2019 euro PCR

TARGET AC 2-year follow up results

B Xu, Y Saito, A Baumbach, H Kelbæk, N van Royen, M Zheng, M Morel, P Knaapen, T Slagboom, TW Johnson, G Vlachojannis, KE Arkenbout, L Holmvang, L Janssens, A Ochala, S Brugaletta, CK Naber, R Anderson, H Rittger, S Berti, E Barbato, GG Toth, L Maillard, C Valina, P Buszman, H Thiele, V Schächinger, A Lansky, W Wijns

On behalf of the TARGET All Comers Investigators

Potential conflicts of interest

Speaker's name : Bo Xu

☑ I do not have any potential conflict of interest to declare

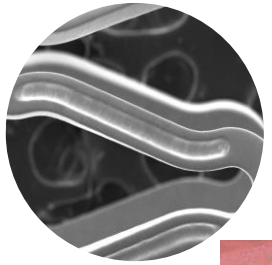
Why this study?

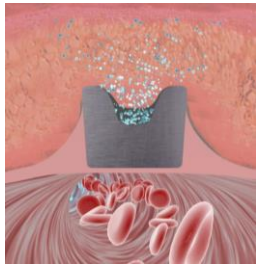
- The FIREHAWK stent (Shanghai MicroPort Medical Group, Shanghai, China), a thin strut cobalt-chromium stent which contains sirolimus with biodegradable polymer applied to recessed abluminal grooves, is designed to minimize polymer burden and reduce drug concentrations in the vessel wall.
- The TARGET All Comers study recently reported non-inferiority of target lesion failure at 12 months with the FIREHAWK stent compared to the XIENCE durable polymer, everolimus-eluting stent.
- In the present study, we report the 2-year clinical outcomes of the TARGET All Comers study.

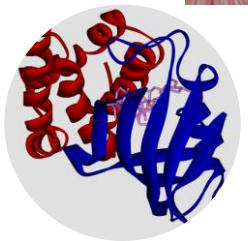
Lansky A, et al. Lancet 2018

What did we study?

Firehawk™ TARGET eluting stent







Platform	Stent material	CoCr (L605) with abluminal grooves
	Strut thickness	0.0034”(86 µm)
	Number of links	2 or 3
Carrier	Bioresorbable polymer	D,L-PLA
	Coating	Abluminal
Drug	Sirolimus	0.30 µg/mm^2
	Release profile	90% release in 90 days

How was the study executed?

Clinical Trial Design: TARGET All Comers

Open label, non-inferiority trial
All patients with symptomatic CAD eligible for DES implantation (no lesion/vessel limitations)

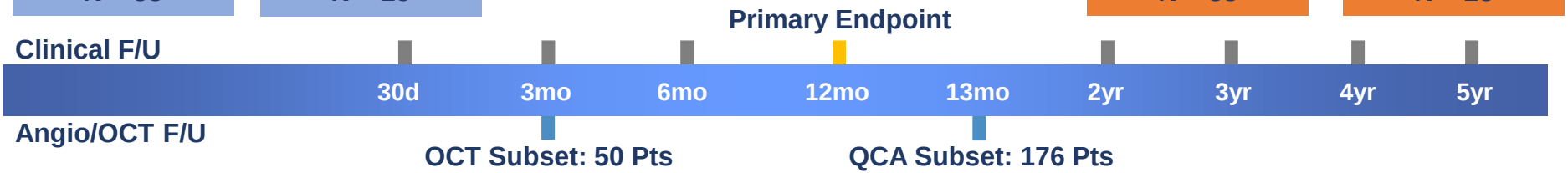
1,656 patients, 20 sites in Europe
Subsets: OCT 50 pts; QCA 176 pts
Risk-based monitoring

FIREHAWK SES
N = 828

- **Angio F/U** N = 88
- **OCT F/U** N = 25

XIENCE EES
N = 828

- **Angio F/U** N = 88
- **OCT F/U** N = 25



Primary Endpoint: TLF (DoCE) = Cardiac Death, Target Vessel MI, ID-TLR at 12mo
Powered Secondary Endpoints: in-stent late loss at 13mo; neointimal thickness at 3mo
Secondary Endpoints: TLF at 30d, 6mo, 2-5 yrs; PoCE (all death, all MI, any revascularization) at each F/U time point; QCA parameters at 13mo; OCT parameters at 3mo

ClinicalTrial.gov Identifier: NCT02520180

How was the study executed?

- **Steering Committee:** W Wijins (Chair),

  A Lansky, A Baumbach, B Xu, M Zheng, L Artus-Jacenko

- **CEC:** Baim Institute, U.S.

