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BIOCOMPATIBILITY OF A NOVEL NON-DRUG ELUTING BIOABSORBABLE STENT IN PORCINE CORONARY ARTERIES: AN OPTICAL COHERENCE TOMOGRAPHY AND HISTOLOGY STUDY

Poster Contributions
Hall C
Monday, March 31, 2014, 9:45 a.m.-10:30 a.m.

Session Title: Bioresorbable and Drug-Eluting Balloon Technologies
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Background: Bioabsorbable arterial stents (BAS) are emerging as a new paradigm for treatment of coronary disease by promoting vascular restoration rather than just alleviating the obstruction but caging the vessel segment with a metal stent. We aimed to evaluate mechanical integrity and biocompatibility of a novel non-drug eluting, poly-L-lactic acid (PLLA) BAS (Amaranth Medical, Mountain View, CA) featuring unique polymer synthesis and processing for improved balance of strength and flexibility.

Methods: Porcine coronary arteries were treated with a novel BAS (n=28) and clinically used BMS (Liberte® Boston Scientific, Natick, MA, n=19) as a control under intra vascular ultrasound (IVUS) guidance. Optical coherence tomography (OCT) and histological evaluation was performed at 28 days (BAS=19, BMS=13) and at 90 days (BAS= 9, BMS= 6).

Results: All stents were successfully delivered to their target segments. The acute recoil of BAS was negligible and comparable with BMS. Key OCT and histology parameters are in the table. At 90 days the inflammation score for BAS was higher than for BMS but it was moderate and within expected range for a degrading PLLA scaffold at this time point.

Conclusion: Out to 90 days of follow-up, the novel non-drug eluting BAS showed a favorable mechanical integrity and biocompatibility comparable to that of a contemporary BMS. Further long-term investigation of this device is therefore warranted.

Follow up	Stent	OCT		Histology			
		NIT (mm)	%AS	NIT (mm)	Peri Strut Inflammation (Score)	Endothelial Coverage (Score)	Fibrin Deposition (Score)
28 Days	BAS	0.28±0.11	31.1±8.7%	0.35±0.1	0.2±0.63	4/4	0.5±0.36
	BMS	0.25±0.14	28.5±10.9%	0.27±0.1	0.05±0.13	4/4	0.52±0.38
90 Days	BAS	0.29±0.1	33.4±9%	0.44±0.16	1.37±1.2*	4/4	0
	BMS	0.25±0.2	27.9±16%	0.32±0.24	0.11±0.17*	4/4	0
*p<0.05; Endothelial Coverage of 4 = Fully covered							