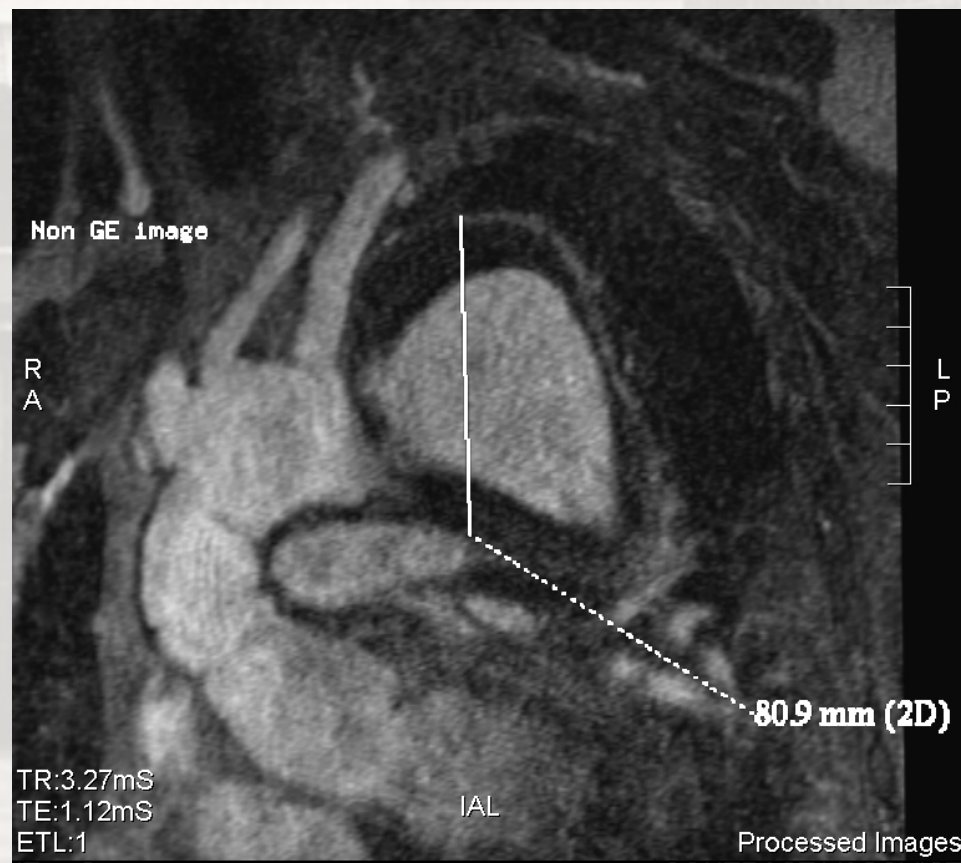


Example of late Complication: Aneurysmal Dilation of the Dissected Aorta (8.0 cm) in 2 years

2007



2009

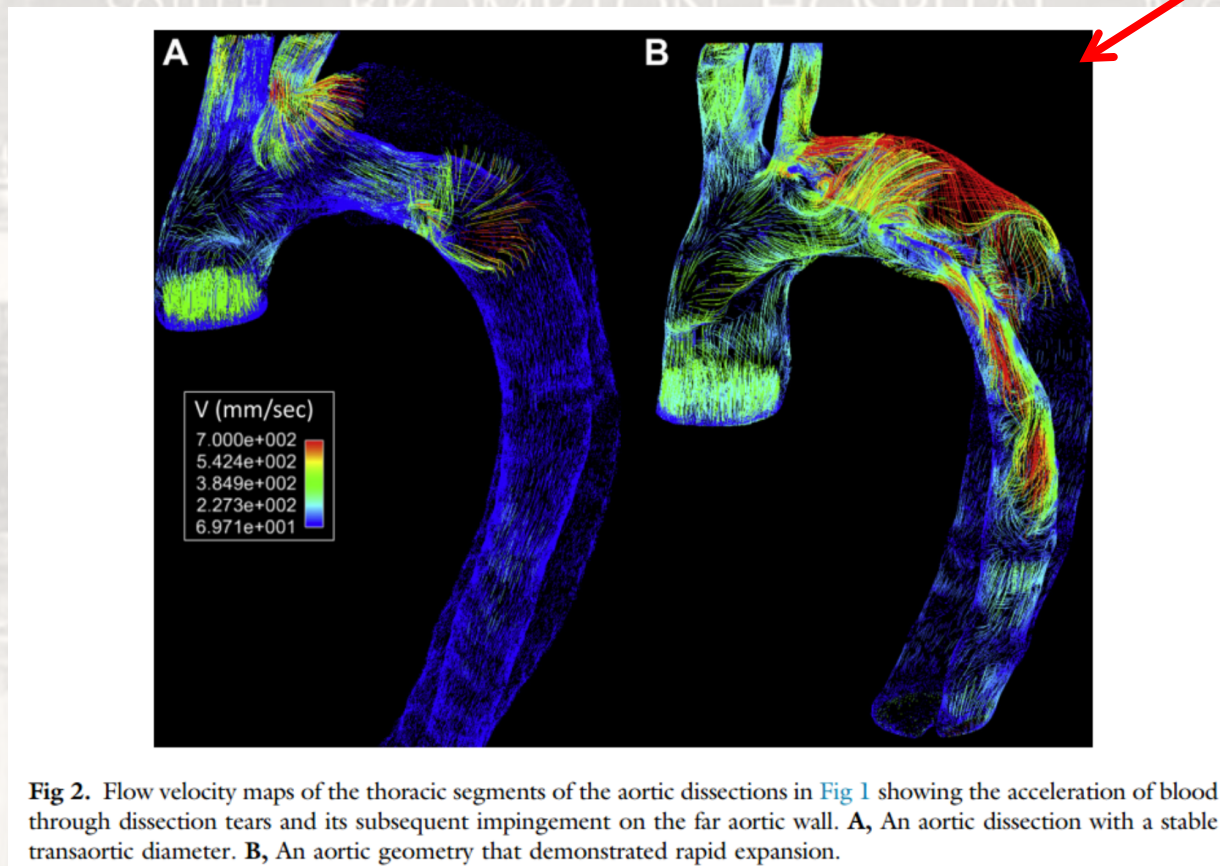


53y.o male

Rapidly Expanding False lumen

Larger Tear site = More Time Averaged Wall Shear Stress

E.Shang, B.Jackson, J.Bavaria, et al (JVS 2015)



Rapid
Expansion

Aortic Enlargement and Late Reoperation After Repair of Acute Type A Aortic Dissection

Andreas Zierer, MD, Rochus K. Voeller, MD, Karen E. Hill, BS,
Nicholas T. Kouchoukos, MD, Ralph J. Damiano, Jr, MD, and Marc R. Moon, MD

Division
Barnes

The fate of the distal aorta after repair of acute type A aortic dissection

James C. Hal
David Spielvo

Supplem
able on

Fate of the Residual Distal and Proximal Aorta After Acute Type A Dissection Repair Using

Evolution of Aortic Dissection After Surgical Repair

Rossella Fattori, MD, Letizia Bacchi-Reggiani, MSc, Paola Bertaccini, MD,
Gabriella Napoli, MD, Francesca Fusco, MD, Massimo Longo, MD,
Angelo Pierangeli, MD, and Giampaolo Gavelli, MD

Patients after aortic dissection repair still have long-term unfavorable prognosis and need careful monitoring. The purpose of this study was to analyze the evolution of aortic dissection after surgical repair in correlation to anatomic changes emerging from systematic magnetic resonance imaging (MRI) follow-up. Between January 1992 and June 1998, 70 patients underwent surgery for type A aortic dissection. Fifty-eight patients were discharged from the hospital (17% operative mortality) and were followed by serial MRI for 12 to 90 months after surgery. In all, 436 postoperative MRI examinations were analyzed. In 13 patients (22.5%) no residual intimal flap was identified, whereas 45 patients (77.5%) presented with distal dissection, with a partial thrombosis of the false lumen in 24. The yearly aortic growth rate

was maximum in the descending aortic segment (0.37 ± 0.43 cm) and was significantly higher in the absence of thrombus in the false lumen (0.56 ± 0.57 cm) ($p < 0.05$). There were 4 sudden deaths, with documented aortic rupture in 2. Sixteen patients underwent reoperation for expanding aortic diameter. In all but 1 patient, a residual dissection was present (in 13 without any thrombosis of the false lumen). Close MRI follow-up in patients after dissection surgical repair can identify the progression of aortic pathology, providing effective prevention of aortic rupture and timely reoperation. Thrombosis of the false lumen appears to be a protective factor against aortic dilation. ©2000 by Excerpta Medica, Inc.

(Am J Cardiol 2000;86:868-872)

From the Departments of Cardiothoracic | approximately tw

Changes were analyzed separately in the thoracic and abdominal segments.

Results. In early CT, thoracic false lumen was patent in 85 patients (69.7%), and abdominal false lumen was patent in 111 patients (91.0%). Among these, the false lumen remained patent after a mean interval of 33.6 months in 69 patients (81.1%) and 105 patients (94.6%), respectively. In 58 patients (47.5%), the descending aorta

descending aortic dilatation after repair of acute type I dissection, but also shrinkage of thoracic false lumen in some patients. These findings can be used as control data for determining the benefit of more extensive or new surgical approaches.

(Ann Thorac Surg 2009;87:103-8)

© 2009 by The Society of Thoracic Surgeons

ic False Dissection

ID, Euisuk Chung, MD,
MD, PhD

Bandung Hospital, Bandung,
medicine,

ore. Dilatation occurred more fre-
aorta and in patients with patent
larger aortic diameter, Marfan
age, and male sex. Meanwhile,
alse lumen occurred in 36 patients
ge occurred in 23 of 24 patients
losed and narrow false lumens in

ostoperative characteristics of false
for predicting both dilation and
how not only a high incidence of

Do we have a problem with
the distal aorta after repair
of acute type A dissection?

....

YES

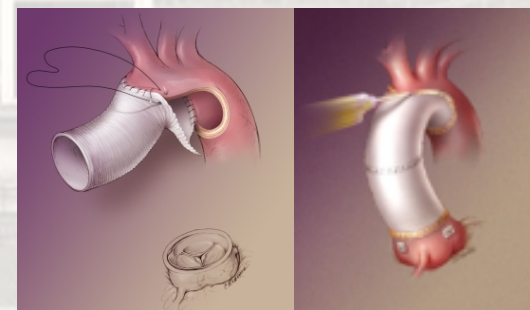
Especially if we use a **COMPOSITE** index of Index
Operation Failure: 1. Aortic Death; 2. Reoperation; 3.
Aneurysm > 6.0 cm.



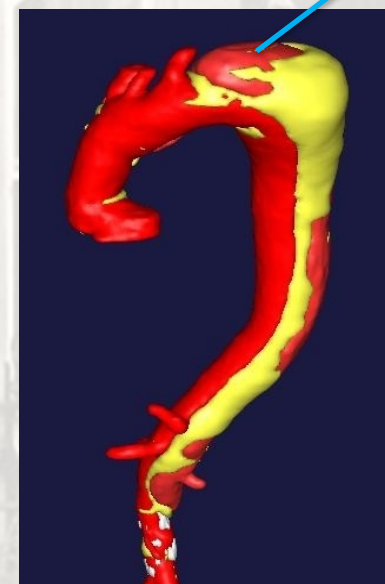
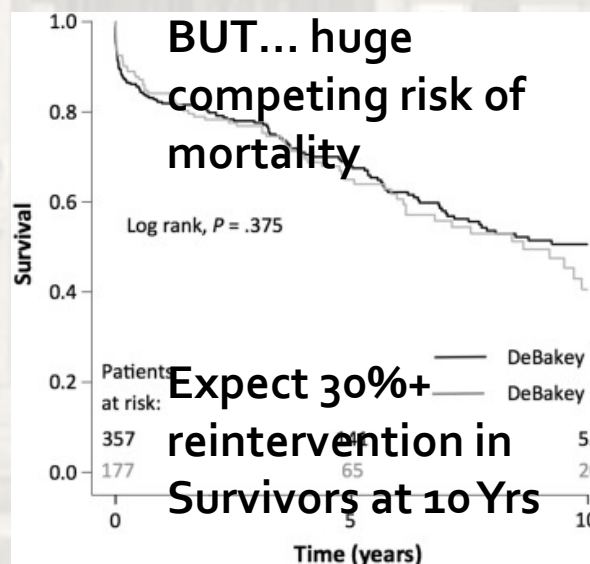
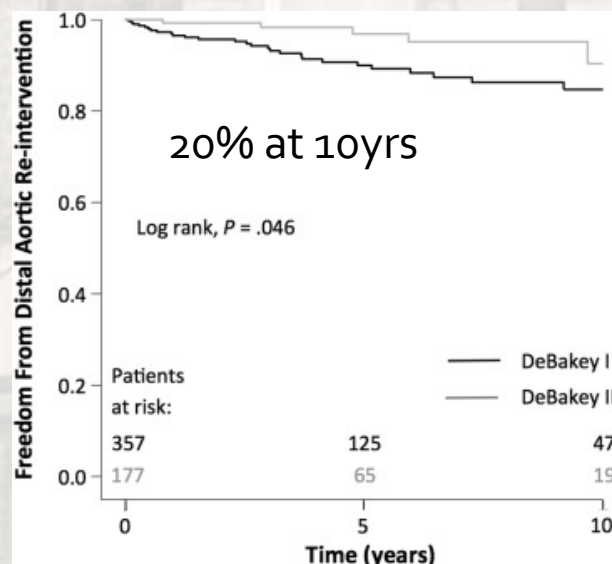
So how should we handle the ARCH?

