Welcome to the 8th European Bifurcation Club 12-13 October 2012 - Barcelona

BiOSS Lim
First-in-Men registry

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European Bifurcation Club

EBC

Conflict of interests:

- Consultant fee Balton, Polnad

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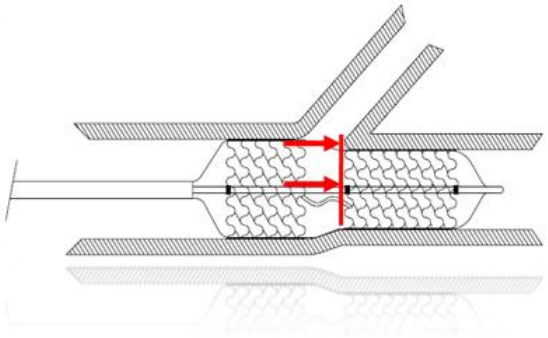
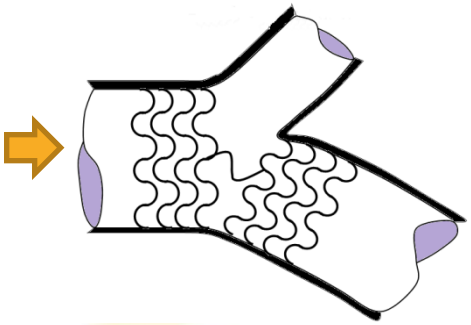
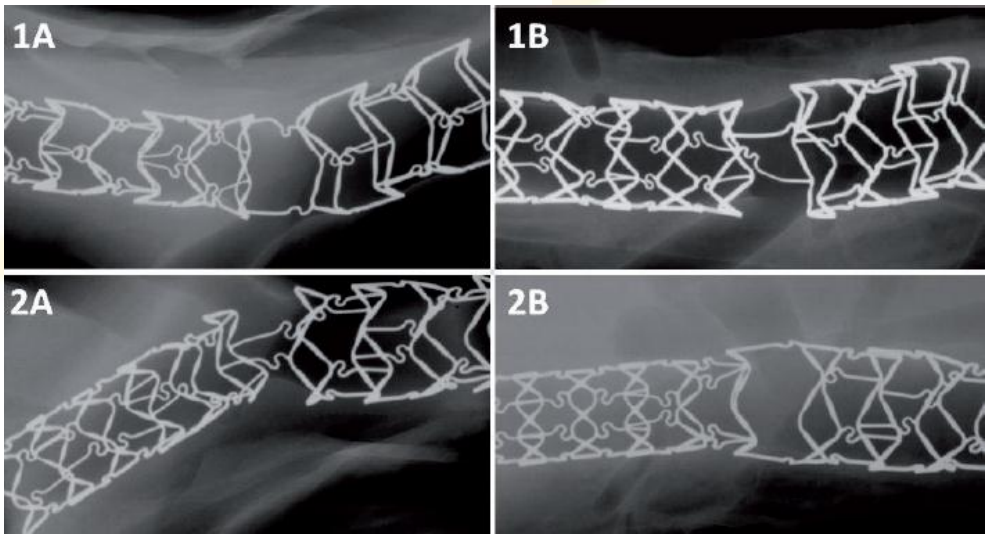
BIOSS program 2012

- *First randomised study with dedicated bifurcation stent (POLBOS) is at the final!*
- *Second randomised study with sirolymus eluting version is ongoing (www.clinicaltrials.gov number: NCT01430364).*
- *Two registries (Expert and LIM) ongoing.*
- *Separate LM registry ongoing!*

How BIOSS works?
By preventing carina displacement & matching bifurcation anatomy







BIOSS LIM registry

FIM data

Participating centers

- CSK MSWiA – Warsaw, Poland – Robert J. Gil – 26 pts
- National Heart Hospital – Sofia – 12 pts – D. Vassilev
- “Medica Core” Heart Hospital – Ruse – 1 pt – D. Vassilev

38 pts in total followed for up to 6 months

BiOSS Registry

safety and feasibility study

- Primary end-point – MACE 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

Methods

- Inclusion criteria
  - All patients with all types coronary bifurcation stenosis without STEMI
  - Able to take 12 DAP
  - Serum creatinine <2.0 mg/dl

- Exclusion criteria – lack of informed consent & STEMI

No vessel location restrictions – LM included!

