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Lorenz Räber1, Gary S. Mintz2, Konstantinos C. Koskinas1, Thomas W. Johnson3, Niels R. Holm4, Yoshinubo Onuma5, Maria D. Radu6, Michael Joner7,8, Bo Yu9, Haibo Jia9, Nicolas Meneveau10,11, Jose M. de la Torre Hernandez12, Javier Escaned13, Jonathan Hill14, Francesco Prati15, Antonio Colombo16, Carlo di Mario17, Evelyn Rega18, Davide Capodanno19, William Wijns20, Robert A. Byrne21, and Giulio Guagliumi22*

Coordinating editor: Prof Patrick W. Serruys, MD, PhD, Imperial College, London, UK


1Department of Cardiology, Bern University Hospital, Bern, Switzerland; 2Cardiovascular Research Foundation, New York, NY, USA; 3Bristol Heart Institute, University Hospitals Bristol NHSFT, Bristol, UK; 4Department of Cardiology, Aarhus University Hospital, Aarhus, Denmark; 5Department of Interventional Cardiology, Cardialysis, Thoraxcenter, Erasmus MC, Rotterdam, The Netherlands; 6The Heart Center, Rigshospitalet, Copenhagen University Hospital, Copenhagen, Denmark; 7Deutsches Herzzentrum München, Technische Universität München, Munich, Germany; 8DZHK (German Center for Cardiovascular Research), partner site Munich Heart Alliance, Munich, Germany; 9Department of Cardiology, 2nd Affiliated Hospital of Harbin Medical University, The Key Laboratory of Myocardial Ischemia, Chinese Ministry of Education, Harbin, China; 10Department of Cardiology, University Hospital Jean Minjoz, 25000 Besancon, France; 11EAP3920, University of Burgundy Franche-Comté, Besancon, France; 12Department of Cardiology, IDIVAL, Hospital Universitario Marques de Valdecilla, Santander, Spain; 13Hospital Clinico San Carlos IDISSC and Universidad Complutense, Madrid, Spain; 14Department of Cardiology, King’s College Hospital, London, UK; 15Department of Cardiology, San Giovanni Hospital, Rome, Italy & CLI Foundation, Rome, Italy; 16Interventional Cardiology Unit, Cardio-Thoracic-Vascular Department, San Raffaele Scientific Institute, Milan, Italy; 17Structural Interventional Cardiology, Careggi University Hospital, Florence, Italy; 18Department of Cardiovascular Surgery, Zürcher University Hospita, Zürich, Switzerland; 19Division of Cardiology, Cardio-Thoraco-Vascular and Transplant Department, CAST, Rodolico Hospital, AOU Policlinico-Vittorio Emanuele, University of Catania, Catania, Italy; 20The Lambe Institute for Translational Medicine and Curam, National University of Ireland Galway, Saolta University Healthcare Group, Galway, Ireland; 21Deutsches Herzzentrum München, Technische Universität München, Munich, Germany; 22Cardiovascular Department, Ospedale Papa Giovanni XXIII, Bergamo 24127, Italy; 23Department of Cardiology Hospital Universitario de la Princesa, Madrid, Spain; 24Royal North Shore Hospital, The University of Sydney, Sydney, Australia; 25Columbia University Medical Center, New York, USA; and 26Department of Health Sciences Research, Mayo Clinic, Rochester, USA

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This Consensus Document is the first of two reports summarizing the views of an expert panel organized by the European Association of Percutaneous Cardiovascular Interventions (EAPCI) on the clinical use of intracoronary imaging including intravascular ultrasound (IVUS) and optical coherence tomography (OCT). The first document appraises the role of intracoronary imaging to guide percutaneous coronary interventions (PCIs) in clinical practice. Current evidence regarding the impact of intracoronary imaging guidance on cardiovascular outcomes is summarized, and patients or lesions most likely to derive clinical benefit from an imaging-guided intervention are identified. The relevance of the use of IVUS or OCT prior to PCI for optimizing stent sizing (stent length and diameter) and planning the procedural strategy is discussed. Regarding post-implantation imaging, the consensus group recommends key parameters that characterize an optimal PCI result and provides cut-offs to guide corrective measures and optimize the stenting result. Moreover, routine performance of
intracoronary imaging in patients with stent failure (restenosis or stent thrombosis) is recommended. Finally, strengths and limitations of IVUS and OCT for guiding PCI and assessing stent failures and areas that warrant further research are critically discussed.

**Keywords**  
Intracoronary imaging • Optical coherence tomography • Intravascular ultrasound • Percutaneous coronary intervention (PCI) • Coronary artery disease

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**Preamble**  
This Consensus Document, which is the first of two reports summarizing the views of an expert panel organized by the European Association of Percutaneous Cardiovascular Interventions (EAPCI), appraises current evidence on clinical indications for intracoronary imaging and provides consensus opinion regarding use, strengths, and limitations of intravascular ultrasound (IVUS) and optical coherence tomography (OCT) based also on the best current practice.

**Expert committee: selection criteria, organization, and consensus development**  
The consensus group was selected by the Scientific Documents and Initiatives Committee of the EAPCI based on the acknowledged expertise in intracoronary imaging and the origin from different geographical areas. During the first meeting in August 2017, the expert committee discussed the documents content, the perspectives and scopes, the methods of data searching and assigned lead authors for each document. Authors conducted literature searches [peer review literature with special attention to the publications in the last 5 years, existing level of evidence, randomized clinical trials, meta-analyses, registries, including a systematic research for the derivation of the meta-analysis (Figure 1)] and drafted the document outline. Consensus on the final document was found during several meetings and conference calls as well as two revisions of the draft document by all expert committee members. The key points of each chapter are summarized in summary boxes. The relationships and industry information for all members, writing committee, and peer reviewers are published in the Supplementary Material.

**Introduction**  
Coronary angiography is the traditional imaging modality for visual evaluation of coronary anatomy and guidance of percutaneous coronary interventions (PCIs). However, the derived two-dimensional lumenogram cannot depict the arterial vessel wall, and thus evaluate vessel dimensions and plaque characteristics, nor directly assess the acute procedural result, but also improves clinical outcomes. In spite of this, the adoption of intracoronary imaging remains limited in routine clinical practice and highly heterogeneous according to geographic region. Over the past decades, IVUS and OCT have progressively evolved with respect to technical performance (higher resolution imaging), and procedural aspects (faster pullback, automatic vessel/lumen and plaque burden detection and measurements, and co-registration with angiography). This has enabled their use as clinical tools used routinely or in selected cases.

