BIOLUX P-III All-Comers
Real-World Experience with Passeo-18 Lux Paclitaxel-Coated Balloon in Infra-inguinal Artery: 12-month Results in Critical Limb Ischemia Patients

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Disclosure

Speaker name:

Prof. Dr. Thomas Zeller

I have the following potential conflicts of interest to report:

- [X] Consulting : BIOTRONIK
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)

- [ ] I do not have any potential conflict of interest

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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 Infrainguinal arteries, in a Real-World Environment

PRIMARY ENDPOINTS:

- Freedom from MAE[1] at 6 months
- Freedom from CD-TLR[2] at 12 months

(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 Study Incl./Excl. Criteria

Inclusion Criteria

- Lesion(s) in the **infrainguinal arteries** suitable for endovascular intervention, treated with or scheduled to be treated with the Passeo-18 Lux drug coated balloon

Exclusion Criteria

- Failure to successfully cross the target lesion with a guide wire

BIOLUX P-III is **the only Infrainguinal arteries Real -World Registry :**

- ✓ No patient characteristic limitations
- ✓ No lesion characteristic limitations
- ✓ Use of additional devices allowed
- ✓ 47 sites, 16 countries (EU, Australia, Asia)

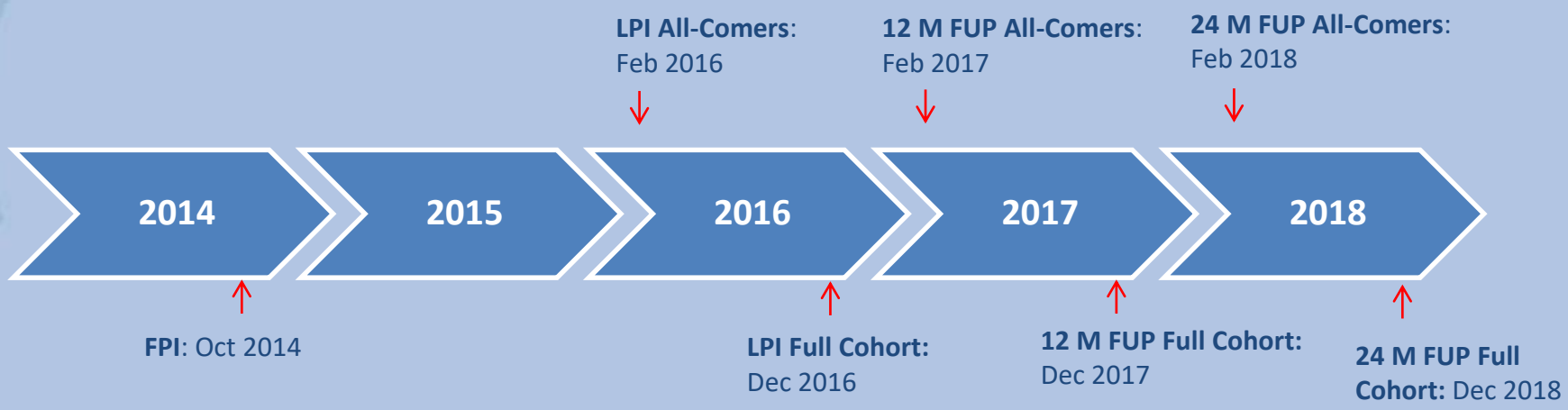
BIOLUX P-III Cohorts

All-Comers Cohort

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

Full Cohort

- N= **882** Subjects
- Enrolment was extended to complete some predefined subgroups



