



Intravascular Imaging Best Practice Protocol

Intravascular ultrasound (IVUS) and optical coherence tomography imaging (OCT) modalities have been developed and validated to help interventional cardiologists improve stent implantation. Multiple studies and meta-analyses have shown intravascular imaging to improve PCI outcomes. The advantages of IVUS are years of experience, imaging is mostly feasible without pre dilatation, the penetration of the vessel walls, particularly the adventitia allows true vessel size and excellent assessment of plaque burden, which facilitates optimal stent dimensions and landing zones. Predictors of stent failure, such as fractures, dissections and under expansion are also well studied. IVUS uses no contrast and can have co-registration assistance. The advantages of OCT are 10x better resolution compared to IVUS with easier to interpret imaging as well with better tissue characterization (protrusion, dissections) and thrombus detection. Although both modalities possess advantages and limitations, there are fundamental differences that are described below (6):

Table 1 Advantages and disadvantages of intravascular ultrasound and optical coherence tomography for PCI guidance and optimization

IVUS	OCT
<p><i>Advantages</i></p> <ul style="list-style-type: none"> • Extensive clinical experience → IVUS has been used clinically for almost three decades • Pre-intervention imaging is possible in most patients without pre-dilation • Penetration to the adventitia allows mid-wall or true vessel stent sizing • Extensive research regarding impact of IVUS guidance of the procedural result as well as clinical outcomes • IVUS predictors of restenosis are well established • Better guidance for CTO techniques (e.g. wire re-entry) <p><i>Disadvantages</i></p> <ul style="list-style-type: none"> • Images can be difficult to interpret • Tissue characterization is limited • Thrombus detection is challenging • Assessment of stent-strut tissue coverage not possible (low resolution) • Assessment of strut malapposition is limited • Low-resolution of the longitudinal view 	<p><i>Advantages</i></p> <ul style="list-style-type: none"> • 10x 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) • Better tissue characterization (calcium) • Better suited for thrombus detection • Images are clearer and easier to interpret • OCT predictors of restenosis and stent thrombosis are well established • More user friendly due to rapid availability of reliable automatic analyses (i.e. accurate lumen profile) <p><i>Disadvantages</i></p> <ul style="list-style-type: none"> • Additional contrast • Flushing is necessary to clear the lumen of blood to visualize the vessel wall • Pre-dilation may be necessary pre-intervention to allow blood to be flushed from the lumen • Limited penetration of OCT • 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

Determining which patients should be considered for intravascular ultrasound to help assist in decision making for possible intervention as well as optimization of revascularization should be based on the procedural strategy and current recommendations.