1. *Standard Hemi-Arch*

- Straightforward, anyone can do it
- No need for complex ACP approaches
- May have residual Malperfusion
- Significant risk of late attrition from distal aortic disease



6.8 cm
@ 3 yrs



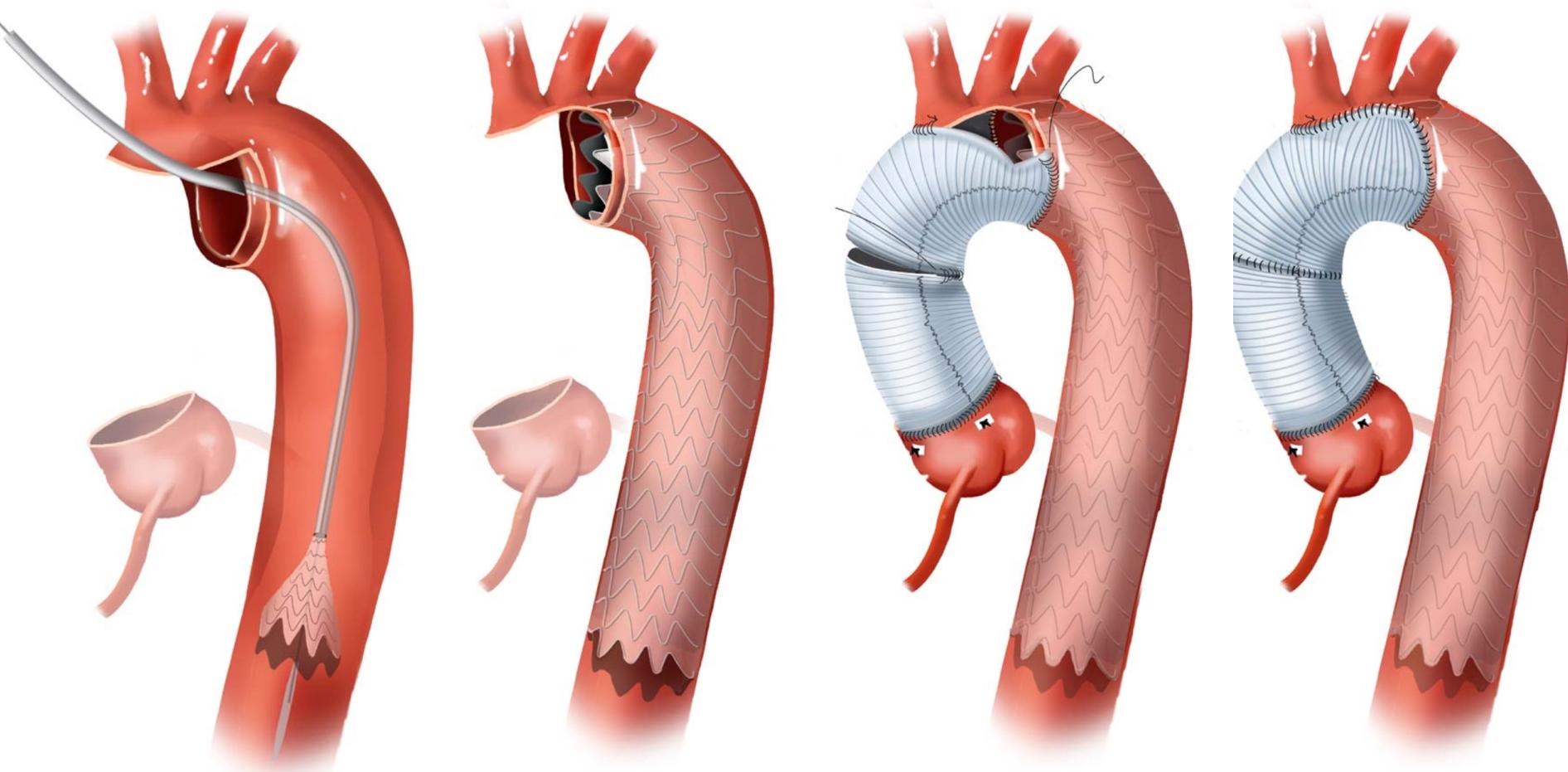
Rylski, Bavaria, Desai:
Ann Thor Surg 2014

So how should we handle the ARCH?

2. *Acute Type A antegrade TEVAR “Stented Elephant Trunk”*

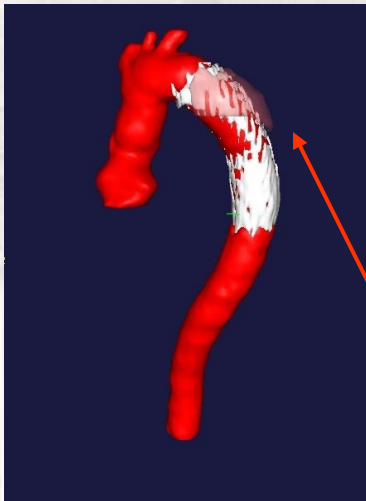
Pochettino, Szeto, Bavaria; ATS 2009

Vallabhajosyula, Pochettino, Szeto, Desai, Bavaria; JTCVS 2013



Problems: Acute Type A “Stented Elephant Trunk”

Potential Issues



Type I endoleaks
that are impossible
to resolve



Long stent (>15 cm –
paralysis risk

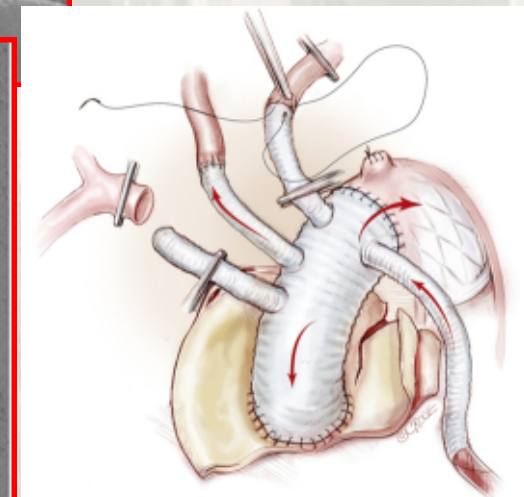
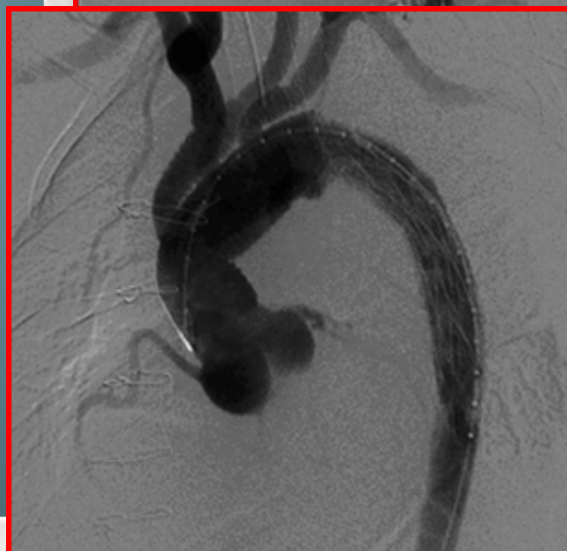
Short Stent – less
remodelling

Persistent false
lumen in abdominal
Aorta

- 25% of Patients will thrombose FL without stent – would be stented unnecessarily!
- 30-40% for total Arch?

- >25% of pts will require reintervention TEVAR to obliterate total Thoracic FL

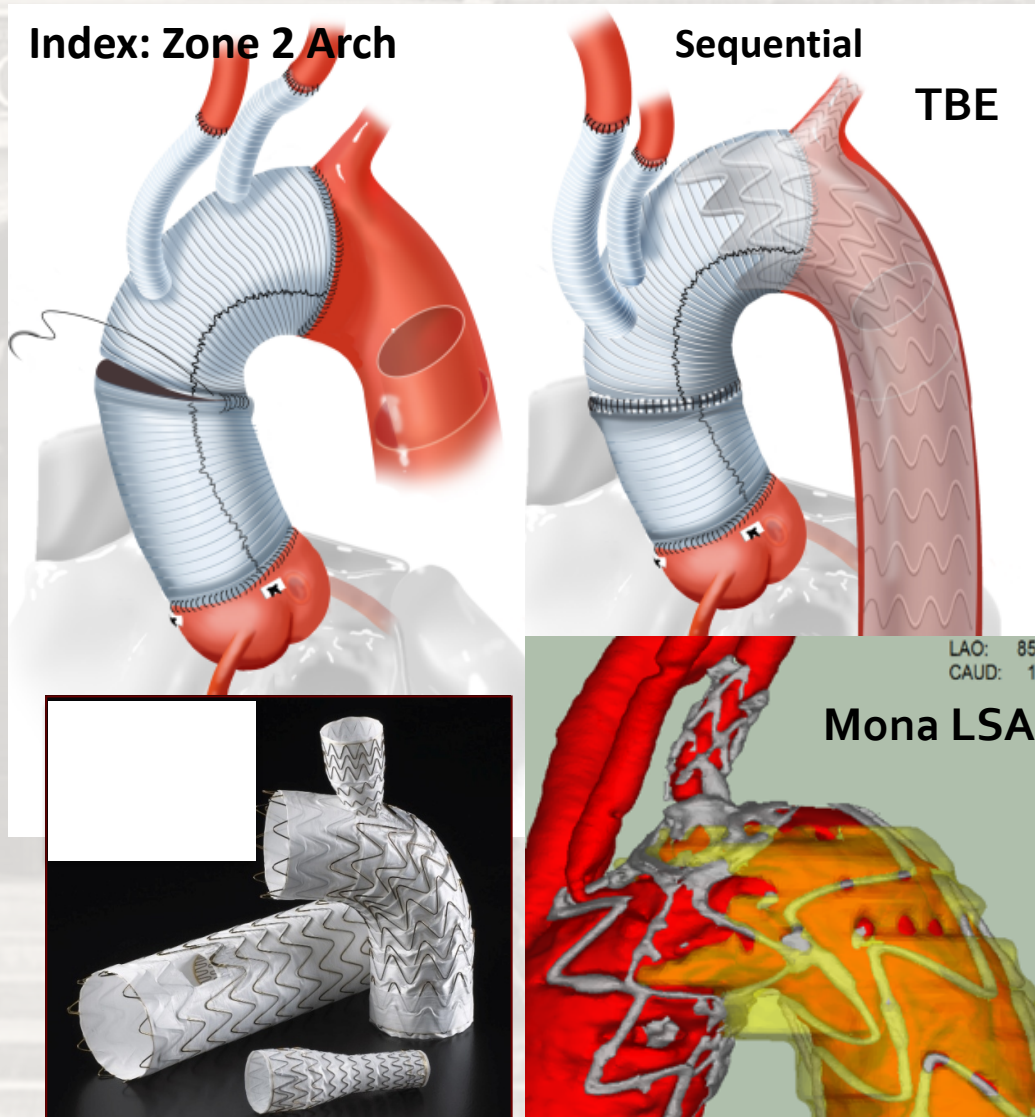
Conventional total Arch with Frozen Elephant Trunk: Standard Zone 3 Arch FET



