



TCTAP 2017

Updated DES Trials: Contemporary and Future Devices

Adnan Kastrati



Technische Universität München



Deutsches Herzzentrum München
des Freistaates Bayern
Klinik a. d. Technischen Universität München



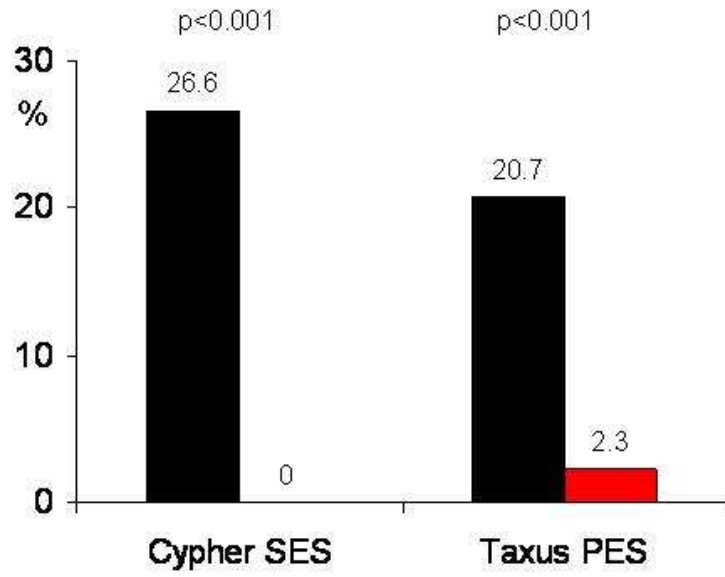
Disclosures

I hold patents related to DES technology

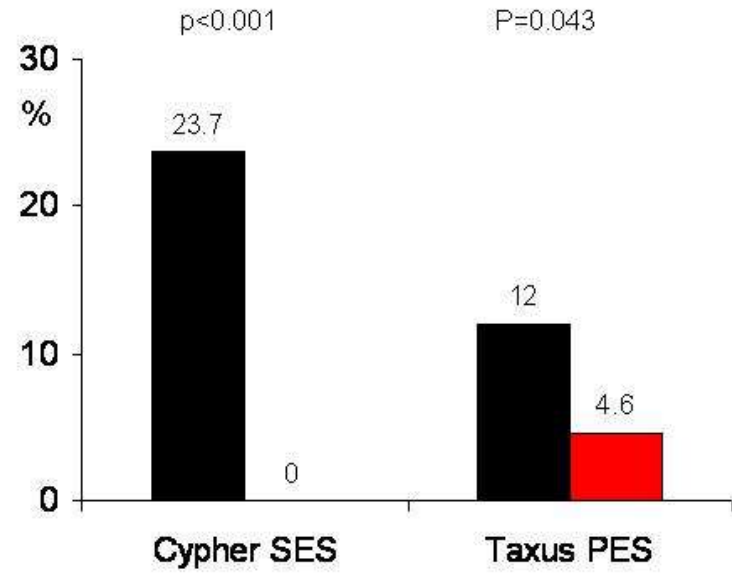


DES: the great success in prevention of restenosis

Binary Angiographic Restenosis



Target Lesion Revascularization



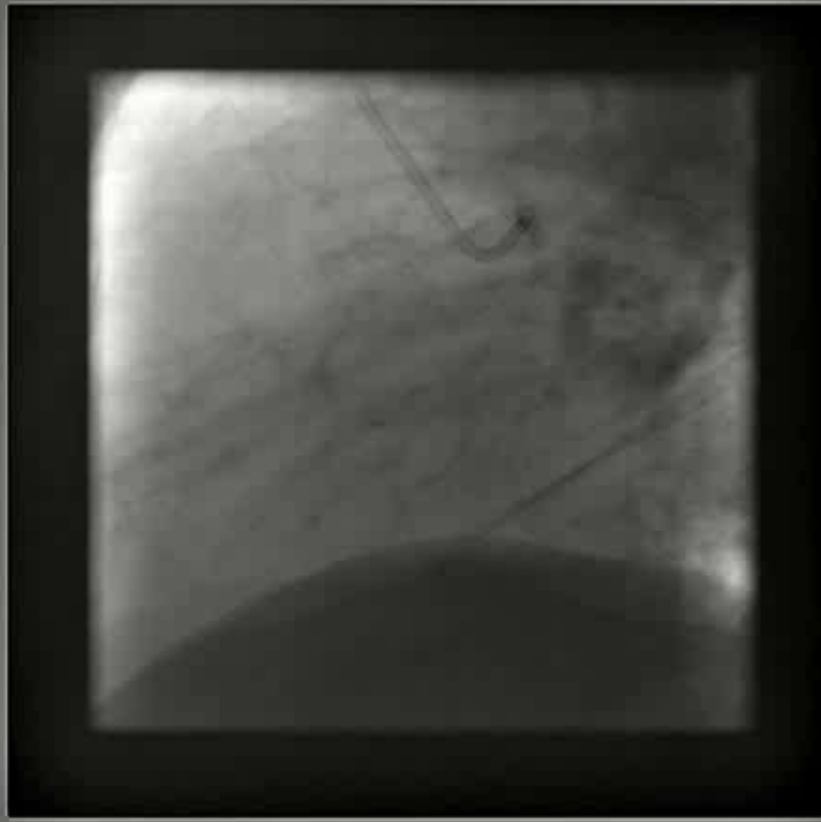
■ Comparator bare metal stent

RAVEL & TAXUS IV, NEJM 2002 & 2004

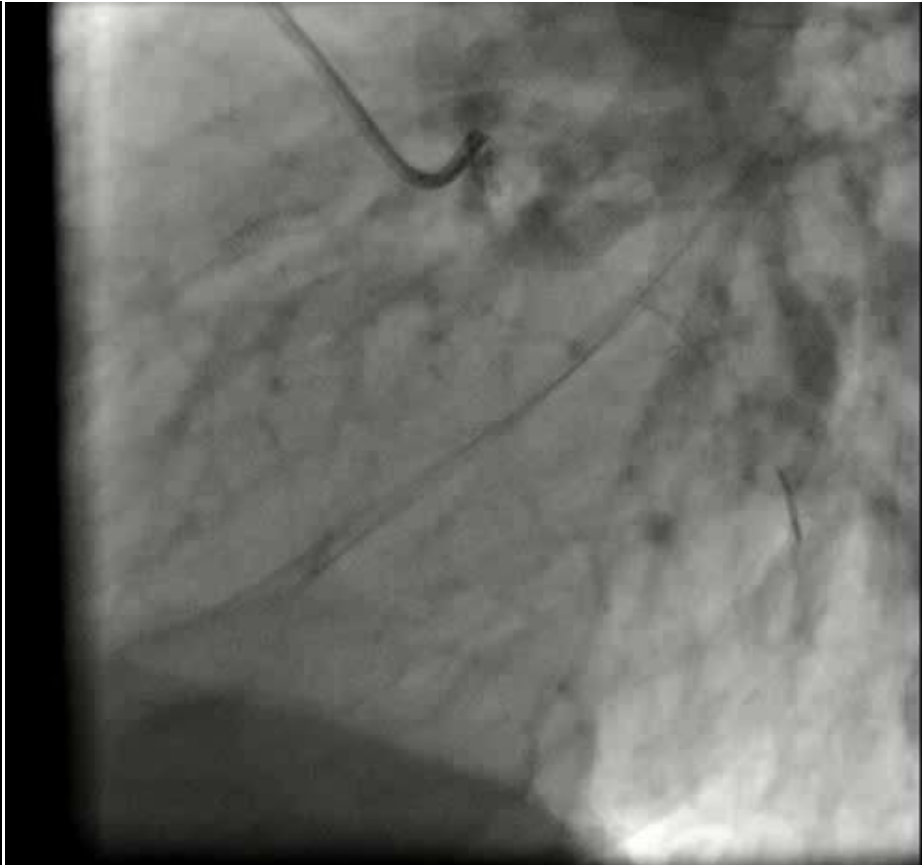
The downside of 1° generation DES

75 yr old patient, 1° generation SES in LCx (PL branch),
September 2005

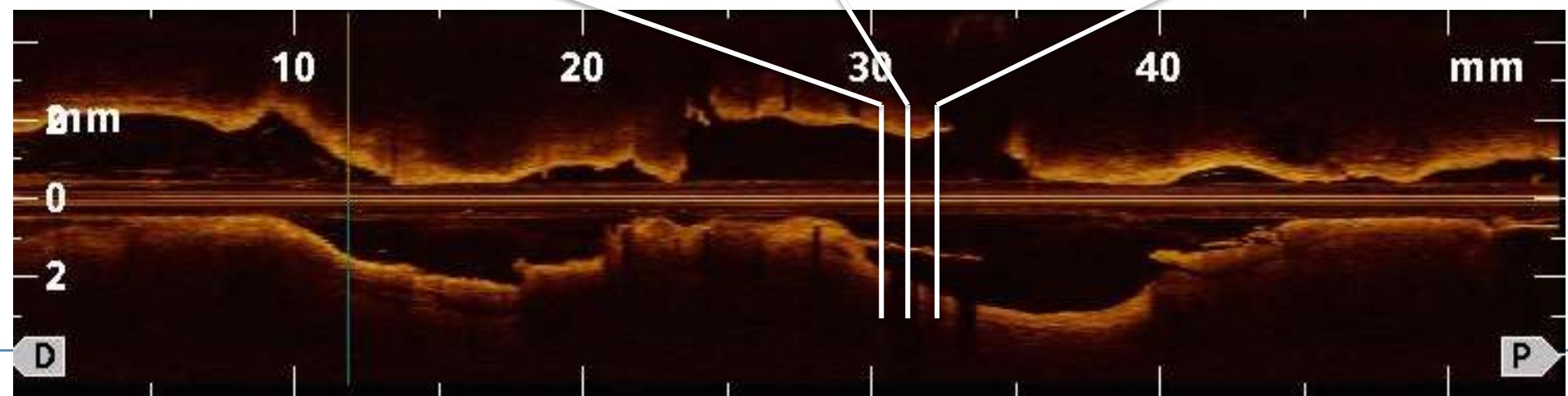
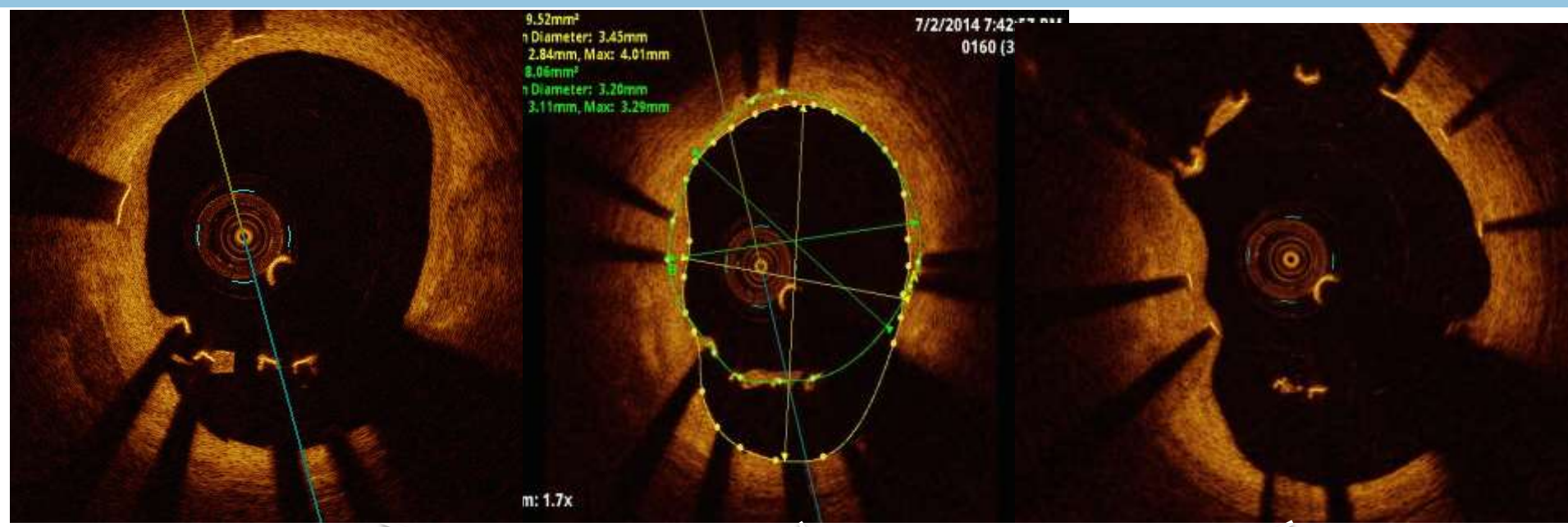
Oct 2010



