

DCB in BTK: 12-month results of AcoArt BTK Italy study

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Disclosure

- **Speaker name: Francesco Liistro**
- **I have the following potential conflicts of interest to report:**
- **Consulting: Medtronic, Philips, Biotronic, Boston Scientific**
- **Employment in industry**
- **Stockholder of a healthcare company**
- **Owner of a healthcare company**
- **Other(s)**
- **I do not have any potential conflict of interest**

ACOART BTK: Study Design and Key Eligibility Criteria

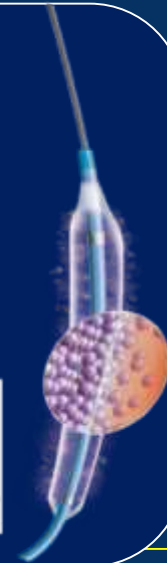
CLI
120 Lesions

• Key Inclusions

Study Device:
Litos DCB (ACOTEC Ltd)



- drug coating with paclitaxel of 3 $\mu\text{g} / \text{mm}^2$, magnesium stearate as excipient
- dual shaft lubrication
- three folded balloon
- balloon sizes with broad matrix
- useable length 40cm or 300cm



6-month
Angiography

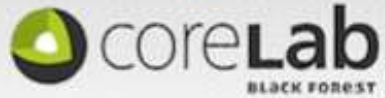
12-month Duplex
Clinical follow-up

- **Primary Endpoint: 6-month Late Loss by independent core lab**
- **Secondary Endpoints: Occlusive 6-month Restenosis; 12-month TLR**

Patients Clinical Characteristics

	LITOS	POBA	P value
Patients Nr	52	53	
Mean age	75.4±8.6	74.80±8.8	0.7
Male gender	39(75)	41(77)	0.4
BMI	23.38±3.46	23.31±3.49	0.92
Diabetes	52(100)	49(93)	0.06
Ever smoked	24(46)	28(53)	0.3
Hypertension	41(81)	46(87)	0.3
Dyslipidemia	27(52)	33(62)	0.2
Creatinine (mg/dL)	1.46±1.54	1.31±1.09	0.5
Hb(gr/dL)	12.04±1.86	12.12±1.59	0.8
WBC(x1000)	7.59±2.60	7.33±2.14	0.5
Number of limb	54	55	0.9
Rutherford class 4	4(7)	4(7)	0.7
5-6	50(93)	51(93)	
Inflow Treatment	15(28)	11(20)	0.2

Lesion Characteristics (corelab data)



	LITOS (62 lesions)	POBA(66 lesions)	P value
ATA	40(64.5)	44(66.7)	0.9
PTA	9(14.5)	9(13.6)	
PA	3(4.8)	5(7.6)	
TPT	4(6.5)	4(6.1)	
TPT-PA	3(4.8)	2(3.0)	
TPT-PTA	3(4.8)	2(3.0)	
De Novo	57(92)	58(88)	
Restenotic	5(8)	8(12)	0.6
CTO	42(68)	44(67)	0.8
Calcification*			
0	6(9.7)	9(13.6)	0.3
1	11(17.7)	9(13.6)	
2	4(6.5)	0(0)	
3	16(25.8)	16(24.2)	
4	22(35.5)	28(42.4)	
na	3(4.8)	4((6.1)	

Lesion and procedural Characteristics (Corelab data)



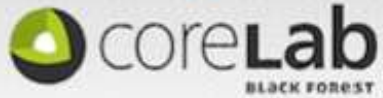
	LITOS DCB (62)	POBA(66)	p
Lesion Length	168.3±109.1	187.9±113.3	0.3
RVD pre	2.68±0.43	2.74±0.19	0.4
MLD pre	0.23±0.38	0.24±0.41	0.8
DS% pre	91.5±13.9	90.9±14.9	0.8
Balloon Diameter	2.94±0.31	2.91±0.29	0.5
Inflation pressure	14.21±1.96	14.24±2.28	0.92
Inflation Time	274.75±71.25	152.23±61.35	<0.001
MLD post	2.04±0.53	1.88±0.33	0.03
%DS post	23.37±17.28	30.01±17.3	0.03
Treatment length	208.7±105	225.4±101.4	0.36

Lesion and procedural Characteristics (Corelab data)



	LITOS DCB (62)	POBA(66)	P value
TVA pre(mm ²)	180.81±57.8	162.9±164.11	0.5
TVA post	491.55±308.49	525.44±330.34	0.5
Dissection	32(51)	35(53)	0.9
A	0(0)	1(1.5)	
B	17(27.4)	21(31.8)	
C	1(1.6)	2(3)	0.3
D	13(21)	11(16.7)	
F	1(1.6)	0(0)	
Dissection resolved	31(96.9)	35(100)	0.5
Outflow post impaired	1(1.6)	0(0)	0.3

Angiographic Outcome at 6 Months



Lesion available

RVD

MLD

DS%

LLL

TVA (mm²)

TVAL(%)

Restenosis >50%

Occlusion

LITOS

58/62(93.3)

