

How to Optimize Drug-Coated Balloon in Femoropopliteal Lesions



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Treatment Goal for DCB Angioplasty



- Good immediate and long-term patency
- Leaving nothing behind as possible to avoid stent-related problems



Challenges to DCB



- Long lesions:
 - *more plaque burden, higher risk of dissection*
- Calcification:
 - *difficult to dilate, more residual stenosis, higher risk of dissection, insufficient drug delivery*
- ISR lesions:
 - *remaining neointimal burden (residual stenosis)*



IN.PACT Global Long Lesion Imaging Cohort



Lesions (N)	164
Lesion Type:	
de novo	83.2% (134/161)
restenotic (no ISR)	16.8% (27/161)
ISR	0.0% (0/161)
Lesion Length	26.40 ± 8.61 cm
Total Occlusions	60.4% (99/164)
Calcification	71.8% (117/163)
Severe	19.6% (32/163)
RVD (mm)	4.594 ± 0.819
Diameter Stenosis (pre-treatment)	90.9% ± 14.2
Dissections: 0	37.9% (61/161)
A-C	47.2% (76/161)
D-F	14.9% (24/161)

Procedural Characteristics	
Device Success ^[1]	99.5% (442/444)
Procedure Success ^[2]	99.4% (155/156)
Clinical Success ^[3]	99.4% (155/156)
Pre-dilatation	89.8% (141/157)
Post-dilatation	39.1% (61/156)
Provisional Stent	40.4% (63/156)
LL 15-25 cm:	33.3% (33/99)
LL > 25 cm:	52.6% (30/57)

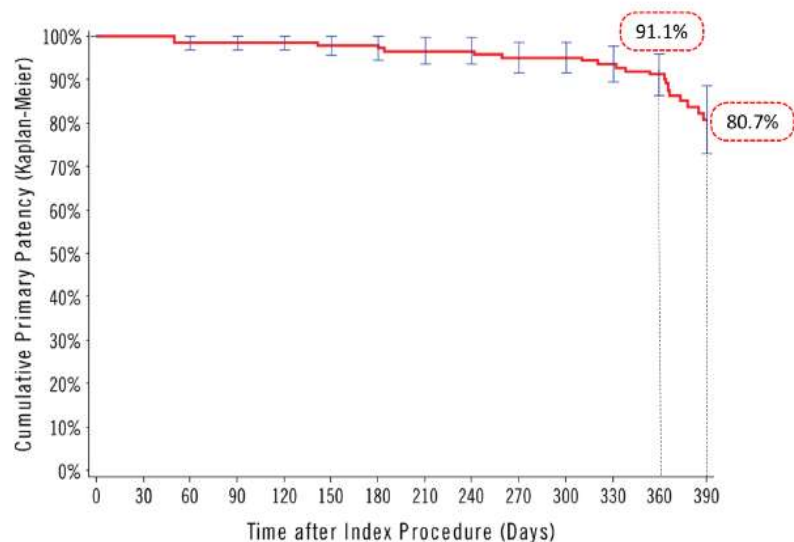
- 1. Device success:** successful delivery, inflation, deflation and retrieval of the intact study balloon device without burst below the RBP
- 2. Procedure success:** residual stenosis of ≤ 50% (non-stented subjects) or ≤ 30% (stented subjects) by core lab (if core lab was not available then the site reported estimate was used)
- 3. Clinical success:** procedural success without procedural complications (death, major target limb amputation, thrombosis of the target lesion, or TVR) prior to discharge



IN.PACT Global Long Lesion Imaging Cohort

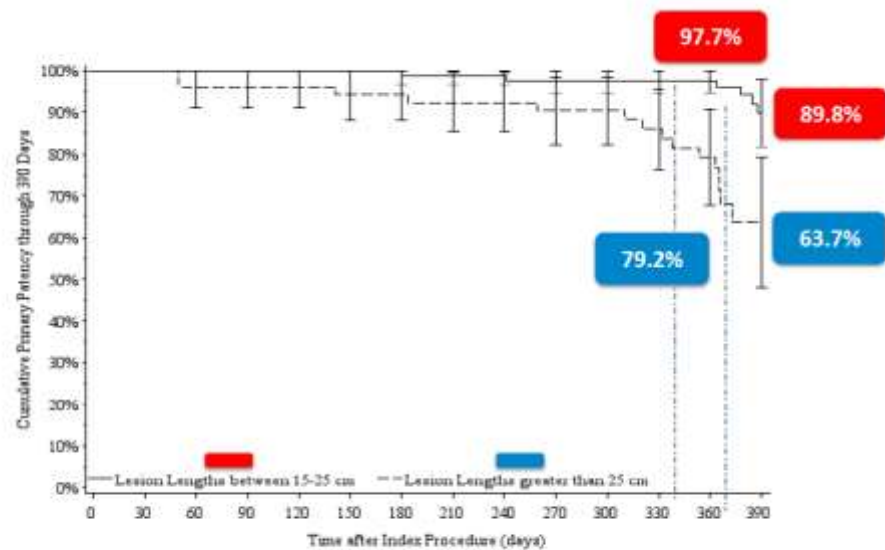


Overall primary patency



Number of subjects at risk*	Baseline (day 0)	6 mo	12 mo
IN.PACT™ DCB	157	142	119

Primary patency: long vs. very long



Number of subjects at risk	Baseline (day 0)	6 mo	12 mo
Lesion Length 15-25 cm	100	92	81
Lesion Length >25 cm	57	50	38

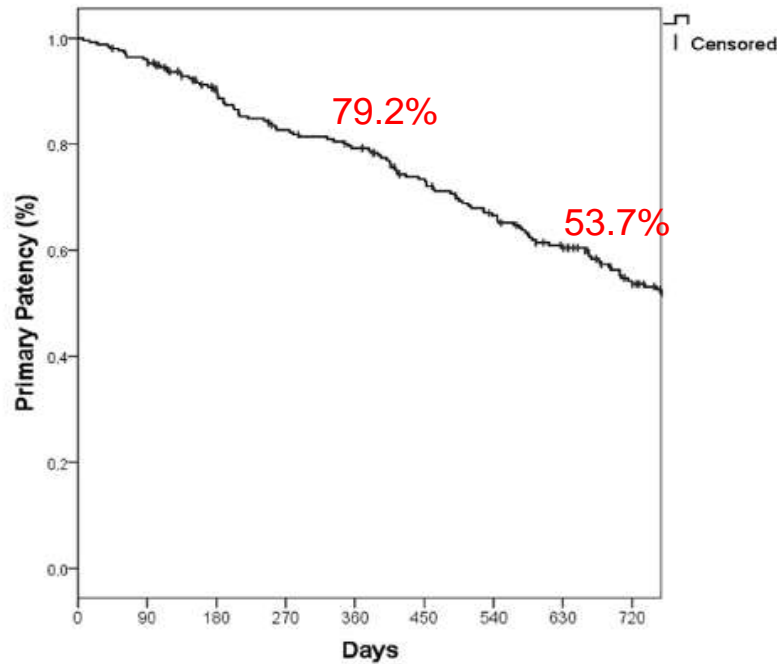


DCB: Leipzig Data



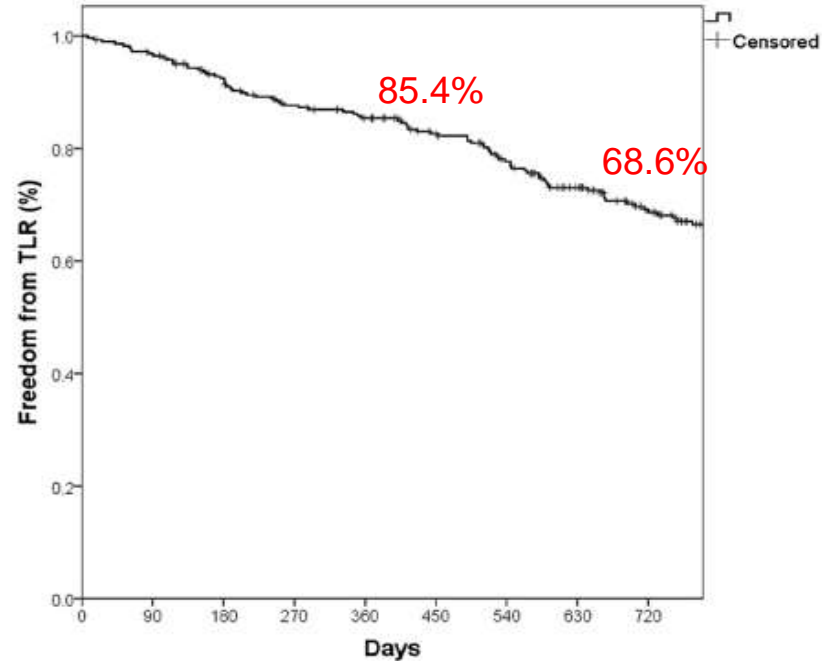
288 limbs (260 patients), Lesion length 24 cm, CTO 65%, ISR 37%, InPACT DCB

