Table 1a. Baseline Characteristics-Unadjusted Analysis Variable Name

	Orbital atherectomy (N=91)	Rotational atherectomy (N=131)	P value
Age (Years)	67.44 ±8.85	70.34 ±10.83	**0.036**
Female	38 (41.8%)	37 (28.2%)	**0.001**
BMI (kg/m2)	35.25 ±4.79	34.54 ±5.48	0.318
Smoker (n)	18 (19.78%)	17 (12.98%)	0.173
Hypertension (n)	85 (93.40%)	126 (96.18%)	0.351
Dyslipidemia (n)	84 (92.30%)	120 (91.60%)	0.851
Premature CAD (n)	2 (2.20%)	7 (5.34%)	0.244
Prior MI (n)	28 (30.77%)	55 (41.99%)	0.090
Prior Heart Failure (n)	22 (24.18%)	27 (20.61%)	0.531
Prior Valve Surgery (n)	0 (0%)	2 (1.53%)	0.238
Prior PCI (n)	40 (43.96%)	76 (58.01%)	**0.039**
Prior CABG (n)	11 (12.08%)	31 (23.66%)	**0.030**
Dialysis (n)	7 (7.69%)	9 (6.87%)	0.817
Cerebrovascular Disease (n)	9 (9.89%)	20 (15.26%)	0.244
Peripheral Vascular Disease (n)	11 (12.08%)	26 (19.85%)	0.128
Chronic Lung Disease (n)	7 (7.69%)	18 (13.74%)	0.162
Diabetes Mellitus (n)	60 (65.93%)	78 (59.54%)	0.366
Pre PCI LVEF (%)	54.24±10.73	51.89±1.41	0.147
ACS (n)	14 (15.4%)	21 (16.0%)	0.764
Unstable Angina (n)	58 (63.7%)	83 (63.4%)	0.954
Stable Angina (n)	18 (19.8%)	22 (16.8%)	0.571

CRT-200.29

Evaluation Of Lesion Flow Coefficient For The Detection Of Coronary Artery Disease In Patient Groups From Two Academic Medical Centers

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BACKGROUND In this study, lesion flow coefficient (LFC: ratio of % area stenosis [%AS] to the square root of the ratio of the pressure drop across the stenosis to the dynamic pressure in the throat region), that combines both the anatomical (%AS) and functional measurements (pressure and flow), was assessed for application in a clinical setting.

METHODS The population consisted of patient-level pressure, flow, anatomical details from 251 vessels. Eighty-four vessel data was obtained from the clinical protocol approved by the Institutional Review Board at the University of Cincinnati and the research and development committee at the Cincinnati Veteran Affairs Medical Center. One hundred and sixty seven data points were obtained from the study by van de Hoef et al., 2012, based on a similar protocol approved by the institutional ethics committee at Academic Medical Center-Amsterdam.Patients of 18 years or above with an abnormal stress test indicating reversible ischemia were considered for enrollment into the study. Patients with by-pass grafts, baseline serum Creatinine > 2.5 mg/dl, pregnant women, and significant co-morbid conditions that incapacitated the patients from the consent process were excluded from the study.Fractional flow reserve (FFR), Coronary flow reserve (CFR), hyperemic stenosis resistance index (HSR) and hyperemic microvascular index (HMR) were calculated. Anatomical data was corrected for the presence of guidewire and the LFC values were calculated.

RESULTS LFC correlated significantly when the FFR (pressure-based), CFR (flow-based), and anatomical measure %AS were combined ($r = 0.64$; $p<0.05$). Similarly, LFC correlated significantly when HSR, HMR, and %AS were combined ($r = 0.72$; $p<0.05$). LFC was able to significantly ($p < 0.05$) distinguish between the two concordant and the two discordant groups of FFR and CFR, corresponding to the clinically used cut-off values (FFR=0.80 and CFR=2.0). The LFC could also significantly ($p < 0.05$) distinguish between the normal and abnormal microvasculature conditions in the presence of non-significant epicardial stenosis, while the comparison was borderline significant ($p = 0.09$) in the presence of significant stenosis.

CONCLUSION LFC, a parameter that combines both the anatomical and functional end-points, has the potential for application in a clinical setting for CAD evaluation.

CRT-200.30

Three Years Follow-up Of The Eraci IV Registry - A Modified Syntax Score For The Treatment Of Multiple Vessel Disease And Left Main Stenosis

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PURPOSE To evaluate the long term efficacy and safety of newer drug eluting stent generations (2-DES) for the treatment of multiple vessel disease and left main stenosis compared to first generation of DES (1-DES) and to validate a new score based in functional revascularization of coronary artery disease.

