The Vascular Concepts - PRONOVA Durable Polymer Sirolimus Eluting Stent A Review of Indian Registry Results

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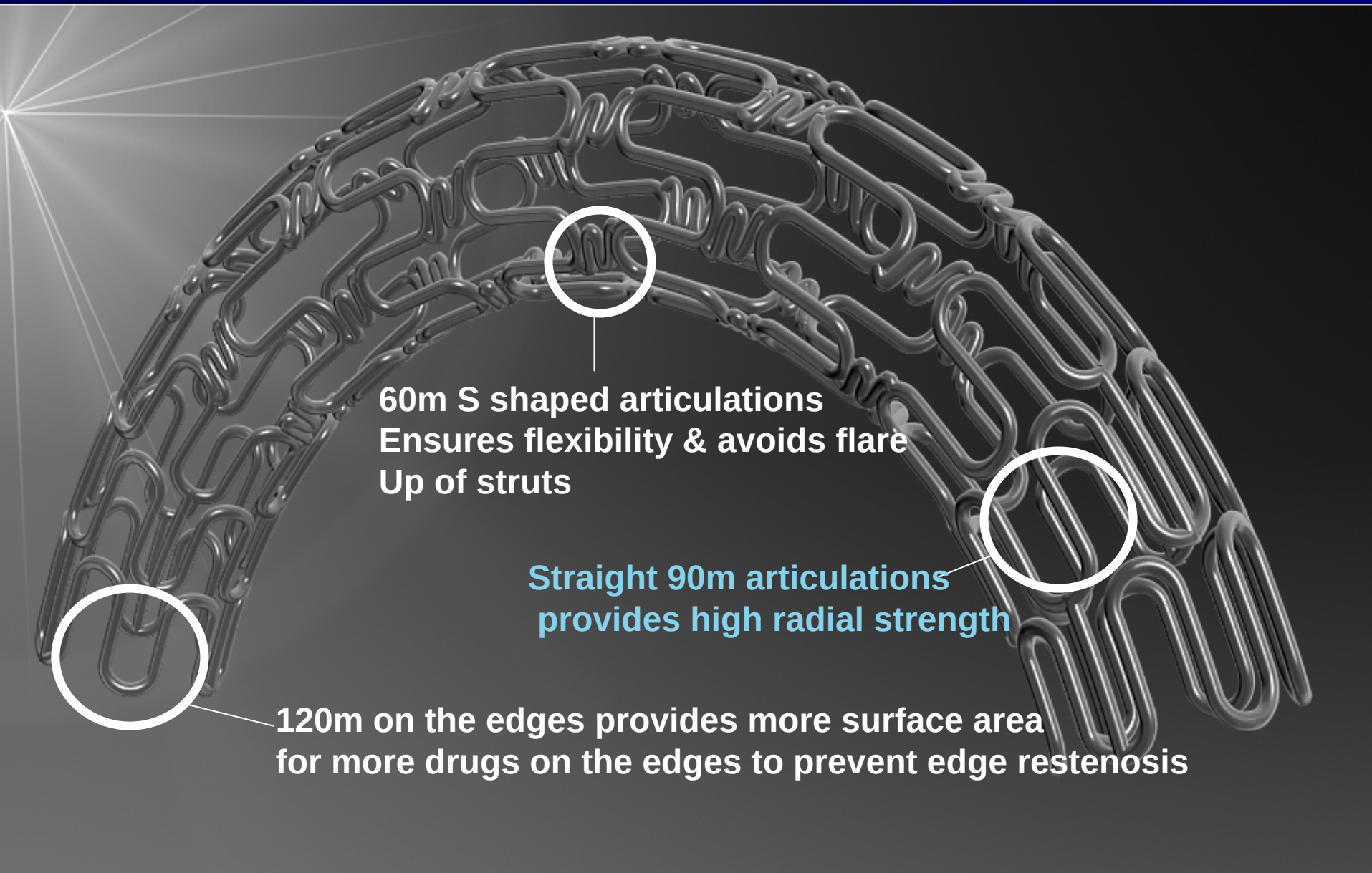
Presenter Disclosure Information
Nothing to Disclose

Name:

