TCTAP 2022

YONSEI UNIVERSITY

Leave Nothing Behind with Atherectomy with Jetstream

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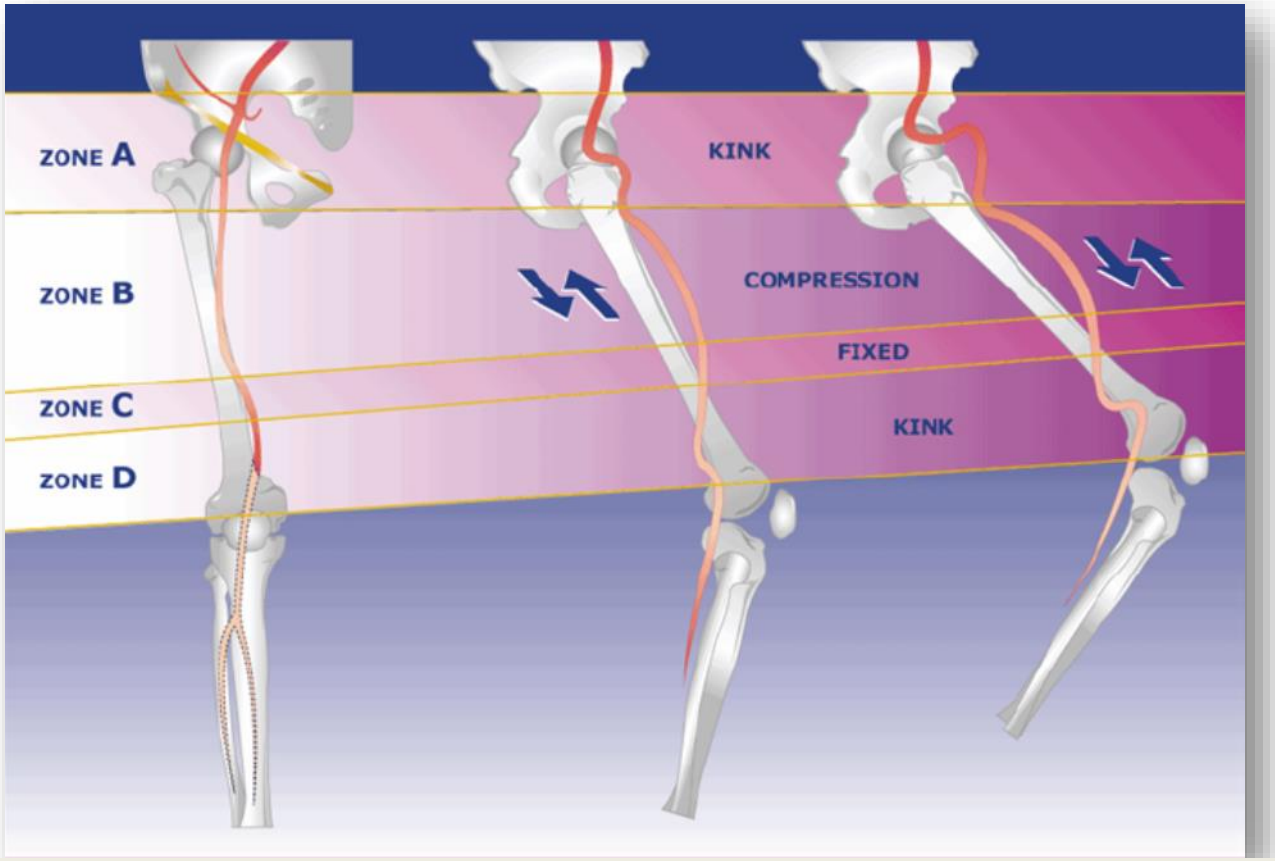
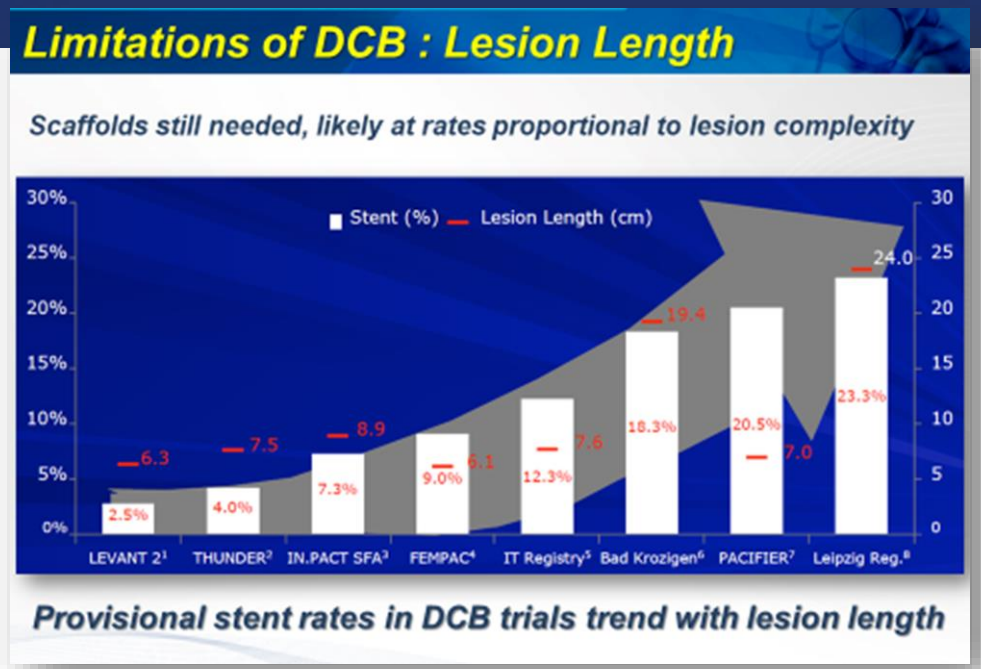
Unique anatomy & Biomechanics

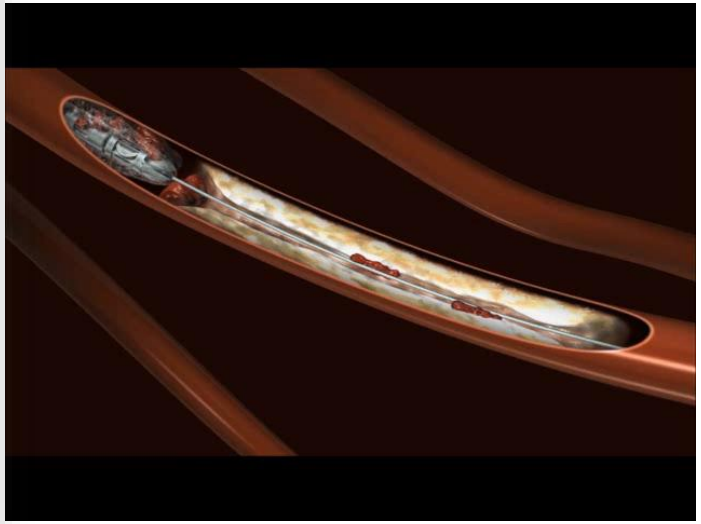


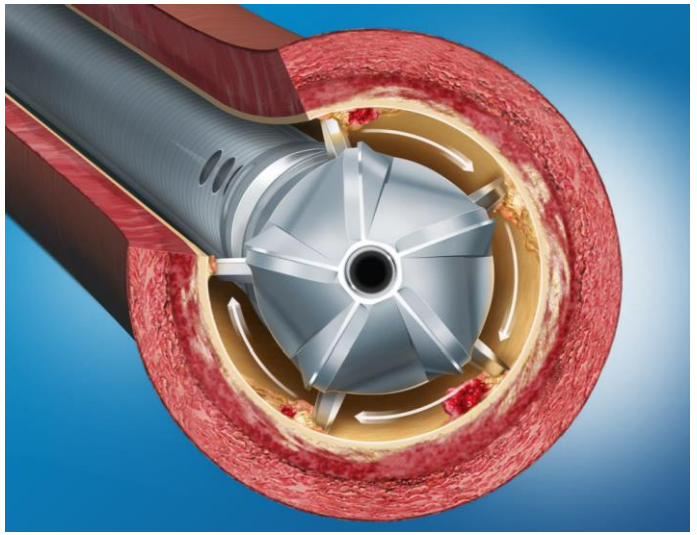
- *High prevalence of diffuse/calcified/thrombotic disease*
- *Different mechanical forces → deformed in multiple directions by leg movement*

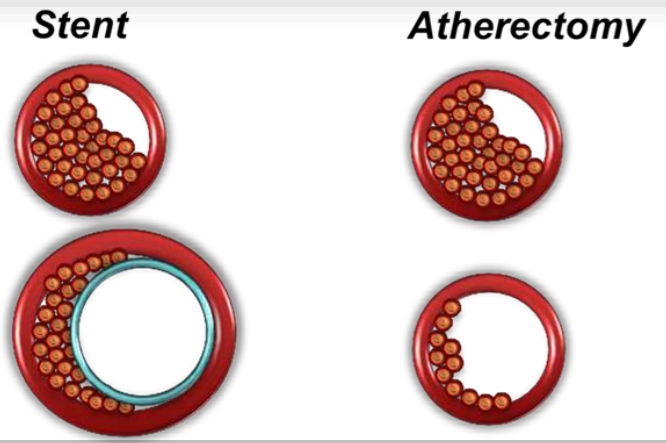
Artherectomy and Anti-restenotic Tx



RAART







Atherectomy enlarges the vascular lumen by removing tissue with little vessel stretching where as balloon angioplasty and stenting have their predominant effect as a direct result of vessel stretching

Calcium Reduces DCB Efficacy

- 60 pts with SFA stenosis or occlusion treated with DCB
- CTA, DSA, and IVUS used to quantify the calcium burden
- At 1 year, greater calcification was associated with:
  - patency- 50% for 270°-360° vs 100% for 0°-90°
  - ankle-brachial index
  - late lumen loss and TLR
- DEFINITIVE AR: directional atherectomy + DCB vs DCB alone

	DCB	Atherectomy + DCB	Atherectomy + DCB (Severe Ca^{2+})
Technical Success	64.2%	89.6%	84.2%
Bail--out stent	3.7%	0%	5.3%
Flow- limiting Dissection	19%	2%	0%