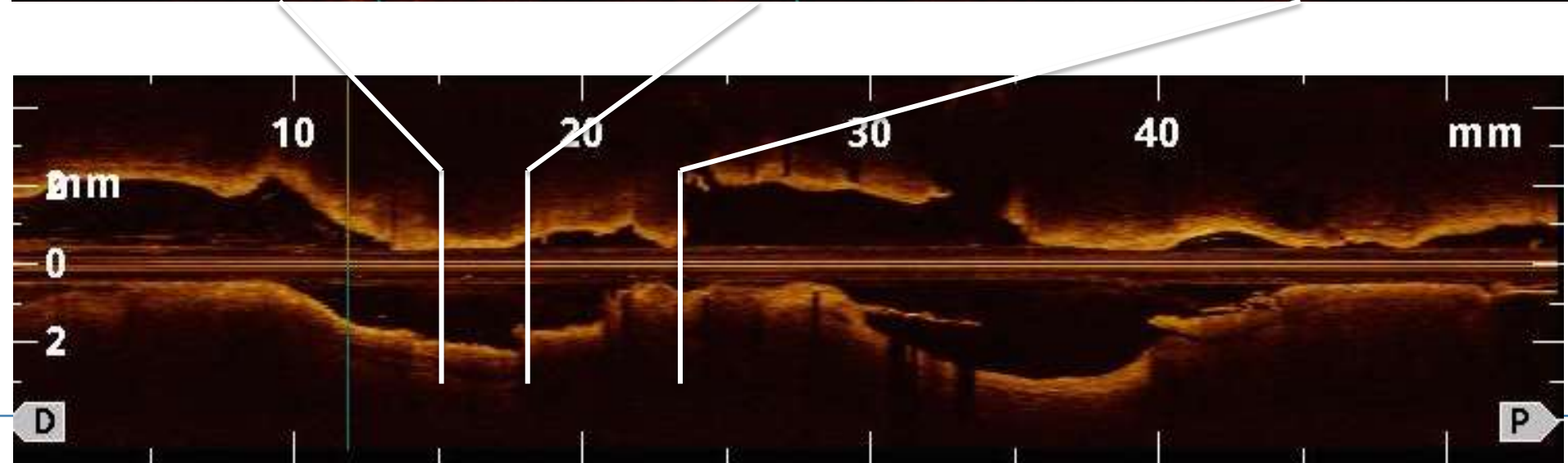
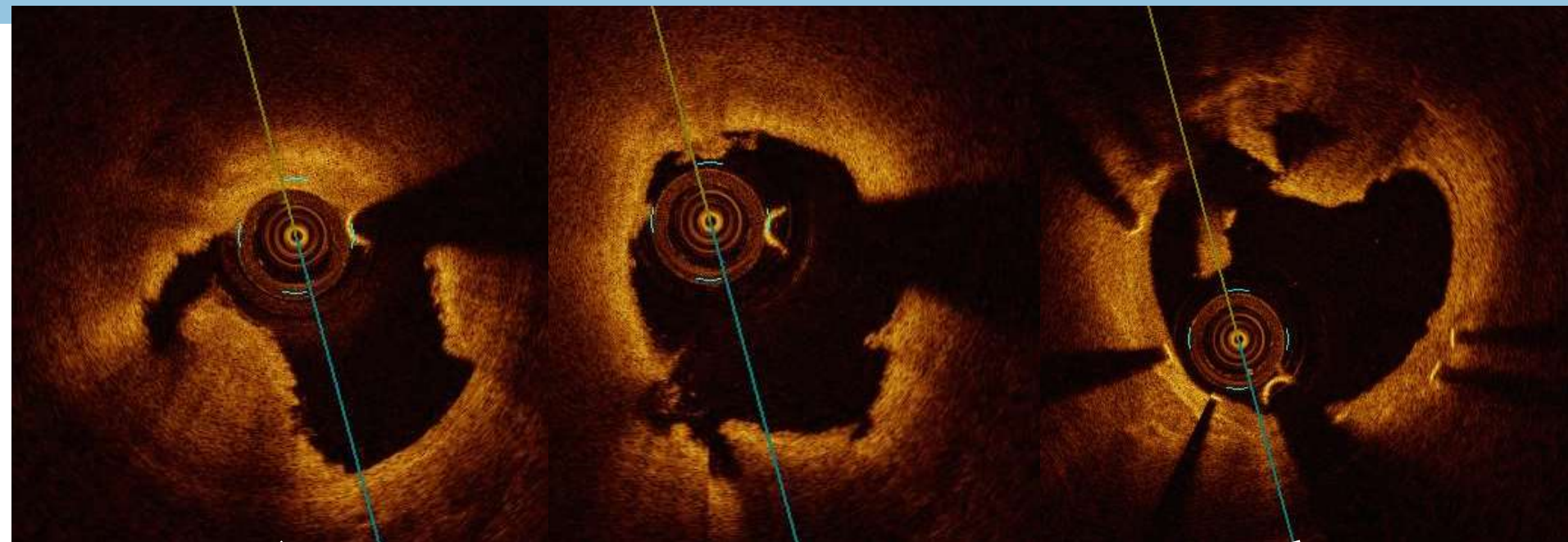
June 2014



