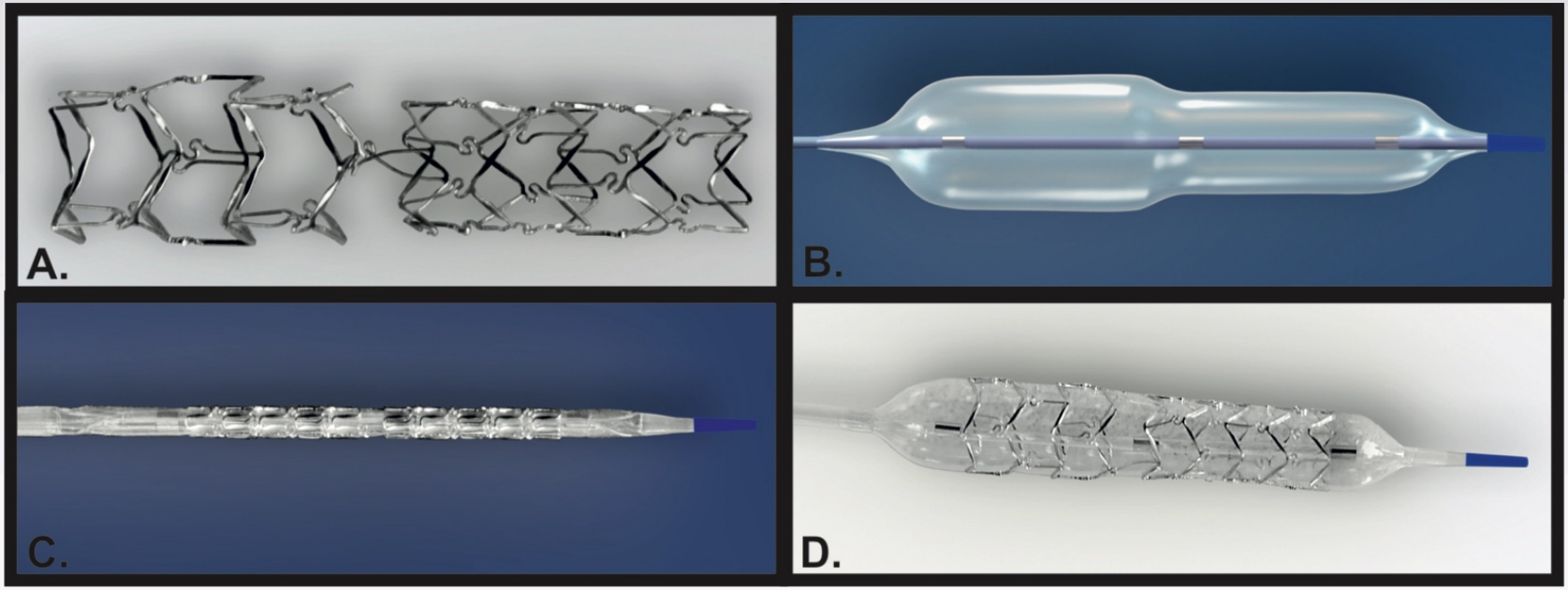
EBC

My missing bifurcation study

POLBOS 3

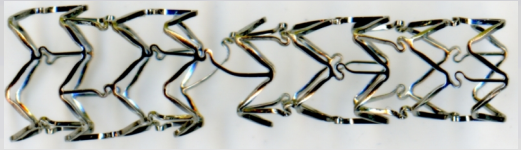
Robert J. Gil, MD, PhD, FESC
Mossakowski Medical Research Centre, Polish Academy of Sciences
Invasive Cardiology Dept., Central Hospital of the Internal Affairs Ministry, Warsaw, Poland

Bifurcation Optimization Stent System - BiOSS® (Balton, PL)



The BiOSS® is a coronary, dedicated balloon-expandable bifurcation stent. The platform is made of 316L stainless steel (strut thickness 120 µm) and is coated with a biodegradable polymer that elutes sirolimus – BiOSS Lim (drug concentration: 1.2 µg/mm^2) or paclitaxel – BiOSS Expert (drug concentration: 1.0 µg/mm^2).

BiOSS® stent Clinical Programme



BiOSS® Expert vs regular DES for mechanisms of lumen enlargement assessed with IVUS (n=32) Int J Cardiovasc Imaging (2013) 29:1667–1676

BiOSS® Expert First-In-Men (n=63)
EuroIntervention. 2012 Jul 20;8(3):316-24.