Primary Patency



At risk 254 243 215 192 182 162 144 125 101

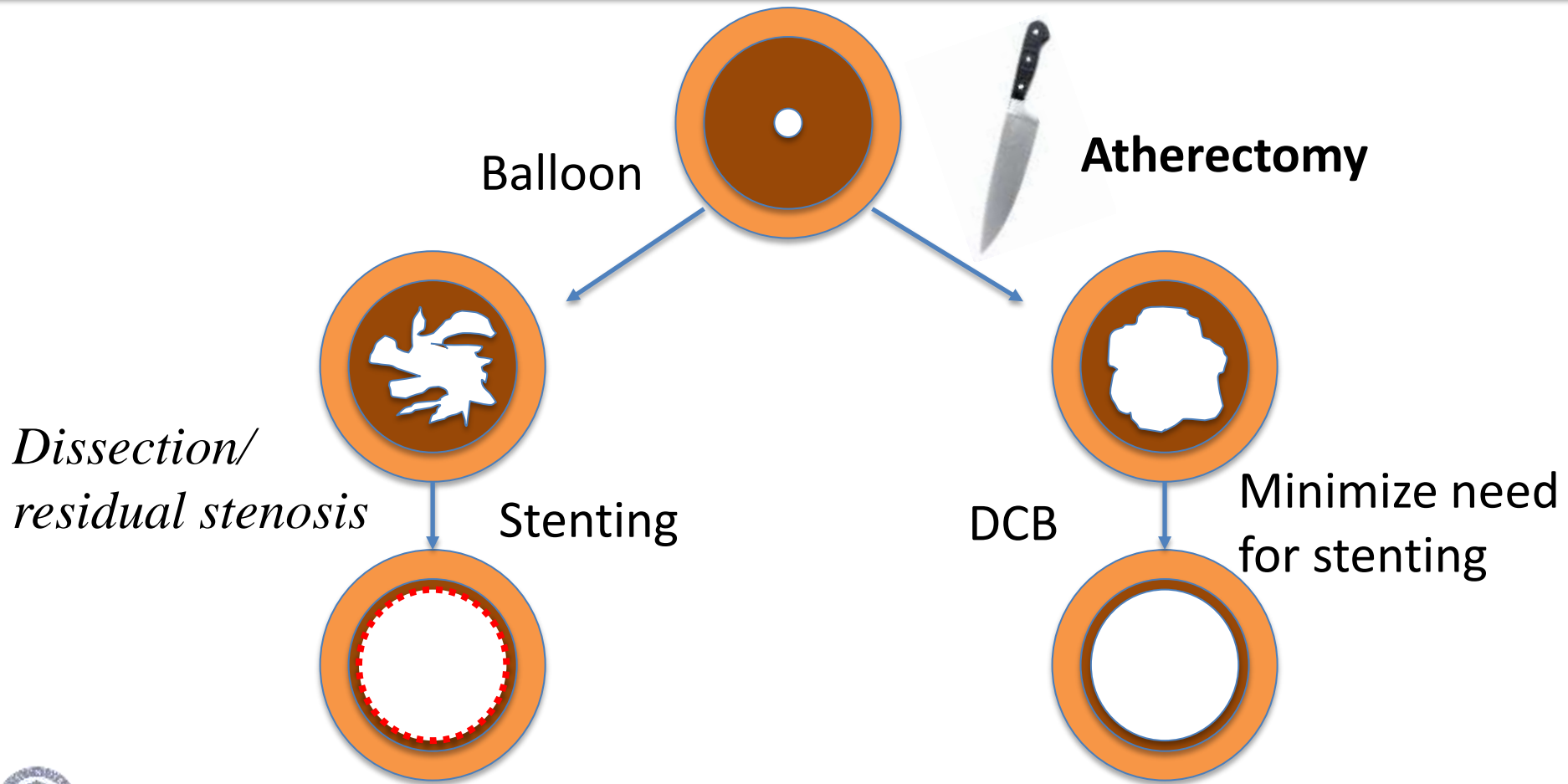
TLR-free Survival



At risk 282 271 252 234 223 205 187 163 135



Role of Atherectomy in Long Lesions



Benefits of Atherectomy



- Debulking (Plaque burden reduction) & luminal gain
- Removal of calcium and thrombus
- Less dissection
- Side branch preservation
- Improved drug delivery

But no reduction of restenosis !



