2019 euro PCR

A serial optical frequency domain imaging study of early and late vascular responses of sirolimus-eluting stent with bioresorbable polymer for treatment of STEMI and stable angina pectoris patients

- *Final results of* ***MECHANISM-ULTIMASTER***

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Potential conflicts of interest

Speaker's name : Yoshihiro Morino

☑ I have the following potential conflicts of interest to declare:

Participation in a company sponsored speaker's bur: Terumo corporation

Receipt of grants / research supports: Terumo corporation

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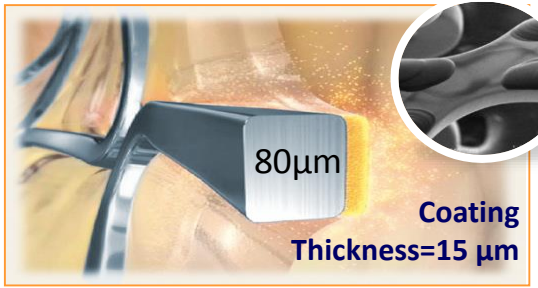
Backgrounds and Aim

- The **Ultimaster**® stent is a new **reduced-dose sirolimus**-eluting stent (SES) that uses an **abluminal bioresorbable coating** on a thin-strut (bioresorbable polymer; BP- SES).



- Although bioresorbable polymer technology may **theoretically promise improved healing of treated segments**, clinical trials to characterize their effects on the vessel remain limited.

- The time course of early and convalescent vascular healing has not been fully elucidated in ST-elevation myocardial infarction (STEMI) or stable coronary artery disease (CAD).

- *Accordingly, the aim of this study was **to assess early and late vascular healing in response** to BP-SES in the treatment of patients with STEMI and stable CAD using optical frequency domain imaging (OFDI).*

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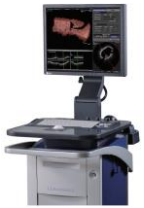
Study outline, Methods, and Analyzable cases



OFDI

MECHANISM-UM
STEMI
n=106

Withdraw consent: N=3

MECHANISM-UM
Stable CAD
n=101

	Baseline OFDI	1M OFDI FU	3M OFDI FU	12M OFDI FU
STEMI	**N=50** Index PCI OFDI	**n=48** OFDI analyzable		**n=39** OFDI analyzable
STEMI	**N=53** Index PCI OFDI		**n=51** OFDI analyzable	**n=45** OFDI analyzable
Stable CAD	**N=50** Index PCI OFDI	**n=47** OFDI analyzable		**n=42** OFDI analyzable
Stable CAD	**N=51** Index PCI OFDI		**n=49** OFDI analyzable	**n=45** OFDI analyzable

Japanese 21 enrolling sites

Standard qualitative and quantitative OFDI parameters *(by independent core labo) were compared.*

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Baseline characteristics

	STEMI (n=103)	Stable CAD (n=101)	P value
Patient characteristics			
Age, yo	66.2 ± 10.8	68.0 ± 9.6	0.19
Gender, Male, n (%)	84 (81.6)	73 (72.3)	0.12
Diabetes mellitus, n (%)	51 (49.5)	47 (46.5)	0.67
Dyslipidemia, n (%)	80 (77.7)	81 (78.6)	0.66
Hypertension, n (%)	71 (68.9)	81 (78.6)	0.065
Smoking, n (%)	64 (62.1)	46 (45.5)	0.017
30 ≤ eGFR < 60, eGFR <30, n (%)	24/1 (23.3/0.97)	31/1 (31.3/1.0)	0.49
Peak CK value, IU/L	180 (36-3520)	91 (22 – 304)	< 0.001
Lesion and procedural characteristics			
LAD, LCX, RCA, n (%)	28 (27.2) /17(16.5) /58 (56.3)	73 (36.6)/ 22 (21.8) /42 (41.6)	0.11
Used stent number, n	1.21 ± 0.41	1.20 ± 0.45	0.83
Used stent diameter, mm	3.23 ± 0.69	3.02 ± 0.65	0.021
Total stent length, mm	29.6 ± 13.2	30.1 ± 14.3	0.83
Final minimal lumen diameter, mm	2.57 ± 0.45	2.58 ± 0.44	0.73
Final % diameter stenosis, %	13.69 ± 7.82	11.13 ± 10.13	0.051

