

performed in three, high output, invasive cardiology centers in Poland, Bulgaria and Spain. Patients with STEMI or Medina type 001 bifurcation lesions were excluded from the registry. Provisional T-stenting was obligatory strategy. An angiographic control was planned at 12 months in all patients. The primary end-point of the study is the rate of death, myocardial infarction, in-stent thrombosis and target lesion revascularization (TLR) after 12 months. At TCT2013 complete data will be available.

Results: Sixty patients with stable CAD or NST-ACS (78.3% vs 21.7%, respectively) were included into this prospective, feasibility and safety assessment registry. The average age of enrolled patients (71.7% males) was 66.4±11.3 yrs. There were 46 (76.7%) patients with hypertension, 23 (38.3%) with diabetes and 17 (28.3%) with prior MI. Additionally, 28 patients (46.7%) underwent prior PCI, while 6 (10%) patients had previous CABG. In 46.7% of cases the lesion was localized in LMS, followed by 45% in LAD, 6.7% in LCx and 1.7% in RCA. According to Medina classification true bifurcations were present in 80%. All BioSS stents were implanted successfully (avg. pressure 14 atm). The mean nominal stent parameters were as followed: 3.67±0.40mm x 2.98±0.39mm x 17.13±2.06mm. In 8 (13.3%) cases the second stent was implanted within the side branch. In 5 cases (8.3%) asymptomatic increase in TnI level was observed. At six months all patients were uneventful (out-of-hospital MACE rate 0%). Up to now control angiography after 12 months was performed at 78% of patients and TLR was 6.4%.

Conclusions: Dedicated bifurcation sirolimus-eluting stent BioSS LIM is a feasible device with promising safety profile and short-term clinical effectiveness. Long-term data is pending.

TCT-30

Abstract Withdrawn

Bioabsorbable Vascular Scaffolds

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TCT-31

ABSORB EXTEND: An Interim Report on the 24-month Clinical Outcomes from the First 250 Patients Enrolled

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Background: The safety and performance of the Absorb Bioresorbable Vascular Scaffold (Absorb BVS) (Abbott Vascular, Santa Clara, CA) has been previously established in 131 patients from Cohort A and Cohort B of the First-in-Man ABSORB trial. Results out to 3 years have been presented in 100 patients from the ABSORB Cohort B trial. At 36 months, the MACE rate was 10.0%, with no scaffold thrombosis reported. ABSORB EXTEND was initiated as a global continued access study (outside of the US) to expand experience with the Absorb BVS to different geographies. Additionally, patients were treated for longer coronary lesions than those in the ABSORB trial using either longer scaffold lengths or planned overlap of the Absorb BVS.

Methods: ABSORB EXTEND is a prospective, single-arm, open-label clinical study that will enroll approximately 800 patients at up to 100 sites. Included are patients with lesions ≤ 28 mm in length and reference vessel diameter of 2.0 - 3.8 mm (as assessed by on-line QCA or IVUS). Treatment of a maximum of two de novo native coronary artery lesions, each in a different epicardial vessel, is permitted.

Results: Interim 12-month data in the first 250 ABSORB EXTEND study patients has been previously presented. Patients included 35% with unstable angina, 29% with prior MI and 25% with diabetes mellitus. The mean RVD was 2.58 mm and mean lesion length was 11.7 mm. In these 250 patients, the MACE and TVF rates were 4.4% and 4.8% respectively. Long-term, 24-month follow-up data will be available for these patients in October 2013 and will provide substantial data on the long-term safety and performance of the Absorb BVS in a larger population of patients, including those with planned overlapping and dual vessel treatment. Clinical composites and component end points will be presented out to 24 months.

Conclusions: Long-term outcomes in approximately 250 patients at 24 months (the largest patient cohort reported at this time point to date) from ABSORB EXTEND will provide further insight into the safety and efficacy of the Absorb BVS in patients with longer lesions.

TCT-32

First Report of the Four Year Clinical Results of The ABSORB Trial Evaluating the Absorb Everolimus Eluting Bioresorbable Vascular Scaffold in the Treatment of Patients with de Novo Native Coronary Artery Lesions

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Background: The ABSORB Cohort A trial results demonstrated the safety of Absorb BVS (Abbott Vascular, Santa Clara, CA, USA) in 30 patients with single de novo native coronary artery lesions, with a low long-term MACE rate at 5 years (3.4%) and no scaffold thrombosis. The ABSORB Cohort B trial, a continuation of that assessment with a modified Absorb BVS, enrolled 101 patients at 12 sites in European and Asia Pacific regions in 2009.

Methods: The patients of the ABSORB Cohort B trial were divided into 2 groups, Cohort B1 (45 patients) having imaging follow-up performed at 180 days and 2 years and Cohort B2 (56 patients) having imaging follow-up performed at 1 and 3 years. Key clinical endpoints include scaffold thrombosis, ischemia driven MACE (ID-MACE) and its components at 30 days, 6, 9 and 18 months, and 1, 2, 3, 4 and 5 years.

