Intravascular imaging techniques in decision making during PCI with scaffold implantation

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20 minutes (plus translation about 10 minutes)

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Harbin - 2016

Why stent?

1 . **Support for 3 month**

(prevent recoil and remodeling)

2. **Antiproliferative drug for short term**

(avoid hyperplasia)

after that we do not need it!

after this time implant is not neceesary and harmful

Why?

Mechanical problems

- Vasomotor reaction
- No natural curves of artery
- Malaposition
- Struts in sidebranches
- Stent fracture

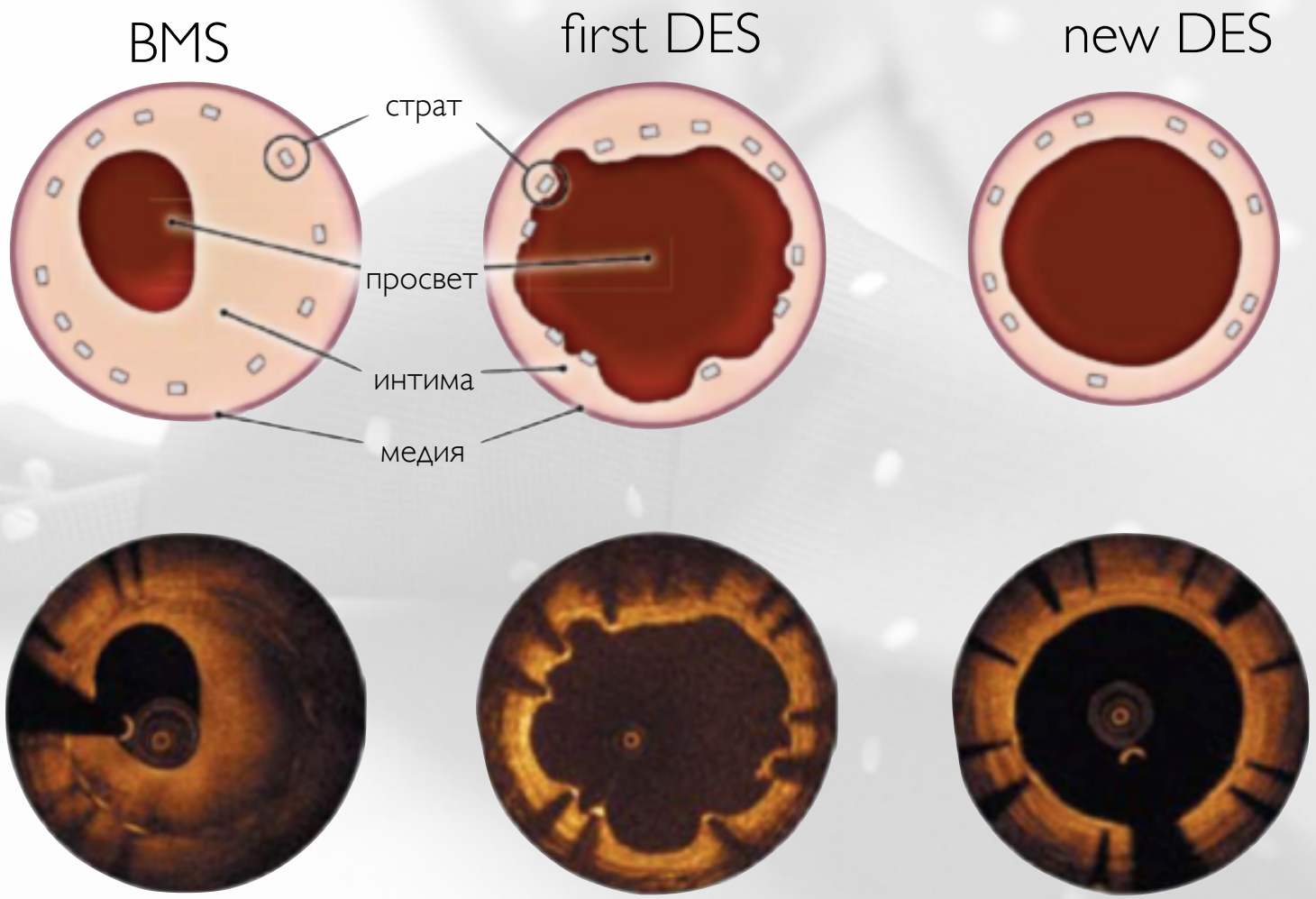
Biological reactions

- Metal can cause hyperplasia (Ni)
- High dose of the sirolimus can cause microaneurysms
- Late tissue reaction to polymer
- Abnormal vessel wall

as result

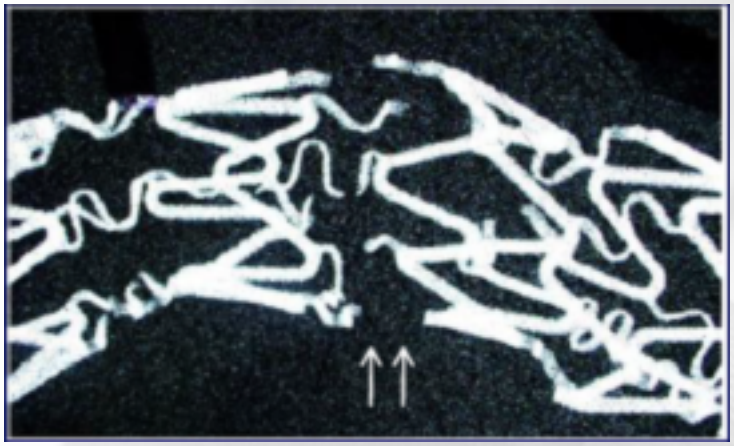
- trombosis
- neoatherosclerosis

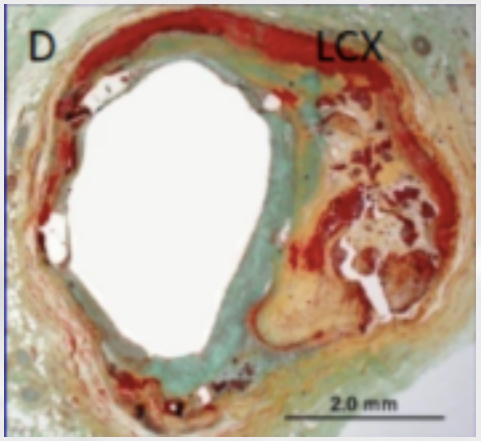
Vascular healing after stent

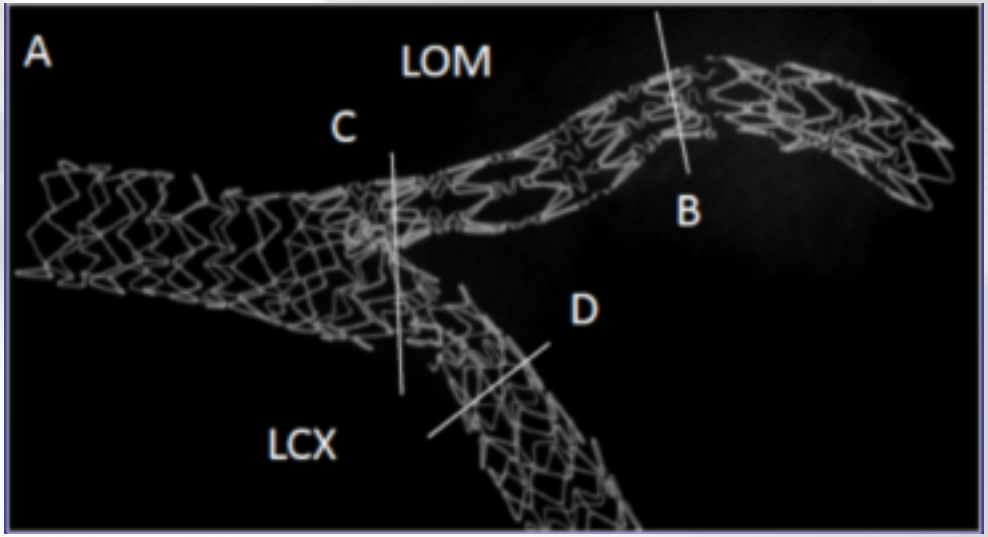


Stefanini G., Holmes D. N Eng J Med 2013;368:254-65

Stent fracture





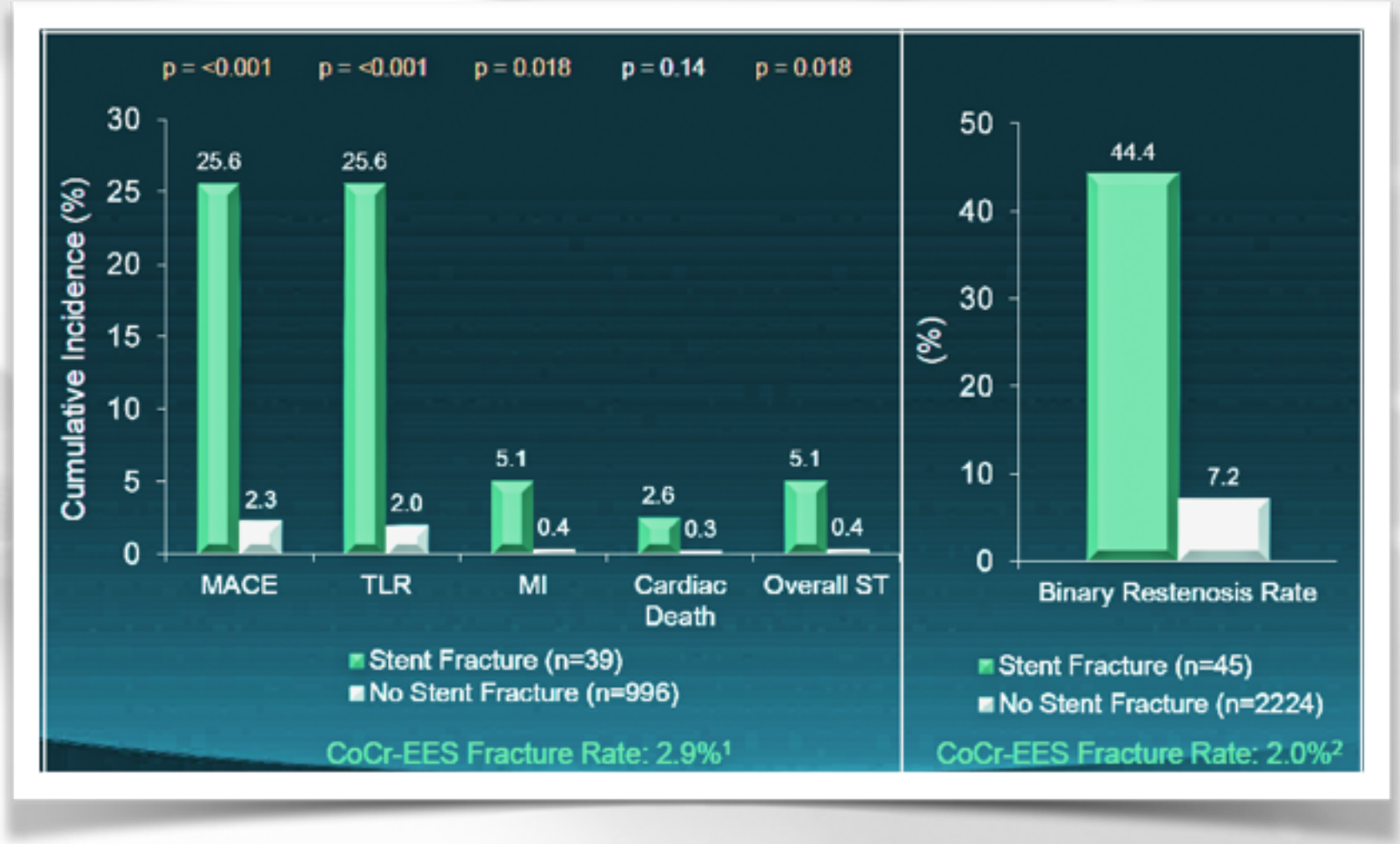


Amoung 177 DES
in CVpath registry in 51 (29%)

complete fracture in 9 cases

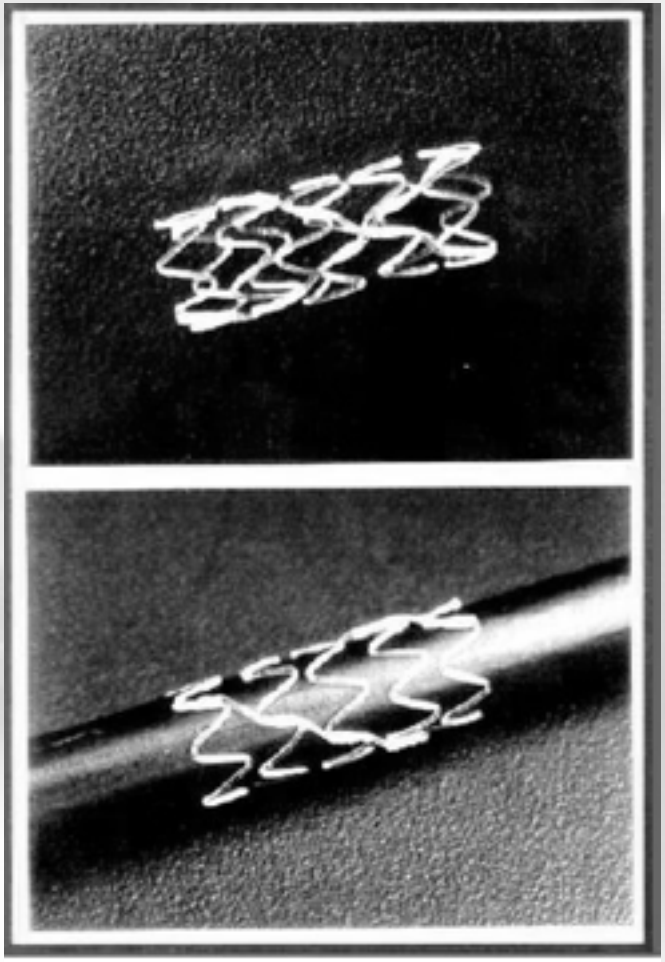
Nakazawa G, et al Jacc 2009 типа

Events are more often

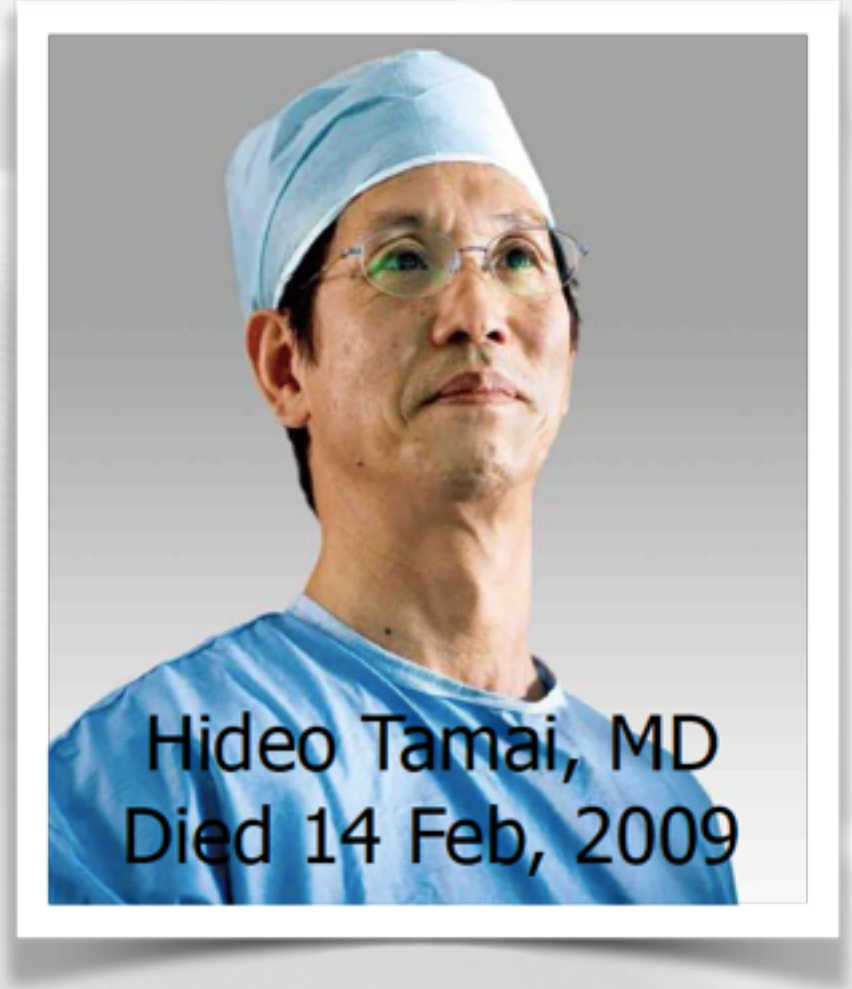


Kuramitsu et al. Circ Cardiovacsular Int 2012; 5(5):663-71

Igaki-Tamai stent 2000

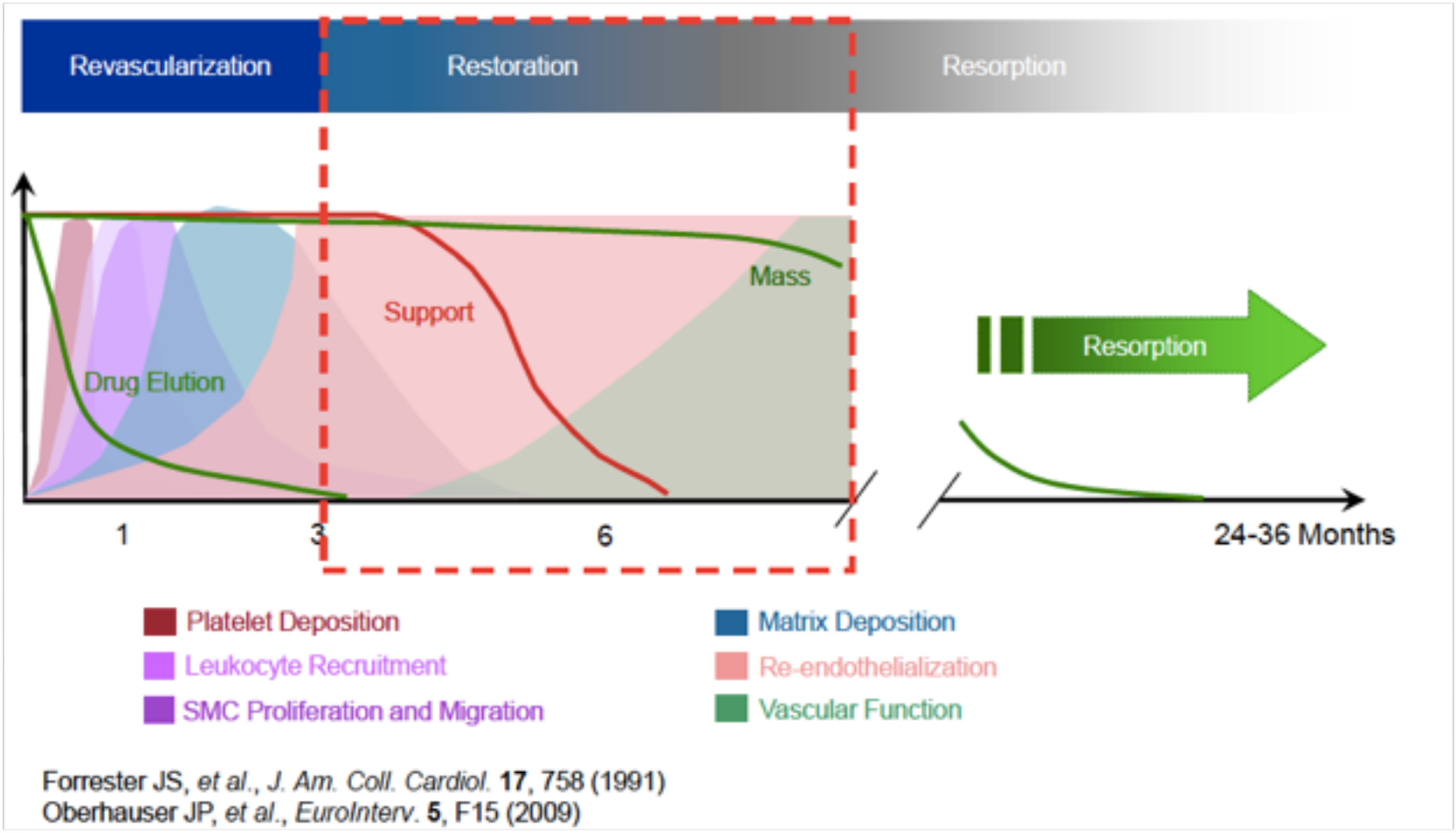


Tamai et al, CCI 2001



Igaki-Tamai		PLLA
Abbott Absorb		PLLA + PDDLA +everolimus
Reva ReSolve		Poly (DTE carbonate) sirolimus
Elixir DESolve		PPLLA + myolimus
Biotronic Dreams		Mg + paclitaxel