Proximal stent malapposition – No thrombus

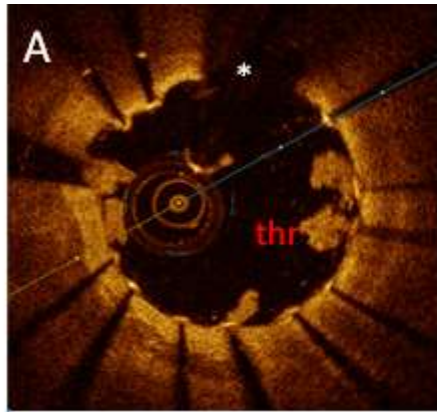


Ruptured distal plaque and stent thrombosis

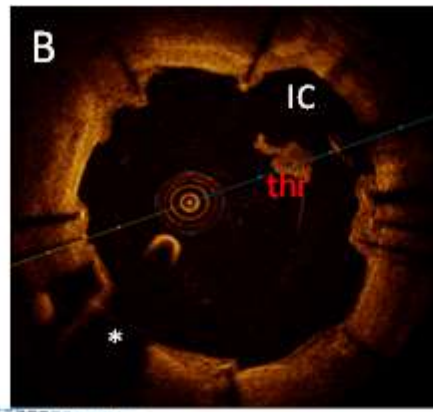


PRESTIGE Project: 217 pts with ST and OCT

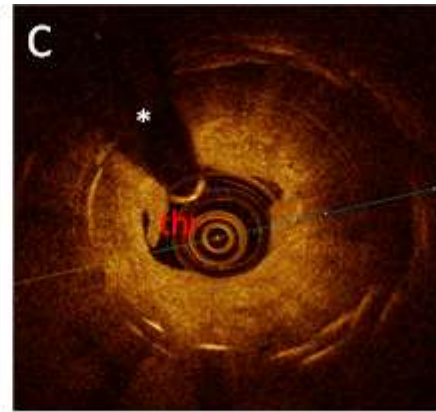
Late and Very Late ST



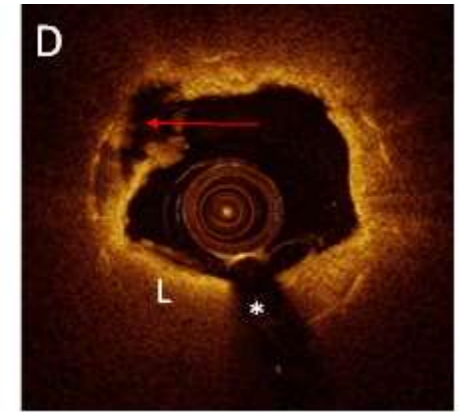
Uncovered struts



Interstrut cavities



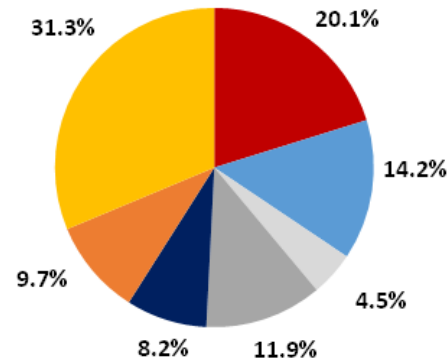
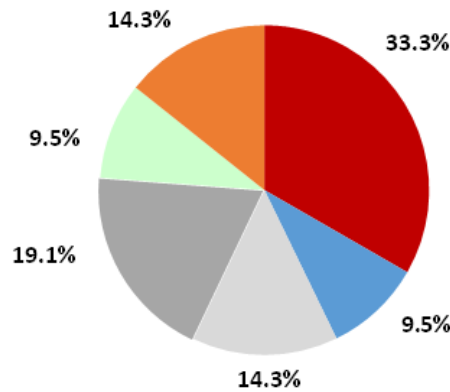
Severe restenosis



Neoatherosclerosis

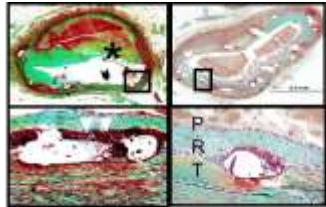
(A) Late

(B) Very late



- Uncovered struts
- Restenosis
- Malapposed struts
- Other
- Underexpansion
- No dominant cause identifiable
- Neoatherosclerosis

From 1° generation to 2° generation DES

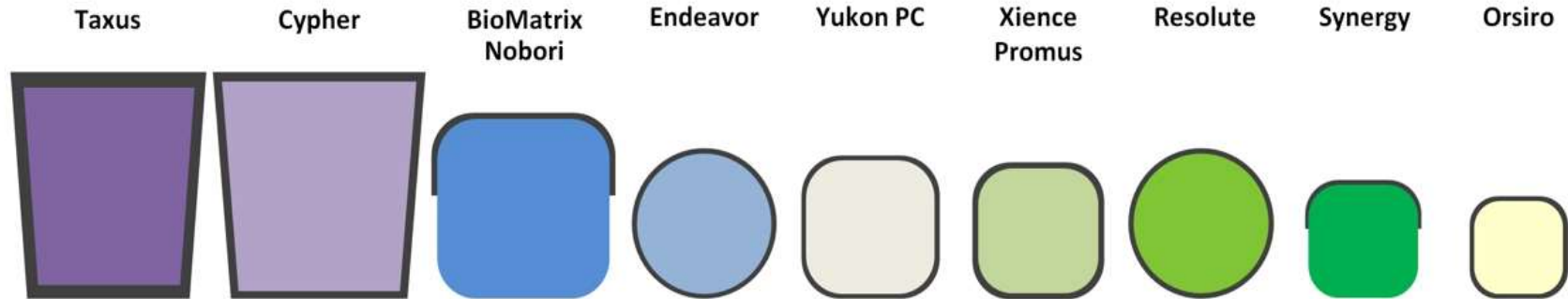


Delayed arterial healing:
Main limitation of 1° gen. DES

Byrne, Joner, Kastrati. Minerva Cardiol 2009

Targets of improvement vs. 1° gen. DES

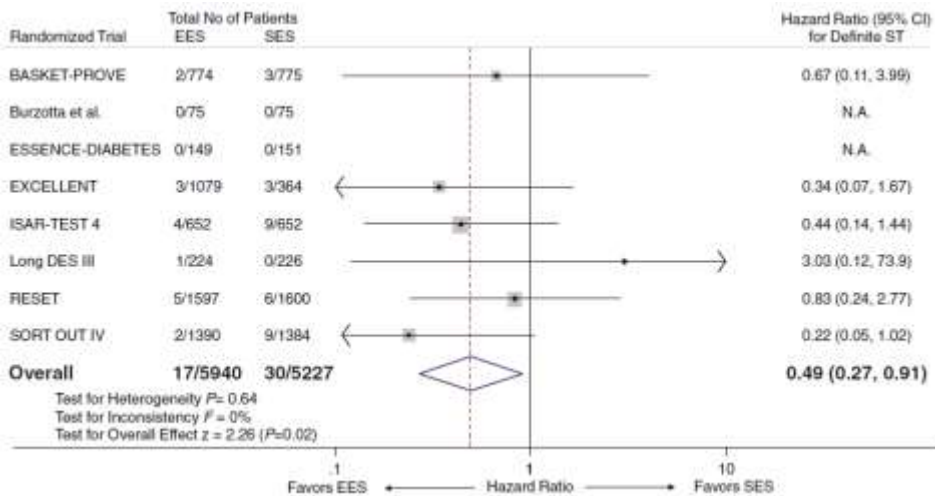
- Stent material and strut thickness
- Polymer coating
- Antiproliferative drug



