K-POP Study Clinical Outcomes

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Disclosure

- Consulting:
  - Genoss, S&G
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  - Medtronic, Cook Medical, Boston Scientific, Otsuka Korea, Dong-A ST, Samjin Pharm, Cordis
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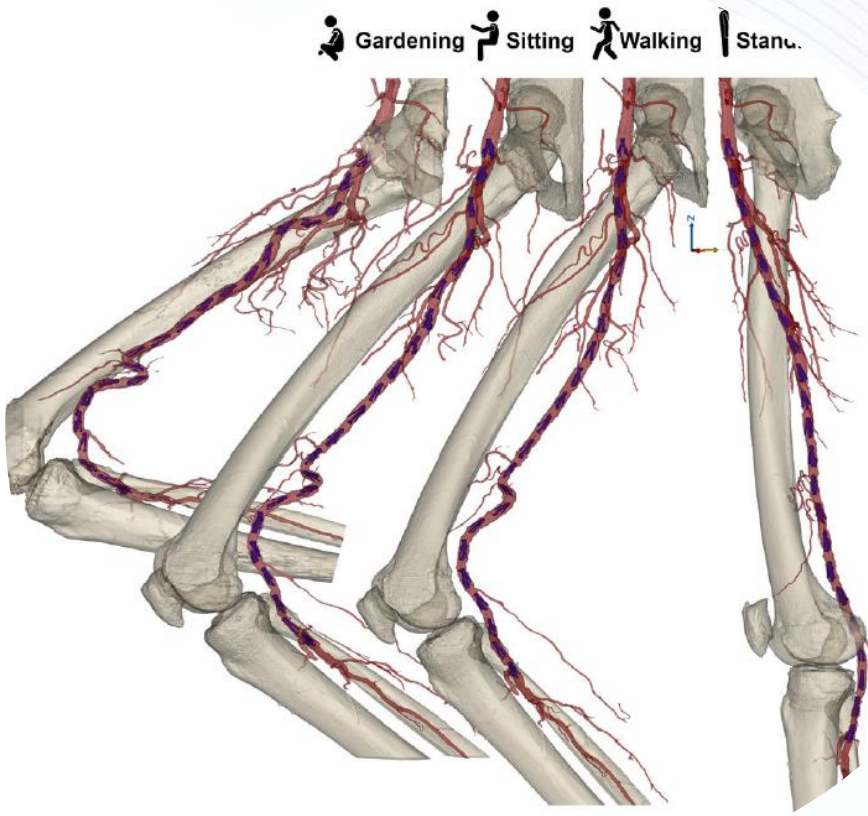
  - Medtronic, Cook Medical, Abbott, Cordis
- Proctoring:
  - Medtronic, Edwards

Background

- PA is affected by knee joint movement.
- PA is considered a no-stent zone.
- Stent placement is reserved for suboptimal results after PTA, such as flow-limiting dissection or significant residual stenosis.
- Limited evidence for endovascular therapy and surgery for PA disease.



MacTaggart J, Ann Surg 2019;270:180–187

RCT: BNS vs Balloon for Isolated Popliteal Lesions

Procedural data

*Provisional stenting 25.2% in PTA group

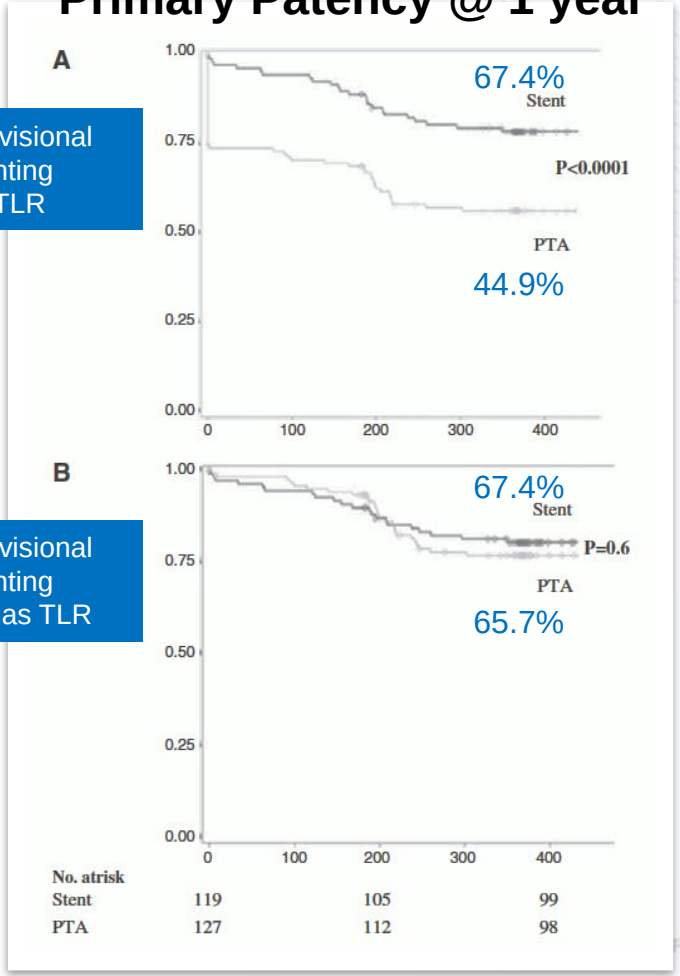
	Stent (n=119)	PTA (n=127) *
Length of lesion, mm	41.3±31	43.2±28
Occlusion, %	32.8	33.1
Target-lesion diameter stenosis, %		
Preintervention	92.9±7	92.5±7
Postintervention	12.9±24.8	11.6±12.5
Procedural success, %	100	100
Number of patent IPAs after procedure, %		
1	58.5	50.6
2	39.0	47.1
3	2.4	3.8
ABI preintervention	0.63±0.38	0.69±0.45
ABI postintervention	0.94±0.28	1.0±0.40

