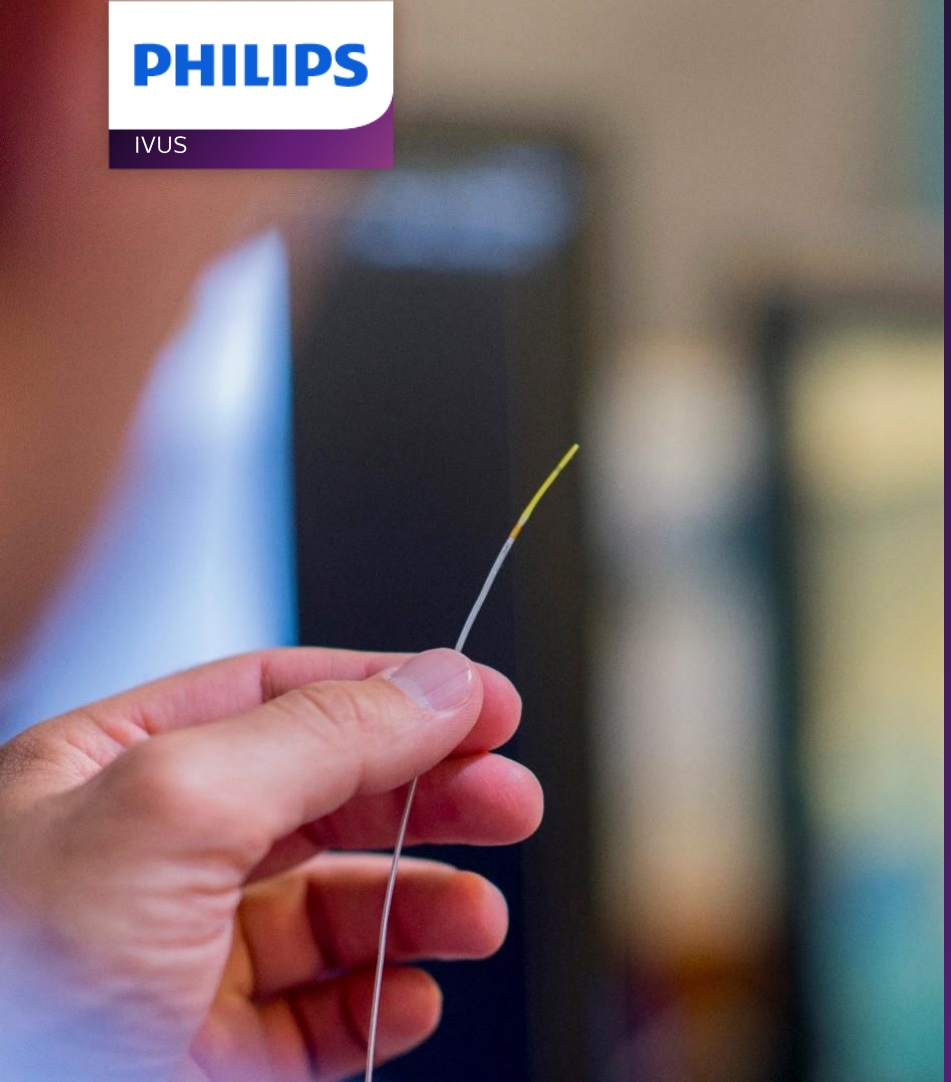
PHILIPS

IVUS

# Coronary IVUS

Image Guided Therapy – Devices
2021

innovation you



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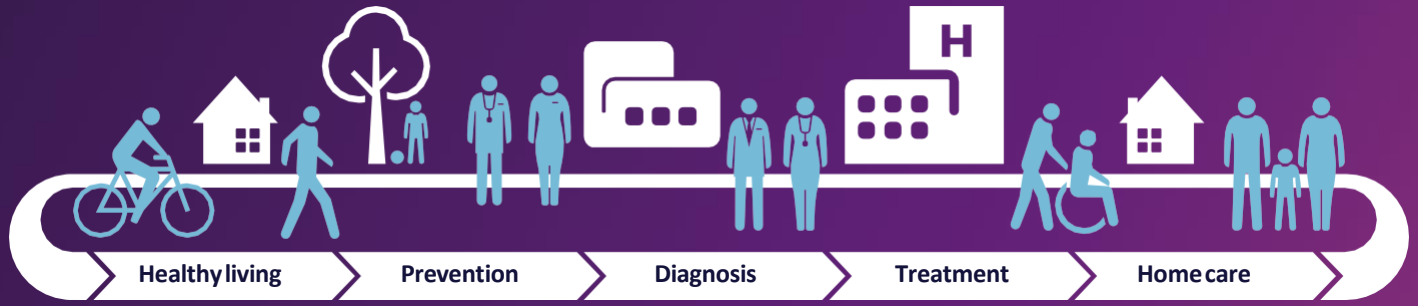
# Contents

# Philips IGT-D

## Image Guided Therapy - Devices

# Ready to take on the healthcare challenge?




**At Philips, we take a holistic view of people's health journeys**, starting with healthy living and prevention, precision diagnosis and personalized treatment, through to care in the home – where the cycle to healthy living begins again.

# **Seamless care** – designed to meet our customers' pressing needs

**Simplifying**
data and insight gathering

**Removing**
excess costs

**Driving**
improved treatment and outcomes

**Giving**
patients and staff a better experience

# Our vision for Image Guided Therapy

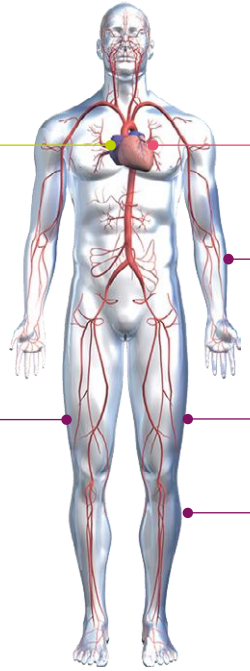
We're leading in thought and action so that our patients can get home faster and healthier, and stay there,
**living the lives they love.**

# IGT-devices

**An extensive and differentiated portfolio for a new value proposition**

**Lead management & EP**
Lead locking devices
Mechanical and laser extraction sheaths
Rescue occlusion balloon

**Superficial femoral & popliteal arteries**
PV IVUS
Laser atherectomy  Atherectomy
Support catheters
Drug coated balloons
Scoring balloons



**Coronary**
Coronary IVUS
Pressure & flow wires
Scoring balloons
Laser atherectomy

**Dialysis access**
Peripheral vascular IVUS
Scoring balloon

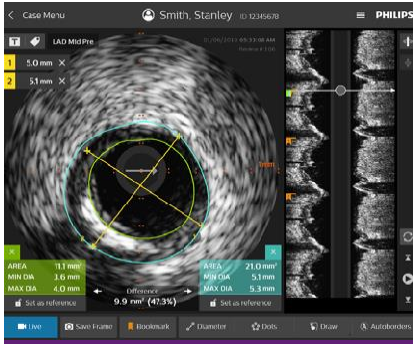
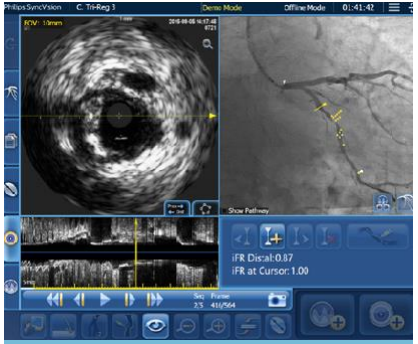
**Venous**
Peripheral vascular IVUS

**Below the knee**
Laser atherectomy,  Atherectomy
Peripheral vascular IVUS
Support catheters

Coronary  Peripheral  Lead management

# Image Guided Therapy

## Coronary devices

| IVUS imaging | Physiology | Therapies | Advanced imaging solutions |
|---|---|---|---|
|  |  |  |  |
| Eagle Eye Platinum, Refinity & Revolution | Verrata Plus & Verrata | ELCA, AngioSculpt & AngioSculptX | SyncVision |

Your partner in complex PCI

# What is CAD

# Coronary arteries

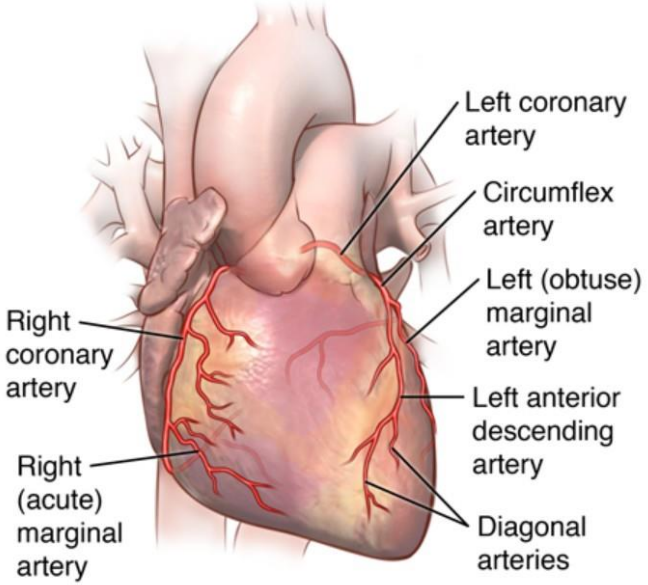
**There are 2 main coronary arteries of the heart**

The left main coronary artery (LMCA) supplies blood to the cardiac muscle on the left side of the heart (the l ventricle and left atrium). The LMCA divides into branches:

- The left anterior descending artery branches off the left main coronary artery and supplies blood to the front of the left side of the heart.
- The circumflex artery also branches off the left main coronary artery and encircles the heart muscle. This artery supplies blood to the outer side and back of the heart.

The right coronary artery (RCA) supplies blood to the cardiac muscle on the right side of the heart (right ventricle and the right atrium) and the SA (sinoatrial) and AV (atrioventricular) nodes, which regulate the heart rhythm. The right coronary artery divides into smaller branches, including the right posterior descending artery and the acute marginal artery. Together with the left anterior descending artery, the right coronary artery helps supply blood to the middle or septum of the heart.

- Smaller branches of the coronary arteries include: obtuse marginal (OM), septal perforator (SP), and diagonals.



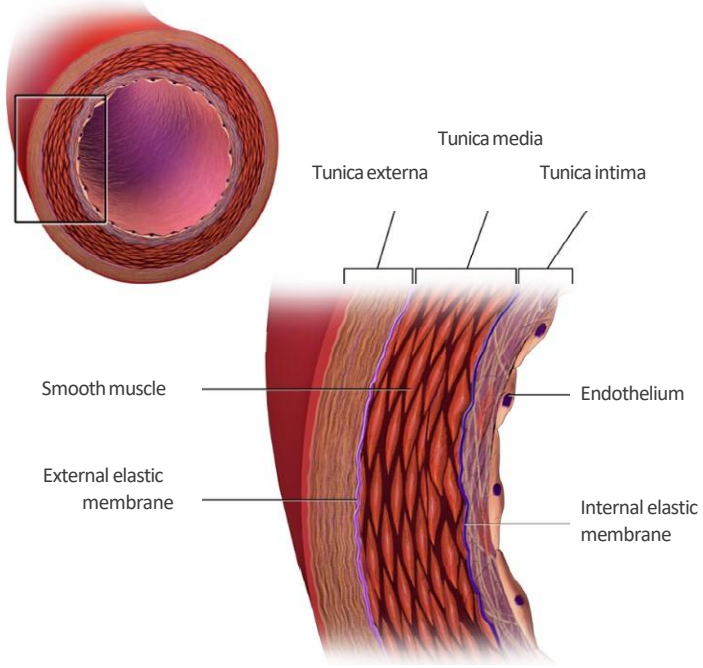
# Structure of an artery

**The wall of an artery consists of three layers**

The innermost layer (tunica intima), is simple endothelium surrounded by a connective tissue basement membrane with elastic fibers.

The middle layer (tunica media), is primarily smooth muscle and is quite often the thickest layer, provides support for the vessel but also changes vessel diameter to regulate blood flow and blood pressure.

The outermost layer (tunica externa or tunica adventitia), attaches the vessel to the surrounding tissue. This layer is connective tissue with varying amounts of elastic and collagenous fibers. The connective tissue in this layer is quite dense where it is adjacent to the Tunic media, but it changes to loose connective tissue near the periphery of the vessel.



# Coronary artery disease (CAD)

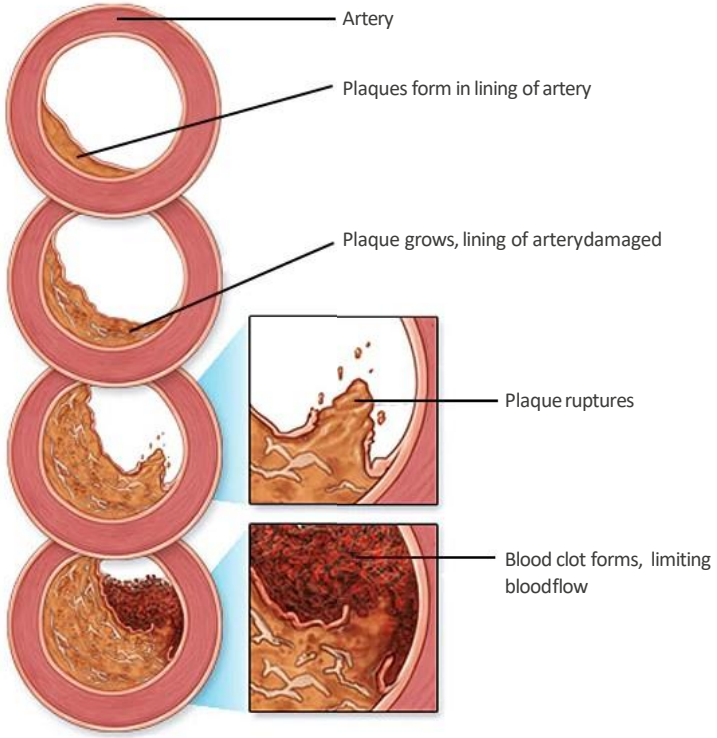
## What is CAD?

Coronary artery disease develops when the major blood vessels that supply your heart with blood, oxygen and nutrients (coronary arteries) become damaged or diseased. Cholesterol-containing deposits (plaque) in your arteries and inflammation are usually to blame for coronary artery disease.

When plaque builds up, it narrows your coronary arteries, decreasing blood flow to your heart. Eventually, the decreased blood flow may cause chest pain (angina), shortness of breath, or other coronary artery disease signs and symptoms. A complete blockage can cause a heart attack.

Coronary artery disease is thought to begin with damage or injury to the inner layer of a coronary artery, sometimes as early as childhood. The damage may be caused by various factors, including:

- Smoking
- High blood pressure
- High cholesterol
- Diabetes or insulin resistance
- Sedentary lifestyle

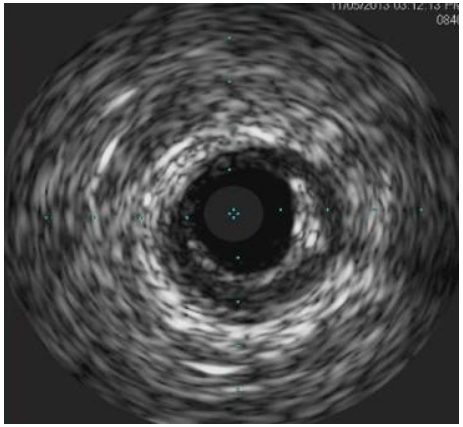


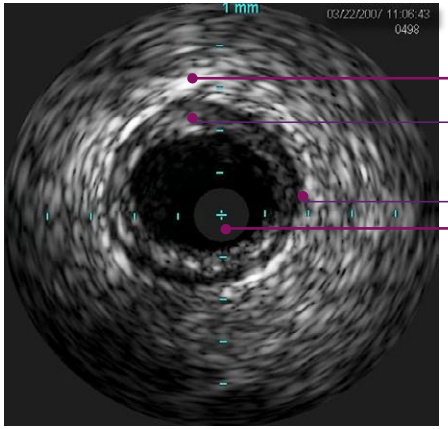
# What is IVUS

# What is IVUS?

**Intravascular ultrasound**

- When electricity stimulates a crystal, sound waves are released
- The sound hits tissue and is reflected to a varying degree
- Crystals then receive those reflected signals and code them back into electrical impulses
- Those impulses can construct a sophisticated image using computing power






**Adventitia**
White ring

**Intima**

**Media**
Black ring

**Dead Zone**
Catheter

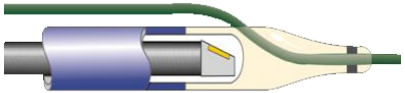
# Two ways to acquire IVUS signals

## Digital IVUS - Eagle Eye Platinum

A series of fixed 64 ultrasound devices that scan sections of the vessel in turn, whilst computers to build the image, 20MHz greyscale.

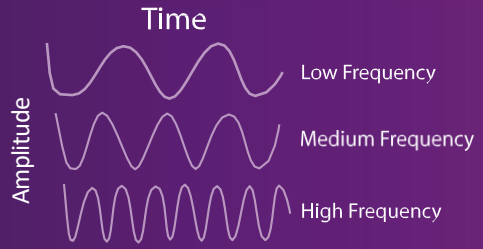
## Rotational IVUS - Refinity & Revolution

A single IVUS catheter that spins within a sheath and uses computers to build the image in real-time from the sections that come in bit by bit, 45MHz greyscale.



