REVA FANTOM II

Performance and healing patterns by OCT
Two-year serial follow-up

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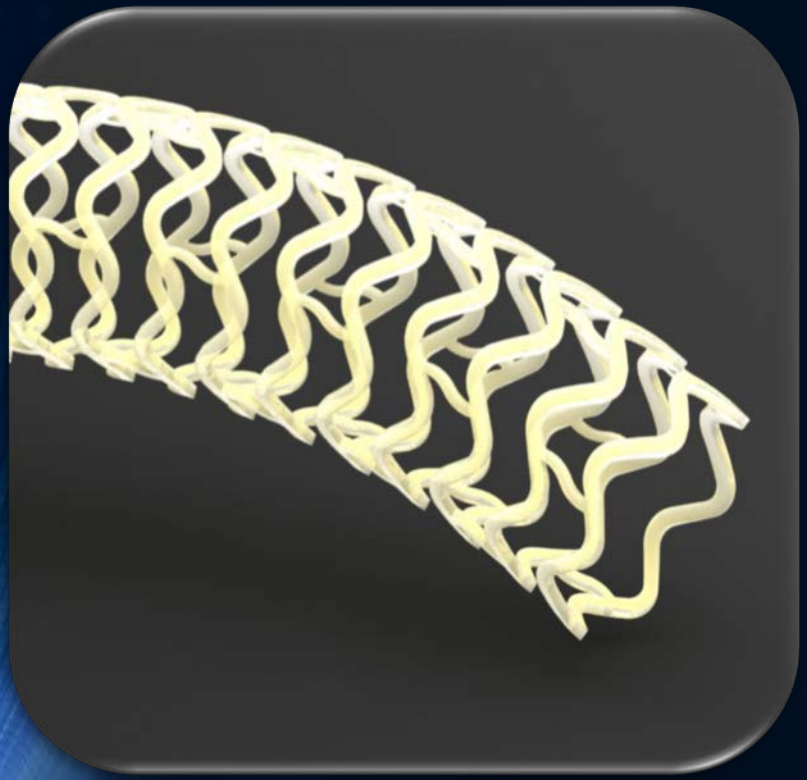
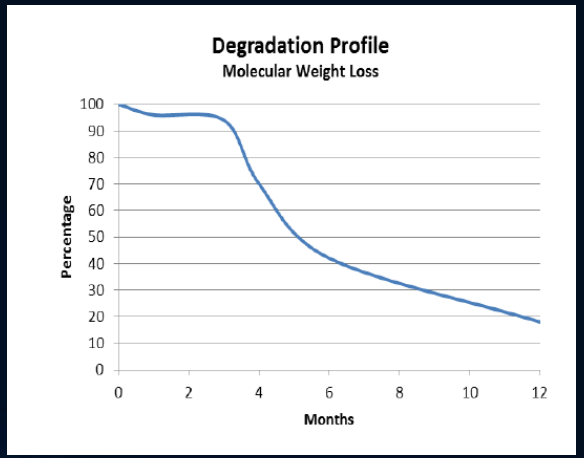
On behalf of the FANTOM II investigators

euro PCR

The FANTOM BRS

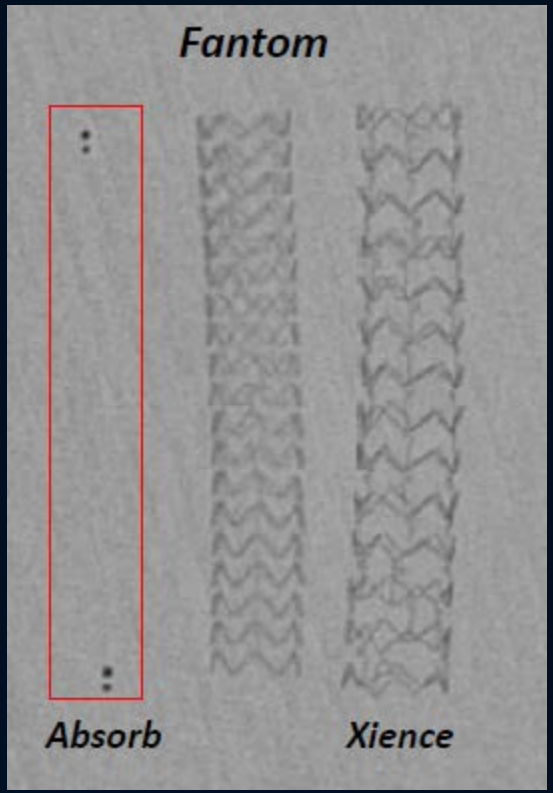


- Desaminotyrosine based polycarbonate backbone
- Strut thickness 125µm
- Sirolimus eluting for 3 months
- Full resorption within 3-4 years



FANTOM angiographic signature

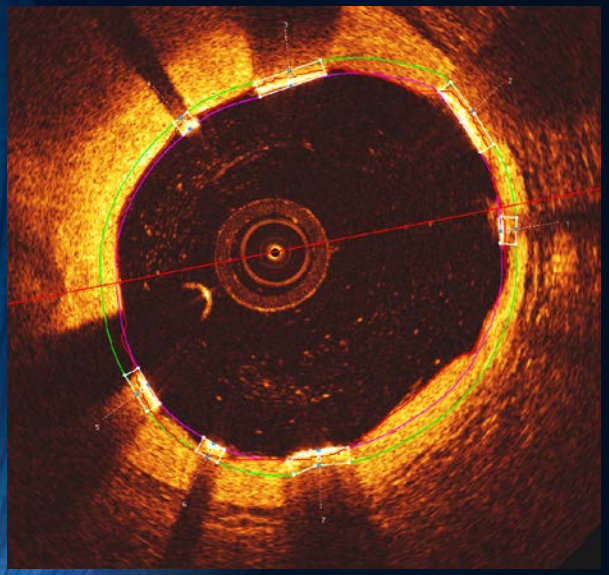
- Radiopacity
- Covalently bound iodine in the polycarbonate backbone



