

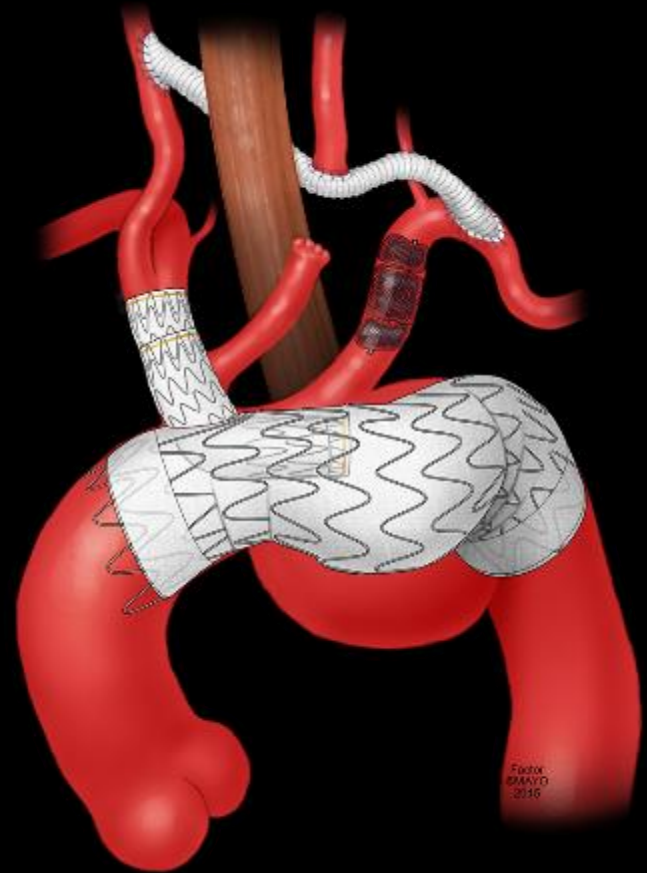
RETROGRADE BRANCH

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Director of Endovascular Therapy

Division of Vascular and Endovascular Surgery





CRITICAL ISSUES

AORTIC ENDOGRAFTING 2016



FACULTY DISCLOSURE

- Consulting*
Cook Medical Inc., WL Gore
- Research grants*
Cook Medical Inc., WL Gore, Atrium Maquet
- Investigational, off-label use of devices
Gore TBE and CEX devices

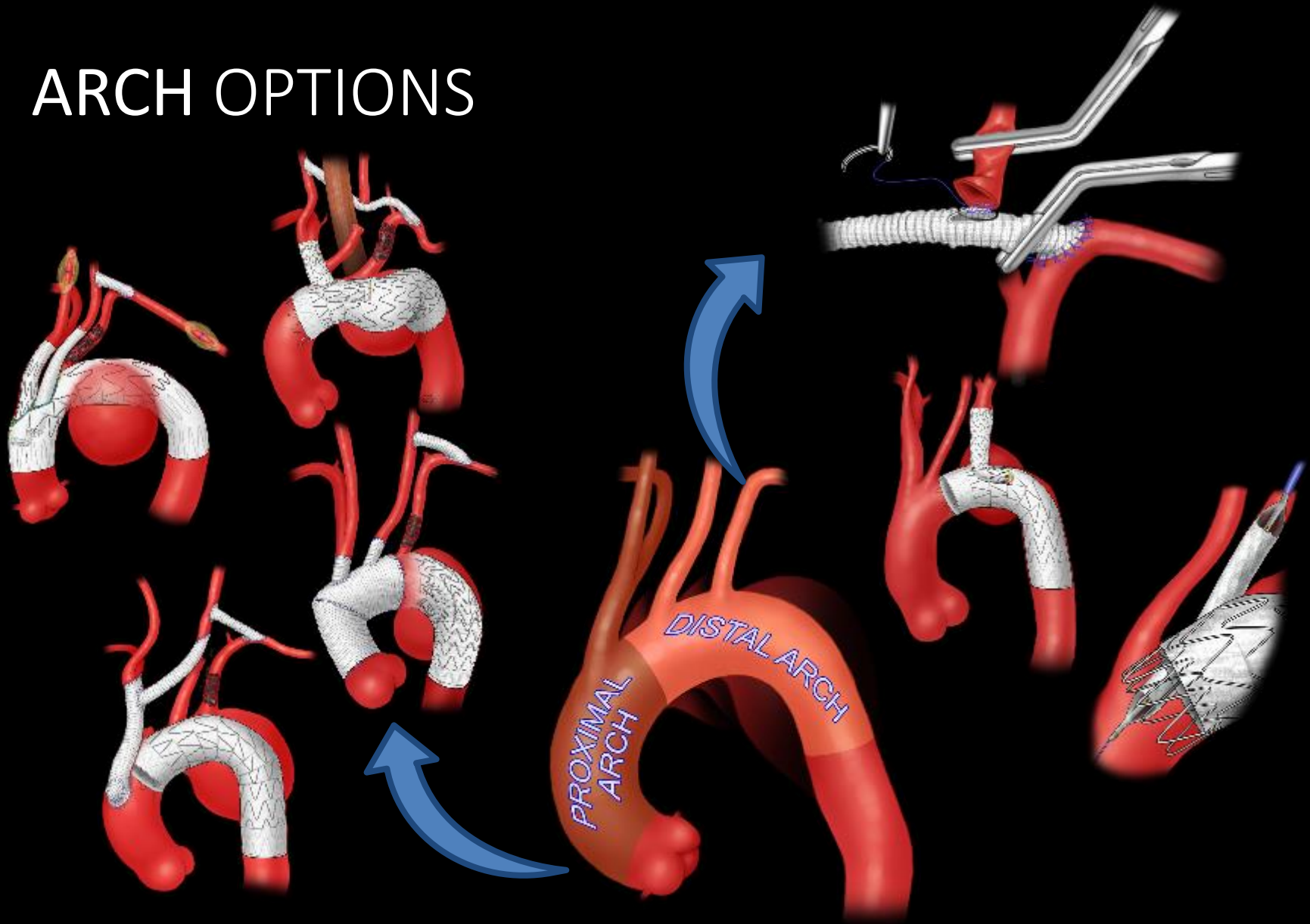
* All consulting fees and grants paid to Mayo Clinic

