revascularization (12.5%). A total of 53 lesions were treated robotically with the majority being complex (77.3% ACC/AHA type B2/C) (Table). Clinical procedural success and device technical success were 97.5 % (n=39 of 40) and 90.0 % (n= 36 of 40) respectively. The single clinical failure was a chronic total occlusion treated manually with antegrade wire escalation 2 weeks later. The three technical failures were due to bailout atherectomy (n=1), inadequate guidewire tip control to navigate a tortuous vessel (n=1), and an inability to advance a stent robotically through the side strut of a previously placed stent (n=1).

ACC/AHA type A B1 B2 C	1 (1.9) 11 (20.8) 8 (15.1) 33 (62.2)
Primary lesion length (mm)	19.0±9.5
Primary lesion stenosis (%) Pre Post	82.7±9.9 0.6±4.1
Stents deployed per case (#)	1.57±0.90
Lesions treated per case (#)	1.32±0.65
Vessel treated LAD RCA LCx	26 (49.0) 10 (32.0) 17 (18.9)
Procedure time (min)	40.7 +/- 21.6
Procedural radiation exposure Fluoroscopy time (min): Dose area product time (cGy/cm2)	17.6 +/- 5.7 7162 +/- 5424
Contrast volume (mL)	172 +/- 65.1
Access site Radial Femoral	26 (65.0) 14 (35.0)

CONCLUSION The second generation CorPath GRX system for robotic-assisted PCI is safe, effective and achieves high rates of clinical and technical success in a cohort of patients with complex coronary disease.

CATEGORIES OTHER: Pre-Clinical/First In-Human Studies

TCT-125

Ultrahigh Molecular Weight Polyethylene Membrane for Use in Vascular Stent Graft Applications — Preliminary Evidence From an Ovine Peripheral Implantation Model

Harold Smelt,[1] Wei Cheng,[2] Steven Tyler,[3] Renu Virmani[4]
[1]DSM Biomedical, Geleen, Netherlands; [2]DSM Biomedical B.V., Geleen, Netherlands; [3]PQ Bypass, San Mateo, California, United States; [4]CVPath Institute, Inc., Gaithersburg, Maryland, United States

BACKGROUND Availability of graft material suitable for stent graft application is rather limited and ePTFE remains almost the only choice for small profile stent grafts. Here we demonstrate in a 90 days animal study based on ovine model peripheral artery stenting, that an UHMWPE membrane (Dyneema Purity® Membrane) shows great promise as an alternative graft material for use in vascular stent graft applications. In comparison to typical ePTFE, this thin and highly porous UHMWPE membrane is mechanically strong and isotropic with a breaking strength of ~20 MPa, and hence is particularly suitable for making low profile stent grafts.

METHODS UHMWPE Membrane is manufactured via a proprietary gel-extrusion and bi-axially stretching process which leads to a highly porous and thin (3 g/m2 and < 20 μm thick) membrane. The UHMWPE Membrane covered stents used in this study were produced via a proprietary lamination process that encapsulates the nitinol stent. Four sheep (Ovis aries) weighing 50-60 kg were used for the current animal study. For each sheep, one test article and one control article Gore® Viabahn® covered-stent with CARMEDA® bioactive heparin surface (Gore-CA) were introduced via femoral access to the carotid or iliofemoral artery. On the day of termination (day 90) angiography was performed, where after animals were sacrificed and the target artery segments containing the test articles or the control articles were explanted. Before processing samples for further histological analysis, explanted arteries were grossly radiographed and photographed for macroscopic evaluation of vessel intactness and stent expansion.

RESULTS Angiography shows that all implanted stent grafts, both test articles and control articles, in all four sheep were widely patent at 90 days. Histological analysis of both longitudinal and transverse sections of all implanted stent grafts, both test articles and control articles, show comparable graft apposition, tissue reaction and inflammatory response. In addition, histological results corroborate the widely patent status of the implanted stent graft at 90 days. Fig3 gives an example of the histological images of longitudinal and transverse sections of the stent graft in the right carotid artery for both UHMWPE covered stent and Gore-CA.

CONCLUSION The results from angiographical and histological analyses performed on all implanted stent grafts show that the UHMWPE covered stent does not exhibit inferior performance when compared to Gore-CA. Such findings suggest great promise of Dyneema Purity® Membrane to be used as an alternative synthetic graft material for vascular covered-stent, particularly low profile covered-stent applications.