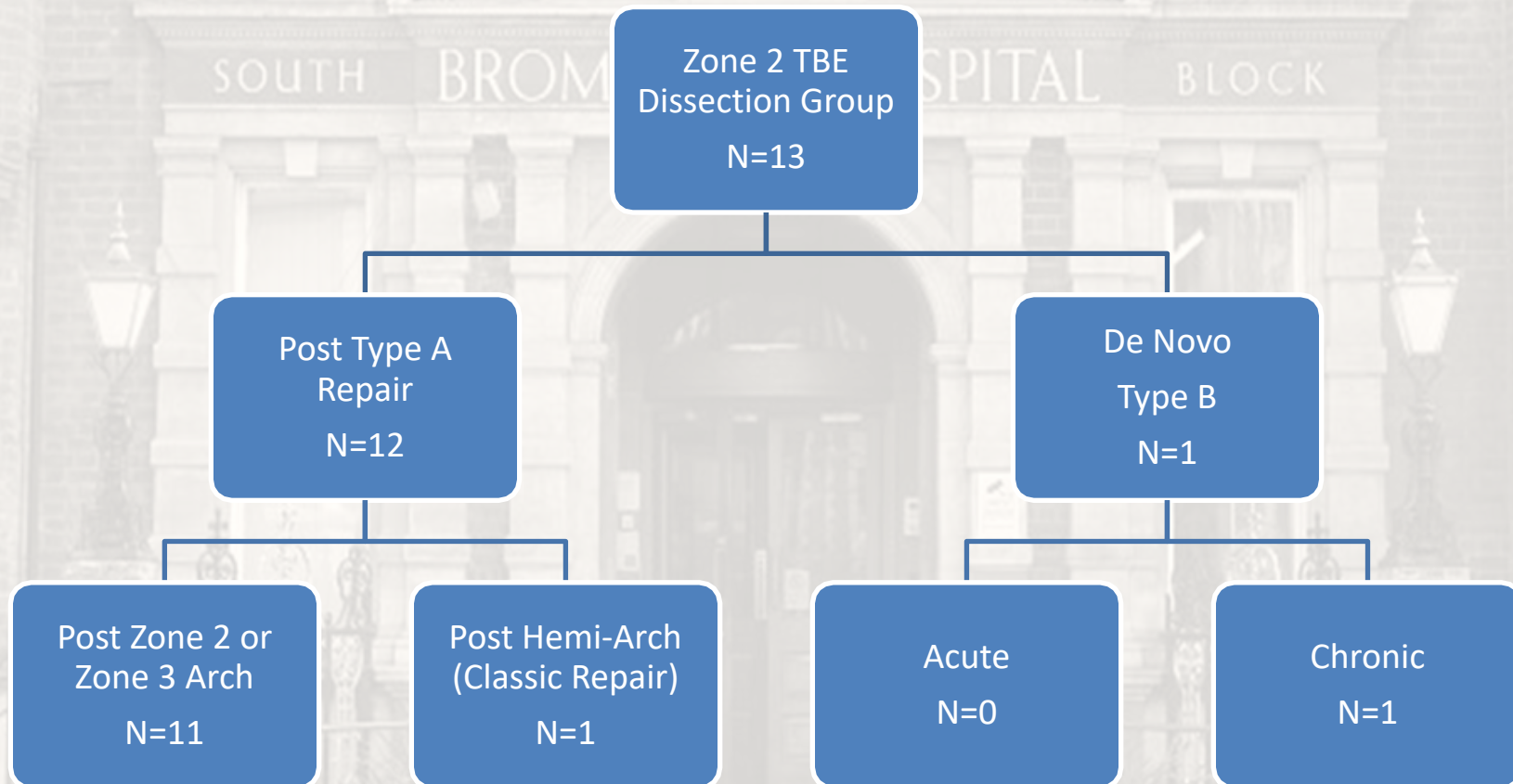
So how should we handle the ARCH?

3. Zone 2 Arch with Sequential Branched TEVAR completion

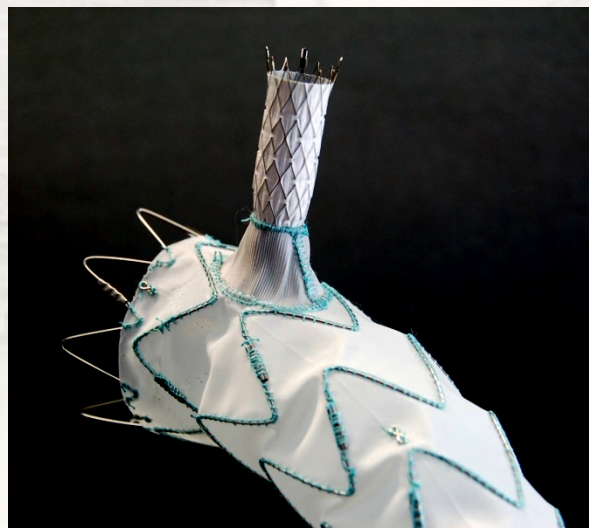
- Advantages
 - Simpler Distal Anastomosis at Index operation
 - Can address most complex arch tears and eliminate flap in proximal head vessels
 - Shorter ACP times than Total Z3 FET
 - Definitive TEVAR options in future
 - Avoids TEVAR when not needed; 20- 35% of time
 - Less risk of Recurrent laryngeal nerve injury (important!)



Zone 2 TBE (Penn initial E+C FDA Early Feasibility Trial)



Ready for broader applications in type AAD? The near future



Low profile branch
technology

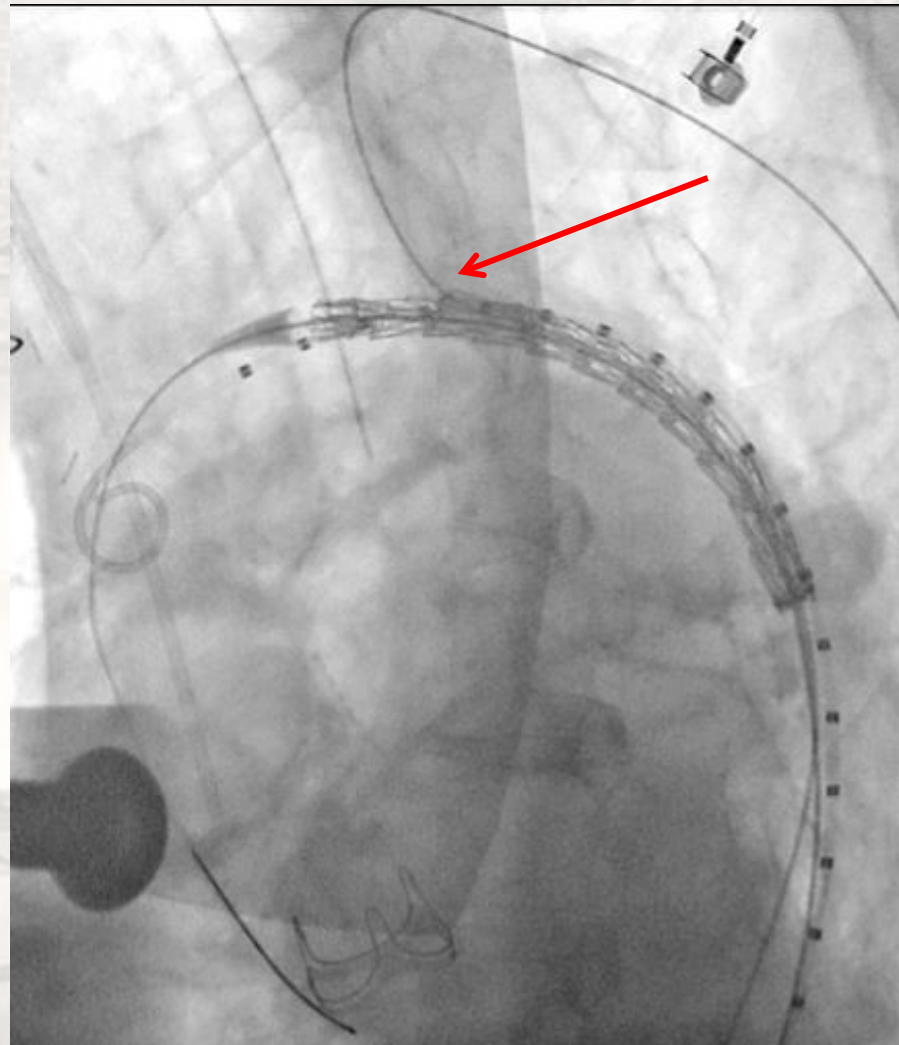


Expanding Indications

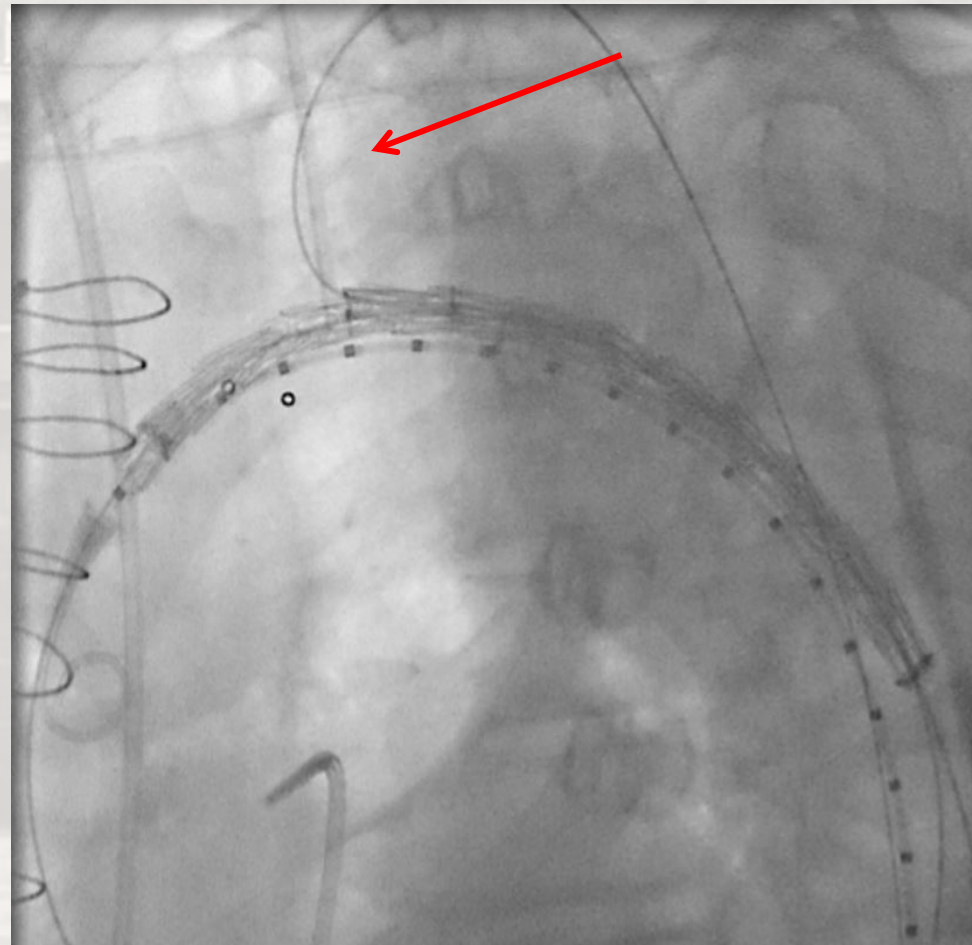
- Total-arch solutions
- Ascending aorta
- Dissection-specific devices
- Type A dissections
- More long-term data

***Technology on the horizon,
but not successful and not
approved***

Zone 2 TBE after Type A with “Zone 2 Arch” Repair (10 days post type A repair)



