

Erasmus MC

Universitair Medisch Centrum Rotterdam



Application of Bioabsorbable Scaffolds for Bifurcation Lesions

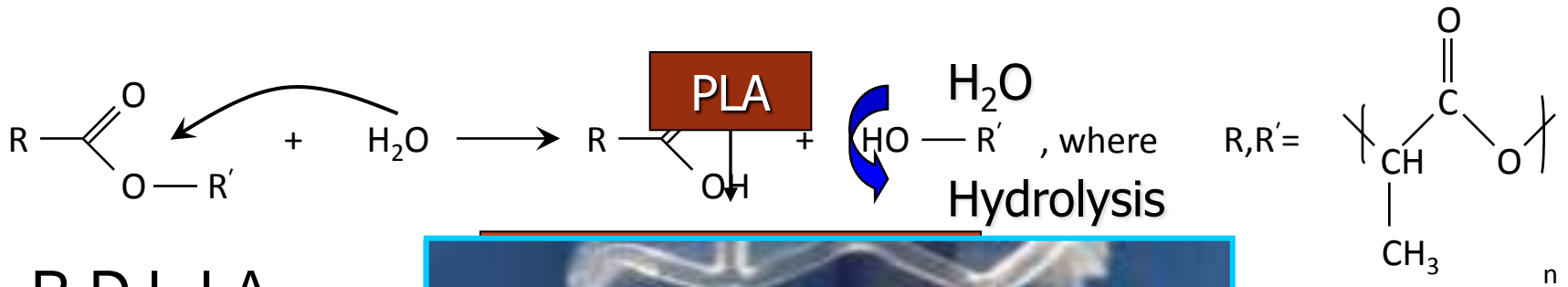
Yoshinobu Onuma, Robert-Jan van Geuns and Patrick W. Serruys

Thoraxcenter, Erasmus MC

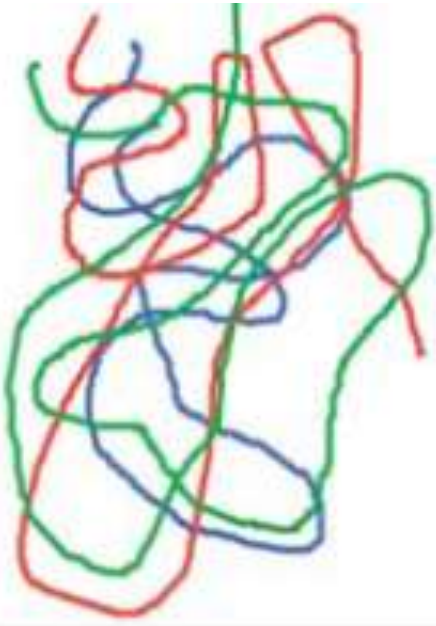
On behalf of ABSORB A, B and EXTEND investigators

Polylactide Degradation Mechanism

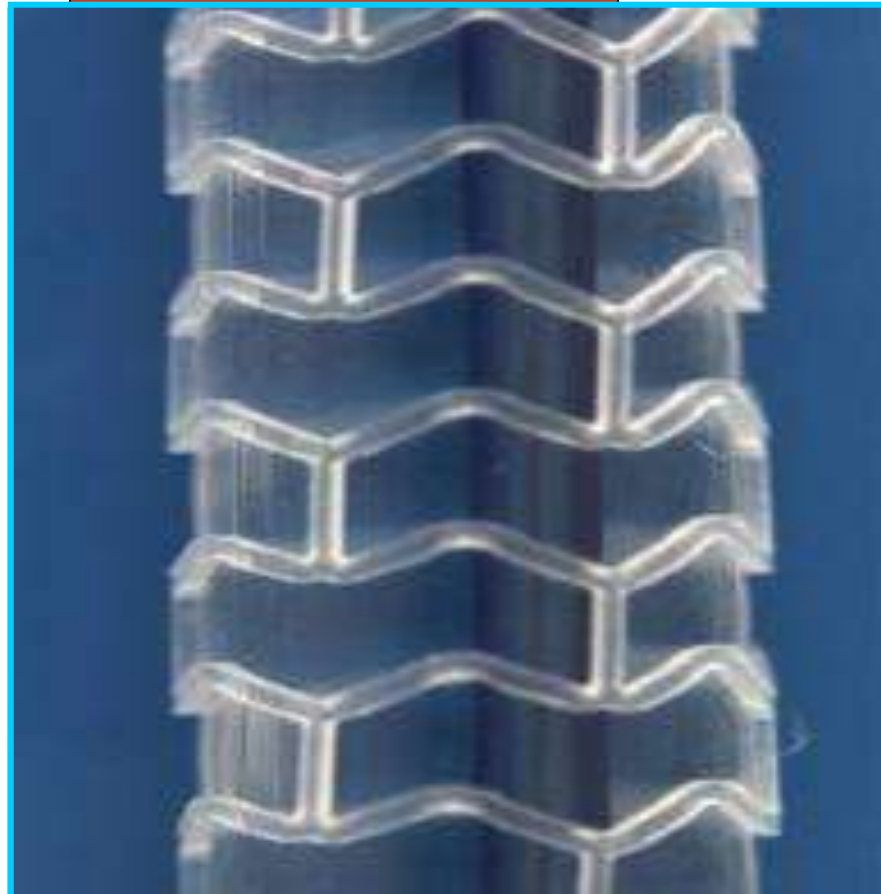
Hydrolysis via Random Chain Scission of Ester Bonds



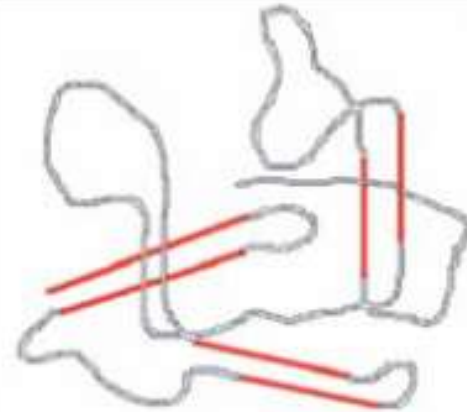
P-D,L-LA



Amorphous



P-L,L-LA

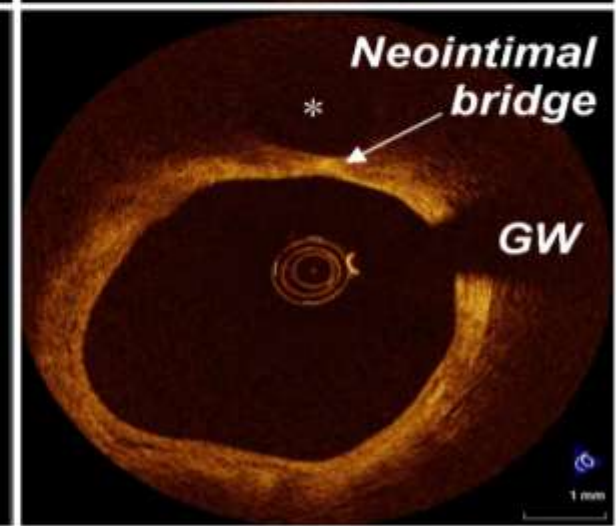
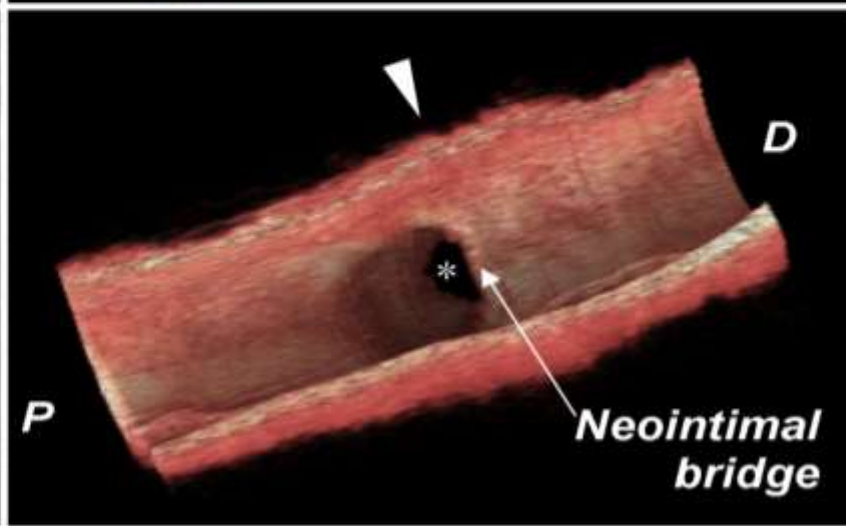
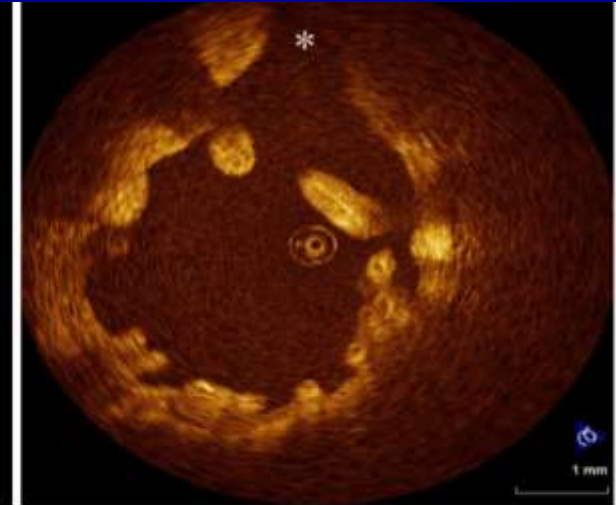
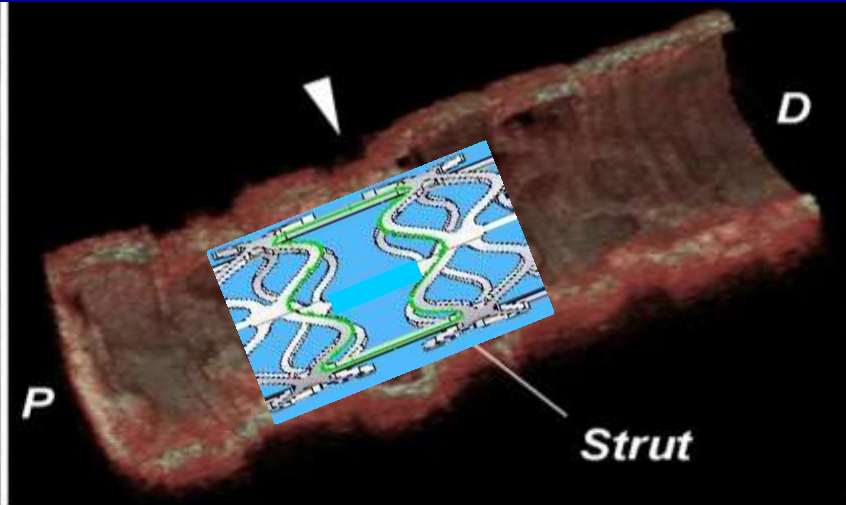
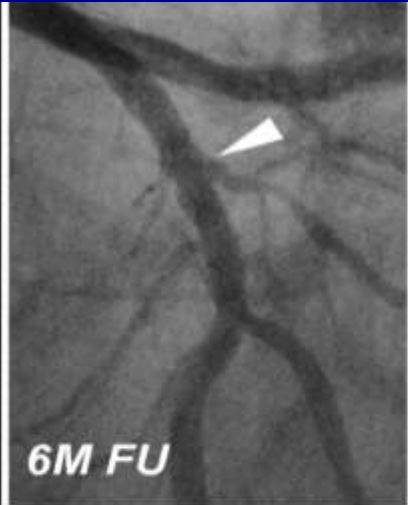


Semicrystalline

Overview

- **What do we know from previous studies?**
- **Issues with bifurcation**
- **Phantom studies**
- **Fenestration**
- **2-device strategies**
 - **ABSORB + ABSORB**
 - **Hybrid**
- **Conclusion**

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)



