**TCT-533**

**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) in coronary arteries of 51 healthy swine. Angiography and OCT imaging were performed 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±1.0 mm2, 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: 39 kg, 2 months: 47 kg, 3 months: 58 kg). 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±0.4 mm2, 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 >30% increase at 3 months (7.6±2.2 mm2) and an additional 30% at 3 months (10.3±2.5 mm2). Importantly, it 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 biodegradable 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 neointima proliferation in contrast with the engaged coronary treated with BMS.

**CATEGORIES CORONARY:** Stents: Biodegradable Vascular Scaffolds

**KEYWORDS** Biodegradable scaffolds, Coronary artery, Stent

**TCT-534**

A Novel Magnesium Biodegradable 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 biodegradable 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, biodegradable scaffold (MBRS).

**METHODS** Six stents (MBRS = 3 vs BMS = 3) were implanted (1:1:1 A:R:CD) and followed up at 6 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±1.0 mm2, 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: 39 kg, 2 months: 47 kg, 3 months: 58 kg). 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±0.4 mm2, 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 >30% increase at 3 months (7.6±2.2 mm2) and an additional 30% at 3 months (10.3±2.5 mm2). Importantly, it 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 biodegradable 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 neointima proliferation in contrast with the engaged coronary treated with BMS.

**CATEGORIES CORONARY:** Stents: Biodegradable Vascular Scaffolds

**KEYWORDS** Biodegradable scaffolds, Coronary artery, Stent

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

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**BACKGROUND** The safety and efficacy of the Absorb(®) 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 35%. Lesion complexity was...
B2/Cin 56.6% with mean lesion length by QCA of 24.1 mm with a mean RVD of 2.6 mm and a mean lumen obstruction of 66.1%. Pre-dilation was performed in 94% and post-dilation in 59%. The mean scaffold length was 27.4 mm with 36% of cases using ≥2 stents and 26% of cases using overlapping scaffolds. OCT or IVUS was used in 30%.

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3 regions, but this was not observed in the SRSB group.

ST in 1 pt. (0.3%); all ST were early including one acute ST except of

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ned stent thrombosis (ST) occurred in 6 pts. (2.0%) and over the ST in 1 pt. (0.3%); all ST were early including one acute ST except of two case of definite ST which occurred at days 40 and 84, respectively. Overall MACE (death, MI, TVR) rate was 6.4% (9/297).

CONCLUSIONS

This registry including patients with ACS and complex patient and lesion subsets as well as longer follow-ups are needed to define the role of BVS in daily practice.

CATEGORIES CORONARY: Stents; Biosorbable Vascular Scaffolds

KEYWORDS

Biosorbable scaffold, Registry

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Neointimal Response to Everolimus-Eluting Biosorbable Scaffolds Implanted at Bifurcated Coronary Segments: Insights from Optical Coherence Tomography

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BACKGROUND

Tissue formation at coronary bifurcations is related to vascular endothelial stress, and postmortem pathological studies have described different patterns of neointimal coverage between the outer wall and inner wall at coronary bifurcations treated with first-generation drug-eluting stents (DES). Current everolimus-eluting biosorbable scaffolds (BRS) have thicker struts compared to their metallic counterparts, and could therefore have a stronger influence on vascular endothelial shear stress compared to DES. However, the neointimal coverage of bifurcation lesions treated with BRS has not been adequately studied. In the current study, we sought to evaluate the vascular response to BRS struts deployed at bifurcation segments using optical coherence tomography (OCT).

METHODS

This study included 37 patients (51 bifurcation lesions) examined with coronary angiography including OCT 11.0 ± 2.1 months after BRS implantation. Cross-sectional area (CSA) of the bifurcation lesion with a side branch more than 1mm using OCT were analyzed every 200μm. All images were divided into 3 regions according to the sheath pressure on half of the circumference of the vessel opposite to the ostium (OO), the side branch ostium (SO), and the vessel wall adjacent to the ostium (AO). All struts in OO, AO, and SO regions were classified as covered or uncovered. The thickness of coverage was measured in each CSA, and the averaged neointimal thickness (NIT) was calculated. Additionally, to evaluate the impact of the side branch size on neointimal proliferation, we classified side branches according to the ratio of the diameter of the side branch ostium (Ds) to the diameter of main branch (Dm).

RESULTS

The mean age of the study population was 57.11 years. Mean BRS diameter and length were 3.1±0.37 and 21.0±5.7mm, respectively. The mean diameter of all side branches was 1.59±0.55mm. Overall, there was a significant difference in NIT among the 3 examined regions (OO, 119±68 vs. AO, 94±35 vs. SO, 80±41μm, p<0.05). In addition, a significant difference was observed in the percentage of uncovered struts among the 3 regions (OO, 0.43 vs. AO, 1.4 vs. SO, 4.8%, p<0.02). Lesions were divided into 2 groups based on a median value of Ds/Dm of 0.318 (large ratio side branch group = LRSB, n=26; and small ratio side branch group = SRSB, n=25). In the LRSB group, there was a significant difference in NIT (OO, 128.61±1.61 vs. AO, 11.9±1.3 vs. SO, 8.7, p<0.01) and in the percentage of uncovered struts (OO, 0.38 vs. AO, 2.0 vs. SO, 8.7, p<0.01) between the 3 regions, but this was not observed in the SRSB group.

CONCLUSIONS

Different patterns of neointimal coverage are observed between the outer wall and inner wall of coronary bifurcation lesions treated with everolimus-eluting BRS. Neointimal coverage is least at and adjacent to large side branches.

CATEGORIES CORONARY: Biosorbable Vascular Scaffolds

KEYWORDS

Biosorbable scaffold, Remodeling