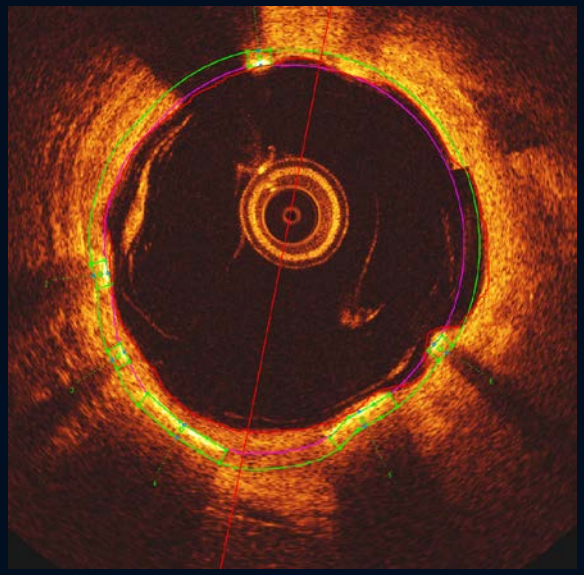
FANTOM BRS by 3D OCT

3D OCT by St Jude OPTIS

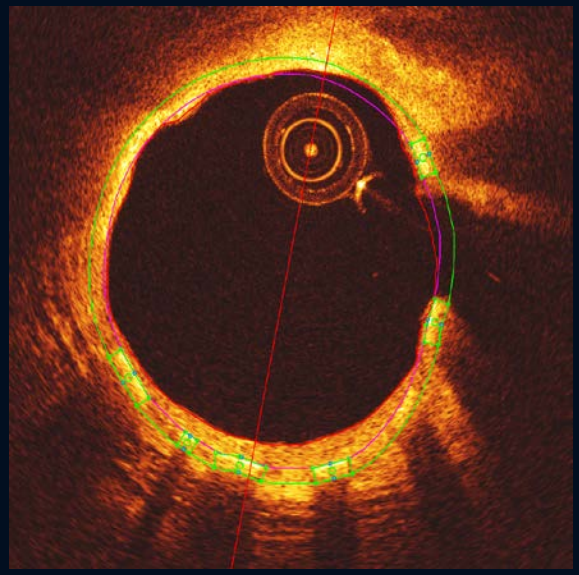
FANTOM OCT signature



Baseline

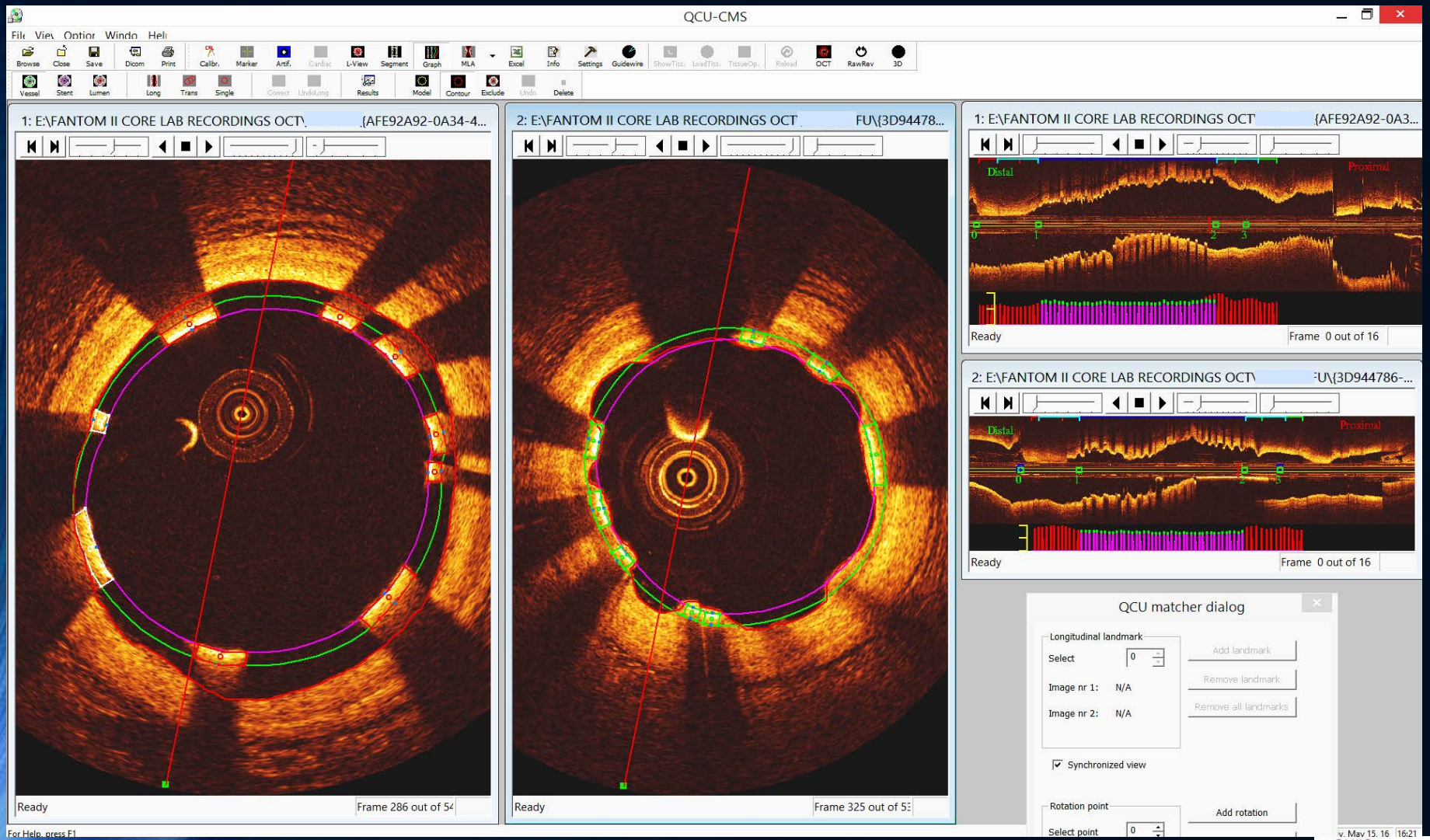


6 month FU

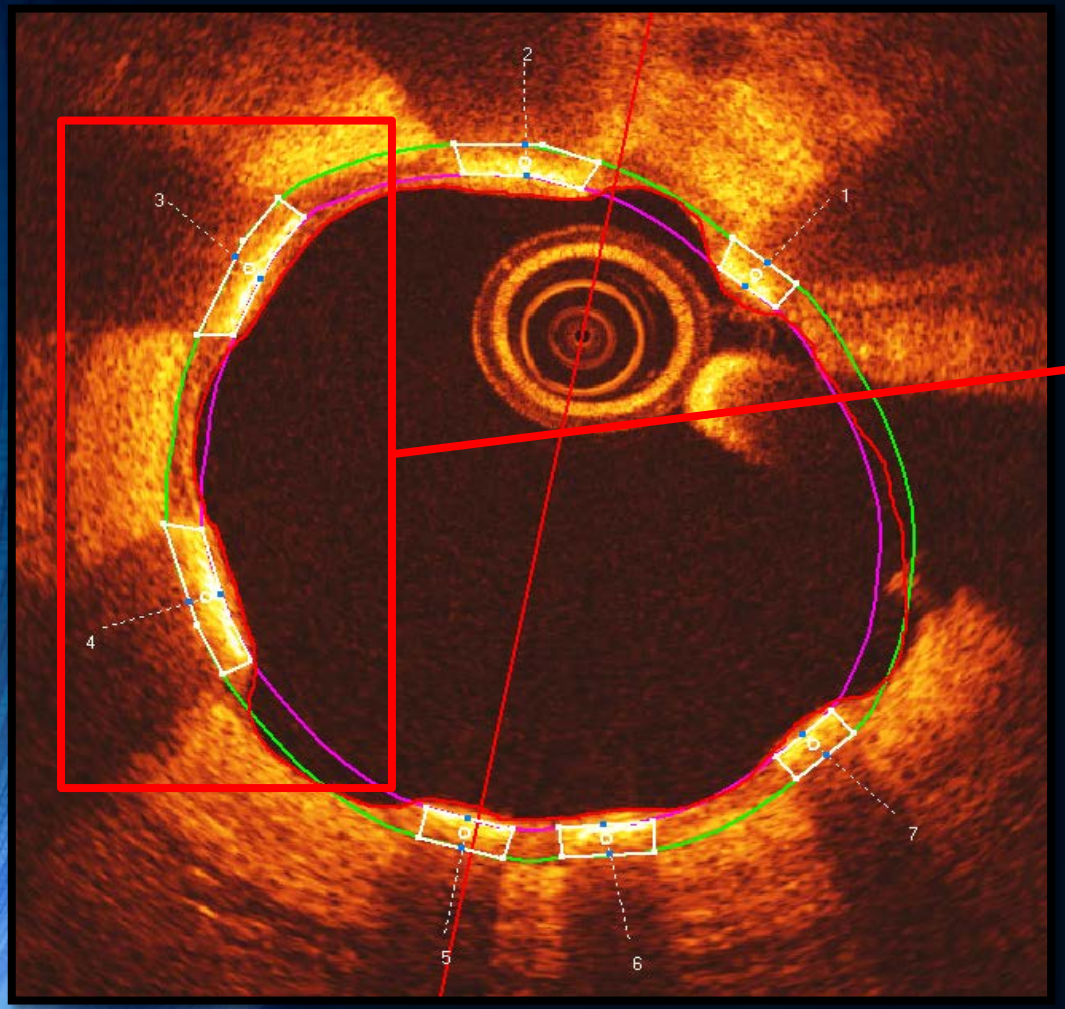


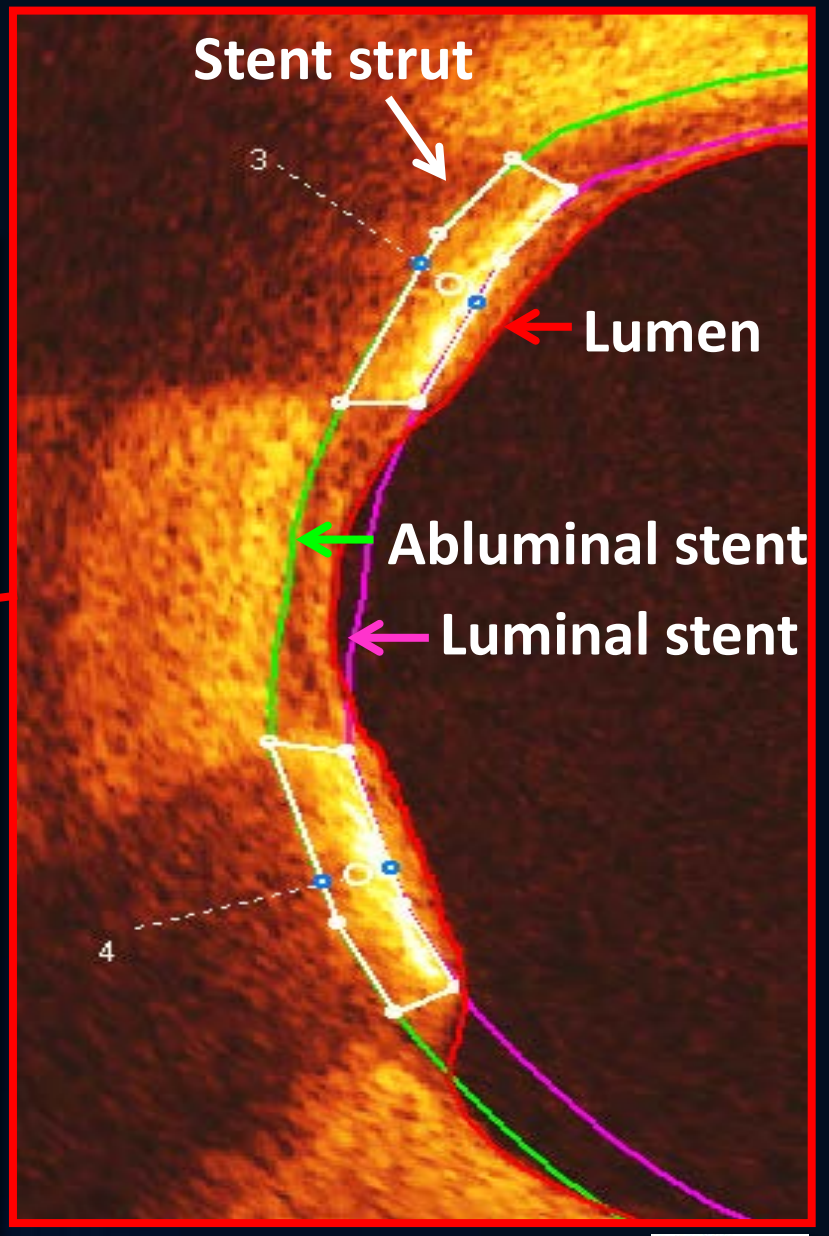
24 month FU

REVA FANTOM II – OCT analysis



Customized analysis

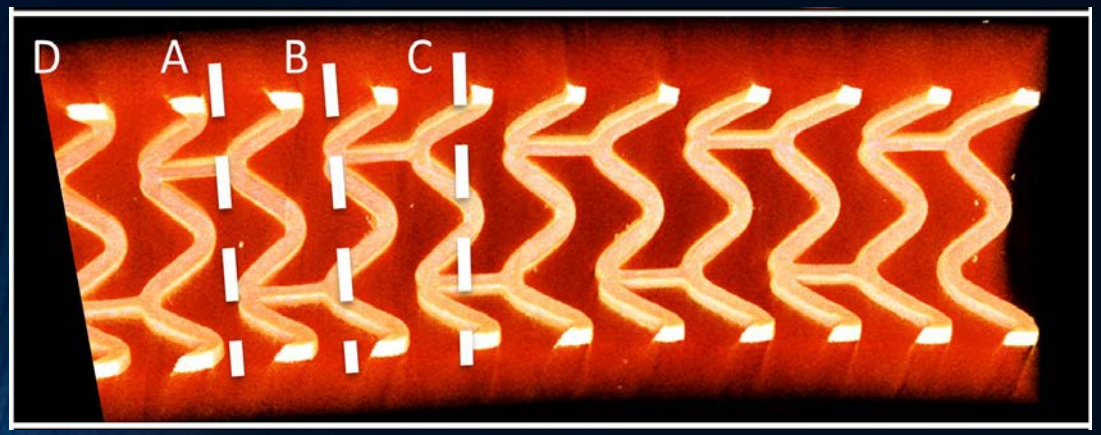


