

Abluminal groove-filled
biodegradable polymer-coated
FIREHAWK SIROLIMUS-ELUTING STENT

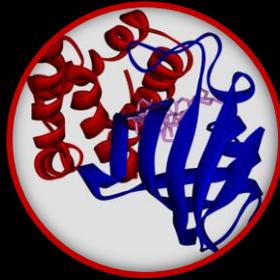
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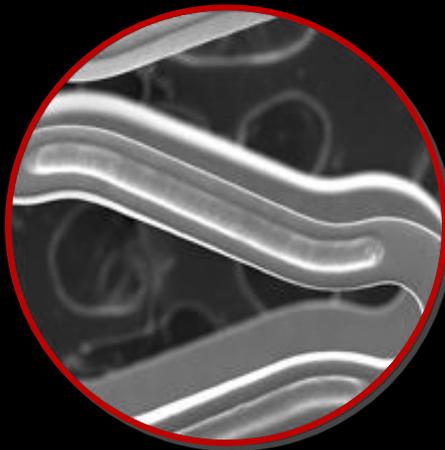
Pusan National University Hospital

CONCEPT AND POTENTIAL BENEFIT OF *FIREHAWK*

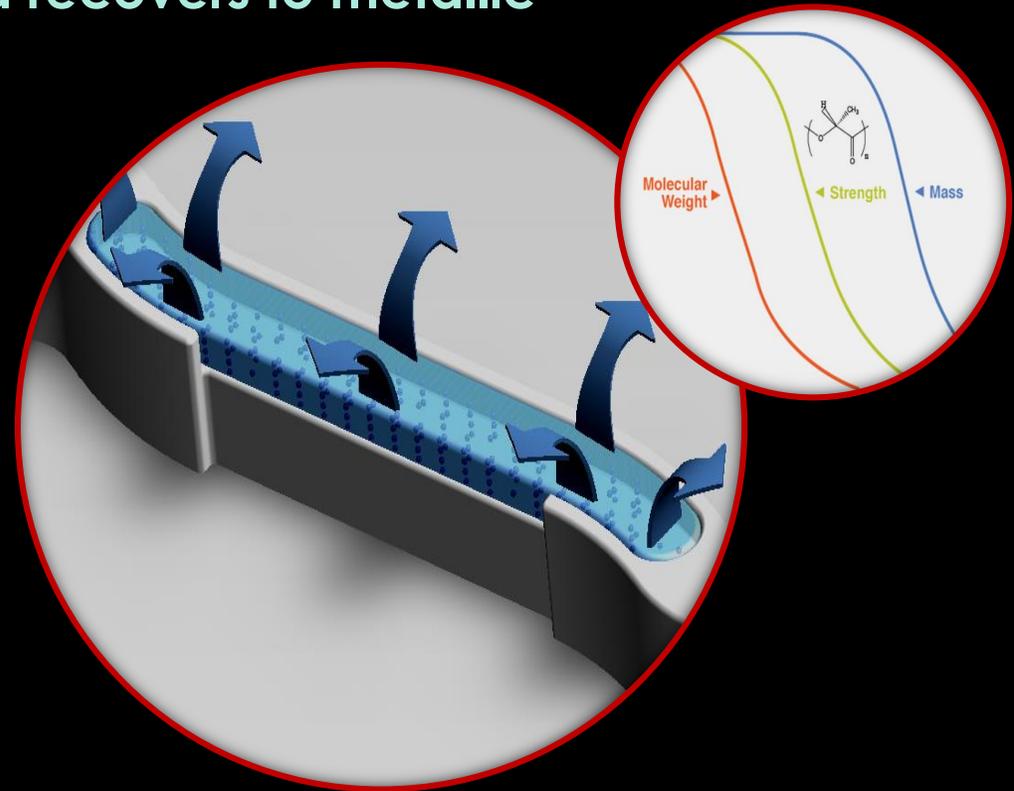
1. Sirolimus



2. Co-Cr stent platform with abluminal grooves

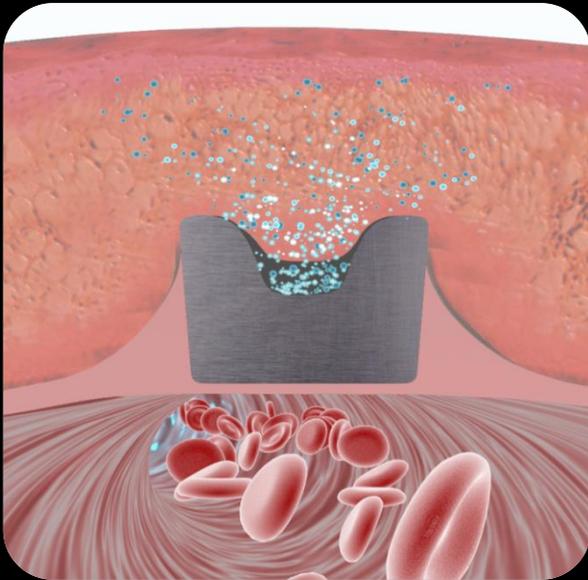


3. D,L-PLA absorbed after 6-9 months and recovers to metallic surface

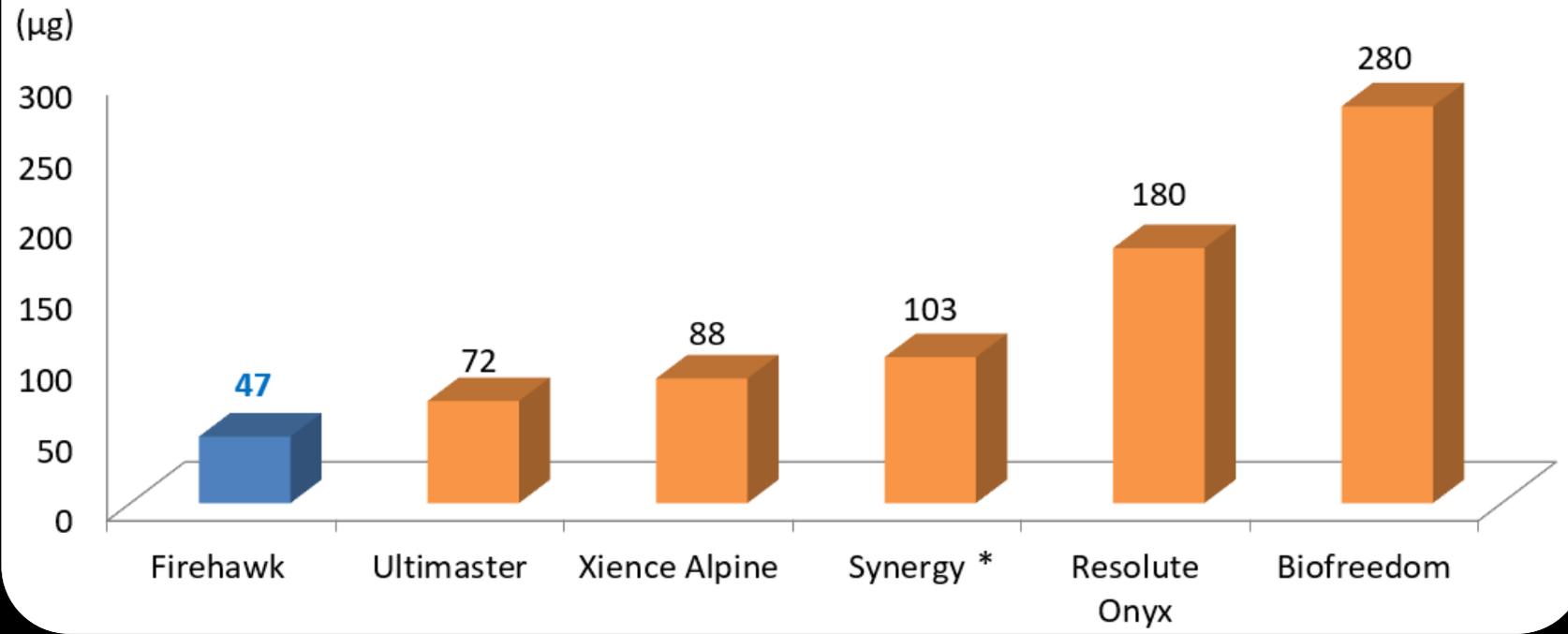


MINIMIZED DRUG

1. Sirolimus dose
3ug/mm

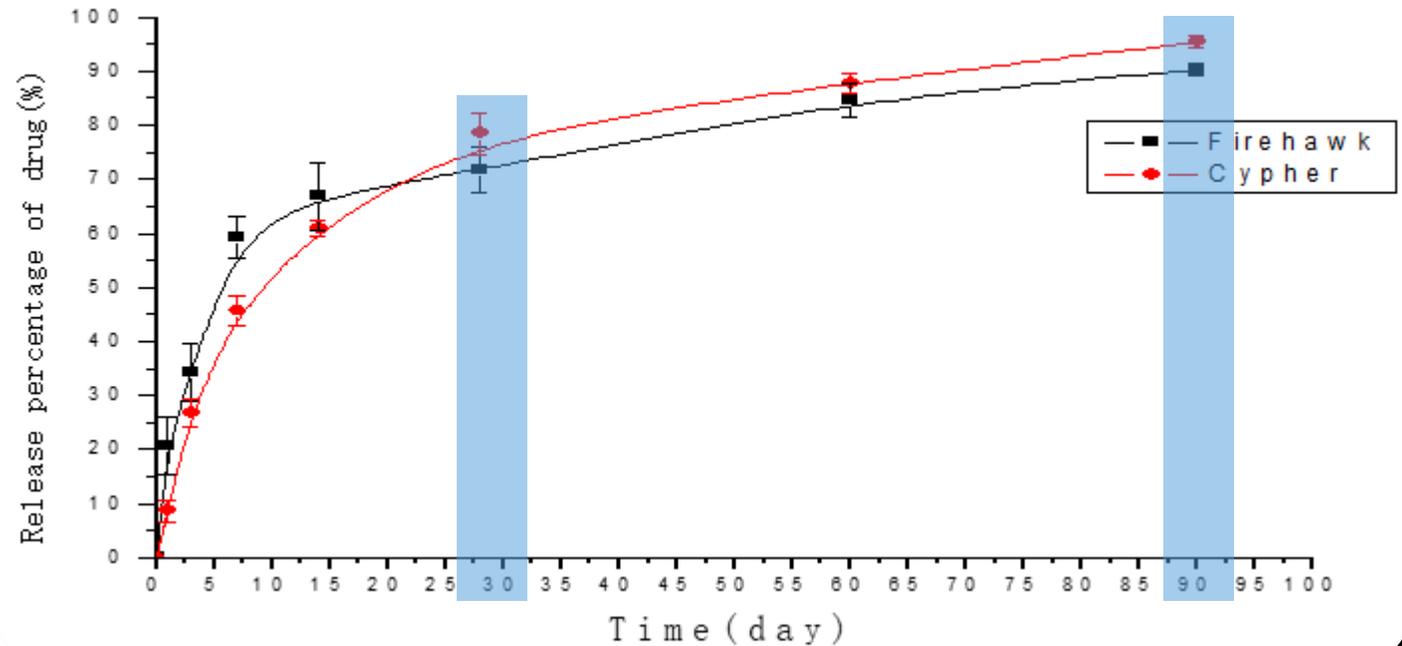
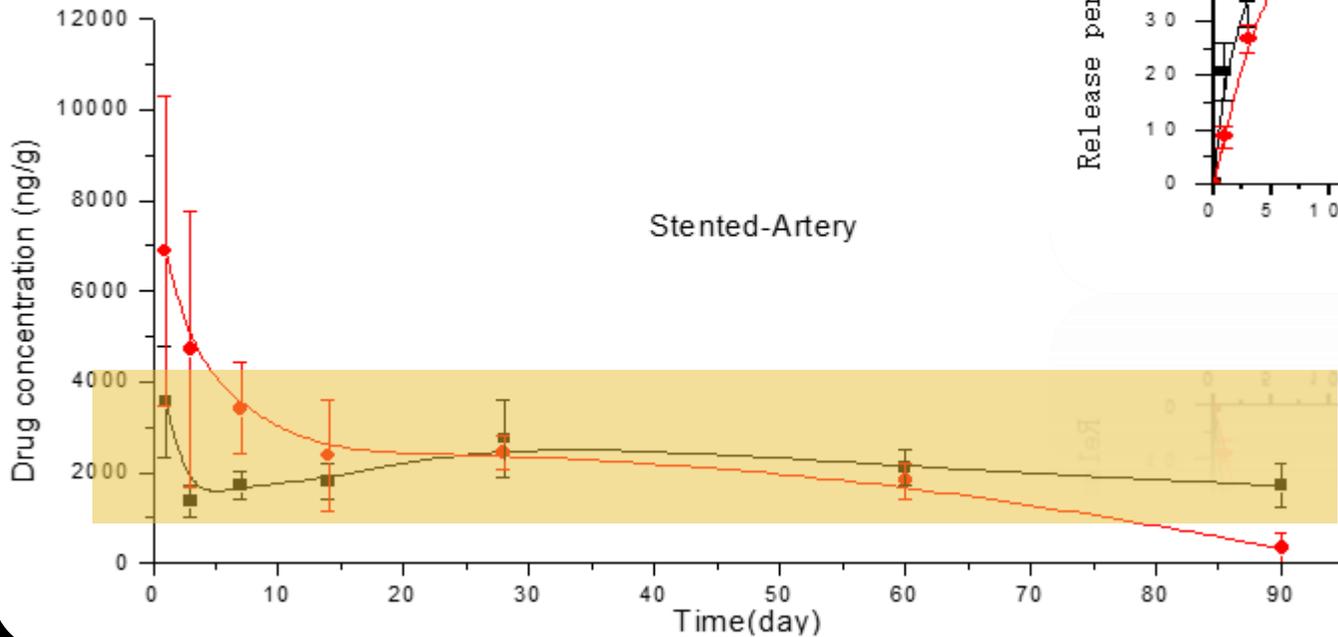


Drug Dosage (μg)
(comparison per 3.0*18mm stent)



