Femoropopliteal Intervention: How to Choose Proper Device (DCB, DES or Atherectomy…)

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Presenter Disclosure Information

Within the past 12 months, the presenter or their spouse/partner have had a financial interest/arrangement or affiliation with the organization listed below.

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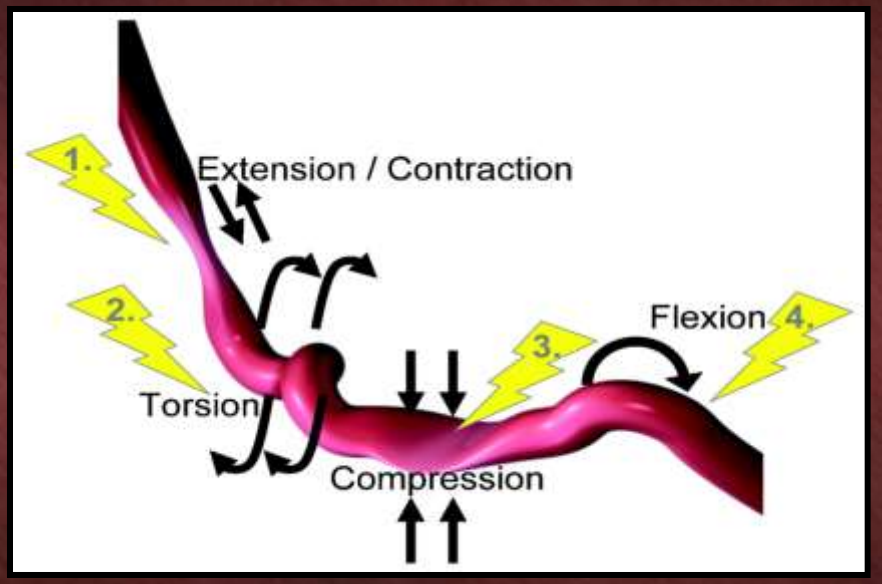
- ***Founder, Arizona Medical Systems***
- ***Owner/Inventor, ORACLE Thrombus Removal System***

Patents *-- RF, Snares, Wires, Balloon Catheters, Covered Stents, Devices for Arterial Venous Connection, Devices for LV and RV Closure, Vascular Access Patents*

SFA/Popliteal Intervention – Nature of the Problem

- Occlusion predominates over stenosis
- Diffuse disease common
- Low flow/high resistance
- Coexistant disease of distal run-off vessels
- Triplanar intermittent mechanical stresses



4th Annual Symposium

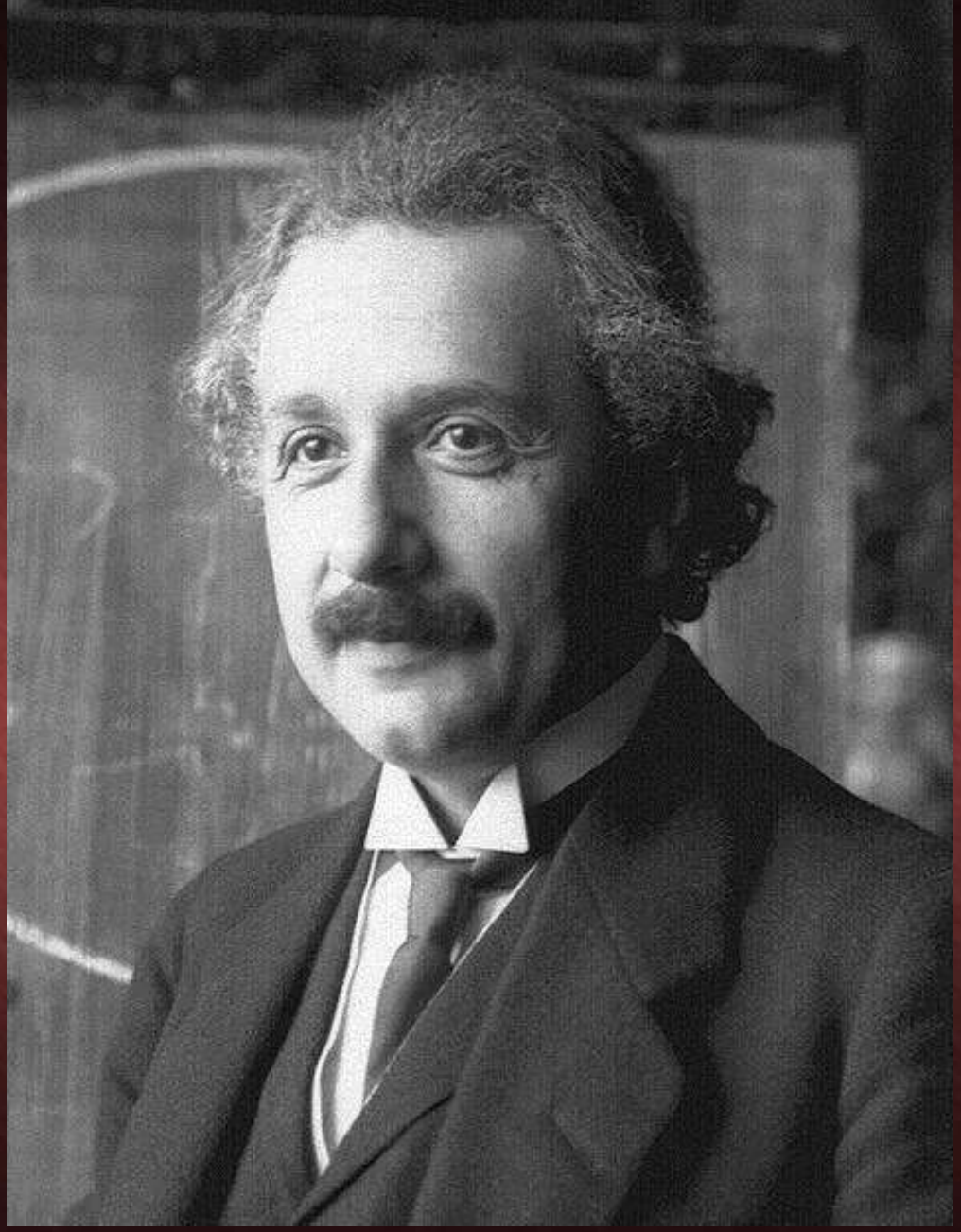
Cardiovascular Disease Management:
A Case-Based Approach

Richard R. Heuser, MD, FACC
Program Director

October 13 & 14, 2016
Arizona Biltmore, Phoenix, Arizona

Nursing Symposium will take place
October 12, 2016 from 12:00 – 5:00 pm

SAVE THE DATE
For more information, please visit www.promedicacme.com



THE PRESENT AND FUTURE

STATE-OF-THE-ART REVIEW

Peripheral Artery Disease

Evolving Role of Exercise, Medical Therapy, and Endovascular Options

Jeffrey W. Olin, DO,[a] Christopher J. White, MD,[b] Ehrin J. Armstrong, MD, MSc,[c] Daniella Kadian-Dodov, MD,[a] William R. Hiatt, MD[d]

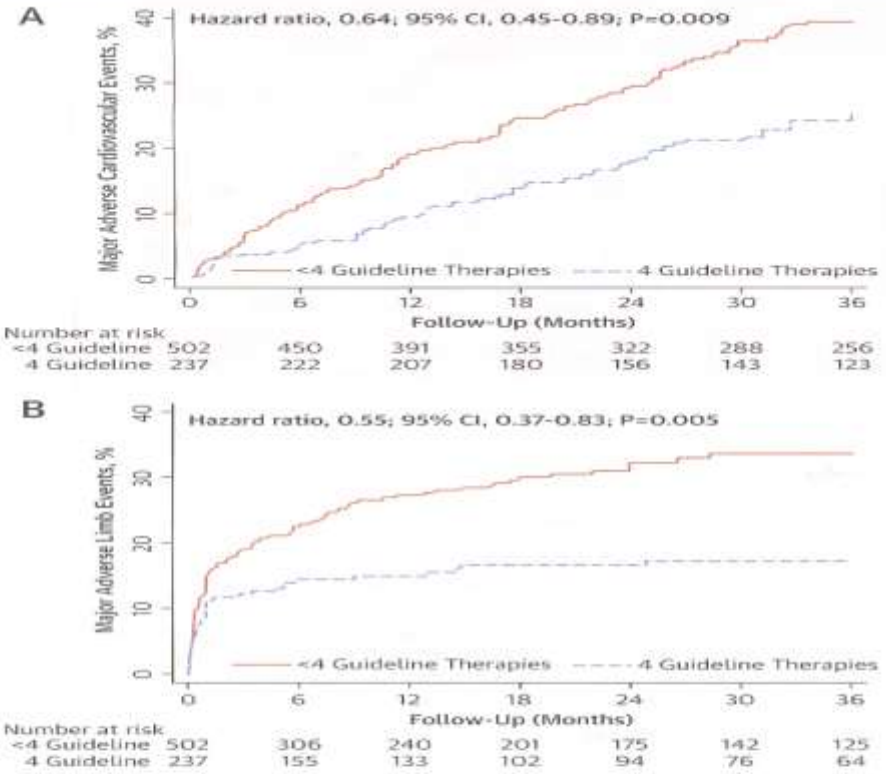
CENTRAL ILLUSTRATION **The Peripheral Artery Disease Prescription**

Decrease the Risk of MI, Stroke, and CV Death	Improve Symptoms, Quality of Life, and Prevent Amputation
• Discontinue Tobacco Use	• Discontinue Tobacco Use
• Walking Program	• Walking Program
• Control Blood Pressure to Goal -ACE Inhibitor	• Cilostazol
• High-Dose Statin Therapy	• Good Foot Care -Moisturizing cream, nail care, treat and prevent tinea, orthotics to prevent abnormal pressure points
• Antiplatelet Therapy	• Revascularization

Olin, J.W. et al. J Am Coll Cardiol. 2016; 67(11):1338–57.

Management of patients with peripheral artery disease: recommendations for improving outcomes and quality of life. ACE = angiotensin-converting enzyme; CV = cardiovascular; MI = myocardial infarction.

FIGURE 1 Adherence to Guideline-Recommended Medical Therapies and Outcomes in PAD



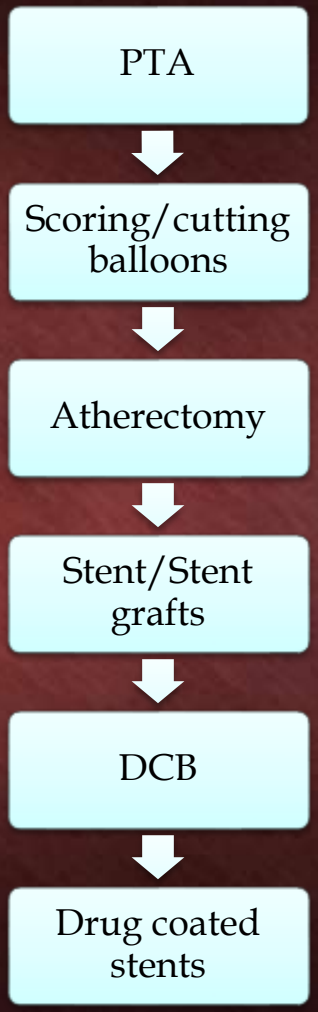
Among patients with symptomatic peripheral artery disease (PAD) undergoing lower-extremity angiography, adherence to the guideline-recommended therapies of an antiplatelet agent, statin, angiotensin-converting enzyme inhibitor, and abstention from smoking is associated with a significant reduction in **(A)** major adverse cardiovascular events and **(B)** major adverse limb events. Reproduced with permission from Armstrong et al. (12). CI = confidence interval; PAD = peripheral artery disease.

VAPOR (Vascular Physician Offer and Report) trial is currently evaluating methods to improve physician-patient interactions to encourage patients with PAD to abstain from smoking (62).

PHARMACOTHERAPY TO IMPROVE CLAUDICATION SYMPTOMS

Cilostazol is a type III phosphodiesterase inhibitor with a number of properties, but the mechanism by

Current Endovascular Options



* Denotes not currently FDA approved

Optimal PTA Inflation Time

Optimizing PTA with prolonged balloon inflations reduces dissection severity and rate & hence need for further intervention

Peripheral PTA: Effect of Short versus Long Balloon Inflation Time on the Morphologic Results

3 minutes is optimal

	Inflation Time (sec)		
	30	180	*P*-Value
Major dissection (grades 3 or 4)	[illegible]	5	10
Minor or no dissection (grades 1 and 2)	21	32	.010
Further interventions (Stent, repeat dilatation, dilation with larger diameter)	20	9	.017
Residual stenosis (>30%)	12	5	.097
Complication (embolization, thrombosis)	1	1	-
Mean ankle-brachial index (before,	0.66, 0.87	0.65, 0.84	

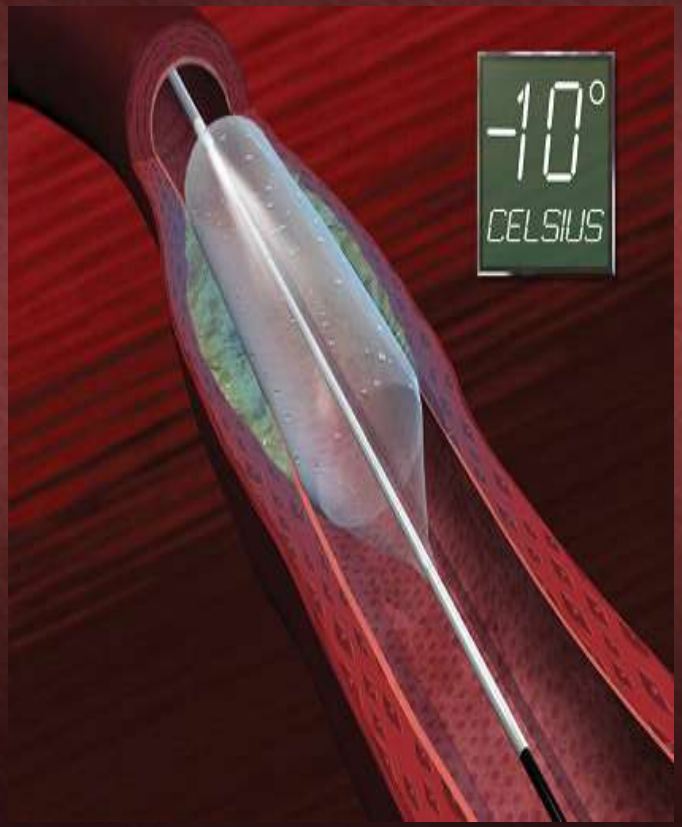
- Inflation times of 180 seconds improve immediate infrainguinal PTA results vs. a short dilation strategy
- Significantly fewer major dissections and a modest reduction of residual stenoses are observed

1. N. Zorger et al. Peripheral Arterial Balloon Angioplasty: Effect of Short versus Long Balloon Inflation Times on the Morphologic Results. J Vasc Interv Radiol. 2002

PolarCath - Effects of Cold Therapy

Unique combination of mechanical & biological effects:

- Altered Plaque Response
- Reduced Elastic Recoil
- Smooth Muscle Cell Apoptosis



Limitations of Current Endovascular Treatments for Femoropopliteal Artery

Endovascular Procedures	
PTA	**Stents**
• restenosis rates of 30-60% at 1 year[1] • TLR rates of 17.5% to as high as 54.9% at 1 year[3,4]	• restenosis rates of 20-40% at 1 year[2] • ongoing stimulus for restenosis • "*no stent zones*" segments limit use in femoropopliteal artery • concerns of stent fracture • permanent implants limit future treatment options

Reference: (1) Dick et al.; Laird et al. (2) Laird et al.; Armstrong et al 3. Dake M et al; 4. Laird JR et al. .

TABLE 6 Comparative Femoral-Popliteal Trials

Clinical Trial Name (Ref. #)	Device	N	Lesion length (mm)	Restenosis (%)	IC/CLI (%)	TLR (%)	De Novo (%)	Occlusions (%)	RVD (mm)
FAST (110)	PTA	121	45 ± 28	38.6	96.5/3.5	18.3	59.5	24.8	5.1
	BMS	123	45 ± 27	31.7	97.5/2.5	14.9	65.9	36.6	5.3
ABSOLUTE (108)	PTA	53	92 ± 75	63.0	87/13	31	100	32	NR
	BMS	51	101 ± 75	37.0*	88/12	28	100	37	NR
ASTRON (109)	PTA	39	65 ± 46*	61.1	97/3	NR	100	39	NR
	BMS	34	82 ± 67	34.4*	91/9	NR	100	38	NR
ZILVER (100)	PTA	238	63 ± 41	67.2	90.7/8.5	17.5	24.7	NR	NR
	DES	241	66 ± 39	16.9*	90.2/8.9	9.5*	29.6	NR	NR
Zeller (104)	DES	97	195 ± 65	30.4	91.7/7.2	21.5	55.7	62.9	NR
	DCB	131	194 ± 86	23.9	81/16.8	19.3	48.1	52.7	NR
THUNDER (111)	PTA	54	74 ± 67	44.0	NR	48	30	26	4.7
	DCB	48	75 ± 62	17.0*	NR	10	38	27	5.2
FEMPAC (102)	PTA	42	47 ± 42	47.0	93/7	17	34	19	5.1
	DCB	45	40 ± 44	19.0*	96/4	7	35	13	5.2
IN.PACT SFA (112)	PTA	111	88 ± 51	47.6	93.7/6.3	20.6	94.6	19.5	4.68
	DCB	220	89 ± 48	17.8*	95/5.0	2.4*	95	25.8	5.0
LEVANT-2 (106)	PTA	160	63 ± 40	47.4	91.9/8.1	37.5	87.5	21.9	4.8
	DCB	316	63 ± 41	34.8*	92.1/7.9	38	83.9	20.6	4.8
PACIFIER (113)	PTA	47	66 ± 55	32.4	95.7/4.3	21.4	82.9	38.3	4.9
	DCB	41	70 ± 53	8.6*	95.5/4.5	7.1	68.2	22.7	4.96

*$p < 0.05$.

