Early Vascular Healing of ORSIRO-SES vs RESOLUTE-ZES

HATTRICK-OCT trial

Tuomas Kiviniemi, MD, PhD

Turku University Hospital

Finland

Potential conflicts of interest

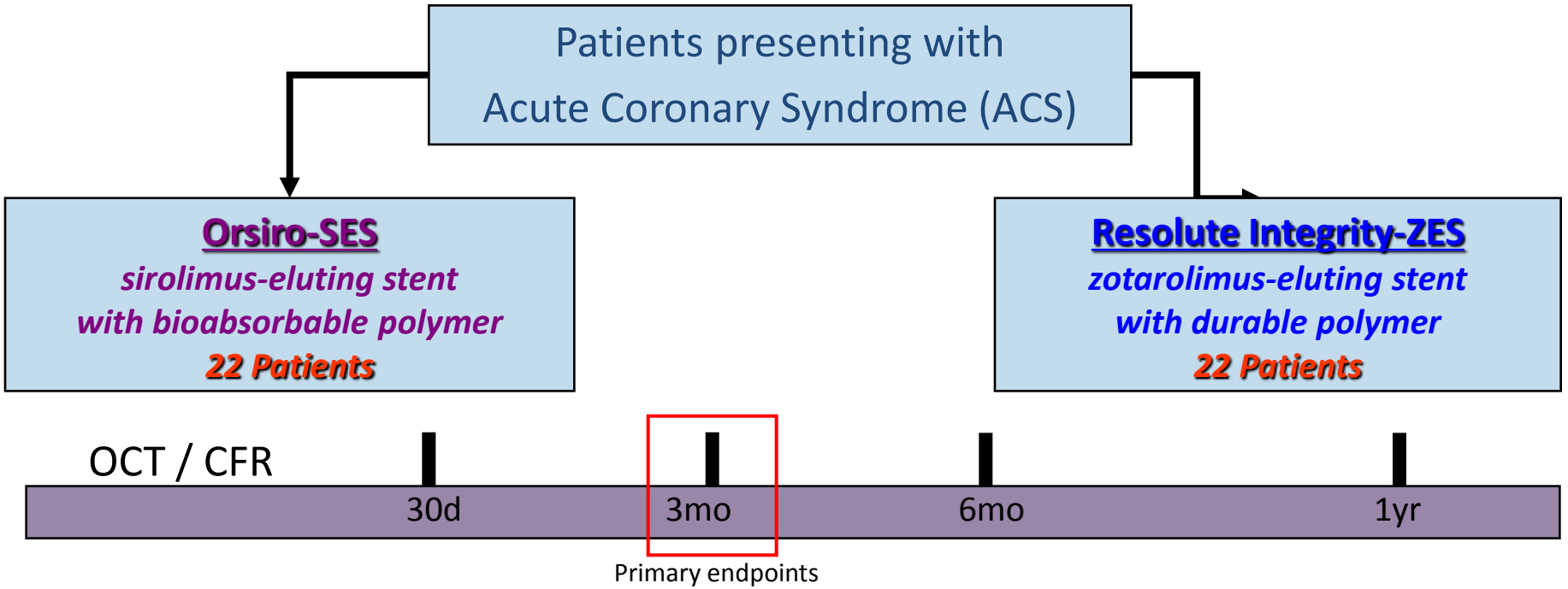
Speaker's name: Tuomas Kiviniemi

☐ **I have the following** potential conflicts of interest to report:

- ☐ Research contracts
- ☐ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

☒ **I do not have any potential conflict of interest**

HATTRICK-OCT



Primary Endpoint: Stent strut coverage at 3 months

Secondary Endpoint: Coronary flow reserve at 3 months

Investigators:

P Karjalainen, Principal Investigator (PI)
Heart center, Satakunta Central Hospital, Finland

T Kiviniemi, Co-Principal Investigator (PI)
Heart center, Turku University Hospital, Finland

A Ylitalo, M Pietilä, J Mikkelsson, V Varho, J Sia, K Nyman, KEJ Airaksinen

Background

- Delayed vascular healing of 1st generation DES may predispose patients to stent thrombosis
  - inadequate endothelialisation of stent struts
  - local coronary vasodilator dysfunction
- Drug, polymer and stent platform may affect the speed of healing process

