EuroPCR 2019
Trial updates and registries – Clinical outcomes after DES implantation: impact of strut thickness
Hotlines and Late-Breaking Trials

11:09-11:16, Wednesday, 22 May, 2019
Theatre Bordeaux

DESSOLVE III: 36-month update

A randomised comparison of a sirolimus-eluting bioabsorbable polymer-coated stent vs. an everolimus-eluting durable polymer stent in an all-comer population

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On behalf of DESSOLVE III investigators

Disclosure Statement of Financial Interest

Patrick W. Serruys, MD. PhD.

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship	Company
• Grant/Research Support • Consulting Fees/Honoraria	• Abbott • Biosensors • Boston Scientific • Medtronic • Philips/Volcano • Sinomedical Sciences Technology • SMT • Xeltis

Why this study?

- **MiStent drug-eluting stent with a fully absorbable polymer coating containing and embedding a micro-crystalline sirolimus into the vessel wall was developed to overcome limitations of current durable polymer DES eluting amorphous sirolimus.**

- **DESSOLVE III is a prospective, multi-centre, all-comers randomized controlled trial (n=1,398), demonstrating non-inferiority of the MiStent vs. the Xience in terms of device-oriented composite endpoint (DOCE) up to two years [1,2].**

- **It remained to be elucidated whether the 9-month cytostatic neointimal inhibition by crystalline sirolimus has a beneficial effect during a longer term follow-up (up to 5 years per protocol).**

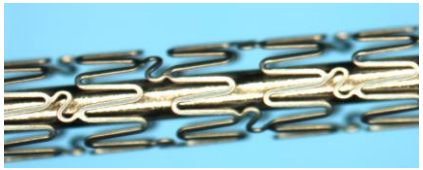
1. de Winter et al. Lancet. 2018;391:431-440.
2. Katagiri et al. EuroIntervention. 2019 Feb 5. pii: EIJ-D-18-00944.

MiStent SES®

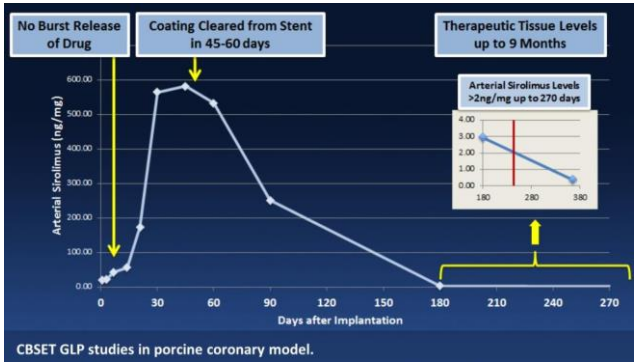
The MiStent SES ® is a fully absorbable polymer coating containing and embedding a micro-crystalline sirolimus into vessel wall

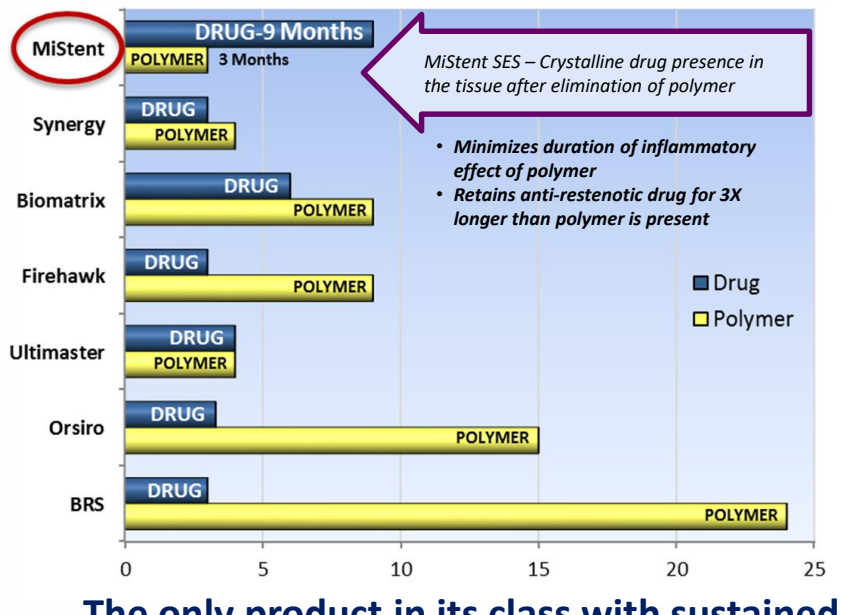
Thin-Strut Stent

- *Cobalt-chromium*
- *Strut thickness 64 microns*



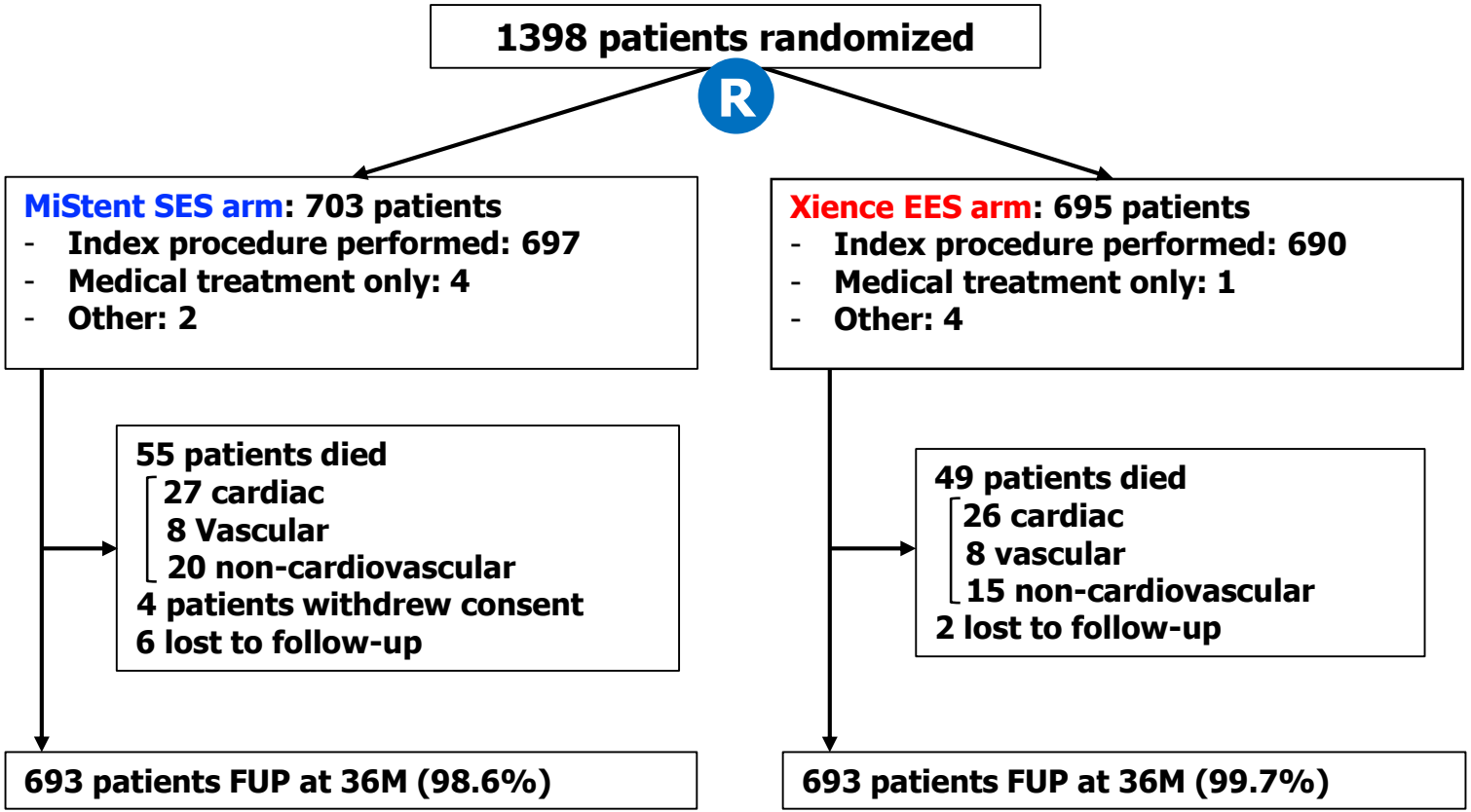
No drug burst, early absorption of polymer, continued drug elution for 9 months





