

The logo for LING (Limb Ischemia Network Group) features the word "LING" in white capital letters. The letters are positioned over a stylized graphic of three curved, overlapping brushstrokes in dark blue, red, and yellow. The background of the slide is light blue with large, faint, light blue brushstrokes.

LING

Role of vessel prep in Critical Limb Ischemia

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Conflict of Interest - Disclosure

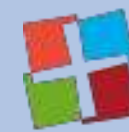
Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship

Company

1. Honoraria for lectures: CR Bard, Boston Scientific AB Medica, Volcano, Optimed GmbH, Straub Medical, Terumo, Biotronik, Veryan
2. Honoraria for advisory board activities: Veniti, Optimed GmbH, Straub Medical, Biotronik, Veryan, Boston Scientific, Philips
3. Participation in clinical trials: Biotronik, CR Bard, Veryan, Straub Medical, Veniti, Boston Scientific, LimFlow, Terumo, Philips, Optimed, IPmedical
4. Research funding: Biotronik, Boston Scientific, Veryan, Veniti, AB Medica, Philips, CR Bard, Optimed

Different world BTK



SFA: Debulking with directional atherectomy (DA) has resulted in lumen gain and improved patency. Early results from the DEFINITIVE AR study with combination therapy suggest trends favoring DA and DCB treatment over DCB alone in calcified lesions

Anti-restenotic therapy with drug-coated balloons (DCB) have shown superior patency and lower re-intervention rates versus PTA also for BTK interventions

Technical challenges:

- Calcium burden:
- Dissection:
- Lumen gain:



How to improve vessel compliance?
Probably underestimated BTK? How to decrease?
How to achieve enough/stable lumen?



Questions and challenges for the interventionalist

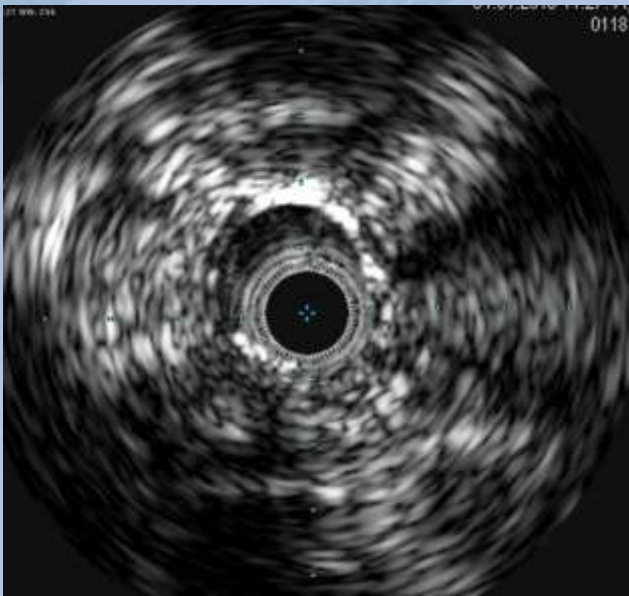
- What is the optimal diagnostic modality to analyse target vessel?
- Which is the optimal recanalization modality?
- How to maintain lumen?

Hypothesis

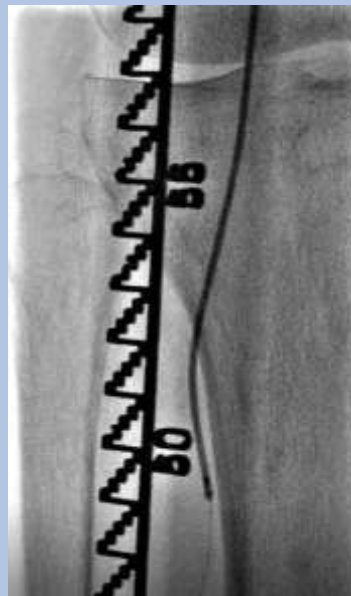
IVUS guided atherectomy plus DCB angioplasty for BTK lesions in patients with CLI may lead to effective lumen gain with less dissection (technical hypothesis) and improved clinical outcome (clinical hypothesis)

PRESTIGE Pilot – Phoenix Atherectomy and Stellarex DCB clinical investigation in infrapopliteal interventions

Lesion preparation strategy with **Phoenix**
atherectomy before DCB **IVUS** guided