FDA E/C Arm Emergency/Compassion

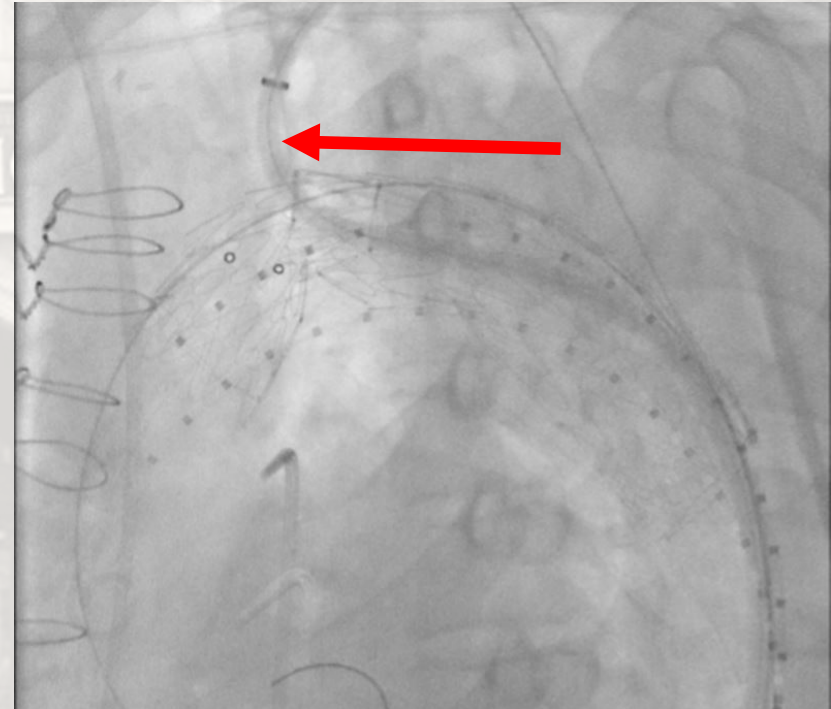


Note Wire position to AVOID Wire wrap

Zone 2 TBE (12 mm Portal) in “Residual” Type A Dissection (Downstream Aorta) 10 days

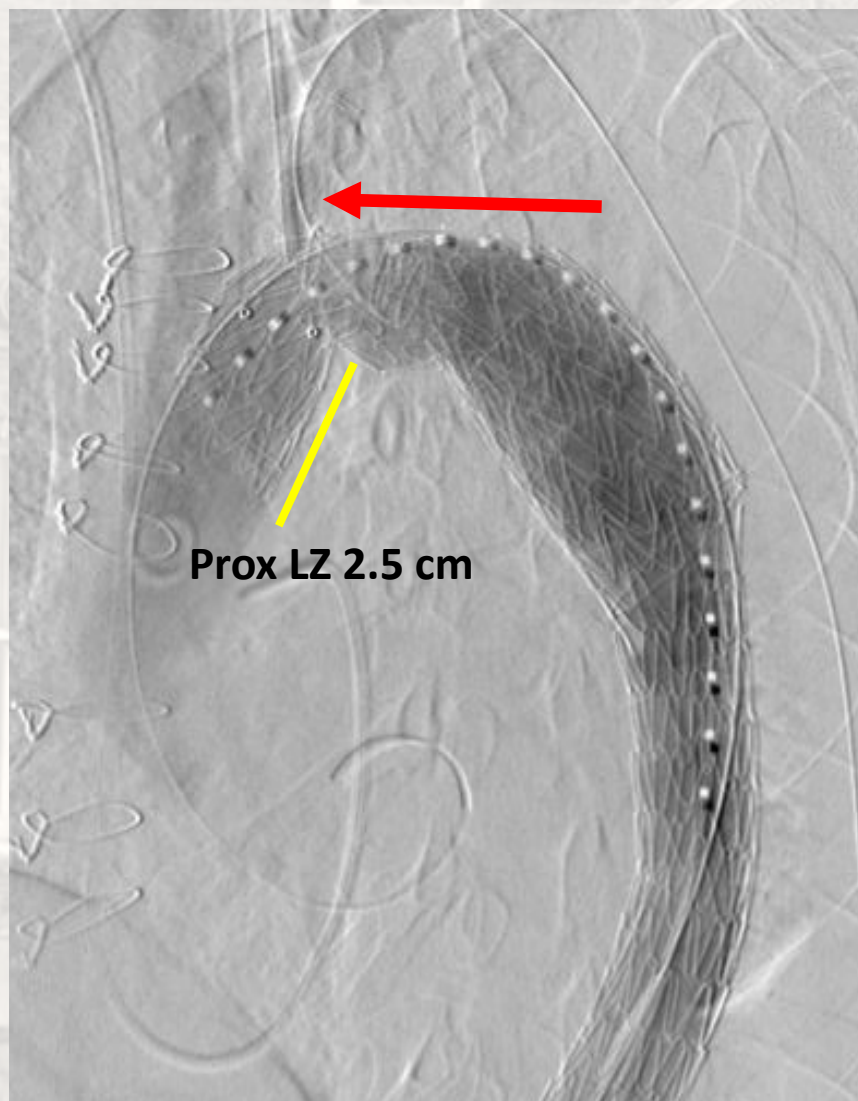


3 cm Dacron LZ previously constructed with Zone 2 Arch (10 days earlier)



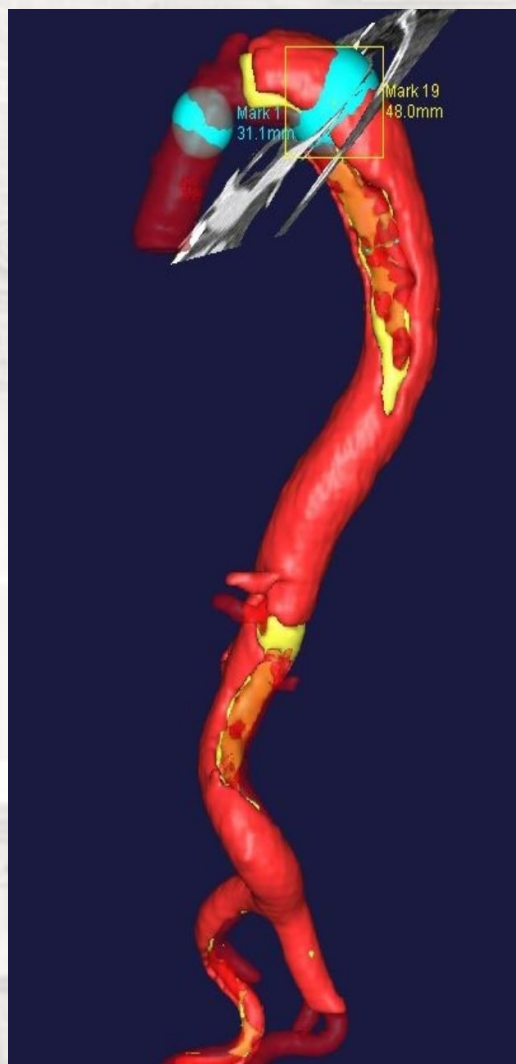
Side branch sheath positioned in LSA
Note nice horizontal access

Zone 2 TBE Dissection (12 mm LSA Portal)

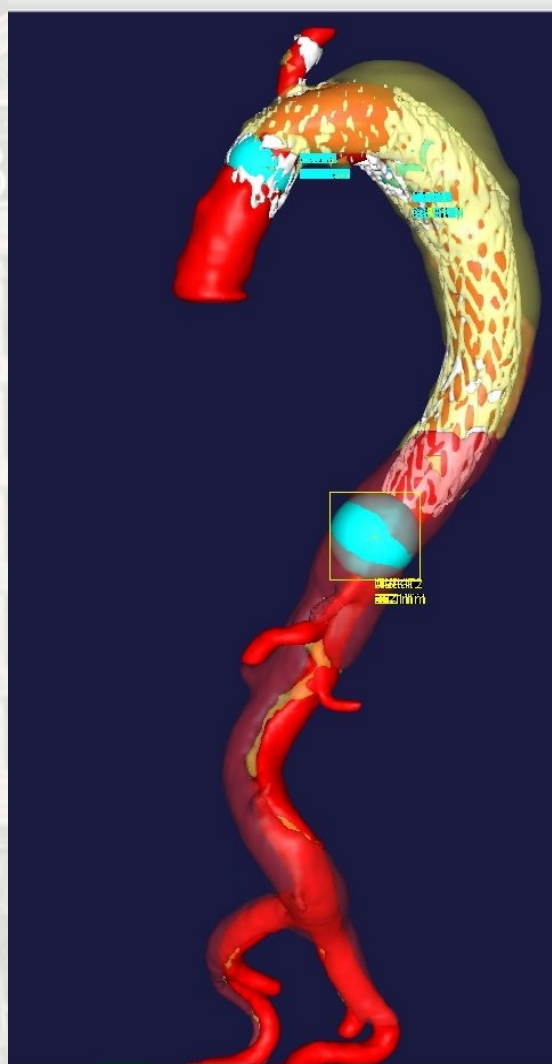


Side Branch deployed in Left Subclavian Artery

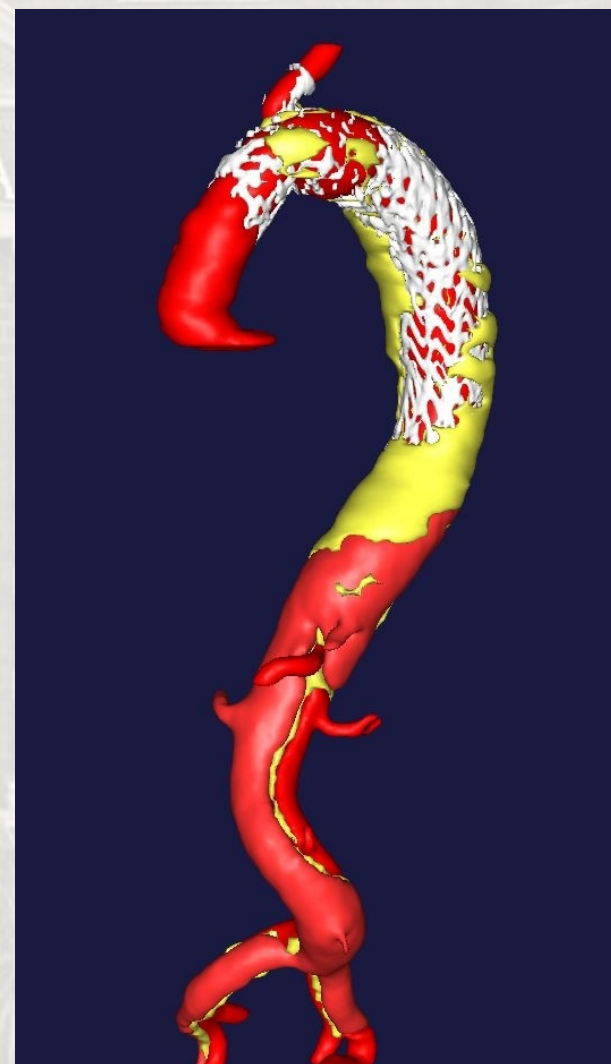
Zone 2 Arch Reconstruction + TBE TEVAR



Pre-op



30 Days Post op



12 Months Post
op

Zone 2 TBE Arch graft (FDA Early Feasibility study – trial/on label Penn Data (Total = 23)

- Aneurysm = 9 (age = 68)
 - Prior Cardiac Surgery = 33%
 - 89% atherosclerotic disease
 - 8 mm LSA portal = 78%
 - 12-15 mm LSA Branch
 - 67% needed distal TEVAR extension
- Dissection = 13 (age = 60)
 - Prior Cardiac Surgery = 39%
 - 92% after Type A Dissection
 - 12 mm Portal = 85%
 - 15 mm LSA Branch = 85%
 - 85% needed distal TEVAR extension