A

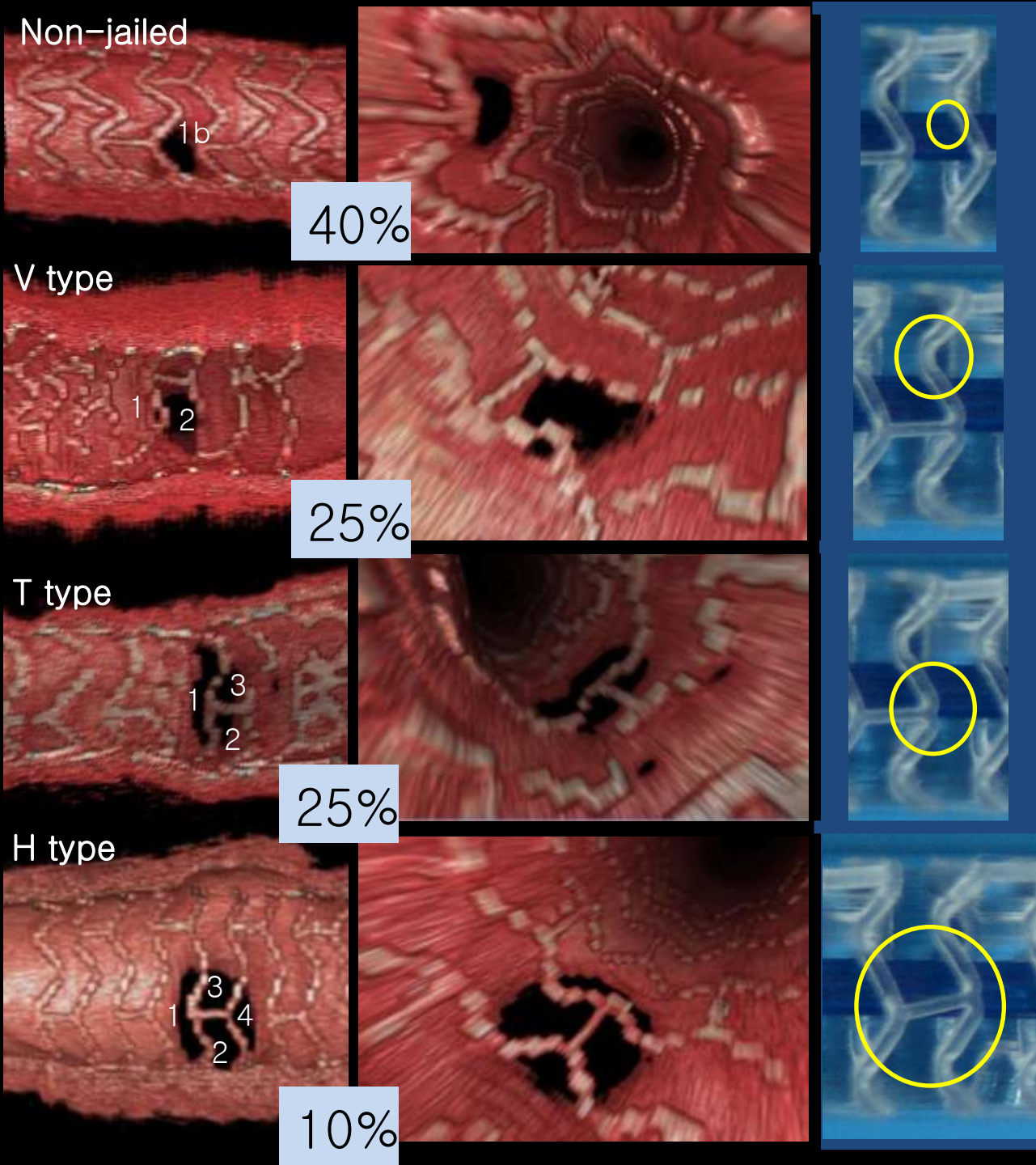
B

C

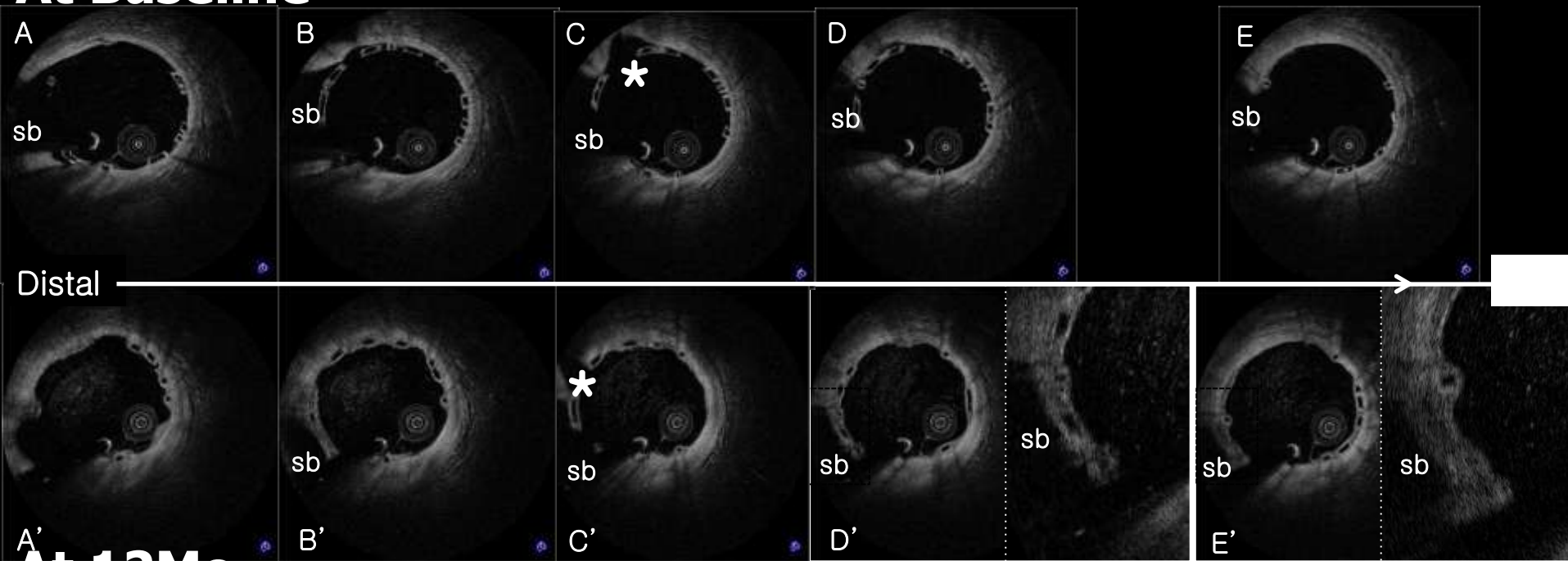
**Today, with 3-D OFDI
we can further
evaluate the
bioresorption process.**

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)

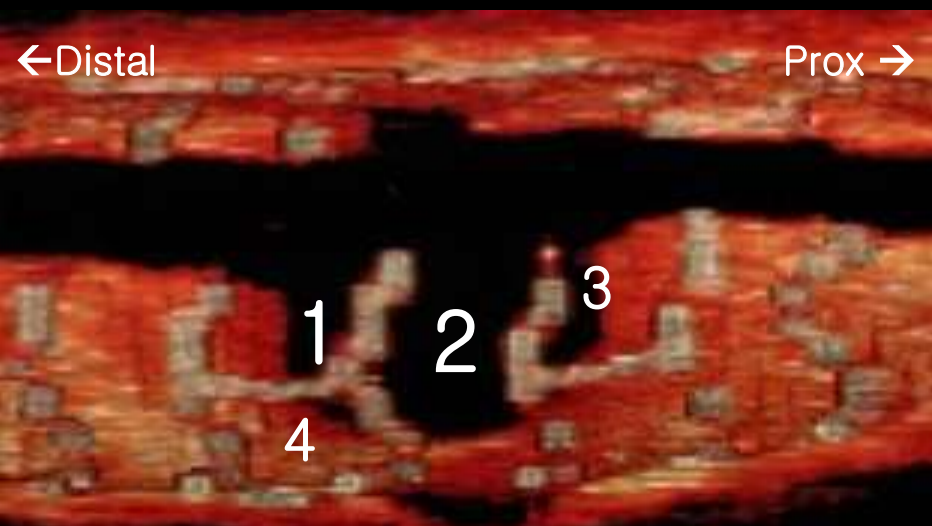
**Absorb Cohort B
(n=17)**



At Baseline



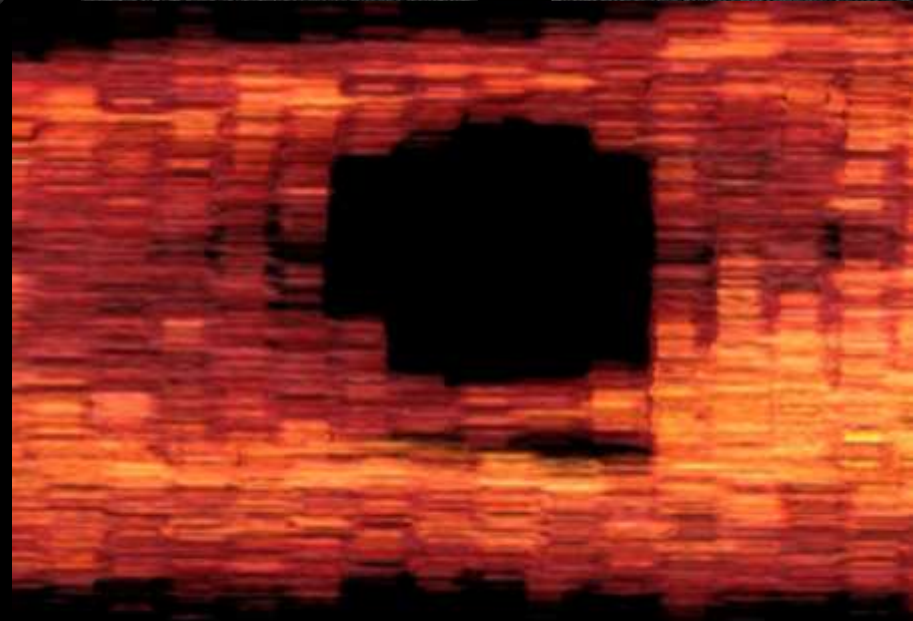
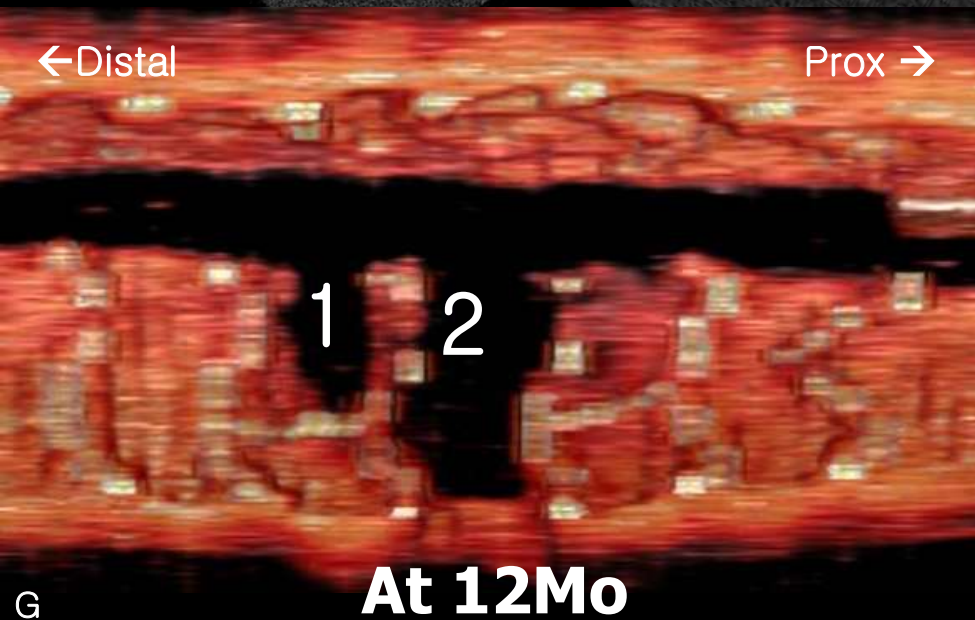
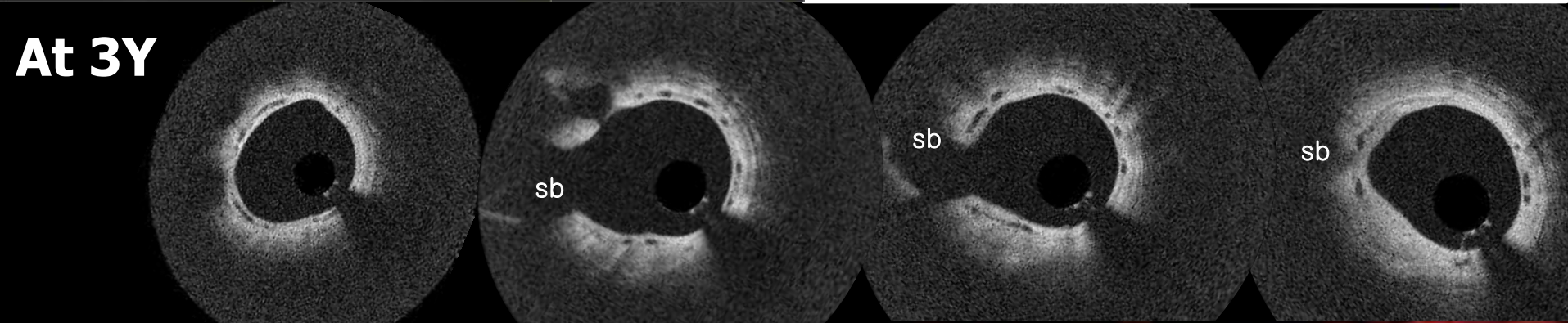
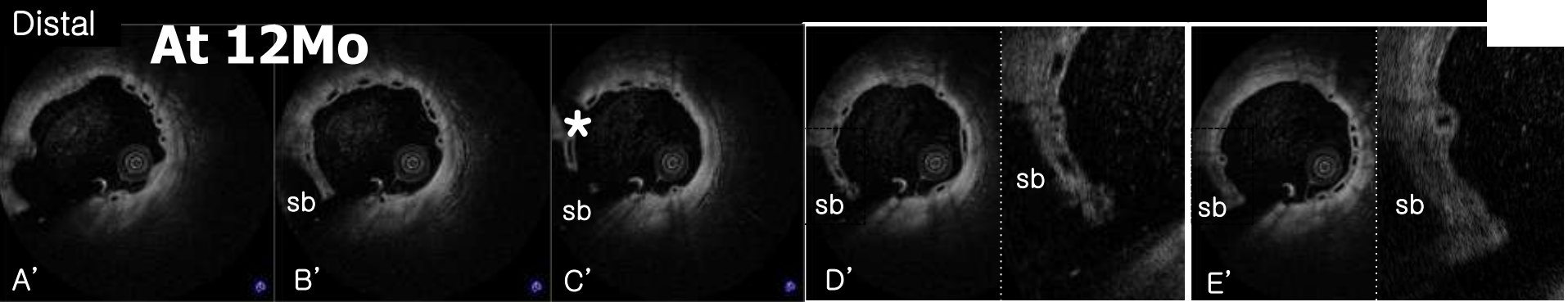
At 12Mo

