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RESOLUTE All Comers

International Multicentre DES Clinical Trial

12-Month Results Summary:
Resolute DES Matches Xience V DES

RESOLUTE All Comers 12-Month Summary

Innovative Trial:

- RESOLUTE All Comers is an innovative, large, real-world study that reflects the complexities of daily clinical practice

Strong Results with Primary Endpoint Met:

- Resolute DES matches Xience V DES in primary endpoint of TLF
- Resolute DES shows numerically lower TLF, MACE and TVF
- Resolute DES shows excellent performance across all clinical efficacy and safety endpoints

Compelling Results in Complex Patients:

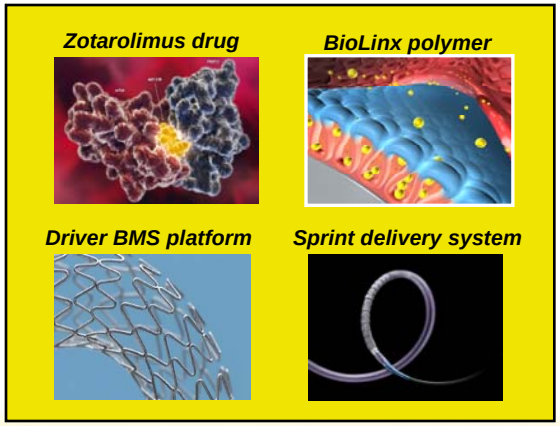
- Resolute DES shows strong performance

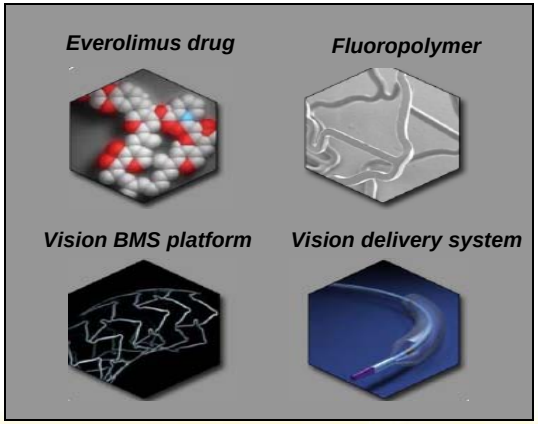
Excellent clinical results establish Resolute DES as a strong choice in complex daily practice

RESOLUTE All Comers was not specifically designed or powered for complex patient subset analysis.

Leading Second-Generation DES Go Head-to-Head for the First Time

	Resolute DES	Xience V DES
Strut design	Modular, round, edgeless	Laser-cut, rectangular
Stent material	F-562 cobalt alloy	L-605 cobalt alloy
Crossing profile* (mm)	1.12	1.20
Cell area*	1.0 mm^2	3.7 mm^2
Polymer	BioLinx *Overall hydrophilic blend*	Fluoropolymer *Hydrophobic polymer*
Drug	Zotarolimus *85% eluted by 60 days and completely eluted by 180 days*	Everolimus *Completely eluted by 120 days*





*3.5 x 18 mm stent

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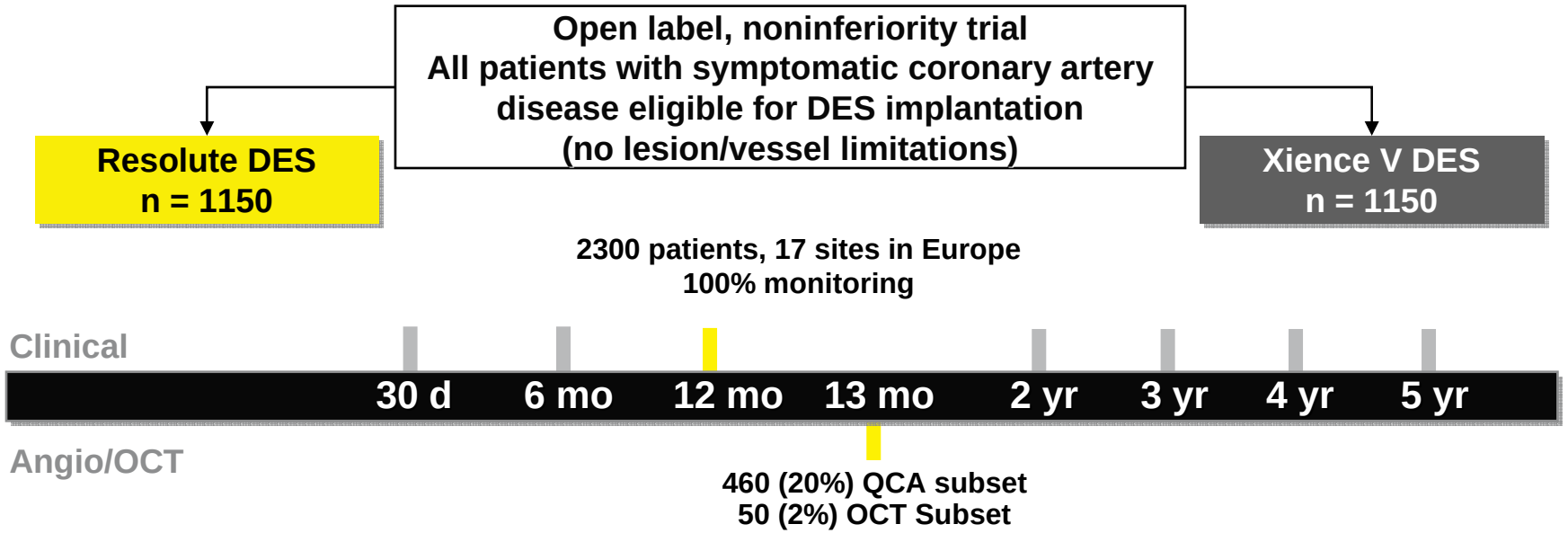
Innovative RESOLUTE All Comers Trial Design

