Angioplasty Summit
TCT Asia Pacific

BEACON Registry : An All-Comers Trial of the Biolimus A9-Eluting Stent

28 April 2006 (Fri)
0945hours

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National Heart Centre, Singapore

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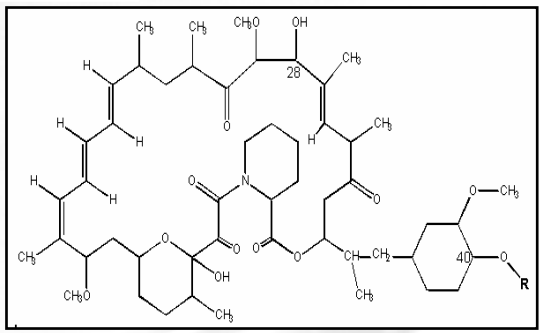
BioMatrix™ Stent ~Component~

- S-Stent™
- Quadrature design, high flexibility

- PLA polymer, bioabsorbable
- Simultaneous release of drug and polymer



- Biolimus A9
- Sirolimus Analogue, more lipophilic, faster release

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BEACON Registry
Biolimus Eluting A9 Coronary stent Obviating luminal Narrowing

- Begun on 23-Dec-2004.
- Designed to evaluate continued safety and efficacy of the BioMatrix Biolimus A9-eluting stent
- Broader patient demographic population with more complex disease, representative of actual clinical practice

The First Biolimus A9 DES study in Asia!

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Study Sites


•Max Hospital
•Siriraj Hospital
•Sarawak General Hospital
•National Heart Center,
•National University Hospital,
•Mt Elizabeth Hospital,
•Gleneagles Hospital
•Harapan Kita,
•Medistra Hospital

BEACON Registry

- **Description:**
  - Prospective, multinational, multicenter, observational web-based registry
- **Objective:**
  - Assessment of clinical outcomes in patients receiving the BioMatrix™ Stent
- **Enrollment:**
  - 1000 patients from 9 sites in Asia
  - Patient data collected at 1, 3, 6, and 12 months following stent implant
- **Primary Endpoint:**
  - Target vessel revascularization (TVR) rates
- **Secondary Endpoints:**
  - MACE rate
  - Correlation TLR, lesion characteristics and patient comorbidities

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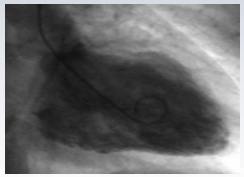
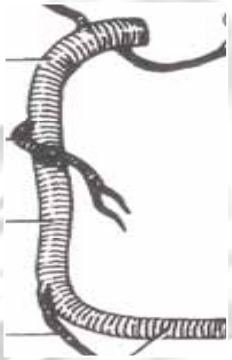
Inclusion Criteria

- MI ≥ 72hrs (≤ 2x CKMB norm)
- Lesion length ≤ 28mm
- Reference diameter 2.5-4.0mm

Exclusion Criteria

- Cardiogenic Shock
- LVEF < 30%
- Aorto ostial
- Left main ≥ 50%
- Severe calcification
- Thrombotic lesions
- Excessive tortuosity
- Extreme angulation 90°
- Bypass graft (LIMA, SVG)





BEACON: Current Status

- Ongoing data collection & analysis.
- Enrollment (31-Mar-2006):575 patients.
- Includes patients that meet BEACON criteria, and additional patients representing “real world” clinical practice (all comers).

