

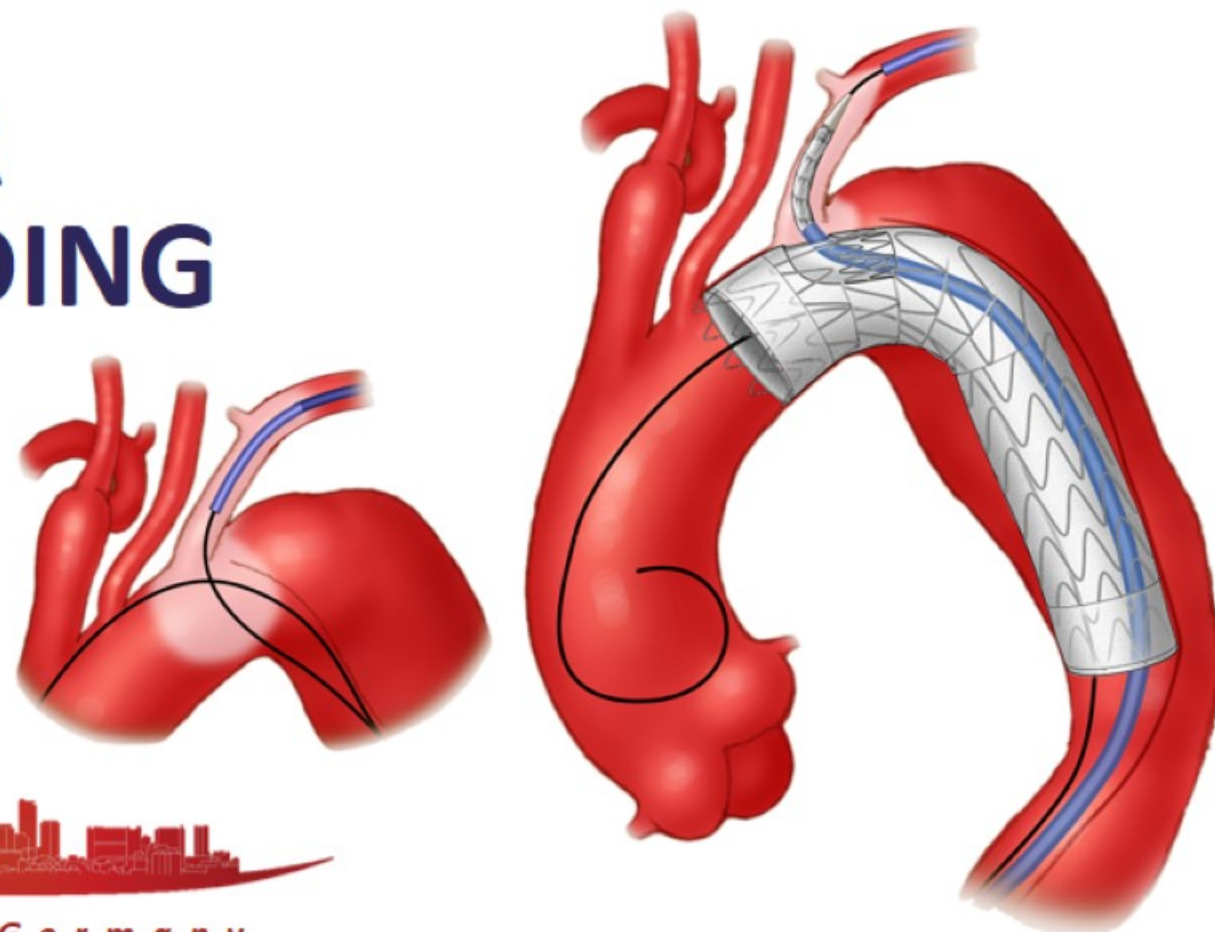
BRANCH GRAFT FOR PROXIMAL DESCENDING THORACIC AORTA

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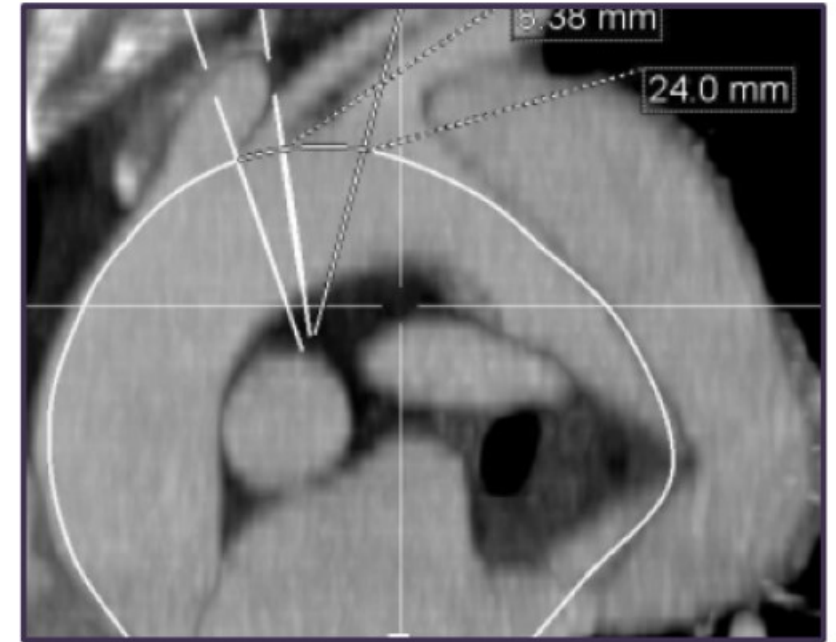


