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Ultimaster Tansei technical features and results in left main and bifurcation approach

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Conflict of Interest

Speaker's name : Antonio Serra

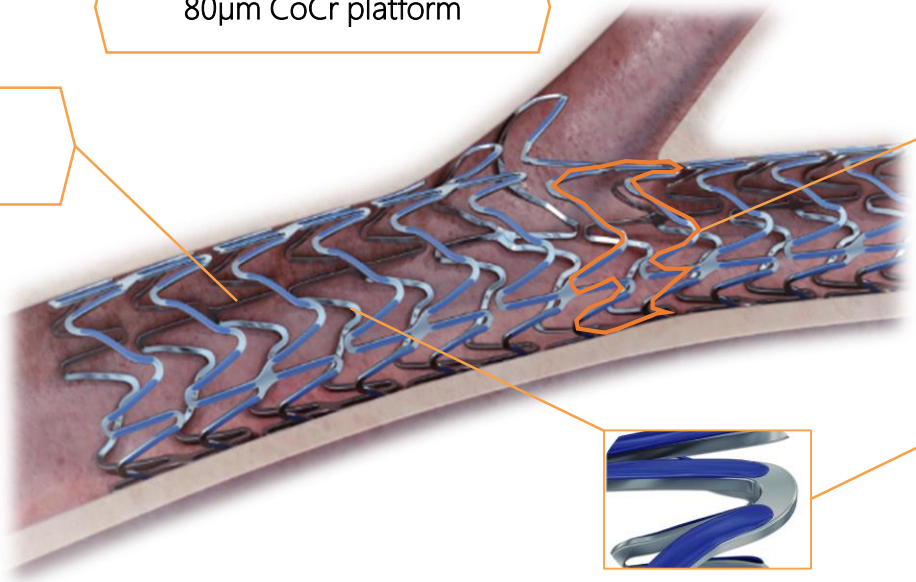
☑ I do not have any potential conflict of interest to declare

Key features of Ultimaster™ to facilitate bifurcation treatment

80µm CoCr platform

Open cell, 2-link design
Easy side branch access

Cell opening diameter 2.2mm (for 3.0mm stent)



Gradient coating
maintains polymer integrity
when overexpanded[2]

Good overexpansion capacity[1]
up to 5.8mm with Ultimaster™

Proximal optimization (POT)

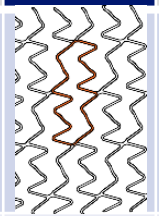
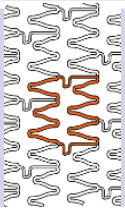
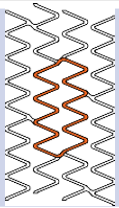
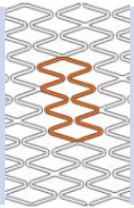
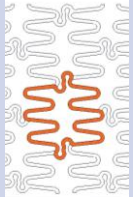
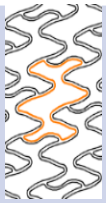
1. Ng J et al. Int J Cardiol 2016;221:171–9; 2. Saito N et al. Medical Devices: Evidence and Research 2016:9;33-43.

New “open cell” DES workhorse and model designs

	Synergy	Xpedition	Res. Onyx	Ultimaster	BioMatrix A	Orsiro
2.25	Small vessel (8 crowns, 2-4 connectors)	Small vessel (6 crowns, 3 connectors)	Small vessel (6.5 crowns, 2 connectors)	Small vessel (8 crowns, 2 connectors)	Small vessel (6 crowns, 2 connectors)	Small vessel (6 crowns, 3 connectors)
2.50						
2.75			Medium vessel (8.5 crowns, 2 connectors)			
3.00	Workhorse(8 crowns, 2-4 connectors)					
3.50		Large vessel (9 crowns, 3 connectors)	Large vessel (9.5 crowns, 2.5 connectors)	Large vessel (8 crowns, 2 connectors)	Large vessel (9 crowns, 3 connectors)	Large vessel (6 crowns, 3 connectors)
4.00	Large vessel (10 crowns, 2-5 connectors)					
4.50			Extra-Large vessel (10.5 crowns, 2.5 connectors)			
5.00						

