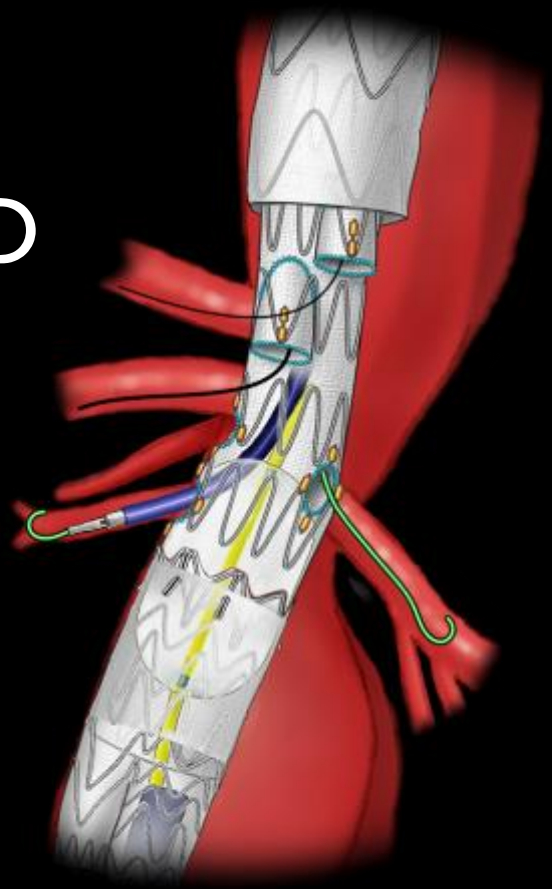
ENDOVASCULAR REPAIR OF TAAAs WITH FENESTRATED/BRANCHED STENT GRAFTS

Bernardo C. Mendes MD
Randall R. DeMartino MD
Gustavo S. Oderich MD

Aortic Center, Division of Vascular and Endovascular Surgery, Mayo Clinic, Rochester



tct2018 30th ANNIVERSARY
SEPTEMBER 21-25, 2018
SAN DIEGO, CA

MAYO CLINIC

FACULTY DISCLOSURES

Bernardo C. Mendes MD – No disclosures

Randall R. DeMartino MD – No disclosures

Gustavo S. Oderich MD

- 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

OPEN TAAA REPAIR

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

MAYO CLINIC

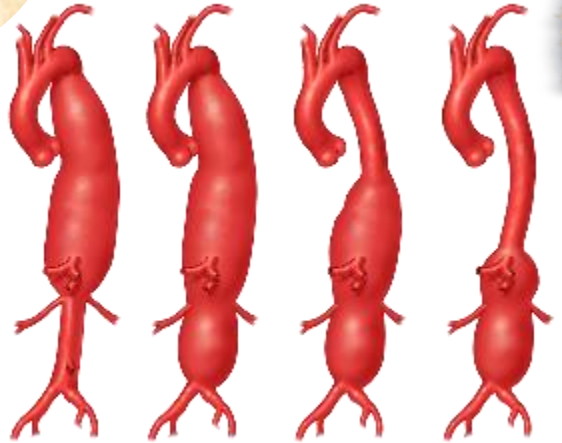
IMPROVING RESULTS

Experience with 1509 patients undergoing thoracoabdominal aortic operations

Lars G. Svensson, MD, PhD, E. Stanley Crawford
Joseph S. Coselli, MD, and Hazim J. Safi, MD, *H.*

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]



	Incidence of Paraplegia	
	Crawford (1993)	Coselli (2016)
EXTENT I	15%	1%
EXTENT II	31%	5%
EXTENT III	7%	4%
EXTENT IV	4%	1%

Svensson L (Crawford ES) et al. J Vasc Surg 1993
Coselli et al. J Thorac Cardiovasc Surg 2016;151:1323-38

