CONTROVERSES ET ACTUALITES EN CHIRURGIE VASCULAIRE

CONTROVERSIES & UPDATES IN VASCULAR SURGERY

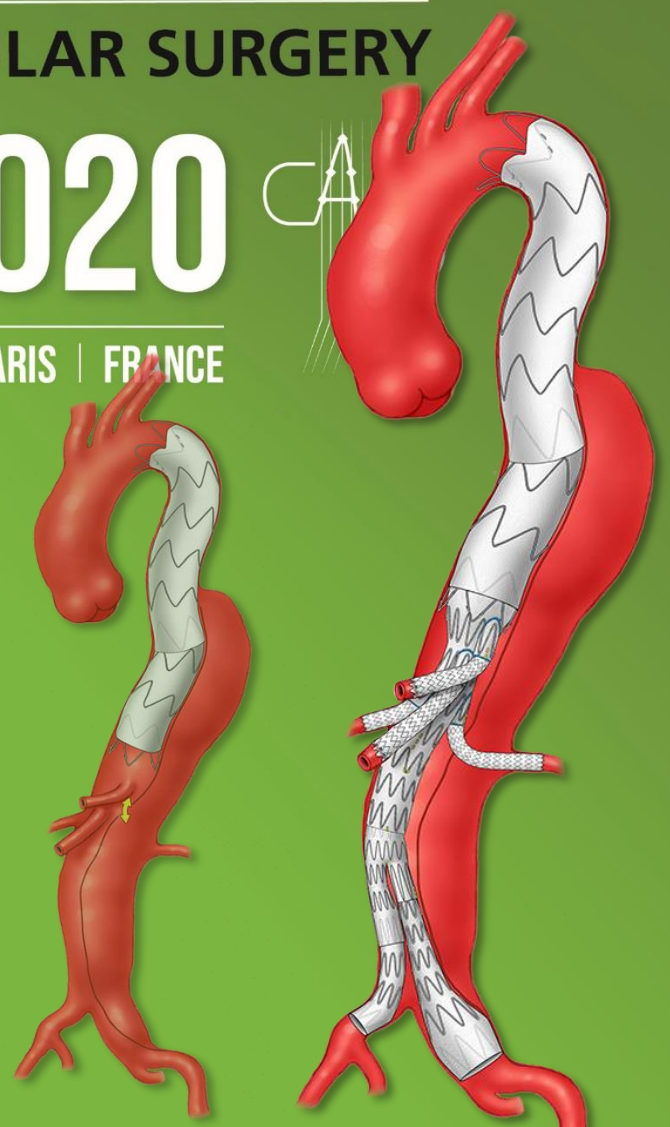
JANUARY 23-25 2020

MARRIOTT RIVE GAUCHE & CONFERENCE CENTER | PARIS | FRANCE

FBEVAR for TAAAs

Gustavo S. Oderich MD

Professor of Surgery
Director of Aortic Center
Chair, Vascular and Endovascular Surgery
Mayo Clinic, Rochester MN



MAYO CLINIC

Disclosures

Gustavo S. Oderich

- Consulting: Cook Medical, WL Gore, GE Healthcare, Syntactx
- Research support: Cook Medical and GE Healthcare

All consulting fees, honorarium and research grants paid to Mayo Clinic

THE HOUSTON LEGACY

Experience with 1509 patients undergoing thoracoabdominal aortic operations

Lars G. Svensson, MD, PhD, E. Stanley Crawford, MD,† Kenneth R. Hess, MS, Joseph S. Coselli, MD, and Hazim J. Safi, MD, *Houston, Texas*

1,509 patients
Mortality 10%
SCI 16%

1,896 patients
Mortality 16%
SCI 10%

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

Outcomes of 3309 thoracoabdominal aortic aneurysm repairs

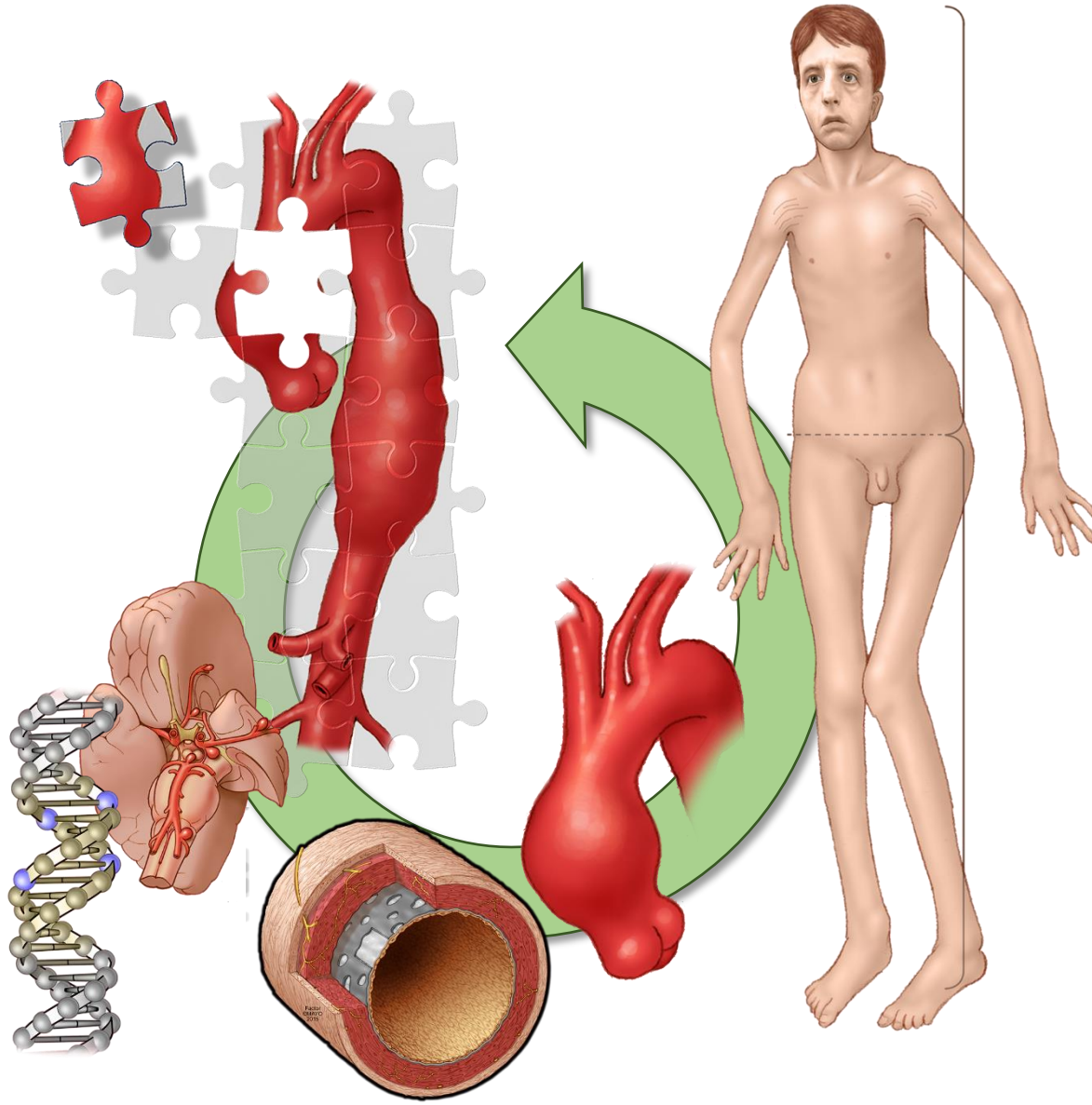
Joseph S. Coselli, MD,[a,d,e] Scott A. LeMaire, MD,[a,b,c,d,e] Ourania Preventza, MD,[a,d,e] Kim I. de la Cruz, MD,[a,d,e] Denton A. Cooley, MD,[d] Matt D. Price, MS,[a,d] Alan P. Stolz, MEd,[a,d] Susan Y. Green, MPH,[a,d] Courtney N. Arredondo, MSPH,[b] and Todd K. Rosengart, MD[a,c,d,e]

3,309 patients
Mortality 7%
SCI 10%

Svensson L (Crawford) et al. J Vasc Surg 1993
Estrera A (Safi H) et al. Ann Surg 2015
Coselli et al. J Thorac Cardiovasc Surg

Choice of repair

- Genetically triggered disease
- Age/clinical risk
- Prior arch/TAA repair
- Landing zone
- Atheromatous debris
- Renal-mesenteric targets
- Iliofemoral access



ENDOVASCULAR TAAA REPAIR
Cleveland Clinic experience

189 patients (Mean age, 71 yo)
Extent I-IV TAAAs
Elective Mortality 6%

Contemporary Analysis of Descending Thoracic and Thoracoabdominal Aneurysm Repair

A Comparison of Endova

Roy K. Greenberg, MD; Qingsheng Lu, MD;
Michael C. Moon, MD; Adrian V. Herr

406 patients (Mean age, 71 yo)
Extent I-IV TAAAs
Elective Mortality 3%

Branched endog

Roy Greenberg, MD, Matthew Eagleton, MD, and Tara Mastracci, MD

Fenestrated and branched endovascular aneurysm repair outcomes for type II and III thoracoabdominal aortic aneurysms

Matthew J. Eagleton, MD, Matthew Follansbee, BS, Katherine Wolski, MPH, Tara Mastracci, MD, and **Yuki Kuramochi, BScN,** *Cleveland, Ohio*

354 patients (Mean age, 74 yo)
Only Extent II-III TAAAs
Elective Mortality 4.8%

Greenberg RK et al. Circulation 2008

Greenberg RK et al. J Thorac Cardiovasc Surg 2008

Eagleton M et al. J Vasc Surg 2016

RENAL FENS v BRANCHES

- **606 patients with 1134 renal Fens**

Twelve-year results of fenestrated endografts for juxtarenal and group IV thoracoabdominal aneurysms

Tara M. Mastracci, MD, Matthew J. Eagleton, MD, Yuki Kuramochi, BScN, Shona Bathurst, and Katherine Woleki, MPH, *Cleveland, Ohio*

	n (Percent)
Renal stent occlusion	22 (1.9%)

- **133 patients with 235 renal branches**

Standard off-the-shelf versus custom-made multibranched thoracoabdominal aortic stent grafts

Charlene C. Fernandez, BS, Julia D. Sobel, BS, Warren J. Gasper, MD, Shant M. Vartanian, MD, Linda M. Reilly, MD, Timothy A. M. Chuter, MD, and Jade S. Hiramoto, MD, *San Francisco, Calif*

	n (Percent)
Occlusion or stenosis requiring intervention	21 (18%)

Mastracci T et al. J Vasc Surg 2015

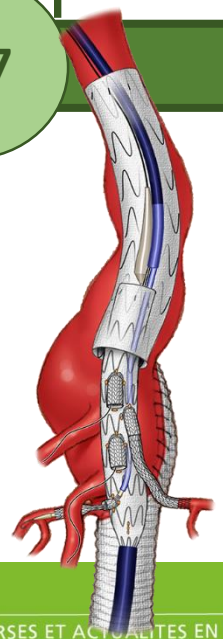
Fernandez et al. J Vasc Surg 2012

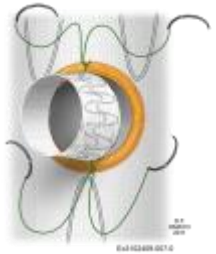
MAYO CLINIC F-BEVAR PROGRAM

2007

PMEG

- Description of techniques (Fens, mini-cuffs and branches)





2010

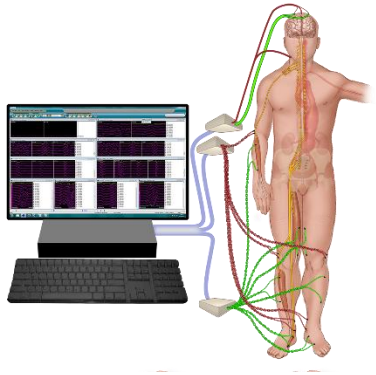
ZFEN trial and others

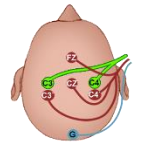
- Fast IRB process
- Industry engagement