+



+

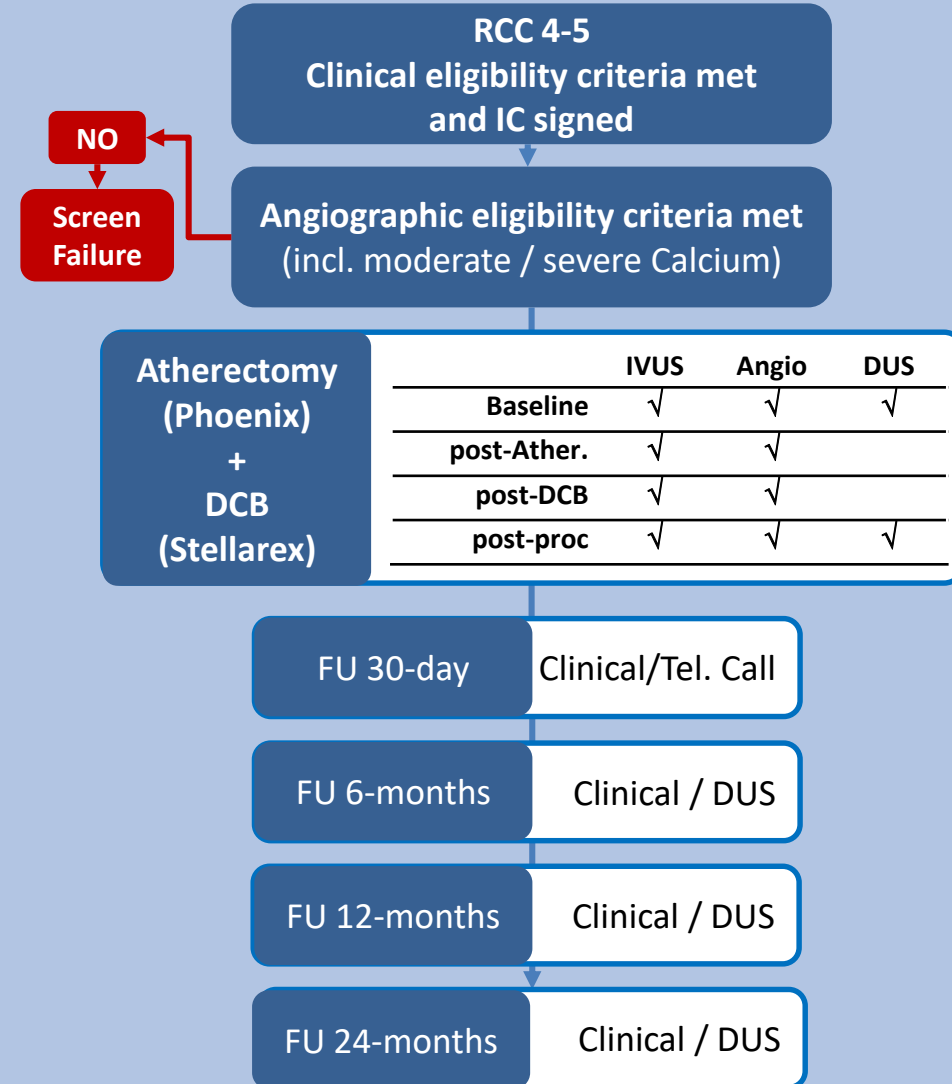


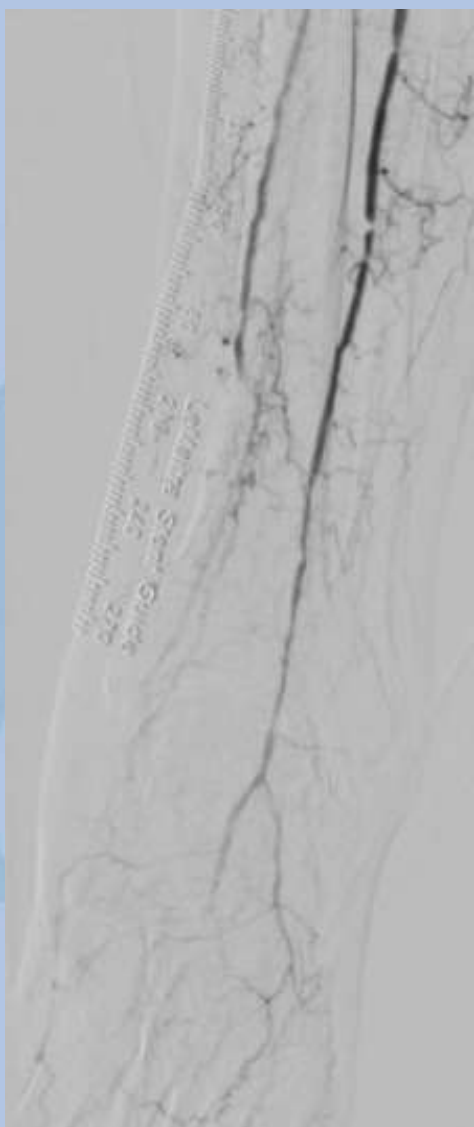
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Phoenix Atherectomy and Stellarex DCB clinical investigation in infrapopliteal interventions

ClinicalTrials.gov Identifier: NCT03744572, PI M.Lichtenberg

- Prospective, single-arm, multi-center
- N=75
- **Objective:** assess safety and efficacy of an IVUS-guided lesion preparation strategy with Phoenix atherectomy before DCB in CLI patients with BTK disease and moderate/severe calcium
- **Primary Endpoints:**
 - **Efficacy:** Patency at 6 months (freedom from TLR and TL occlusion by DUS)
 - **Safety:** freedom from MALE and/or 30-day perioperative death
- **Angio, IVUS, DUS Core-lab adjudication**