- **DSMB:** Cardialysis, The Netherlands

- **Data Management:** ICON, Ireland

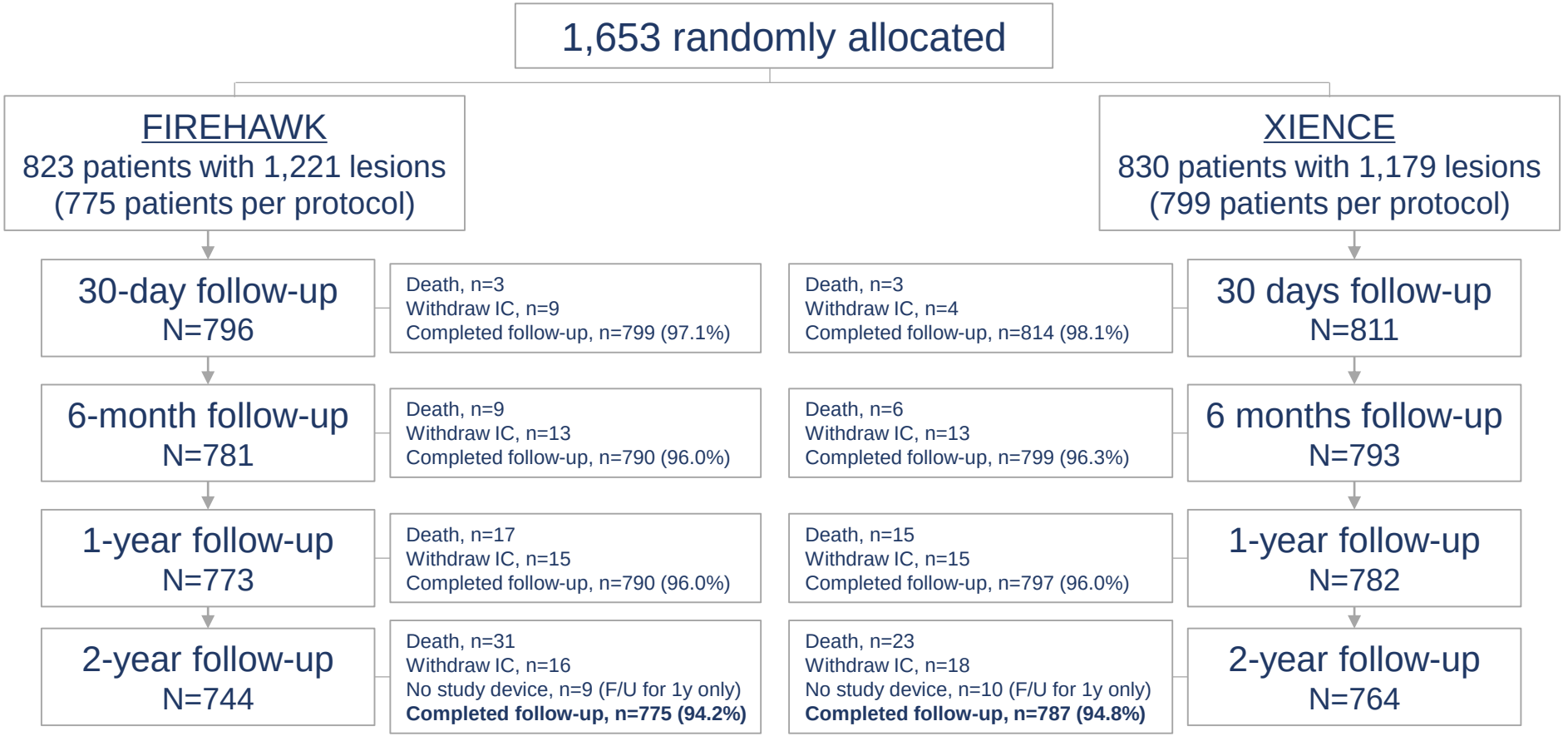
- **OCT Core Lab:** Cardialysis, The Netherlands

- **Angiographic Core Lab:** Cardialysis, The Netherlands & CCRF, China

How was the study executed?

PI	City	Country	Patients, N
Dr. H. Kelbæk	Roskilde	Denmark	218
Dr. P. Knaapen/Prof van Royen	Amsterdam	The Netherlands	166
Dr. T. Slagboom	Amsterdam	The Netherlands	143
Dr. T. Johnson	Bristol	UK	124
Dr. G. Vlachojannis	Rotterdam	The Netherlands	119
Dr. K. Arkenbout	Blaricum	The Netherlands	113
Dr. L. Holmvang	Copenhagen	Denmark	106
Dr. L. Janssens	Bonheiden	Belgium	99
Prof A. Ochala	Katowice	Poland	67
Dr. S. Brugaletta	Barcelona	Spain	57
Prof Dr. O. Bruder	Essen	Germany	56
Dr. R. Anderson	Cardiff	UK	54
Dr. H. Rittger	Fürth	Germany	53
Dr. S. Berti	Massa	Italy	53
Dr. E. Barbato	Aalst	Belgium	51
Dr. G. Toth	Graz	Austria	50
Dr. L. Maillard	Aix en Provence	France	49
Dr. C. Valina	Bad Krozingen	Germany	35
Prof P. Buszman	Dabrowa Gornicza	Poland	28
Prof Dr. H. Thiele	Leipzig	Germany	12
Dr. V. Schächinger	Fulda	Germany	2