RESOLUTE All Comers Trial Design

Co-PIs: Profs. Serruys, Silber, Windecker



Primary endpoint: TLF (ARC-defined): Cardiac death, target vessel MI, clinically indicated TLR at 12 months
Secondary endpoint (powered): % Diameter stenosis (in-stent) at 13 months
Secondary endpoints: TLF at 30 d, 6 months, 2–5 yr; Composite (all death, all MI, any revascularisation) at each FU time point; angiographic and optical coherence tomography (OCT) parameters at 13 months
Drug therapy: ASA and clopidogrel/ticlid >6 months (per guidelines)

Patient Eligibility

Inclusion Criteria

Coronary artery disease

- Stable angina
- Silent ischemia
- Acute coronary syndrome including UA, NSTEMI and STEMI

Lesion characteristics

- Number of lesions: no limitation
- Number of vessels: no limitation
- Lesion length: no limitation

Written informed consent

Exclusion Criteria

Known allergy to

Aspirin, clopidogrel, heparin, cobalt alloy, everolimus, zotarolimus, contrast material, polymer coating

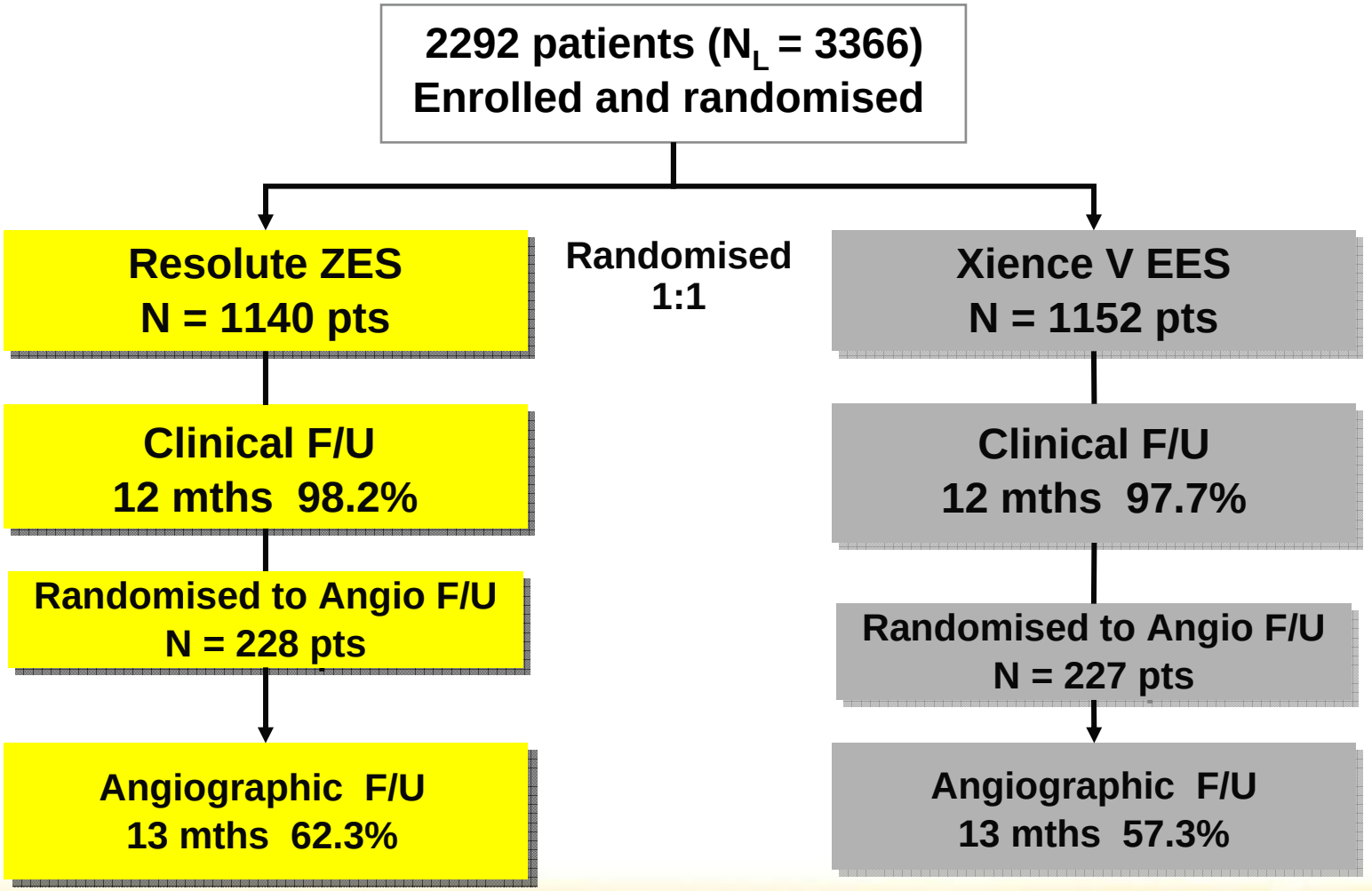
Planned, elective surgery within 6 months of PCI

Unless dual anti-platelet therapy could be maintained

Pregnancy

Participation in another trial

Clinical and Angiographic Follow-Up



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Enrollment Reflects Complex Real-World Practice