GOOD TISSUE PENETRATION

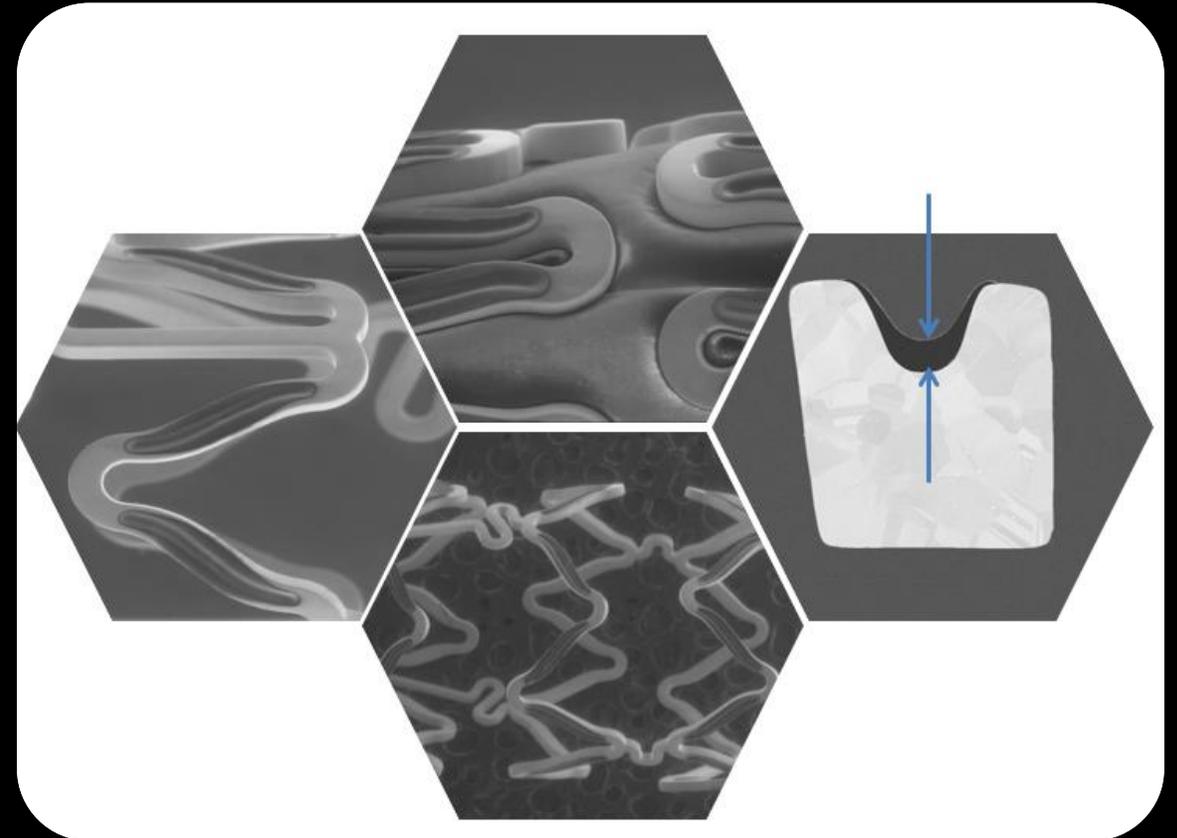
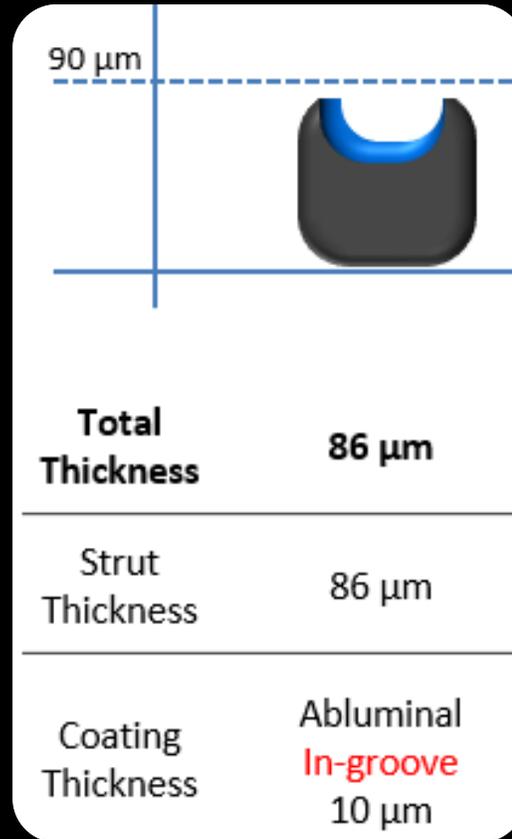
1. similar tissue concentration even with 1/3 dosage



2. Drug release
75% at 1mon, 90% at 3mon

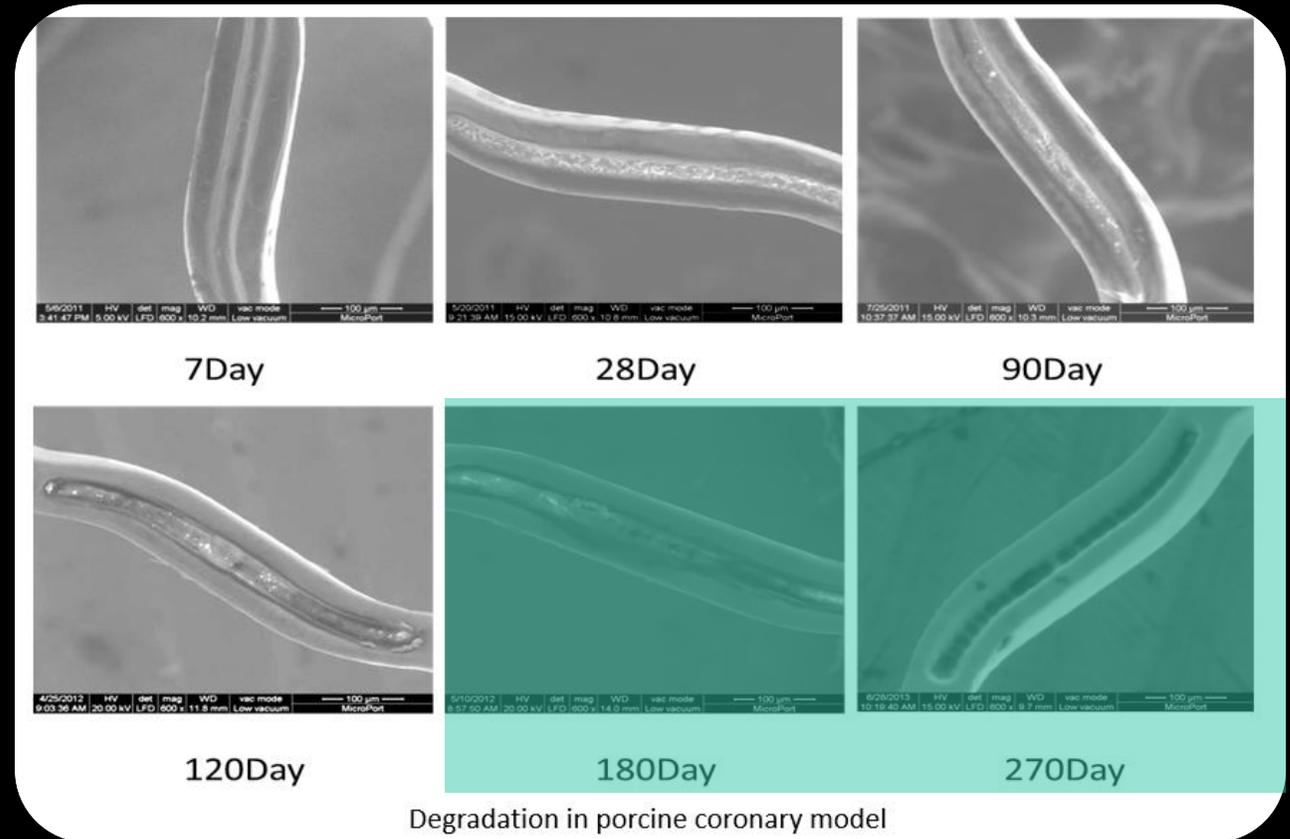
ABLUMINAL GROOVE DESIGN

1. Groove on surface
2. Depth of groove:
1/3
3. Coating **10um**
4. Total strut thickness
86um
5. **No coating peel off**
during delivery &
post dilatation



