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safety and performance of the Absorb BVS in a larger population of patients, including those with longer lesions and dual vessel treatment. Clinical composites and component end points will be presented out to 12 months.
Conclusions: Clinical and angiographic outcomes from the First-in-Man ABSORB trial have demonstrated the safety and efficacy of the Absorb BVS in lesions ≤ 14 mm. Interim outcomes in 250 patients at 12 months, (the largest patient cohort reported at this time point to date) from ABSORB EXTEND will provide further insight into the longer-term safety and efficacy of the ABSORB BVS in patients with longer lesions.

TCT-35

Evaluation of the Absorb Everolimus Eluting Bioresorbable Vascular Scaffold (Absorb BVS) in the Treatment of Patients with de Novo Native Coronary Artery Lesions: 3 Year Clinical Results of the ABSORB Cohort B1 Trial

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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 between March and November 2009.
Methods: The patients of the ABSORB Cohort B trial were divided into 2 groups, Cohort B1 (45 patients, enrolment from March 19 to August 20, 2009) having angiographic follow-up performed at 180 days and 2 years and Cohort B2 (56 patients, enrolment from August 21 to November 6, 2009) having angiographic follow-up performed at 1 and 3 years. Key clinical endpoints include 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 Cohort B, clinical data up to 2 years for the full cohort of 101 patients (Group B1 and B2) are currently available and are summarized hereafter. 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 which15% 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%. In these 101 patients, 2 year results showed an ID-MACE rate of 9.0% and no scaffold thrombosis. The angiographic results for Cohort B1 demonstrated an angiographic late loss at 180 days of 0.19 mm and at 2 years of 0.27 mm. This value of 0.27 mm at 2 years was similar to the late loss in Cohort B2 at 1 year (0.27 mm).The 3-year clinical results for Cohort B1 will be presented. Clinical and imaging results at 3-year for all patients in Cohort B will be available in 2013.
Conclusions: Three year clinical follow-up data of Cohort B1 is pending.

TCT-36

Circumferential distribution of the neointima tissue at 6 months and 2 at years follow-up after a bioresorbable scaffold implantation. A serial optical coherence tomography study

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Background: Recent reports have demonstrated that the healing process after the deployment of a bioresorbable scaffold (BRS) leads to the development of fibromuscular tissue that covers the vessel wall. However the distribution of the neointima over the vessel wall remains unclear. In this study we evaluated the circumferential distribution of the neointima tissue developed after a BRS implantation at 6 months and at 2 years follow-up.
Methods: We analyzed data from 20 patients who had undergone an Abbott Vascular BRS 1.1 implantation and have been investigated with optical coherence tomography (OCT) at baseline, immediate after scaffold implantation, at 6 months and at 2 years follow-up. In the acquired sequences an experienced operator detected the luminal and the scaffold borders and then the circumferential thickness of the neointima was measured at 1 degree interval with the use of dedicated software. The symmetry of the neointima tissue was defined as the ratio minimum/maximum neointima thickness.
Results: The lumen area decreased at 6 months but there was no difference between the 2 follow-up time points [7.56 (6.37-7.98)mm2 vs. 6.28 (4.89-7.05)mm2 at 6 months, P<0.001; vs. 6.06 (5.01-7.11)mm2 at 2 years, P=0.851]. The mean neointima thickness was increased at 2 years [192 (174-232) μm vs. 254 (230-288) μm, P<0.0001] and the symmetry index of the neointima was higher [0.06 (0.02-0.09) vs. 0.27 (0.24-0.34), P<0.0001] at this time point suggesting a more homogenous distribution. Full circumferential coverage of the vessel wall by neointima tissue was seen in 90% of the studied frames, at 2 years. In 79% of the analyzed frames the minimum neointima thickness was >65μm at this time point.
Conclusions: We analyzed, for the first time serial OCT data, to investigate the neointima evolution and its circumferential distribution after a BRS implantation. It was found that a thick neointima tissue develops which at 2 years covers, in most of the frames, the whole circumference of the vessel wall. Hence, the Abbott Vascular BRS 1.1 can be regarded as a potentially useful device for the passivation of high risk plaques.

TCT-37

Five-year Clinical Outcomes and Non-invasive Angiographic Imaging Results With Functional Assessment After Bioresorbable Everolimus-eluting Scaffold Implantation in Patients with De Novo Coronary Artery Disease