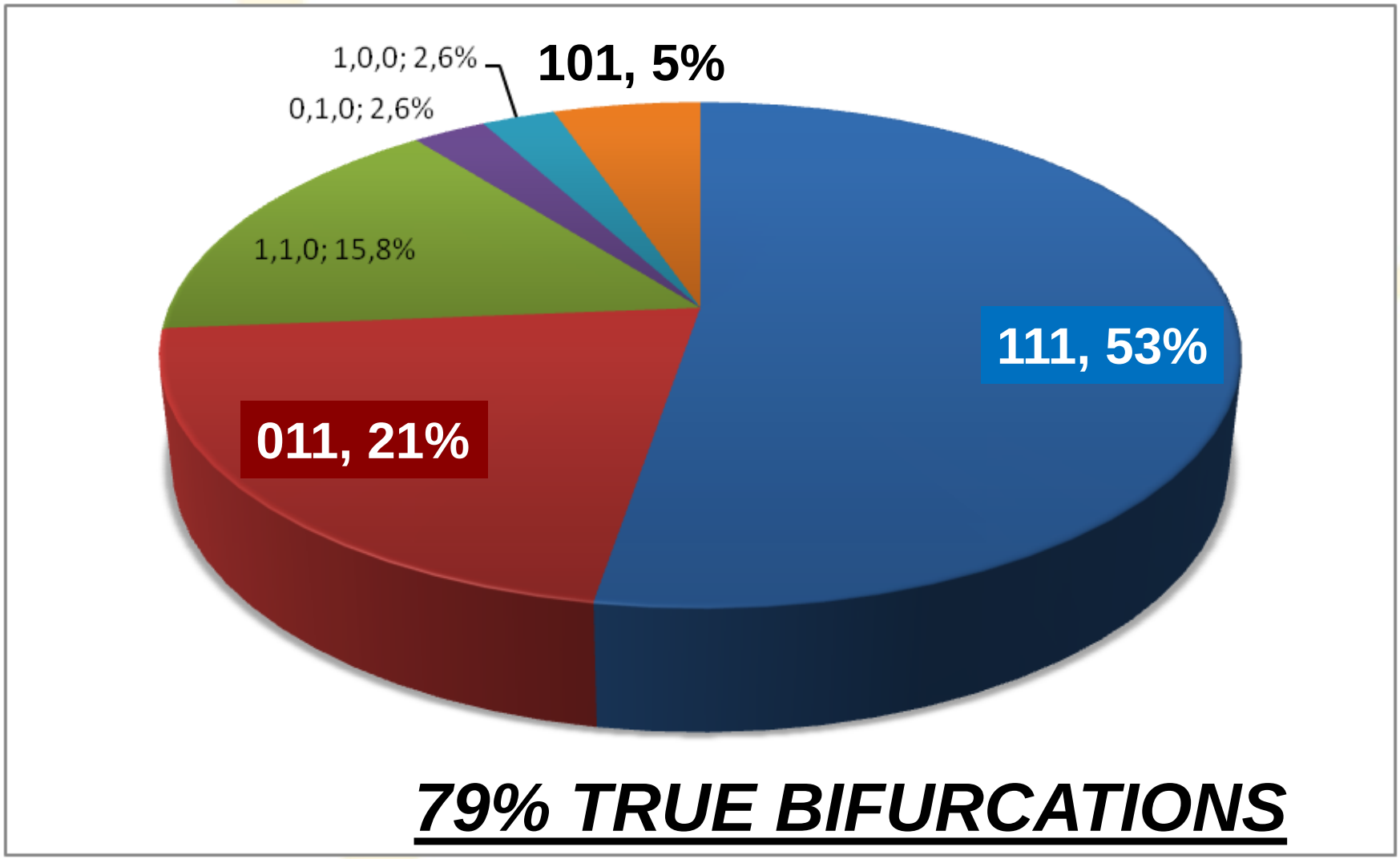
BiOSS implantation protocol

- Wiring both branches
- MV predilatation (B/A ratio = 0.8 – 1.0)
- SB predilatation according to operator decision
- BiOSS implantation – 10-12 atm at least 20 sec!
- Stent postdilatation – Bottle balloon
- SB postdilatation if SB ostial %DS >70% (operator decision, not mandatory per protocol)
- KBI not required!
- IVUS mandatory for all LM cases

