2019 euro PCR

A multicenter prospective registry of a novel tapered sirolimus-eluting stent for long coronary lesions

Dr. Pierfrancesco Agostoni, MD, PhD

Interventional Cardiologist

HartCentrum, Ziekenhuis Netwerk Antwerpen (ZNA) Middelheim, Belgium

On Behalf of Morpheus-Global Investigators

Disclosure Statement of Financial Interest

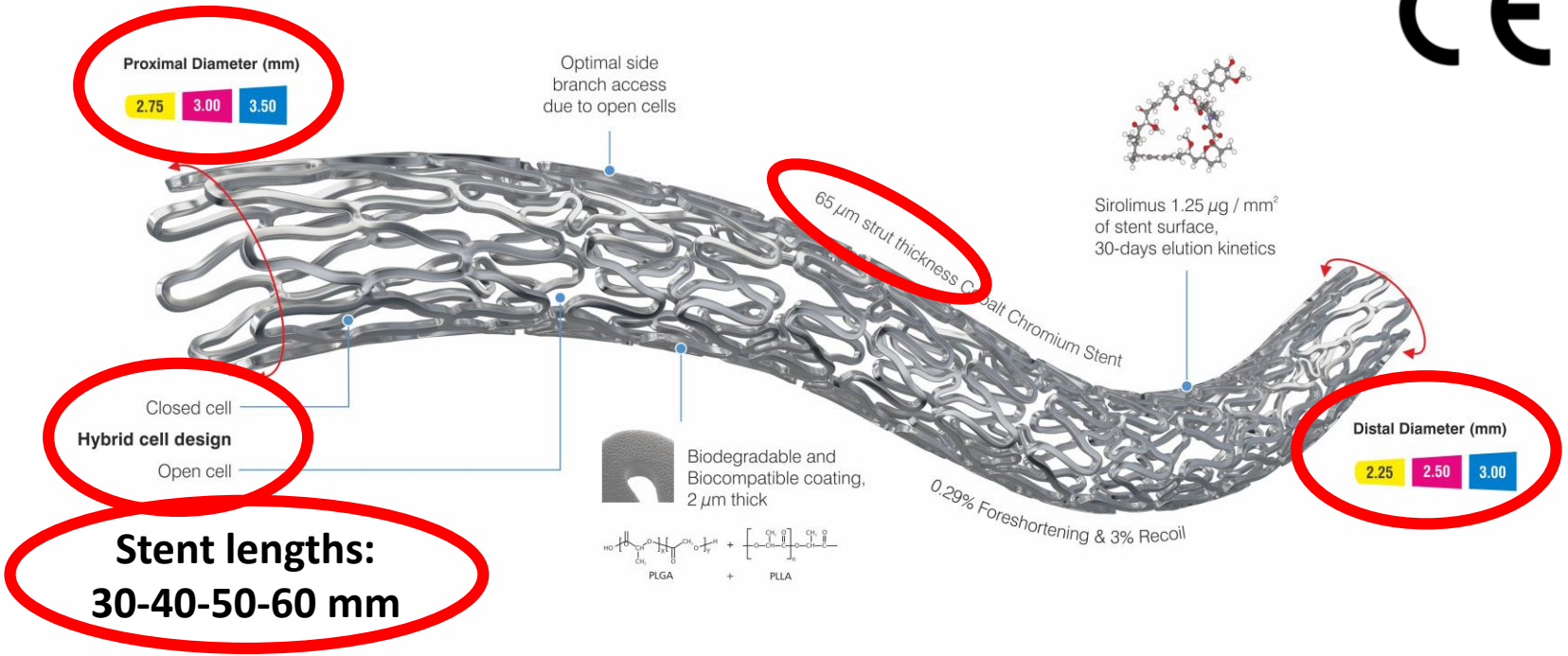
I do have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation, they are:

Affiliation/Financial Interest:	**Name of Organization:**
Grant/ Research support	Meril Life Sciences Pvt. Ltd.