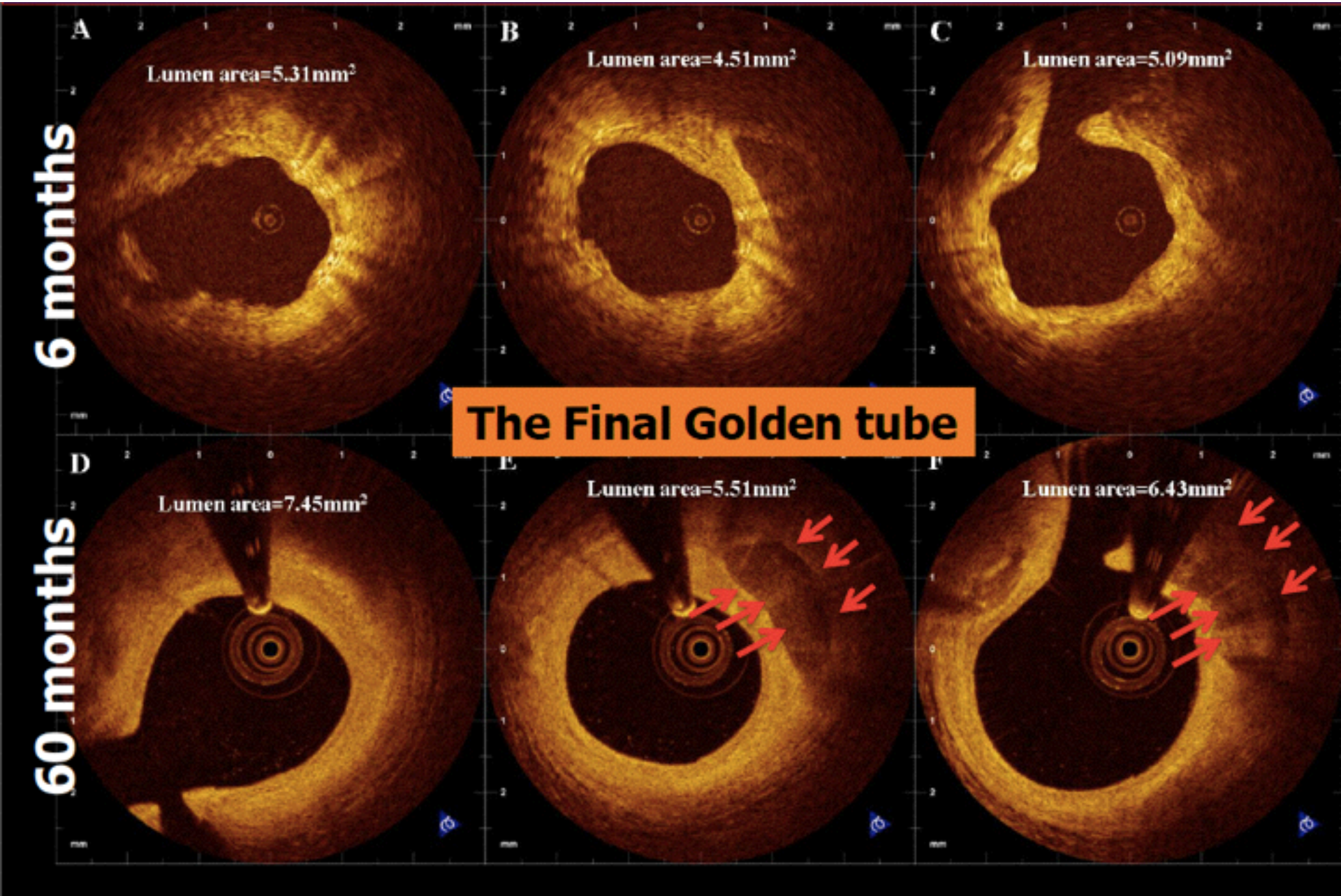
ABSORB

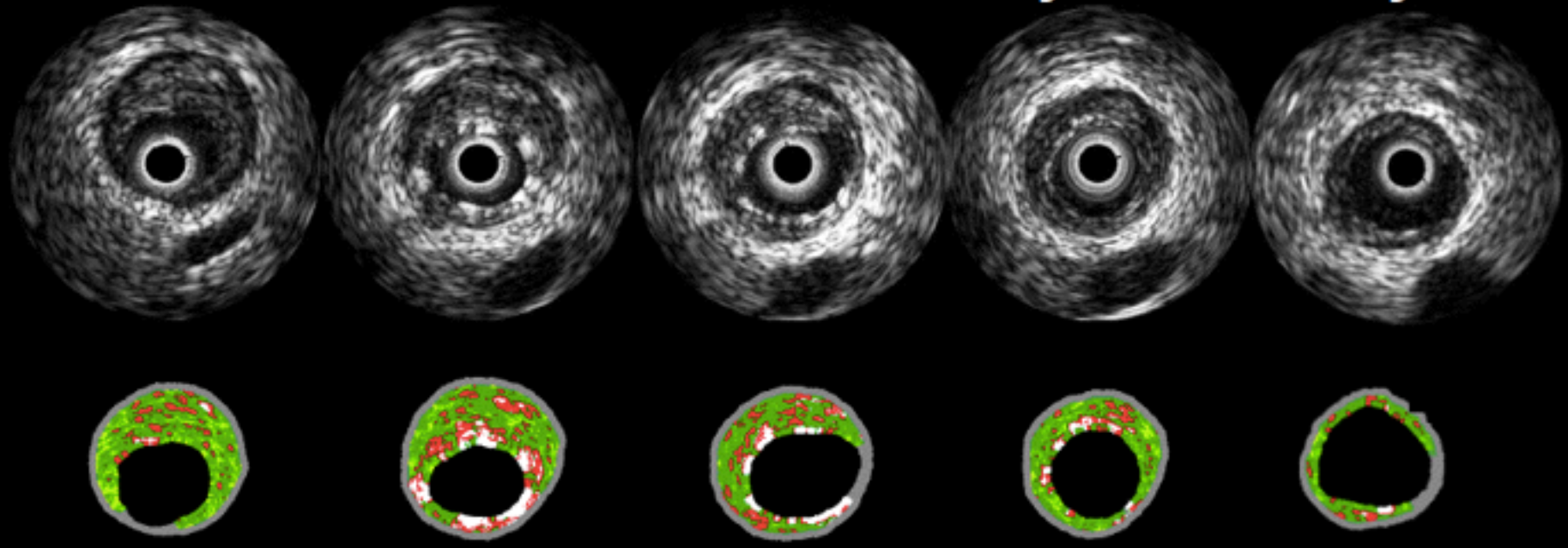


Forrester JS, *et al.*, *J. Am. Coll. Cardiol.* **17**, 758 (1991)
Oberhauser JP, *et al.*, *EuroInterv.* **5**, F15 (2009)

“Golden tube”

= lumen + homogenious endothelisation + vasomotor function





	Pre-PCI	Post-PCI	6 months	2 years	5 years
Mean lumen area (mm^2)	6.95	6.17	6.56	↗	6.96
Plaque area (mm^2)	8.78	9.17	7.54		7.57
Vessel area (mm^2)	15.72	15.34	14.09		14.52

Mechanical problems

- Block vasomotor reaction
- No natural curves of artery
- Malaposition
- Struts in sidebranches
- Stent fracture

?

Biological reactions

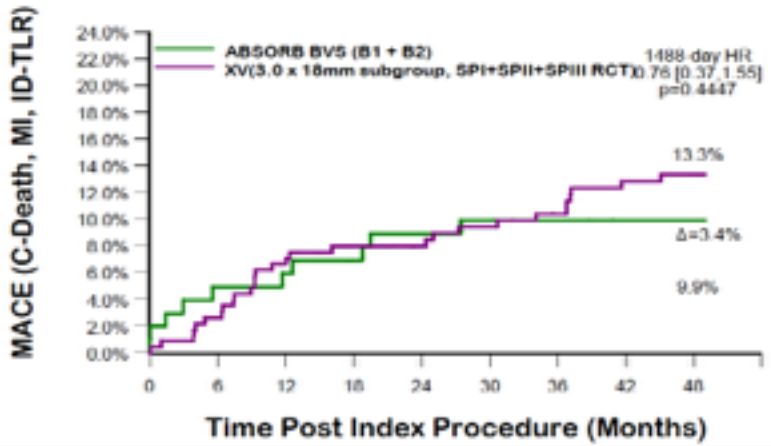
- Metal can cause hyperplasia (Ni)
- High dose of the sirolimus can cause microaneurysms
- Late tissue reaction to polymer
- Abnormal vessel wall

+ plaque regression
+ MRI, CT
+ Mechanotransduction
+ CABG easier in future

There is evidence data showing superiority of Absorb over the DES and BMS in long term period

ABSORB Cohort B

KM Estimate of MACE Rate in Patients Treated with Absorb vs. Patients Treated with a Single 3.0x 18 mm Metallic XIENCE V



Time After Index Procedure (days)								
	0	37	194	284	393	758	1123	1488
Absorb BVS (B1+B2) At Risk	101	99	96	96	94	91	89	86
XIENCE V (3.0 x 18 mm subgroup, SPI+SPII+SPIII RCT) At Risk	227	224	219	211	204	191	182	174

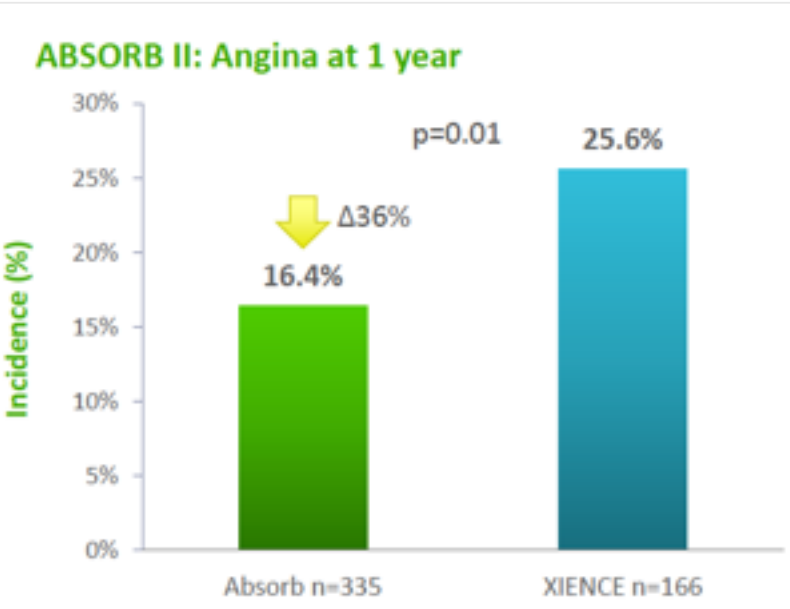
P-values are not from formal hypotheses testing and are displayed for exploratory purpose only.

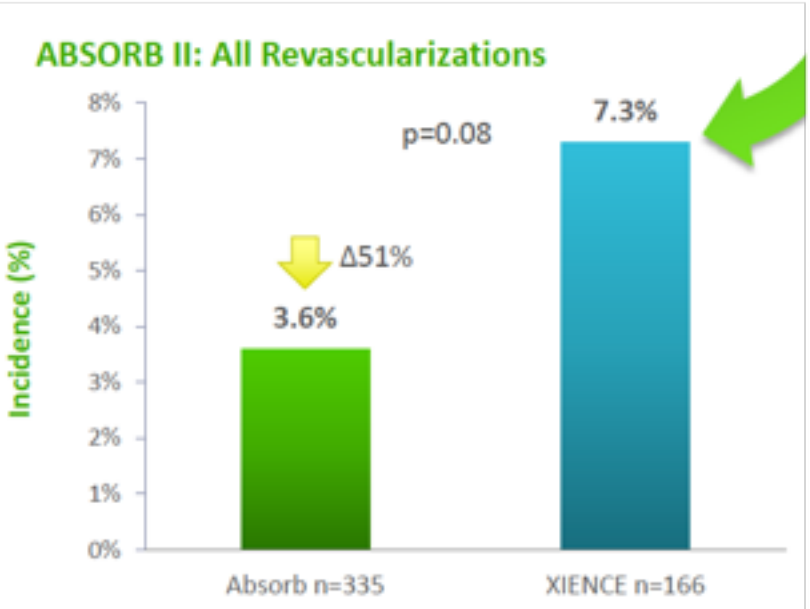
ABSORB Cohort B – 4 year Clinical Results, E. Christiansen, ACC 2014

Abbott Vascular

18

There is evidence data showing superiority of Absorb over the DES and BMS in long term period





Analysis excludes events that occurred in-hospital or ≤7 days post-PCI.

1. P. Serruys, ABSORB II 1 Year Clinical Outcomes, TCT 2014

ALL-COMERS

GABI-R
Design: All-comers registry
N=5000

AIDA
Design: RCT vs XIENCE
N=2690
1° endpoint: 2-year TVF

ABSORB FIRST
Design: Prospective, multi-center, global registry
N= ~1800
1° endpoint: Scaffold thrombosis, cardiac death, myocardial infarction, revascularization, MACE, TLF, and

REPARA
Design: All-comers registry
N=1500
1° endpoint: 1-year MACE

EVERBIO II
Design: Non-inferiority
RCT EES vs BES vs BVS
N=240
1° endpoint: Late lumen loss at 9 months

BVS EXPAND[12]
Design: All-comers registry
N=300
1° endpoint: 1-year MACE

GHOST EU
Design: All-comers registry
N= continuous enrolment
1° endpoint: TVF

ASSURE
Design: All-comers registry
N=180
1° endpoint: Safety and efficacy

FRANCE ABSORB
Feasibility: De novo lesions
N=2000
1° endpoint: 1-year MACE

COMPLEX POPULATIONS

ACS

POLAR-ACS
Design: ACS registry
N=100
1° endpoint: Safety, clinical device, procedure, success and in-hospital MACE

MI

ISAR ABSORB MI
Design: Non-inferiority vs EES
N=260
1° endpoint: % diameter stenosis at 6-8 months

PRAGUE 19
Design: STEMI (STEMI Killip I/II)
N=100
1° endpoint: Clinical outcomes

TROFI II
Design: STEMI vs XIENCE
N=190
1° endpoint: 6-month, neo-intimal healing score

CTO & BIFURCATIONS

ABSORB CTO
Feasibility: CTO
N=35
1° endpoint: Safety & performance

PABLOS
Feasibility: Bifurcations
N=30
1° endpoint: Device, procedural, main & side branches

MVD & LONG LESIONS

IT - DISAPPEARS
Design: MVD and Long Lesion Registry
N=1000
1° endpoint: Safety and efficacy

SIMPLE TO MODERATELY COMPLEX POPULATIONS

ABSORB II
Design: Randomized 2:1 Absorb BVS:Xience
N=501
1° endpoint: Vasomotion and lumen diameter after the index procedure and at 3 years

ABSORB COHORT A
Design: Allocated (non-randomized)
N=30
1° endpoint: Safety & performance ID-MACE

ABSORB EXTEND
Design: Prospective, single-arm, open-label clinical study
N= ~800
1° endpoint: ID-MACE

ABSORB COHORT B
Design: Allocated (non-randomized)
N=101
1° endpoint: Safety & performance

ADDITIONAL LARGE RCTs - IN PROGRESS

ABSORB III
Design: RCT
N= ~2250
1° endpoint: TLF at 1 year

ABSORB JAPAN
Design: RCT
N= ~400
1° endpoint: TLF at 1 year

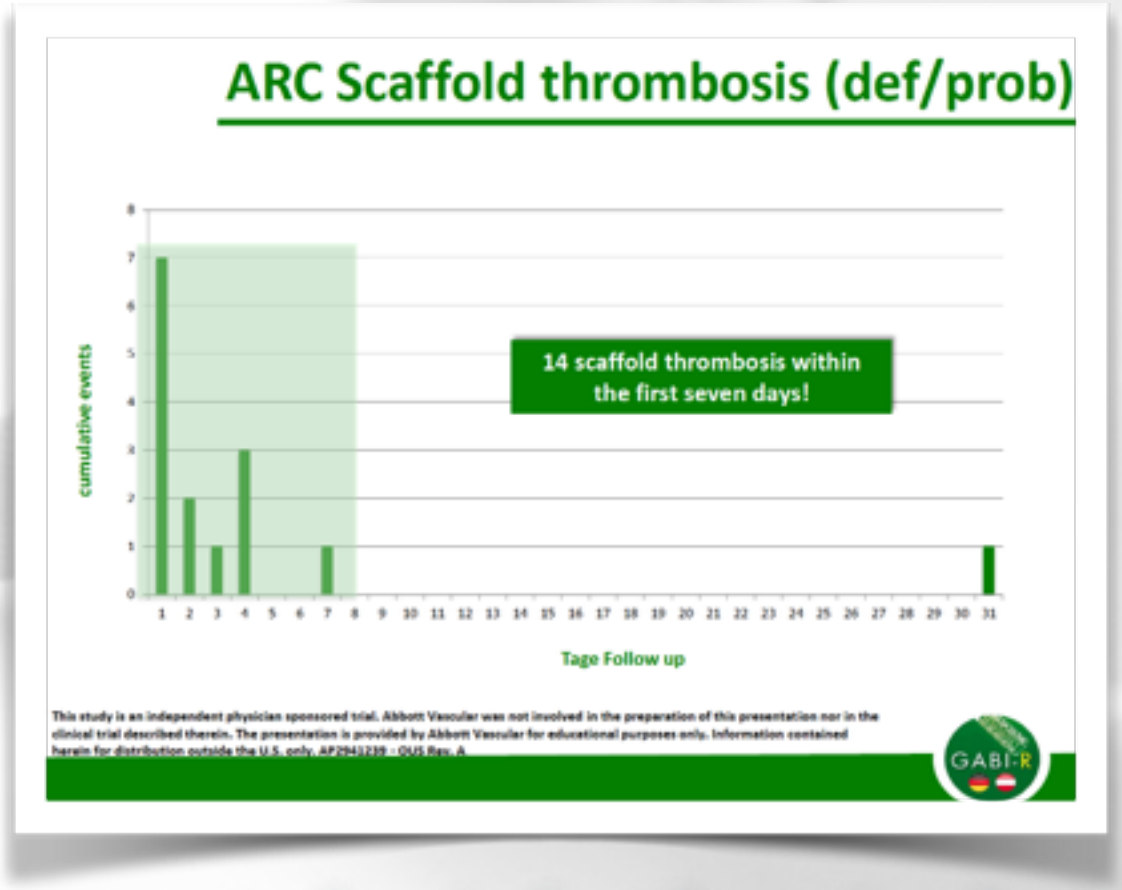
ABSORB CHINA
Design: RCT
N= ~440
1° endpoint: In-segment late loss at 1 year