MAYO CLINIC

TWO DECADES OF FENESTRATED GRAFTS

J.Parodi
Buenos Aires

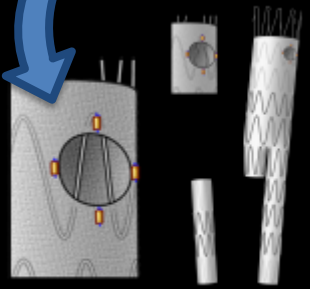
T. Browne
Perth

M.Lawrence-Brown & D. Hartley
Perth

J.Anderson
Adelaide

1991 1997 1998

<u>Animal testing</u>
Fenestrated stent deployed over balloon



<u>First implant</u>
Single left renal fenestration

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

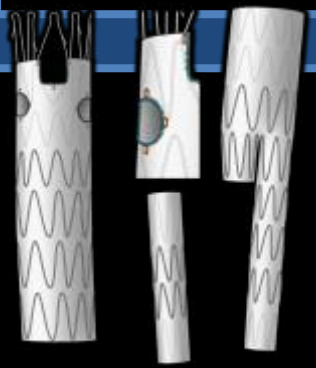
MAYO CLINIC

DEVICE REFINEMENTS

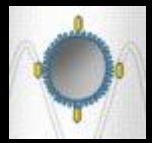
W. Stelter
Germany

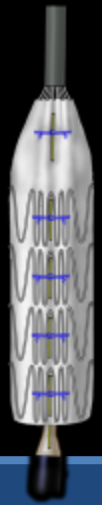
1998

- Separated fenestrated and bifurcated components

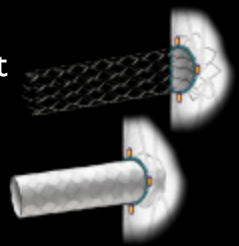


- Diameter Reducing ties





- Stent alignment



- Reinforced fenestrations
- Pivot fenestrations
- Pre-loaded system

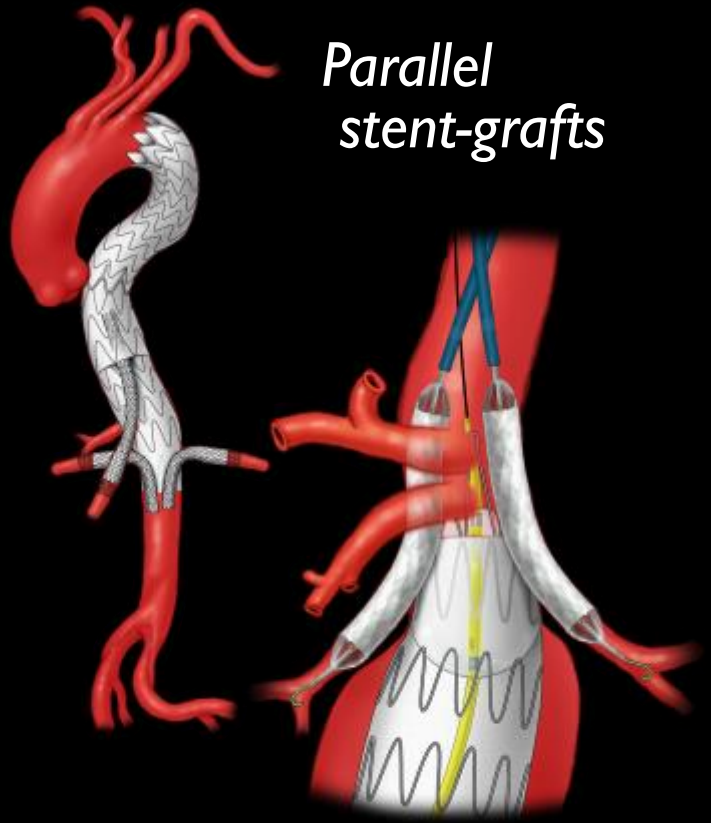
2015

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

MAYO CLINIC

ENDOVASCULAR OPTIONS

Parallel stent-grafts



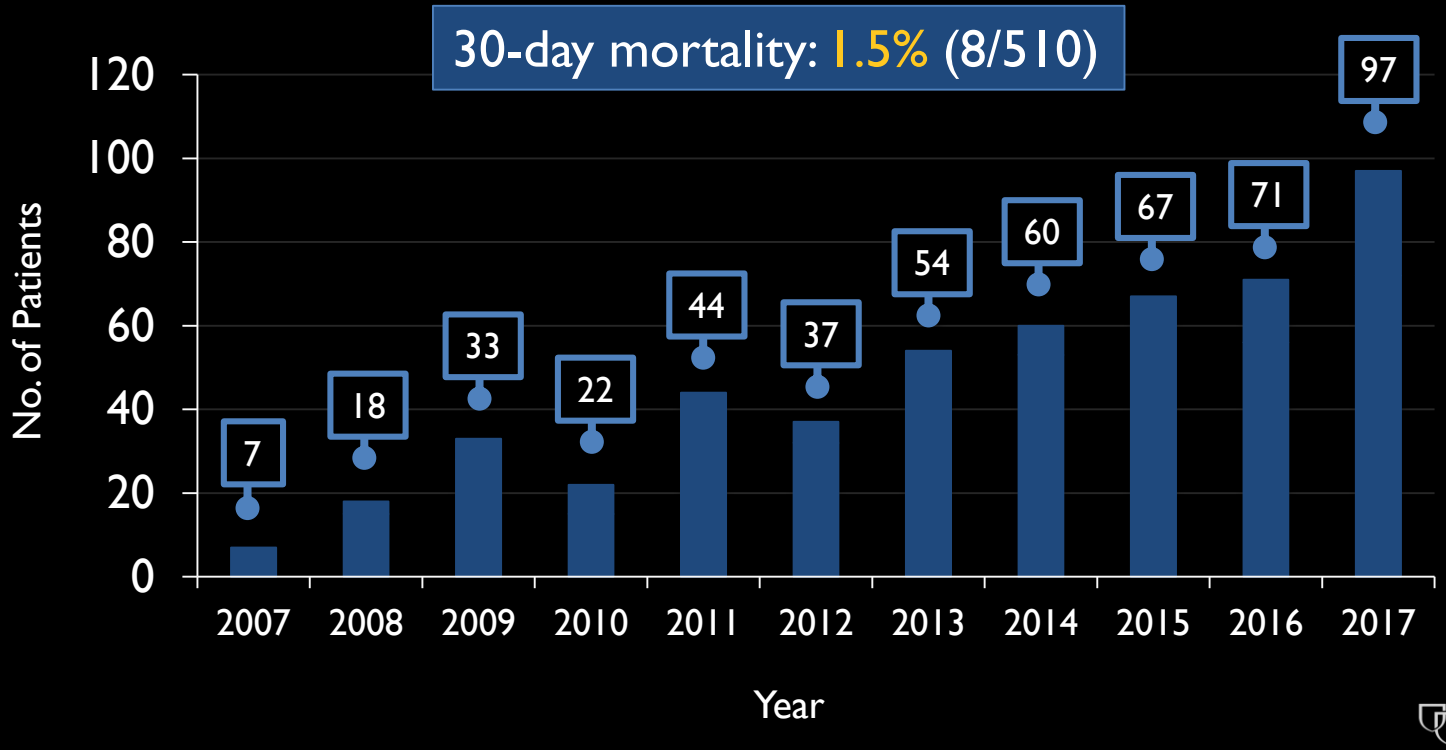
Fenestrated and branched stent-grafts

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 F-BEVAR PROGRAM

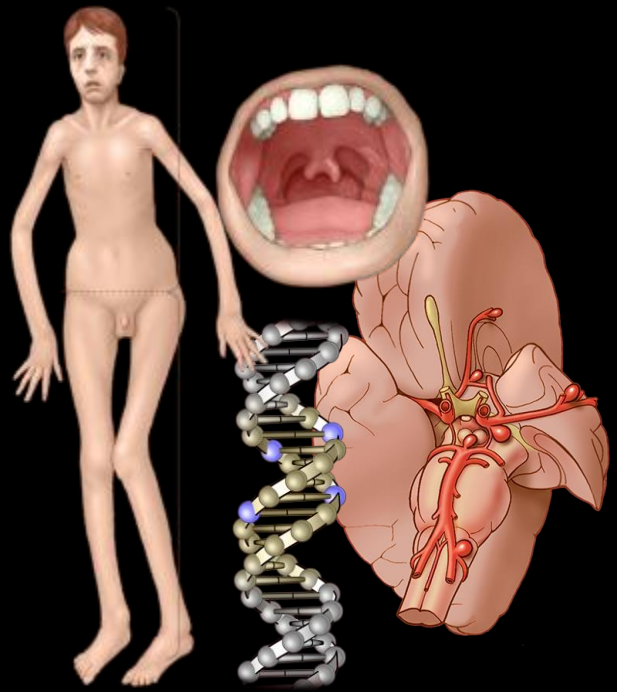
510 consecutive patients (2007-2017)



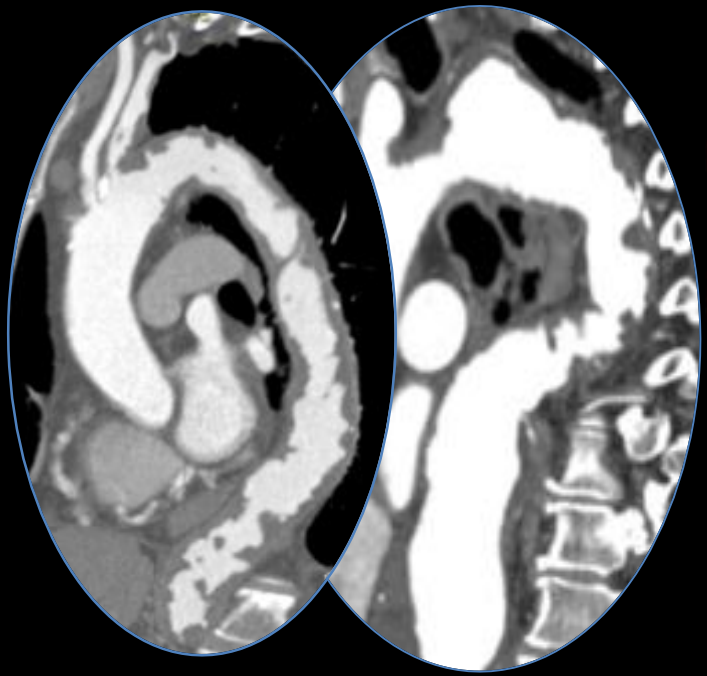
MAYO CLINIC

PATIENT SELECTION

Genetically Triggered Aortic Diseases



'Shaggy Aorta'

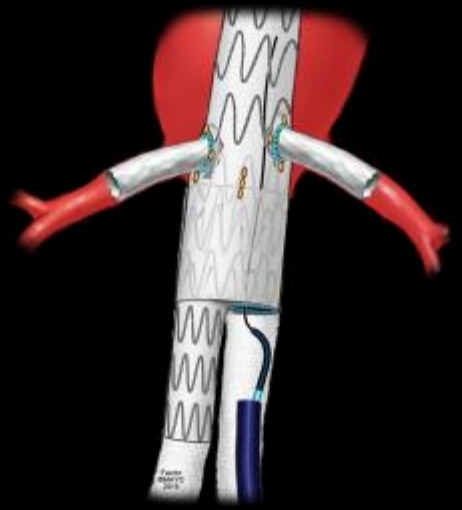


Unsuitable target

31st Annual Meeting
19-22 September, 2017
Lyon Congress Center
Lyon, France

LEARNING CURVE IN 334 PATIENTS TREATED BY F-BEVAR 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
Major adverse events	33%	58%	32%	21%	21%	<.001
30-day reinterventions	9%	9%	10%	6%	2%	<.001

