i2 summit 2007

INNOVATION IN INTERVENTION

American College of Cardiology in co-sponsorship with SCAI

Late Breaking Emerging Technologies at i2 2007

Ron Waksman, M.D., FACC, SCAI

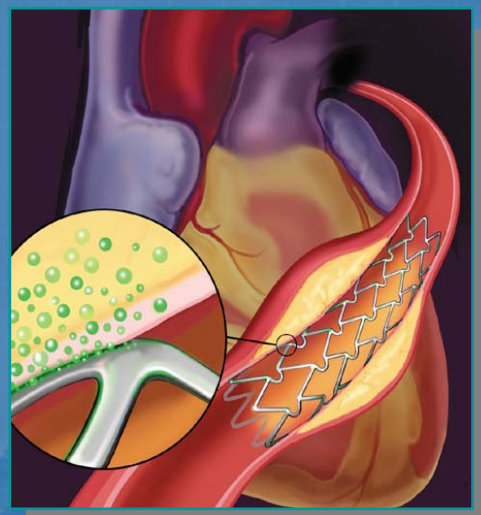
i2 summit 2007

INNOVATION IN INTERVENTION

American College of Cardiology in co-sponsorship with SCAI

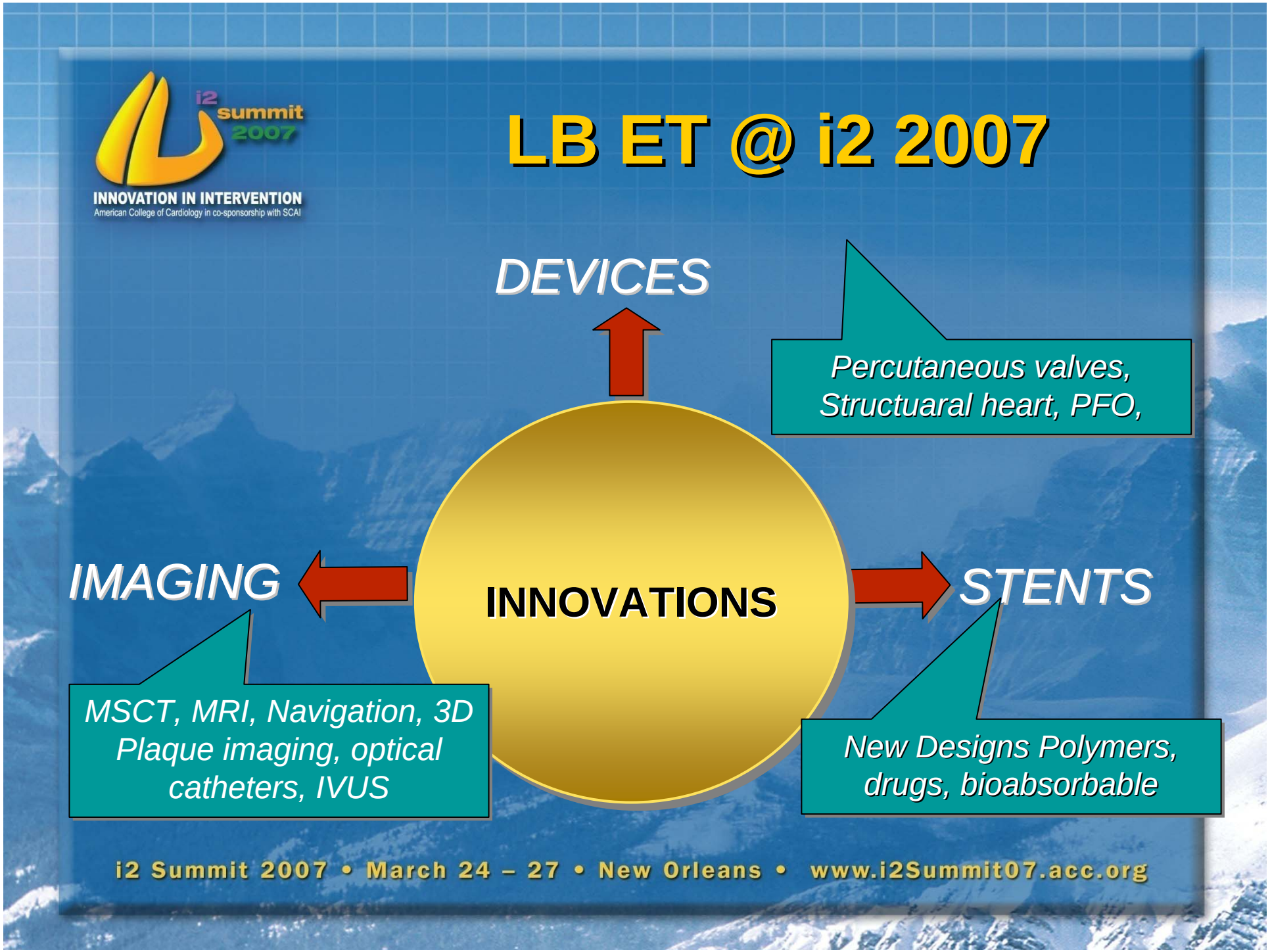
LB ET @ i2 2007

- This is an exciting time for
- Interventional cardiologists
- Patients
- Inventors
- Medical Community



INNOVATION BEYOND IMAGINATION

i2 Summit 2007 • March 24 – 27 • New Orleans • www.i2Summit07.acc.org


i2 summit 2007
INNOVATION IN INTERVENTION
American College of Cardiology in co-sponsorship with SCAI
LB ET @ i2 2007
DEVICES
Percutaneous valves, Structuaral heart, PFO,
IMAGING
MSCT, MRI, Navigation, 3D Plaque imaging, optical catheters, IVUS
INNOVATIONS
STENTS
New Designs Polymers, drugs, bioabsorbable
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New stents Solutions

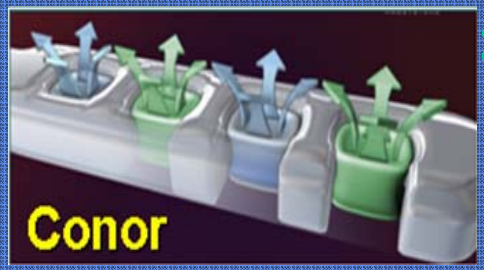
1. New coating (absorbable coating, no coating)
2. New Biological target: (*Endothelium, thrombosis, inflammation*)
3. New drug (less cytostatic or cytotoxic)
4. New technique of elution (reservoir, dual elution)
5. Pro Healing approach (EPC capture)
6. Pro Healing approach +Sirolimus or Paclitaxel
7. Complete Absorbable metallic or polymeric platform
8. New Stent Design for challenging targets bifurcations

New DES Programs

• NO Donors	Blue Medical
• Biolimus A9	Biosensors, Terumo, Devax
• Zotarolimus	Zomax, Endeavor CR
• Pimecrolimus	Biotronik, Conor, Avantac
• Melatonin	Blue Medical
• Gleevec	Novartis
• Everolimus	Guidant
• Tacrolimus	Sorin
• EPC Progenitors	Orbus
• Restin-NG	AVI Biopharma
• Genistein	Sahajanand
• Paclitaxel Balloon	B- Braun
• Bioabsorbable	Guidant, Biotronik, Reva
	More More More !!!!!

Advanced Approaches to Drug Release

- Bioabsorbable polymers



BioFlex I
Biosensors

- Controlled polymer application

- Non polymer release
  (porous surface)

- Bioabsorbable stents

Late Breaking Clinical Trials I

The ABSORB Trial

Six Month Angiographic and IVUS results from this First-in-Man Evaluation of a Fully Bioabsorbable Everolimus-Eluting Coronary Stent

Patrick W. Serruys, MD, PhD and John A. Ormiston, MD

On behalf of the ABSORB Investigators

Thoraxcenter, Erasmus Medical Center, Rotterdam, the Netherlands

Auckland City Hospital, Auckland, New Zealand

24th March 2007

11:00-11:10

La Nouvelle Orleans C

Study Design

Single, *de-novo* lesion → **3.0 mm n = 30** → **BVS Stent**

- Sponsor: Abbott Vascular
- Primary Investigators:
  - J Ormiston MD
  - PW Serruys MD, PhD
- DSMB: J Tijssen PhD, T Lefèvre MD, P Urban MD
- CEC: C Hanet MD, D McClean MD, V Umans MD
- Angiographic and IVUS Corelab: Cardialysis (Rotterdam, NL)

- Prospective, open label, FIM
- 3.0 x 12mm stents (3.0 x 18mm* stents available after enrolment start and used in 2 pts)
- 6 sites EU, NZ

Rotterdam, NL, Patrick Serruys (16)
Krakow, PL, Dariusz Dudek (6)
Auckland, NZ, John Ormiston (5)
Arhus, DN, Leif Thuesen (3)
Aalst, BE, Bernard de Bruyne
St Denis, F, Bernard Chevalier

QCA results (26 pts)

Pre-Procedure	
Lesion length (mm)	8.66 ± 3.97
RVD (mm)	2.78 ± 0.47
MLD (mm)	1.10 ± 0.26
DS (%)	59 ± 12
Acute gain (mm)	1.24 ± 0.42
Post-procedure	
MLD (mm)	2.33 ± 0.32
DS (%)	17 ± 7
In stent late loss (mm)	**0.44 ± 0.35**
Proximal late loss (mm)	**0.25 ± 0.32**
Distal late loss (mm)	**0.25 ± 0.23**
6 months follow-up	
MLD (mm)	1.88 ± 0.29
DS (%)	27 ± 14

Matched views

Late loss (26pts)

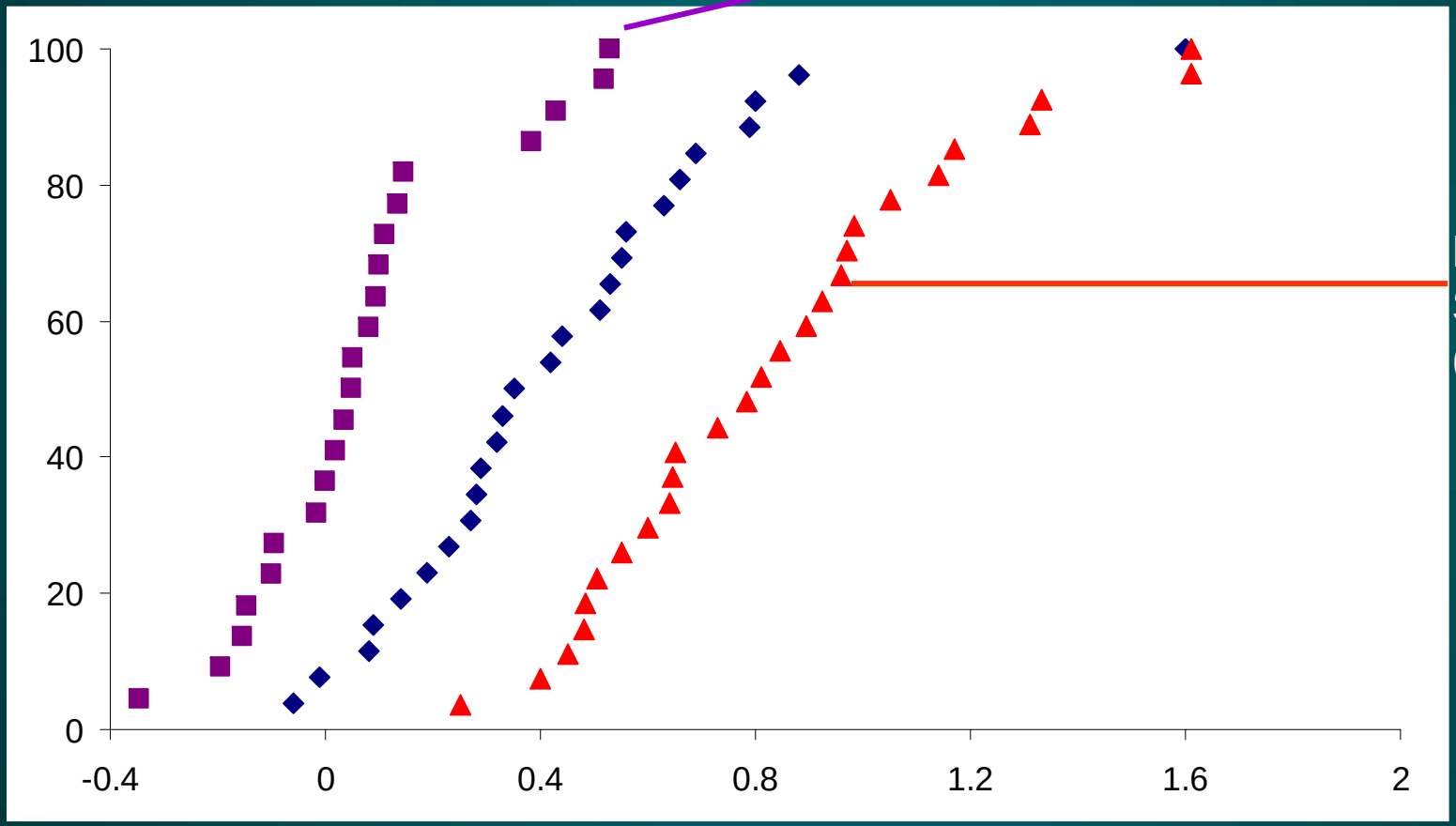
Mean: 0.07 ± 0.23mm,

95%CI [-0.03, 0.17mm]

Median: 0.05mm,

25, 75% percentile [-0.10, 0.14mm]

EES loss of pts with 3.0 x 18mm for single lesion from SPIRIT FIRST and II (n=22)

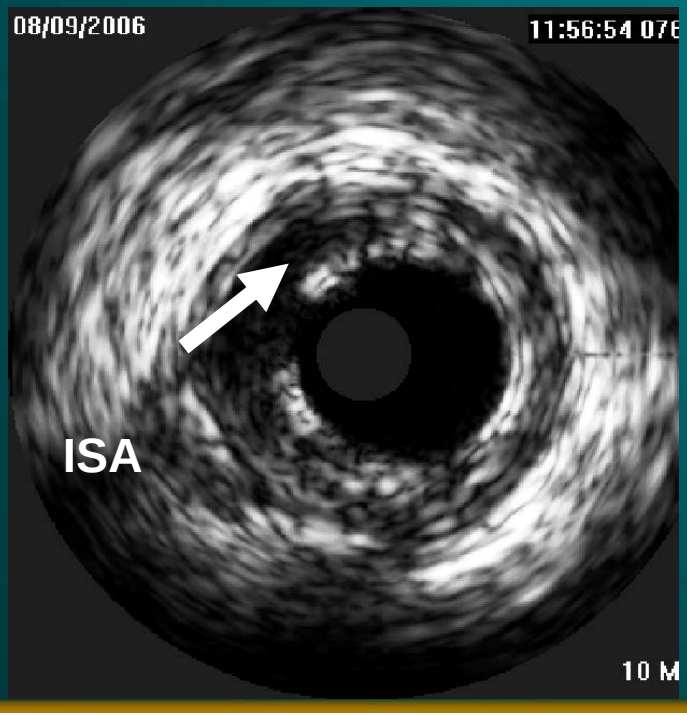


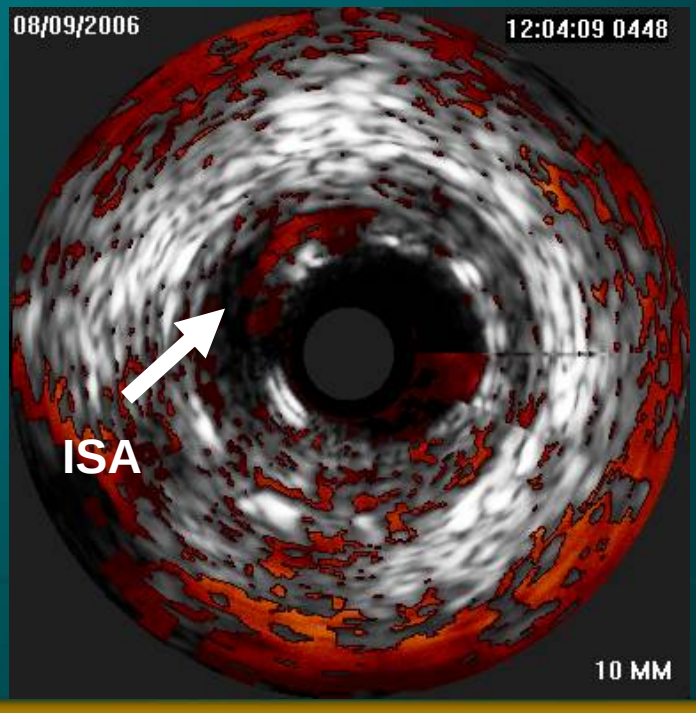
BMS loss from SPIRIT FIRST (n=27)*

Unmatched views

Incomplete Apposition (20 MHz) — 26 Patients

Acute Incomplete Apposition	23 % (6/26)
6-Month Follow-Up:	
Resolved Incomplete Apposition	8 % (2/26)
Persisting Incomplete Apposition	15 % (4/26)
Late Acquired Incomplete Apposition	27 %(7/26)