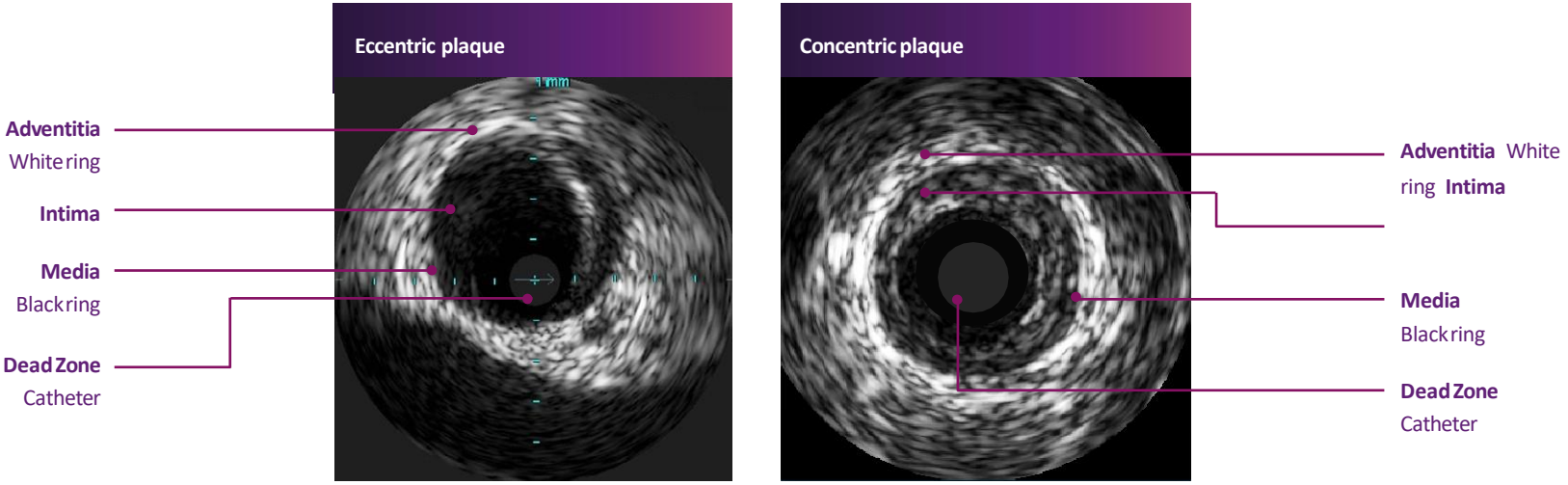
## MHz – megahertz

MHz refers to the frequency of the soundwave. A higher frequency will increase the resolution but reduce the depth penetration.



# Plaque geometry

Atherosclerotic plaques typically have different geometries. The two types of geometry you will see are:

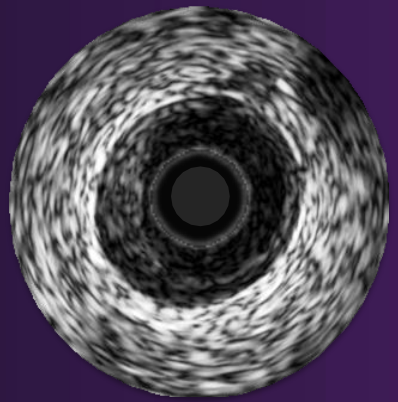



Eccentric plaques are distributed non-circumferentially in the vessel; this makes the assessment of disease by angiography especially prone to underestimation or overestimation depending on the angle of view.

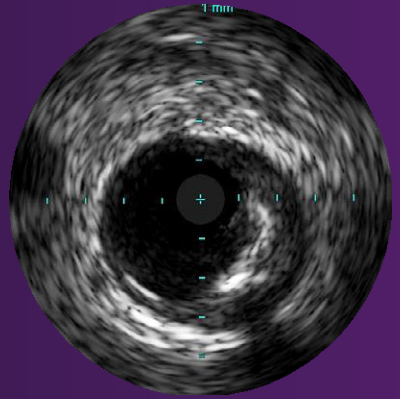
Concentric plaques are distributed circumferentially in the vessel and tend to occur in areas of negative remodeling; use of angiography alone could result in too large a stent diameter.

# Four different types of plaque

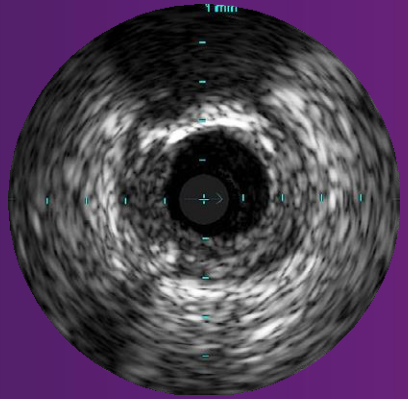
**1. Soft (fatty)**
Echolucent light gray flecks



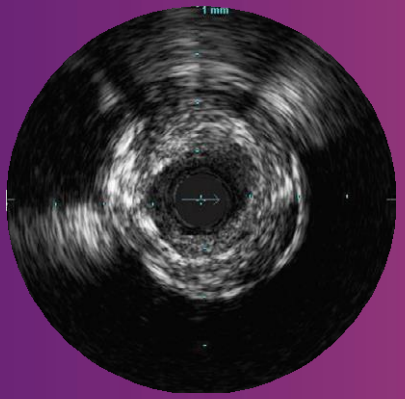
**2. Fibrous**
Echogenic, light gray with white surfaces



**3. Calcified**
Highly echogenic, white areas with shade

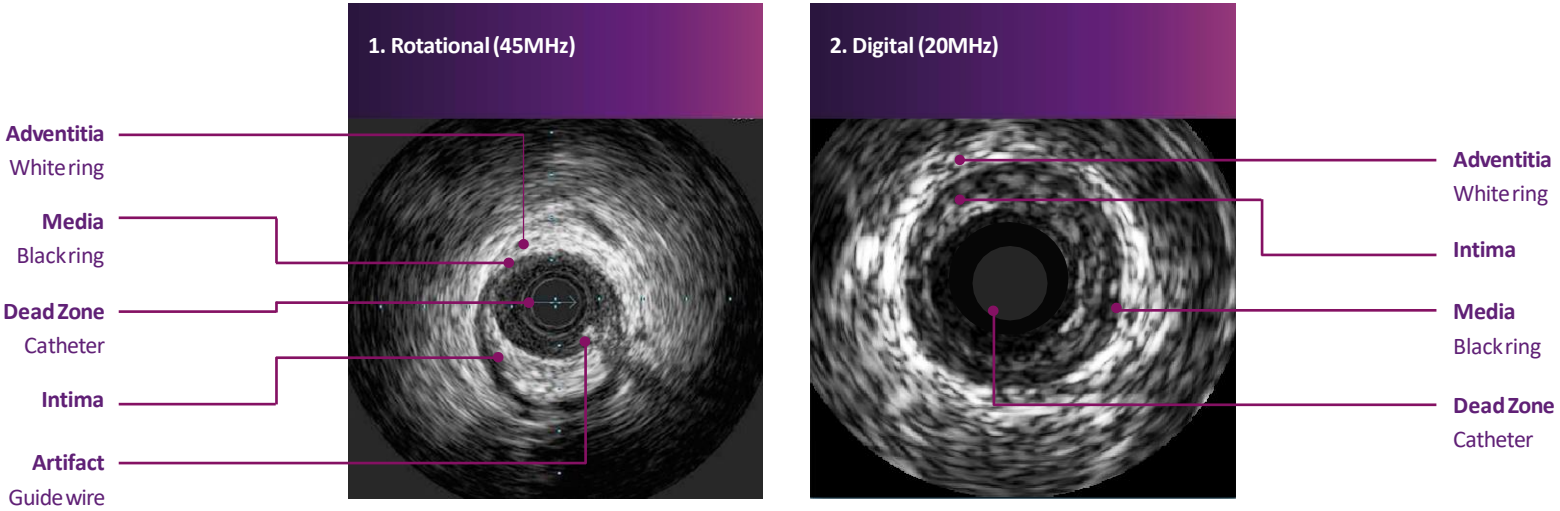


**4. Mixed plaque**
Mixed plaque is a combination of tissues of varying echogenicity



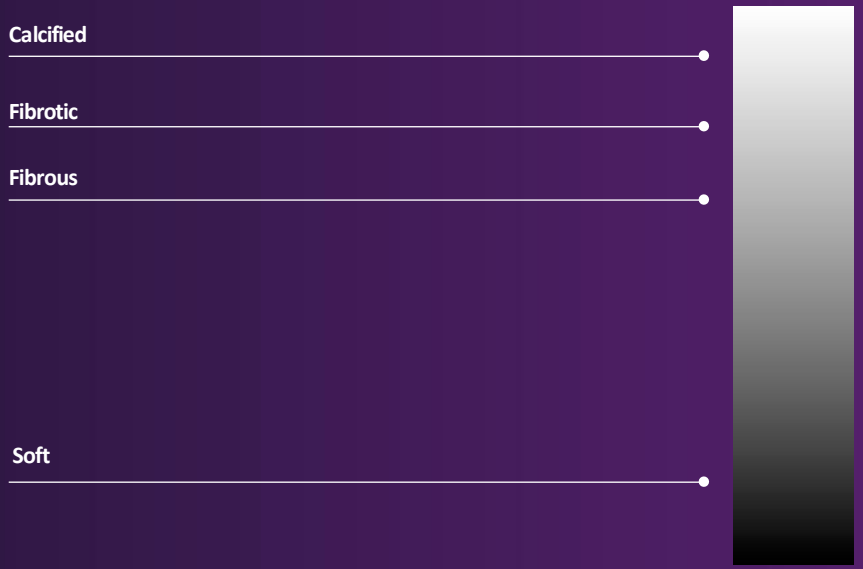
# Two types of IVUS image

**Rotational & digital**



# Grayscale levels

## Plaque composition




Calcium is indicated by very bright areas with acoustic shadowing that blocks out the image behind. This shadow occurs because the high density of calcium dampens the ultrasound echo.

Fibrous plaques have an intermediate echogenicity between soft (echolucent) atheroma and highly echogenic calcified plaques. Fibrous plaques exhibit little or no acoustic shadowing.

Plaque definition should be determined by reviewing the entire segment, not just the image slice with the smallest lumen CSA.

# Why perform IVUS in CAD

# What beneficial information does intravascular ultrasound provide?

- Vessel sizing
- Length of lesions
- Type of plaque
- Measurement of plaque/stenosis
- Optimized treatment strategies based on morphology and geometry
- Detection of dissections & complications with PCI

# IVUS adds a third dimension

**An angiogram only provides a 2D image of a vessel lumen, referred to as lumen imaging[1]**

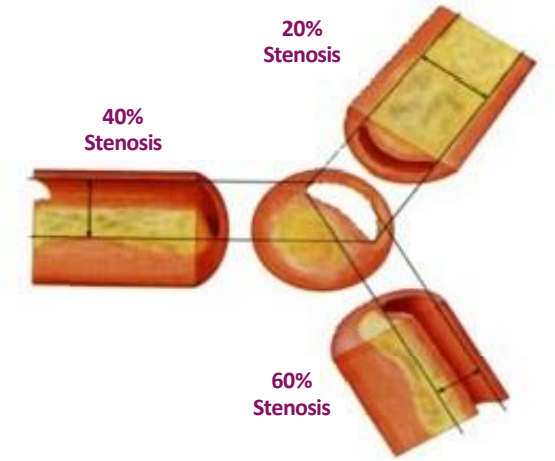
- The clinical problem involves a 3D vessel and lesion

**With 2D coronary angiography:**

- Depending on the angle of the x-ray arm producing the angiogram, a value for % stenosis may be established that does not reflect the true narrowing of the vessel[2]
- An under- or over-estimation of a lesion's severity may result[3]

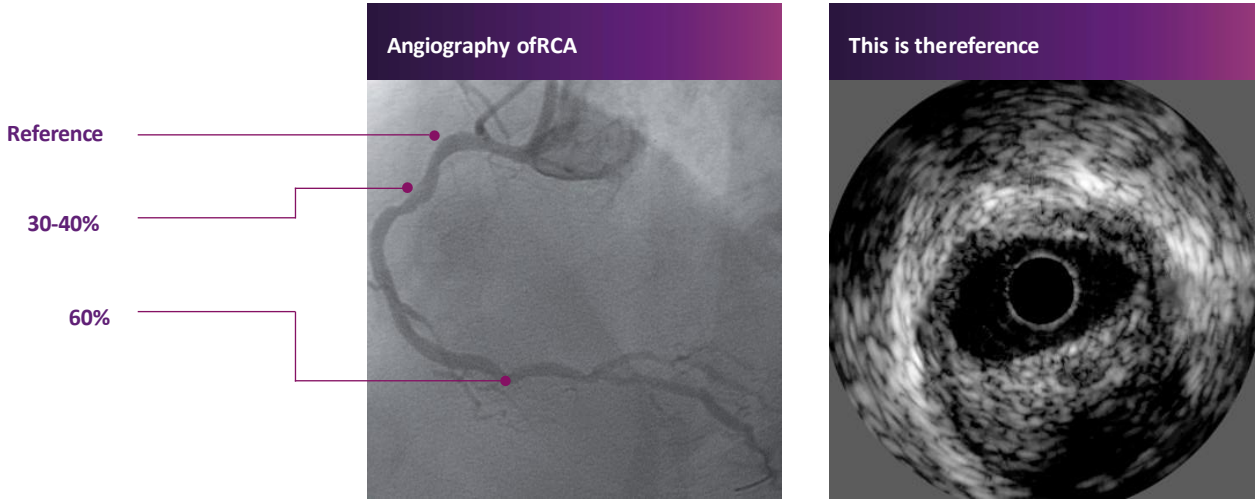
**As a 3D modality, IVUS can accurately identify disease, assess its significance and provide valuable additional information:[4,5]**

- Assess plaque burden and lesion morphology[4,6]
- Detect acute complications[6,7]
- Provide accurate measurements for device selection[4]
- Assess adequacy of stent deployment[5]



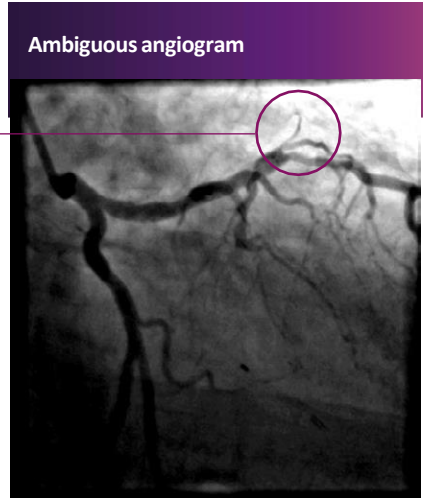

1. McDaniel MC, et al. JACC Cardiovasc Interv. 2011;4(11):1155-67.
2. Topol EJ, Nissen SE. Circulation. 1995;92(8):2333-42.
3. Pijls NH, et al. J Am Coll Cardiol. 2010;56(3):177-84.
4. McDaniel MC, et al. JACC Cardiovasc Interv. 2011;4(11):1155-67.
5. Bonello L, et al. Arch Cardiovasc Dis. 2009;102(2):143-51.
6. Porto I, et al. Cardiovasc Ultrasound. 2004;2:18.
7. Yip A, S J. Cardiovasc Diagn Ther. 2015;5(1):37-48.

# Angiography vs IVUS



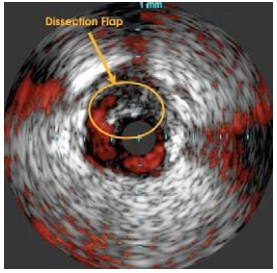
# Angiography alone is not enough:

**Dissection?**
**Calcium?**
**Thrombus?**
**Stenosis?**

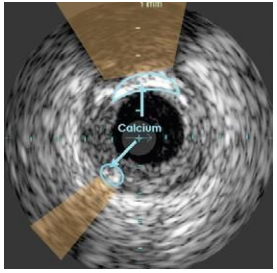



Without IVUS, how would you know which condition to treat from this angiogram?

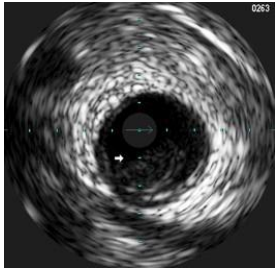
**Dissection**



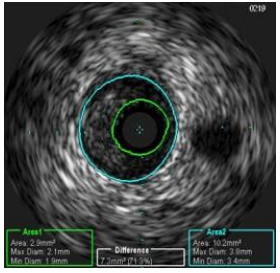

**Calcium**




**Thrombus**



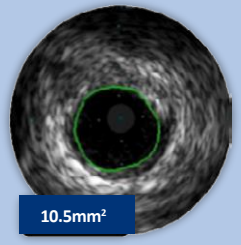
**Stenosis**



# IVUS provides information to guide treatment decisions throughout the procedure

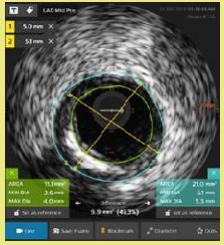
## Pre-procedure

Identify disease location, assess significance and detect acute complications



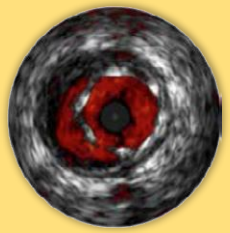

## Peri-procedure

Select appropriate treatment strategy dependent on lesion morphology and select appropriate devices



## Post-procedure

Post-treatment assessment to optimize procedural outcomes



# Pre-procedure IVUS

## Plan the intervention

### 1. Identify disease & assess significance[1,2]

**Lesion severity**

- Cross sectional lumen area
- Vessel diameter
- Plaque burden
- Calcification
- Sub-intimal thickening
- Thrombus

**In case of ambiguous angiogram**

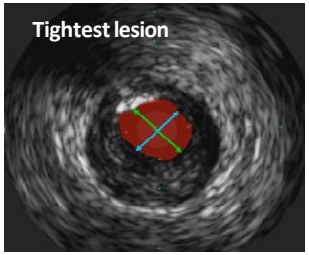
- Diffuse reference vessel disease
- Lesion foreshortening
- Angulations
- Eccentricity
- Hazy lesions

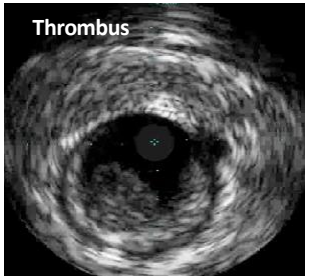
**Side-branches**

- Presence of vascular remodeling

### 2. Detect acute complications[2,3]

- Plaque rupture
- Spontaneous dissection
- Thrombus




1. McDaniel MC, et al. JACC Cardiovasc Interv. 2011;4(11):1155-67.
2. Porto I, et al. Cardiovasc Ultrasound. 2004;2:18.
3. Yip A, S J. Cardiovasc Diagn Ther. 2015;5(1):37-48.

