BIOLUX P-III All-Comers
Real-World Experience with Passeo-18 Lux Paclitaxel-Coated Balloon in Infra-Inguinal artery: 12-month Results in Diabetic Patients

Prof. Dr. Marianne Brodmann,
Graz University Hospital, Austria
On behalf of the BIOLUX P-III investigators

Disclosure

Speaker name:

Professsor Marianne Brodmann

I have the following potential conflicts of interest to report:

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

- [ ] 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 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 Real-World Registry investigating DCB in Infrainguinal arteries :**

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

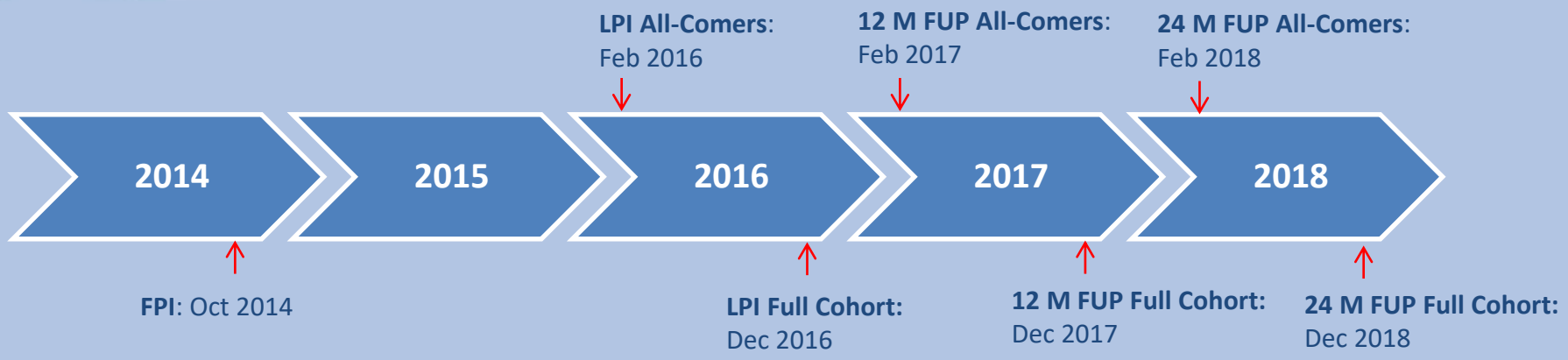
BIOLUX P-III Cohorts

All-Comers Cohort

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

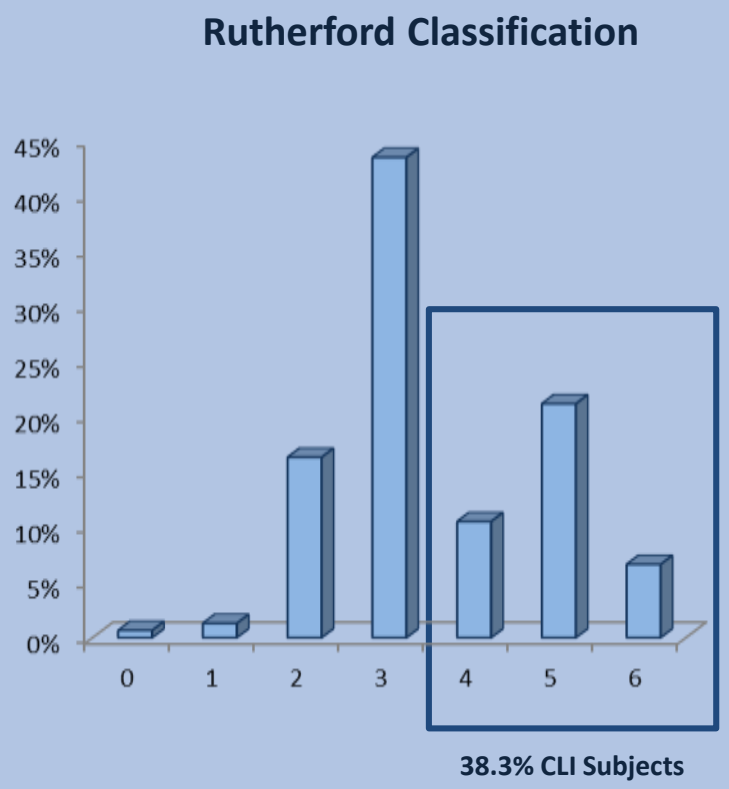
Full Cohort

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



Baseline Characteristics All-Comers

# Subjects	N = 700
Age, yrs (mean ± SD)	70.0 ± 10.2
Male (n, %)	439 (62.7%)
Hypertension (n, %)	595 (85.0%)
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

