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New Approach to Treating Thrombus Containing Lesions: Inspire MGuard

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Disclosure Statement of Financial Interest

Within the past 12 months, the presenter or their spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

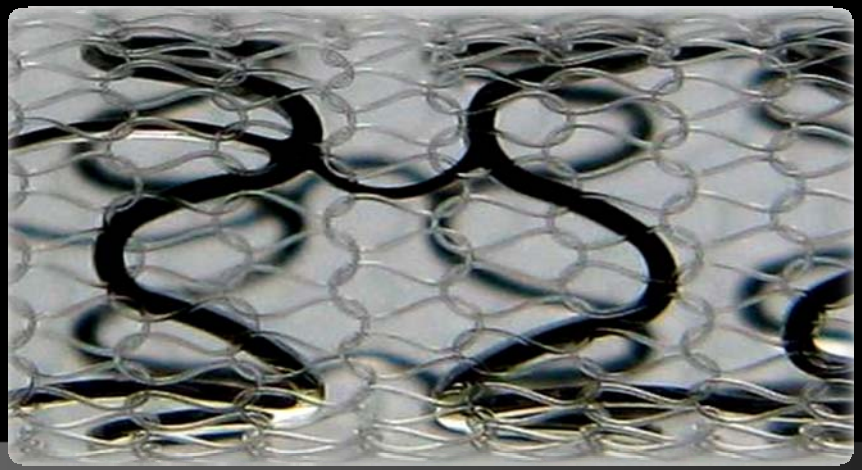
Physician Name	Company/Relationship
Eberhard Grube, MD	Inspire MD (C) Boston Scientific (G,C,SB) Labcoat (C) Cordis JnJ (C) Abbott (C) Biosensors (G,E,C,SB) Orbus Neich (C)

Key

G – Grant and or Research Support E – Equity Interests S - Salary
C – Consulting fees, Honoraria R – Royalty Income I – Intellectual Property Rights
SB – Speaker's Bureau O – Ownership OF – Other Financial Benefits

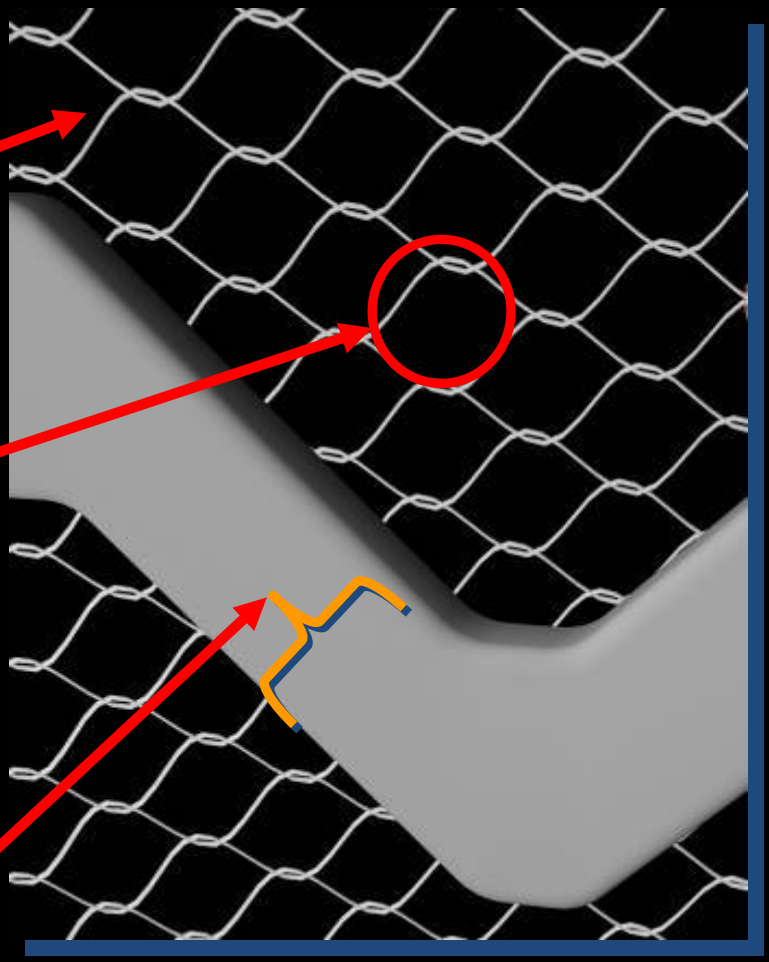
Background

- MGuard^{TM} (InspireMD Ltd.) is a combination of an ultra-thin polymer net attached to the external surface of a bare metal stent, designed to provide embolic protection and to reduce vessel injury during coronary interventions.