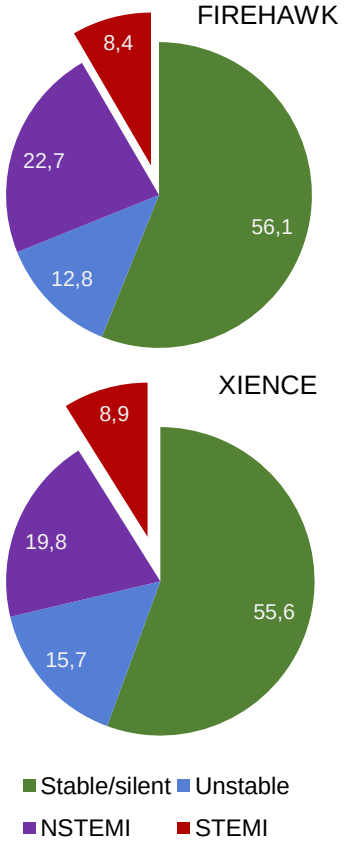
How was the study executed?



What are the essential results?

Patient and Lesion Characteristics

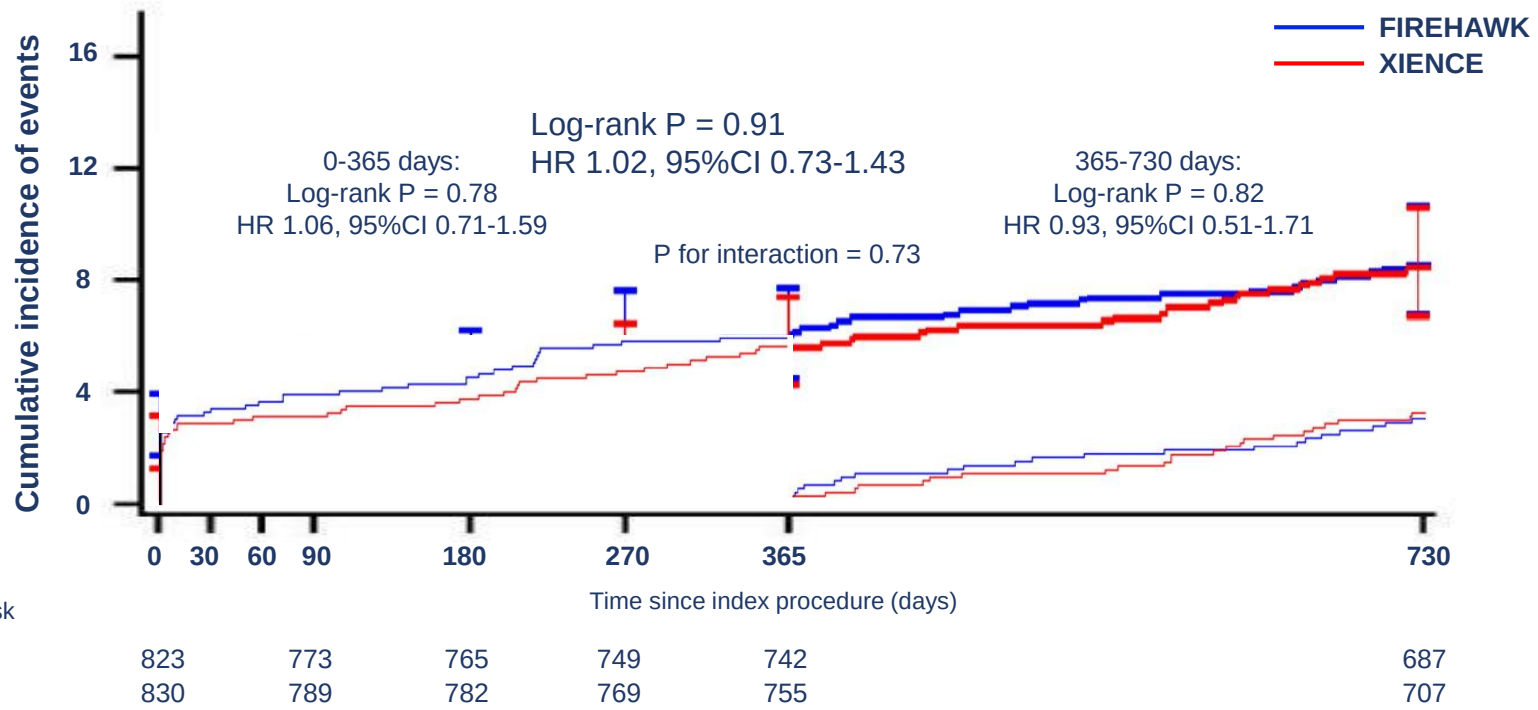
	FIREHAWK, N=823	XIENCE, N=830
Age, years	64.9±9.8	65.3±10.5
Male	78.1% (641/821)	76.4% (634/830)
Diabetes mellitus	24.0% (197/821)	23.0% (191/830)
Previous MI	21.7% (178/821)	24.8% (206/830)
Lesions per patient	1.5±0.8	1.4±0.7
Any chronic total occlusion	6.0% (47/789)	6.4% (51/792)
Any in-stent restenosis	5.6% (43/766)	7.3% (57/777)
Reference vessel diameter, mm (QCA)	2.77±0.49	2.77±0.52
Lesion length, mm (QCA)	19.0±11.8	18.8±12.4
Stents per patient	1.7±1.0	1.7±1.0