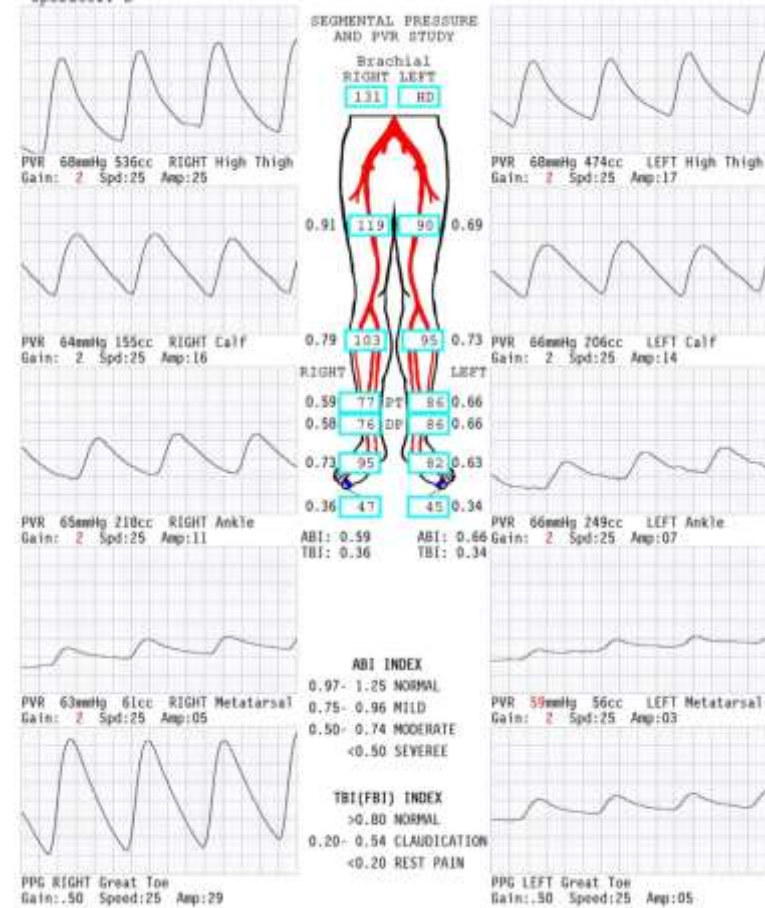


Claudication, both legs

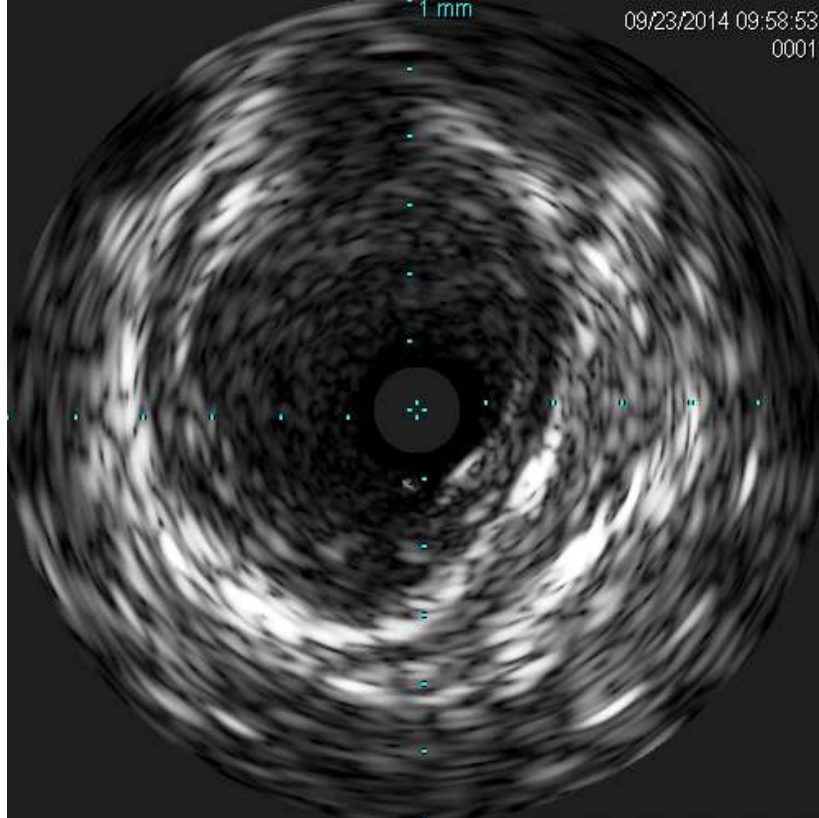
ESRD on HD

HTN

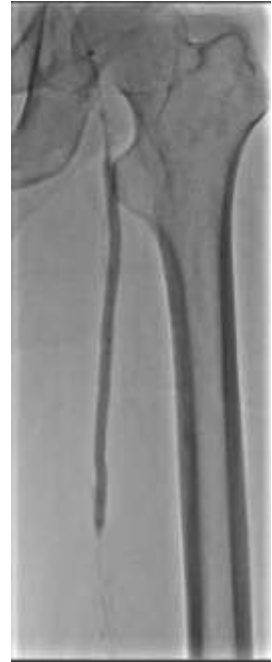
DM



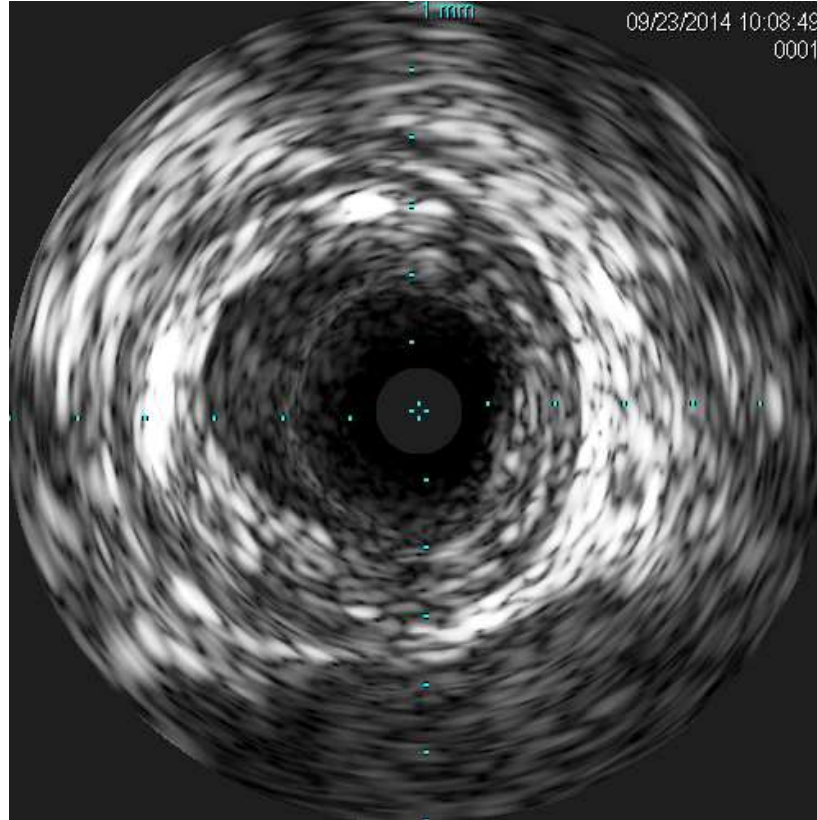
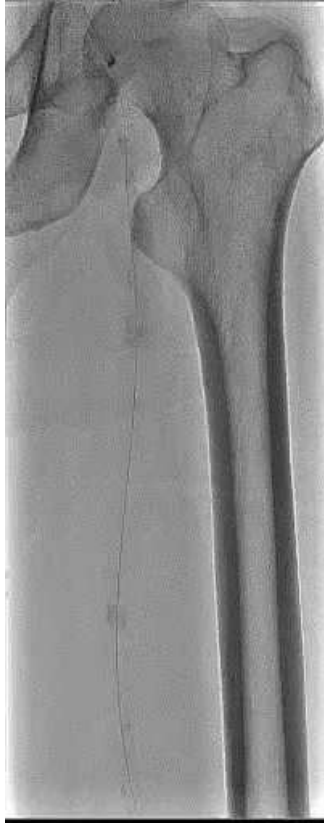
Intraluminal Balloon Angioplasty



Balloon Angioplasty



After Balloon Angioplasty



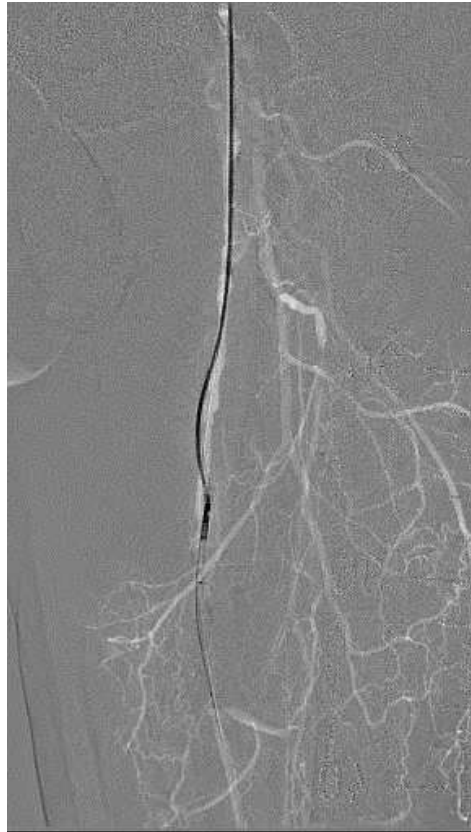
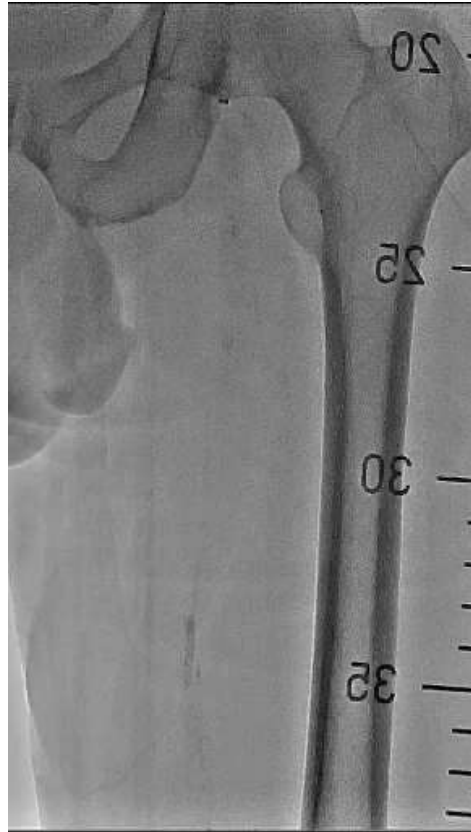
M/64

(KIK, #7704710)

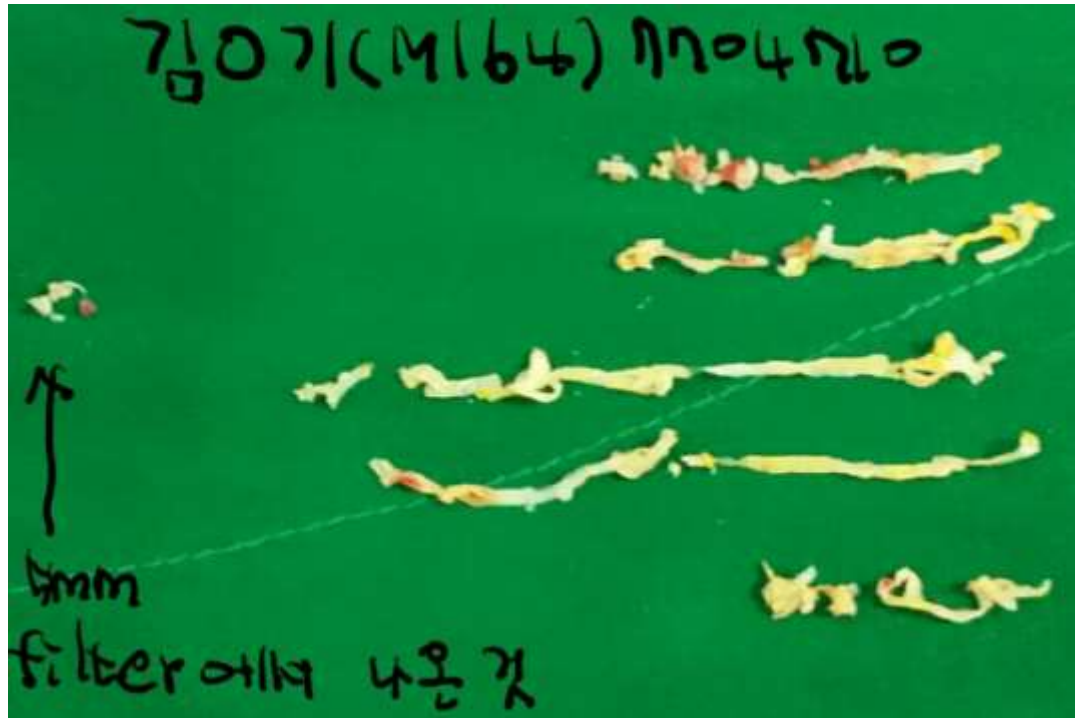
- CC: Claudication, both legs
- PHx:
 - DM
 - Old CVA
 - A-fib
 - CAD (2VD)