Demographics

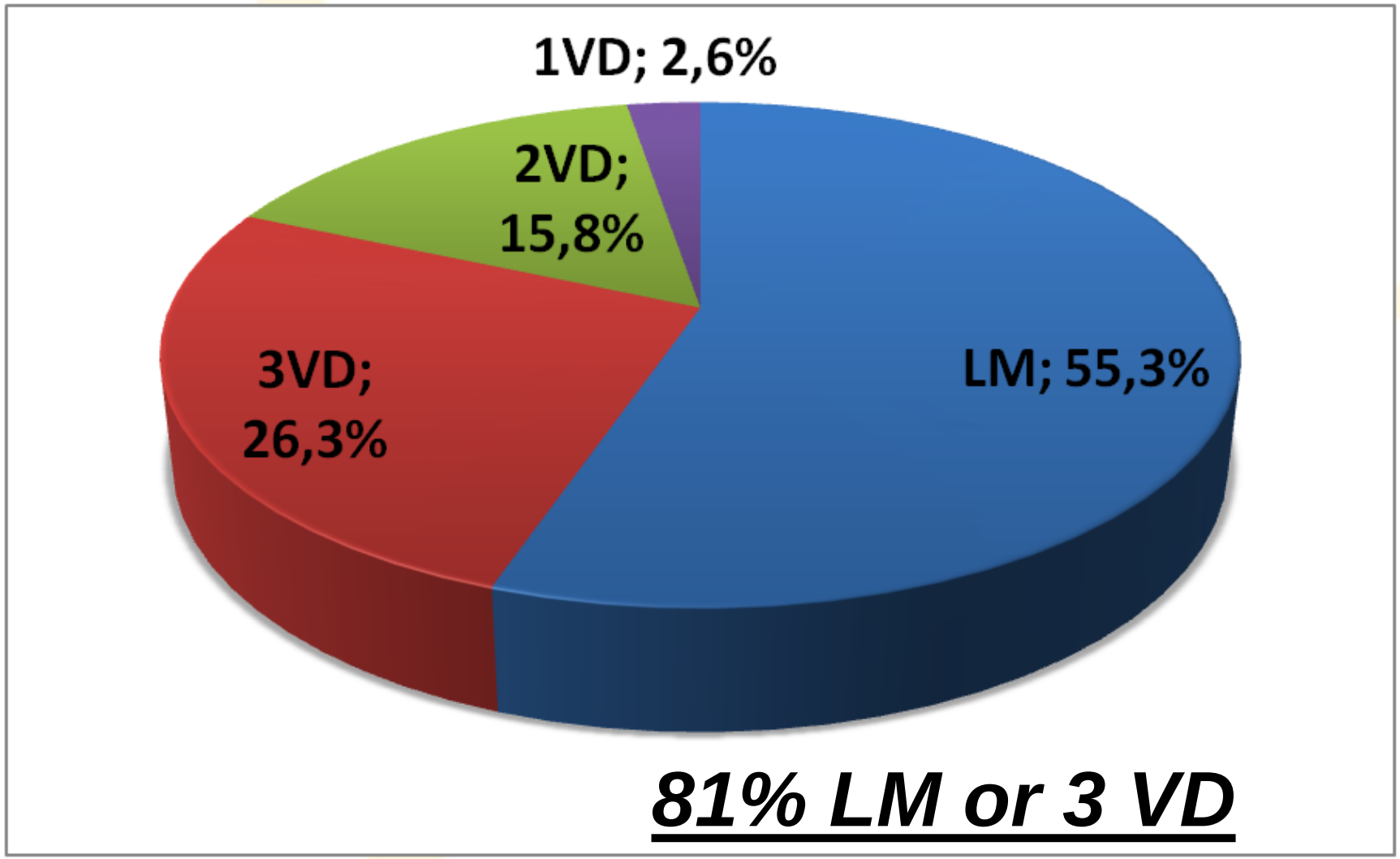
	No	%
Age	67.7±11	
Women	13	**34.2%**
Stable IHD	35	**92.1%**
UA/NSTEMI	3	**7.9%**
Hypertension	32	**84.2%**
Dyslipidemia	33	**86.8%**
Diabetes	14	**36.8%**
Prior MI	14	**36.8%**
Prior PCI	21	**55.3%**
CABG	5	**13.2%**
carotid	4	**10.5%**
CKD	10	**26.3%**
Smoking	9	**23.7%**