TEVAR FOR TAAs & TYPE B DISSECTIONS

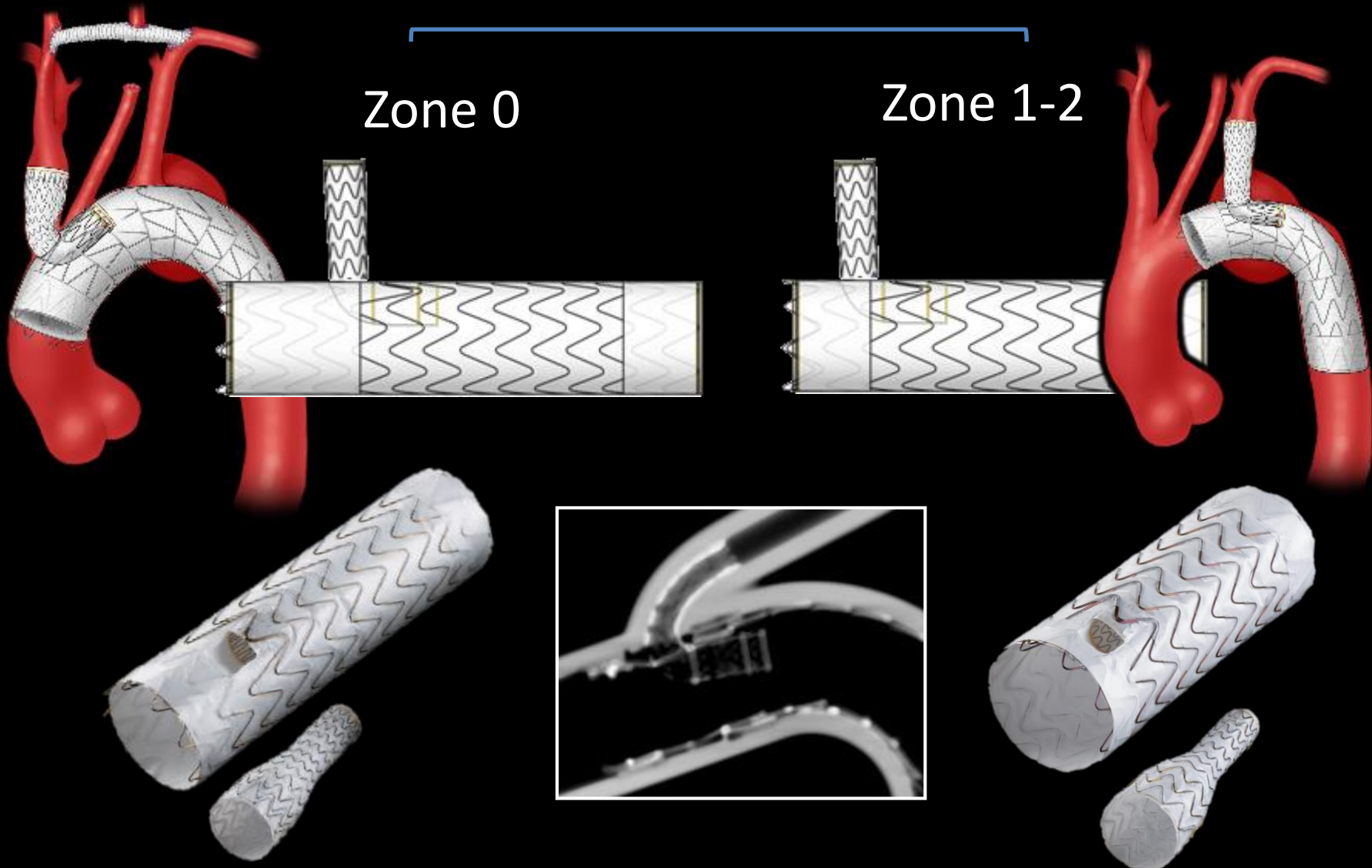
Benchmark results

	n	Indication	Mean age	Zone 0 to 2	30-day Mortality	Stroke/TIA
C-TAG Aortic Catastrophes (2009)	59	Complicated TBD/ TT	62	-	12%	15%
SVS Meta-analysis (2011)	99	Acute TBD	59	35%	11%	10%
STABLE Trial (2012)	40	Acute TBD	58	63%	5%	10%
MOTHER Registry (2013)	114	Acute TBD	61	61%	11%	6%
	195	Chronic TBD	63	44%	13%	7%
	670	TAAs	71	37%	5%	5%