- **What is the early healing pattern of 2nd and 3rd generation DES?**

Aims

To compare at 3 months follow-up

hybrid sirolimus-eluting stent with bioabsorbable polymer (Orsiro®)

vs.

zotarolimus-eluting stents with durable hydrophilic polymer (Resolute Integrity®)

- Tissue coverage and apposition by optical coherence tomography (OCT)
- Vasodilator response by invasive coronary flow reserve (CFR) assessment
- Prospective, randomized, multicenter trial

(ClinicalTrials.gov Identifier: NCT01391871)

Methods - OCT Analysis

NIH

Strut Level Analysis:

Cross-sectional OCT images were analyzed at 1-mm interval (every 5 frames)

-Neointimal hyperplasia (NIH) thickness, µm

- Distance between the vessel wall to the endo-luminal surface of the strut
- NIH thickness inside every strut was measured

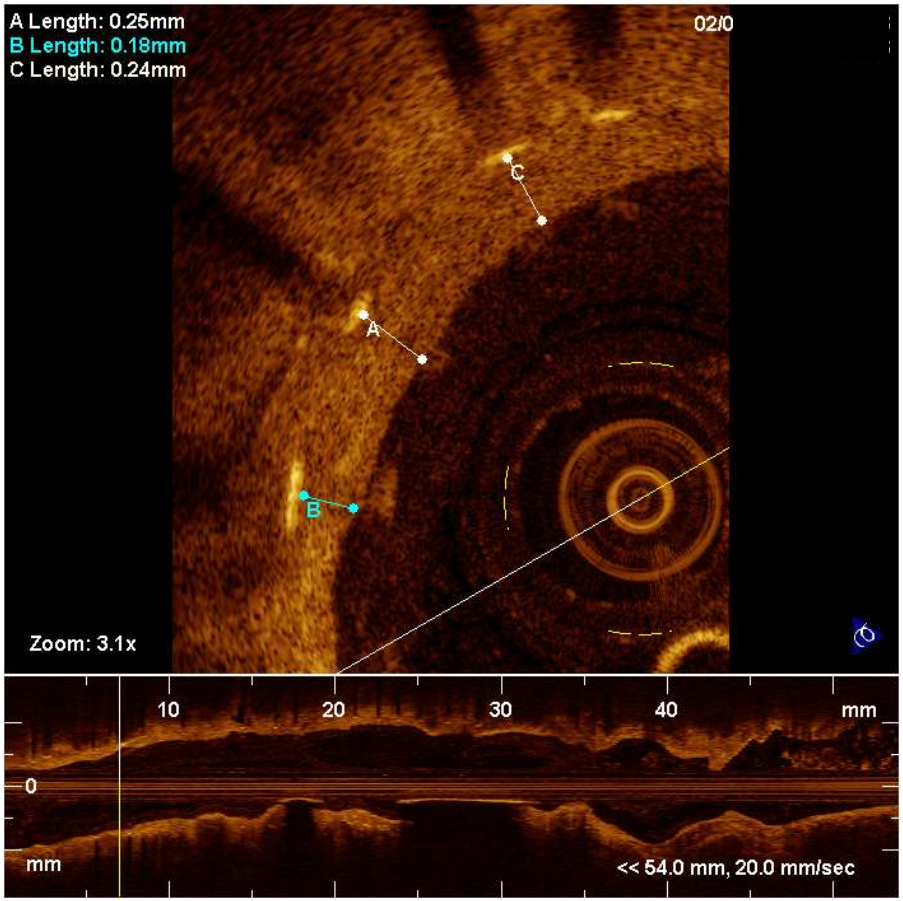
-NIH Area

- % NIH area

$$\frac{\text{-Stent area (SA) - Lumen area (LA)}}{\text{Stent area (LA)}}$$

- NIH area (mm^2)

SA – LA (mm^2)