Ng J et al. International Journal of Cardiology 221 (2016) 171–179

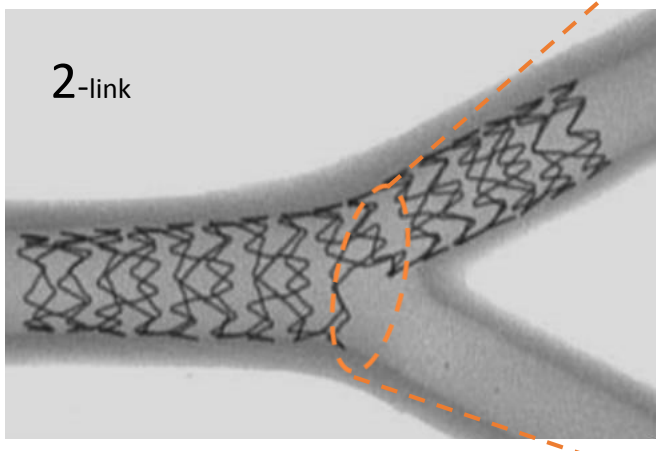
Open cell, 2-link Ultimaster® design

3.5mm	Ultimaster	Xience	Synergy	Resolute Onyx	BioMatrix Alpha	Orsiro
Stent design						
Side-branch access (cell length)	21.5 mm	16.1 mm	14.7 mm	15.2 mm	13.8 mm	11.7 mm

"2-link" design :
Large stent cell size
Facilitates wire crossing from main vessel to side branch

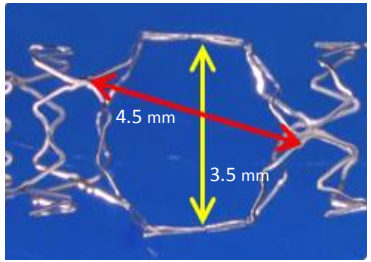
Ultimaster™ design
Open cell, 2-link per ring in all sizes

Cell expansion provides an optimal access to side branch and facilitates complex 2-stent techniques : Culotte, DK mini crush and TAP



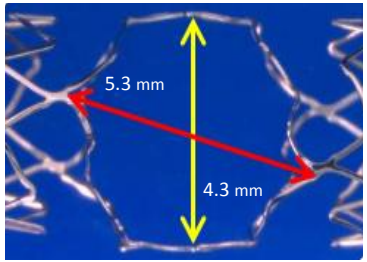
Designed for excellent side-branch access

