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Acute and Chronic Recoil Comparison Between Novel Thinner-Strut Sirolimus-Eluting Coronary Scaffold and Regular-Strut Scaffolds in Normal Porcine Coronary Arteries

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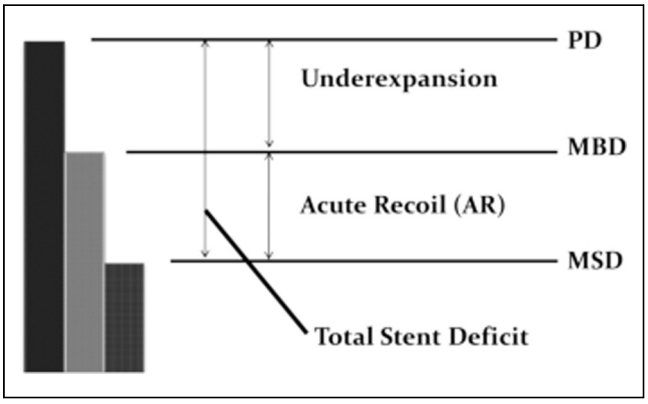
BACKGROUND Due to deliverability and thrombogenicity concerns, efforts are being made to decrease the strut thickness of the bioresorbable stents without compromising radial strength and durability. This study aimed to evaluate the scaffold expansion of the novel sirolimus-eluting scaffolds with 120μm and 150μm strut thickness (AMA-120 or -150, Amaranth Medical, Mountain View, CA), compared to Absorb BVS using previously described (TCT2014) methods.

METHODS A total of 125 scaffolds (32 AMA-120; 46 AMA-150 and 47 Absorb) were implanted (stent-to-artery ratio: 1.1:1) in coronary arteries of 51 healthy swine. Angiography and OCT imaging were performed at post-implant, 28-day and 90-day follow up. Minimum balloon diameter (MBD) of the last inflated balloon at the highest pressure and minimum stent diameter (MSD) immediately after the last balloon deflation were assessed by QCA. % Acute Recoil (AR) was defined as (MBD-MSD)/MBDx100%. Projected Diameter (PD) was defined as the stent diameter to be achieved per compliance chart at the pressure used. Accordingly, % Under-expansion (in vivo stent response to arterial elastic forces regardless of "native" recoil) was defined as (PD-MBD)/PDx100%. Total Stent Deficit is the sum of the % under-expansion and % AR = (PD-MSD)/PDx100% (FIGURE). Additionally, % Late Recoil (LR) was examined by OCT and defined as (inner scaffold area at post-procedure - inner scaffold area at follow-up)/ inner scaffold area at post-procedure.



RESULTS The results are summarized in the TABLE. There was no significant difference in % AR between AMA-120, AMA-150 and Absorb. %Under-expansion of AMA-150 was slightly higher than AMA-120 and similar to Absorb. Consequently, Total Stent Deficit showed the same trend as the under-expansion. The % LR in AMA BVS groups was less or similar to that in Absorb BVS at 28 days and 90 days.

		AMA 120	AMA 150	Absorb BVS	P Value
QCA	%ACUTE RECOIL	1%±8%	2%±8%	3%±7%	0.32
	%UNDERXPANSION	2%±7%	6%±7%	7%±9%	0.04
	TOTAL STENT DEFICIT	3%±8%	8%±9%	10%±7%	0.001
OCT	% Late Recoil (DAY 28)	-2%±8%	3%±4%	7%±7%	0.02
	% Late Recoil (DAY 90)	-1%±7%	-5%±15%	3%±11%	0.17

CONCLUSIONS The novel 120μm sirolimus-eluting bioresorbable scaffold demonstrated acute and chronic radial strength in vivo equivalent or better than its regular-thickness counterpart or Absorb BVS.

CATEGORIES CORONARY: Bioresorbable Vascular Scaffolds

KEYWORDS Bioresorbable scaffold, Recoil, Strut profile

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A Novel Magnesium Bioresorbable Stent Allows Coronary Vascular Restoration and Positive Remodeling in a Large Animal Model: A Sequential Optical Coherence Tomography Study

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BACKGROUND Long-term follow-up of bioresorbable scaffolds evidenced vascular dimensional restoration, in contrast to the vascular caging characteristic in permanent metallic stents (BMS). We aim to evaluate the chronic, in vivo, vascular changes following the coronary implantation of a novel non-drug eluting, magnesium-based, bioresorbable scaffold (MBRS).

METHODS Six stents (MBRS=3 vs BMS=3) were implanted (1.1:1 B:A ratio by angiography) in RCA of juvenile swine and evaluated by OCT at baseline, 1, 2 and 3 months. Morphometry was assessed at every time point in stented and reference segments.

RESULTS The non-stented reference segments demonstrated a progressive increase in lumen area (1 month=8.0±1.0mm2, 2 months=10.5±2.0 mm2, 3 months=10.7±1.9 mm2) that was aligned with the mean growth of the animal (1 month= 39kg, 2 months= 47kgs, 3 months= 58kgs). As expected, there was no geometrical changes in the BMS stents. BMS did not display modifications in their stent area (6.0±0.3 mm2, at each time point) or lumen area (1 and 2 months=5.6±0.4mm2, 3 months= 6.0±0.6 mm2) with a consistent neointimal obstruction (1 and 2 months=0.1±0.1%, 3 months=0.0±0.1%). In contrast, MBRS showed a gradually progressive increase in stent area from 1 month (5.8±0.5 mm2) to a >30% increase at 3 months (7.6±2.2 mm2) and an additional 30% at 3 months (10.3±2.5 mm2). Importantly is to note that at three month the stent area in MBRS (10.3±2.5 mm2) is exactly the same as the reference segment (10.7±1.9 mm2). In parallel, the luminal area increase accordingly (1 month=4.4±0.6 mm2, 2 months=6.5±2.1, 3 months=8.2±1.5 mm2). The neointimal obstruction observed in MBRS remained constantly minimal (1 month=0.2±0.1%, 2 months=0.2±0.0%, 3 months=0.2±0.1%).

CONCLUSIONS In this preliminary experimental study, the novel bare magnesium-based bioresorbable stent was associated with dimensional restoration and vascular adaptability to remodel outward to match the physiological and dimension requirements of the coronary artery without excessive neointimal proliferation in contrast with the encaged coronary treated with BMS.

CATEGORIES CORONARY: Stents: Bioresorbable Vascular Scaffolds

KEYWORDS Bioabsorbable scaffolds, Coronary artery, Stent

TCT-535

5 year experience with the Absorb bioresorbable vascular scaffold: The Maasstad Absorb Registry

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BACKGROUND The safety and efficacy of the Absorb™ (Abbott) bioresorbable vascular scaffold (BVS) has been documented in lower-risk patient and lesion subsets with "real-world" outcome data being scarce. Here we report the experience gathered with the BVS primarily in daily practice at a high-volume Dutch center.

METHODS Between July 2009 - January 2015, 297 patients (330 lesions) were treated with BVS. Registry data collection is ongoing and gathered prospectively in-hospital, at 1 and 6 months and then yearly up to 5 years.

RESULTS Mean follow-up time was 323 days (median 236 days) with 44% of patients having at least 1 year of follow-up. Clinical presentation of pts. (73% male, mean age 59 years, 16% diabetes, 25% with previous PCI and/or CABG) was ACS in 55%. Lesion complexity was