Endeavor Resolute

A New Generation DES

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Summit TCT Asia, Seoul, April 2009

Unmet Clinical Needs in DES Era

- Diabetic vascular disease
  - (Colombo et al AJC, 2006)
- Diffuse/Multi vessel disease
  - (Colombo et al TCT 2005)
- Chronic renal failure
  - (Waksman et al CCI, 2006)
- Chronic Total Occlusions
  - (Abbas et al AJC, 2005)
- Left Main/Ostial disease
  - (Tierstein et al ACC 2006)

Unmet Clinical Needs in the DES era

TLR and MACE rates remain high in patients at the highest clinical risk of TLR

Diabetics

- 20% MACE @ 2 yr – STENT Group Database, *Stuckey, PCR 2008*
- 23.2% TLR @ 5 yr – Diabetes-where are we?, *Banning, PCR 2008*

Small Vessels

- 12.8% MACE @ 9 mo – TAXUS ATLAS Small Vessel – *Turco, TCT 2007*

Multi-Vessel Disease

- 17.6% MACCE @ 3 yr – Long Term Follow Up After Multivessel DES, *Bruyne, TCT 2007*
- 13.8% TLR @ 8 mo— What's Now: Cypher, Moses, *DES Summit 2008*

RESOLUTE Study Objectives

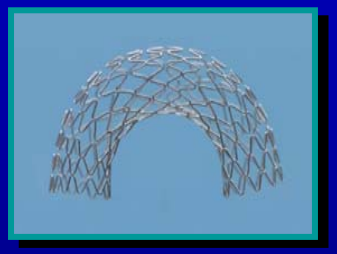
- Improve clinical outcomes in more complex lesions
- Maintain current safety profile seen with Endeavor DES

By

- Extending the drug elution to match the potentially delayed healing times of complex lesions
- Combat the sustained stimulus to the proliferative response

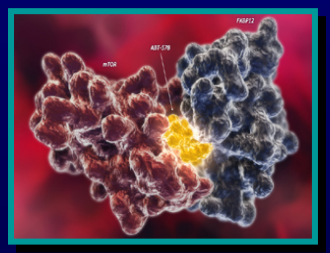
Endeavor RESOLUTE Drug Eluting Stent System

Retains three components of the Endeavor Coronary Stent System



Driver Cobalt Chromium Stent

Endeavor Delivery System



Zotarolimus Antiproliferative Drug

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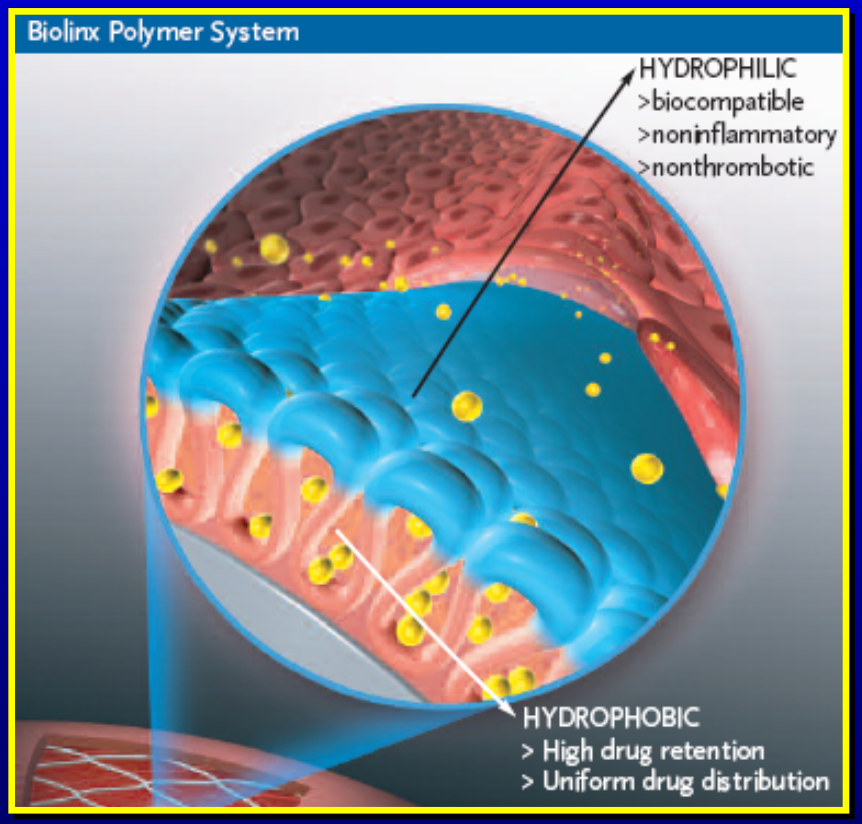
BioLinx Polymer



Components of a safe polymer:

- **Mimics the body's chemistry**
- **Allows reliable drug elution**
- **Compatible with stent delivery**

Biocompatible BioLinx polymer system design:

- **Non-inflammatory and non-thrombotic**
- **Rapid and functional endothelial healing**

A biostable polymer that applies the basics of membrane structure will provide sustained drug elution over time while maintaining biocompatibility

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The BioLinx Polymer System

C10 Polymer

Based primarily on hydrophobic butyl methacrylate to provide adequate hydrophobicity for zotarolimus

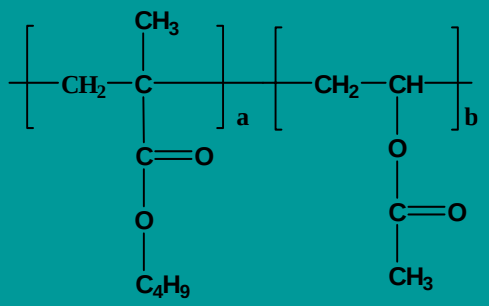
C19 polymer

Manufactured from a mixture of hydrophobic hexyl methacrylate and hydrophilic vinyl pyrrolidinone and vinyl acetate to provide enhanced biocompatibility

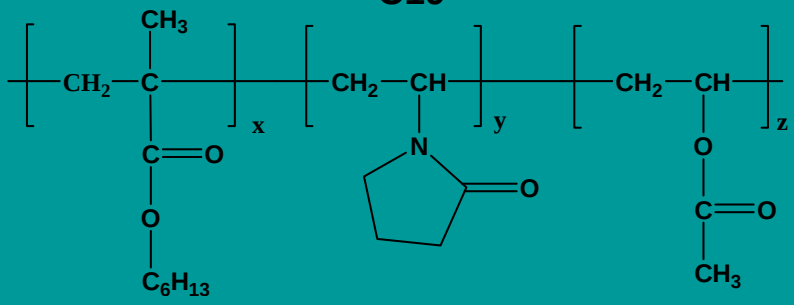
Polyvinyl pyrrolidinone (PVP)

Hydrophilic polymer increases initial drug burst and enhances biocompatibility

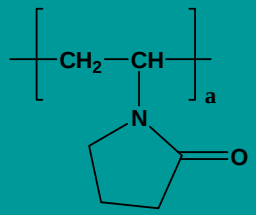
C10



C19



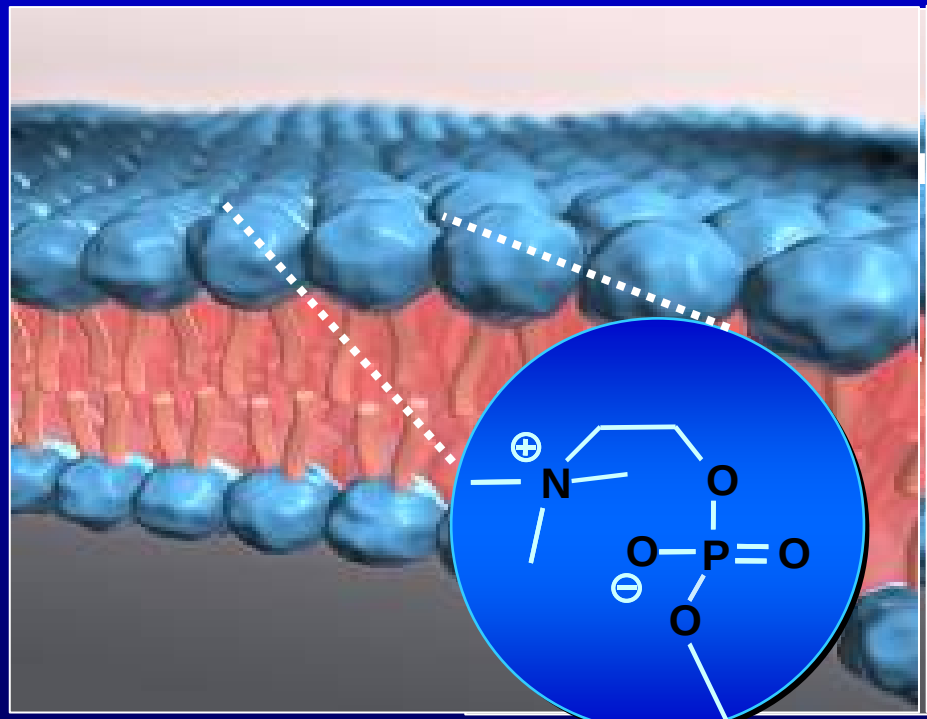
PVP



Medtronic Polymer Technologies

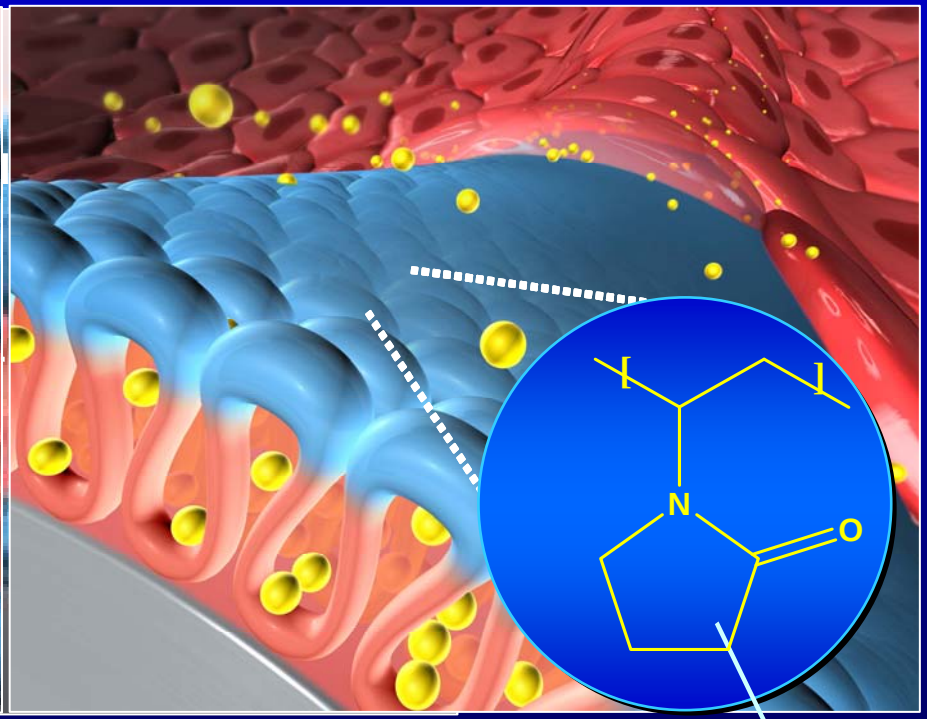
PC and BioLinx Polymers

Endeavor: **PC Technology**



Hydrophilic
Phosphorylcholine
(PC) Headgroup

Endeavor Resolute: **BioLinx**



Hydrophilic
Vinyl pyrrolidinone
groups

Both PC and BioLinx mimic the body's chemistry and are biocompatible.

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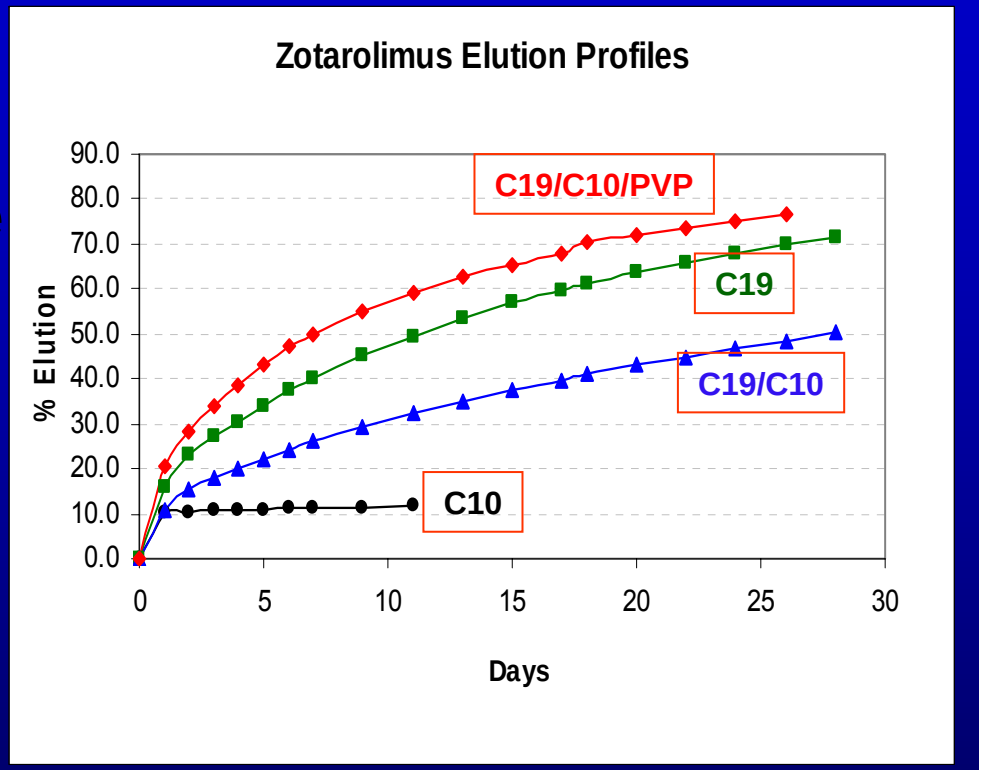
Drug Elution Control

- **C10 polymer** is lipophilic/hydrophobic and aids in control of drug release, alone it locks in the drug
- **C19 polymer** is primarily hydrophilic making it more biocompatible and aids in drug elution
- **PVP** is hydrophilic, increases the initial drug burst and enhances the elution rate