ABSOLUTE = Balloon Angioplasty Versus Stenting With Nitinol Stents in the Superficial Femoral Artery; ASTRON = Balloon angioplasty versus stenting with nitinol stents in intermediate length superficial femoral artery lesions; BMS = bare-metal stent; CLI = critical limb ischemia; CS = covered stent; DCB = drug-coated balloon; DES = drug-eluting stent; FAST = The Femoral Artery Stenting Trial; FEMPAC = Femoral Paclitaxel Trial; IC = intermittent claudication; IN.PACT SFA = Randomized Trial of IN.PACT (Paclitaxel) Admiral Drug-Coated Balloon (DCB) vs. Standard Percutaneous Transluminal Angioplasty (PTA) for the Treatment of Atherosclerotic Lesions in the Superficial Femoral Artery (SFA) and/or Proximal Popliteal Artery (PPA); LEVANT-2 = The Lutonix Paclitaxel-Coated Balloon for the Prevention of Femoropopliteal Restenosis; NR = not reported; PACIFIER = Paclitaxel-coated Balloons in Femoral Indication to Defeat Restenosis; PTA = percutaneous transluminal (balloon) angioplasty; RVD = reference vessel diameter; THUNDER = Local Taxan With Short Time Contact for Reduction of Restenosis in Distal Arteries; TLR = target-lesion revascularization; ZELLER = Drug-coated balloons vs. drug-eluting stents for treatment of long femoropopliteal lesions; ZILVER = PTX Randomized Trial.

TABLE 8 Comparative Tibial-Peroneal Trials

Clinical Trial Name (Ref. #)	Device	N	Lesion length (mm)	Restenosis (%)	IC/CLI (%)	TLR (%)	De Novo (%)	Occlusions (%)	RVD (mm)
ACHILLES (120)	PTA	101	27 ± 21	42.9	NR	16.5	98.2	75.4	2.6
	DES	99	27 ± 21	22.4*	NR	10.0	94.7	81.3	2.6
DESTINY (121)	BMS	66	19 ± 10	36.0	0/100	35.0	100	17.0	2.9
	DES	74	16 ± 10	17.0	0/100	8.0*	100	15.0	3.0
YUKON-BTX (122)	BMS	79	31 ± 9	44.4	58.2/41.8	17.5	100	21.5	3.0
	DES	82	30 ± 8	19.4*	48.8/51.2	9.7	100	23.2	3.0
DEBATE-BTK (123)	PTA	67	131 ± 79	74.0	0/100	43.0	NR	82.1	2.9
	DCB	65	129 ± 83	27.0*	0/100	18.0	NR	77.5	2.9
IN.PACT DEEP CLI (124)	PTA	119	129 ± 95	35.5	0.8/99.2	13.1	88.2	45.9	12.9
	DCB	239	102 ± 91	41.0	0/100	9.2	77.2	38.6	10.2
IDEAS (125)	DCB	25	148 ± 57	57.9	NR	13.6	NR	12.0	NR
	DES	27	127 ± 47	28.0*	NR	7.7	NR	23.0	NR

*$p < 0.05$.

ACHILLES = Comparing Angioplasty and DES in the Treatment of Subjects With Ischemic Infrapopliteal Arterial Disease; DEBATE-BTK = Drug-Eluting Balloon in Peripheral Intervention for Below the Knee Angioplasty Evaluation trial; DESTINY = Drug Eluting Stents in the Critically Ischemic Lower Leg; IDEAS = Infrapopliteal Drug Eluting Angioplasty Versus Stenting for the Treatment of Long-segment Arterial Disease: The IDEAS-I Randomized Controlled Trial; IN.PACT DEEP CLI = Randomized Study of IN.PACT Amphirion™ Drug Eluting Balloon vs. Standard PTA (Percutaneous Transluminal Angioplasty) for the Treatment of Below the Knee Critical Limb Ischemia; YUKON-BTX = YUKON-drug-eluting Stent Below The Knee - Prospective Randomized Double-blind Multicenter Study; other abbreviations as in **Table 6**.

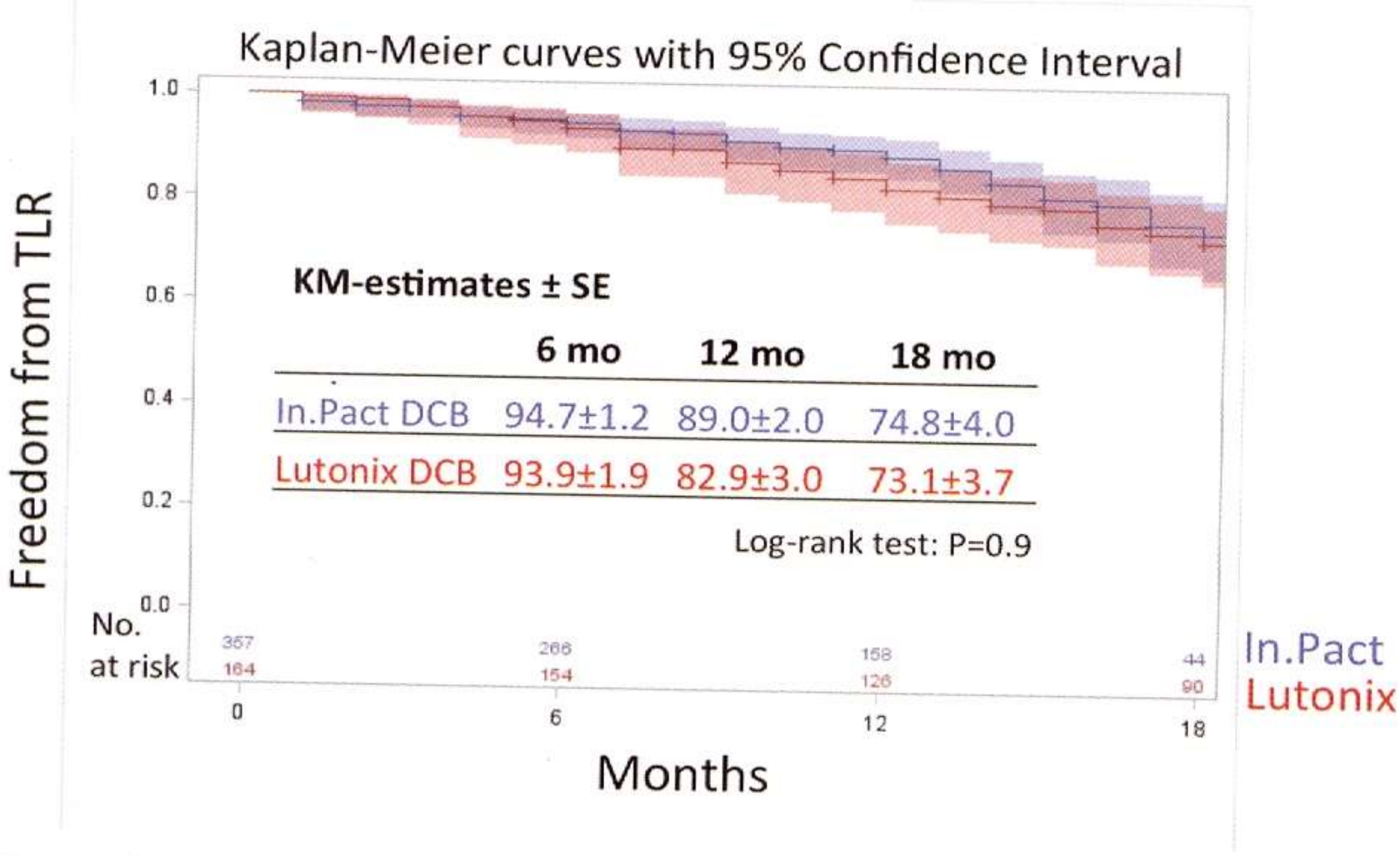
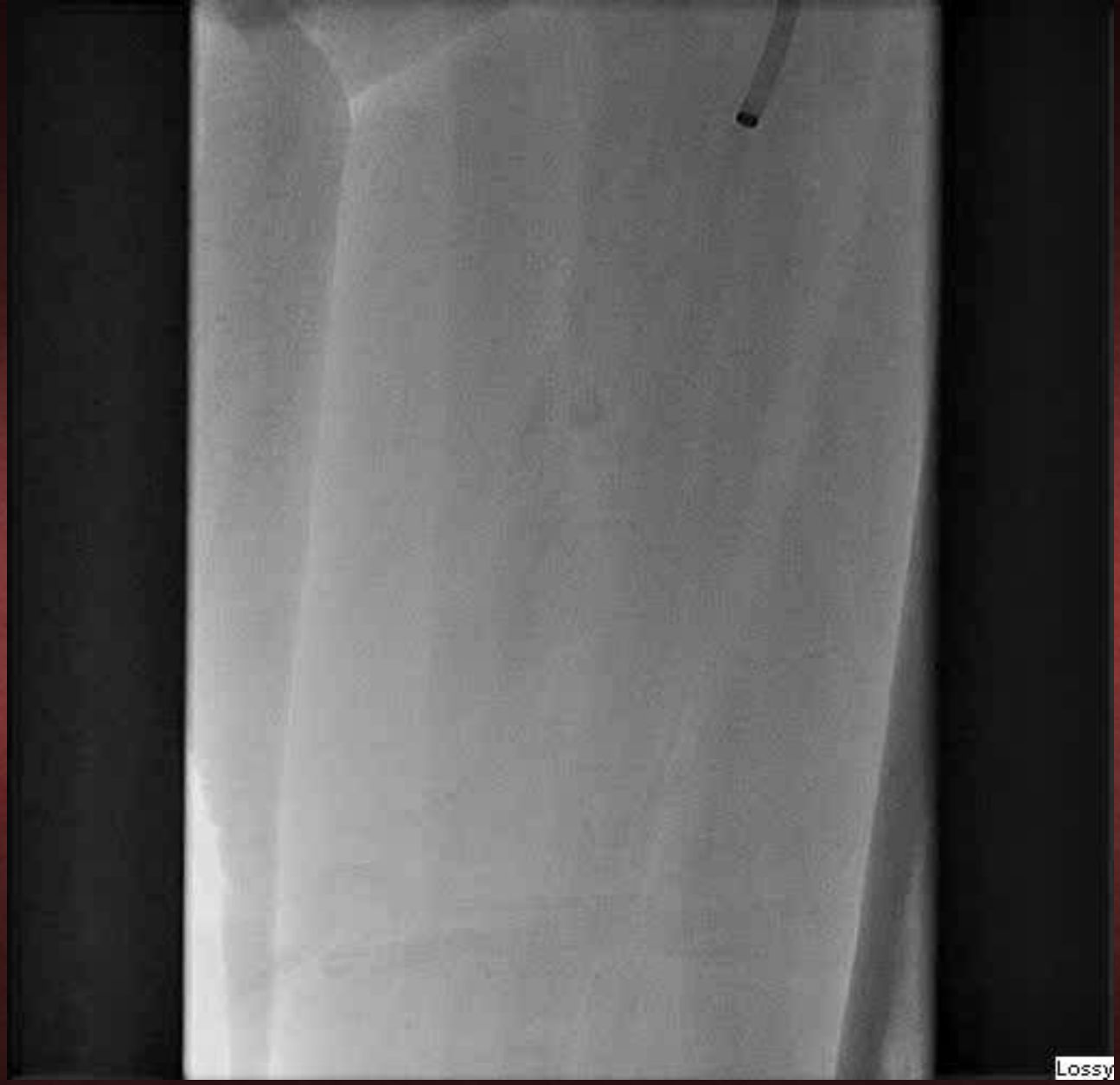


Figure 1. Target lesion revascularization. Presented at the 2016 Leipzig Interventional Course (LINC).

