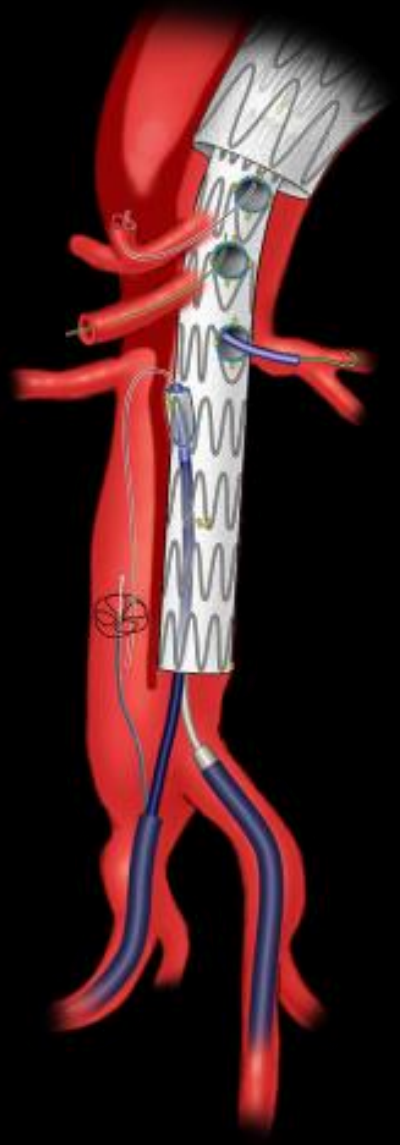
OUTCOMES OF ENDOVASCULAR TAAA REPAIR



Gustavo S. Oderich MD

Professor of Surgery
Director of Aortic Center
Director of Advanced Endovascular Aortic Program
Division of Vascular and Endovascular Surgery

HAS2018
THE HOUSTON AORTIC SYMPOSIUM

MAYO CLINIC

FACULTY DISCLOSURES

- Consulting*
  Cook Medical Inc., WL Gore, GE Healthcare
- Research grants*
  Cook Medical Inc., WL Gore, GE Healthcare
- Investigational, off-label use of devices
  Cook Fenestrated and Branched Grafts, Gore Branched Technology

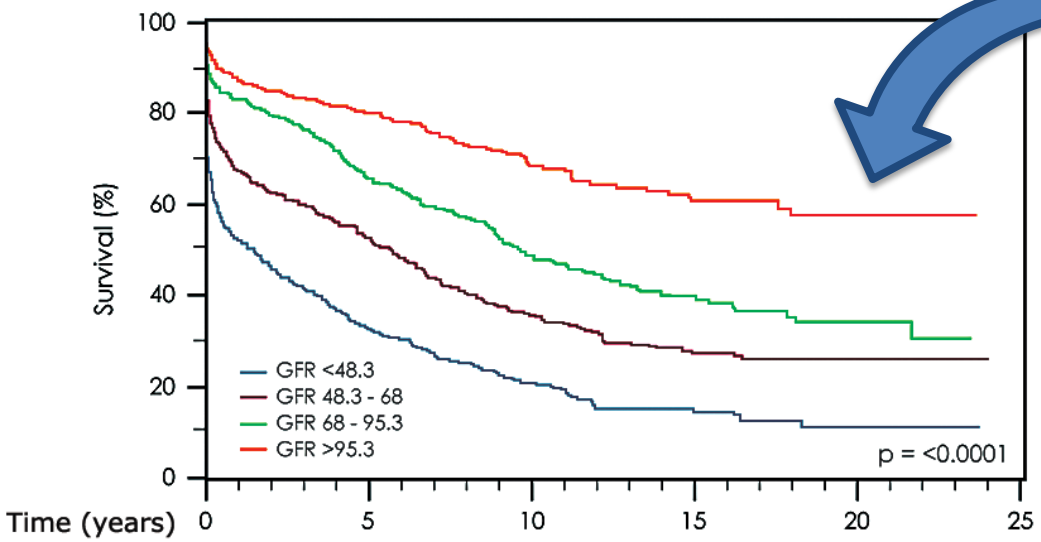
* All consulting fees and research educations grants paid to Mayo Clinic

1,896 TAAA REPAIRS

ASA Paper

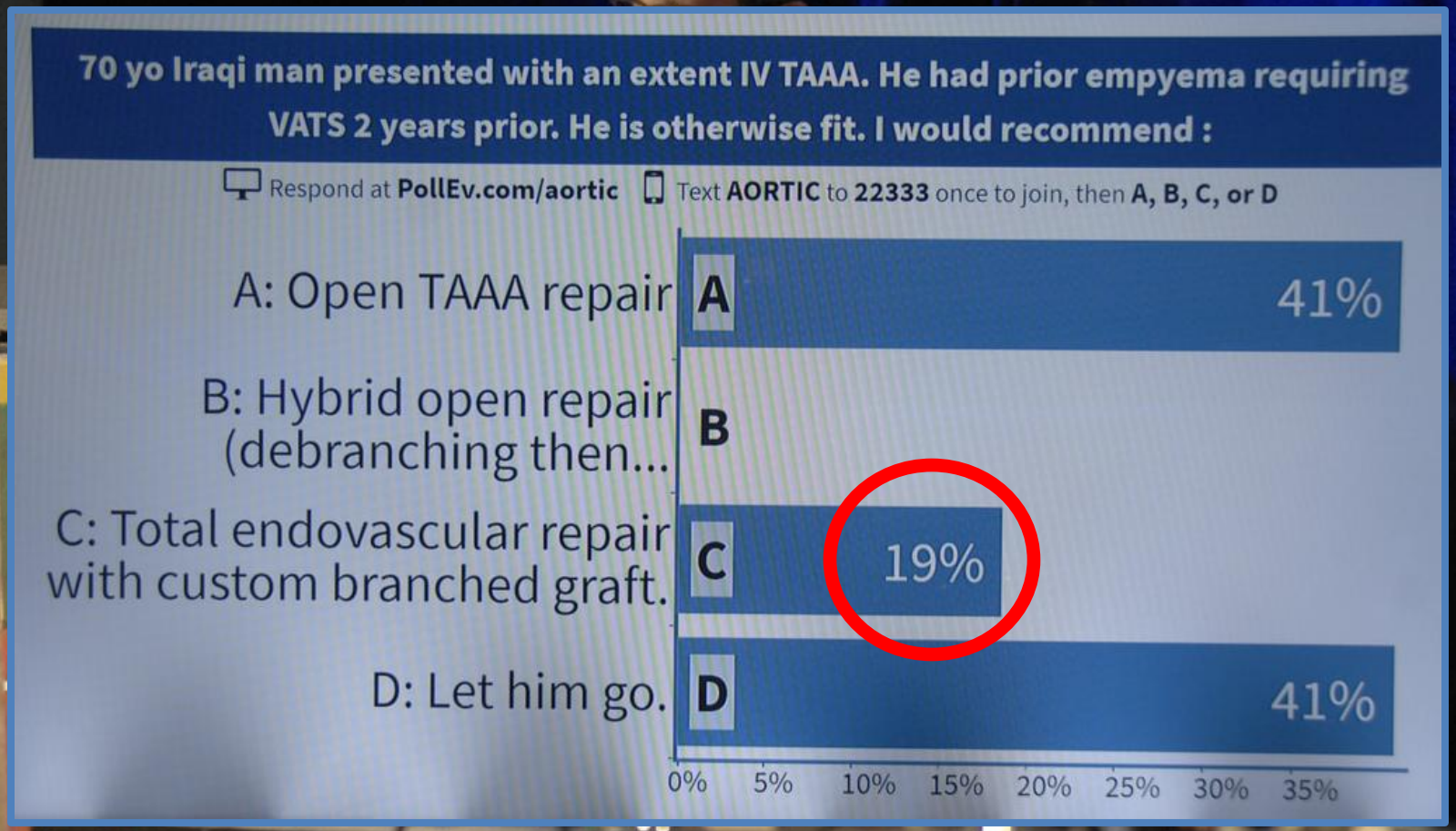
A Quarter Century of Organ Protection in Open Thoracoabdominal Repair

Anthony L. Estrera, MD, Harleen K. Sandhu, MD, MPH, Kristofer M. Charlton-Ouw, MD, Rana O. Afifi, MD, Ali Azizzadeh, MD, Charles C. Miller III, PhD, and Hazim J. Safi, MD



- Mean age, 64 years-old
- 30-day mortality:
  - All patients: 15.9%
  - Normal eGFR: 5.2%
- Major adverse events
  - Dialysis, 16.6%
  - Stroke, 5%
  - Spinal cord injury,9.6%

Estrera A (Safi H) et al. Ann Surg 2015;262(4):600-8


70 yo Iraqi man presented with an extent IV TAAA. He had prior empyema requiring VATS 2 years prior. He is otherwise fit. I would recommend :
Respond at PollEv.com/aortic
Text AORTIC to 22333 once to join, then A, B, C, or D
A: Open TAAA repair
A
41%
B: Hybrid open repair (debranching then...
B
C: Total endovascular repair with custom branched graft.
C
19%
D: Let him go.
D
41%
0%
5%
10%
15%
20%
25%
30%
35%

eTAAA REPAIR

Contemporary results of large aortic centers

Author, Year	n	IV/I-III	Mean age	30-day mortality	SCI	Paraplegia	Dialysis
Kasprzak et al (2014)	83	30/53	71	7.2%	20 %	13%	5%
Bisdas T et al (2015)	142	12/130	70	2.8%	16 %	8%	
Dias N et al (2015)	72	17/55	68	6.9%	31 %	21%	
Katsargyris et al (2015)	218	54/164	69	7.8%	10 %	2%	
Maurel et al (2015)	204	85/119	71	6.9%	4%	1%	5%
Eagleton et al (2016)	354	0/354	74	4.8%	9%	4%	3%
Fernandez et al (2016)	133	73/60	71	7.8%		5%	10%

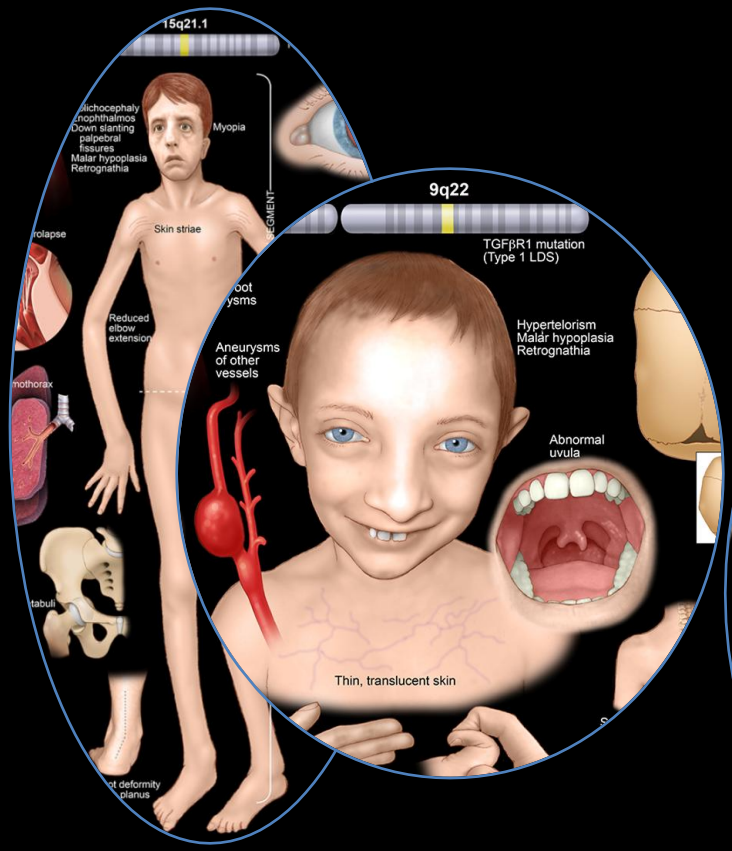
MOVING TARGET…

- Learning curve: patient selection and team experience
- Strategies to prevent spinal cord injury
- Changes in device design, delivery system, and bridging stents