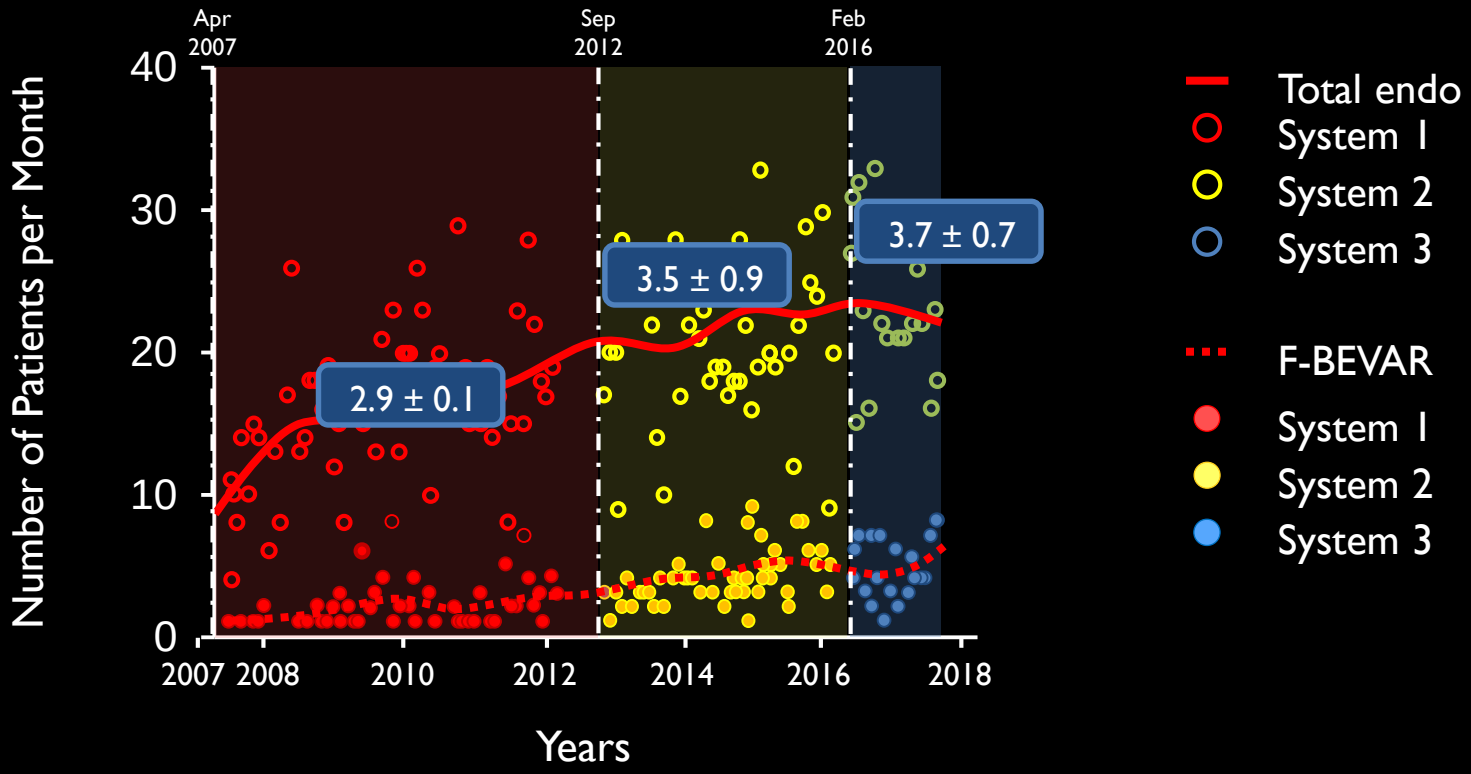


ESVS2017
LYON, FRANCE

Oderich et al (unpublished data)

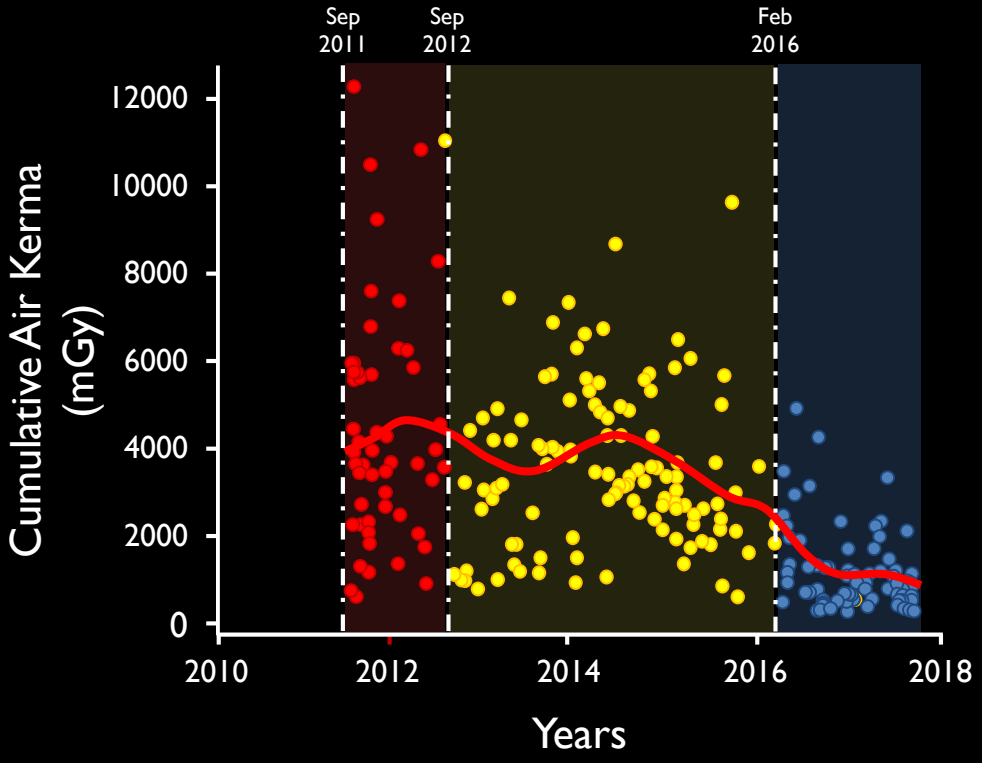
MAYO CLINIC

INCREASING VOLUME



MAYO CLINIC

EFFECTIVE DOSE



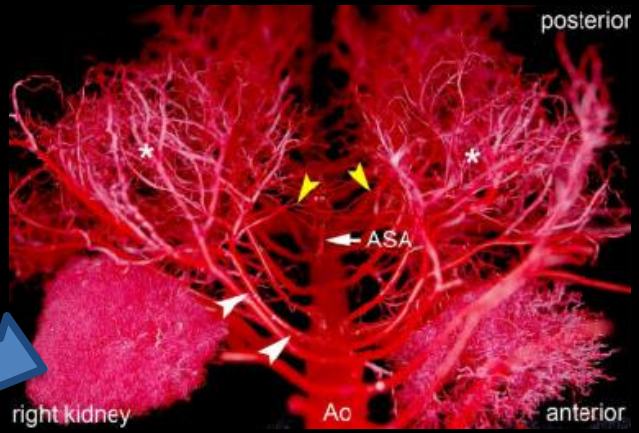
Mean radiation Dose (mGy)

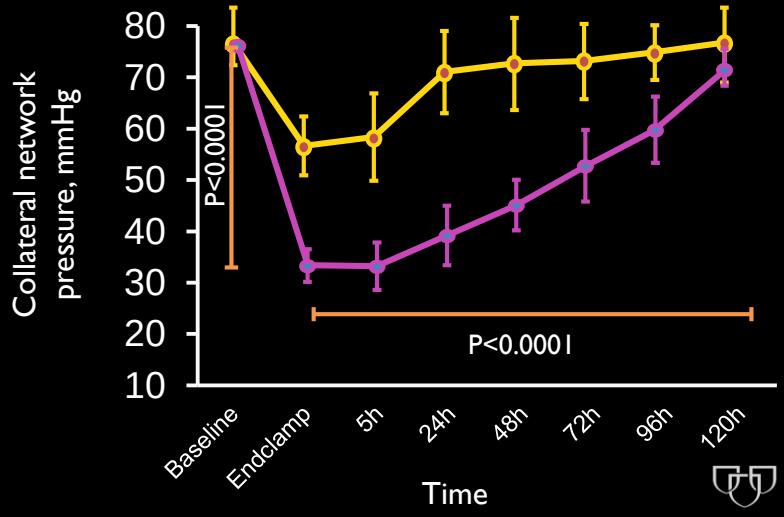
System 1	3892 ± 2258
System 2	3556 ± 1939
System 3	1213 ± 946

MAYO CLINIC

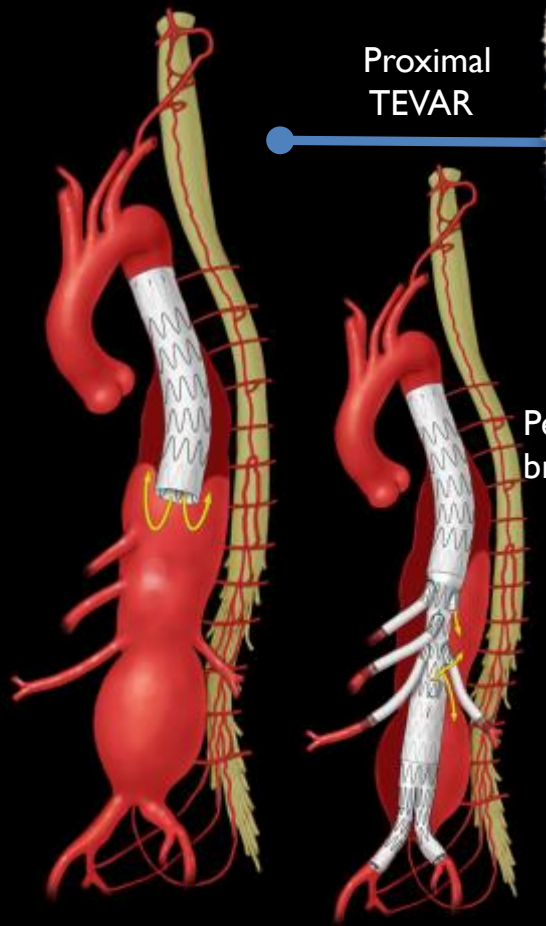
MOVING TARGET…

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


posterior
ASA
right kidney
Ao
anterior


Collateral network pressure, mmHg
80
70
60
50
40
30
20
10
P<0.0001
P<0.0001
Baseline
Endclamp
5h
24h
48h
72h
96h
120h
Time

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

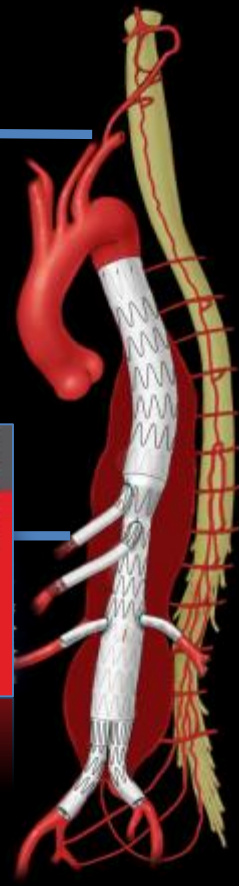
Perfusion branches

Editor's Choice — Temporary Aneurysm Sac Perfusion as an A
Prevention of Spinal Cord Ischemia After Branched Endovasc
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