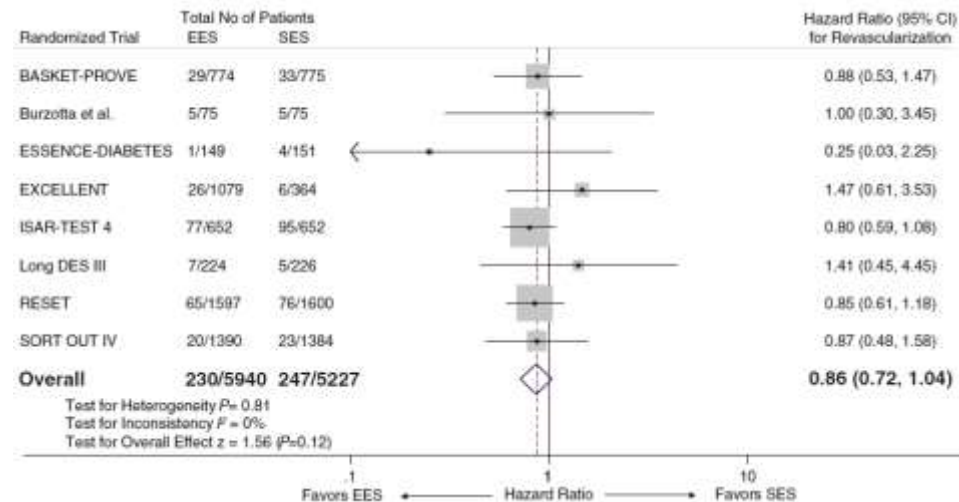
	Taxus	Cypher	BioMatrix Nobori	Endeavor	Yukon PC	Xience Promus	Resolute	Synergy	Orsiro
Platform material	SS	SS	SS	CoCr	SS	CoCr PtCr	CoCr	PtCr	CoCr
Strut thickness (µm)	132	140	120	91	87	81	91	74	60
Polymer type	Durable	Durable	Biodegradable	Durable	Biodegradable	Durable	Durable	Biodegradable	Biodegradable
Polymer material	SIBS	PEVA/PBMA	PDLLA	MPC/LMA/HPMA/3-MPMA	PDLLA	PBMA/PVDF-HFP	PBMA/PHMA/PVP/PVA	PLGA	PLLA
Coating distribution	Circumferential	Circumferential	Abluminal	Circumferential	Circumferential	Circumferential	Circumferential	Abluminal	Circumferential
Polymer thickness (µm)	22	13	10	6	5	8	6	4	7
Additional coating	-	-	-	-	-	-	-	-	Silicon carbide
Drug released	Paclitaxel	Sirolimus	Biolimus	Zotarolimus	Sirolimus	Everolimus	Zotarolimus	Everolimus	Sirolimus