METHODS The ERACI IV Registry is a multicenter and prospective open label study that evaluated a chromium cobalt rapamycin second generation DES (Firebird-2™, Microport Inc. Shangai, China) for the treatment of patients with multiple vessel coronary artery disease including left main stenosis and indication for myocardial revascularization with angiographic evidence of severe coronary obstructions (Stenosis ≥70% by visual estimation). Exclusion criteria were prior PCI in the previous 6 months or previous DES at any time, myocardial infarction in the preceding 72 hours, reduction in ejection fraction (< 35%), Patients with one coronary artery lesion excluding left main disease and more than one total occlusion, severe valvular heart disease, limited life expectancy, prior cerebrovascular accident, neutropenia or thrombocytopenia, double antiplatelet therapy intolerance or impossibility to receive long-term therapy or not amenable for the implantation of DES. 15 participating sites included 225 consecutive patients who signed Informed Consent Form, 11.8% of the overall PCI performed in those centers, in accordance with the ERACI III population which included identical number of patients treated with 1st generation DES (Cypher, Cordis-Johnson&Johnson, Miami Lakes, FL, USA) and Taxus Express (Boston Scientific Corp., Boston, MA, USA). Primary end point was the incidence of major adverse cardiovascular events (MACCE) in the Firebird 2 arm and subsequently an indirect comparison with ERACI III patients (1st generation DES) was done. The end point was recorded at 30 days, 6, 12, 18, 24 and 36 months of follow-up. Secondary end points include the incidence of target lesion and vessel revascularization (TLR and TVR respectively) and stent thrombosis. Dual antiplatelet therapy (DAPT) was required for all patients. Aspirin 100 mg was administrated orally at least 1 hour prior to catheterization and an oral loading dose of thienopyridines (P2Y12): either clopidogrel (300 to 600 mg), prasugrel (60 mg) or ticagrelor (180 mg). In ERACI IV, DAPT was mandatory for 6 months but strongly recommended for the entire follow up period and includes either clopidogrel (75 mg/day), prasugrel (10 mg/day) or ticagrelor (90 mg/12 hours). As part of revascularization strategy, the protocol suggested that prasugrel and/or ticagrelor should be preferred P2Y12 selected in patients with diabetes, complex left main or higher Syntax score. An independent blind clinical events committee adjudicated all reports events of MACCE and other clinical events, including stent thrombosis and ERACI IV followed Good Clinical Practice and Argentina dispositions for Clinical registries. Revascularization strategy was planned prior to the procedure with the objective of achieve complete functional revascularization (CFR), meaning that PCI was consider functional if no residual severe stenosis (≥70%) remained in any major epicardial vessel and all severe stenosis had been treated successfully with stents, to achieve this strategy staged procedures were allow. Provisional stent strategy in all bifurcations was recommended and lastly severe stenosis in vessels < 2.0 mm was strongly discouraged and usually none attempted. In ERACI IV patients, original SS was calculated, however we also used a modification of the original SS, excluding from the analysis all intermediate lesions and also severe stenosis in vessels<2.0mm; in stent restenosis was scored as heavy calcified stenosis. In ERACI IV sample size was estimated in accordance with the population included in ERACI III-DES arm. In such study, incidence of the primary endpoint of MACCE at 1 year of follow-up among patients treated with 1st generation DES, 12% of MACCE and 7% of death/MI/CVA. Taking in account that second generation DES reported a

reduction of major adverse events of 50% during the first and second year in comparison with 1st generation of DES, using a two-sided test for differences in independent binomial proportions with an a level of 0.05, we estimated that, for a power of 80% we needed to include 225 patients to detect differences between both kind of stents. Continuous variables were compared using ANOVA with Bonferroni correction. Categorical variables were compared using x2 analysis or Fisher's exact test. Continuous variables were expressed as mean + SD and categorical variables as percentages. Freedom from survival endpoints at follow-up was obtained using Kaplan-Meier curves and compared by log-rank test. Since these treatment comparisons were not randomized, we used multivariable statistical methods to adjust for possible confounding factors. Univariate and multivariate Cox regression analysis were performed using SPSS v. 17.0 to determine independent predictors of outcome at follow-up (all variables introduced in block in a single step). Variables of statistical significance after univariate analysis and clinically relevant covariates including all demographic, clinical, angiographic, and procedural variables were included into the model. We also performed a propensity score to analyzed results in matched population of patients. The propensity score was constructed using a logistic model. The univariate analysis included age, sex, diabetes, hypertension, hypercholesterolemia, smoking, prior MI, proximal left anterior descending disease, three vessel CAD, left main stenosis, prior BMS implantation and unstable angina symptoms as variables. We used a greedy matching algorithm to identify pairs of patients, one of whom received a 1st generation DES and one of whom received a Firebird 2.

