

ATLANTA-FME (France & Middle East)

Interim French Experience

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Polyzene-F[®] Stent Clinical Program



First In Man
Completed

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Purpose

To assess DAPT and thromboembolic events in patients undergoing PCI with CATANIA stent in real world medical practice

Primary Endpoints

- Thromboembolic events (Stent thrombosis according to ARC)

Secondary Endpoints

- MACE (cardiac death, MI and TLR)

Registry
2014

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Interim Analysis of the French experience (n=379)

Study Design

- A retrospective, multicenter review of a prospective database with the CATANIA stent in France and the Middle East
- Data reviewed include 1, 6, and 12-month post PCI
 - Demographics
 - CV history and comorbidities
 - Coronary lesions angiographic characteristics
 - Procedural data and stents used
 - Antithrombotic treatments
- Current interim analysis concentrated on French patients with completed 12 month follow-up.

Population

- All patients underwent PCI with CATANIA stent
- There was no exclusion criteria

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Co-morbidities	n=379
Prior MI	13%
Prior PCI	19%
Prior CABG	4.5%
Diabetes	21%
HTN	61%
Hypercholesterolemia	61%
Chronic renal failure	6%
Smoking	40%

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Clinical Characteristics	n=379
LVEF (n=110)	
< 30	4%
≥ 30 and ≤ 50	36%
> 50	60%
Procedural indication	
Stable angina	37.3%
ACS	62.7%

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Lesion Characteristics	
Target vessel	
Left main	3%
LAD	35%
LCX	14%
RCA	39%
SVG / bypass graft	2%
Other	9%
Lesions treated per patient	1.32 ± 0.59
Ostial lesion	14%
Bifurcation	2%
Lesion Median length (range)	15 (3 - 58)
Median RVD (range) mm	3 (2- 4.5)

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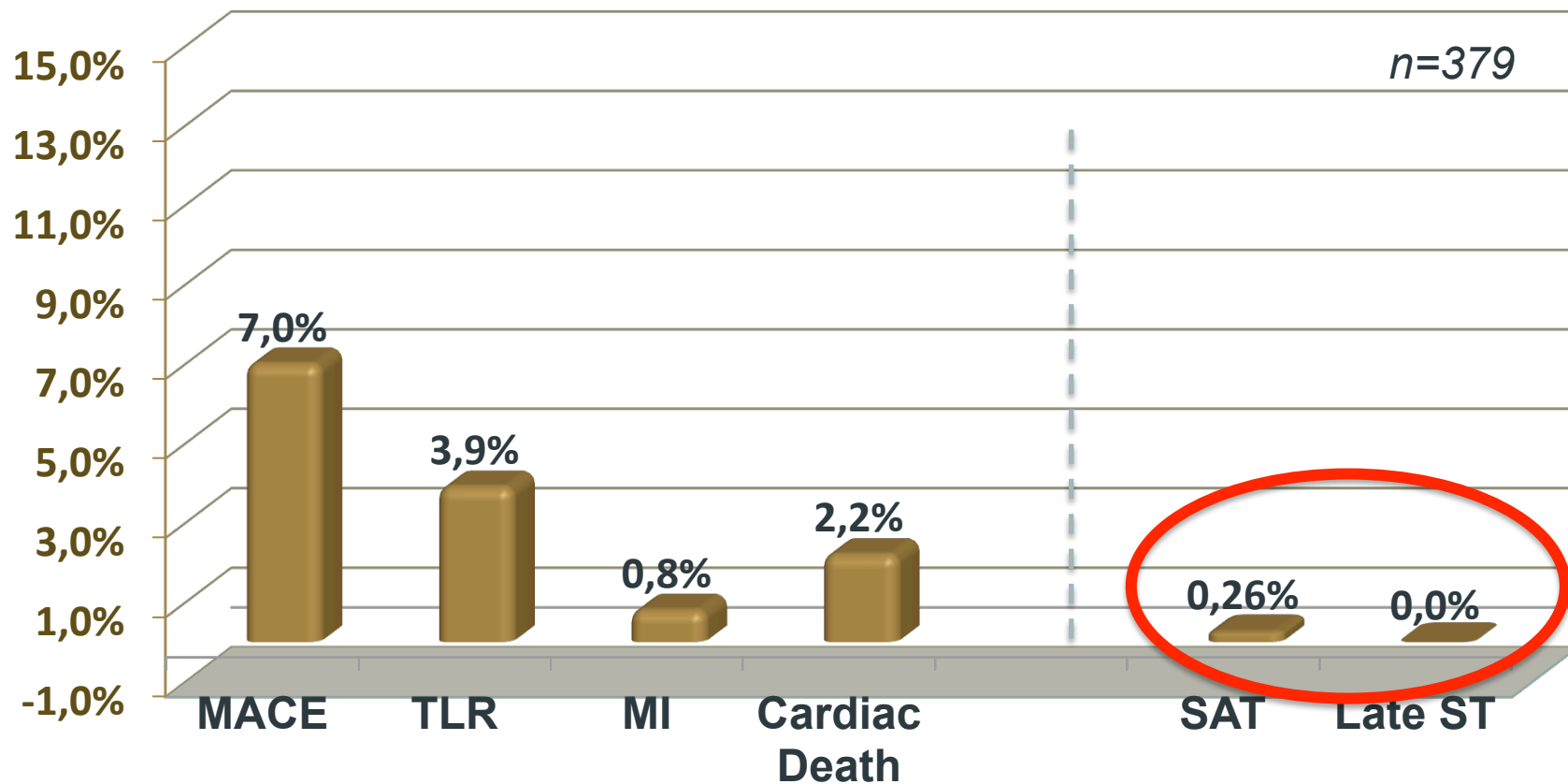
Interim French Experience