Results 1: Clinical Outcomes at 12 Months

Incidence of all cause death and cardiac event at 12 Months

	STEMI (n=103)	Stable CAD (n=101)	HR	P value
All cause death	2 (1.9)	1 (1.0)	1.19 (0.90-1.57)	0.22
DOCE	7 (6.8)	2 (2.0)	1.25 (0.94-1.66)	0.12
Cardiac death	2 (1.9)	0 (0)	1.20 (0.91-1.59)	0.19
Target-vessel MI	4 (3.9)	0 (0)	1.04 (0.79-1.37)	0.79
Clinically-driven TLR	5 (4.9)	2 (2.0)	1.22 (0.92-1.62)	0.16
Stent thrombosis	1 (1.0)	0 (0)	1.05 (0.79-1.38)	0.76

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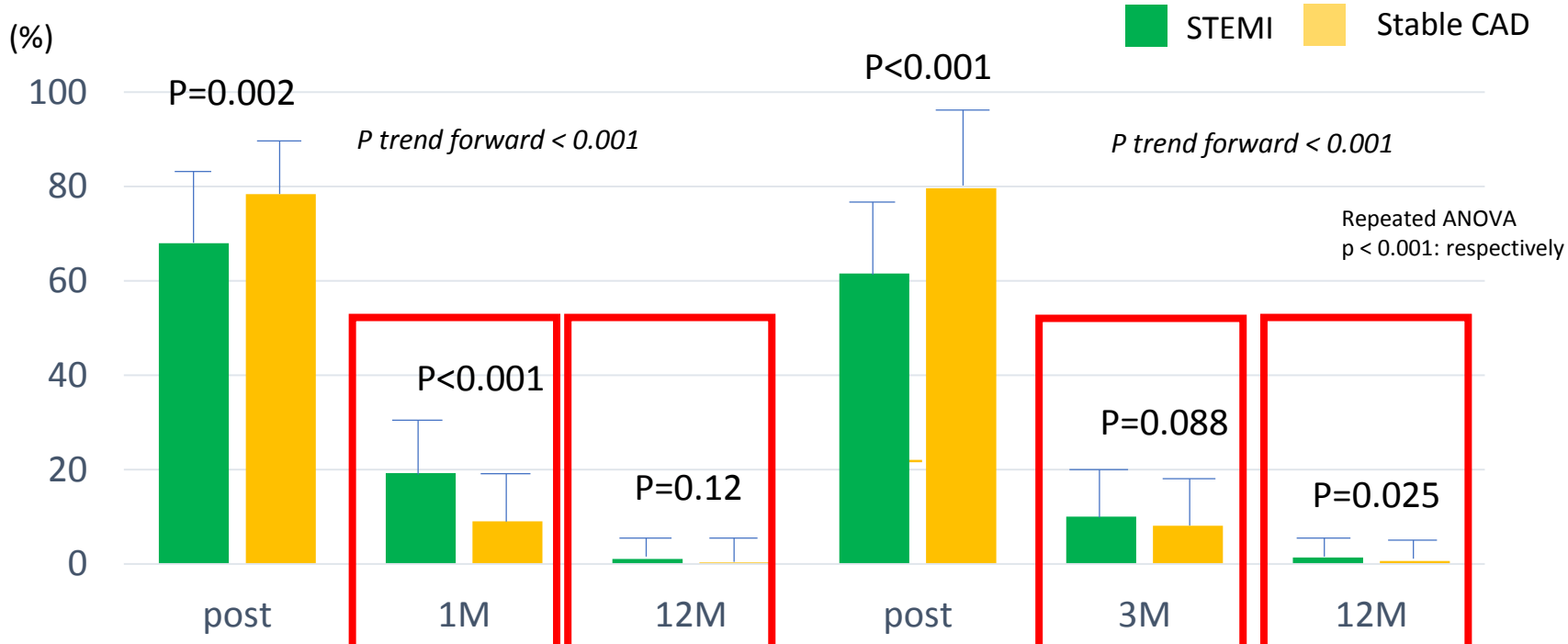
Result 2: %uncovered strut by OFDI (primary endpoint)



STEMI (%)	68.01 ± 17.88	19.27 ± 11.73	1.11 ± 1.73	61.55 ± 18.69	10.07 ± 7.23	1.40 ± 2.12
Stable CAD (%)	78.39 ± 18.61	9.04 ± 8.17	0.66 ± 1.16	79.62 ± 14.14	8.11 ± 7.66	0.66 ± 1.16

