Mechanisms of Very Late Bioresorbable Scaffold Thrombosis

The INVEST Registry

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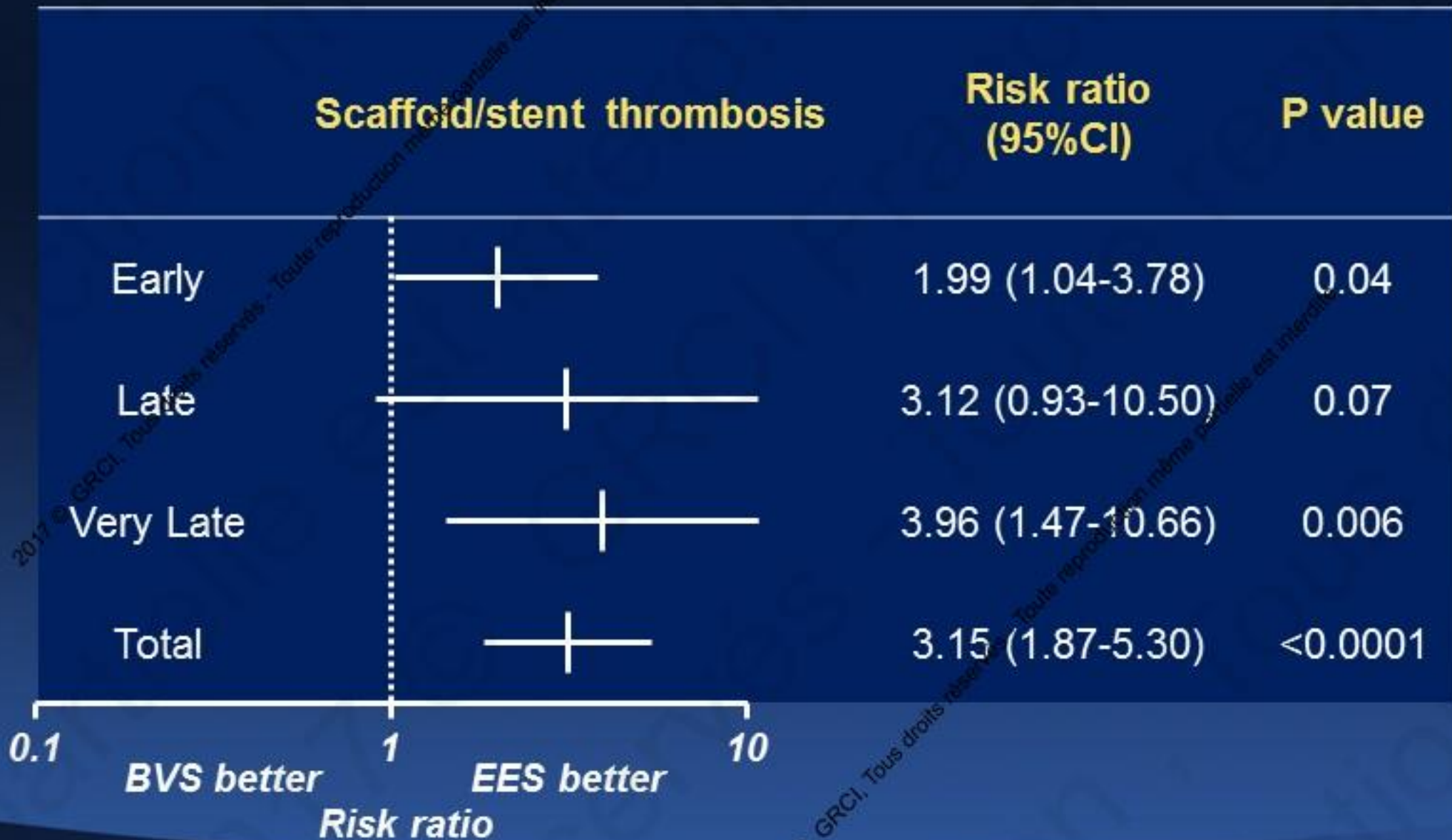
DÉCLARATION DE LIENS D'INTÉRÊT AVEC LA PRÉSENTATION

Intervenant : Nicolas Amabile, Paris

Je déclare les liens d'intérêt suivants : Abbott

Meta-analysis at 2 years

Scaffold/stent thrombosis			Risk ratio (95%CI)	P value
Early			1.99 (1.04-3.78)	0.04
Late			3.12 (0.93-10.50)	0.07
Very Late			3.96 (1.47-10.66)	0.006
Total			3.15 (1.87-5.30)	<0.0001

0.1   1   10

BVS better   **EES better**

Risk ratio

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Very late (>1 year) definite or probable stent/scaffold thrombosis in 7 RCTs

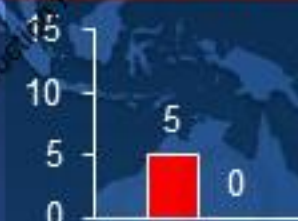■ *ABSORB BVS (N=27)* ■ *EES (N=3)*
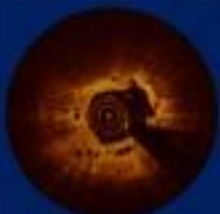
ABSORB II: Lancet 2016, ABSORB III: ACC 2017, ABSORB Japan: EuroPCR 2017, ABSORB China: EuroPCR 2017, AIDA: NEJM 2017, EVERBIO II: IJC 2017, TROFI II: TCT 2016

Underlying mechanisms of VLScT in 4 cases

Underlying mechanism		Case 1	Case 2	Case 3	Case 4
	Malapposition with discontinuity		✓		✓
	Malapposition without discontinuity	✓			
	Uncovered	✓		✓	✓
	Lumen loss	✓	✓		✓

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Räber et al. JACC 2015

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Design

- **DESIGN:** Retrospective, international registry

- **OBJECTIVE:** To elucidate mechanisms underlying VLScT as assessed by optical coherence tomography.

