drugs, including a diuretic). A subset of patients (n=129) is being followed to 3 years post-RDN (35 consented to laboratory assessments to 3 years). The primary endpoint is change in office-based BP from baseline. Data collection includes office-based BP measurement every 6 months, renal function, electrolytes, and medication usage.

Results: A total of 34 patients have reached the 3 year follow-up time point (9 with labs). Baseline BP was 175/98±12/11 mmHg. Mean SBP change post-RDN was -18.0±16.6 mm Hg at 1 month, -28.4 ± 17.6 mm Hg at 6 months, -27.6 ± 16.3 mm Hg at 2 years and -31.3 ± 14.9 mm Hg at 3 years. Medication usage remained similar to baseline with 35% aldosterone antagonist, 85% beta blocker and 82% calcium channel blocker use at baseline and at 3 years; diuretic use 91% and 88%, angiotensin receptor antagonists 71% and 76%, and ACE inhibitors 50% and 59% at baseline and 3 years, respectively. At 3 years estimated glomerular filtration rates (eGFR) declined by -13.2±12.1 from a baseline of 82.2±16.1 mL/min/m^2.

Conclusions: Among patients with full 3 year follow-up, RDN results in significant, sustained lowering of SBP in patients with treatment-resistant hypertension and a baseline SBP > 160 mm Hg. Antihypertensive medication usage was similar at baseline and 3 years.

CRT-4

Multi-center, First-in-man Evaluation Of The Myolimus-eluting Bioresorbable Coronary Scaffold: 6-month Clinical And Imaging Results

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Aims: To evaluate the clinical safety and effectiveness of the DESolve™ Myolimus-Eluting Bioresorbable Coronary Scaffold (BCSS)in patients with single de novo native coronary artery lesions through clinical endpoints and multiple imaging modalities.

Methods and Results: Background: The DESolve BCSS is a novel drug eluting device that combines a PLLA-based scaffold coated with a bioresorbable polylactide-based polymer and the drug Myolimus. Myolimus, a macrocyclic lactone mTOR inhibitor has demonstrated potent anti-proliferative properties in two First-in-Man (FIM) trials using Elixir's metallic Myolimus-eluting coronary stents. Drug dose is 3 mcg per mm of scaffold length; the same dose used in the FIM studies. Sixteen patients with single, de novo coronary artery lesions were enrolled in this prospective, multi-center, single-arm FIM study. One patient did not receive a study stent and was deregistered. The 15 remaining patients are being analysed for multiple clinical endpoints: Device and Procedure Success; Major Adverse Cardiac Events (MACE), a composite endpoint of cardiac death, target vessel MI, and clinically-indicated target lesion revascularization (CI-TLR); clinically-indicated Target Lesion and Target Vessel Revascularization, (CI-TVR) and stent thrombosis assessed at 1, 6 and 12 months and annually to 5 years. Multiple assessments by angiographic, IVUS and OCT at 6 months were completed. An additional analysis using multislice computed tomography (MSCT) will be completed at 12 and 24 months. At 6 months, the in-scaffold late lumen loss was 0.19 ± 0.19 by QCA, the % volume obstruction was 7.18 ± 3.37 by IVUS, and by OCT 98.68 ± 2.44% of struts were demonstrated as covered. There was one MACE event, a TLR, during the follow-up period. Detailed clinical and imaging results through 12 months will be presented.

Conclusion: The DESolve™ Myolimus-Eluting BCSS demonstrated both excellent safety and effectiveness in this FIM study, thus warranting further clinical evaluation of the novel technology in larger clinical studies. Detailed clinical and imaging results through 12 months will be presented.

CRT-5

Why Patients Presenting with Acute Myocardial Infarction Undergoing Primary Percutaneous Coronary Intervention and Treated with Prasugrel are Switching Back to Clopidogrel

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Background: The reasons for switching from prasugrel back to clopidogrel after percutaneous coronary intervention (PCI) in acute myocardial infarction (AMI) are unclear, but are frequently practiced. The study aims to compare the characteristics and in-hospital outcomes of patients initially given prasugrel but was switched back to clopidogrel versus those who were continued on prasugrel on discharge.

Methods: The study included a cohort of 152 consecutive AMI patients who were first loaded with prasugrel and underwent PCI. Patients were categorized into switched therapy to clopidogrel on discharge (Switched, n=58) and continued therapy on prasugrel on discharge (Continued, n=94). Patient and procedural characteristics, as well as PCI-related complications and in-hospital outcomes were evaluated.

