BIOLUX P-III
Passeo-18 Lux All-comers Registry: 24-month results in BTK patients

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CCI on behalf of the BIOLUX P-III investigators

Disclosure

Speaker name: Professor Gunnar Tepe

- ❑ I have the following potential conflicts of interest to report:
  - ❑ Receipt of grants/research support
  - ☒ Receipt of honoraria and travel support
  - ❑ Participation in a company-sponsored speaker bureau
  - ❑ Employment in industry
  - ❑ Shareholder in a healthcare company
  - ❑ Owner of a healthcare company
- ❑ I do not have any potential conflict of interest

BIOLUX P-III Study Design

DESIGN	Prospective, global, multi-centre, Real-World All-Comers registry
STUDY GOALS	Further investigate Passeo-18 Lux DCB Efficacy and Safety in Infra-inguinal arteries, in a Real-World Environment
PRIMARY ENDPOINTS	Freedom from MAE[1] at 6 months Freedom from CD-TLR[2] at 12 months
INCLUSION CRITERIA	Any patient with an infra-inguinal artery lesion suitable for endovascular treatment with Passeo-18 Lux drug-coated balloon
EXCLUSION CRITERIA	Failure to cross the lesion with the guide wire was the only exclusion criteria

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(1) Major Adverse Event : Composite of device and procedure related mortality through 30 days, major target limb amputation and clinically driven target lesion revascularization (TLR). MAE are adjudicated by an independent Clinical Events Committee

(2) Clinically driven TLR is any re-intervention performed for ≥50% diameter stenosis (visual estimate) at the target lesion after documentation of recurrent clinical symptoms of the patient

BIOLUX P-III Cohorts

All-Comers Cohort

N = 700 subjects, Representative sample of consecutive subjects treated with Passeo-18 Lux DCB

Full Cohort

N = 882 subjects, 1084 lesions

Extended enrolment to complete some predefined subgroups

☒ **CLI**	451 subjects	☒ **Heavily calcified**	167 subjects
☒ **Diabetes**	418 subjects	☒ **TASC C**	199 subjects
☒ **BTK**	151 subjects	☒ **TASC D**	150 subjects
		☒ **ISR**	103 subjects

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BIOLUX P-III: Baseline Characteristics BTK

# Subjects	N = 151
Age, yrs (mean ± SD)	72.3 +/-10.0
Male	73.5% (111/151)
Hypertension	84.1% (127/151)
Hyperlipidemia	60.3% (91/151)
Smoking	48.0% (72/150)
Current Smokers	*27.8% (20/72)*
History of PAOD	51.7% (78/151)
Previous peripheral surgeries	41.7% (63/151)
Diabetes	62.9% (95/151)
Coronary Artery Disease	39.7% (60/151)
Cerebrovascular Disease	18.5% (28/151)
Renal Disease	36.4% (55/151)
Rutherford Category ≤3	24.0%
4	12.4%
5	41.3%
6	22.3%

Lesion Characteristics		N=185
Lesion Length, mm (mean ± SD)		79.2 ± 71.9
Reference Vessel Diameter mm (mean ± SD)		3.0 ± 0.6
Diameter Stenosis (%)		86.2 ± 12.7
Calcification	None	57/184 (31.0%)
	Mild	60/184 (32.6%)
	Moderate	49/184 (26.6%)
	Heavy	18/184 (9.8%)
TASC Classification	A	59/176 (33.5%)
	B	31/176 (17.6%)
	C	37/176 (21.0%)
	D	49/176 (27.8%)

☞ **76 % CLI**

☞ **69.0% of lesions calcified**

☞ **48.8% lesions are TASC C/D**

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BIOLUX P-III: Lesion location, procedure details BTK

Lesion Location	N (%)
ATA	63 (34.1%)
PTA	46 (24.9%)
Tibioperoneal trunc	40 (21.6%)
Peroneal artery	36 (19.5%)

