

Prestige Pilot Study: IVUS guided Phoenix atherectomy and Stellarex DCB angioplasty in BTK interventions

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On behalf of the Prestige Study Investigators



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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, Veniti, 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
3. Participation in clinical trials: Biotronik, CR Bard, Veryan, Straub Medical, Veniti, TVA Medical, Boston Scientific, LimFlow, Terumo
4. Research funding: Biotronik, Boston Scientific, Veryan, Veniti, AB Medica

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?

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)

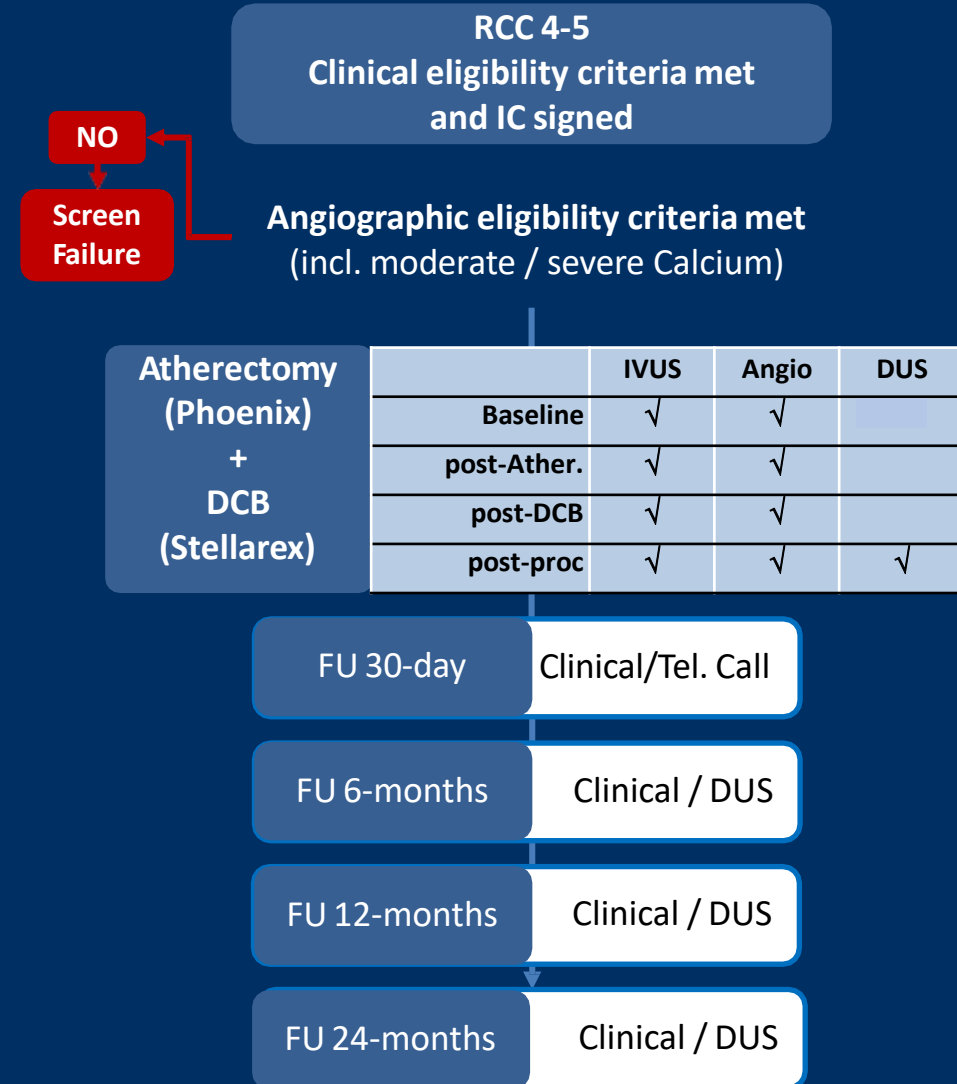


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Phoenix Atherectomy and Stellarex DCB clinical investigation in infrapopliteal interventions