MEDINA TYPES



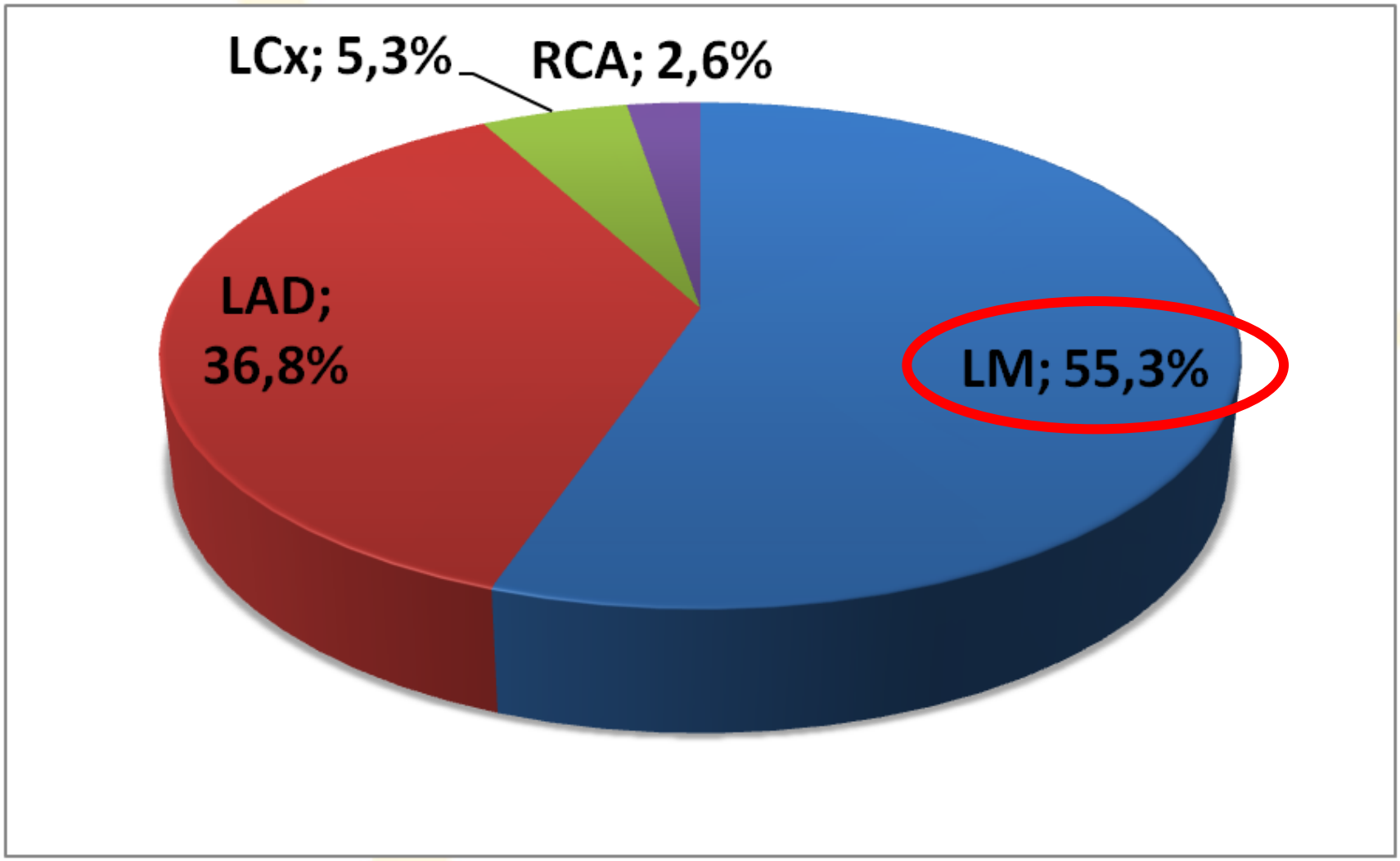
79% TRUE BIFURCATIONS

NUMBER OF VESSELS DISEASE



81% LM or 3 VD

TREATED VESSELS



Procedural characteristics

	No	%
MV predilatation	21	55,30%
SB predilatation	12	31,60%
Both branches predilatation	7	18,40%
Nominal stent diameter in MV [mm]	3,76±0,37	
Nominal stent diameter in MB [mm]	3,11±0,34	
Nominal stent length [mm]	16,40±1,51	
SB postdilatation	29	76,30%
FKB	19	50%
Additional stent in SB*	6	15,80%
Fluoroscopy time [min]	18,04±8,4	
Contrast volume [ml]	166±55	
Vascular access femoral/radial	23,7%/76,3%	
Guiding catheter 6F/7F	84,2%/15,8%	

* - 2 Cypher, 4 Alex stents

Angiographic parameters whole group

	pre stenting	post stenting	p
Main vessel			
MV - RVD [mm]	3,68±0,61	3,71±0,43	NS
MV - %DS	63±13%	2±12%	< 0,001
Main branch			
MB - RVD [mm]	3,15±0,51	3,08±0,44	NS
MB - %DS	69±17%	6±18%	< 0,001
MB lesion length	12±1,8		
Side branch			
SB - RVD [mm]	2,75±0,32	2,84±0,34	NS
SB - %DS	66±19%	37±14%	< 0,001
SB lesion length	3,8±1,1		
Angle alpha [degrees]	60±11	58±13	NS
Angle A [degrees]	69±14	61±19	NS

LM group

	pre stenting	post stenting	p
Main vessel			
MV - RVD [mm]	4.03 ± 0.41	4.15 ± 0.52	NS
MV - %DS	41 ± 11%	3 ± 9%	< 0.001
