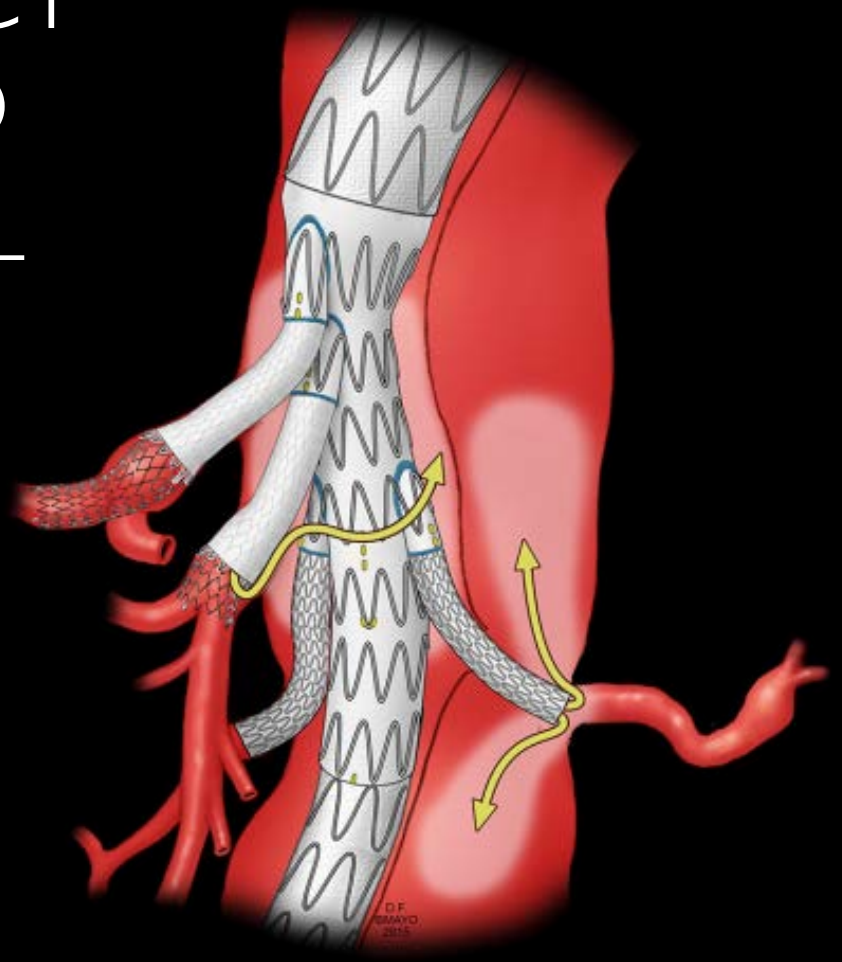
COMPLETION CBCT IS MANDATORY TO ASSESS TECHNICAL SUCCESS DURING F-BEVAR



Gustavo S. Oderich MD

Director of Aortic Center

Professor of Surgery

Rochester, Minnesota – United States

CACVS2018

PARIS

MAYO CLINIC

CONTROVERSES ET ACTUALITÉS EN CHIRURGIE VASCULAIRE
CONTROVERSIES & UPDATES IN VASCULAR SURGERY
JANUARY 25-27 2018
MARRIOTT RIVE GAUCHE & CONFERENCE CENTER
PARIS, FRANCE
WWW.CACVS.ORG
PROGRAMME FINAL
FINAL PROGRAM
ACCREDITATION E.ACCME

MAYO CLINIC

FACULTY DISCLOSURE

Gustavo S. Oderich MD

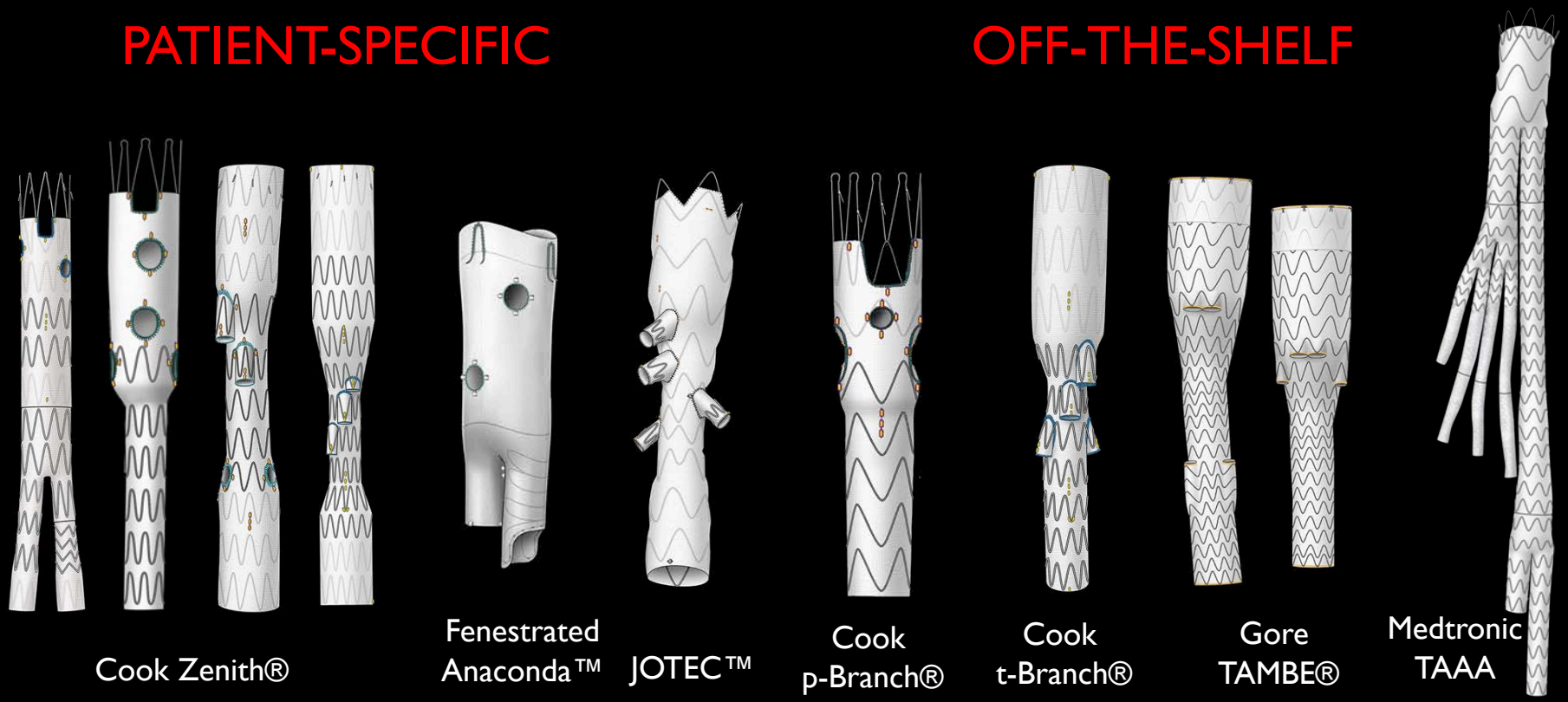
- Consulting, DSMB, CEC*
  Cook Medical Inc. and WL Gore
- Research and educational grants*
  Cook Medical Inc., WL Gore, GE Healthcare

* All consulting fees and grants were paid to Mayo Clinic

VISCERAL BRANCH DEVICES

PATIENT-SPECIFIC

OFF-THE-SHELF



Cook Zenith®

Fenestrated Anaconda™

JOTEC™

Cook p-Branch®

Cook t-Branch®

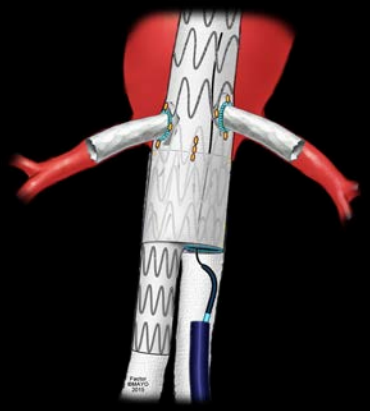
Gore TAMBE®

Medtronic TAAA

FDA APPROVED	CE MARK	CE MARK	CE MARK	PIVOTAL TRIAL	TRIAL DESIGN	TRIAL DESIGN	MULTICENTER IDE
Juxtarenal	Pararenal TAAA	Pararenal	TAAA	Pararenal	TAAA	TAAA	TAAA

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

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

ESVS2017
LYON, FRANCE

Oderich et al (unpublished data)

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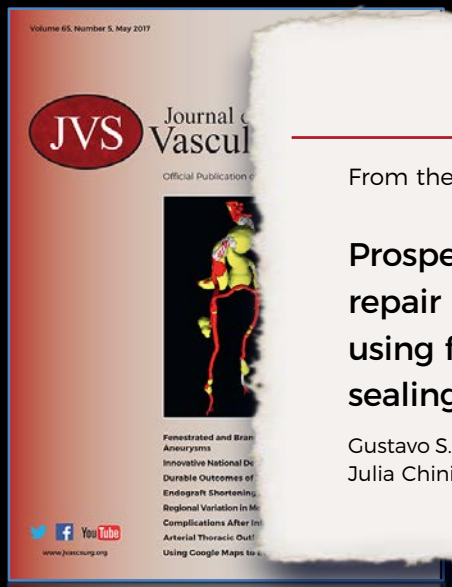
Society for Vascular Surgery 2016 VASCULAR ANNUAL MEETING

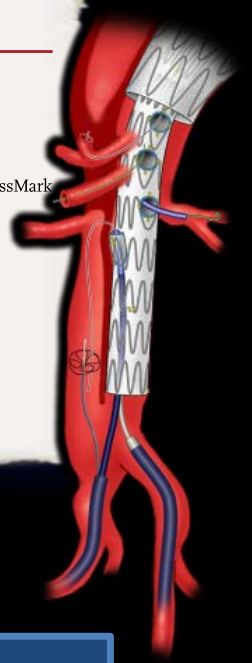


CLINICAL RESEARCH STUDIES

From the Society for Vascular Surgery

Prospective, nonrandomized study to evaluate endovascular repair of pararenal and thoracoabdominal aortic aneurysms using fenestrated-branched endografts based on supraceliac sealing zones

Gustavo S. Oderich, MD,[a] Mauricio Ribeiro MD, PhD,[a,b] Jan Hofer, RN,[a] Jean Wigham, RN,[a] Stephen Cha, MS,[c] Julia Chini,[a] Thanila A. Macedo, MD,[d] *and* Peter Gloviczki, MD,[a] *Rochester, Minn; and Ribeirão Preto, Brazil*



VAM2016 WASHINGTON, DC

30 day mortality 0.5% (1/225)