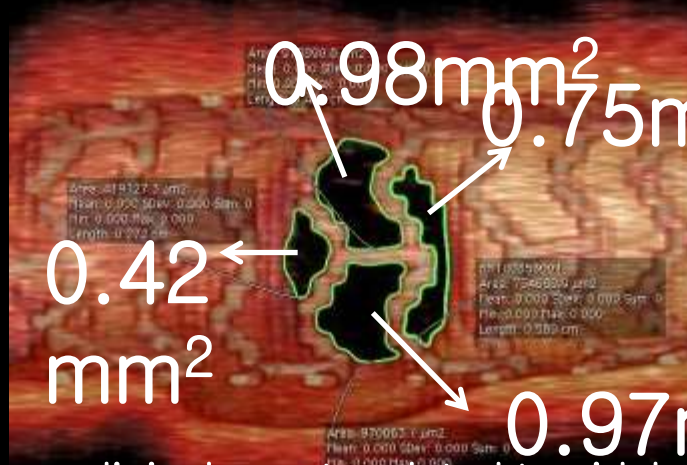


At Baseline



At 12Mo





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
Ostium area
free from
Strut, mm²

2.13±1.1 1.93±1.0 1.31±0.5 0.03

0.58 ± 0.12 0.33 ± 0.12 0.33 ± 0.12 0.03

**However, these studies
excluded a major
sidebranches > 2mm**

No. of
Compartment
Ostium area
free from Strut,
mm²

1.18±0.41 0.001 0.28

0.64 0.47 ± 0.38 0.68±0.38 0.002 0.02

P(1Y-3Y)

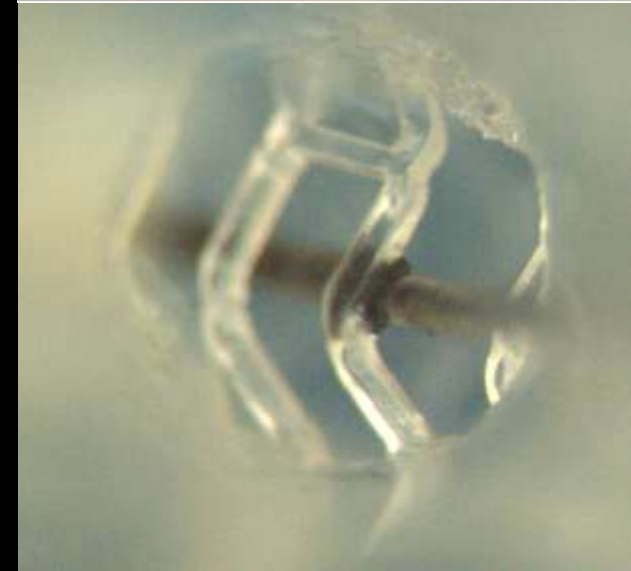
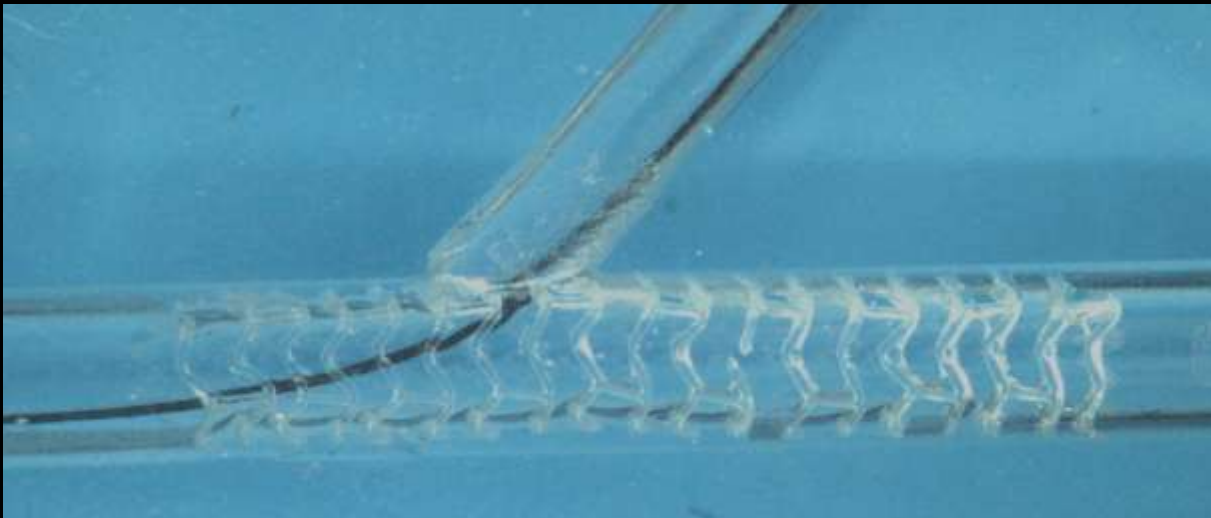
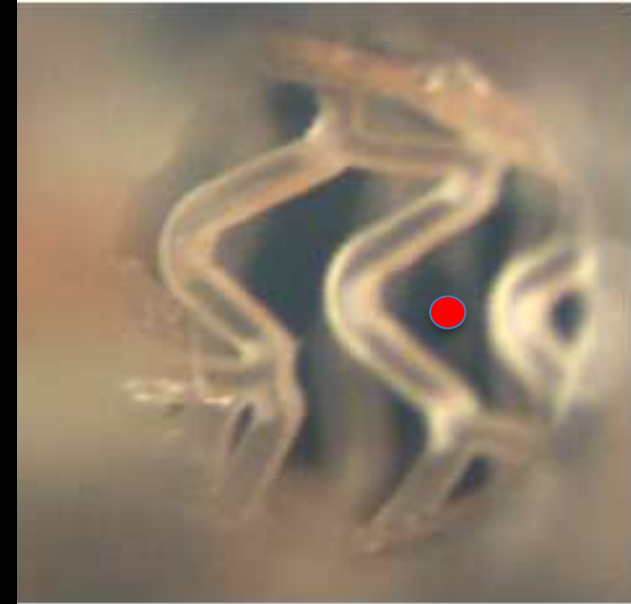
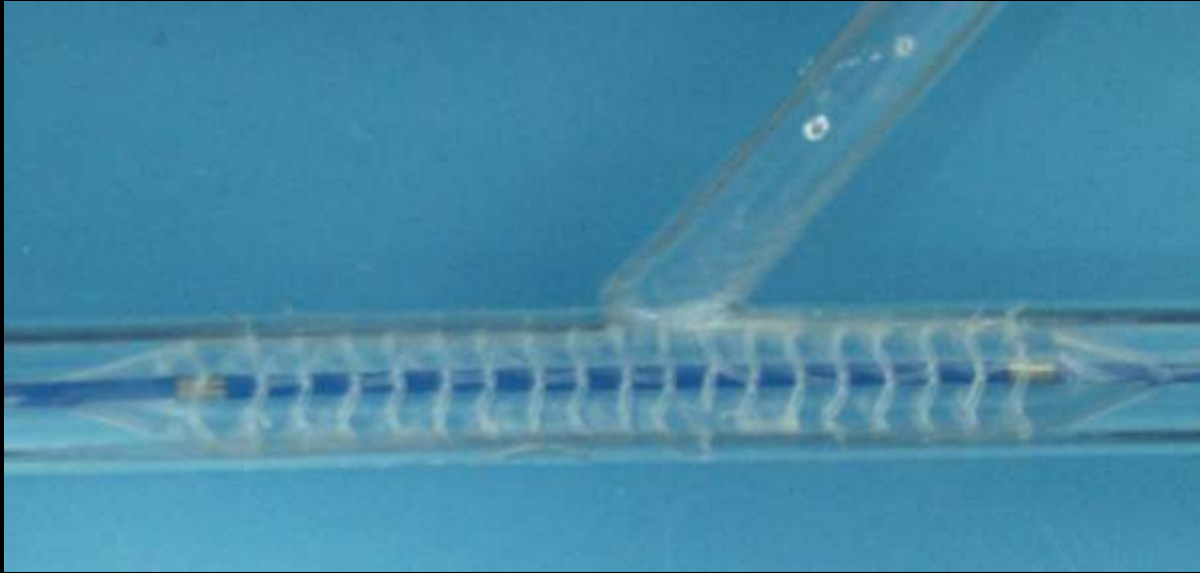
Overview

- **What do we know from previous studies?**
- **Issues of bifurcation treatment with BVS**
- **Phantom studies**
- **Fenestration**
- **2-device strategies**
 - **ABSORB + ABSORB**
 - **Hybrid**
- **Conclusion**

Limit of expansion

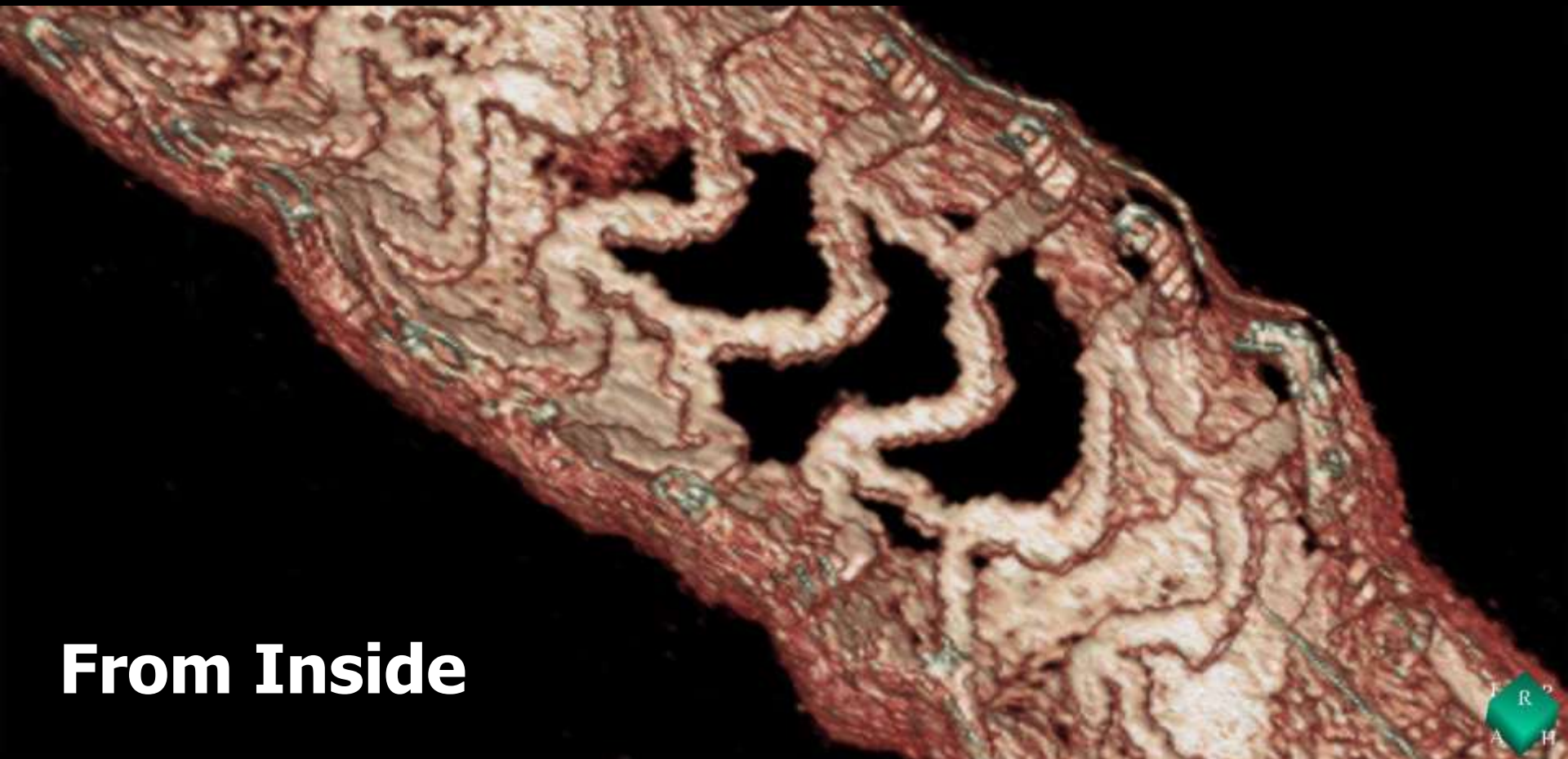
- **Key issue with the ABSORB scaffold (information not available for all the other bioresorbable scaffolds):**
 - Limited range of expansion**
 - 2.5 mm scaffold → up to 3.0mm**
 - 3.0 mm scaffold → up to 3.5mm**
 - 3.5 mm scaffold → up to 4.0mm**
- **Beyond that range, breakability of struts can be observed.**
- **Is sidebranch fenestration safe?**