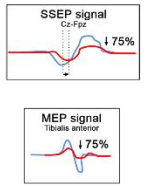
2013

Spinal cord ischemia protocol

- Routine CSF drainage
- Neuromonitoring
- Staging





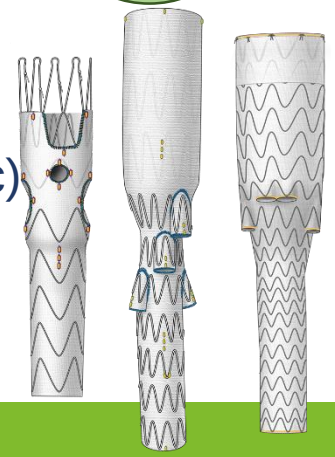


2019

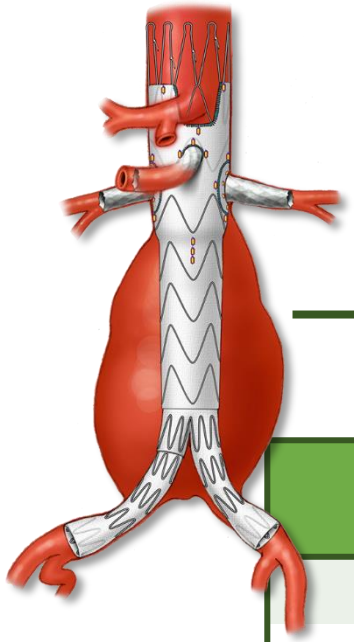
>650 implants

Prospective PS-IDE

- Full access to Cook technology (arch, ascending, TAAA, iliac)
- High enrollment
- Expansion to other industry trials

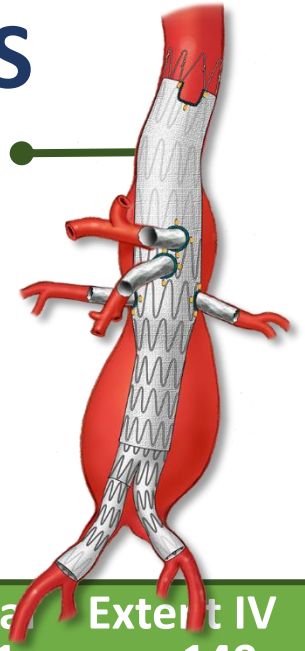


605 CONSECUTIVE PATIENTS

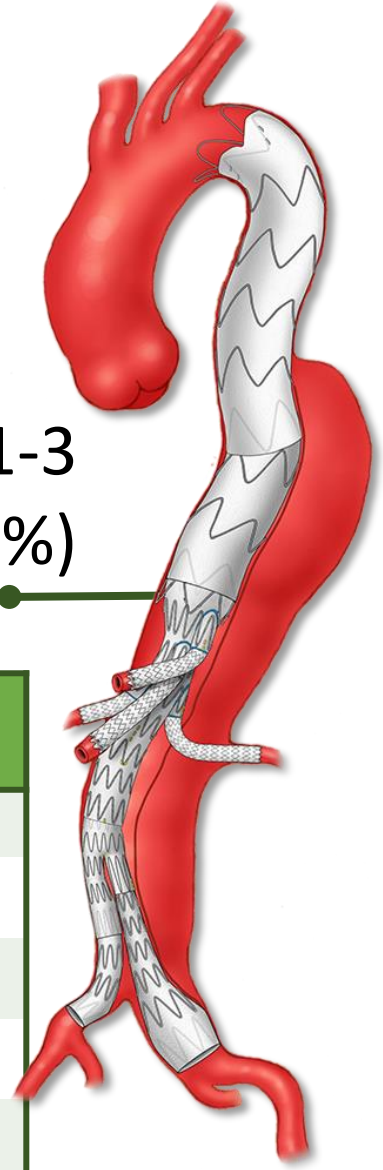


251 pararenal AAAs (46%)

149Extent 4 TAAA (23%)



205 Extent 1-3 TAAA (31%)



	Overall n = 605	Pararenal n = 251	Extent IV n = 149	Extent I-III n = 205	P value
			Percent		
Mortality	**2**	**1**	**2**	**3**	.05
New-onset dialysis	1	1	2	2	.24
Paraplegia	**1**	**0.5**	**1**	**3**	.004
Major Stroke	1	1	1	1.5	.60

Learning Curve of Fenestrated and Branched Endovascular Aortic Repair for Pararenal and Thoracoabdominal Aortic Aneurysms

Gustavo S. Oderich, Giuliano de A. Sandri, Emanuel T.R. Tenorio, Mauricio S. Ribeiro, Jan Hofer, Thanila Macedo, Stephan Cha, Peter Gloviczki, Aleem K. Mirza

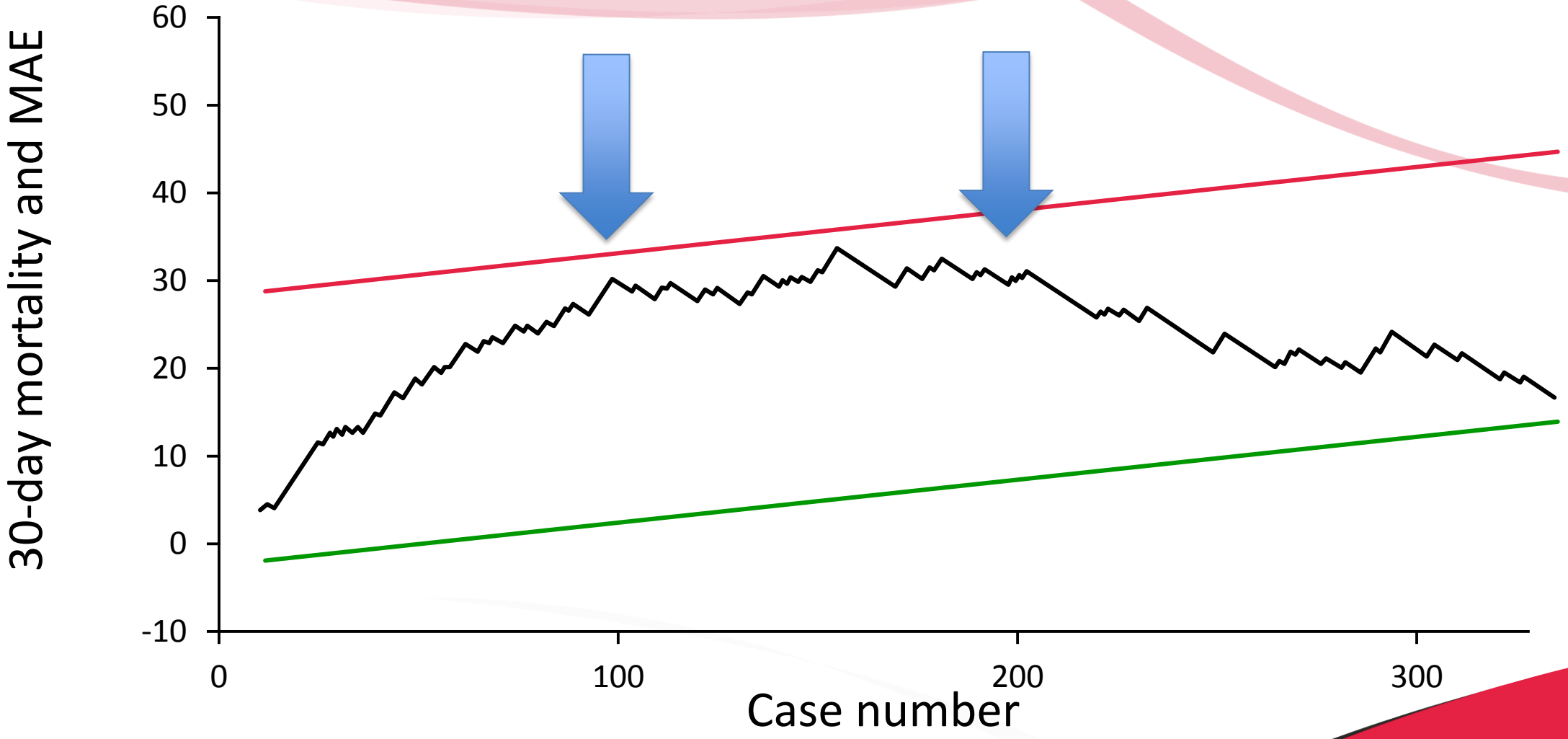
	All n = 334	Q1 n = 81	Q2 n = 84	Q3 n = 85	Q4 n = 84	P value
30 day mortality	2%	6%	2%	**1%**	**0%**	0.009
Major adverse event	33%	58%	32%	**21%**	**21%**	<.001
30-day reinterventions	9%	9%	10%	**6%**	**2%**	<.001

Mirza A et al (Oderich). J Vasc Surg (in press)

31st ANNUAL MEETING LYON, FRANCE

esvs Lyon 2017

Cumulative sum (CUSUM)