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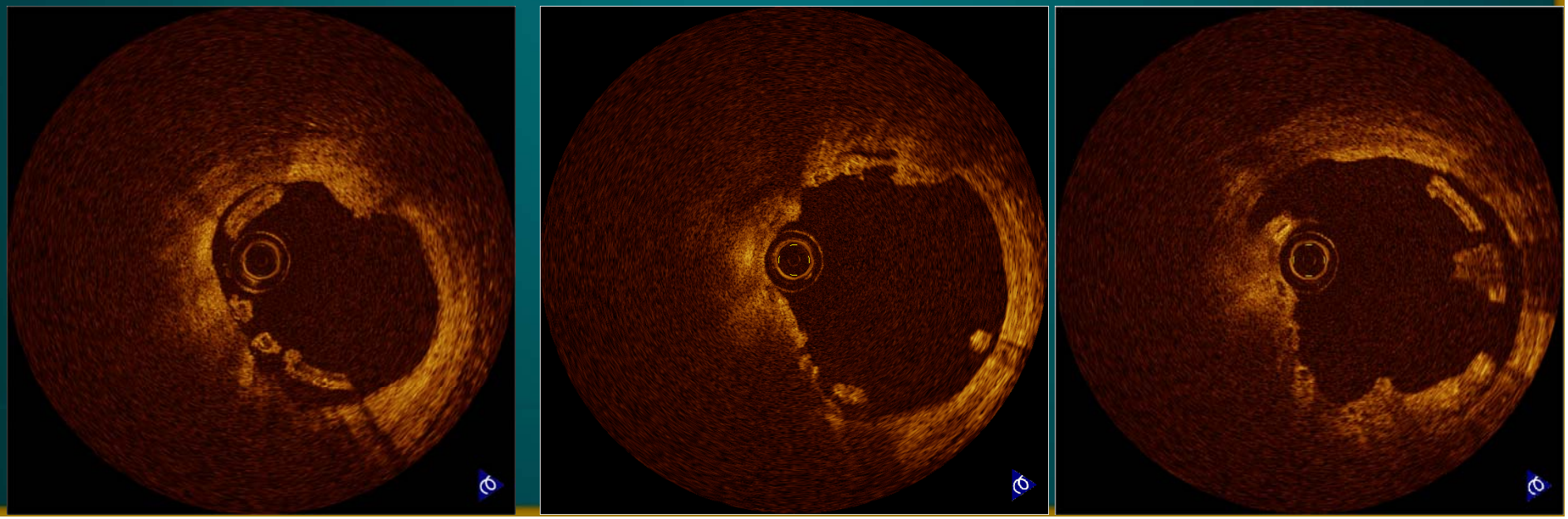
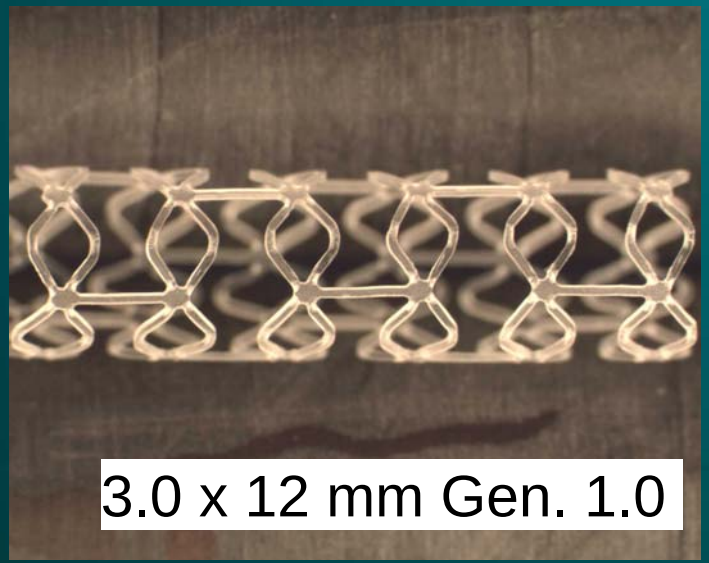
Pt 31119-006 (OCT)



Conclusions

At 6 months follow-up Everolimus eluting from a bioabsorbable polymer is safe and effective:

- **Acceptable in-stent late loss (0.44mm) possibly driven by bioactive remodelling or mechanical late recoil which is being addressed by a modification of the stent design**



3.0 x 12 mm Gen. 1.0

3.0 x 12 mm Gen. 1.1

Conclusions

At 6 months follow-up Everolimus eluting from a bioabsorbable polymer is safe and effective:

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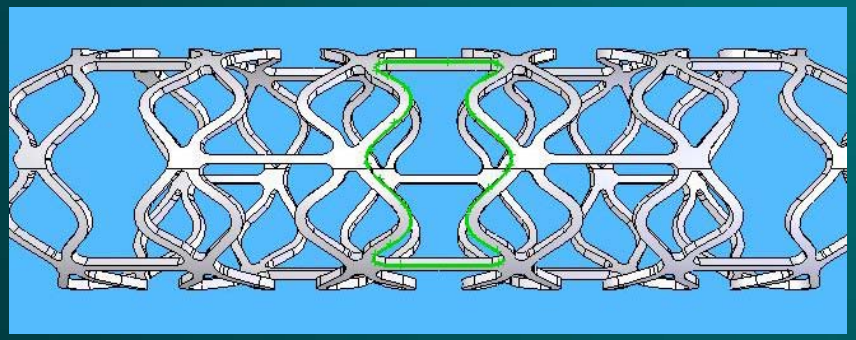
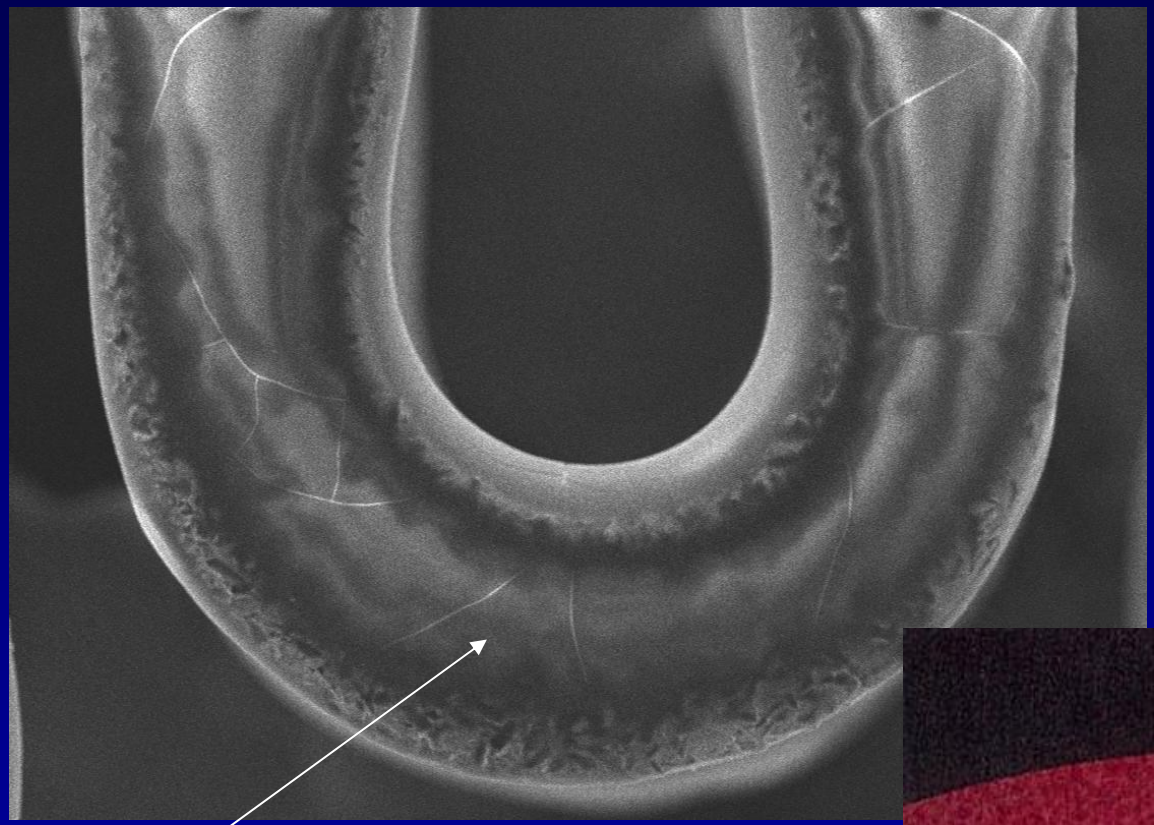


3.0 x 12 mm Gen. 1.0

3.0 x 12 mm Gen. 1.1

Freedom Stent

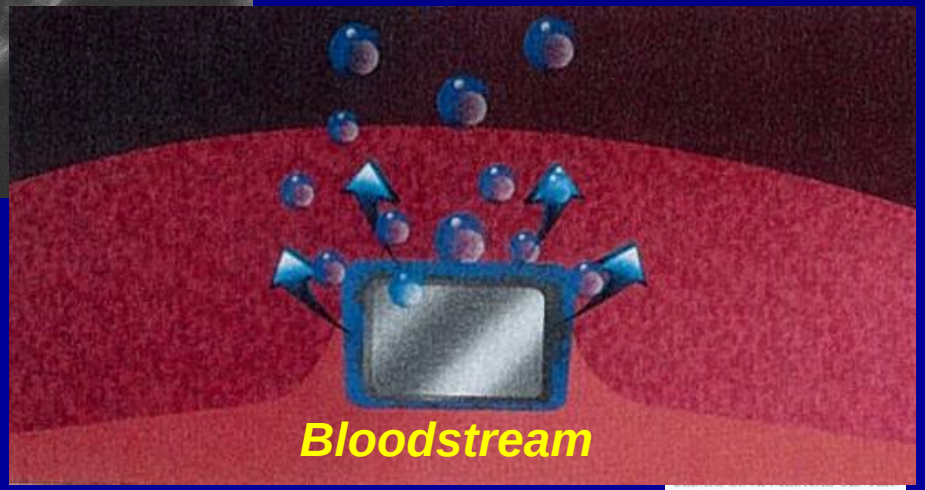
Biolimus A9® Drug



Pure Biolimus A9 impregnated in metal stent surface

FOCUSED DRUG RELEASE:

- Abluminal drug coating targets primarily blood vessel walls
- Only small amounts are released into bloodstream

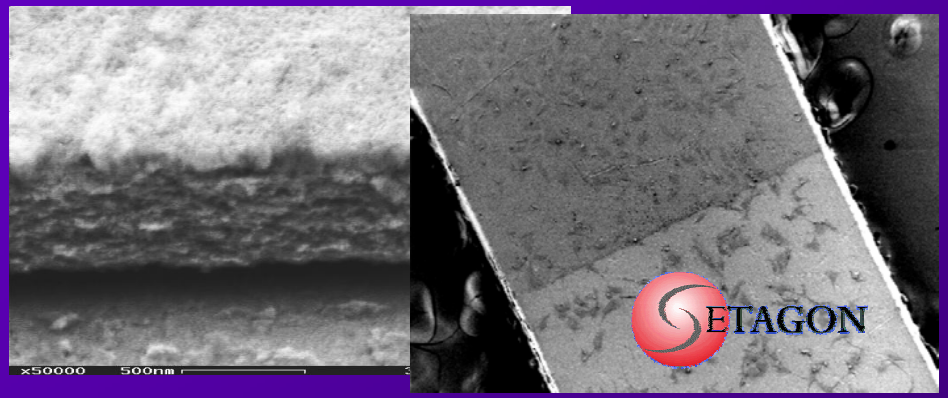


BIOSENSORS INTERNATIONAL

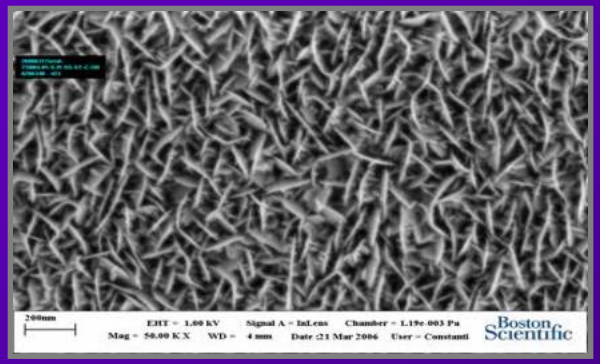
Surfaces to Encourage Cell Growth

Bioactive surfaces to accelerate functional endothelialization

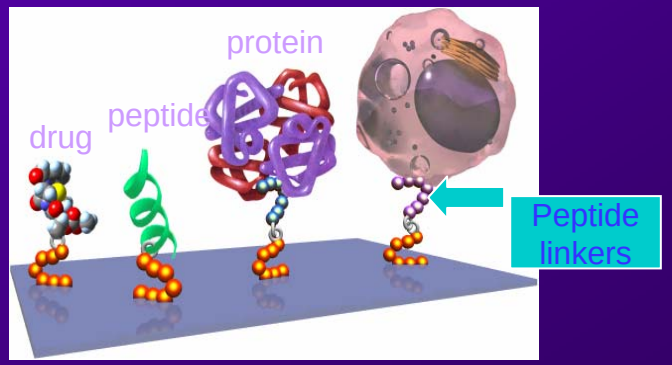
Orbus – EPC Capture



Nanotextured Surfaces



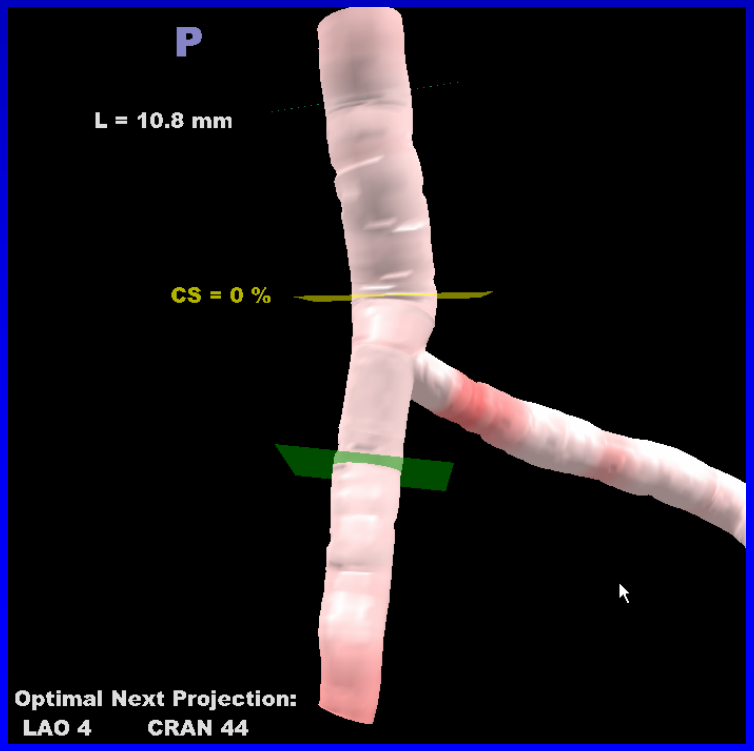
Example of IrOx



Cell specific peptide linkers

Takaaki Shiono, Shigeru Saito, Hideaki Kaneda,
Yusuke Miyashita, Saeko Takahashi, Hiroshi Domae
Heart Center of Shonankamakura General Hospital, Kamakura, Japan

Three-dimensional analysis in treatment with Left Main Trunk !