The BioLinx Polymer System blends C10, C19 and PVP for optimum elution

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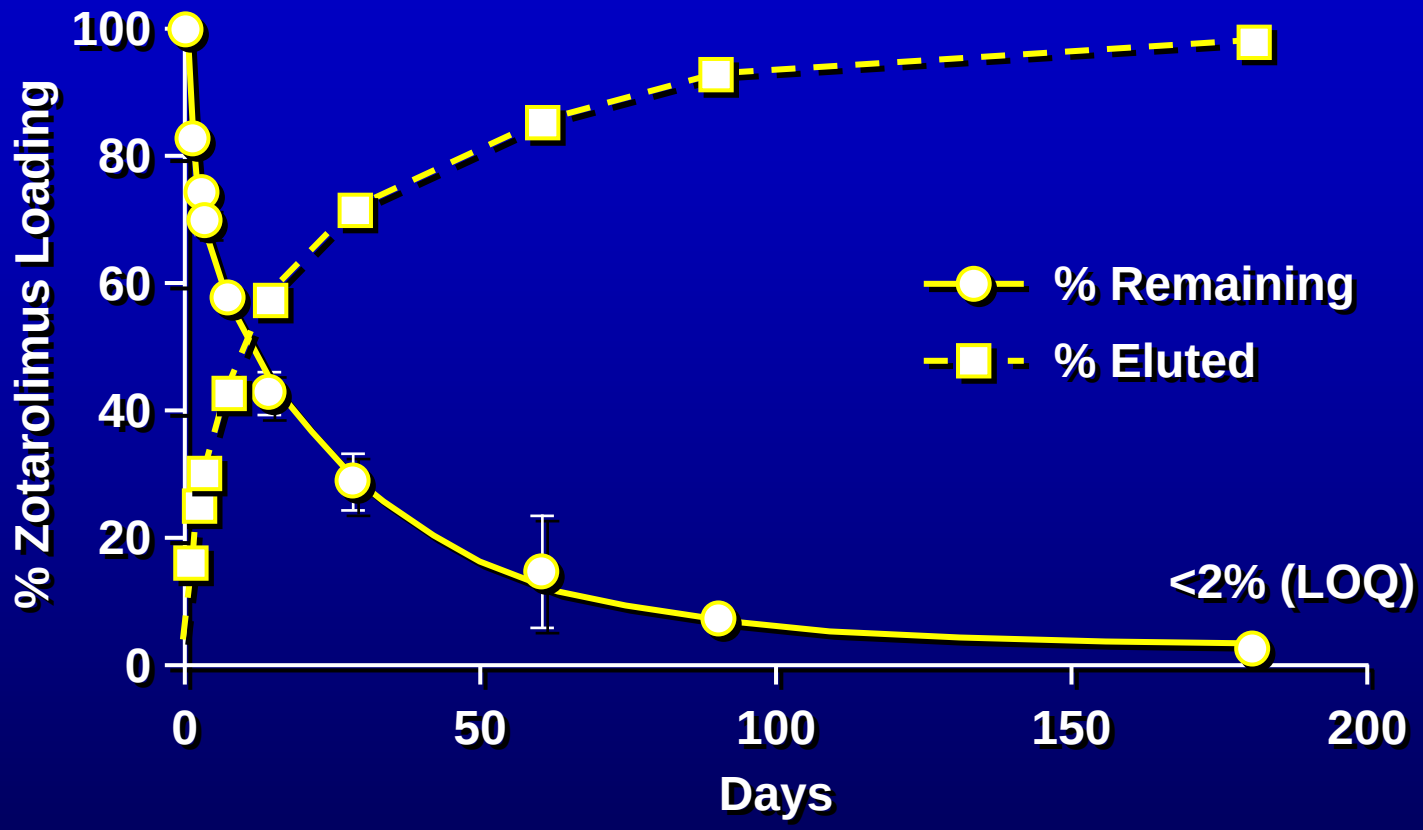
BioLinx Polymer in vivo Elution



Greater than 85% of the drug is eluted at 60 days
Complete drug content exhausted by 180 days

Carter et al TCT 2006

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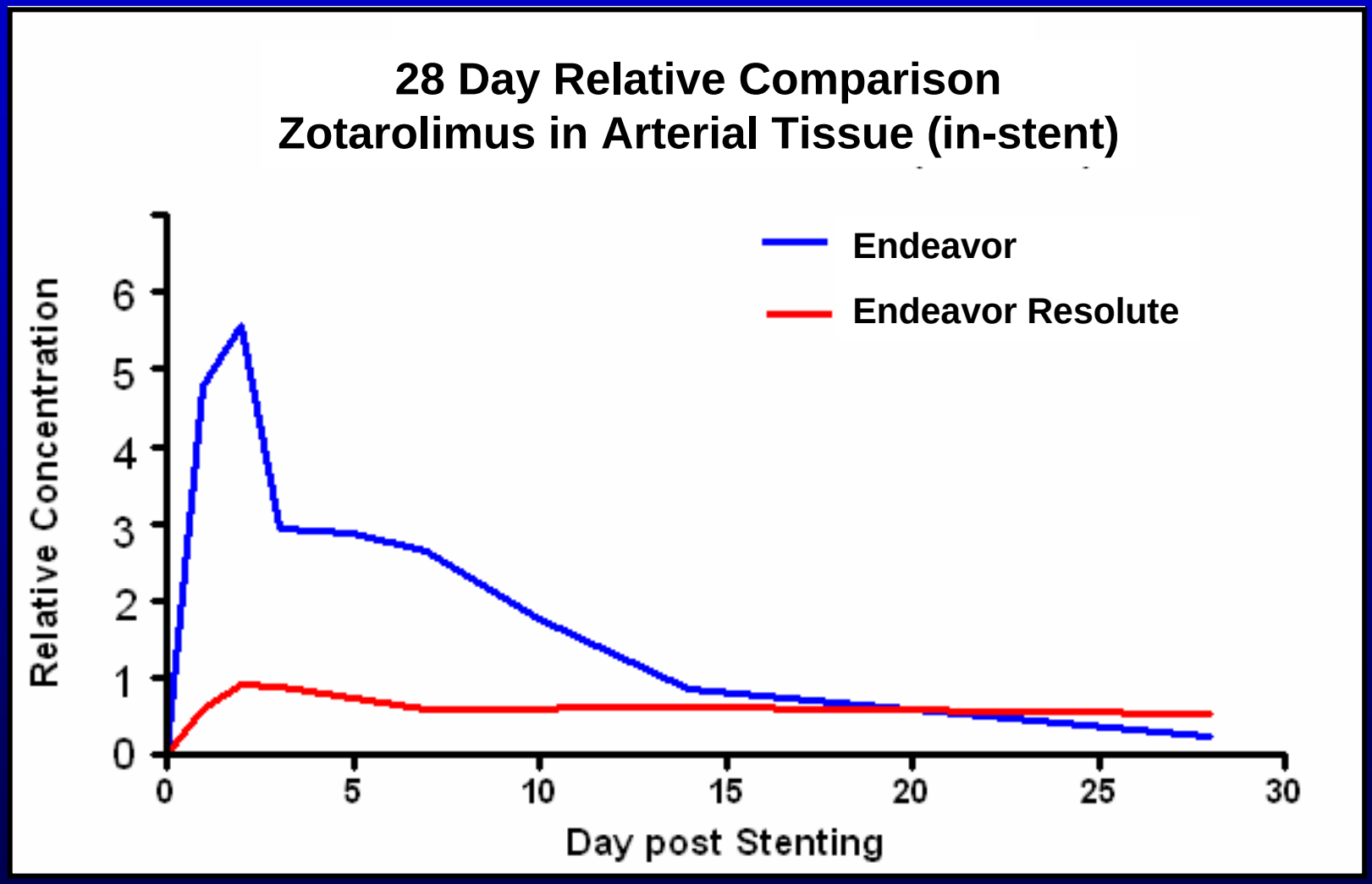
In-Vivo Tissue Concentration vs Endeavor



Data on file at Medtronic, Inc.

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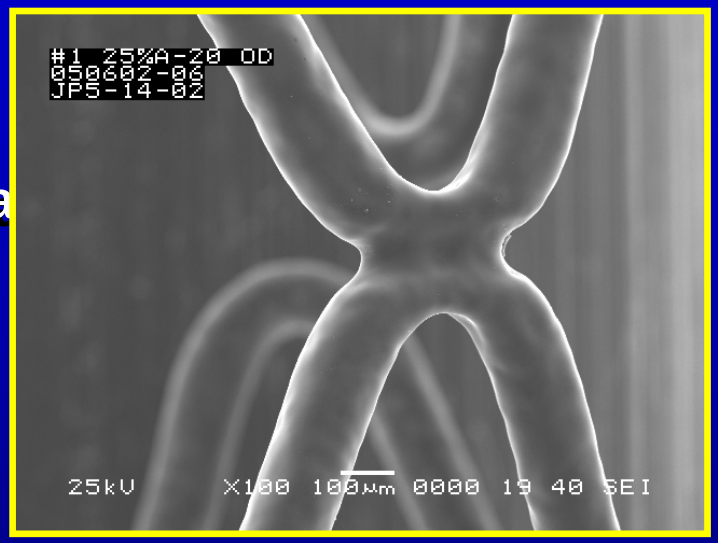
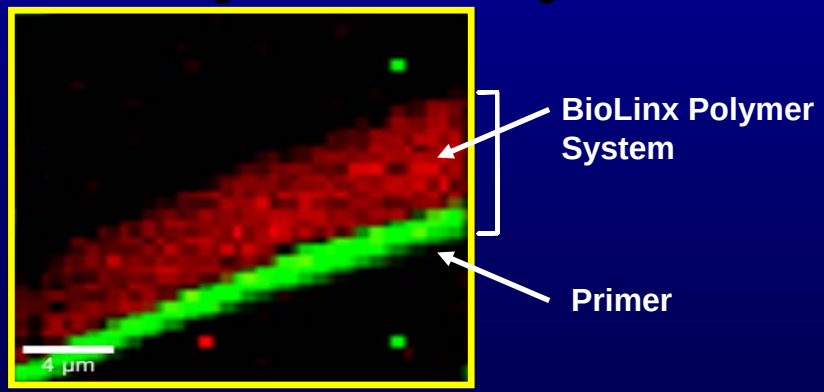
BioLinx Designed as Robust & Durable

BioLinx Polymer System provides a durable & robust coa



A deployed stent after tracking 3 times in a 5 Fr guide catheter*

The stent surface is primed to improve adhesion of the BioLinx Polymer System



Atomic Force Microscopy (AFM) studies indicate that the interface between the BioLinx Polymer System and the primer is very strong*

Polymer Performance Requirements

Biodegradation
Kinetics / Products

Solubility

Biocompatibility

Durability

Hydrophilicity

Biocompatibility

Hydrophobicity

Sterilizability

Packaging
Requirements

Biocompatibility

Stability

Drug Elution
Rate

Polymer Blend

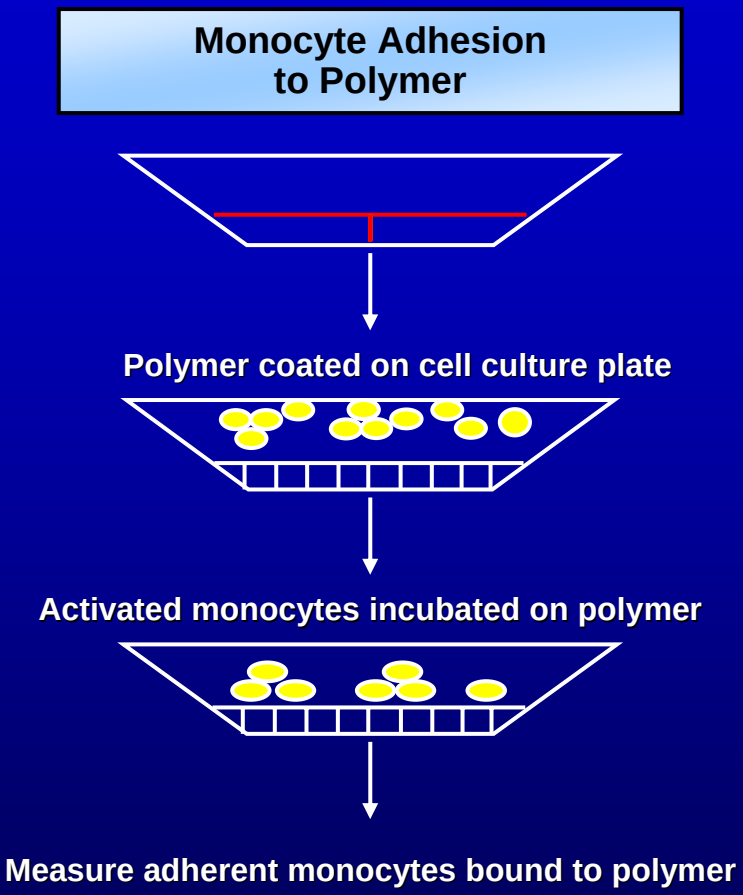
Biocompatible Polymer → Product Safety

Polymer Biocompatibility

- An ideal polymer would not provoke an inflammatory response such as monocyte binding and the release of chemotactic factors and cytokines.

Carter et al. American Journal of Drug Delivery. 2003;1:157.

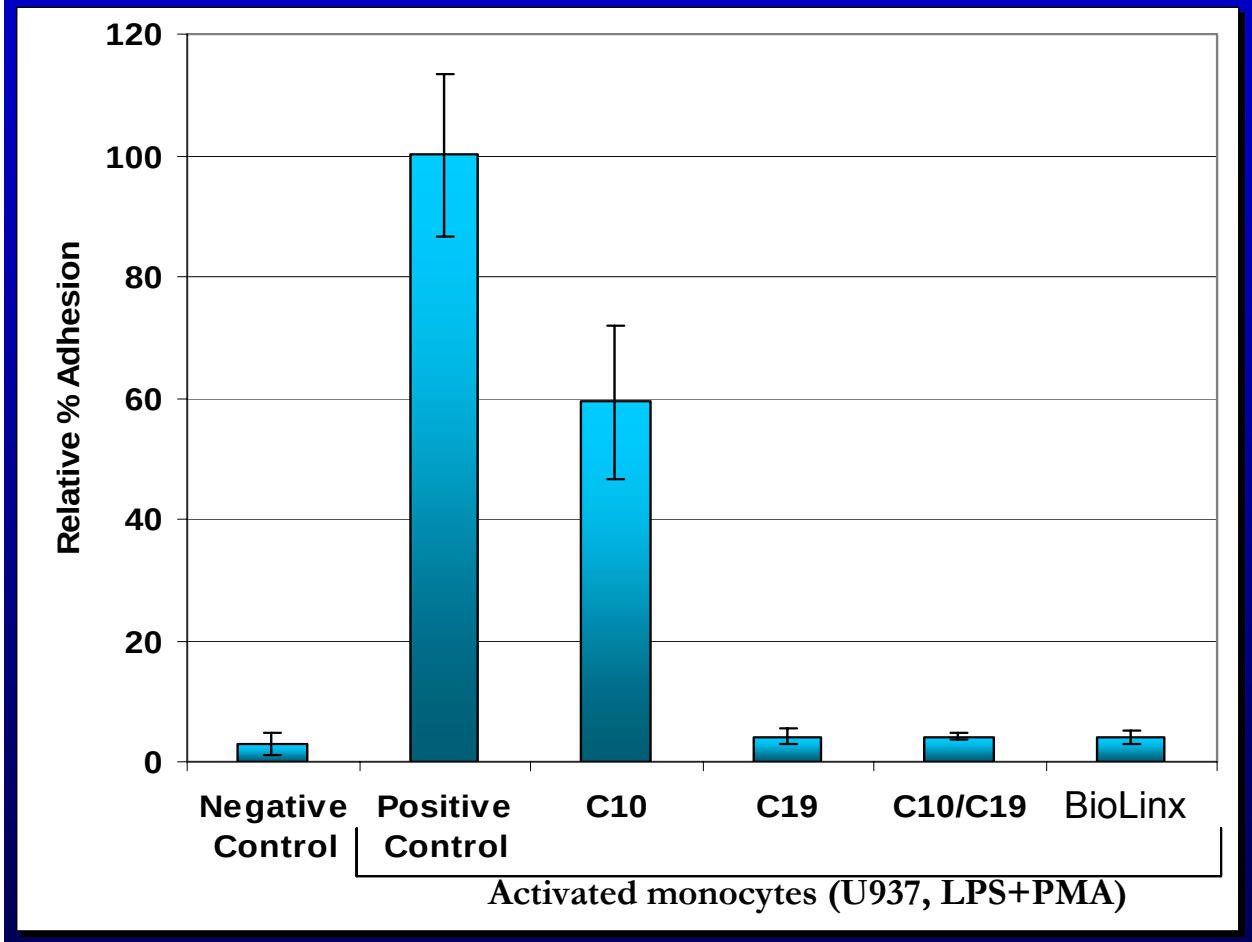
Inflammatory Profiling of Polymer Coatings



- Neutrophil-platelet and monocyte-platelet aggregates have been identified in the peripheral blood of patients with coronary artery disease and may be markers of disease activity.[1,2]
- Numerous human histopathological studies in which leukocytes, mainly of the monocyte lineage, have been identified at all stages of development of the atherosclerotic plaque, from fatty streaks to mature atheroma.[3]

1. Ott I, Neumann FJ, Gawaz M, Schmitt M, Schomig A. Increased neutrophil-platelet adhesion in patients with unstable angina. *Circulation*. 1996;94:1239–1246.
2. Furman MI, Benoit SE, Barnard MR, Valeri CR, Borbone ML, Becker RC, Hechtman HB, Michelson AD. Increased platelet reactivity and circulating monocyte-platelet aggregates in patients with stable coronary artery disease. *J Am Coll Cardiol*. 1998;31:352–358.
3. Ross R. Atherosclerosis: an inflammatory disease. *N Engl J Med*. 1999;340:115–126.

