

REVA FANTOM II

Performance and healing patterns by OCT

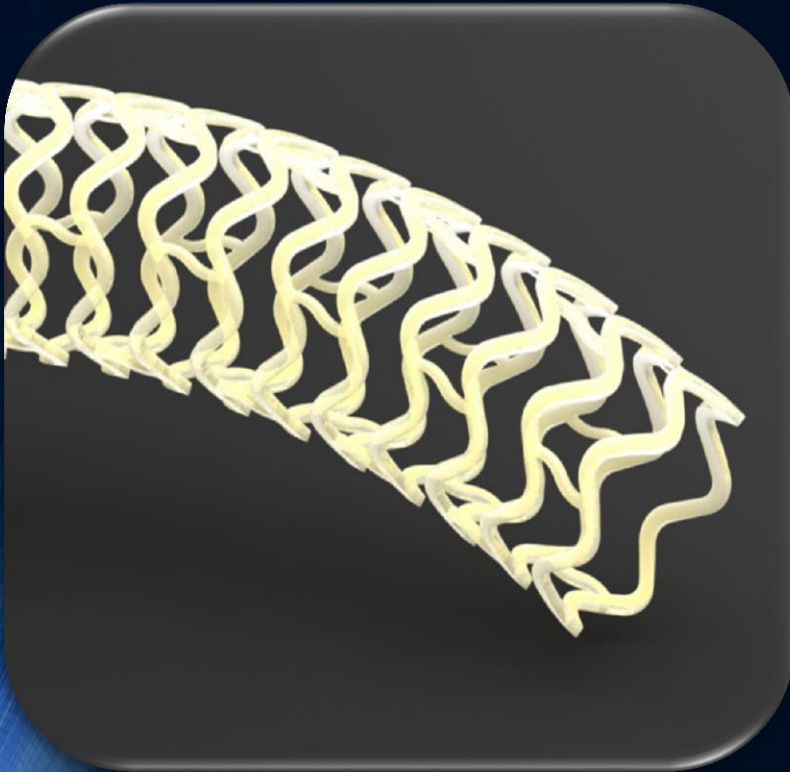
Niels Ramsing Holm

Aarhus University Hospital, Denmark

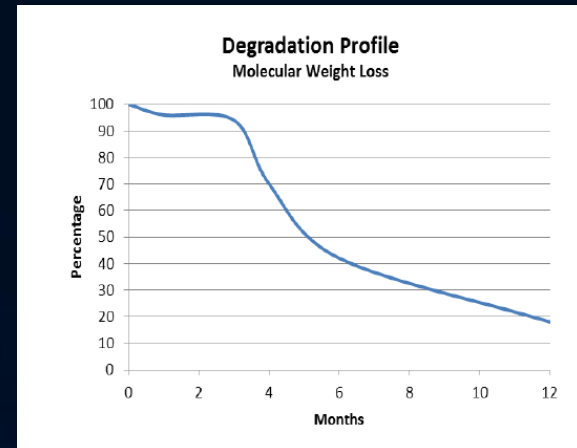
JO SIMONSEN, EMIL NIELSEN HOLCK, DIDIER CARRIÉ, NOBERT FREY,
MATTHIAS LUTZ, JOACHIM WEBER-ALBERS, DARIUS DUDEK, BERNARD
CHEVALIER, JOUKE DIJKSTRA, JENS LASSEN, JEFFREY ANDERSON, EVALD
HØJ CHRISTIANSEN, ALEXANDRE ABIZAID, NIELS RAMSING HOLM

On behalf of the FANTOM II investigators

The FANTOM BRS

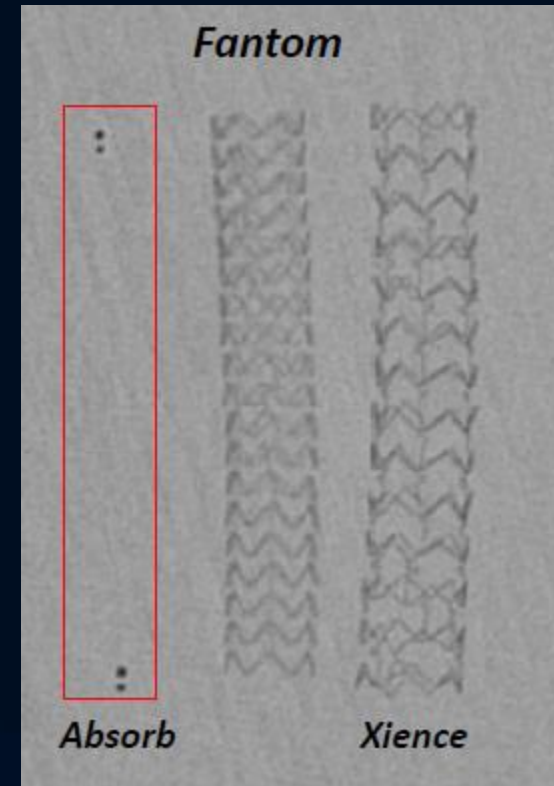


- Desaminotyrosine based polycarbonate backbone
- Strut thickness 125 μ m
- Sirolimus eluting for 3 months
- Full resorption within 3-4 years