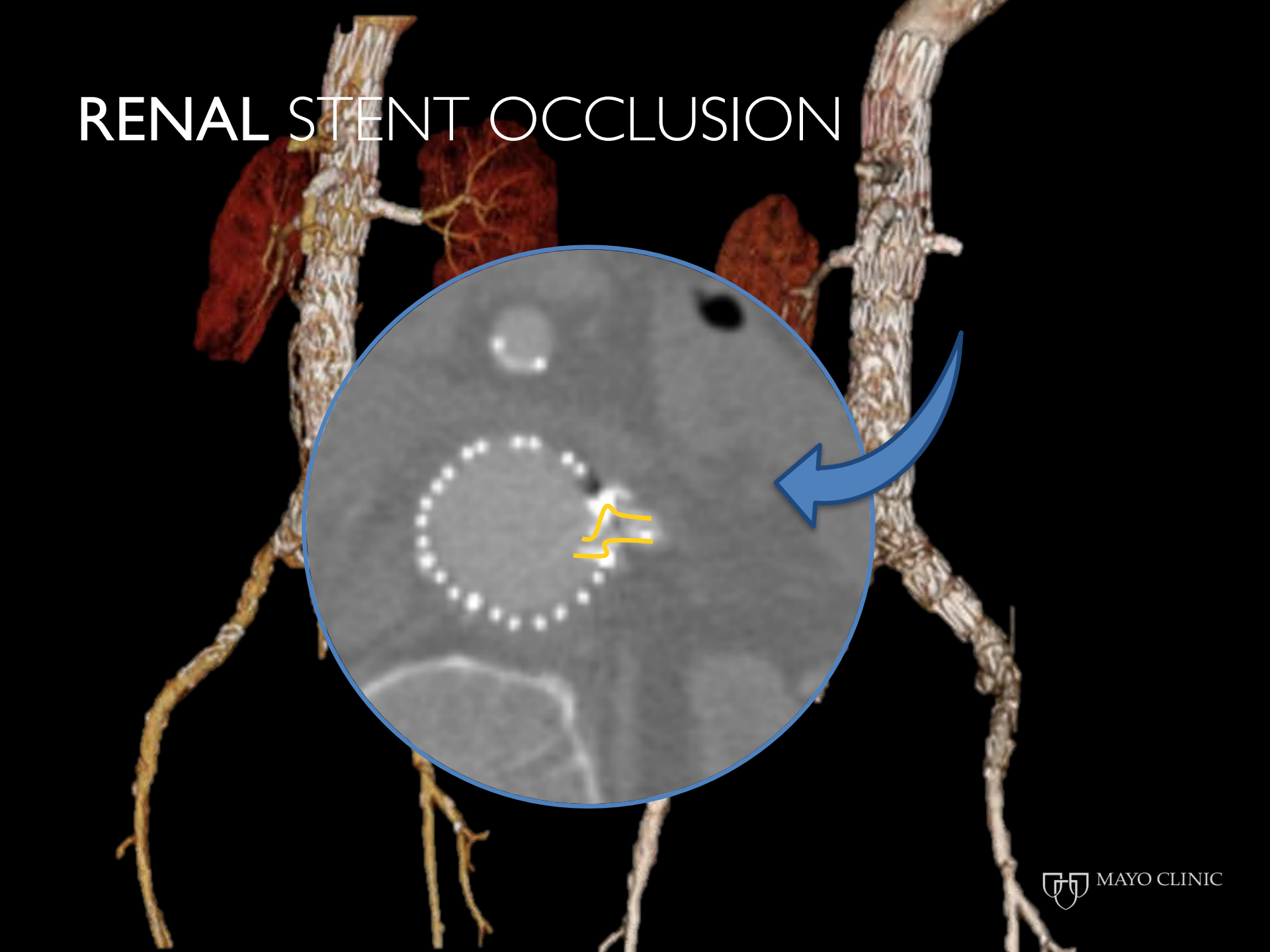
Journal of Vascular Surgery 2017

MAYO CLINIC

The more complex, the greater the risk of failure…

- Endoleaks
- Branch related complications

RENAL STENT OCCLUSION



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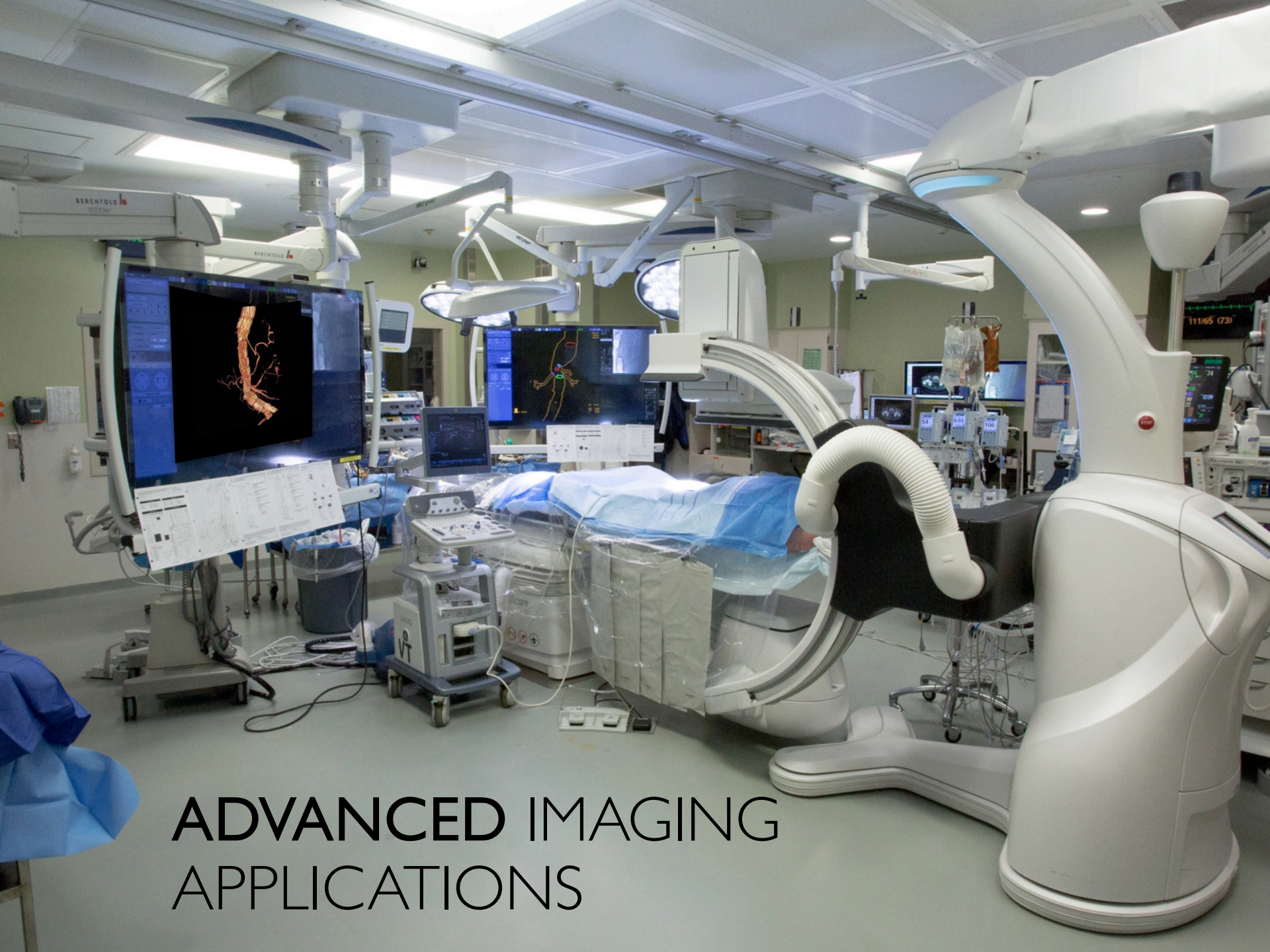
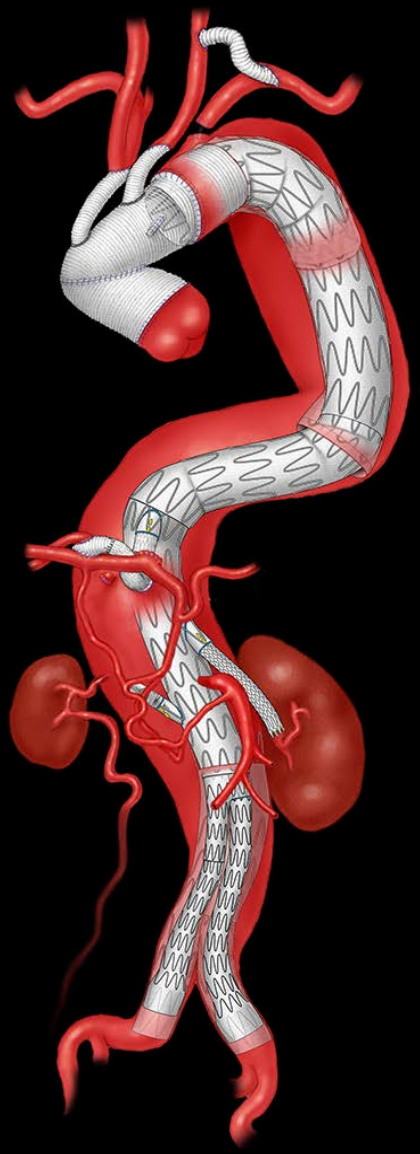


ADVANCED IMAGING APPLICATIONS

IMPACT OF FUSION OVERLAY AND CONE BEAM CT ON RADIATION EXPOSURE AND TECHNICAL EVALUATION OF F-BEVAR



Emanuel Tenorio MD PhD, Gustavo S. Oderich MD, Giuliano Sandri MD, Pinar Ozbek, Jussi Karkkainen MD PhD, Thanila A Macedo MD, Terri Vrtiska MD

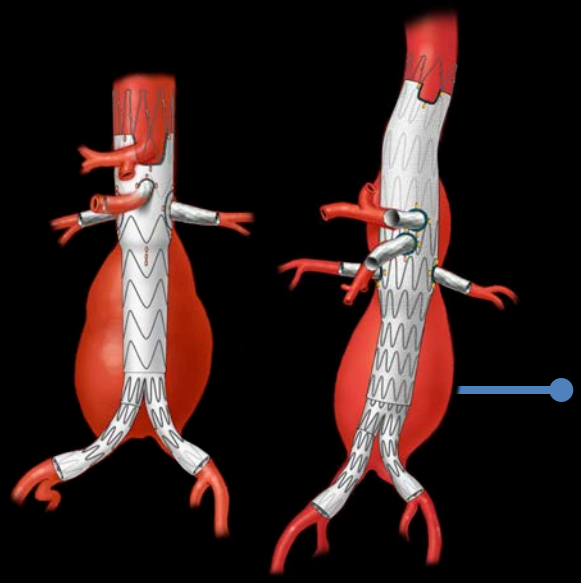
Division of Vascular and Endovascular Surgery and Department of Radiology and Epidemiology, Mayo Clinic

MAYO CLINIC

PATIENTS

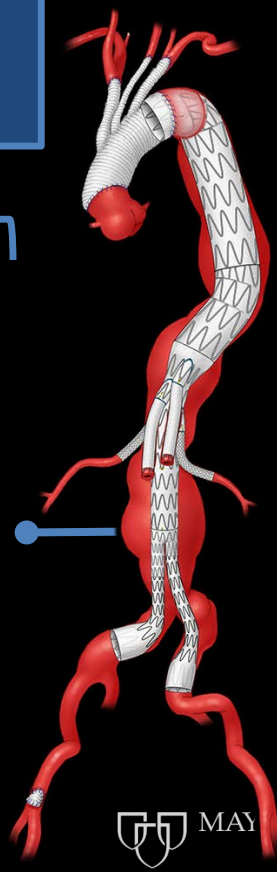
386 patients enrolled (April 2007-April 2017)

219 without FUSION/ CBCT (56%)	167 with FUSION/ CBCT (44%)



281 pararenal or Extent IV (73%)