3.10±0.62

1.56±0.85

42.9±29.9

0.51±0.60

440.75±308.83

5.87±23.16

22(37.9)

5(8.6)

POBA

62/66(93.9)

2.61±0.52

0.56±0.65

79.7±24.2

1.31±0.72

217.34±.236.34

51.37±36.27

54(87.1)

30(48.4)

p value

0.9

<0.001

<0.001

<0.001

<0.001

<0.001

<0.001

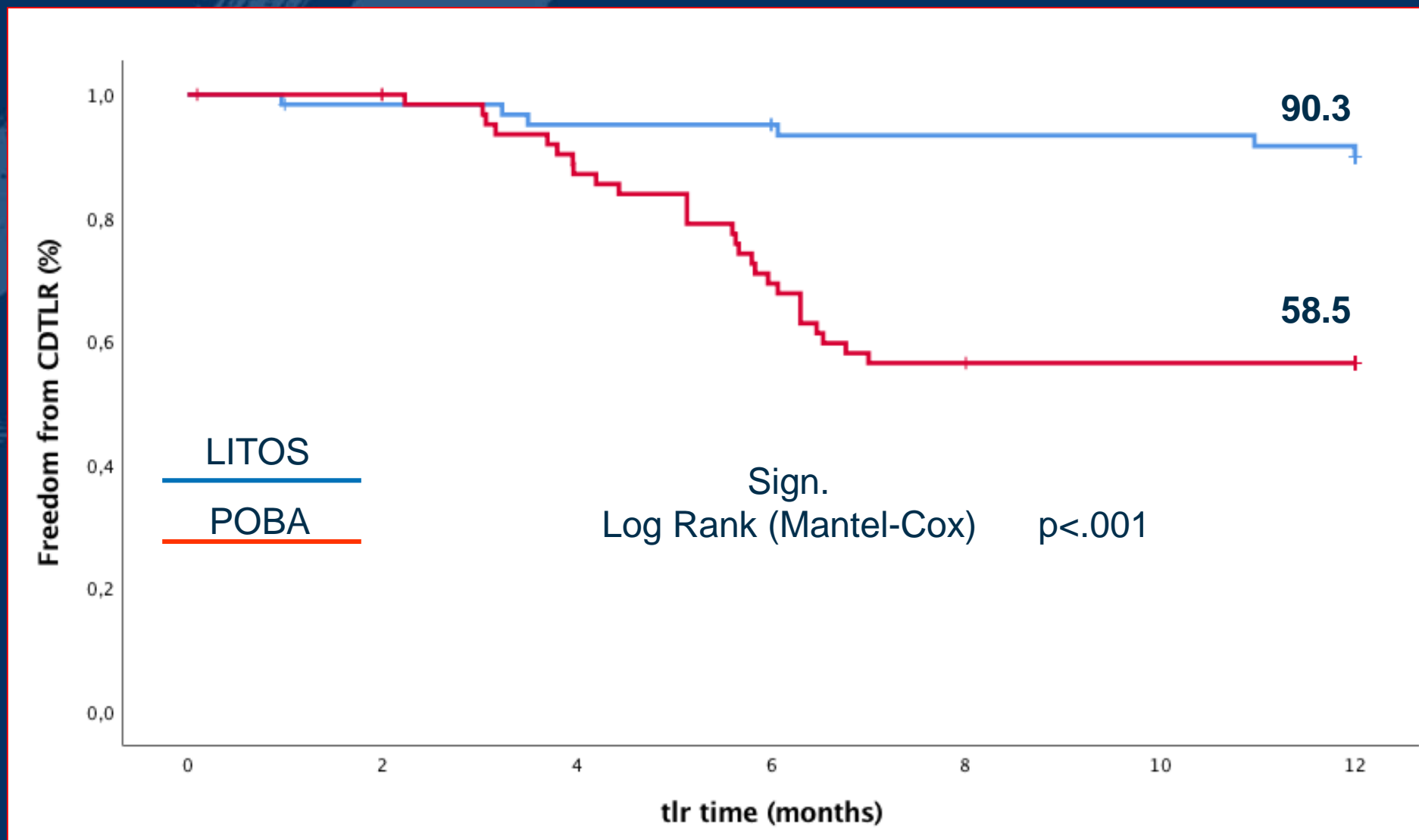
<0.001

<0.001

Clinical Outcome at 12-months

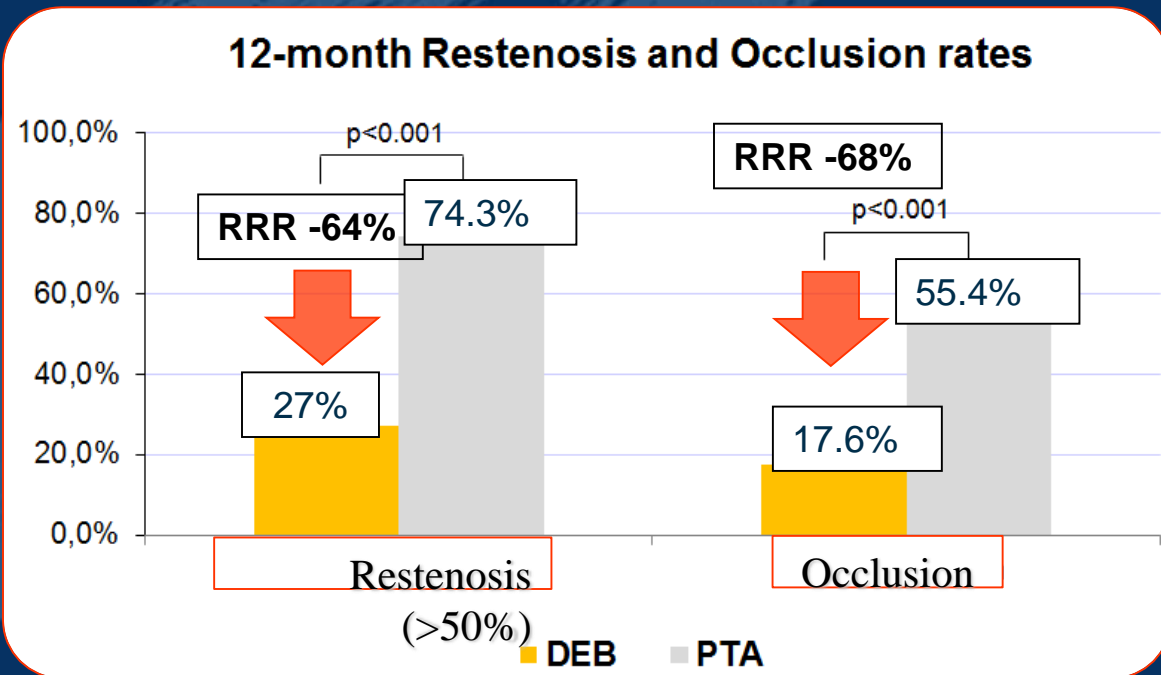
	LITOS	POBA	p value