Φ 2.25–3.0 mm



NC balloon catheter
Φ4.0 mm, NP
Area: 9.62 mm²

Φ 3.5–4.0 mm

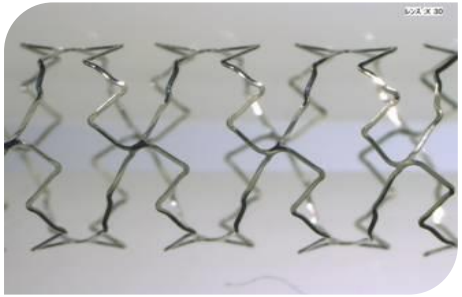


NC balloon catheter
Φ5.0 mm, NP
Area: 14.5 mm²

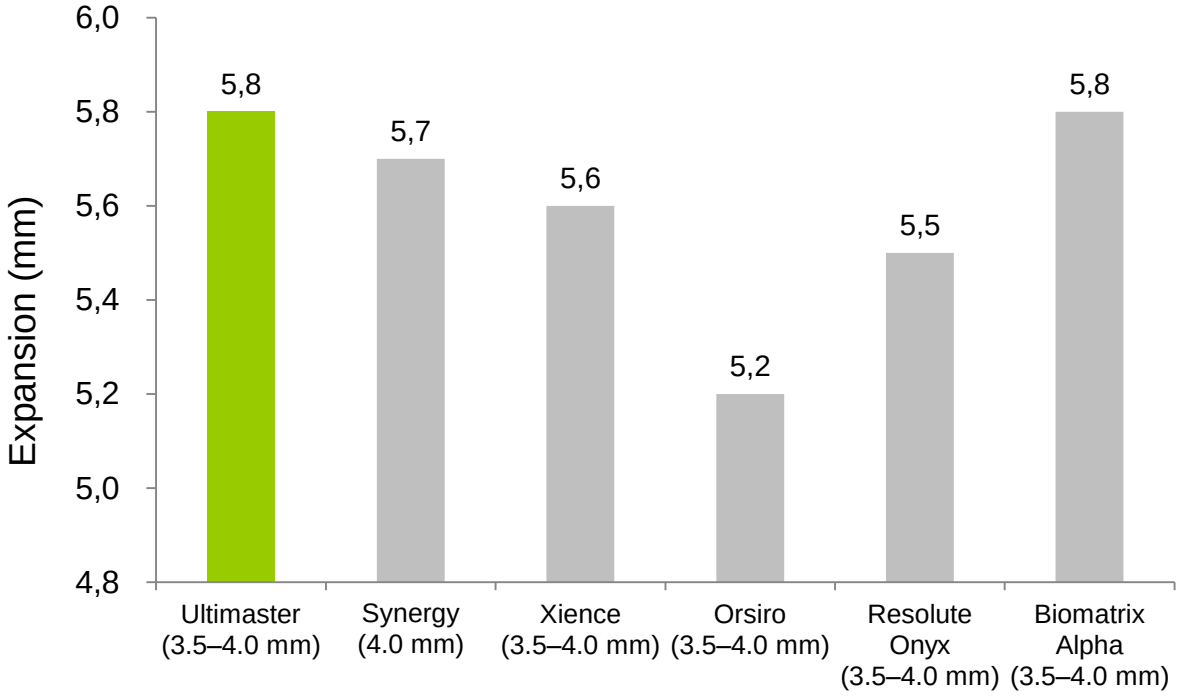
Ultimaster™ : Capacity of overexpansion

8 crowns, 2-link x ring allow overexpansion without compromise of the structure and function of the stent

Important in LM bifurcation



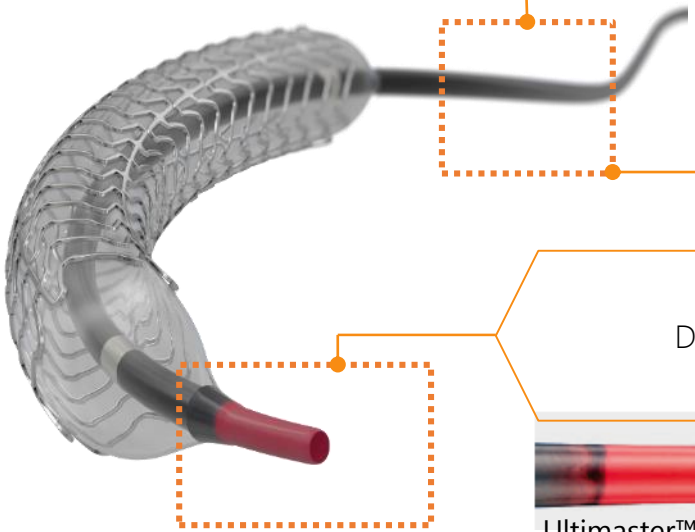
Over-expansion for each design was tested with successive post-dilations using first a 5.0×12 mm non compliant balloon followed by a 6.0×15 mm semi-compliant balloon with a pressure of 14 ATM for the largest designs.



Ng J et al. Int J Cardiol. 2016;221:171–9.

Ultimaster™ Tansei™

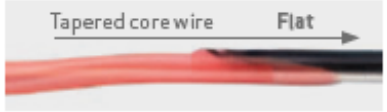
- ✓ Increase in pushability
- ✓ Better tip performance