A 75 year old woman presents with resting left foot pain. Her ABI on the left is .5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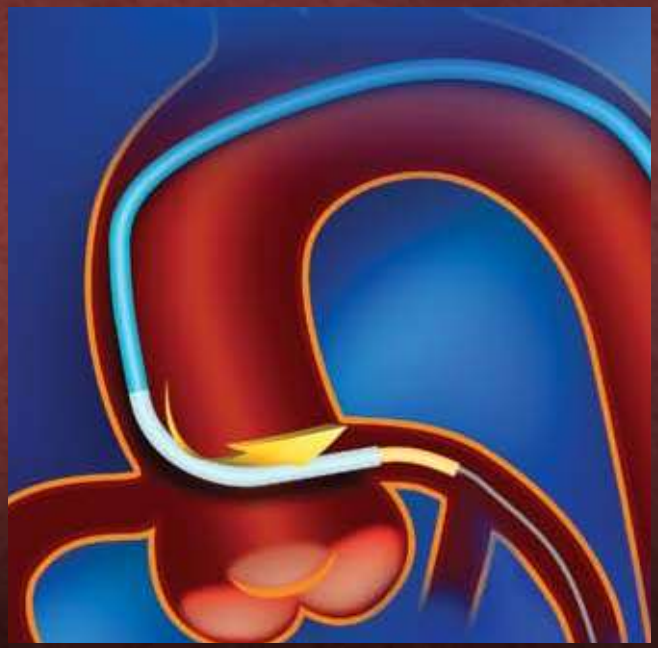
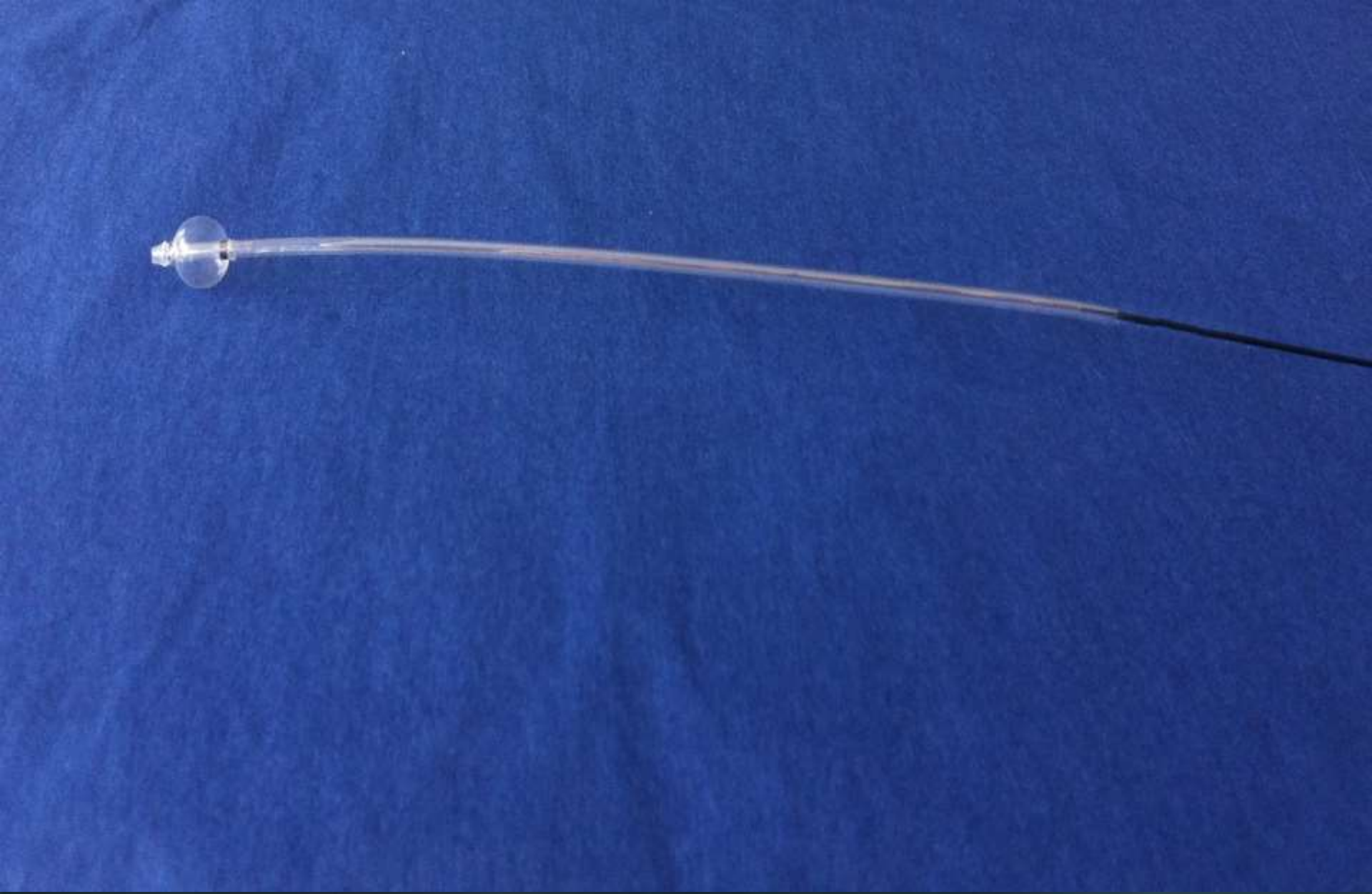
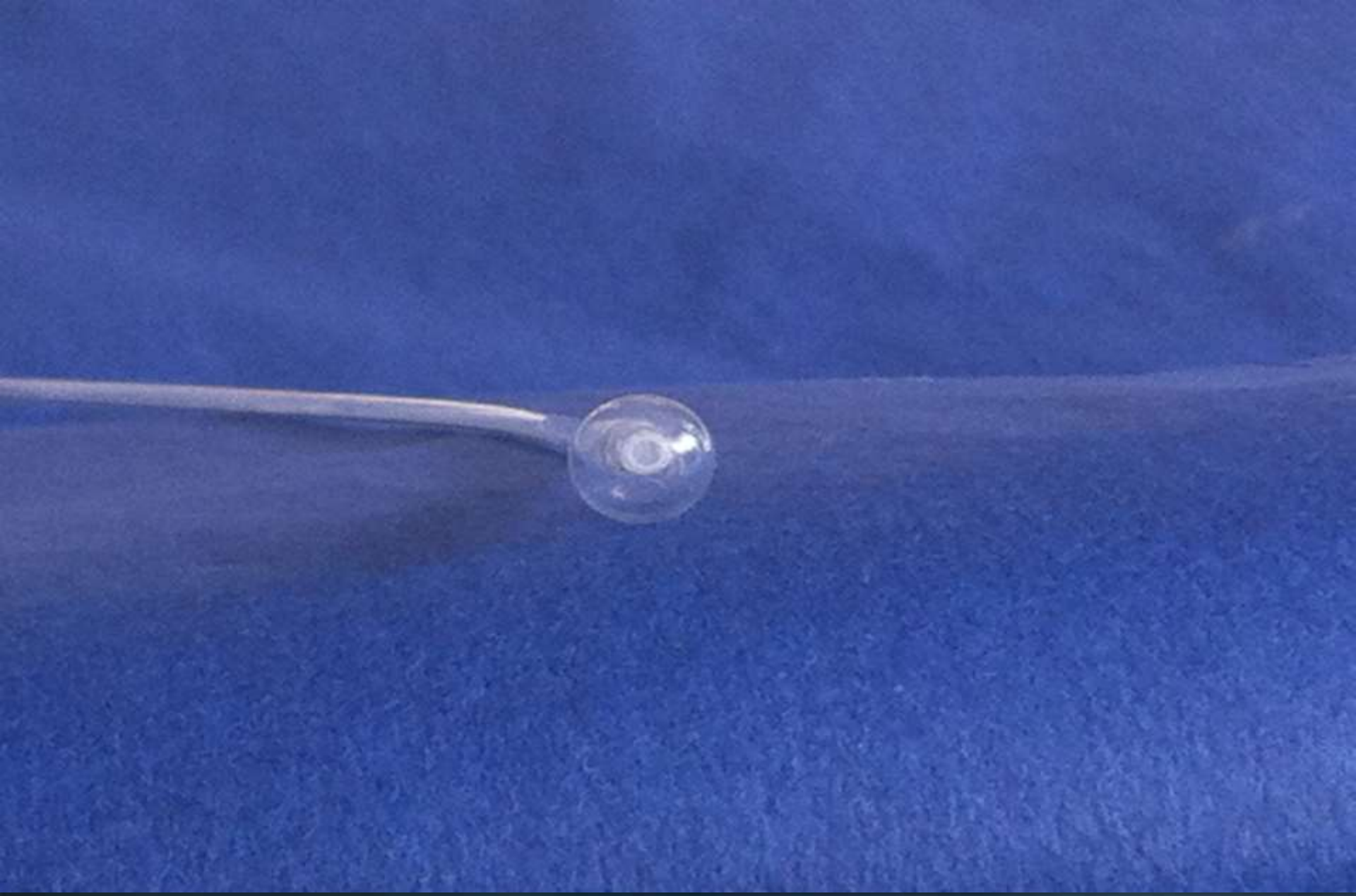
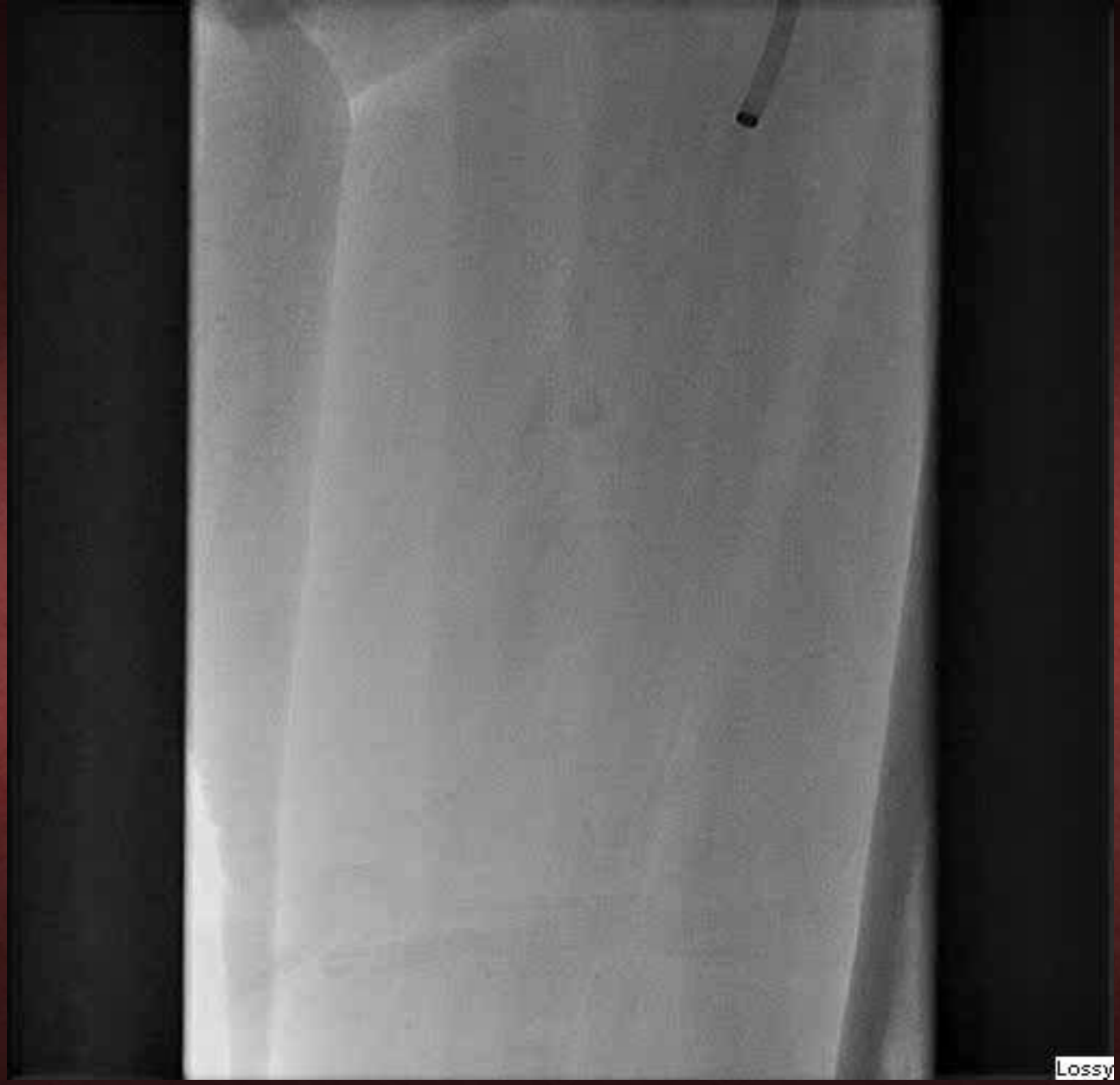
Guide Extension Catheter





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R. Heuser


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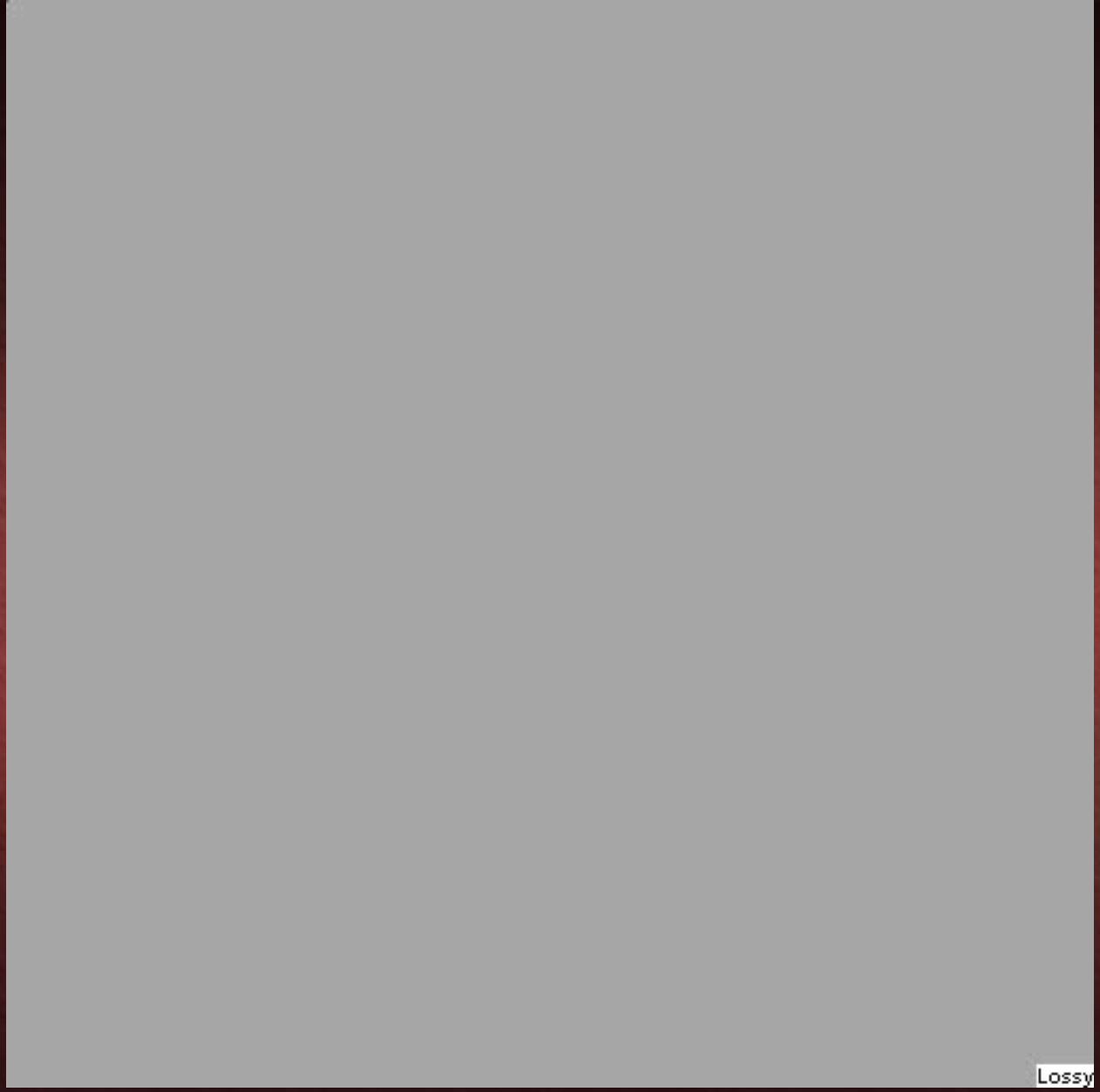
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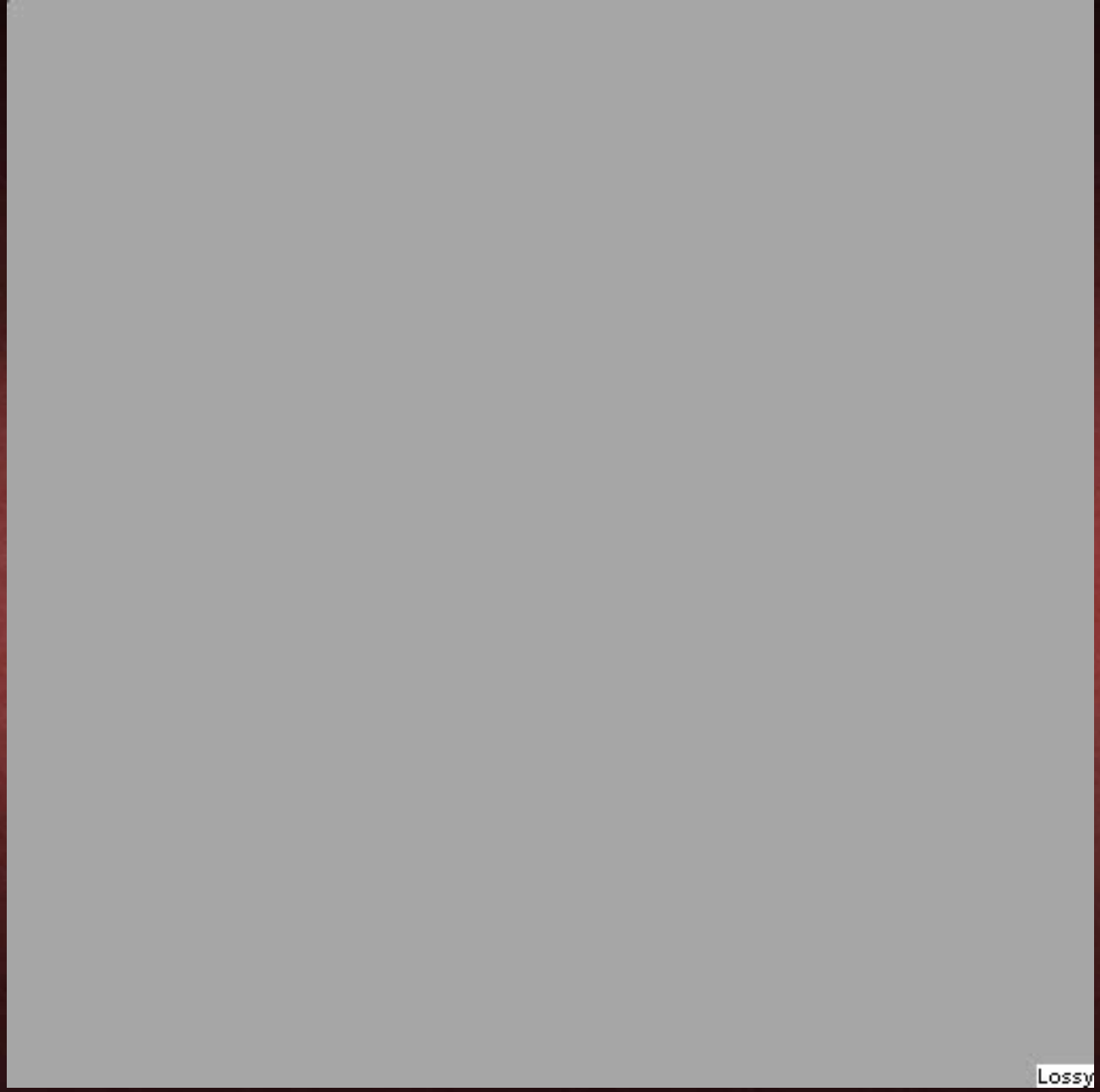
73 year old female with smoking history. She has had multiple PTA procedures of her left SFA. Finally, 3 years ago, she underwent Fem-Pop grafting of her left leg. Following this procedure, her graft became infected requiring surgical removal of the graft. She presents with exercise limiting claudication.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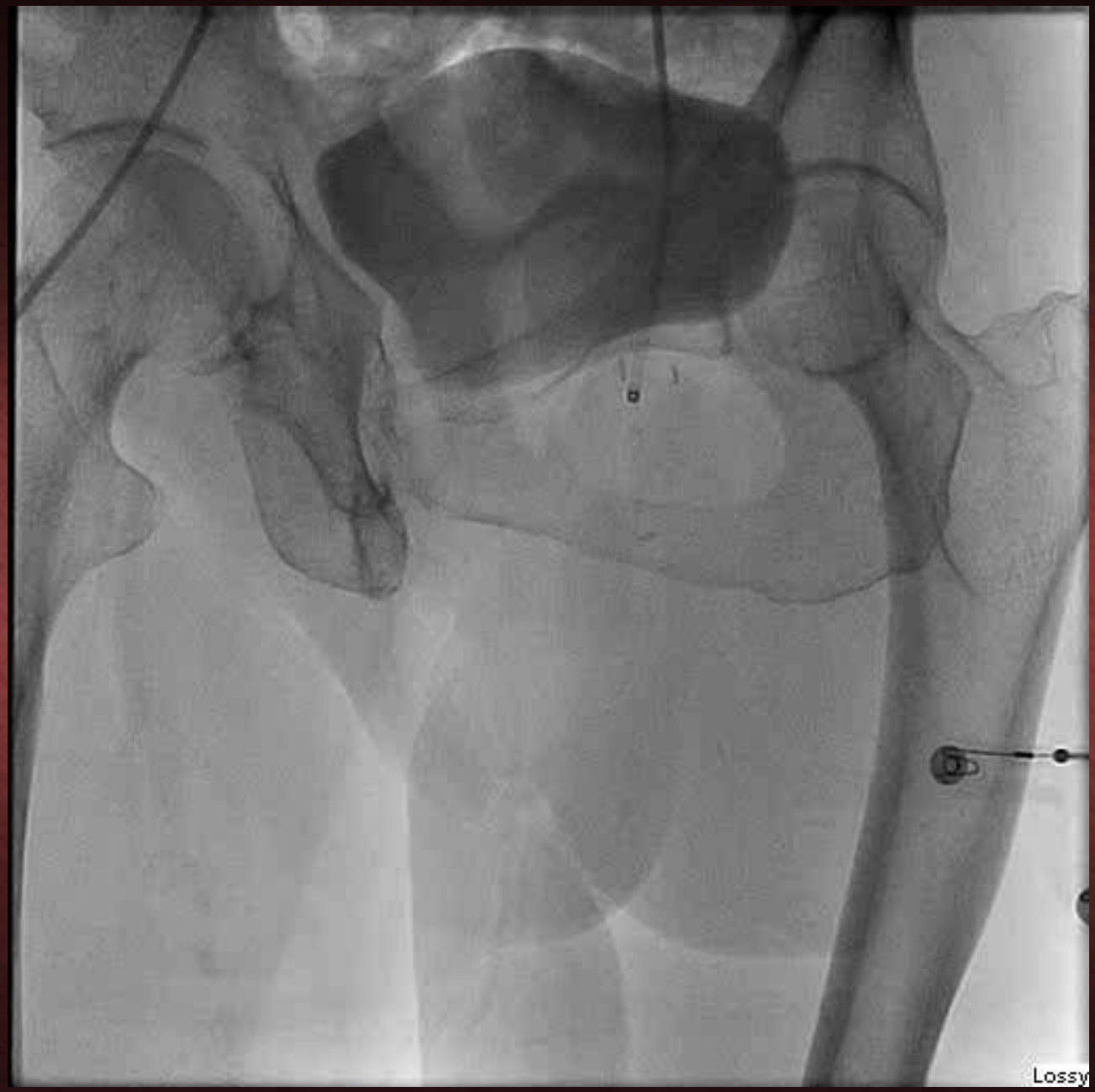
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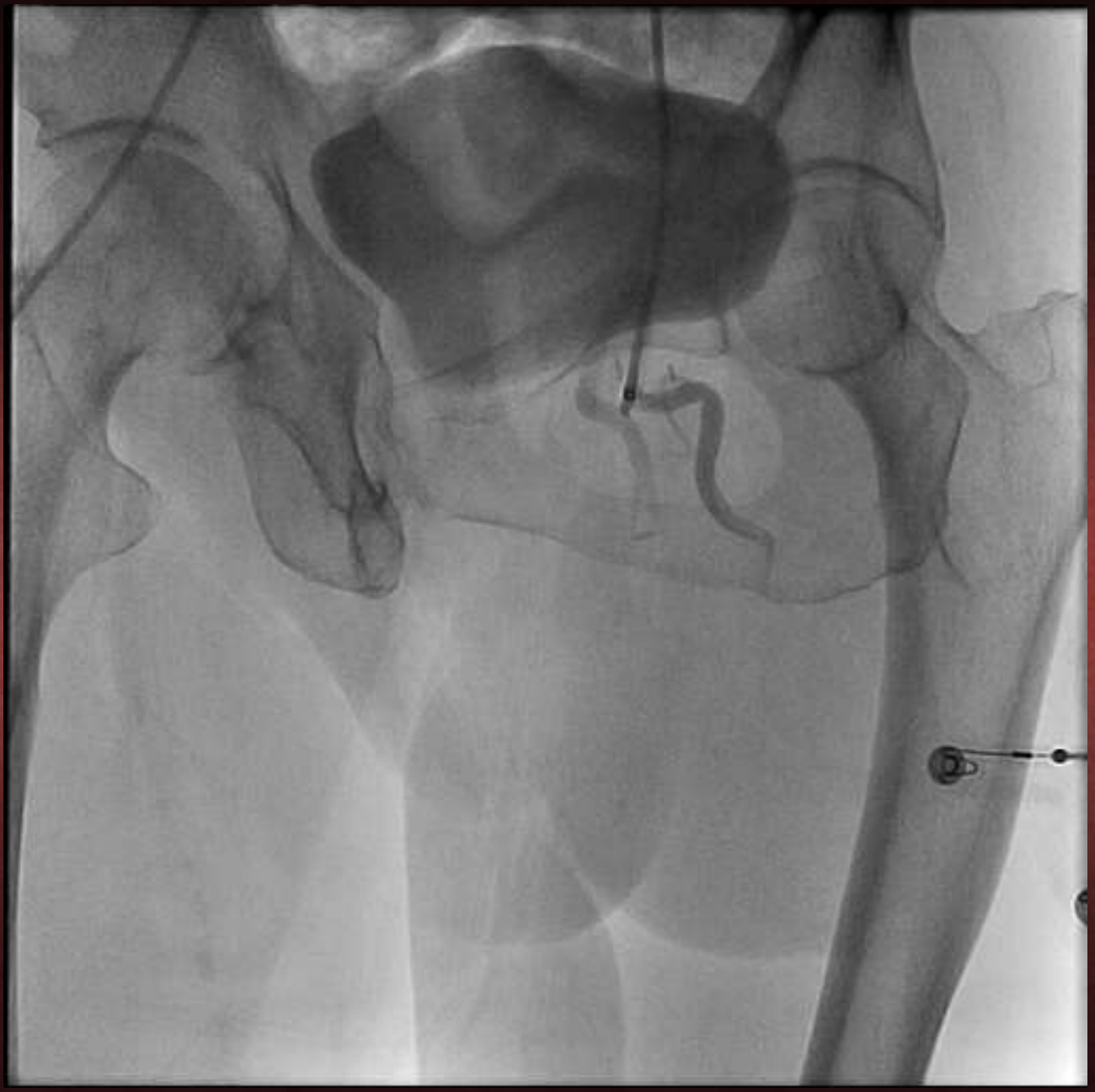