- **PRINCIPAL INVESTIGATORS**
Lorenz Räber, MD PhD
Stephan Windecker, MD
Bern University, Switzerland

Map markers: Bad Segeberg, Amsterdam, Hamburg, Rotterdam, Utrecht, Giessen, Leuven, Munich, Wien, Zurich, Clermont, Bern, Bolognini, Toulouse, Pau, Nimes, Bellvitge

Hong Kong · Singapore

INVEST (INdependent OCT registry on VEry late bioresorbable Scaffold Thrombosis) registry investigators

Core Laboratory Bern	Kyohei Yamaji		**Giessen**	Holger Nef
	Yasushi Ueki			Niklas Boeder
	Lorenz Räber		**Leuven**	Tom Adriaenssens
			Singapore	Joshua P Loh
Imaging committee	Kyohei Yamaji		**Nimes**	Benoit Lattuca
	Yasushi Ueki		**Amsterdam**	Joanna J. Wykrzykowska
	Nicolas Amabile		**Bellvitge**	Josep Gomez-Lara
	Lorenz Räber		**Utrecht**	Leo Timmers
Statistics	Kyohei Yamaji		**Bad Segeberg**	Mohamed Abdel-Wahab
	Alexios Karagiannis		**Hamburg**	Felix Meincke
			Toulouse	Benjamin Honton
			Zurich	Crochan J. O'Sullivan
Participating centers			**Bolognini**	Alfonso Ielasi
Clermont	Geraud Souteyrand		**Pau**	Nicolas Delarche
Rotterdam	Joost Daemen		**Wien**	Günter Christ
Munich	Jens Wiebe		**Hong Kong**	Joe KT Lee
	Petra Hoppmann		**Hong Kong**	Michael Lee

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Methods

Analysis	**2 experienced analysts**
Analysis interval	**0.2mm**
ROI	**5mm margins, scaffold with vs. without thrombus**
Analysis software	**Medis QCU-CMS**
Assessment of leading mechanism	**Consensus meeting**

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Patient Characteristics (N=36)

Patient age at index PCI	53±11 years
Male	33 (92%)
BMI	26.2±3.8 kg/m²
Hypertension	17 (47%)
Family history of CAD	13 (36%)
Current smoker	15 (42%)
Dyslipidemia	17 (47%)
Diabetes	8 (22%)
Previous MI	11 (31%)
Previous PCI	13 (36%)
LVEF	52±10%

Time between index PCI and VLScT : 21.9 ± 7.97 months

Lesion Characteristics (N=38)

LAD	16 (43%)
LCX	5 (14%)
RCA	17 (45%)
Bifurcation	8 (21%)
Calcified	5 (13%)
CTO	2 (5.3%)
Imaging at index PCI	
OCT	9 (25%)
IVUS	2 (5.6%)
Number of scaffolds used	1.3±0.57
Scaffold overlap	9 (24%)
Total scaffold length	29.5±15.7

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PSP

Pre-dilatation (88%)

Balloon diameter: 2.81±0.46mm

Sizing appropriate (44%)

RVD <2.5mm: 6.2%

BVS diameter <RVD – 0.25mm: 6.2%

BVS diameter ≥RVD + 0.25mm: 44%

Post-dilatation (60%)

Maximal balloon diameter: 3.45±0.44mm

Balloon pressure: 16.6±4.3atm

Balloon pressure ≥16atm: 34%

PSP applied (24%)