Disclosure

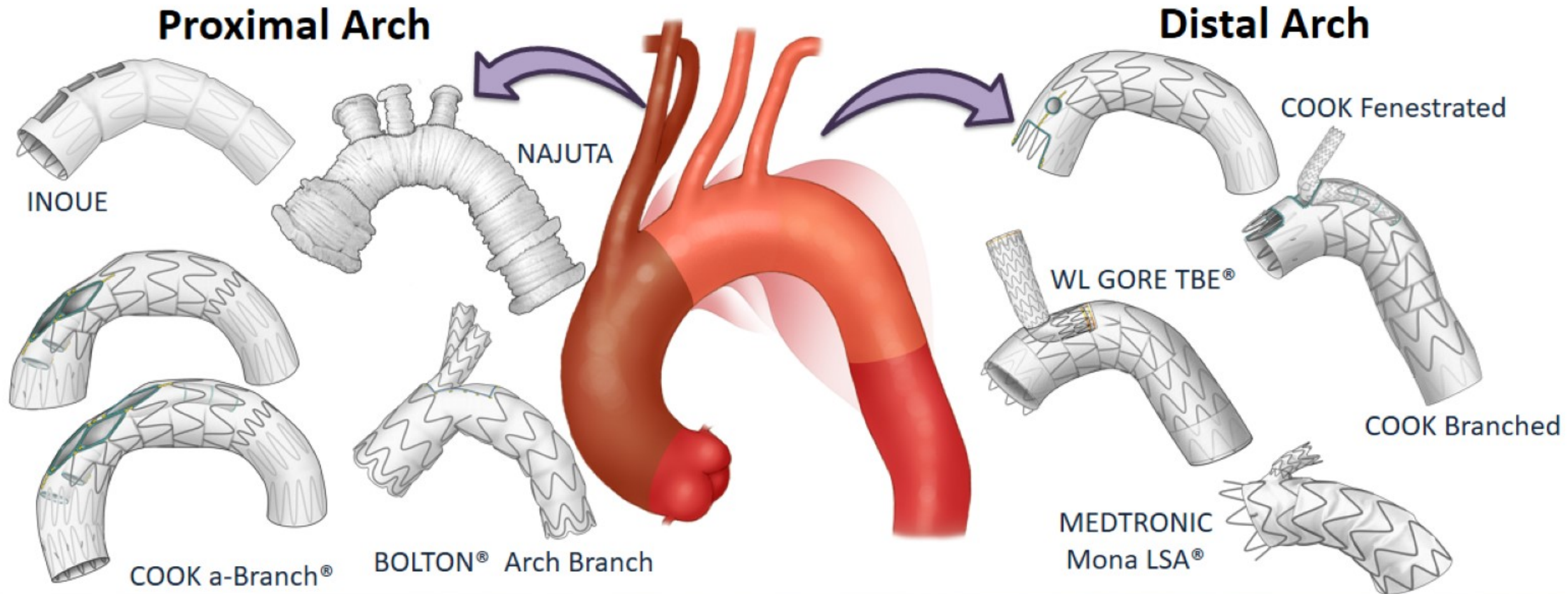
- Consulting: Cook Medical Inc., WL Gore and GE Healthcare
 - Research grants: Cook Medical Inc., WL Gore, GE Healthcare
- * All consulting fees and grants paid to Mayo Clinic

Distal Arch Branch Facts

- 35%-60% of TEVAR patients need LSA coverage¹
- Only 10% of patients in the STABLE trials achieved >20mm seal distal to LSA²
- LSA coverage (without revascularization) has been associated with stroke and spinal cord injury¹
- Short seal zone (<10mm) is associated with higher rates of proximal entry flow, retrograde dissection and thoracic enlargement²



