nitinol-based, self-expanding stents for the treatment of iliac lesions similar to those in this study. Core laboratories were utilized for independent confirmation of angiography and duplex ultrasound findings. All site reported MAEs were adjudicated by an independent Clinical Events Committee.

RESULTS For the BIOFLEX-I study of patients with iliac disease treated with the Astron stent, the primary endpoint was met. The 12-month composite endpoint of MAE was 2.1% (3/146) ($p<0.001$) 95 % CI [0.4%, 5.9%]. The 30 day mortality rate was 0.7% (1/146) 95 % CI [0.0%, 3.8%]. Target lesion revascularization (TLR) rates at 12 months were 1.4% (2/146) 95 % CI [0.2%, 4.5%], and 12-month index limb amputation was 0.0% (0/146) 95 % CI [0.0%, 2.5%]. The secondary endpoint of primary patency was 89.8% (115/128) 95 % CI [83.3%, 94.5%] at 12 months.

CONCLUSION The 12-month outcomes of the BIOFLEX-I study for the Astron stent in iliac indications demonstrate a low MAE rate, high primary patency, and a low rate of TLR. This supports the safety and efficacy of the self-expanding, nitinol stent for treatment of atherosclerotic lesions in the iliac arteries.

CRT-304

Drug Coated Balloon (DCB) Angioplasty Versus Conventional Angioplasty for the Treatment of the Superficial Femoral Artery and PI-Segment In Pad-Patients - Updated Interim Results Of The Freeride Study

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BACKGROUND The use of paclitaxel coated DCB during percutaneous transluminal angioplasty (PTA) treatment of the femoropopliteal lesions in PAD patients might result in a significant reduced restenosis rate. Thus, the FREERIDE study investigates the inhibition of restenosis by the FREEWAY DCB versus plain balloon (POBA) in the treatment of occluded or stenotic lesions in the superficial femoral artery (SFA) and popliteal arteries (PI segment).

METHODS 280 patients will be randomized either to FREEWAY DCB or to POBA in 23 centers worldwide. The primary endpoint is clinically driven target lesion revascularization rate (TLR) at 6 months. Secondary endpoints include late lumen loss and patency rate at 6 months, TLR at 12 and 24 months follow up (FU), improvement in Rutherford classification and Ankle-Brachial index (ABI) and MAE.

RESULTS Until today over 100 patients have been enrolled, over 80 of them completed the 6 month FU. At 6 months FU positive trends are observed for the TLR rate (7.1 % vs. 16.7 % after POBA) and MAE (7.1 % vs 23.4 % after POBA). Furthermore there are positive trends in the patency rate and in the improvement of Rutherford classification after FREEWAY PTA vs. POBA.

CONCLUSION The continuously updated interim results indicate that FREEWAY DCB might provide an advantage for angioplasty in SFA and PI-segment lesions. DCB might overcome the existing limitations in the treatment of peripheral disease.

CRT-305

Randomized Clinical Trial Favors the Use Of Drug-coated Balloons Over Plain Balloons for the Postdilatation of Nitinol Stents in the SFA and PI Segment to Lower Restenosis Rate

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BACKGROUND Stents are needed in up to 50 % of all peripheral interventions where PTA with plain or drug-coated balloons alone will not reopen the vessel sufficiently. Nevertheless, the restenosis rate of stents is still a major limitation of peripheral arterial interventions. Drug-coated balloons potentially overcome the problem of in-stent restenosis when used for postdilatation after primary nitinol stenting in the SFA and PI segment.

METHODS The Freeway Stent Study is a prospective, randomized, international trial started in 15 centers in Germany and Austria. 200 patients will be enrolled and randomized equally to primary nitinol stenting followed by either DCB (Freeway™) or plain balloon postdilatation. Primary endpoint is clinically driven target lesion revascularization (TLR) at 6 months, secondary endpoints include further clinical and safety evaluations like shift in Rutherford classification and ABI, LLL, patency rate and MAE.

RESULTS Over 170 patients have been enrolled to date, of which over 130 have finished the 6 months and 100 the 12 months follow-up. The results highly favor the use of Freeway™ DCB over plain balloon based on clinically driven TLR (only 2.9 % vs. 11.9 % at 6 months and 9.1 % vs. 18.0 % at 12 months). This is supported by a statistically significant better clinical outcome for PAD patients treated with DCB as postdilatation device regarding primary patency rate, ABI and Rutherford classification at six months.

CONCLUSION The use of DCB as postdilatation device is investigated in a new approach to decrease the restenosis rate after nitinol stenting in the SFA and PI segment. The latest interim results of the Freeway Stent Study show that DCB might significantly lower the in-stent restenosis rate in the treatment of PAD patients.

CRT-306

Particulates from Hydrophilic Coated Guiding Sheaths Embolize to the Brain

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BACKGROUND Peripheral vascular interventions frequently employ guiding sheaths with hydrophilic coatings raising the concern for the embolization of this material clinically as increasingly documented.

