follow-up; 441days, interquartile range; 150-503 days) did not differ between the two groups (p=0.59). One-year TLR free rate was 95.7 ± 2.1% in the small BRS group and 92.5 ± 2.1% in the large BRS group. There were no differences between groups with regards to definite stent thrombosis with was 1 late thrombosis in the small BRS group and 1 acute thrombosis in the large BRS group.

CONCLUSIONS Percutaneous coronary intervention using small BRS was associated with comparable outcomes when compared to larger BRS with no observed increase in adverse events.

CATEGORIES CORONARY: Bioresorbable Vascular Scaffolds

KEYWORDS Bioresorbable scaffold, Small coronary vessels, Target lesion revascularization

TCT-526

An in-vivo multi-modality imaging study of the Absorb everolimus-eluting bioresorbable scaffold in complex coronary bifurcations

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BACKGROUND This in-vivo study sought to provide insights regarding the feasibility and safety of performing complex bifurcation techniques with the Absorb everolimus-eluting bioresorbable vascular scaffold (BVS, Abbott Vascular, Santa Clara, US).

METHODS Twenty Adult New Zeeland white rabbits were anaesthetized and a long 6 Fr arterial sheath was placed in the carotid artery extending to the distal aorta. Heparin was administered. Bifurcation stenting procedures of the aorta-iliac bifurcation (70° angle) were performed with 3.0x28 mm BVS using the following techniques: main-vessel (MV) stenting with ballooning of side branch (SB) through the BVS struts (Provisional stenting, n=5), T-and protrusion (TAP, n=5), modified T (n=5) and culotte (n=5) stenting. Proximal optimization technique with 3.5 mm non-compliant (NC) balloons at 16 atm and mini-kissing balloon post-dilatation with 3.0 NC balloons at 5 atm were performed in all procedures. Angiography, optical coherence tomography (OCT) and post-procedural micro-computed tomography (micro-CT) were performed.

RESULTS In all procedures angiographic results were excellent with no evidence of dissection or SB compromise. Re-crossing through BVS struts with guidewires and balloons +/- second BVS (TAP + culotte procedures) was smooth. Provisional stenting optimally opened the SB ostium without deforming the BVS. On OCT there was no malapposition and micro-CT revealed good SB aperture and a single connector fracture was present in the MV in 1 of the 5 cases. Modified T stenting (SB stented first, n=5) and TAP stenting (MV stented first, n=5) resulted in complete coverage of the SB ostium and carina. In both techniques no significant malapposition was present. On Micro-CT, no strut fractures were present following modified T stenting, whilst in 3 out of 5 TAP procedures single strut fractures were noted, these did not cause luminal compromise. Culotte stenting (n=5) resulted in complete coverage of the bifurcation with an extensive proximal segment of double-layered scaffold struts. In 3 of the 5 culotte procedures, OCT revealed significant circumferential malapposition at the level of the bifurcation. On micro-CT there was distortion of MV and SB scaffolds at the level of the bifurcation with single strut fractures present in all 5 cases. These fractures did not cause luminal compromise.

CONCLUSIONS In this non-diseased in-vivo aorta-iliac bifurcation model, it was feasible to perform complex bifurcation stenting using Absorb BVS with excellent angiographic results. Provisional stenting with additional TAP stenting seems a reasonable standard approach for most bifurcation lesions. When a 2-stent technique is planned from the outset, modified T-stenting was the most promising with no evidence of significant malapposition or scaffold disruption on OCT and micro-CT, respectively. Finally, culotte stenting frequently caused significant circumferential malapposition, scaffold distortion and strut fractures, the clinical impact of which is unknown.

CATEGORIES CORONARY: Stents: Bioresorbable Vascular Scaffolds

KEYWORDS Bifurcation stenting, Bioabsorbable scaffolds, OCT

TCT-527

Long-term Clinical Outcomes of Patients Treated With The Everolimus-eluting Bioresorbable Vascular Scaffold. The BVS Expand Study

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BACKGROUND Multiple studies have proven safety and feasibility of the BVS bioresorbable scaffold. However, most of these studies were restricted by rather non-complex lesions or short follow-up.