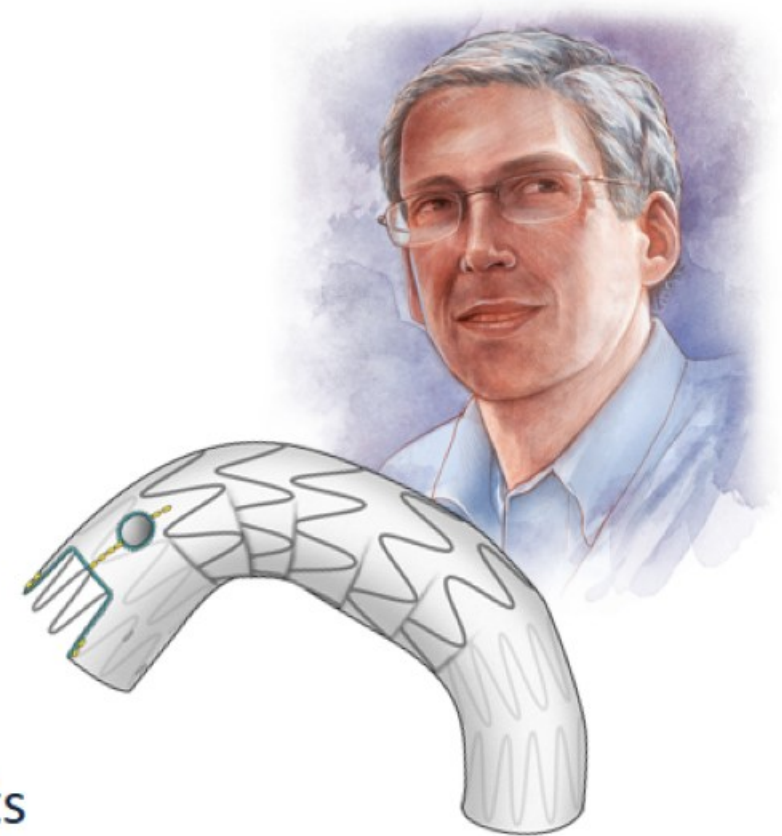
Options for Arch Branch Incorporation



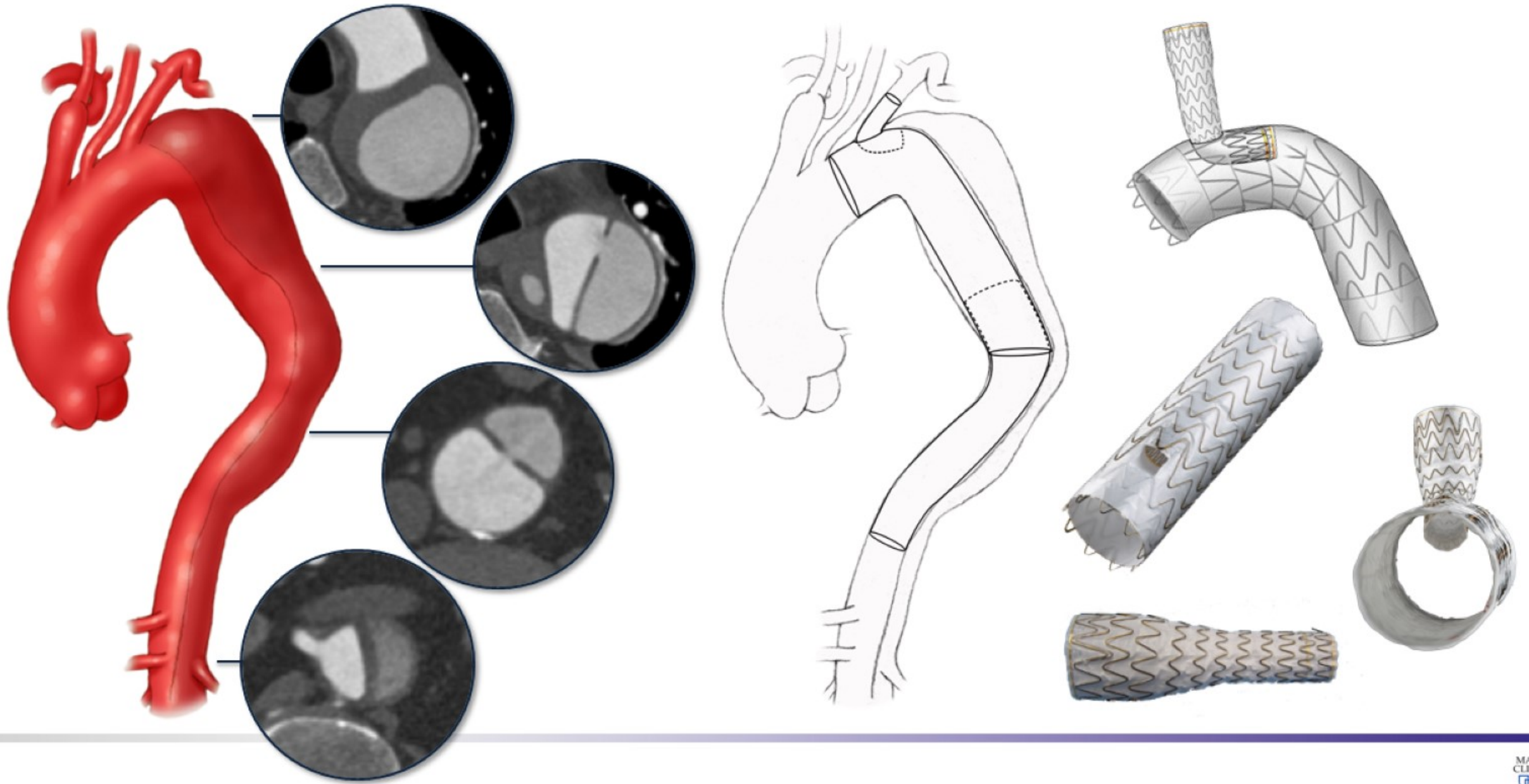
Cook Fenestrated Stent-Graft

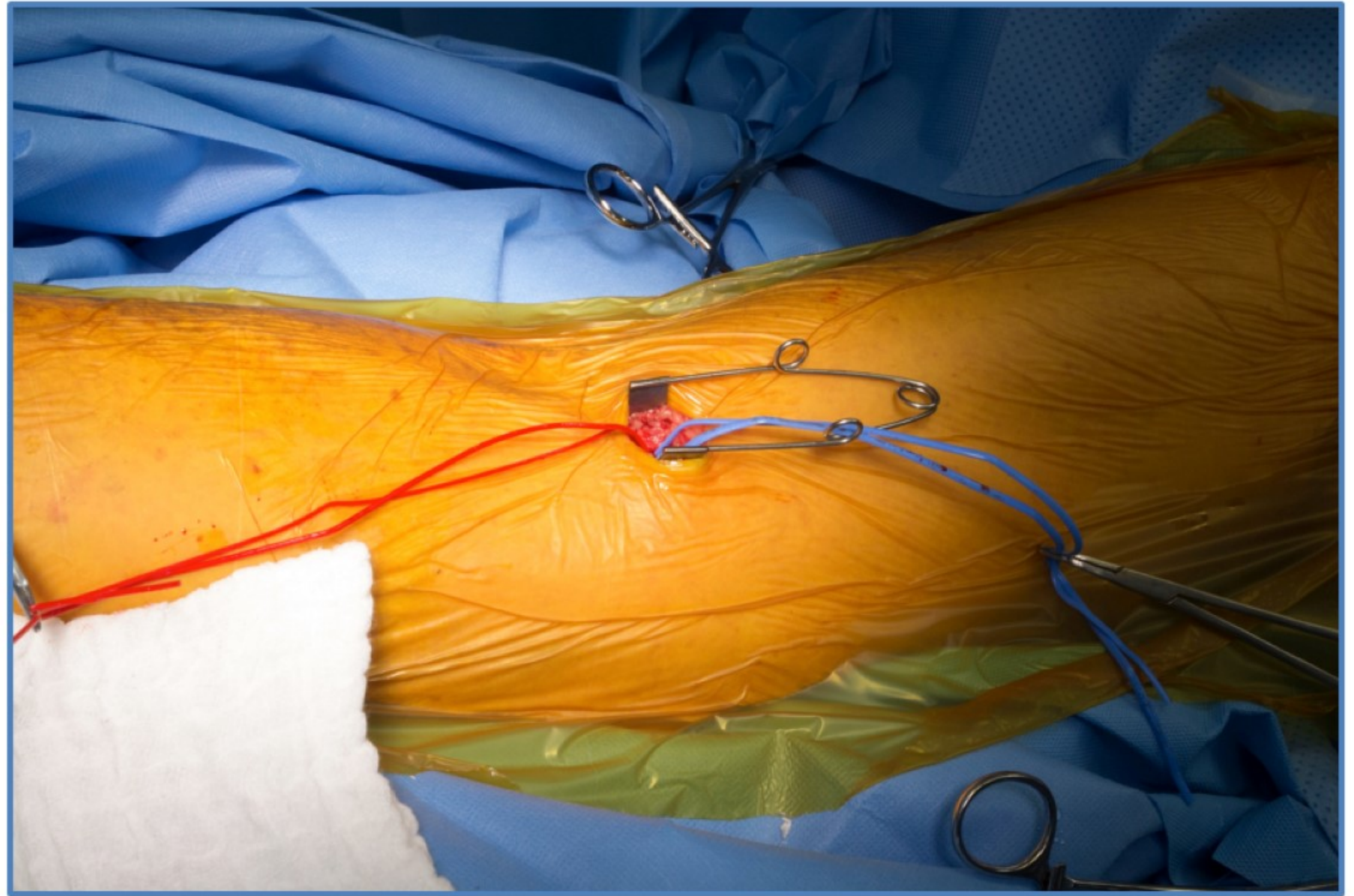
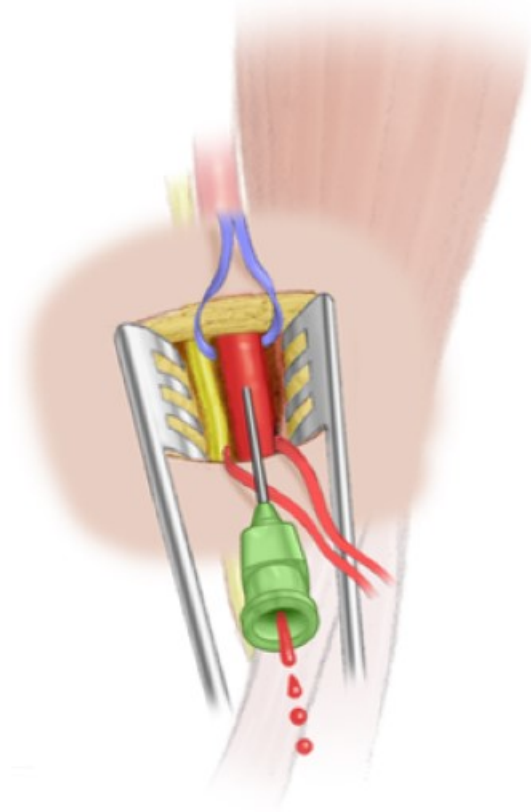
	Cleveland Clinic n = 15	Hamburg Group n = 15
Reference	JVS 2014	JVS 2016
Zone 1-2	14 (9%)	15
30-day mortality	1 (7%)	3 (20%)
Any stroke	1 (7%)	2 (13%)
Type IA endoleak	1 (7%)	0
Retrograde dissection	0	0