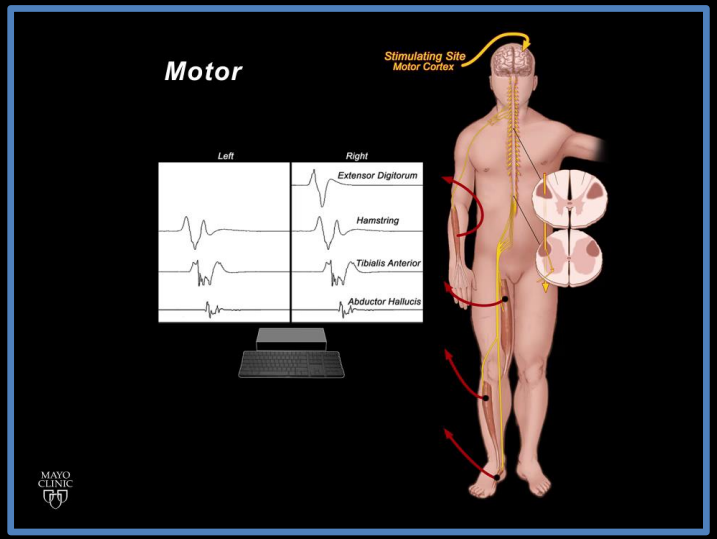
	No TASP	TASP	P
Any SCI	23%	13%	.001
Paraplegia	21%	3%	.02

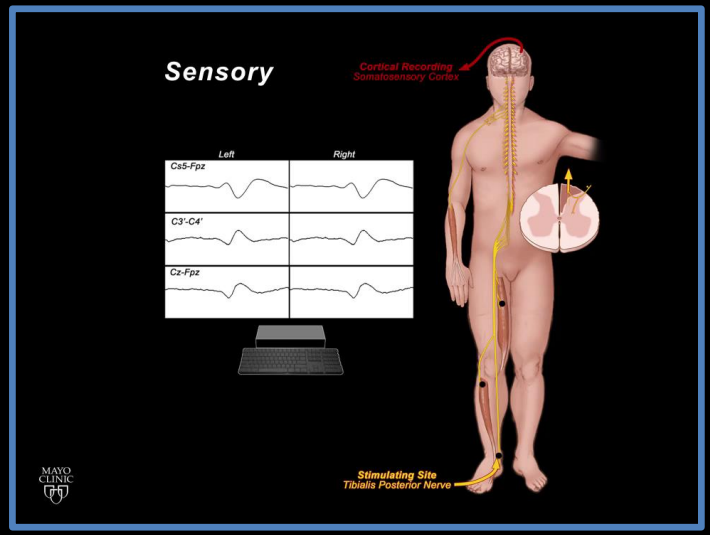


O'Callaghan A et al. J Vasc Surg 2015
Kasprzak et al. Eur J Vasc Endovasc Surg 2014

MAYO CLINIC

SPINAL CORD INJURY PREVENTION





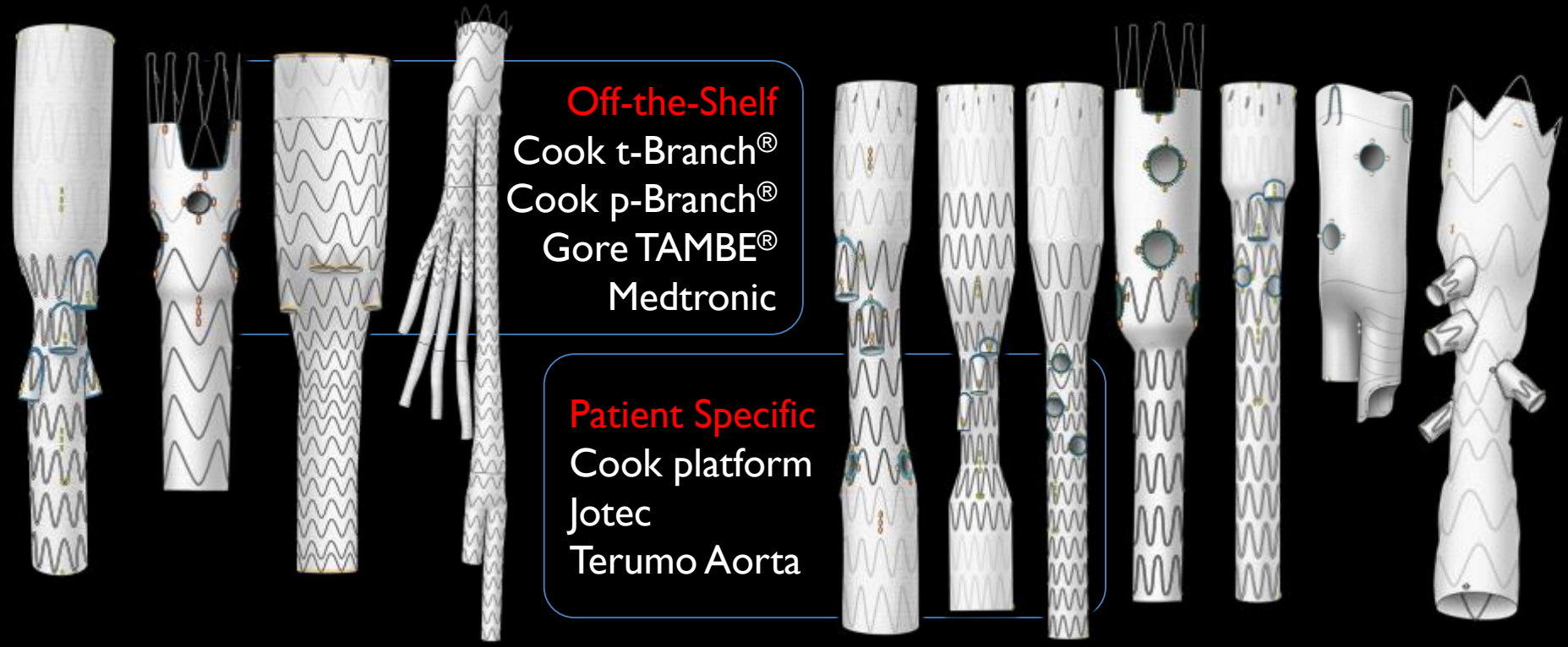
- Staged aortic coverage
- Permissive hypertension
- CSF drainage 48-72 hours
- Neuromonitoring

- Early limb reperfusion
- Selective temporary sac perfusion (TASP)
- Near infrared spectroscopy (NIRS)

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

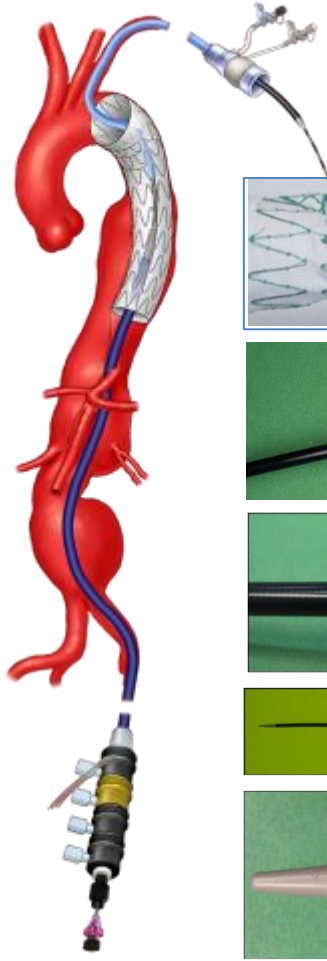


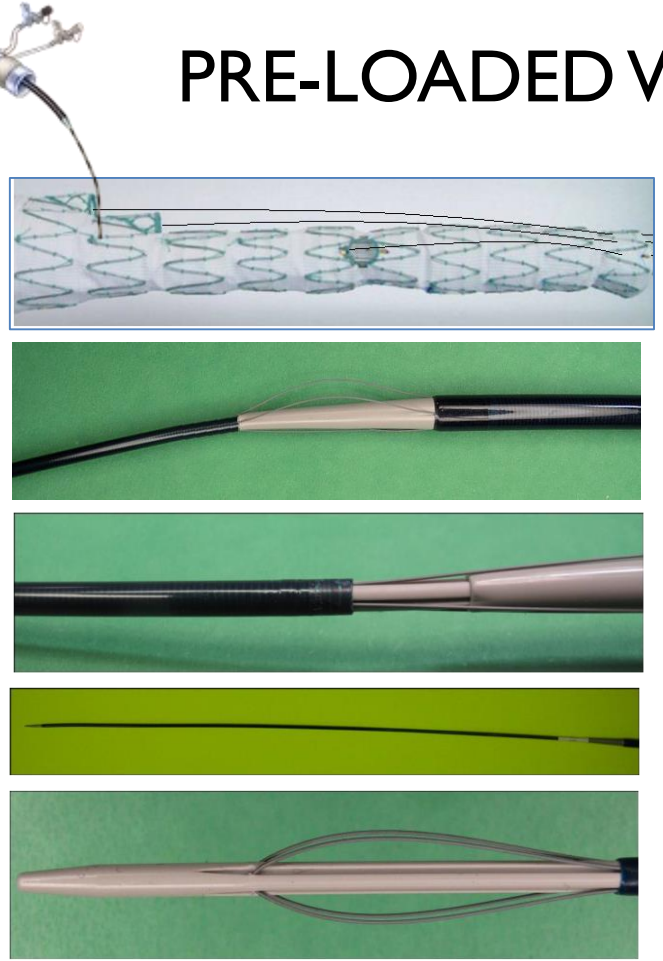
Off-the-Shelf
Cook t-Branch®
Cook p-Branch®
Gore TAMBE®
Medtronic