Reduced Monocytic Adhesion to BioLinx Polymer System



Hydrophobic polymer (C10) induces the greatest inflammatory response

Hydrophilic polymer (C19) does not provoke an inflammatory response

The BioLinx polymer system (with a hydrophilic surface) maintains the favorable biocompatibility feature of the hydrophilic C19

Polymer	Contact Angle
C10	118^0
C19	91^0
C10 + C19 (30:70)	84^0
BioLinx	94^0

Activated monocytes do not bind to polymer blends containing C19

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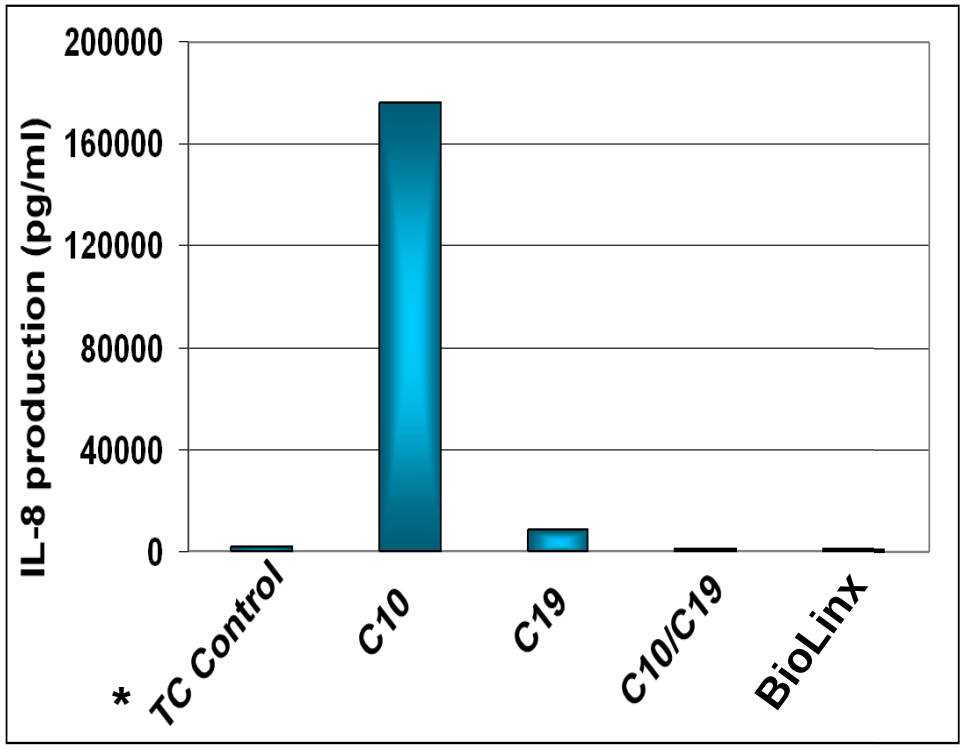
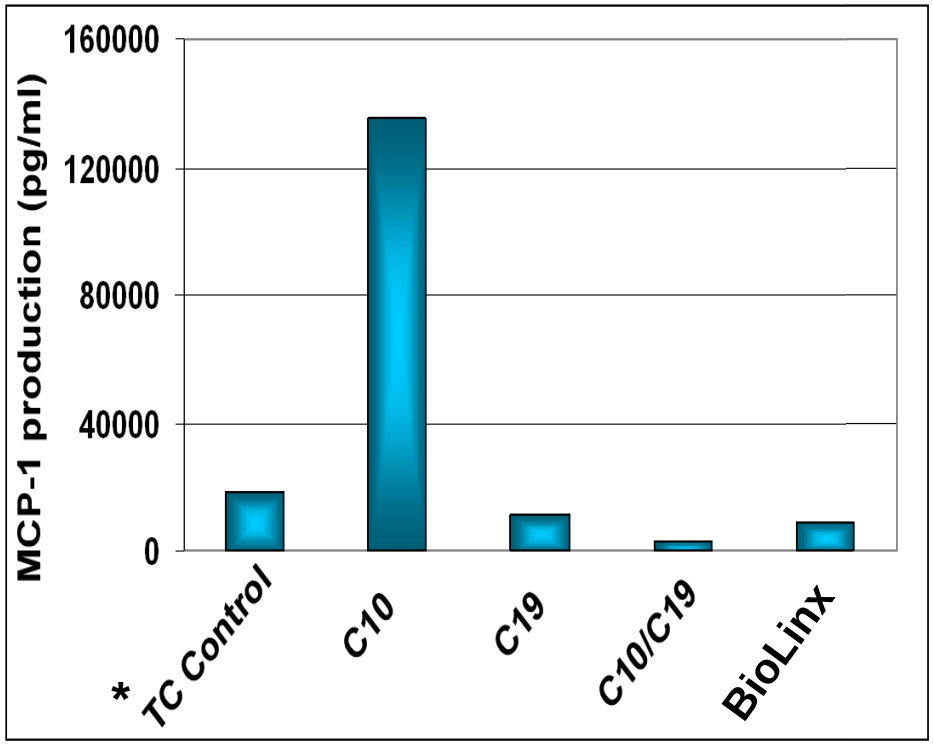
Cytokine Production by Monocytes

Interleukin-8



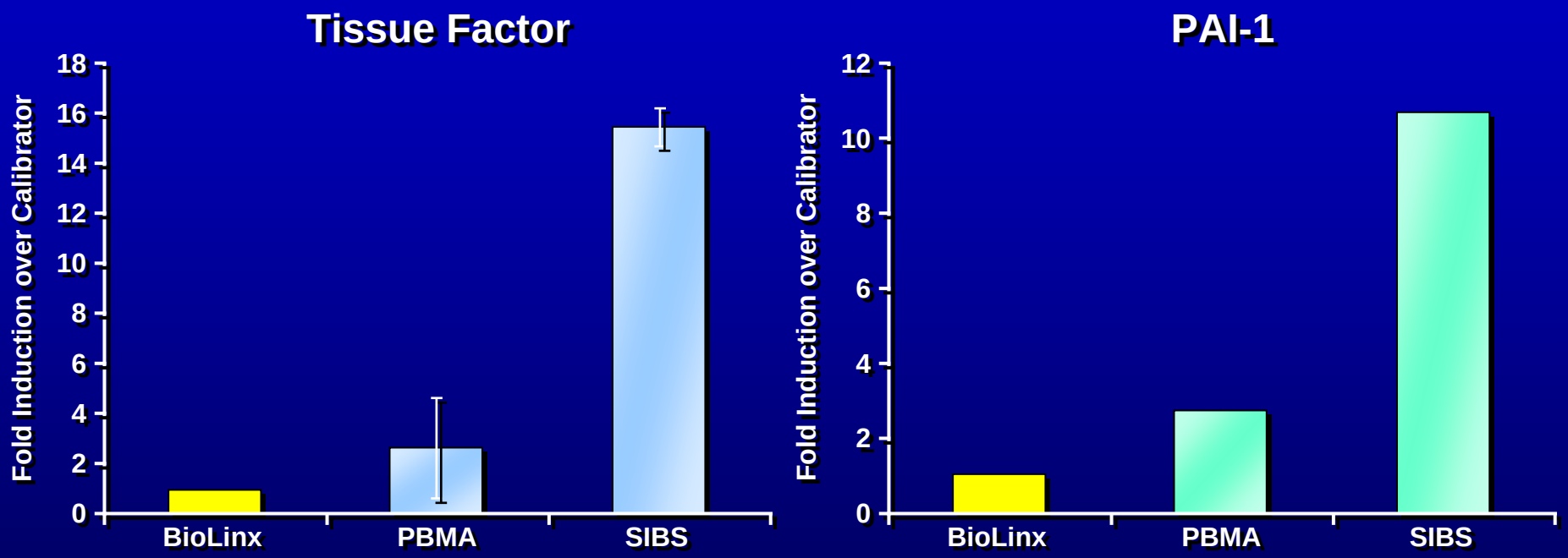
Monocyte Chemoattractant-1



Monocytes cultured on polymer blends containing the hydrophilic C19 release low levels of inflammatory cytokines into the cell culture media

* TC= Tissue Culture Polystyrene

Polymer Induced Up-Regulation of Prothrombotic Genes In Vitro



The BioLinx Polymer System does not exhibit increased induction of the prothrombotic genes Tissue Factor and PAI-1. Conversely, competitive DES polymers greatly induce the expression of these prothrombotic genes.

PBMA: Polybutyl methacrylate [Cypher cap coat]
SIBS: Styrene-Isobutylene-Styrene Triblock Copolymer [Taxus]

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In Vivo

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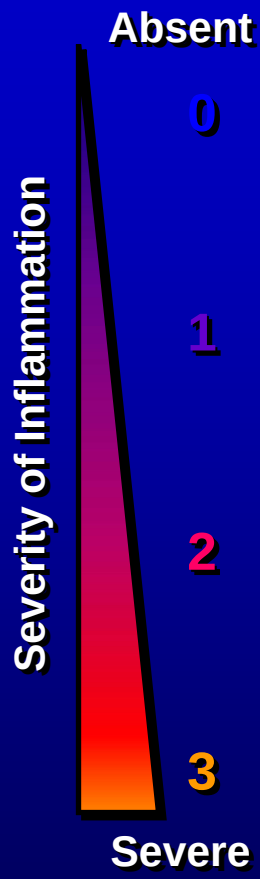
What Is an Inflammation Score?



0 3 or fewer struts with 10 or fewer inflammatory cells surrounding the struts

1 3 to 6 struts with 10 or fewer inflammatory cells surrounding the struts

2 Greater than 6 but less than 50% of the struts with 10 or fewer inflammatory cells surrounding the struts

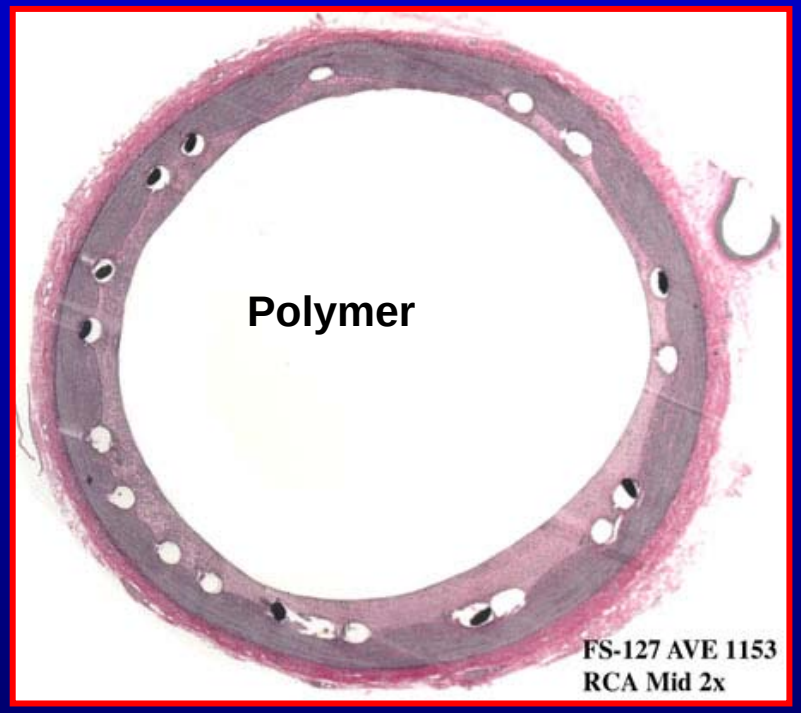
3 Greater than 10 inflammatory cells surrounding 50% or more struts

An inflammation score of 1 or less is highly desirable

Schwartz RS, et al. Preclinical evaluation of drug-eluting stents for peripheral applications: recommendations from an expert consensus group. Circulation 2004:110: 2498-2505.