RESULTS Baseline clinical, demographic, angiographic and procedural characteristics of the two studies were similar. Briefly compared to ERACI III 1st generation DES, ERACI IV had greater number of diabetic patients (p=0.01), more patients with Braunwald IIB/IIIC angina (p<0.001) and more 3 vessels plus left main compromise (p=0.003); in contrast elderly patients (p=0.02) and with high cholesterol (p=0.04) are more frequent in ERACI III. All other clinical, demographic and procedural variables were not significant different. In ERACI IV, 27.2% of patients had overlapping stents, 14.2% of bifurcations were treated. Completeness of revascularization either anatomic (CAR) or CFR were achieved similarly in both studies, CAR was 48% and 50.2% in ERACI III and IV respectively, p=0.63; whereas CFR was 88.4% vs 82% in ERACI III and IV respectively, p=0.08 ERACI IV patients were classified at low SS in 33.8%, intermediate in 32.4% and high in 33.8%. However, when we used the modified SS, patients with low SS rose to 54.9%, intermediate dropped to 27.9% and only 17.2% of ERACI's patients scored at high SS. At hospital discharge all patients either in ERACI III, DES arm or ERACI IV are taken P2Y12, although in ERACI III, clopidogrel was the only P2Y12 available whereas in ERACI IV clopidogrel was used in 58.7% and more active P2Y12 such as prasugrel and ticagrelor was taking in 27.2 % and 14.1% respectively. At 1 year compared to ERACI III DES-, DES -2 of ERACI IV had a significantly lower incidence of each component of the primary end point: death (0.4% vs 3.1%, respectively p =0.03), death/MI/CVA (0.9% vs 6.7% respectively p<0.001), TVR (1.8% vs 8.9% respectively, p=0.001) and MACCE (2.2% vs 12%, respectively p<0.001). SET was not significantly different between ERACI III and IV 1.8% and 0.4% respectively p=0.18. At 2 years of follow up, in spite of patients in ERACI IV had slightly progression of adverse events, those remained significantly lower than ERACI III PCI arm. The benefit for ERACI IV DES-2 remained at 3 years follow-up; incidence of the composite of death/MI/CVA (4.9% vs. 13.7%, respectively P<0.001); unplanned new revascularization (5.3% vs. 14.2%, respectively P<0.001) and MACCE (9.3% vs 22.7% vs. P<0.001), were significantly lower in ERACI IV 2nd generation DES compared to the 1st generation DES. Incidence of stent thrombosis was lower in ERACI IV arm, although not significantly, (0.9% vs. 3.1% in ERACI IV and III respectively, p=0.13). Very late stent thrombosis was not seen in ERACI IV patients. Cumulative 3-year events of the two groups were described in Table 1. Beyond one year there was a low progression events rate in patients treated with DES-2 from 2.2% to 9.3% and was significantly lower compared to DES-1 arm of ERACI III, from 12% to 22.7% p=0.001, these differences were driven by high occurrence events rate in DES-1, death, 6 patients, spontaneous MI, 8 patients and unplanned new revascularization in 12 patients. Of interest TVR or TLR in those patients either with intermediate lesions or severe lesions in small vessels was only 3.8%.

At 3 years survival curves of freedom from MI, death/MI/stroke, and MACCE were significant in favor to DESs-2. Because ERACI IV study was not randomized, we performed a propensity score matching to control for differences between DES-2 and DES-1 treated patients. We were able to match 108 patients who received a DES-2 with 108 patients who received a DES-1. At three years all end points and each of the components of them are significantly lower in the group of ERACI IV DES-2 patients, meaning that events progression were lower in unmatched and matched population. As was described in Table 2, death, death/MI / stroke, unplanned revascularization and MACCE were significantly lower in the matched cohort of patients. Of interest Residual Syntax Score (RSS) and Residual ERACI Score (RES) were significantly different. The mean RSS of this study was 8.7 +/- 5.9 which was significantly higher than RES which was 3.5 +/- 4.6 (p=0.003) and in only 34.4% of patients RSS and RES had an agreement defined as no more than two points difference between them. Furthermore, 48% of patients in the study had RSS <8 vs only 93.5% if we used our RES (p=0.002). Low events rates at 3 years are in agreement with numbers observed with our RES. Incidence of the composite of death/ MI/CVA (3.6% vs. 9.3%, respectively p= 0.001); unplanned new revascularization (4% vs. 11.6%, respectively p=0.003) and MACCE (16.9% vs 6.7% p=0.01), were all significantly lower in ERACI IV DES-2 compared to the 1st DES. Stent thrombosis was not significantly different but lower in ERACI IV (0.9% vs 3.1%, respectively p=0.09), in fact beyond one year SET was not seen. At 3 years of follow-up, the advantages of DES-2 compared to DES-1, remained both in diabetics, 8.7% vs. 36.2%, respectively (P<0.001) and non -diabetics 9.6% vs. 19.1%, respectively (p=0.01). In ERACI IV MACCE rate at 3 years was similar in diabetics and no- diabetics (8.7% and 9.6% respectively p=0.9).