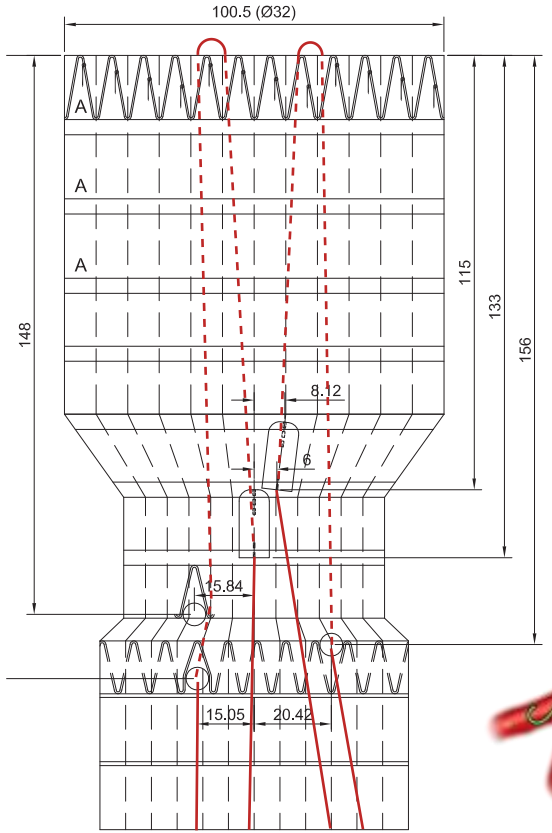
Patient Specific
Cook platform
Jotec
Terumo Aorta

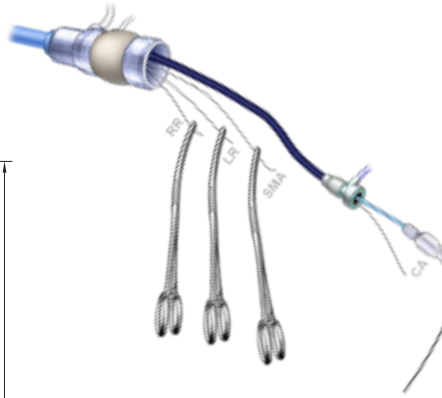
MAYO CLINIC

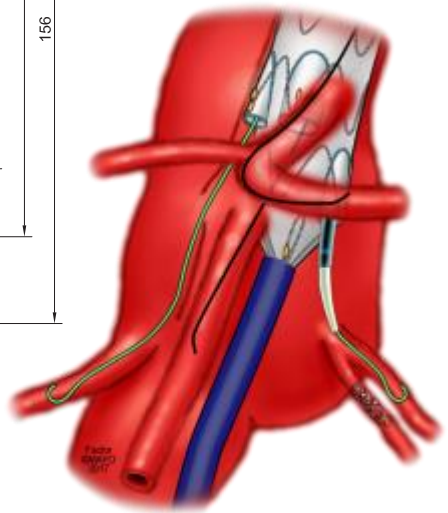
PRE-LOADED WIRE SYSTEM











What are the state-of-the-art results of eTAAA using fenestrated-branched endografts?

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%**

Update on the first 250 patients enrolled in a prospective, non-randomized study to evaluate F-BEVAR for complex aortic aneurysms

Gustavo S. Oderich MD, Emanuel Tenorio MD PhD, Bernardo C. Mendes MD, Randall R. DeMartino MD, Jan Hofer RN, Jean Wigham RN, Stephen Cha MS and Thanila A. Macedo MD

Division of Vascular and Endovascular Surgery and Departments of Radiology, Epidemiology and Biostatistics

Journal Thoracic Cardiovasc Surg 2018 (in preparation)

MAYO CLINIC

METHODS

- Prospective, non-randomized study (2013-present)
- Off-the-shelf and patient-specific fenestrated and branched stent-grafts
- Clinical data adjudicated by Clinical Event Committee and Data Safety Monitoring Board
- Imaging independently reviewed by vascular radiology
- End-points:
  - 30-day mortality and major adverse events
  - Patient survival and freedom from aortic death
  - Target vessel patency, instability and freedom from reinterventions

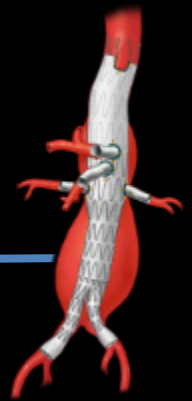
PATIENTS

292 patients enrolled (April 24th, 2018)

42 patients await device implantation

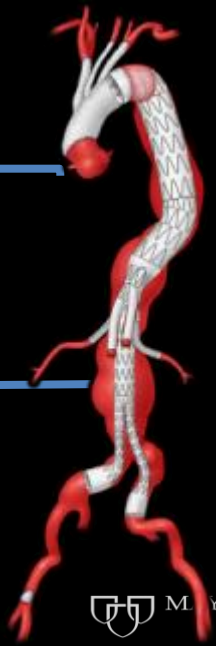
250 patients had implantation with > 30-day follow up

91 pararenal (37%)



63 Extent 4 TAAA (25%)

96 Extent 1-3 TAAA (38%)



MAYO CLINIC

	Overall n = 250	Pararenal n = 91	Extent IV n = 63	Extent I-III n = 96	P value
	Percent or Mean ± Standard Deviation				
Mean age (years ± SD)	75±8	76±7	75±7	73±8	0.06
Age > 80 years	27	32	22	26	0.40
Male gender	71	74	83	61	0.009
Hypertension	91	88	89	95	0.23
Cigarette smoking	86	82	89	88	0.38
Hypercholesterolemia	84	82	87	83	0.69
Coronary artery disease	52	48	60	51	0.31
Chronic Kidney Disease III-V	50	49	56	48	0.53
Chronic pulmonary disease	37	35	30	44	0.17
Congestive heart failure	10	8	14	11	0.42
Prior aortic repair	42	16	27	77	<0.0001
Chronic Dissection	8	0	0	20	<.0001
Aneurysm diameter (mm)	66±11	63±10	65±9	70±13	0.0002

STENT DESIGN

954 renal-mesenteric arteries (3.8/patient)
211 patients (85%) had ≥ 4-vessels

	Overall n = 250	Pararenal n = 91	Type IV n = 63	Type I-III n = 96	P value
	n (Percent) or Mean ± Standard Deviation				
Total target vessels	954	353	246	355	
Vessels per patient	3.9±0.5	3.9±0.5	3.9±0.5	3.8±0.5	0.4
Fenestrations	631 (66)	308 (87)	218 (89)	105 (30)	<0.001
Directional branches	284 (30)	6 (2)	28 (11)	250 (70)	<0.001
Double-wide scallops	39 (4)	39 (11)	0	0	<0.001