105 Extent I-III TAAA (27%)

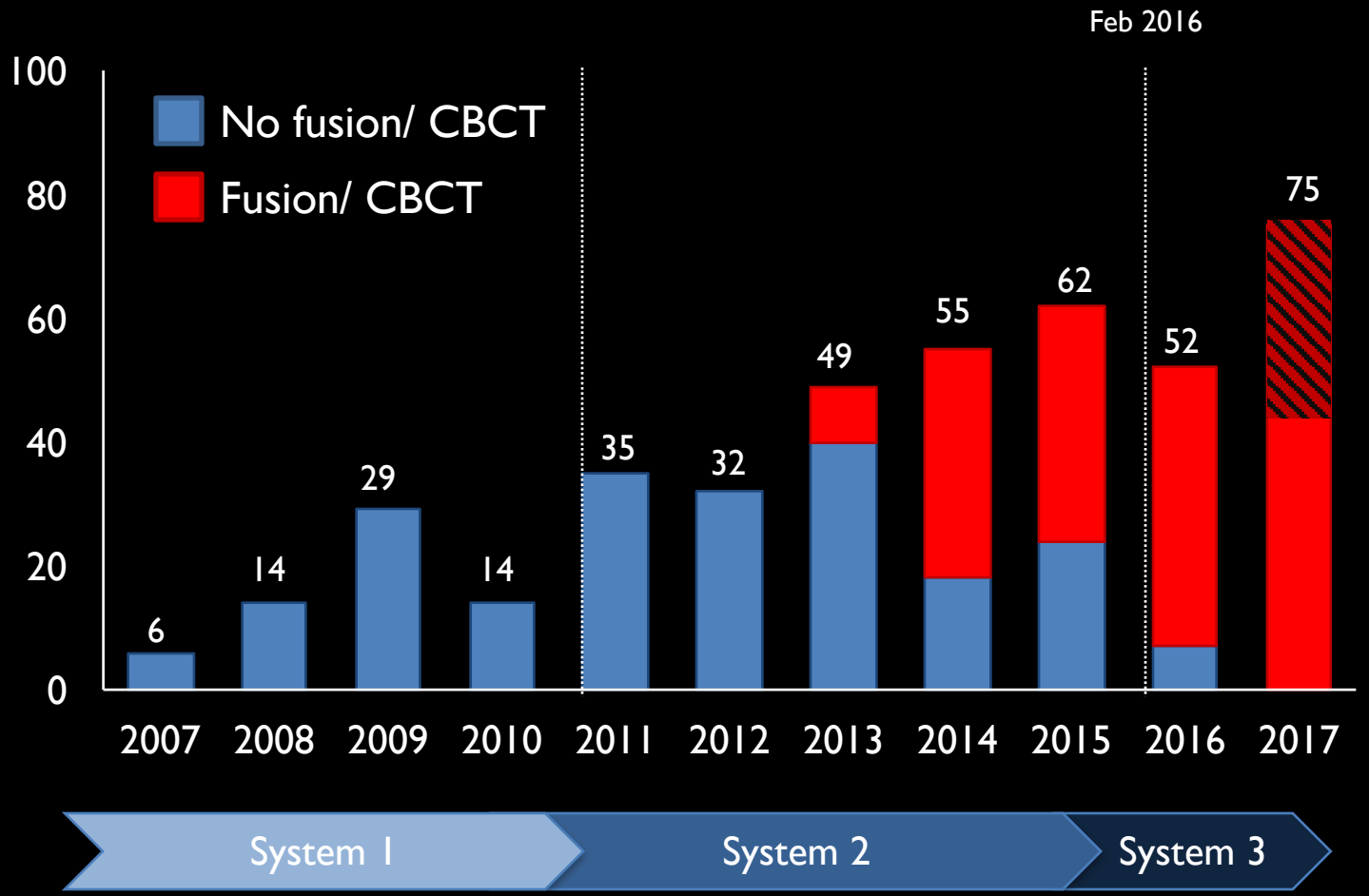


HYBRID ROOM SYSTEMS

	Specification	Years	Units	Advanced applications
System 1	Siemens Axiom	2002-2011	1	No
System 2	Siemens Zeego	2011-2015	1	Fusion/ CBCT
System 3	GE Discovery IGS 740	2016-2018	2	Fusion/ HD CBCT/ Digital Zoom

USE OF FUSION & CBCT

423 patients



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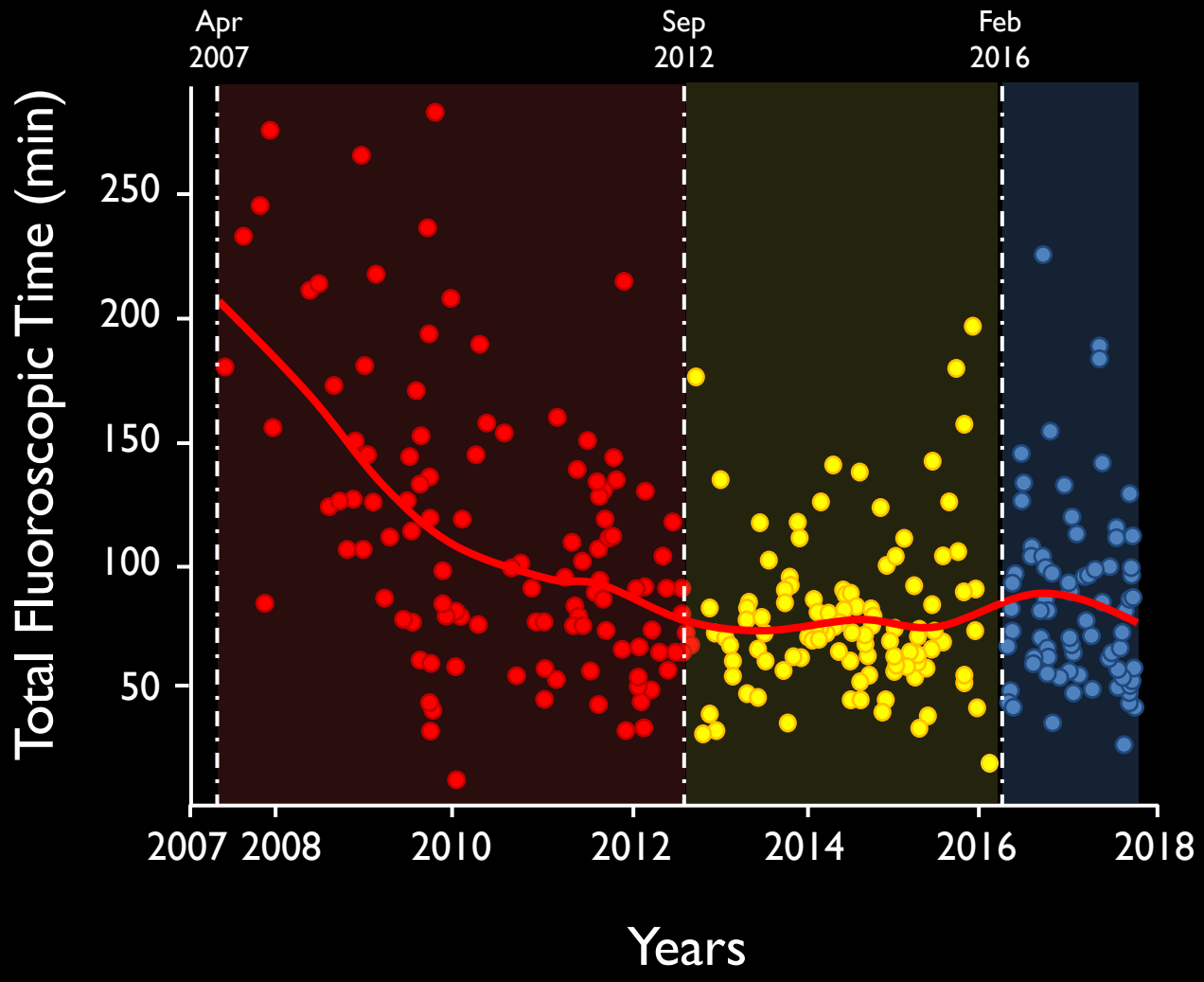
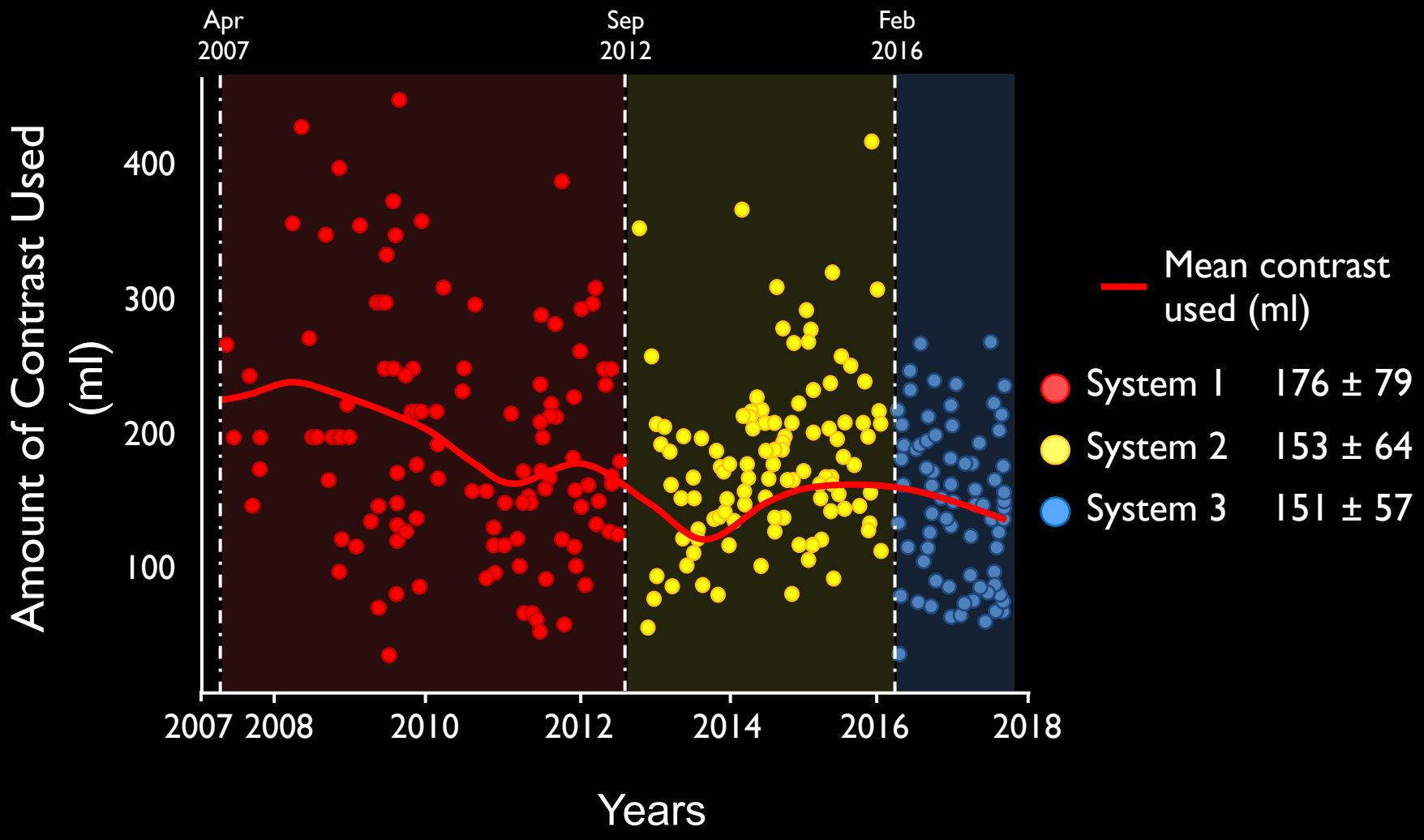
FLUOROSCOPY TIME