BiOSS® Expert Left Main Registry (n=54)
J Interven Cardiol 2014;9999:1-10

POLBOS I: BiOSS® Expert vs regular DES randomized trial (120/123)
Can J Cardiol. 2015 May;31(5):671-8

BiOSS® Lim First-In-Men n=60
J Interv Cardiol. 2015 Feb;28(1):51-60. doi: 10.1111/joic.12180.

POLBOS II: BiOSS® Lim vs regular DES randomized trial (n=102/100)
EuroIntervention 2015;11-online publish-ahead-of-print November 2015

BiOSS® Lim Left Main Registry n=75
EuroIntervention. 2015 Oct 15;11(6). pii: 20150313-02

12-month intravascular ultrasound observations from BiOSS® First-In-Man studies (n=32)
Int J Cardiovasc Imaging (2016) accepted

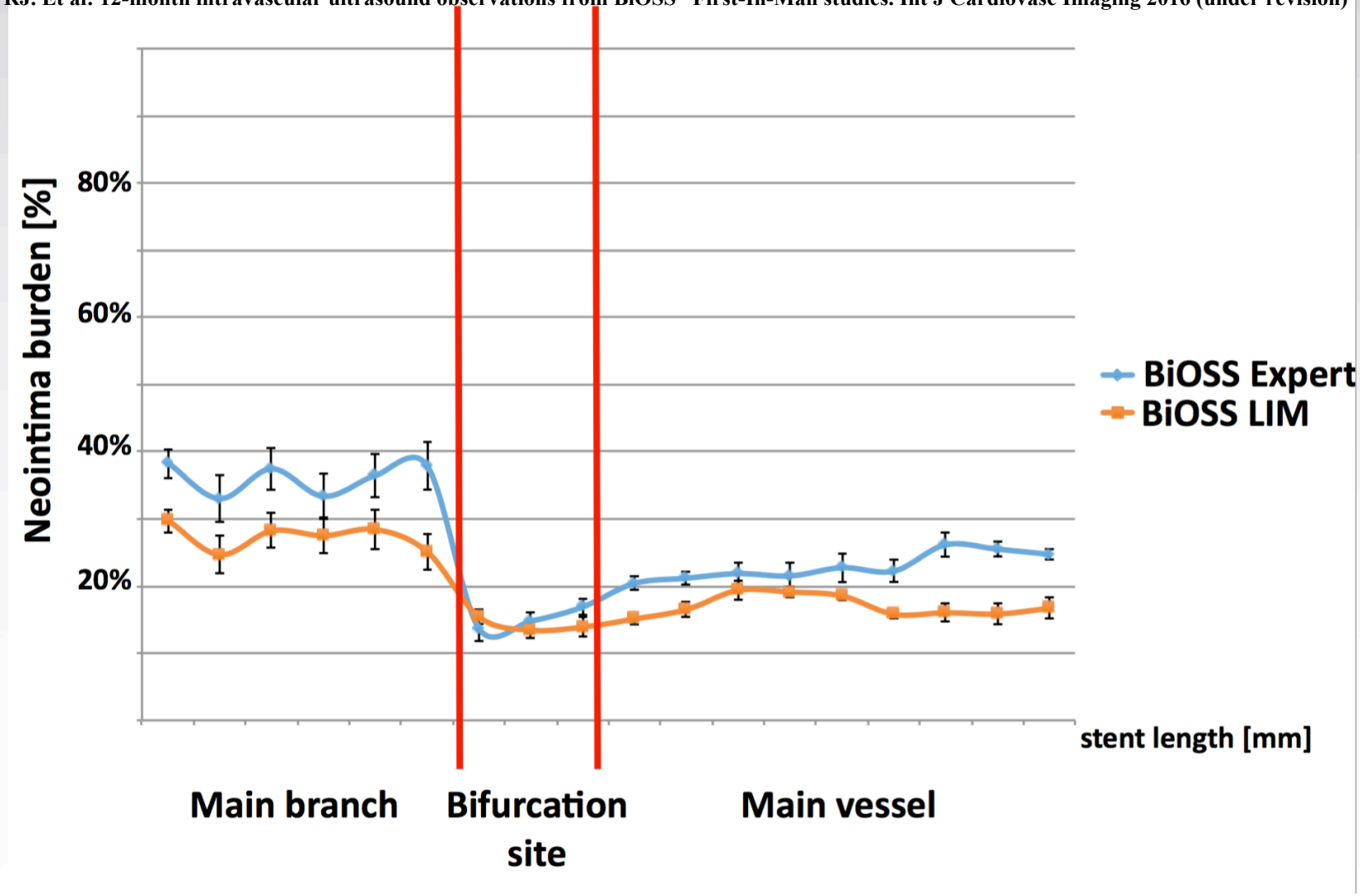
BiOSS vs regular DES – Intravascular Ultrasound Study

