DIDACTICS
DEVELOPMENT
DISTRIBUTION

Combined popliteal & BTK DCB-treatment in CLI patient : risky or not ?

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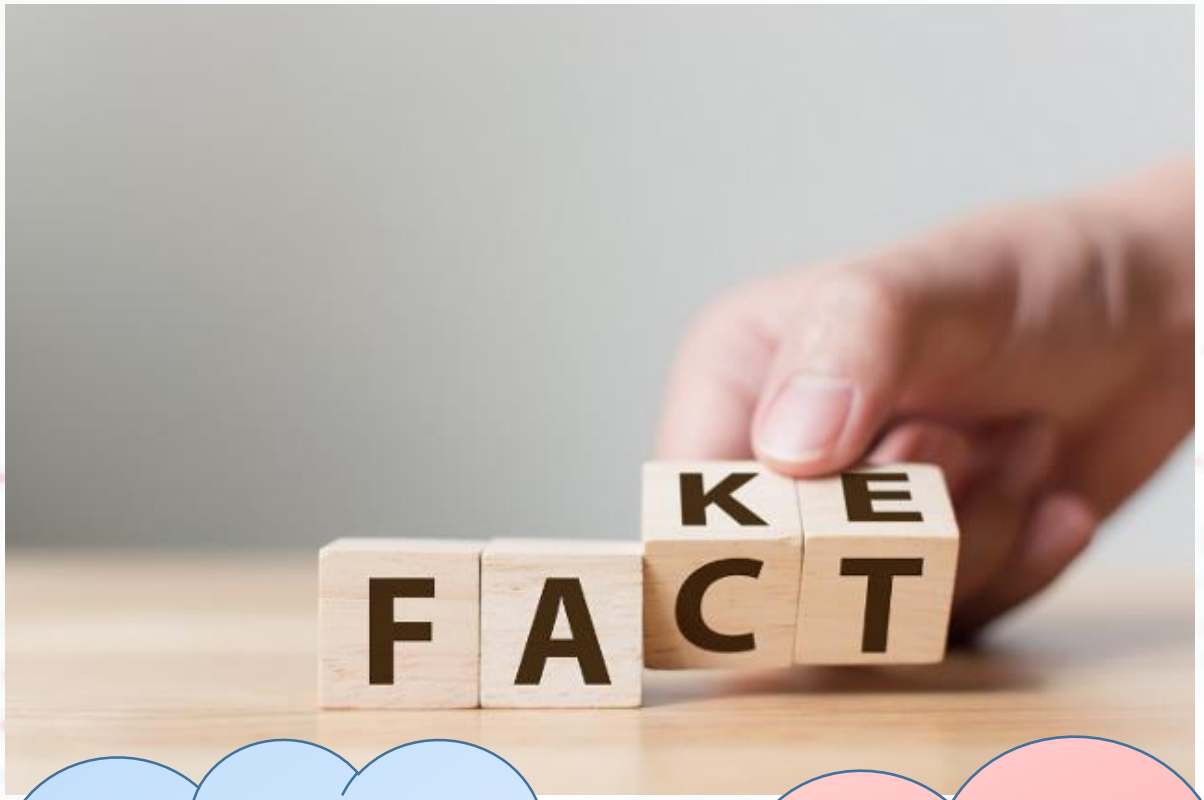
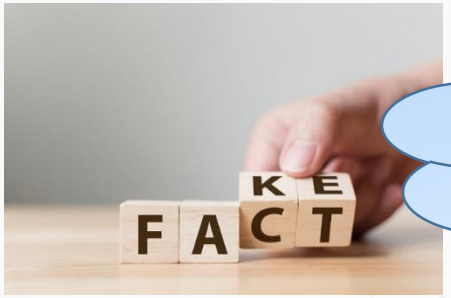


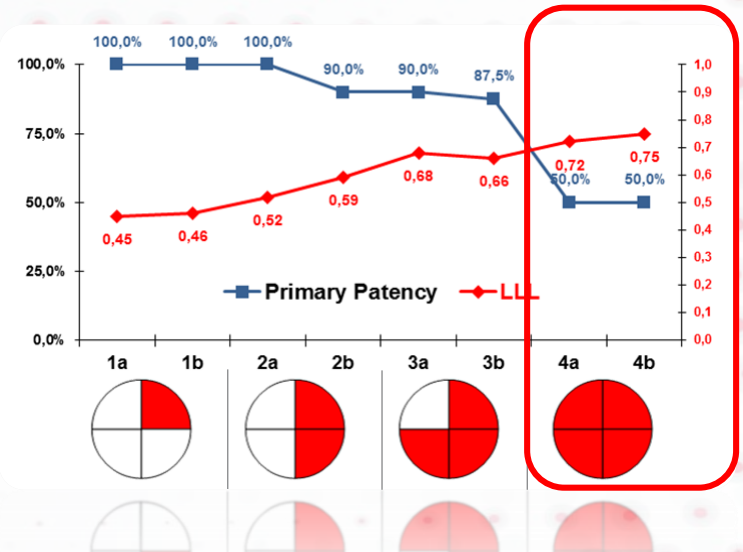
DCB don't work in Calcium

DCB are dangerous

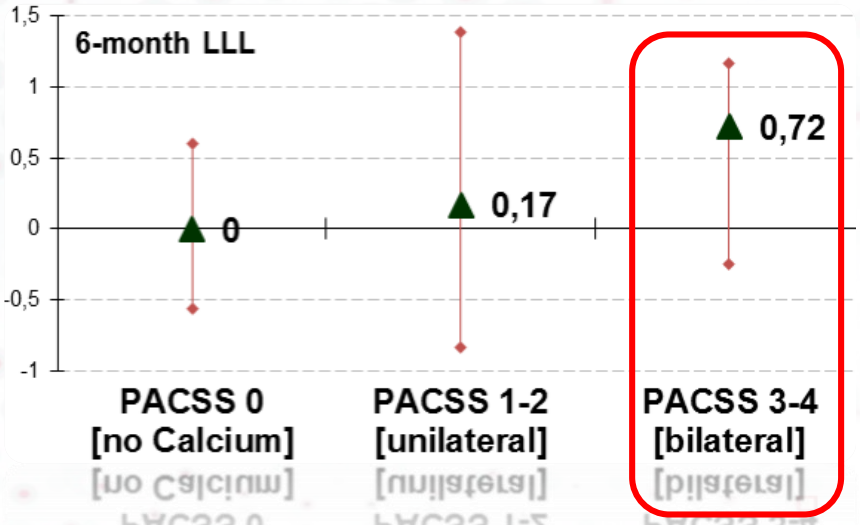


DCB don’t work in Calcium

- **Circumferential Calcium more severe vs. longitudinal as defined by 4 Calcium scoring systems [1-2-3-4]**