MAYO CLINIC

CONTRAST VOLUME



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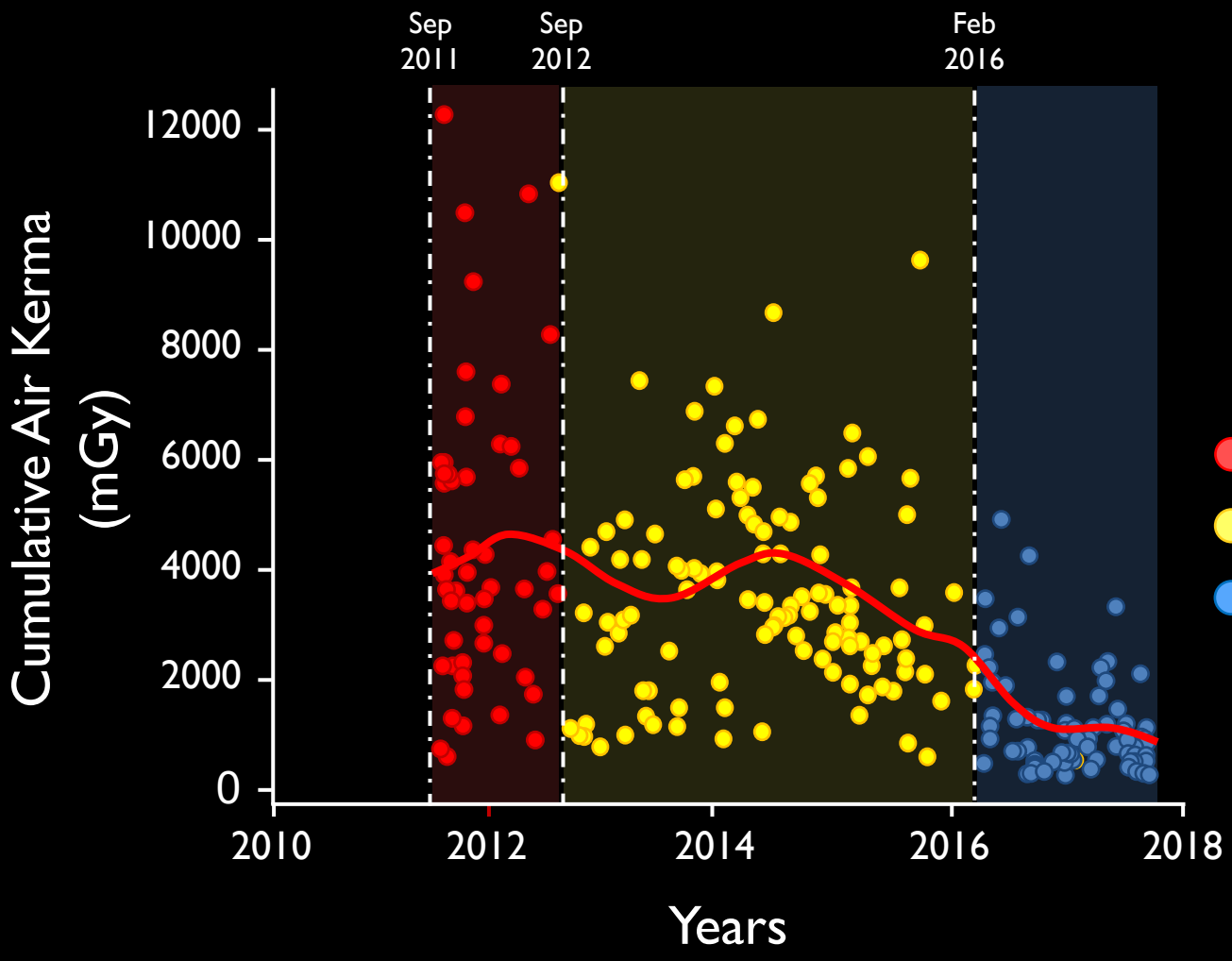
EFFECTIVE DOSE



Mean radiation Dose (mGy)

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

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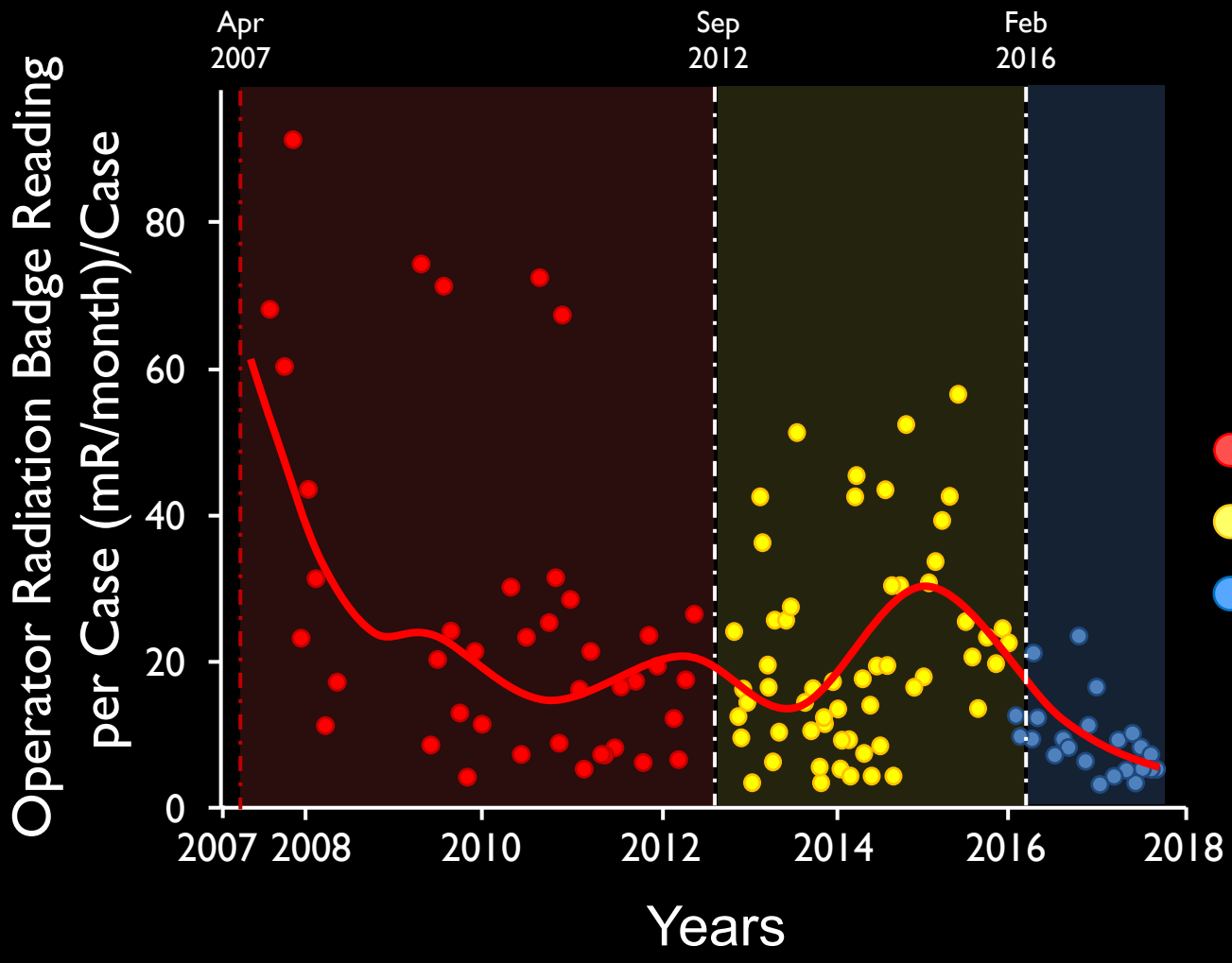
OPERATOR DOSE PER CASE



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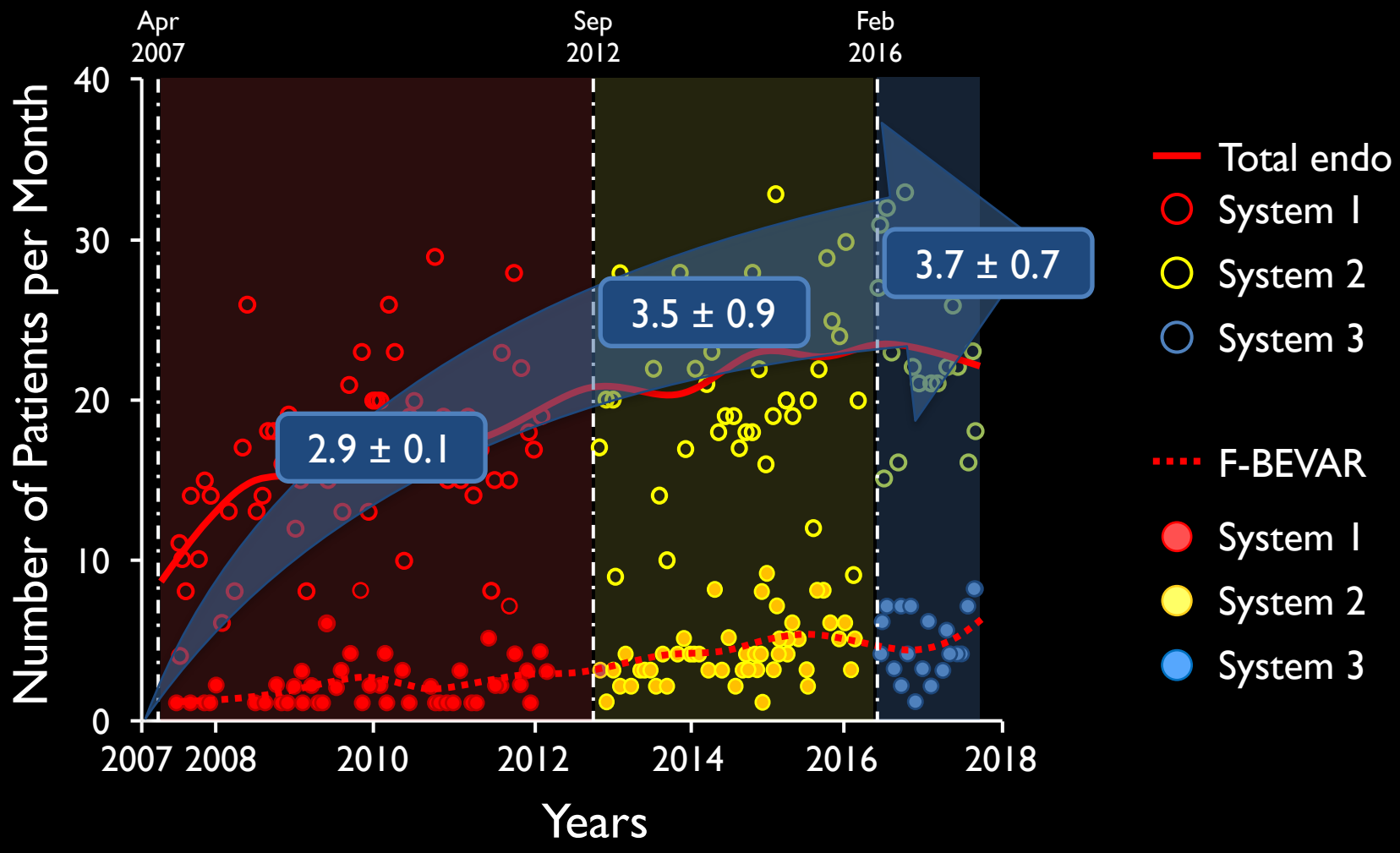
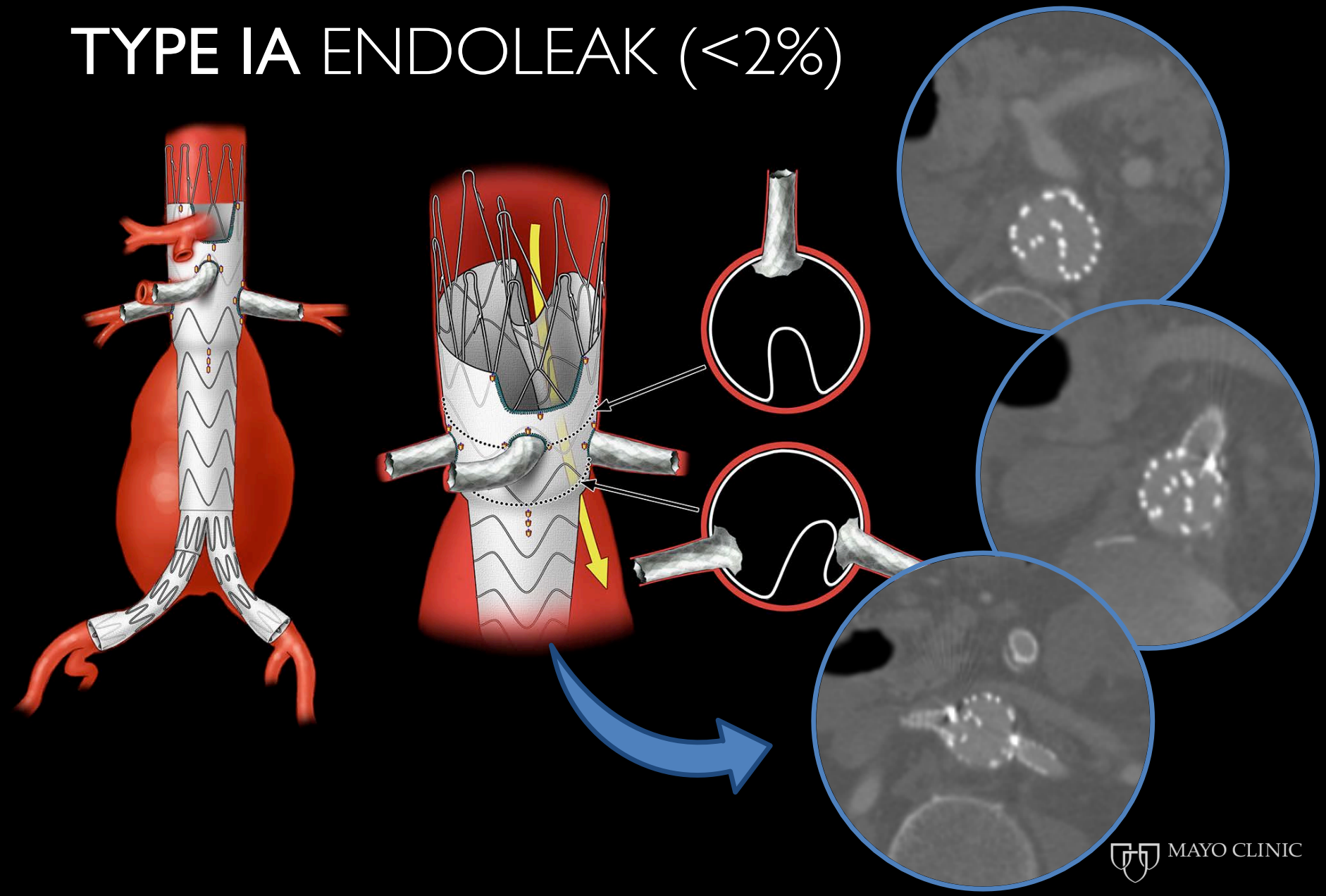
INCREASING VOLUME



