

Abbott Vascular Everolimus-Eluting Bioresorbable Vascular Scaffold Components

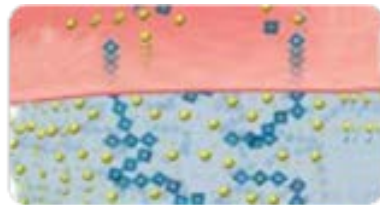
Bioresorbable Scaffold

- Poly (L-lactide) (PLLA)
- Based on proven MULTI-LINK pattern
- Naturally resorbed, fully metabolized*



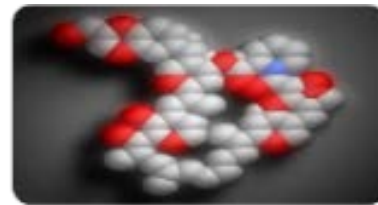
Bioresorbable Coating

- Poly (D,L-lactide) (PDLLA)
- Naturally resorbed, fully metabolized



Everolimus

- Similar dose density and release rate to XIENCE V



XIENCE V Delivery System

- World-class deliverability

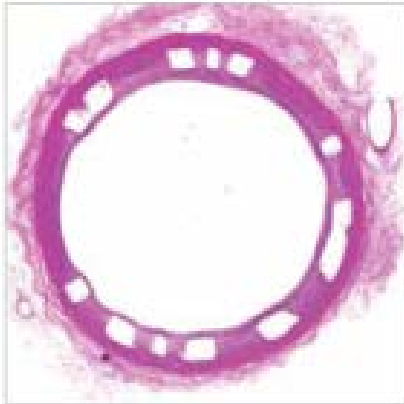


*Except for platinum markers
All illustrations are artists' renditions

Design Requirements of a Fully* Bioresorbable Scaffold: Three Phases of Functionality

Absorb works in 3 phases to deliver VRT

Revascularizes



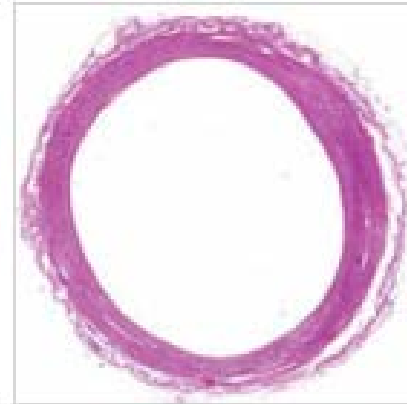
Revascularizes like
a best-in-class DES, XIENCE

Restores

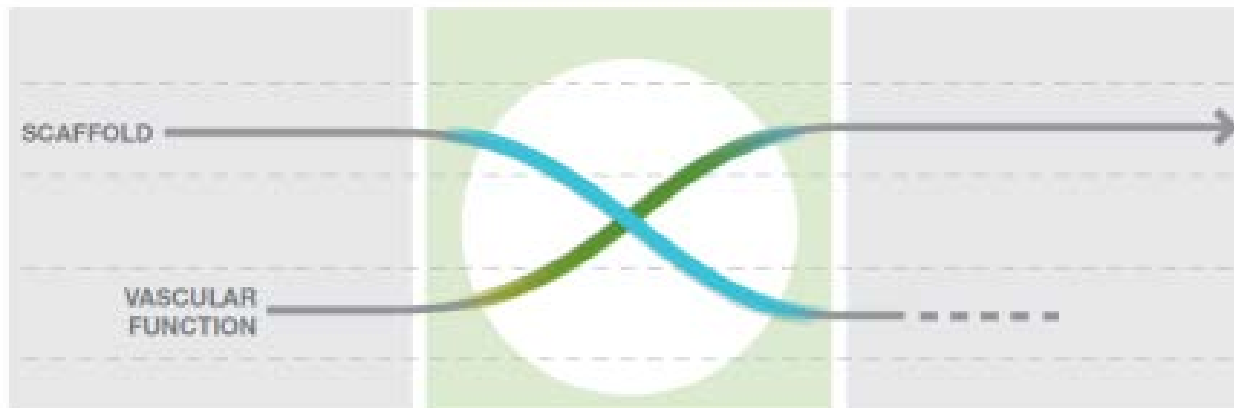


Enables natural vessel function
for improved long-term outcomes

Resorbs



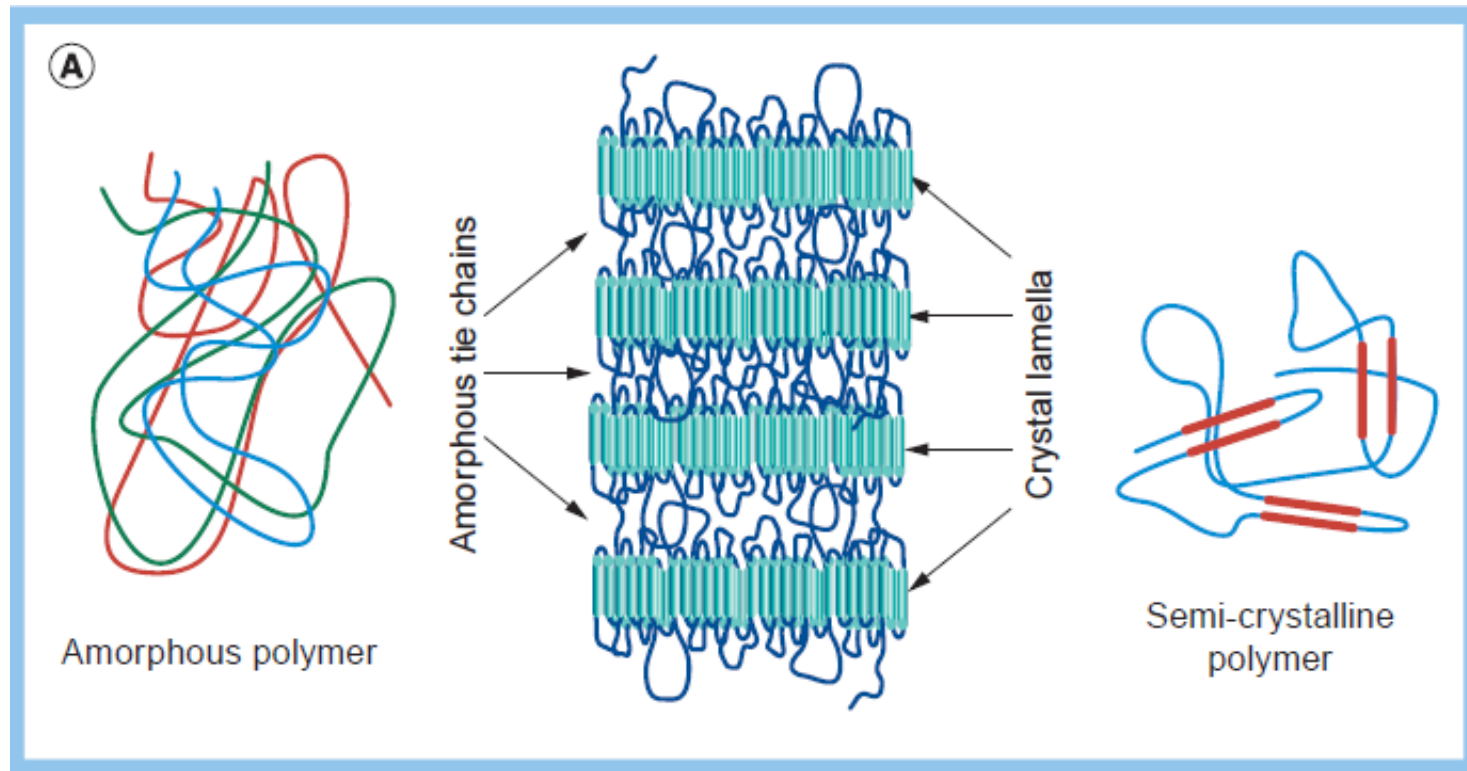
Resorbs leaving
no scaffold behind*



Everolimus-eluting ABSORB bioresorbable vascular scaffold: present and future perspectives

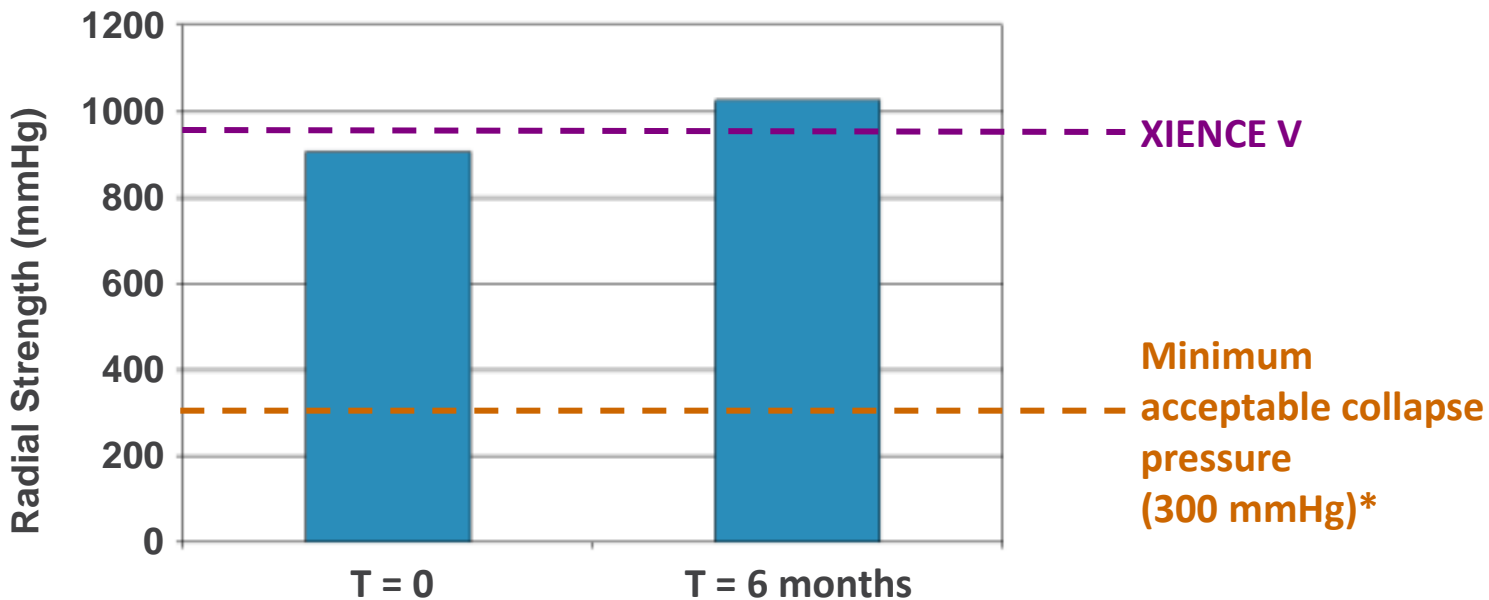
Expert Rev. Med. Devices 9(4), 327–338 (2012)

Salvatore Brugaletta^{1,2},
Hector M
Garcia-Garcia¹,
Yoshinobu Onuma¹
and Patrick W Serruys*¹



Absorb Vessel Support Over Time

Absorb Radial Strength



ABSORB appears to maintain adequate support for at least as long as is needed

Devices subjected to simulated physiologic environment (fatigue testing). Tests performed at and data on file at Abbott Vascular.

*Agrawal, CM, et.al. *Biomaterials*. 1992; 13: 176-182.