Rastan A, Circulation 2013;127:2535

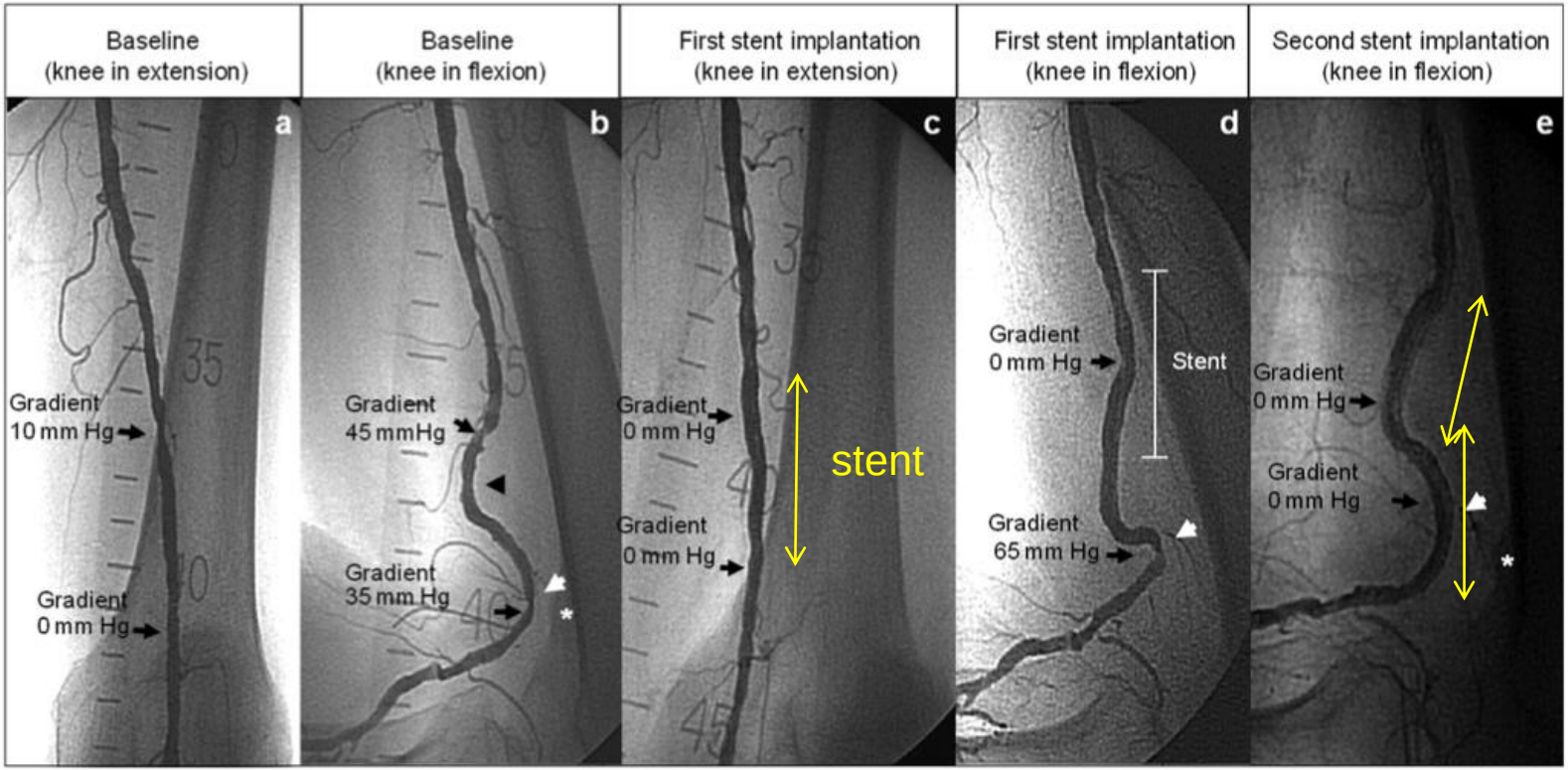
Primary Patency @ 1 year

Provisional stenting as TLR

Provisional stenting not as TLR



Stent in distal SFA/Popliteal artery



J Invasive Cardiol 2011;23:431

Nitinol Woven Stent (Supera)

Treatment of Complex Atherosclerotic Popliteal Artery Disease With a New Self-Expanding Interwoven Nitinol Stent

12-Month Results of the Leipzig SUPERA Popliteal Artery Stent Registry

Dierk Scheinert, MD, Martin Werner, MD, Susanne Scheinert, MD, Anett Paetzold, Ursula Banning-Eichenseer, MD, Michael Piorkowski, MD, Matthias Ulrich, MD, Yvonne Bausback, MD, Sven Bräunlich, MD, Andrej Schmidt, MD

Leipzig, Germany

Objectives We examined the efficacy and durability of a new interwoven self-expanding nitinol stent system in the treatment of complex popliteal artery lesions in unselected patients.

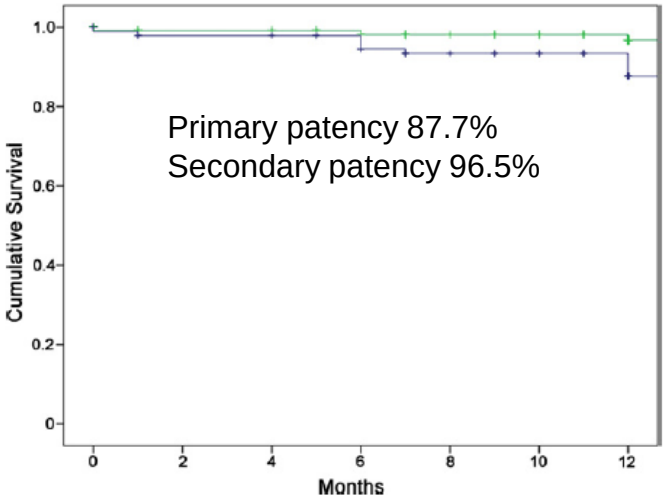
Background The optimal endovascular treatment strategy for atherosclerotic popliteal artery disease is not known.

Methods We retrospectively analyzed the data gathered in 101 consecutive patients presenting with atherosclerotic, popliteal arterial disease, who underwent implantation of 125 stents. The patients were followed for 12 months by Doppler ultrasound examinations, stent roentgenograms, and estimation of Rutherford-Becker class (RBC) and ankle-brachial index (ABI).

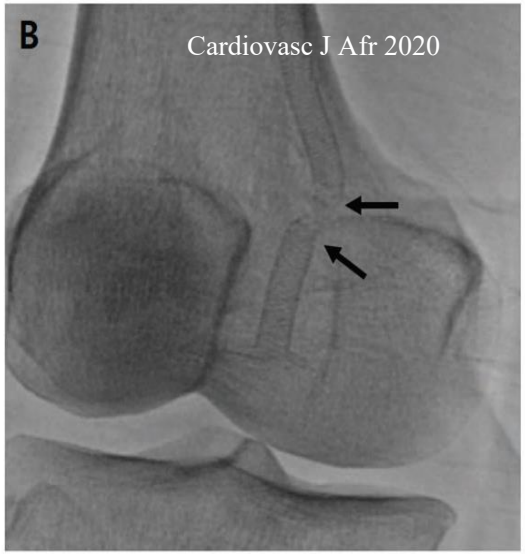
Results The mean age of the patients was 73.1 years, and 52.5% were men. Total occlusions were present in 48 patients (47.5%). The mean stent length was 84.3 ± 45.1 mm (range 40 to 240 mm). A <30% residual stenosis was achieved in 98.0% of procedures. The 6- and 12-month primary patency rates were 94.6 ± 2.3% and 87.7 ± 3.7%, respectively, and the secondary patency rates 97.9 ± 1.5% and 96.5 ± 2.0%, respectively. Between baseline and 12 months of follow-up, mean ABI increased from 0.58 ± 0.15 to 0.97 ± 0.18, and mean RBC decreased from 3.1 ± 0.9 to 1.4 ± 0.8 ($p < 0.001$ for both comparisons). Radiographs performed on 51 patients, at a mean of 15.2 months, confirmed the absence of stent fractures in 100% of examinations.

Conclusions Over a 12-month observation period, the patency rate and durability of SUPERA stents implanted for severe popliteal artery disease were high. (J Am Coll Cardiol Intv 2013;6:65–71)