2.9±0.1 **3.5±0.9** **3.7±0.7**

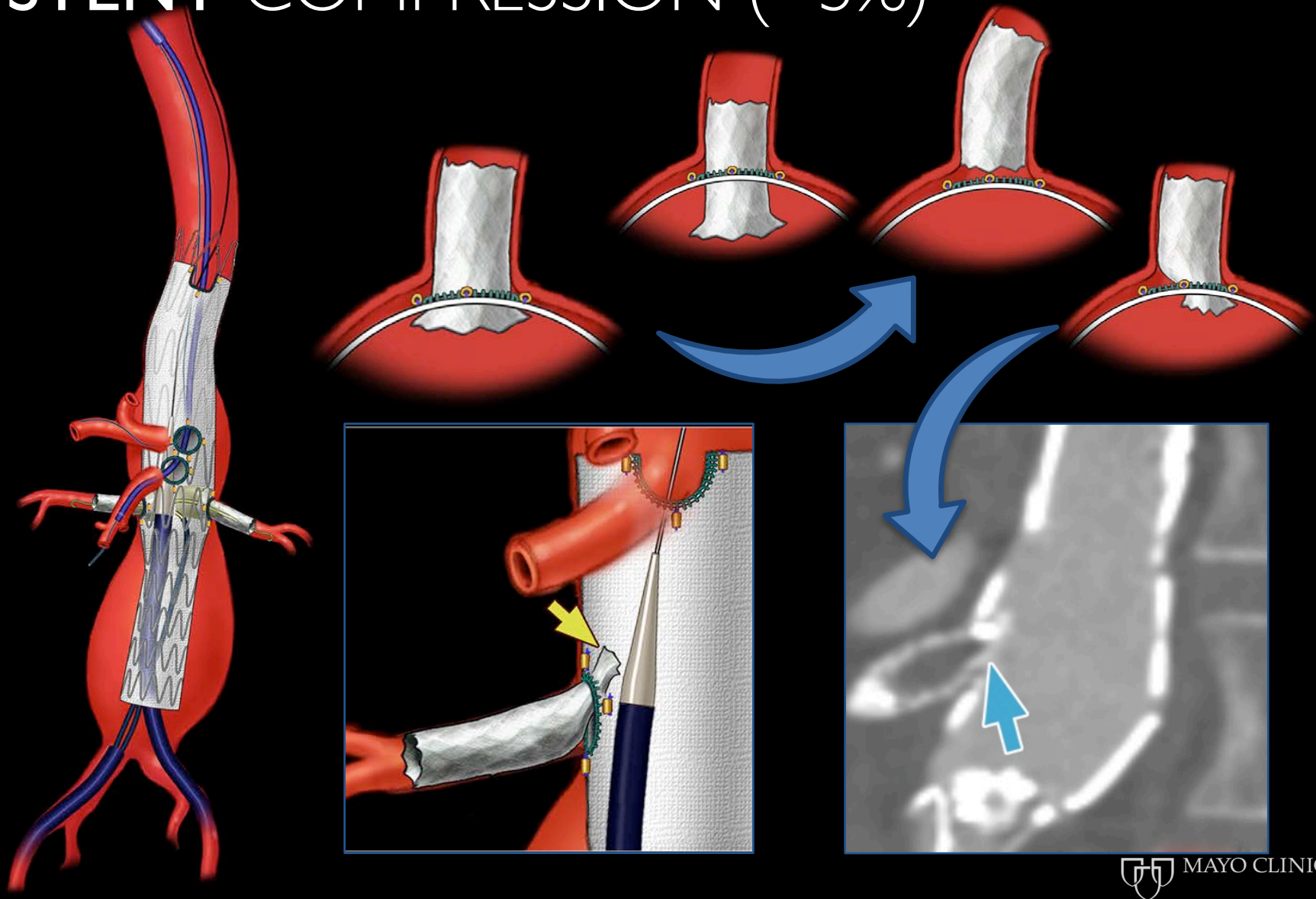
MAYO CLINIC

TYPE IA ENDOLEAK (<2%)



MAYO CLINIC

STENT COMPRESSION (~5%)



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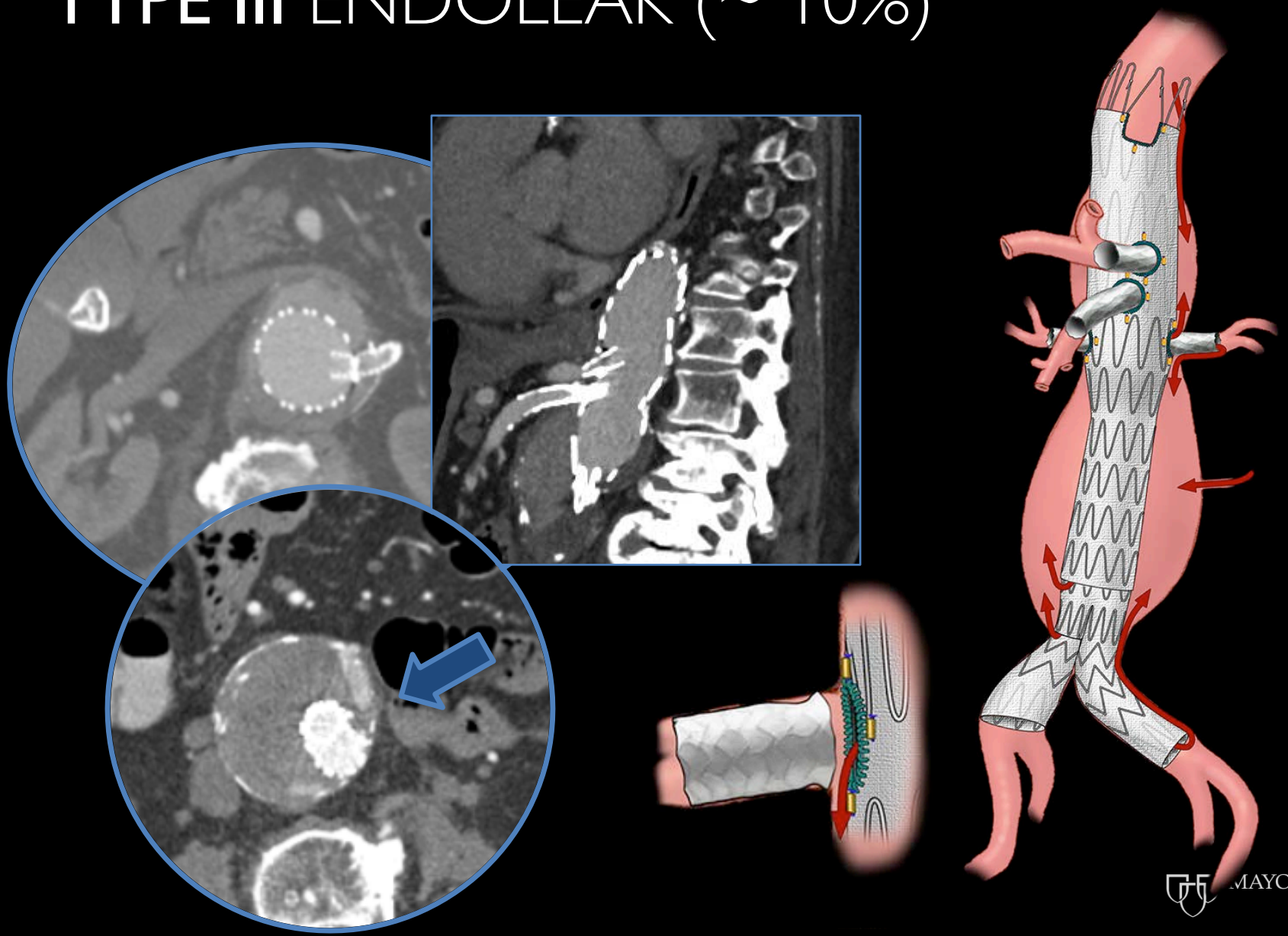
TYPE III ENDOLEAK (~ 10%)



