Table. Clinical Outcomes Through 4 Years

	0~1 Year			1~4 Year(s)			0~4 Years		
	FIREHAWK n=227	CoCr-EES n=231	Log-rank p	FIREHAWK n=226	CoCr-EES n=229	Log-rank p	FIREHAWK n=227	CoCr-EES n=231	Log-rank p
TLF, % (n)	2.2 (5)	2.2 (5)	0.98	2.2 (5)	4.0 (9)	0.30	4.4 (10)	6.1 (14)	0.43
PoCE, % (n)	3.5 (8)	7.3 (17)	0.07	5.8 (13)	7.9 (18)	0.38	9.2 (21)	15.1 (35)	0.053
Death, % (n)	0.4 (1)	0.9 (2)	0.57	1.8 (4)	1.7 (4)	0.99	2.2 (5)	2.6 (6)	0.78
Cardiac Death, % (n)	0.4 (1)	0 (0)	0.32	0.4 (1)	0.4 (1)	0.99	0.9 (2)	0.4 (1)	0.56
MI, % (n)	1.3 (3)	2.2 (5)	0.49	0 (0)	1.3 (3)	0.08	1.3 (3)	3.5 (8)	0.14
Q Wave MI	0 (0)	0 (0)	N/A	0 (0)	0.4 (1)	0.32	0 (0)	0.4 (1)	0.32
Non Q Wave MI	1.3 (3)	2.2 (5)	0.49	0 (0)	0.9 (2)	0.16	1.3 (3)	3.1 (7)	0.21
TV-MI	1.3 (3)	1.7 (4)	0.72	0 (0)	0.9 (2)	0.16	1.3 (3)	2.6 (6)	0.33
Any Revascularization, % (n)	1.8 (4)	4.8 (11)	0.07	4.5 (10)	6.2 (14)	0.43	6.2 (14)	11.0 (25)	0.07
iTLR, % (n)	0.4 (1)	0.4 (1)	0.99	1.8 (4)	3.5 (8)	0.16	2.2 (5)	4.0 (9)	0.33
Definite/Probable ST, % (n)	0 (0)	0 (0)	N/A	0 (0)	0.4 (1)	0.32	0 (0)	0.4 (1)	0.32

coronary lesions. We for the first time report the 4-year clinical outcomes.

METHODS A total of 458 patients (vessel size between 2.25~4.0mm and lesion length $\leq$ 24mm) were enrolled in the TARGET I RCT. The primary non-inferiority endpoint was in-stent late lumen loss (LLL) at 9 months. Secondary endpoints were target lesion failure (TLF), a composite of cardiac death, target vessel myocardial infarction (TV-MI), or ischemia-driven target lesion revascularization (iTLR), and patient-oriented composite endpoint (PoCE), a composite of all death, all MI, or any repeat revascularization. Clinical follow-up (f/u) was scheduled at 1 month, 6 and 12 months, and annually up to 5 years for all enrolled patients. All adverse clinical events were adjudicated by an independent committee.

RESULTS Previous reports have demonstrated FIREHAWK stent was non-inferior to CoCr-EES for the primary endpoint of 9-month in-stent LLL (0.13±0.24 mm vs. 0.13±0.18 mm, p for non-inferiority <0.0001), and the two groups had similar clinical outcomes at 1 year. 445 (97.2%) patients completed 4-year clinical f/u. There were still no significant differences between groups up to 4 years in terms of any composite endpoints or individual components (Table). However, a landmark analysis at 1 year showed non-significant trends of lower incidences of MI (0% vs. 1.3%, log-rank p=0.08) and iTLR (1.8% vs. 3.5%, log-rank p=0.16) in favoring FIREHAWK group between 1 year and 4 years. Furthermore, the 4-year rate of PoCE was 9.2% in FIREHAWK group and 15.1% in CoCr-EES group, respectively, with a borderline difference (log-rank p=0.053). No definite/probable stent thrombosis (ST) was documented in FIREHAWK group through 4 years.

CONCLUSIONS In TARGET I RCT, the 4-year f/u results confirmed that the novel FIREHAWK stent had a durable safety and efficacy profile, which was comparable to the best-in-class CoCr-EES in single de novo coronary lesions. (ClinicalTrials.gov Identifier: NCT01196819)

CATEGORIES CORONARY: Stents: Drug-Eluting

KEYWORDS Drug-eluting stent, bioabsorbable, Long-term clinical outcomes, Randomized clinical trial

TCT-568

Multi-Center, Randomized Evaluation of the Elixir DESyne® Novolimus Eluting Coronary Stent System with Biodegradable Polymer Compared to a Zotarolimus-Eluting Coronary Stent System: 4-Year Results from the EXCELLA BD Study®

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BACKGROUND A non-inferiority study evaluating the long-term safety and effectiveness of the Elixir DESyne® BD Novolimus Eluting Coronary Stent System (NECSS), a Co-Cr stent with a biodegradable polymer compared to the control Endeavor Zotarolimus Eluting Coronary Stent System (ZECSS) (Medtronic, Santa Rosa, CA).

METHODS 149 patients were randomized 3:1, either to the DESyne BD NECSS or to the Endeavor ZECSS. Patients were analyzed for the primary endpoint (non-inferiority and superiority) of in-stent late lumen loss (LLL) assessed by qualitative coronary angiography (QCA) at 6 months. Secondary endpoints were evaluated at 1, 6, 9, and 12 months and annually through 5 years, and included a device-orientated composite endpoint (DoCE) defined as: cardiac death, target vessel MI, clinically-indicated target lesion revascularization (TLR); clinically-indicated target vessel revascularization (TVR); and stent thrombosis. Lesions were also evaluated for 6-month angiographic endpoints including: in-segment LLL, percent diameter stenosis, post-procedure minimal lumen diameter, and angiographic binary restenosis (ABR) (≥50%). A subset of patients underwent 6-month intravascular ultrasound (IVUS) evaluation.

RESULTS The study met the primary endpoint demonstrating both non-inferiority and superiority of the DESyne BD NECSS compared to the control (0.12±0.15 vs 0.67±0.47, p<0.001). Six-month in-stent ABR was significantly lower for DESyne BD (0% vs 7.9%, p=0.003). Excellent clinical results were demonstrated for both devices with sustained low clinical event rates observed through 36 months (Table 1). Long-term clinical results through 48 months will be presented.

CONCLUSIONS The DESyne BD NECSS demonstrated both non-inferiority and superiority over Endeavor for in-stent late lumen loss at 6 months. Clinical events remained low through 36 months; clinical results through 48 months will be presented.

Table 1. Angiographic, IVUS and Clinical Results

	DESyne BD	Endeavor	p-value
Angiographic Results			
Baseline RVD (post-procedure)	3.00±0.37	3.08±0.35	0.21
6 month angiographic/IVUS			
In-stent Late Lumen Loss	0.12±0.15	0.67±0.47	<0.001
% neointimal volume	3.6±4.2	20.7±14.2	<0.001
Clinical Results			
6-month DoCE (%)	2.7	3.2	1.00
Clinically-indicated TLR	1.8	3.2	0.52
12 month DoCE (%)	2.7	3.2	1.00
Clinically-indicated TLR	1.8	3.2	1.52
24 month DoCE (%)	2.7	3.2	1.00
Clinically-indicated TLR	1.8	3.2	1.52
36 month DoCE (%)	5.4	6.5	0.68
Clinically-indicated TLR	2.7	6.5	0.30

CATEGORIES CORONARY: Stents: Drug-Eluting

KEYWORDS Biodegradable polymer, DES, Novolimus