What are the essential results?

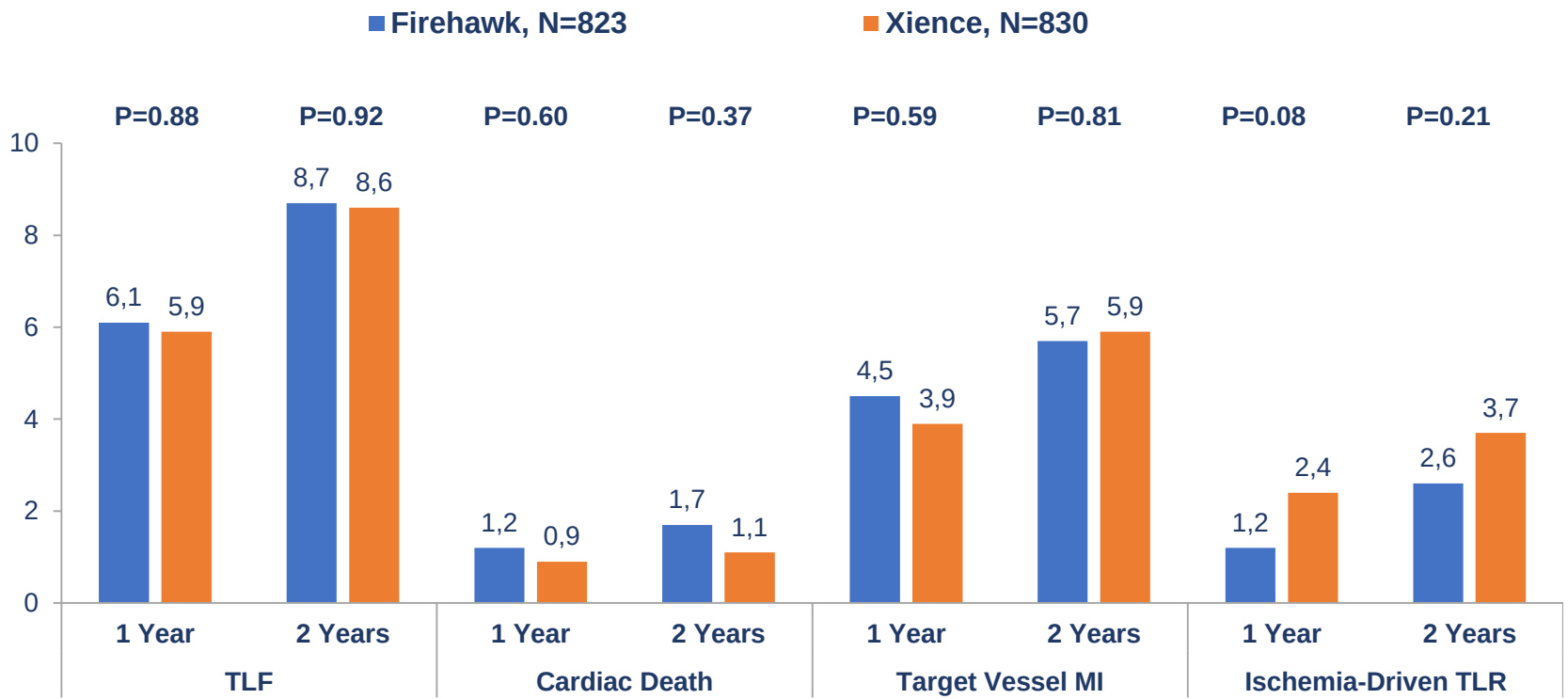
Target Lesion Failure

Landmark analysis at 1 year



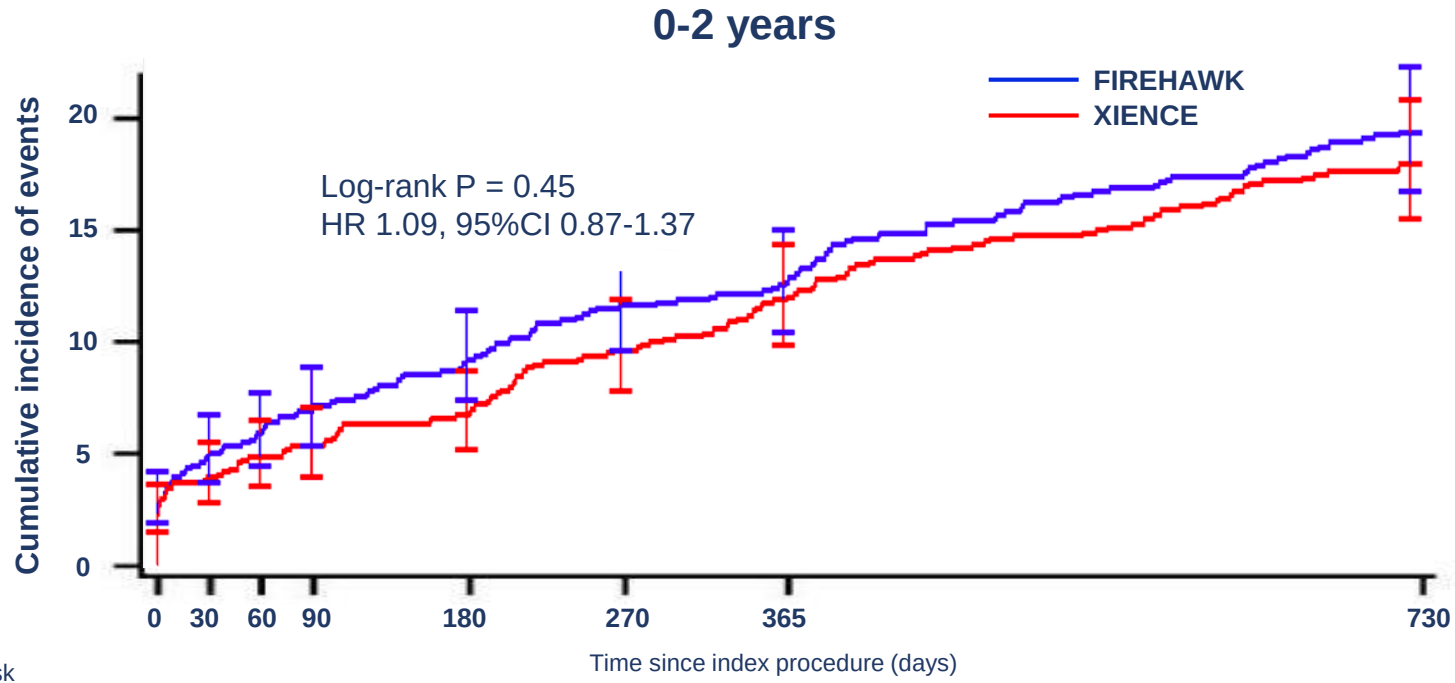
What are the essential results?

TLF and components through 2 years



What are the essential results?

PoCE (a composite of death, MI, or revascularization)

