Ranger DCB: An Essential Choice for Treating Popliteal Artery

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What is reason of popliteal artery occlusion or stenosis

- Thrombotic occlusion
- Atherosclerosis
  - Plaque
  - Dissection
  - Calcification
- Compression
  - (entrapment syndrome or by Baker’s cyst)

What is reason of popliteal artery occlusion or stenosis

- Thrombotic occlusion → Thrombectomy
  - AngioJet
- Atherosclerosis
  - Plaque
  - Dissection
  - Calcification
- Compression → Surgical approach
  - (entrapment syndrome or by Baker's cyst)

What is the crucial consideration in the pop. artery PTA procedure?

Avoid bail-out stenting

Leave-nothing-behind therapies

1. Mechanical stress
2. No option after stent failure
   - Surgical conversion
   - Re-do procedure

During balloon angioplasty

- The rate of severe dissection was reported as high as 60%
- A bailout stenting was performed in 11% ~ 27% of the previous population.

Circ Cardiovasc Interv 2012; 5: 831–840.
NEJM 2008; 358: 689–699.

How to avoid making large dissection

Journal of Geriatric Cardiology (2018) 15: 254–260

Research Article

· Open Access ·

Use of rotational atherectomy for reducing significant dissection in treating de novo femoropopliteal steno-occlusive disease after balloon angioplasty

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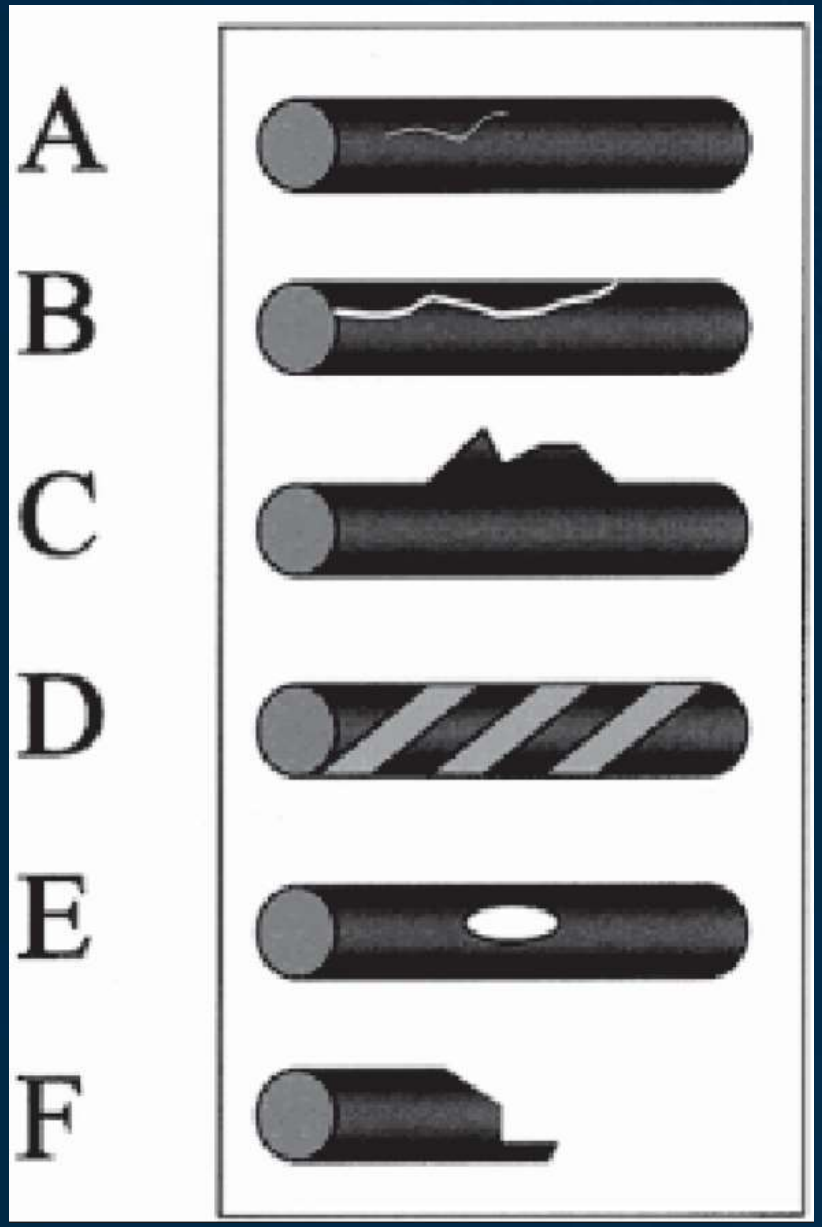
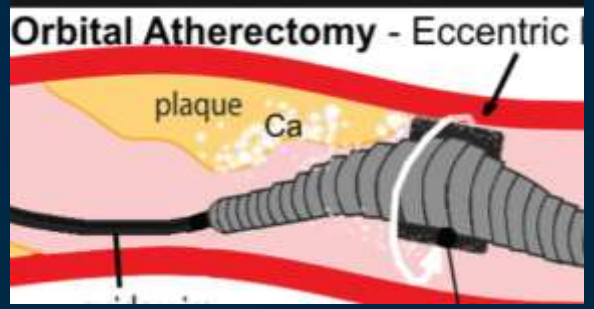
	Without atherectomy, $n = 17$	Atherectomy $n = 42$	*P*-value
Lesion character			
Lesion length, mm	104.1 ± 74.2	83.3 ± 63.6	0.284
Reference diameter, mm	5.05 ± 0.82	4.92 ± 0.67	0.533
MLD, mm	0.80 ± 0.80	0.84 ± 0.68	0.845
Diameter stenosis	83.5% ± 15.8%	82.7% ± 13.1%	0.852
Dissection type			
Less than type A	0	11 (26.2%)	0.024
B	2 (11.8%)	13 (31.0%)	0.190
C	9 (52.9%)	12 (28.6%)	0.077
D	3 (17.6%)	5 (11.9%)	0.678
E	1 (5.9%)	1 (2.4%)	0.497
F	2 (11.8%)	0	0.079
Dissection with subintimal space filling (type C-F dissection)	15 (88.2%)	18 (42.9%)	0.001
Recoil (> 20) after balloon	7 (41.2%)	8 (19.0%)	0.103
Possible indication for bail-out stenting (> 30% recoil or type E, F dissection)	4 (23.5%)	1 (2.4%)	0.021
Gradual ballooning	9 (52.9%)	23 (54.8%)	0.899



TH Kim et.al Journal of Geriatric Cardiology (2018) 15: 254~260

How to avoid making large dissection

1. Orbital Diamondback 360° atherectomy system (CSI, St. Paul, MN, USA)



2. Phoenix atherectomy system (Volcano Corp. San Diego, CA, USA).

3. JetStream athetectomy system (Boston Scientific, Marlborough, MA, USA).

Table 3. Univariate and multivariate analysis for risk of significant dissection.

	P value	Odd ratio	95% CI
Univariate analysis			
Age	0.236	0.968	0.91–1.02
Diabetes	0.319	1.758	0.57–5.33
Occlusion	0.084	6.731	0.77–58.7
MLD	0.896	0.953	0.46–1.97
Minimal calcium	0.294	1.750	0.61–4.98
Severe calcium	0.918	0.933	0.25–3.48
Gradual ballooning	0.637	0.779	0.27–2.19
Balloon to reference vessel ratio	0.242	0.244	0.023–2.59
Oversize ballooning	0.095	0.30	0.073–1.23
Use of atherectomy device	0.005	0.10	0.020–0.494
Multivariate analysis			
Occlusion	0.292	3.53	0.33–36.8
Oversize ballooning	0.287	0.42	0.09–2.04
Use of atherectomy device	0.013	0.12	0.025-0.642

MLD: minimal lesion diameter.

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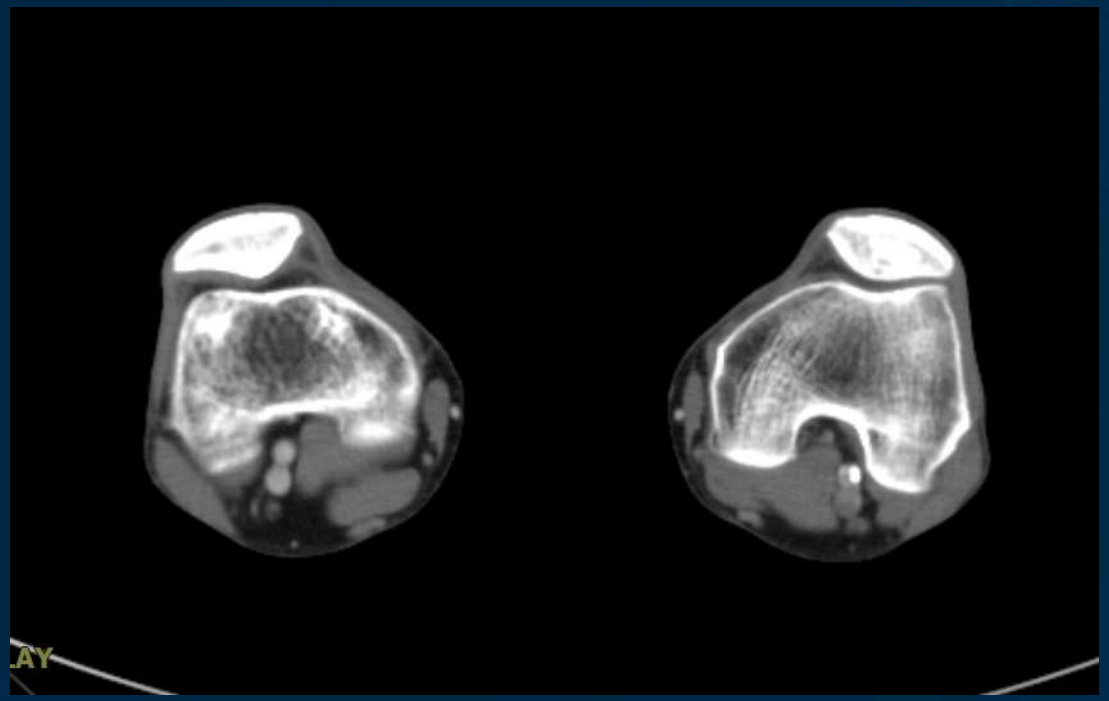
How to avoid bail-out stenting

1. Do atherectomy before ballooning
2. Avoid intentional subintimal approaches (no knuckle technique at P2)
3. Don’t use oversize balloon

Case #1: Directional atherectomy

for calcified or protruding plaque lesion

- 63/M
- HTN
- DM, insulin
- Dyslipidemia
- DVT
  - Lupus anticoag. Ab (+)
  - Protein C activity 46%
- Had claudication
  - ABI (1.19/0.72)