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



3-D reconstruction of OFDI-OCT (TERUMO)

Distal

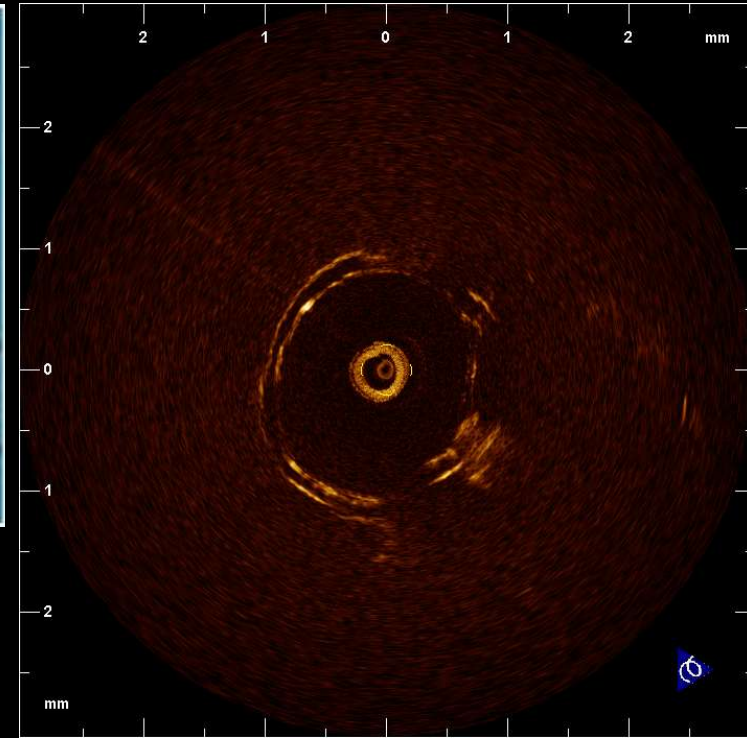
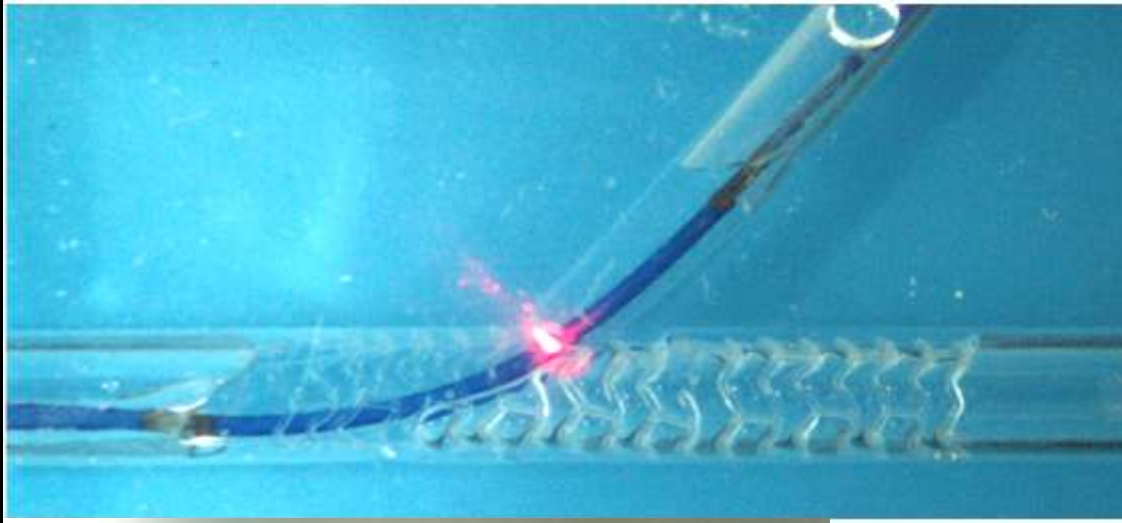


From Inside

Proximal



Side-branch fenestration (2.5 x 13 mm, 8atm)

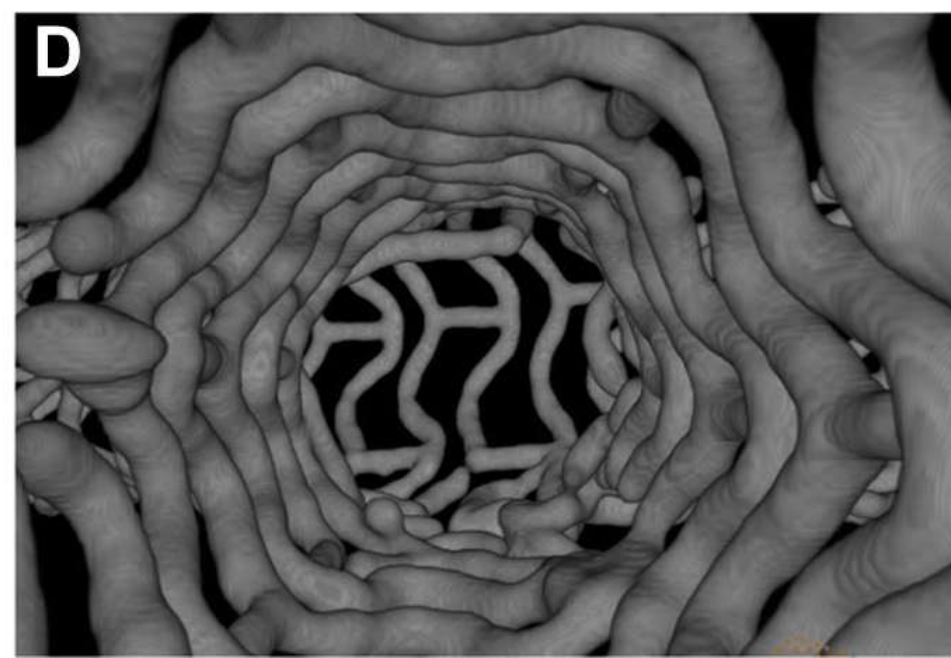
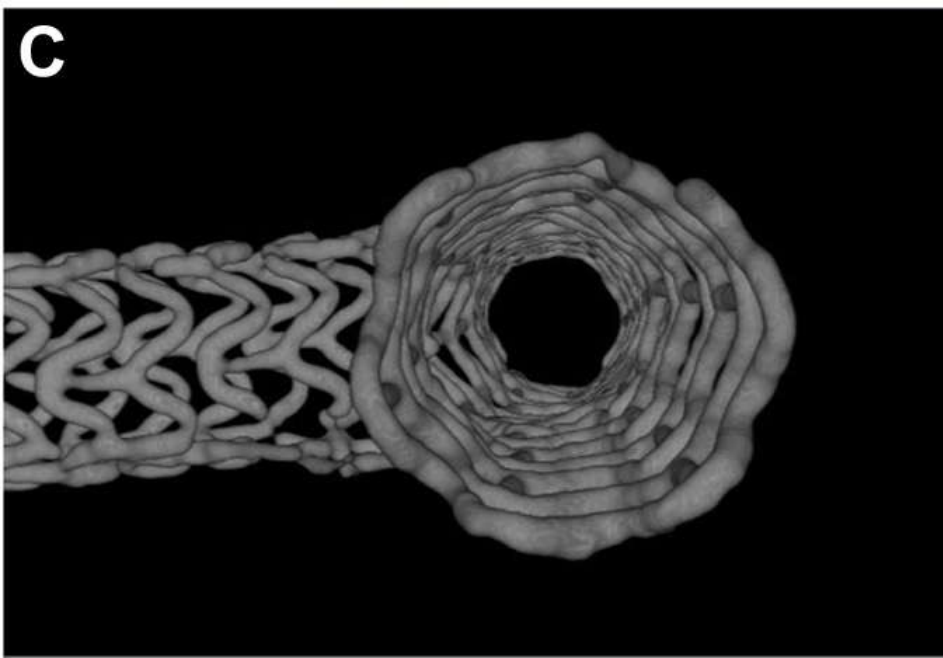
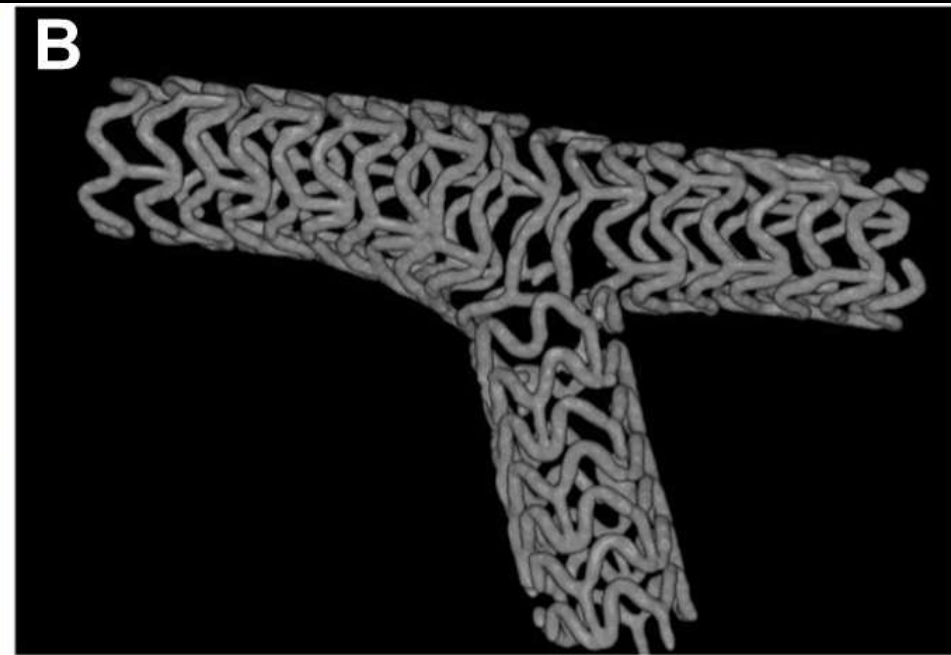
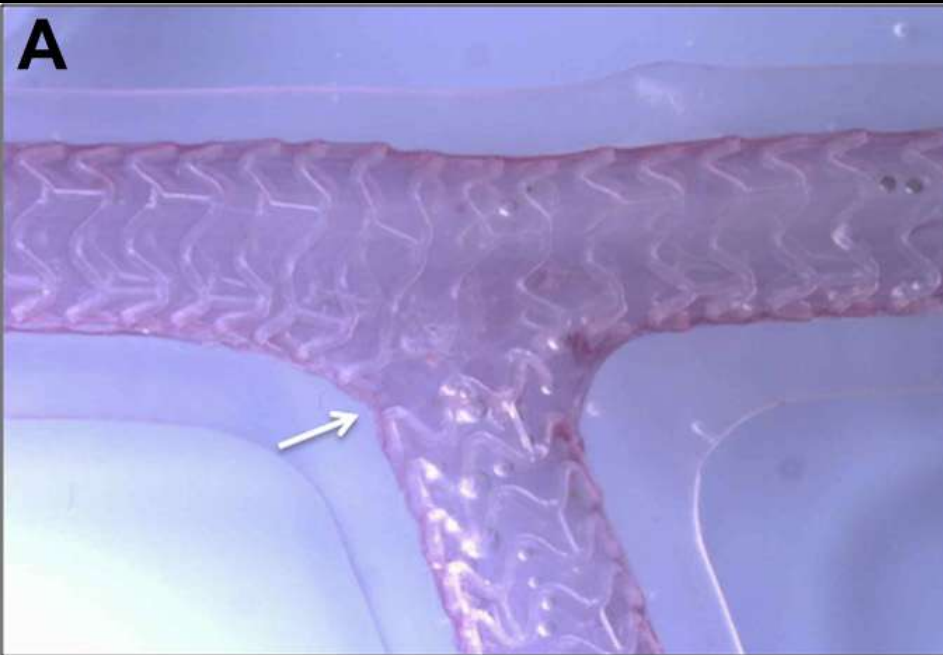