N =101, Single-center retrospective registry in Leipzig



Supera Stent Fractures in Popliteal Artery



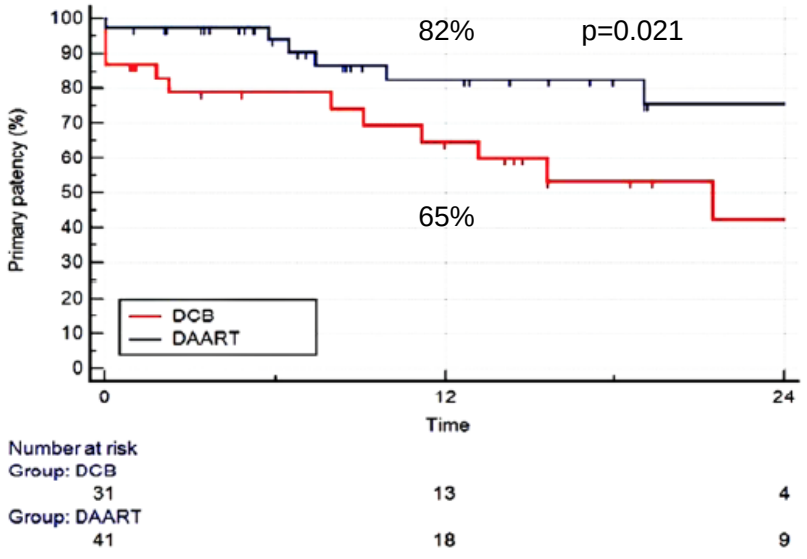
DAART vs DCB Alone

Single-center retrospective study

Bail-out stenting 16% (DCB) vs 5% (DAART), p=0.13

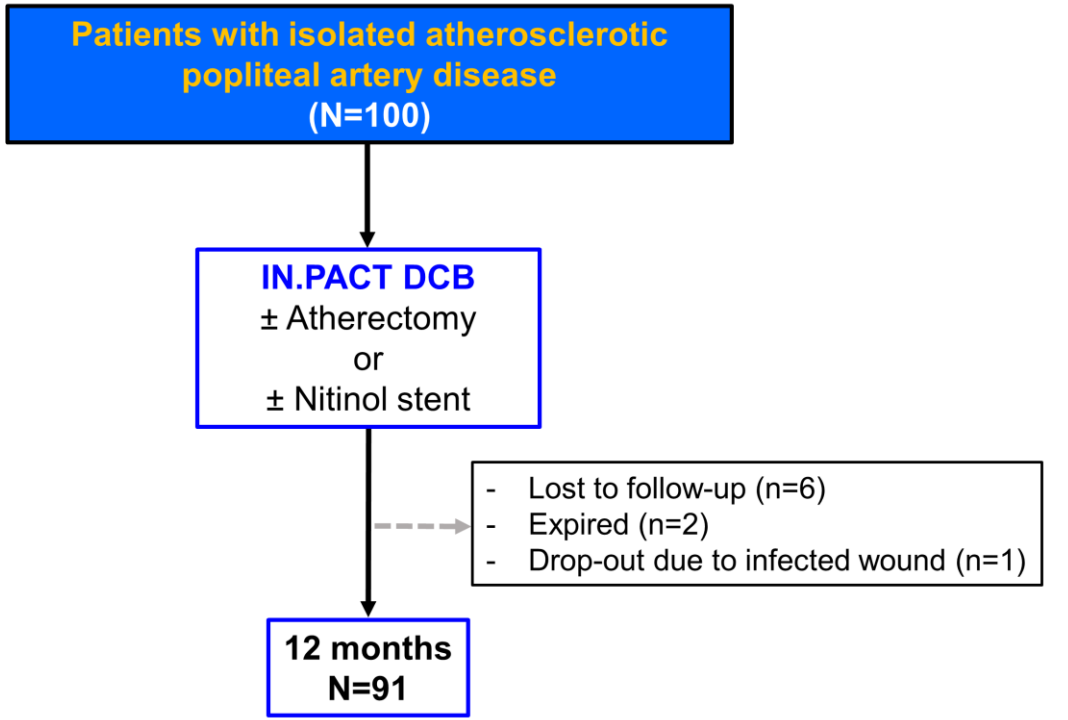
	(n=31)	(n=41)	
Characteristics	DCB	DAART	p
Contrast volume, mL	121±45	160±62	0.009
Dose area product, Gy·m^2	26.4 (0.6–663.4)	36.4 (0.6–197.6)	0.160
Atherectomy devices			
SilverHawk		8 (20)	
TurboHawk		23 (55)	
Pantheris		6 (15)	
HawkOne		4 (10)	
Drug-coated balloons			
In.Pact	32 (78)	28 (86)	0.326
Freeway	6 (15)	2 (7)	0.277
Lutonix	3 (7)	0	0.126
Passeo Lux	0	2 (7)	0.101
Concomitant procedures			
Iliac arteries	3 (10)	5 (12)	0.738
Superficial femoral artery	10 (32)	11 (27)	0.618
Technical success	26 (84)	38 (93)	0.242

Primary Patency



Stavroulakis K, J Endovasc Ther 2017;24:181

K-POP: A Multicenter Prospective Registry



- Primary endpoint: Primary patency at 12 months
- Secondary endpoint: Freedom from target lesion revascularization at 12 months

Baseline Clinical Characteristics

	N = 100		N = 100
Age (years)	65.7 ± 10.8	Rutherford	
Male	77 (77.0)	2/3	63 (63.0)
Hypertension	69 (69.0)	4	10 (10.0)
DM	65 (65.0)	5	23 (23.0)
Dyslipidemia	44 (44.0)	ABI	0.71 ± 0.25
CKD	28 (28.0)		
Dialysis	16 (16.0)		
CAD	31 (31.0)		
Current smoker	20 (20.0)		
Previous stroke	8 (8.0)		

Lesion & Procedural Data

	N = 100		N = 100
Total occlusion	45 (45.0)	Subintimal approach	15 (15%)
Lesion length (mm)	93.7± 53.7	Combined targets	45 (26.7)
Severe calcification	23 (23.0)	- Iliac	4 (4.0)
Popliteal artery		- CFA	5 (5.0)
- P1 involvement	74 (74.0)	- BTK	33 (33.0)
- P2 involvement	76 (76.0)		
- P3 involvement	48 (48.0)	Additional Tx	28 (28.0)
Distal SFA involvement	44 (44.0)	Atherectomy	17 (17.0)
TASC II lesion types		- Hawk family	7 (7.0)
- B	50 (50.0)	- Jetstream	8 (8.0)
- C	11 (11.0)	- Rotarex	2 (2.0)
- D	21 (21.0)	Provisional stenting	11 (11.0)
Run-off vessel ≤1	35 (35.0)		

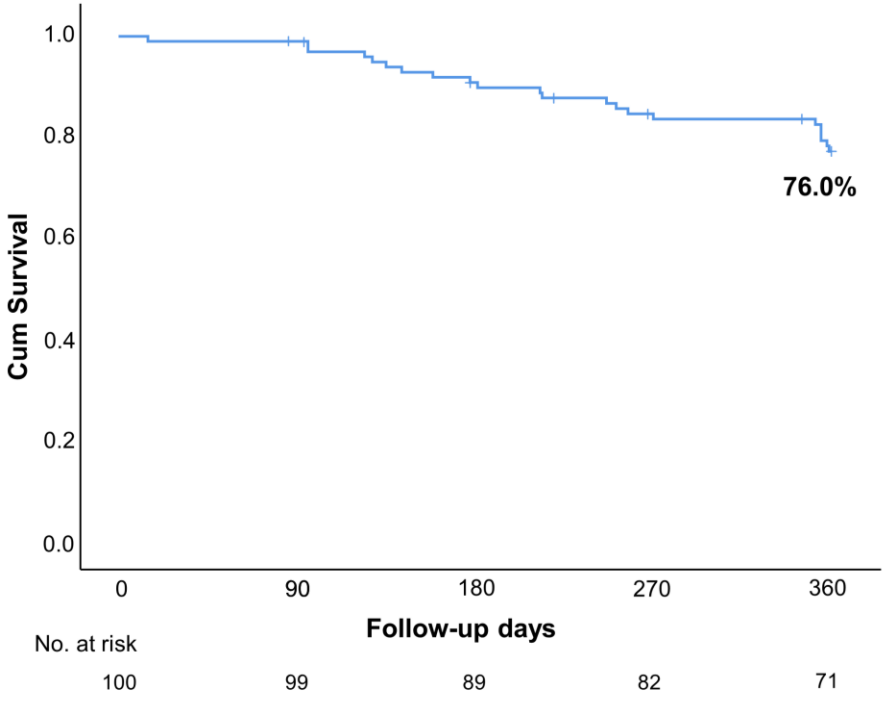
Immediate Outcomes

	N = 100
Procedural success	100 (100)
Major complications	0
Minor complications	4 (4.0)
Arterial perforation	3 (3.0)
- Popliteal artery*	1*
- Other target sites	2
Macroembolism	0
Access site hematoma	1 (1.0)
Post ABI	0.93 ± 0.15