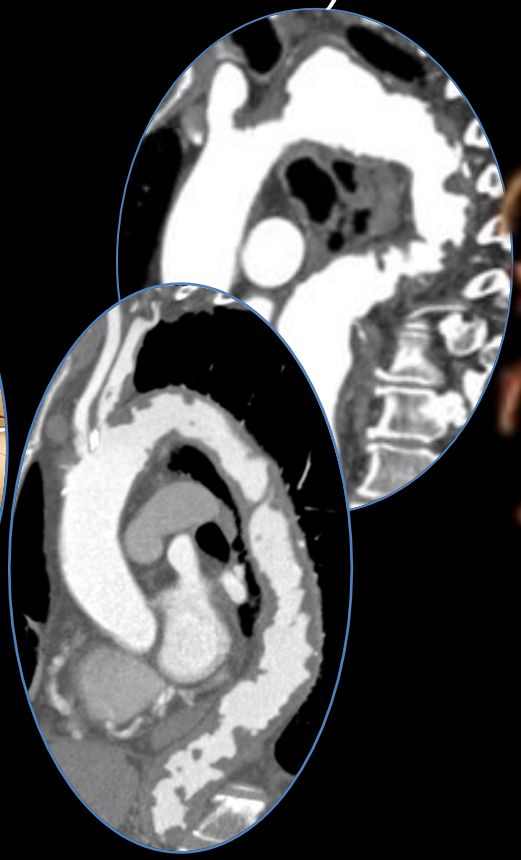
MAYO CLINIC

PATIENT SELECTION

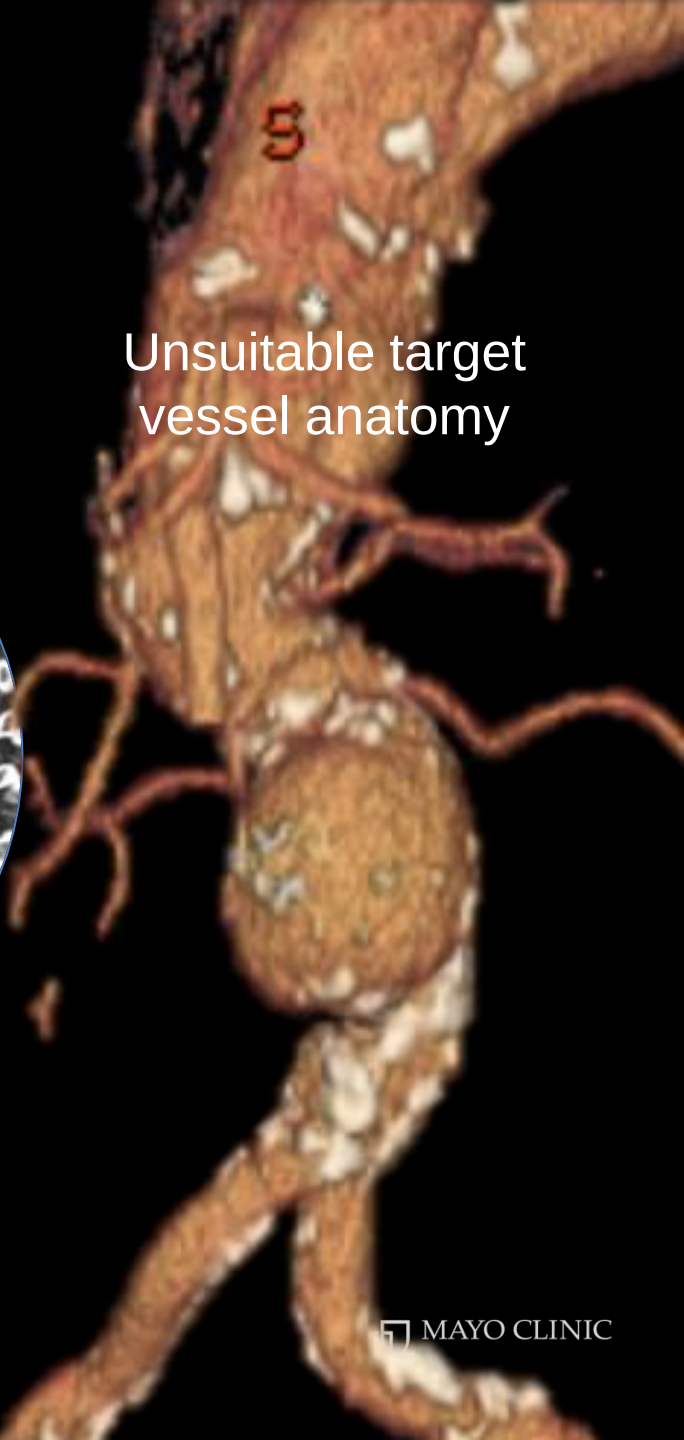
Genetically Triggered Aortic Diseases (GenTADs)



Excessive aortic debris ('Shaggy Aorta)



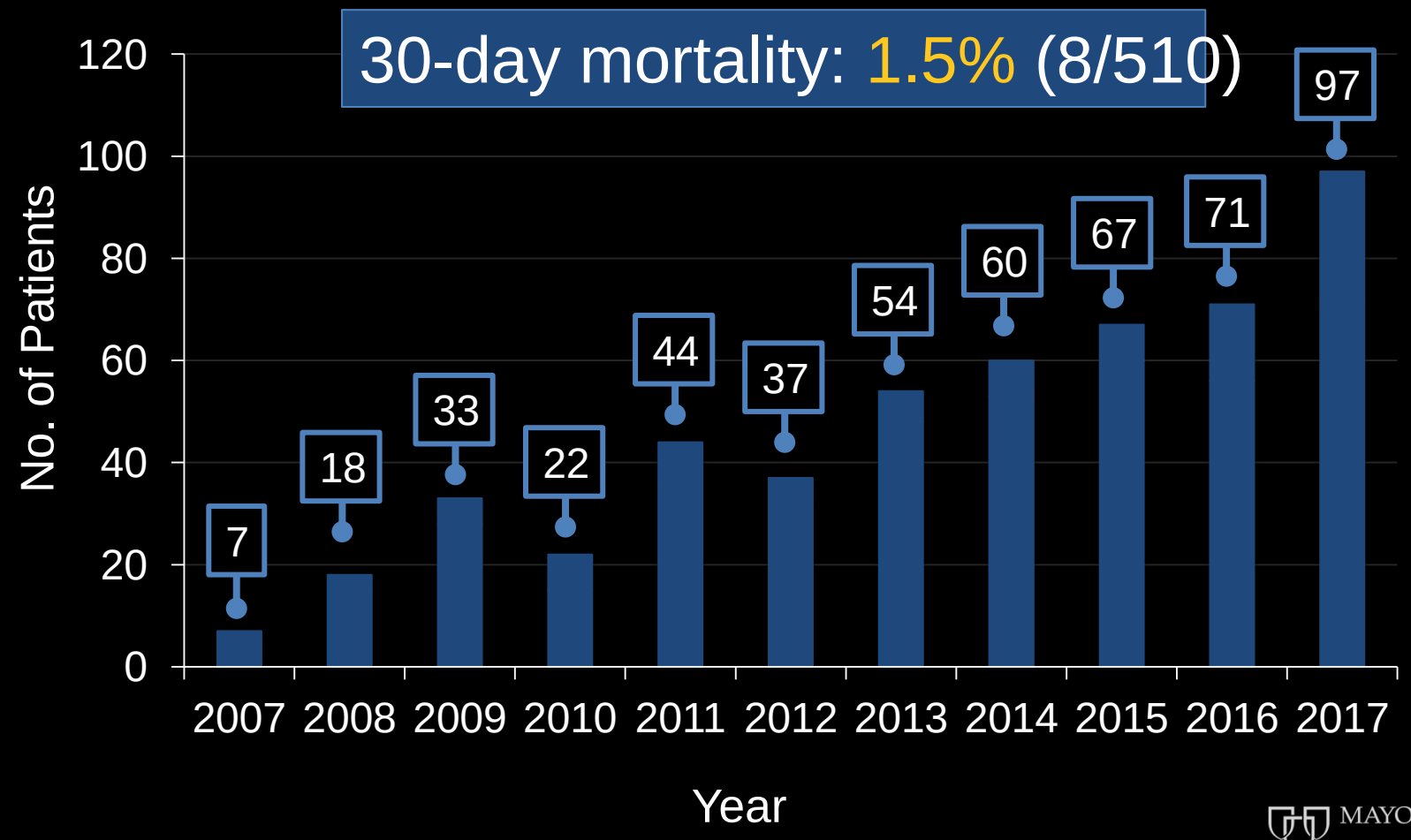
Unsuitable target vessel anatomy



MAYO CLINIC

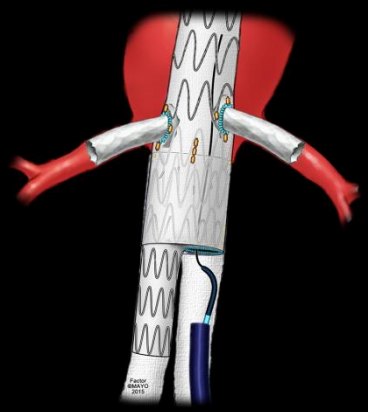
MAYO CLINIC F-BEVAR PROGRAM

510 consecutive patients (2007-2017)



MAYO CLINIC

LEARNING CURVE IN 334 PATIENTS TREATED BY FENESTRATED-BRANCHED ENDOVASCULAR REPAIR FOR COMPLEX AORTIC ANEURYSMS



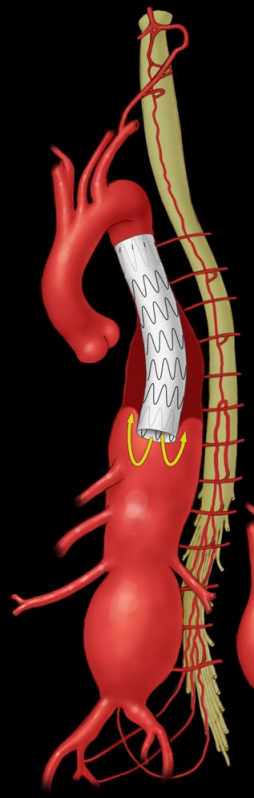
	All n = 334	Q1 n = 81	Q2 n = 84	Q3 n = 85	Q4 n = 84	P value
30 day mortality	2%	6%	2%	1%	0%	0.009
Any major adverse event	33%	58%	32%	21%	21%	<.001
30-day reinterventions	9%	9%	10%	6%	2%	<.001