PHYSICIAN-SPONSORED INVESTIGATIONAL DEVICE EXEMPTION (IDE) STUDY

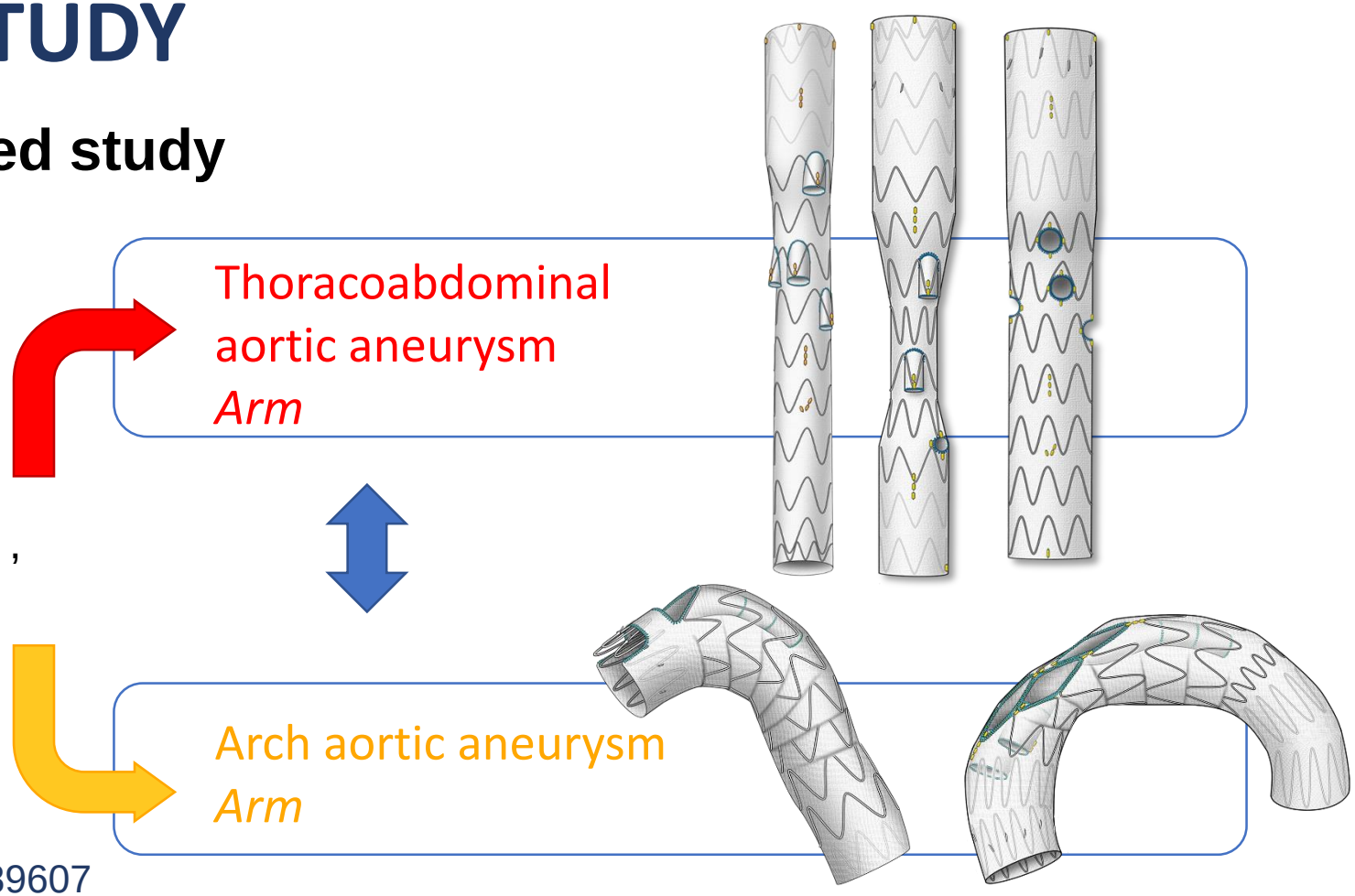
Prospective, non-randomized study

Inclusion criteria

- Thoracoabdominal and aortic arch aneurysms and chronic dissections

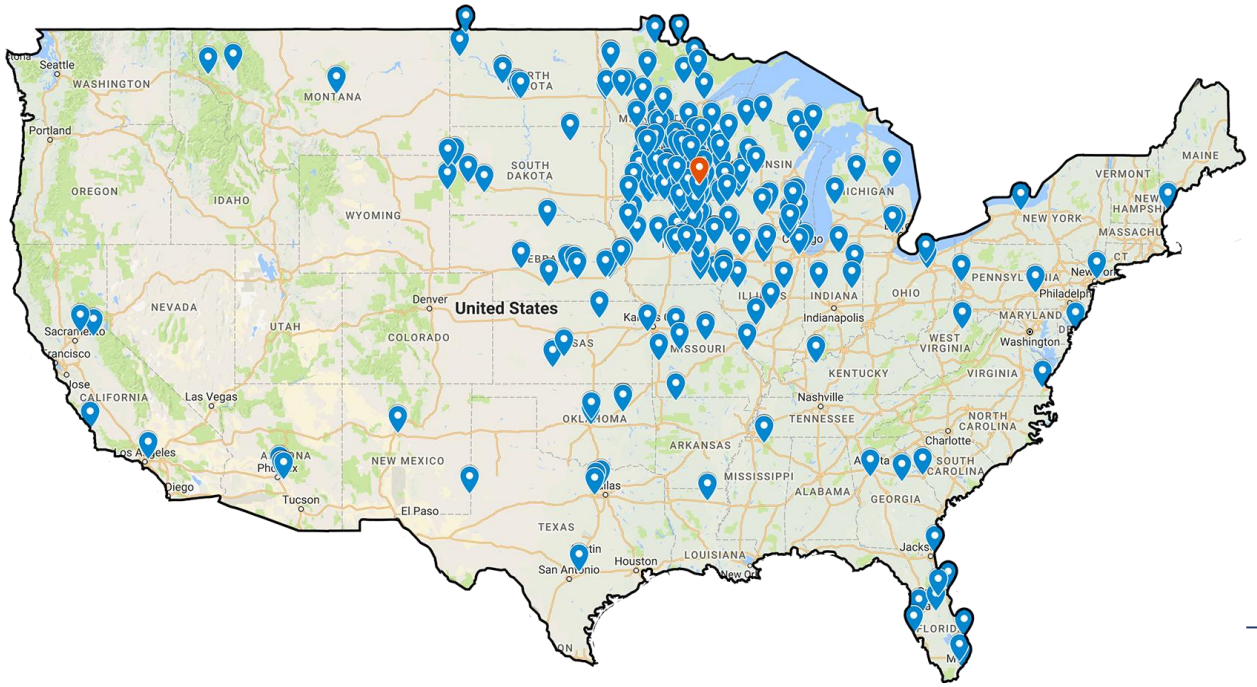
Protocol design

- QOL questionnaires, imaging and clinical exam at dismissal, 2 months , 6 months and annually for 5 years
- Independent monitoring and clinical event adjudication
- Annual FDA reporting