METHODS A peripheral stent and delivery system (SDS) were deployed in the iliac and/or carotid arteries of 23 Yucatan miniswine via femoral or carotid artery access. SDS were deployed through a Cook® Flexor Ansel Guiding Sheath with a hydrophilic coating (AQ® hydrophilic coating). In one non-stented control animal, only the guiding sheath was advanced. Animals were euthanized at 3, 30, 90 & 180 days post intervention and brains removed for histopathology. In addition, coating material from the surface of a non-deployed guiding sheath was examined microscopically.

RESULTS The coated guiding sheath was associated with intravascular accumulation of an amorphous, non-refractile, non-crystalline, and non-birefringent embolic foreign material in sections of porcine brain which, on H&E staining, appeared lightly basophilic and slightly stippled. Material was observed at all time points and in all major regions of the brain, involving 52% of all test animals, and in the non-stented control animal. The incidence of embolic material was higher (63%) with carotid access than femoral access (20%). Evidence of adverse effects related to embolized material was limited to a single incidence of focally extensive chronic infarction in one brain.

In vitro incubation of the coated guiding sheath was associated with progressive separation and sloughing of its hydrophilic coating. Microscopic assessment of the sloughed hydrophilic coating was interpreted to be morphologically consistent with the emboli observed in the brains of animals exposed to the coated guiding sheath.

CONCLUSIONS The hydrophilic coating of Cook® Flexor Ansel Guiding Sheaths sloughed and embolized to the brain during deployment in a porcine model. Based on the increased reporting of embolic events involving hydrophilic coatings of interventional devices, further monitoring, documentation, and consideration of the potential side-effects of this embolized material in clinical scenarios is warranted.

CRT-307

Gender Differences in Patients with Lower Extremity Peripheral Artery Disease Referred for Endovascular Intervention

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BACKGROUND Lower extremity peripheral artery disease (PAD) affects approximately 8 million people in the US. Endovascular intervention is frequently performed in patients with symptomatic PAD. However, gender differences in patients referred for endovascular intervention are not well defined.

METHODS We retrospectively analyzed 530 patients who were referred for peripheral angiography at a tertiary care center in 2013. Patients were followed up for a median of 11.3 months. Outcomes of interest included extent of disease on semi-quantitative peripheral angiography, type of procedural intervention, and target vessel revascularization.

RESULTS Of the 530 patients, 320 (60.4%) were men and 210 (39.6%) were women. Demographic and clinical characteristics are presented in Table 1. The majority of patients underwent endovascular intervention (men 76% vs women 80%, $p=0.29$). Outcomes of interest are presented in Table 2.

CONCLUSION In a contemporary cohort of patients referred for endovascular intervention, despite fewer clinical comorbidities in women, there were no significant gender differences in burden of PAD or procedural outcomes.

Table 1

	Men (n=320)	Women (n=230)	p-value
Age (years)	69.9 [62.25-78.0]	73.33 [66.0-80.25]	0.35
Race (%)			<0.001
White	70.3	46.4	
Black	7.2	23.0	
Hispanic	19.7	26.3	
Asian	0.6	1.4	
Other	2.2	2.9	
Body mass index (kg/m^2)	28.2 [25.0-27.4]	28.4 [27.4-30.5]	0.89
Medical history (%)			
Diabetes mellitus	51.6	53.3	0.64
Hypertension	83.7	89.0	0.004
Hyperlipidemia	80.0	84.3	0.16
Coronary artery disease	64.0	50.0	0.002
Prior peripheral artery revascularization	24.1	24.3	1.00
Tobacco use	27.4	11.8	<0.001
Medication use (%)			
Aspirin	57.5	49.5	0.60
Clopidogrel	51.9	45.7	0.84
Cilostazol	11.6	5.7	0.06
Statin	63.4	53.8	0.43
Insulin	17.8	12.9	0.81
Laboratory data			
White blood cell count (x 10^3 cells/mL)	7.7 [6.2-8.9]	10.3 [6.0-9.1]	0.99
Neutrophil/lymphocyte ratio	2.86 [1.65-3.50]	1.97 [1.65-3.53]	0.70
Platelet count (x 10^3 cells/uL)	214 [170-250]	259 [192-309]	<0.001
Creatinine (mg/dL)	1.38 [0.90-1.30]	1.17 [0.71-1.60]	<0.001
LDL-cholesterol (mg/dL)	86 [62-104]	92 [64-116]	0.14
HDL-cholesterol (mg/dL)	46 [36-53]	55 [44-78]	<0.001
Triglycerides (mg/dL)	149 [92-187]	130 [81-200]	0.015
Glucose (mg/dL)	132 [90-149]	129 [89-149]	0.99
Resting ankle-brachial index (ABI)			
Right	0.75 [0.69-0.98]	0.67 [0.41-0.97]	0.10
Left	0.79 [0.65-1.03]	0.56 [0.59-0.99]	0.07
Critical limb ischemia with ABI ≤0.4 (%)	42.8	42.4	0.93
Continuous data are presented as median [interquartile range]			

