The MiStent SES. The patients had a primary intervention at either of 4-months, 6-months or 8-months. Multislice Computed Tomography Angiography as a Non-invasive Angiographic and Functional Assessment of the 18-Months Performance of a Novel Drug-Eluting Bio-resorbable Coronary Scaffolding Device (ABSORB Cohort B Trial) Koen Nieman1, Yoshihisa Onuma2, Robert-Jan van Geuns3, Bernard De Bruyne4, Leif Thuesen5, Peter Smith6, Jacques Koolen7, Dougal McClean8, Bernard Chevalier9, Ian Meredith10, John Ormiston11, Patrick Serruys12,1 Thorax Center, Rotterdam, Netherlands, 2ThorasCenter, Rotterdam, Rotterdam, 3Erasmus MC, Rotterdam, Netherlands, 4N/A, Aulst, Belgium, 5Department of Cardiology, Aarhus University Hospital, Skejby, Denmark, Aarhus, Denmark, 6Maasstad Hospital Rotterdam, Rotterdam, The Netherlands, 7Catharina hospital Eindhoven, Eindhoven, The Netherlands, 8Cochrarch Hospital, Genk, Belgium, 9Johns Hopkins University, Baltimore, Australia, 10Associate Professor, University of Auckland Medical School, Auckland, New Zealand, 11Professor Interventional Cardiology, Rotterdam, The Netherlands.

Background: To investigate with coronary CT angiography the mid-term outcome of a percutaneously implanted, bio-resorbable, coronary scaffolding device. Methods: As part of the ABSORB trial (A Clinical Evaluation of the Bioabsorbable Everolimus Eluting Coronal Stent System in the Treatment of de Novo Native Coronary Artery Lesions) 71 patients underwent non-invasive coronary CT angiography 18 months after implantation of an everolimus eluting, bio-resorbable scaffold (IVUS 1.1, Abbott Vascular, Santa Clara, CA) for treatment of obstructive coronary artery disease. Using semi-automatic vessel extraction, cross-sectional lumen and vessel areas were measured at 1-mm longitudinal intervals including 5 mm beyond the scaffold borders. Acquired MSCT data was further processed for calculation of fractional flow reserve flow in another independent corelab (Heart Flow, CA, USA).

Results: At 180 days there were no deaths, three non-Q-wave myocardial infarctions and four ischaemia driven target lesion revascularizations. CT angiographic image quality allowed qualitative evaluation in 67 patients, and quantitative evaluation in 61 patients. The mean lumen area within the scaffolded site was 5.1 ± 1.4 mm², compared to the 7.1-mm² nominal cross-sectional scaffold area. The average minimal lumen area measured 3.5 ± 1.0 mm², and the area stenosis was 23 ± 22% (range -64.2 – 72.0%). Significant coronary obstruction was qualitatively assessed in a single patient. The mean plaque area (vessel minus lumen area) measured 8.9 ± 3.4 mm². Coronary luminal enlargement up to 13.3 mm² was observed in one other patient. The non-invasive functional assessment (functional flow reserve according to MSCT) is ongoing and the complete results will be presented at the time of meeting.

Non-invasive evaluation by cardiac CT demonstrated good angiographic results 18 months after implantation of a bio-absorbable coronary scaffolding device. The feasibility of non-invasive FFR will be presented at the time of meeting.

TCT-S82
Eighteenth Month Clinical and Imaging Results from the DESSOLVE I First-in-Human Trial of the MiStent® SES with Absorbable Polymer John Ormiston1, James Stewart2, Mark Webster3, Mathias Vrolix4, Robert Whittborn5, Dennis Donoho6, Charlene Knape7, Alexandru Lansky8, Hirum Bezzera9, Peter Fitzgerald10, David Kandzari11, William Wijns12,1 Dercy Angiography Unit, Auckland, New Zealand, 2Auckland City Hospital, Auckland, New Zealand, 3Hospital Oost-Limburg, Genk, Belgium, 4Lumley-Venticinque’s Hospital, Melbourne, Victoria, Australia, 5Micell Technologies, Durham, NC, 6Yale School of Medicine, New Haven, USA, 7Case Western Reserve University, Cleveland, OH, 8Stanford University Medical Center, Stanford, California, 9Piedmont Heart Institute, Atlanta, USA, 10Cardiovascular Center Aalst, Aalst, Belgium.

