group (67% vs. 41%, p<0.001). In particular, this difference stemmed from an increase of access site-related bleeding (21% vs. 7%, p<0.001) and cardiac death (41% vs. 25%, p<0.001) in the FF group. The adjusted multivariable regression analysis confirmed radial approach as an independent outcome predictor (OR 0.53 CI 95% 0.29-0.96, p=0.037).

Conclusions: Transradial approach use for PCI requiring IABP support positively impacts peri-procedural outcome by means of a significant access-site-related bleeding and cardiac death prevention. Thus, its use seems strongly recommended in patients at increased risk of bleeding, such as those admitted for an ACS.

TCT-32
Neurological complications following PCI - incidence and trends during a period of transition from femoral to radial access. Observational data from the british cardiovascular intervention society PCI database
Karim Ratib1, Mamun Maman2, Adrian Largé1, Samar Arnaus3, Helen Routledge3, Peter Ludman4, Doug Fraser2, Jim Nolan1
1University Hospital of North Staffordshire, Stoke-on-Trent, UK, 2Manchester Royal Infirmary, Manchester, UK, 3Worcestershire Royal Hospital, Worcester, WRR IDD, UK, 4University Hospital Birmingham, Birmingham, UK

Background: There has been a significant increase in use of transradial access (TRA) for PCI in the UK. Early on in the TRA learning curve, procedures are associated with more catheter exchanges, longer screening times and with more contrast use. These factors are all associated with increased risk of periprocedural neurological complications (NC). Using the British Cardiovascular Intervention Society PCI database we assessed changes in NC through a period of transition during which radial access became the dominant access for PCI.

Methods: This study includes data collected by the British Cardiovascular Intervention Society under the auspices of the Central Cardiac Audit Database. We performed a retrospective analysis of the BCIS database between January 2006 and December 2010. The data was split into 2 cohorts based on access site: either radial or femoral (mixed access site use and other access sites were excluded from the analysis). NC was defined as a periprocedural TIA, ischemic stroke or hemorrhagic stroke.

Results: Between 2006 and 2010 a total of 348,092 procedures were recorded exclusively using either transradial (TRA) or transfemoral (TFA) access. Over 5 years, the use of TRA for PCI increased from 17.1% to 50.8% of procedures. There was no difference in the incidence of NC through a period of transition during which radial access became the dominant access for PCI.

Conclusions: These results are reassuring and suggest that a switch from TFA to TRA is not associated with any increased risk of periprocedural neurological complications.

TCT-33
Intracoronary Optical Coherence Tomography and Histology of Overlapping Everolimus-Eluting Bioresorbable Vascular Scaffolds in a Porcine Coronary Artery Model: The Potential Implications for Clinical Practice
Vasim Farooq1, Patrick Serruys2, Jung Heo1, Bill Gogas3, LAURA Perkins4, Yoshinobu Onuma5, Roberto Diletti6, Maria Rada7, Lorent Riber7, Christos Bourantas8, Eric van Remortel8, Ravindra Pawar9, Richard Raposa9, Jennifer Powers10, Heleen Beusekom11, Hector Garcia-Garcia11, Renu Virmani11
1Thorus Center, Erasmus MC, Rotterdam, The Netherlands, 2Professor Interventional Cardiology, Rotterdam, The Netherlands, 3ThoraxCenter, Rotterdam, The Netherlands, 4Abbott Vascular, Mattapom, VA, 5Thoraxcenter, Rotterdam, The Netherlands, 6Rigshospitalet, COPENHAGEN, Denmark, 7Bern University Hospital, Bern, Switzerland, 8Cardialysis, Rotterdam, The Netherlands, 9Abbott, Santa Clara, CA, 10Abbott Vascular, Santa Clara, CA, 11CVPath Inc, Gathersburg, United States

Background: The everolimus-eluting Bioresorbable Vascular Scaffold (Absorb) is a novel approach to treating coronary lesions. A persistent inflammatory response, fibrin deposition and delayed endothelialisation have been reported with overlapping first-generation drug eluting stents. We report optical coherence tomography and histological findings in a porcine coronary artery model after implantation of overlapping Absorb or Xience V stents using an evololimus eluting bioresorbable scaffold on top of the Absorb

Methods: 41 overlapping Absorb and overlapping XV devices (3.0x12 mm) were implanted in the main coronary arteries of 17 non-atherosclerotic pigs with a balloon artery ratio of 1.1:1 (10% over-stitch). Implanted coronary arteries were evaluated by OCT at 28 (Absorb: n=11, XV: n=7) and 90 days (Absorb: n=11, XV: n=8), with immediate histological evaluation following euthanasia at the same time points. One animal from each time point was evaluated with scanning electron microscopy alone.