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**

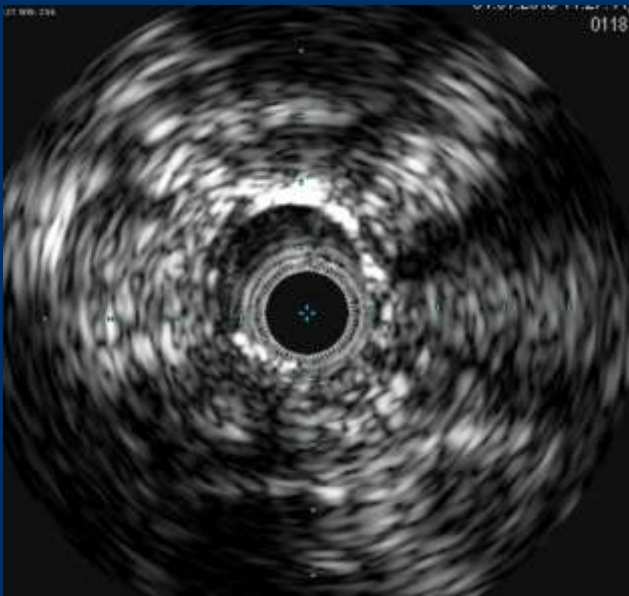


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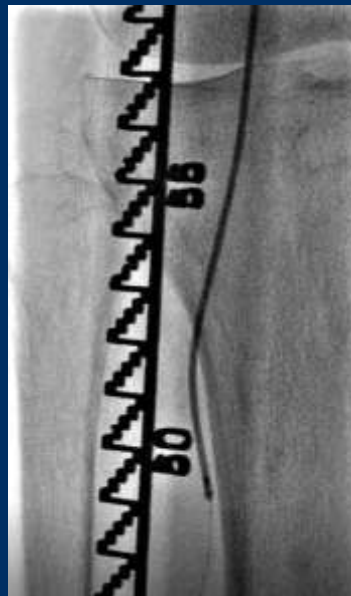
in infrapopliteal interventions

PI M. Lichtenberg and T. Zeller

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



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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=50)
Age in years	
n	50
Mean (SD)	79.90 (8.77)
Min–Max	<u>55.0 – 95.0</u>
Median (IQR)	81.5 (76.0 – 86.0)
Gender	
Female	9 (18.0)
Male	41 (82.0)

Variables	Statistics (N=50)
BMI (kg/m²)	
n	47
Missing (%)	3 (6.0)
Mean (SD)	<u>26.88 (4.70)</u>
Min–Max	19.5 – 39.6
Median (IQR)	25.6 (23.5 – 29.5)

Variables	Statistics (N=50)
Renal Disease	
No	30 (60.0)
Yes	<u>20 (40.0)</u>
Hypertension	
No	4 (8.0)
Yes	46 (92.0)
Hyperlipidemia	
No	8 (16.0)
Yes	42 (84.0)
Diabetes Mellitus	
No	22 (44.0)
Yes	28 (56.0)
Type Diabetes Mellitus	
Missing (%)	22 (44.0)
Type I	1 (2.0)
Type II	27 (54.0)

Variables	Statistics (N=50)
Insulin Dependent	
Missing (%)	22 (44.0)
No	9 (18.0)
Yes	<u>19 (38.0)</u>
Smoking Status	
Missing (%)	3 (6.0)
Current	4 (8.0)
Never	19 (38.0)
Stopped	24 (48.0)
History of Cardiac Diseases	
No	21 (42.0)
Unknown	1 (2.0)
Yes	28 (56.0)
Myocardial Infarction	
Missing (%)	1 (2.0)
No	41 (82.0)
Yes	8 (16.0)
Angina Pectoris	
Missing (%)	1 (2.0)
No	48 (96.0)
Yes	1 (2.0)