Background: The MiStent SES (Micell Technologies, Durham, NC) is an investigational DES characterized by use of crystalline sirolimus and a fully absorbable polymer. Methods: The DESSOLVE I FIH clinical trial was designed to evaluate the initial and long-term efficacy and safety of the MiStent SES in a defined group of patients. Results: The initial 4-months, 6-month and 8-month evaluations demonstrated an in-stent LLL of 0.01, 0.21 and 0.10 respectively as assessed by core laboratory quantitative angiography. Imaging with OCT demonstrated thin, homogeneous coverage with high rates of stent strut coverage at 6 and 8 months, 93% and 96%, with a low rate of stent strut malapposition. The IVUS also demonstrated minimal neointimal hyperplasia with a neointimal volumetric index of 0.8 mm³/mm at 8 months. Conclusions: The MiStent SES demonstrates sustained efficacy and safety through 18 months post-procedure.

TCT-S83
Multi Center, Prospective, Randomized, Single Blind, Consecutive Enrollment Evaluation a Novelolimus-Eluting Coronary Stent System with Bioabsorbable Polymer Compared to a Zotarolimus-Eluting Coronary Stent System: 12-Month Clinical and 6-Month Angiographic and IVUS Results: the EXCELLA BD Study Alexandre Abizaid1, Roberto Botelho2, Joachim Schofer3, Stefan Verheyse4, Ricardo Costa5, Luis Fernando Tanajura6, Katsuhisa Waseda7, Lynn Morrison8, Sara Toyloy9, Peter Fitzgerald10,1 Visiting Professor Columbia University, São Paulo, Brazil, 2Triangulo Heart Institute, Uberlândia, Brazil, 3Medicare center Prof Mathey, Prof Schofer, Hamburg University Cardiovascular Center, Hamburg, Germany, 4Antwerp Cardiovascular Center, ZNA Middelheim, Antwerp, Belgium, Antwerp, Belgium, 5INSTITUTO DALEZANNEZE DE CARDIOLOGIA, SÃO PAULO, Brazil, 6Dante Pazzanne, São Paulo, Brazil, 7Stanford University Medical Center, Stanford, CA, 8elisir medical corporation, Sunnyvale, CA, 9elisir Medical Corporation, Sunnyvale, CA, 10Cardiovascular, Stanford, California.

Background: To evaluate the safety and effectiveness of the Elixis DESynetMD BD Non-invasive Eluting Coronary Stent System (CSS) with a bioabsorbable polymer compared to the Endeavor Zotarolimus Eluting Coronary Stent System through the assessment of clinical, angiographic, and IVUS endpoints. Methods: A total of 149 patients were randomized 3:1, either to the Elixis DESynet BD Novolimus Eluting CSS loaded with 5mcg per mm of stent length of Novolimus, a sirolimus based bioabsorbable polymer, eluted via a bioabsorbable polylactide-based polymer, or to the Endeavor Zotarolimus-eluting CSS loaded with 10mcg per mm of stent length of Zotarolimus eluted via a durable phospholipid choline polymer. All patients were analyzed for the primary endpoint of in-stent lumen loss (ILL) assessed by QCA at 6 months.