Procedure

Antegrade puncture

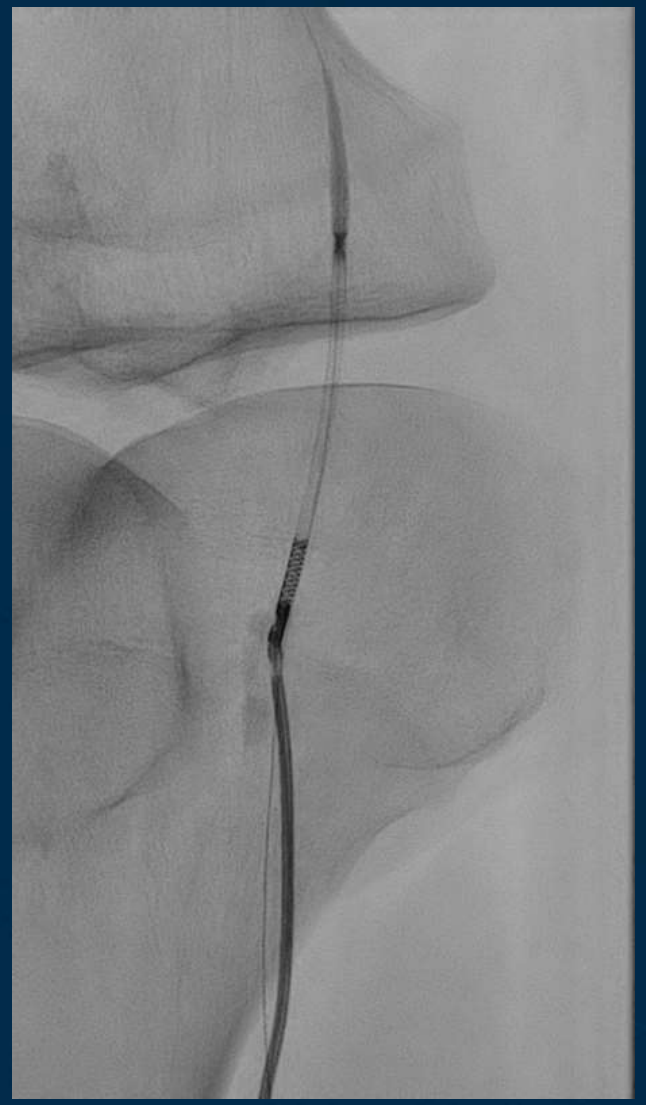
Occlusion

ANSL0 sheath

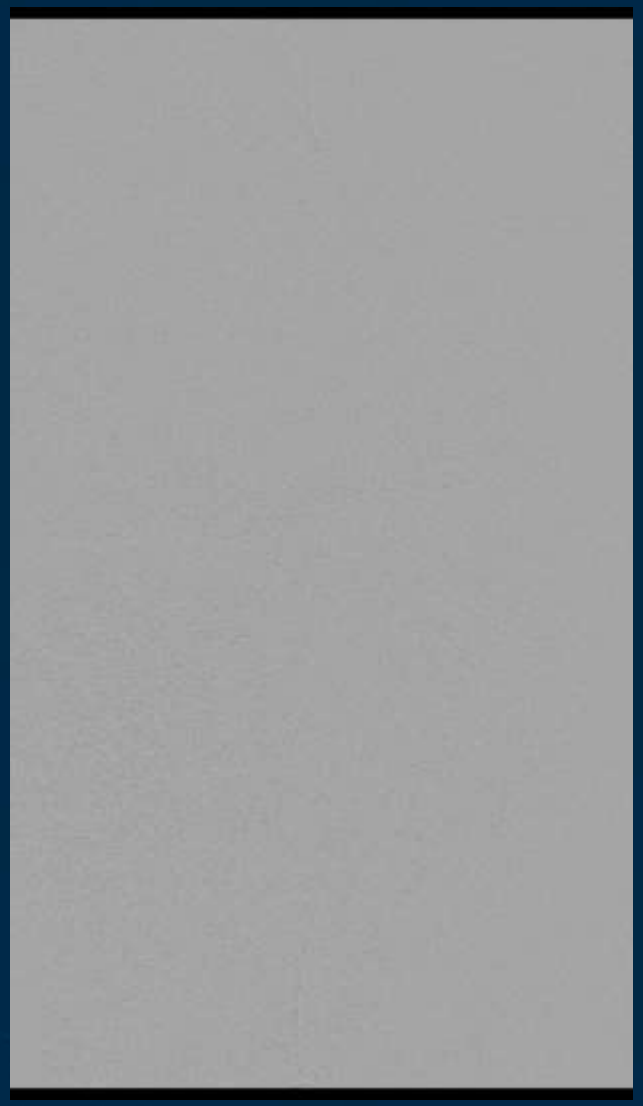
Smart masking system

Procedure

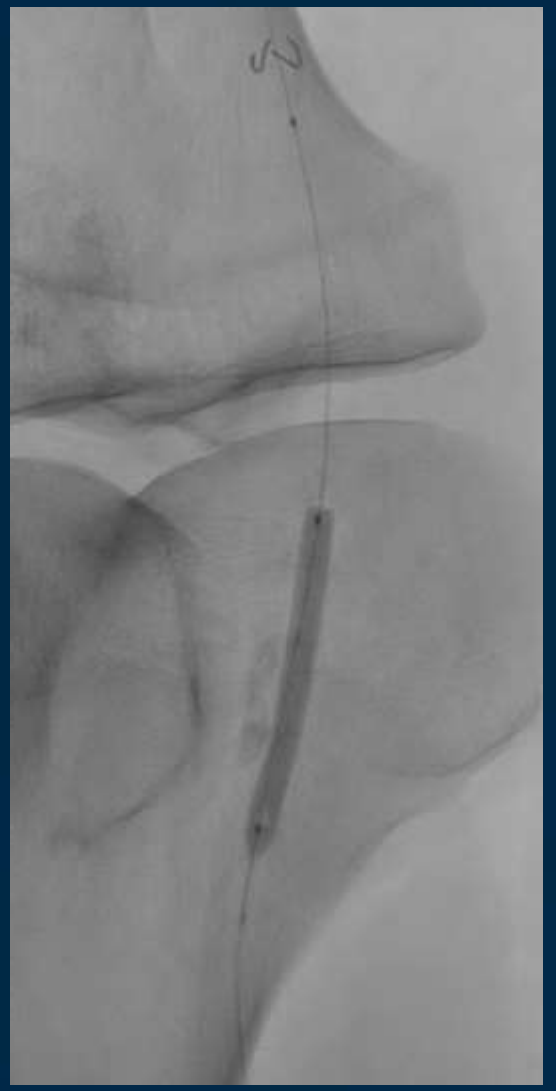
Directional atherectomy



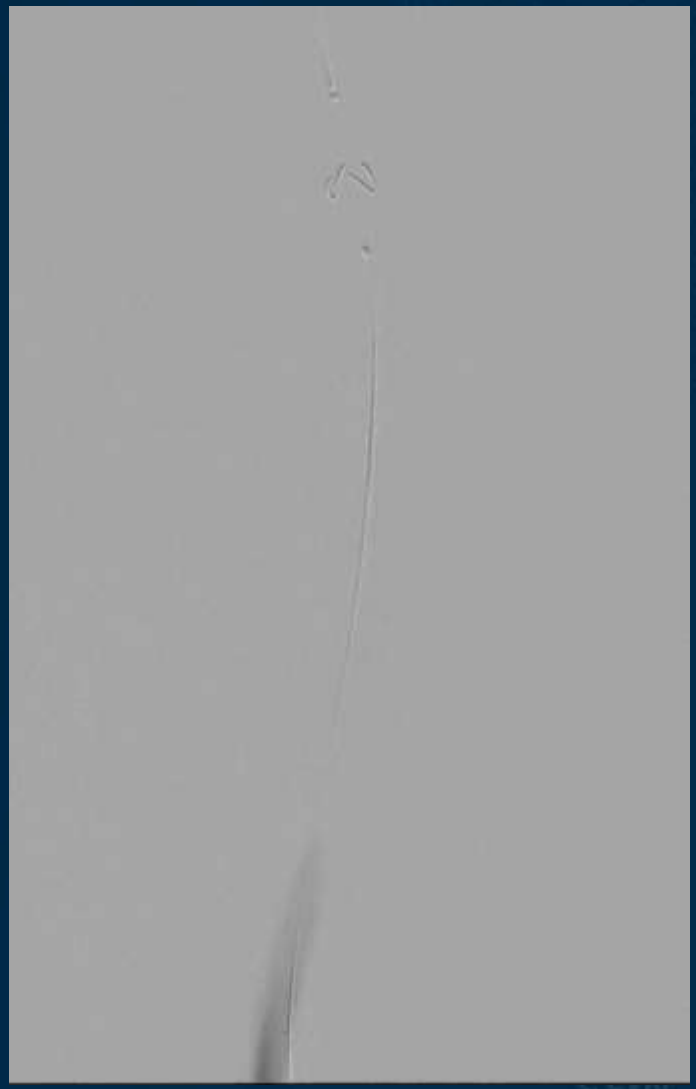
Restore the flow



Balloon angioplasty



Recoil and residual stenosis after balloon



Procedure

- Check pressure gradient using 4Fr. Glide catheter

- No PG
- I don't try to grind it perfectly

- Then, Ranger DCB

ABI
(1.19/0.72)

-> 0.98/1.09

Which atherectomy is better?

Rotational atherectomy

- Evenly peel off the thick irregular intimal layer

Directional atherectomy

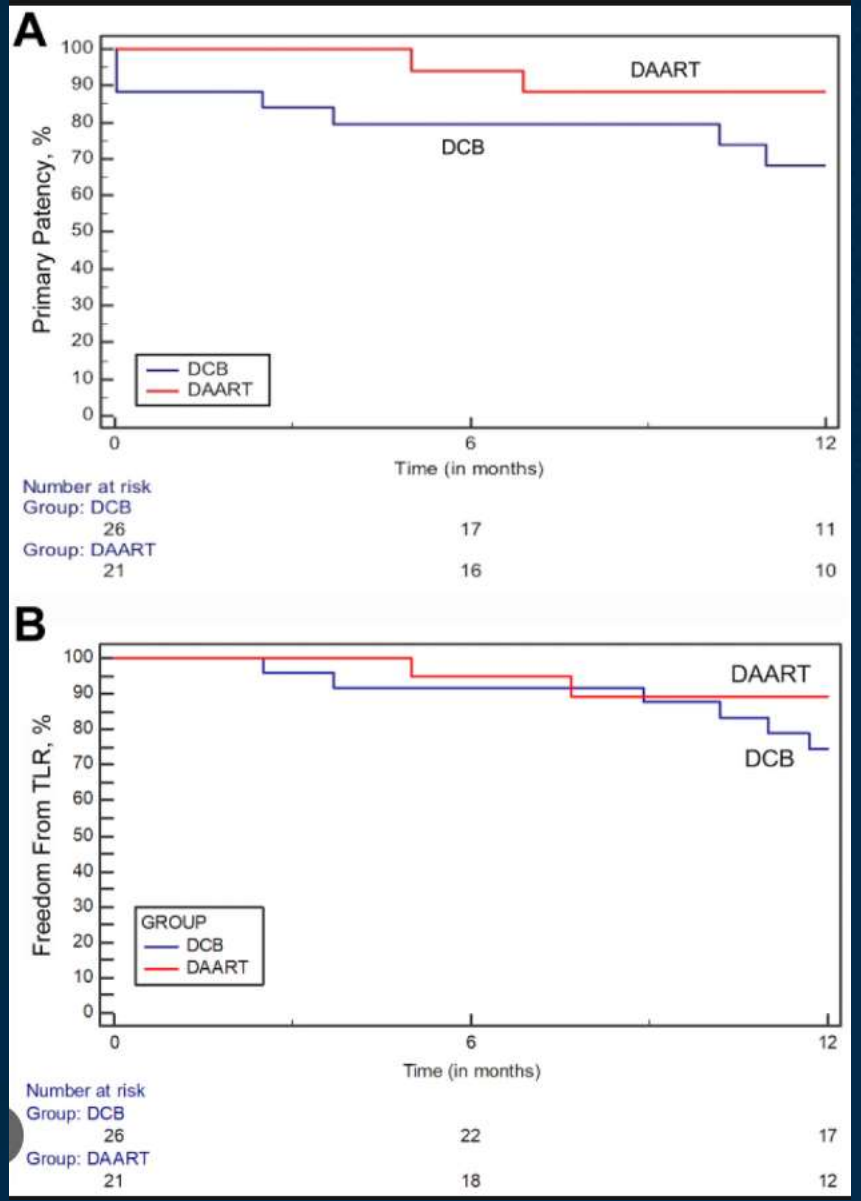
- It is better to debulking strategy.
- Protruding lesion
- Aneurysmal degeneration of the popliteal artery was seen more often after DAART
  - (7% vs 0% for DCB alone, p=0.25).
- Popliteal artery injury was observed in 2 patients treated using DAART (5% vs 0% for DCB alone, p=0.5)

Journal of Endovascular Therapy 2015 https://doi.org/10.1177/152660281560819

Directional atherectomy before DCB

For isolated pop artery disease

- Bailout stenting was more common in without atherectomy group
  - (16% vs 5% for DAART, p=0.13)
- The 12-month primary patency rate was significantly higher in the DAART group
  - 65% vs 82%; p=0.021
- What made outcome difference?
  - Atherectomy prior to DCB leads to better paclitaxel penetration into the arterial wall and improved drug uptake.
  - Aggressive mechanical plaque excision

