The Serial follow-up of jailed side branches after implantation of bioresorbable scaffold – Insights from the ABSORB Cohort B trial using three-dimensional optical coherence tomography

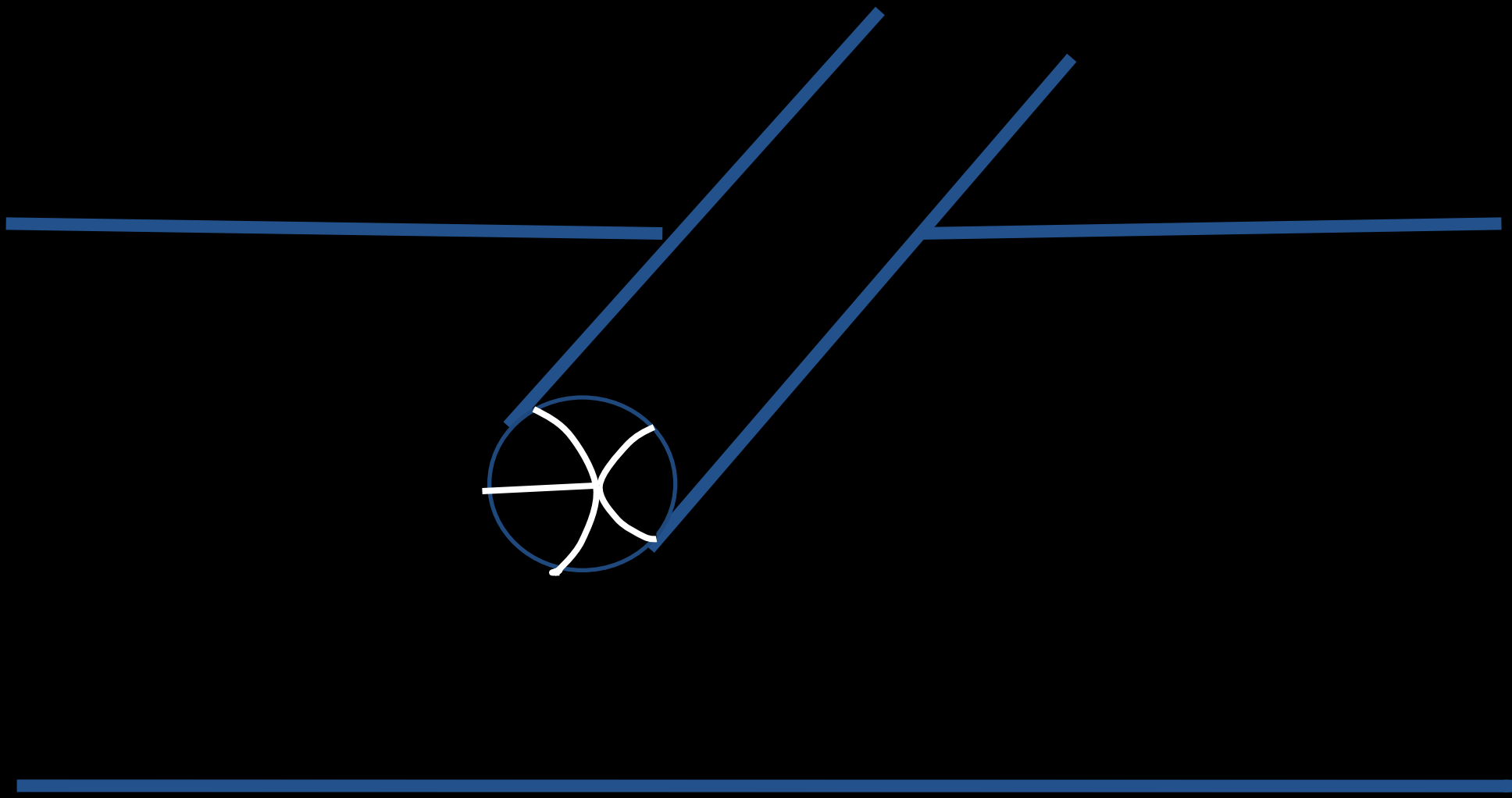
Yoshinobu Onuma MD, PhD*
Shimpei Nakatani, MD*
Maik Grundeken, MD#
Robert-Jan van Geuns, MD, PhD*
John A Ormiston MD$
Patrick W Serruys MD, PhD##
On behalf of investigators of ABSORB cohort B

***Thoraxcenter, Erasmus MC, Rotterdam, The Netherlands**
#Academic Medical Centre, Amsterdam, the Netherlands
$ Auckland City Hospital, Auckland, New Zealand
Imperial College London

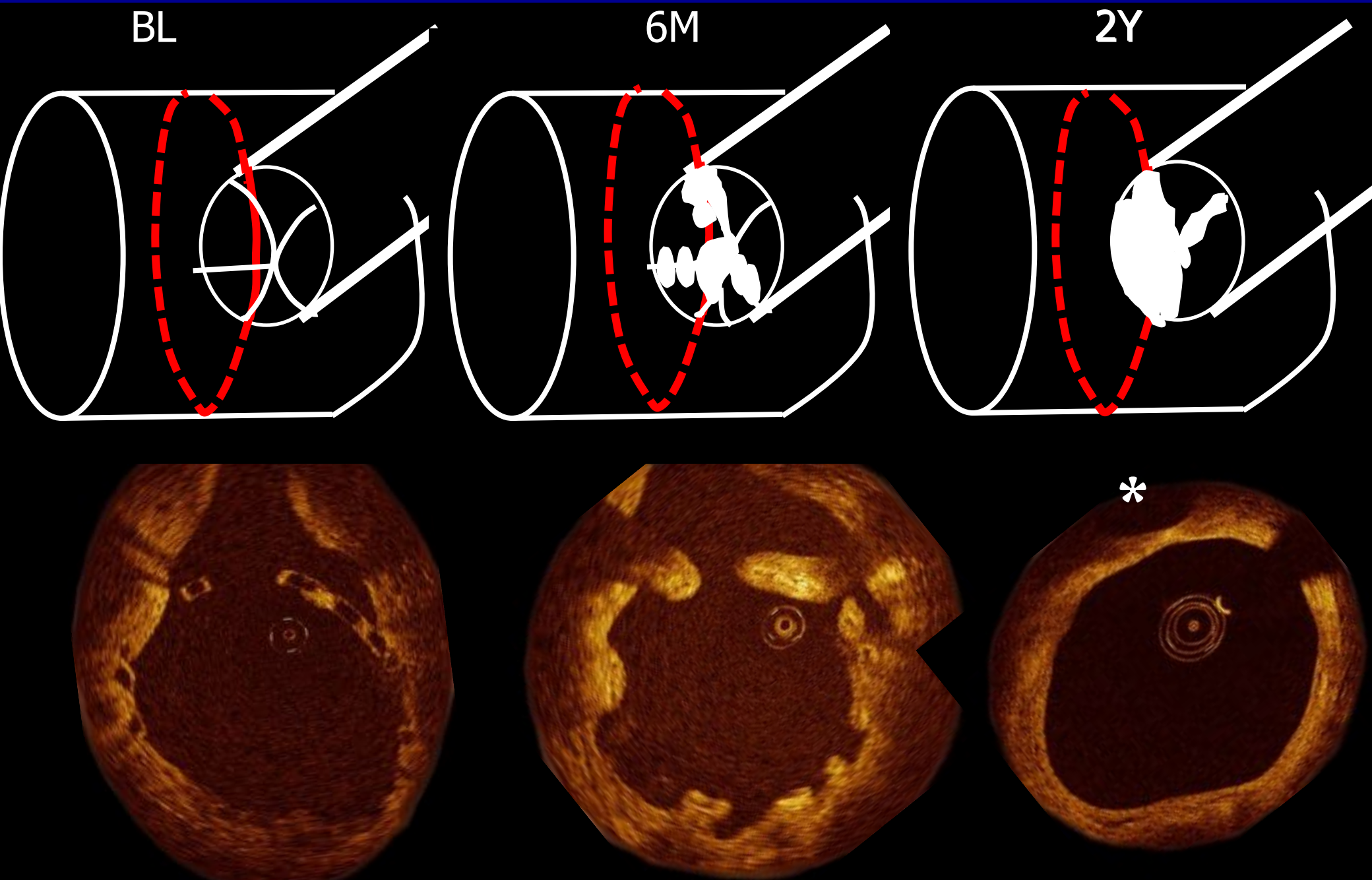
Background:

- Bioresorbable scaffolds consisting of poly-lactide are inherently programmed to bioresorb in three years.
- It is still unknown how the struts implanted in front of a side branch behave during bioresorption.
- The purpose of this study was to assess the fate of bioresorbable struts jailing side branch ostia at 6, 12, 24 36 and 60 months after implantation of the everolimus-eluting Absorb scaffold with **three-dimensional (3-D) optical coherence tomography** (OCT) reconstruction.