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Clinical Presentation
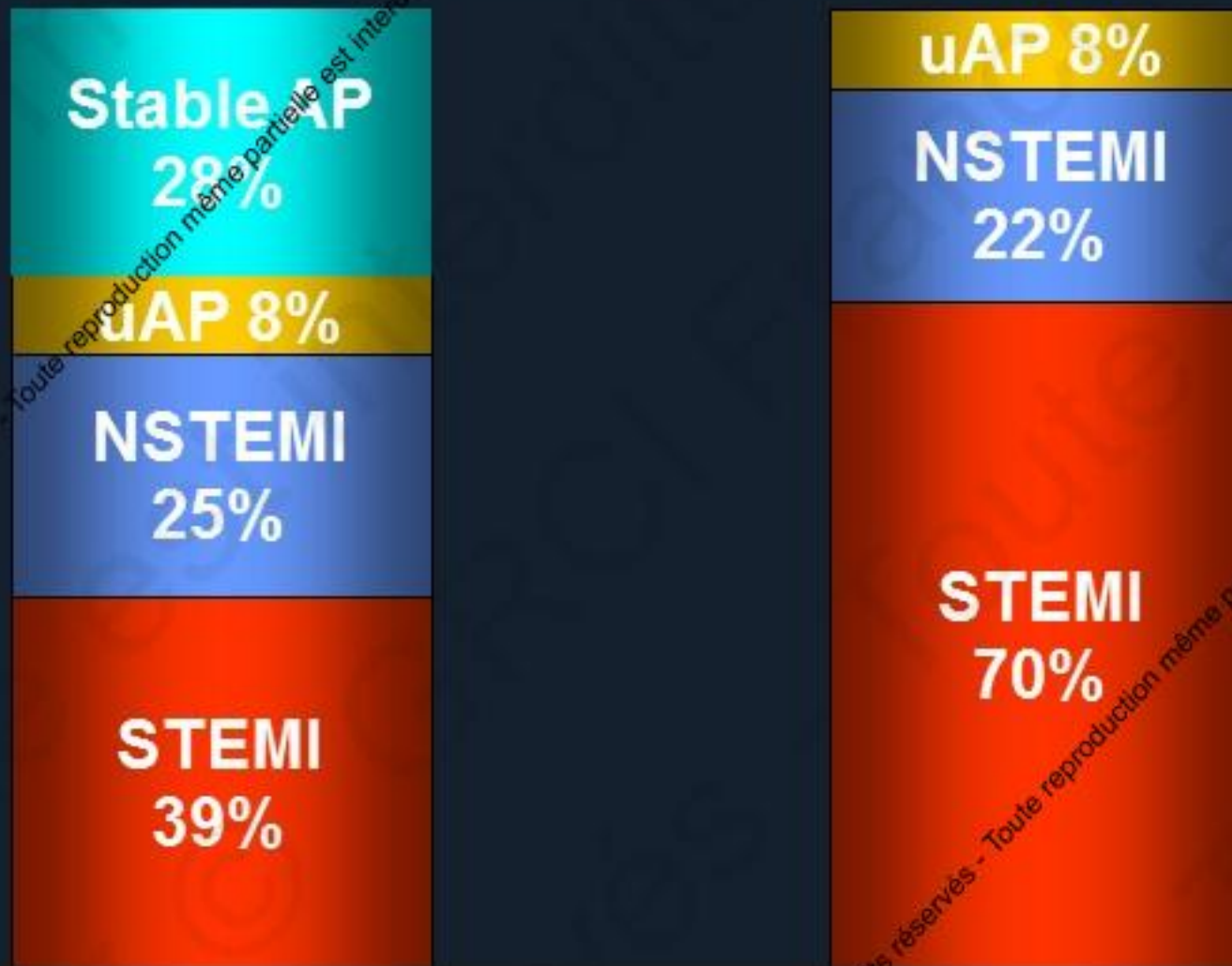
Dual antiplatelet therapy