The only product in its class with sustained drug elution in the absence of polymer

Patient flow chart of the DESSOLVE III trial up to 3 years



Patient characterstics

Characteristic	MiStent SES (n= 703)	Xience EES (n= 695)	p value
Age (years)	66.4± 10.7	66.3± 10.7	0.90
Male	70.3 %	73.8 %	0.14
Body Mass Index (kg/m^2)	27.9± 4.4	28.1±4.5	0.55
Risk Factors			
Current smoker	26.6 %	26.4 %	0.955
Diabetes Mellitus	26.6 %	27.1 %	0.811
Hypertension	71.5 %	75.4 %	0.10
Hypercholesterolemia	60.8 %	60.0 %	0.76
Family history of CAD	39.0 %	38.2 %	0.76
History of:			
Previous MI	27.1 %	27.7 %	0.78
Peripheral Artery Disease	9.3 %	10.5 %	0.47
Previous PCI	33.7 %	35.6 %	0.44
Previous CABG	7.3 %	9.5 %	0.13
Heart Failure	7.3 %	7.5 %	0.86
Renal Insufficiency*	6.7 %	6.7 %	0.98
Indication			0.78
Stable angina	41.1 %	41.3 %	
Acute coronary syndrome	48.9 %	48.7 %	
Unstable angina	23.0 %	23.9 %	
Non-ST elevation MI	21.2 %	19.1 %	
ST-elevation MI	14.7 %	15.7 %	

Lesion characteristics

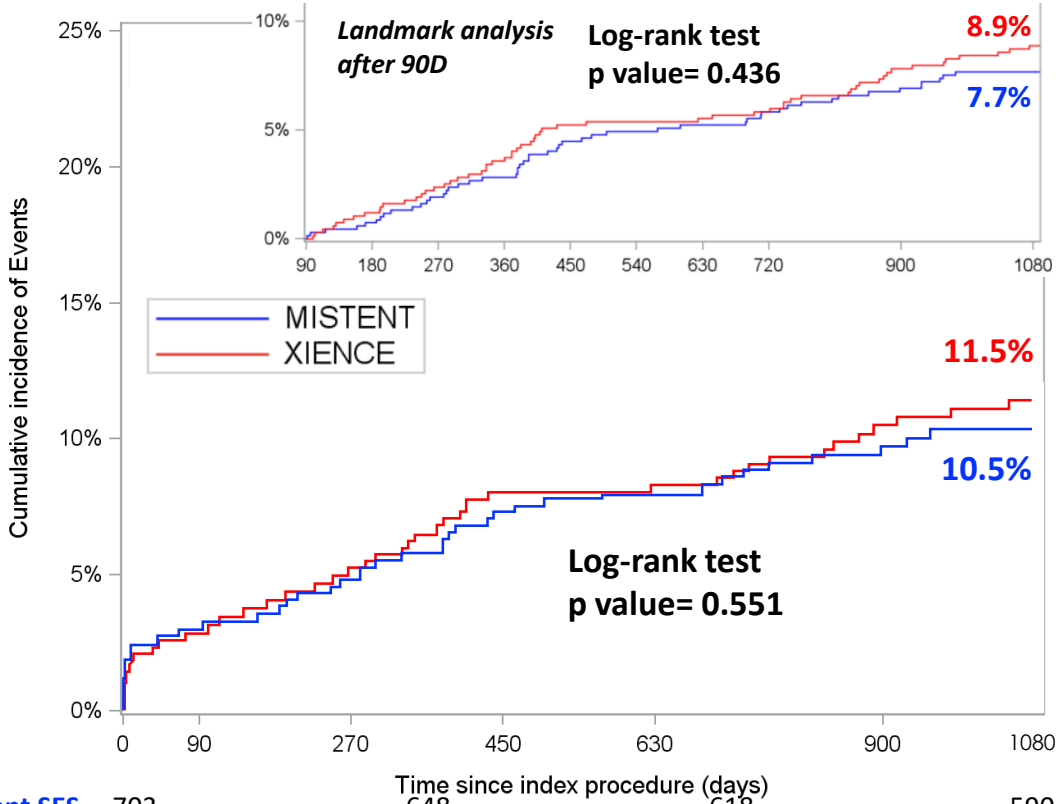
	MiStent SES n=1037 lesions	Xience EES n=993 lesions	p value
Vessel Location:			
LAD	41.5 %	39.7 %	0.41
LCX	26.1 %	26.1 %	0.98
RCA	30.3 %	31.9 %	0.42
Left Main	1.5 %	1.4 %	0.8
Bypass graft	0.6 %	0.9 %	0.39
Number of lesions treated	1.49± 0.83	1.44± 0.78	0.26
Index PCI performed	99.1 %	99.3 %	0.78
TIMI flow pre-procedure			0.68
Flow 0	8.9 %	9.4 %	
Flow 1	3.5 %	3.3 %	
Flow 2	18.0 %	15.6 %	
Flow 3	62.4 %	64.0 %	
Not done	7.2 %	7.7 %	
Restenotic Lesion	3.0 %	3.1 %	0.86
Small Vessel (≤ 2.75 mm)	40.7 %	40.8 %	0.97
Long Lesion (> 18 mm)	56.2 %	47.1 %	<0.001
Bifurcation Involved	7.4 %	6.9 %	0.68

