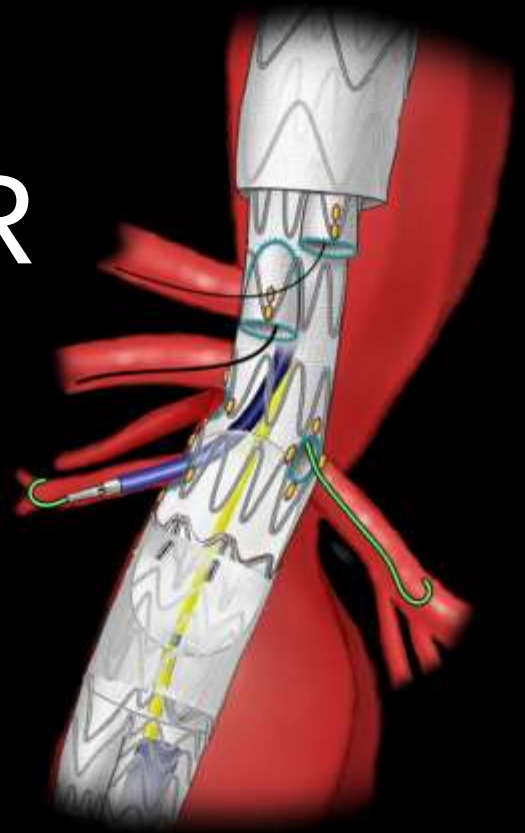
COMPLEX ENDOVASCULAR REPAIR

Gustavo S. Oderich, Randall DeMartino and Bernardo Mendes

Division of Vascular and Endovascular Surgery



HTDI2018
milan - italy

MAYO CLINIC

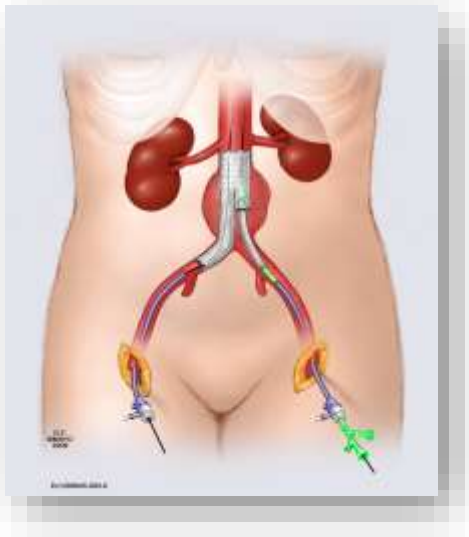
DISCLOSURE

- Consulting fees (All paid to Mayo)
  Cook Medical Inc., WL Gore, GE Healthcare
- Research grants (All paid to Mayo)
  Cook Medical Inc., WL Gore, GE Healthcare

ENDOVASCULAR REVOLUTION

Transfemoral Intraluminal Graft Implantation for Abdominal Aortic Aneurysms

J.C. Parodi, MD*, J.C. Palmaz, MD†, H.D. Barone, PhD, *Buenos Aires, Argentina, and San Antonio, Texas*



Short-term benefits of EVAR:

- Lower mortality and morbidity
- Less blood loss and transfusion requirements
- Shorter hospital stay

Annals of Vascular Surgery 1991
DREAM trial. N Eng J Med 2004;351:1607-18
EVAR-1 trial. Lancet 2005; 365: 2179-86
OVER trial. JAMA 2009

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Long-Term Outcomes of Abdominal Aortic Aneurysm in the Medicare Population

Marc L. Schermerhorn, M.D., Dominique B. Buck, M.D., A. James O'Malley, Ph.D., Thomas Curran, M.D., John C. McCallum, M.D., Jeremy Darling, B.A., and Bruce E. Landon, M.D., M.B.A.

Age	EVAR	Open	RR
Overall	1.6%	5.2%	3.2
67-69	0.9%	2.8%	3.2
70-74	1.1%	3.5%	3.1
75-79	1.5%	5.3%	3.4
80-84	2.6%	7.8%	3.0
>85	3.7%	7.8%	3.4

Schermerhorn et al: N Engl J Med 373:328, 2015

TRENDS IN EVAR OUTCOMES (2001-2008)

	2001	2002	2003	2004	2005	2006	2007	2008
Death (all ages)	2.2%	2.1%	1.6%	1.2%	1.5%	1.6%	1.6%	1.4%
Conversion to Open Repair	2.2%	2.1%	1.6%	0.9%	0.9%	0.5%	0.6%	0.3%

Schermerhorn et al: N Engl J Med 373:328, 2015

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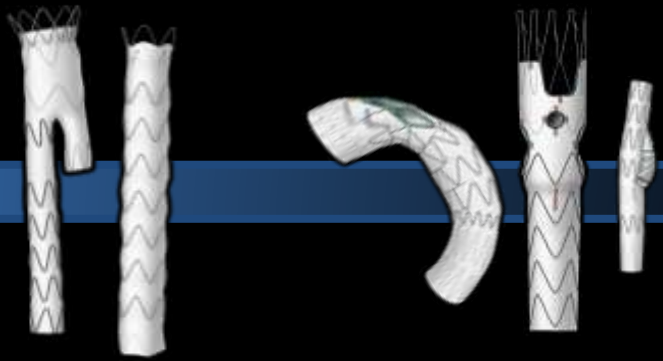
ENDOVASCULAR DEVICES



CT SCANNING

INTRAOP IMAGING

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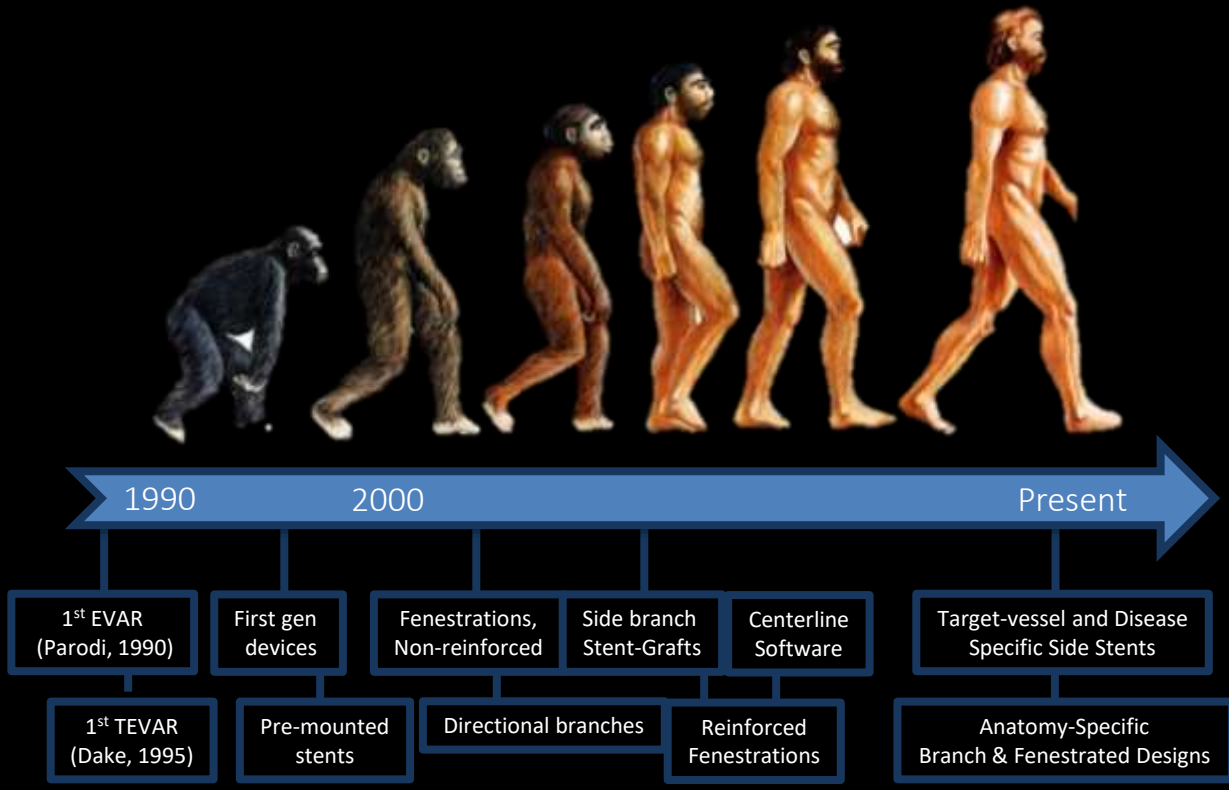
EVOLUTION TOWARDS BRANCH INCORPORATION



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SOME OF MANY FACES ON FEVAR DISSEMINATION

J. Anderson
Adelaide

T. Chuter
San Francisco

K. Ivancef
Malmo

R. Greenberg
Cleveland

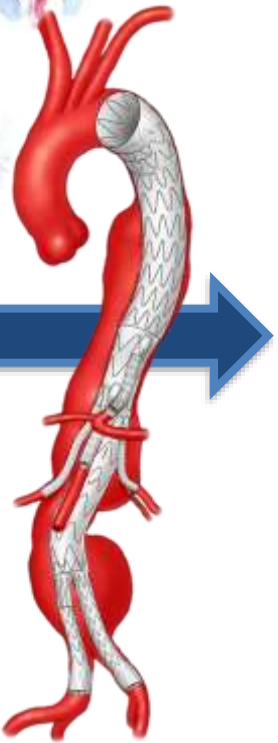
Eric Verhoeven

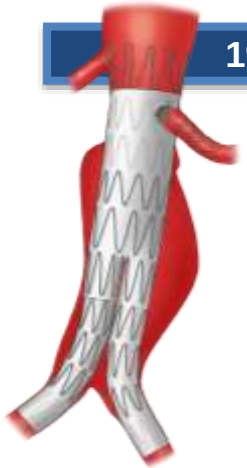
Stephan Haulon

Matt Eagletton

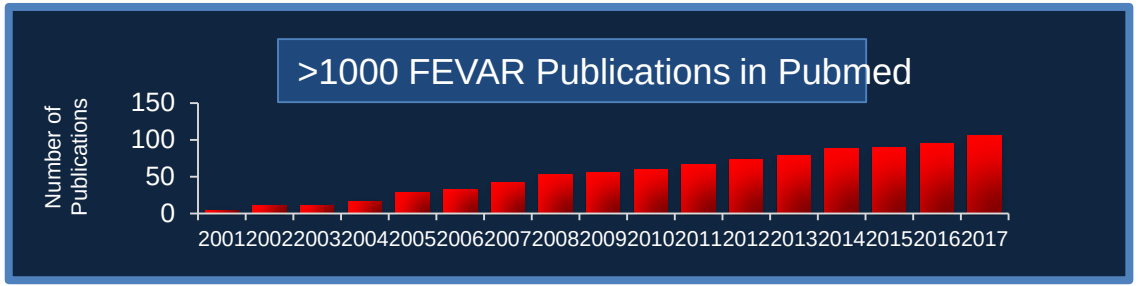
Tim Resch

Marcelo Ferreira





1998 to present



In Oderich Atlas of Fenestrated, Branched and Parallel Techniques, Springer 2016

eTAAA REPAIR RESULTS

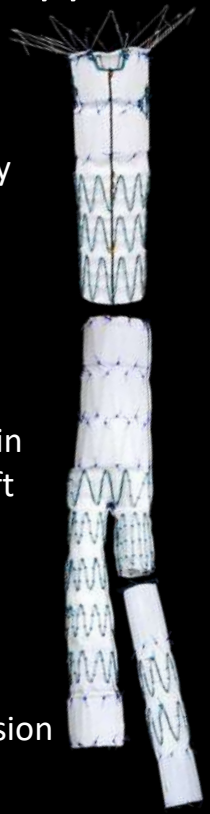
Author, Year	n	IV/I-III	Mean age	30-day mortality	SCI	Paraplegia	Dialysis
Kasprzak et al (2014)	83	30/53	71	7.2%	20%	13%	5%
Bisdas T et al (2015)	142	12/130	70	2.8%	16%	8%	
Dias N et al (2015)	72	17/55	68	6.9%	31%	21%	
Katsargyris et al (2015)	218	54/164	69	7.8%	10%	2%	
Maurel et al (2015)	204	85/119	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%
Oderich et al (2016)	185	112/73	74	4.0%	5%	3%	1%
Baba/Ohki et al (2017)	44	0/44	74	4.5%	16%		2%
Total	1435	383/1052	71	5.4%	14%	7%	5%

EVAR LANDSCAPE

Aneurysm Type	Study design	EVAR VS OPEN REPAIR	Findings
AAA	Prospective, randomized trials	Superior	Lower mortality and morbidity
Thoracic	Prospective pivotal study Large national dataset analysis	Superior	Lower mortality, morbidity and SCI
Pararenal	Prospective pivotal study Prospective PS-IDEs Multiple meta-analysis	Superior? in higher risk groups	Lower mortality and morbidity
TAAA	Prospective PS-IDEs Large single-center experiences	Superior? in higher risk groups	Lower mortality compared to historical open surgical results
Arch	Large hybrid experiences Recent device trials	?	?
Ascending	Few case series	?	?