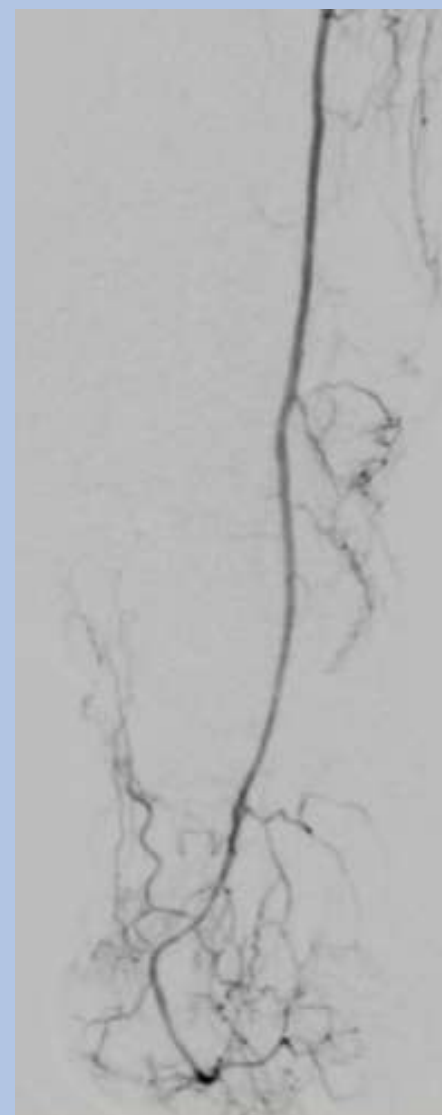
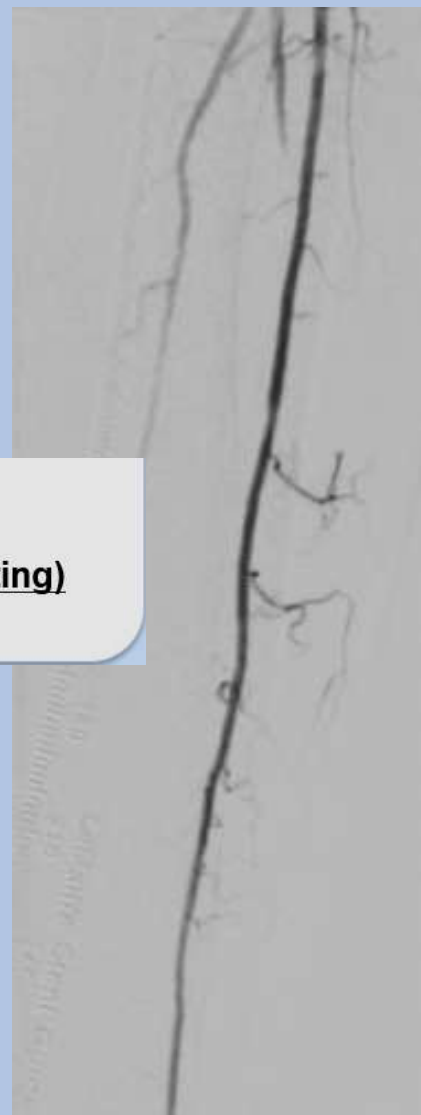




Phoenix 1.8mm (5F non-deflecting)

Minimum vessel diameter 2.5mm

130 and 149cm lengths



Core Lab Adjudication



	Baseline	Post-Phoenix atherectomy	Post-DCB Procedure	6mo	12mo	24mo
Angio	X	X	X			
IVUS	X	X	X			
DUS	X (prior to discharge)			X	X	X

Demographics

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Variables	Statistics (N=35)
Age in years	
n	35
Mean (SD)	<u>80.43 (9.13)</u>
Min–Max	55.0 – 95.0
Median (IQR)	82.0 (77.0 – 86.0)
Gender	
Female	8 (22.9)
Male	27 (77.1)

Variables	Statistics (N=35)
BMI (kg/m²)	
n	33
Missing (%)	2 (5.7)
Mean (SD)	<u>26.81 (4.74)</u>
Min–Max	19.5 – 38.6
Median (IQR)	25.9 (23.2 – 29.8)

Variables	Statistics (N=35)
Renal Disease	
No	19 (54.3)
Yes	<u>16 (45.7)</u>
Hypertension	
No	1 (2.9)
Yes	34 (97.1)
Hyperlipidemia	
No	5 (14.3)
Yes	30 (85.7)
Diabetes Mellitus	
No	15 (42.9)
Yes	<u>20 (57.1)</u>
Type Diabetes Mellitus	
Missing (%)	15 (42.9)
Type I	1 (2.9)
Type II	19 (54.3)

Variables	Statistics (N=35)
Smoking Status	
Current	4 (11.4)
Never	14 (40.0)
Stopped	17 (48.6)
History of Cardiac Diseases	
No	15 (42.9)
Unknown	1 (2.9)
Yes	<u>19 (54.3)</u>
Myocardial Infarction	
Missing (%)	1 (2.9)
No	28 (80.0)
Yes	6 (17.1)
Angina Pectoris	
Missing (%)	1 (2.9)
No	33 (94.3)
Yes	1 (2.9)

**Renal insufficiency
(GFR < 40 ml/min): 46% (16/35)**

Clinical symptoms

Variables	Statistics (N=35)
Rutherford Classification Target Limb	
4	12 (34.3)
5	<u>23 (65.7)</u>
Pain in the Legs*	
Missing (%)	1 (2.9)
0	2 (5.9)
2	2 (5.9)
3	8 (23.5)
4	5 (14.7)
5	7 (20.6)
6	2 (5.9)
7	4 (11.8)
8	3 (8.8)
9	1 (2.9)
Pain in the Legs* (continuous)	
n	34
Missing (%)	1 (2.9)
Mean (SD)	<u>4.59 (2.20)</u>
Min–Max	0.0 – 9.0
Median (IQR)	4.5 (3.0 – 6.0)