Variable, %	Resolute stent N = 1140 patients	Xience V stent N = 1152 patients
Age, years (mean ± SD)	**64.4 ± 10.9**	**64.2 ± 10.8**
Men	**76.7%**	**77.2%**
Diabetes mellitus	**23.5%**	**23.4%**
Insulin treated	**8.4%**	**7.1%**
Arterial hypertension	**71.1%**	**71.3%**
Hyperlipidemia	**63.9%**	**67.7%**
Current smoker	**26.5%**	**26.5%**
Premature CAD in first degree relative	**34.1%**	**36.7%**
Prior myocardial infarction	**28.9%**	**30.4%**
Prior percutaneous coronary intervention	**31.8%**	**32.1%**
Prior coronary artery bypass grafting	**10.0%**	**9.5%**
Stable angina	**33.5%**	**36.1%**
Unstable angina	**19.4%**	**18.9%**
AMI (within 12 hr)	**15.4%**	**17.8%**
AMI (within 72 hr)	**28.9%**	**28.8%**

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Enrollment Reflects Complex Real-World Practice

Variable, %	Resolute stent N = 1140 patients	Xience V stent N = 1152 patients
Left ventricular ejection fraction <30%	**2.8%**	**2.1%**
Multi-vessel disease	**58.4%**	**59.2%**
Target vessel location (per patient)		
Left main	**2.2%**	**2.5%**
Left anterior descending	**52.6%**	**48.6%**
Left circumflex	**33.0%**	**32.9%**
Right coronary	**37.3%**	**41.3%**
Bypass graft	**2.5%**	**2.4%**
Number of treated lesions per patient	**1.5 ± 0.7**	**1.5 ± 0.8**
SYNTAX score	**15 ± 9**	**15 ± 9**
≥1 small vessel (RVD ≤2.75 mm)	**67.8%**	**67.4%**
≥1 lesion length >18 mm	**18.2%**	**21.2%**
≥1 bifurcation/trifurcation	**16.9%**	**17.7%**
≥1 total occlusion	**16.3%**	**17.2%**
≥1 In-stent restenosis	**8.1%**	**8.0%**
Complex[1] use	**67.0%**	**65.6%**

[1]Complex patient definition: Bifurcation, bypass graft, ISR, AMI <72 hr, LVEF <30%, unprotected LM, >2 vessels stented, renal insufficiency or failure (creatinine >140 µmol/L), lesion length >27 mm, >1 lesion per vessel, lesion with thrombus or TO (preprocedure TIMI = 0). With the exception of long lesions (treatable with a single 38-mm length stent), Resolute DES currently is not specifically approved for the patient subsets noted in this complex patient definition.

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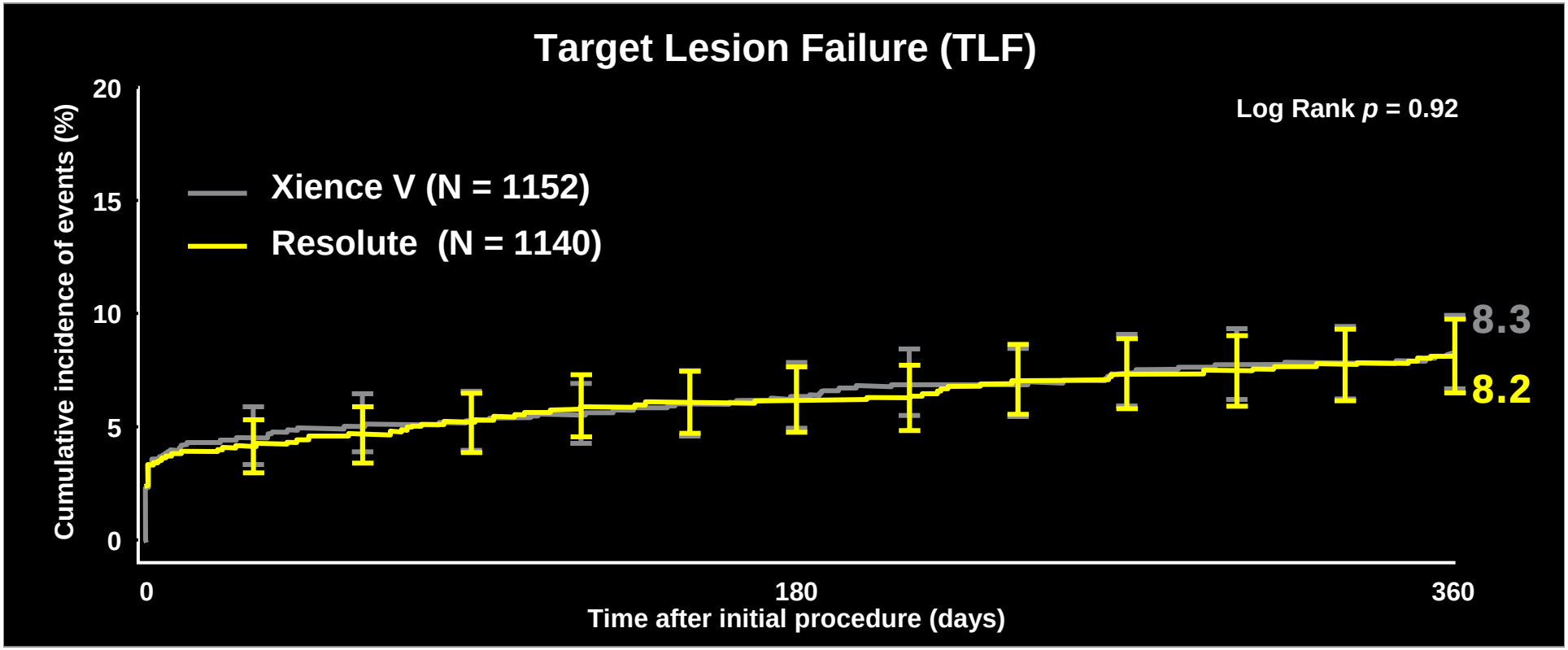
Procedural Characteristics
Excellent Deliverability in Challenging Cases