ZENITH® FENESTRATED

FDA approval in April 2012



Proximal Main Body Graft

Distal Main Body Graft

Leg Extension Graft

Scallop
Scallops along the graft's proximal edge are 10 mm wide and 6–12 mm high.

Small Fenestration
Small fenestrations are 6 mm wide and 6 or 8 mm high.

Large Fenestration
Large fenestrations range from 8–12 mm in diameter.

- Infrarenal neck ≥4 mm and <15 mm
- Max 3 fenestrations, 2 of same type

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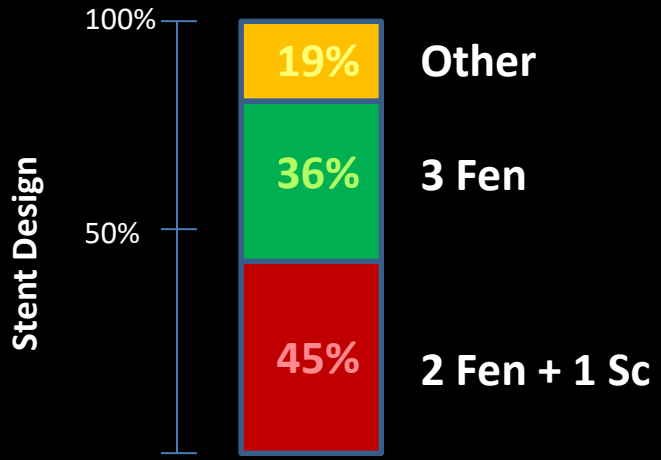
ZFEN ANNUAL DEVICE REQUESTS

8,620 ZFEN endografts ordered since approval!



Cook Medical direct communication

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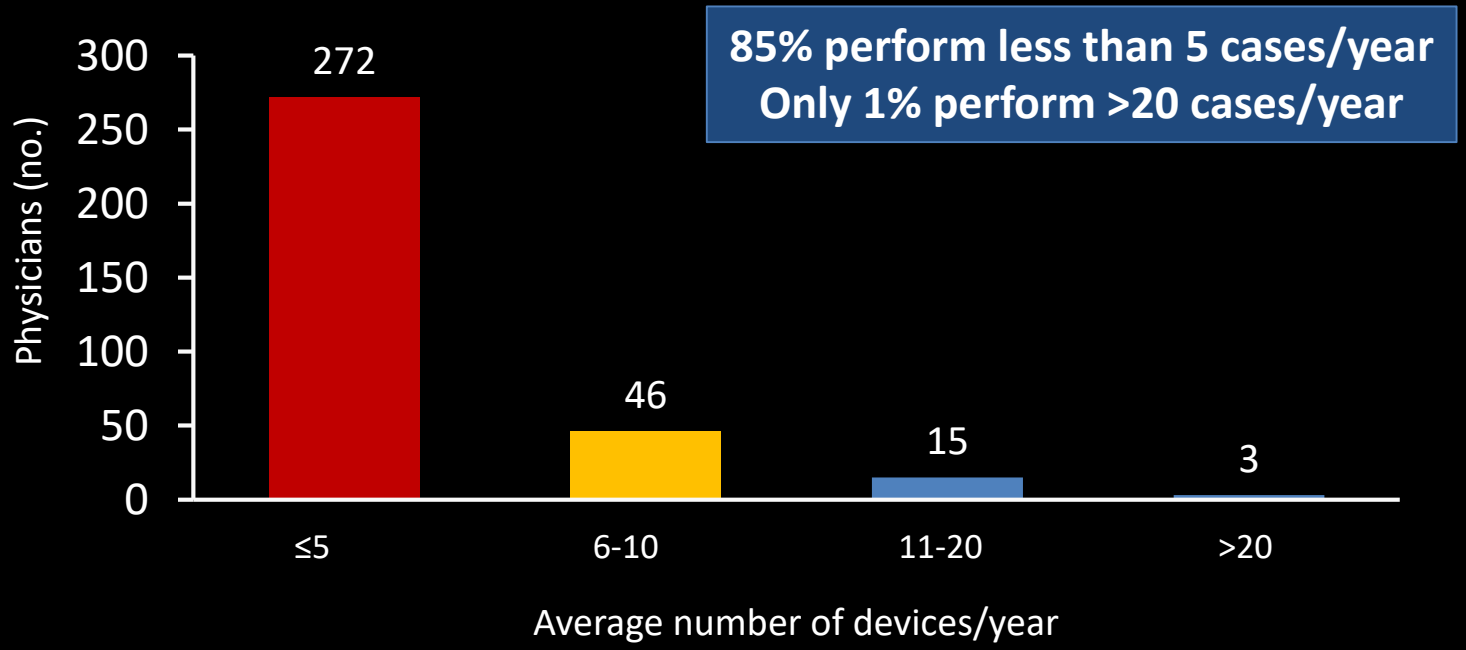
VOLUME OF CASES PER SURGEON



Simons J et al. J Vasc Surg 2018

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CLINICAL APPLICATION OF ZFEN

Maximum of 3 fenestrations

- 4-14mm neck
- 2/3 patients with complex AAAs do not qualify for ZFEN due to insufficient neck length

Mendes/ Oderich et al. J Vasc Surg 2014

PHYSICIAN MODIFICATIONS OF ZFEN

"in the last two years, all ZFENs have been modified to lengthen landing zone…"




Courtesy of Jesse Manunga, Minneapolis MN

UPCOMING TRIALS AND STENT DESIGN

ZFENPlus (Cook Medical)
- Pararenal and Extent IV
- Design Freeze and IDE submission

TAAAPlus (Cook Medical)
- Extent I-III
- Design Freeze and IDE submission

FDA approval of Cook IDEs
Site selection
IRB submissions (Late 2019)

2019

2020

TAMBE (WL Gore)
- Pararenal and Extent IV
- Design Freeze a
IDE submission

TAMBE Patient Enrollment (May 2019)

MEDTRONIC TAAA Multicenter PS-IDE
- Extent I-IV
- Early feasibility study

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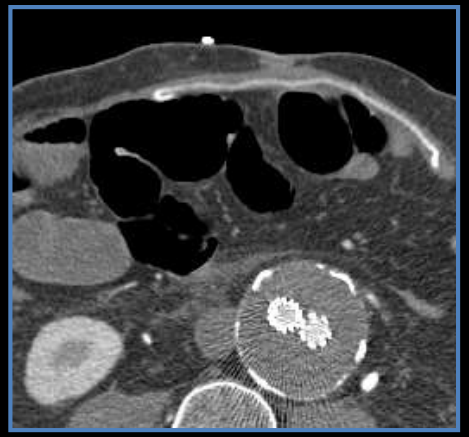

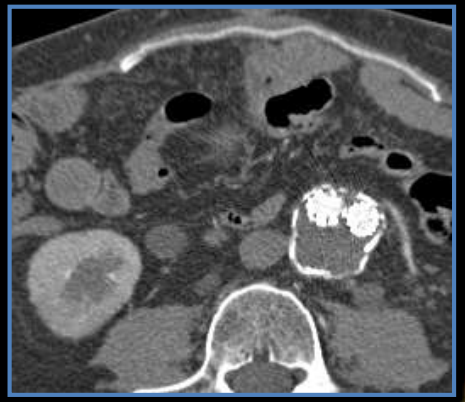

April 7, 2007

TRIAL DESIGN

Prospective, non-randomized study:

- Aortoiliac, pararenal, TAAA and arch aneurysms
- Chronic aortic dissections

Endovascular arm

- Two FDA approved IDE protocols
- QOL questionnaires, imaging and clinical exam
- Independent monitoring and event adjudication

Open surgical arm

- QOL questionnaires, imaging and clinical exam

ClinicalTrials.gov - NCT01937949 and NCT02089607

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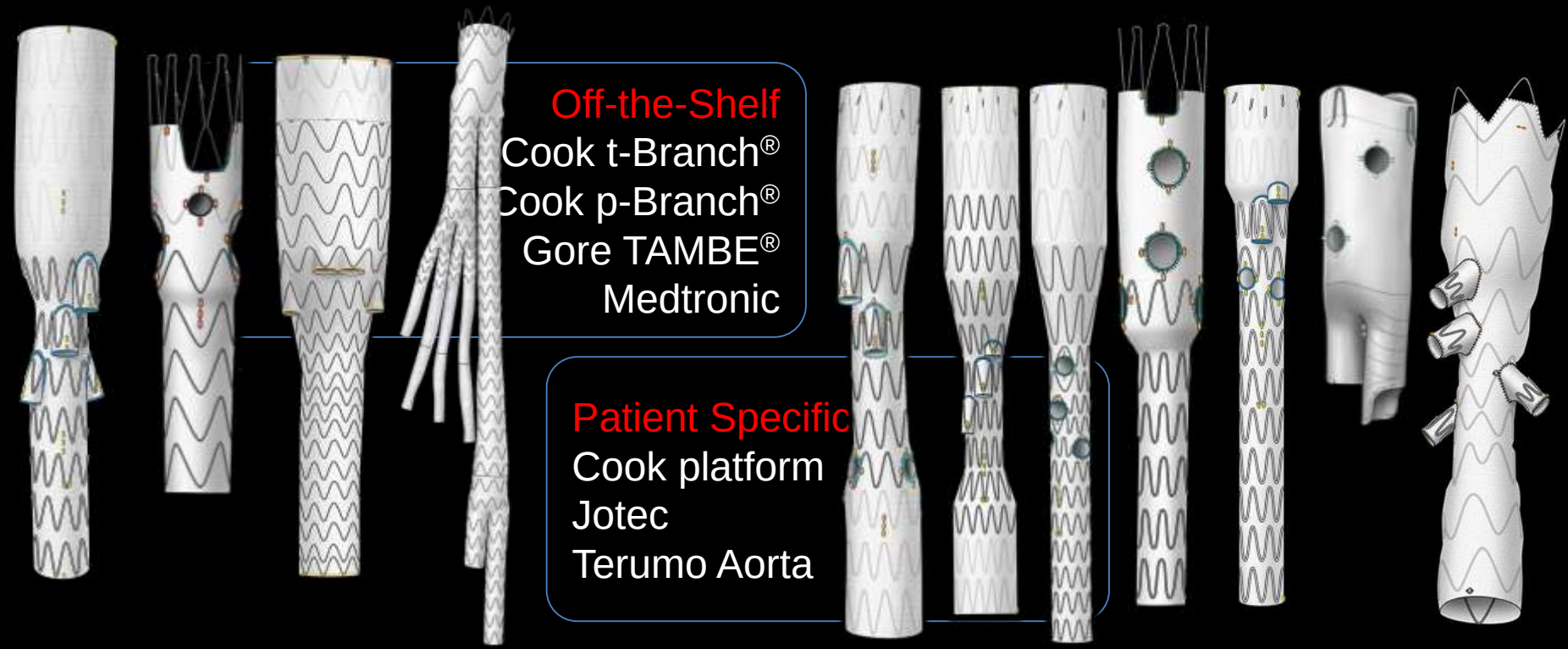
STENT DESIGNS

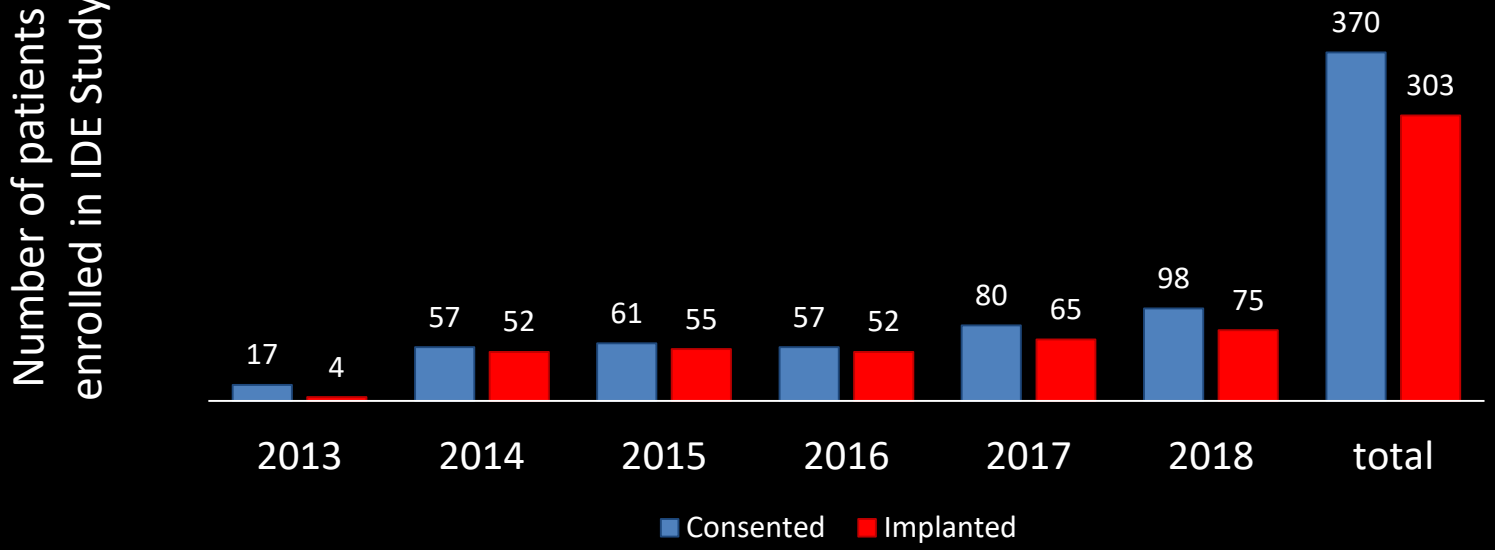


Off-the-Shelf
Cook t-Branch®
Cook p-Branch®
Gore TAMBE®
Medtronic

Patient Specific
Cook platform
Jotec
Terumo Aorta

MAYO CLINIC

PATIENTS CONSENTED AND IMPLANTED IN ONGOING IDE STUDIES (2013-2018)



