Six Month Results of the Global BIOLUX P-III All-Comers Registry using Drug Coated Balloon in Infra-Inguinal Artery Disease

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CCI on behalf of the BIOLUX P-III Investigators

Disclosure

Speaker name: **Prof. Dr. Gunnar Tepe**

I have the following potential conflicts of interest to report:

- ☐ 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

Participating Sites

204 Subjects Reached 6 Month FUP

			# Subject enrolled	#Subjects enrolled up to 25th Jan 2016
Pr G. Tepe (CCI)	**RoMed Klinikum Rosenheim**	**Germany**	**3**	36
Pr M. Brodmann	Medical University Graz	Austria	72	120
Pr T. Zeller	Universitäts-Herzzentrum Freiburg - Bad Krozingen	Germany	28	84
Dr J. K. Christensen	Kolding Hospital	Denmark	15	28
Dr L. Spak	VUSCH East Slovak Cardiology Institute	Slovakia	12	42
Pr C. Binkert	Kantonspital Winterthur	Switzerland	12	19
Dr H. Schröder	Jüdischen Krankenhaus Berlin	Germany	11	20
Pr G. Nano,	Policlinico San Donato	Italy	8	15
Dr M. Araujo	Hospital Universitaro Severo Ochoa	Spain	7	16
Dr L. Yo	Catharina Ziekenhuis Eindhoven Hospital	Netherlands	6	13
Dr J. Dahm	Herz-und Gefässzentrum Göttingen	Germany	5	18
Pr F. Hammer	Cliniques Universitaires Saint-Luc	Belgium	5	6
Dr S. Houthoofd	UZ Leuven	Belgium	5	10
Dr M. Lichtenberg	Klinikum Arnsberg	Germany	3	10
Dr S. Kum	Changi General Hospital	Singapore	2	4
Pr J.L. Magne	Centre Hospitalier Universitaire de Grenoble	France	2	7
Dr J.M. Romero	Hospital Universitari Santa Creu i Sant Pau	Spain	3	8
Dr D. Kretzschmar	Universitätsklinikum Jena	Germany	2	6
Dr E. Alejandre-Lafont	Universitätsklinikum Giessen und Marburg	Germany	2	14
Dr D. Henroteaux	CHR de la Citadelle de Liège	Belgium	1	13
Later initiated sites			0	171
			204	660

All-Comers Design

DESIGN:

Prospective, international, multi-centre, All-Comers registry, with pre-defined subgroups

700+ subjects

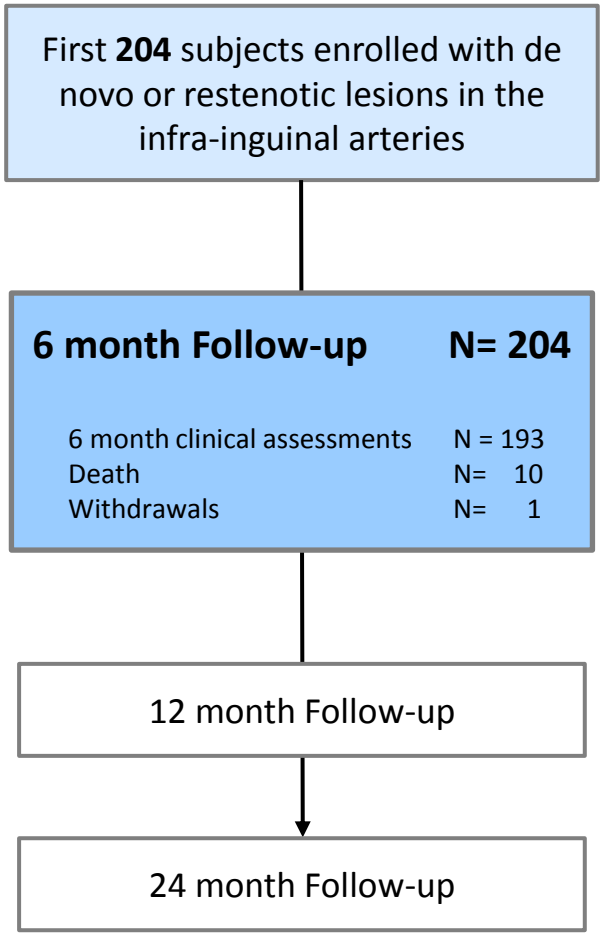
PRIMARY ENDPOINTS:

Clinical:

Freedom from MAE[1] at 6 months

Performance:

Freedom from CD-TLR[2] at 12 months



(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

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

Baseline Characteristics

Age, yrs (mean ± SD), [Min; Max]	70.2 ± 10.4 [44.0 ; 94.0]
Male (n, %)	123 (60.3%)

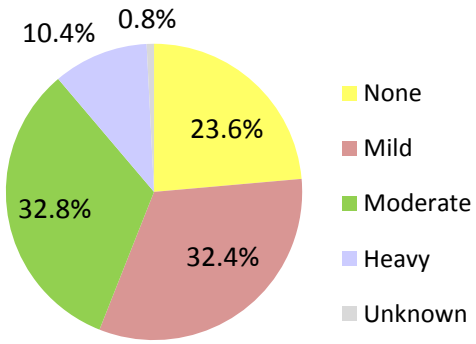
Medical History	**N= 204**	**%**
Hypertension	176	86.3%
Hyperlipidemia	144	70.6%
Smoking	139	68.1%
Current Smokers	53	38.1%
History of PAOD	121	59.3%
Previous PVI /Surgeries	113	55.4%
Diabetes	97	47.5%
Coronary Artery Disease	78	38.2%
Cerebrovascular Disease	50	24.5%

Lesion Characteristics

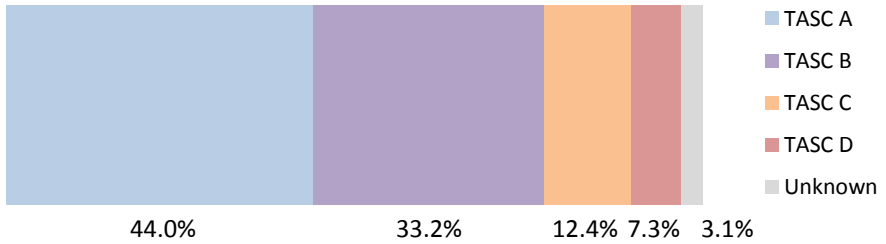
Lesion Characteristics	N= 259
Lesion Length, mm (mean ± SD)	74.3 ± 69.9
Reference Vessel Diameter, mm (mean ± SD)	4.7 ± 1.0
Diameter Stenosis (%)	85.8 ± 13.8
De Novo Lesion (n, %)	136 52.5%
Re-Stenosis (n, %)	39 15.1%
In Stent Restenosis (n, %)	32 12.4%
Occlusion (n, %)	52 20.1%

Lesion Locations	N = 259	%
Common Femoral	2	0.8
Superficial Femoral Artery	148	57.1
Femoro-Popliteal	8	3.1
Popliteal Artery	59	22.8
Anterior Tibial Artery	14	5.4
Posterior Tibial Artery	3	1.2
Tibioperoneal Trunc	11	4.2
Peroneal Artery	4	1.5
Combination of Infrapopliteal Arteries	3	1.2
Other (Bypass, Illiac)	7	2.7

Calcification



TASC Classification



Procedure Details

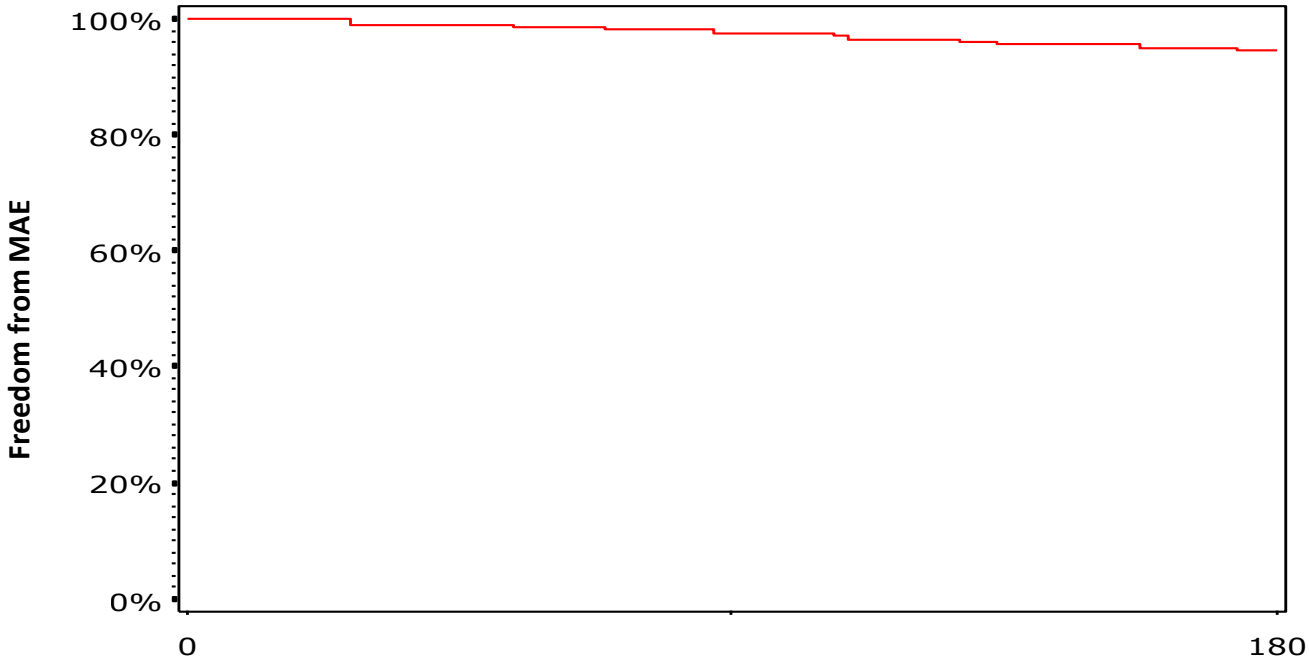
	N= 259	%
Lesion treated with DCB **only**	213	82.2