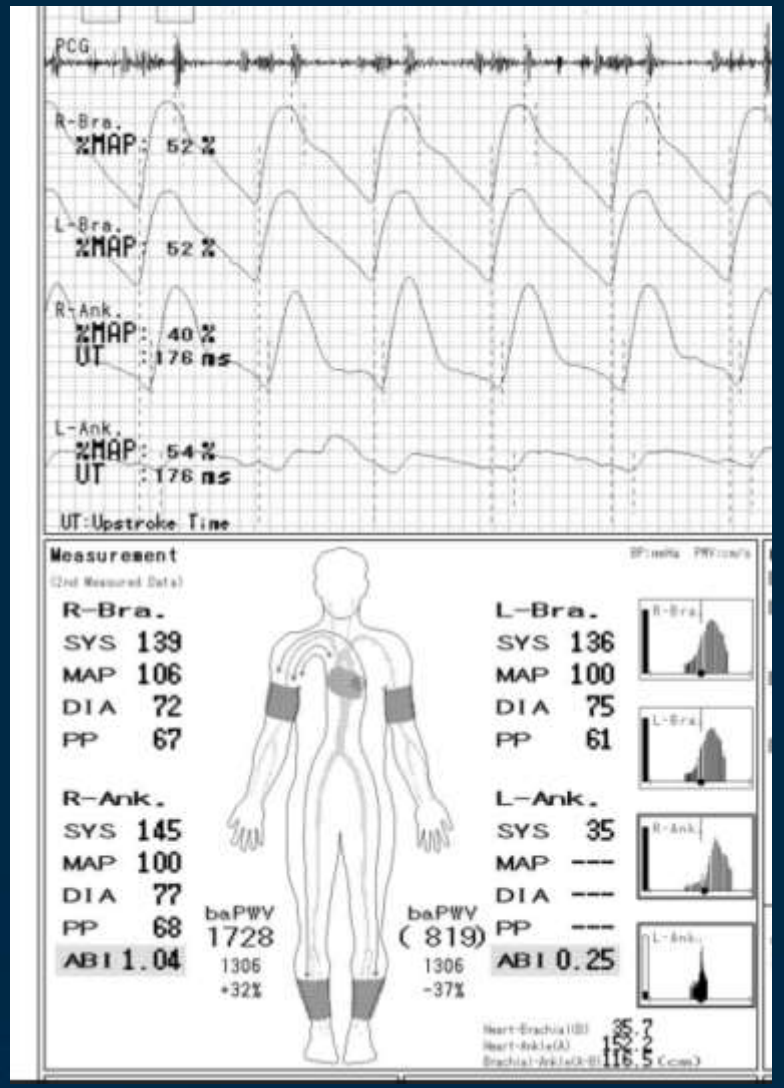


Journal of Endovascular Therapy 2017 Apr;24(2):181-188.

Case #2: Rotational atherectomy before DCB

M/57, Claudication

- HTN
- Exsmoker
- LV dysfunction without coronary disease (EF = 43%)

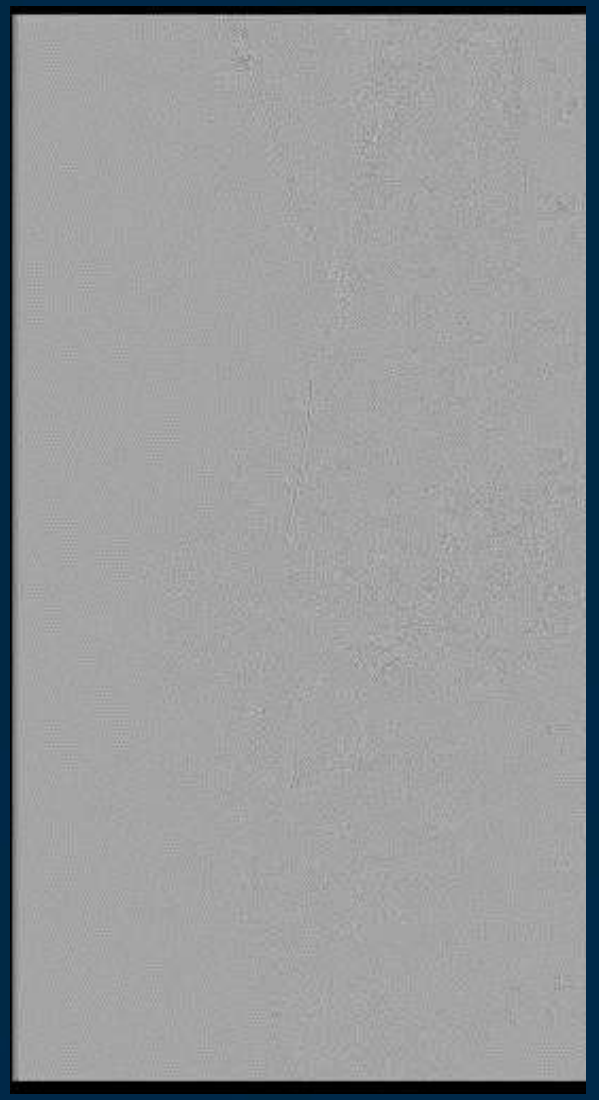


Procedure

Embo-shield filter

Jet-stream atherectomy

Post atherectomy



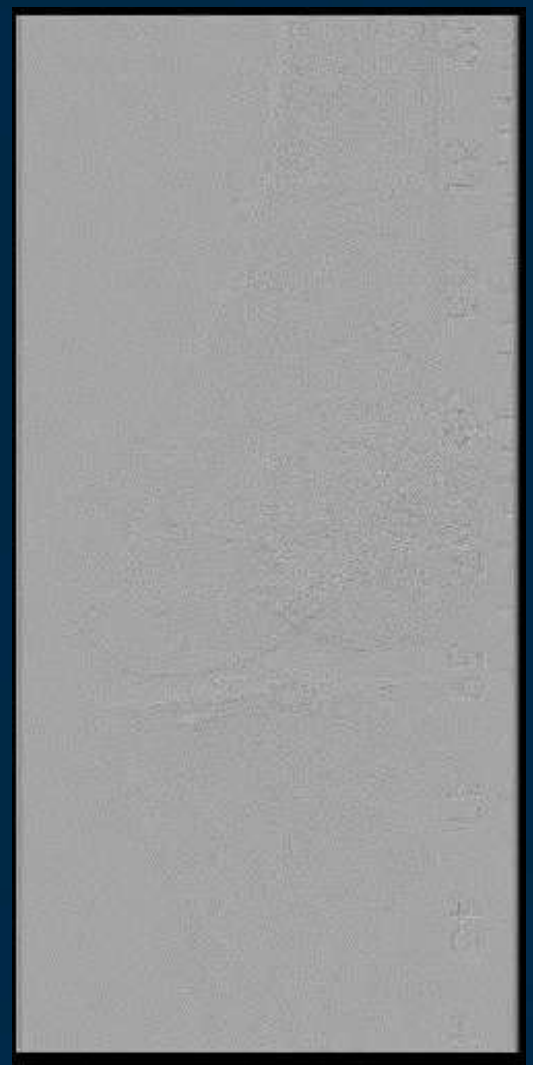
6x 40 balloon

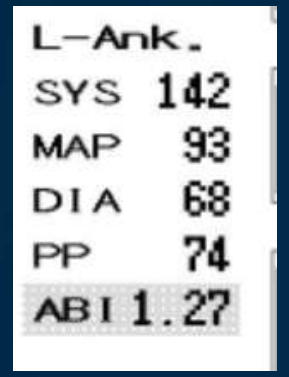
Procedure

Post balloon angiography, no visible dissection

6 x 80 Ranger

After DCB





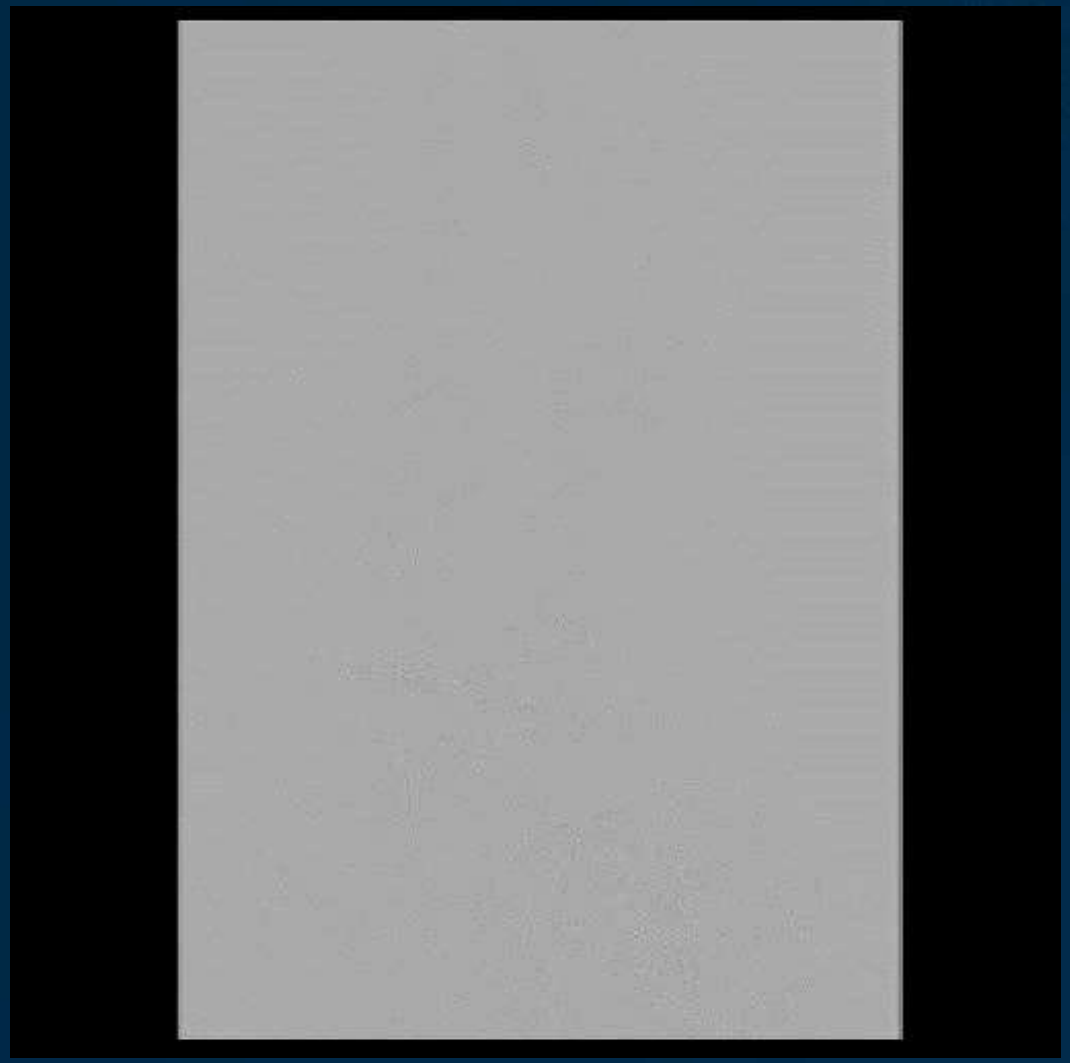
Jetstream: Preemptive treatment before Ranger DCB

Irregular surface

Smooth surface

Case # 3: preemptive atherectomy

F/72 ABI 0.5/1.01, Claudication, DM, HTN, coronary disease, PAD (prev. PTA, 1 year ago)



