

# **Sessions: Dedicated stents for distal left main stenosis.**

**Left main treatment with BiOSS stents (Balton, PL).**

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# Disclosure Statement of Financial Interest

**Within the past 12 months, I Robert J. Gil or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.**

## **Affiliation/Financial Relationship**

- Grant/Research Support
- Consulting Fees/Honoraria
- Major Stock Shareholder/Equity
- Royalty Income
- Ownership/Founder
- Intellectual Property Rights
- Other Financial Benefit

## **Company**

- NA
- BALTON, Abbott Vascular, Medtronic, Boston Scientific, Eli Lilly, Astra Zeneca
- NA
- NA
- NA
- NA
- NA

## Methods

### Registries

#### Inclusion criteria:

- **patients with all types of coronary bifurcation to be treated with PTS**
- **able to take DAP for 12 months**
- **serum creatinine <2.0 mg/dl**

**Exclusion criteria – lack of informed consent and STEMI pts**

# BiOSS<sup>®</sup> in distal LM treatment

## Safety and feasibility studies

- **Primary end-point**
  - comp. MACE (death, ST, MI, TLR), event rates at 12 months
- **Secondary end-points**
  - Device performance – implantation failure rates
  - Periprocedural safety – rate of periprocedural SB compromise (SB closure rates, elev. CK-MB)
  - Angiographic (after 9 months):
    - Late Lumen Loss (LL)
    - Percent Diameter Stenosis (%DS)
    - Binary restenosis rate

Baseline clinical characteristics		BiOSS Expert N = 54 (%)	BiOSS LIM N = 74 (%)	Pooled data N = 128 (%)
Age [years]		65.6 ± 11.5	67 ± 9	66.7 ± 8
Women [%]		10 (18.5)	17 (23)*	27 (21.1)
Hypertension		42 (77.8)	65 (87.8)*	107 (83.6)
Hypercholesterolemia		38 (70.4)	63 (85.1)*	101 (78.9)
Diabetes type 2		15 (27.8)	26 (35.1)*	41 (32)
Prior MI		28 (51.9)	41 (55.4)	69 (53.9)
Prior PCI		29 (53.7)	40 (54.1)	69 (53.9)
CABG		9 (16.7)	15 (20.3)	24 (18.8)
Peripheral artery disease		2 (3.7)	4 (5.4)	6 (4.7)
Chronic kidney disease		9 (16.7%)	11 (14.9)	20 (15.6)
<b>Clinical indication for PCI</b>				
	planned PCI	47 (87)	59 (79.7)*	106 (82.8)
	UA/NSTEMI	7 (13)	15 (20.3)*	22 (17.2)
	STEMI	0	0	0

Baseline angiographic characteristics		BiOSS Expert N = 54 (%)	BiOSS LIM N = 74 (%)	Pooled data N = 128 (%)
SYNTAX score		21.52 ± 6.58	22.42 ± 4.38*	21.92 ± 3.78
Multivessel disease		36 (66.7)	61 (82.4)*	97 (75.8)
Functional LIMA on LAD		6 (11.1)	8 (10.8)	14 (10.9)
Lesion type				
	A	0	0	0
	B1	18 (33.3)	26 (35.2)	44 (34.4)
	B2	25 (46.3)	36 (48.5)	61 (47.7)
	C	9 (16.7)	12 (16.3)	23 (17.9)

Parameter	BiOSS Expert N = 54 (%)	BiOSS LIM N = 74 (%)	Pooled data N = 128 (%)
Device success	54 (100)	73 (98.6)	127 (99.2)
MV predilatation	28 (51.9)	38 (51.4)	66 (51.6)
SB predilatation	13 (24.1)	14 (18.9)	27 (21.1)
both branches predilatation	12 (22.2)	9 (12.2)*	21 (16.4)
nominal stent diameter in MV [mm]	4.07 ± 0.26	4.05 ± 0.32	4.06 ± 0.31
nominal stent diameter in MB [mm]	3.36 ± 0.26	3.32 ± 0.33	3.34 ± 0.31
nominal stent length [mm]	16.61 ± 1.72	17.57 ± 2.81	17.17 ± 2.41
SB postdilatation	34 (63)	26 (35.1)*	70 (54.7)
FKB	36 (66.7)	35 (47.3)*	71 (55.5)
POT	13 (24.1)	18 (24.3)	31 (24.2)
additional stent in SB	14 (25.9)	11 (14.9)*	25 (19.5)