Death	4(7.7%)	7(13.2%)	0.2
TLR	6/62(10)	27/66(41)	<.001
Major Amputation	0	0	-
Complete Healing at 12 months	42/47(89.4)	35/47(74.5)	0.05

Freedom from CDTLR at 12 months

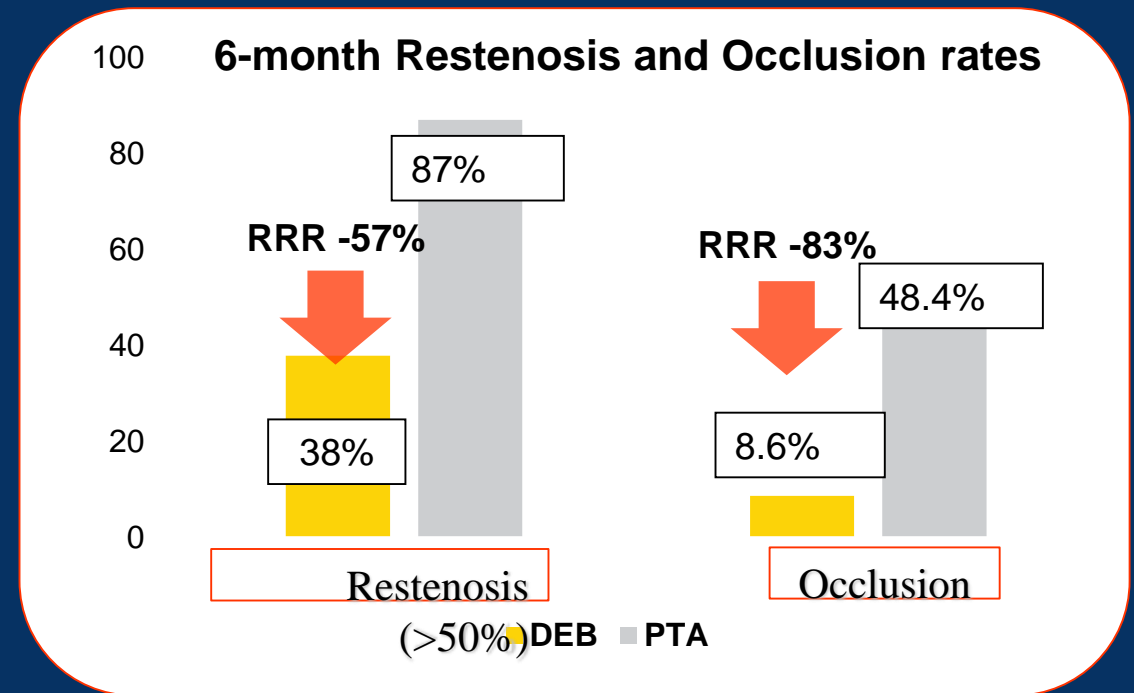


REPETITA IUVANT

DEBATE BTK



ACOART BTK



Nr eligible Lesions **74 (92.5%)** 74 (94.9%)

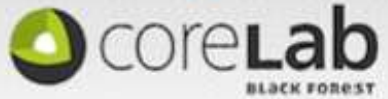
Lesion Assessment: ANGIO **67 (90.5%)** 68 (91.9%)