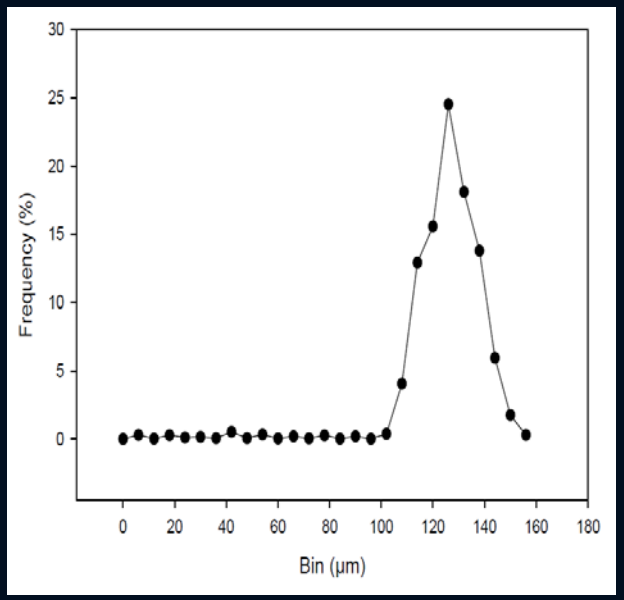


QCU-CMS, Leiden University Medical Center, The Netherlands

REVA FANTOM II

OCT analysis optimized and validated by micro-CT

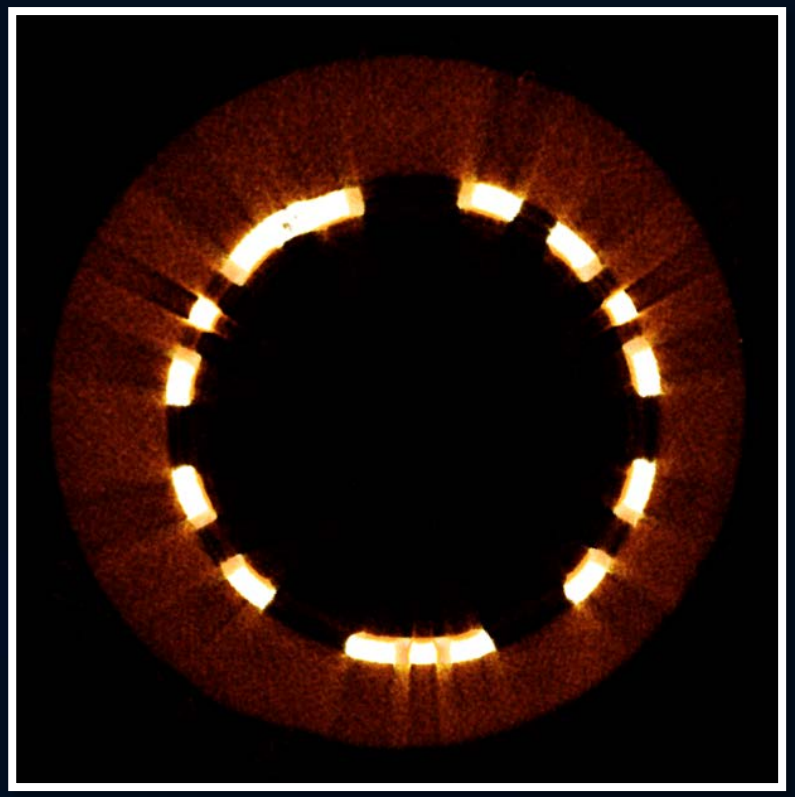




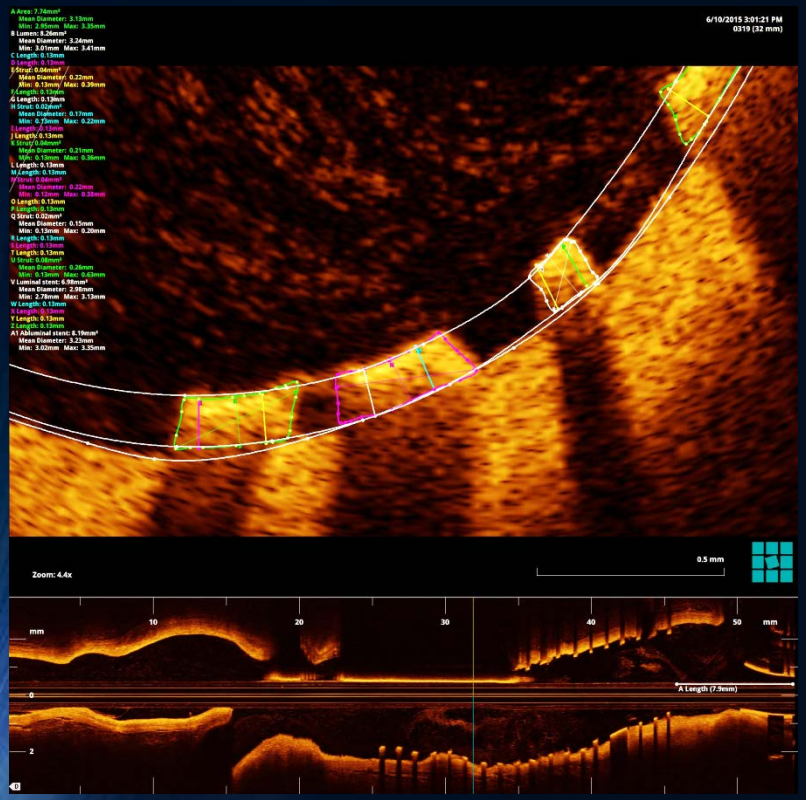
Strut thickness by micro-CT

REVA FANTOM II

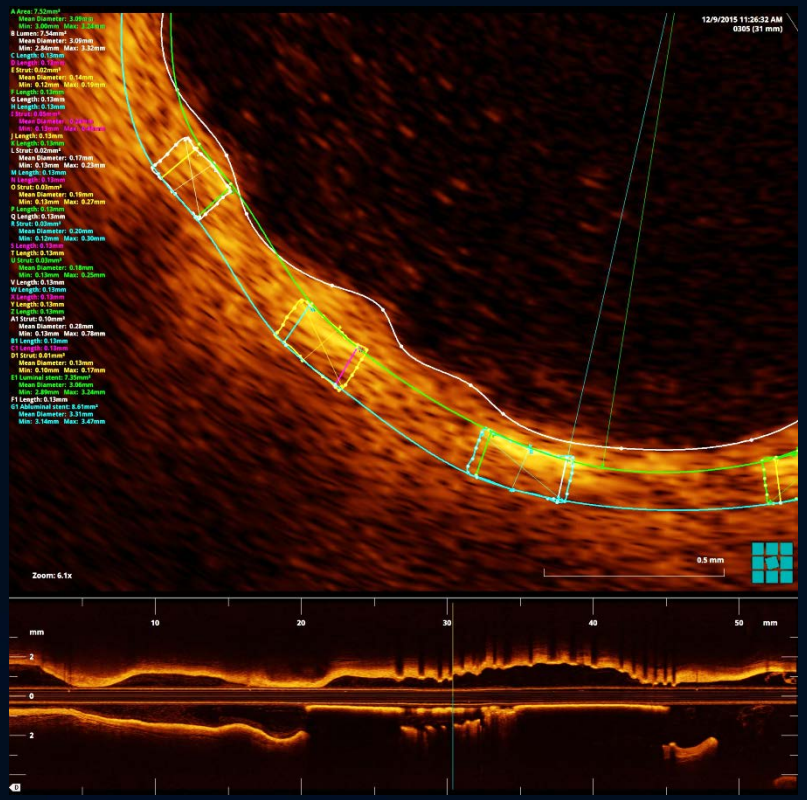
OCT analysis optimized and validated by micro-CT