Procedural characteristics

	MiStent SES n=1037 lesions	Xience EES n=993 lesions	p value
Direct stenting	30.8 %	33.2 %	0.23
Maximum pressure (atm)	13.6± 3.7	13.7± 3.5	0.63
Maximum balloon length (mm)	15.9± 4.0	16.3± 4.3	0.17
Maximum balloon diameter (mm)	2.51± 0.41	2.47± 0.40	0.08
Stent characteristics			
Number of stents used per lesion	1.23± 0.56	1.23± 0.60	0.93
Total stent length (mm)	24.2± 12.8	25.0± 14.9	0.19
Overlapping stent	22.0 %	22.3 %	0.87
Post-stenting balloon dilatation	43.4 %	40.7 %	0.22
Maximum pressure (atm)	16.5± 4.0	16.7± 3.7	0.33
Maximum balloon length (mm)	14.2± 4.7	14.2± 5.3	0.82
Maximum balloon diameter (mm)	3.22±0.54	3.17± 0.56	0.23
TIMI flow post-procedure			0.78
Flow 0	0.2 %	0.3 %	
Flow 1	0.1 %	0.2 %	
Flow 2	1.3 %	1.6 %	
Flow 3	93.3 %	91.9 %	
Not done	5.1 %	5.9 %	

The primary endpoint (DOCE/TLF)

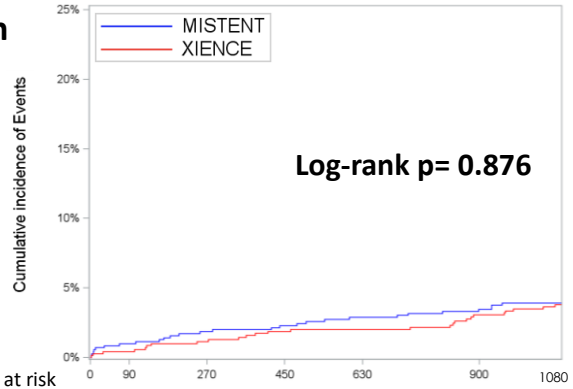
-defined as the composite of cardiac death, TV-MI, CI-TLR-



MiStent SES	703	648	618	590
Xience EES	695	643	621	591

Components of DOCE/TLF and ST

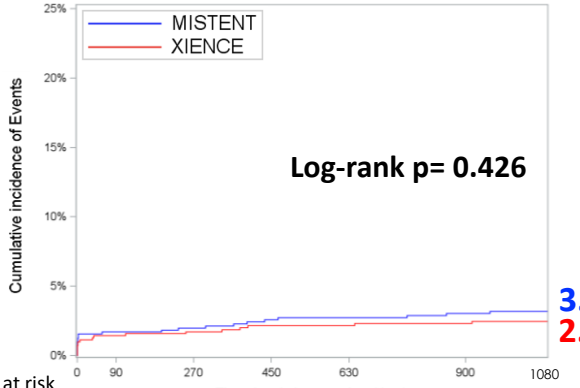
Cardiac death



3.9%
3.8%

N at risk				
MISTENT	703	674	657	633
XIENCE	695	677	666	644

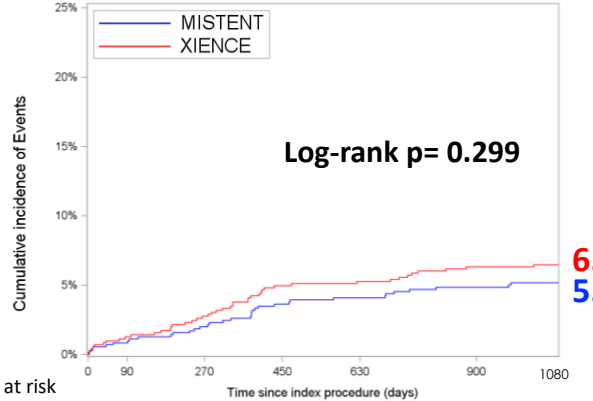
Target vessel MI



3.2%
2.5%

N at risk				
MISTENT	703	661	641	615
XIENCE	695	664	650	627

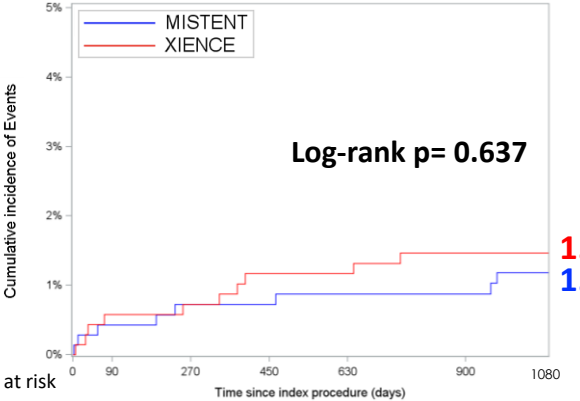
CI-TLR



6.5%
5.2%

N at risk				
MISTENT	703	658	629	603
XIENCE	695	652	631	602

Def or Prob ST

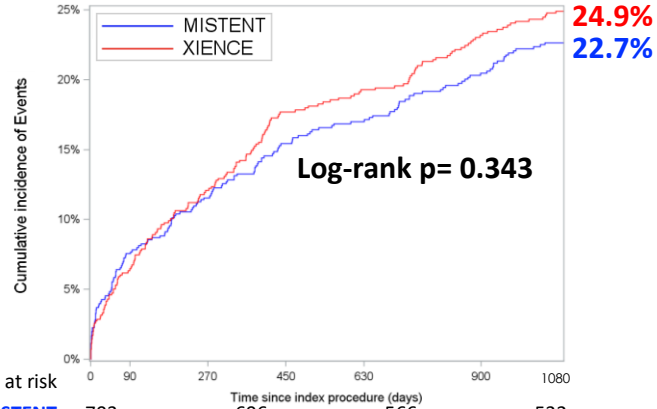


1.5%
1.2%

N at risk				
MISTENT	703	671	654	628
XIENCE	695	672	658	635

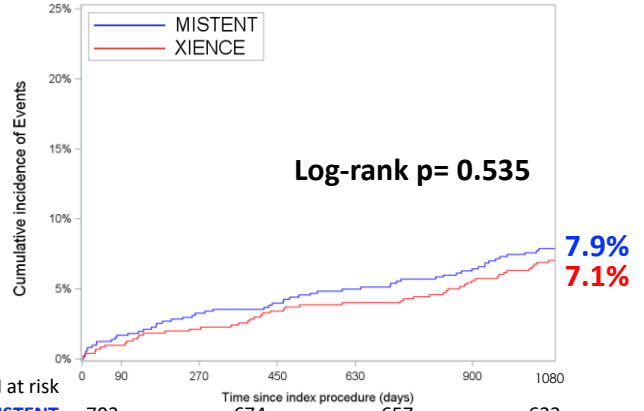
POCE (all-cause death, any MI, any revascularization)

POCE



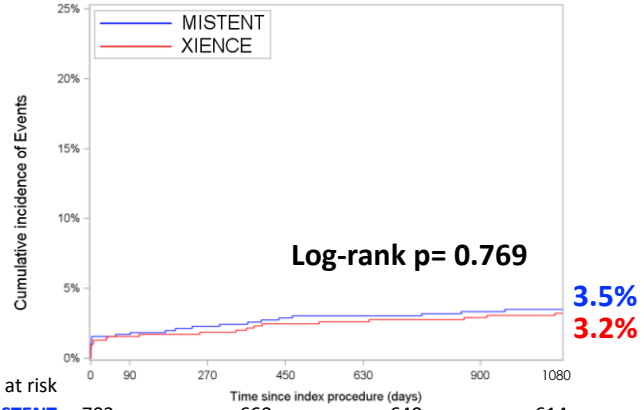
N at risk				
MISTENT	703	606	566	532
XIENCE	695	592	558	520