1. Updated Exit Port

Tapered core wire at the level of the exit port

Improved coaxial alignement



Ultimaster™ Tansei™

Ultimaster™

3. Innovative Tip

Durable & flexible material

Rounded tip design

Ultimaster™ Tansei™

Ultimaster™

2. Advanced shaft technology

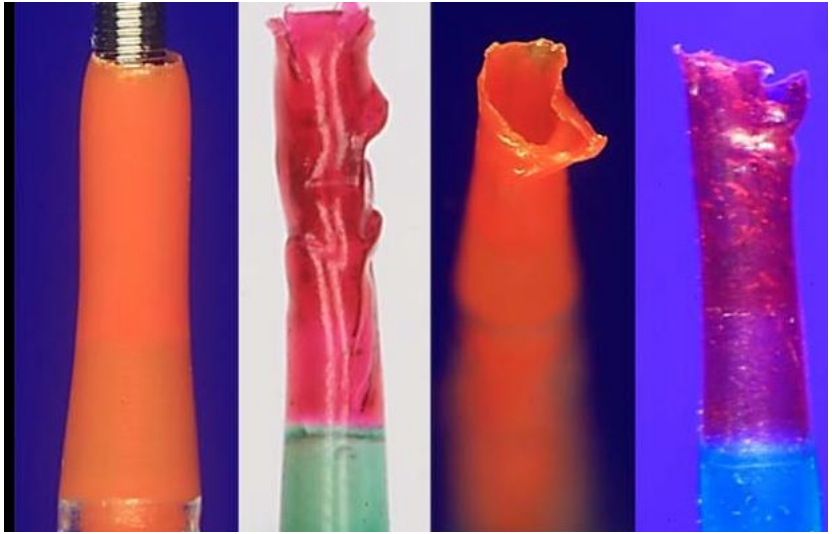
Stronger hypotube

Bench test ISCD-523-31-18 performed by, and on file at, Terumo Corporation.

Balloon tip damage: calcified lesions vs. bifurcations

Extended durability [8]

After crossing the calcified lesion model 3 times

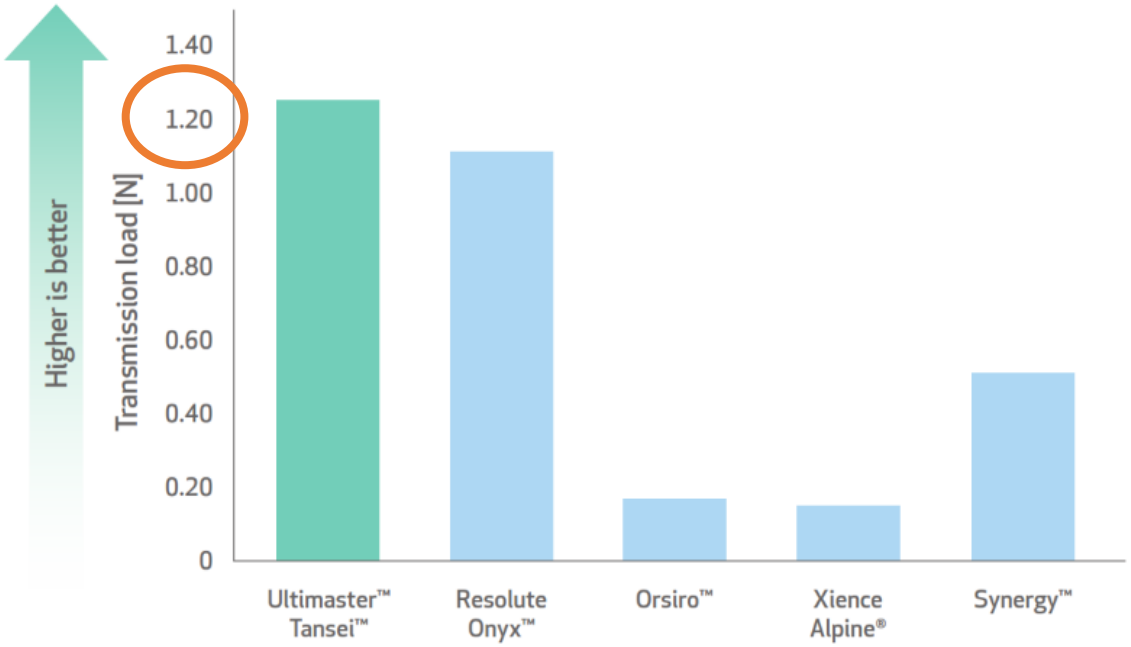


Balloon tip damage after passage between stent struts into the side branch

Barkholt TO et al. Catheter Cardiovasc Interv 2017;doi:10.1002/ccd.27441; 2.

Pushability with poor guiding catheter support

Transmission load at the distal end, when applying **2N force** at the proximal end.



Transmission load at the distal end, when the guiding catheter back-up is disengaged by pushing

Ultimaster in LM data from a worldwide registry

E-ULTIMASTER registry

4 continents, 50 countries, 376 sites

Study enrolment completed, follow-up ongoing

> 37,000 patients enrolled

Interim analysis
1-year follow-up
n=25,990 patients

Patients treated in LM
N=840

- **Patients treated only in LM n=202**
- **Patients treated in LM with bifurcation n=165**
- **Patients treated in LM plus one or more other vessels n=473**

CLINICAL FOLLOW-UP

0 d → 3 m → 1 y

An independent Clinical Event Committee reviewed and adjudicated all endpoint-related serious adverse events

