New Horizons for IR

James Benenati MD

Miami Cardiac & Vascular Institute
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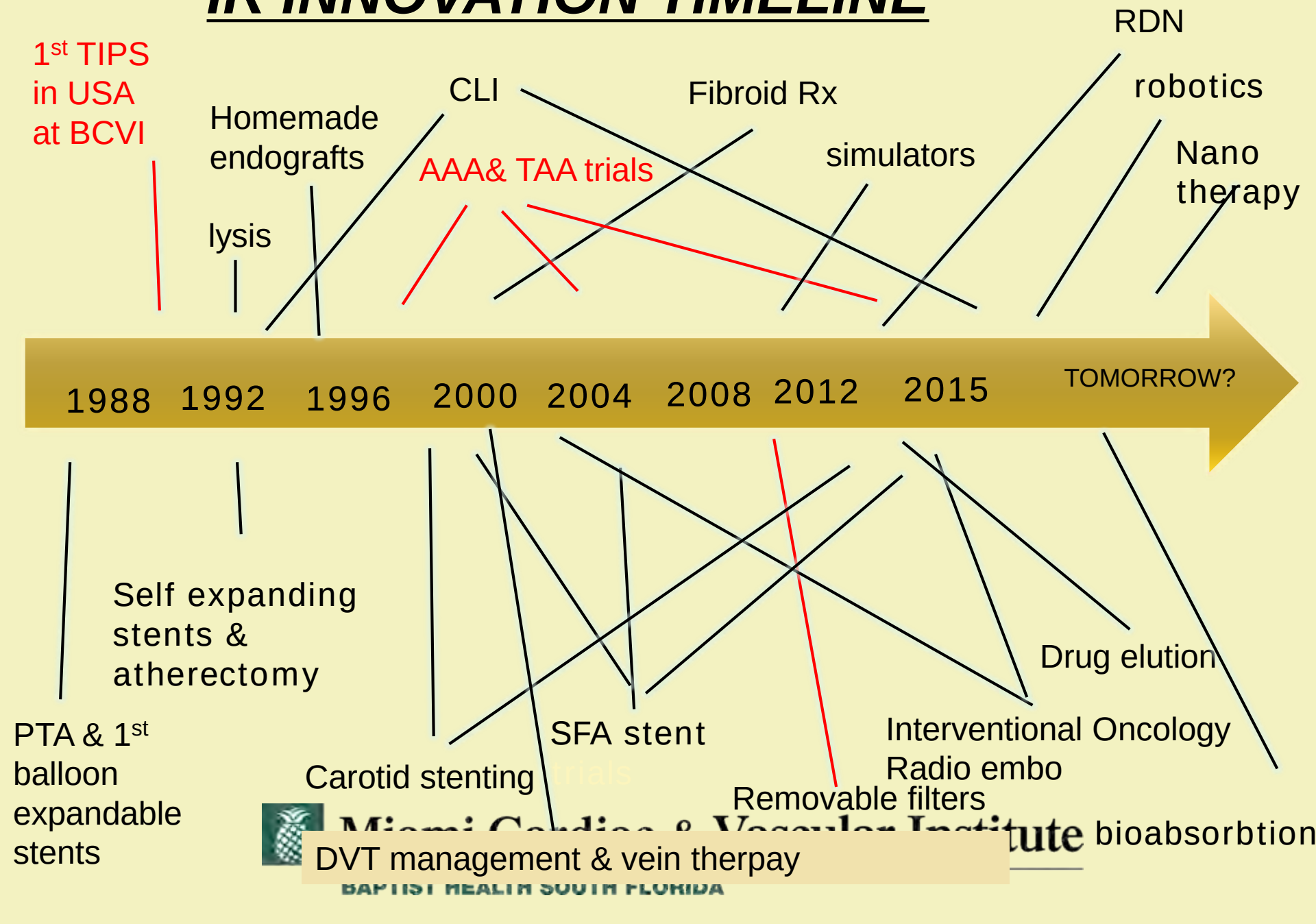
IR INNOVATION TIMELINE



Subintimally dissect it

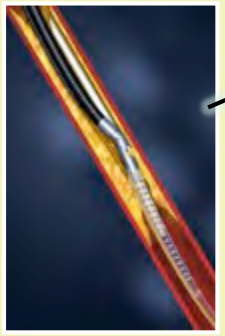
Balloon it

Stent it

Drug it

PAD

Sand it!!!

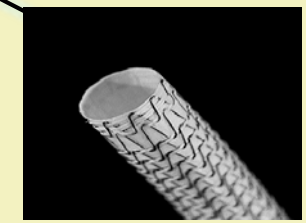


Excise it

Laser it

Freeze it

Remote it



Graft it

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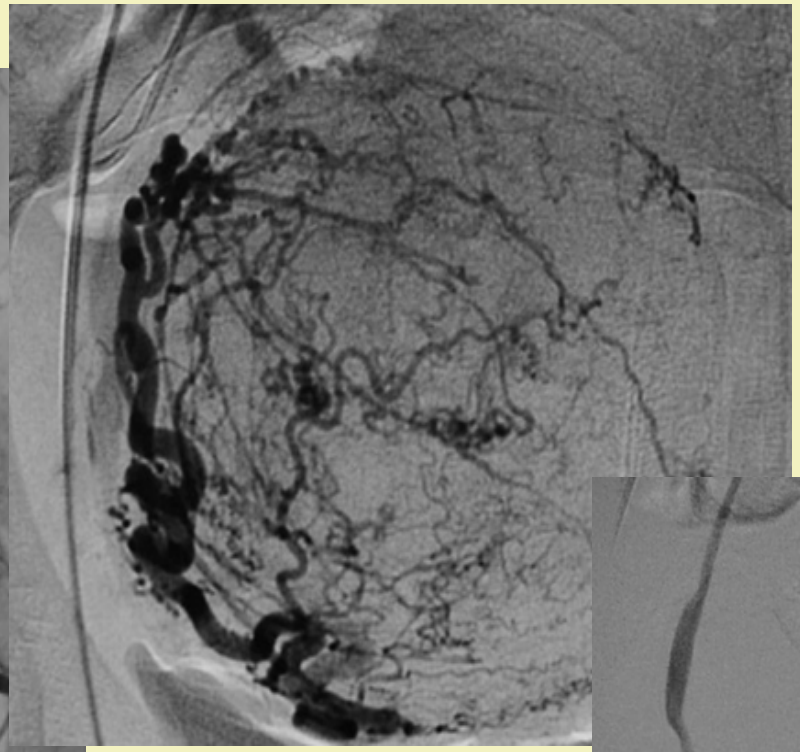
0°
31 cm

Uterine Fibroid Embolization

Publications and trials began in 1997

Now standard practice in USA



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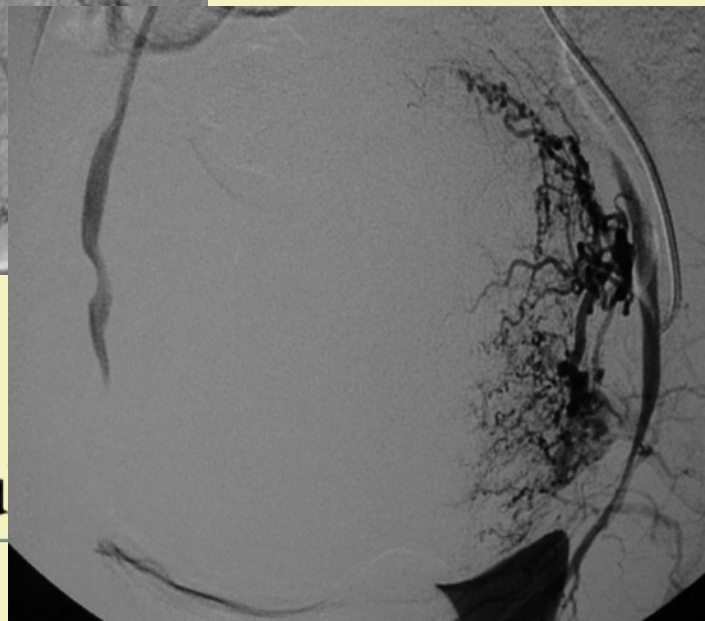

Participation in CREST and numerous other industry and FDA sponsored trials

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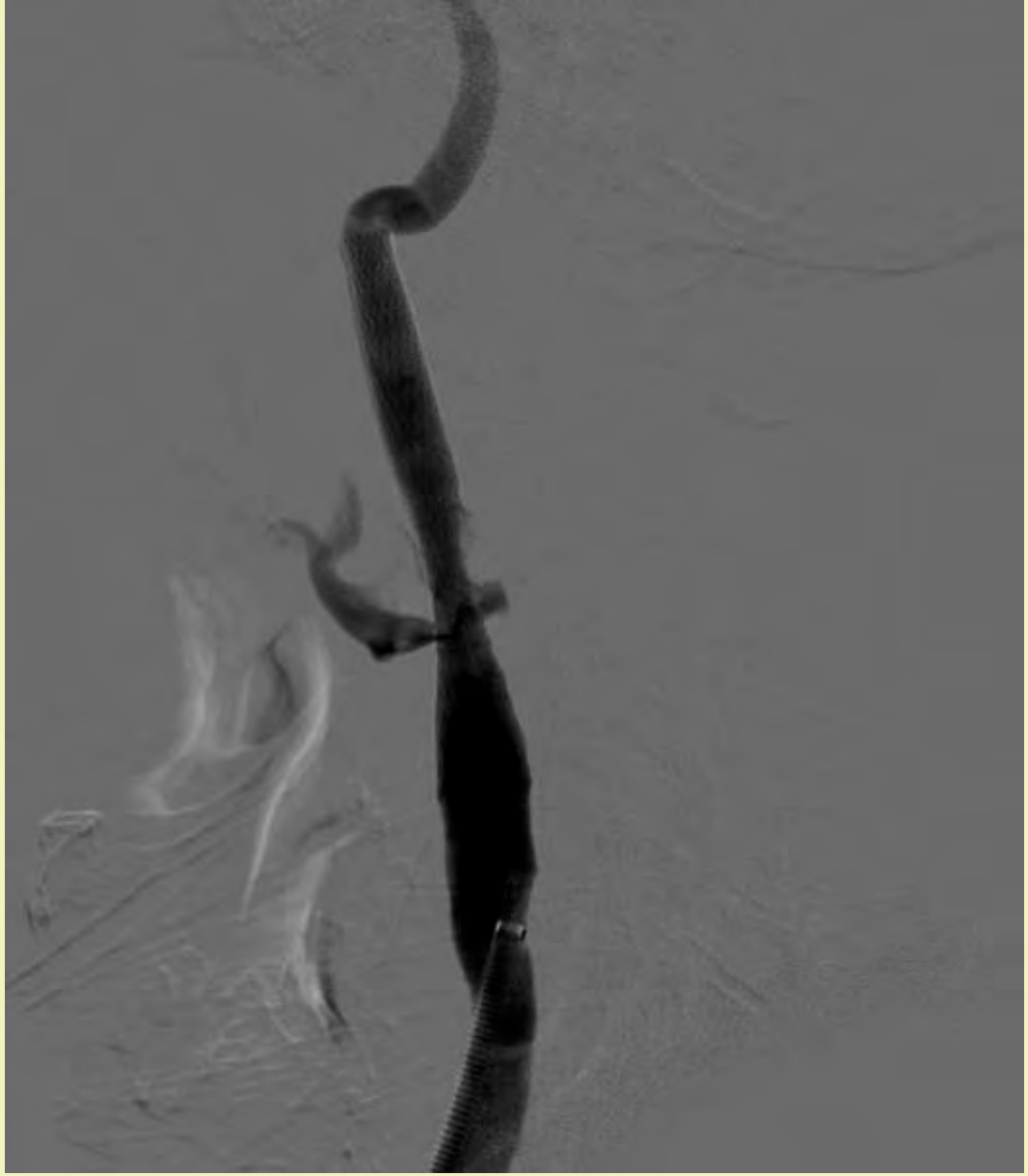

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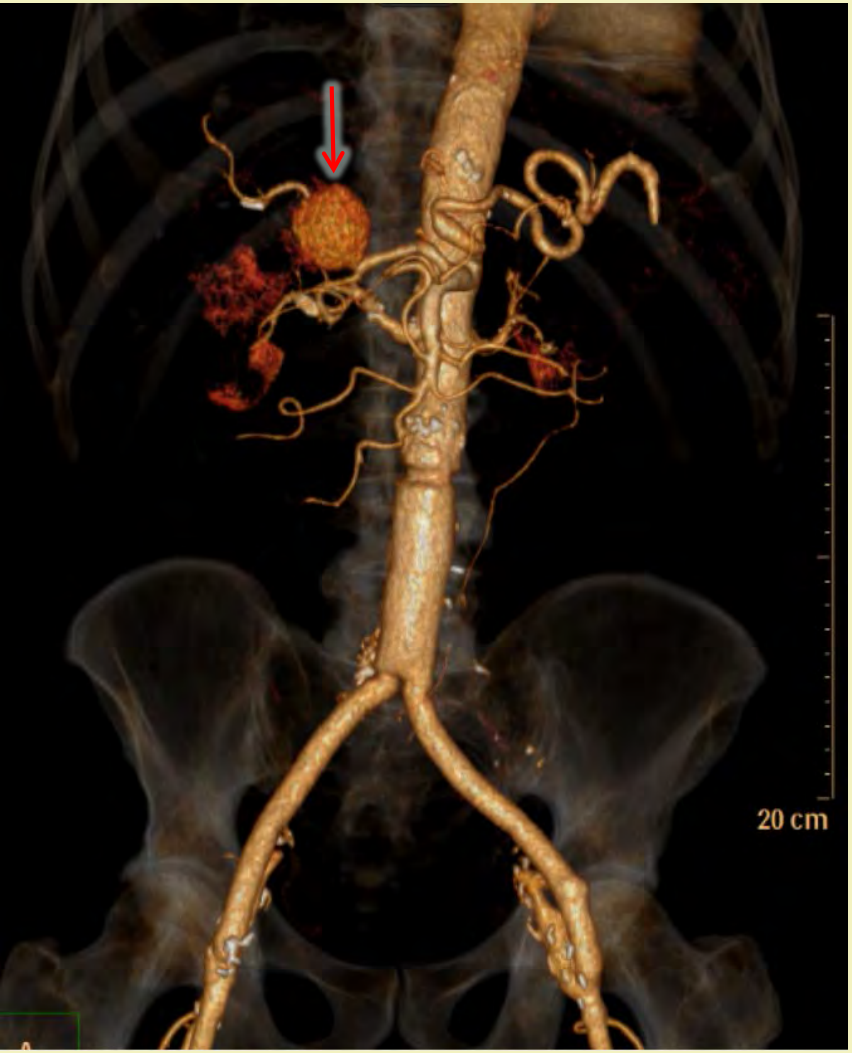
Publications leading to FDA approval of optional filters



Publication on treatment of visceral artery aneurysms with one of the largest series reported

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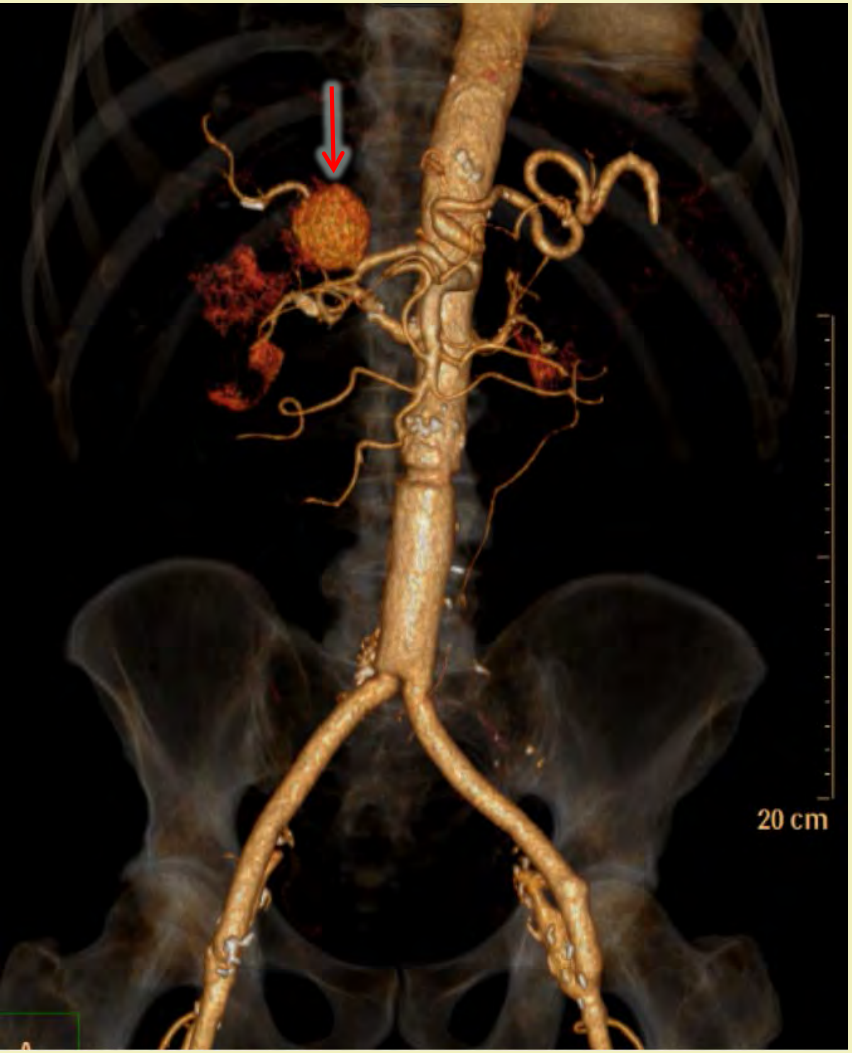

Publication on treatment of visceral artery aneurysms with one of the largest series reported

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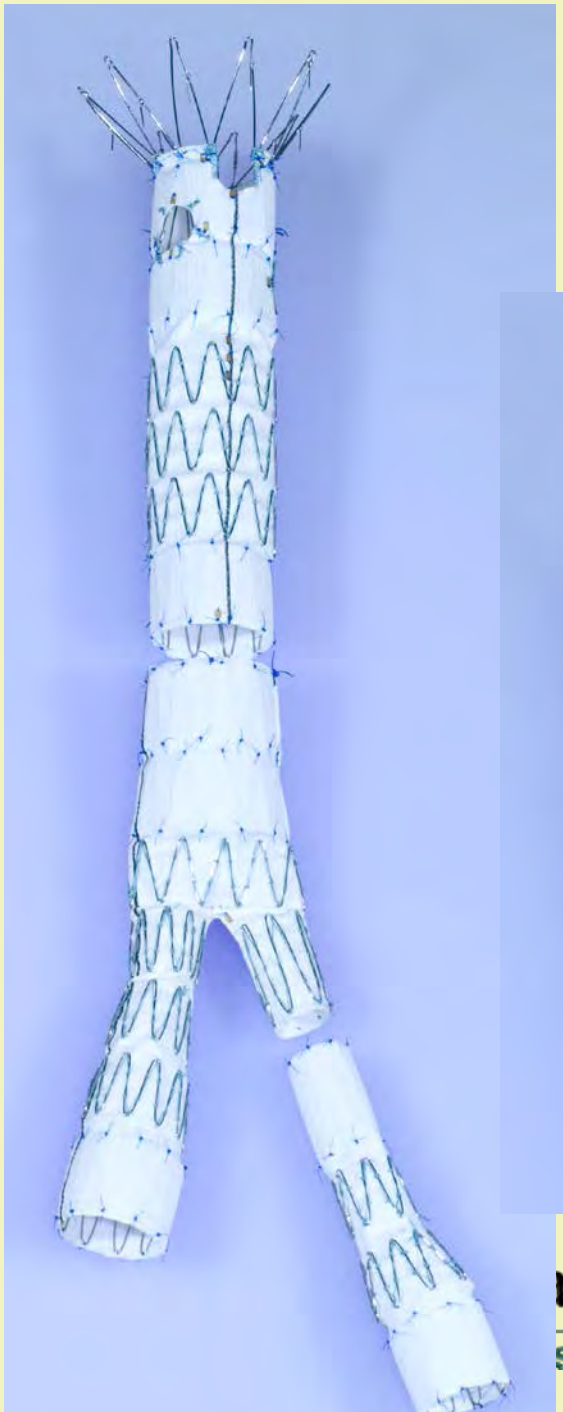
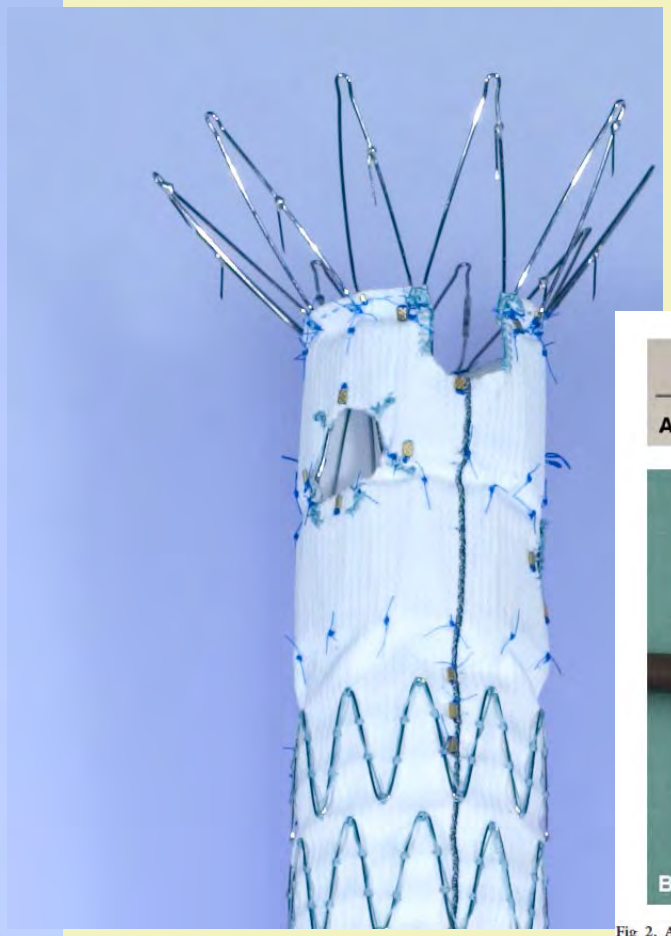
Snorkel graft

- Parallel graft alongside the main aortic endoprosthesis to maintain flow in a covered branch vessel.

Cook

Fenestrations and scallops





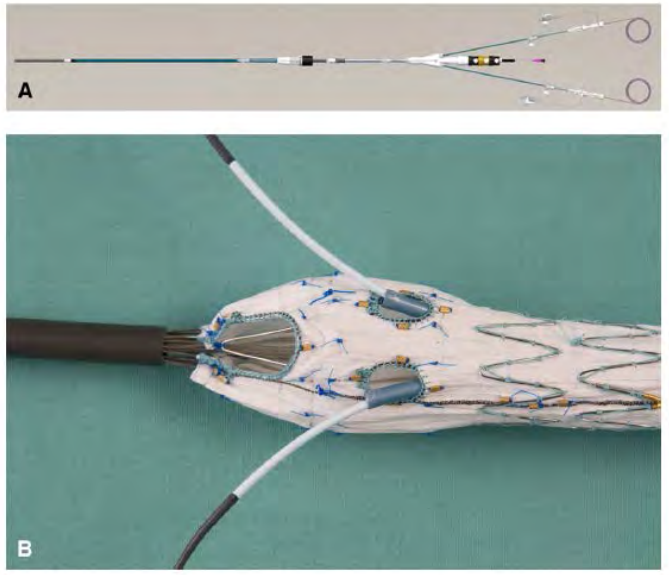


Fig 2. A, Preloaded fenestrated delivery system manufactured by Cook Inc delivery system manufactured by Cook Inc. The device consists of a sheath into which the fenestrated device is loaded along with two catheters and sheaths, mounted on trigger wires that traverse both of the renal arteries. The catheters can then be advanced over the wires to exit the fenestrations allowing renal access with specifically designed catheters (B).