Lesion assessed

58/62(93.3)

62/66(93.9)

Angiographic outcome in baseline Occlusion

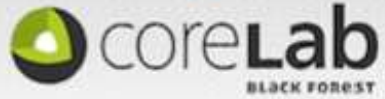


	LITOS	POBA	P value
Baseline occlusion	42(62)	44(66)	
Treated length	238.06±103.38	255.47±95.88	0.42
LLL (mm)	0.54±0.62	1.48±0.60	<0.001
TVA 6-month (mm ²)	512.25±333.59	212.27±247.12	<0.001
TVAL(%)	6.44±26.20	64.31±32.68	<0.001
Reocclusion	4(9.5)	28(63.6)	<0.001
Restenosis (>50%)	17(40.5)	38(86.4)	<0.001

Reocclusion Δ 54%

RRR 85%

Angiographic outcome in baseline Stenosis



	LITOS	POBA	P value
Baseline stenosis	20(38)	22(34)	
Treated length	147.16±80.53	157.64±80.03	0.6
LLL (mm)	0.45±0.57	0.98±0.83	0.02
TVA 6-month (mm ²)	304.89±199.43	227.23±219.25	0.24
TVAL(%)	4.80±16.45	26.73±29.85	0.006
Occlusion	1(5)	2(9)	0.53
Restenosis (>50%)	5(25)	16(72)	0.002