Combination therapy		%
DCB + Stent[1]	30	11.6
DCB + Scoring / Cutting /Rotational Devices	13	5.0
DCB + Scoring / Cutting /Rotational Devices + Stent	3	1.2

(1) Only planned stenting - not bailout stenting

Freedom From MAE

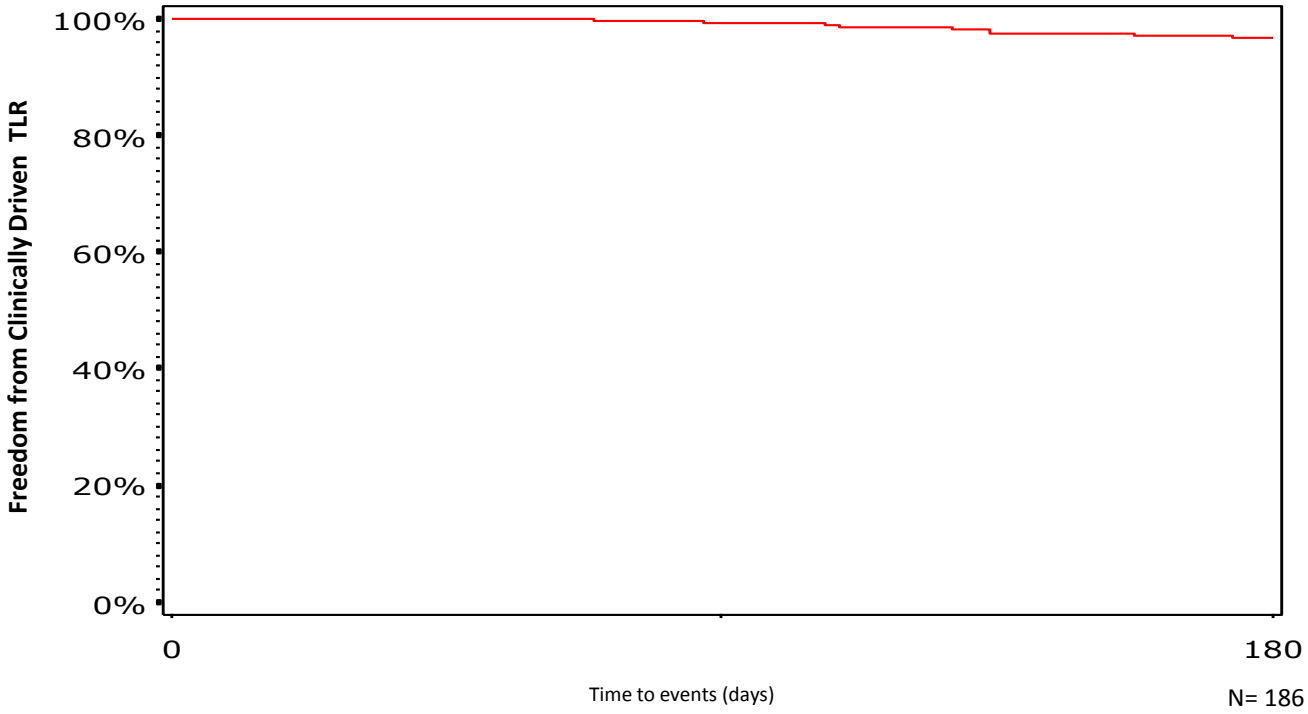
(adjudicated by an independent CEC)