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**Does intracoronary imaging improve clinical outcomes following percutaneous coronary intervention?**  
**Intravascular ultrasound vs. angiography**  
In the era of bare metal stents (BMS), several RCTs showed significant favourable effect of IVUS guidance over angiographic guidance alone on restenosis and target lesion revascularization (TLR) rates, with a neutral effect on mortality and myocardial infarction (MI) (Supplementary material online, Table S1). Among these trials, the IVUS-XPL (lesion length >28 mm), and CTO-IVUS (chronic total occlusions) trials showed significant reductions in major adverse cardiac events (MACE) with IVUS guidance. The benefit was driven by a reduction in repeat revascularization for restenosis in both trials. A meta-analysis of seven RCTs (3192 patients) including only DES-treated patients confirmed the superiority of IVUS guidance vs. angiographic guidance alone in reducing MACE [odds ratio (OR) 0.60, 95% confidence interval 0.46–0.77], cardiovascular mortality [OR 0.46 (0.21–1.00)] and stent thrombosis [OR 0.49 (0.24–0.99)]. The duration of follow-up in these studies ranged between 12 and 24 months. These findings were confirmed in a subsequent patient-level meta-analysis including 2345 patients from RCTs of new-generation DES. Significant reduction in MACE, TLR, and TVR was also shown in a meta-analysis of RCTs specifically in patients with complex lesions. An updated meta-analysis performed by the present group including eight RCTs (3276 patients) confirmed the superiority of IVUS-guided PCI for reduction of MACE and ischaemia-driven TLR following DES implantation (Figure 1).

Several points require consideration when interpreting these findings. First, the fact that most individual RCTs with DES showed a directionally favourable trend but no significant superiority of routine IVUS guidance (despite achieving larger post-intervention stent dimensions) is likely explained by the limited power of the individual studies. The inclusion of non-complex lesions, and at least in part the absence of pre-
specified guidance protocol represent additional limitations. Indeed, significant MACE reduction was observed in studies assessing patients with long lesions and chronic total occlusions, as well as in meta-analyses of all available RCTs. Notwithstanding these benefits, the effects of the use of intracoronary imaging in an all comers setting remains to be established.

Notably, the pooled benefit emerged despite the fact that predefined stent optimization targets were not reached in many of the enrolled patients (Figure 2). It should also be noted that, although pre-specified expansion targets in imaging-guided PCI are not always achievable, it is reasonable to assume that these targets do guide operators in attempting to achieve the goals and potentially result in increasing minimum stent area (MSA). Whether a higher rate of acute procedural optimization or alternative optimization targets might result in an incremental improvement in clinical outcomes is unclear. Another unknown factor is the potential effect of a systematic implementation of quantitative coronary analysis to assist angiography-guided PCI as compared to visual estimation alone.

Observational studies of IVUS-guided PCI with DES reported consistent reductions in ischaemic outcomes. Owing to the lack of

Figure 1 Forrest plot summarizing the effects of intravascular ultrasound-guided percutaneous coronary intervention as compared with angiography-guided percutaneous coronary intervention on cardiovascular outcomes.
randomization, considerable differences in patient and lesion characteristics were observed at baseline. Moreover, additional unmeasured confounding factors are also likely to be differentially distributed between the comparison groups. The largest observational study including 8583 ‘all-comer’ patients (ADAPT DES) showed most pronounced benefit of IVUS guidance in patients with acute coronary syndromes (ACS) and complex lesions. In a meta-analysis of 20 studies (including three RCTs), the benefit of IVUS guidance with respect to mortality and MACE was particularly pronounced in ACS patients or complex lesions (left main, bifurcation, CTO, or long lesions).

Intravascular ultrasound-guided left main percutaneous coronary intervention

The clinical value of IVUS-guided PCI has been studied in one small RCT including 123 elderly patients (age >70 years) undergoing revascularization with second-generation DES. At 2 years, IVUS guidance resulted in a lower risk of MACE, which was driven by a significant reduction in TLR. Extensive evidence exists to support IVUS-guided left main PCI in non-randomized studies. In the largest study including 1670 patients with left-main lesions treated with DES, propensity score-matched analyses showed that IVUS guidance was associated with reduced MACE (cardiac death, MI, or TLR) within 3 years (11.3% vs. 16.4%, \( P = 0.04 \)). MACE reduction was largely driven by all-cause mortality and not by MI or TLR, leaving open the question regarding the mechanism of the observed survival benefit. Larger stents with better expansion, more frequent stent post-dilatation and less use of two-stent techniques in IVUS-guided interventions were also observed in this study, which identified IVUS-guided revascularization as independently associated with MACE reduction, predominantly in the subgroup of patients with distal left-main lesions [hazard ratio (HR) 0.54 (0.34–0.90)]. In the observational MAIN-COMPARE study, a trend for lower mortality was demonstrated, yet again without a difference in MI or TLR. A meta-analysis of 10 studies showed significantly lower risk of all-cause death, cardiac death and stent thrombosis for IVUS-guided left-main interventions. The observed reduction in mortality without clear mechanistic explanation suggests that the results in these studies may be influenced by the presence of residual confounding factors.

Optical coherence tomography vs. angiography

Currently, there are relatively limited data for OCT-guided interventions and there is no RCT of clinical outcomes with OCT-guided vs. angiography-guided PCI. One registry study reported a reduced rate of cardiac death and MACE in patients who underwent OCT-guided interventions. Additional observational studies showed larger final in-stent minimum lumen diameter (MLD) and a reduction in the number of stents used with OCT-guided primary PCI. The importance of pre-stent assessment by OCT was highlighted in the non-randomized ILUMIEN-I study. Pre-stenting imaging changed the PCI strategy more frequently (57%) compared with imaging performed after stent implantation (27% of cases).

In the randomized DOCTORS trial including 240 patients with non-ST-segment elevation ACS, OCT-guided PCI was associated with a small but significant improvement in the primary endpoint,
post-procedural fractional flow reserve (FFR) compared with angiography-guided PCI. This benefit was mainly driven by improved stent expansion. In the OCTACS study, 100 ACS patients were randomized to either OCT-guided or angiography-guided implantation of newer-generation DES; OCT-guidance resulted in a lower proportion of uncovered struts at 6 months (4.3% vs. 9.0%, \( P < 0.01 \)). Similarly, the DETECT OCT study showed a superior stent coverage at 3 months (7.5% vs. 9.9%, \( P = 0.009 \)) when OCT-guidance PCI was applied in 894 stable CAD patients. The randomized ILUMIEN-III trial compared the effects of OCT-guided, IVUS-guided, and angiography-guided PCI on stent expansion. The study was not powered for clinical outcomes, and the primary efficacy endpoint was post-PCI minimum lumen area (MLA). Non-inferiority of OCT vs. IVUS and superiority of OCT vs. angiography was tested. OCT was not found to be superior to angiography with respect to MLA but led to significantly improved minimum and mean stent expansion and fewer untreated dissections and persisting major malapposition. These results have to be interpreted against the background of relatively simple lesion morphology and the efforts to optimize the results in all three groups by experienced operators. The impact of OCT-guided vs. angiography-guided PCI is being investigated further in RCTs currently underway ILUMIEN-IV (NCT0350777/) and OCTOBER trials (NCT03171311).