**Renal insufficiency
(GFR < 40 ml/min): 40% (20/50)**

Clinical symptoms

Variables	Statistics (N=50)
Rutherford Classification Target	
Limb	
4	15 (30.0)
5	<u>35 (70.0)</u>
Pain in the Legs*	
Missing (%)	1 (2.0)
0	3 (6.0)
2	2 (4.0)
3	12 (24.0)
4	6 (12.0)
5	8 (16.0)
6	6 (12.0)
7	6 (12.0)
8	5 (10.0)
9	1 (2.0)
Pain in the Legs* (continuous)	
n	49
Missing (%)	1 (2.0)
Mean (SD)	<u>4.71 (2.21)</u>
Min–Max	0.0 – 9.0
Median (IQR)	5.0 (3.0 – 6.0)

Variables	Statistics (N=50)
WIFI Classification	
Missing (%)	10 (20.0)
0	1 (2.0)
1	4 (8.0)
2	9 (18.0)
3	5 (10.0)
4	15 (30.0)
5	4 (8.0)
6	1 (2.0)
7	1 (2.0)
WIFI Classification (continuous)	
n	40
Missing (%)	10 (20.0)
Mean (SD)	<u>3.25 (1.50)</u>
Min–Max	0.0 – 7.0
Median (IQR)	4.0 (2.0 – 4.0)
Wound Grade	
0 - No Wound	11 (22.0)
1 - Minor tissue loss (<2 toe amps)	35 (70.0)
2 - Major tissue loss (>=3 to amps)	4 (8.0)



Target Lesion Location / length / RVD

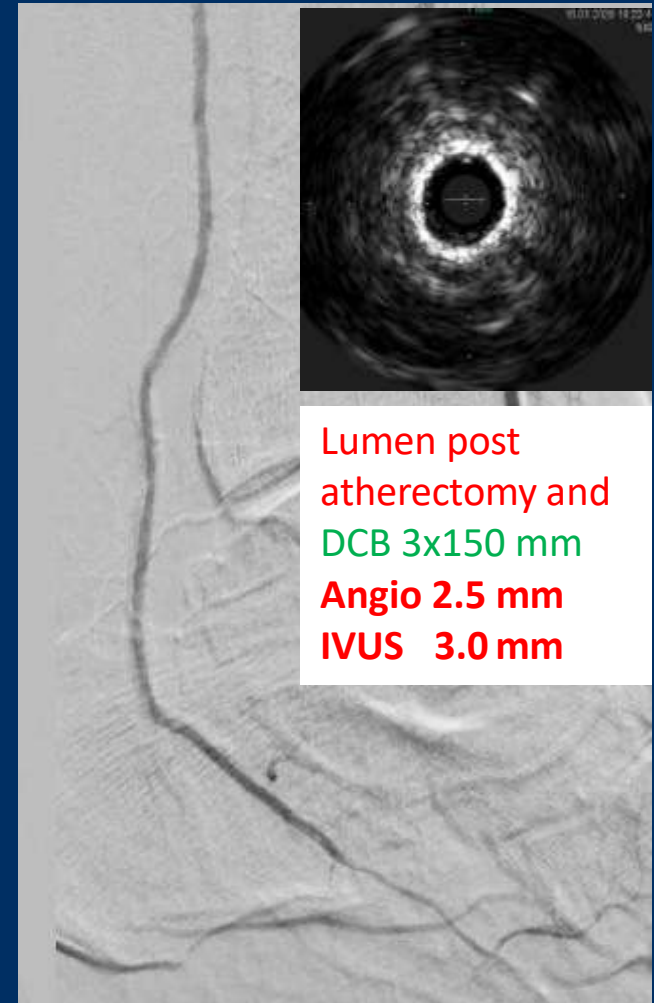
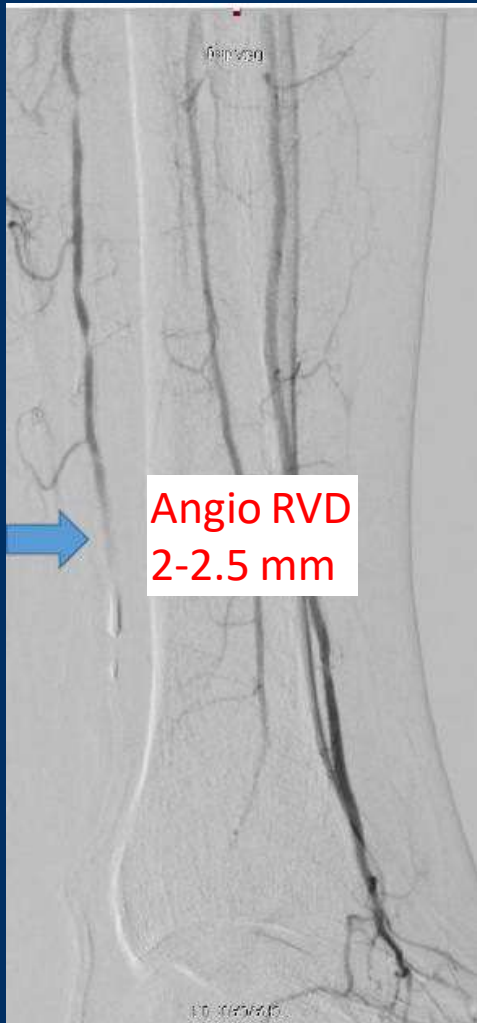