Baseline patient characteristics

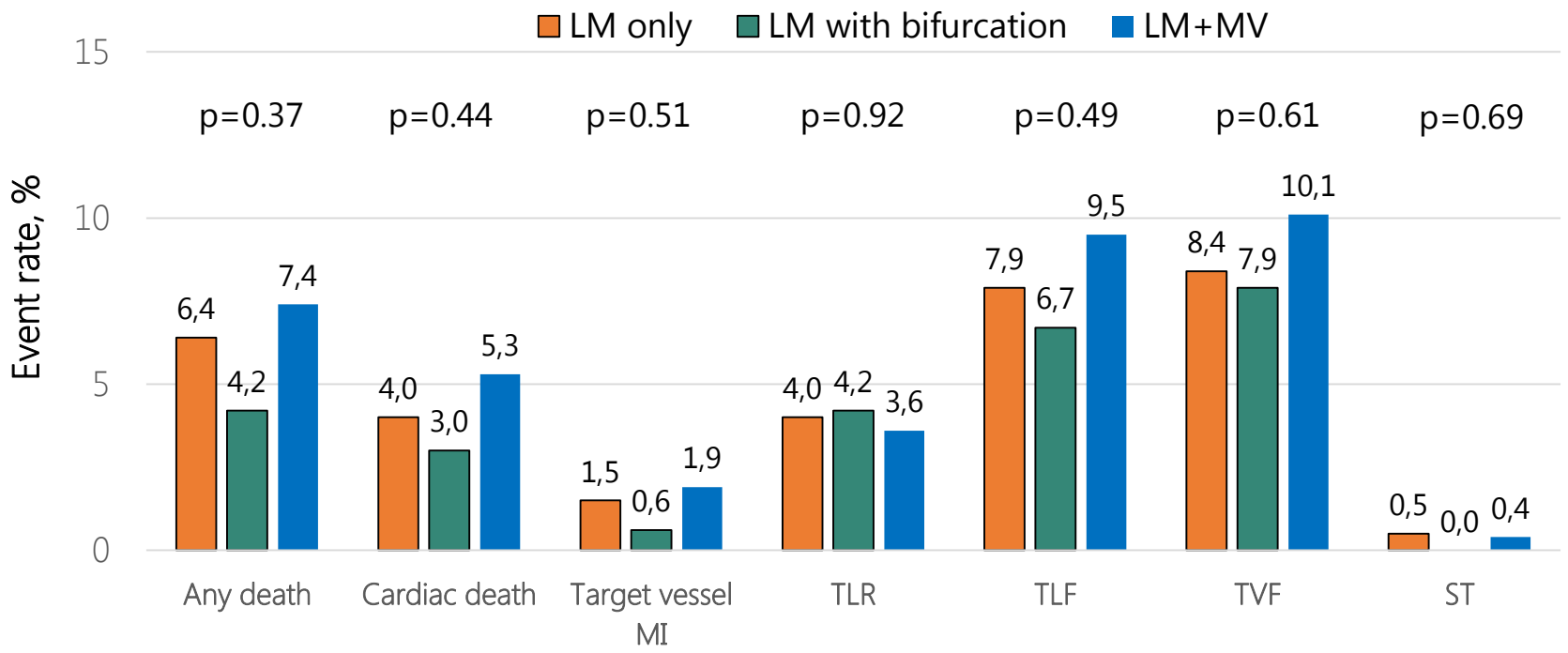
	LM only n=202	LM bifurcation N=165	LM with MV n=473	P-value
Age, years	68,0±11,0	70,0±10,7	69,3±10,6	0,18
Gender, male %	72,8	72,7	75,1	0,75
Current smoking, %	13,8	15,8	16,6	0,68
Diabetes, %	33,2	35,8	32,6	0,75
Hypertension, %	69,8	79,8	71,5	0,07
Hypercholesterolemia,%	56,8	66,7	64,1	0,11
Renal impairment, %	12,4	21,2	14,2	0,04
Previous PCI, %	36,2	43,8	35,7	0,17
Previous CABG, %	27,8	15,4	18,9	0,008
ACS, %	42,1	35,2	44,6	0,11

CABG: coronary artery bypass, ACS: acute coronary syndrome.