REVA FANTOM II



Baseline



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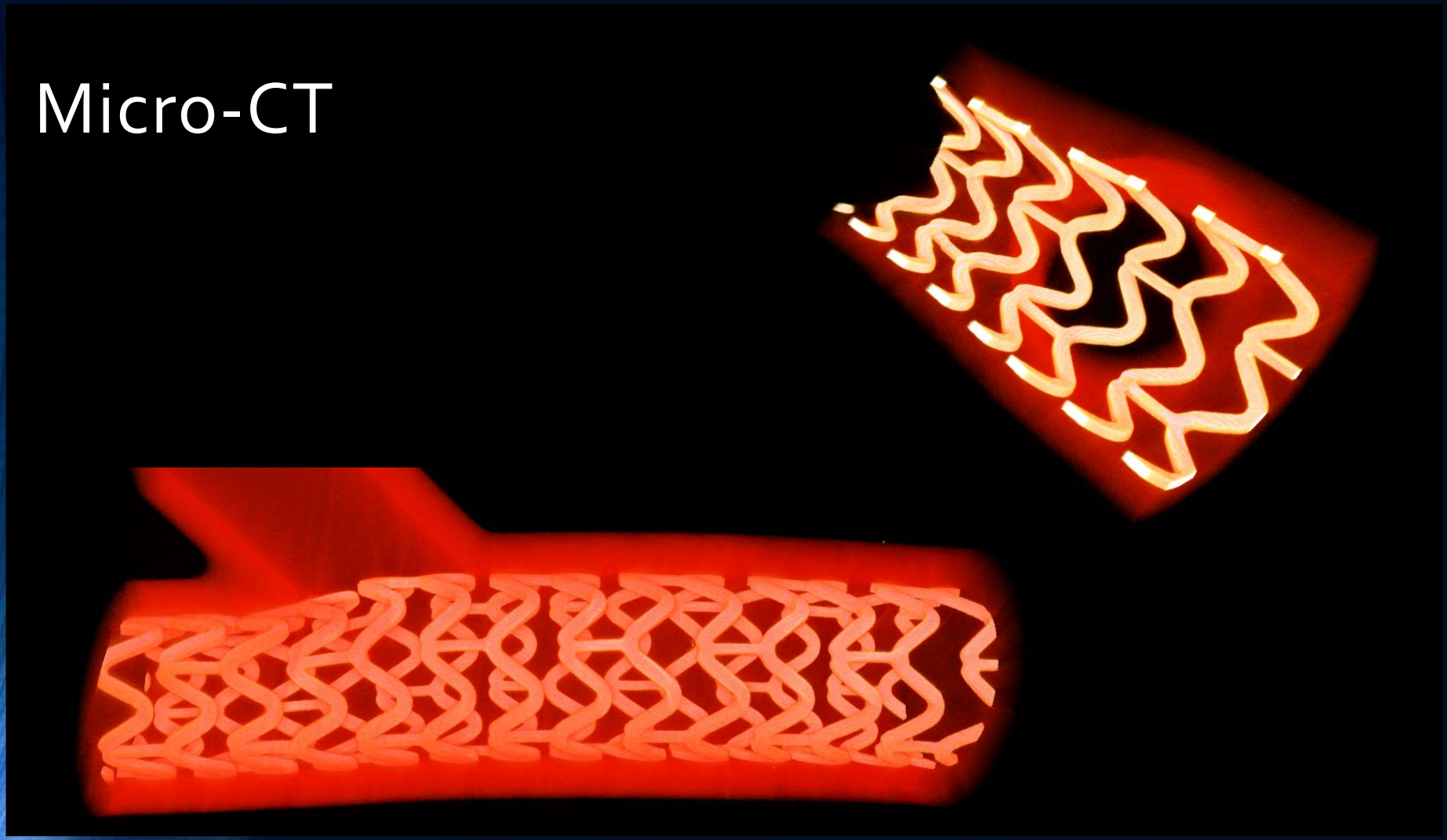
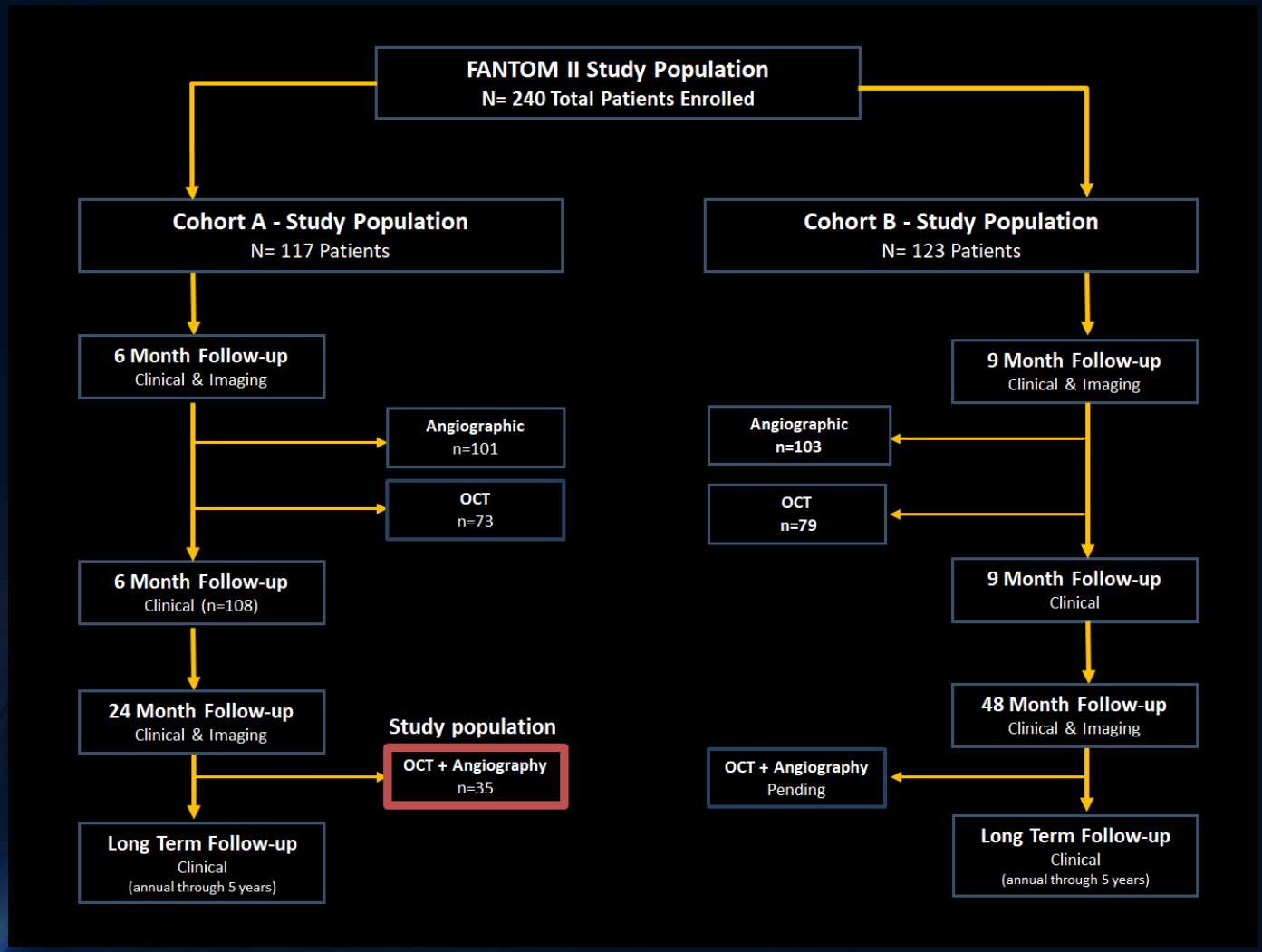
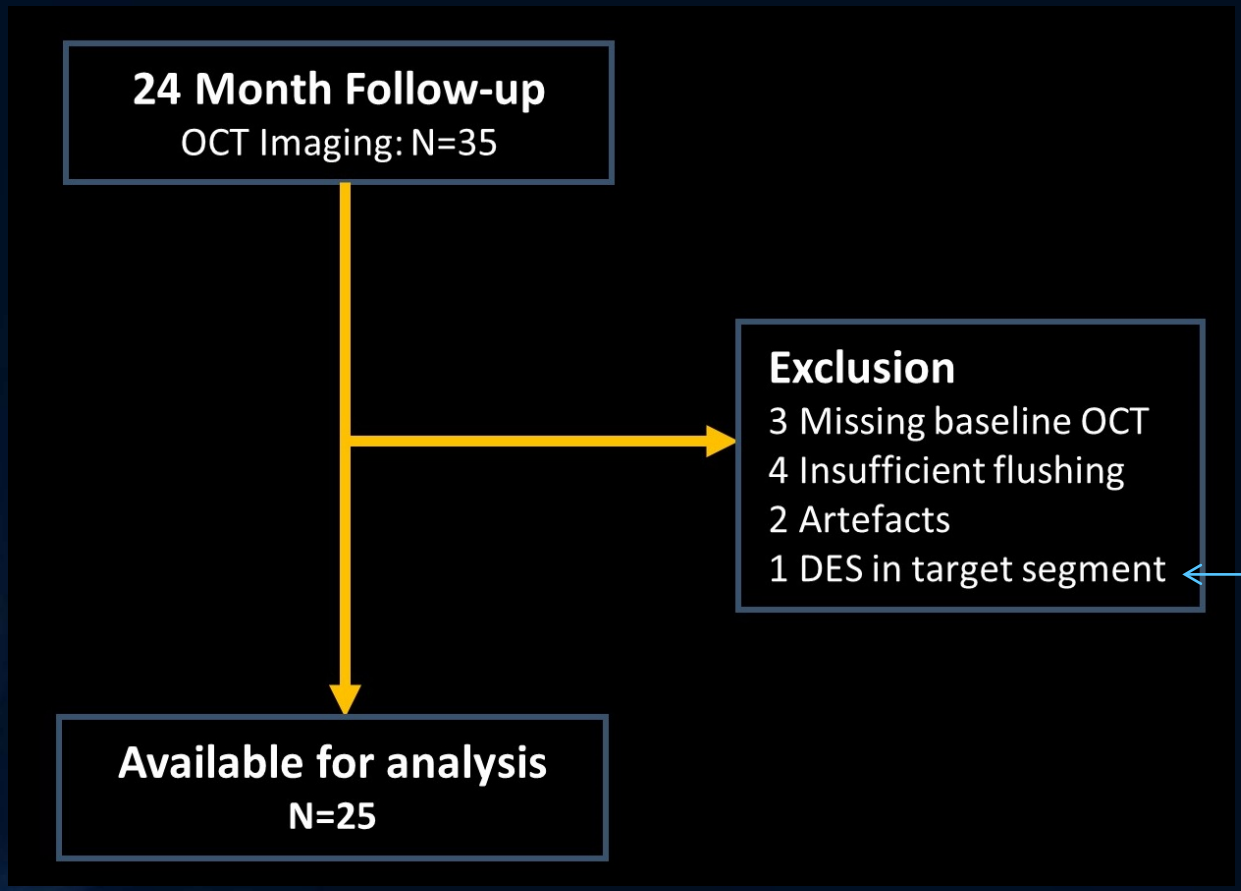
FANTOM in bifurcations