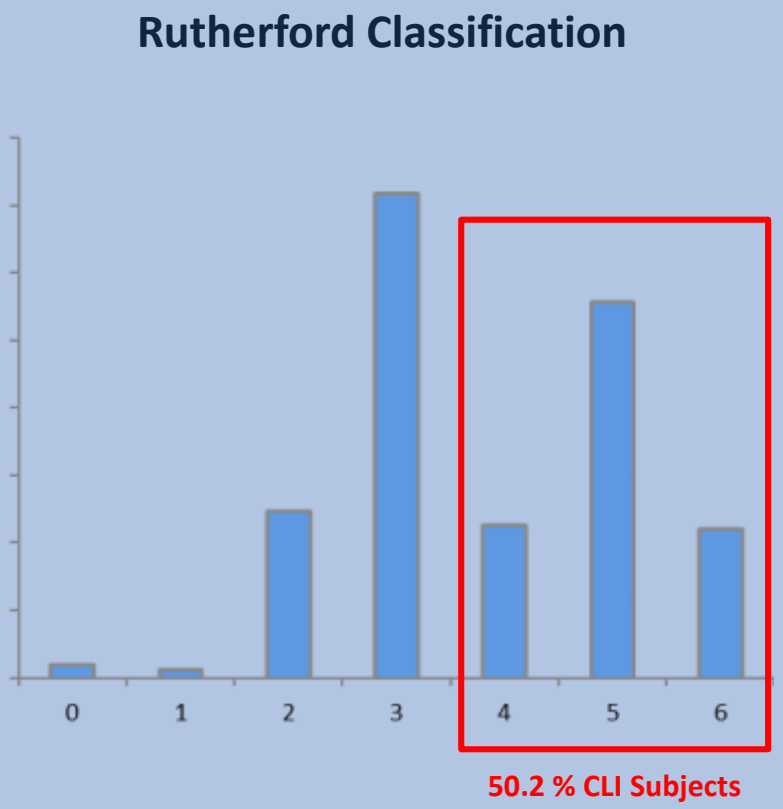


BIOLUX P-III All-Comers
12-month Results
Diabetics Subgroup

Baseline Characteristics Diabetics

N=330

Age, yrs (mean ± SD)	69.9+/-9.4
Male (n, %)	222 (67.3%)
Hypertension (n, %)	293 (88.8%)
Hyperlipidemia (n, %)	230 (69.7%)
Smoking (n, %)	210 (63.6%)
Current Smokers	*69* (32.9%)
History of PAOD (n, %)	207 (62.7%)
Previous PVI /Surgeries (n, %)	178 (53.9%)
Coronary Artery Disease (n, %)	171 (51.8%)
Cerebrovascular Disease (n, %)	72 (21.8%)
Renal Disease (n, %)	140 (42.4%)
ABI target limb (mean± SD)	0.7+/-0.2



Lesions Characteristics Diabetics

Lesion Characteristics	N=409
Lesion Length, mm (mean ± SD)	83.8 ± 72.3
Reference Vessel Diameter, mm (mean ± SD)	4.7 ± 1.1
Diameter Stenosis (%)	86.6 ± 13.1
De novo Lesion (n, %)	230 (56.2)
Occlusion (n, %)	92 (22.5)
In Stent Restenosis (n, %)	40 (9.8)
Re-Stenosis (n, %)	47 (11.5)
Calcification (n,%) None Mild Moderate Heavy	 88 (21.6) 130 (31.9) 129 (31.7) 60 (14.7)
TASC Classification (n,%) A B C D	 157 (38.8) 121 (29.9) 79 (19.5) 48 (11.9)

Lesion location	N = 409
Common femoral (n, %)	3 (0.7)
SFA (n, %)	219 (53.5)
Popliteal artery (n, %)	91(22.2)
ATA (n, %)	27 (6.6)
PTA (n, %)	16 (3.9)
Tibioperoneal trunc (n, %)	16 (3.9)
Peroneal artery (n, %)	10 (2.4)
Others (n, %)	27 (6.6)

