NEW ENGLAND CENTER FOR STROKE RESEARCH

OCT Evidence of Reduced Thrombogenicity on Surface Modified FD

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Introduction

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- In vitro- Pipeline Flex Embolization Device + Shield Technology TM (Shield)-surface modification consisting of a 3nm thick modified phosphorylcholine is less thrombogenic.[1]
- Hypothesis- Shield has less thrombus formation in vivo as compared to uncoated Pipeline Embolization Devices (PED) regardless of dual antiplatelet therapy (DAPT)

[1]G Girdhar et al. J Thromb Thrombolysis. 2015;40:437-443

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Optical Coherence Tomography

- OCT- uses near infra-red light for HR imaging
- Catheter- DragonFly (St. Jude Medical)-
  - 54mm HR pullback
  - 20mm rapid exchange with 2.7F profile
  - 0.014’ guidewire and 6G guide catheter compatible

Comparison

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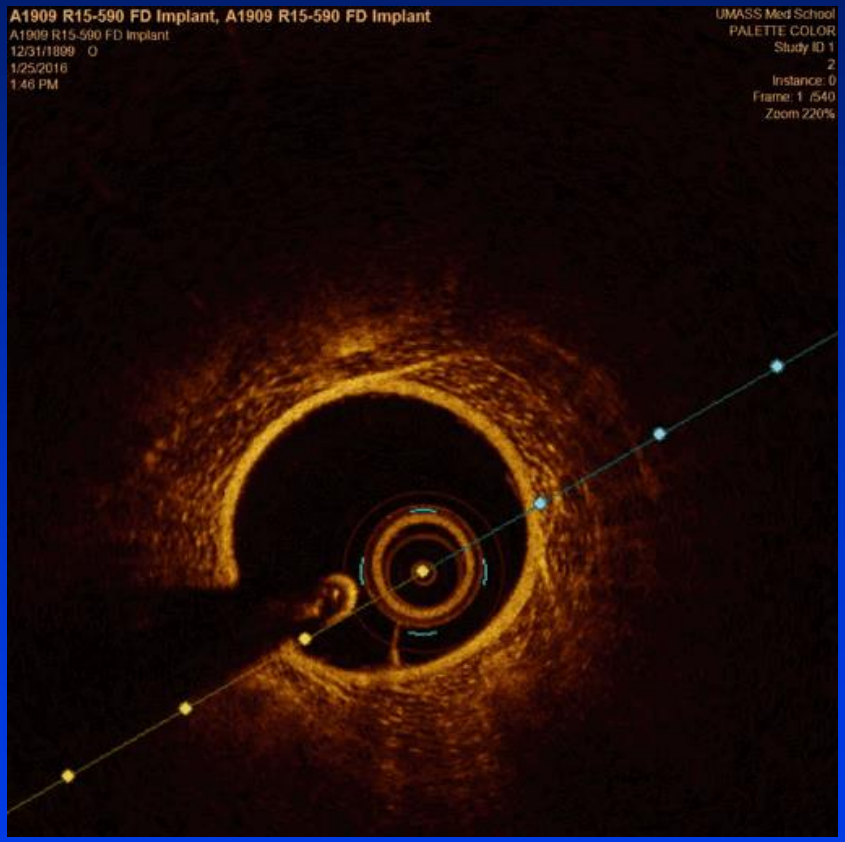
DSA