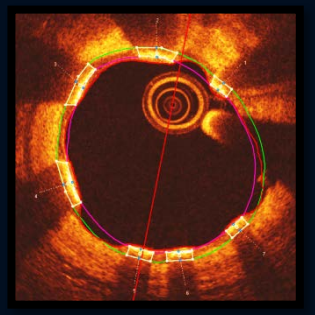
Patient flow chart

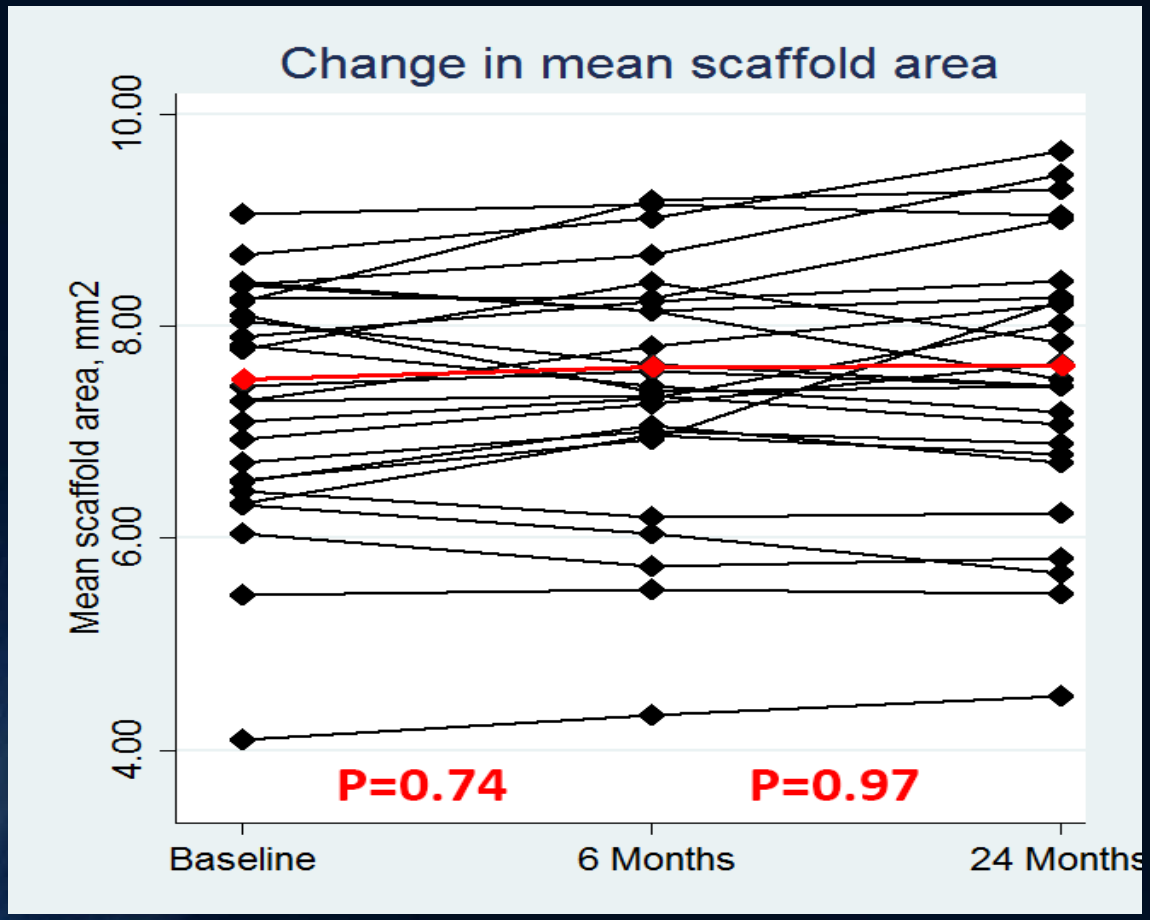


Analysis flow chart



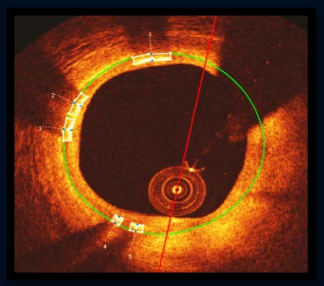
Mean scaffold area

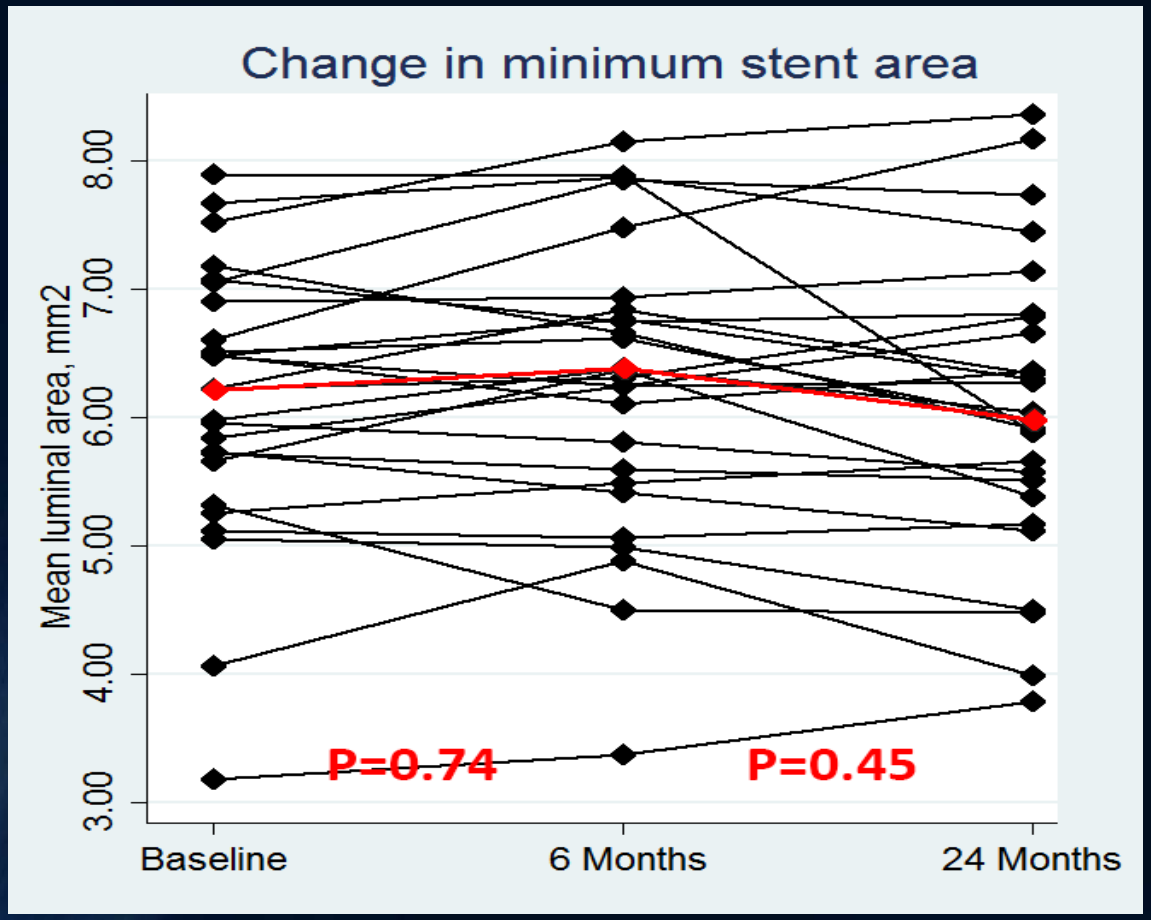




7.32±1.14 mm² 7.43±1.19 mm² 7.45±1.28 mm²

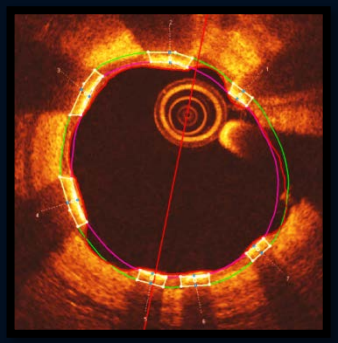
Minimal scaffold area