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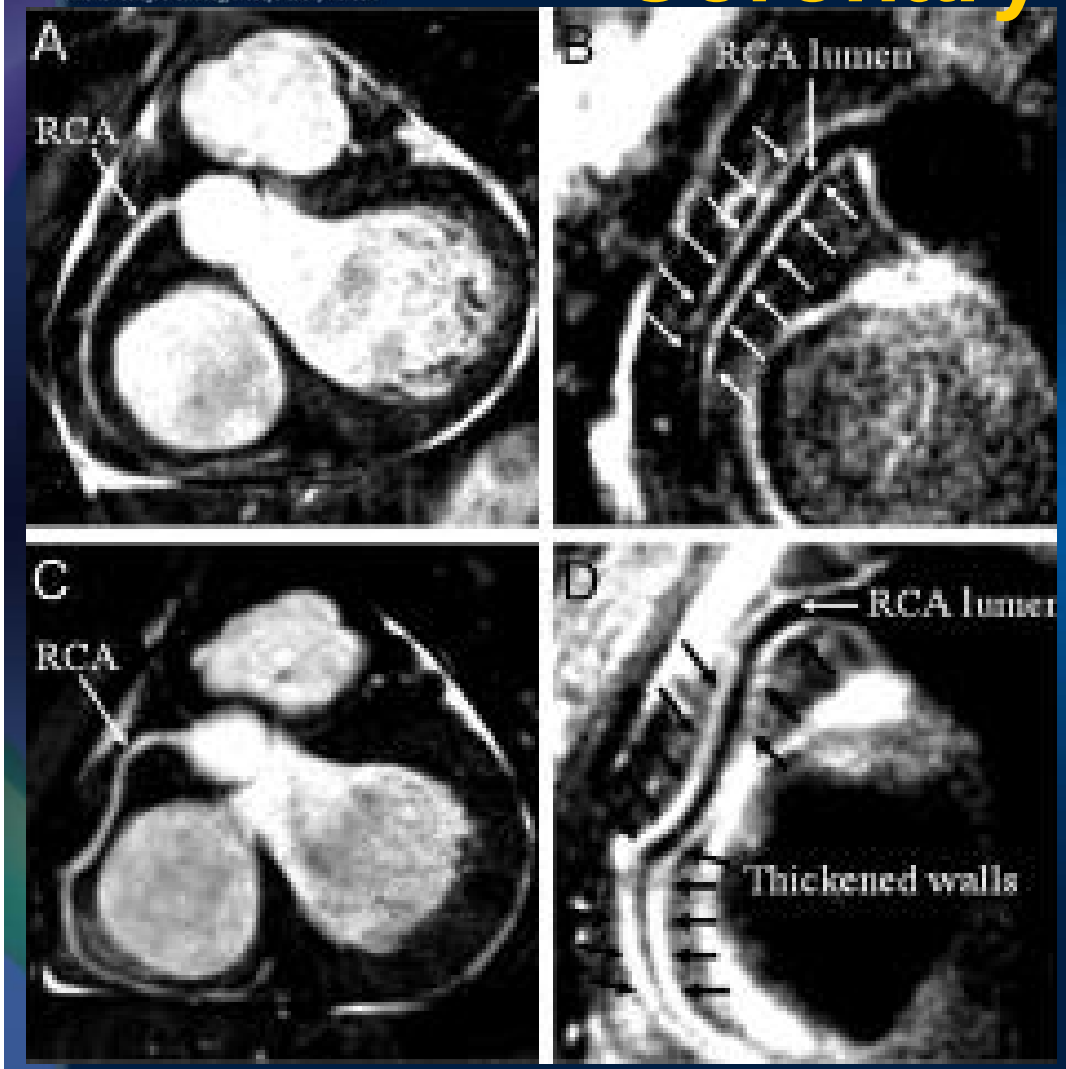
Coronary wall imaging



136 DM patients
- **63 nephropathy**
- **73 normalbuminuria**

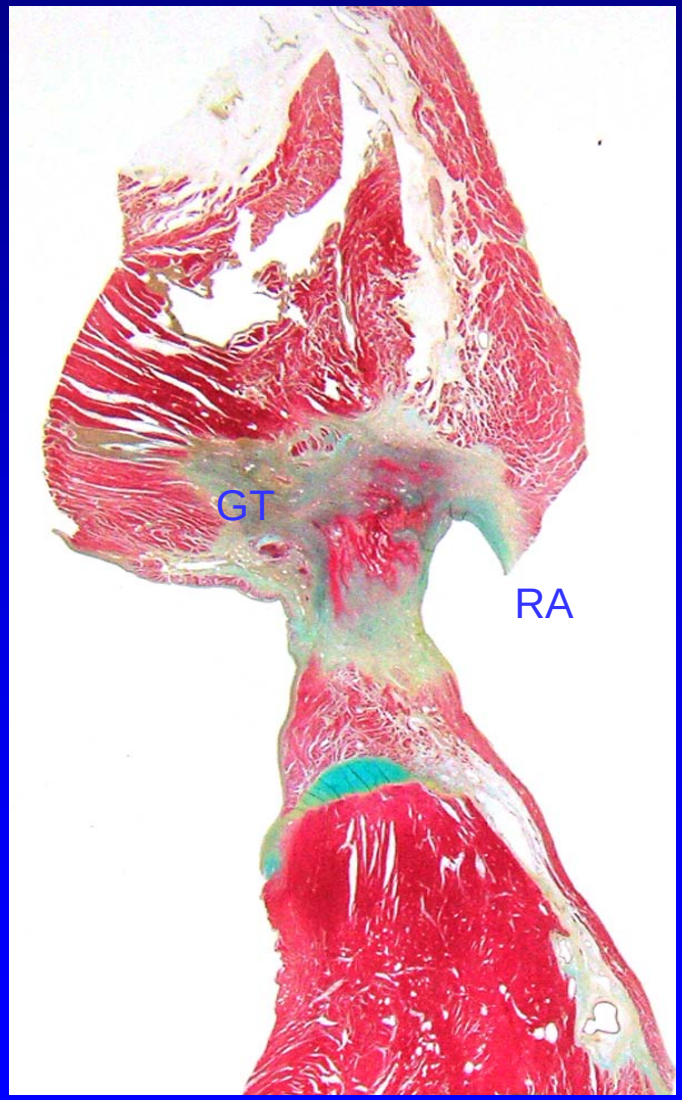
Coronary stenoses
- **10% nephropathy**
- **0% normalbuminuria**

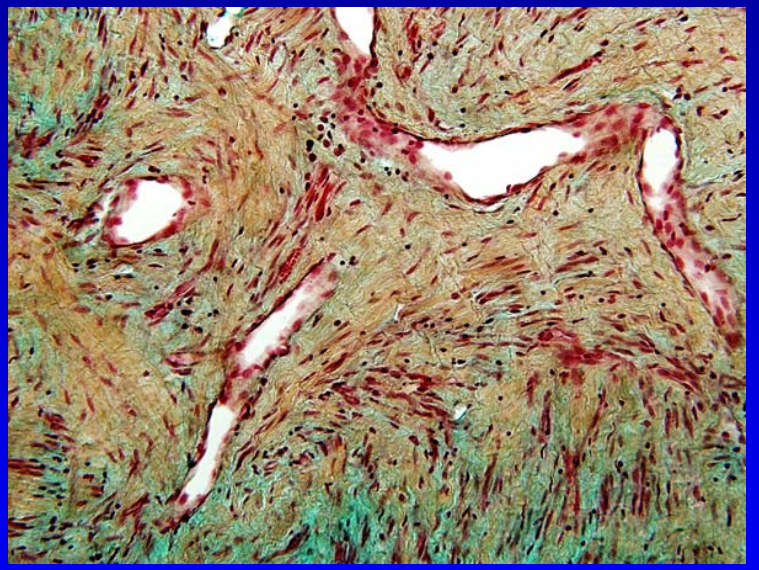
Coronary plaque burden

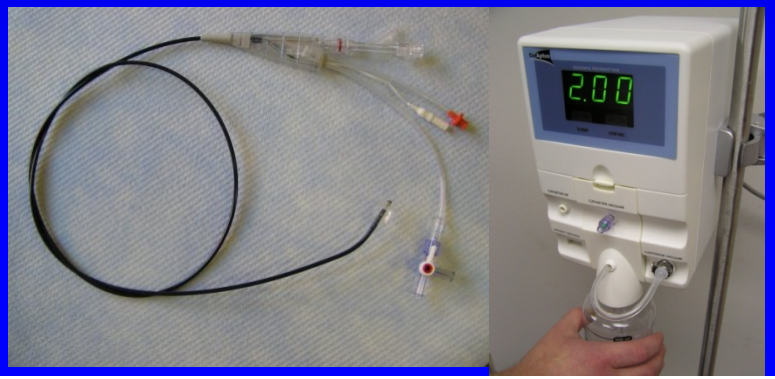
Mean RCA wall thickness
- **1.7±0.3 nephropathy**
- **1.3±0.3 normalbuminuria**

Kim WJ, et al, *Circulation* 2007;115:228-35

CoAptus Patent Foramen Ovale Closure System PFOCS



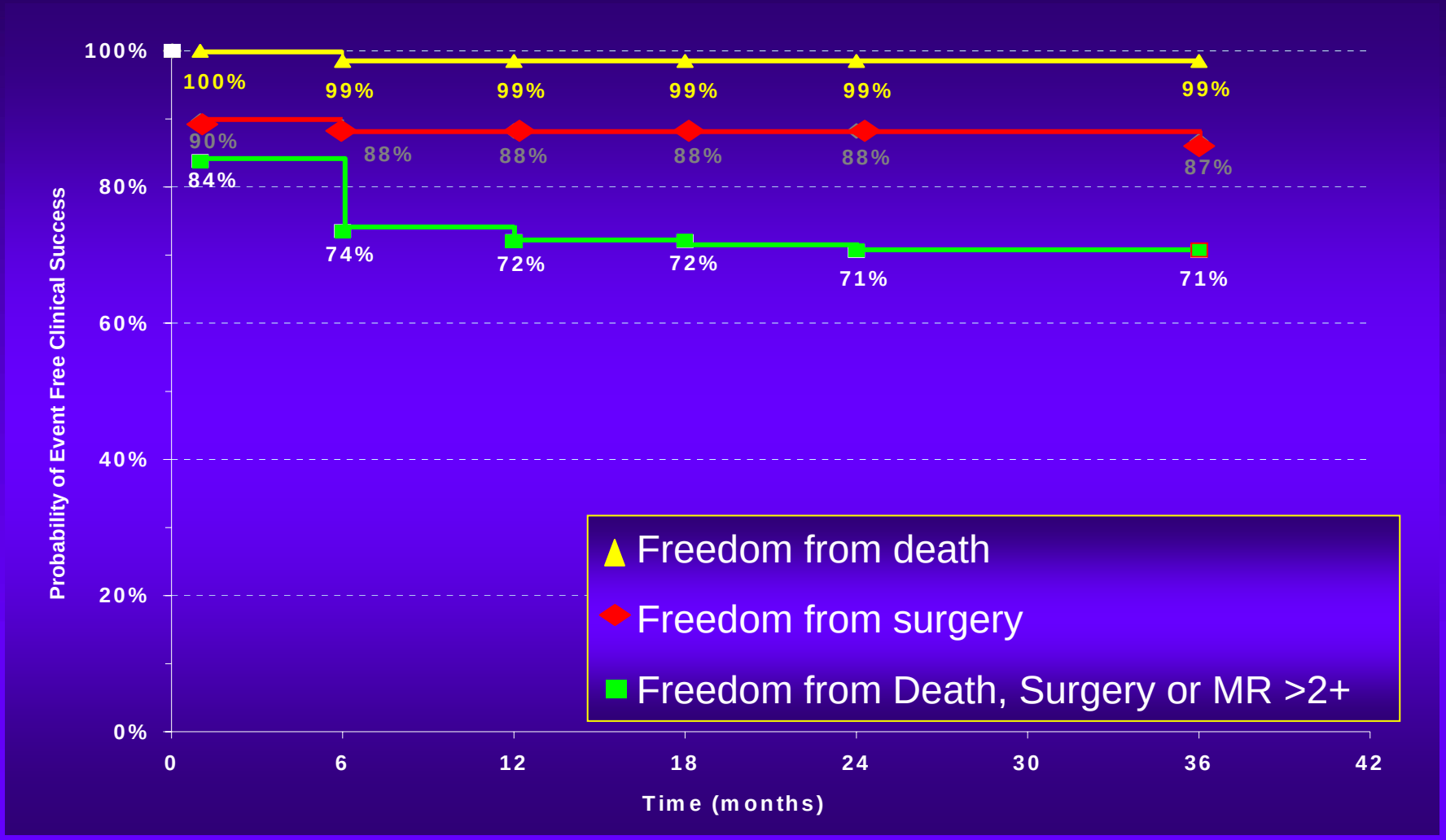




CoAptus Medical Corporation

EVEREST II UPDATE

Event Free Clinical Success Kaplan-Meier
Patients with Acute Procedural Success
(N = 68)



ISAR-SHOCK

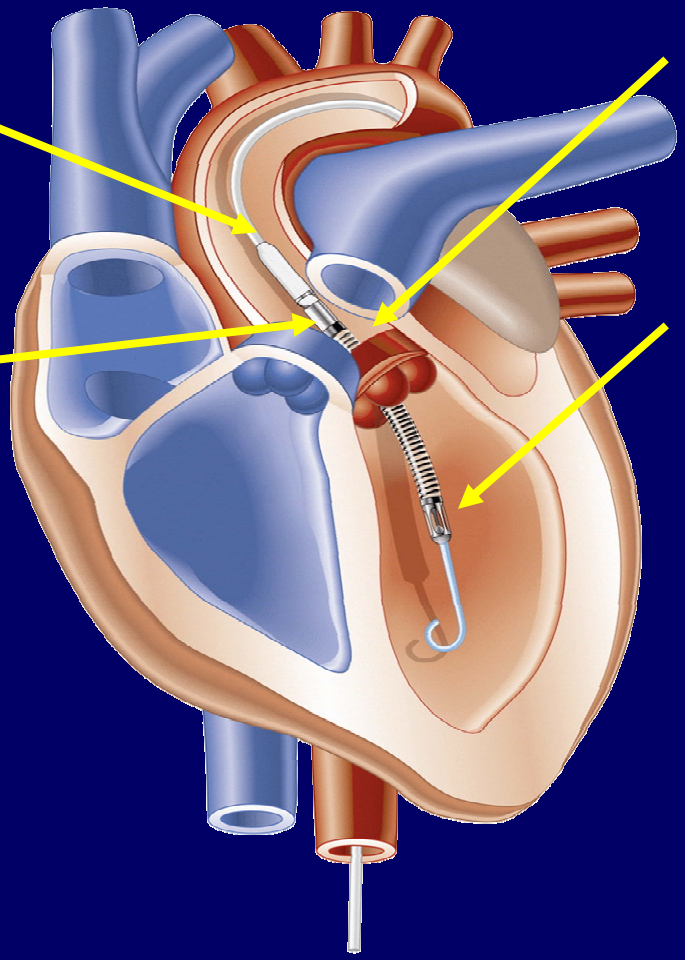
Left Ventricular Assist Device (Impella LP 2.5) Versus Intraaortic Ballon Counterpulsation For Patients With Cardiogenic Shock by Myocardial Infarction : A Prospective, Randomized, Two-Center Trial