### Intravascular ultrasound vs. optical coherence tomography

Recently, two dedicated RCTs directly compared OCT-guided vs. IVUS-guided PCI with respect to surrogate and clinical endpoints. ILUMIEN-III addressed the question whether OCT-guided PCI using a specific optimization protocol is comparable to IVUS-guided PCI. A total of 450 patients were enrolled (median lesion length 15.5 mm; exclusion of left-main and CTO lesions; 36% ACS patients). The primary endpoint, MLA, was non-inferior following OCT-guided vs. IVUS-guided PCI. Minimum and mean stent expansion with OCT-guided PCI was comparable to IVUS-guided PCI and significantly improved vs. angiography-guided PCI. Untreated major dissections [OCT 14% vs. IVUS 26% vs. angiography 19%, \( P \) (OCT vs. IVUS) = 0.009, \( P \) (OCT vs. angiography) = 0.25] and major malapposition [11% vs. 21% vs. 31%, respectively; \( P \) (OCT vs. IVUS) = 0.02, \( P \) (OCT vs. angiography) <0.0001] were less frequent in the OCT group compared with the IVUS and angiography groups. Post-dilation was required to achieve a stent expansion of at least 90% in both the proximal and distal halves of the stent relative to the respective reference segment—a unique OCT criterion introduced in this trial. Notably, the protocol-mandated expansion target was achieved in only 41% of OCT-guided cases and the difference in MLA was minimal compared with the IVUS group, in which no expansion criteria were predefined.

The OPINION RCT included 829 patients with relatively simple lesions (lesion length 18 mm) and tested whether OCT-guided PCI using a lumen-based approach was non-inferior to IVUS-guided PCI with respect to the clinical endpoint of target vessel failure within 12 months post-PCI. It is thus the first OCT study formally powered for a clinical endpoint. The primary endpoint did not differ between groups (5.2% vs. 4.9%, \( P \) for non-inferiority <0.05). In addition, in-stent MLA as assessed by quantitative coronary angiography at 8 months was similar and binary restenosis was identical between groups.

### Critical appraisal of current evidence: intravascular ultrasound or optical coherence tomography vs. angiography

The ILUMIEN-III and OPINION trials consistently showed that OCT is non-inferior to IVUS for PCI guidance with respect to the acute procedural result, as well as mid-term clinical outcomes. Although a dedicated RCT is required to address the superiority of OCT-guidance vs. angiography-guidance, the aforementioned studies suggest that the superior clinical outcomes defined by RCTs on IVUS guidance in selected patients are likely applicable to OCT-guidance. Consistent with this, a recent network meta-analysis including 17 882 patients who underwent angiography-, IVUS-, or OCT-guided implantation in 17 RCTs and 14 observational studies demonstrated that IVUS- or OCT-guidance was associated with significant reductions in MACE and cardiovascular mortality vs. angiographic guidance, without efficacy differences between IVUS and OCT.

It is the consensus opinion of this expert group that IVUS and OCT are equivalent (and superior to angiography) in guiding and optimizing most PCI procedures. Both modalities can identify features of optimal stent implantation (expansion, apposition, and complications), as well as mechanisms of stent failure that cannot be captured using coronary angiography alone. However, the benefits and limitations of each modality require consideration (Table 1).

Owing to lower tissue penetration, especially in lipid-rich tissue, OCT is limited for assessing plaque burden and detecting vessel size as delineated by the external elastic membrane (EEM) in the presence of diffuse disease—an approach used for IVUS-guided stent sizing. IVUS is the preferred modality for assessment and treatment of ostial left-main lesions (due to frequent inability of OCT to visualize the ostium as proper blood clearance may be challenging). CTO lesions and patients with renal insufficiency (due to the potential for lower volume or minimal contrast PCI). In contrast, due to its higher resolution, OCT is more accurate for detecting lumen or stent-related morphologies with potential clinical impact, including thrombus and culprit plaque identification in patients with suspected ACS; residual edge dissection, incorrect wire positions and stent malapposition immediately after stenting. Whether the higher accuracy in the detection of aforementioned findings has the potential to translate into improved cardiovascular outcomes remains unknown. Optical coherence tomography is more user-friendly as the pullback acquisition is faster, and reliable automatic analyses are made available immediately. Furthermore, stent-related findings are easier to interpret with OCT.

The results of available studies should be interpreted in the context of best clinical practice standards. First, newer-generation DES and technical refinements of stenting procedures have resulted in overall improvements of the safety and efficacy of coronary interventions. The SYNTAX II study reported the outcomes in patients prospectively enrolled and treated with a combined protocol incorporating coronary physiology-based revascularization, IVUS-guided stenting, thin strut stent implantation, and contemporary CTO revascularization techniques. The primary analysis showed improved clinical outcomes in comparison with historical control. Although the contribution of IVUS-guided PCI cannot be exactly defined, it may have contributed to the excellent outcomes in this high risk population (likely in combination with a favourable effect of physiological assessment). Second,
Table 1  Advantages and disadvantages of intravascular ultrasound and optical coherence tomography for PCI guidance and optimization