WIFI Classification (continuous)	
n	33
Missing (%)	2 (5.7)
Mean (SD)	<u>2.94 (1.48)</u>
Min–Max	0.0 – 6.0
Median (IQR)	3.0 (2.0 – 4.0)

Wound Grade	
Missing (%)	1 (2.9)
0	11 (32.4)
1	22 (64.7)
2	1 (2.9)

Ischemia Grade (continuous)	
n	34
Missing (%)	1 (2.9)
Mean (SD)	1.68 (0.98)
Min–Max	0.0 – 3.0
Median (IQR)	2.0 (1.0 – 2.0)

Foot Infection Grade (continuous)	
n	35
Mean (SD)	0.63 (0.65)
Min–Max	0.0 – 2.0
Median (IQR)	1.0 (0.0 – 1.0)



Target Lesion Location / length / RVD



TL Location	N = 71
Popliteal Segment III	4
TP Trunk	15
Anterior Tibial Artery	26
Peroneal Artery	19
Posterior Tibial Artery	7
TL Calcification	
Mild	27.8%
Moderate	36.1%
Severe	36.1%
Lesion length	
10 - < 20 cm	2.8%
> 20 cm	97.2%

Variables	Statistics (N=36)
Lesion Length (mm)	
n	36
Mean (SD)	137.78 (84.65)
Min-Max	20.0 – 300.0
Median (IQR)	120.0 (65.0 – 200.0)
Reference Vessel Diameter based on angio (mm)	
n	36
Mean (SD)	2.99 (0.40)
Min-Max	2.0 – 4.0
Median (IQR)	3.0 (3.0 – 3.0)
Reference Vessel Diameter based on IVUS (mm)	
n	32
Missing (%)	4 (11.1)
Mean (SD)	4.07 (0.70)
Min-Max	3.1 – 5.9
Median (IQR)	4.1 (3.6 – 4.5)



1.08 mm

Procedure details

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IVUS analysis performed pre atherectomy

Missing (%)	3 (8.3)
No	8 (22.2)
Yes	25 (69.4)

IVUS analysis performed post atherectomy

Missing (%)	3 (8.3)
No	1 (2.8)
Yes	32 (88.9)

IVUS analysis performed post DCB PTA

Missing (%)	3 (8.3)
No	2 (5.6)
Yes	31 (86.1)

IVUS analysis performed post adjunctive therapy

Missing (%)	27 (75.0)
No	9 (25.0)

Phoenix Device Used

P18130K (1.8mm)	17 (47.2)
P18149K (1.8mm)	19 (52.8)

Any Target Vessel Dissection Post Phoenix

No	33 (91.7)
Yes	3 (8.3)

Number of Stellarex DCB Balloons used

1	21 (58.3%)
2	14 (38.9%)
3	1 (2.8%)

Total DCB Treatment Length (mm)

Mean (SD)	151.60 (78.94)
Min–Max	20-300

Technical success analysis – lumen gain



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Pre-procedure diameter stenosis

n	36
Mean (SD)	<u>93.81 (5.62)</u>
Min–Max	80.0 – 100.0
Median (IQR)	92.5 (90.0 – 99.5)



Post atherectomy diameter stenosis

n	34
Missing (%)	2 (5.6)
Mean (SD)	<u>46.78 (13.16)</u>
Min–Max	19.5 – 78.9
Median (IQR)	46.7 (39.1 – 55.5)



Post atherectomy + DCB diameter stenosis

n	33
Missing (%)	3 (8.3)
Mean (SD)	<u>26.92 (13.14)</u>
Min–Max	12.6 – 91.9
Median (IQR)	24.8 (21.7 – 26.9)