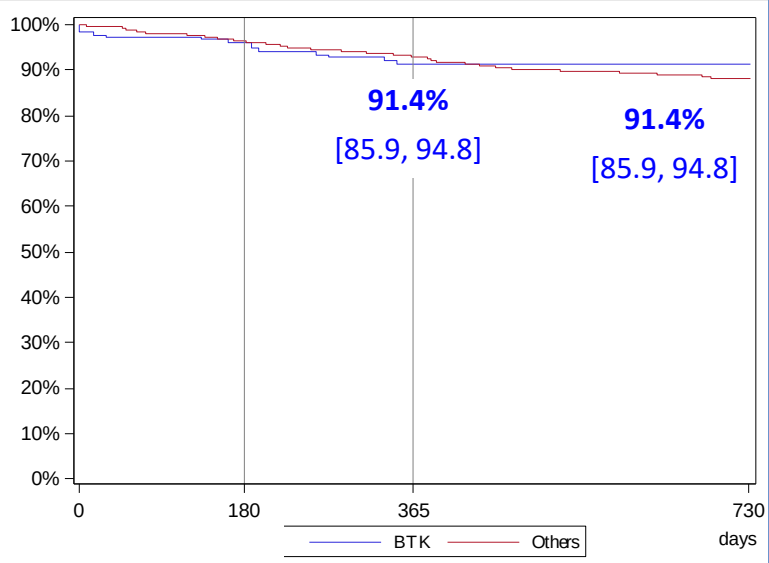
Vessel Preparation	135/185	73.0%
Pre-dilation	124/135	91.9%
Cutting/scoring balloon	2/135	1.5%
Atherectomy	6/135	4.4%

Technical success[1]	181/185	97.8%

(1) Technical success: Successful completion of the endovascular procedure and immediate morphological success with ≤ 50% residual diameter reduction of the treated lesion (visual estimation)

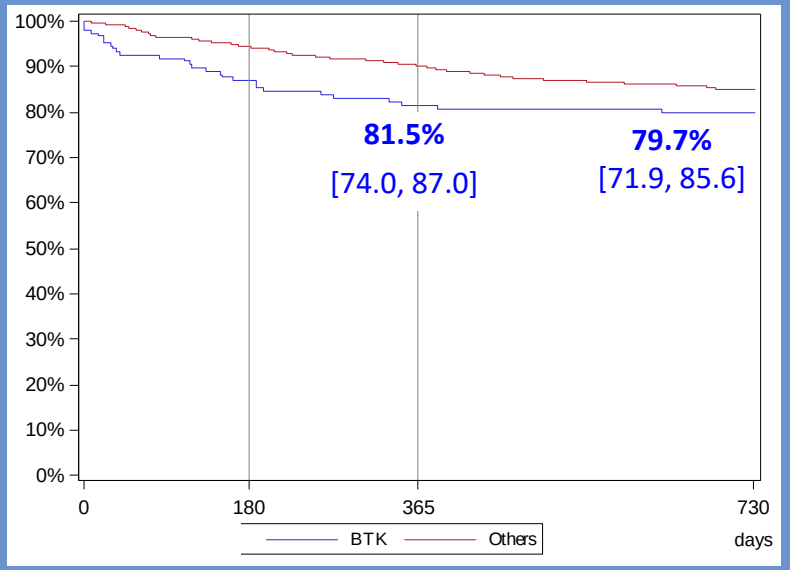
BIOLUX P-III: 24-month outcomes BTK

Freedom from clinically driven[1] TLR



#lesions at risk	181	149	133	39
#events	3	7	14	14

Freedom from Major Adverse Events[2]



#subjects at risk	147	116	101	30
#events	3	19	26	28

Key Baseline Characteristics	
TASC C/D	48.8%
CLI	76.0%
Calcification	69.0% (36.4 % moderate/heavy)