- **78.3% of lesions calcified**
- **46.4% moderate to heavy calcified lesions**
- **31.4% lesions are TASC C/D**
- ***16.8% BTK lesions***

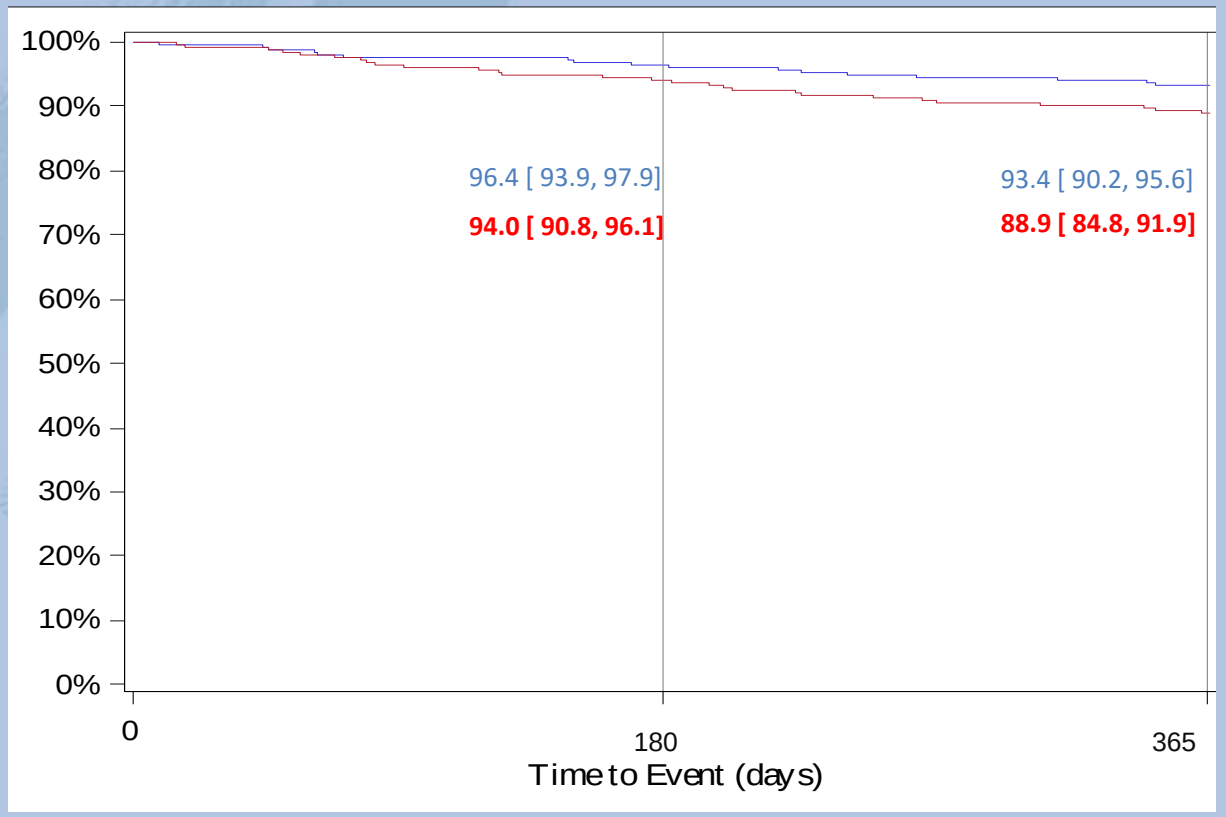
Procedure Details Diabetics

Vessel preparation	71.1 % (291/409)
Pre-dilation	65.3% (267/409)
Cutting/scoring balloon	3.2(13/409)
Rotational thrombectomy	2.9% (12/409)
Atherectomy	1.5% (6/409)

Technical success[1]	98.8% (404/409)
Bailout Stenting	15.2% (62/409)