Main branch			
MB - RVD [mm]	3.3 ± 0.32	3.41 ± 0.29	NS
MB - %DS	57 ± 12%	4 ± 8%	< 0.001
MB lesion length	10±2,8		
Side branch			
SB - RVD [mm]	3.1 ± 0.42	3.02 ± 0.23	NS
SB - %DS	46 ± 17%	21 ± 15%	< 0.01
SB lesion length	4.8 ± 0.7		

Non – LM group

	pre stenting	post stenting	p
Main vessel			
MV - RVD [mm]	**3.47 ± 0.41**	**3.54 ± 0.32**	**NS**
MV - %DS	**69 ± 8%**	**2 ± 17%**	**< 0.001**
Main branch			
MB - RVD [mm]	**2.9 ± 0.22**	**2.98 ± 0.36**	**NS**
MB - %DS	**81 ± 15%**	**8 ± 13%**	**< 0.001**
MB lesion length	**13±2,6**		
Side branch			
SB - RVD [mm]	**2.62 ± 0.12**	**2.65 ± 0.33**	**NS**
SB - %DS	**83 ± 14%**	**51 ± 16%**	**< 0.02**
SB lesion length	**3.4 ± 1.2**		

Follow-up

	30 days	3 Mo	6 Mo
Death	0	0	0
MI	4 (10.5%)*	0	0
Stroke	0	0	0
ST	0	0	0
TLR	0	0	1 (2.6%)
PCI in another vessel	0	5 (16.6%)	0

TOTAL MACE RATE 2.6%!

Conclusions:

- The results from BIOSS LIM FIM are extremely promising for treatment of complex (distal LM, pts with 3VD) bifurcation coronary artery disease!
- Angiographic follow-up will be available very soon!
- Presenter personal opinion: We are really very close to really perfect device for simple treatment of coronary bifurcation stenoses!!!