REFERRAL PATTERN

33 states, 3 countries

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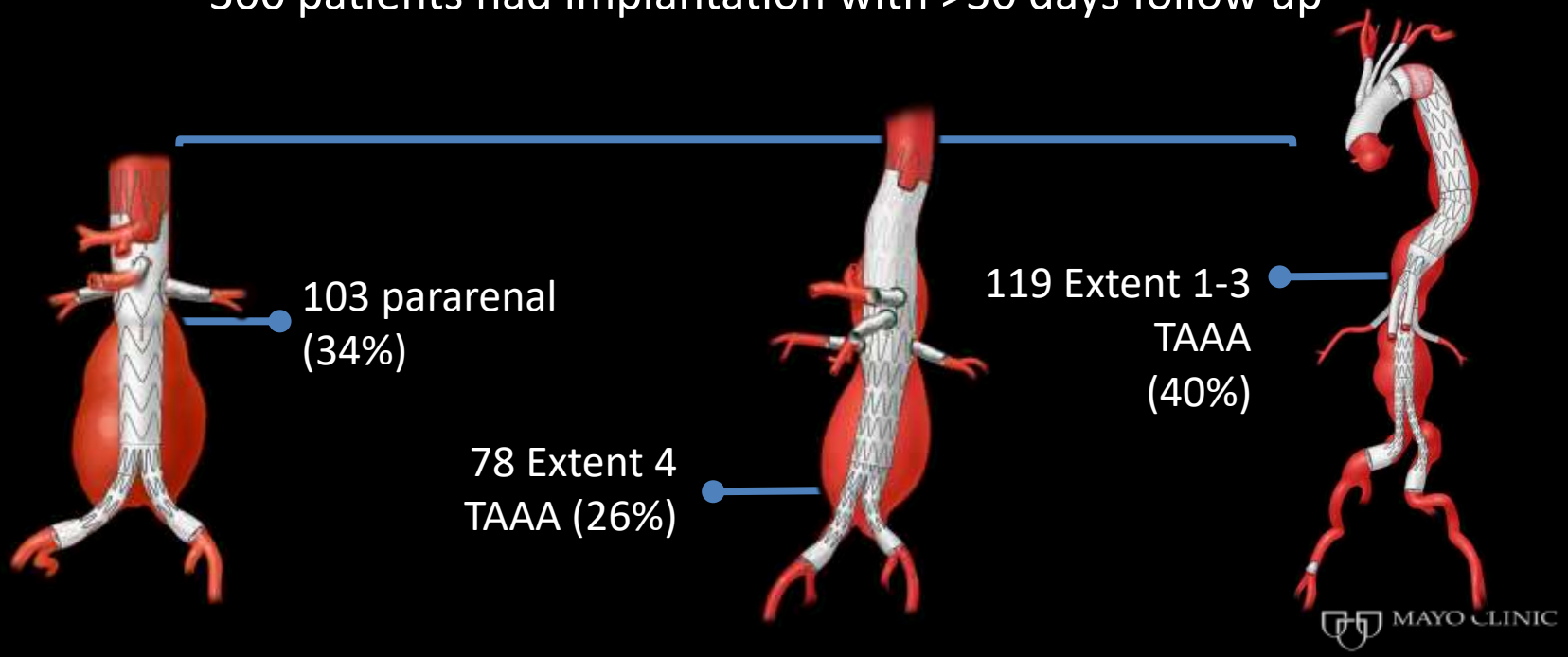
STUDY PATIENT

370 patients consented
42 patients waiting implantation/ 18 withdrawn
300 patients had implantation with >30 days follow up



	Overall n = 300	Pararenal n = 103	Extent IV n = 78	Extent I-III n = 119	P value
	Percent or Mean ± Standard Deviation				
Mean age (years ± SD)	74±8	76±7	74±8	73±8	**.04**
Age > 80 years	76 (26)	31 (30)	18 (23)	27 (23)	.38
Male gender	212 (71)	76 (75)	64 (82)	72 (61)	**.004**
Cigarette smoking	245 (82)	82 (80)	65 (83)	98 (83)	.84
Hypertension	267 (90)	88 (86)	69 (88)	110 (93)	.23
Hypercholesterolemia	247 (83)	82 (80)	67 (86)	98 (83)	.62
Coronary artery disease	150 (50)	49 (48)	45 (58)	56 (47)	.32
Chronic pulmonary disease	99 (33)	32 (31)	21 (27)	46 (39)	.19
Chronic Kidney Disease III-V	137 (46)	48 (47)	37 (47)	52 (44)	.87
Congestive heart failure	30 (10)	7 (7)	10 (13)	13 (11)	.38
Prior aortic repair	137 (46)	16 (16)	25 (32)	96 (81)	**<.0001**
Chronic Dissection	22 (7)	0	0	22 (19)	**<.0001**
Aneurysm diameter (mm)	66±12	62±10	64±11	69±12	**<.0001**

STENT DESIGN

1144 renal-mesenteric arteries (3.9/patient)
250 patients (83%) had ≥ 4-vessels*

	Overall n = 300	Pararenal n = 103	Type IV n = 78	Type I-III n = 119	P value
	Percent or Mean ± Standard Deviation				
Total target vessels	1144	399	306	439	
Vessels per patient	3.9±0.6	3.9±0.6	3.9±0.5	3.8±0.6	.30
Fenestrations	745 (65)	342 (86)	270 (88)	133 (30)	<.001
Directional branches	350 (31)	8 (2)	36 (12)	306 (70)	
Double-wide scallops	49 (4)	49 (12)	0	0	

* All patients with <4-vessels had variations from normal anatomy (e.g. single kidneys, pelvic transplants, celio-mesenteric trunks, etc)

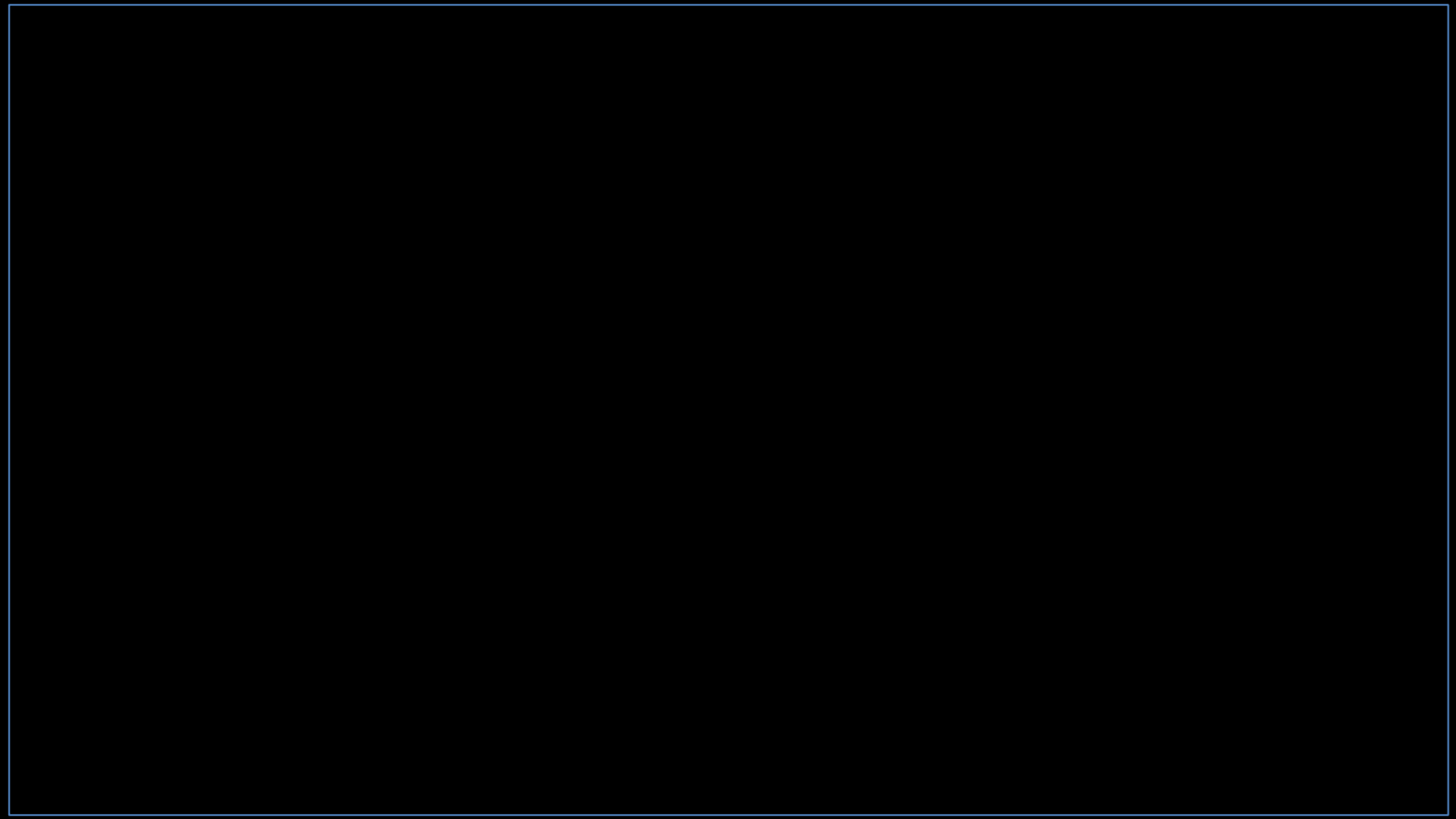
PROCEDURE DETAILS

Technical success was 99.2%

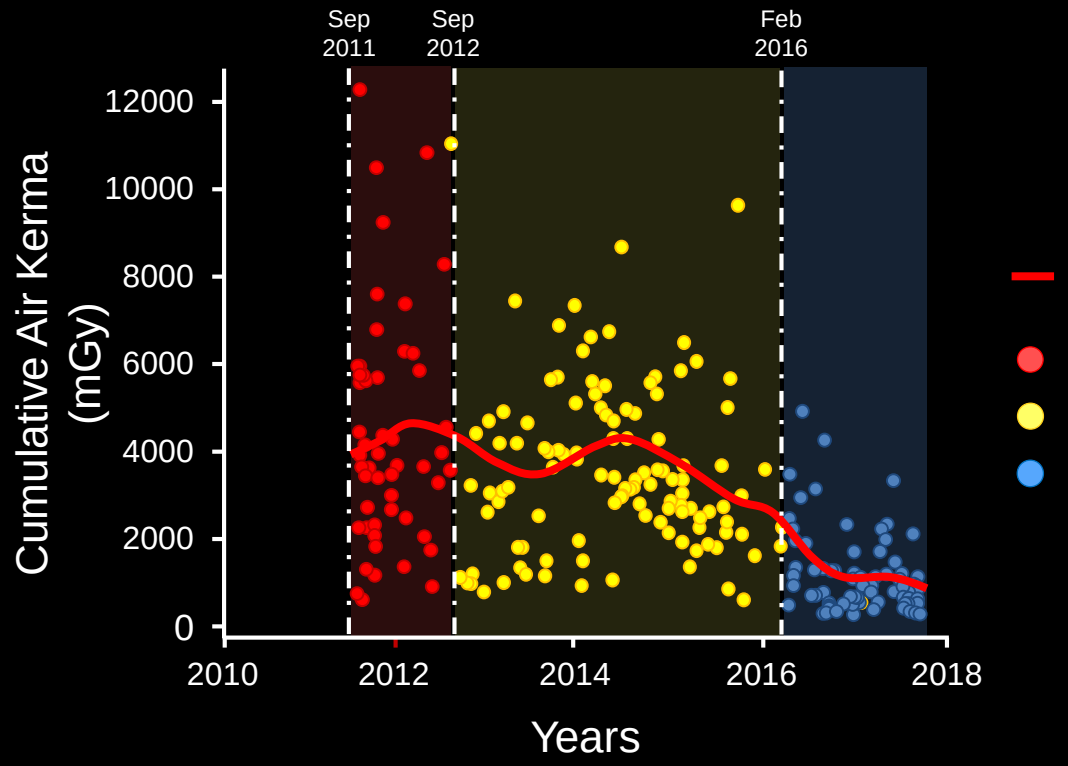
	Overall n = 300	Pararenal n = 103	Extent IV n = 78	Type I-III n = 119	P value
	n (Percent) or Mean ± Standard Deviation				
General anesthesia	100	100	100	100	NA
CSF drainage	188 (63)	19 (19)	58 (74)	111 (94)	**<.001**
Neuromonitoring	214 (72)	23 (23)	75 (96)	116 (98)	**<.001**
Upper extremity approach	272 (91)	76 (74)	78 (100)	118 (99)	**<.001**
Percutaneous femoral	250 (84)	87 (85)	65 (83)	98 (83)	.89
Contrast volume (cc)	154±56	134±46	156±51	171±63	**<.0001**
Fluoroscopy time (min)	83±32	74±26	81±33	92±34	**.0002**
Total radiation dose (mGy)	2203±1817	1918±1647	2529±1925	2183±1867	**0.13**
Total Endo time (min)	165±63	147±52	161±64	185±66	**.0001**
EBL (ml)	445±502	347±415	423±553	550±521	**.014**