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

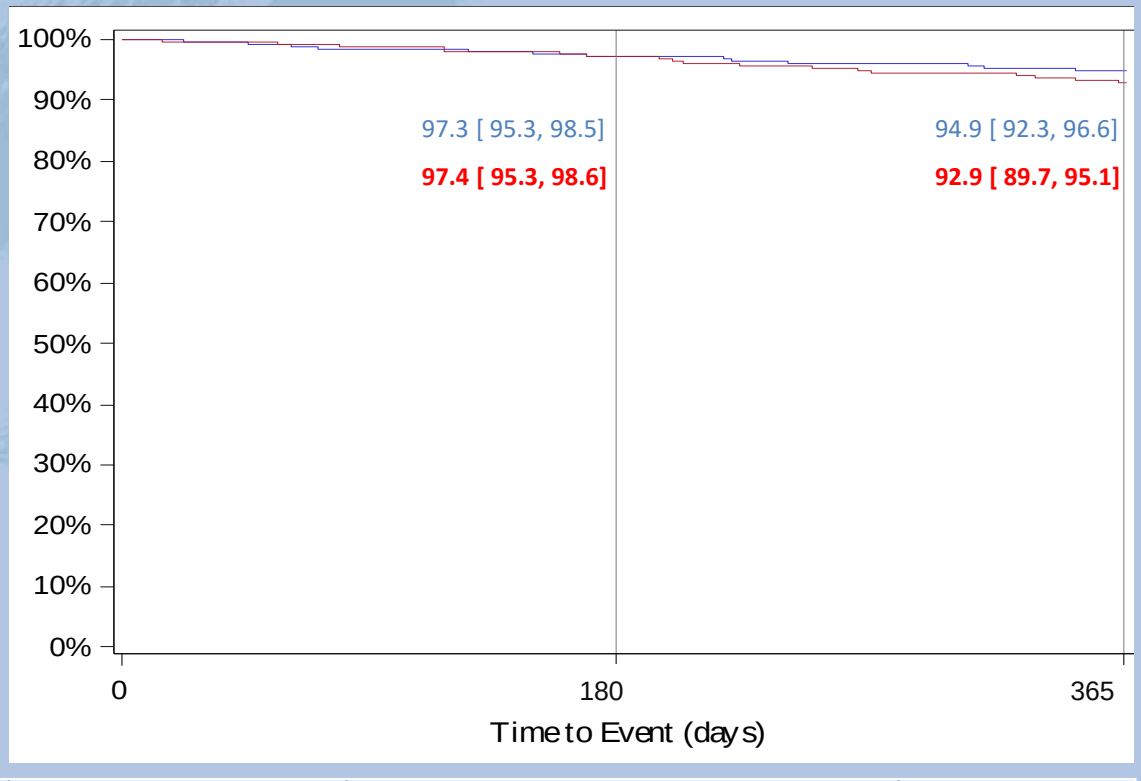
Major Adverse Events[1] Diabetics



	Description	180 days	365 days
Diabetics	Left at risk (baseline: 330)	288	237
	Events	19	34
Non Diabetics	Left at risk (baseline: 370)	341	289
	Events	13	23