CATEGORIES ENDOVASCULAR: Peripheral Vascular Disease and Intervention

TCT-126

First Experience with the Coronary Sinus Reducer System for the Management of Refractory Angina in Patients Without Obstructive Coronary Artery Disease

Francesco Giannini,[1] Luca Baldetti,[2] Alfonso Ielasi,[3] Neil Ruparelia,[4] Francesco Ponticelli,[5] Azeem Latib,[1] Satoru Mitomo,[6] Antonio Esposito,[7] Anna Palmisano,[7] Alaide Chieffo,[1] Antonio Colombo[8]
[1]Interventional Cardiology Institute San Raffaele Hospital, Milan, Milan, Italy; [2]IRCCS San Raffaele Hospital, Milan, Milan, Italy; [3]Ospedale Bolognini, Seriate, Bergamo, Italy; [4]Hammersmith Hospital, London, United Kingdom; [5]IRCCS San Raffaele Hospital, 20100, Milan, Italy; [6]IRCCS San Raffaele Scientific Institute, Milan, Milan, Italy; [7]Experimental Imaging Center, Department of Radiology, San Raffaele Scientific Institute, Milan, Milan, Italy; [8]Interventional Cardiology Institute San Raffaele Hospital - Stamford Hospital - Columbia University - Centro Cuore Columbus, Milan, Milan, Italy

BACKGROUND Refractory angina following angiographically successful PCI is common and microvascular dysfunction (CMD) seems the underlying mechanism. As no data are available on Reducer performance in these patients, we tried to address this issue.

METHODS Between 2015 and 2016, 8 patients underwent coronary angiography due to refractory angina and non-invasive evidence of ischemia. All had previously undergone at least one PCI. All had non-obstructed epicardial coronary arteries (absence of plaques, <50% narrowing, or a negative FFR test in case of intermediate lesions) and underwent compassionate Reducer implantation for microvascular angina.

RESULTS Population age was 61.5 (50-68) years. 4 (50%) were women. All were on OMT (median number of anti-ischemic drugs was 3, range: 2-4). Median LVEF was 58.0 (55.0-61.5)%. No cases of death, coronary angiography/PCI or hospitalization for angina were noted at follow-up. CCS class improved from 3 (3-4) to 1.5 (1-3); p=0.014. At 1 year, this benefit was maintained for 3 of the 5 patients assessed. Discontinuation of at least one drug was possible in 3 (37.5%) patients. An improvement at the SAQ (Seattle Angina Questionnaire) scores was observed: physical limitation 46.0 (IQR 40.5-53.3) to 64.0 (IQR 53.0-80.0), p=0.028; angina stability 40.0 (21.3-43.0) to 80.0 (58.0-100.0), p=0.028; angina frequency 47.0 (33.0-58.0) to 66.0 (56.0-80.0), p=0.028; treatment satisfaction 40.0 (26.8-73.3) to 75.0 (66.0-82.0), p=0.063; quality of life 26.5 (17.8-39.0) to 56.0 (53.0-60.0), p=0.018. At the six-minute walk test, the distance walked increased from 266 (238.5-372.8) to 360 (341-420) metres, p=0.018; and the Borg scale scores reduced from 4.0 (3.0-5.0) to 0.0 (0.0-2.5), p=0.042. 3 patients underwent stress cardiac magnetic resonance with myocardial perfusion reserve index (MPRI) calculation. MPRI of the ischemic segments increased after Reducer implantation from 1 to 2.06 in patient 1 (p=0,023), 1.08 to 1.38 in patient 4 (p=0,004) and 1 to 2.85 in patient 5 (p=0,052). LV MPRI showed an increase from 2.25 to 3.08 in patient 1 (p=0,028), 1.25 to 1.51 in patient 4 (p=0,004) and 1.33 to 2.20 in patient 5 (p<0,001).

CONCLUSION This preliminary experience suggests that Reducer is safe and may have a role in the management of patients presenting with refractory angina in spite of complete epicardial revascularization with PCI and OMT.

CATEGORIES OTHER: Pre-Clinical/First In-Human Studies

TCT-127

Optical Coherence Tomography and Histopathological Preclinical Evaluation of an Enhanced Polytetrafluoroetylene (PTFE) Covered Stent in a Peripheral Swine Animal Model: Addressing the Anatomical Challenges of the Lower Limb Stenting Procedure

Armando Mellez,[1] Krista N. Dillon,[1] Dane A. Brady,[1] Luciano Curado,[2] Alexander Moreira,[3] Serge Rousselle[1]
[1]Altaire Pathology, Thurmont, Maryland, United States; [2]Goiania, Goiás, Brazil; [3]CMS Medical, São Paulo, São Paulo, Brazil

BACKGROUND Covered stents are widely used to address numerous areas of need in peripheral intervention.However, PTFE covered stents have a known relative inflexibility which makes deliverability difficult and associated with a high restenosis rate. In this study we aim to evaluate the performance and vascular response of a new peripheral covered stent in a large animal model as compared to a commercially available PTFE covered stent.