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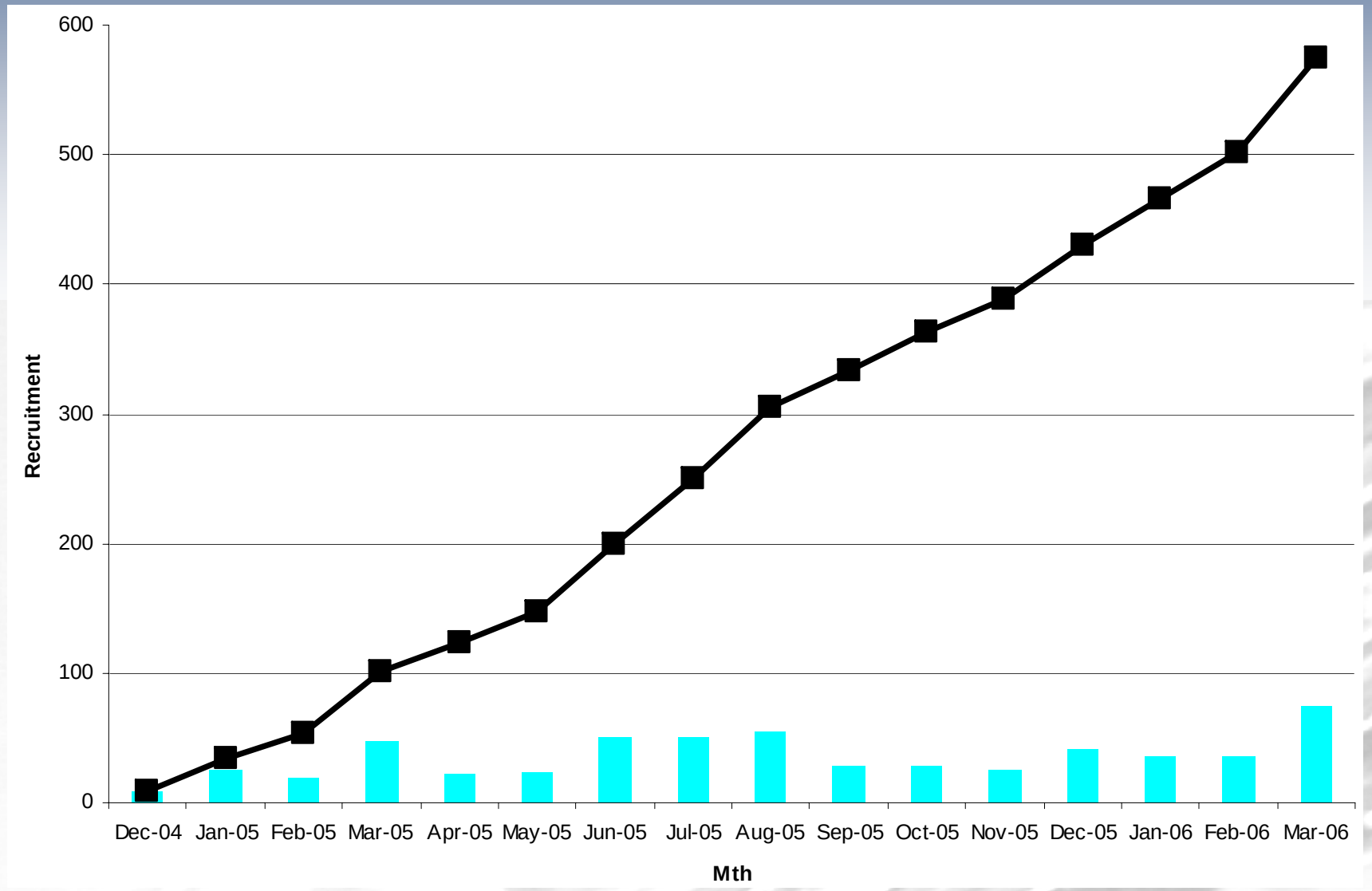
Cumulative Enrollment