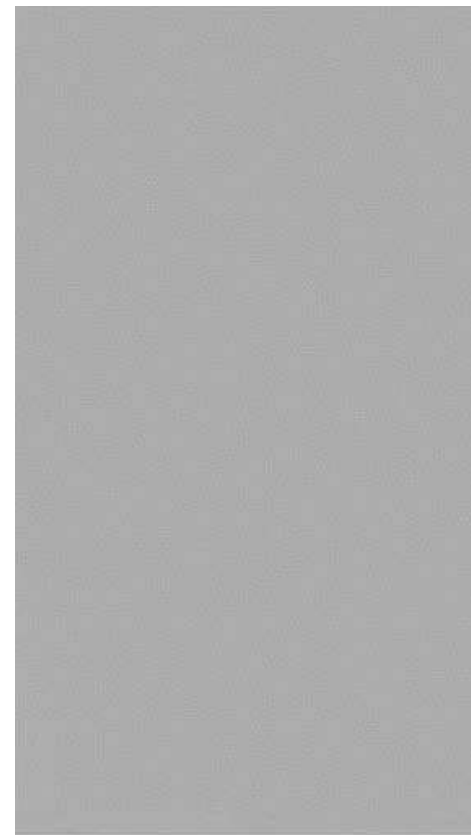
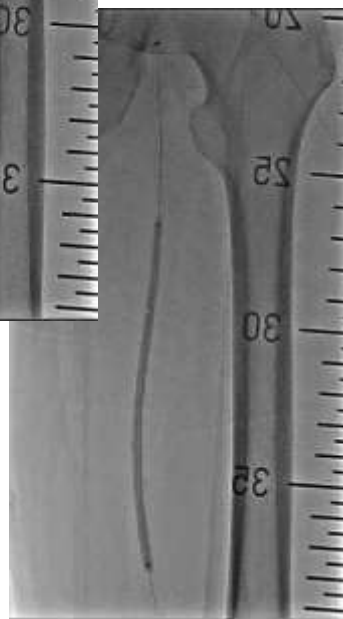
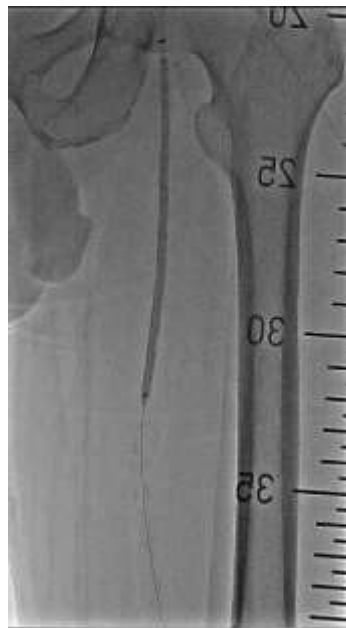
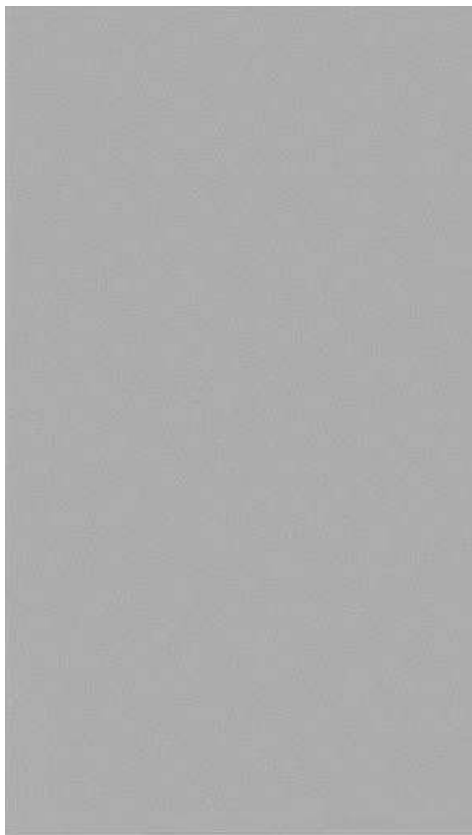
Silverhawk Atherectomy



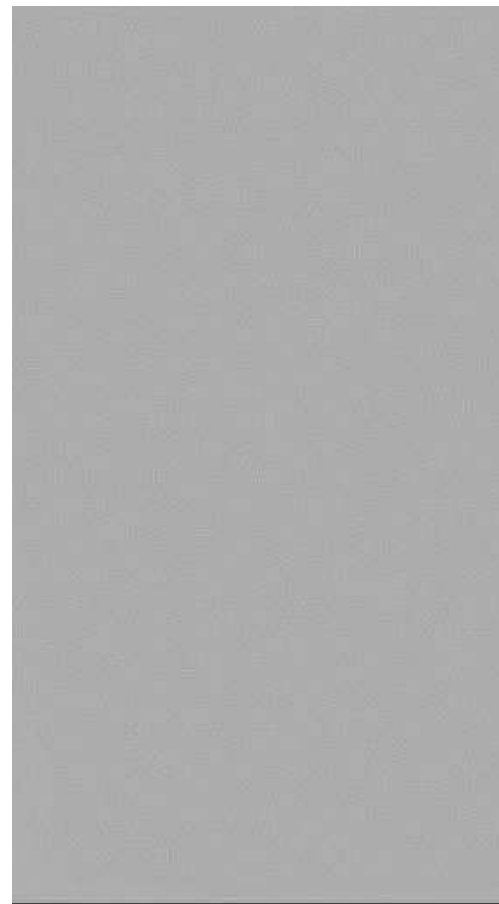
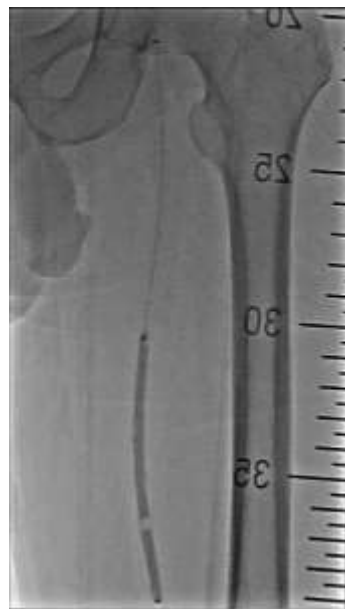
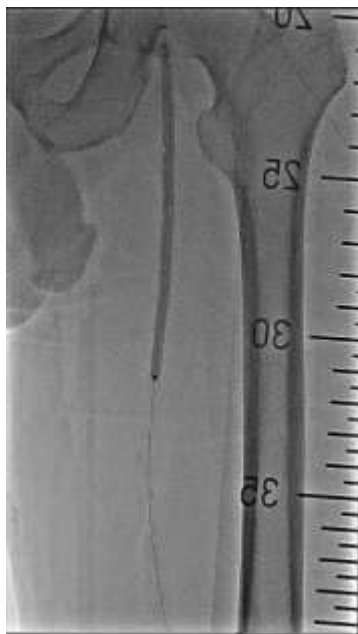
Excised and Embolized Atheroma



Predilatation

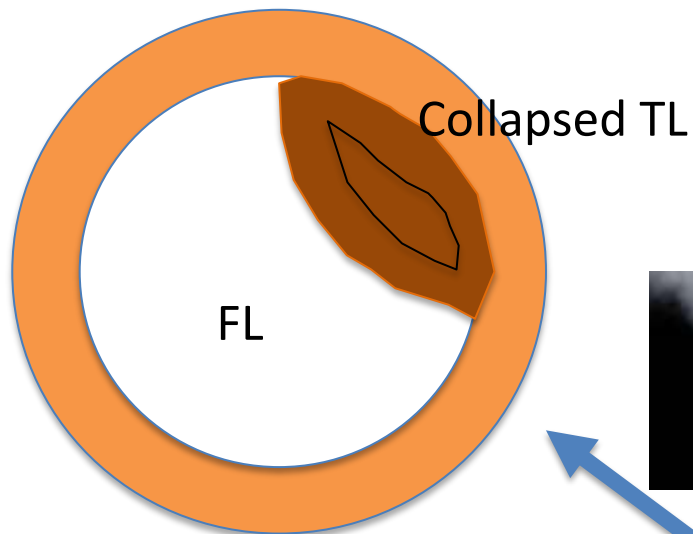


In.PACT DCB



CTO: Lumen Morphology after Balloon Angioplasty

Subintimal Approach



No protruding atheroma

Intraluminal Approach



*Protruding atheroma
& dissection flap*

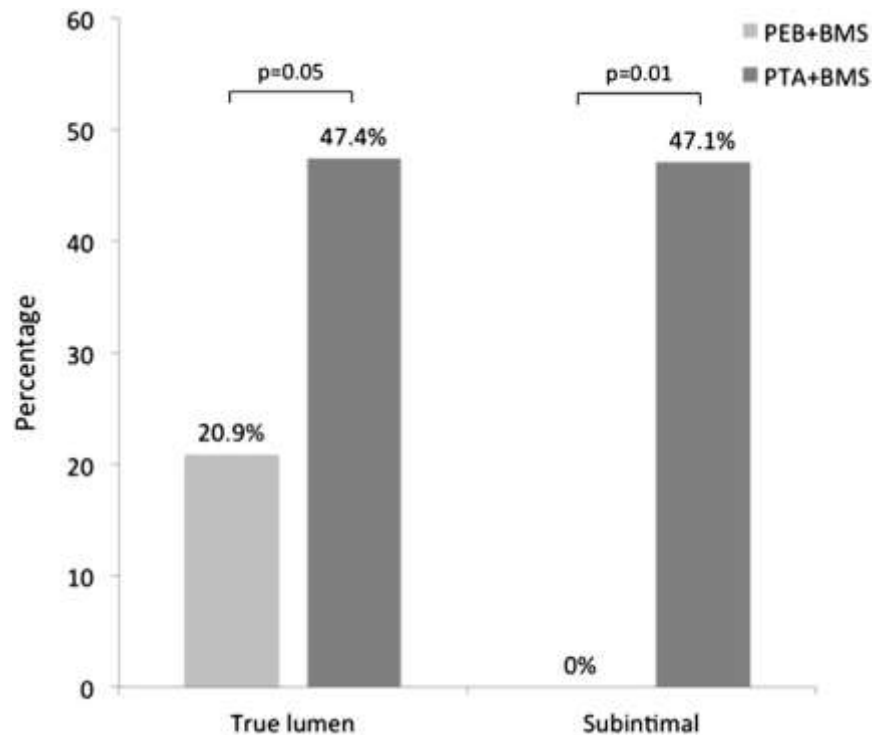
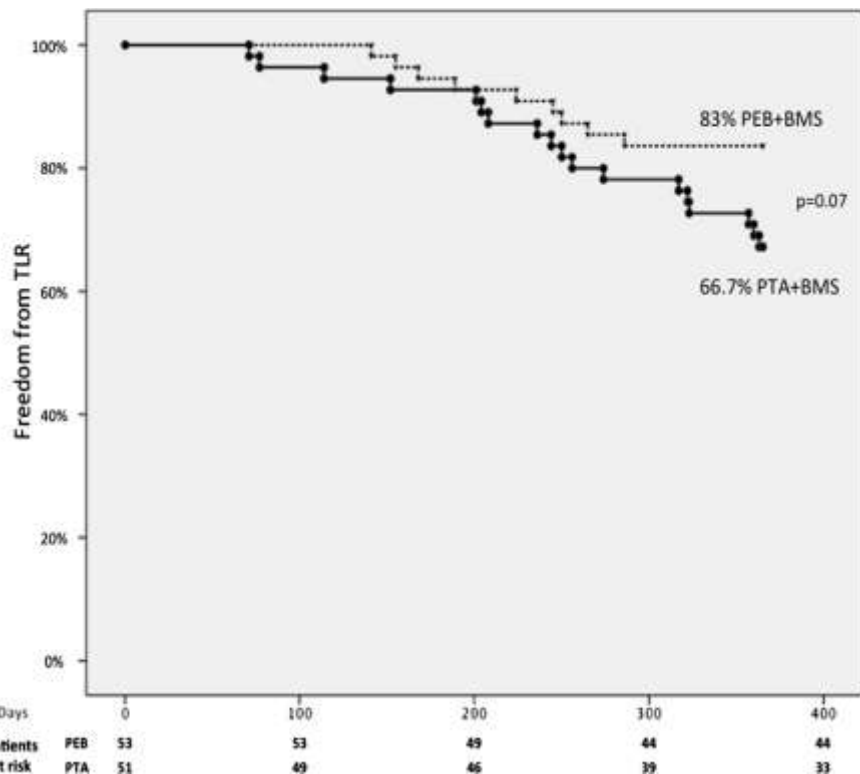