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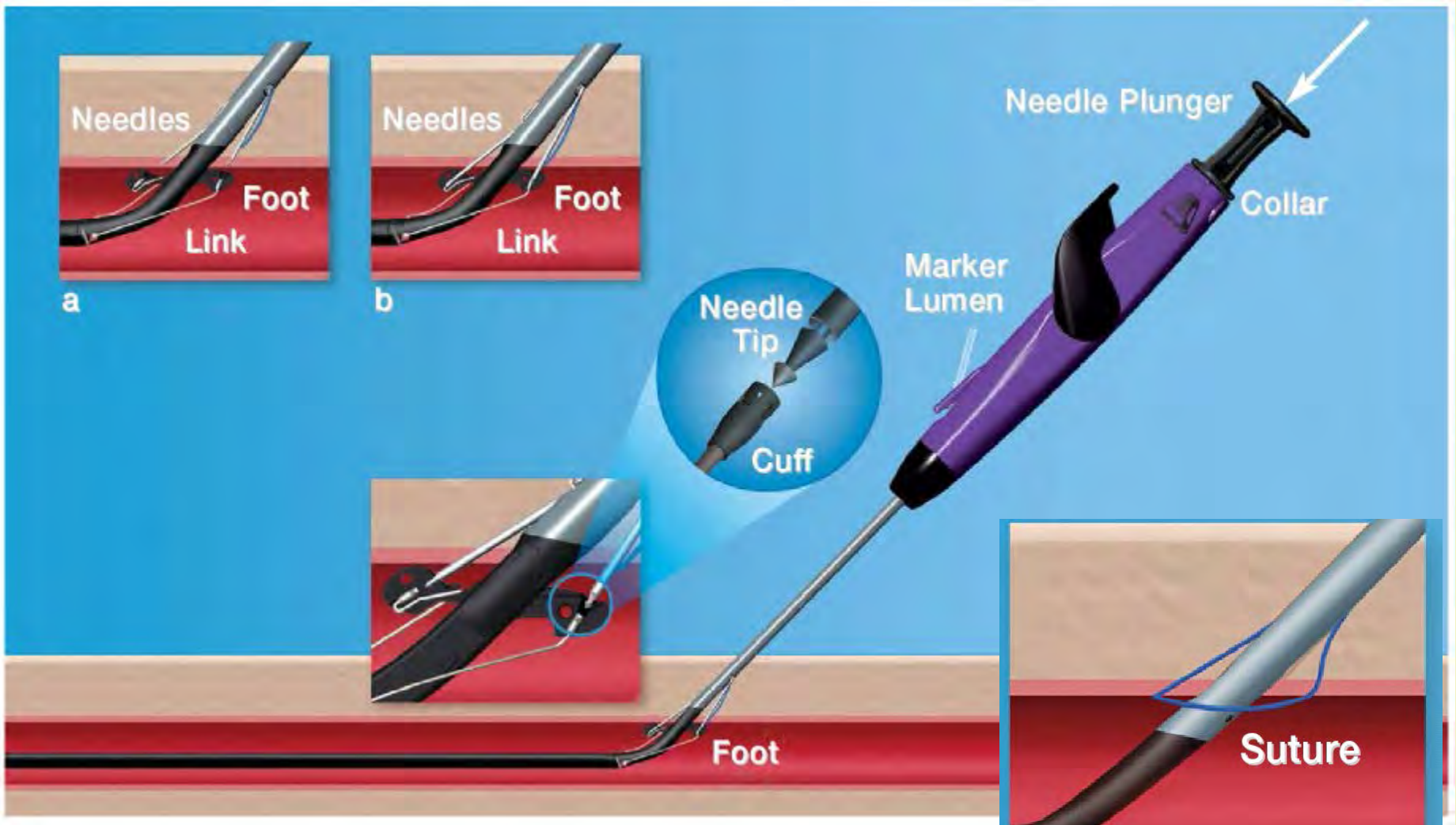
Proglide Perclose



Diagnostic Angiogram

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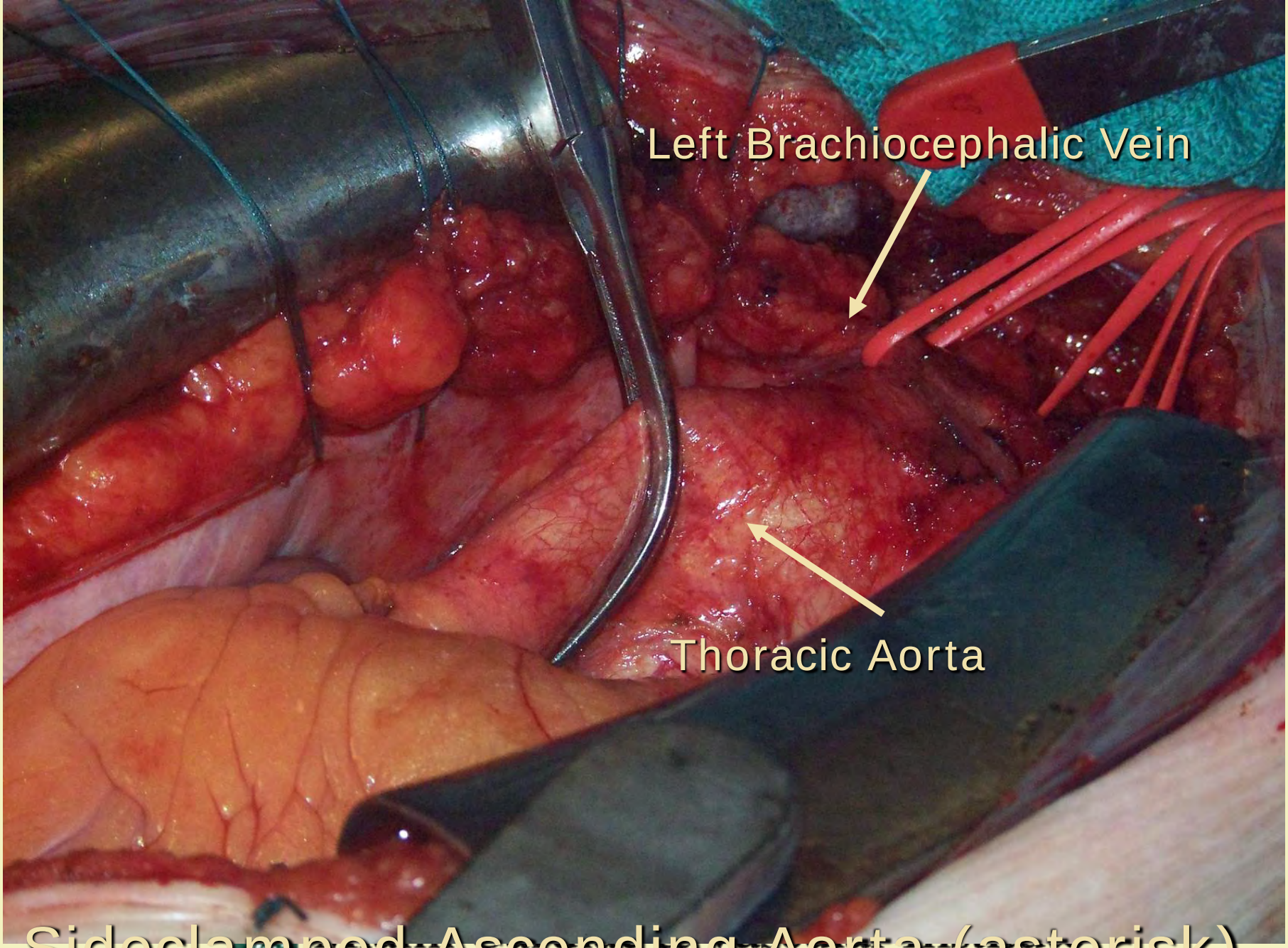

Sideclamped Ascending Aorta (asterisk)

Final

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Final

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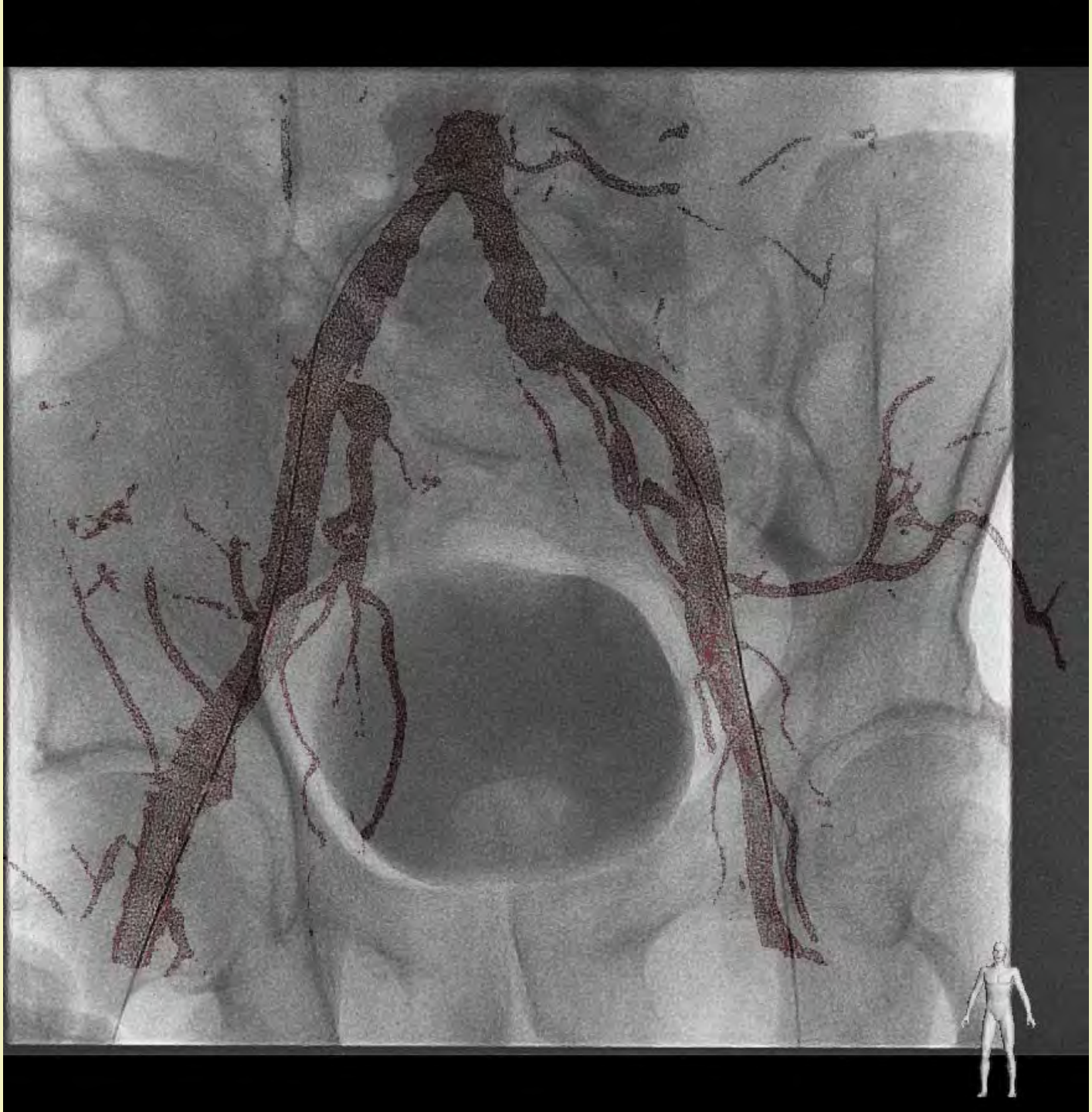
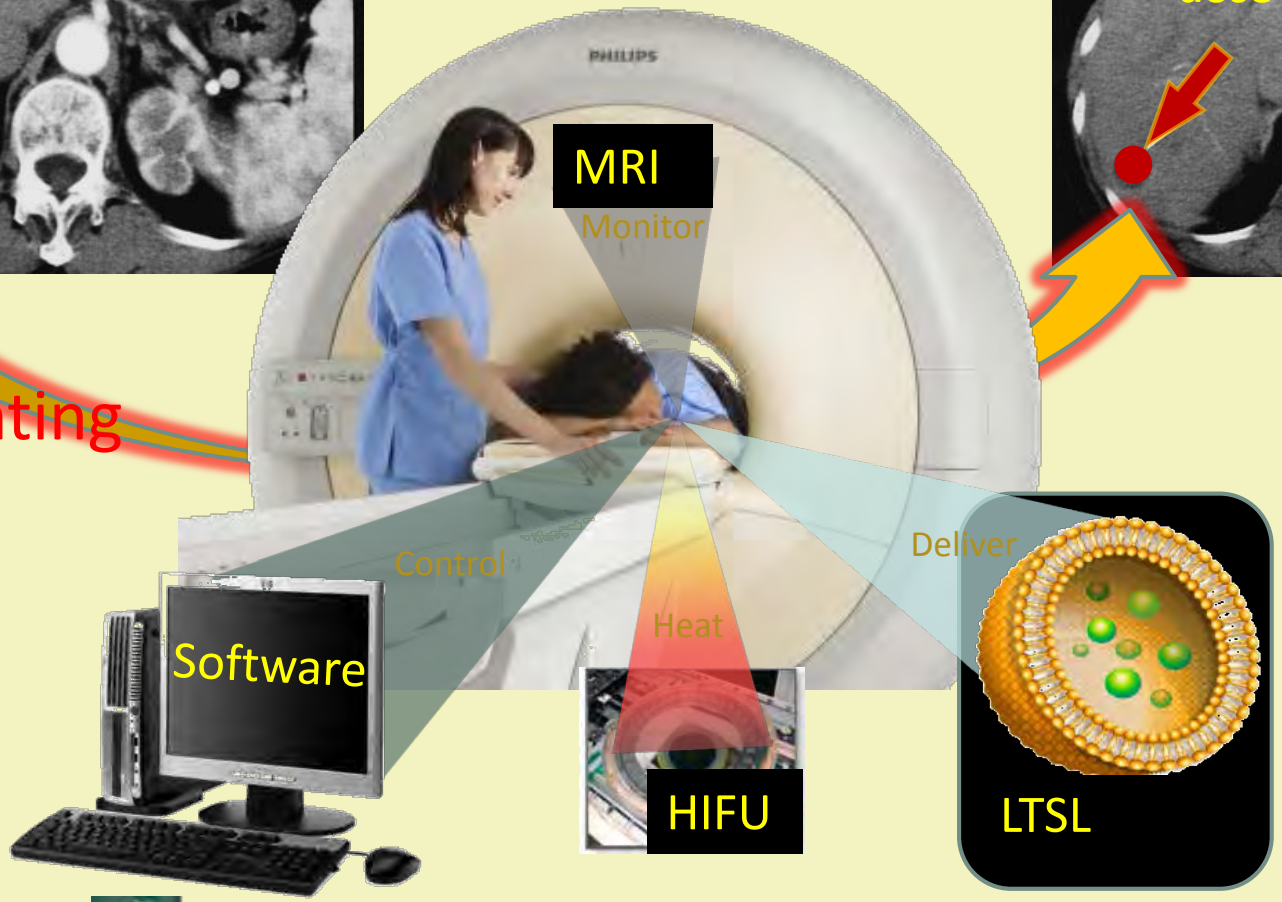


MRI Guided Drug Delivery

Dose painting – spatio-temporal



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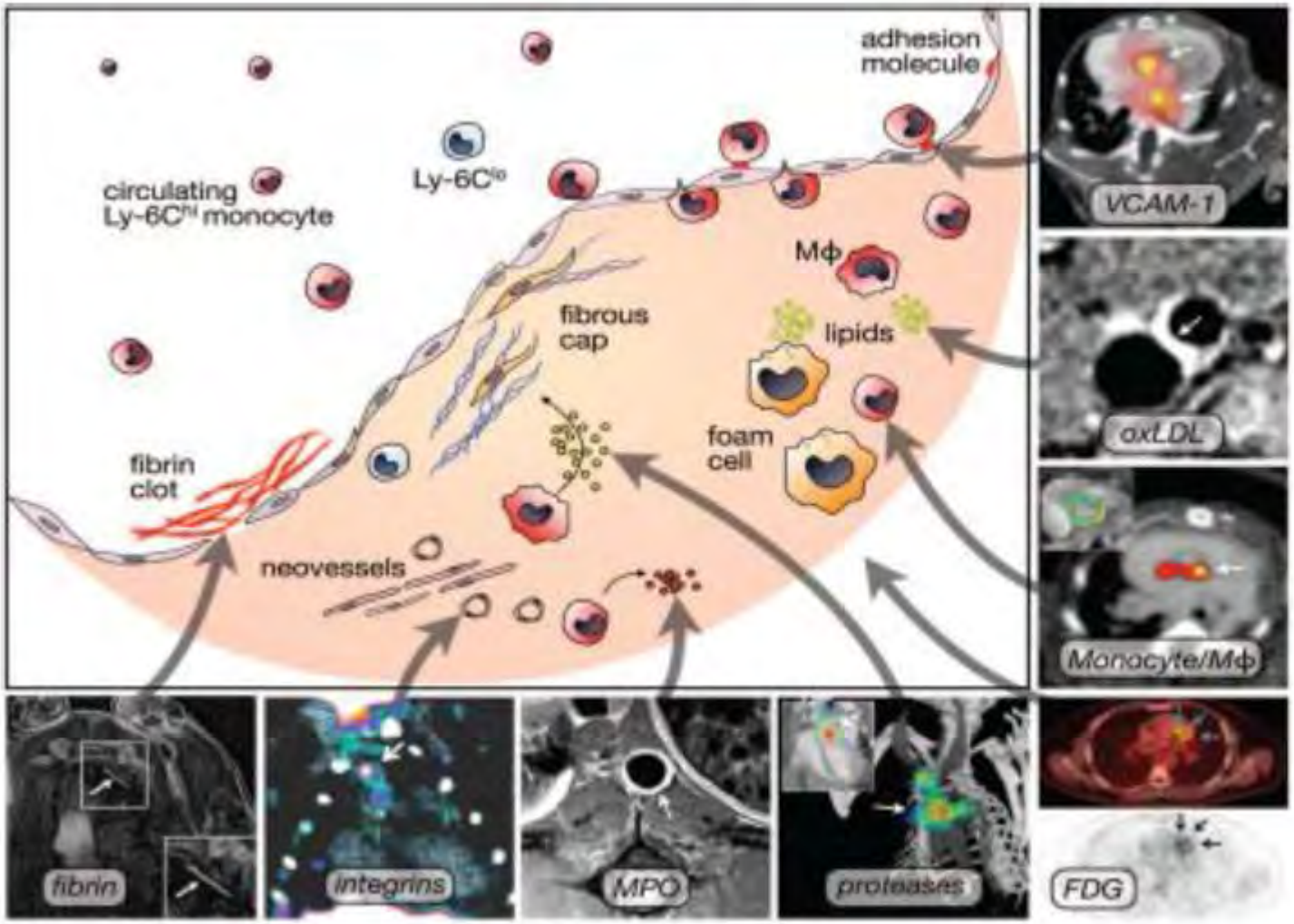
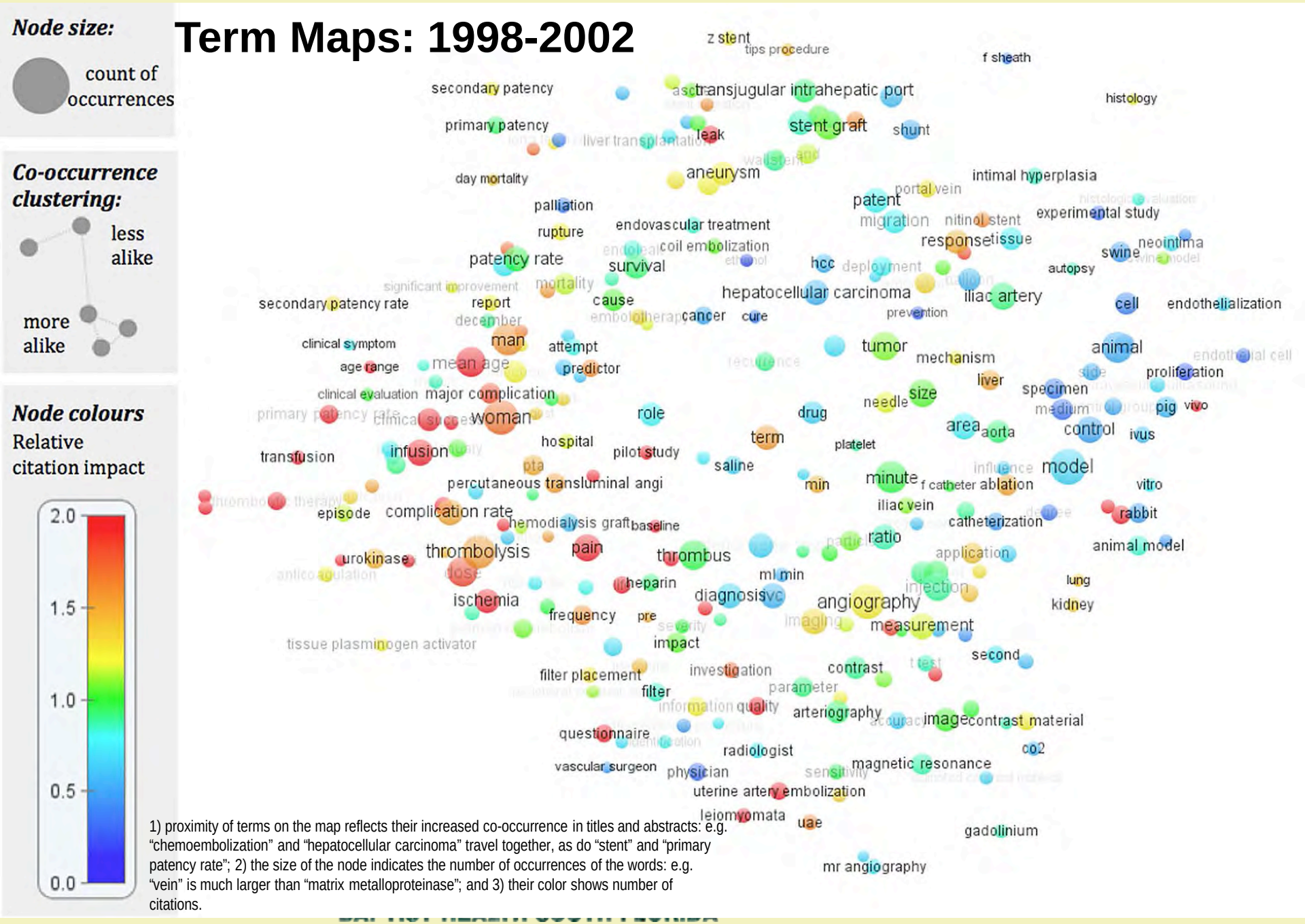
Molecular Imaging in Atherosclerosis



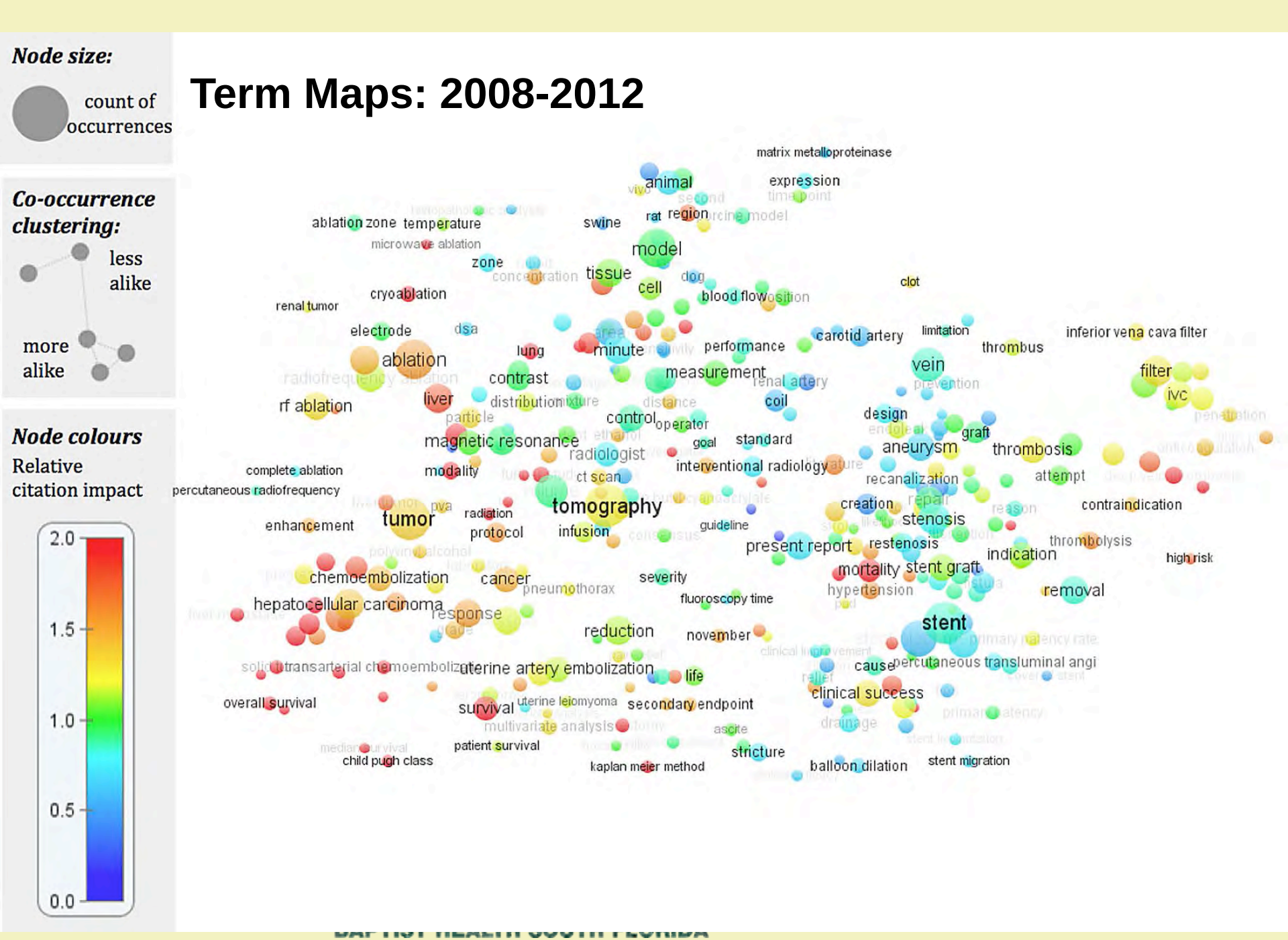
Leuschner and Nahrendorf, Circ Res 2011

Term Maps: 1998-2002



1) proximity of terms on the map reflects their increased co-occurrence in titles and abstracts: e.g. “chemoembolization” and “hepatocellular carcinoma” travel together, as do “stent” and “primary patency rate”; 2) the size of the node indicates the number of occurrences of the words: e.g. “vein” is much larger than “matrix metalloproteinase”; and 3) their color shows number of citations.