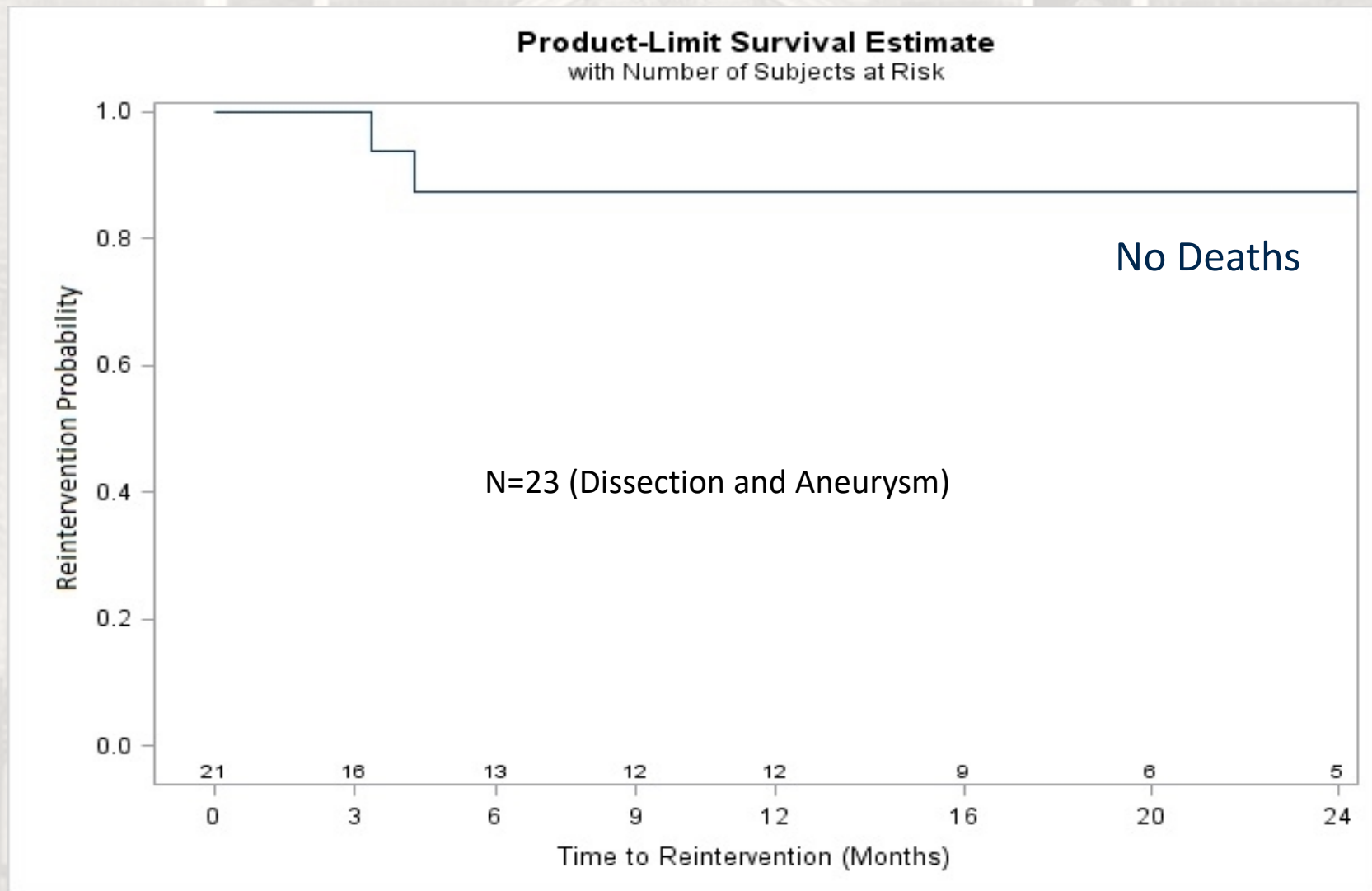
Zone 2 Outcomes to Date

	All Patients	Aneurysm	Dissection
N	22	9	13
Post-Op CVA	9.1% (2)	11.1% (1)	7.7% (1)
Reintervention within 30 days	0.0%	0.0%	0.0%
Reintervention within 1 Year	9.1% (2)	11.1% (1)	7.7% (1)
30 Day Mortality	0.0%	0.0%	0.0%
Mortality to Date	0.0%	0.0%	0.0%

Months from TEVAR	Number of Patients Completing Post Op Visit to date
In-Hospital/Discharge	100.0%
1 Month	86.0%
6 Months	63.6%
12 Months	63.6%
24 Months	63.6%

Excellent Outcomes to date!!

Zone 2 TBE Freedom from Intervention to Date



*One Zone 2 to Zone 0 (compassionate use) conversion due to proximal Type 1 endoleak which allowed stent migration; Patient doing well at 2 year follow-up

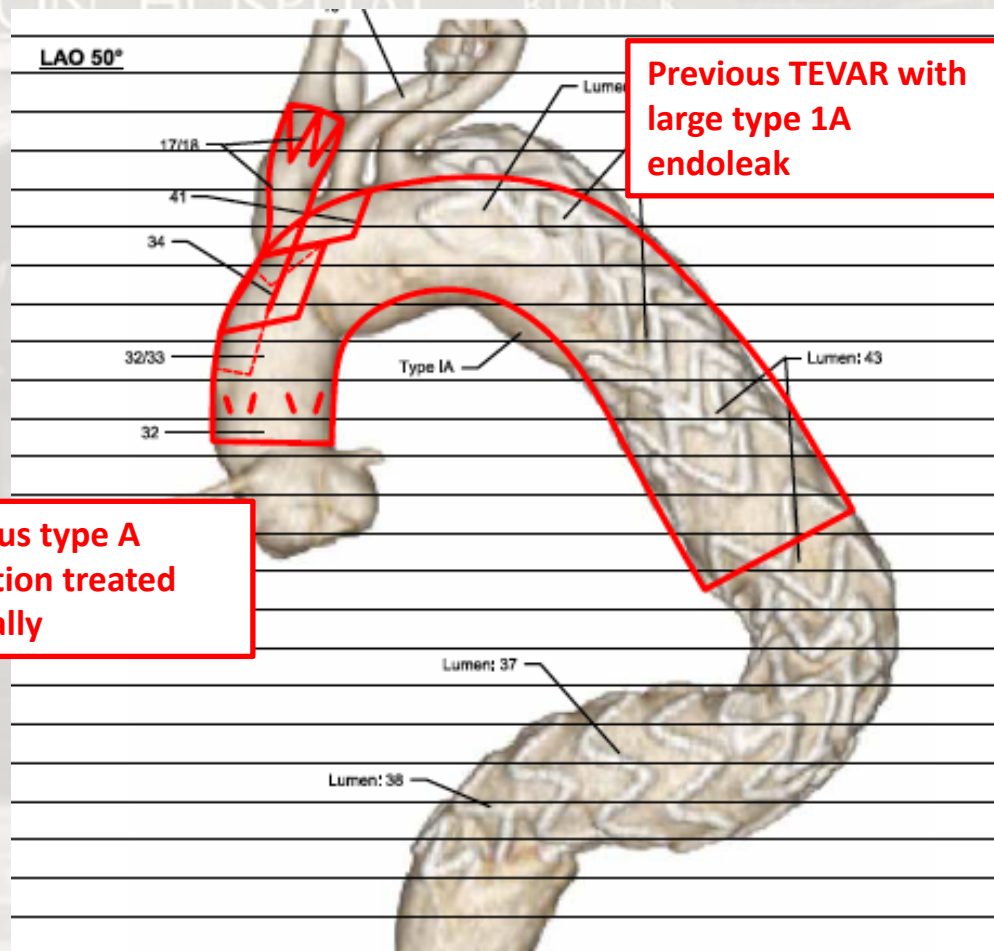
**One proximal extension of Zone 2 TBE due to endoleak; Patient doing well at 1 year follow-up

- Patients turned down for surgery for frailty or old age at MDT
- Special cases
 - Previous TEVAR

Future case

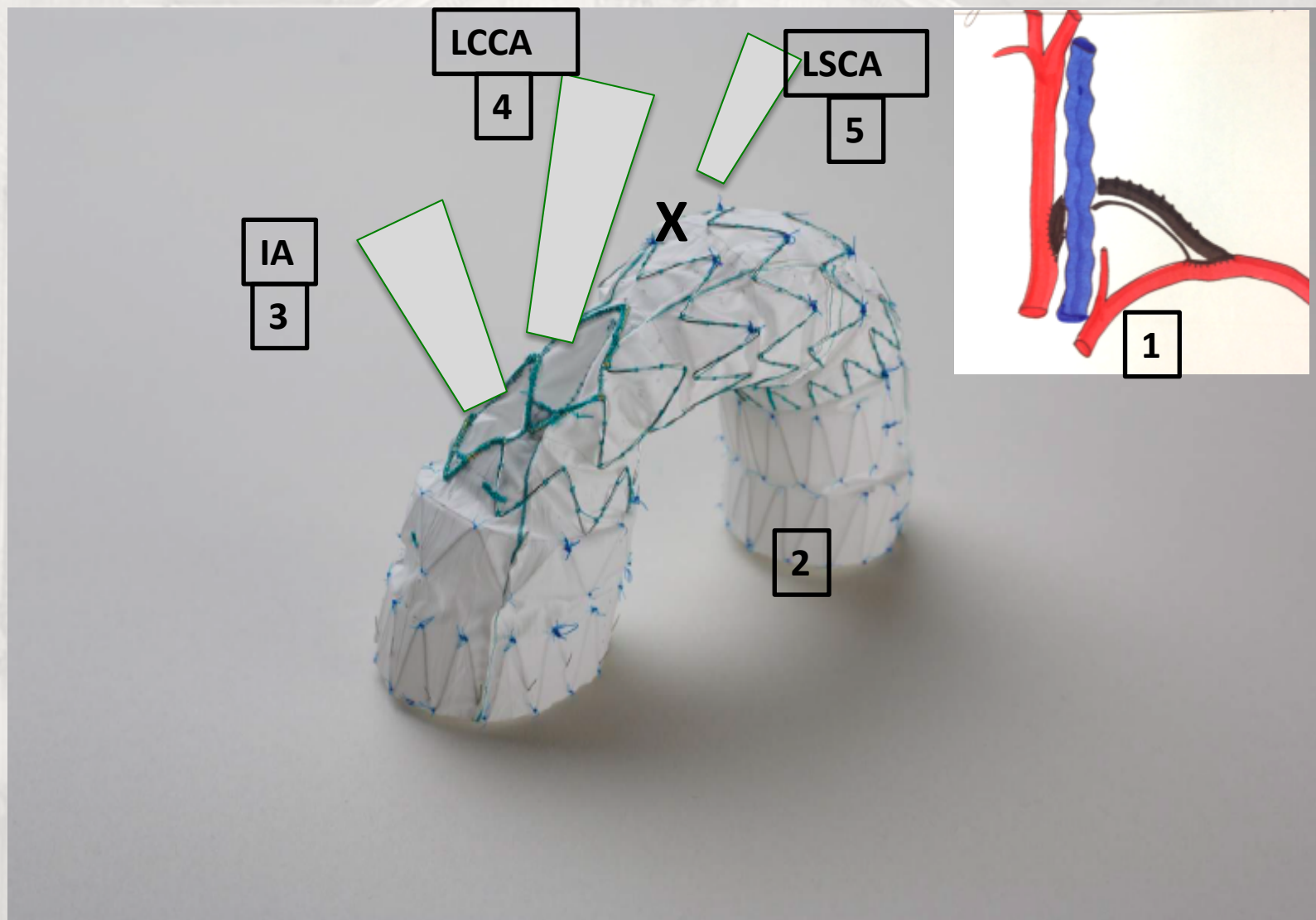
Previous TEVAR with large type 1A endoleak

Previous type A dissection treated surgically



Total endovascular arch repair?