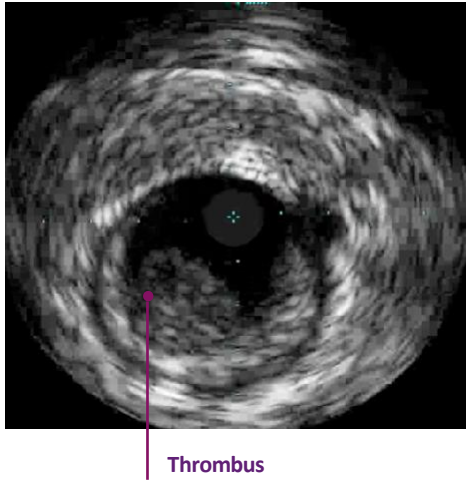
# Thrombus

**Blood clot within the vessel**

One of the hardest things to determine is thrombus. Many times it is missed altogether on angiography and can only be seen with IVUS. Thrombus will typically appear as an irregular shape within the vessel and may be moving with flow through the vessel.

It can be much easier to see in a moving IVUS video, rapid review, or by using ChromaFlo imaging than in a single still frame.

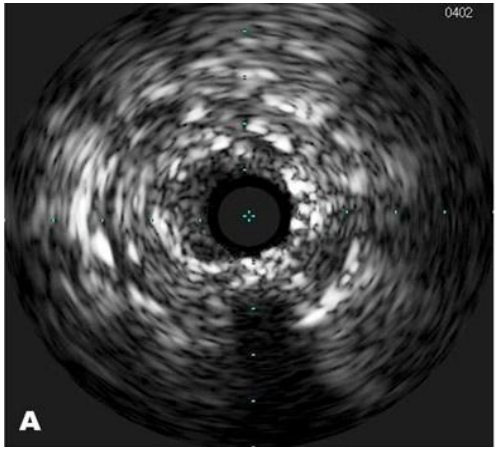
**Stent thrombosis (ST)** is a thrombotic occlusion of a coronary stent. This is usually an acute process in contrast to restenosis, which is a gradual narrowing of the stent lumen due to neointimal proliferation. Stent thrombosis often results in an acute coronary syndrome, while restenosis often results in symptoms of angina.

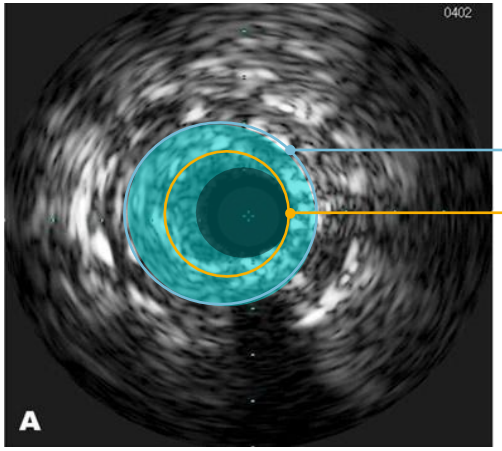


# In-stent restenosis (ISR)

## Plaque within stent

ISR can be classified as >50% diameter stenosis at stent's inside or edges, with different ISR morphologies predicting different TLR rates at 1-year[1,2]. Several factors with both biological and/ or procedural causes contribute to the nature of ISR[3]




**Biologic causes**

- Reaction to metal or polymer
- Drug resistance
- Thrombosis

**Procedural causes**

- Stent under-expansion/mal-apposition
- Stent fracture
- Edge trauma
- Geographical miss

1. Mehran R, Dangas G, Abizaid AS, et al. Angiographic patterns of instent restenosis: classification and implications for long-term outcome. Circulation 1999;100:1872–8.
2. Solinas E, Dangas G, Kirtane AJ, et al. Angiographic patterns of drug eluting stent restenosis and one-year outcomes after treatment with repeated percutaneous coronary intervention. Am J Cardiol 2008;102:311–5.
3. Mintz GS. "Clinical Utility of Intravascular Imaging and Physiology in Coronary Artery Disease". J Am Coll Cardiol 2014;64:207–22.

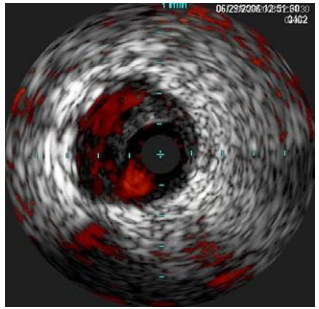
# Dissection

## Intimal tear resulting in the formation of a ‘false’ and ‘true’ lumen

Tears in the plaque that are parallel to the vessel wall with visualization of blood flow in the false lumen.

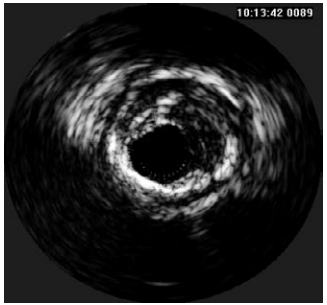
Can be difficult to detect live. Most often occurs at a juncture between varying densities:

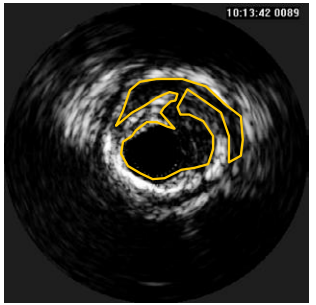
- Stent/soft plaque
- Calcium to soft plaque
- Soft plaque to wall



Example of ChromaFlo imaging highlighting a dissection

## Deep wall dissection




Concentric lesion
Percutaneous transluminal coronary angioplasty
Shearing force opposite the calcified segment

# Peri-procedure

## Select the appropriate treatment strategy and use of devices

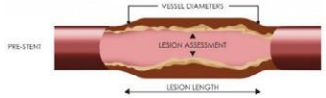
**Assess lesion morphology and identify the need for pre-treatment**[1]

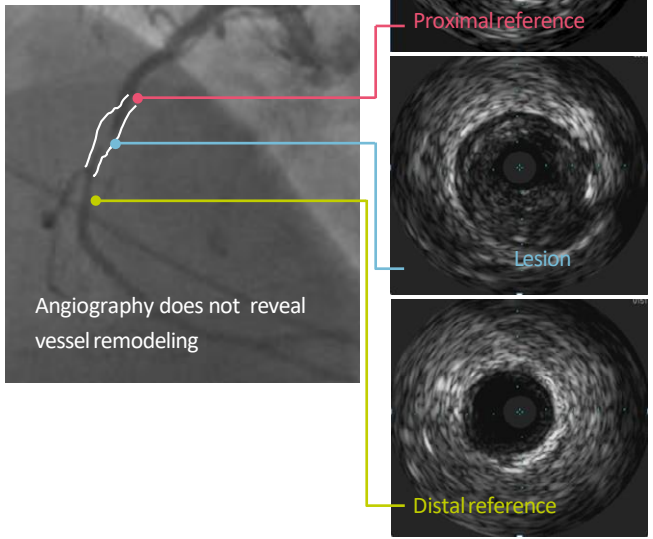
- Superficial or deep calcification
- Lesion tissue types to identify thin-cap fibroatheroma

**Perform measurements to help select appropriate device(s)**[1]

- Vessel & lumen diameter
- Area & lesion length
- Lesion preparation
- Define appropriate landing zones
- Stent selection and sizing

IVUS allows you to select appropriate proximal and distal reference segments. Having **a defined, optimal PCI criteria** from these references, **significantly reduces MACE**[2] compared to angiography alone.




1. McDaniel MC, et al. JACC Cardiovasc Interv. 2011;4(11):1155-67.
2. Zhang J et al. The ULTIMATE trial. Intravascular Ultrasound-Guided Versus Angiography-Guided Implantation of Drug-Eluting Stent in All-Comers. Journal of the American College of Cardiology (2018), doi.org/10.1016/j.jacc.2018.09.013

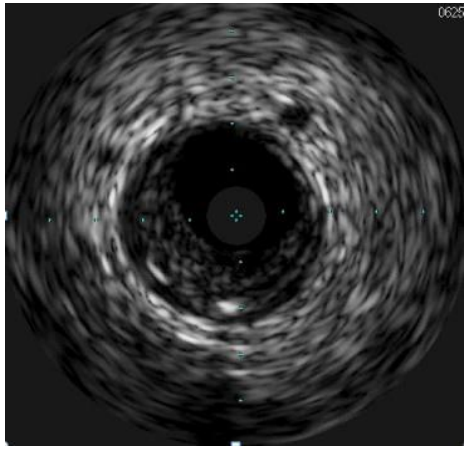
# Peri-procedure

## Vessel measurements

**Vessel diameter**

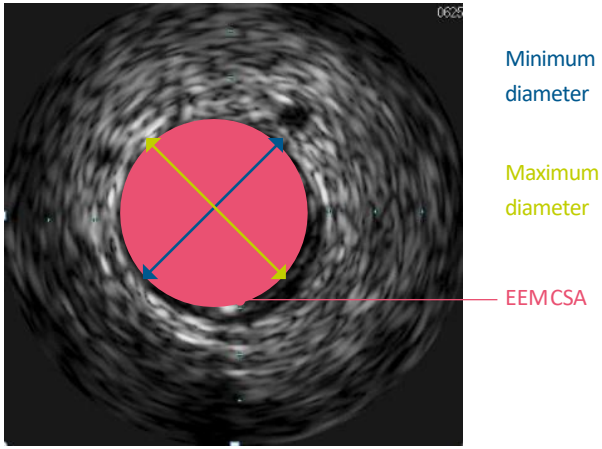
Measure adventitia to adventitia (EEM to EEM)

- Maximum diameter
- Minimum diameter



**Vessel/external elastic membrane cross-sectional area (EEM CSA)**

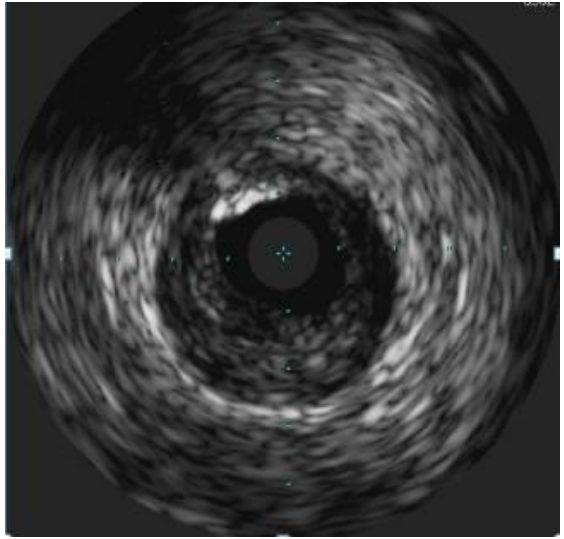
- Vessel area measured at the site of external elastic membrane (outer boundary of media)
- Cross-sectional area inside of adventitia

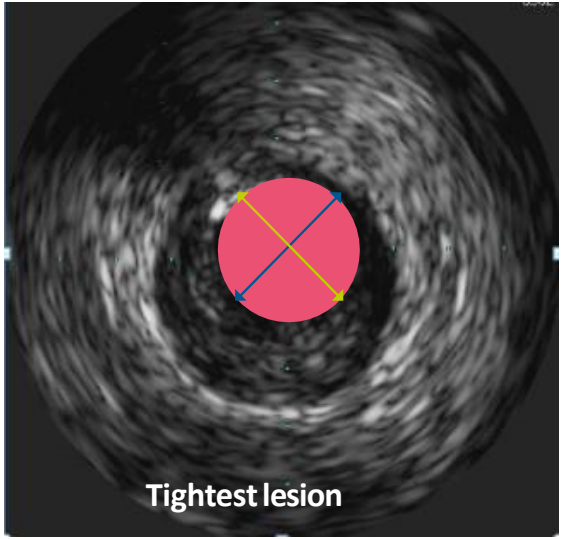



Mintz, G. and Nissen S. et al. ACC Clinical Expert Concensus Document on IVUS JACC Vol. 37, No. 5, 2001 April 2001: 1478-92

# Peri-procedure

## Lumen measurements






**Lumen diameter**
- Measured intima to intima
- Maximum diameter
- Minimum diameter

**Minimal lumen diameter (MLD)**
- Smallest lumen diameter within lesion segment

**Lumen area**
- Cross-sectional area inside of lumen

**Minimal lumen area (MLA)**
- Smallest Lumen CSA within lesion segment

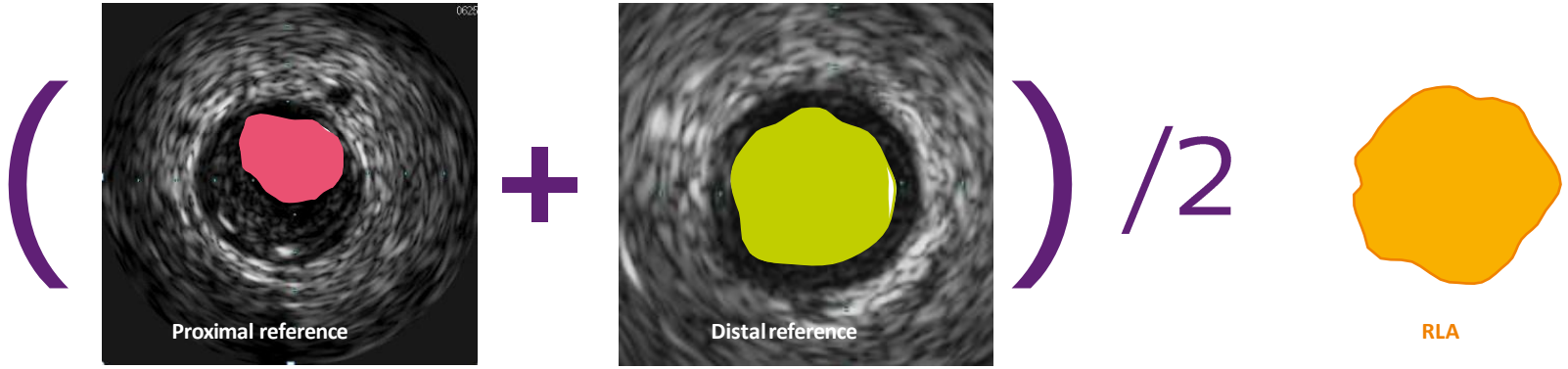
Mintz, G. and Nissen S. et al. ACC Clinical Expert Concensus Document on IVUS JACC Vol. 37, No. 5, 2001 April 2001: 1478-92

# Peri-procedure

## Calculation of reference lumen area

**Reference lumen area (RLA)**

RLA is the average of proximal lumen CSA & distal lumen CSA




Reference diameter can be measured in the same manner

=

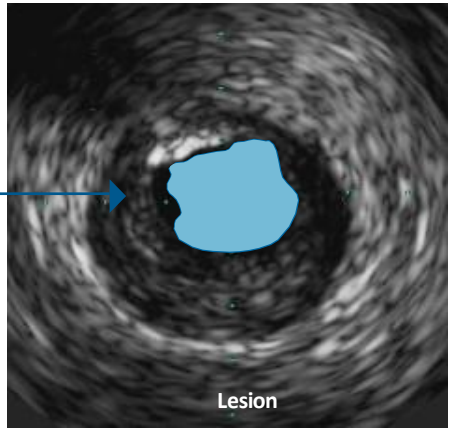
Mintz, G. and Nissen S. et al. ACC Clinical Expert Concensus Document on IVUS JACC Vol. 37, No. 5, 2001 April 2001: 1478-92

# Peri-procedure

## Calculation of % stenosis

**Reference lumen area (RLA)**
Average of proximal lumen CSA & distal lumen CSA

**Minimal lumen area (MLA)**
Smallest lumen CSA within lesion segment




**% stenosis = [(RLA – MLA) / RLA] x 100**

Mintz, G. and Nissen S. et al. ACC Clinical Expert Concensus Document on IVUS JACC Vol. 37, No. 5, 2001 April 2001: 1478-92

# Peri-procedure

## Calculation of plaque burden

**Remember**

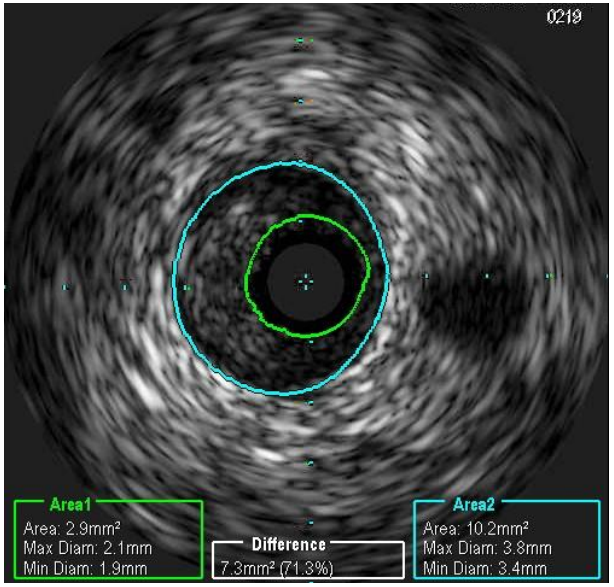
- Atheroma area (or plaque + media) = (EEM CSA – MLA)
- Plaque burden = [(Atheroma CSA)/ EEM CSA] x100

**Example*:**

[(10.17- 2.92)/10.17] x 100=

71.29% plaque burden

**% of plaque burden can be measured and calculated from a single IVUS frame.**




EEM

Lumen

*Numbers have been rounded to one decimal place on IVUS image

# Peri-procedure

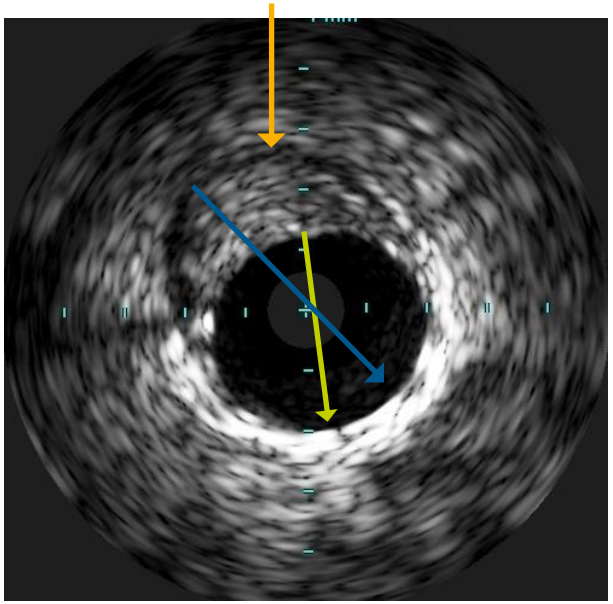
## PCI stent sizing

**Several methods and techniques are used including:**

a. Stent sizing for remodelled vessels: "Mid-wall calculation" Using distal reference (vessel diameter + lumen diameter)/2 = approximate stent size.

b. 80% of average (distal & proximal) reference diameters

**Positively remodelled vessel**



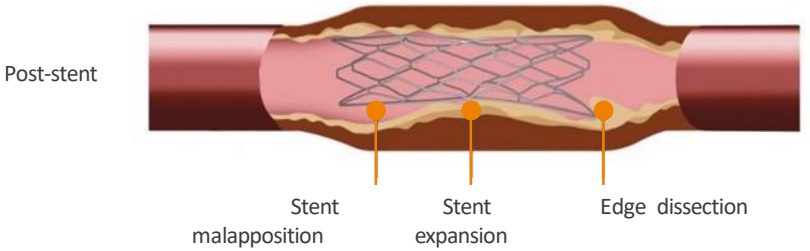
Mintz G et al. American College of Cardiology Clinical Expert Consensus Document on Standards for Acquisition, measurement and Reporting of Intravascular Ultrasound.. J Am Coll Cardiol. 2001;37(5):1478-1492.