CONCLUSIONS Second generation DES in patients with complex lesions subsets together with a functional PCI strategy were associated with a remarkable lower incidence of adverse events at 3 years of follow-up compared with first DES generation, the benefit was also seen in in diabetic population. Finally, long term outcome of this prospective, observational, multicenter study strongly validates our lesion PCI assessment and scoring and the revascularization PCI strategy used in the study.

Table IV

	ERACI IV	ERACI III	RR (CI 95%)	P value
Death				
1 year FU	1 (0.4%)	7 (3.1%)	0.13 (0.17 to 1.13)	0.03
2 years FU (cumulative)	5 (2.2%)	7 (3.1%)	0.71 (0.23 to 2.21)	0.56
3 years FU (cumulative)	6 (2.7%)	13 (5.7%)	0.46 (0.17 to 1.19)	0.07
Acute myocardial infarction				
1 year FU	1 (0.4%)	6 (2.7%)	0.16 (0.01 to 1.36)	0.057
2 years FU (cumulative)	3 (1.3%)	10 (4.4%)	0.29 (0.08 to 1.07)	0.049
3 years FU (cumulative)	4 (1.8%)	14 (6.2%)	0.27 (0.08 to 0.8)	0.01
Non-fatal CVA				
1 year FU	0 (0%)	5 (2.2%)	0.49 (0.45 to 0.54)	0.07
2 years FU (cumulative)	1 (0.4%)	7 (3.1%)	0.14 (0.01 to 1.15)	0.07
3 years FU (cumulative)	2 (0.9%)	7 (3.1%)	0.57 (0.1 to 1.9)	0.23
Death/MI/CVA				
1 year FU	2 (0.9%)	15 (6.7%)	0.12 (0.02 to 0.55)	<0.001
2 years FU (cumulative)	8 (3.6%)	21 (9.3%)	0.35 (0.15 to 0.82)	0.013
3 years FU (cumulative)	11 (4.9%)	31 (13.7%)	0.35 (0.18 to 0.68)	<0.001
Unplanned revascularization				
1 year FU	4 (1.8%)	20 (8.9%)	0.18 (0.06 to 0.55)	0.001
2 years FU (cumulative)	9 (4.0%)	26 (11.6%)	0.31 (0.14 to 0.69)	0.003
3 years FU (cumulative)	12 (5.3%)	32 (14.2%)	0.33 (0.17 to 0.67)	<0.001
MACCE (Death/MI/CVA/TVR)				
1 year FU	5 (2.2%)	27 (12%)	0.16 (0.06 to 0.44)	<0.001
2 years FU (cumulative)	15 (6.7%)	38 (16.9%)	0.35 (0.18 to 0.66)	0.001
3 years FU (cumulative)	21 (9.3%)	51 (22.7%)	0.35 (0.20 to 0.60)	<0.001
Stent thrombosis (Definitive/probable)				
1 year FU	2 (0.9%)	6 (2.7%)	0.32 (0.06 to 1.64)	0.28
2 years FU (cumulative)	2 (0.9%)	7 (3.1%)	0.28 (0.05 to 1.36)	0.17
3 years FU (cumulative)	2 (0.9%)	7 (3.1%)	0.24 (0.05 to 1.15)	0.15

Cumulative events at 3 years of follow-up.

CI= Confidence interval; CVA= Cerebrovascular accident; FU= Follow-up ; MACCE= major adverse cardiovascular events; MI= Myocardial infarction; RR=Risk ratio; TVR= Unplanned revascularization-target vessel revascularization

Table 5. Propensity score analysis between ERACI III and ERACI IV studies; n= 216

	ERACI III	ERACI IV	RR (CI 95%)	Sig level
Any cause of death (%)	3.7	0.9	0.25 (0.02 to 2.20)	0.21
Myocardial Infarction - MI (%)	5.6	0.9	0.16 (0.02 to 1.36)	0.09
Cerebrovascular accident - CVA (%)	1.9	0.0	0.2 (0.009 to 4.11)	0.29
Death/MI/CVA (%)	8.3	1.9	0.22 (0.04 to 1.00)	0.05
Non-planned revascularization (%)	12.0	2.8	0.23 (0.06 to 0.78)	0.01
MACCE (%)	16.7	3.7	0.22 (0.07 to 0.6)	0.005

MACCE: Major adverse cardiovascular events, the composite of death, myocardial infarction, CVA and target vessel revascularization.