Inner branches concept for total endovascular repair







The Journal of Thoracic and Cardiovascular Surgery

Volume 148, Issue 4, October 2014, Pages 1709–1716



Evolving technology/basic science

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^e,

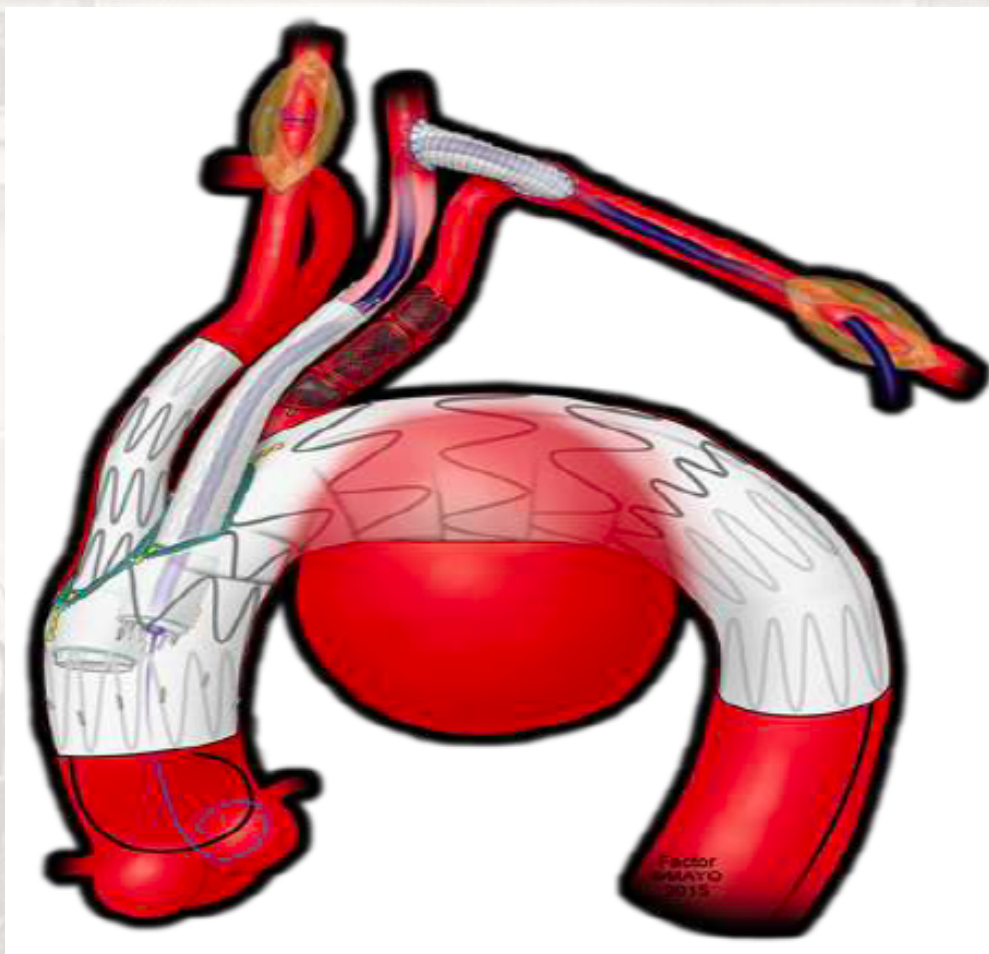
38 Patients in 2014, Technical success 32 pts.

30-day mortality rate was 13%, cerebrovascular events in 6 pts

Mortality was higher in the early experience group (30%) versus the remainder (7.1%)

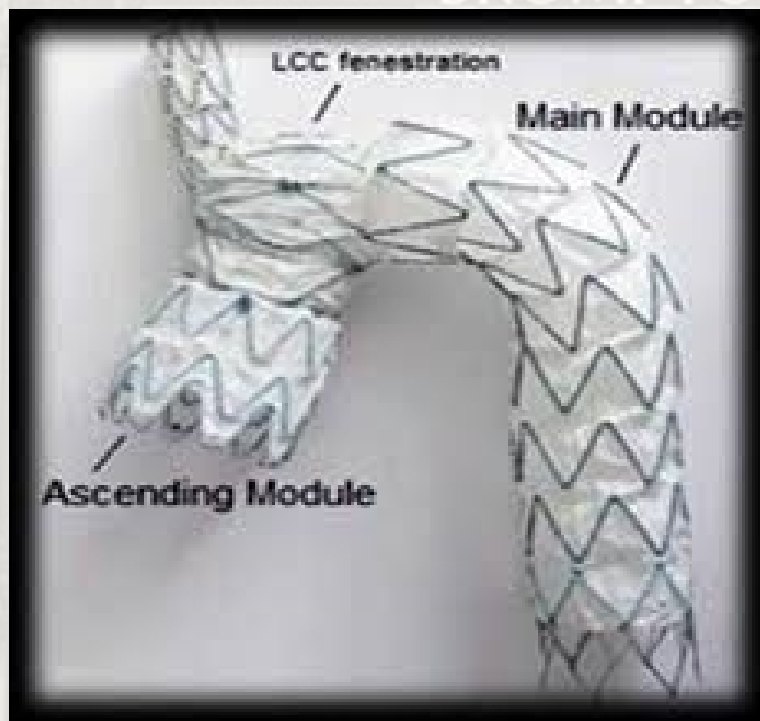
Currently over than 200 procedures worldwide.

The end product



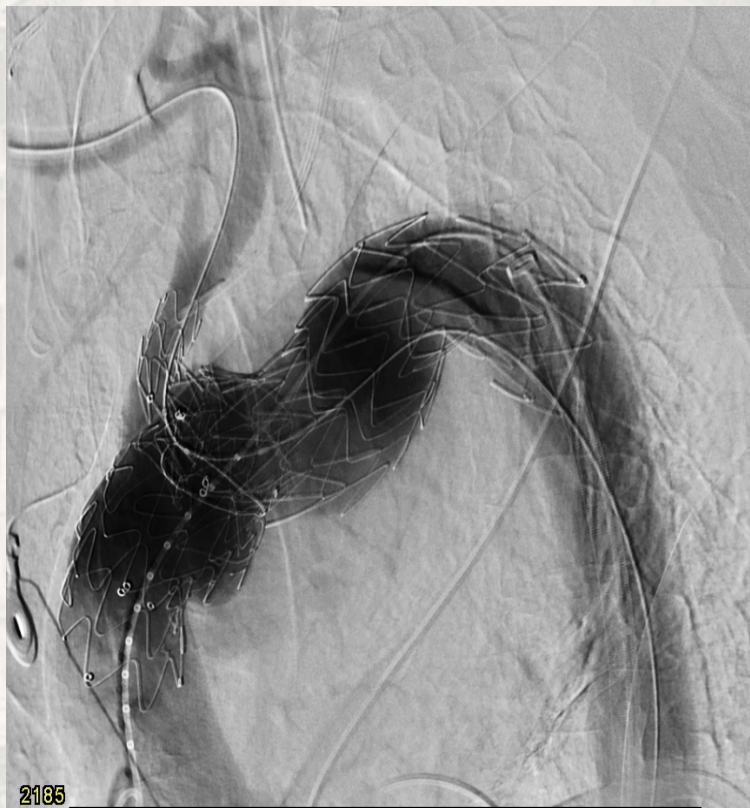
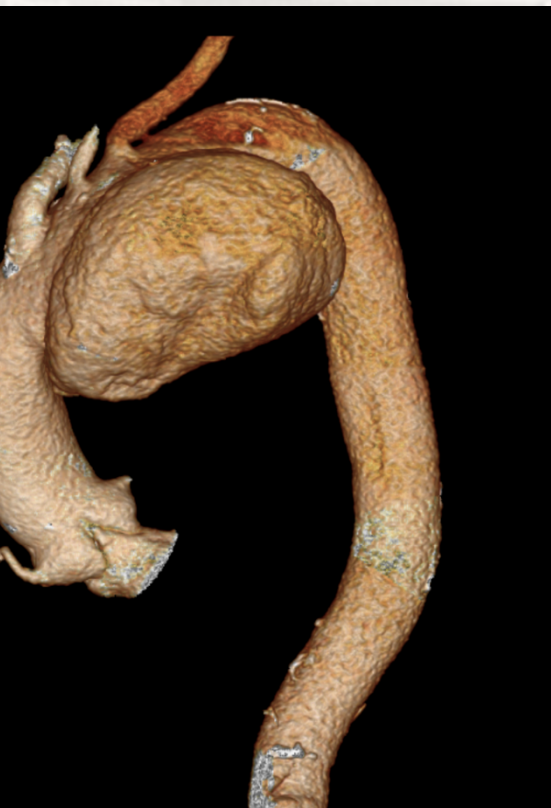
Total endovascular arch repair?

The NEXUS device



NEXUS Endovascular repair concept

Pre and Post-TEVAR (NEXUS)
10 Aug 2020 CT



Follow up CTA 16 June 2021:
Patient complained back and neck pain
Distal migration and evolution of endoleak!



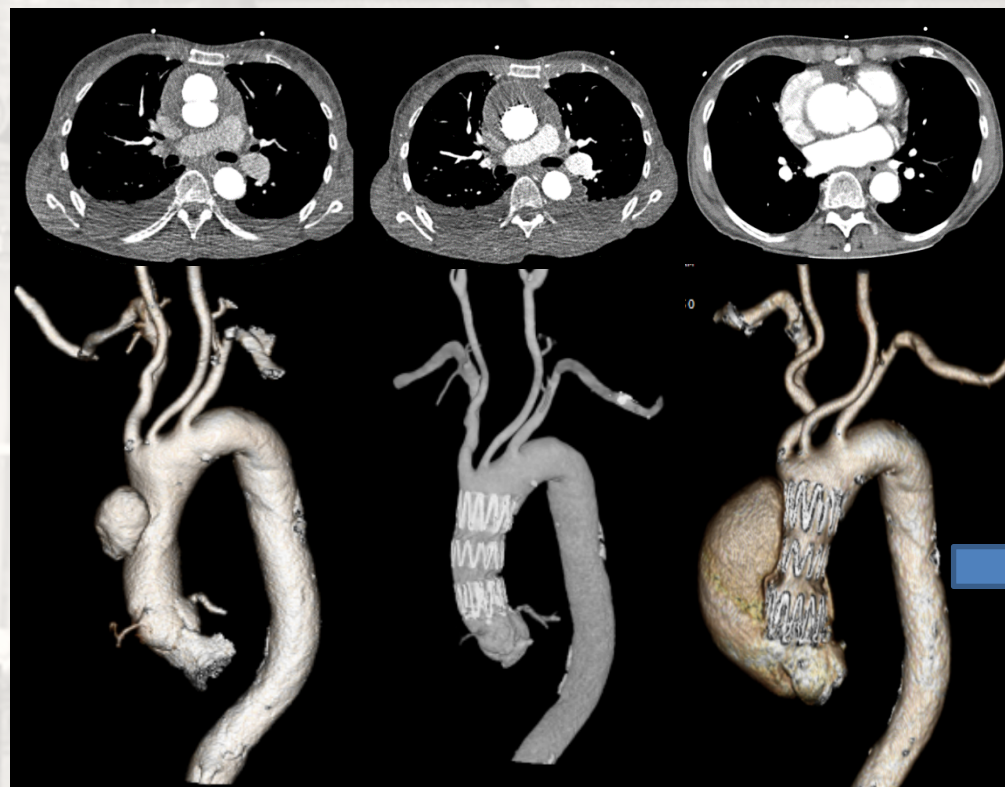
Conclusions on Management of the Arch

- There are Multiple Ways to manage the ARCH in an Acute Type A Dissection
- Management of type A dissection is likely to change with increased sophistication, and emerging endo technology (TBE):
 - In Patients with < 10-15 years life expectancy (>65) Use Classic Hemi-Arch
 - In Patients with an arch tear or distal Malperfusion FET
 - In patients < 65 and stable Zone 2 Arch with possible (60%) SEQUENTIAL Arch branch TEVAR

Total endovascular solutions in the aortic arch (in highly selected cases) are still associated with complex procedures, intraprocedural mortality and stroke >10%, endoleak formation, device migration or erosion and unpredictable mid-term outcomes!