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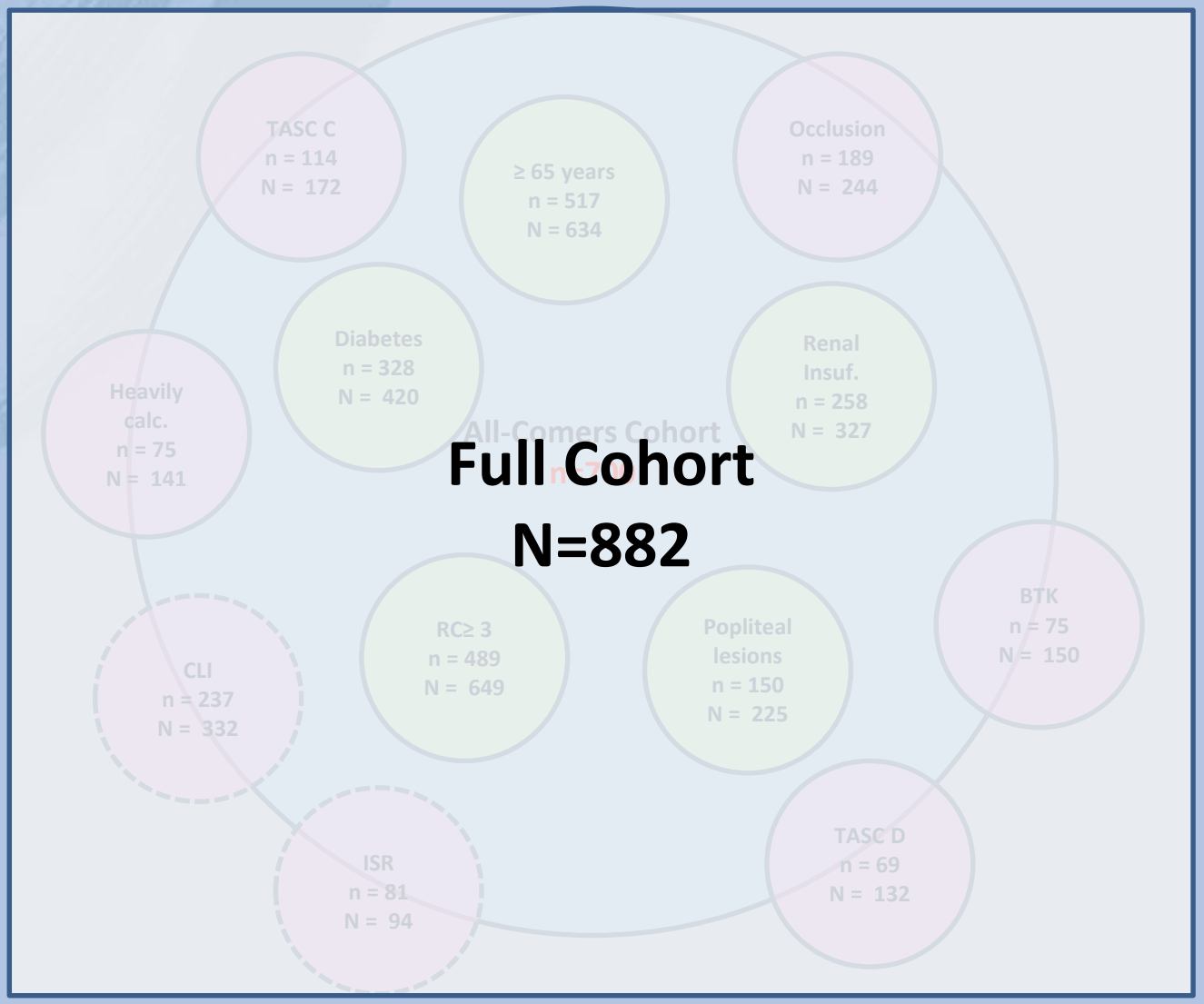
BIOLUX P-III Cohorts and Subgroups