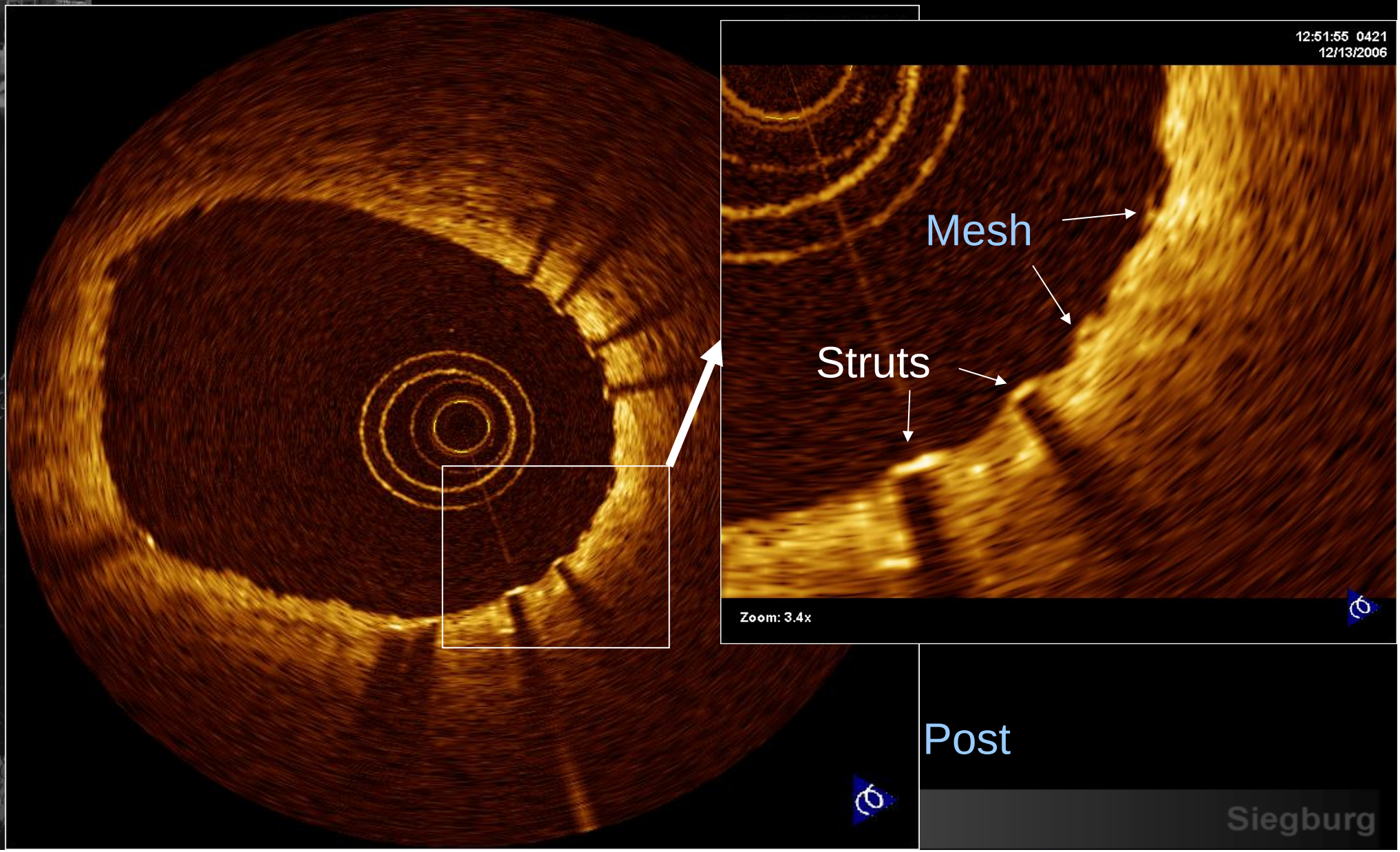
MGuard™

- A stent wrapped with a micron level fiber mesh
- 10-20 µm single, knitted PET fiber providing flexibility and strength
- ~180x150 µm apertures
- Same look and feel as a standard stent