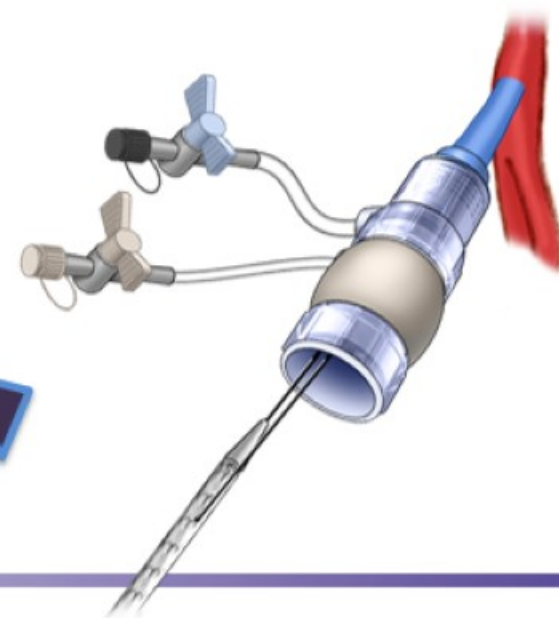
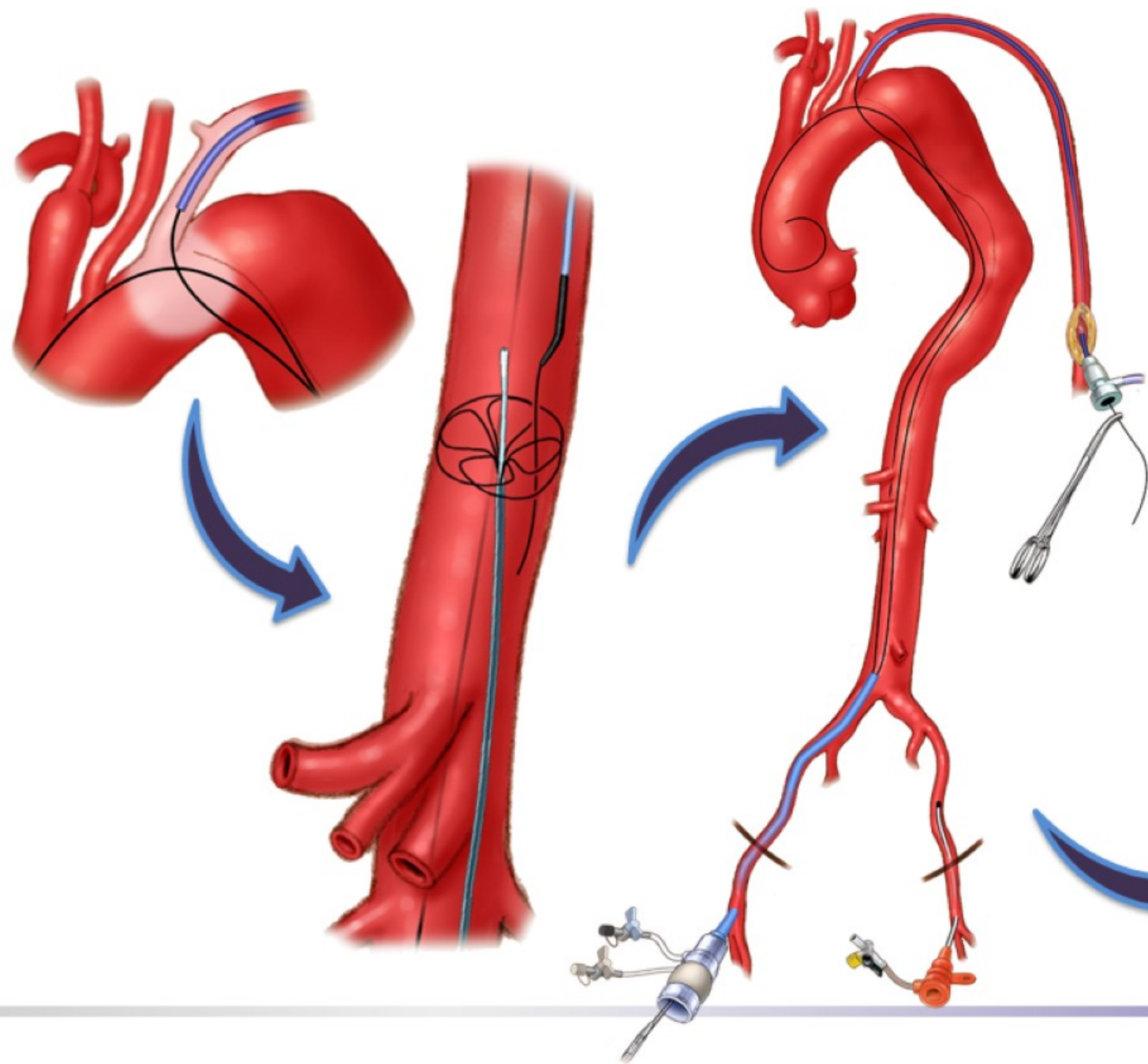
- Misalignment = arch manipulations = stroke risk
- No strut free fenestrations larger than 12mm limit its use for the innominate artery