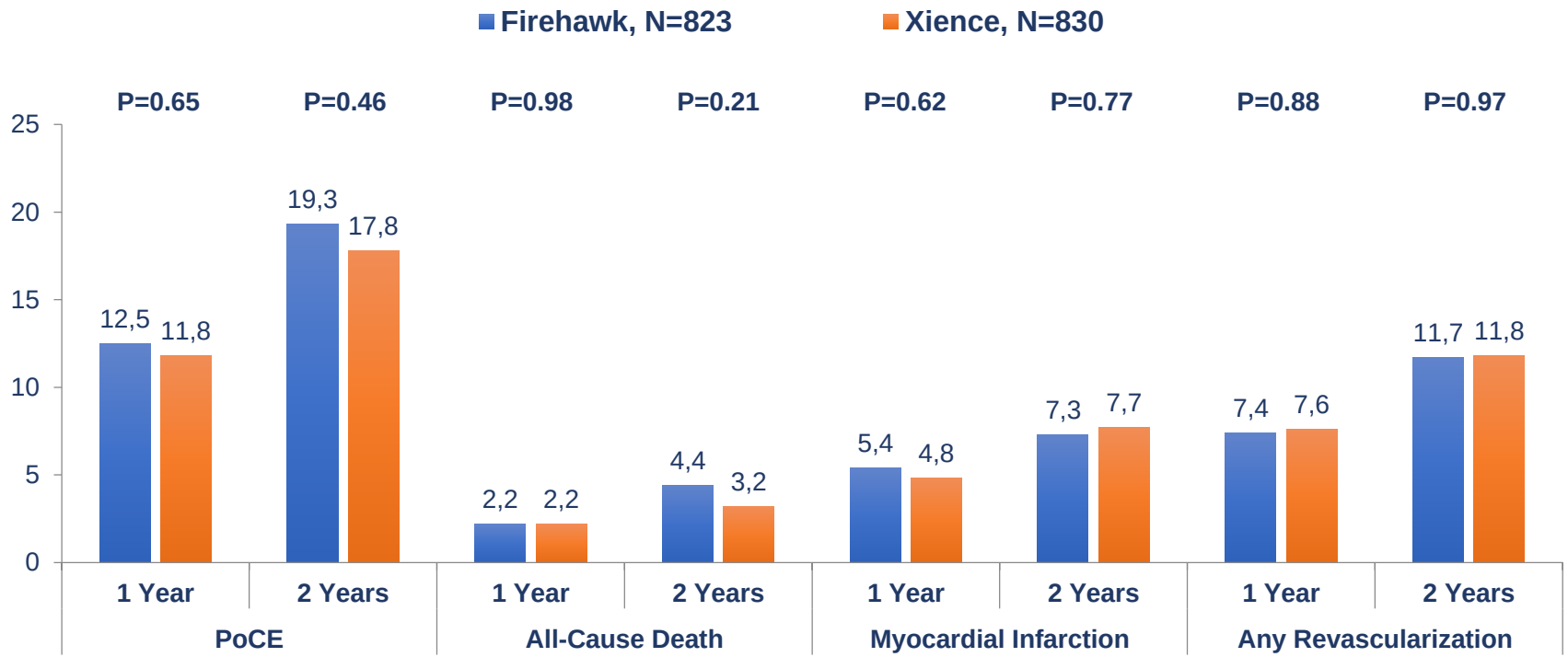


No. at risk

FIREHAWK	823	753	735	711	701	628
XIENCE	830	775	763	737	718	650

What are the essential results?