ISAR-SHOCK

M. Seyfarth, G. Fröhlich, D. Sibbing, L. Bott-Flügel,
I. Bauer, J. Dirschinger, A. Kastrati, A. Schömig

ACC 2007

Impella LP 2.5 System:
A Catheter-based Rotary Axial Blood Pump

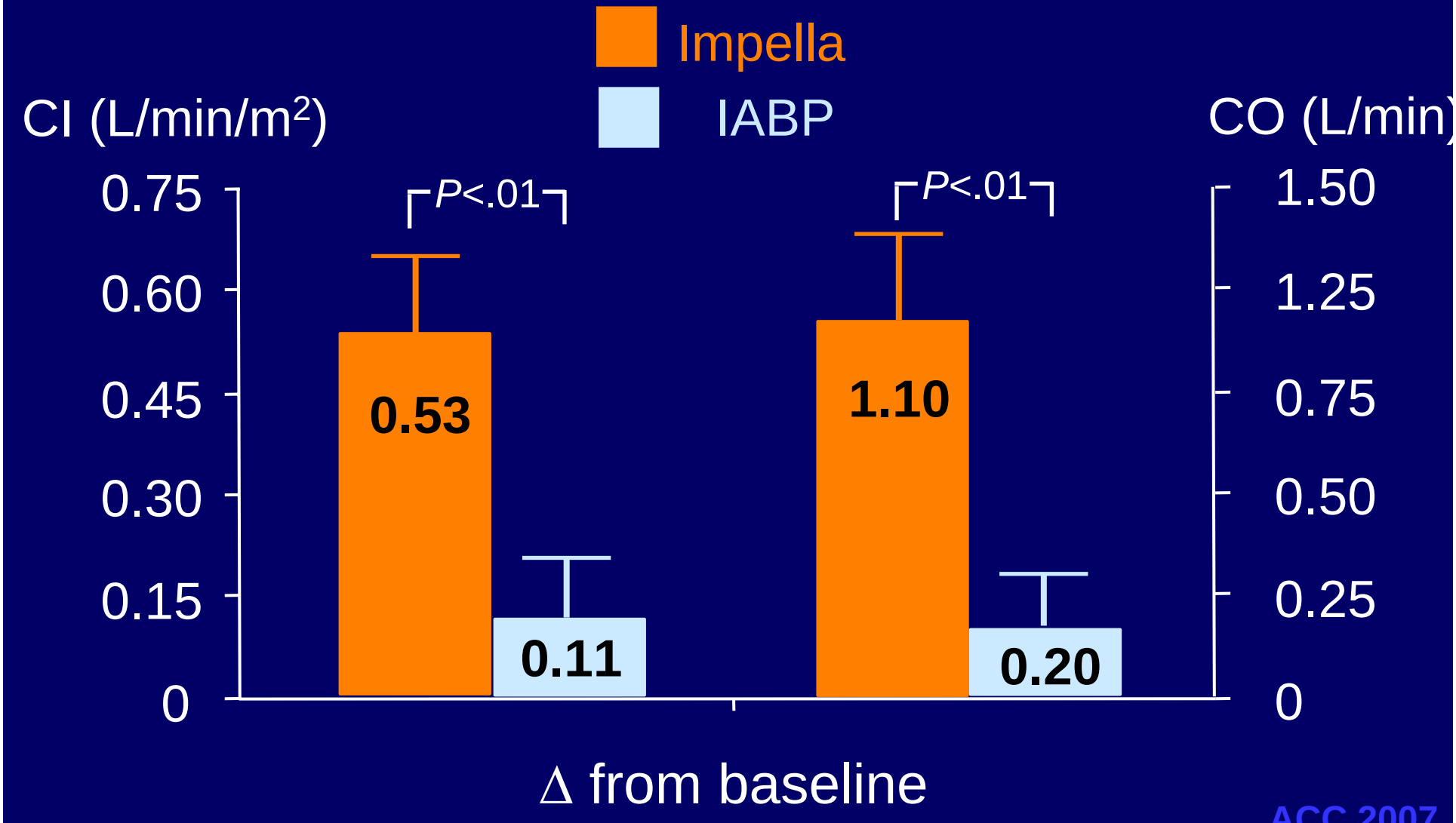


- Maximal pump flow: 2.5 L/min
- Percutanous femoral approach using a 13 F sheath.

ISAR-SHOCK

Primary End Point

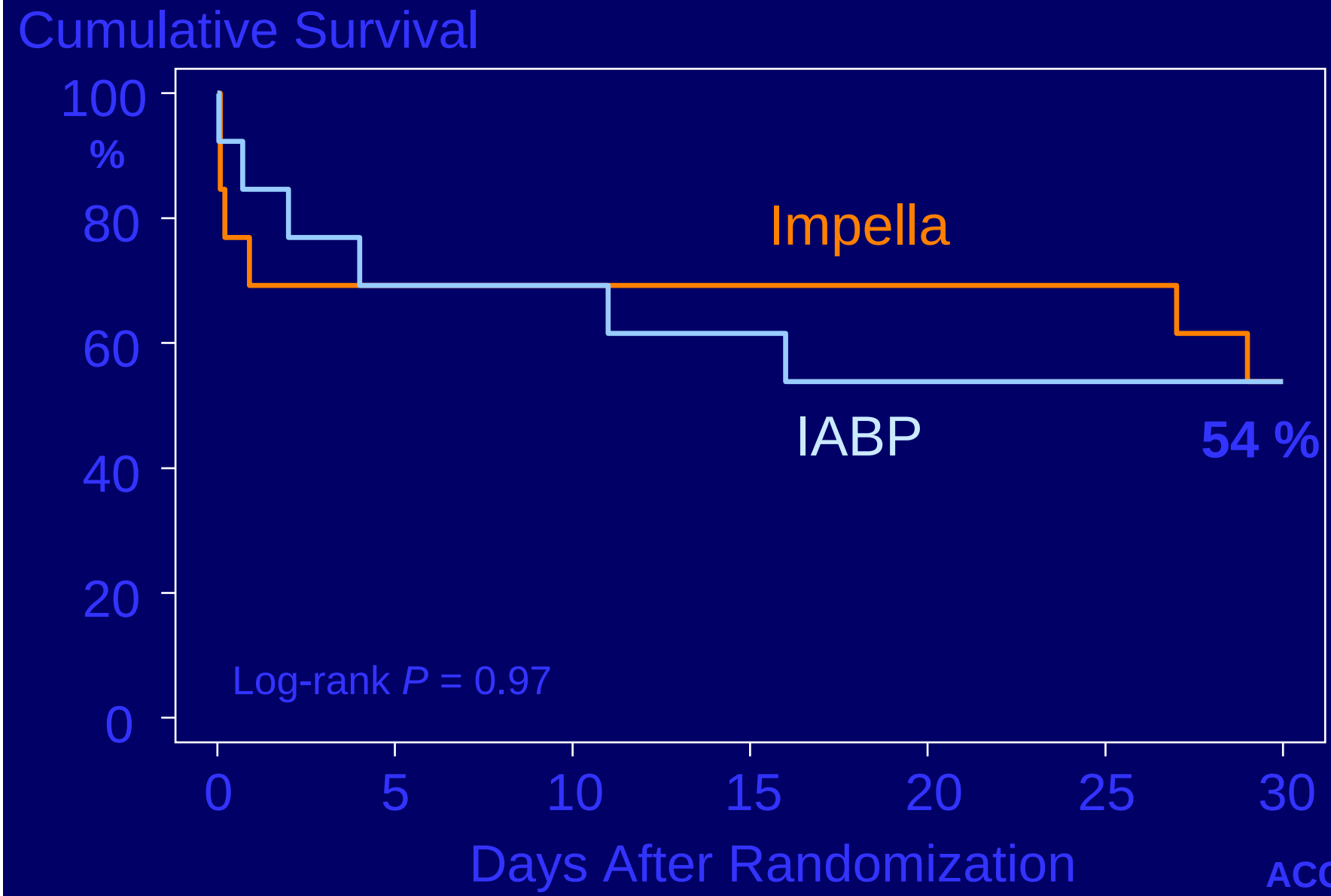
Change of Cardiac Index after 20 min of Support



ACC 2007

ISAR-SHOCK

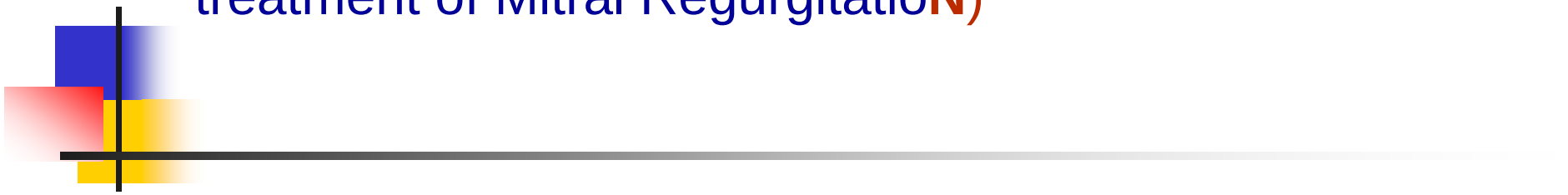
30 day - Survival



ACC 2007

EVOLUTION

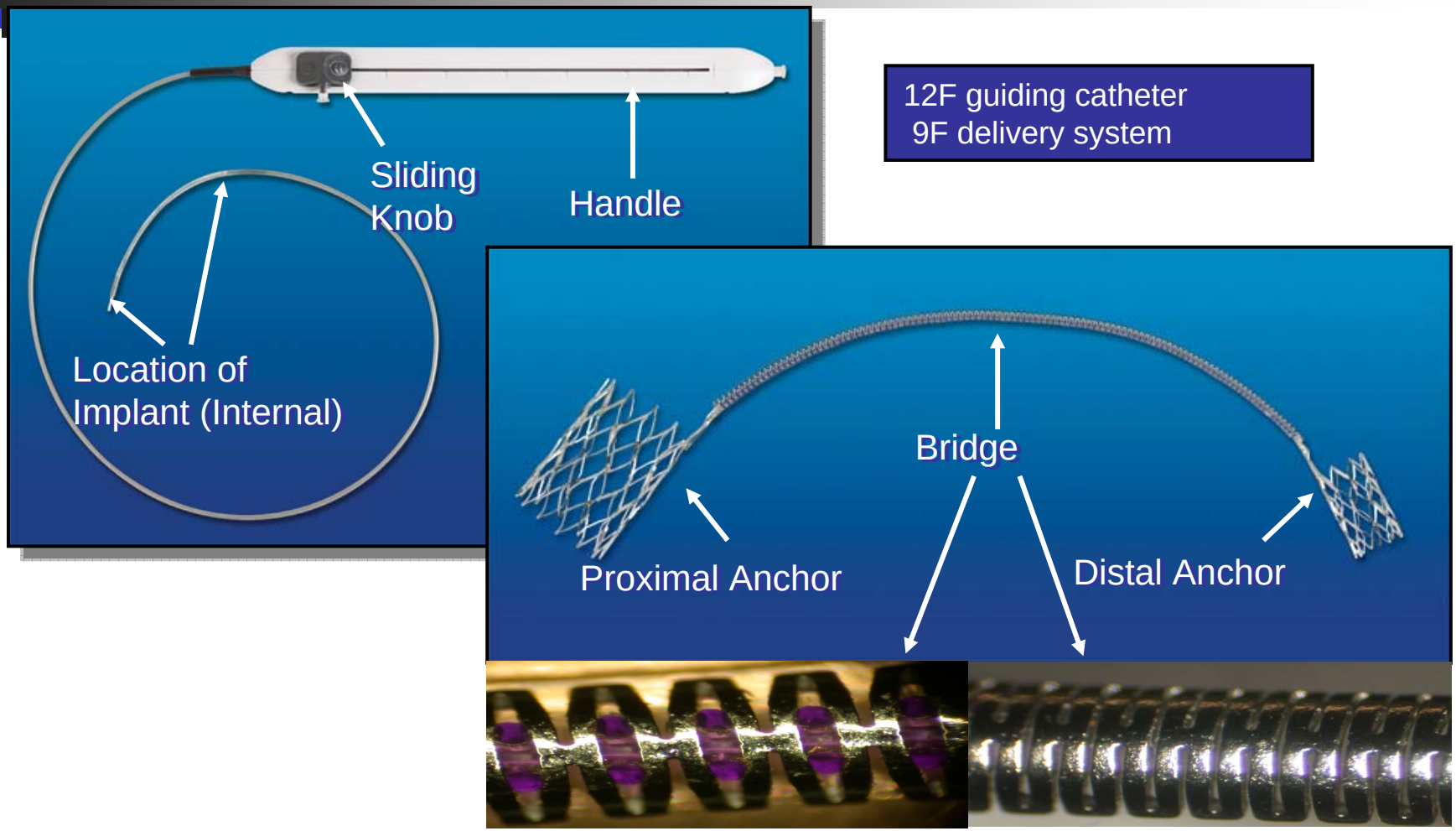
(Clinical **EV**aluation **O**f the Edwards **L**ifesciences PercUTaneous MItral AnnulOplasty System for the treatment of Mitral Regurgitatio**N**)