OCT



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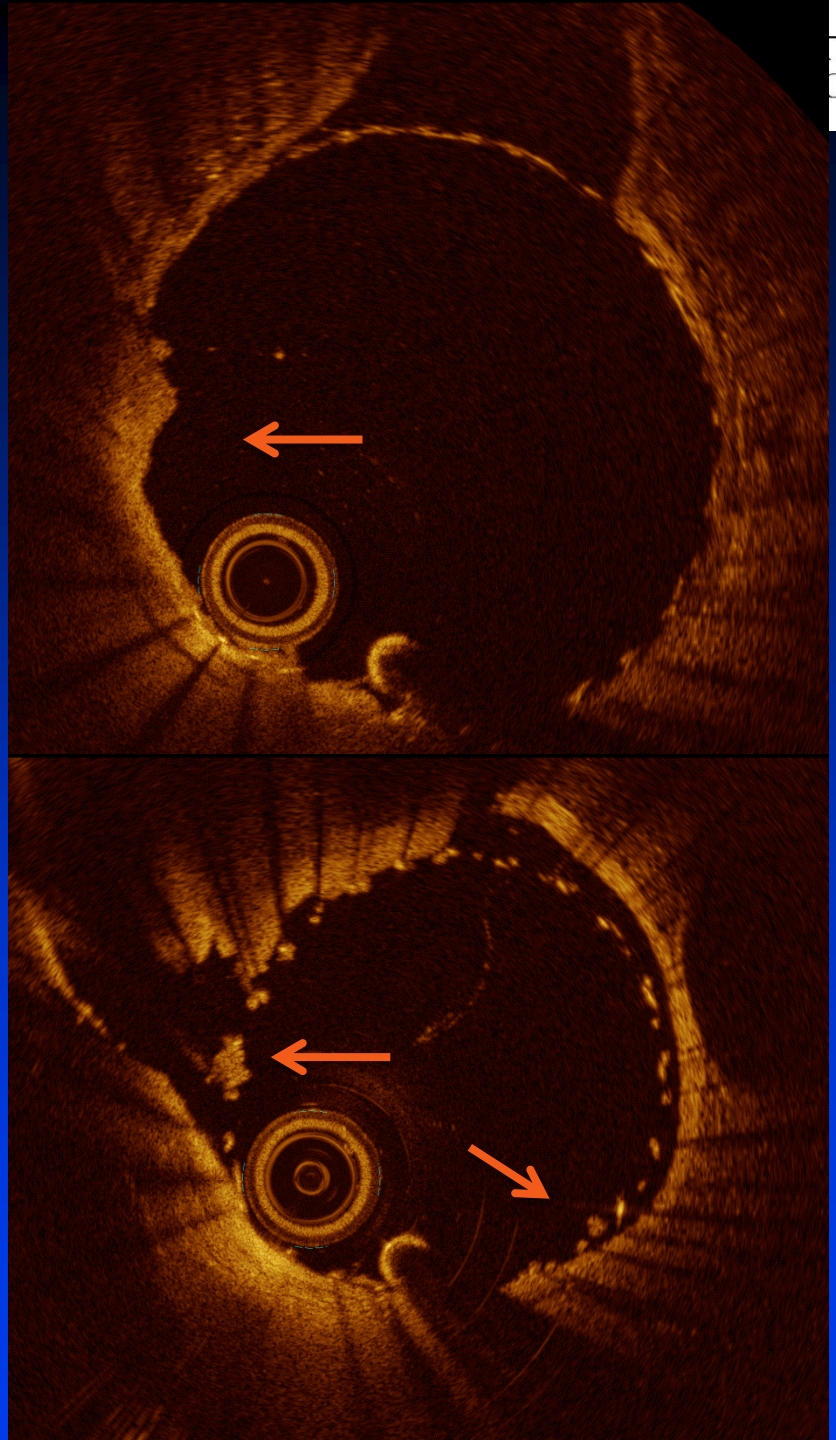
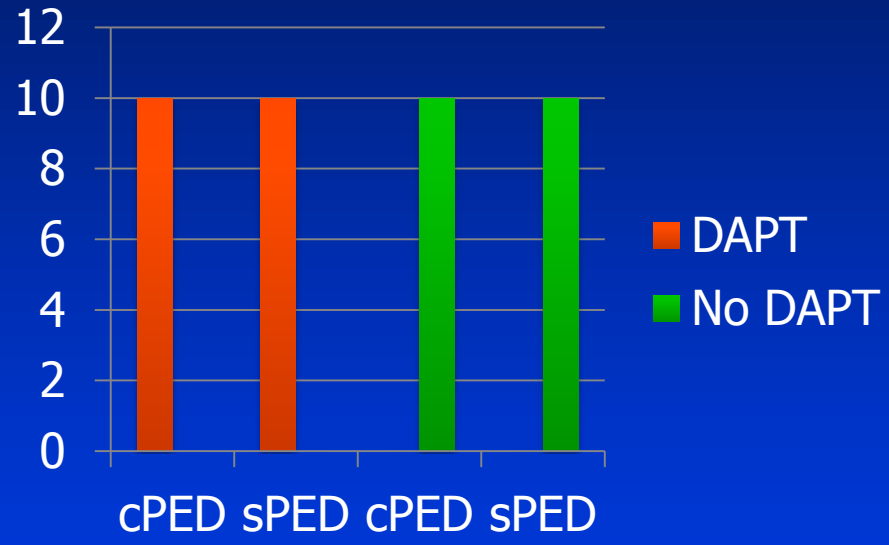
Comparison