Results: 1407 cross-sections were analysed by OCT and 148 cross-sections analysed histologically. At 28 days in the overlap, OCT analyses indicated 80.1% of Absorb struts and 99.4% of XV struts to be covered (p<0.0001), corresponding to histological observations of struts with cellular coverage of 75.4% and 99.6% respectively (p<0.001). Uncovered struts were almost exclusively related to the presence of ‘stacked’ Absorb struts, i.e. with a direct overlay configuration. At 90 days overlapping Absorb and overlapping XV struts demonstrated >99% strut coverage by OCT and histology, with no evidence of a significant inflammatory process, and comparable % volume obstructions.

Conclusions: In porcine coronary arteries implanted with overlapping Absorb, strut coverage is dependent on the overlay configuration of Absorb struts at 28 days and not at 90 days. The potential clinical implications of increased strut thickness in the management of long lesions & coronary bifurcations may have important clinical (e.g. duration of antiplatelet therapy) and design considerations (e.g. longer devices & the requirement of dedicated bifurcation devices to avoid overlapping the device) for current and future devices with bioresorbable platforms.

TCT-34
ABSORB EXTEND: An Interim Report on the 12-month Clinical Outcomes from the First 250 Patients Enrolled
Antonio Bartorelli1
1Associate Professor University of Milan-Centro Cardiologo Monzino, Milan, Italy

Background: The safety and performance of the Absorb Bioresorbable Vascular Scaffold (BVS) System (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 2 years have been presented in 101 patients from the ABSORB Cohort B trial. At 12 months, the MACE rate was 6.9%, with no scaffold thrombosis reported, which was sustained out to 2 years with a MACE rate of 9.0%. Following this trial, 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 is planning to enroll up to 1,000 subjects at up to 100 sites. Included are patients with lesions ≥ 28 mm in length and reference vessel diameter of 2.0 - 3.3 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 patients enrolled in ABSORB EXTEND will be available for the first time in October 2012 and will provide additional data on the
was increased at 2 years [192 (174-232) mm²]. At 2 years, in 79% of the analyzed frames the minimum neointima thickness was 0.27 mm. The differential 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 defined as the ratio minimum/maximum neointima thickness.

Methods: The patients of the ABSORB Cohort B trial were divided into 2 groups, Cohort B1 (45 patients, enrollment from March 19 to August 21, 2009) having angiographic follow-up performed at 180 days and 2 years and Cohort B2 (56 patients, enrollment 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, 12 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+B2) are currently available and are summarized hereafter. The mean age was 72 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%. 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 2015.

Conclusions: Three year clinical follow-up data of Cohort B1 is pending.

TCT-36
Circumferential distribution of the neointima thickness at 6 months and 2 at years follow-up after a bioresorbable scaffold implantation. A serial optical coherence tomography study
Christos Bourantas1, Vasim Farooq2, Hector M. Garcia-Garcia2, Yoshinobu Onuma4, Patrick Serruys5, Yaojun Zhang6, Christos Bourantas1, Vasim Farooq2, Hector M. Garcia-Garcia3, Jacques Koolen7, Maasstad Hospital Rotterdam, Rotterdam, The Netherlands

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 BRS implantation at 6 months and at 2 years follow-up.

Methods: We analyzed data from 20 patients who had undergone an Abbott Vascular BVS 1.5 implantation and have been investigated with optical coherence tomography (OCT) at baseline, 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 index of the neointima tissue was defined as the ratio of 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 (4.89-7.11) mm² at 6 months, P<0.001; vs. 6.06 (5.01-7.11) mm² at 2 years, P=0.851]. The mean thickness of neointima was increased at 2 years [192 (174-232) μm vs. 254 (230-280) 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 0.27 mm 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 1.5 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
Yoshinobu Onuma4, Koen Nieman1, Mark Webster2, Leif Thuesen4, Dariusz Dudek5, John Ormiston6, Patrick W. Serruys7
1Thorax Center, Rotterdam, Rotterdam, 2Thorax Centre, Rotterdam, Netherlands, 3Auckland City Hospital, Auckland, New Zealand, 4Department of Cardiology, Aarhus University Hospital, Skejby, Denmark, Aarhus, Denmark, 5University Hospital, Krakow, Poland, 6Associate Professor, University of Auckland Medical School, Auckland, New Zealand, 7Thoraxcenter, Erasmus Medical Center, Rotterdam, Netherlands

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, USA). At 5 years, 25 patients underwent 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 stent 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 mm² 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)
Michael Haude1, Raimund Erbel2, Paul Erne3, Stefan Verheyen4, Paul Vermeer6, Hubertus Degen1, Dirk Bosee5, Ron Wakeman5, Neil Weissman5, Francesco Pratt1, Jacques Koolen7
1Städtische Kliniken Neuss, Lukaskrankenhaus GmbH, Neuss, Germany, 2West German Heart Center, Essen, Germany, 3Lucerner Kantonsspital, Lucern, Switzerland, 4Antwerp Cardiovascular Center, ZNA Middelheim, Antwerp, Belgium, 5MedStar Health Research Institute, Washington, USA, 6Rome Heart Research, Rome, Italy, 7Catharina Hospital Eindhoven, Netherland, N/A

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 6 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 months 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. In 6 patients virtual histology (VH) data showed a significant decrease in the dense calcium by 39.5% (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.