ADVANCED IMAGING

MAYO CLINIC



EFFECTIVE DOSE



Mean radiation Dose (mGy)

System 1	3892 ± 2258
System 2	3556 ± 1939
System 3	1213 ± 946

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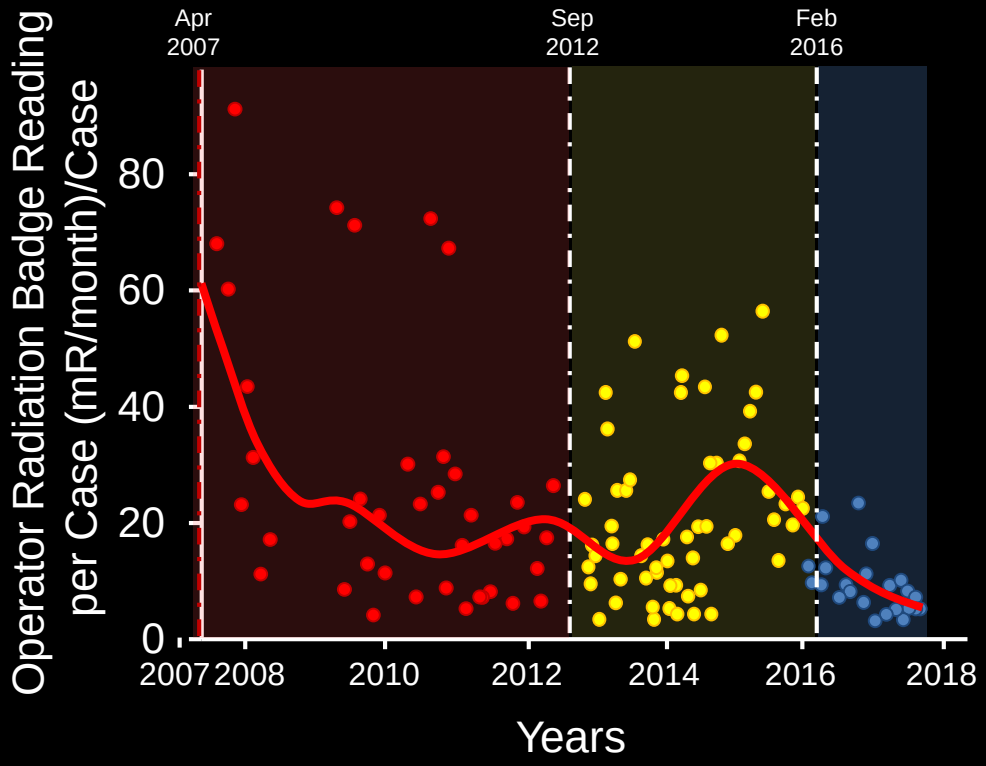
OPERATOR DOSE PER CASE



Mean radiation Dose (mR)

System 1	26 ± 3
System 2	20 ± 2
System 3	9 ± 4

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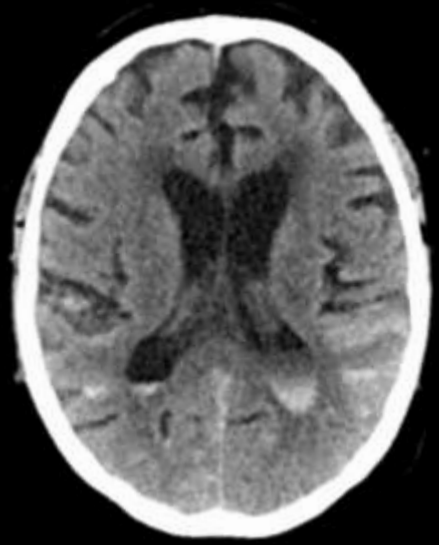
30-DAY RESULTS

Two (0.7%) 30-day deaths (no in-hospital death)

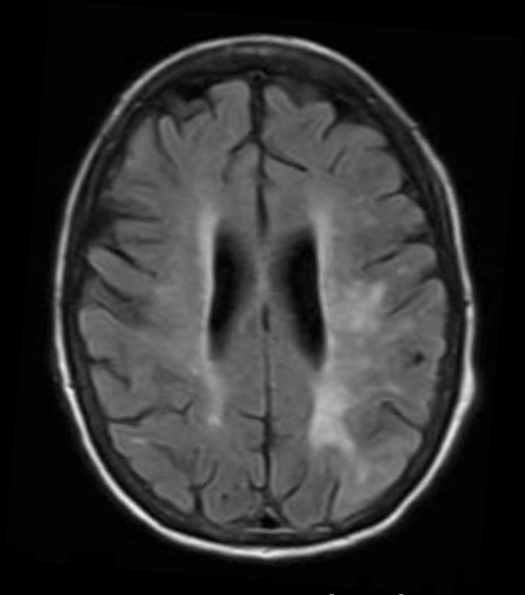
	Overall n = 300	Pararenal n = 103	Extent IV n = 78	Extent I-III n = 119	P value
	n (Percent)				
Any MAE	82 (27)	22 (22)	21 (27)	38 (32)	.20
Death	2 (0.7)	0	1 (1)	1 (1)	**.55**
EBL >1L	25 (8)	4 (4)	6 (8)	13 (16)	**.06**
AKI by RIFLE criteria	43 (14)	11 (11)	15 (19)	17 (14)	.28
New-onset dialysis*	3 (1)	1 (1)	1 (1)	1 (1)	.95
Myocardial infarction	10 (3)	4 (4)	5 (6)	1 (1)	**.09**
Respiratory failure	6 (2)	1 (1)	2 (3)	3 (3)	.65
Spinal cord injury	13 (4)	1 (1)	0	12 (10)	.004
Stroke	2 (1)	1 (1)	1 (2)	0	.50
Bowel ischemia	4 (2)	3 (3)	1 (2)	0	.19

INTRACRANIAL HEMORRHAGE



Subarachnoid and intraventricular hemorrhage

Intracerebellar hemorrhage



Intracerebral hemorrhage

SPINAL CORD INJURY

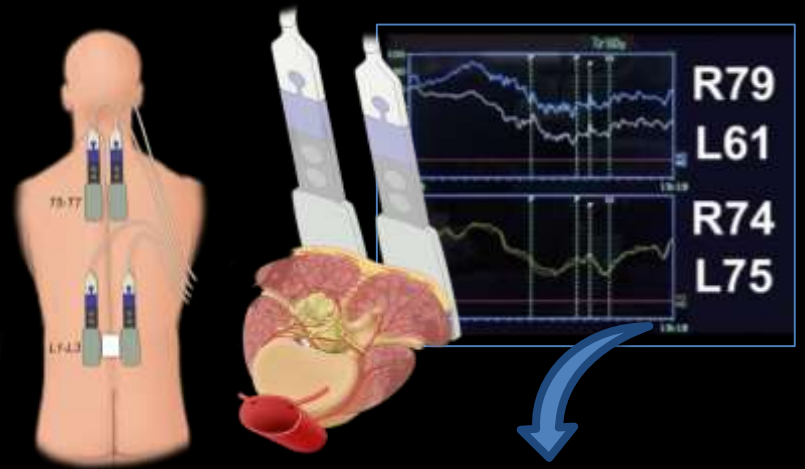
13 patients (4%) had any spinal cord injury
Permanent deficit in 4 patients (1%)

	Overall n = 300	Pararenal n = 103	Type IV n = 78	Type I-III n = 119	P value
	n (Percent)				
Any spinal cord injury	13 (4)	1 (1)	0	12 (10)	.004
Grade 1-2 (paraparesis)	5 (42)	0	-	5 (42)	
Grade 3a-c (paraplegia)	8 (58)	1 (100)	-	7 (58)	
Resolution					.31
No improvement	1 (8)	0	-	1 (8)	
Partial (ambulatory)	3 (23)	1 (100)	-	2 (17)	
Complete improvement	9 (69)	0	-	9 (75)	

CHANGES IN PRACTICE

- Eliminated spinal drainage:
  - Extent IV TAAAs
  - First stage procedures
  - Most Extent III TAAA repairs

- Changed protocol from routine pressure controlled drainage (10cmH2O, max 20 ml/Hr) to selective drainage guided by decline in Near Infrared Spectroscopy (NIRS) or symptoms



No Decline in SO_2 or Symptoms

Check patency only (1-2ml/ hr)

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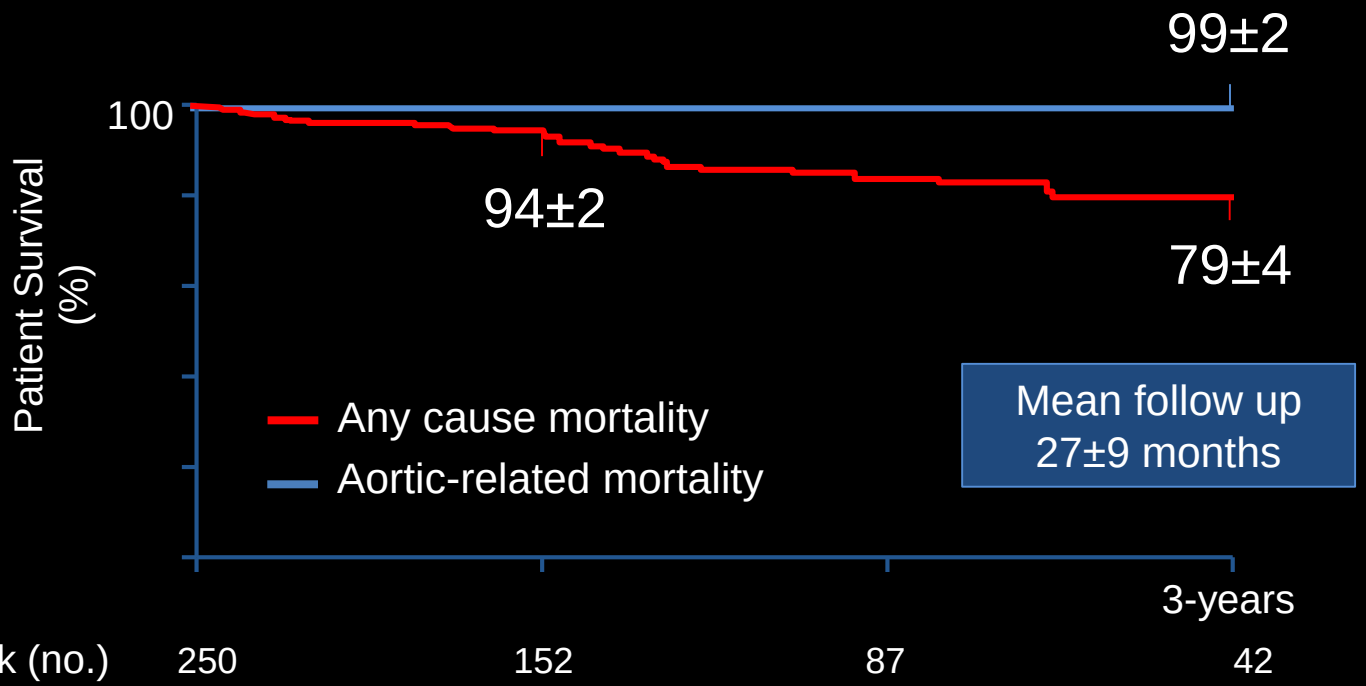
PATIENT SURVIVAL