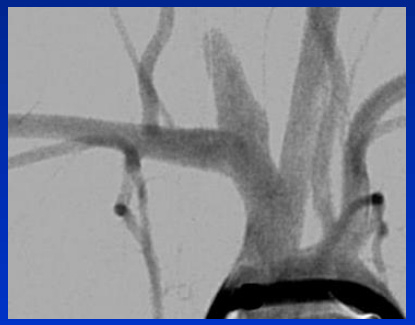
DSA s/p Angioplasty



Methods: study design, protocol

- Rabbit Elastase-aneurysm model
- 4 groups, 10 rabbits in each group: (cPED- Pipeline Classic, sPED- Pipeline Flex with Shield technology)



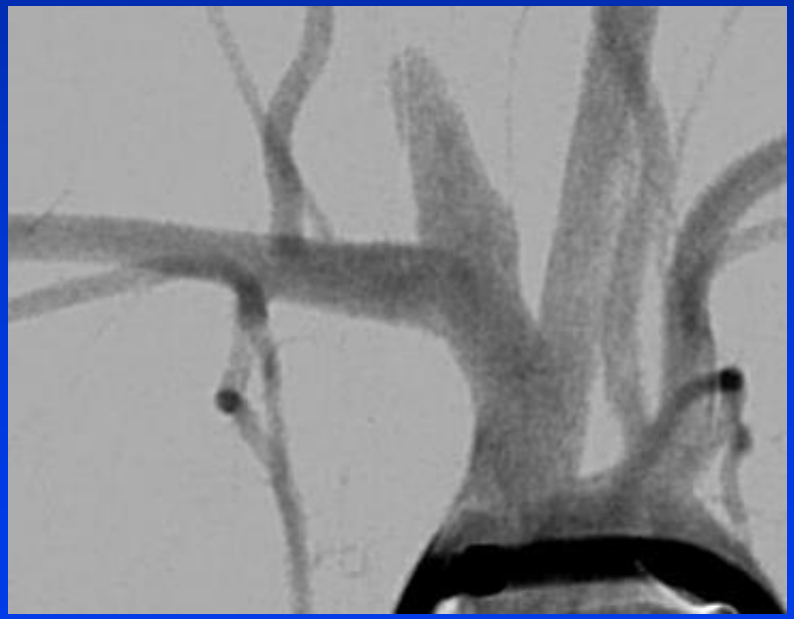


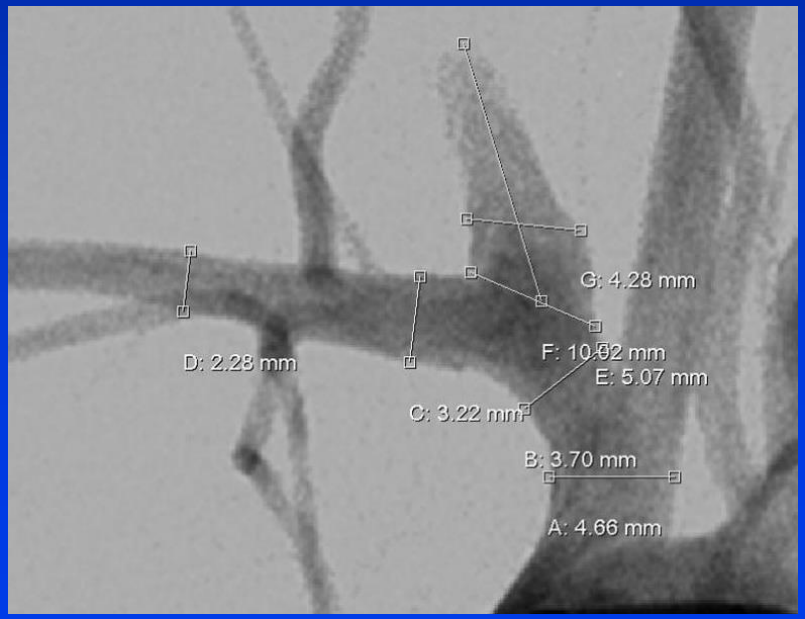
- DAPT group- 10mg/kg/day clopidogrel and ASA, p.o. 5 days prior implant to 30 days
- OCT used for assessing: **Clot formation on the surface of device**

Baseline Data

	Groups				p value
	cPED		sPED		
	no DAPT	DAPT	no DAPT	DAPT	
aneurysm characteristics (mean±SD)					
neck size (mm)	4.1 ± 1.3	3.9 ± 1.0	3.8 ± 0.7	4.3 ± 1.8	0.7801
height (mm)	7.7 ± 2.2	7.6 ± 2.1	5.0 ± 1.6	7.7 ± 2.3	0.3292
parent vessel (mean±SD)					
proximal to aneurysm (mm)	3.7 ± 0.3	3.6 ± 0.4	4.0 ± 0.6	3.9 ± 0.4	0.1788
distal to aneurysm (mm)	3.7 ± 0.8	3.5 ± 0.5	3.6 ± 0.4	3.9 ± 0.8	0.5787
distal subclavian (mm)	2.2 ± 0.2	2.2 ± 0.3	2.3 ± 0.3	2.4 ± 0.4	0.2956
device (mean±SD)					
diameter size (mm)	4.0 ± 0.3	4.1 ± 0.3	4.0 ± 0.3	4.2 ± 0.3	0.6028

