Events at 5 years	Diabetic Patients			Non-Diabetic Patients		
	EES (n=153)	PES (n=172)	p-value	EES (n=744)	PES (n=730)	p-value
Death	15.7% (24)	14.5% (25)	0.77	7.7% (57)	9.3% (68)	0.25
Myocardial Infarction	9.2% (14)	13.4% (23)	0.23	6.6% (49)	11.1% (81)	<0.01
Target Vessel Revascularization	9.2% (14)	15.7% (27)	0.08	7.0% (52)	10.4% (76)	0.02
Target Lesion Revascularization	7.2% (11)	11.0% (19)	0.23	6.0% (45)	9.2% (67)	0.02
Def./Prob. Stent Thrombosis	5.9% (9)	7.6% (13)	0.55	2.6% (19)	5.5% (40)	<0.01
MACE (Primary Endpoint)	24.8% (38)	34.3% (59)	0.06	17.1% (127)	23.0% (168)	<0.01

Conclusions: At 5-years EES was superior with regards to efficacy and safety to PES in non-diabetic patients. In diabetic patients a late trend towards reduction of MACE was observed with EES compared to PES, mainly driven by a lower rate of TVR.

TCT-590

Three-Year Clinical Follow-Up of the FIREHAWK Abluminal Groove-Filled Biodegradable Polymer Sirolimus-Eluting Stent in the Treatment of Single De Novo Native Coronary Lesions: The TARGET I Trial

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Background: We sought to investigate the long-term outcomes of an abluminal groove-filled biodegradable polymer sirolimus-eluting stent FIREHAWK (MicroPort Medical, Shanghai, China) compared to an everolimus-eluting stent (EES) XIENCE V in the randomized TARGET I trial.
Methods: A total of 458 patients with single de novo native coronary lesions < =24 mm in length and a coronary artery >=2.25 to < =4.0 mm in diameter were enrolled in the TARGET I study, a prospective, randomized, non-inferiority trial. The primary endpoint was in-stent late lumen loss (LLL) at 9-month follow-up. The secondary endpoint, target lesion failure (TLF), was defined as the composite of cardiac death, target vessel myocardial infarction (TV-MI), and ischemia-driven target lesion revascularization (iTLR). Clinical follow-up was scheduled at 1-, 6- and 12-month, and annually up to 5 years for all enrolled patients. All adverse clinical events were adjudicated by an independent committee.
Results: Previously reported results demonstrated FIREHAWK stent was non-inferior to XIENCE V EES for the primary endpoint of 9-month in-stent LLL (0.13±0.24 mm vs. 0.13±0.18 mm, p=0.94; difference and 95% confidence interval 0.00 [-0.04, 0.04] mm; p for non-inferiority < 0.0001), and had a comparable clinical outcome at 2 years. There were still no significant differences between the two groups up to 3 years, and no definite/probable stent thrombosis occurred in FIREHAWK group. (Table)

Table. Clinical Outcomes through 3 Years

	1 Year			2 Years			3 Years		
	FIREHAWK, n=227	XIENCE V, n=231	p	FIREHAWK, n=226	XIENCE V, n=231	p	FIREHAWK, n=221	XIENCE V, n=228	p
Clinical Follow-Up, % (n/N)	99.6 (226/227)	100 (231/231)	0.50	99.6 (226/227)	100 (231/231)	0.50	97.4 (221/227)	98.7 (228/231)	0.34
Death, % (n)	0.4 (1)	0.9 (2)	1.00	0.4 (1)	0.9 (2)	1.00	1.8 (4)	1.8 (4)	1.00
Cardiac Death	0.4 (1)	0 (0)	1.00	0.4 (1)	0 (0)	1.00	0.9 (2)	0.4 (1)	0.62
Myocardial Infarction, % (n)	1.3 (3)	2.2 (5)	0.72	1.3 (3)	2.6 (6)	0.50	1.4 (3)	3.1 (7)	0.34
Q Wave MI	0 (0)	0 (0)	-	0 (0)	0 (0)	-	0.0 (0)	0.4 (1)	1.00
Non Q Wave MI	1.3 (3)	2.2 (5)	0.72	1.3 (3)	2.6 (6)	0.50	1.4 (3)	2.6 (6)	0.50
TV-MI	1.3 (3)	1.7 (4)	1.00	1.3 (3)	1.7 (4)	1.00	1.4 (3)	2.2 (5)	0.72
ITLR, % (n)	0.4 (1)	0.4 (1)	1.00	0.9 (2)	0.9 (2)	1.00	1.8 (4)	1.3 (3)	0.75
Any Revascularization, % (n)	1.8 (4)	4.8 (11)	0.07	2.2 (5)	6.1 (14)	0.04	4.5 (10)	7.5 (17)	0.19
TLF, % (n)	2.2 (5)	2.2 (5)	1.00	2.7 (6)	2.6 (6)	0.97	4.1 (9)	3.5 (8)	0.75
PoCE (composite of all cause death, all MI, and any revascularization), % (n)	3.5 (8)	7.4 (17)	0.07	4.0 (9)	8.7 (20)	0.04	7.2 (16)	11.0 (25)	0.17
Definite/Probable Stent Thrombosis, % (n)	0 (0)	0 (0)	-	0 (0)	0 (0)	-	0.0 (0)	0.4 (1)	1.00