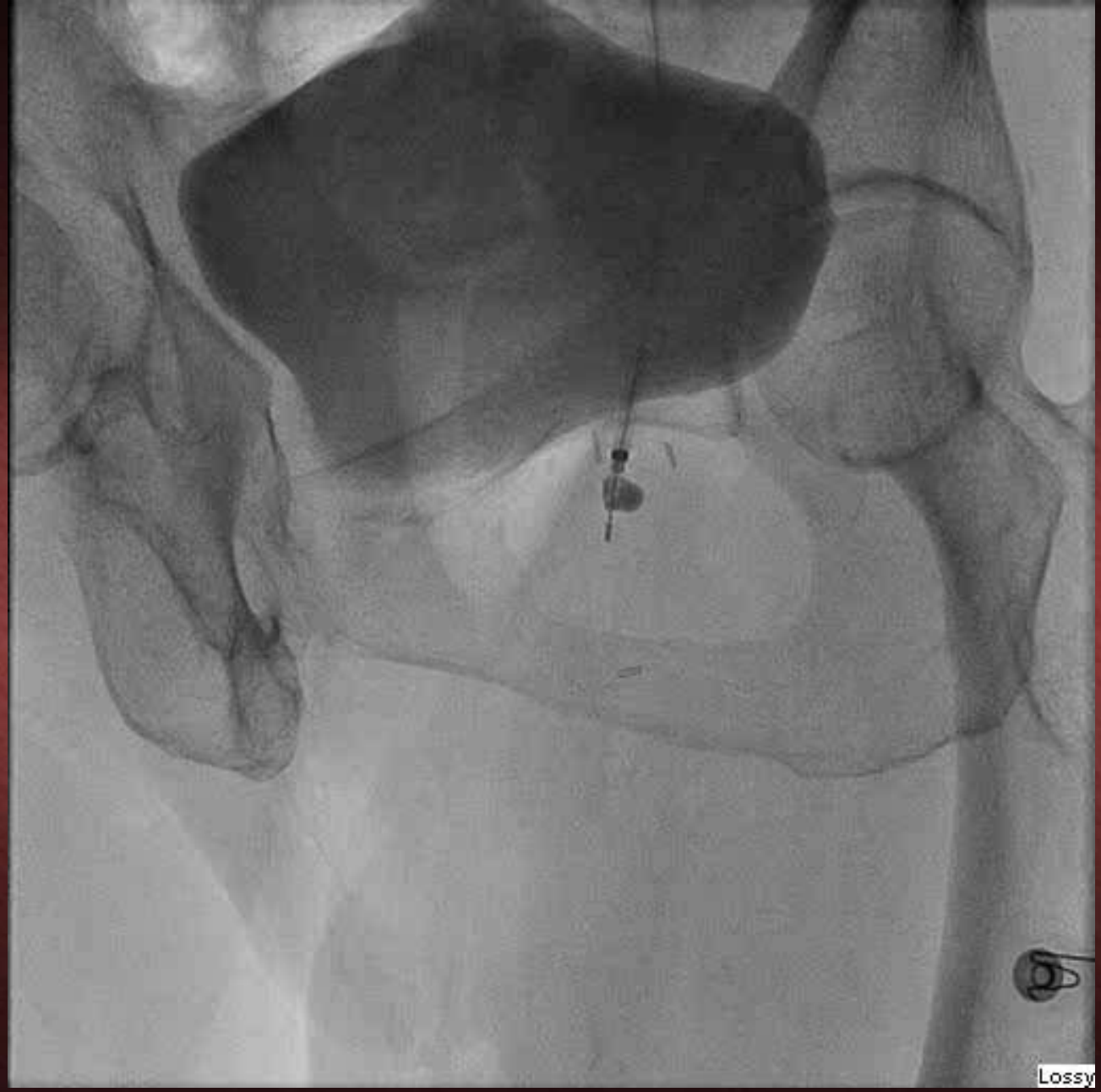
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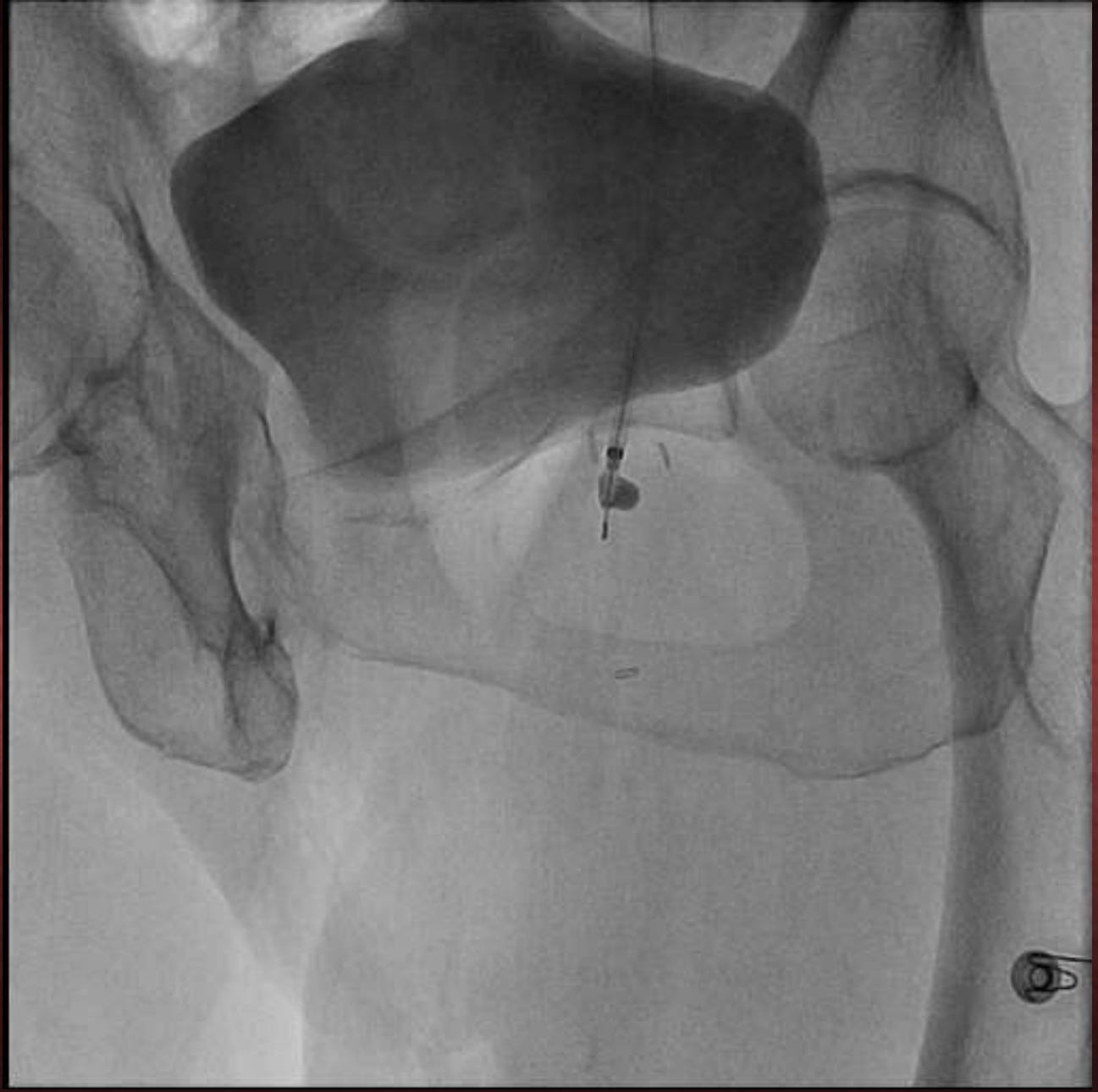
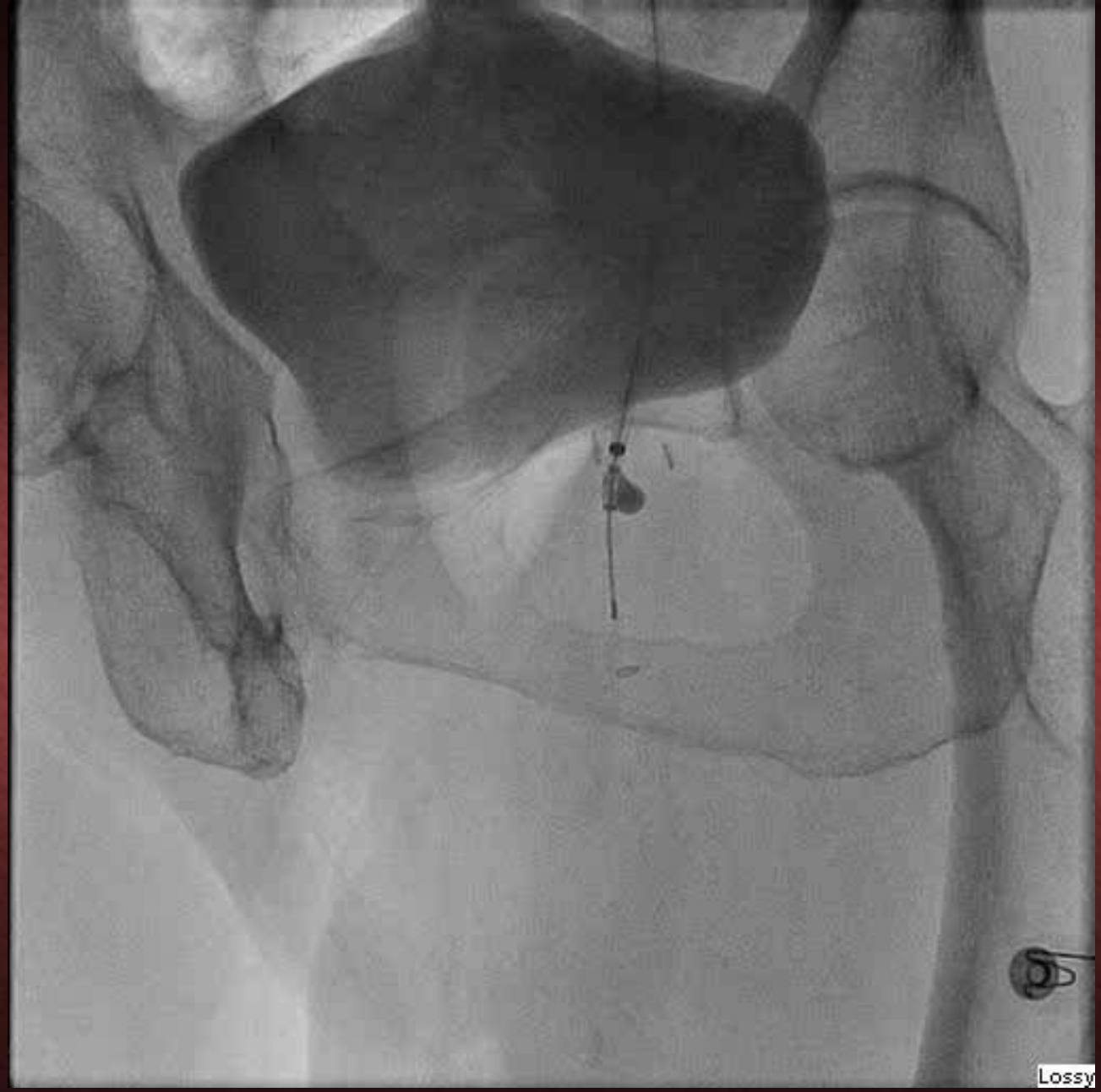



Lossy

R. Heuser


Lossy


Lossy

DCB vs. DES in Long Lesions

Propensity based analysis to define similar cohorts in a real world experience

	DCB N=131	DES N=97
Lesion length	19.4 ±8.6cm	19.5 ±6.5cm
Restenotic lesions	52%	44%
Total occlusion	53%	63%

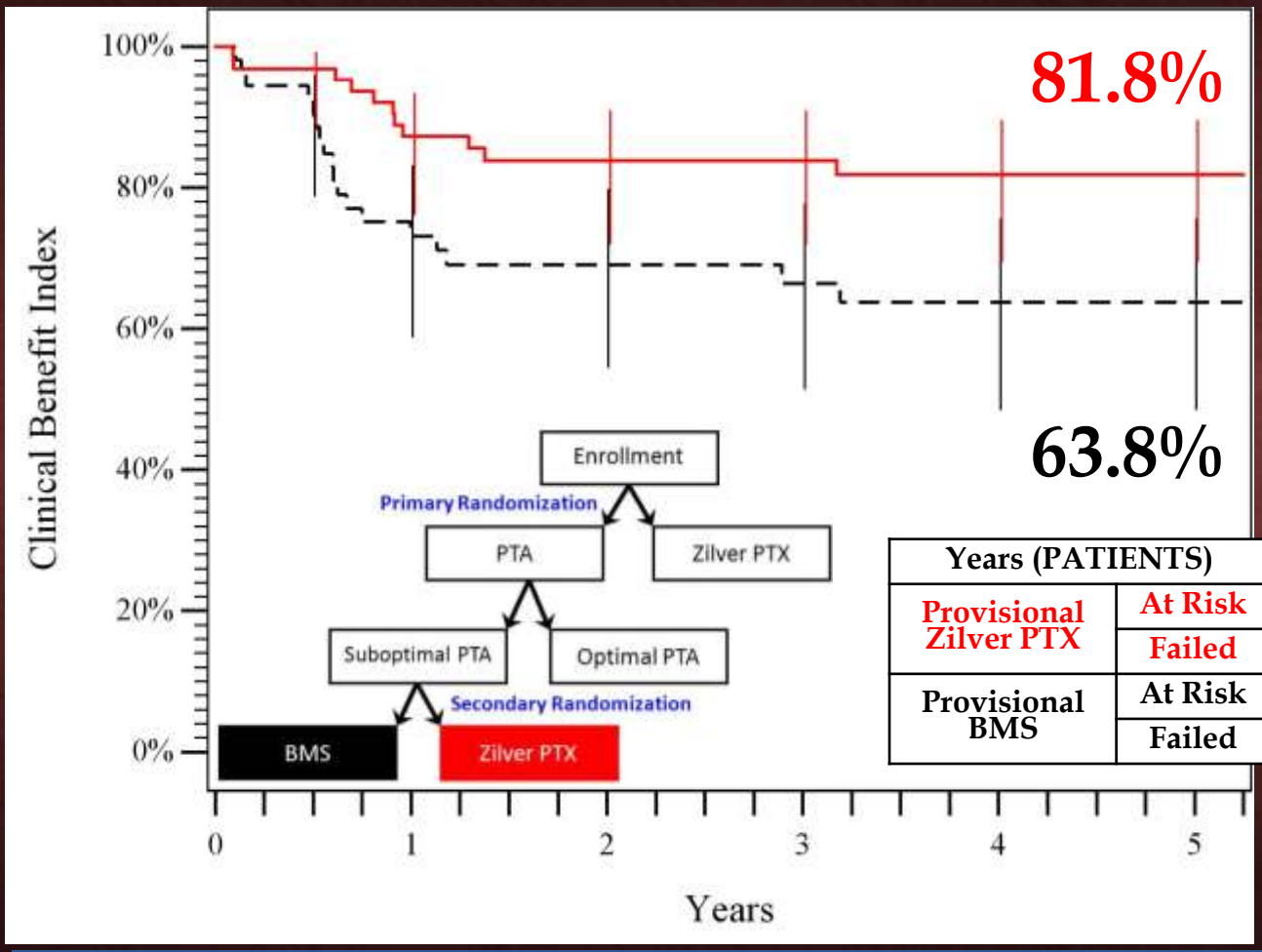
Zeller T, *et al.*, JEVT; 21(3):359-68, 2014 Jun.