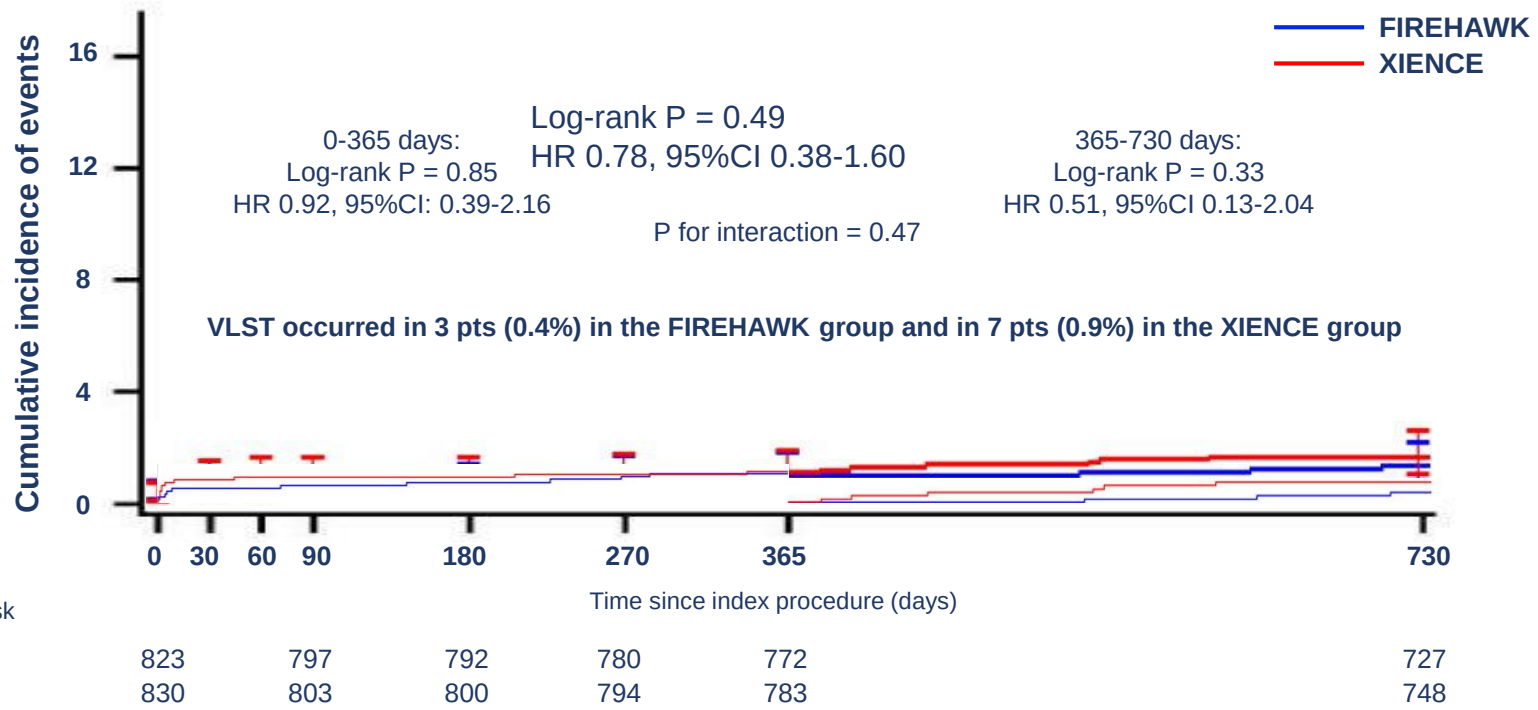
PoCE and components through 2 years



What are the essential results?

Definite/probable stent thrombosis

Landmark analysis at 1 year

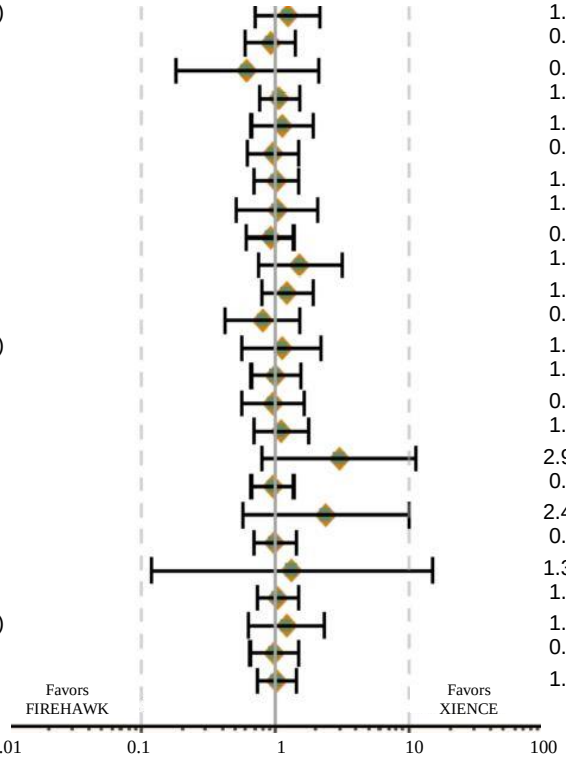


No. at risk						
FIREHAWK	823	797	792	780	772	727
XIENCE	830	803	800	794	783	748

What are the essential results?

Subgroup Analysis of 2-year TLF

	N	Target Lesion Failure, % FIREHAWK/Events (%)	Target Lesion Failure, % XIENCE/Events (%)	Hazard ratio (95% CI)	P interaction
Diabetes	388	27 (14.5)	22 (12.2)	1.23 (0.70-2.16)	0.46
No diabetes	1263	41 (6.9)	46 (7.5)	0.91 (0.60-1.39)	
STEMI	143	4 (6.2)	7 (10.4)	0.61 (0.18-2.10)	0.40
No STEMI	1507	64 (9.0)	61 (8.4)	1.07 (0.75-1.51)	
ACS	728	28 (8.3)	26 (7.5)	1.12 (0.66-1.92)	0.69
No ACS	922	40 (9.1)	42 (9.5)	0.96 (0.62-1.48)	
(N)STEMI/Stable	1259	53 (8.7)	51 (8.6)	1.02 (0.69-1.49)	>0.99
No (N)STEMI/Stable	391	15 (8.8)	17 (8.5)	1.03 (0.51-2.06)	
Any small vessel	1123	46 (8.3)	49 (9.1)	0.92 (0.61-1.37)	0.23