ClinicalTrials.gov - NCT01937949 and NCT02089607

MAYO CLINIC F-BEVAR PROSPECTIVE NON-RANDOMIZED PHYSICIAN-SPONSORED IDE STUDY

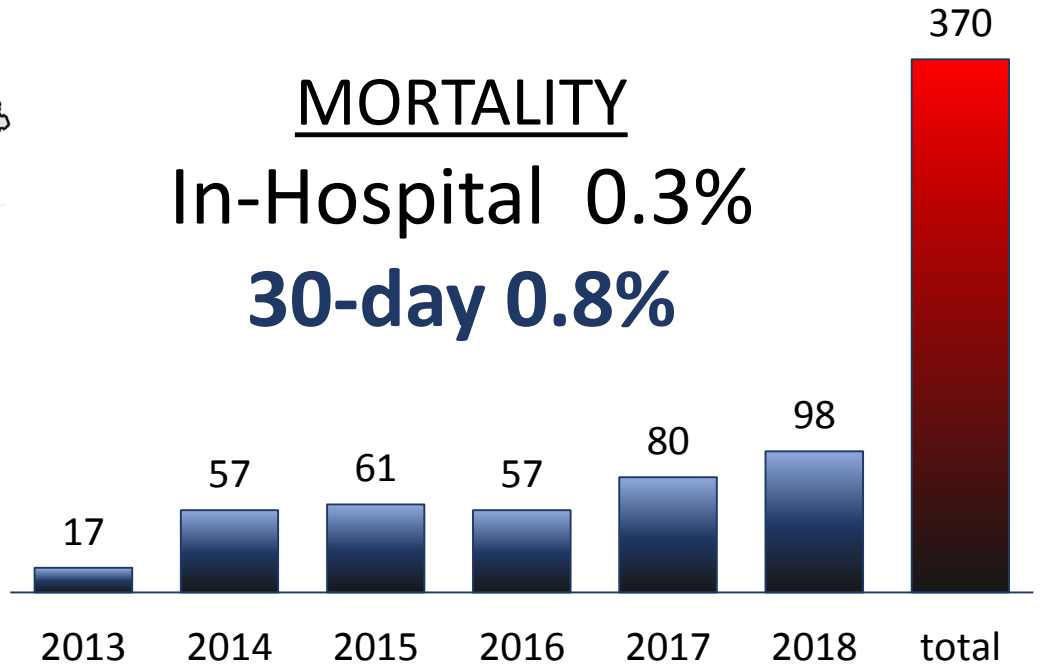


370 patients enrolled

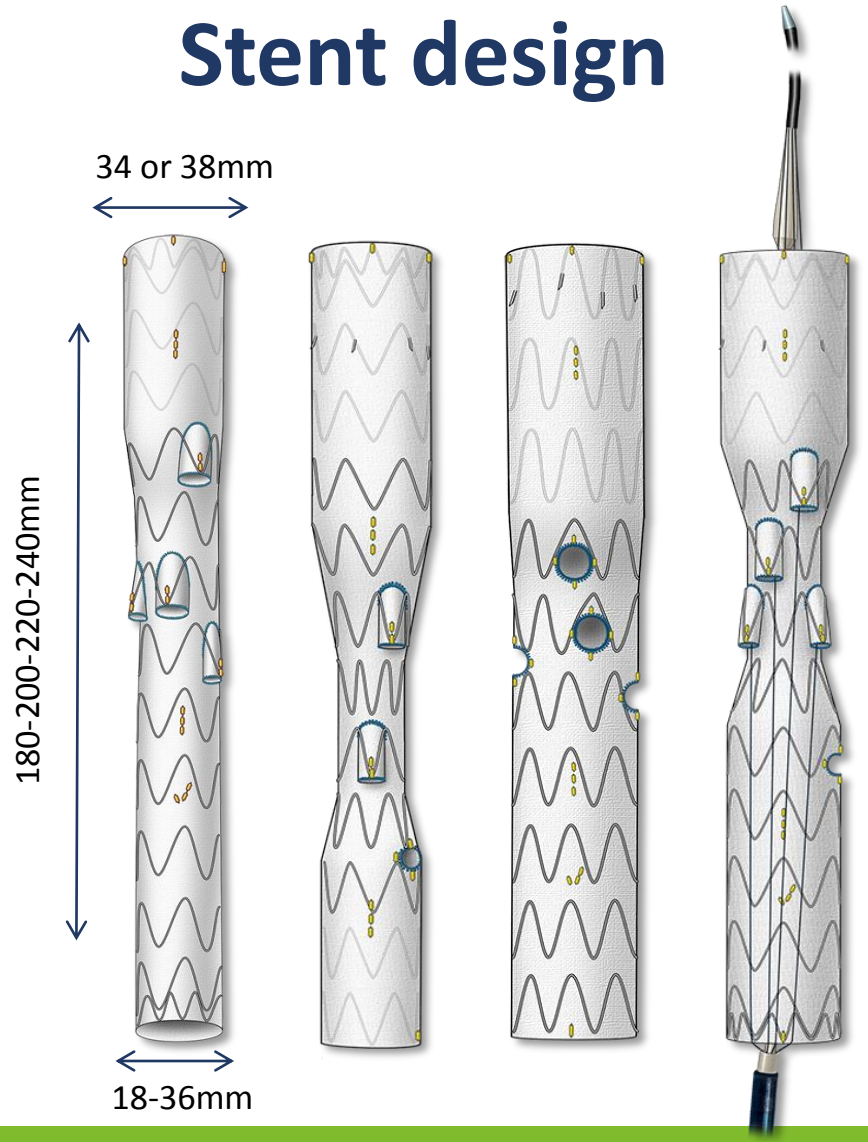
MORTALITY

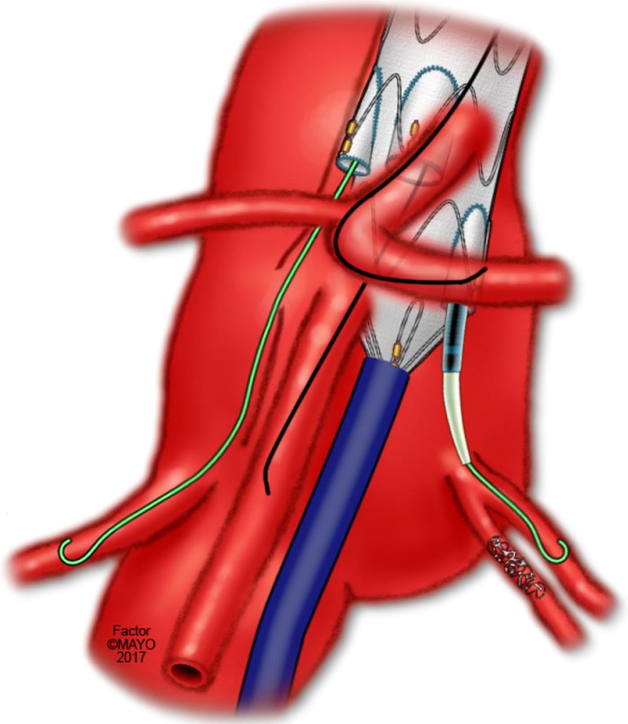
In-Hospital 0.3%

30-day 0.8%



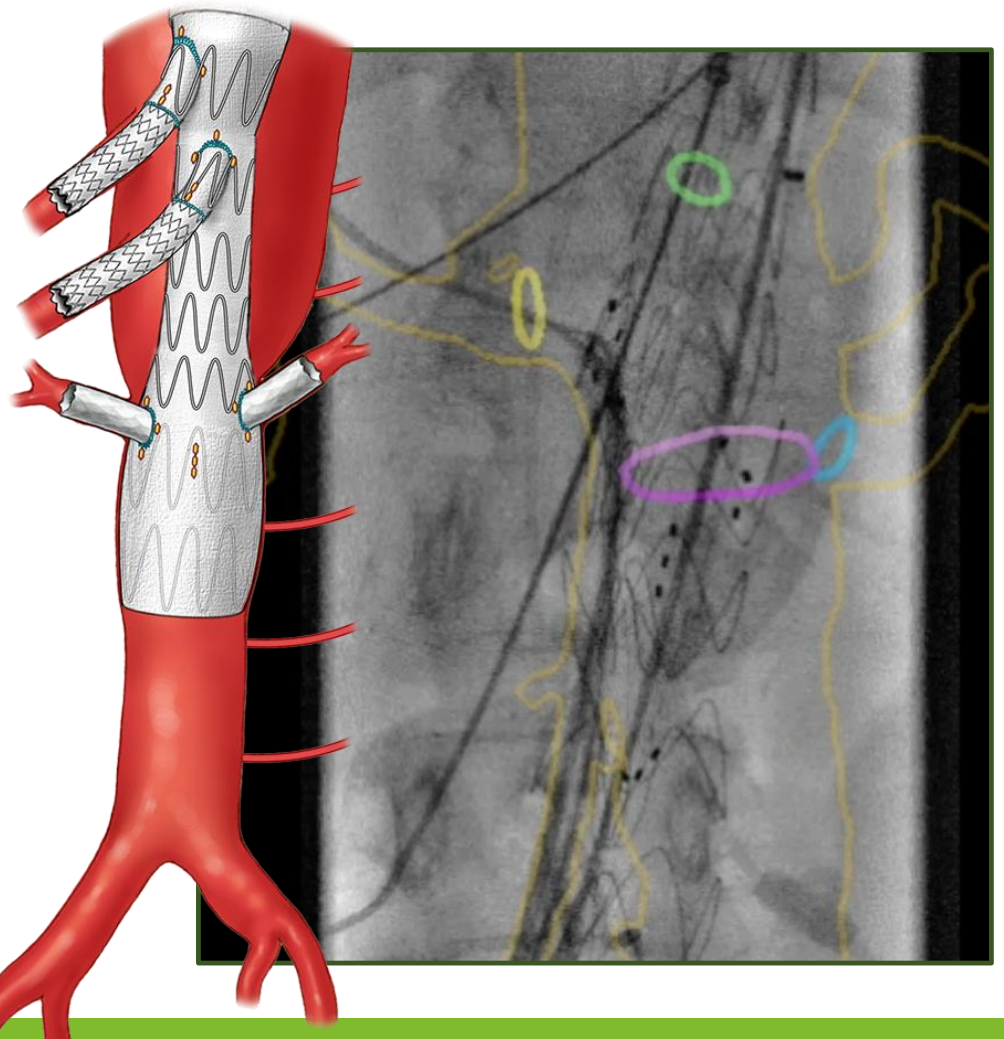
Stent design

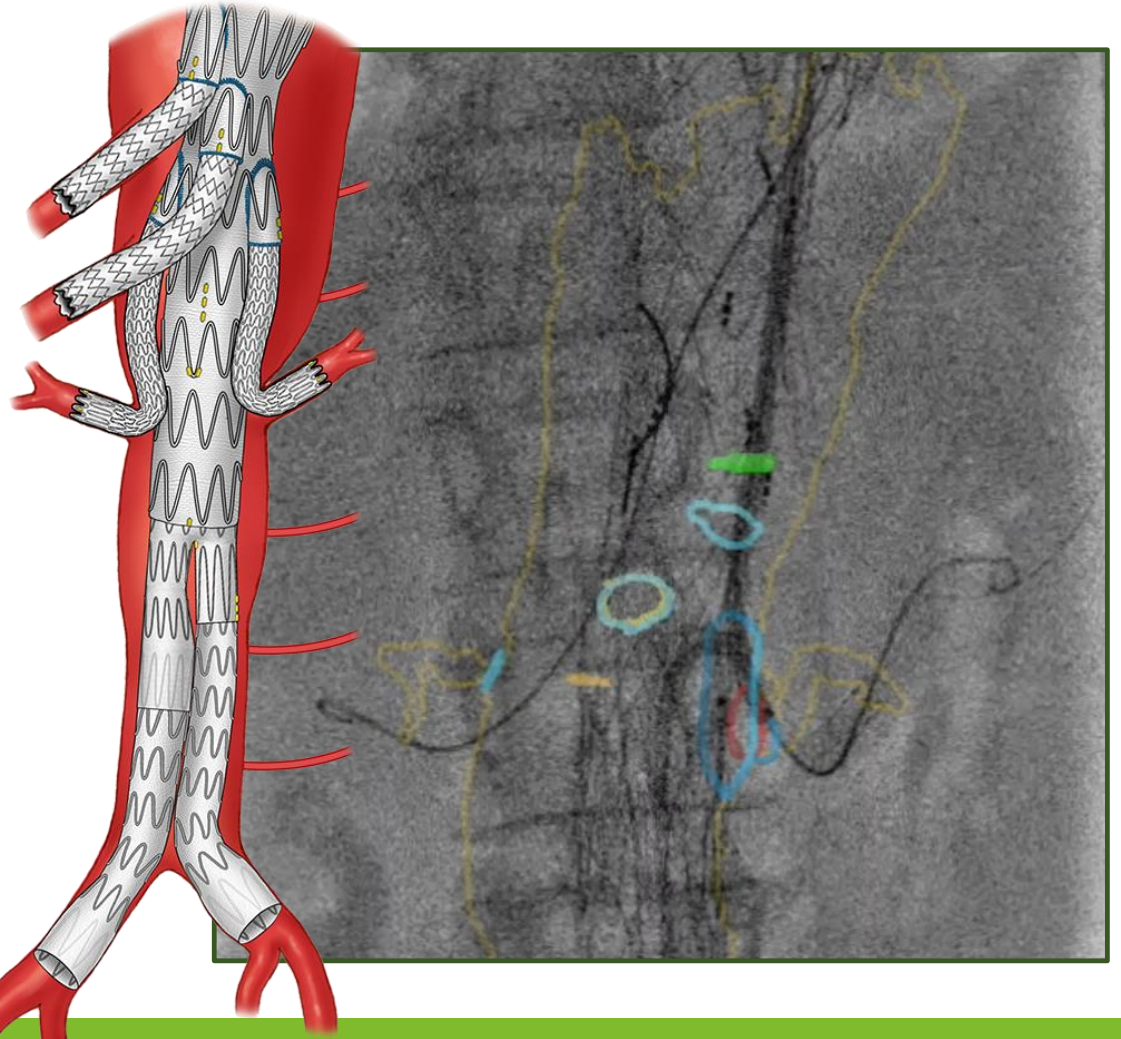




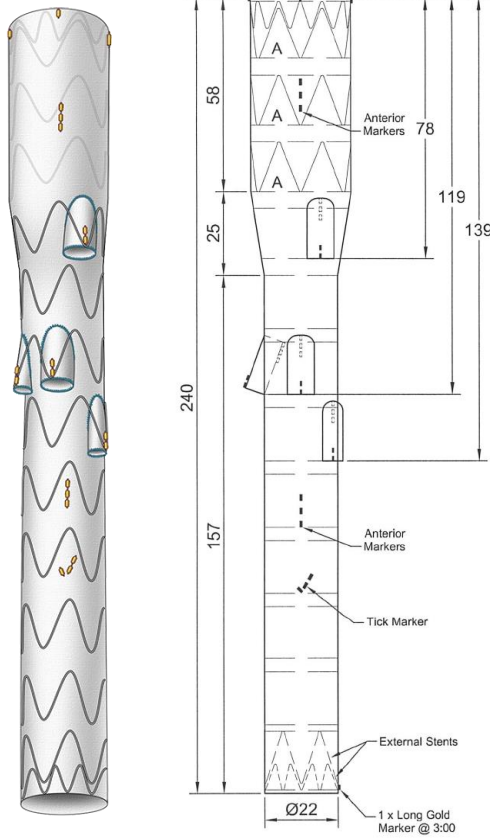
- Patient specific 3-5 fenestrations or branches
- Low profile (18 or 20Fr)
- Optional preloaded renal/mesenteric guidewires