n = # subjects from the subgroup in the All-Comers population

N = # subjects from the subgroup in the Full Cohort population

Not pre defined subgroup

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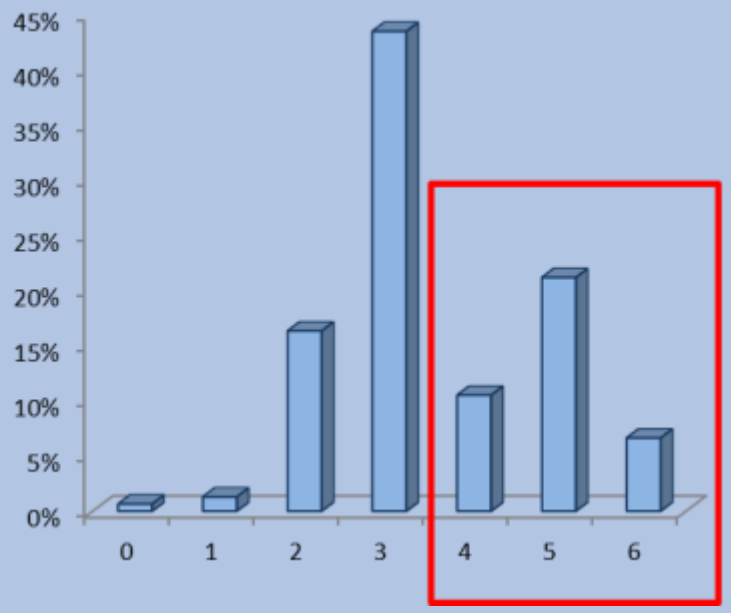
Baseline Characteristics All-Comers

# Subjects	N = 700
Age, yrs (mean ± SD)	70.0 ± 10.2
Male (n, %)	439 (62.7%)
Hypertension (n, %)	594 (84.9%)
Hyperlipidemia (n, %)	472 (67.4%)
Smoking (n, %)	483 (69.0%)
Current Smokers	*191 (39.5%)*
History of PAOD (n, %)	411 (58.7%)
Previous PVI /Surgeries (n, %)	373 (53.3%)
Diabetes (n, %)	330 (47.1%)
Coronary Artery Disease (n, %)	295 (42.1%)
Cerebrovascular Disease (n, %)	145 (20.7%)
Renal Disease (n, %)	255 (36.4%)
ABI target limb (mean± SD)	0.7 ± 0.2

Rutherford Classification



38.3% CLI subjects

BIOLUX P-III Real-World All-Comers Registry
12 Month Results Using Passeo-18 Lux DCB
Critical Limb Ischemia

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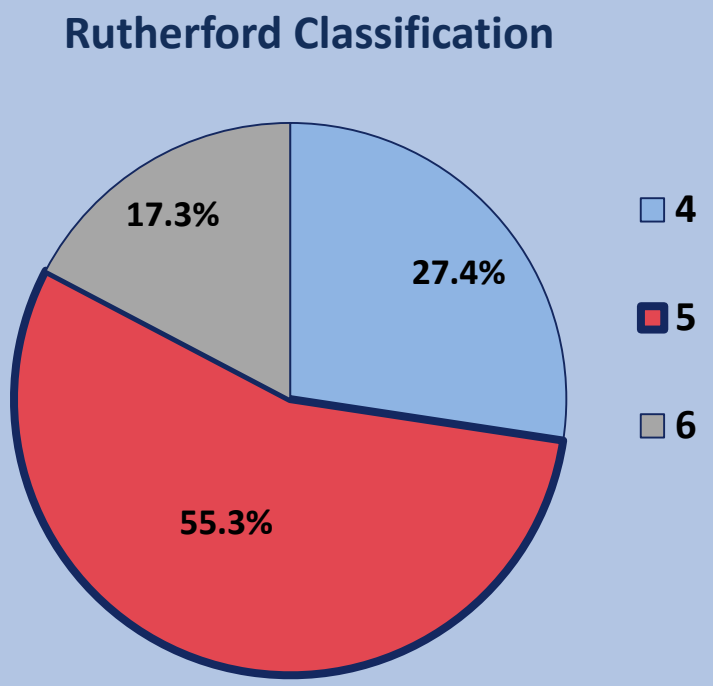
Baseline Characteristics CLI