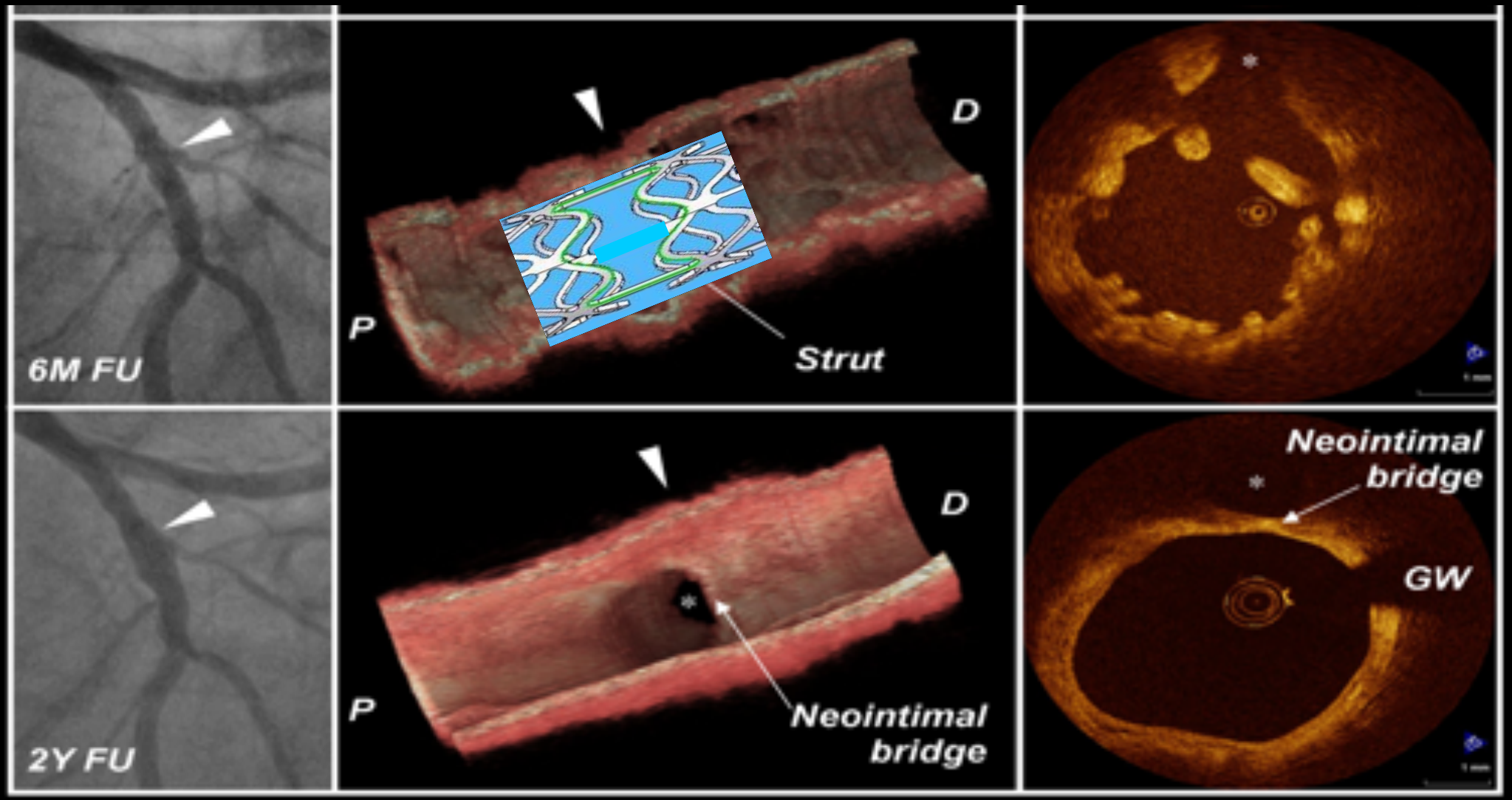
Why 3D OCT? In the ABSORB Cohort A trial…



Why 3D OCT? In 2008, we speculated



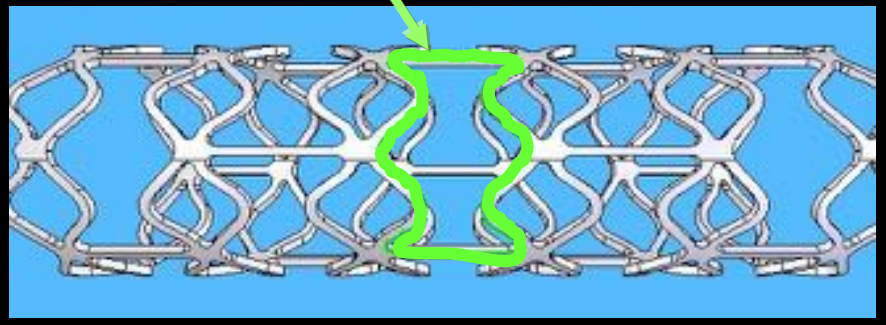
In the ABSORB Cohort A trial, Bioresorption of jailed side branch are real phenomenon. (M2/3, 1-3mm/s, 15-20fps) Okamura et al. EHJ 2010)



Absorb Cohort B

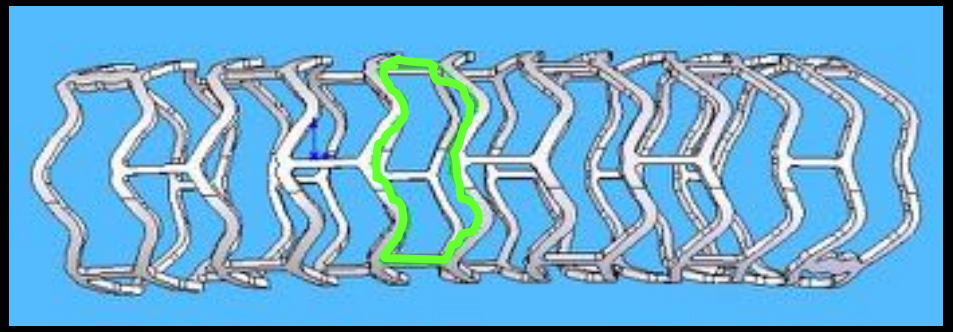
Larger MCUSA

N=30



ABSORB 1.0

N=101



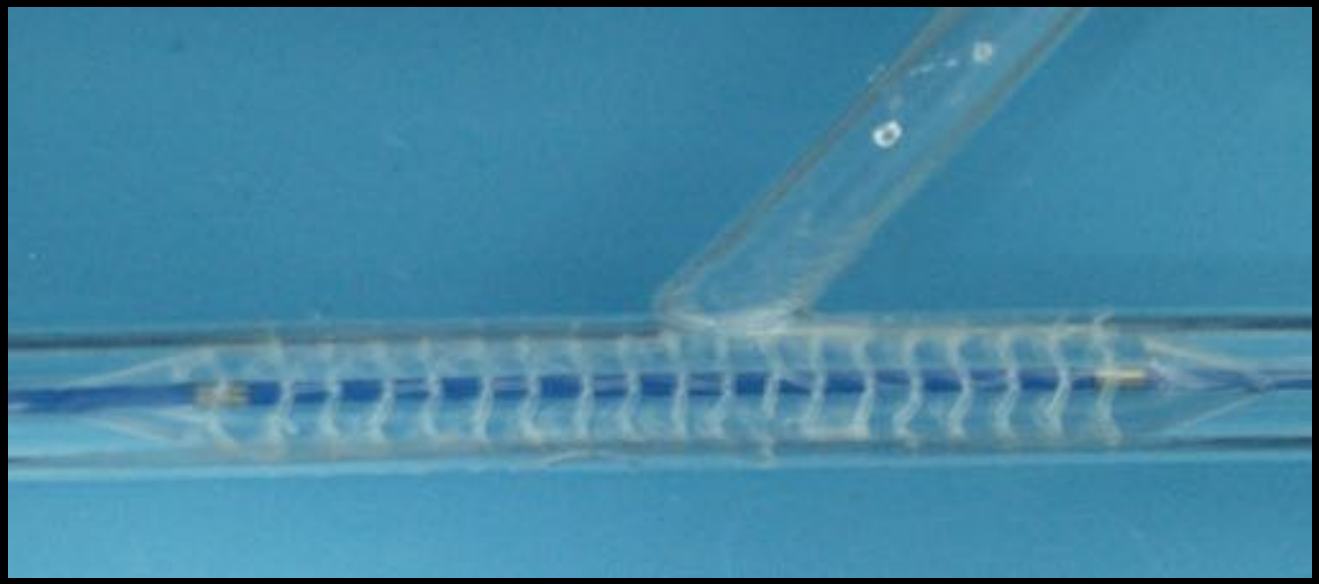
Absorb 1.1

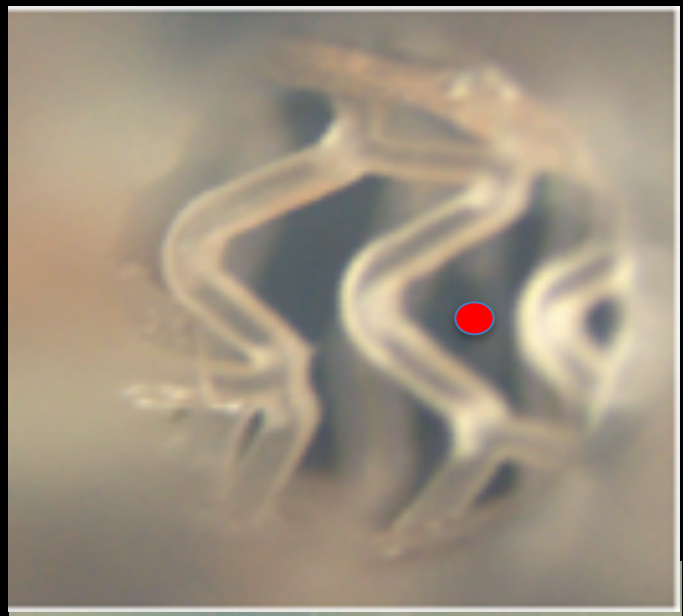
- **Lower MCUSA**
  (***maximum circular unsupported surface area***)