94.4% *SE 0.0163*
CI95% [90.2, 96.9]

MAE (composite of procedure or device related death within 30 days post index procedure, CD-TLR, Target Limb Major amputation)	**11**	**94.4%**
Death	1	99.5%
Clinically Driven Target Lesion Revascularization	8	96.8%
Target Limb Major Amputation	2	99.0%

Freedom From Clinically Driven Target Lesion Revascularization[1]



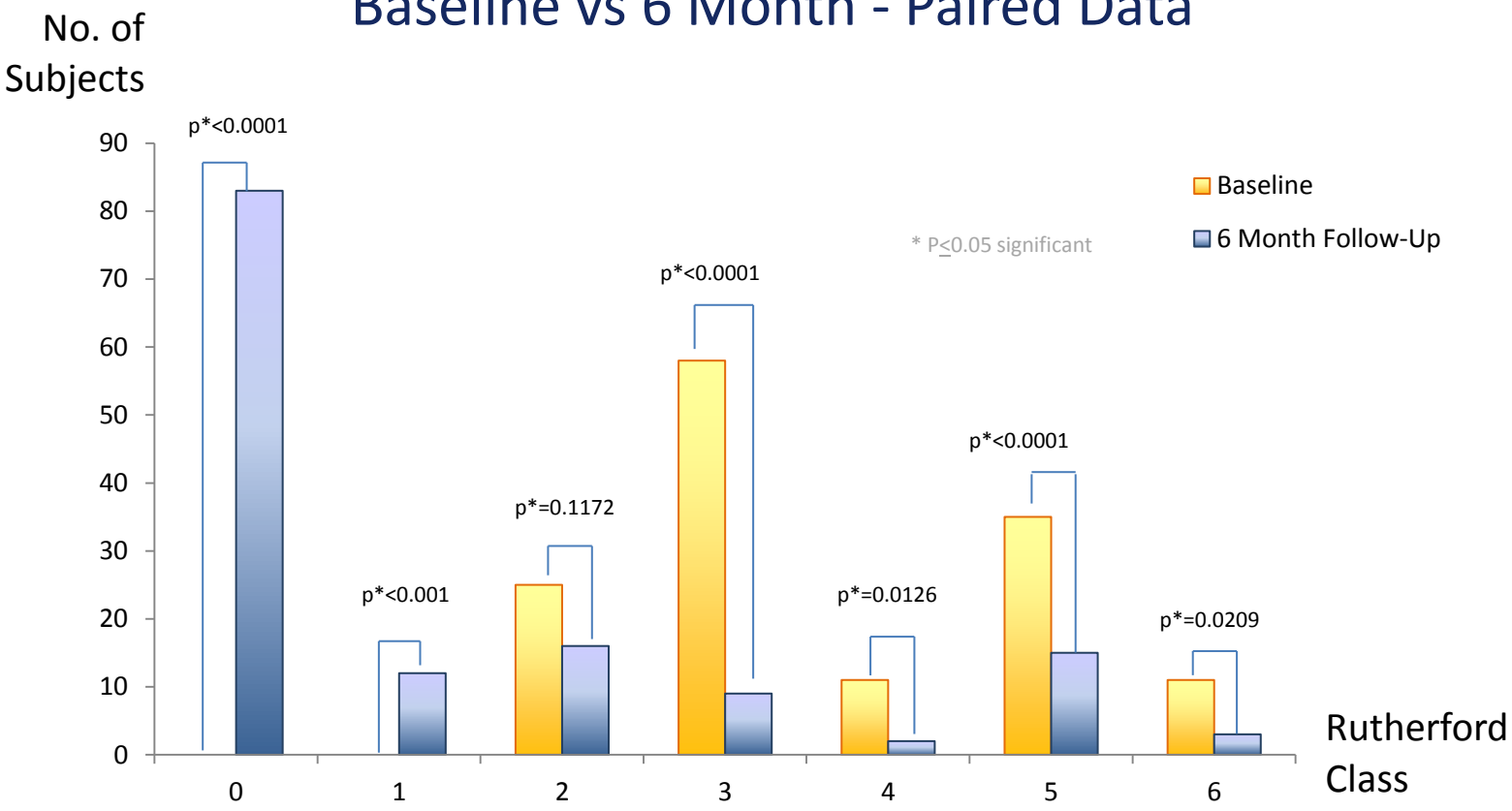
96.8% *SE 0.0112*
CI95%[93.7, 98.4]