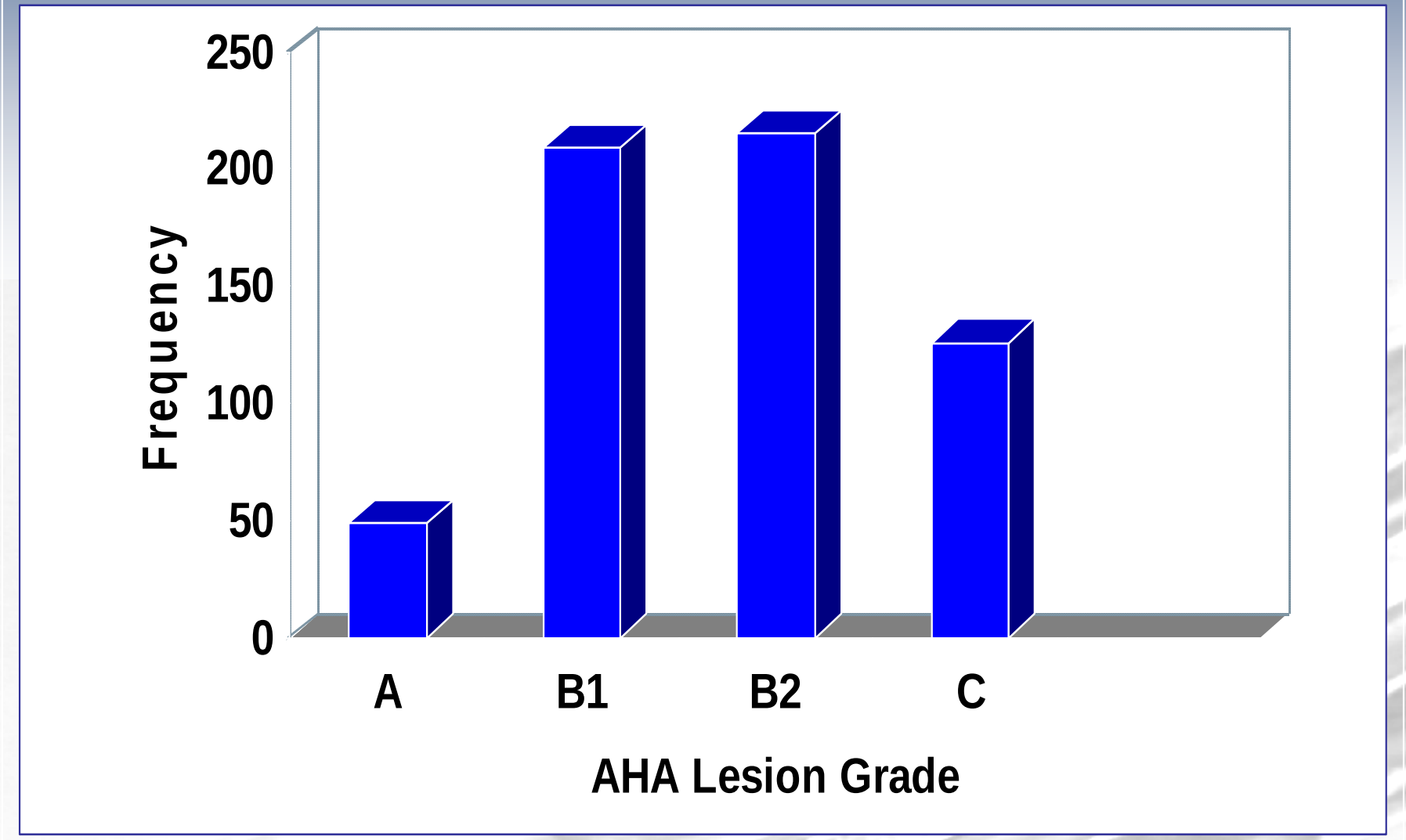
Patient Demographics Cardiovascular Risk Factors

N = 443 Patients	BioMatrix
Gender (♂:♀)	76%: 24%
Age (years, range 36-89)	60%±10
Diabetes	**41.2%** (181/439)
Hypertension	**66.2%** (290/438)
Dyslipidemia	**72.4%** (318/439)
History of Smoking	**40.3%** (178/439)
Family History of CAD	**21.4%** (94/439)
Prior MI	**34.8%** (153/438)
Previous PCI	**26.9%** (119/443)
Previous CABG	**5.6%** (25/443)