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

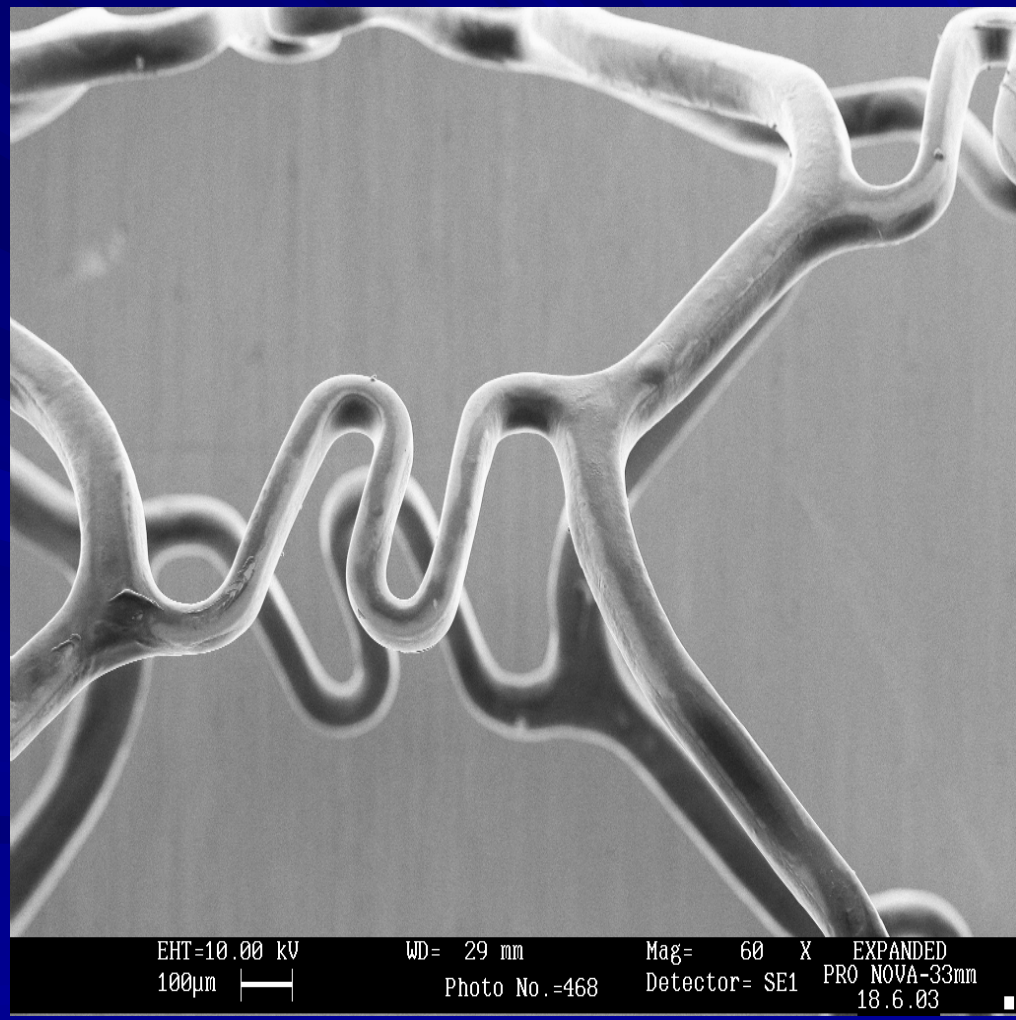
Company Name	Relationship

Pronova Stent Design
Unique Combination of Flexibility & Radial strength

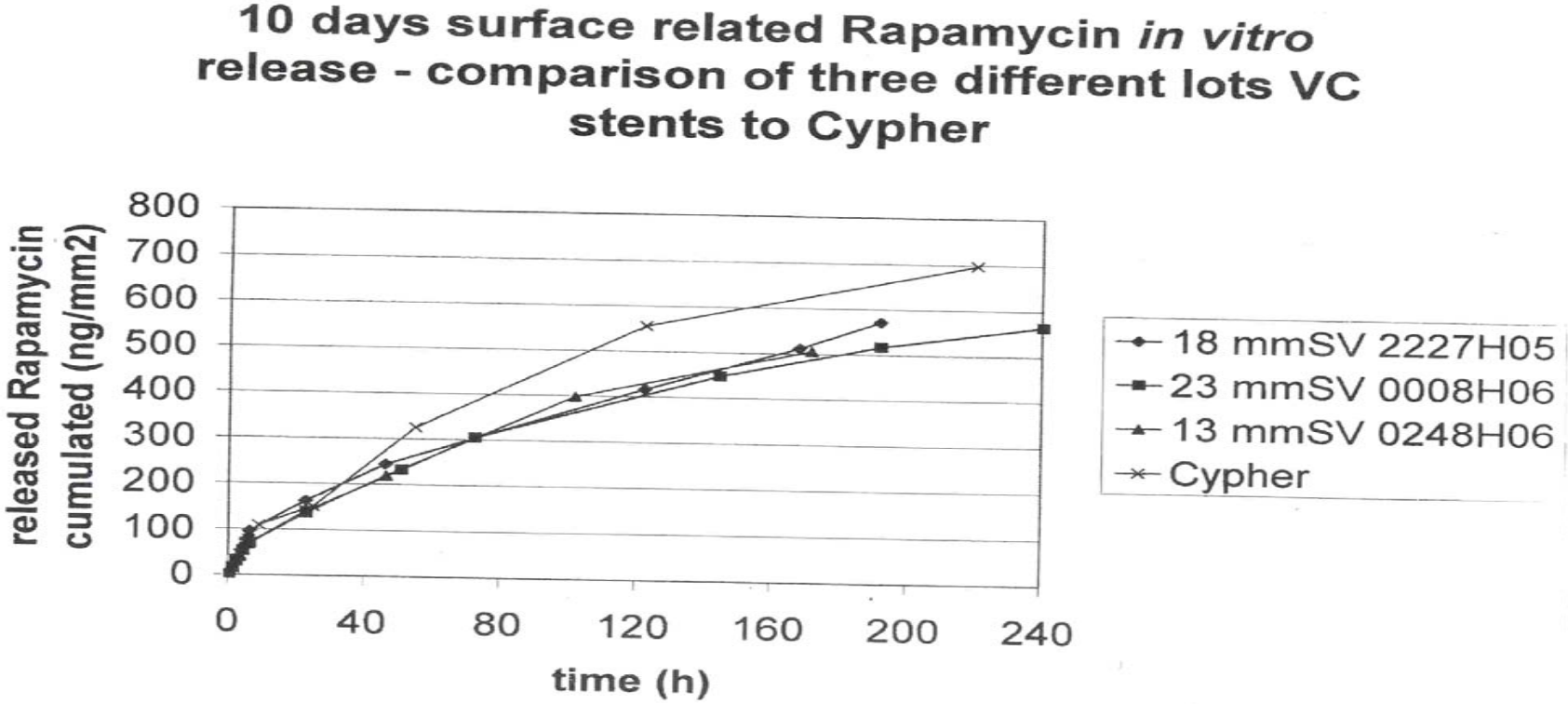


POLYMER TECHNOLOGY

- Proprietary blend of polymers-copolymer
  Biostable polymer
- Non inflammatory-Established Implants Usage
- Screened for Class VI biocompatibility