(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

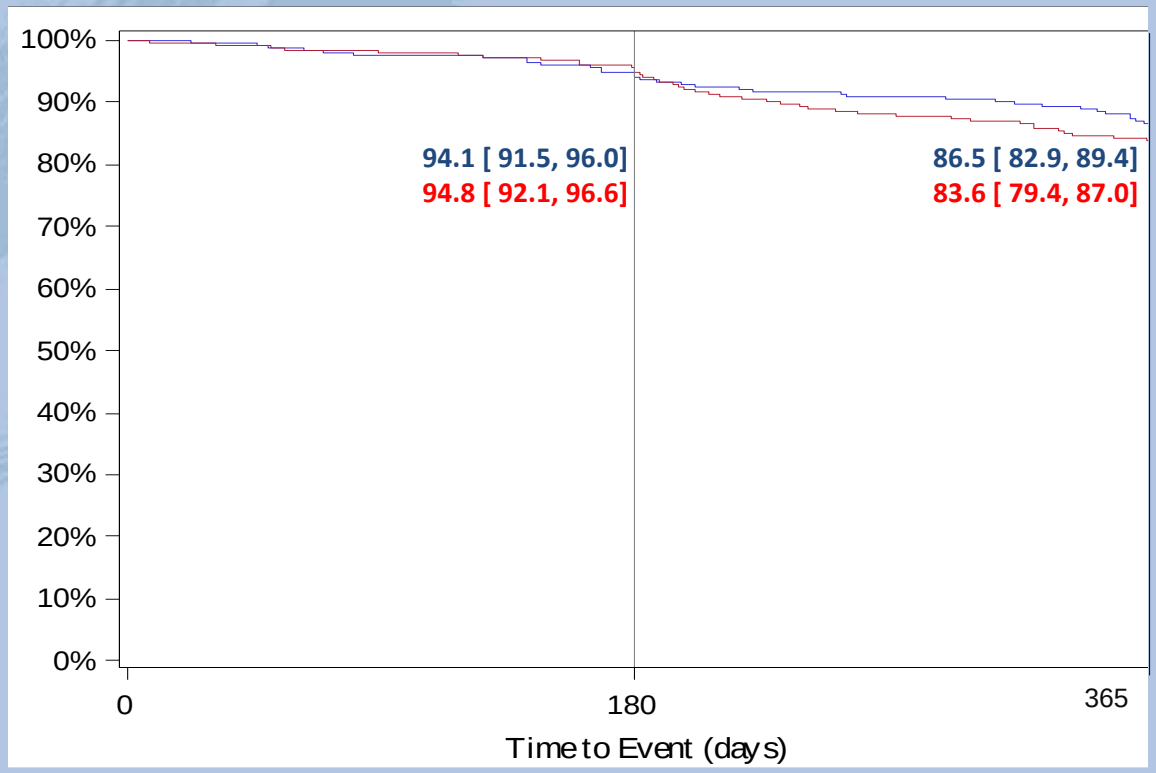
Freedom for CD-TLR[1] Diabetics



	Description	180 days	365 days
Diabetics	Left at risk (baseline: 409)	363	300
	Events	10	26
Non Diabetics	Left at risk (baseline: 455)	425	360
	Events	12	22

(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

Primary Patency[1] Diabetics

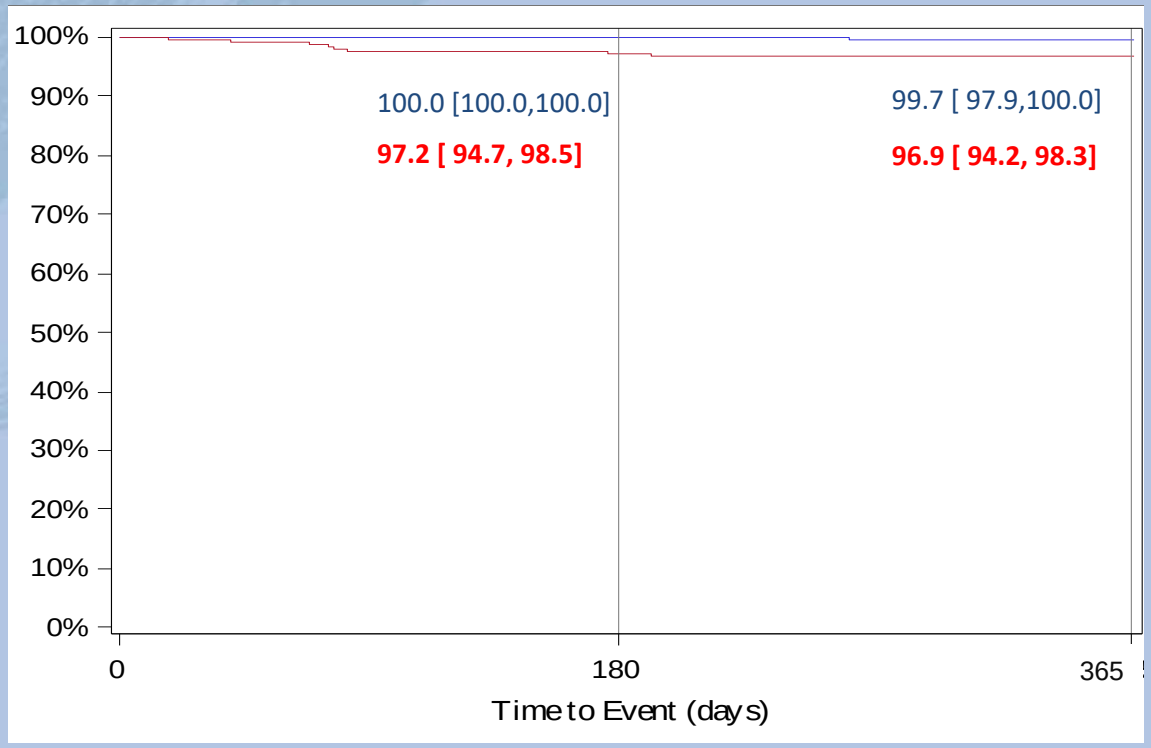


	Description	180 days	365 days
Diabetics	Left at risk (baseline: 409)	353	272
	Events	20	60
Non Diabetics	Left at risk (baseline: 455)	411	328
	Events	26	57