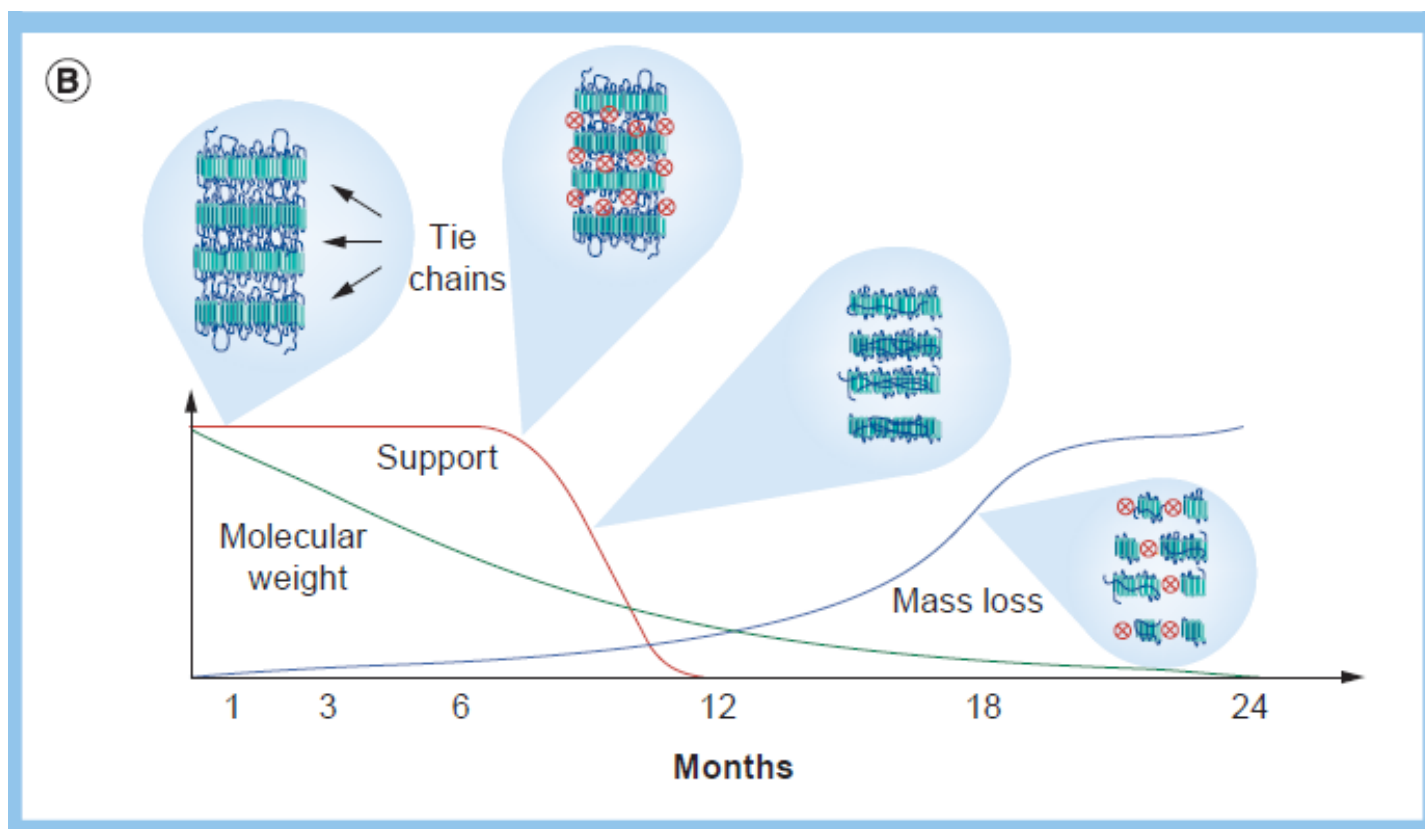
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6-EH-4-2567-01 09/2012 REV A

Everolimus-eluting ABSORB bioresorbable vascular scaffold: present and future perspectives

Expert Rev. Med. Devices 9(4), 327–338 (2012)

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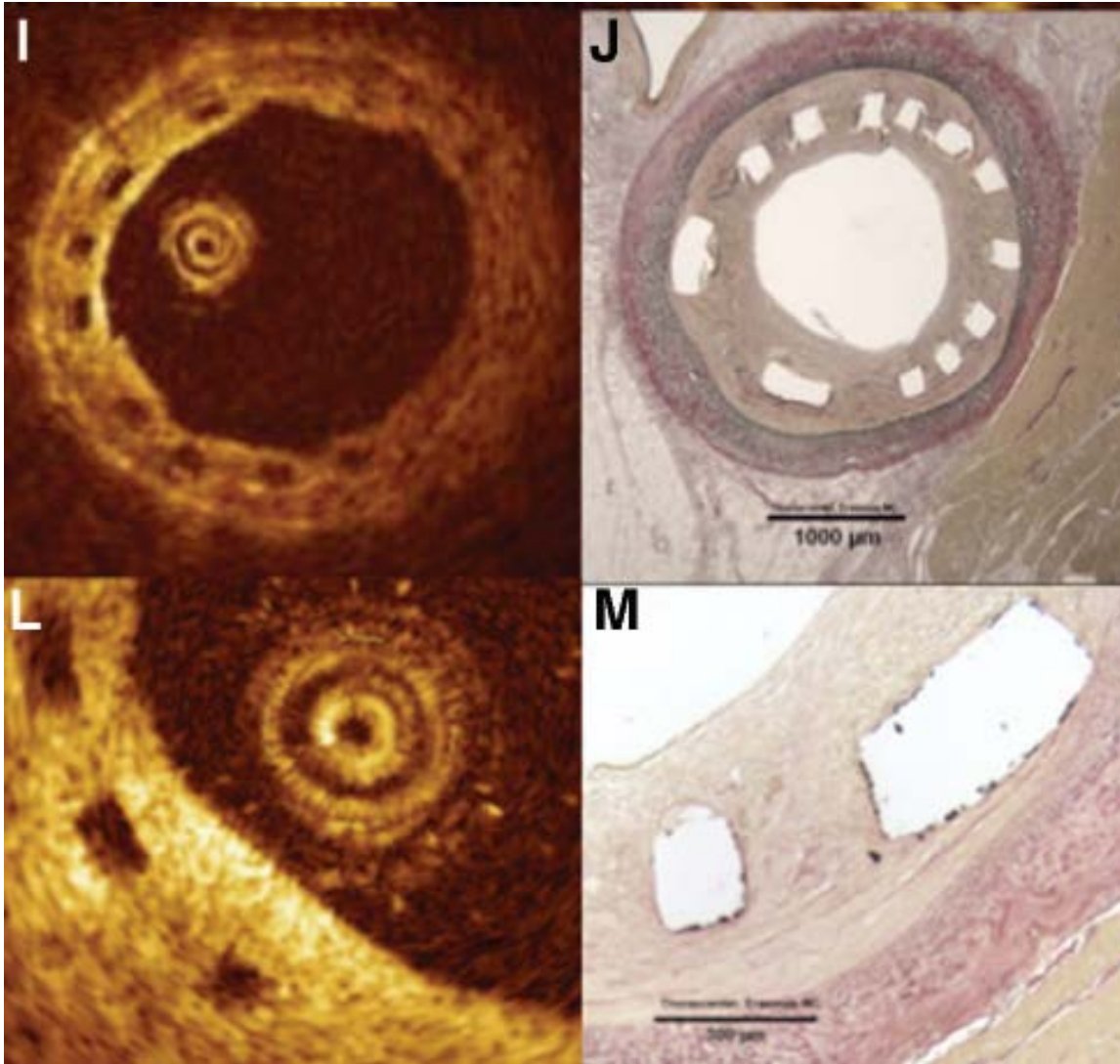


Intracoronary Optical Coherence Tomography and Histology at 1 Month and 2, 3, and 4 Years After Implantation of Everolimus-Eluting Bioresorbable Vascular Scaffolds in a Porcine Coronary Artery Model

An Attempt to Decipher the Human Optical Coherence Tomography Images in the ABSORB Trial

Yoshinobu Onuma, MD*; Patrick W. Serruys, MD, PhD*; Laura E.L. Perkins, DVM, PhD;
Takayuki Okamura, MD; Nieves Gonzalo, MD; Hector M. García-García, MD, PhD;
Evelyn Regar, MD, PhD; Marika Kamberi, PhD; Jennifer C. Powers, BS; Richard Rapoza, PhD;
Heleen van Beusekom, PhD; Willem van der Giessen, MD, PhD; Renu Virmani, PhD

Circulation. 2010;122:2288-2300.



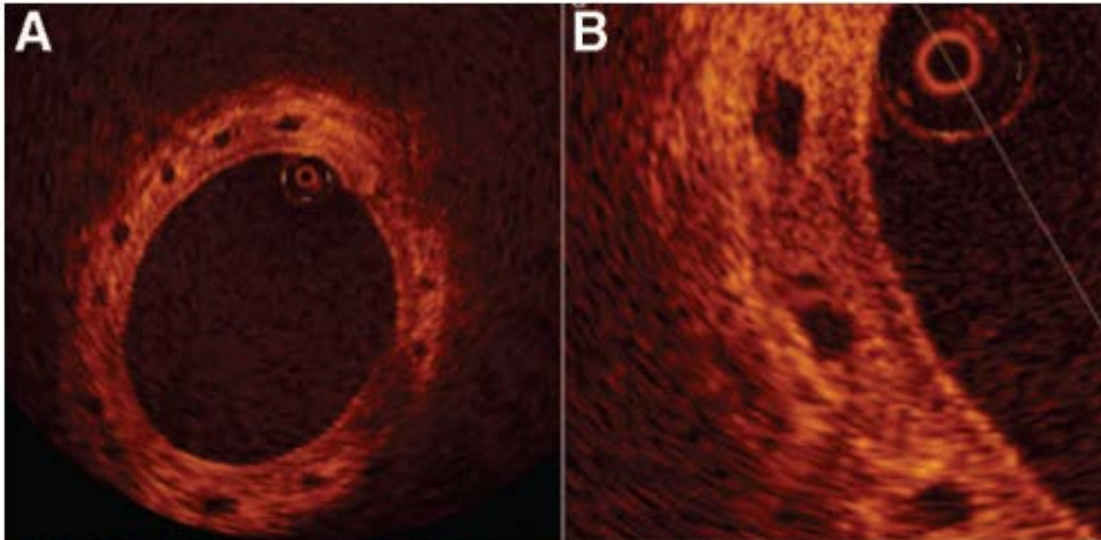
**OCT – HISTOLOGY FINDINGS
28 DAYS**

Intracoronary Optical Coherence Tomography and Histology at 1 Month and 2, 3, and 4 Years After Implantation of Everolimus-Eluting Bioresorbable Vascular Scaffolds in a Porcine Coronary Artery Model

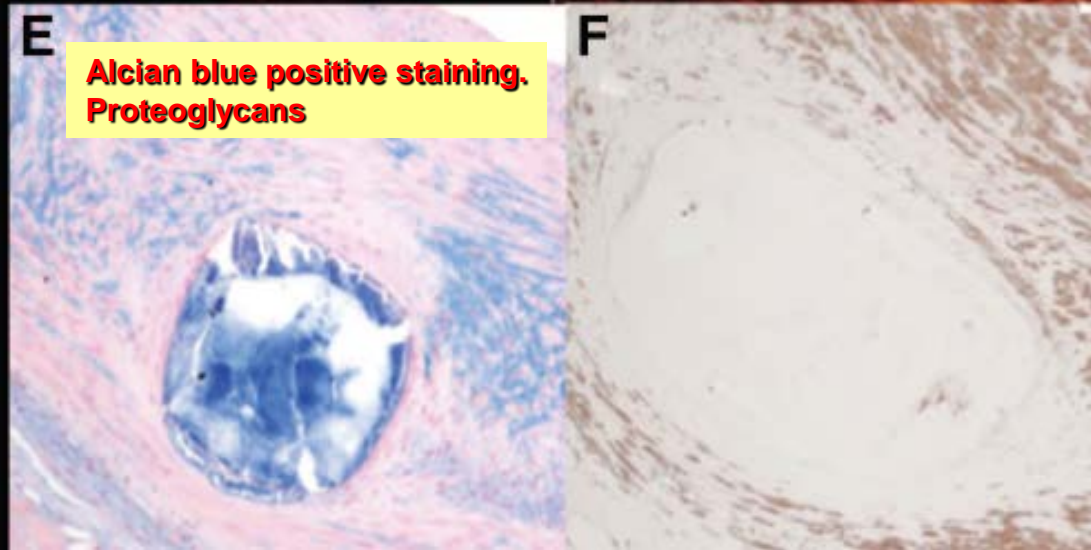
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Circulation. 2010;122:2288-2300.