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Background: Multimodality imaging of the first-in-man trial using fully resorbable everolimus-eluting scaffold (BVS, Abbott Vascular, Santa Clara, USA) demonstrated at 2 years the bioresorption of the device while preventing restenosis. Nevertheless, the long-term safety and efficacy of this therapy remain to be documented.
Methods: In the ABSORB cohort A trial, 30 patients with a single de novo coronary artery lesion were treated with the fully resorbable everolimus-eluting ABSORB scaffold (Abbott vascular, CA, US). The patients underwent MSCT imaging at 5 years. Acquired MSCT data was analyzed in an independent corelab (Cardialysis, Netherlands) for quantitative analysis of lumen dimensions, and was further processed for calculation of fractional flow reserve in another independent corelab (Heart Flow, CA, USA).
Results: Five-year clinical follow-up is available in 29 patients since one patient withdrew consent after 6 months. At 46 days, one patient experienced a single episode of chest pain and underwent a target lesion revascularization with slight troponin rise after the procedure. At 5 years, the ID-MACE of 3.4% remained unchanged. Clopidogrel was discontinued in all but one patient. There has been no stent thrombosis reported. Two non-cardiac deaths were reported; one from duodenal perforation, the other from Hodgkin's disease. At 5 years, 18 patients underwent MSCT scan. All scaffolds were patent with an average minimal lumen area of 3.4±1.4 mm^2 with an average area stenosis of 29±23%. Out of 18 cases, non-invasive FFR analysis was feasible in 13 cases. The median of FFR-CT in the distal segment was 0.83 [interquartile range: 0.81, 0.94].
Conclusions: Five-year clinical results have demonstrated a sustained low MACE rate without any late complication such as stent thrombosis. MSCT assessment was feasible after placement of Bioresorbable scaffold and non-invasive FFR can be also assessed in the selected cases.

TCT-38

Two-Year Clinical Data Of Cohort 1 And Multi-Modality Imaging Results Up To 1-Year Follow-Up Of The BIOSOLVE-I Study With The Paclitaxel-Eluting Bioabsorbable Magnesium Scaffold (DREAMS)

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Background: In order to assess the intermediate term safety, clinical performance and the bioabsorption process of the Paclitaxel-Eluting Bioabsorbable Magnesium Scaffold (DREAMS) 2-year clinical data of cohort 1 and multi-modality imaging outcomes up to 1 year follow-up are reported.
Methods: Forty-six subjects were enrolled in the first-in-man BIOSOLVE-I study, and assigned to two different cohorts with different invasive follow-up schedules. Clinical follow-up for both cohorts is scheduled at 1, 6, 12, 24 and 36 months, angiographic and IVUS follow-up for cohort 1 at 6 months and for cohort 2 at 12 months. A subgroup of patients underwent OCT and vasomotion testing. The primary endpoint is Target Lesion Failure (TLF), defined as the composite of cardiac death, target vessel myocardial infarction and clinically driven target lesion failure, at 6 months for cohort 1 and at 12 month for cohort 2.
Results: Clinical: TLF rate at 12-month was 7.0% including two clinically driven target lesion revascularizations and one peri-procedural target vessel myocardial infarction occurring during 12-month follow-up angiography. No cardiac death or scaffold thrombosis was observed. Twenty-four month clinical data of cohort 1 will be available upon presentation. Angiographic: In-scaffold late lumen loss was 0.52±0.39 at 12 months. Vasoconstriction after acetylcholine was documented by quantitative coronary angiography (delta=-10.04%; p=0.0008) followed by vasodilatation after nitroglycerine (delta=8.69%; p<0.0001) which demonstrates the uncaging aspect of the absorption process already at 6-month follow-up with no further change at the 12-month follow-up. IVUS: Six-month virtual histology (VH) data showed a significant decrease in the dense calcium by 39.5% (p=0.0015) which remains stable until 12-month follow-up. This decrease of dense calcium is interpreted as a surrogate assessment for the bioabsorption process of the scaffold material.

Conclusions: DREAMS shows excellent safety and efficacy data up to 2 years in cohort 1 of the BIOSOLVE-I trial. Multi-modality imaging documented the absorption process and the uncaging aspect of this device already at 6 months.

TCT-39

6-Month Angiographic Follow-up of the Novel DESolveTM Myolimus-Eluting Bioresorbable Coronary Scaffold for the Treatment of Non-Complex Coronary Lesions – Results from the DESolve I First-In-Man Trial

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Background: The DESolveTM Myolimus-Eluting Bioresorbable Coronary Scaffold (Elixir Medical Corporation, Sunnyvale, CA) is a novel bioresorbable vascular scaffold device that combines a PLLA-based scaffold coated with a potent antiproliferative sirolimus analog agent Myolimus (3 mcg per mm of scaffold length).
Methods: A total of 15 patients with single de novo coronary artery lesions ≤14mm in vessels 2.5-3.75 mm in diameter were enrolled in this prospective, multi-center, single-arm, first-in-man study, and underwent serial angiographic studies at baseline/index and 6 months follow-up. Primary endpoint was angiographic in-scaffold late lumen loss, as determined by quantitative coronary angiography (QCA) analysis performed by an independent angiographci core laboratory.
Results: Overall, 14 patients/lesions were available for paired analysis. The Right coronary artery was the most prevalent lesion location (43%) and lesion class according to the ACC/AHA classification demonstrated type A in 36%, type B1 in 29% and type B2 in (36%). Baseline QCA showed mean lesion length, reference diameter (RD), minimum lumen diameter (MLD) and % diameter stenosis (DS) of 8.95±2.64mm, 2.65±0.32mm, 0.81±0.29mm and 70.0±10.5%, respectively. During procedure, predilatation was performed in 93%, postdilatation was performed in 29%, and final TIMI flow was achieved in 100%. Final and 6-month follow-up QCA analyses are shown in the Table. Overall, there was only 1 case of in-segment binary restenosis, which involved the proximal edge outside the scaffold.