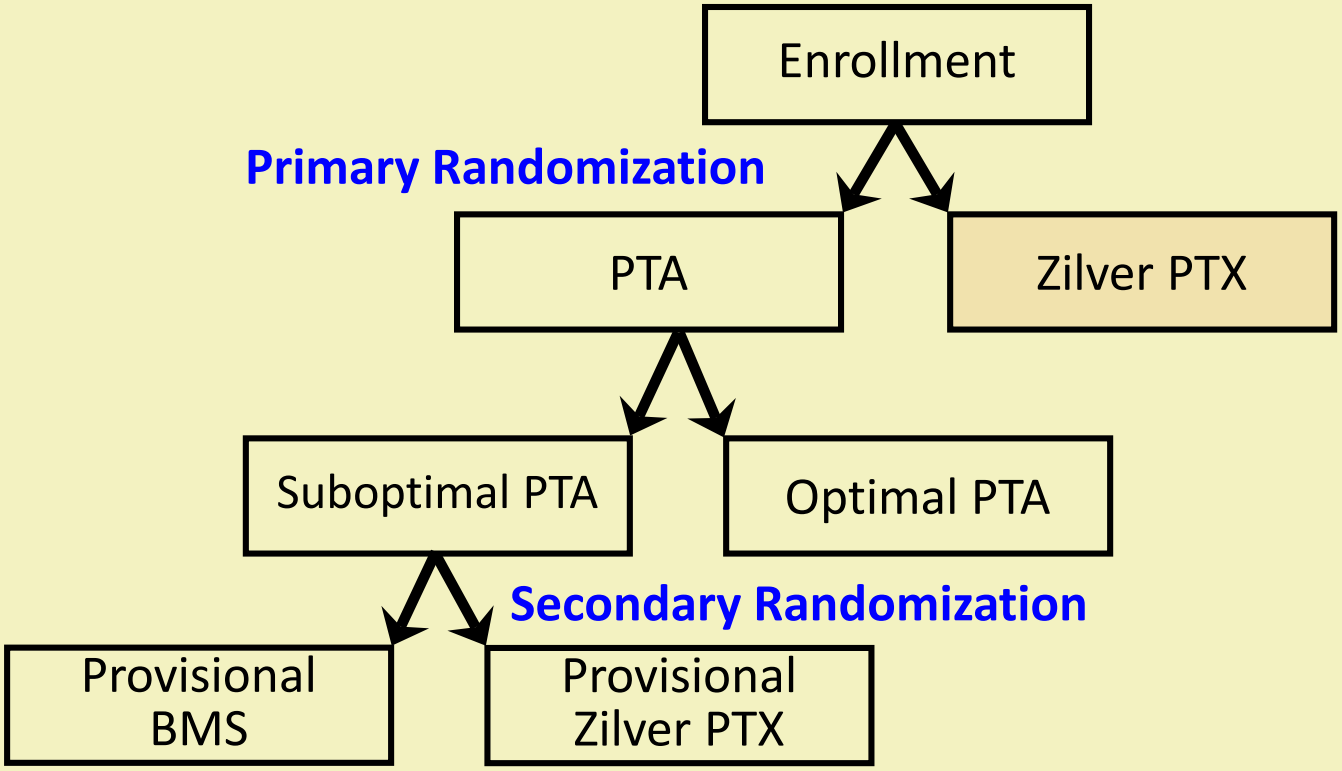
Term Maps: 2008-2012



Volume Growth Trend for Select Endovascular Procedures			
Procedure	2005	2011	Change
Coronary Artery Stent or Angioplasty	465,000	373,000	-20%
Lower Extremity Arterial Angioplasty	105,000	175,000	67%
Renal Artery Angioplasty	21,000	8,000	-62%
Endovascular Aortic Aneurysm Repair	29,000	33,000	14%
Carotid Stent	13,000	12,000	-8%
Thoracic Aortic Aneurysm Repair	N/A	4,000	N/A
Venous Ablation (RF or Laser)	25,000	125,000	400%
Venous Angioplasty	187,000	303,000	62%
Transcatheter Embolization	23,000	35,000	52%
Mechanical Thrombectomy	N/A	8,000	N/A

Some Specifics

Zilver PTX Study Design



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Patient Demographics and Comorbidities

	PTA	Zilver PTX	*p*-value
Patients	238	236	
Age (years)	68 ± 11	68 ± 10	0.88
Male	64%	66%	0.70
Height (in)	66 ± 4	67 ± 4	0.55
Weight (lbs)	179 ± 44	180 ± 40	0.62
Diabetes	42%	50%	0.11
High cholesterol	70%	76%	0.12
Hypertension	82%	89%	0.02*
Past/current smoker	84%	86%	0.70

* Statistically significant

Baseline Lesion Characteristics

		PTA	Zilver PTX	*p*-value
Lesions		251	247	
Normal-to-normal lesion length (mm)		63 ± 41	66 ± 39	0.36
Stenosed lesion length (mm)[1,2]		53 ± 40	55 ± 41	0.71
Diameter stenosis (%)[1]		78 ± 17	80 ± 17	0.38
Total occlusions		27%	33%	0.20
***De novo* lesions**		94%	95%	0.68
Lesion calcification[1]	**None**	5%	2%	< 0.01*
	Little	38%	26%	
	Moderate	22%	35%	
	Severe	35%	37%	

[1] Angiographic core lab assessment

[2] Region with > 20% diameter stenosis

* Statistically significant

Outline

- Study design and baseline characteristics
- Safety results through 5 years
  - Stent integrity
- Effectiveness results through 5 years
  - Zilver PTX vs. standard care
  - Provisional Zilver PTX vs. Provisional BMS
- Conclusions

5-year Stent Integrity

Study Period	Number of New Events	Fracture Rate[1]
Enrollment	0	0.0%
1-year	4	0.9%
3-year	3	1.9%
5-year	0	1.9%

[1] Kaplan-Meier estimates

Zilver PTX has excellent durability in challenging SFA environment

Outline

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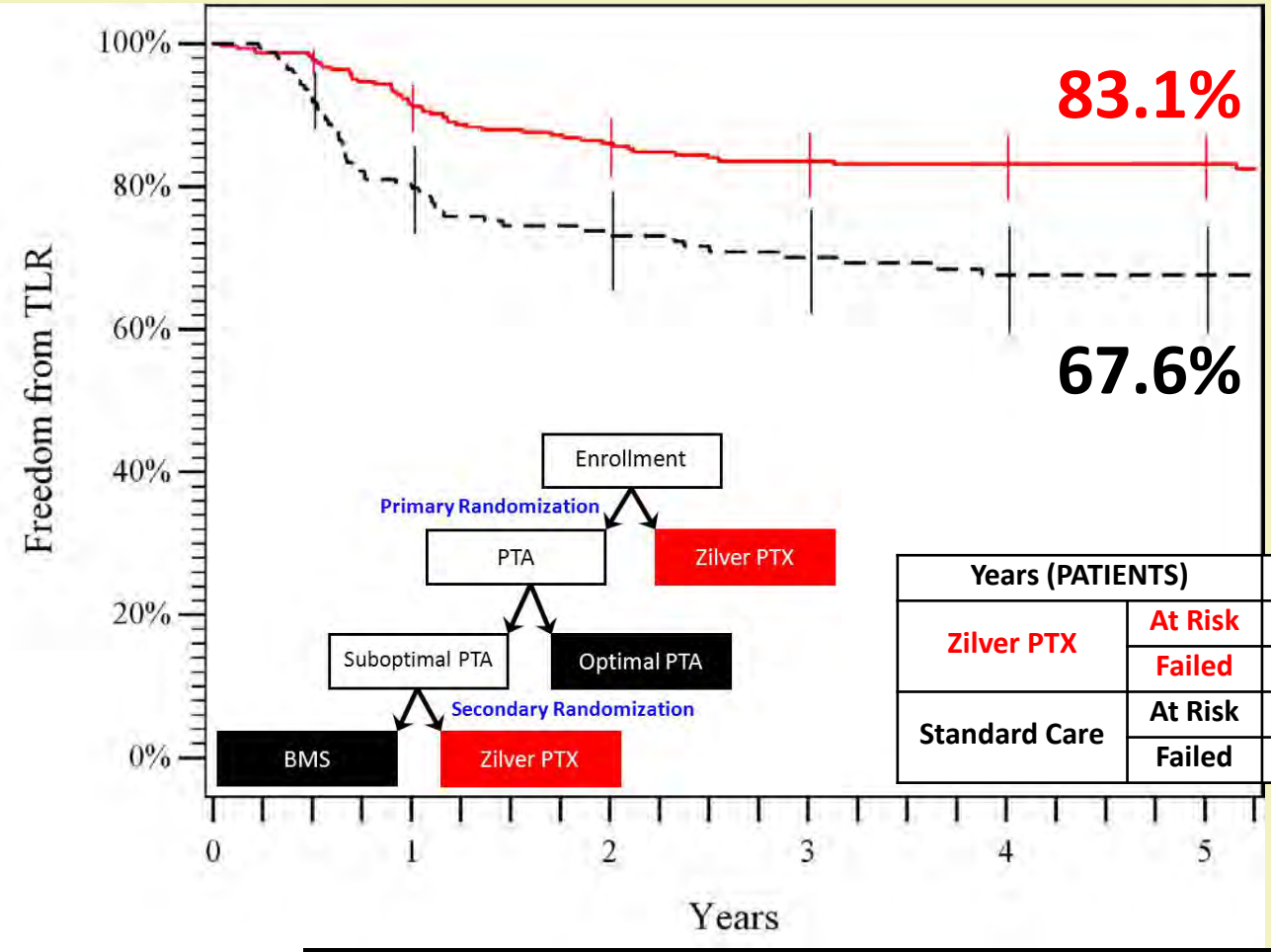
- Conclusions

5-year Freedom from TLR

Zilver PTX vs. Standard Care



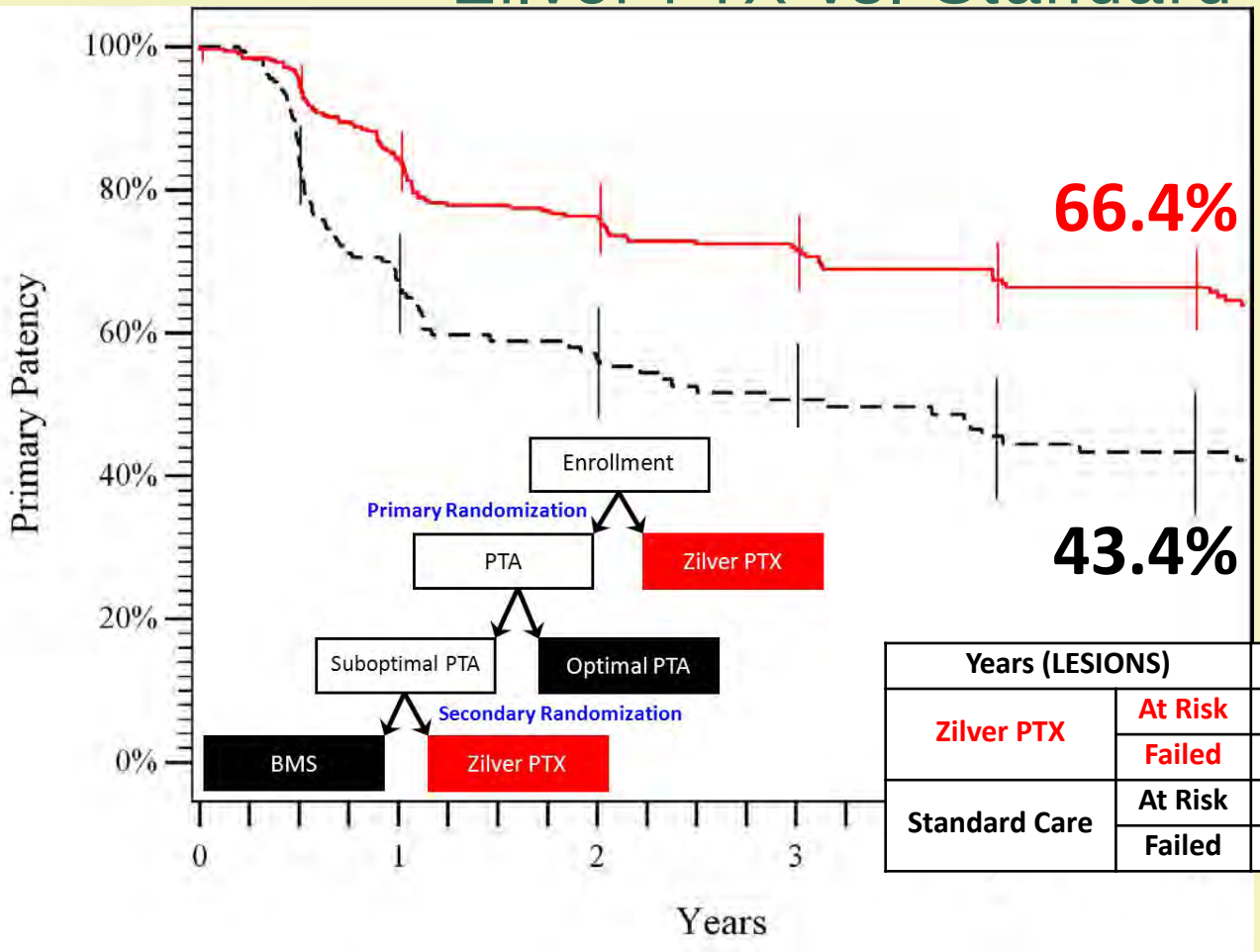
$p < 0.01$
log-rank

Years (PATIENTS)		0	1	2	3	4	5
Zilver PTX	At Risk	305	260	220	187	164	133
	Failed	0	25	40	46	47	47
Standard Care	At Risk	172	125	106	88	78	69
	Failed	0	33	44	48	51	51

At 5 years, Zilver PTX demonstrates a 48% reduction in reintervention compared to standard care

5-year Primary Patency (PSVR < 2.0)

Zilver PTX vs. Standard Care

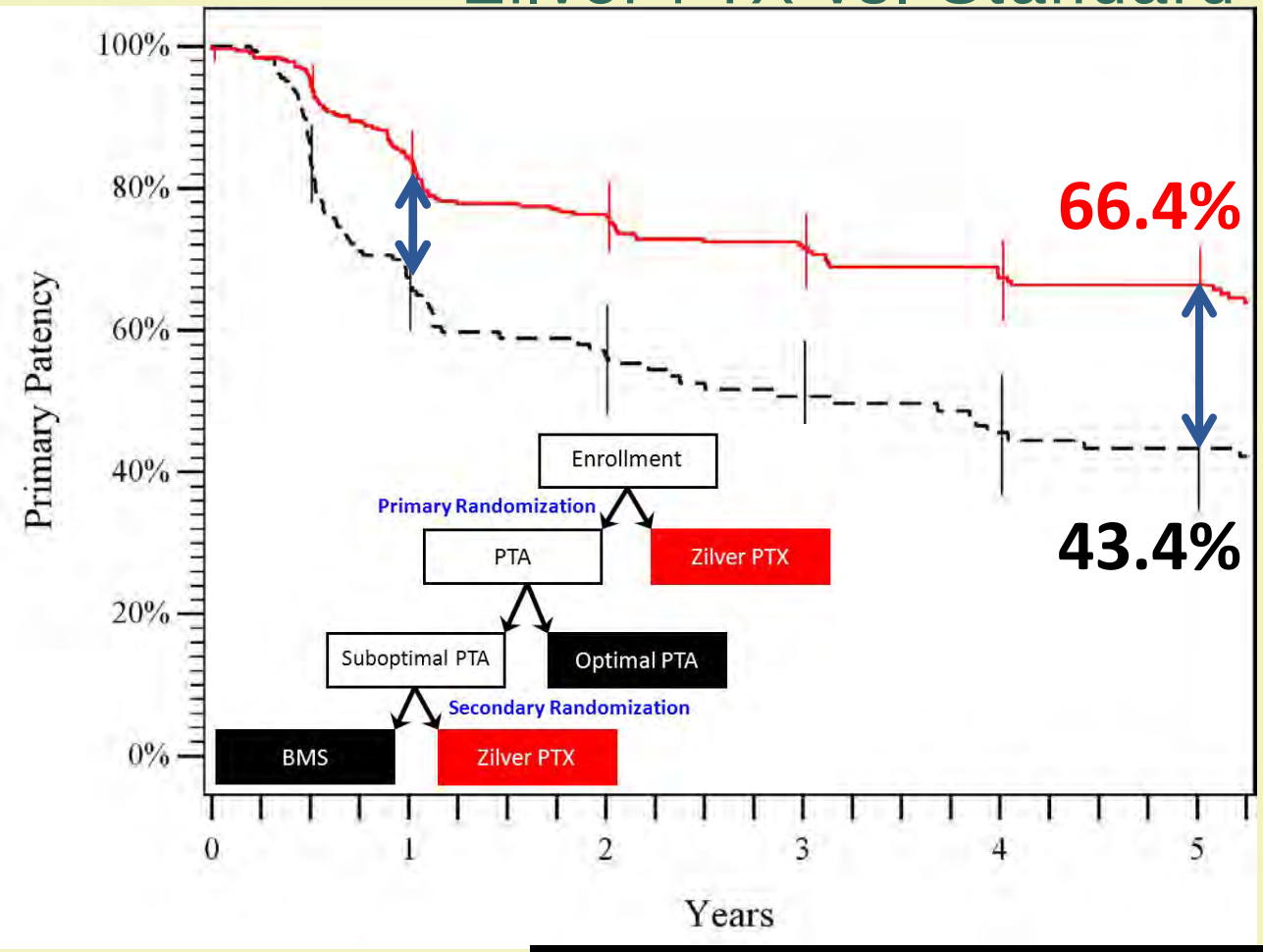


Years (LESIONS)		0	1	2	3	4	5
Zilver PTX	At Risk	318	246	199	163	137	109
	Failed	1	48	71	83	92	94
Standard Care	At Risk	183	108	64	52	44	38
	Failed	0	57	73	79	84	86

At 5 years, Zilver PTX demonstrates a 41% reduction in restenosis compared to standard care

5-year Primary Patency (PSVR < 2.0)