Biocompatibility of the BioLinx Polymer

Porcine coronary artery implants at 28 days



Inflammation score 0.10 ± 0.21

Inflammation score 0.11 ± 0.38

Both BioLinx coated and bare metal Driver stents had low inflammatory scores

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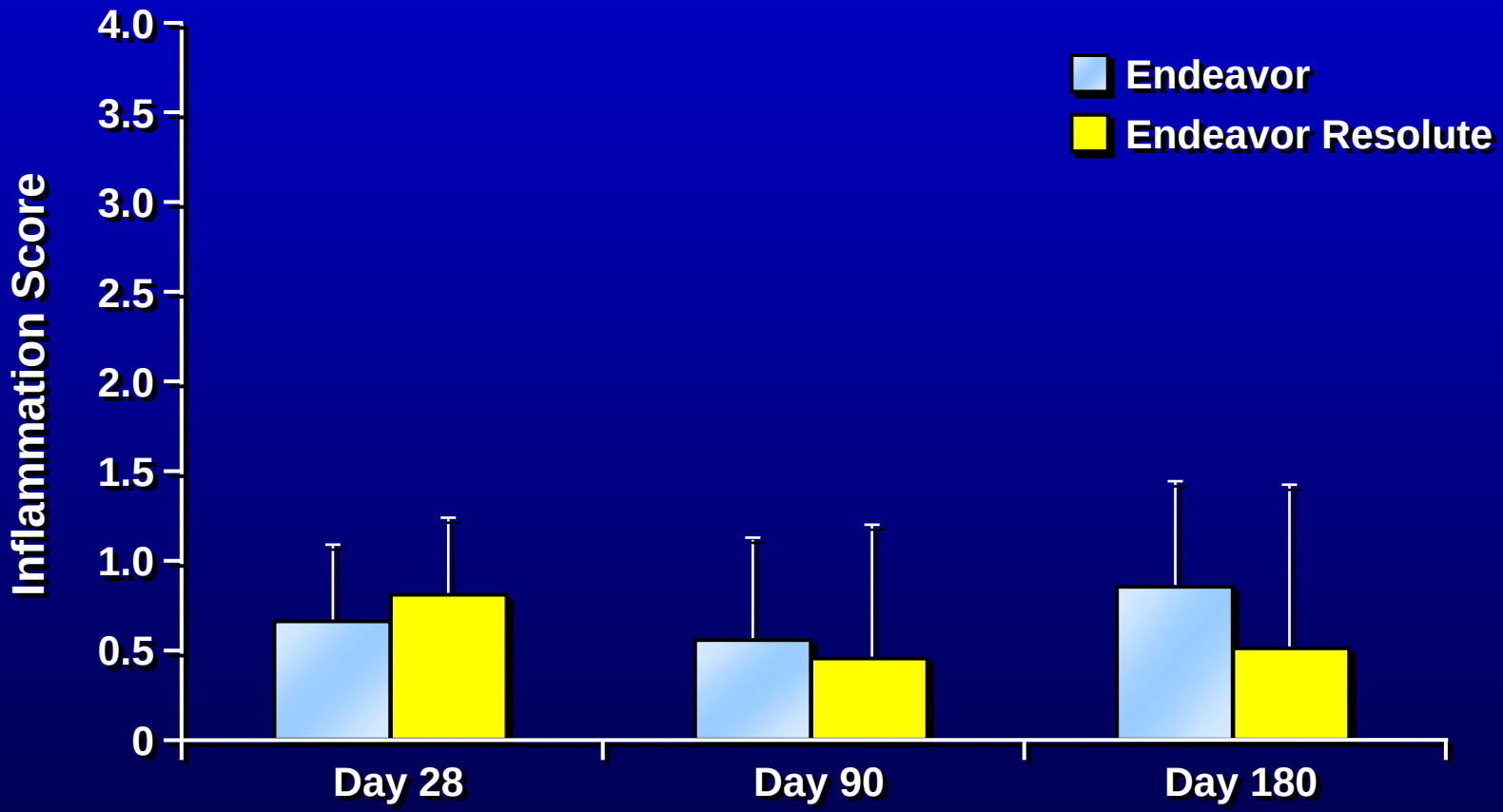
Equivalent Biocompatibility to Endeavor



Carter, A, In Vivo Performance of a Novel Co-polymer System for Extended Release of Zotarolimus in a Next Generation Drug Eluting Stent **TCT 2006**

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Biocompatibility of the BioLinx Polymer

Implant Group	% Struts with Fibrin	Fibrin Score	% Endothelial coverage	% Struts with Granuloma	% Struts with Giant Cells	% Struts with RBCs	Mean Inflamm Score
BioLinx Poly n=13	42.51±18.1	0.82±0.4	100.00±0.0	0.00±0.00	17.91±9.70	2.43±3.08	0.10±0.21
Bare Control n=12	34.58±18.6	0.67±0.4	100.00±0.0	0.29±1.01	17.70±9.99	3.77±7.70	0.11±0.38
p-value	0.29	0.30	n/a	0.31	0.96	0.57	0.95

No significant difference in inflammatory responses between BioLinx polymer coated stents and Driver

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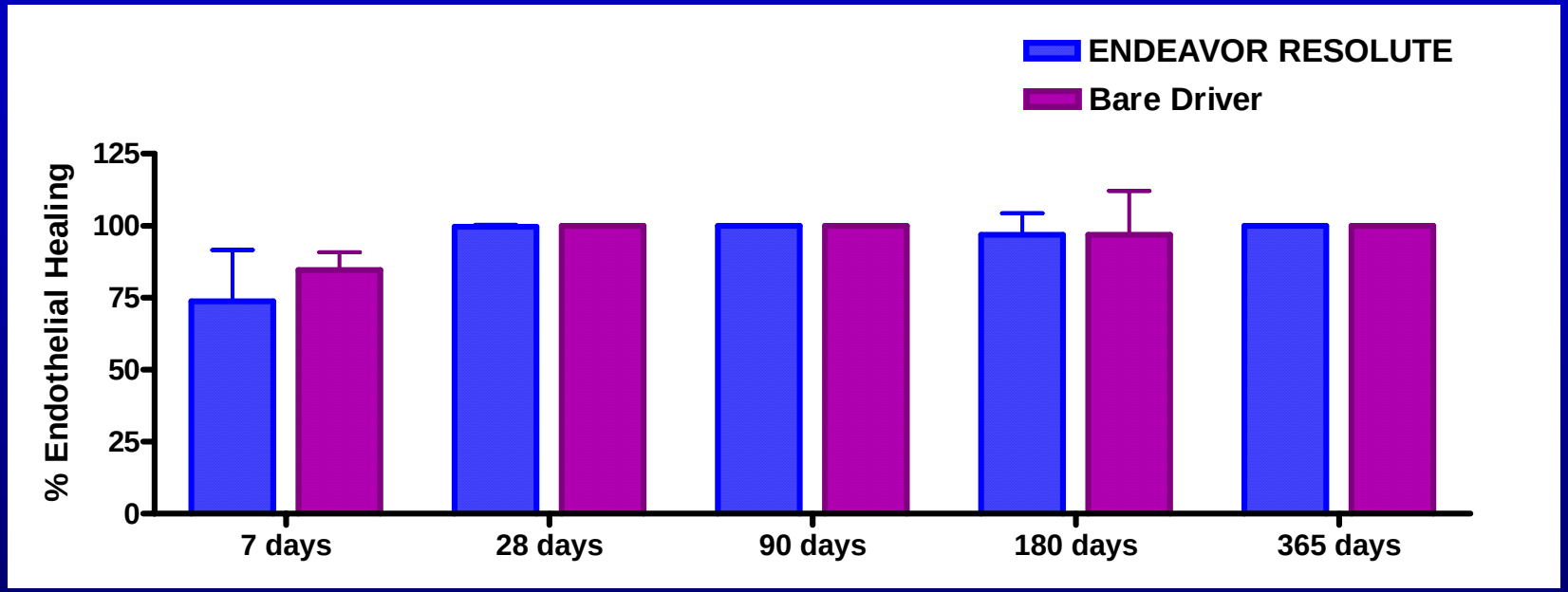
Endeavor Resolute Endothelial Healing

Complete endothelialization present after 28 days



Full endothelialization achieved by 28 days with no aneurysms, incomplete apposition, medial necrosis, late thrombosis or filling defects

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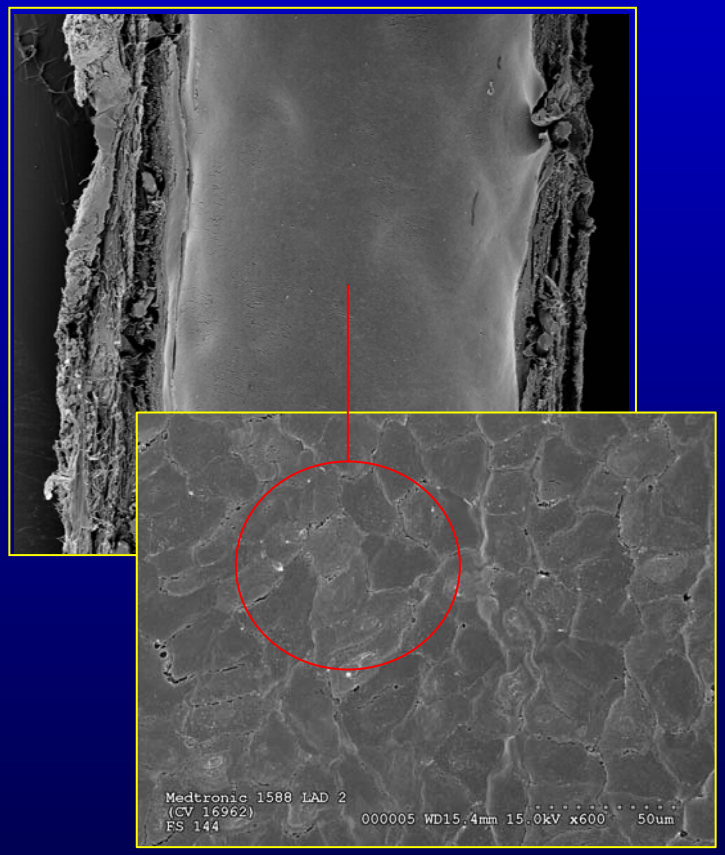
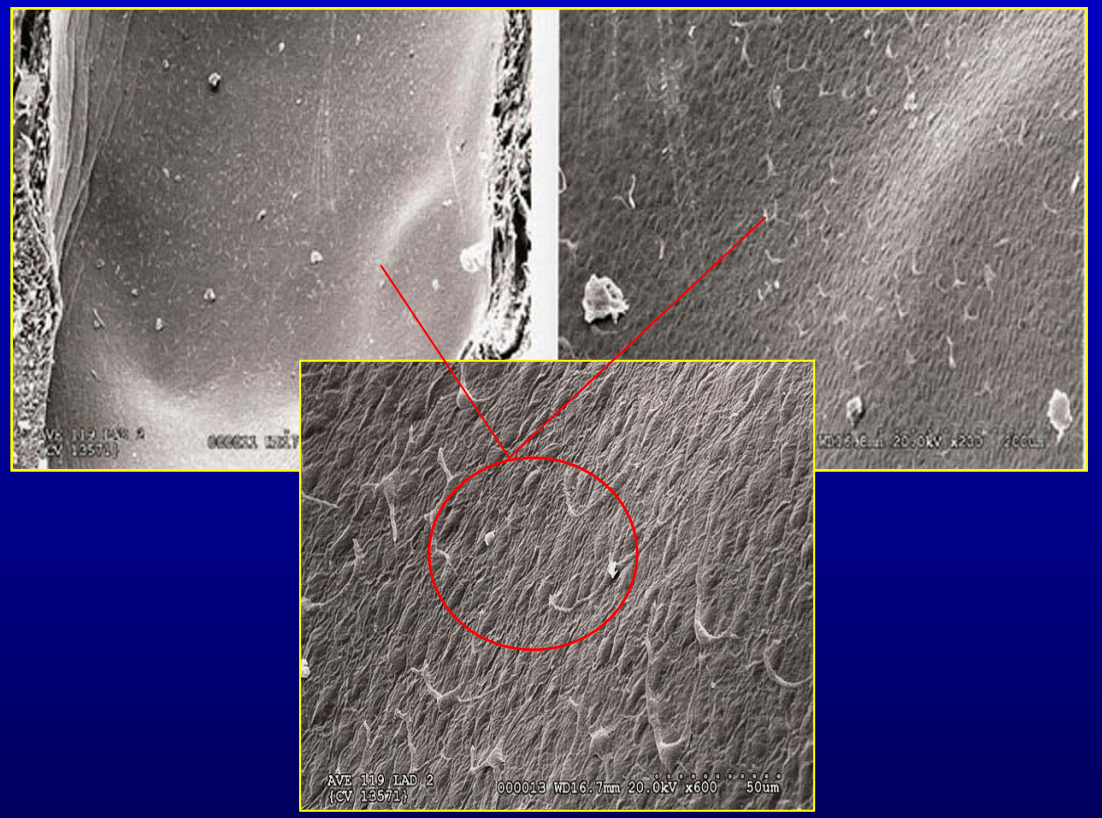
Endeavor Resolute Endothelial Healing

SEM Analysis

28 day Small Vessel Safety Study (FS144)



180 day Safety Study (FS129)



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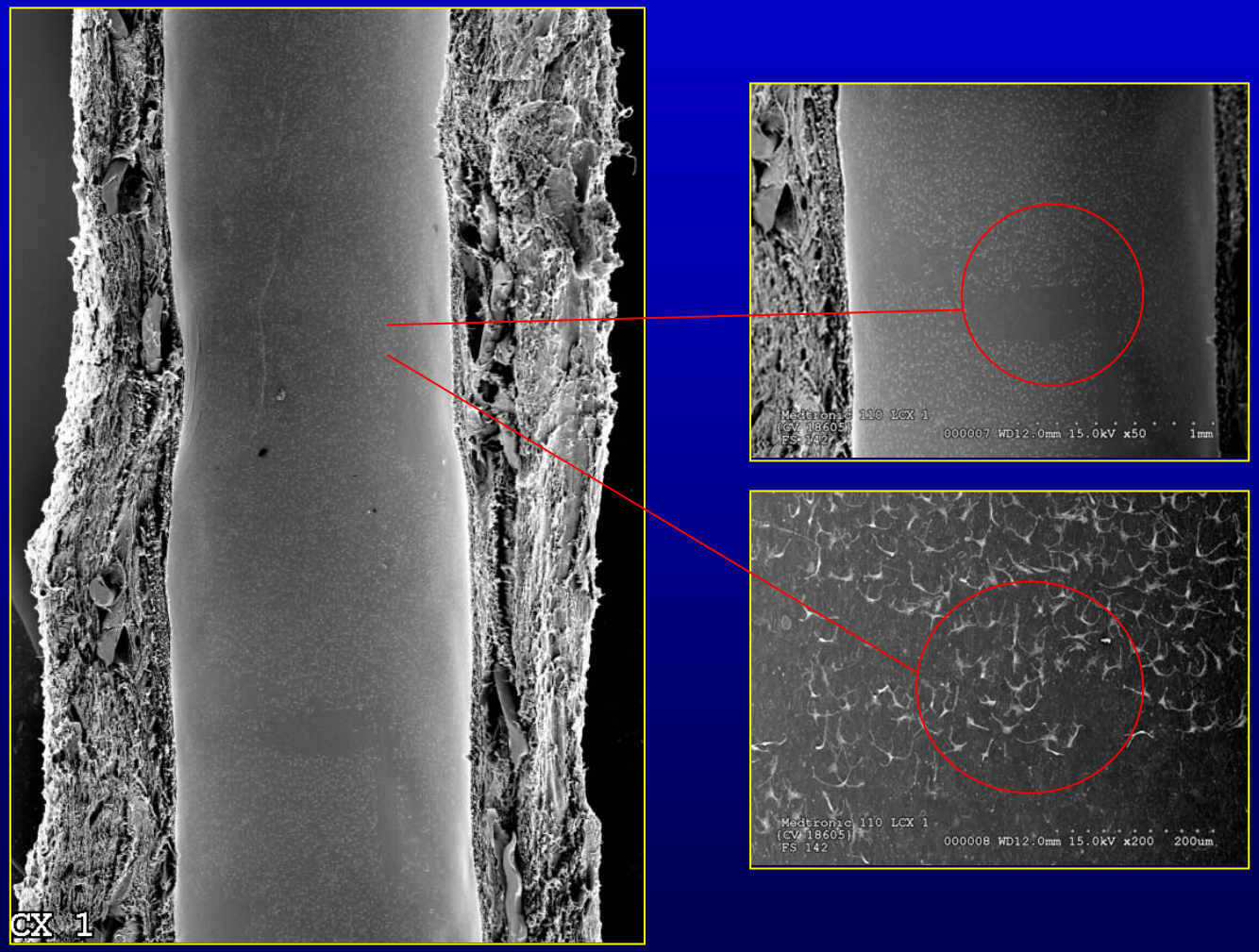
Endothelial Healing at 365 Days



Sequential SEM views showing confluent endothelialization of the luminal surface at 365 days.