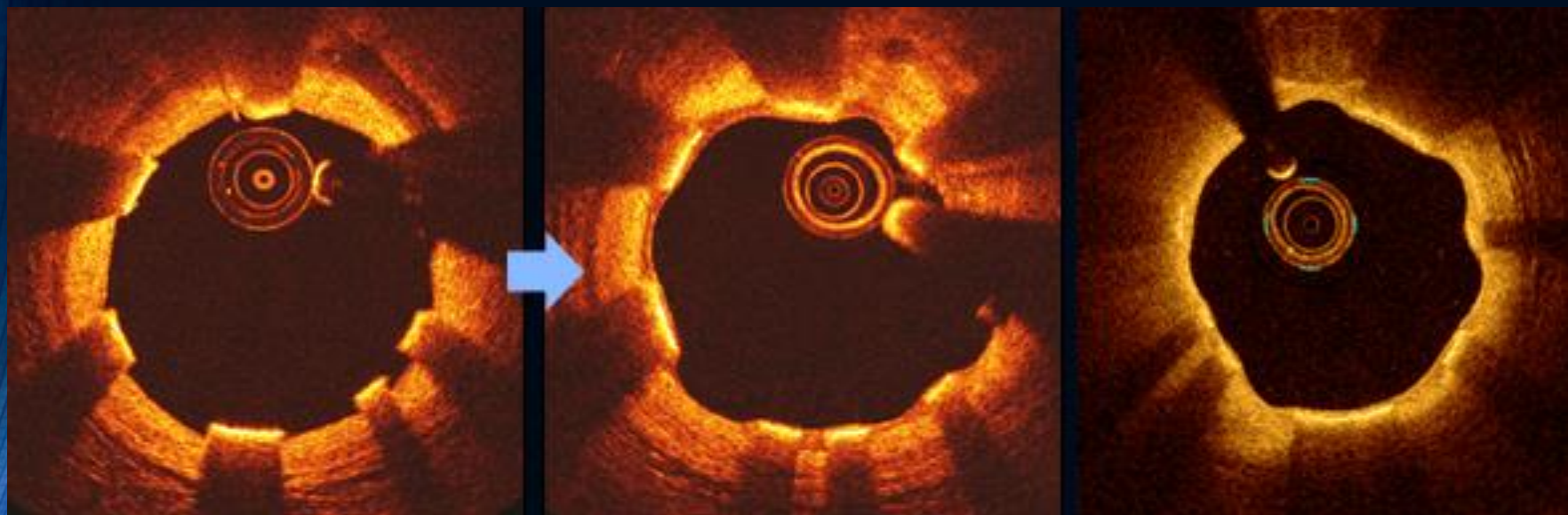


FANTOM angiographic signature

- Radiopacity
- Covalently bound iodine in the polycarbonate backbone



FANTOM OCT signature



Baseline

6 month FU

9 month FU

FANTOM BRS by 3D OCT

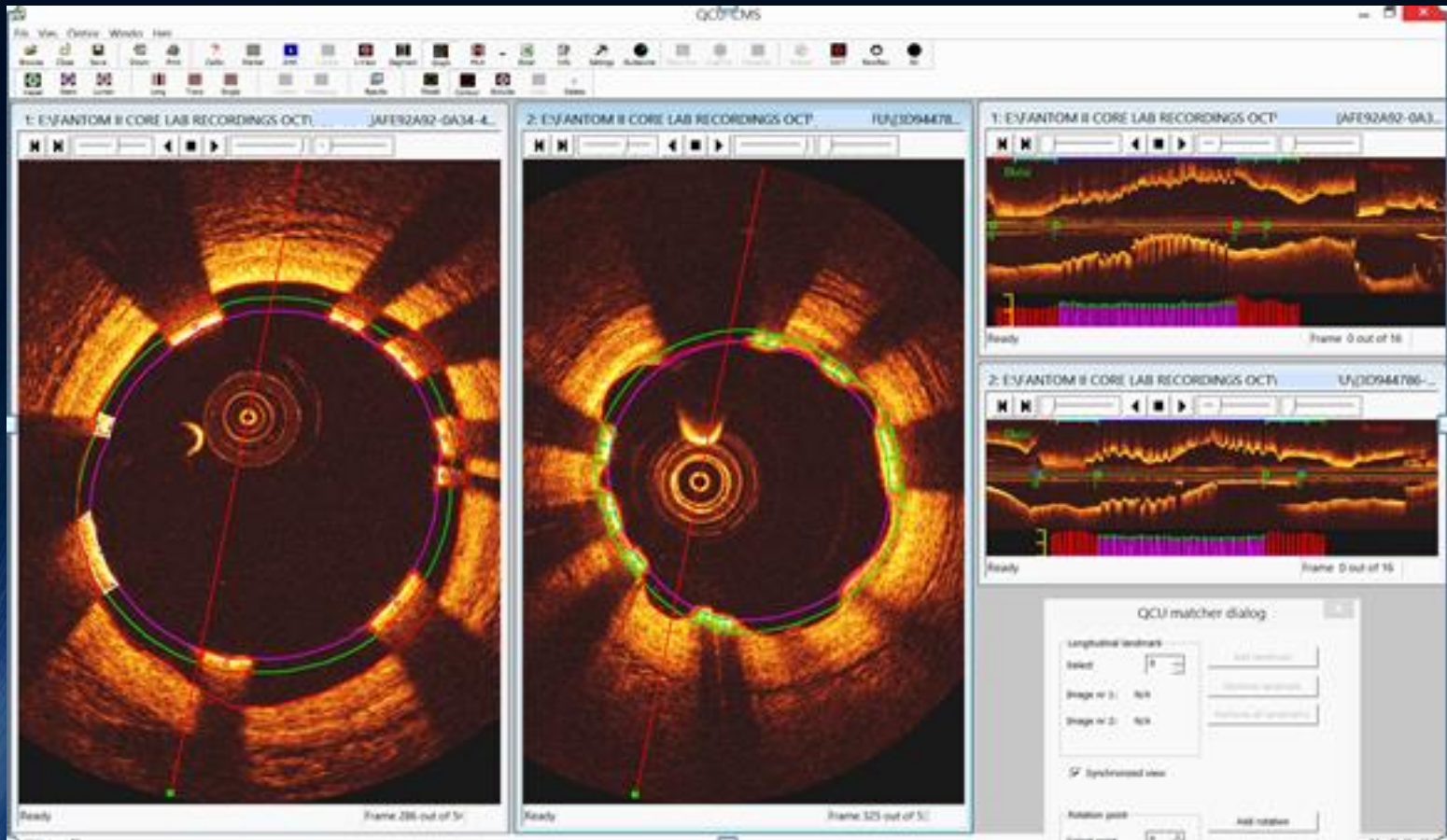


3D OCT by St Jude OPTIS

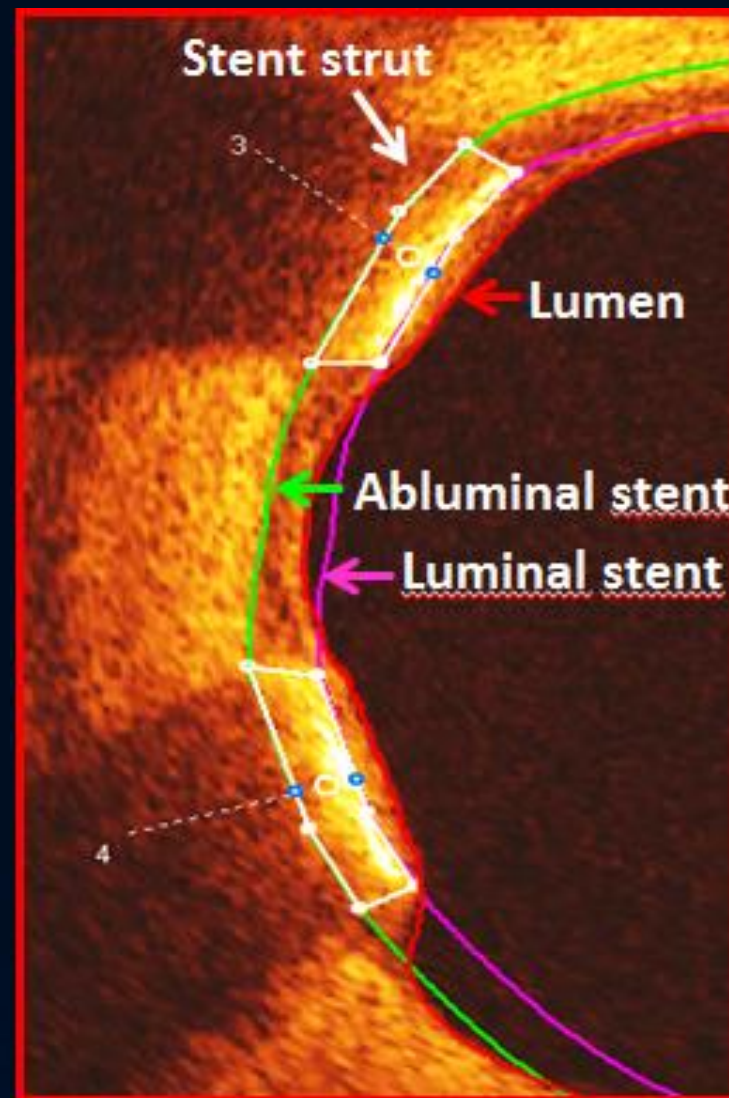
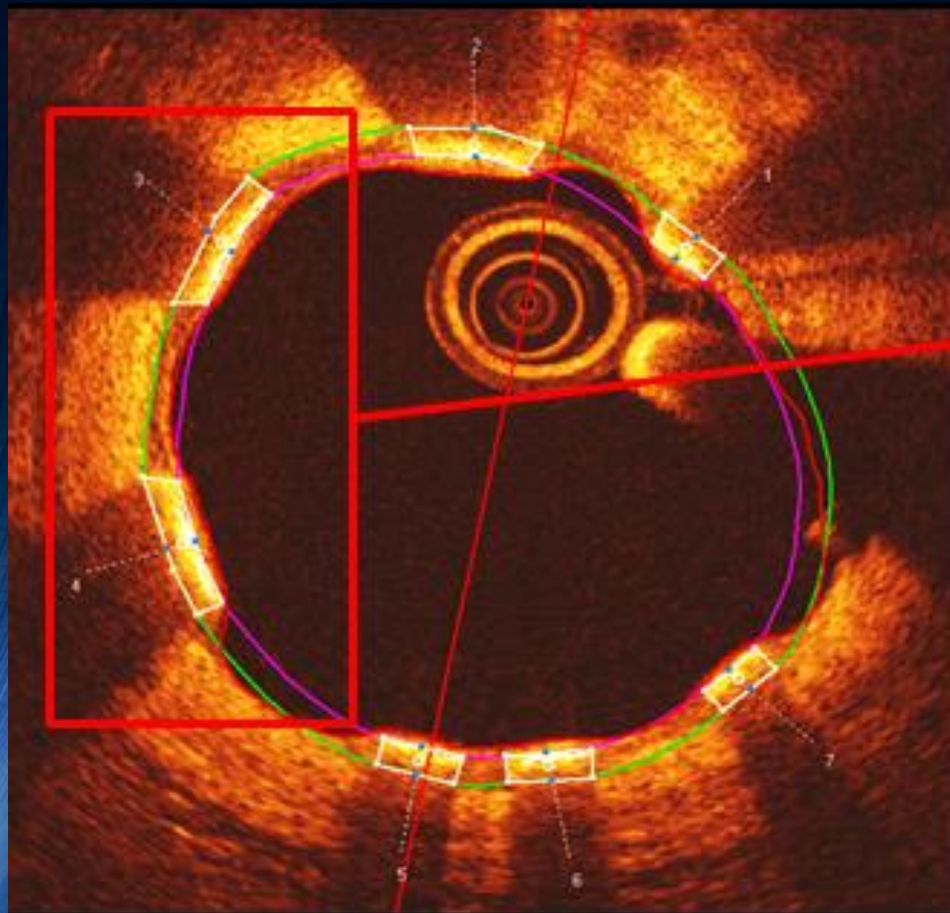
3D OCT by St Jude OPTIS