ABSORB IV
Design: RCT
N= ~3000
1° endpoint: Angina within 1 year

Apart from the results in these well controlled trials, there are plenty of examples of great results with ABSORB in many physician driven studies and registries

GABI-R
Ghost-EU
Examination
REPARA

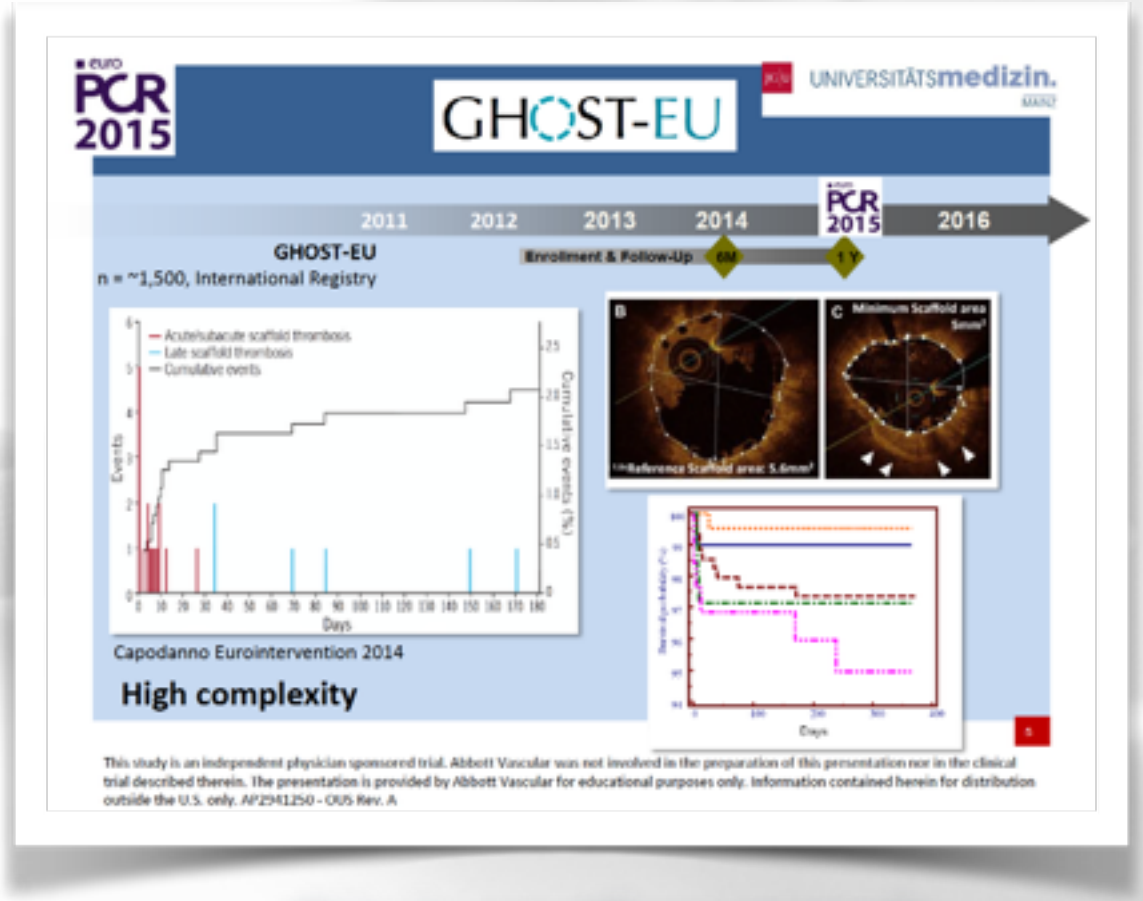
While the results for ABSORB are great, there is still a small amount of MACE happening, especially in the short period, which is comparable to the rate seen in the best in class DES



and

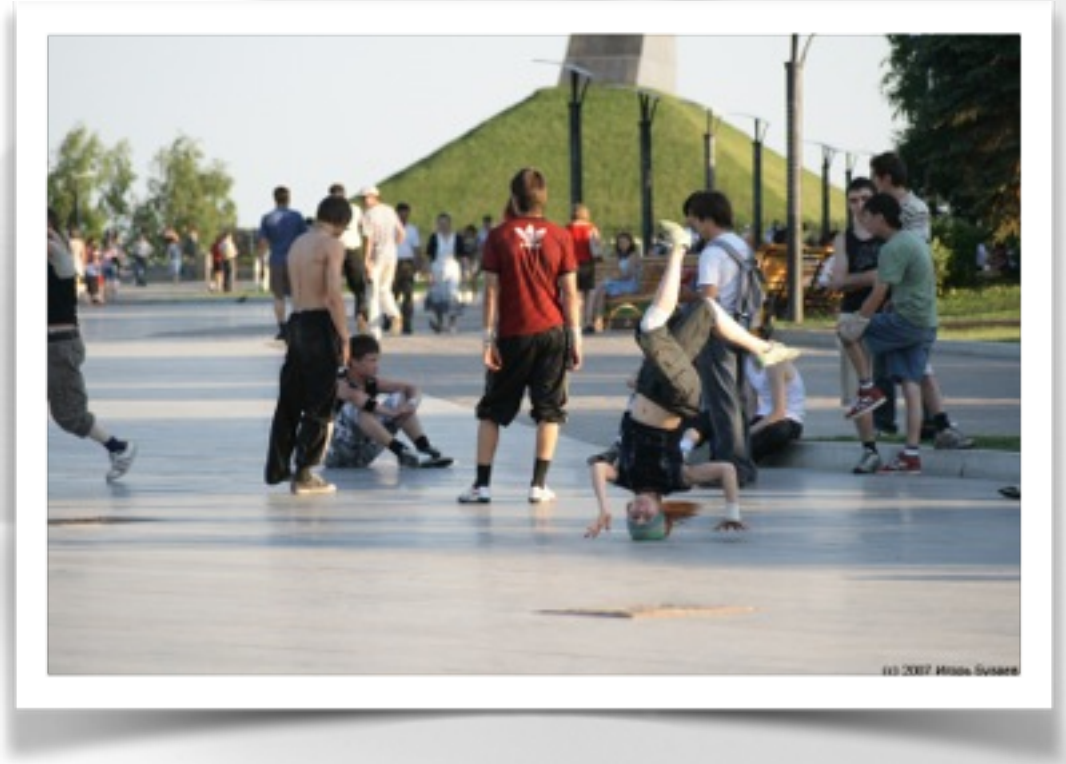
they happen most often in first 2 weeks after implantation

While the results for ABSORB are great, there is still a small amount of MACE happening, especially in the short period, which is comparable to the rate seen in the best in class DES



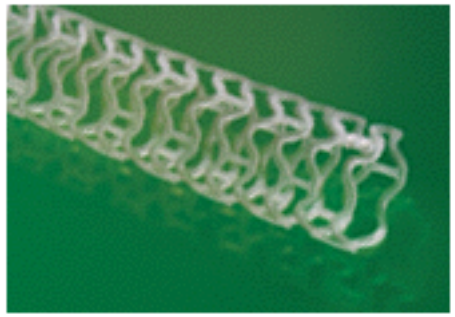
this is another sample

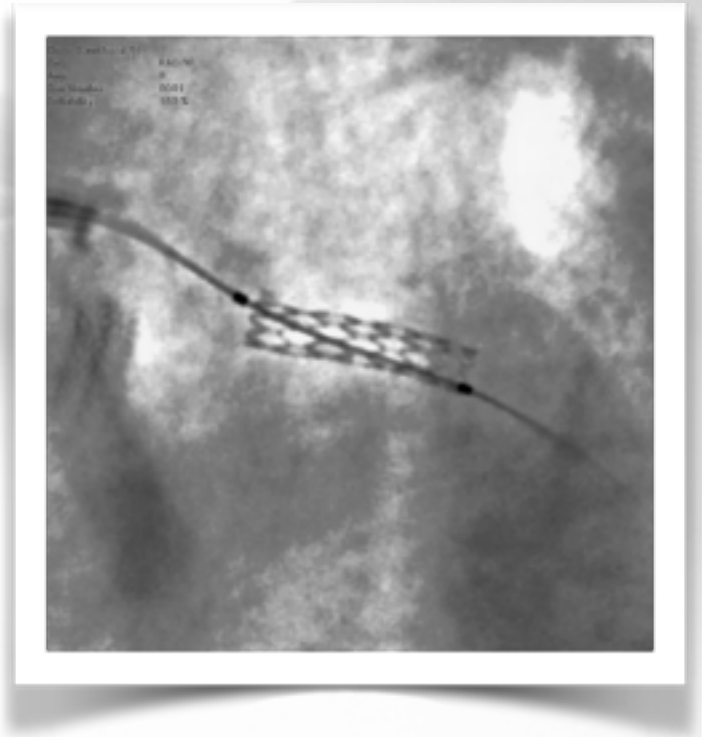
It has been proposed that these events can be result of malapposition or inadequate preparation of lesion (predilation) which is true for the stents and scaffolds



but scaffold is different material, because …

Stents can be well visualized by X-ray and there are a lot of helpful tools (i.e. StentBoost) for the implantation control





but scaffold

1. Invisible on X-ray
2. Fragile
3. Thick

and…

ABSORB is different

Storage

Deliverability

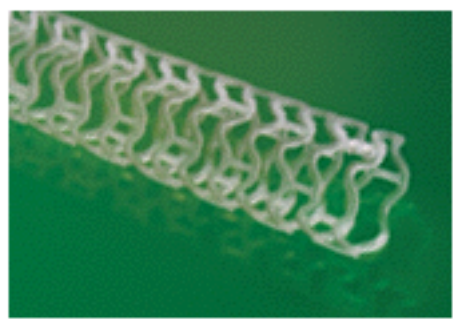
- single insertion
- thick delivery
- thick strats / overlap
- less flexibility
- multiple attempts damage device
- distal lesion prior

Preparation

- calcium
- tortuosity
- predilation (>40% RS)

Opening

- stages
- radial force

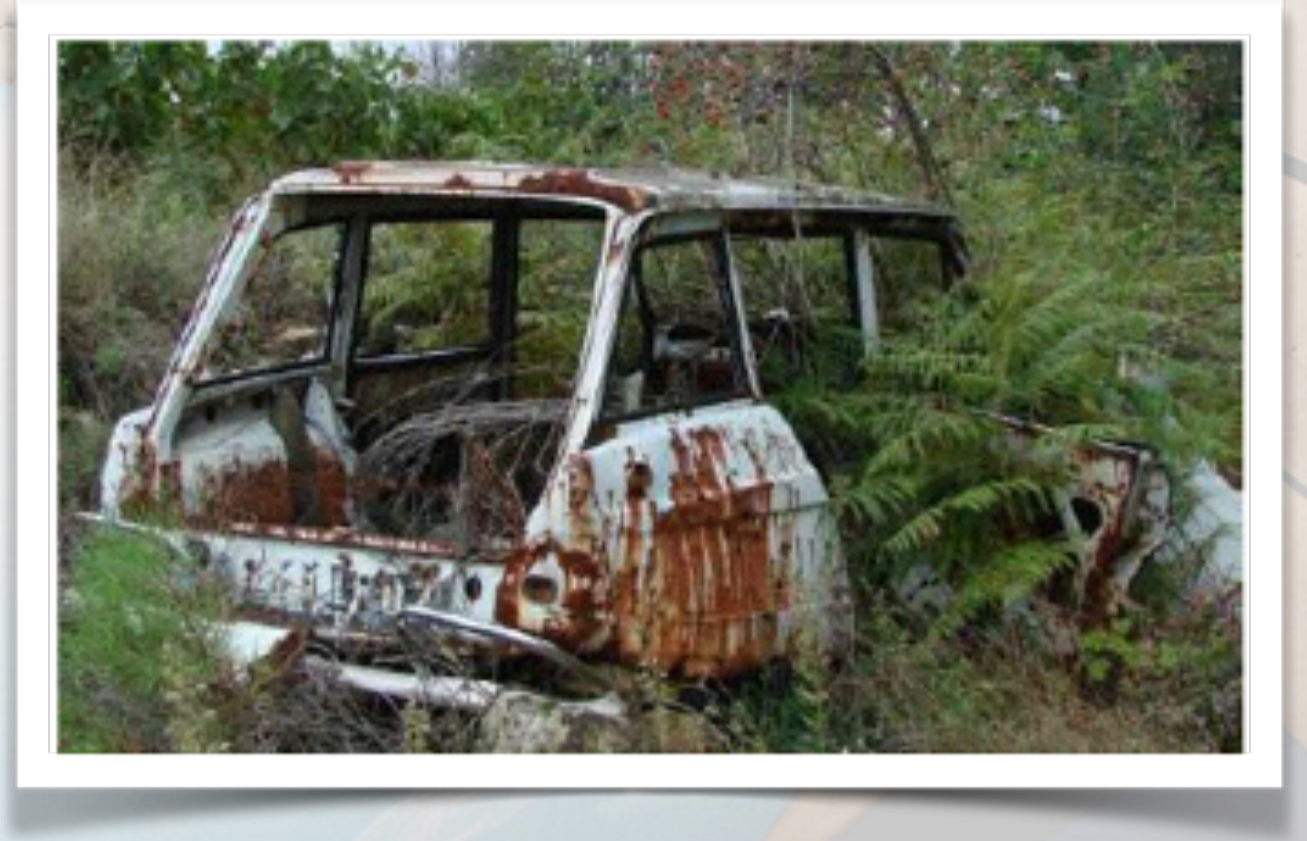


Careful patient selection

Size

- limited
- 0.5 mm / ?1 mm
- fracture / avoid overexpand
- adequate apposition
- non compliant postdilatation
- 3 - 28 mm max (toxic)

This is the price for the absense of this



in our gardens...

On label complications

Abrupt closure - MI
Aneurysm
Perforation
Rupture
Spasm
Trombosis
Dissection

and most of them, fortunately,
we never see in our cathlabs
because we...

Take into account a lot of things

Storage

Deliverability

- single insertion
- thick delivery
- thick struts / overlap
- less flexibility
- multiple attempts damage device
- distal lesion prior

Preparation

- calcium
- tortuosity
- predilation (>40% RS)

Opening

- stages
- radial force

Different device than stent

Can we control all of them?

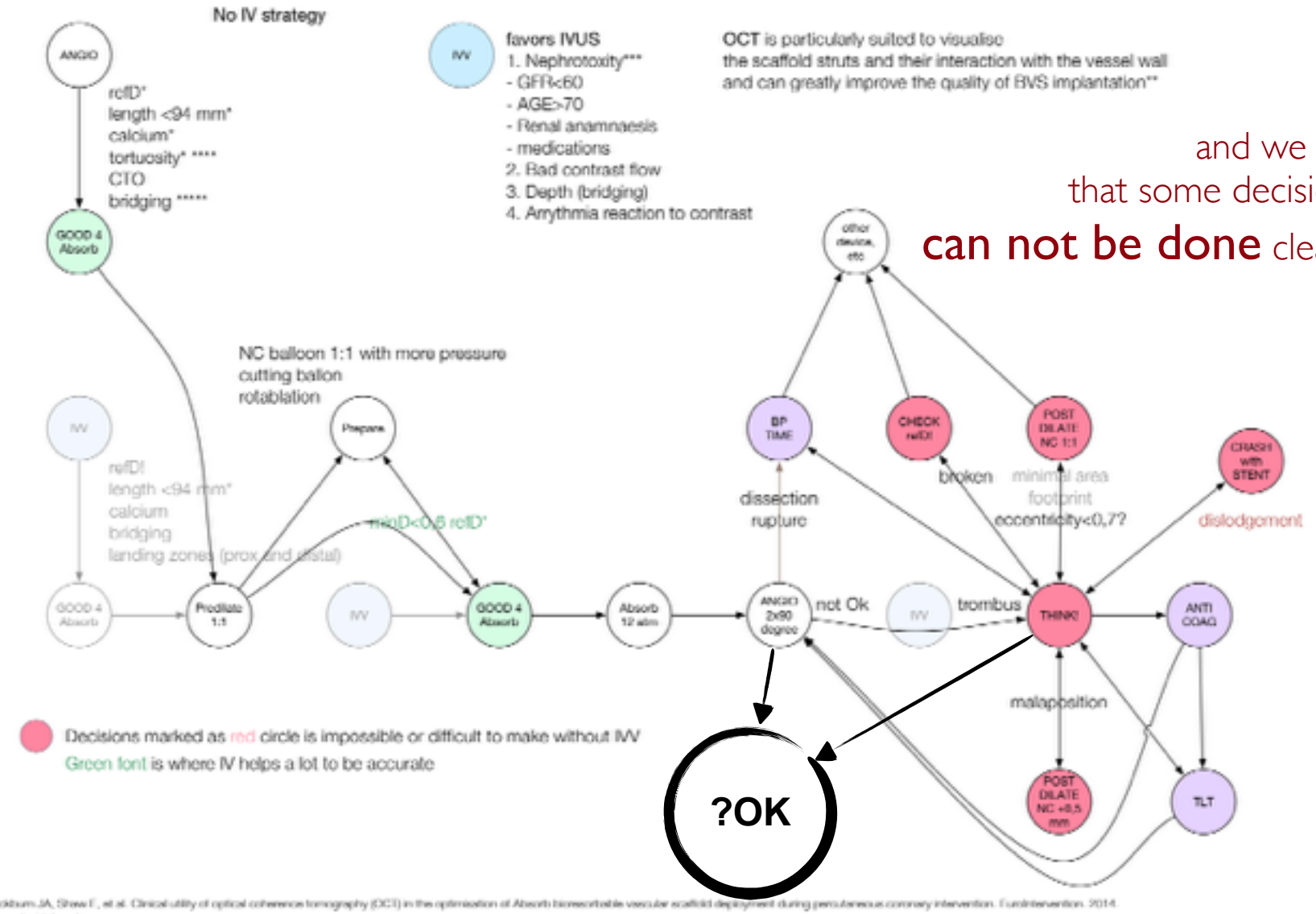
Careful patient selection

Size

- limited
- 0.5 mm / ?1 mm
- fracture / avoid overexpand
- adequate apposition
- non compliant postdilatation
- 3 - 28 mm max (toxic)