Best Practices Pre-Revascularization

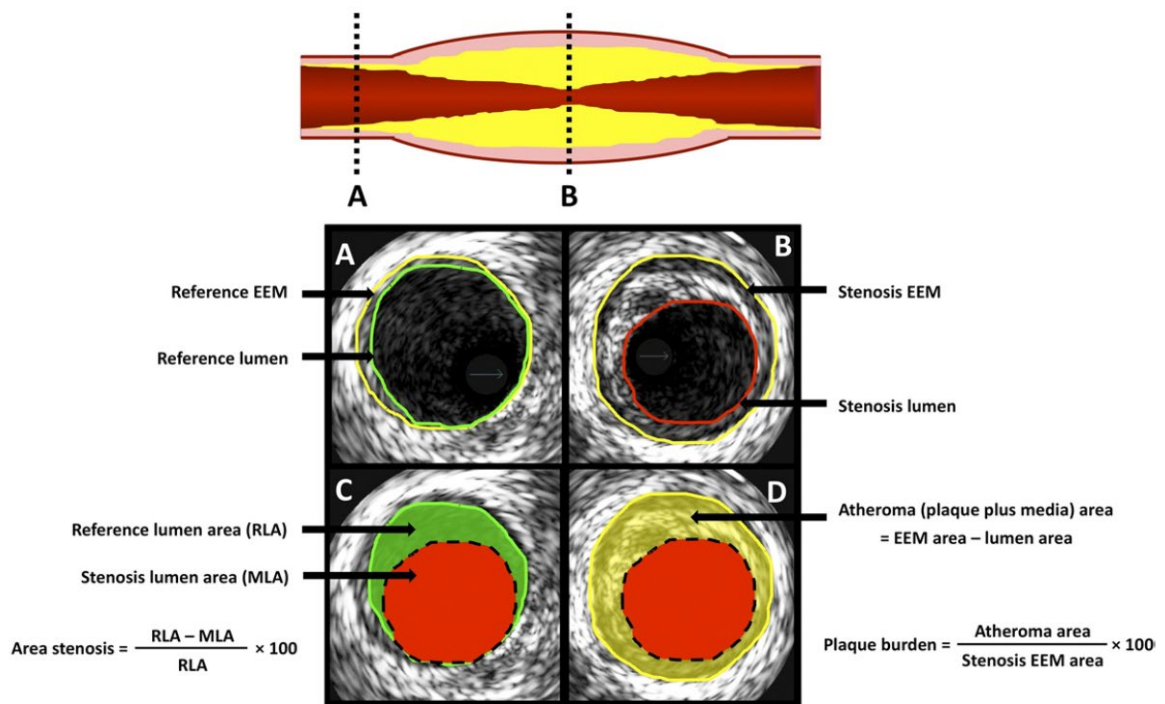
1. Assessment for the need for functional testing with IFR or FFR. We strongly encourage functional testing for intermediate or questionable lesions:
2. Assessment of complex lesions (left main, bifurcation, long lesions >28mm, CTO)
3. Assess lesion preparation for stenting, i.e. heavy calcium that might need atherectomy. Evidence of large arc (>180 degree) should be considered for more aggressive preparation.
4. Appropriate measurements for optimal stent sizing (recommend using distal reference measurements).
 - a. EEM to EEM measurement with recommendation to downsize per quarter size based on the assessment of the distal reference with regards to plaque burden, angulation. Example is 3.53 to 3.5.
5. Appropriate measurements for optimal stent length to minimize geographical miss.
6. Recommend pre and post intra-coronary nitroglycerin use to help improve imaging.

Best Practices Proper Measurements

The operator should be well versed in proper measurements to help with accurate measurements for stent sizing and length.