Gil RJ et al.: Int J Cardiovasc Imaging 2013; DOI 10.1007/s10554-013-0264-0

	DES		BiOSS		p	
	pre	post	pre	post	pre	post
MLA target [mm^2]	2.87±0.78	6.08±2.01	2.99±0.82	6.49±2.2	0.68	0.68
Lumen Area PL [mm^2]	4.78±1.49	7.86±2.08	3.89±0.98	7.84±1.99	0.06	0.97
Lumen Area DL [mm^2]	5.21±3.18	7.46±2.2	4.78±2.18	6.44±1.85	0.66	0.17
LA window [mm^2]	4.86±2.44	7.63±2.03	3.99±1.19	6.52±1.64	0.21	0.1
Window length (mm)	2.31±0.38	1.76±0.52	2.09±0.50	2.21±0.37	0.79	0.01

Change of neointima burden in particular parts of the analyzed BiOSS® stents.

Gil RJ. Et al: 12-month intravascular ultrasound observations from BiOSS® First-In-Man studies. Int J Cardiovasc Imaging 2016 (under revision)



Clinical results

	BiOSS LIM Registry		BiOSS Expert Registry		P (12 mo)
	30 days n = 60	12 Mo n = 60	30 days n = 63	12 Mo n = 63	
death	0	1 (1.7%)	0	2 (3.2%)	NS
MI	0	1 (1.7%)	0	0	NS
ST	0	0	0	0	NS
TLR	0	5 (8.3%)	0	7 (11.3%)	NS
clinically-driven TLR	0	1 (1.7%)	0	3 (4.8%)	NS
TVR	0	7 (11.7%)	0	9 (14.3%)	NS

BiOSS®: Expert + Lim in LMS

Bil J et al.: J Interven Cardiol 2014;27:242-252
Gil RJ et al.: EuroIntervention 2015, Oct 15;11(6).

Endpoints 12 months	BiOSS Expert N = 54 (%)	BiOSS LIM N = 74 (%)	Pooled data N = 128 (%)
MACE	5 (9.3)	7 (9.5)	12 (9.4)
death	0	0	0
cardiac death	0	0	0
MI	0	2 (2.7)	2 (1.6)
stroke	0	0	0
ST	0	0	0
TLR	5 (9.3)	5 (6.8)#	10 (7.8)
TVR	5 (9.3)	9 (12.2)	10 (7.8)

p = 0.07

Pooled data POLBOS 1 and POLBOS 2

12-month clinical results

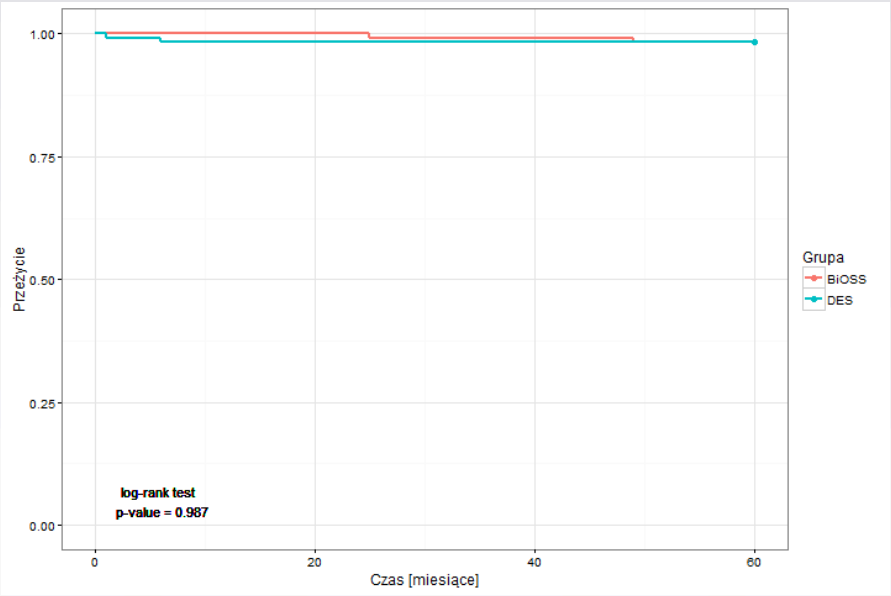
Parameter	Total	BiOSS Group	rDES Group	P
	N (%)	N (%)	N (%)	
MACE	58 (13.0%)	28 (12.6%)	30 (13.5%)	0.771
death	9 (2%)	3 (1.4%)	6 (2.7%)	0.503
MI	11 (2.5%)	4 (1.8%)	7 (3.1%)	0.544
TLR	42 (9.4%)	24 (10.8%)	18 (8.1%)	0.336