(N= 237 subjects)

Age, yrs (mean ± SD)	71.3+/-10.0
Male (n, %)	141 (59.5%)
Hypertension (n, %)	204 (86.1%)
Hyperlipidemia (n, %)	140 (59.1%)
Smoking (n, %)	133 (56.1%)
Current Smokers	*57* (42.9%)
History of PAOD (n, %)	129 (54.4%)
Previous PVI /Surgeries (n, %)	120 (50.6%)
Diabetes (n, %)	150 (63.3%)
Coronary Artery Disease (n, %)	111 (46.8%)
Cerebrovascular Disease (n, %)	61 (25.7%)
Renal Disease (n, %)	110 (46.4%)
ABI target limb (mean± SD)	0.6+/-0.3



Lesion Characteristics CLI

Lesion Characteristics	N=301	
Lesion Length, mm (mean ± SD)	77.2+/-60.9	
Reference Vessel Diameter, mm (mean ± SD)	4.4+/-1.1	
Diameter Stenosis (%)	87.4+/-12.5	
De novo Lesion (n, %)	160	53.2
Occlusion (n, %)	74	24.6
In Stent Restenosis (n, %)	32	10.6
Re-Stenosis (n, %)	35	11.6
Calcification (n,%)		
None	67	22.3
Mild	110	36.5
Moderate	96	31.9
Heavy	28	9.3
TASC Classification (n,%)		
A	119	39.7
B	95	31.7
C	51	17.0
D	35	11.6

Lesion Location	N	%
Common femoral	3	1.0
SFA	137	45.5
Popliteal artery	83	27.6
ATA	29	9.6
PTA	13	4.3
Tibioperoneal trunc	9	3.0
Peroneal artery	12	4.0
Dorsalis Pedis	1	0.3
Other	14	4.7

- **77.7% of lesions calcified**
- **41.2% moderate to heavy calcified lesions**
- **28.6% lesions are TASC C/D**
- ***21.3 % BTK lesions***

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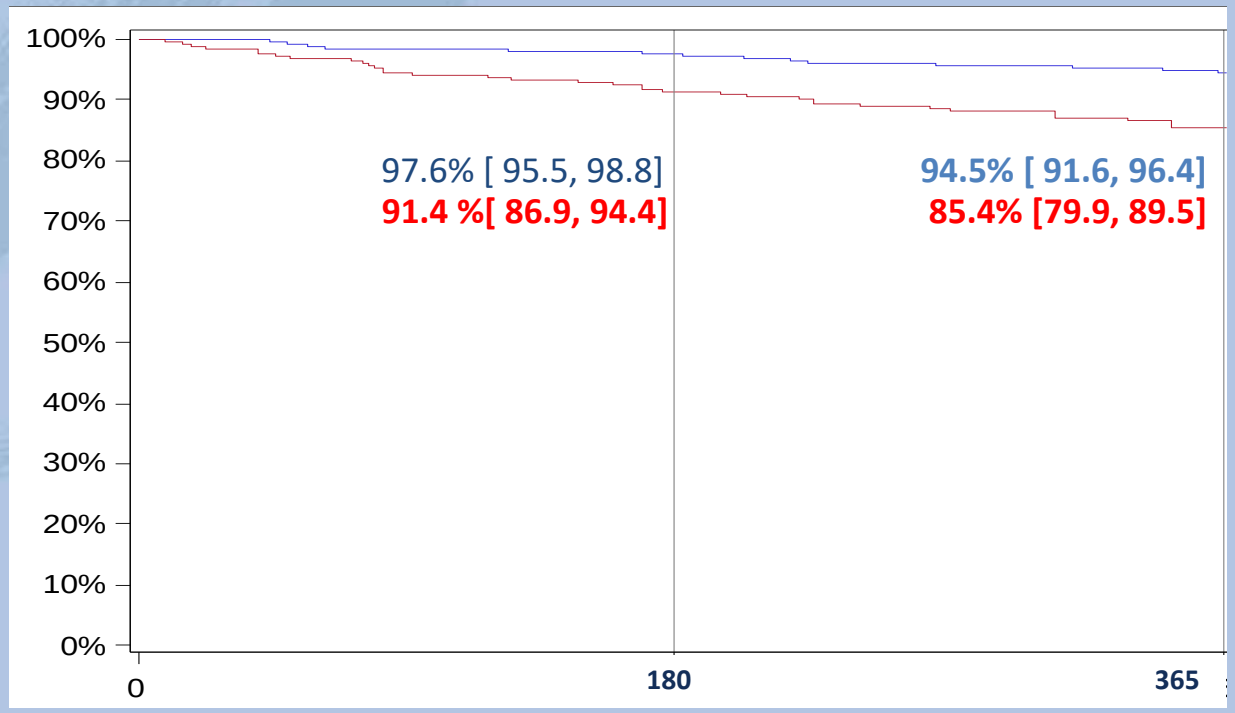
Procedure Details CLI