POLYMER ABSORPTION AT 9m

1. Established absorbable **Poly lactide acid (PLA)**
2. Drug release at **3m**,
PLA absorbed at **6-9m**



120D9λ

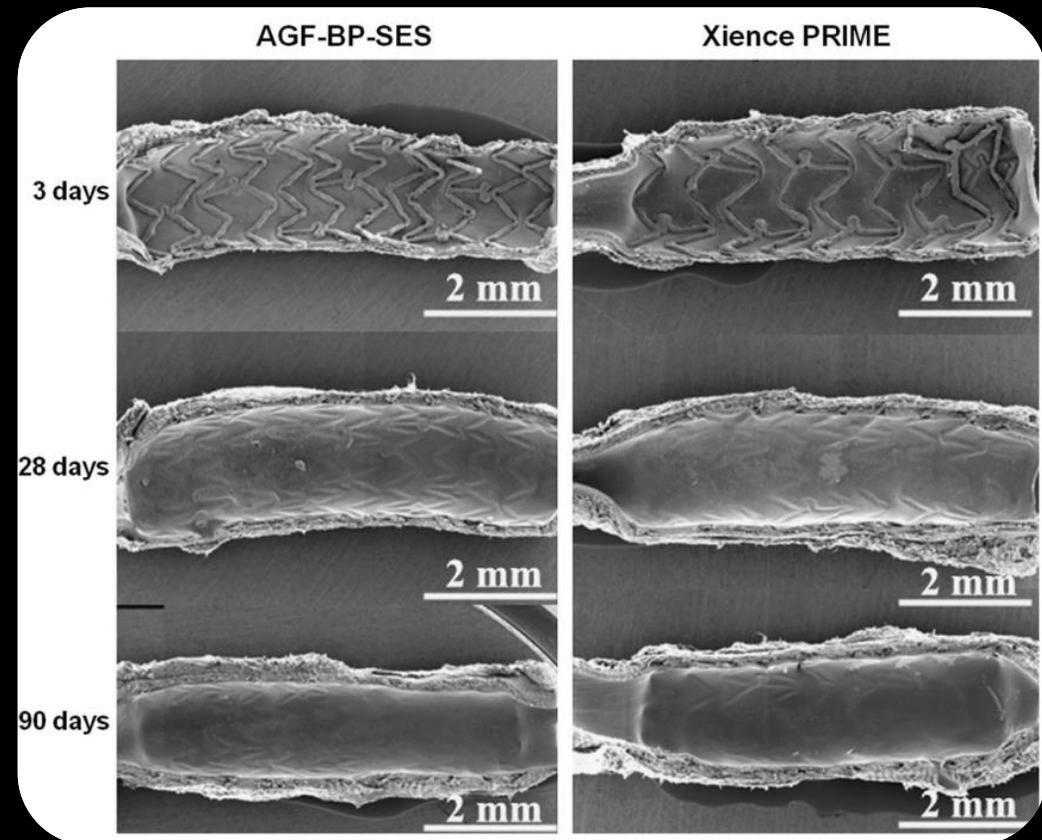
180D9λ

270D9λ

BIODEGRADABLE-POLYMER DES

1. **low** inflammation score
comparable results /c Xience

2. **Similar** healing response at 3m
comparable results /c Xience



Stent	Uncovered struts (%)	Malapposition (%)	Neointimal thickness (μm)
Biodegradable polymer DES			
SYNERGY (everolimus) ¹⁹	<1	1	70
SYNERGY (everolimus) ¹⁴	5.5	3	200*
Ultimaster DES ²²	4.8	NA	60
ALEX (sirolimus) ¹⁵	3.9	0.12	40
MiStent (sirolimus) ¹⁶	7.3	0.4	2.6
BuMA (sirolimus) ¹⁷	6.8	1.3	70
EXCEL II (sirolimus) ²⁰	6.5	1.4	80
Firehawk Target OCT (sirolimus)	0.1	1.0	75
Durable polymer DES			
XIENCE (everolimus) ²³	4.7	0	45
XIENCE Target OCT (everolimus)	0	1.2	82

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XIENCE (everolimus) ²³	4.7	0	45