Mimic the Natural Artery Tapering and Avoid Stent Overlap

World's First and only Tapered Coronary Drug-eluting Stent System

CE



Rationale Behind Tapered DES

- Despite the advancement in stent platform, polymer and techniques, treatment of **very long coronary lesions** remains a **challenge** even with DES
- The biomechanical interaction between the stent and the coronary artery is a significant concern due to the **complex geometric feature of the artery**, especially when arterial diameter changes to a significant degree over the length of the stent (**tapering**). This is mainly observed in **long diffused coronary vessels**
- **Multiple short stents with variable diameters** are often implanted (**overlapping**) to match adequately the size of **long tapered lesions**
- The purpose of a **long tapered stent system** is to “fill the gap” in this setting

Morpheus-Global Registry

NCT02901353

Study Objective:

- Purpose of this registry is to evaluate **safety** and **performance** of the **BioMime™ Morph** sirolimus-eluting coronary stent system in very long (**length up to 56mm**) coronary lesions in native coronary arteries with reference vessel diameter of **2.25mm** to **3.50mm**

Primary Outcome Measure:

- **Freedom from target lesion failure (TLF: cardiac death, vessel related-MI, TLR)** at 6 months and up to 24 months

Secondary Outcome Measures:

- **MACE (TLF)** at 1, 6, 12 and 24 months; "*Defined as a composite of **cardiac death**, **myocardial infarction attributed to the target vessel** or **ischemia-driven TLR***"
- **Target vessel failure** at 1, 6, 12 and 24 months; "*Defined as cardiac death, myocardial infarction attributed to the target vessel, or target vessel revascularization*"
- **Academic Research Consortium defined stent thrombosis** at 1, 6, 12 and 24 months; "*Definite, probable and possible stent thrombosis during acute, subacute, late and very late phase*"

Study Design

Prospective, single-arm, multi-centre, observational, real-world registry

Approximately 500 patients to be enrolled from The Netherlands, UK, Italy, Finland, Hungary, Bulgaria, Slovakia, Saudi Arabia, Jordan, South Africa, Indonesia and Malaysia

Baseline assessment, Informed Consent Process and Eligibility Testing

Index Procedure for the target lesion (length ≤ 56mm)

Clinical Follow-up at 1 Month, 6 Months, 12 Months, and 24 Months

- Freedom from target lesion failure (TLF) at 6 months and up to 24 months
- MACE (TLF) and ARC defined stent thrombosis at 1, 6, 12, and 24 months
- Other Outcomes Measured: Device and Procedure Success

Key Eligibility Criteria

Inclusion criteria	Exclusion Criteria
• The patient must be at least 18 years old • Significant native coronary artery stenosis (>50% by visual estimate) with lesion length of ≤56mm • The patient or guardian agrees to the protocol requirements and the schedule of follow-up and provides informed written consent, as approved by the appropriate Institutional Review Board/Ethical Committee of the respective clinical site	• Patients contraindicated to any of the following medications: aspirin, heparin, clopidogrel or other antiplatelet agents, cobalt-chromium, contrast agents and sirolimus • An elective surgical procedure is planned that would necessitate interruption of antiplatelet drugs during the first 6 months post enrolment • Patients who are actively participating in another drug or device investigational study