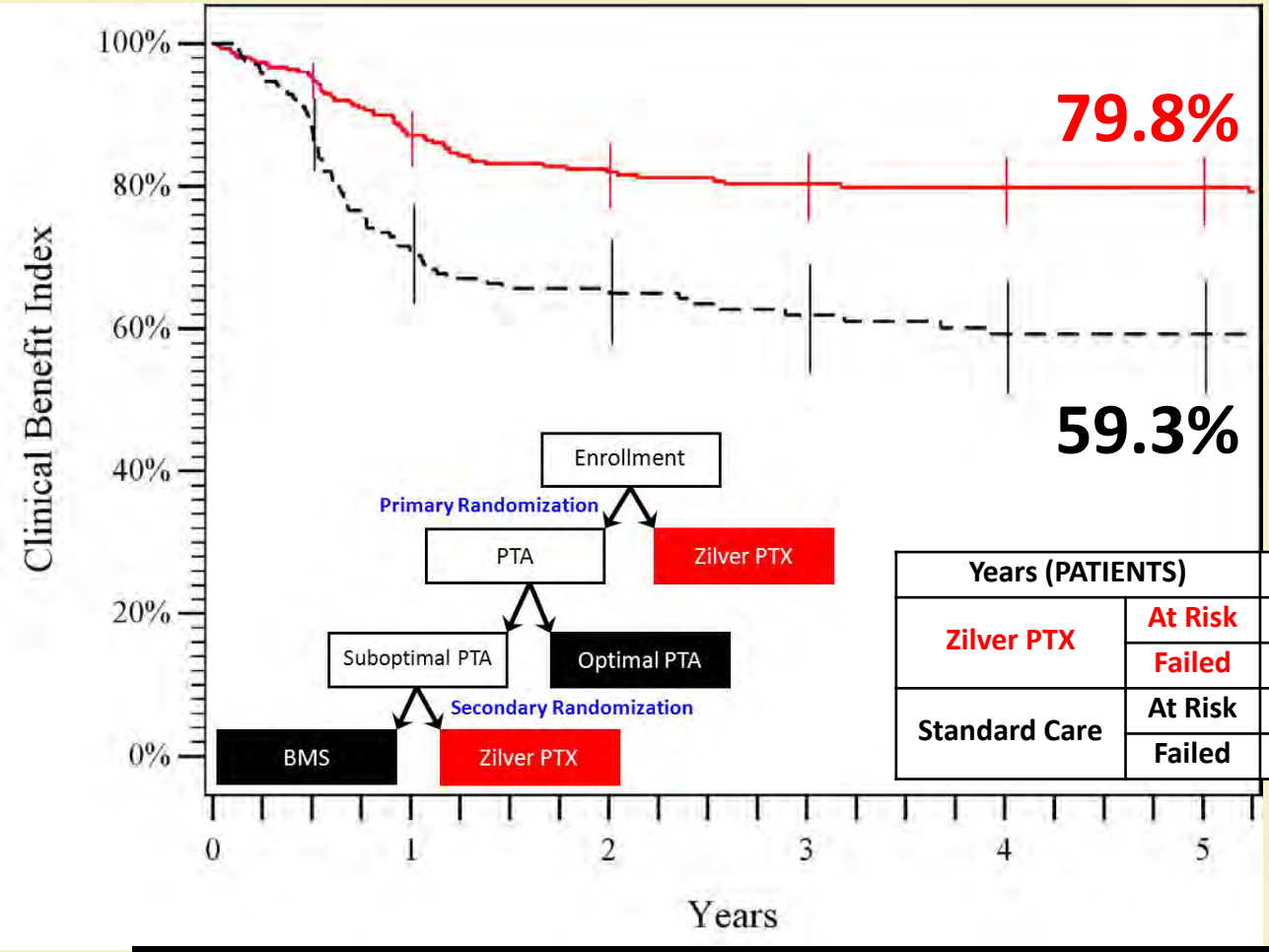
Zilver PTX vs. Standard Care



From 1-5 years, the relative separation increases by 35%

5-year Clinical Benefit Index

Zilver PTX vs. Standard Care



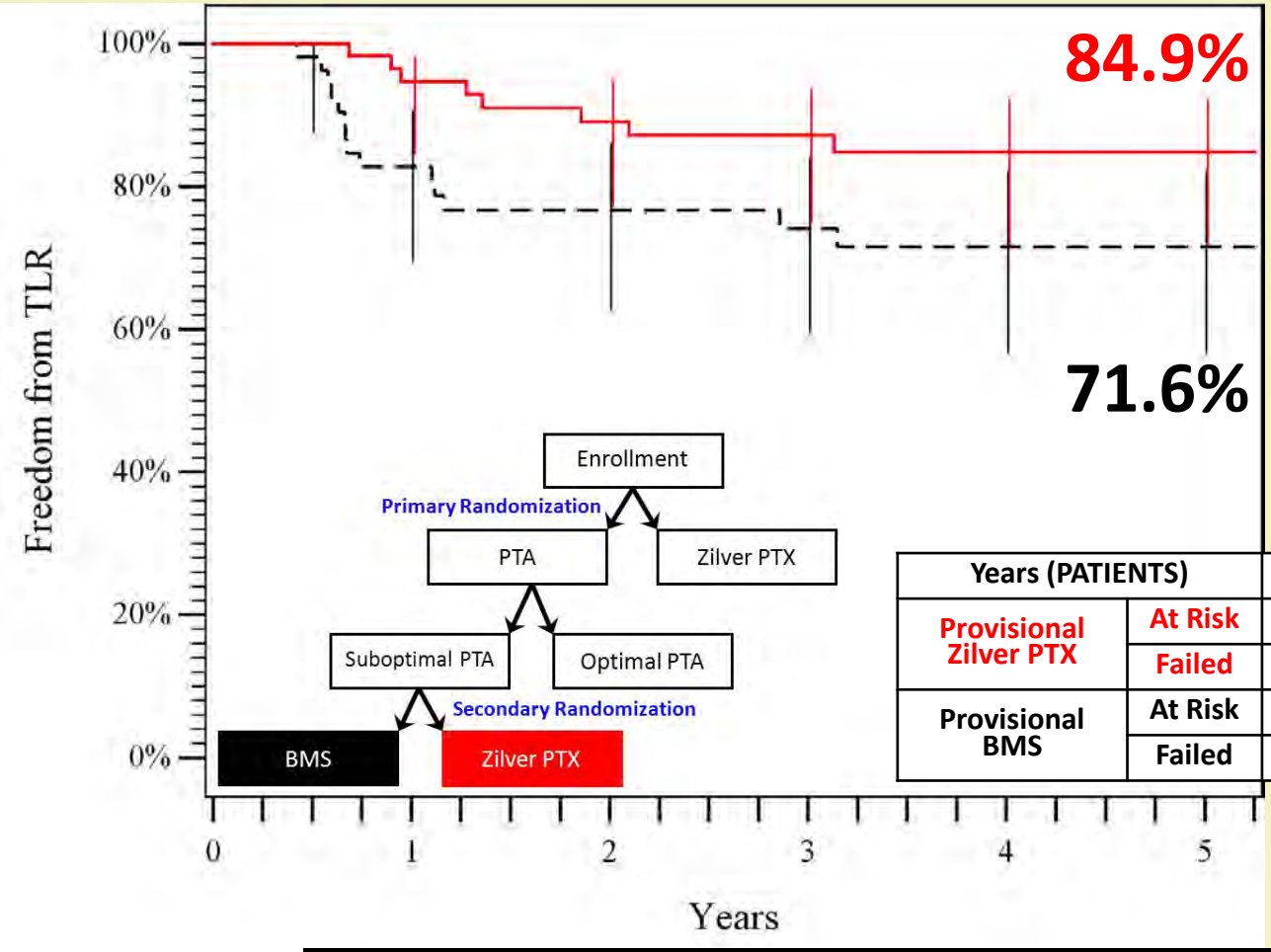
$p < 0.01$
log-rank

Years (PATIENTS)		0	1	2	3	4	5
Zilver PTX	At Risk	301	247	206	179	158	129
	Failed	0	38	52	56	57	57
Standard Care	At Risk	170	109	94	76	67	60
	Failed	0	48	56	61	64	64

At 5 years, Zilver PTX has a superior rate of freedom from persistent or worsening claudication, rest pain, ulcer, or tissue loss

5-year Freedom from TLR

Provisional Zilver PTX vs. BMS



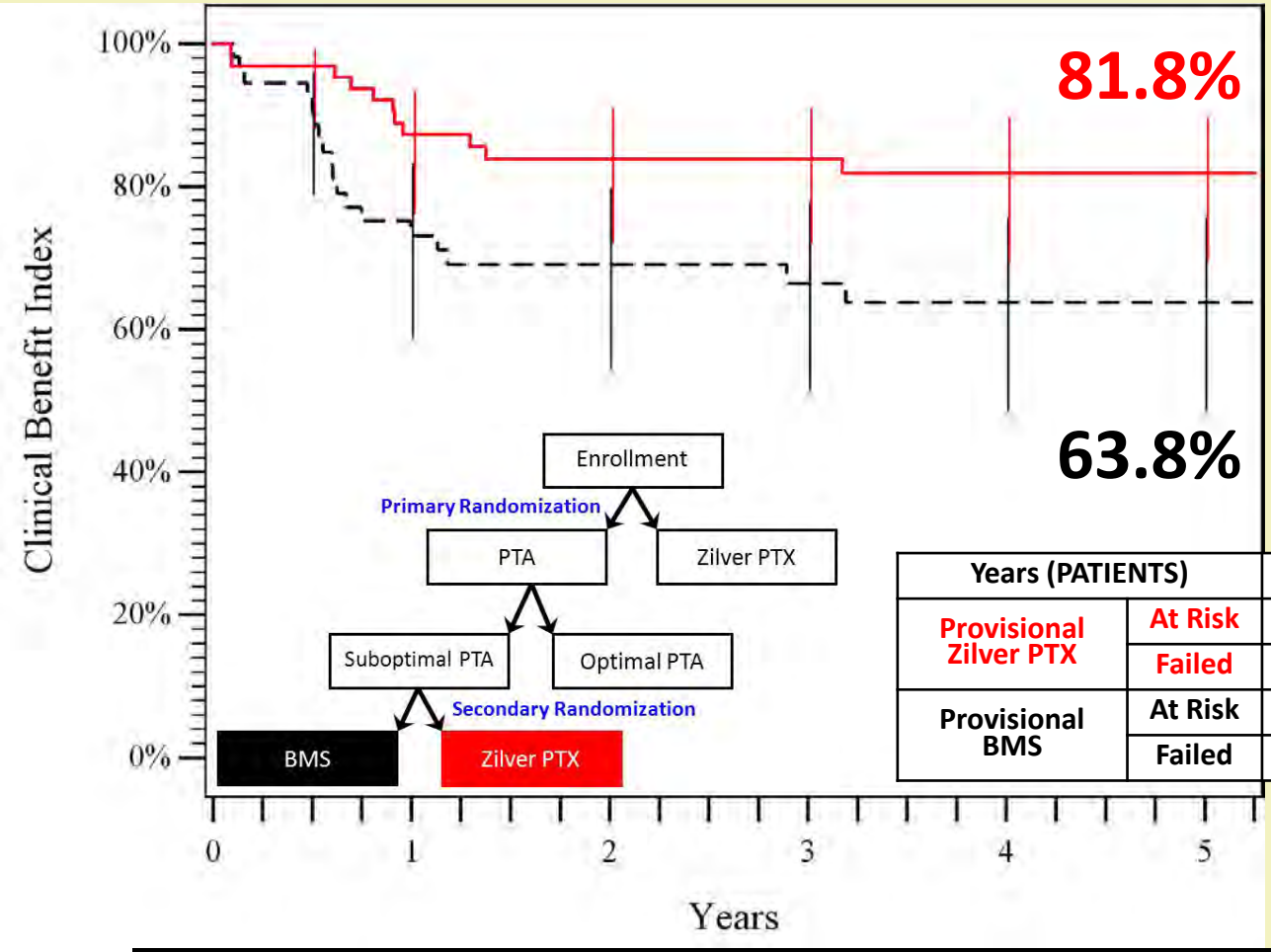
$p = 0.06$ log-rank

Years (PATIENTS)		0	1	2	3	4	5
Provisional Zilver PTX	At Risk	60	53	47	39	34	31
	Failed	0	3	6	7	8	8
Provisional BMS	At Risk	54	41	36	29	27	23
	Failed	0	9	12	13	14	14

At 5 years, Zilver PTX demonstrates a 47% reduction in reintervention compared to BMS

5-year Clinical Benefit Index

Provisional Zilver PTX vs. BMS



$p = 0.02$ log-rank

Years (PATIENTS)		0	1	2	3	4	5
Provisional Zilver PTX	At Risk	64	54	48	42	38	34
	Failed	0	8	10	10	11	11
Provisional BMS	At Risk	54	36	32	25	23	20
	Failed	0	14	16	17	18	18

At 5 years, Zilver PTX has a superior rate of freedom from persistent or worsening claudication, rest pain, ulcer, or tissue loss

Conclusions for 5-year Zilver PTX RCT

- As the first randomized controlled SFA device trial with
  5-year follow-up, these results with the Zilver PTX stent provide important insights regarding long-term outcomes for endovascular treatment
- 5-year data for Zilver PTX versus standard care
  - Greater than 40% reduction in reintervention and restenosis
  - Superior clinical benefit
  - These benefits increase with time – results with Zilver PTX continue to diverge from standard care over 5 years with no late catch-up
- 5-year results confirm long-term superiority of Zilver PTX versus bare metal stents

CC: severe right calf pain when walking

- **Hx:** 64 M former smoker with diabetes, HTN presents with 6-month **severe, life-style limiting right calf claudication (Rutherford III)**. Progressed from 100-200 yards to 50-100 feet starting 2 weeks ago.
- **PMH:**
  - Prior mid to distal R SFA stents, 2012
  - Subsequent R fem-pop bypass, 2012 – right asymptomatic until 6 months ago
  - Cardiac risk factors: diabetes, HTN, former smoker (quit 2.5 years ago; 50+ pack-year hx)
- **Pertinent Meds:** ASA 81mg qday, Coumadin

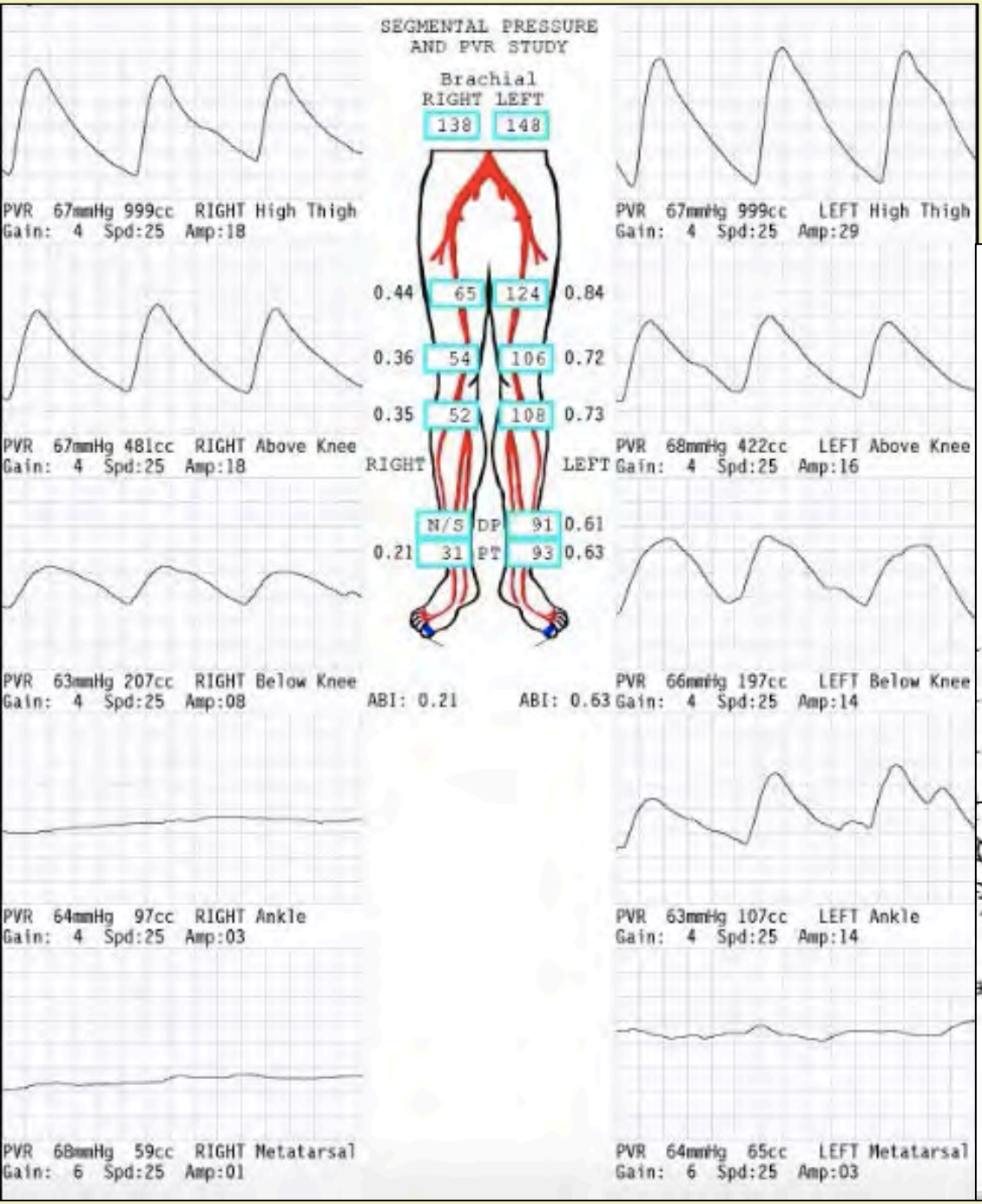
Exam/Labs:

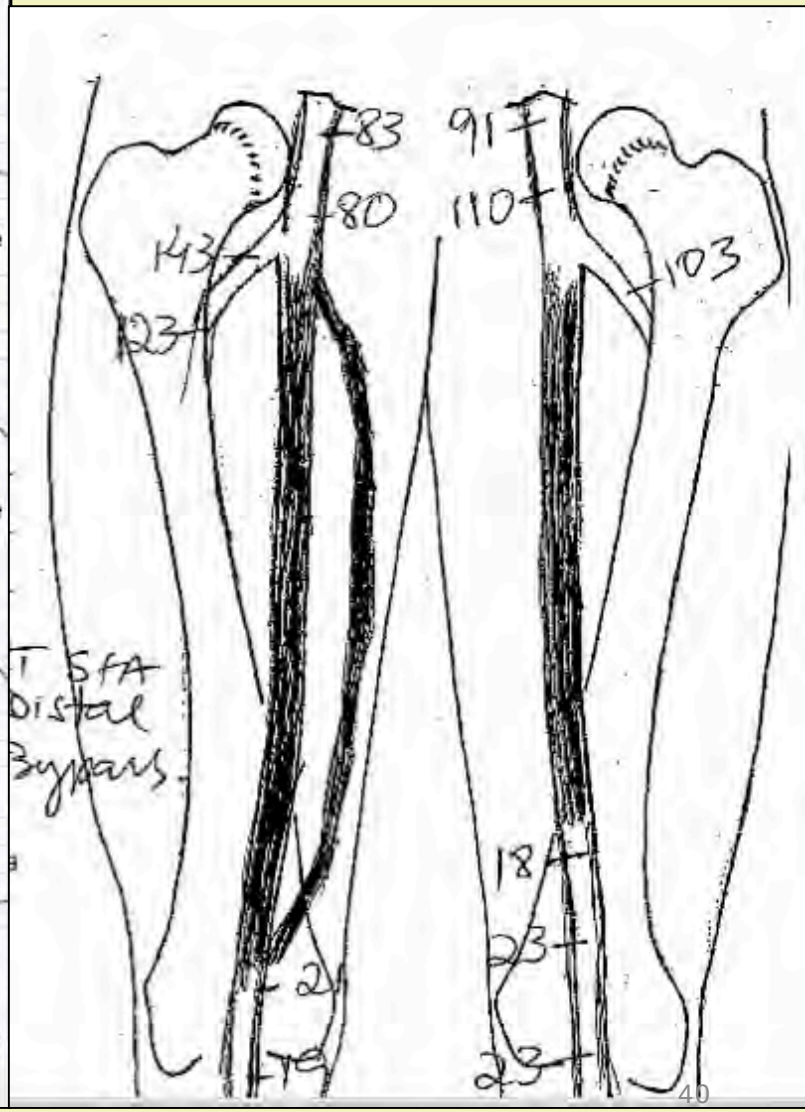
- **Physical Exam:**
  - Right foot and toes asymmetrically cold, dusky without ulceration or skin breakdown
  - Pulse Exam:

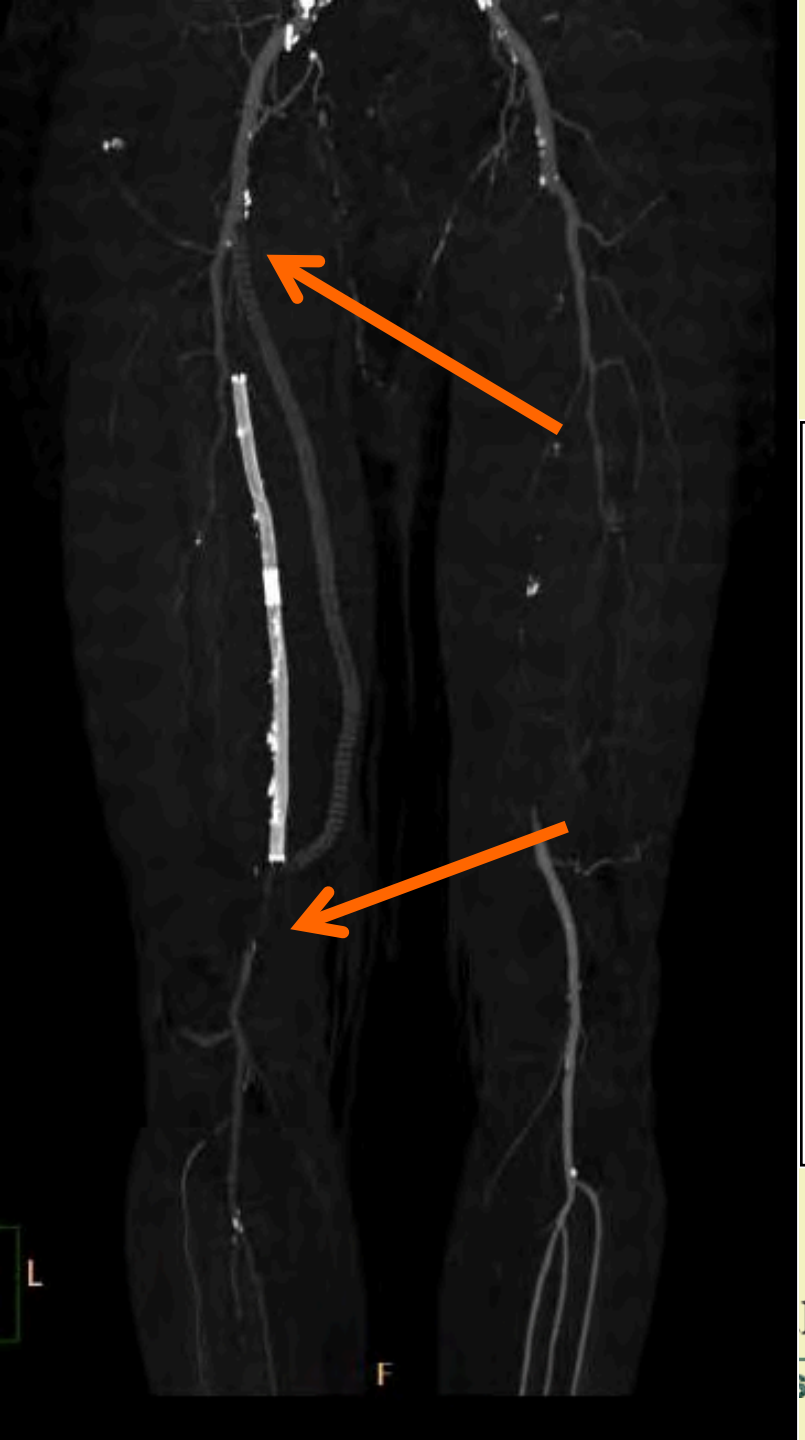
	Right	Left
Femoral	2+	2+
Popliteal	NP	NP
Dorsalis Pedis a.	ND	D2
Post tibialis a.	ND	D2

- **Labs:** CBC wnl; Cr: 1.28 (GFR 57), INR 1.6 (stopped Coumadin 4 days prior)

Arterial LE Non-invasive







CTA LE Runoff, 10/27

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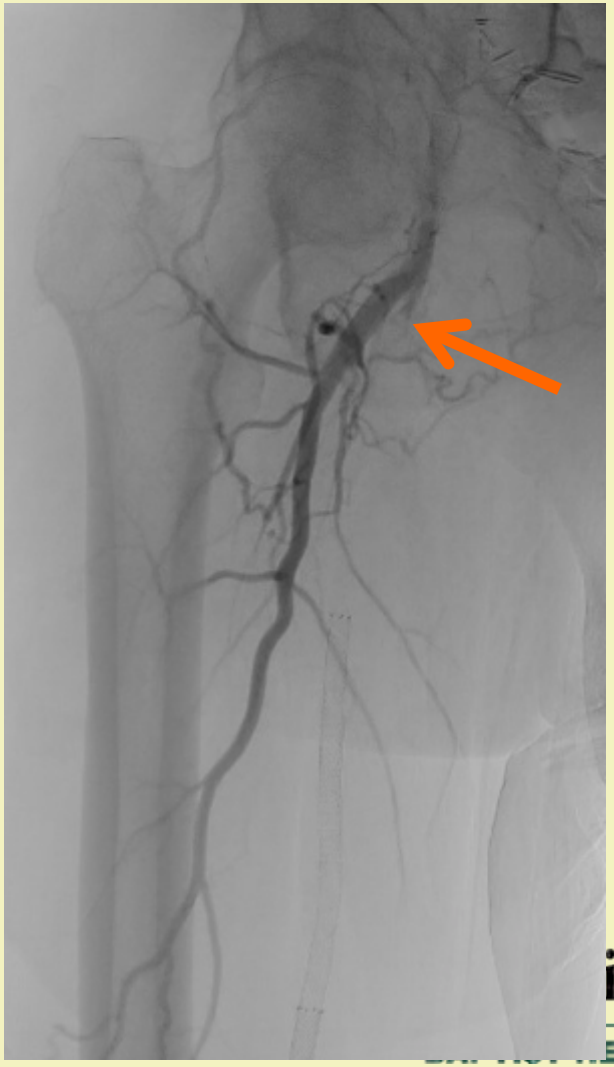
Left CFA retrograde access

Run-off of Right lower extremity
(via 6 Fr Destination sheath terminating in R EIA)

R prox thigh



R dist thigh

R tibioperoneal

Plan: Recanalize long-segment SFA occlusion including occluded stents

Antegrade recanalization
(4-Fr Quickcross + 035 Glidewire)