2° generation DES Clinical Evidence vs. 1° generation DES

RCTs of Xience vs. Cypher Definite ST

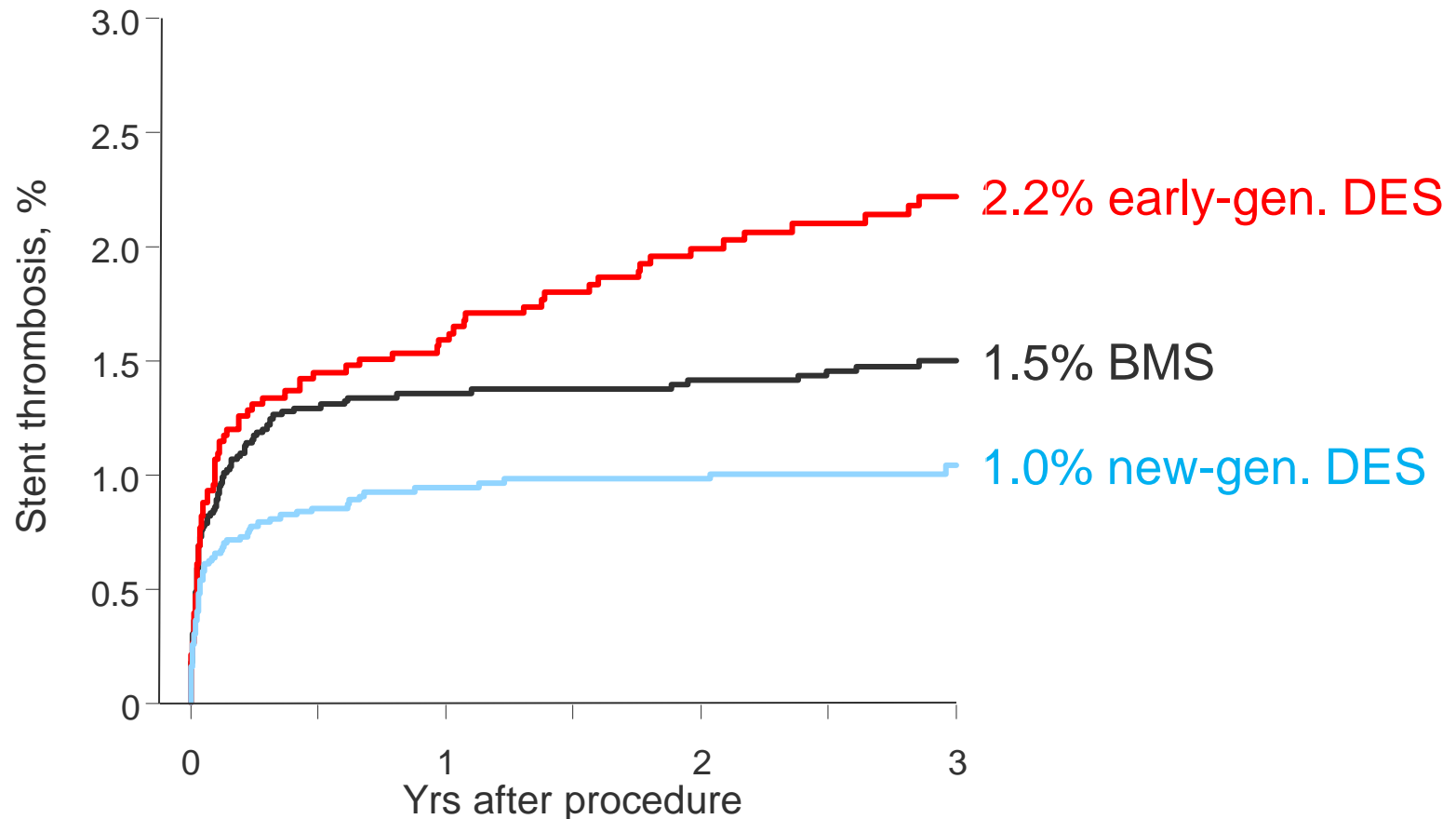


RCTs of Xience vs. Cypher TLR



2° generation DES Clinical Evidence vs. 1° generation DES

18,334 pts with stents



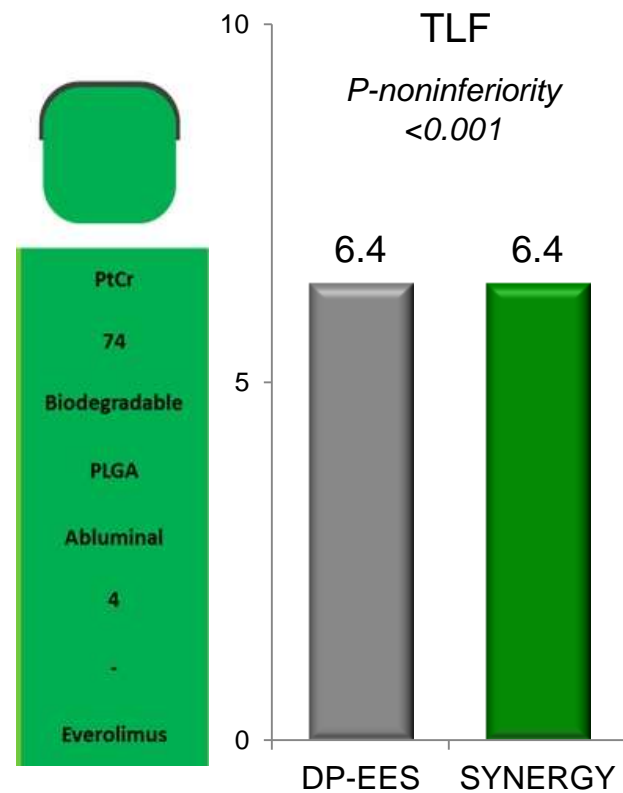