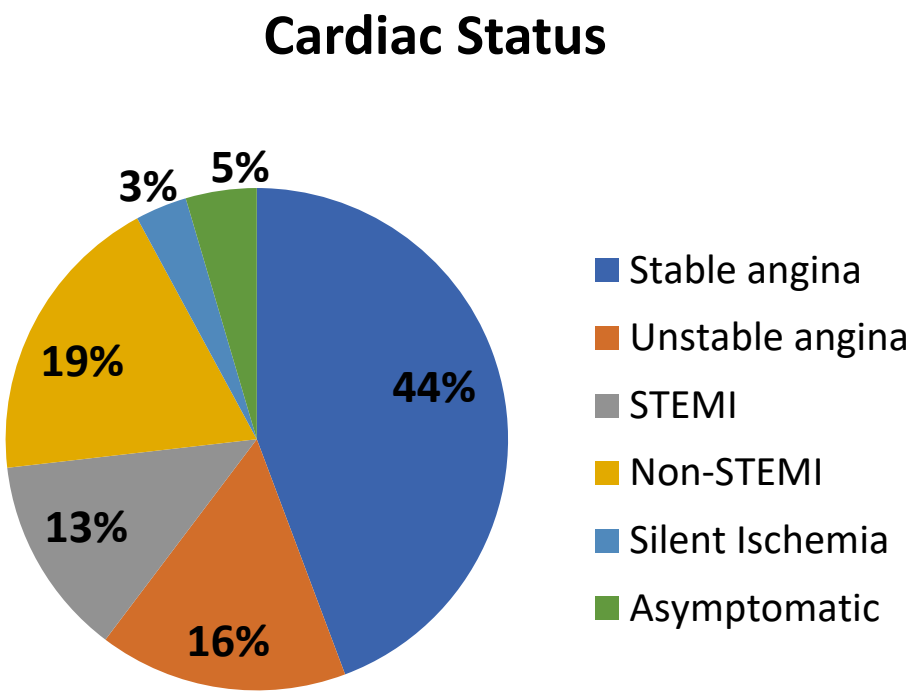
Investigating Sites

Investigating Site	Country	Investigator	# Enrolled
St.Antonius Nieuwegein	The Netherlands	Dr. P. Agostoni	118
VUmc Research BV	The Netherlands	Dr. Paul Knaapen	72
Specialised Hospital of active treatment in cardiology-Yambol	Bulgaria	Dr. Farhat Fouladvand	71
Ospedale Maria Paterrno Arezzo	Italy	Dr. Antonino Nicosia	60
Oulu University Hospital	Finland	Dr. Kari Kervinen	27
Stredoslovenski ristav srdcovfch a ceivnych chorôb, a.s. (SÚSCCH)	Slovakia	Dr. Martin Hudec	21
University Malaya Medical Centre (UMMC)	Malaysia	Dr. Ramesh Singh Arjan Singh	18
Queen Elizabeth Hospital- II (Queen-2)	Malaysia	Dr. Liew Houng Bang	14
University of Semmelweis	Hungary	Prof. Dr. Bela Merkely	13
Panorama MediClinic	South Africa	Dr. Clive Corbett	10
Vincent Pallotti Hospital	South Africa	Dr. Saleem Dawood	10

Investigating Site	Country	Investigator	# Enrolled
UHW, Cardiff Centre, UK	UK	Dr Anirban Choudhury	8
Azienda Ospedaliera Cannizaro	Italy	Dr. Salvatore Tomasello	7
Freeman Hospital, Newcastle	UK	Prof. Azfar Zaman	6
Life Flora Hospital	South Africa	Dr. Anthony Becker	6
King Fehad Military Medical Complex	Saudi Arabia	Dr. Khalid Al Faraidy	6
Derriford Hospital, Plymouth	UK	Dr Girish Vishwanathan	5
University of Debrecen	Hungary	Dr. Szűk Tibor & Dr. Vajda	3
Mediwest Research Center Oy	Finland	Dr. Jussi Sia	2
Linksfield Park Medical Centre	South Africa	Dr. Riaz Garda	2
Netcare Union Hospital	South Africa	Dr. C. Zambakides	1
Gateway Hospital, Umhlanga, KZN	South Africa	Dr. Daivd Gillmer	1
Jordan Hospital	Jordan	Dr. Imad Al Haddad	1