REVA FANTOM II – OCT analysis

OCT billede af baseline og FU strut



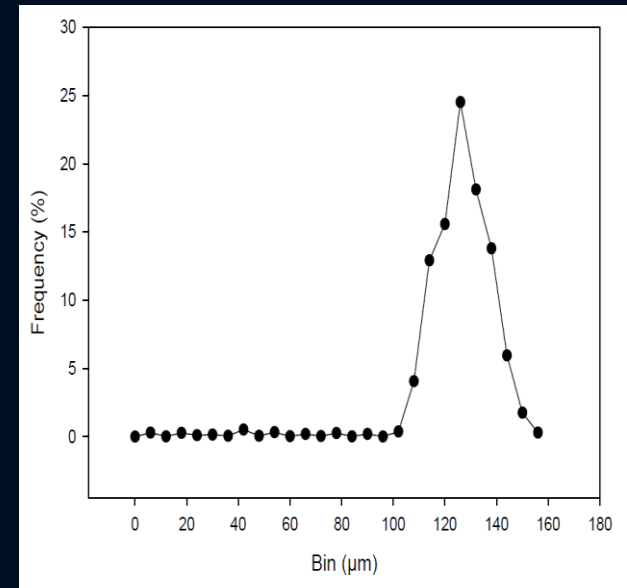
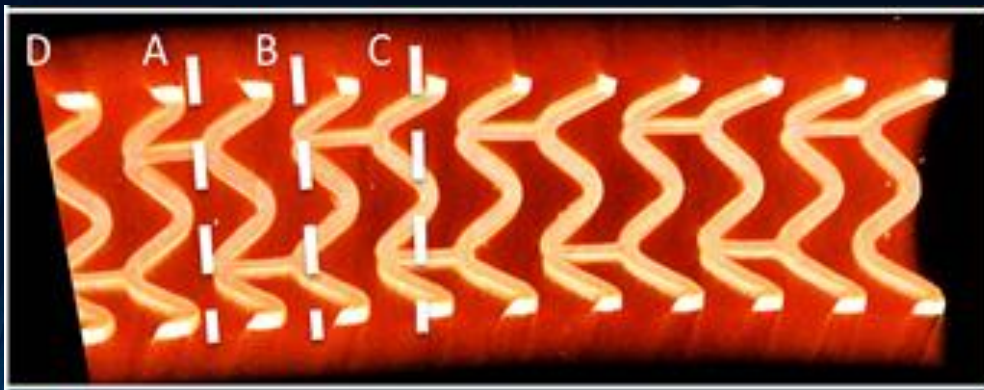
Customized analysis



QCU-CMS, Leiden University Medical Center, The

REVA FANTOM II

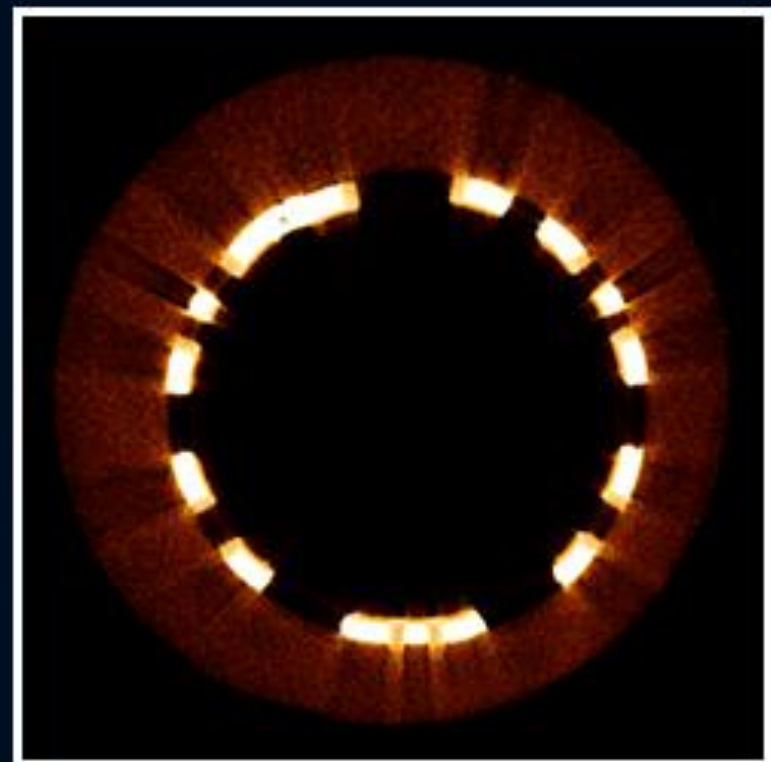
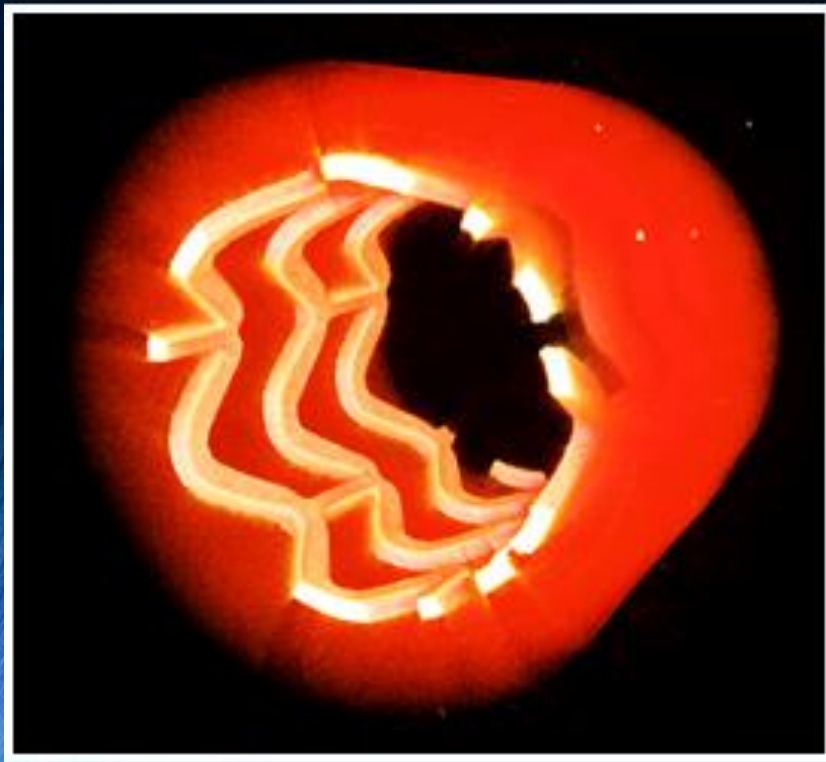
OCT analysis optimized and validated by micro-CT