93.81%

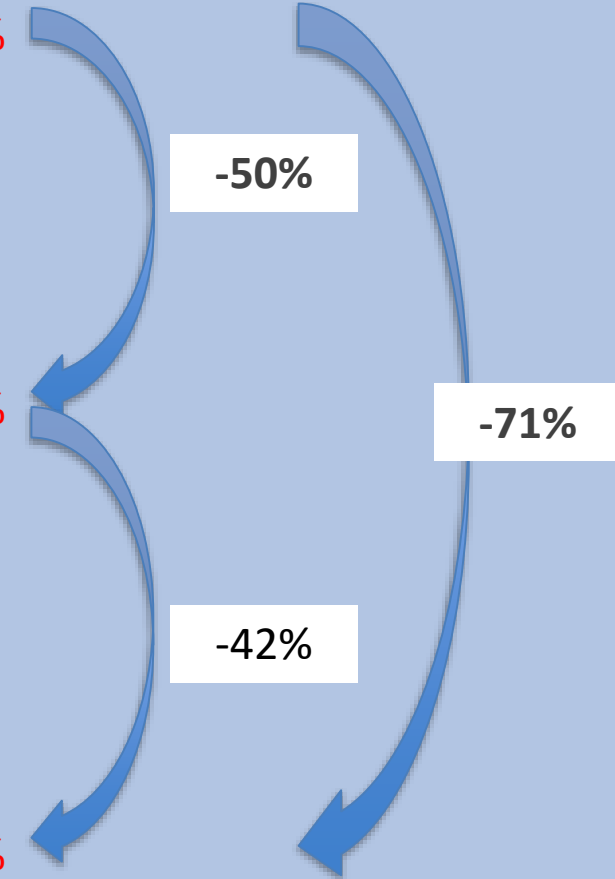
46.78%

26.92%

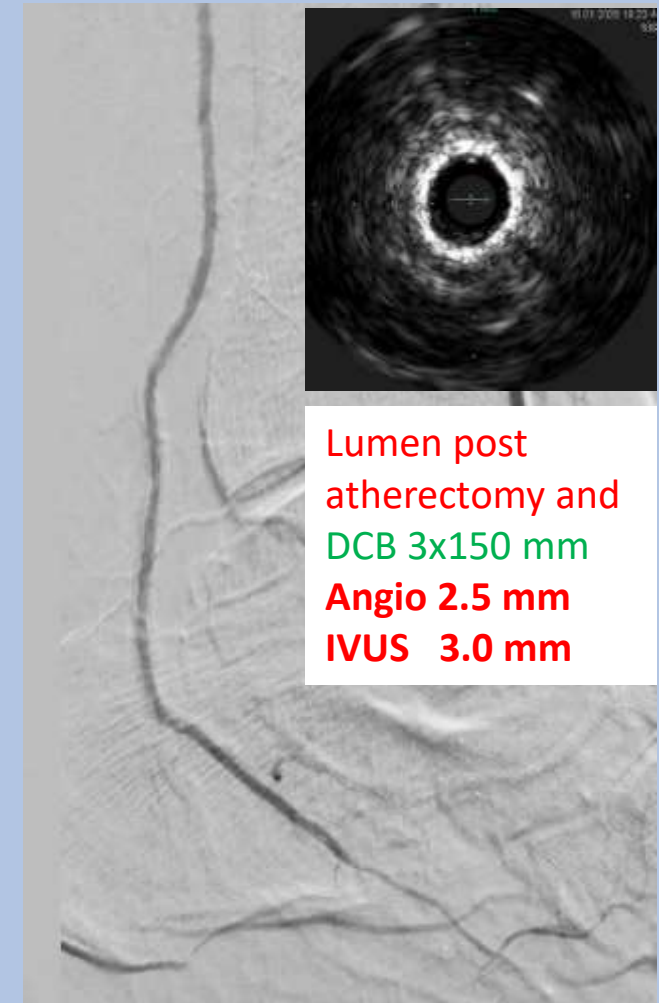
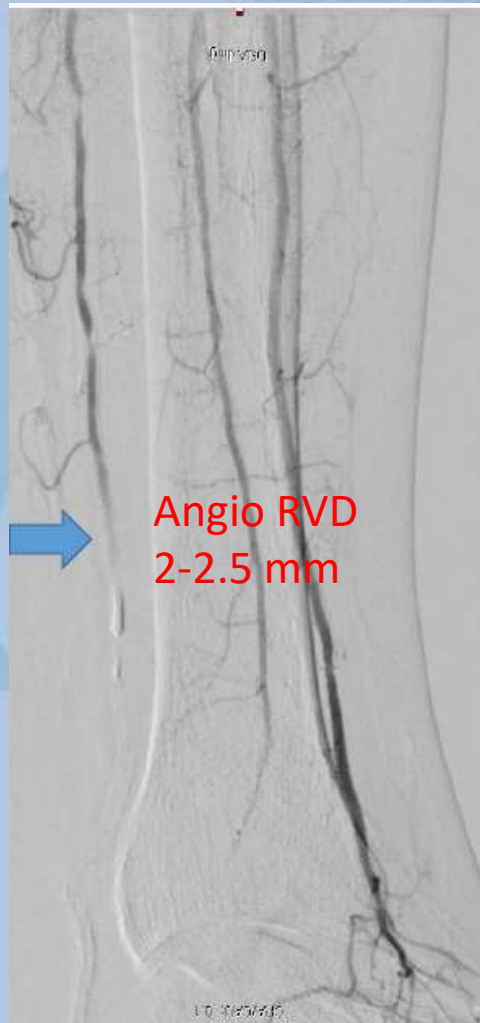
-50%

-42%

-71%



Case example (Prof. Korosoglou, Weinheim)



Technical safety analysis

Adjunctive therapy (post balloon)	8 (28.6)
Any dissection post atherectomy and DCB	7 (19.4%)