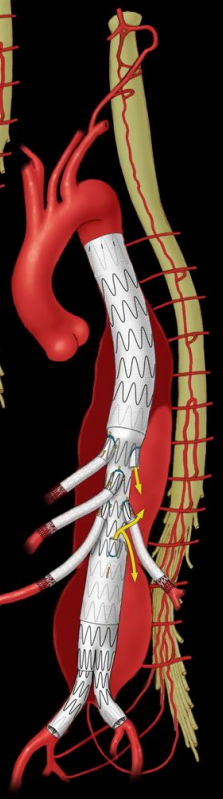
Oderich et al (unpublished data)

MOVING TARGET…

- Learning curve: patient selection and team experience
- Strategies to prevent spinal cord injury
- Changes in device design, delivery system, and bridging stents

MAYO CLINIC

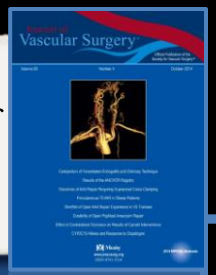




Proximal TEVAR

Staged endovascular repair of thoracoabdominal aortic aneurysms limits incidence and severity of spinal cord ischemia

Adrian O'Callaghan, MD, Tara M. Mastracci, MD, and Matthew J. Eagleton, MD, *Cleveland, Ohio*



	1-Stage	2-Stage	P
Any SCI	38%	11%	.02
Permanent	16%	0%	.03

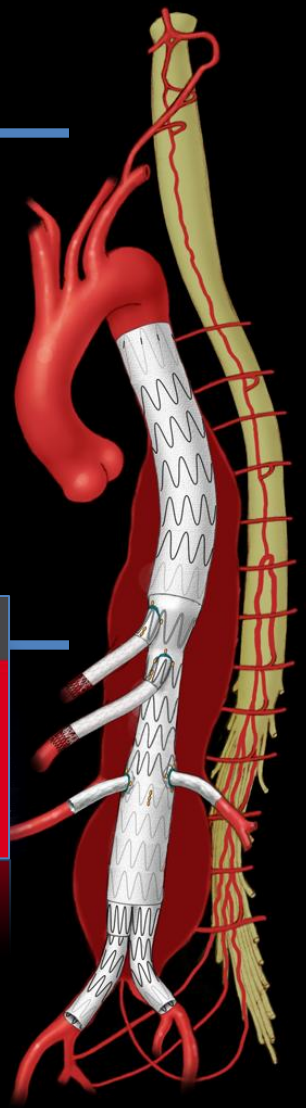
Perfusion branches

Editor's Choice — Temporary Aneurysm Sac Perfusion as an Adju
Prevention of Spinal Cord Ischemia After Branched Endovascular
Thoracoabdominal Aneurysms CME

P.M. Kasprzak *, K. Gallis, B. Cucuruz, K. Pfister, M. Janotta, R. Kopp

Department of Surgery, Vascular and Endovascular Surgery, University Hospital, University of Regensburg, Franz-Josef-Strauss-Allee 11, 93053

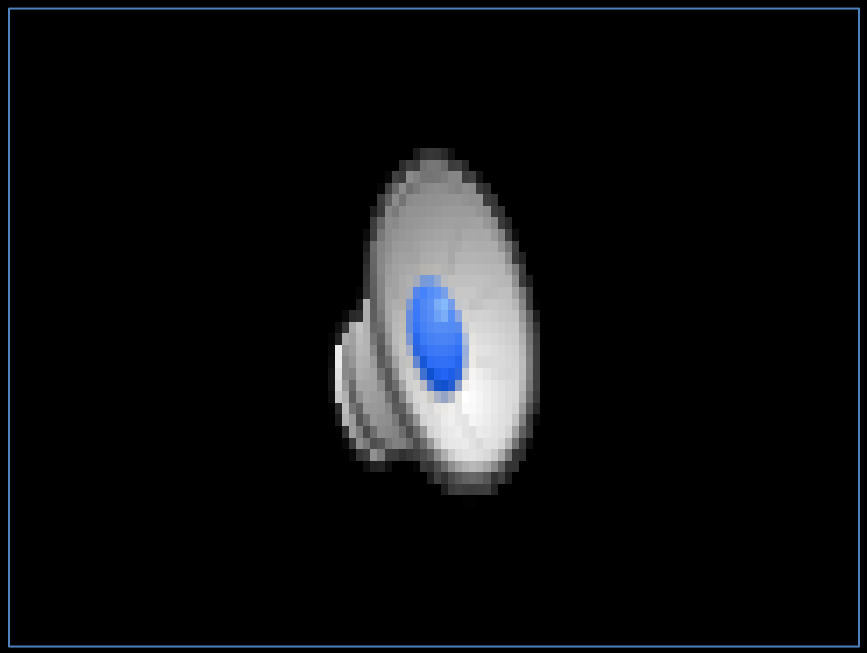
	No TASP	TASP	P
Any SCI	23%	13%	.001
Paraplegia	21%	3%	.02

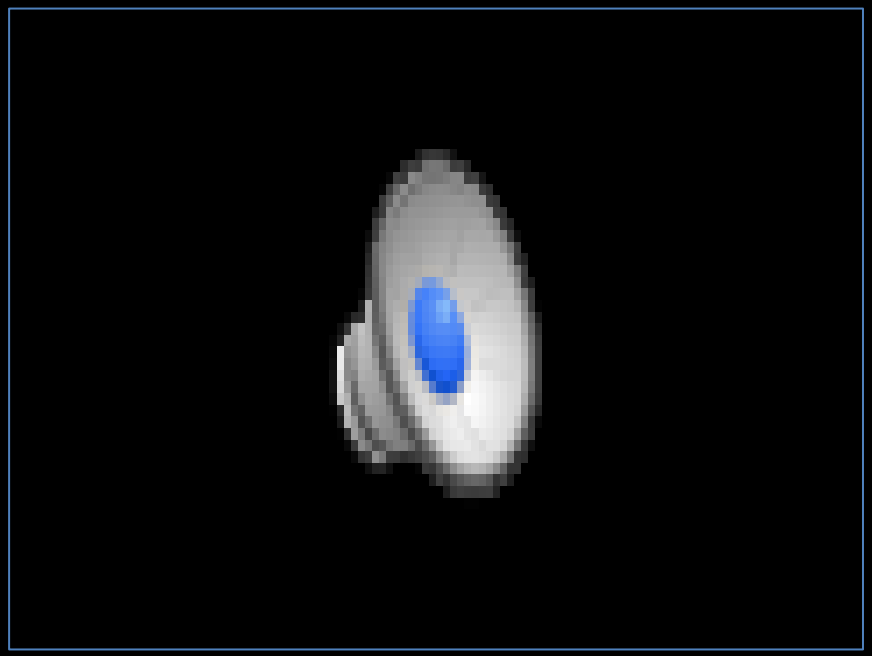


O'Callaghan A et al. J Vasc Surg 2015
Kasprzak et al. Eur J Vasc Endovasc Surg 2014

MAYO CLINIC

SPINAL CORD INJURY PREVENTION





- Staged aortic coverage
- Permissive hypertension
- CSF drainage 48-72 hours
- Neuromonitoring
- Early limb reperfusion
- Selective temporary sac perfusion (TASP)

MAYO CLINIC

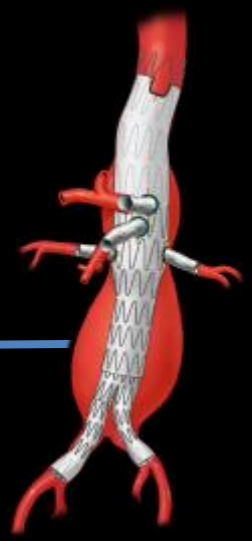
PATIENTS

274 patients enrolled (January 30th, 2018)

42 patients await device implantation

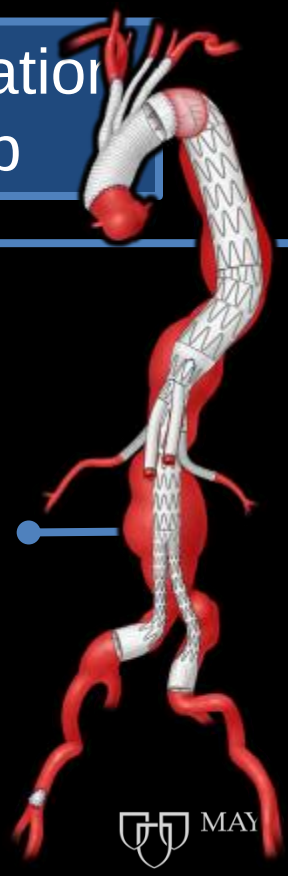
232 patients had implantation with > 30-day follow up

84 pararenal (36%)



62 Extent 4 TAAA (27%)

86 Extent 1-3 TAAA (37%)



MAYO CLINIC

30-DAY RESULTS

One (0.5%) 30-day or in-hospital death

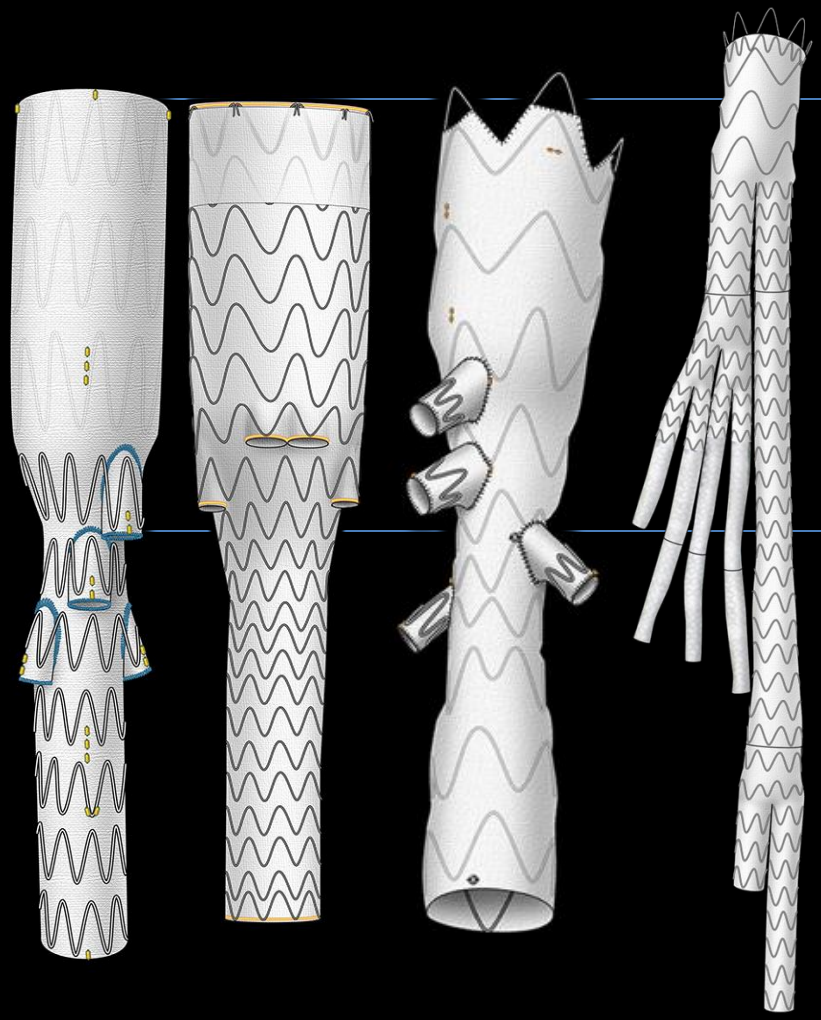
	Overall n = 232	Pararenal n = 84	Extent IV n = 62	Extent I-III n = 86	P value
	Percent				
Any MAE	53 (23)	17 (20)	16 (26)	20 (23)	0.72
EBL >1L	20 (9)	4 (5)	5 (8)	11 (13)	0.17
↓ eGFR >50%	18 (8)	5 (6)	8 (13)	5 (6)	0.20
New-onset dialysis	3 (1)	1 (1)	1 (2)	1 (1)	0.96
Myocardial infarction	10 (4)	4 (5)	5 (8)	1 (1)	0.12
Respiratory failure	5 (2)	1 (1)	2 (3)	2 (2)	0.69
Any Spinal Cord Injury	10 (4)	1 (1)	0	9 (10)	0.05
Permanent Paraplegia	2 (1)	1 (1)	0	1 (1)	0.69
Major stroke	2 (1)	1 (1)*	1 (2)	0	0.53
Bowel ischemia	4 (2)	3 (4)	1 (2)	0	0.2