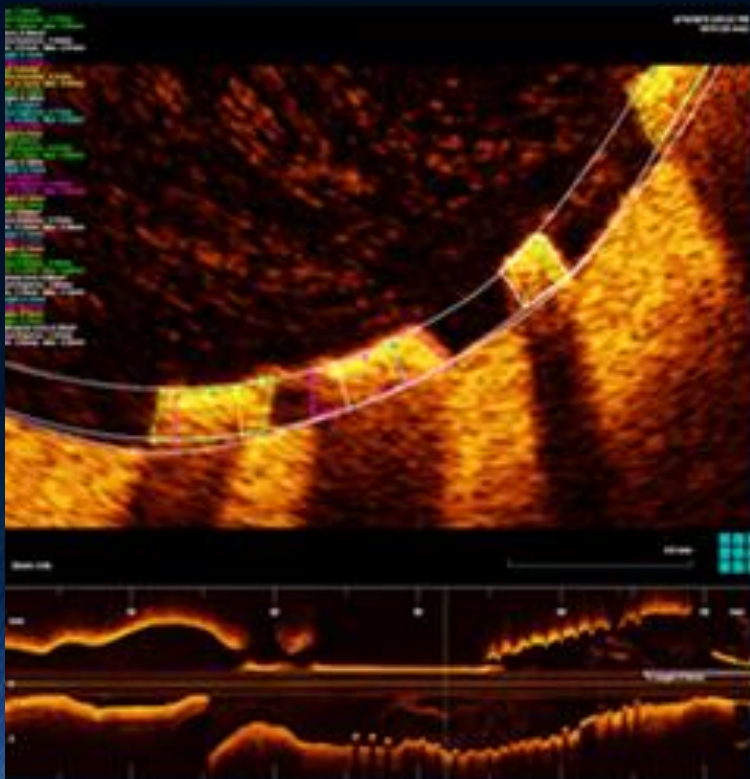
Strut thickness by micro-CT

REVA FANTOM II

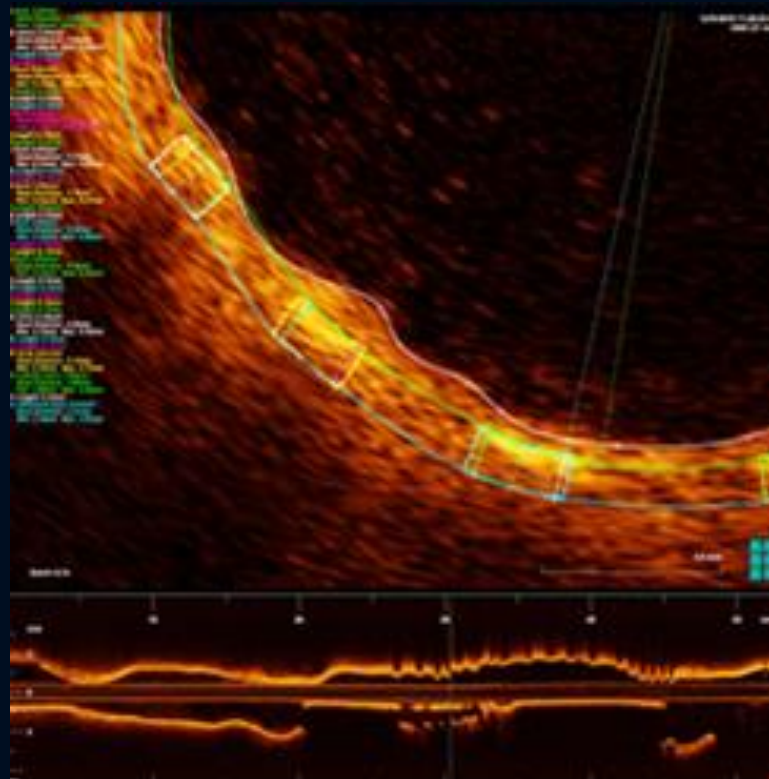
OCT analysis optimized and validated by micro-CT