Dissection after BTK PTA

DEBELLUM

15.0% PTA

30.7% DCB

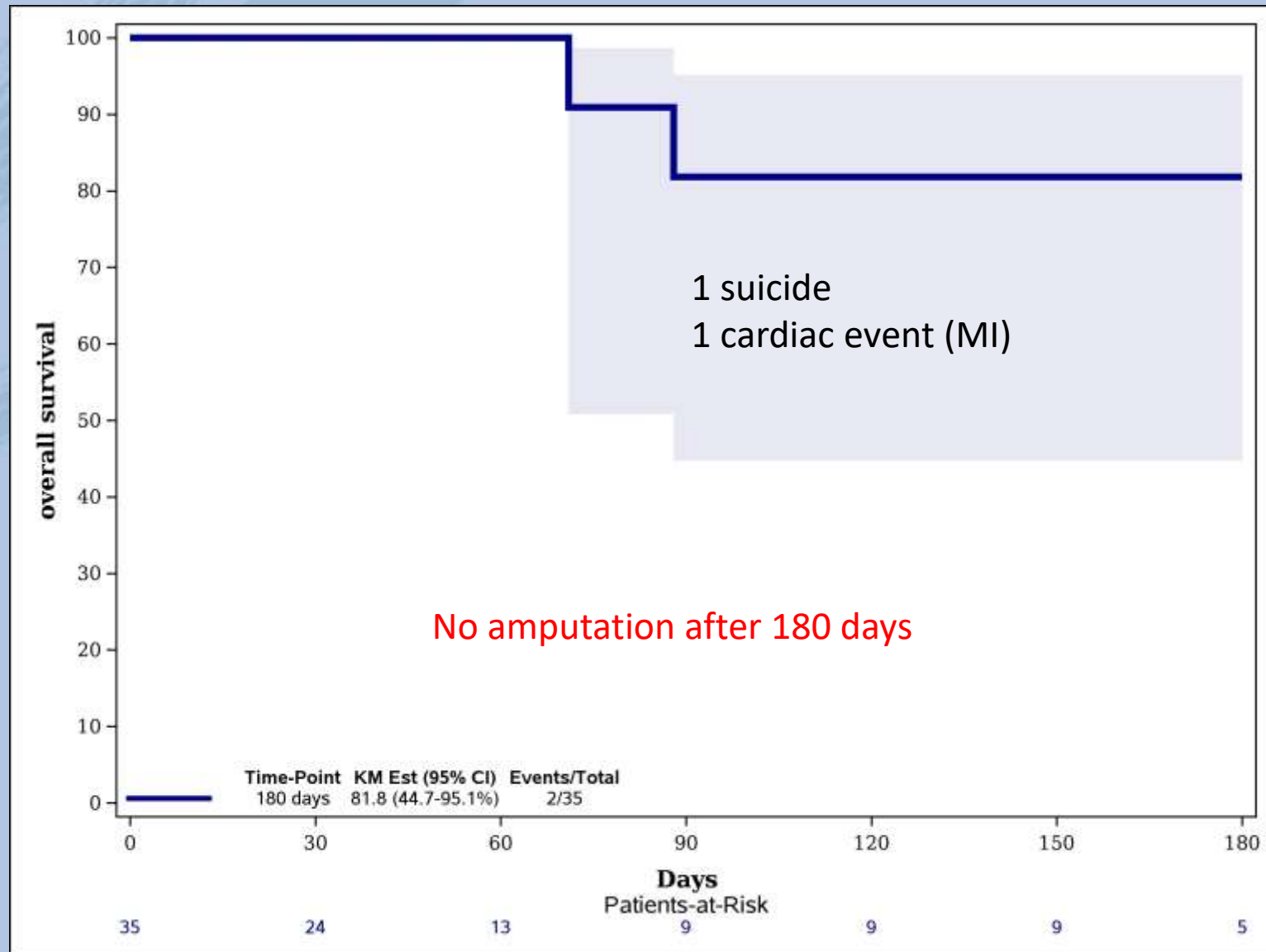
IN.PACT™ DEEP

12.3% PTA

19.2% DCB

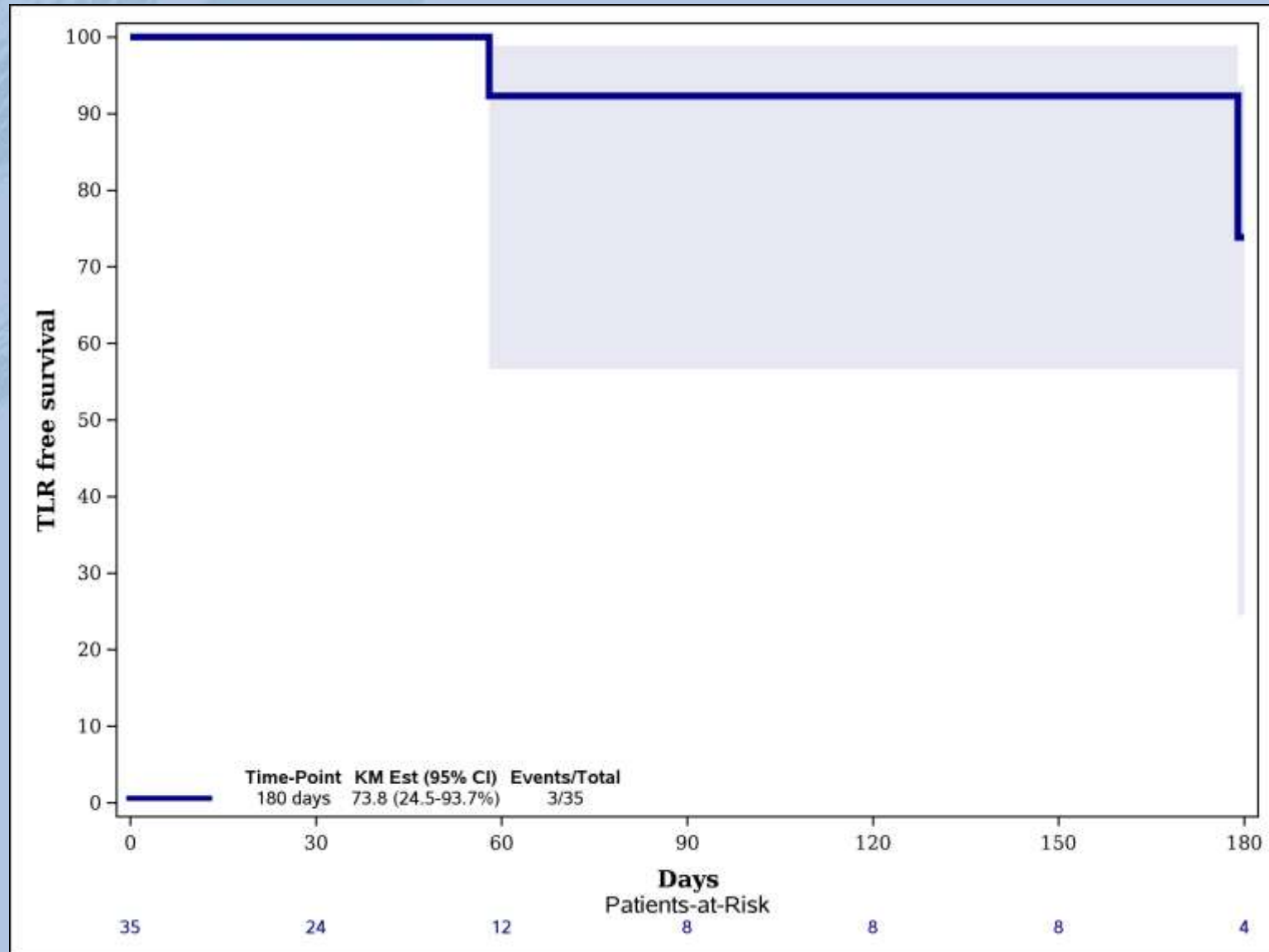