Interim Results and Case Experience

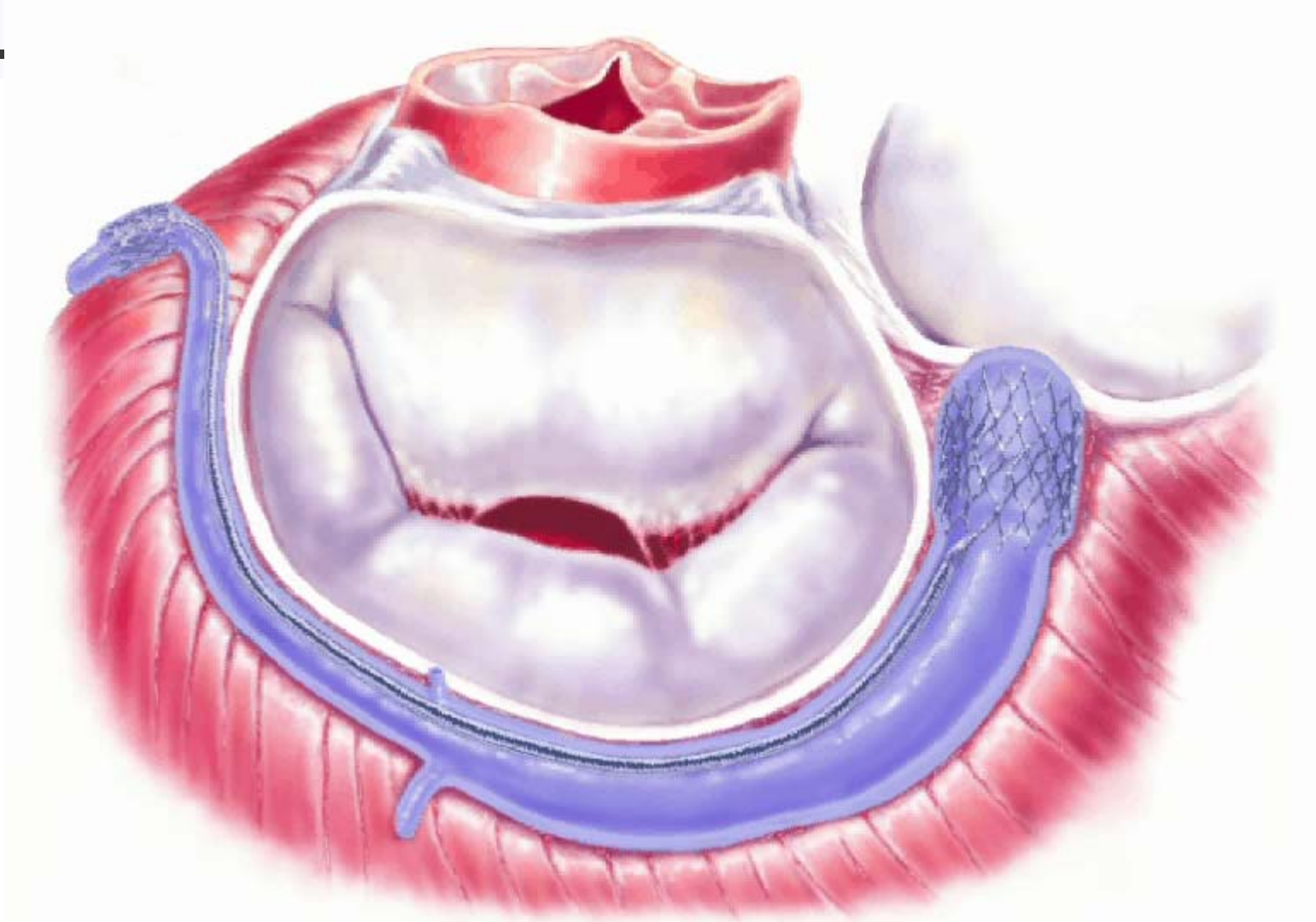
Karl Heinz Kuck, MD,
Hamburg, Germany

Edwards MONARC System



12F guiding catheter
9F delivery system

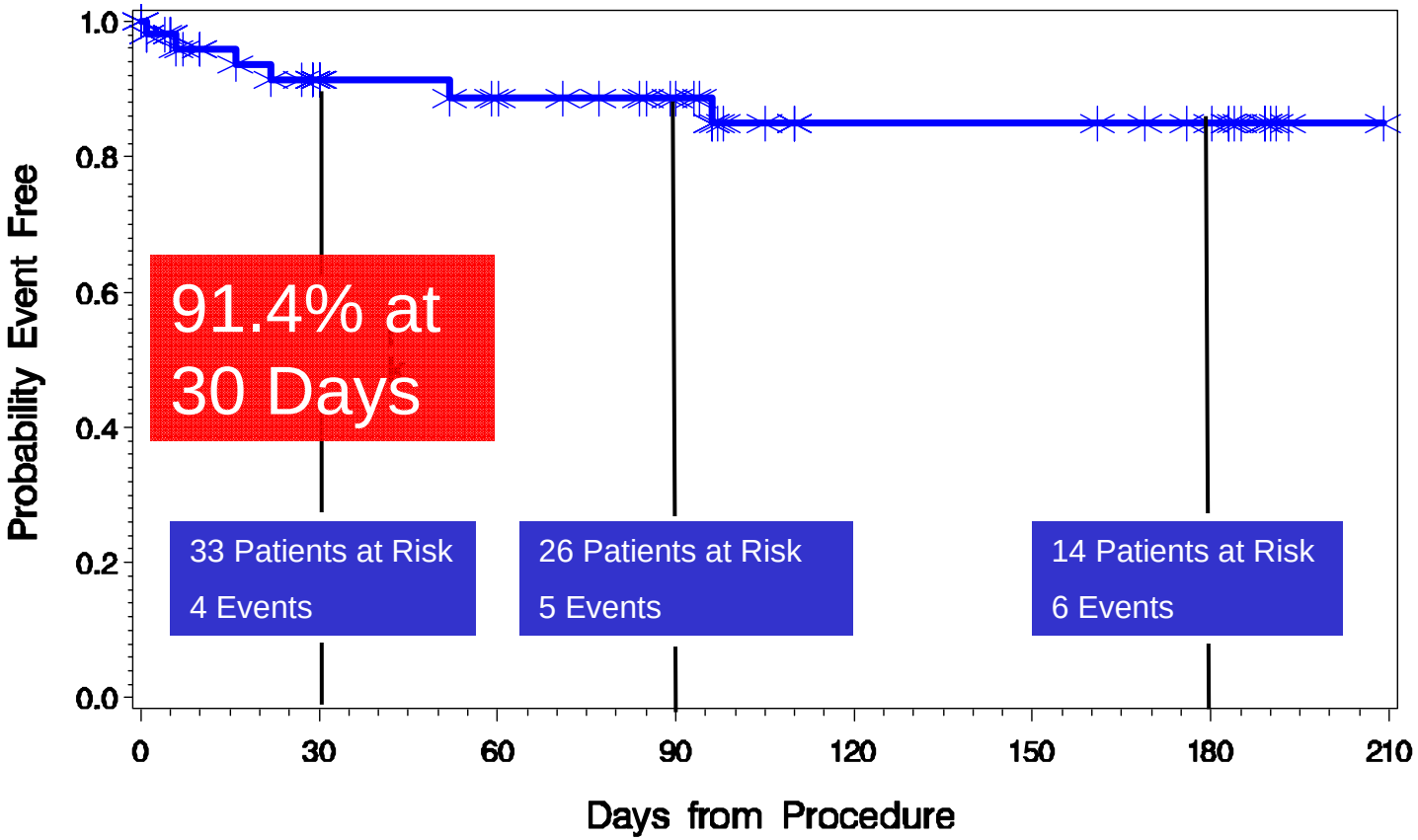
The MONARC system
Delayed Release-*in situ*



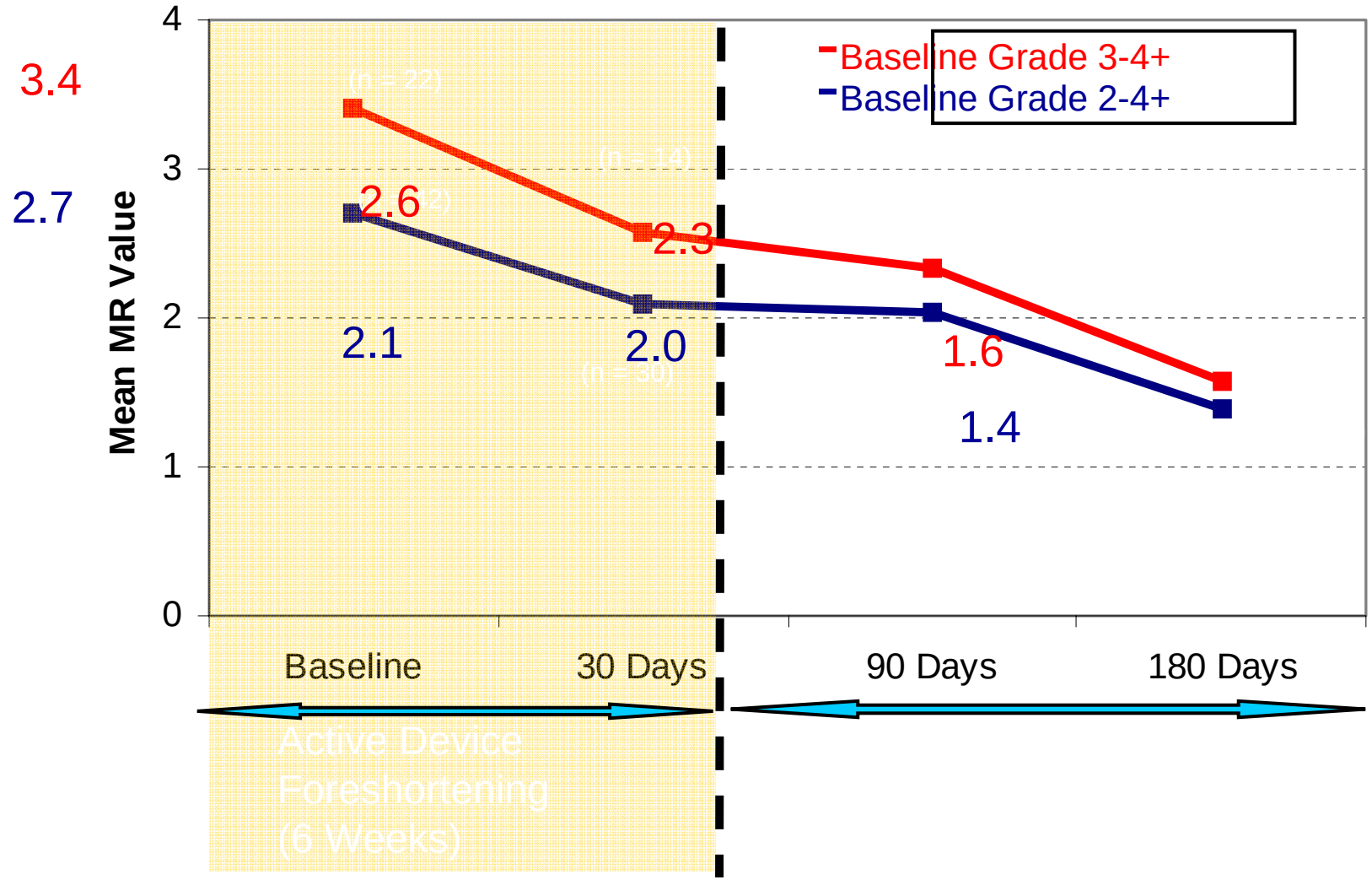
30-day interim safety (n=48 implants): Primary endpoint analysis

EVENT FREE SURVIVAL:

Death, MI, Cardiac Tamponade



EVOLUTION study interim performance data

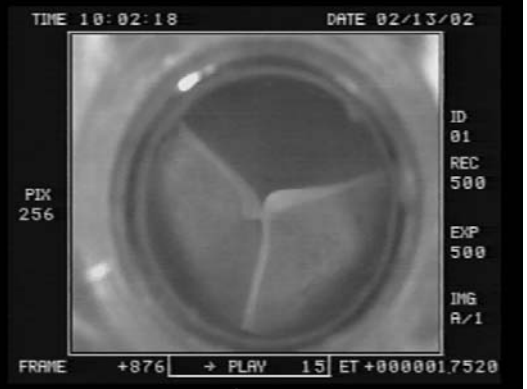


ST. PAUL'S HOSPITAL
PROVIDENCE HEALTH CARE

Transcatheter Aortic Valve Replacement Vancouver Experience

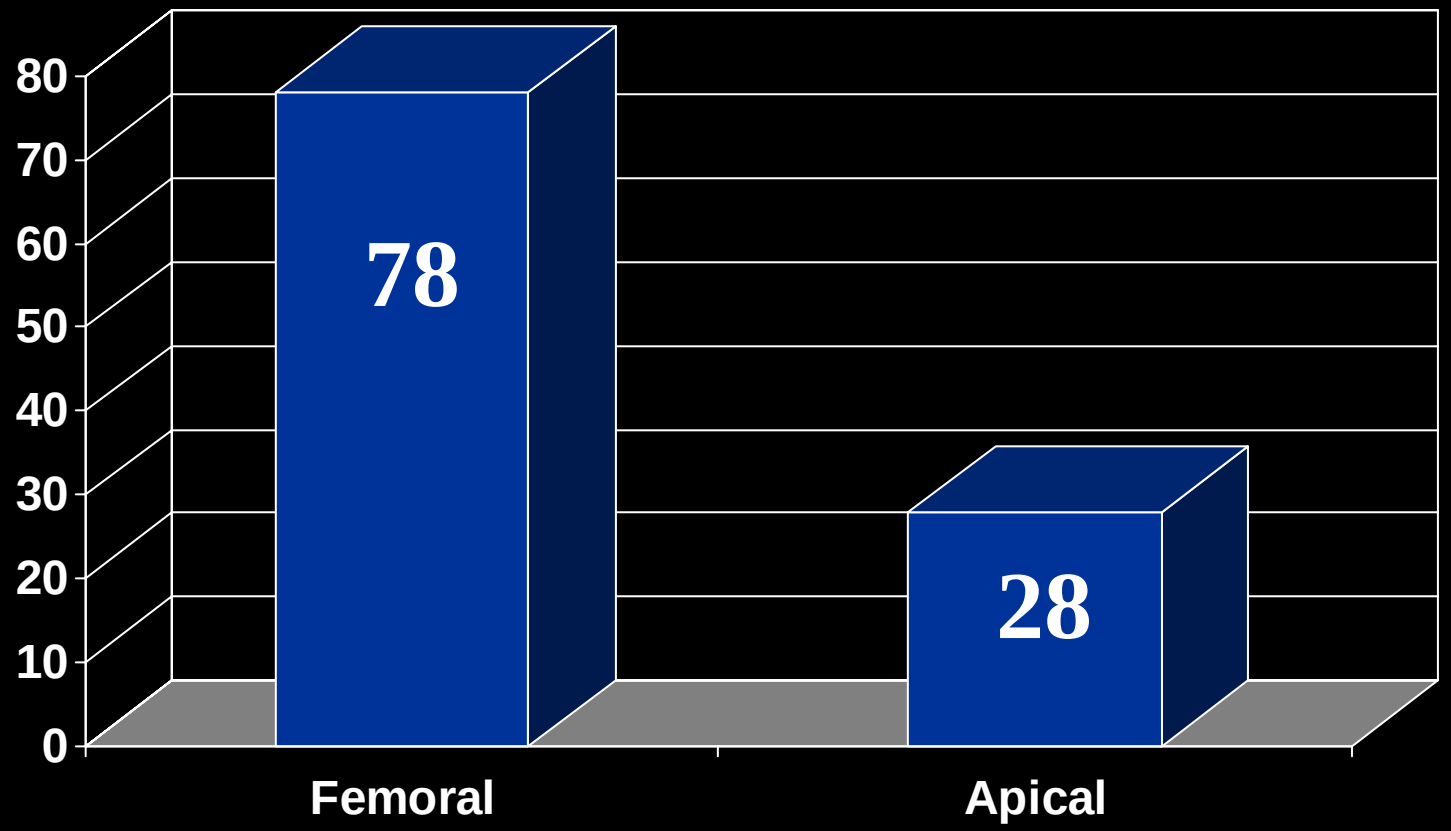
John Webb MD

St Paul's Hospital, University of British Columbia
Vancouver, Canada



HEART CENTRE
AT ST. PAUL'S HOSPITAL

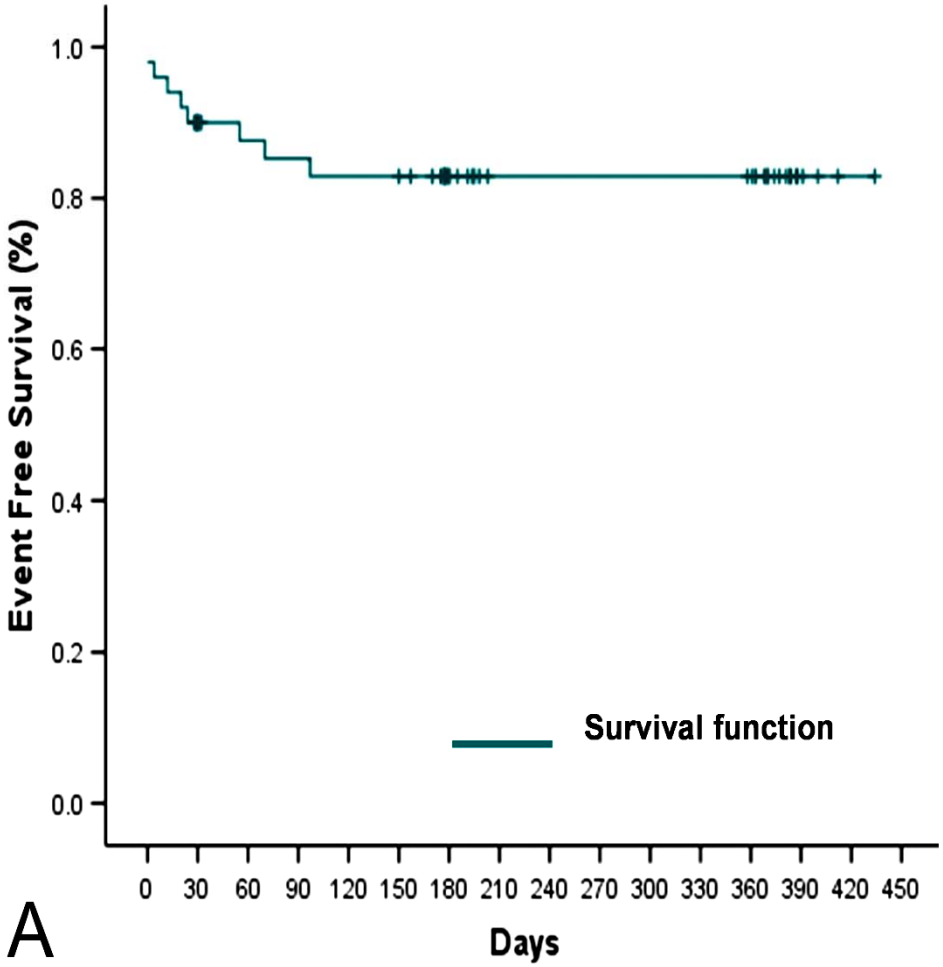
Vancouver TAVR Registry
N = 106

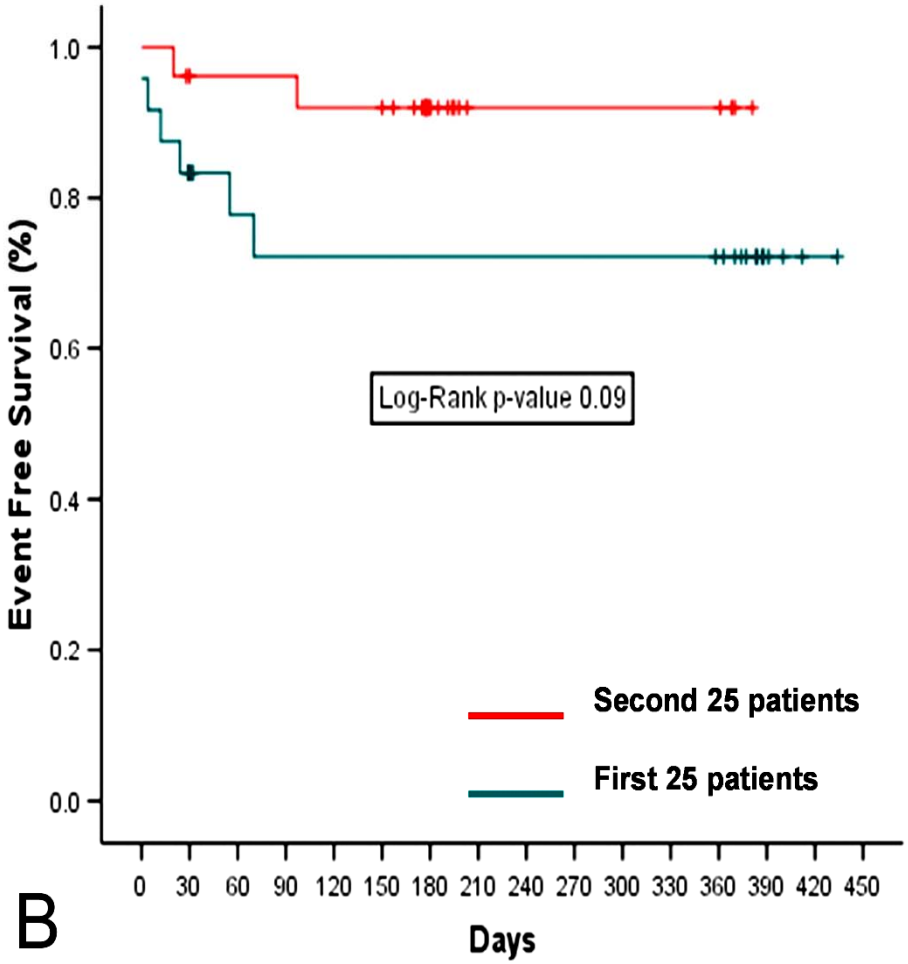


HEART CENTRE AT ST. PAUL'S HOSPITAL

Late Survival without Valve Failure

(note: predicted 72% Survival at 30 days)