Baseline patient characteristics

	LM only n=202	LM bifurcation N=165	LM with MV n=473	P-value
Radial access, %	66,3	69,7	67,7	0,79
Calcified lesions, % per lesion	24,0	43,6	33,2	<0.01
Ostial lesions, % per lesion	35,3	18,2	19,2	<0.01
Imaging				
IVUS, %	19,8	32,9	22,2	0,01
OFDI, %	9,6	14,8	7,0	0,02
Direct stenting, %	36,6	17,6	48,0	<0.01
Post-dilatation, %	60,9	86,1	77,6	<0.01
N° of stents implanted per patient, mean ± SD	1,2±0,6	1,6±0,7	2,2±1,2	<0.01
Total implanted stent length per patient, mm, mean ± SD	24,6±17,4	37,5±20,4	48,4±31,9	<0.01

Clinical outcomes at 12 months



MI: myocardial infarction; TLR: target lesion revascularization; TLF: target lesion failure; TVF, target vessel failure; Stent thrombosis: Definite stent thrombosis

Ultimaster in bifurcation

E-ULTIMASTER registry
4 continents, 50 countries, 376 sites

Study enrolment completed, follow-up ongoing
> 37,000 patients enrolled

Interim analysis
1-year follow-up or death
n=25,990 patients

Patient treated in bifurcation
n=3372

CLINICAL FOLLOW-UP

0 d → 3 m → 1 y

An independent Clinical Event Committee reviewed and adjudicated all endpoint-related serious adverse events

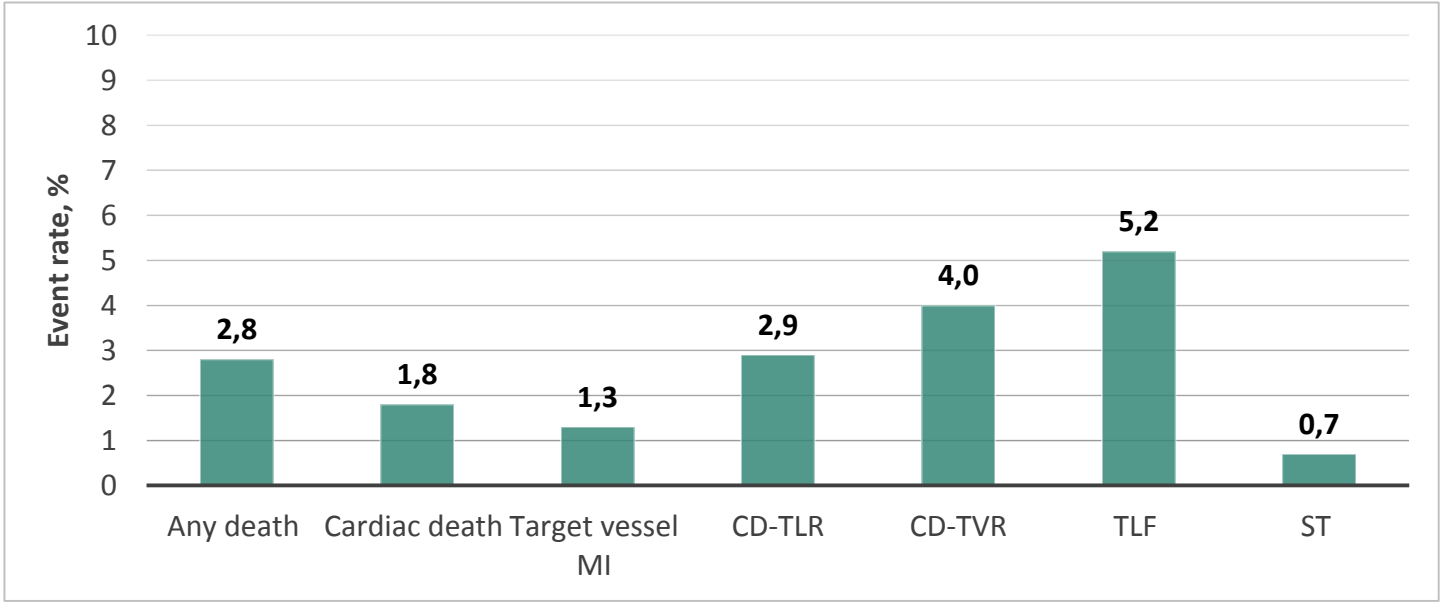
Baseline characteristics

Patient characteristics	All bifurcation n=3372
Mean age, year	**65,8±11,1**
Male patients, %	**77,0**
Hypertension, %	**64,9**
Diabetes, %	**27,3**
Dyslipidaemia, %	**58,8**
Current smoker, %	**21,0**
Renal impairment, %	**9,1**
Previous PCI, %	**29,6**