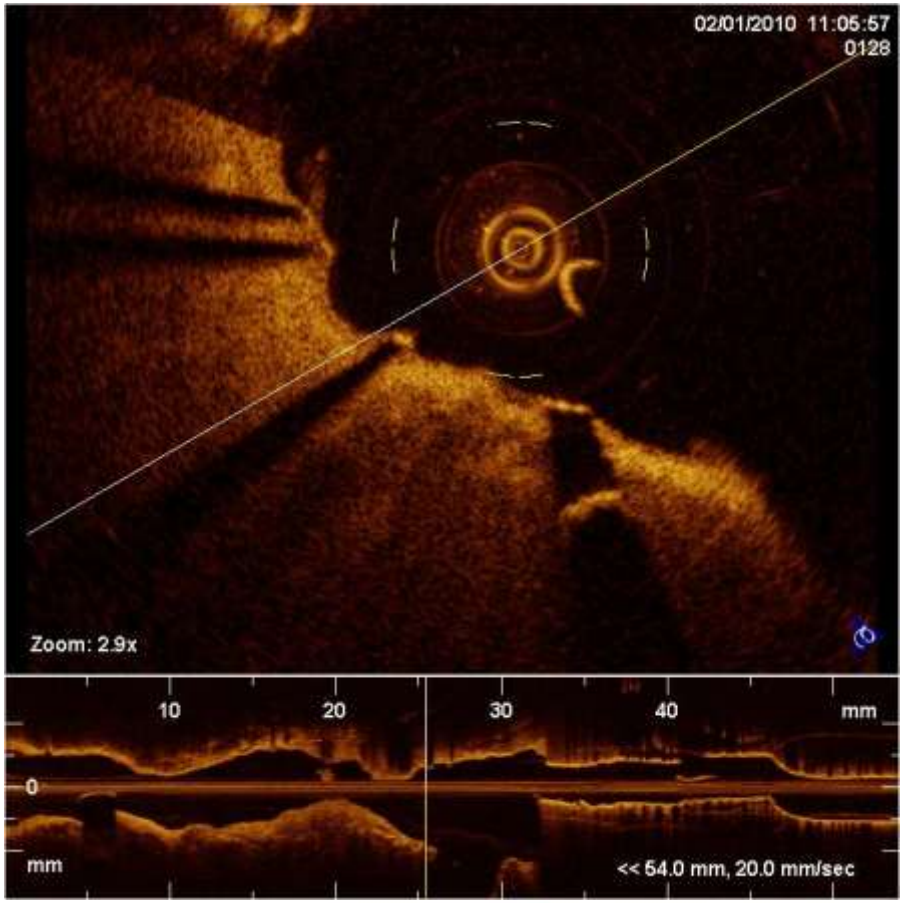


Methods - OCT Analysis

Strut coverage

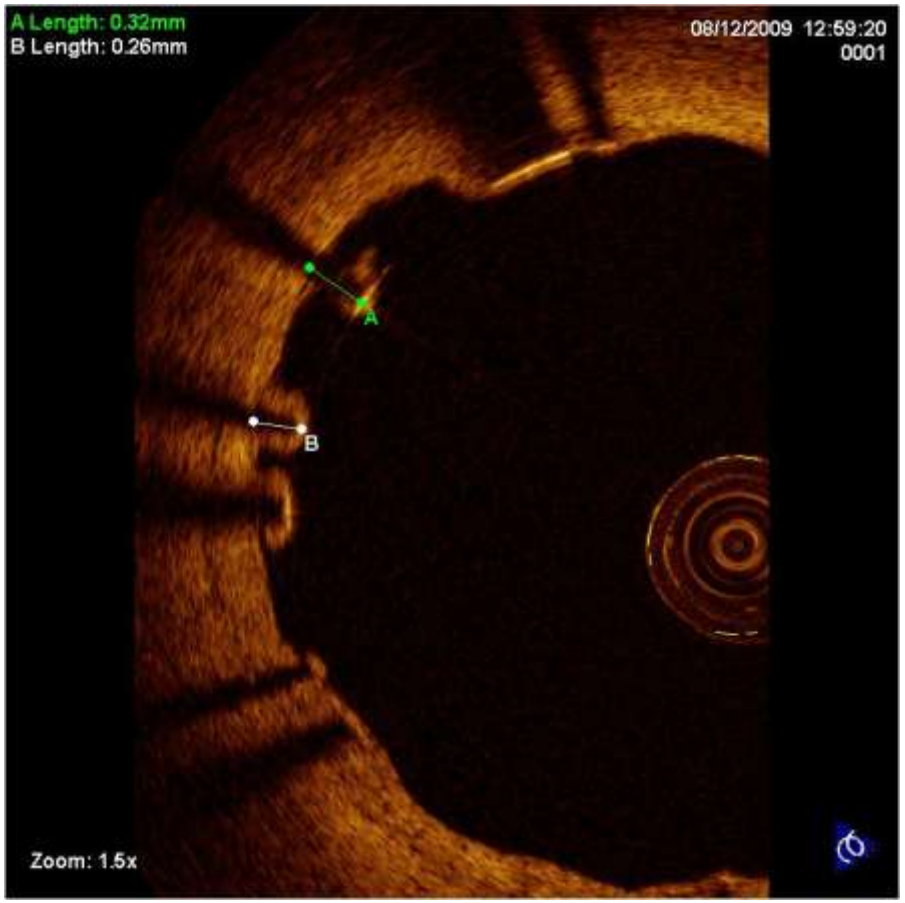
Binary Strut Coverage (%)