REVA FANTOM II



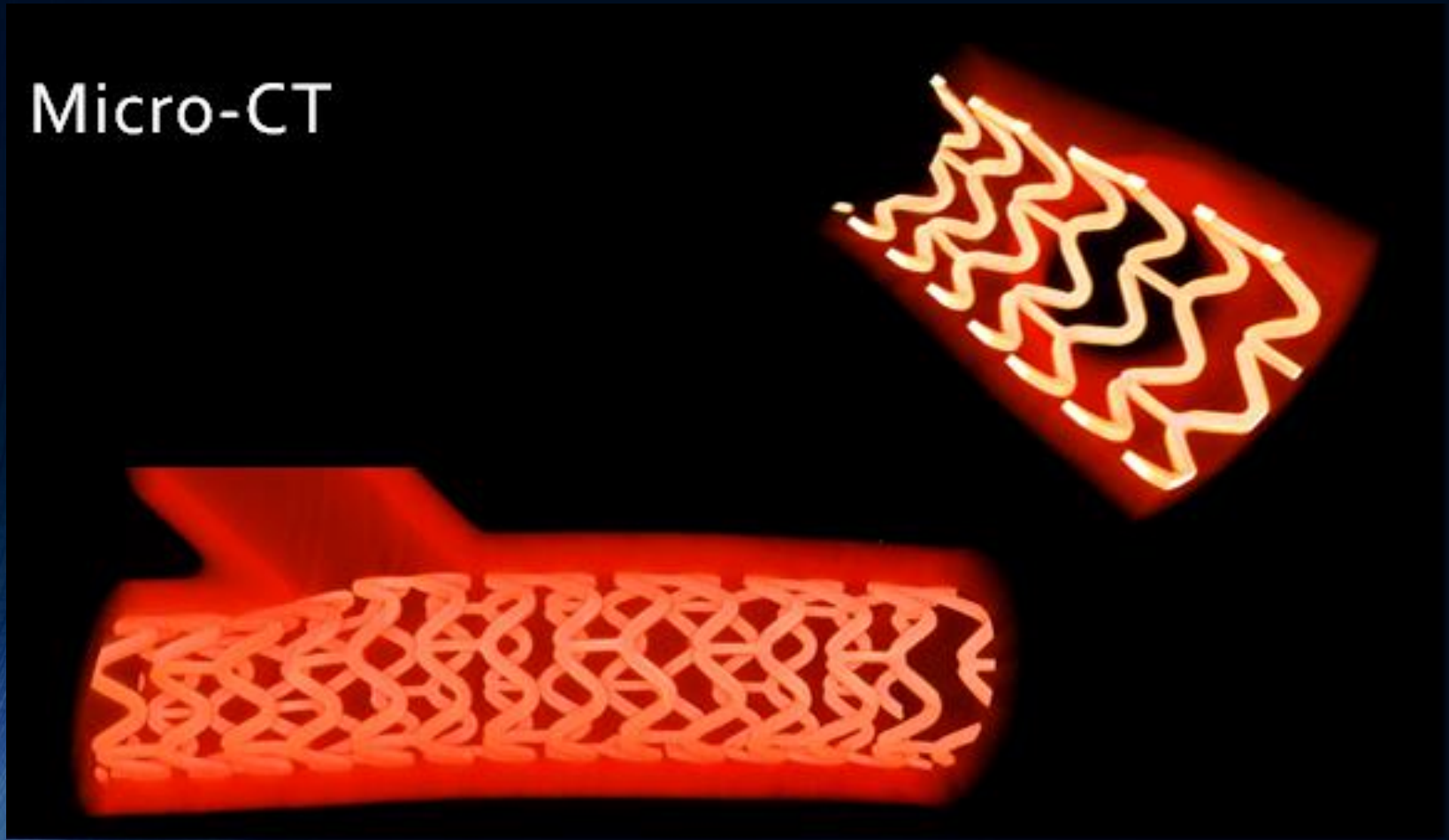
Baseline

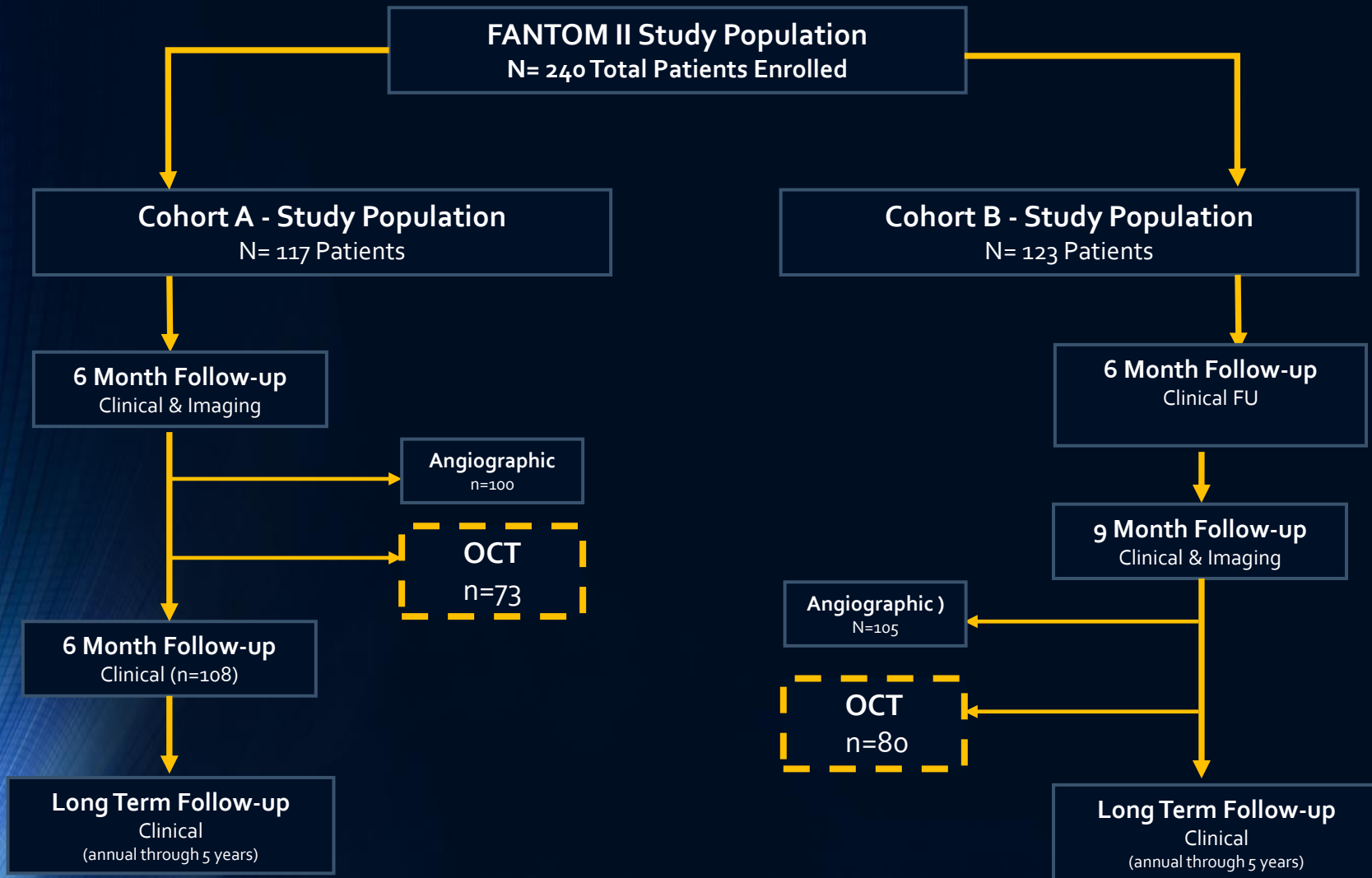


FU

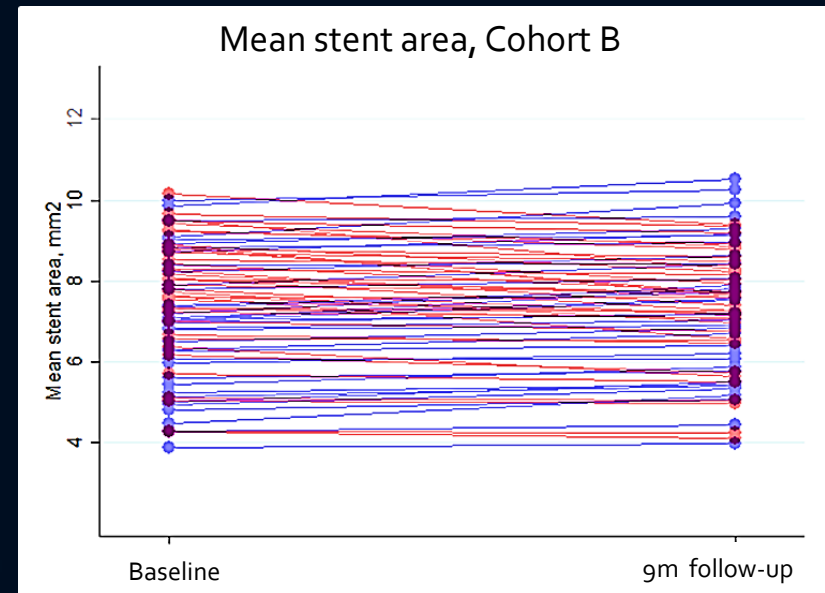
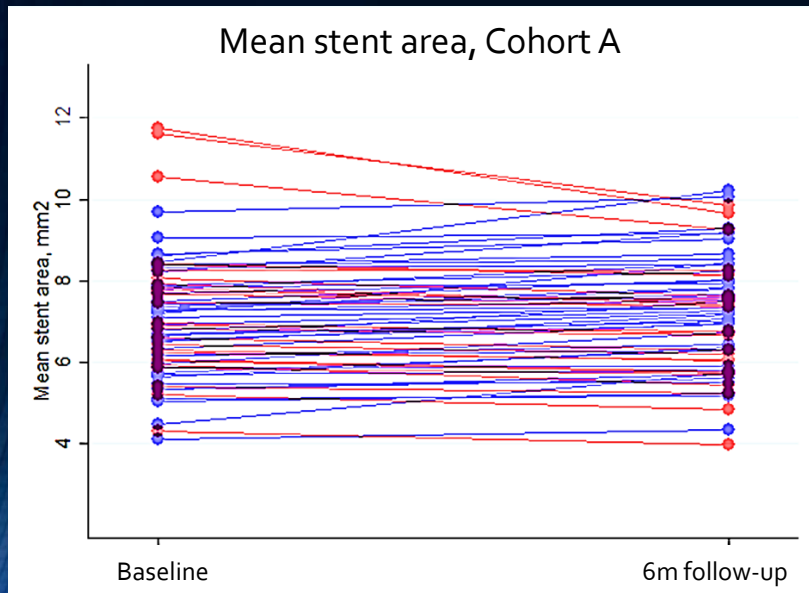
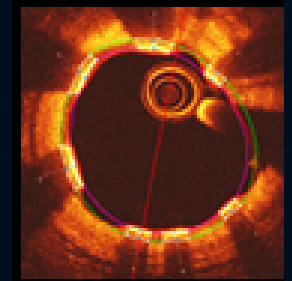
FANTOM in bifurcations

FANTOM II



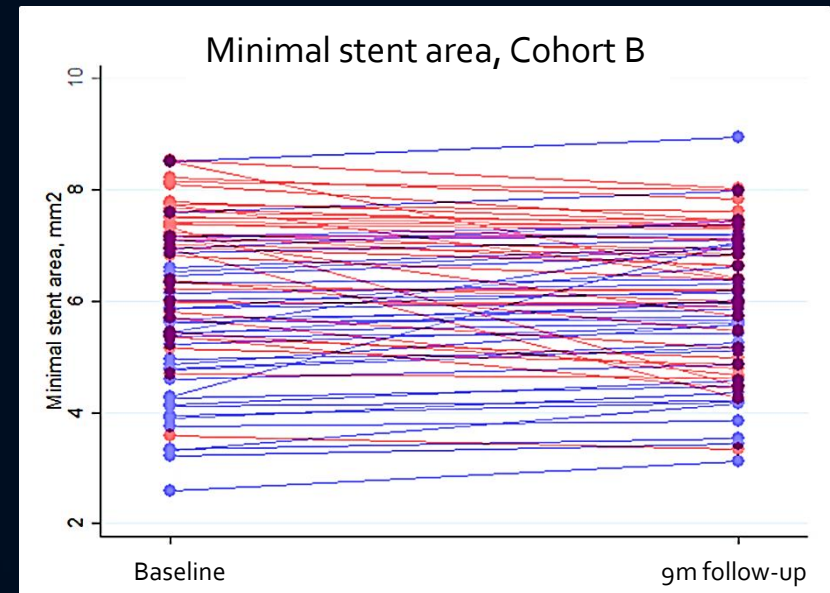
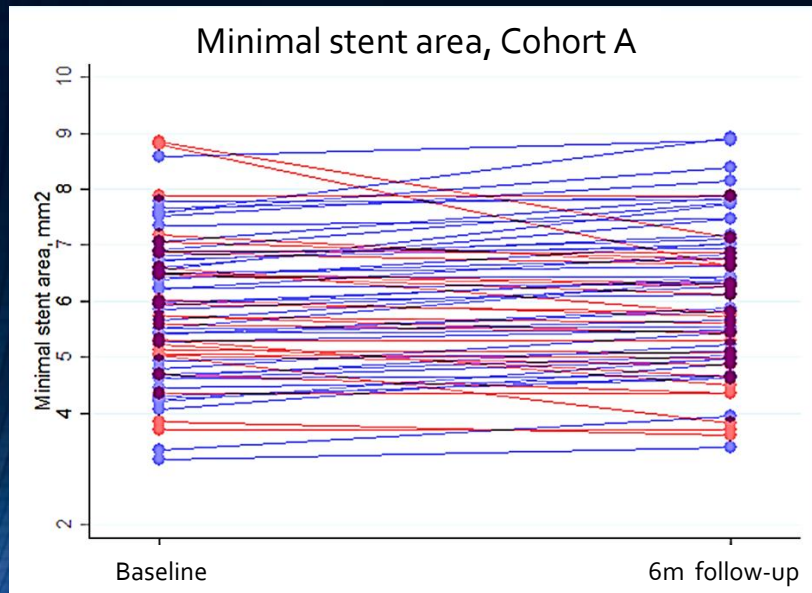
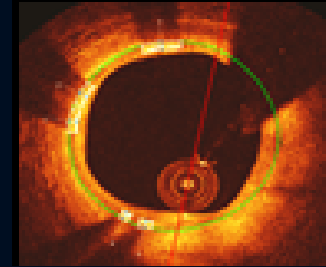