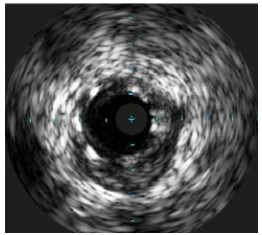
# Post-procedure IVUS

## Optimize procedural outcomes

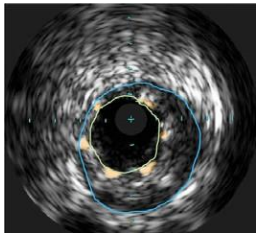
**Assess adequacy of stent expansion, apposition, mechanical complications and mechanisms:**

- Geographical miss
- Major edge dissections
- Apposition
- Plaque protrusion

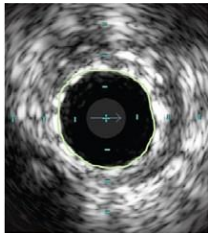


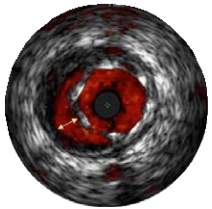
Undersized stent



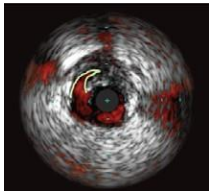
Still undersized post high-pressure inflations



Minimum stent area above a certain threshold



Avoiding major malapposition



Absence of significant edge dissection

Bonello L, et al. Arch Cardiovasc Dis. 2009;102(2):143-51.

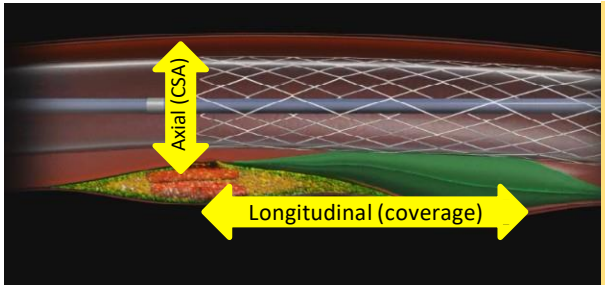
# Post-procedure IVUS

## Geographical miss (GM)

**Inadequate stent deployment or suboptimal placement**

**Axial GM:** Under or over inflation of a stent or balloon in which the ratio between the size of the largest balloon (at its maximum inflation pressure) and the reference vessel diameter was δ0.9 or >1.3.

**Longitudinal GM:** A deployed stent which does not cover an injured or significantly diseased segment at one or both of the edges.




**STLLR study reported:** 66.5% of stents had "geographic miss," associated with 3 times the MI and 2 times the TVR.[1]

**Stent optimization (STOP) study reported:** IVUS-guidance increased the proportion of cases where optimal stent CSA (cross-sectional area) was achieved (21% & 54% vs 81%) following high pressure deployment and post dilation[2]

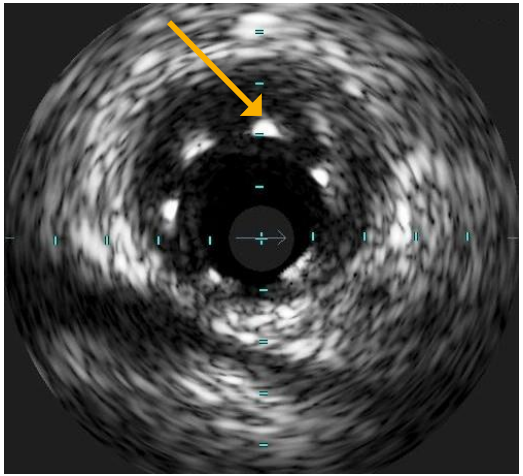
1. Costa et al. The Impact of Stent Deployment Techniques on Clinical Outcomes of Patients Treated With the CYPHER® Stent (S.T.L.L.R.) Am J Cardiol 2008 Jun 15;101(12):1704-11.
2. Rana O et al. The impact of routine intravascular ultrasound guided high-pressure post-dilation after drug-eluting stent deployment. J Invasive Cardiol 2014;26(12):640-646.

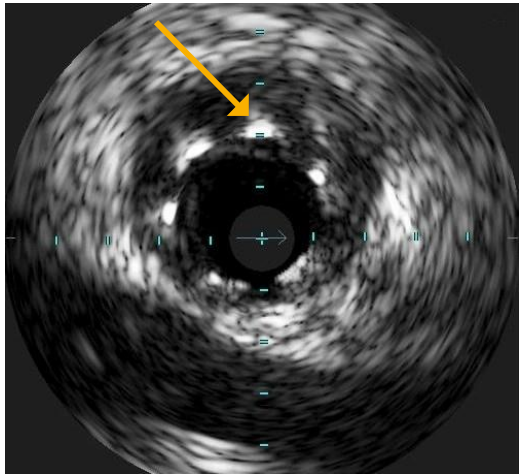
# Post-procedure IVUS

## Malapposed stents

**Stent malapposition (SM):** also referred to as incomplete stent apposition, is defined by the separation of at least one stent strut from the intimal surface of the arterial wall with evidence of blood behind the strut, without involvement of side branches.

This phenomenon, commonly identified by intravascular ultrasound (IVUS) imaging studies, may be detected early, at the time of stent implantation (and classified as acute) or later, at follow-up (therefore classified as late).[1]



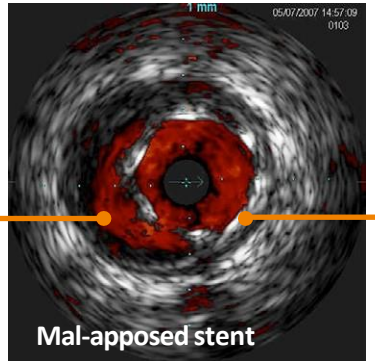


1. Karalis I, Ahmed TAHN, Jukema JW. Late acquired stent malapposition: why, when and how to handle? Heart 2012;98:1529-1536.

# Post-procedure IVUS

## Stent malapposition

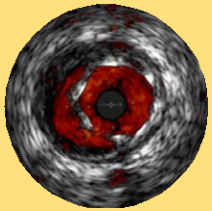
It is possible to see malapposition with grayscale IVUS but ChromaFlo imaging enhances the differential between vessel and stent by highlighting the blood flow red.



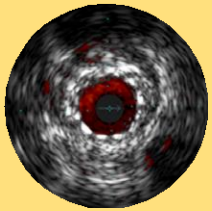

Blood flow behind stent

Stent in contact with vessel wall

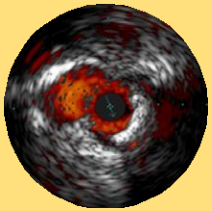
## Use ChromaFlo for easy image interpretation



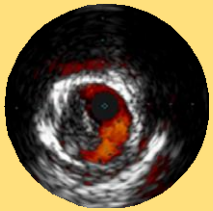
**Mal-apposed stent**



**Well-apposed stent**



**Bifurcation** – absence of plaque in carina can influence provisional stenting strategy

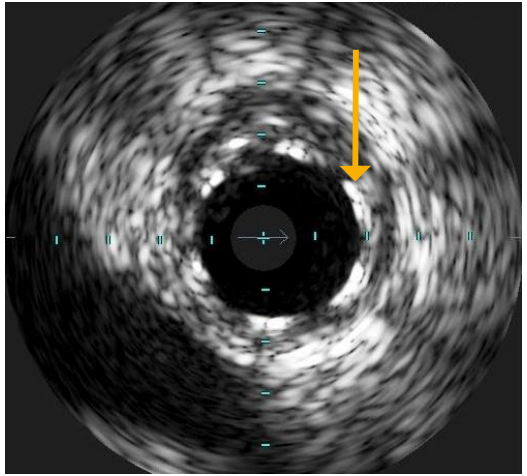


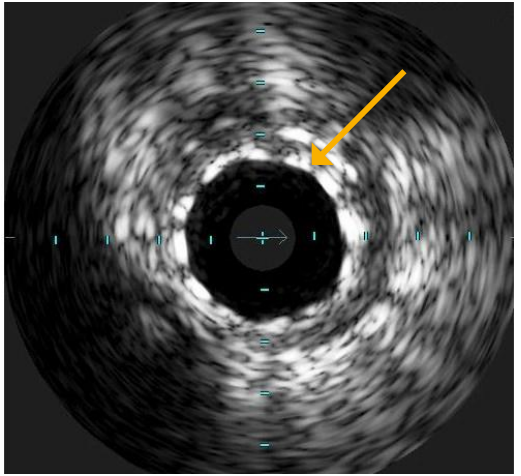
**Thrombus**

# Post-procedure IVUS

## Well apposed stents

Both examples below show the stent well apposed against the vessel wall. No blood flow is observed between the stent struts and the intima.





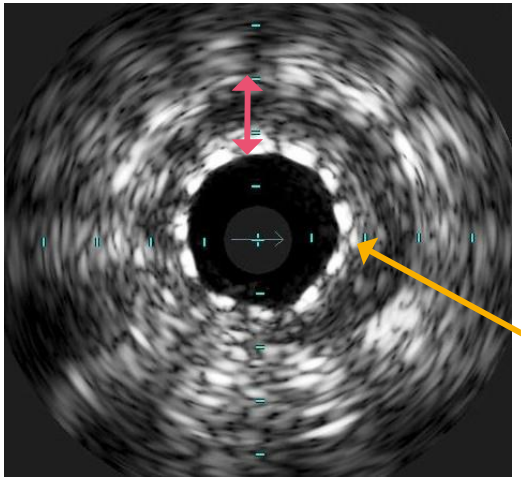
1. Karalis I, Ahmed TAHN, Jukema JW. Late acquired stent malapposition: why, when and how to handle? Heart 2012;98:1529-1536.

# Post-procedure IVUS

**Opposed but undersized/under deployed stent**

An example of a placed stent which appears to be well apposed, no space or blood flow is visible between the stent and the vessel wall but in this image the stent may be slightly undersized or under deployed.

It is only possible to determine if the stent was undersized or under deployed if you have all of the information pertaining to the placed stent.



# Post-procedure IVUS

## Under-expanded stent

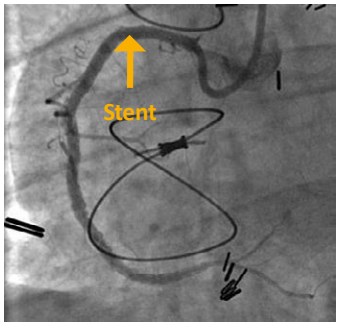
Looking at these two angiograms, it is hard to determine how well the stent inside the vessel has been deployed.

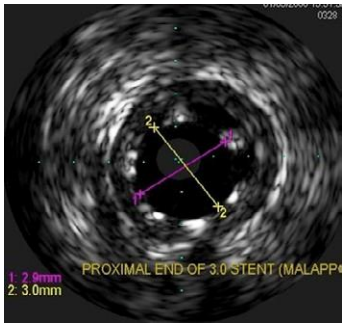
By using IVUS, displayed in the corresponding images, it is now possible to see that the angio on the top has a malapposed, under-expanded stent.

Provided with this information, the physician case went back in, post dilated the stent and ended up with the result you see in the bottom image.

It is extremely likely that if IVUS had not been performed, there is a good chance that the under- expansion of the stent may have been missed.

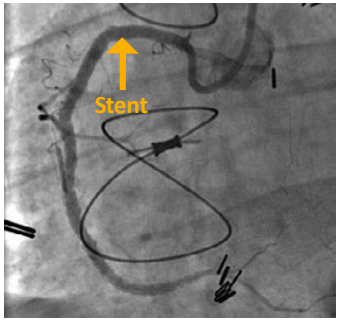
Lumen at proximal stent site with normal appearance

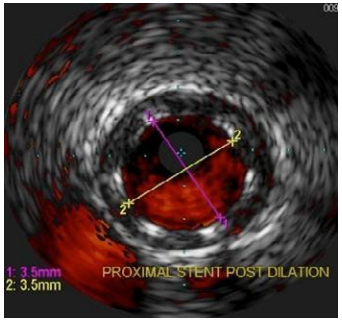




Final angio with optimal expansion




# Our products

# CORE precision guided therapy system

**The choice of imaging and physiology on a single platform**

**CORE integrated & CORE mobile system**

- Choice of multiple imaging and physiology tools on a single platform, only Philips offers digital IVUS and iFR
- Convenience of an integrated or mobile solution
- Intuitive interface for the ultimate in ease of use

# IntraSight

## Interventional applications platform

**Smart. Simple. Seamless.**

As the number of cath lab patients grows, so does the need to work smarter and faster.

Philips IntraSight offers you a comprehensive suite of clinically proven imaging, physiology and co-registration* tools on a modern, secure platform that will help you simplify complex interventions, speed routine procedures and improve lab efficiencies.

These best-in-class interventional tools ultimately allow you to go beyond the angiogram and complete your view of the target vessel so you can make fast, informed clinical decisions.

IntraSight is built on a modern, scalable platform that will be ready to provide you with new innovations and tools as they become available in the future.

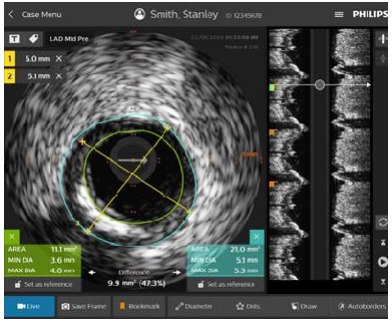
For more information, go to **www.philips.com/IntraSight**

*Co-registration tools available within IntraSight 7 configuration via SyncVision

# Coronary IVUS

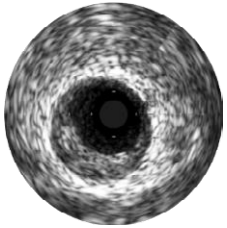
## Intravascular ultrasound

**Rotational IVUS:**
Refinity, Revolution & SpinVision



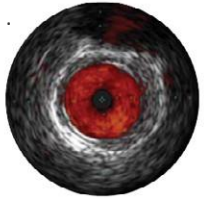

Quick and easy to use measurement, annotation and labelling tools

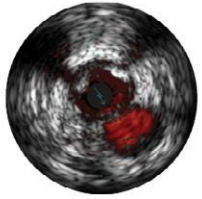
**Digital IVUS:**
Eagle Eye Platinum & Eagle Eye Platinum ST

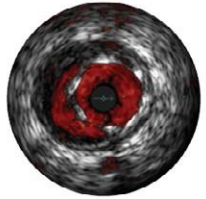


**ChromaFlo imaging:**
Provides clear confirmation of stent apposition and lumen size

.

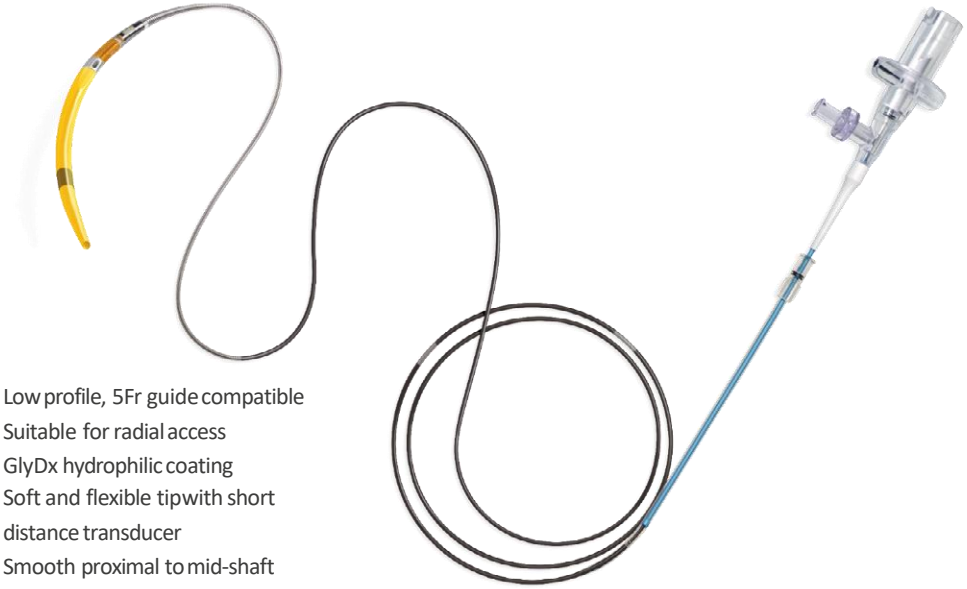






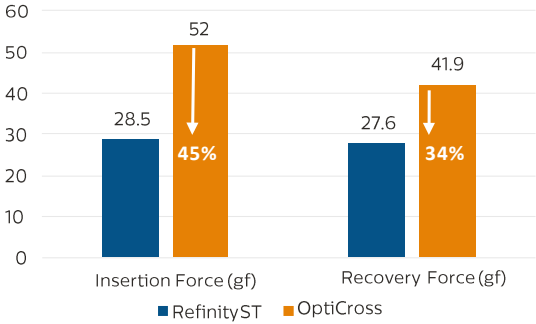
# Refinity

## Our next generation rotational IVUS catheter



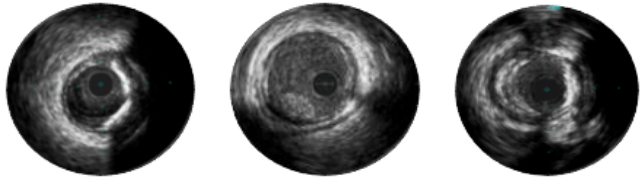
- Low profile, 5Fr guide compatible
- Suitable for radial access
- GlyDx hydrophilic coating
- Soft and flexible tip with short distance transducer
- Smooth proximal to mid-shaft transition