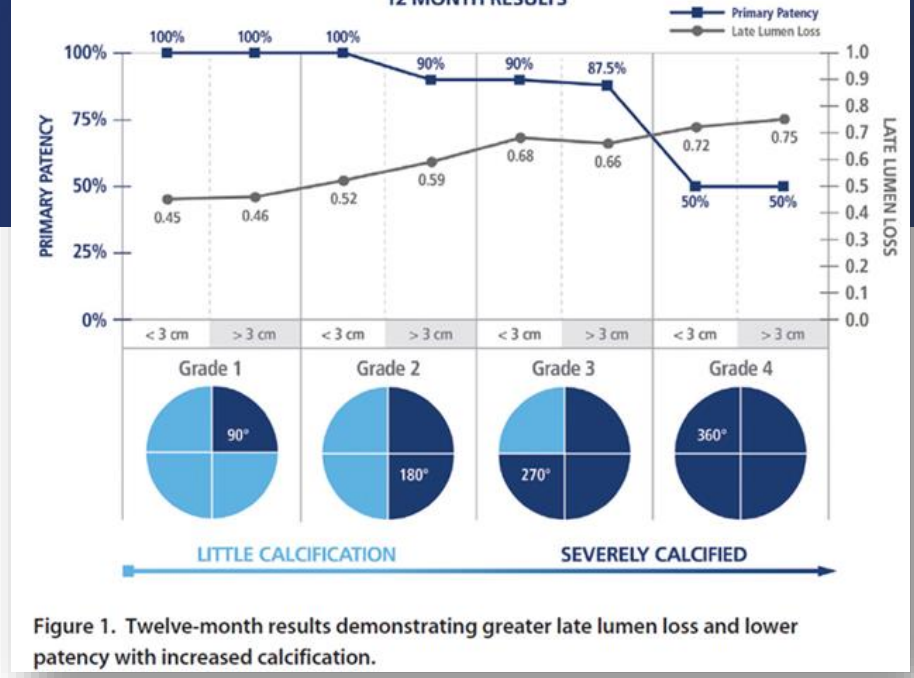
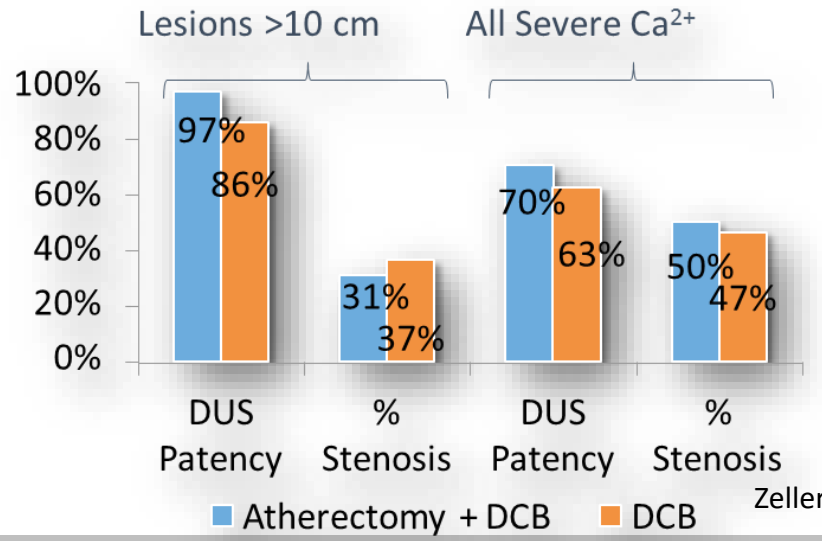


Figure 1. Twelve-month results demonstrating greater late lumen loss and lower patency with increased calcification.

Fanelli F, et al. Cardiovasc Intervent Radiol. 2014 ;37(4):898--907.



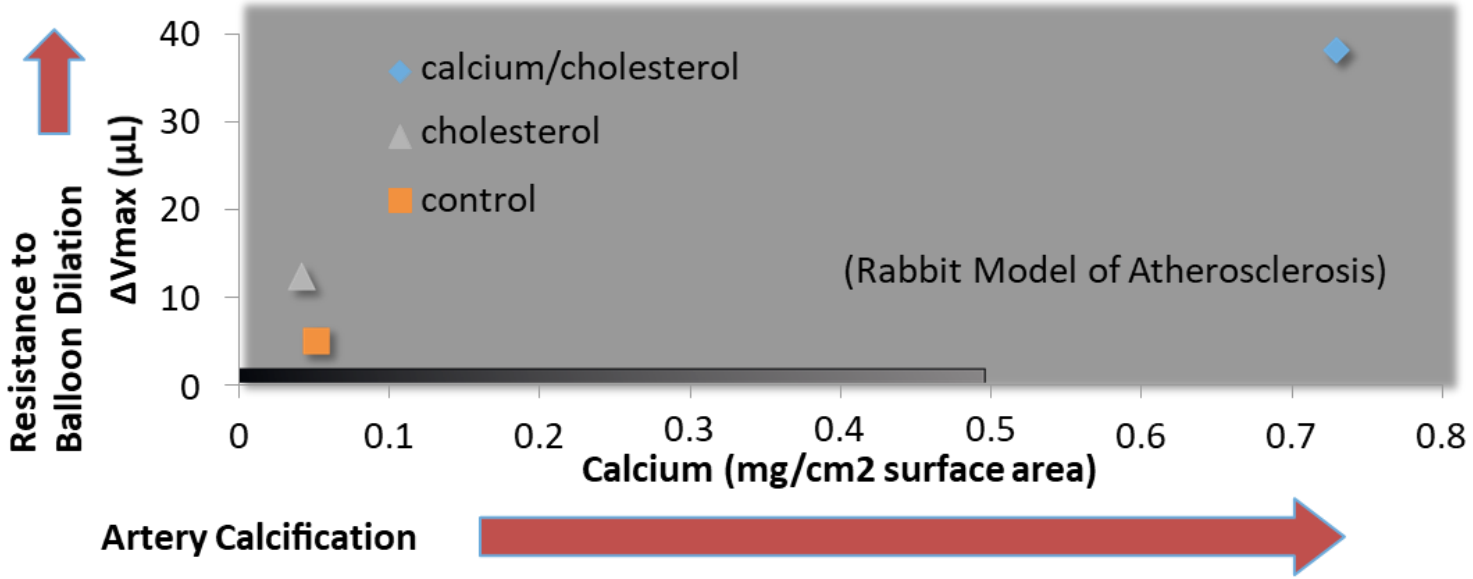
Zeller, VIVA 2014.

Calcium Makes More Complications

- **Calcium is heavily present in peripheral lesions[1]**
- **Presence of calcium necessitates greater balloon pressures[2,3]**
- **Plaques associated with arterial dissections commonly have significant calcium deposits[5]**

1. Bishop, et al. Ann Vasc Surg. 2008;22:799--805. 2. Demer. Circulation. 1991;83:2083--2093.
3. Makam. J Invasive Cardiol. 2013;25(2):85--8.

Calcium Increases Arterial Resistance to Balloon Dilation[2]



Calcium Limits Vessel Expansion[4]

Significant difference in vessel compliance leads to overstretch in non-diseased tissue causing dissections, recoil, excessive injury, and poor outcomes

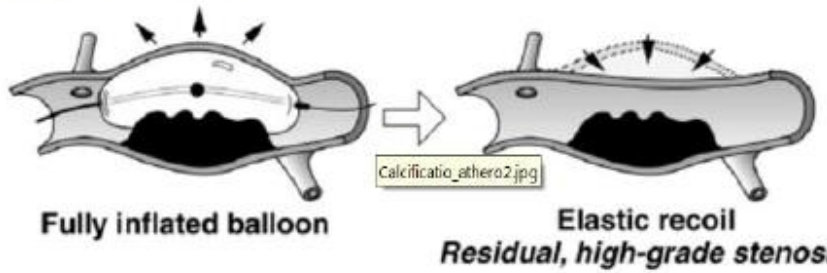


Figure 12.1. Elastic Recoil After PTCA of Calcified Lesions

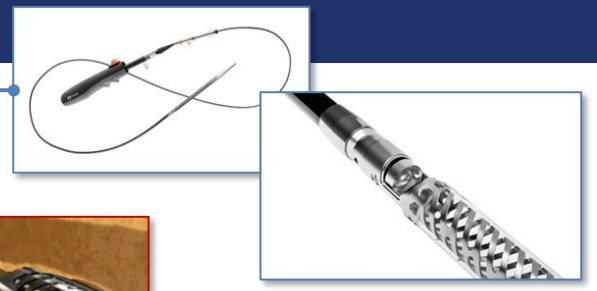
Rather than cracking the hard, calcified atheroma, PTCA causes stretching of the contralateral plaque-free wall segment and ineffective dilatation.

Freed MS, Safian RD; Manual of Interventional Cardiology, Ch. 12, 245-254

4. Fanelli F, et al. Cardiovasc Intervent Radiol. 2014 ;37(4):898--907.
5. Fitzgerald, et al. Circulation. 1992;86(1):64--70.

Current Available Arterectomy Devices

Directional Atherectomy
- Hawkone (Medtronic)
- Pantheris (Avinger)



Orbital Atherectomy
- Diamondback 360 (CSI)

Rotational Atherectomy
- JetStream (Boston Scientific)
- Phoenix (Volcano)

Photoablation Atherectomy
- Turbo-Elite & Turbo-Tandem (Spectranetics)
- Eximo b-laser atherectomy

- Rotarex

– atherectomy & thrombectomy

When and Where?

Anatomical Location

DA	RA	OA	Laser	Location
X	X	X	X	Above-knee
X		X	X	Below-knee

Plaque Composition

DA	RA	OA	Laser	Composition
X		X		Ca^{2+}
X	X	X	X	Soft
	X		X	Thrombus

Lesion Morphology

Morphology	DA	RA	OA	Laser
Focal	X			X
CTO	X	X		X
Eccentric	X	X		
Concentric	X	X	X	X

In-Stent Restenosis

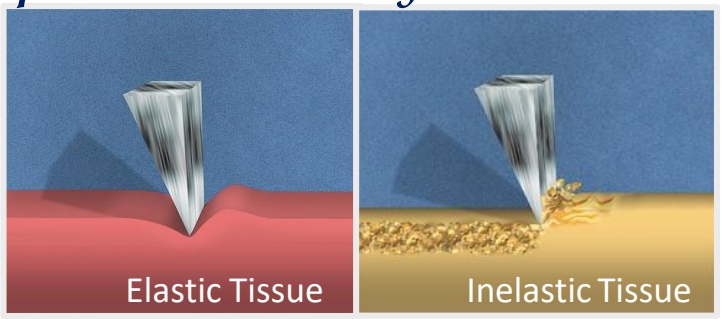
ISR	DA	RA	OA	Laser
Indication				X

Individual operator experience and preference are likely the primary influencers in device selection.

Rotational Device Characteristics

- *Front-cutting*
  - *Immediately engage the lesion*
  - *Facilitate guidewire placement across a CTO*
- *Differential cutting*
  - *Cut one material while sparing another based on differences in composition*
  - *Elastic tissue (vessel wall) deflects away from the atherectomy device while inelastic tissue (plaque) is selectively ablated*

Jetstream (Boston Scientific)



ACTIVE ASPIRATION:
The only atherectomy device with Active Aspiration

CONCENTRIC LUMENS:
Rotational, expandable blades maximize luminal gain through debulking

JETSTREAM Catheter : XC and SC

JETSTREAM XC Catheters

XC 2.1/3.0mm

XC 2.4/3.4 mm

(SFA & Popliteal Sizes)

JETSTREAM SC Catheters

SC 1.6mm

SC 1.85mm

(Tibial Sizes)

Confirm the Minimum Vessel Diameter ***Proximal to the Lesion***

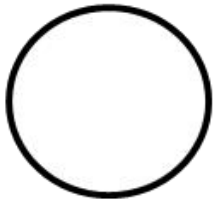
Minimum Vessel Diameter Blades Down	**3.5 mm**
Minimum Vessel Diameter Blades Up	**4.5 mm**

Minimum Vessel Diameter Blades Down	**3.0 mm**
Minimum Vessel Diameter Blades Up	**4.0 mm**

Minimum Vessel Diameter Blades Down	**2.75 mm**

Minimum Vessel Diameter Blades Down	**2.5 mm**

JETSTREAM Advantages

	JETSTREAM	vs	HAWK-series
Running Time	3.5 min		50 minutes
Luminal Shape			
In-Stent Restenosis, In-Stent Occlusion, Calcium Indication	O		X
BTK Indication	O		X
Cutting Tip Design			

Jetstream Clinical Studies

Pathway PVD study

172 patients at 9 European centers

51% had lesions with moderate to high calcium, 31% total occlusions

74% TLR-free at 12 months

Patients with diabetes had MAE rates and clinical improvement similar to those without diabetes

Jetstream Calcium Study

26 pts with moderately to severely calcified femoropopliteal artery lesions

Lumen area increased significantly after treatment with Jetstream; calcium reduction was responsible for 86% of the lumen increase