Procedure

Reference image

Atherectomy without filter

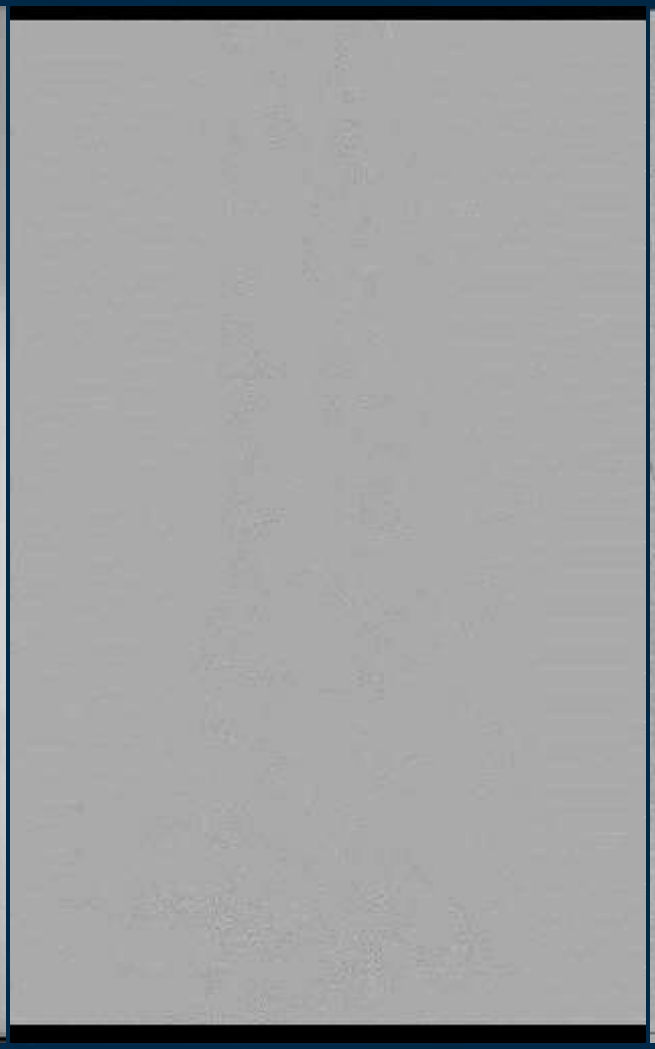
F/U DSA

Sterling balloon 4 x 60

Coyote balloon (2.5mm, 100mm)12atm

Ranger 4 x 80

Final angio ABI 1.03/1.04



How to avoid bail-out stenting

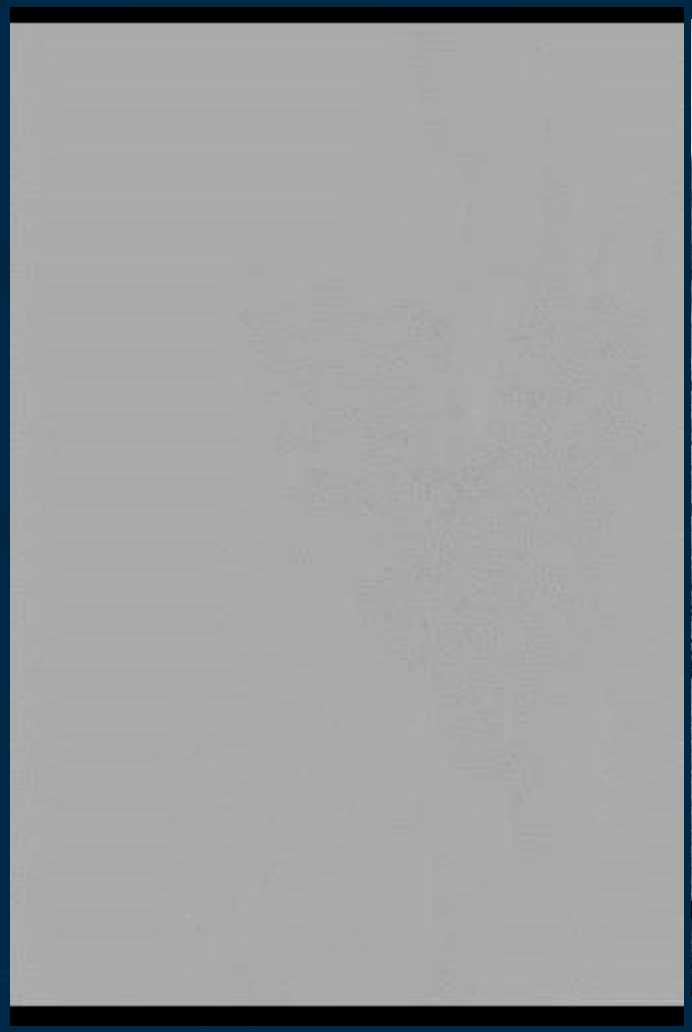
1. Do atherectomy before ballooning
2. Avoid intentional subintimal approaches (no knuckle technique at P2)
3. Don’t use oversize balloon

Case #4, Bailout stenting

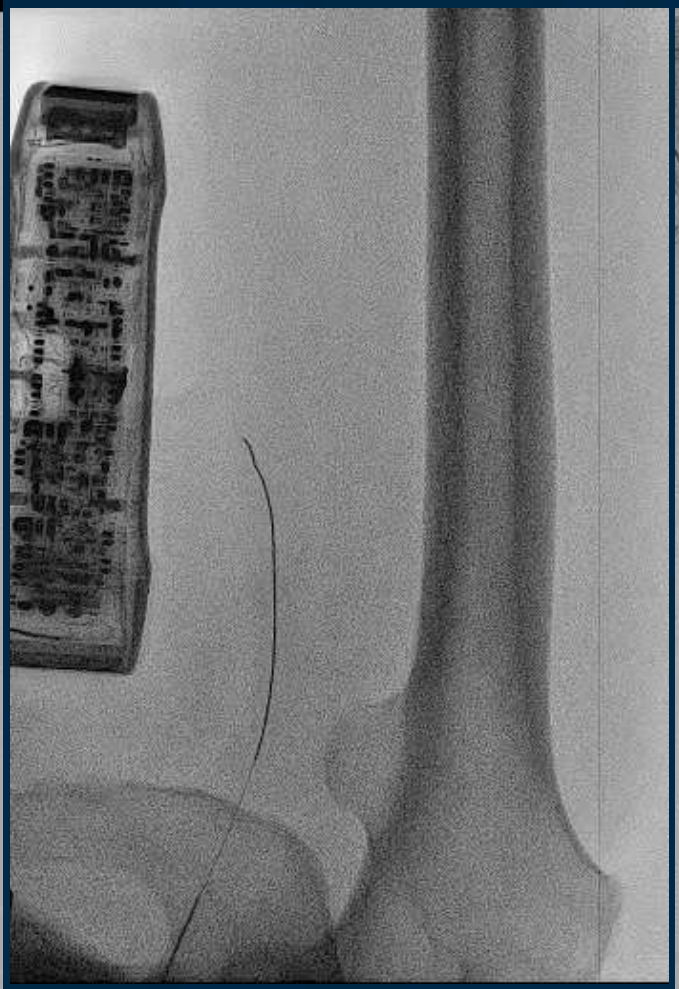
M/76, Critical limb ischemia, ABI 0.65/1.03