PROCEDURAL DETAILS

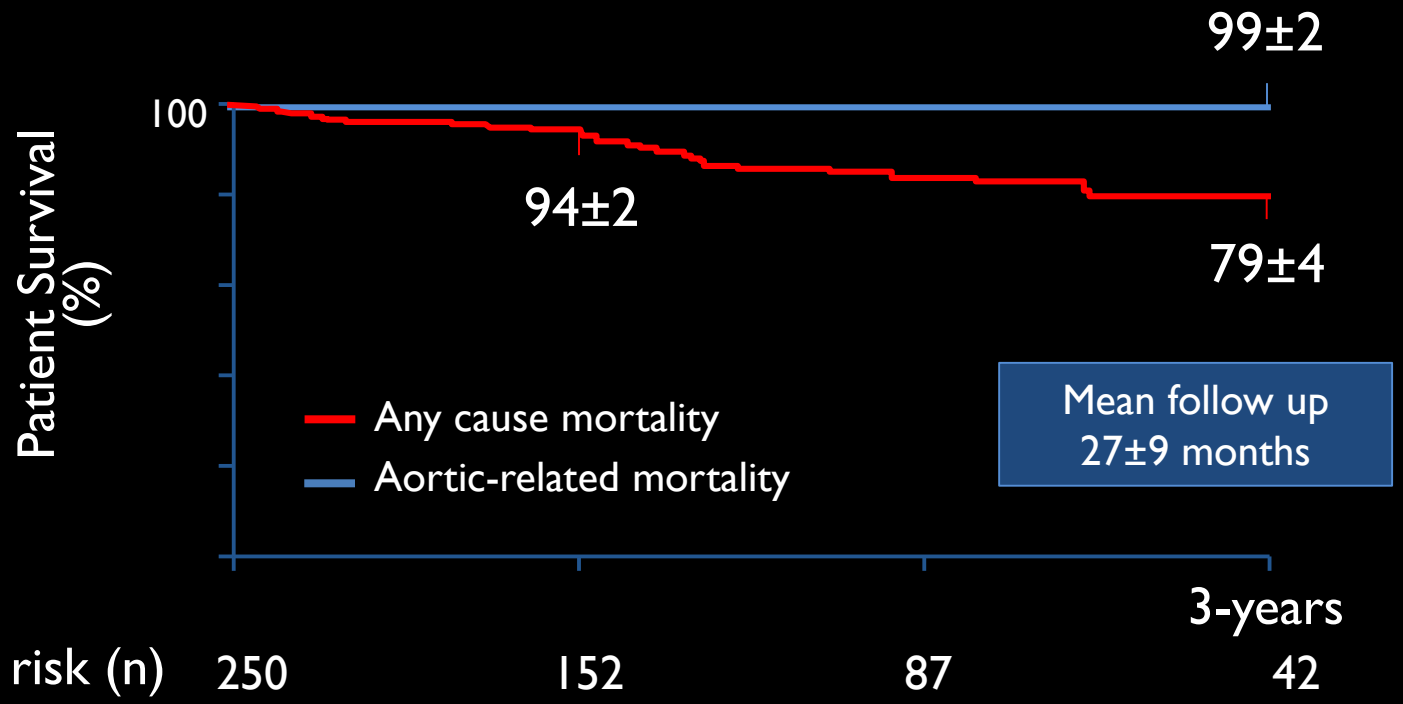
	Overall n = 250	Pararenal n = 91	Extent IV n = 63	Type I-III n = 96	P value
	n (Percent) or Mean ± Standard Deviation				
General anesthesia	100	100	100	100	NS
Brachial access	92	79	100	100	<0.001
Percutaneous femoral	81	87	79	78	0.56
CSF drainage	68	23	90	97	<0.001
Neuromonitoring	38	12	33	95	<0.001
Total OR time (min)	168±63	151±52	167±65	185±67	0.002
Contrast volume (cc)	156±57	136±47	156±53	174±62	<0.001
Fluoroscopy time (min)	83±33	75±27	83±34	91±35	0.0031
Radiation dose (mGy)	2398±1891	2085±1696	2880±1967	2379±1968	0.036
EBL (ml)	449±521	347±429	451±585	548±545	0.03
Technical success	99.4	99.7	100	98.6	0.06

30-DAY RESULTS

One (0.4%) 30-day or in-hospital death

	Overall n = 250	Pararenal n = 91	Extent IV n = 63	Extent I-III n = 96	P value
	Percent				
Any MAE	28	22	30	32	0.30
EBL >1L	10	4	8	16	0.03
Acute Kidney Injury	12	11	21	8	0.06
New-onset dialysis	1	1	2	1	0.94
Myocardial infarction	4	4	8	1	0.09
Respiratory failure	2	1	3	3	0.59
Paraplegia	3	1	0	6	0.03
Major stroke	1	1	2	0	0.50
Bowel ischemia	2	3	3	1	0.54

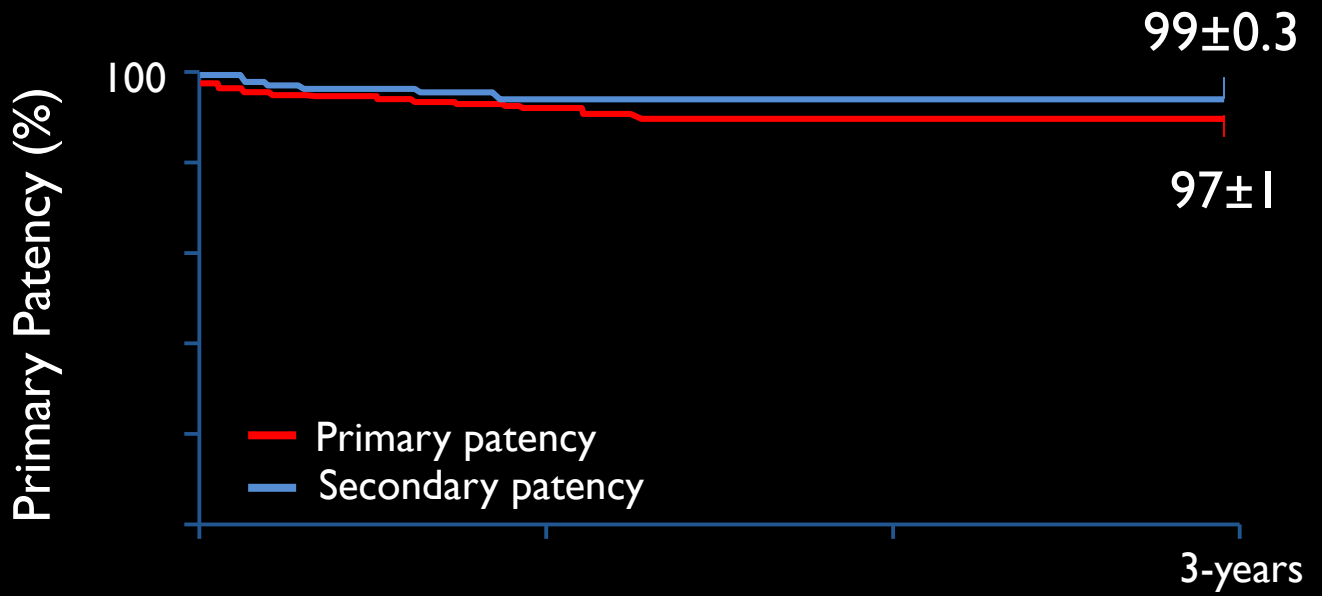
PATIENT SURVIVAL



MAYO CLINIC

TARGET VESSEL PATENCY

All renal-mesenteric target vessels

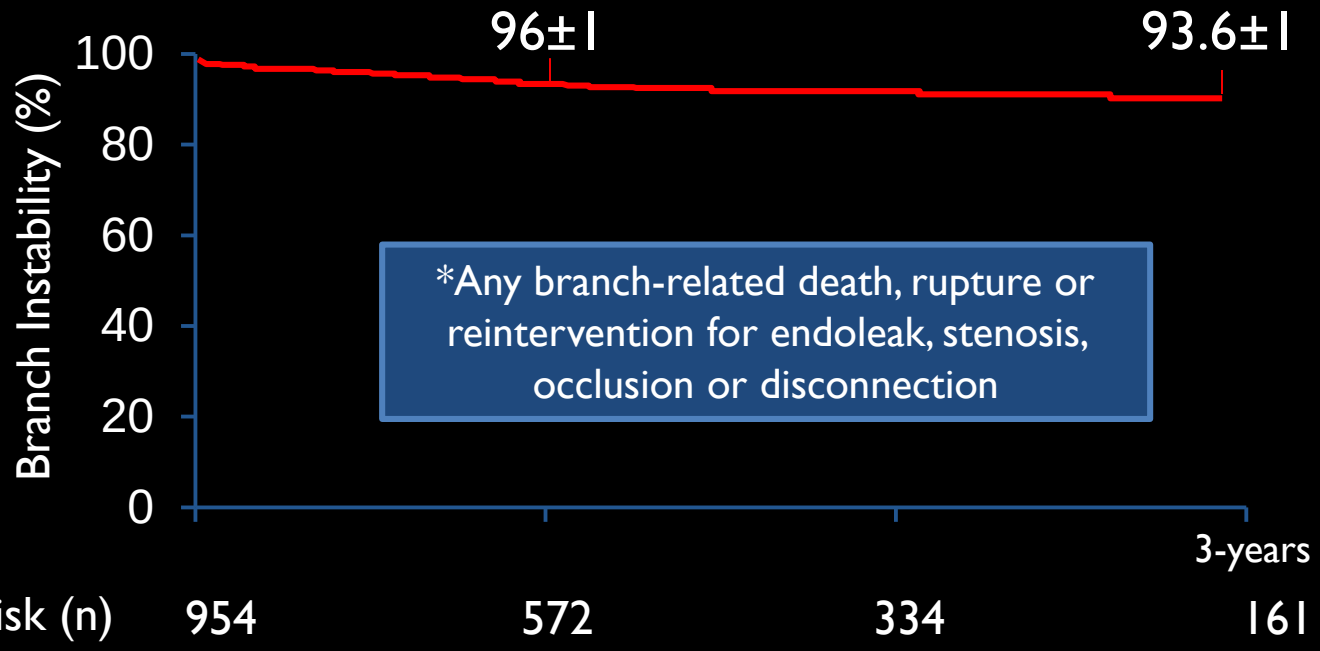


At risk (n)				
Primary patency	954	587	344	169
Secondary patency	954	590	351	174