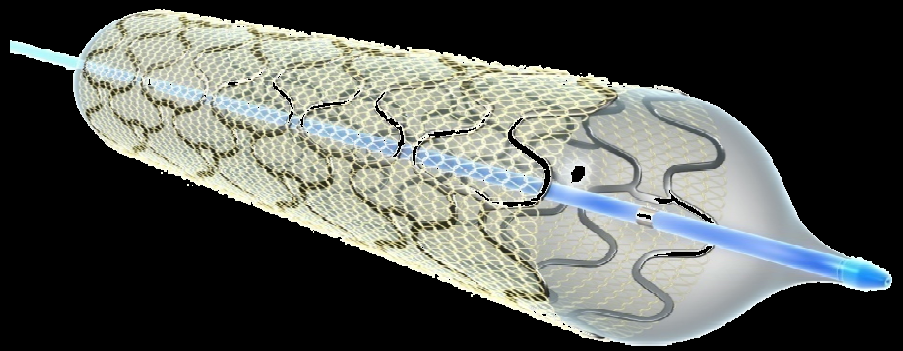
Struts: (80-100 microns)

MGuard (Inspire-MD) – Case Example



Background

- The aim of the First in Man (FIM) trial was to evaluate the efficacy and safety of the MGuard™ in PCI of human coronary vein grafts (VG) and native coronaries.



Methods

- The trial involved MGuard™ stenting-based PCI at 2 medical centers.
- Primary endpoint was 30 days major adverse cardiac events (MACE).
- Secondary endpoint:
  - Device success
  - Procedural success
  - TIMI flow post procedure
  - 6 Months MACE
  - 6 Months Late Lumen Loss

Trial Organization

- Enrolling centers
  - Siegburg, Germany
  - Trier, Germany
- Monitoring, e-CRF management
  - Krauth Ltd., Hamburg, Germany
- Angiographic Core lab
  - CRF, New York, USA
- Independent Clinical event committee
  - CRF, New York, USA

Patient Selection criteria

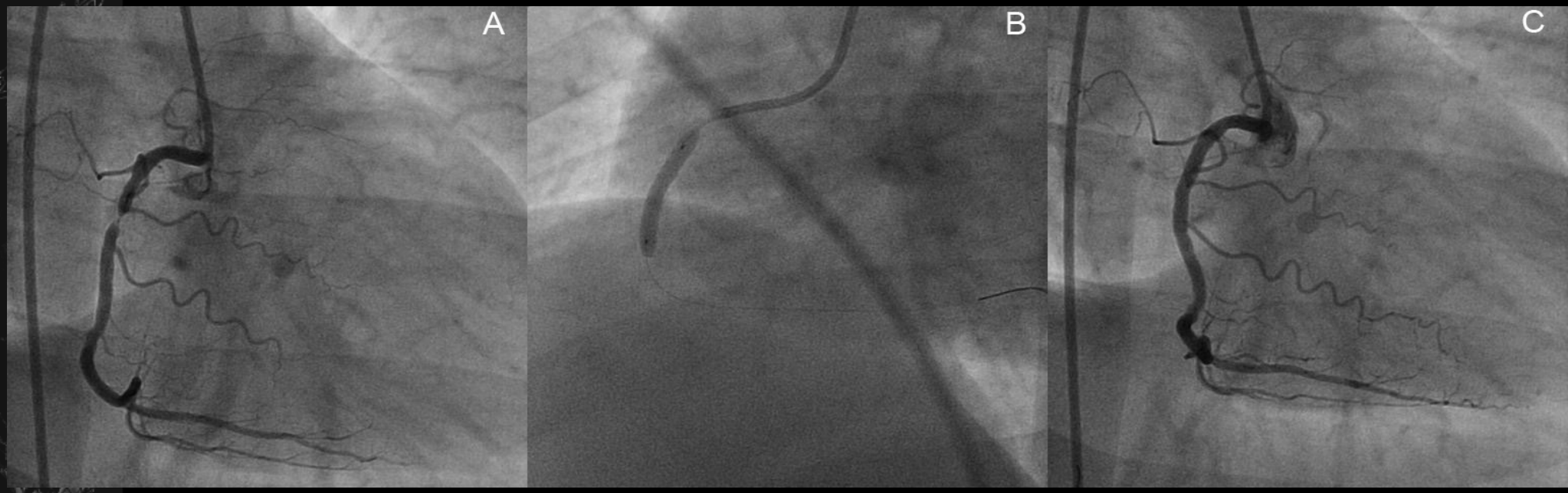
- Inclusion
  - A target de-novo lesion in native coronaries or degenerated vein graft
  - diameter stenosis ≥50% but <100%,
  - reference vessel diameter ≥2.5mm and ≤4.5 mm,
  - TIMI flow ≥1,
- Exclusion
  - Requirement to treat ≥1 coronary lesion urgently
  - LVEF<25%
  - Stroke or transient ischemic attack within 60 days
  - Baseline CPK values > 3 times the ULN
  - Creatinine≥2.0 mg/dl,
  - Excessive vessel calcification or tortuousity,
  - Recent bleeding event.