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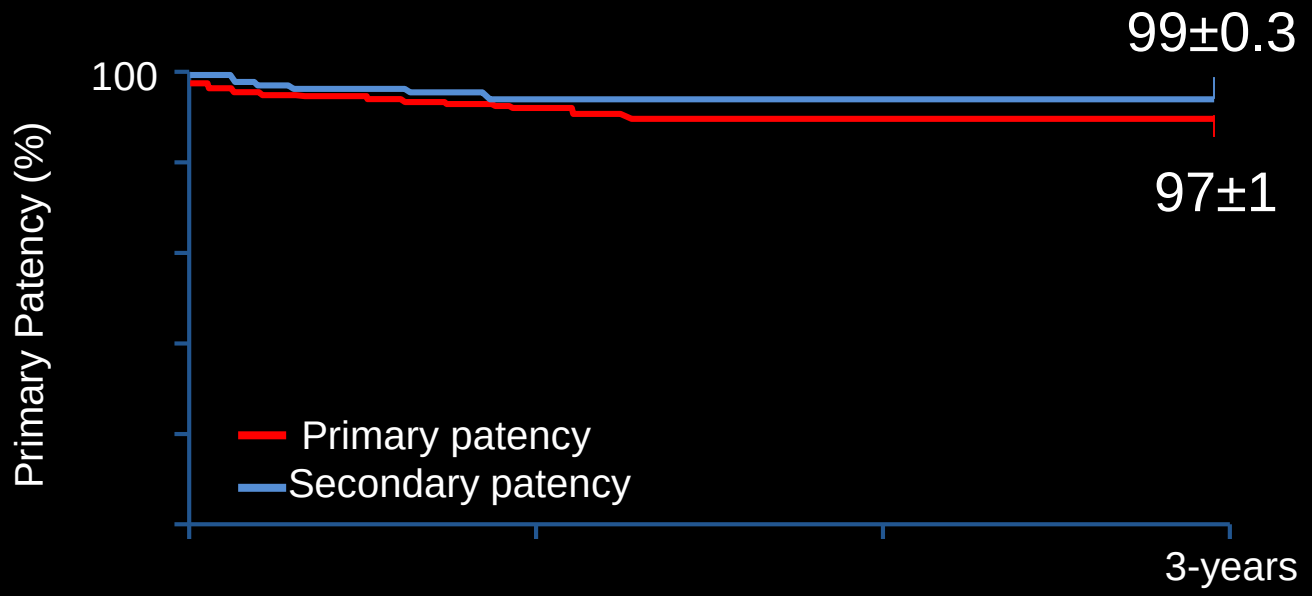
TARGET VESSEL PATENCY

All renal-mesenteric target vessels



At risk (no.)				
Primary patency	954	587	344	169
Secondary patency	954	590	351	174

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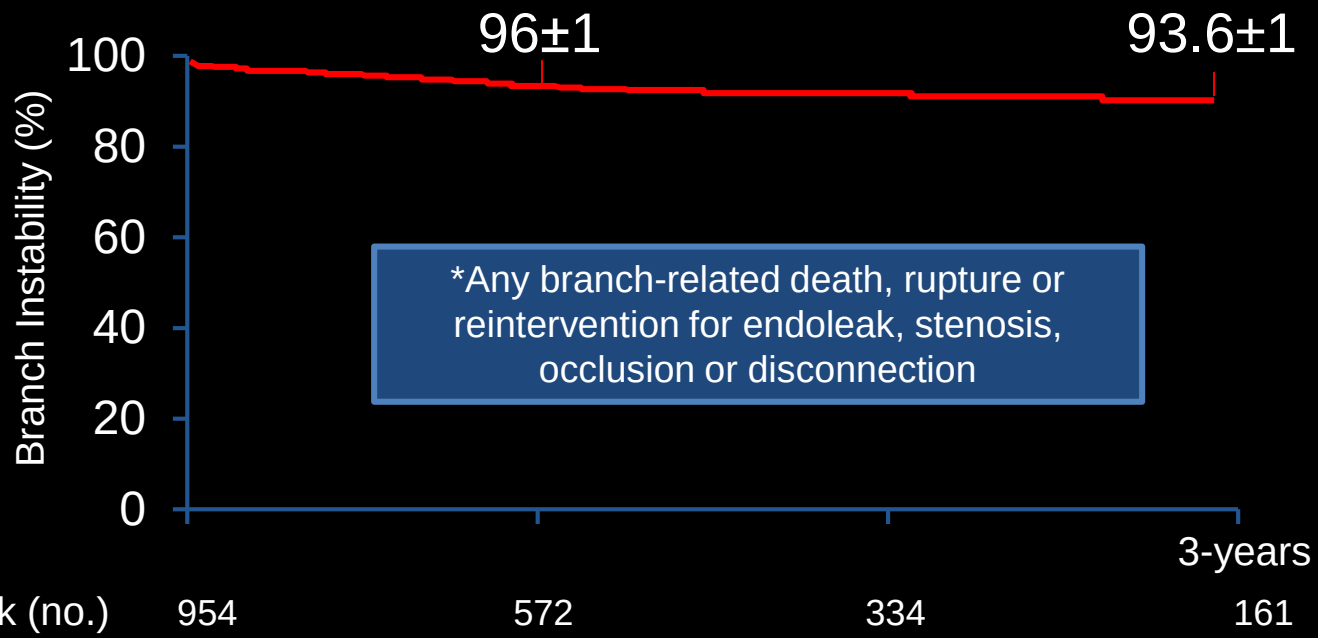
TARGET VESSEL INSTABILITY*

All renal-mesenteric target vessels



MAYO CLINIC

Prospective assessment of health-related quality of life changes in treated by Fenestrated and Branched Endografts

Giuliano de A. Sandri, MD, Gustavo Oderich, MD, Emanuel Tenorio MD PhD, Jan Hofer, RN, Jean Wigham, RN, Alisa Diderrich, RN, Thanila Macedo, MD, Stephen Cha, MS

VAM 2017

SAN DIEGO, CALIFORNIA

J Vasc Surg 2018, in press

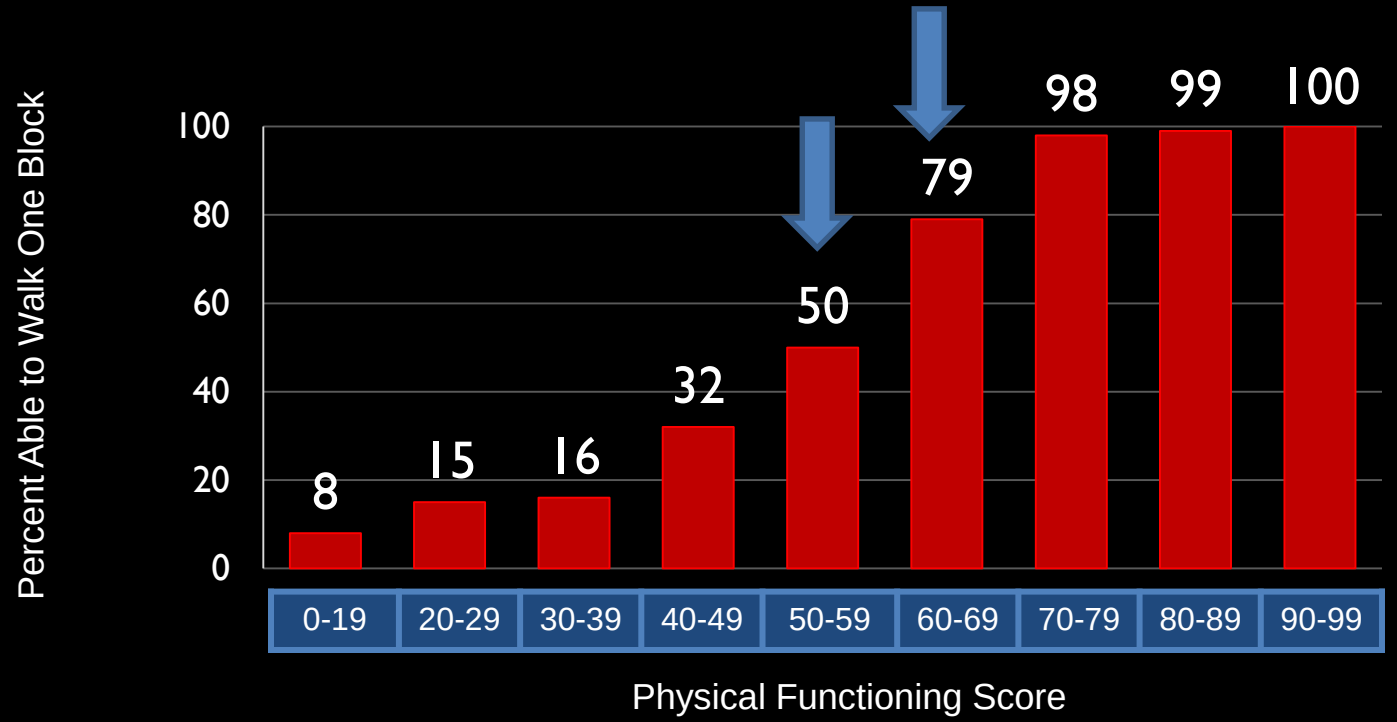
MAYO CLINIC

BASELINE QOL MEASURES

497 questionnaires were analyzed (3.1 per patient)

Baseline SF 36 components (0-100)	PAA n = 57	TAAA n = 102	P value
Physical component scores			
Physical Functioning	66±24	57±25	0.032
Role-physical	68±35	47±42	0.001
Pain Index	71±22	62±26	0.013
General Health Perceptions	73±16	66±19	0.014
Mental component scores			
Vitality	61±18	53±23	0.018
Social Functioning	86±18	77±25	0.02
Role-emotional	83±28	75±38	0.14
Mental Health Index	80±15	75±19	0.11
Physical Component Scale	44±9	39±10	0.002
Mental Component Scale	54±8	52±11	0.16

HOW MANY PATIENTS CAN WALK ONE BLOCK?



Ware JE, Snow KK, Kosisnki M, Gandek B. SF-36 Health Survey Manual and Interpretation Guide. Boston: The Health Institute, 1993.