All-cause death



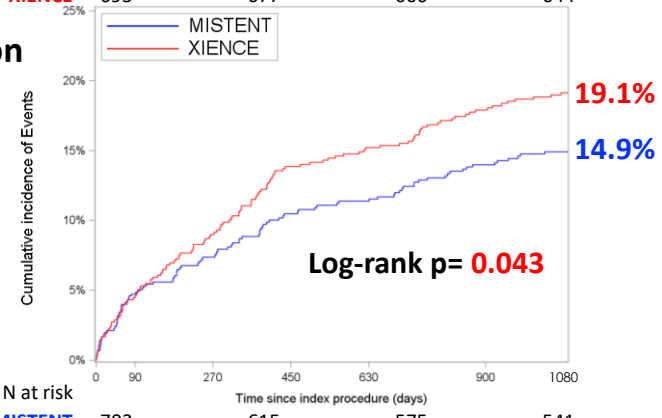
N at risk				
MISTENT	703	674	657	633
XIENCE	695	677	666	644

Any MI



N at risk				
MISTENT	703	660	640	614
XIENCE	695	663	648	624

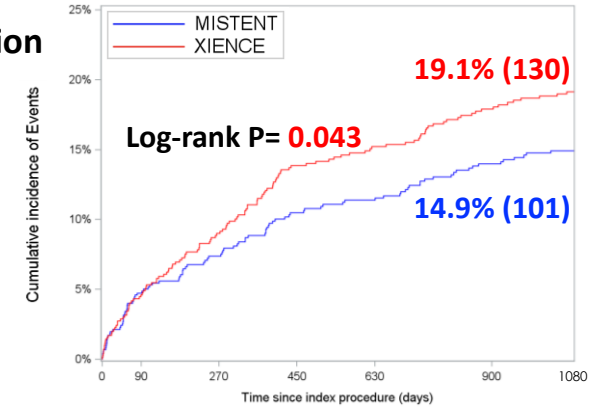
Any revascularization



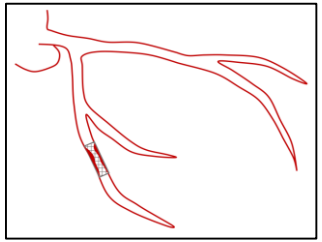
N at risk				
MISTENT	703	615	575	541
XIENCE	695	600	566	528

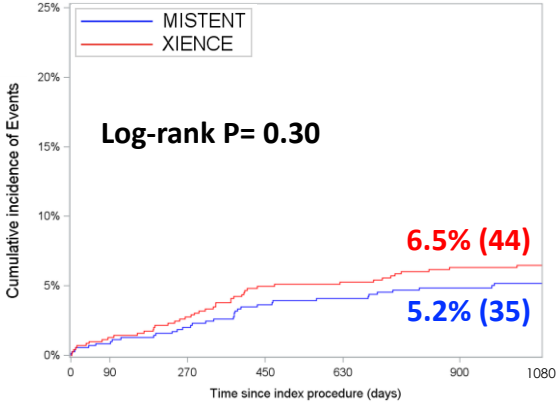
Revascularization

Any revascularization

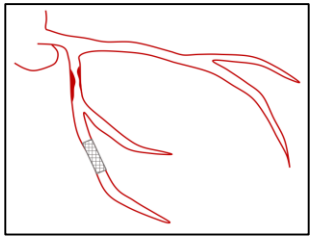


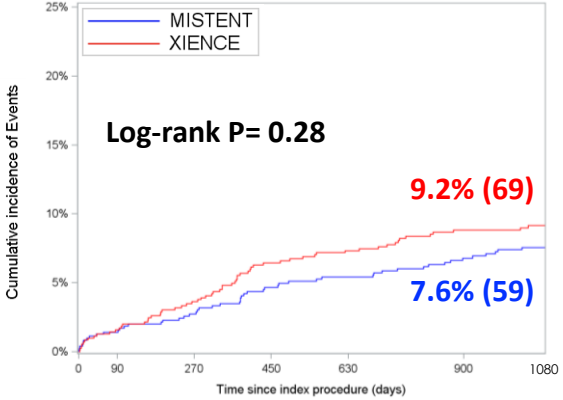
Clinically-indicated TLR



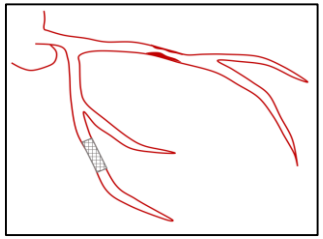


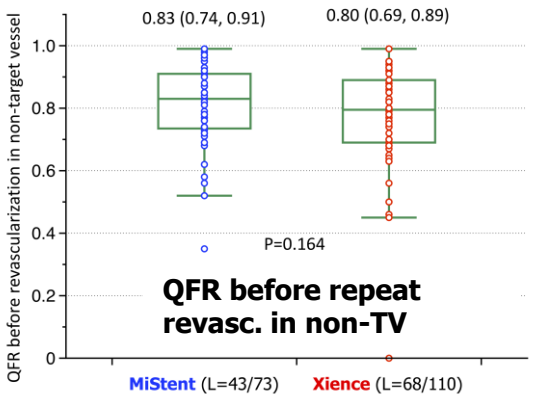
Clinically-indicated TVR





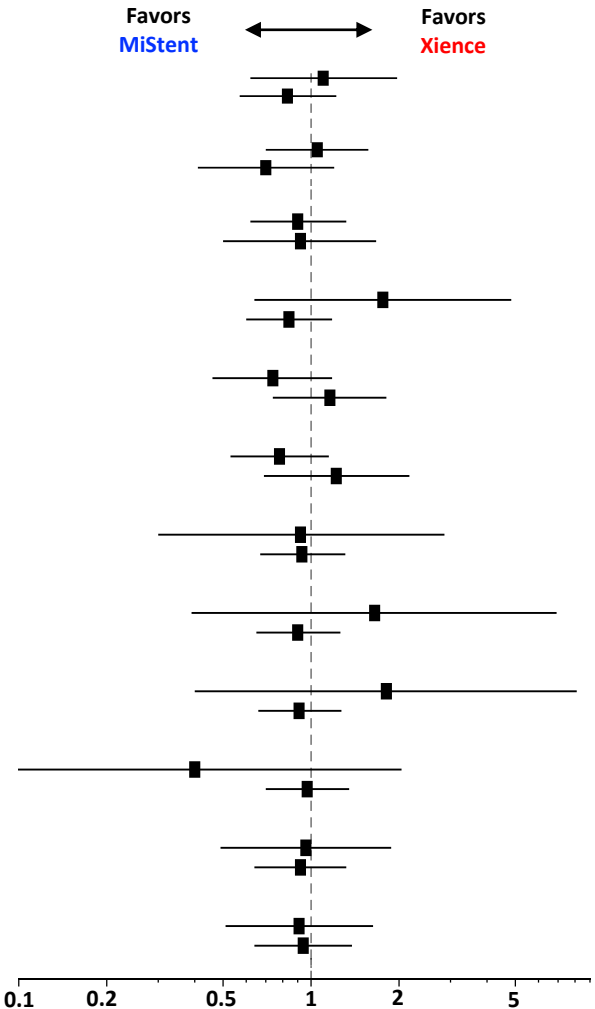
Non-TV revascularization





Subgroup analyses for the primary endpoint (DOCE/TLF)