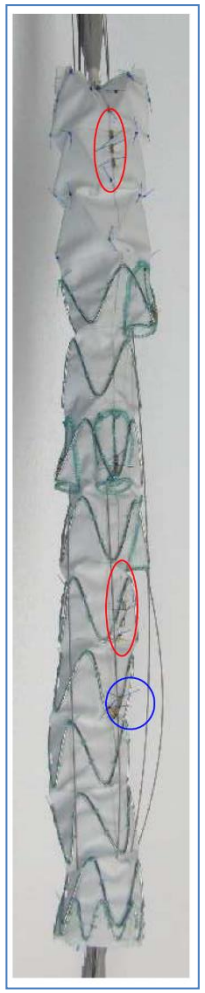
Branches vs fenestrations

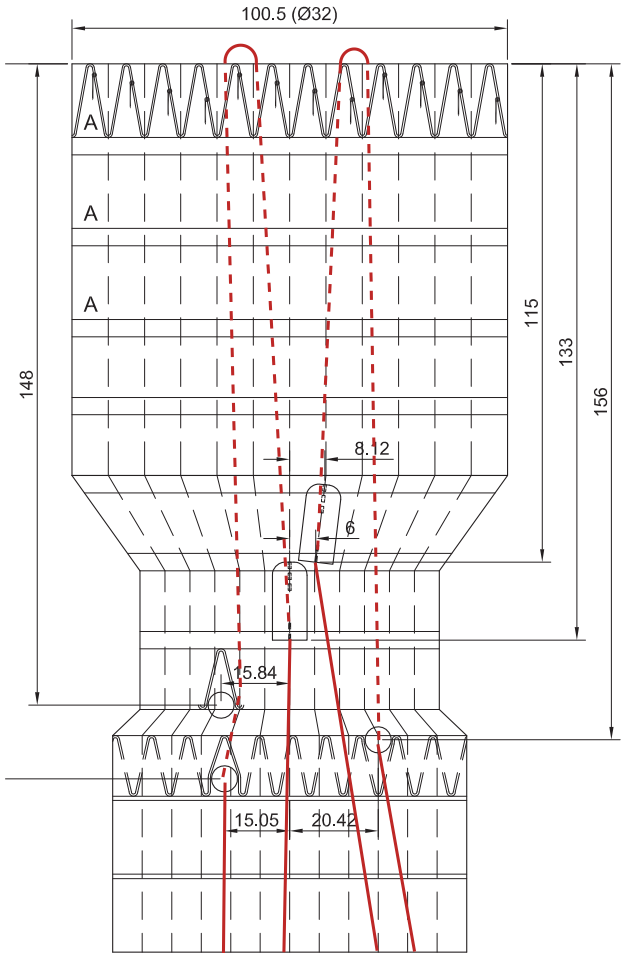


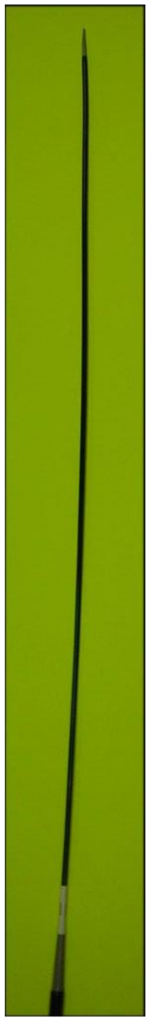


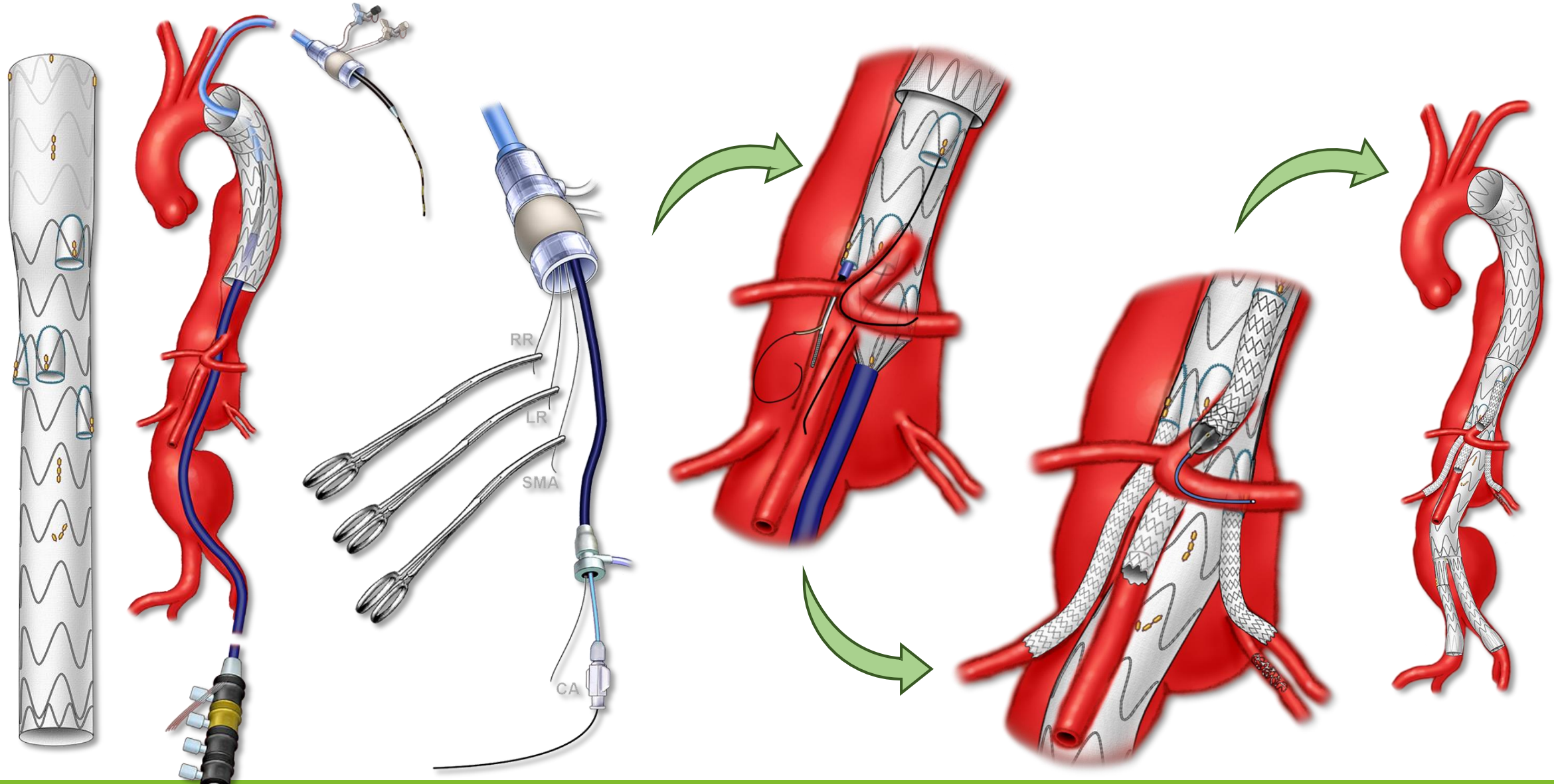
Preloaded guidewire system





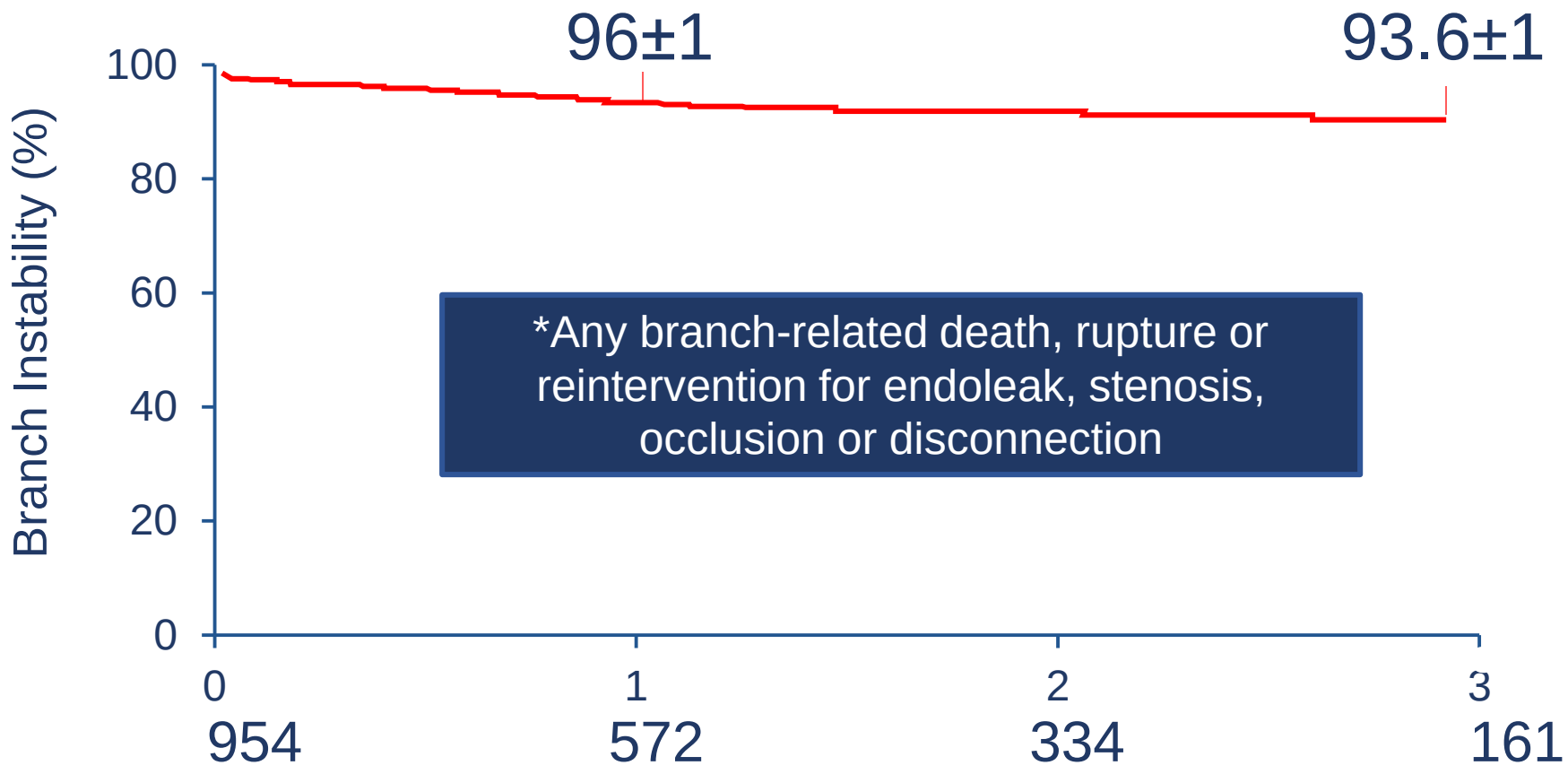




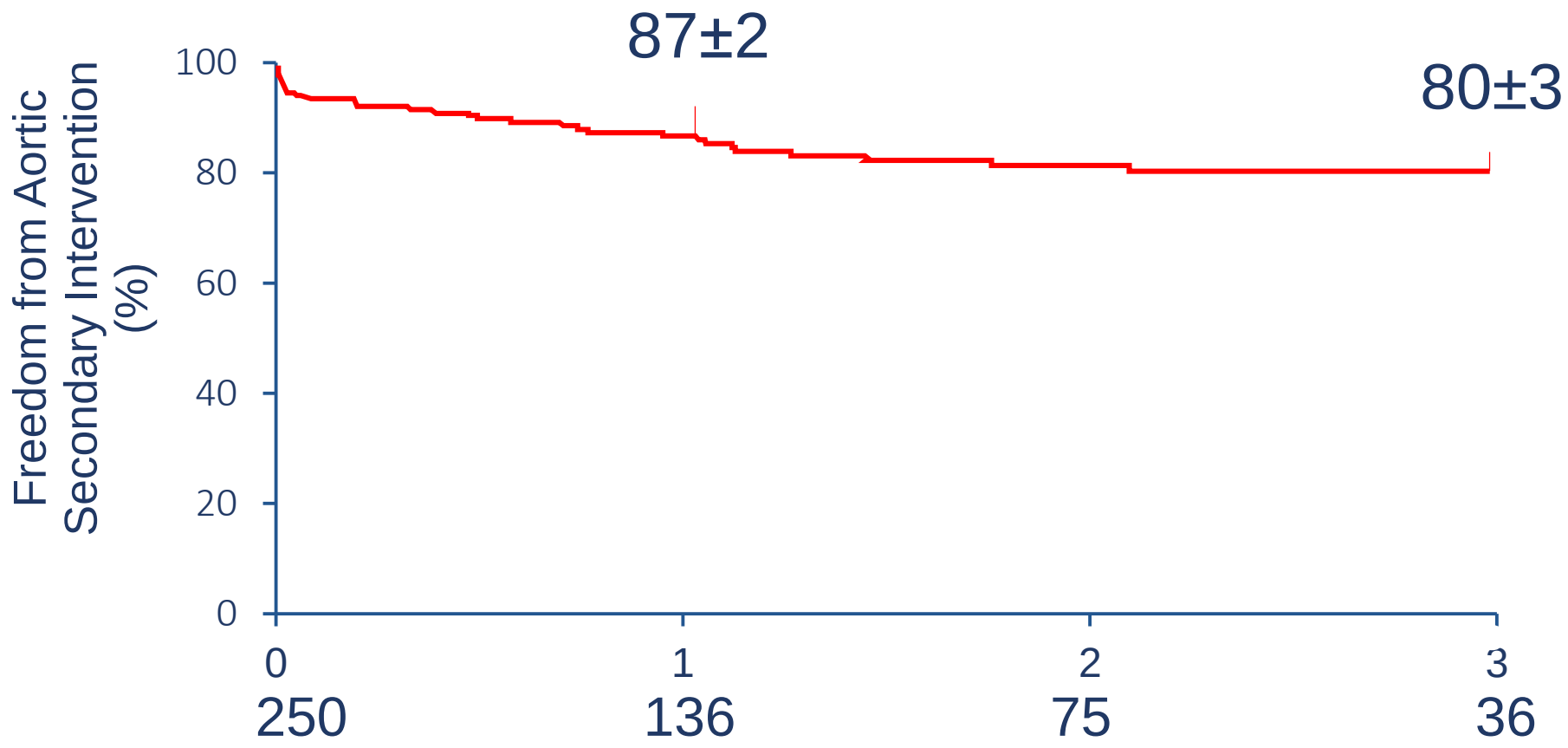

RR
LR
SMA
CA

TARGET VESSEL INSTABILITY*

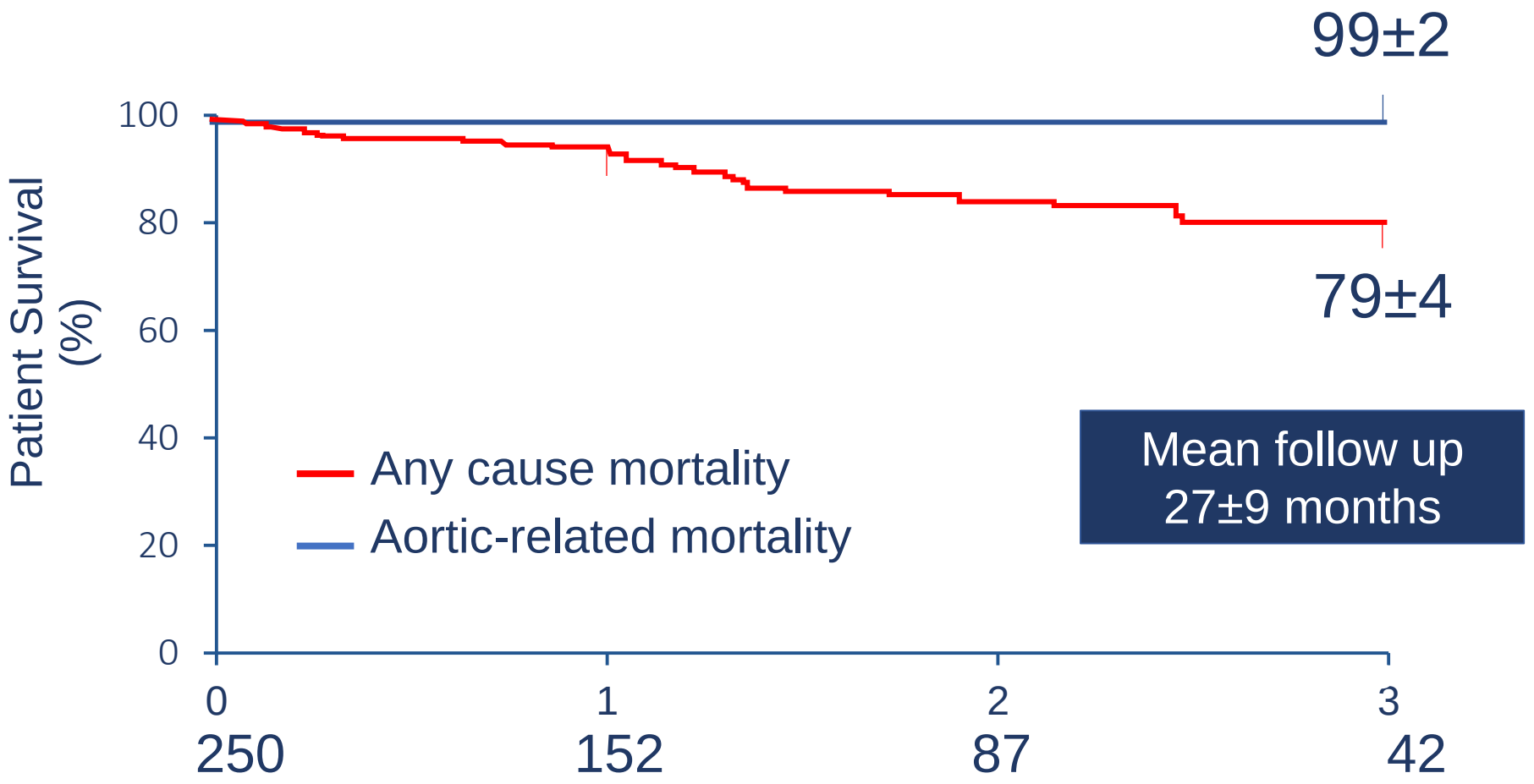
All renal-mesenteric target vessels

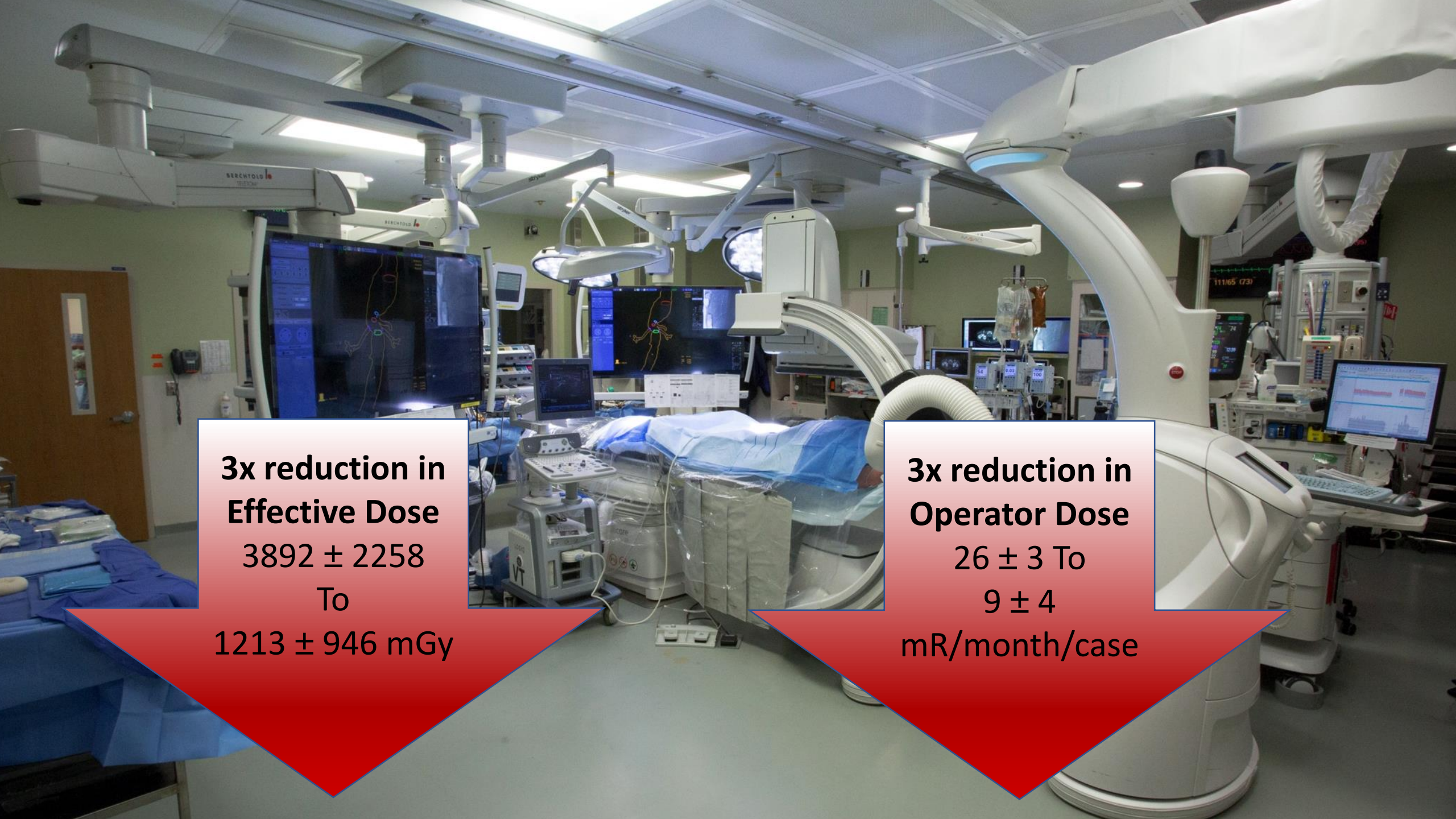


AORTIC REINTERVENTION



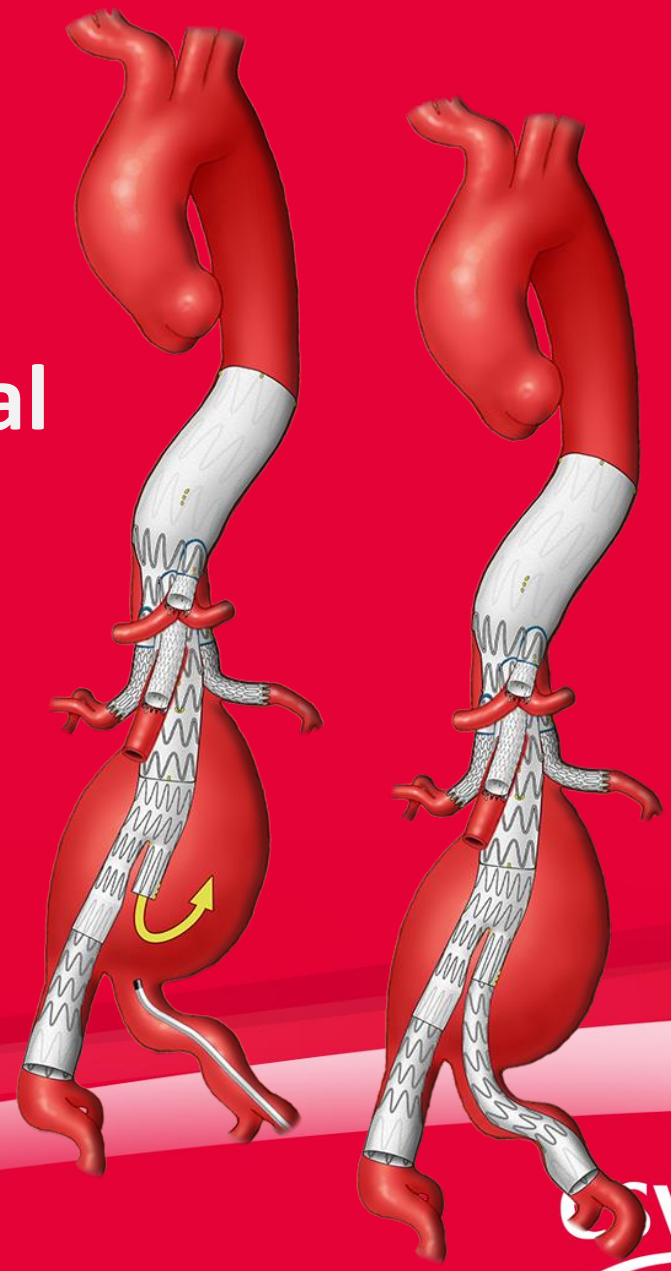
PATIENT SURVIVAL




3x reduction in Effective Dose
3892 ± 2258
To
1213 ± 946 mGy
3x reduction in Operator Dose