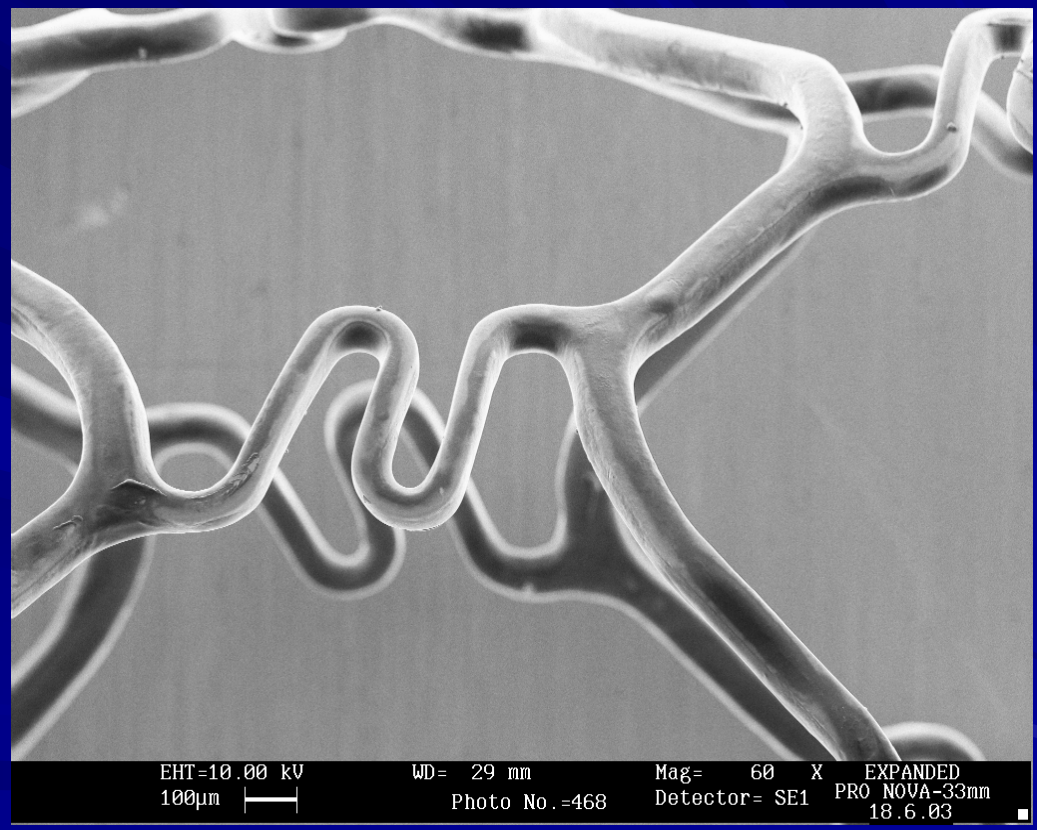


Release Kinetics

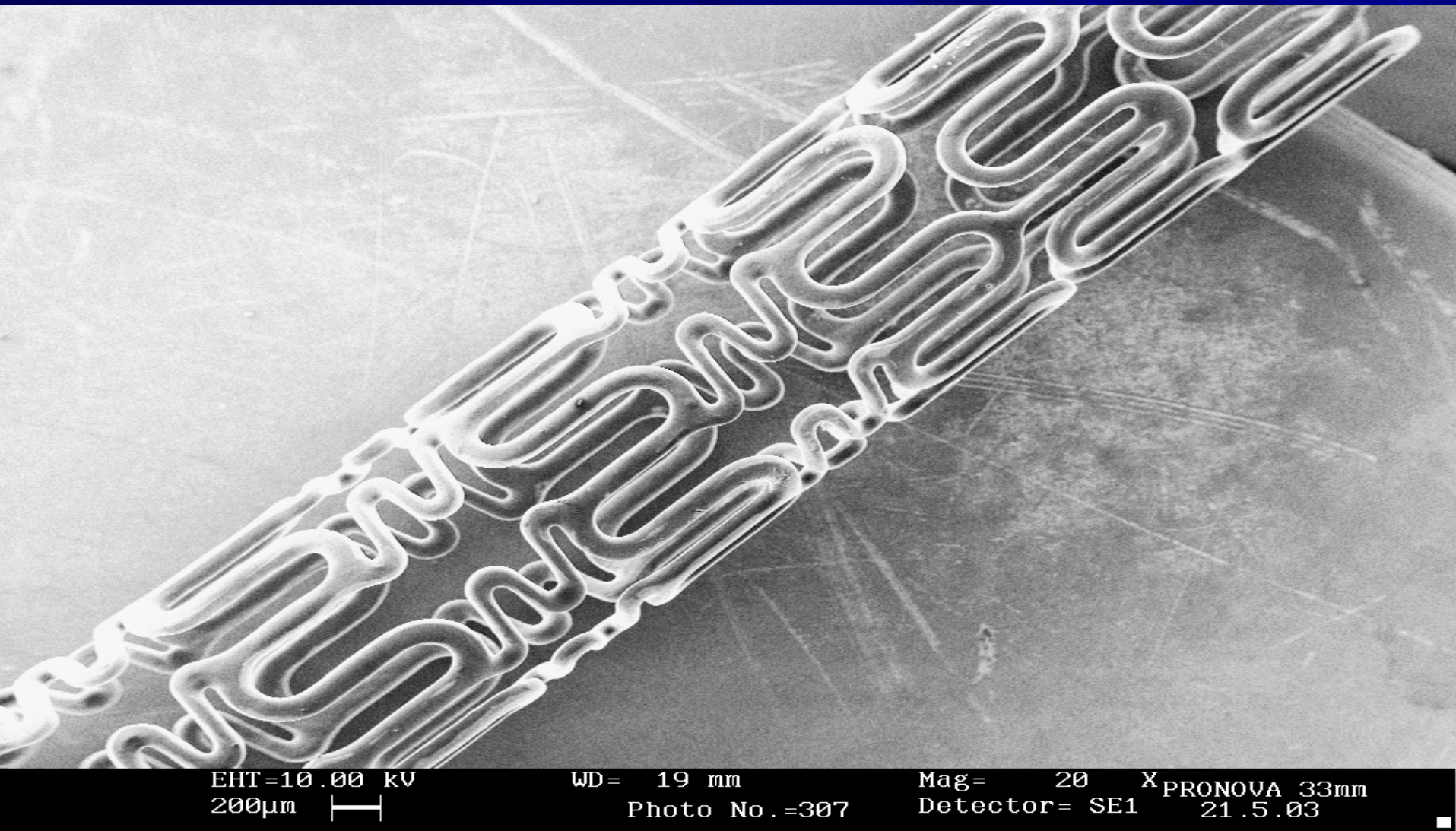


COATING TECHNOLOGY

- Pronova uses a patented "*Vibrational Technology*"
- This technology ensures coating integrity and uniform surface coverage -key to release profiles