TL Location	N = 96
Popliteal Segment III	7
TP Trunk	22
Anterior Tibial Artery	36
Peroneal Artery	24
Posterior Tibial Artery	7
TL Calcification	
Mild	20.4%
Moderate	40.8%
Severe	38.8%
Lesion length	
10 - < 20 cm	2.0%
> 20 cm	98%

Lesion Length (mm)	
n	51
<u>Mean (SD)</u>	<u>134.61 (82.27)</u>
Min-Max	20.0 – 300.0
Median (IQR)	120.0 (60.0 – 200.0)
Baseline Reference Vessel Diameter based on <u>angio (mm)</u>	
n	51
<u>Mean (SD)</u>	<u>3.00 (0.44)</u>
Min-Max	2.0 – 4.0
Baseline Reference Vessel Diameter based on <u>IVUS (mm)</u>	
n	35
Missing (%)	16 (31.4)
<u>Mean (SD)</u>	<u>4.24 (0.70)</u>
Min-Max	3.3 – 6.2

1.24 mm

Case example (Prof. Korosoglou, Weinheim)



Procedure details

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Variables	Statistics (N=51)
IVUS catheter used	
Missing (%)	9 (17.6)
Yes	42 (82.4)
IVUS analysis performed pre atherectomy	
Missing (%)	6 (11.8)
No	10 (19.6)
Yes	35 (68.6)
IVUS analysis performed post atherectomy	
Missing (%)	6 (11.8)
No	1 (2.0)
Yes	44 (86.3)
IVUS analysis performed post DCB PTA	
Missing (%)	6 (11.8)
No	3 (5.9)
Yes	42 (82.4)
IVUS analysis performed post adjunctive therapy	
Missing (%)	42 (82.4)
No	9 (17.6)
Phoenix Device Used	
Missing (%)	1 (2.0)
P18130K (1.8mm)	21 (41.2)
P18149K (1.8mm)	29 (56.9)

Number of Stellarex DCB Balloons used

1	30 (60.0%)
2	19 (38.0%)
3	1 (2.0%)

Total DCB Treatment Length (mm)

Mean (SD)	148.98 (78.40)
Min–Max	20-300

Technical success analysis – lumen gain (Angio analysis)