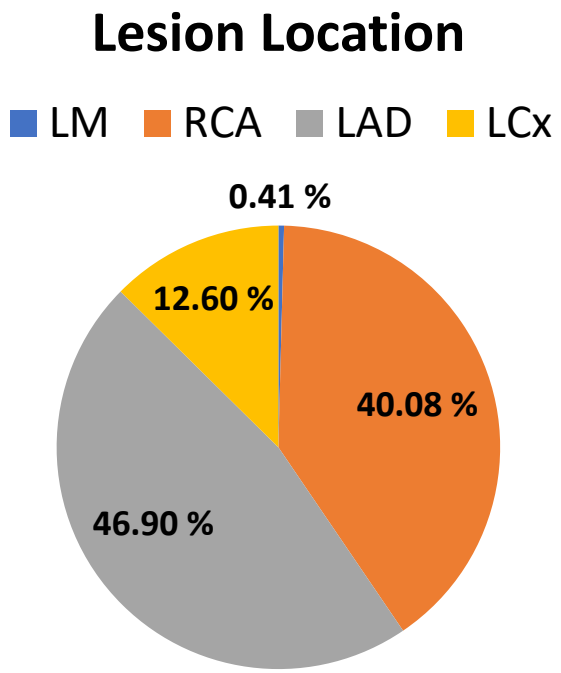
Baseline Demographics

Characteristics	n = 482
Age, Years, (Mean±SD)	65.35± 10.49
Male, n(%)	365 (75.73)
Diabetes mellitus, n (%)	**153 (31.74)**
Current smokers, n (%)	**109 (22.61)**
Hypertension,n (%)	**339 (70.33)**
Hyperlipidaemia, n (%)	**322 (66.80)**
Renal insufficiency, n (%)	34 (7.05)



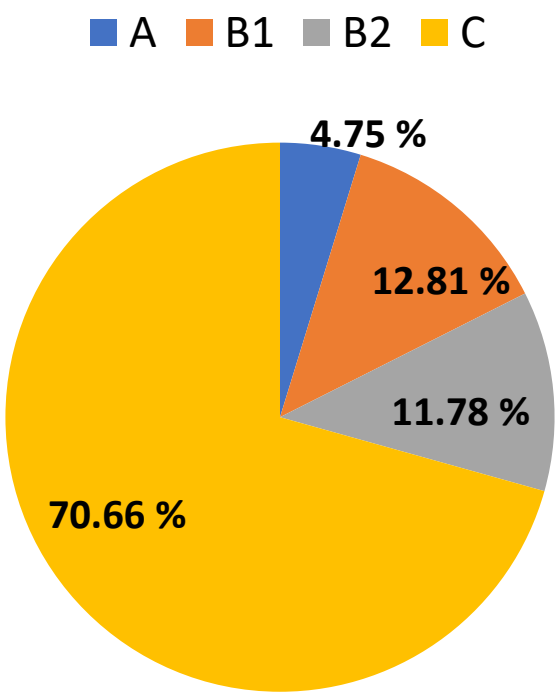
Lesion Characteristics

Lesion characteristics	n=484
Total no. of lesion treated with study device, n	484
Total occlusion, n (%)	198 (40.91)
Stenosis, n (%)	
De novo	458 (94.63)
In-stent	19 (3.93)
Lesion Type, n (%)	
Severely calcified	116 (23.97)
CTO	**169 (34.92)**
Diffuse	152 (31.40)
Long (≥ 46mm)	**330 (68.18)**
Thrombus	41 (8.47)
Other (Critical, Discrete, Tandem)	17 (3.51)