	MISTENT	XIENCE	Hazard Ratio (95% CI)	P-value	P-value for interaction
Any Diabetes					0.43
Yes	12.9% (24/186)	11.8% (22/187)	1.10 (0.62-1.97)	0.74	
No	9.3% (48/517)	11.2% (57/508)	0.83 (0.57-1.22)	0.36	
ACS					0.24
Yes	11.8% (49/414)	11.3% (46/408)	1.05 (0.70-1.57)	0.82	
No	8.0% (23/289)	11.5% (33/287)	0.70 (0.41-1.20)	0.20	
Gender					0.96
Male	10.1% (50/494)	11.3% (58/513)	0.90 (0.62-1.32)	0.60	
Female	10.5% (22/209)	11.5% (21/182)	0.92 (0.50-1.67)	0.78	
Renal insufficiency					0.17
Yes	21.3% (10/47)	13.0% (6/46)	1.76 (0.64-4.84)	0.27	
No	9.5% (62/656)	11.2% (73/649)	0.84 (0.60-1.18)	0.32	
Any Small Vessel (<=2.75mm)					0.17
Yes	9.3% (31/334)	12.6% (40/317)	0.74 (0.46-1.18)	0.20	
No	11.3% (41/363)	9.9% (37/373)	1.16 (0.74-1.81)	0.52	
Any Long Lesion (>18 mm)					0.20
Yes	10.9% (49/450)	13.9% (53/382)	0.78 (0.53-1.15)	0.21	
No	9.3% (23/247)	7.8% (24/308)	1.22 (0.69-2.17)	0.49	
Any Bifurcation treated					0.98
Yes	10.7% (6/56)	11.5% (6/52)	0.92 (0.30-2.86)	0.89	
No	10.3% (66/641)	11.1% (71/638)	0.93 (0.67-1.31)	0.69	
Left Main treated					0.4
Yes	33.3% (5/15)	21.4% (3/14)	1.65 (0.39-6.92)	0.49	
No	9.8% (67/682)	10.9% (74/676)	0.90 (0.65-1.26)	0.55	
Bypass Lesion treated					0.36
Yes	57.1% (4/7)	33.3% (3/9)	1.81 (0.40-8.11)	0.44	
No	9.9% (68/690)	10.9% (74/681)	0.91 (0.66-1.27)	0.60	
Any Restenotic Lesion					0.28
Yes	7.7% (2/26)	18.5% (5/27)	0.40 (0.08-2.04)	0.27	
No	10.4% (70/671)	10.9% (72/663)	0.97 (0.70-1.35)	0.87	
Multivessel Disease treated					0.90
Yes	11.9% (18/151)	12.9% (16/124)	0.96 (0.49-1.88)	0.91	
No	9.9% (54/546)	10.8% (61/566)	0.92 (0.64-1.32)	0.65	
Any Overlapping Stent index procedure					0.93
Yes	13.4% (22/164)	14.7% (23/156)	0.91 (0.51-1.63)	0.74	
No	9.4% (50/533)	10.1% (54/534)	0.94 (0.64-1.38)	0.74	



The essentials to remember

- ***Why?*** **To assess whether the 9-month cytostatic neointimal inhibition by crystalline sirolimus has a beneficial effect during the long-term follow-up.**

- ***What?*** **Three-year clinical outcomes of the MiStent drug-eluting stent with a fully biodegradable polymer containing a microcrystalline sirolimus vs. the Xience durable polymer everolimus-eluting stent.**

- ***How?*** **Randomizing 1398 all-comers PCI patients either to MiStent or Xience.**

- ***What are the results?*** **Three-year DOCE was 10.5% and 11.5% in the MiStent and Xience arm, respectively (p=0.551). Definite or probable stent thrombosis rate remained low and statistically similar 1.2% and 1.5% (p=0.637) between the stents.**

- ***Why is this important?*** **The efficacy and safety of the MiStent containing a microcrystalline sirolimus up to 3 years has been confirmed as compared to the best-in class second-generation DES, the Xience in a large all-comers population.**

CARDIALYSIS
Clinical Trial Management - Core Laboratories

ECRI European Cardiovascular Research Institute

K. Arkenbout, J ten Berg, H. Boersma, P. Buszman, G. Cayla, Gerrit-Anne van Es, M. Ferrari, D. Fischer, S. Garg, P. Goube, B. Hamer, S. Hofma, S. James, G. Jessurun, K. Koch,

ECRI/Cardialysis - THANK YOU

M. Kosmider, S. Levesque, P. Lurz, K. Milewski, M. Noutsias, Y. Onuma,T. Oude Ophuis, B. Rensing, W. Rutsch, R.P.T. Troquay, G.J. Vlachojannis, W. Wijns, R. de Winter, J. Wöhrle, R. Wyderka, A. Zurakowski

Thank you

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G. Jessurun, MD	Treant Zorggroep loc. Scheper Ziekenhuis Emmen
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R. Wyderka, MD	Zgierski Centrum Kardiologii Med-Pro, Zgierz

Thank you

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M. Kosmider, MD	Oddzial Kardiologiczny PAKS, Bełchatów
R. Wyderka, MD	Zgierski Centrum Kardiologii Med-Pro, Zgierz

Why is this important?

- In an all-comers population, the MiStent sirolimus-eluting bioabsorbable polymer-coated stent had a similar efficacy and safety up to three-year follow-up, when compared with the Xience everolimus-eluting durable-polymer stent.

- This report provides a promising option of a drug-eluting stent in our daily practice.

Thank you

TRIAL ORGANIZATION

Steering Committee
- Prof. Patrick W. Serruys (chair)
- Prof. R. de Winter
- Prof. W. Wijns
- Gerrit-Anne van Es

DSMB
- Prof. S. James (Chair)
- Prof. H. Boersma
- Dr. J ten Berg

CRO
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CEC
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- Prof. W. Rutsch
- Dr. S. Garg
- Dr. G.J. Vlachojannis

Core lab (OCT and angiography)
- Dr. Y. Onuma; Cardialysis B.V. Rotterdam, the Netherlands
- Dr. K. Takahashi

Sponsor: European Cardiovascular Research Institute (ECRI)