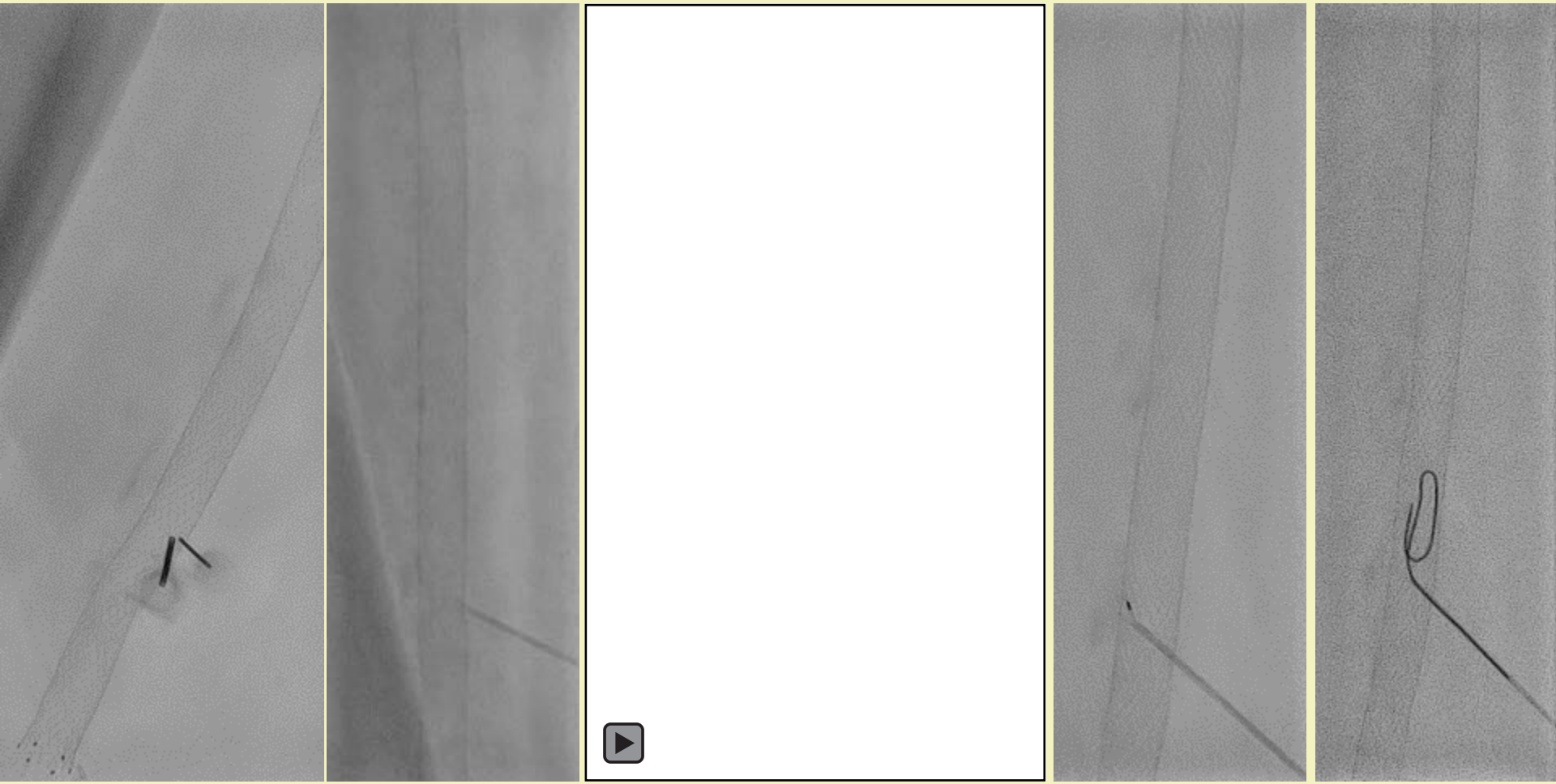
Initially select occluded fem-pop bypass graft

Subsequently select occluded SFA

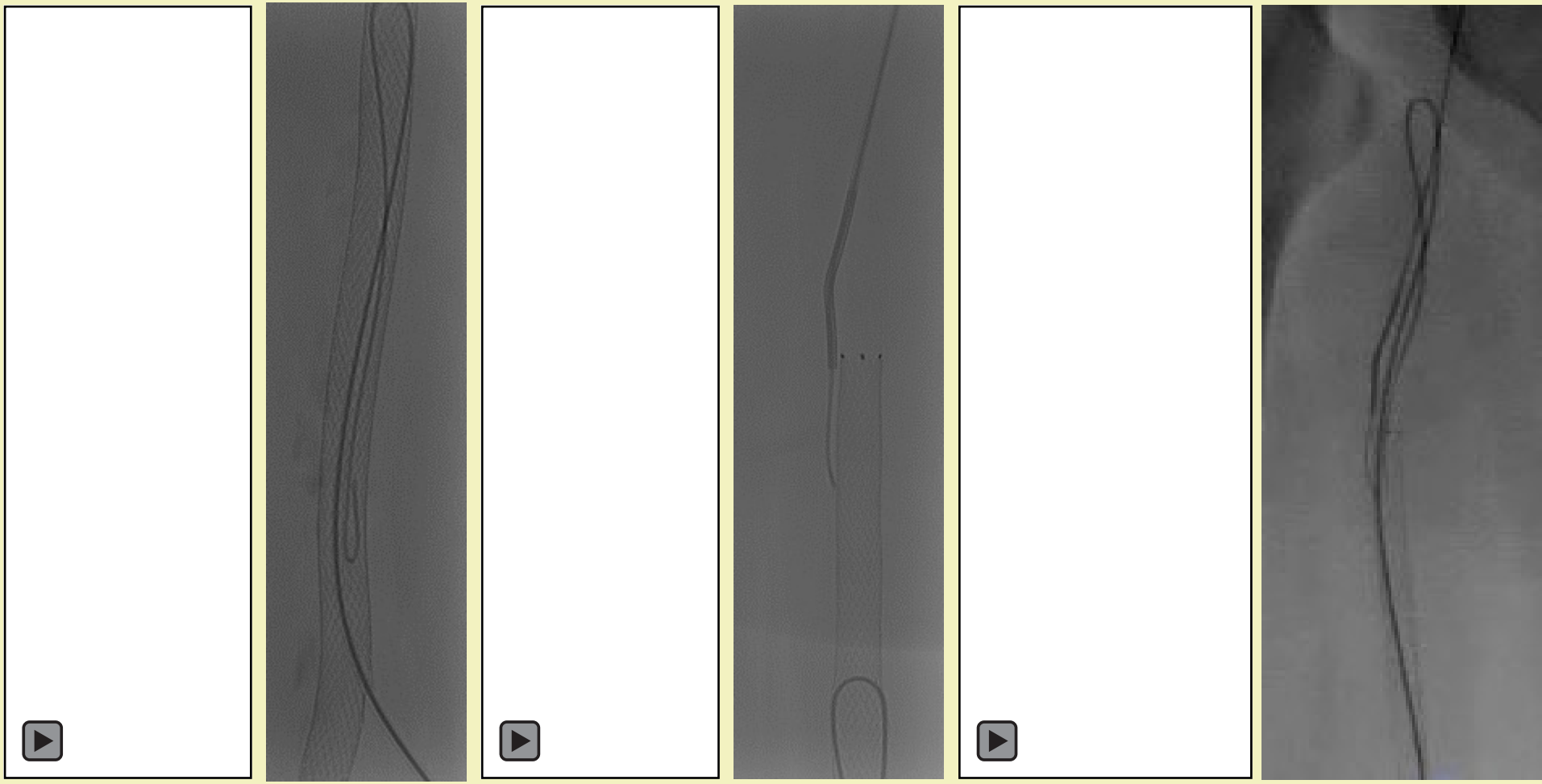
Despite multiple attempts, could not recanalize occluded stent

Retrograde access of occluded R SFA stent

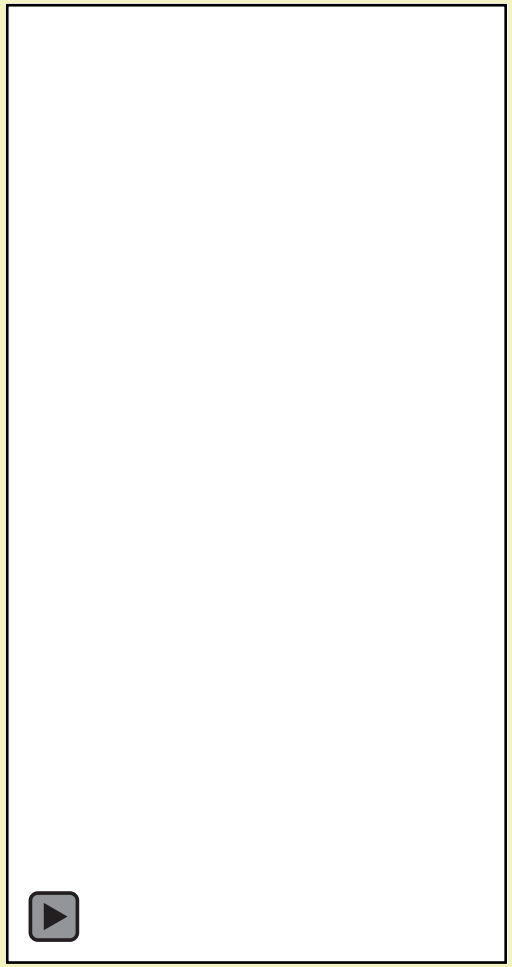
(Thigh everted; re-prepped; fluoro-guided access with Micropuncture needle + 018 Nitrex wire)



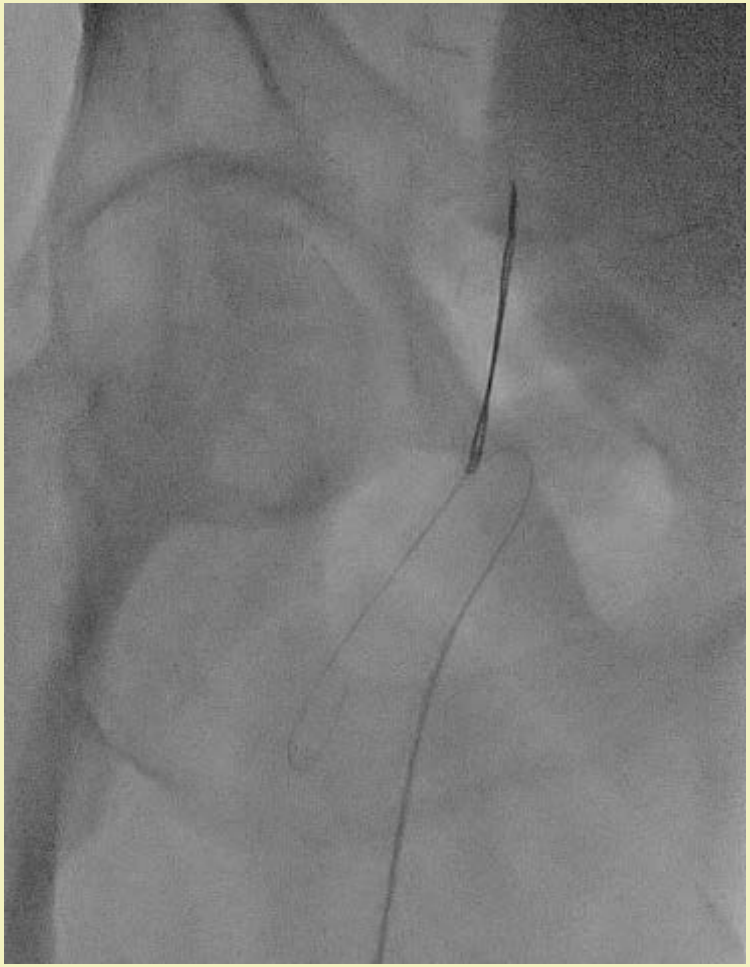
Upsized to 035 system: micropuncture sheath → 035 Glidewire + 4-Fr Glide Cobra catheter

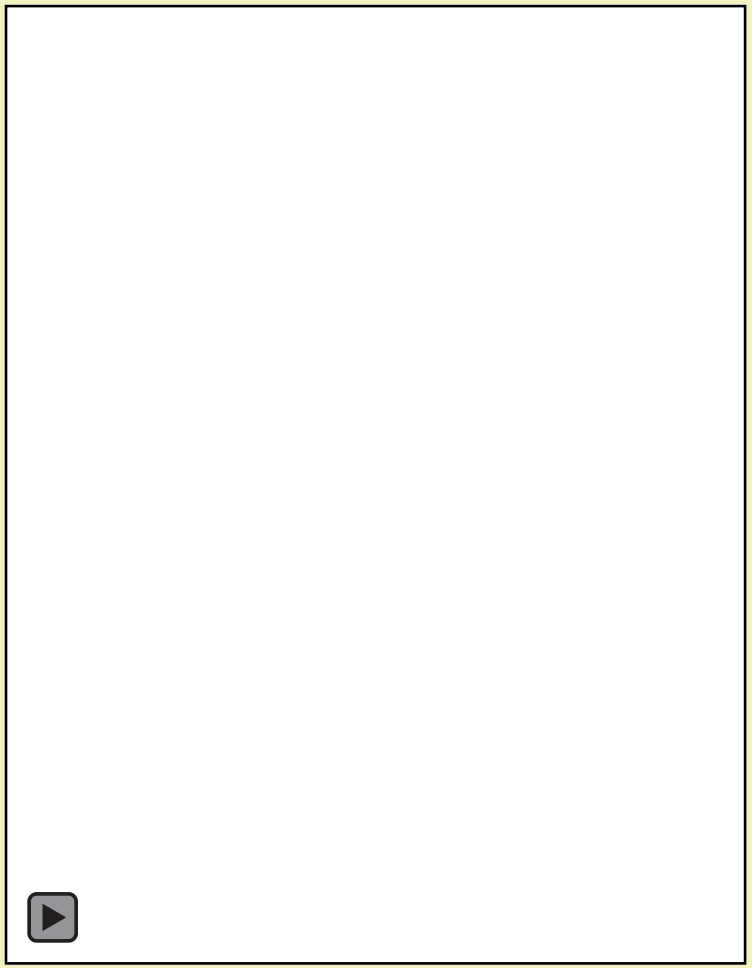


Attempted to get intraluminal

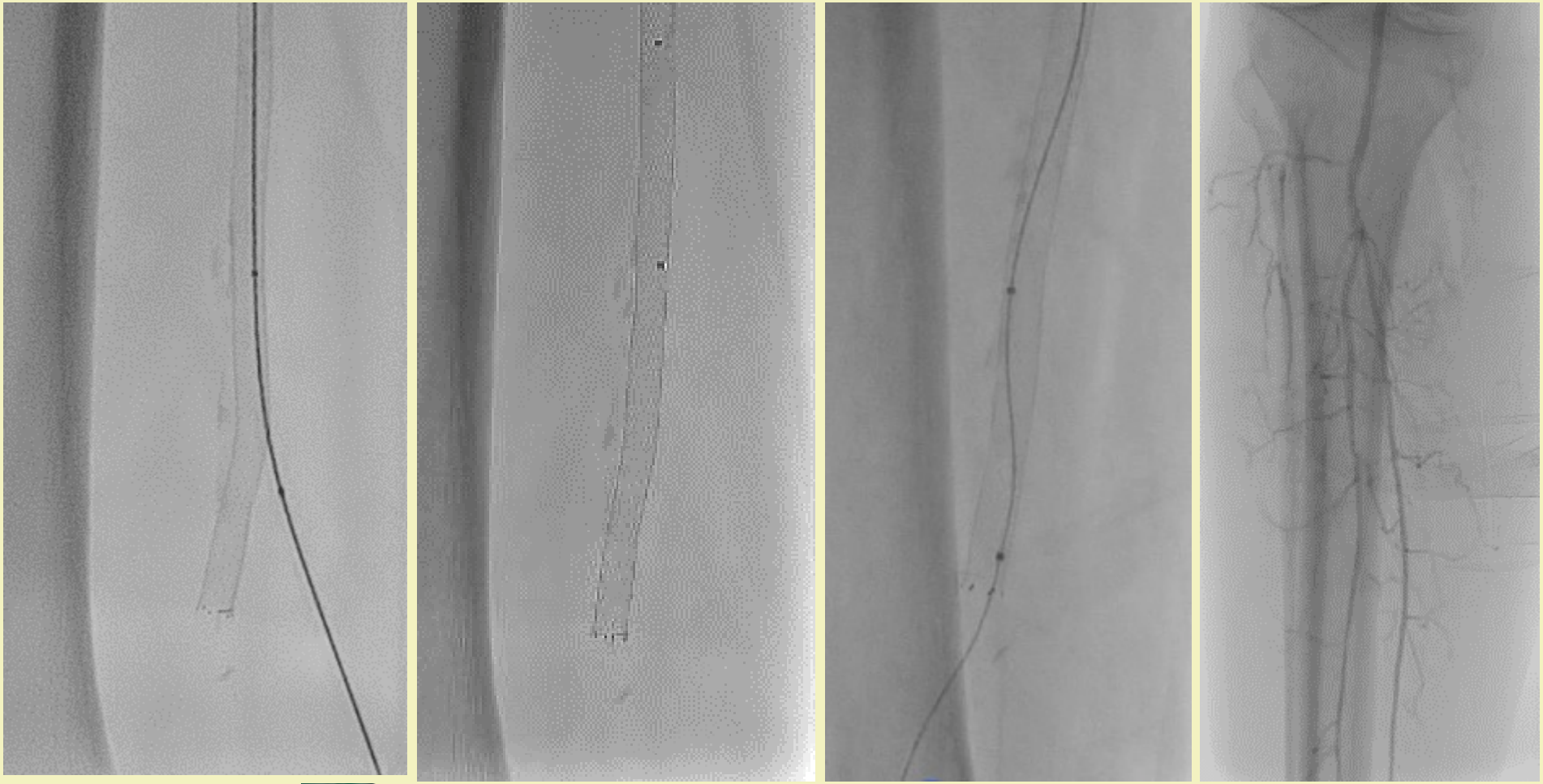


Snared Glidewire from L CFA access; through-and-through access with Exchange-Length Super Stiff Amplatz



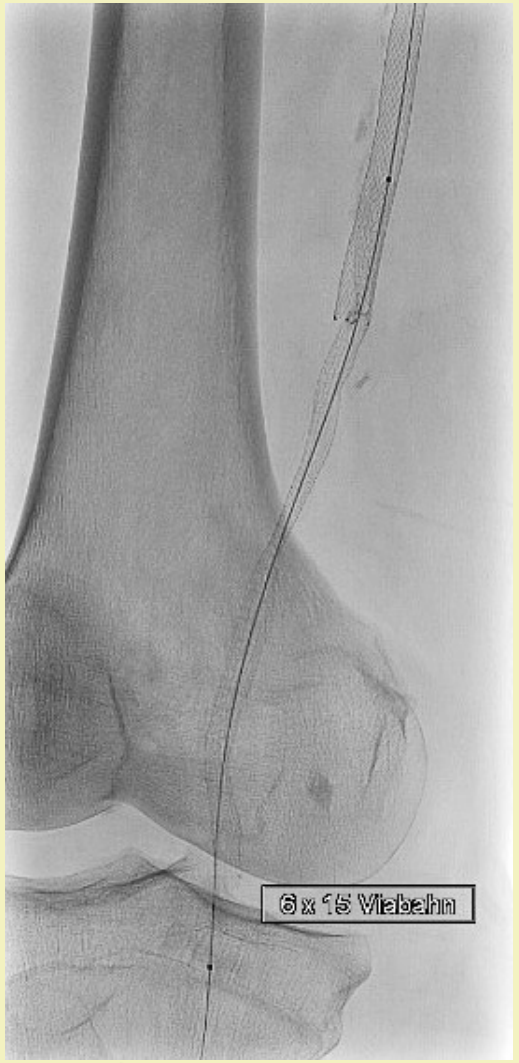


From L CFA up-and-over approach attempted to recanalize occluded R SFA stents with antegrade approach using 4-Fr Quickcross catheter and Glidewire



Recanalization

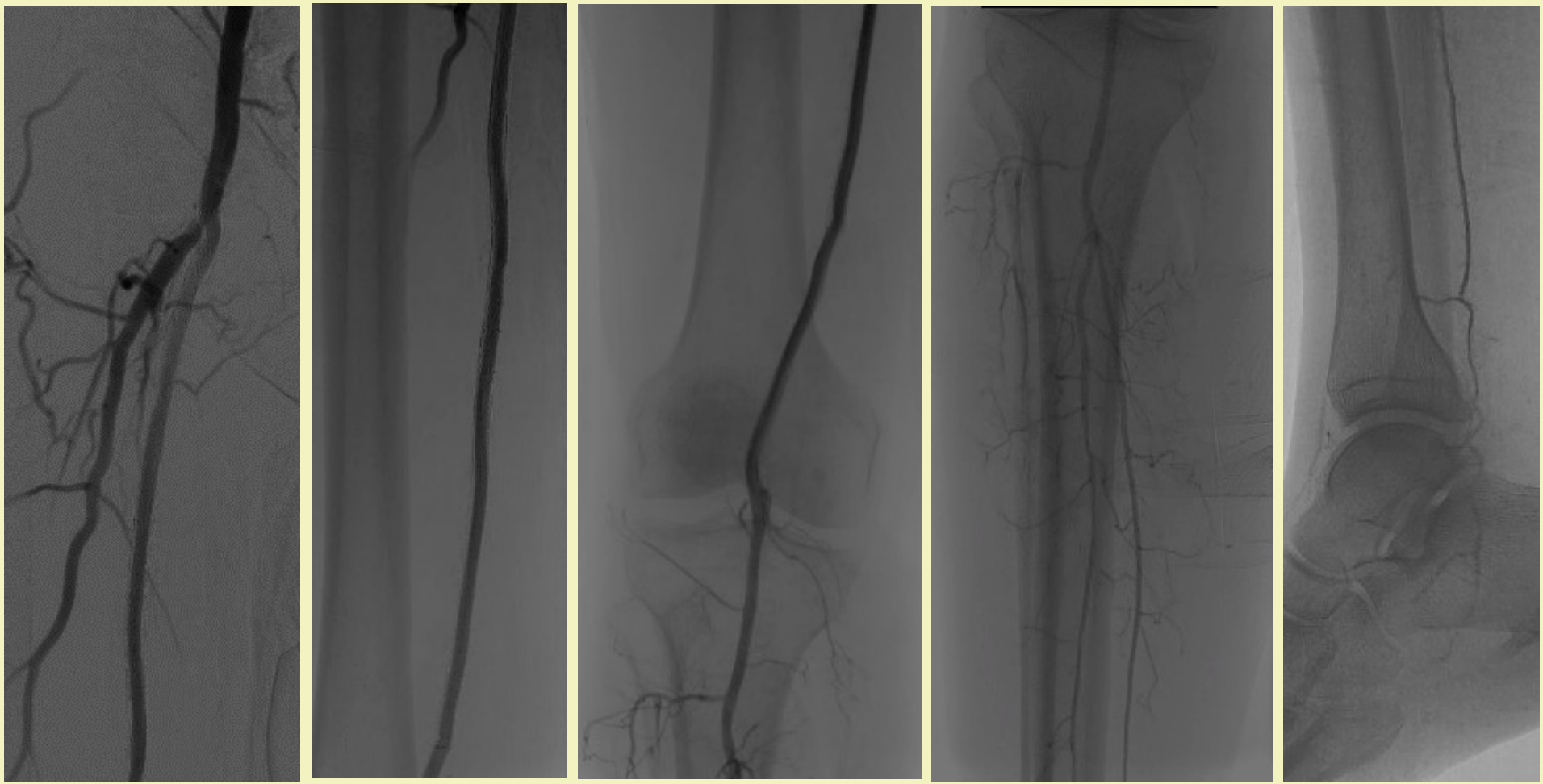
- Pullback angiogram demonstrated no acute thrombus
- Predilated entire occluded SFA segment with 5 mm balloon
- Deployed 4 overlapping 6 mm x 15 cm Viabahn stent grafts



Recanalization

- A 7 x 4 cm DES (Zilver PTX) extended into distal R CFA
- Entire segment postdilated to 6 mm