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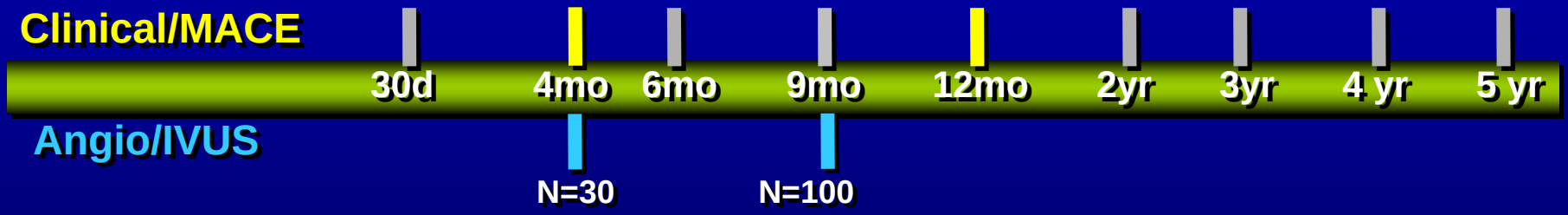
RESOLUTE Clinical Trial Design

Single *De Novo* Native Coronary Artery Lesions
Lesion Length: 14-27mm
Stent Diameters: 2.5, 3.0, 3.5mm
Stent Lengths: 18, 24, 30mm (8/9mm bailout)
Drug Dose: 1.6 μg/mm^2 stent surface area
Antiplatelet therapy for 6 months
Pre-dilatation required

Endeavor Resolute Stent

130 Patients (9 additional PK Sub-Study Patients enrolled after original 130 patients)
12 Sites (New Zealand and Australia)



Primary Endpoint: Late lumen loss (in-stent) at 9 mths by QCA

Secondary Endpoints: MACE at 30 days, 6, 9 and 12mths and IVUS and angiographic parameters at 9mths

30 pt Subset: 4mth MACE and angiographic, IVUS parameters*

*Meredith et al: EuroInterv 2007; 3:50-53

Resolute Investigational Centres

Investigator	Institution	n
Prof. Ian Meredith *	Monash Medical Centre	25
Prof. Stephen Worthley	Royal Adelaide Hospital	17
Dr. Rob Whitbourn	St. Vincent's Hospital (Melbourne)	13
Dr. Darren Walters	Prince Charles Hospital	13
Dr. Dougal McClean	Christchurch Hospital	12
Dr. Mark Horrigan	Austin Health Medical Center	12
Dr. John Ormiston	Auckland City Hospital	8
Dr. Gerry Wilkins	Dunedin Hospital	8
Dr. Randall Hendriks	Fremantle Hospital	7
Dr. Phillip Matsis	Wellington Hospital	7
Dr. John Ormiston	Mercy Hospital	4
A/Prof. David Muller	St. Vincent's Hospital (Sydney)	4

* Study Principal Investigator

*Meredith et al: EuroInterv 2007; 3:50-53

Core Labs

QCA Core Lab
Brigham and Women's Hospital, Boston, MA, USA
Jeffrey J. Popma, MD

IVUS Core Lab
Cardiovascular Core Analysis Lab
Stanford Interventional Cardiology, CA, USA
Peter Fitzgerald, MD

Data Coordinating Center
Harvard Clinical Research Institute, Boston, MA, USA
Donald Cutlip, MD, MSc

Clinical Events Committee/DSMB
Harvard Clinical Research Institute, Boston, MA, USA
Donald Cutlip, MD

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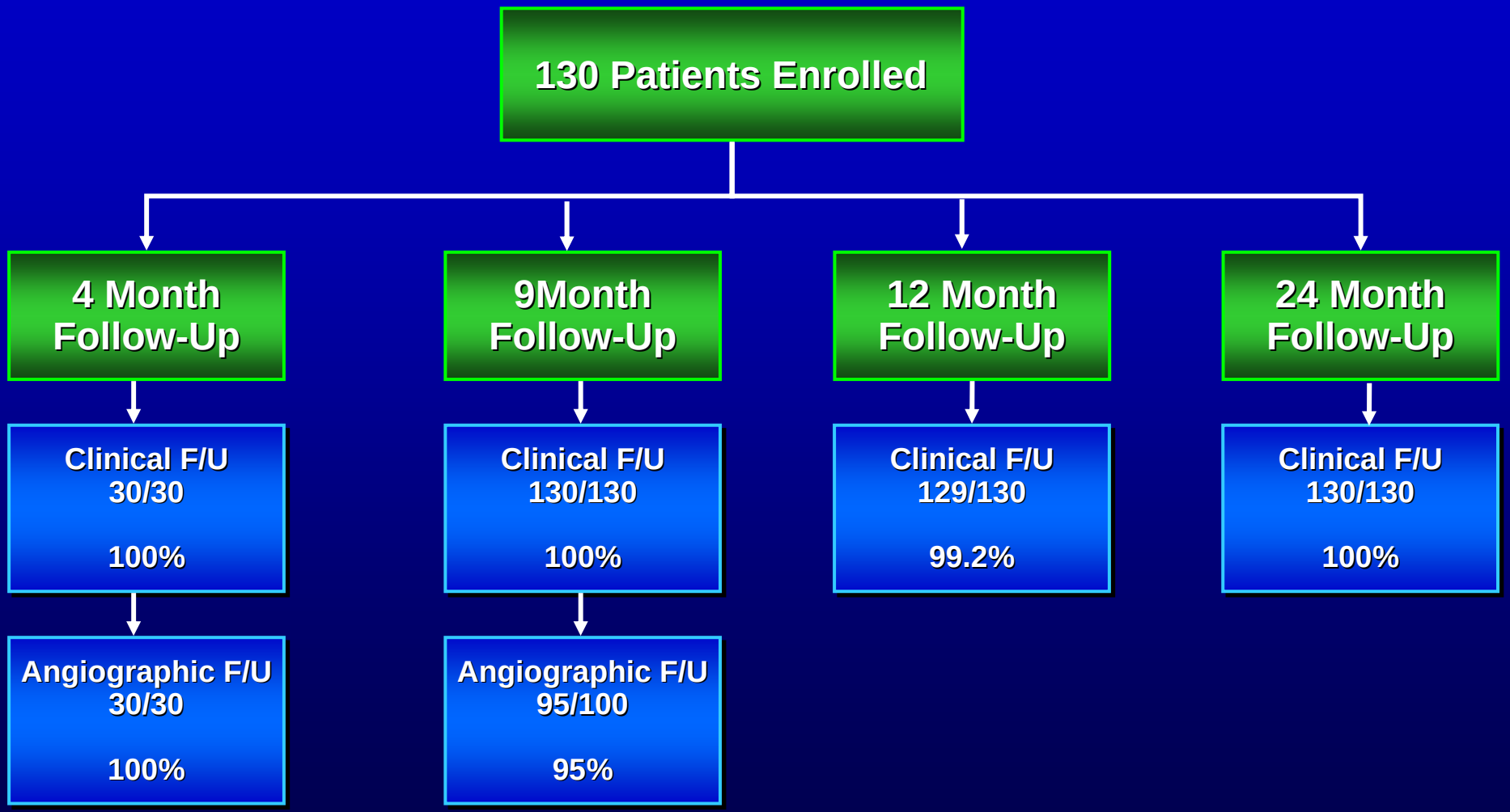
Patient Flowchart



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Patient Demographics

		n =130
Male	75.4%	(98/130)
Age	61 ±10yrs	(130)
Prior MI	45.7%	(59/129)
Prior PCI	18.5%	(24/130)
Diabetes Mellitus	17.7%	(23/130)
Insulin Dependent	2.3%	(3/130)
Unstable Angina	29.7%	(38/128)
Hyperlipidemia	94.6%	(123/130)
Current Smoker – within last 30 days	22.3%	(29/130)

*Meredith et al: EuroInterv 2007; 3:50-53

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Procedural Characteristics

N=130 patients, 131 lesions

LAD (%)	34.4% (45/131)
B2/C Lesions (%)	81.7% (107/131)
Pre-procedure RVD (mm)	2.81 ± 0.41
Lesion Length (mm)	15.49 ± 6.23
Pre-procedure MLD (mm)	0.82 ± 0.34
Pre-procedure DS (%)	70.50 ± 11.42

Device success	99.2% (130/131)
Procedure success	96.2% (125/130)

Device success <50% residual in-stent % ds with assigned stent

Procedure success <50% residual in-stent % ds & without in-hospital MACE

*Meredith et al: EuroInterv 2007; 3:50-53

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Angio, IVUS and Clinical 4 Month Subset

Angio/IVUS	In-stent	n=30	In-segment
Late Loss (mm)	0.12±0.26		0.05±0.20
% DS	7.18±7.86		17.74±7.57
ABR (%)	0		0
Neointimal Volume			3.72 ± 4.21 mm^3
Neointimal Volume %			2.23 ± 2.43 (24)

clinical		
MACE (%)	**3.3**	**(1/30)**
Non Q-Wave MI	**3.3**	**(1/30)**

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9 month Angiographic Results

n=96	In-stent	In-segment
Pre-procedure RVD (mm)		2.79 ± 0.40
Lesion Length (mm)		15.87 ± 6.51
MLD (mm) pre		0.82 ± 0.35
post	2.74 ± 0.41	2.33 ± 0.44
Acute Gain	1.91 ± 0.47	1.51± 0.50
9 mo f/u MLD (mm)	2.51 ± 0.48	2.21 ± 0.45
Late Loss (mm)	0.22 ± 0.27	0.12 ± 0.27
Late Loss Index	0.12 ± 0.16	0.08 ± 0.21
9 mo f/u % DS	10.13 ± 12.63	21.08 ± 10.62
ABR n (%)		

*Meredith et al: EuroInterv 2007; 3:50-53

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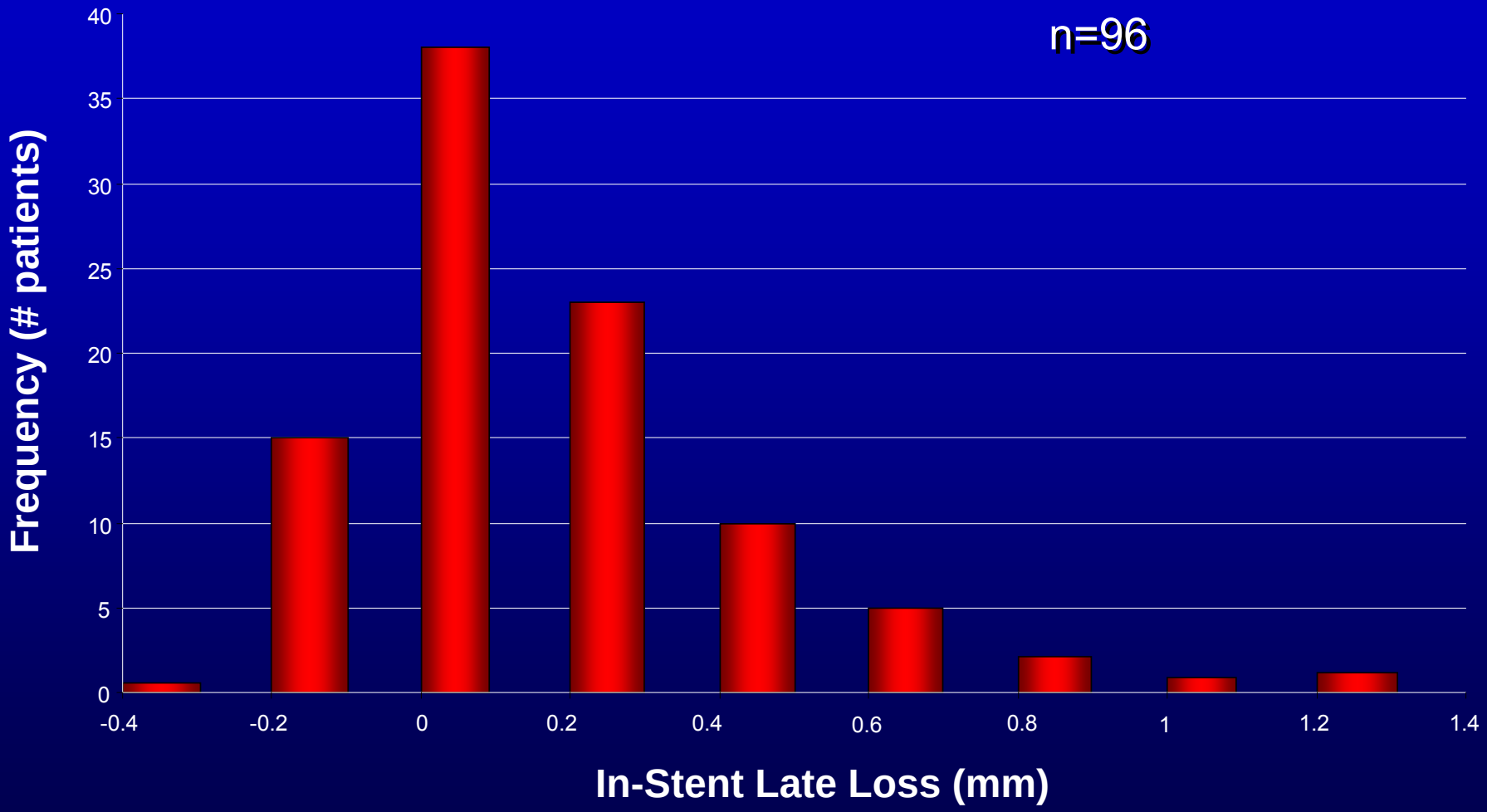
Endeavor RESOLUTE