Study population

- 41 patients were enrolled.
- According to the protocol , the endpoints analysis is per protocol and therefore includes only 33 single stent procedures

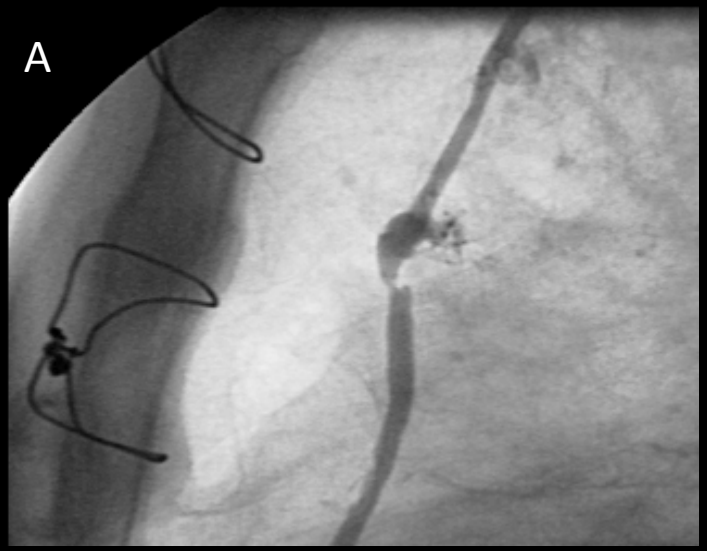
Results – Case #1 (SA)

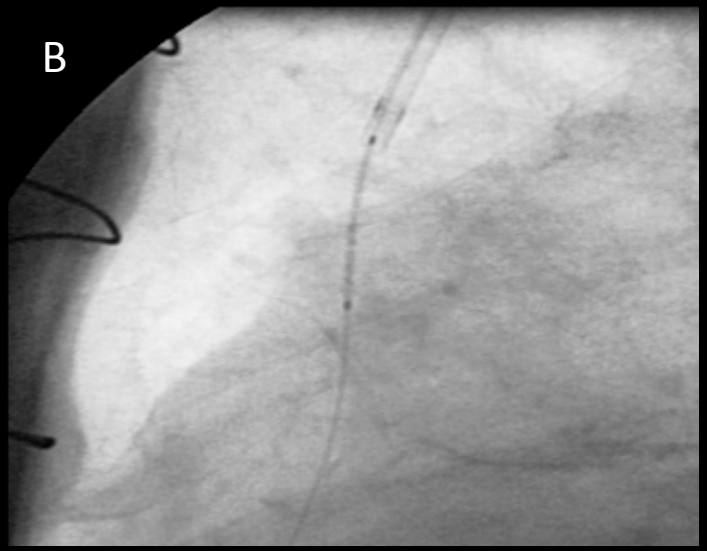
A) RCA lesion - pre stenting
B) MGuard™ stent deployment
C) Final Result



Results – Case #2(HK)