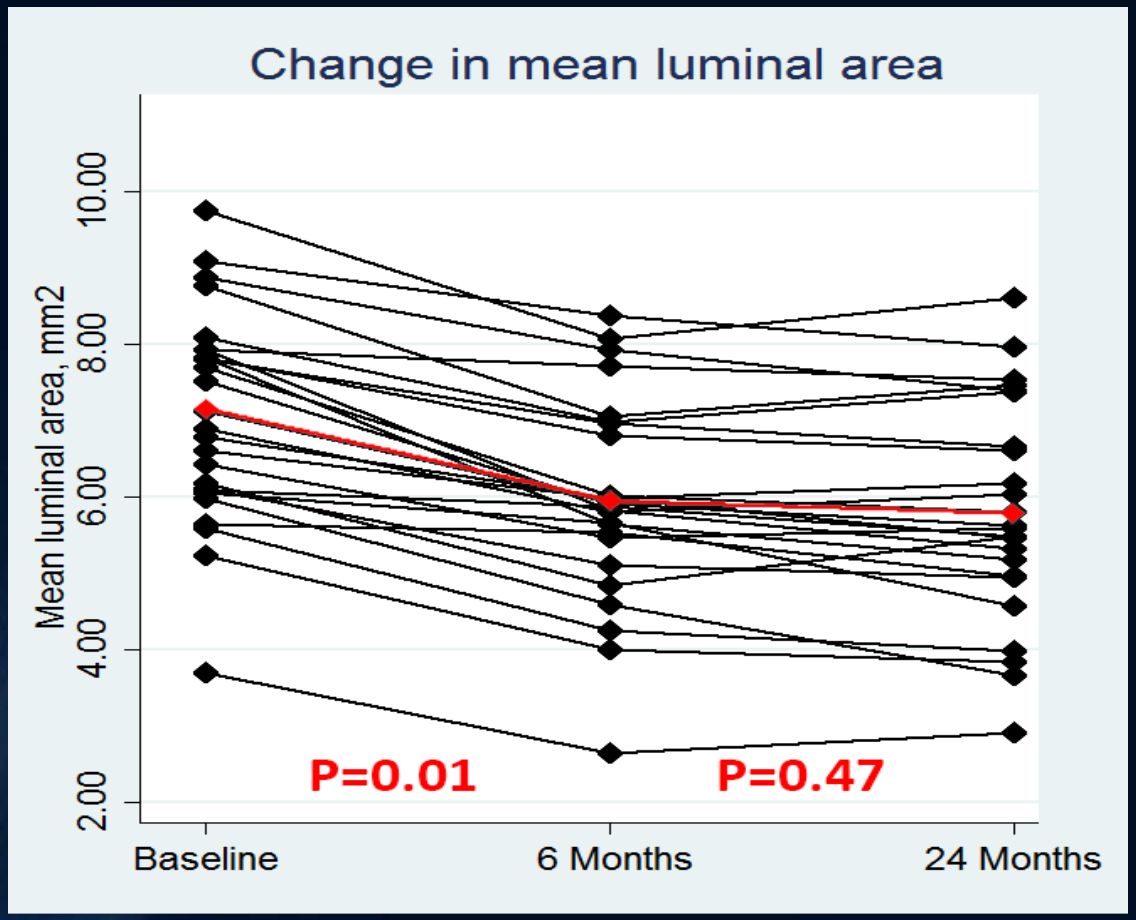




6.14±1.09 mm² 6.25±1.16 mm² 5.99±1.17 mm²

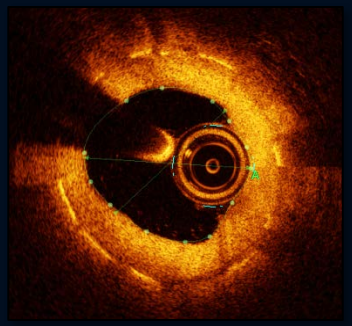
Mean lumen area

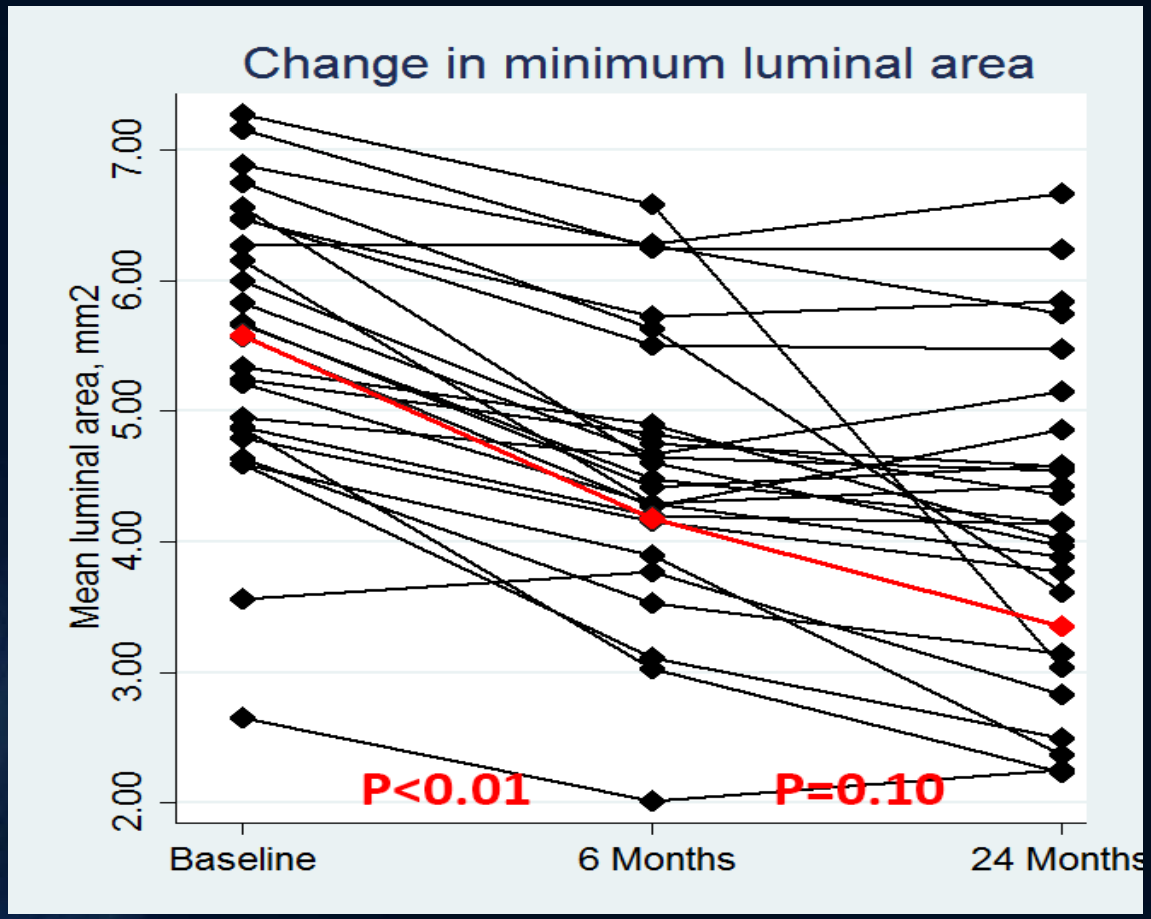




7.09±1.38 mm² 6.01±1.32 mm² 5.87±0.19 mm²

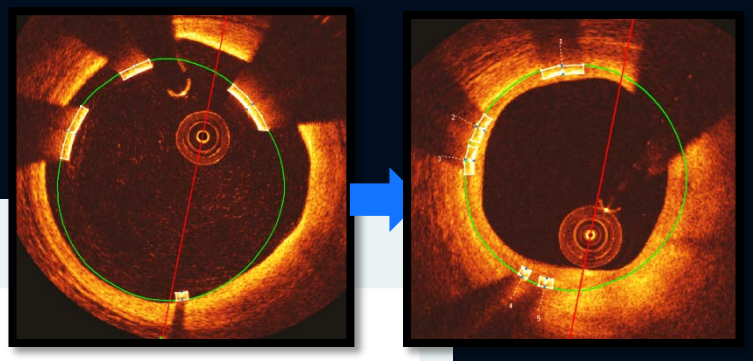
Minimal lumen area

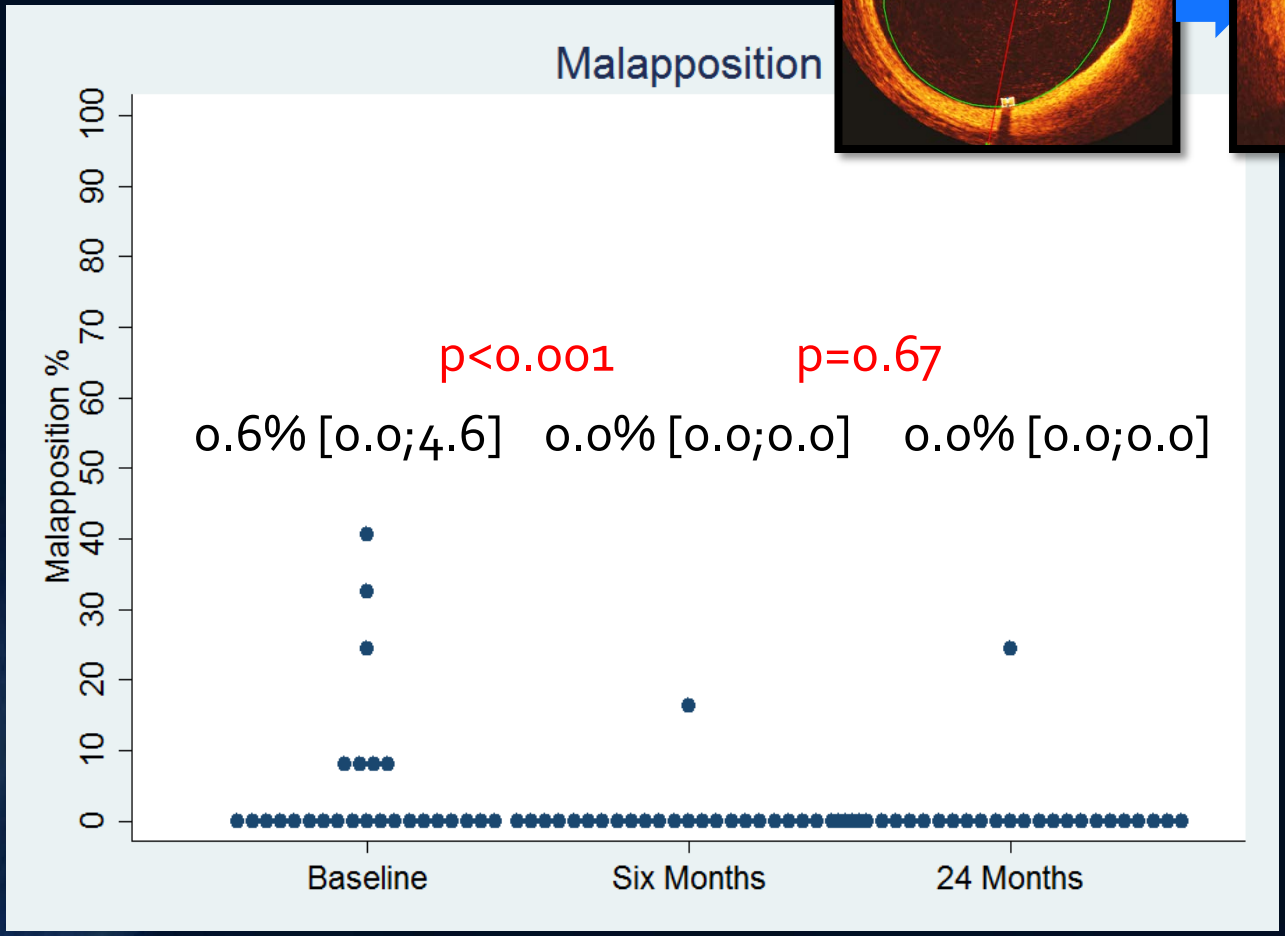