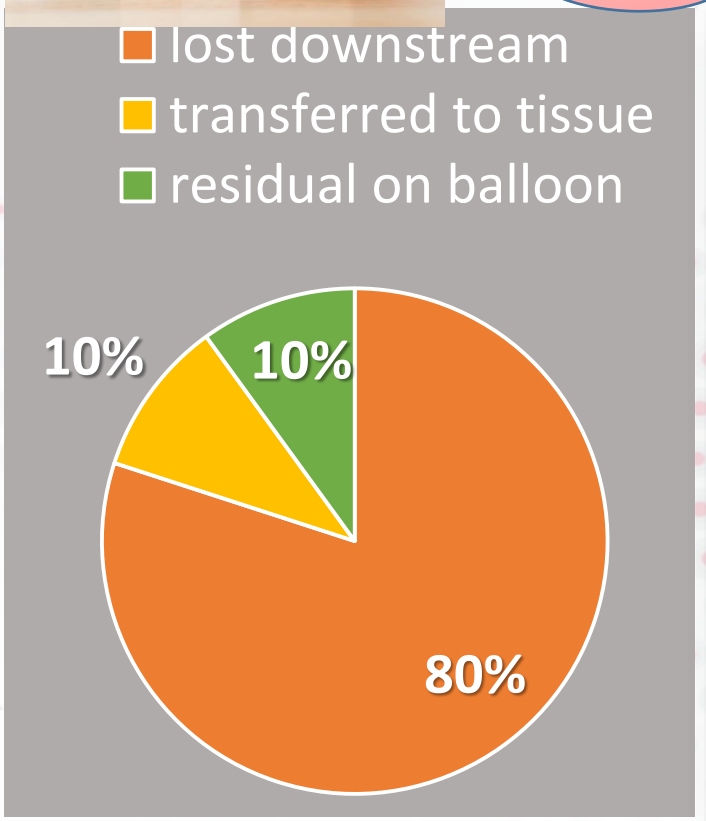
Fanelli F, Cannavale A, Gazzetti M, Lucatelli P, Wlderk A, Cirelli C, d'Adamo A, Salvatori FM. Calcium burden assessment and impact on drug-eluting balloons in peripheral arterial disease. Cardiovasc Intervent Radiol. 2014 Aug;37(4):898-907

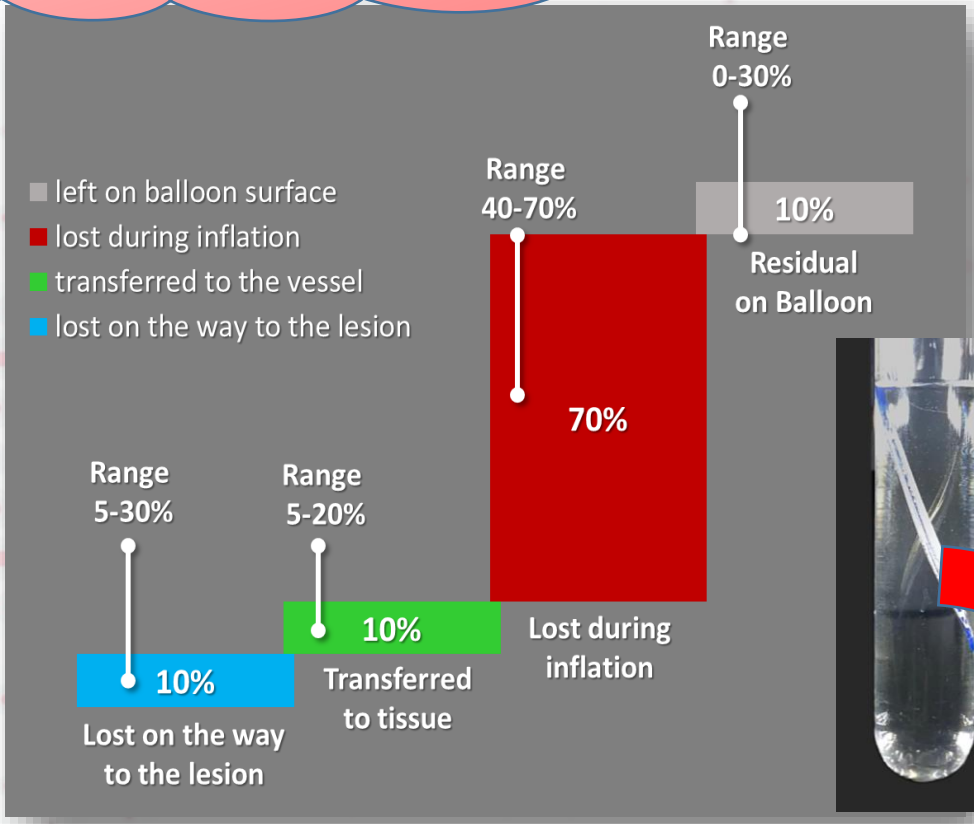


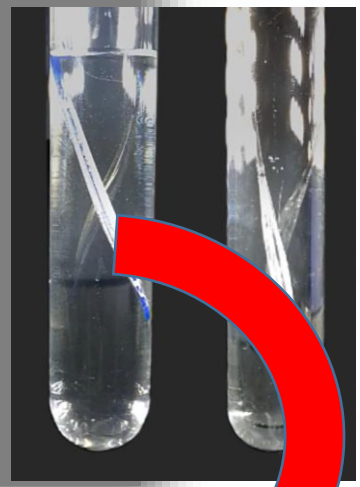
Tepe G, Beschorner U, Ruether C, Fischer I, Pfaffinger P, Noory E, Zeller T. Drug-Eluting Balloon Therapy for Femoropopliteal Occlusive Disease: Predictors of Outcome With a Special Emphasis on Calcium. J Endovasc Ther. 2015 Oct;22(5):727-33