A

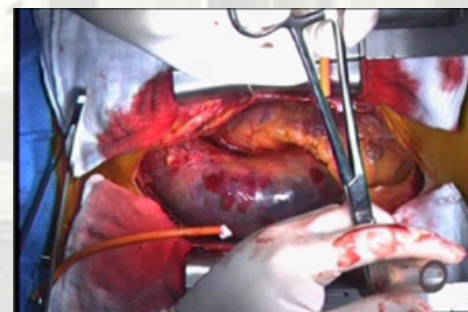
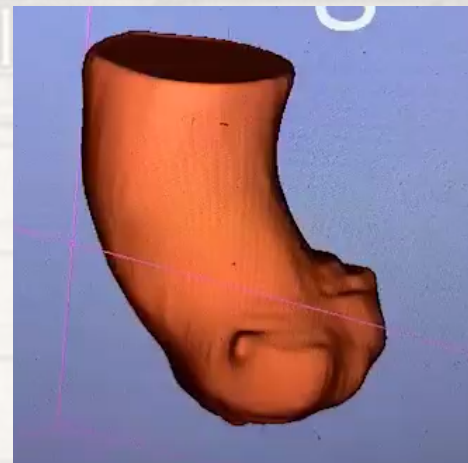
Evolution after successful proximal stent-grafting



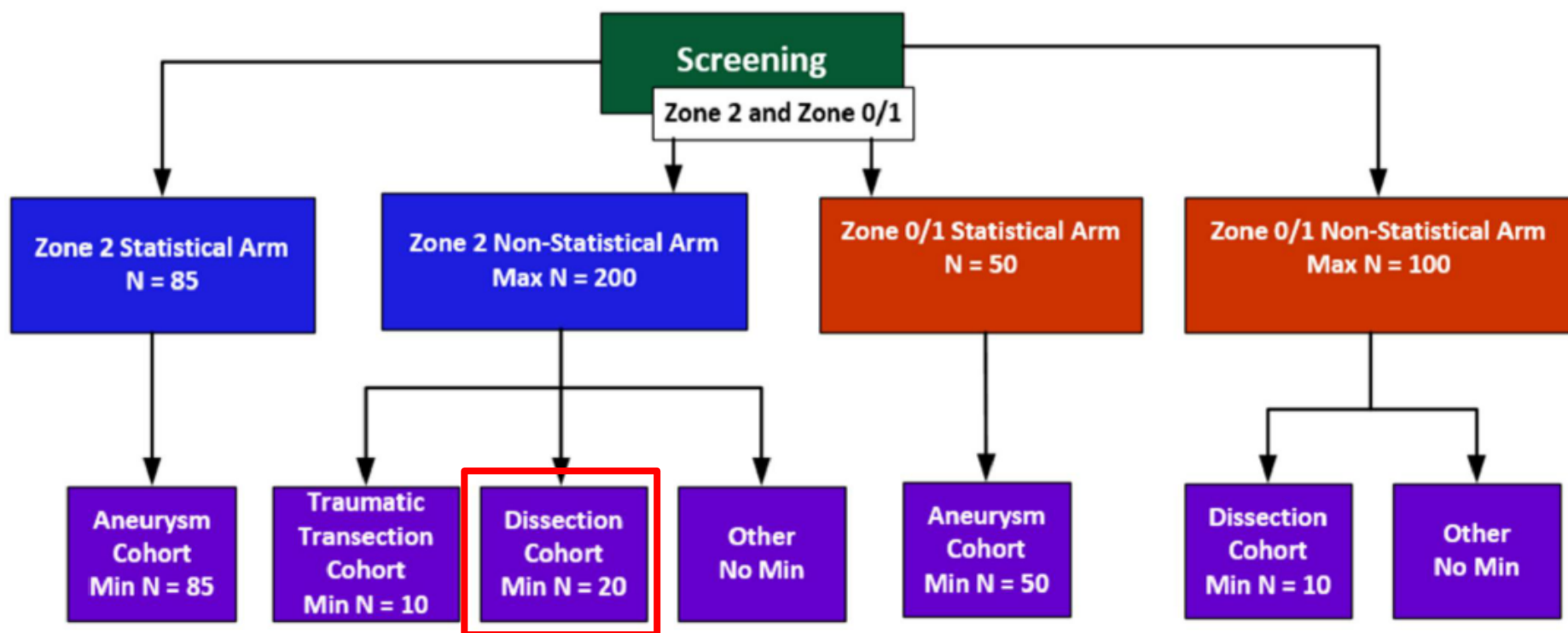
Pre-TEVAR

At discharge

16 months F/U

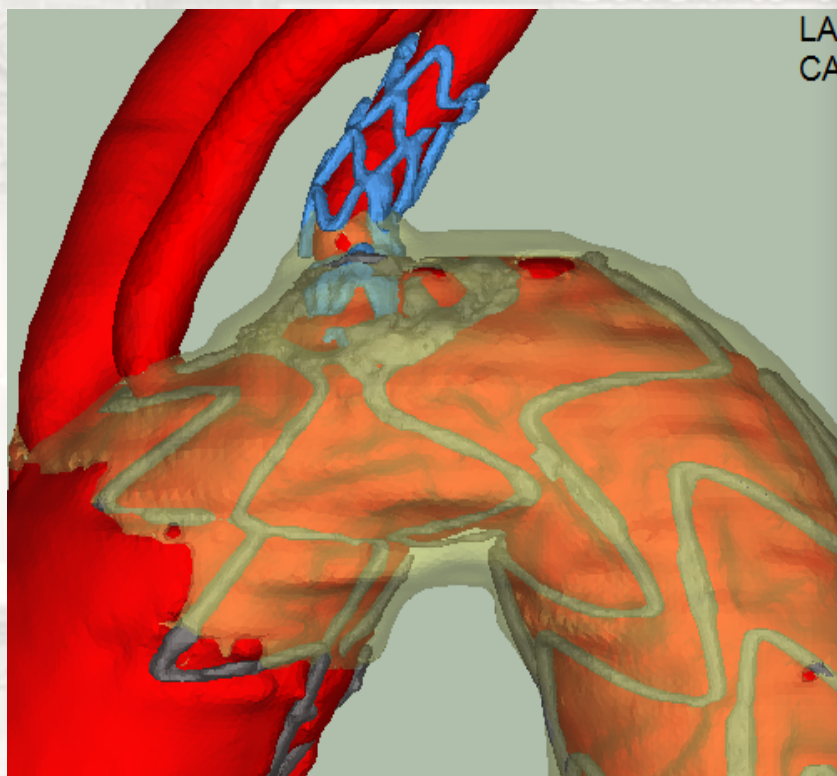


U.S. FDA TBE Pivotal Clinical Trial Design



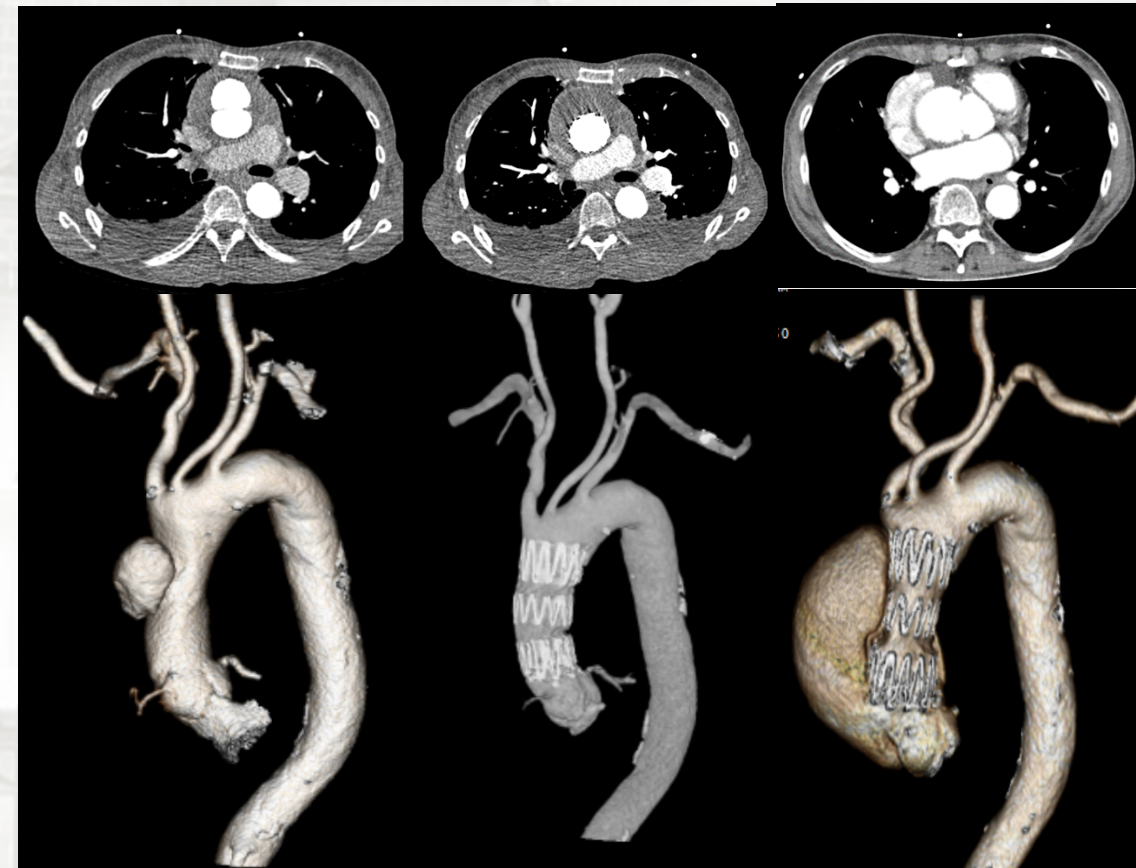
Concept could equally apply to: Medtronic Mona LSA

Arch Branched graft





A lifetime of speciality ***Interventional Repair of type a aortic dissection***



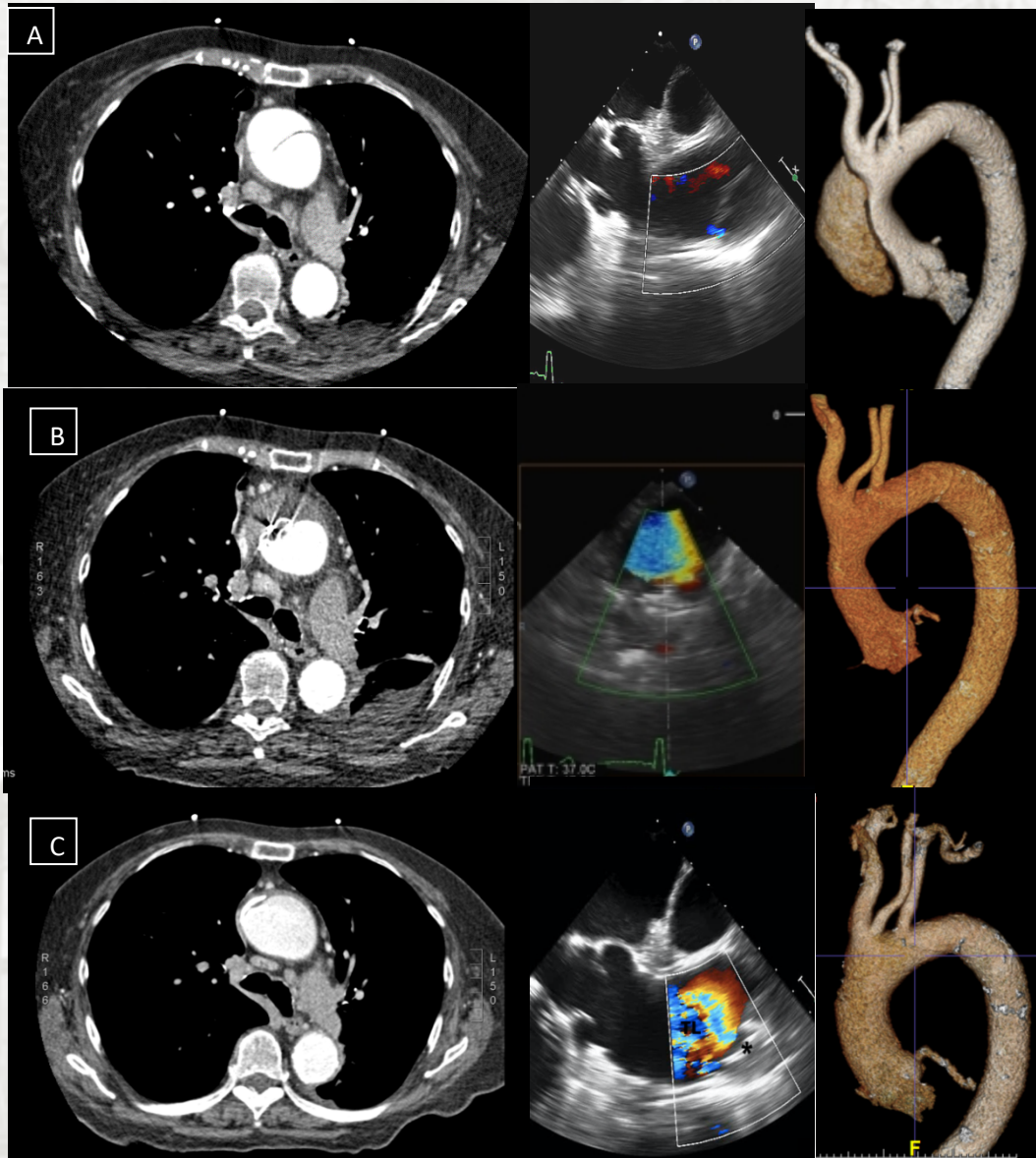
Pre-TEVAR

At discharge

16 months F/U

2- and 3-dimensional images of proximal aortic dissection before (A) and after stent-graft (B) with successful remodelling, but later total erosion of distal stent-edge at 16 months (C).