* Hemorrhagic, spinal drain-related

MOVING TARGET…

- Learning curve: patient selection and team experience
- Strategies to prevent spinal cord injury
- Changes in device design, delivery system, and bridging stents

STENT DESIGNS



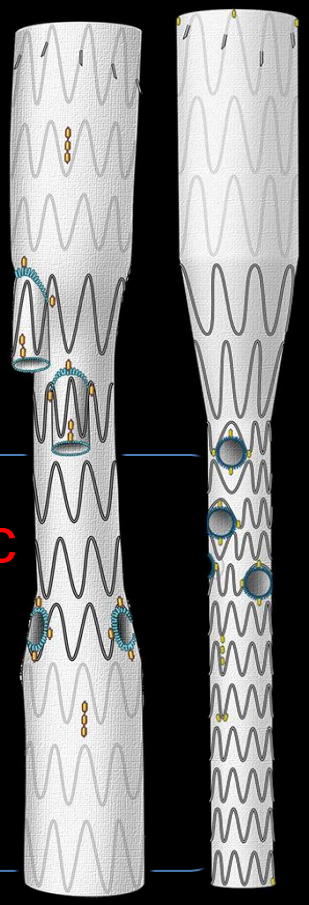
Off-the-Shelf

Cook t-Branch®

Gore TAMBE®

Medtronic

Jotec

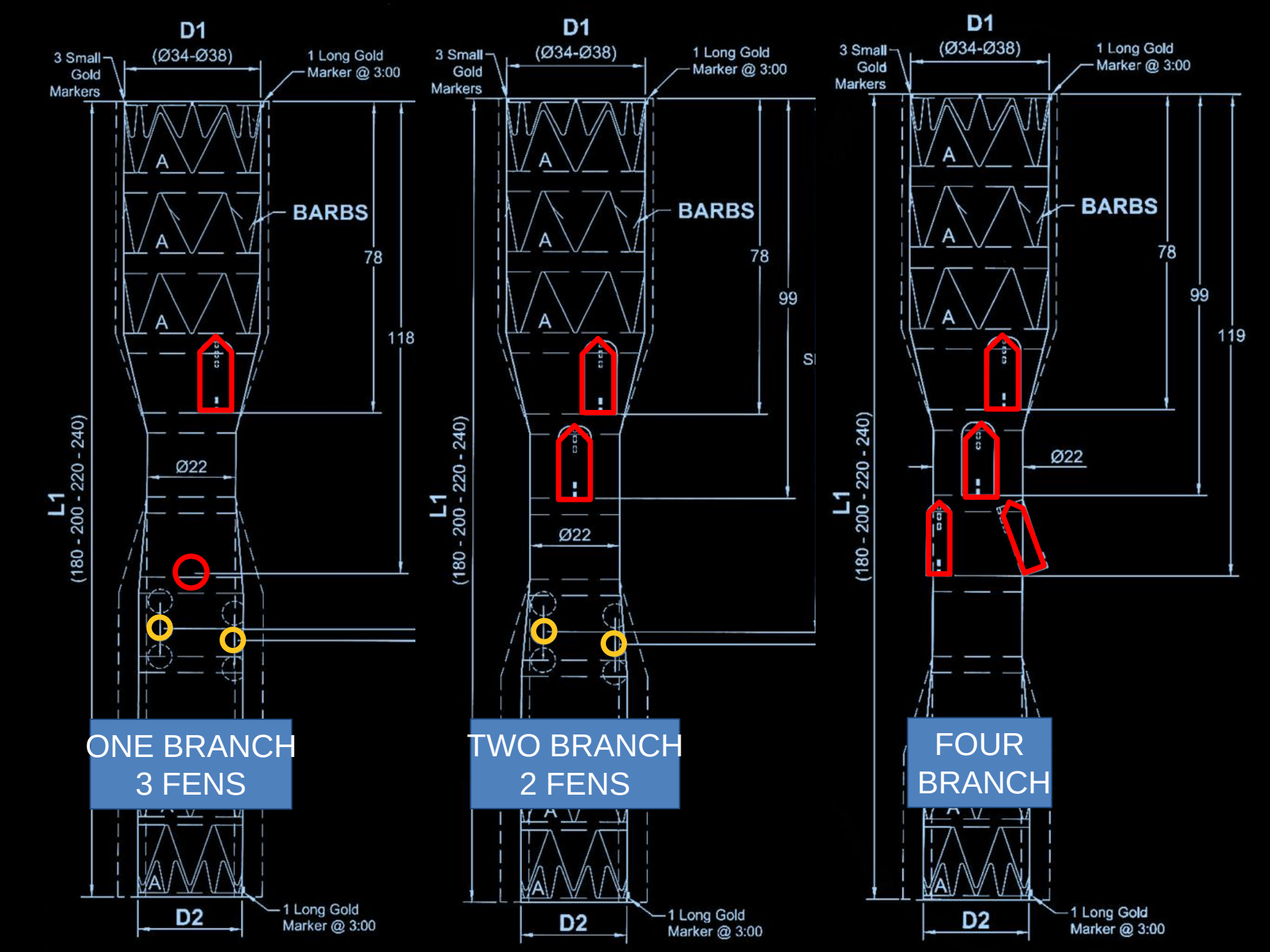


Patient Specific

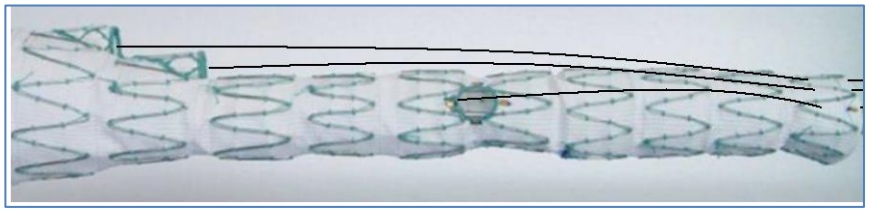
Cook platform

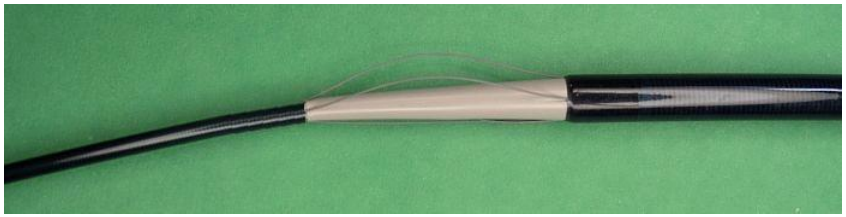
- Any design with fenestrations ± branches

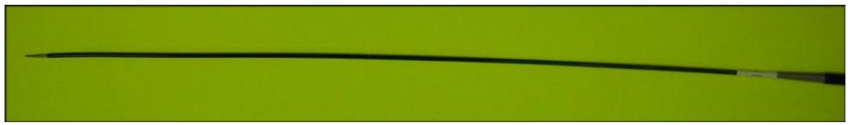
MAYO CLINIC

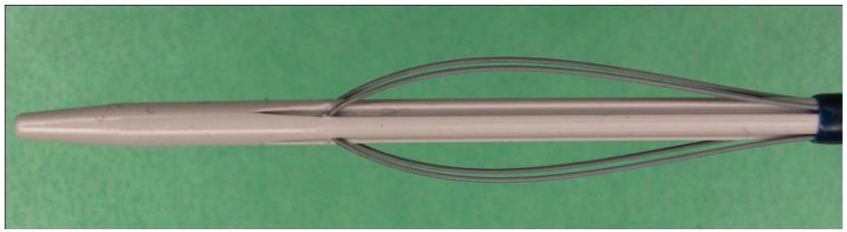

D1
(Ø34-Ø38)
3 Small Gold Markers
1 Long Gold Marker @ 3:00
A
BARBS
78
118
L1
(180 - 200 - 220 - 240)
Ø22
D2
1 Long Gold Marker @ 3:00
ONE BRANCH
3 FENS
D1
(Ø34-Ø38)
3 Small Gold Markers
1 Long Gold Marker @ 3:00
A
BARBS
78
99
L1
(180 - 200 - 220 - 240)
Ø22
D2
1 Long Gold Marker @ 3:00
TWO BRANCH
2 FENS
D1
(Ø34-Ø38)
3 Small Gold Markers
1 Long Gold Marker @ 3:00
A
BARBS
78
99
119
L1
(180 - 200 - 220 - 240)
Ø22
D2
1 Long Gold Marker @ 3:00
FOUR
BRANCH