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

<sup>#</sup> p = 0.07

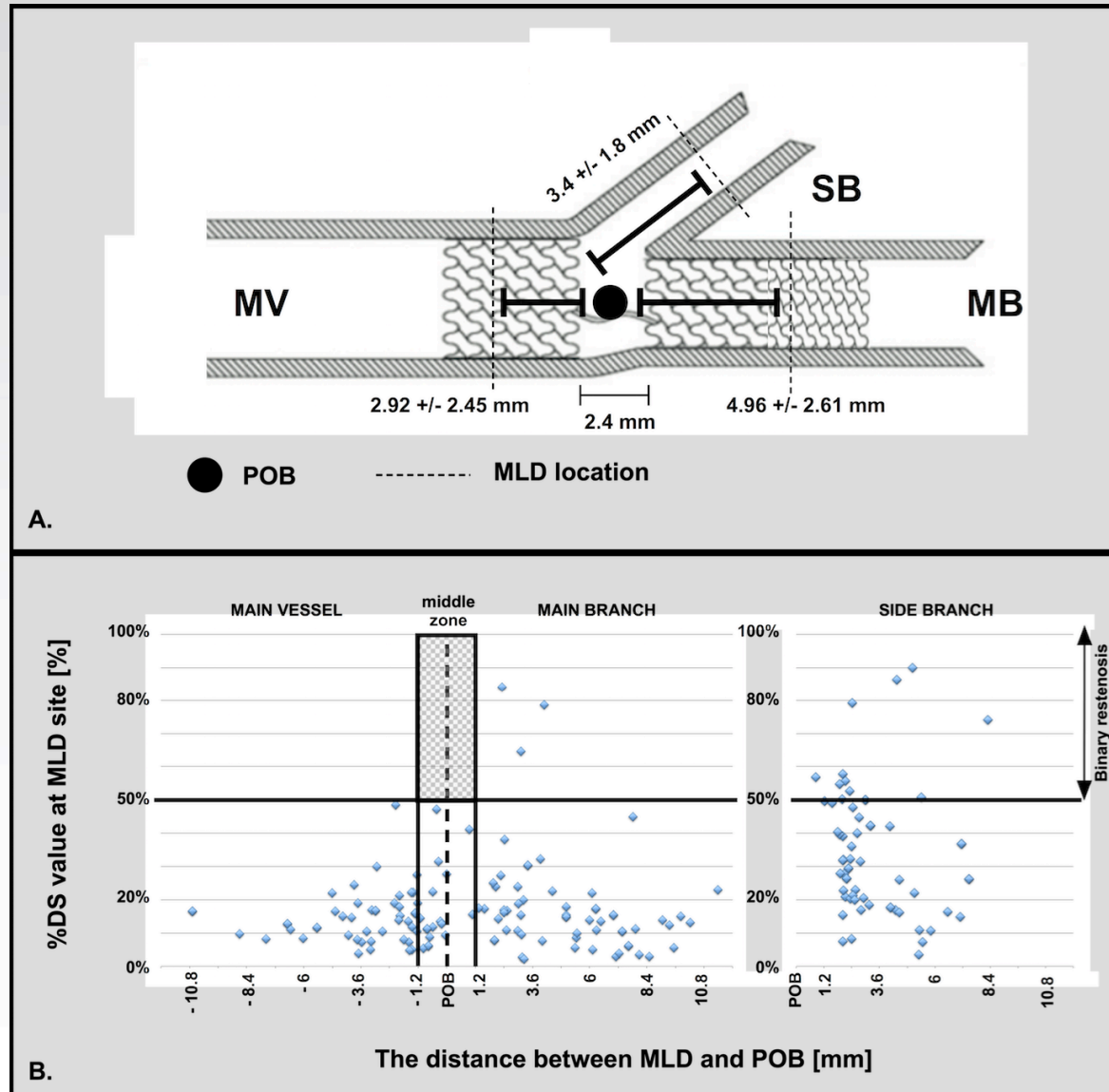
## BiOSS Expert: Restenosis pattern

No	Time [month]	Type	Localization			TLR	Treatment
			MV	MB	SB		
1.	6.5	Focal*	-	+	+	clinically-driven	CABG
2.	11	Diffuse* <sup>#</sup>	-	+	-	angiographically-driven	CABG
3.	12	Focal	-	+	-	angiographically-driven	POBA
4.	13	focal	-	+	-	angiographically-driven	DES
5.	10.5	focal	-	+	-	angiographically-driven	POBA

\*FKB – yes, #POT - yes

## BiOSS LIM: TLR cases

No.	1.	2.	3.	4.	5.
Time to TLR [month]	6	9	11	6	12
Type	focal	focal	focal	diffuse	focal
BiOSS stent diameter [mm]	3.5x3	3.5x2.75	3.5x3	3.5x2.75	4.25x3.75
BiOSS stent length [mm]	18	18	15	18	18
FKB	+	-	+	-	+
POT	-	-	-	+	-
DES in SB	+	-	+	+	+
Medina type at baseline	0,1,1	1,0,1	1,0,1	1,0,1	1,1,1,
Medina type at FU	0,0,1	0,1,0	0,0,1	0,1,1	0,0,1
MLD-POB in MV at FU [mm]*	-	-	-	-	-
MLD-POB in MB at FU [mm]*	-	2.31	-	4.09	-
MLD-POB in SB at FU [mm]*	3.4	-	4.3	0.84	5.02
Treatment	DES	POBA	DES	DES	POBA