1. Fanelli F, Cannavale A, Gazzetti M, Lucatelli P, Wlderk A, Cirelli C, d'Adamo A, Salvatori FM. Calcium burden assessment and impact on drug-eluting balloons in peripheral arterial disease. Cardiovasc Intervent Radiol. 2014 Aug;37(4):898-907
2. Dattilo R, Himmelstein SI, Cuff RF. The COMPLIANCE 360° Trial: a randomized, prospective, multicenter, pilot study comparing acute and long-term results of orbital atherectomy to balloon angioplasty for calcified femoropopliteal disease. J Invasive Cardiol. 2014 Aug;26(8):355-60
3. Rocha-Singh KJ, Zeller T, Jaff MR. Peripheral arterial calcification: prevalence, mechanism, detection, and clinical implications. Catheter Cardiovasc Interv. 2014 May 1;83(6):E212-20
4. Patel MR, Conte MS, Cutlip DE, Dib N, Geraghty P, Gray W, Hiatt WR, Ho M, Ikeda K, Ikeno F, Jaff MR, Jones WS, Kawahara M, Lookstein RA, Mehran R, Misra S, Norgren L, Olin JW, Povsic TJ, Rosenfield K, Rundback J, Shamoun F, Tcheng J, Tsai TT, Suzuki Y, Vranckx P, Wiechmann BN, White CJ, Yokoi H, Krucoff MW. Evaluation and treatment of patients with lower extremity peripheral artery disease: consensus definitions from Peripheral Academic Research Consortium (PARC). J Am Coll Cardiol. 2015 Mar 10;65(9):931-41. doi: 10.1016/j.jacc.2014.12.036. Erratum in: J Am Coll Cardiol. 2015 Jun 16;65(23):2578-9

DCB are dangerous

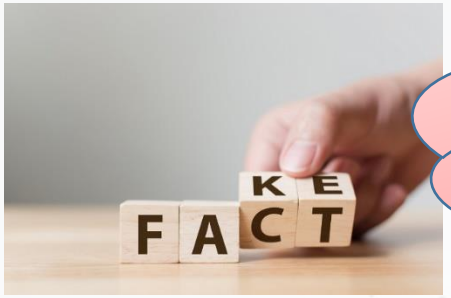






Mass effect : obliteration of microcirculation distally (cfr atherosclerotic debris)

Drug effect : potential local tissue toxicity



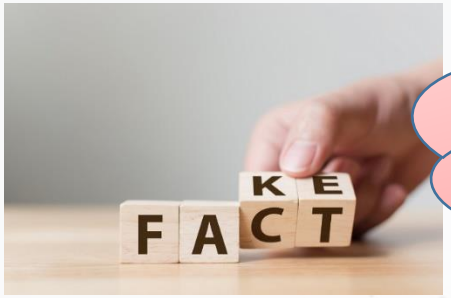
DCB are dangerous

Histological section based analysis of downstream non-target organs (skeletal muscle and coronary band) associated with PTX @ 28 & 90 days post treatment in different concentrations

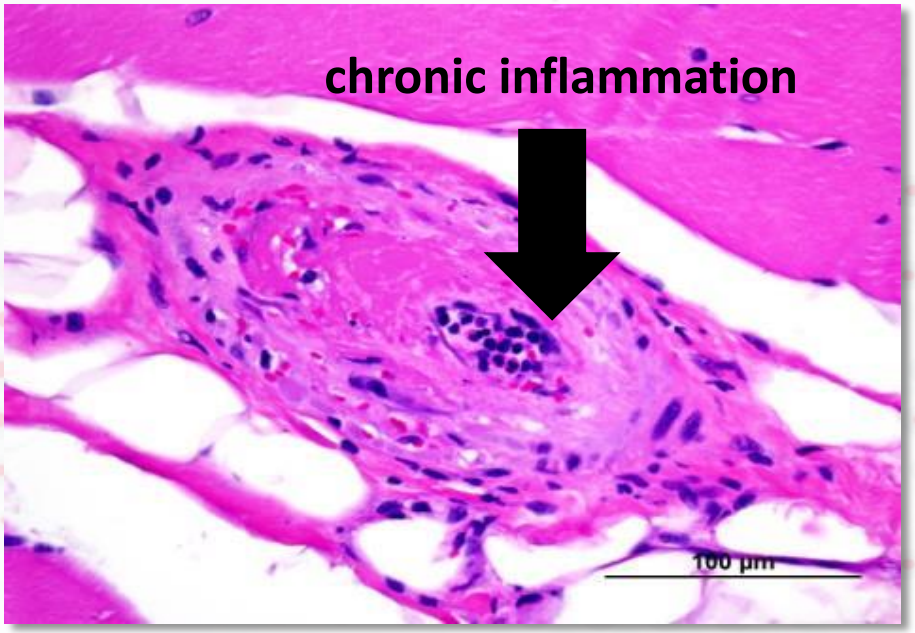
	Survival Treatment & Arteries	Lutonix 035		IN.PACT		P-value	
Paclitaxel concentration in downstream tissues (ng/g)		Skeletal muscle	Coronary band	Skeletal muscle	Coronary band	Skeletal muscle	Coronary band
	28-day (1x, n=5)	1.3 (0.6-2.3)	1.5 (1.1-65.8)	60.8 (32.6-118.1)	189.0 (134.0-700.0)	0.009	0.02
	28-day (3x, n=5)	3.7 (1.3-10.9)	31.5 (5.9-54.1)	170.9 (19.7-221.5)	871.0 (567.5-1315.0)	0.08	0.009
	90-day (3x, n=4)	0.6 (0.5-6.4)	2.7 (0.0-25.5)	16.1 (12.8-319.2)	158.0 (6.3-1178.0)	0.009	0.05