<table>
<thead>
<tr>
<th>IVUS</th>
<th>OCT</th>
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<tr>
<td><strong>Advantages</strong></td>
<td><strong>Advantages</strong></td>
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<tr>
<td>- Extensive clinical experience → IVUS has been used clinically for almost three decades</td>
<td>- 10× higher resolution compared with IVUS → OCT can detect fine details which are missed by IVUS (edge dissections, tissue coverage of stent struts, and malapposition that is below the resolution of IVUS)</td>
</tr>
<tr>
<td>- Pre-intervention imaging is possible in most patients without pre-dilation</td>
<td>- Better tissue characterization (calcium)</td>
</tr>
<tr>
<td>- Penetration to the adventitia allows mid-wall or true vessel stent sizing</td>
<td>- Better suited for thrombus detection</td>
</tr>
<tr>
<td>- Extensive research regarding impact of IVUS guidance of the procedural result as well as clinical outcomes</td>
<td>- Images are clearer and easier to interpret</td>
</tr>
<tr>
<td>- IVUS predictors of restenosis are well established</td>
<td>- OCT predictors of restenosis and stent thrombosis are well established</td>
</tr>
<tr>
<td>- Better guidance for CTO techniques (e.g. wire re-entry)</td>
<td>- More user-friendly due to rapid availability of reliable automatic analyses (i.e. accurate lumen profile)</td>
</tr>
<tr>
<td><strong>Disadvantages</strong></td>
<td><strong>Disadvantages</strong></td>
</tr>
<tr>
<td>- Images can be difficult to interpret</td>
<td>- Additional contrast</td>
</tr>
<tr>
<td>- Tissue characterization is limited</td>
<td>- Flushing is necessary to clear the lumen of blood to visualize the vessel wall</td>
</tr>
<tr>
<td>- Thrombus detection is challenging</td>
<td>- Pre-dilation may be necessary pre-intervention to allow blood to be flushed from the lumen</td>
</tr>
<tr>
<td>- Assessment of stent-strut tissue coverage not possible (low resolution)</td>
<td>- Limited penetration of OCT</td>
</tr>
<tr>
<td>- Assessment of strut malapposition is limited</td>
<td>- Compared with IVUS, there is limited research evidence on OCT-guided vs. angiography-guided PCI with respect to surrogate endpoints and no RCT powered for clinical outcomes</td>
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<tr>
<td>- Low-resolution of the longitudinal view</td>
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</table>

Although RCTs are of greater value for shaping recommendations in the hierarchy of evidence, practical limitations of performing large, adequately powered RCTs comparing imaging-guided vs. conventional PCI should be taken into account. Along these lines, IVUS was associated with a significant clinical benefit in the largest of the available RCTs and in pooled analyses of all individual RCTs. Third, the benefits of intracoronary imaging depend largely on the interpretation and the operators’ reaction to these findings. Image acquisition alone will not be sufficient to impact on outcomes. Positive impact will require proper technique, correct imaging interpretation and adequate reaction to the findings. Therefore, it is important to implement quantitative measurements, and develop practical algorithms to allow stent guidance and optimization based on standardized criteria. The frequent failure to achieve stent expansion cut-off values (by the study protocols) suggest how relevant pre-stent imaging is to guide appropriate lesion preparation.

**Which patients and lesions should be considered for intracoronary imaging during percutaneous coronary intervention?**

Guidance of procedural strategy and optimization of the stenting result are major clinical indications for intracoronary imaging. This is in accordance with current guidelines, and in agreement with the views of interventional cardiologists (see Box 1).

**Box 1 Clinical indications and expected effects of intravascular ultrasound- or optical coherence tomography-guided PCI**

- IVUS-guided PCI improves clinical outcomes in selected patients with long lesions and CTOs. Limited data from RCTs suggest that IVUS and OCT-guided PCI are equally effective in achieving these benefits.
- Patients with left-main lesions should be considered for imaging-guided interventions by means of IVUS, or OCT in non-ostial left main lesions, due to particular challenges in angiographic evaluation and procedural complexity, and because of the clinical sequelae of a suboptimal result in this context.
- There is stronger evidence on the advantages of intravascular imaging to guide stenting in complex lesion morphology and in patients presenting with ACS, with less benefit in simpler lesions or patients with more stable clinical presentation.
- OCT for guidance of PCI is more user-friendly as the interpretation is simpler and automatic analyses are available immediately.
- Additional indications favouring OCT include identification of mechanisms of documented stent failure (stent thrombosis and restenosis), and guidance of BRS implantation (Table 2).
- Patients at high risk of developing contrast-induced acute kidney injury can benefit from IVUS-guided PCI due to the potential for lower volume of contrast.
How to perform intracoronary imaging and which criteria should be used for stent implantation and optimization with intravascular ultrasound and optical coherence tomography?

Image acquisition

Intravascular imaging-guided PCI should start, if possible, prior to stent implantation. Prior to stenting, intravascular imaging can assess plaque composition and distribution (calcification, lipid-rich plaque) and identify the need for more aggressive (rotational atherectomy, cutting, or scoring balloons to induce calcium fractures) or less aggressive (direct stenting to avoid lipid embolization) lesion preparation, and facilitate choice of stent size (diameter and length).3,29,30 Imaging is recommended to be performed using a motorized pullback device, with continued control of the image quality during acquisition. Occasionally, a manual pullback is required with IVUS to verify focal and specific findings detected during the automatic pullback. Low profile, open lumen imaging catheters require purging to exclude air and to ensure optimal image quality. The imaging run should start at least 20 mm distal to the lesion and end at the left main or RCA ostium to include the longest vessel segment possible; using OCT the survey mode (75 mm) is thus preferable for pre-PCI imaging. If the imaging catheter does not cross the lesion prior to stenting, or if the flush is insufficient to clear blood from the lumen (in OCT cases), balloon pre-dilatation may be used to facilitate image acquisition.

Establishing a correlation of the intracoronary imaging findings and the angiogram is important for further angiography-guided actions like identification of stent landing zones. Co-registration of IVUS or OCT images with angiography is the ideal technique for this purpose. IVUS and OCT allow the assessment of reference lumen and reference vessel dimensions (as delineated by the EEM) at the proximal and distal, non-diseased, reference sites; IVUS can also assess the vessel dimensions (delineated by the EEM) at the site of minimal lumen diameter. The term EEM is used throughout this document to describe the interface between media and adventitia.

Plaque composition

Calcific plaque

Coronary angiography has low sensitivity, but a relatively high positive predictive value for detection of calcific plaque.39 Intravascular ultrasound and particularly OCT are valuable for detection, localization, and quantification of coronary calcification. OCT can visualize calcified plaque without artefacts,40 penetrate calcium to a certain degree, and thus evaluate its thickness more accurately than IVUS.41,42 Extensive target lesion calcification may adversely impact the PCI procedure by affecting the ability for effective dilatation of a coronary stenosis and is associated with greater likelihood of stent underexpansion. In lesions with maximum circumferential extension of calcium >180° by IVUS, greater calcific burden was associated with a smaller stent area and greater stent eccentricity.43 The presence of OCT-detected fractures following lesion preparation was associated with greater stent expansion in a small-scale observational study.44 Similarly, an OCT-based study suggested that lesions with calcium pools with a maximum angle >180°, maximum thickness >0.5 mm, and length >5 mm are at increased risk for stent under-expansion.45 but there is no evidence of an impact of lesion calcification on clinical PCI outcomes.

