endpoint was 6.5% in the BES arm vs 7.1% in the EES arm (p=NS). Between the BES and EES arm no significant differences were observed in cardiac death 0.5% vs 1.3%, MI 4.5% vs 5.4%, TVR 3.5% vs 2.7% and TLR 2.7% vs 2.2, respectively. Definite and probable stent thrombosis rate was 0.74% in BES and 1.79% in EES (p=0.25).
Conclusions: Despite high complexity of lesions in the LL subgroup, good clinical outcomes and low rate of revascularization were observed at 12 months post-procedure with both types of drug eluting stents. Stent thrombosis rate was relatively low despite multiple overlapping stents. Our findings confirm the safety efficacy of both drug-eluting stents for treatment of patients with long lesions in coronary arteries.

TCT-581

Multislice Computed Tomography Angiography as a Non-invasive Angiographic and Functional Assessment of the 18-Months Performance of a Novel Radiolucent Bio-resorbable Coronary Scaffolding Device (ABSORB Cohort B Trial)

Koen Nieman[1], Yoshinobu Onuma[2], Robert-Jan van Geuns[3], Bernard De Bruyne[4], Leif Thuesen[5], Peter Smits[6], Jacques Koolen[7], Dougal McCLean[8], Bernard Chevalier[9], Ian Meredith[10], John Ormiston[11], Patrick Serruys[12]
[1]Thorax Centre, Rotterdam, Netherlands, [2]ThoraxCenter, Rotterdam, Rotterdam, [3]Erasmus MC, Rotterdam, Netherlands, [4]N/A, Aalst, Belgium, [5]Department of Cardiology, Aarhus University Hospital, Skejby, Denmark, Aarhus, Denmark, [6]Maasstad Hospital Rotterdam, Rotterdam, The Netherlands, [7]catharina hospital eindhoven netherlands, Eindhoven, The Netherlands, [8]Christchurch Hospital, Christchurch, New Zealand, [9]ICPS, Massy, France, [10]Monash University, Melbourne, Australia, [11]Associate Professor, University of Auckland Medical School, Auckland, New Zealand, [12]Professor 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 Coronary 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 (BVS 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 in another independent corelab (Heart Flow, CA, USA).
Results: At 180 days there were no deaths, three non-Q-wave myocardial infarctions and four ischemia 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 lumen 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.
Conclusions: Noninvasive 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-582

Eighteen Month Clinical and Imaging Results from the DESSOLVE I First-in-Human Trial of the MiStent® SES with Absorbable Polymer

John Ormiston[1], James Stewart[2], Mark Webster[2], Mathias Vrolix[3], Robert Whitbourn[4], Dennis Donohoe[5], Charlene Knape[5], Alexandra Lansky[6], Hiram Bezerra[7], Peter Fitzgerald[8], David Kandzari[9], William Wijns[10]
[1]Mercy Angiography Unit, Auckland, New Zealand, [2]Auckland City Hospital, Auckland, New Zealand, [3]Hospital Oost-Limburg, Genk, Belgium, [4]St Vincent's Hospital, Melbourne, Victoria, [5]Micell Technologies, Durham, NC, [6]Yale School of Medicine, New Haven, USA, [7]Case Western Reserve University, Cleveland, OH, [8]Stanford University Medical Center, Stanford, California, [9]Piedmont Heart Institute, Atlanta, USA, [10]Cardiovascular 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 on a thin strut (64um) cobalt-chromium stent. The stent coating is eliminated from the stent in 45-60 days with full absorption of the polymer by 90 days. 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.
Methods: The DESSOLVE I FIH clinical trial is a single-arm study conducted at 5 international sites. Thirty patients with discrete de novo lesions (2.5-3.5 mm vessel diameter and ≤20 mm length) in native coronary arteries were implanted with a single MiStent SES. The patients had a primary intervention at either of 4-months, 6-months or 8-months with a subsequent intervention at 18-months. Angiography and IVUS were used to evaluate the amount of neointimal hyperplasia and stent apposition, and OCT for vessel healing and stent coverage. Clinical events were assessed at 8-months, 12-months and 18-months.
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, homogenous 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 findings supported minimal neointimal hyperplasia with a neointimal volume index of 0.8mm3/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.

TCT-583

Multi Center, Prospective, Randomized, Single Blind, Consecutive Enrollment Evaluation a Novolimus-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 Abizaid[1], Roberto Botelho[2], Joachim Schofer[3], Stefan Verheye[4], Ricardo Costa[5], Luiz Fernando Tanajura[6], Katsuhisa Waseda[7], lynn morrison[8], Sara Toyloy[9], Peter Fitzgerald[10]
[1]Visiting Professor Columbia University, São Paulo, Brazil, [2]Triangulo Heart Institute, Uberlândia, Brazil, [3]Medicare center Prof Mathey, Prof Schofer, Hamburg University Cardiovascular Center, Hamburg, Germany, [4]Antwerp Cardiovascular Center, ZNA Middelheim, Antwerp, Belgium, Antwerp, Belgium, [5]INSTITUTO DANTE PAZZANESE DE CARDIOLOGIA, SAO PAULO, Brazil, [6]Dante Pazzanese, São Paulo, Brazil, [7]Stanford University Medical Center, Stanford, CA, [8]elixir medical corporation, Sunnyvale, CA, [9]Elixir Medical Corporation, Sunnyvale, CA, [10]Cardiovascular, Stanford, California

Background: To evaluate the safety and effectiveness of the Elixir DESyneTM BD Novolimus 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 Elixir DESyne BD Novolimus Eluting CSS loaded with 5mcg per mm of stent length of Novolimus, a sirolimus metabolite, 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 phosphoryl choline polymer. All patients were analyzed for the primary endpoint of in-stent late lumen loss (LLL) assessed by QCA at 6 months. Moreover, all patients underwent evaluation for the secondary endpoints including the Device-orientated 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 LLL, 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-584

Nine Month Imaging and Twelve Month Clinical Results from the DESSOLVE II Randomized Trial of the MiStent® SES with Absorbable Polymer

William Wijns[1], Mathias Vrolix[2], Stefan Verheye[3], Danny Schoors[4], Ton Slagboom[5], Marcel Gosselink[6], Edouard Benit[7], Walter Desmet[8], Saquib Chowdhary[9], Alexandra Lansky[10], Hiram Bezerra[11], Peter Fitzgerald[12], David Kandzari[13], John Ormiston[14]
[1]Cardiovascular Center Aalst, Aalst, Belgium, [2]Hospital Oost-Limburg, Genk, Belgium, [3]Antwerp Cardiovascular Center, Antwerp, Belgium, [4]Brussels University Hospital, Brussels, Belgium, [5]Onze Lieve Vrouwe Gasthuis, Amsterdam, Netherlands, [6]Isala Klinieken, Zwolle, Netherlands, [7]Heart Center Hasselt, Hasselt, Hasselt, [8]Catholic University Leuven, Leuven, Belgium, [9]Wythenshawe Hospital, Manchester, United Kingdom, [10]Yale School of Medicine, New Haven, USA, [11]Case Western Reserve University, Cleveland, OH, [12]Stanford University Medical Center, Stanford, California, [13]Piedmont Heart Institute, Atlanta, USA, [14]Mercy 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

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