9 Month Late Loss Distribution



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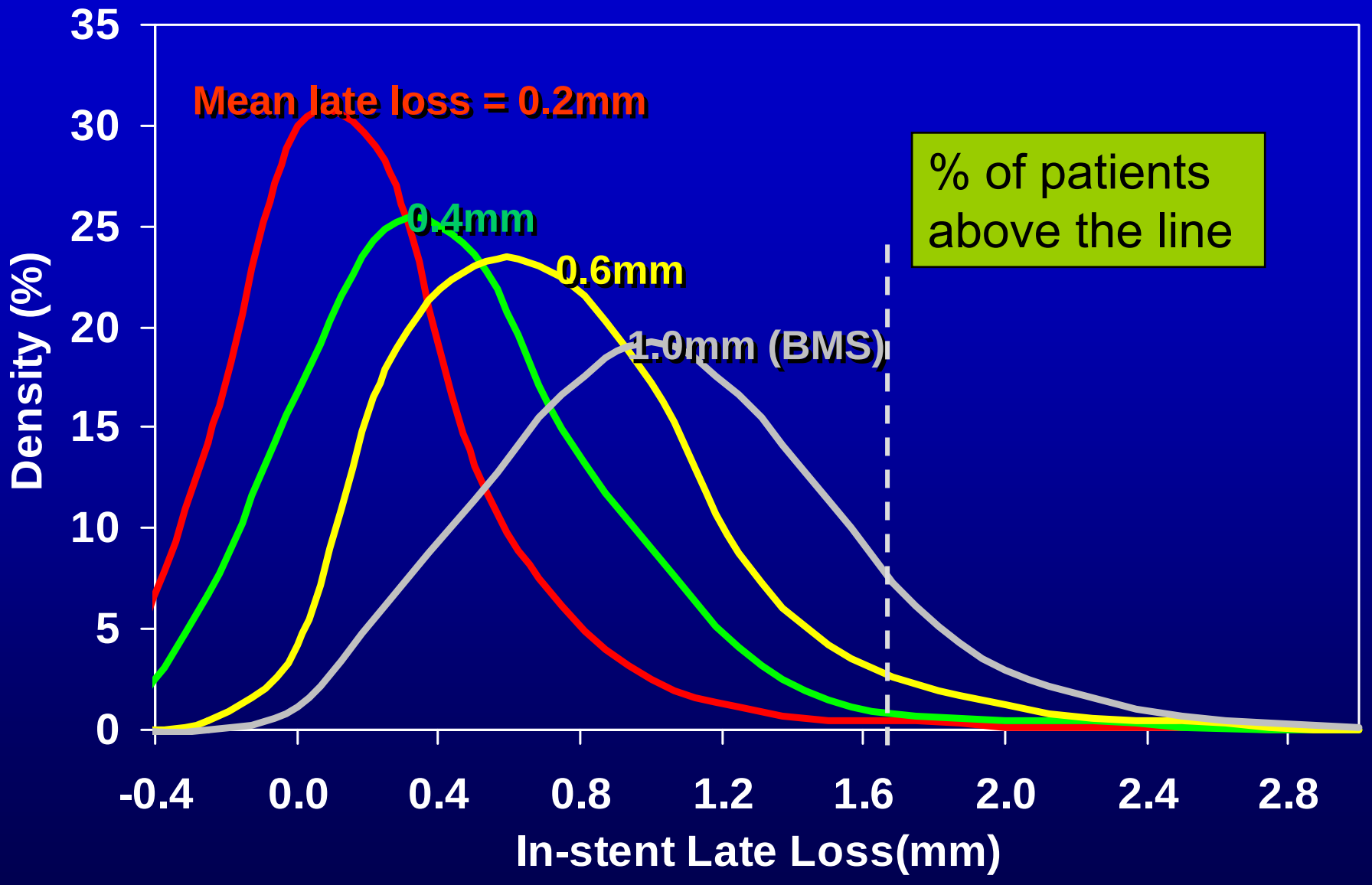
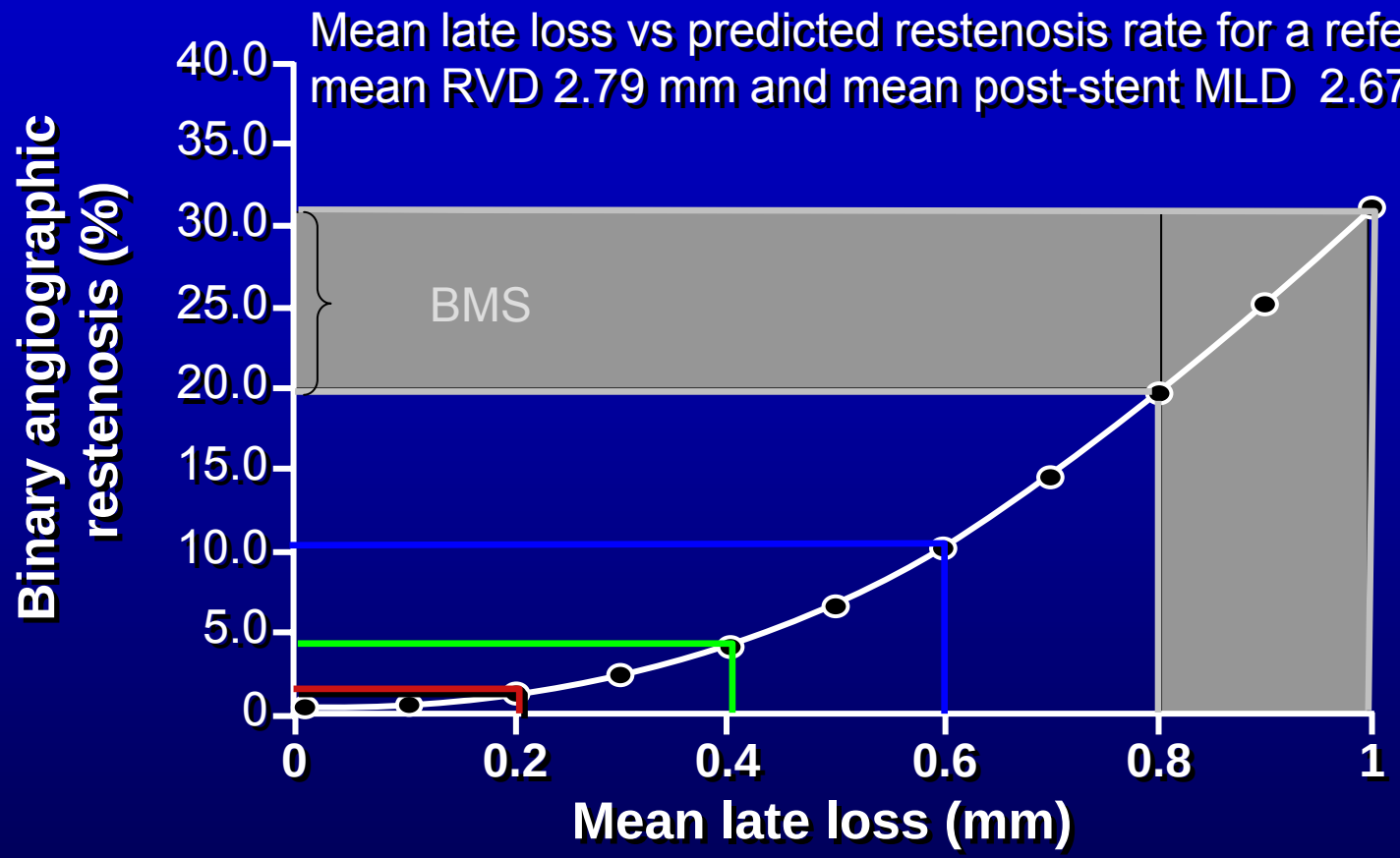
Late Loss Distribution



Mauri L, Kuntz R Circulation (2005, 111:3435-3442).

Relationship between LLL & ABR

Generalized Model of Binary Angiographic Restenosis versus mean DES Late Loss



The relationship of mean late loss in a stent to binary angiographic restenosis is curvilinear

Mauri et al. Circulation. 2005;111:3435.

Endeavor RESOLUTE

9 month Angiographic Results

n=96	In-stent	In-segment
Pre-procedure RVD (mm)		2.79 ± 0.40
Lesion Length (mm)		15.87 ± 6.51
MLD (mm) pre		0.82 ± 0.35
post	2.74 ± 0.41	2.33 ± 0.44
Acute Gain	1.91 ± 0.47	1.51± 0.50
9 mo f/u MLD (mm)	2.51 ± 0.48	2.21 ± 0.45
Late Loss (mm)	0.22 ± 0.27	0.12 ± 0.27
Late Loss Index	0.12 ± 0.16	0.08 ± 0.21
9 mo f/u % DS	10.13 ± 12.63	21.08 ± 10.62
ABR n (%)	1 (1%)	2 (2.1%)

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Endeavor RESOLUTE

9 month IVUS Volumetric Analysis

	Post Procedure	Follow up	*p value*
EEM Volume (mm^3)	330.6 ± 112.3 (69)	332.5 ± 114.3 (68)	0.923
Stent Volume (mm^3)	168.8 ± 57.3 (89)	169.2 ± 57.4 (88)	0.957
NIH Volume (mm^3)	0.6 ± 1.4 (89)	6.6 ± 7.8 (88)	<.001
Volume Obstruction (%)	NA	3.7 ± 4.0 (88)	NA
Minimal Luminal Area (mm^3)	6.4 ± 1.8 (98)	6.1 ± 1.8 (91)	0.231

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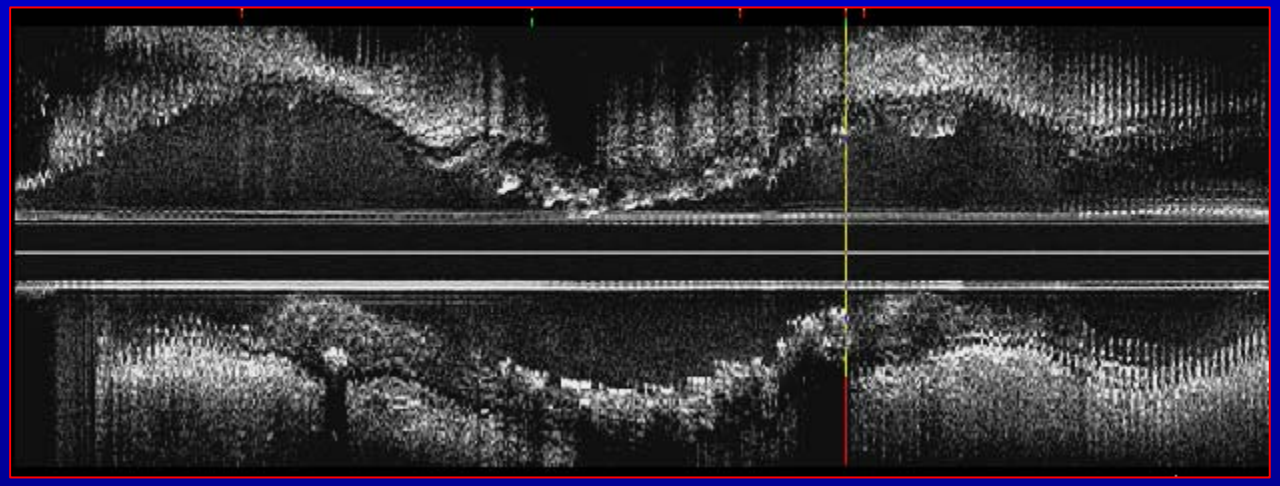
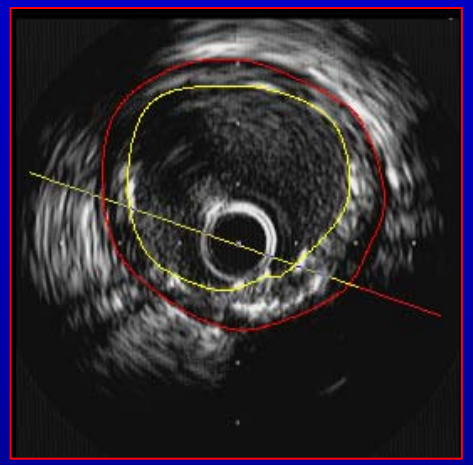
RESOLUTE Case 6602 021

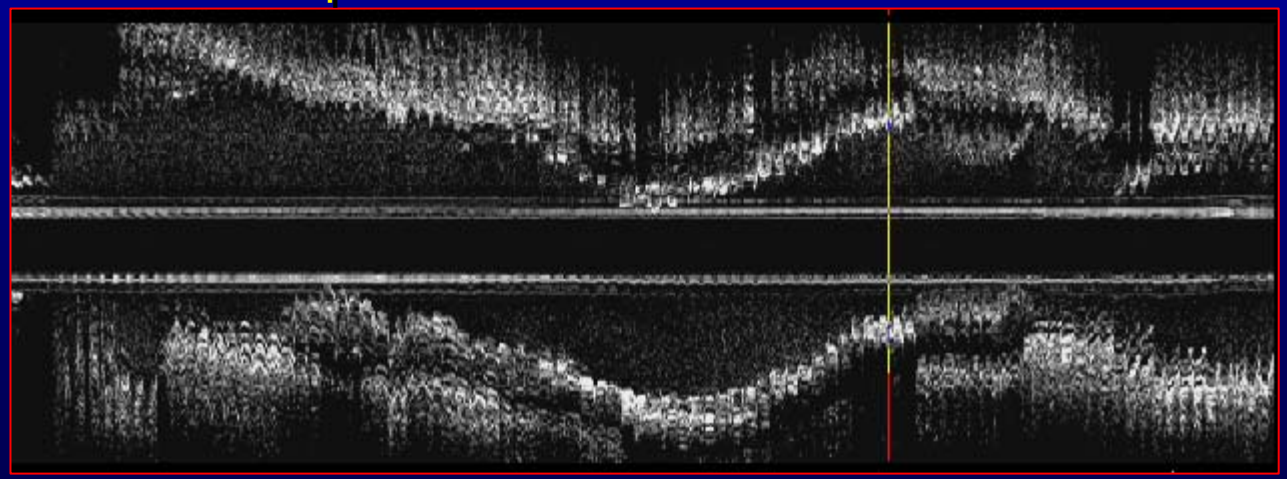
LAD 3.5x18 mm

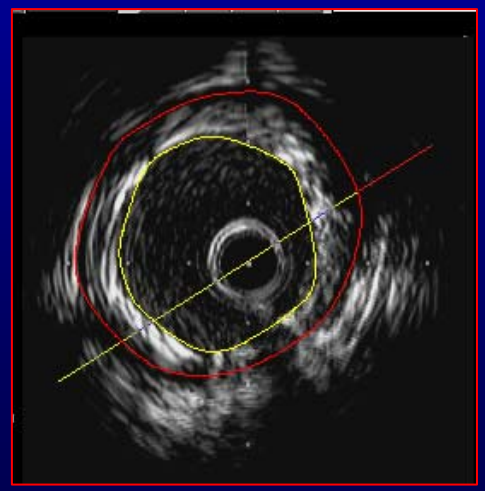
Post Stent





9mth Follow up





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Endeavor RESOLUTE

IVUS Stent Incomplete Apposition

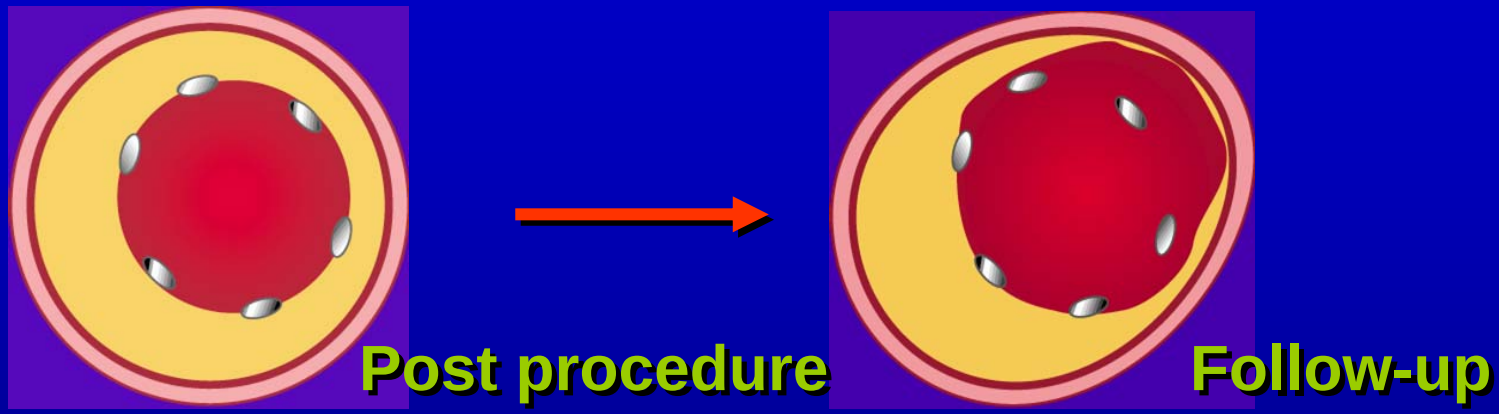
n=96

		Patient Number	edge : body
Baseline		21.9% (21/96)	12 : 9
9-month F/up			
	Persistent	17.0% (15/88)	7 : 8
	Resolved	4.5% (4*/88)	4 : 0
	Late IA	6.8% (6#/88)	2 : 4