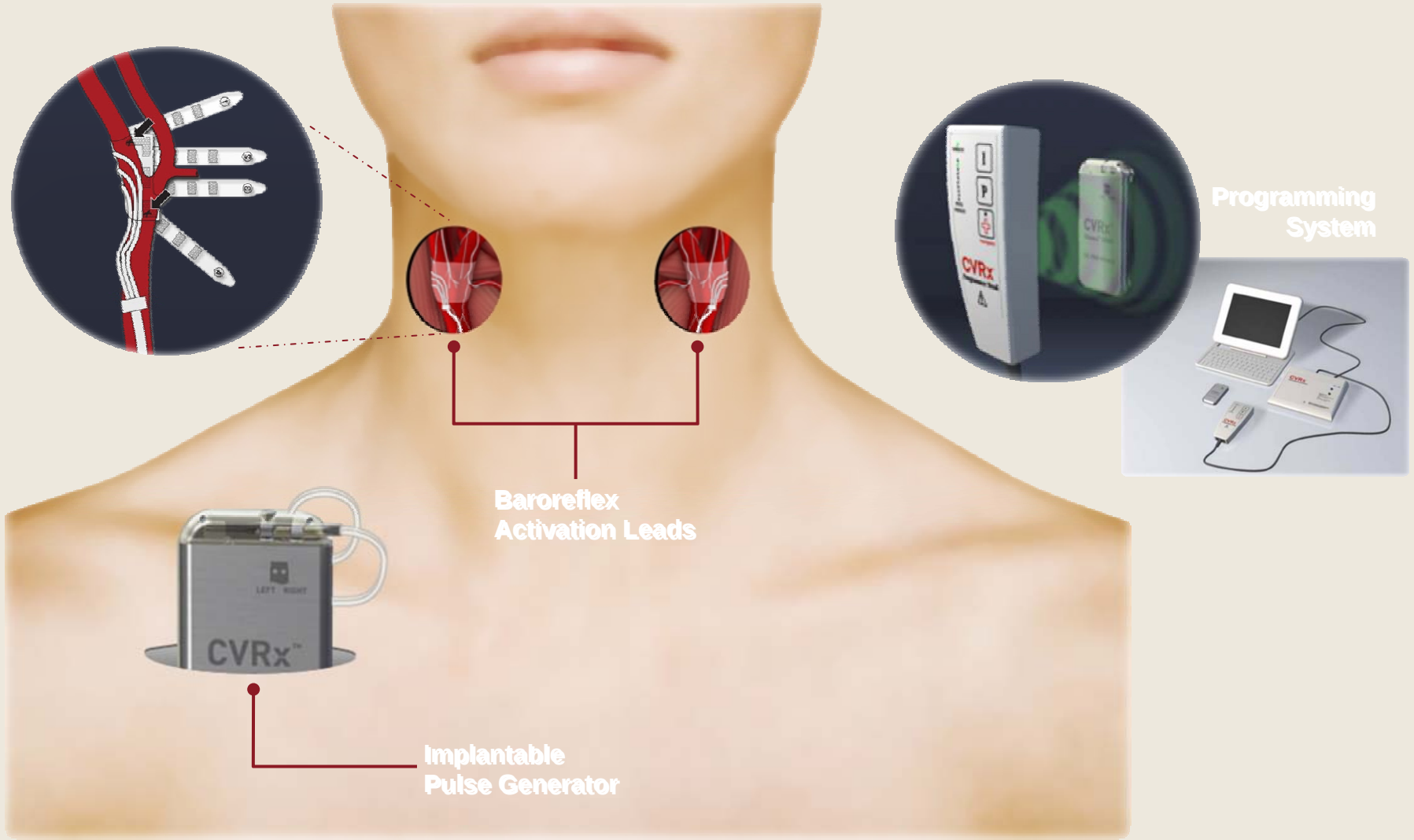
Chronic Treatment of Resistant Hypertension with an Implantable Medical Device: Preliminary Results of Two European and United States Trials of the Rheos™ Baroreflex Hypertension Therapy™ System

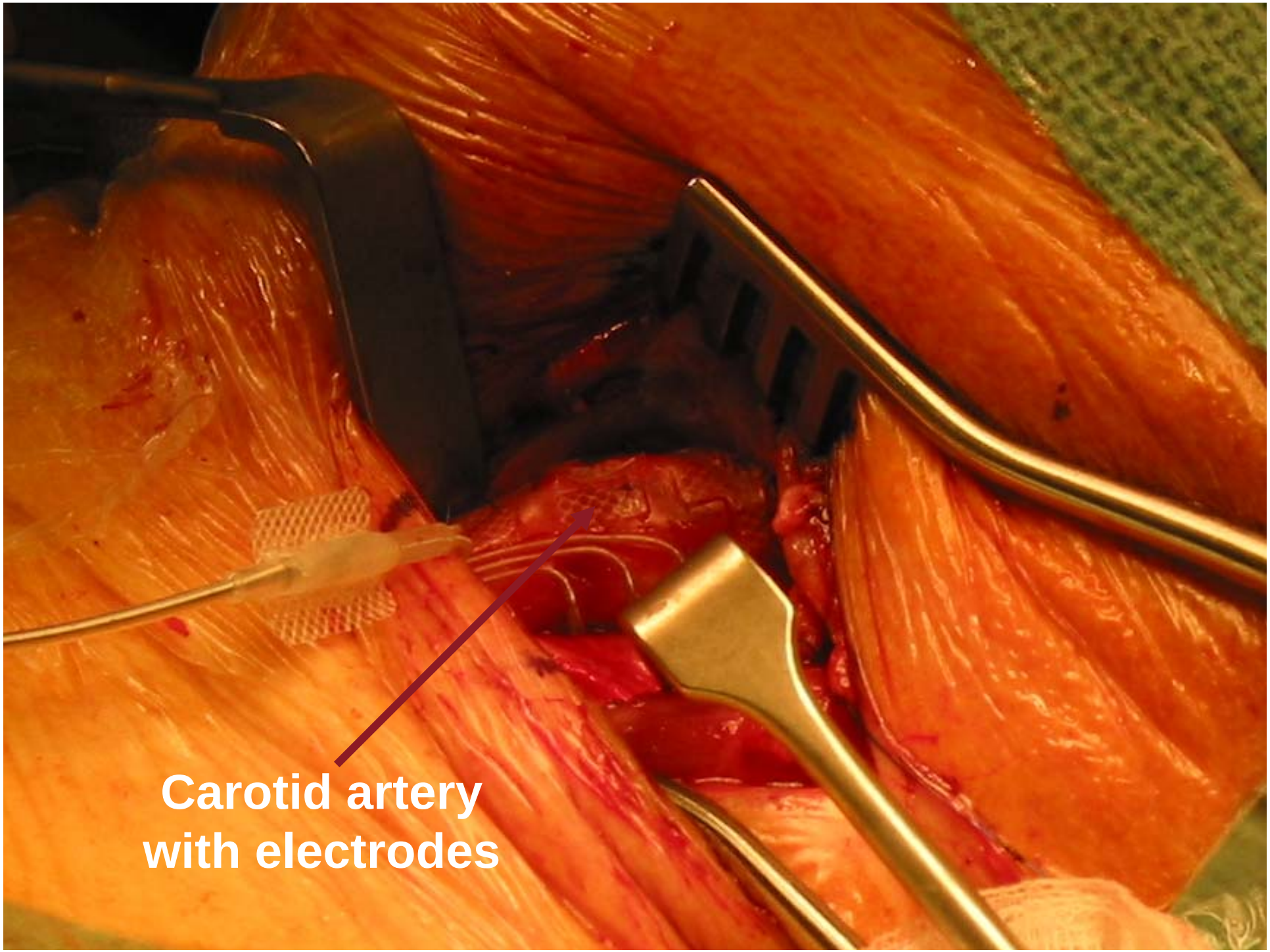
Peter de Leeuw[1], John Bisognano[2], Robert Cody[3]

for the DEBuT-HT and Rheos Feasibility Investigators

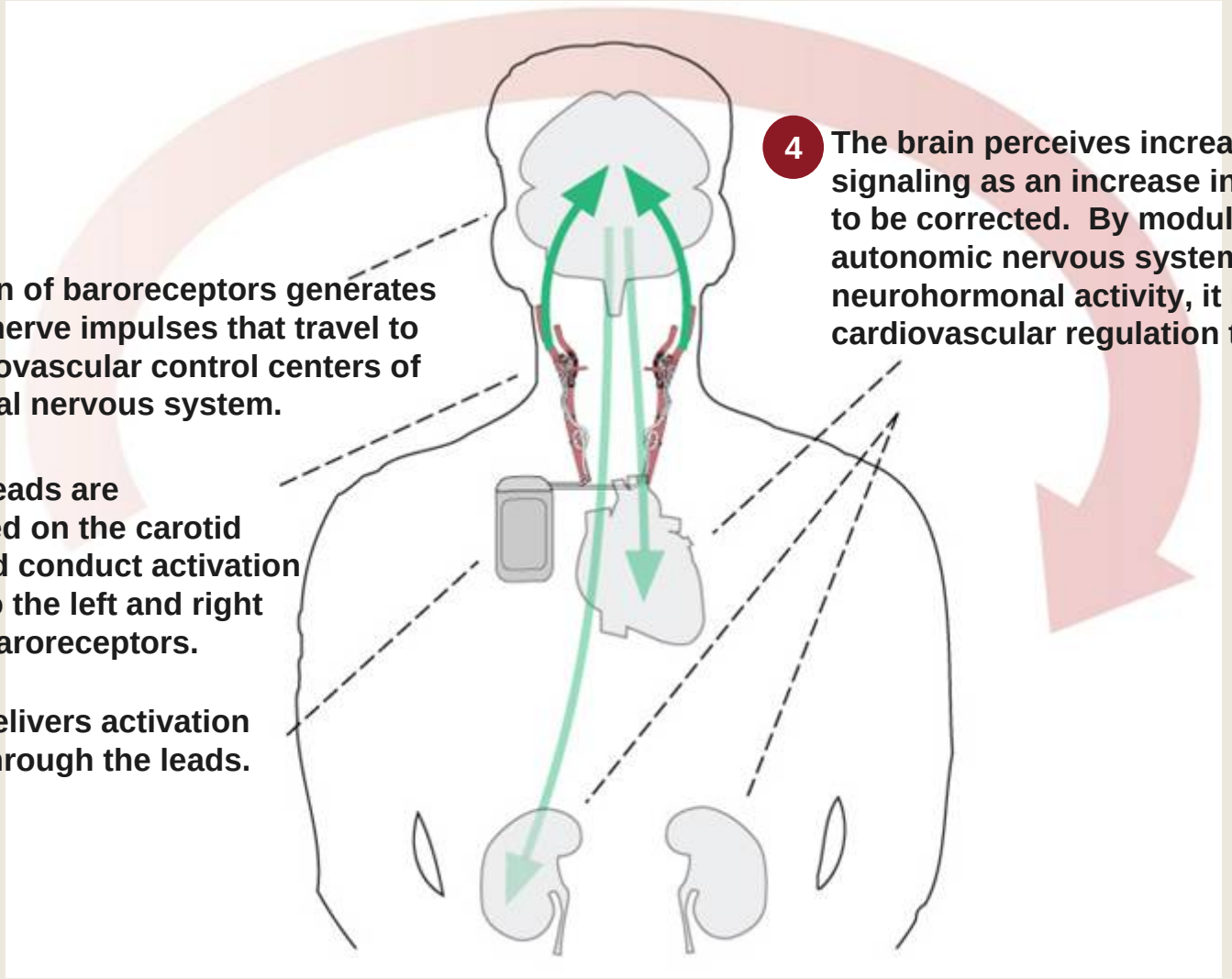
[1]Academisch Ziekenhuis Maastricht (AZM), The Netherlands
[2]University of Rochester, USA
[3] CVRx, Inc., USA

The CVRx® Rheos System




Carotid artery
with electrodes

Mechanisms of Baroreflex Hypertension Therapy



1 Device delivers activation energy through the leads.

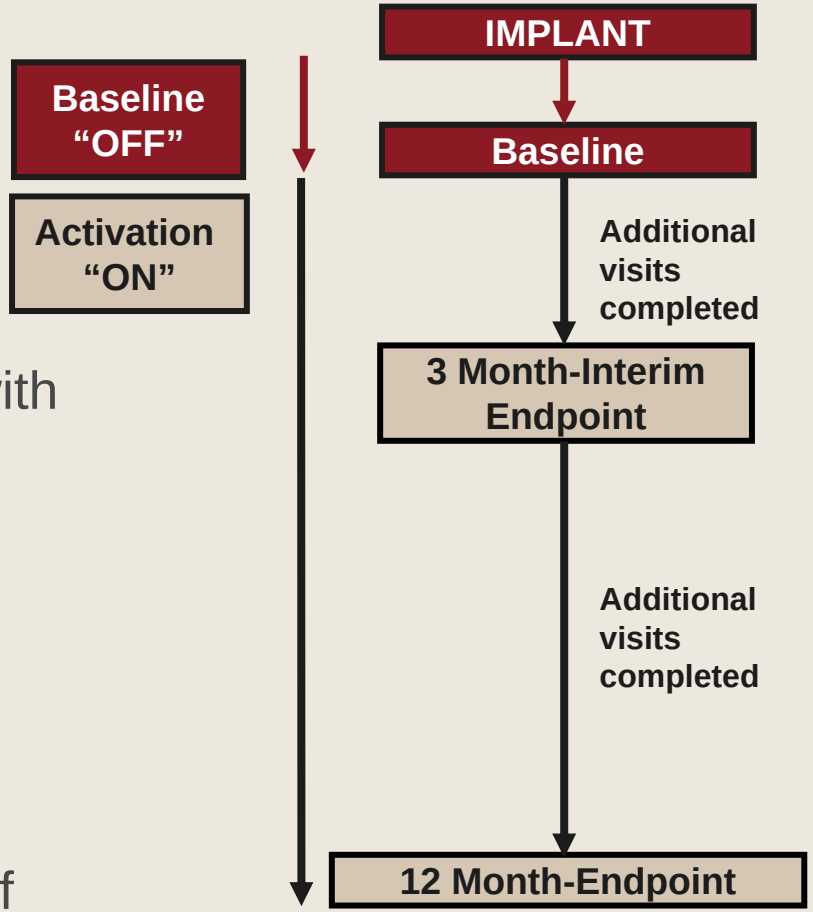
2 Carotid leads are positioned on the carotid sinus and conduct activation energy to the left and right carotid baroreceptors.