MAYO CLINIC

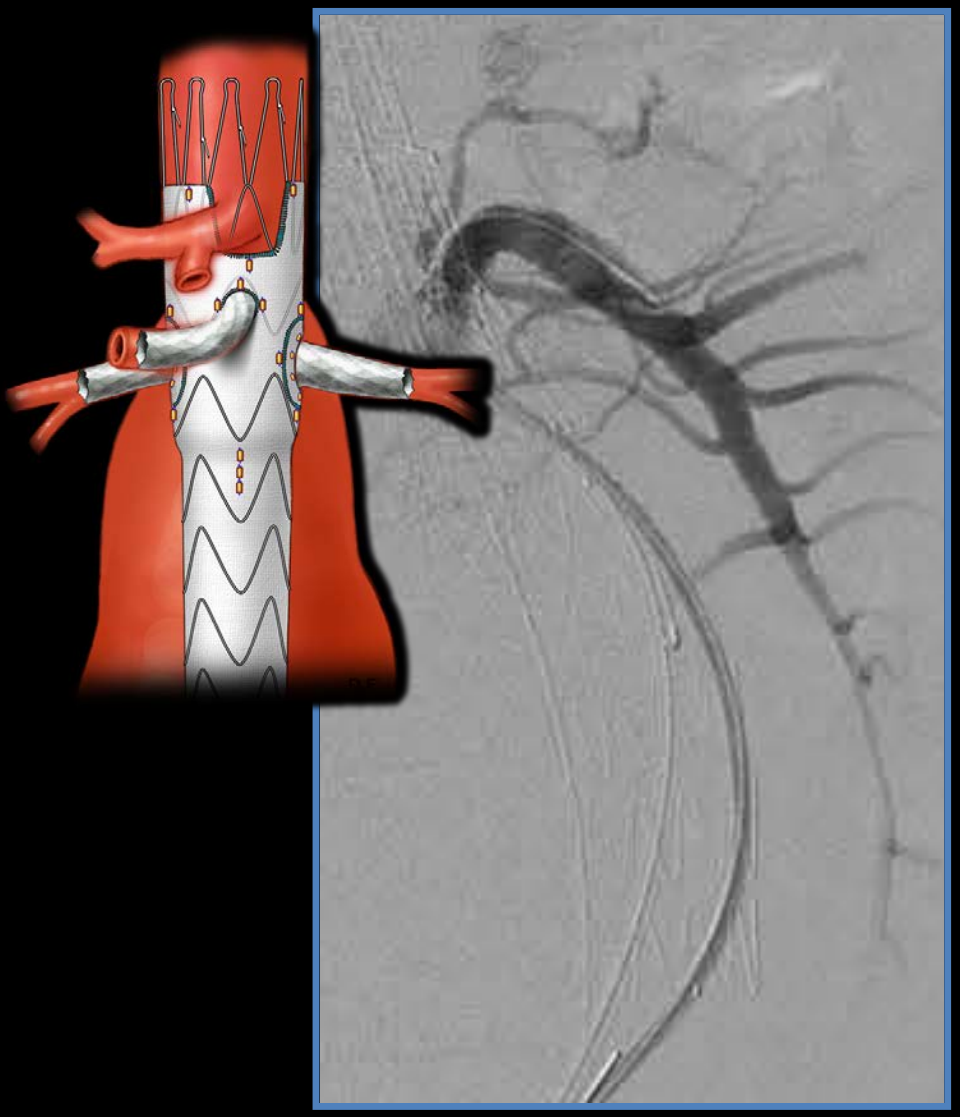
F-BEVAR WITHOUT CBCT

18 of 219 patients (8%)

Positive finding by CTA warranting reintervention	n	Secondary Interventions
Branch stent compression or kink	5	
Renal-mesenteric	5	Redo stent/PTA
Iliac	1	Redo stent/PTA
Endoleak	7	
Type IIIC	6	Redo stent in 5, renal bypass in 1
Type IA (with stent infolding in 1)	2	Cuff in 1, Palmaz stent in 1
Flow-limiting dissection	2	
Common iliac artery with occlusion	1	Embolectomy + Redo stent
External iliac artery	1	Stenting
SMA coverage by single-wide scallop	2	Stenting x 1, Bypass x 1
Celiac stent malpositioning	1	Stent relocation, redo stent
Total	18	

ALL PATIENTS REQUIRED SECONDARY PROCEDURES

MAYO CLINIC



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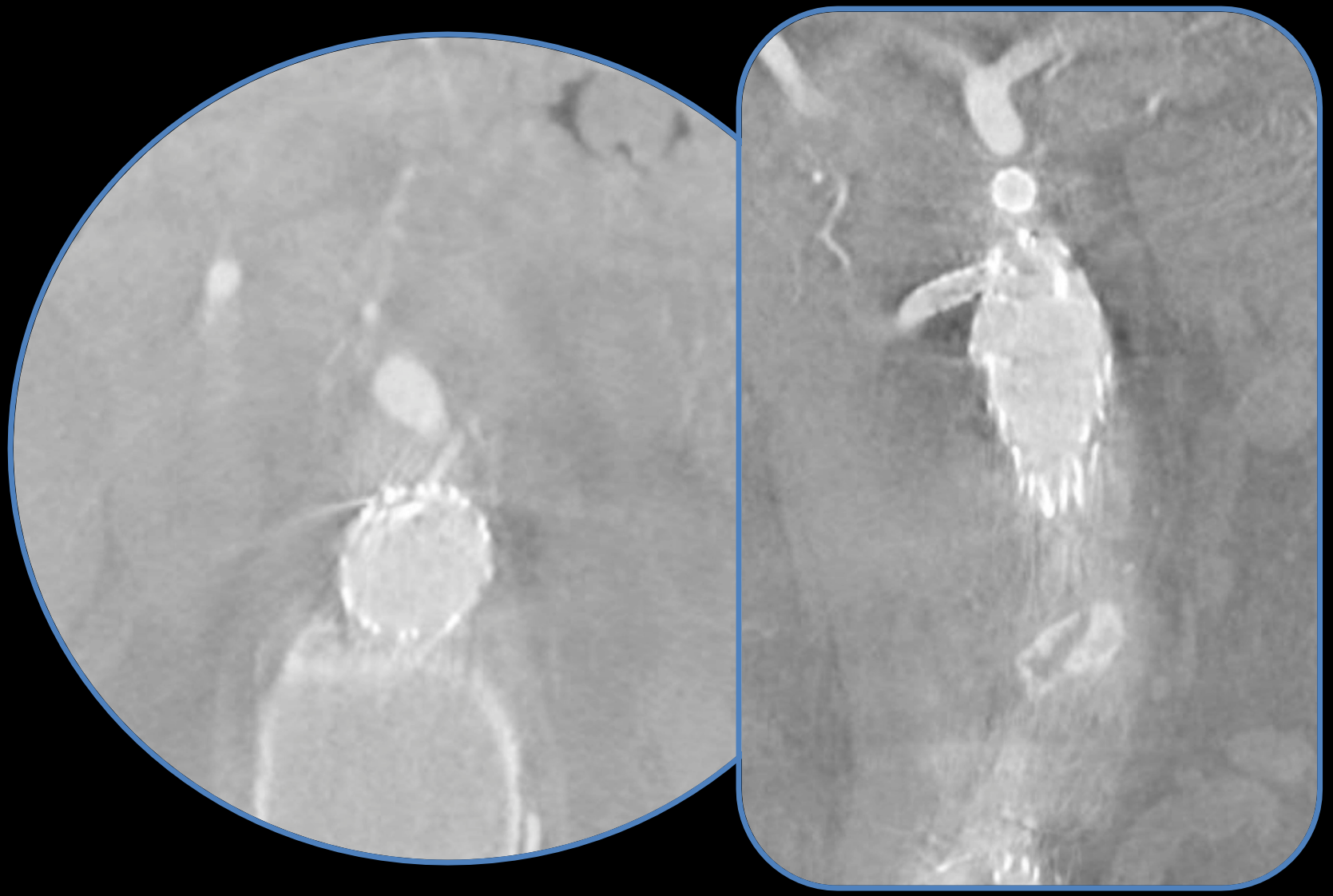
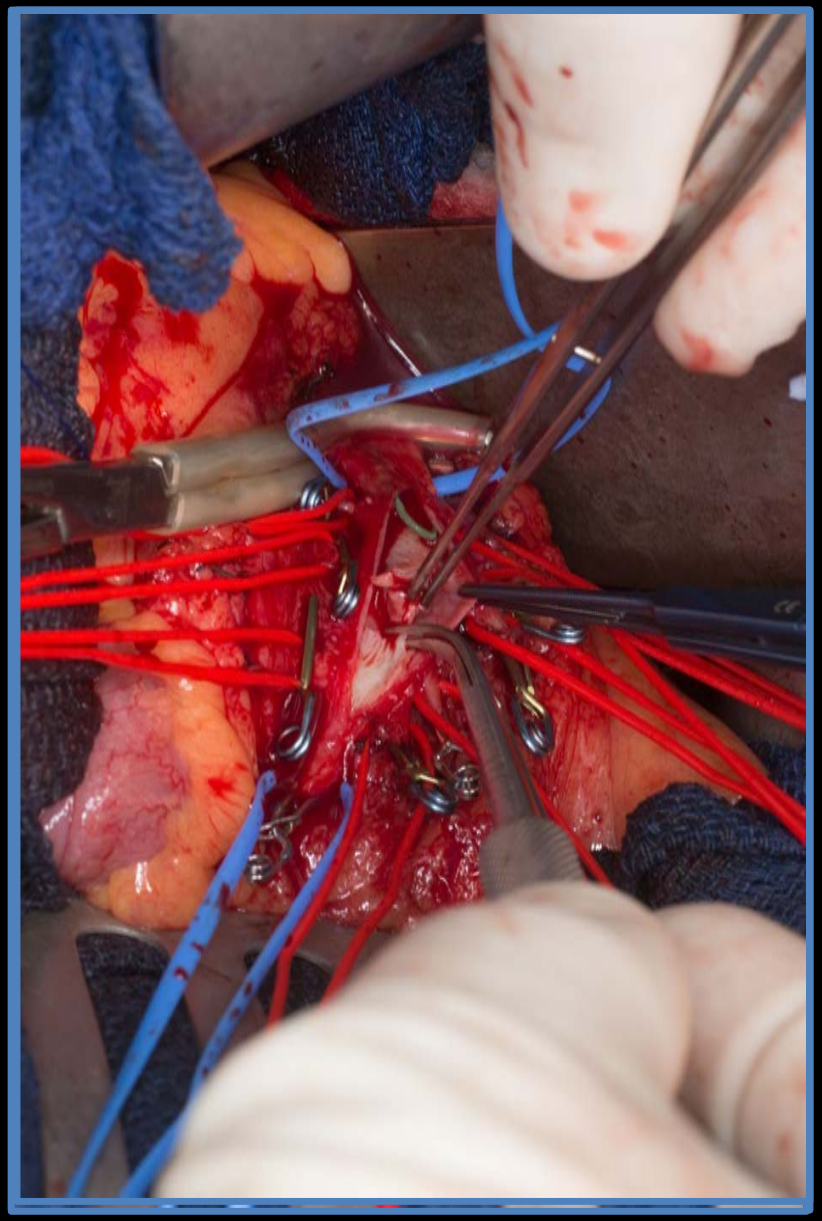
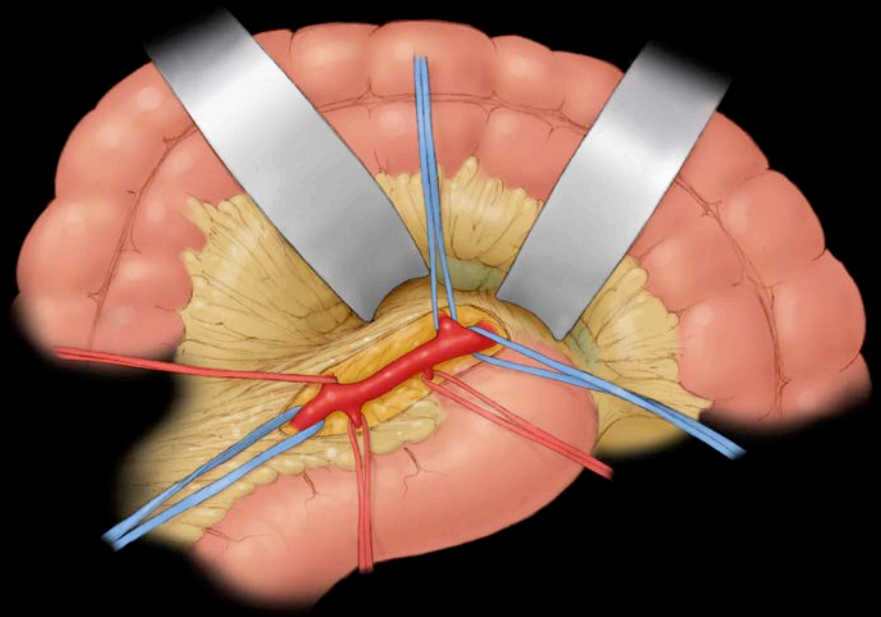
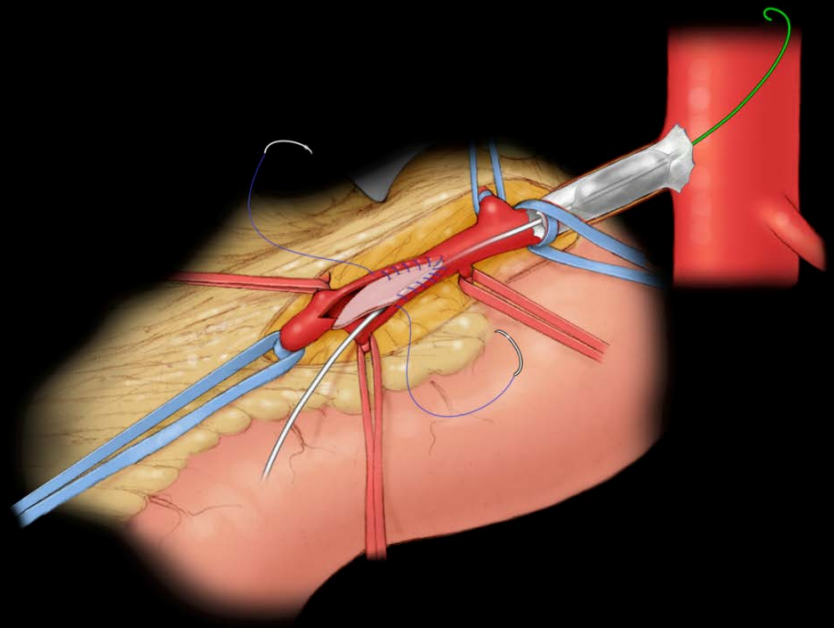
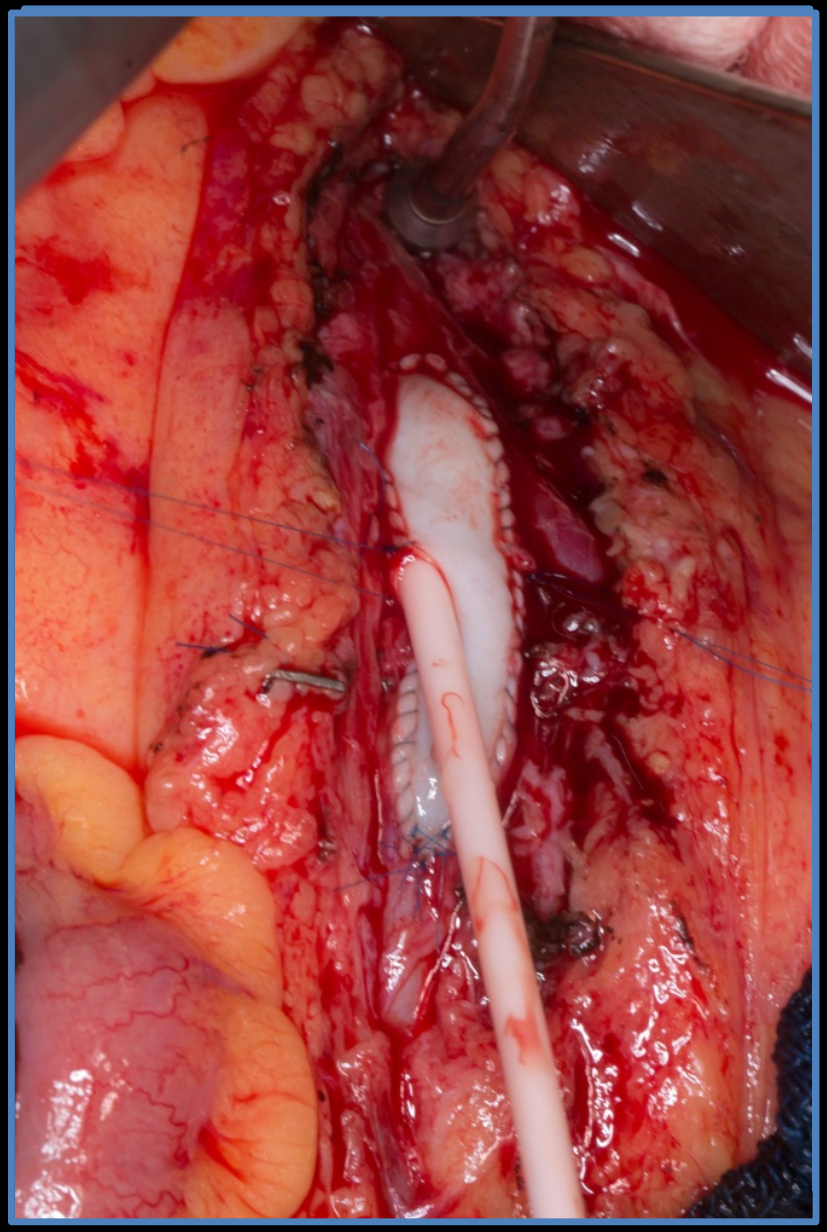