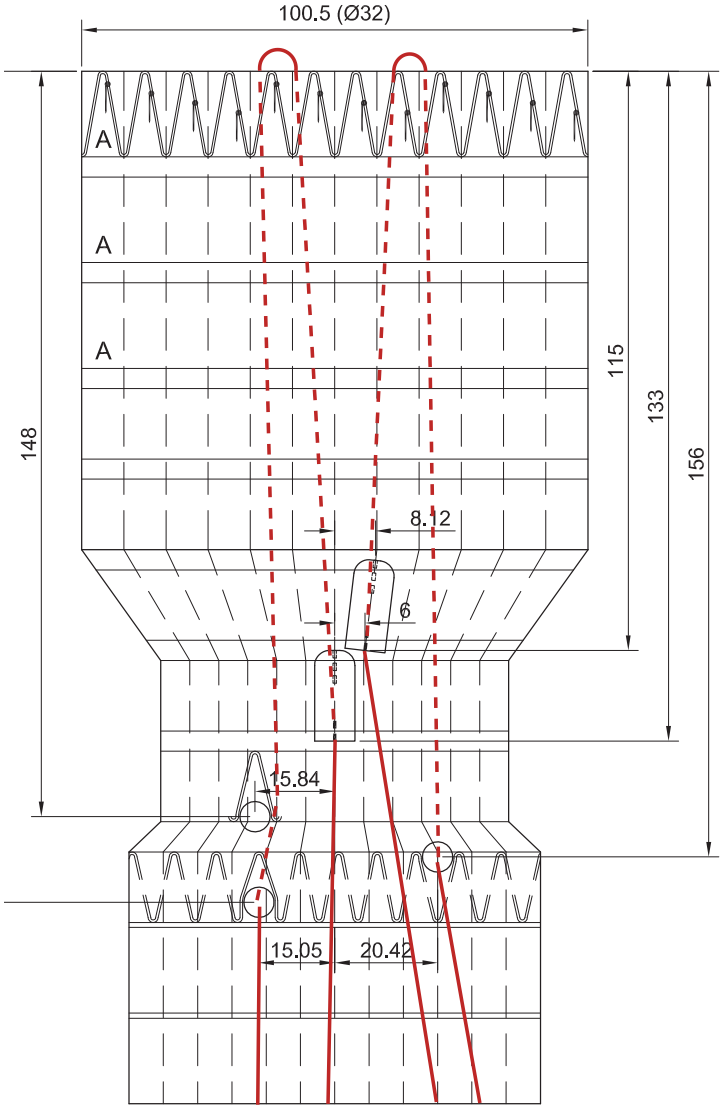
PRE-LOADED WIRE SYSTEM

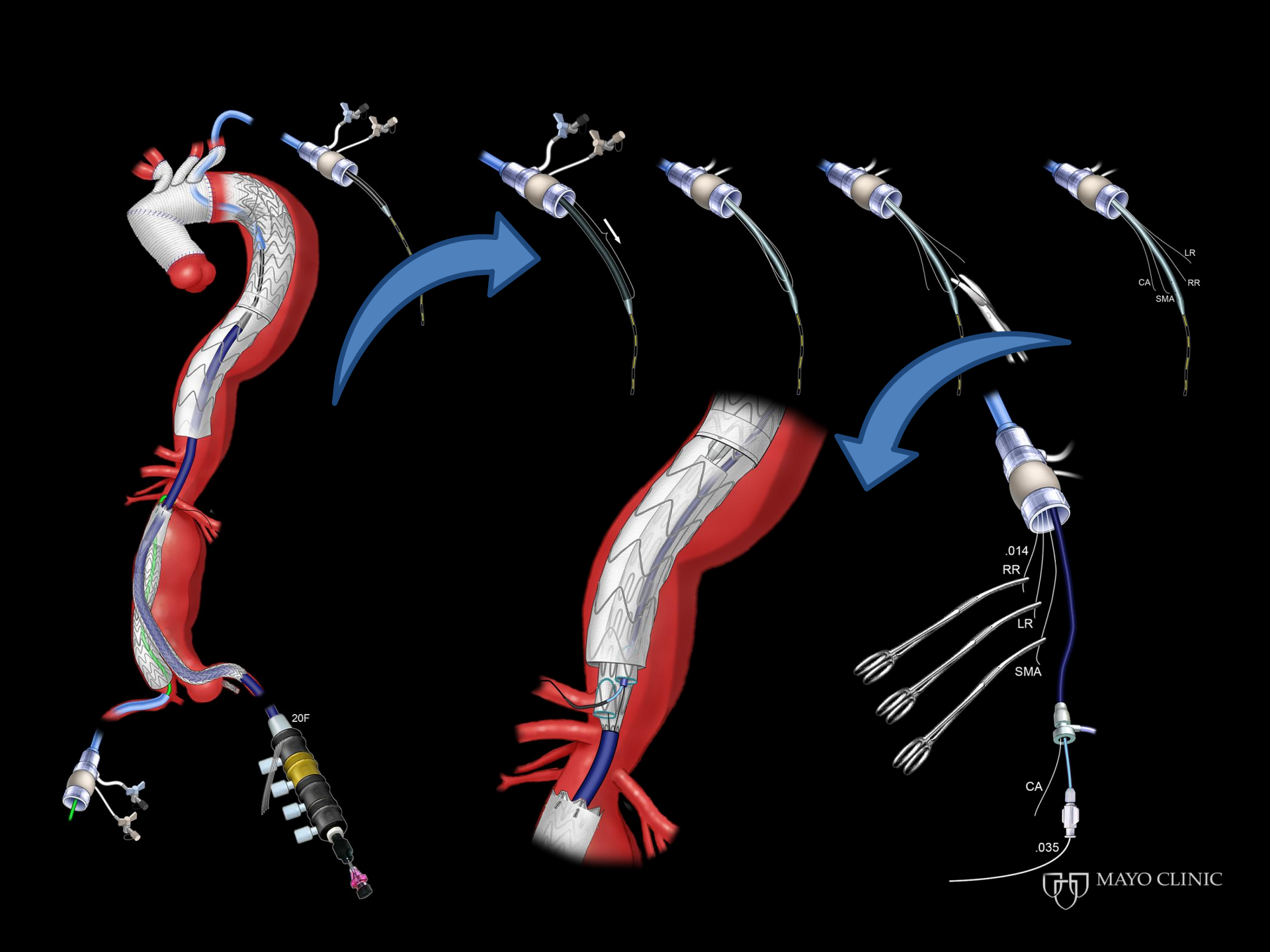











20F
LR
RR
CA
SMA
.014
RR
LR
SMA
CA
.035
MAYO CLINIC

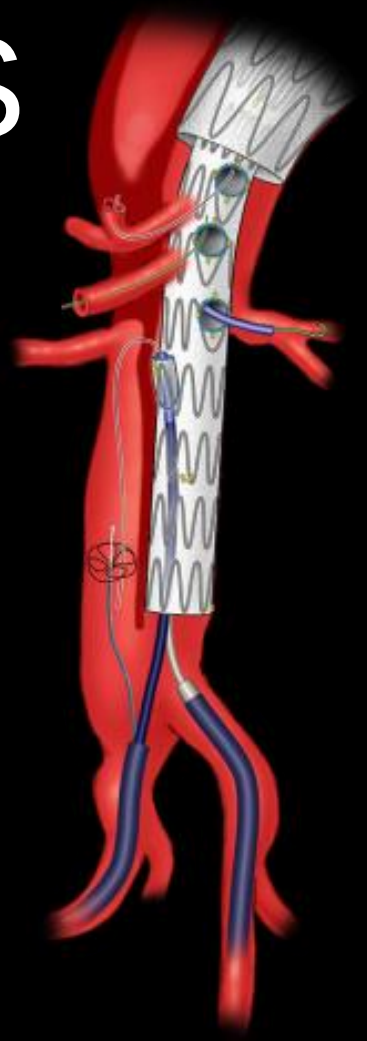
VBX® BALLOON EXPANDABLE STENT

	Viabahn	VBX
Length	5, 7.5, 10-cm	39, 59, 79 mm
Diameter	6-9 mm	5-9 mm
Sheath profile	7-9 Fr	7-8 Fr

MAYO CLINIC

What are the **state-of-the-art results**…after overcoming the learning curve of F-BEVAR?

UNITED STATES FENESTRATED-BRANCHED RESEARCH CONSORTIUM

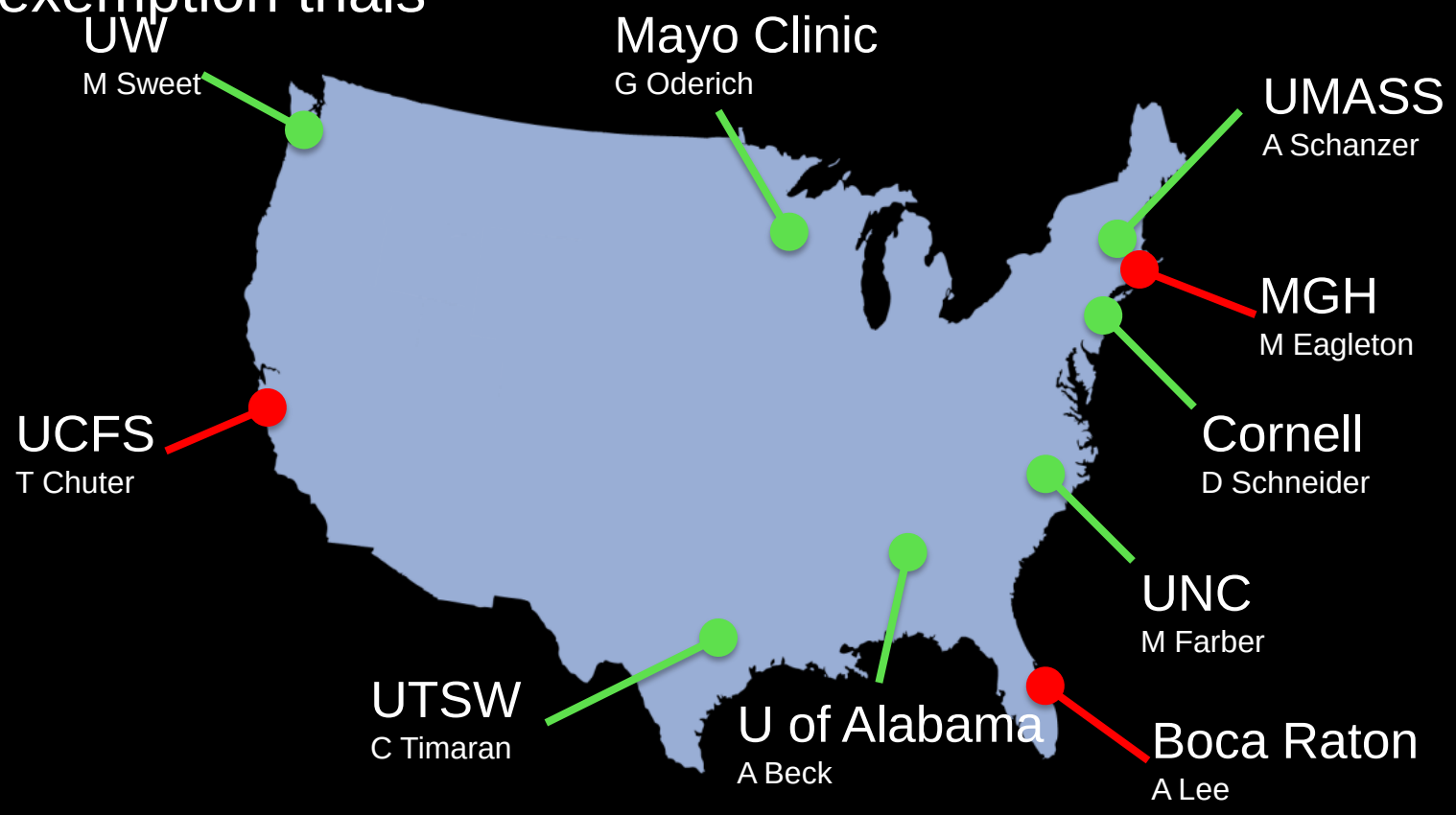


HAS2018
THE HOUSTON AORTIC SYMPOSIUM

Manuscript in preparation (unpublished data)

MAYO CLINIC

- 10 ongoing prospective, non-randomized physician-sponsored investigational device exemption trials



US IDE CONSORTIUM

- Prospective, non-randomized PS-IDE study
  - External auditing, FDA auditing
  - Clinical Event Committee/ DSMB
  - Independent radiological review of imaging
- Off-the-shelf or patient-specific fenestrated/ branched endograft devices
- Modern, preloaded, lower-profile designs
- Novel bridging stent-grafts (Viabahn, VBX)
- Does not include “learning curve”
- Large numbers in shorter period (True ‘state-of-the-art’ contemporary experience)