Scanned Electron Microscopic ANALYSIS



CLINICAL USAGE AND REGISTRIES

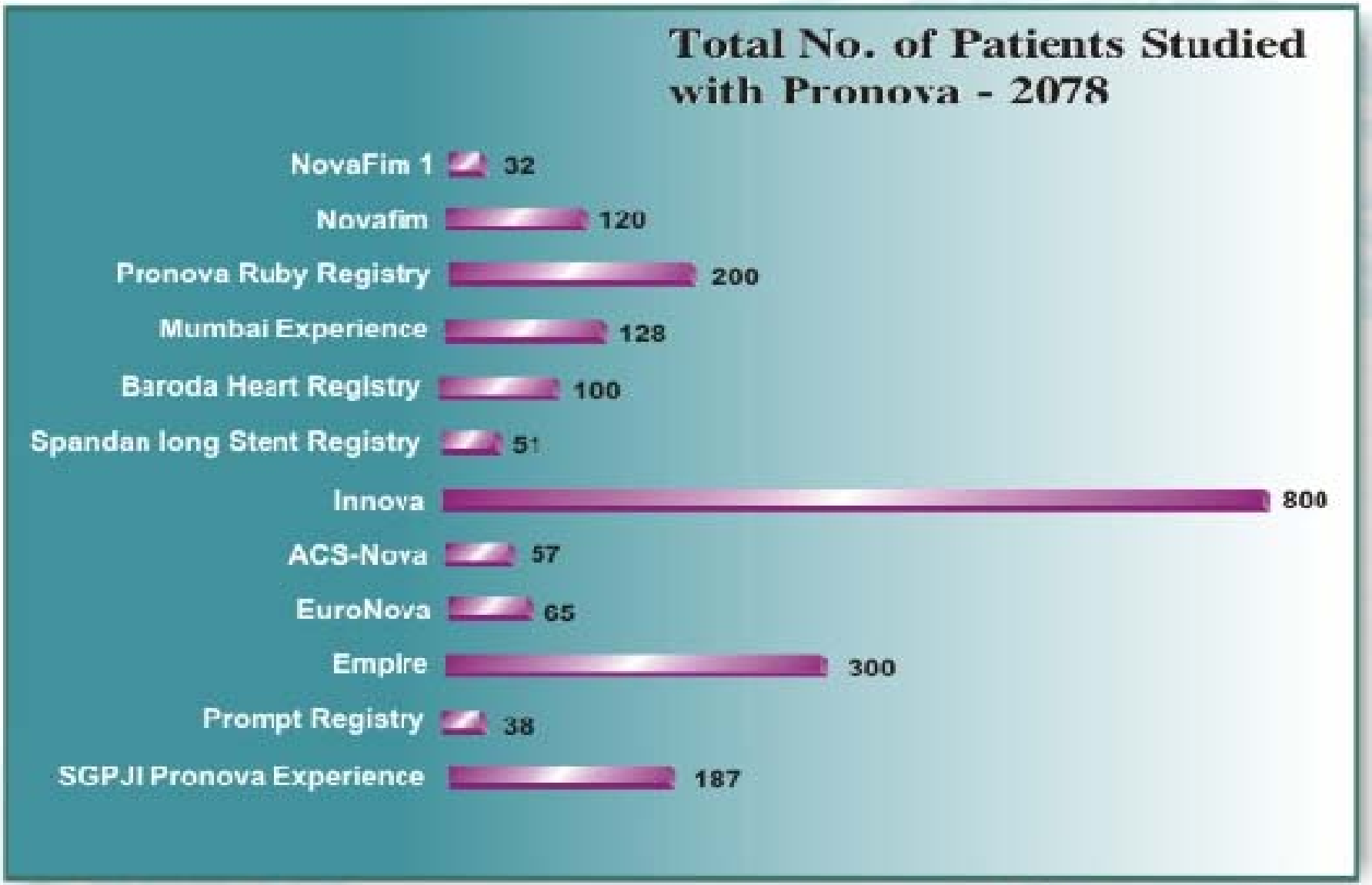
Till now >25000 stents deployed since June 2004

and 2078 patients studied in various registries

Pronova Clinical History

Total number deployed

> 25,000 stents in Asia



Focus on

Empire Registry (Single Centre)

Innova Registry (Multicentre)

Euronova Registry (Euro single Centre)

Empire Registry
Single centre 300 patients

EMPIRE REGISTRY

Escorts Multiple Pronova Implantation Registry

Objective :

To study the Safety and Efficacy of Sirolimus Coated Pronova Stents in Real World patients

Study Design:

Single Center Registry

No. of Patients Enrolled : 300 **(Sept 2005 till Jan 2006)**

Angiographic FU (6 months) – 100 patients

Clinical FU (6 mths) – 300 patients

All patients requiring PTCA were included,

Post CABG patients were excluded

EMPIRE Registry Contd.