DCB and DES in Long Lesions 12 Month Follow Up

	DCB N=131	DES N=97
Restenosis PSV>2.4	24%	30%
TLR	16%	19%

Zeller T, *et al.*, JEVT; 21(3):359-68, 2014 Jun.

5-year Clinical Benefit Index
Provisional Zilver PTX vs. BMS



Provisional Zilver PTX

$p = 0.02$ log-rank

Provisional BMS

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

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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

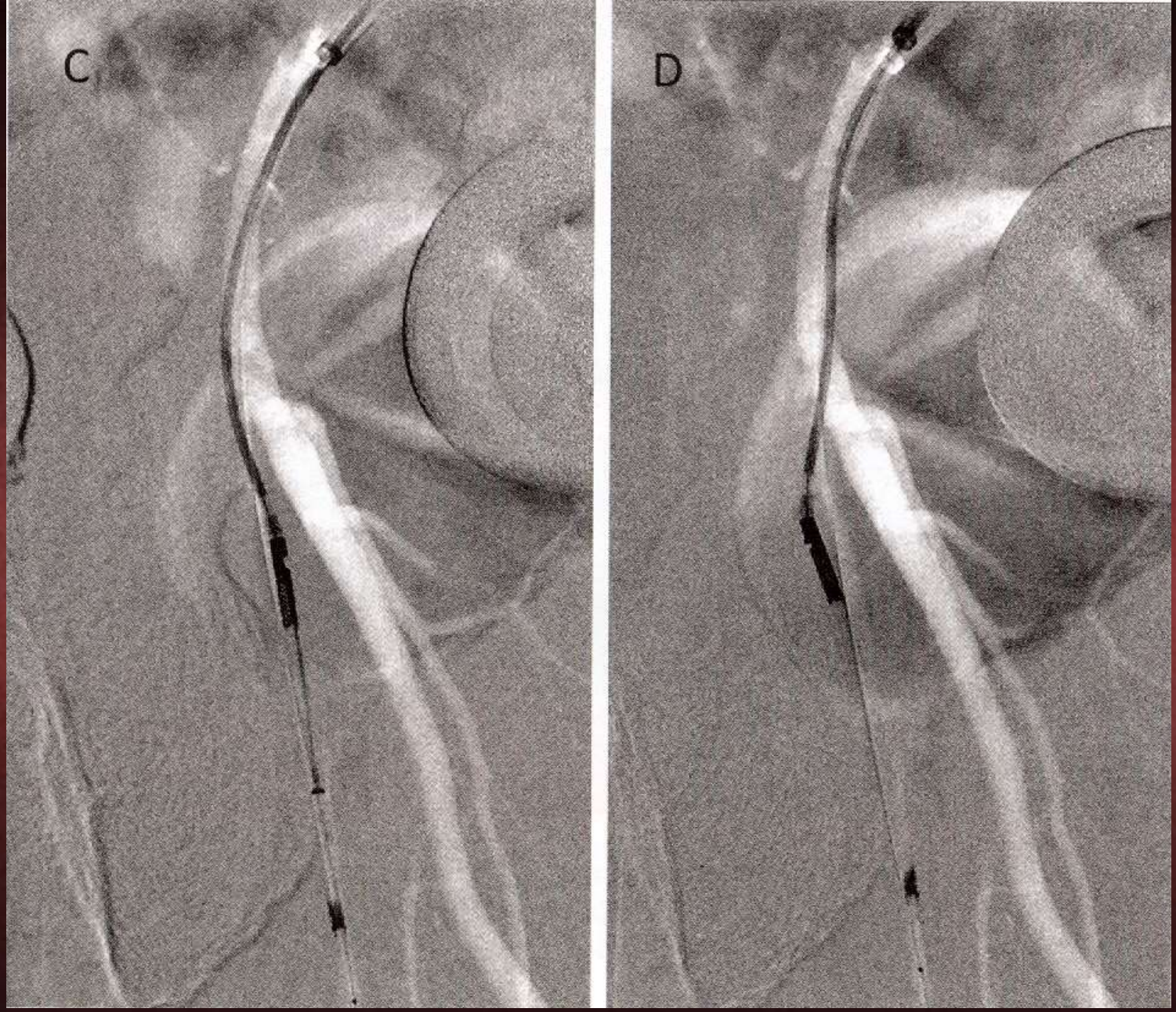
Zilver PTX has excellent durability in challenging SFA environment

So, What's the Potential of DCB in PAD?

- **BIG**
  - Currently replaced PTA
  - Nothing left behind favors first intervention with DCB over BMS
  - DES reasonable first intervention option
- **Tons of excitement** over combination therapy
  - i.e. Atherectomy +DCB
    - REALITY

Sabine Steiner, MD, MSc


A
B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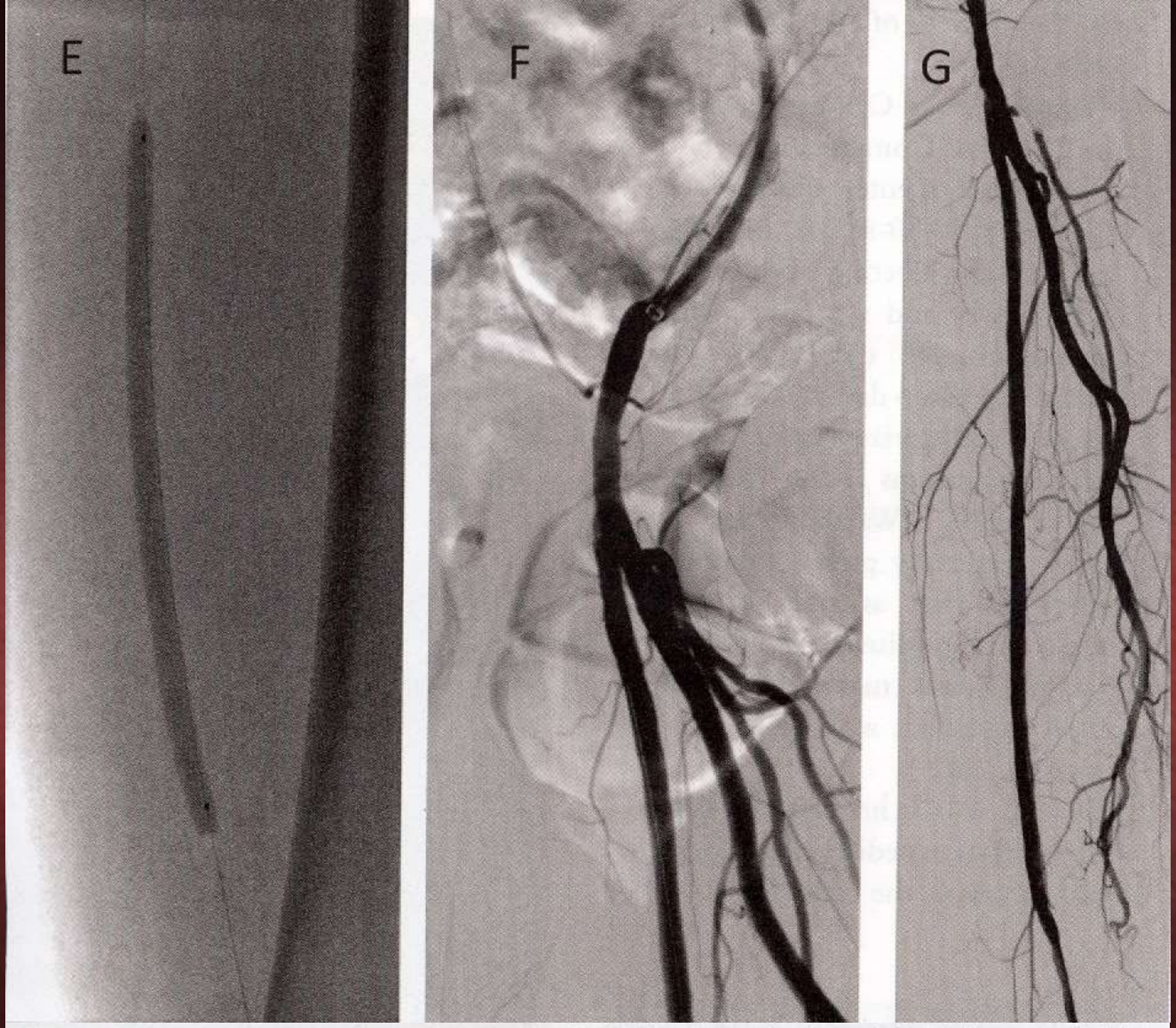


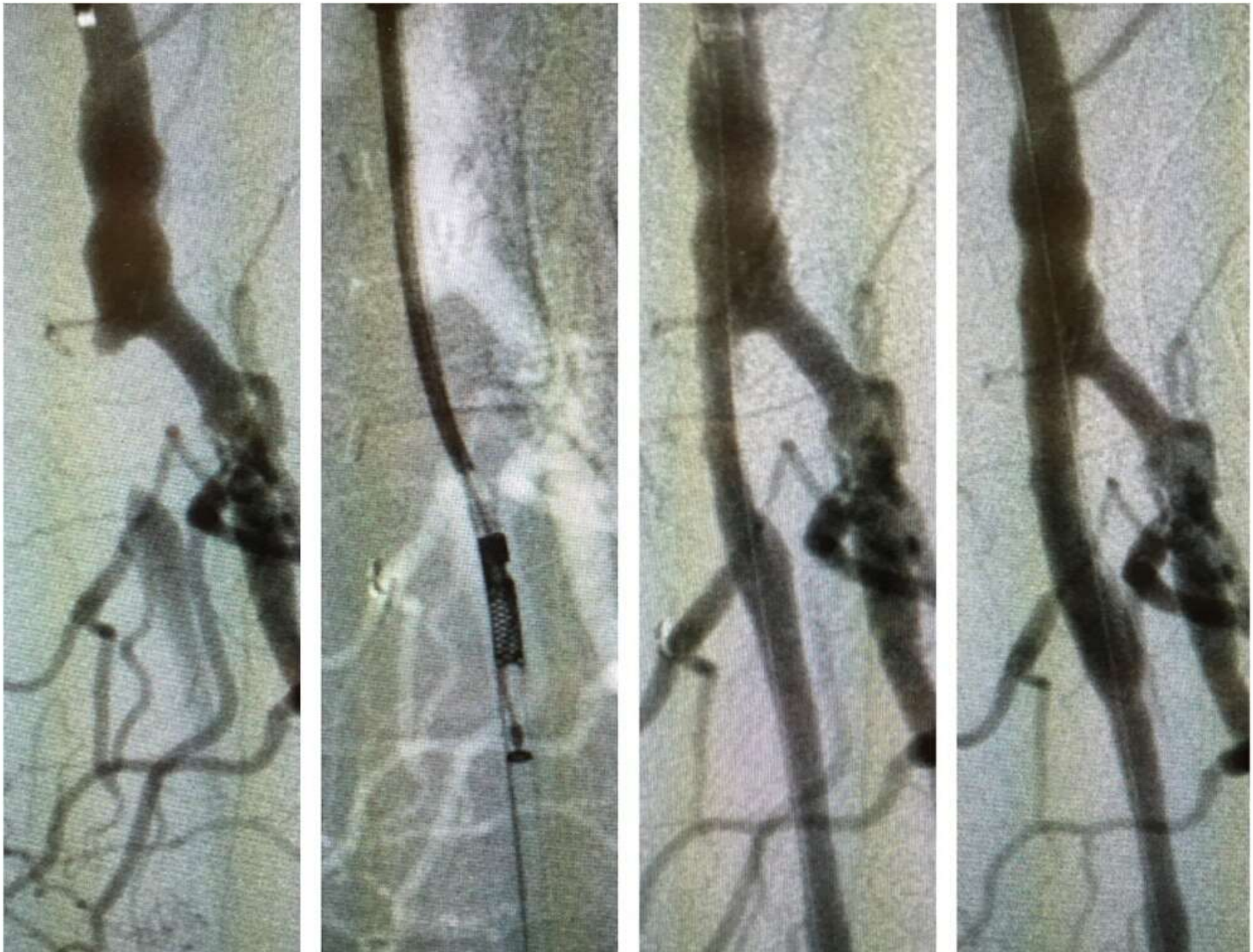
Figure 2. A sample case from the study. A-B) Flush occlusion of the left superficial femoral artery (SFA). C-D) After antegrade lesion crossing, mechanical debulking using the Turbohawk device (ev3/Medtronic) with distal embolic protection. E) Angioplasty of the SFA with 3 drug-eluting balloons (IN.PACT Pacific 2x5/120, 5/80mm). F-G) Good final results without relevant residual stenosis.