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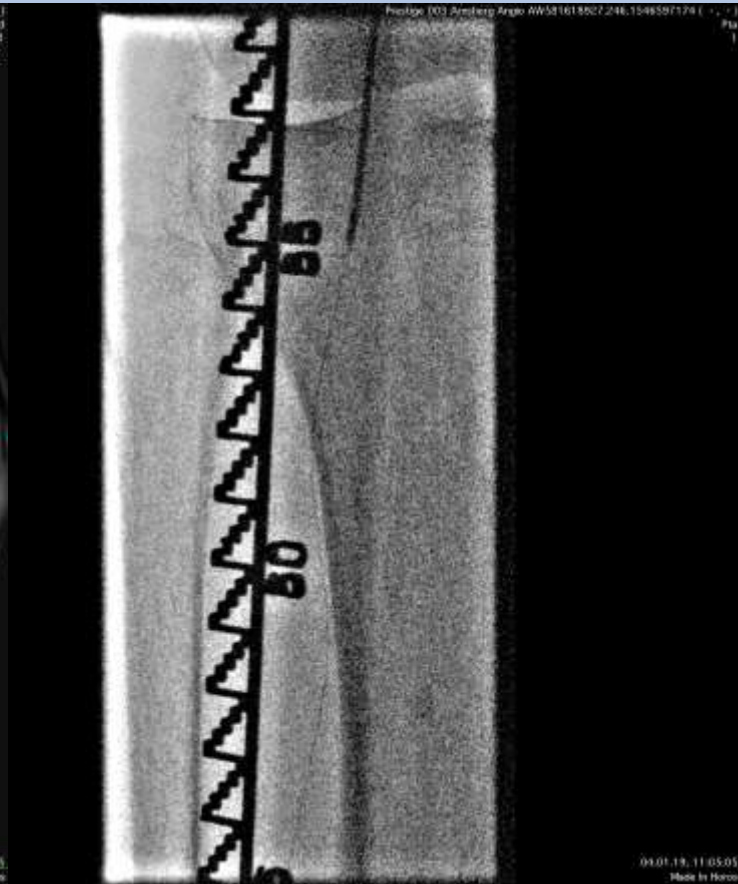
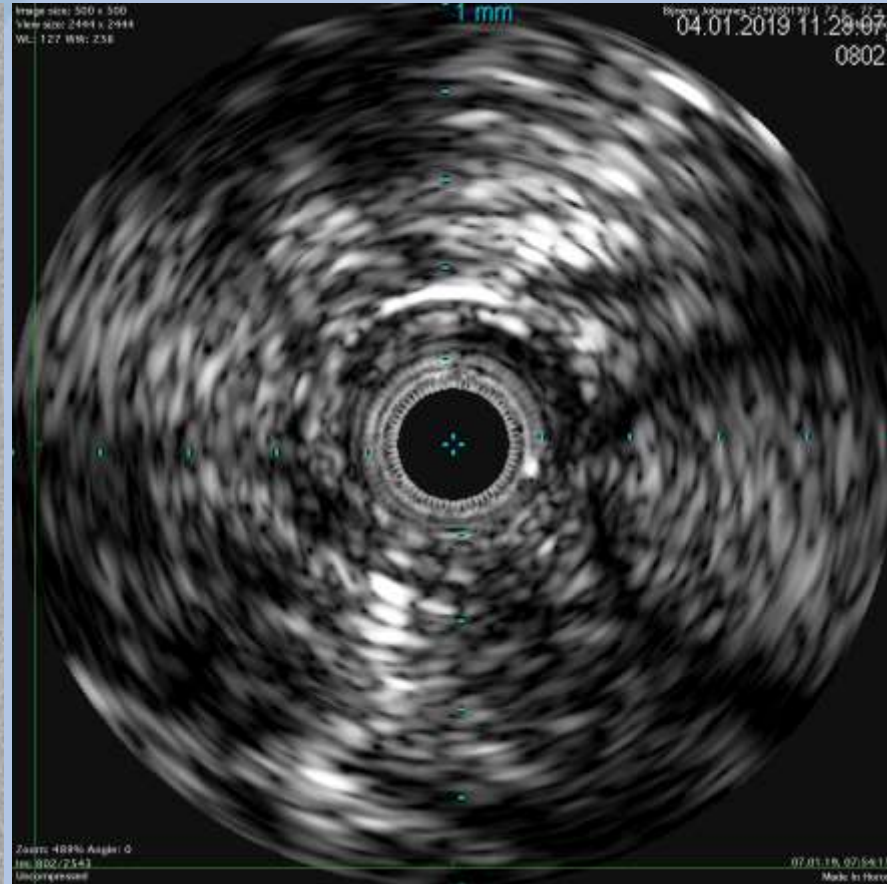