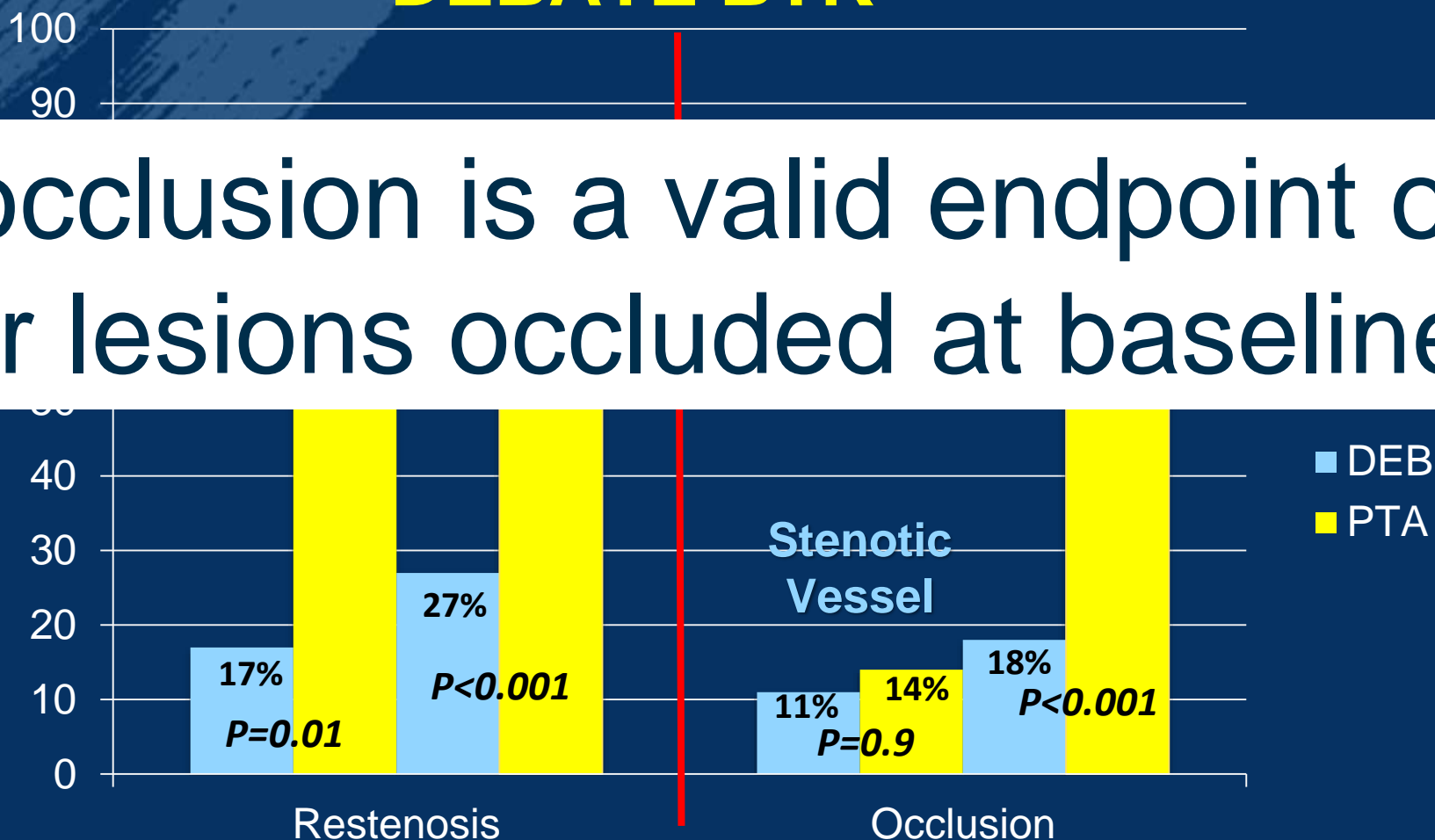
Restenosis Δ 47%

RRR 65%

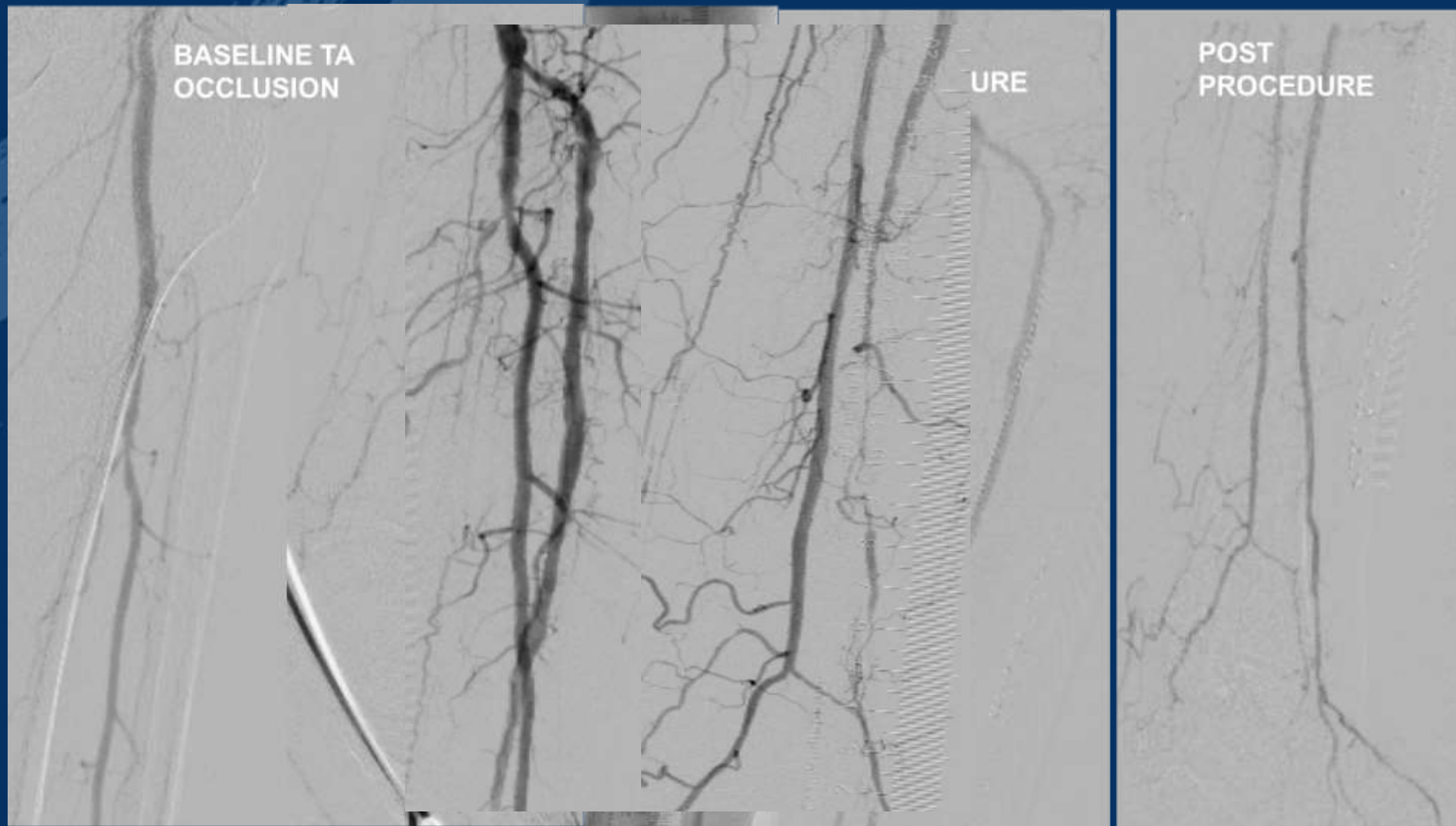
Restenosis / Occlusion in occluded and stenotic vessels

DEBATE BTK

Reocclusion is a valid endpoint only
for lesions occluded at baseline!