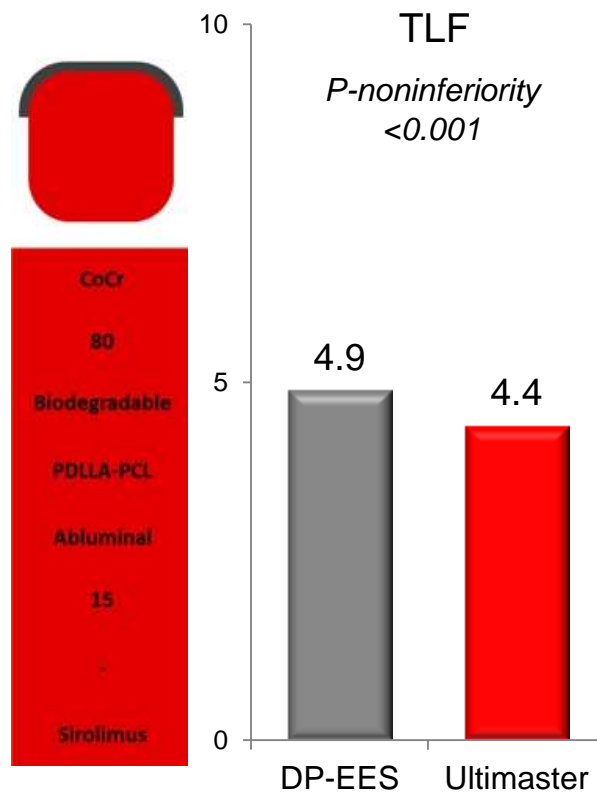
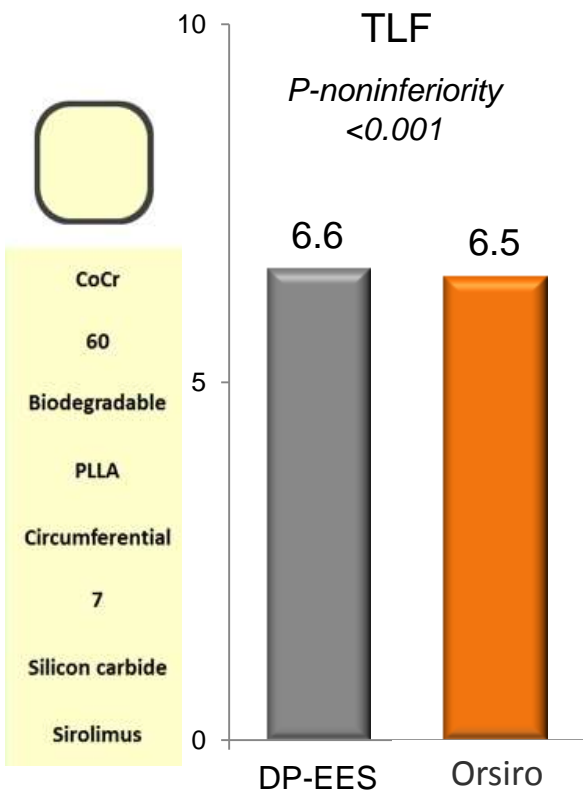
Tada et al, JACC Interv 2013

Thin-strut DES With Biodegradable Polymer Coatings

Orsiro

Ultimaster

Synergy

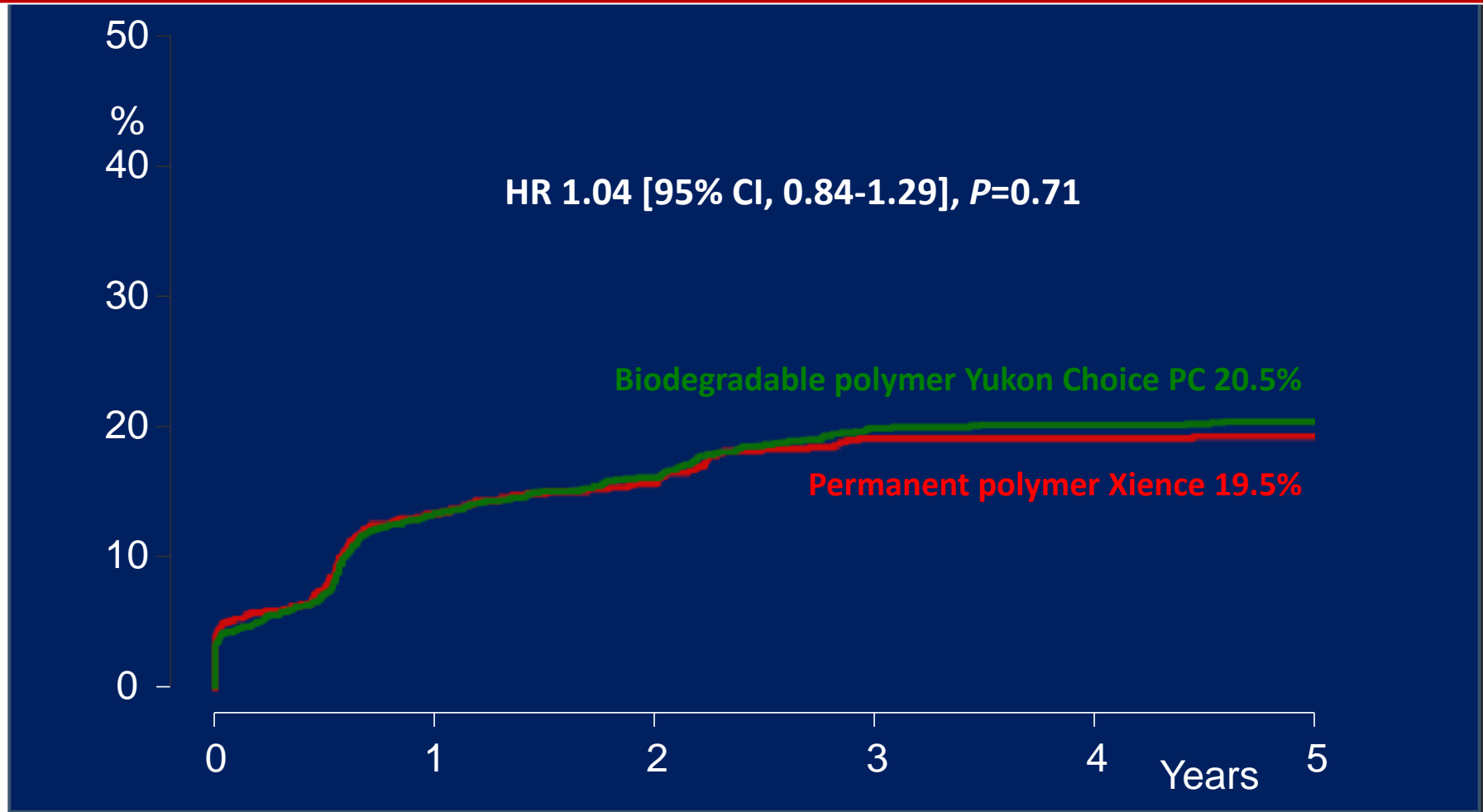


BIOSCIENCE Trial
(N=2119)