**OCT – HISTOLOGY FINDINGS
2 YEARS**

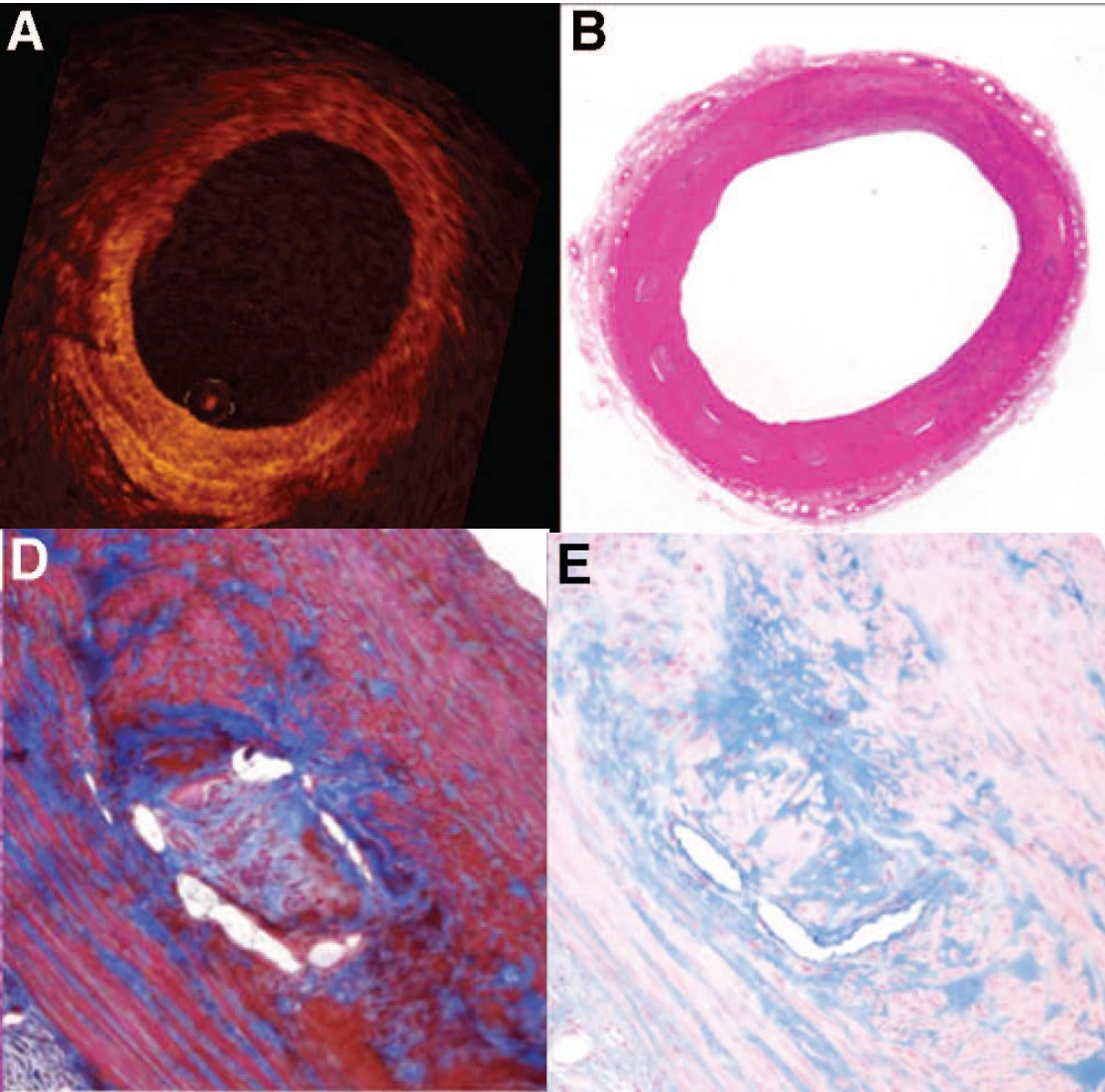


Intracoronary Optical Coherence Tomography and Histology at 1 Month and 2, 3, and 4 Years After Implantation of Everolimus-Eluting Bioresorbable Vascular Scaffolds in a Porcine Coronary Artery Model

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Circulation. 2010;122:2288-2300.



OCT – HISTOLOGY FINDINGS 3 YEARS

Staining with trichrome demonstrates the connective tissue replacement composition of the strut footprint (D), with Alcian Blue demonstrating the proteoglycan matrix (E, blue).

Caso clinico

- G.A.M. , donna di anni 70, ipertesa.
- Aprile 2005: ricovero per SCA-NSTE: stenosi 90% prox-LAD → 1 DES
- Settembre 2012 : angor da marcia : stenosi 90% lunga mid-LAD → 2 DES
- Marzo 2013 : ripresa angor : stenosi edge distale DES mid-LAD: DES distale ai precedenti.



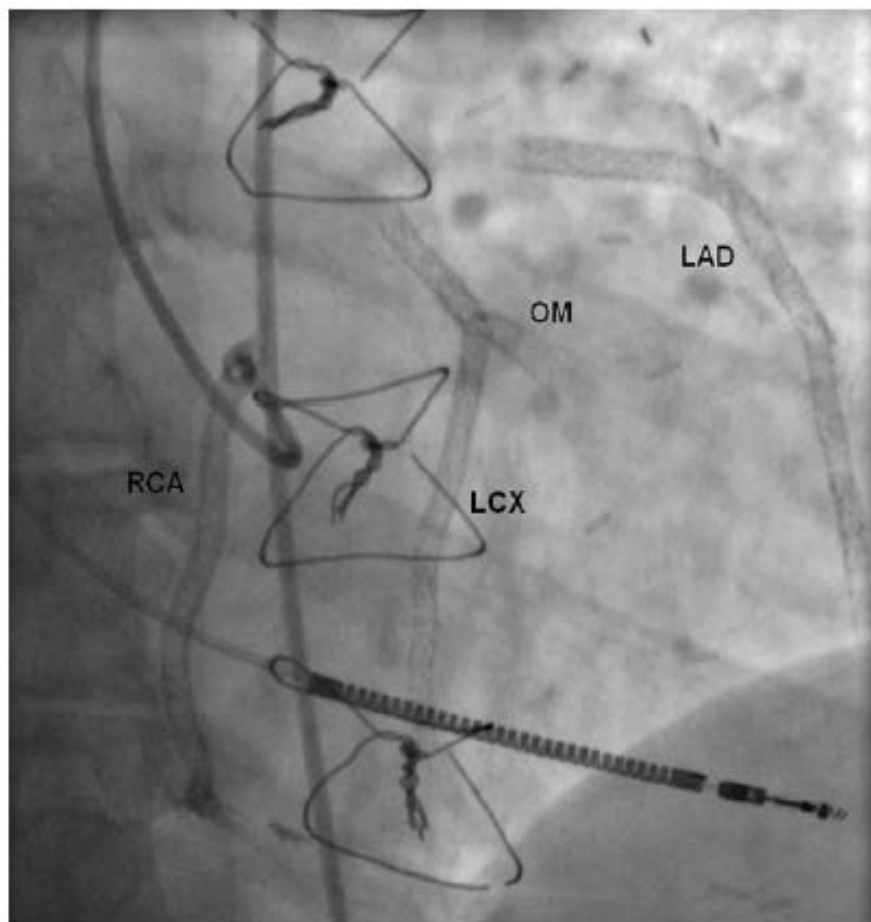
A Heart With 67 Stents

Rami N. Khouzam, MD, Rajvir Dahiya, MD, Richard Schwartz, MD

Mineola, New York

Journal of the American College of Cardiology

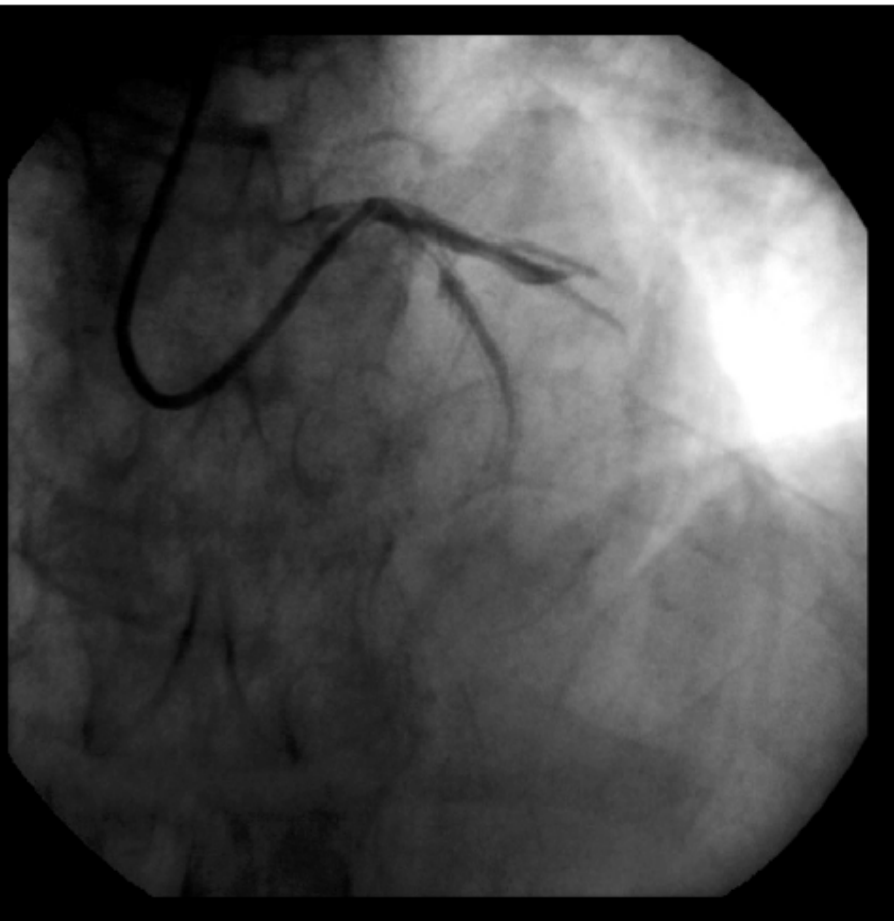
Vol. 56, No. 19, 2010



Case report - Coronary
Surgical extraction of occluded stents: when stenting
becomes a problem

Rony Atoui, Siamak Mohammadi, Dominique Shum-Tim*

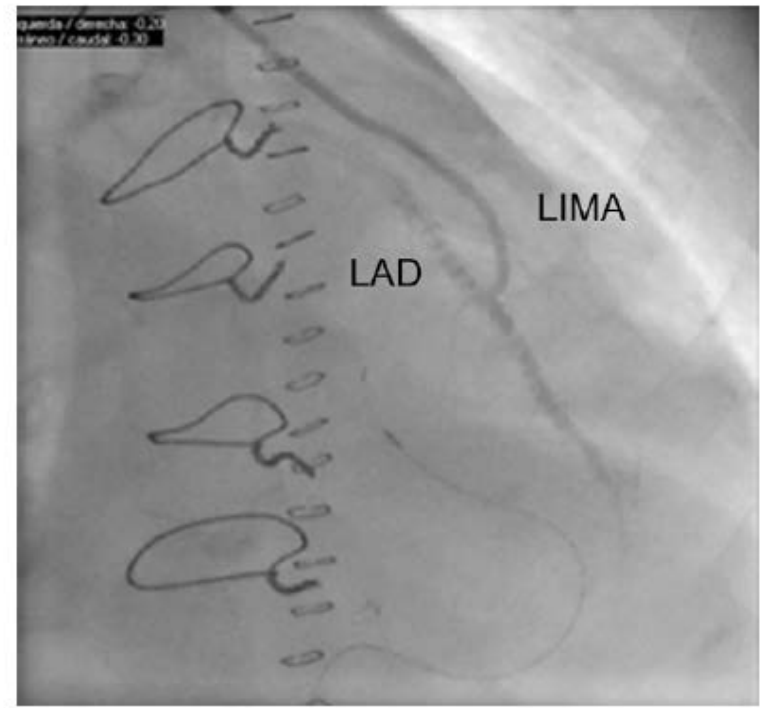
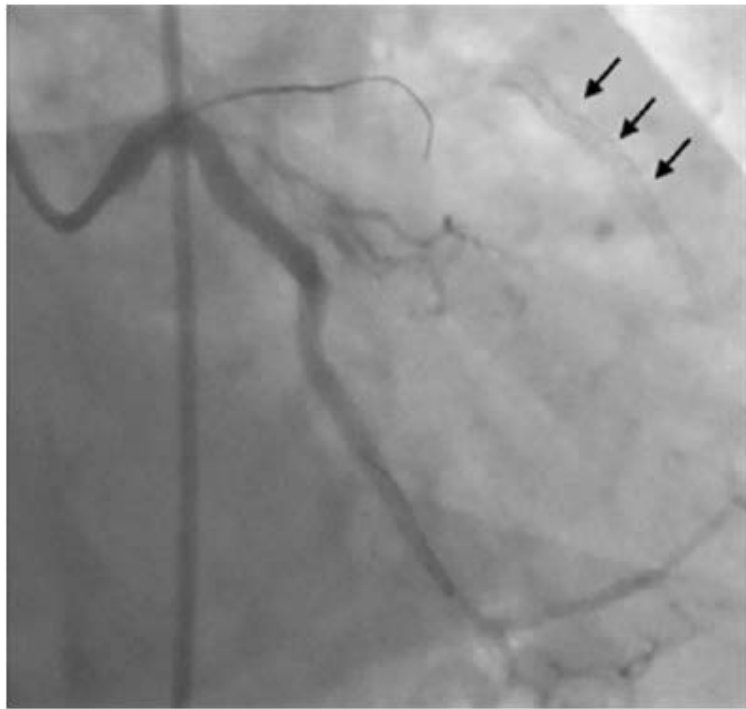
Division of Cardiothoracic Surgery, Department of Surgery, McGill University Health Center, 1650 Cedar Avenue, Montreal, Quebec, H3G 1A4, Canada



Coronary Bypass Grafting to a “Full-Metal Jacket” Left Anterior Descending Artery

María J. Mataró, MD, Gemma Sánchez-Espín, MD, Carlos Porras, MD,
José M. Melero, MD, Eduardo Olalla, MD, PhD, and Miguel Such, MD, PhD

Department of Cardiovascular Surgery, Hospital “Virgen de la Victoria,” Málaga, Spain