JET Registry

Post-market registry of 241 patients at 37 US centers

Mean lesion length 16 cm, 48% calcium grade 3 or 4, 36% total occlusions

22.8% 12-month restenosis rate
81.7% TLR/TVR-free rate at 12 months

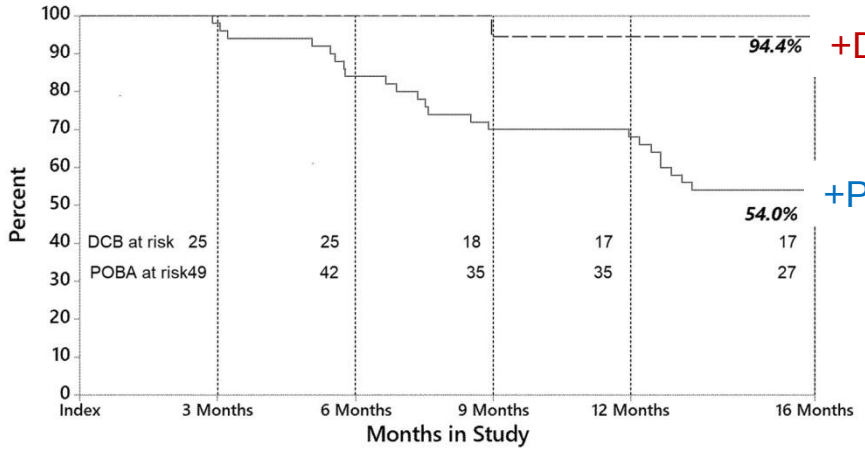
Zeller et al. J Endovasc Ther 2009;16:653–662.
Sixt et al. Ann Vasc Surg 2011; 25:520-529.
Maehara A, et al. EuroIntervention 2015; 19;11:96-103.
Garcia LA, et al. LINC 2017

JET-SCE -Jetstream + DCB vs Jetstream + PTA

- *Retrospective study of patients receiving Jetstream atherectomy to treat femoropopliteal obstructive disease*

- *N=75*
- *Treated Apr 2012 -Dec 2014 - adjunctive PTA (N=50)*
- *Treated Dec 2014–Jul 2016 -adjunctive DCB (N=25)*
- *Median treated length (p=0.053)*
  - *Adjunctive PTA: 15 cm*
  - *DCB: 10 cm*

KM Estimate for Freedom from TLR
Jetstream + DCB vs Jetstream + PTA



TLR rates at 16 months were significantly reduced with DCB
Atherectomy with adjunctive DCB (94.4%)
compared with
Atherectomy with adjunctive PTA (54.0%)
(94.4% vs 54%; p = 0.002)

Shammas NW, et al. Cardiovasc Revasc Med. 2018.

Long-Term Outcomes After Percutaneous Lower Extremity Arterial Interventions With Atherectomy vs. Balloon Angioplasty

— Propensity Score-Matched Registry —

Adam Janas, MD, PhD; Piotr P. Buszman, MD, PhD; Krzysztof P. Milewski, MD, PhD; Szymon Wiernek, MD, PhD; Ksenia Janas, MD; Maciej Pruski, MD; Wojciech Wojakowski, MD, PhD; Aleksandra Błachut, MD; Wojciech Picheta, MD; Pawel Buszman, MD, PhD; Stefan Kiesz, MD

Circ J 2017; **81:** 376–382
doi:10.1253/circj.CJ-16-0856

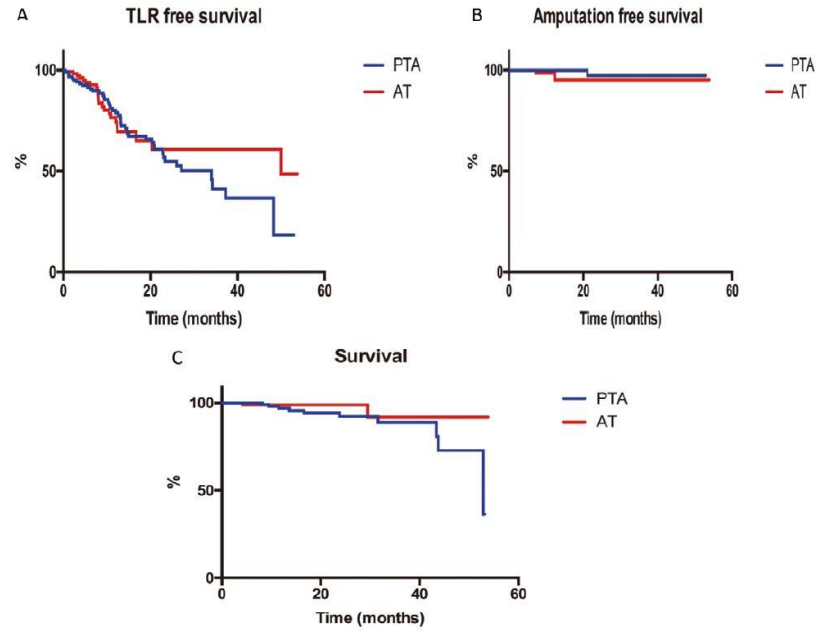


Figure 4. Kaplan-Meier analysis of (**A**) target lesion revascularization (TLR)-free survival; (**B**) amputation-free survival; and (**C**) overall survival after propensity score matching. AT, atherectomy; PTA, percutaneous transluminal angioplasty.

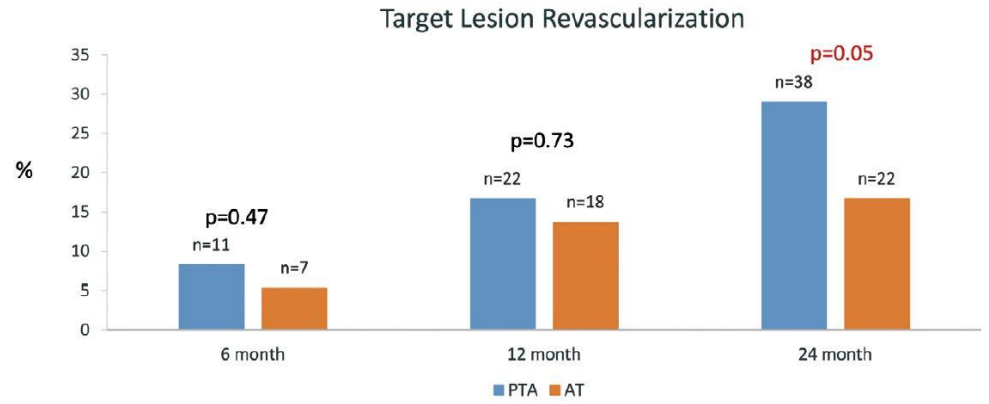


Figure 2. Target lesion revascularization at 6 months, 1 year and 2 years after propensity score matching. AT, atherectomy; PTA, percutaneous transluminal angioplasty.

Outcomes of Adjunctive Drug-Coated Versus Uncoated Balloon after Atherectomy in Femoropopliteal Artery Disease

Ann Vasc Surg 2020; 68: 391–39

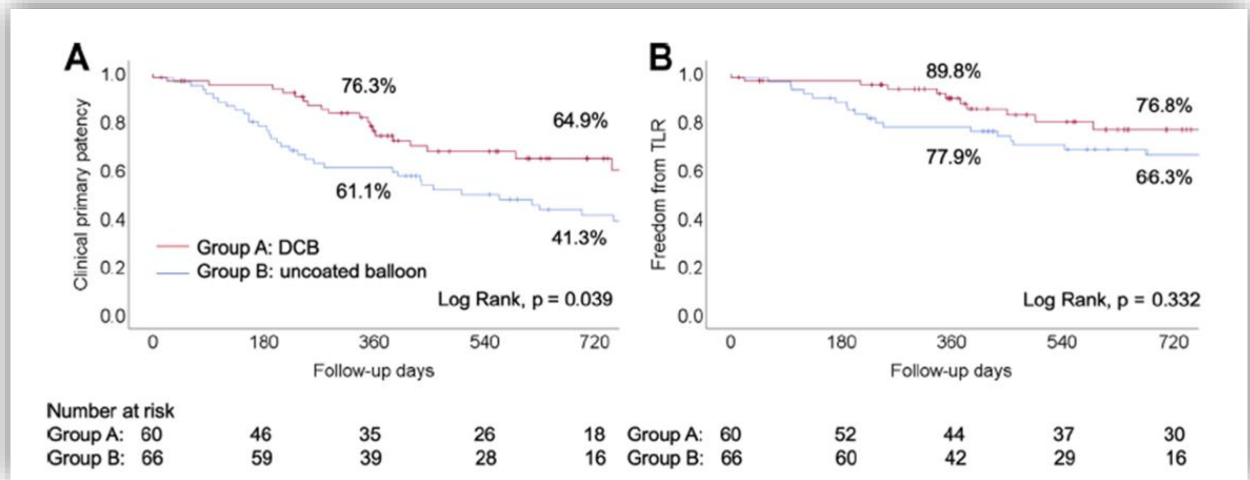
Yun-Jeong Lee,[1] Young-Guk Ko,[2] Chul-Min Ahn,[2] Sung-Jin Hong,[2] Jung-Sun Kim,[2] Byeong-Keuk Kim,[2] Donghoon Choi,[2] Myeong-Ki Hong,[2] and Yangsoo Jang,[2] Jeju-si and Seoul, Republic of Korea

- *115 pts, 126 femoropopliteal disease, atherectomy*
- *Group A : 66 DCB vs. Group B: 60 POBA*
- *July 2009 to March 2018*

Variables	All lesions (n = 126)	Atherectomy and DCB (group A, n = 66)	Atherectomy and uncoated balloon (group B, n = 60)	P-value
Atherectomy device				
Directional	…6.2)	37 (56.1)	59 (98…	
Rotational	30 (23.8)	29 (43.9)	1 (1.7)	

Native lesion

In-stent Restenosis



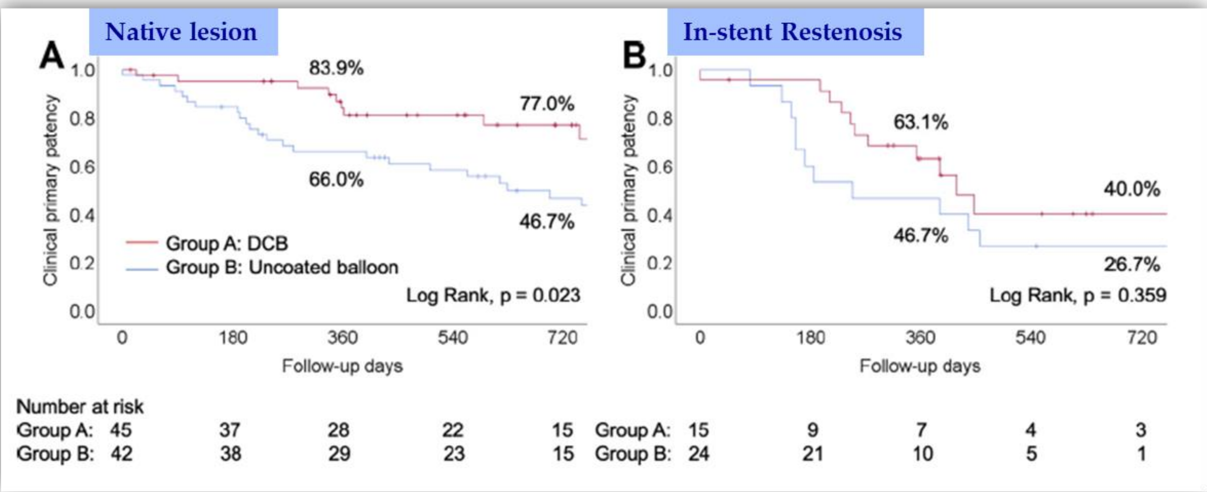


Table III. Cox proportional hazard regression analysis for factors associated with loss of clinical patency after atherectomy