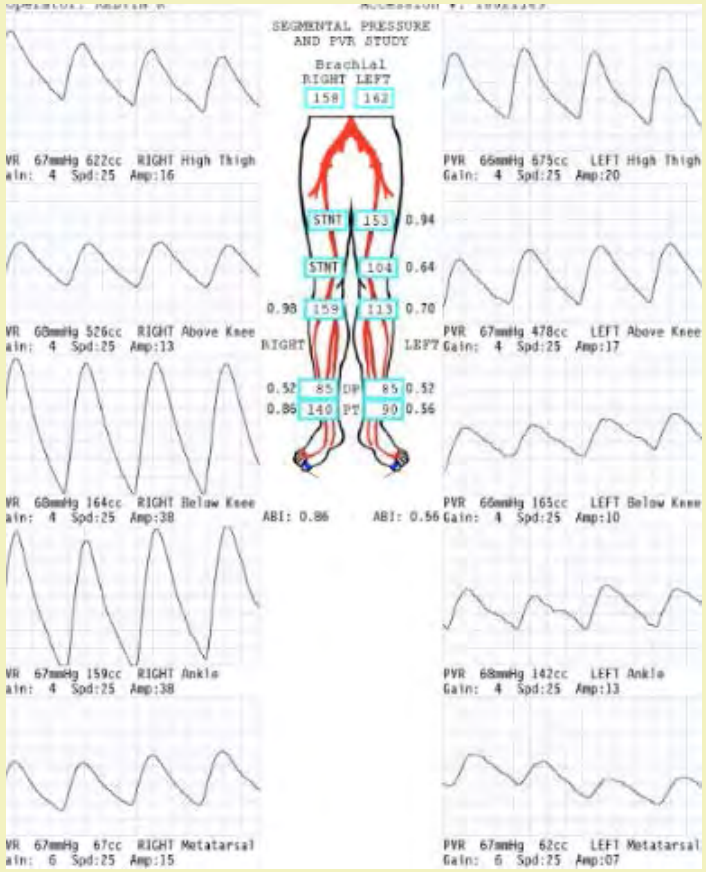
Final Angiogram

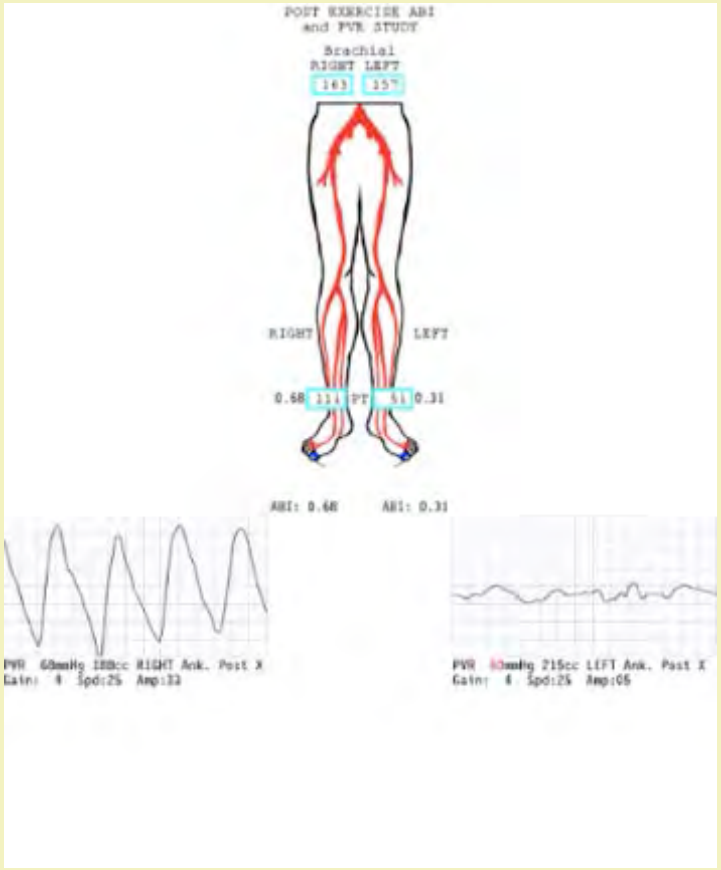


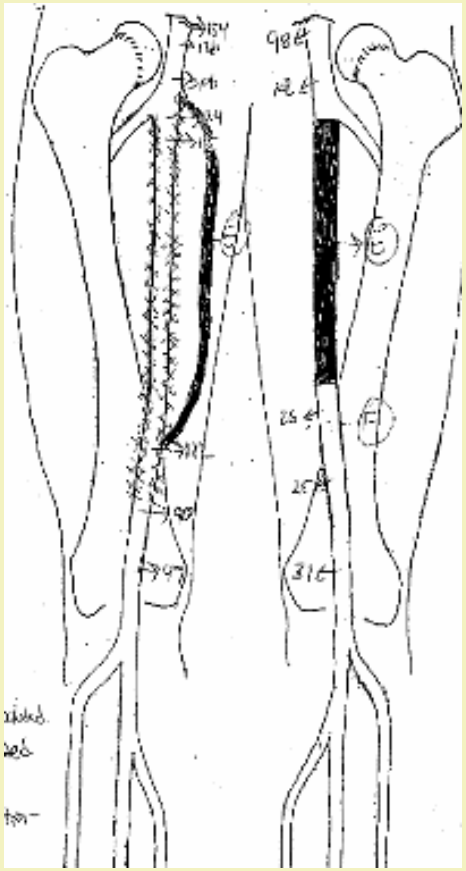
Immediate Postprocedure Plan

- Left CFA closure:
  - 6-Fr Angioseal Evolution
- Plavix loaded (300 mg)
- Bridged to Coumadin with Lovenox
- Arterial LE Noninvasive eval the following morning

Arterial LE Noninvasive, 11/1







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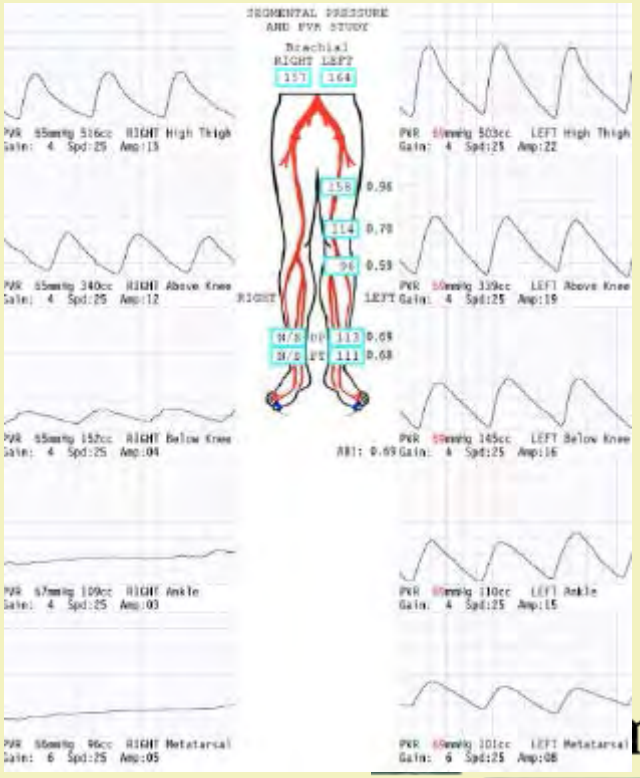
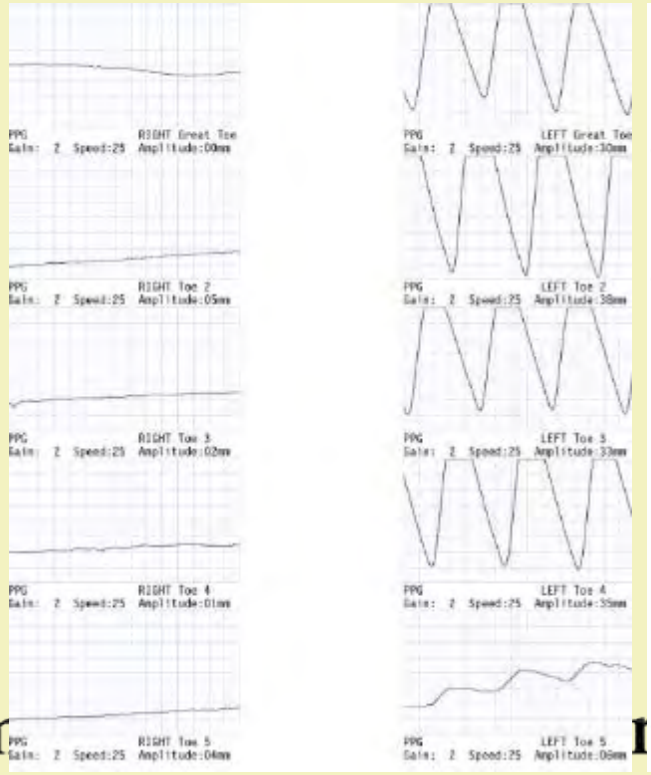
Postprocedure Management

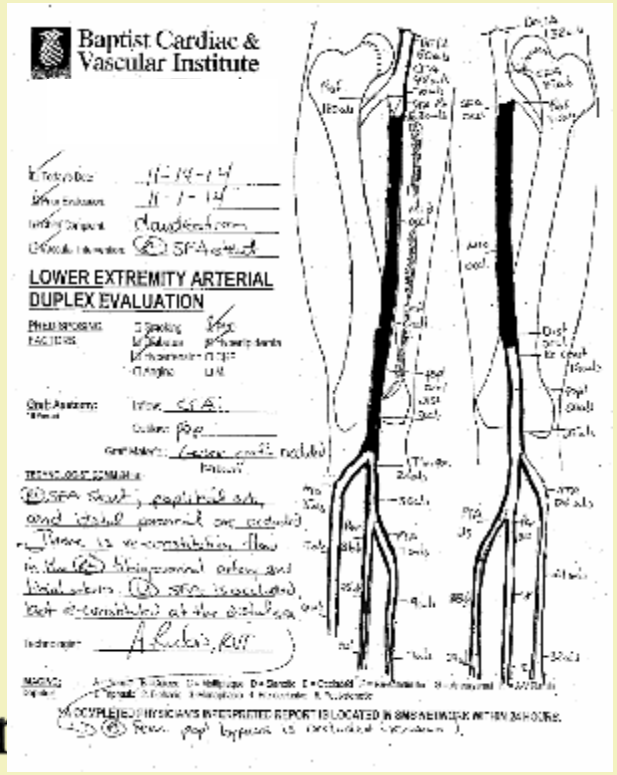
- Plavix 75 mg daily x 3 months
- Hold ASA 81 mg daily until 3 months
- Encouraged to continue exercise
- Will follow-up with Dr. Benenati before leaving for NJ or in 1 month

2 weeks later (11/16)…

- Presents with cold, acutely painful right foot



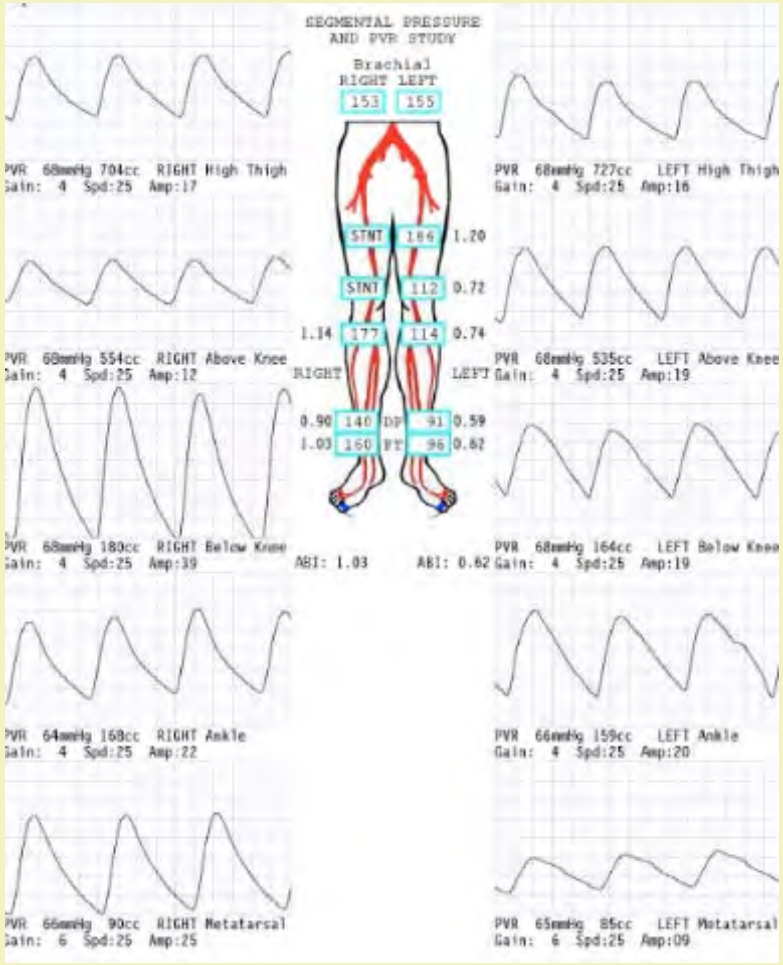


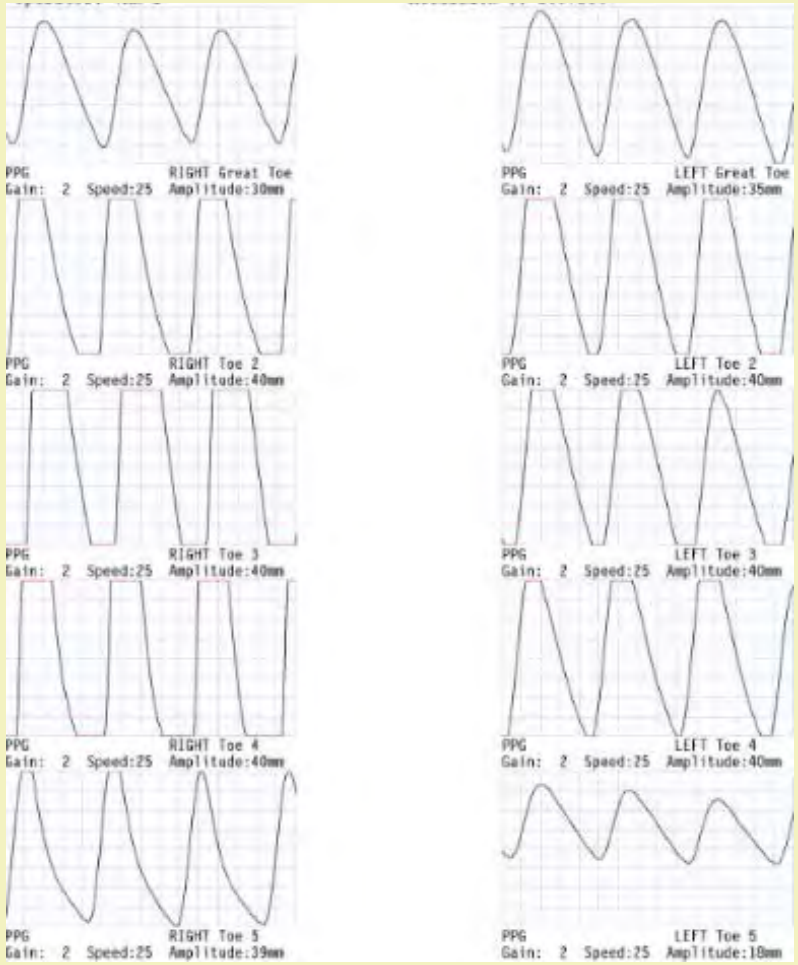


Following heparinization and overnight thrombolysis

Overlapping DES (6x100, 6x80) deployed distally

Postprocedure Noninvasive, 11/18

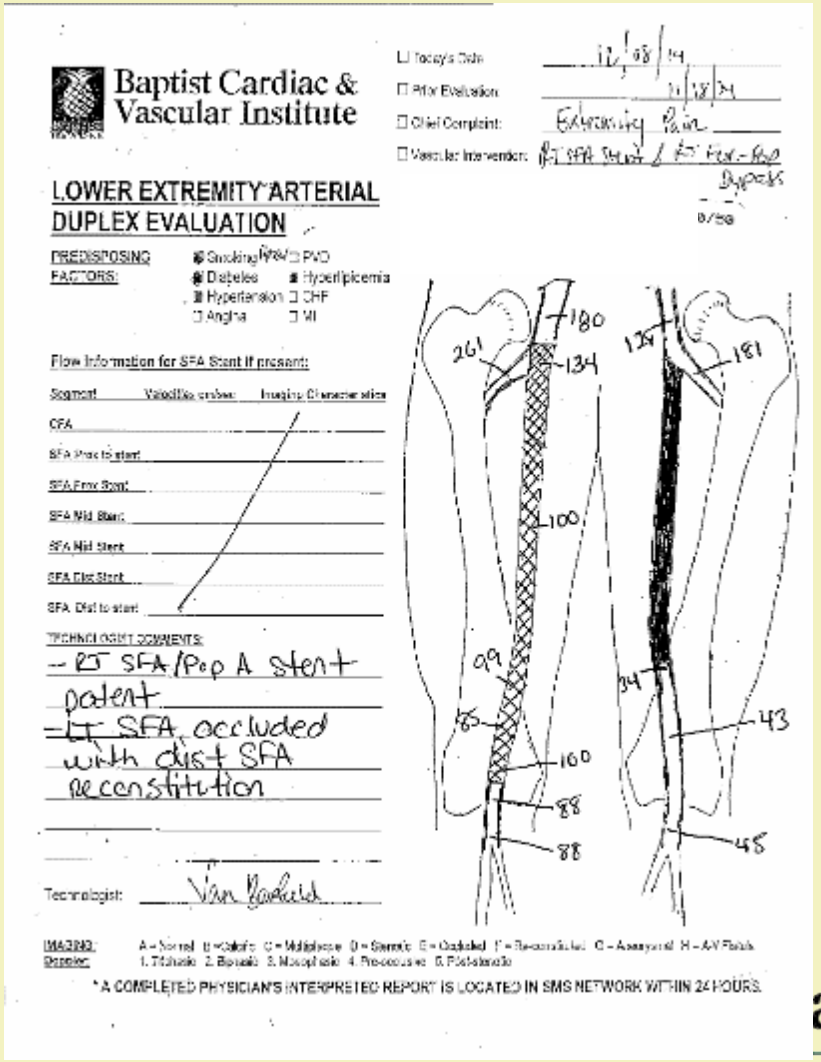




Postprocedure Plan

- Following successful right SFA/Pop A. recanalization:
  - Postprocedure AKI – improved on discharge
  - Prescribed anticoagulation + dual antiplatelet
  - Follow-up as outpatient in 1 month

Follow-up, 12/8



Baptist Cardiac & Vascular Institute

LOWER EXTREMITY ARTERIAL DUPLEX EVALUATION

Today's Date: 12/08/14
Prior Evaluation: 11/18/14
Chief Complaint: Exercising Pain
Vascular Intervention: RT SFA Stent & RT Fem-Pop Bypass

PREDISPOSING FACTORS: Smoking (Hx) PVD; Diabetes; Hyperlipidemia; Hypertension; CHF; Angina; MI

Flow Information for SFA Stent if present:

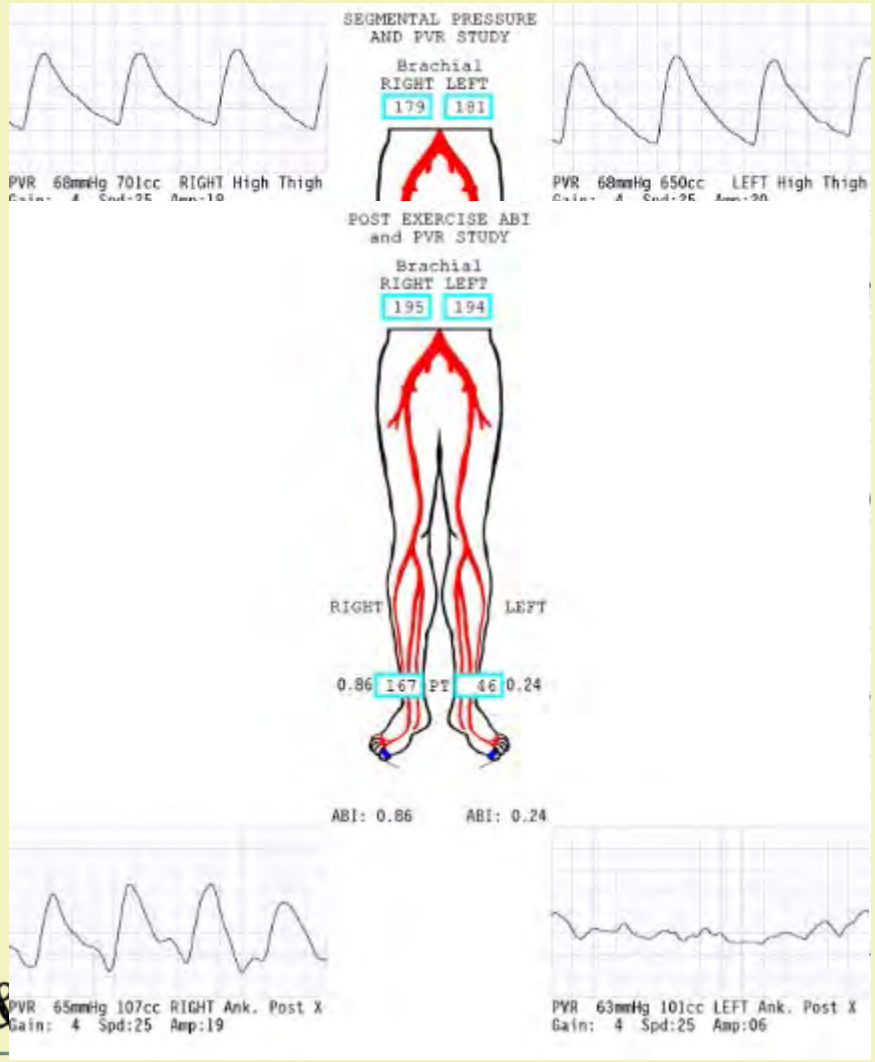
Segment	Velocities (cm/sec)	Imaging Characteristics
CFA		
SFA Prox to stent		
SFA Prox Stent		
SFA Mid Stent		
SFA Mid Stent		
SFA Dist Stent		
SFA Dist to stent		

TECHNOLOGIST COMMENTS:
- RT SFA/Pop A stent patent
- LT SFA occluded with dist SFA reconstitution

Technologist: Van Garland

IMAGING: A=Normal B=Stenotic C=Multilesion D=Stenotic E=Occluded F=Reconstructed G=Aneurysmal H=AV Fistula
Doppler: 1. Triphasic 2. Biphasic 3. Monophasic 4. Pre-occlusive 5. Pulsatile

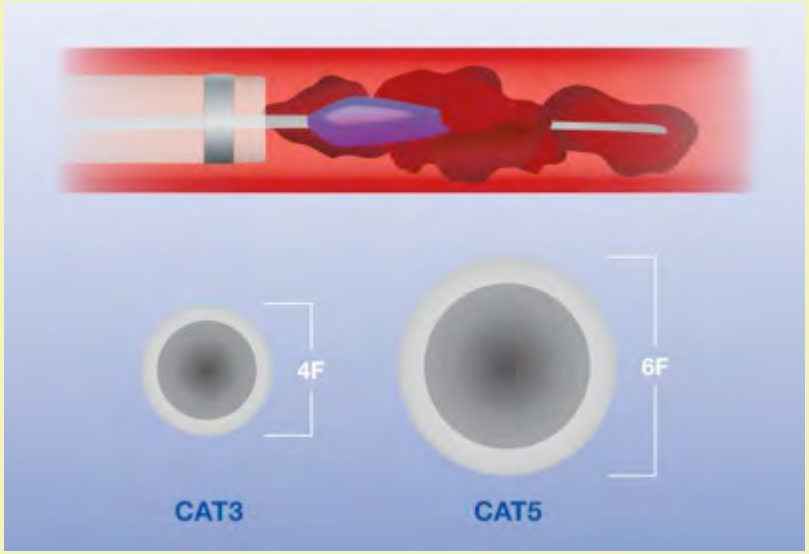
*A COMPLETED PHYSICIAN'S INTERPRETED REPORT IS LOCATED IN SMS NETWORK WITHIN 24 HOURS.