METHODS Six swine were enrolled(45±1 kg). Superficial femoral arteries recieved Solaris (Scitech, Sao Paulo, Brazil) or Fluency (Bard, Tempe, AZ). Stents utilized were 40 mm long for both groups and implanted aiming for a 1.1:1 ratio. Following implantation, animals were recovered and followed for 30 days. At 30 day post-implantation all stents were evaluated under optical coherence tomography (OCT), explanted and subjected to stent integrity analysis and histopathological evaluation.

RESULTS 11 stents were evaluated (Solaris n=6, Fluency n=5). The operator described the Solaris stent as demonstrating a higher navigability when compared to the Fluency stent. The hydrophilic coated delivery system of the Solaris stent allowed a smoother release of the device without any sudden "jump" and greater geographical precision at implantation. At 30 days, OCT revealed a similar stent area for both groups (Solaris 25.8±4.7 vs Fluency 24.7±5mm2). However, Solaris demonstrated a higher lumen area (Solaris 18±4.2mm vs Fluency 13.9±3.4mm2) with a lower neointimal area (Solaris 7.8±1.8 vs Fluency 10.8±2.4mm2) compared to control. This led to a higher percentage stenosis in the control group (Solaris 31.9±7 vs Fluency 44.8±6%). The integrity analysis of the stents via radiographs revealed no fractures in any stent from either group. The results of the histopathological evaluation will be presented in the meeting.

CONCLUSION The Solaris PTFE-covered peripheral stent demonstrated a resistance to fracture with increased flexibility and navigability and better conformability to artery curvature. The release system allowed for an accurate geographical delivery and the components of the device produced a lower OCT morphometrically-assessed neointimal response when compared to the control group.

CATEGORIES ENDOVASCULAR: Peripheral Vascular Disease and Intervention

ACUTE BRS RESULTS

Abstract nos: 128 - 132

TCT-128

Relationship between bioresorbable vascular scaffold technique and acute recoil

Hirofumi Hioki,[1] Salvatore Brugaletta,[2] Luis Ortega-Paz,[3] Kohki Ishida,[4] Ander Regueiro,[1] Xavier Freixa,[5] Victoria Martin Yuste,[6] Monica Masotti,[2] Manel Sabate[7]
[1]Hospital Clinic, Barcelona, Spain; [2]Hospital Clinic Barcelona, Barcelona, Spain; [3]Hospital Clínic of Barcelona, Barcelona, Spain; [4]Kitasato University Hospital, Sagamiharashi, Japan; [5]Hospital Clinic of Barcelona, Toronto, Spain; [6]hospital clinic barcelona, barcelona, Spain; [7]Hospital Clínic; University of Barcelona, Barcelona, Spain

BACKGROUND Proper bioresorbable vascular scaffold (BVS) implantation has shown to reduce device-related events. Whether it could affect acute recoil immediately BRS implantation is unknown. We aimed to analyze relationship between BRS implantation technique and BVS acute recoil.

METHODS In our institution, we identified 158 consecutive patients (mean age 58 years, 79% male, 78% acute coronary syndrome) who received BVS implantation from April 2012 to March 2017. Absolute acute recoil (AAR) was measured by the difference between mean diameter of final balloon (X) and mean lumen diameter of scaffold immediately after balloon deflation (Y). Relative acute recoil (RAR) was defined as (X-Y)/X and expressed as a percentage. The PSP scores, which analyze the goodness of BVS implantation, previously developed in the GHOST registry, were evaluated for each patient included in this study.

RESULTS The AAR and RAR (median [interquartile range]) were 0.12mm [0.04-0.25] and 3.9% [1.4-8.0]. Compared to the patients with PSP-3 lower than median value, patients with PSP-3 higher than median value had a significantly lower AAR (0.09mm vs. 0.15mm, $p < 0.05$) and RAR (2.6% vs. 5.1%, $p < 0.05$). Inversely, PSP-1 and PSP-2 scores were not associated with acute recoil. Within PSP score variables, correct BVS sizing was significantly associated lower degree of AAR and RAR compared to oversizing (0.06mm vs. 0.16mm, $p < 0.05$; 2.0% vs. 5.1%, $p < 0.05$, respectively). Multivariate analysis showed that correct BVS sizing significantly reduce the incidence of AAR (OR, 0.18; 95%CI 0.07-0.47). ST-elevation myocardial infarction (OR, 0.48; 95%CI, 0.21-1.12), pre-dilation (OR, 0.93; 95%CI, 0.35-2.46), post-dilation with NC balloon larger up to 0.5mm (OR, 1.52; 95%CI, 0.70-3.28), and BVS: reference vessel diameter ratio (OR, 0.92; 95%CI, 0.43-1.96) were not associated with AAR.