	Univariate analysis		Multivariate analysis	
Variables	HR (CI)	*P*-value	HR (CI)	*P*-value
Hypertension	0.51 (0.25–1.04)	0.064	0.48 (0.23–1.01)	0.053
ESRD	1.87 (1.01–3.45)	0.044	1.88 (0.93–3.78)	0.078
Critical limb ischemia	2.02 (1.20–3.42)	0.009	1.47 (0.81–2.65)	0.204
TASC II type D lesion	2.58 (1.52–4.40)	<0.001	1.86 (0.94–3.68)	0.074
Total occlusion	1.67 (0.99–2.82)	0.053	1.06 (0.55–2.04)	0.865
ISR lesion	2.25 (1.32–3.83)	0.003	1.95 (1.11–3.42)	0.020
DCB use	0.57 (0.33–0.98)	0.041	0.53 (0.30–0.93)	0.026
Directional atherectomy	0.78 (0.39–1.55)	0.471		
First 30 atherectomy cases	1.06 (0.58–1.91)	0.859		

Table IV. Cox proportional hazard regression analysis for factors associated with loss of clinical patency after atherectomy plus drug-coated balloon

	Univariate analysis		Multivariate analysis	
Variables	HR (CI)	*P*-value	HR (CI)	*P*-value
Age	0.94 (0.91–0.98)	0.001	0.94 (0.90–0.99)	0.016
Male	0.37 (0.15–0.92)	0.032	0.65 (0.21–2.06)	0.464
Hypertension	0.36 (0.12–1.07)	0.067	0.61 (0.15–2.43)	0.480
ESRD	2.33 (0.94–5.74)	0.067	1.32 (0.44–4.02)	0.622
TASC II D	4.43 (1.88–10.44)	0.001	1.60 (0.55–4.66)	0.388
Total occlusion	2.26 (0.97–5.27)	0.060	1.30 (0.46–3.65)	0.619
ISR lesion	3.77 (1.54–9.19)	0.004	2.90 (0.97–8.68)	0.057
Provisional stenting	11.91 (3.06–46.31)	<0.001	9.78 (2.20–43.46)	0.003
Directional atherectomy	0.71 (0.29–1.71)	0.439		

Clinical Investigation

Osamu Iida, MD[1], Kazushi Urasawa, MD[2], Yoshisato Shibata, MD[3], Yoshito Yamamoto, MD[4], Hiroshi Ando, MD[5], Masahiko Fujihara, MD[6], Tatsuya Nakama, MD[7], Yusuke Miyashita, MD[8], Shinsuke Mori, MD[9], Juan Diaz-Cartelle, MD[10], and Yoshimitsu Soga, MD[11]

Clinical Safety and Efficacy of Rotational Atherectomy in Japanese Patients with Peripheral Arterial Disease Presenting Femoropopliteal Lesions: The J-SUPREME and J-SUPREME II Trials

Journal of Endovascular Therapy 2021

Purpose: The purpose of the J-SUPREME (J-S) and J-SUPREME II (J-SII) trials was to evaluate the performance of the Jetstream Atherectomy System for the treatment of Japanese patients with symptomatic occlusive atherosclerotic lesions in the superficial femoral and popliteal arteries. **Materials and Methods:** The J-S and J-SII trials were both prospective, multicenter, single-arm clinical trials. Patients in J-S underwent Jetstream atherectomy followed by percutaneous transluminal angioplasty (PTA), whereas those in J-SII had adjunctive drug-coated balloon (DCB) treatment following atherectomy. Patients were adults with Rutherford category 2, 3, or 4 and had stenotic, restenotic, or occlusive lesion(s) with a degree of stenosis ≥70 in the superficial femoral artery and/or proximal popliteal artery. In J-S, lesions were required to be calcified, and in J-SII lesions were required to be severely calcified. **Results:** A total of 50 patients were enrolled in J-S (mean age 72.3±8.7 years, lesion length 82.0±41.5 mm, 36% calcification PACSS Grade 3, 22% Grade 4) and 31 patients in J-SII (mean age 72.5±7.7 years, lesion length 122.6±55.6 mm, 19.4% calcification PACSS Grade 3, 77.4% Grade 4). No bailout stenting or bypass conversions were required. No major adverse events (MAEs) were reported for either trial through 1 month. The 6-month primary patency for J-S, with PTA alone following atherectomy, was 40.4% (19/47). The 6-month primary patency for J-SII, with DCB treatment following atherectomy, was 96.7% (29/30). At 6-month post-procedure, 79.2% (38/48) of patients in J-S, and 100% (30/30) of patients in J-SII had improved by at least 1 Rutherford category. **Conclusion:** J-SUPREME trial results demonstrate procedural safety and efficacy of the Jetstream Atherectomy System and J-SII showed sustained patency through 6 months following combination treatment with Jetstream atherectomy and DCB.

J-SUPREME : Jetstream + PTA

➔ Procedural Safety and efficacy

J-SUPREME II – Jetstream + DCB

➔ Patency maintenance after

Jetstream and DCB combination

Table 3. Per-Protocol Endpoints, Clinical Outcomes, and MAEs.

	J-SUPREME (N=50)	J-SUPREME II (N=31)
Lesion success rate[a]	NA	80.6% (25/31)
Procedural success rate[b]	100% (50/50)	100% (31/31)
Reduction in lesion stenosis[c]	36.1±14.4%	34.6±16.0%
Primary patency at 6 months	40.4% (19/47)[d]	96.7% (29/30)[e]
Primary sustained clinical improvement[f]	79.2% (38/48)	100% (30/30)
Hemodynamic improvement[g]	68.1% (32/47)	73.3% (22/30)
MAE[h]: 1 month	0%	0%
All causes of deaths	0%	0%
Target limb major amputation	0%	0%
Target lesion revascularization	0%	0%
MAE: 6 months	10.0% (5/50)	0%
Target limb major amputation	0%	0%
Target lesion revascularization	10.0% (5/50)	0%
MAE: 12 months	26.0% (13/50)	NA
Target limb major amputation	0%	NA
Target lesion revascularization	26.0% (13/50)	NA
All deaths through follow-up	2.0% (1/50)	0%

JET-RANGER Clinical Study

Enrolling

Clinical Study Overview: JET-RANGER (Investigator sponsored IDE)*	
Title	JETStream AtheRectomy With Adjunctive Paclitaxel-Coated BallooN Angioplasty vs Plain Old Balloon AnGioplasty Followed by Paclitaxel-Coated Balloon in Treating ComplEx Denovo FemoRopopliteal Arterial Disease (JET-RANGER)
Principal Investigator/ Sponsor	**Nicolas W. Shammas, MD** Midwest Cardiovascular Research Foundation
Objective	Test the hypothesis that **Jetstream atherectomy followed by DCB** (Ranger or IN.PACT Paclitaxel Drug Coated Balloon) **improves target lesion revascularization at 1 year follow-up when compared to balloon angioplasty followed by DCB** in the treatment of femoropopliteal arterial de novo disease
Study Design	**Prospective, multicenter, randomized study** **Jetstream + DCB vs PTA + DCB (2:1 randomization)**
Patients	**255 patients at up to 25 US sites** Rutherford category 2-4 and ≥70% de novo stenosis with: lesion length ≥10 cm, or chronic total occlusion (any length) in the SFA and/or popliteal artery, or calcification of ≥ grade by PACCS
Endpoints	**Effectiveness**: Target Lesion Revascularization at 1 Year: intra-procedural bail out stenting of the index lesion is considered meeting a TLR endpoint. **Safety**: Major Adverse Events (MAE) at 30 days: unplanned amputation, total mortality or TLR at 30 days (TLR includes bail out stenting)

Recruitment Status :	Enrolling by invitation
Estimated Primary Completion Date :	November 2022
Estimated Study Completion Date :	November 2022

ClinicalTrials.gov Identifier: NCT03206762

*IDE approval received from the FDA

Tips of Rotational atherectomy

1. *Slow advancement – 1mm/1sec, Don't strong push !!*
   - ✓ *High pitch sound or rotational failure ➔ static/slower procedure*
2. *Intermittent cool down – 30sec/flushing (Rex mod)*
   - ✓ *Prevent Wire & device stucking / Advancement failure*
3. *Distal protection device – usually recommended, especially in CLI pts*
   - ✓ *Small balloon for resistance to advancement of filter device*
4. *Steep aortic bifurcation angle – fluoroscopic guided device transfer*
5. *Don't perforem intra-sheath – device can stuck in side of sheath or sheath fracture*

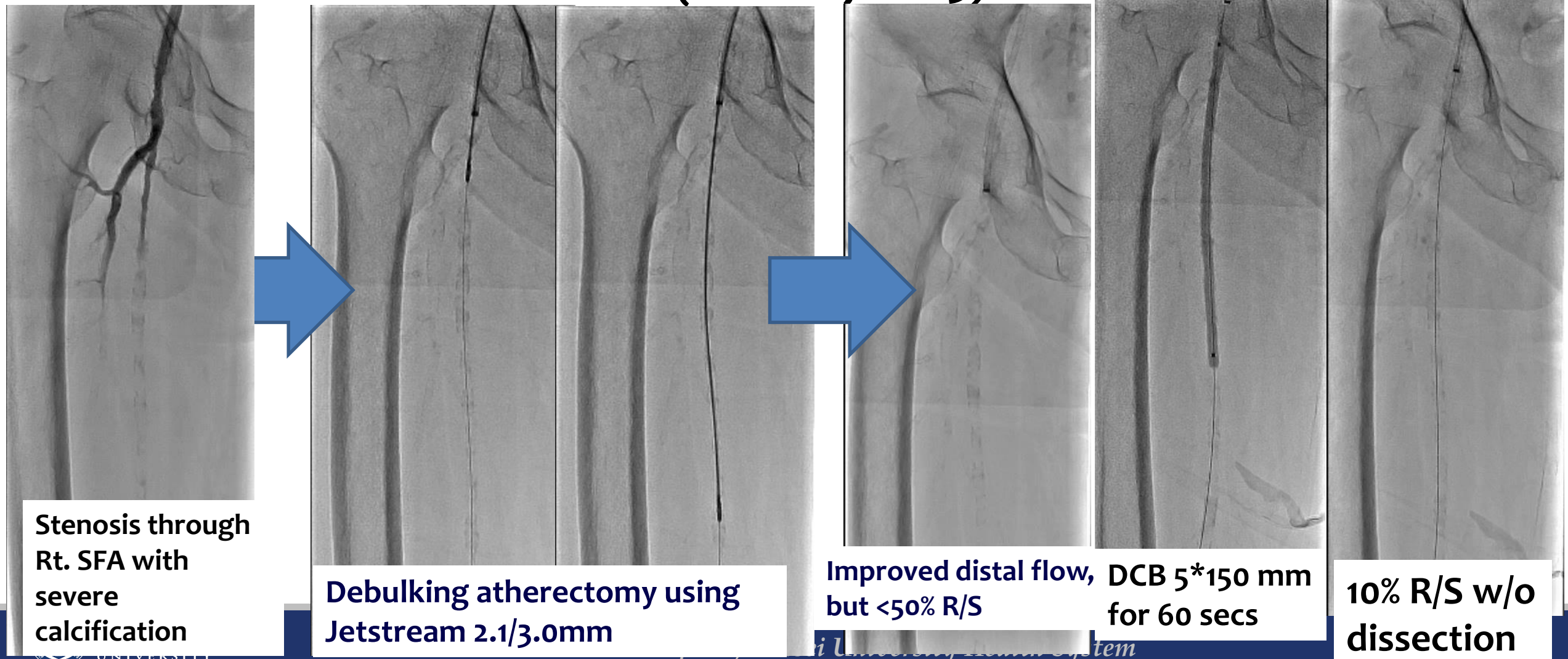
Benefit & Limitation of Rotational atherectomy

- *Benefit*
  - *Long & tight lesion*
  - *Circumferential calcium*
  - *Active aspiration*
  - *Concentric Lumen*
- *Limitation*
  - *Distal embolization*
  - *Wire & Device stucking*
  - *Learning curve*
  - *Passage failure – BTK lesion*

Case Rotational atherectomy F/67

C.C : Ulceration at both 2nd toe (Rutherford 5)