CLINICAL EVIDENCE OF *FIREHAWK*

TARGET I

RCT, n=458
Simple lesion
vs. Xience

TARGET II

Registry, n=730
Complex lesion

TARGET AC

RCT, n=1,656
Real world all comer
vs. Xience

1

2013

2

2015

3

2018

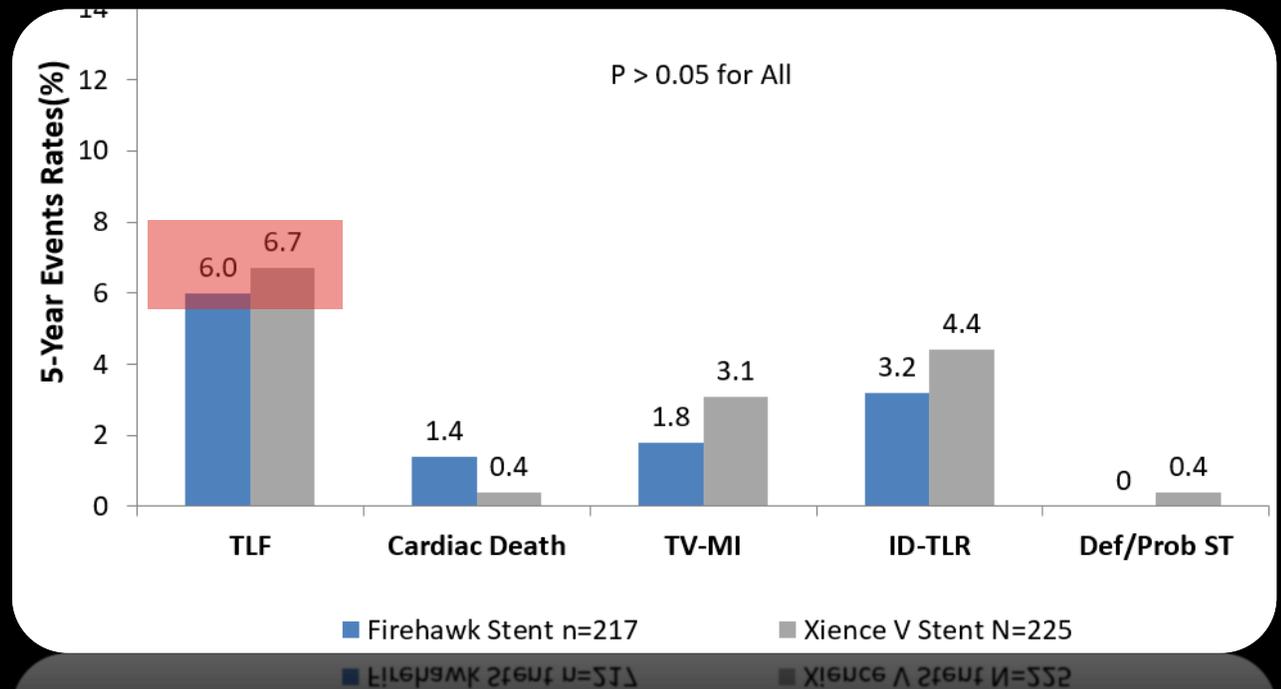
SIMPLE SINGLE CORONARY LESIONS IN CHINA

TARGET I

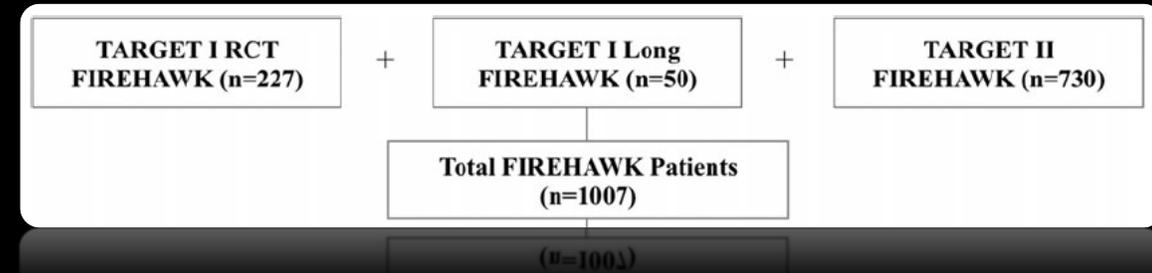
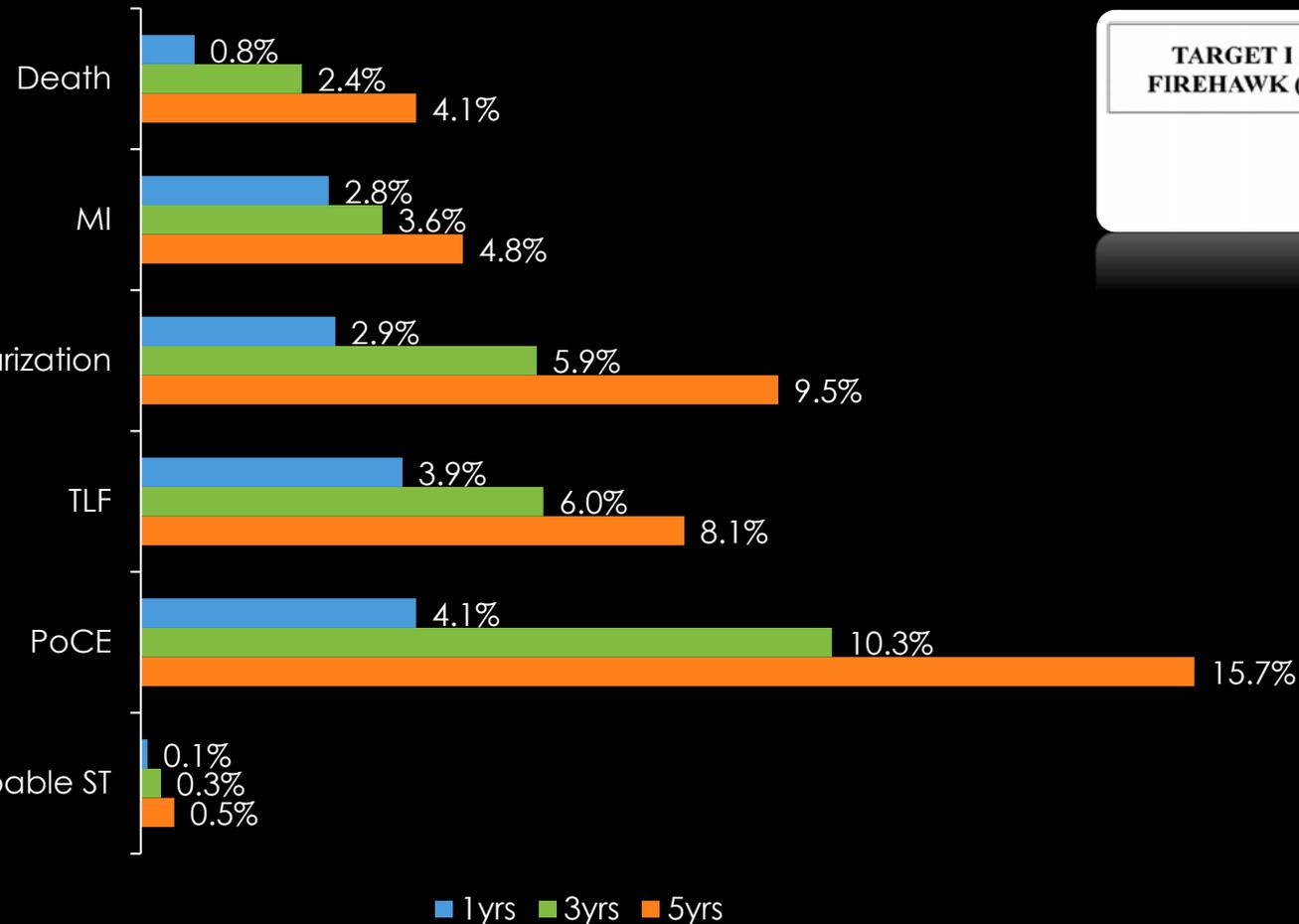
Firehawk 217 vs. Xience 225



TARGET I 5yrs outcomes

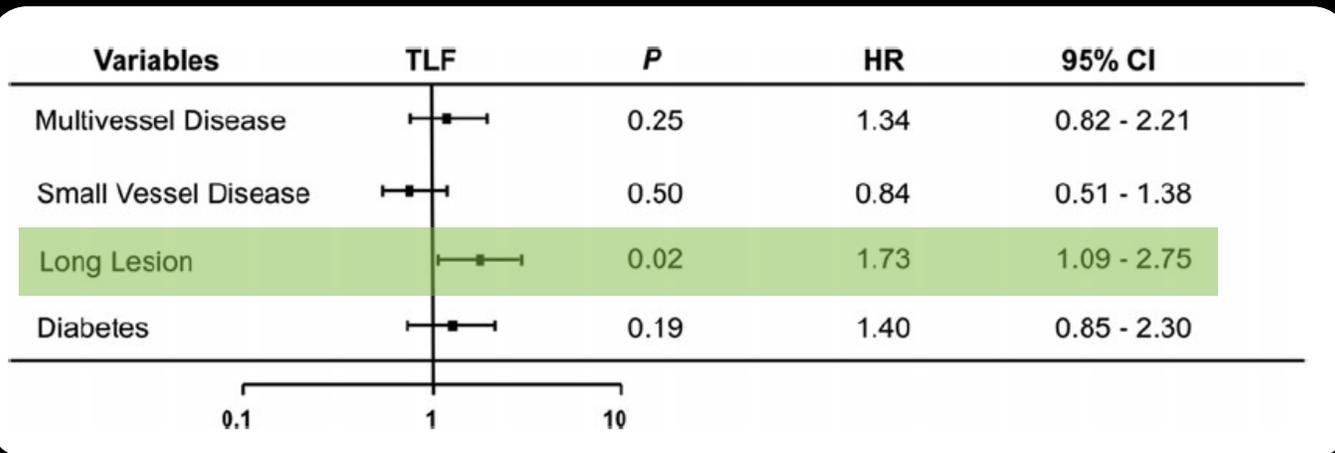


PATIENT-LEVEL POOLED ANALYSIS FROM TARGET I & II TRIALS