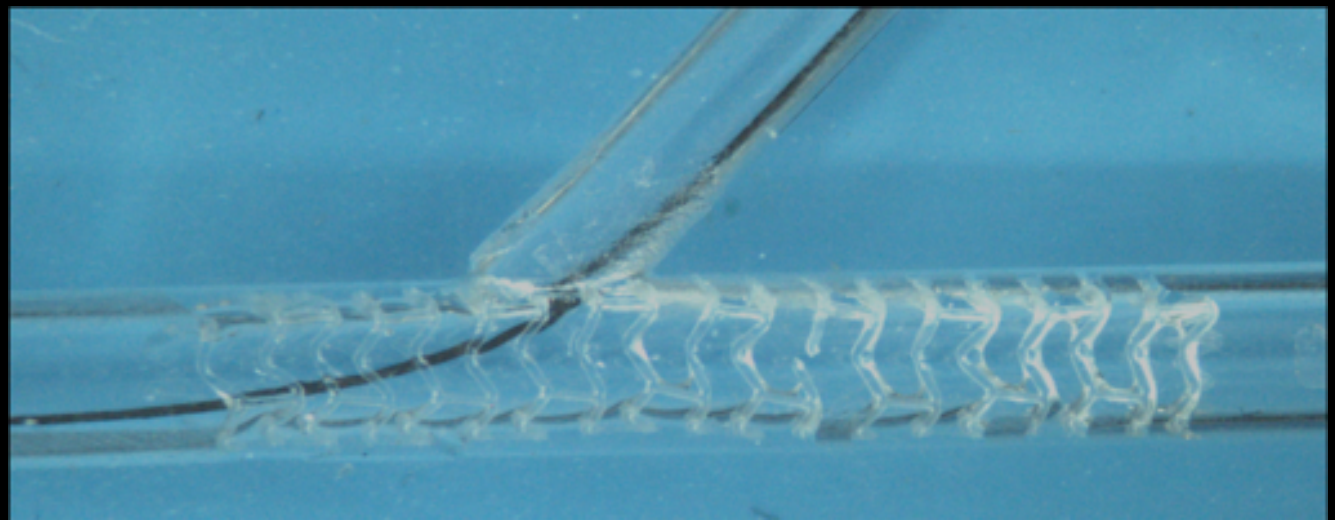
- **More even support of arterial wall**
- **More uniform strut distribution**
- **Lower late stent area loss**
- **Higher radial strength**
- **Improved stent retention**
- **Unchanged:**
  - **Material**
  - **Strut thickness**

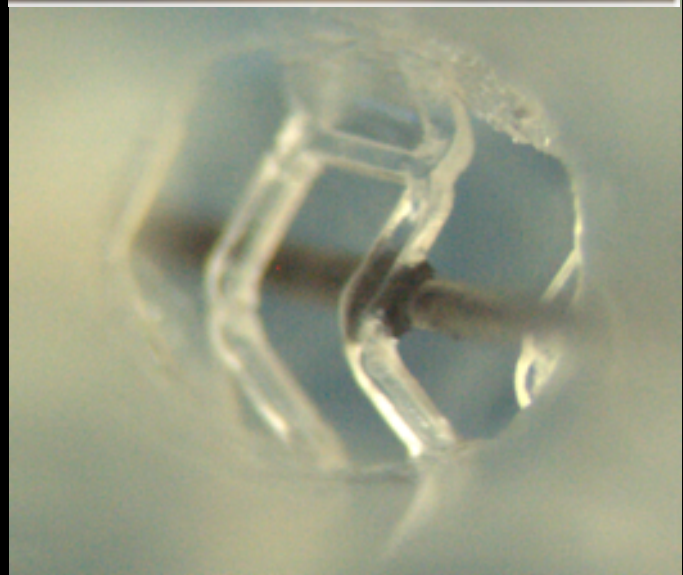
Photos taken by and on file at Abbott Vascular.

What is the feasibility of 3-D OCT reconstruction? In-vitro experiment



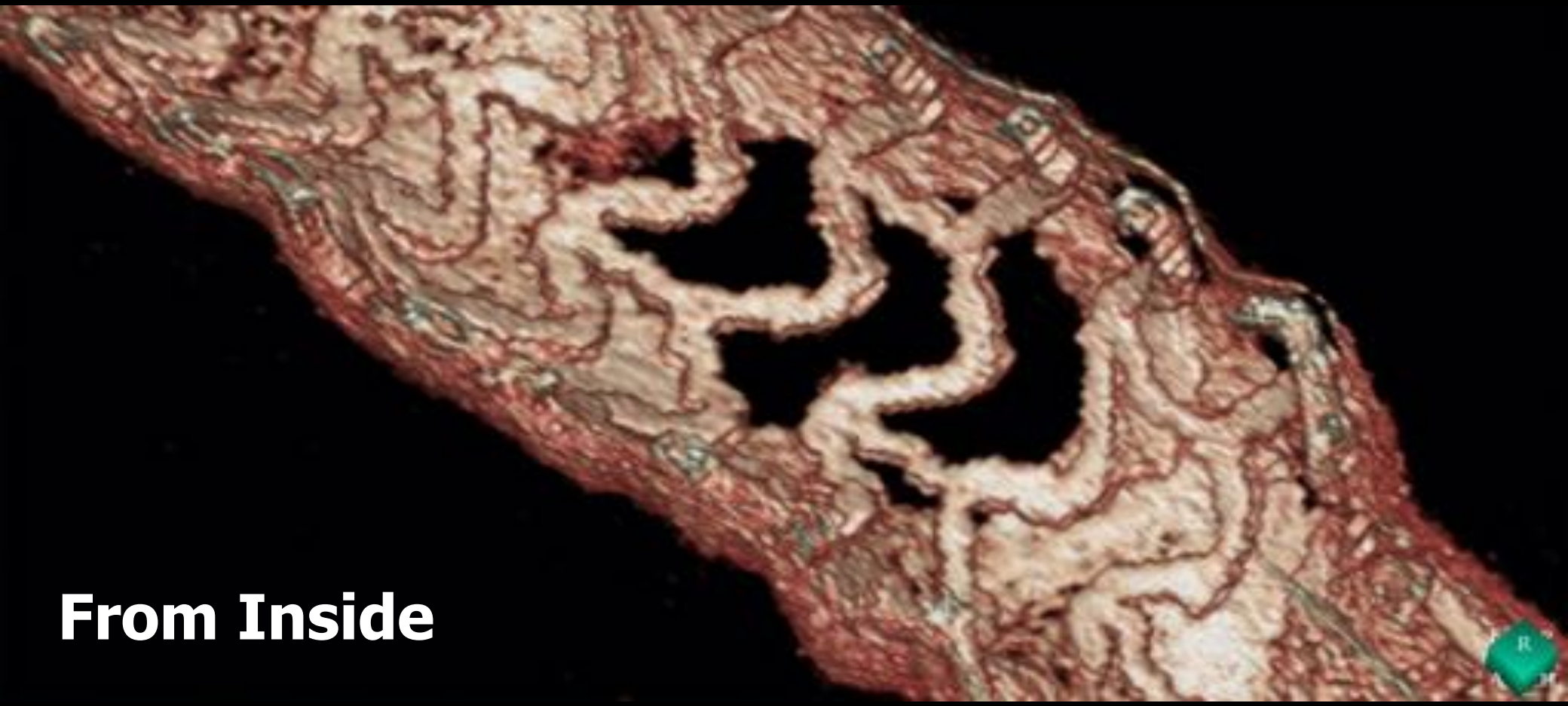






3-D reconstruction of OFDI-OCT (TERUMO)

Distal

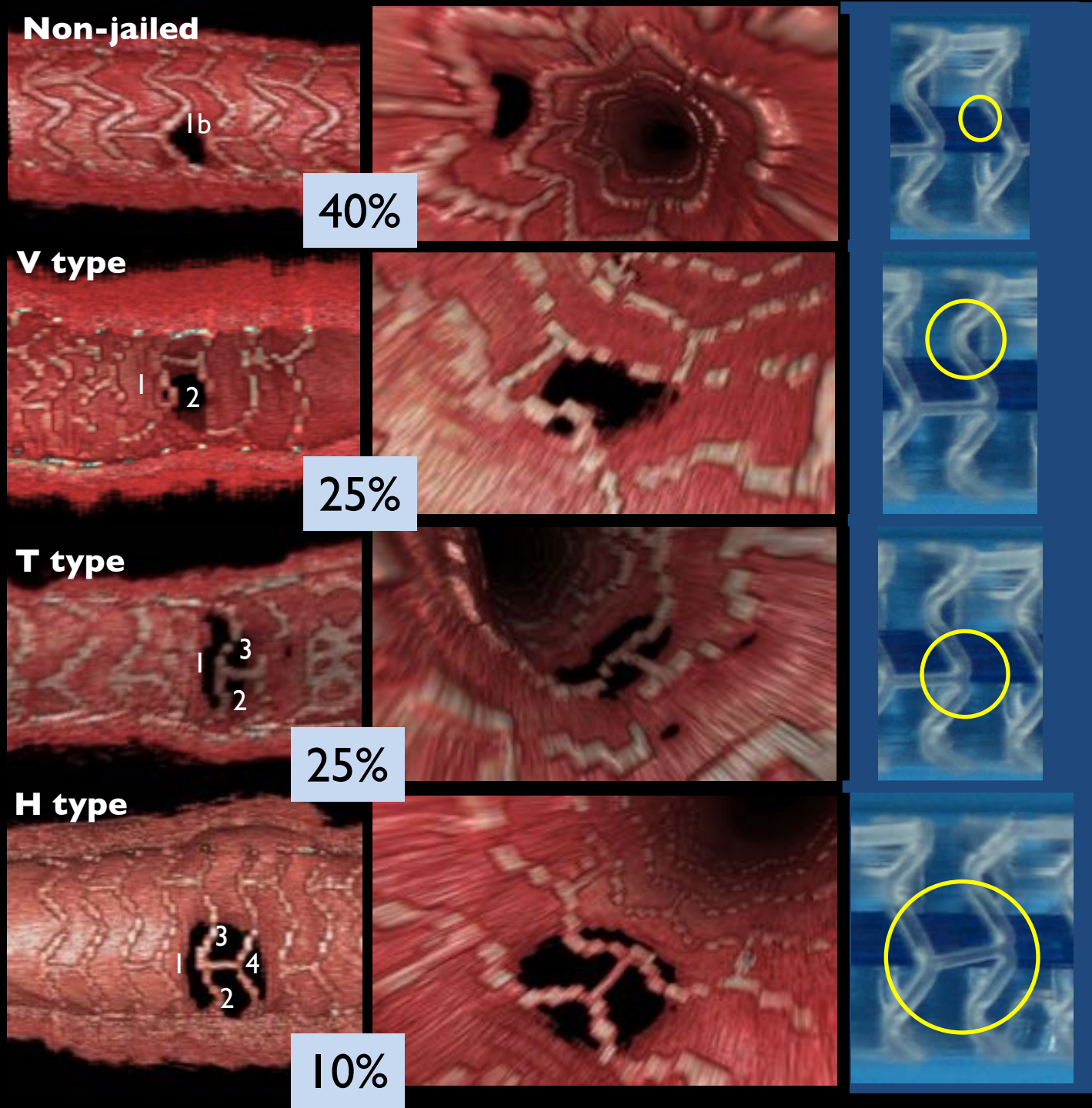


Proximal

Today, with 3-D OFDI we can further evaluate the bioresorption process.