ABI : Rt. 0.21 / Lt. 0.13



Stenosis through Rt. SFA with severe calcification

Debulking atherectomy using Jetstream 2.1/3.0mm

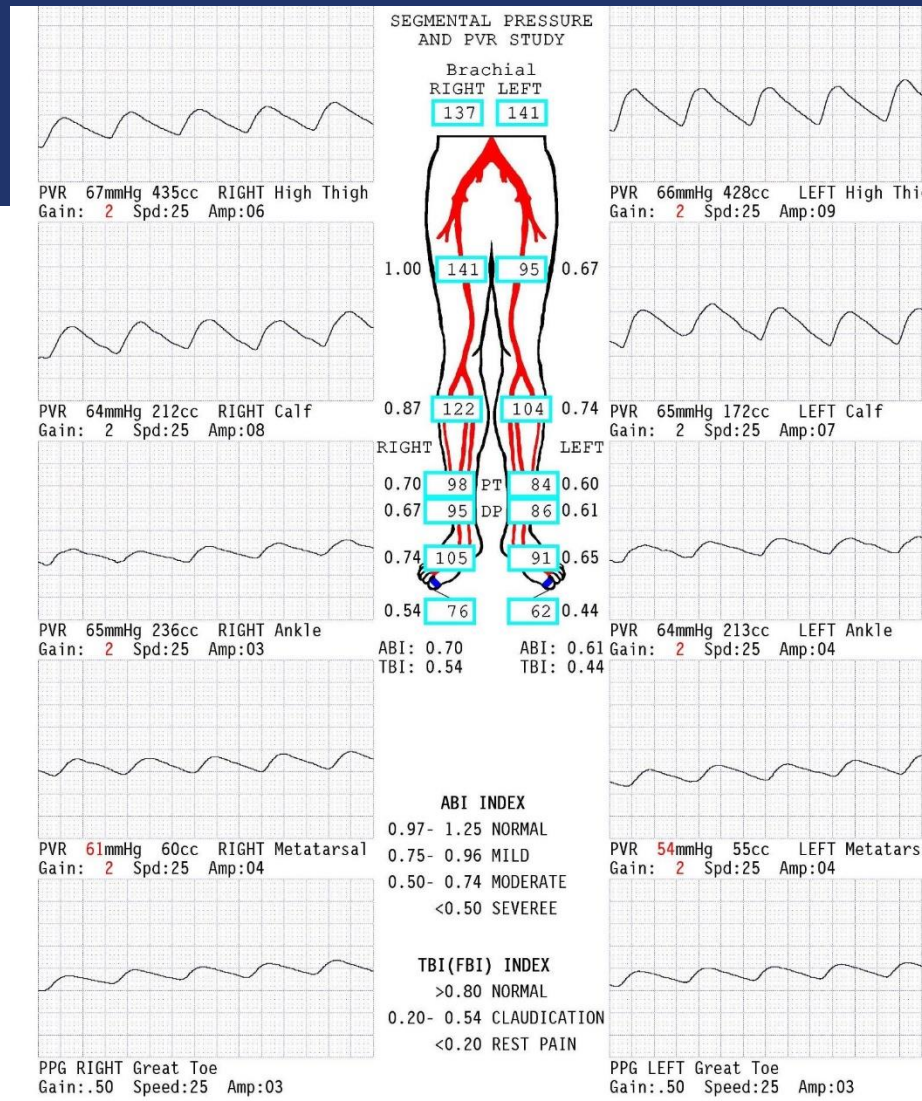
Improved distal flow, but <50% R/S

DCB 5*150 mm for 60 secs

10% R/S w/o dissection

Case – M/84 yo

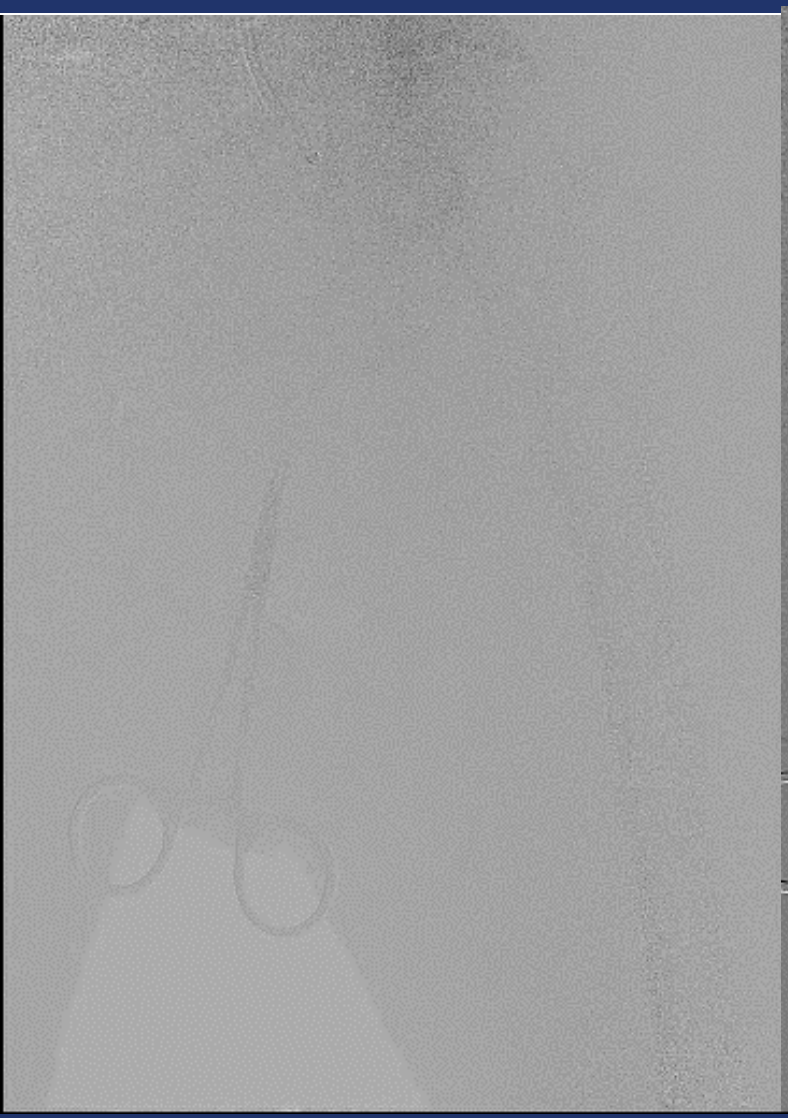
- *Chief complaint*
  - *Claudication(both, Rutherfold 3, 1YA)*
- *PHx*
  - *Poor controlled DM (HbA1C 9.5%)*
  - *BPH*
  - *Ex-smoker(0.5pack/d X 24yrs, 40YA D/C)*
- *Lab*
  - *BUN/Cr : 26.7 mg/dL / 1.29 mg/dL(eGFR 53 ml/min/1.73m²)*
  - *T.Chol/TG/HDL/LDL : 192/175/50/107 mg/dL*