Vessel Preparation	72.1% (217/301)
Pre-dilation	63.5% (191/301)
Cutting/scoring balloon	3.3% (10/301)
Rotational thrombectomy	4.0% (12/301)
Atherectomy	2.3% (7/301)

Technical success[1]	99.3% (299/301)
Bailout Stenting	14.3% (43/301)

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

Major Adverse Events[1] – CLI



	Description	180 days	365 days
CLI	Left at risk (baseline:237)	192	154
	# Events	19	31
Non CLI	Left at risk (baseline:382)	365	316
	# Events	9	20

(1) Major Adverse Event : Composite of freedom from 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

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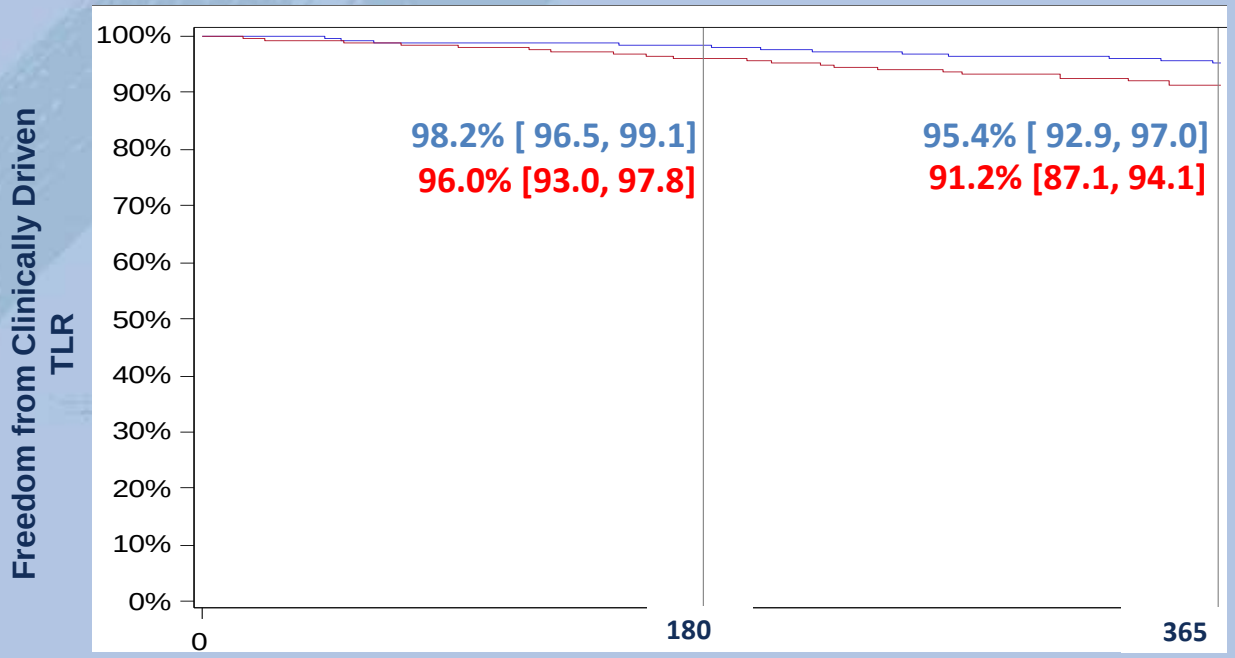
Freedom From Clinically Driven Target Lesion Revascularization[1] – CLI