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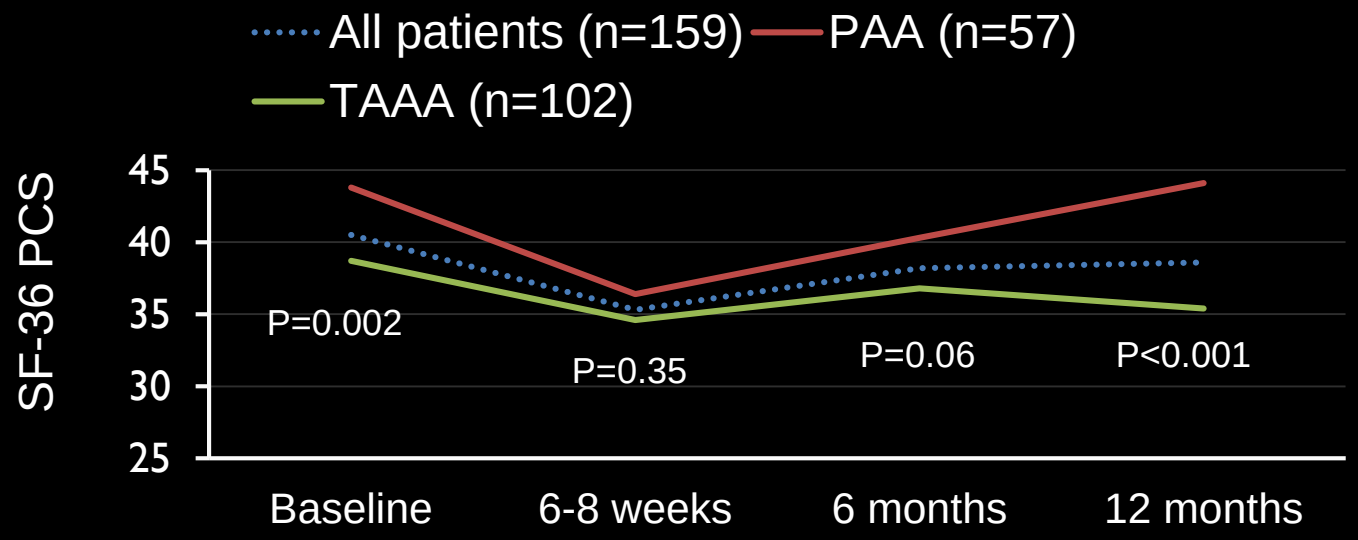
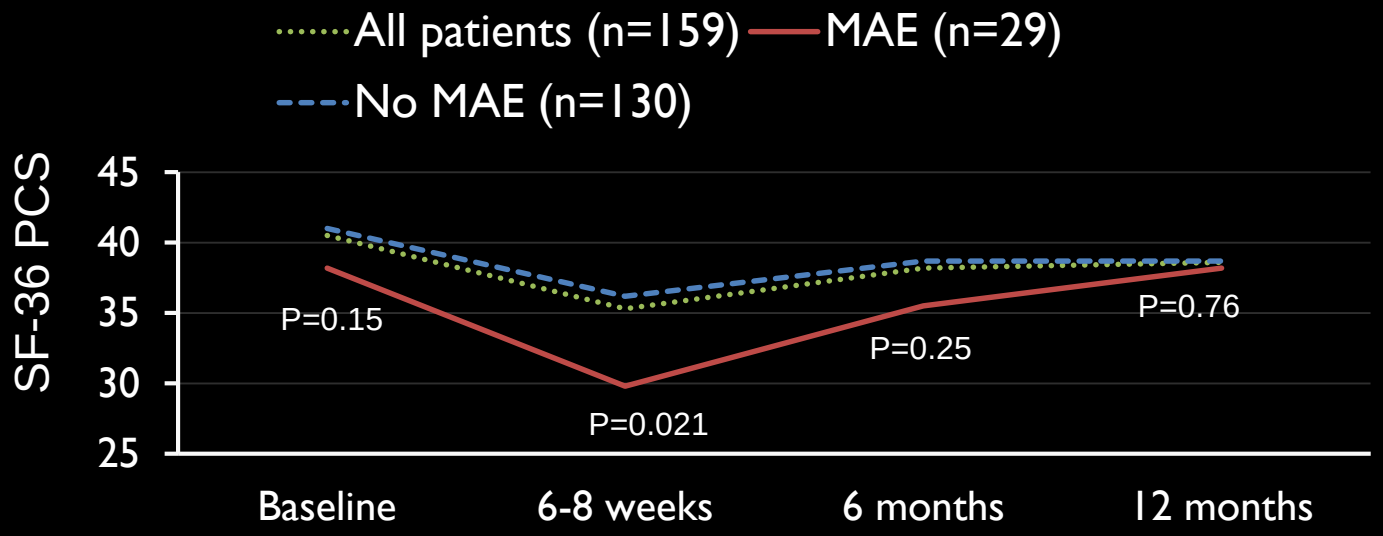
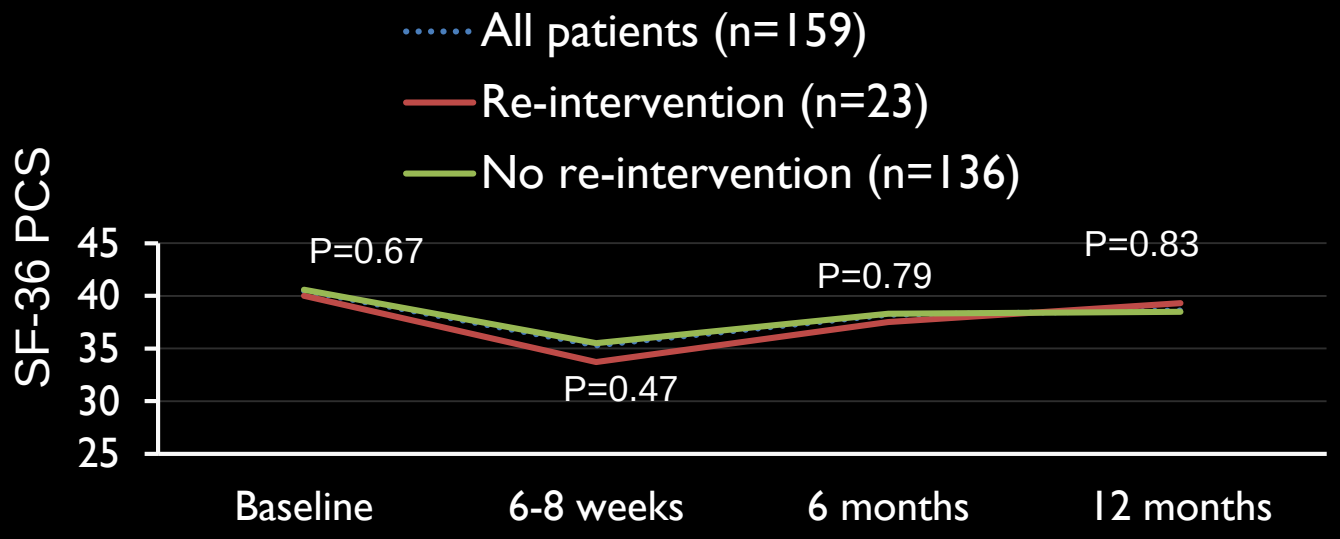
PHYSICAL COMPONENT SCORES (PCS)



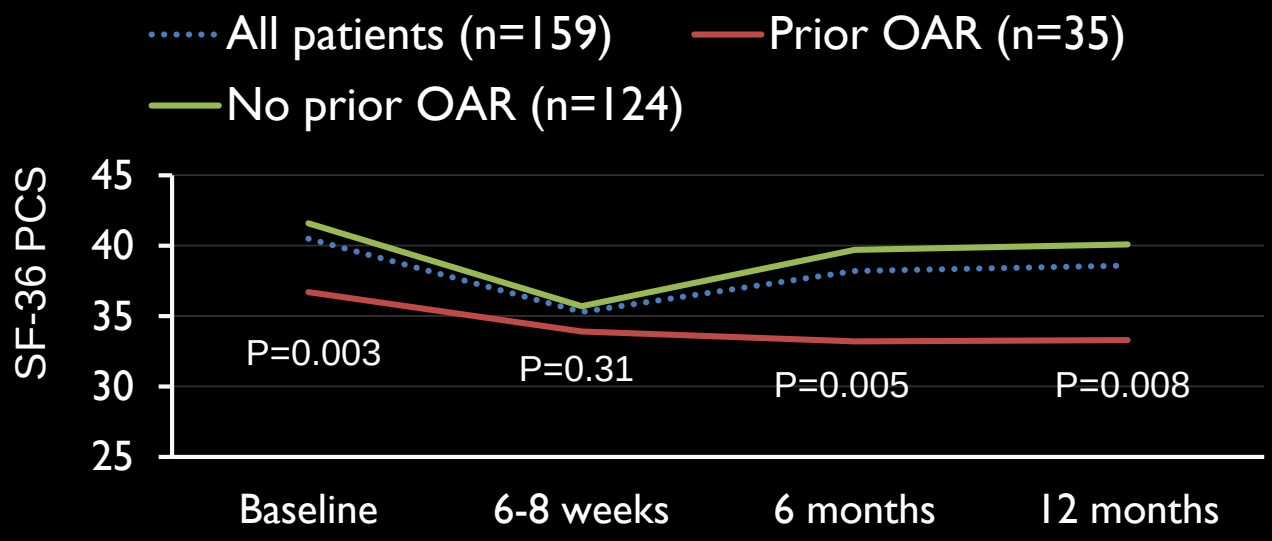
MAJOR ADVERSE EVENTS & PHYSICAL SCORES



REINTERVENTION & PHYSICAL SCORES

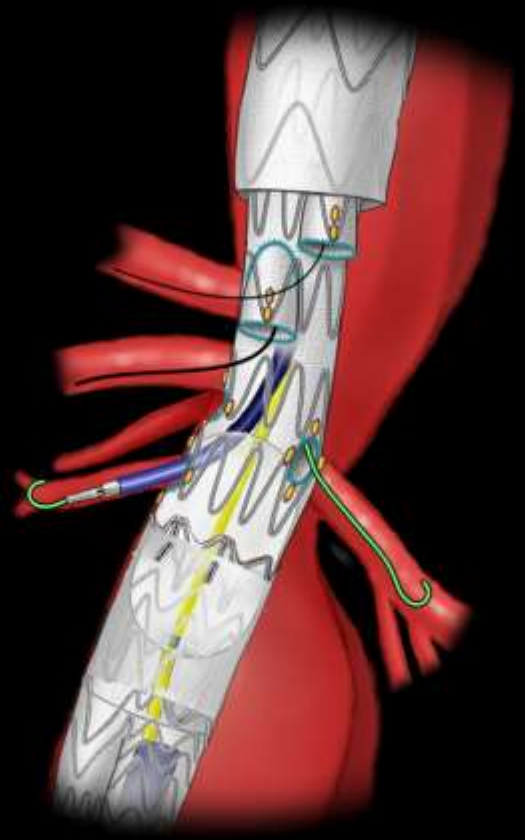


PRIOR OPEN REPAIR & PHYSICAL SCORES



UNITED STATES FENESTRATED-BRANCHED RESEARCH CONSORTIUM

Gustavo S. Oderich, Mark Farber, Darren Schneider, Andy Schanzer, Adam Beck, Carlos Timaran, Matt Eagleton and Matthew Sweet



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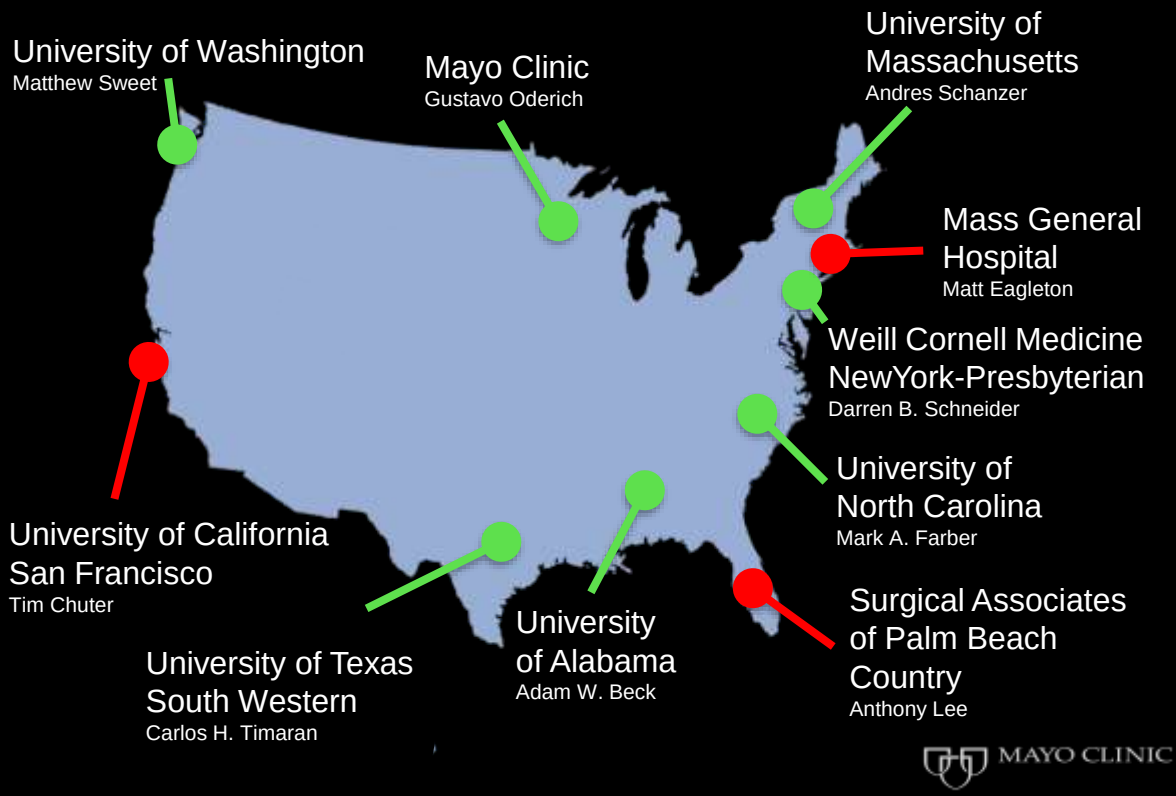
US FENESTRATED-BRANCHED RESEARCH CONSORTIUM