3 Activation of baroreceptors generates afferent nerve impulses that travel to the cardiovascular control centers of the central nervous system.

4 The brain perceives increased afferent signaling as an increase in BP that needs to be corrected. By modulating autonomic nervous system and neurohormonal activity, it influences cardiovascular regulation to reduce BP.

Feasibility Trial Design

- Subjects implanted at both European and US centers
  - Multi-drug resistant systolic hypertension (SBP ≥ 160 mmHg; DBP ≥ 90 mmHg)
  - 3+ anti-hypertensive medications with 1 diuretic for more than 2 months
  - Must not have hypertension secondary to a treatable cause
  - Acceptable adherence to treatment
  - Anti-hypertensive medications constant during the first 3 months of active treatment per protocol design

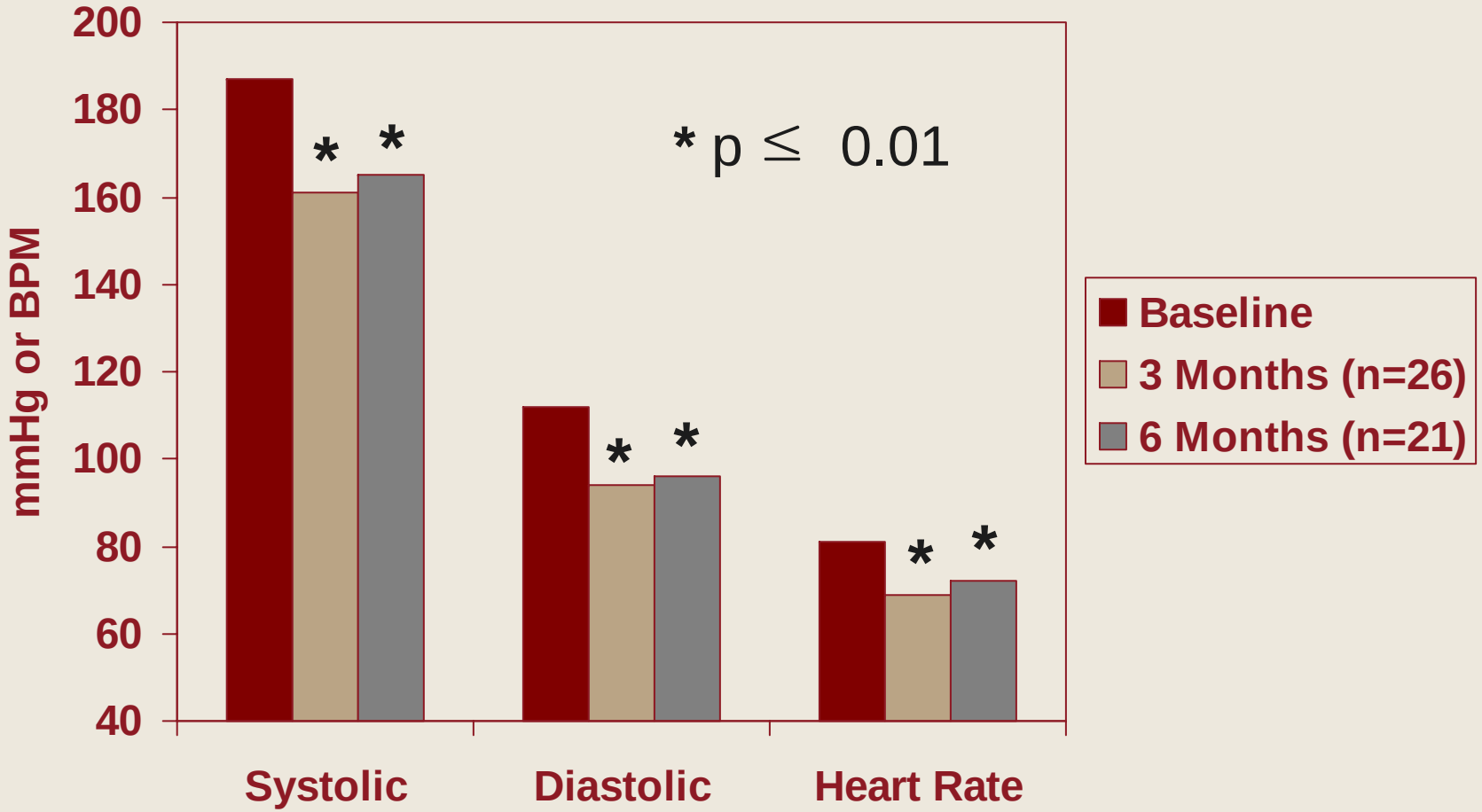


Baseline Characteristics (N=27)

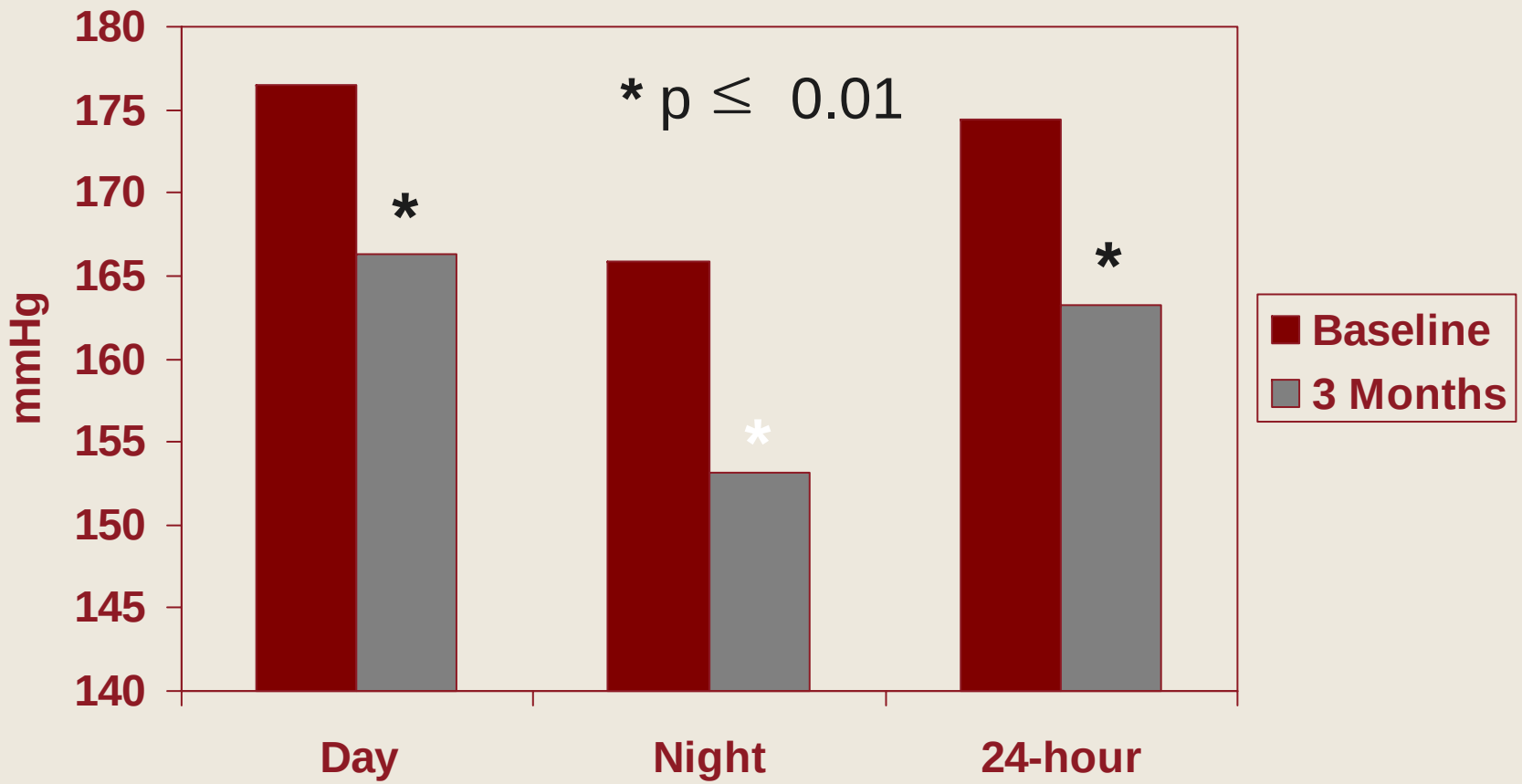
Location	17 Europe, 10 US
Gender	13 female, 14 male
Race	23 Caucasian, 4 African American
Age (mean years ± sd)	52 ± 10
BMI (mean kg/m^2 ± sd)	32 ± 6
# Antihypertensive Meds (mean ± sd)	5.7 ± 2
OC Systolic BP (mean mmHg ± sd)	187 ± 30
OC Diastolic BP (mean mmHg ± sd)	112 ± 21
Heart Rate (mean bpm ± sd)	81 ± 11

OC = Office Cuff

Office Cuff Blood Pressure and Heart Rate

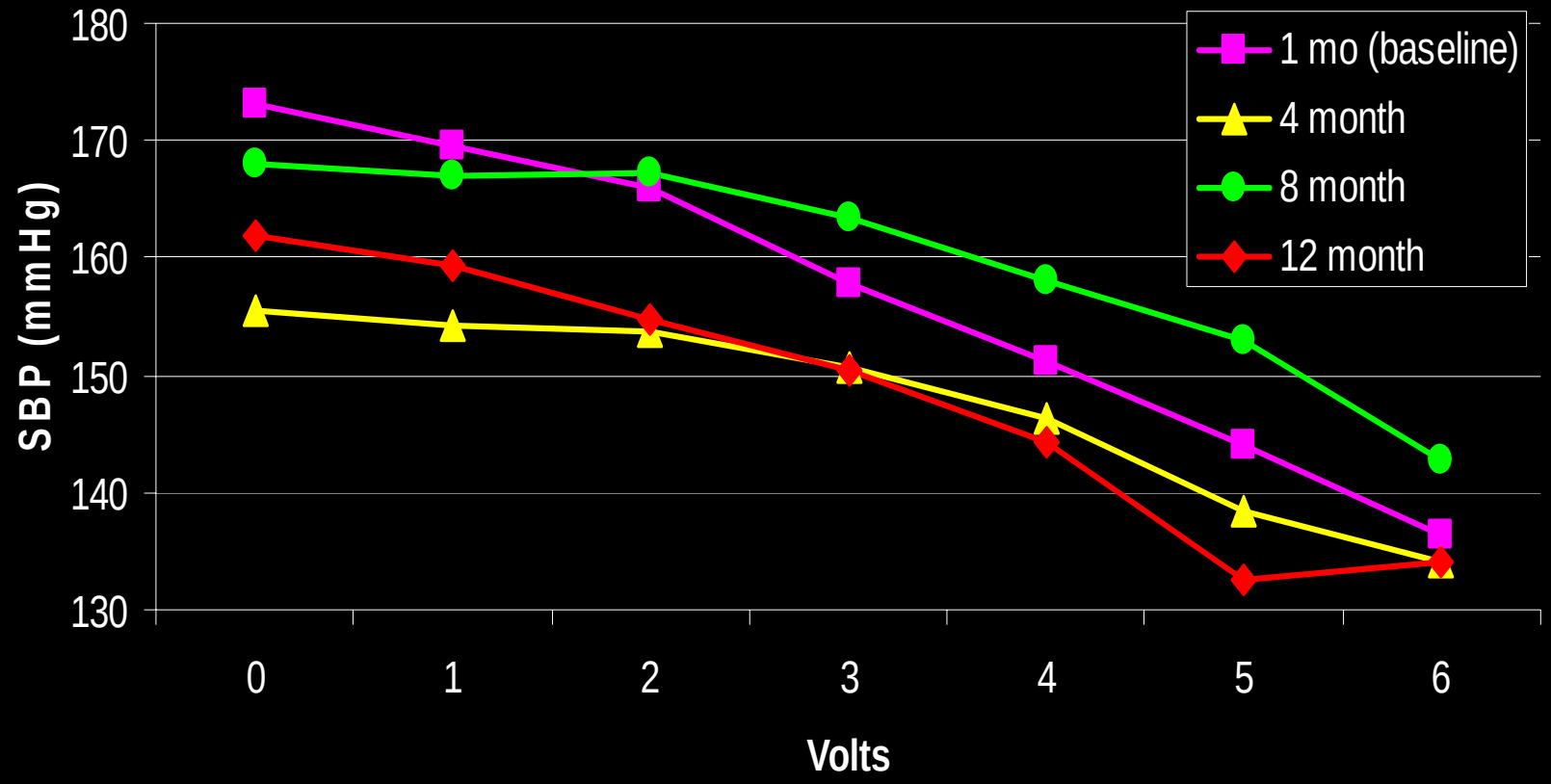


Ambulatory 24-h Systolic Blood Pressure (N=22[#])



[#] Limited to ambulatory results with at least 70% of readings available

Dose Response through 12-months (N=5)



Conclusions

- Baroreflex hypertension therapy demonstrates clinically meaningful and sustained reduction in blood pressure in subjects with drug resistant hypertension
- The therapy shows an acceptable safety profile
- These findings merit further investigation of this chronic device-based approach for hypertension management
- A randomized, blinded pivotal trial recently approved by FDA has been initiated

A Novel Device for the Enhancement of Percutaneous Coronary Intervention in Bifurcation Lesions: First-In-Man Experience

Yaron Almagor, David Meerkin, Thomas Ischinger, Eberhard Grube, Ralf Muller, Ronald J. Solar.