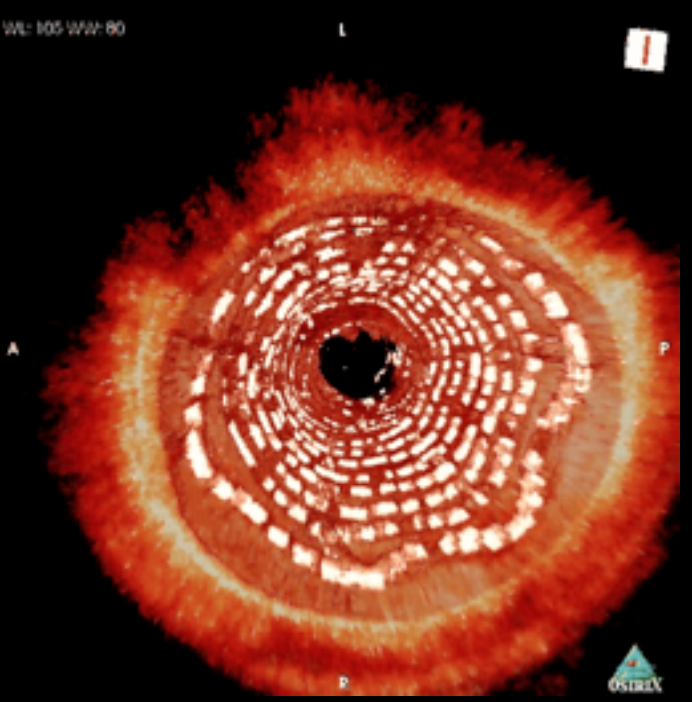
Classification of Jailed sidebranch ostium according to number of compartment created by the overhanging struts with different configuration (e.g. V, T and H type)

Absorb Cohort B (n=17)