## Exceptional deliverability




Refinity ST insertion and recovery forces are significantly lower ($p<0.001$) than OptiCross*

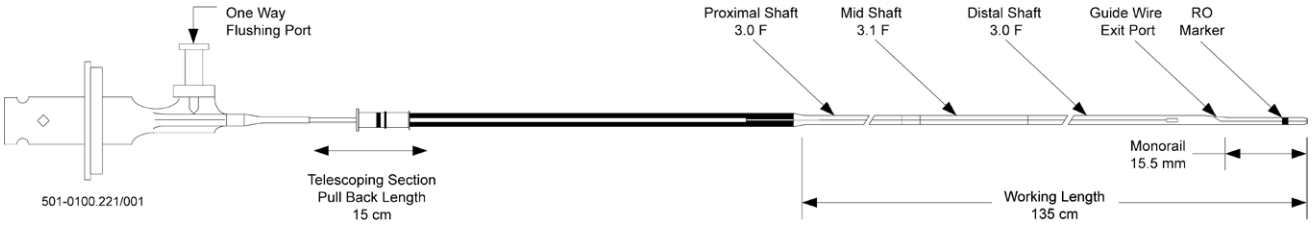
## 45 MHz, high resolution imaging



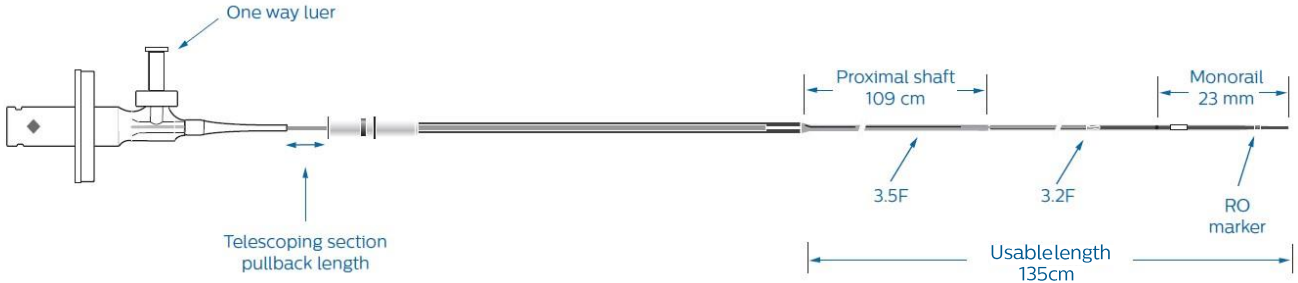
* Data on file at Philips. Bench testing was conducted with three rotational IVUS catheters: Refinity ST, Revolution, OptiCross through a tortuous model

# Refinity & Revolution

## Rotational IVUS catheters




**Refinity**




**Revolution**

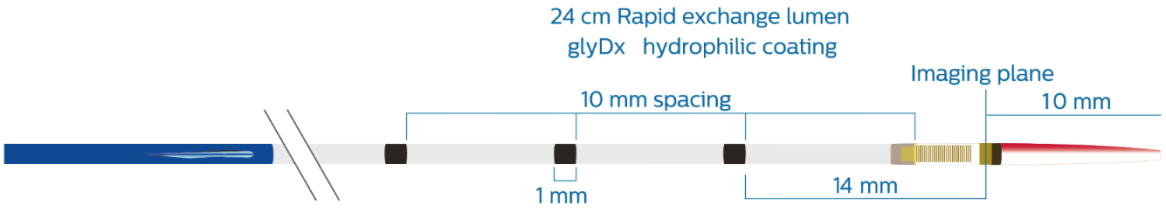
# Eagle Eye Platinum

**Phased-array, digital IVUS catheter**

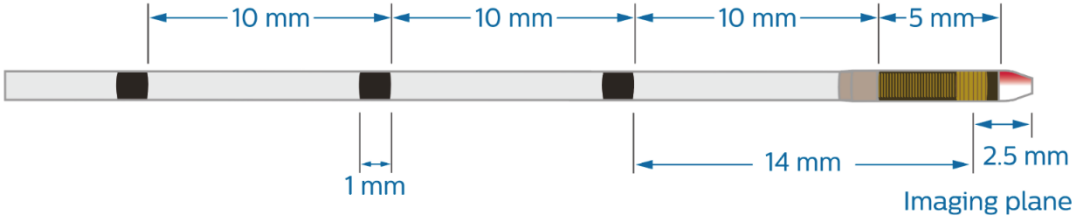
- Fast, plug-and-play simplicity
- Quick, convenient length estimation
- ChromaFlo imaging
- Unique SyncVision IVUS & iFR co-registration compatibility
- Standard & short-tip variations

# Eagle Eye Platinum

**Phased-array, digital IVUS catheter**




**Eagle Eye Platinum**

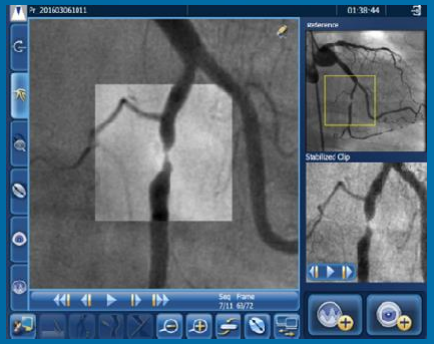



**Eagle Eye Platinum ST**

# SyncVision advanced imaging solution

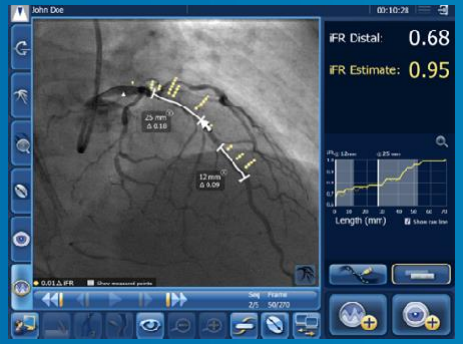
**iFR & IVUS co-registration with angiographic enhancement**

## Advanced angiography: **Angio+**



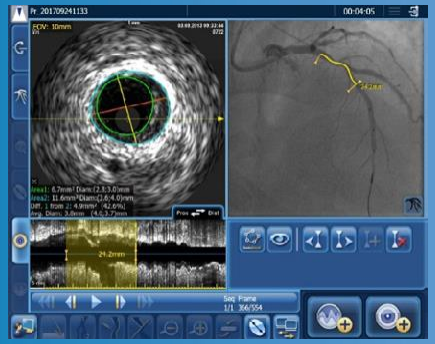
- Vessel enhancement for clarity visualizing vessels
- QCA in real-time
- Device detection (stabilization & enhancement) to enable precise delivery

## Advanced physiologic Imaging: **iFR co-registration**

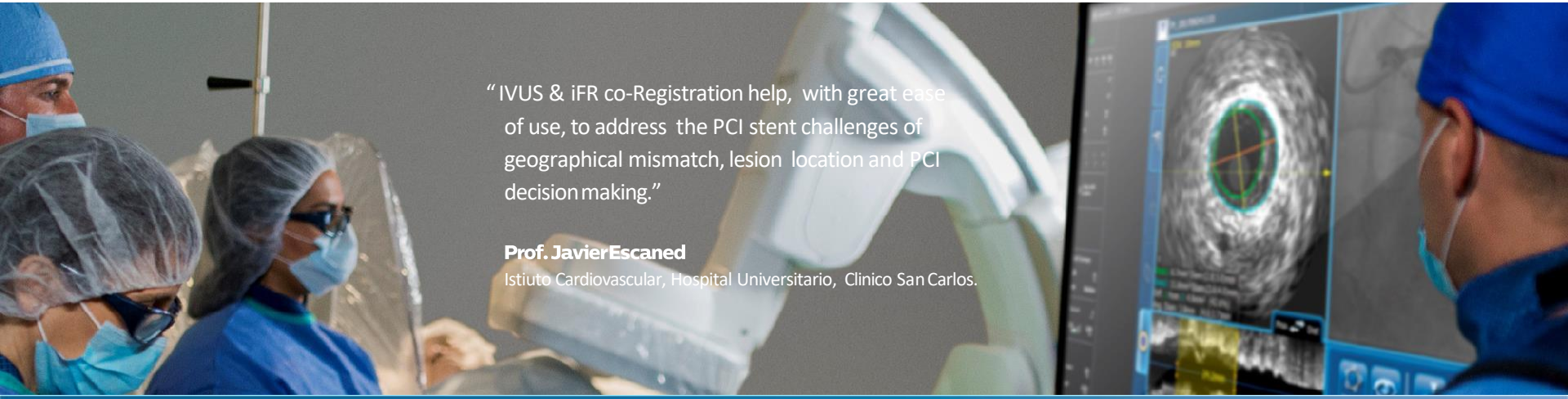



- iFR drop is displayed on angiogram to identify regions of ischemia
- Length measurement without pullback device to size stent
- Estimate post-procedure iFR

## Advanced IVUS imaging: **IVUS co-registration**



- Localization of IVUS with angiography to help avoid geographic miss
- Easy length/area/diameter measurements with manual pullback to size stent



"IVUS & iFR co-Registration help, with great ease of use, to address the PCI stent challenges of geographical mismatch, lesion location and PCI decision making."

**Prof. Javier Escaned**
Istiuto Cardiovascular, Hospital Universitario, Clinico San Carlos.

- Accurate vessel sizing and length measurement without a pullback device
- Localization of IVUS images with angio co- registration is designed to help reduce the risk of geographic miss, which study data suggests may occur in 66.5% of PCIs[1]
- Use with fast, plug and play digital IVUS unique to Philips IGT-D

- Precise lesion severity, location and length assessment
- Visualization of pressure gradients to facilitate stent planning
- Use with FFR or the simplified workflow of hyperemia-free iFR

1. Costa et al. Impact of Stent Deployment Procedural Factors on Long-term Effectiveness and Safety of Sirolimus- Eluting Stents (Final results of the Multicenter Prospective STLLR Trial), Am J Cardiol 2008 Jun 15;101(12):1704-11

# Clinical data

# Guidelines

| ESC/EACTS 2018 guidelines[1] (actual wording) | Class | Level of evidence |
|---|---|---|
| IVUS should be considered to assess the severity of unprotected left main lesions | IIa | B |
| IVUS should be considered to optimize treatment of unprotected left main lesions | IIa | B |
| IVUS or OCT should be considered in selected patients to optimize stent implantation | IIa | B |
| IVUS and/or OCT should be considered to detect stent-related mechanical problems leading to restenosis | IIa | C |
| IVUS or OCT to assess mechanisms of stent failure | IIa | C |

Class IIa: “should be considered”,
Class IIb: “may be considered.”

| ACC/AHA/SCAI 2011 guidelines[2] use IVUS: | Class | Level of evidence |
|---|---|---|
| For the assessment of angiographically indeterminate left main CAD | IIa | B |
| 4 to 6 weeks and 1 year after cardiac transplantation to exclude donor CAD, detect rapidly progressive cardiac allograft vasculopathy, and provide prognostic information | IIa | B |
| To determine the mechanism of stent restenosis | IIa | C |
| For the assessment of non-left main coronary arteries with angiographically intermediate coronary stenoses (50% to 70% diameter stenosis) | IIb | B |
| For guidance of coronary stent implantation, particularly in cases of left main coronary artery stenting | IIb | B |

Class IIa: “is reasonable”,
Class IIb: “may be considered.”

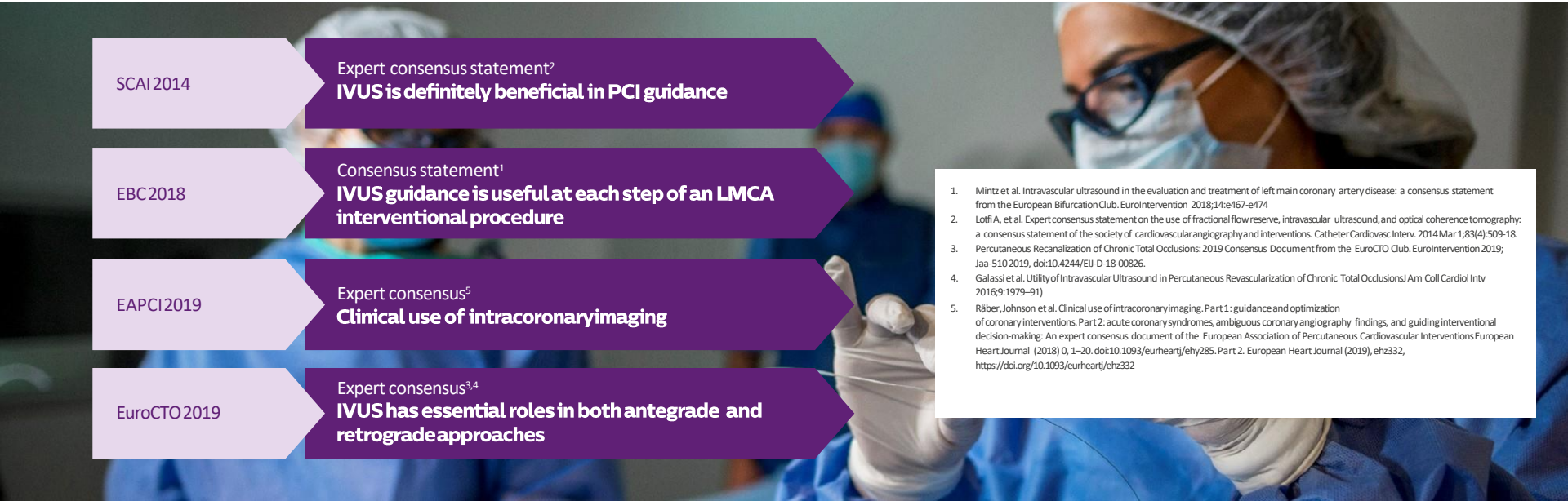
1. Neumann et al. 2018 ESC/EACTS Guidelines on myocardial revascularization. EuroIntervention 2019;14:1435-1534
2. Levine G et al, 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention. Circulation 2011;124:e574–e651..

# Consensus statements

**Society statements advocating the use of IVUS**

"For determining optimal stent deployment (complete stent expansion and apposition and lack of edge dissection or other complications after implantation)."

"For determining the size of the vessel undergoing stent implantation"



| | |
|---|---|
| SCAI 2014 | Expert consensus statement[2] **IVUS is definitely beneficial in PCI guidance** |
| EBC 2018 | Consensus statement[1] **IVUS guidance is useful at each step of an LMCA interventional procedure** |
| EAPCI 2019 | Expert consensus[5] **Clinical use of intracoronary imaging** |
| EuroCTO 2019 | Expert consensus[3,4] **IVUS has essential roles in both antegrade and retrograde approaches** |

1. Mintz et al. Intravascular ultrasound in the evaluation and treatment of left main coronary artery disease: a consensus statement from the European Bifurcation Club. EuroIntervention 2018;14:e467-e474
2. Lotfi A, et al. Expert consensus statement on the use of fractional flow reserve, intravascular ultrasound, and optical coherence tomography: a consensus statement of the society of cardiovascular angiography and interventions. Catheter Cardiovasc Interv. 2014 Mar 1;83(4):509-18.
3. Percutaneous Recanalization of Chronic Total Occlusions: 2019 Consensus Document from the EuroCTO Club. EuroIntervention 2019; Jaa-510 2019, doi:10.4244/EIJ-D-18-00826.
4. Galassi et al. Utility of Intravascular Ultrasound in Percutaneous Revascularization of Chronic Total Occlusions J Am Coll Cardiol Intv 2016;9:1979–91)
5. Räber, Johnson et al. Clinical use of intracoronary imaging. Part 1: guidance and optimization of coronary interventions. Part 2: acute coronary syndromes, ambiguous coronary angiography findings, and guiding interventional decision-making: An expert consensus document of the European Association of Percutaneous Cardiovascular Interventions European Heart Journal (2018) 0, 1–20. doi:10.1093/eurheartj/ehy285. Part 2. European Heart Journal (2019), ehz332, https://doi.org/10.1093/eurheartj/ehz332

# A preponderance of evidence shows

**IVUS benefits patients**

Level of evidence (Highest)

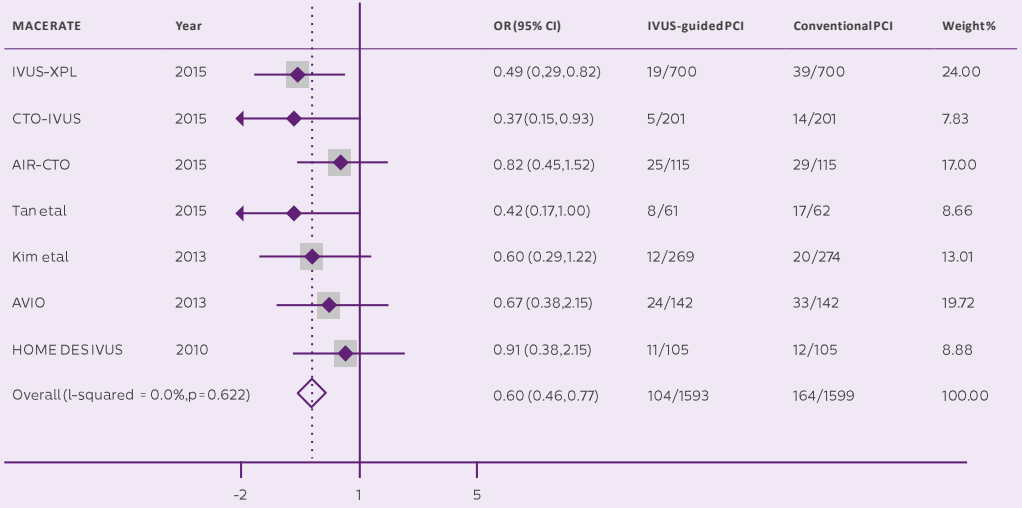
| | | |
|---|---|---|
| Meta-analyses of RCT | Reported evidence showing that IVUS-guidance has a significant impact on hard clinical endpoints even using new generation DES and in high risk coronary anatomy. | 1. Elgendy et al. 2016<br>2. Shin et al. 2016 |
| Large randomized control trials | Significantly lower rate of MACE with IVUS-guided PCI driven by a reduction in TLR. | 3. IVUS-XPL, Hong et al. 2015<br>4. ULTIMATE, Zhang J et al. 2018 |
| Large meta-analysis | IVUS-guided PCI with drug-eluting stents, was associated with a significant reduction in hard endpoints; ST, MI, all cause of death or cardiac death. | 5. Ahn et al. 2014 |
| Observational studies | • Significantly reduced stent thrombosis, MI and cardiac death with IVUS-guided PCI.<br>• Use of IVUS led to a change in PCI strategy in 74% of cases.<br>• IVUS guidance has the greatest beneficial impact in complex lesion subsets. | 6. ADAPT-DES, Witzenbichler B et al. 2014<br>7. DEFINITION registry, Chen et al. 2017<br>8. SCAAR LM registry, Andell et al. 2017<br>9. ADAPT-DES 2-yr follow-up. Maehara et al. 2018. |

# Meta-analyses of RCT

# Elgendy meta-analysis

**IVUS guided DES-implantation was associated with a significant reduction of MACE, cardiovascular mortality and stent thrombosis**

- Includes 7 RCTs
- 3,192 patients
- Including only DES patients




At a mean of 15 months, routine IVUS-guided PCI was associated with a significant reduction in:

**37% of MACE**
(6.5% versus 10.3%; OR, 0.60; 95% CI, 0.46–0.77; P<0.0001)

**38% of ischemia-driven target lesion revascularization**
(4.1% versus 6.6%; OR, 0.60; 95% CI, 0.43–0.84; P=0.003)

**58% of cardiovascular mortality**
(0.5% versus 1.2%; OR, 0.46; 95% CI, 0.21–1.00; P=0.05)

**54% of stent thrombosis**
(0.6% versus 1.3%; OR, 0.49; 95% CI, 0.24–0.99; P=0.04)

Elgendy I.Y, Mahmoud A.N, Elgendy A.Y, et al. Outcomes With Intravascular Ultrasound- Guided Stent Implantation. A Meta-Analysis of Randomized Trials in the Era of Drug- Eluting Stents. J Am Coll Cardiol, 2016;68:569-70.