Patient Profile

Diabetics : 32%

Prior MI : 67%

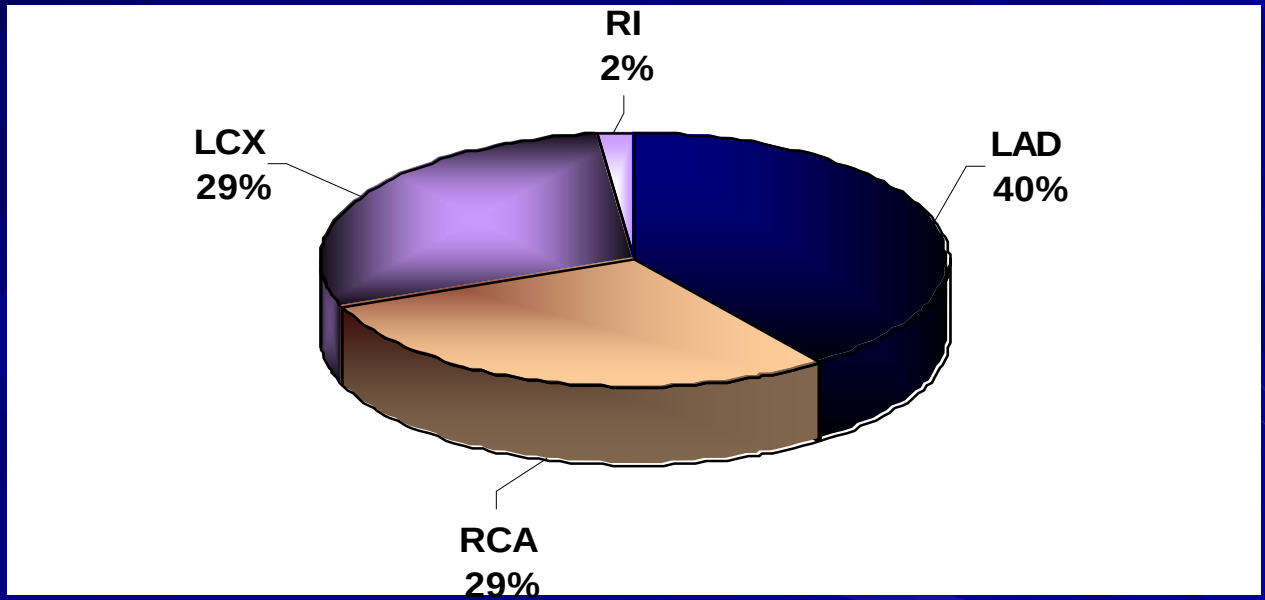
Hypertensive : 58%

Angina : 87%

Family History : 31%

Smokers : 36%

Lesion Demography



Stent Details

No. of Stents Used : 386

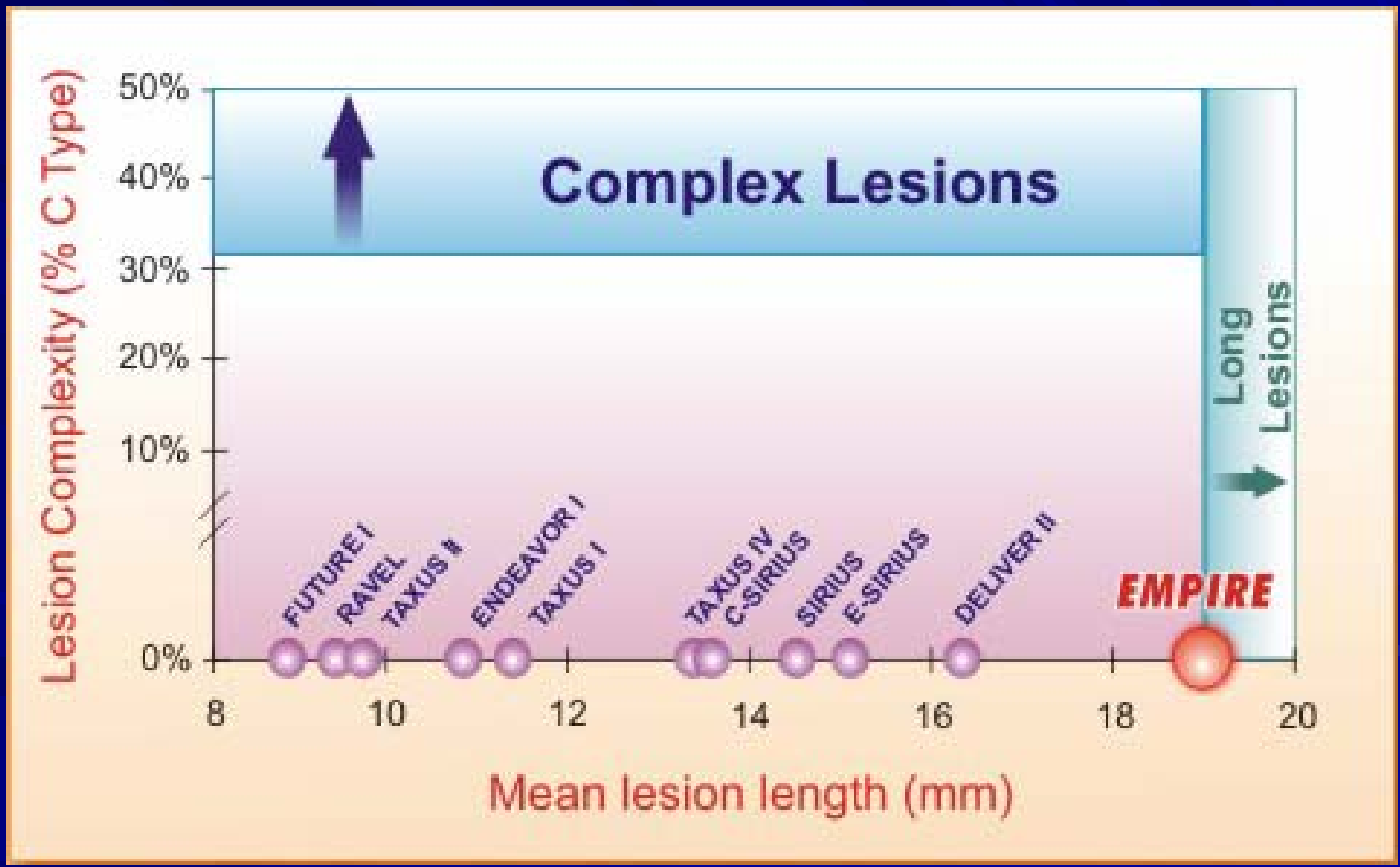
Average Length of Stent : 21.4 mm

Average Diameter of Stent : 2.92 mm

No. of Stent / Pt : 1.29

EMPIRE Registry Contd.

Showing complexity of lesion compared to other registries



EMPIRE Registry Contd.