Conclusions: In the multicenter randomized TARGET I trial, the 3-year follow-up results confirmed that the novel FIREHAWK stent had a durable safety and efficacy profile, which was comparable to the XIENCE V EES for the treatment of single de novo native coronary lesions. (ClinicalTrials.gov Identifier: NCT01196819)

TCT-591

Safety and Efficacy of the biodegradable polymer Biolimus-eluting stent versus the durable polymer Everolimus-eluting stent in all-comers undergoing PCI: Pooled analysis of the COMPARE II and NEXT trials at 1 year

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Background: Drug-eluting stents with biodegradable polymers have been developed to reduce the risk of very late adverse events. Distinct studies have indicated non-inferiority of the biodegradable polymer-coated biolimus-eluting stent (Nobori™; BES) compared to the durable polymer-coated everolimus-eluting stent (Xience™ or Promus™; EES) with regards to safety and efficacy at 1 year. However, these trials were not powered to detect differences in low-frequency events.
Methods: The all-comers COMPARE II and NEXT clinical trials randomly assigned 5942 patients to BES or EES and is at present the largest pooled analysis of BES in all-comers requiring percutaneous coronary intervention (PCI). The pre-specified composite endpoint was target vessel failure (TVF) defined as cardiac death, target vessel related myocardial infarction (MI), or clinical-indicated target vessel revascularization (TVR-CD).
Results: The pooled unadjusted 1-year clinical outcomes of the 5942 study patients (8094 lesions) are tabulated. Covariate adjusted analyses accounting for baseline imbalances between trials confirmed non-significant differences between stent type and clinical outcomes. The trend for a higher definite stent thrombosis rate in the BES group was by multivariate analysis less prominent (HR 2.05 [CI95% 0.75-5.60]; p=0.16).

Events at 1 Year	BES (n=3412)	EES (n=2530)	P-value
All-cause death	2.0% (68)	2.0% (50)	1.0
Cardiac death	1.1% (39)	1.0% (26)	0.71
Myocardial infarction	3.1% (104)	2.9% (73)	0.76
Target lesion revascularization (All)	3.4% (115)	3.5% (88)	0.83
Target lesion revascularization (CD)	2.5% (84)	2.5% (63)	1.0
Target vessel revascularization (All)	5.0% (172)	5.0% (127)	1.0
Target vessel revascularization (CD)	3.6% (122)	3.8% (97)	0.63
Stent thrombosis (definite)	0.5% (17)	0.2% (5)	0.08
Stent thrombosis (definite / probable)	0.5% (18)	0.4% (10)	0.57
Target vessel failure	6.4% (219)	6.7% (169)	0.71

Conclusions: At 1-year the biodegradable polymer-coated BES has similar safety and efficacy outcomes as the durable polymer-coated EES. Longer follow-up data is needed to determine the role of biodegradable polymer-coated BES in real world clinical practice.

TCT-592

Lower Five Year Event Rates In The Genous Endothelial Progenitor Cell Capturing Stent Compared With A Drug Eluting Stent In De-novo Coronary Artery Lesions With A High-risk Of Restenosis; A Randomized Controlled Trial

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Background: These are the first long-term randomized adjudicated trial data of five year results of the Genous bio-engineered endothelial progenitor cell capturing stent (OrbusNeich BV, Fort Lauderdale, FL, USA) compared with a paclitaxel-eluting stent(PES).
Methods: In this prospective randomized trial, patients with de-novo coronary artery lesions carrying a high risk of restenosis (chronic total occlusion,lesion length > 23mm,vessel diameter < 2.8mm or any lesion in a diabetic patient) were randomized 1:1 to the Genous or a PES. The current primary endpoint is adjudicated target vessel failure (TVF) at 5-years, a composite of cardiac death, myocardial infarction (MI) and target vessel revascularization. Clinical event rates were estimated by Kaplan-Meier method and compared with a log-rank test.
Results: A total of 193 patients were included with complete follow-up in 97% of the subjects. The primary endpoint of TVF was similar at 5 years with Genous 23.8% vs