(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

Major Amputations Diabetics

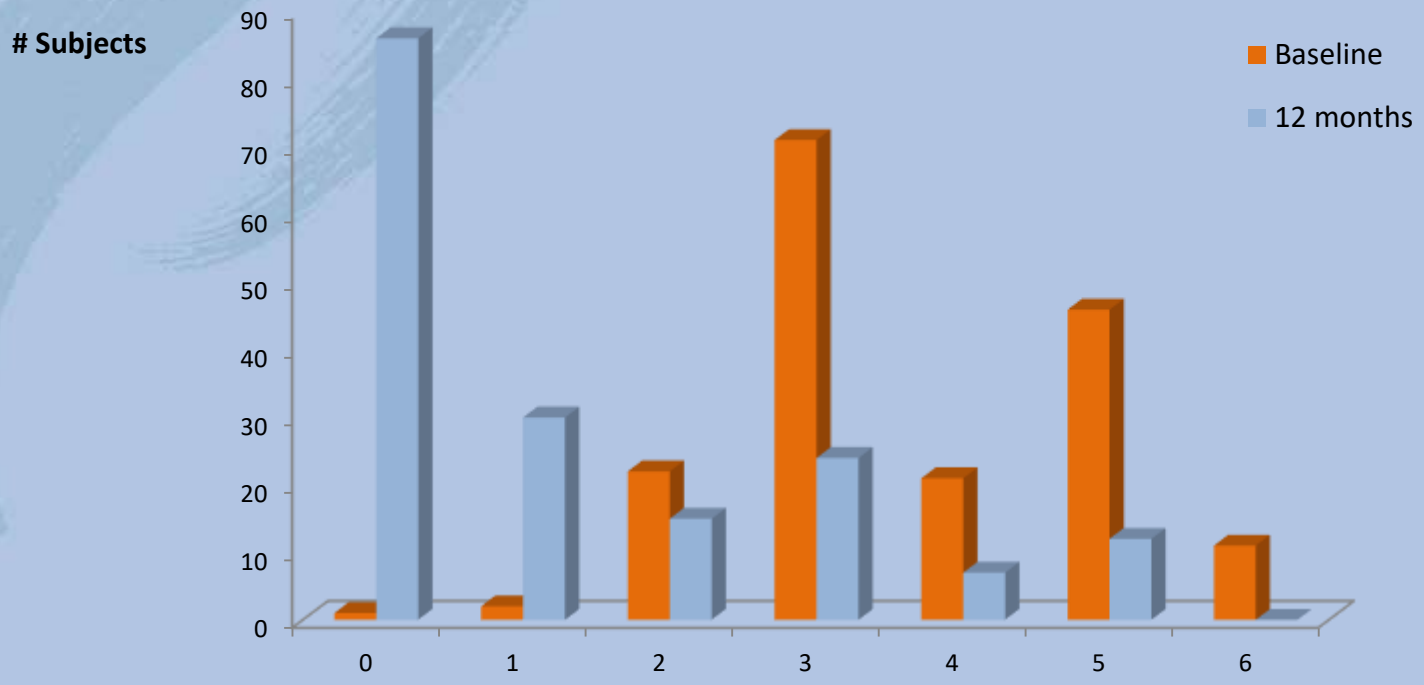


	Description	180 days	365 days
Diabetics	Left at risk (baseline: 331)	299	259
	Events	9	10
Non Diabetics	Left at risk (baseline: 374)	356	311
	Events	0	1

Change in Rutherford Classification

Diabetics

Baseline vs 12 months – paired data



81.6% Diabetics subjects improved significantly in Rutherford Class at 12 months compared to baseline

Conclusion

- 12-month results of BIOLUX P-III All-Comers further confirm Passeo-18 Lux safety and effectiveness in **Diabetics patients**
  - **83.6% Primary Patency**
  - **92.9% Freedom from Clinically-Driven TLR**
  - **11.1% MAE**
  - **3.1% Major Amputations**
  - **81.6% of CLI** subjects improved significantly in Rutherford classification ($p<0.001$) at 12 months

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