# Shin meta-analysis

**IVUS guided DES-implantation was associated with a significant reduction of MACE**

- Meta-analysis with individual patient–level data
- 3 RCTs including high risk coronary anatomy (long lesions or CTO)
- 2,345 randomized patients, all were treated for long lesions or chronic total occlusions (CTO)
- Including only new generation of DES
- Notably, in the present study, the primary endpoint did not include TLR
- IVUS-guided new-generation DES implantation in longlesions and CTO was associated with favourable outcomes forMACE
- MACE was defined as a composite of cardiac death, myocardial infarction, or stent thrombosis

# Shin meta-analysis

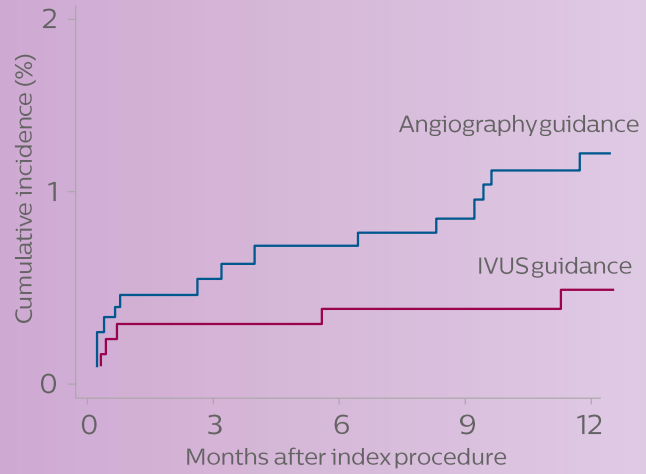
**IVUS guided DES-implantation was associated with a significant reduction of MACE**

**At 1 year**

Major adverse cardiac events had occurred in 0.4% of the patients who underwent IVUS-guided DES implantation versus 1.2% of those who underwent angiography-guided DES implantation.

(Hazard ratio [HR]: 0.36; 95% confidence interval [CI]: 0.13 to 0.99; p = 0.040)

**MACE by intention-to treat analysis**
Hazard ratio: 0.36 (95% CI: 0.13-0.99)
Log Rank: P = 0.040




Shin et al. Effects of Intravascular Ultrasound–Guided Versus Angiography-Guided New- Generation Drug-Eluting Stent Implantation. Meta-Analysis With Individual Patient–Level Data From 2,345 Randomized Patients. J Am Coll Cardiol Intv 2016;9:2232–9.

# Large randomized control trials

# IVUS-XPL

## IVUS–guided vs angiography-guided everolimus-eluting stent implantation

- Randomized control trial (RCT)
- 1400 patients treated with EES stent ε 28 mm

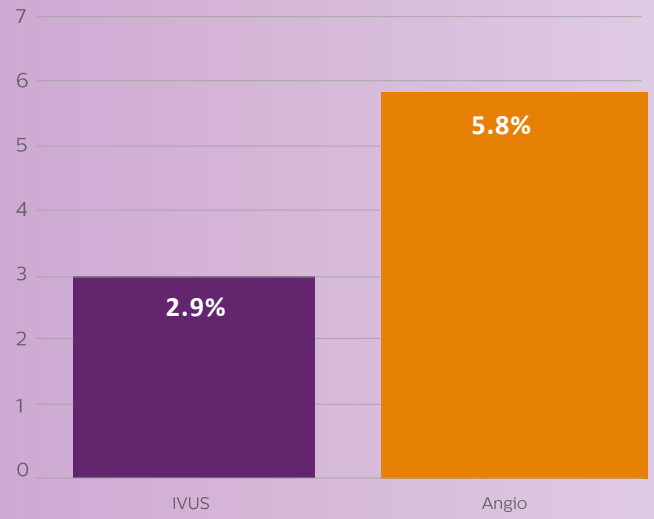
**At 1 year**

IVUS-guided group had a 52% reduced risk of MACE compared with the angiography-guided group.

**(2.9% vs 5.8%, (hazard ratio [HR], 0.48 [95% CI, 0.28 to 0.83]; P = .007).**

These differences were primarily due to lower risk of target lesion revascularization.

**All population MACE%**




Hong et al. Effect of Intravascular Ultrasound–Guided vs Angiography-Guided Everolimus-Eluting Stent Implantation. The IVUS-XPL Randomized Clinical Trial - JAMA 2015;314:2155-63

# IVUS-XPL

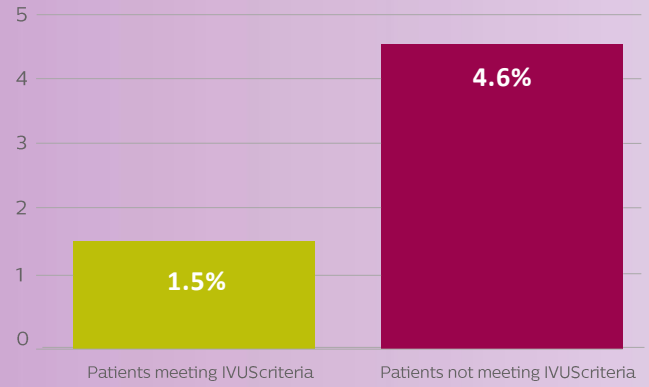
## IVUS–guided vs angiography-guided everolimus-eluting stent implantation

**Imaging standardization with IVUS defined criteria for optimum stent deployment:**

**MSA > minimum lumen at distal**

Patients who did not meet IVUS criteria for optimum stent deployment had a significantly higher incidence of MACE compared with those who met IVUS criteria **(4.6% vs 1.5%, p = 0.020)**

**MACE rate in IVUS-guided group only**




Hong et al. Effect of Intravascular Ultrasound–Guided vs Angiography-Guided Everolimus-Eluting Stent Implantation. The IVUS-XPL Randomized Clinical Trial - JAMA 2015;314:2155-63

# IVUS-XPL: 5 year follow up

**Compared with angiography-guided stent implantation, IVUS-guided stent implantation resulted in a significantly lower rate of major adverse cardiac events up to 5 years**

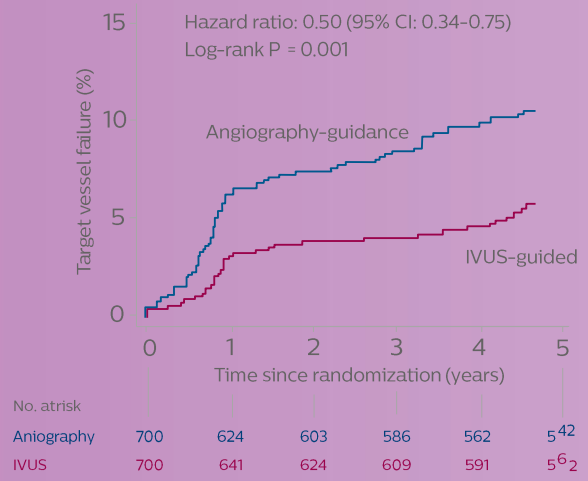
| | IVUS-guidance (n=700) | Angiography-guidace (n=700) | Hazard ratio (95% CI) | Log-rank *P* value |
|---|---|---|---|---|
| **Primary end point** | | | | |
| MACE | 36 (5.6%) | 70 (10.7%) | 0.50 (0.34–0.75) | 0.001 |
| **Secondary end point** | | | | |
| Cardicac death | 6 (0.9%) | 14 (2.2%) | 0.43 (0.17–1.12) | 0.074 |
| Target lesion related MI | 4 (0.6%) | 6 (0.9%) | 0.67 (0.19–2.36) | 0.525 |
| Ischemia-driven TLR | 31 (4.8%) | 55 (8.4%) | 0.54 (0.33–0.89) | 0.007 |
| Stent Thrombosis | 2 (0.3%) | 2 (0.3%) | 1.00 (0.14–7.10) | 1.000 |
| Acute | 1 (0.1%) | 1 (0.1%) | | |
| Sub-acute | 1 (0.1%) | 0 | | |
| Late | 0 | 1 (0.1%) | | |

Myeong-Ki Hong, MD. PhD on behalf of the IVUS-XPL trial investigators,, "IVUS-XPL: Five-Year Outcomes From a Randomized Trial of Intravascular Ultrasound-Guided vs Angiography-Guided PCI of Long Coronary Lesions", TCT 2019. Moscone Center, San Francisco, CA. 29 September 2019.

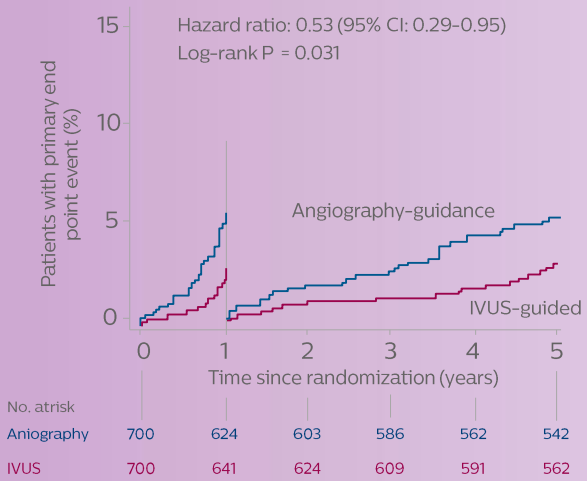
# IVUS-XPL: 5 year follow up

**Sustained 5-year clinical benefits resulted from both within 1 year and from 1 to 5 years post-implantation even in the current DES implantation era**

## At 5 years




## Between 1 and 5 years



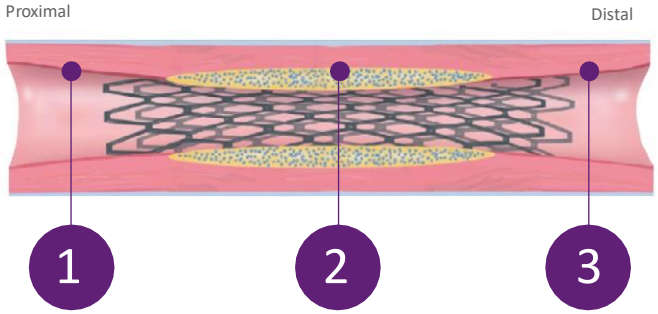

Myeong-Ki Hong, MD. PhD on behalf of the IVUS-XPL trial investigators,, "IVUS-XPL: Five-Year Outcomes From a Randomized Trial of Intravascular Ultrasound-Guided vs Angiography-Guided PCI of Long Coronary Lesions", TCT 2019. Moscone Center, San Francisco, CA. 29September 2019.

# ULTIMATE trial

**Intravascular ultrasound-guided versus angiography-guided implantation of drug-eluting stent in all-comers**

- 8 sites, randomized prospective trial, IVUS or angiography guided PCI in China
- 1,448 all comer patients
- In both arms, all lesions were post dilated with non-compliant balloon inflated at >18 atm

**Imaging standardization with 3 IVUS defined criteria, pre & post PCI**




Plaque burden at the 5-mm proximal or distal to the stent edge <50%.

Expansion satisfactory - minimal lumen CSA in stented segment >5mm², or 90% of distal reference lumen CSA.

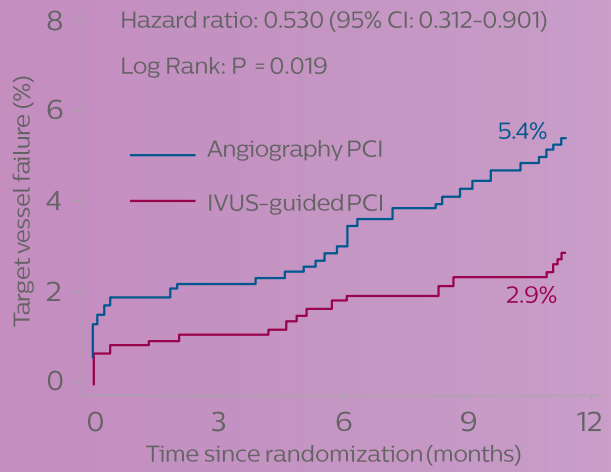
No edge dissection involving media with length >3mm.

Zhang J et al. The ULTIMATE trial. Intravascular Ultrasound-Guided Versus Angiography-Guided Implantation of Drug-Eluting Stent in All-Comers. Journal of the American College of Cardiology (2018) Dec 18;72(24):3126-3137, doi. org/10.1016/j.

# ULTIMATE trial

**Intravascular ultrasound-guided versus angiography-guided implantation of drug-eluting stent in all-comers**

**Primary endpoint based on patient-level comparison**




**47%**

**reduced risk of TVF* at one year using IVUS-guided PCI.**

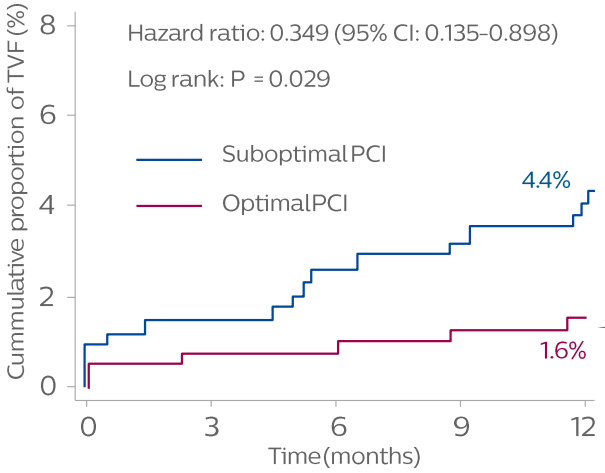
*(cardiac death, target vessel MI and clinically driven TVR)

Zhang J et al. The ULTIMATE trial. Intravascular Ultrasound-Guided Versus Angiography-Guided Implantation of Drug-Eluting Stent in All-Comers. Journal of the American College of Cardiology (2018) Dec 18;72(24):3126-3137, doi. org/10.1016/j.

# ULTIMATE trial

**Intravascular ultrasound-guided versus angiography-guided implantation of drug-eluting stent in all-comers**

**Primary endpoint for patients who met/didn't meet IVUS criteria**




**Where optimal IVUS criteria was achieved, patients had the lowest event rates**

Only 1.6% TVF at 12 months when optimal IVUS - guided PCI criteria was met in all comer patients

Zhang J et al. The ULTIMATE trial. Intravascular Ultrasound-Guided Versus Angiography-Guided Implantation of Drug-Eluting Stent in All-Comers. Journal of the American College of Cardiology (2018) Dec 18;72(24):3126-3137, doi. org/10.1016/j.