Key Baseline Characteristics	
TASC C/D	28.6%
Calcification	77.7% (41.2% moderate/heavy)

	Description	180 days	365 days
CLI	Left at risk (baseline:301)	253	205
	# Events	11	23
Non CLI	Left at risk (baseline:457)	437	379
	# Events	8	20

(1) Any re-intervention performed for ≥ 50% diameter stenosis (visual estimate) at the target lesion after documentation of recurrent clinical symptoms of the patient adjudicated by an independent CEC

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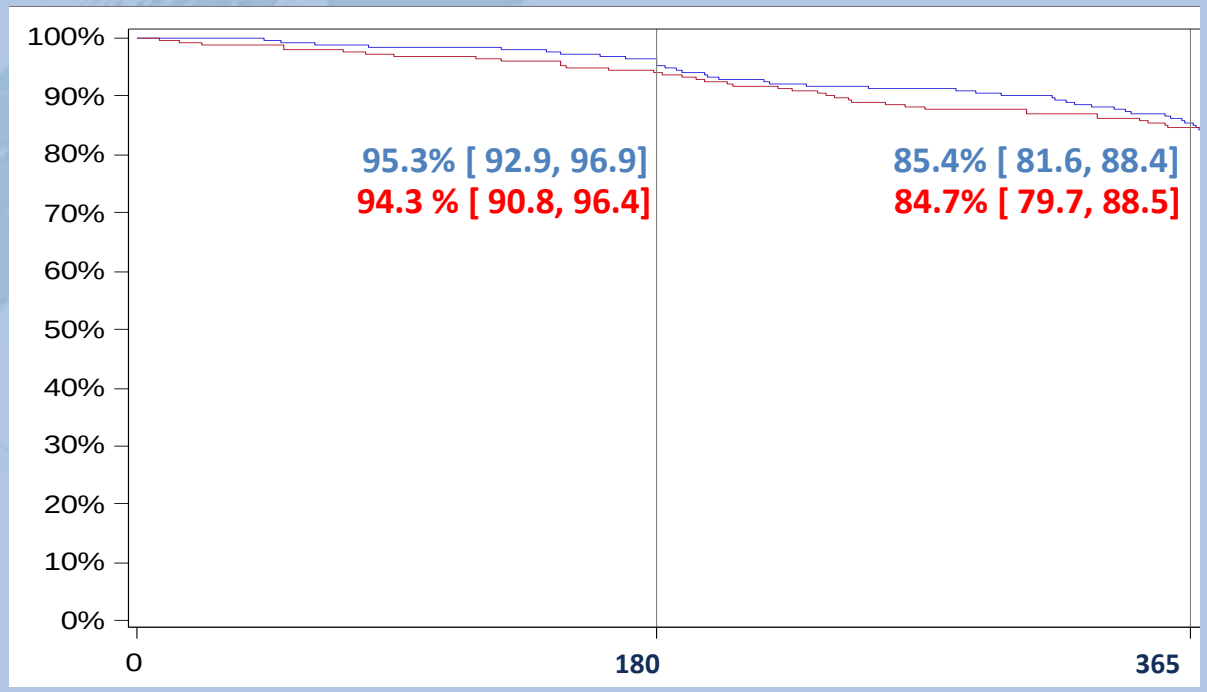
Primary Patency[1] – CLI