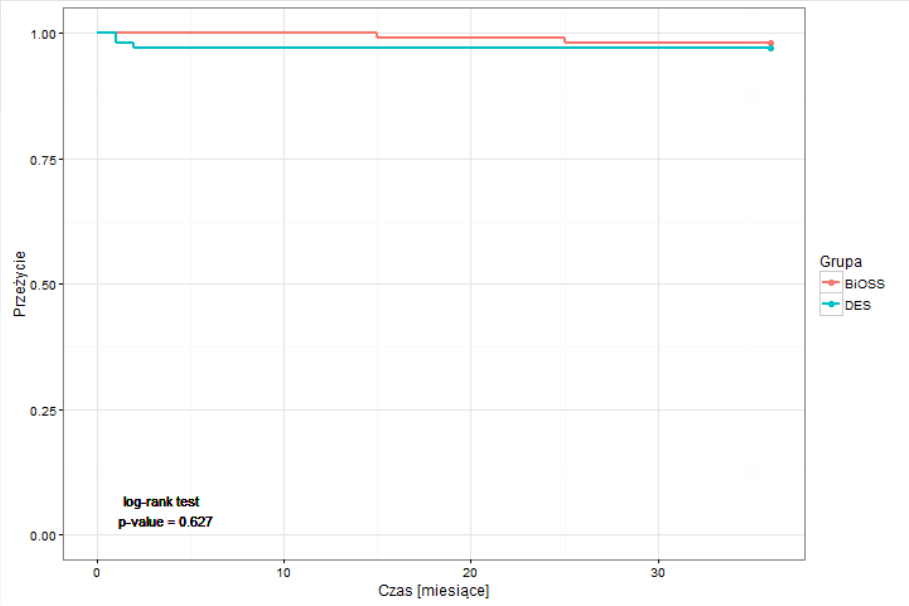
12-month clinical results showing type of stent distribution

Parameter	Total n = 445	BiOSS Expert n = 120	BiOSS LIM n = 102	DES limus n = 155	DES PES n = 68	P
	N (%)	N (%)	N (%)	N (%)	N (%)	
MACE	58 (13%)	16 (13.3%)	12 (11.8%)	17 (10.9%)	13 (19.1%)*	0.277
Death	9 (2%)	2 (1.7%)	1 (1.0%)	4 (2.6%)	2 (2.9%)	0.78
MI	11 (2.5%)	2 (1.7%)	2 (2.0%)	5 (3.2%)	2 (2.9%)	0.84
TLR	42 (9.4%)	14 (11.7%)	10 (9.8%)	8 (5.2%)	10 (14.7%)*	0.08