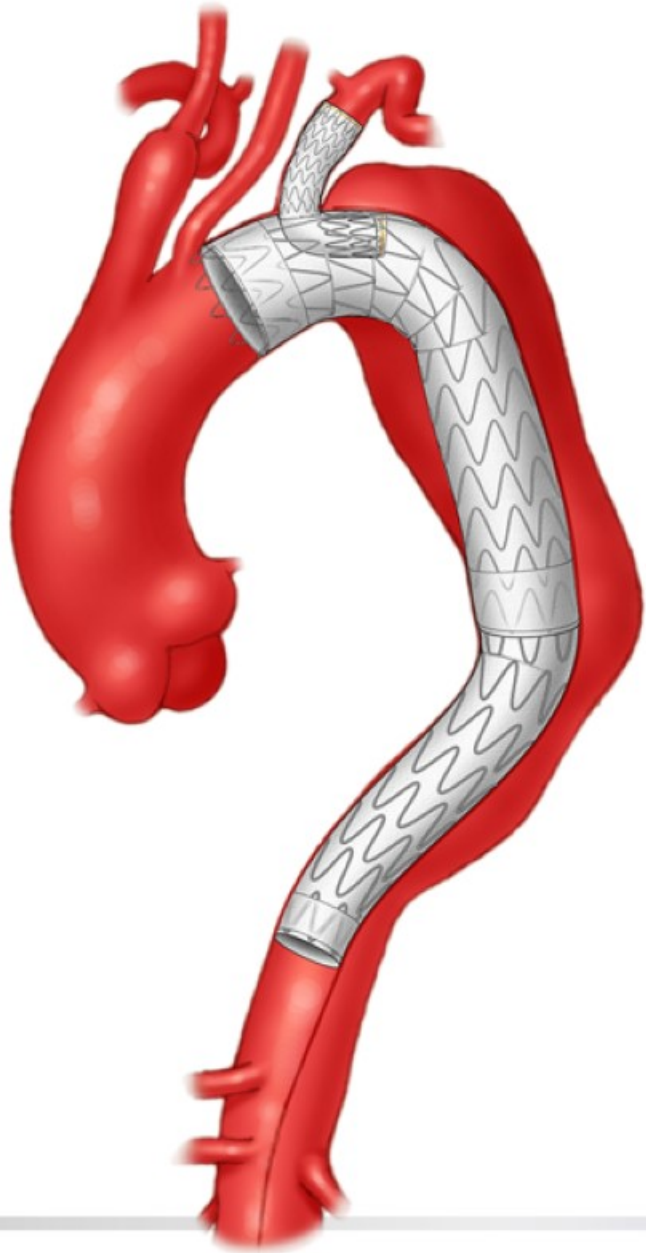
73-year-old male with chronic post-dissection thoracic aneurysm







ZONE 2
GORE TBE



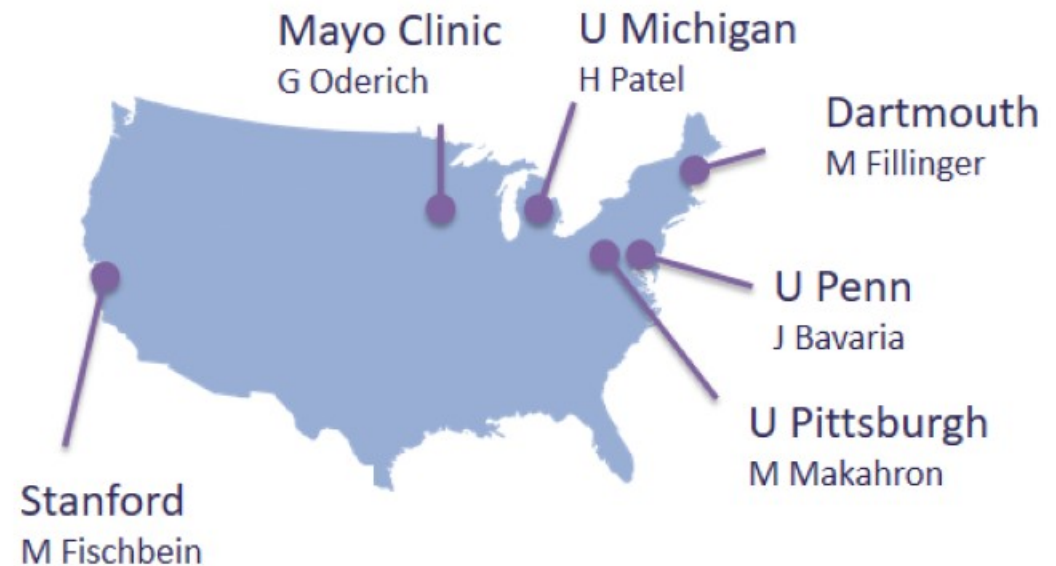
Mayo Clinic experience

Case	Year	Age/ Sex	Indication	Zone	Contrast (ml)	Fluoro time (min)	OR time (min)	Follow up (days)	Outcome
1	2015	75M	Aneurysm	0	191	27	95	1031	Wound infection
2	2015	62M	Aneurysm	2	45	12	62	935	No complications
3	2016	58M	Aneurysm	2	55	14	58	755	No complications
4	2017	73M	Dissection	2	160	19	115	226	No complications
5	2017	80M	Aneurysm	2	152	27	154	180	No complications
6	2017	63M	Dissection	2	120	24	112	36	No complications
7	2018	82F	Dissection	2	66	21	113	33	No complications
8	2018	48M	Aneurysm	2	53	18	95	33	No complications
9	2018	55M	Dissection	2	62	17	87	50	No complications
10	2018	76M	Aneurysm	0	40	16	64	30	No complications

Gore TBE® Feasibility Study

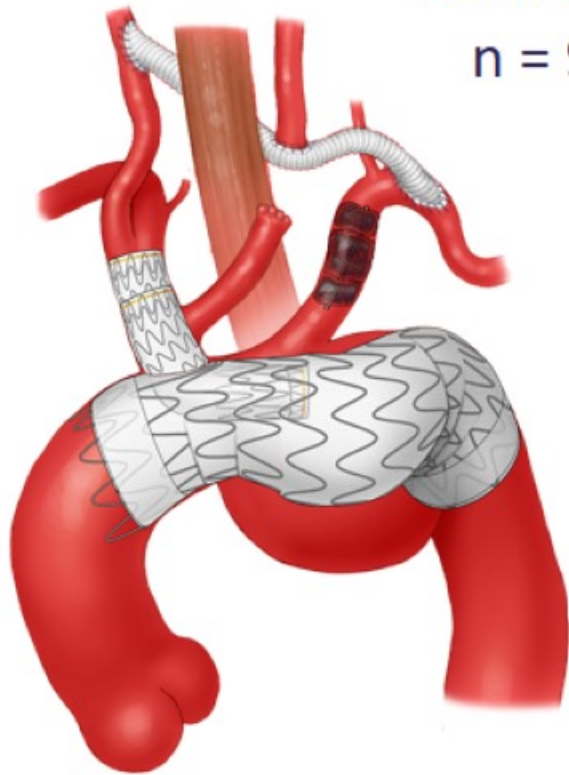
- Prospective, non-randomized trial in six US sites
- National Principal Investigator: Michael Dake MD - Stanford University
- Six clinical sites