Results: In the ABSORB Cohort B trial, the mean age was 62 years, 72% of patients were male, 17% of patients were current tobacco users. Patients with diabetes: 17%, hypertension: 66%, hypercholesterolemia: 85%, family history of CAD: 55%, stable angina: 68%, of which 15% having stable angina with CCS classification of III or IV. Patients with unstable angina: 15%, 2% with unstable angina of Braunwald Class III. Lesion location was RCA (33%), LAD (43%), LCX (22%) and Ramus (1%), with ACC/AHA lesion classification of A for 1% of patients, B1 for 55%, B2 for 40% and C for 4%. Clinical data up to 3 years showed an ID-MACE rate of 10.0% with no events of scaffold thrombosis. Late loss at 3 years was 0.29 ± 0.43mm. Quantitative IVUS results revealed mean scaffold area and mean lumen area enlargement between baseline and 3 years. The scaffold enlargement at 3 years was confirmed by OCT. Furthermore, OCT results confirmed earlier pre-clinical data showing that the scaffold is resorbed by 3 years. Overall, clinical outcomes from the ABSORB Cohort B Trial (Groups 1 and 2) confirm the performance and safety of the Absorb BVS out to 3 years.

Conclusions: Four-year data are currently being collected. The long-term 4-year clinical results for Cohort B1 will be presented and will provide further insight into the longer-term safety and efficacy of the Absorb BVS.

TCT-33

Bioresorbable Vascular Scaffold Use in Coronary Bifurcation Lesions

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Background: The use of bioresorbable vascular scaffolds (BVS) in percutaneous coronary intervention (PCI) has been restricted to simple lesions. Few centers are now utilizing BVS in complex lesions including bifurcations. The aim of this study was to evaluate device success and short-term clinical outcomes of BVS implanted in bifurcation lesions at our centers.

Methods: We evaluated patients treated with BVS for bifurcation lesions between May 2012 and June 2013.

Results: A total of 49 consecutive bifurcation lesions in 40 patients (82.5% male, mean age 63.8 years) were identified. True bifurcations were observed in 63.3%. The main bifurcation site was the left anterior descending artery/diagonal branch (73.5%). Intracoronary vascular ultrasound was used in 89.8%. Pre-dilation and post-dilation were performed in all cases. Device success was achieved in 98.0%: a BVS was substituted for a drug-eluting stent in one case where BVS could not be delivered to the side-branch across the main-branch BVS. Details of double-stenting techniques including final kissing balloon inflation are shown in Table 1. On final intracoronary imaging, there was no overt evidence of scaffold structural disruption. At median follow-up of 157 days, there was no death, target vessel revascularization, follow-up myocardial infarction or stent thrombosis.

Conclusions: These preliminary results suggest that bifurcation lesions can possibly be successfully treated with BVS. Intravascular ultrasound guidance and meticulous technique may be important to optimize clinical outcome.

	49 bifurcations	Utilized double-stenting technique		Stent type		FKBI
				Main branch	Side branch	
Single-stenting	36	-		BVS	-	6/36
Double-stenting as a crossover from provisional strategy	1	TAP		BVS	DES (a BVS could not pass through MB-BVS strut)	0
Systematic double-stenting	7	4 T-stenting	3	BVS	BVS	2
			1	BVS	DES	0
		3 mini-crush	2	BVS	BVS	1
			1	BVS	DES	0
Stenting only at SB-ostium	5	-		-	BVS	0

TCT-34

The appearance of jailed side branches post-procedure, at 6, 12, 24 and 36 months following implantation of bioresorbable vascular devices – Insights from the ABSORB Cohort B trial using three-dimensional optical coherence tomography

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Background: Everolimus-eluting ABSORB Bioresorbable vascular scaffolds consisted of poly-lactide are programmed to bioresorb approximately in three years. It is still unknown how the struts implanted in front of a side branch behave during bioresorption. The purpose of this study was to assess the fate of bioresorbable struts jailing side branch ostia at 6, 24 months (cohort B1) or at 12 and 36 months after implantation of the BVS (cohort B2), with three-dimensional (3-D) optical coherence tomography (OCT) reconstruction.

Methods: The ABSORB Cohort B trial is a multicentre single-arm trial to assess the safety and performance of the BVS. Fourier domain-OCT pullbacks were obtained at a pullback speed of 20 mm/s and 3-D rendering are computed. The area and the number of strut-free compartments at side branch ostium delineated by the BVS struts were evaluated. The endo- and abluminal coverages of the struts present at the ostium of sidebranch were quantified at 6, 12, 24 and 36 month follow-up.