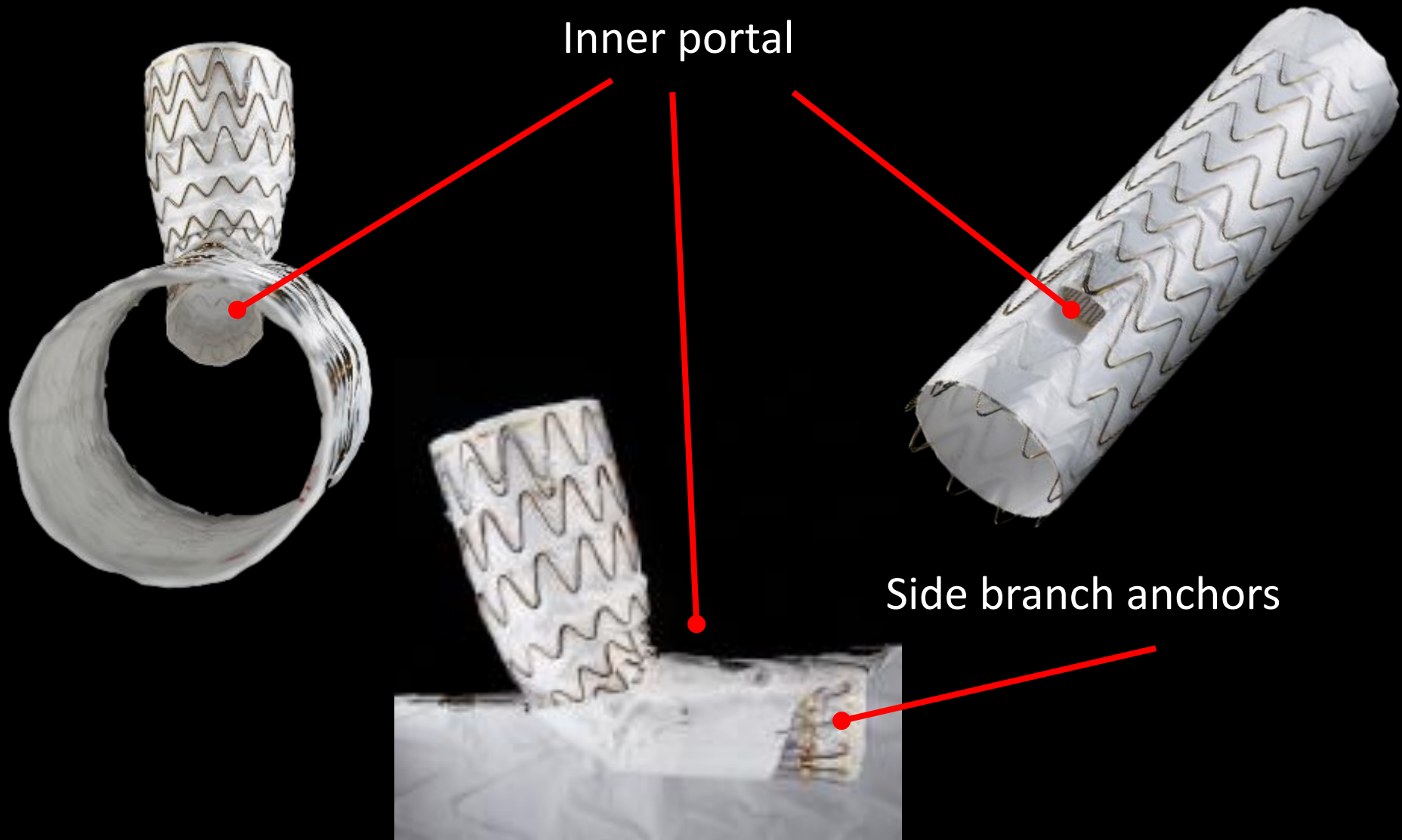
ARCH OPTIONS



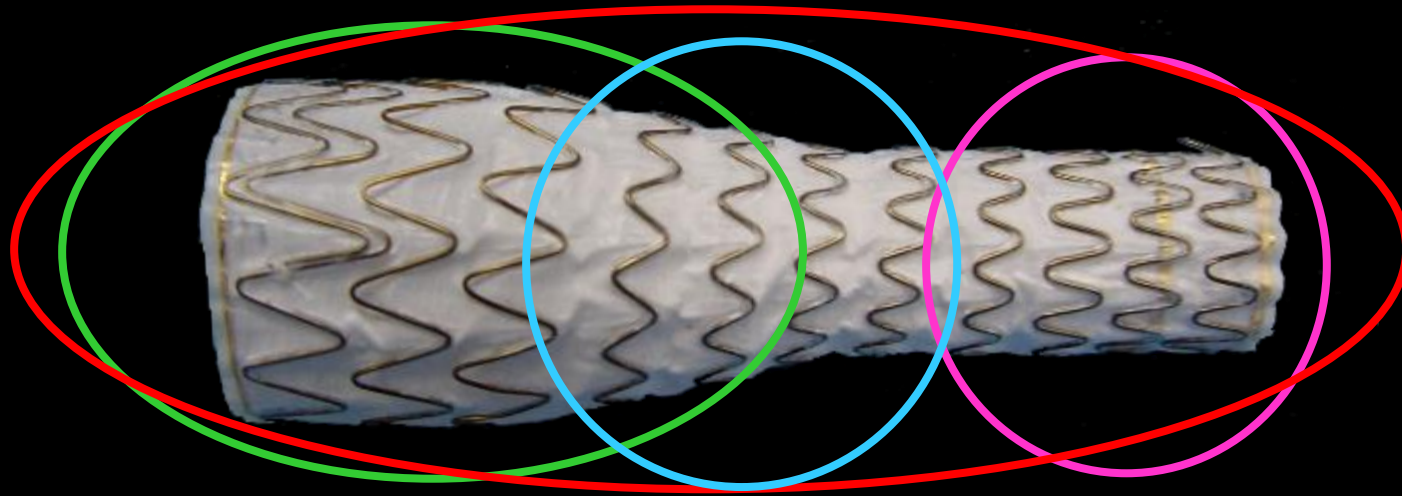
GORE[®] THORACIC BRANCH