METHODS This is an investigator initiated, prospective, mono-center, single-arm study. Inclusion criteria were patients presenting with NSTEMI, stable, unstable angina, or silent ischemia caused by a de novo stenotic lesion in a native previous untreated coronary artery. Lesions with a Dmax (proximal and distal mean lumen diameter) within the upper limit of 3.8 mm and the lower limit of 2.0 mm by online QCA were obligatory. Exclusion criteria were patients with a history of CABG, presentation with cardiogenic shock, bifurcation lesions requiring kissing balloon post-dilatation, STEMI patients requiring immediate stent implantation, allergies or contra-indications to antiplatelet therapy, female patient with child bearing potential not taking adequate contraceptives or currently breast-feeding, expected survival of less than one year. Procedural outcomes and clinical outcomes were assessed.

RESULTS From September 2012 to January 2015, 250 patients with 335 lesions were enrolled in this study. A total of 445 BVS were placed with a mean number of implanted scaffolds/ patient of 1.37. Pre-dilatation was performed in 89.8%. Predilatation balloon: artery ratio was 1.05±0.23. Post-dilatation was performed in 54.3%. In 14.5% baseline imaging using IVUS was used; OCT in 24.9%. Bifurcation was present in 21.4%, calcification in 42.2% and total occlusions in 4.2%. In 38.0% there were AHA classification type B2/ C lesions. Mean lesion length was 22.10±13.90 mm. Pre-procedural reference vessel diameter (RVD) was 2.42±0.74mm, minimal lumen diameter (MLD) 0.91±0.45mm and percentage diameter stenosis (%DS) 59.13± 0.72. Post-procedural QCA characteristics were as followed: RVD 2.77±0.46 mm, MLD 2.30±0.42 mm and %DS 16.90±9.04. Median follow-up period was 559 days (interquartile range [IQR], 371-733 days). Up to 12 months three patients died (all cardiac death) with a Kaplan Meier estimate of 1.4% at one year. Rate of all myocardial infarction (MI) was 4.1%, definite scaffold thrombosis (ST) 1.4%, target lesion revascularization (TLR) and target vessel revascularization (TVR) were 3.7%. Non-target vessel revascularization (non-TVR) was 3.8%. Major cardiac adverse events (MACE, a composite endpoint of cardiac death, TLR and all MI) at one year was 5.5%.

CONCLUSIONS Long-term results in a mixed group of patients imply that BVS usage is associated with favorable clinical outcomes.

CATEGORIES CORONARY: Bioresorbable Vascular Scaffolds

KEYWORDS Bioabsorbable scaffolds, Coronary artery disease, PCI - Percutanoeus Coronary Intervention

TCT-528

Bioabsorbable Vascular Scaffold Overexpansion: Insights from in-vitro post-expansion experiments

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BACKGROUND While Bioresorbable Vascular Scaffolds (BVS) are increasingly used in clinical practice, behavior when post-dilated beyond their recommended maximum over-expansion diameter remains sparsely documented.

METHODS We examined the post-expansion behavior of the Bioresorbable Vascular Scaffold (3.0mm and 3.5mm Absorb BVS; Abbott Vascular, Santa Clara, CA) after over-expansion with Non-Compliant (NC) balloons of increasing diameters. After each oversizing step, the scaffolds were measured and inspected for strut disruption using

microscope and Optical Coherence Tomography imaging. Point force mechanical measurements on single scaffold struts were also performed to evaluate the mechanical response of individual struts.

RESULTS 3.0mm and 3.5mm scaffold sizes could be post-expanded up to 1 mm above their nominal diameters without any strut fracture when deployed without an external constraining model. Over-expansion with balloon sizes 1.5 mm above the scaffold nominal diameter produced strut fractures in both sizes: 3.0mm scaffolds oversized with NC balloon resulted in more strut fracture sites (on average 12.7 ± 3.9) as compared to oversized 3.5mm scaffolds (1.3±1.2). Importantly, when overexpansion of a series of 3.0mm and 3.5mm scaffolds was repeated using a constrained silicon lesion model, only post-expansion with NC balloon 0.5mm larger than nominal size could be performed without causing strut fractures. The point force single strut compression analysis shows that post-dilated rings with fractures had the lowest local focal strength; overexpanded ring segments without fractures had also a lower focal mechanical strength than normal segments (expanded at nominal pressure). Maximum point force measured for fractured, overexpanded without fracture and normal ring were respectively: 0.17, 0.29 and 0.44 N for BVS 3.0mm size ($p < 0.01$); and 0.19, 0.30 and 0.33 N for BVS 3.5mm size ($p < 0.01$).