*** 2 films not able to be reviewed**
 # 1 LIA associated with positive remodeling

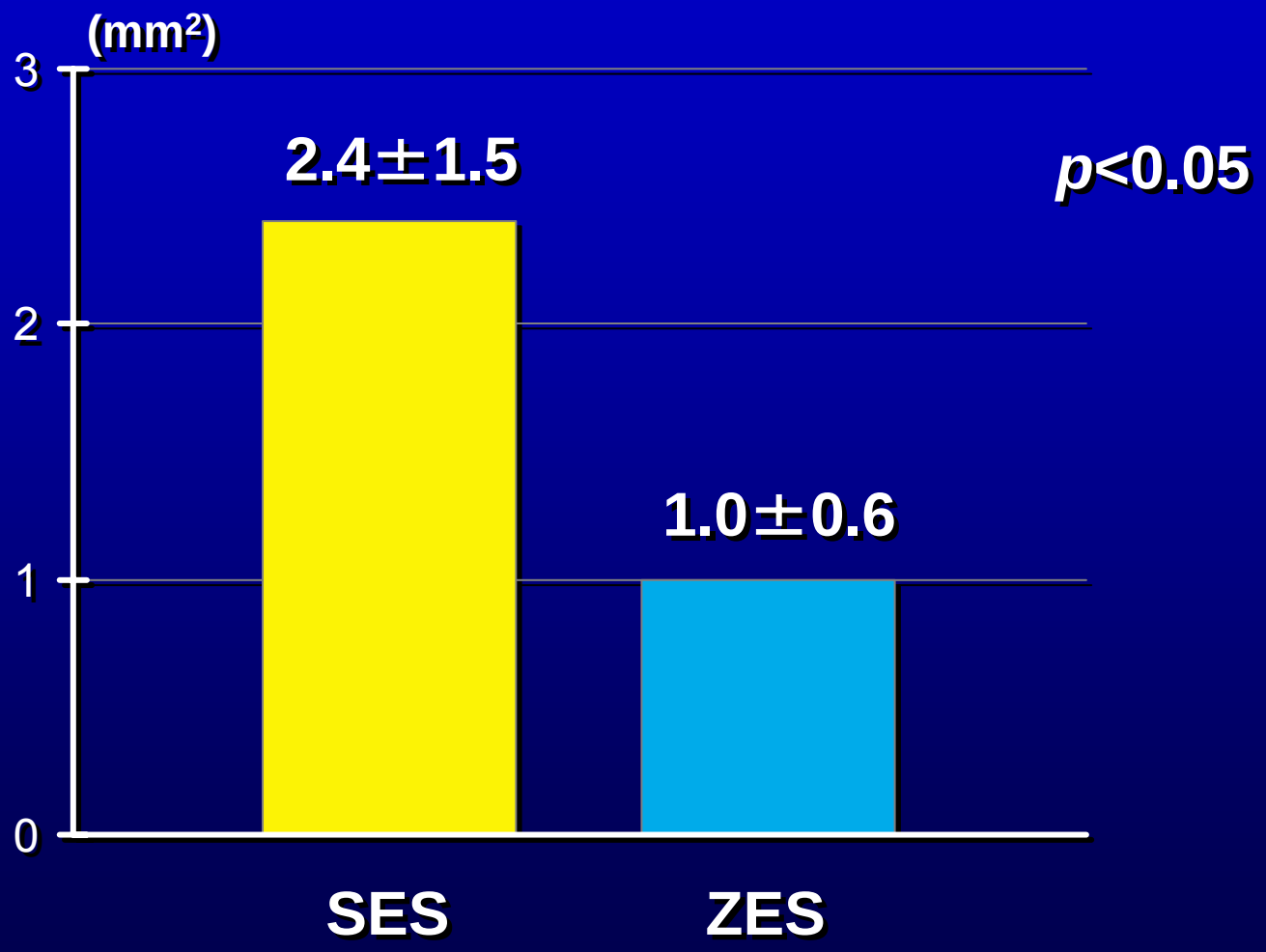
IVUS Analysis

Incomplete stent apposition



- LISA is defined as separation of at least 1 stent strut from the vessel wall, with evidence of blood flow behind the strut, where post-stent implantation IVUS had revealed complete apposition.
- The LISA cross-sectional image is identified as the most visually representative section at follow up.
- Corresponding post implantation cross-sections are identified based on length from stent edge or peri-vascular landmarks.

LISA Area by IVUS at Follow Up



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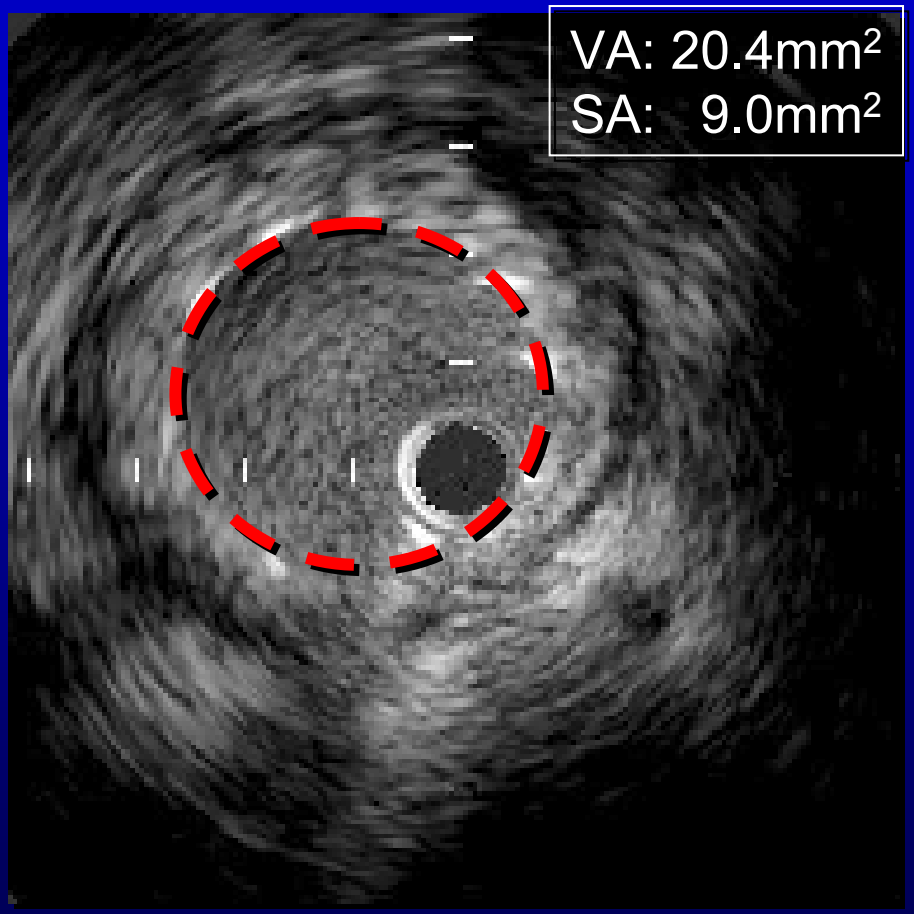
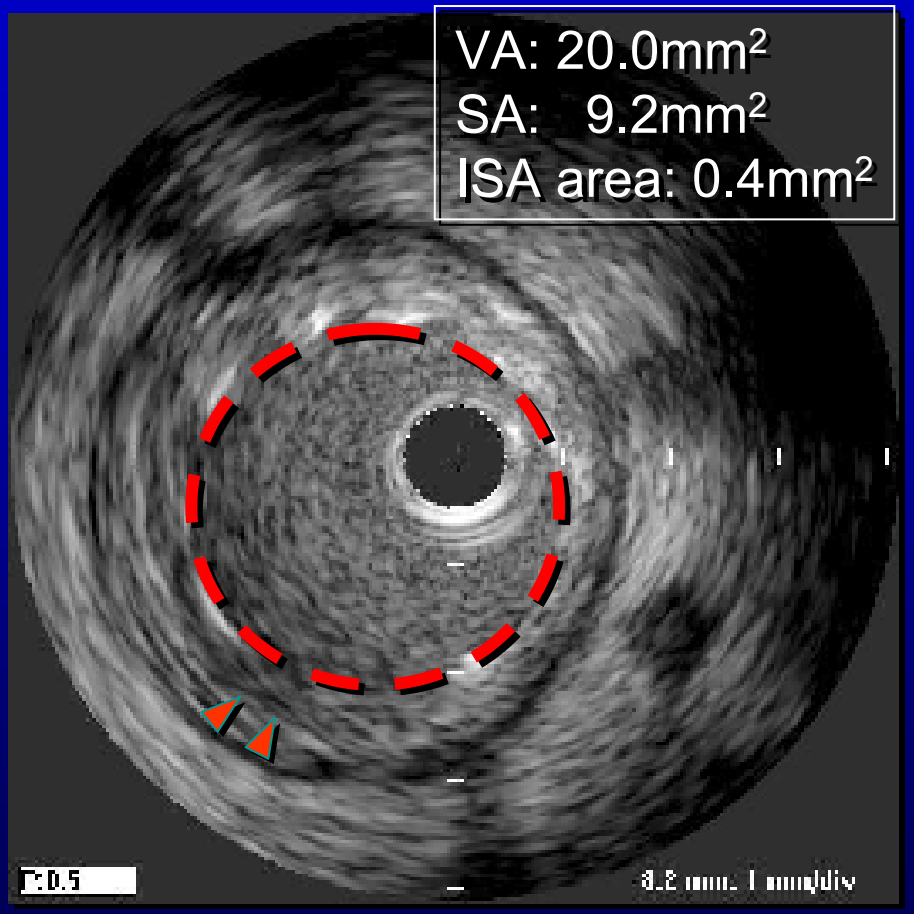
Case Example: ZES



Baseline



Follow-up

6622_008

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RESOLUTE Clinical Events to 24 months

	9 months n=130 patients n=131 lesions	12 months n=129 patients, 130 lesions	24 months n= 130 patients, 131 lesions
Death (all) - % (#)	1.5 (2)	2.3 (3)	3.1 (4)
Cardiac	0.8 (1)	0.8 (1)	0.8 (1)
MI (all) - % (#)	5.4 (7)	5.4 (7)	5.4 (7)
Q Wave	0	0	0
Non Q wave	5.4 (7)	5.4 (7)	5.4 (7)
Death (cardiac) + MI (all) - % (#)	6.2 (8)	6.2 (8)	6.2 (8)
Stent Thrombosis (all) - % ()	0	0	0
0-30 days	0	0	0
31-360 days	0	0	0
TLR - % (#)	0	0.8 (1)	1.5 (2)
TVR (non-TL) - % (#)	0	0	0
TVR - % (#)	0	0.8 (1)	1.5 (2)
MACE - % (#/)	6.9 (9)	8.5 (11)	10 (13)
TVF - % (#/)	6.2 (8)	7.0 (9)	7.7 (10)

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RESOLUTE NQMI to 12 months

		Comments
57 year old	Prox RCA Type C Lesion	Acute Marginal side branch of obstructed by lesion during post dilatation
67 year old	Mid RCA Type B2 Lesion	No reflow of PDA, prior to stenting
65 year old	Mid RCA Type C Lesion	RV Marginal branch has decreased flow after balloon dilatation prior to stenting
52 year old	Mid LAD Type C Lesion	Decreased flow in 1st diagonal side after post balloon dilatation
51 year old	1st OMA Type C Lesion	Prior MI with MB still 2x baseline at time of intervention
50 year old	Mid LAD	Wire trauma leading to plaque rupture during follow- up angiography
75 year old	Mid LAD	Fully patent stent at follow-up. Non Q-wave MI due to lack of anti-coagulation during IVUS

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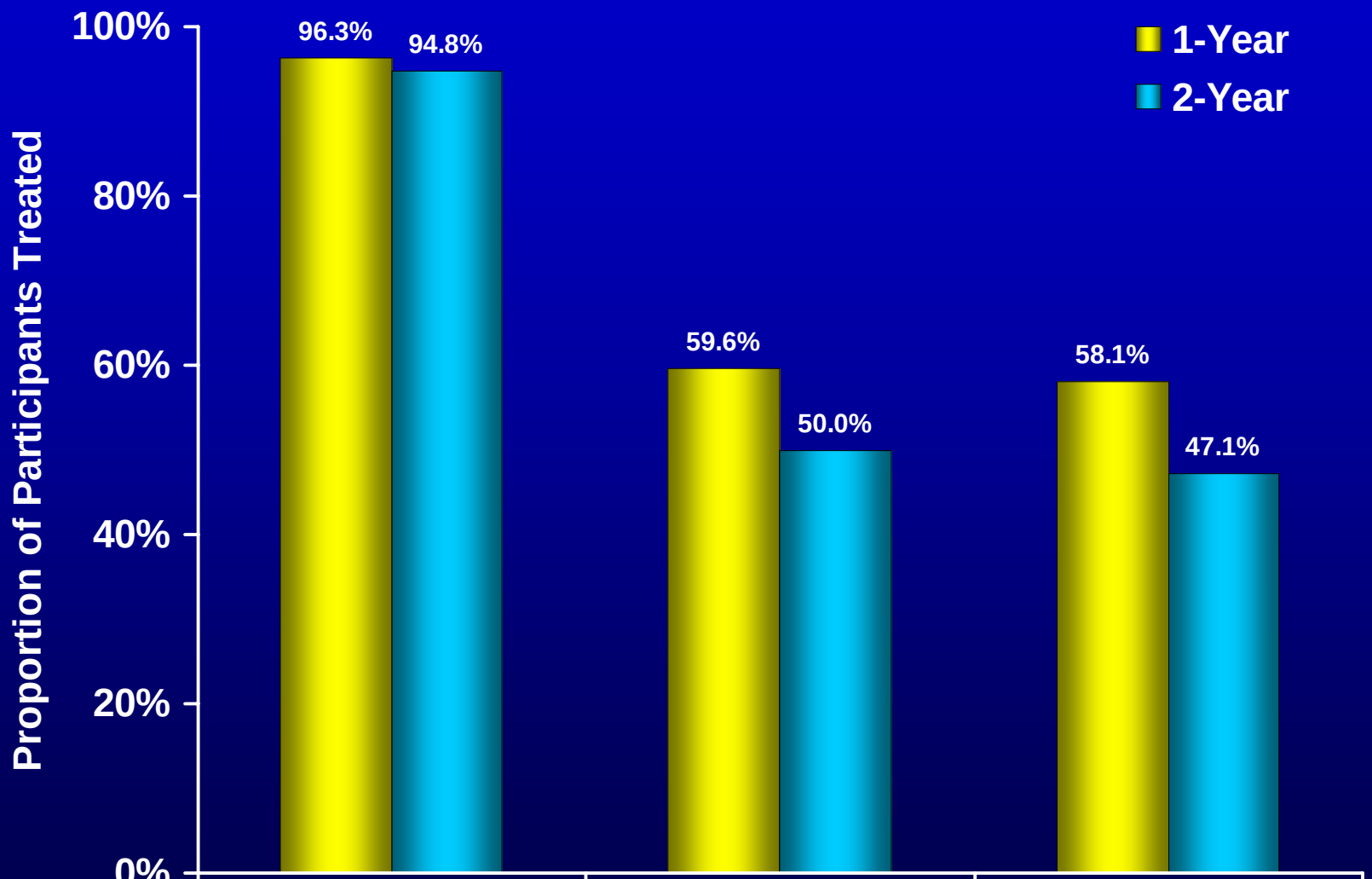
Endeavor RESOLUTE