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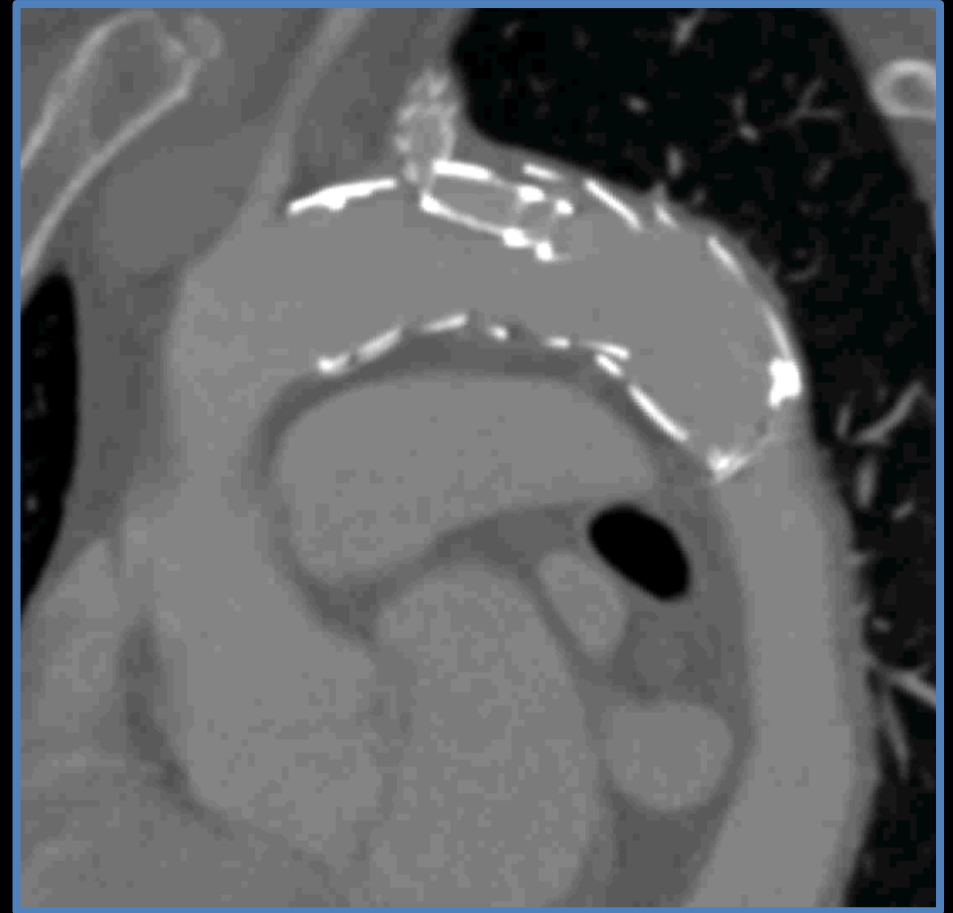
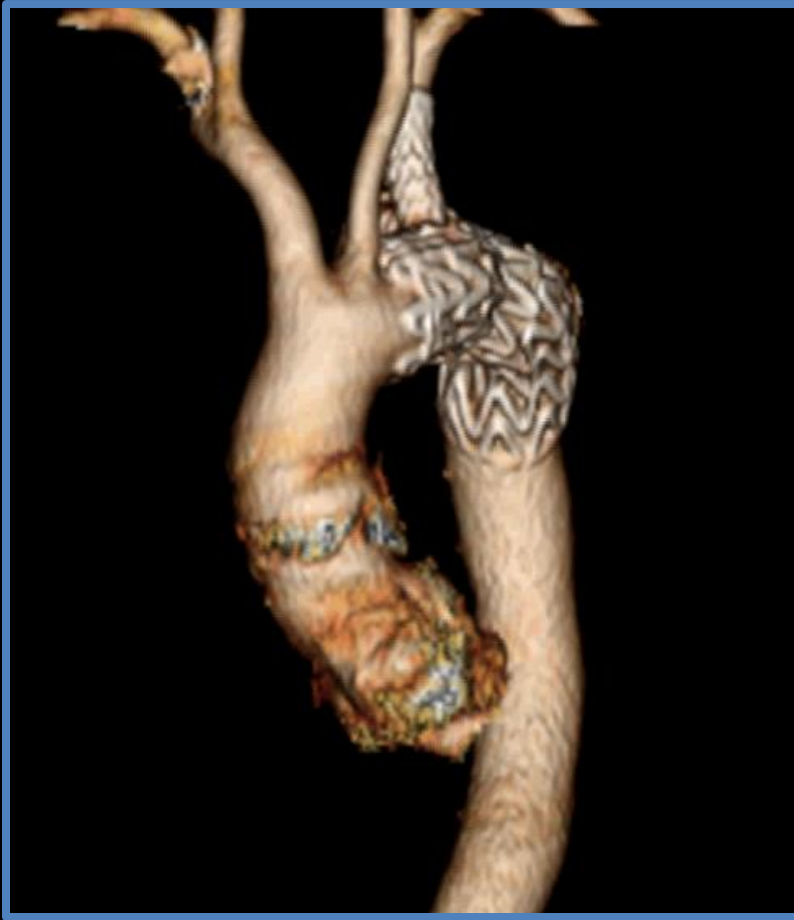
Branch Vessel Segment