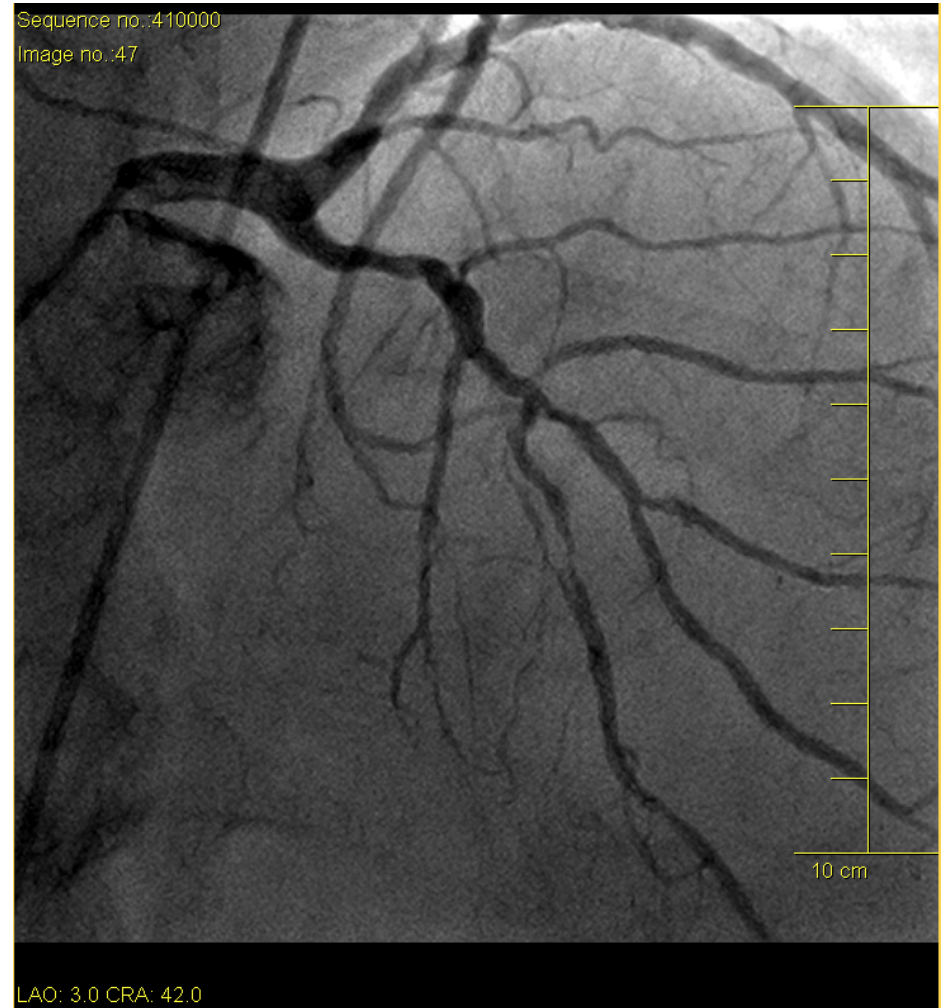
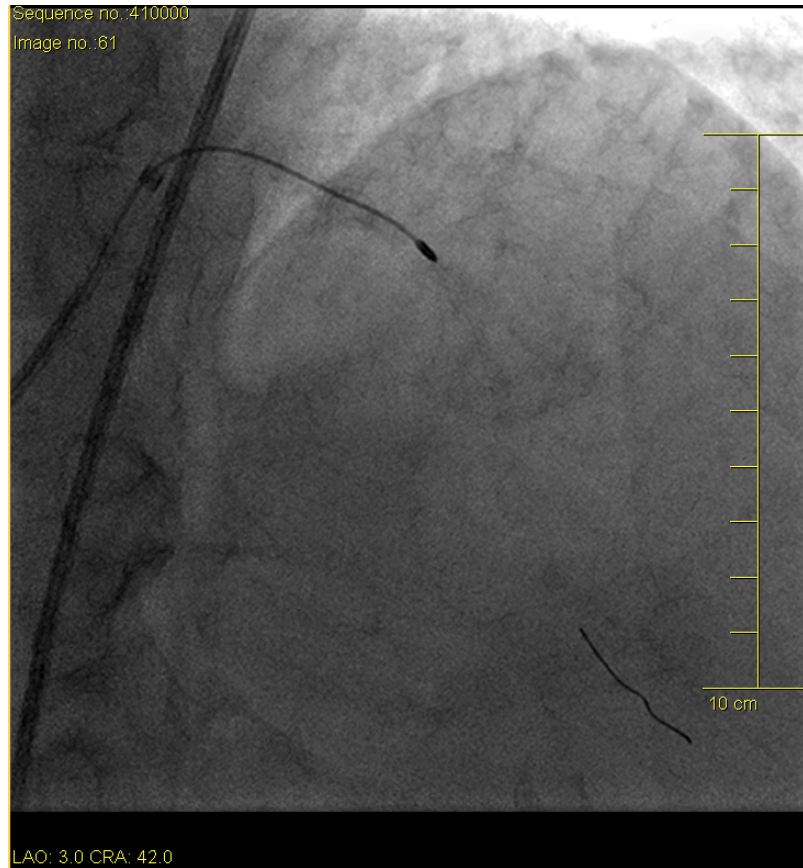
Case report: full "Scaffold" Jacket with BVS after Rotablator on LAD.

- 66 year old man
- Patient had hypertension and dyslipidemia as cardiovascular risk factors.
- ACS with two vessels disease: RCA and LAD.
LVEF 42%.

Case report: full "Scaffold" Jacket with BVS after Rotablator on LAD.



Case report: full "Scaffold" Jacket with BVS after Rotablator on LAD.



Case report: full "Scaffold" Jacket with BVS after Rotablator on LAD.

- We implanted two BVS in overlap (2.5x28 mm distal and 3.0x28 mm proximal).
- We performed IVUS control on LAD.
- On the basis of the IVUS images we decided to optimize the result with NC balloons 3 and 3.5 mm.
- Good final result was achieved.

Case report: full "Scaffold" Jacket with BVS after Rotablator on LAD.



Caso clinico

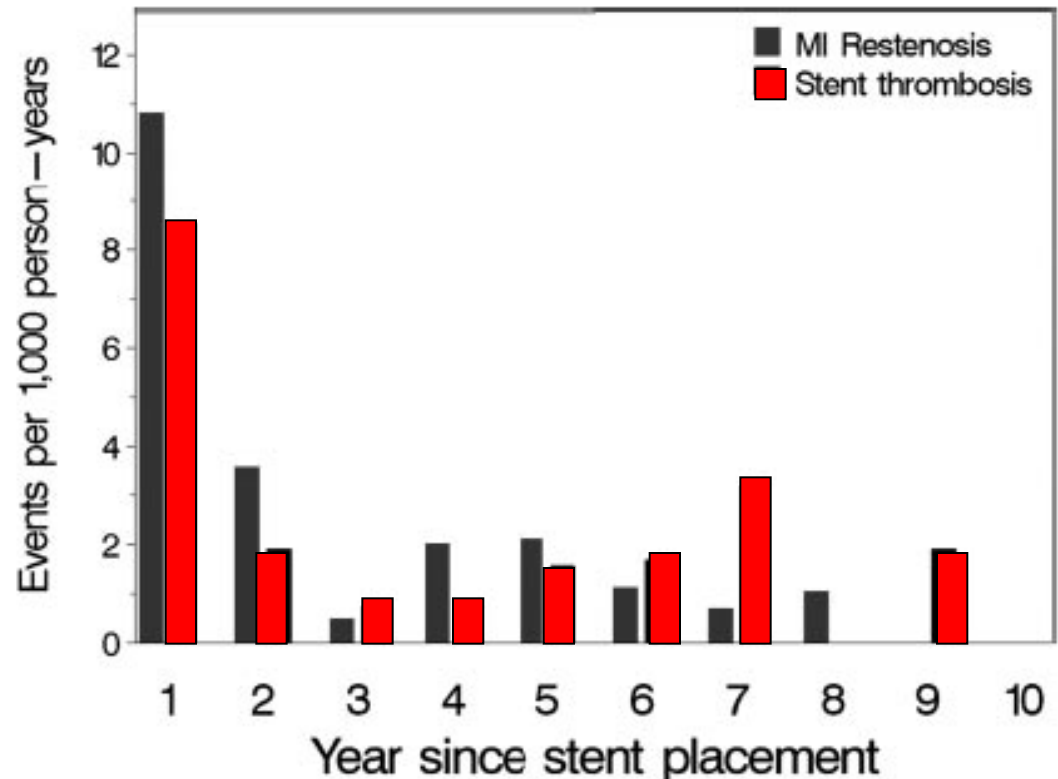
- Z.M. , uomo di anni 83 , diabete tipo II, ex fumatore.
- Maggio 2006: ricovero per SCA-NSTE: stenosi 90% prox-RCA → 1 BMS.
- Benessere sino al Novembre 2011 : sospensione di ASA per TURP. Una settimana dopo sospensione , prima dell'intervento ricovero per STEMI inferiore.



Outcomes of Stent Thrombosis and Restenosis During Extended Follow-Up of Patients Treated With Bare-Metal Coronary Stents

Circulation November 20, 2007

Brendan Doyle, MB, BCh; Charanjit S. Rihal, MD, MBA; Crochan J. O'Sullivan, MB, BCh;
 Ryan J. Lennon, MS; Heather J. Wiste, BA; Malcolm Bell, MB, BS, FRACP;
 John Bresnahan, MD; David R. Holmes Jr, MD



| No. at Risk | 4503 | 4255 | 4127 | 4017 | 3886 | 3692 | 3428 | 2619 | 1677 | 882 |
|------------------|------|------|------|------|------|------|------|------|------|-----|
| No. of events | | | | | | | | | | |
| MI Restenosis | 47 | 15 | 2 | 8 | 8 | 4 | 2 | 2 | 0 | 0 |
| Stent thrombosis | 37 | 8 | 3 | 3 | 6 | 6 | 9 | 0 | 2 | 0 |

Early and late coronary stent thrombosis of sirolimus-eluting and paclitaxel-eluting stents in routine clinical practice: data from a large two-institutional cohort study

Joost Daemen, Peter Wenaweser, Keichi Tsuchida, Linda Abrecht, Sophia Vaina, Cyrill Morger, Neville Kukreja, Peter Jüni, Georgios Sianos, Gerrit Hellige, Ron T van Domburg, Otto M Hess, Eric Boersma, Bernhard Meier, Stephan Windecker, Patrick W Serruys