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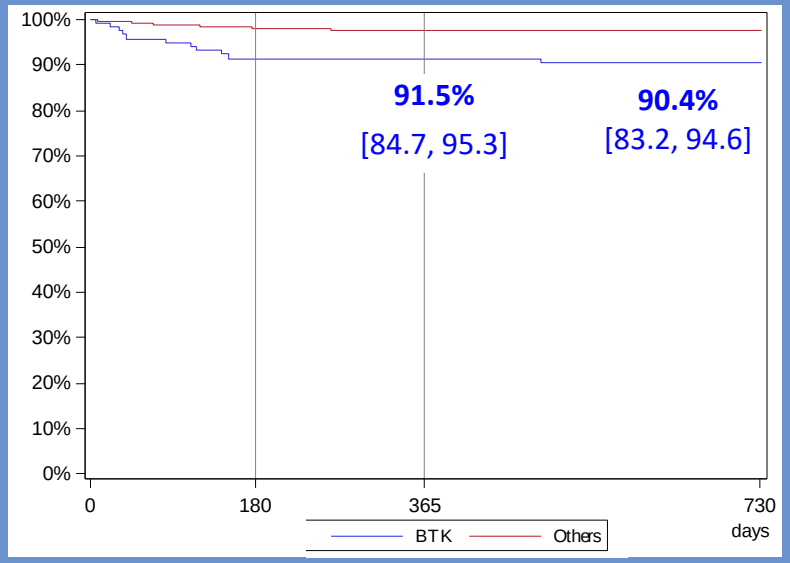
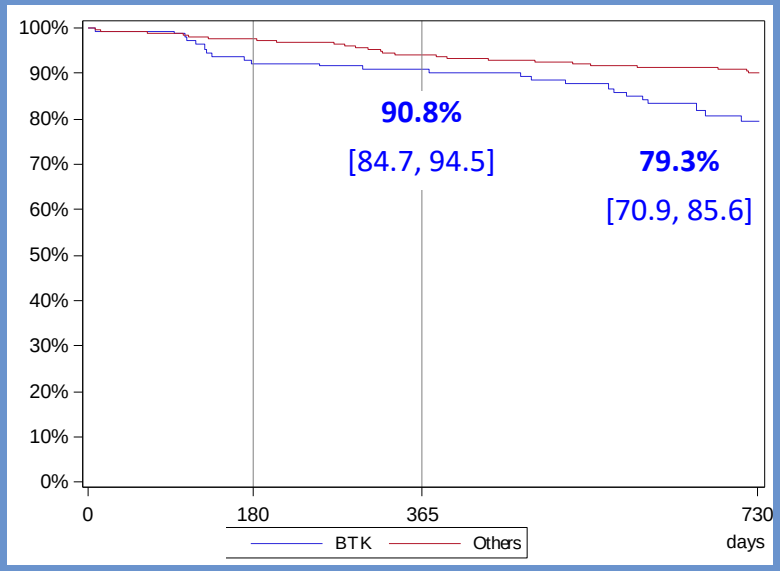
BIOLUX P-III: 24-month outcomes BTK

Freedom from major target limb amputation



#limbs at risk	123	99	92	25
#events	0	10	10	11

Survival



#subjects at risk	150	127	119	37
#events	0	11	13	26

→ Only 1 major amputation between 6 months and 2 years

Key Baseline Characteristics	
TASC C/D	48.8%
CLI	76.0%
Calcification	69.0% (36.4% moderate/heavy)

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BIOLUX P-III BTK 24-month outcomes in context

	BIOLUX P-III BTK subgroup	Lutonix BTK Registry
# Subjects	151	371
Lesion length (mm +/- SD)	79.2 ± 71.9	121+/-98.7
RC 5	50/121 (41.3%)	242/370 (65.4%)
RC 6	27/121 (22.3%)	0%
Diabetics	95/151 (62.9%)	237/371 (63.9%)
Freedom from cd TLR*	91.4%	73.9%
Major target limb amputation*	9.6%	7.1%
All cause of death*	20.7%	21.7%
Bailout	1.1%	nc

LUTONIX® DCB Interim 24 Month Outcomes from Global BTK Registry; M. Lichtenberg, D. Scheinert. LINC 2019 * KM estimates

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Crude Mortality Rates in BIOLUX P-III

	12 months[1]	24 months[2]
BIOLUX P-III Full cohort	6.2% (54/878)	10.3% (90/878)
BIOLUX P-III BTK	8.6% (13/151)	17.2% (26/151)
BIOLUX P-III SFA+P1	5.7% (34/593)	8.8% (52/593)
BIOLUX P-III Non CLI	2.9% (13/451)	5.5% (25/451)

(1) 365 days – (2) 730 days

BIOLUX P-III Full Cohort: Is the PTX dose a risk factor?