Pre-procedure diameter stenosis

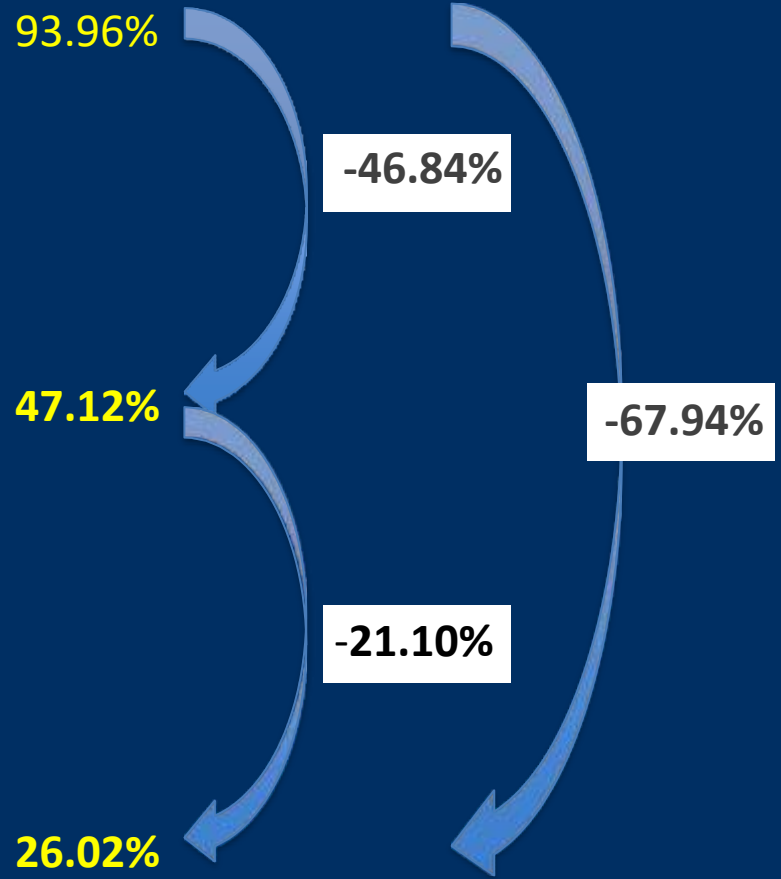
n	51
Mean (SD)	<u>93.96 (5.97)</u>
Min–Max	80.0 – 100.0
Median (IQR)	95.0 (90.0 – 99.0)

Post atherectomy diameter stenosis

n	46
Missing (%)	5 (9.8)
Mean (SD)	47.12 (16.31)
Min–Max	19.5 – 100.0
Median (IQR)	46.7 (37.0 – 56.2)

Post atherectomy + DCB diameter stenosis

n	45
Missing (%)	6 (11.8)
Mean (SD)	26.02 (12.06)
Min–Max	6.9 – 91.9
Median (IQR)	24.3 (21.3 – 28.1)



Syntactx
managing innovation

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Technical safety analysis (Angio analysis)

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Any Target Vessel Dissection Post Phoenix

Missing (%)	1 (2.0)
No	46 (90.2)
Yes	4 (7.8)

Any Target Vessel Dissection Post Stellarex

No	40 (80.0)
Yes	10 (20.0)