CONCLUSIONS In our experiments, only overexpansion with 0.5mm NC balloon was feasible for BVS deployed inside an arterial lesion model. Over-expansion of the BVS scaffold beyond recommended post-dilation limits can lead to strut disconnections and local loss of mechanical support.

CATEGORIES CORONARY: Bioresorbable Vascular Scaffolds

KEYWORDS Bifurcation stenting, Bioabsorbable scaffolds, Post-dilatation

TCT-529

Incidence of persistent, resolved, and late incomplete scaffold apposition after bioresorbable scaffold implantation in ST-segment elevation myocardial infarction. A BVS-STEMI-first substudy

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BACKGROUND The natural history of incomplete scaffold implantation (ISA) after BVS implantation in thrombotic lesions of STEMI has not been elucidated. We evaluated the incidence of persistent, resolved and late ISA after BVS implantation in STEMI.

METHODS The BVS-STEMI-first is a cohort study that enrolled 39 consecutive patients previously admitted with STEMI and treated with BVS at the index procedure that consented to undergo invasive follow-up by angiography and OCT at 6 months. Twenty of thirty nine patients had also undergone OCT post implantation. In this subgroup, serial analysis of OCT parameters was performed. Moreover, all malapposed struts were identified on a frame-level basis (0.2mm interval) for both pullbacks, and plotted in spread-out maps. The presence of persistent, resolved, and late ISA was then estimated on a scaffold level, by visual assessment of the maps and inspection of synchronized pullbacks. Persistent ISA was defined as presence of malapposed struts both at baseline and follow-up, resolved as malapposed struts at baseline that were apposed at follow-up, while late as new occurrence of malapposed struts at follow-up.

RESULTS Mean and minimal lumen area were reduced at follow-up ($p<0.001$). There was no significant difference for proximal or distal reference lumen area, or for scaffold area. The number of malapposed struts was non-significantly reduced from baseline to follow-up (1.4% vs.0.8%, $p=0.16$). Malapposition distance increased from baseline to follow-up ($p<0.001$), however there was no significant difference in the mean ISA area between the two intervals ($p=0.48$). Spread-out maps illustrating strut apposition post-implantation and at follow-up are presented in the Figure. There were 3 patients (15%) with persistent ISA, 11 patients (55%) with resolved ISA, and 6 patients (30%) with late ISA.

	Post-implantation	Follow-up	p-value
Mean Lumen area(mm^2)	7.54±1.72	6.77±1.98	<0.001
Minimal Lumen area(mm^2)	5.81±1.49	4.89±1.92	<0.001
Proximal Reference area(mm^2)	7.30±2.08	6.69±2.52	0.10
Distal Reference area(mm^2)	6.41±3.22	7.21±3.67	0.29
Mean Scaffold/Stent area(mm^2)	8.01±1.78	8.27±1.98	0.17
Min Scaffold/Stent area(mm^2)	6.58±1.89	6.48±1.97	0.66
Mean ISA area(mm^2)	0 [0-0.027]	0 [0-0.034]	0.48
Scaffold/stent-level ISA(>5%) n(%)	3(15.0)	1(5.0)	0.33
Strut-level analysis			
Struts analyzed	4521	5227	
Malapposed struts	65 (1.44)	43 (0.82)	0.16
Malapposition distance(μm)	210[130-400]	818[518-1238]	<0.001

CONCLUSIONS In the follow-up of BVS in STEMI, the majority of cases with acute ISA are resolved. However, a fraction might remain malapposed, while the incidence of late ISA is not negligible. Further studies are warranted to evaluate the prognostic significance of these findings.

CATEGORIES CORONARY: Bioresorbable Vascular Scaffolds

KEYWORDS Bioresorbable scaffold, Malapposition, Optical coherence tomography

TCT-530

Biological Efficacy of a Novel Thin-Strut Sirolimus-Eluting Bioresorbable Scaffold in a Porcine Coronary Artery Model

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BACKGROUND The first commercially available bioresorbable scaffold (BRS) Absorb has strut thickness of 150 microns, significantly more than contemporary drug-eluting stents. As such, it has potential for lower deliverability and for higher thrombogenicity. Therefore, decreasing the BRS strut thickness with no adverse effect on its biomechanics appears desirable. In this study, we aimed to evaluate the biological efficacy of a novel sirolimus-eluting BRS (Amaranth