DAPT Use to 24 Months



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RESOLUTE: DAPT

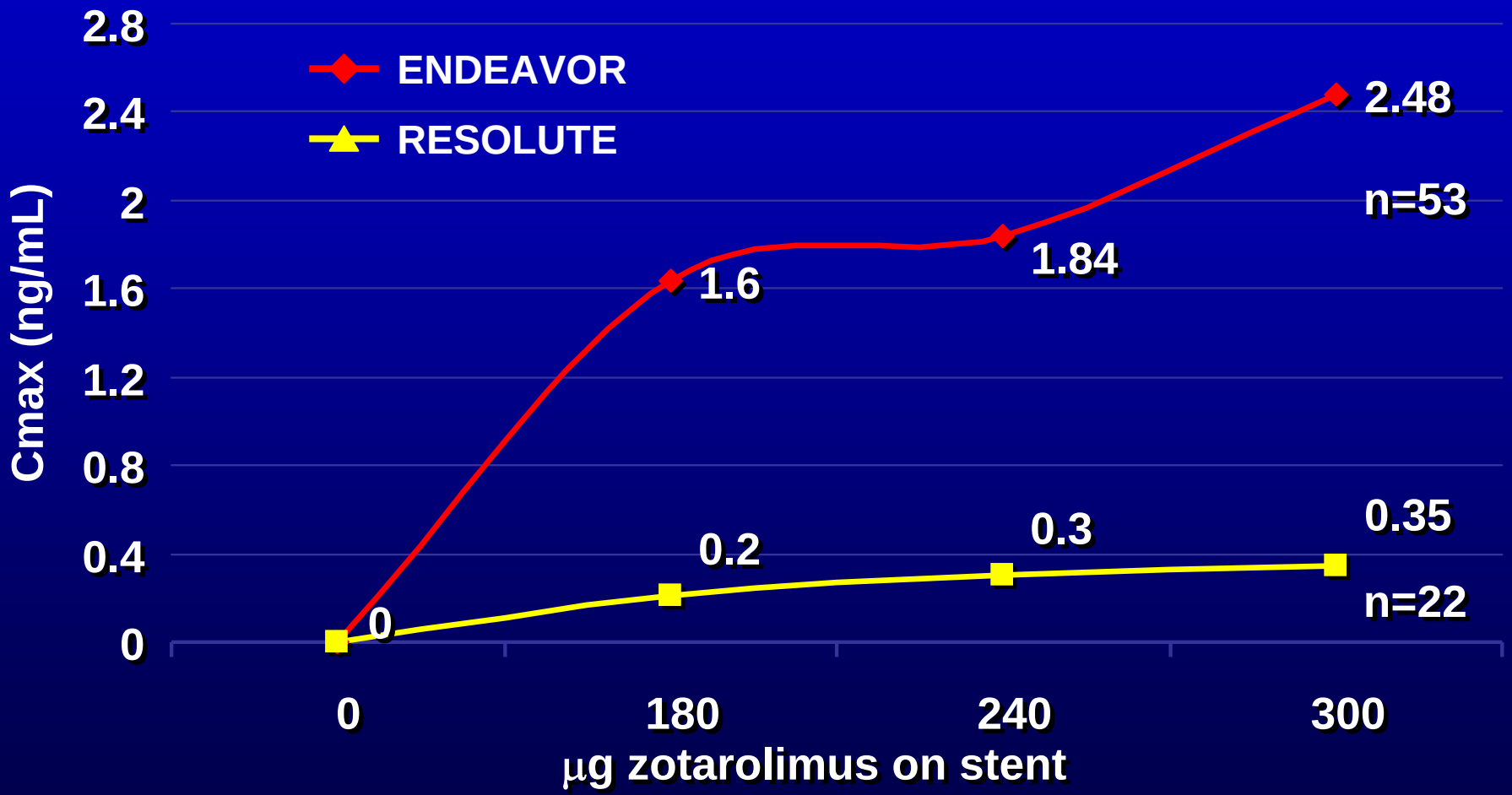
Patients with a Surgical Procedure

History	Index Procedural Info	Time DAPT	Event Description	Outcome up to 12M FU
69 yo male Diabetic	Mid RCA 3.5x30mm stent	1.3 months	Laparoscopy; small bowel resection	No MACE
38 yo female Non-diabetic	Mid RCA 3.5x18 mm stent	3.0 months	Pericardial window for pericarditis	No MACE
66 yo male Non-diabetic	1st Obtuse Marginal 2.5x18 mm stent	3.0 months	Anterior bowel resection for cancer	No MACE
77 yo female Non-diabetic	Mid RCA 3.0x24 mm stent	3.3 months	Total hip replacement	No MACE
71 yo male Non-diabe				
75 yo male Non-diabe				
76 yo male Non-diabe				
61 yo female Non-diabetic				
54 yo male Non-diabe				
59 yo male Non-diabetic	1st Obtuse Marginal 3.0x30 mm stent	3.6 months	Total laryngectomy and neck dissection	No MACE
58 yo, male Non-diabetic	PDA 3.0x18mm stent	6.0 months	Surgical repair of retinal detachment	No MACE
68 yo female Non-diabetic	Mid LAD 2.5x18 mm stent	6.0 months	Arthroscopic surgery of shoulder	No MACE
65 yo male Non-diabetic	Mid RCA 3.5x30 mm stent	6.1 months	Elective cholecystectomy	No MACE
64 yo male Non-diabetic	1st Obtuse Marginal 3.0x18 mm stent	6.3 months	Elective Cardioversion for atrial flutter	No MACE
75 yo male Non-diabetic	Mid LAD 2.5x18 mm stent	6.5 months	Patient died	Yes: Death, non-cardiac, melanoma with metastasis

- **15 Patients discontinued AP Therapy and had surgical procedures**
  - **5 females**
  - **10 males**
  - **1 diabetic**
  - **No deaths, MI, or stent thrombotic events**

RESOLUTE PK Sub Study

Comparison with Endeavor



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Endeavor RESOLUTE
Study Conclusions

- PK confirmed design premise and expands safety margins of drug
- Consistent neo-intimal suppression with a minimal focal ABR
- Low 30 day and 9 month procedure-related MACE with no stent thromboses
- No significant safety concerns at 2 yrs

Results from this trial provide a platform for use in more complex patient and lesion cohorts.

Expanding Clinical Proof

Comprehensive and robust clinical program

- More than 6000 patients to be enrolled in RESOLUTE Clinical program
- Approximately 5000 patients will be Endeavor Resolute patients
- 2 year results of RESOLUTE data presented at TCT,2008
- Enrolment complete for RESOLUTE All Comers (Nov, 2008)
- Enrollment is in process for RESOLUTE US and RESOLUTE Intl

RESOLUTE Clinical Program

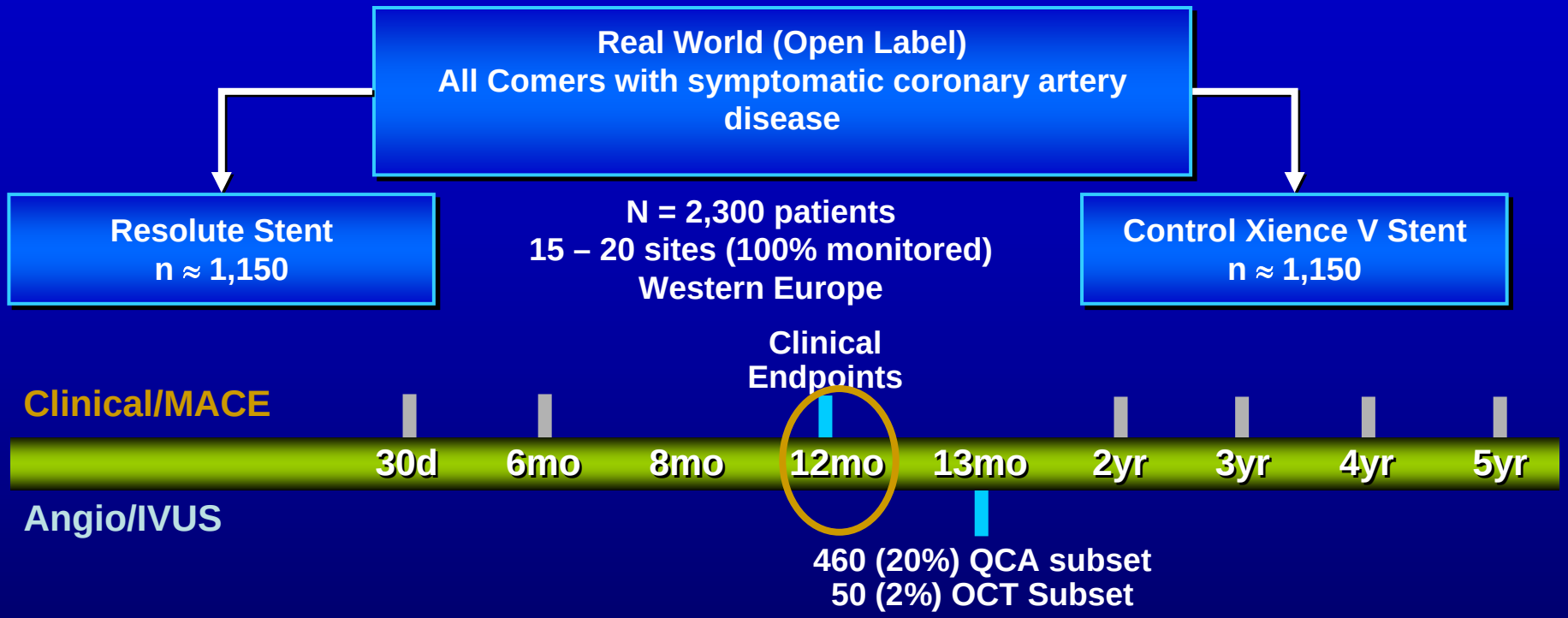
RESOLUTE	Single Arm First-in-Human (n=139)	2yr
RESOLUTE AC*	1:1 RCT** vs. Xience® (R=1,150,X=1,150)	
RESOLUTE Intl	Non-RCT Observational (R=2,200)	
RESOLUTE US	2.5 – 3.5 Clinical Non-RCT vs. Hx Control (R=1,112)	
	2.5 – 3.5 Angio / IVUS Non-RCT vs. Hx Control (R=100)	
	2.25 Angio Non-RCT (R = 129)	
	4.0 Angio Non-RCT (R = 58)	
	38 mm+ – Long Lesion Non-RCT (R = TBD)	
RESOLUTE Japan	Non-RCT (R ≈ 100)	

** Resolute AC: Resolute All Comers; **: RCT: Randomized Clinical Trial*

+ Trial details and design TBD

RESOLUTE All Comers

Co-PIs: Profs. Serruys, Silber, Windecker



Primary Endpoint: Composite - Cardiac Death, Target Vessel MI, TLR @ 12mo
Secondary Endpoints: Composite @ 30d, 6mo, 2 – 5 yr; angiographic & optical coherence tomography (OCT) parameters @ 13 mo
Drug Therapy: ASA and clopidogrel/ticlid ≥6 months (per guidelines)

RESOLUTE US

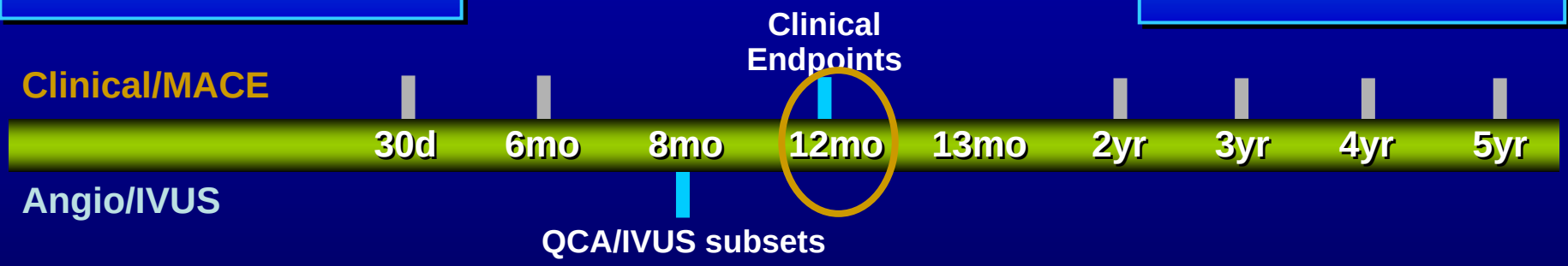
Co-PIs: M Leon, L Mauri, A Yeung

***De Novo* Native Coronary Lesion**
Vessel Diameter: 2.25-4.2 mm
Lesion Length: ≤ 27 mm

Resolute Stent
2.25 Angio (n = 129)
2.5 – 3.5 Clinical (n = 1,112)
2.5 – 3.5 Angio/IVUS (n = 100)
4.0 Angio (n = 58)

N = 1,399 patients
125 sites
United States

Hx Controls
Performance Goals



Primary Endpoints:
2.25 Angio → In-Segment %DS @ 8 mo / Key 2°EP TLF @ 12 mo
2.5 – 3.5 Clinical →Target Lesion Failure @ 12 mo
2.5 – 3.5 Angio/IVUS → In-Stent LLL @ 8 mo
4.0 Angio → In-Segment LLL @ 8 mo
Drug Therapy: ASA and clopidogrel/ticlid ≥6 months (per guidelines)

RESOLUTE International

Co-PIs: Dr. Belardi / Profs Neumann & Widimský

Real World (Open Label)
All Comers with symptomatic coronary artery disease

N = 2,200 patients
~100 sites
International

Primary Endpoint: Composite - Cardiac Death & Target Vessel MI @ 12mo
Secondary Endpoints: ARC Definite and Probable Stent Thrombosis @ 12 mo
Drug Therapy: ASA and clopidogrel/ticlid ≥6 months (per guidelines)