26 ± 3 To
9 ± 4
mR/month/case

CONE BEAM CT PROTOCOL

Prospective assessment of a protocol using neuromonitoring, early limb reperfusion and selective temporary aneurysm sac perfusion to prevent spinal cord injury during fenestrated-branched endovascular aortic repair



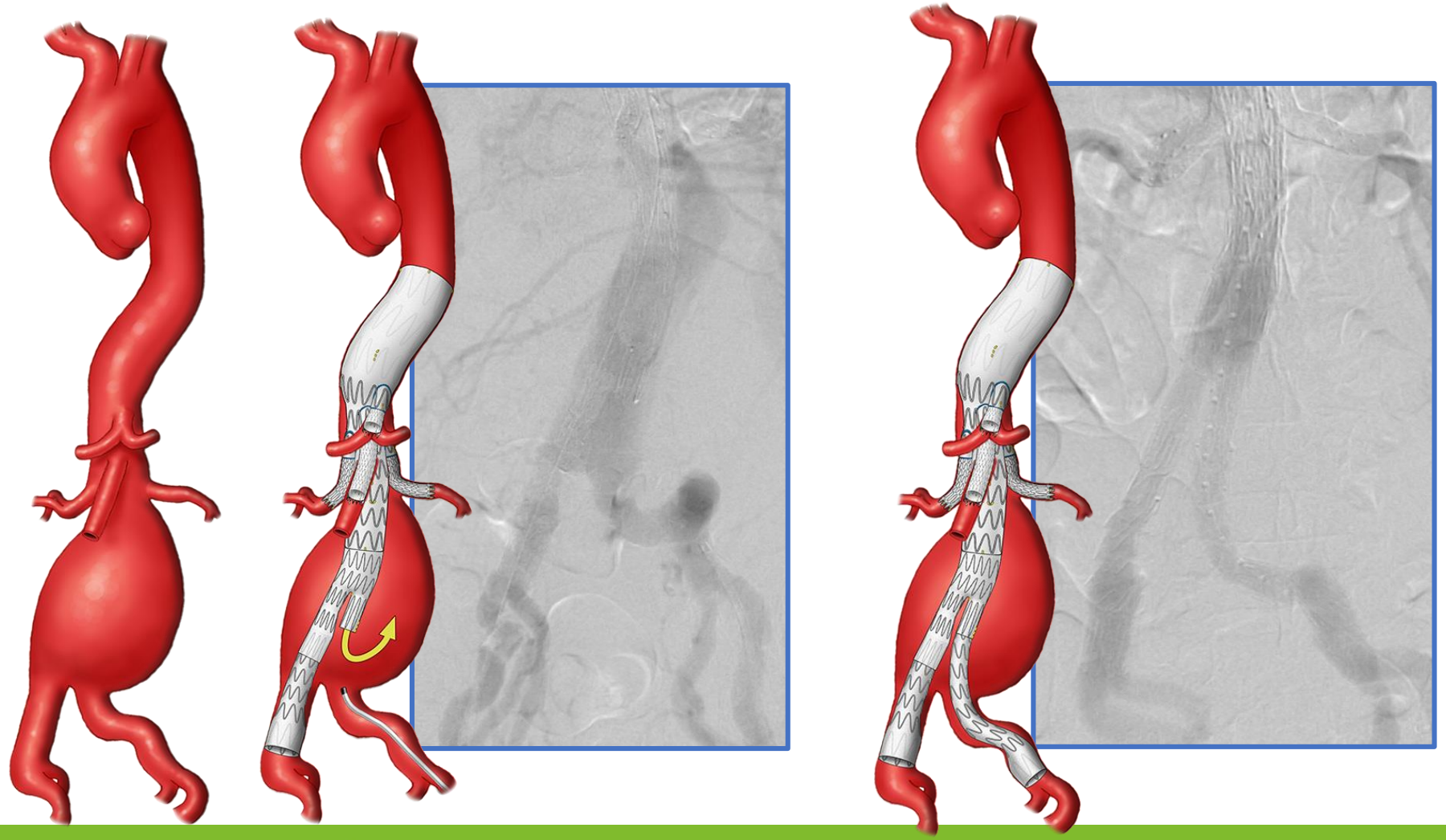
Emanuel R. Tenorio MD PhD, Gustavo S. Oderich MD, Jussi M. Kärkkäinen MD PhD, Bernardo C. Mendes MD, Jan Hofer RN, Randall R. DeMartino MD, Peter V. Banga MD and Stephen Cha MS.

Mayo Clinic Aortic Center, Rochester, MN, United States

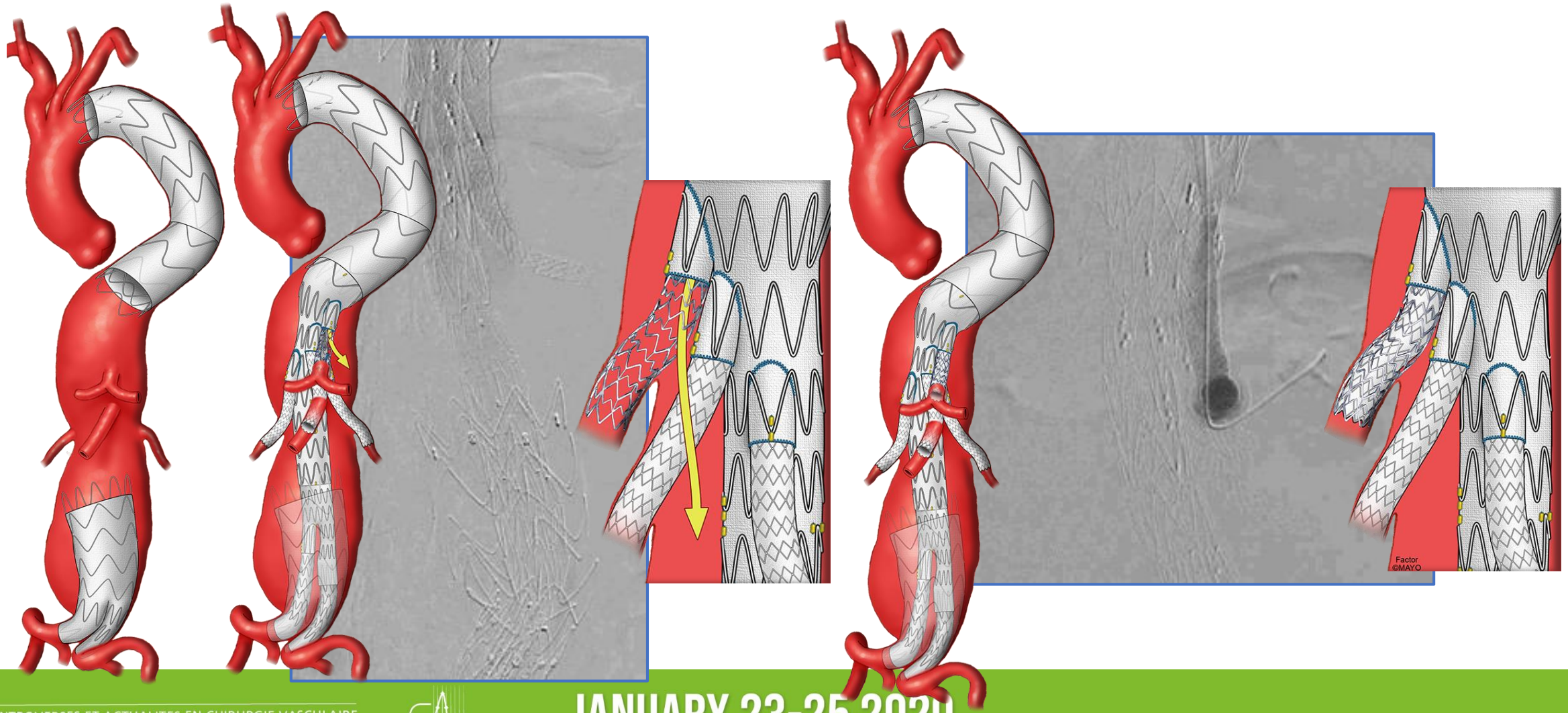
ESVS 32nd Annual Meeting
24–28 September 2018