Short occlusion,

TKR state,

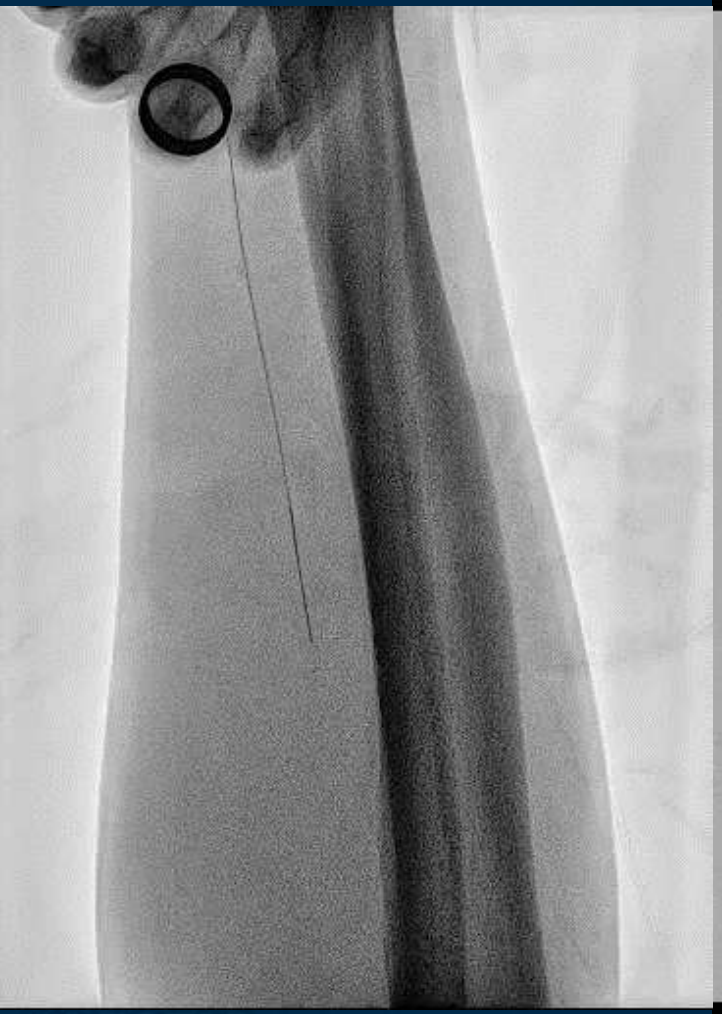


Decided to do bilateral approach



Procedure

Pedal puncture

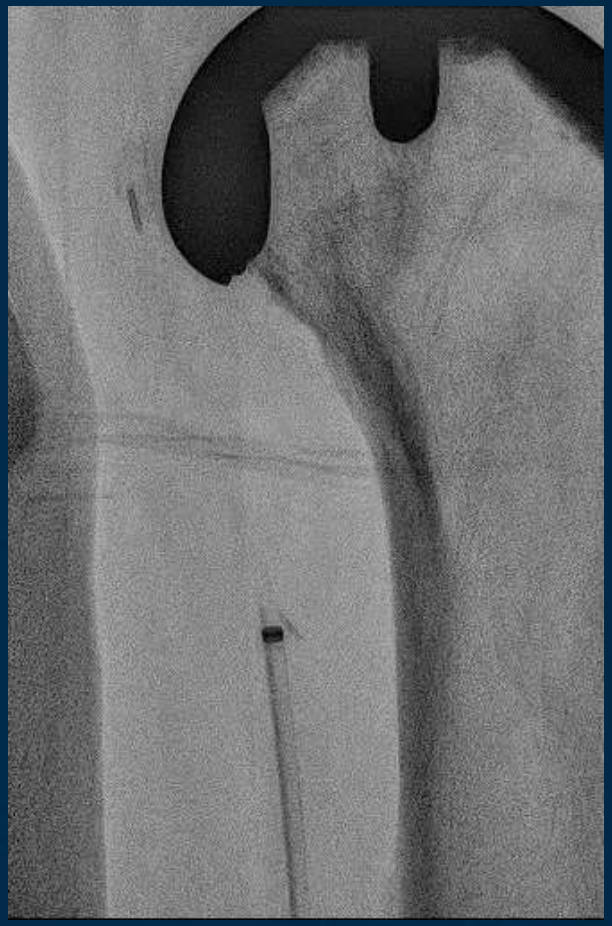


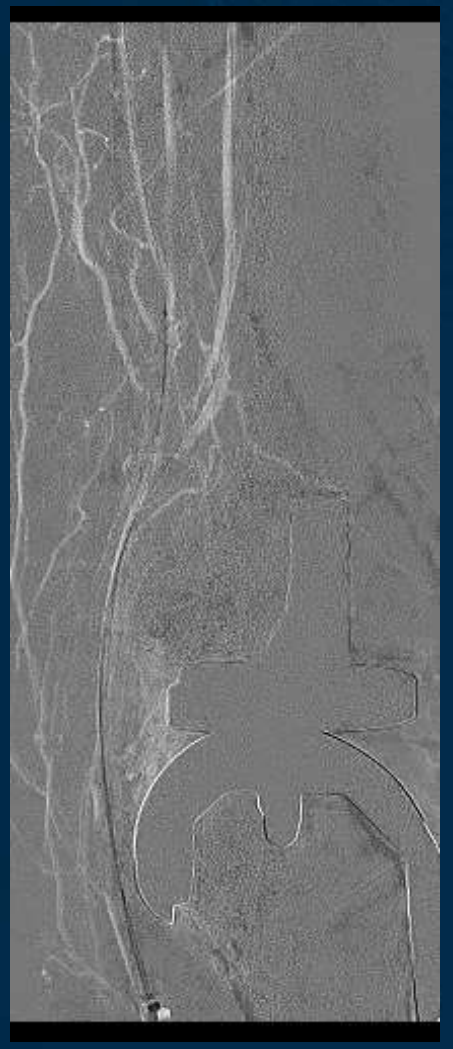
Only lateral view

CXI with 0.014 Command wire, Knuckle wire

Procedure

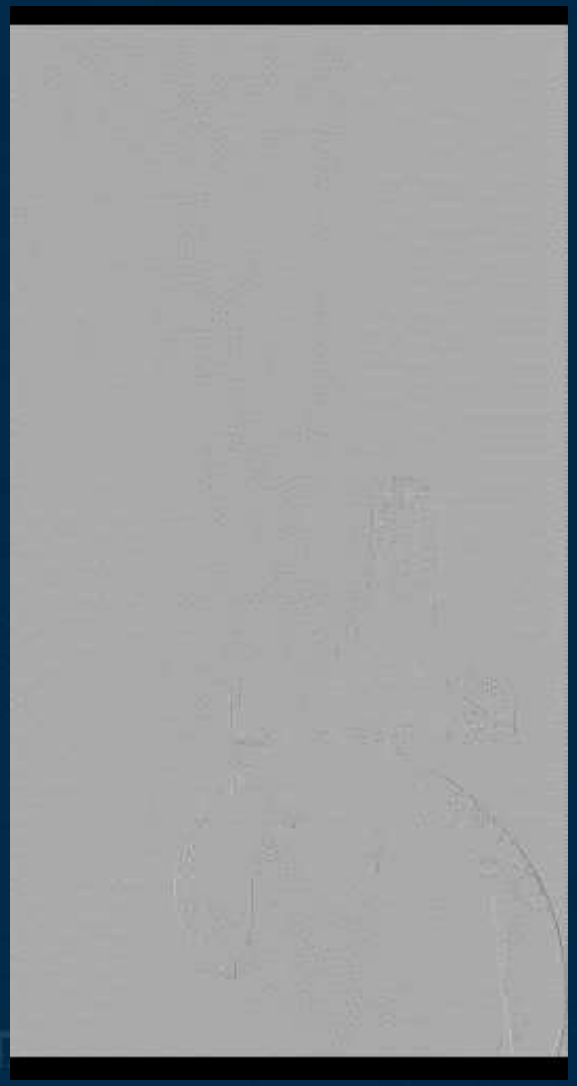
Externalization ***PTA balloon*** ***Dissection*** ***Sterling (2.5mm, 80mm) ATA*** ***PTA***





Procedure and clinical outcome

After the long duration balloon (2.5 to 4mm for pop)



Supera stent (5mm, 80mm)

Sx. free for 3 years F/U

Dedicated stent or stent-graft outcome

Viabahn and Supera stent

- Viabahn stent graft for SFA including popliteal artery
  - 1 year patency : 66% (SFA without pop involve 84%)

- Supera stent for popliteal artery

Tab. I. Summary of studies of SUPERA stents implanted in the popliteal artery.

STUDY NAME	NUMBER OF PATIENTS	CLAUDICANT, %	CLTI, %	MEAN LESION LENGTH, MM	MODERATE OR SEVERE CALCIFICATION, %	OCCLUDED SEGMENT, %	PRIMARY PATENCY AT 1YR, %	PRIMARY PATENCY AT 2 YR, %	PRIMARY PATENCY AT 3 YR, %	STENT FRACTURE AT 1 YR, %
Goltz (2012)	40	25	75	-	-	88	68	-	-	0
Leon (2013)	34	26	74	119	-	44	79	-	-	0
Scheinert (2013)	101	67	23	58	52	48	88	-	-	0
San Norberto (2019)	46	36	64	112	64	44	90	72	70	0

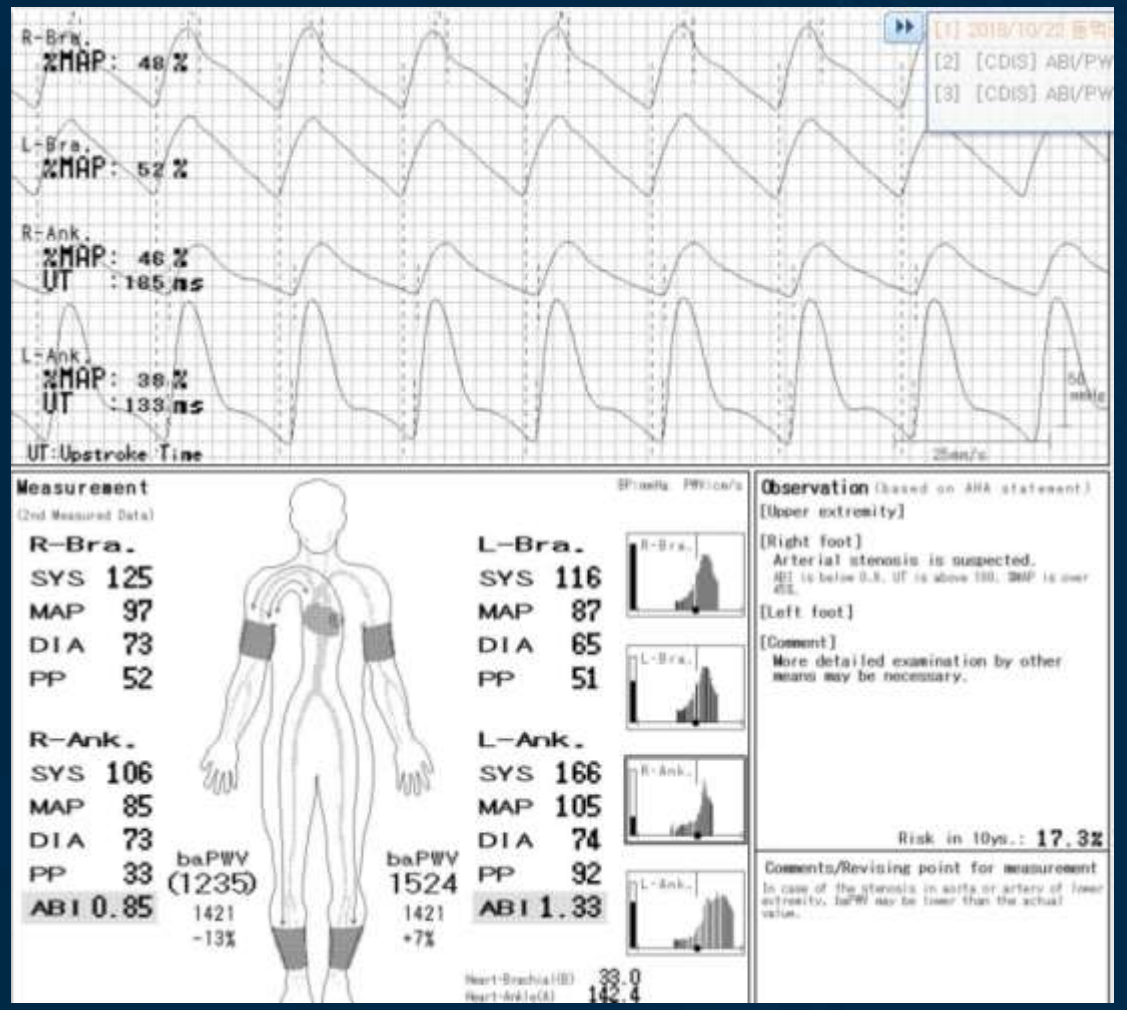
CLTI – Chronic limb threatening ischemia

DOI:https://doi.org/10.1016/j.jvir.2007.07.011

Case # 5, Luminal wiring

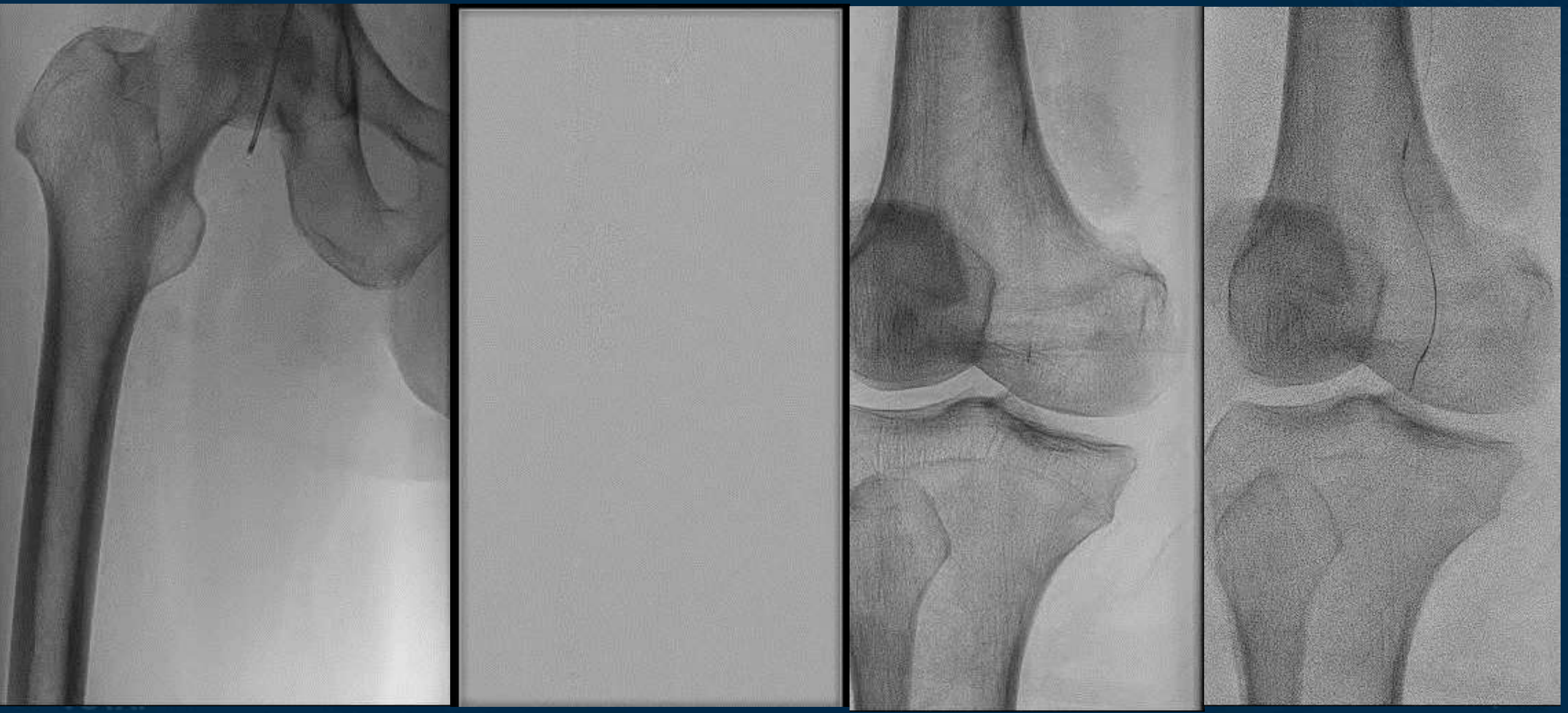
A 65/M patient with claudication

1. NSTEMI, CAD (1VD)
2. Anemia
3. Back pain d/t spinal stenosis
4. Hoarseness d/t motorcycle TA
5. Impingement syndrome of shoulder
6. Weight loss 3~4kg /1 month