Lipid-rich plaque

Stenting of attenuated plaque as assessed by greyscale IVUS,46–49 or lipid-rich plaques as assessed by IVUS-virtual histology,50 OCT,51 and near infrared spectroscopy (NIRS) has been consistently associated with a higher risk of post-procedural MI, distal embolization, and no reflow phenomenon. The clinical implications of these observations

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<td>Stent thrombosis</td>
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Box 2 Pre-PCI detection of calcium and lipid plaque by optical coherence tomography and intravascular ultrasound

- OCT, in contrast to IVUS, can often assess calcium thickness.
- Total calcium arc >180° and increased calcium thickness >0.5 mm are associated with greater risk of stent underexpansion.
- Evidence of calcium fractures following lesion preparation is associated with improved stent expansion.
- In case of large (>180°) calcium pools and absence of calcium fracture following the initial lesion preparation, a more aggressive lesion preparation should be considered.
- Although stenting of lipid-rich plaques is related to an increased risk of peri-procedural MI and no reflow, the procedural consequences of lipid/necrotic pool detection by OCT or IVUS prior to PCI remain unclear.
nonetheless remain unclear. The use of a distal protection filter in NIRS-detected lipid rich lesions did not reduce peri-procedural MI rates in the randomized CANARY study (potentially because of issues caused by the insertion of filters per se).\textsuperscript{52}

**Selection of optimal stent sizing**

**Stent diameter**

Stent underexpansion is a powerful predictor of early stent thrombosis and restenosis after DES implantation according to numerous IVUS studies,\textsuperscript{53-56} pointing to the importance of appropriate stent sizing and expansion. Several potential approaches have been proposed for selection of stent diameter (Figure 3). More conservative approaches advocate a stent diameter based on the smallest reference lumen dimensions. Progressively larger stent diameters would be chosen by accounting for the mean (average of proximal and distal) reference lumen dimension; the largest reference lumen dimensions (proximal or distal); or considering the smallest reference EEM area (by IVUS or OCT). Even more aggressive approaches by IVUS (not applicable to OCT) are based on a media-to-media (or mid-wall approach) at the site of the minimal lumen diameter (Figure 3). From a practical standpoint, the use of the distal lumen reference (either EEM or lumen based) represents a straightforward approach to safely apply, with subsequent post-dilatation of the mid- and proximal part of the stent. When applying a lumen based approach, the use of the mean lumen diameter with up rounding the stent diameter for 0–0.25 mm was recommended in the OPINION study. When applying an EEM based approach, the use of the mean EEM diameter (derived from two orthogonal measurements, or only from one measurement in case the visibility of the EEM is limited to approximately 180°) was recommended with down rounding the stent diameter to the nearest 0.25 mm. In terms of feasibility, the distal EEM was visible for >180° in 77% of patients included in the ILUMIEN 3 study. An important exception to this strategy may be long lesions with large diameter changes (e.g. mid-LAD to LM lesion).

![Figure 3](https://academic.oup.com/eurheartj/advance-article-abstract/doi/10.1093/eurheartj/ehy285/5001185)

**Figure 3** Intravascular ultrasound- and optical coherence tomography-based stent sizing approaches. Illustrative case of a proximal LAD stenosis as displayed by angiography and longitudinal views of intravascular ultrasound and optical coherence tomography. The cross section at the distal reference, the minimal lumen area site and the proximal reference are depicted for intravascular ultrasound and optical coherence tomography. The measurements of various sizing approaches are provided in the lower right panel. The external elastic membrane distance or the mid-wall to mid-wall approach can be used by intravascular ultrasound at the position of the minimum lumen area, whereas optical coherence tomography often fails to visualize the vessel boundaries at this position (?), due to the limited penetration depth in lipid tissues. An external elastic membrane-based approach at the proximal and/or distal reference segment can be used by intravascular ultrasound. The use of optical coherence tomography for such a strategy depends on the visibility of the external elastic membrane within the external elastic membrane segment. A lumen-based approach is similarly feasible for both intravascular ultrasound and optical coherence tomography.
In certain lesion subsets (e.g., long stenoses, vessels located distal to a CTO or location involving a myocardial bridge), assessment of vessel size may be important to rule out negative vessel remodelling, and to ensure that the selected stent size does not imply a risk of vessel rupture.

Criteria for stent sizing need to be viewed in light of certain differences in lumen detection by means of IVUS vs. OCT: minimum lumen area (MLA) derived by OCT is smaller (~10%) compared with IVUS, which may affect lesion severity assessment.57,58 Similarly, lumen dimension assessment at the reference site results in smaller measurements by OCT vs. IVUS59 (with the exception of one study25) and this may affect stent diameter selection.58,59

Intravascular ultrasound guidance results in larger stent diameter, greater angiographic MLD and MSA, and implantation of more and longer stents compared with angiographic guidance.5,21,60 When comparing IVUS vs. OCT guidance, the largest available study including 809 patients in Japan34 (OPINION) reported a small but significant difference in the average stent size (OCT 2.92 ± 0.39 mm vs. IVUS 2.99 ± 0.39 mm, P = 0.005) when applying a lumen-based stent sizing approach. However, this did not translate into differences in angiographic in-stent MLD immediately after stent implantation or at 8-month angiographic follow-up. In the OPINION imaging sub-study including 103 patients, the lumen-based OCT strategy was associated with a trend for non-significantly smaller minimal and mean stent area.61 In the ILLUMIEN III study, in which an EEM based distal reference sizing approach was applied, no difference in the stent diameter was observed.33

**Box 3 Stent sizing by intracoronary imaging**

- The beneficial effect of imaging-guided PCI does not appear to be strictly linked to the algorithm used for stent sizing by IVUS or OCT.
- From a practical standpoint, a distal lumen reference based sizing may represent a safe and straightforward approach with subsequent optimization of the mid and proximal stent segments. Specifically, the mean distal lumen diameter with up rounding stent (0–0.25 mm) may be used (e.g. 3.76 → 4.0 mm), or the mean EEM (2 orthogonal measurements) with down rounding to the nearest 0.25 mm stent size (e.g. 3.76 → 3.5 mm).
- When using OCT, an EEM reference based sizing strategy appears feasible, although more challenging than a lumen based approach for routine clinical practice.
- Appropriate selection of the landing zone is crucial as residual plaque burden (<50%) and particularly lipid rich tissue at the stent edge is associated with subsequent restenosis.
- Co-registration of angiography and IVUS or OCT is a useful tool to determine stent length and allows for precise stent placement.

**Stent length**

The importance of proper selection of stent length is highlighted by the consistent identification of incomplete lesion coverage as one of the predictors of stent failure (stent thrombosis or restenosis)1,62,63 and MACE.64 Avoidance of definition of the landing zone within an area of residual plaque burden (e.g. >50%)63 and particularly lipid-rich plaque is clinically important, as this has been linked to subsequent stent edge restenosis following new-generation DES implantation.65–67 In addition, incomplete stent coverage of lipid pools has been associated with an increased risk of post-procedural MI.48

Co-registration of intracoronary imaging and angiography is an important tool to facilitate stent length selection and precise implantation. This technique is available for clinical practice69 and simplifies imaging-guided stent deployment.