ESVS Valencia 2018

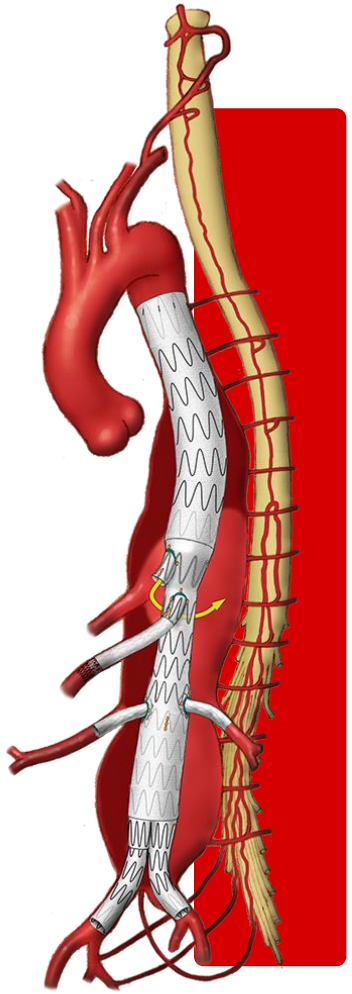
TASP via contralateral gate of bifurcated device



TASP via directional branch using bare metal stent



TEMPORARY ANEURYSM SAC PERFUSION (TASP)



9/232 patients (4%) required sac perfusion

Mean closing time, 22±16 days

	Aneurysm Extent	First Exam	Day of Sac closure	Exam After Sac Closure	Exam at 30 Days Follow Up
1	Extent II	Grade 0	Day 45	No	Grade 0
2	Extent II	Grade 3c	Day 30	No	Grade 2
3	Extent III	Grade 0	Day 22	No	Grade 0
4	Extent II	Grade 0	Day 26	Grade 3a	Grade 0
5	Extent II	Grade 0	Day 46	No	Grade 0
6	Extent II	Grade 0	Day 10	No	Grade 0
7	Extent II	Grade 3c	Day 14	No	Grade 0
8	Extent III	Grade 0	Day 4	No	Grade 0
9	Extent IV	Grade 0	Day 2	No	Grade 0

Spinal cord injury by aneurysm extent

One (0.5%) 30-day death

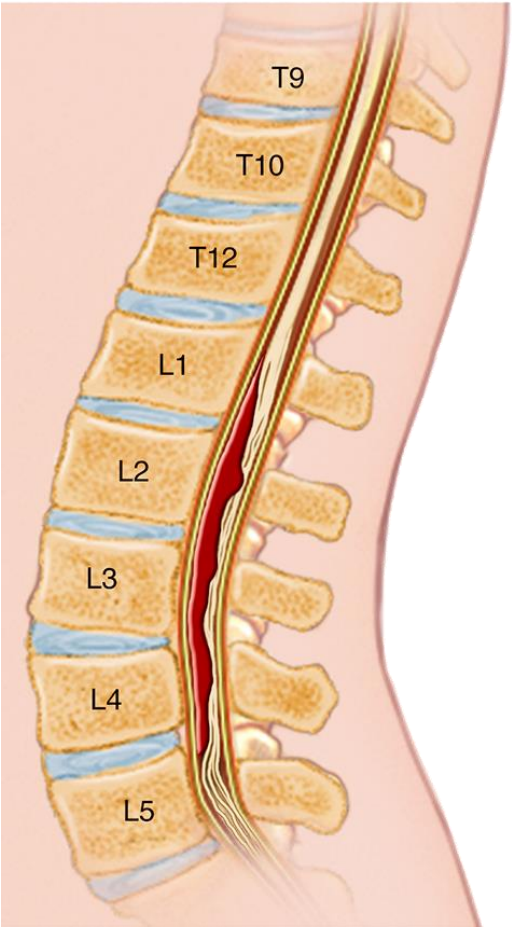
(Intra-cranial hemorrhage from spinal drain complication)

	Overall n = 232	Pararenal n = 84	Extent IV n = 62	Extent III n = 24	Extent I-II n = 62	P value
			n (%)			
Any major adverse event	53 (23)	17 (20)	16 (26)	3 (13)	17 (27)	.41
Any spinal cord injury	10 (4)	1 (1)	0	3 (13)	6 (10)	.002
Grading classification						
1-2 (paraparesis)	4 (2)	0	0	2 (8)	2 (3)	.01
3a-c (paraplegia)	6 (3)	1 (1)	0	1 (4)	4 (7)	.08
Permanent paraplegia	2 (1)	1 (1)	0	0	1 (2)	.73

Probable mechanism of spinal cord injury

10 patients (4%)

	n	%
Hemodynamic compromise	6	60
Embolic	2	20
Spinal hematoma	**2**	**20**



Cerebrospinal Fluid Drainage Complications During First Stage and Completion Fenestrated-Branched Endovascular Aortic Repair

Jussi M. Kärkkäinen, Nolan Cirillo-Penn, Indrani Sen, Emanuel Tenorio, William Mauermann, George Gilkey, Timothy Kaufmann and Gustavo Oderich

From the Society for Vascular Surgery

Cerebrospinal fluid drainage complications during first stage and completion fenestrated-branched endovascular aortic repair

Jussi M. Kärkkäinen, MD, PhD,[a] Nolan C. Cirillo-Penn, MD,[a] Indrani Sen, MD,[a] Emanuel R. Tenorio, MD, PhD,[a] William J. Mauermann, MD,[b] George D. Gilkey, MD,[b] Timothy J. Kaufmann, MD, MS,[c] *and* Gustavo S. Oderich, MD,[a] *Rochester, Minn*

J Vasc Surg 2019

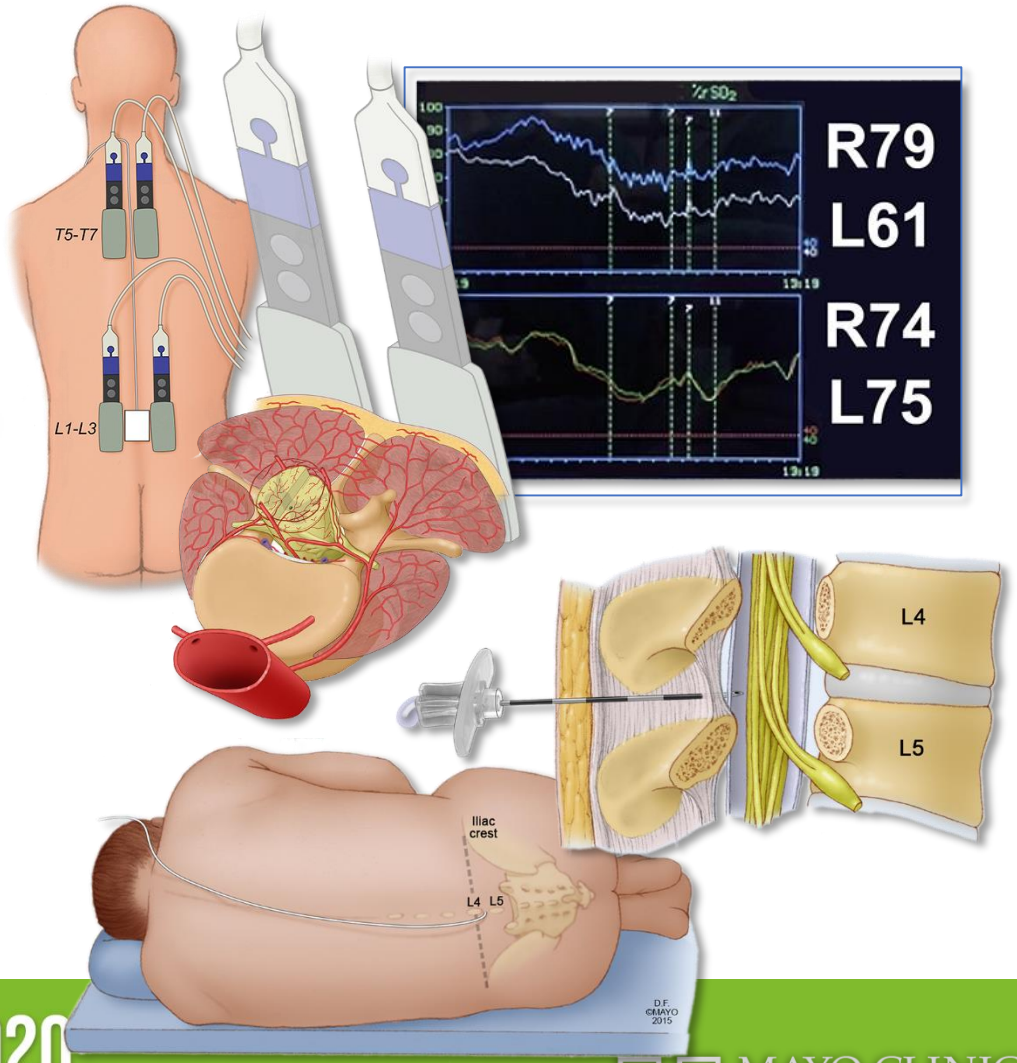
293 consecutive IDE trial patients during 5-year study period

187 pts with 240 endovascular procedures with CSF drain

CSFD-related complications	n	% / patients
Any complication	21	10
Severe	8	4
Spinal hematoma	6	3
Intracranial hemorrhage	3	2
Moderate	9	5
Minor	4	1

EVOLUTION OF SCI PREVENTION PROTOCOL

- Recommend temporary sac perfusion based on intraoperative neuromonitoring and NIRS
- Eliminated prophylactic CSF drainage and use only therapeutic drainage if symptoms of SCI
- Restrict placement to small group (<5) CV anesthesiologists and neuro-radiologists using fluoroscopic guidance whenever possible



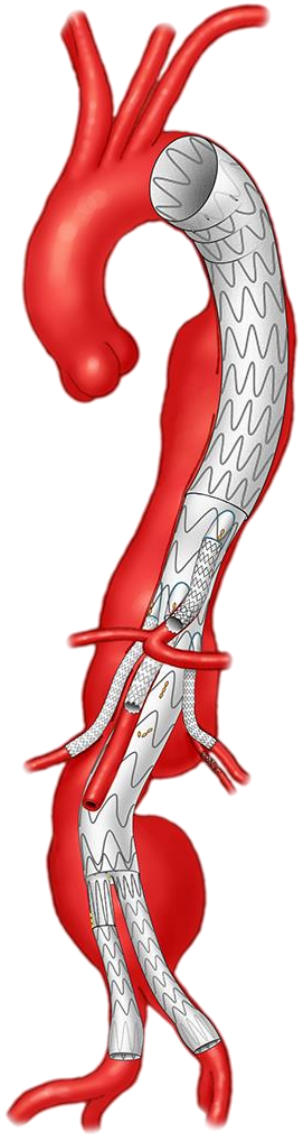
SOCIETY FOR CLINICAL VASCULAR SURGERY

BOCA RATON

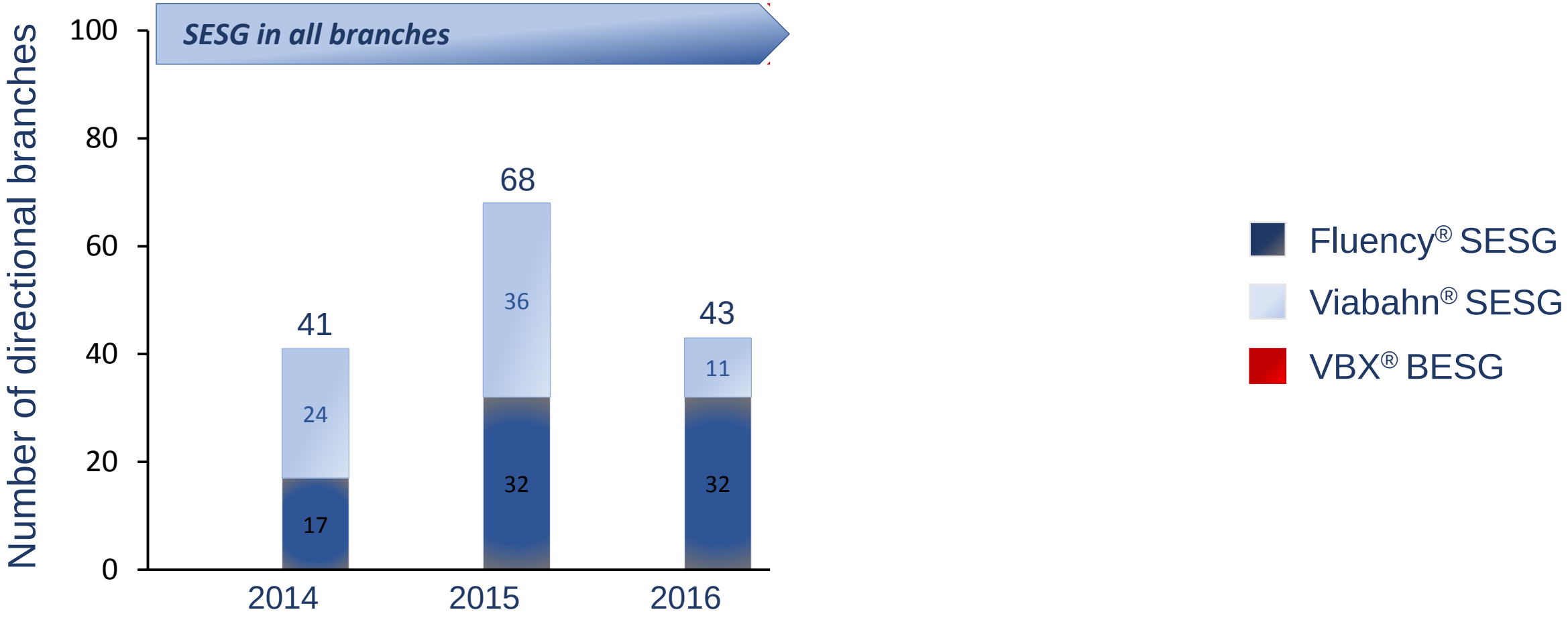
47TH ANNUAL SYMPOSIUM | MARCH 16 - 20, 2019