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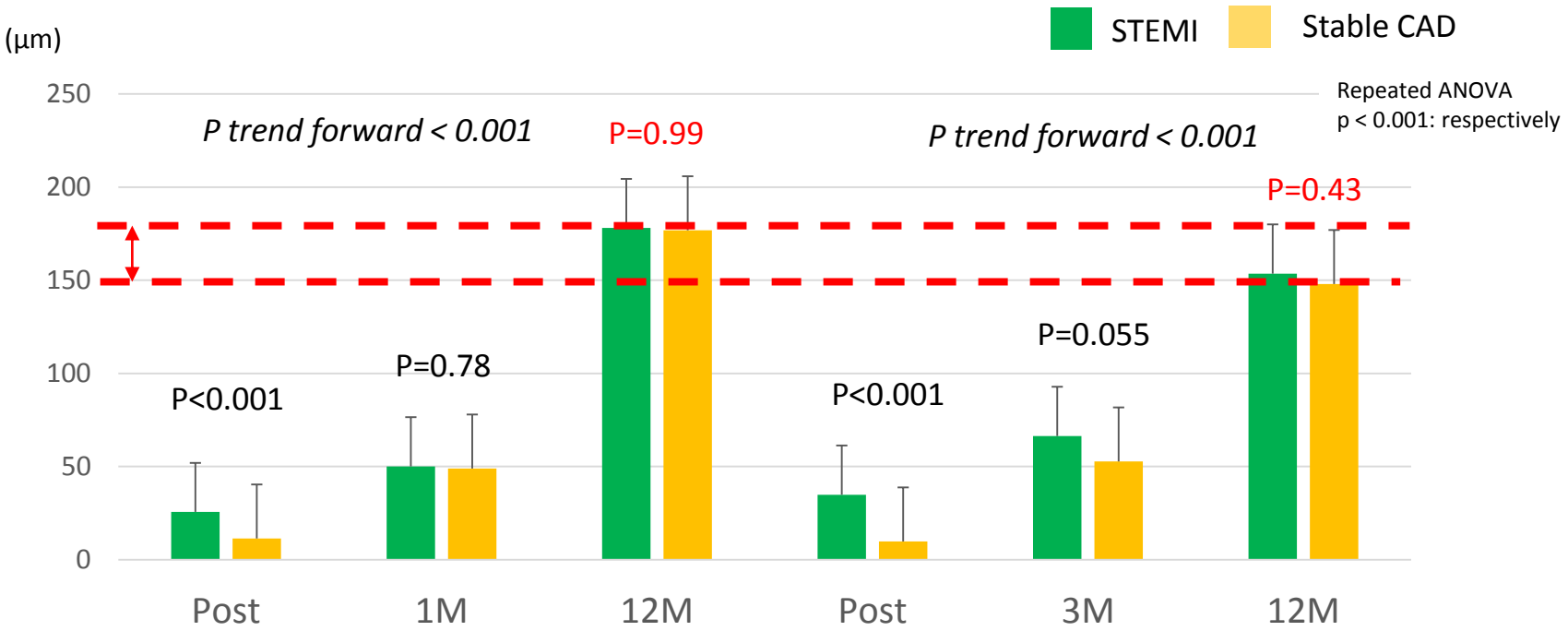
Result3 : Average In-stent Tissue Thickness by OFDI

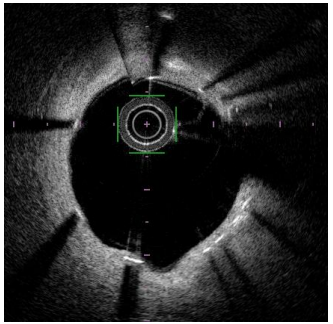


STEMI(um)	25.58 ± 24.28	50.01 ± 22.16	178.01 ± 79.26	34.87 ± 30.74	66.34 ± 31.71	153.60 ± 56.73
Stable CAD(um)	11.44 ± 16.24	48.95 ± 176.89	176.89 ± 74.35	9.80 ± 10.17	52.71 ± 18.34	147.95 ± 63.14

Result 4: Serial Changes of Peri-strut low-intensity area (PLIA) score

: Surrogate marker of immature neointima or peri-strut inflammation

*Grade **0*** – no PLIA



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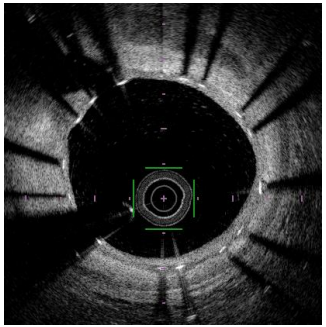
*Grade **1*** – only around the struts



