MLD MAX CLINICAL DECISION MAKING WORKSHEET

Pre-PCI | Strategize

MORPHOLOGY

High Calcium[1]
Criteria:
>180 degrees
>0.5 mm thickness
>5 mm in length

Common Practice:[2] NC Balloon, IVL, Cutting/Scoring Balloon, or Atherectomy

Note *Nodular Calcium: Atherectomy. Not recommended to do balloon deployment prior to atherectomy, due to creation of dissection.*

LENGTH

Select Landing Zones[3]
Visually scan for largest luminal area in lumen profile proximally and distally

Place landing zones in healthy tissue (as determined by greatest EEL visualization)

Adjust to select an available stent length

Note *In the absence of EEL to represent healthy tissue find the largest lumen to avoid areas of TCFA or lipid pools so as to not land your stent edge in these high risk areas*[4]

DIAMETER[5]

Measure Vessel Diameter
Take EEL measurements at each reference (lumen if EEL not visible)

Choose Stent Diameter
Use the distal reference measurements to select stent diameter

EEL Measurements
Average two perpendicular EEL measurements
Round down to the next quarter size, **unless** already at a stent size

Lumen Measurements
Use automatic measurements at **distal** reference
Round up to the next quarter size, **even if** already at a stent size

Choose Post Dilatation Balloon Diameter
Distal Balloon: Use distal reference measurement
Proximal Balloon: Use proximal reference measurement

Post-PCI | Optimize

MEDIAL DISSECTION

Address Significant Dissection[4]
Criteria: Dissection penetrates medial layer, and is greater than 1 quadrant arc

Common Practice:[4,5] Place an additional stent, particularly for distal dissections

APPOSITION

Address Gross Malapposition
Criteria: Malapposition indicator shows longer than 3 mm[5] of significant (≥0.3 mm from wall[6]) malapposition

Common Practice:[4] If stent is fully expanded, dilate with semi-compliant balloon at low pressure

XPANSION

Confirm Expansion[4,7]
Criteria: ≥80% acceptable, ≥90% expansion is optimal

Common Practice:[8] If not achieved, post-dilate with non-compliant balloon; use target diameter measurement and round up to next available balloon size

Note *After one post-dilatation, physican discretion should be used for further treatment*

Strategize — Pre-PCI

MORPHOLOGY

At which location (in millimeters) does the Minimum Lumen Area (MLA) occur? _____ mm

Is high calcium present in the vicinity (plus/minus 10 mm) of the MLA? yes / no

What, if any, vessel preparation or strategy could be chosen to address this morphology?

LENGTH

Where should the distal and proximal reference markers be placed (from millimeters to millimeters), why? _____ mm → _____ mm

After adjusting your references, what stent length do you recommend? _____ mm

DIAMETER

What are the External Elastic Lamina (EEL) measurements at the distal and proximal reference points? (or Lumen if EEL is not visible)

Distal: _____ mm ☐ EEL ☐ Lumen

Proximal: _____ mm ☐ EEL ☐ Lumen

Which diameter stent do you recommend? _____ mm

What size post-dilatation balloon would you recommend for each segment?

Distal: _____ X _____ mm

Proximal: _____ X _____ mm

Optimize — Post-PCI

MEDIAL DISSECTION

Are there any medial dissections? Identify the location (in millimeters). yes / no _____ mm

What would you do next?

Common Practice:[4,5]
Place additional stent (particularly for *distal* dissections) _____ X _____ mm

APPOSITION

Is the apposition considered major or minor?

Major:

Minor:

What would you do next?

Common Practice:
If stent is fully expanded, dilate with semi-compliant balloon at low pressure.[4] If stent expansion has not been achieved, post-dilate with non-compliant balloon[8] _____ X _____ mm

XPANSION

What is the minimum expansion (%EXP) in the stented segment? _____

What would you do next?
Which segment, if any, would you treat for under expansion, why?