Mean stent area



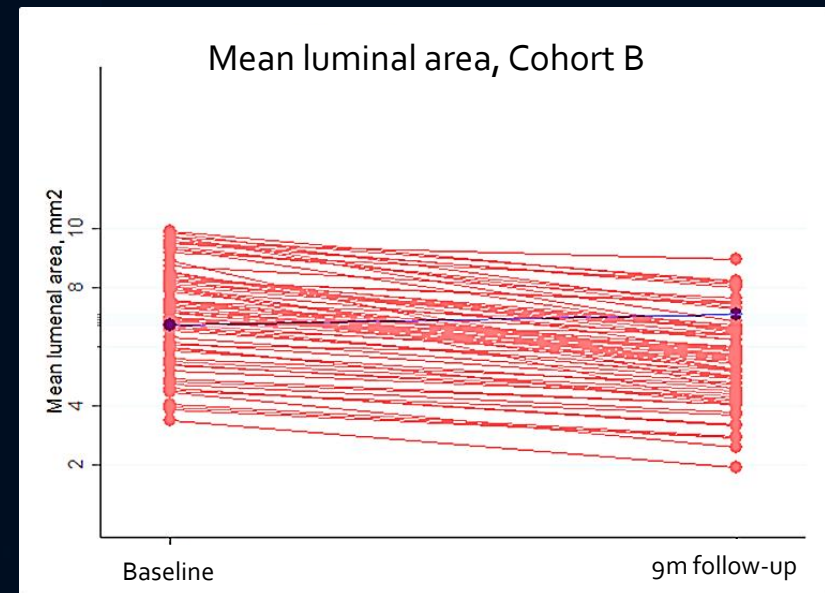
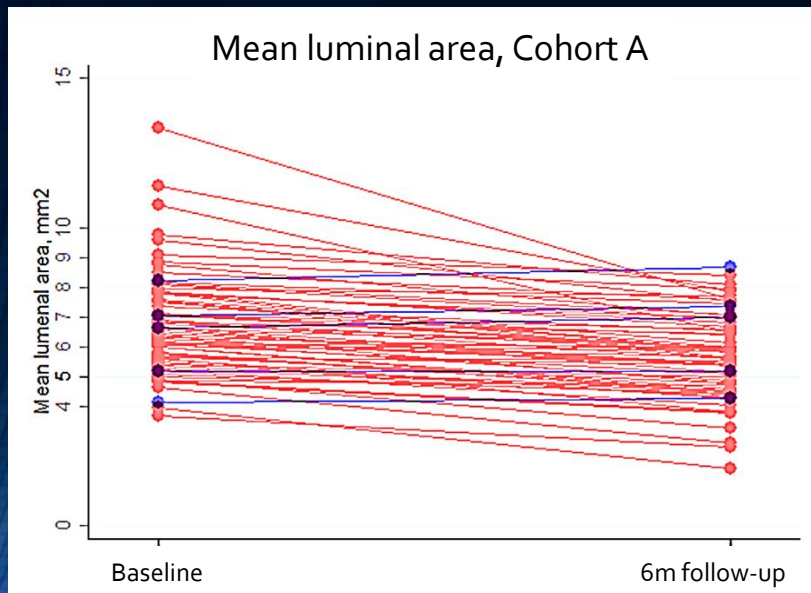
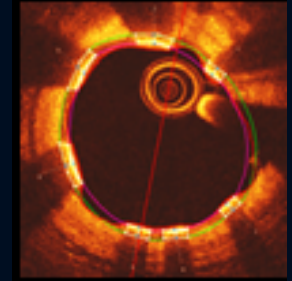
		Baseline	Follow-up	Difference	p-value
Mean stent area (mm ²)	Cohort A	7.1 (1.5)	7.2 (1.4)	0.1 (-0.02;0.24)	0.12
	Cohort B	7.4 (1.6)	7.3 (1.5)	-0.1(-0.2;0.0)	0.16

Minimal stent area



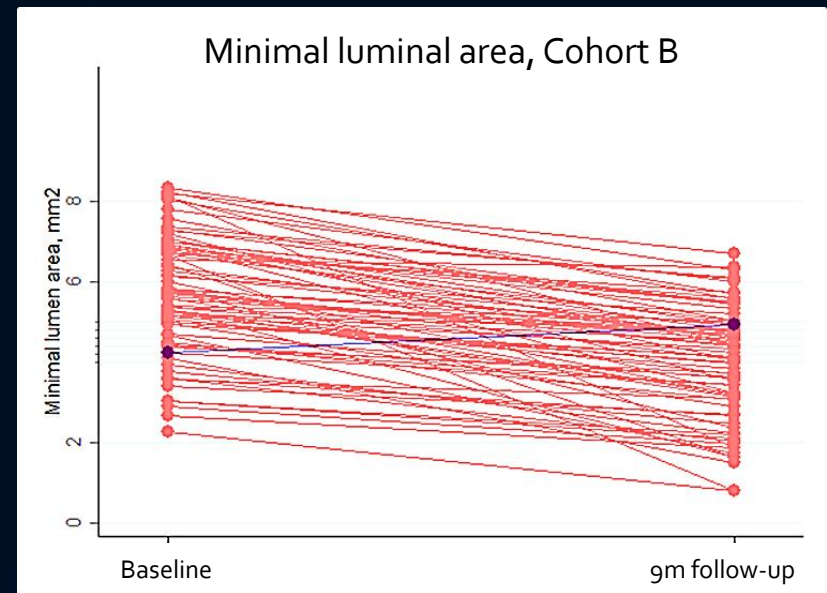
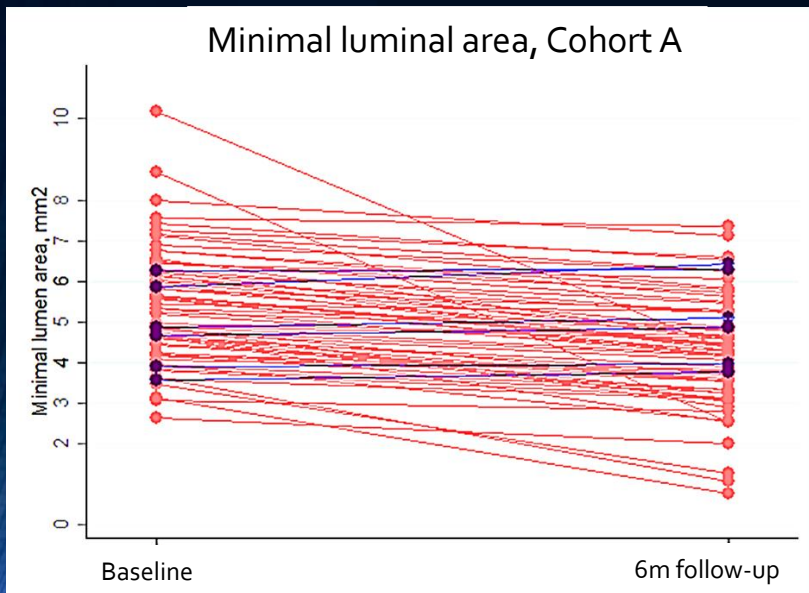
		Baseline	Follow-up	Difference	p-value
Minimal stent area (mm ²)	Cohort A	7.1 (1.5)	7.2 (1.4)	0.1 (-0.02;0.24)	0.12
	Cohort B	6.1 (1.4)	6.0 (1.3)	-0.1(-0.2;0.1)	0.43

Mean lumen area



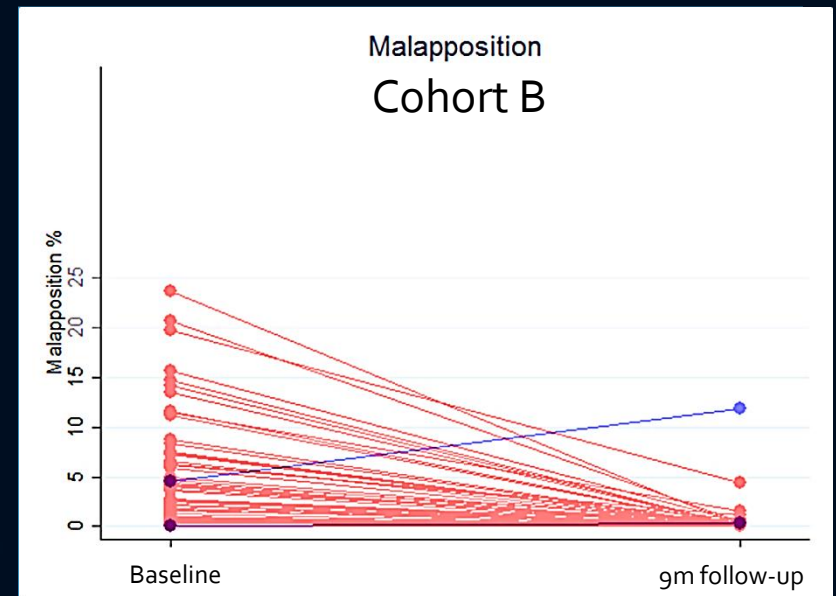
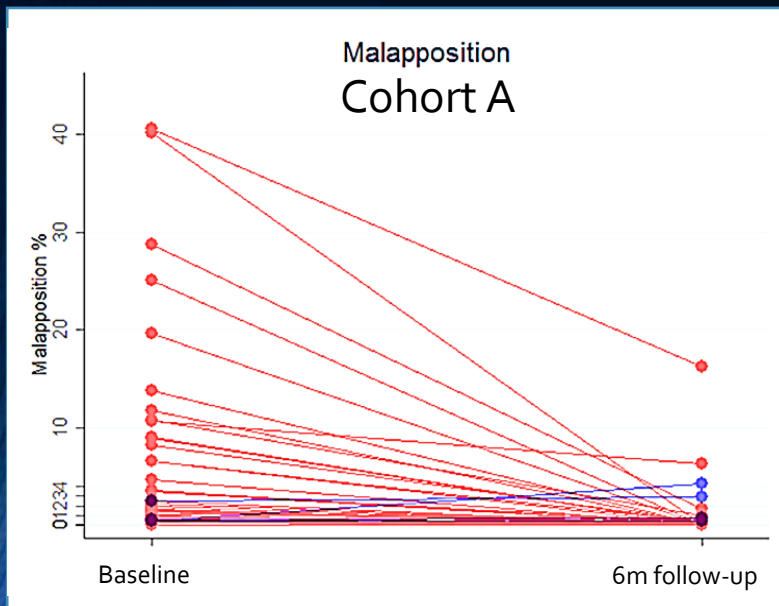
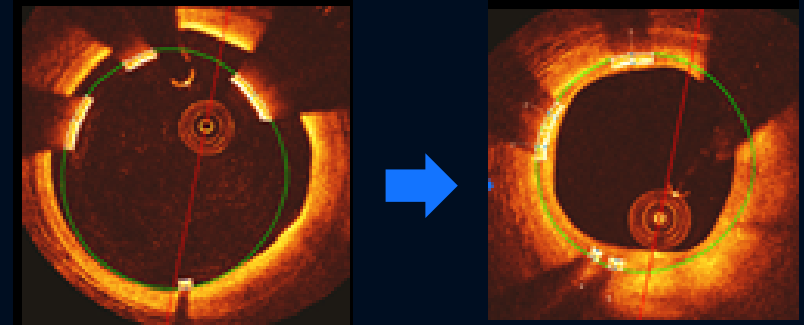
		Baseline	Follow-up	Difference	p-value
Mean lumen area (mm ²)	Cohort A	6.8 (1.7)	5.7 (1.4)	-1.1 (-1.3;-0.9)	<0.0001
	Cohort B	7.1 (1.6)	5.6 (1.5)	-1.6 (-1.7;-1.4)	<0.0001