Stents used	
# CATANIA Stent	472
Stent per patient	1.4 ± 0.6
Stent per lesion	1.1 ± 0.31
Mean stent length (mm)	17.1 ± 6.1
Diameter (mm)	3.07 ± 0.46

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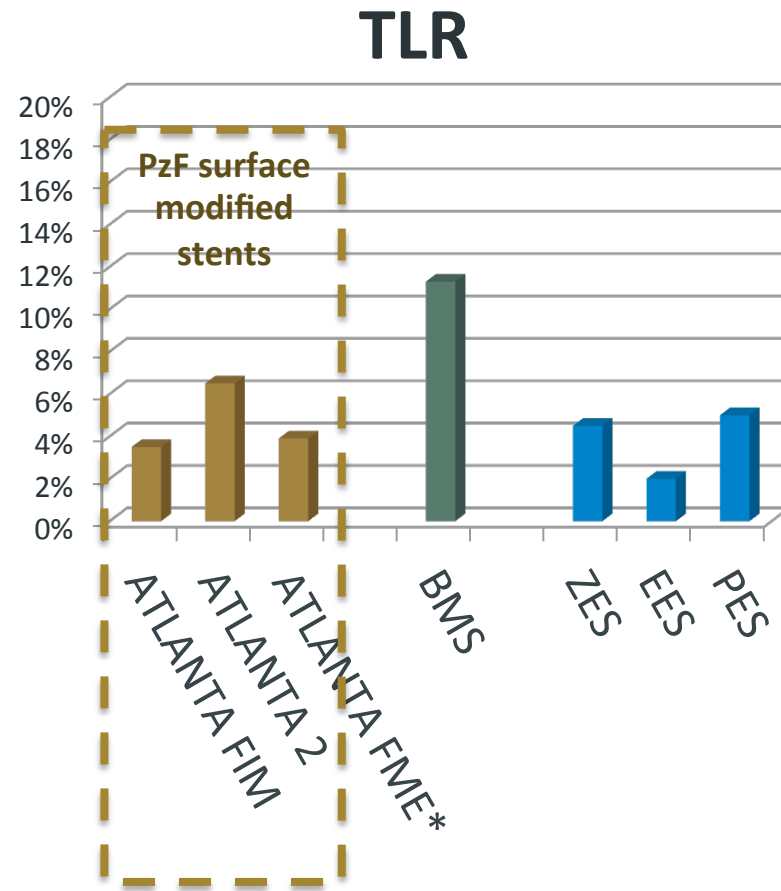
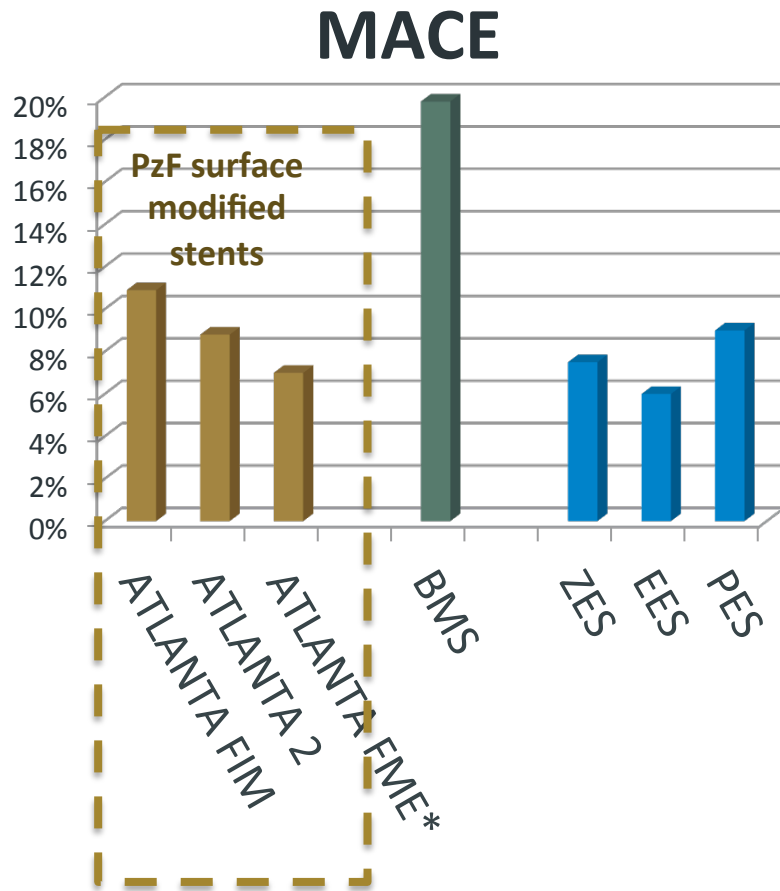
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3.9% TLR; No (0) LST



ATLANTA FME included the CATANIA™ Coronary Stent System with the same PzF surface modification as COBRA PzF.