3D -OCT after fenestration



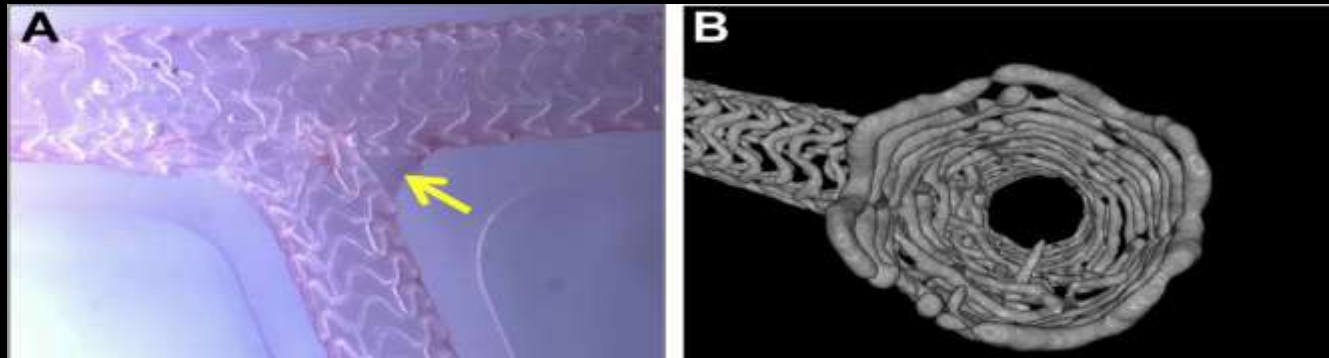
T-scaffold in phantom

Dzavik, Colombo JACC intervention 2013

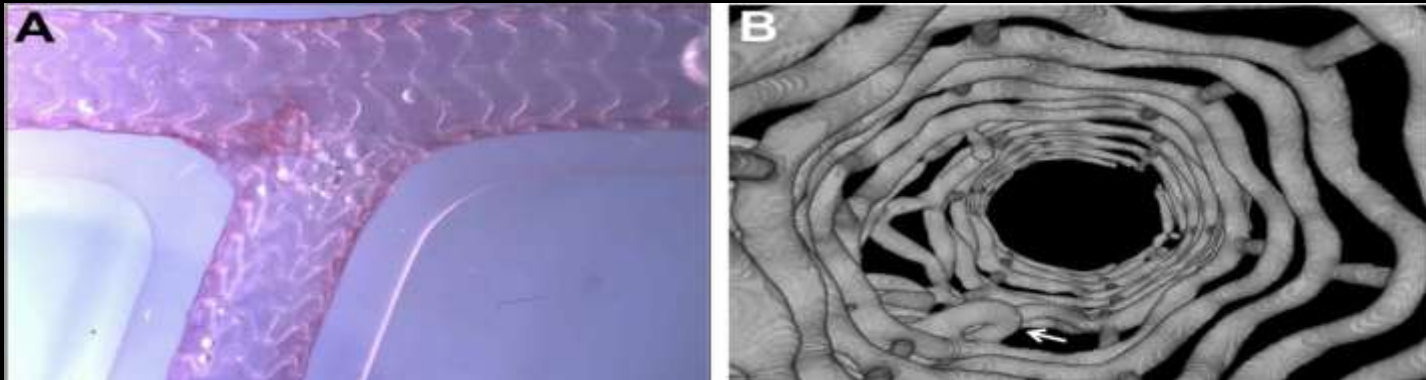


Double crush

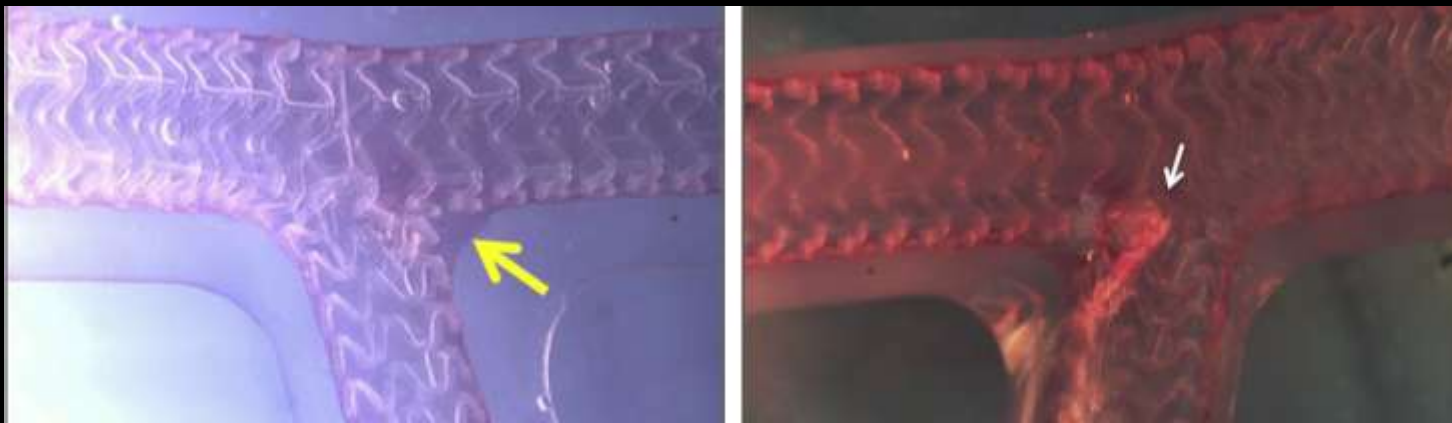
Dzavik, Colombo JACC intervention 2013



Mini crush



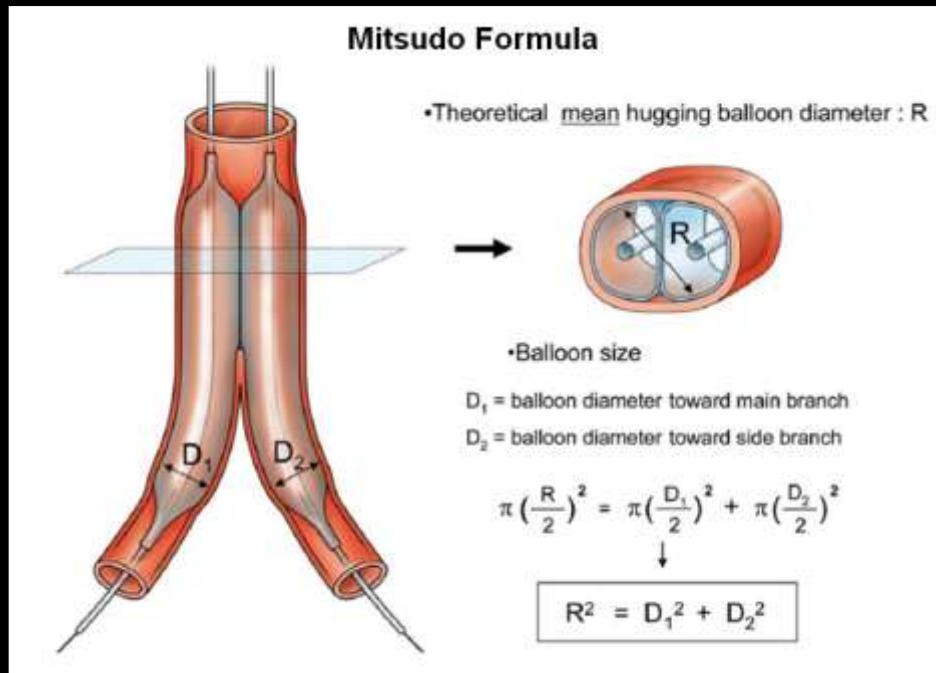
Culotte



Limit of expansion

Kissing balloon is not recommended

Simultaneous balloon inflations will cause damage of proximal scaffold rings, if kissing balloons are over-sized



Example:

$D_1 = 3.32$ mm

Main Branch Balloon

$D_2 = 2.81$ mm

Side Branch Balloon



$R = 4.36$ mm

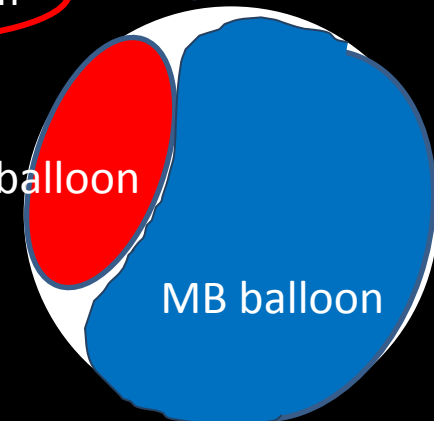
Kissing Balloons

SB balloon

MB balloon

Morino, Y., et al. *Circ J.* 2008; 72: 886-892.