**Percutaneous coronary intervention optimization after stent implantation**

Following stent implantation, IVUS/OCT can detect correctable abnormalities related to the stent and underlying vessel wall, such as underexpansion, geographic plaque miss, strut malapposition, and stent edge dissection; these abnormalities have been associated with adverse PCI outcomes.1 Findings that represent possible targets for stent optimization are shown in Figure 4 and Take home figure.

While both techniques can be used in this context, OCT has proven to be superior in the detection of malapposition and stent edge dissections.33 Optical coherence tomography as compared to IVUS has a unique value for detecting thrombus, which is often indicative of mechanical or anticoagulation problems.
average (proximal and distal) reference area. In recent IVUS trials, the presence of a MSA greater than the distal reference lumen area was associated with a very low adverse event rate (1.5% within 1 year). Considering that the requirement for achieving >90% expansion was frequently out of reach (Figure 2), this expert group believes that the cut-off >80% for the MSA (relative to average reference lumen area) appears to be a reasonable approach to adopt in clinical practice. In the DOCTORS study, the optimal cut-off value of stent expansion able to predict FFR >0.90 was >79.4%.30

Malapposition
In contrast to underexpansion (i.e. MSA that is substantially smaller than the average reference lumen areas), malapposition refers to the lack of contact of stent struts with the vessel wall. Stent underexpansion and malapposition can co-exist or occur independently. Malapposition can occur either in the acute, post-procedural period, or it may develop later, possibly as a result of an underlying vascular process of inflammation and positive (outwards) remodelling of the vessel wall. When malapposition is identified at follow-up, it may represent either persistent (i.e. ongoing since the time of implantation), or late acquired malapposition; a differentiation of these two entities is not possible in the absence of imaging immediately post stenting.

While stent underexpansion is a major IVUS predictor of early stent thrombosis or restenosis, no clear link exists between acute malapposition (in the absence of underexpansion) and subsequent stent failure, as acute malapposition may subsequently resolve. Malapposition can be more reliably detected by OCT compared with...
IVUS, translating into a higher proportion of malapposed stent struts identifiable by OCT (up to 50% of stents implanted under OCT evaluation) vs. IVUS (about 15% of stents implanted under IVUS evaluation). Prospective studies have shown little or no relationship between malapposition that is detected during routine imaging and subsequent events. Acute malapposition did not emerge as an independent predictor of stent thrombosis in studies with imaging immediately after stent placement. Still, on the basis of the investigated populations a protective effect of optimal stent apposition in high-risk populations cannot be excluded. In contrast, studies of stents presenting with thrombosis have consistently identified malapposition as a frequent underlying stent abnormality and showed a higher incidence and extent of malapposition in stent segments with vs. without thrombus. Three recent registries performed OCT in patients with definite stent (BMS or DES) thrombosis. In two studies (PRESTIGE and PESTO) malapposition (unclear whether persistent or late acquired) emerged as a frequent finding: 27% and 60%, respectively, in acute stent thrombosis (within 24 h of implantation), 6% and 44%, respectively in subacute stent thrombosis (1–30 days,) and 10% and 44%, respectively in late stent thrombosis (between 30 days and 1 year post-PCI). These observations were consistent with smaller OCT registries. Moreover, malapposition was among the three leading mechanisms in studies investigating patients with very late stent thrombosis (>1 year following stent implantation). In line with these observations, malapposition has been associated with increased thrombogenicity in in vitro studies.

Notwithstanding current uncertainties regarding the clinical relevance and potential sequelae of different modes of malapposition, the findings of large stent thrombosis registries, in concert with in vitro investigations, suggest that extensively malapposed struts should be avoided following stent implantation and should be corrected when anatomically feasible. As it relates to clinical guidance (corrective treatment or not), malapposition is not merely a binary (yes/no) phenomenon, as has been addressed in most studies, but can be quantified in a two-dimensional (or even a three-dimensional) fashion. Regarding thresholds for corrective post-dilatation, although there are no robust data, there is informative evidence to provide some guidance. One consideration is the association between the axial distance of incomplete stent apposition (ISA) and the subsequent integration by neointimal tissue; in determining the axial extent of ISA, differences in strut thickness across different stents should also be considered. Serial OCT studies observed that struts with ISA distance <0.35 mm undergo full neointimal integration at follow-up. In agreement with this observation, a detailed analysis of patients with very late stent thrombosis reported minimal ISA distance within the thrombosed segments ranging between 0.3 and 0.6 mm, and longitudinal length between 1.0 and 2.1 mm. The risk for extensive acute malapposition is increased in bifurcation PCI, a situation in which visualization by three-dimensional OCT may be helpful (Figure 4D). As complex bifurcation stenting requires rewiring of freshly implanted stents, malapposition constitutes a particular problem due to the risk of accidental abluminal rewiring.

**Tissue prolapse**

Tissue prolapse (typically defined as tissue extrusion from inside the stent area) may include either lesion protrusion or, in the
Box 4 Criteria to assess optimal stent result

- A relative stent expansion of >80% (MSA divided by average reference lumen area) should be obtained in routine clinical practice.
- An MSA of >5.5 mm² by IVUS and > 4.5 mm² by OCT should be achieved in non-left main lesions.
- The clinical relevance of acute malapposition is uncertain. Nonetheless, extensive malapposition after stent implantation should be avoided and corrected, if anatomically feasible. Early strut coverage may be promoted by full apposition.
- Acute malapposition of <0.4 mm with longitudinal extension <1 mm or malapposition should not be corrected as spontaneous neointimal integration is anticipated. This cut-off requires prospective validation.
- Late acquired malapposition represents an established cause of late and very late stent thrombosis.
- Tissue prolapse after stent implantation has been identified as an OCT predictor of early stent thrombosis and has been related to adverse short-term prognosis following PCI. The volume of prolapsed tissue by OCT has been associated with unstable plaque morphology as well as with post-PCI myocardial injury.

In a large multicenter OCT registry including 780 patients (50% with ACS), irregular protrusion was more common in patients treated for MI and was an independent predictor of 1-year clinical outcomes, primarily driven by TLR. Evidence exists that tissue prolapse in the context of ACS is more likely to have consequences than in more stable (non-ACS) clinical setting as suggested by the CLI-OPCI and HORIZONS-AMI substudies.