Single insertion

This is X-ray only strategy to implant device



* on label

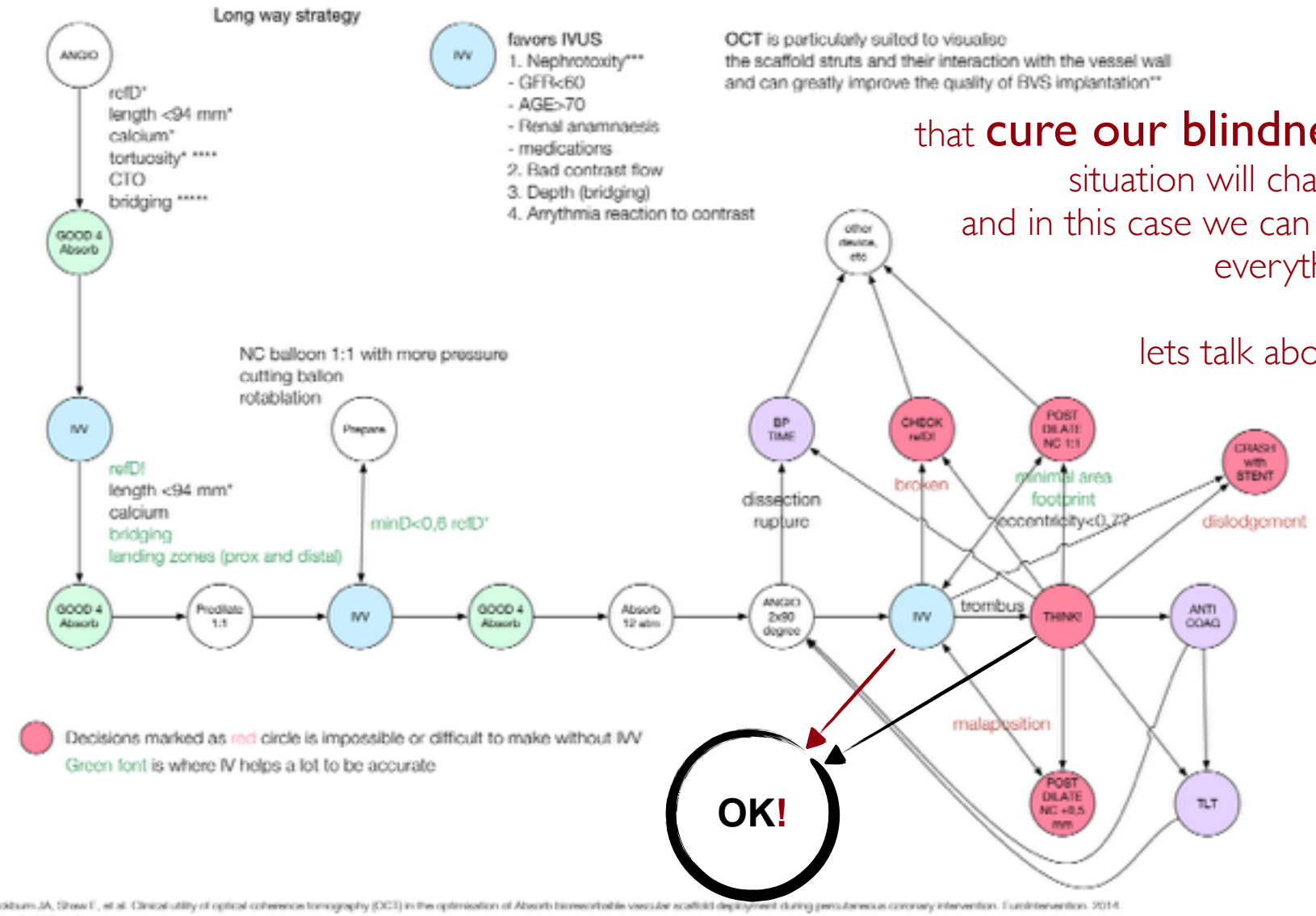
**Abdelwahab LK, Cockburn JA, Shaw E , et al. Clinical utility of optical coherence tomography (OCT) in the optimisation of Absorb bioresorbable vascular scaffold deployment during percutaneous coronary intervention. EuroIntervention. 2014

*** http://www.escardio.org/guidelines/

**** Yuki Ishibashi, MD, PhD; Yoshinobu Onuma, MD; Takashi Muramatsu, Lessons learned from acute and late scaffold failures in the ABSORB EXTEND trial EuroIntervention 2014; 9-online publish-ahead-of-print January 2014

***** Shimpei Nakatani, MD; Yoshinobu Onuma, MD; Yuki Ishibashi Early (before 6 months), late (6-12 months) and very late (after 12 months) angiographic scaffold restenosis in the ABSORB Cohort B trial //EuroIntervention 2015;10:1288-1298 published online ahead of print February 2014

but if we will put something to the protocol



that **cure our blindness**
situation will change
and in this case we can see
everything

lets talk about...

* on label

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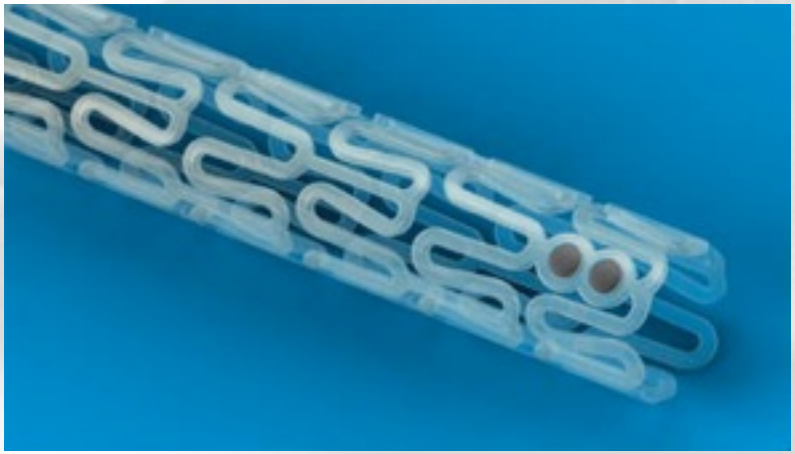
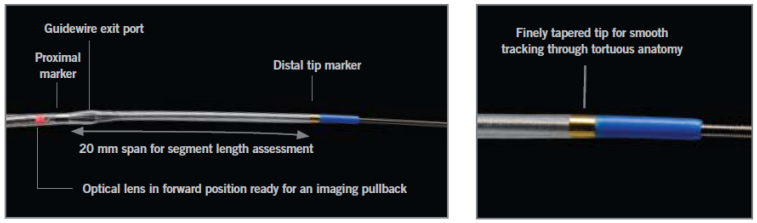
Intravascular imaging techniques in decision making during scaffold implantation

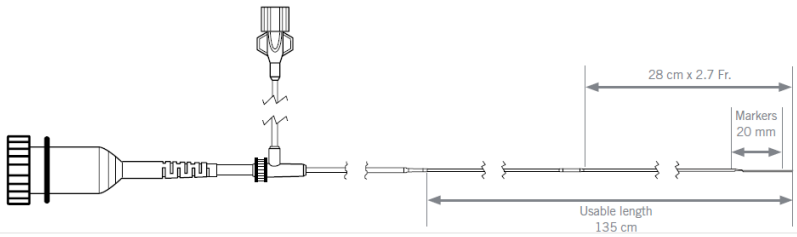


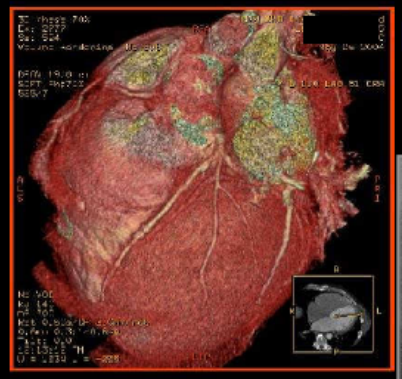
and the doctor can be like
'tiger with two wings'

OCT device



The Dragonfly imaging catheter is state-of-the-art, with a finely tapered tip and hydrophilic coating for effortless delivery and dual marker bands to aid in accurate placement of the ultra-fine lens.



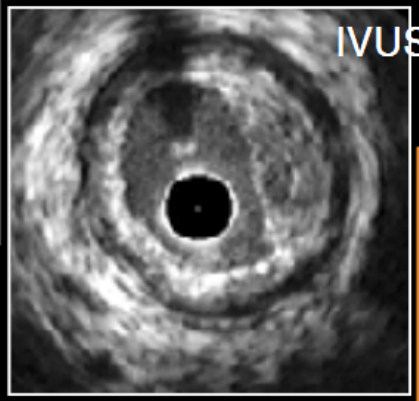


КТ с 3D реконструкцией

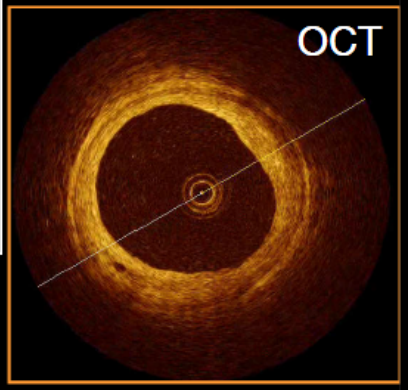
600μm

Коронарография

200μm



100μm



10μm

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MINI-FOCUS ISSUE: OPTICAL COHERENCE TOMOGRAPHY

Clinical Research

Consensus Standards for Acquisition, Measurement, and Reporting of Intravascular Optical Coherence Tomography Studies

A Report From the International Working Group for Intravascular Optical Coherence Tomography Standardization and Validation

Guillermo J. Tearney, MD, PHD, *Writing Committee Co-Chair,**

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ACC CLINICAL EXPERT CONSENSUS DOCUMENT

American College of Cardiology Clinical Expert Consensus Document on Standards for Acquisition, Measurement and Reporting of Intravascular Ultrasound Studies (IVUS)

A Report of the American College of Cardiology Task Force on Clinical Expert Consensus Documents

Developed in Collaboration with the European Society of Cardiology
Endorsed by the Society of Cardiac Angiography and Interventions

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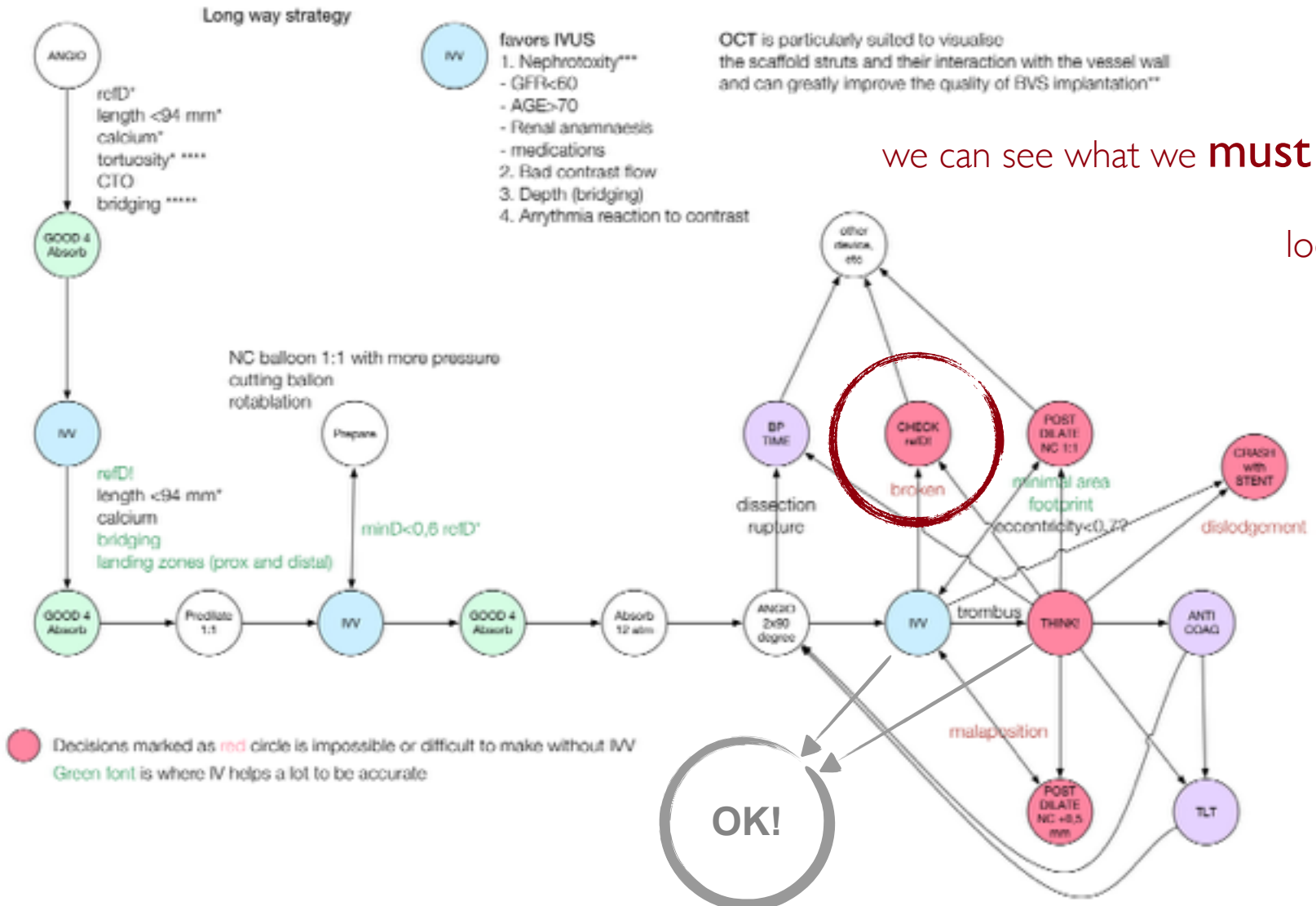

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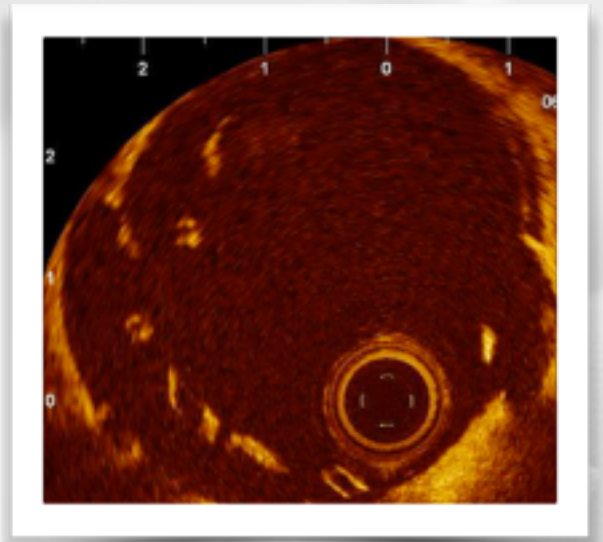
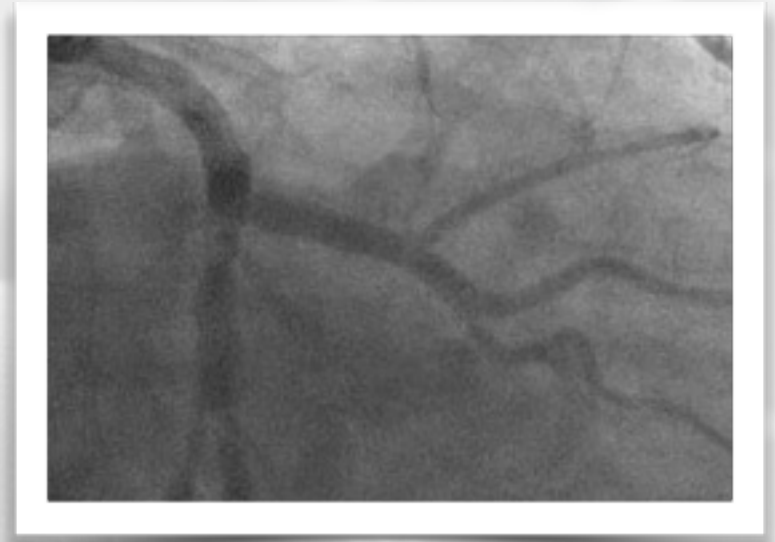
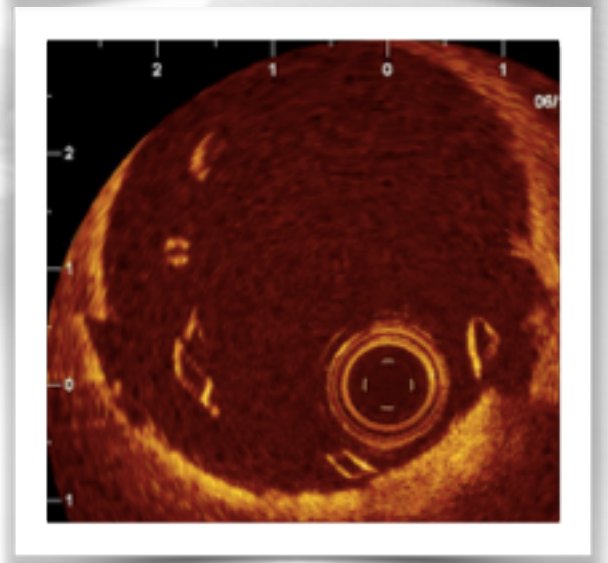
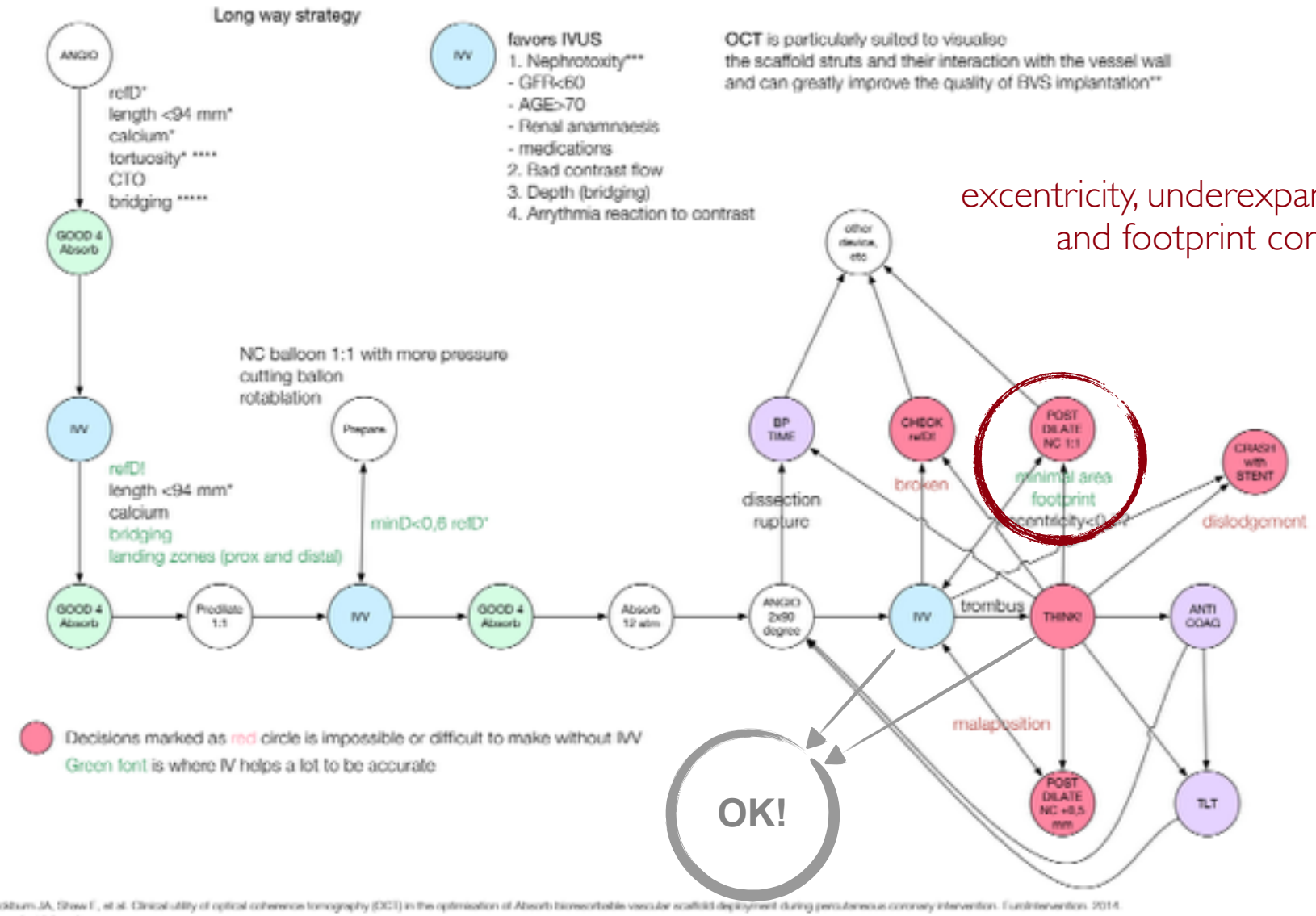
The the scaffold fracture can be X-ray invisible







decision: we need the stent to prevent MACE



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Post-dilate?