K-M Curves for POLBOS 1 and POLBOS 2

Cardiac death



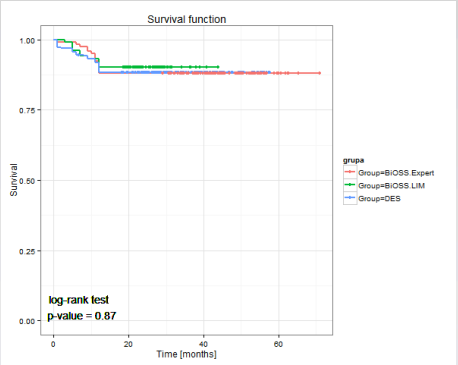


POLBOS 1

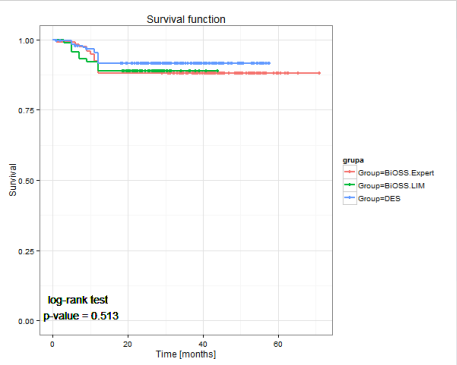
POLBOS 2

WHOLE POPULATION

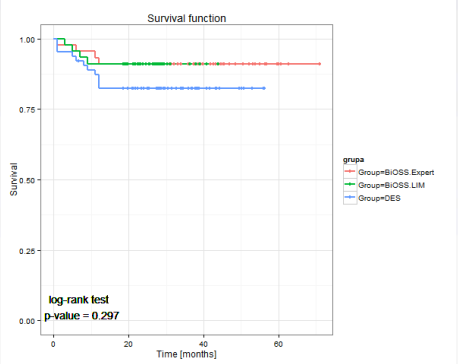
MACE

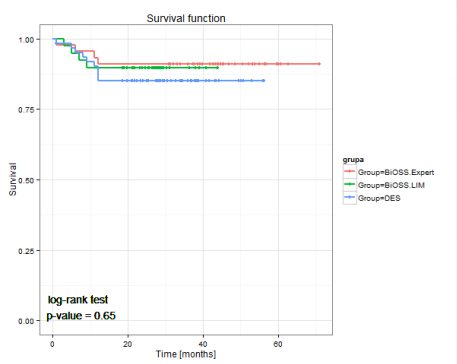


TLR

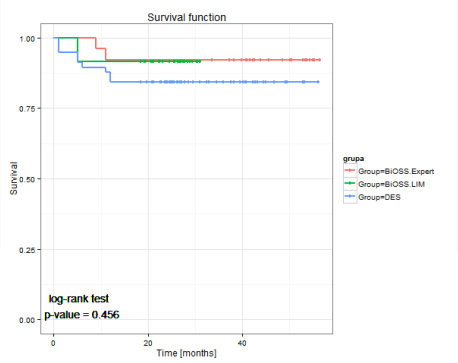


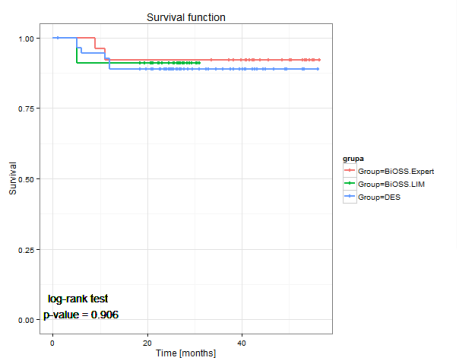
DIABETIC SUBGROUP



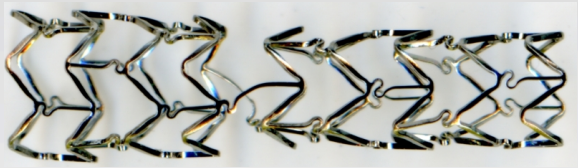


LM SUBGROUP