Dissection

Large edge dissections by IVUS have been reported as correlates of early stent thrombosis and these dissections were commonly characterized by their depth (at least disrupting the medial layer), their lateral extension (>60°) as well as their length (>2 mm). Owing to its higher resolution, OCT can identify less-extensive edge dissections which are missed by IVUS. Therefore, the incidence of OCT-reported edge dissections is at least two-fold higher compared with IVUS-reported dissections; this was confirmed in the OCT vs. IVUS arms of the ILUMIEN-3 trial. In the CLI-OPCI II Study, dissections >200 μm at the distal (but not proximal) stent edge by OCT emerged as an independent predictor of MACE (HR 2.5). In contrast, in an observational study including 780 patients who underwent post-procedural OCT, stent edge dissections (detected in 28.7% of patients) were not associated with adverse 1-year clinical outcomes. In line with IVUS studies, stent edge dissections are considered among OCT-defined predictors of early stent thrombosis. However, subtle abnormalities (i.e. minor edge dissection) are unlikely to be clinically significant and possibly do not require correction. Detection of intra- and extramural haematomas by IVUS or OCT may be relevant, as these findings usually appear as edge stenosis by angiography and can be misdiagnosed as stent vessel mismatch or spasm. The progression of uncovered haematoma may lead to early stent thrombosis.

Optimization of bioresorbable scaffold implantation

In contrast to permanent metallic stents, where optimal implantation techniques have been investigated extensively in imaging studies, intracoronary imaging was not routinely recommended for bioresorbable vascular scaffold implantation. Notably, due to inherent mechanical limitations of bioresorbable materials, and radio-lucency of devices, accurate lesion preparation, device sizing and procedure optimization (i.e. complete expansion without fracture or malapposition) may be even more critical when implanting bioresorbable scaffolds. Retrospective analyses demonstrated that post-procedural lumen eccentricity and asymmetry are related to target lesion failure. Intracoronary imaging is of importance to detect structural abnormality such as acute disruption and discontinuities at follow-up which are not detectable on angiography due to radio-lucency of devices. Although not shown in prospective trials, malapposition at the time of implantation may adversely impact subsequent tissue coverage and incorporation of the scaffold into the vessel wall, which in turn may create a thrombogenic nidus during the process of scaffold dismantling.

Assessment of mechanisms of stent failure

This expert panel highly recommends intracoronary imaging in the setting of stent failure. Imaging facilitates identification of the mechanisms of restenosis or stent thrombosis, guides appropriate treatment, minimizes the risk of subsequent stent failure events, and raises awareness of any potential device related concerns.

Restenosis and stent thrombosis in metallic drug-eluting stents

Identifiable causes of restenosis other than intimal hyperplasia include chronic underexpansion (in approximately 18–40%), stent fracture (<5%), and neoatherosclerosis (i.e. >1 year of DES.
implantation). The first two abnormalities can be readily detected by IVUS or OCT, whereas the latter is a finding defined by OCT.98 Regarding stent fracture, this can be identified more readily by means of three-dimensional OCT imaging compared with two-dimensional imaging alone. For approximately 60% of restenosis cases, the leading mechanism cannot be assessed beyond the (expected) presence of neointimal hyperplasia. In contrast, stent thrombosis has multiple underlying mechanisms and most of these are recognizable by intracoronary imaging (Figure 5).53,99,100 Optical coherence tomography, as opposed to IVUS, can distinguish thrombus from other tissue components, and is therefore, considered the preferred imaging technique for stent thrombosis.

**Figure 5** Optical coherence tomography and intravascular ultrasound findings in the context of stent and scaffold thrombosis. (A) A significantly undersized stent suggestive of persistent malapposition 1 year after implantation (A1) was demonstrated. This finding was left uncorrected. Two years later (A2), an occlusive stent thrombosis occurred after cessation of aspirin. (B) Extensive evaginations as an indicator of positive vessel wall remodeling in a Cypher stent implanted 4 years previously. No thrombus is visible as thrombolysis was administered prior optical coherence tomography. (C) Uncovered stent struts in the region of multiple overlapping stents with small multiple protruding thrombi. (D) A typical in-stent fibroatheroma (6–12 o’clock, stars) with a ruptured cap (arrow) and white thrombus is depicted, suggestive of neatherosclerosis. Disease progression at the stent edge may be a trigger of stent thrombosis (E). Although most mechanisms of scaffold thrombosis are identical with metallic drug-eluting stents, stent discontinuity (i.e., previously apposed scaffold struts that subsequently migrate into the lumen) represents a specific finding in scaffold thrombosis (F). (G) A stent thrombosis occurring at a bifurcation lesion (three-dimensional, thrombus red, and stent blue) is illustrated and (H) a markedly underexpanded stent with thrombus distal to the underexpanded segment. (I) ‘Pros and Cons’ of intravascular ultrasound and optical coherence tomography in the assessment of stent thrombosis is illustrated. The longitudinal view is illustrated on the left hand and cross sections from outside (I1) and inside (I2) the thrombotic region. In the longitudinal view and I2, the thrombus mass is attenuating the light and stent struts are no longer visible (dotted red line and ?) whilst intravascular ultrasound readily depicts the struts. Also, the outer vessel wall (green line), which is indicative of positive remodelling, can only be seen by intravascular ultrasound. Conversely, subtle details like stent strut coverage and peri-strut low intensity regions can only be depicted by optical coherence tomography (I1).
However, in some cases the presence of large amounts of thrombus can make the assessment of stent struts and the outer vessel wall challenging by OCT due to light attenuation, and IVUS may be preferred (Figure 5 I). Restoration of TIMI III flow with subsequent administration of GP IIb/IIIa inhibitors and staged OCT represents a strategy previously applied to enhance analysis of the underlying stent thrombosis aetiology.