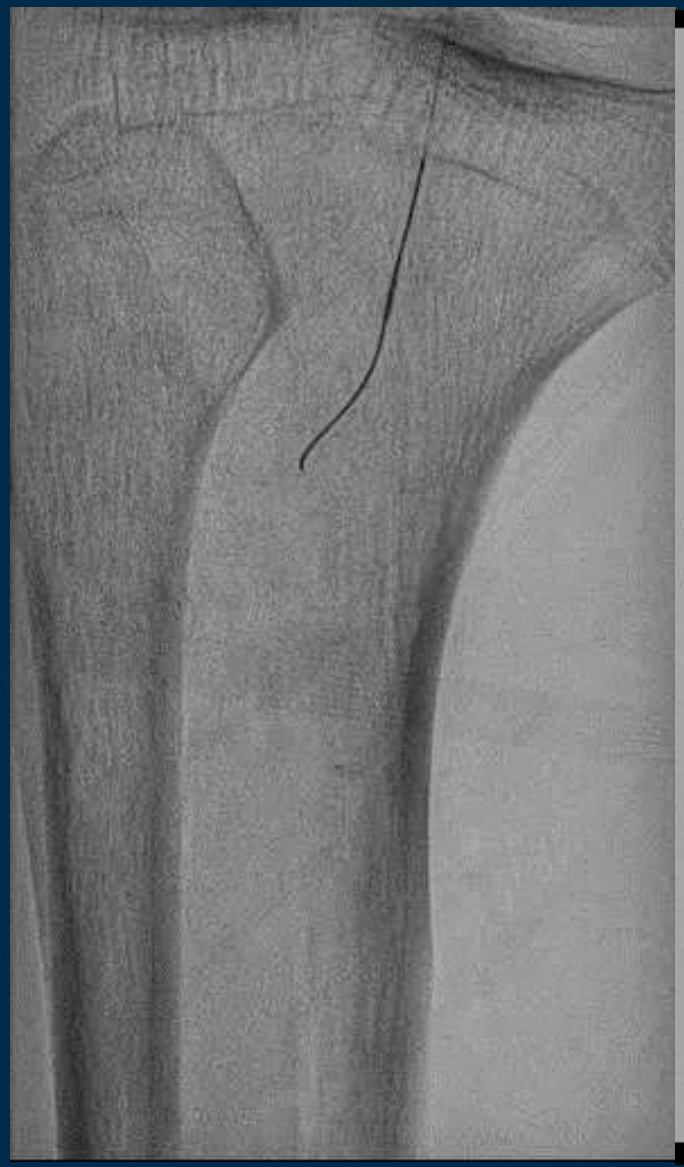
Wiring to true lumen (don’t use knuckle technique)

Dissection *Confirmation CXI* *0.014Regalia*

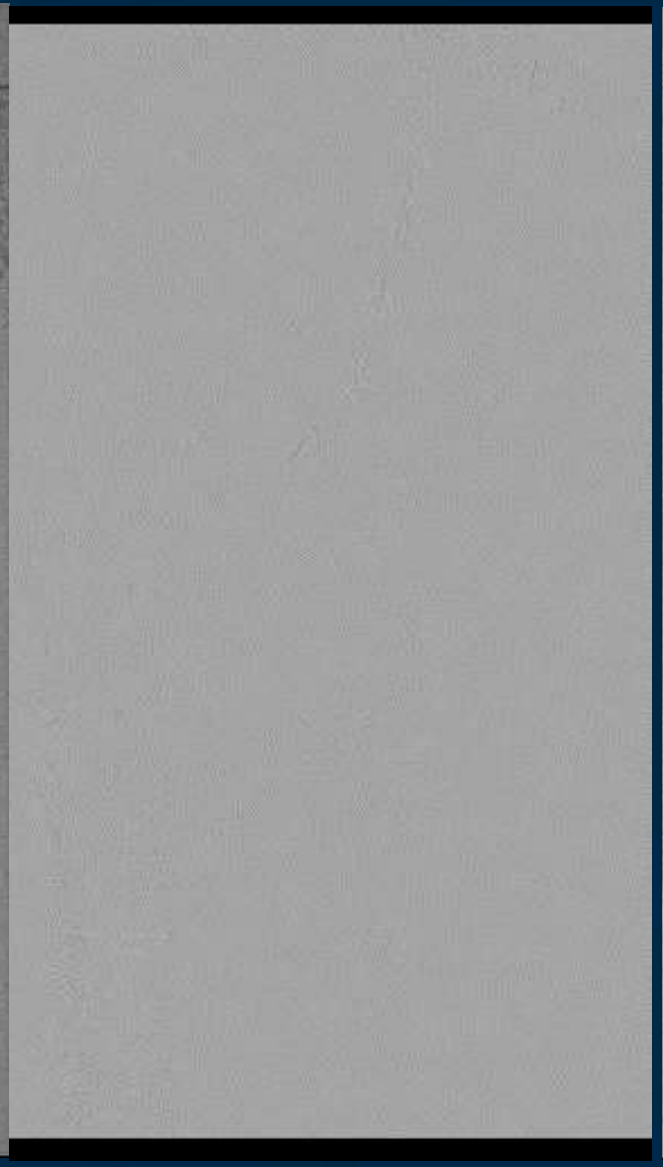


Wiring to true lumen (don’t use knuckle technique)

Wire stuck



DSA confirmation



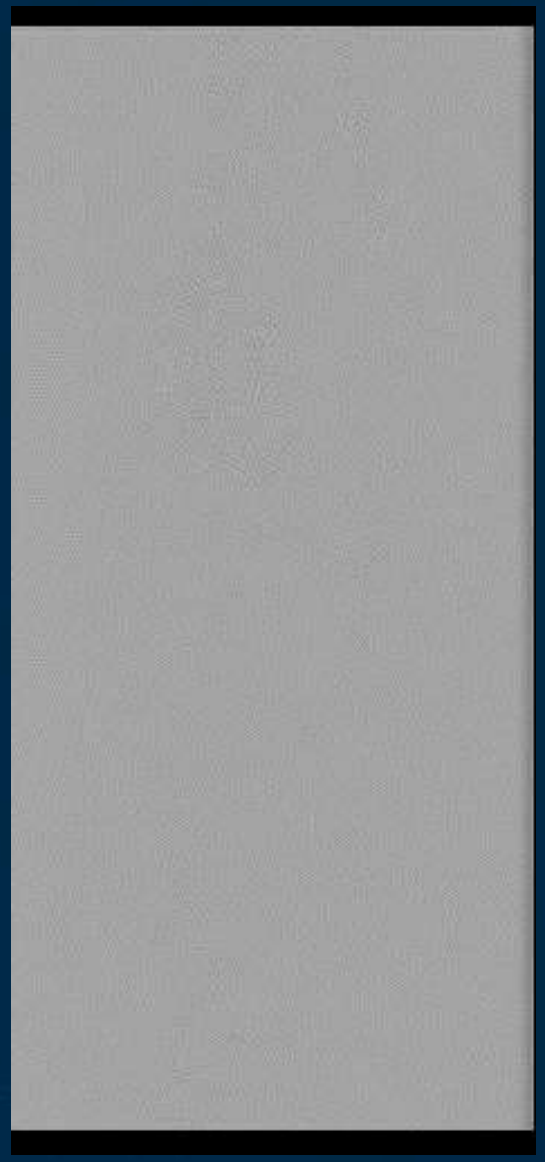
Regalia with CXI

Command ES with CXI

Wiring to true lumen (don’t use knuckle technique)

Coyote 2.5, 100mm

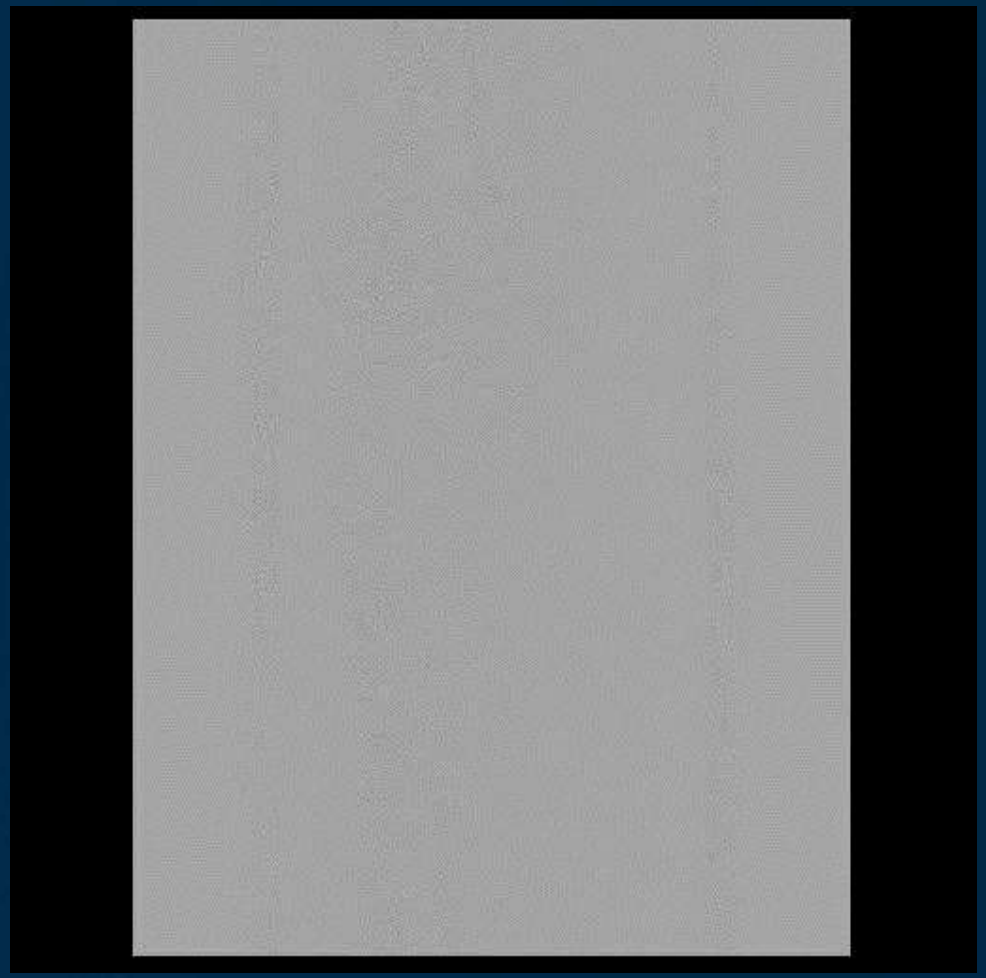
PTA occlusion

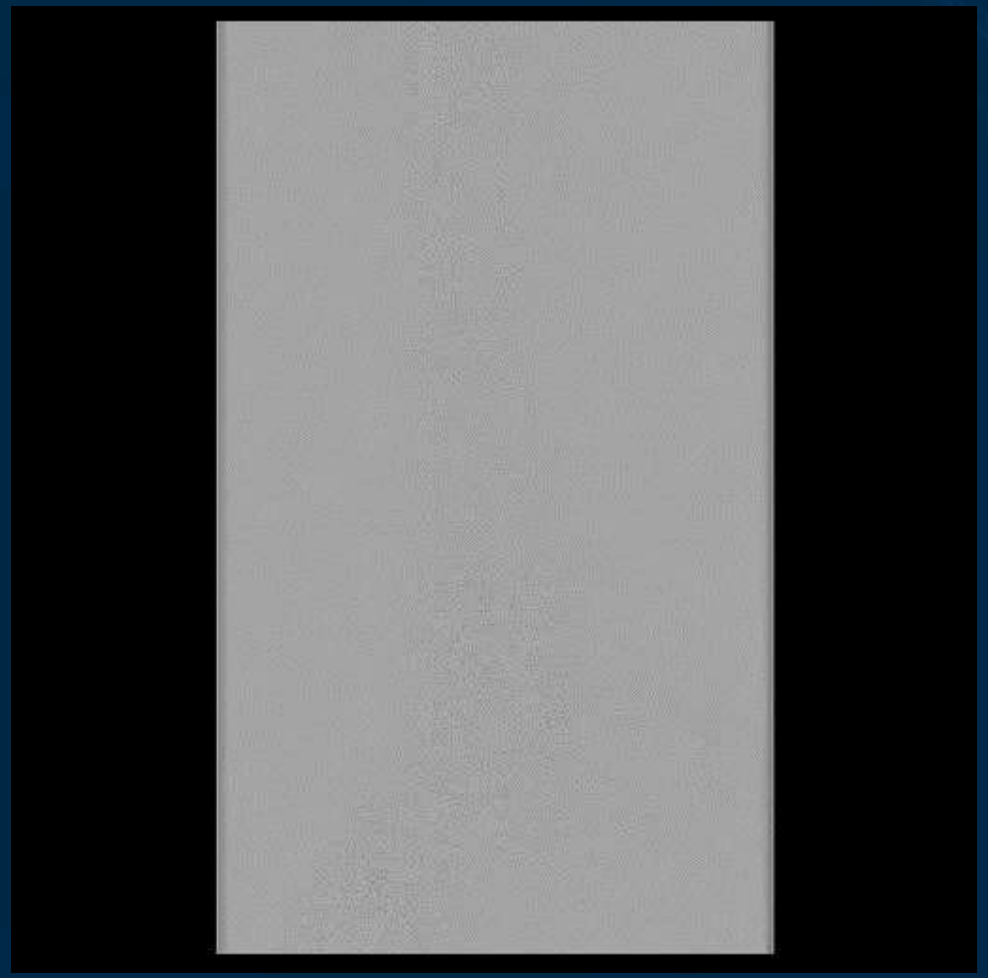


Coyote 2.5, 100mm

Mustang 4x 60 then Ranger (6mm, 80mm)