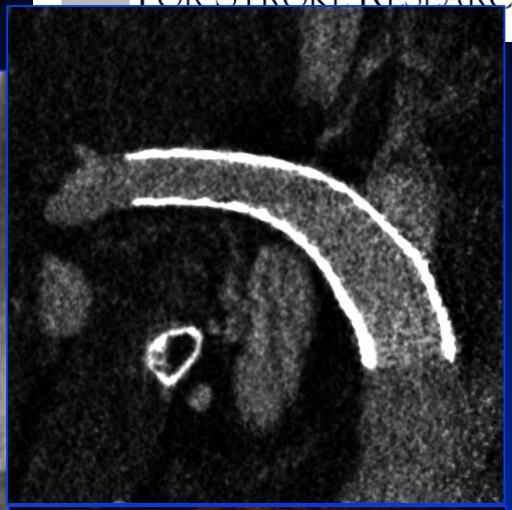
One-way ANOVA

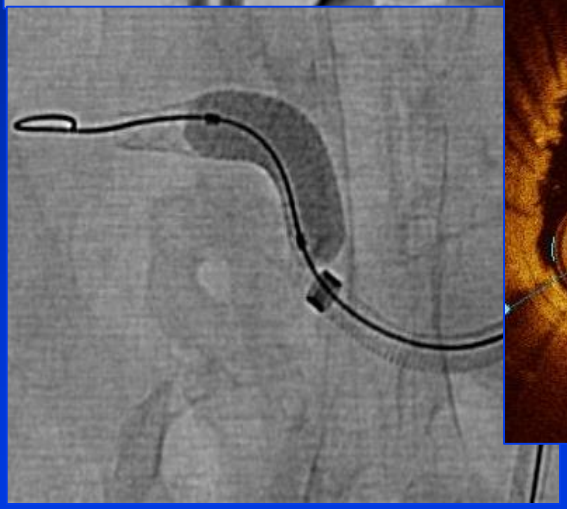


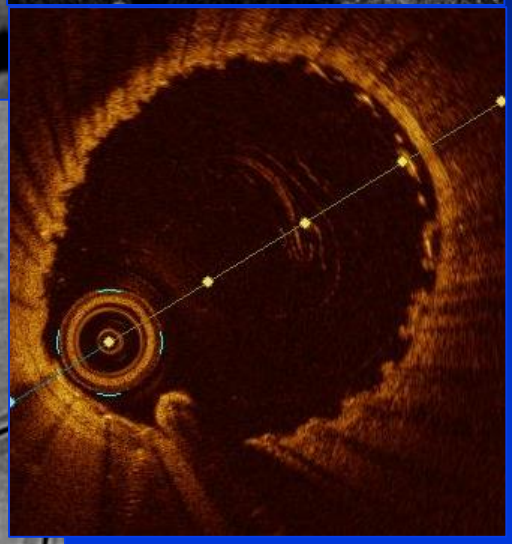


Methods: imaging protocol

- FD implant:
  1) DSA: pre-implant
  2) VasoCT: pre-implant
  3) DSA: post-implant
  4) OCT: post-implant
  5) DSA: post-angioplasty
  6) OCT: post-angioplasty
  7) VasoCT: post-angioplasty





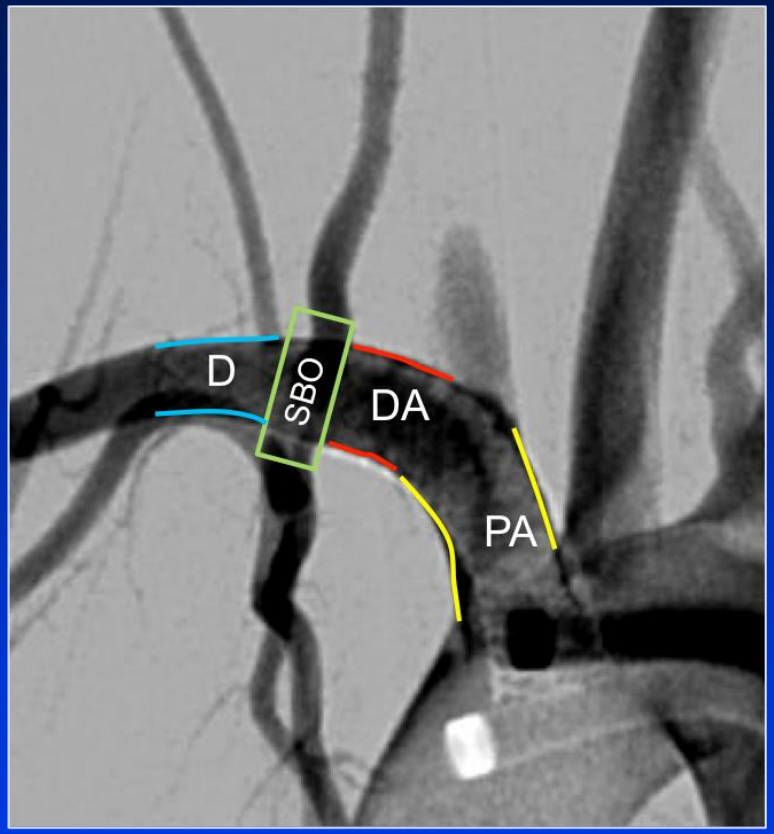


Blood clearance for OCT – power injection

- **5ml/s, 3.5s, Omnipaqe 240mgI/ml**

Methods: Thrombus Quantitation

- After implant, optical coherence tomography (OCT, Dragonfly, St Jude) was performed before and after angioplasty, and at terminal follow-up.
- Thrombus formation was assessed at 4 locations along the implant as present or absent