Restenosis pattern in CTO treated with DCB

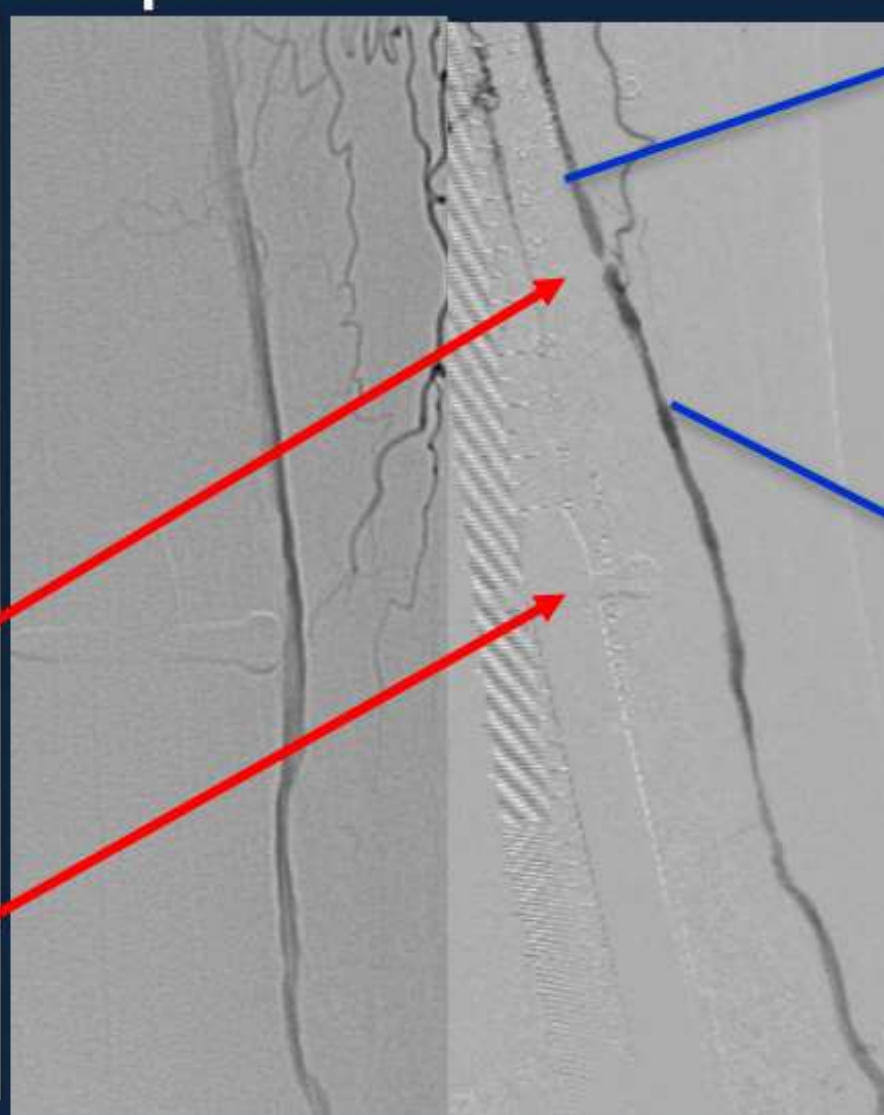
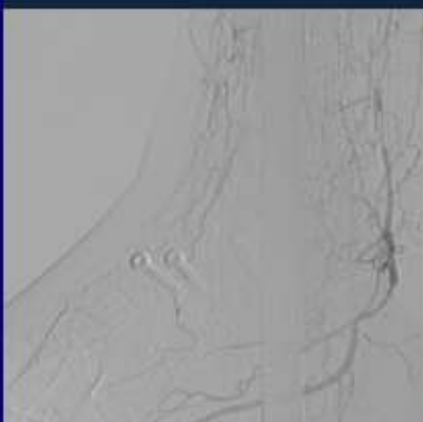
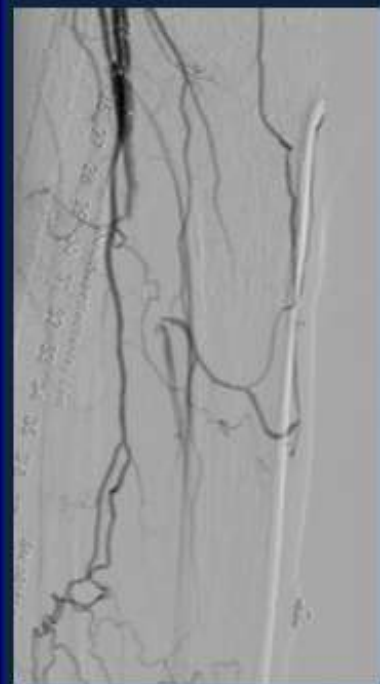


DCB undersized

**DEB
shrunk**

Post procedure

6 months



No touch → No effect!