Results: Moreover, all patients underwent evaluation for the secondary endpoints including the Device-oriented Composite Endpoint (DOCE) defined as: cardiac death, MI not clearly attributable to a non-intervention vessel, and clinically-indicated target lesion revascularization; clinically-indicated Target Vessel Revascularization (TVR), and stent thrombosis at 1, 6, 9, and 12 months and annually through 5 years. Lesions were also evaluated for angiographic endpoints: at 6 months including: in-segment LLD, percent diameter stenosis, minimal lumen diameter post-procedure and at 6 months, and angiographic binary restenosis (ABR) (≥50%). A subset of patients underwent intravascular ultrasound (IVUS) evaluation including percent (%) neointimal obstruction at 6 months.

Results: The study met the primary endpoint demonstrating both non-inferiority and superiority of the DESyne BD compared to the control (0.12±0.15 vs 0.67±0.47, p<0.001), additionally, in-stent ABR was significantly lower for DESyne BD (0% vs 7.9%, p<0.003). Excellent clinical results at 6 months were demonstrated for both devices. Clinical results through 12 months and additional angiographic and IVUS results will be presented.

Conclusions: The study met the primary endpoint demonstrating both non-inferiority and superiority of the DESyne BD compared to the control. Clinical results through 12 months and complete angiographic and IVUS results will be presented.

TCT-S84
Nine Month Imaging and Twelve Month Clinical Results from the DESSOLVE II Randomized Trial of the MiStent® SES with Absorbable Polymer William Wijns1, Mathias Vrolix2, Stefan Verheyse3, Danny Schoors4, Tom Slagboom5, Marcel Gosselink6, Edouard Benit7, Walter Desmet8, Sara Toyloy9, Peter Fitzgerald10,1 Cardiovascular Center Aalst, Aalst, Belgium, 2Hospital Oost-Limburg, Genk, Belgium, 3Antwerp Cardiovascular Center, Antwerp, Belgium, 4Brussels University Hospital, Brussels, Belgium, 5Instituto Dante Pazzanese de Cardiologia, Sao Paulo, Brazil, 6Stanford University Medical Center, Stanford, California, 7Piedmont Heart Institute, Atlanta, USA, 8Mercy Angiography Unit, Auckland, New Zealand.

Background: The MiStent SES (Micell Technologies, Durham, NC) is an investigational drug-eluting stent (DES) developed to address unfavorable late-term outcomes such as healing and stent coverage. Clinical events were assessed at 8-months, 12-months and 18-months. Clinical results were assessed by core laboratory quantitative angiography. Imaging with OCT demonstrated thin, homogeneous coverage with high rates of stent strut coverage at 6 and 8 months, and 96% and 93%, with a low rate of stent strut malapposition. The IVUS also demonstrated minimal neointimal hyperplasia with a neointimal volumetric index of 0.8 mm³/mm at 8 months. Long-term clinical outcomes and angiographic, OCT and IVUS analyses at 18-months will be presented.

Conclusions: The MiStent SES demonstrates sustained efficacy and safety through 18 months post-procedure.

TUESDAY, OCTOBER 23, 8:00 AM–10:00 AM
as stent thrombosis. These events are hypothesized to be associated in part with durable polymers of current DES. The MiStent SES uses a unique combination of components, a crystalline formulation of sirolimus and a fully absorbable polymer on a thin-strut, cobalt chromium stent platform. The polymer coating is eliminated from the stent in 45-60 days with complete absorption in 90 days. Sirolimus is simultaneously released into the surrounding tissue as a controlled elution.

Methods: The DESSOLVE II clinical trial is a 2:1 randomized study conducted at 26 sites evaluating the MiStent SES for superiority in late lumen loss as compared to the control stent, the Medtronic Endeavor Sprint (Santa Rosa, CA). Patients with discrete de novo lesions (2.5-3.5 mm vessel diameter and ≤27 mm length) in native coronary arteries were acceptable for inclusion in the trial. A total of 183 patients were randomized into either the MiStent SES or Endeavor Sprint and patients had follow-up at 30 days, 6, 9, and 12-months post-procedure. Angiography was conducted at 9-months with two subgroups: 38 patients imaged using optical coherence tomography (OCT) and 29 patients participated in endothelial function testing (EFT). Results: The MiStent SES was superior to Endeavor for the primary endpoint analysis of late lumen loss. The OCT revealed a mean of 2.0% uncovered struts with good suppression on neointimal hyperplasia. EFT demonstrated an overall return of endothelial function with no incidence of vasoconstriction in either the test or control group. Additional secondary endpoint data will be presented.