N= 186

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

Change in Rutherford Classification

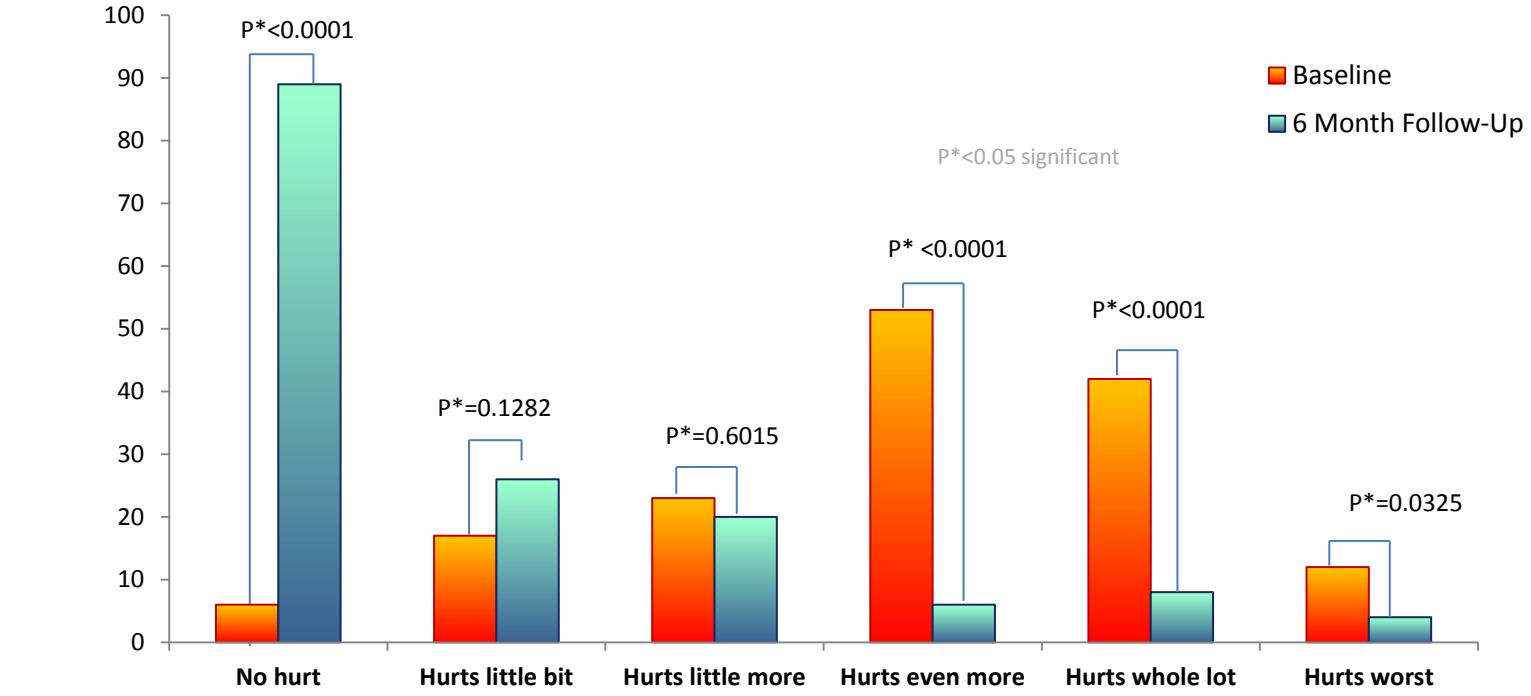
Baseline vs 6 Month - Paired Data



80.0% of all subjects improved significantly in Rutherford Class at 6 months compared to baseline

Change in Pain Scale[1]

Baseline vs 6 Month - Paired Data



80.4% of all subjects improved significantly in Pain Scale at 6 months compared to baseline

(1) Wong-Baker FACES® Pain Rating Scale

Conclusion

- BIOLUX P-III is a real **All-Comers Registry** evaluating the performance of DCB in daily practice in respect to patient and lesion characteristics and combination therapy
- 6 Months results of the first 200 subjects present comparable safety and performance results:
  - **96.8 % Freedom from Clinically Driven Target Lesion Revascularization**
  - **80.0 %** of subjects improved significantly in **Rutherford classification** ($p<0.001$)
  - **80.4%** subjects experienced significantly **less pain** at 6 months compared to baseline ($p<0.001$)
- Further **subgroup analysis** will reveal even more insight in daily routine practice – specifically DCB in combination therapy

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