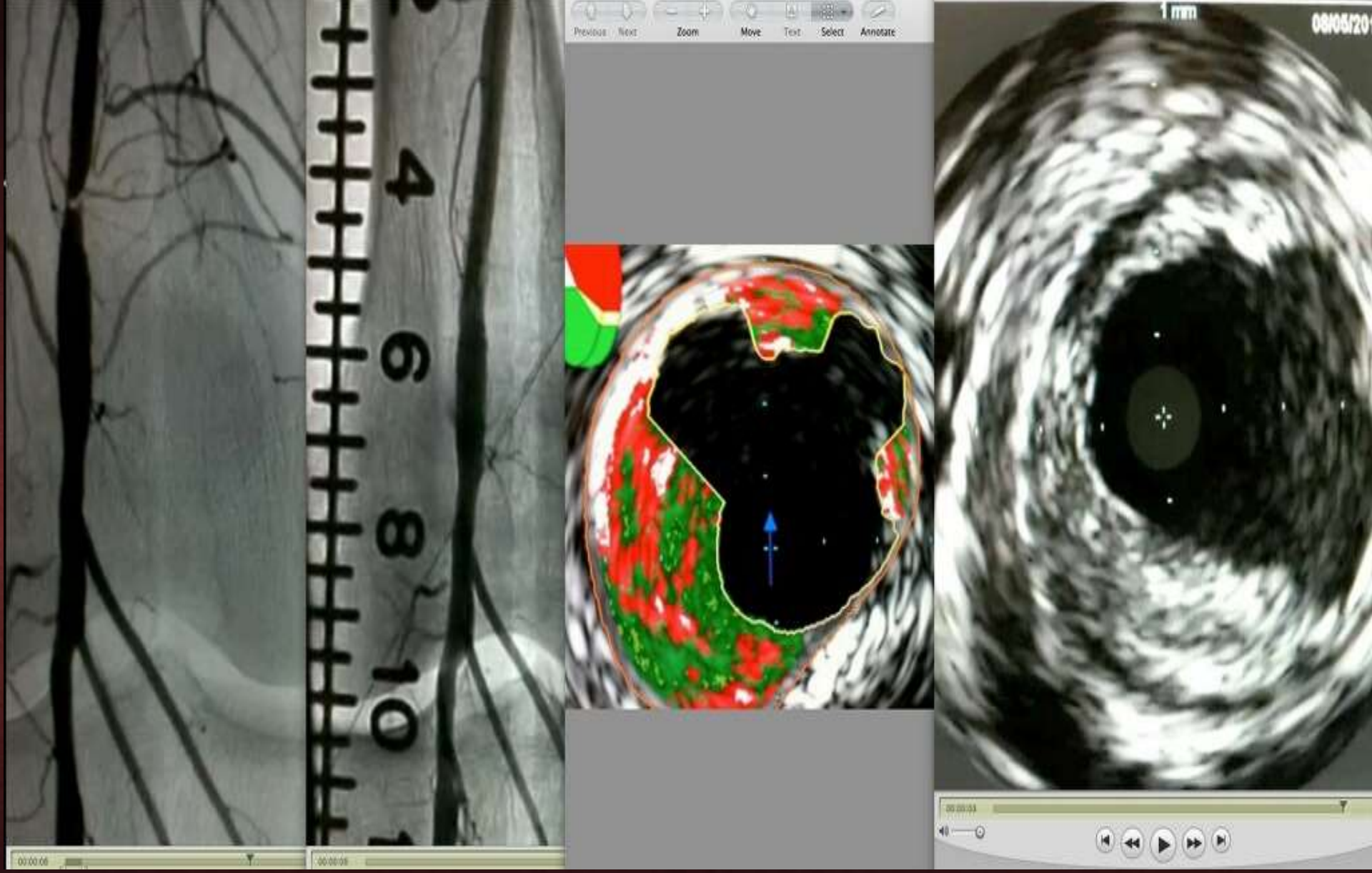
DEB In.PACT SFA

- Silverhawk/Turbohawk
- Primary patency 78.9% vs 50.1% with balloon
- Freedom from TLR 91% DCB vs. 72.2% PTA

Silverhawk/Turbohawk Definite LE

- 95% salvage in CLI
- 78% patency in claudicates 12 months (seem to be equal in diabetics and non-diabetics)

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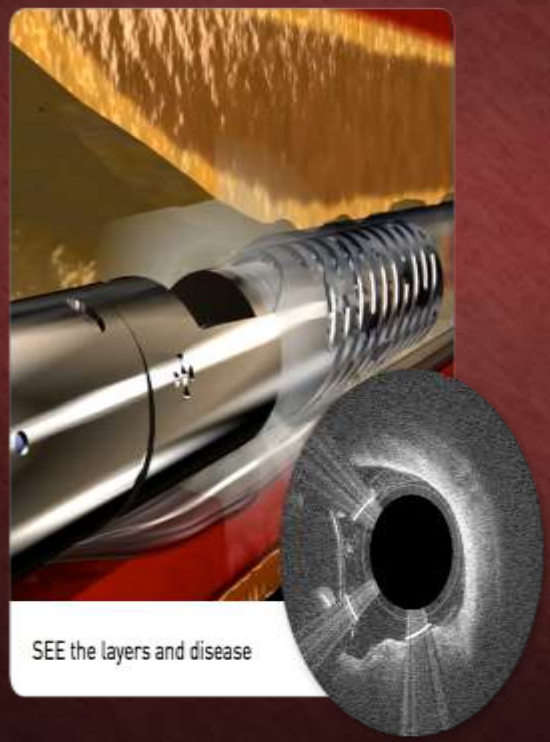
PANTHERIS BENEFITS

VISUALIZE AND REALIZE

SEE

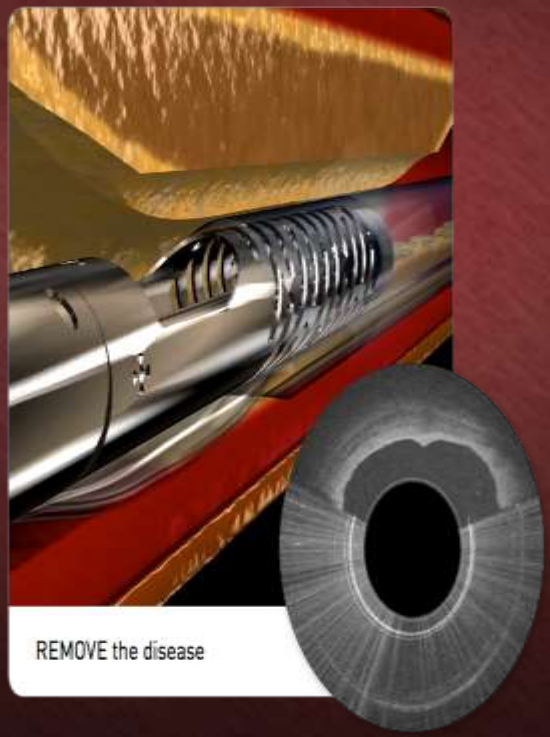


SEE the layers and disease

DIRECT

DIRECT treatment to preserve the EEL

REMOVE



REMOVE the disease

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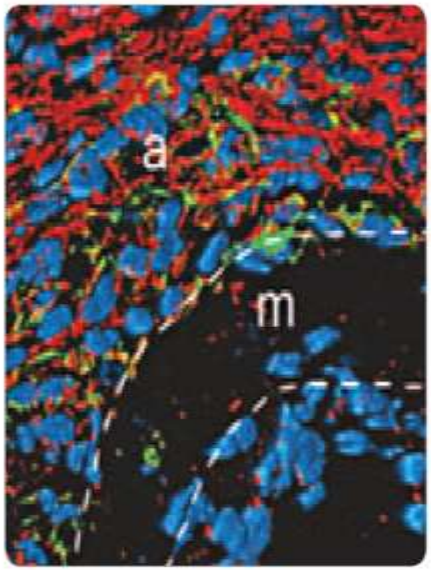
SCIENTIFIC THEORY

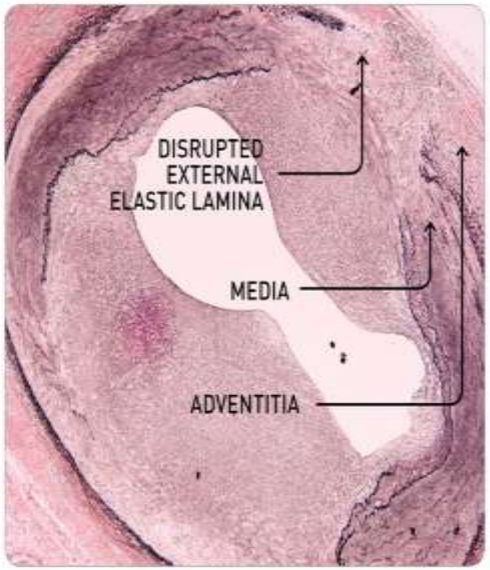
MULTI-LEVEL EVIDENCE DEMONSTRATING ADVENTITIAL DISRUPTION ACCELERATE RESTENOSIS

CELLULAR LEVEL[2]



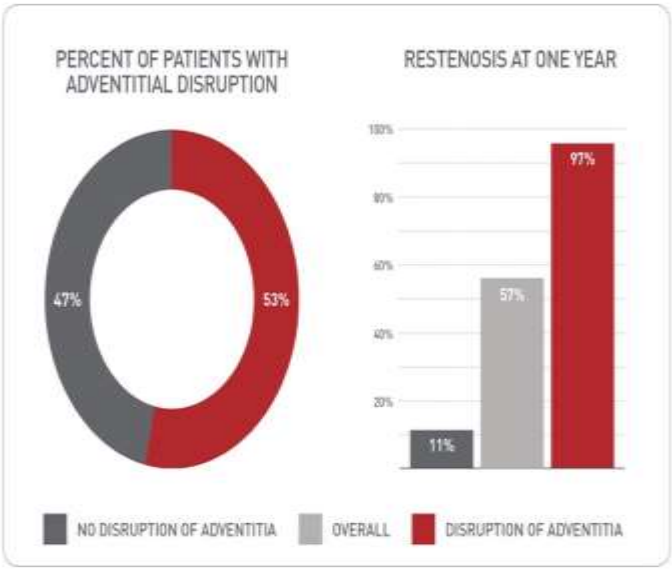
A peer reviewed study from Sanford Burnham Institute demonstrates that disrupting the black line causes stem cells to migrate inward from the adventitia, forming neointimal hyperplasia.

HISTOLOGIC LEVEL[1]



The above histology image shows a balloon overstretch injury model demonstrating that disruption to the black line leads to accelerated restenosis.

CLINICAL LEVEL[3]

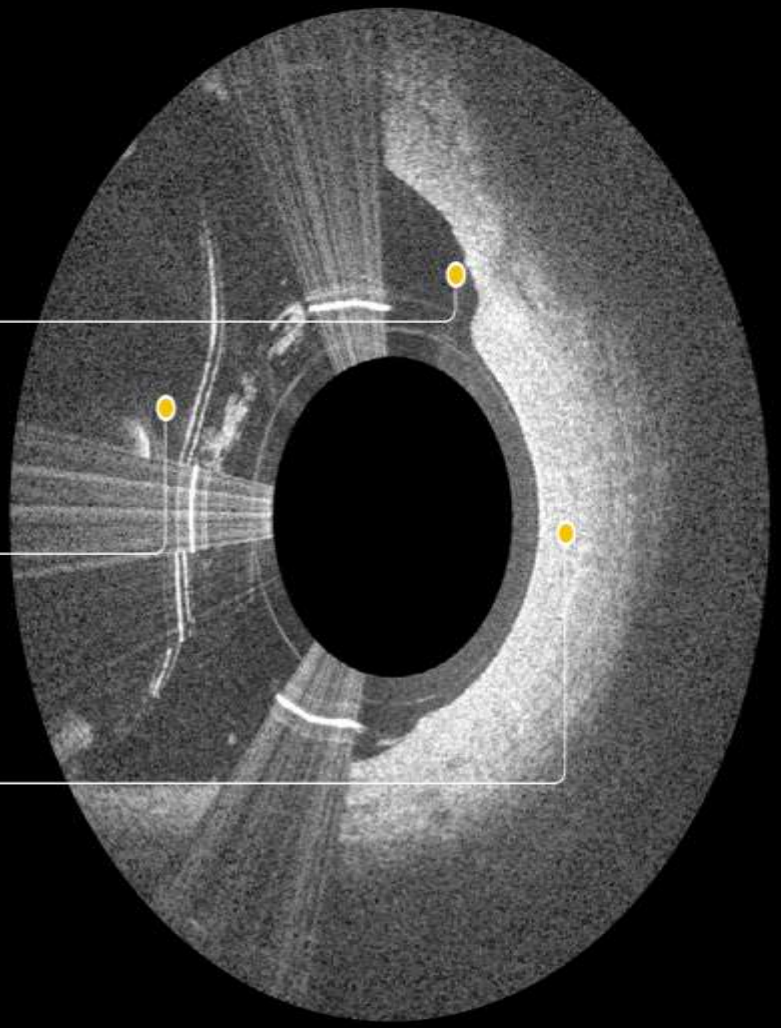


One hundred and sixteen (116) patients were treated with directional atherectomy at Mount Sinai Medical Center, NY. Adventitial injury were identified in 62 (53%) of patients. Restenosis, measured by duplex, was significantly higher in patients with adventitial or medial injury (97%, 60/62) as compared to those without (11%, 6/54). The results suggest that adventitial or medial injury is the primary cause of restenosis in TASC A/B lesions treated with directional atherectomy.

[1] Pathology image on file at AvingerCath, Stanford MU Rev Res 2013;36: 134-144.
[2] Tigges, Komatsu, SciAdv.gr. Sanford-Burnham Medical Research Institute, Cancer Center, La Jolla, Calif.
[3] Prakash Krishnan, MD. ACC Moderated Poster Contributions Session Title: Endovascular Therapy: State of the Science I Abstract Category: 34. Vascular - Pathophysiology - Clinical Presentation Number: 1120-35

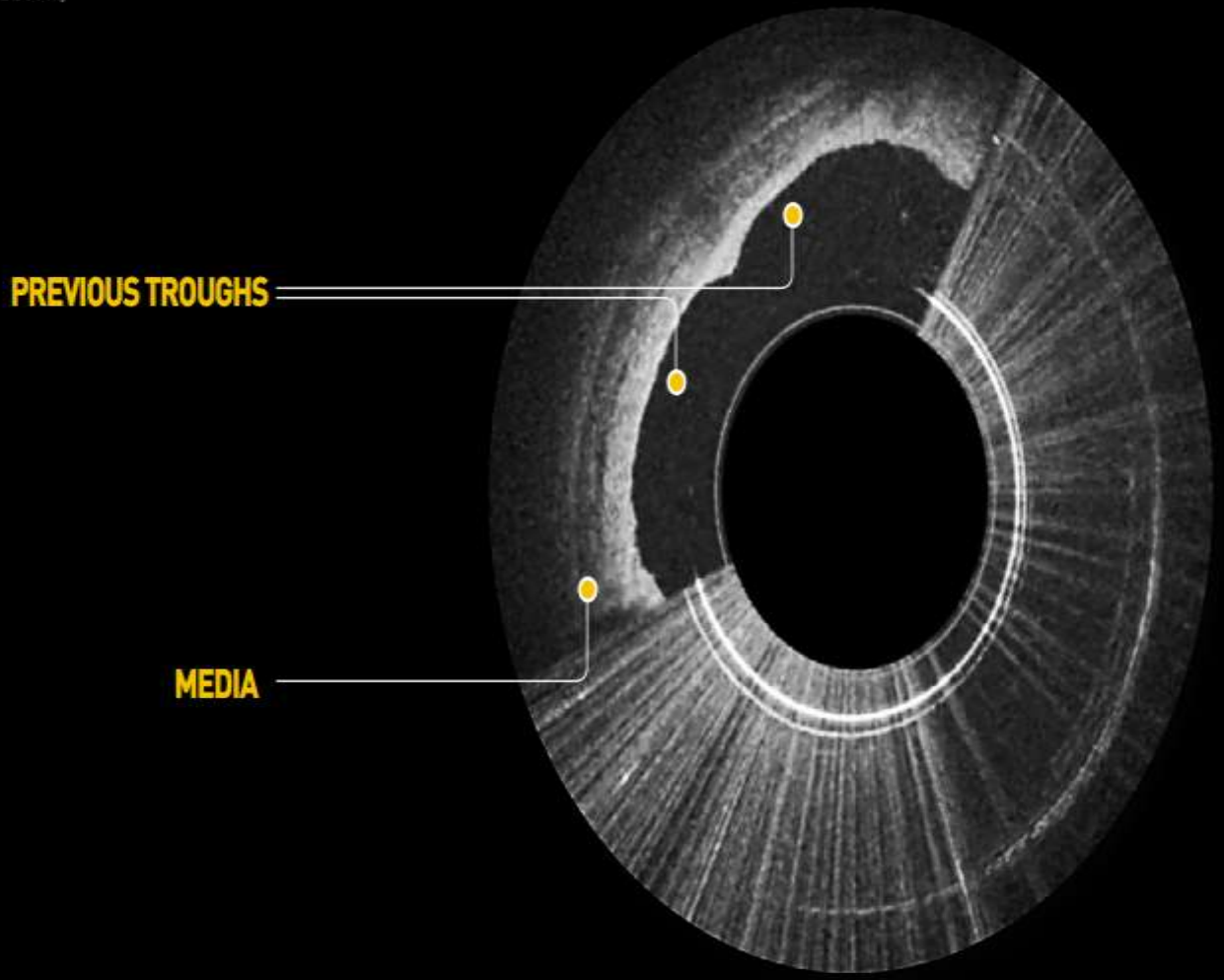
PANTHERIS OCT IMAGE

SEE DISEASE AND OTHER FEATURES (ACTIVE)

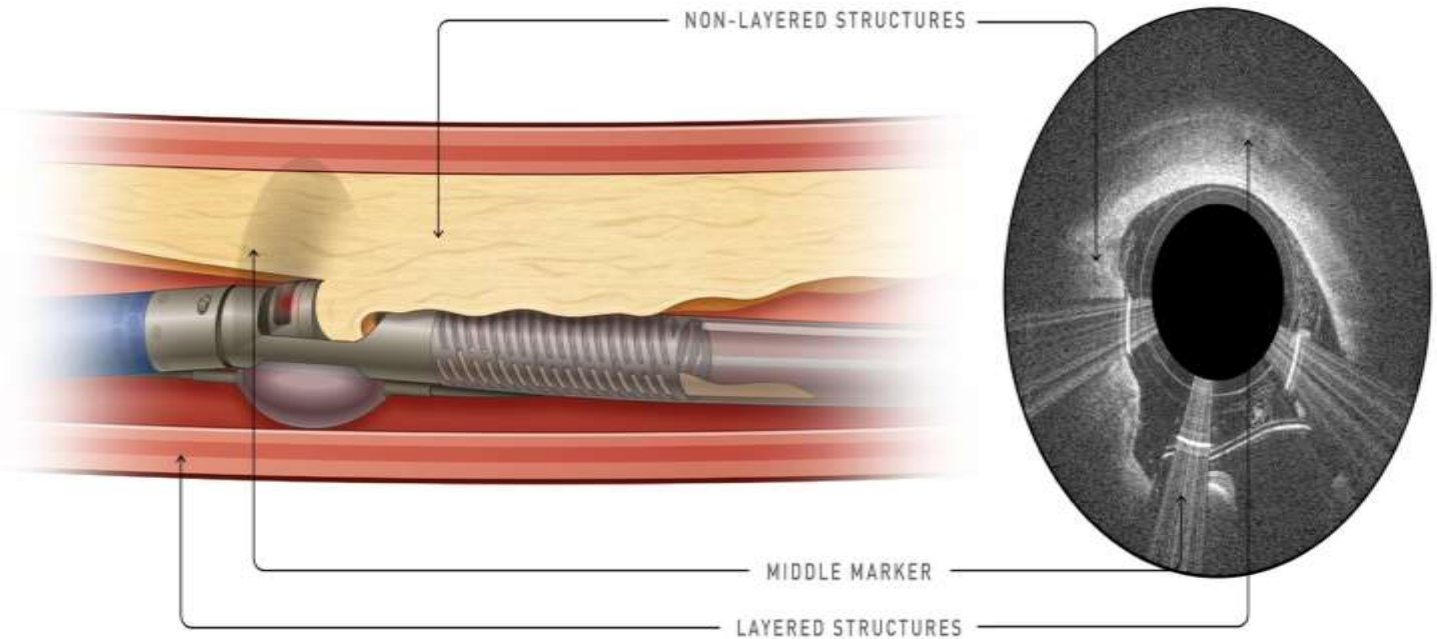


PANTHERIS OCT IMAGE

SEE PREVIOUS TROUGHS (PASSIVE)