DCB

To reduce intimal hyperplasia



DEBATE-SFA RCT trial: PEB+BMS vs. PTA+BMS

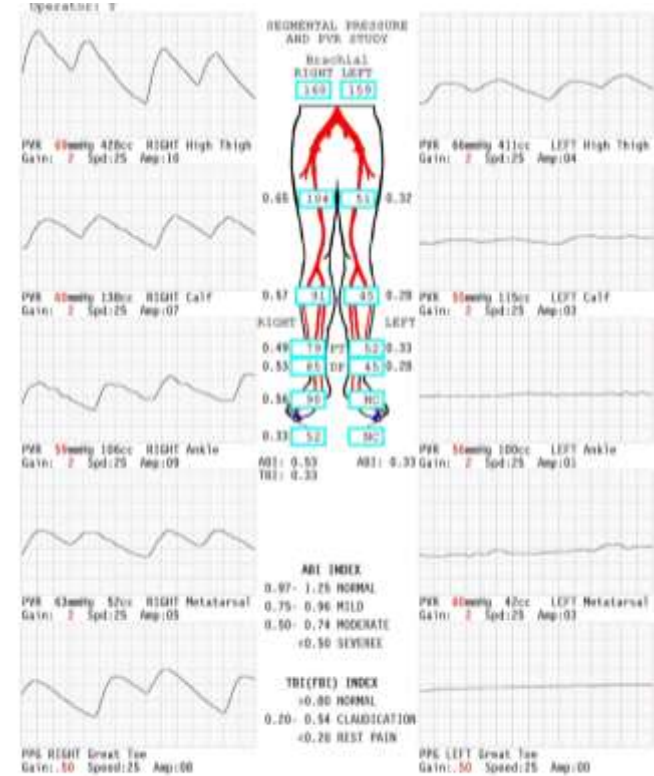


Liistro F, JACC Intv 2013





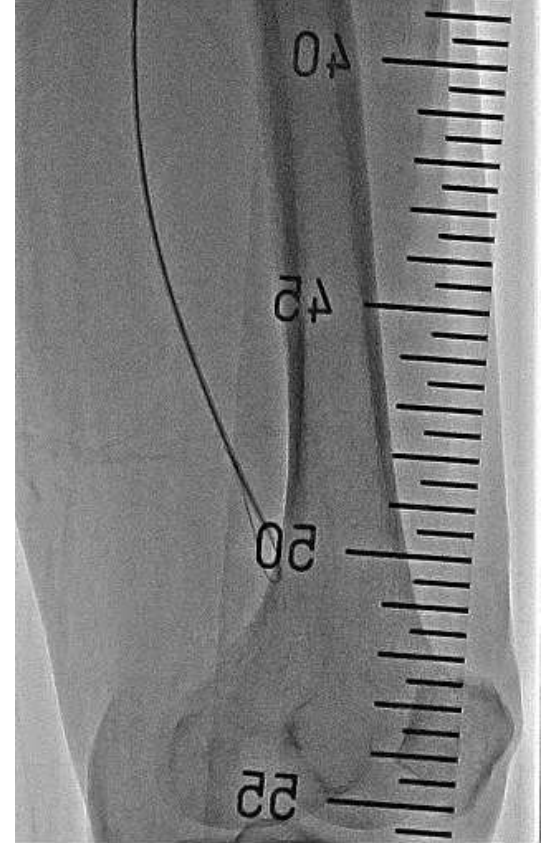
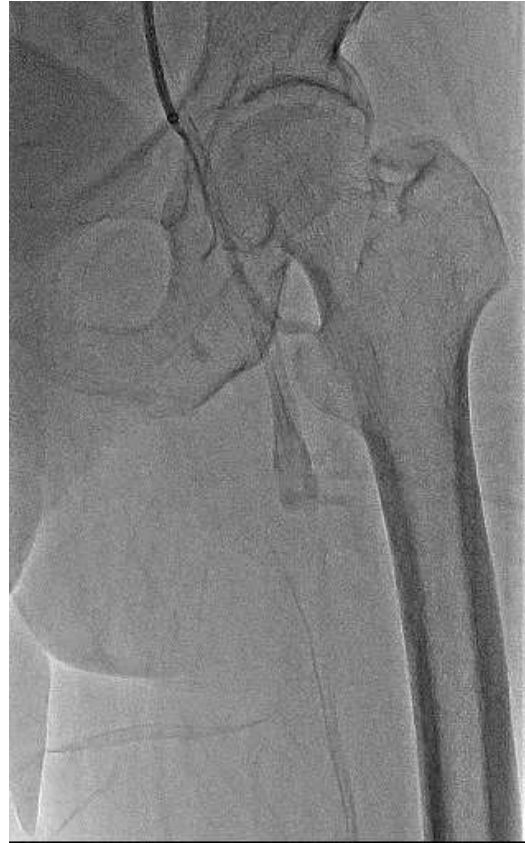
- CC: Lt. foot, toe necrosis & ulcer (Rutherford 5)
- Risk factors:
 - HTN, Dyslipidemia