TIME IS BRAIN

INDIGO™ System – Percutaneous Mechanical Thrombectomy

- Mechanical Clot Engagement and Extraction
  - Unique separator allows clot engagement and extraction into the Indigo catheter without losing access
  - Maximized extraction lumen for efficient clot removal



INDIGO™ System – Percutaneous Mechanical Thrombectomy

- Simple and effective
  - Easy-to-use single operator design
  - Penumbra MAX Pump delivers almost pure vacuum and allows for hands free aspiration assistance, with no time limits

MAX™ Pump

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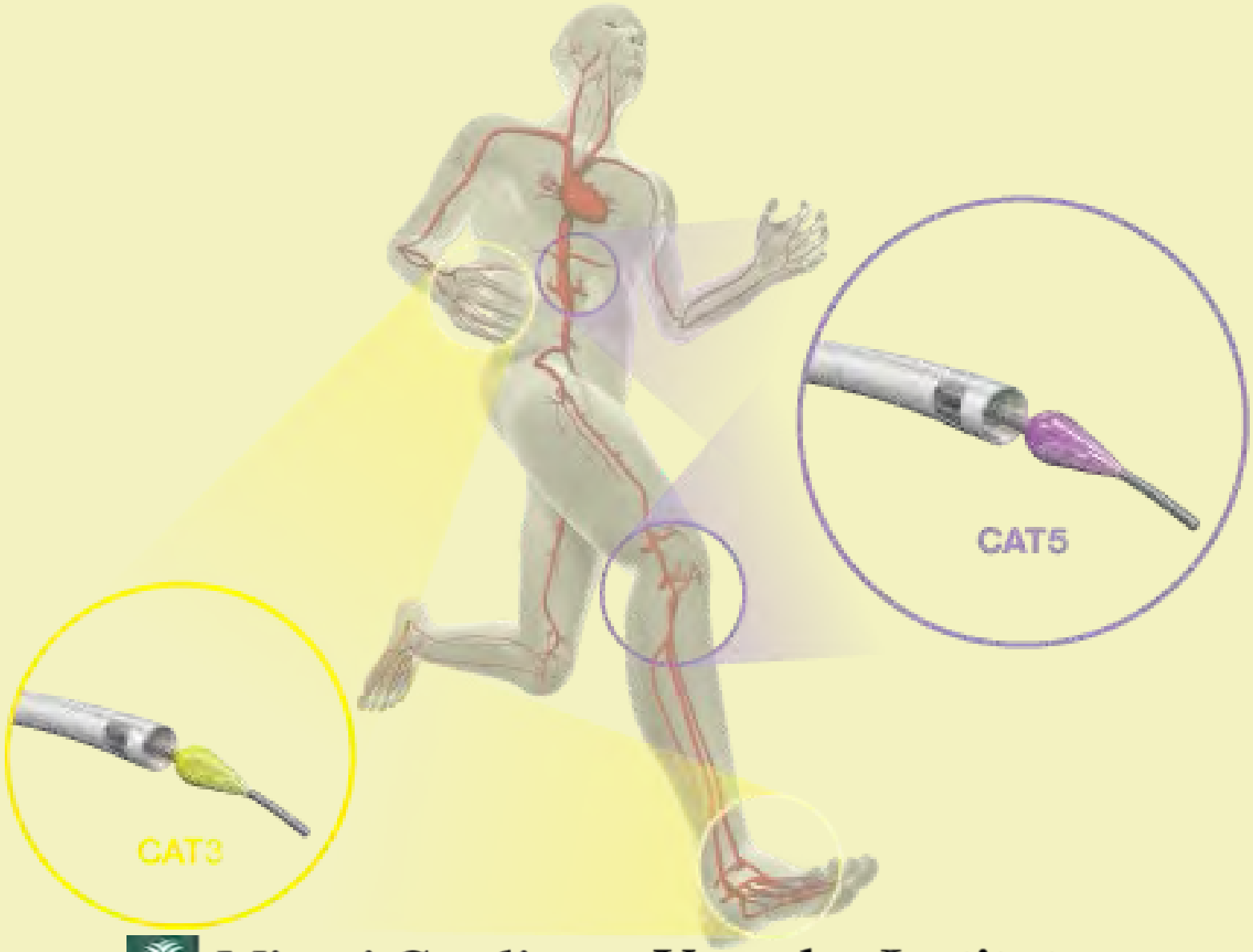

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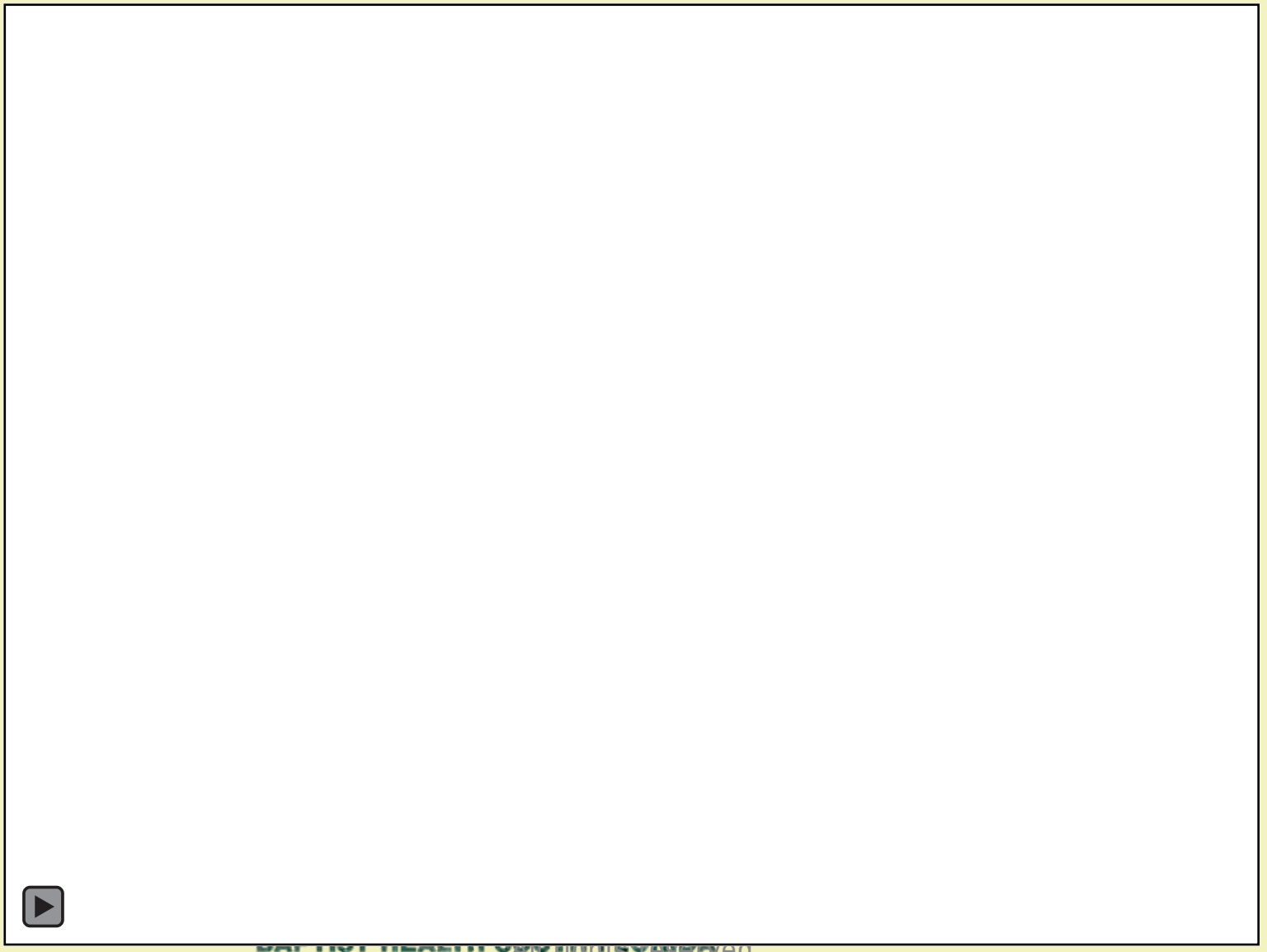
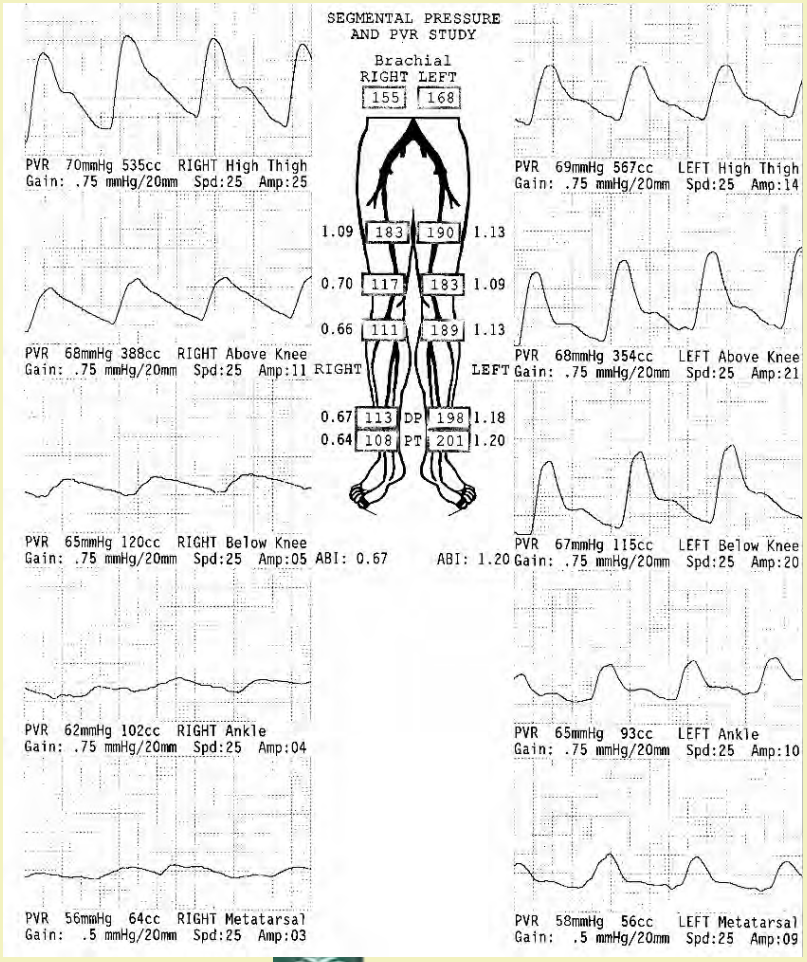
INDIGO VIDEO

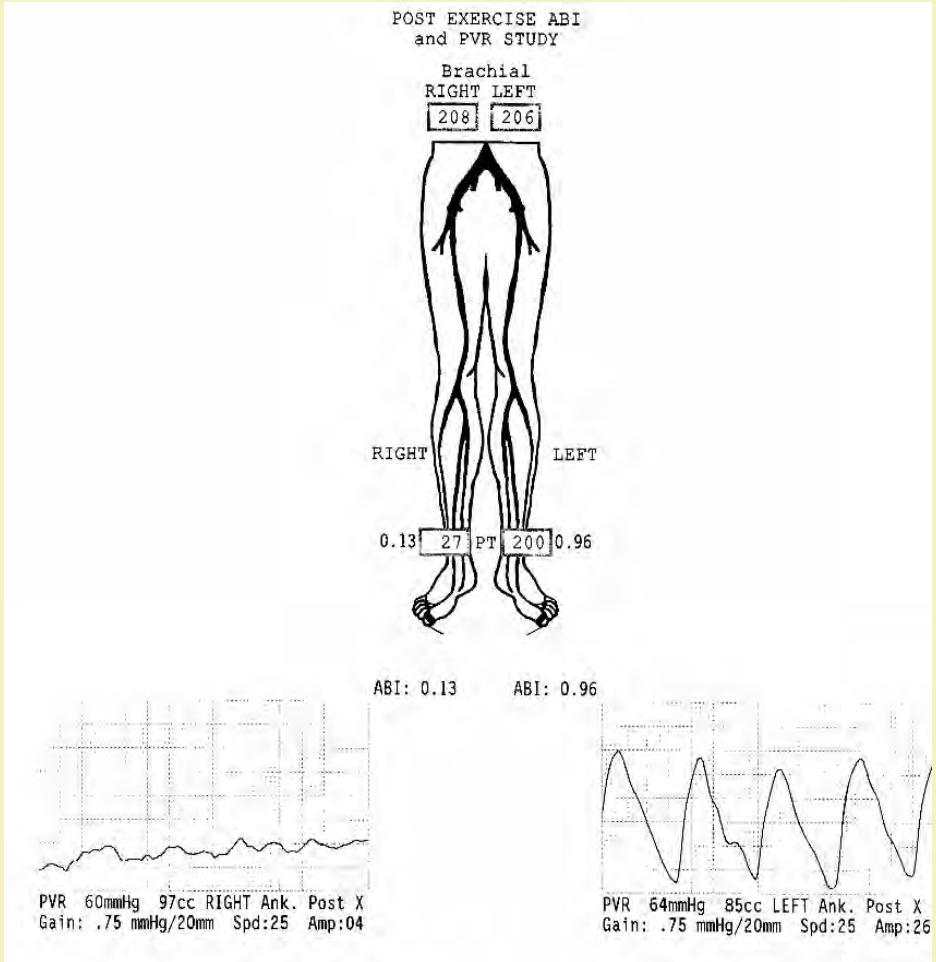


History

- 57 y/o male former heavy smoker, non-compliant with statin therapy.
  - Presented with 6 months of progressive right calf claudication.
    - First noticed when he was running between airport gates.