CENTURY-2 Trial
(N=1123)

EVOLVE-2 Trial
(N=1684)

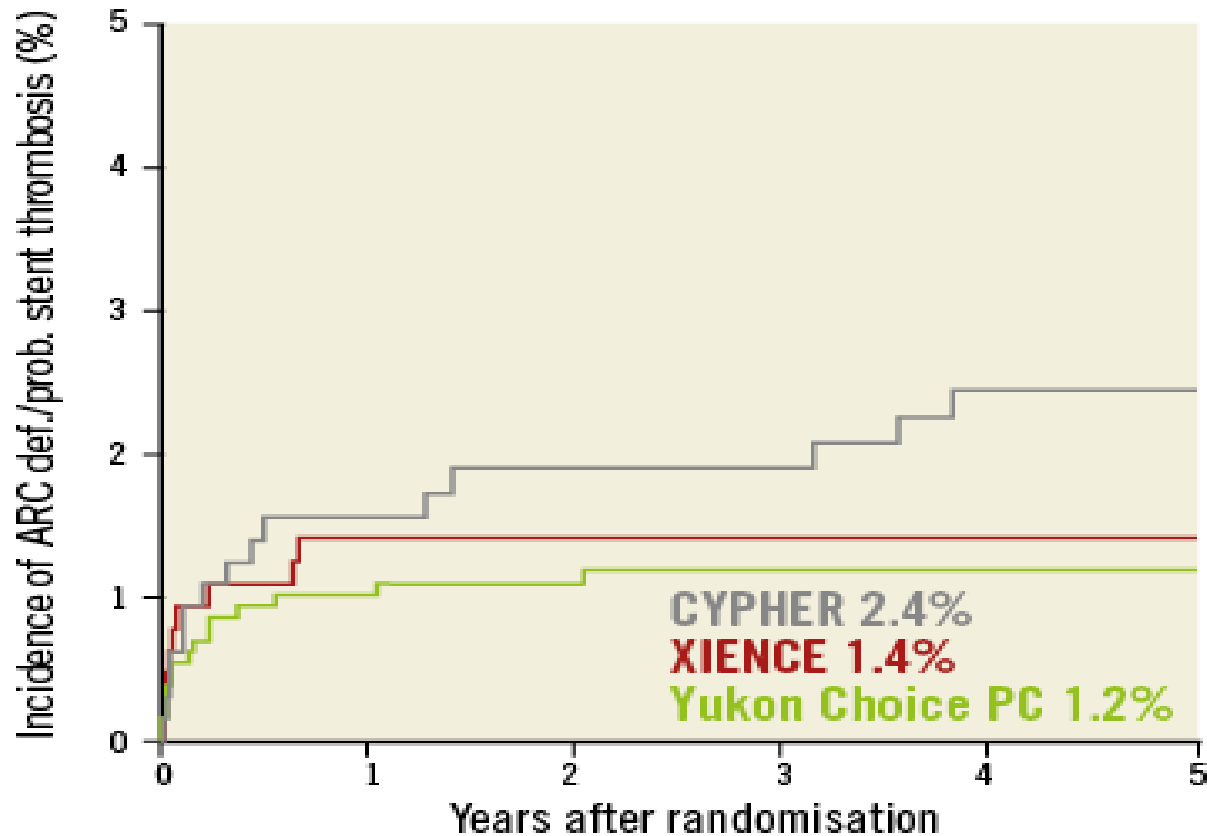
Cardiac death/target vessel MI/TLR



Kufner et al, Eurointervention 2016

ISAR-TEST 4: Final 5-year data in 2,603 pts

Definite/probable stent thrombosis

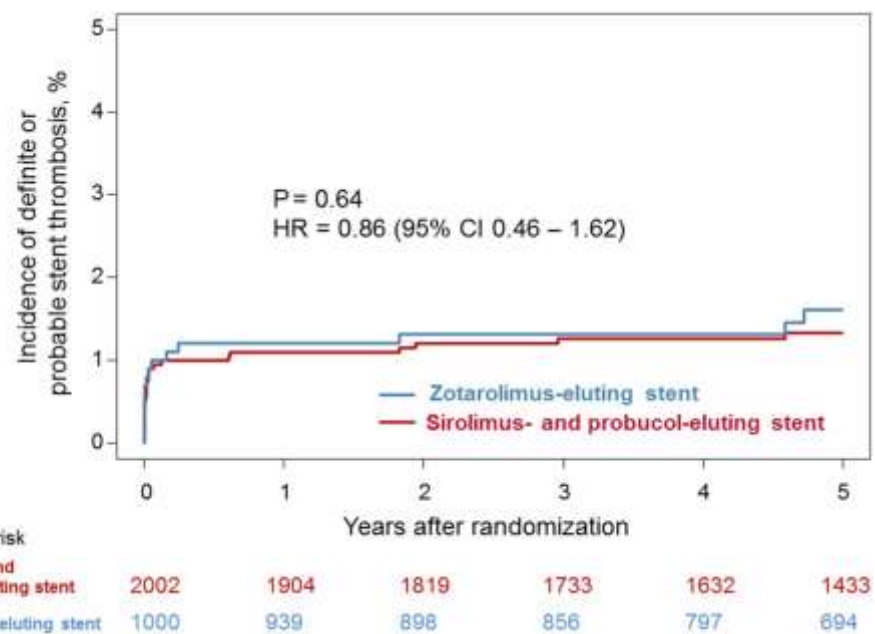
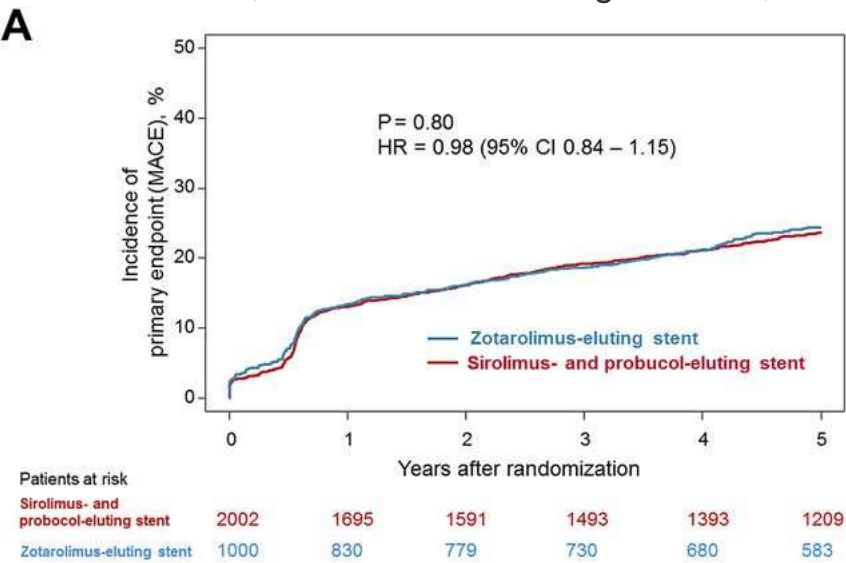