Final DSA and clinical results





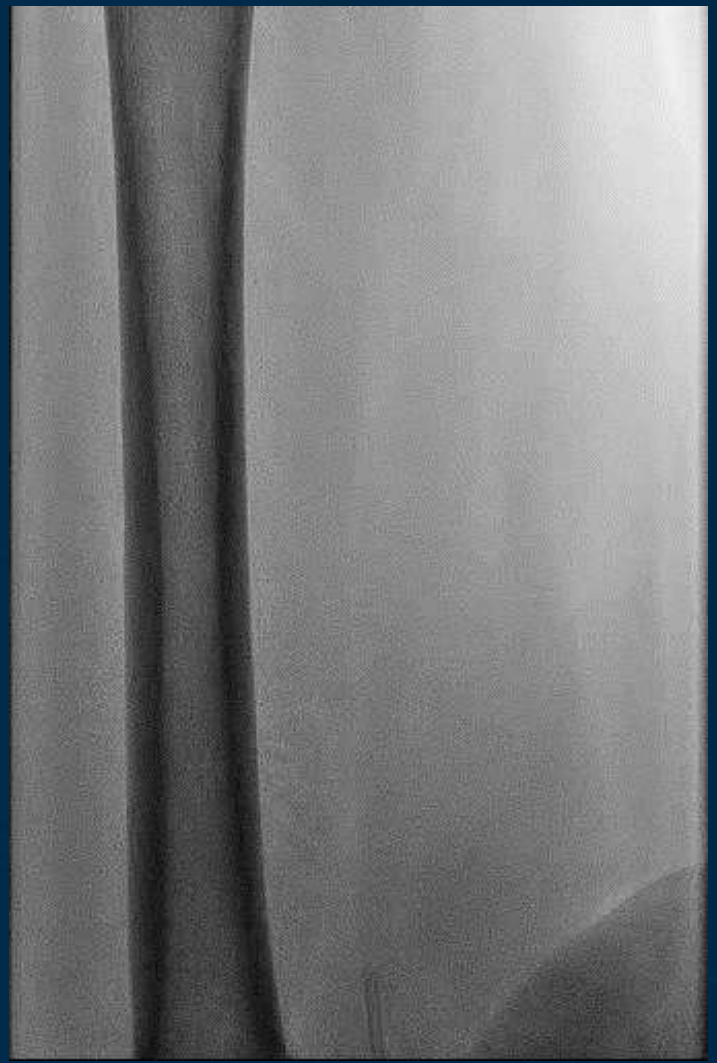
- ABI
  - 0.85/1.33 to 1.02/1.25
- Symptom free for 5 years

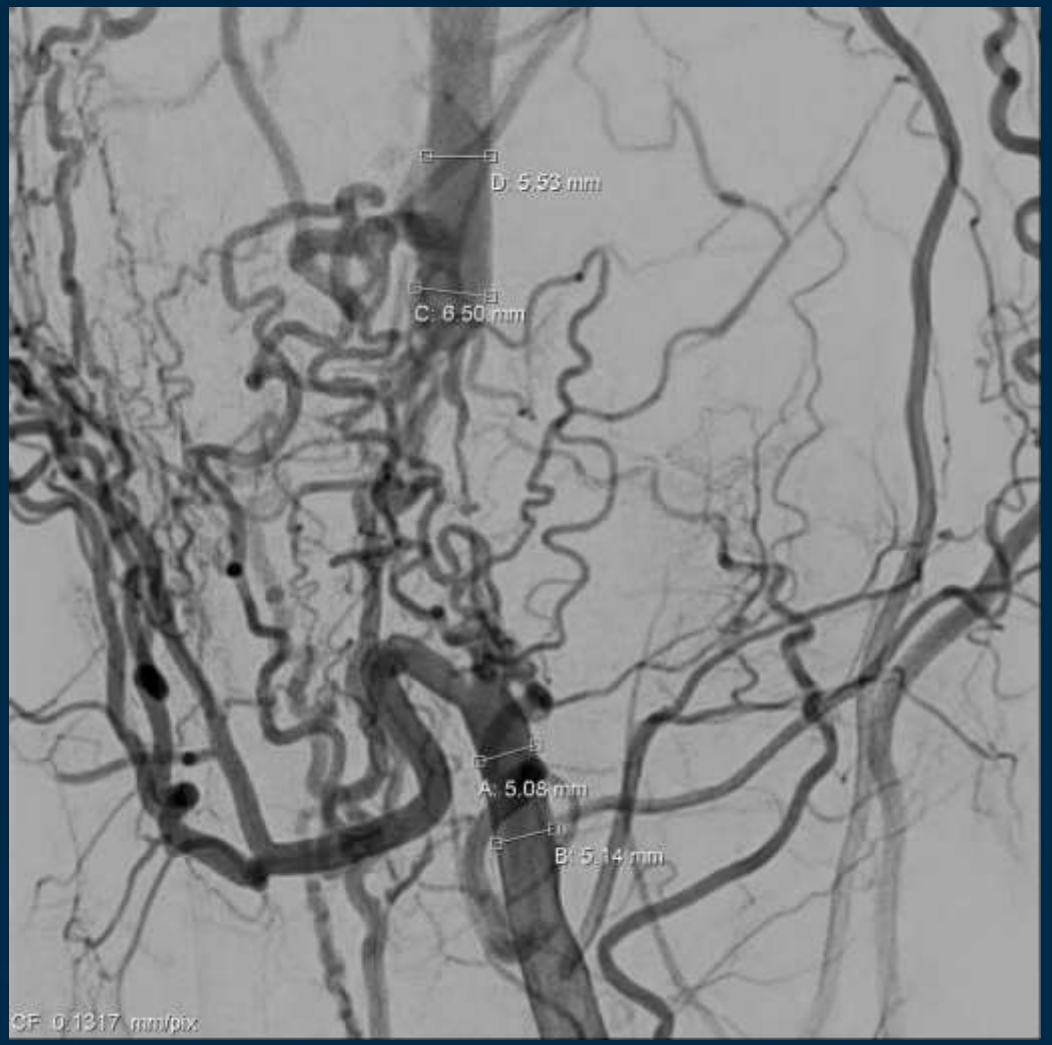
How to avoid bail-out stenting

1. Do atherectomy before ballooning
2. Avoid intentional subintimal approaches (no knuckle technique at P2)
3. Don’t use oversize balloon

Case #6, Find microchannel, for atherectomy

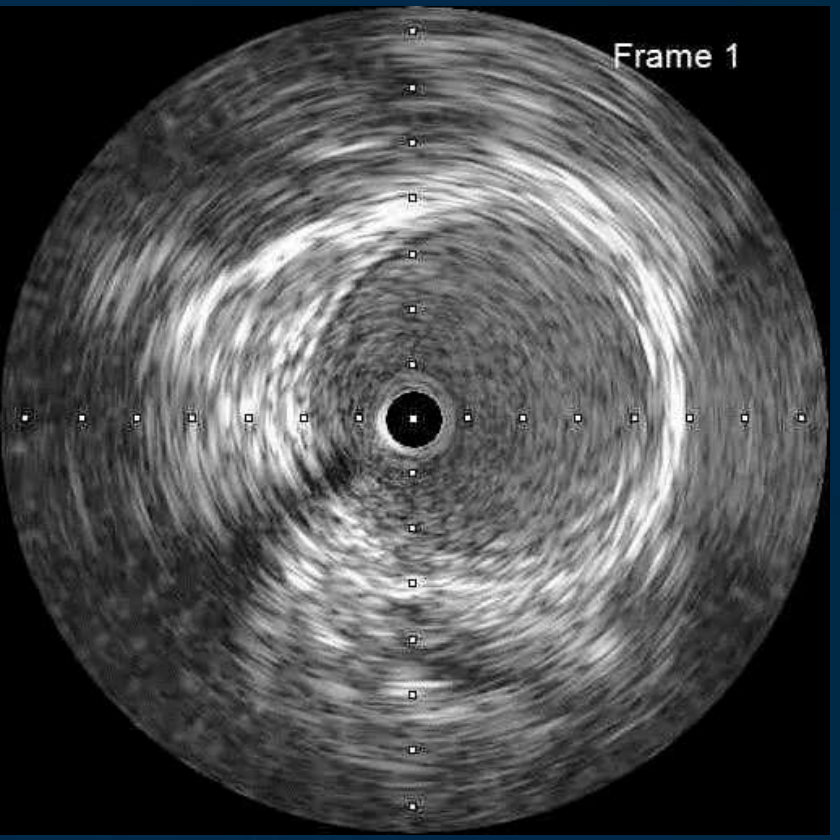
Using Smart masking system ***0.014 Thruway wire crossing*** ***Direxion Transcend Microcatheter***