CBAS[®] lumen
Tapered Flex Segment

Internal Portal Segment

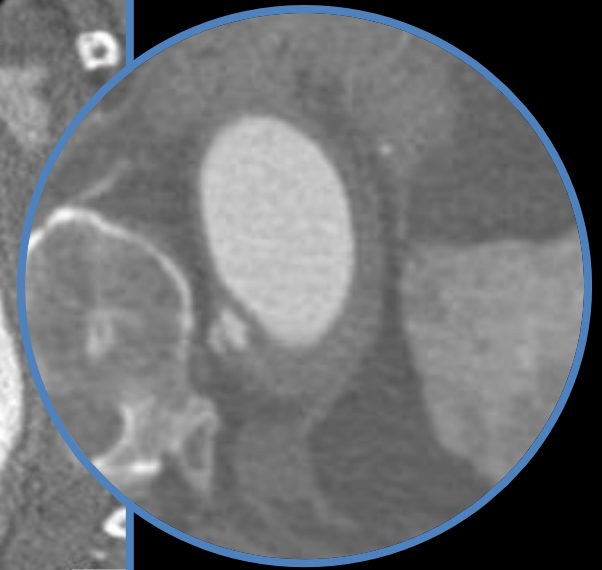
62M with 5-cm saccular aneurysm

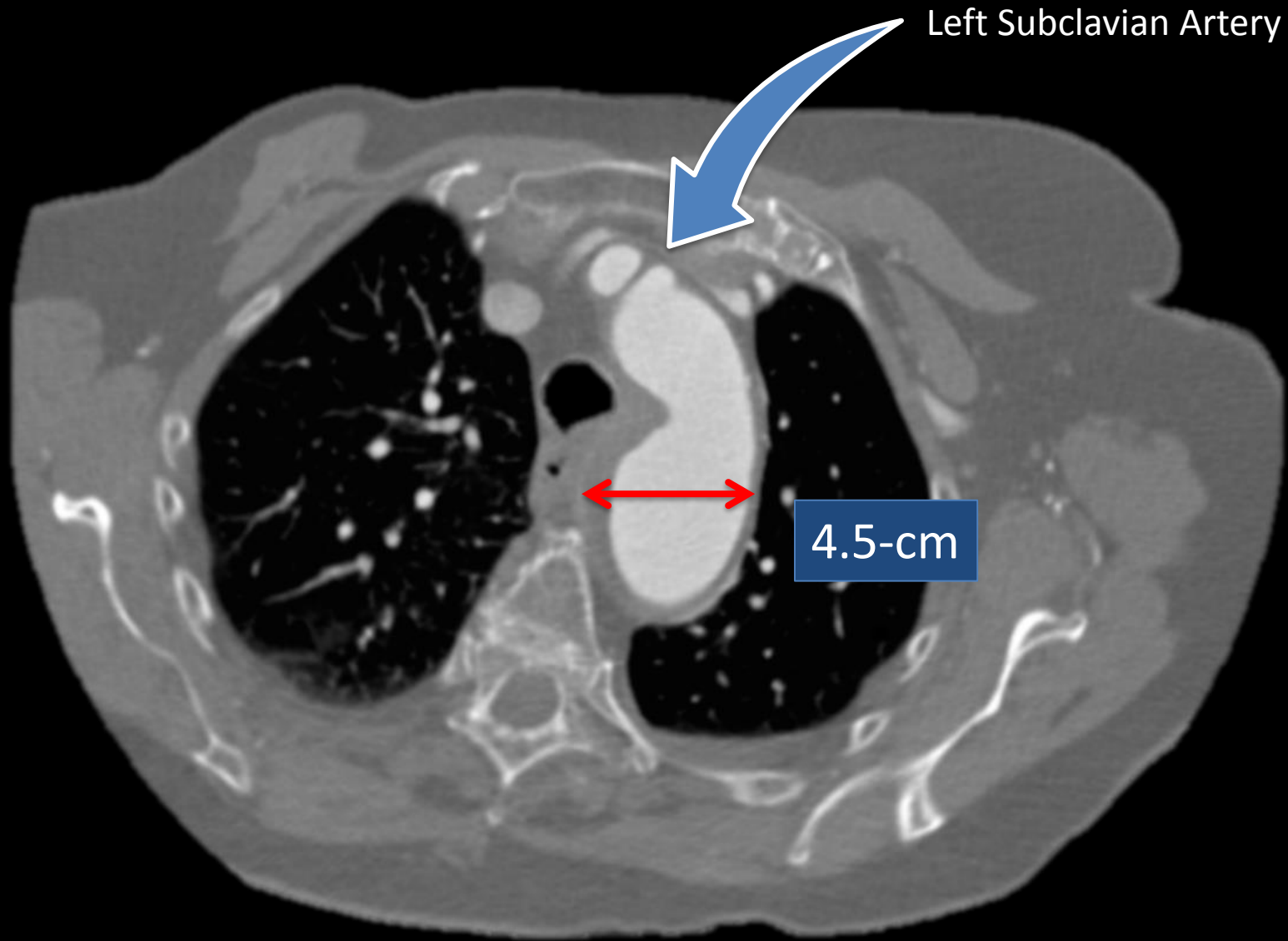




- Dismissed postoperative day 1
- 1-year follow up with no endoleak or complications