ABI 0.53/0.33



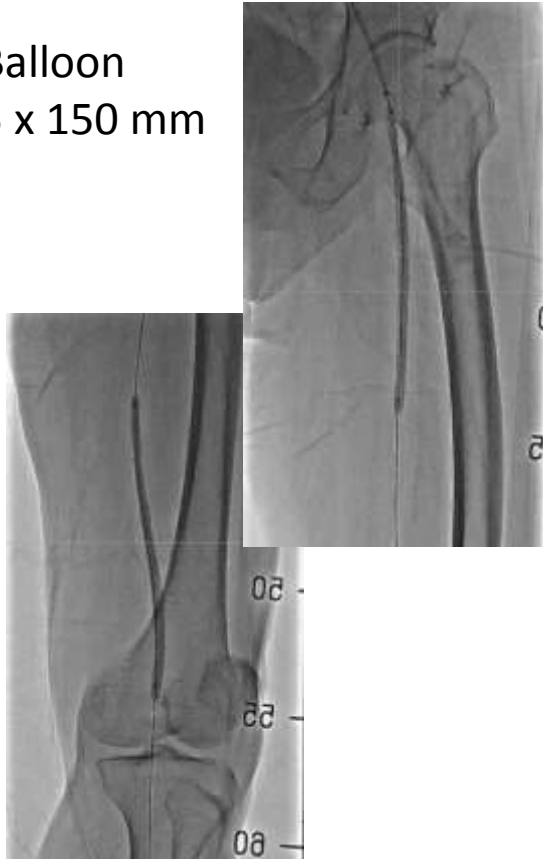
Subintimal Angioplasty



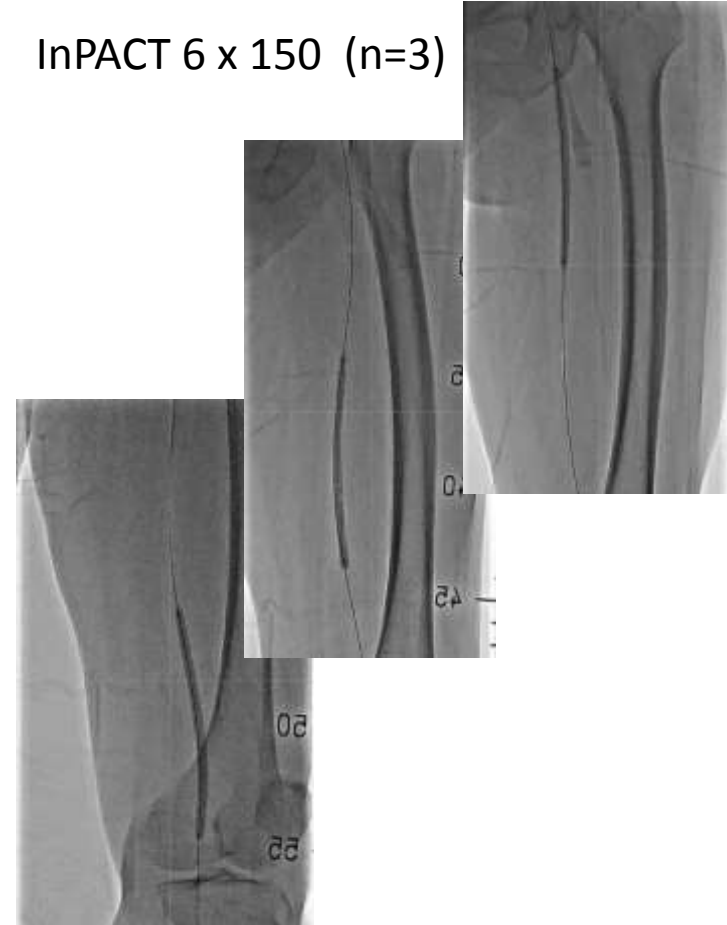
DCB after Predilation



Balloon
5 x 150 mm

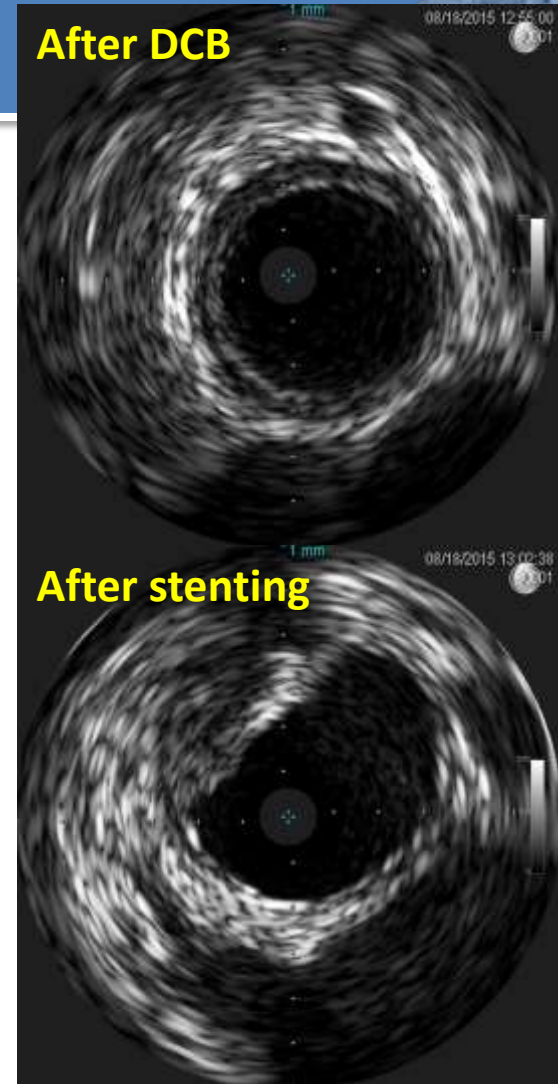


InPACT 6 x 150 (n=3)



Stenting

Absolut Pro 7 x 80



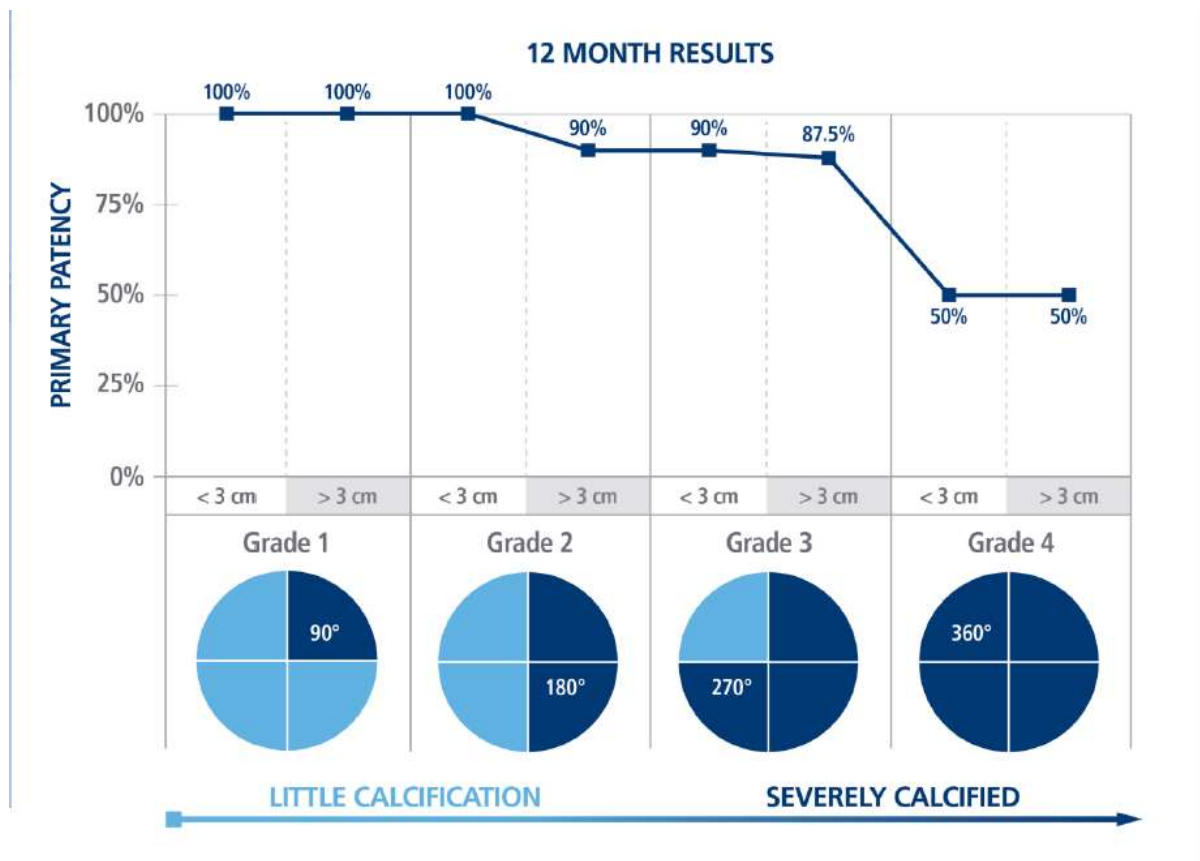
Problems with Calcified Lesions



- Difficult to cross
- Difficult to dilate
- More residual stenosis
- Higher risk of dissection
- Insufficient drug delivery



Calcium: a Challenge for DCBs



Fanelli J Endovas Ther 2012;19:571-580

Severance Cardiovascular Hospital, Yale University School of Medicine, New Haven, CT
Fanelli et al. Cardiovasc Intervent Radiol (2014;37:898)



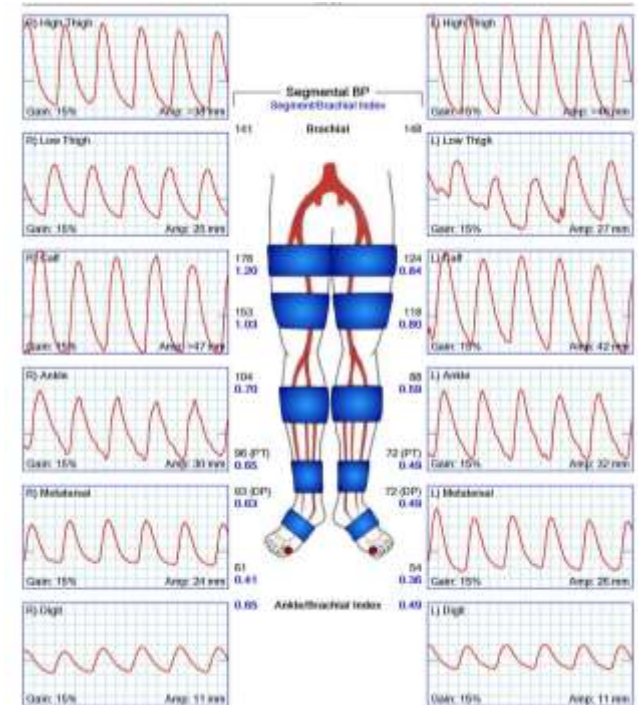
M/71 (LWS, #3275132)



Sx: Claudication: Lt > Rt
(Rutherford 3)

PHx:

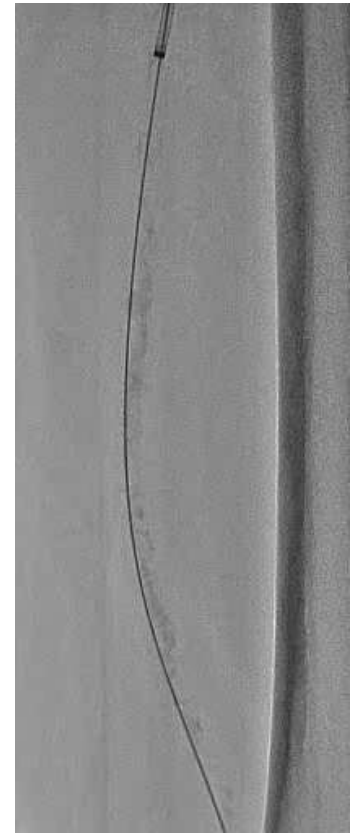
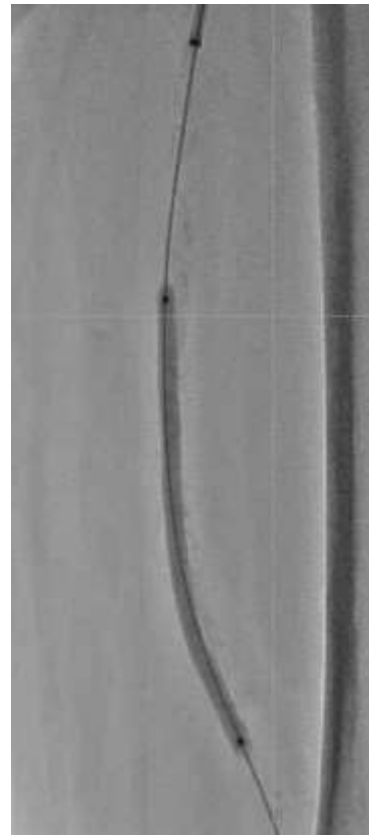
- DM, HTN
- CAD (LM & 3VD)
- S/P PCI with stents (2003/3)