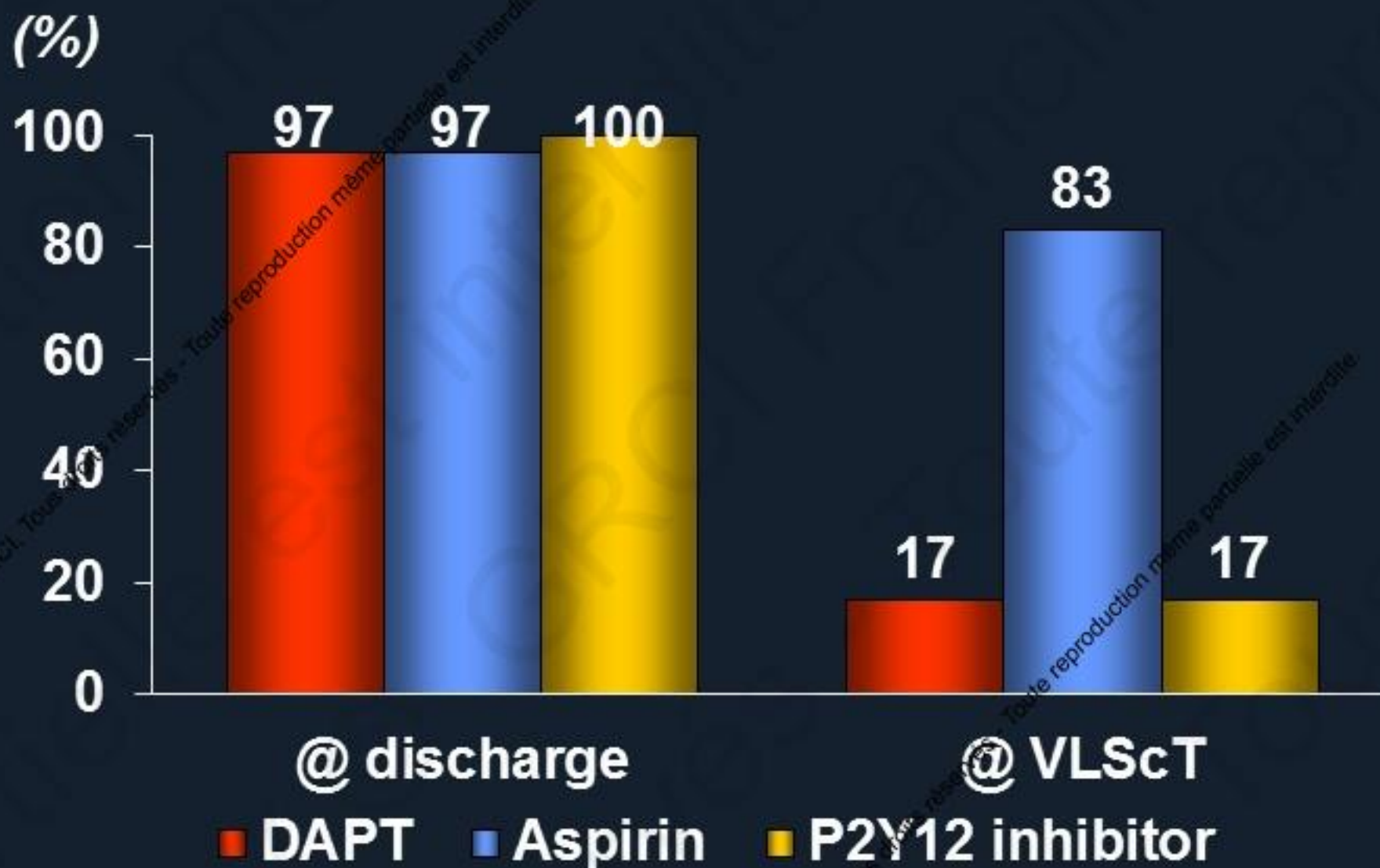
Discontinuity (16/38, 42.1%)
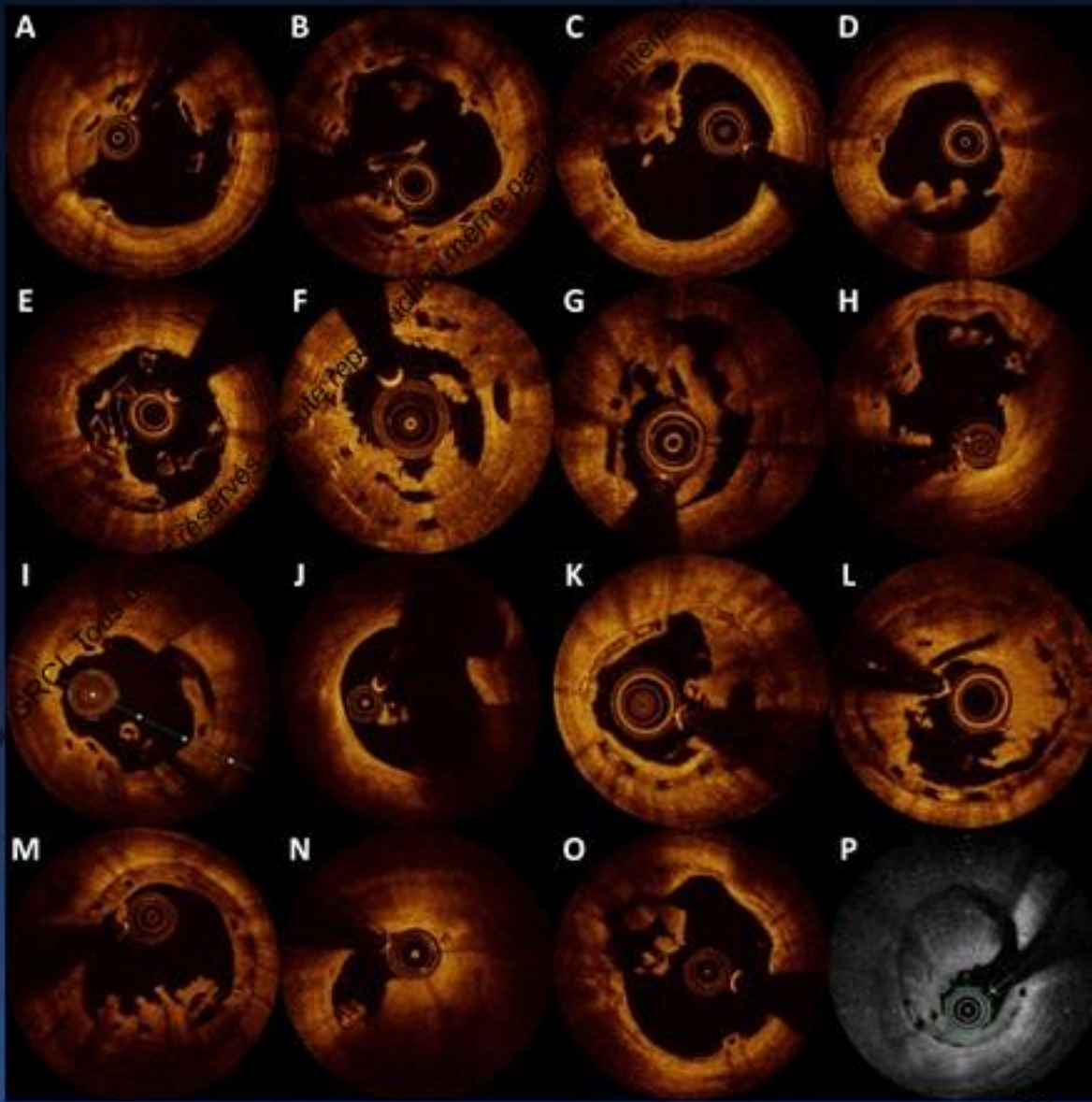
Definition