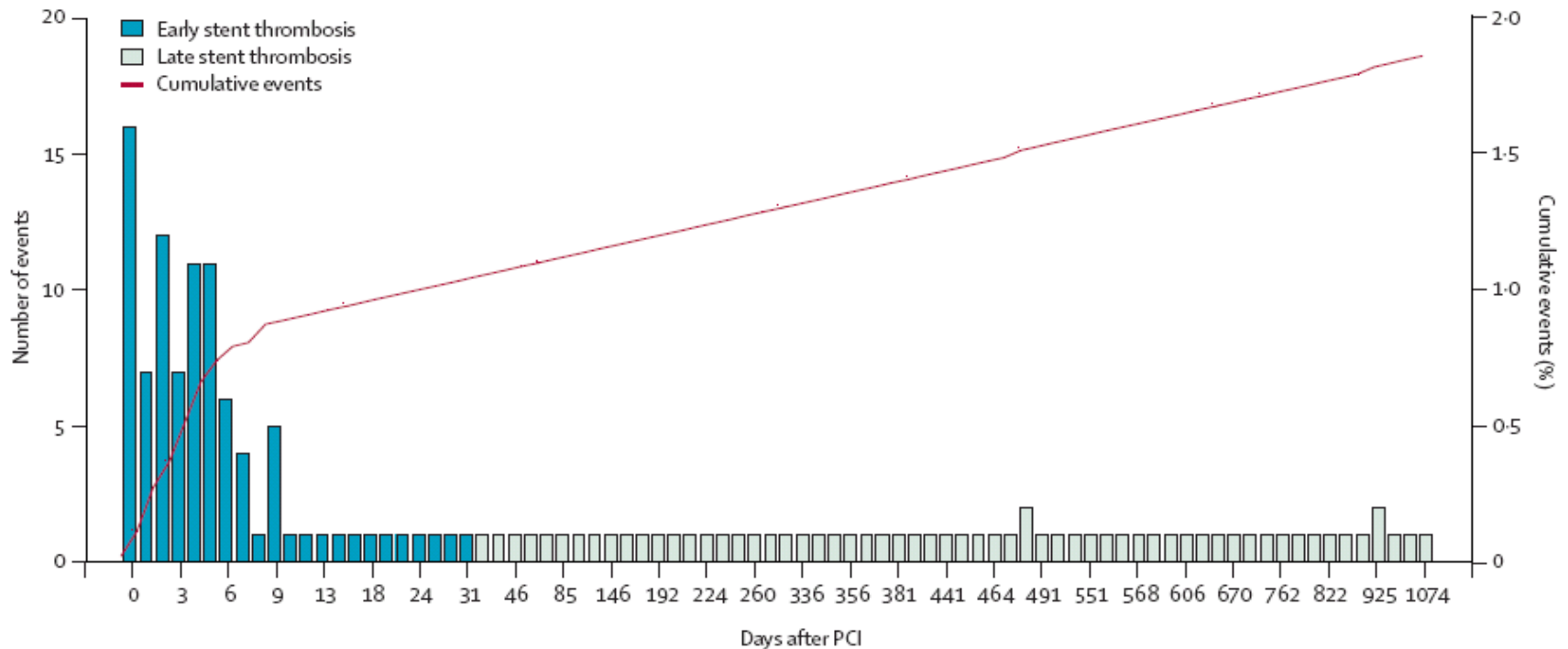
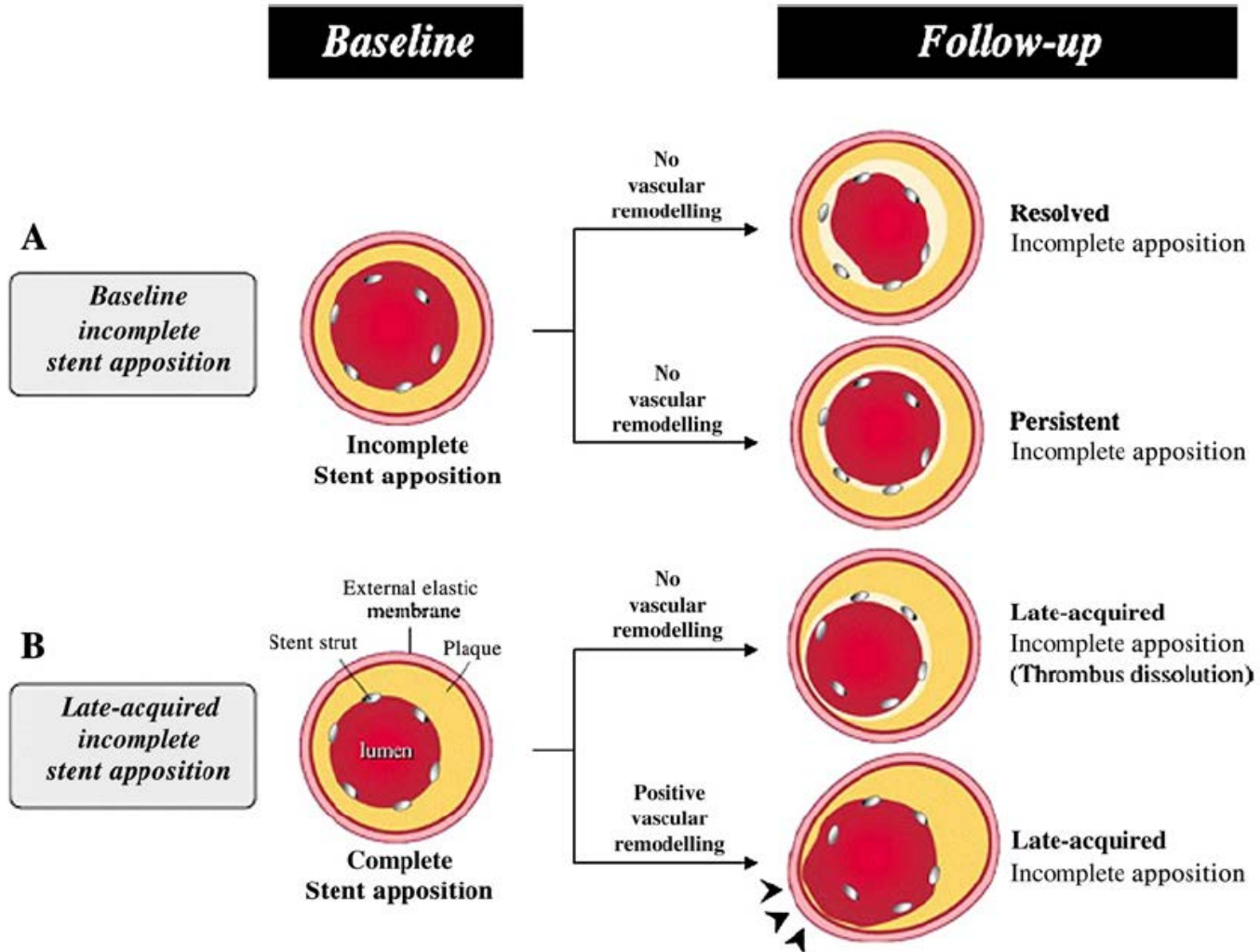


Figure 2: Occurrence and frequency of stent thrombosis over time

Late acquired stent malapposition: why, when and how to handle?

Heart 2012;98:1529–1536.

Ioannis Karalis,¹ Tarek A H N Ahmed,¹ J W Jukema^{1,2,3,4}



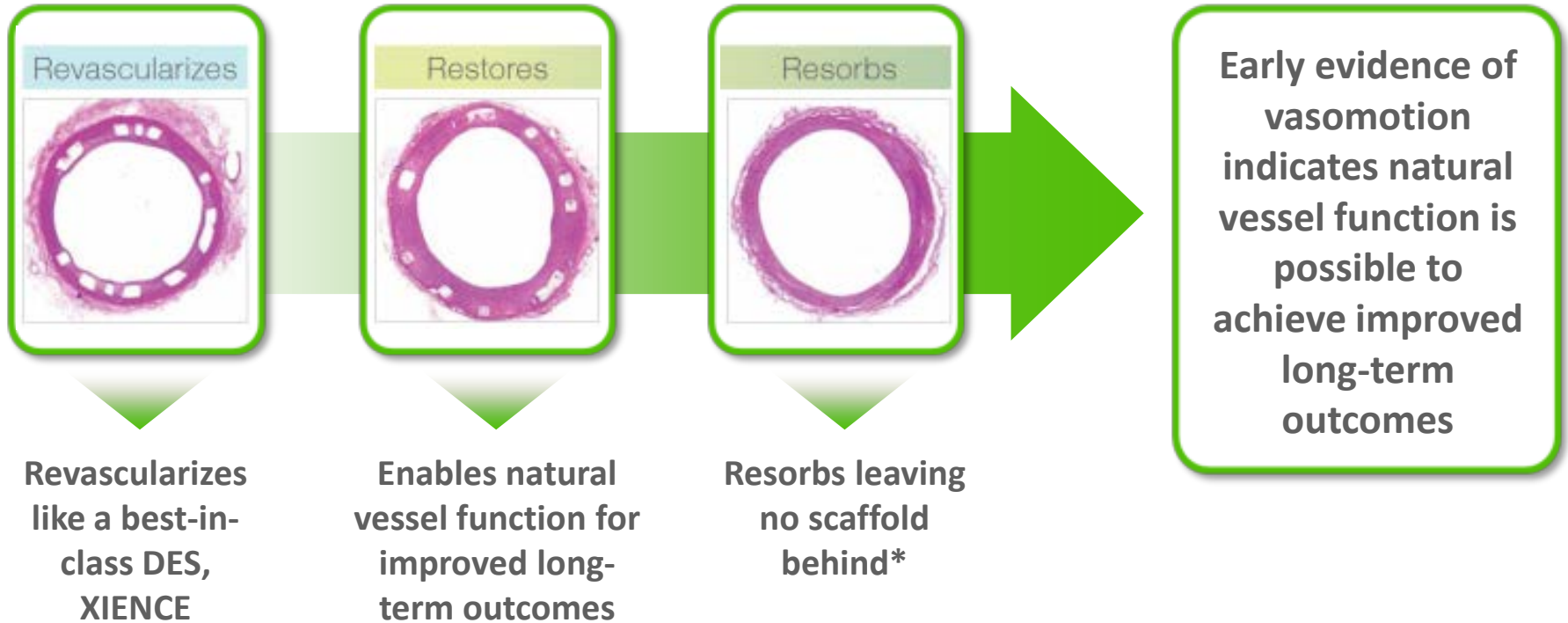
A bioabsorbable everolimus-eluting coronary stent system (ABSORB): 2-year outcomes and results from multiple imaging methods

Lancet 2009; 373: 897-910

Patrick W Serruys, John A Ormiston, Yoshinobu Onuma, Evelyn Regar, Nieves Gonzalo, Hector M Garcia-Garcia, Koen Nieman, Nico Bruining, Cécile Dorange, Karine Miquel-Hébert, Susan Veldhof, Mark Webster, Leif Thuesen, Dariusz Dudek



Absorb Bioresorbable Vascular Scaffold: Three Phases of Functionality

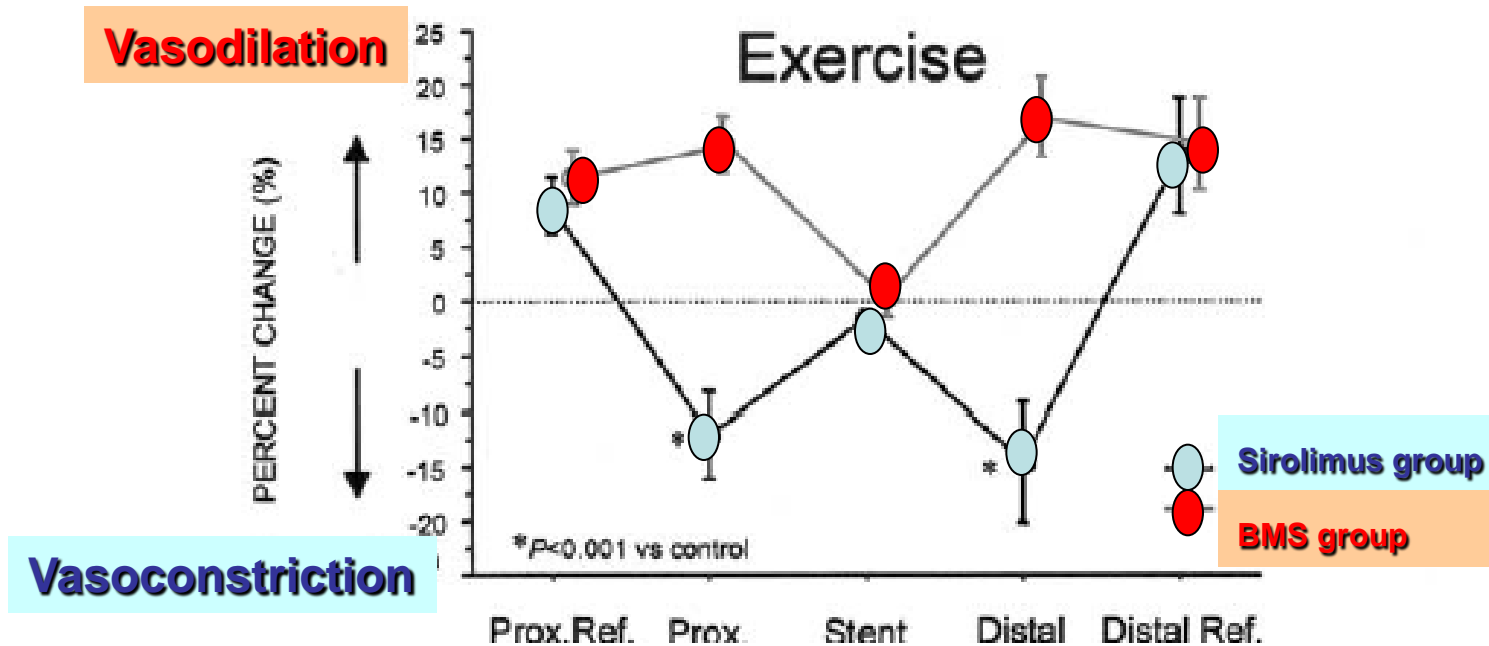


Vascular Reparative Therapy

Sirolimus-Eluting Stents Associated With Paradoxical Coronary Vasoconstriction

Mario Togni, MD, Stephan Windecker, MD, Rosangela Cocchia, MD, Peter Wenaweser, MD, Stephane Cook, MD, Michael Billinger, MD, Bernhard Meier, MD, FACC, Otto M. Hess, MD, FACC
Bern, Switzerland

JACC Vol. 46, No. 2, 2005
July 19, 2005:231-6



Endothelial-dependent vasomotion in a coronary segment treated by ABSORB everolimus-eluting bioresorbable vascular scaffold system is related to plaque composition at the time of bioresorption of the polymer: indirect finding of vascular reparative therapy?