Table 2

	Men (n=320)	Women (n=230)	p-value
Extent of disease (%)			0.74
Mild or moderate disease	12.5	10.5	
Isolated severe suprapopliteal disease	31.3	32.4	
Isolated severe infrapopliteal disease	15.6	13.3	
Severe multilevel disease	40.6	43.8	
	Men (n=243)	Women (n=168)	
Type of procedural intervention (%)			
Stent placement	59.3	54.8	0.42
Use of adjunctive device therapy (e.g. atherectomy, re-entry device)	33.3	36.9	0.46
Target vessel revascularization (%)	11.9	16.3	0.16

CRT-308

Minimal Plaque Surface Area and Minimal Luminal Area Needed for Effective Atherectomy using the JetStream Navitus in Treating In-Stent Restenosis of Femoral Artery in a Porcine Model

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BACKGROUND The JetStream Navitus (JS) atherectomy device is a rotational cutter with aspiration capability designed to treat infrainguinal arterial obstructive disease. JS XC can be operated with blades down (BD) (2.1 or 2.4 mm perimeter) or blades up (BU) (3.0 or 3.4 mm perimeter) to treat femoropopliteal obstructive disease. It is unclear whether an orbital effect is present while operating the JS leading to a larger minimal luminal area (MLA) than predicted based on device size. Also, the minimum MLA and plaque surface area (PSA) needed in a typical size femoral artery (5-6 mm) for the device to be effective has not been defined. Using an in-stent restenosis (ISR) porcine model and intravascular ultrasound (IVUS) assessment of lesions these questions were addressed.

METHOD 4 pigs (8 limbs) were implanted with overlapping SMART (Cordis) nitinol self-expanding stents using an overstretch balloon/stent model. ISR was treated 1 month after stent implantation with an initial 2 blades down (BD) runs followed by 4 BU runs. IVUS measurements were performed at baseline, after 2 BD runs, and after each BU run on a total of 24 lesions. Minimal luminal area (MLA, mm2) and plaque surface area (PSA, %) were obtained. 1-sample Wilcoxon signed-rank test was performed between MLA obtained after BU runs and theoretical maximal MLA of the XC 2.4-3.4 cutter with BU. MLA and PSA at baseline were plotted against net MLA and PSA gain (BU - baseline) respectively. The minimum MLA and PSA at baseline needed for a positive increase in MLA and reduction in PSA were determined.

RESULTS The femoral artery mean diameter was 4.7 mm. A strong correlation was present between MLA at baseline and after BU runs (Pearson correlation p=0.006) and between PSA at baseline and after BU runs (p<0.0001). An approximate MLA ≤ 9.0 mm2 or PSA ≥ 60% were needed to see a positive effect of atherectomy on treated lesion (i.e. increase in MLA or reduction in PSA). Theoretical MLA achievable from the XC BU 2.4-3.4 device is 9.08 mm2 (A = πr2 using r=3.4/2=1.7mm). No difference is seen between this calculated MLA and the IVUS measured MLAs after BU runs using 1-sample Wilcoxon test indicating no orbital effect of the device on tissue cutting.

CONCLUSION JS XC 2.4-3.4 BU achieved positive cutting of ISR tissue inside a 4.7 mm femoral artery when the baseline lesion MLA was ≤ 9.0 mm2 or PSA ≥ 60% on IVUS. No orbital cutting was seen with the JS BU as MLA obtained after treatment was not different from theoretical MLA.

CRT-309

Impact of Duration of Statin Medication on Clinical Outcomes in Patients Undergoing Percutaneous Transluminal Angioplasty for Atherosclerotic Peripheral Arterial Disease

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BACKGROUND Recently, it was reported that statins are associated with lower rates of major adverse cardiovascular events and amputations in critical limb ischemia (CLI) patients (pts). However, the impact of statin administration duration on clinical outcomes for pts undergoing percutaneous transluminal angioplasty (PTA) due to peripheral arterial disease (PAD) is uncertain.

METHODS A total 286 pts underwent PTA for PAD from Oct 2004 to Feb 2013 from prospective PTA registry was enrolled. Major adverse cardiovascular and extremity events (MACEEs) were defined as the composite end-point consisted of cardiac death, myocardial infarction, repeat PTA, and amputation. The incidence of MACEEs according to statin duration up to 1-year was evaluated.

RESULTS The incidences of total MACEEs was in 33.2% (95/286 pts); cardiac death 7 (2.4%), myocardial infarction 3 (1.0%), major and minor amputation 56 (19.6%), repeat PTA 46 (16.1%). Not only the univariate logistic regression analysis, but also in multivariate logistic regression adjusted by age, gender, hypertension, diabetes, cerebrovascular accident, and chronic renal failure, there was significant risk reduction for MACEES in statin use duration 180 and 360 days group, not in statin use duration 30 and 90 days (Table).

CONCLUSIONS In our study, prolonged statin duration at least longer than 6 months was associated with reduced risk of MACEES compared with shorter statin duration in pts undergoing PTA for PAD.