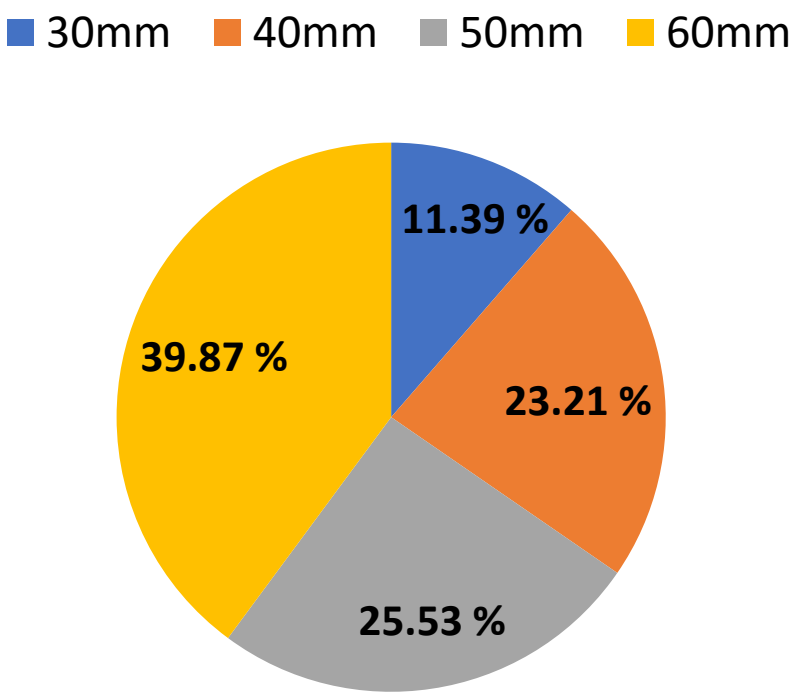


Lesion and Stent Characteristics

AHA/ACC Lesion Classification



Stent Length (mm)



Clinical Outcomes

Events n (%)	In-hospital (n = 482)	1-month FU (n = 470)*	6-month FU (n = 350)*
All cause death	0 (0.0)	3 (0.64)	7 (2.00)
Cardiac death	0 (0.0)	2 (0.43)	4 (1.14)
Non-cardiac death	0 (0.0)	1 (0.21)	3 (0.86)
MI	1 (0.21)	2 (0.43)	3 (0.86)
Q-Wave	0 (0.0)	1 (0.21)	1 (0.29)
Non Q-Wave	1 (0.21)	1 (0.21)	2(0.57)
ID-TLR	0 (0.0)	2 (0.43)	7 (2.00)
Definite ST	0 (0.0)	2 (0.43)	2 (0.57)
MACE	1 (0.21)	6 (1.28)	14 (4.00)
Freedom from TLF	481 (99.79)	464 (98.72)	336 (96.00)

* Follow-up ongoing

Device Success	98.34% (474 out of 482 subjects)
Procedure Success	98.96% (477 out of 482 subjects)

Conclusions

- This study shows that BioMime Morph seems **safe and effective** in **very long** (length up to 56 mm) **coronary lesions** in native coronary arteries with reference vessel diameter 2.25 mm to 3.50 mm
- A **single long tapered BioMime Morph** system is often enough for treating **long diffused lesions in tapered arteries**, and therefore the arterial wall can be saved from over-exposure to drug/metal (due to overlap) and its related adverse events such as delayed healing, peri-procedural myocardial infarction, risk of target lesion revascularization and very late stent thrombosis, due to the use of multiple stents
- The cumulative **MACE** rate was **1.28%** at **1-month** follow-up and **4%** at **6-month** follow-up
- The **freedom from TLF** was reported in **98.72%** and **96%** of patients at **1-month** and **6-month follow-up**, respectively
- Long-tapered DES can be considered as an **extremely interesting alternative** for **long diffused de novo coronary lesions with tapered anatomy** in routine clinical practice, provided these preliminary data are confirmed at completion of the study

2019 euro PCR

THANK YOU

BACK UP SLIDES

Study Status

Site reported reasons for device failure in 8 patients:
1. Balloon of the stent rupture at 10 ATM during deployment, with incomplete stent expansion requiring post dilatation (balloon 3.0 x 12 NC). Good final result.
2. No BioMime Morph stent placed. Long stent could not cross the lesion to distal RCA
3. Calcified vessel, BioMime Morph couldn't pass lesion
4. Due to calcification not possible to place BioMime Morph stent
5. Unable to pass lesion with stent, when retrieving in guide-wire stent gets stuck, one strut was bend, other stent was placed instead
6. Primary attempt with BioMime Morph stent but stent does not pass in mid-segment and when retrieving the stent also strut visible proximally. Stent not placed.
7. Stent was placed subintimal
8. The study device did not cross the lesion; another type of DES was use to achieve procedure success

Site reported reasons for procedure failure in 5 patients:
1. No BioMime Morph stent placed. Long stent could not cross the lesion to distal RCA
2. Due to calcification, not possible to place BioMime Morph stent
3. Unable to pass lesion with stent, when retrieving in guide-wire stent gets stuck, one strut was bend
4. Primary attempt with BioMime Morph stent but stent does not pass in mid-segment and when retrieving the stent also strut visible proximally. Stent not placed.
5. Stent was placed subintimal