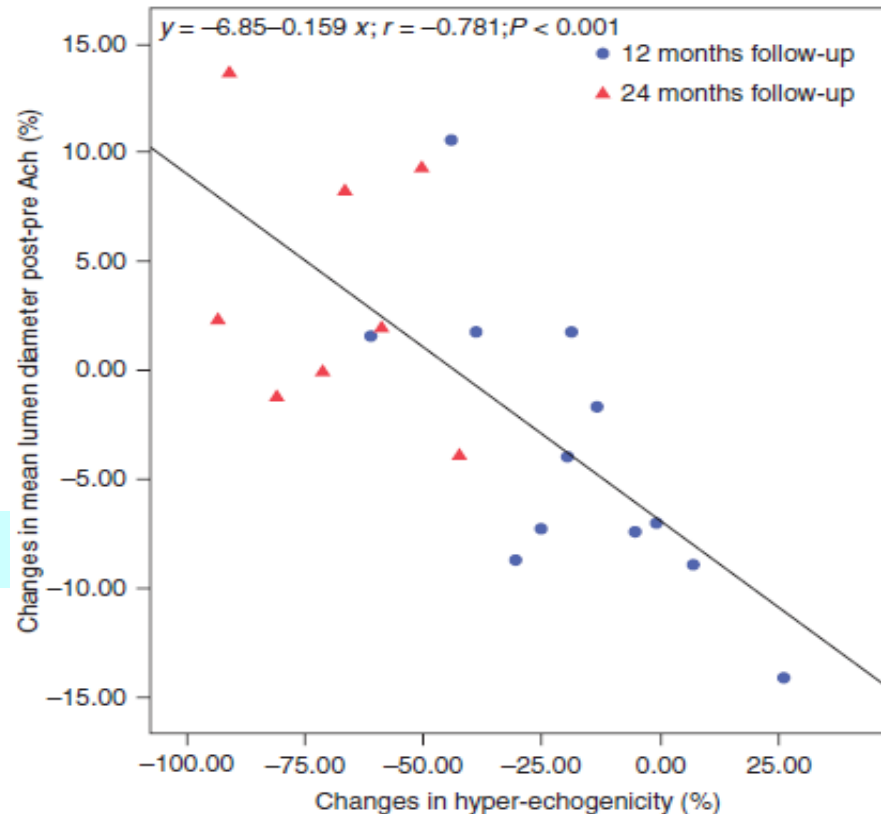
European Heart Journal (2012) 33, 1325–1333

Salvatore Brugaletta^{1,2†}, Jung Ho Heo^{1†}, Hector M. Garcia-Garcia^{1,3}, Yasim Farooq¹, Robert Jan van Geuns¹, Bernard de Bruyne⁴, Dariusz Dudek⁵, Pieter C. Smits⁶, Jacques Koolen⁷, Dougal McClean⁸, Cecile Dorange⁹, Susan Veldhof⁹, Richard Rapoza¹⁰, Yoshinobu Onuma¹, Nico Bruining¹, John A. Ormiston¹¹, and Patrick W. Serruys^{1*}

I.c. Acetylcholine administration

Vasodilation

Vasoconstriction



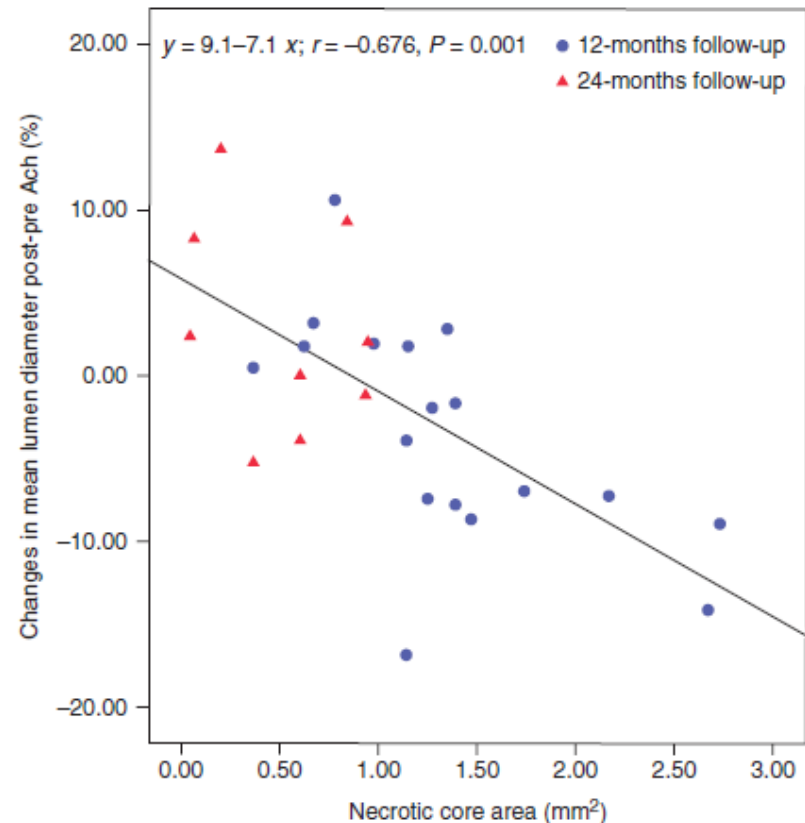
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Vasodilation

Vasoconstriction



A further step towards vascular reparative therapy

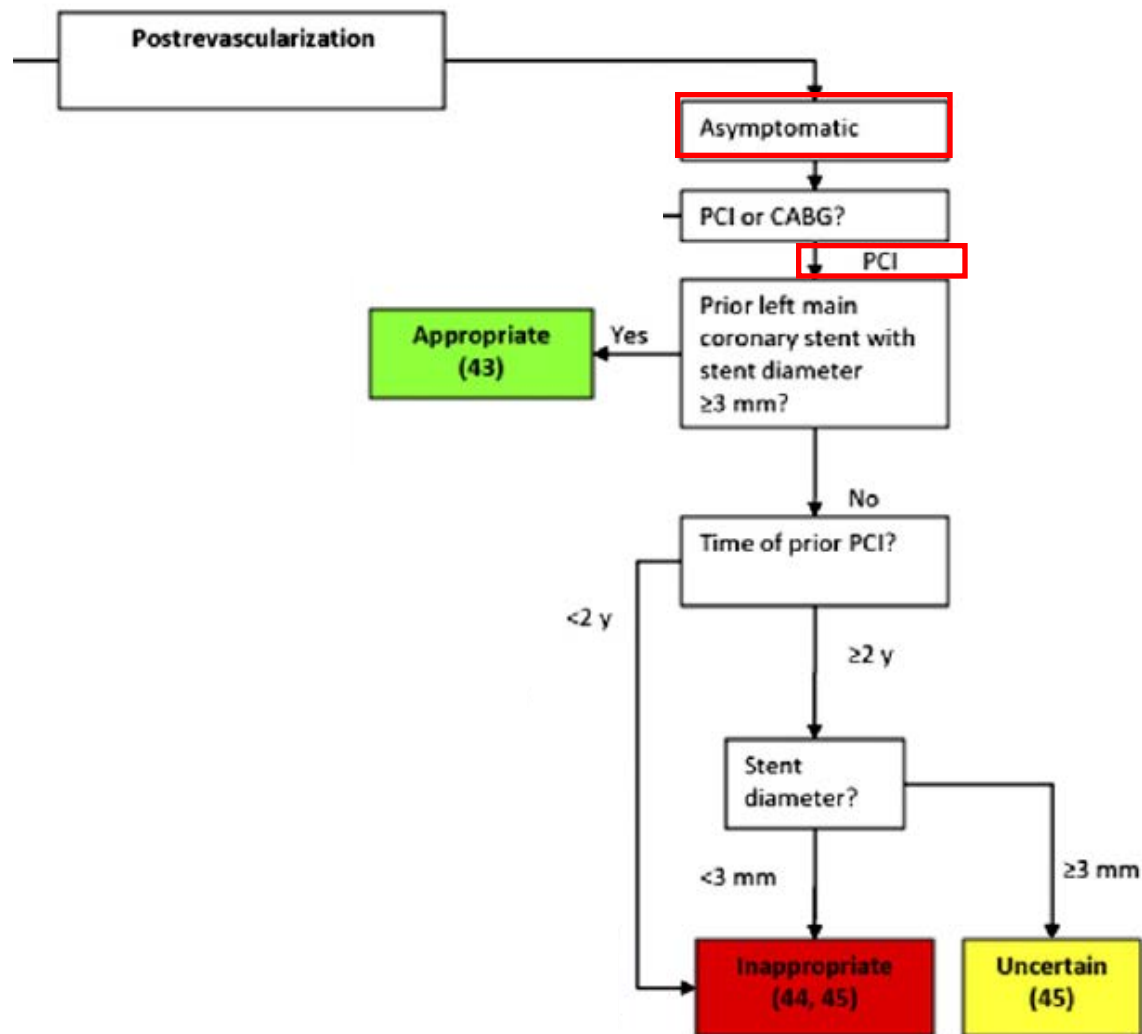
Roberto Corti*

Department of Cardiology, Universitätsspital Zurich, Rämistrasse 100, 8091 Zurich, Switzerland

Even though preliminary, the reported results seem to indicate hope for the vascular reparative therapy aimed for.

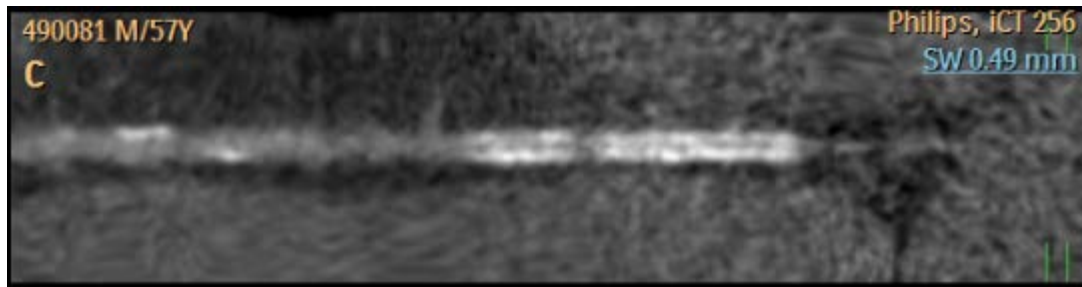
ACCF/SCCT/ACR/AHA/ASE/ASNC/NASCI/SCAI/SCMR 2010 Appropriate Use Criteria for Cardiac Computed Tomography

A Report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, the Society of Cardiovascular Computed Tomography, the American College of Radiology, the American Heart Association, the American Society of Echocardiography, the American Society of Nuclear Cardiology, the North American Society for Cardiovascular Imaging, the Society for Cardiovascular Angiography and Interventions, and the Society for Cardiovascular Magnetic Resonance





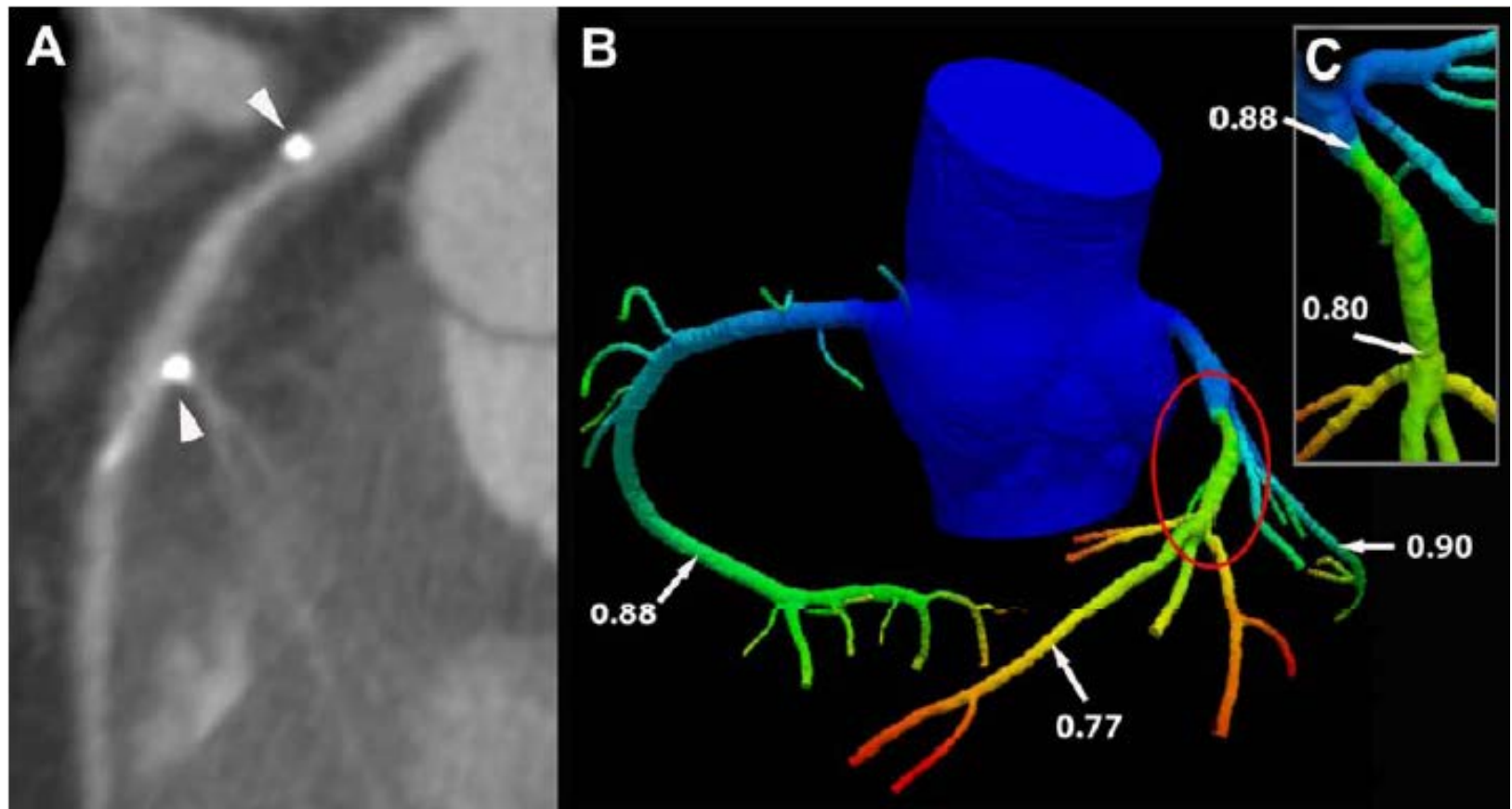
CD stent diametro 2.5 mm



Multislice Computed Tomography Angiography for Non-invasive Assessment of the 18-Months Performance of a Novel Radiolucent Bioresorbable Vascular Scaffolding Device (ABSORB Trial)