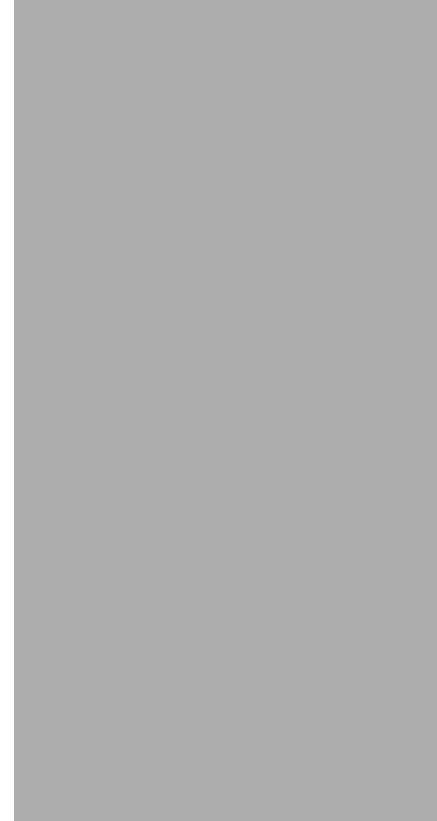
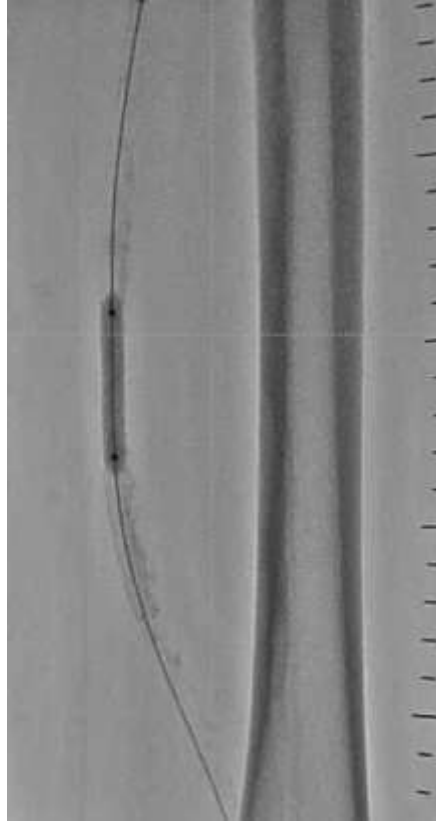
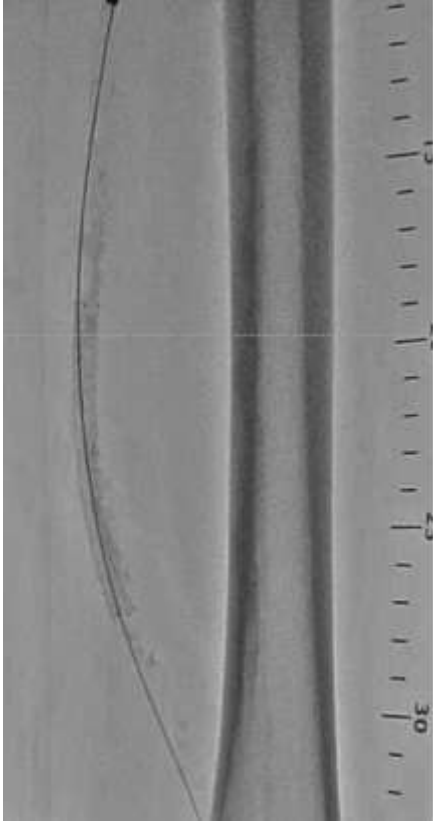
ABI 0.65/0.45



Lt. SFA



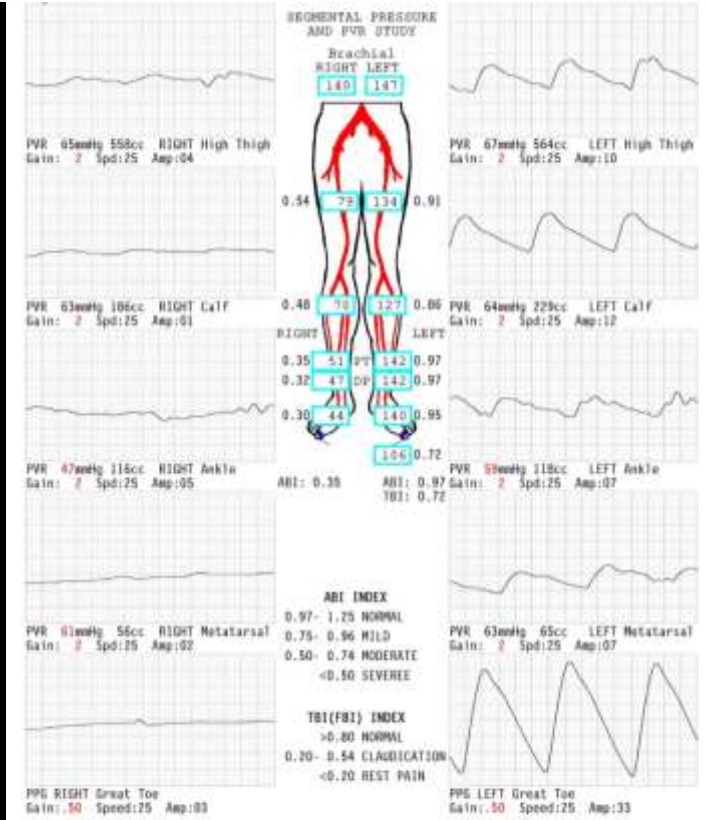
Bail-out Stenting



M/61, (PMI, #6865847)



- CC: Claudication, Rt. leg (Rutherford 3)
- PHx: HTN, smoker



ABI 0.35/0.97

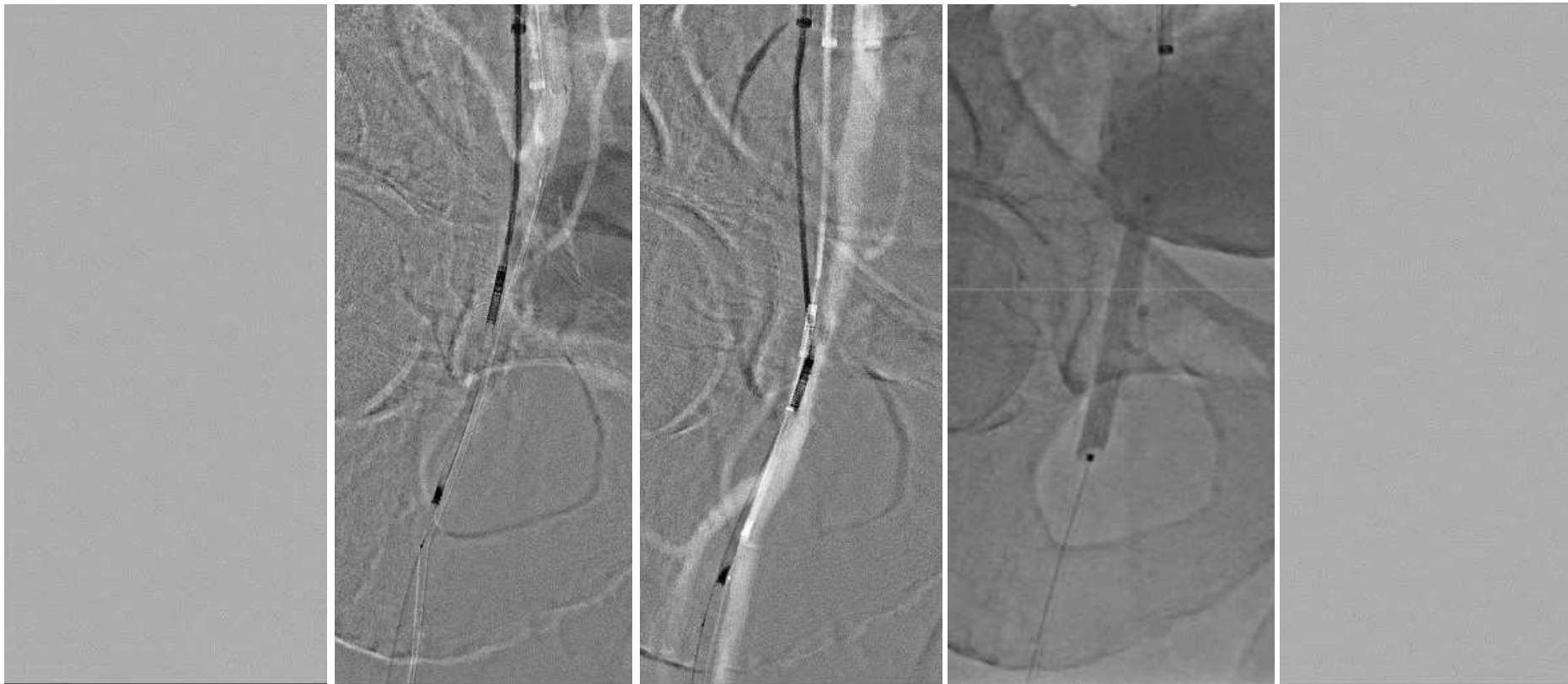


DAART: Atherectomy + DCB



Turbohawk

InPACT 7 x 40 mm



Role of IVUS in Femoropopliteal Artery Interventions



Peripheral

Shared and Differential Factors Influencing Restenosis Following Endovascular Therapy Between TASC (Trans-Atlantic Inter-Society Consensus) II Class A to C and D Lesions in the Femoropopliteal Artery