	Resolute stent N = 1140 patients N = 1661 Lesions	**Xience V stent N = 1152 patients N = 1705 Lesions**	*p-value*
Lesions treated per patient	1.46 ±0.73	1.48 ±0.77	*NS*
Lesion Length (mm)	11.89±7.50	12.15±7.86	*NS*
No. of stents per patient	1.9 ± 1.2	2.0 ± 1.3	0.02
Stent length per patient (mm)	34 ± 24	37 ± 26	0.02
Pre-stent balloon dilatation	69.5%	70.2%	*NS*
Implantation of study stent	98.0%	96.9%	*NS*
Lesion success	98.9%	99.1%	*NS*
Device success	97.0%	96.6%	*NS*
Procedure success	94.6%	94.2%	*NS*

Resolute Matches Xience V DES in Primary Endpoint



TLF = Cardiac death, target vessel MI, clinically indicated TLR.
Error bars indicate a point-wise two-sided 95% confidence interval (±1.96 * SE).
Standard error based on the Greenwood formula.

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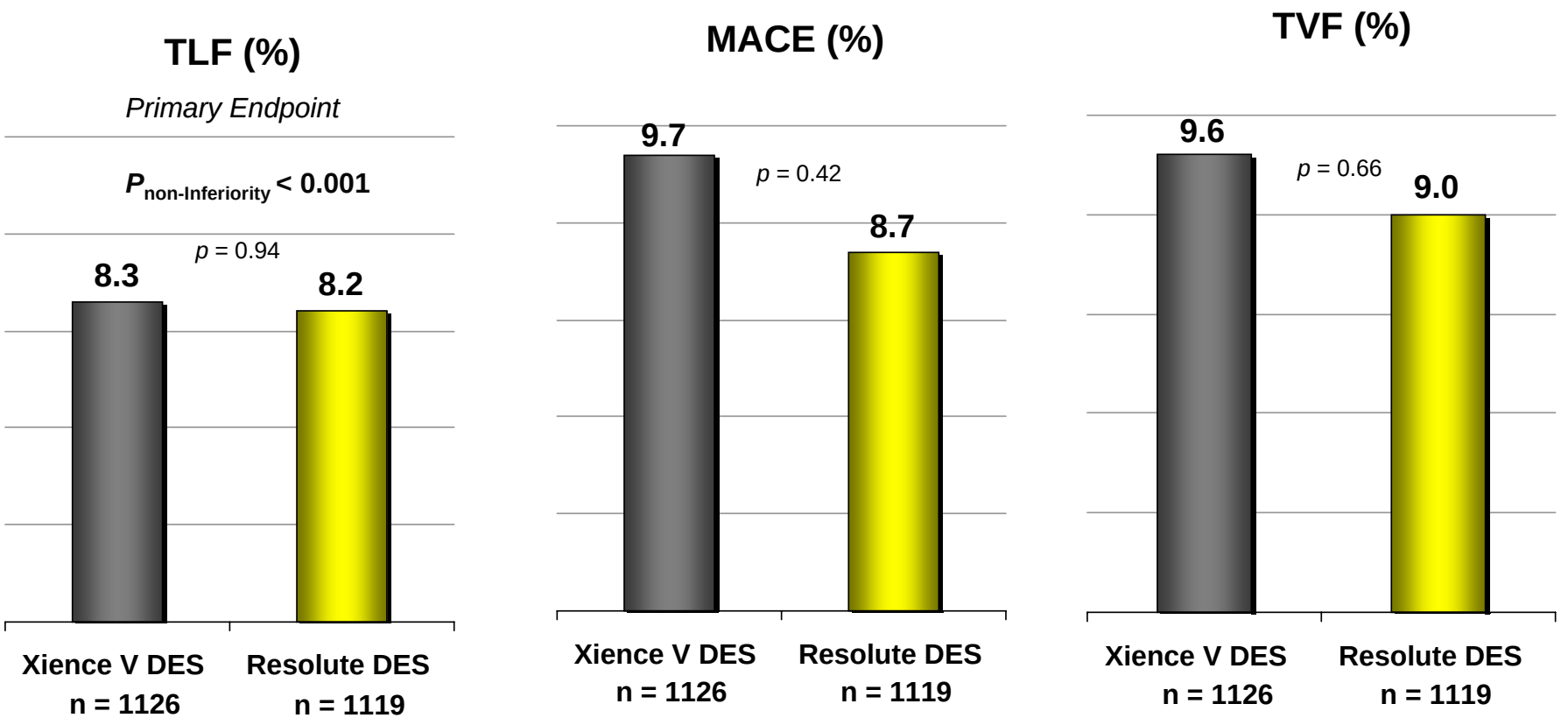
Resolute DES Is Numerically Lower in Composite Endpoints



TLF = Cardiac death, target vessel MI, clinically indicated TLR.
Noninferiority *p*-value calculated based on a prespecified noninferiority margin of 3.5%.
Other *p*-values are based on Fisher's Exact Test and are unadjusted for multiple comparisons.
RESOLUTE All Comers was not specifically designed or powered to individually compare MACE and TVF.