Koen Nieman, MD, PhD Patrick W. Serruys, MD, PhD Yoshinobu Onuma, MD
Robert-Jan van Geuns, MD, PhD Hector M. Garcia-Garcia, MD, PhD Bernard de
Bruyne, MD, PhD Leif Thuesen, MD Pieter C. Smits, MD, PhD Jacques J. Koolen,
MD, PhD Dougal McClean, MD Bernard Chevalier, MD Ian Meredith, MD John
Ormiston, MD, PhD



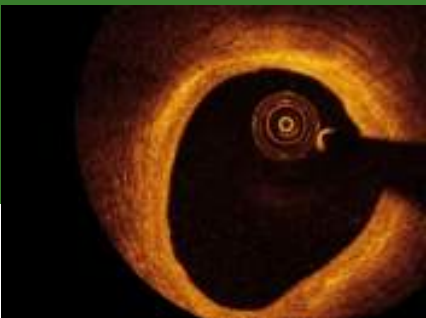
A revolution in art: Jackson Pollock a Palazzo Reale Milano , dal 24 Settembre



Jackson Pollock helped create a new art movement known as Abstract Expressionism

UNA RIVOLUZIONE IN CARDIOLOGIA INTERVENTISTICA

A Fully Bioresorbable Vascular Scaffold



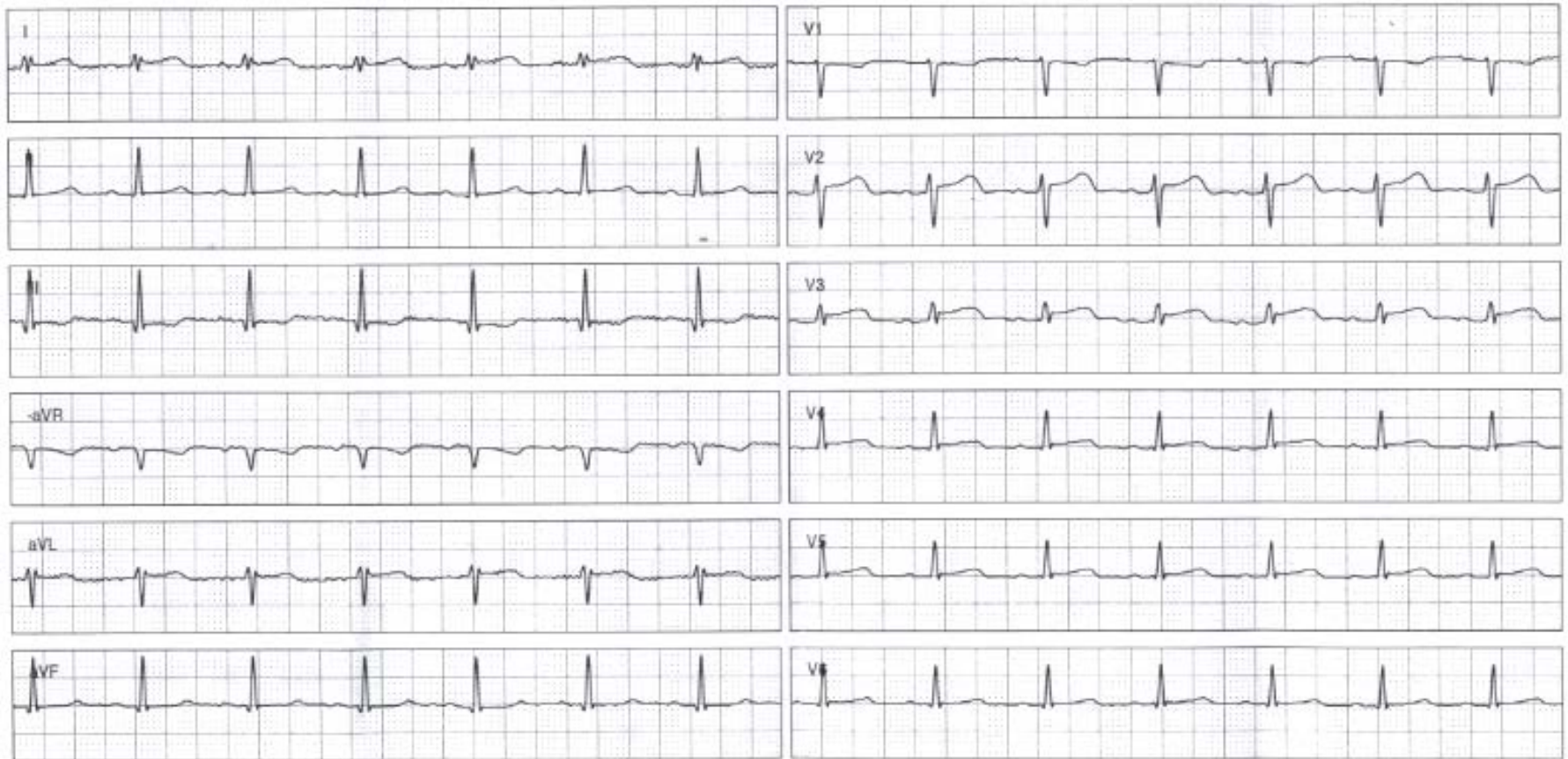
©2012 Abbott. All rights reserved.

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Case report of STEMI and BVS

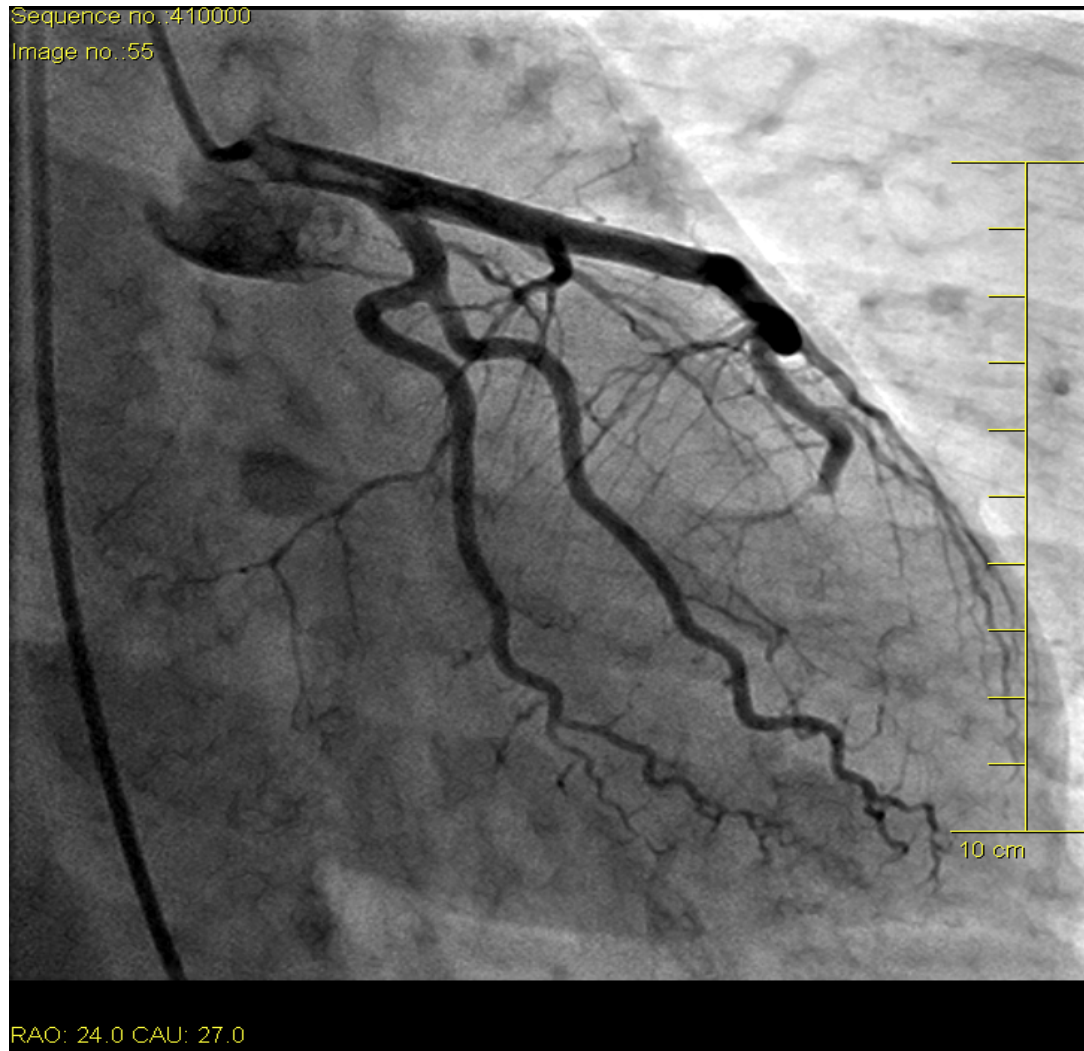
- 20 year old girl.
- No family history nor risk factors for CAD.
- She was taking oral contraceptives for over 3 years.
- Onset of chest pain the evening before hospital admission.
- ECG showed ST elevation V2-V4 and the coronary.
- ECHO showed akinetic apex with LVEF 40%.

Case report of STEMI and BVS



Case report of STEMI and BVS

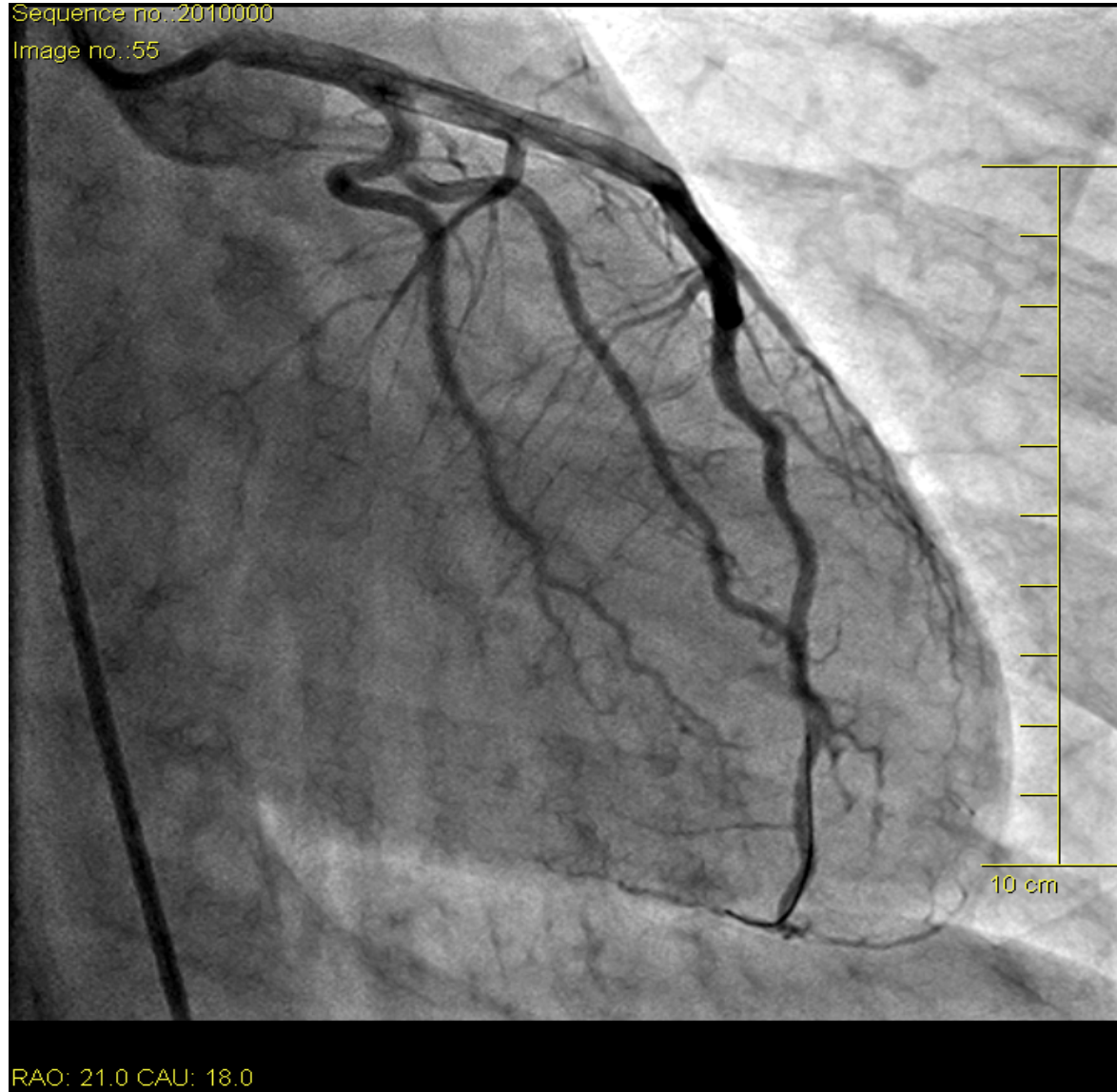
Coronary angiogram showed an occlusion of the middle segment of LAD.