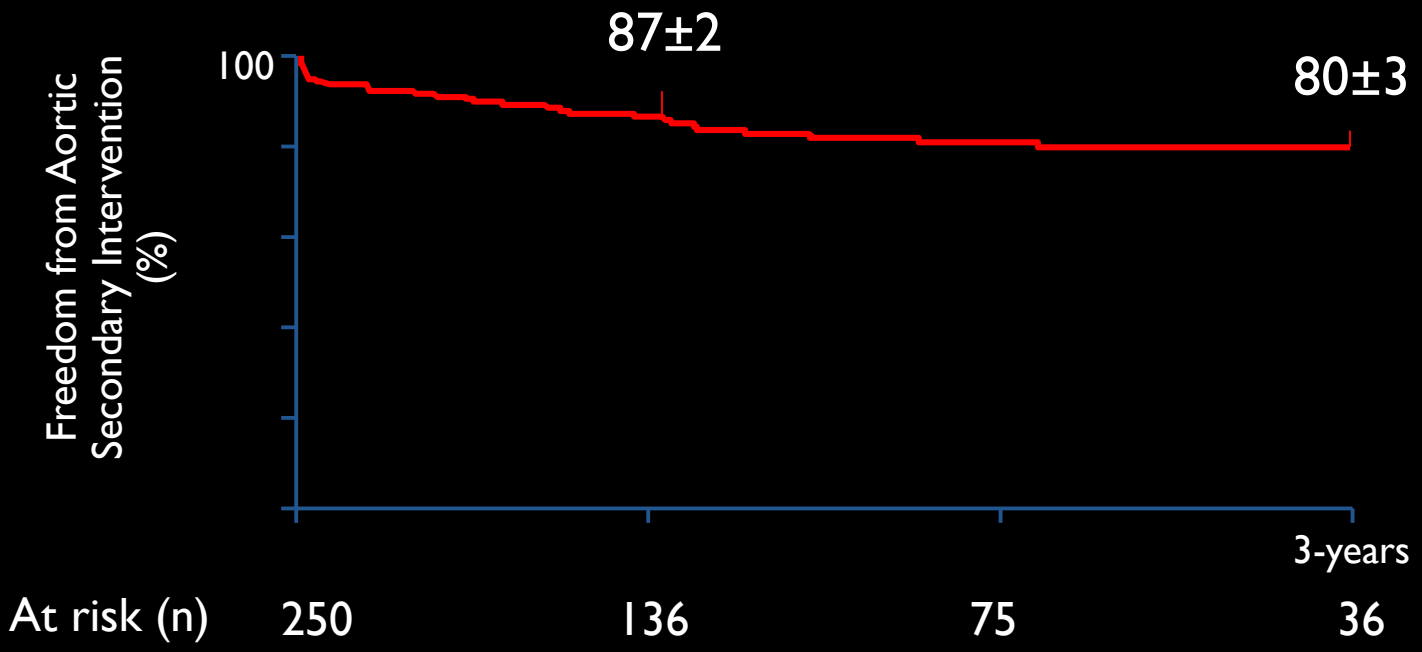
MAYO CLINIC

TARGET VESSEL INSTABILITY*

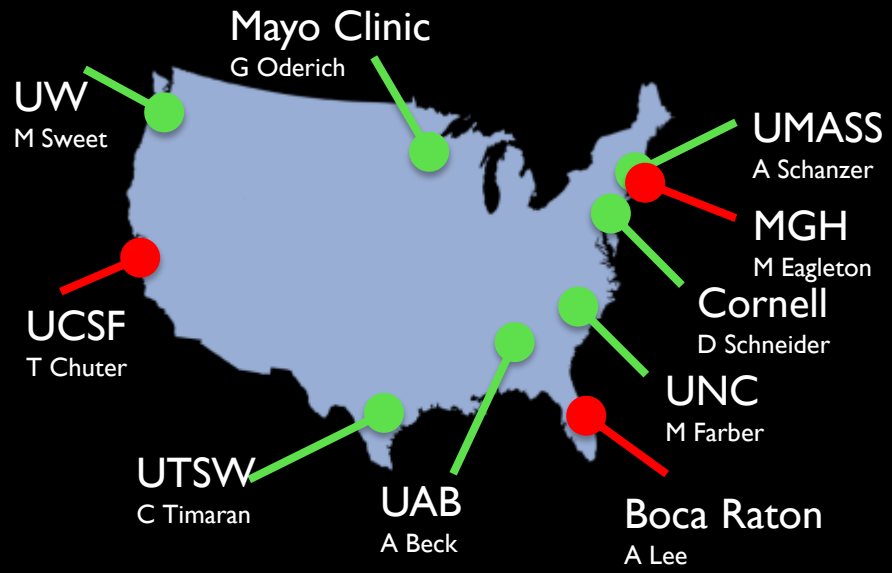
All renal-mesenteric target vessels



AORTIC REINTERVENTION



MAYO CLINIC



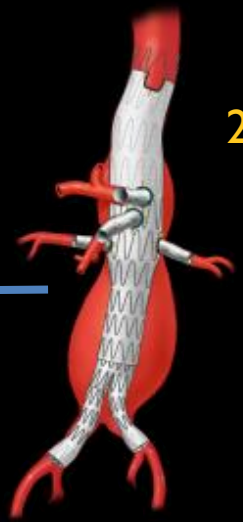
UNITED STATES FENESTRATED-BRANCHED RESEARCH CONSORTIUM

MAYO CLINIC

PATIENTS

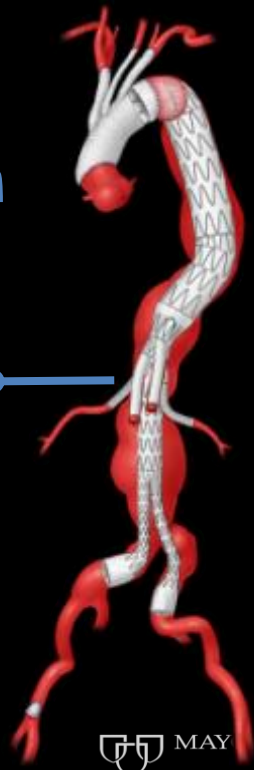
661 patients enrolled
(January 1st, 2018)

232 pararenal
(36%)