Key Baseline Characteristics	
TASC C/D	28.6%
Calcification	77.7% (41.2% moderate/heavy)

	Description	180 days	365 days
CLI	Left at risk (baseline:301)	248	191
	# Events	16	40
Non CLI	Left at risk (baseline:457)	424	341
	# Events	21	63

(1) Defined as freedom from >50% restenosis in the target lesion as indicated by a duplex ultrasound peak systolic velocity ratio (PSVR) >2.5 or by visual assessment of an angiogram with no clinically driven reintervention

(2) DUS not mandated _ KM curve based on last contact date

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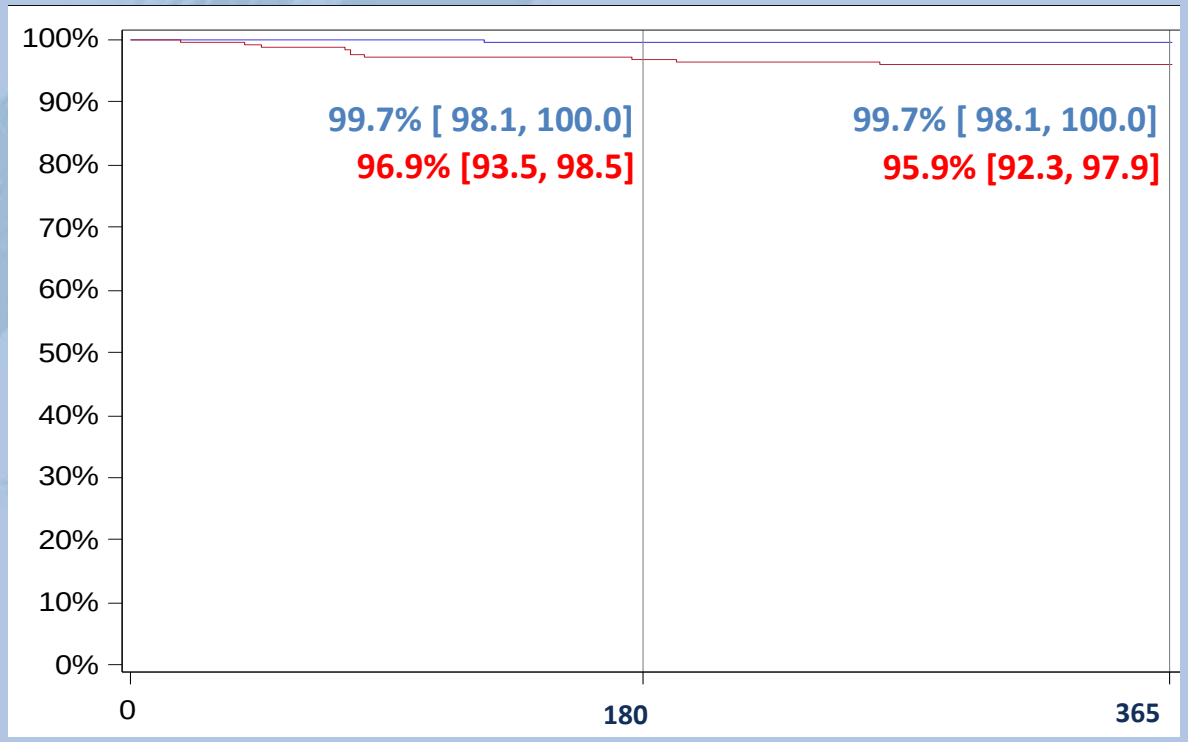
Major Amputations– CLI



Key Baseline Characteristics	
TASC C/D	28.6%
Calcification	77.7% (41.2% moderate/heavy)

	Description	180 days	365 days
CLI	Left at risk (baseline:239)	205	175
	# Events	7	9
Non CLI	Left at risk (baseline:384)	374	334
	# Events	1	1