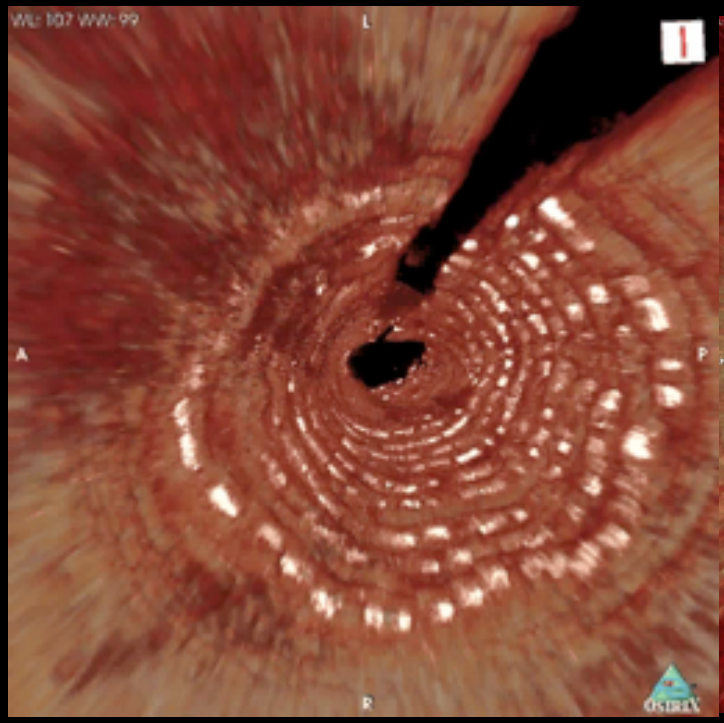


3D OCT is also feasible at FUP

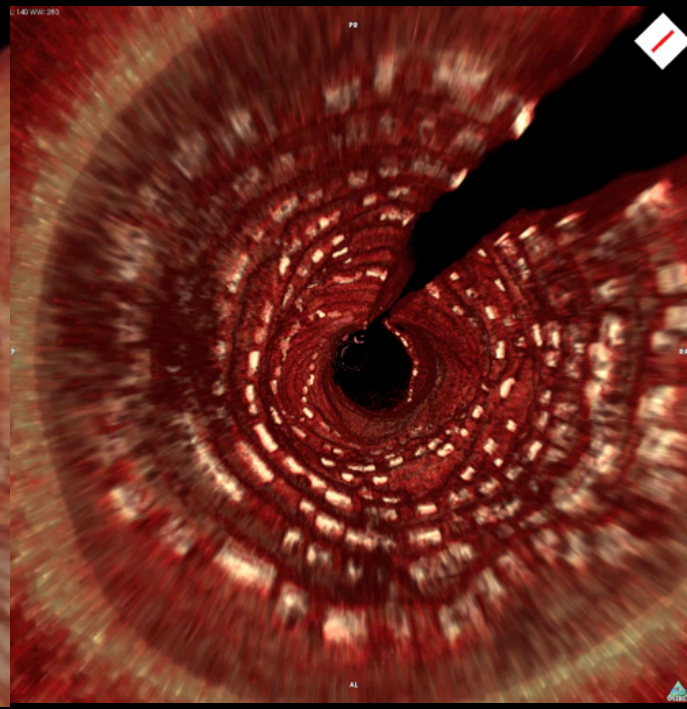
BL

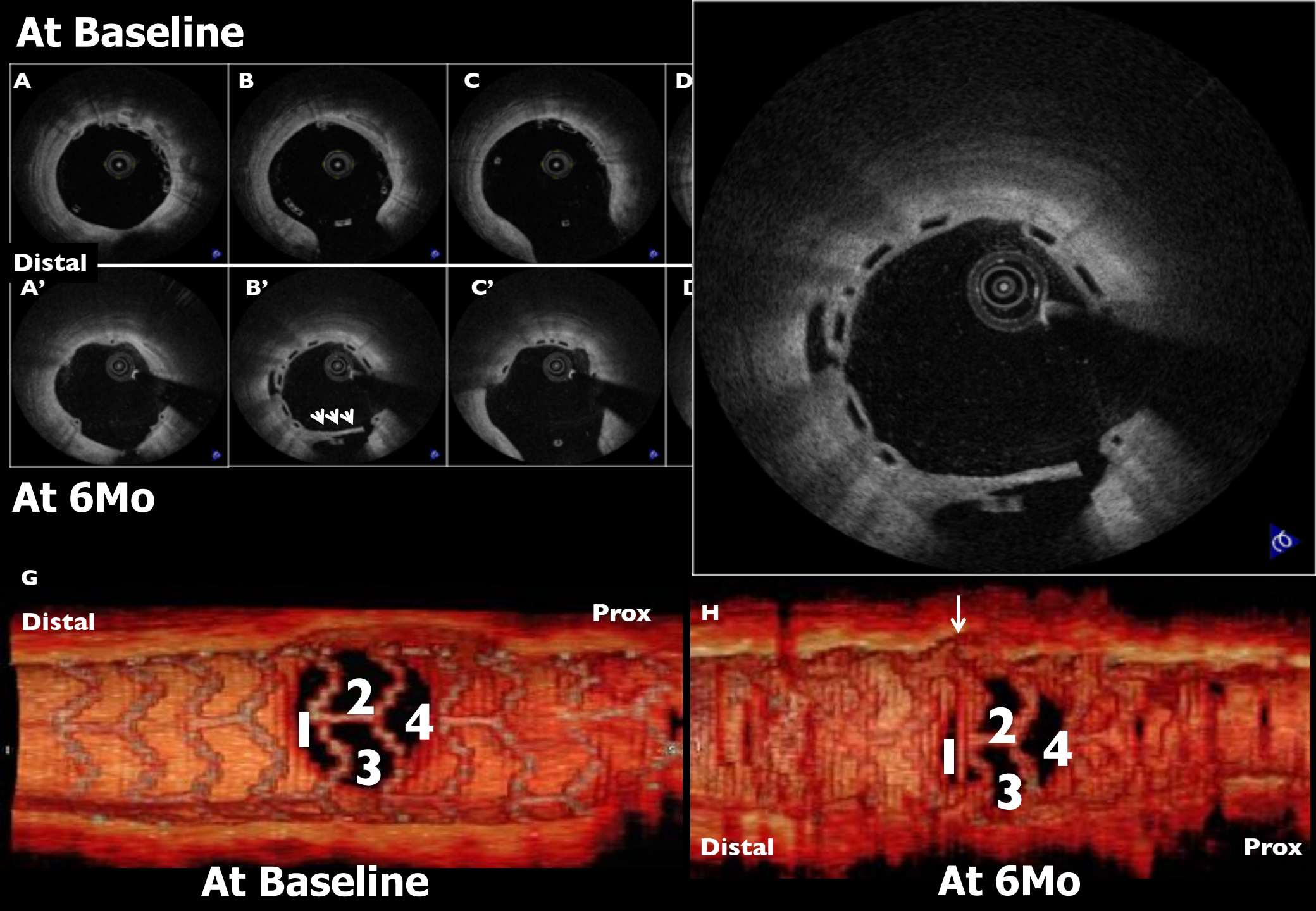


6M



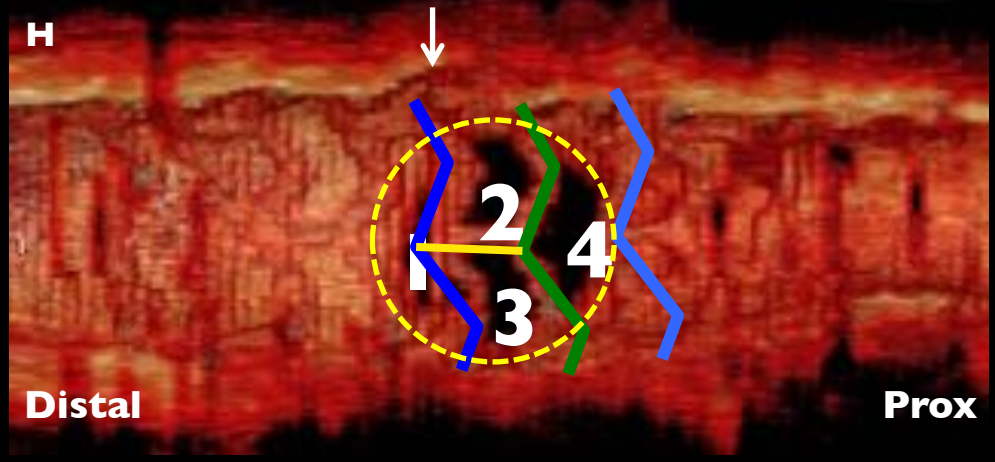
24M



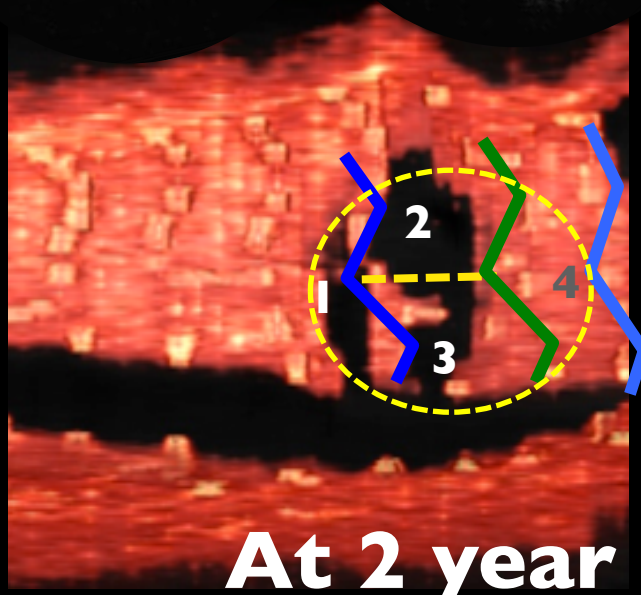

At Baseline
A
B
C
D
Distal
A'
B'
C'
D
At 6Mo
G
Distal
Prox
1
2
3
4
At Baseline
H
1
2
3
4
Distal
Prox
At 6Mo