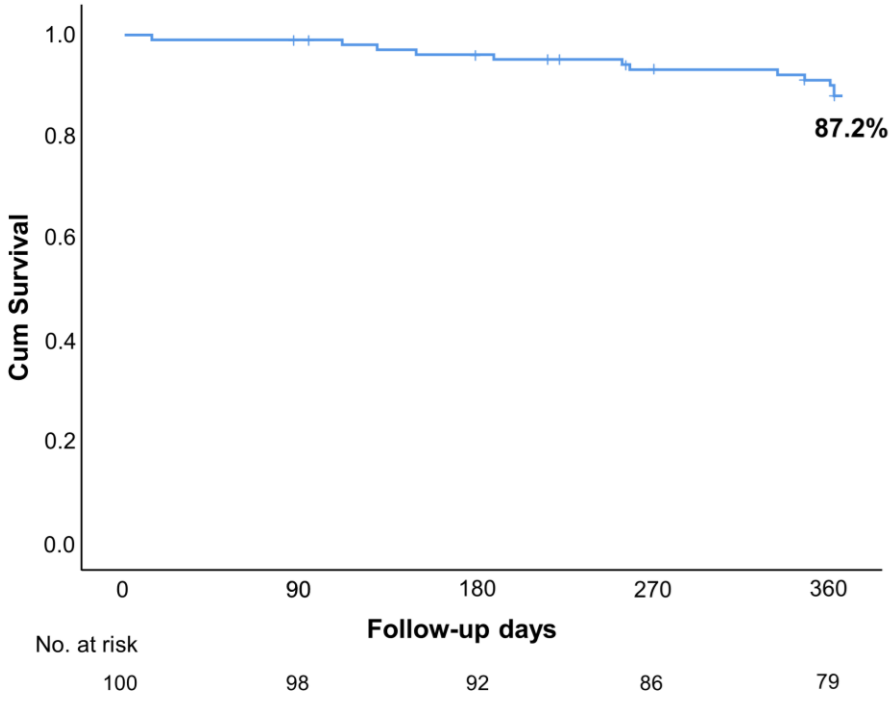
**perforation by atherectomy device*

Clinical Outcomes @ 12 Months

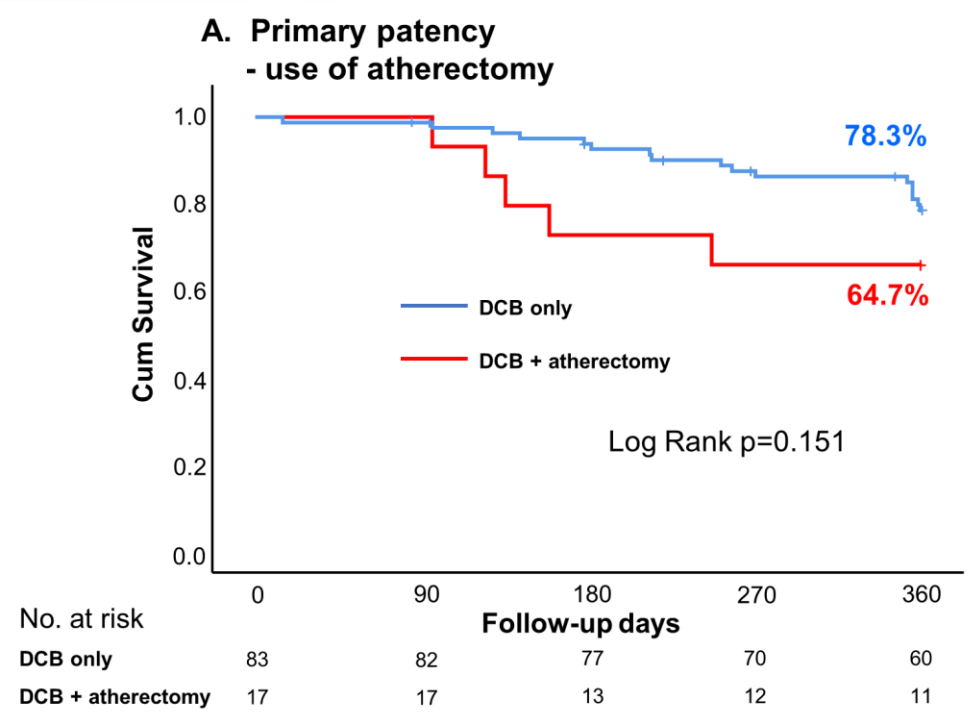
Primary patency

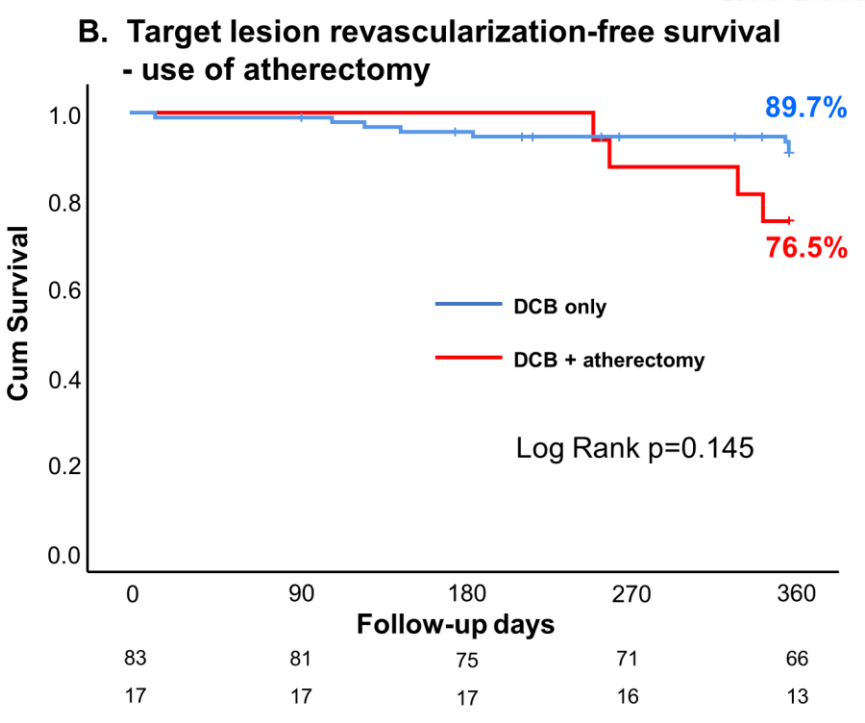


TLR-free survival

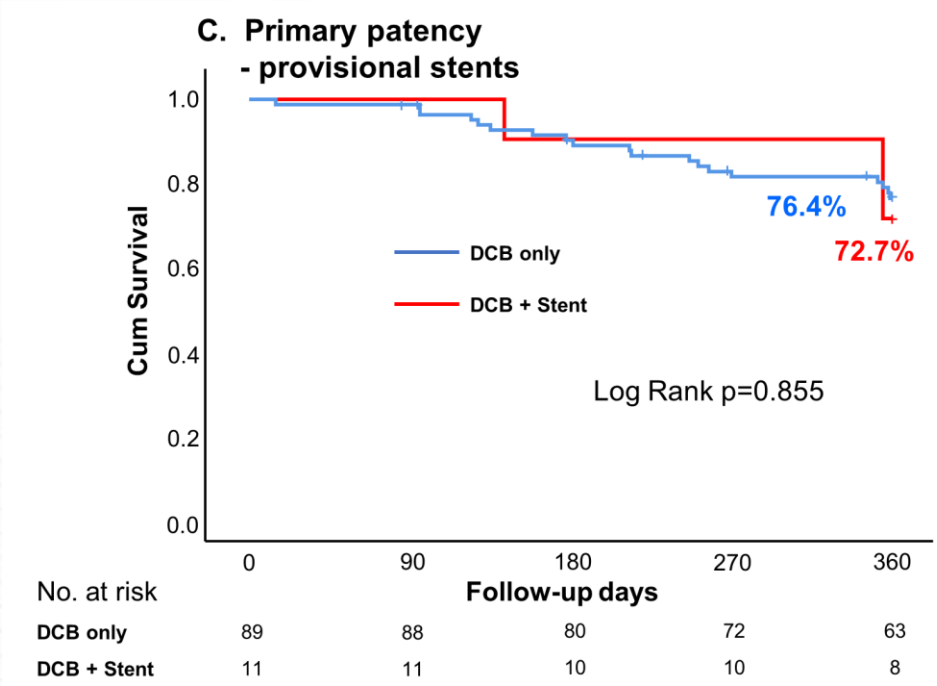


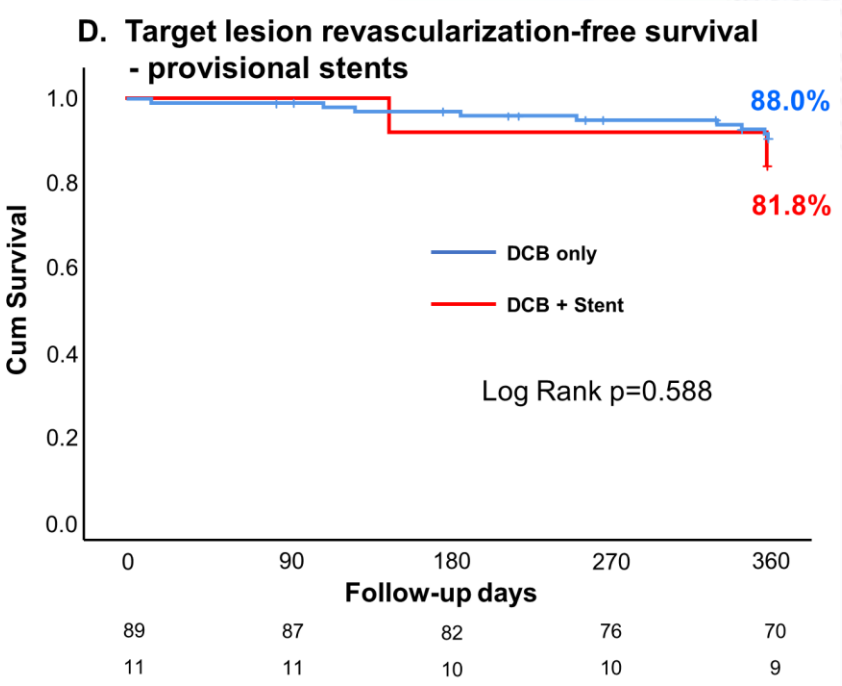
DCB vs. Atherectomy + DCB





DCB vs. DCB + provisional stenting





Predictors for Loss of Patency

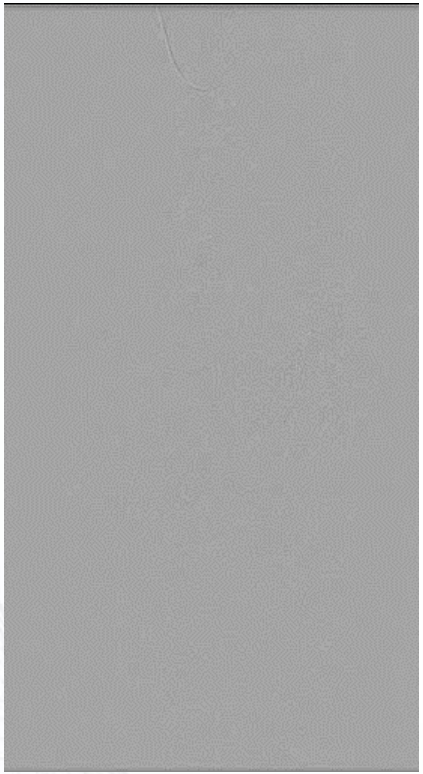
	Univariate analysis			Multivariate analysis		
	HR	95% CI	p	HR	95% CI	p
Distal 1/3 of SFA involvement	1.88	0.82-4.28	0.135	2.26	0.98-5.23	0.056
Lesion length (mm)	1.01	1.00–1.02	0.019	1.00	1.00-1.01	0.357
Total occlusion	2.35	0.99–5.55	0.051	2.74	1.15-6.57	0.023
TASC II D lesion	2.04	0.87–4.83	0.103	1.54	0.56-4.23	0.399

Outcomes of EVT in Popliteal Artery Disease

Investigator	Study design	Modality	Lesion length	Primary patency @ 1y	TLR @ 1 y
Rastan A et al. (2013)	RCT	BMS (n=119) POBA (n=127)/ Prov stent 25.2%	42 mm	67.4% vs. 44.9% (p=0.002)	14.7% vs. 44.1%
Soga Y. et al. (2013)	Retrospective	POBA (n=103)/ Prov stent 14.6%	45.0 mm	75.5%	?
Scheinert D et al. (2013)	Retrospective	Supera (n=101)	58.4 mm	87.7%	6.9%
Norberto E et al. (2020)	Retrospective	Supera (n=50)	?	89.6%	6%
Stavroulakis K et al. (2017)	Retrospective	DCB (n=31) DAART (n=41)	47/42 mm	65% vs. 82% (p=0.021)	25.8% vs. 12.2%
K-POP	Prospective	DCB (n=100)/ Atherectomy 16.3% Prov stent 12.8%	93.7 mm	76%	12.8%

F/66, Claudication (R2)