Results: Baseline demographics and procedural characteristics of both groups were similar. Patients who switched to clopidogrel on discharge had significantly longer hospital stay, and intensive care unit stay trended longer. Switched patients had significantly higher incidence of blood transfusions. Major bleeding, hematocrit drop, hematoma and urgent coronary artery bypass grafting (CABG) also trended higher in patients who switched therapy.

Concomitant coumadin therapy was significantly higher in the switched therapy group, whereas aspirin therapy was similar in both groups. No in-hospital mortality or myocardial infarction occurred in either groups (Table).

Conclusion: In-hospital bleeding complications requiring blood transfusion, need for urgent CABG and concomitant coumadin therapy are the main reasons for switching of antiplatelet therapy from prasugrel to clopidogrel prior to discharge.

In-hospital outcomes and concomitant therapy on discharge

	Switched to clopidogrel (n=58)	Continued on prasugrel (n=94)	P value
Length of stay in intensive care unit (days)	1.1 ± 1.5	0.7 ± 1.0	0.051
Overall hospital length of stay (days)	4.3 ± 4.3	2.9 ± 1.8	0.021
Death or Q wave myocardial infarction	0	0	-
Coronary artery bypass grafting	3 (5.2%)	0	0.054
Blood transfusion	7 (12.1%)	0	<0.001
Major bleeding	4 (6.9%)	1 (1.1%)	0.070
Hematocrit drop >15%	5 (8.5%)	1 (1.1%)	0.060
Hematoma	4 (6.9%)	1 (1.1%)	0.070
Concomitant coumadin therapy on discharge	10 (17.2%)	5 (5.3%)	0.017

CRT-6

Safety and Efficacy of Ultrasound-guided Thrombin Injections at the 'Neck' of Pseudoaneurysms

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Background: Thrombin injection has been the treatment of choice for iatrogenic arterial pseudoaneurysms (PSAs). However, certain morphological features of the PSA, i.e. neck width and length, occasionally precludes the use of this treatment option using the current recommended technique.

Methods: Between March 2008 and June 2012, 146 consecutive patients who underwent thrombin injection for post percutaneous coronary intervention related PSAs were retrospectively studied. The technique of injecting as superficial and as far from the PSA tract is compared with injecting at the 'neck' of the PSA.

Results (Table) Ninety-one patients had superficial thrombin injection (STI) and 55 patients had neck thrombin injection (NTI). Baseline characteristics were similar in both groups. At the time of injection, all patients were on dual antiplatelet therapy and 9.6% were on oral anti-coagulation therapy without significant difference between both groups.

Patients in the NTI cohort tended to have 'shorter' neck. The NTI technique utilized lesser amount of Thrombin with a trend to a higher success rate and lesser recurrence. The two patients in the NTI group with recurrent PSA on follow-up imaging study were both on Coumadin and both PSAs were successfully treated with re-injection of Thrombin. No serious complications were observed including thromboembolism, limbischemia, aneurysm rupture, or abscess formation.

Conclusion: Femoral pseudoaneurysm closure using the NTI technique is a safe and efficacious treatment modality. This offers a non-surgical treatment option for PSAs with morphological features not ideal for the usual STI technique.

	NTI (n = 56)	STI (n = 91)	P value
Amount of thrombin[IU]			
Mean (SD)	994.55 (920)	1501.52 (1384.7)	0.02
Neck length [mm]:			
Min; max	0; 2.43	0.13; 3.3	
Mean (SD)	0.76 (0.56)	1.06 (0.66)	NS
Neck width [mm]:			
Min; max	0.1; 2.0	0.1; 2.3	
Mean (SD)	0.67 (0.47)	0.78 (0.47)	NS
Number of sacs:			
1	37 (66.1%)	57 (62.6%)	
2	15 (26.8%)	28 (30.8%)	
3	4 (7.1%)	6 (6.6%)	NS
Success	56 (100%)	87 (96.7%)	NS
Recurrence	2 (3.8%)	11 (12.6%)	NS

CRT-7

Angiographic Results Of The Dior® Drug-coated Balloon For De Novo Coronary Lesions: Results From The Valentines II Trial

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Background: In the Valentines II trial, the use of second-generation DIOR® paclitaxel drug-coated balloon (DCB) as adjunct therapy to plain old balloon angioplasty (POBA) has shown good clinical outcomes in patients with de novo coronary lesions with low rates of major adverse cardiac events (MACE). We report the quantitative coronary angiography (QCA) results of the subset of patients who underwent angiographic follow-up.