1. Safety & efficacy for **5yrs**
2. Relatively **low** clinical event

PATIENT-LEVEL POOLED ANALYSIS FROM TARGET I & II TRIALS



1. Predictor for TLF
Long lesion only!!
2. **predilation-sizing-postdilation**
No affect on outcome

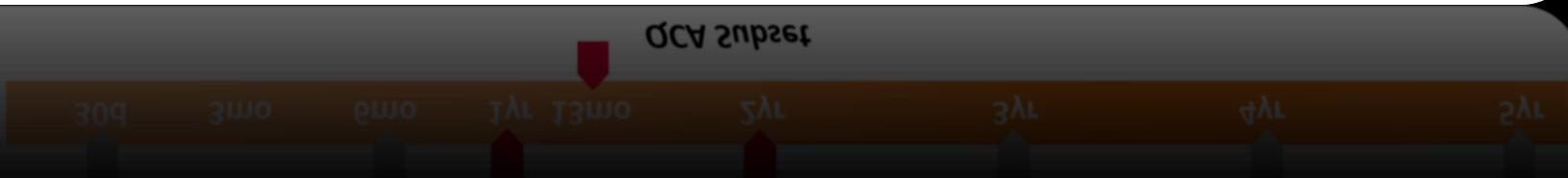
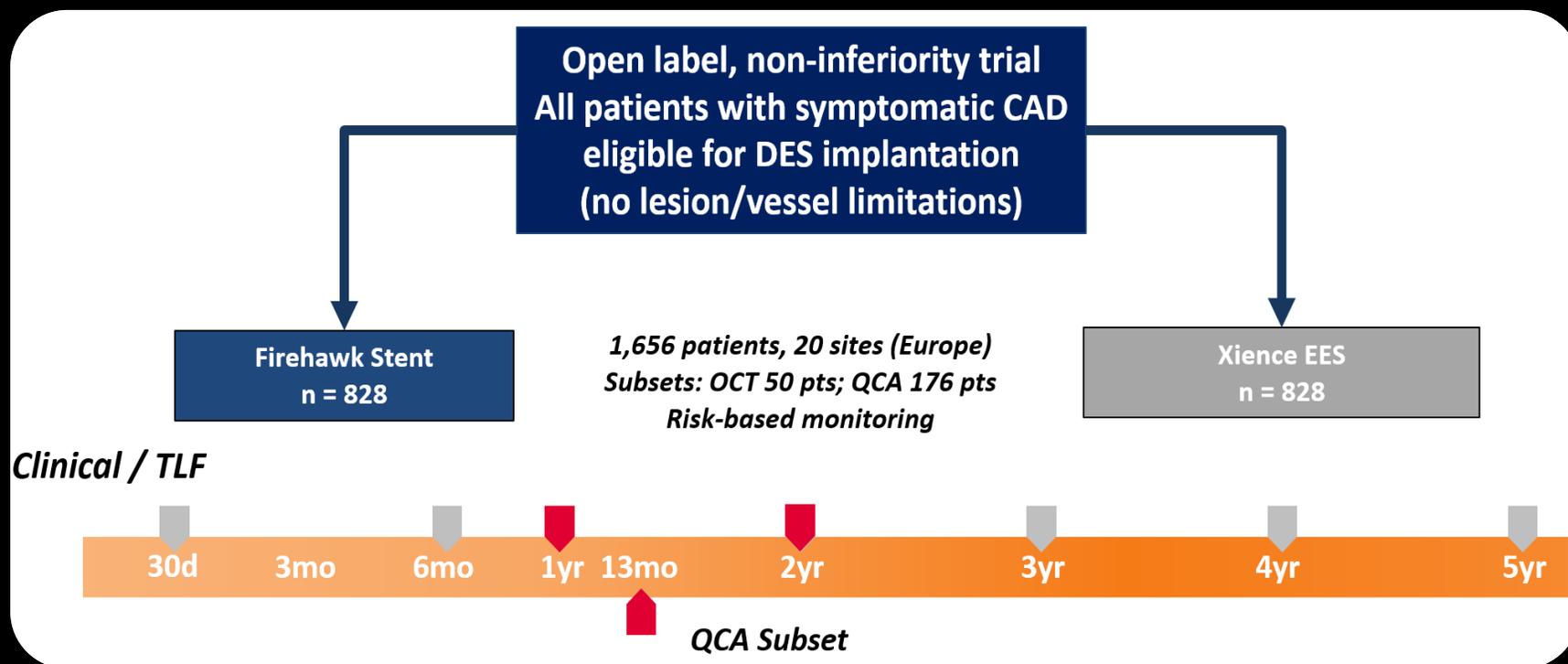
Variable	Variable present	Variable absent	TLF	
			Hazard ratio (95% CI)	P
Optimal pre-dilatation	9.0%	8.1%	1.13 (0.57, 2.26)	0.72
Optimal vessel sizing	8.3%	7.8%	1.10 (0.53, 2.27)	0.79
Optimal post-dilatation	7.7%	8.4%	0.92 (0.54, 1.58)	0.76