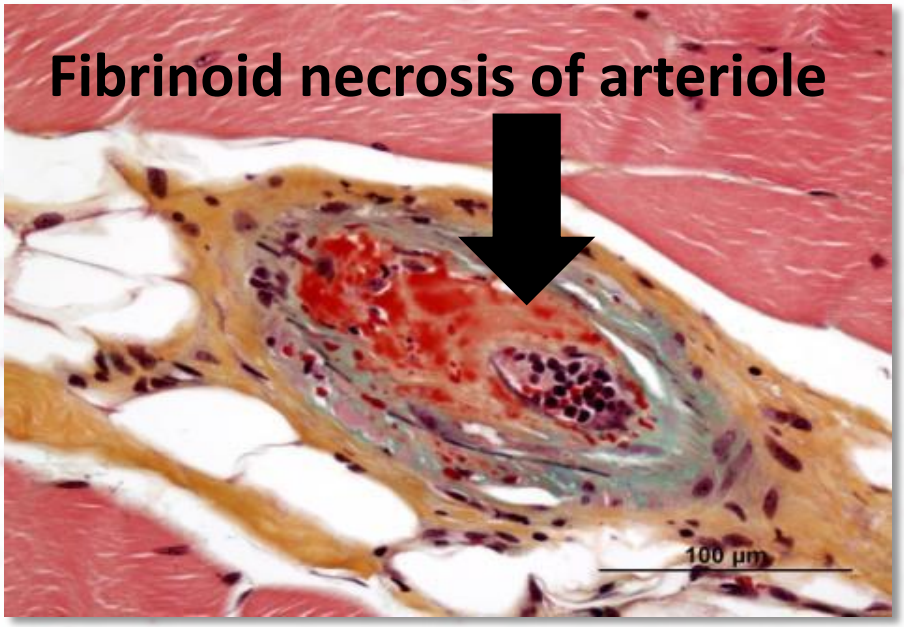
	Survival Treatment & Arteries	Lutonix 035	IN.PACT	P-value
Number of micro-vessels with paclitaxel- associated findings	28-day (1x, n=5)	1 (0-2)	4 (2-12)	0.03
	28-day (3x, n=5)	1 (0-12)	26 (11-34)	0.07
	90-day (3x, n=4)	0 (0-3)	11 (5-15)	0.02

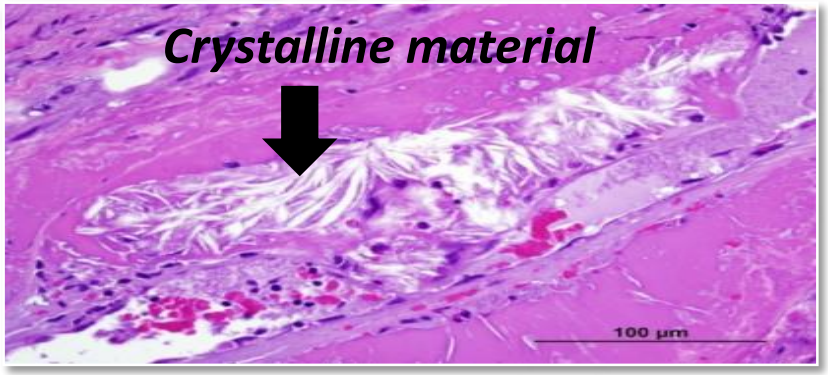
Kolodgie FD et al. J Vasc Interv Radiol 2016 Sep,27(11), 1676-1685 ; with the courtesy of Aloke Finn, CVPath institute Gaithersburg, USA



DCB are dangerous







Kolodgie FD et al. J Vasc Interv Radiol 2016 Sep,27(11), 1676-1685 ; with the courtesy of Aloke Finn, CVPath institute Gaithersburg, USA

Patient characteristics

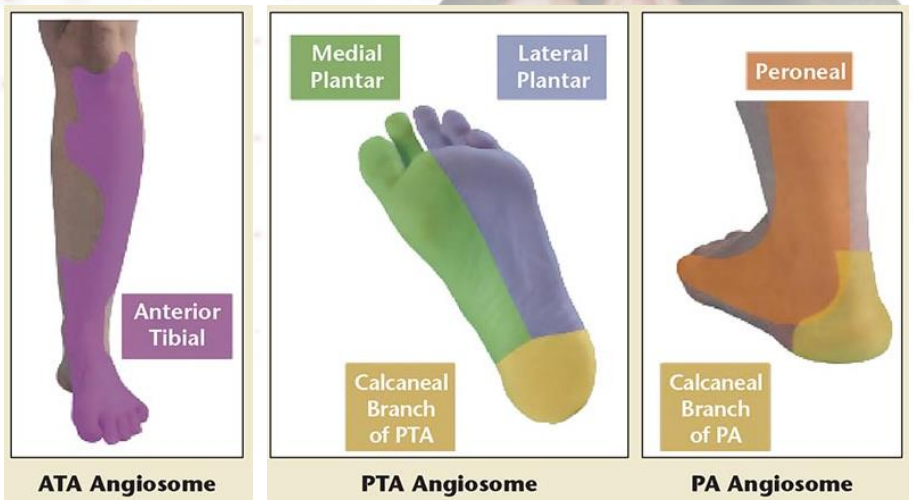
Female patient, 79 years

Non healing ulcer left foot since 6 weeks

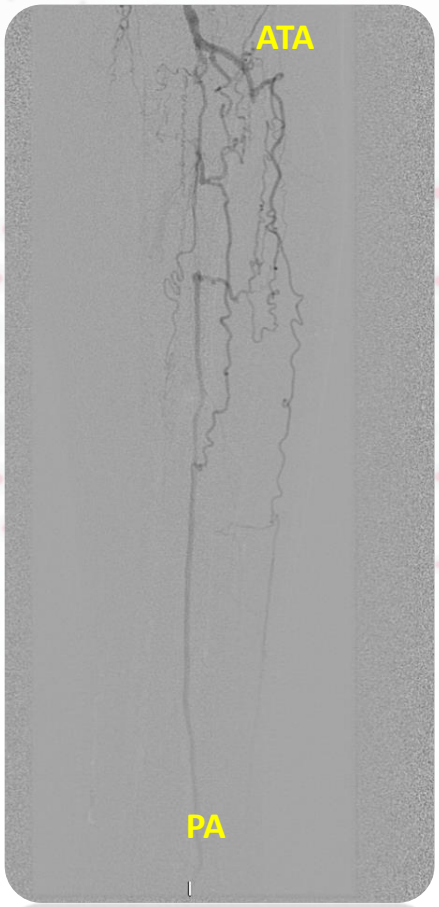
Severe pulmonary Obstructive disease
Coronary disease

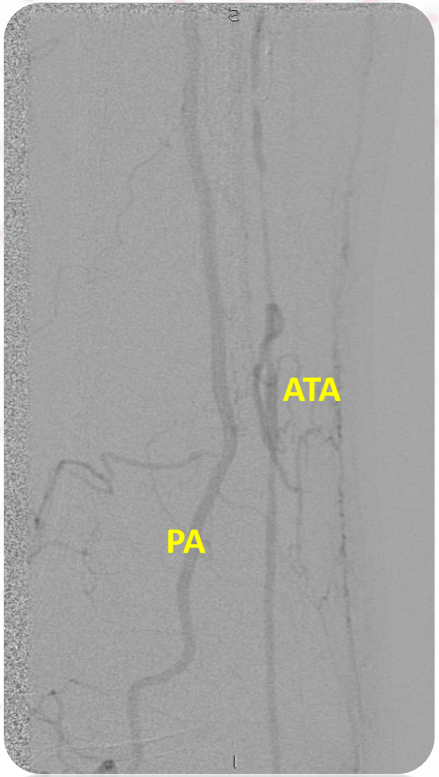
IDDM type 2
Hypercholesterolemia
Arterial Hypertension