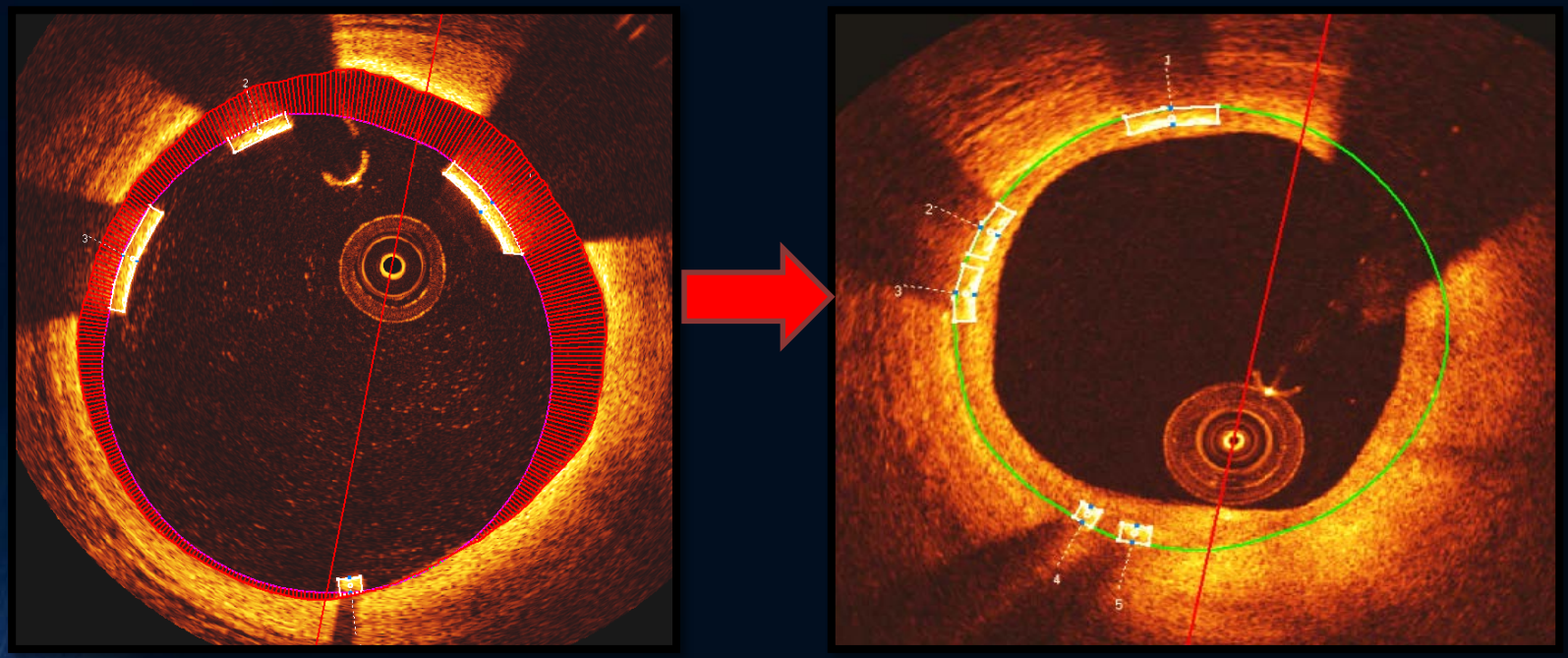
5.58±1.09 mm² 4.65±1.10 mm² 4.10±1.21 mm²

Malapposition





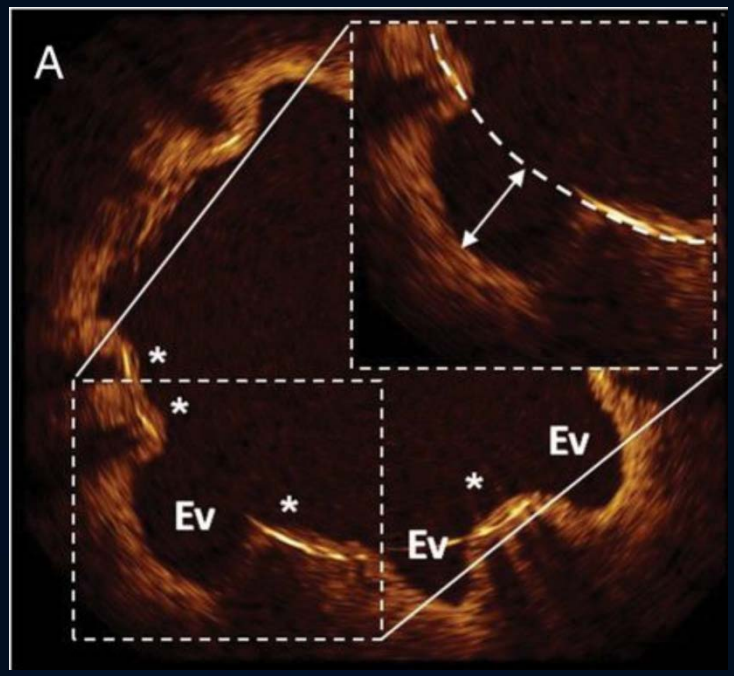
Extra-stent lumen



24 months follow-up cohort	baseline	6 months	24 months
Extra stent lumen area (mm^2)	0.04[0.03;0.19]	0.01[0.00;0.03]	0.00[0.00;0.01]
		p<0.001	p=0.05