Abbreviations: PSP, predilation-sizing-postdilation; TLF, target lesion failure; CI, confidence interval.

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TARGET ALL COMERS

1. **European** experience with *Firehawk* in post-market setting
2. **Minimal** exclusion criteria
3. **TLF** (Cardiac death, target vessel MI, and clinically driven TLR) at 12m



TARGET ALL COMERS

4. *baseline characteristics*

65yrs old

- 78%** male
- 24%** DM
- 60%** HTN
- 22%** previous MI
- 6%** Renal insufficiency
- 30%** presented MI
- 74%** small lesion <3.0mm
- 62%** long lesion
- 6%** CTO
- 20%** multivessel treated

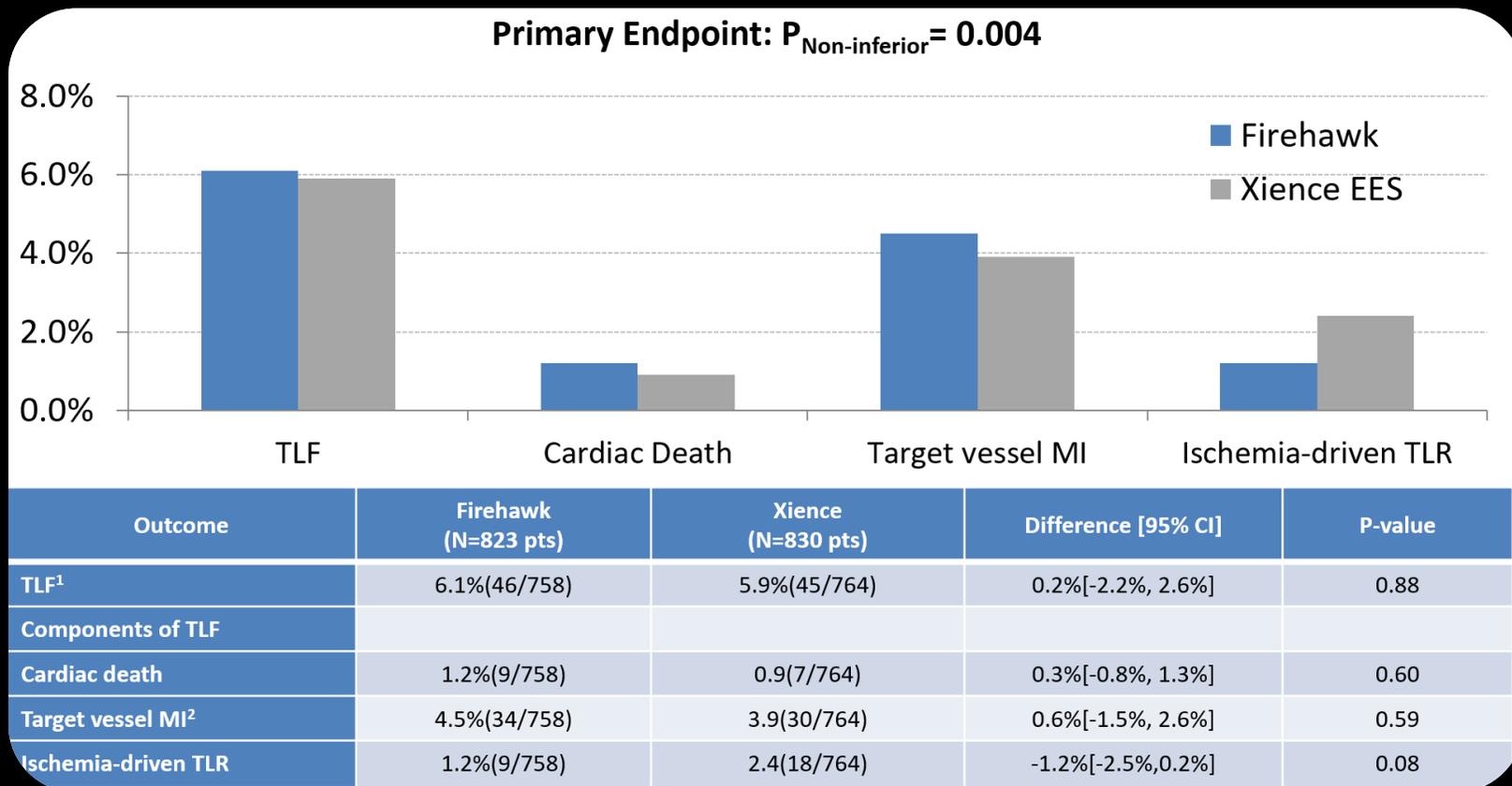
5. *Procedural characteristics*

- 3.07mm** stent diameter
- 26.7mm** stent length
- 1.1** number of implanted stents
- 42%** LAD as target lesion
- 6%** mod-sev calcification
- 42%** lesion Type C
- 33%** bifurcation
- 4.3%** in-stent restenosis
- 9.5%** total occlusion