Minimal lumen area



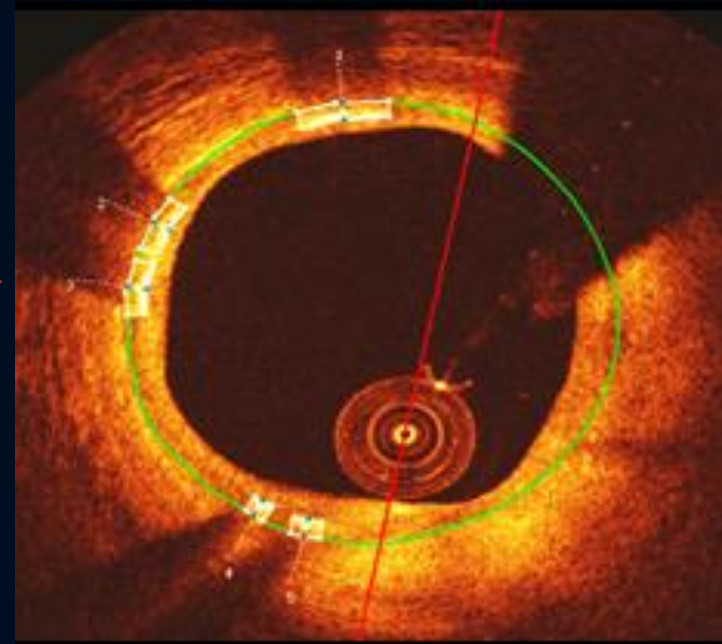
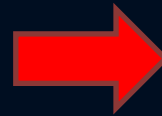
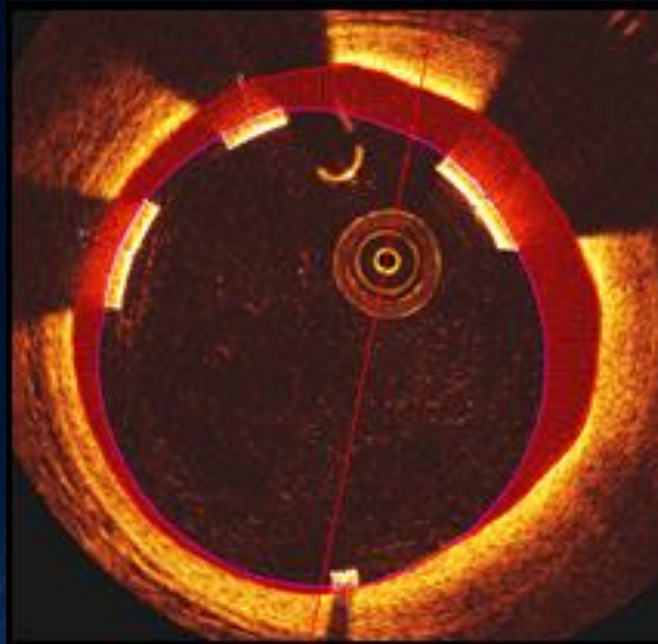
		Baseline	Follow-up	Difference	p-value
Minimal lumen area (mm ²)	Cohort A	6.8 (1.7)	5.7 (1.4)	-1.1 (-1.3;-0.9)	<0.0001
	Cohort B	5.7 (1.4)	4.0 (1.4)	-1.7(-1.9;-1.4)	<0.0001

Malapposition



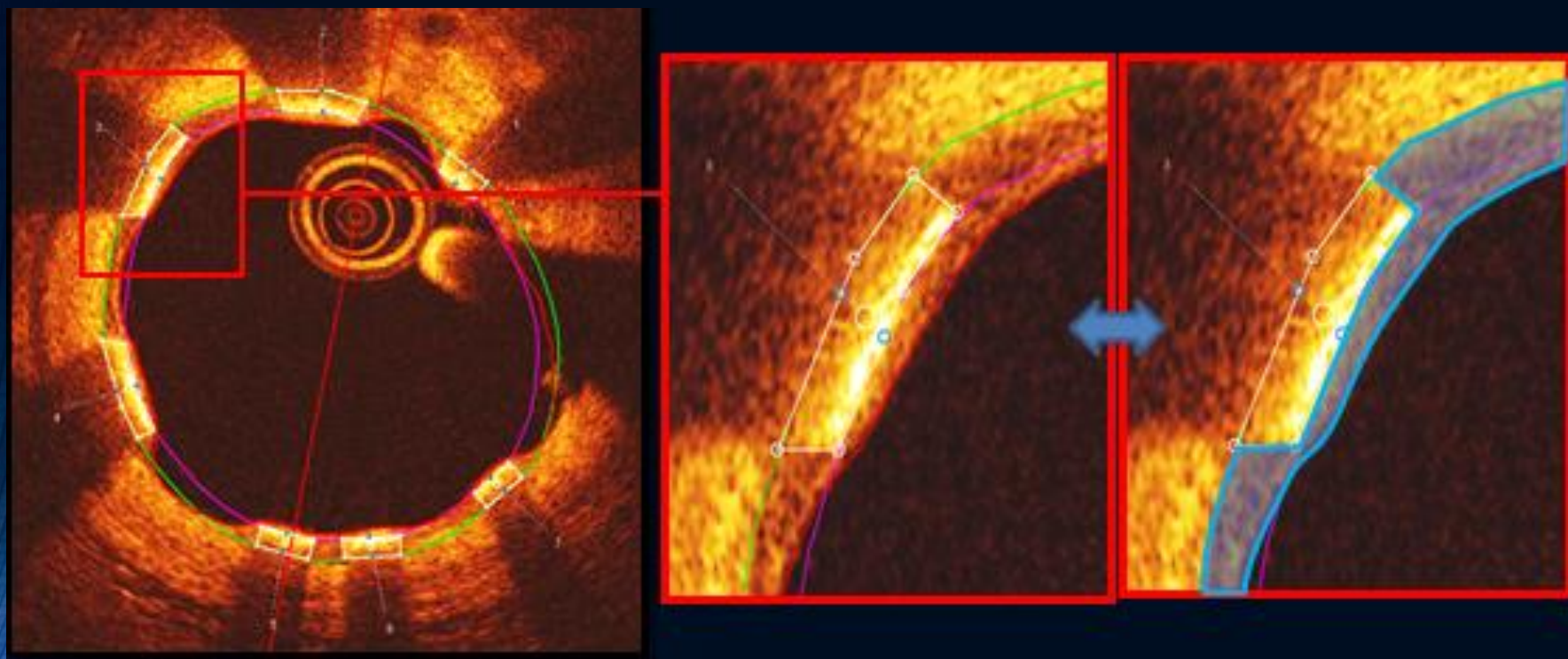
		Baseline	Follow-up
Malapposition	Cohort A	0.8% (0.0;3.5)	0.0% (0.0;0.0)
	Cohort B	1.6% (0.1;5.2)	0.0% (0.0;0.0)

Extra-stent lumen



		Baseline	Follow-up
Extra stent lumen area (mm ²)	Cohort A	0.05 (0.02;0.13)	0.00 (0.00;0.02)
Extra stent lumen area (mm ²)	Cohort B	0.08 (0.03;0.18)	0.00 (0.00;0.02)