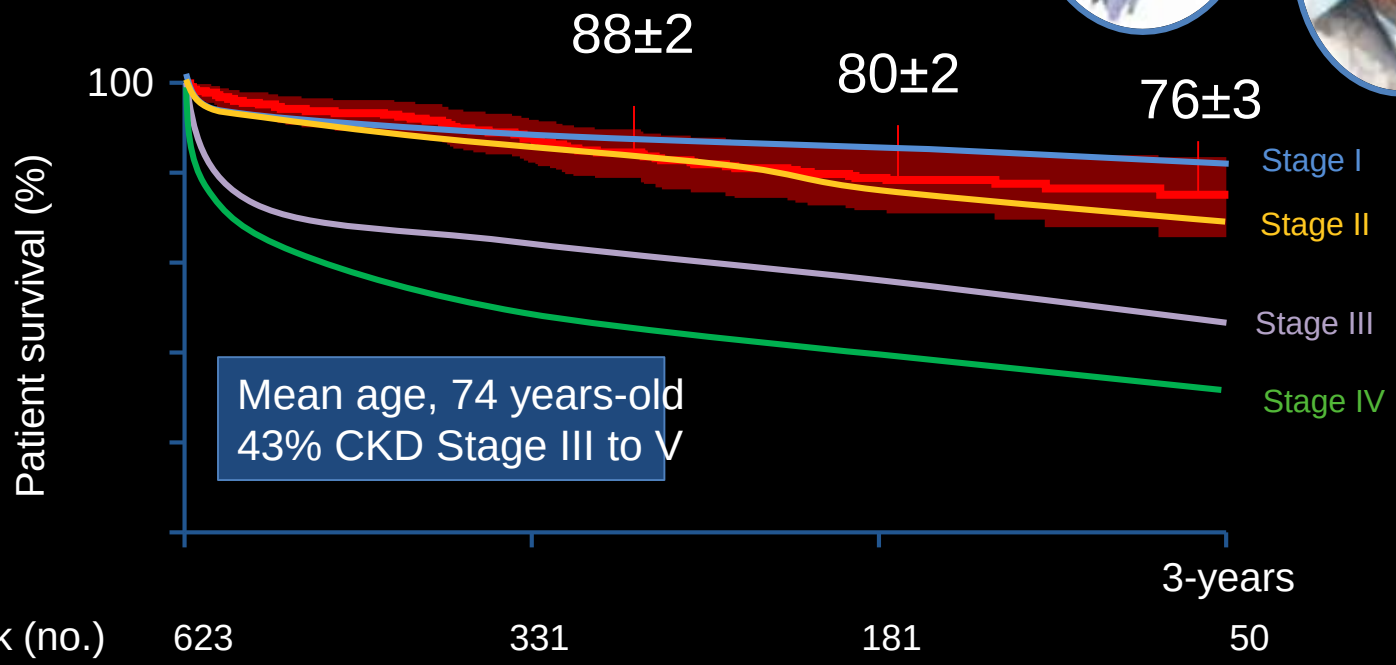
- 10 US sites
- Prospective, physician-sponsored studies
- Monitored, audited
- Similar device design with selective use of fenestrations and branches



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

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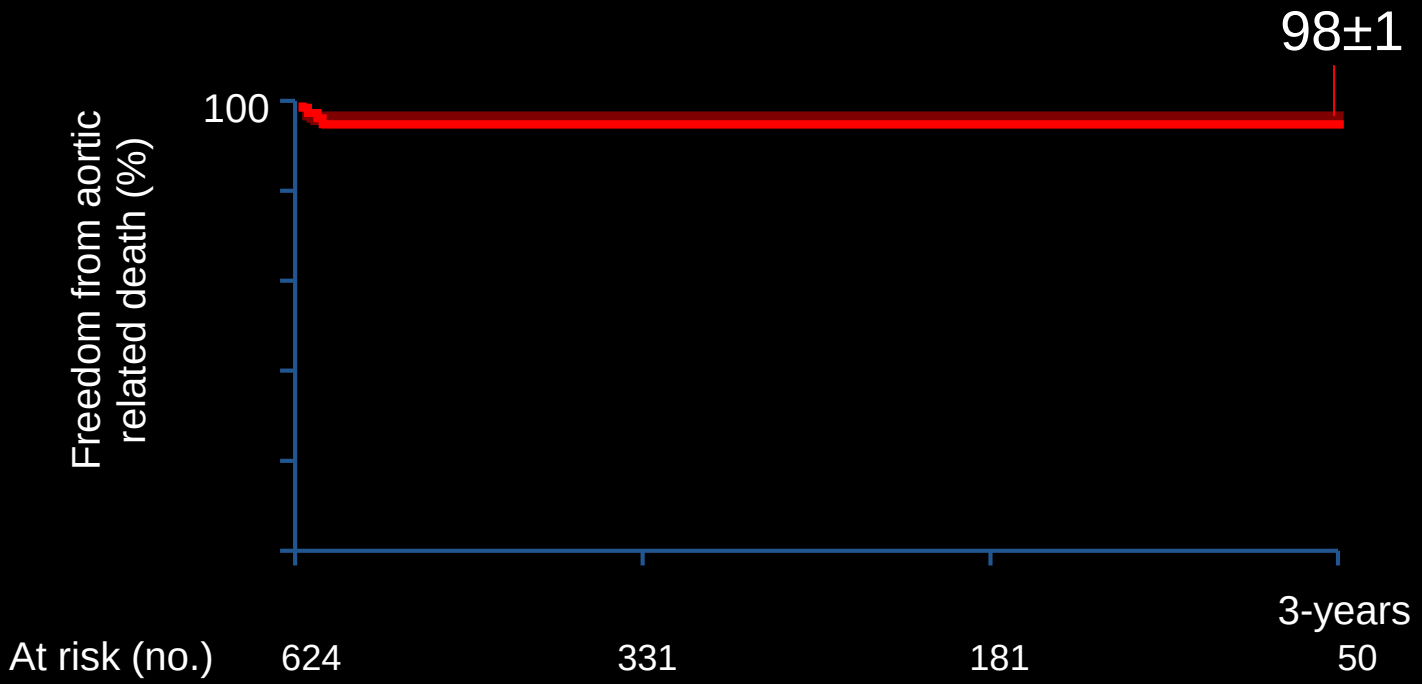
AORTIC RELATED DEATH



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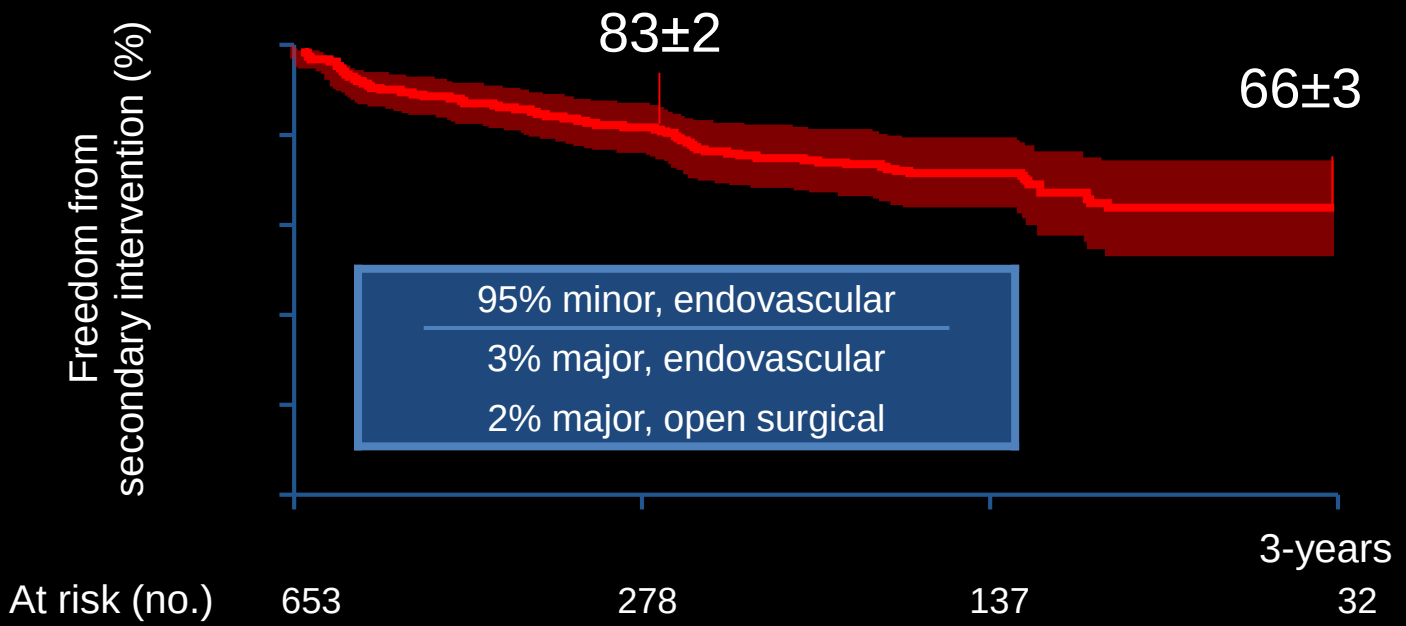
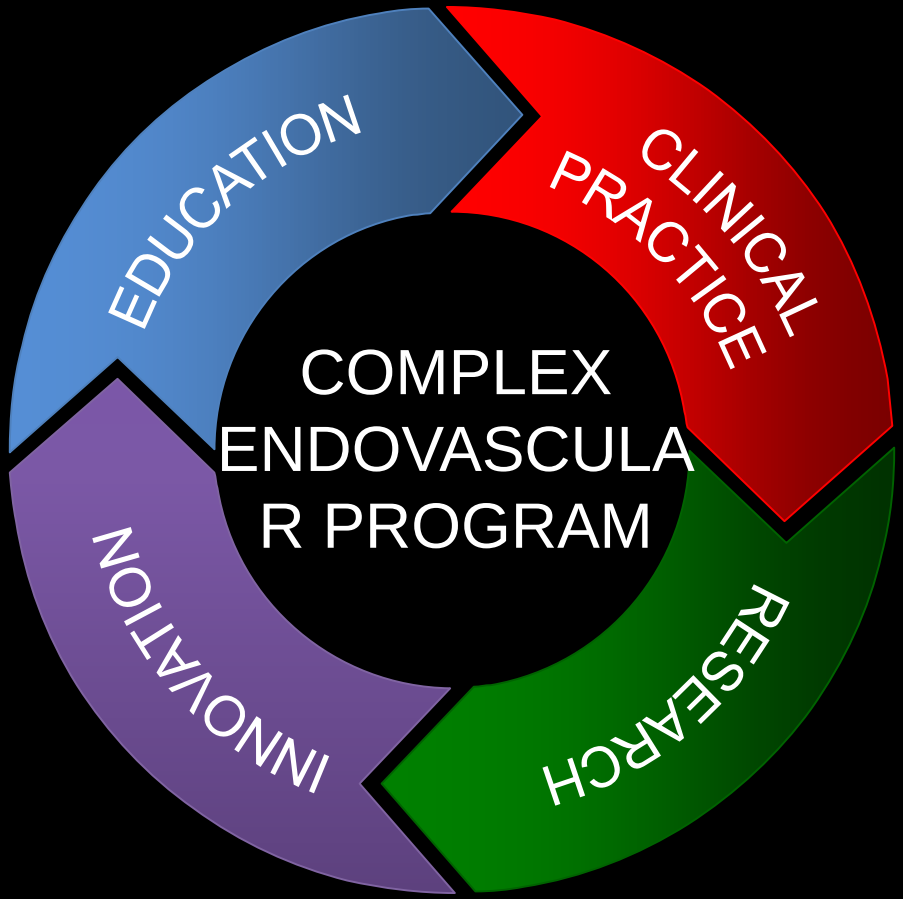
SECONDARY INTERVENTIONS