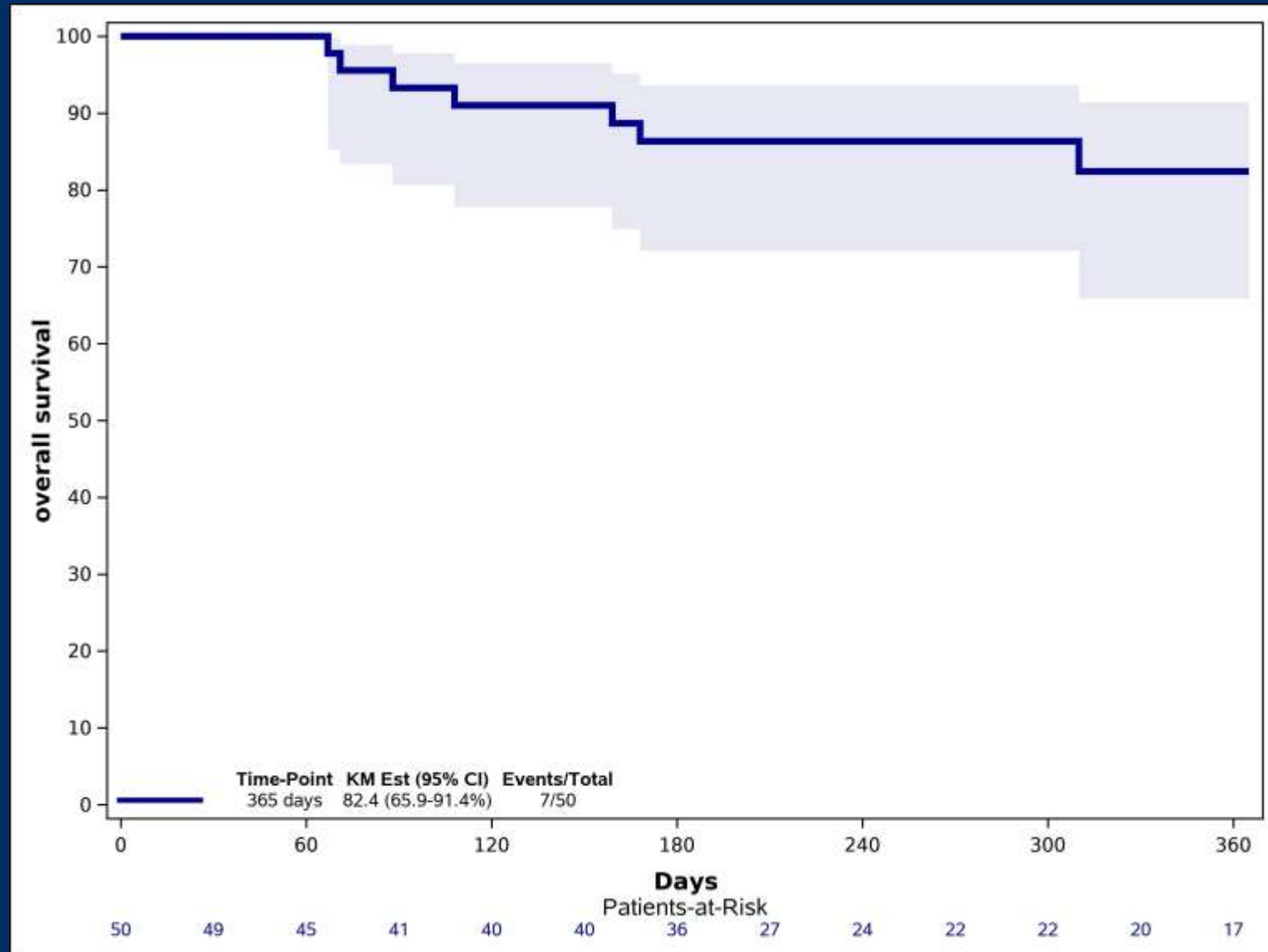
Dissection after BTK PTA

DEBELLUM

30.7% DCB

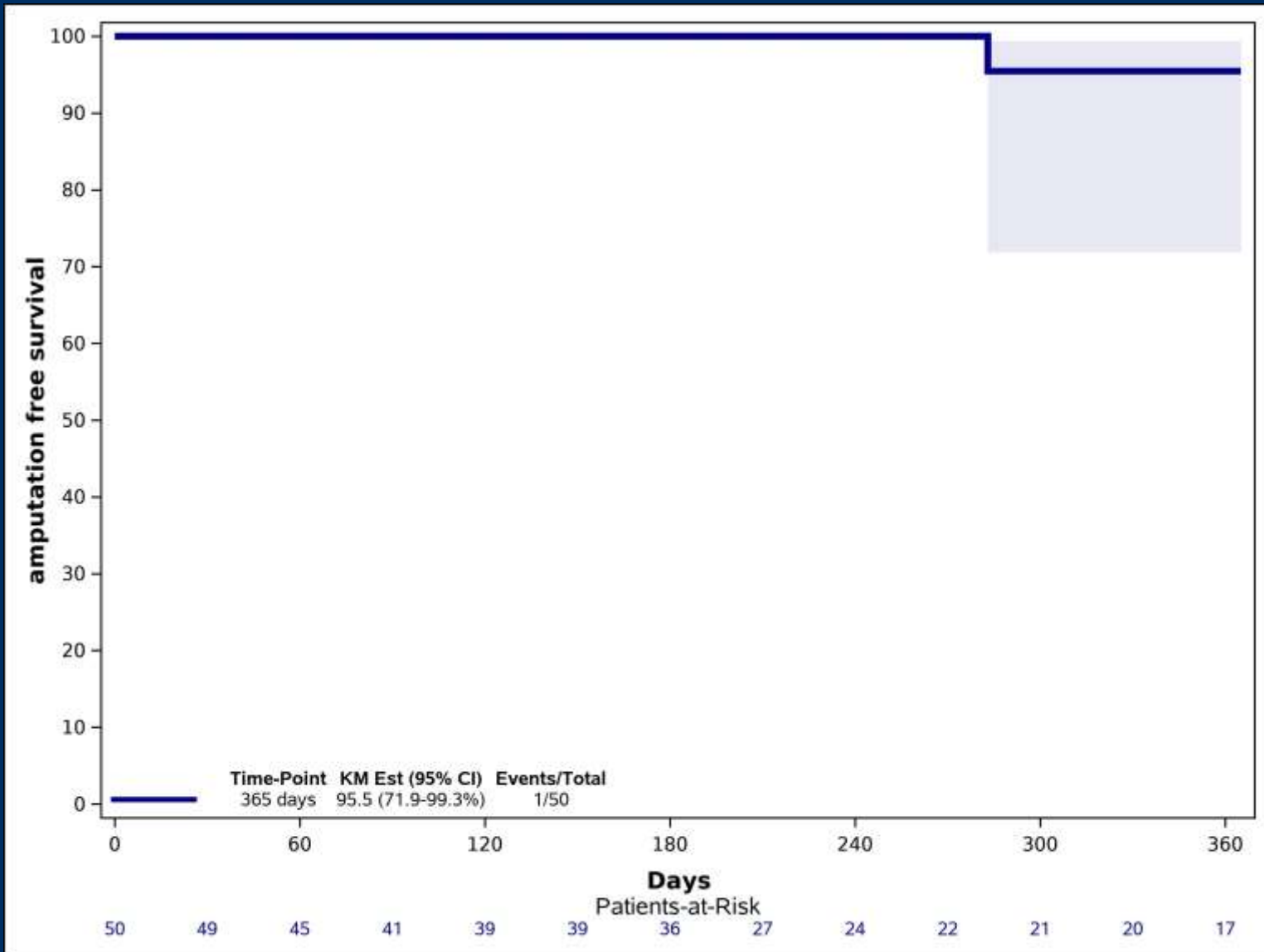