Kufner et al, Eurointervention 2016

ISAR-TEST 5: Final 5-year data in 3,002 pts

Polymer-free, dual drug (sirolimus+probucol)-eluting stent

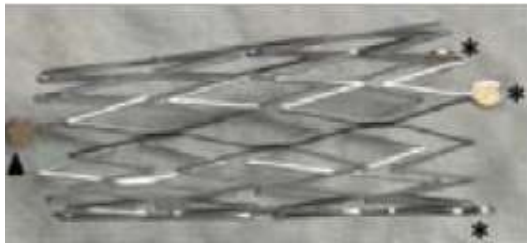
Cardiac death, MI related to the target vessel, or TLR



Kufner et al, JACC Interv 2016

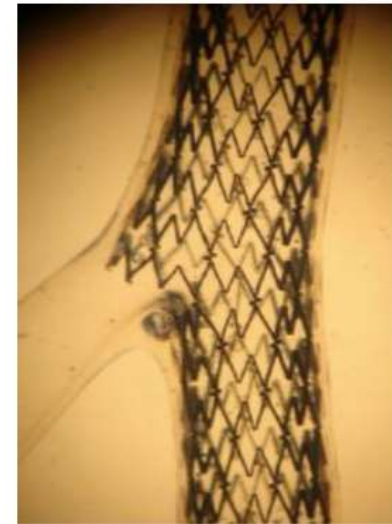
Dedicated DES: Bifurcation Self-expanding Stents

AXXESS



Material	Nitinol
Strut thickness	150 um
Drug	Biolimus
Clinical studies	YES (Axxess+, Diverge)
RCTs	NO (Cobra trial ongoing)
CE mark	Yes
Future outlook	< profile, LM version, >flaring for angles >70

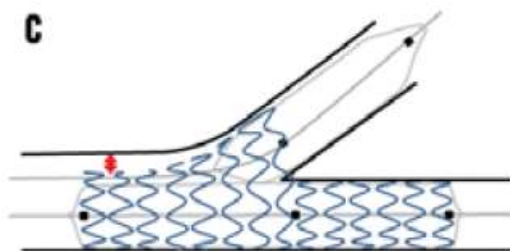
STENTYS



Material	Nitinol
Strut thickness	102-133 um
Drug	Paclitaxel, Sirolimus
Clinical studies	YES (Open 1, Open 2)
RCTs	NO
CE mark	Yes
Future outlook	< profile, ballon expandable version

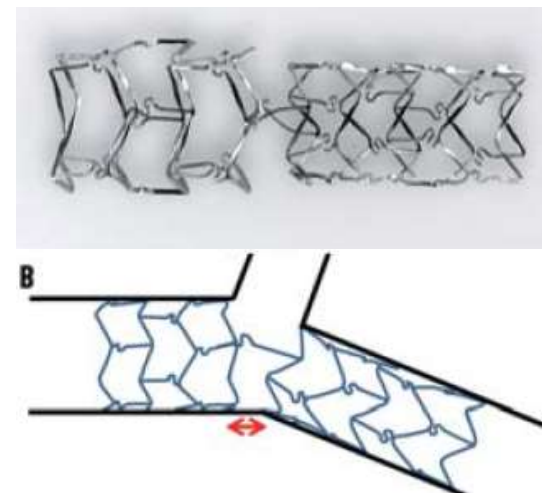
Dedicated DES: Bifurcation Stents

Nile PAX Stent



Material	CoCr
Strut thickness	73 um
Drug	Paclitaxel
Clinical studies	YES (1 multicenter registry)
RCTs	NO
CE mark	Yes
Future outlook	Sirolimus+BP coating (Nile SIR)

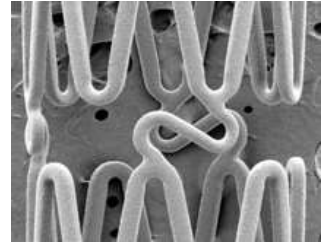
BIOSS



Material	Stainless steel
Strut thickness	120 um
Drug	Paclitaxel (EXPERT), Sirolimus (LIM)
Clinical studies	YES (FIM EXPERT, FIM LIM)
RCTs	YES (Small-scale POLBOS-1)
CE mark	Yes
Future outlook	Everolimus/Zotarolimus + CoCr stent

A few upcoming LBCT/Trial Updates at PCR 2017

DESSOLVE III (NCT02385279), a 1.404 patient trial: noninferiority regarding 1-year TLF of **MiStent**, a sirolimus-eluting, cobalt-chromium (64 μ), biodegradable-polymer based device vs. **Xience**



Angiolite trial (NCT03049657), a 220 patient trial: noninferiority regarding angiographic late loss of **Angiolite**, a sirolimus-eluting, cobalt-chromium (75-85 μ), durable-polymer based device vs. **Xience** in Spain



Final 5-year results of the CENTURY II study, a 1,123 patient trial: noninferiority regarding TLF of **Ultimaster**, a sirolimus-eluting, cobalt-chromium (80 μ), biodegradable-polymer based device vs. **Xience**



OCT findings of the PRISON IV trial (NCT01516723), a 330 CTO patient trial of **ORSIRO**, a sirolimus-eluting, cobalt-chromium (60 μ), biodegradable-polymer based device vs. **Xience**



Development of dedicated DES to special lesion subsets (bifurcation, ostial, left main) should continue to be the target of future work.

Although current DES with thin struts, permanent or biodegradable polymer layer or no polymer at all provide excellent efficacy and safety, avoidance of permanent presence of metal will continue to be an important goal of future work.