OJS #8157929

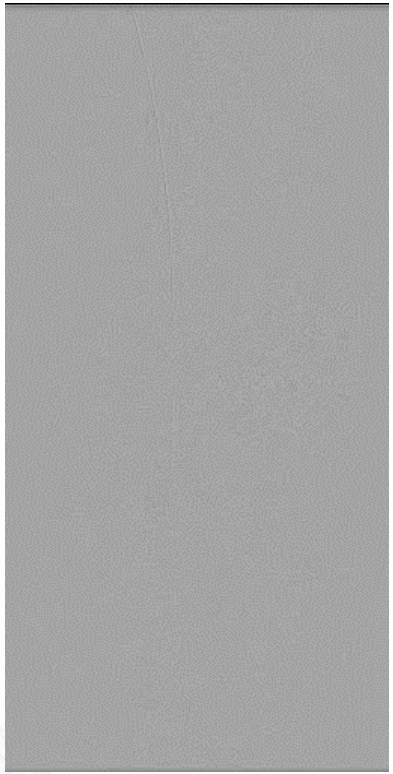


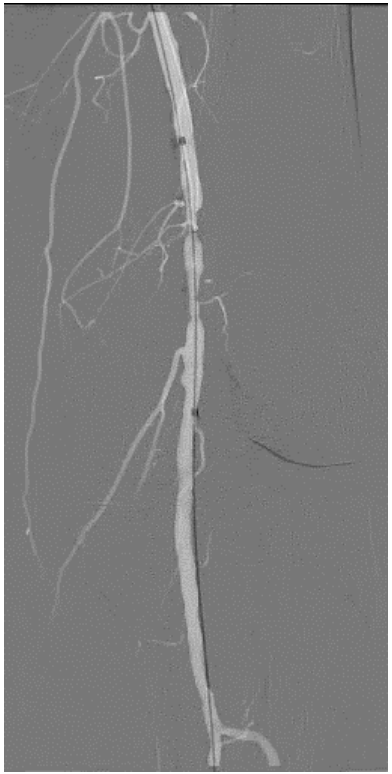
Ballloon 6 x 20 mm

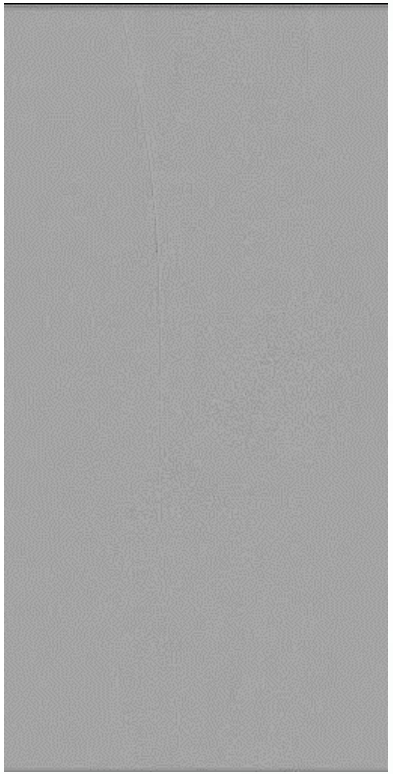
Ballloon 6 x 20 mm

DCB

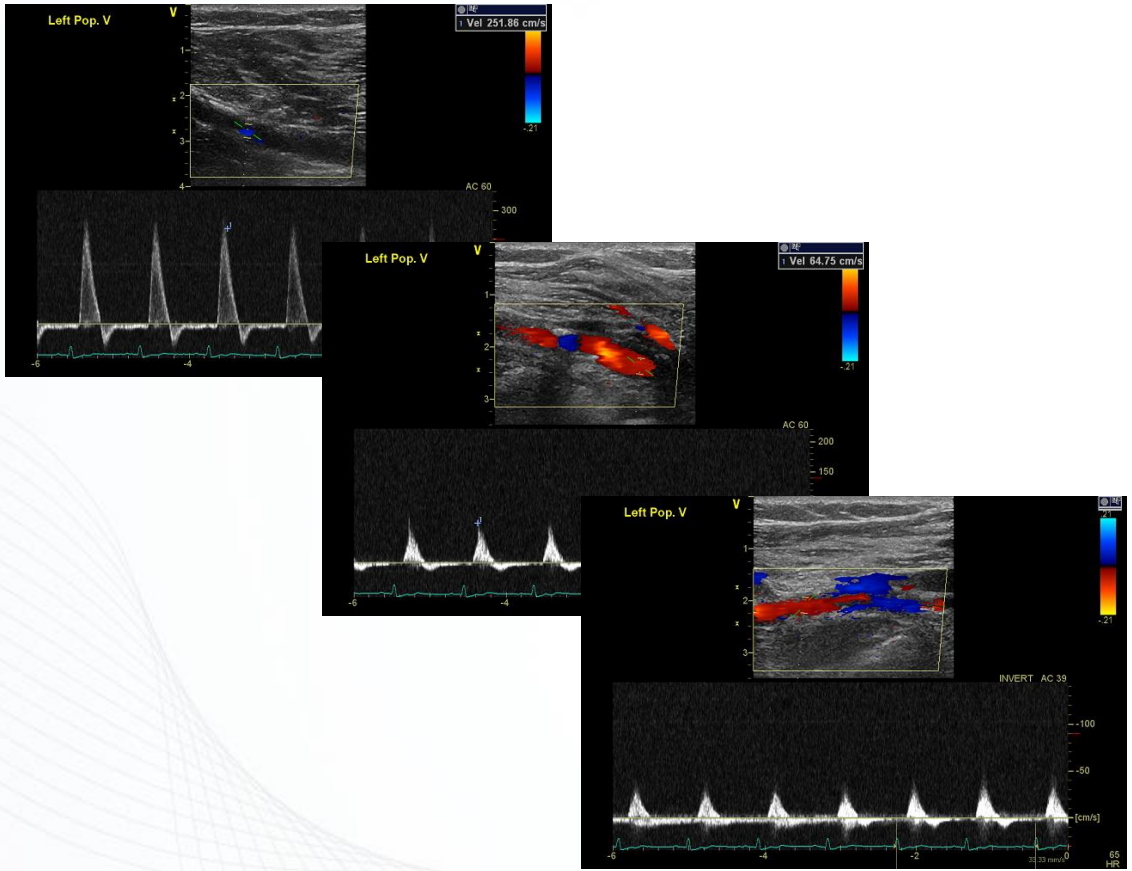
IN.PACT 6 x 60 mm

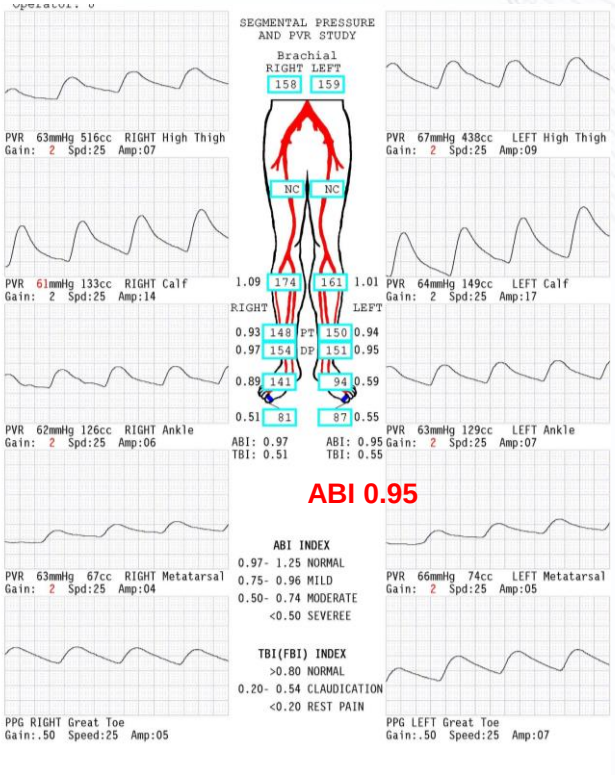






Follow-up @ 1 year



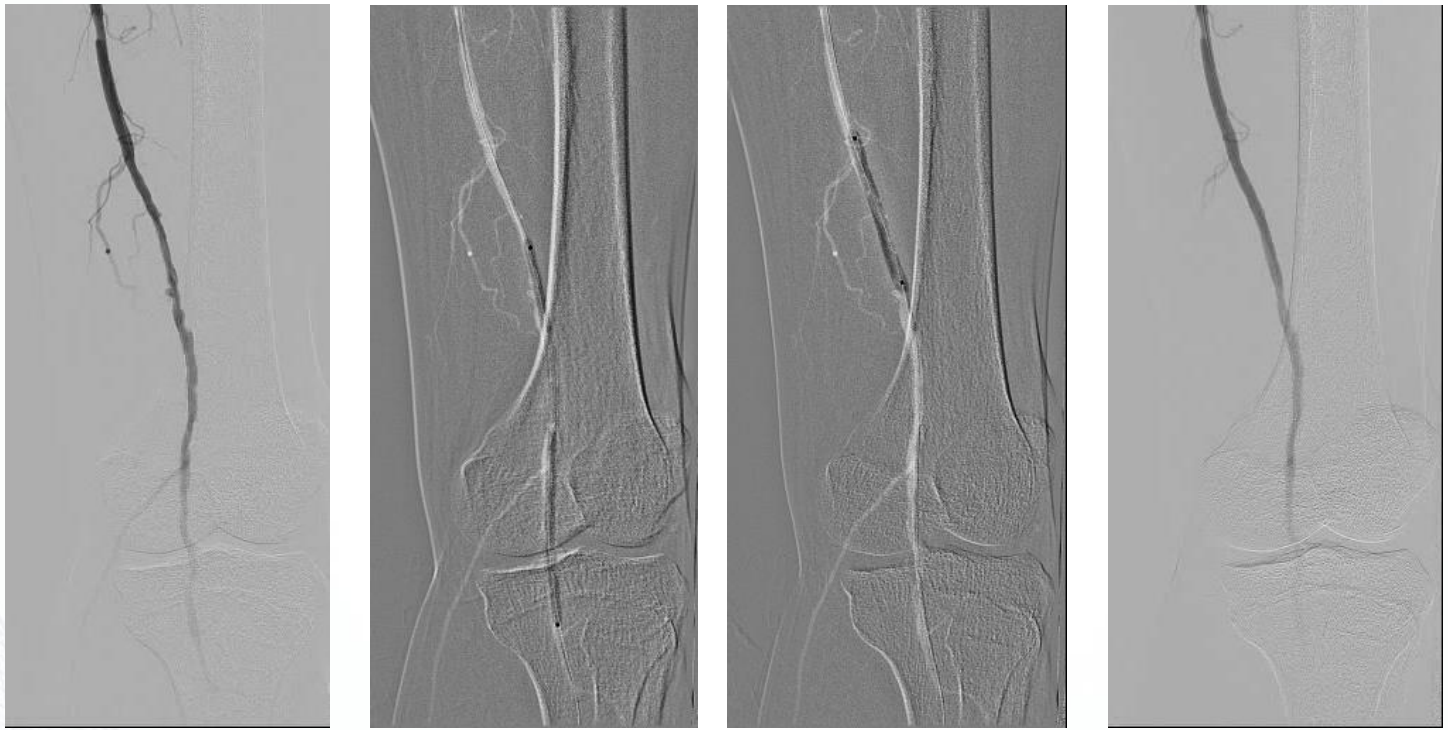


M/61, Claudication (R3)