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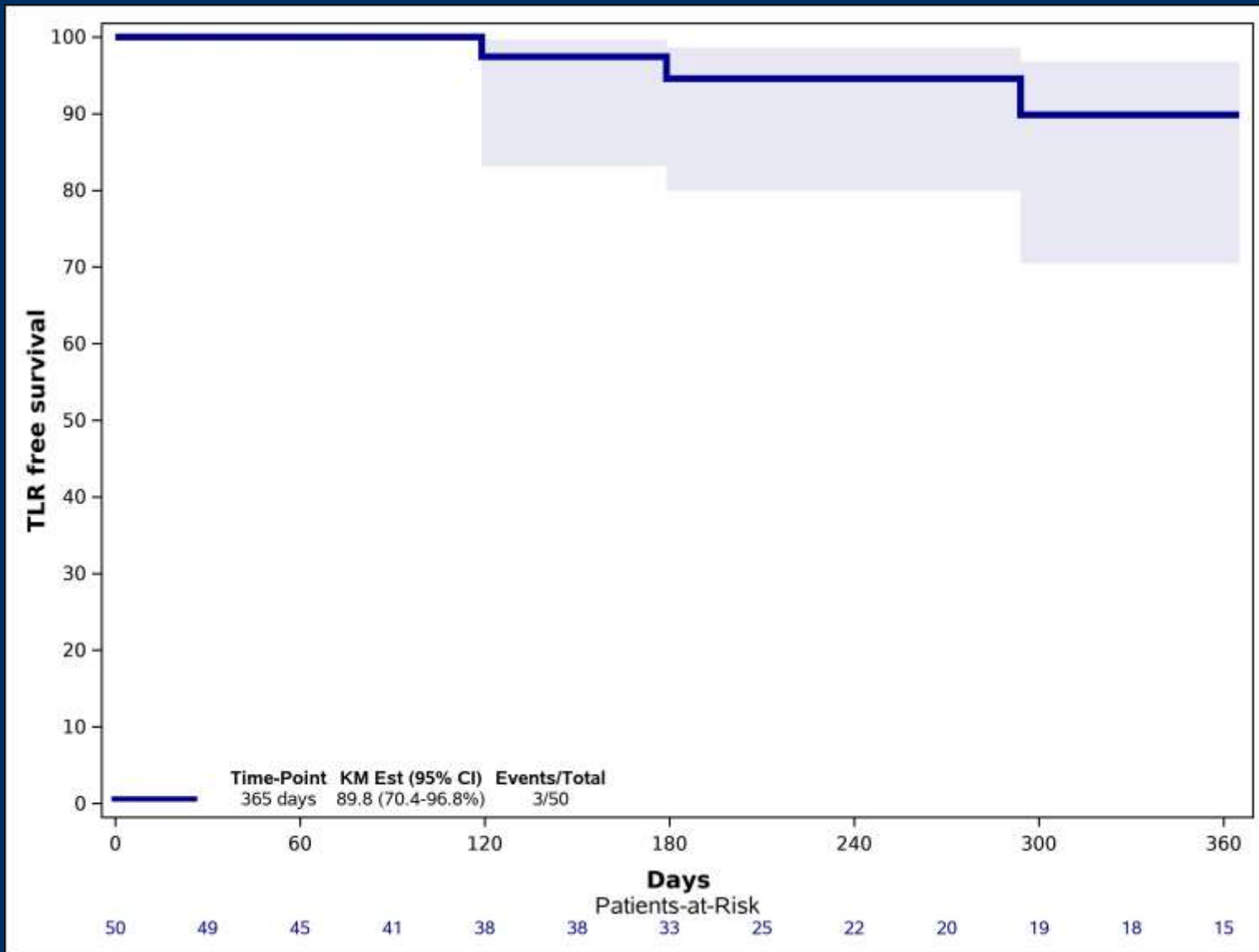
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Preliminary efficacy analysis