TARGET ALL COMERS

- 6. TLF at 12m
6.1% Firehawk vs.
5.9% Xience

- 7. QCA at 13m
0.17mm Firehawk vs.
0.11mm Xience
 mean diff. *0.05mm*
p=0.48



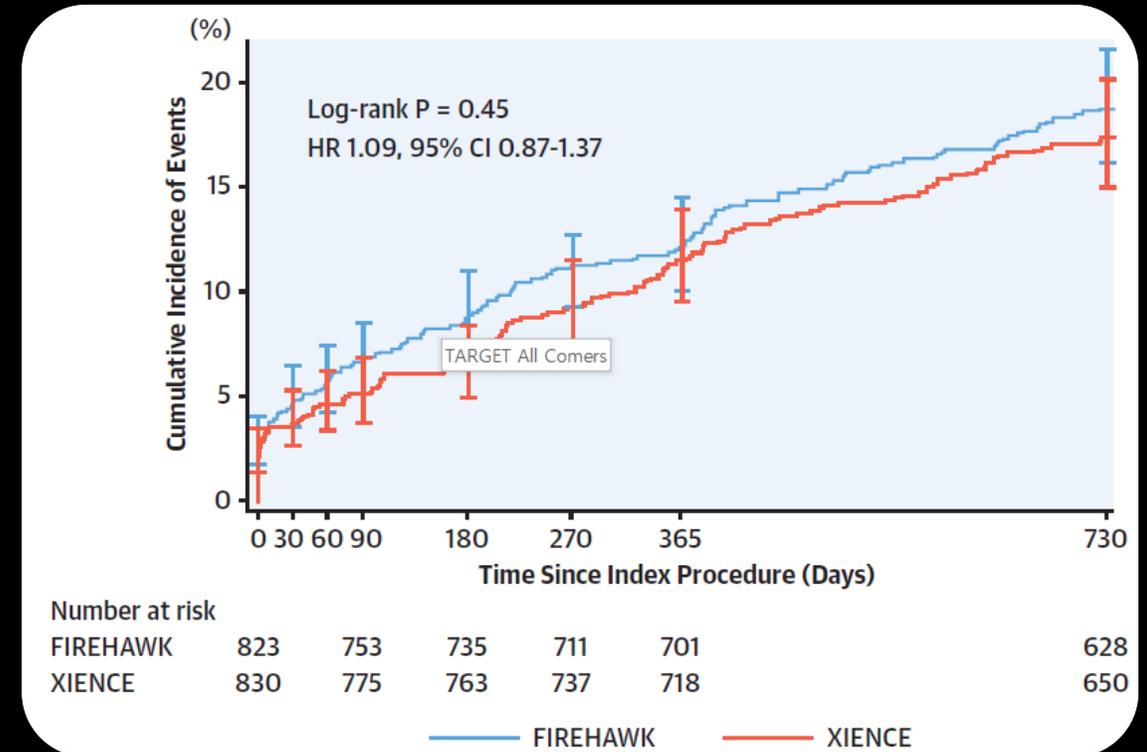
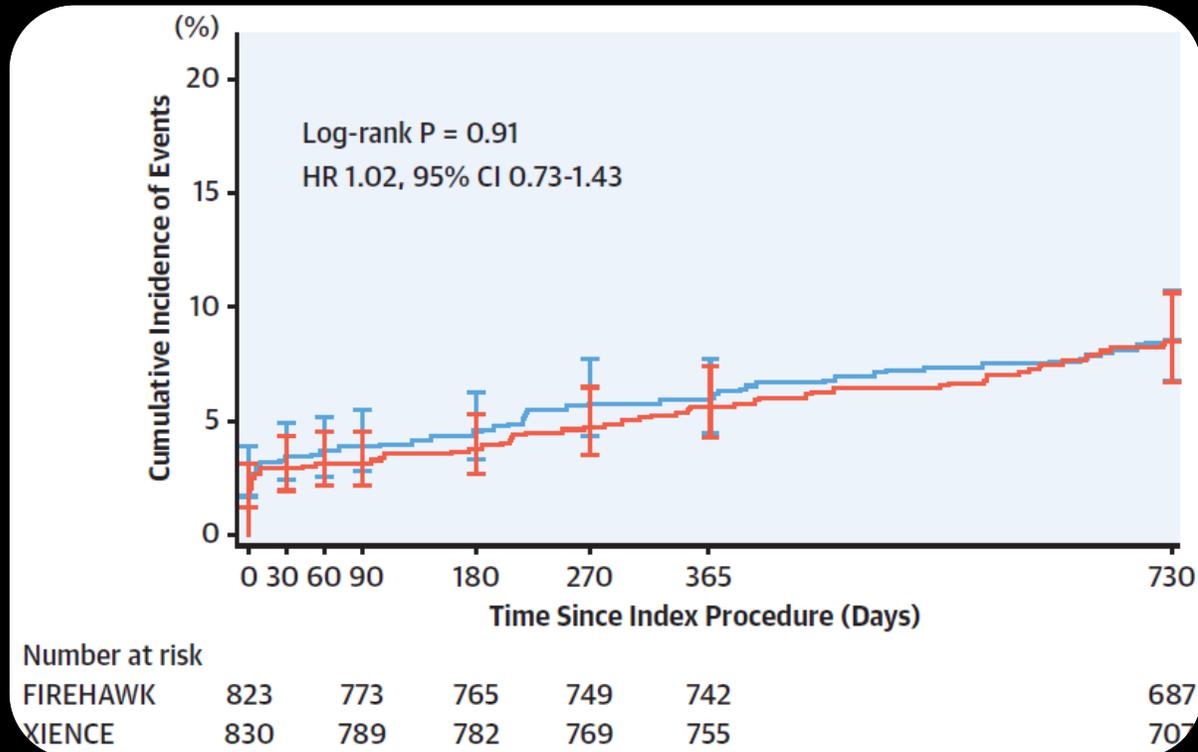
TARGET ALL COMERS 2yrs

1. TLF at 24m

8.7% Firehawk vs. 8.6% Xience

2. PoCE (death, any MI, any revasc)

19.3% Firehawk vs. 17.8% Xience



Number at risk	0	30	60	90	180	270	365	730
XIENCE	830	789	782	769	755			707
FIREHAWK	823	773	765	749	742			687

Number at risk	0	30	60	90	180	270	365	730
XIENCE	830	775	763	737	718			650
FIREHAWK	823	753	735	711	701			628

TARGET ALL COMERS **complex lesion**

1. TARGET ALL Comer **subanalysis**
Firehawk vs. Xience
according to low risk vs. **high risk (84%)**
2. **TLF** as primary endpoint
3. **High risk** clinical & lesion features
old age, AMI, CKD, NYHA III, prev. stent
long lesion, small or large vessel, ISR, CTO, LM
severe tortuosity, calcification, bifurcation

Variable	Low-risk (n = 251)	High-risk (n = 1,334)
Age > 75 years	0/251 (0.0%)	289/1,334 (21.7%)
Acute myocardial infarction	0/251 (0.0%)	493/1,333 (37.0%)
Renal insufficiency	0/251 (0.0%)	103/1,334 (7.7%)
Lesion length > 24 mm	0/251 (0.0%)	445/1,156 (38.5%)
RVD <2.25 mm	0/251 (0.0%)	295/1,261 (23.4%)
RVD >4.0 mm	0/251 (0.0%)	27/1,261 (2.1%)
NYHA class ≥III	0/251 (0.0%)	190/1,334 (14.2%)
Prior stent implantation within 1 year	0/251 (0.0%)	57/1,334 (4.3%)
Lesions treated per patient		
Any in-stent restenosis	0/251 (0.0%)	100/1,260 (7.9%)
Any chronic total occlusion	0/251 (0.0%)	98/1,275 (7.7%)
Any target lesion in LMT	0/251 (0.0%)	37/1,261 (2.9%)
Any target lesion in graft	0/251 (0.0%)	30/1,261 (2.4%)
Any severe calcification	0/251 (0.0%)	36/1,261 (2.9%)
Any severe tortuosity	0/251 (0.0%)	28/1,261 (2.2%)
Any bifurcation treatment	0/251 (0.0%)	140/1,261 (11.1%)
Any multiple vessel treatment	0/251 (0.0%)	304/1,233 (24.7%)