CLINICAL FOLLOW UP Results

In Hospital MACE – 0%

30 Days MACE (N=300)

SAT	**0 %**
Death	**0.33 % (1)**
MI	**Nil**
Urgent PCI	**Nil**
Urgent CABG	**0.33% (1)**

(CABG & Death was in the same pt.)

6 Months MACE (N=299)

Death - 1% (n=3)
MI 0
Re - intervention – 1% (n=3)
TLR – 0.66% (n=2)
Non TLR – 0.33% (n=1)
Angina Persisting – 6.73% (n=20)
Intervention could not be done

EMPIRE REGISTRY Contd. Angiographic Result

6-8 Months QCA Data

- Total No. of Angiographic FU – 101 patients (33.3 %)
- Total No. of stents – 126
- Percentage Restenosis – 12.6 % (16/126 stents)
- Late Loss – 0.45 mm
- Average Length of Re-stenosed stent – 25.2 mm

2nd Registry

INNOVA REGISTRY

Multicentre 950 patients

Innova Registry

The INdian NOVA Registry on Pronova Sirolimus Eluting Stent

Innova Registry Commenced from – June 2005

The First Multi-center Registry of DES in India focusing on Real World patients

Study Objective

To Evaluate Immediate & 6 months clinical Outcomes of Pronova SES in the Real World Clinical Setting in Indian Population

(on model of RESEARCH registry of Cypher)

PRIMARY ENDPOINTS…

30 Day and 6 Month MACE

- Acute Closure
- Death
- MI
- Other Events

Innova Registry contd.

INCLUSION CRITERIA…

All patients Eligible for Stenting

EXCLUSION CRITERIA

None

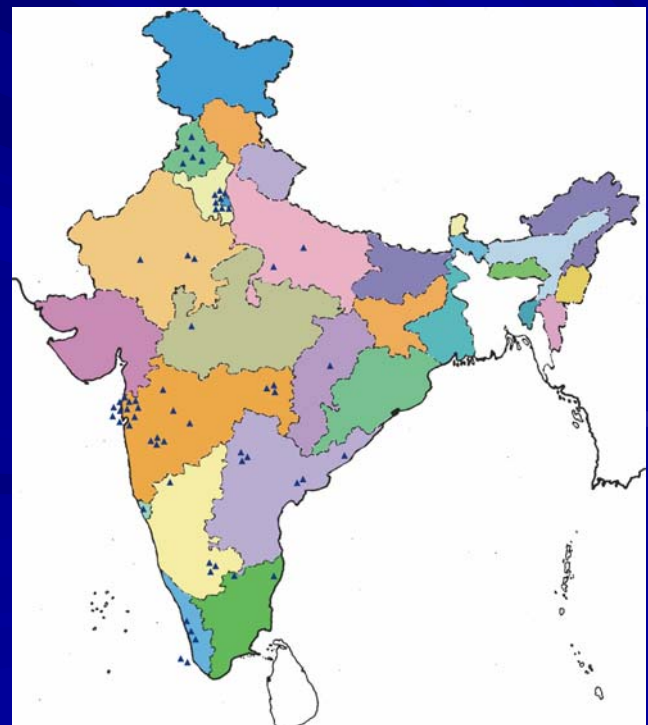
All patients deployed with ProNOVA Stent is enrolled in the Study.

Study Design

Total Sites : 49 hospitals

Investigators : 88

950 patients



Innova Registry Contd.

Clinical Follow up Data

- **Teleconference with the Patient**
- **Follow up Visit of the Patient to hospital**

