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%) 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%) had previous CABG. In 46.7% of cases the lesion was localized in LMS and in 25.7% in LAD. RCA was involved in 17.1% of cases. In 32.8% of cases the lesions were complex. Device success was achieved in 98.0%: a BVS was substituted for the side branch in 44.7% and a second stent was implanted within the side branch in 5 cases (8.3%). At 6 months all patients were uneventful (out-of-hospital MACE rate 0%). At TCT2013 full 12-month follow-up data will be available. An increase in TnI level was observed. Up to now control angiography after 12 months was performed in all cases. True bifurcations were observed in 63.3%. The main intracoronary imaging, there was no overt evidence of scaffold structural disruption. At median follow-up of 157 days, there was no death, scaffold thrombosis or MACE. The ABSORB Cohort B trial, a continuation of that assessment with a modified Absorb BVS, enrolled 101 patients at 12 sites in Europe and Asia Pacific regions in 2009. Clinical follow-up data are still pending. All BioSS stents were implanted successfully (avg. pressure 14 atm). The mean nominal stent parameters were as follows: 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 in 12% 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

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**Bioabsorbable Vascular Scaffolds**

**Moscone West, 3rd Floor, Room 3018**

**Tuesday, October 29, 2013, 1:00 PM–3:15 PM**

**Abstract nos: 31-39**

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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 113 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. Additional 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 using either longer scaffold lengths or planned overlap of the Absorb BVS. ABSORB EXTEND was initiated as a global continued access study (outside of the US) to expand experience with the Absorb BVS to different geographies. Additional 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.

**Results:** At 24 months, the MACE rate was 13.2%, with no scaffold thrombosis reported. Results 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%) 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%) had previous CABG. In 46.7% of cases the lesion was localized in LMS and in 25.7% in LAD. RCA was involved in 17.1% of cases. In 32.8% of cases the lesions were complex. Device success was achieved in 98.0%: a BVS was substituted for the side branch in 44.7% and a second stent was implanted within the side branch in 5 cases (8.3%). At 6 months all patients were uneventful (out-of-hospital MACE rate 0%). Up to now control angiography after 12 months was performed in 12% 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-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 Europe 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: 65%, hypercholesterolemia: 85%, family history of CAD: 55%, stable angina: 78%, 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%). Intravascular 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 metedical technique may be important to optimize clinical outcomes.
ORALS

Tuesday, October 29, 2013, 1:00 PM–3:15 PM

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 consist 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 biore sorption. 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. The number of 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 quantitated 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 baselines to 6 months, but significantly reduced from 6 months to 2 years. In the Cohort B2, there was a 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, 2Y: 0.68±0.35mm2) 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 side 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 stuts.

Methods: In our series, 20 coronary bifurcated lesions were treated with provi sional 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 ultrasonicographic (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±1.1 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 aposition 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 nor distorted. The table summarizes the findings.

TCT-36

One-year Clinical Outcomes of Diabetic Patients Treated With Everolimus-Elluting 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. The primary end point was assessed by a composite of major adverse cardiac events (MACE), including cardiac death, myocardial infarction, and target lesion revascularization.

Methods: This interims 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 (78.5% 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).