EuroIntervention

Impact of post-dilation on the acute and one-year clinical outcomes of a large cohort of patients treated solely with the Absorb Bioresorbable Vascular Scaffold

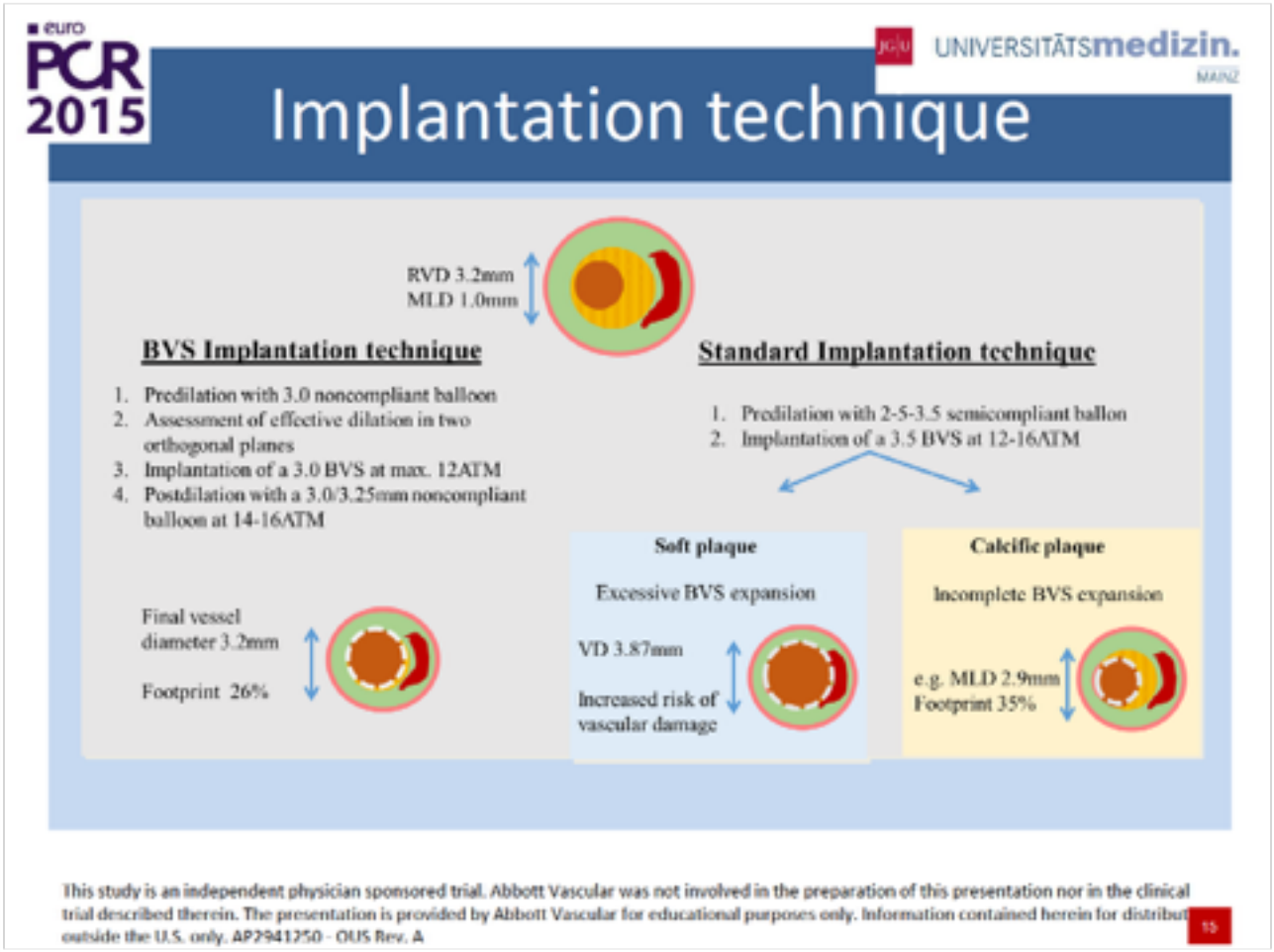
José De Ribamar Costa Jr[1]*, MD, PhD; Alexandre Abizaid[1], MD, PhD; Antonio L. Bartorelli[2], MD; Robert Whitbourn[3], MD; Robert Jan van Geuns[4], MD, PhD; Bernard Chevalier[5], MD; Marcos Perin[6], MD, PhD; Ashok Seth[7], MD; Roberto Botelho[8], MD, PhD; Patrick W. Serruys[4], MD, PhD; on behalf of the ABSORB EXTEND Investigators

Post-dilation does not make worse outcomes.
Should be done if necessary

what is the necessary?

EuroIntervention 2015;11-online publish-ahead-of-print May 2015

Footprint concept



Tommaso Gori
University Medical Center Mainz, Germany

Footprint concept

An independent bench comparison of two bioresorbable drug-eluting coronary scaffolds (Absorb and DESolve) with a durable metallic drug-eluting stent (ML8/Xpedition)

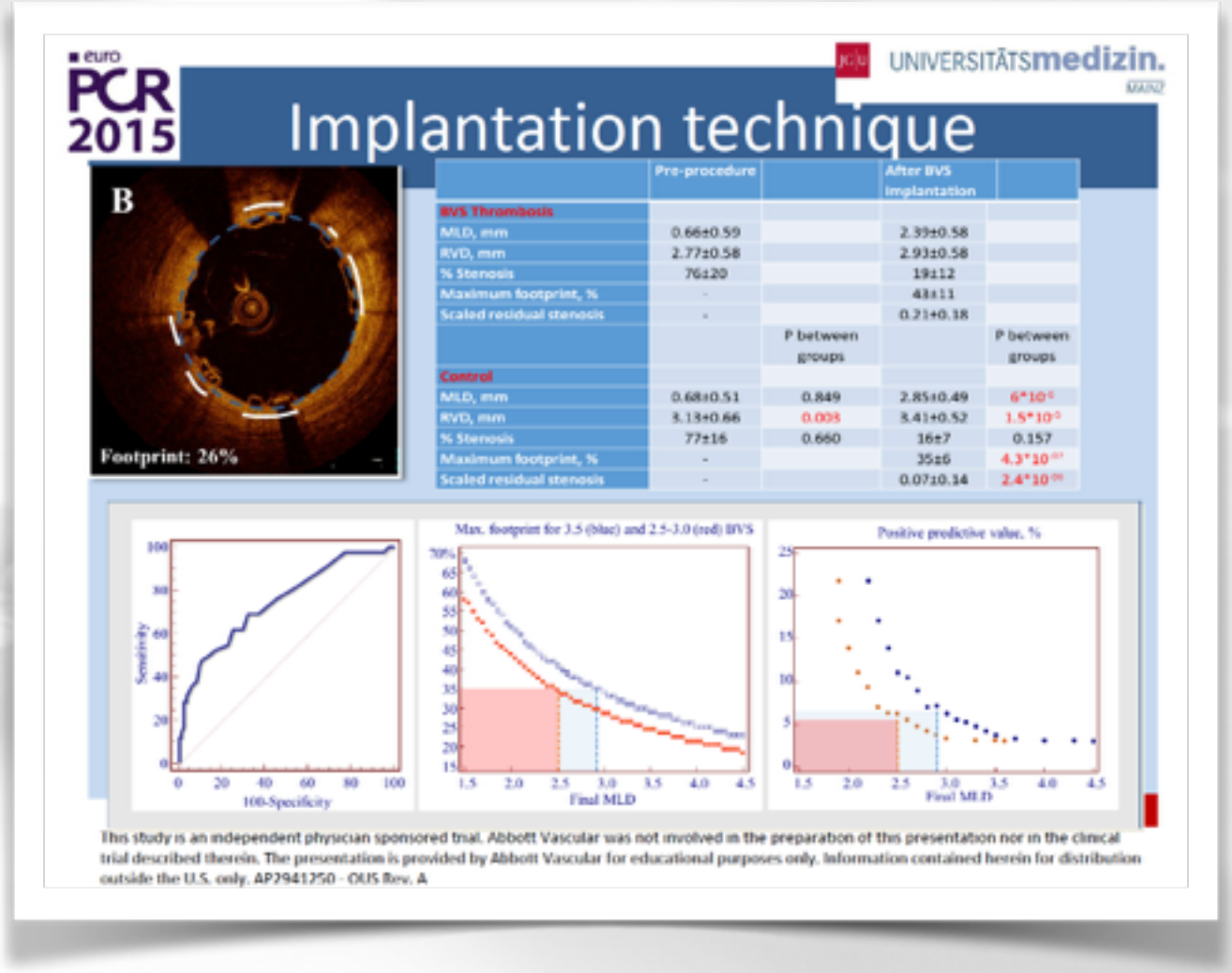
John A. Ormiston[1,2,3*], MBChB; Bruce Webber[1], MHSc; Ben Ubod[1], BSN; Olivier Darremont[4], MD; Mark W.I. Webster[1,2,3], MBChB

1. Mercy Angiography, Auckland, New Zealand; 2. Auckland City Hospital, Auckland, New Zealand; 3. University of Auckland School of Medicine, Auckland, New Zealand; 4. Clinique Saint-Augustin, Bordeaux, France

The manufacturers report that the percentage of vessel wall covered by a 3.0 mm stent/scaffold deployed at nominal pressure is 13%, 27% and 30% for Xpedition, Absorb and DESolve, respectively

EuroIntervention 2015;10-online publish-ahead-of-print February 2015

Footprint concept



Tommaso Gori
University Medical Center Mainz, Germany

Footprint concept

euro PCR 2015

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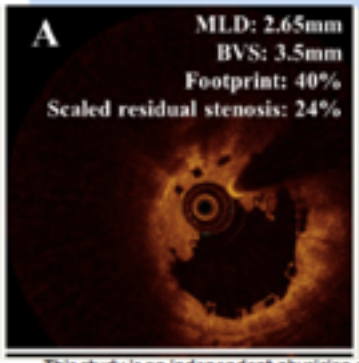
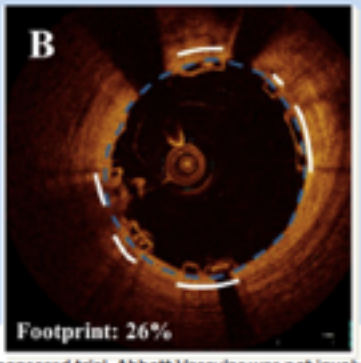
There is more to incomplete expansion