$$\frac{\text{Number of strut sections covered}}{\text{Total number of strut sections examined}} \times 100$$



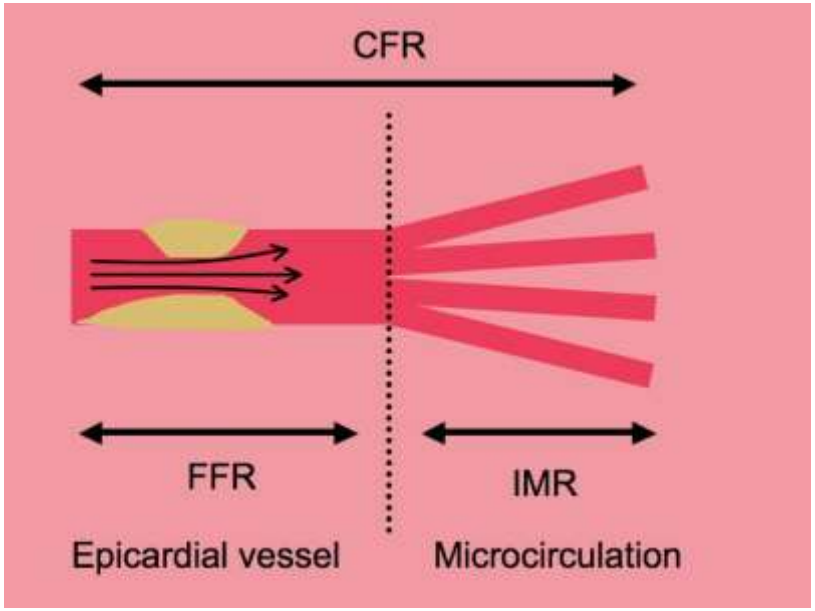
Methods - OCT Analysis
Malapposition

- Strut detachment from the vessel wall



Methods

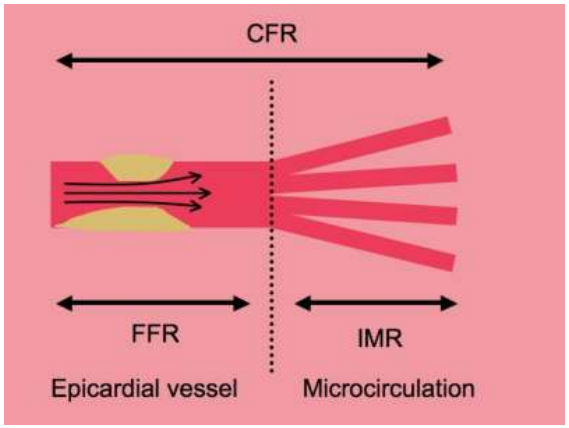
Invasive CFR, FFR and IMR



- Coronary flow reserve CFR
- Fractional flow reserve FFR
- Index of microcirculatory resistance