Site	Principal Investigator
Stanford	Michael Fischbein MD
U Pittsburgh	Michael Singh MD
Dartmouth	Mark Fillinger MD
Mayo Clinic	Gustavo Oderich MD
U Penn	Joseph Bavaria MD
U Michigan	Himanshu Patel MD

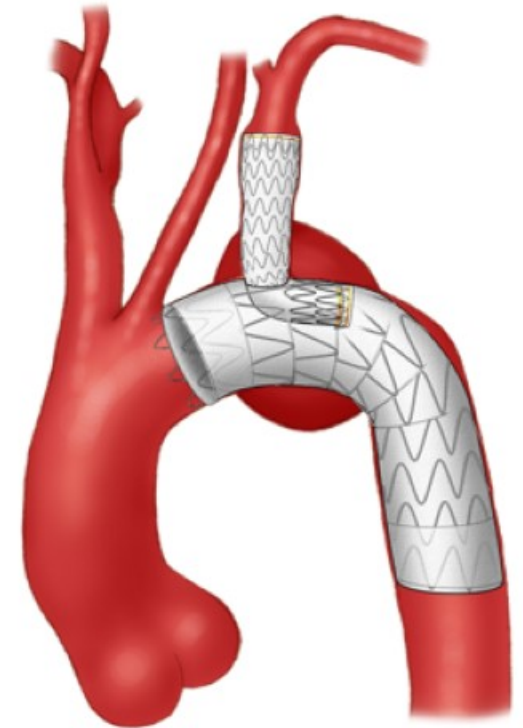
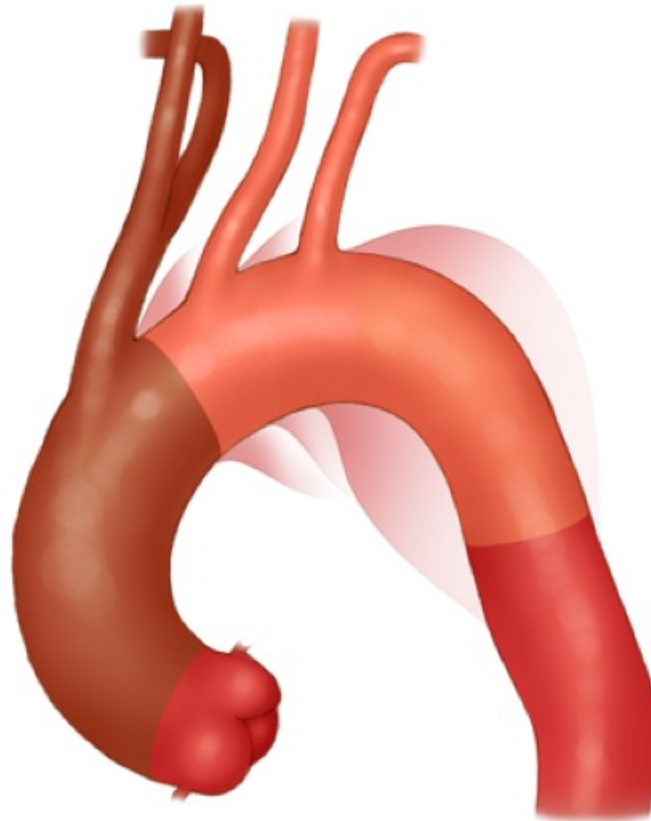


Patient enrollment

ZONE 0-1
n = 9



ZONE 2
n = 31



Procedural details

	Zone 2 n = 31	Zone 0 n = 9
Access Successful	100%	100%
Deployment Successful	100%	100%
Procedural Survival	100%	100%
Side Branch Patent	100%	100%
Procedure Time (min,SD)	210.9 (115.3)	220.9 (94.6)
Range	(85, 560)	(95, 378)
Length of Stay (days)	4.9 (4.0)	14.4 (13.5)
Range	(1, 19)	(3, 43)

Early results (<30 days)

	Zone 2 n = 31	Zone 0 n = 9
Patient Survival	100% (31/31)	100% (9/9)
Stroke	3.6% (1/31)	25% (2/9)
Spinal Cord Ischemia	30% (0/31)	0%(0/9)
Left Ankle Brachial Index		
Preop (Mean, Std Dev)	1.1 (0.13)	1.1 (0.13)
Postop (Mean, Std Dev)	1.1 (0.15)	1.2 (0.31)
Preop Brachial Ratio (Left/Right)	1.0 (0.05)	1.2 (0.07)
Postop Brachial Ratio (Left/Right)	1.0 (0.07)	1.0 (0.08)
Length of stay (days)	5 (4)	20 (14)

2-year results

	Zone 2 n = 31	Zone 0 n = 9
Aortic-related death	3.6% (1/31)	0% (0/9)
Aortic reintervention	3.6% (1/31)	0% (0/9)

- Zone 2 death POD 113
 - rupture of ascending aortic aneurysm
- Zone 2 Reintervention
 - distal device migration > cervical debranching with Zone 0 TBE procedure



Branch patency (Core Lab assessment)

- One asymptomatic LSA occlusion at 6 months
- One conversion to carotid-subclavian bypass due to need for proximal arch extension with Zone 0 TBE at 2-years