Three recent cohort studies investigated correlates of stent thrombosis occurring at various time points after stent implantation. One or several leading mechanisms responsible for thrombus formation could be identified in...
the majority of patients (>90%). Reassuringly, the interpretations of the operating physicians were in agreement with those of experts in 70% of cases in the PESTO registry. The main causes for stent thrombosis in the DES subgroups are reported in Figure 6. In patients with early stent thrombosis, malapposition, underexpansion, and edge dissections were the predominant abnormalities. At variance to previous IVUS studies, malapposition was a relatively frequent finding by OCT. In patients with very late DES thrombosis, malapposition, neatherosclerosis, uncovered struts and underexpansion were frequently observed. A tailored treatment approach according to the specific OCT findings (e.g. additional stent in case of neatherosclerosis, post-dilatation in case of underexpansion or malapposition) appears clinically reasonable, although prospective data to support such a treatment strategy are lacking. The 2014 ESC guidelines on myocardial revascularization, which were published prior to publication of the three OCT registries, considered a Class IIa C recommendation for the performance of intracoronary imaging in stent failure by IVUS or OCT.38

Scaffold thrombosis

The Absorb BVS scaffold is the only bioresorbable device that has undergone extensive scientific evaluation in adequately powered RCTs. Individual studies101 and meta-analyses102,103 suggested an increased risk of scaffold thrombosis at all-time points following implantation and particularly beyond one year. Although many experts acknowledge the potential for intracoronary imaging-guided scaffold implantation to mitigate scaffold failures, no RCT to date has addressed the relevance of imaging-guided scaffold implantation and one was stopped prematurely (OPTICO BVS; NCT02683356) following retraction of ABSORB BVS. No one of the conducted clinical trials on ABSORB BVS was convincingly able to provide insights into the failure mechanisms. Of note, OCT analyses of scaffold thrombosis by means of OCT within the first year after implantation identified underexpansion and malapposition (due to undersizing or lack of adequate expansion) as predominant findings.94,104

The largest cohort study on very late ABSORB BVS scaffold thrombosis studied by OCT—the Independent OCT Registry on Very Late Biosorable Scaffold Thrombosis (INVEST)105—included 36 patients with available OCT at the time point of the thrombotic event; 31% of patients had serial OCT imaging. The leading associated finding was a new bioresorption-specific phenomenon called strut discontinuity (43%). Strut discontinuity or dismantling is present (according to study definition) when struts are dislocated into the lumen despite initial full apposition, and even despite some degree of tissue coverage as shown by intercurrent OCT recordings, or in case of acute malapposition with subsequent discontinuity or in presence of acute scaffold fracture.95,105 The newly described mechanism of Absorb BVS failure has not been observed with metallic DES and potentially explains the increased risk of very late scaffold thrombosis. Unravelling of a resorption-specific failure mechanism may permit the development of treatment strategies and provide guidance for improvements in the design of newer-generation devices. Device failures of newer-generation scaffolds should systematically undergo evaluation by intracoronary imaging, preferably OCT.

Potential limitations of intravascular imaging

The clinical value of intracoronary imaging for PCI guidance is widely acknowledged,1 but potential limitations should be considered. One of the key limitations of intracoronary imaging is the additional time required for imaging. The cost of IVUS and OCT is a notable consideration, and is acknowledged as a potential limitation by practicing interventional cardiologists. A dedicated analysis addressing the cost-effectiveness of IVUS during PCI with DES showed that IVUS-guided interventions are cost-effective, particularly when used in patients at a greater risk of restenosis.106 In view of substantial geographic variability in the clinical use of IVUS and/or OCT in daily practice, ranging from routine use in Japan to selected use in most other countries2 to very limited use in countries with no reimbursement, we recommend and encourage imaging-guided PCI primarily in settings with the most robust evidence of a clinical benefit (Table 3). Adequate training in the acquisition of images and interpretation of findings is an additional essential factor that may be addressed by integrating training in structured interventional fellowships and by ensuring basic imaging skills for all coronary interventionists and advanced experience with IVUS and/or OCT in at least selected operators in each medium and large-volume interventional catheterization laboratory. With current small diameter imaging device iterations, complications directly related to imaging are exceedingly rare, as shown in a systematic review.60 In a large registry of patients undergoing
OCT-guided or IVUS-guided PCI (>3600 procedures), imaging-related complications were infrequent (0.6%), self-limiting or easily treatable with no major adverse events. One potential limitation is the deliverability of imaging catheters in some complex lesion subsets, e.g. heavily calcified, tortuous, angulated anatomies, where accurate imaging could be of potential benefit. Refinements in imaging technology such as co-registration [angiography and intracoronary imaging (roadmap)], lower-profile and more deliverable catheters with faster pullbacks, higher resolution technology (IVUS), and fully automated software to support pre- and post-stent assessment are expected to further improve the ease of use and therefore penetration in daily clinical practice.

### Table 3  Summary of randomized trials comparing optical coherence tomography vs. angiography and/or intravascular ultrasound for percutaneous coronary intervention guidance

<table>
<thead>
<tr>
<th>Study</th>
<th>Year of publication</th>
<th>Number of patients</th>
<th>Age (years)</th>
<th>ACS (%)</th>
<th>Follow-up (months)</th>
<th>Stent type</th>
<th>Optimization criteria</th>
<th>Number of patients/lesions not achieved criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>ILUMIEN</td>
<td>3</td>
<td>146/146/158a</td>
<td>67/66/66</td>
<td>34/36/36</td>
<td>1</td>
<td>DES</td>
<td>MSA of at least 90% in both the proximal and distal halves of the stent relative to the closest reference segment</td>
<td>82/140 (58.6%)</td>
</tr>
<tr>
<td>OPINION</td>
<td>2017</td>
<td>405/412</td>
<td>69/68</td>
<td>13/11</td>
<td>12</td>
<td>DES</td>
<td>(1) In-stent MLA ≥90% of the average reference lumen area. (2) Complete apposition of the stent. (3) Symmetric stent expansion defined by minimum lumen diameter/maximum lumen diameter ≥0.7. (4) No plaque protrusion, thrombus, or edge dissection with potential to provoke flow disturbances</td>
<td>NA</td>
</tr>
<tr>
<td>DOCTORS</td>
<td>2016</td>
<td>120/120</td>
<td>60/61</td>
<td>100/100</td>
<td>6</td>
<td>DES or BMS</td>
<td>(1) In-stent MLA &gt;80% of reference lumen area. (2) Additional stent implantation(s) were to be performed to rectify incomplete lesion coverage. (3) Use of GP IIb/IIIa inhibitors and aspiration thrombectomy were to be considered systematically if thrombus was present.</td>
<td>NA</td>
</tr>
<tr>
<td>OCTACS</td>
<td>2015</td>
<td>50/50</td>
<td>62/63</td>
<td>100/100</td>
<td>6</td>
<td>DES</td>
<td>(1) MSA &gt;90% of the distal/proximal reference vessel lumen area. (2) No significant malapposition defined as ≥3 struts per CSA detached &gt;140 µm from the underlying vessel wall. (3) No significant edge dissection (causing minimum lumen area &lt;4 mm²). (4) No significant residual stenosis (causing minimum lumen area &lt;4 mm²)</td>
<td>NA</td>
</tr>
</tbody>
</table>

CSA, cross sectional area; NA, not available.

*aAngiography/IVUS/OCT arm.

### Supplementary material

Supplementary material is available at European Heart Journal online.

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Clinical use of intracoronary imaging

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