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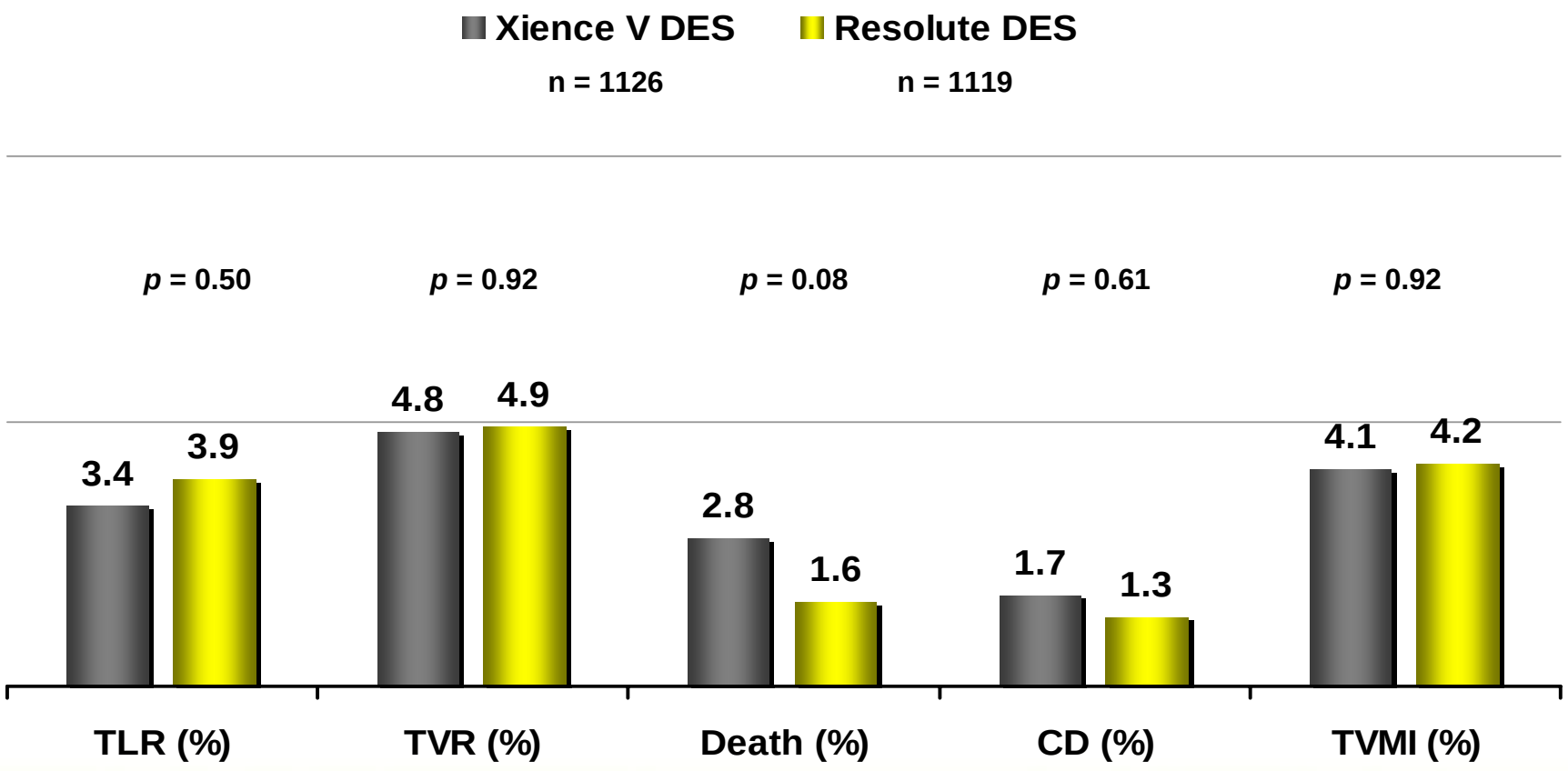
Resolute DES Shows Excellent Performance Across All Clinical Efficacy and Safety Endpoints



p-values are based on Fisher's Exact Test.
p-values for outcome differences are unadjusted for multiple comparisons.
RESOLUTE All Comers was not specifically designed or powered to individually compare endpoints shown above.

RESOLUTE All Comers

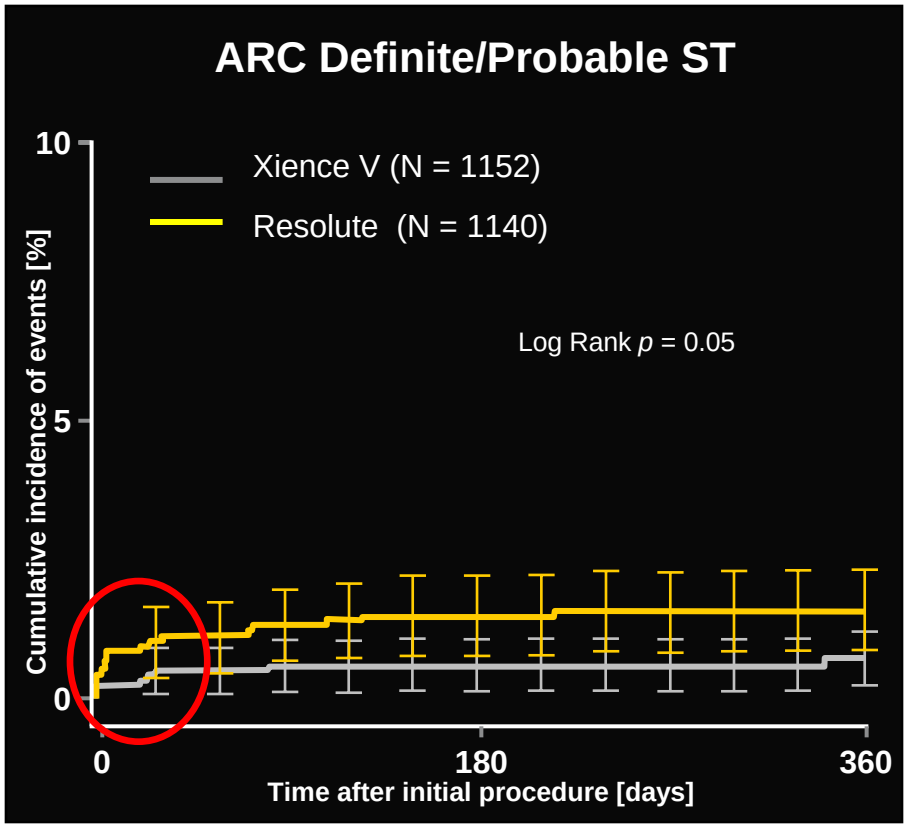
No Significant Difference in Stent Thrombosis