Methods

Invasive CFR, FFR and IMR



- Thermodilution-derived CFR
- I.v. adenosine infusion

Results - Baseline characteristics

	SES-BP (Orsiro) 22 pts	*ZES-DP (Resolute Integrity) 22 pts*	*P*
Age (mean ± SD)	62.5 ± 9.7	61.8 ± 12.1	0.83
Male	18 (82%)	17 (74%)	0.72
Diabetes	0	0	1.00
Indication			
STEMI	12 (54.5%)	11 (50.0%)	0.77
NSTEMI	9 (40.9%)	8 (36.4%)	1.00
Unstable AP	1 (4.5%)	3 (13.6%)	0.35
Pre TIMI	1.7 ± 1.4	1.9 ± 1.2	0.58
Post TIMI	3.0	2.9 ± 0.3	0.16
Stent length	18.0 ± 3.4	17.5 ± 3.2	0.65
Stent diameter	3.2 ± 0.3	3.2 ± 0.3	0.71

Results - OCT measurements

	SES-BP (Orsiro) n=22	ZES-DP (Resolute Integrity) N=22	p
Patient-level analysis			
Frames analysed	425	425	1.0
Struts per frame	11.5 ± 0.7	12.9 ± 1.2	<0.001
Mean lumen area (mm^2)	6.4 ± 1.4	7.3 ± 1.7	0.06
Mean stent area (mm^2)	6.7 ± 1.6	7.5 ± 1.5	0.09
Mean NIH area (μm^2)	464 ± 252	540 ± 322	0.39
Mean NIH percentage (%)	6.8 ± 2.8	7.4 ± 4.5	0.61
Strut-level analysis			
Struts analysed	4897	5467	0.12
Mean NIH (µm)	69.1 ± 58.2	76.5 ± 82.9	0.15
Uncovered struts	189 (3.9%)	495 (8.9%)	<0.001
Malapposed struts	126 (2.6%)	292 (5.3%)	<0.001
Stent-level analysis			
Uncovered struts (%)	3.9 ± 3.2	8.9 ± 6.9	0.019
Uncovered struts >5%/stent	7 (31.8%)	14 (63.6%)	0.069
Malapposed struts (%)	2.7 ± 3.8	4.3 ± 9.5	0.605