„Isolated malapposed struts that could not be integrated in the expected circularity of the device in at least 1 cross section"
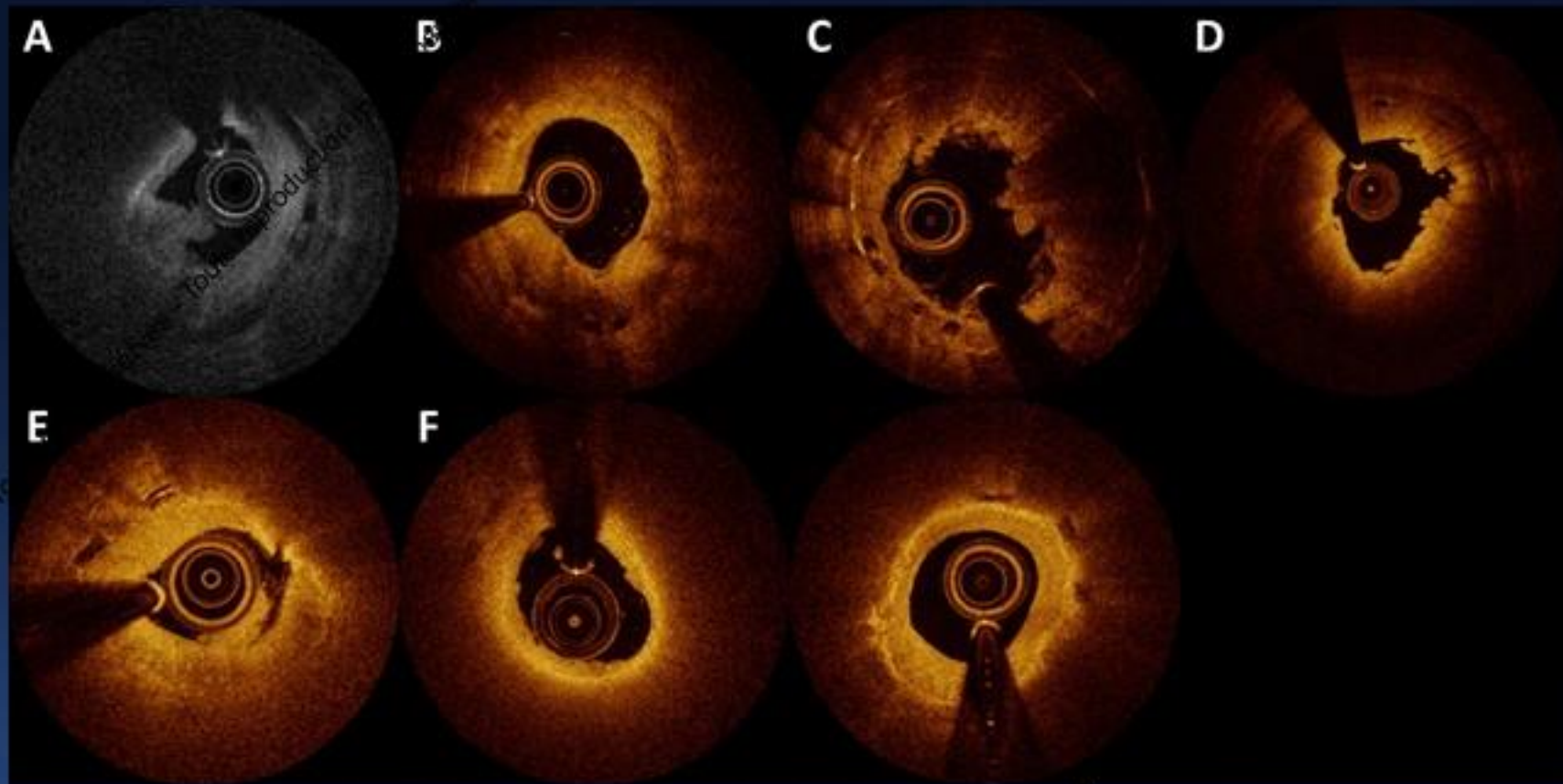
16 cases with discontinuity as key mechanism
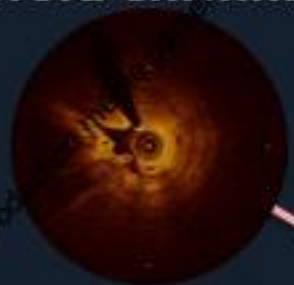
Discontinuity as a leading cause of VLScT