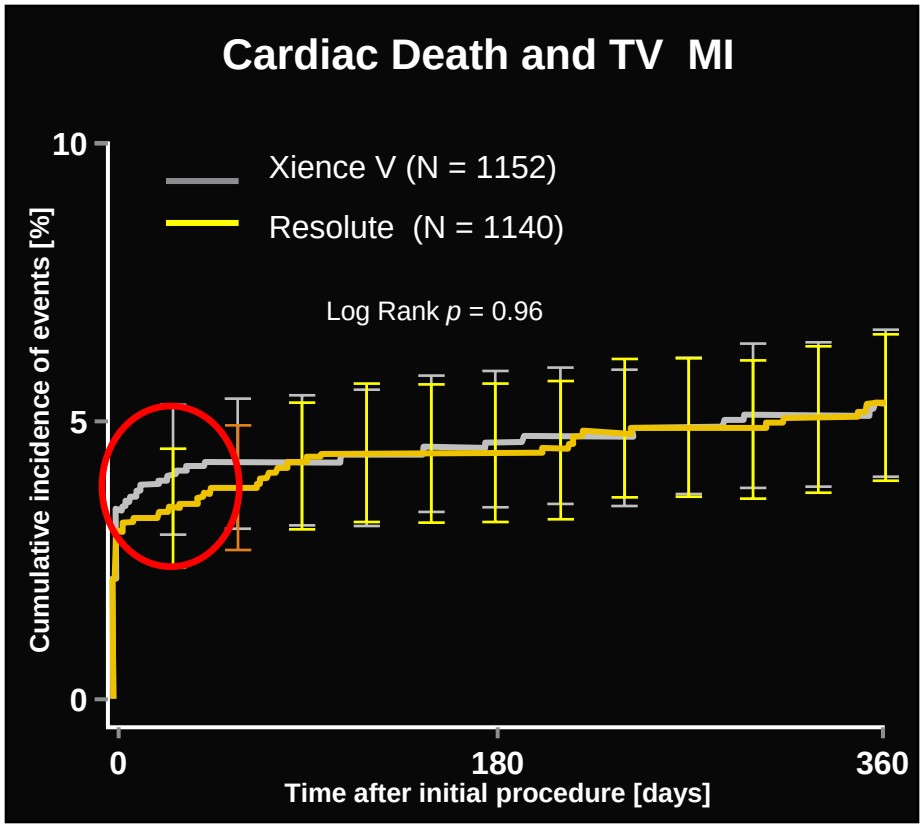
- Overall rates of ARC def/prob ST were low for an all-comer trial
- No significant difference in late ST between Resolute and Xience V DES
- Resolute overall ST rate driven primarily by early events and not statistically different vs. Xience V DES
  - 56% of Resolute ST occurred within 5 days of procedure
- Stent thrombosis had no effect on CD/TVMI rate at 12 months

ST (ARC Def/Prob)	Acute (0–1 day)	Subacute (2–30 days)	Late (31–360 days)	All
Resolute DES (%)	**0.4**	**0.7**	**0.6**	**1.6**
Xience V DES (%)	**0.2**	**0.4**	**0.2**	**0.7**
***p*-value**	*NS*	*NS*	*NS*	*NS*

p-values are based on Fisher's Exact Test.
p-values for outcome differences are unadjusted for multiple comparisons.
Per protocol, a statistical difference was declared if the two-sided *p*-value was less than 0.05
RESOLUTE All Comers was not specifically designed or powered to individually compare endpoints shown above.

Early Stent Thrombosis Events Did Not Translate to Differences in CD/TVMI Rates





Error bars indicate a point-wise two-sided 95% confidence interval (±1.96*SE). Standard Error based on the Greenwood Formula.
p-values for outcome differences are unadjusted for multiple comparisons.