Results: procedure and complications

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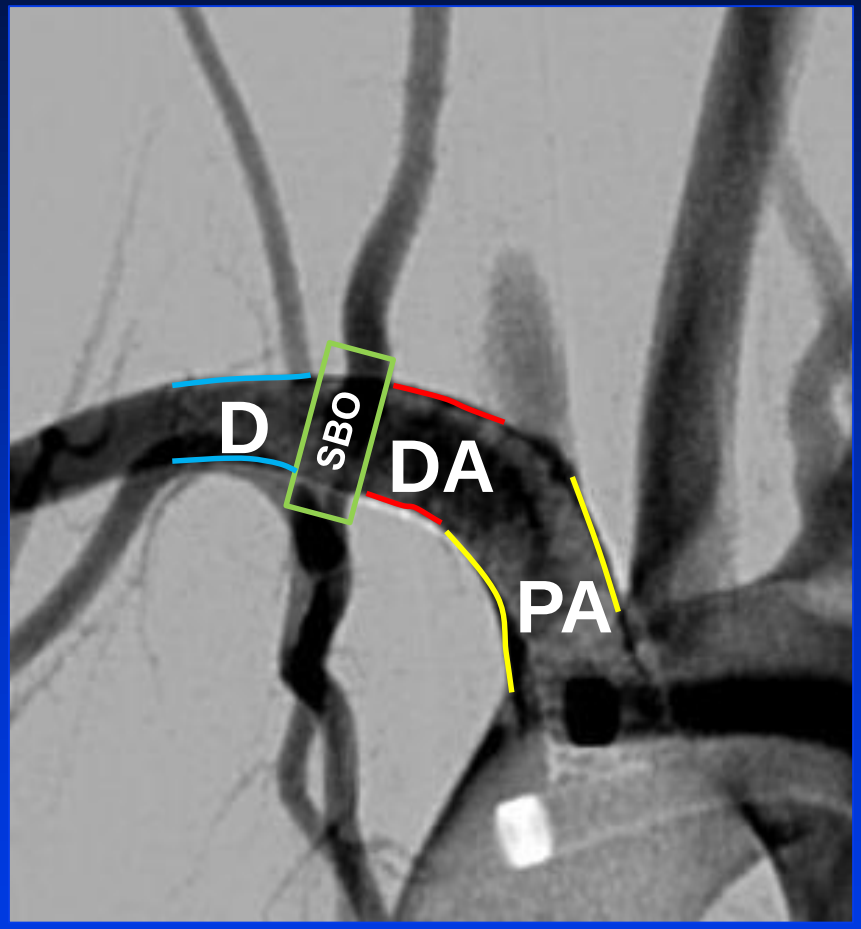
FD implant:

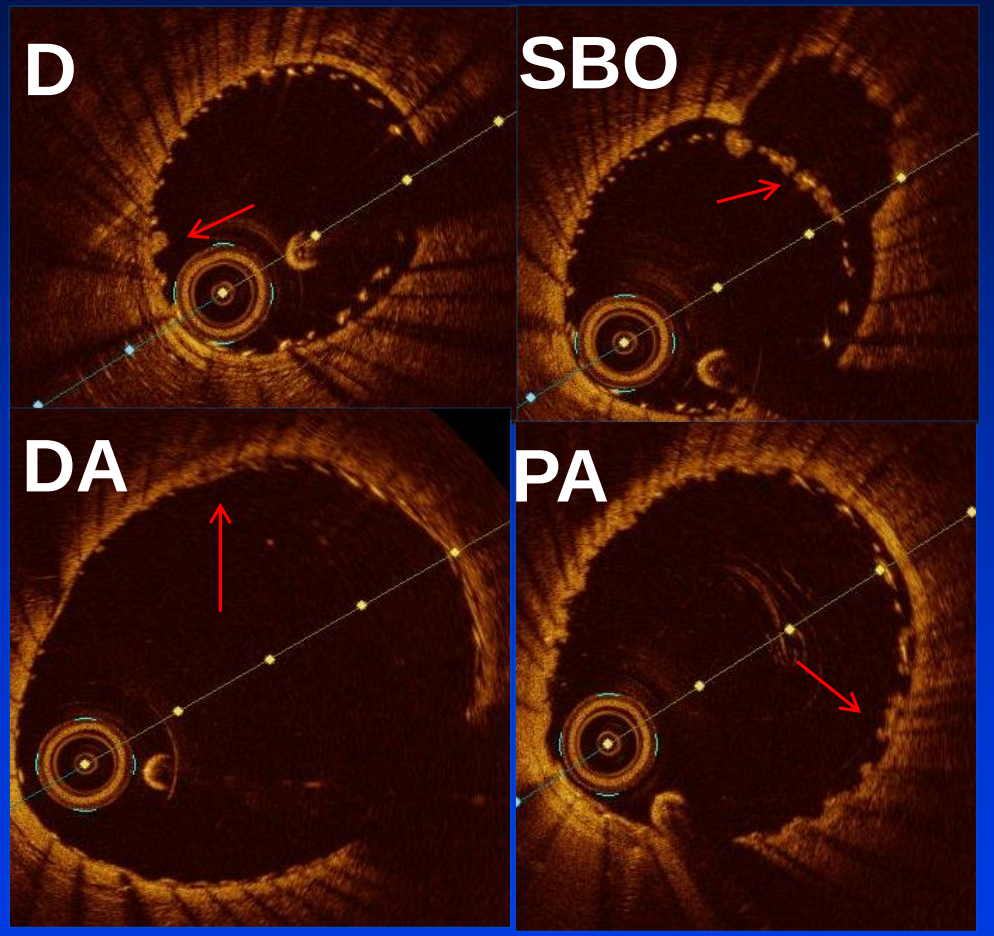
- 45 devices implanted,
  - 44 cases complete neck coverage (98%)
- no vessel perforation,
- 1 vessel dissection: innominate artery, proximal to FD (2%), blood flow not compromised – kept in study
- **No visible thromboembolic complication on DSA**

Results: clot formation

D- distal, DA- distal to the aneurysm, PA- proximal to the aneurysm, SBO- side branch origin