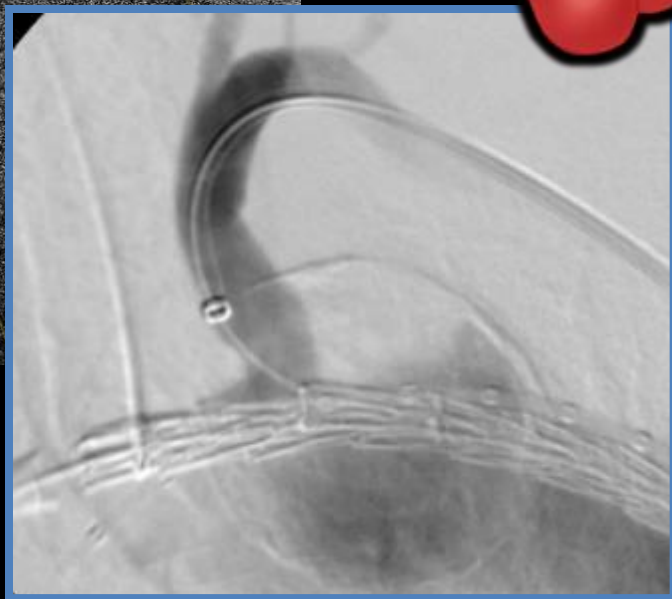
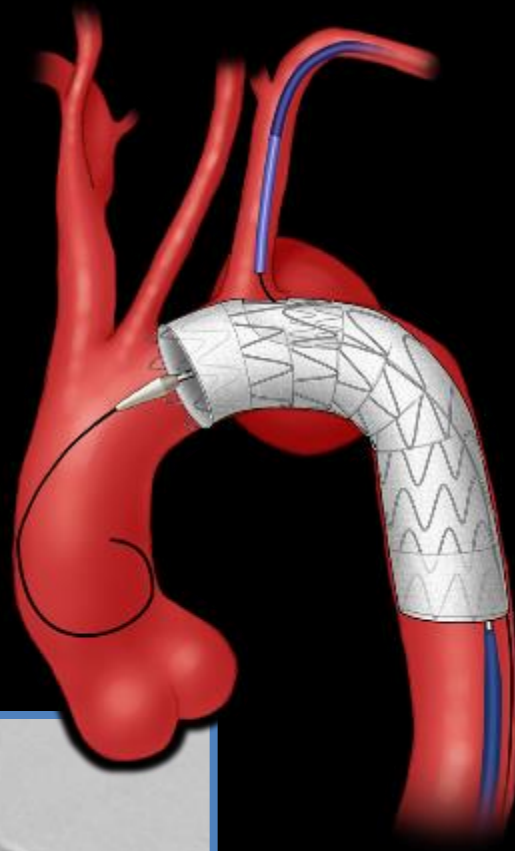
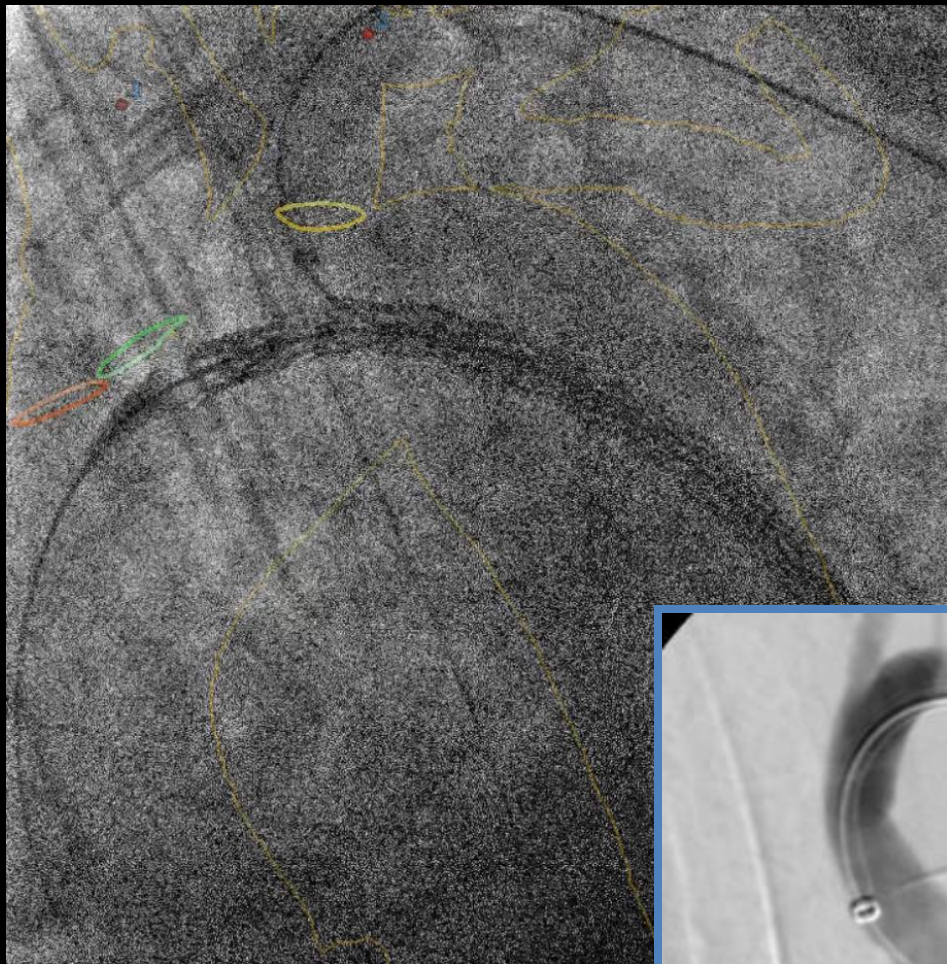
*81-year-old female with recurrent IMH and
PAU associated with intercostal artery*