No small vessel	421	17 (8.9)	13 (6.0)	1.52 (0.74-3.13)	
Any long lesion	850	44 (10.4)	34 (8.5)	1.22 (0.78-1.91)	0.27
No long lesion	570	16 (6.1)	23 (7.8)	0.80 (0.42-1.51)	
Multivessel treatment	304	19 (11.9)	15 (10.7)	1.11 (0.57-2.19)	0.81
No multivessel treatment	1209	43 (7.5)	45 (7.6)	1.00 (0.66-1.53)	
Any bifurcation lesion	597	27 (9.2)	28 (9.7)	0.96 (0.56-1.63)	0.72
No bifurcation lesion	947	36 (8.0)	34 (7.3)	1.11 (0.69-1.77)	
Total occlusion	98	8 (18.6)	3 (7.0)	2.99 (0.79-11.29)	0.11
No total occlusion	1483	58 (8.2)	61 (8.6)	0.95 (0.67-1.37)	
Any ISR lesion	100	5 (12.2)	3 (5.3)	2.40 (0.57-10.05)	0.28
No ISR lesion	1443	58 (8.3)	59 (8.5)	0.98 (0.69-1.41)	
Left main treated	25	2 (13.3)	1 (10.0)	1.32 (0.12-14.53)	0.83
No left main treated	1519	61 (8.4)	61 (8.2)	1.03 (0.72-1.47)	
Any overlapping stents	344	20 (12.2)	17 (10.1)	1.22 (0.64-2.33)	0.57
No overlapping stents	1200	43 (7.4)	45 (7.7)	0.98 (0.64-1.48)	
All	1653	68 (8.7)	68 (8.6)	1.02 (0.73-1.43)	