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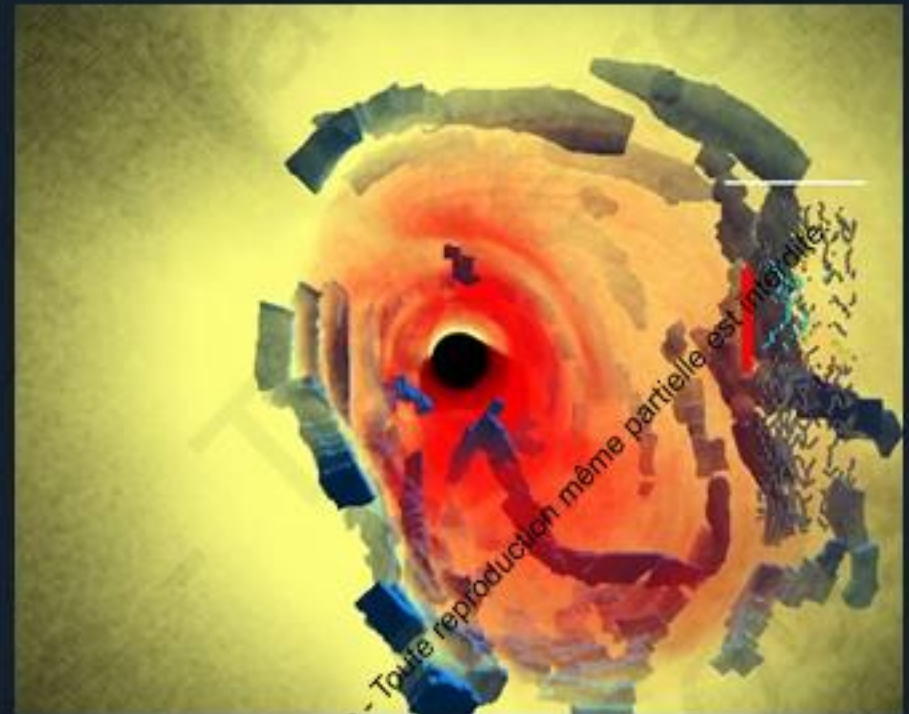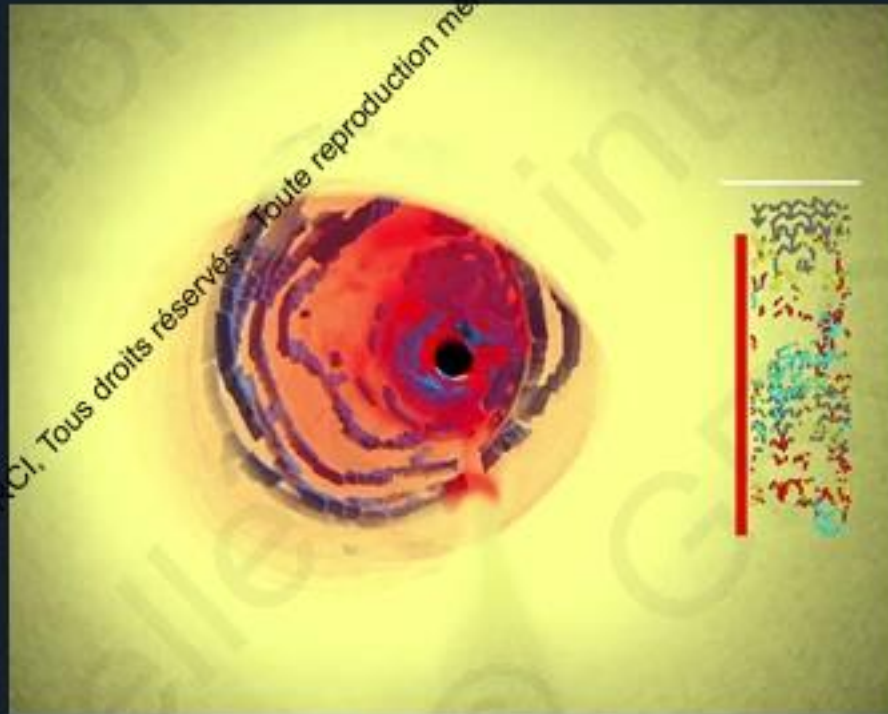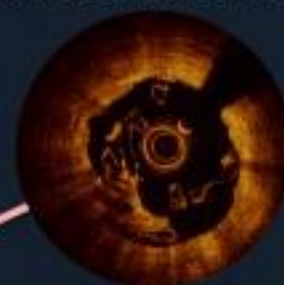
Malapposition (7/38, 18.4%)
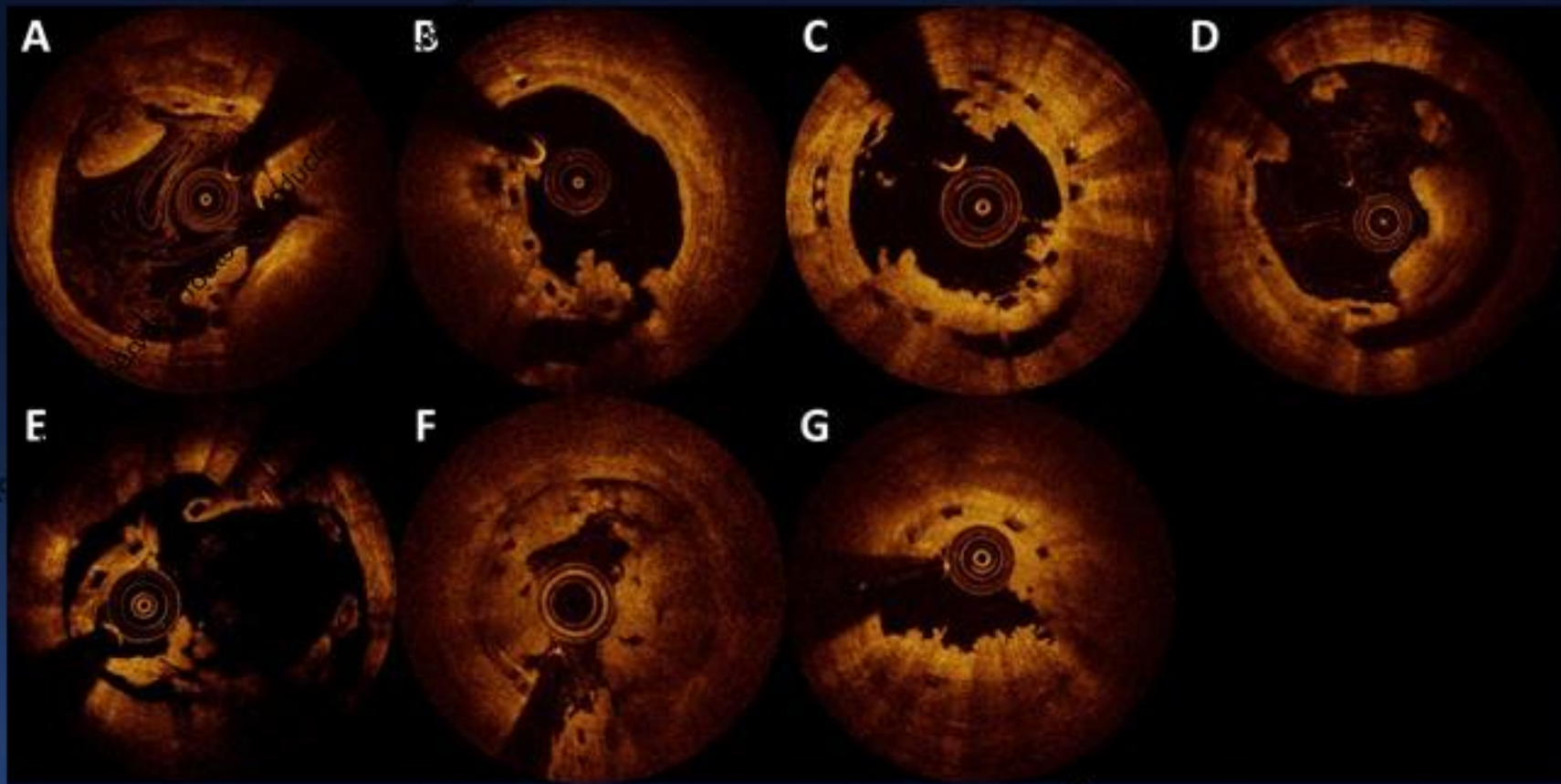
Neoatherosclerosis (7/38, 18.4%)