Conclusions: The MiStent SES is an innovative drug eluting stent with sirolimus in a fully absorbable polymer demonstrating a superior performance as compared to the Endeavor Sprint DES. OCT shows stent coverage at 9-months with a return of endothelial function.

Drug-Coated Balloon
Hall D
Tuesday, October 23, 2012, 8:00 AM–10:00 AM
Abstract nos: 585-600

TCT-585
Six Month Results of the BIOLUX P-IJ First In Man Study Comparing a Paclitaxel Releasing Balloon Catheter versus an Uncoted Balloon Catheter in Femoropopliteal Lesions
Dierk Scheinert1, Schalte Karl-Ludwig2, Zeller Thomas3, Andrej Schmidt4, Ralf Langhof5, Aljuscha Rastan2, Peter Pfaffinger6, Johannes Lammer7, Gunnar Tepe4
1Pfarkrankenhaus Leipzig, Zentrum für Gefäßmedizin, Leipzig, Germany, 2Charité Berlin, Vascular Center Berlin, Ev. Hospital König Elisabeth Herzberge, Berlin, Germany, 3University Heart Centre Freiburg Bad Krozingen, Bad Krozingen, Germany, 4Romed Klinikum Rosenheim, Rosenheim, Germany, 5University Hospital Vienna, Vienna, Austria

Background: The aim of this first in human study is to assess safety and performance of the Biox-18 Lux Paclitaxel releasing PTA balloon (DCB) versus the uncoated Passo-18 balloon catheter (POBA) for the treatment of stenosis and occlusion of femoropopliteal arteries.

Methods: Between October 2010 and August 2011, 60 subjects presenting with stenosis or occlusion of femoropopliteal arteries were consecutively enrolled in this international, multicentre, randomized, controlled study. Primary endpoint of the study is the late follow-up of the lesions (LLL) at 6 months assessed by an independent corelab using quantitative vascular angiography (QCA). Secondary endpoints are binary restenosis (BR) at 6 months, target lesion revascularization, change in mean ankle brachial index and Rutherford classification and major adverse events (MACE) at 6 and 12 months.

Results: Thirty-four men (56.7%) were enrolled in 5 sites. Mean age was 70.7±10.1 (range 45-90) years. Half of the subjects were treated with the Paclitaxel releasing balloon (study group) and the other half with the uncoated balloon catheter (control group). The majority of subjects presented with hypertension (73.3%), followed by smoking (68.3%), history of PAD (63.3%), hypertenidemia (61.7%) and diabetes mellitus (33.3%). Almost two thirds (56.7%) of the subjects were in Rutherford Class 3 and 26.7% were in Class 2. LLL at 6 months was significantly better with 0.5±0.7mm in the DCB group versus 1.0±1.0mm in the POBA group (p=0.033). Three (11.5%) subjects presented with BR in the DCB group versus 9 (34.6%) in the POBA group (p=0.048). The overall MACE rate is identical in both groups with 4 (15%) MACEs each. ABI improvement was the same in both groups from baseline (0.7±0.2) to 6 months (0.9±0.2). Clinical outcome in Rutherford Class was slightly better in the DCB group with an improvement from 3.0±0.8 at baseline to 1.6±1.4 at 6 months versus 2.9±0.8 to 1.7±1.3 in the POBA group.

Conclusions: Six month Results are consistent with previously published data and confirm the safety and efficacy of DCB for the treatment of symptomatic femoropopliteal disease. LLL and BR Results were significantly better in the DCB group compared with POBA.