Lesion/procedure characteristics	All bifurcation n=3372
Present with ACS, %	**48,1**
Radial access, %	**81,4**
Num of lesions identified, %	**2,0±1,1**
Num of stents/pt, n	**1,7±1,0**
Total stent length/pt, mm	**37,3±24,3**
Imaging used (IVUS+OFDI), %	**13,8**
Direct stenting, % per lesion	**29,3**
Post dilatation, % per lesion	**55,2**

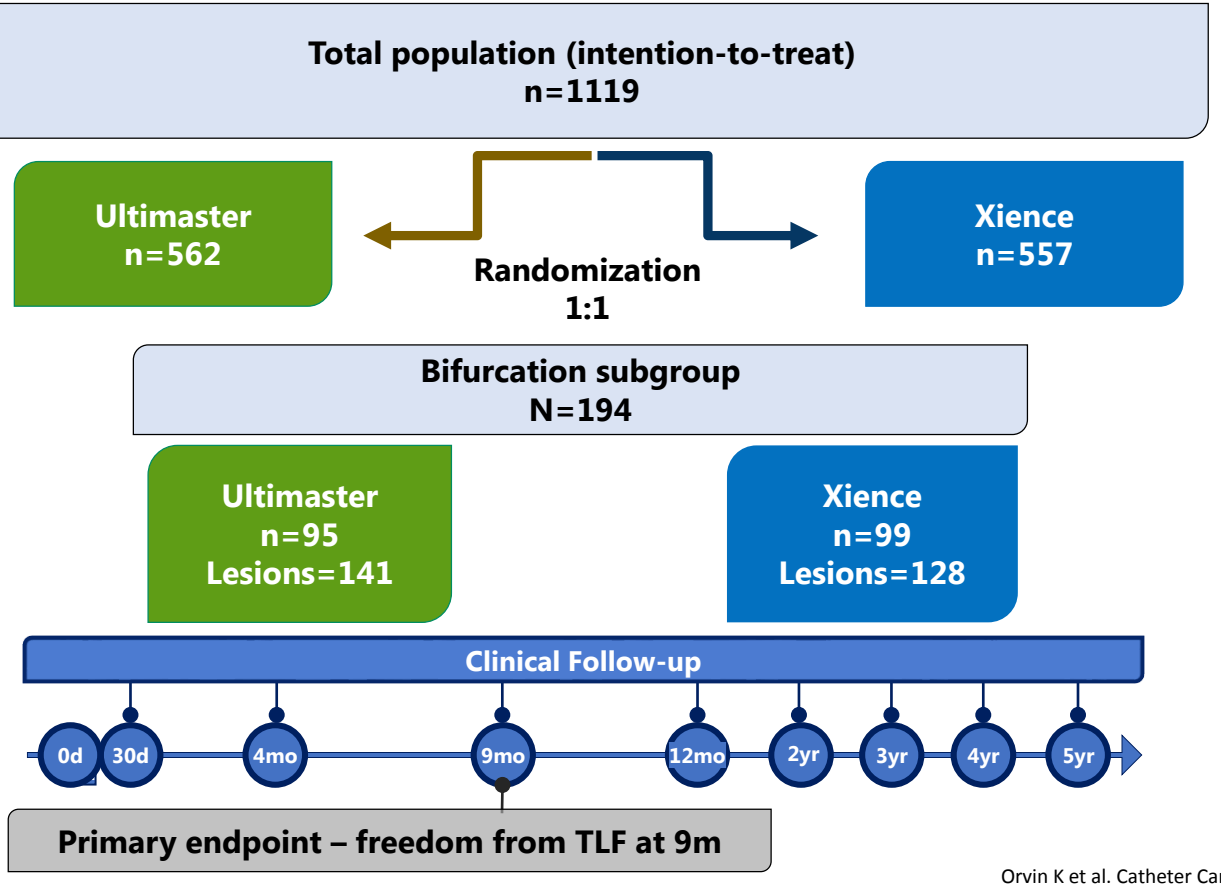
1-year clinical outcomes

All bifurcation, n=3372 patients



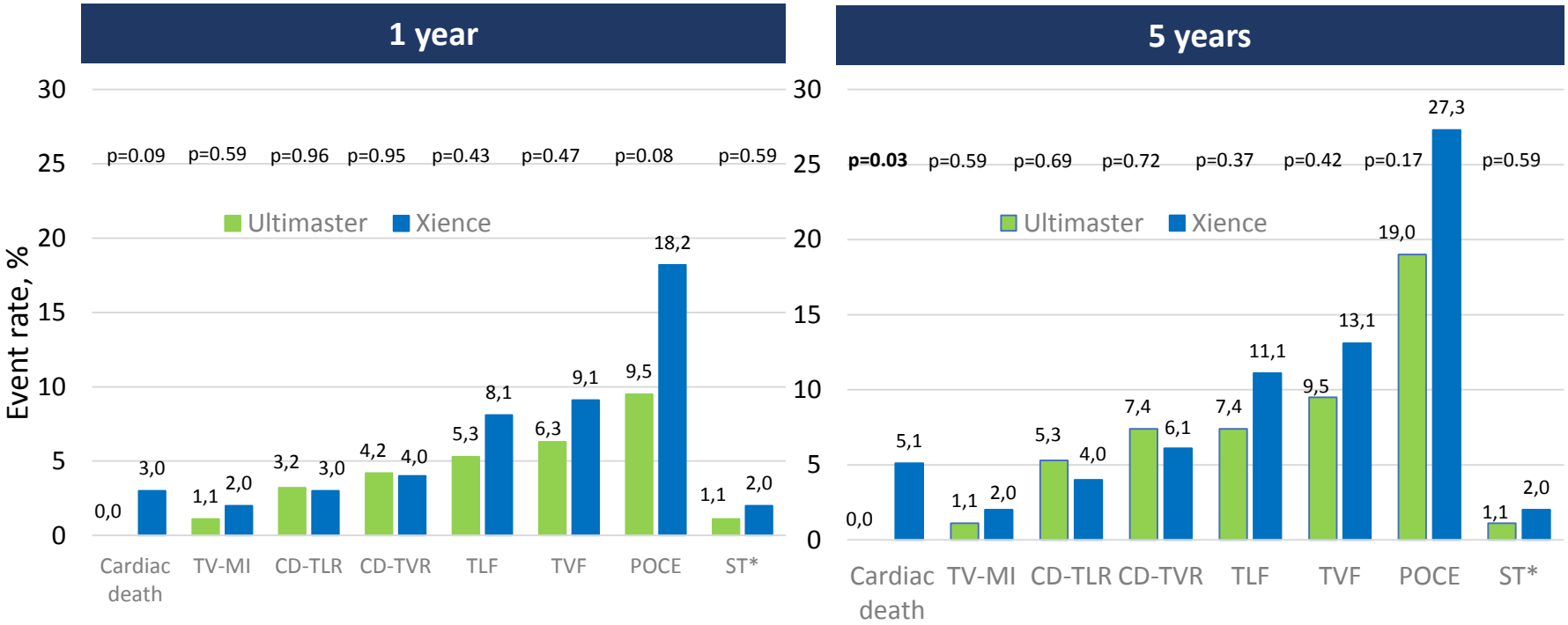
MI: myocardial infarction; **CD-TLR**: clinically driven target lesion revascularization; **CD-TVR**: clinically driven target vessel revascularization; **TLF**: target lesion failure; **Stent thrombosis:** Definite+probable stent thrombosis

CENTURY II randomized controlled trial bifurcation subgroup



Orvin K et al. Catheter Cardiovasc Interv. 2016; 87:1092-100

CENTURY II bifurcation
Long term clinical outcomes



TV-MI: target vessel myocardial infarction; **CD:** clinically driven; **TLR**: target lesion revascularization; **TVR**: target vessel revascularization; **TLF**: target lesion failure, a composite endpoint of cardiac death, TV-MI and CD-TLR; **TVF**: target vessel failure, a composite endpoint of cardiac death, TV-MI and CD-TVR; **POCE**: patient-oriented composite endpoint of any death, any MI and any coronary revascularization; **ST**: definite and probable stent thrombosis

Orvin K et al. Catheter Cardiovasc Interv. 2016; 87:1092-100

Conclusions

- In complex patients treated for left main coronary artery disease, either isolated or with bifurcation or multivessel disease, the Ultimaster DES showed good clinical outcomes at 1 year.
- In patients treated in bifurcation, data from both registry and randomized trial showed excellent performance of Ultimaster DES.
- New features in Ultimaster Tansei stent introduced further innovative technology into current Ultimaster DES, to facilitate complex PCI such as LM and bifurcation treatment.