Cox regression:
Mortality in BIOLUX P-III up to 730 days

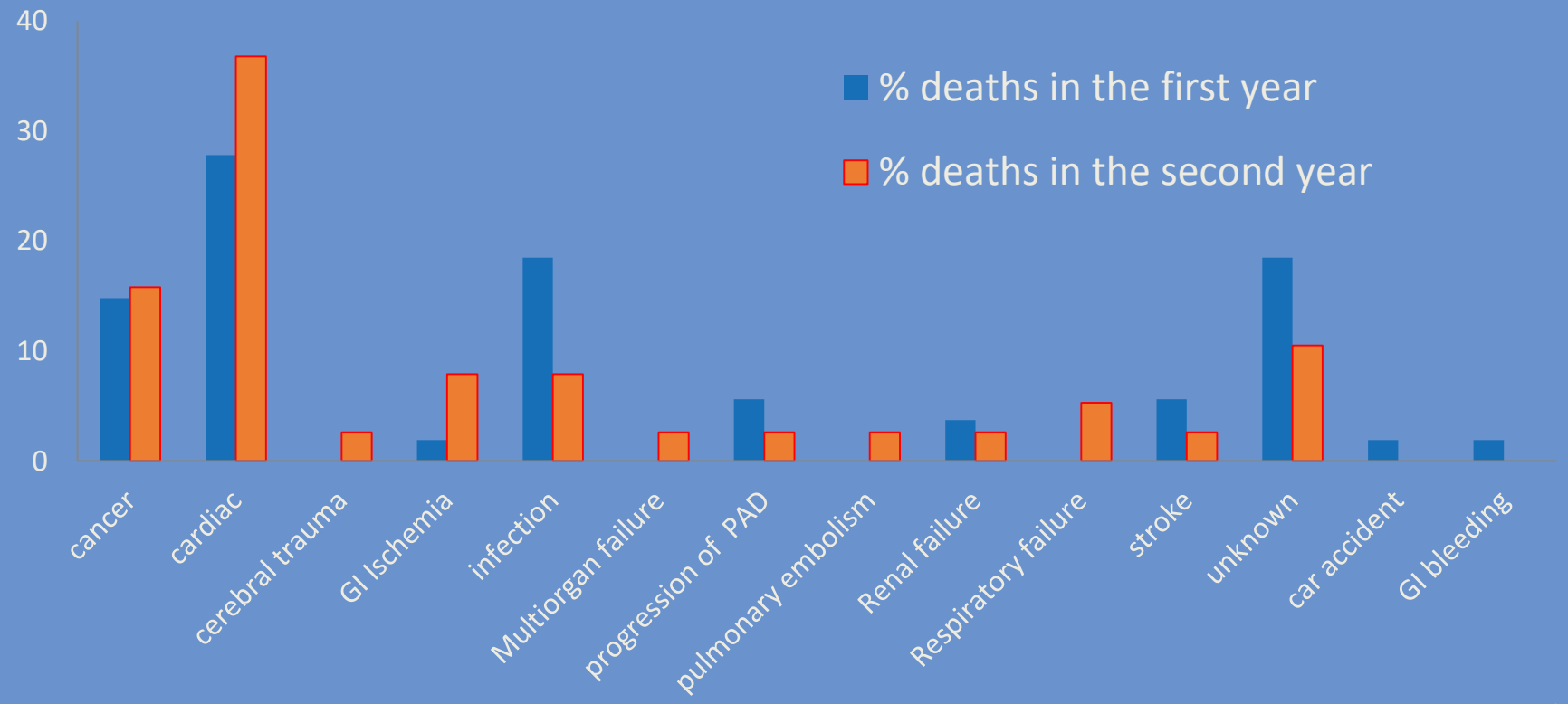
Parameter	Standard Error	Chi-Square	p-value	Hazard Ratio
Paclitaxel Dose, mg	0.04123	0.0014	**0.9700**	0.998
Age, years	0.01393	11.6359	0.0006	1.049
Diabetes	0.25008	6.9299	0.0085	0.518
Renal disease	0.25028	12.3958	0.0004	0.414
Cancer	0.31420	3.4197	0.0644	0.559
CLI (RC>3)	0.25497	14.4314	0.0001	0.380
Lesion length, mm	0.00179	0.1892	0.6636	1.001
No. of balloons	0.21726	0.0287	0.8656	0.964

PTX dose distribution vs deaths up to 730 days

Deaths by dose category						
PTX dose mg	**=<5**	**5-10**	**11-15**	**16-20**	**>20**	**total**
# deaths	40	27	12	6	5	90
mortality (%)	10.75	9.22	10.17	11.32	11.90	10.25
p-value: 0.6876						

⇒ **NO dose dependency for the mortality rate in the Full Cohort is observed**

BIOLUX P-III: Causes of death in the Full-Cohort



- No significant difference in the distribution of causes of death during the 1st compared to the 2nd year in P-III (Fisher-test p-value = 0.3293)
- All death cases have been adjudicated by a clinical events committee as not being related to the device/procedure

BIOLUX P-III BTK : Conclusion

- 24-month outcomes of Passeo-18 Lux in BTK arteries show safety and efficacy in patients with advanced PAD stage (22.3 % RCC6):
  - 91.4% Freedom from Clinically-Driven TLR
  - 9.6 % Major Target Limb amputation
- In BIOLUX P-III full-cohort
  - No increase of mortality in PTX treated patients in the 2nd year of follow-up is seen
  - No relationship between PTX exposure and mortality has been observed through 24 months
  - Causes of death do not differ significantly between the first and the second year
- These data support the benefit of Passeo-18 Lux DCB for the treatment of infra-popliteal arteries
- Ongoing long term follow-up will provide further insight into Passeo-18 Lux safety

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