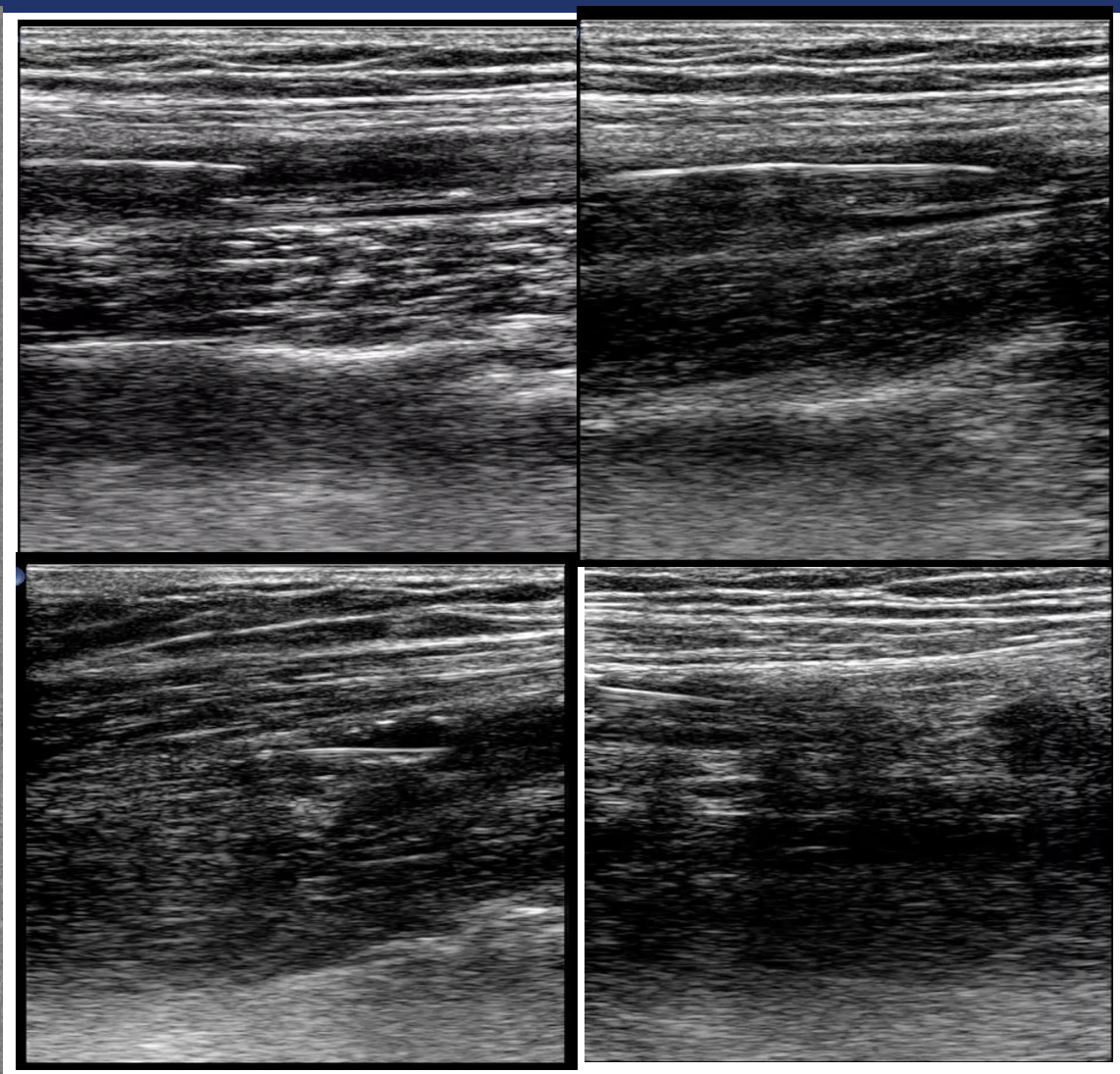


ABI(Ankle / Brachial Index)
→ Rt: 0.70 / Lt: 0.61

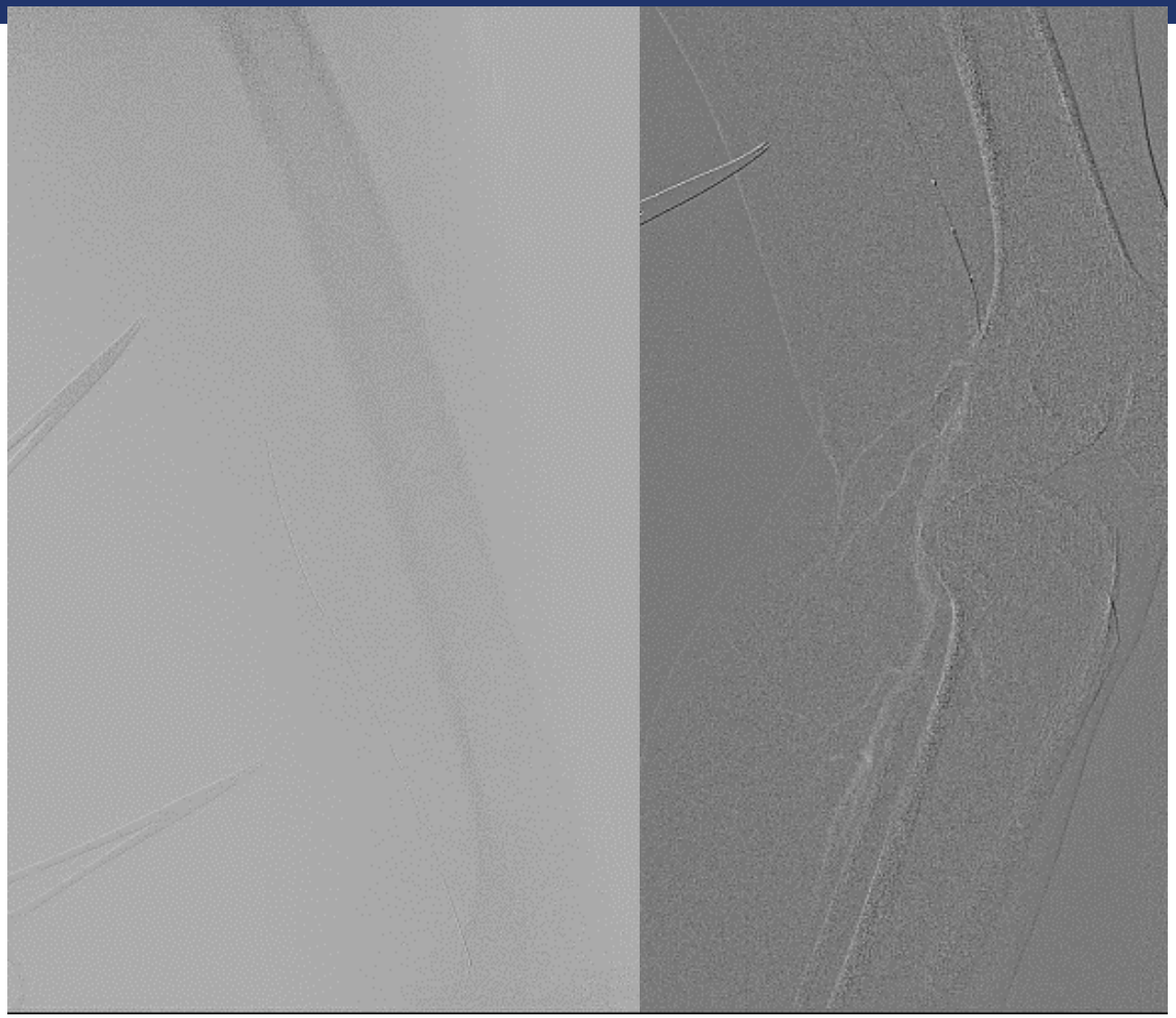
CT Lower Extremity Angio

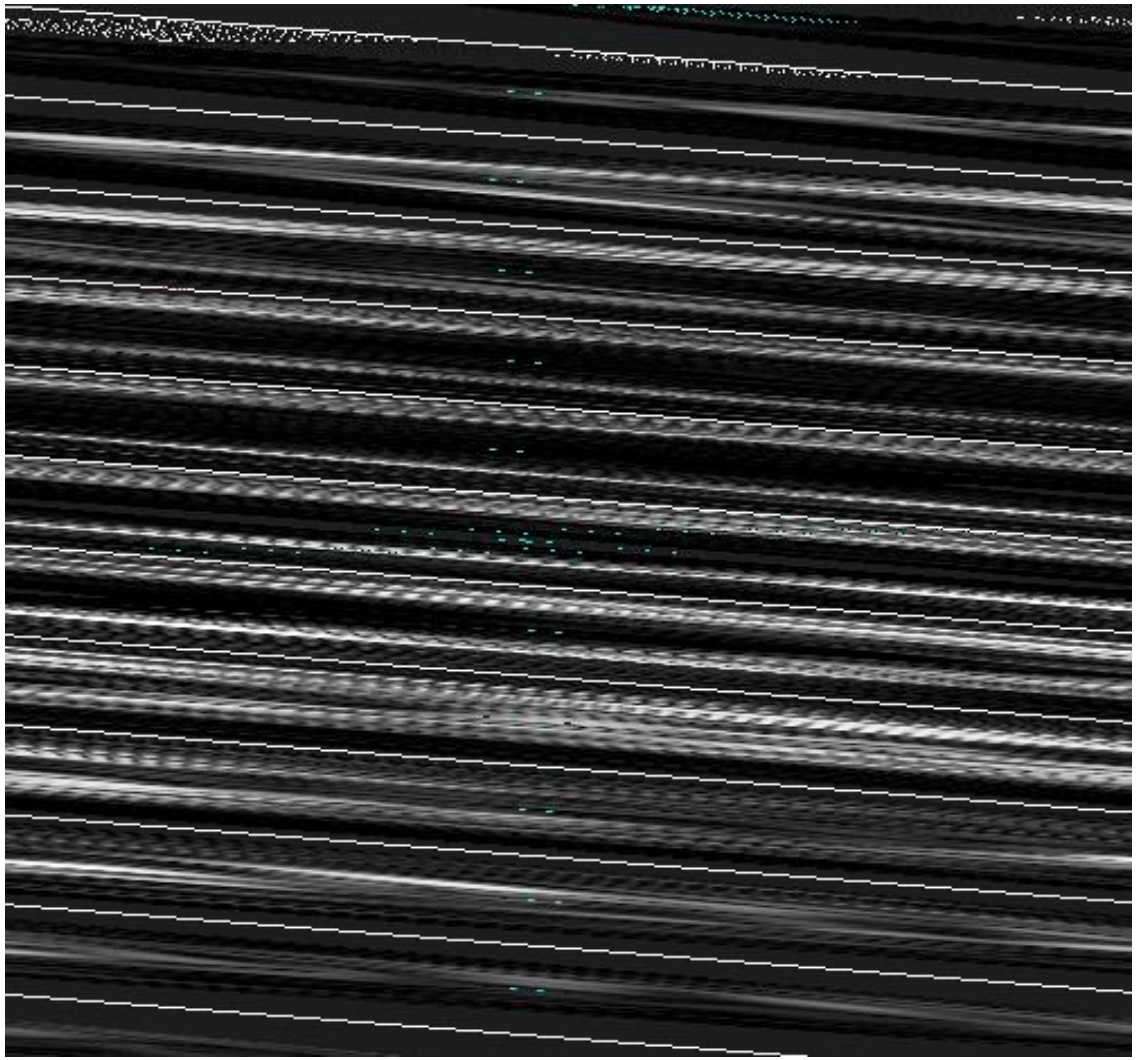
Lt SFA – ultrasound guided wiring



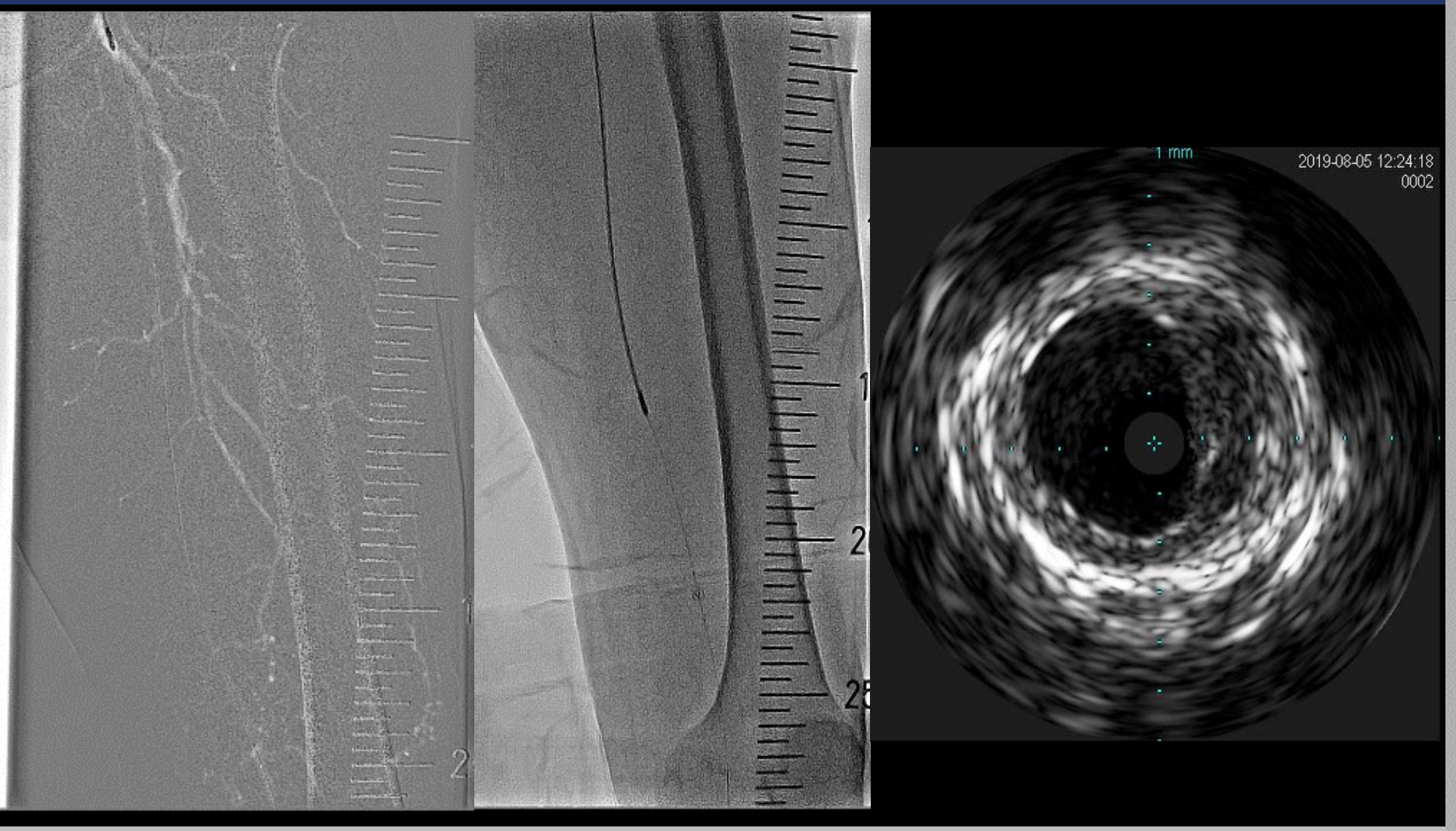


Intraluminal wiring & IVUS

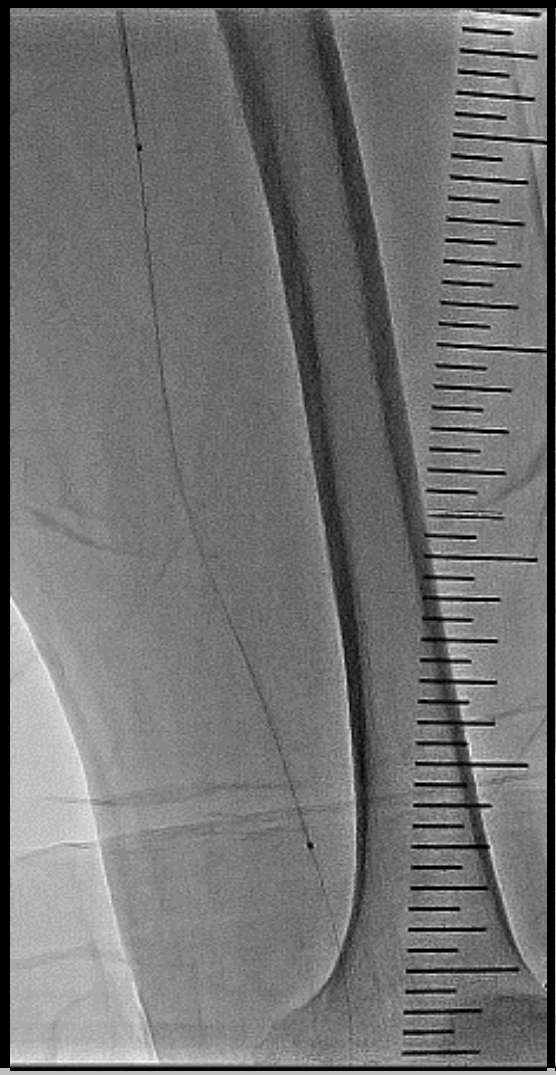


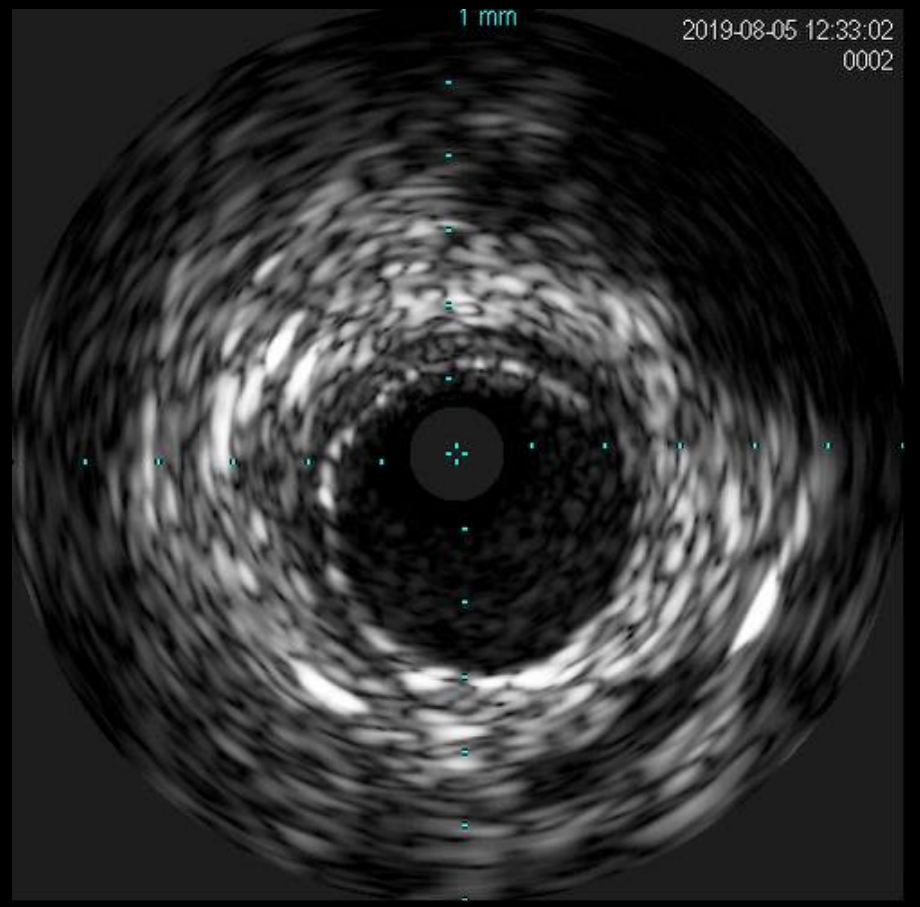


Jetstream Atherectomy & post-IVUS

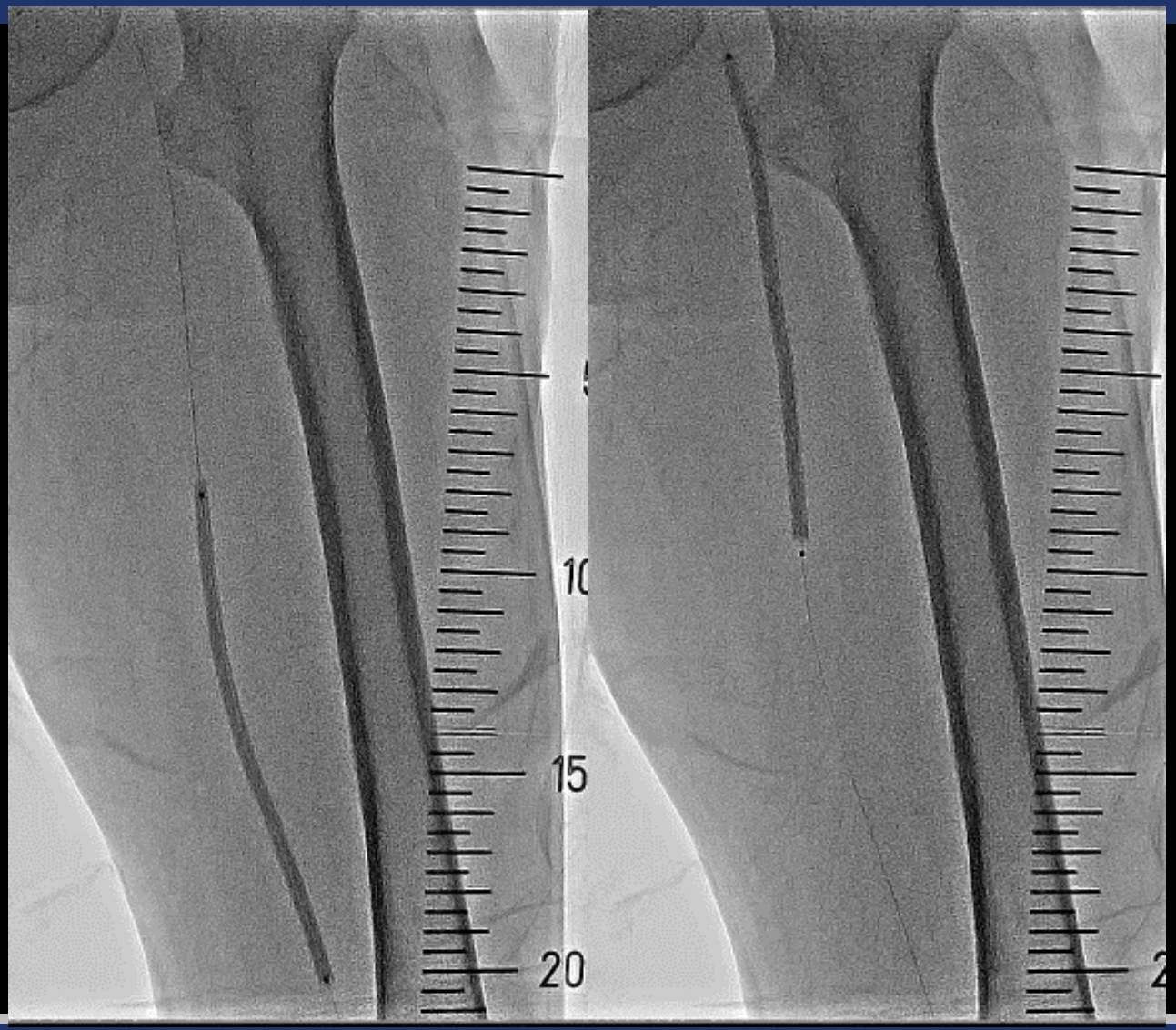


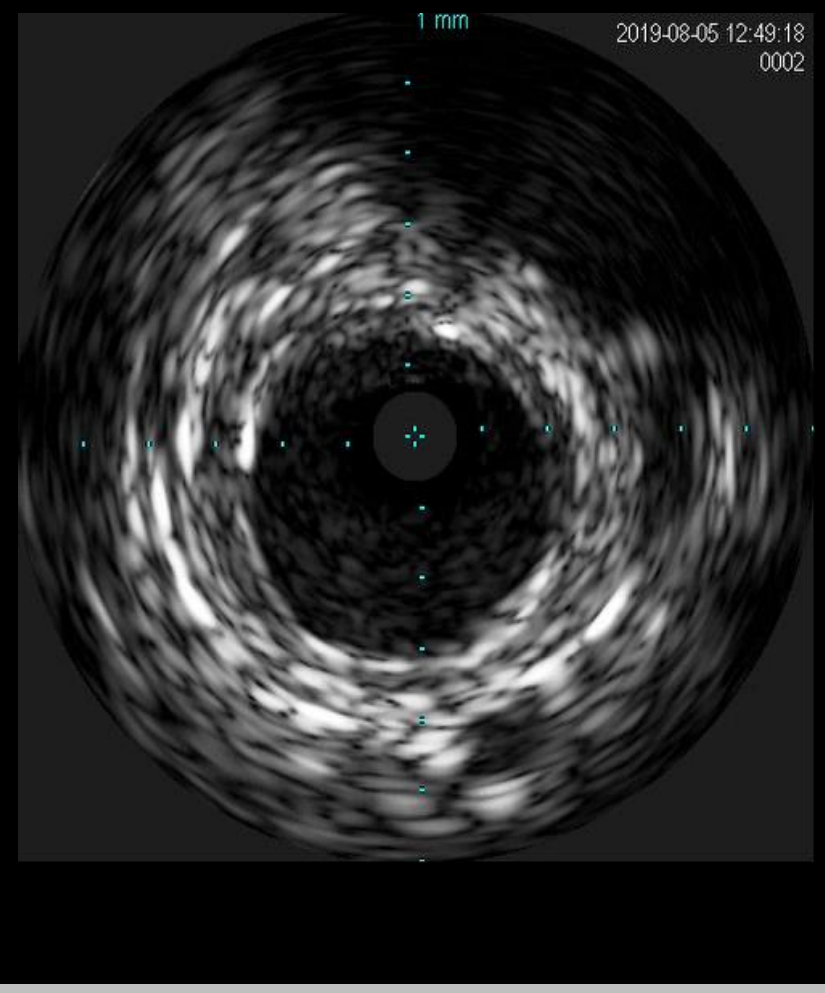
POBA- NC balloon (5x200) – post IVUS



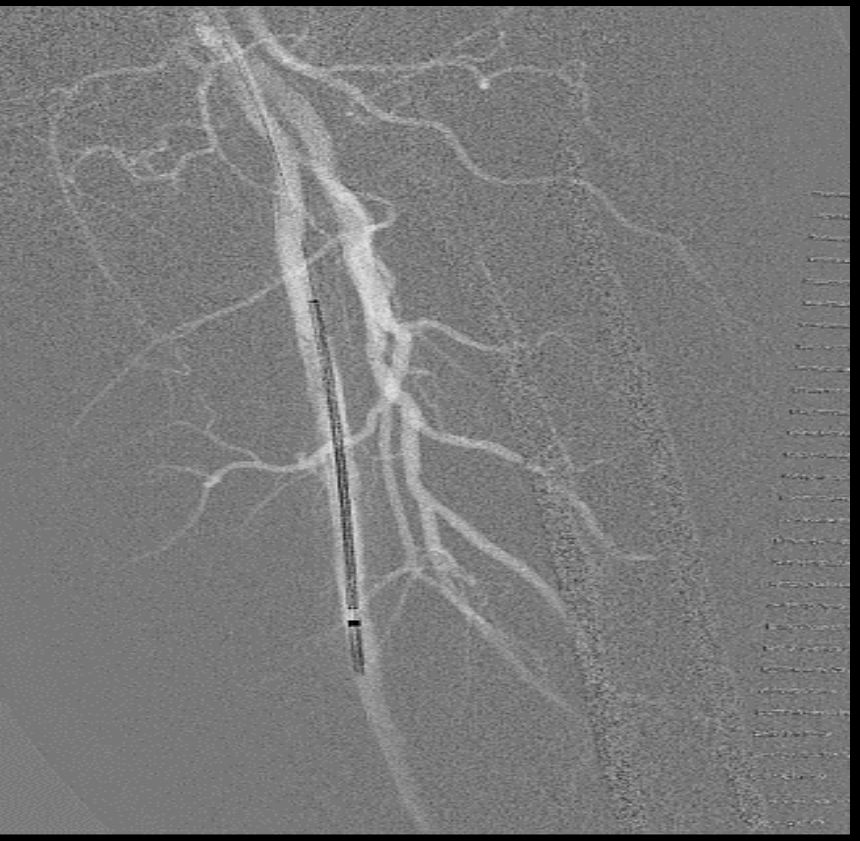


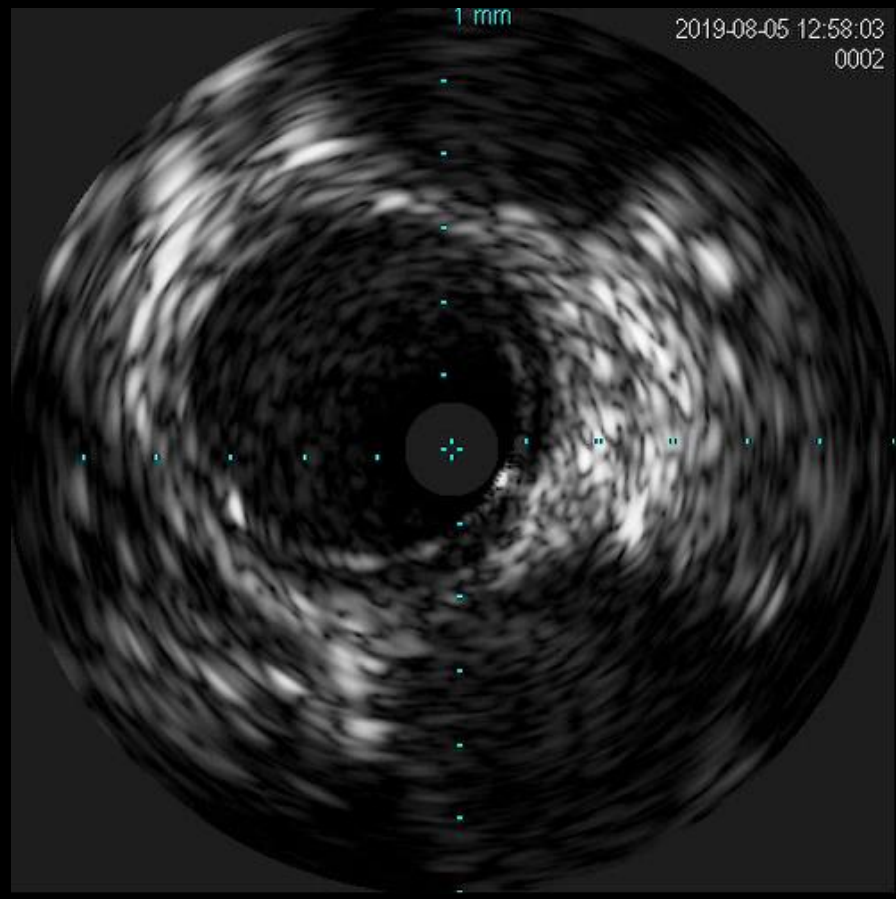
DCB(5x150)



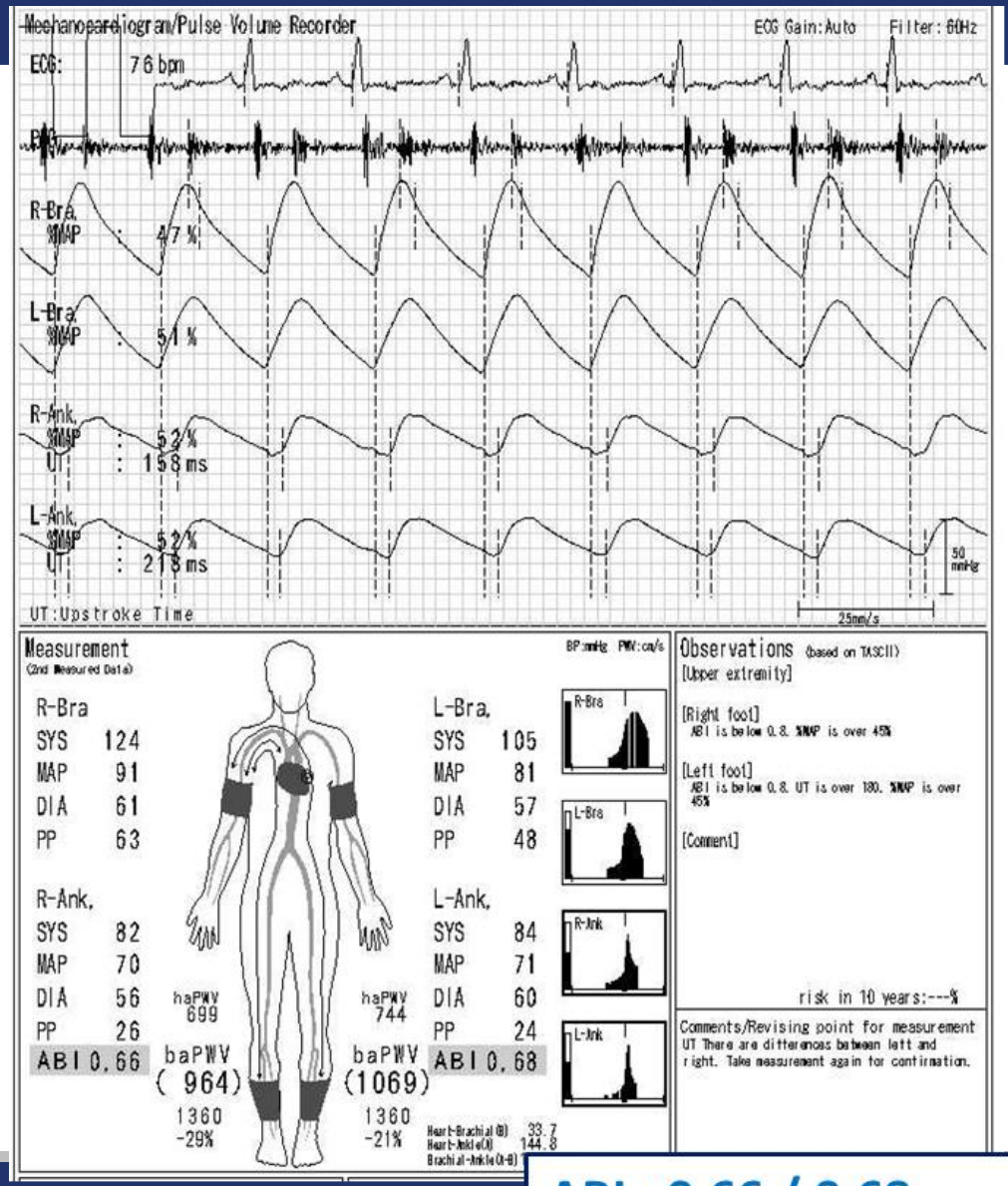


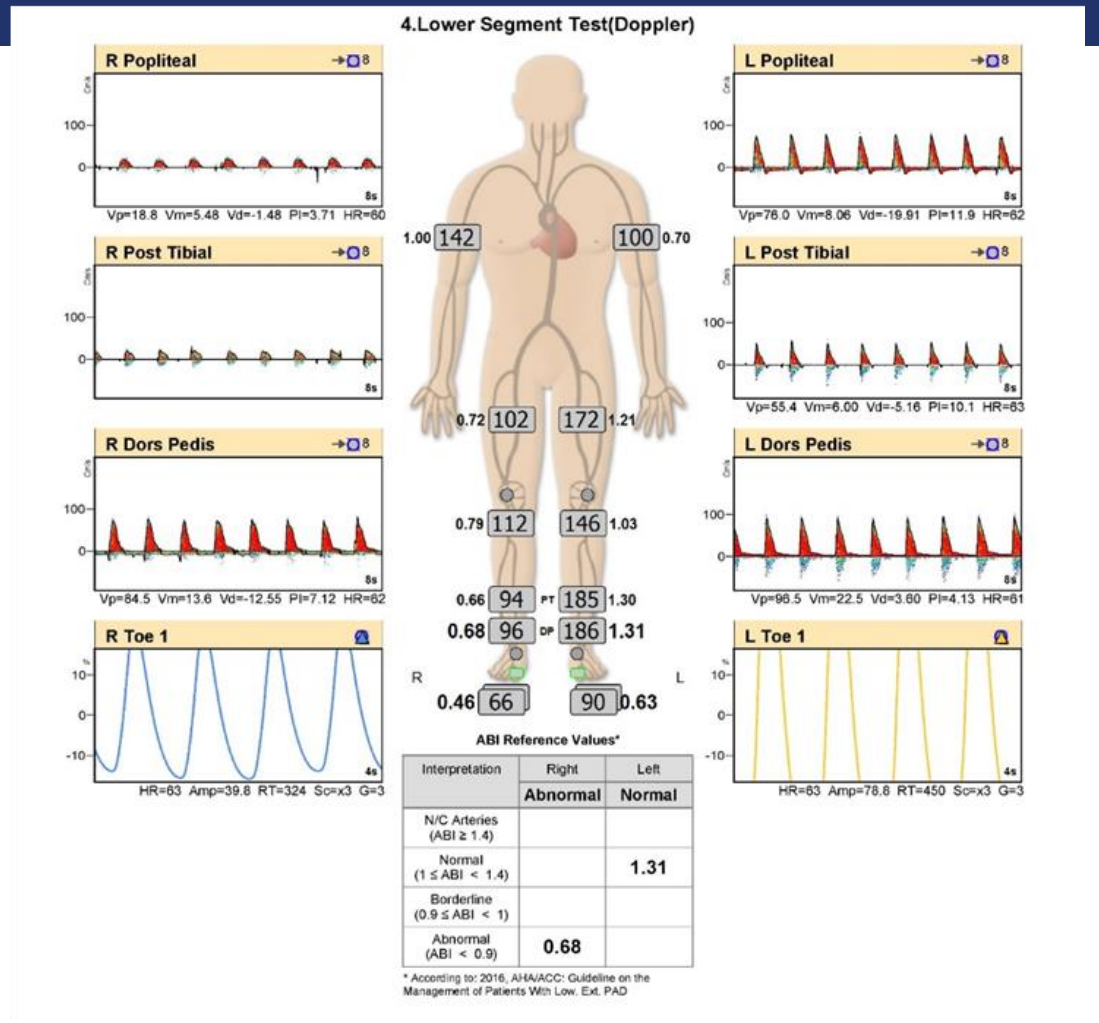