Underlying mechanisms

Underexpansion or scaffold shrinkage

Others

Scaffold discontinuity

Neoatherosclerosis

Malapposition

11%
11%
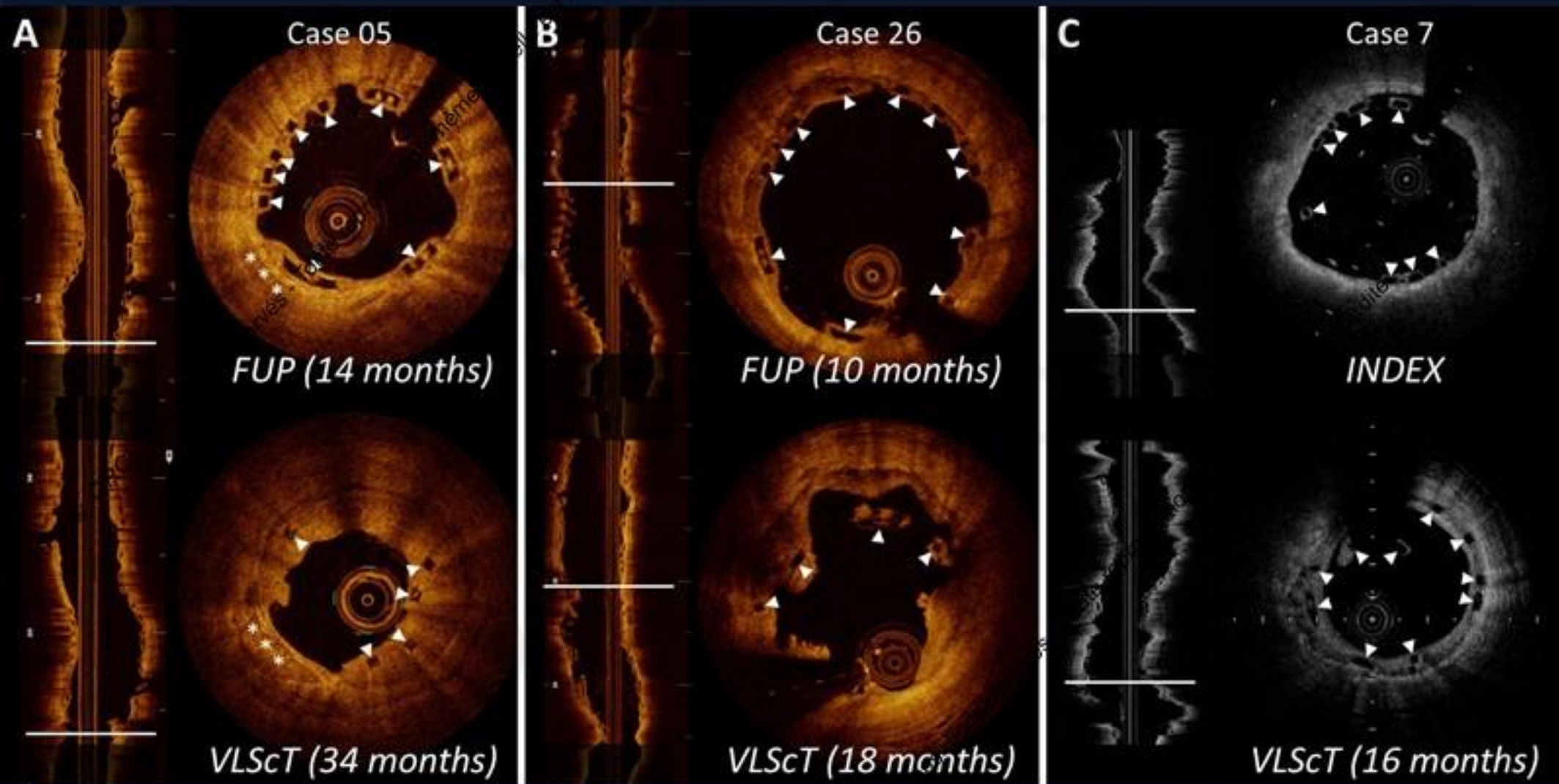42%
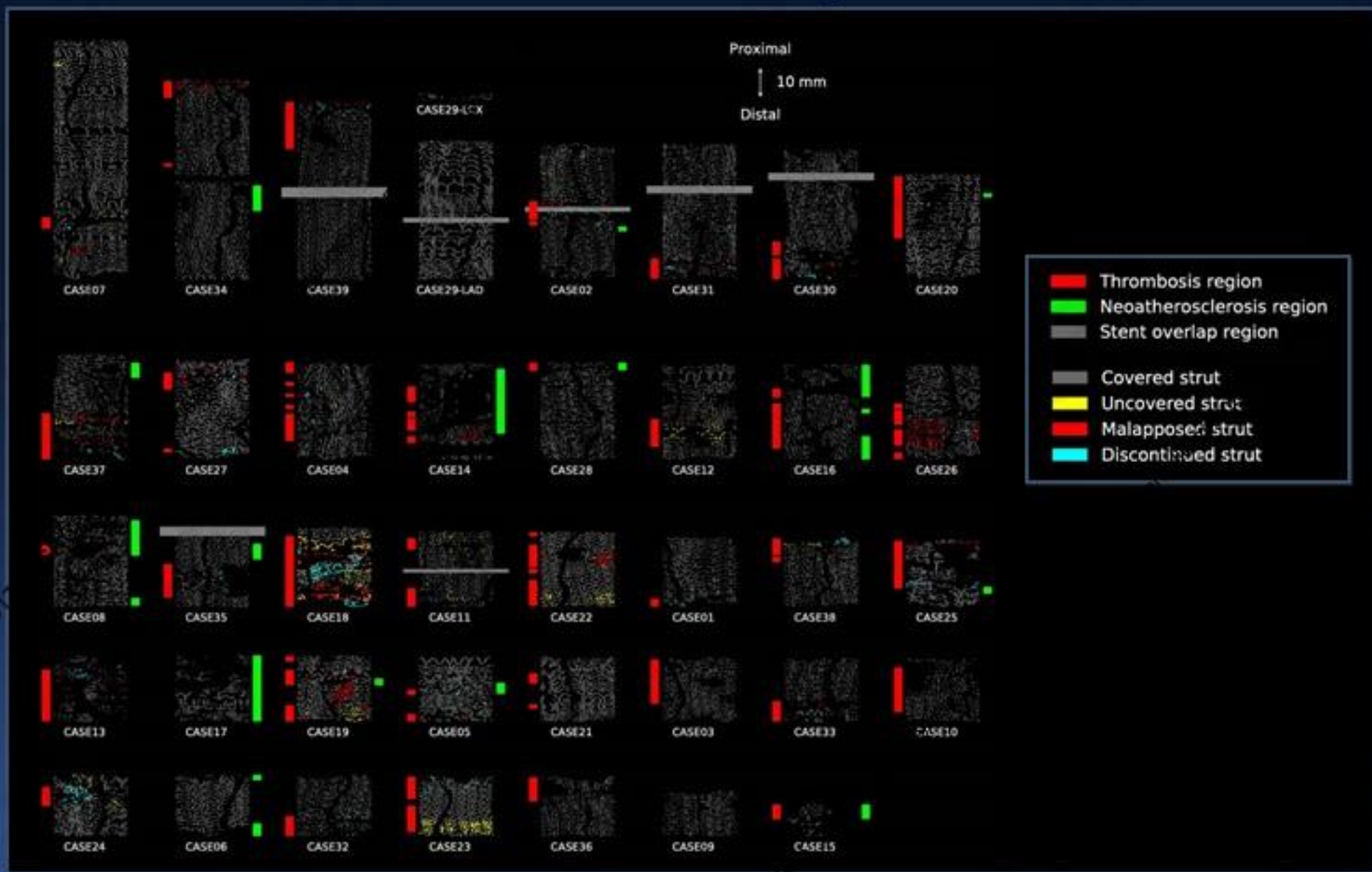18%
18%