Late Lumen Loss for BiOSS®

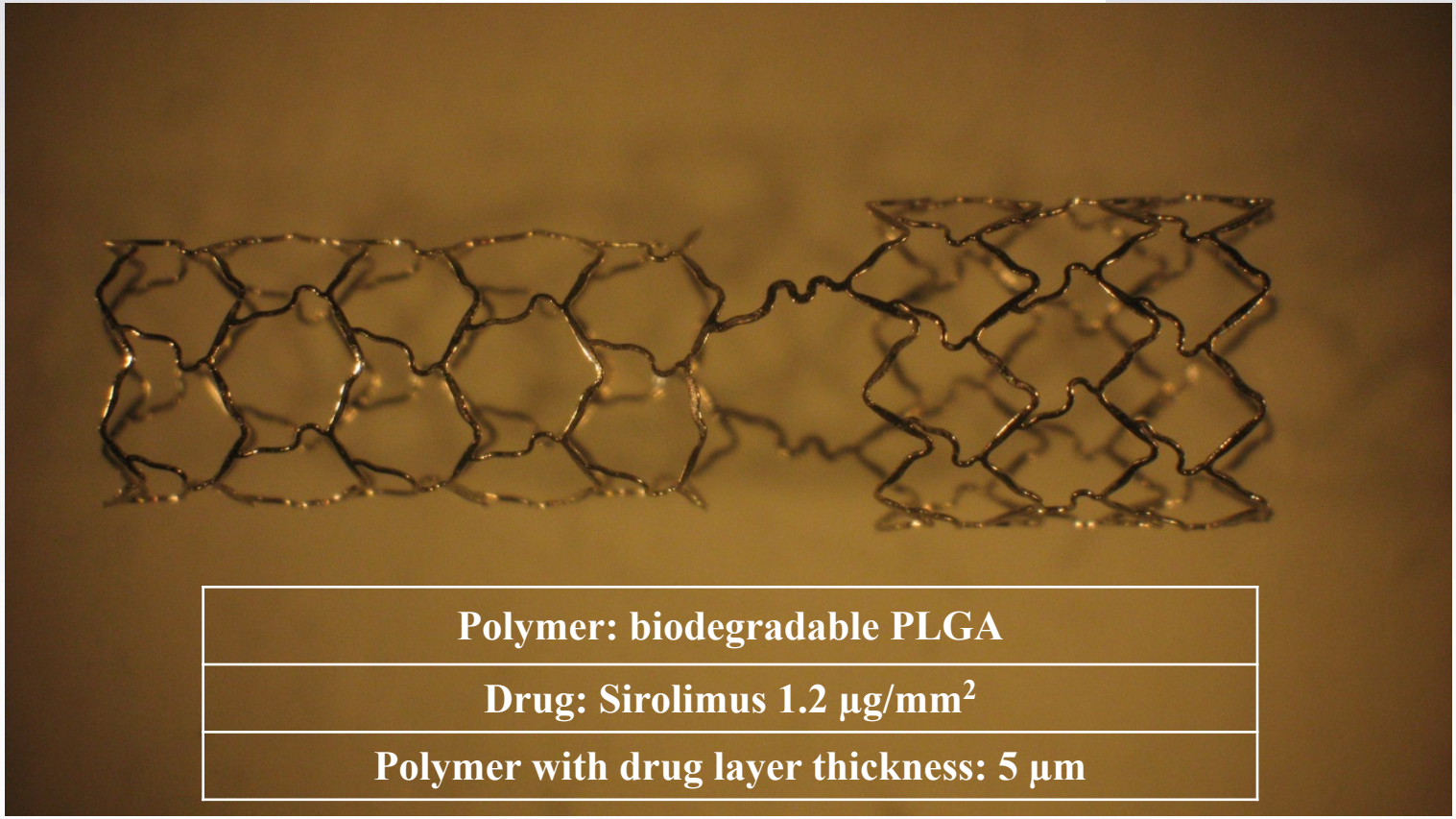


		All	LMS	non-LMS
BiOSS LIM	**MV**	0.35 ± 0.07	0.39 ± 0.11	0.31 ± 0.05
	MB	0.34 ± 0.09	0.37 ± 0.12	0.32 ± 0.07
	SB	0.18 ± 0.06	0.16 ± 0.04	0.19 ± 0.08
BiOSS Expert	**MV**	0.46 ± 0.18*	0.58 ± 0.21*	0.34 ± 0.14
	MB	0.39 ± 0.16	0.26 ± 0.14*	0.52 ± 0.18*
	SB	0.04 ± 0.02*	0.09 ± 0.01*	-0.05 ± 0.02*

* BiOSS LIM vs BiOSS Expert

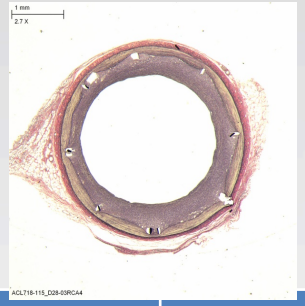
BIOSS® Lim C(rCo)