Grant givers: Micell Technologies, Durham, NC, USA. Stentys, Paris, France

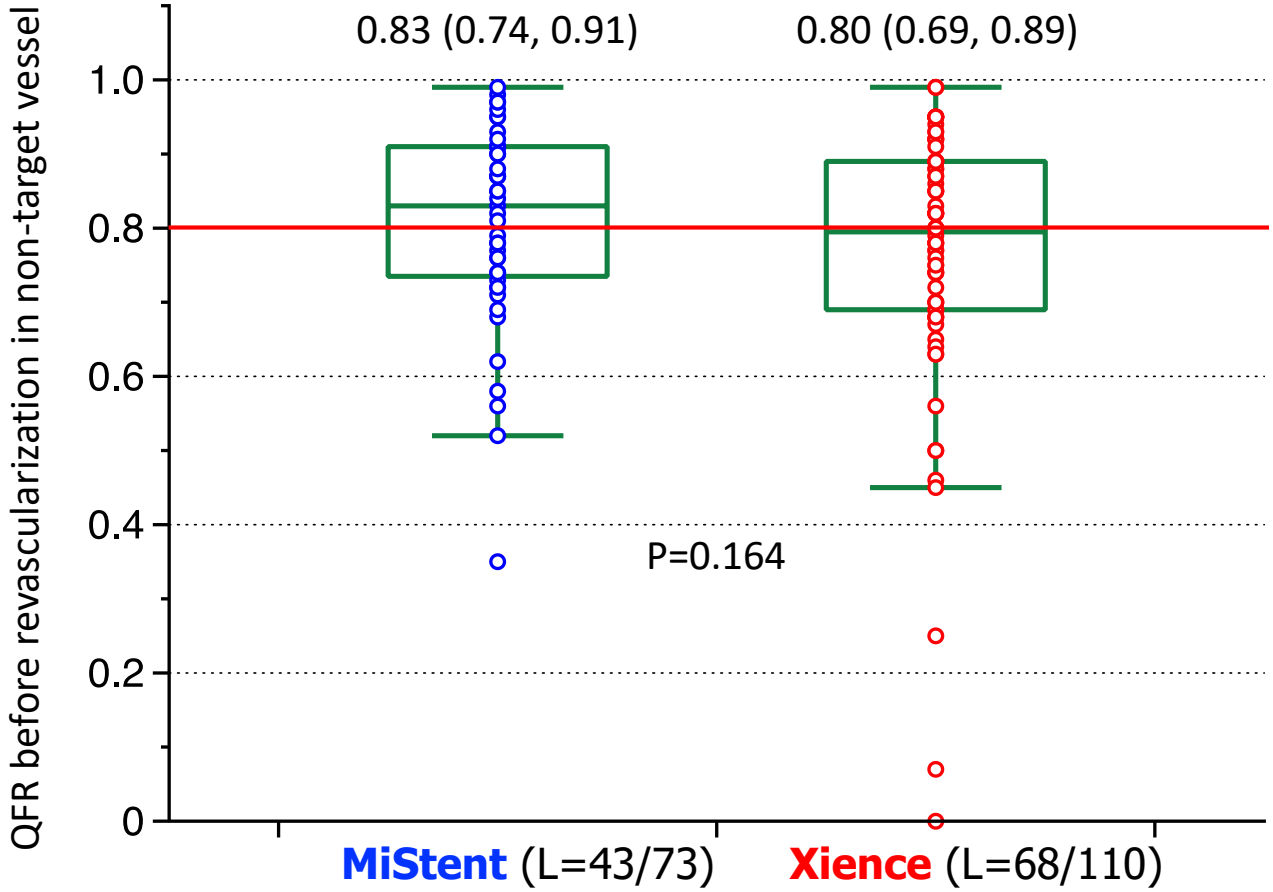
ECRI European Cardiovascular Research Institute