Results: Serial 3D-OCT images were available in total 26 side branches (13 in cohort B1 and 13 in cohort B2). In the Cohort B1, the number of compartment and average ostium area free from jailing struts did not change from baseline to 6 months, but significantly reduced from 6 months to 2 years. In the Cohort B2, there was similarly a reduction of the number of compartments and the ostium area from baseline to one year. However, from one year to 3 years, there was late enlargement of the sidebranch ostium area (1Y: 0.47±0.64mm², 3Y: 0.68±0.38mm²) without changing the number of compartment. The thickness of the strut coverage was greater at the abluminal surface compared to endoluminal strut side at followup.

Conclusions: The ostial area jailed by bioresorbable scaffold decreased up to 2 years due to growing tissue between the struts, but late ostium area enlargement was observed at 3 years.

TCT-35

Changes In Bioabsorbable Scaffold Geometry After Kissing Balloon Inflation In Bifurcated Coronary Lesions

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Background: In vitro and in vivo geometry of metallic single stent implantation in coronary bifurcated lesions after kissing balloon (KB) intervention, has been well studied. The same analysis of bioabsorbable vascular scaffolding (BVS) had not yet

been reported. Our own in vitro observations with BVS showed integrity and no device fracture after KB inflation when a ≤2.5 mm balloon diameter was inflated through the struts.

Methods: In our series, 80 coronary bifurcated lesions were treated with provisional BVS strategy. In 21 out of 80 lesions, we performed final KB inflation after BVS implantation. The reason for side branch (SB) intervention was ostial angiographic stenosis (present before BVS implantation in 14 lesions, and appearing after it in 7). IVUS studies were performed in 3 conditions: before treatment, immediately after BVS and after KB inflation. Measurements were performed at the proximal scaffold segment, before SB origin, under SB origin and at the distal segment. This study analyzes the ultrasonographic (IVUS) findings after BVS implantation and after KB inflation. For KB technique, the balloon diameter inflated in the MV was always 0.5 mm minor than BVS diameter and the SB balloon diameter was 2 or 2.5 mm.

Results: BVS diameter was 3.10 ± 0.39 mm and the mean inflation pressure was 15±1 atm. The MV balloon diameter was 2.8±0.3 mm (0.5 mm minor than BVS diameter in all cases). The SB balloon diameter was 2.3±0.2 mm and the inflation pressure of both balloons was 7-8 atm. Integrity of the device was always observed after KB. Good apposition of the proximal BVS and angiographic improvement of the SB origin was always obtained. Geometry of the BVS may be modified after KB technique, but not distorted. The table summarizes the findings.

	After BVS	After KB inflation	p
Proximal BVS area	7.48±1.73	7.95±1.99	0.03
AI at proximal stent	0.85±0.06	0.86±0.05	0.93
Before SB origin area (mm ²)	6.70±1.99	7.53±2.04	<0.01
AI before SB origin	0.81±0.08	0.80±0.07	0.88
After SB origin BVS area (mm ²)	6.03±1.76	5.89±1.67	0.77
AI after SB origin	0.85±0.06	0.82±0.07	0.04
Distal BVS area (mm ²)	6.99±2.03	7.01±1.72	0.98
AI at distal BVS	0.84±0.06	0.84±0.05	0.71

Conclusions: Final KB inflation in bifurcated coronary lesions treated with BVS is feasible, without inducing fracture or important distortion of the scaffold.

TCT-36

One-year Clinical Outcomes of Diabetic Patients Treated With Everolimus-Eluting Bioresorbable Vascular Scaffolds: A Pooled Analysis From the ABSORB Cohort B and the ABSORB EXTEND Trials.

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Background: The aim of this study was to evaluate clinical outcomes of diabetic versus non-diabetic patients when treated with the Absorb Bioresorbable Vascular Scaffold (BVS) at 1-year follow-up.

Methods: This interim post-hoc analysis included 101 patients of the ABSORB Cohort B trial and the first consecutive 450 patients of the ABSORB EXTEND trial with at least 1-year follow-up. These 2 trials had similar inclusion and exclusion criteria; 136 diabetic patients were compared to 415 non-diabetic patients. Primary end point was assessed by a composite of major adverse cardiac events (MACE), including cardiac death, myocardial infarction, and target lesion revascularization.

Results: There were no significant differences in baseline patient demographics and lesion characteristics between diabetic and non-diabetic patients treated with the Absorb BVS, except for the prevalence of hypertension requiring medications (75.0% in diabetics vs. 61.4% in non-diabetics, p=0.004). The cumulative incidence of MACE did not differ between diabetic and non-diabetic patients treated with the Absorb BVS at 1-year follow-up (3.7% vs. 5.1%, p=0.64). One patient out of 136 diabetic patients experienced definite late scaffold thrombosis (ST), whereas four ST events (1 definite and 1 probable subacute ST, and 1 definite and 1 possible late ST) were observed in the 415 non-diabetic patients. The incidence rate of definite/probable ST was thus 0.7% in diabetic group and 0.7% in non-diabetic group (p=1.0).