221 Extent 4
TAAA (33%)

208 Extent
1-3 TAAA
(31%)

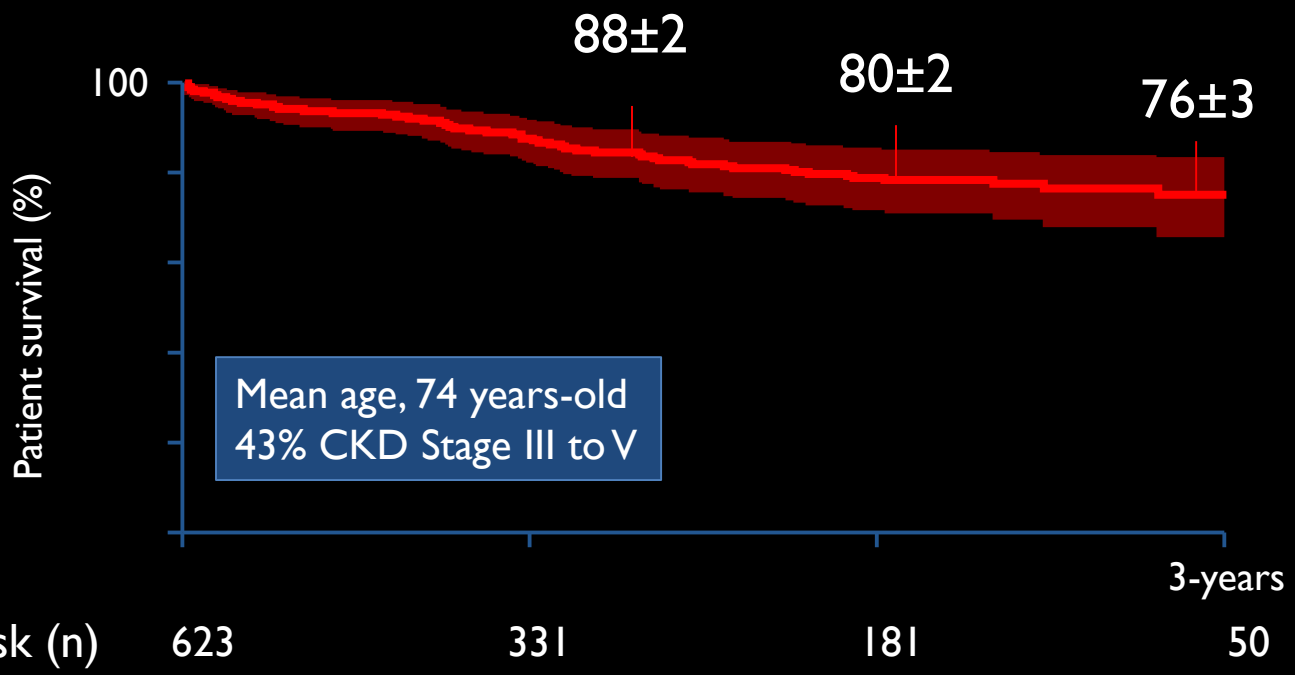


MAY CLINIC

30-DAY OUTCOMES

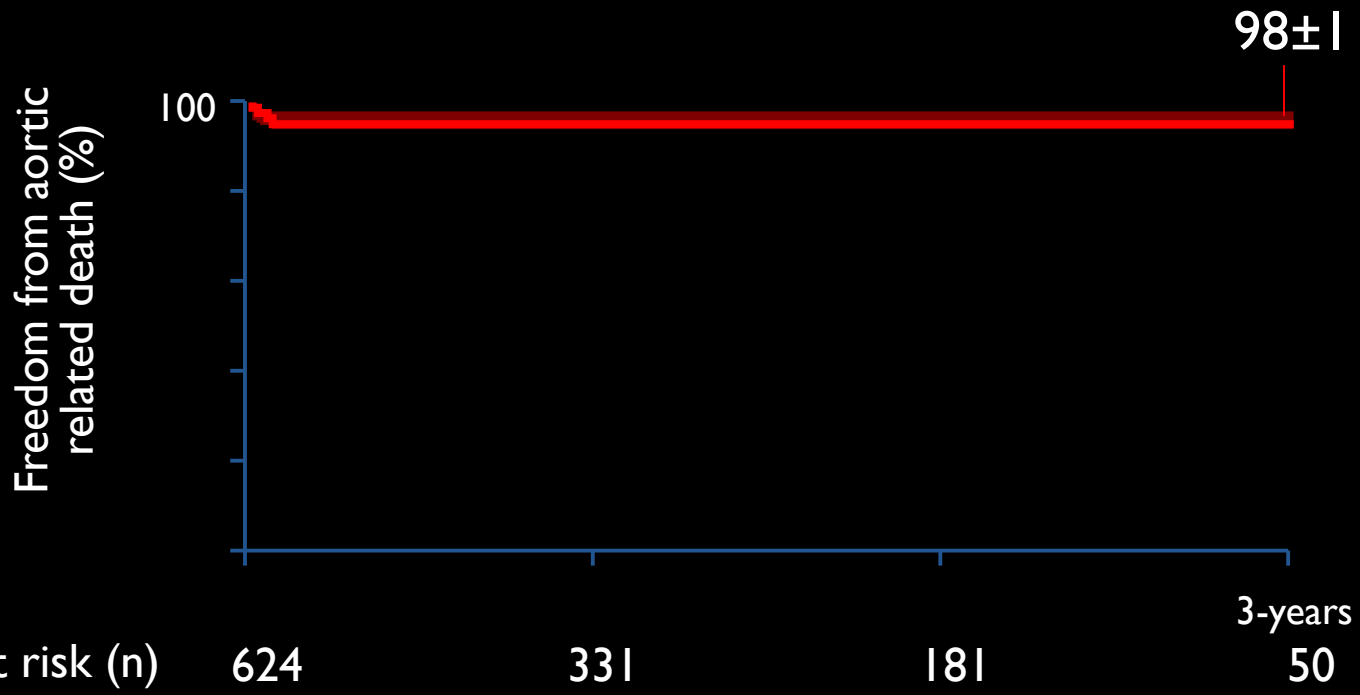
	Overall n = 661	Pararenal n = 232	Extent IV n = 221	Extent I-III n = 208	P value
	n (Percent)				
Any Mortality	13 (2)	3 (1)	5 (2)	5 (2)	0.82
Any MAE	97 (15)	26 (11)	33 (15)	38 (18)	0.11
EBL >1L	29 (5)	6 (3)	9 (4)	14 (7)	0.10
Acute Kidney injury	36 (5)	7 (3)	14 (6)	15 (7)	0.11
Myocardial infarction	12 (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

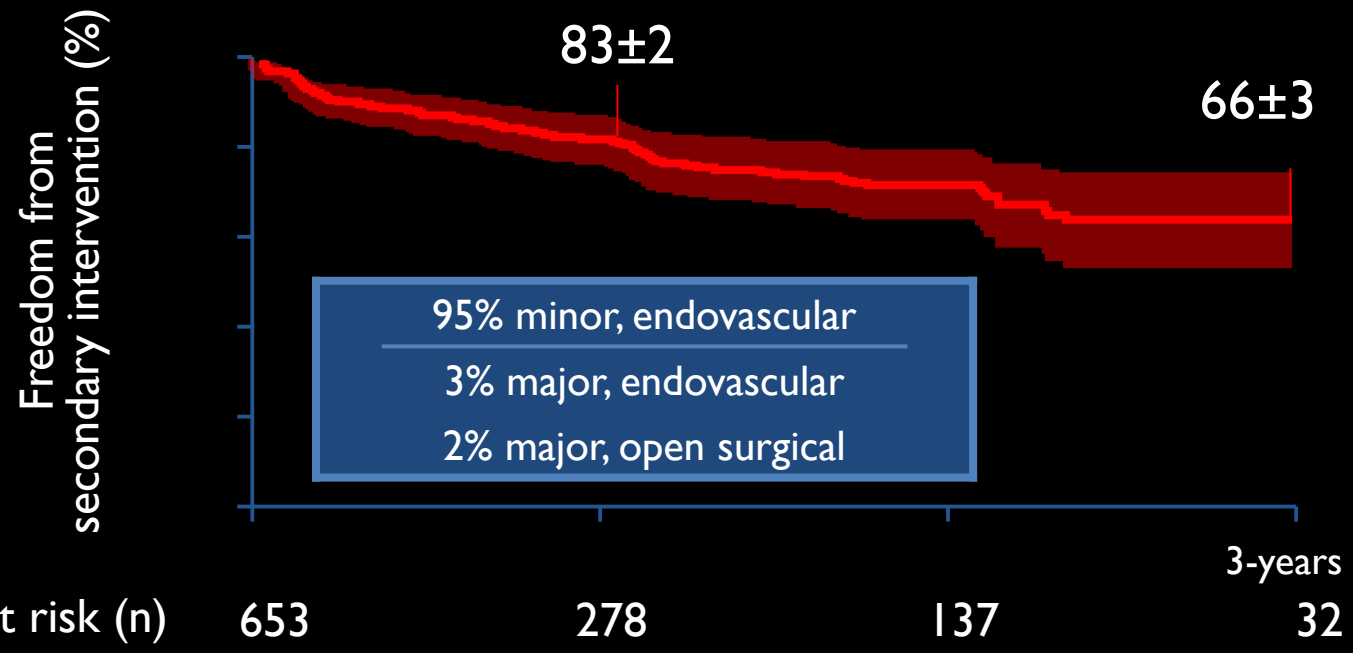


MAYO CLINIC

AORTIC RELATED DEATH

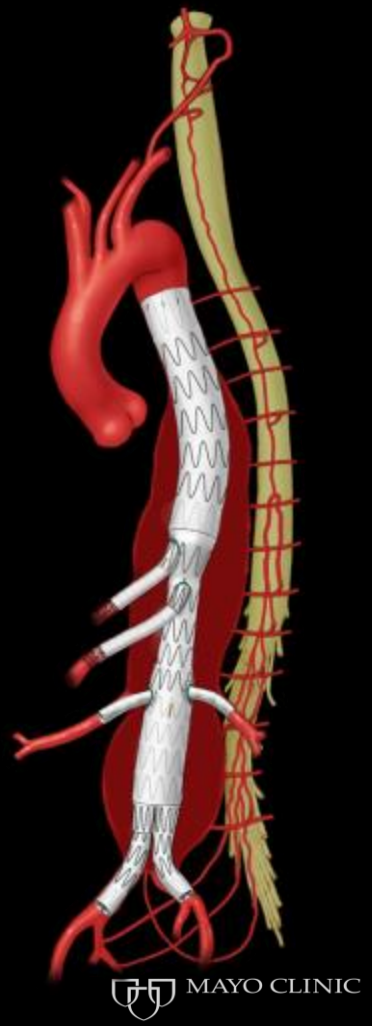


SECONDARY INTERVENTIONS



CONCLUSIONS

- Outcomes of eTAAA repair continue to improve as a reflection of team experience and adoption of protocols to prevent spinal cord injury
- The technique has the potential to significantly reduce morbidity and mortality compared to open surgical repair
- Important considerations are learning curve, need for optimal imaging and familiarity with advanced endovascular techniques
- Limitations are access to technology, physician training, cost, surveillance and need for reinterventions




MAYO CLINIC
150
Years
SERVING HUMANITY