Variable	In-Scaffold (N=14)
Final	
- RD, mm	2.77±0.25
- MLD, mm	2.60±0.19
- % DS	8.1±7.9
- Acute gain, mm	1.79±0.39
Follow-up at 6 months	
- RD, mm	
- MLD, mm	2.41±0.28
- % DS	12.6±11.4
- Late lumen loss, mm	0.19±0.19

Conclusions: The DESolve device demonstrated excellent performance in non-complex coronary lesions including high acute gain and optimal expansion at postprocedure as demonstrated by the low final %DS. At 6-month follow-up, there was relatively low in-scaffold late lumen loss (0.19mm), suggesting efficacy of this new technology on inhibiting neointimal hyperplasia.

TCT-40

Incidence and Acute Clinical Outcomes of Small Side Branch Occlusion After Implantation of Everolimus-eluting Bioresorbable Vascular Scaffold in the ABSORB-EXTEND Single-arm Trial

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Background: Side branch occlusion (SBO) contributes to the periprocedural myocardial infarction (MI), which has been associated with unfavorable late clinical outcomes. However, the incidence and acute clinical outcomes of SBO after bioresorbable vascular scaffold (BVS) implantation has been unexplored.
Methods: Amongst consecutive 469 patients who were enrolled in the ABSORB-EXTEND single-arm trial from January 2010 to January 2012, a total of 1127 side branches in 435 patients were evaluated. Although major side branches ≥ 2 mm in diameter was excluded per protocol, any visible side branches originating within to-be-scaffolded segment or its 5 mm-proximal and -distal margins were included in the angiographic assessment. SBO was defined as a reduction in thrombolysis in myocardial infarction (TIMI) flow to grade 0 or 1.
Results: Pre-procedure reference vessel diameter (RVD) and percent diameter stenosis were 2.62 mm and 58.6 % in the main vessel, and 1.18 mm and 20.0 % in the side branch, respectively. Post-procedure SBO was observed in 67 out of 1127 side branches (5.9 %), while it was 9 out of 537 side branches with a RVD of > 1.0 mm (1.7 %). Amongst 67 occluded side branches, 60 (89.6 %) were originated within the obstruction segment in the main vessel, which was automatically delineated by quantitative coronary angiography. Periprocedural Non-Q-wave MI (NQMI) according to the protocol definition was adjudicated in 5 patients (mean ratio of peak CK and CKMB to upper limit of normal were 2.82 and 4.61, respectively) amongst 61 patients with the angiographic evidence of SBO post-procedure (8.2 %).

Clinical events	SBO (N=61)	Non-SBO (N=374)	Relative Risk (95% CI)	p value
In-hospital events*, % (n)				
Cardiac death	0.0 (0/61)	0.0 (0/374)	N/A	N/A
Myocardial infarction	8.2 (5/61)	0.5 (2/374)	15.3 (3.0, 77.3)	0.001
Q-wave	0.0 (0/61)	0.0 (0/374)	N/A	N/A
Non-Q-wave	8.2 (5/61)	0.5 (2/374)	15.3 (3.0, 77.3)	0.001
Ischemia driven target lesion revascularization	0.0 (0/61)	0.0 (0/374)	N/A	N/A
Major adverse cardiac events	8.2 (5/61)	0.5 (2/374)	15.3 (3.0, 77.3)	0.001
30-days events (%)				
Cardiac death	0.0 (0/61)	0.0 (0/357)	N/A	N/A
Myocardial infarction	8.2 (5/61)	1.4 (5/357)	5.9 (1.8, 19.6)	0.008
Q-wave	0.0 (0/61)	0.8 (3/357)	0	1
Non-Q-wave	8.2 (5/61)	0.6 (2/357)	14.6 (2.9, 73.7)	0.001
Ischemia driven target lesion revascularization	0.0 (0/61)	0.0 (0/357)	N/A	N/A
Major adverse cardiac events	8.2 (5/61)	1.4 (5/357)	5.9 (1.8, 19.6)	0.008

SBO, side branch occlusion; N/A, not available. Analysis was performed by Fisher's exact test.
*In-hospital is defined as hospitalization ≤ 7 days post-procedure.

Conclusions: Although 5.9 % of small side branches occluded after BVS implantation, the incidence of periprocedural MI was quite limited.

DES: Long Term Results

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TCT-41

The Impact of Left Main Disease on Long-term Clinical Outcomes Among Patients Treated With The Unrestricted Use of Everolimus-Eluting, Sirolimus-Eluting, and Paclitaxel-Eluting Stents: A Substudy of the Bern-Rotterdam Cohort

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Background: The impact of left main (LM) revascularization with the unrestricted use of drug-eluting stents (DES) on long-term clinical outcomes is still a matter of debate.