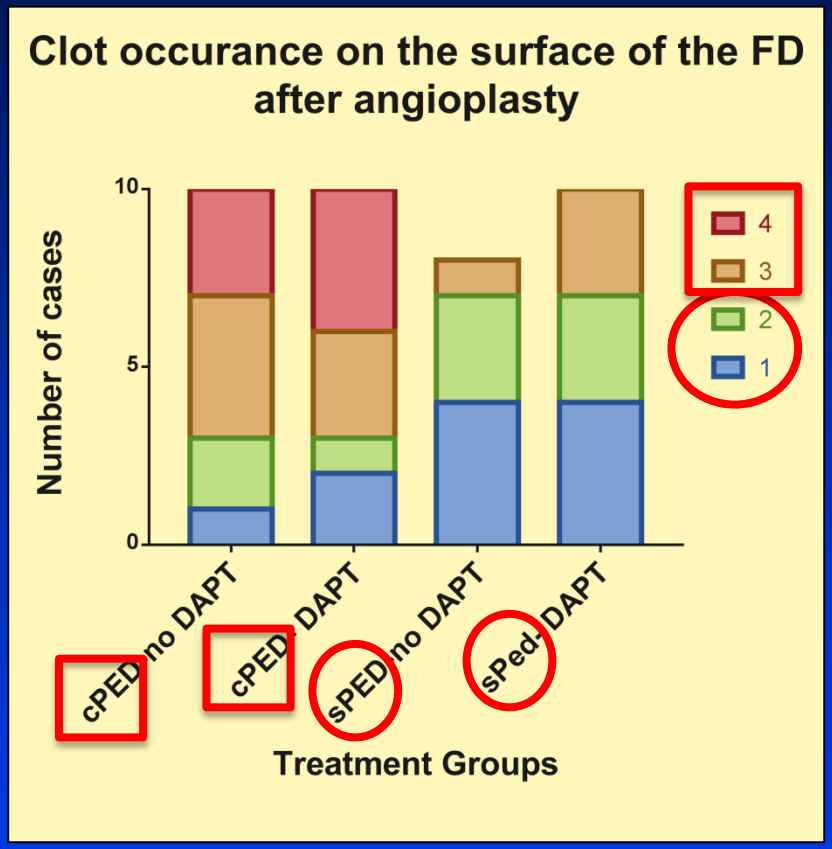


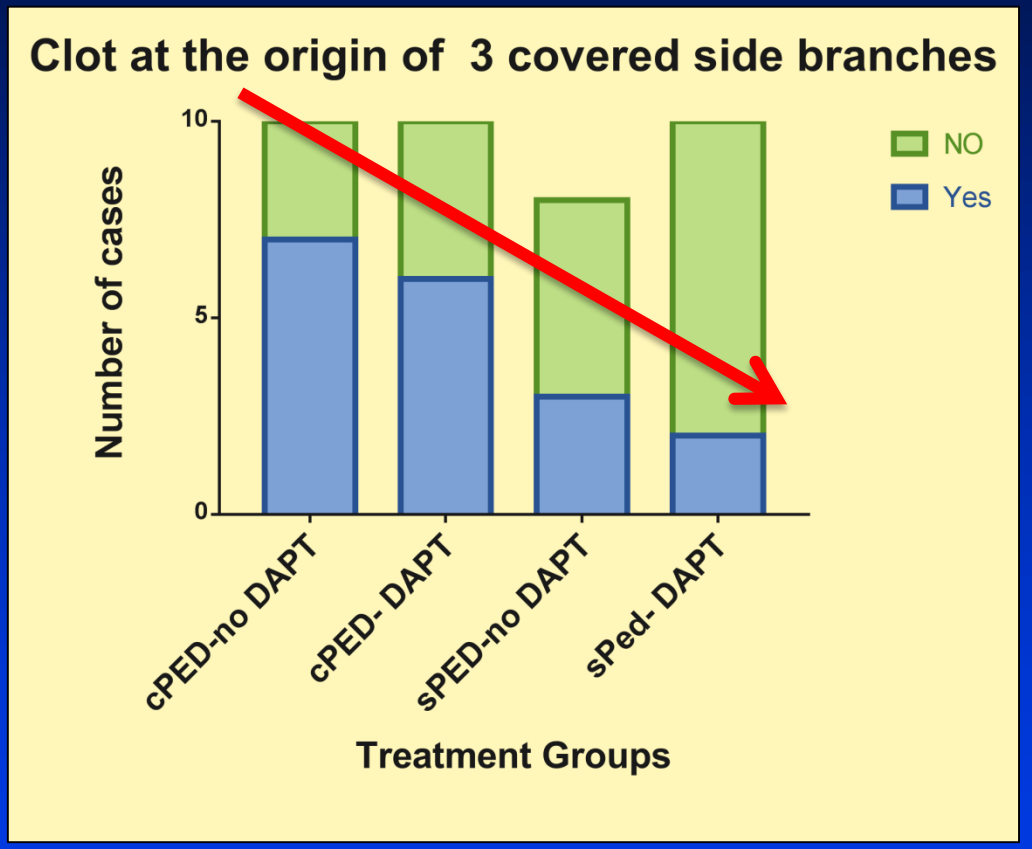
Score: 0-4



cPED – NO DAT, score:4

Results: clot formation





Results

- Animals receiving DAPT had a significant reduction in PRU values (69±28 vs 247±41, p=0.0039) and non-significant reduction in ARU (649±31 vs 659±9, p=0.2)
- **Shield significantly reduced the presence of clot formation (p<0.0001)**
- Clot formation was not associated with DAPT (p=0.4) or neck size (p=0.7).

Conclusion

- Shield technology reduces acute thrombus formation regardless of DAPT has been confirmed in vivo using OCT
- Shield reduces thrombus at SBOs
- OCT offers quantifiable insight into the device-anatomy interface

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- **UMass Collaborations**
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