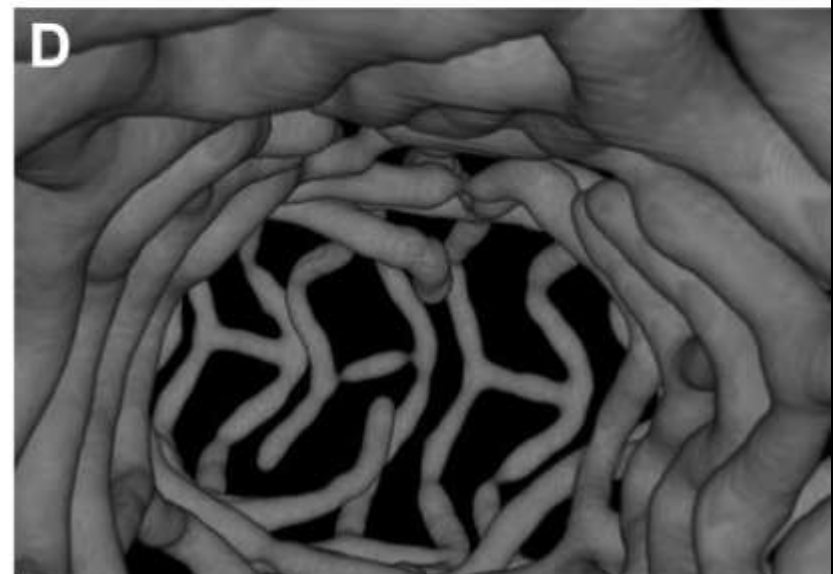
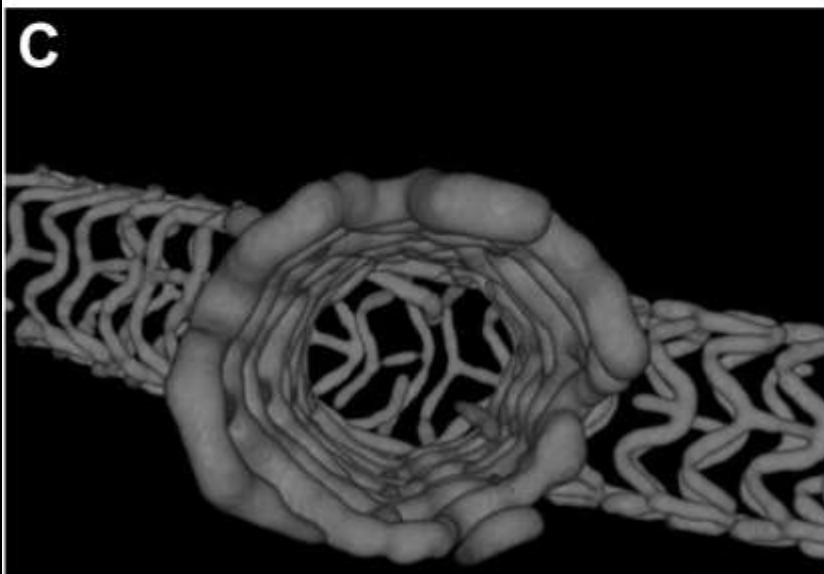
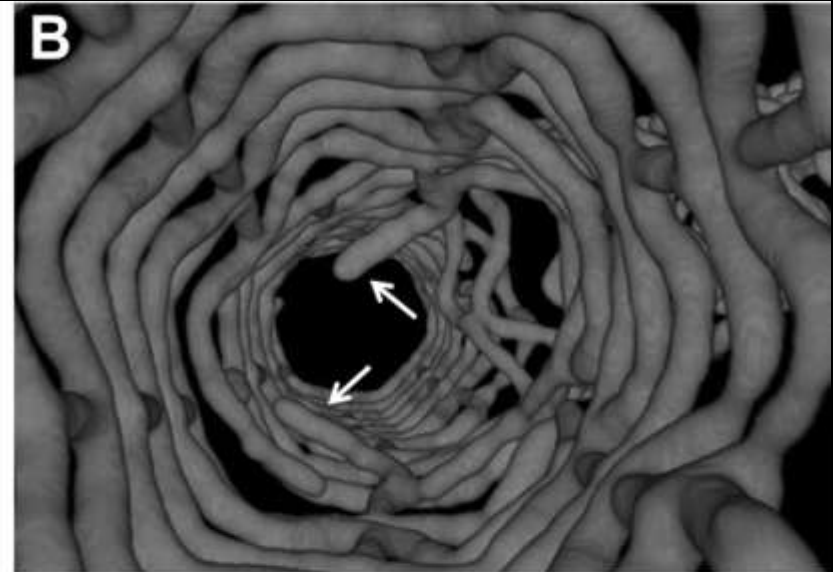
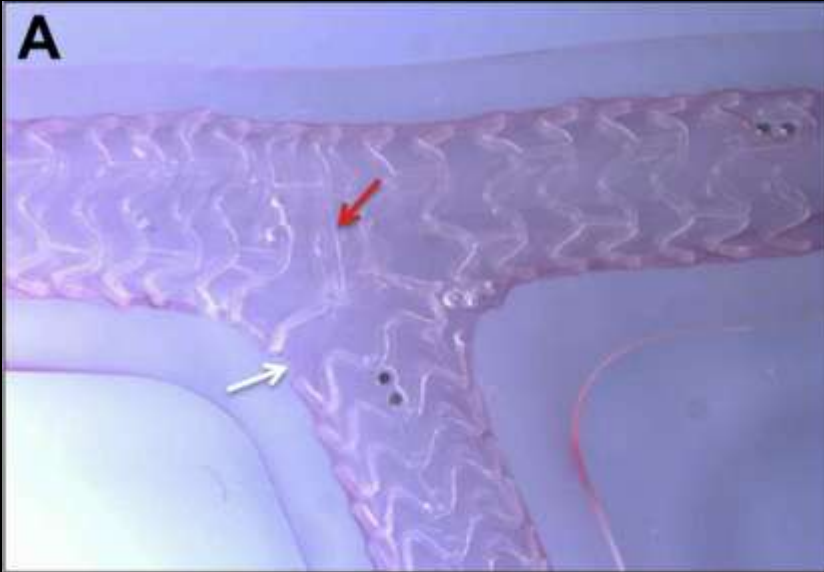
SEVERE OVER-EXPANSION



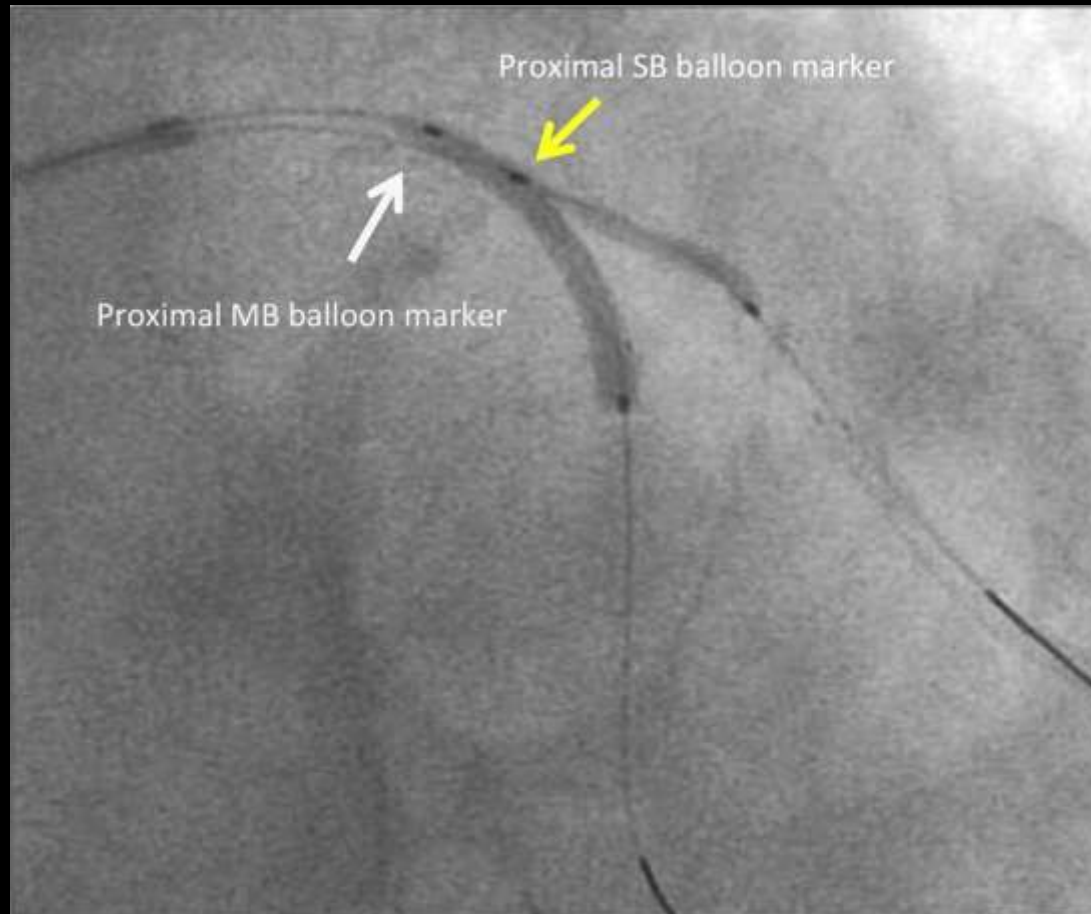
T-scaffold in phantom

Dzavik, Colombo JACC intervention 2013

Kissing balloon with 2.5mm at 10atm and 3.0mm balloon at 10atm resulted in disruption of a ring



Hug (or snuggle)



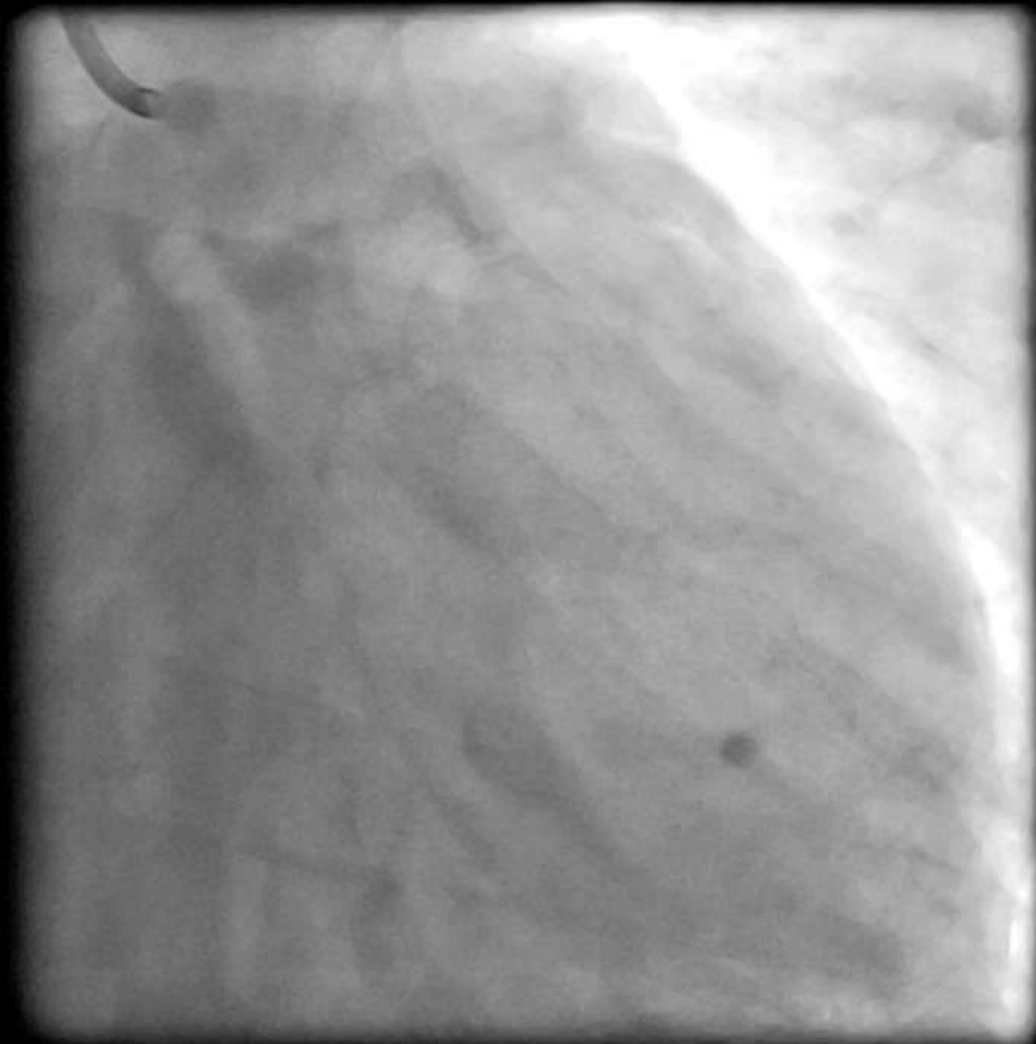
To avoid any potential damage to the proximal part of mainbranch scaffold, hug ballooning or sequential kissing is recommended

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CASE: SB fenestration to restore flow

- **68 year-old male**
- **Presenting with non-STEMI**
- **Bifurcation lesion with a small 2nd Diagonal sidebranch (1.7mm)**



CASE: SB fenestration to restore flow

- **68 year-old male**
- **Presenting with non-STEMI**
- **Bifurcation lesion with a small 2nd Diagonal sidebranch (1.7mm)**



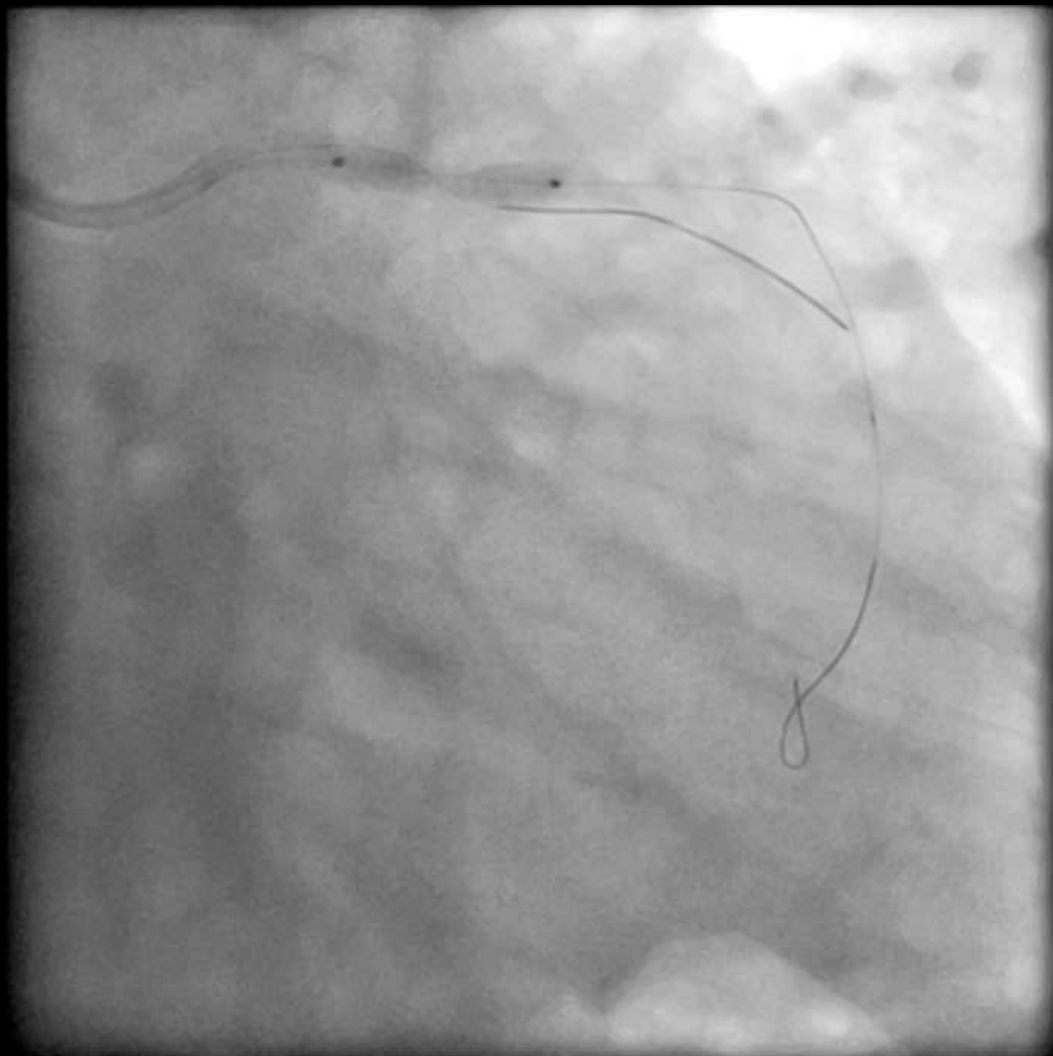
CASE: SB fenestration to restore flow

- **A small sidebranch, but guidewires (Hi-Torque PILOT) were crossed to the LAD and 2nd Diagonal branch**
- **Predilatation with a 2.5mm compliant balloon**