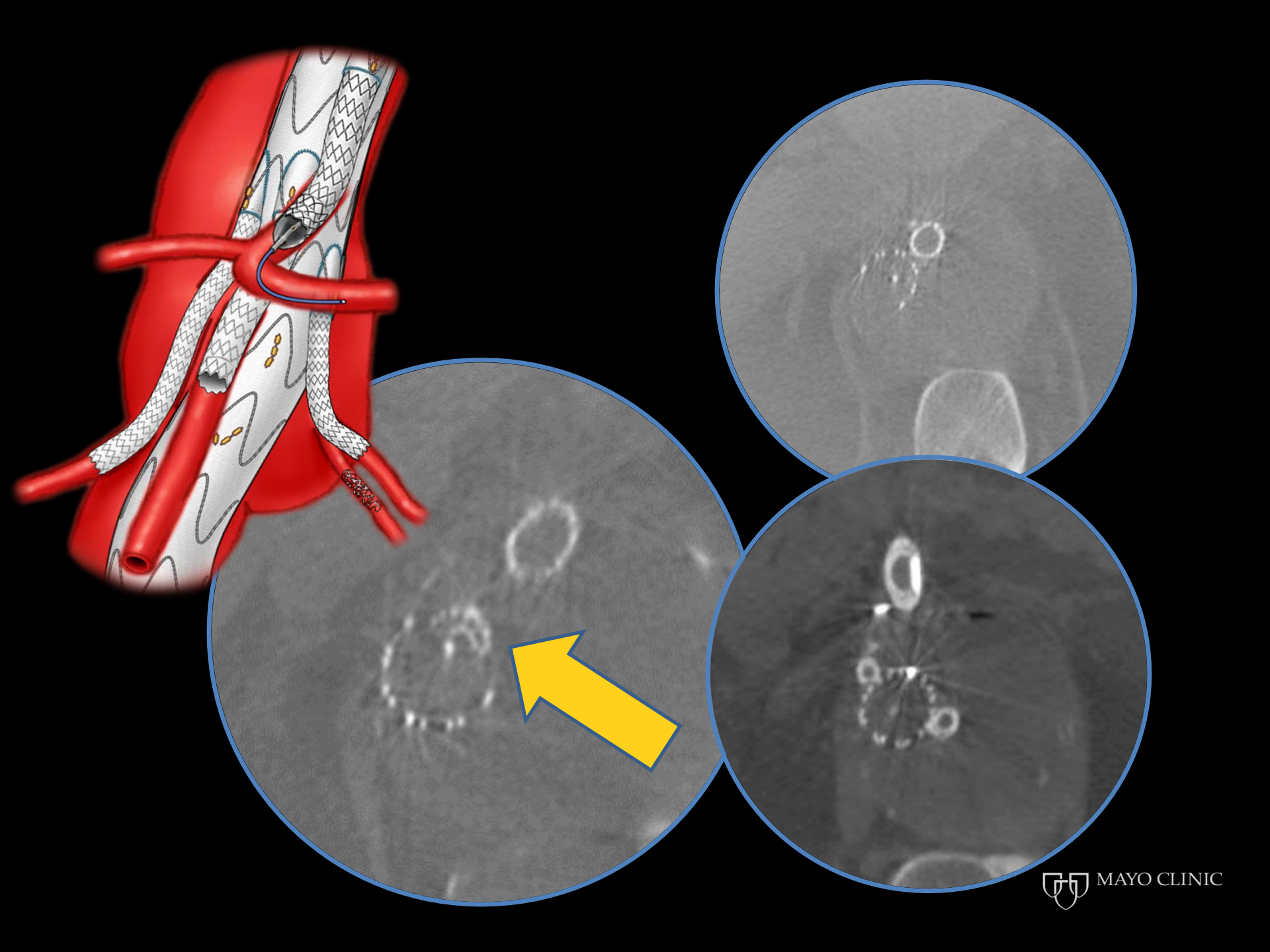








No postoperative complications


MAYO CLINIC

F-BEVAR WITH CBCT

14 of 167 patients (8%)

Positive finding by CBCT warranting intraoperative revision	n	Type of revision
Branch stent compression or kink	4	
Renal-mesenteric	4	Redo stent/PTA
Endoleak	6	
Type IA	1	Cuff thoracic extension
Type IIIC	5	Thoracic extension x 1, redo stent x4
Flow-limiting dissection	2	
External iliac artery	1	Redo stent
SMA dissection/ occlusion	1	Removal of dissected flap + ROMS
IIA coverage	1	Recanalization and stent
Celiac stent malpositioning	1	Relocation, Redo Stent
Total	14	

ALL REVISIONS PERFORMED AT TIME OF INDEX PROCEDURE

30-DAY OUTCOMES

	Without CBCT n = 219	With CBCT n = 167	P value
30-day mortality	4%	1%	.049
30-day reintervention	10%	4%	<.022
Reintervention prior to discharge	9%	2%	<.004
Major adverse events	43%	19%	.001
Estimated blood loss >1L	27%	9%	.001
Acute kidney injury	16%	5%	.002
New onset dialysis	1%	1%	.7
Myocardial infarction	5%	5%	.7
Respiratory failure	6%	2%	0.029
Paraplegia	2%	2%	.28
Stroke	2%	4%	.28
Bowel ischemia	3%	1%	.29

PROSPECTIVE, NON-RANDOMIZED STUDY TO EVALUATE CONE BEAM COMPUTED TOMOGRAPHY FOR ASSESSMENT OF STANDARD AND COMPLEX EVAR

Emanuel Tenorio MD PhD, Gustavo S. Oderich MD, Giuliano Sandri MD, Pinar Ozbek, Bernardo Mendes MD, Jussi Karkkainen MD, Terri Vrtiska MD, Thanila Macedo MD, Stephen Cha MS and Peter Gloviczki MD