EDUCATION
CLINICAL PRACTICE
RESEARCH
INNOVATION
COMPLEX ENDOVASCULAR PROGRAM

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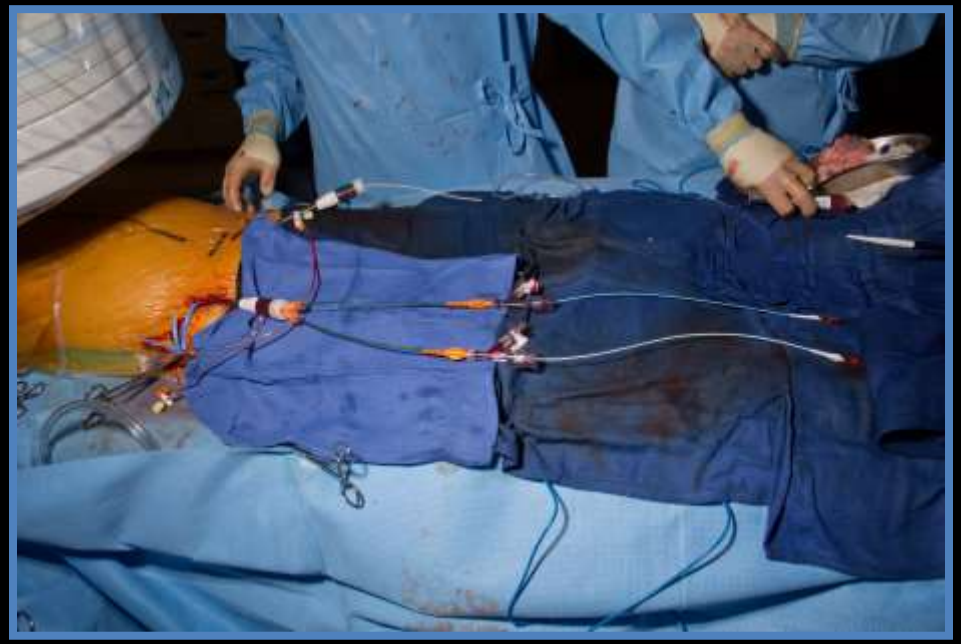
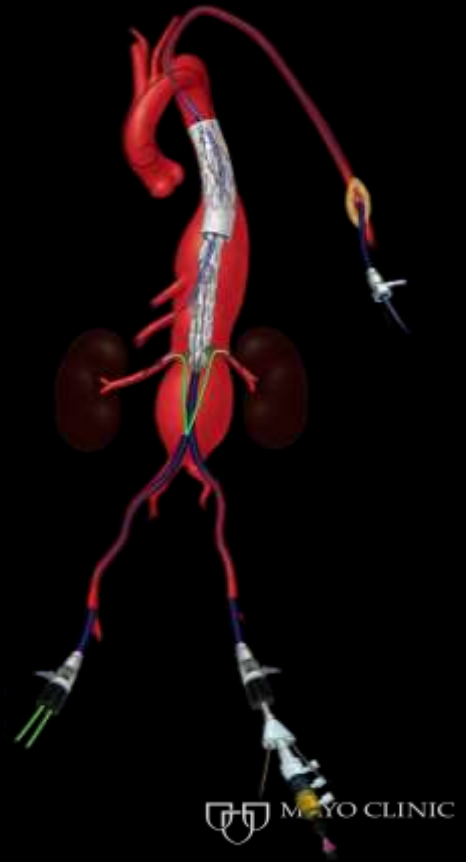
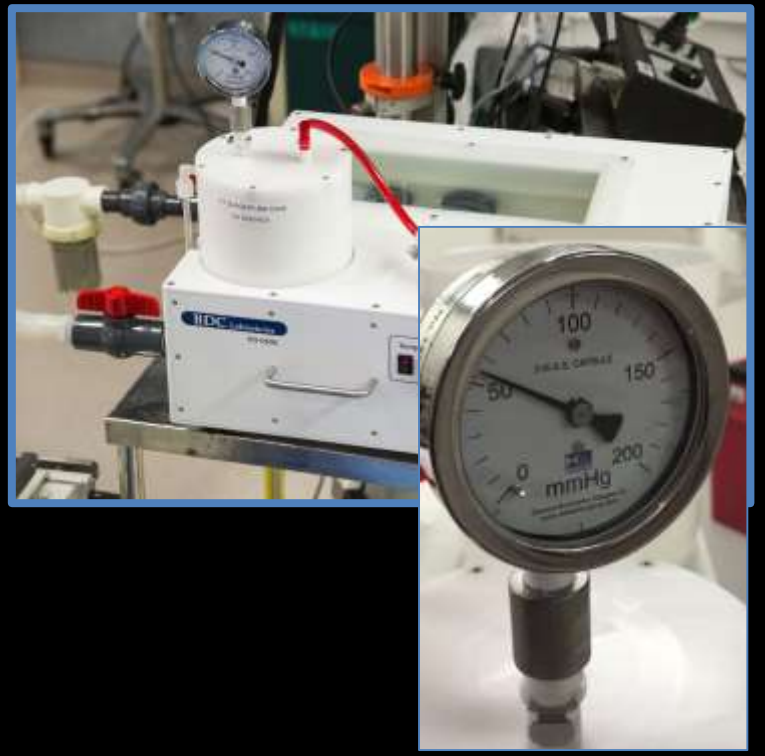
HOW CAN SIMULATION HANDLE THIS COMPLEX SETUP?







- 3D aortic branch model
- Fluid pump with physiologic conditions (Temp 36 °C, pulsatile flow at mean pressure of 80 mmHg)

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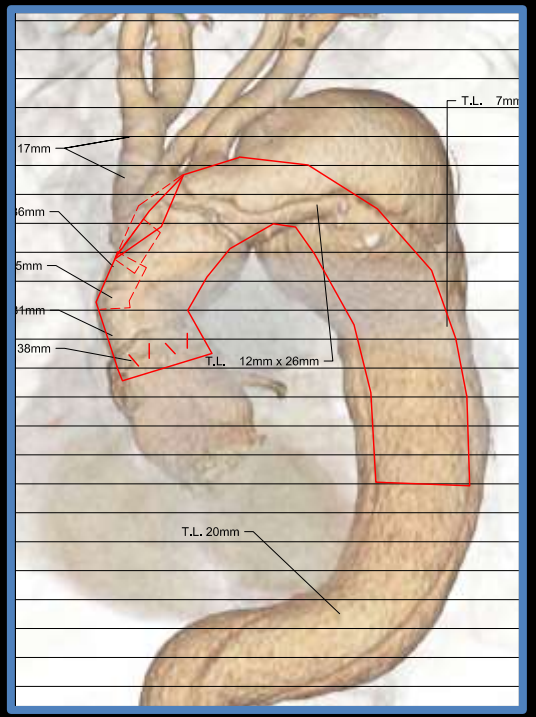
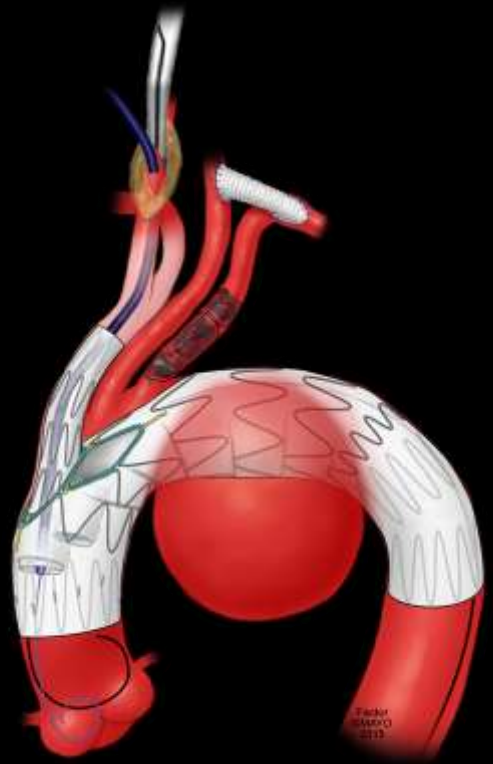
SIMULATION ANGIO

REAL CASE ANGIO

79-year-old male with prior ascending repair and large arch aneurysm





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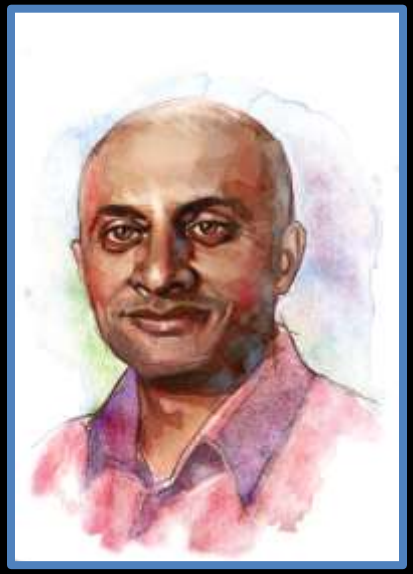
REHEARSAL DEBRIEFING



Cherrie Abraham
Montreal, Canada

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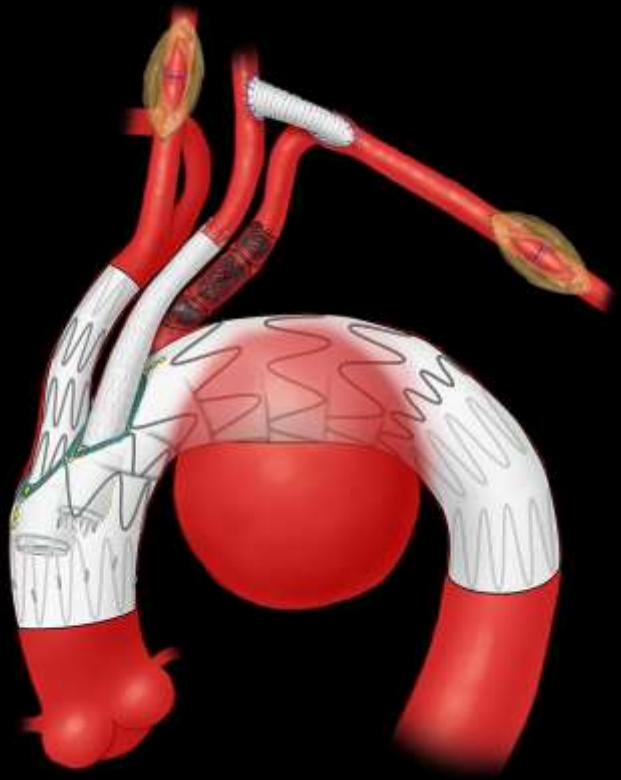
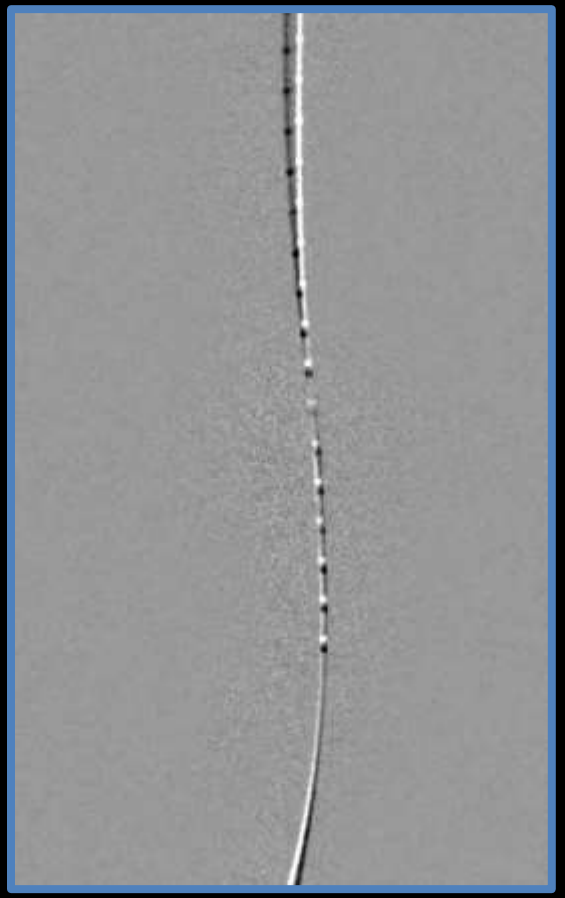


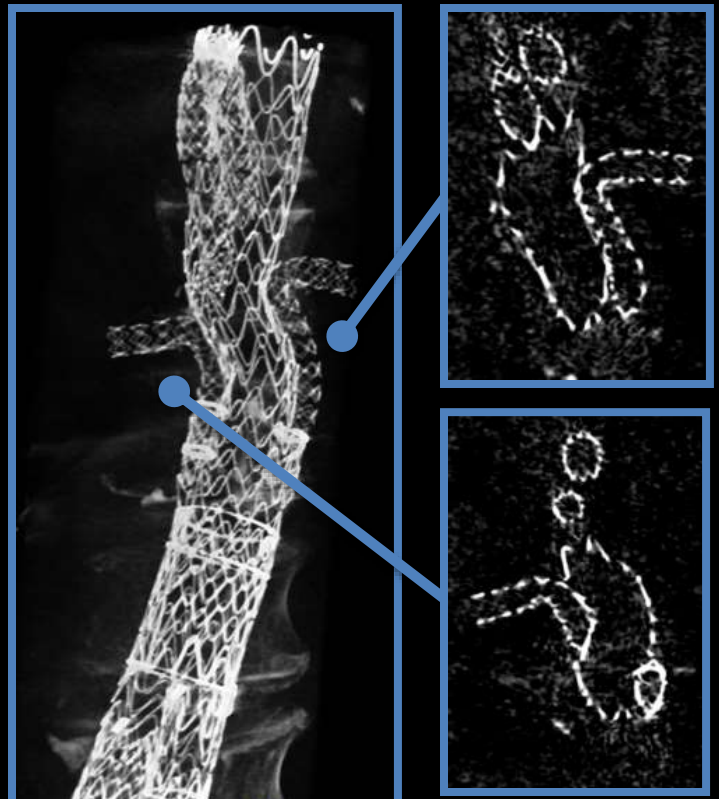
LINIC

79-year-old male with 9-cm pararenal aortic aneurysm

SIMULATION ANGIO



REAL CASE ANGIO



CONCLUSION

- Complex endovascular repair should be part of any major aortic center and has the potential to substantially reduce the mortality and morbidity of open surgical repair in patients with arch and TAAAs

- Newer technology needs to be assessed against established ”gold standard” before widespread adoption

- We still have a lot of work ahead to solve issues of physician access, dissemination, training, cost, surveillance and reinterventions