Stent Insertion(Innova™, 6x80) for flow limiting dissection & IVUS





Fu ABI





ABI : 0.66 / 0.68 → **ABI : 0.68 / 1.31**

My Recent Strategy for Device Selection for femoropopliteal lesion

✓Clear Vessel with Visible thrombi/Recent Onset/graft vessel - No wire resistance

➔AngioJet with thrombolysis ± POBA or BMS

✓Mixed lesion with mild calcification

➔ Wiring Resistance

- ➔ High ➔ Jetstream + DCB
- ➔ Low ➔ Rotarex + POBA/DCB

✓Long CTO with calcification

➔Mild calcification/No big resistance ➔ Consider Rotarex first

➔Moderate to severe calcification ➔ Sono/Angio-guided truelumen wiring

➔ Jetstream + DCB ➔ Bailout BMS

➔Mixed wiring ➔ IVUS or Balloon response

- ➔ > 85 % true lumen wiring ➔ atherectomy device ➔ DCB
- ➔ < 85 % NC balloon ➔ DCB or DES
- ➔ Good response to balloon response ➔ DCB
- ➔ Dissection + ➔ Consider focal DES/BMS

Take Home Message

1. Complex F-P lesions (Long, calcified, CTO lesions etc) lesions still remain challenging for simple angioplasty and DCB.

2. Lesion Characteristic (Calcium/long lesions) should be considered for selection of proper Atherectomy ➔ Increased Lumen Gain, less bail-out stenting & more patency.

3. Efficacy of RAART is a logical treatment strategy for use in long, complex, and calcified lesions for effective immediate procedural success and maintenance of patency.

Thank you for kind attention !!

With the Love of God, Free Humankind from Disease and Suffering