CASE: SB fenestration to restore flow

- **A BVS 3.0x18mm was implanted crossing the 2nd Diagonal branch.**



CASE: SB fenestration to restore flow

- **After implantation of a BVS, the patient experienced chest pain with ST elevation.**
- **Angiography revealed a decrease in the flow to the 2nd diagonal decreased (TIMI 2)**



CASE: SB fenestration to restore flow

- **After recrossing a wire, the BVS was fenestrated toward 2nd diagonal with a Trek 1.5 x 12 mm balloon.**



CASE: SB fenestration to restore flow

- The flow to the 2nd diagonal recovered (TIMI3)

3D-OCT (endoscopic view from prox to distal)

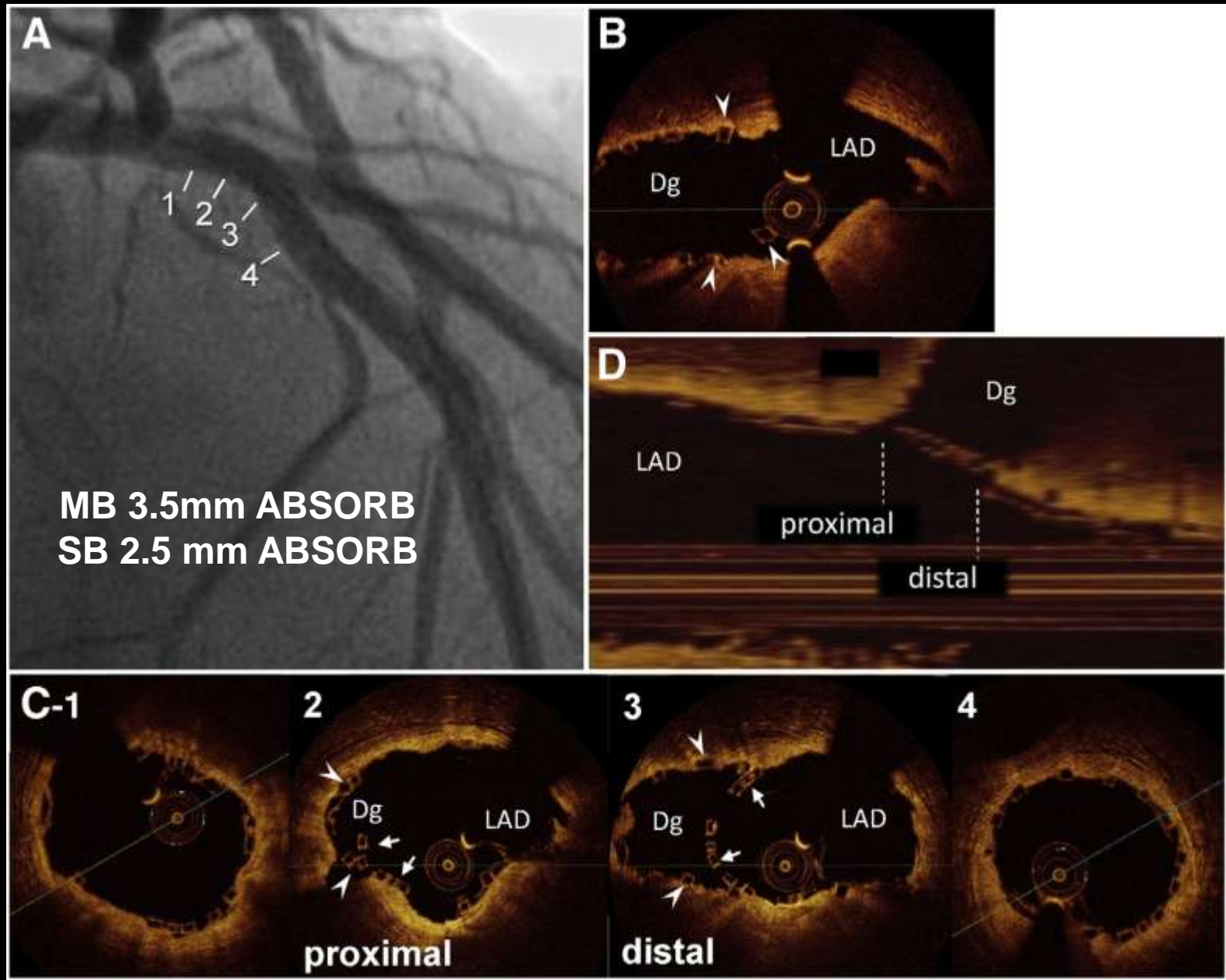


CASE: SB fenestration to restore flow

- **Final angiogram**
- **No significant CK-MB rise**
- **Patient remained uneventful at 30 days**



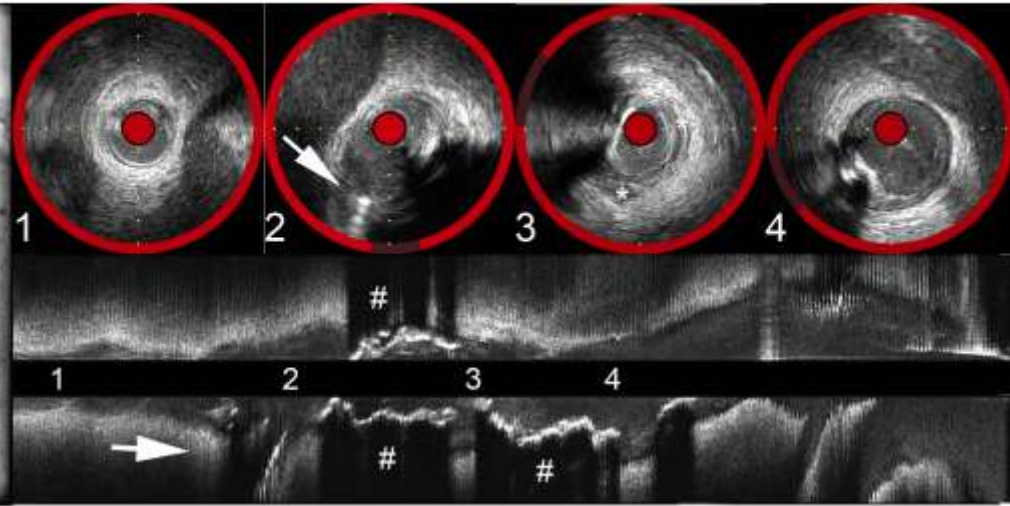
2-device strategies



CTO / Bifurcation - culotte

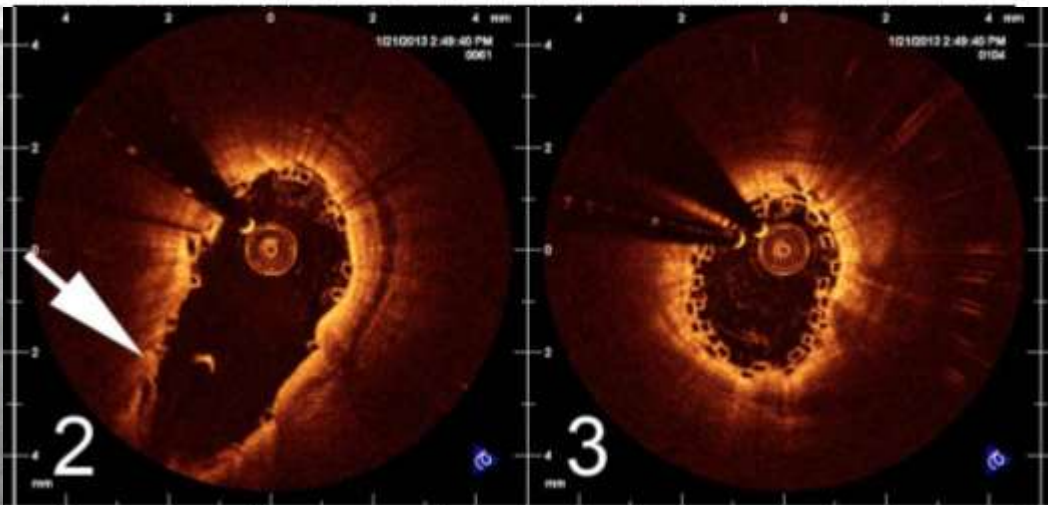
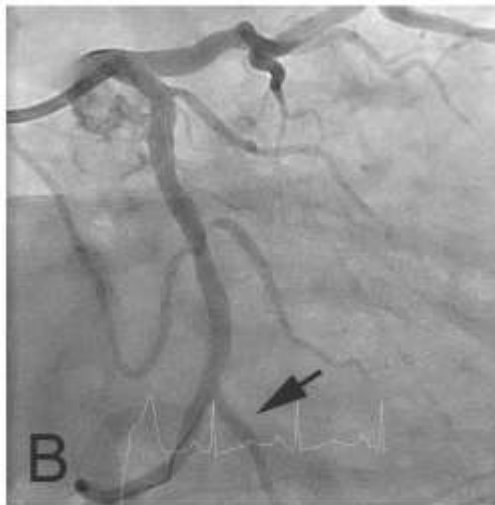
Angio pre-procedure