WIFI SCORE	Screening (N=50)	30-day FU (N=46)	6-Month FU (N=33)	12.Month FU (N=15)
Mean (SD)	3.25 (1.50)	1.44 (0.88) →	0.87 (1.06) →	1.00 (1.36)
Min–Max	0.0 – 7.0	0.0 – 3.0	0.0 – 3.0	0.0 – 5.0
Median (IQR)	4.0 (2.0 – 4.0)	1.0 (1.0 – 2.0)	1.0 (0.0 – 1.0)	1.0 (0.0 – 2.0)

Rutherford	Screening (N=50)	Discharge (N=49)	30-Day Follow-up (N=46)	6-Month Follow-up (N=33)	12-Month Follow-up (N=19)
Missing (%)		49 (100)	34 (73.9)	7 (21.2)	
0				1 (3.0)	2 (10.5)
1				9 (27.3)	5 (26.3)
2			1 (2.2)	6 (18.2)	4 (21.1)
3				2 (6.1)	3 (15.8)
4	15 (30.0)			1 (3.0)	2 (10.5)
5	35 (70.0)		11 (23.9)	7 (21.2)	3 (15.8)

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 data at 6 months are promising in terms of safety and efficacy for a debulking plus DCB strategy in CLI patients with BTK vessel lesions