Results - OCT measurements

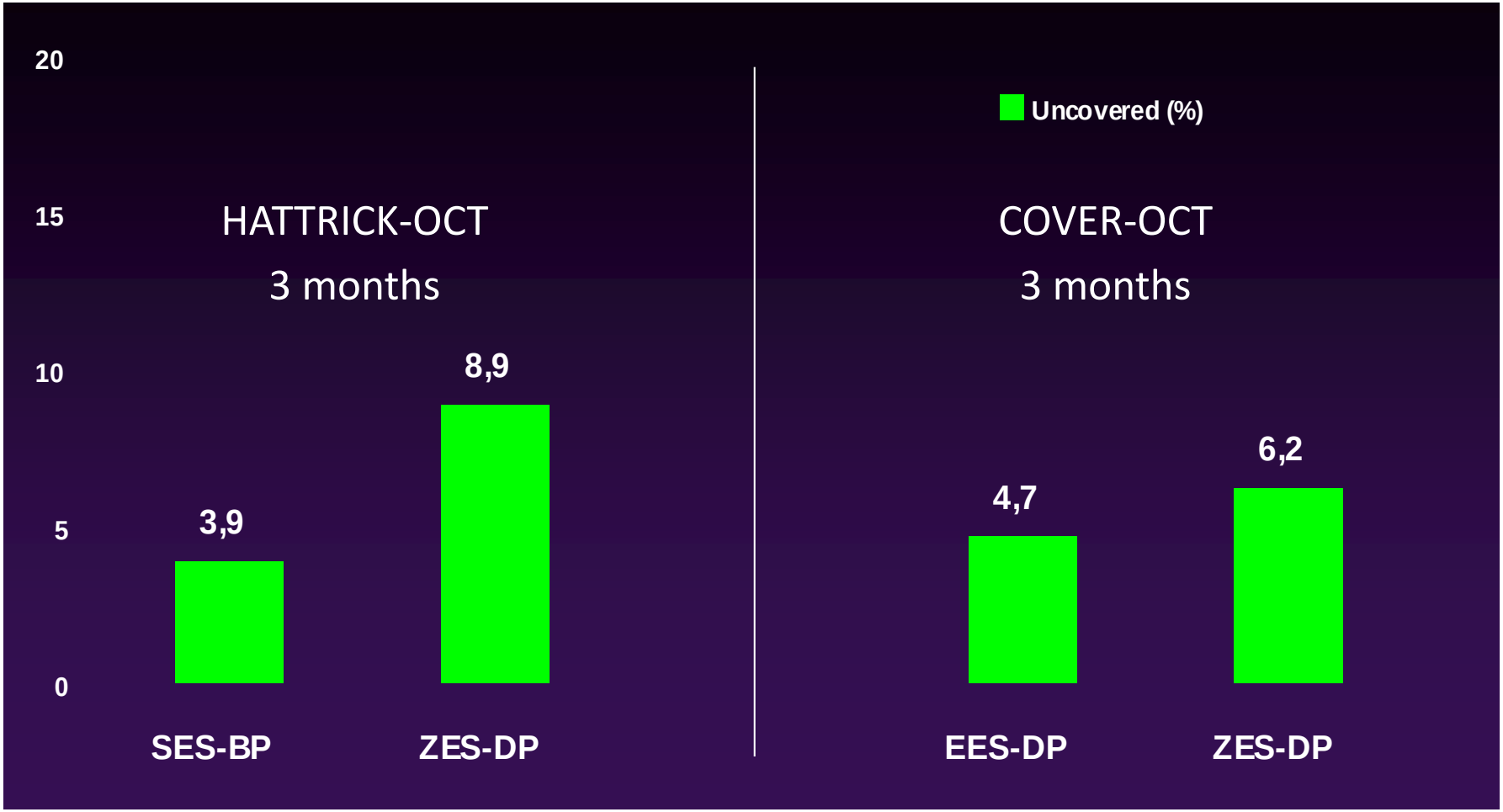
	SES-BP (Orsiro) n=22	ZES-DP (Resolute Integrity) N=22	p
Patient-level analysis			
Frames analysed	425	425	1.0
Struts per frame	11.5 ± 0.7	12.9 ± 1.2	<0.001
Mean lumen area (mm^2)	6.4 ± 1.4	7.3 ± 1.7	0.06
Mean stent area (mm^2)	6.7 ± 1.6	7.5 ± 1.5	0.09
Mean NIH area (μm^2)	464 ± 252	540 ± 322	0.39
Mean NIH percentage (%)	6.8 ± 2.8	7.4 ± 4.5	0.61
Strut-level analysis			
Struts analysed	4897	5467	0.12
Mean NIH (µm)	69.1 ± 58.2	76.5 ± 82.9	0.15
Uncovered struts	189 (3.9%)	495 (8.9%)	<0.001
Malapposed struts	126 (2.6%)	292 (5.3%)	<0.001
Stent-level analysis			
Uncovered struts (%)	3.9 ± 3.2	8.9 ± 6.9	0.019
Uncovered struts >5%/stent	7 (31.8%)	14 (63.6%)	0.069
Malapposed struts (%)	2.7 ± 3.8	4.3 ± 9.5	0.605

Results - Functional assessment

	SES-BP (Orsiro) (n=18)	ZES-DP (Resolute Integrity) (n=16)	p
Echocardiography			
LVEF (%)	66.0 ± 8.2	62.0 ± 12.2	0.27
Culprit vessel wall hypokinesis/akinesis	3 (13 %)	4 (18 %)	0.81
Invasive hemodynamics			
FFR	0.87 ± 0.07	0.87 ± 0.06	0.93
CFR *	3.0 ± 1.3	3.2 ± 1.0	0.56
IMR	19.2 ± 8.1	22.7 ± 13.0	0.32

* Patients with FFR<0.80 excluded.

HATTRICK and previous studies



Conclusions

- Sirolimus-eluting stents with bioabsorbable polymer were more completely covered compared to zotarolimus-eluting stents with durable polymer at 3 months after PCI for ACS
- No significant difference in the vasodilator response was seen
- Further large scale clinical studies addressing shorter dual antiplatelet drug therapy with these newer generation DES are needed