Incomplete vessel expansion → Impaired flow

Incomplete scaffold expansion → Reduced local pressure

→ Increased blood – BVS interactions

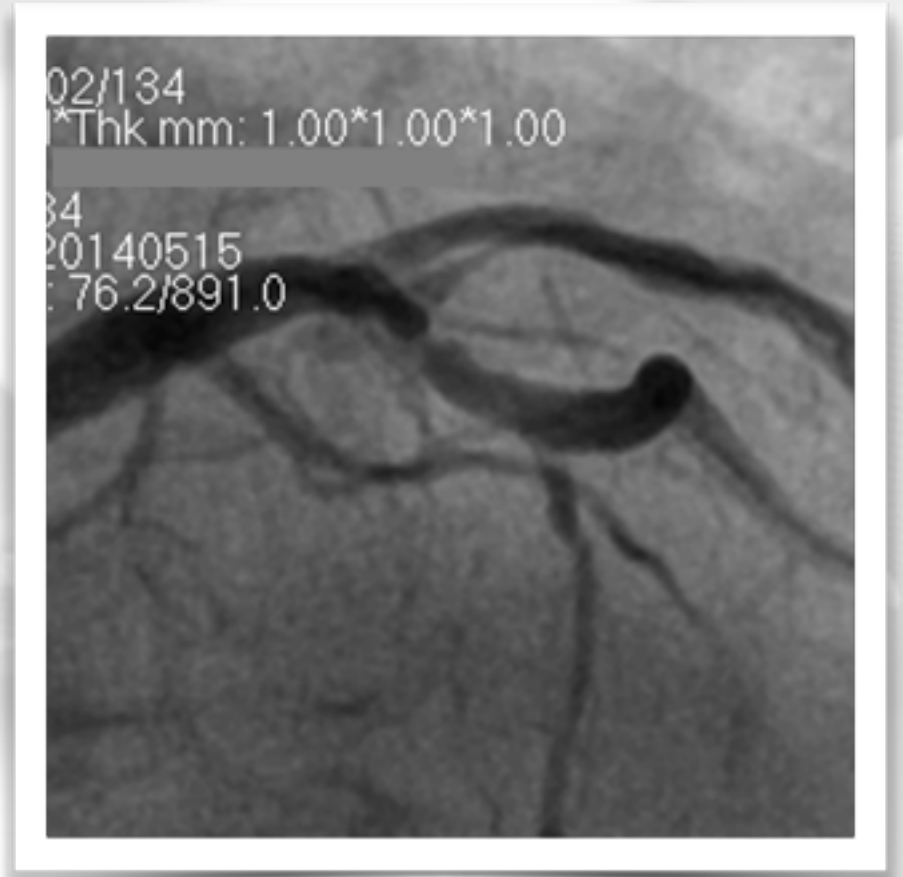




13

Tommaso Gori
University Medical Center Mainz, Germany

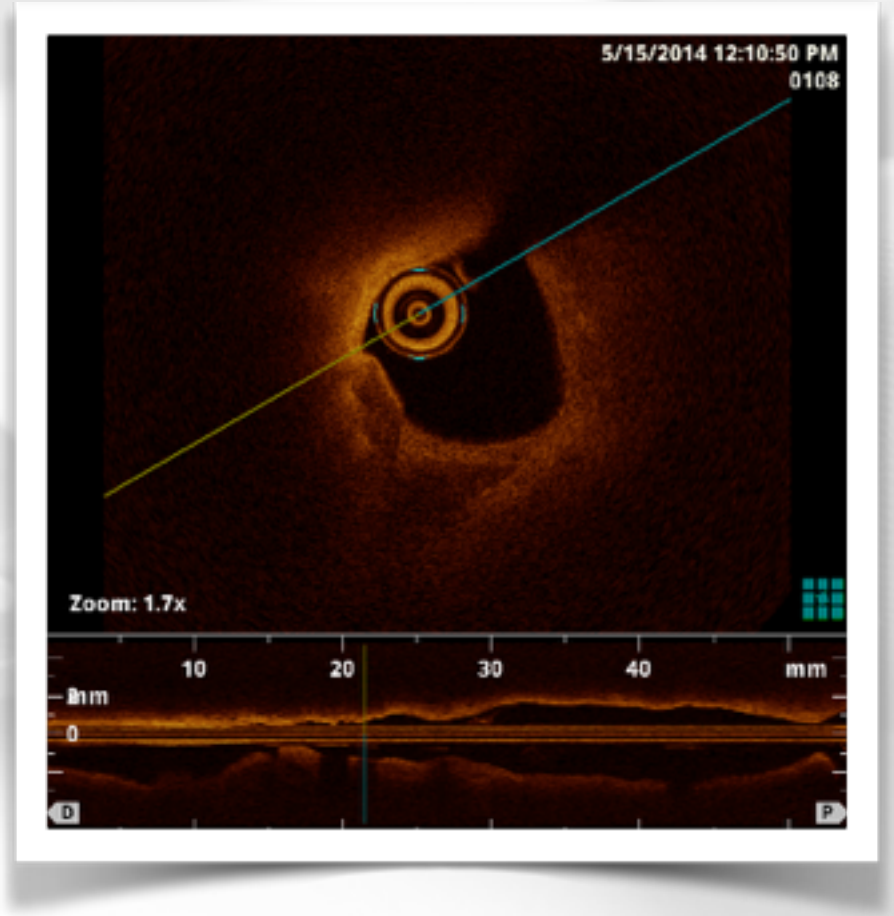
Calcium, dissection, eccentricity

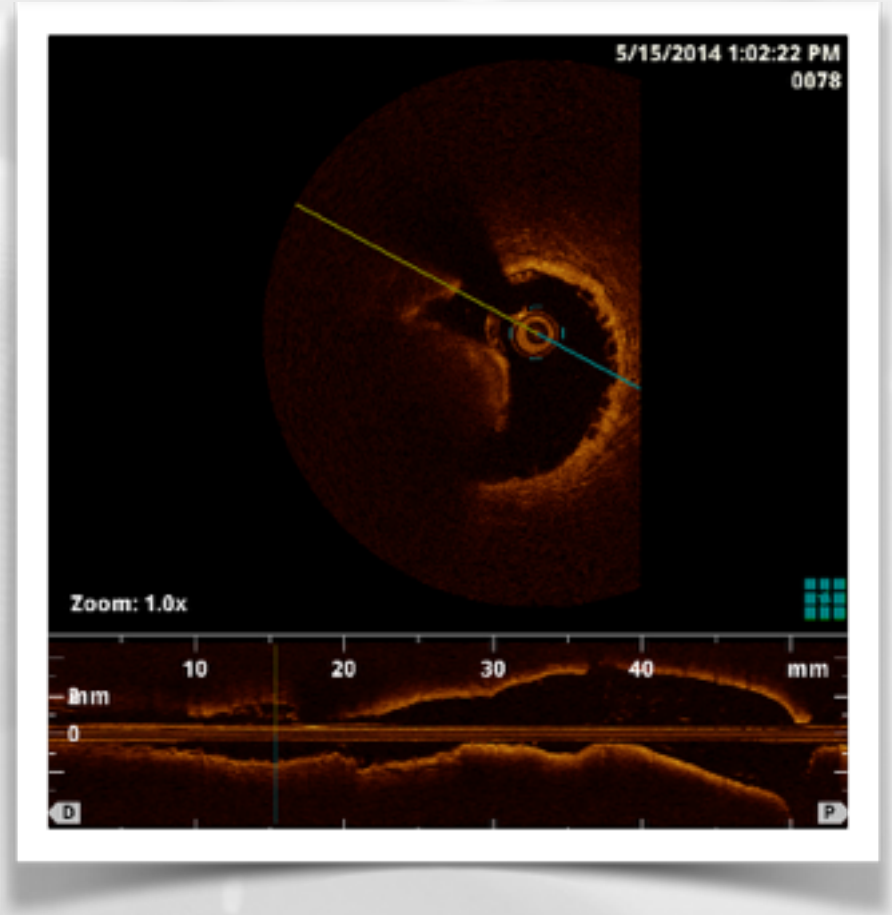


pre-op

implantation

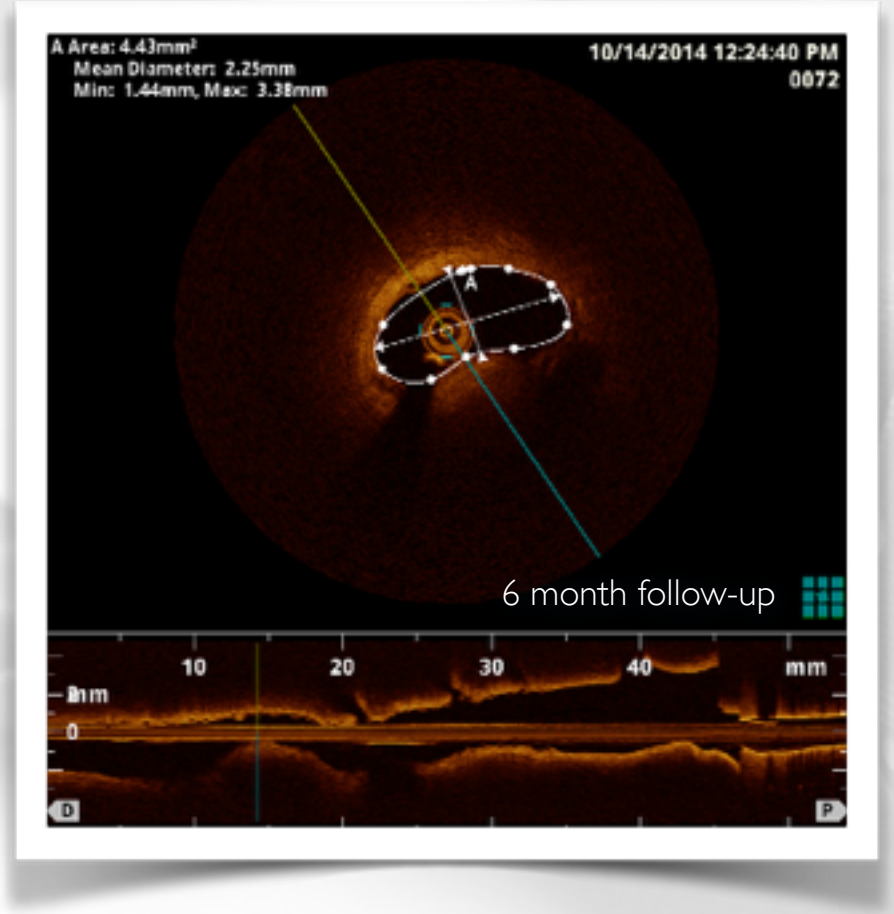
Eccentricity





decision: post-dilate, follow-up

Excentricity



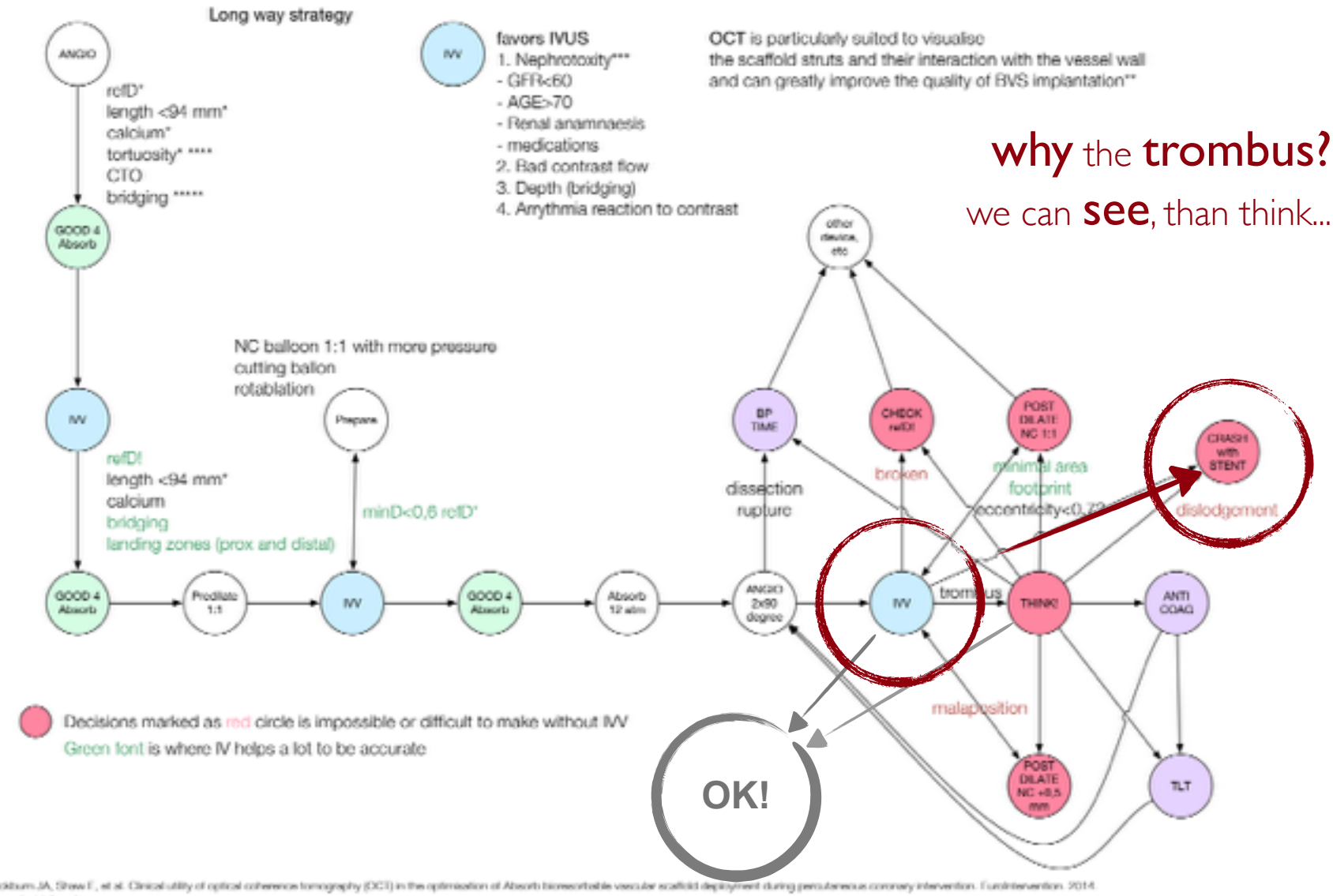
$$IE = (3{,}38 - 1{,}44)/3{,}38 = 0{,}57$$

take into account
lower **radial strength**

Table 1. Stent and scaffold radial strengths assessed by pressure (atm) required to reduce cross-sectional area by 25% (Mercy and Elixir testing).

Area reduction	ML8/Xpedition Mercy test (atm)	Absorb Mercy test (atm)	*p*	Absorb Elixir test (atm)	DESolve Elixir test (atm)	*p*
25%	1.6±0.1	1.4±0.2	0.02	1.3±0.1	1.1±0.1	0.02

EuroIntervention 2015;10-online publish-ahead-of-print February 2015



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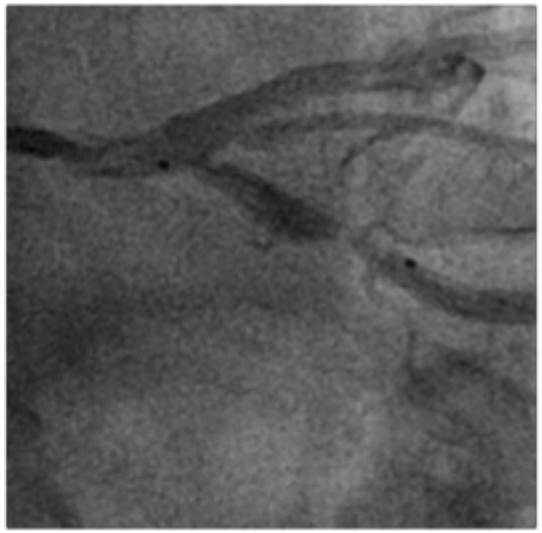
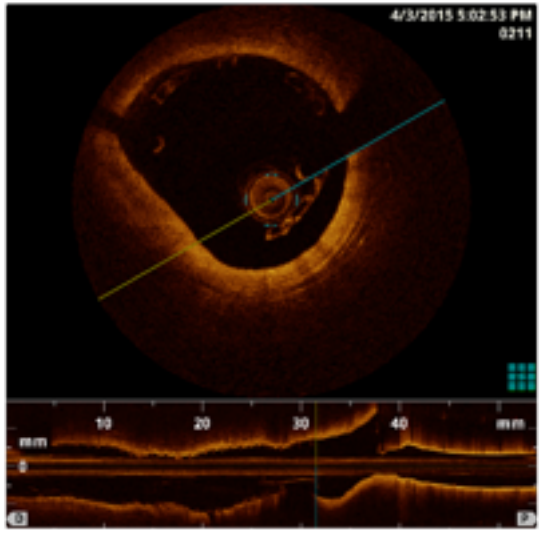
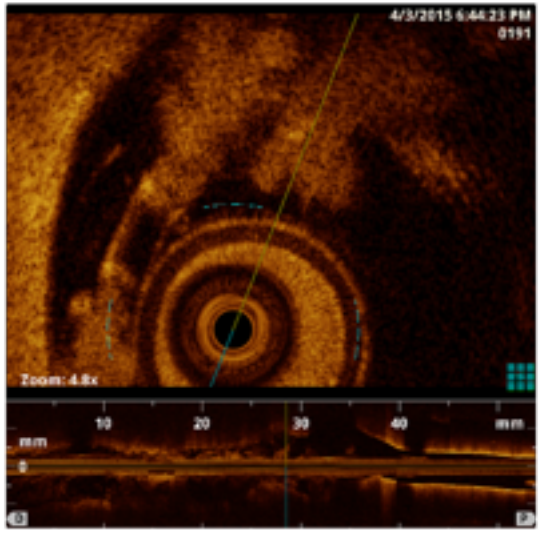
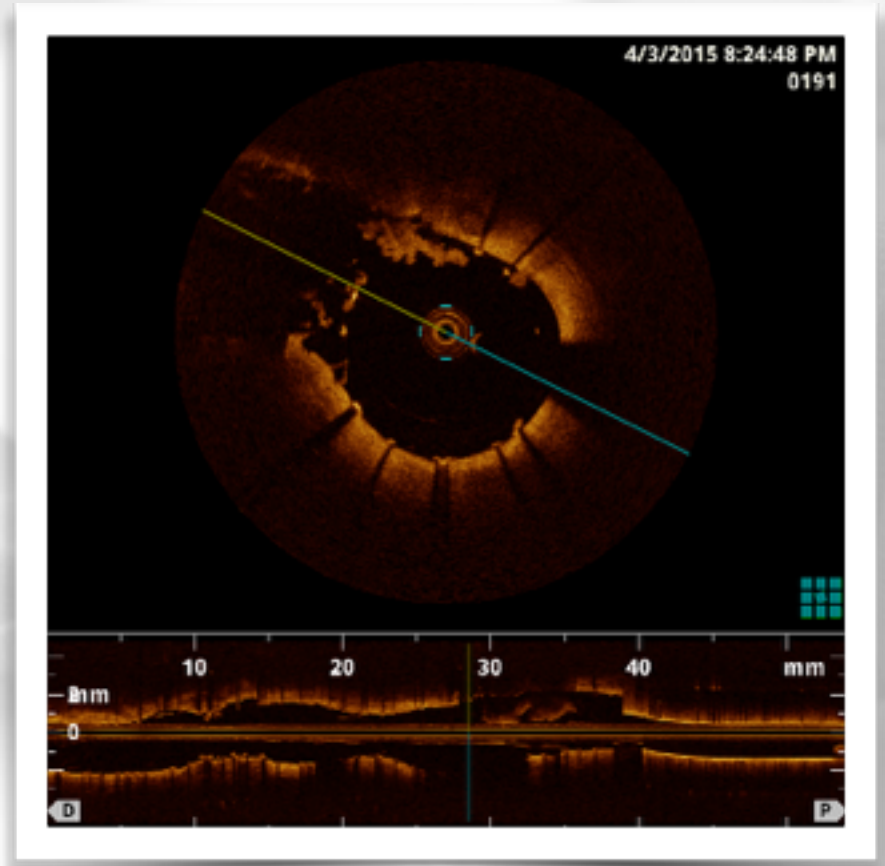
Dislogement

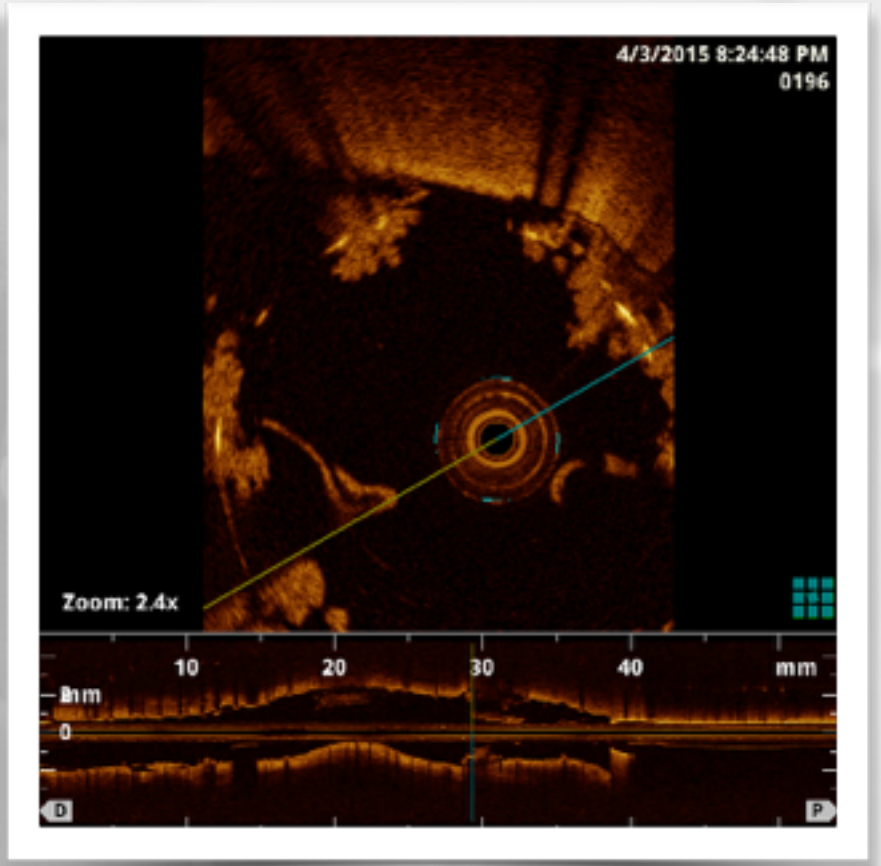




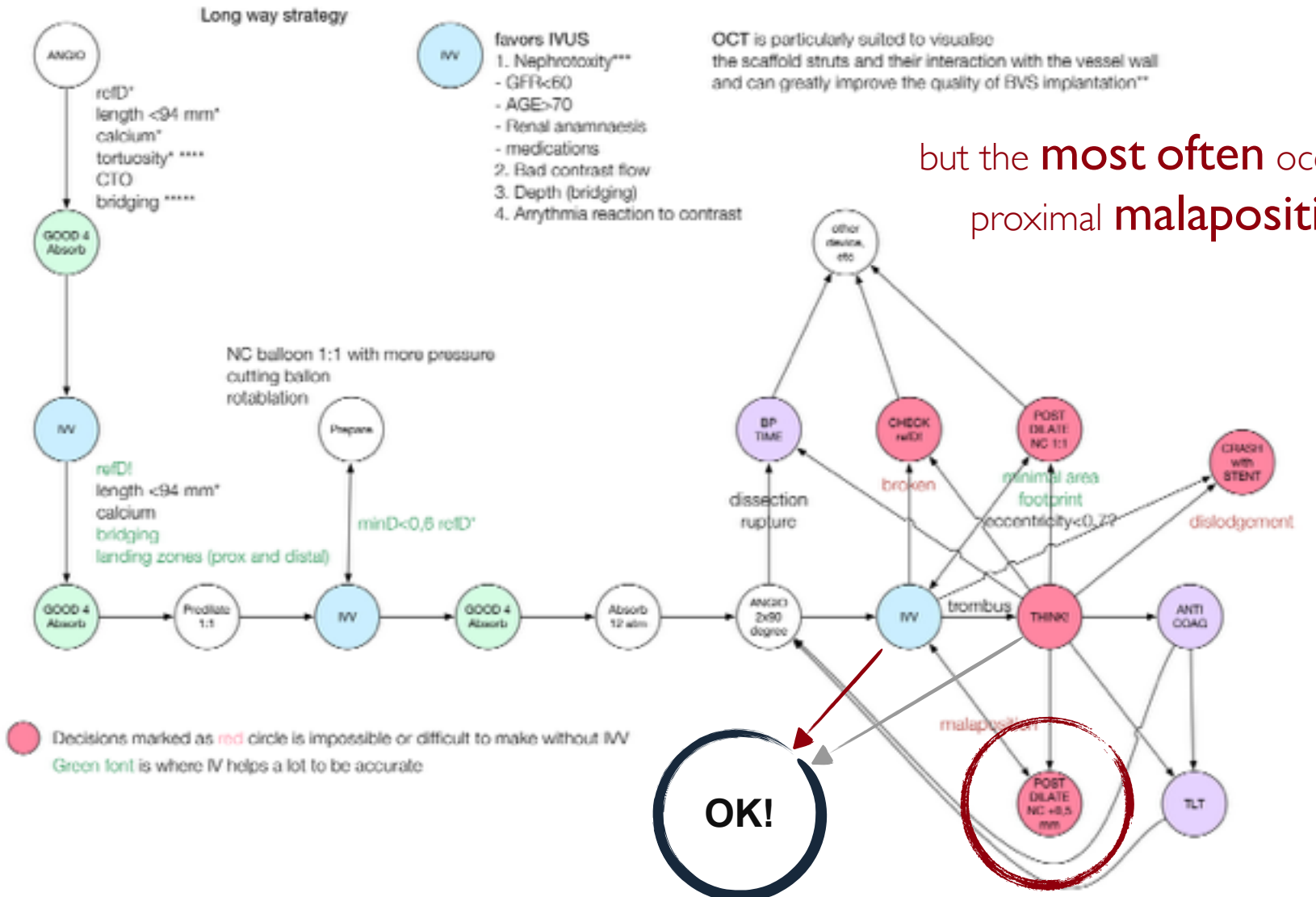


Dislogement





decision: crush by another stent



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ABSORB Biodegradable Stents Versus Second-Generation Metal Stents