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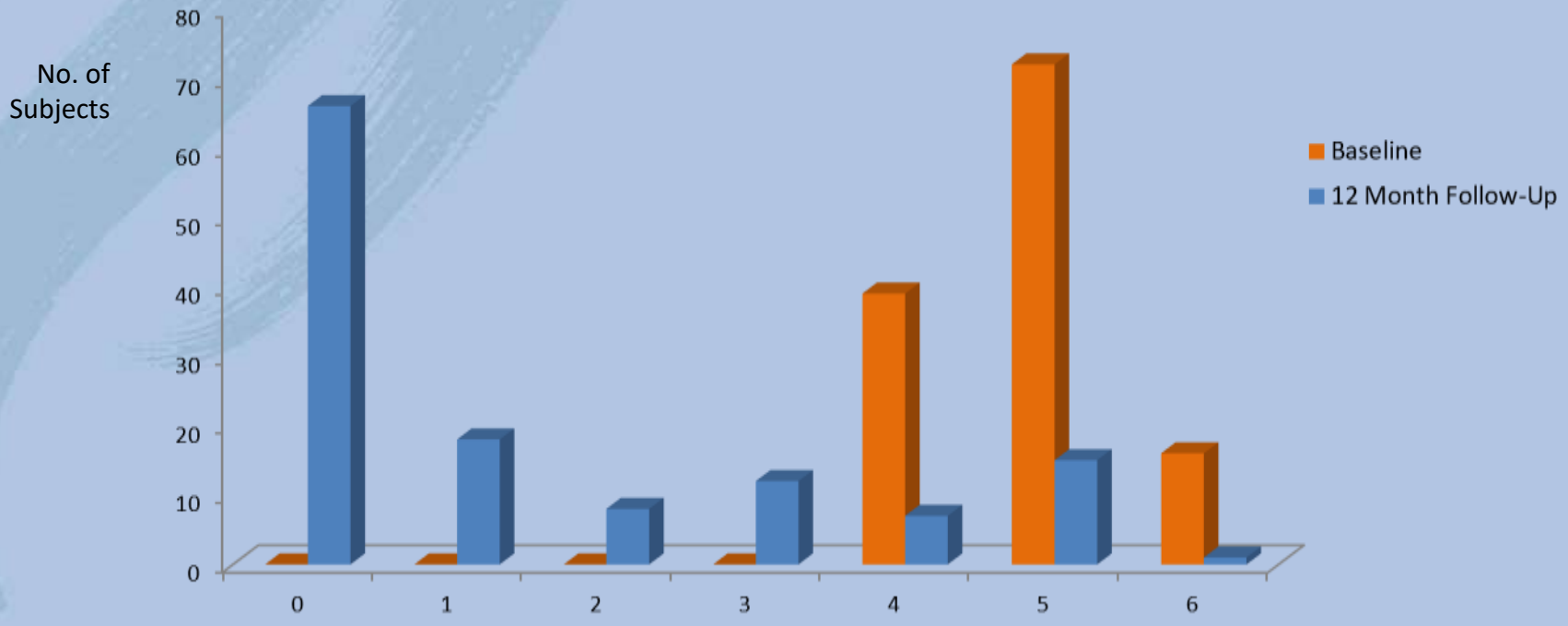
Change in Rutherford Classification

Baseline vs 12 Month - Paired Data - **CLI**



87.4% of **CLI** subjects improved significantly in Rutherford Class at 12 months compared to baseline

Conclusion

- 12-month results of BIOLUX P-III all-comers registry further confirm Passeo-18 Lux safety and effectiveness in **CLI patients**
  - **84.7% Primary Patency**
  - **91.2% Freedom from Clinically-Driven TLR**
  - **14.6% MAE**
  - **4.1% Major Amputations**
  - **87.4 % of CLI** subjects improved significantly in Rutherford classification ($p<0.001$) at 12 months
- In a subset of high risk patients, Passeo-18 Lux maintains excellent 12-month clinical outcomes

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