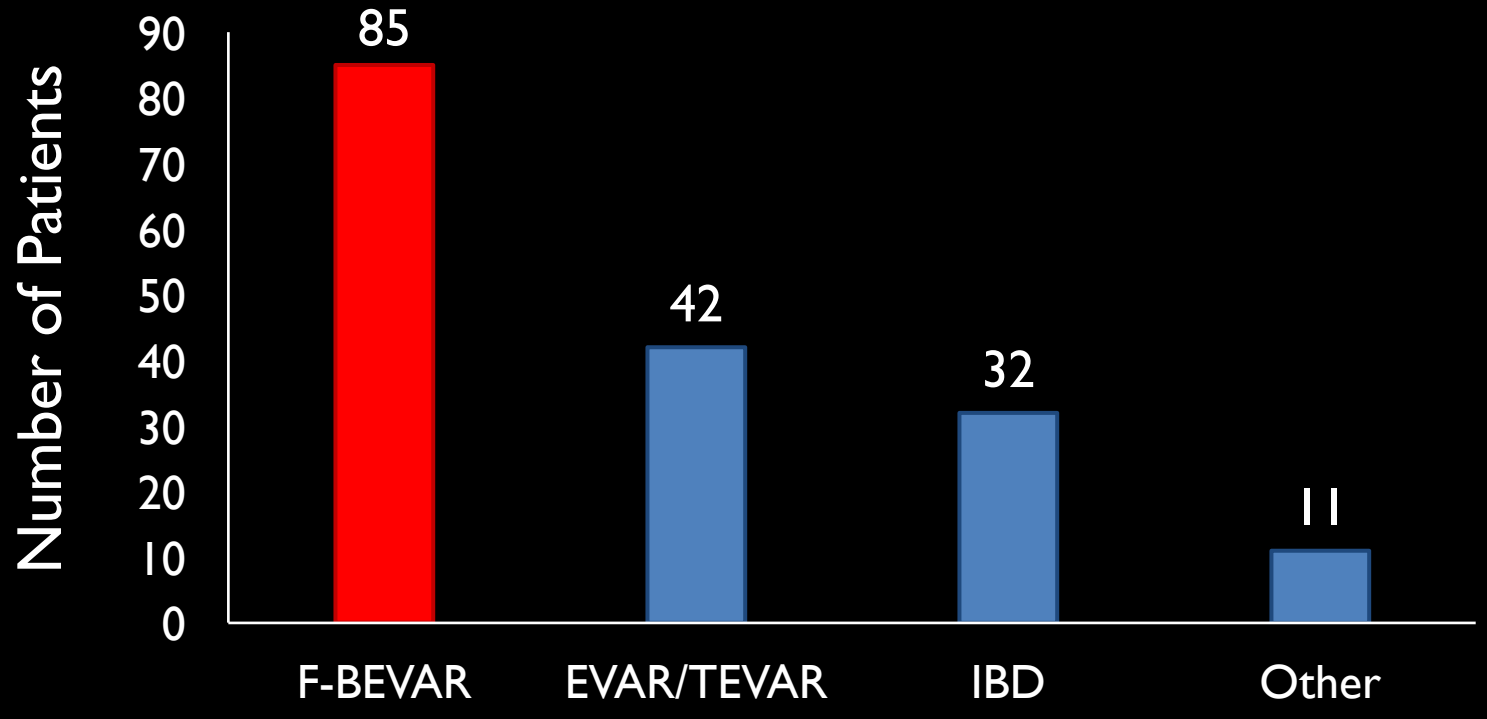
VAM2018
BOSTON MA

Abstract submitted for presentation

MAYO CLINIC

PATIENTS

155 patients had 170 endovascular aortic aneurysm procedures



POSITIVE FINDINGS BY CBCT

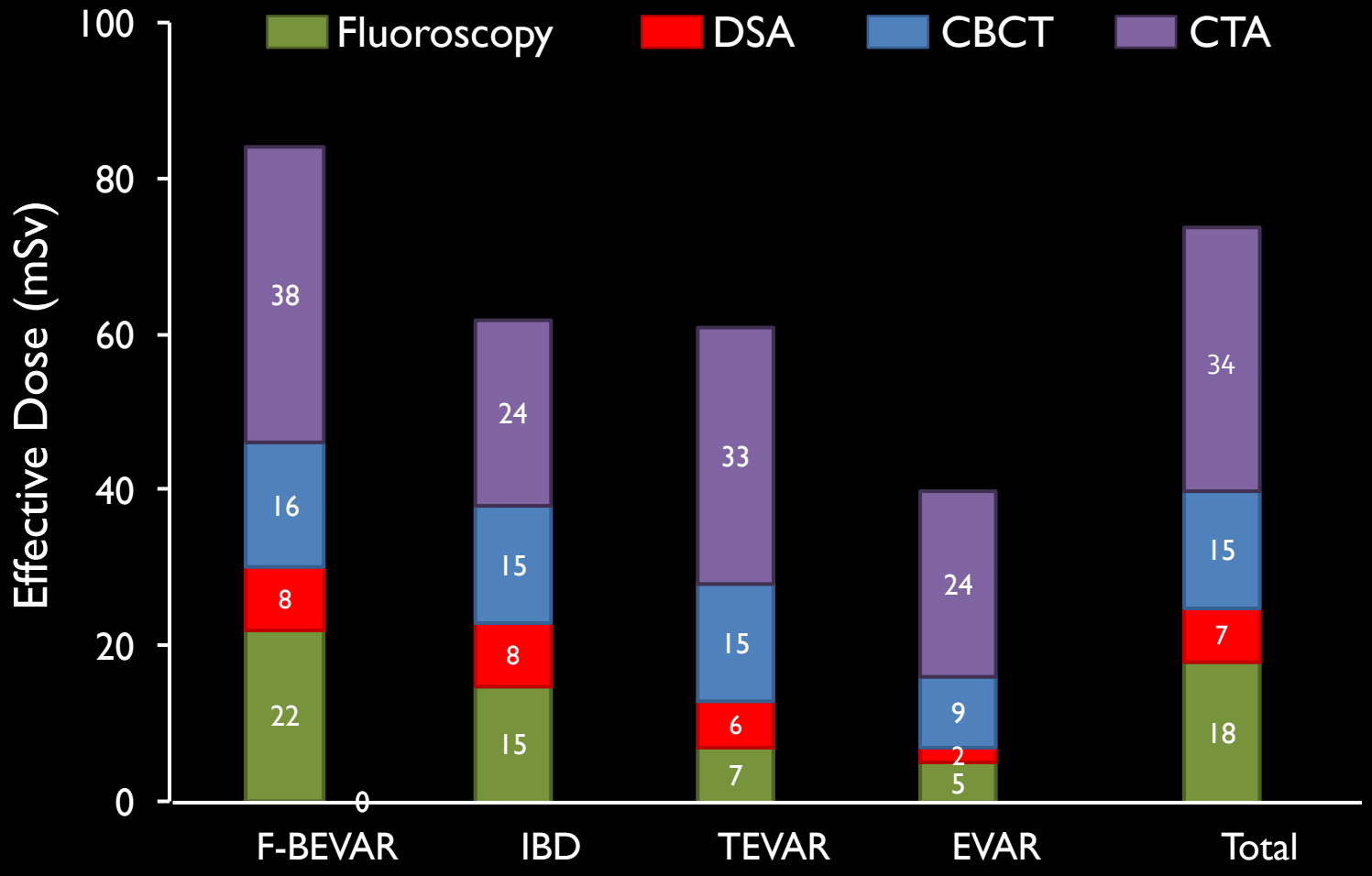
- 43 patients (29%) had 49 positive findings
  - F-BEVAR 35% vs other 16% (p=0.01)

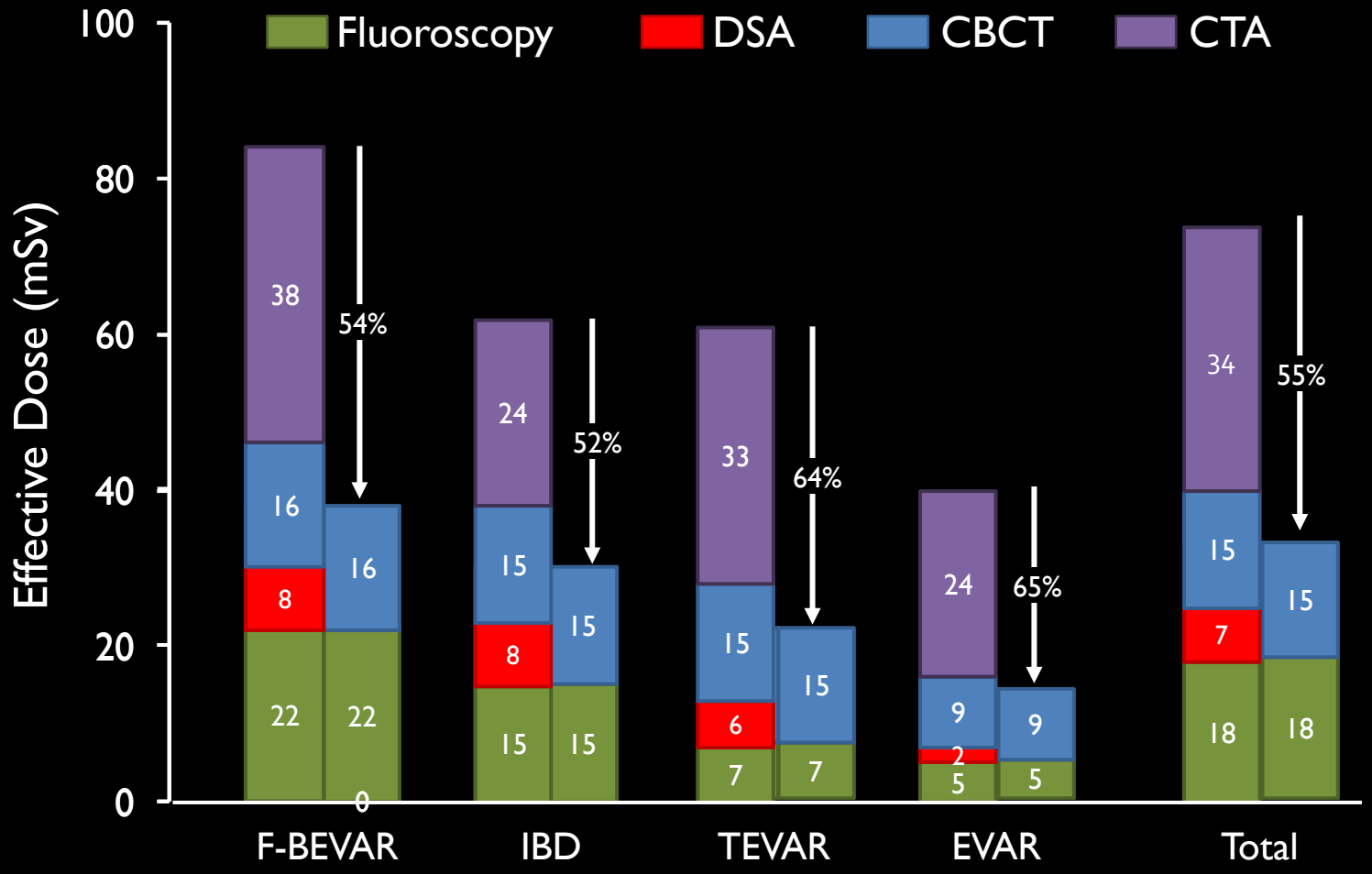
	n	Immediate Finding
Stent compression or kink	26	17%
Type I or III endoleak	16	10%
Arterial dissection or thrombus	7	5%

- 28 patients (18%) required immediate revision
- 15 patients (11%) had minor findings observed

DSA VS CBCT

- DSA alone would not have detected findings in 34 of the 43 patients (79%)
- 21 patients (62%) with negative DSA had immediate revisions based on CBCT findings
- 4 patients (2.5%) had CTA findings prompting interventions in three (2%), despite negative DSA and CBCT
  - Type IB endoleak > distal iliac limb extension
  - Femoral artery occlusion > patch angioplasty
  - Compressed renal stent > redo stenting
  - Internal iliac branch Type IC endoleak > observation


Fluoroscopy
DSA
CBCT
CTA
Effective Dose (mSv)
100
80
60
40
20
0
38
16
8
22
0
24
15
8
15
33
15
6
7
24
9
2
5
34
15
7
18
F-BEVAR
IBD
TEVAR
EVAR
Total


Fluoroscopy
DSA
CBCT
CTA
Effective Dose (mSv)
100
80
60
40
20
0
38
16
8
22
16
22
0
54%
24
15
8
15
15
52%
33
15
6
7
15
7
64%
24
9
2
5
9
5
65%
34
15
7
18
15
18
55%
F-BEVAR
IBD
TEVAR
EVAR
Total

CONCLUSION

- Secondary reinterventions remain one of the most significant limitations of EVAR – standard or complex
- CBCT has allowed immediate assessment to identify technical problems that are not easily detected by DSA
- Immediate revision of these problems avoid unecessary secondary interventions and may decrease morbidity associated with serious complications
- CBCT can also be applied by multiple specialties in a variety of other percutaneously guided interventions, including endoleak embolization, vessel catheterization, tissue biopsy or ablation, etc