Catania PzF Trials- 12-month Clinical Outcomes Compared with Published Data



* Interim analysis – French experience

Cat- Tamburino 2009, 2012
Titan- Karjalainen 2008

ZES – Lotan 2009
EES – Stone 2008

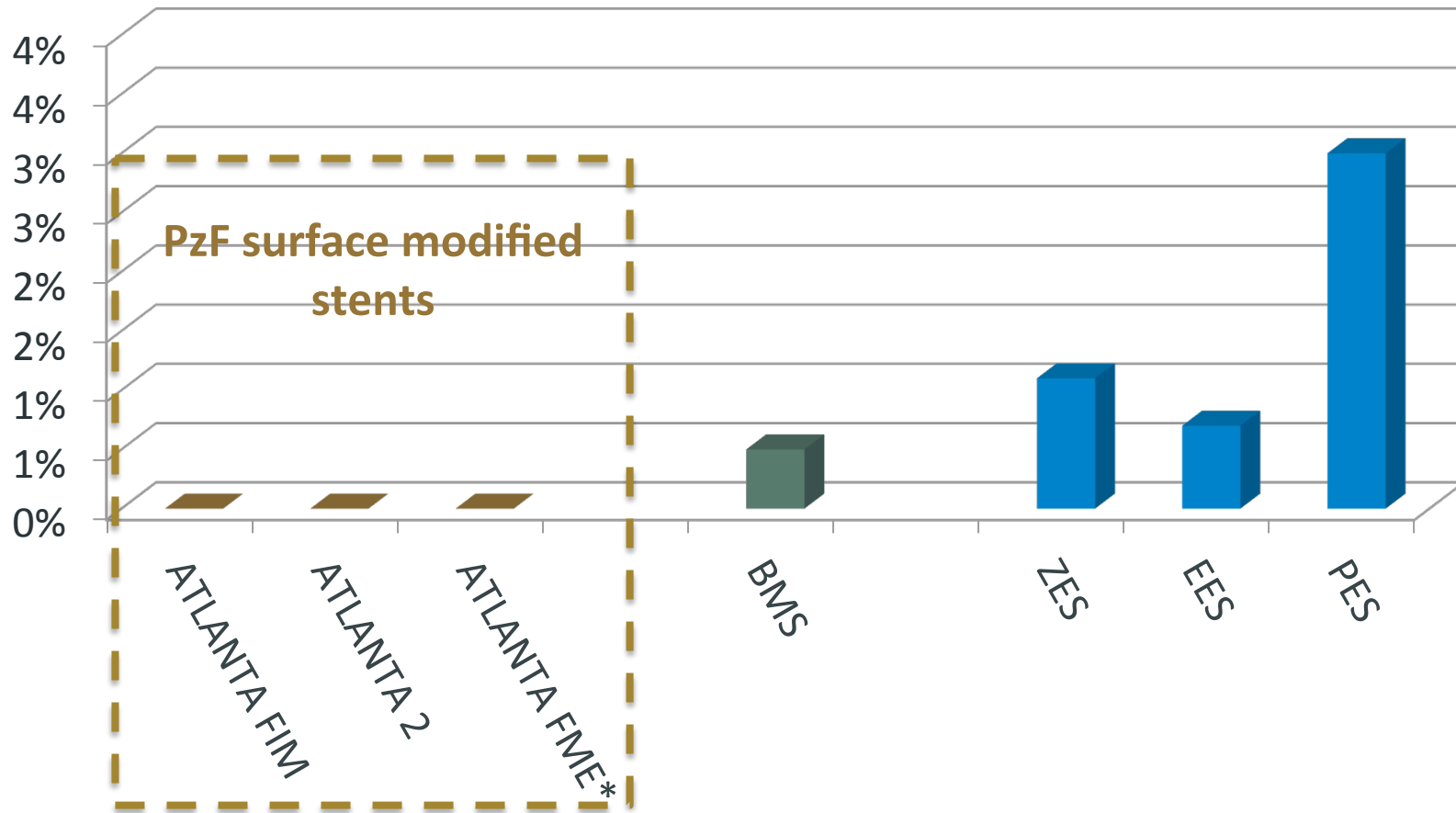
PES – Kedhi 2010
BMS – Stone 2004

SES- Pache 2005

ATLANTA, ATLANTA II, ATLANTA FME and REVEAL included the CATANIA™ Coronary Stent System with the same PzF surface modification as COBRA PzF.

Stent Thrombosis

Late Stent Thrombosis



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Summary and Conclusions

Polyzene-F modified stents resulted in excellent clinical outcomes

- 3.9% Target Lesion Revascularization (TLR)
- 7.0% Major Adverse Cardiac Events (MACE)

Polyzene-F modified stents resulted in low thrombosis rates in Atlanta FR

- 0.26% subacute stent thrombosis
- 0% late stent thrombosis

Study is ongoing. Further analysis will be performed at completion.