Figure 1. Basic IVUS Measurements

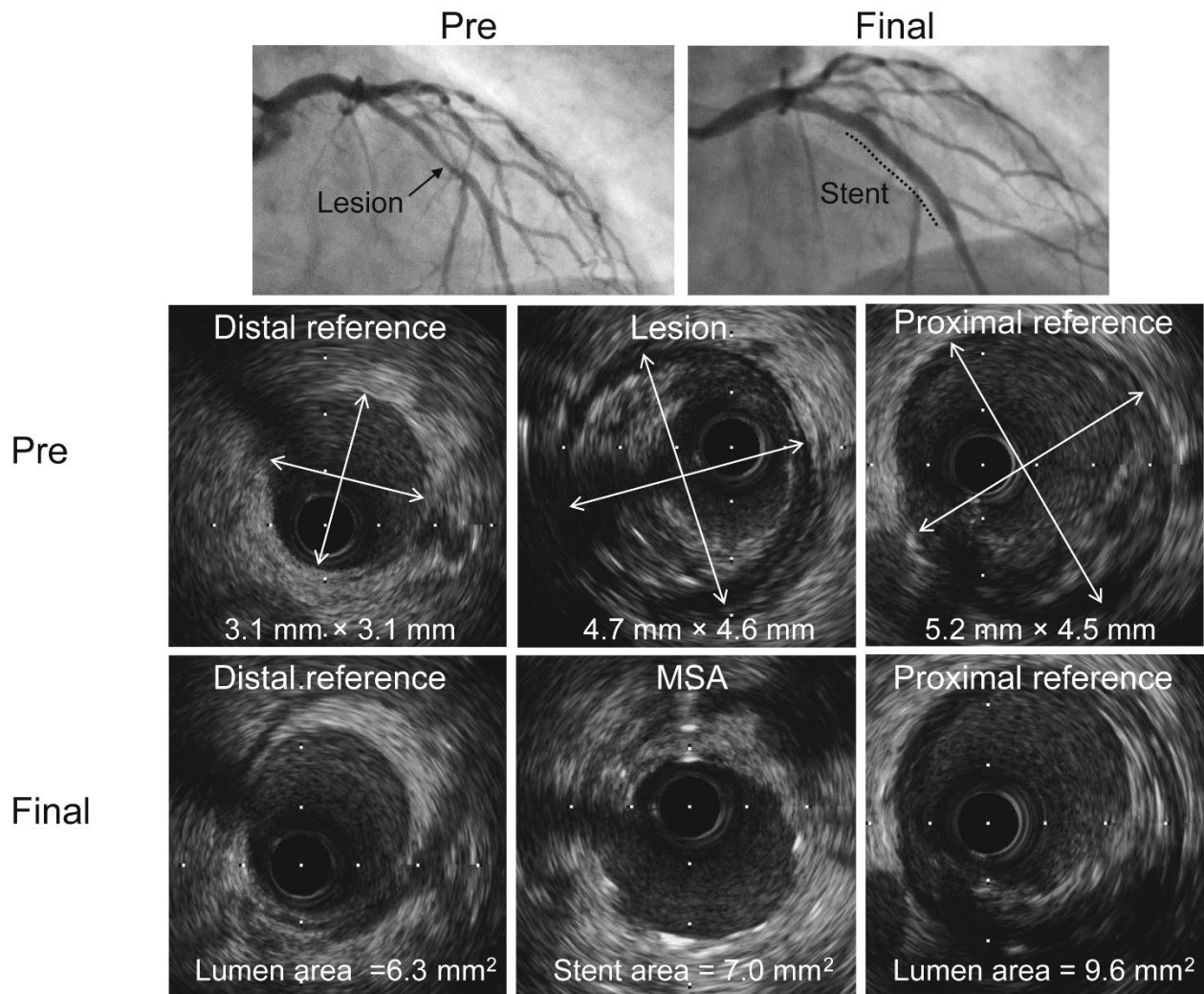
A is from the proximal reference, and **B** is from the most severe stenosis representing the minimal lumen area. **C** illustrates the calculation of area stenosis, which compares the stenosis lumen to the reference lumen. This is in contrast to plaque burden (**D**), which compares the stenosis lumen to the stenosis external elastic membrane (EEM). Due to arterial remodeling, the plaque burden is not usually the same as area stenosis and therefore should not be used to assess stenosis severity. MLA = minimal lumen area; RLA = reference lumen area.



(2)