TCT-586
Impact Of Restenosis Pattern On Angiographical Outcomes After Paclitaxel-Eluting Balloon Angioplasty For Drug-Eluting Stent Restenosis
Shunsuke Kudo1, Kazushige Kadota1, Seiji Habara2, Takashi Tada3, Hirotsuki Tanaka4, Yasushi Fukui5, Naoki Oki6, Harumi Katoh6, Tsuyoshi Goto7, Kazuaki Mitsudo7
1Kurarishi Central Hospital, Kurashiki, Japan

Background: Previous studies of drug-eluting stent (DES) restenosis have shown that the morphologic pattern of in-stent restenosis (ISR) is an important predictor of outcomes after plain balloon angioplasty or repeat DES placement. However, there is no data available on the relationship between the restenosis pattern and angiographical outcomes after paclitaxel-eluting balloon (PEB) angioplasty.

Methods: From September 2008 to August 2011, 304 lesions were treated with PEB for ISR lesions after DES implantation. All of the initial DES were implanted in de novo lesions (Sirolimus-eluting stent: 156, Paclitaxel-eluting stent: 53, Zotarolimus-eluting stent: 52, Everolimus-eluting stent: 31, Biolimus-eluting stent: 12). We divided these lesions into two groups: focal lesions and nonfocal lesions, which were diffuse, proliferative and total lesions. We investigated the angiographic restenosis pattern and the restenosis rate at follow-up coronary angiography (CAG). Follow-up CAG was performed at 6 months after procedure.

Results: The angiographical follow-up rate was 91.1% (277 lesions: 99 focal lesions, 178 nonfocal lesions). The binary restenosis rate was 18.2% in focal lesions and 29.2% in nonfocal lesions (p=0.04). The figure shows the restenosis patterns at baseline and follow-up of the lesions which restenosed for the second time. The recurrent restenosis pattern at follow-up remained the same in 64.3%, became worse in 7.1% and improved in 28.6%.

Conclusions: After PEB angioplasty for DES ISR lesions, the morphologic pattern of ISR is also an important predictor of the outcomes. Most of the recurrent ISR patterns are the same or better than preprocedural ISR patterns.

TCT-587
Drug-Coated Balloon For De Novo Coronary Lesions: Results From The Valentines II Trial
Ron Waksman1, Antonio Serru2, Alfredo Rodriguez2, Rembert Poggie von Strandmann3, Stefanie Stabinke4, Rebecca Torguson4, Joshua Loh5, Fazlal Malik5
1Georgetown University, Washington, DC, 2Hospital de Sant Pau y Santa Creu, Barcelona, Spain, 3Otamendi Hospital, Buenos Aires, Argentina, 4Eurocor GmbH, Bona, Germany, 5Medstar Washington Hospital Center, Washington, DC, 6National Heart Foundation Hospital & Research Institute, Dhaka, Bangladesh

Background: Drug-coated balloons (DCB) have emerged as a potential alternative in treating in-stent restenosis; however, their role in the treatment of de novo lesions is unclear. This study aimed to evaluate the safety and efficacy of the second-generation DIOR DCB as an adjunct to plain old balloon angioplasty (POBA) for the treatment of de novo coronary lesions.

Methods: Valentines II was designed as a prospective, multicenter, multinational, Web-based registry. Eligible patients with stable or unstable angina, and/or documented ischemia on stress testing with de novo lesions of 50% stenosis were prospectively enrolled. Patients underwent POBA followed by DCB. In cases of suboptimal angiographic success (TIMI flow <3 and/or residual stenosis of >30%), additional bail-out bare metal stenting (BMS) was left to the operator’s discretion. The primary endpoint was 6-9 months major adverse cardiac events (MACE: all cause death, myocardial infarction, target vessel revascularization and vessel thrombosis). A subset of patients underwent angiography follow-up.

Results: 109 lesions in 103 patients were treated. Mean age was 62.6 ± 10.2 years; 79.6% were male. Lesion stenosis at baseline and post treatment was 83.3 ± 9.5% and...