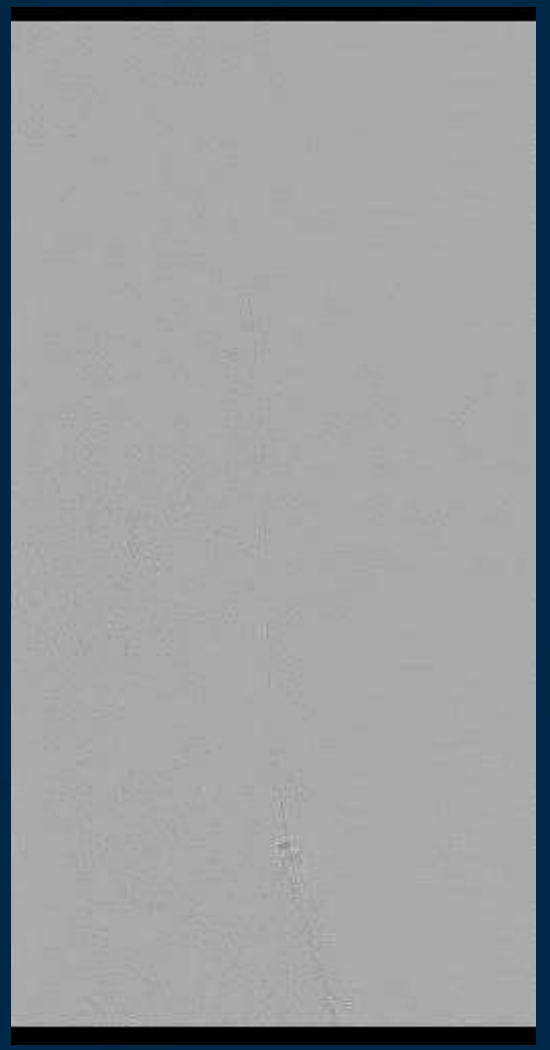
Procedure

IVUS

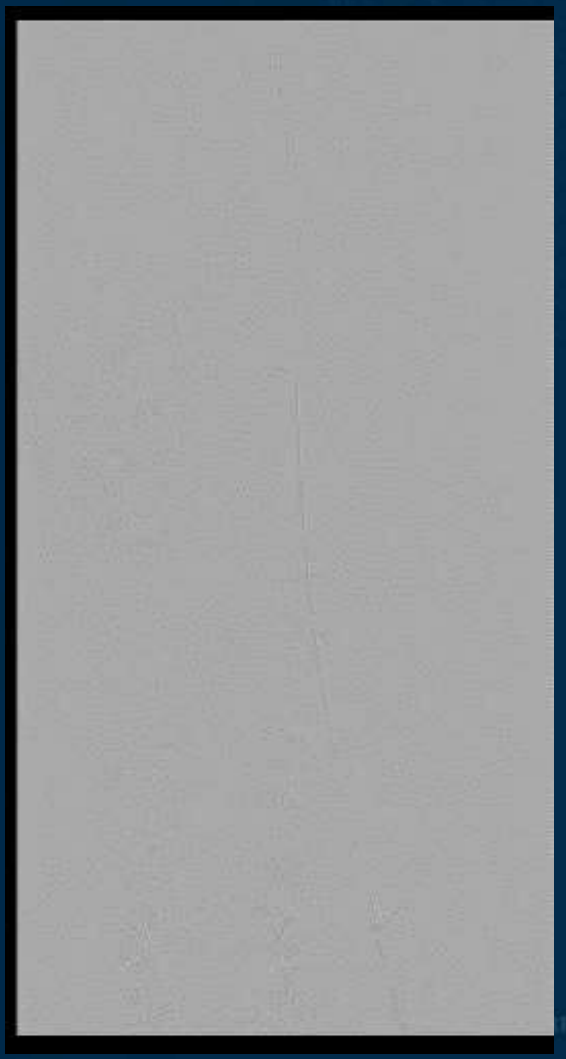


Jetstream

After Jetstream

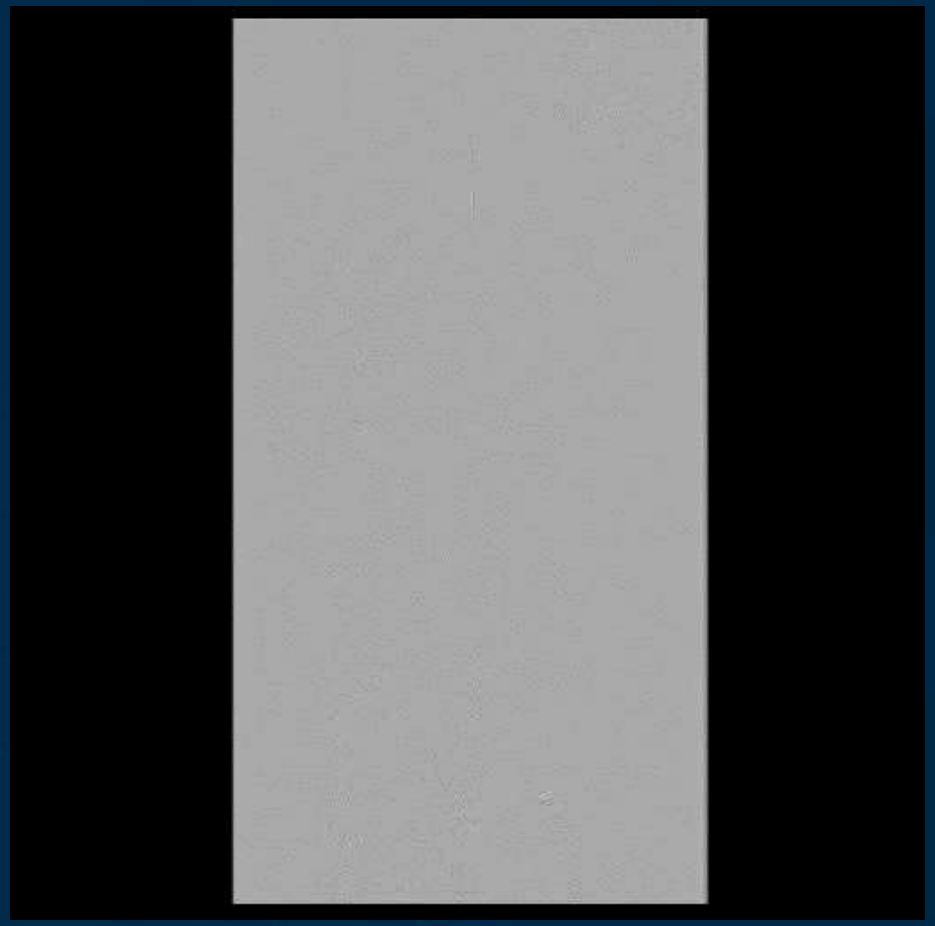


Sterling 4mm, 40mm balloon

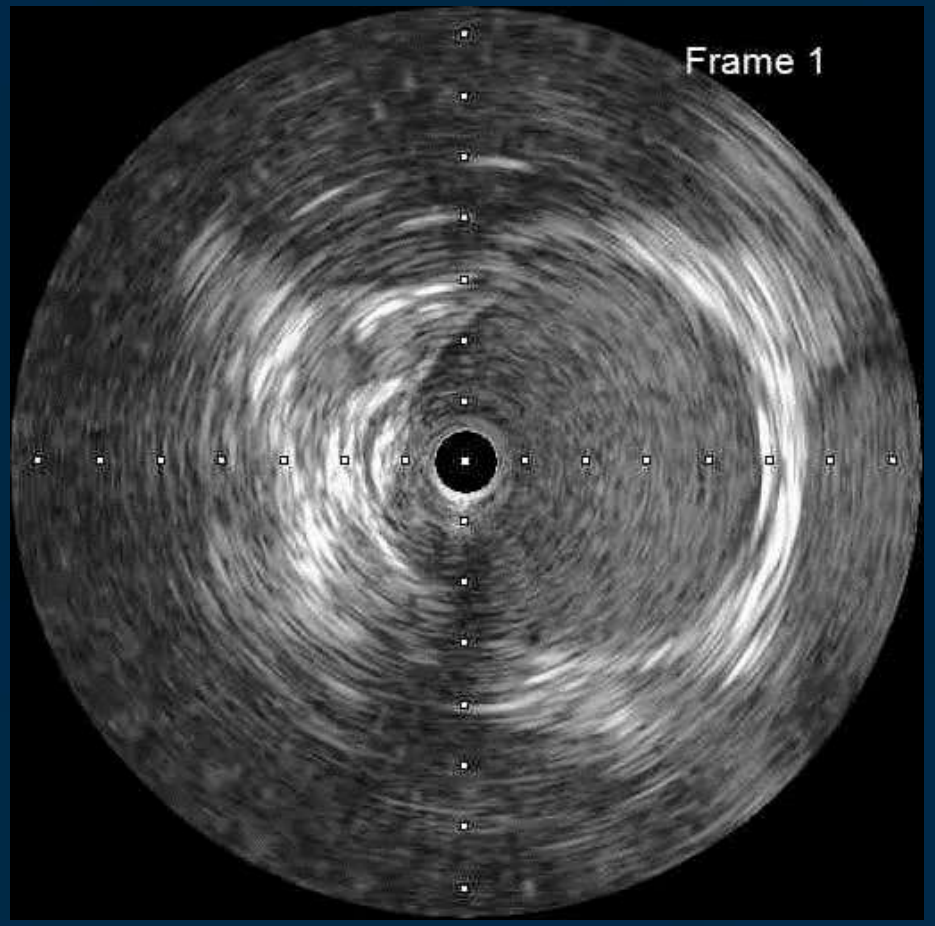


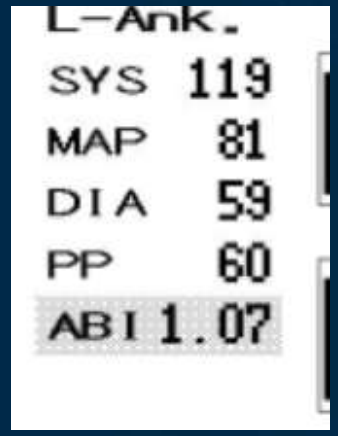
Gradual balloon size up

5mm balloon and 6mm Ranger balloon



Final IVUS

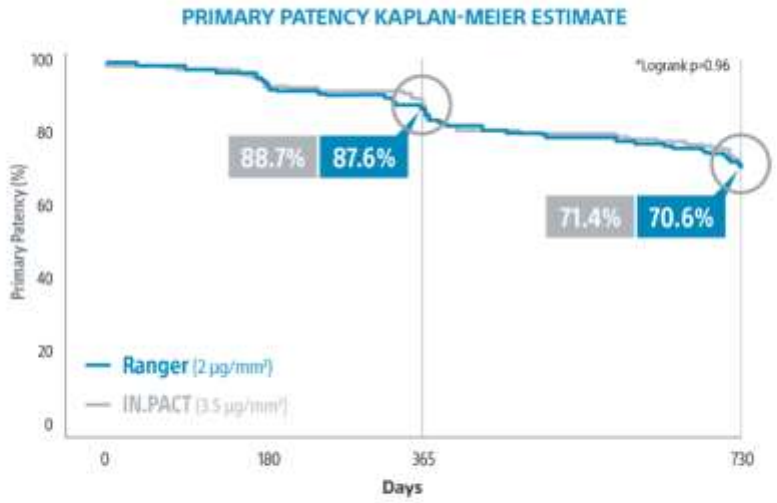




Ranger Outcome studies

Ranger demonstrated similar primary patency[1] with half the total drug dose.[2]

12-Month Results Published in European Heart Journal



At time point zero: **Ranger** n=207 **IN.PACT** n=207

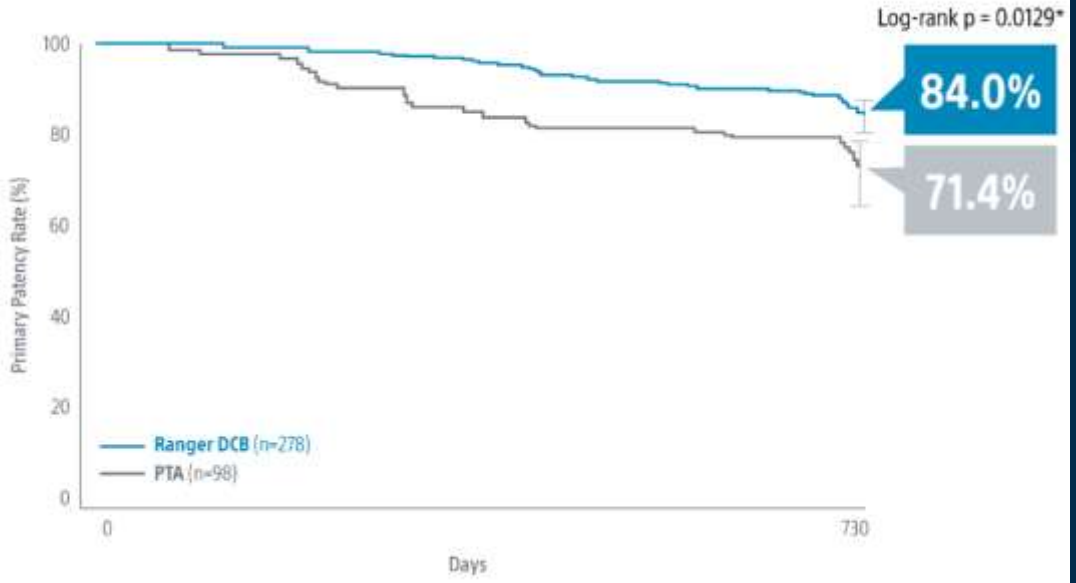
*Log-rank p-value compares the entire K-M curves from time zero to full two-year follow-up window.

RANGER II SFA Pivotal Trial[1]

Prospective, Multi-Center, Randomised Controlled Trial Ranger Drug-Coated Balloon vs. Uncoated Balloon (3:1). Follow-up through 5-Years.

Ranger DCB demonstrated exceptional outcomes at 2-Years.

2-YEAR KAPLAN-MEIER PRIMARY PATENCY ESTIMATE



1. RANGER II SFA RCT 2-Year Results presented by Ravish Sachar, MD. VIVA 2021.

Summary

- In popliteal artery intervention, minimizing dissection can help prevent the need for bailout stenting.
- To achieve leave-nothing-behind strategy
  - Wiring is important (without using a knuckle wire technique)
  - Atherectomy can be helpful.
  - Use proper size (or slightly less than reference diameter) of the balloon
- Lastly, the Ranger DCB can lead to longer-term benefits.