CARDIALYSIS Clinical Trial Management - Core Laboratories

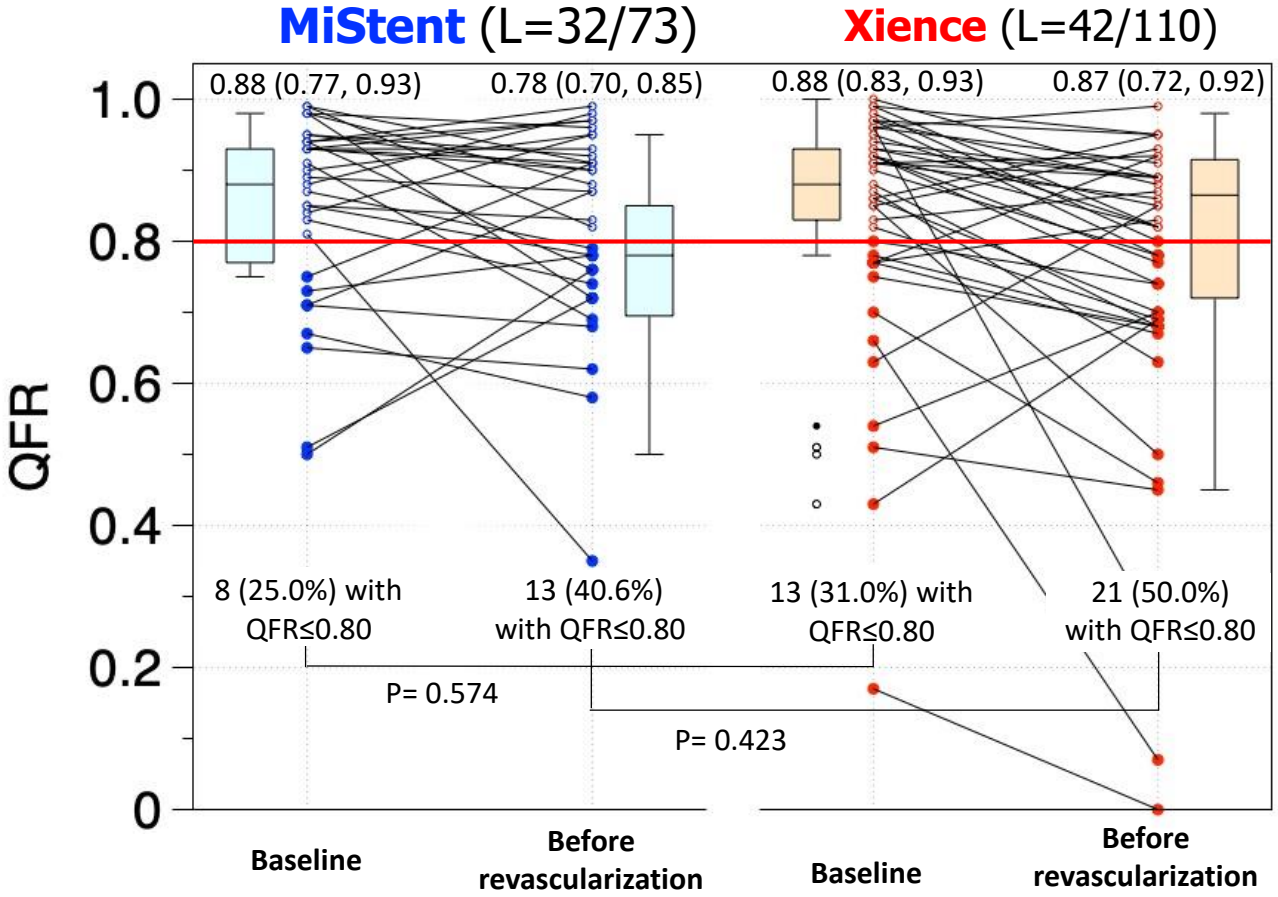
MICELL TECHNOLOGIES

- Backup

QFR before non-TV revascularization

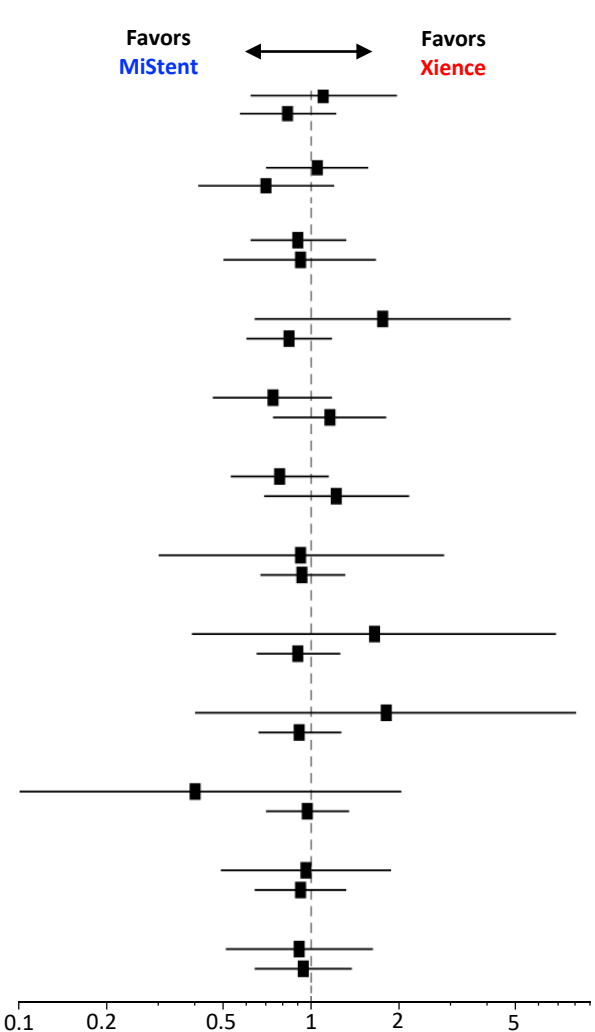


Non-target vessel revascularization



Subgroup analyses of the primary endpoint

	MISTENT	XIENCE	Hazard Ratio (95% CI)	P-value	P-value for interaction
Any Diabetes					0.43
Yes	12.9% (24/186)	11.8% (22/187)	1.10(0.62-1.97)	0.74	
No	9.3% (48/517)	11.2% (57/508)	0.83(0.57-1.22)	0.36	
ACS					0.24
Yes	11.8% (49/414)	11.3% (46/408)	1.05(0.70-1.57)	0.82	
No	8.0% (23/289)	11.5% (33/287)	0.70(0.41-1.20)	0.20	
Gender					0.96
Male	10.1% (50/494)	11.3% (58/513)	0.90(0.62-1.32)	0.60	
Female	10.5% (22/209)	11.5% (21/182)	0.92(0.50-1.67)	0.78	
Renal insufficiency					0.17
Yes	21.3% (10/47)	13.0% (6/46)	1.76(0.64-4.84)	0.27	
No	9.5% (62/656)	11.2% (73/649)	0.84(0.60-1.18)	0.32	
Any Small Vessel (<=2.75mm)					0.17
Yes	9.3% (31/334)	12.6% (40/317)	0.74(0.46-1.18)	0.20	
No	11.3% (41/363)	9.9% (37/373)	1.16(0.74-1.81)	0.52	
Any Long Lesion (>18 mm)					0.20
Yes	10.9% (49/450)	13.9% (53/382)	0.78(0.53-1.15)	0.21	
No	9.3% (23/247)	7.8% (24/308)	1.22(0.69-2.17)	0.49	
Any Bifurcation treated					0.98
Yes	10.7% (6/56)	11.5% (6/52)	0.92(0.30-2.86)	0.89	
No	10.3% (66/641)	11.1% (71/638)	0.93(0.67-1.31)	0.69	
Left Main treated					0.4
Yes	33.3% (5/15)	21.4% (3/14)	1.65(0.39-6.92)	0.49	
No	9.8% (67/682)	10.9% (74/676)	0.90(0.65-1.26)	0.55	
Bypass Lesion treated					0.36
Yes	57.1% (4/7)	33.3% (3/9)	1.81(0.40-8.11)	0.44	
No	9.9% (68/690)	10.9% (74/681)	0.91(0.66-1.27)	0.60	
Any Restenotic Lesion					0.28
Yes	7.7% (2/26)	18.5% (5/27)	0.40(0.08-2.04)	0.27	
No	10.4% (70/671)	10.9% (72/663)	0.97(0.70-1.35)	0.87	
Multivessel Disease treated					0.90
Yes	11.9% (18/151)	12.9% (16/124)	0.96(0.49-1.88)	0.91	
No	9.9% (54/546)	10.8% (61/566)	0.92(0.64-1.32)	0.65	
Any Overlapping Stent index procedure					0.93
Yes	13.4% (22/164)	14.7% (23/156)	0.91(0.51-1.63)	0.74	
No	9.4% (50/533)	10.1% (54/534)	0.94(0.64-1.38)	0.74	



What are the essential results?

DOCE

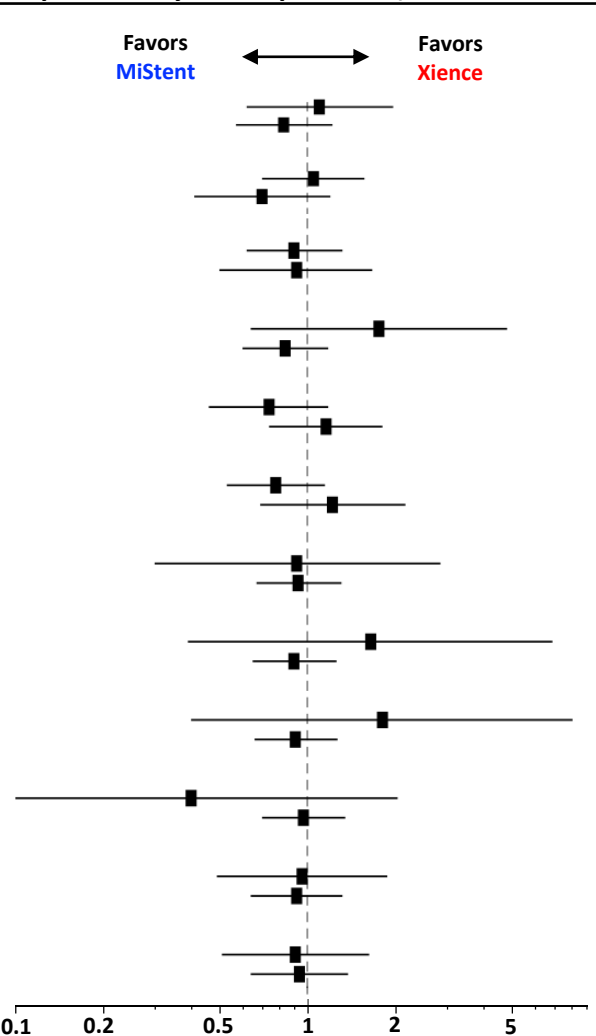
Outcome	MISTENT	XIENCE	Difference (95% CI)	p-value
DOCE	10.5%	11.5%	-1.1 (-4.4, 2.2)%	0.55
Cardiac Death	3.9%	3.8%	0.1 (-1.9,2.2)%	0.88
Target-Vessel MI	3.2%	2.5%	0.7 (-1.0, 2.5)%	0.43
Clinically-indicated TLR	5.2%	6.5%	-1.3 (-3.8, 1.2)%	0.30