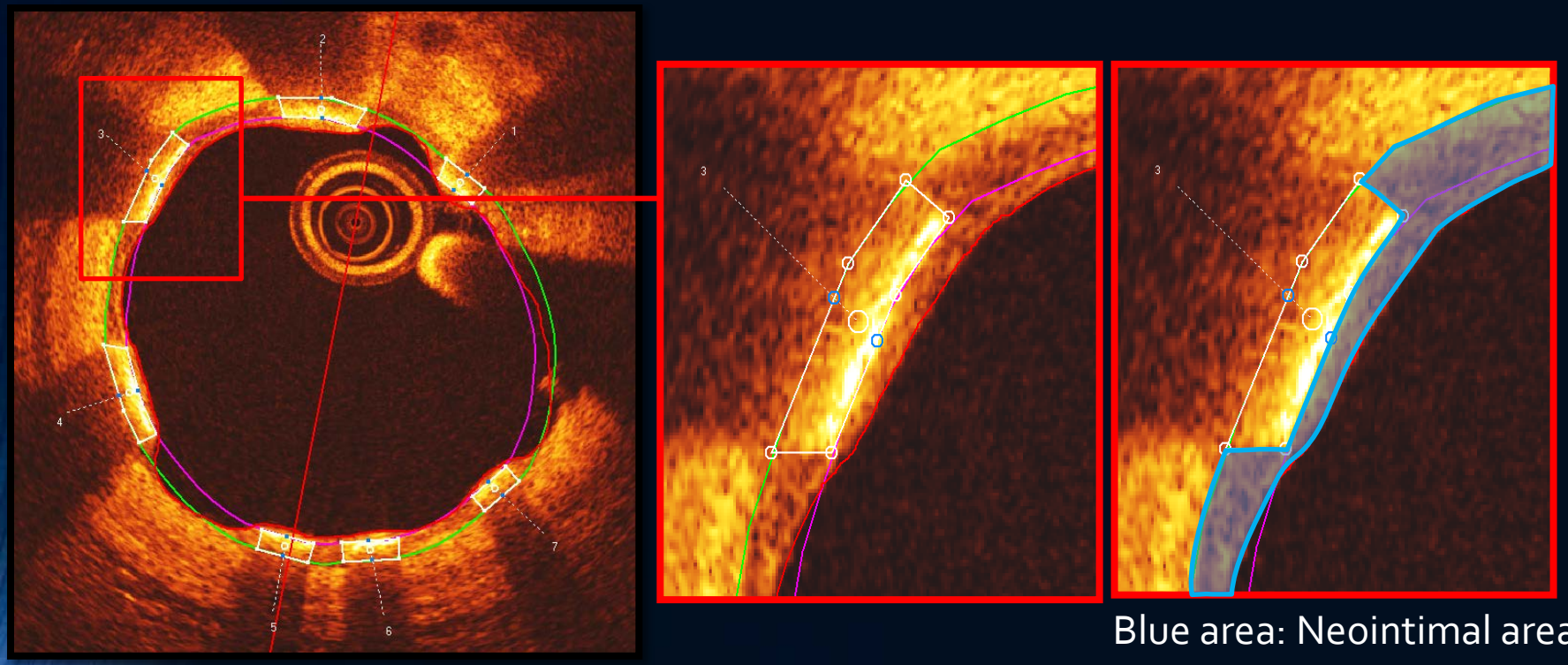
Extra-stent lumen

No evaginations or late scaffold detachment after 24 months



Example in permanent DES. Radu et al. EHJ 2017

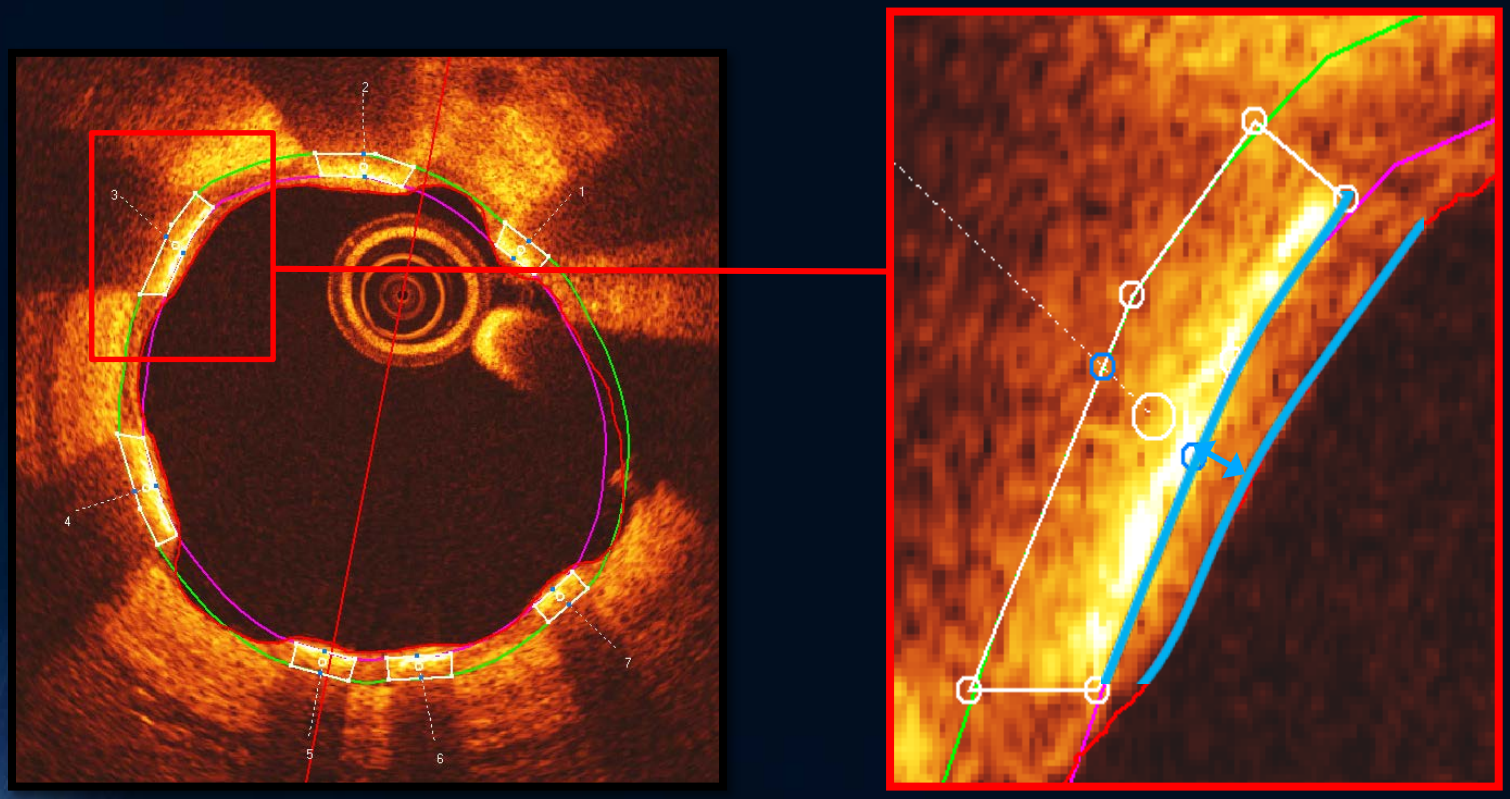
Neointimal area



Blue area: Neointimal area

24 months follow-up cohort	6 months	24 months	p-value
Mean neointimal area (mm^2)	1.20±0.31	1.52±0.37	<0.001

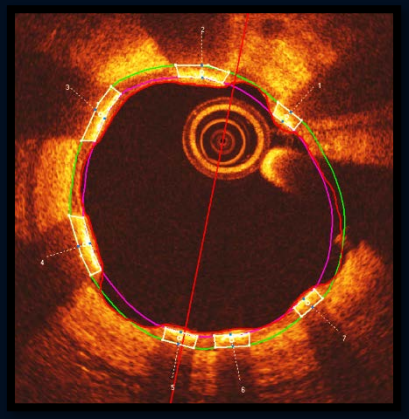
Neointimal thickness

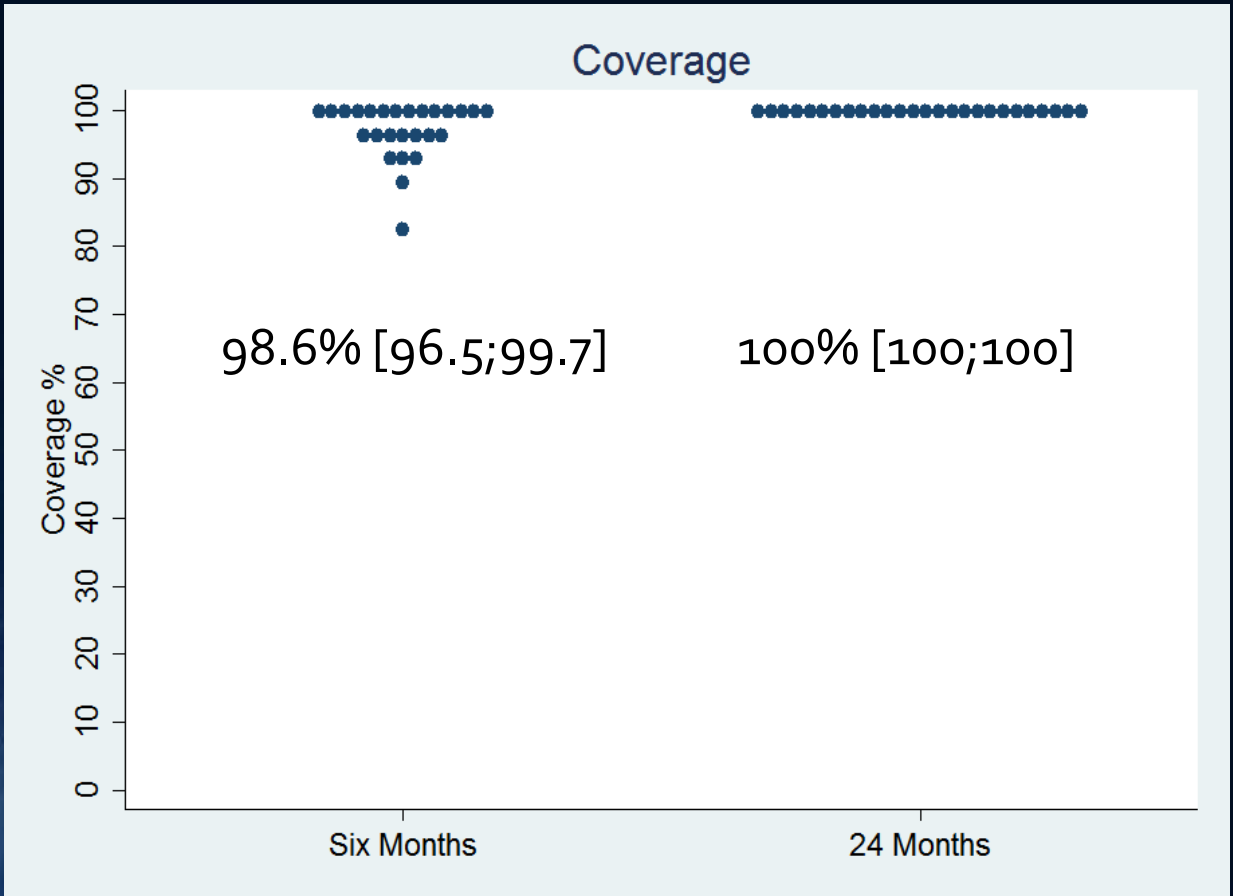


24 month follow-up cohort	6 months	24 months	p-value
Mean neointimal thickness (µm)	51[36;67]	79[53;110]	0.01

Median (IQR)

Strut coverage

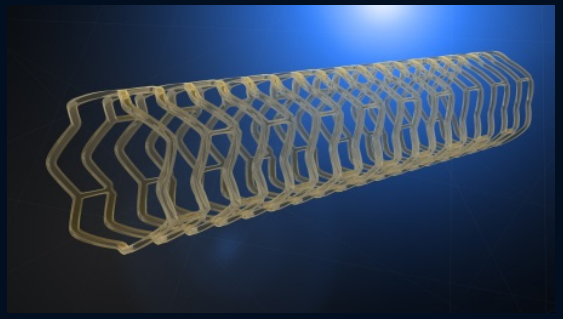




Strut-level results in 24m follow-up cohort

Conclusion

The Fantom BRS show promising healing patterns after 24 months:



- Complete strut coverage
- Slight decrease in lumen area due to limited additional neointimal growth – mainly in cases with small acute MLA
- No stent area reduction – no late recoil
- Excellent resolution of acute malapposition and still no acquired malapposition and no evaginations detected after 24 months