_____ mm → _____ mm

_____ mm → _____ mm

If yes, what size NC balloon would you use?
Balloon diameter and length:

_____ X _____ mm _____ ATM

_____ X _____ mm _____ ATM

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1. Fujino, A. et al. A new optical coherence tomography-based calcium scoring system to predict stent under expansion. *EuroIntervention*, April 2018; 13(18):e2182-e2189.
2. Sorini Dini, C. et al. Contemporary approach to heavily calcified coronary lesions. *Interventional Cardiology Review*, 2019;14(3):154–63.; Seth, A. et al. Optimising stent deployment in contemporary practice: The role of intracoronary imaging and non-compliant balloons. *Interventional Cardiology Review*, 2017;12(2):81–4.; Okura, H. et al. Mechanisms of acute lumen gain following cutting balloon angioplasty in calcified and noncalcified lesions. *Catheterization and Cardiovascular Interventions*, 2002: Vol. 57:429–436.; Abdel-Wahab, M. et al. The randomized PREPARE-CALC Trial. *Circ Cardiovasc Interv*, October 2018: 11:e007415.; Levine, G. et al. 2011 ACCF/AHA/SCAI Guidelines for PCI. *Catheterization and Cardiovascular Interventions*, 2012: Vol 79:453–495.; Kini, A. et al. Optical Coherence Tomography Assessment of the Mechanistic Effects of Rotational and Orbital Atherectomy in Severely Calcified Coronary Lesions. *Catheterization and Cardiovascular Interventions*, 2015; 86:1024–1032.; Okamoto, N. et al. Procedural and one-year outcomes of patients treated with orbital and rotational atherectomy with mechanistic insights from optical coherence tomography. EuroIntervention, 2019;14:1760-1767., Chambers, J. et al. ORBIT II Trial. *JACC: Cardiovascular Interventions*, May 2014: Vol 7, NO 5: 510-8.; Lee, M. et al. Multicenter Registry of Real-World Patients With Severely Calcified Coronary Lesions Undergoing Orbital Atherectomy: 1-Year Outcomes. *The Journal of Invasive Cardiology*, April 2018: Vol. 30, No. 4, 121-124.; Brinton, T. et al. Feasibility of Shockwave Coronary Intravascular Lithotripsy for the Treatment of Calcified Coronary Stenoses. Circulation, 2019; 139:834–836.; Ali, Z. et al. OCT Characterization of Coronary Lithoplasty for Treatment of Calcified Lesions. *JACC: Cardiovascular Imaging*, August 2017: Vol. 10, No. 8, Pages 897–906.
3. Prati, F. et al. The CLI-OPCI II Study. *JACC: Cardiovascular Imaging*, 2015: Vol 8, No. 11:1297-305.
4. Kubo, T. et al. Application of Optical Coherence Tomography in Percutaneous Coronary Intervention. *Circulation Journal*, September 2012: Vol. 76, 2076-2083.
5. Ali, Z. et al. ILUMIEN III: Optimize PCI. *Lancet* 2016, 388:2618-2628.
6. Souteyrand, G. et al. PESTO French Registry. *European Heart Journal*, 2016:37:1208-1216.
7. Meneveau, N. et al. DOCTORS Study. *Circulation*, September 2016, 134:906-917.; Zhang, J. et al. The ULTIMATE Trial. *Journal of the American College of Cardiology*, Dec 2018: Vol 72, No 24:3126-37.; Russo, R. et al. The AVID Trial. *Circ Cardiovasc Intervent*, April 2009; 2:113-123.; De Jaegere, P. et al. MUSIC Study. *European Heart Journal*, February 1998:19,1214-1223.
8. Romagnoli, E. et al. Drug-Eluting Stenting: The Case for Post-Dilation. *JACC Cardiovascular Interventions*, 2008:1:22–31.; Seth, A. et al. Optimising stent deployment in contemporary practice: The role of intracoronary imaging and non-compliant balloons. *Interventional Cardiology Review*, 2017;12(2):81–4.; Gerbay, A. et al. Impact of very high pressure stent deployment on angiographic and long-term clinical outcomes in true coronary bifurcation lesions treated by the mini-crush stent technique. *Indian Heart Journal*, 2017:Vol. 69:32–36.

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Abbott International BVBA
Park Lane, Culliganlaan 2B, 1831 Diegem, Belgium, Tel: 32.2.714.14.11

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