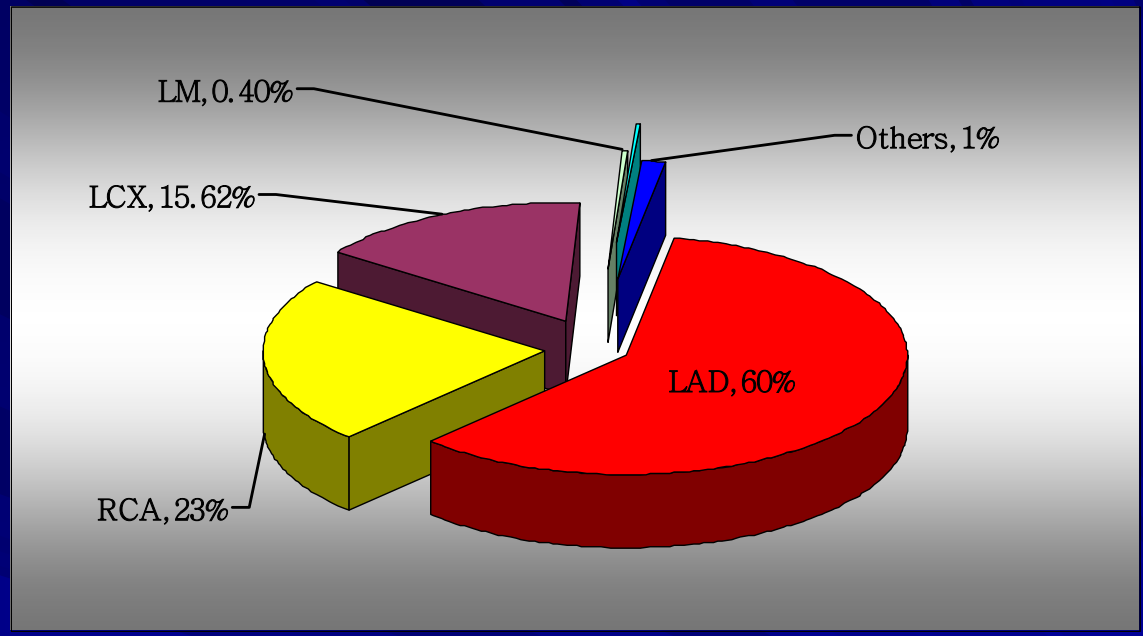
Clinical details

Patient Enrolled : 950
Male/Female : 81% / 19%
Average Age : 54 years

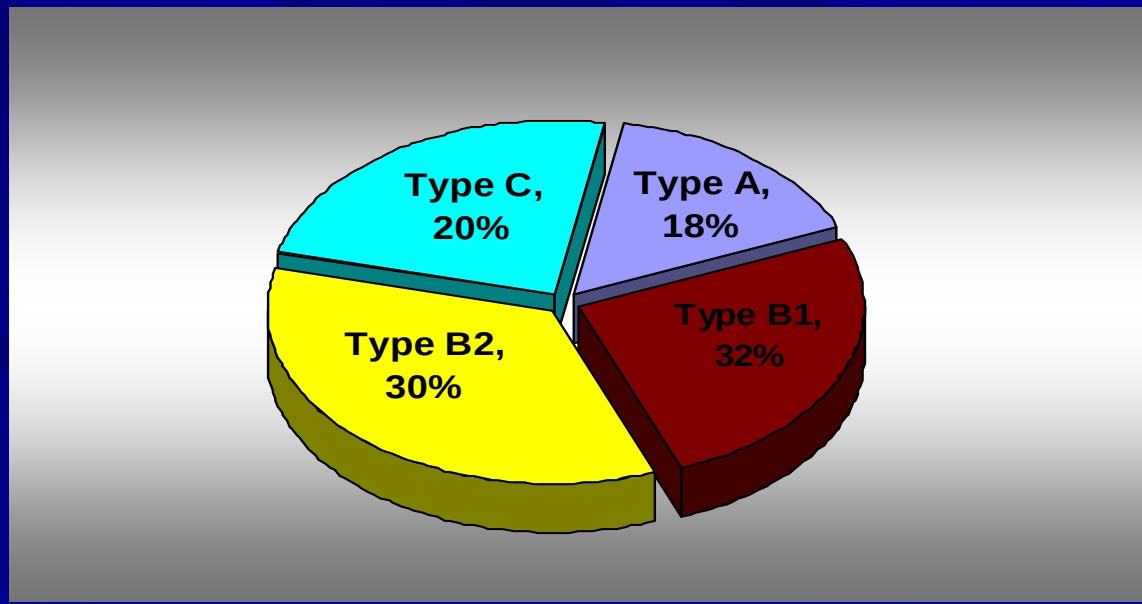
Diabetics: 28.5% (Type II DM : 85.5%, IDDM:14.5%)
Hypertensive 42.1%
Smoker 14.1%
Family History 12.75%
Hyperlipidemia 13.5%
Obesity 8.5%

Innova Registry Contd.