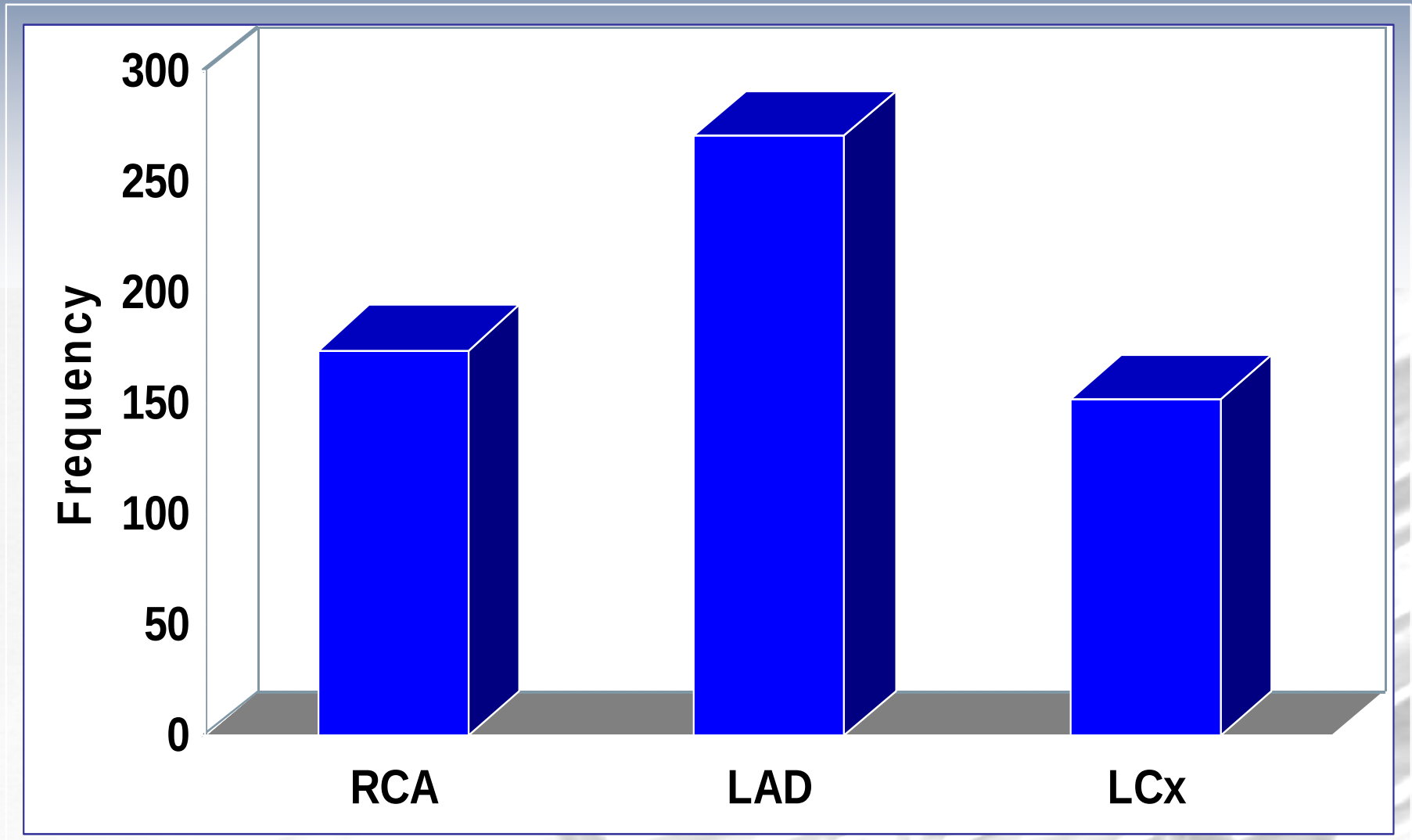
Patient Demographics

N = 443 Patients	BioMatrix
Stable Angina	**59.2%** (261/441)
Unstable Angina	**27.9%** (123/441)
CCS Class	
I	**13.2%** (33/250)
II	**60.4%** (151/250)
III	**24.8%** (62/250)
IV	**1.6%** (4/250)
LVEF	**62%±14**
LVEF < 50%	**15.9%** (51/320)