Jetstream atherectomy LHK, #3460319

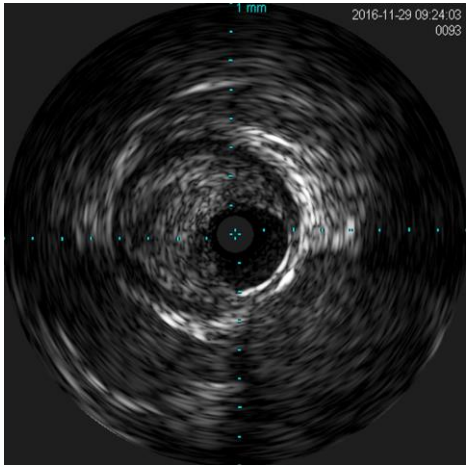
DCB

IN.PACT 5 x 150, 6 x 60 mm

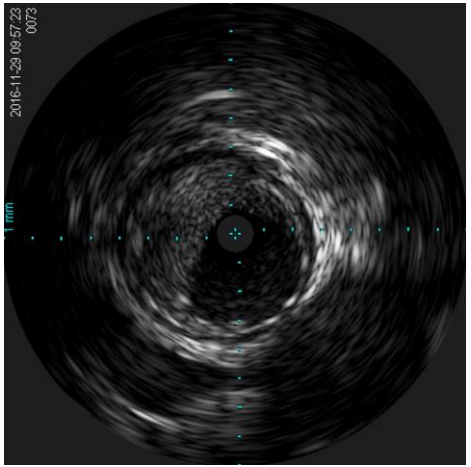


IVUS

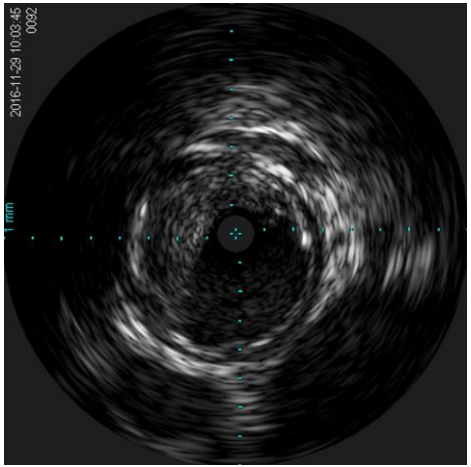
Before athrectomy



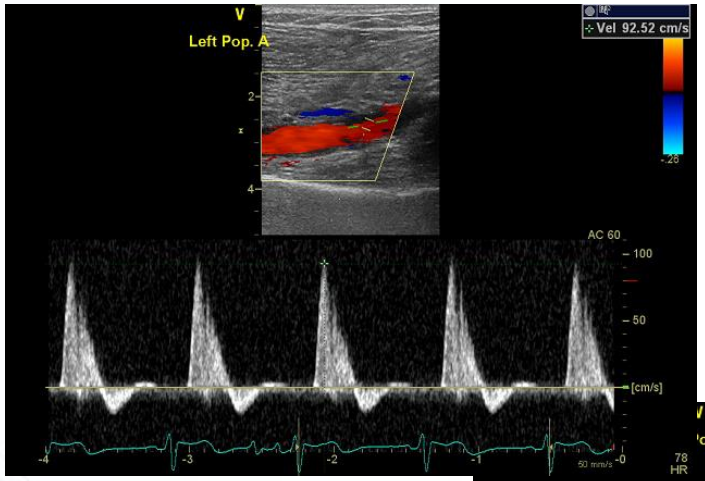
After athrectomy

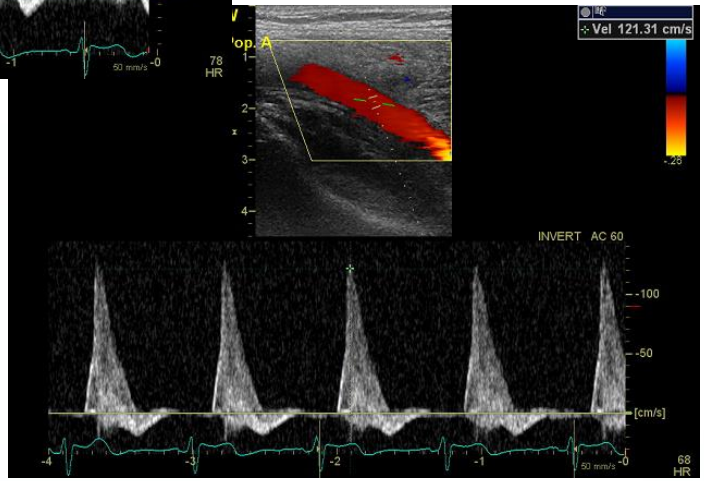


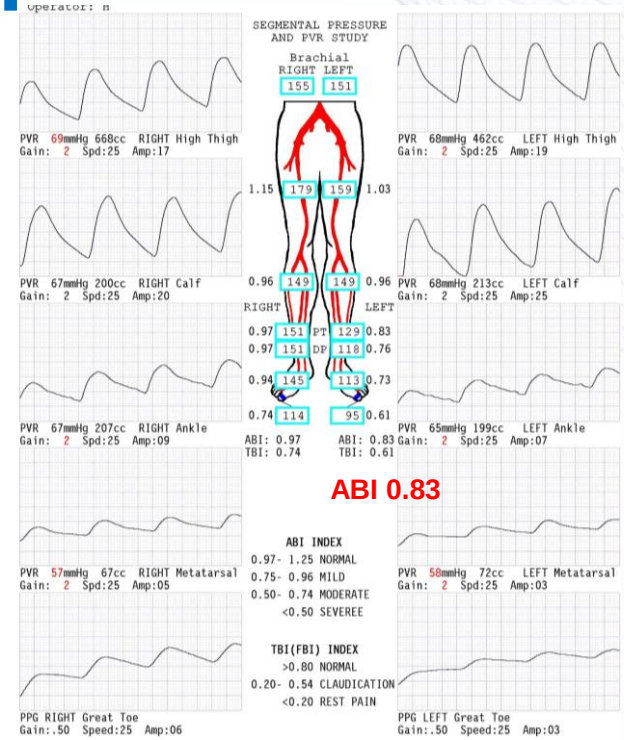
After DCB



Follow-up @ 1 year

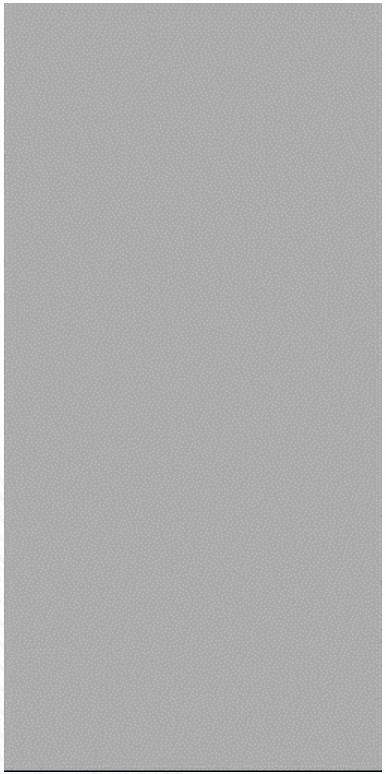


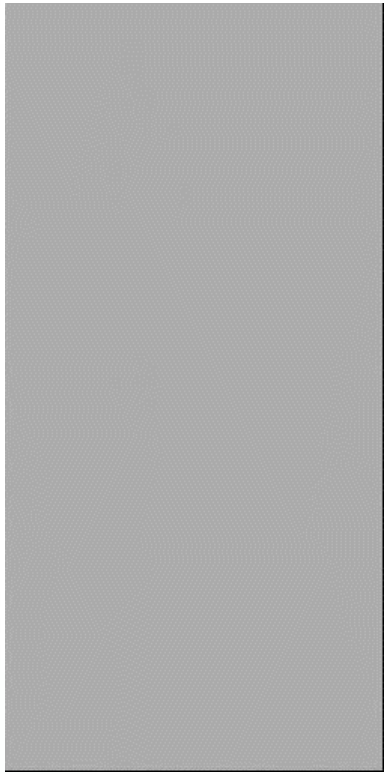


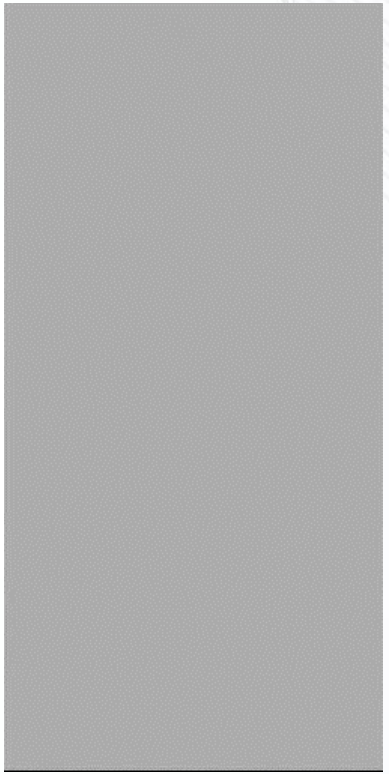


M/77,

after cutting balloon **IN.PACT 6 x 60 mm**

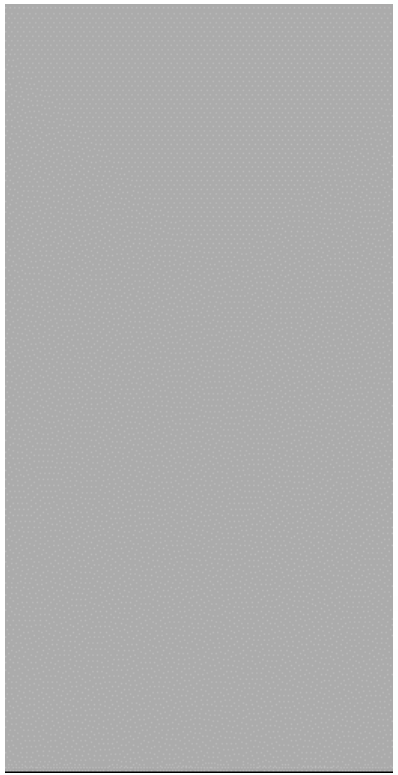


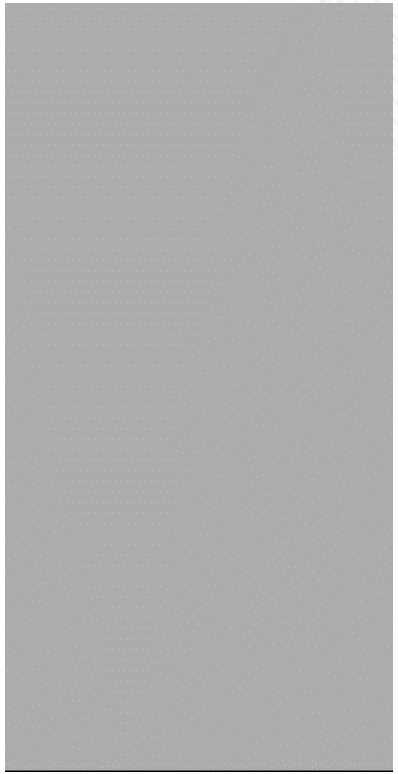




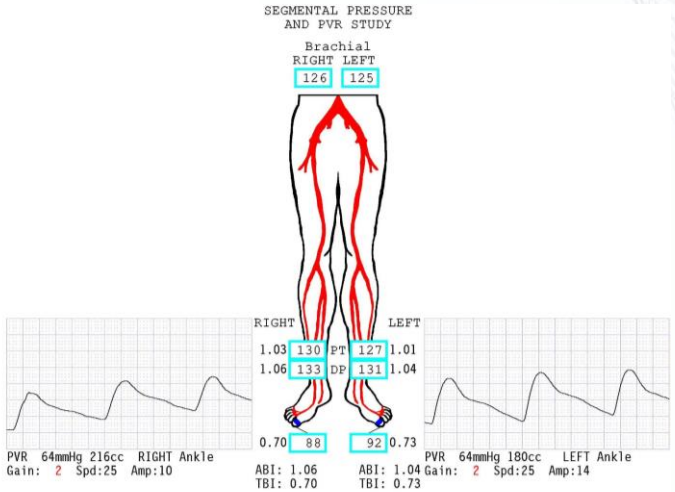
Bail-out Stenting

Supera 6 x 60 mm





Follow-up @ 1 year



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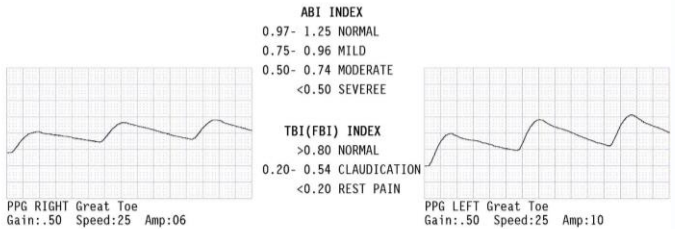

DDx: Non-atherosclerotic Pathologies

- Entrapment
- Aneurysm
- Adventitial cystic disease
- Buerger’s disease
- Vasculitis

Take Home Messages

- Th K-POP study data showed favorable results of DCB-based treatment. Randomized controlled studies are required to compare the efficacy of different treatment modalities objectively.
- Whether plaque modification by atherectomy may improve the outcomes of DCB in popliteal artery disease also needs to be investigated in the future clinical studies.
- We have to know that there are uncommon non-atherosclerotic pathologies of popliteal artery disease which show poor outcomes after EVT and that some pathologies may require surgical treatment.