Lesion Detail

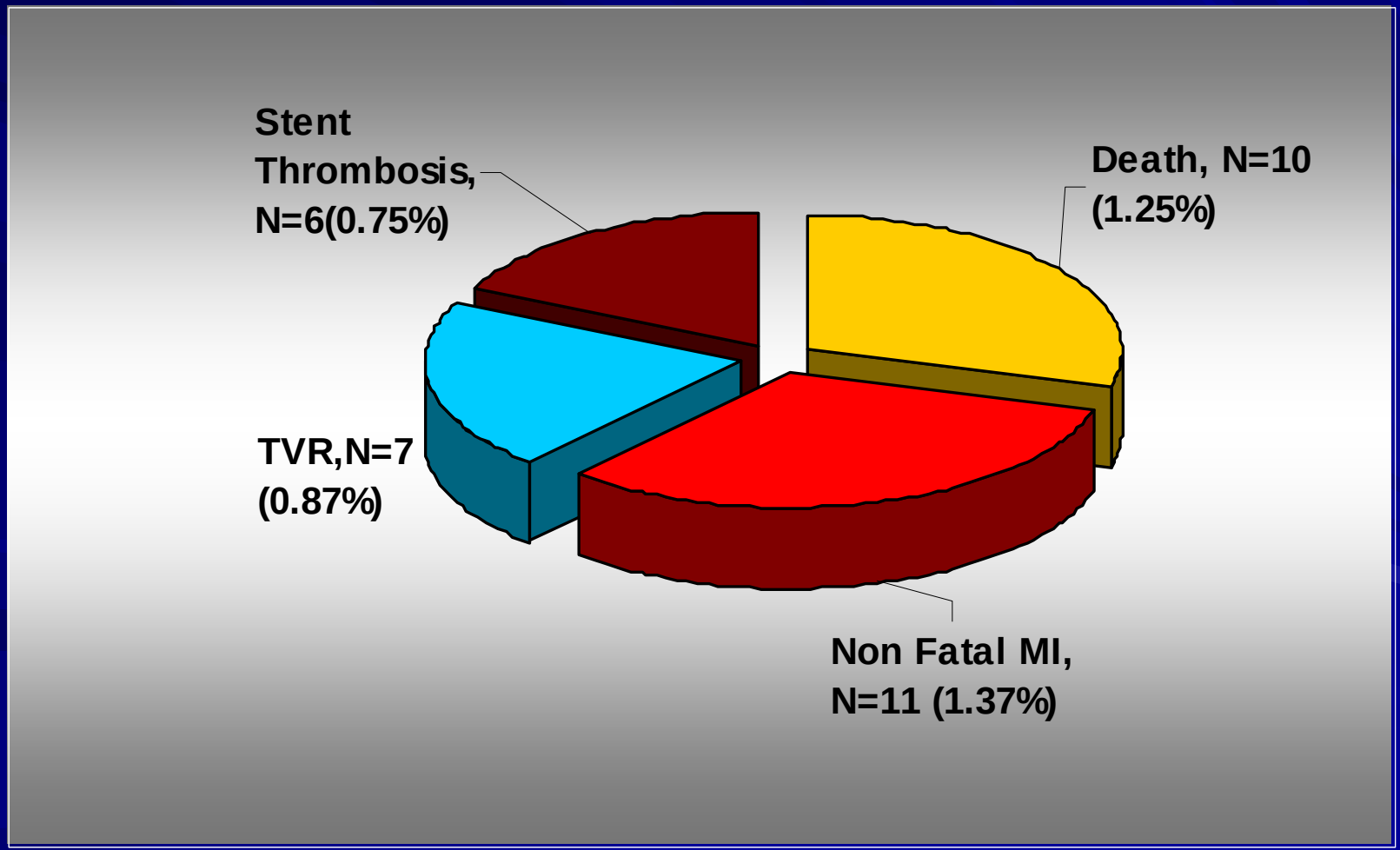


Lesion Type

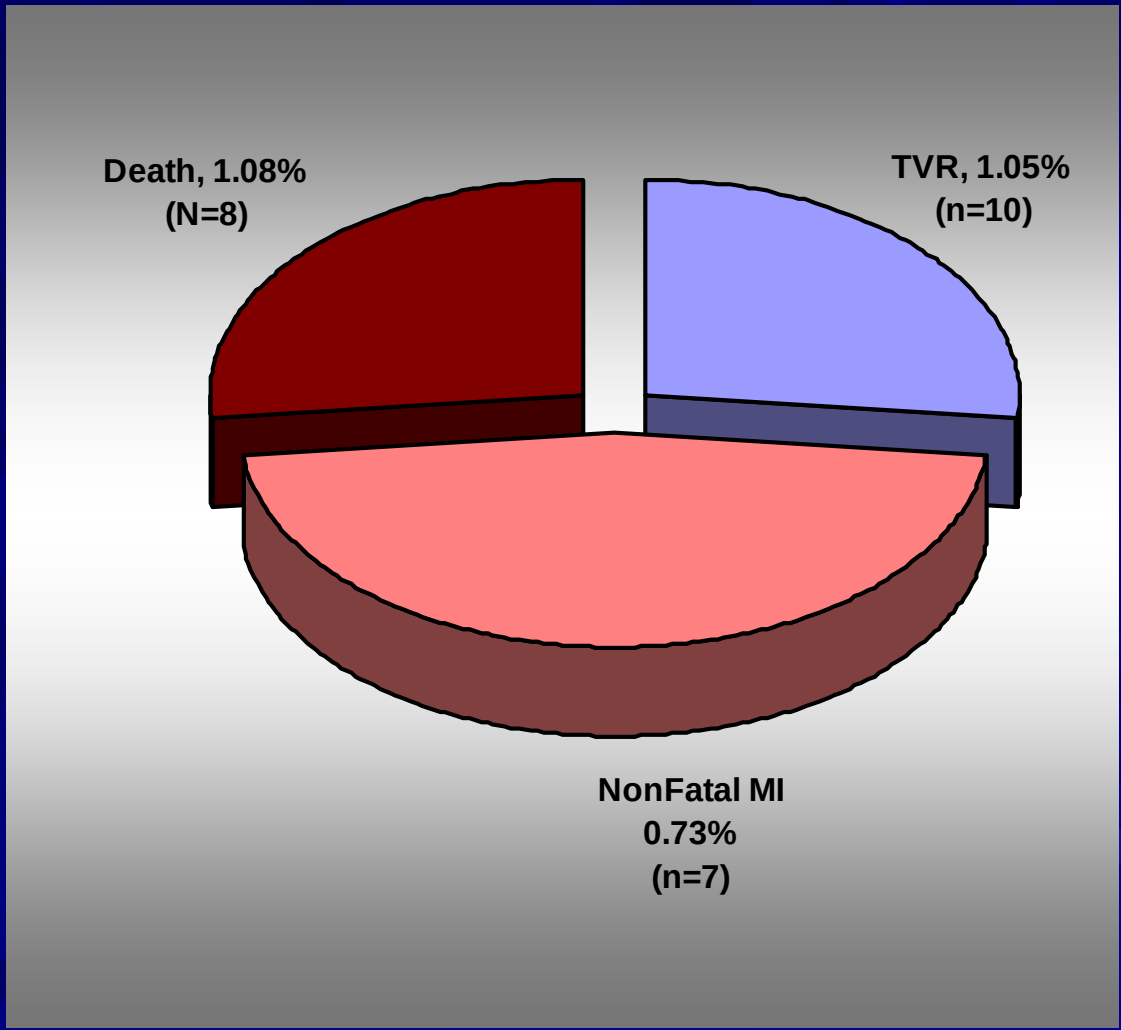


Innova Registry contd.

30 Day MACE



Innova 6 Months MACE



Death- 5 Patients, Lung Cancer- 1 pt, Myasthenia Gravis- 1 pt
MI- 2 pts, Suicide - 1

Innova Registry - Facts

- **The design of the “Innova” trial is much more robust than the “Research” Registry of Cypher - Twice the number of patients with over fifty centers.**
- **The results of the Innova trial are comparable to the Research registry and the mid term and long term results look encouraging.**
- **Pronova SES deployment had a 100% success rate, and the 30 day results are comparable to any other Drug Eluting Stent.**
- **The 6 months clinical follow-up results with Pronova looks promising and comparable with other DES.**

Euro Nova Registry

Single centre 65 patients

A Multicentric European Study on ProNOVA Sirolimus Eluting Stent

65 patients

Prof Thomas Ischinger MD, FESC, FACC
Munich Hospital, Germany

EuroNova…….Angiographic Follow-Up Data

- MLD Pre PCI : 0.78 mm
- MLD Post PCI : 2.67 mm
- MLD at FUP : 2.07 mm
- Early Gain : 1.89 mm
- Late Loss : 0.60 mm

Angiographic In-Segment Restenosis 8%

EuroNova……Conclusion

- Pronova in the Real World Patients enrolled in this trial is Safe, with No Cardiac Death, MI & Stent Thrombosis reported at 30 days & 6 months
- The Stent Design exhibit some unique features like Superior flexibility and Low Profile
- Pronova is highly effective with low clinical & angiographic Restenosis rates
- A comparable Late loss is seen with Pronova in complex & multiple lesions

Thus,

- The average late loss with Pronova SES of 0.50 mm vs. 0.17 mm of Cypher is possibly attributable to the different biostable polymeric system used.

- From the Registries and Clinical trials its evident that Pronova SES is a safe with more late loss perhaps resulting in better long term results

"I know all about safety. That's why I never get hurt."