Methods: Valentines II trial prospectively enrolled 103 patients with de novo lesions of >50% stenosis who presented with angina and/or documented ischemia on stress testing. Patients underwent POBA followed by DCB, and in cases of suboptimal angiographic success additional bail-out stenting was performed. Primary endpoint was MACE at 6-9 months. A subset of patients underwent angiographic follow-up with QCA.

Results: For the study population, MACE, target vessel revascularization and target lesion revascularization rates were 8.7%, 6.9% and 2.9% respectively. Angiogram was performed in 35 patients (34%) at mean follow-up of 227 ± 40 days. The QCA results are shown (Table). Late-luminal loss at follow-up was 0.38 ± 0.39 mm and binary restenosis was 14.3%.

Conclusion: The result of the Valentines II trial angiographic cohort demonstrates the efficacy of second generation DIOR® DCB as adjunct to POBA in treating patients with de novo coronary lesions. This approach achieved low late-luminal loss and binary restenosis at intermediate-term angiographic follow-up and should be considered for patients and lesions not suitable for drug-eluting stents.

Variables	Patients and lesions, n=35
Baseline	
Reference vessel diameter (mm)	2.40 ± 0.51
Diameter stenosis (%)	65.06 ± 14.16
Minimum luminal diameter (mm)	0.84 ± 0.38
Lesion length (mm)	10.45 ± 5.25
After procedure	
Diameter stenosis (%)	
In-balloon	20.04 ± 9.34
In-segment	21.64 ± 7.34
Minimum luminal diameter (mm)	
In-balloon	1.95 ± 0.47
In-segment	1.91 ± 0.43
Acute gain (mm)	
In-balloon	1.10 ± 0.44
In-segment	1.06 ± 0.40
Follow-up	
Diameter stenosis (%)	
In-balloon	33.65 ± 17.71
In-segment	36.25 ± 17.60
Minimum luminal diameter (mm)	
In-balloon	1.57 ± 0.56
In-segment	1.52 ± 0.58
Late-luminal loss (mm)	
In-balloon	0.38 ± 0.39
In-segment	0.38 ± 0.39
Binary restenosis	
In-balloon	5 (14.3%)
In-segment	6 (17.1%)

CRT-8

Final Results of the Deliver Study - The Impact of the New Resolute Integrity Stent Platform in a Real-world Population With 7740 Patients

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Background: The Resolute Integrity zotarolimus-eluting stent utilizes novel continuous sinusoid technology (CST). With CST, a single cobalt alloy wire is formed into a repeating sinusoidal pattern, wrapped helically and fused to improve conformability, provide greater flexibility and ease of delivery without compromising other important stent design characteristics like radial and longitudinal strength. The objective of the DELIVER study was to evaluate delivery success as well as in-hospital outcome following use of the Resolute Integrity stent in an all-comers large patient population.

Methods: DELIVER is a prospective, multicentre, single arm, open-label, observational study in 163 centers in 33 countries. Patients with coronary artery disease and a lesion of reference vessel diameter of 2.25 to 4.0 mm were eligible for inclusion. Group 1 received the Resolute Integrity stent as the first choice of stent treatment and Group 2 were treated following delivery failure of another stent type. The primary endpoint for the study was delivery success defined as complete passage of the stent across the target lesion with full expansion to the desired diameter at the desired location. Other endpoints are in-hospital clinical outcomes adjudicated by a clinical event committee.

Results: A total of 7740 patients (12165 stents in 10449 lesions) were enrolled between February 2011 and June 2012. Patients suffered from diabetes mellitus in 34.9% and acute myocardial infarction 28.4%. Procedure approach was radial in 46.0%, brachial in 0.6% or femoral in 53.3%. Multiple lesions were treated in 26.9%, pre-dilatation performed in 67.4% and post-dilation in 39.3%. Lesions were de-novo in 94.5% and restenotic in 5.5%. Type B2/C lesions were treated in 58.8%. Reference diameter pre stent implantation was 2.93±0.48mm. The primary endpoint delivery success was high with 98.9% [95% CI 98.7-99.1%] in group I and 98.0% [95% CI 89.1-99.9%] in group 2. Adjudicated