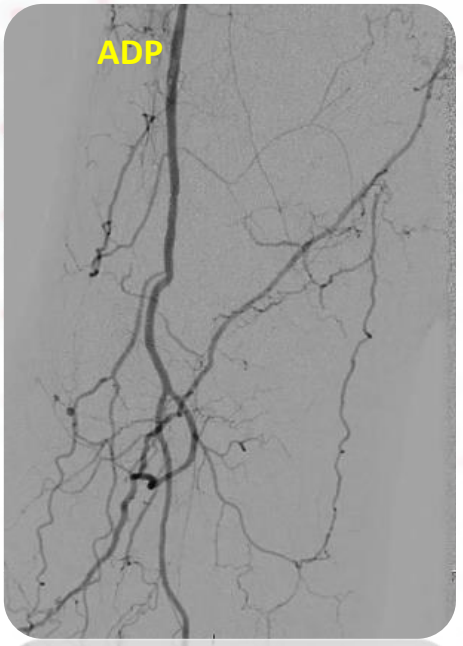
Normal triphasic CFA signal
Weak monophasic popliteal & distal (ATA) signals



Angiography on table

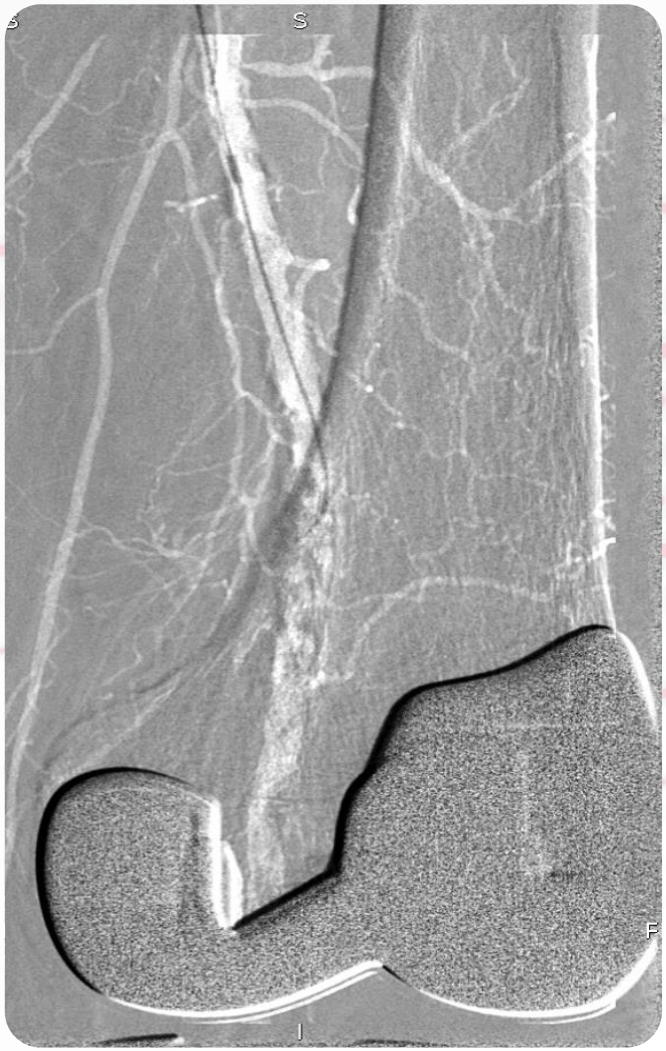






HOW TO START ???

Passage of the lesion



- Antegrade CFA puncture left
- 0.035” hydrophilic workhorse GW
- LP support catheter
- **INTRALUMINAL PASSING ATTEMPT**

Passage of the lesion

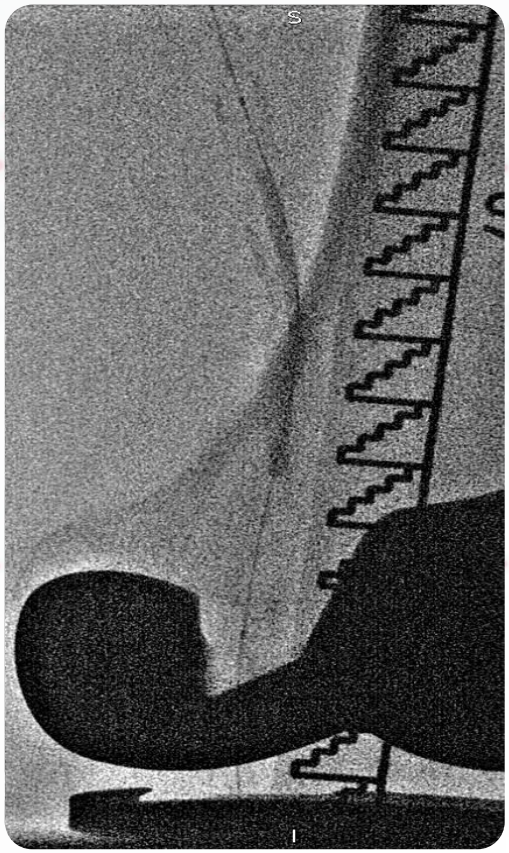
- 0.035” hydrophilic workhorse GW
- LP support catheter
- **INTRALUMINAL PASSING WIRE, THE CATHETER DOESN’T???**

HOW TO CONTINUE???