N=38

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OCT prior to VLScT

7 patients had serial OCT available, of which 3 had scaffold discontinuitiy
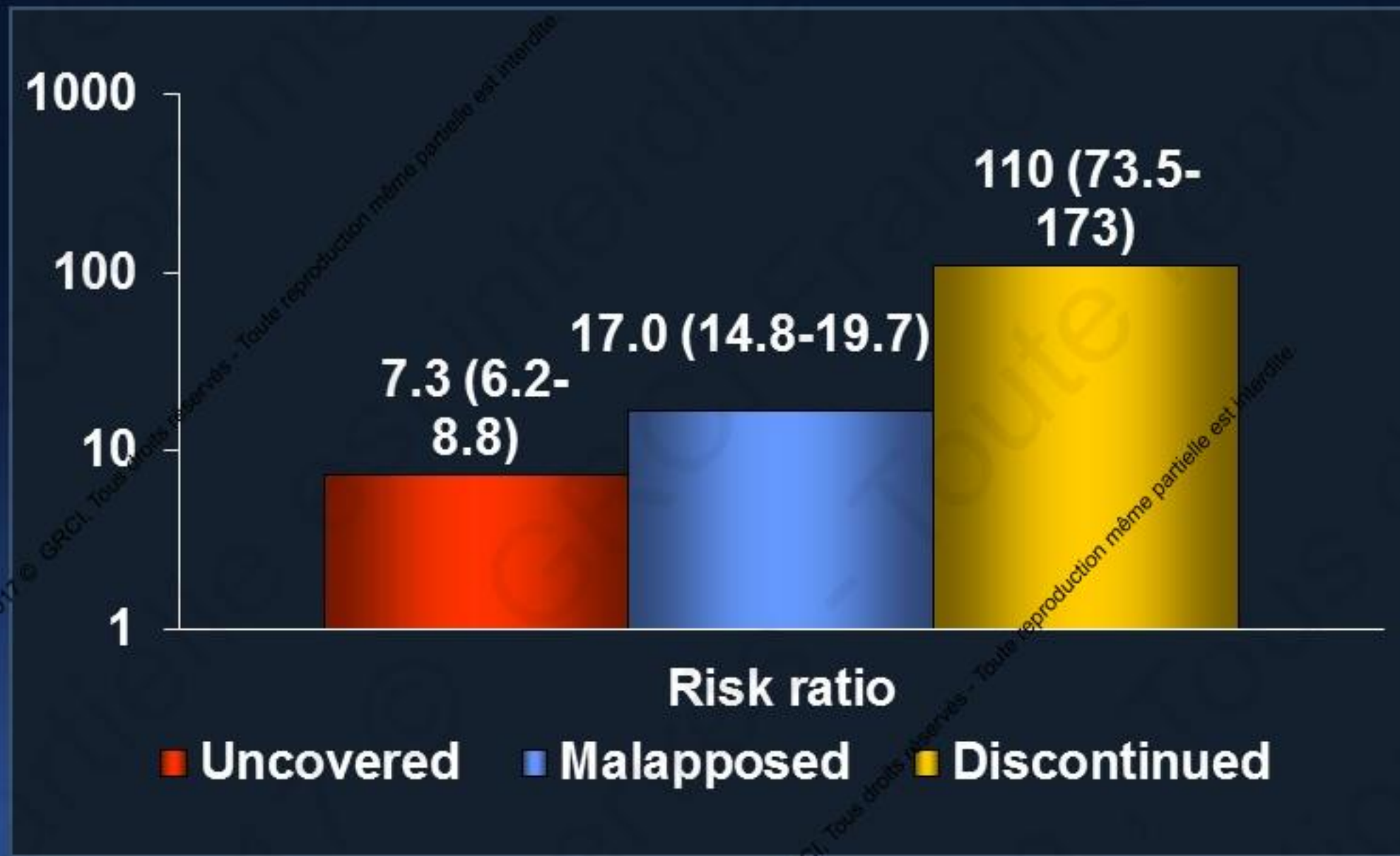

Discontinuity is a late acquired phenomenon

Strut map

Thrombus vs. non-thrombus regions

Limitations

- Sample size limited, however, inclusion of more VLScT than accumulated to date in all RCTS (N=27)

- Retrospective design, potential of selection bias

- Potential morphological changes as a function of pre-treatment or OCT.

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Conclusion

- **Using intracoronary OCT imaging, the INVEST registry discloses multifactorial causes of VLScT.**

- **The leading mechanism underlying VLScT was <u>scaffold discontinuity</u> suggesting an unfavorable resorption related process, followed by malapposition, and neoatherosclerosis.**

- **It remains to be determined whether modifications in scaffold design and optimized implantation techniques may mitigate the risk of VLScT.**

Potential Impact of pre-dilatation