Interventional Repair of type a aortic dissection



pre procedure
(FLIRT)

CT and echo images pre-procedure (A), at discharge (B) and 6-month follow-up (C) showing entry closure false lumen thrombus and shrinkage with true lumen expansion (remodelling) (patient no.2). Star shows the ASD occluder.

At discharge

6 months F/U

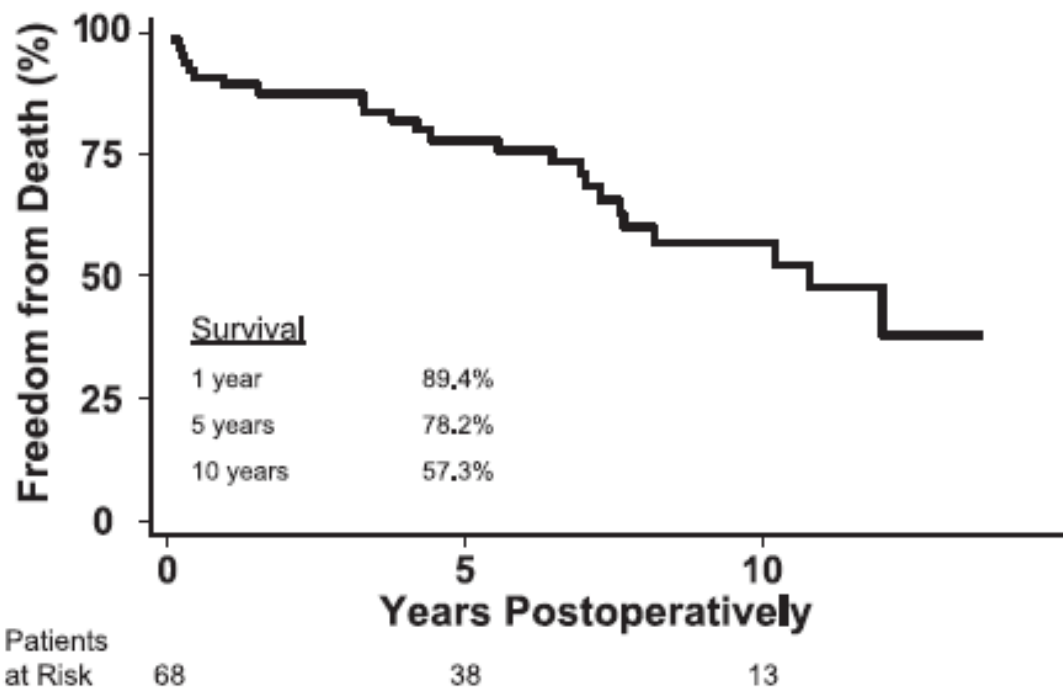
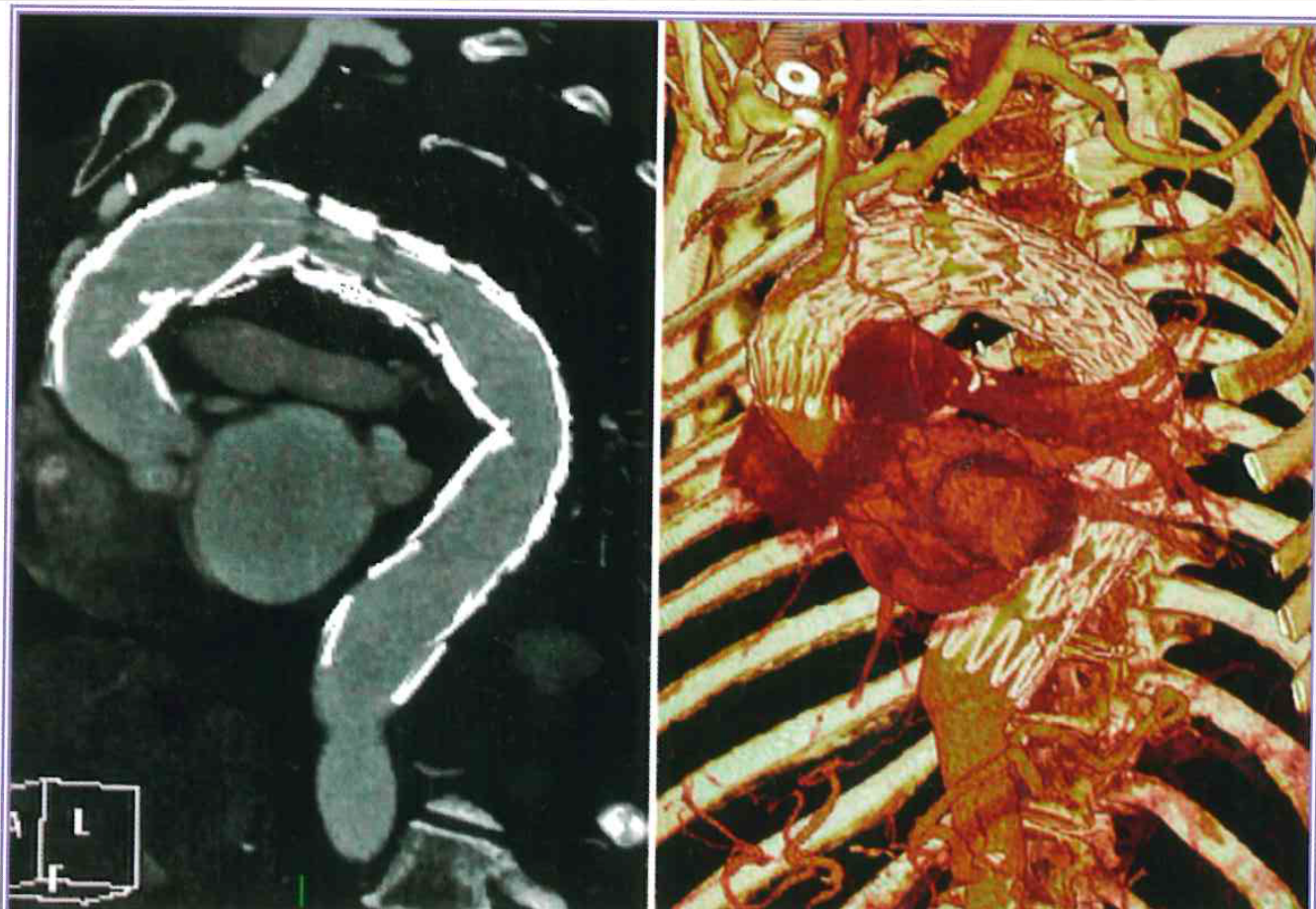


FIGURE 4. Long-term survival after surgery for extensive thoracic aortic dissection.



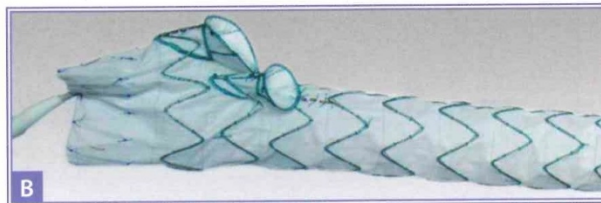
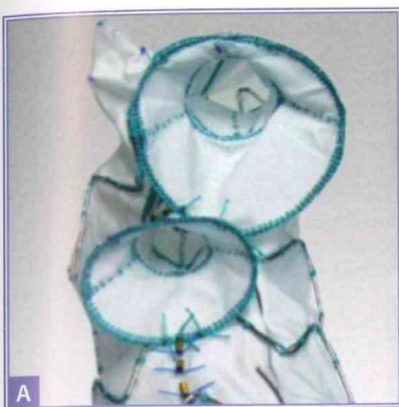


Fig. 16.5 A, B, Arch device with external branches. Courtesy of Cook Medical

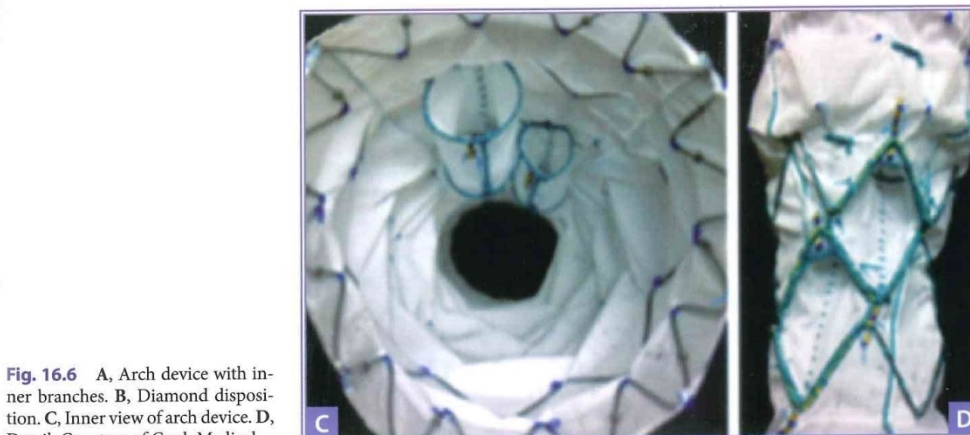
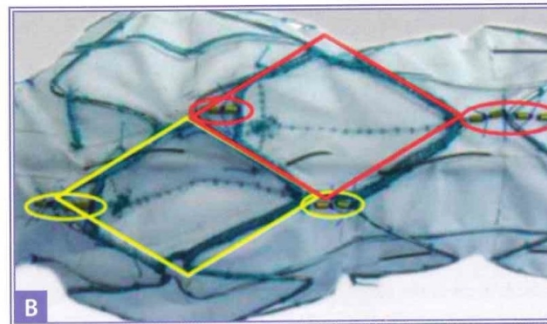
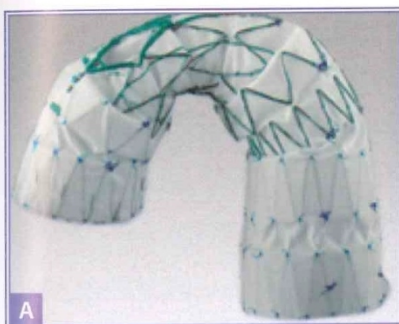
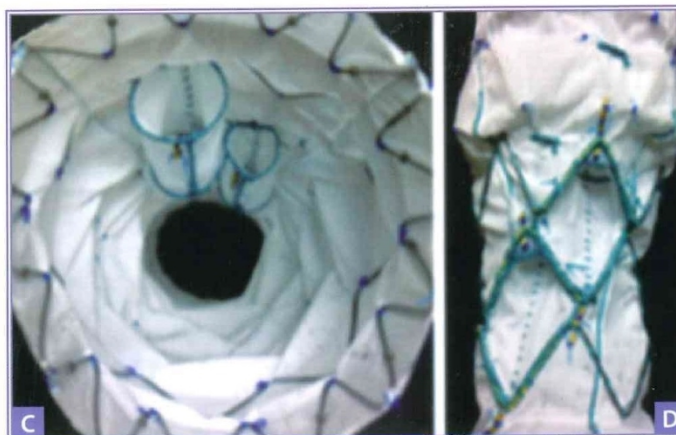


Fig. 16.6 A, Arch device with inner branches. B, Diamond disposition. C, Inner view of arch device. D, Detail. Courtesy of Cook Medical.



Brompton Aortic Centre 2018

Prof J Pepper
cardiac surgeon

Mike Rubens
Imaging

Ulrich Rosendahl
cardiac surgeon

Jullien Gaer
cardiac surgeon

Prof C Nienaber
cardiologist

Maz Mireskandari
vascular surgeon

Nick Cheshire
cardiac surgeon