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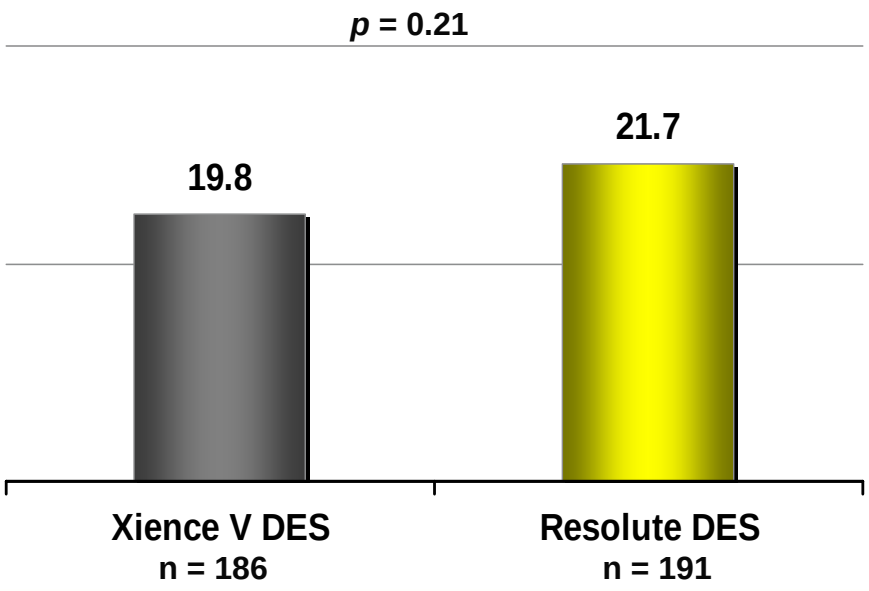
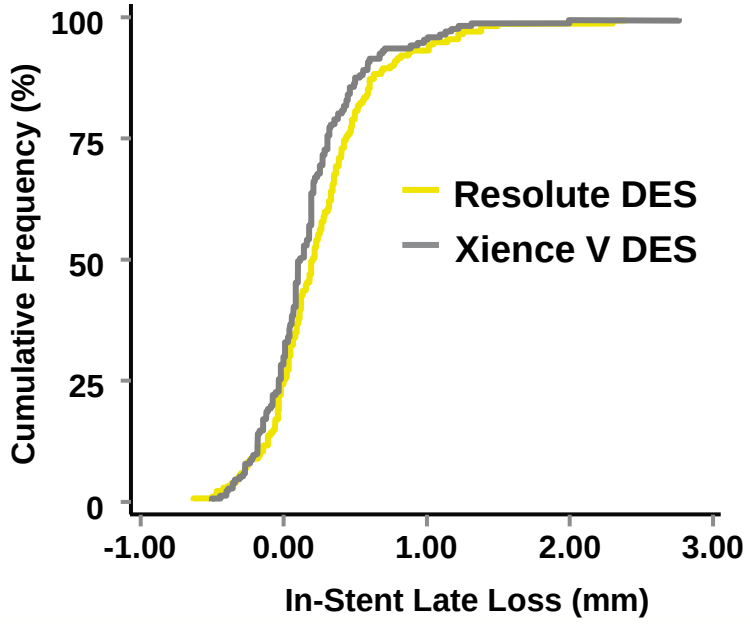
No Significant Difference in Diameter Stenosis or In-Stent Late Loss at 13 months

In-Stent Diameter Stenosis (%)
Powered secondary endpoint
$p_{nonInferiority} = 0.035$



In-Stent Late Loss and Distribution

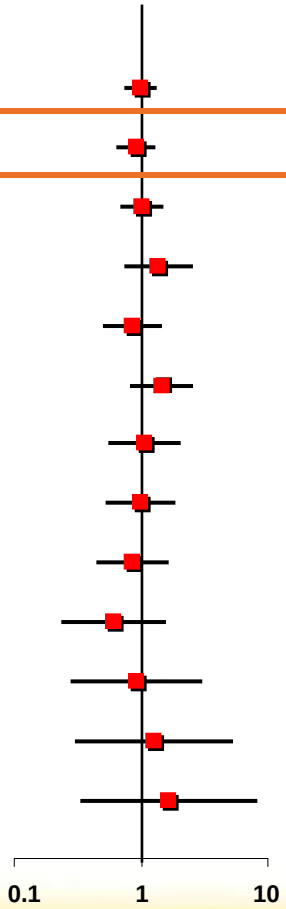
In-stent Late Loss:
Resolute 0.27 mm vs. Xience V 0.19 mm ($p = 0.08$)



Noninferiority *p*-value calculated based on a prespecified noninferiority margin of 5%
Other listed *p*-values are based on t-test and are unadjusted for multiple comparisons.
RESOLUTE All Comers was not specifically designed or powered to compare late loss at 13 months.

Complex Patients Make Up the Largest Subset

Prespecified Subgroups	TLF Odds Ratio [95% CI]	Odds Ratio [95% CI]	*p* value
All Patients (n = 2292)		0.98 [0.73, 1.33]	*NS*
Complex patients (n = 1520)		0.91 [0.64, 1.29]	*NS*
Small vessels ≤2.75 mm (n = 1308)		1.01 [0.69, 1.48]	*NS*
Acute MI (within 72 hr) (n = 662)		1.36 [0.73, 2.57]	*NS*
Multivessel treatment (n = 570)		0.85 [0.50, 1.47]	*NS*
Diabetes (n = 538)		1.45 [0.82, 2.58]	*NS*
Overlapping stents (n = 411)		1.06 [0.55, 2.05]	*NS*
Bifurcations (n = 392)		0.99 [0.52, 1.87]	*NS*
Long lesions >18 mm (n = 381)		0.86 [0.44, 1.67]	*NS*
In-Stent restenosis (n = 182)		0.61 [0.24, 1.57]	*NS*
Renal insufficiency (n = 80)		0.91 [0.28, 3.02]	*NS*
Bypass graft (n = 56)		1.25 [0.30, 5.26]	*NS*
Left Main (n = 54)		1.65 [0.33, 8.21]	*NS*



p-values are based on Fisher's Exact Test. *p*-values for outcome differences are unadjusted for multiple comparisons.
RESOLUTE All Comers was not specifically designed or powered for patient subsets listed above