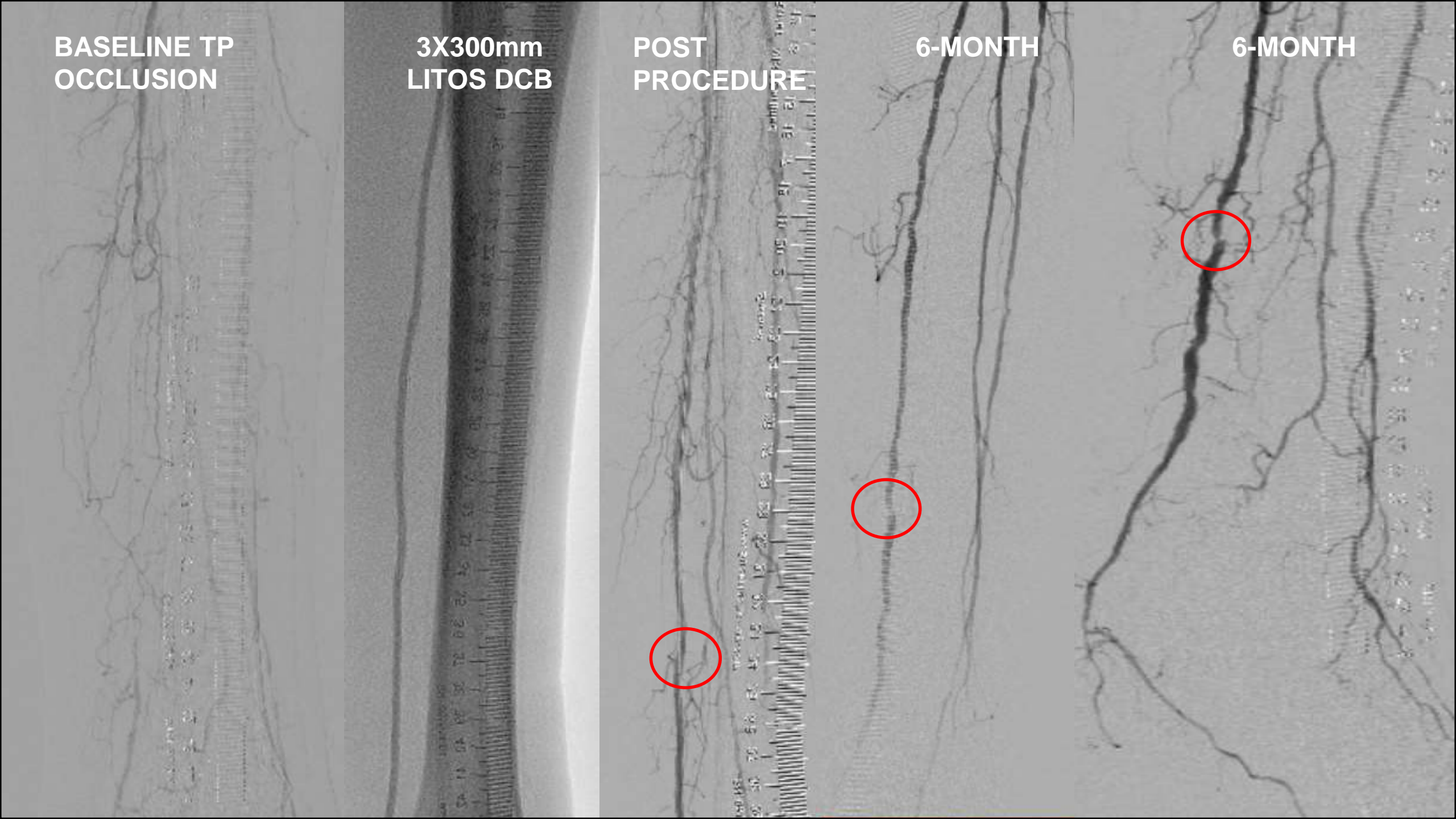
**BASELINE TP
OCCLUSION**

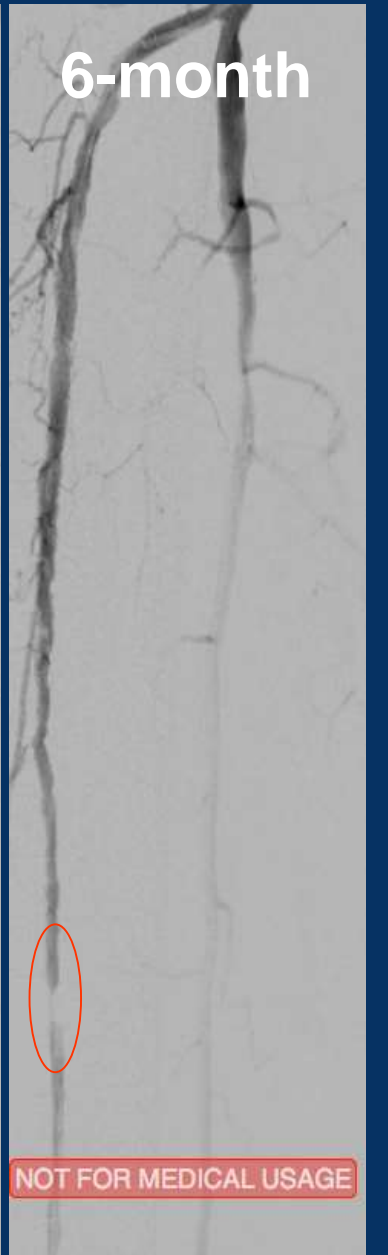
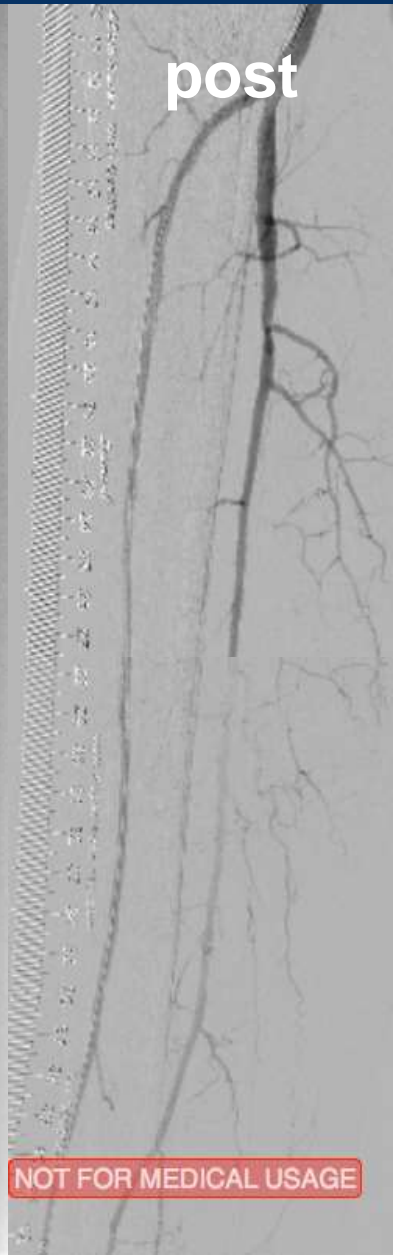
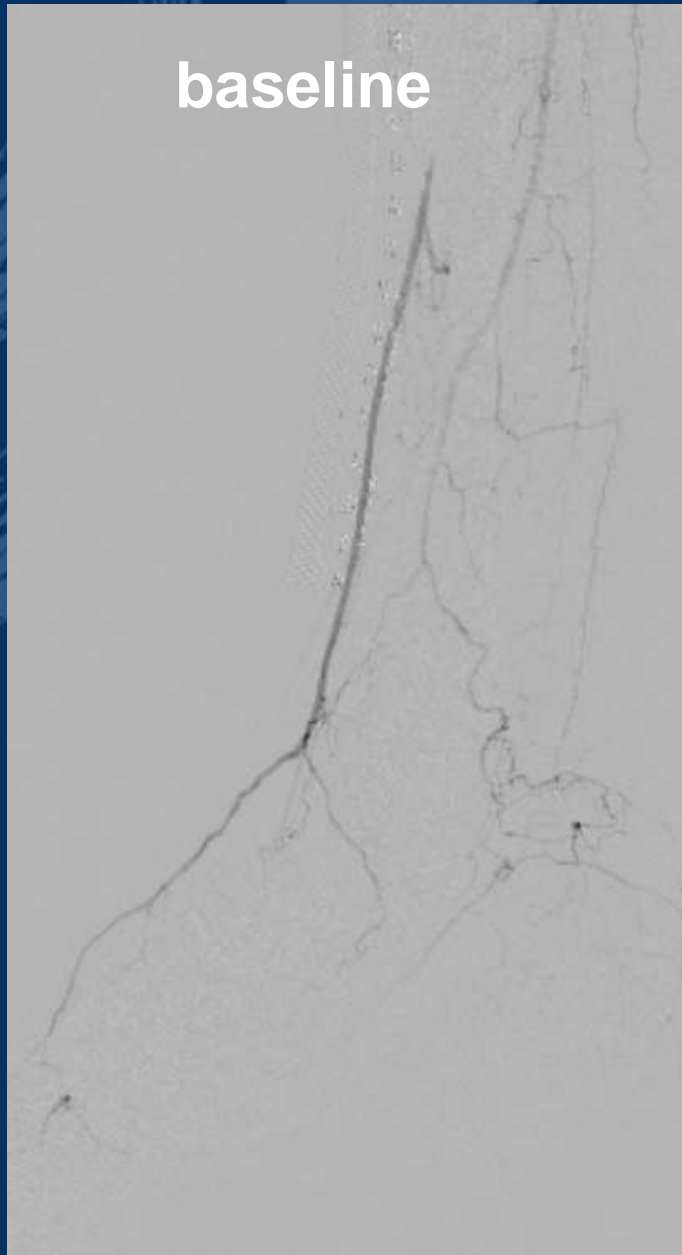
**3X300mm
LITOS DCB**

**POST
PROCEDURE**

6-MONTH

6-MONTH





NOT FOR MEDICAL USAGE

NOT FOR MEDICAL USAGE

NOT FOR MEDICAL USAGE

Conclusion

- **Litos DCB shows efficacy and safety in the treatment of complex BTK lesions in CLI patients at 12 months**
- **Similar results with the same DCB is reported in Multicenter randomized Trial (ACOART II)**
- **The strongest message for clinicians is the drastic reduction of reocclusion showed by DCB in baseline occluded vessels**
- **Restenosis in DCB is often focal compared to POBA**
- **Future studies should include only occluded vessels at baseline (es. Inpact BTK) and the primary endpoint can be vessel reocclusion by Duplex Ultrasound**

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