At 6M

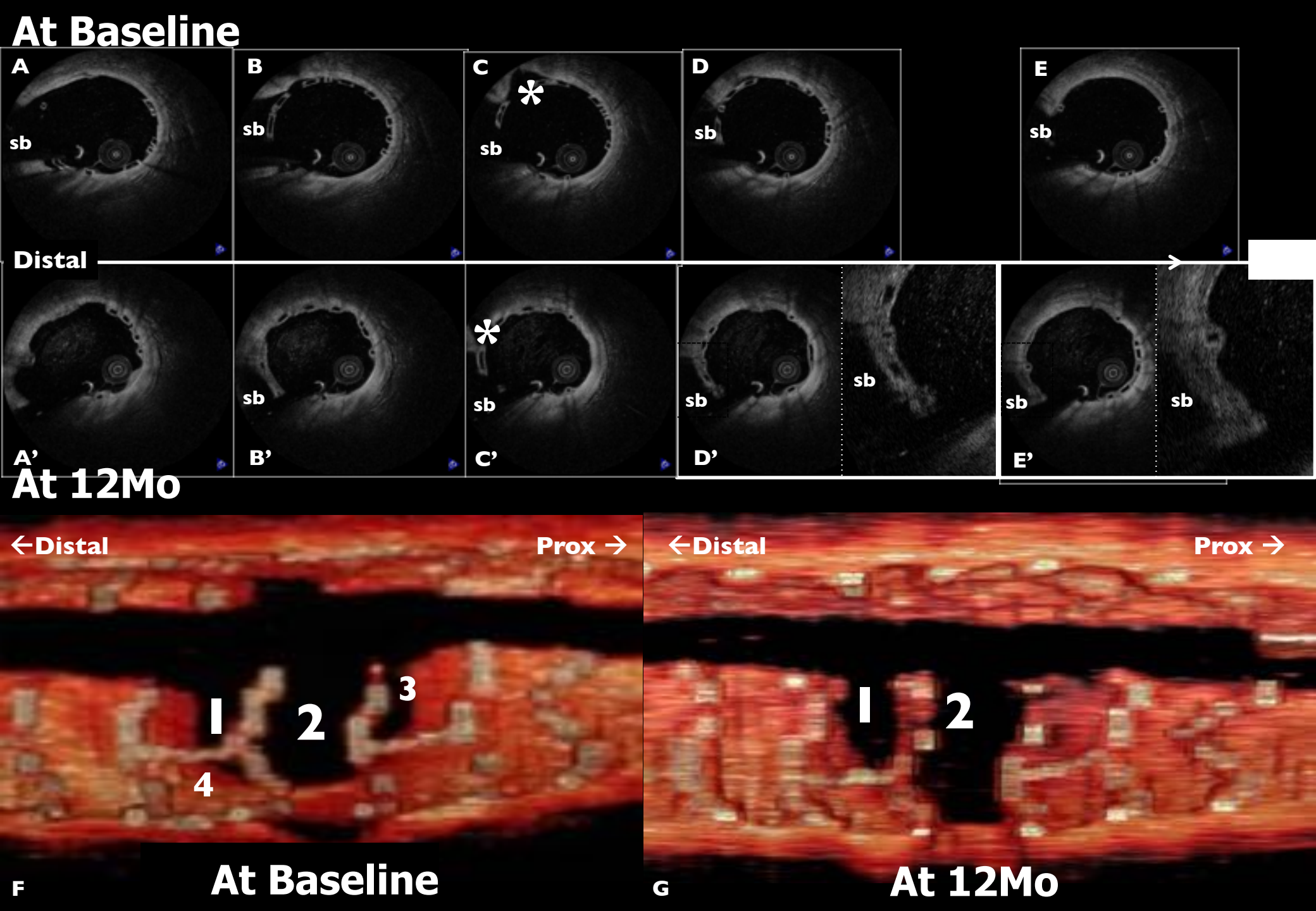
At 2 year

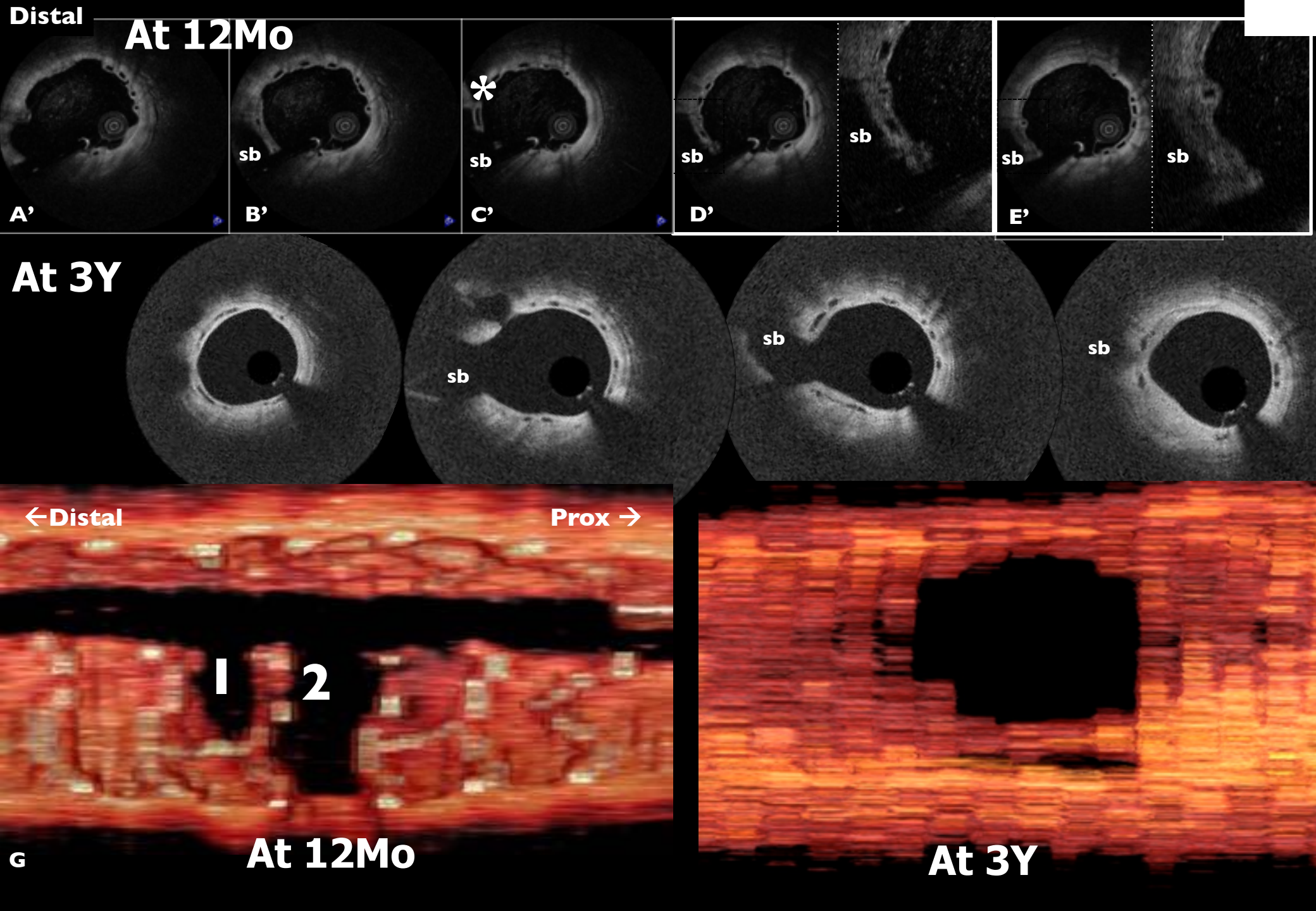


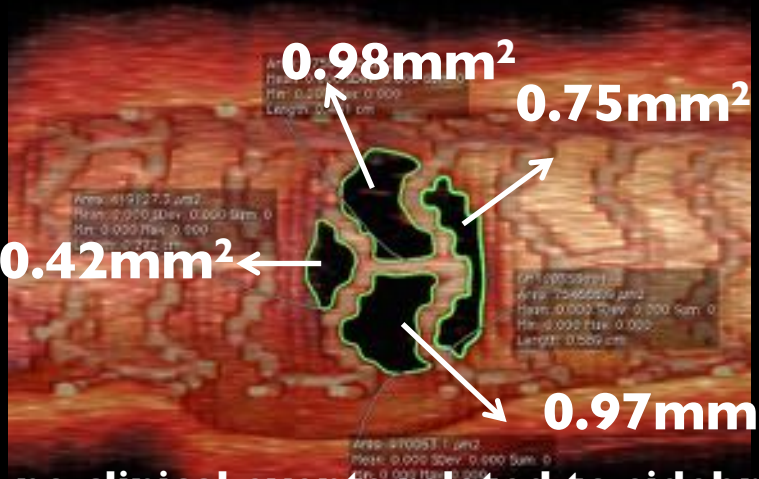
At 6Mo



At 2 year


At Baseline
A
B
C
D
E
sb
*
Distal
A'
B'
C'
D'
E'
At 12Mo
←Distal
Prox →
1
2
3
4
F
At Baseline
G
At 12Mo


Distal
At 12Mo
sb
sb
sb
sb
A'
B'
C'
D'
E'
At 3Y
sb
sb
sb
←Distal
Prox →
1
2
G
At 12Mo
At 3Y

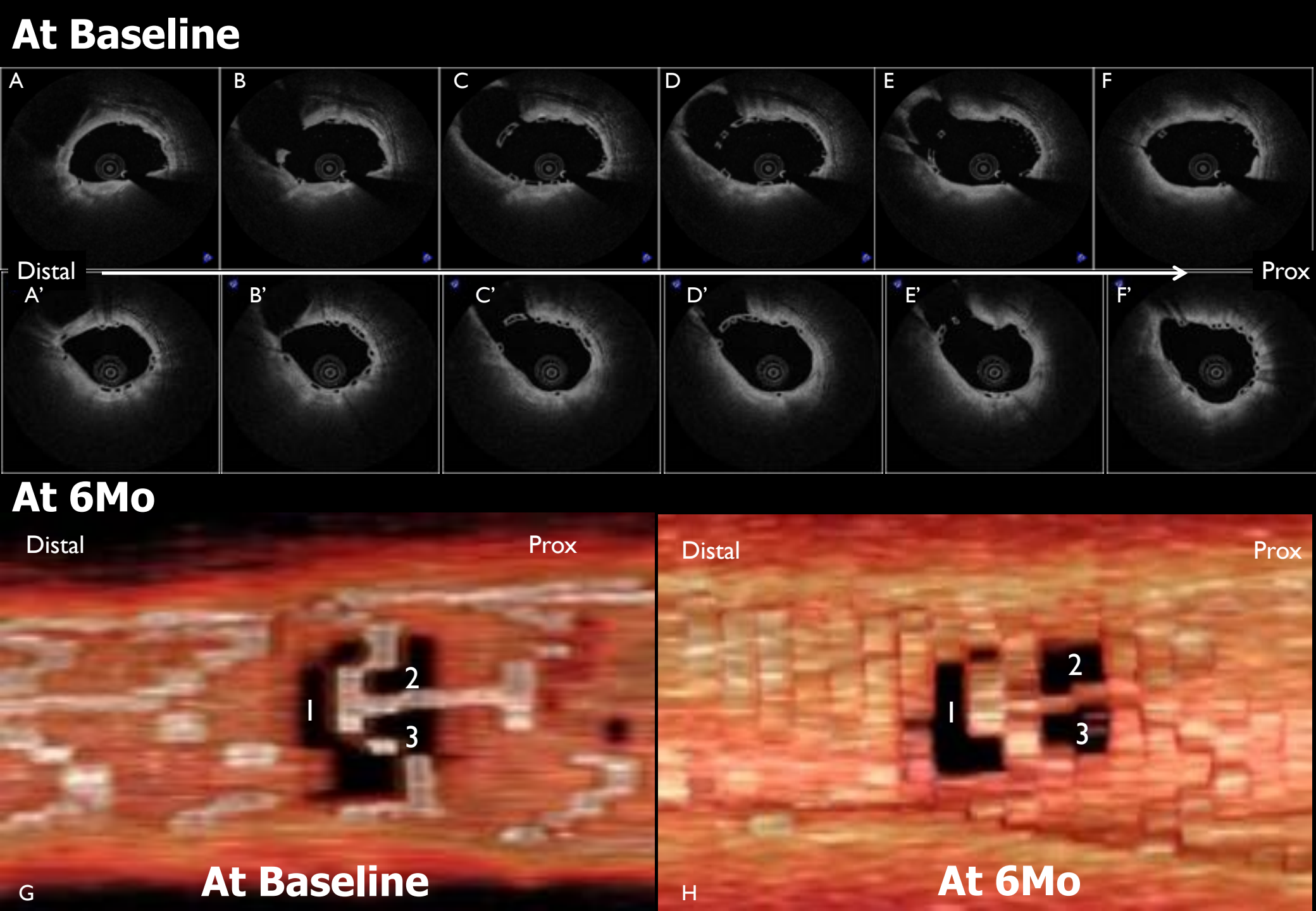


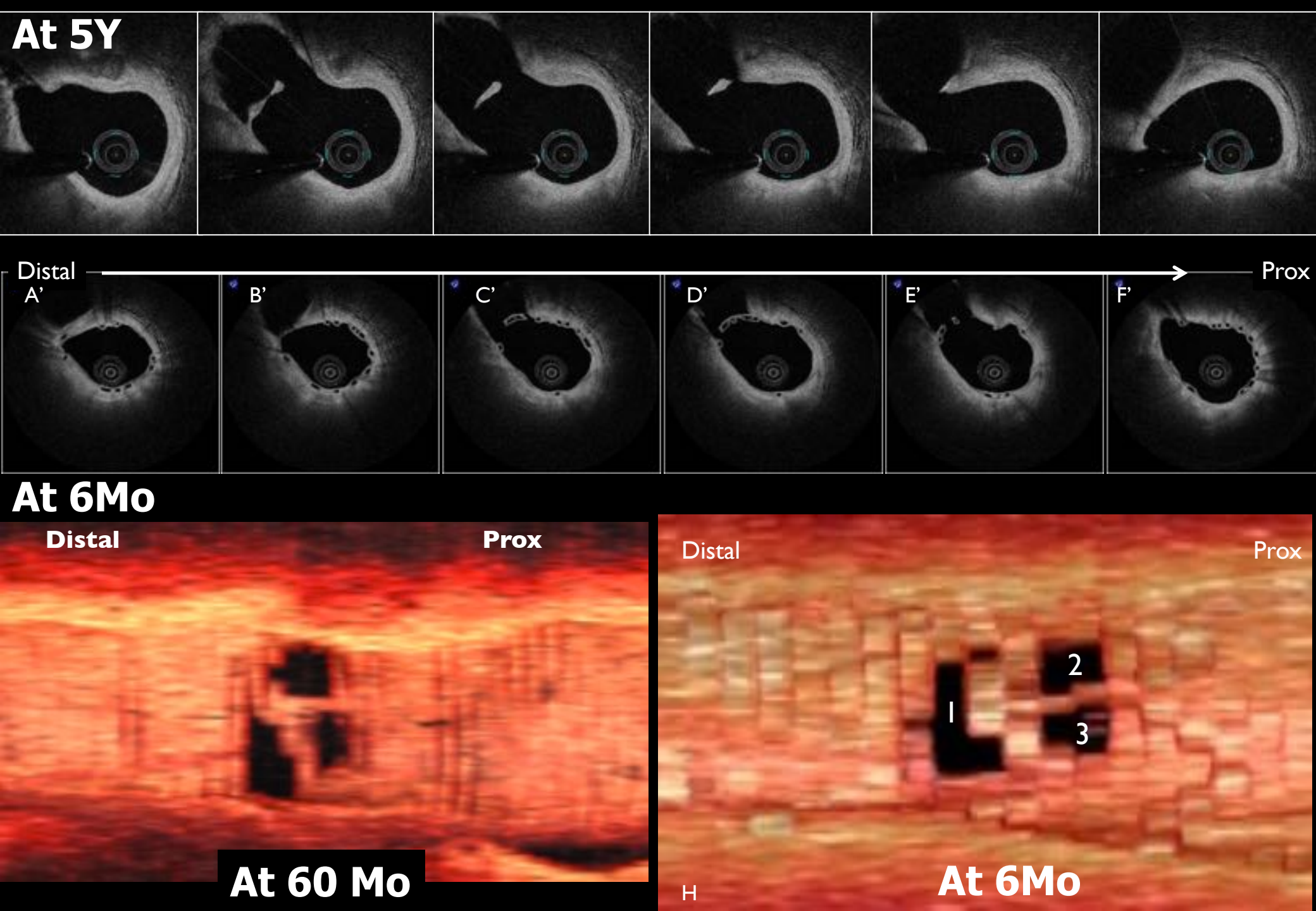
There are no clinical events related to sidebranch.