New slide

# ULTIMATE trial: 3 year follow up

**IVUS guidance associated with a lower risk for 3-year TVF and definite/probable ST**

| | 1Y Follow up | | | | 2Y Follow up | | | | 3Y Follow up | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | IVUS Guidance (n ¼ 724) | Angiographic Guidance (n ¼ 724) | Hazard Ratio (95% CI) | p Value | IVUS Guidance (n ¼ 724) | Angiographic Guidance (n ¼ 724) | Hazard Ratio (95% CI) | p Value | IVUS Guidance (n ¼ 724) | Angiographic Guidance (n ¼ 724) | Hazard Ratio (95% CI) | p Value |
| Number of patients | 722 | 722 | | | 718 | 719 | | | 714 | 709 | | |
| Target vessel failure | 21 (2.9) | 39 (5.4) | 0.53 (0.31–0.90) | 0,02 | 43 (6.0) | 65 (9.0) | 0.65 (0.44–0.95) | 0,03 | 47 (6.6) | 76 (10.7) | 0.60 (0.42–0.87) | 0,01 |
| Cardiac death | 5 (0.7) | 10 (1.4) | 0.50 (0.17–1.45) | 0,19 | 9 (1.3) | 16 (2.2) | 0.56 (0.25–1.26) | 0,16 | 13 (1.8) | 19 (2.7) | 0.68 (0.34–1.38) | 0,28 |
| Target vessel MI | 7 (1.0) | 11 (1.5) | 0.63 (0.25–1.64) | 0,34 | 7 (1.0) | 14 (1.9) | 0.50 (0.20–1.23) | 0,12 | 7 (1.0) | 15 (2.1) | 0.46 (0.19–1.14) | 0,09 |
| Clinically driven TVR | 11 (1.5) | 21 (2.9) | 0.51 (0.25–1.07) | 0,07 | 31 (4.3) | 42 (5.8) | 0.72 (0.45–1.15) | 0,17 | 32 (4.5) | 49 (6.9) | 0.64 (0.41–1.00) | 0,05 |
| All-cause death | 10 (1.4) | 17 (2.3) | 0.58 (0.27–1.28) | 0,17 | 24 (3.3) | 27 (3.8) | 0.88 (0.51–1.53) | 0,65 | 31 (4.3) | 31 (4.4) | 0.99 (0.60–1.63) | 0,98 |
| Clinically driven TLR | 9 (1.2) | 19 (2.6) | 0.47 (0.21–1.03) | 0,05 | 26 (3.6) | 40 (5.6) | 0.63 (0.39–1.04) | 0,07 | 27 (3.8) | 45 (6.3) | 0.59 (0.36–0.94) | 0,03 |
| Target lesion failure | 20 (2.8) | 37 (5.1) | 0.53 (0.31–0.92) | 0,02 | 38 (5.3) | 63 (8.8) | 0.59 (0.39–0.88) | 0,01 | 42 (5.9) | 72 (10.2) | 0.57 (0.39–0.83) | 0,003 |
| Definite/probable ST | 1 (0.1) | 5 (0.7) | 0.20 (0.02–1.70) | 0,1 | 1 (0.1) | 7 (1.0) | 0.14 (0.02–1.15) | 0,03 | 1 (0.1) | 8 (1.1) | 0.12 (0.02–0.99) | 0,02 |

Xiao-Fei Gao, '3-Year Outcomes of the ULTIMATE Trial Comparing Intravascular Ultrasound Versus Angiography-Guided Drug-Eluting Stent Implantation', JACC: CARDIOVASCULAR INTERVENTIONS, VOL. 1 4, NO. 3, 2021

# ULTIMATE trial: 3 year follow up

**IVUS guidance associated with a lower risk for 3-year TVF**

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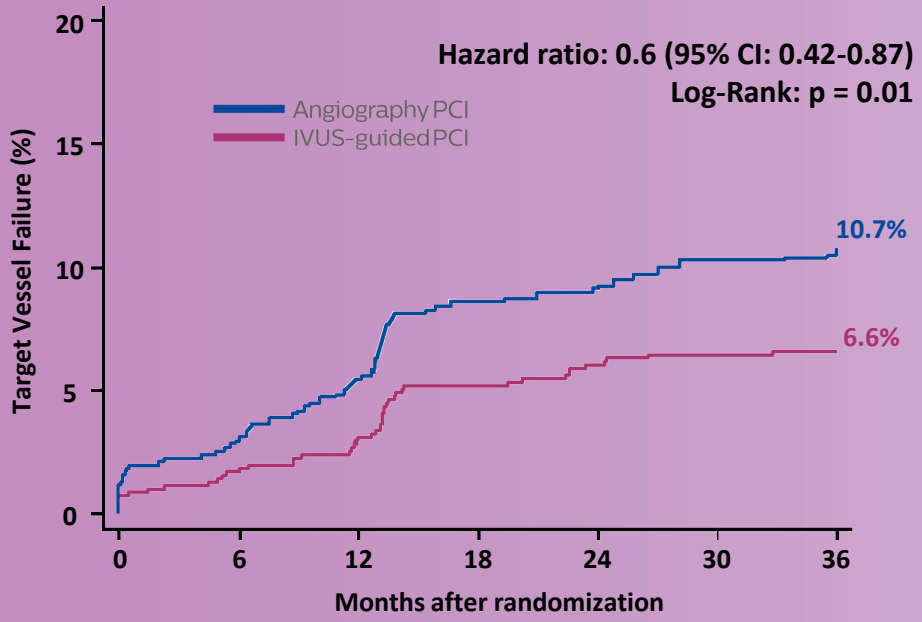
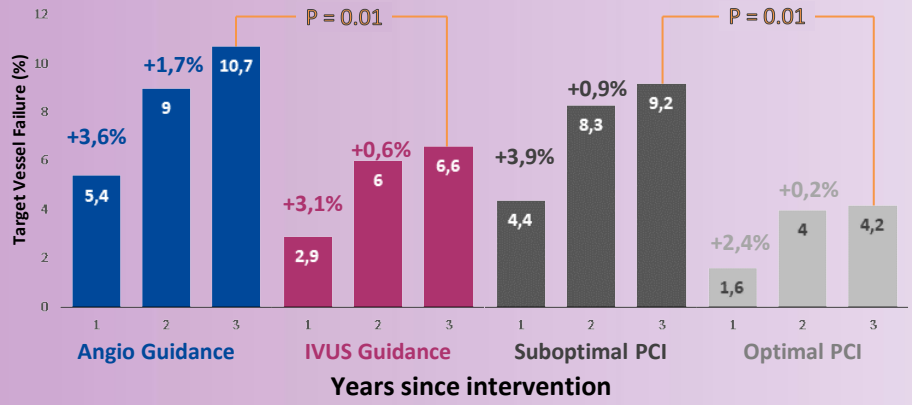



**IVUS guidance associated with a lower risk for 3-year TVF, particularly for patients with IVUS-defined optimal procedures, relative to angiographic guidance among all comers undergoing second generation DES implantation.**




Xiao-Fei Gao, '3-Year Outcomes of the ULTIMATE Trial Comparing Intravascular Ultrasound Versus Angiography-Guided Drug-Eluting Stent Implantation', JACC: CARDIOVASCULAR INTERVENTIONS, VOL. 1 4, NO. 3, 2021

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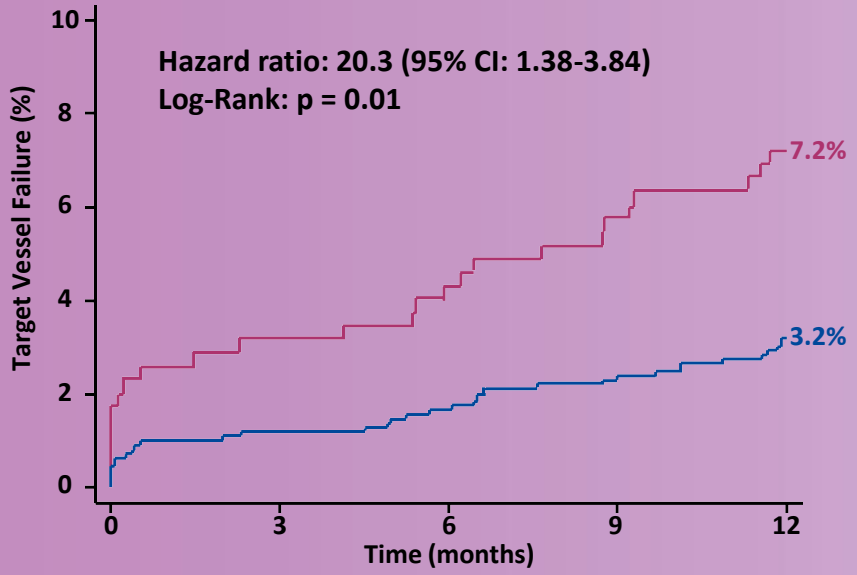
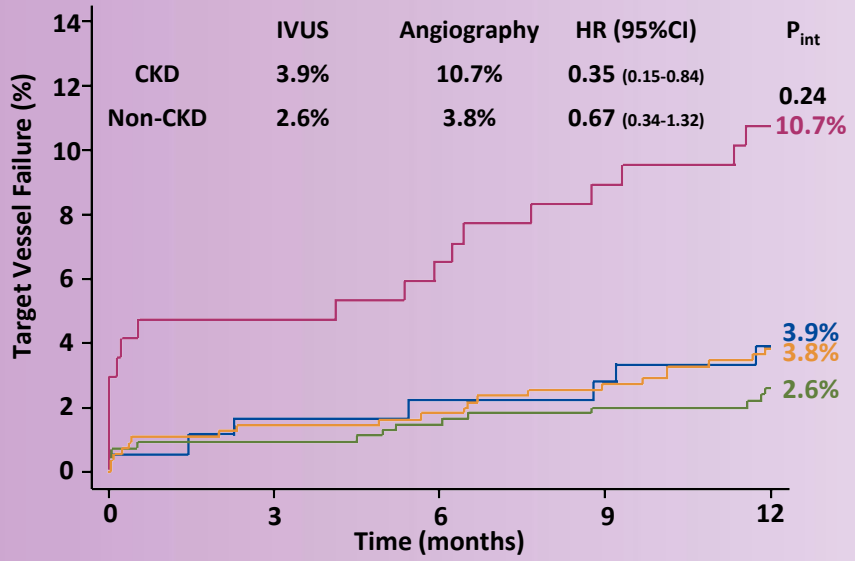
# ULTIMATE CKD:

**CKD patients** undergoing DES implantation associated with a higher risk of TVF at 12 months: the risk of TVF in the CKD patients can be sig...ntly decreased through IVUS guidance.**

**CKD -defined as an estimated glomerular filtration rate (eGFR) <60 mL $min^{-1}$ 1.73 $m^{-2}$- was available in 1,443 patients, of whom 723 were in the IVUS guidance group, and 720 were in the angiography guidance group: CKD was present in 349 (24.2%) patients.




Junjie Zhang, 'Impact of intravascular ultrasound-guided drug-eluting stent implantation on patients with chronic kidney disease: Results from ULTIMATE trial', Catheter Cardiovasc Interv. 2019;93:1184–1193

# Large meta-analysis

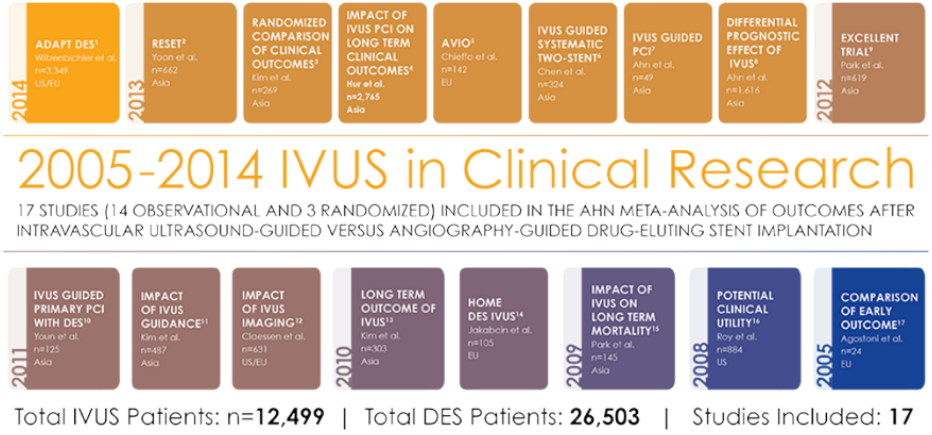
# Ahn meta-analysis

**IVUS-guided PCI was associated with a significant reduction in hard endpoints; MACE & MI**

- Included 17 studies covering 26,503 patients
- 12,499 patients had PCI with IVUS guidance
- Comprehensive analysis reflecting DES studies over a decade

IVUS guided DES-implantation was associated with a significant reduction of hard endpoints:

**25% reduction of MACE**
**43% reduction of MI**



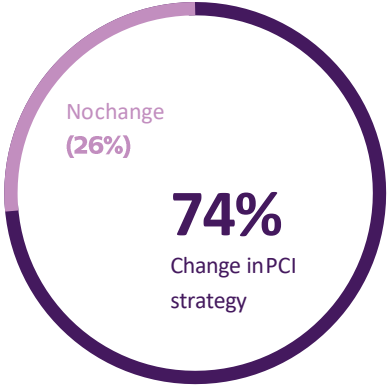

Ahn JM, Kang SJ, Yoon SH, et al. "Meta-Analysis of Outcomes After Intravascular Ultrasound - Guided Versus Angiography-Guided Drug-Eluting Stent Implantation in 26,503 Patients Enrolled in Three Randomized Trials and 14 Observational Studies" J Am Cardiol. 2014;113:1338-1347.

# Large observational studies

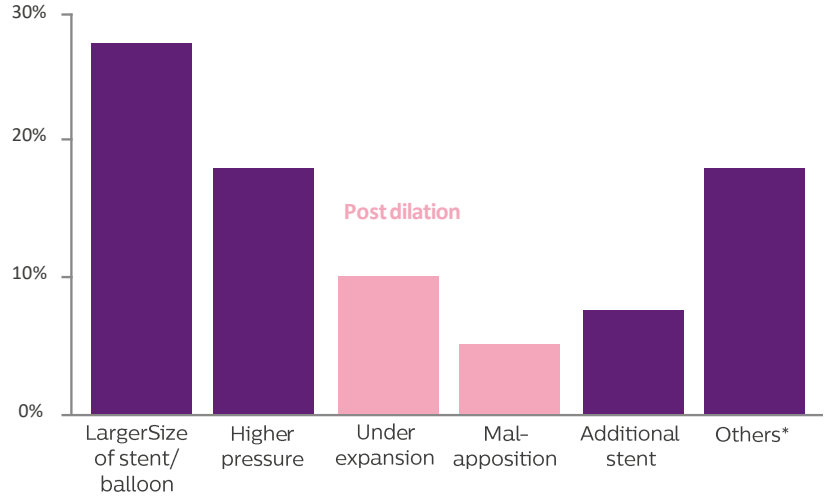
# ADAPT-DES

## Assessment of dual anti-platelet therapy with drug-eluting stents

- Largest study ever conducted with IVUS guidance
- Multi-center global registry with 8583 consecutive patients
- 3349 patients had PCI with IVUS guidance
- 64% Xience / Promus stents




**Investigators were asked if and how IVUS changed their procedure?**



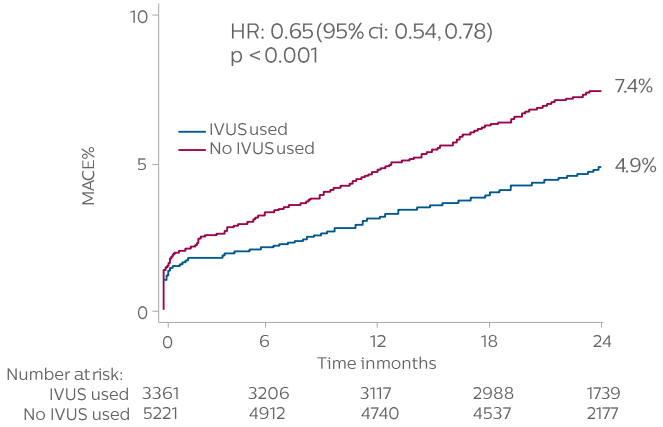

*"Others" category may include a combination of "Higher Pressure", "Under Expansion", "Malapposition", and "Additional Stent".

1. Witzenbichler B et al. Relationship Between Intravascular Ultrasound Guidance and Clinical Outcomes After Drug-Eluting Stents: The ADAPT-DES Study. Circulation 2014 Jan: 129,4;463-470.
2. Maehara et al. Relationship Between Intravascular Ultrasound Guidance and Clinical Outcomes After Drug-Eluting Stents: Two-Year Follow-Up of the ADAPT-DES Study. Circ Cardiovasc Interv. 2018;11:e006243. DOI: 10.1161/CIRCINTERVENTIONS.117.006243.

# ADAPT-DES

**IVUS guided PCI was associated with a significant reduction of cardiac death, and ST in addition to MI and MACE**

Relationship between IVUS use and MACE
(definite/probable ST, cardiac death, MI) within 2 years




# 35%

## reduction in MACE at 2 years

## (4.9% vs. 7.4%, p<0.001)

Data suggests the benefit of IVUS guidance increases from 1 to 2 years.

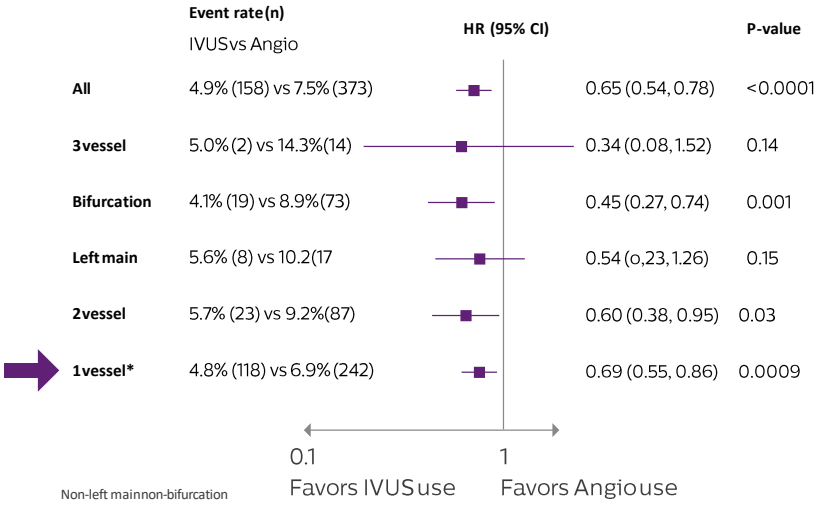
Maehara et al. Relationship Between Intravascular Ultrasound Guidance and Clinical Outcomes After Drug-Eluting Stents: Two-Year Follow-Up of the ADAPT-DES Study. Circ Cardiovasc Interv. 2018;11:e006243. DOI: 10.1161/CIRCINTERVENTIONS.117.006243.