MAYO CLINIC

2018 VASCULAR ANNUAL MEETING
JUNE 20–23
VSweb.org/VAM18
SVS Society for Vascular Surgery

Branch Vessel Durability After Branched and Fenestrated Endovascular Repair of Pararenal and Thoracoabdominal Aortic Aneurysms in the US IDE Experience

Darren B. Schneider MD[1], Mark A. Farber MD[2], Andres Schanzer MD[3], Adam Beck MD[4], Carlos H. Timaran MD[5], Matthew P. Sweet MD[6], Emanuel Tenorio MD, PhD[7] and Gustavo S. Oderich MD[7]
On behalf of the US Branched and Fenestrated IDE Consortium

Outcomes of endovascular repair of post-dissection and degenerative thoracoabdominal aortic aneurysms using fenestrated-branched stent-grafts

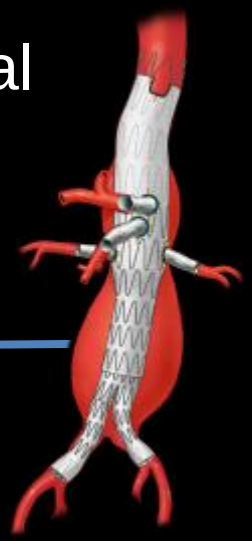
Emanuel Tenorio MD, PhD[1], Gustavo S. Oderich MD[1], Mark Farber MD[2], Darren B. Schneider MD[3], Carlos Timaran MD[4], Andres Schanzer MD[5], Adam Beck MD[6], Matthew Sweet MD[7]
On behalf of the United States Fenestrated-Branched Research Consortium

PATIENTS

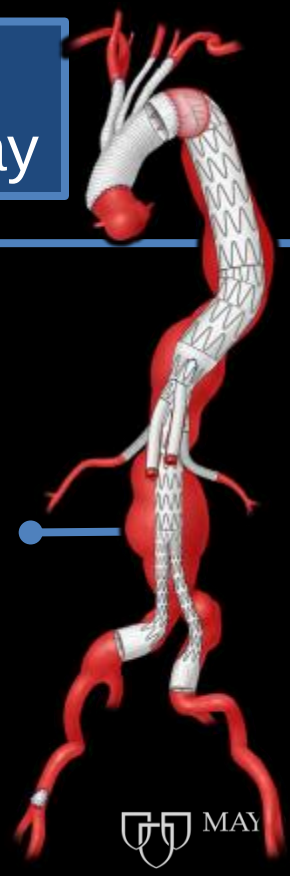
661 patients enrolled (January 1st, 2018)

All patients had implantation with > 30-day follow up

232 pararenal (36%)



221 Extent 4 TAAA (33%)



208 Extent 1-3 TAAA (31%)

MAYO CLINIC

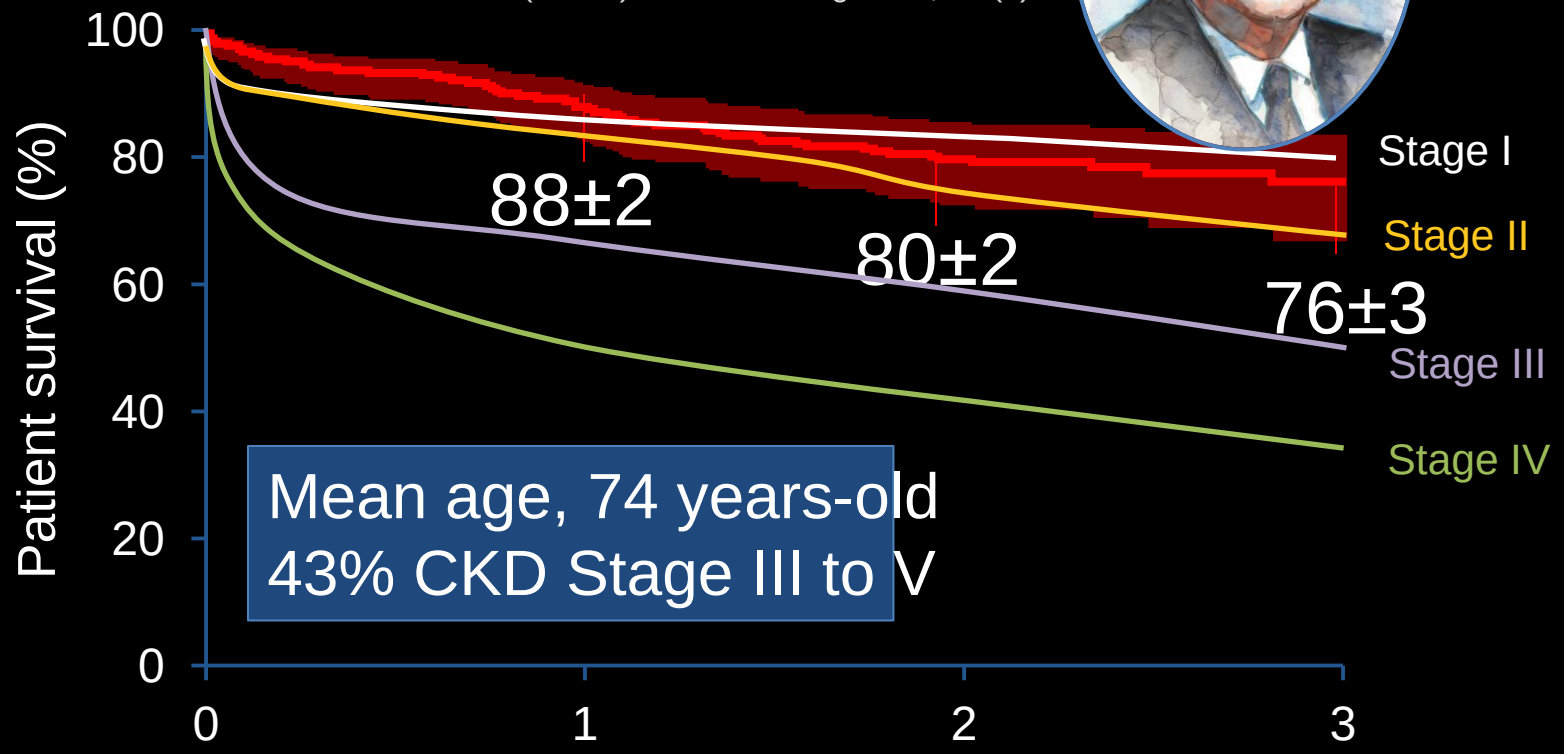
	Overall n = 661	Pararenal n = 232	Extent IV n = 221	Extent I-III n = 208	P value
	n (Percent) or Mean ± Standard Deviation				
Mean age (years ± SD)	73±8	75±7	72±8	73±8	<0.001
Age > 80 years old	148 (23)	74 (32)	34 (15)	40 (19)	<0.001
Male gender	465 (70)	181 (78)	170 (77)	114 (55)	<0.001
Cigarette smoking	500 (76)	169 (73)	181 (82)	150 (72)	0.03
Hypertension	605 (92)	206 (89)	217 (90)	199 (96)	0.02
Hypercholesterolemia	476 (80)	173 (75)	155 (79)	148 (71)	0.54
Coronary artery disease	321 (49)	115 (50)	119 (54)	87 (42)	0.04
Chronic pulmonary disease	282 (43)	96 (41)	91 (41)	95 (46)	0.57
Chronic Kidney Disease III-V	283 (44)	97 (43)	98 (46)	88 (43)	0.93
Congestive heart failure	91 (14)	27 (12)	34 (15)	30 (14)	0.48
Prior aortic repair	288 (44)	57 (25)	91 (41)	140 (68)	<0.001
Diabetes mellitus	92 (14)	34 (15)	32 (14)	26 (13)	0.77
Stroke	77 (12)	27 (12)	26 (12)	24 (12)	0.99
Chronic Dissection TAAA	38 (6)	0	7 (3)	31 (15)	<0.001

30-DAY OUTCOMES

	Overall n = 661	Pararenal n = 232	Extent IV n = 221	Extent I-III n = 208	P value
	n (Percent)				
Any Mortality	13 (2)	3 (1)	5 (2)	5 (2)	0.82
Any MAE	97 (15)	26 (11)	33 (15)	38 (18)	0.11
EBL >1L	29 (5)	6 (3)	9 (4)	14 (7)	0.10
Acute Kidney injury	36 (5)	7 (3)	14 (6)	15 (7)	0.11
Myocardial infarction	12 (2)	4 (2)	7 (3)	1 (0.4)	0.11
Respiratory failure	20 (3)	2 (1)	10 (5)	8 (4)	0.053
Paraplegia	11 (2)	1 (0.4)	1 (0.4)	9 (4)	<0.001
Stroke	12 (2)	3 (1)	4 (2)	5 (2)	0.68
Bowel ischemia	22 (3)	5 (2)	10 (5)	7 (3)	0.37

PATIENT SURVIVAL

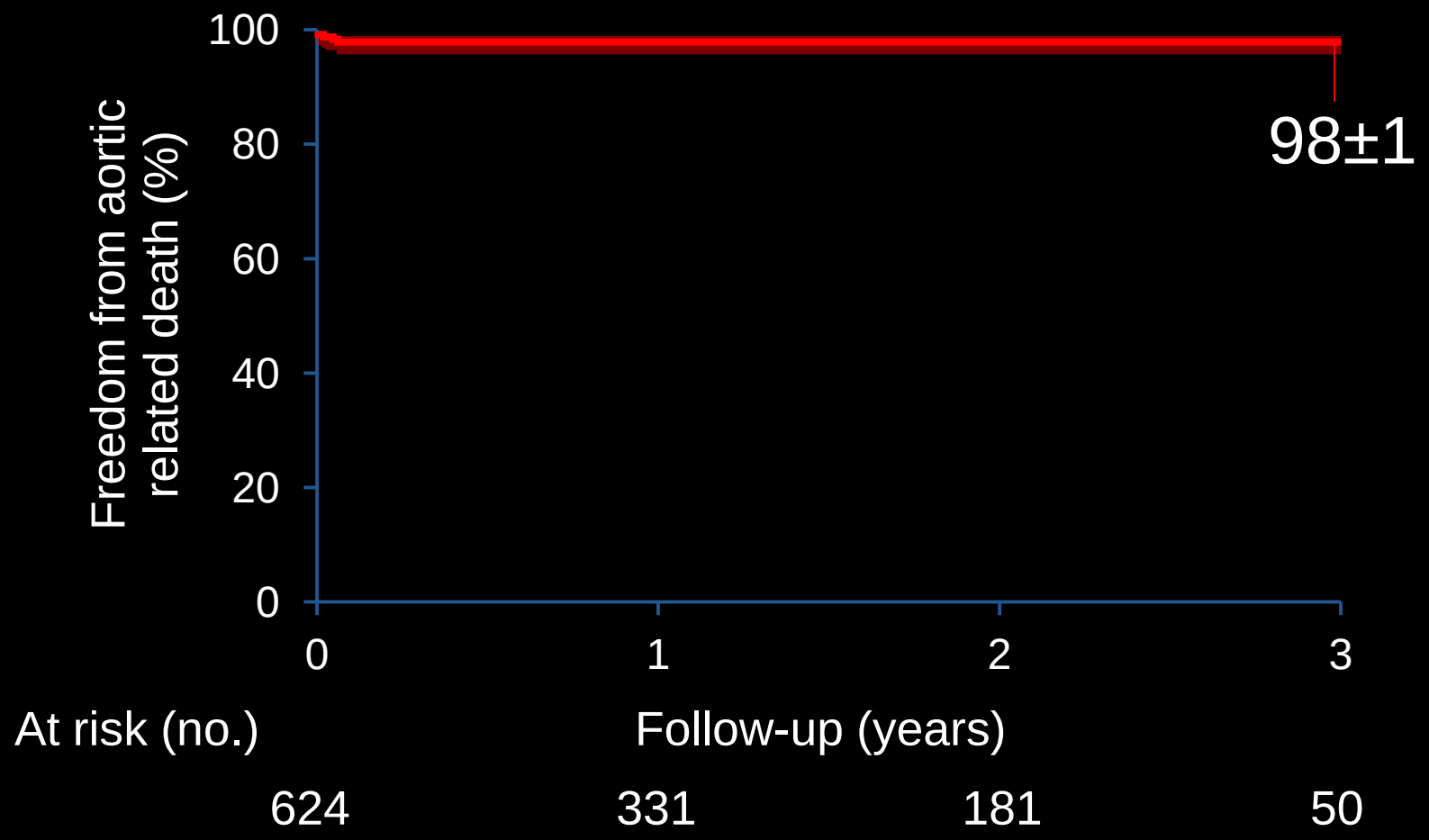
Estrera A (Safi H) et al. Ann Surg 2015;262(4):600-8