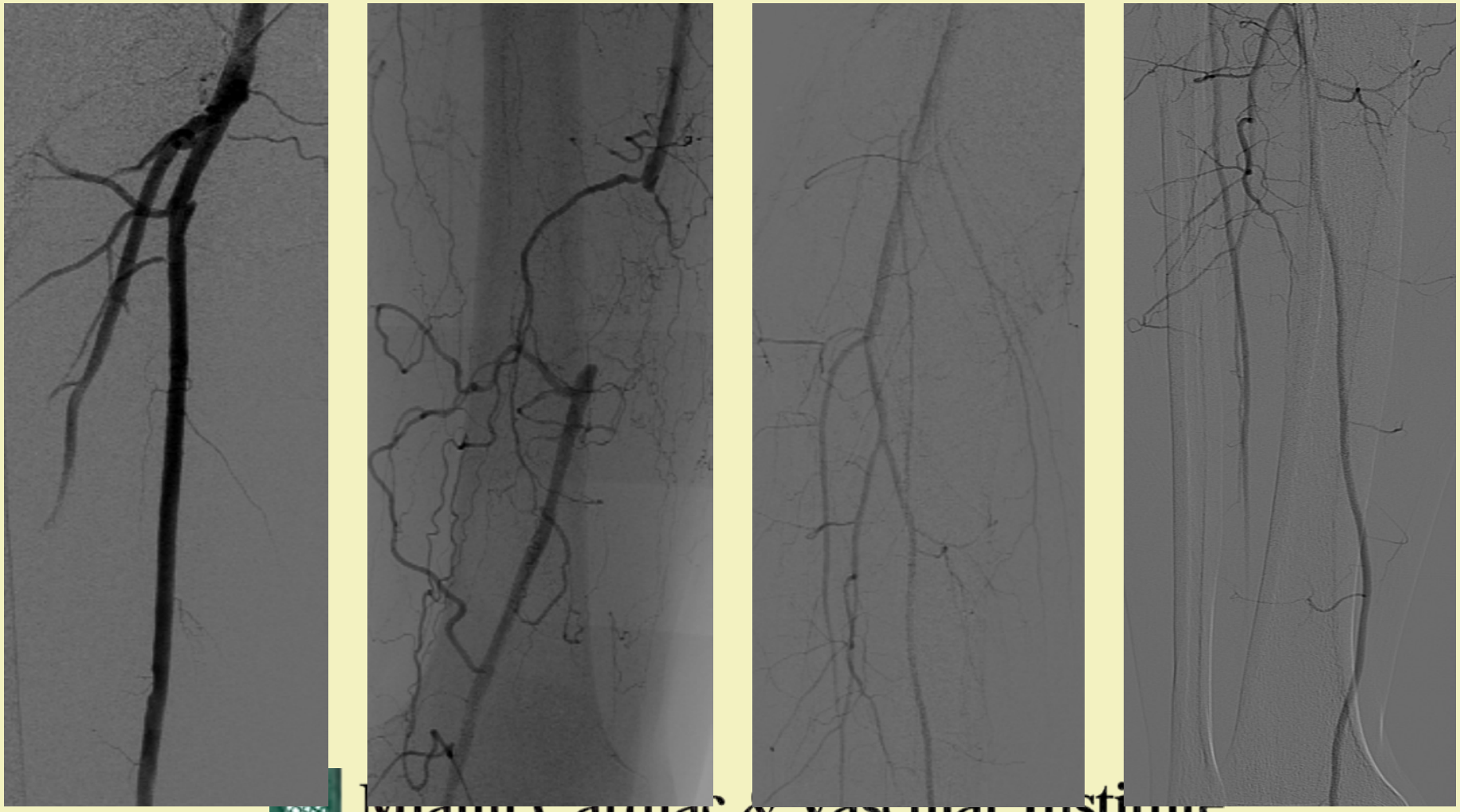
Non-invasive imaging





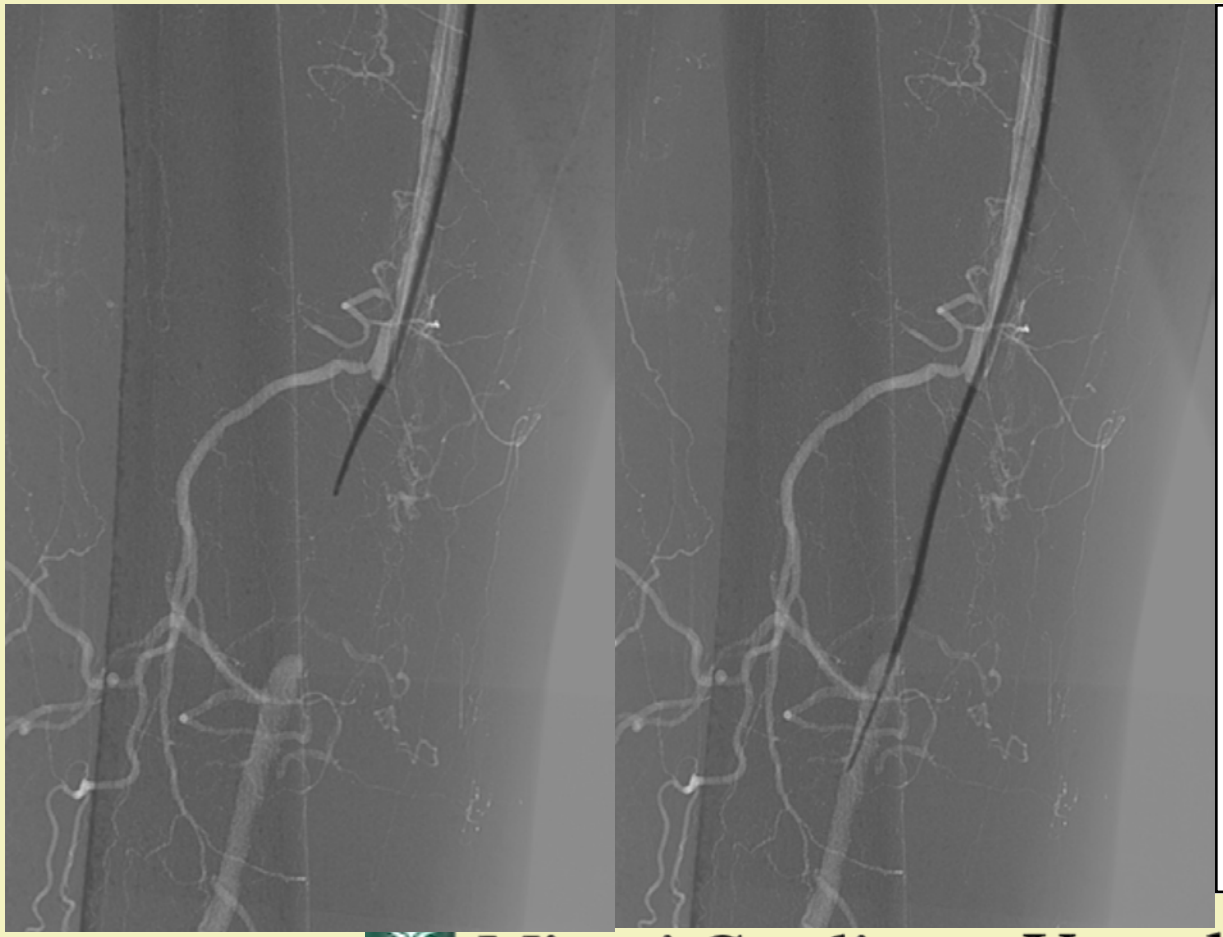
MRA

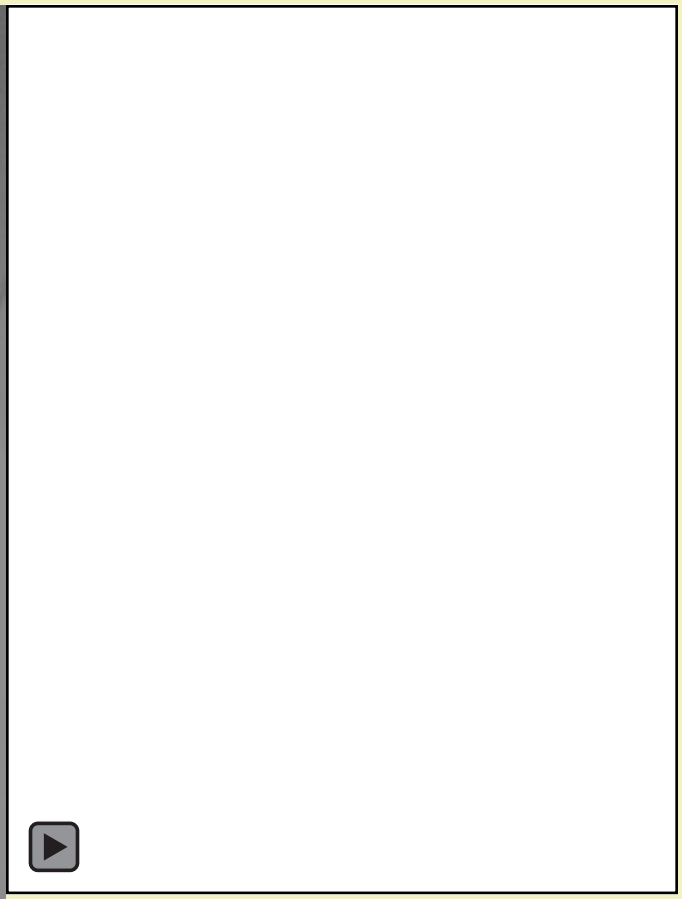
RLE angiogram – Day 1



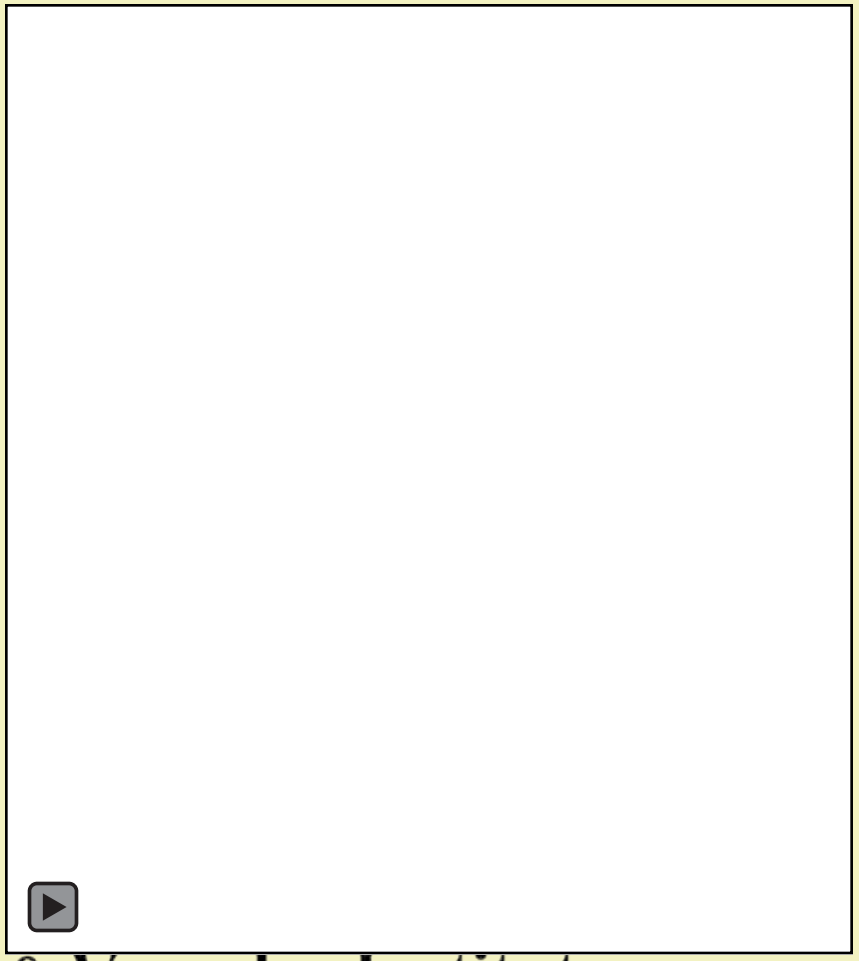
RLE angiogram – Day 1

SFA recanalization – Day 1

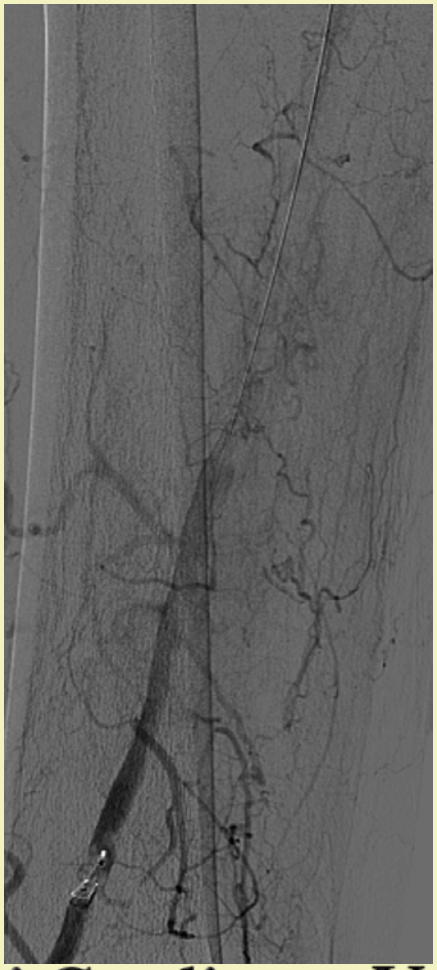


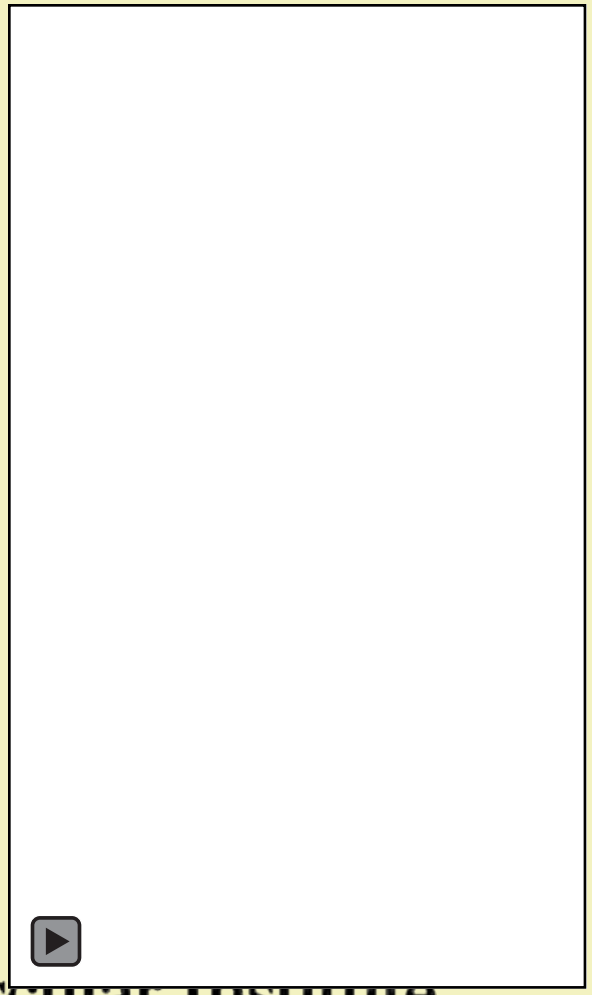


Angiojet with distal protection



Post Angiojet thrombectomy





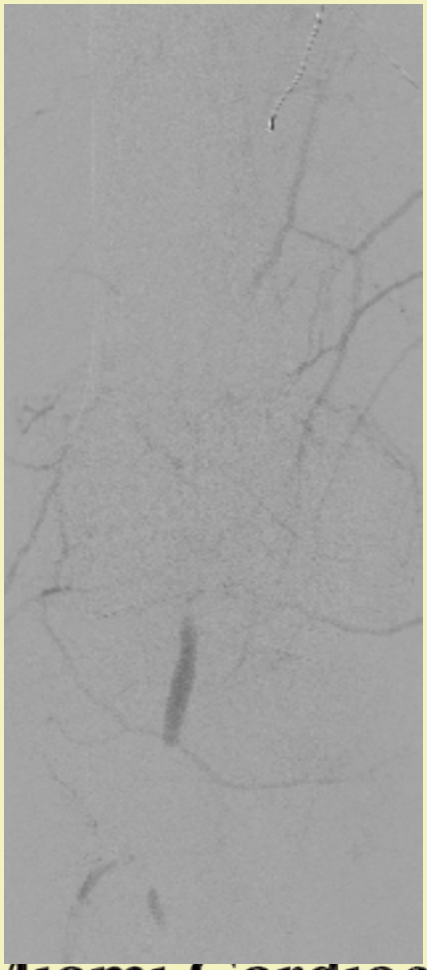
Distal emboli

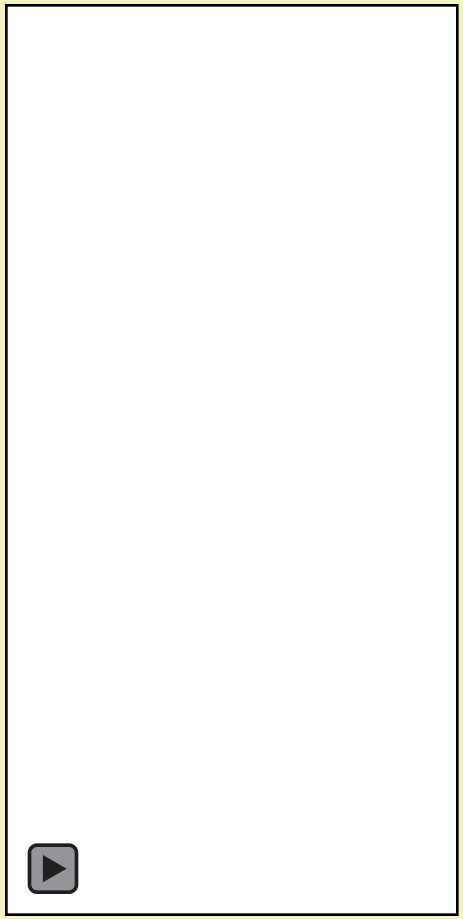
Thrombolysis initiation

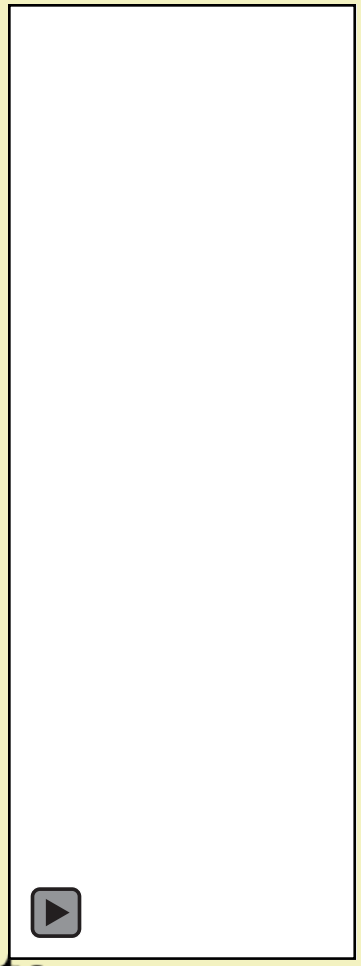
10 cm UniFuse catheter across distal SFA and popliteal artery

180 cm Katzen wire in proximal PTA

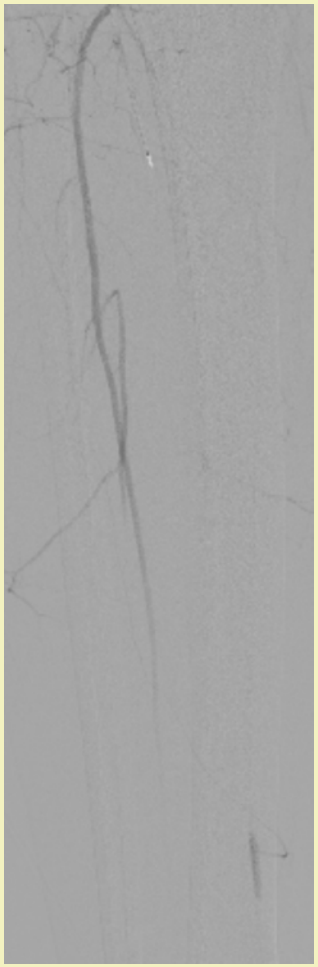
Day 2 – post 24 hours thrombolysis

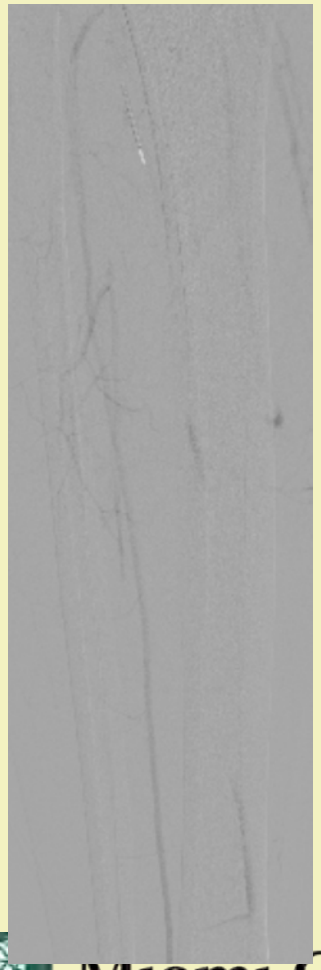


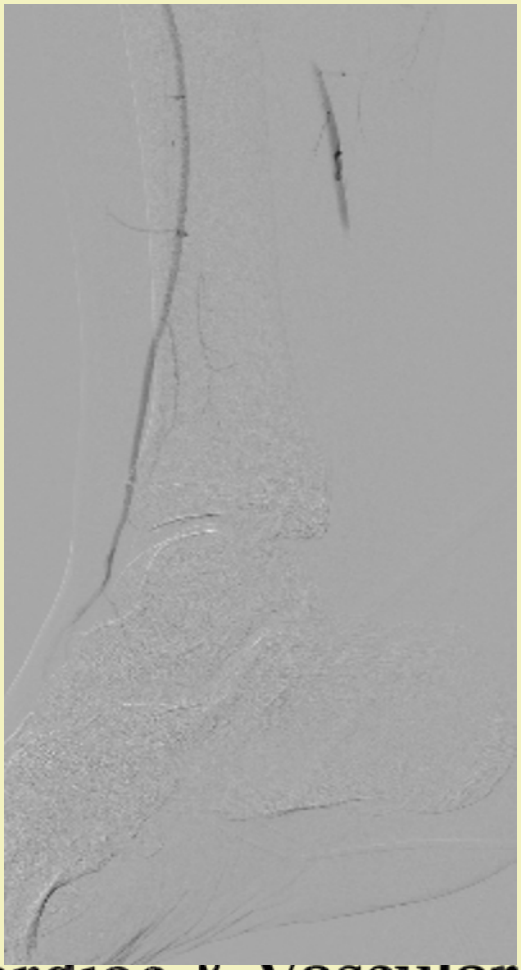




Day 2 – post 24 hours thrombolysis

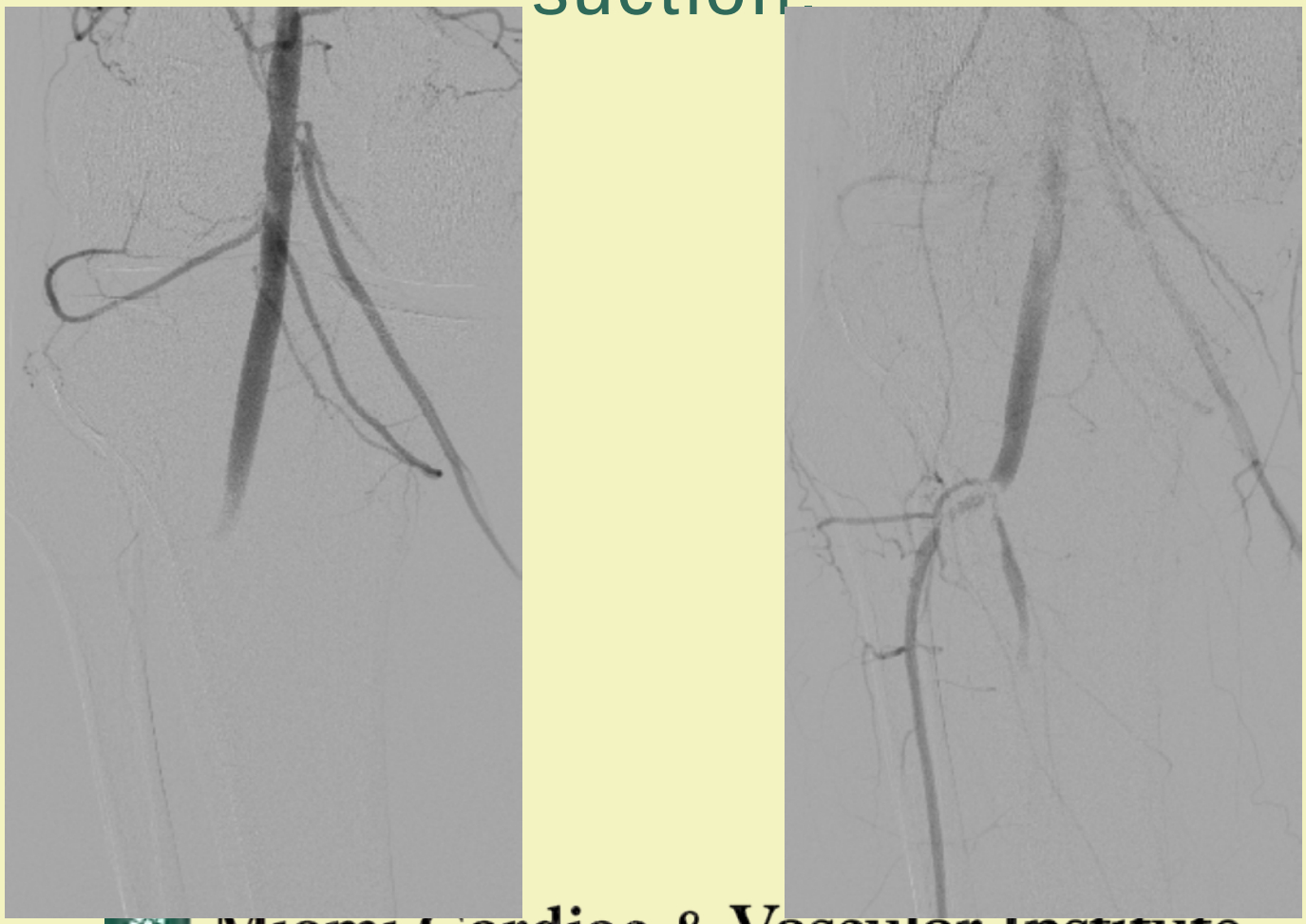




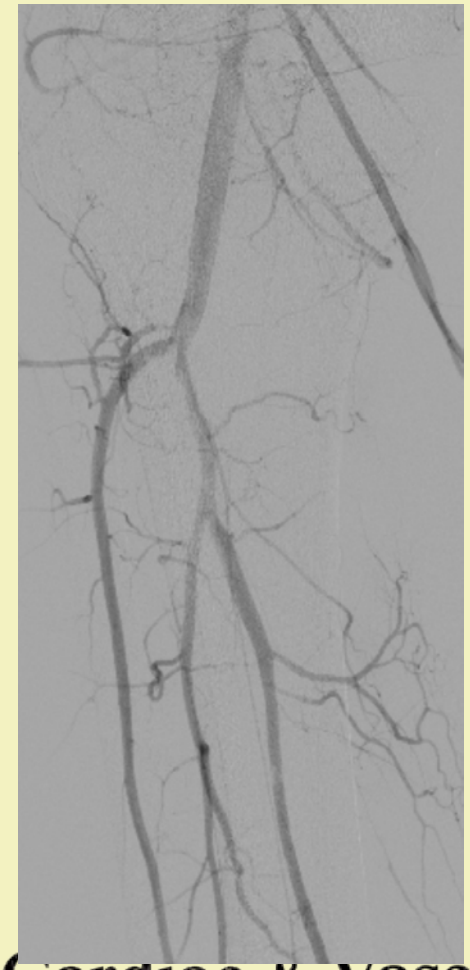


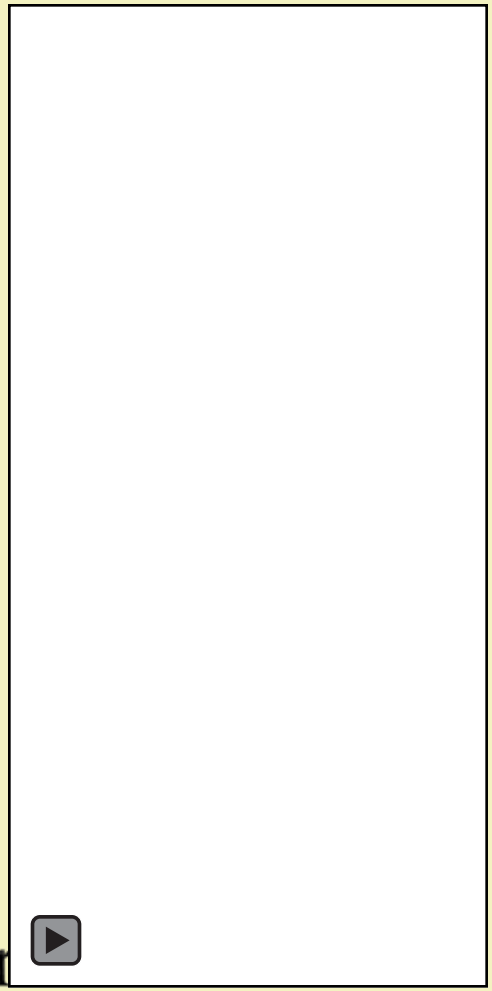
Post tibial artery – standing contrast column

Mechanical Embolectomy:
6F x 0.70 Penumbra Neuron with vacuum suction



RLE angiogram - Post Mechanical Embolectomy with Penumbra





RLE angiogram - Post Mechanical Embolectomy

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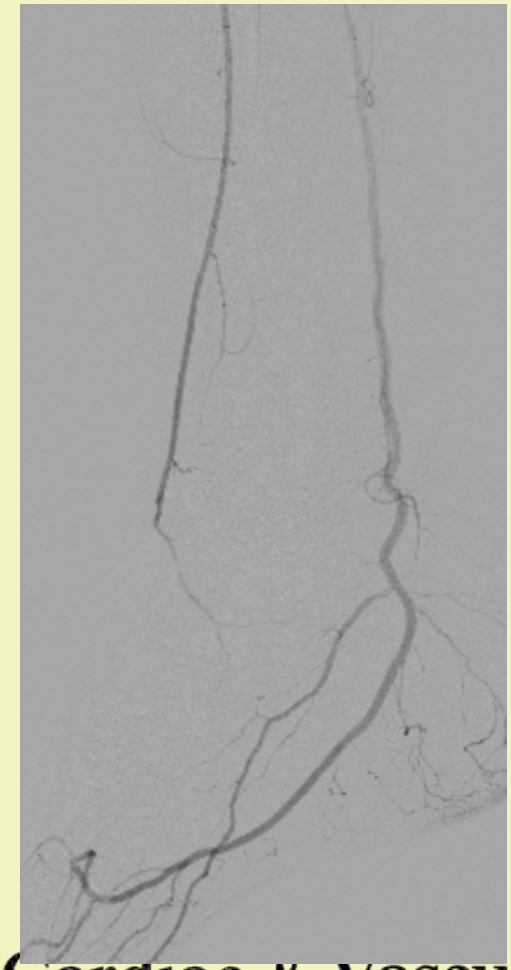
RLE angiogram - Post Mechanical Embolectomy



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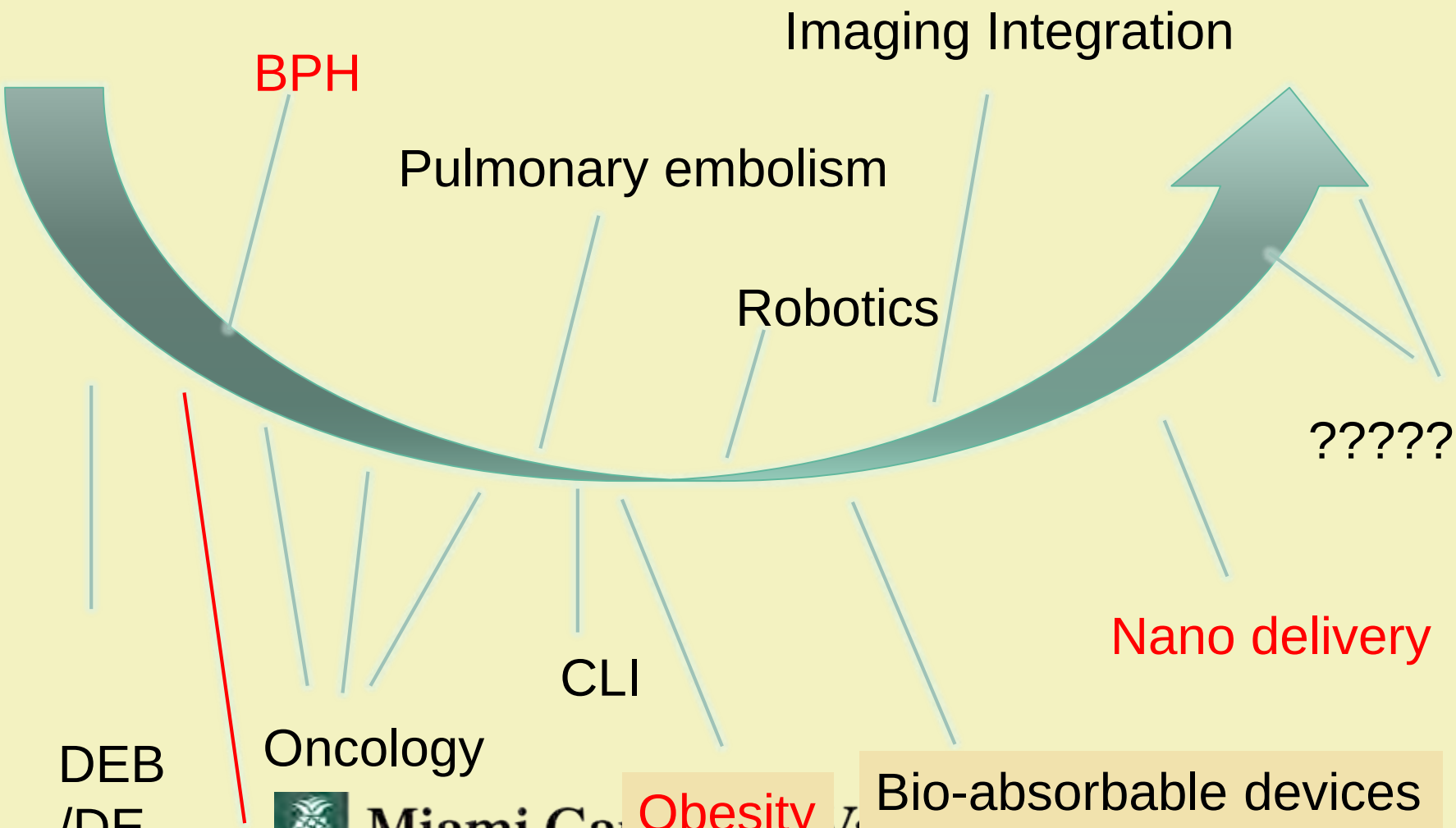
Right SFA: 6mm x 80mm Zilver PTX

Tomorrow: You Don't Want to Don't Miss This!!!



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