OUTCOMES OF DIRECTIONAL BRANCHES USING SELF-EXPANDABLE OR BALLOON-EXPANDABLE STENT GRAFTS DURING ENDOVASCULAR TAAA REPAIR

Tenorio et al (Oderich). J Vasc Surg 2019

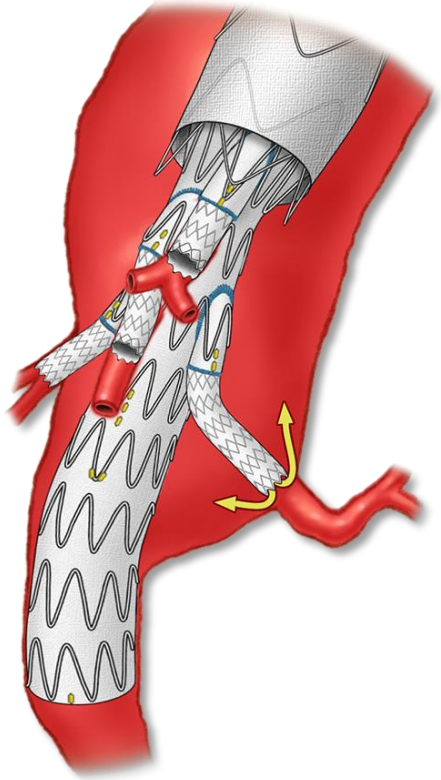


SELECTION OF BRIDGING STENT



TARGET ARTERY OUTCOMES

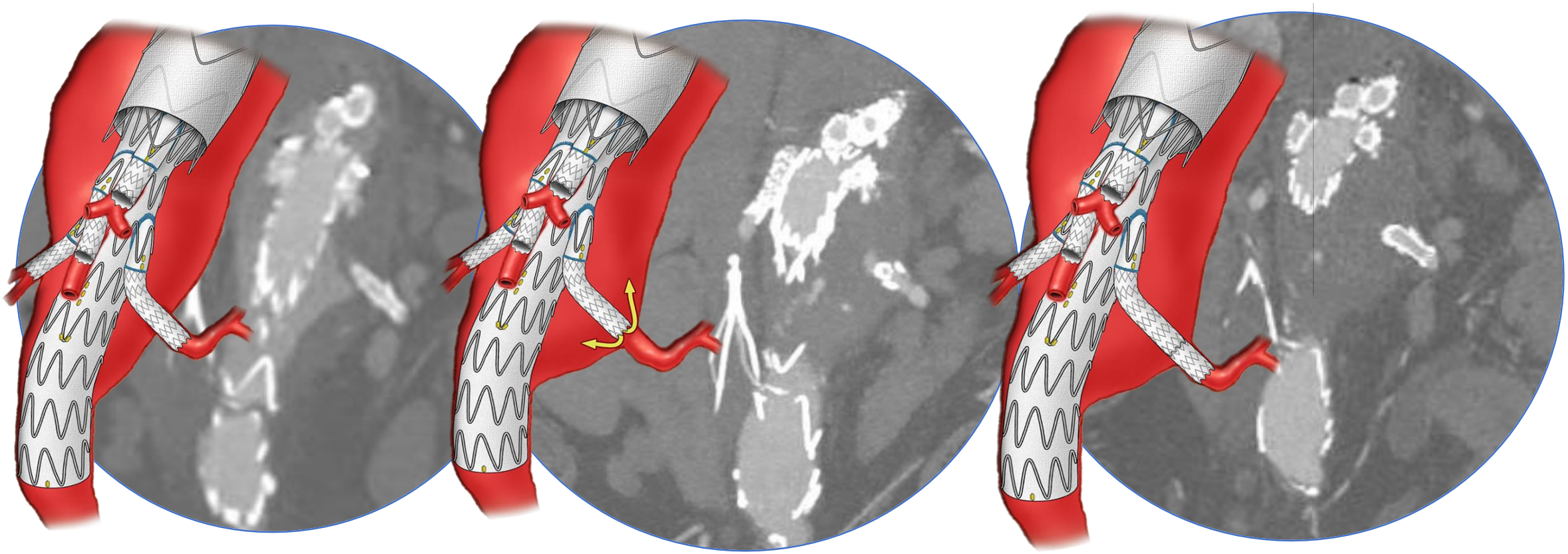
- No branch-related rupture or death



1- Year Kaplan-Meier estimates	SESG n=62/176	BESG n=54/159	P value
All target arteries (n = 335)			
Primary patency	97 ± 2	95 ± 2	.004
Freedom from target artery type IC/IIIC	98 ± 1	92 ± 3	.003
Freedom from target artery reintervention	98 ± 1	88 ± 4	<.0001
Renal artery targets (n = 122)			
Freedom from target artery type IC/IIIC	98 ± 2	83 ± 6	<.0001
Freedom from target artery reintervention	98 ± 1	88 ± 4	<.0001

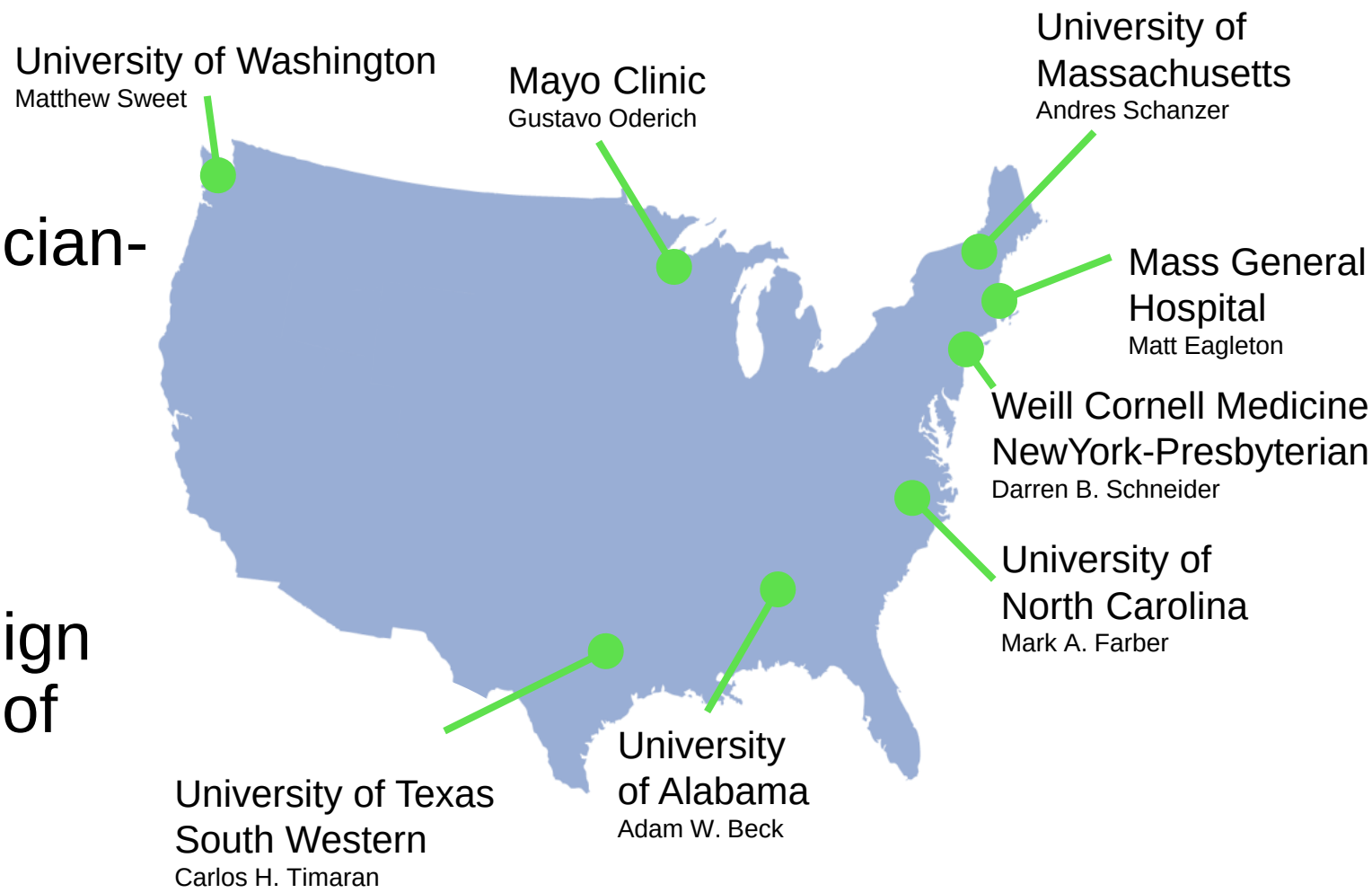
ANALYSIS OF 9 TYPE IC ENDOLEAKS

- 7 renal arteries (6 Left), 7 inner aortic diameter > 30mm, 5 renal arteries upgoing orientation



US FENESTRATED-BRANCHED RESEARCH CONSORTIUM

- 8 US sites
- Prospective, physician-sponsored studies
- Independent monitoring, FDA audited
- Similar device design with selective use of fenestrations and branches



Patient enrollmemt

Site	Principal Investigator	Patients enrolled
Mayo Clinic	Gustavo S. Oderich	390
University of North Carolina	Mark Farber	274
University of Massachusetts	Andres Schanzer	221
UT Southwestern	Carlos Timaran	166
Cornell-Weil Medical Center	Darren Schneider	107
University of Alabama	Adam Beck	77
University of Washington	Matt Sweet	52
Mass General Hospital - Harvard	Matt Eagleton	40
Total		**1327**

Aneurysm extent

Classification	n	30-day mortality (%)
Juxta or pararenal	33	1.2
Extent I TAAA	72	2.4
Extent II TAAA	241	2.1
Extent III TAAA	197	1.8
Extent IV TAAA	429	1.9
Total	1327	**1.7**

121 patients treated for chronic post-dissection TAAAs
30-day mortality, 1.6%

FEVAR long-term effectiveness

Prevention of aortic related death or rupture?

Author	Study Design	n	30-day mortality	Aneurysm Rupture	Aortic-Related Death	Follow up (years)
Mastracci et al (JVS 2013)	Prospective IDE	650	1%	2%	2%	8
Oderich et al (JVS 2014)	Prospective PMA	67	1.5%	0%	1.5%	5
Oderich et al (JVS 2016)	Prospective IDE	127	0%	0%	0%	3.5
Katsargyris et al (JVS 2017)	Retrospective	384	0.5%	0.2%	1%	2
Soler et al (JVS 2019)	Retrospective	57	0%	0%	0%	2
US F-BEVAR Consortium	Registry of IDE	661	2%	0.5%	2.5%	2.5

CONCLUSIONS

- F-BEVAR have expanded the indications of EVAR to patients with TAAAs
- The technique is safe, effective, and has reduced morbidity and mortality associated with conventional open surgical repair
- Main limitations are access to technology, physician training, cost, surveillance and need for secondary reinterventions