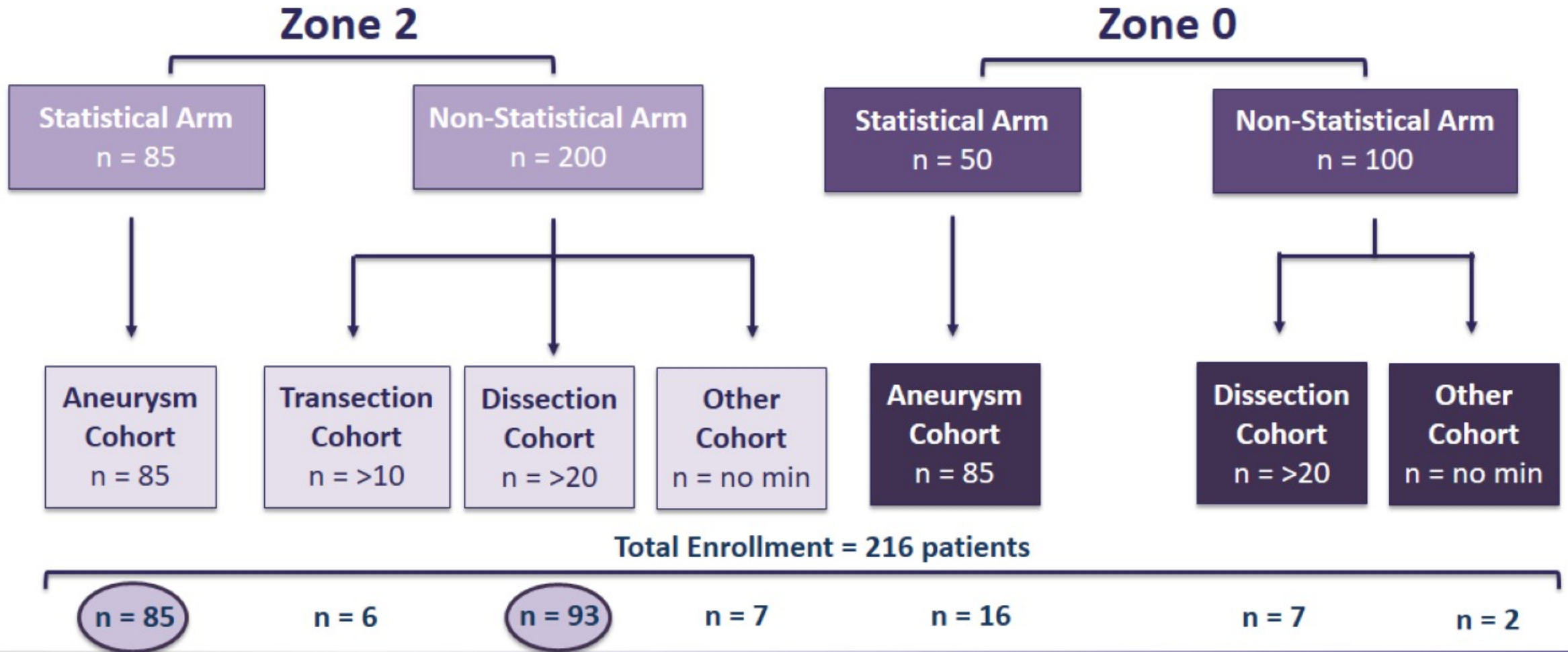
LSA patency	1 Month	6 Months	1 Year	2 Years
Number of Patients	31	29	26	15
Side Branch Patent	31	28	25	13

Endoleaks (Core Lab assessment)

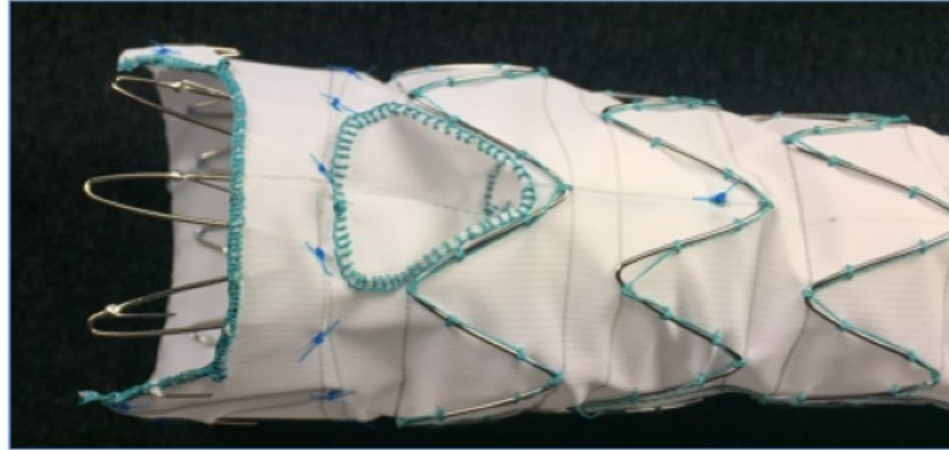
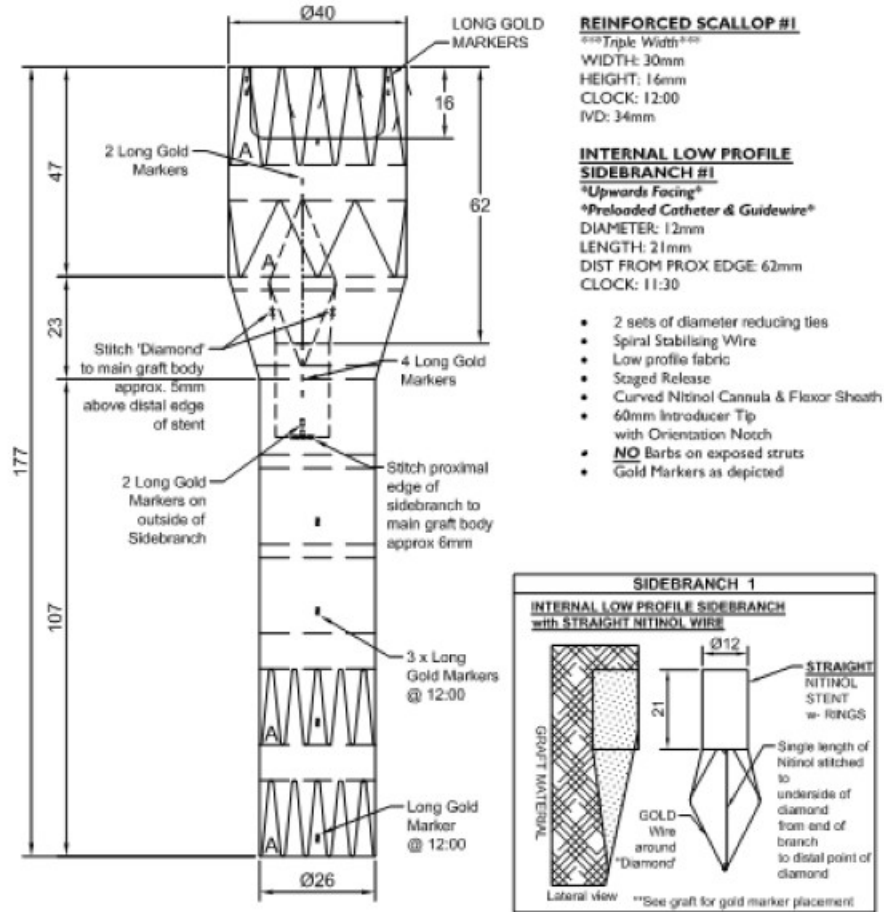
- No type IA endoleak
- 4 patients with type II endoleak
- 1 patient with type III endoleak (spontaneous resolution at 6 months)
- 1 patient with distal migration and no endoleak