# Registries: BiOSS<sup>®</sup> Expert + Lim in LMS (OR for MACE)

## UNIVARIATE LOGISTIC ANALYSIS

Parameter	OR (95% CI)	p-value
Group BiOSS.LIM*	0.710 (0.205 - 1.524)	0.375
Male sex	1.111 (0.321 - 3.472)	0.859
Age	0.875 (0.520 - 1.114)	0.427
True Bifurcation	0.944 (0.795 - 1.024)	0.596
FKB	0.467 (0.158 - 1.546)	0.158
POT	0.324 (0.208 - 0.987)	0.043
SB stent	1.402 (0.925 - 2.592)	0.172
NSTE-ACS	1.961 (0.866 - 5.441)	0.259
HTN	1.426 (0.625 - 6.868)	0.543
DM	1.412 (0.721 - 3.072)	0.659
DM on insulin	3.108 (0.943 - 18.210)	0.068
Dyslipidemia	0.763 (0.577 - 1.471)	0.440
prior MI	0.881 (0.412 - 2.652)	0.873
prior PCI	0.805 (0.347 - 1.937)	0.414
CABG	2.198 (0.667 - 4.009)	0.214

\*1,0 for BiOSS Expert

## MULTIVARIATE LOGISTIC ANALYSIS

Parameter	OR (95% CI)	p-value
POT	0.284 (0.068 - 0.859)	0.025

Bil J et al.: J Interven Cardiol 2014;27:242-252  
Gil RJ et al.: EuroIntervention 2015, accepted

# Registries: BiOSS<sup>®</sup> Expert + Lim in LMS (OR for TLR)

## UNIVARIATE LOGISTIC ANALYSIS

Parameter	OR (95% CI)	p-value
<b>Group BiOSS.LIM*</b>	0.530 (0.305 - 2.524)	0.178
<b>Male sex</b>	1.001 (0.421 - 2.972)	0.759
<b>Age</b>	0.891 (0.720 - 1.224)	0.827
<b>True Bifurcation</b>	0.654 (0.395 - 1.324)	0.396
<b>FKB</b>	0.367 (0.278 - 1.246)	0.078
<b>POT</b>	0.224 (0.108 - 0.767)	0.031
<b>SB stent</b>	1.422 (1.091 - 2.692)	0.045
<b>NSTE-ACS</b>	1.661 (0.766 - 4.341)	0.359
<b>HTN</b>	1.325 (0.735 - 5.368)	0.443
<b>DM</b>	1.612 (0.611 - 3.412)	0.759
<b>DM on insulin</b>	2.808 (1.06 - 12.110)	0.038
<b>Dyslipidemia</b>	0.663 (0.647 - 1.321)	0.540
<b>prior MI</b>	0.781 (0.312 - 2.452)	0.773
<b>prior PCI</b>	0.655 (0.447 - 2.127)	0.314
<b>CABG</b>	1.688 (0.967 - 3.009)	0.314

\*1,0 for BiOSS Expert

## MULTIVARIATE LOGISTIC ANALYSIS

Parameter	OR (95% CI)	p-value
<b>Group BiOSS.LIM</b>	0.462 (0.371 - 2.171)	0.152
<b>POT</b>	0.070 (0.055 - 0.676)	0.014

Bil J et al.: J Interven Cardiol 2014;27:242-252  
 Gil RJ et al.: EuroIntervention 2015, accepted

# Conclusions

**The dedicated bifurcation stent BiOSS (Expert and Lim) proved to be a feasible device, with promising safety and long-term clinical effectiveness in the treatment of distal LMS stenosis.**

The overall TLR was 9.3%.  
There were no death, stent thrombosis, or acute MI

Table 6. Clinical Results

	30 Days			6 Months			12 Months		
	All	I Gr	II Gr	All	I Gr	II Gr	All	I Gr	II Gr
n	54	18	36	54	18	36	54	18	36
Death	0	0	0	0	0	0	0	0	0
MI	8* (14.8%)	3* (16.7%)	5* (13.9%)	0	0	0	0	0	0
Stroke	0	0	0	0	0	0	0	0	0
ST	0	0	0	0	0	0	0	0	0
TVR	0	0	0	0	0	0	0	0	0
TLR	0	0	0	0	0	0	5 (9.3%)	3 (16.7%)	2 (5.6%)

\* Asymptomatic increase in TnI concentration. All, whole group; I Gr, BiOSS  $\leq 4.0$  mm; II Gr, BiOSS  $> 4.0$  mm; MI, myocardial infarction; ST, stent thrombosis; TLR, target lesion revascularization; TVR, target vessel revascularization.

In the univariate regression analysis, the only factor associated with higher risk for TLR was the SYNTAX score value.

BIOSS EXPERT PROVED TO BE A FEASIBLE DEVICE, WITH PROMISING SAFETY AND LONG-TERM CLINICAL EFFECTIVENESS