Left Subclavian Artery

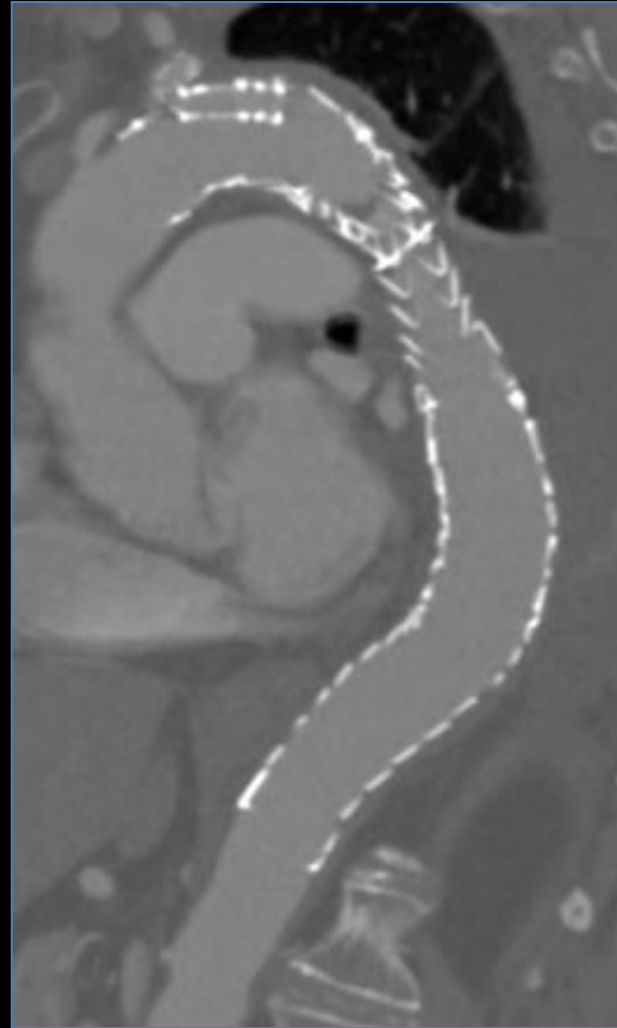
4.5-cm



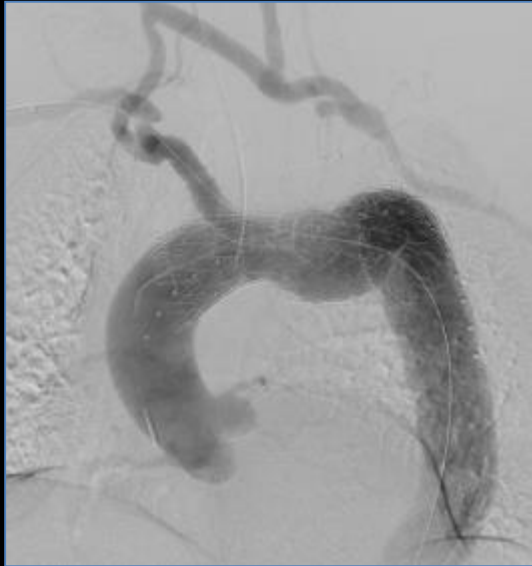
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GE MEDICAL SYSTEMS
Mayo Clinic St. Marys Hospital