Endoleaks	1 Month	6 Months	1 Year	2 Years
Number of Patients	30	27	26	15
Type I	0	0	0	0
Type II	2	4	2	1
Type III	1	0	0	0

Gore TBE® Pivotal trial design



Cook LSA Branch Stent-Graft

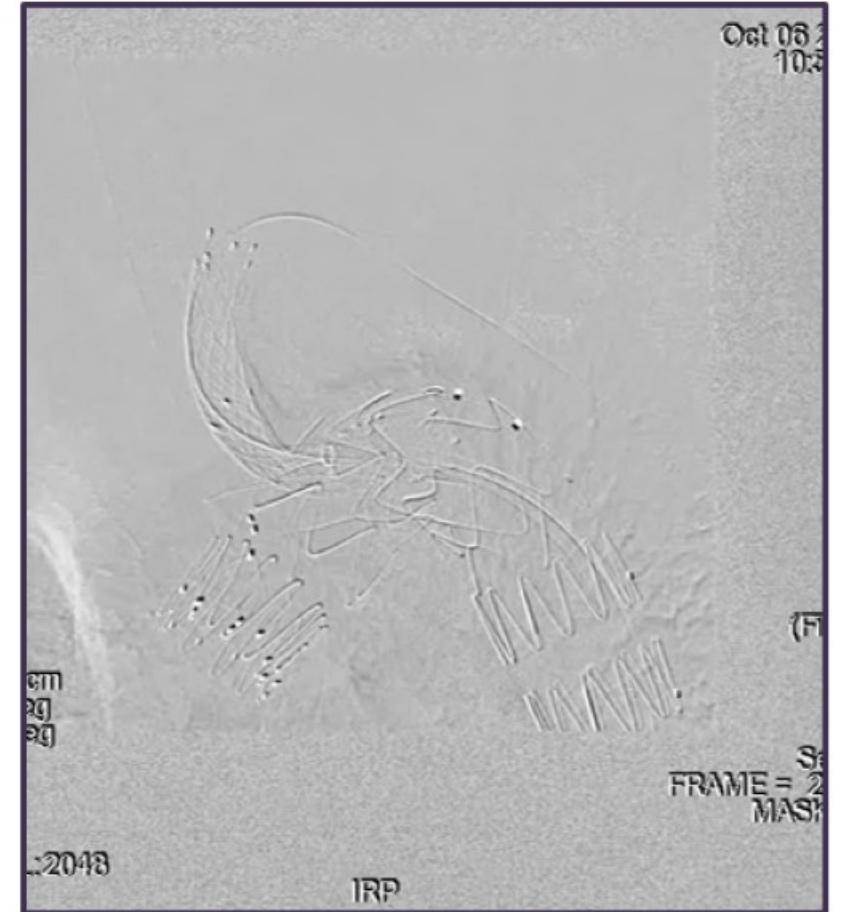
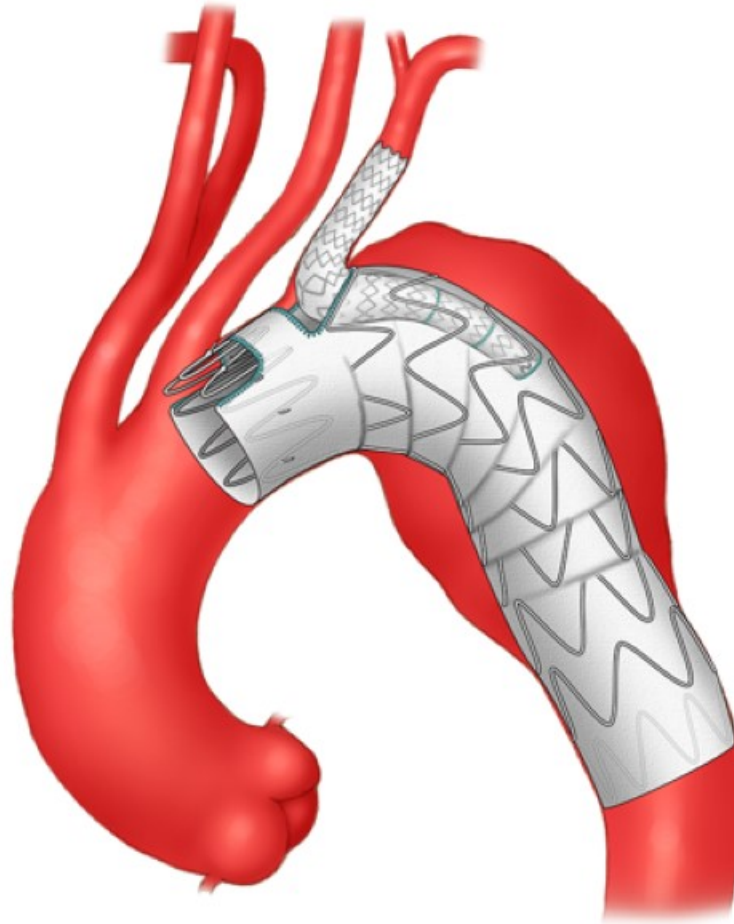


- Stent-graft design parameters
 - 34 to 46mm proximal diameter with triple wide scallop (30mm wide)
 - Triangular LSA fenestration with 12mm retrograde inner branch and preloaded catheter



Stephan's experience

- 8 patients
- No stroke or mortality
- 1 Type IA endoleak



Conclusion

- Distal arch extension is common during TEVAR, with LSA coverage needed in up to 60% of patients
- LSA coverage (without revascularization) has been associated with higher rates of stroke and spinal cord injury
- Preliminary experience with the GORE TBE[®] device in a prospective, non-randomized study shows low morbidity and stroke rates with high patency up to 2-years
- Cook LSA device adds a triple wide scallop for the L CCA, expanding anatomical indications to up to >80% of patients who need LSA revascularization