POCE

Outcome	MISTENT	XIENCE	Difference (95% CI)	p-value
POCE	22.7%	24.9%	-2.3 (-6.7, 2.2)%	0.34
Any death	7.9%	7.1%	0.8 (-1.9, 3.6)%	0.54
Any MI	3.5%	3.2%	0.3 (-1.6, 2.2)%	0.77
Any revascularization	14.9%	19.1%	-3.1 (-8.2, -0.2)%	0.043

Subgroup analyses for the primary endpoint (DOCE/TLF)

	MISTENT	XIENCE	Hazard Ratio (95% CI)	P-value	P-value for interaction
Any Diabetes					0.43
Yes	12.9% (24/186)	11.8% (22/187)	1.10(0.62-1.97)	0.74	
No	9.3% (48/517)	11.2% (57/508)	0.83(0.57-1.22)	0.36	
ACS					0.24
Yes	11.8% (49/414)	11.3% (46/408)	1.05(0.70-1.57)	0.82	
No	8.0% (23/289)	11.5% (33/287)	0.70(0.41-1.20)	0.20	
Gender					0.96
Male	10.1% (50/494)	11.3% (58/513)	0.90(0.62-1.32)	0.60	
Female	10.5% (22/209)	11.5% (21/182)	0.92(0.50-1.67)	0.78	
Renal insufficiency					0.17
Yes	21.3% (10/47)	13.0% (6/46)	1.76(0.64-4.84)	0.27	
No	9.5% (62/656)	11.2% (73/649)	0.84(0.60-1.18)	0.32	
Any Small Vessel (<=2.75mm)					0.17
Yes	9.3% (31/334)	12.6% (40/317)	0.74(0.46-1.18)	0.20	
No	11.3% (41/363)	9.9% (37/373)	1.16(0.74-1.81)	0.52	
Any Long Lesion (>18 mm)					0.20
Yes	10.9% (49/450)	13.9% (53/382)	0.78(0.53-1.15)	0.21	
No	9.3% (23/247)	7.8% (24/308)	1.22(0.69-2.17)	0.49	
Any Bifurcation treated					0.98
Yes	10.7% (6/56)	11.5% (6/52)	0.92(0.30-2.86)	0.89	
No	10.3% (66/641)	11.1% (71/638)	0.93(0.67-1.31)	0.69	
Left Main treated					0.4
Yes	33.3% (5/15)	21.4% (3/14)	1.65(0.39-6.92)	0.49	
No	9.8% (67/682)	10.9% (74/676)	0.90(0.65-1.26)	0.55	
Bypass Lesion treated					0.36
Yes	57.1% (4/7)	33.3% (3/9)	1.81(0.40-8.11)	0.44	
No	9.9% (68/690)	10.9% (74/681)	0.91(0.66-1.27)	0.60	
Any Restenotic Lesion					0.28
Yes	7.7% (2/26)	18.5% (5/27)	0.40(0.08-2.04)	0.27	
No	10.4% (70/671)	10.9% (72/663)	0.97(0.70-1.35)	0.87	
Multivessel Disease treated					0.90
Yes	11.9% (18/151)	12.9% (16/124)	0.96(0.49-1.88)	0.91	
No	9.9% (54/546)	10.8% (61/566)	0.92(0.64-1.32)	0.65	
Any Overlapping Stent index procedure					0.93
Yes	13.4% (22/164)	14.7% (23/156)	0.91(0.51-1.63)	0.74	
No	9.4% (50/533)	10.1% (54/534)	0.94(0.64-1.38)	0.74	



	MISTENT (n= 703)	XIENCE (n= 695)	Hazard Ratio (95% CI)	P-value	P-value for interaction
Any Diabetes					0.43
Yes	12.9% (24/186)	11.8% (22/187)	1.10 (0.62-1.97)	0.74	
No	9.3% (48/517)	11.2% (57/508)	0.83 (0.57-1.22)	0.36	
ACS					0.24
Yes	11.8% (49/414)	11.3% (46/408)	1.05 (0.70-1.57)	0.82	
No	8.0% (23/289)	11.5% (33/287)	0.70 (0.41-1.20)	0.20	
Gender					0.96
Male	10.1% (50/494)	11.3% (58/513)	0.90 (0.62-1.32)	0.60	
Female	10.5% (22/209)	11.5% (21/182)	0.92 (0.50-1.67)	0.78	
Renal insufficiency					0.17
Yes	21.3% (10/47)	13.0% (6/46)	1.76 (0.64-4.84)	0.27	
No	9.5% (62/656)	11.2% (73/649)	0.84 (0.60-1.18)	0.32	
Any Small Vessel (<=2.75mm)					0.17
Yes	9.3% (31/334)	12.6% (40/317)	0.74 (0.46-1.18)	0.20	
No	11.3% (41/363)	9.9% (37/373)	1.16 (0.74-1.81)	0.52	
Any Long Lesion (>18 mm)					0.20
Yes	10.9% (49/450)	13.9% (53/382)	0.78 (0.53-1.15)	0.21	
No	9.3% (23/247)	7.8% (24/308)	1.22 (0.69-2.17)	0.49	
Any Bifurcation treated					0.98
Yes	10.7% (6/56)	11.5% (6/52)	0.92 (0.30-2.86)	0.89	
No	10.3% (66/641)	11.1% (71/638)	0.93 (0.67-1.31)	0.69	
Left Main treated					0.4
Yes	33.3% (5/15)	21.4% (3/14)	1.65 (0.39-6.92)	0.49	
No	9.8% (67/682)	10.9% (74/676)	0.90 (0.65-1.26)	0.55	
Bypass Lesion treated					0.36
Yes	57.1% (4/7)	33.3% (3/9)	1.81 (0.40-8.11)	0.44	
No	9.9% (68/690)	10.9% (74/681)	0.91 (0.66-1.27)	0.60	
Any Restenotic Lesion					0.28
Yes	7.7% (2/26)	18.5% (5/27)	0.40 (0.08-2.04)	0.27	
No	10.4% (70/671)	10.9% (72/663)	0.97 (0.70-1.35)	0.87	
Multivessel Disease treated					0.90
Yes	11.9% (18/151)	12.9% (16/124)	0.96 (0.49-1.88)	0.91	
No	9.9% (54/546)	10.8% (61/566)	0.92 (0.64-1.32)	0.65	
Any Overlapping Stent index procedure					0.93
Yes	13.4% (22/164)	14.7% (23/156)	0.91 (0.51-1.63)	0.74	
No	9.4% (50/533)	10.1% (54/534)	0.94 (0.64-1.38)	0.74