PANTHERIS
LUMIVASCULAR ATHERECTOMY

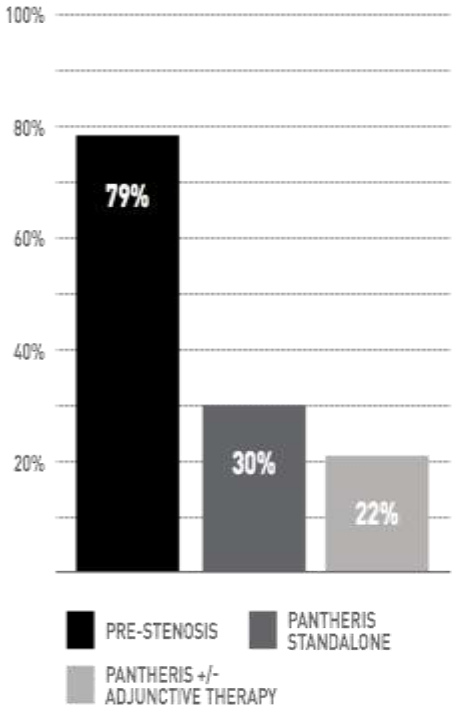


FLUOROSCOPY
Unclear position within artery

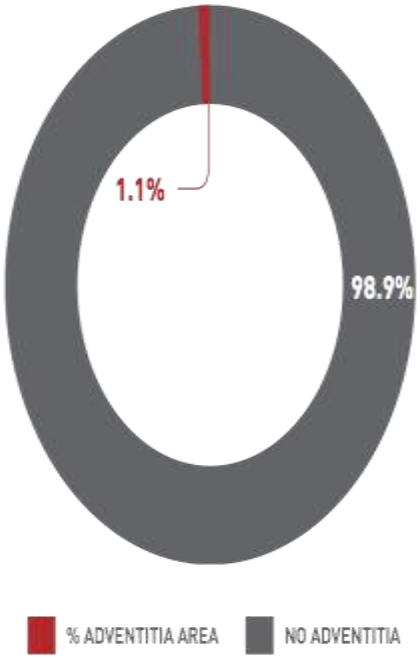
VISION IDE
PANTHERIS CLINICAL DATA

130 PATIENTS | **20** SITES | **164** LESIONS | **7.3 ± 4.1cm** MEAN LESION LENGTH | **SFA-POPLITEAL** LESION LOCATION

LUMINAL GAIN | 72%



ADVENTITIA | ANALYSIS



TLR 6 MONTHS | 8%

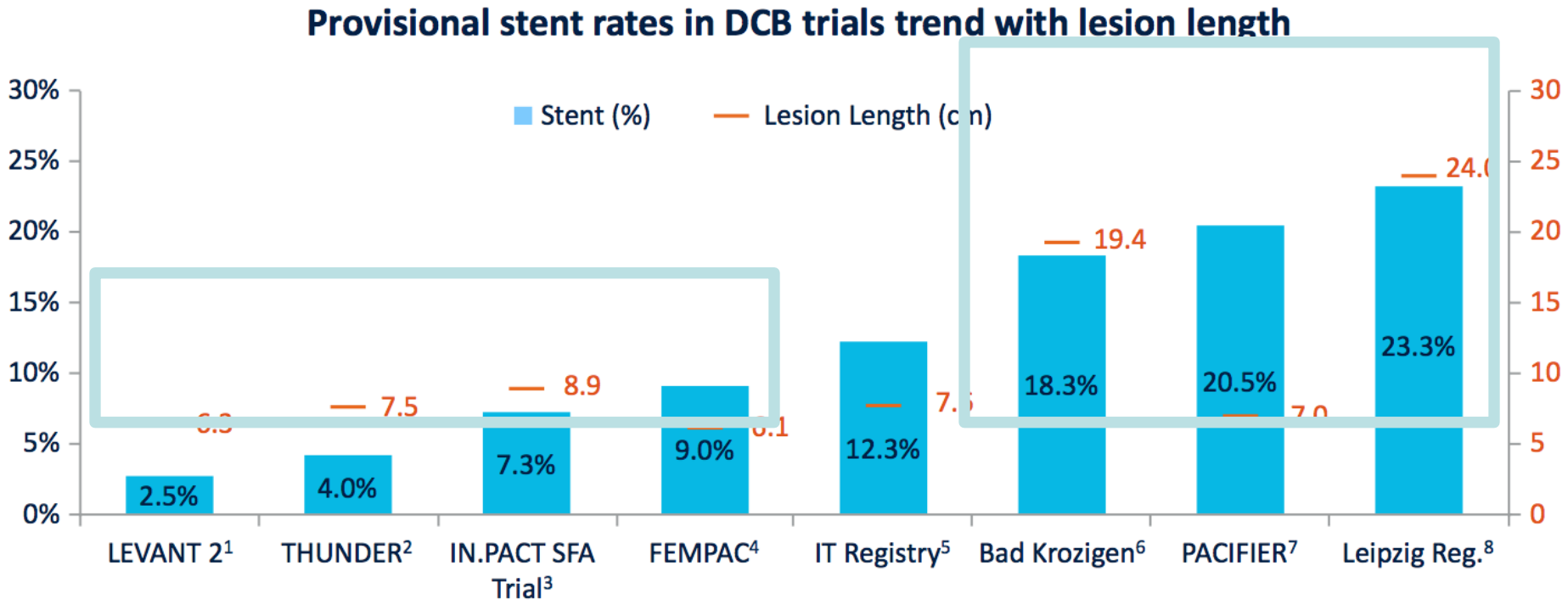
0%
DISSECTIONS

0%
PERFORATIONS

DCBs and Provisional Stent Usage

- Low rates of provisional stent usage in randomized trials
- Real-world data suggests bailout stent rate of 15-30%
  - Higher stent rate in longer lesions

DCBs and Provisional Stent Usage



R. Heuser

Stents do better than PTA, but..

- *Traditionally (STNS),* the longer the lesion, the worse the patency, and there are ↑ late problems
- They don't work well in heavy CA++
- "They keep coming back" and "they are harder to treat"

Real-World Applications

- Outcomes With Long Lesions
- Bailout Stenting
- Calcified Lesions and Adjunctive Atherectomy
- Application to Critical Limb Ischemia

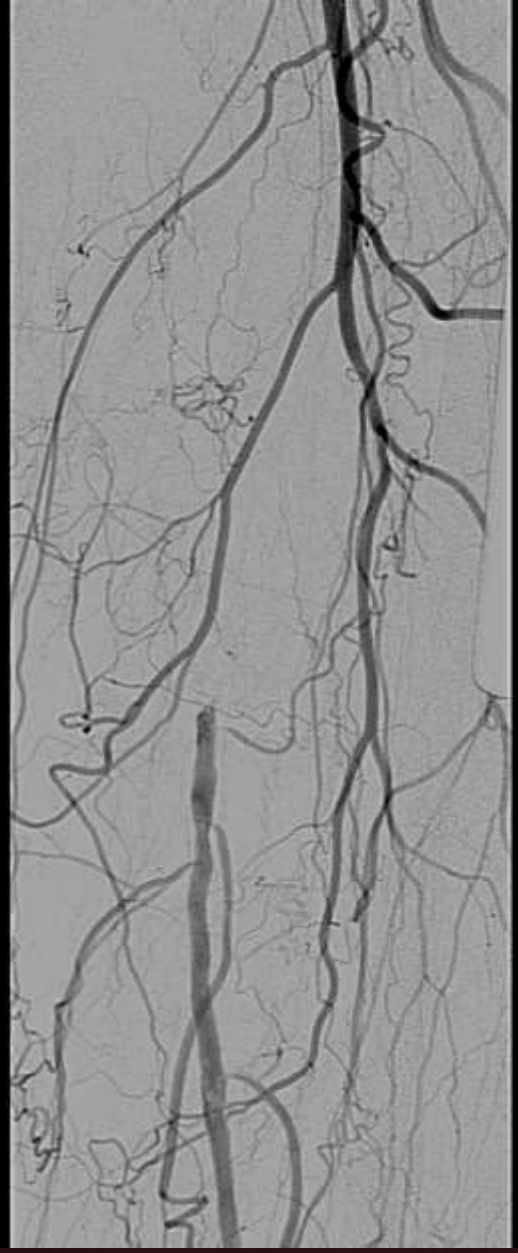
What is "Real World?"

- Clinical trials of DCBs had mean lesion length of 60-90 mm.

- Registries suggest mean lesion lengths of 120 mm in practice.
  - Lutonix global registry: 101mm mean length
  - In.PACT global registry: 122mm mean length

TCT 2015, presented

VS.



2-16

2-10..19

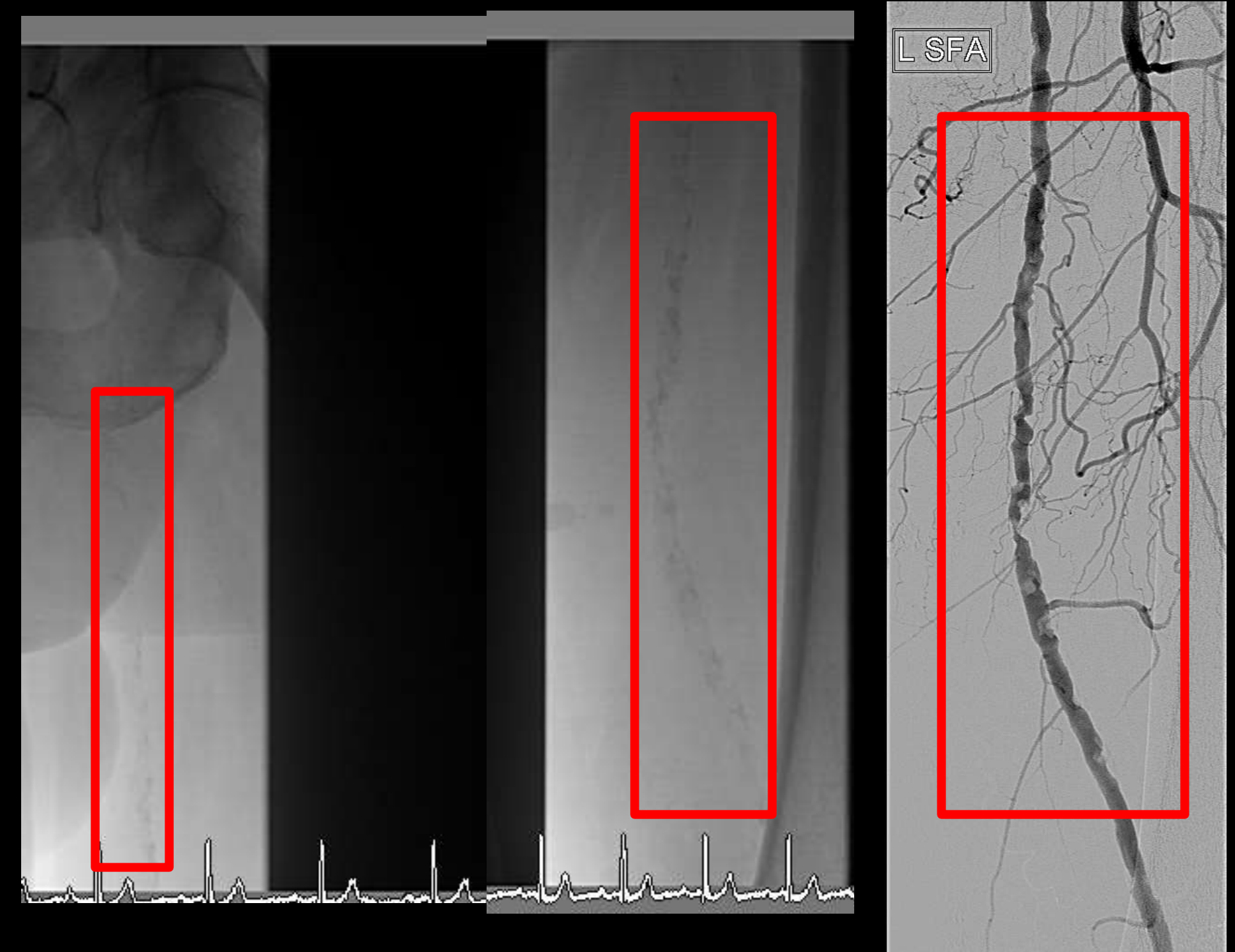
R. Heuser

When to Stent?

- Flow-limiting dissection.
- Persistent stenosis.
- Typically “spot stenting”

DCBs and Calcium

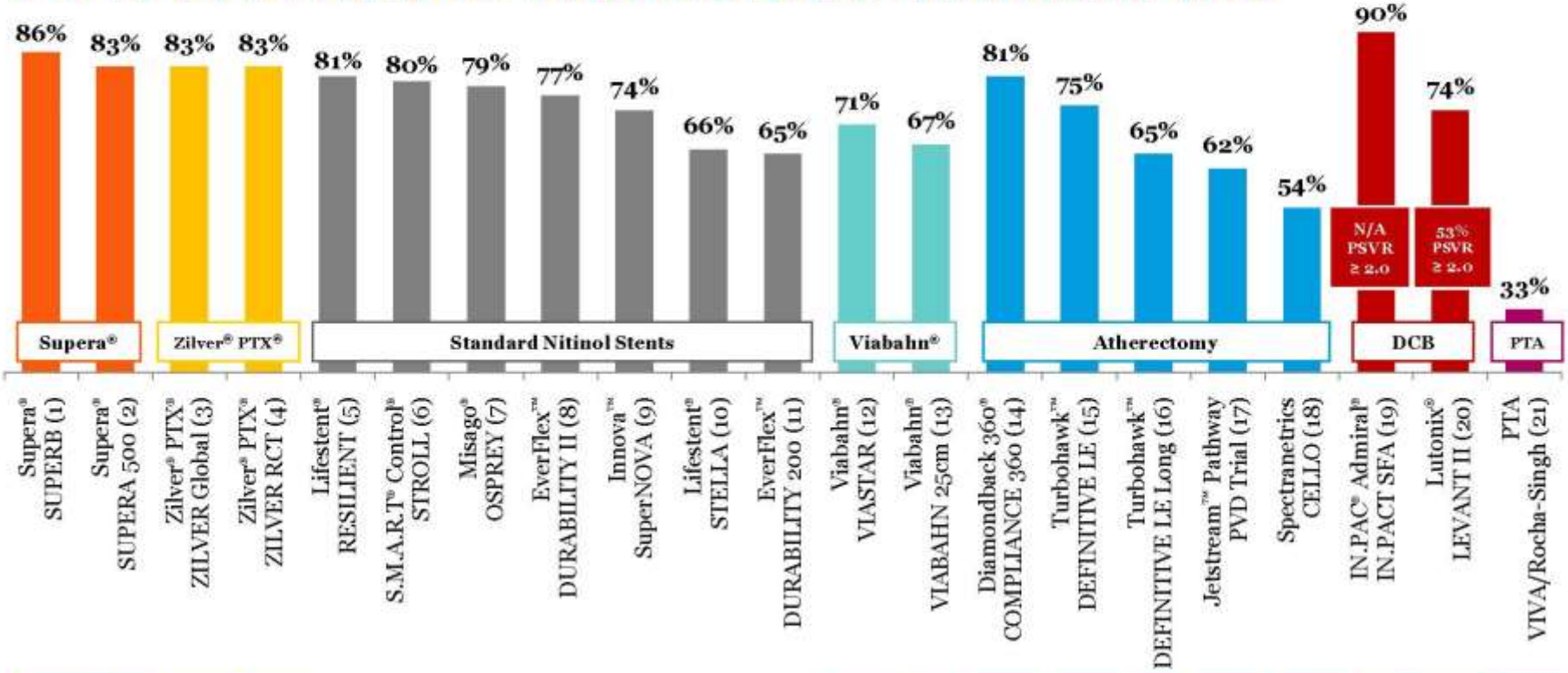
- Trials of DCBs did not include patients with severe calcification.
- Calcium is associated with higher rates of dissection and poor long-term outcomes.
- Modifying calcium may allow lower pressure balloon inflation.