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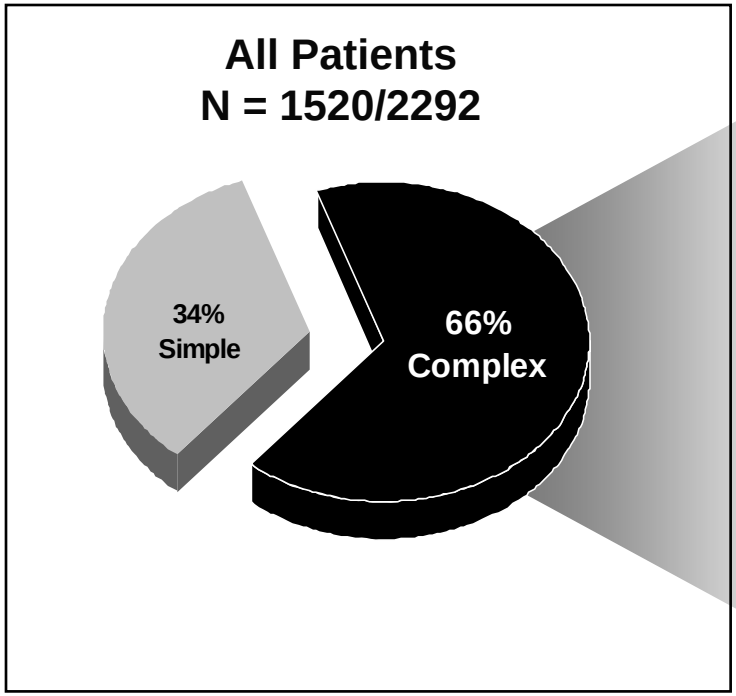
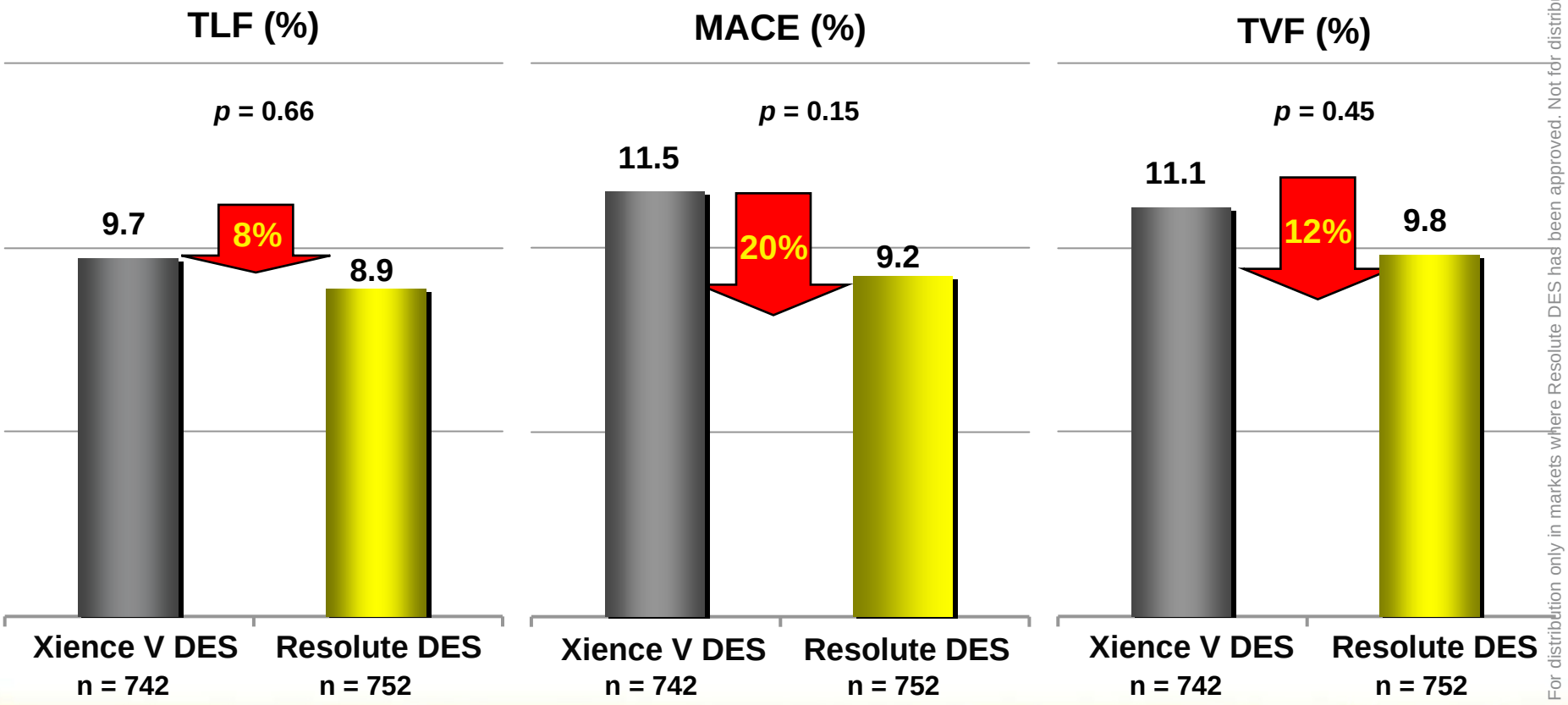
Almost 70% of RESOLUTE All Comers Patients Are Complex



Patient Characteristics	Resolute DES N = 1140 (%)	Xience V DES N = 1152 (%)	*p*-Value
Complex	67.0	65.6	*NS*
AMI (within 72 hr)	28.9	28.8	*NS*
Multivessel treatment (>2)	25.1	24.7	*NS*
Renal insufficiency	4.0	3.1	*NS*
ISR	8.1	8.0	*NS*
Bifurcation	16.9	17.7	*NS*
Unprotected left main	1.6	1.3	*NS*
Bypass graft	2.5	2.4	*NS*
LVEF <30%	2.8	2.1	*NS*
Long lesion (>27 mm)	5.7	6.0	*NS*
Total occlusion	16.3	17.2	*NS*
>1 lesion per vessel	16.4	17.7	*NS*
Thrombus lesion	7.4	6.9	*NS*

With the exception of long lesions (treatable with a single 38-mm length stent), Resolute DES currently is not specifically approved for the patient subsets noted in this complex patient definition.

Resolute DES Shows Strong Performance in Complex Patients



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International Multicentre DES Clinical Trial
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A strong choice for complex daily practice
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