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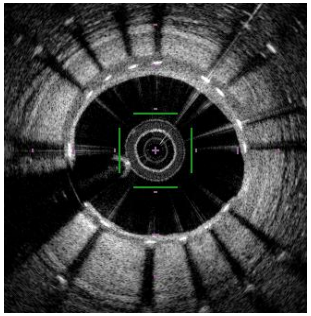
*Grade **2*** – in part of the neointima



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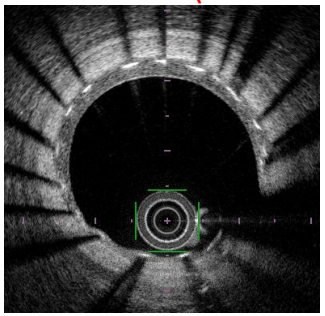
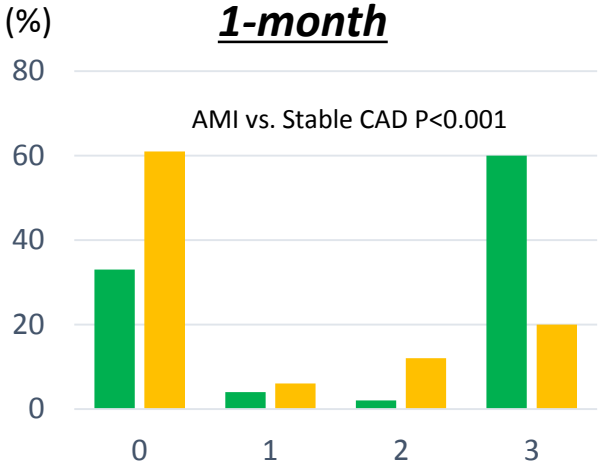
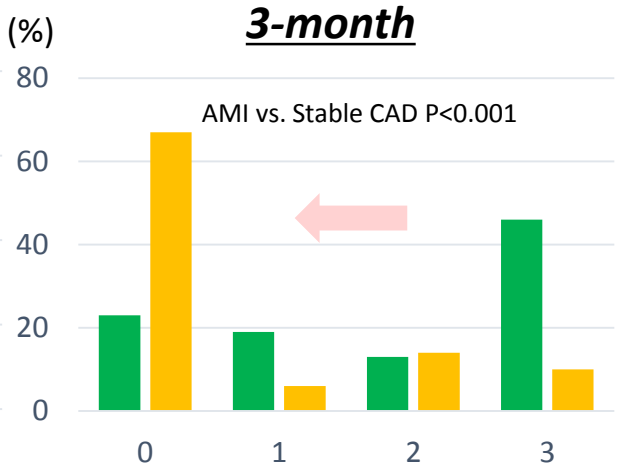
*Grade **3*** in the entire neointima (most **immature**)

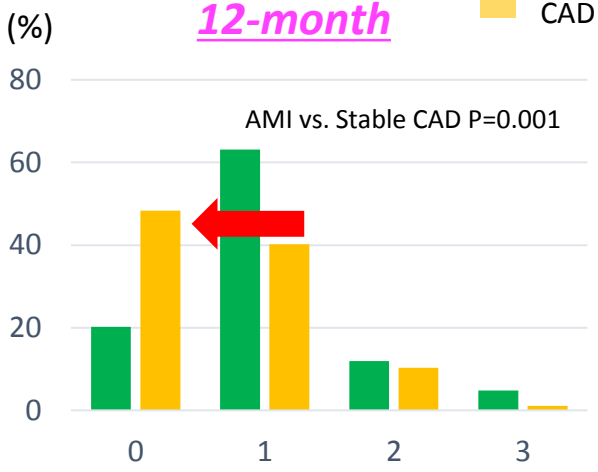


STEMI

Stable CAD







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Summary of Novel Findings and Conclusions

- *Although the strut-coverage in the early-phase after BP-SES implantation were slightly delayed in STEMI patients compared to stable-CAD patients, those differences diminished over time, almost disappearing by 12 months.*

- *The average neointimal thickness of the two cohorts were comparable at 12 months.*

- *Elevated PLIA scores, considered a sign of immature neointima or peri-strut inflammation, were observed in the early phases but significantly improved in both cohorts within 12 months.*

- ***In conclusion, owing to the combination of these multifactorial improvements, qualitatively and quantitatively consistent neointimal stent coverage was achieved by the 12-month timepoint in both pathogenetic groups following BP-SES implantation, suggesting long-term lesion stability of this bioresorbable polymer technology.***