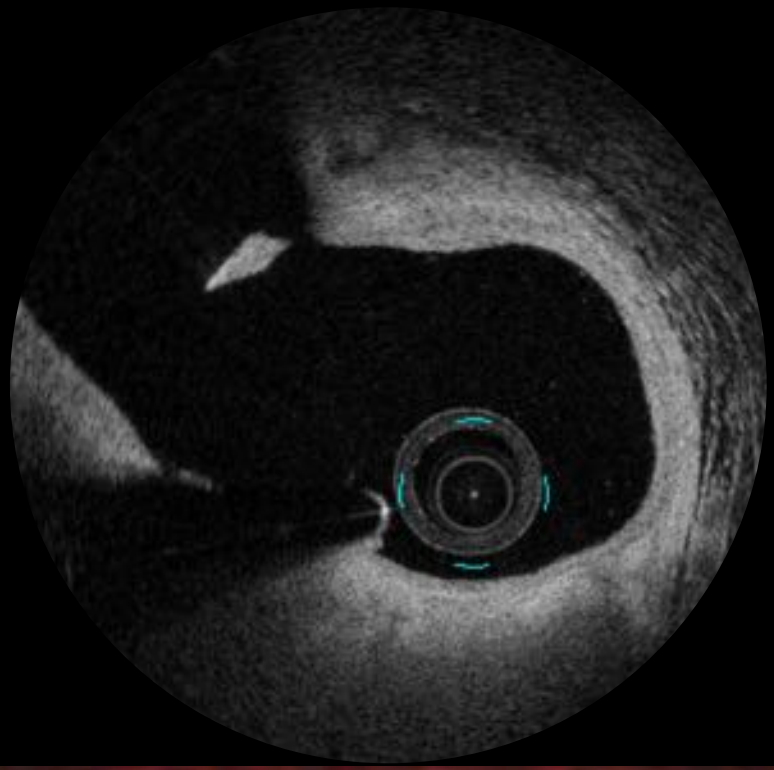
	BL (n=15)	6M (n=15)	2Y (n=13)	p(BL-6M)	p(BL-2y)
No. of Compartment	2.13±1.1 ↘	1.93±1.0 ↘	1.31±0	0.1	0.03
Ostium area free from Strut, mm²	0.58 ± 0.12 ↘		↘	0.3	0.03

Preliminary results
Analysis ongoing for 5Y

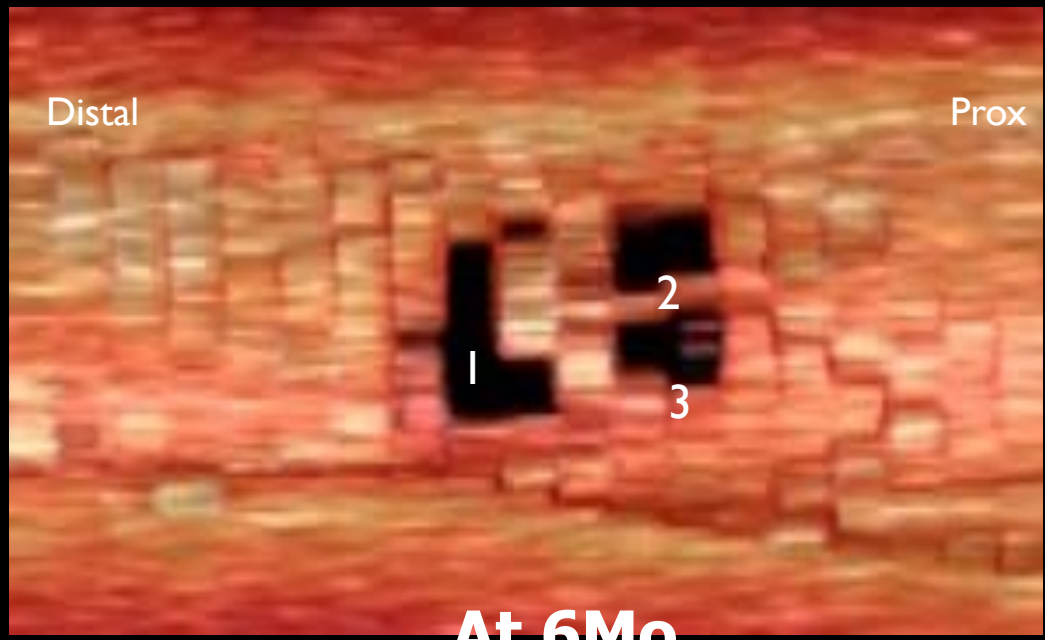
	BL (n=15)	6M (n=15)	36M (n=13)	P(BL-1Y)	P(1Y-3Y)
No. of Compartment	±0.8 ↘	1.4±0.85 ↘	1.18±0.41	0.001	0.28
Ostium area free from Strut, mm²	0.91 ± 0.64 ↘	0.47 ± 0.38 ↗	0.68±0.38	0.002	0.02


At Baseline
A
B
C
D
E
F
Distal
Prox
A'
B'
C'
D'
E'
F'
At 6Mo
Distal
Prox
1
2
3
G
At Baseline
Distal
Prox
1
2
3
H
At 6Mo


At 5Y
Distal
Prox
A'
B'
C'
D'
E'
F'
At 6Mo
Distal
Prox
At 60 Mo
Distal
Prox
1
2
3
H
At 6Mo