Target Lesion Grade

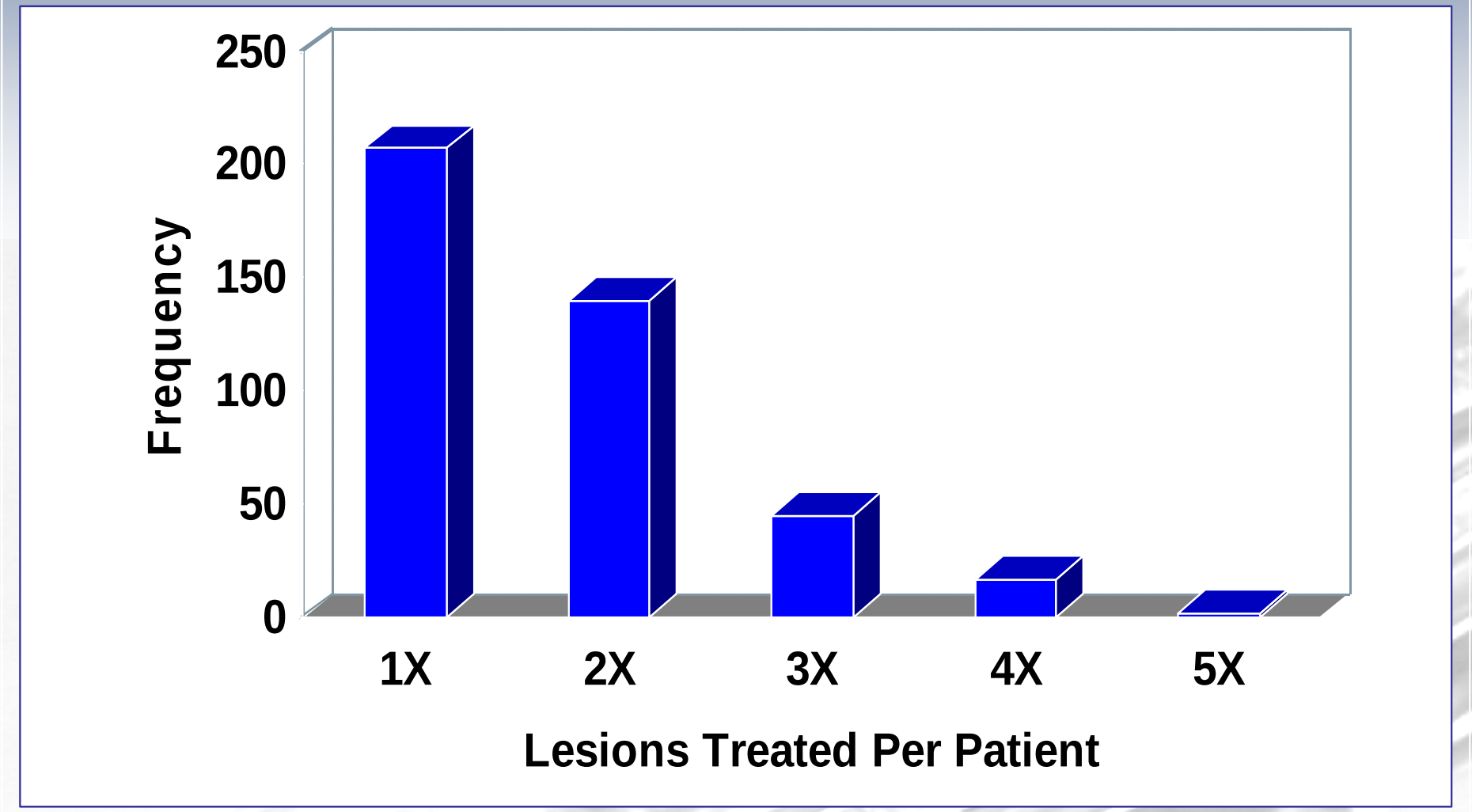


Target Lesion Location



BioMatrix Treated Lesions

Total Patients/Target Lesions/Stents : 411/602/769

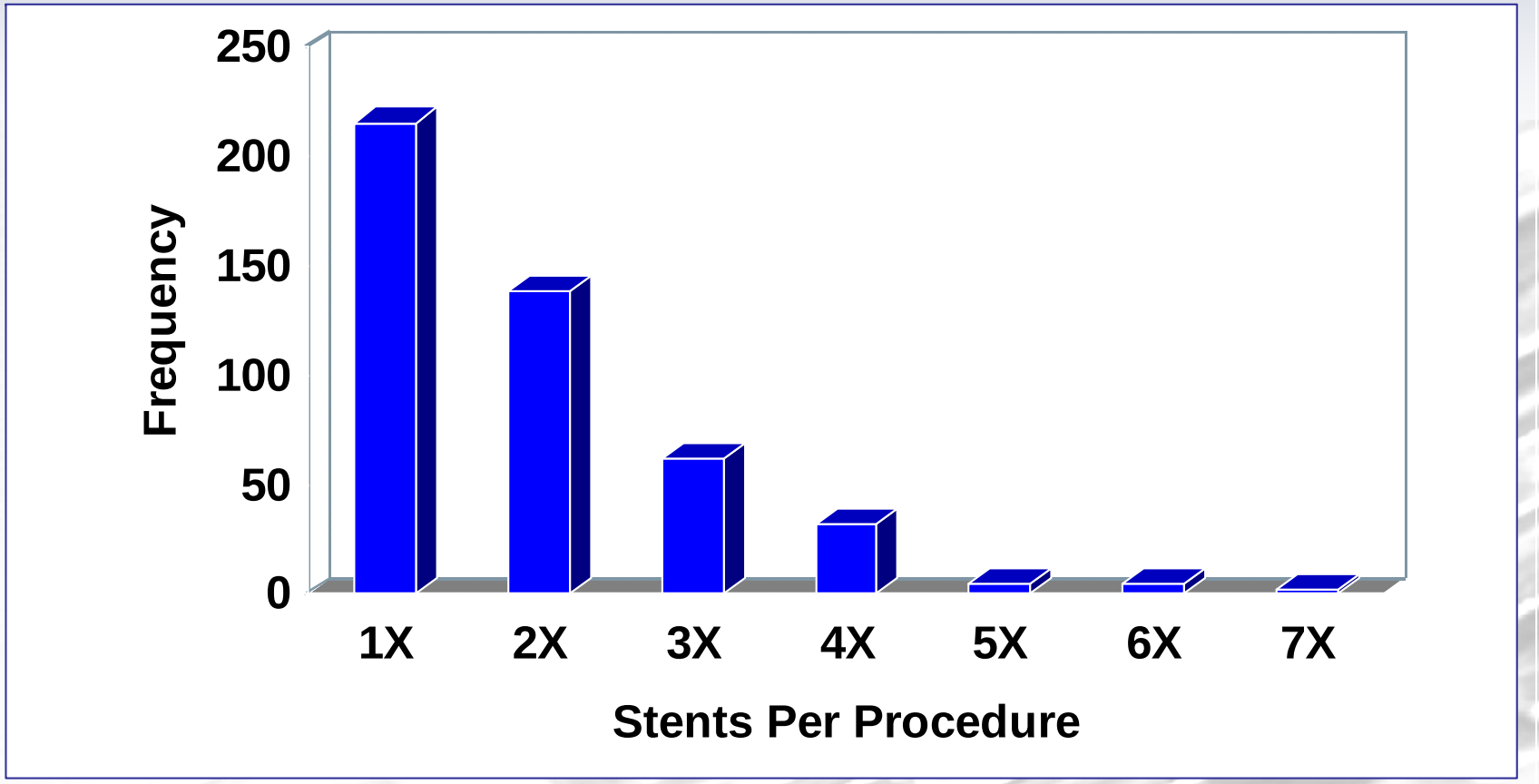


Number of Target Lesion Stents

Mean No Lesions Per Patient 1.46

Mean No Stents Per Patient 1.87

BioMatrix 79% Hybrid 21%



Lesion Characteristics

N = 602 Lesions	BioMatrix
Bifurcation lesions	**15.5%%** (83/537)
Moderate/Severe calcification	**6.5%** (39/602)
Long lesions ≥ 20mm	**38.3%** (227/593)
Small vessel ≤ 2.5mm	**7.3%** (43/593)
CTO	**6.2%** (37/602)
De novo lesions	**94.6%** (512/541)
Restenotic lesions	**4.3%** (23/541)

Angiographic Findings

N = 602 Lesions	BioMatrix
Pre-Procedure RVD (mm)	2.87 ± 0.44
Range	1.47mm – 4.52mm
Post-procedure MLD (mm)	2.93 ±0.43
Range	1.95mm – 4.46mm
Pre-Procedure DS (%)	77.6 ± 14.4
Post-Procedure DS (%)	2.5 ± 5.5
Lesion Length (mm)	18.3 ± 9.5
Range	6mm – 98mm

30-days Hierarchical MACE

MACE	**2.8% (11/395)**
Death	**0.3% (1/395)**
Q Wave MI	**0.5% (2/395)**
Non Q Wave MI	**2.5% (8/395)**
CABG	**0.0% (0/395)**
PTCA	**0.0% (0/395)**
TVR	**0.0% (0/395)**
TLR	**0.0% (0/395)**

Verified, Non-adjudicated MACE, inclusive of real world cases

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Cumulative Hierarchical MACE

MACE	**4.3% (19/443)**
Death	**0.7% (3/443)**
Q Wave MI	**0.5% (2/443)**
Non Q Wave MI	**1.8% (8/443)**
CABG	**0.2% (1/443)**
PTCA	**1.1% (5/443)**
TVR	**0.9% (4/443)**
TLR	**0.2% (1/443)**
Range	***0.3 – 14.2 months***

Verified, Non-adjudicated MACE, inclusive of real world cases

Conclusions

- The BioMatrix stent is the first stent that utilizes a bioresorbable drug carrier, which may offer an advantage to permanent polymer stents.
- The BEACON Registry provides a broad real world clinical experience with the BioMatrix Stent in a diverse patient population.
- Preliminary clinical outcomes at a median follow-up of 7.2 months shows a low MACE rate (5.4%) and a low revascularization rate (1.1%).
- Post procedure MLD was 102% of the pre-procedure RVD.