Osami Iida, MD,* Mitsuyoshi Takahara, MD, PhD,† Yoshimitsu Soga, MD,‡ Kenji Suzuki, MD,§ Keisuke Hirano, MD,|| Daizo Kawasaki, MD,¶ Yoshiaki Shimani, MD,‡ Nobuhiko Suenaga, MD,** Terutoshi Yamaoka, MD,†† Shinzuke Nanto, MD, PhD,‡‡ Masaki Uematsu, MD, PhD*

Amagasaki, Osaka, Kitakyushu, Sendai, Yokohama, Niigatashiya, Kanuma, Fukuoka, and Matsuyama, Japan

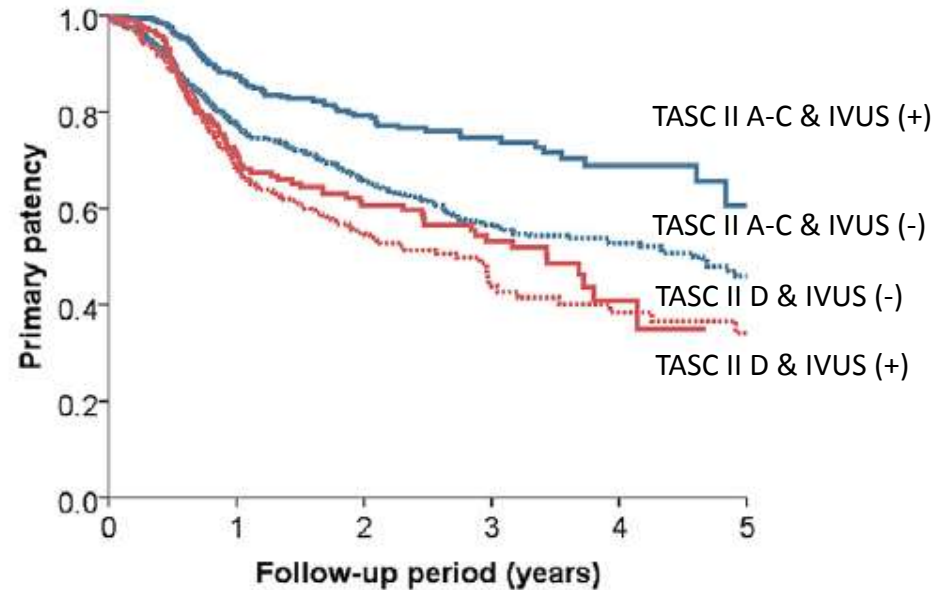
Objective This study sought to investigate factors associated with restenosis after endovascular therapy comparing TASC (Trans-Atlantic Inter-Society Consensus) II classes A to C with class D femoropopliteal (FF) lesions.

Background It is unclear whether the determinants of restenosis for TASC II class D lesions are the same as those for TASC II classes A to C FF lesions.

Methods We studied 2400 limbs from 1,889 consecutive patients (73 ± 17 years of age; 31% women; 30% critical limb ischemia) who underwent successful endovascular therapy for de novo FF lesions. Predictors for restenosis in TASC II classes A to C and class D lesions were assessed using a Cox proportional hazards model.

Results The 5-year primary patency rate was 50% in TASC II classes A to C and 34% in TASC II class D lesions, respectively ($p < 0.001$). Overall, restenosis had a significant interaction with sex and renal failure (both $p < 0.01$). Female sex was a significant risk factor for restenosis in TASC II class D lesions (adjusted hazard ratio [HR]: 1.80, $p < 0.001$) but not TASC II classes A to C lesions (adjusted HR: 1.10, $p = 0.352$). Conversely, renal insufficiency was a significant risk factor for restenosis in TASC II classes A to C lesions (adjusted HR: 1.43, $p < 0.001$) but not TASC II class D lesions (adjusted HR: 0.79, $p = 0.129$). Diabetes mellitus, no stent use, chronic total occlusion, and poor below-the-knee runoff were shared risk factors for restenosis between TASC II classes A to C and class D lesions (all $p < 0.05$).

Conclusions For de novo FF lesions, diabetes, no stent use, chronic total occlusion, and poor below-the-knee runoff were shared restenosis predictors for TASC II classes A to C and class D lesions, whereas renal failure was a predictor for TASC II classes A to C lesions and female sex for TASC II class D lesions. (J Am Coll Cardiol Intv 2014;7:792-8) © 2014 by the American College of Cardiology Foundation



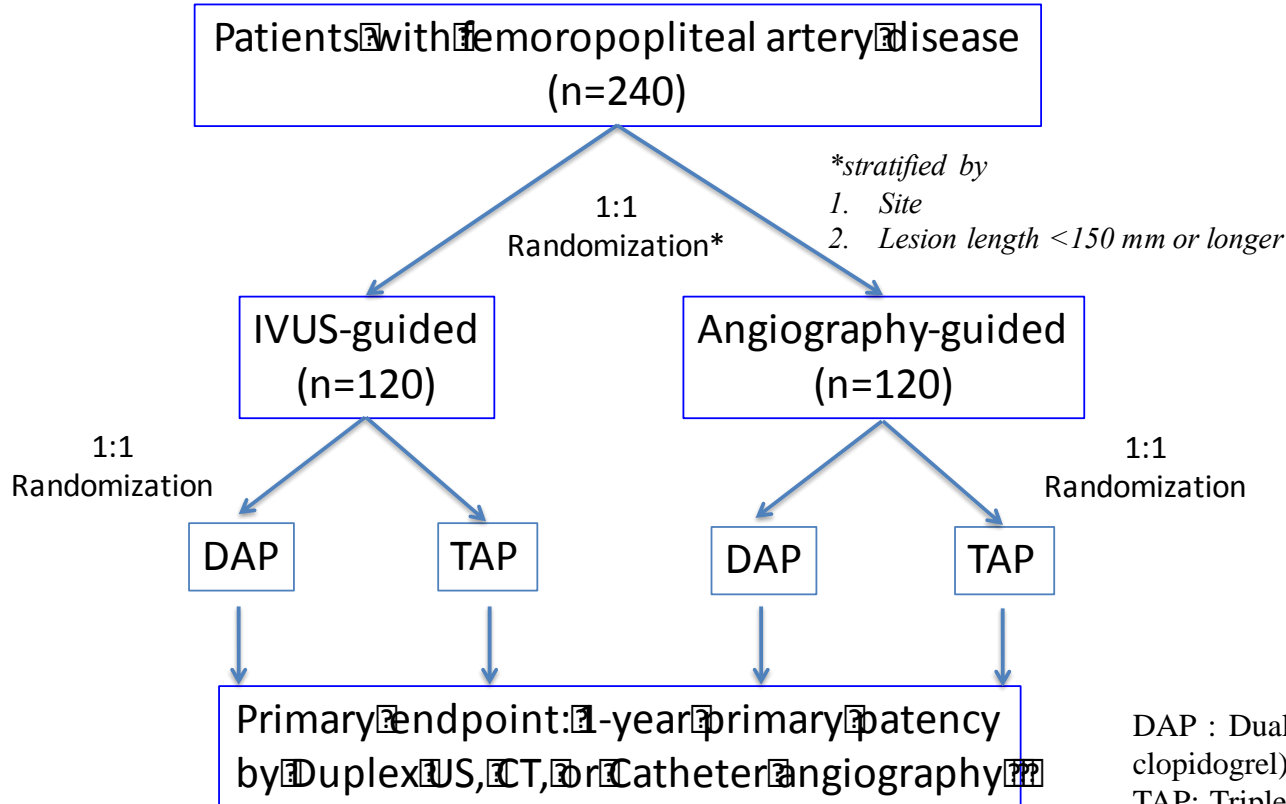
Information by IVUS



- Vessel dimensions => device size selection
- Plaque amount & character
- Extent of calcification: circumferential & longitudinal
- Wire location: intraluminal vs. subintimal
- Severity of dissection



IVUS-DCB Trial



DAP : Dual antiplatelet therapy aspirin + clopidogrel)
TAP: Triple antiplatelet therapy (aspirin + clopidogrel + cilostazol)



“Better” stents for Bail-out



- Flexible
- Resistant to fracture
- Resistant to compression
- Causing less neointimal hyperplasia



Scheinert D, LINC

Schmidt A, JACC Intv 2013;6:65



My suggestions for Optimization of DCB

- Pretreatment with atherectomy (DAART) for long lesions and heavily calcified lesions. (*Be aware of high coast!*)
- Subintimal angioplasty with provisional spot stenting rather than intraluminal angioplasty with long stenting for CTOs
- IVUS image guidance for intervention
- Select better stents for bail-out purpose





**Thank you
for your attention!**