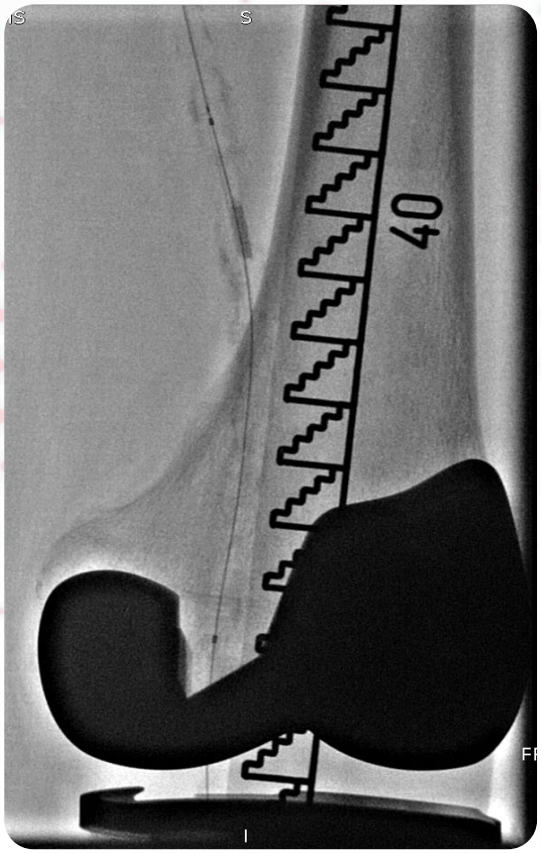
Passage of the lesion

- Exchange to 018” system
- 018” stiff workhorse GW
- Start vessel preparation

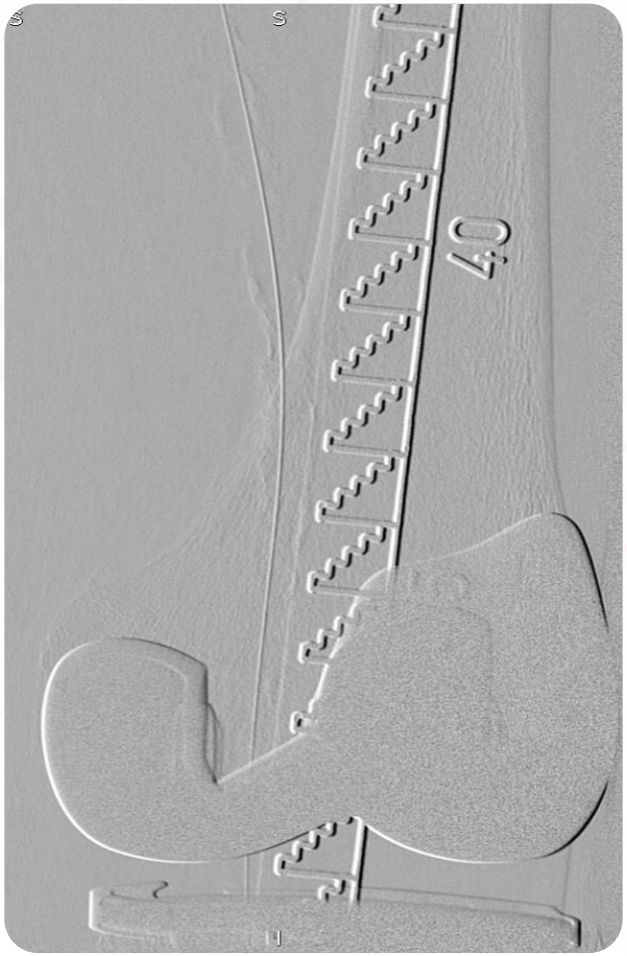
Vessel preparation



018” angioplasty 4-80

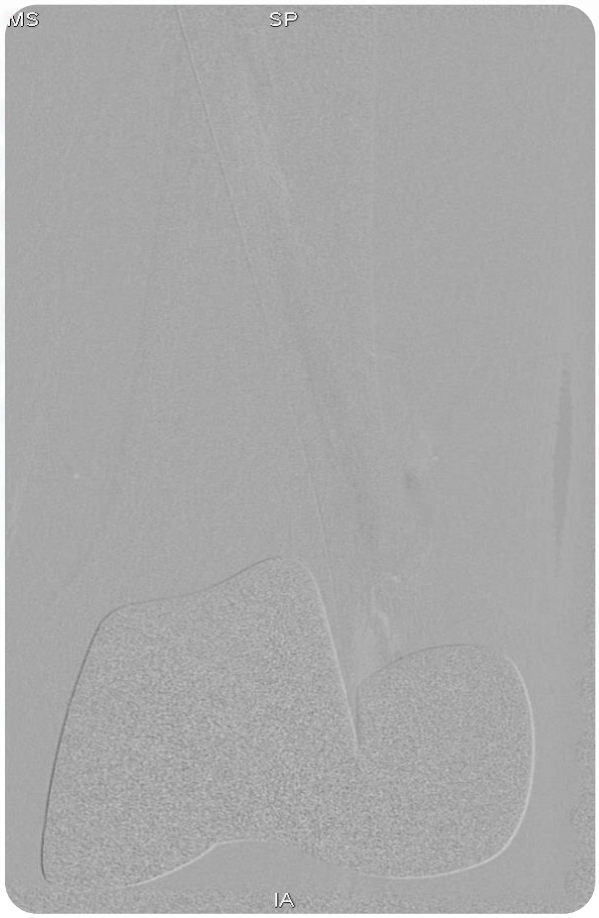


018” angioplasty 6-80



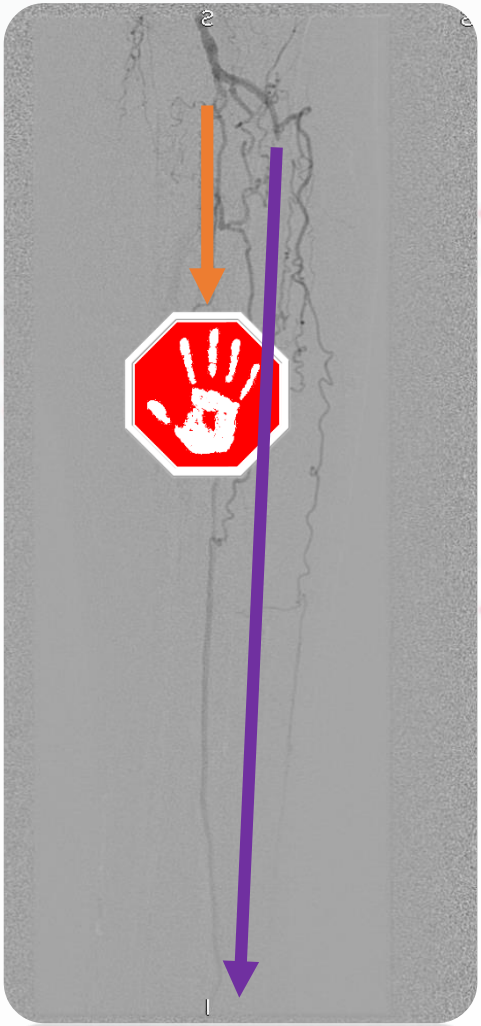
RESULT POST VESSEL PREP
Definitive treatment ???