A Comparison Study of 100 Complex Lesions Treated Under OCT Guidance

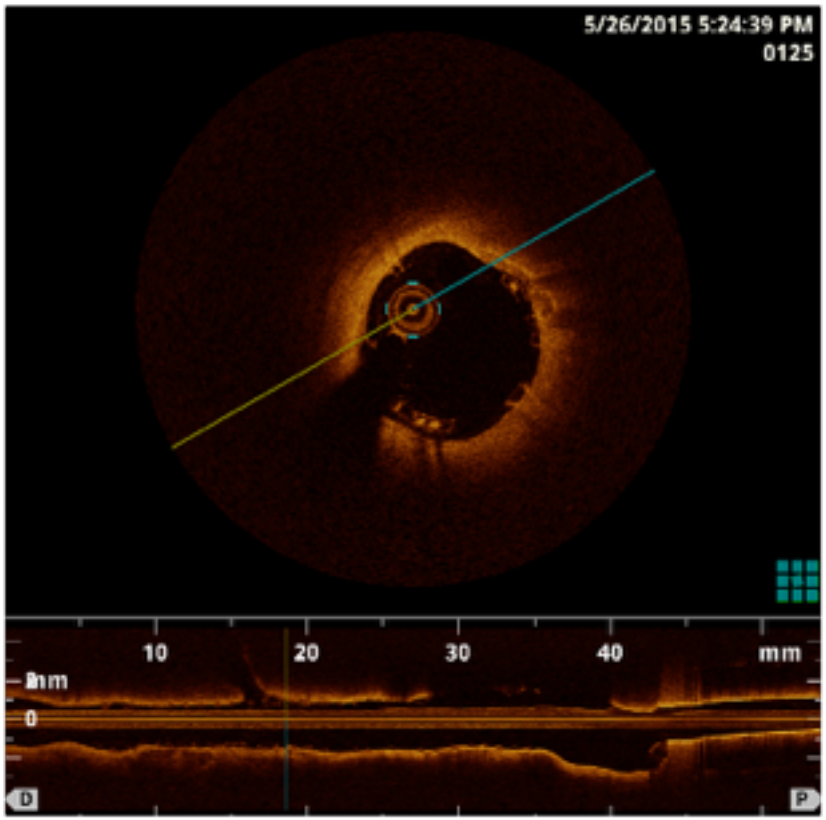
Alessio Mattesini, MD,*† Gioel G. Secco, MD,*‡ Gianni Dall'Ara, MD,*
Matteo Ghione, MD,* Juan C. Rama-Merchan, MD,* Alessandro Lupi, MD,‡
Nicola Viceconte, MD,* Alistair C. Lindsay, MD, PHD,* Ranil De Silva, MD, PHD,*
Nicolas Foin, PHD,§ Toru Naganuma, MD,‖ Serafina Valente, MD,†
Antonio Colombo, MD, PHD,‖ Carlo Di Mario, MD, PHD*

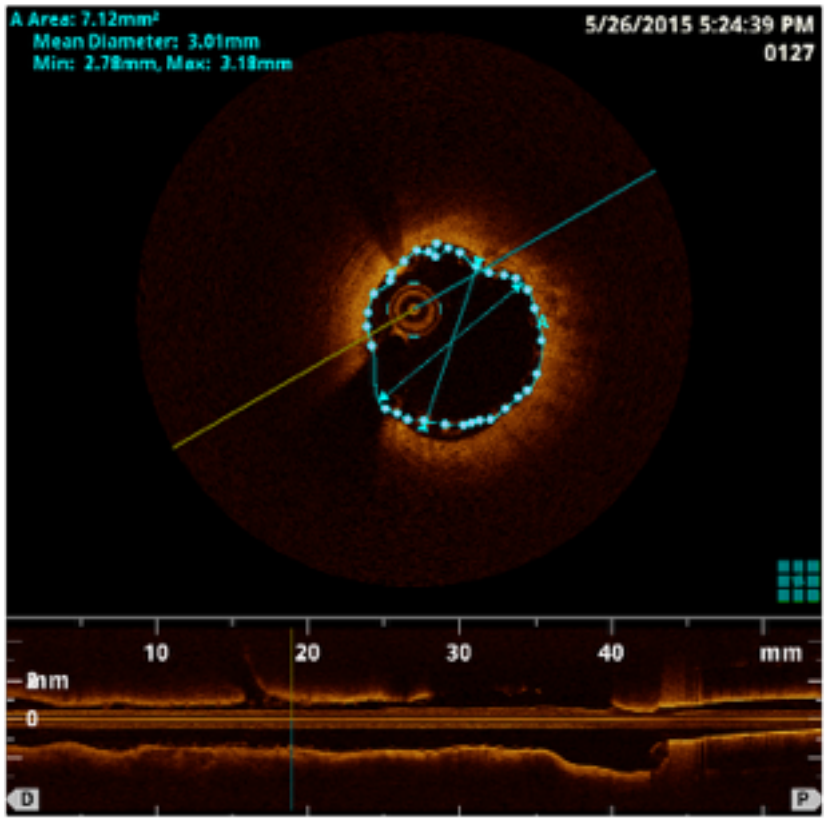
London, United Kingdom; Florence, Novara, and Milan, Italy; and Singapore

40% proximal strut malapposition at the proximal edge was observed in the BVS

J Am Coll Cardiol Intv. 2014;7(7):741-750. doi:10.1016/j.jcin.2014.01.165

Nominal expansion, prox. malaposition

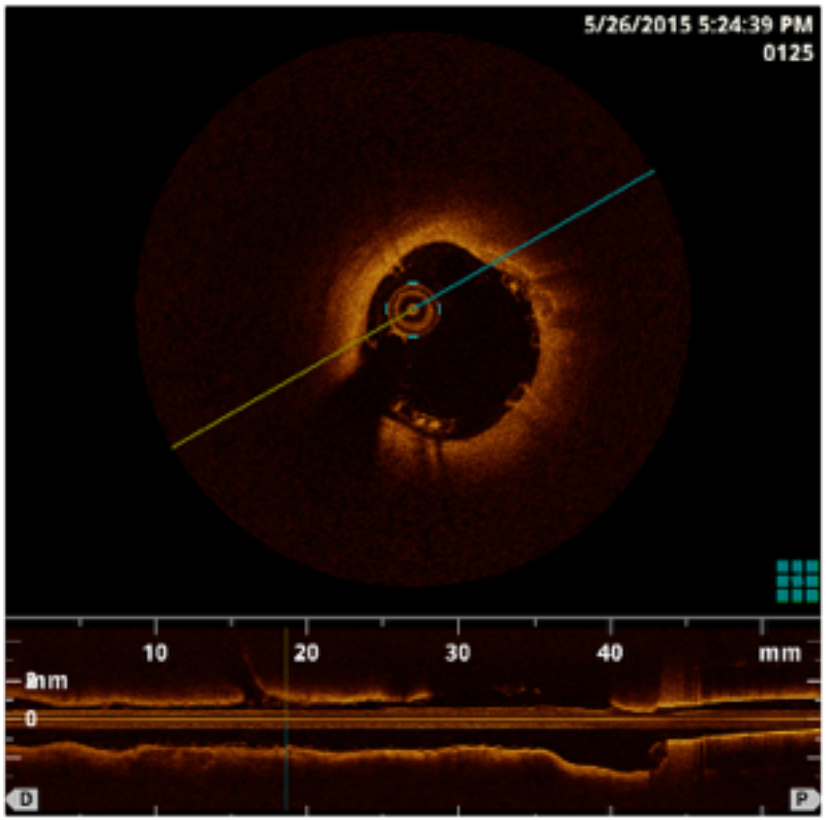


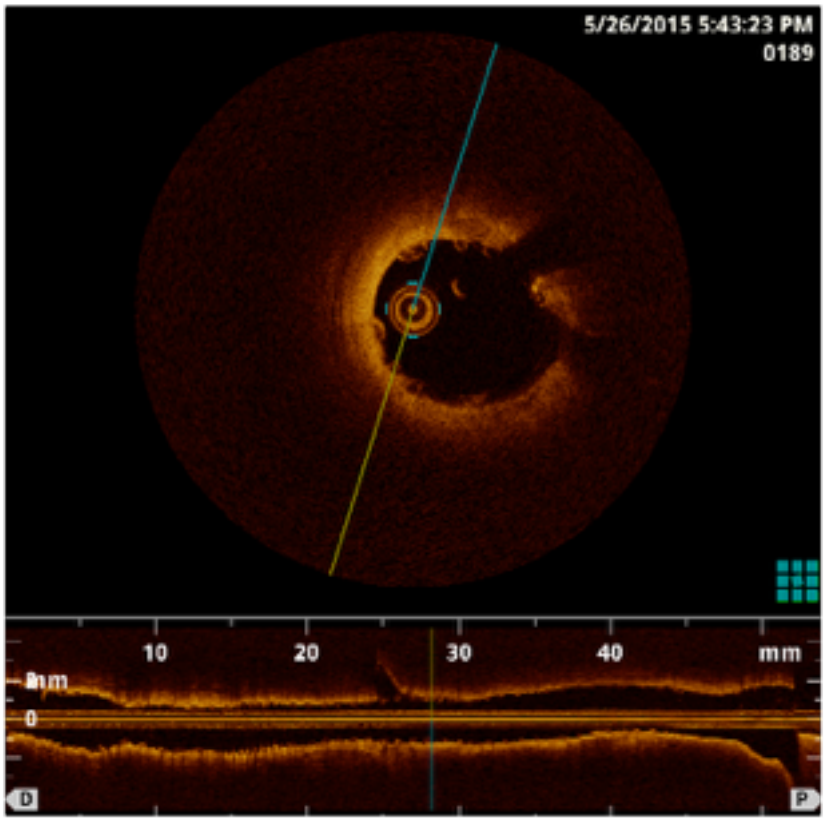


decision: post-dilate

J Am Coll Cardiol Intv. 2014;7(7):741-750. doi:10.1016/j.jcin.2014.01.165

Nominal expansion, prox. malaposition





decision: post-dilate

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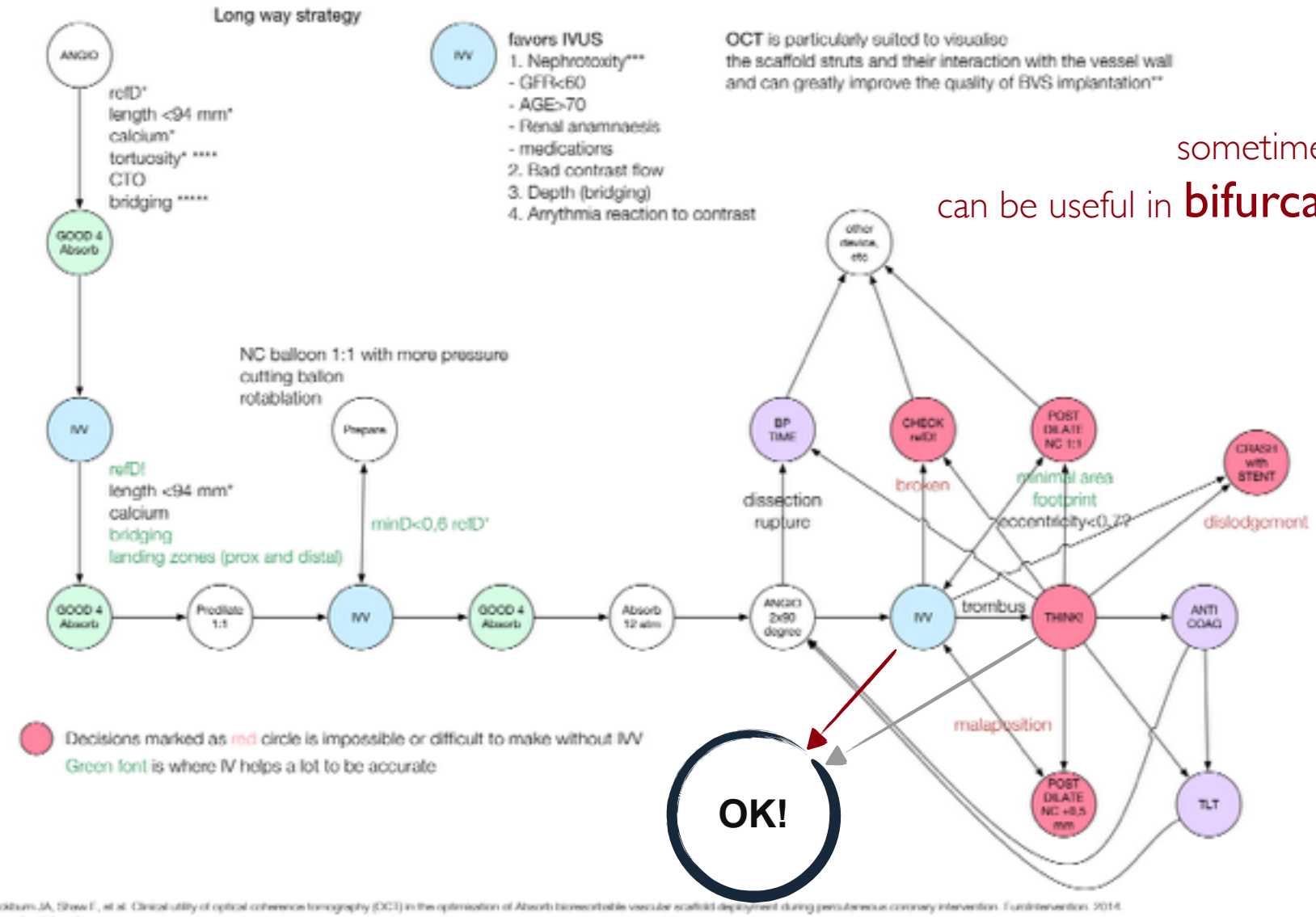

sometimes IVV
can be useful in **bifurcation**

* on label

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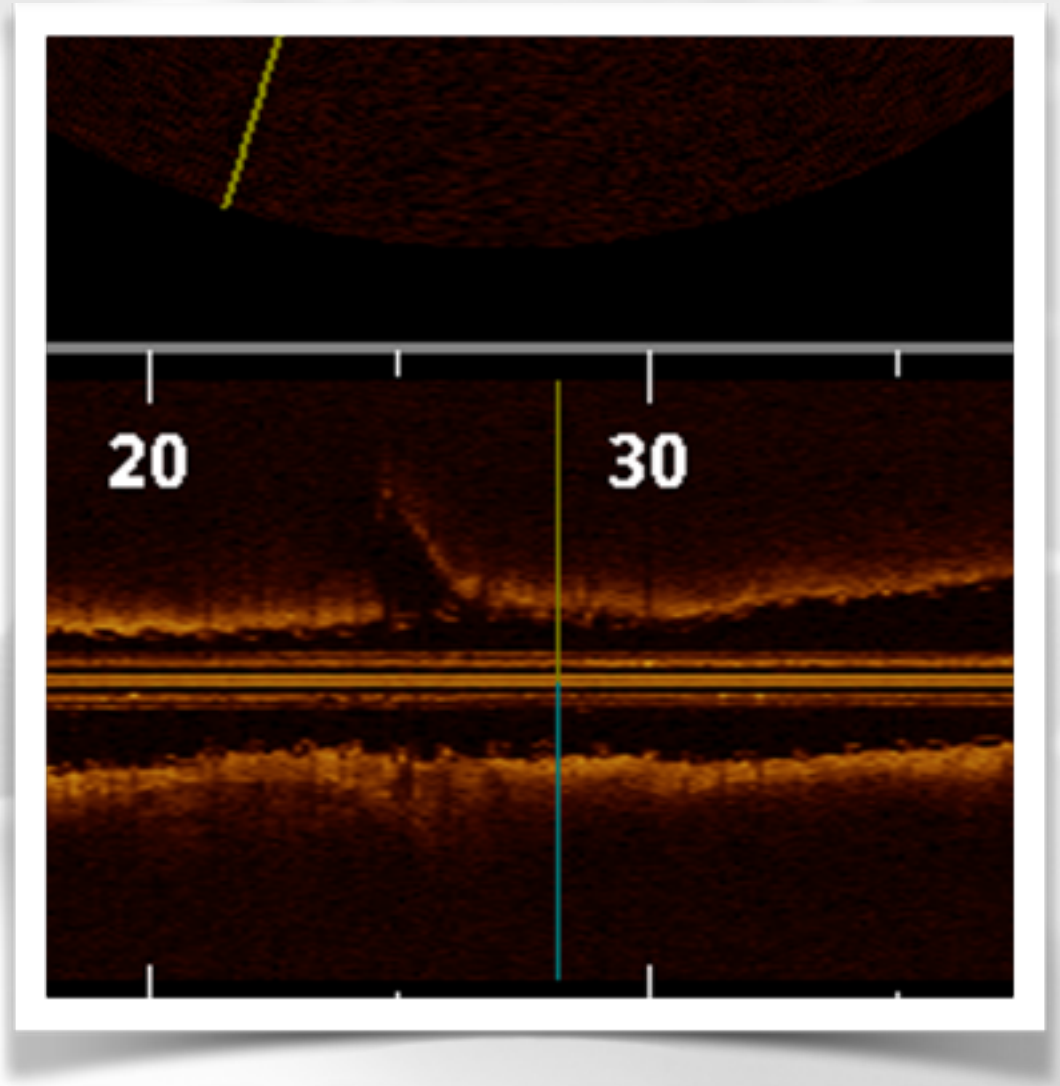
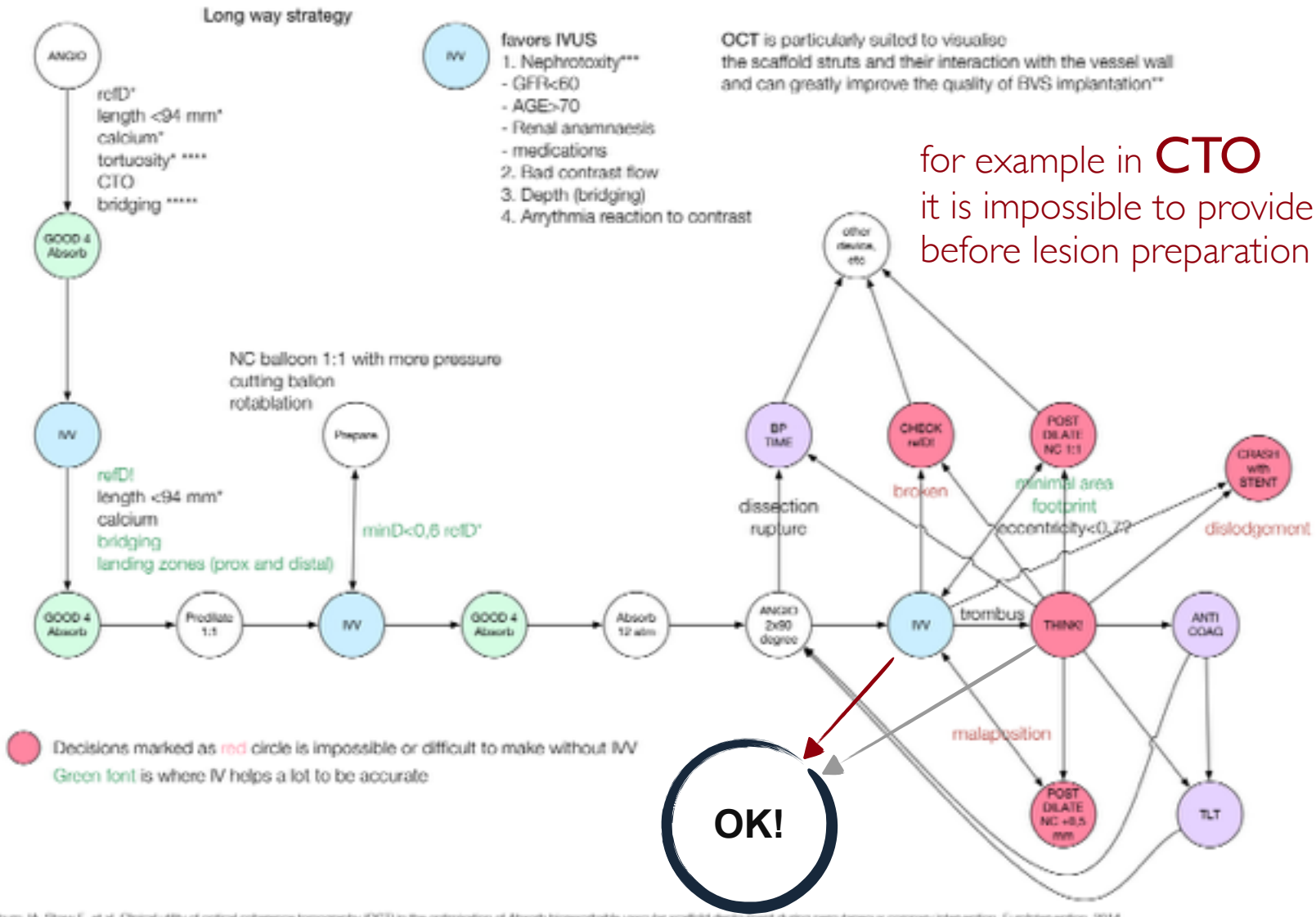
We need to wire close to carina*