L SFA

Application of DCBs to CLI

- Current trials of DCBs were studied in patients with claudication or rest pain
- Little data available in patients with ischemic ulceration
- Note of caution from BTK DCB studies

12-MONTH PRIMARY PATENCY (K-M) FOR SFA ENDOVASCULAR THERAPIES

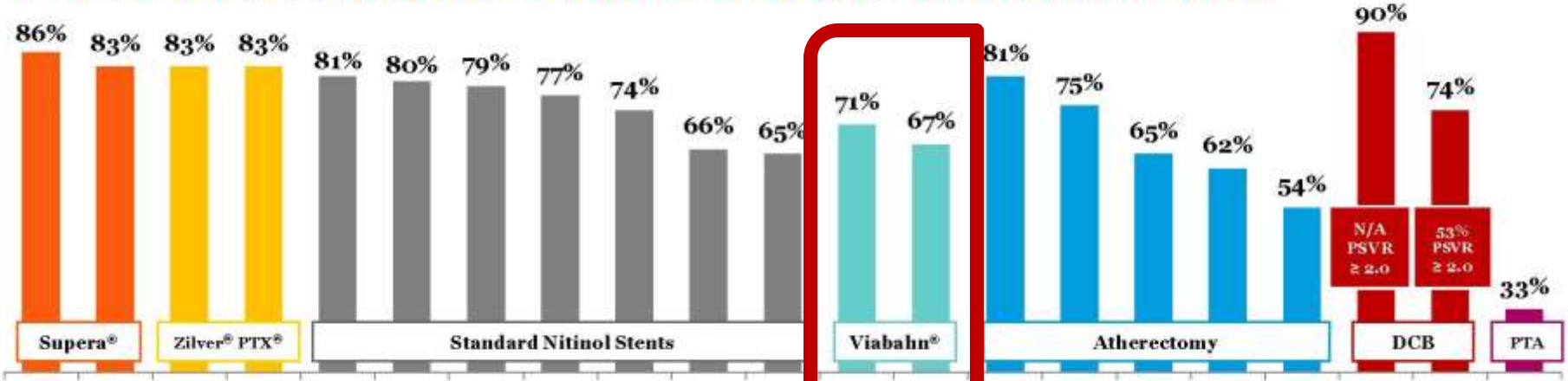


n	264	470	787	241	134	250	261	287	299	58	100	72	71	25	671	232	172	65	220	316	307
cm	7.8	12.6	10	5.5	7.1	7.7	8.4	8.9	9.3	22	24	19	27	5.6	8.1	14.6	2.7	5.6	8.9	6.3	8.7
PSVR	2	2.4	2	2	2.5	2	2	2	2.4	2.4	2.4	2.5	N/A	2.5	2.4	2.4	2.4	N/A	2.4	2.5	N/A

See appendix for sources.
Data differences depicted between these trials may not be statistically significant or clinically meaningful and different clinical trials may include differences in the demographics of the patient populations.

Important Safety Information referenced within

12-MONTH PRIMARY PATENCY (K-M) FOR SFA ENDOVASCULAR THERAPIES



	Supera® SUPERB (1)	Supera® SUPERA 500 (2)	Zilver® PTX® ZILVER Global (3)	Zilver® PTX® ZILVER RCT (4)	Lifestent® RESILIENT (5)	S.M.A.R.T® Control® STROLL (6)	Misago® OSPREY (7)	EverFlex™ DURABILITY II (8)	Innova™ SuperNOVA (9)	Lifestent® STELLA (10)	EverFlex™ DURABILITY 200 (11)	Viabahn® VIASTAR (12)	Viabahn® VIABAHN 25cm (13)	Diamondback 360° COMPLIANCE 360 (14)	Turbohawk™ DEFINITIVE LE (15)	Turbohawk™ DEFINITIVE LE Long (16)	Jetstream™ Pathway PVD Trial (17)	Spectranetics CELLO (18)	IN.PAC® Admiral® IN.PACT SFA (19)	Lutonix® LEVANT II (20)	PTA VIVA/Rocha-Singh (21)
n	264	470	787	241	134	250	261	287	299	58	100	72	71	25	671	232	172	65	220	316	307
cm	7.8	12.6	10	5.5	7.1	7.7	8.4	8.9	9.3	22	24	19	27	5.6	8.1	14.6	2.7	5.6	8.9	6.3	8.7
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See appendix for sources.
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Important Safety Information referenced within


Show Me the Money!

3-Year Economic Analysis of Endovascular Interventions to Treat Femoropopliteal Peripheral Artery Disease

Brian G. DeRubertis, MD

UCLA Division of Vascular Surgery

Los Angeles, California

VIVA 15

Important Safety Information referenced within

Objective

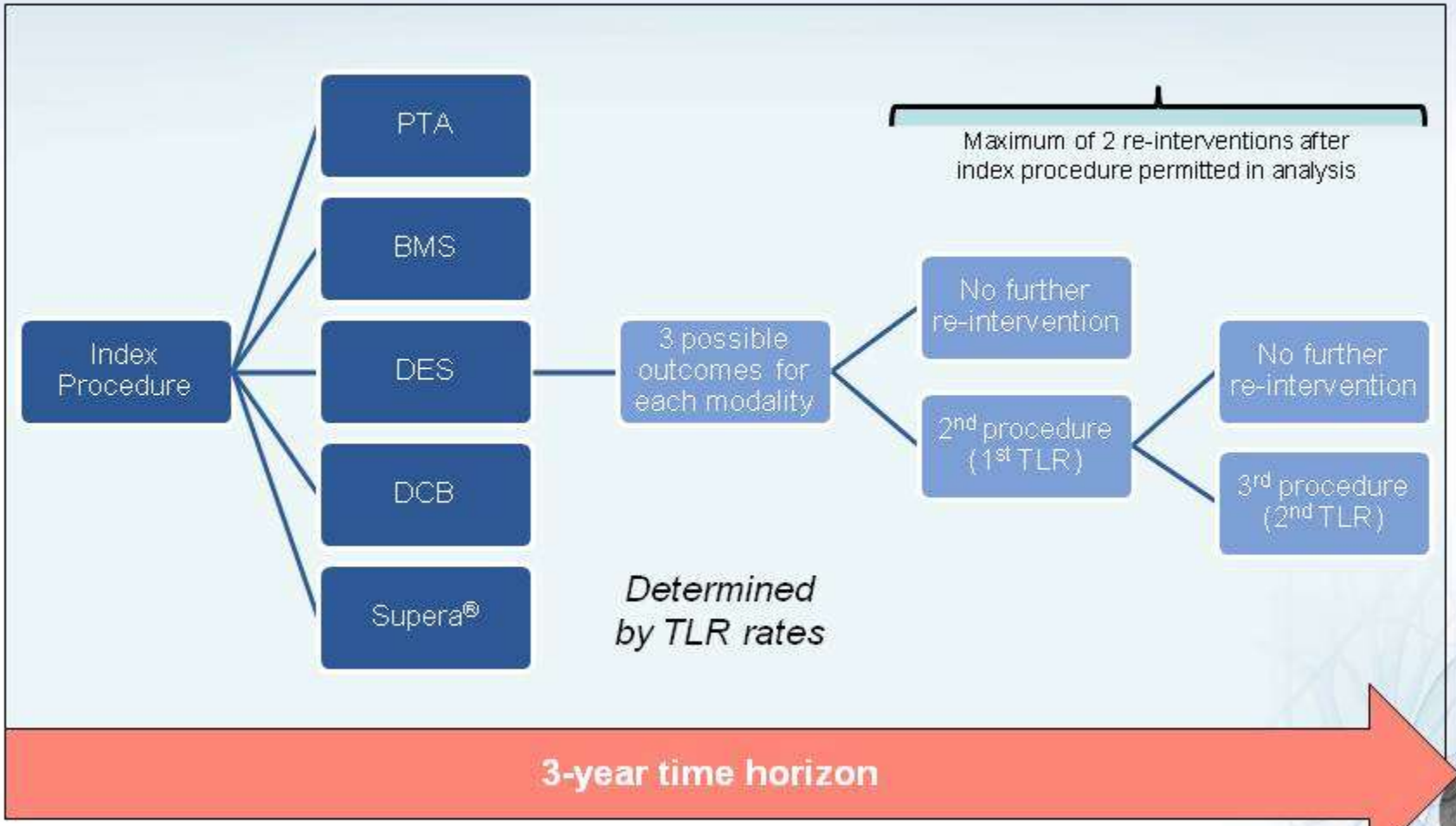
- To evaluate the 3-year economic impact of 5 different endovascular strategies for the treatment of femoropopliteal peripheral artery disease (PAD) from the perspectives of the United States (US) payer and provider

Methods

- 5 endovascular strategies included in the analysis:
  - Angioplasty (PTA)
  - Bare Metal Stent (BMS)
  - Drug Eluting Stent (DES)
  - Drug Coated Balloon (DCB)
  - Interwoven Nitinol Stent (Supera®)
- Risk of TLR was used to estimate the expected number of re-interventions per patient for each strategy

Therapy for SFA/POP Comparison Studies

Model Concept

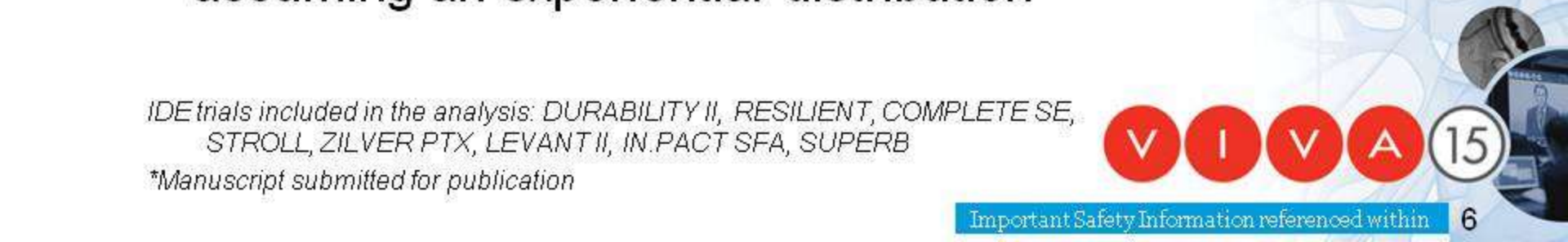


TLR Rates

- Rates were obtained from US investigational device exemption (IDE) studies published in peer-reviewed journals for PTA, BMS, DES, and DCB procedures
- The SUPERB trial provided the risk of TLR with Supera®*
- Only IDE studies were chosen to ensure high quality and consistent clinical trial methodology
- When reported follow-up was less than 3 years, probabilities were extrapolated to estimate the TLR risk assuming an exponential distribution

IDE trials included in the analysis: DURABILITY II, RESILIENT, COMPLETE SE, STROLL, ZILVER PTX, LEVANT II, IN.PACT SFA, SUPERB

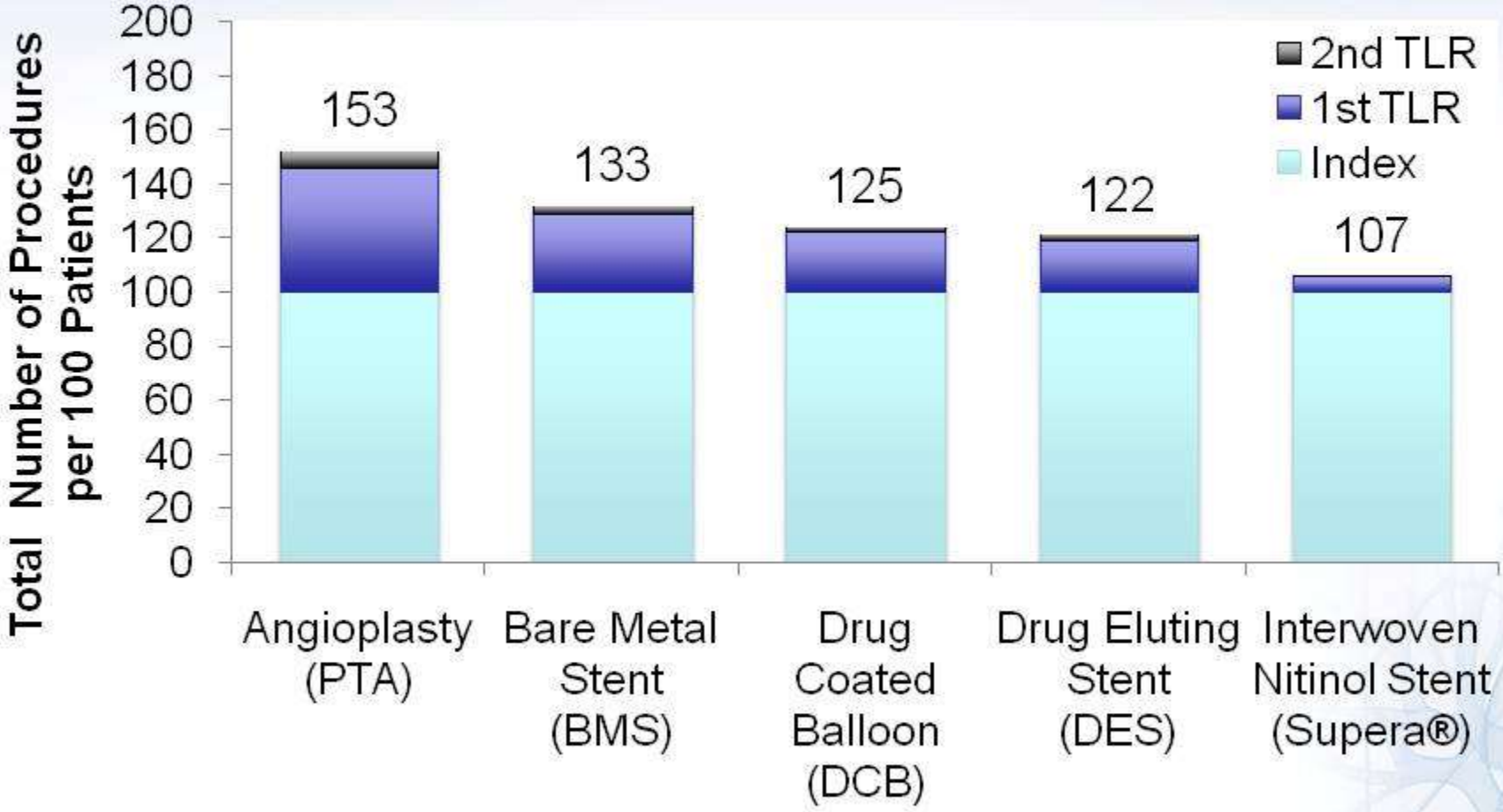
**Manuscript submitted for publication*



Baseline Characteristics From Pooled Studies

Characteristic	PTA	BMS	DCB	DES	Supera®
Patient characteristics					
Mean age (yrs)	67.9	68.0	67.7	67.9	68.7
Male sex	66%	65%	63%	66%	64%
Claudication (Rutherford 2–3)	92%	96%	93%	90%	95%
CLI (Rutherford 4–6)	7%	3%	7%	9%	5%
Diabetes	43%	44%	42%	50%	44%
Hypertension	86%	88%	90%	89%	94%
Hyperlipidemia	77%	84%	88%	76%	87%
History of smoking	83%	80%	79%	86%	80%
ABI pre-treatment	0.71	0.69	0.75	0.67	0.73
Lesion characteristics					
Lesion length (mm)	68	76	74	66	83
Percent diameter stenosis	79%	80%	81%	80%	78%
Severe calcification	20%	31%	9%	37%	45%

Results: Total Number Of Procedures Per 100 Patients Over 3-Years



Results: Payer Perspective, Cost To Medicare Per Patient Over 3-Years

Treatment	Cost to Medicare Per Patient Over 3-Years
Bare Metal Stent (BMS)	$16,158
Angioplasty (PTA)	$15,166
Drug Eluting Stent (DES)	$14,845
Drug Coated Balloon (DCB)	$13,421
Interwoven Nitinol Stent (Supera®)	$13,036

Analysis based on 2015 Medicare national average payment rates

Results: Provider Perspective, Hospital Remaining Payment Over 3-Years

Treatment	Total Hospital Remaining Payment* *(per 100 patients over 3 years)*	Total Number of Procedures *(per 100 patients over 3 years)*	**Average Hospital Remaining Payment* per Procedure** *(over 3 years)*
Supera®	$1.06M	107	**$9,926**
BMS	$1.31M	133	**$9,885**
DES	$1.14M	122	**$9,375**
PTA	$1.31M	153	**$8,588**
DCB	$1.05M	125	**$8,442**

** Remaining payment = facility reimbursement – device costs*

Analysis based on 100 index procedures per treatment strategy

Limitations

- TLR risk was based on statistical modeling using published TLR rates from IDE trials
  - TLR risk may not reflect real world patient outcomes
  - Heterogeneity between trials was not formally incorporated into pooling estimates; although the choice of using only IDE trials helped to mitigate the heterogeneity and sensitivity analysis was conducted to determine the impact of different TLR rates on economic outcomes

- This model did not consider events such as death, amputation, and atherothrombotic complications (MI, stroke, bleeding), which may have cost implications and affect the subsequent risk of clinical events

Conclusions

In this 3-year economic analysis of various treatment modalities:

- From the patient perspective, Supera® has the lowest risk of repeat procedures (TLR)
- From the payer perspective (Medicare), Supera® is an economically attractive (i.e., cost-saving) strategy compared to PTA, BMS, DES, and DCB
- From the provider perspective, Supera® results in the greatest remaining payment per procedure compared to PTA, BMS, DES, and DCB

My Current Algorithm
A reasonable algorithm modified from Armstrong

- DCB use in SFA lesions regardless of length
  - Mean length 160 mm
  - Pre-dilation, 3 minute inflation
- Provisional stenting
  - "Spot" stenting strategy for dissections
- Atherectomy if significant calcification.
  - Optimize results of angioplasty

What is the role of atherectomy and specialty balloons in fem-pop interventions

- Debulking strategies can be applied to the vast majority of patients we encounter for claudication and CLI
- Specialty balloons with anti restenotic agents will be available soon
- Atherectomy is both safe and effective to 12 months in most lesions
  - DEFINITIVE LE study
  - Calcific lesions can be best treated with aggressive rotational or directional devices
  - OASIS/JETSTREAM/DEFINITIVE CA
  - Combined therapy with DCB may afford the best primary patency
  - All combinations need scientific validation and cost benefit analysis
- ISR can be treated effectively with atherectomy as compared to PTA
  - Laser atherectomy- Excite Trial

What about if…

- Can't cross
- Failed multiple intervention…restenosis or re-occlusion
- Very long occlusion
- From the ~origin of the SFA to the popliteal

-- What about if the patient is too "sick" for Fem-Pop surgery

…Stay Tuned

4th Annual Symposium

Cardiovascular Disease Management:
A Case-Based Approach

Richard R. Heuser, MD, FACC
Program Director

October 13 & 14, 2016
Arizona Biltmore, Phoenix, Arizona

Nursing Symposium will take place
October 12, 2016 from 12:00 – 5:00 pm

SAVE THE DATE
For more information, please visit www.promedicacme.com