Preliminary efficacy analysis

Variables	Screening (N=35)	Discharge (N=32)	30-Day Follow-up (N=22)	6-Month Follow-up (N=8)
Wifi Classification	2.94		1.29	0.88
Mean (SD)	2.94 (1.48)		1.29 (0.95)	0.88 (0.83)
Min–Max	0.0 – 6.0		0.0 – 3.0	0.0 – 2.0
Median (IQR)	3.0 (2.0 – 4.0)		1.0 (1.0 – 2.0)	1.0 (0.0 – 1.5)
Pain Scale	4.59		2.89	1.63
Mean (SD)	4.59 (2.20)		2.89 (2.20)	1.63 (1.19)
Min–Max	0.0 – 9.0		0.0 – 7.0	0.0 – 3.0
Median (IQR)	4.5 (3.0 – 6.0)		3.0 (1.0 – 4.0)	2.0 (0.5 – 2.5)
Rutherford Scale	IV (12/34.3%) V (13/65.7%)			I (3/37.5%) II (3/37.5%) V (2/25.0%)

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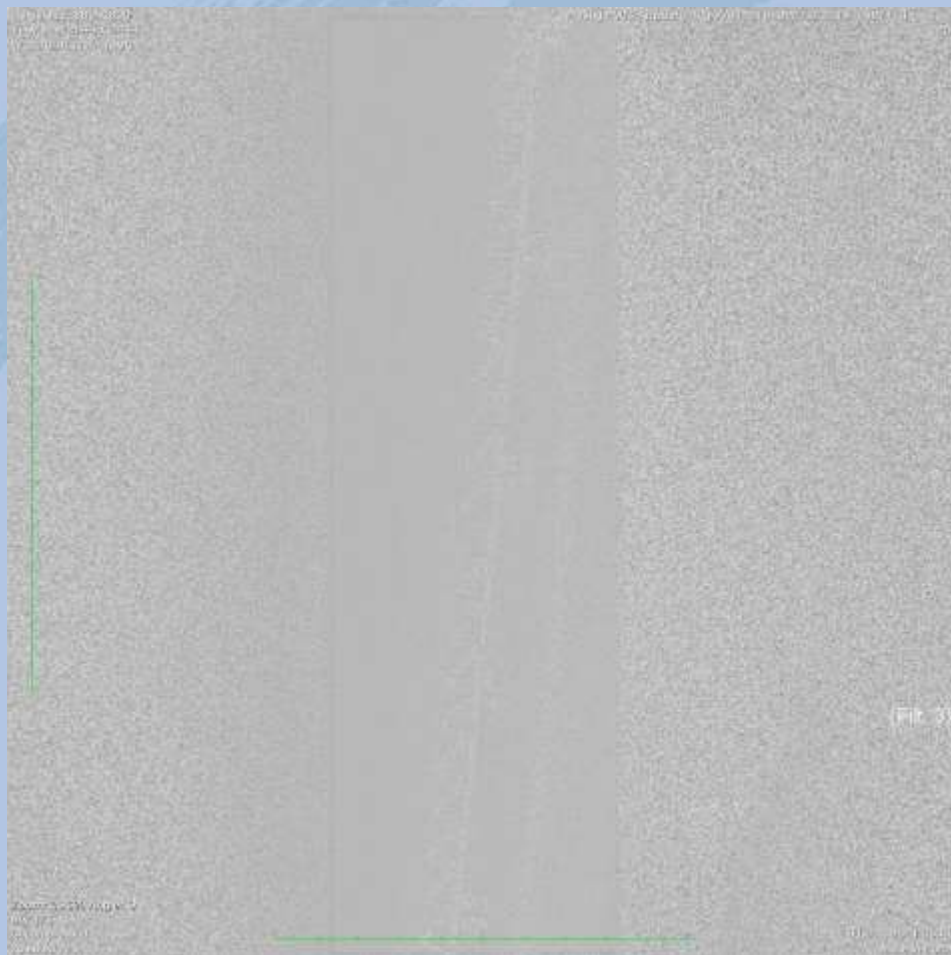


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**PRESTIGE Pilot – Phoenix Atherectomy and
Stellarex DCB clinical investigation
in **infrapopliteal interventions**
PI Prof. T. Zeller and Dr. M. Lichtenberg**



Conclusion

For BTK interventions, there is a need to find...

- appropriate diagnostic modality (IVUS vs Angio)
- optimal revascularisation strategy based on diagnostic modality to achieve optimal lumen gain and to maintain lumen patency until wound healing

Preliminary safety and efficacy data are promising in terms of safety and efficacy for a debulking plus DCB strategy in CLI patients with BTK vessel lesions

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