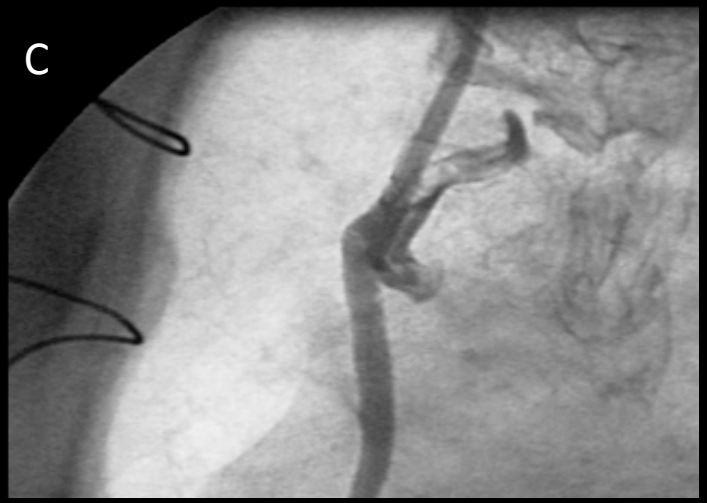
A) SVG lesion

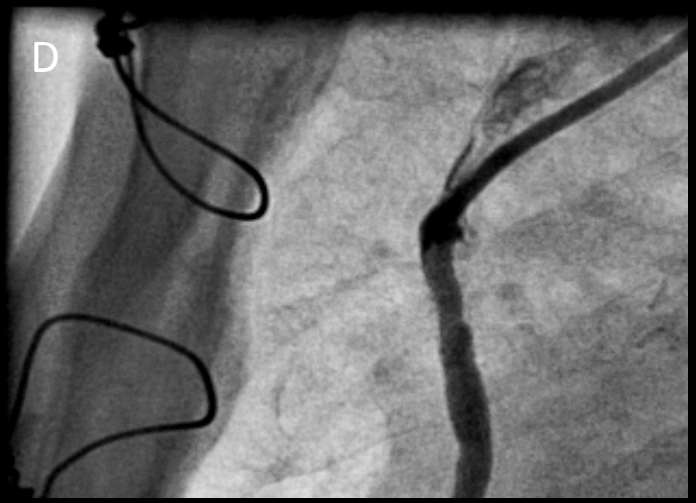




B) MGuard in place

C) Final result





D) Six months F/U

Results – Baseline Patient Characteristics

Age	67.1y±10.6y
Male	76%(25/33)
Diabetes mellitus	39%(13/33)
Hypertension	82%(27/33)
Dyslipidemia	85%(28/33)
Smoking	36%(12/33)
Family history of CAD	24%(8/33)
Prior MI	27%(9/33)
Prior PCI	48%(16/33)
Prior CABG	61%(20/33)
History of CHF	24%(8/33)

Baseline procedure angiographic results

Baseline(n=33)	
SVG Lesion	51.5% (17/33)
SVG age	13.9y±4.4
RCA lesion	15.2% (5/33)
LCX lesion	24.2% (8/33)
LAD lesion	3.0% (1/33)
TIMI 0-1 (pre/post)	3.0% / 0.0%
TIMI 2 (pre/post)	18.2% / 3.0%
TIMI 3 (pre/post)	78.8% / 97.0%
No reflow	0.0% (0/33)
Slow reflow	3.0% (1/33)
Distal embolization	0.0% (0/33)

Results
Primary endpoint – 30 days MACE

MACE	6.1% (2/33)
Cardiac Death	0.0% (1/33)
MI	6.1% (2/33)
QW	3.0% (1/33)
Non-QW	3.0% (1/33)
TLR	3.0% (1/33)
PCI	3.0% (1/33)
CABG	0.0% (0/33)

Results

Secondary endpoints - 6 months MACE and QCA

MACE	15.2% (5/33)
Cardiac Death	0.0% (0/33)
MI	6.1% (2/33)
QW	3.0% (1/33)
Non-QW	3.0% (1/33)
TLR	12.1% (4/33)
PCI	12.1% (4/33)
CABG	0.0% (0/33)

6 months Angiographic results (n=28)	
%DS	32%±19%
LLL	0.63mm±0.57mm
ABR	14.3% (4/28)

Results
Secondary endpoints – in hospital MACE

MACE	3.0% (1/33)
Cardiac Death	0.0% (0/33)
MI	3.0% (1/33)
QW	0.0% (0/33)
Non-QW	3.0% (1/33)
TLR	0.0% (0/33)
PCI	0.0% (0/33)
CABG	0.0% (0/33)

Conclusions

- The 6 months follow-up shows good results for both efficacy and safety endpoints for the Mguard™ stent, considering the unfavorable patient and lesion characteristics.
- In a setting of a single MGuard™ stent procedure, the MGuard™ demonstrates:
  - TLR rates which are superior to known BMS values
  - MACE and MI rates that are superior to published data in similar patient cohorts.
- Larger trials with specific indications are warranted in order to confirm these results in patient subgroups

Thank you