# ADAPT-DES

**IVUS guidance was beneficial in complex and standard* PCI.**

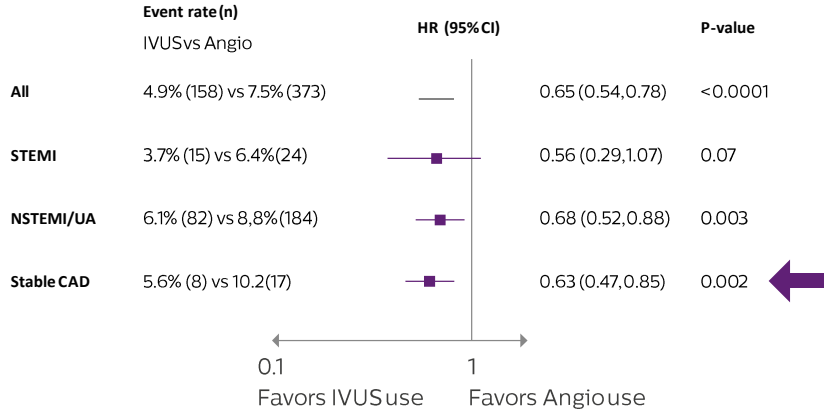
*Single vessel, non-left main bifurcation & stable CAD

## Association of IVUS use with MACE (definite/probable ST, cardiac death, MI) in relation to lesion complexity




Non-left main non-bifurcation

## Association of IVUS use with MACE (definite/probable ST, cardiac death, MI) in relation to index presentation

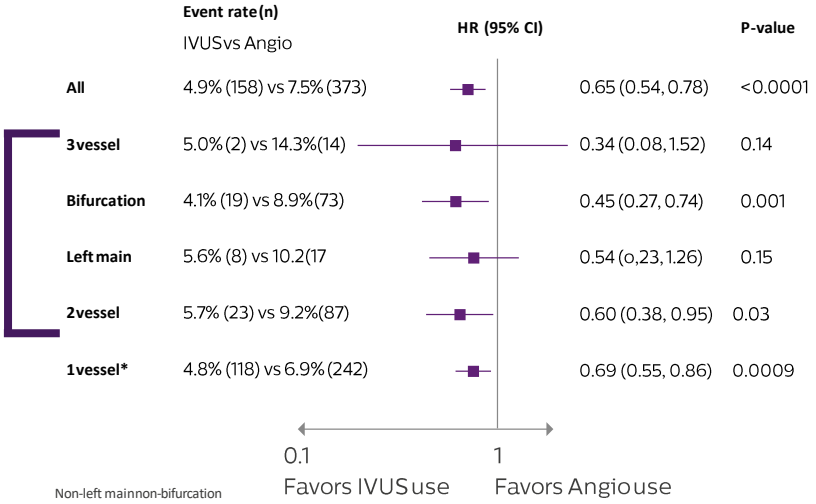



Witzenbichler, Bernhard. "Does IVUS Reduce Stent Thrombosis with DES? Two-year results from the prospective, multicenter ADAPT-DES study." TCT 2013. Moscone Center, San Francisco, CA. 29 October 2013.

# ADAPT-DES

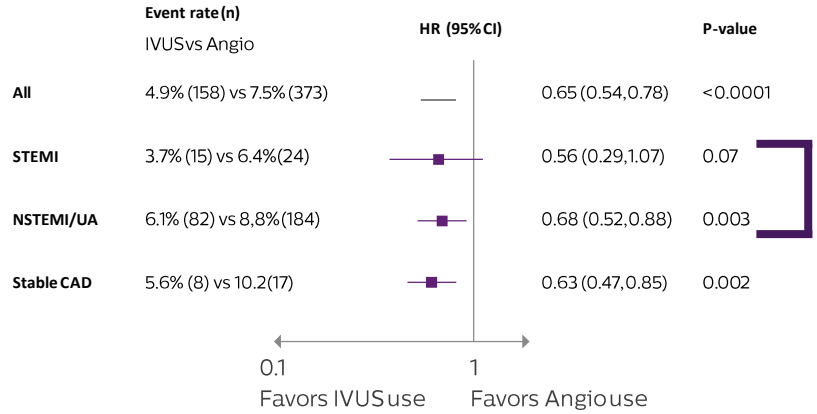
**IVUS guidance was of greatest benefit in complex PCI; multi-vessel, bifurcation, left main and unstable angina patients**

## Association of IVUS use with MACE (definite/probable ST, cardiac death, MI) in relation to lesion complexity




Non-left main non-bifurcation

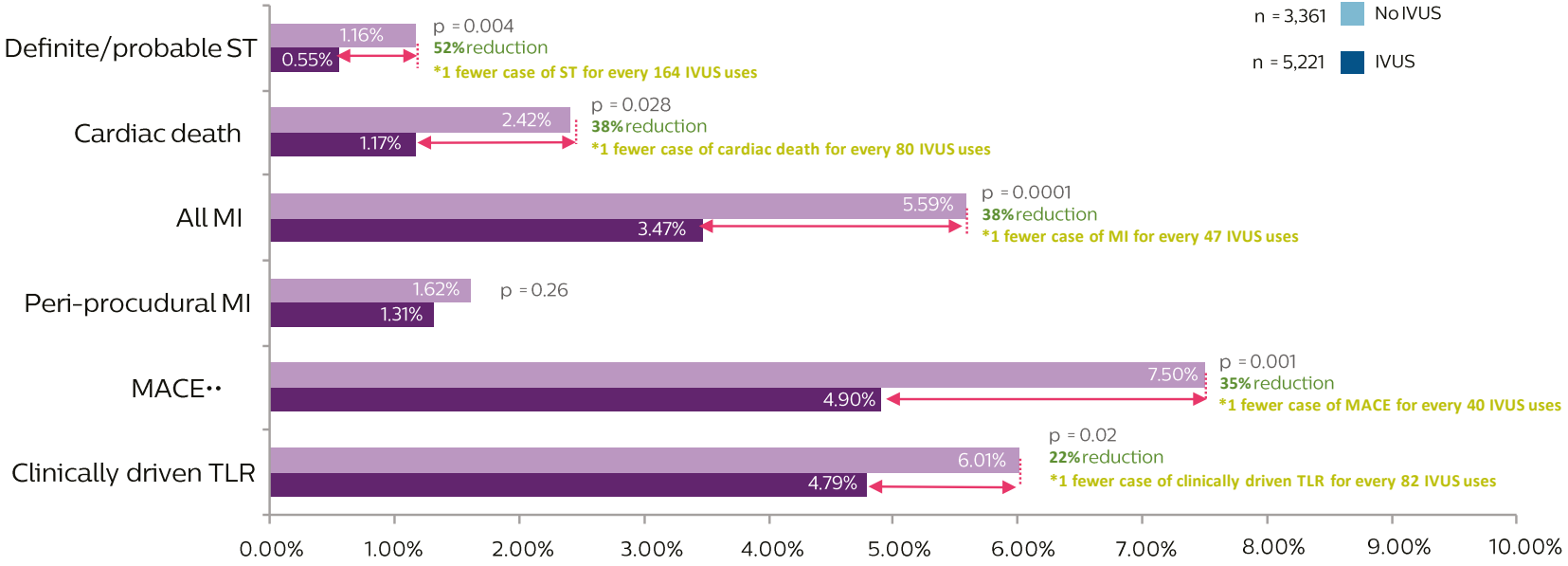
## Association of IVUS use with MACE (definite/probable ST, cardiac death, MI) in relation to index presentation




Witzenbichler, Bernhard. "Does IVUS Reduce Stent Thrombosis with DES? Two-year results from the prospective, multicenter ADAPT-DES study." TCT 2013. Moscone Center, San Francisco, CA. 29 October 2013.

# ADAPT-DES IVUS sub study

**IVUS guidance reduces cardiac death, and ST in addition to MI and MACE within 2 years after DES implantation**




*These calculations have been completed by Volcano and source data from Dr. Witzenbichler's 2013 TCT presentation[1].

**MACE defined as definite/probable ST, cardiac death, and MI.

Witzenbichler, Bernhard. "Does IVUS Reduce Stent Thrombosis with DES? Two-year results from the prospective, multicenter ADAPT-DES study." TCT 2013. Moscone Center, San Francisco, CA. 29 October 2013.

# DEFINITION registry

**IVUS-guided drug-eluting stent implantation is associated with improved clinical outcomes in patients with unstable angina and complex coronary artery true bifurcation lesions**

- Prospective, multi-center registry
- 1465 patients with unstable angina and Medina 1,1,1 & 0,1,1 coronary bifurcation
- Clinical follow up period of up to 7 years
- Importance to reach standardized IVUS criteria to obtain optimal clinical benefit.

**Standardized IVUS criteria:**

Stent symmetry index > 70% Stent expansion > 90%

No malapposition,

No Type B-C dissection

No impairment of blood flow

Patients without optimal IVUS-guided stent expansion had worse outcome than those with optimal IVUS-guided results.

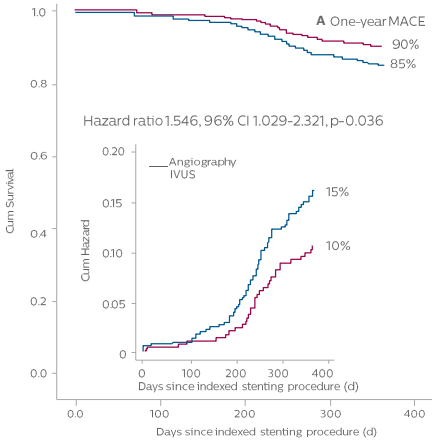
**MACE 16.9% vs 8.6% (p=0.029)**

Chen et al. DEFINITION registry. Intravascular ultrasound-guided drug-eluting stent implantation is associated with improved clinical outcomes in patients with unstable angina and complex coronary artery true bifurcation lesions. The International Journal of Cardiovascular Imaging (2018) 34:1685–1696.

# DEFINITION registry

**Reported evidence showing that IVUS benefits patients with complex coronary artery true bifurcation lesions**

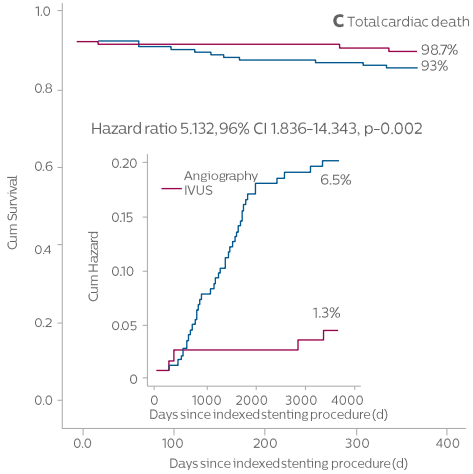
**At 1year**




IVUS-guidance was associated with a significant reduction in Major Adverse Cardiac Events (MACE)

**MACE in IVUS group occurred in 10.0% vs 15.0% (p = 0.036)**

**At 7years**




IVUS-guidance resulted in lower:

- **Cardiac death rate (6.5 versus 1.3%, p = 0.002)**
- **MI (8.4 versus 2.3%, P < 0.001)**

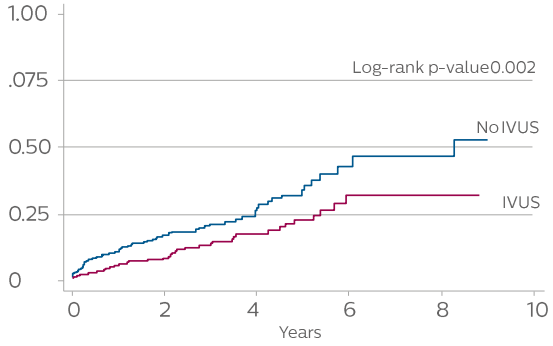
Chen et al. DEFINITION registry. Intravascular ultrasound-guided drug-eluting stent implantation is associated with improved clinical outcomes in patients with unstable angina and complex coronary artery true bifurcation lesions. The International Journal of Cardiovascular Imaging (2018) 34:1685–1696.

# SCAAR left main registry

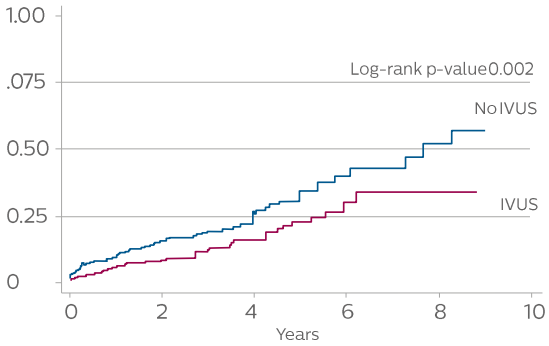
**IVUS-guidance is associated with better outcome in patients undergoing unprotected left main coronary artery stenting compared with angiography guidance alone**

- Prospective, Swedish nationwide observational study.
- 2468 patients who underwent unprotected LMCA PCI between 2005 and 2014 due to CAD or ACS.
- Clinical follow up period of up to 10 years
- Importance to reach appropriate stent size as larger stents were independently associated with improved outcome.

Primary composite endpoint




Mortality

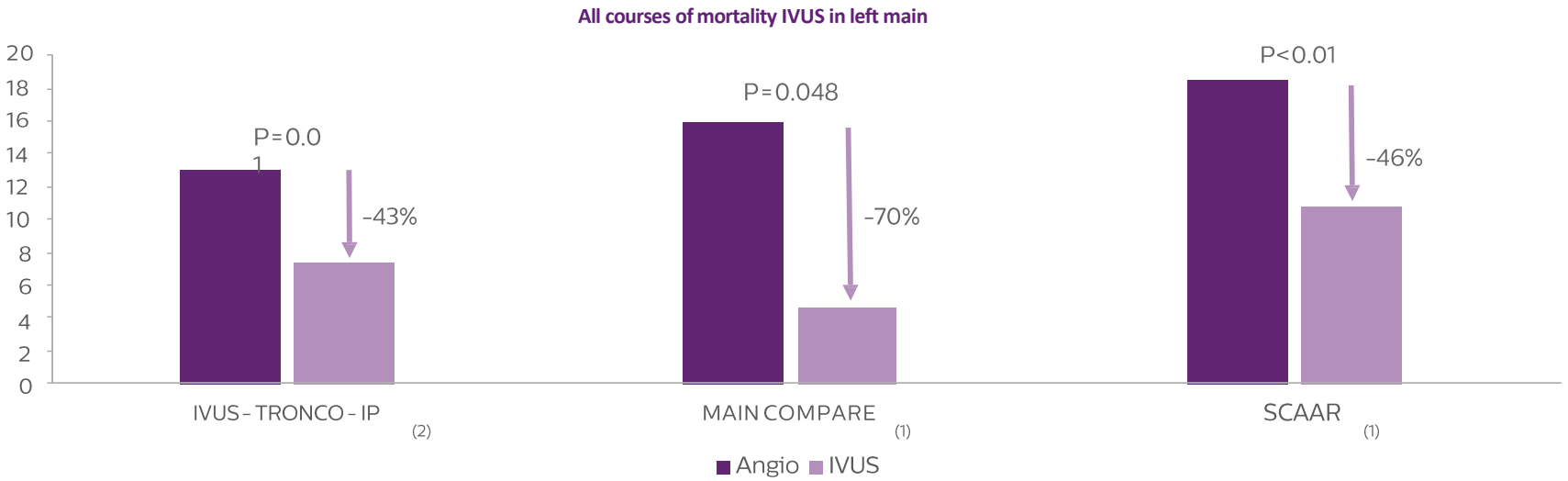



The improvement in outcome was primarily driven by a marked and significant reduction of all-cause mortality (-35% death in total population, -46% death in 340 propensity pair matched population).

1. Andell et al. IVUS in LMCA PCI, Circ Cardiovasc Interv 2017; 10(5).

# Comparison of left main observational studies

**IVUS guidance associated with reduced mortality and MACE rates in LMCA stent implantation[1,2,3]**




**Reduction of all cause of mortality consistently found in all observational studies**

1. Park SJ, et al. MAIN COMPARE. Circ Cardiovasc Interv. 2009;2(3):167-77. 2. de la Torre Hernandez JM, et al. IVUS-TRONCO-ICP, JACC Cardiovasc. Interv. 2014;7(3):244-54. Andell et al. IVUS in LMCA PCI, Circ Cardiovasc Interv 2017; 10(5).

# A preponderance of evidence shows that IVUS benefits patients

**IVUS benefits patients**

Using a standardized IVUS criteria supports optimal clinical benefit

IVUS-XPL, Hong et al. 2015 ULTIMATE, Zhang J et al. 2018 DEFINITION registry, Chen et al. 2017

Multiple studies show patients without optimal IVUS-guided stent expansion had a significantly worse outcome than those with optimal IVUS-guided results.

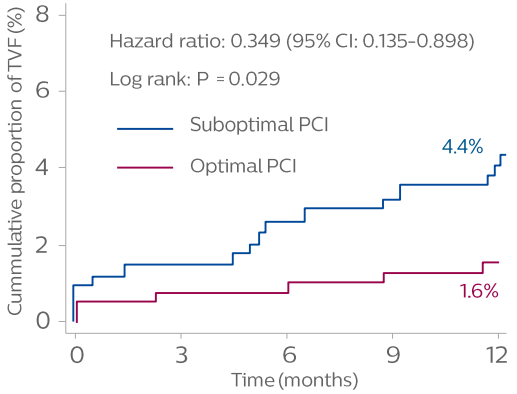
DEFINITION registry, Chen et al. 2017
**MACE 16.9% vs 8.6% (p=0.029)**

**Defined criteria for ULTIMATE**
Zhang J et al. 2018

1. Plaque burden at the 5-mm proximal or distal to the stent edge <50%.
2. Expansion Satisfactory - Minimal lumen CSA in stented segment >5mm2, or 90% of distal reference lumen CSA.
3. No edge dissection involving media with length >3mm.

Only 1.6% TVF at 12 months when optimal IVUS-guided PCI criteria was met in all-comer patients.

**Primary endpoint for patients who met/didn't meet IVUS criteria**



# Glossary

| | |
|---|---|
| ACC | American College of Cardiology |
| AHA | American Heart Association |
| ATM | Atmosphere |
| CAD | Coronary Artery Disease |
| CSA | Cross-Sectional Area |
| DES | Drug Eluting Stent |
| EACTS | European Association for Cardio-Thoracic Surgery |
| EAPCI | European Association of Percutaneous Cardiovascular Interventions |
| EBC | European Bifurcation Club |
| EEM | External Elastic Membrane |
| EP | Electrophysiology |
| ESC | European Society of Cardiology |
| FFR | Fractional Flow Reserve |
| GM | Geographical Miss |
| ICE | Intracardiac Echocardiography |
| iFR | Instantaneous wave-Free Ratio |
| IGT | Image Guided Therapy |
| IGT-D | Image Guided Therapy – Devices |
| IGT-S | Image Guided Therapy – Systems |
| ISR | In-Stent Restenosis |
| IVUS | Intravascular Ultrasound |
| LMCA | Left Main Coronary Artery |
| MACE | Major Adverse Cardiovascular Event |
| MHz | MegaHertZ |
| MI | Myocardial Infarction |
| MLA | Minimum Lumen Area |
| MLD | Minimum Lumen Diameter |
| OCT | Optical Coherence Tomography |
| PCI | Percutaneous Coronary Intervention |
| PV | Peripheral Vascular |
| RCA | Right Coronary Artery |
| RCT | Randomized Control Trial |
| RLA | Reference Lumen Area |
| SCAI | Society for Cardiovascular Angiography and Interventions |
| ST | Stent Thrombosis |
| TLR | Target Lesion Revascularization |
| TVF | Target Vessel Failure |
| TVR | Target Vessel Revascularization |

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