At 60 Mo



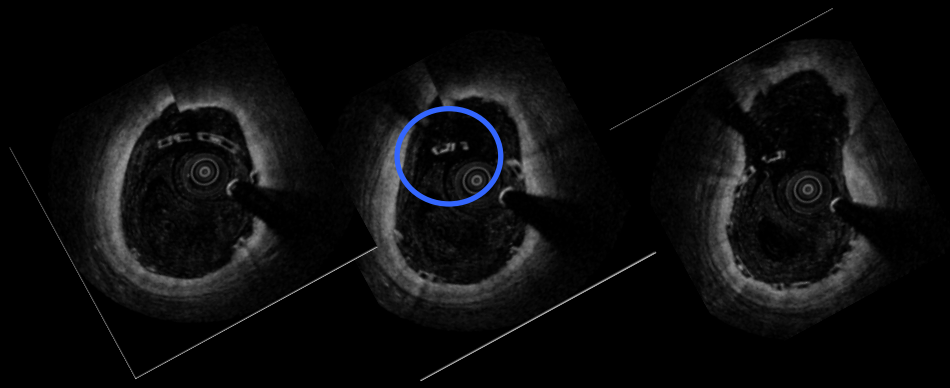
H

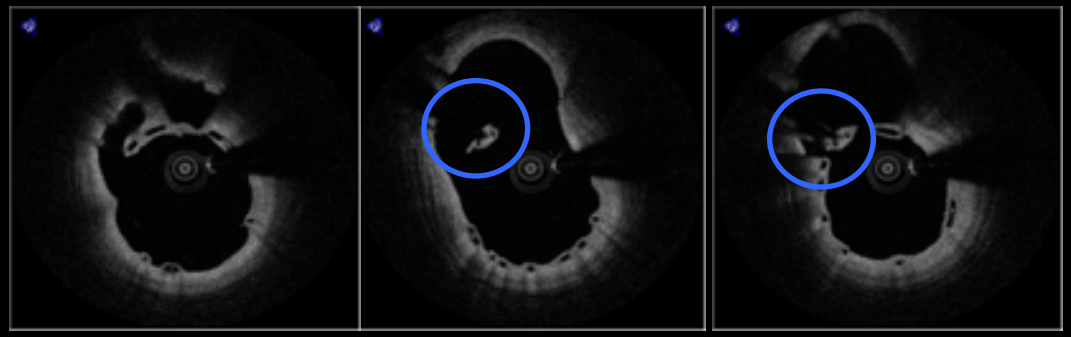
At 6Mo

SB3

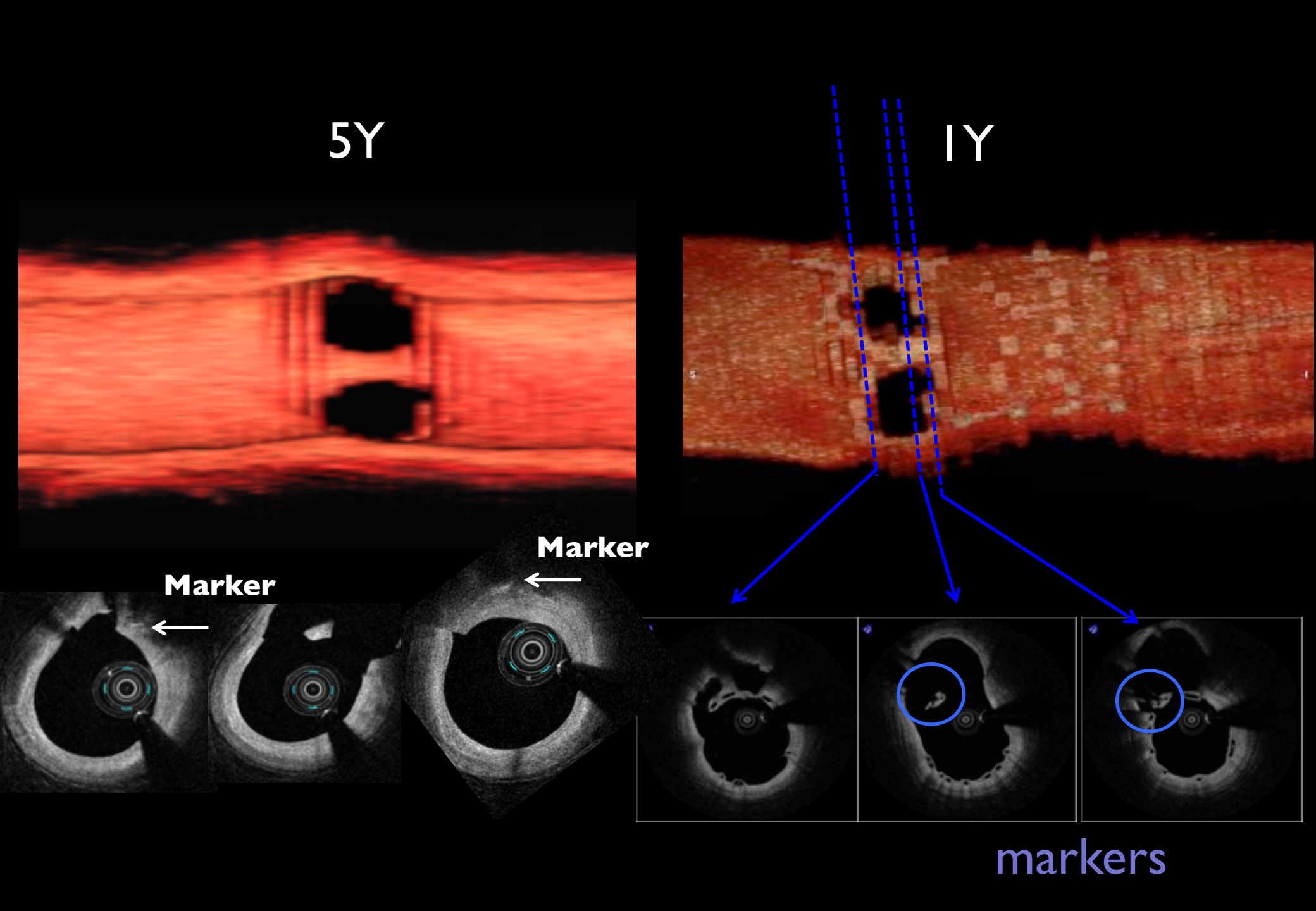
BL

IY



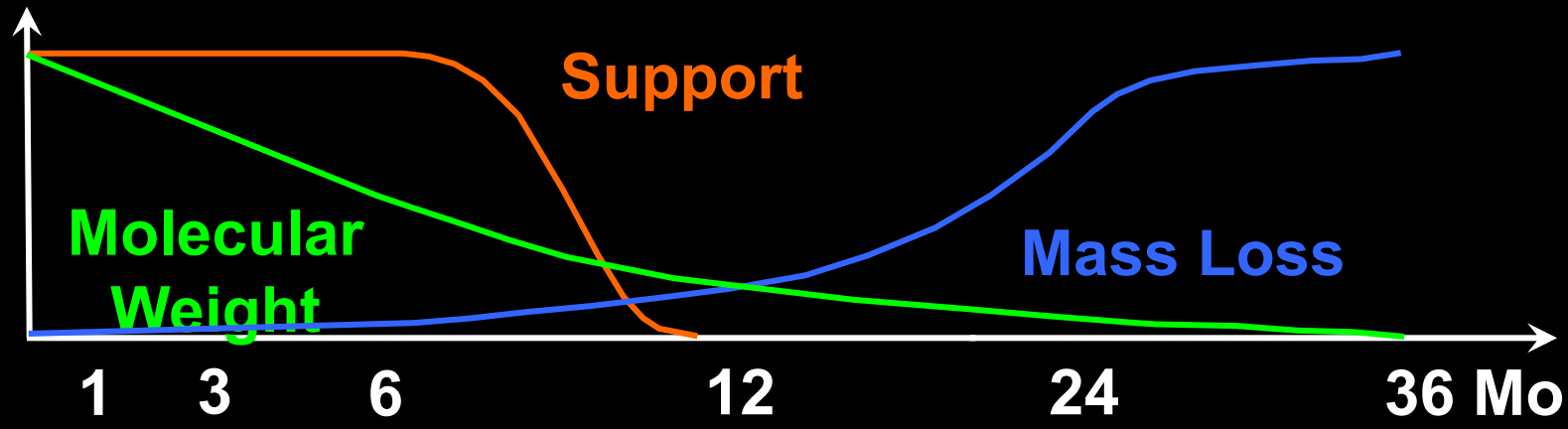


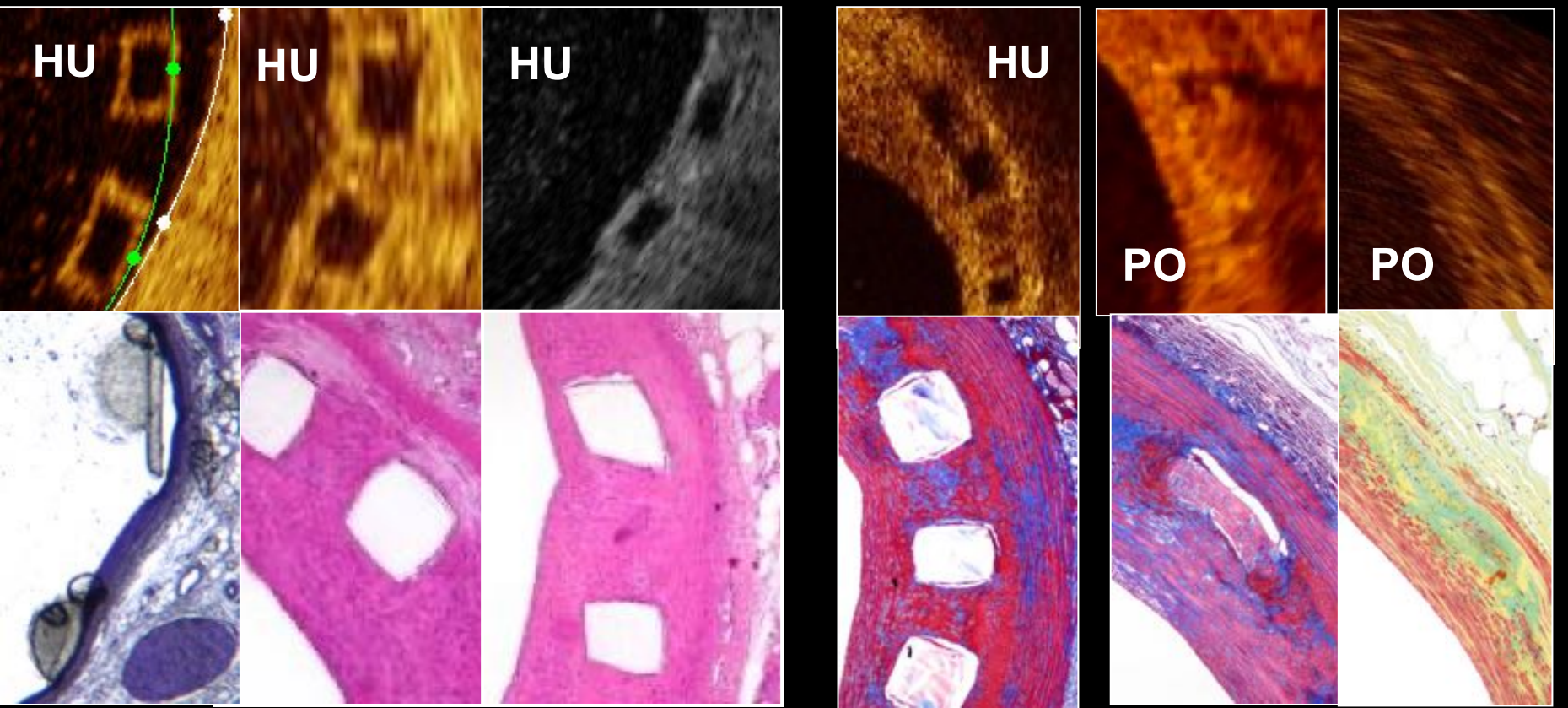
markers


5Y
1Y
Marker
Marker
markers

Bioresorption over time: OCT/histology in animal

Onuma, Serruys Circulation 2010





Limitation

- By design, major side branches were excluded from the trials although some major side branches incidentally included resulted in protocol violation.
- Longitudinal resolution is limited and subject to cardiac motion artefact.

Summary

- **In the ABSORB B trial, OCT 3-D analysis showed that the ostial area free of struts remained unchanged at 6 months compared to baseline. At 12 and 24 months, the ostium area reduced due to growing tissue covering over and between the struts. However there are so far no clinical consequences of this phenomenon.**

- **In the preliminary analysis, the ostium area seems to increase from 1 year to 3 years due to the reduction of neointima and recreation of bifurcation carina.**

- **5 year analysis is ongoing…**