*Absorb everolimus-eluting bioresorbable scaffolds in coronary bifurcations: a bench study of deployment, side branch dilatation and post-dilatation strategies

John A. Ormiston, MBChB; Bruce Webber, MHSc; Ben Ubod, BSN; Mark W.I. Webster, MBChB; Jonathon White, MBChB

EuroIntervention 2014; 10-online publish-ahead-of-print May 2014



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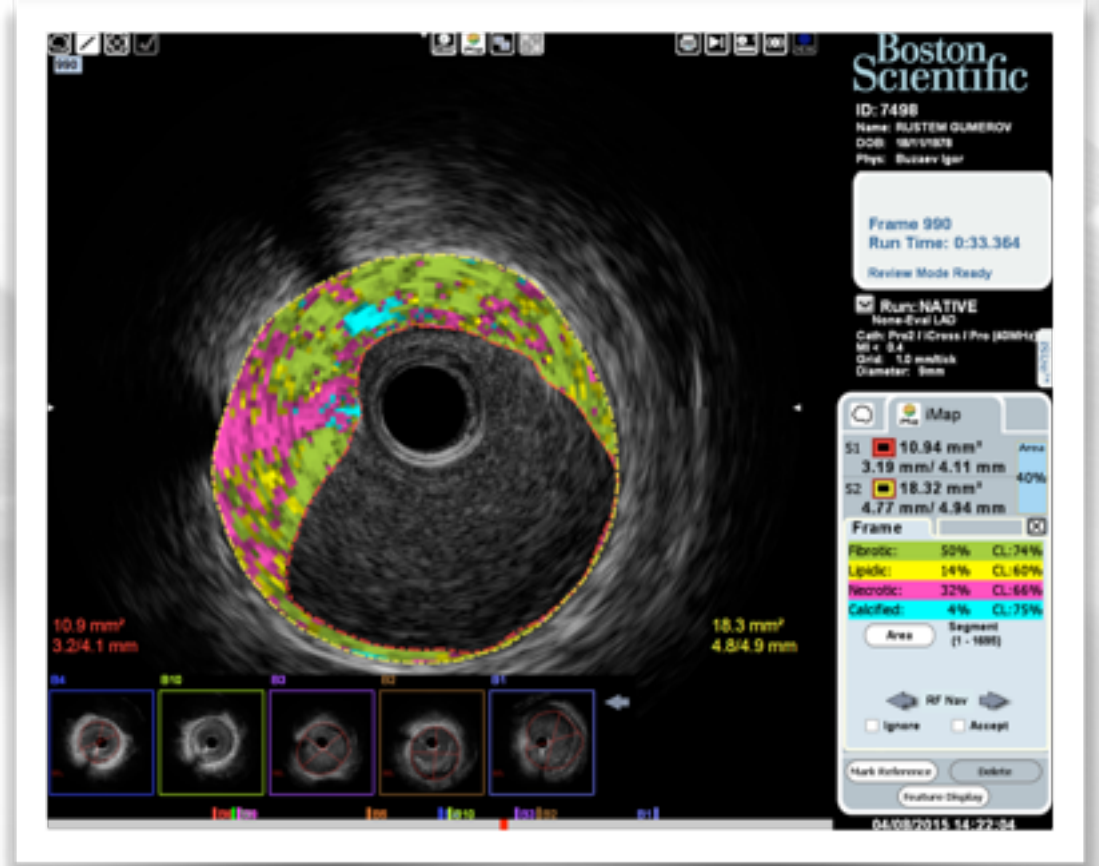
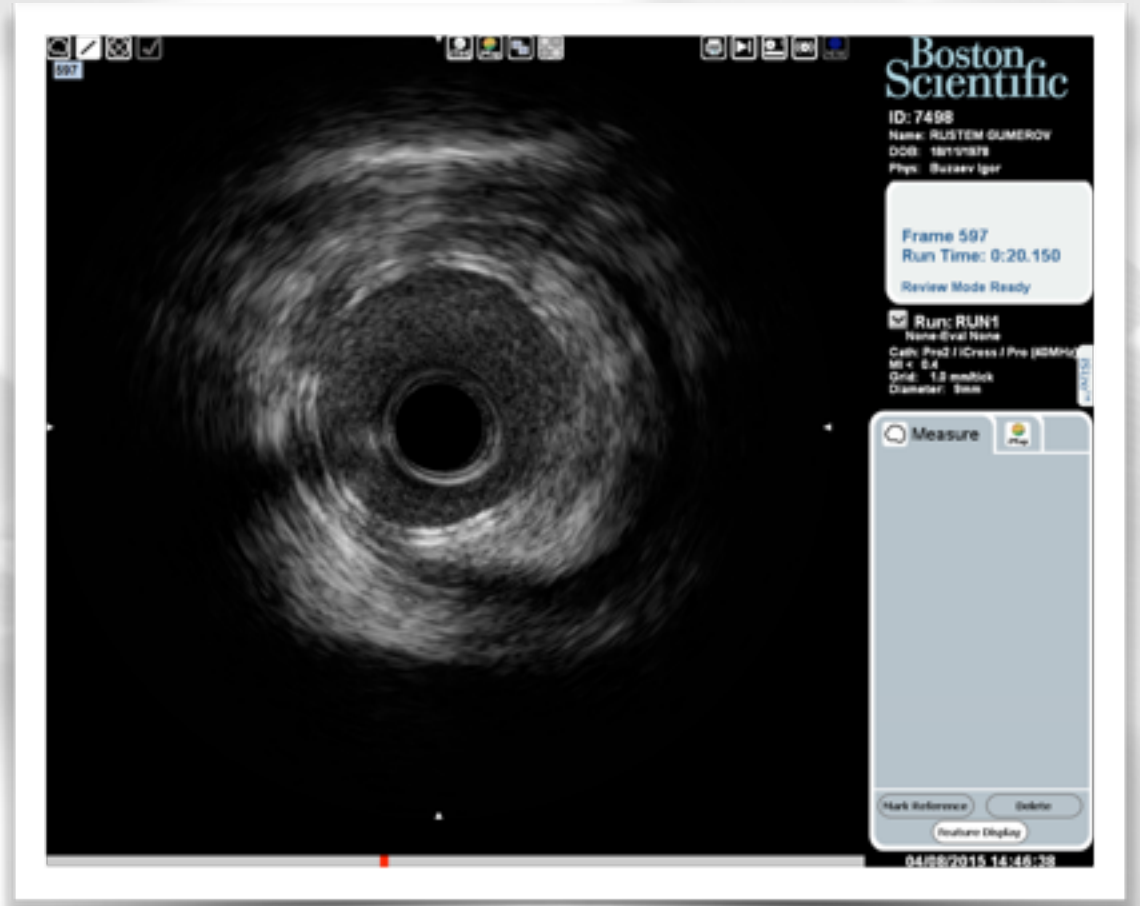
IVUS



1. No contrast nephrotoxity
2. No arrhythmia during exam
3. Distal to critical stenosis (length of the lesion)
4. Muscle bridging
5. Virtual histology, deep calcium

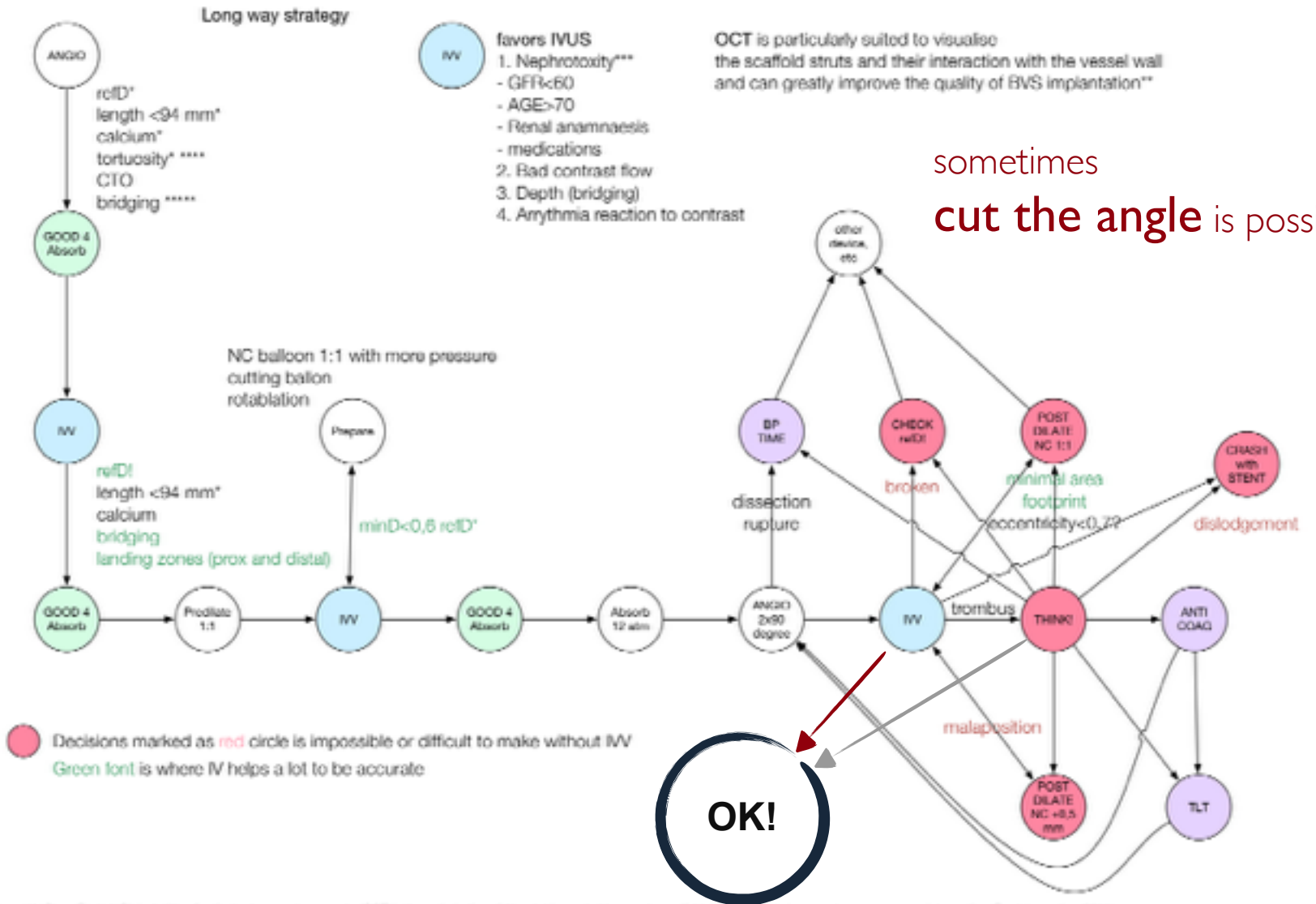
IVUS



1. No contrast nephrotoxity
2. No arrhythmia during exam
3. Distal to critical stenosis (length of the lesion)
4. Muscle bridging
5. Virtual histology, deep calcium

Enough visualization of scaffold

if three IVV is to long for you, there is...



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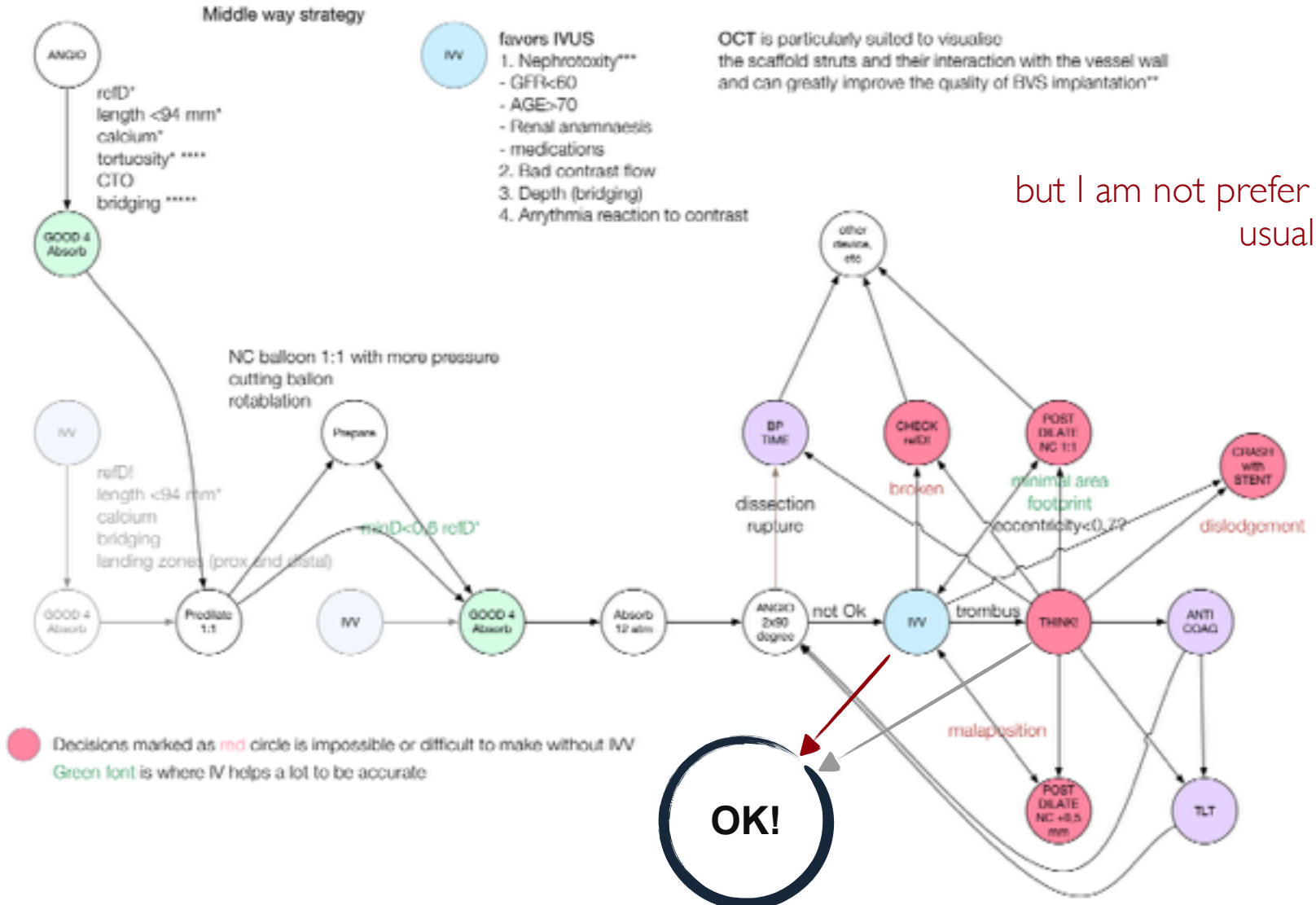
balanced strategy



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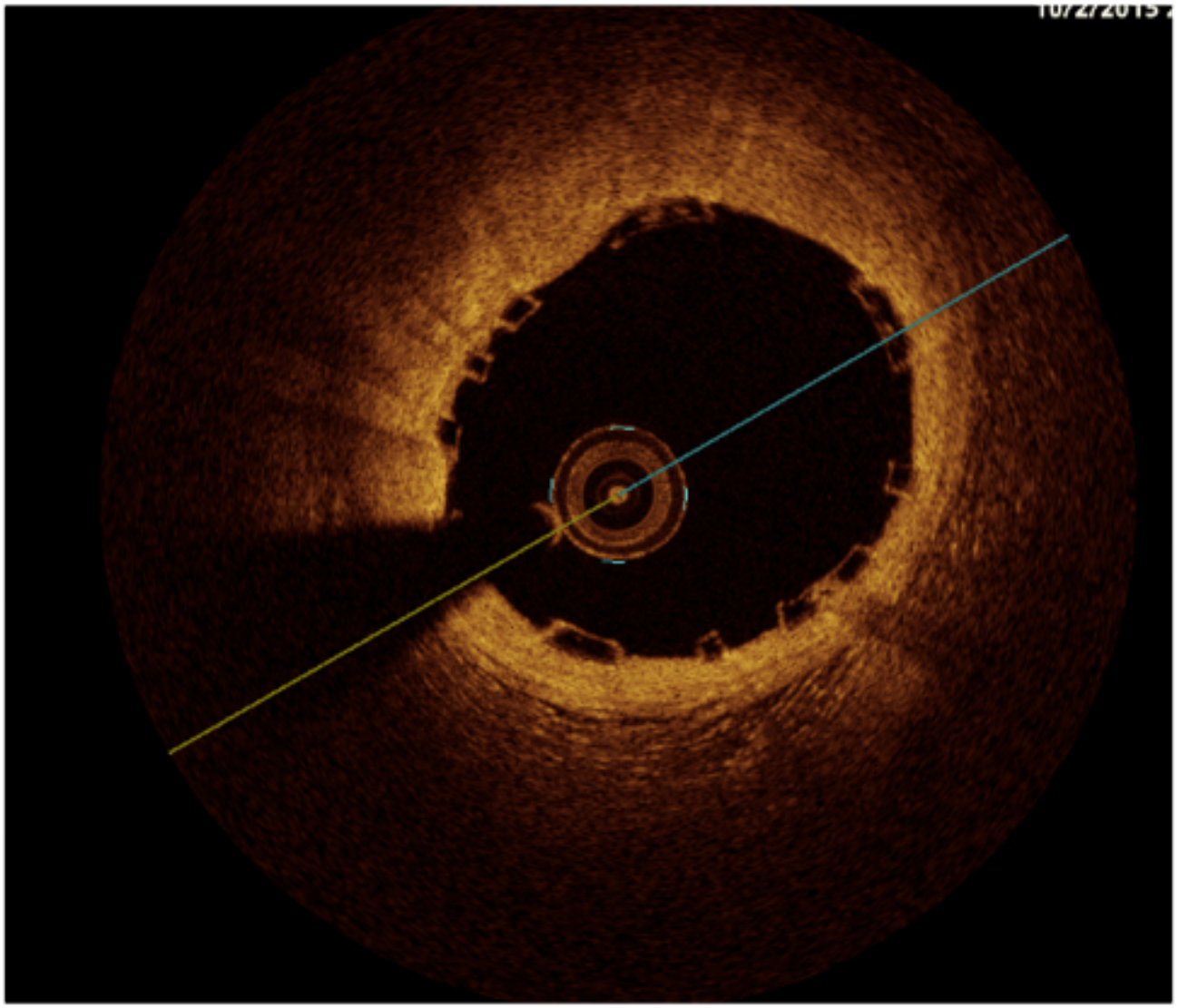

IVV helps a lot, but we are still not sure in what cases OCT or IVUS are significant clinically?

And we need to have clean indications for OCT or IVUS taking into consideration the relatively high price of visualization

The reason and price is not about MACE, is about human life

We started the randomized control trial to understand usefulness and necessity of intravascular visualization during scaffold implantation.

The hypothesis is that inadequate lesion preparation and implantation control could result in worse short-term clinical, angiography or IVV outcome

Intravascular imaging techniques in decision making during PCI with scaffold implantation

Igor Buzaev
Ufa, Russia

20 minutes (plus translation about 10 minutes)

www.buzaev.com
igor@buzaev.com

Harbin - 2016