Case report of STEMI and BVS

- Pre-treatment with ASA 250 mg i.v., loading dose of Ticagrelor 180 mg and Bivalirudin.
- Pre-dilatation with balloons 2.75 and 3.0 x 20 mm.
- Implant BVS 3x18 mm.
- Post-dilated with NC balloon 3 mm.
- Good final result.

Case report of STEMI and BVS



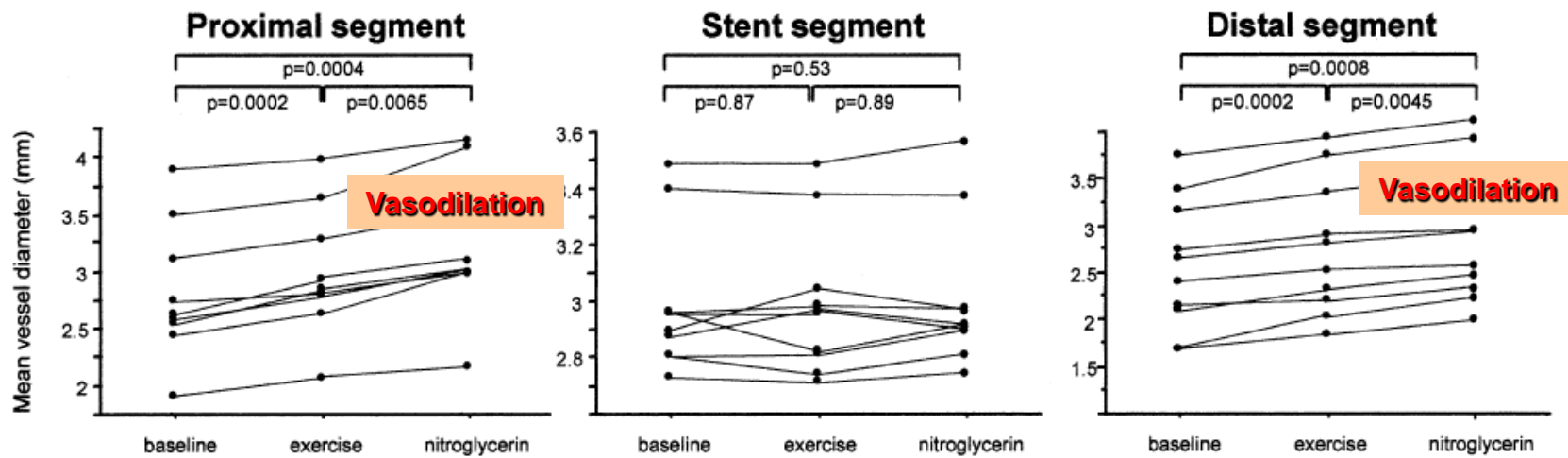


Sirolimus-Eluting Stents Associated With Paradoxical Coronary Vasoconstriction

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Bern, Switzerland

JACC Vol. 46, No. 2, 2005
July 19, 2005:231-6

BMS group

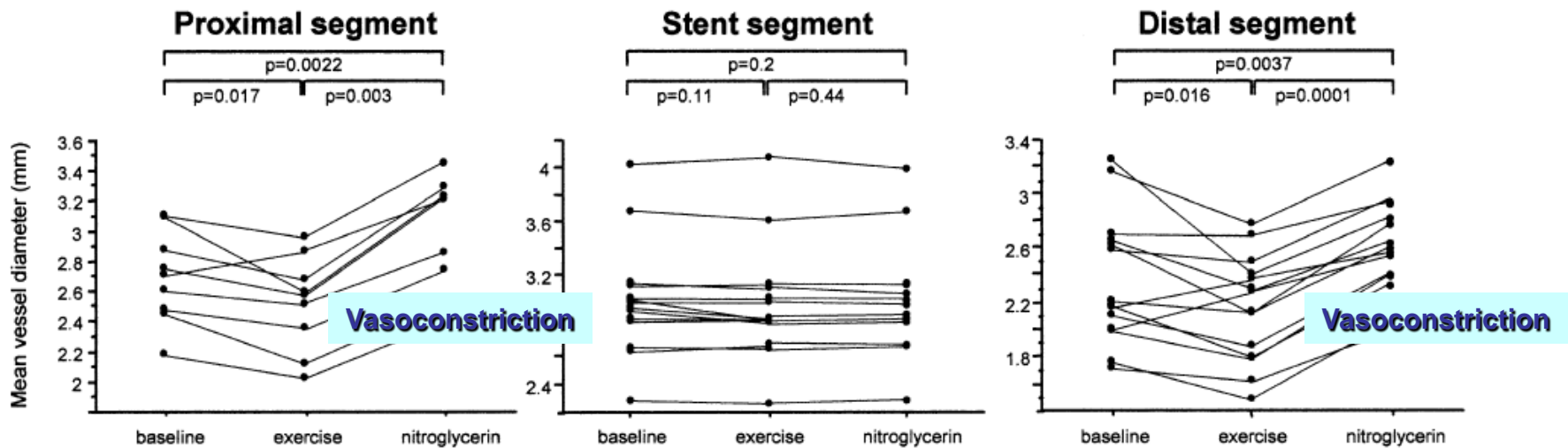


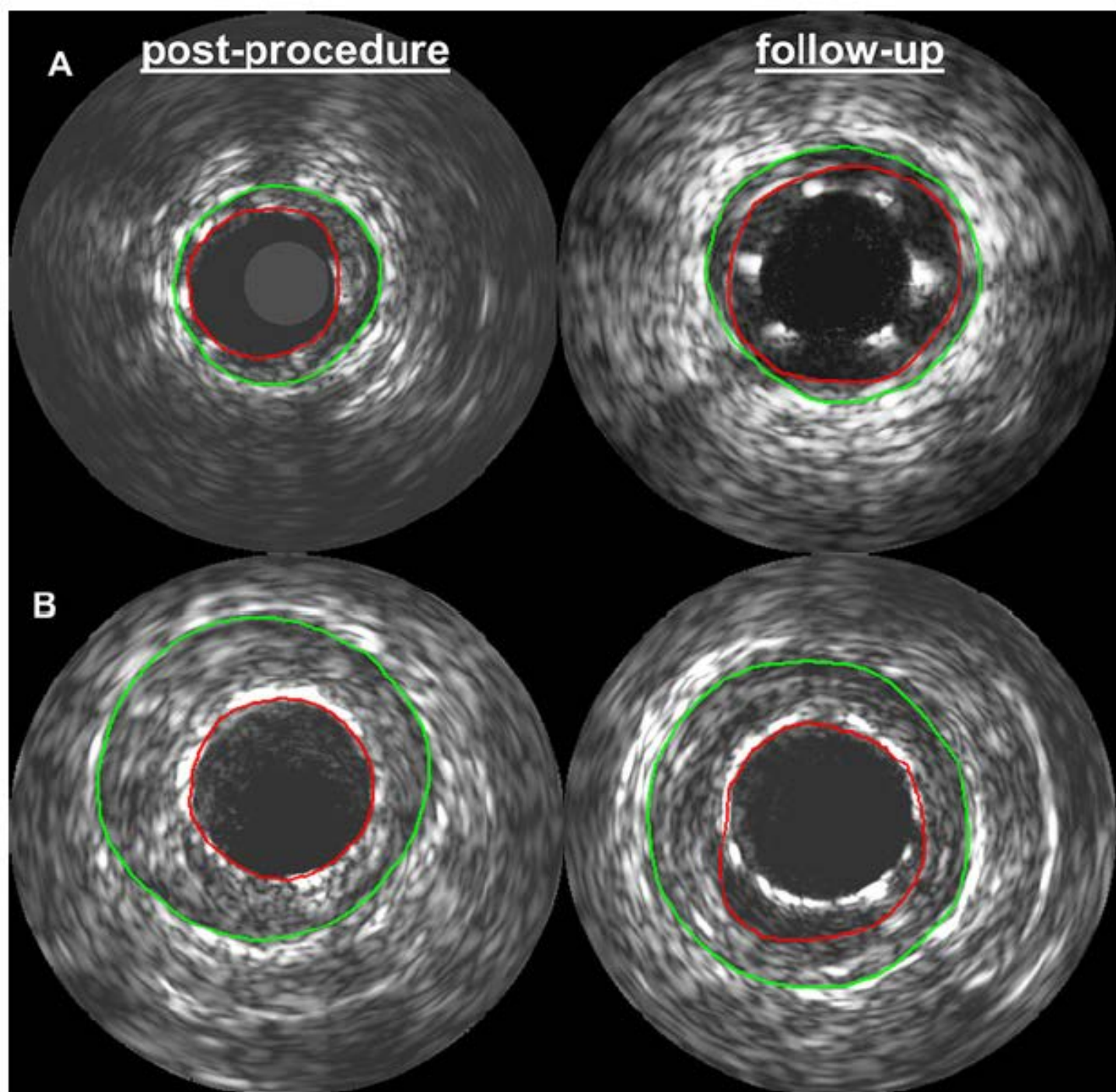
Sirolimus-Eluting Stents Associated With Paradoxical Coronary Vasoconstriction

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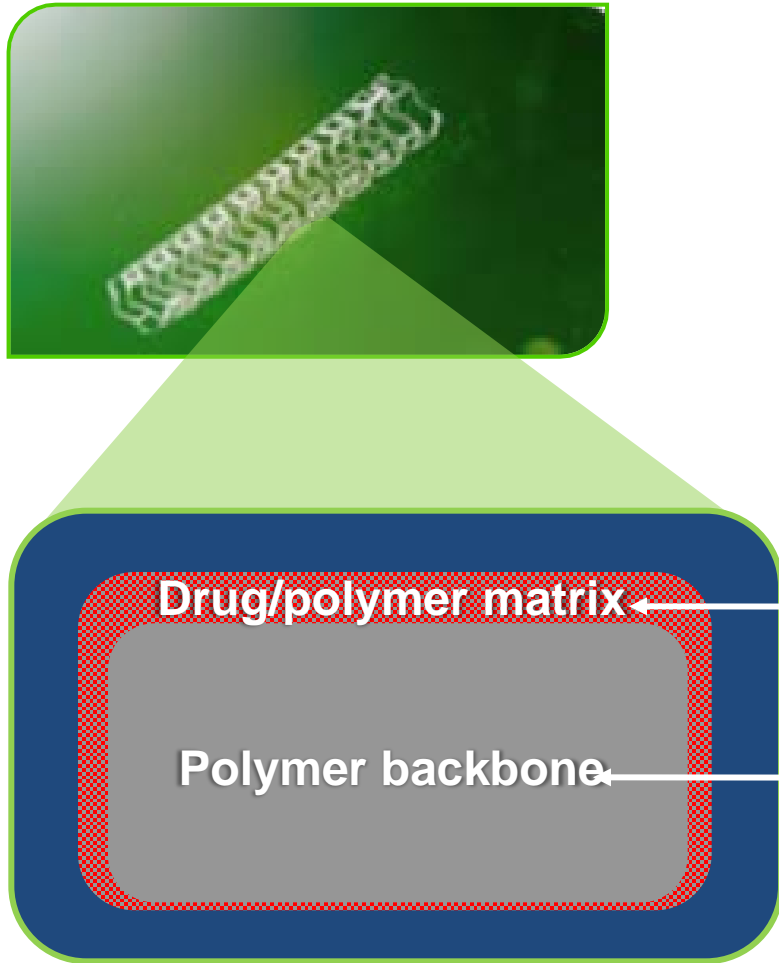
JACC Vol. 46, No. 2, 2005
July 19, 2005:231-6

Sirolimus group





Bioresorbable Polymer



Everolimus/PDLLA Matrix Coating

- Thin layer
- Amorphous (non-crystalline)
- 1:1 ratio of Everolimus/PDLLA matrix
- Conformal coating, 2-4 μm thick
- Controlled drug release

PLLA Scaffold

- Semi-crystalline
- Provides device structure
- Processed for required radial strength

In-Stent Neoatherosclerosis

**A Cause of Late Stent Thrombosis in a Patient With “Full Metal Jacket”
15 Years After Implantation: Insights From Optical Coherence Tomography**

VOL. 5, NO. 7, 2012

Antonios Karanasos, MD, Jurgen M. R. Ligthart, BSc, Evelyn Regar, MD, PhD