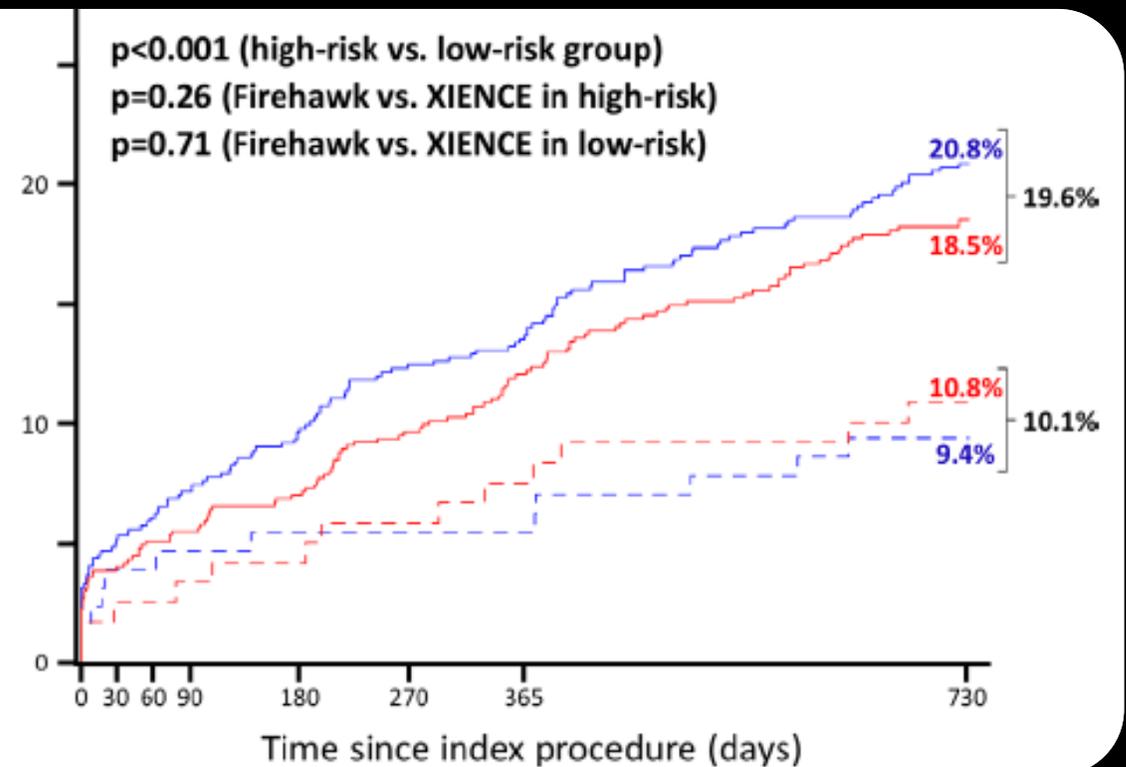
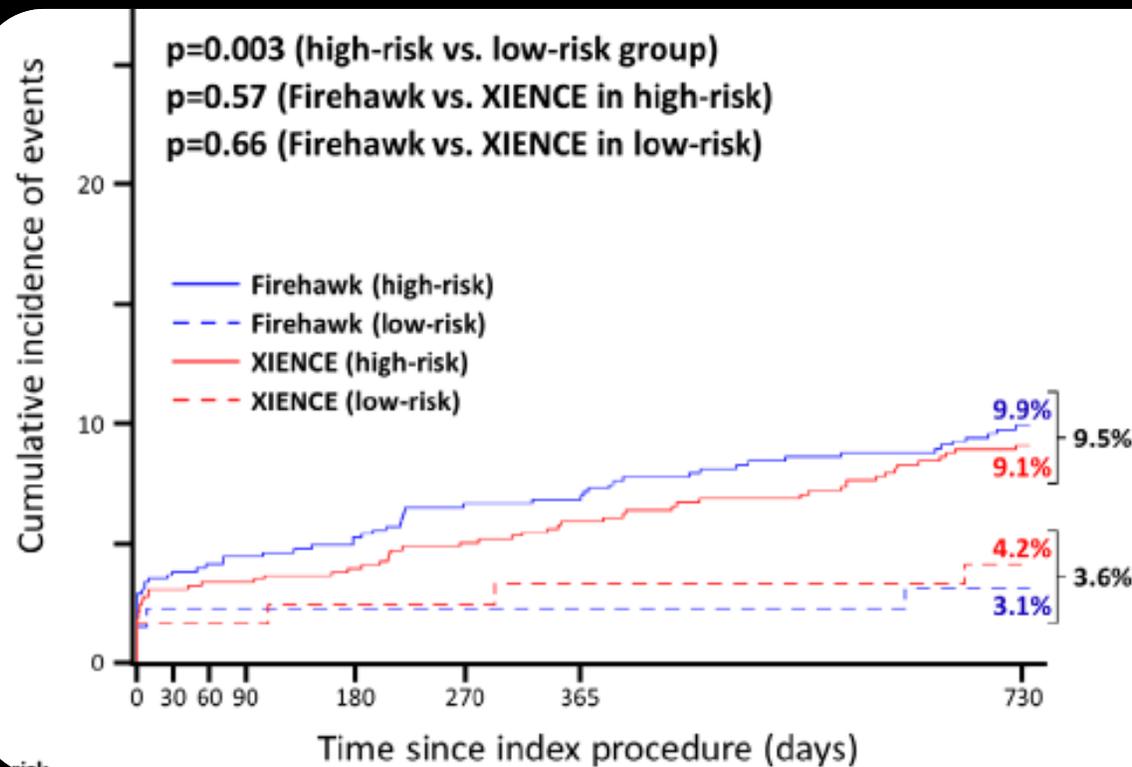
TARGET ALL COMERS **complex lesion**

4. TLF at 24m in high risk

9.9% Firehawk vs. **9.1%** Xience

5. PoCE in high risk

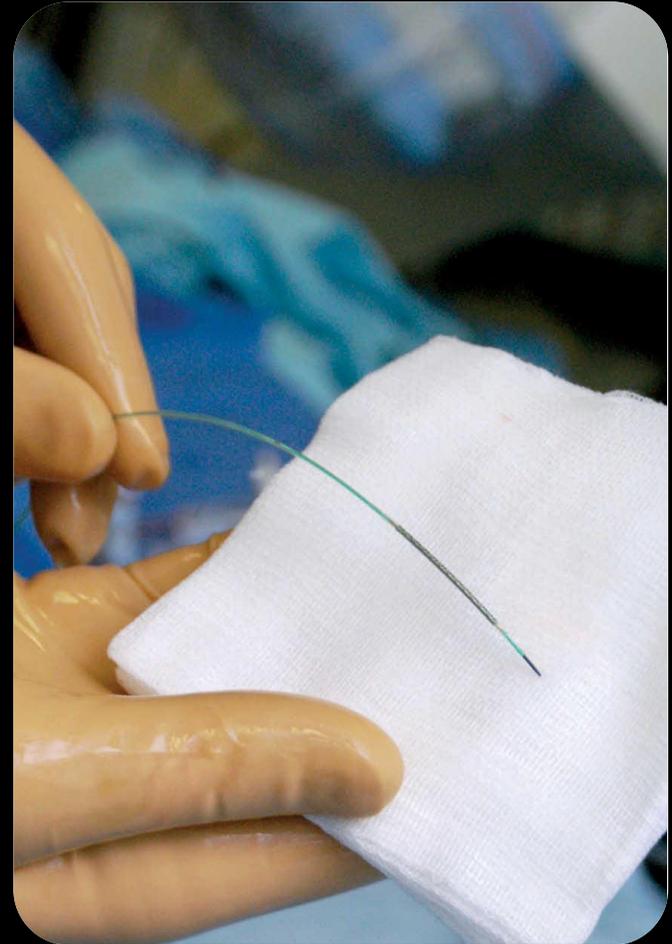
20.8% Firehawk vs. **18.5%** Xience



6. Definite or probable ST **1.7%** Firehawk vs. **2.4%** Xience

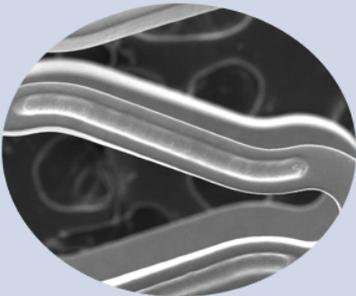
INTERVENTIONIST CAN BE CONFIDENT about Firehawk

1. **similar** safety and efficacy compare to Xience
2. **Relatively low rates** of MI, stent thrombosis, and TLR
3. **without** evidence of a clinical **superiority**



HOWEVER.....

1. questioned about **deliverability** of FIREHAWK

Firehawk DES	Xience EES
	
Laser Cut, Rectangular 	Laser Cut, Rectangular 

86 um Firehawk vs. **81um** Xience

HOWEVER.....

2. **Technical success rate**

92.4% Firehawk vs. 94.8% Xience, $p=0.025$

3. Significantly more lesions could **not be treated**

94.2% Firehawk vs. 95.6% Xience, $p=0.013$

4. **Crossover** 0.7% Firehawk vs. 0 Xience, $p=0.004$

FIREHAWK

Abluminal groove-filled biodegradable polymer-coated sirolimus-eluting stent

“Good and reliable **clinical results**
However, have some **technical issue**”



“Thank you for your attention”