75-year-old men with
enlarging 6cm arch aneurysm

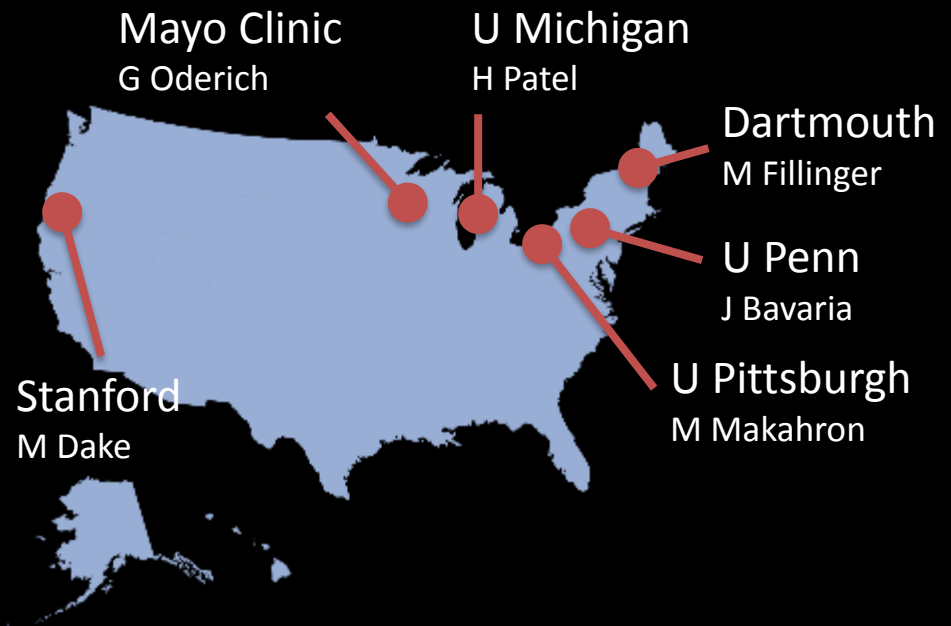


CLINICAL TRIAL SITES

National PI: Michael Dake MD
Stanford University



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



GORE TBE TRIAL OVERVIEW

ZONE 0-1

Early Feasibility

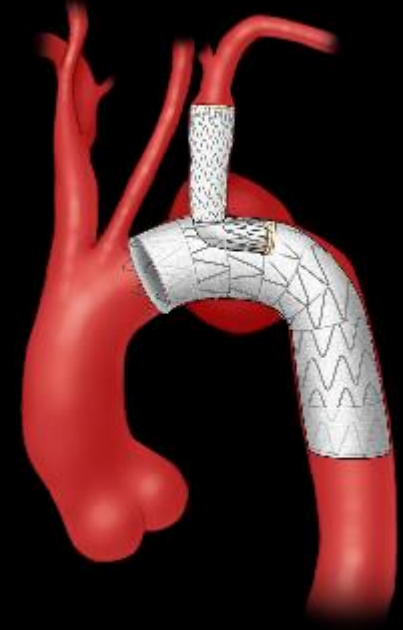
n = 8



ZONE 2

Feasibility

n = 28



PATIENT CHARACTERISTICS

	Zone 2 n = 28	Zone 0/1 n = 8
Mean Age (Std Dev)	74.1 (10.7)	72.3 (8.4)
Male gender	16 (57.1%)	7 (87.5%)
Hypertension	25/28 (89.3%)	8/8 (100%)
Chronic Pulmonary Disease	9/28 (32.1%)	5/8 (62.5%)
Coronary Artery Disease	10/28 (35.7%)	6/8 (75.0%)
Prior aortic surgery	7/28 (25.0%)	1/8 (12.5%)
Thromboembolic event	2/28 (7.1%)	0/8 (0%)

ANATOMICAL CHARACTERISTICS

	Zone 2 n = 28	Zone 0/1 n = 8
Type of Aneurysm		
Fusiform	12 (39.4%)	2 (25.0%)
Saccular	15 (53.6%)	6 (75.0%)
Max Aneurysm Diameter		
Mean (Std Dev)	56.1 (10.7)	64.1 (8.4)
Total Treatment Length		
Mean (Std Dev)	17.3 (8.3)	19.8 (5.1)
Median	14.0	20.0
Range	(10.0, 32.7)	(15.0, 26.5)

PROCEDURAL DETAIL

	Zone 2 n = 28	Zone 0/1 n = 8
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 OUTCOMES (30-DAYS)

	Zone 2 n = 28	Zone 0/1 n = 8
Patient Survival	100% (28/28)	100% (8/8)
Stroke	3.6% (1/28)	25% (2/8)
Spinal Cord Ischemia	3.6% (1/28)	0%(0/8)
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)

ZONE 2 SITE REPORTED OUTCOMES

	Follow-Up Visit CT			
	Procedure or Post-Procedure	1 Month	6 Months	12 Months
Number of Patients	23	22	17	9
Type I	4	0	0	0
Type III	1	0	0	0

- Four patients with procedural Type I endoleaks resolved at 1 mo without intervention
- One patient with post-procedure Type III endoleak resolved at 1 mo without intervention
 - Same patient had Type I endoleak
- No reported endoleaks for Zone 0/1 (n=8)

BRANCH PATENCY

- Side Branch Component Patency – Core Lab
- 1 LSA asymptomatic branch occlusion at 6 months

Zone 2		
	1 Month	6 Months
Number of Patients	24	18
Side Branch Patent	24	17

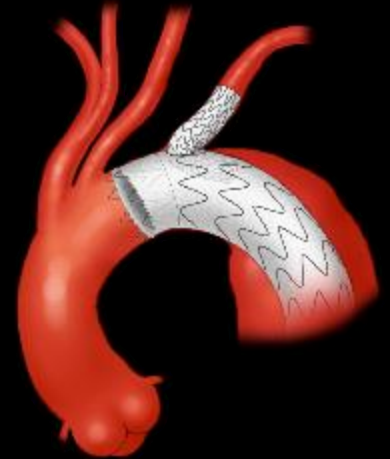
Zone 0/1		
	1 Month	6 Months
Number of Patients	7	5
Side Branch Patent	7	5

Summary of Preliminary Results

- 100% Technical success for Zones 0-2
- 100% Survival at 1 month for Zones 0-2
- Strokes
 - 1 stroke in Zone 2 (3.6%)
 - 2 strokes in Zone 0 (25%)
- Side Branch Patency
 - 1 loss of patency at 6 months in Zone 2
 - No loss of patency in Zone 0

Conclusions

- This prospective non-randomized study shows high technical success with low rate of stroke and branch occlusion (3.6%) for Zone 2 retrograde branch
- Strengths are branch specific bridging stent, use pre-loaded wire system and conformable technology
- Larger clinical experience and longer follow up is needed to determine clinical effectiveness and potential failure mechanisms of retrograde branch design



MAYO CLINIC

150 
Years

SERVING HUMANITY