Study Limitations

- First, the study was powered for the primary composite endpoint of TLF. Thus, the analysis remains underpowered to detect differences in the individual components of the primary endpoint or stent thrombosis.
- Second, early optical coherence tomography and angiographic follow-up sub-studies might contribute to increased revascularizations.
- Third, DAPT duration was guideline-based. However, because randomization was not stratified according to DAPT duration, between group differences may confound outcomes between the stent platforms.

Conclusions

- The 2-year follow-up of the TARGET All Comers study shows similar safety and efficacy profiles of the FIREHAWK and XIENCE stent. The incidence of TLF beyond 1 year was low and comparable for both treatment arms, with a low rate of stent thrombosis in a broad all-comers population.

The essentials to remember

- **Why?**
  - No outcome data beyond 1 year for FIREHAWK stent in all comers population
- **What?**
  - FIREHAWK stent evaluated in an all comers population in Europe
- **How?**
  - 2-year follow-up of the TARGET All Comers randomized trial
- **What are the results?**
  - Similar safety and efficacy profiles of FIREHAWK compared with XIENCE stent at 2 years
- **Why is this important?**
  - 1st outcome data beyond 1 year for FIREHAWK stent in an all comers population from an adequately powered randomized trial

JACC Cardiovascular Interventions

B Xu, Y Saito, A Baumbach, H Kelbæk, N van Royen, M Zheng, M Morel, P Knaapen, T Slagboom, TW Johnson, G Vlachojannis, KE Arkenbout, L Holmvang, L Janssens, A Ochala, S Brugaletta, CK Naber, R Anderson, H Rittger, S Berti, E Barbato, GG Toth, L Maillard, C Valina, P Buszman, H Thiele, V Schächinger, A Lansky, W Wijns, on Behalf of the TARGET AC Investigators. Two-Year Clinical Outcomes of an Abluminal Groove–Filled Biodegradable-Polymer Sirolimus-Eluting Stent Compared With a Durable-Polymer Everolimus-Eluting Stent. *JACC Cardiovasc Interv* (2019); doi: 10.1016/j.jcin.2019.05.001.

What are the essential results?

Clinical Outcomes at 2-year Follow-up (1)

	FIREHAWK, N=778	XIENCE, N=791	Difference (95% CI)	P value
Target lesion failure	8.7% (68)	8.6% (68)	0.1% (−2.6% to 2.9%)	0.92
Target vessel failure	9.9% (77)	9.6% (76)	0.3% (−2.6% to 3.2%)	0.85
PoCE	19.3% (150)	17.8% (141)	1.5% (−2.4% to 5.3%)	0.46
All-cause death	4.4% (34)	3.2% (25)	1.2% (−0.7% to 3.1%)	0.21
Cardiac death	1.7% (13)	1.1% (9)	0.5% (−0.6% to 1.7%)	0.37
Non-cardiac death	2.7% (21)	2.0% (16)	0.7% (−0.8% to 2.2%)	0.38
Any MI	7.3% (57)	7.7% (61)	−0.4% (−3.0% to 2.2%)	0.77
Target vessel MI	5.7% (44)	5.9% (47)	−0.3% (−2.6% to 2.0%)	0.81
Non-target vessel MI	1.8% (14)	2.3% (18)	−0.5% (−1.9% to 0.9%)	0.50

What are the essential results?

Clinical Outcomes at 2-year Follow-up (2)

	FIREHAWK, N=778	XIENCE, N=791	Difference (95% CI)	P value
Any revascularization	11.7% (91)	11.8% (93)	−0.1% (−3.2% to 3.1%)	0.97
Any TVR	6.4% (50)	6.6% (52)	−0.1% (−2.6% to 2.3%)	0.91
Ischemia-driven TVR	4.5% (35)	5.2% (41)	−0.7% (−2.8% to 1.4%)	0.53
Any TLR	4.0% (31)	4.4% (35)	−0.4% (−2.4% to 1.5%)	0.66
Ischemia-driven TLR	2.6% (20)	3.7% (29)	−1.1% (−2.8% to 0.6%)	0.21
Definite ST	1.5% (12)	2.0% (16)	−0.5% (−1.8% to 0.8%)	0.47
Definite or probable ST	1.7% (13)	2.1% (17)	−0.5% (−1.8% to 0.9%)	0.49