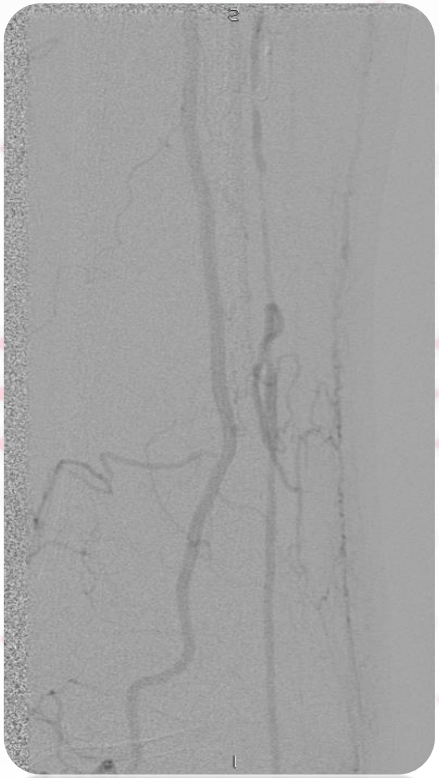
Definitive treatment

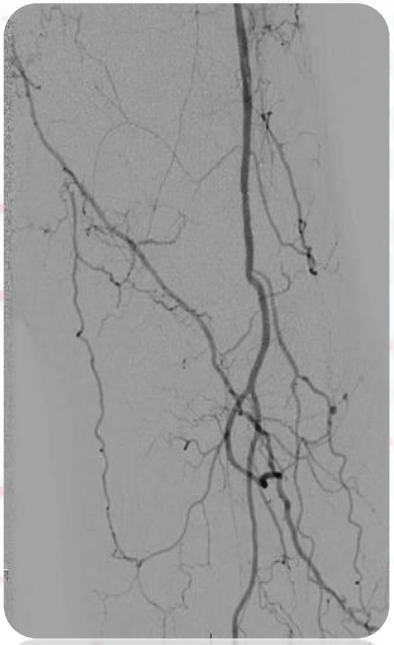


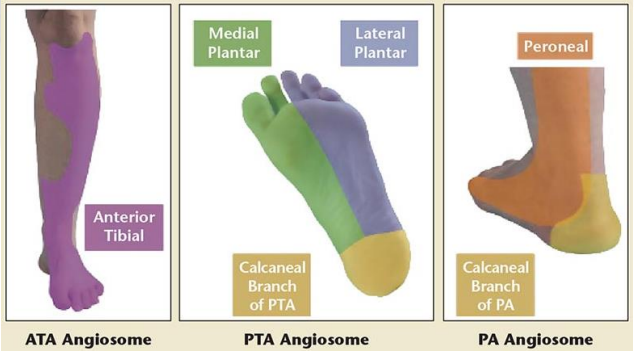
DCB 6-100 ; 180 sec NEED FOR SCAFFOLD?