Neointimal area

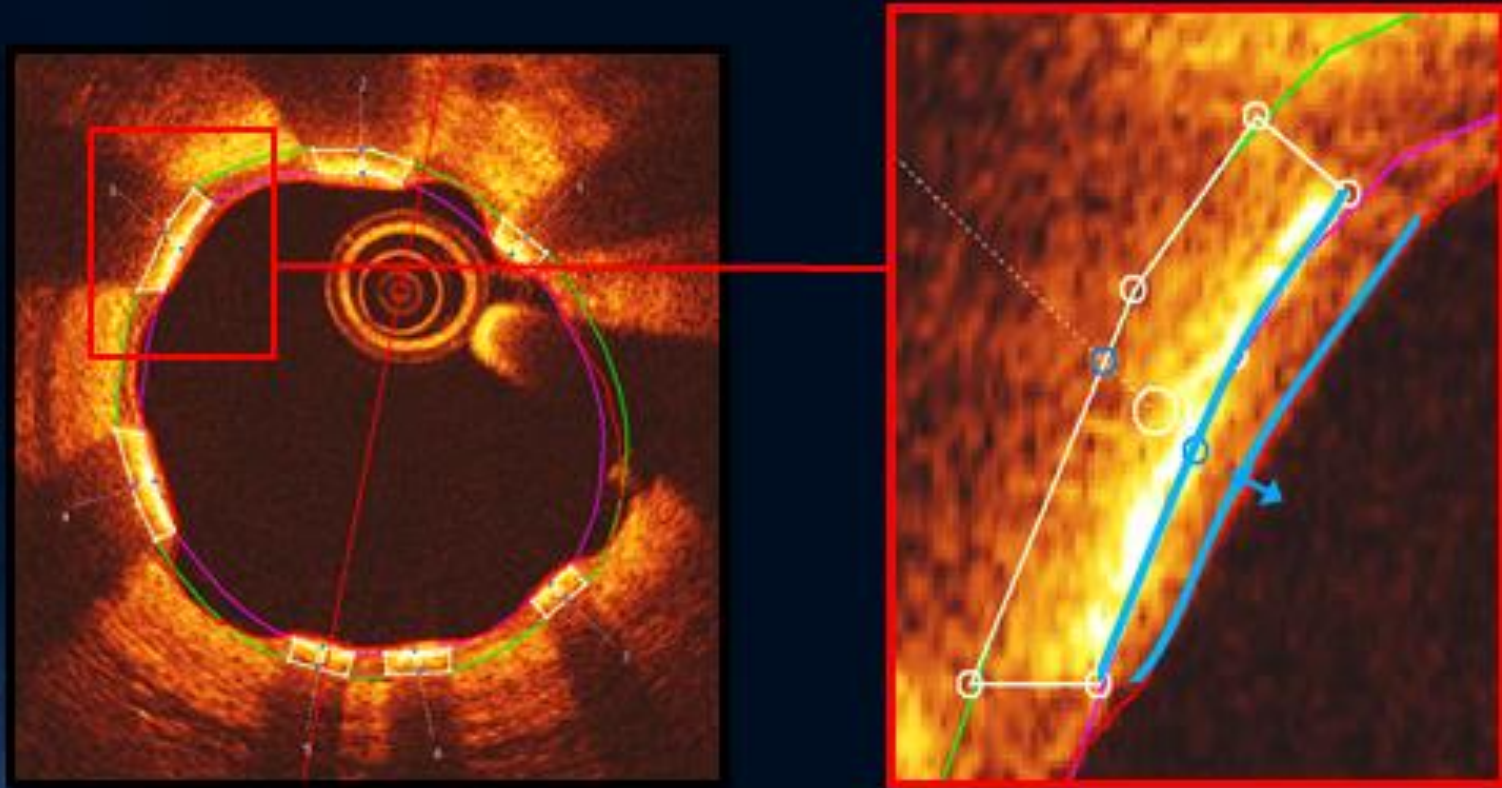
6 months **Cohort A**9 months **Cohort B**Mean neointimal area (mm²)

1.2 (1.0;1.4)

1.4 (1.2;1.7)

Median (IQR)

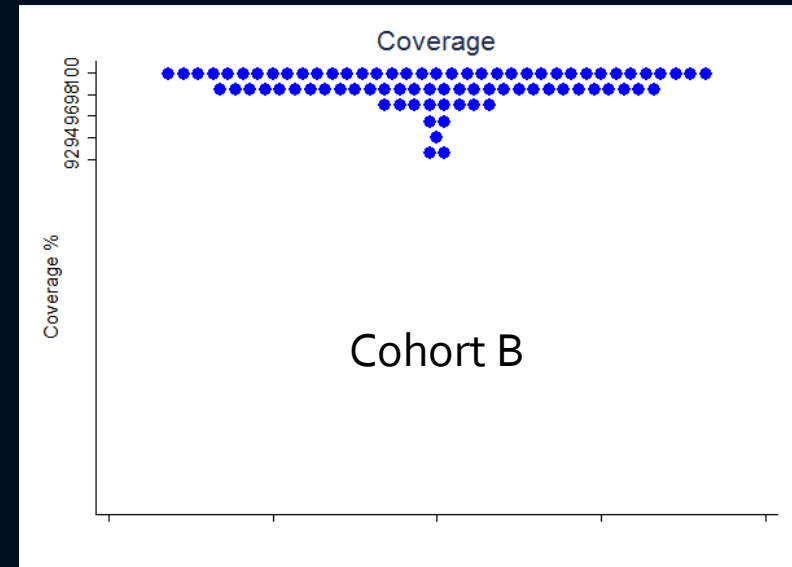
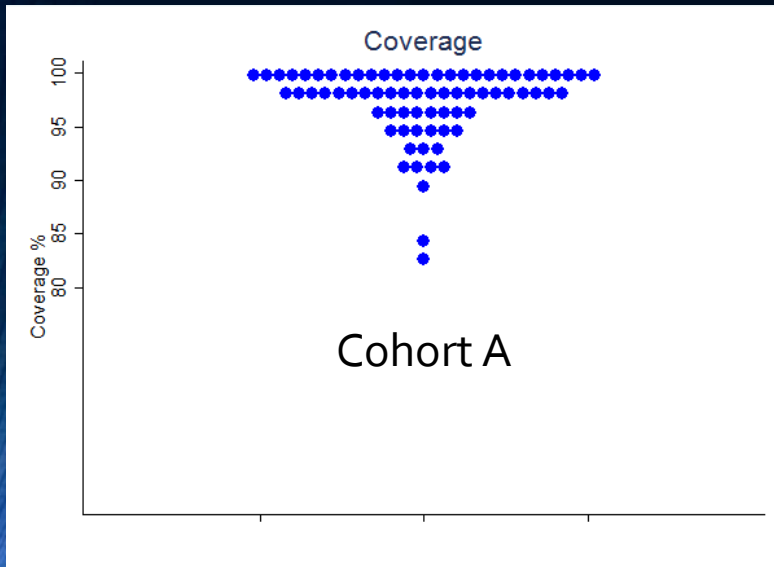
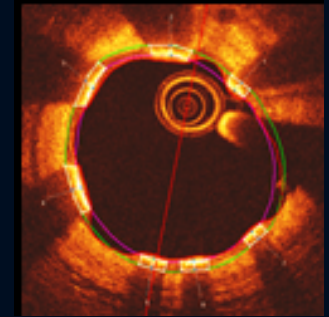
Neointimal thickness



	6 months Cohort A	9 months Cohort B
Mean neointimal thickness (μm)	57 (40;77)	77 (57;105)

Median (IQR)

Strut coverage



6 months **Cohort A**

9 Months **Cohort B**

Covered struts

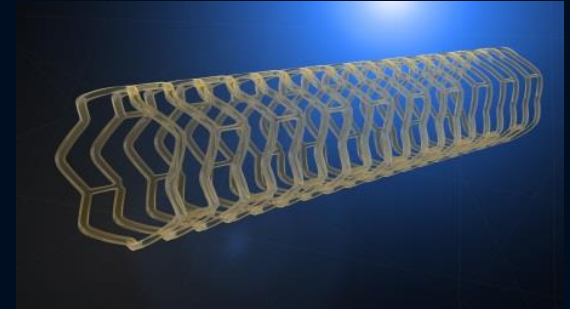
98.1% (95.9;99.4)

99.0% (98.3;100.0)

Strut-level results

Conclusion

The Fantom BRS show promising healing patterns after 6 and 9 months



- OCT properties allows for in-procedure 3D evaluation
- Expected slight decrease in lumen area after 9 months
- No stent area reduction – no late recoil
- High completeness of strut coverage
- Limited neointimal growth
- Excellent resolution of acute extra-stent lumen and malapposition