L605 alloy
Closed cell
Strut thickness 0.07mm

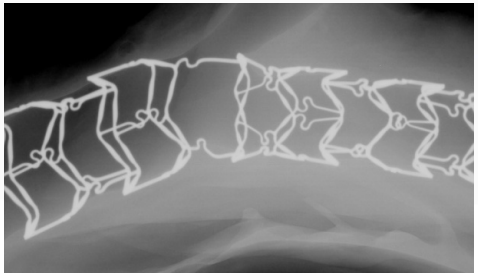


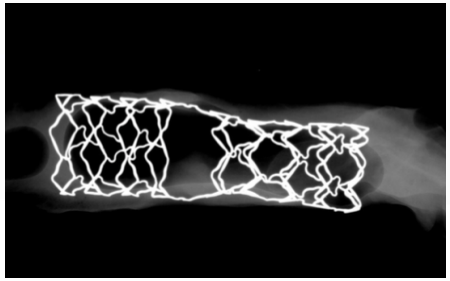
BIOSS Lim® vs BiOSS Lim CrCo® vs Orsiro®

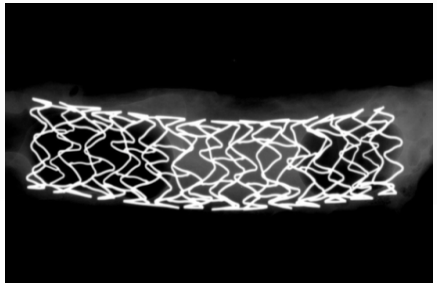
28 days OCT histology data in animal coronaries



	BiOSS Lim (prox)	BiOSS Lim (dist)	BiOSS CrCo	Orsiro	P
Neointimal area (mm^2)	2,19±1,12#	1,58±0,78#	1,03±0,50	1,14±0,21	<0,05
Mean intimal thickness (mm)	0,23±0,12#	0,22±0,14#	0,11±0,03	0,12±0,02	<0,05







Courtesy of Dr K. Milewski, AHP, PL

BIOSS® (Balton, PL) vs Orsiro® (Biotronik, D)

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28 days OCT data in animal coronaries

Parametr	BIOSS COR Lim (C)		ORSIRO		p
	Mean	SD	Mean	SD	
RD mean	3,10	0,161	3,19	0,211	0,141
%AS	0,20	0,067	0,16	0,027	0.293
%DS	0,12	0,029	0,085	0,015	0.069
Neointimal Area	1,5	0,46	1,2	0,25	0.247
Neointimal Thickness	0,36	0,086	0,27	0,051	0.174

Parameters		BIOSS COR (K) n=7	ORSIRO n=6	Kruskal-Wallis p-value
Injury Score	Mean±SD	0.34±0.22	0.09±0.08	0.127
Inflammation Score	Mean±SD	0.33±0.22	0.39±0.21	0.472
Fibrin Score	Mean±SD	1.20±0.23	1.53±0.25	0.197
Endothelialization Score	Mean±SD	1.86±0.32	1.50±0.63	0.393
Neointimal Smooth Muscle Score	Mean±SD	1.86±0.20	1.50±0.35	0.108

Courtesy of Dr K. Milewski, AHP, PL

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First-In-Men BiOSS® CrCo Registry has just started in Poland.

International, multicenter, randomized trial POLBOS 3 with thin struts BiOSS® CrCo is being prepared.

POLBOS 3 randomized study

Patients qualified for PCI in coronary bifurcation lesion (PTS as intention to treat)

⇓

Inclusion/Exclusion criteria met

⇓

Randomization 1:1 (480 pts)

240 pts — BiOSS LIM C

240 pts — Xience/Resolute

80 pts distal LM + 160 pts regular bifurcation

80 pts distal LM + 160 pts regular bifurcation

OCT evaluation in subgroups:

- 3 months (15-20pts)
- 6 months (15-20pts)
- 9 months (15-20pts)

Predilatation

Stent implantation

POT (+) envelope randomization POT (-) POT (+)

SB dilatation and/or KBI

CLINICAL FOLLOW-UP AT

- 30 day
- 6 months
- 12 months

Primary endpoint:

- cumulative MACE (death, MI, ST, TLR)

Secondary endpoints:

- device success
binary restenosis
- OCT results

POLBOS 3 randomized study

Questions to be answered:

1. No of planned pts
2. Endpoints: primary, secondary
3. Implementation of LM into the Study
4. DAPT or single drug, duration
5. OCT substudy: numbers and timing