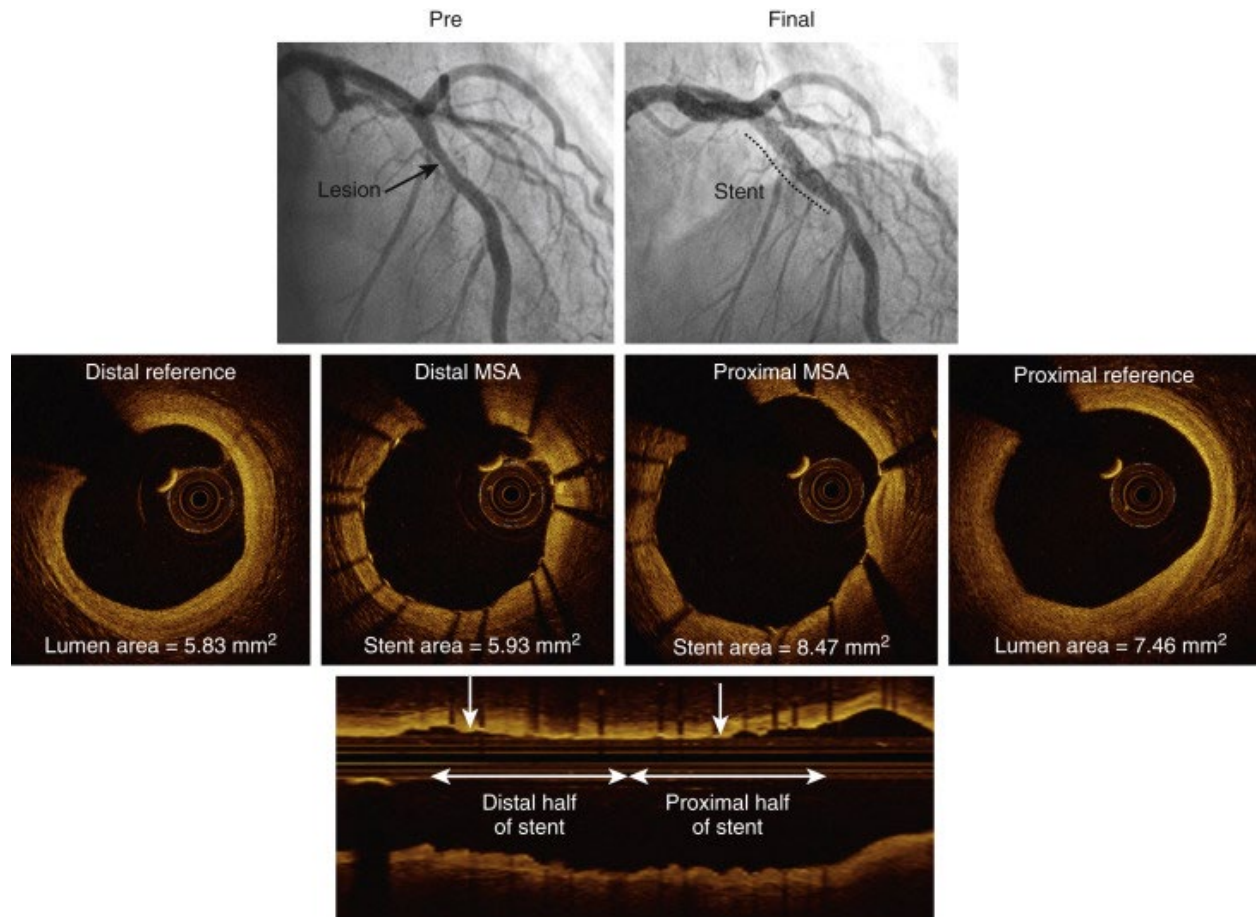
EXAMPLE: IVUS Sizing

Pre IVUS imaging showed distal reference EEM (3.1 x 3.1mm.), proximal reference EEM (5.2 x 4.5mm) and lesion EEM (4.7 x 4.6mm). average diameter rounded down to a 3.5mm stent size due to distal reference appeared normal. Post stent imaging showed MSA 7mm² with stent expansion 88% (measured as MSA/average of the proximal and distal reference lumen area). For IVUS imaging, preferred method for measurement is EEM due to more consistent measurement for mid wall to mid wall. (6)



EXAMPLE: OCT Sizing

Stent sizing based on proximal and distal reference EEL measurements. (OCT imaging excellent for measurement for external elastic lamina wall to wall.) Pre OCT measurements showed proximal EEL 3.48mm and distal EEL 3.14mm. Based on the distal EEL, 3mm stent size was chosen. Post stent expansion area was MSA 5.82mm² distal reference. (6)



Best Practices Post-Stent Assessment

1. Optimize stent expansion.
2. Identify complications such as edge dissection.
3. Assessment of stent failure (hyperplasia, under expansion, stent fracture)

Intravascular imaging has been validated in post stent assessment for stent restenosis, thrombosis and improved MACE. The most consistent and strongest predictor of restenosis and thrombosis is the post stent MSA (minimal stent area) defined as MSA $>5.0\text{mm}^2$ or $>90\%$ of the distal reference lumen area.

Criteria have been validated as a guide for optimal stent deployment:

1. Stent expansion
 - a. MSA $>5\text{mm}^2$ per IVUS non left main lesion
 - b. MSA $>4.5\text{mm}^2$ per OCT non left main lesion
 - c. $> 90\%$ distal reference segment. ($>80\%$ has been accepted if felt $>90\%$ to aggressive)
 - d. FFR $>.90$
2. Plaque burden at the proximal and distal stent edge $<50\%$
3. Absence of large stent edge dissections involving the media and with length >3 mm

Intravascular imaging has been proven through clinical studies and meta-analyses to improve PCI outcomes and likely have the greatest benefit in higher risk patients and more complex lesions. Both modalities have their advantages and limitations and consensus is interventionalist should be familiar with at least one modality to help improve outcomes.

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