At risk (no.)			
623	331	181	50

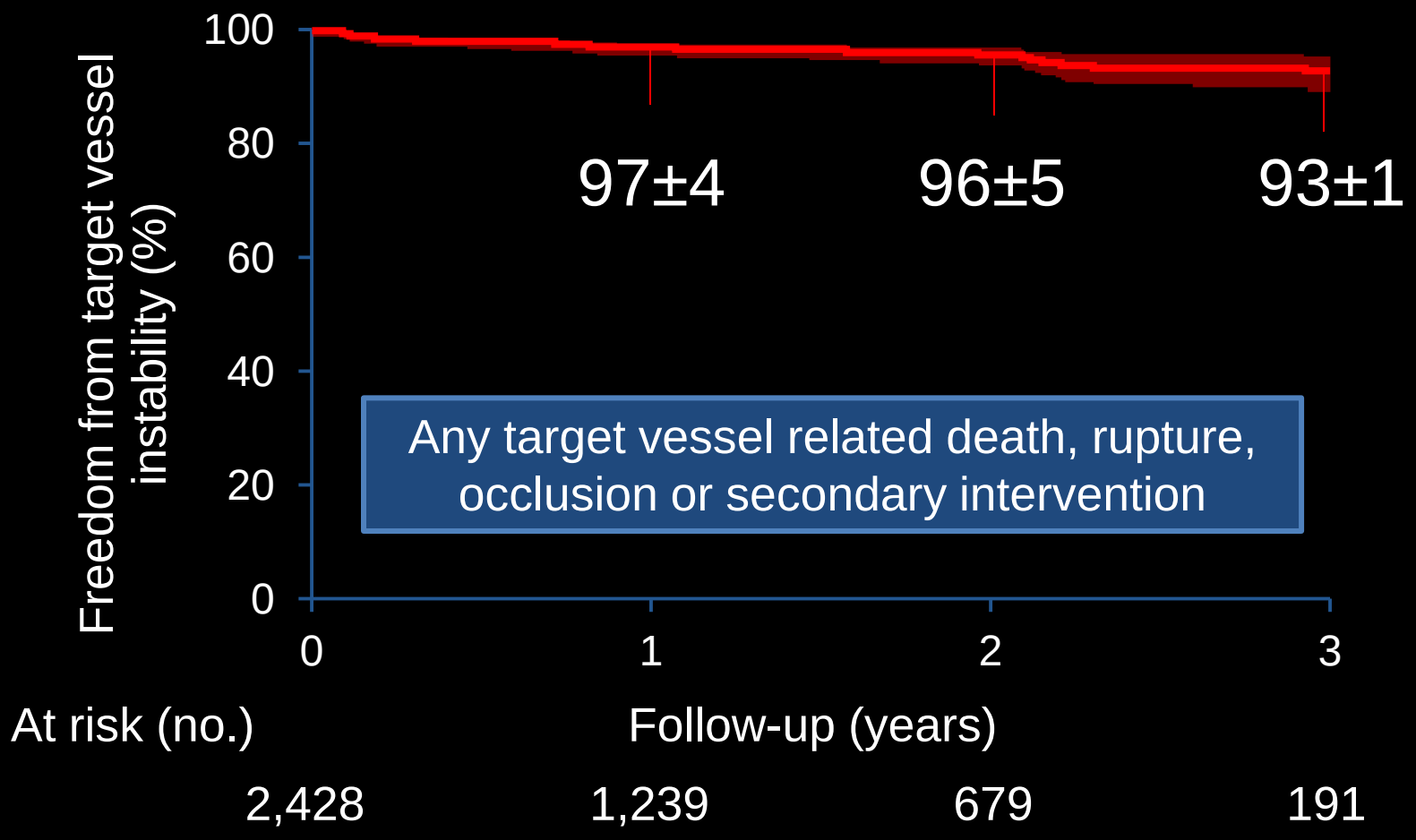
MAYO CLINIC

AORTIC RELATED DEATH



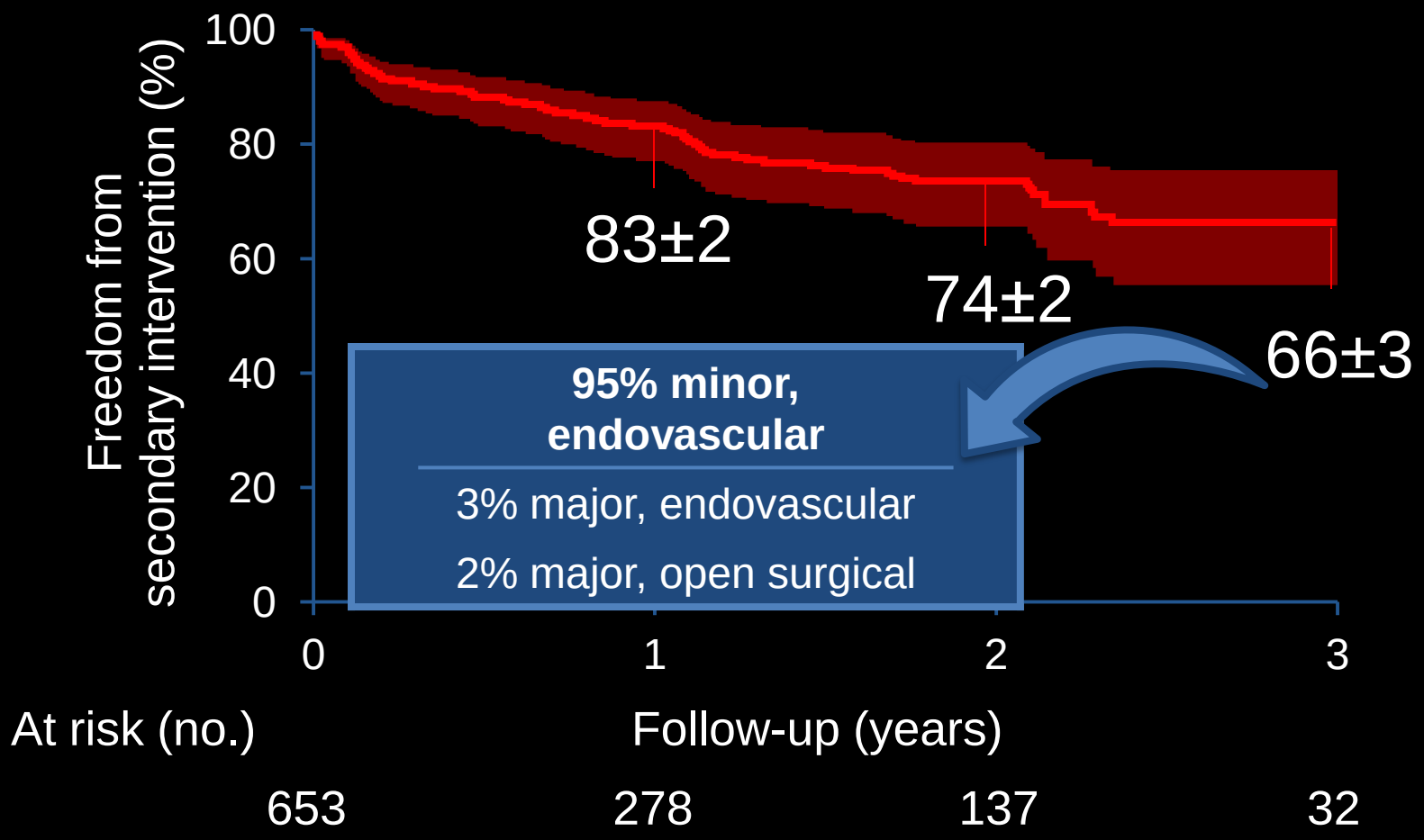
MAYO CLINIC

TARGET VESSEL INSTABILITY



MAYO CLINIC

SECONDARY INTERVENTIONS



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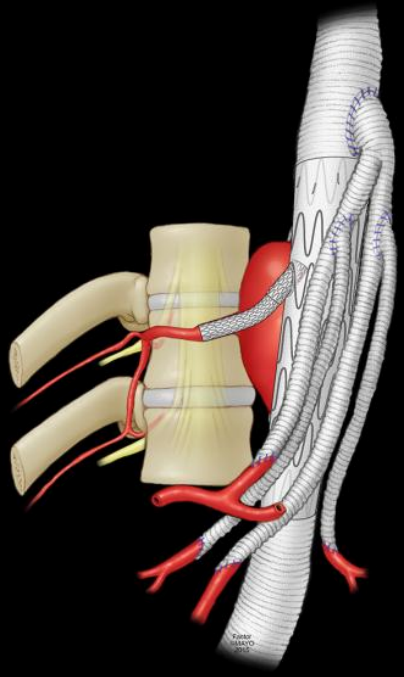
TREATMENT TRENDS & OUTCOMES OF OPEN VERSUS ENDOVASCULAR TAAA REPAIR IN A SINGLE CENTER

Ying Huang MD PhD, Gustavo S. Oderich MD, Mauricio Ribeiro MD PhD, Thomas C. Bower MD, Alberto Pochetino MD, Manju Kalra MBBS, Randall DeMartino MD, Stephen Cha MS and Peter Gloviczki MD