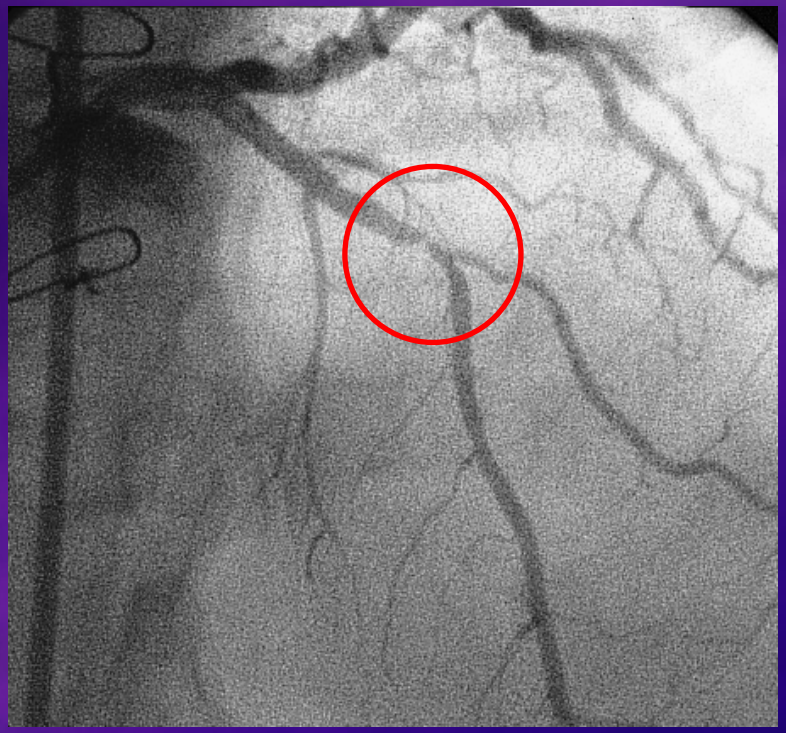
Shaare Zedek Medical Center, Jerusalem, Israel

Bogenhausen Hospital, Munich, Germany
Heart Center, Seigburg, Germany
YMed Inc, San Diego, USA

I2 Summit 2007

Clinical Issues

Bifurcation involvement in a significant number of PCI cases

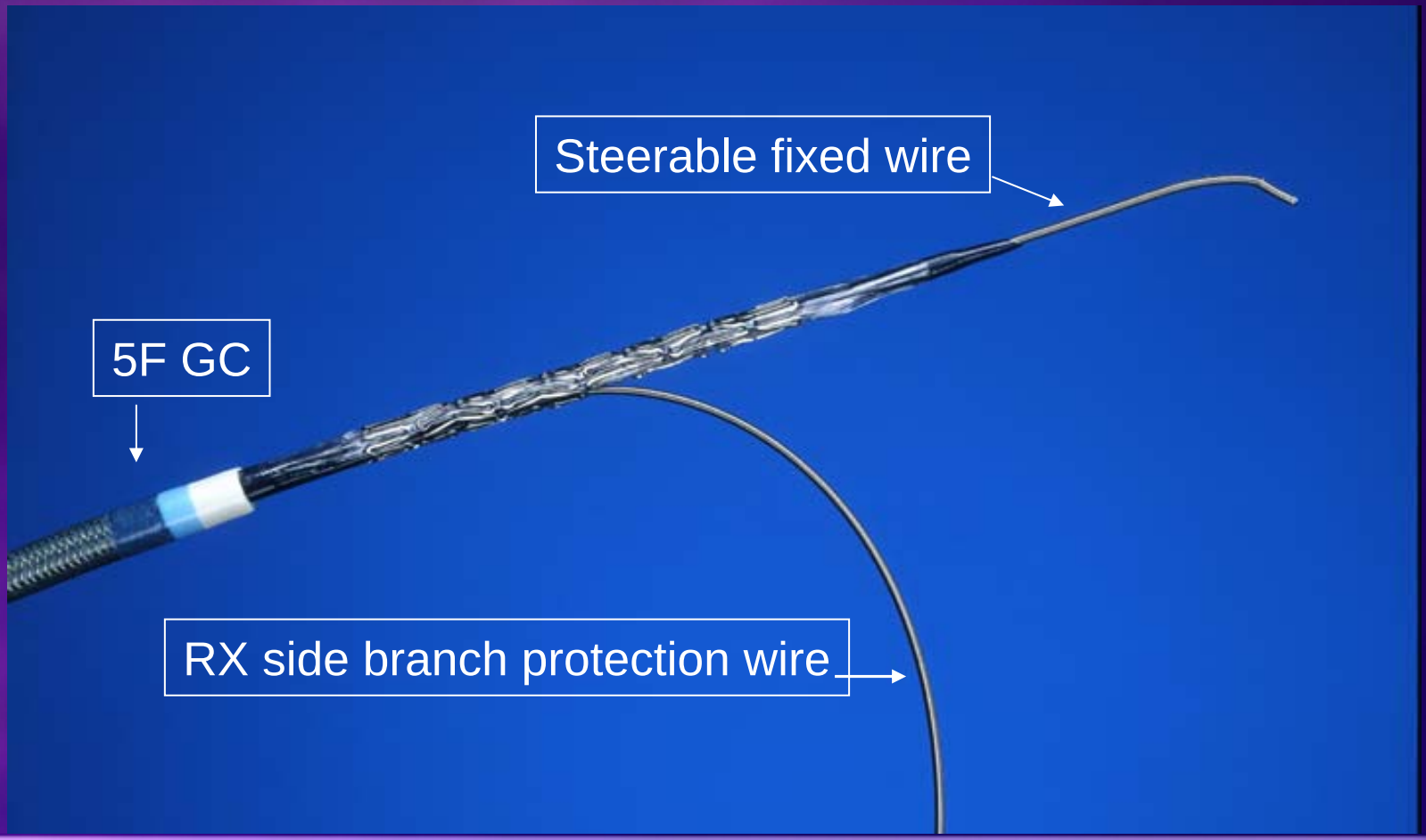


- **True bifurcation**
- **Side branch protection during main branch stenting**
- **Accurate & precise ostial stent placement**

sideKick™

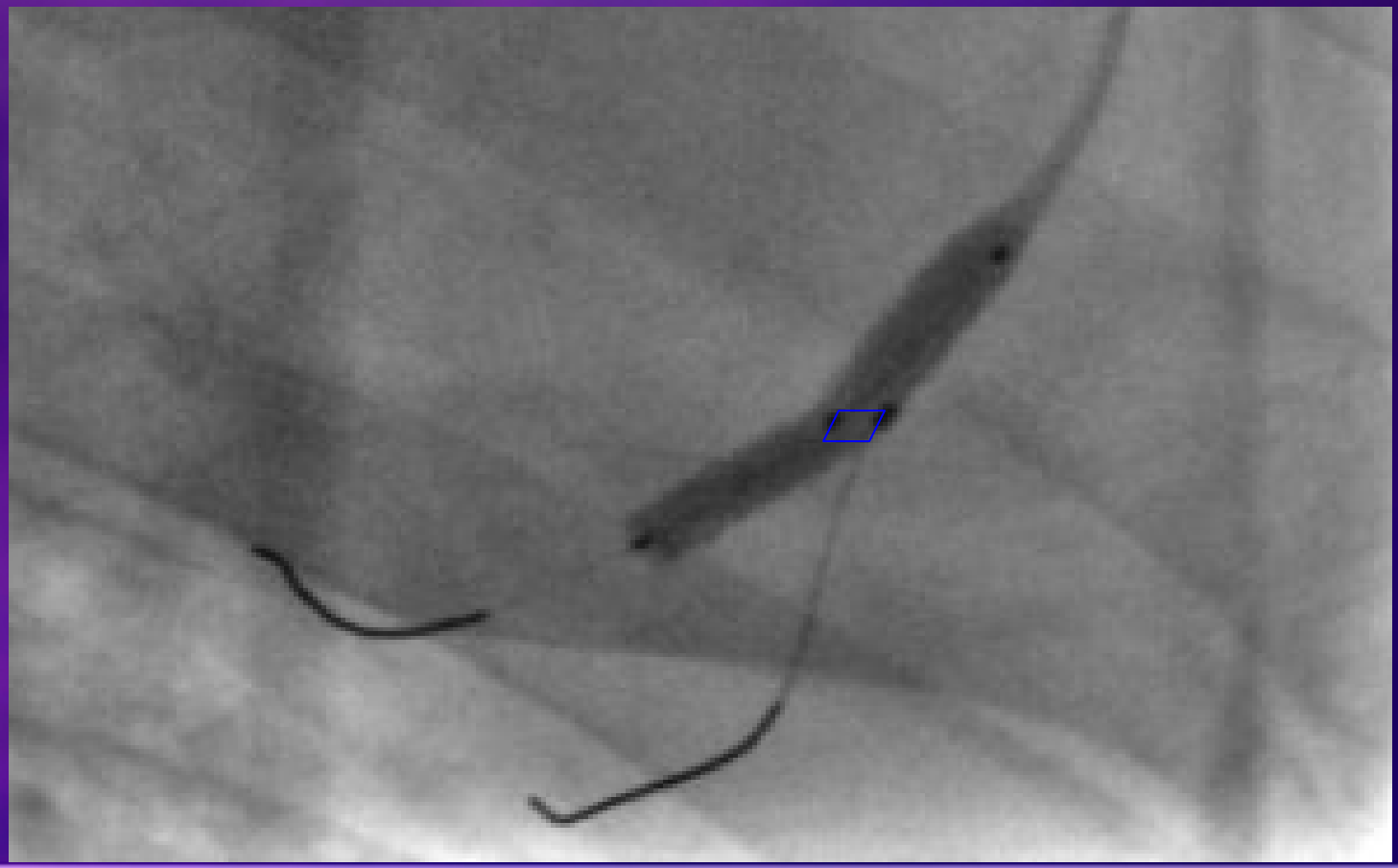
Stent Delivery System

Mid Exit Port Model



For investigational use only.

Unique marker band configuration and torquability allow precise positioning of stent cell to side branch

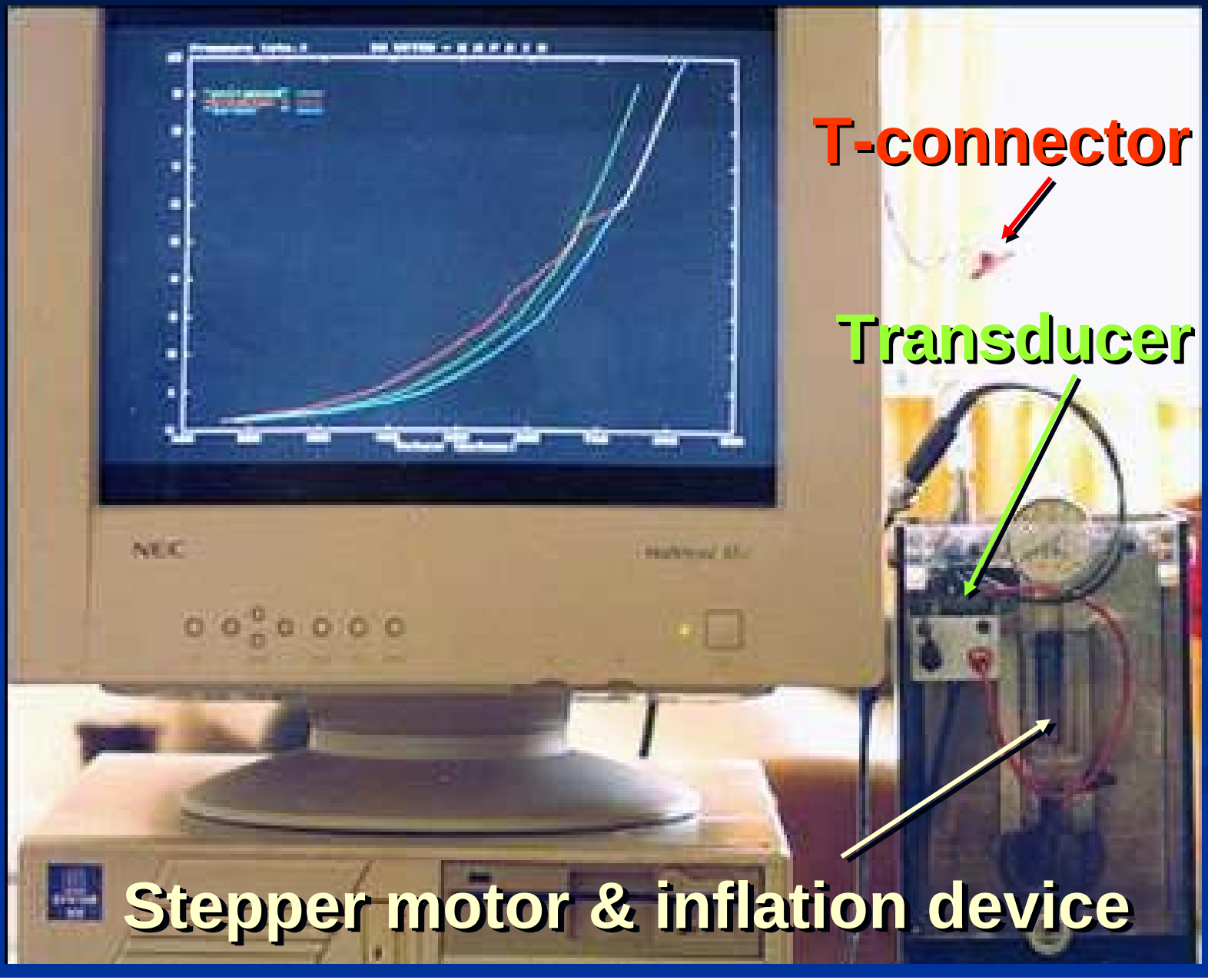


Capsid Trial: Improved Outcomes in patients undergoing Coronary Stenting using Gradual Computerized Angioplasty

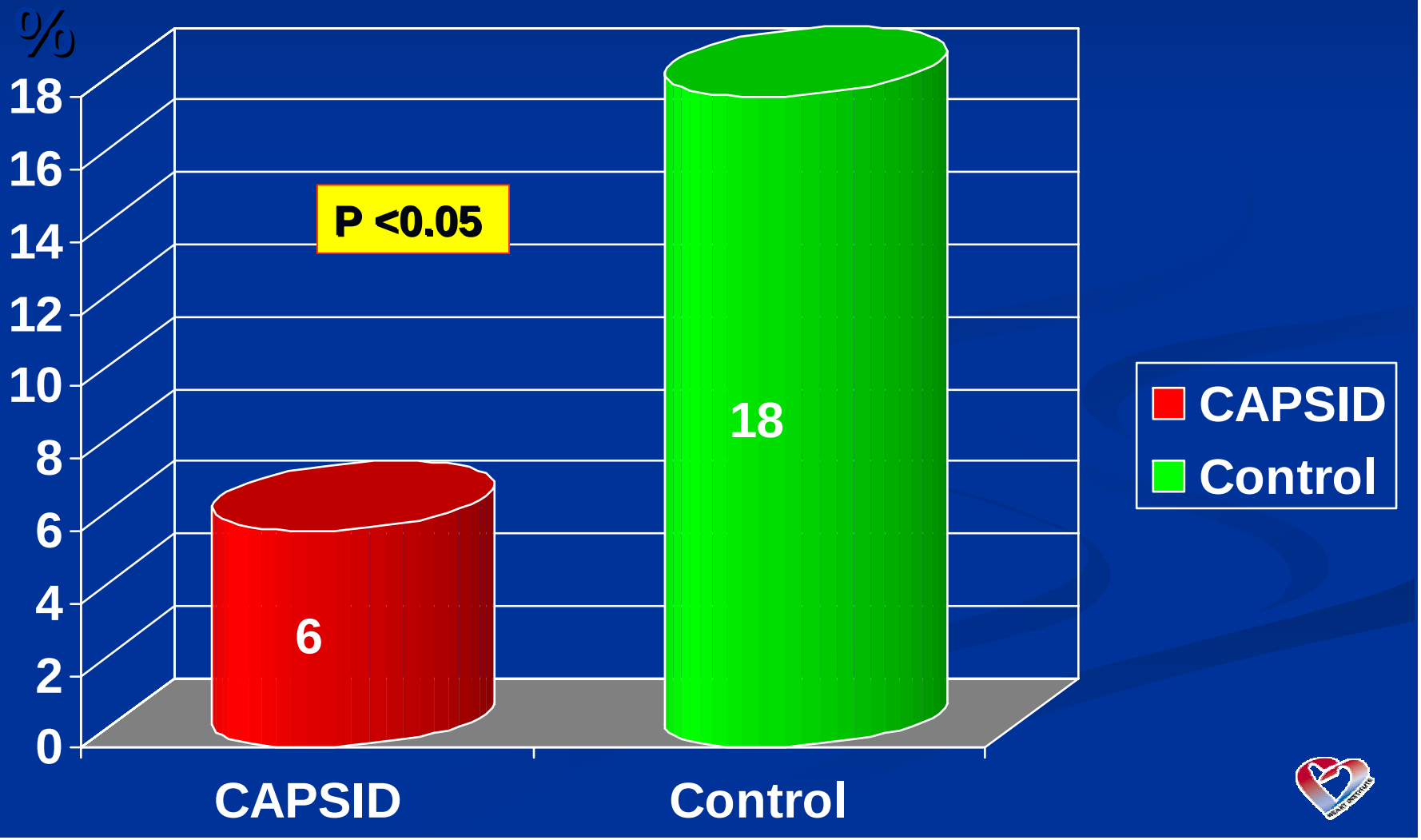
A.T. Weiss, D. Leibowitz, M. Mosseri, H. Danenberg, I. Katz, B. Varshitsky, L. Boguslavsky, H. Nassar, C. Lotan

Heart Institute, Hadassah Hebrew University Medical Center, Jerusalem, Israel

Methods I



Results I
1 Year MACE (Death / MI / TLR)



Conclusions

The use of gradual computerized inflation (CAPSID) resulted in a significant reduction in 12 month AMI, TLR and MACE.

With current problems associated with DES, our results justify further evaluation of this novel technique

Future directions

Improved “user friendly” technology

- Digital touch-screen
- Automatic predefined inflation protocols
- Inflation rate adjusted in real time to vessel resistance (pressure-volume curve)
- Further trials of CAPSID with improved stent design