CONCLUSION Optimized BVS implantation, particularly choosing correct BVS size, could reduce acute recoil. Long-term follow-up is warranted to demonstrate whether AAR is related with clinical outcomes after BVS implantation.

CATEGORIES CORONARY: Bioresorbable Vascular Scaffolds

TCT-129

Long-term Follow-up of BRS Implantation for Complex Coronary Lesions: A Multicentre Experience

Damiano Regazzoli,[1] Azeem Latib,[2] Babu Ezhumalai,[3] Akihito Tanaka,[2] Pier Pasquale Leone,[4] Marco Ancona,[5] Antonio Mangieri,[2] Francesco Giannini,[2] Satoru Mitomo,[6] Ashok Seth,[7] Antonio Colombo[8]
[1]San Raffaele Scientific Institute, Milano, Milan, Italy; [2]Interventional Cardiology Institute San Raffaele Hospital, Milan, Milan, Italy; [3]MIOT International, Chennai, Tamil Nadu, India; [4]San Raffaele Hospital, Milan, Milan, Italy; [5]San Raffaele Hospital, Milan, Italy, Milano, Milan, Italy; [6]IRCCS San Raffaele Scientific Institute, Milan, Milan, Italy; [7]Fortis Escorts Heart Institute, New Delhi, Delhi, India; [8]Interventional Cardiology Institute San Raffaele Hospital - Stamford Hospital - Columbia University - Centro Cuore Columbus, Milan, Milan, Italy

BACKGROUND Incidence of late BVS thrombosis is of concern. Clinical experiences have shown that 'dedicated implantation technique' is a key to decrease ST. The aim of this study was to evaluate the use of 'dedicated implantation technique' in the outcome of BRS.

METHODS We retrospectively analyzed consecutive patients that underwent BVS implantation in three high-volume centers before December 2014, in order to have long clinical follow-up. A total of 492 patients were identified for a total of 763 lesions implanted with BRS using a dedicated implantation strategy from the beginning.

RESULTS Mean age was 60±11 (male sex 90%), 35% of patients were diabetics, left ventricular systolic function (54±8%) and renal function (eGFR 90±25 ml/min) were preserved. The coronary anatomy was predominantly complex, with type B2 or C lesions in 75%, CTOs in 5.6%, bifurcations in 31% and severely calcific lesions in 13%. The dedicated implantation technique included good lesion preparation and debulking (when necessary): predilatation was performed in 99% of cases (cutting balloon 3.5%, scoring balloon 8%, rotational atherectomy 5%). OCT and IVUS were used in 15% and 37% of cases, respectively. Mean scaffold length was 31±16 mm, with a 1:1 high-pressure (21±4atm) postdilatation rate of 99.9%. Angiographic success was achieved in 99.9% of cases. All patients were discharged with dual antiplatelet therapy. Median follow-up was 954 (IQR 760-1130) days and was obtained for 98.8% of patients. Definite or probable scaffold thrombosis occurred in 0.6% (3 pts) of patients ay 1 year and remained stable at 2 and 3 year. Rate of target lesion failure (cardiovascular death, target vessel MI, TLR) was 3.8%, 6.1% and 7.1% at 1, 2 and 3 years follow-up respectively. All the patients were in dual antiplatelet therapy at 1 year and 51% of patients did not discontinue DAPT at last contact.

CONCLUSION This large multicenter registry enrolled patients with high prevalence of complex disease and showed good outcomes. The use of a dedicated implantation technique seems to be a mandatory aspect in order to achieve good long term results when implanting BVS. The role of long term DAPT in this setting must be furtherly addressed.

CATEGORIES CORONARY: Bioresorbable Vascular Scaffolds

TCT-130

Comparison of Bioresorbable Scaffold Measurements between Intravascular Ultrasound and Quantitative Coronary Angiography in the ABSORB Japan Trial

Kozo Okada,[1] Yasuhiro Honda,[2] Hideki Kitahara,[2] M. Brooke Hollak,[3] Paul G. Yock,[2] Jeffrey J. Popma,[4] Hajime Kusano,[5] Wai-Fung Cheong,[6] Krishna Sudhir,[5] Peter J. Fitzgerald,[2] Takeshi Kimura[7]