ESVS2016

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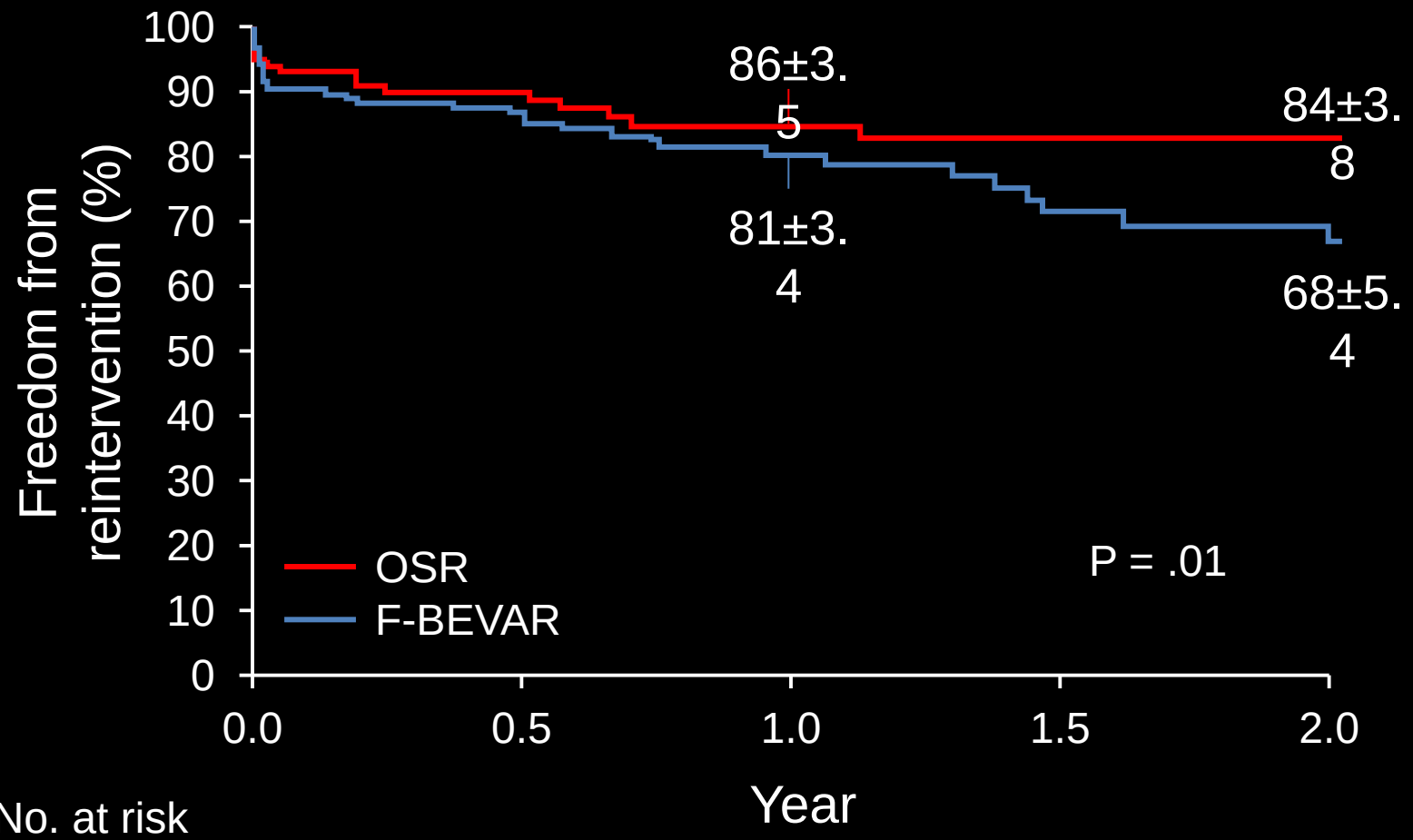
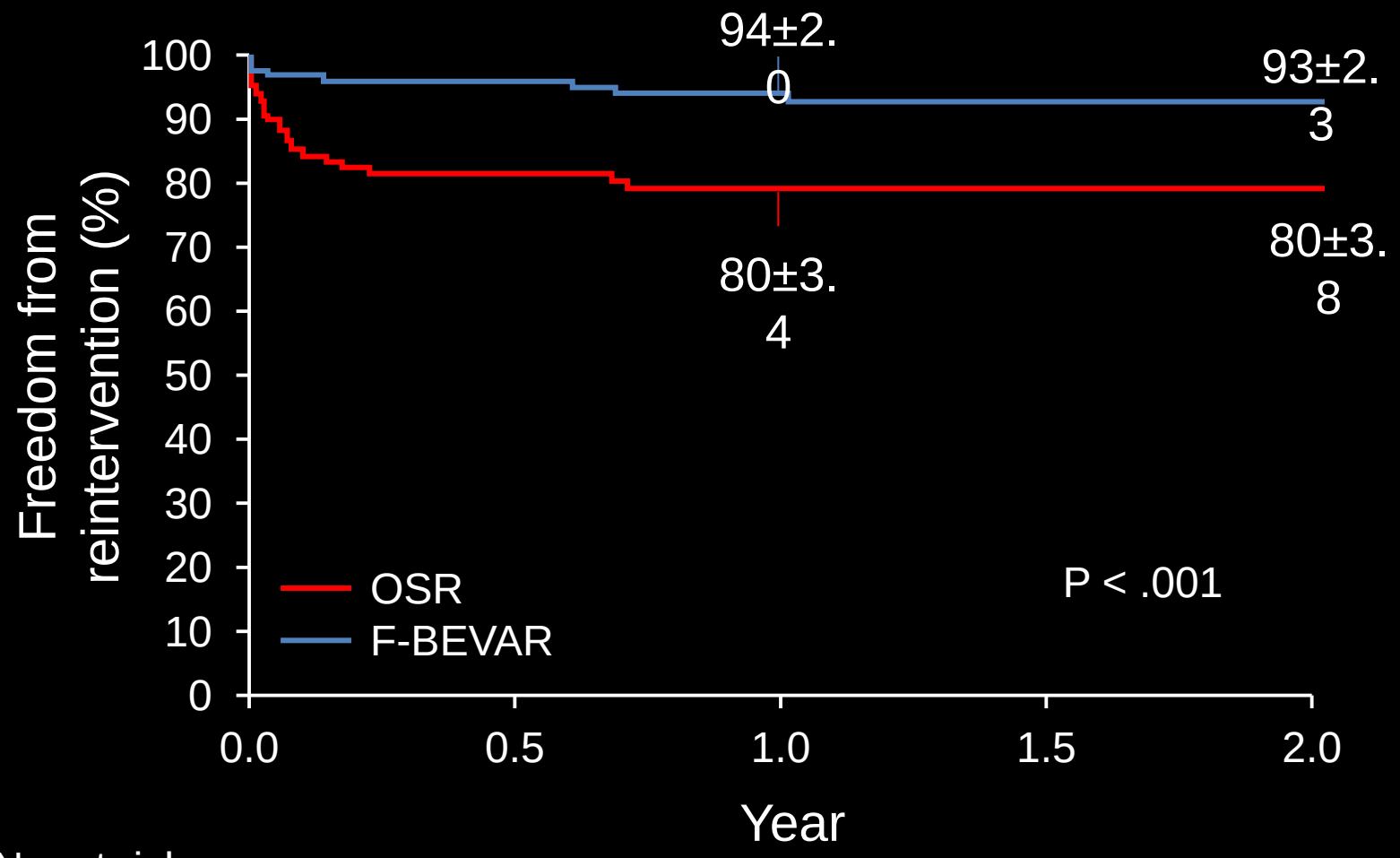
AORTIC REINTERVENTION



No. at risk			
OSR	127	58	39
F-BEVAR	160	63	26

MAYO CLINIC

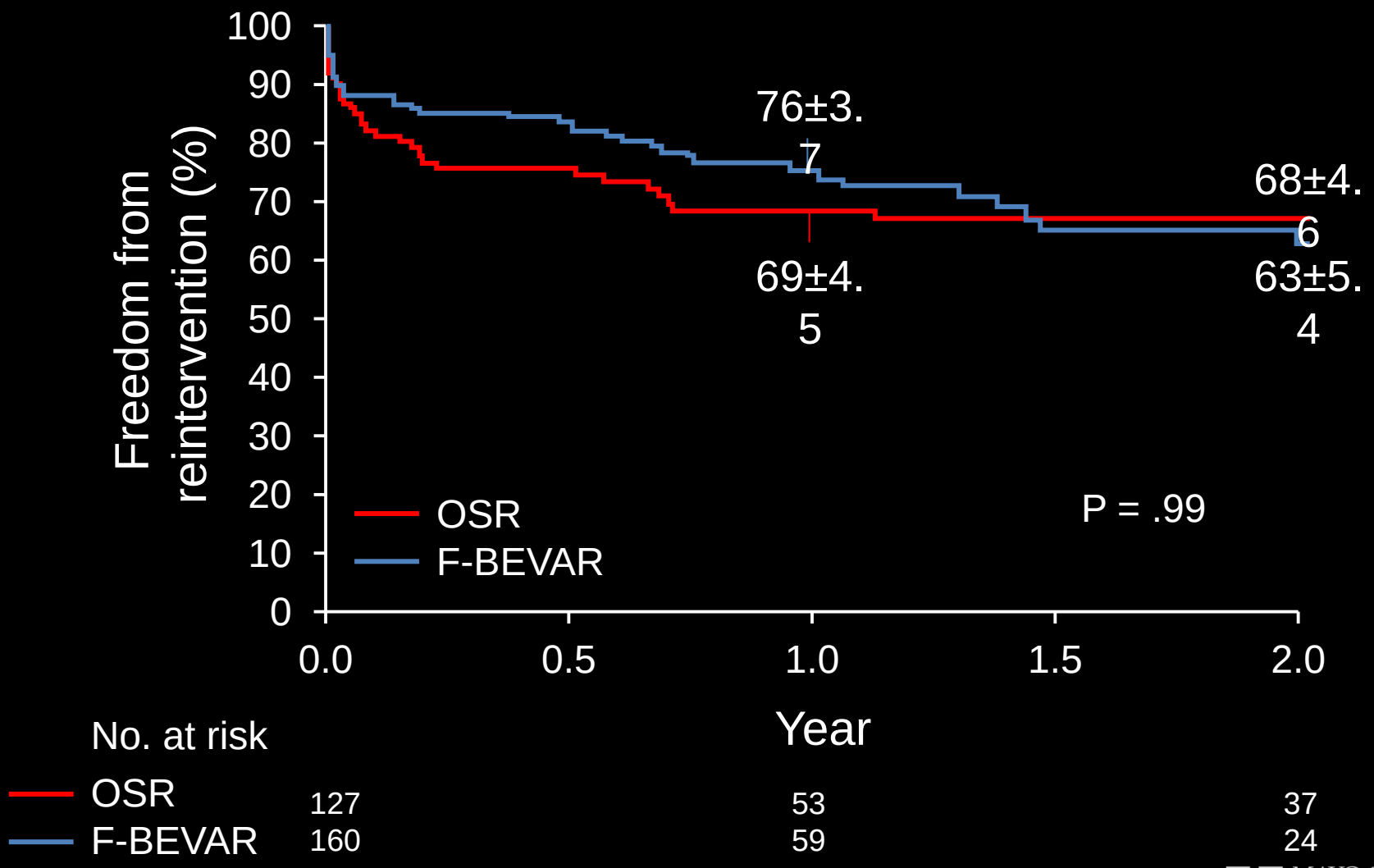
NON-AORTIC REINTERVENTION



No. at risk			
OSR	127	61	44
F-BEVAR	160	72	31

MAYO CLINIC

ANY REINTERVENTION



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CONCLUSIONS

- Outcomes of eTAAA repair continue to improve as a reflection of team experience and adoption of specific protocols to prevent spinal cord injury
- The technique is safe, effective, and has the po nd m
- Im e, need for optimal imaging and familiarity with advanced endovascular techniques

- Unquestionably, a 71-year Iraqi male with a large TAAA and suitable anatomy should have endo TAAA repair, and not an open repair…


MAYO CLINIC
150
Years
SERVING HUMANITY