Strategy below the knee

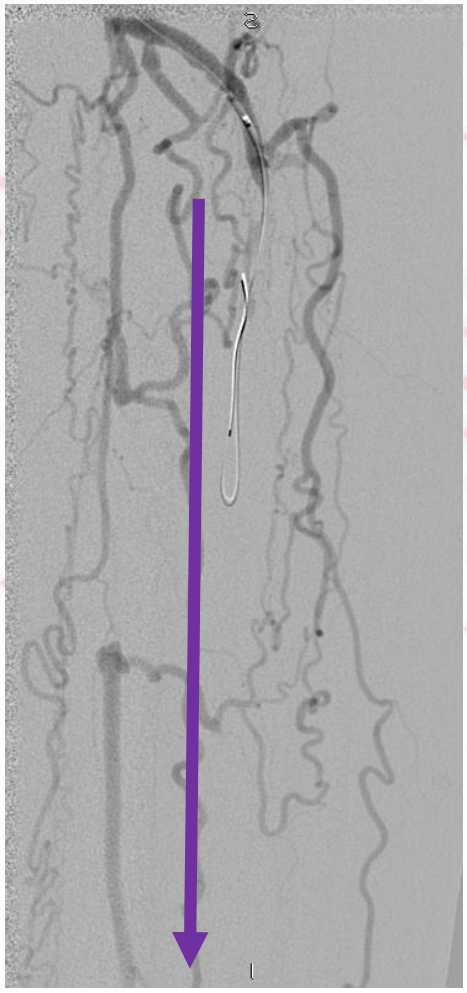


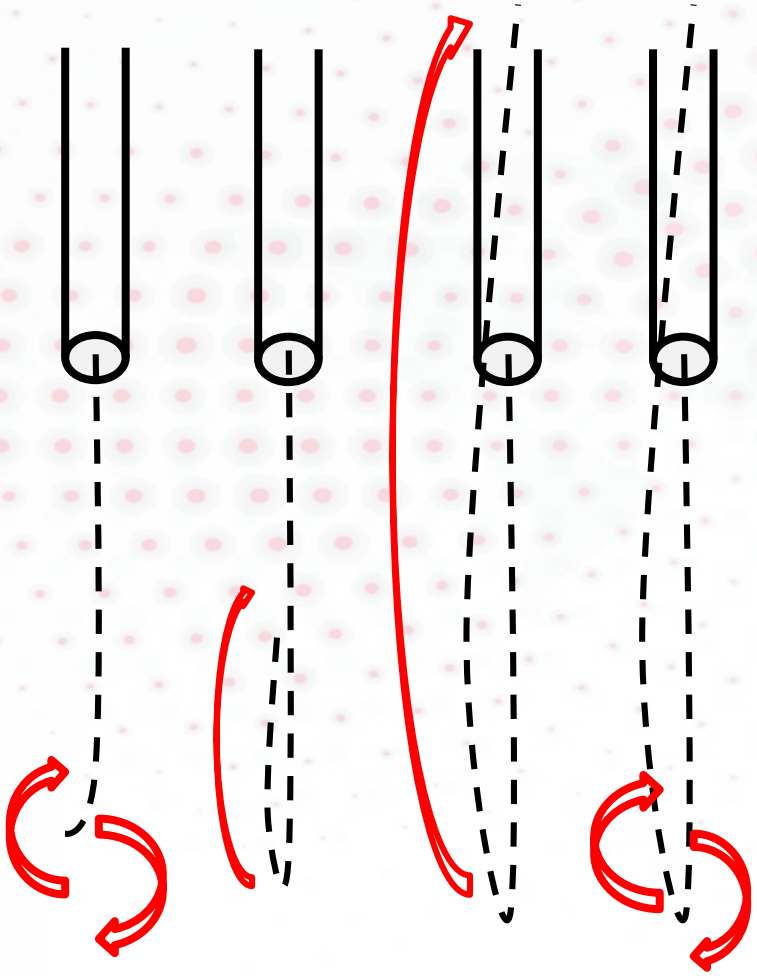




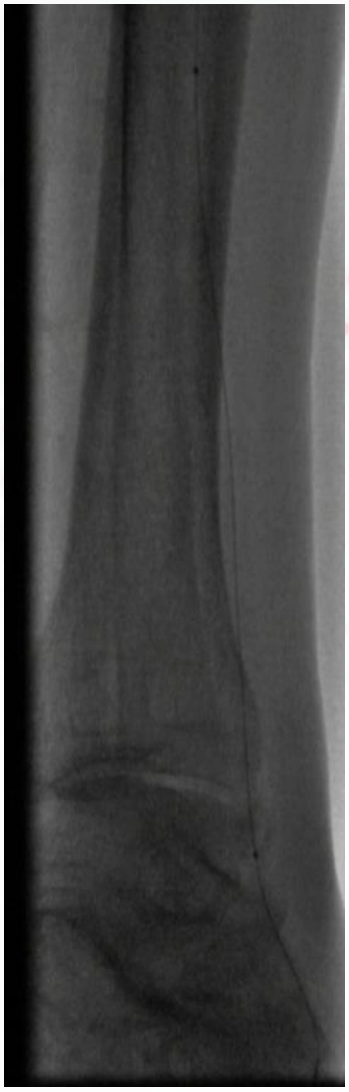


Technique below the knee





Treatment below the knee



- POBA 0.014 LP, long balloons ?
- DCB 0.014 LP long balloons ?
- Bail-out stenting : SX? BX? BMS? DES? BVS?

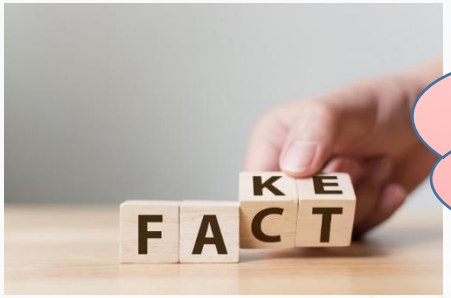
Final result

DCB work… also in Calcium

	LUTONIX		IN.PACT GLOBAL			ILLUMENATE Global[7]	RANGER Global[8]
	Global[1]	Long Lesion[2]	Long Lesion[3]	CTO[4]	Clinical[6]	Stellarex	
Follow-up	691 subjects Complete follow-up CEC & site-reported outcomes	107 & 102 subjects for safety & effectiveness, respectively; Core lab-adjudicated	157 subjects Complete follow-up; Core lab-adjudicated	126 subjects Complete follow-up; Core lab-adjudicated	1406 subjects Complete follow-up; CEC & site-reported outcomes	371 subjects Complete follow-up; Core lab-adjudicated	172 subjects complete follow-up
Key Lesion Characteristics							
Length (cm)	10.1cm	21.3cm	26.4cm	22.9cm	12.1cm	7.5cm	12,9cm
CTO (%)	31.2%	52.1%	60.4%	100.0%	35.5%	31.3%	na
Ca^{2+} (%)	50.2%	78.9%[2]	71.8%	71.0%	68.7%	56.2%[7]	26%
12-m Outcomes *							
PPR(%)	NR	68.9%	91.1%	85.3%	NR	81.4%	84.0%
FF TLR/CD-TLR(%)	94.3%	87.8%	94.0%	89.1%	92.6%	94.8%	89,0%

1. Thieme, M., et al. (2017). JACC Cardiovasc Interv.
2. Bard Lutonix Instructions for Use BAW1387400r3, Section 10.5. Moderate to severe calcification reported; amputations not reported (NR).
3. Presented by Scheinert D, PCR Paris, France 2015.
4. Presented by Tepe G, CX London, UK 2016.
5. Presented by Brodmann M, VIVA Las Vegas, USA 2015.
6. Presented by Jaff M, VIVA Las Vegas, USA 2016; IN.PACT Global Clinical cohort includes imaging cohort subjects from Long Lesion, CTO, and ISR cohorts, as well as subjects enrolled outside the three imaging cohorts.
7. Presented by Zeller T, LINC Leipzig, Germany 2017. Moderate to severe calcification reported.
8. M Lichtenberg, CIRSE 2017

***Primary patency definitions(KM estimates shown):** LEVANT PSVR ≤ 2.5 & FF TLR at day 365;IN.PACT PSVR ≤ 2.4 & FF CD-TLR at day 360;ILLUMINATE PSVR < 2.5 & FF CD-TLR



DCB are NOT dangerous

12-Month Key Safety Outcomes

	LEVANT II[1]		Global[2]	IN.PACT SFA[3]	IN.PACT Global Long[4]	IN.PACT Global CTO[5]	IN.PACT Global ISR[6]	IN.PACT Global Clinical[7]	ILLUMINATE FIH	ILLUMINATE EU RCT	ILLUMINATE US Pivotal	ILLUMINATE Global
	PTA	Lutonix 035		PTA	IN.PACT Admiral							
Subjects	160	316	691	111	220	157	126	131	1406	80	328	300	371
All Thrombosis				3.7% (4/107)	1.4% (3/207)	3.7% (5/134)	4.3% (5/115)	0.8% (1/124)	2.9% (38/1311)				
Revasc. due to Thrombosis	0.7% (1/140)	0.4% (1/285)	1.3% (8/634)										
Major Amputation	0.0% (0/140)	0.3% (1/286)	0.5% (3/635)	0.0% (0/107)	0.0% (0/207)	0.0% (0/134)	0.0% (0/115)	0.0% (0/124)	0.2% (3/1311)	0.0%	0.0%	0.0%	0.3%

1. Rosenfield K, et al. NEJM:373:145-53 (2015).
2. Presented by Laurich C, SVS Chicago 2015.
3. Tepe G, et al. Circ 131:495-502 (2015).
4. Presented by Scheinert D, PCR Paris
5. Presented by Tepe G, Charing Cross London 2016.
6. Presented by Brodmann M, VIVA Las Vegas 2015.
7. Presented by Jaff M, VIVA Las Vegas 2016; includes subjects of imaging cohorts

THERE DOESN'T SEEM TO BE ANY IMPACT ON SAFETY