IVUS post recanalisation & pre-dilatation



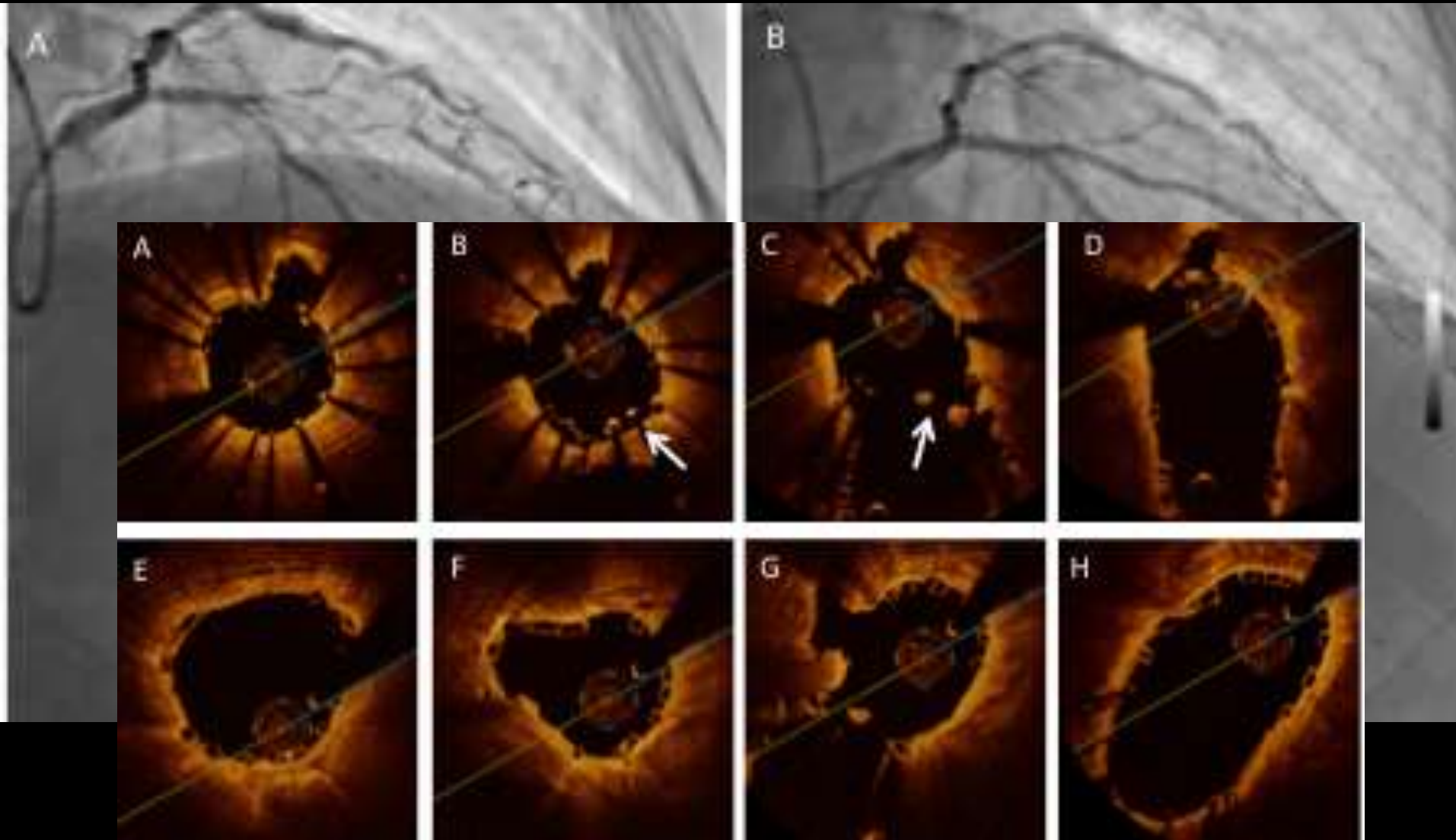
distal

proximal



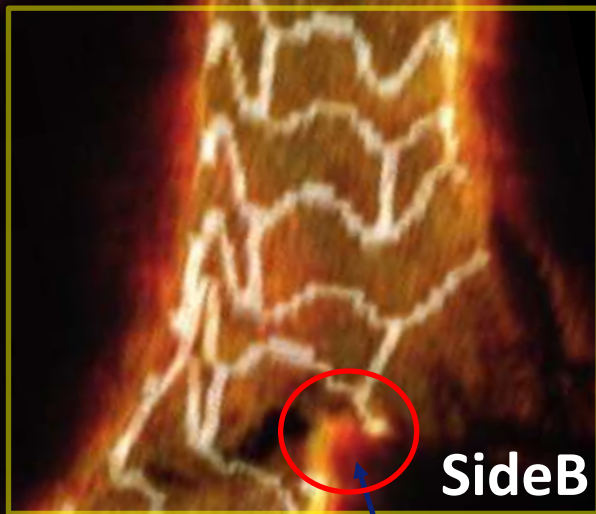
Angio & OCT final result

Bifurcation -hybrid

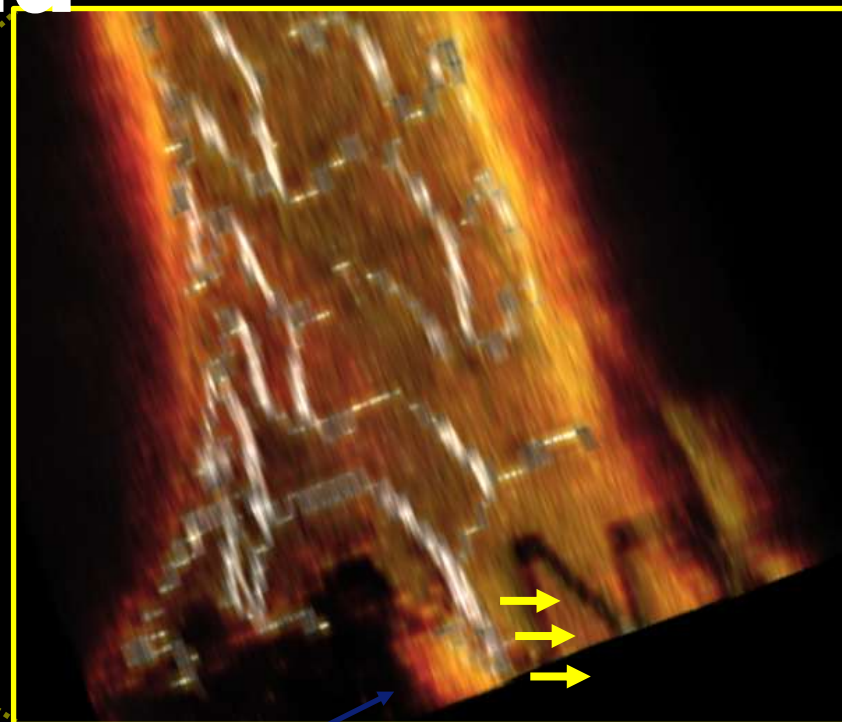


Bifurcation - hybrid

PMV



SideB



→ Shadow of metallic stent

Carina

BVS strut was partially migrated into the side branch without damaging strut continuities

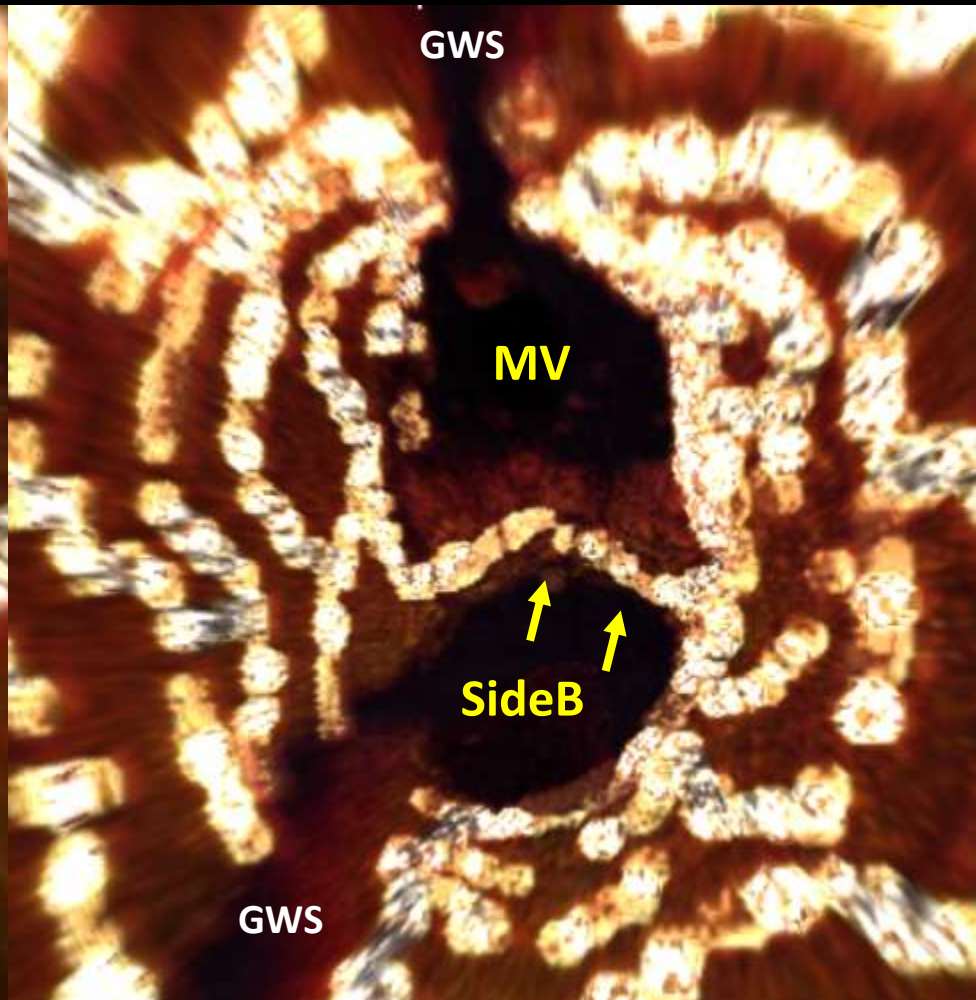
DMV

Bifurcation -hybrid

Pullback from DMV



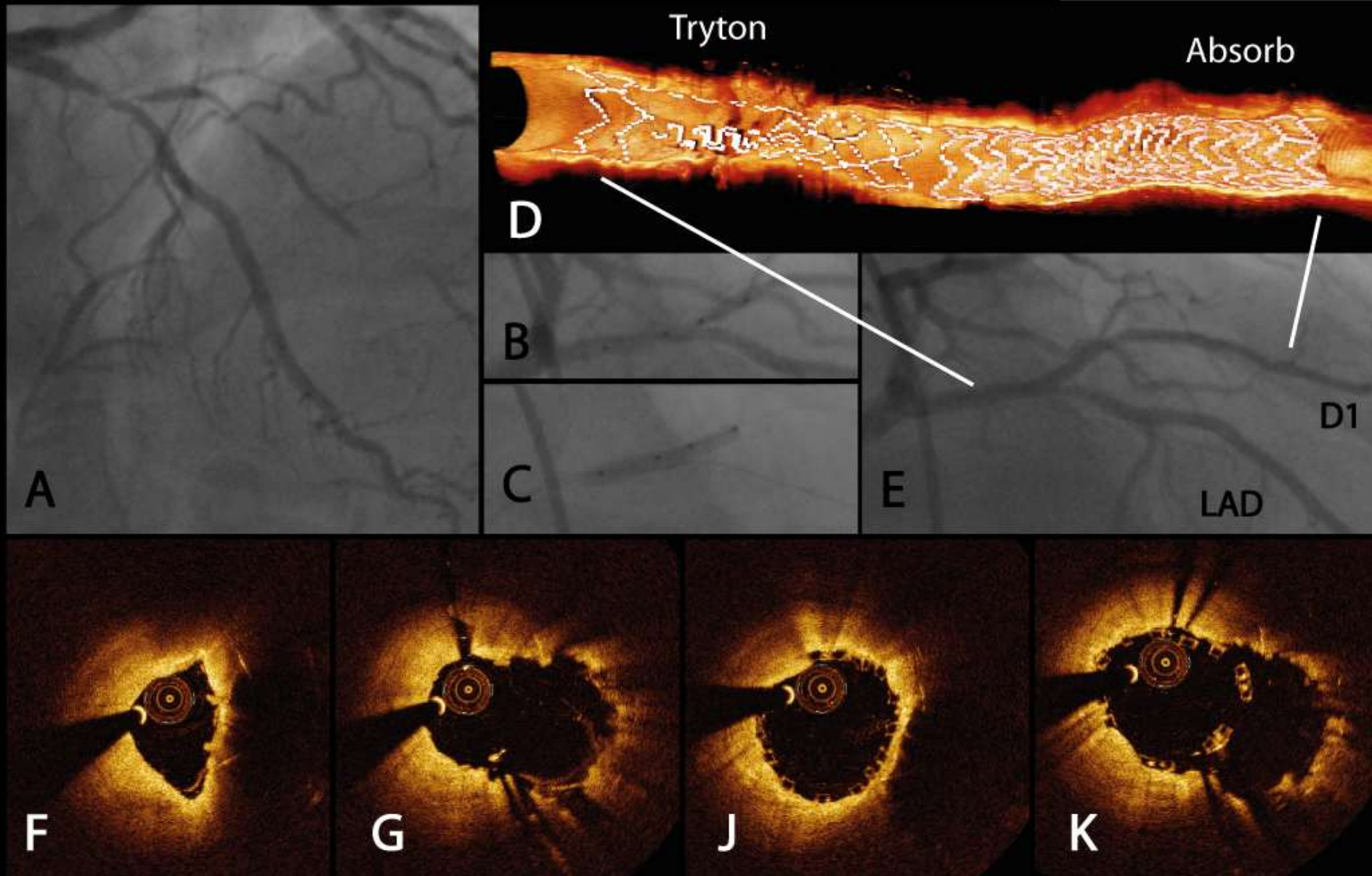
Pullback from side branch



Incomplete visualization of hoop
at bifurcation carina

Complete visualization of hoop
at bifurcation carina

Bifurcation -hybrid



Conclusions

- **Previous ABSORB studies showed at long term a disappearance of jailing struts in front of small sidebranch. However, no data are available for large sidebranches.**
- **Phantom studies showed a feasibility of sidebranch fenestration (2.5mm) and implantation with 2-device techniques. However, because of the limited expansion capability of the ABSORB scaffold, kissing balloon is not recommended. Hug(snuggle) or sequential kissing could be used to correct malapposition after sidebranch fenestration.**
- **Case studies showed a feasibility of bifurcation treatment with ABSORB scaffolds (SB fenestration, 2-scaffold techniques or hybrid). Provisional strategy seems to be the most practical approach. Clinical outcomes should be investigated in a large population.**