Aortoiliac and femoral interventions:
Drug-eluting devices in the femoropopliteal segment
Standards for LEAD evaluation with IVUS (+OFDI)

*Japanese expert consensus*

**Masahiko Fujihara MD**
**Kishiwada Tokushukai Hospital**
**Osaka Japan**
COI Disclosure

Speaker name:

**Masahiko Fujihara, MD**

I have the following potential conflicts of interest to report:

- Consulting; Century Medical, Nipro, Terumo, Cordis
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s) Boston Scientific, Medtronic, GORE
In endovascular work, Procedural and Clinical success is needed.

Make it Open and Keep it Open.

PRE 2Y POST
Which areas need Imaging?
femoropopliteal area is vital
The use of IVUS resulted in a significant reduction the restenosis after EVT.

IVUS is as important as DCB strategy

DCB Size 5.56 → 5.93 mm
Vessel diameters evaluated by IVUS are larger than those evaluated by Angio

Iida O. J Endovasc Ther. 2022;29(3):343-349.

About 50% ΔRVD \geq 1 \text{ mm}.

IVUS > Angiography

IVUS-assessed RVD was more likely to be different by angiography is small vessels, CTO, bilateral calcification, and history of stent implantation

EEM = External Elastic Membrane
Determining the DCB size according to IVUS- or AIUSevaluated External Elastic Membrane (EEM)

Which is the precise vessel diameter?
Age 76  Male Rutherford 3  Hypertension Smoker ABI 0.67

<table>
<thead>
<tr>
<th>Stenosis Length</th>
<th>148.10 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Stenosis Diameter</td>
<td>75.30 %</td>
</tr>
<tr>
<td>Minimum Lesion Diameter (MLD)</td>
<td>0.97 mm</td>
</tr>
<tr>
<td>User Defined MLD</td>
<td>0.97 mm</td>
</tr>
<tr>
<td>Proximal Diameter</td>
<td>4.13 mm</td>
</tr>
<tr>
<td>Distal Diameter</td>
<td>4.74 mm</td>
</tr>
<tr>
<td>Expected Diameter</td>
<td>3.91 mm</td>
</tr>
<tr>
<td>Maximum Diameter</td>
<td>4.76 mm</td>
</tr>
<tr>
<td>Stenosis Area</td>
<td>0.73 mm²</td>
</tr>
<tr>
<td>% Stenosis Area</td>
<td>93.90 %</td>
</tr>
<tr>
<td>Plaque Area</td>
<td>116.50 mm²</td>
</tr>
<tr>
<td>Stenosis Symmetry</td>
<td>0.78</td>
</tr>
<tr>
<td>Contour correction</td>
<td>None</td>
</tr>
<tr>
<td>Calibration object</td>
<td>Distance 10 mm</td>
</tr>
<tr>
<td>Calibration factor</td>
<td>0.290 mm/px</td>
</tr>
<tr>
<td>Series</td>
<td>12</td>
</tr>
<tr>
<td>Image</td>
<td>24</td>
</tr>
</tbody>
</table>
Distal Reference
EEM 6.3x6.6 mm
Minimum Lumen Area (MLA) after balloon dilatation

After balloon angioplasty, measure the **MLA** in the cross-section with the smallest lumen area in the whole lesion. If the section with MLA contains a dissection, do not include the dissection area in the MLA.

Clinical Investigation

Impact of Baseline and Postprocedural Intravascular Ultrasound Findings on 1-Year Primary Patency After Drug-Coated Balloon Treatment of Femoropopliteal Lesions

Kazunori Horie, MD1, Akiko Tanaka, MD1, Masataka Taguri, PhD2, and Naoto Inoue, MD1

Abstract
Purpose: Drug-coated balloons (DCBs) are commonly used for endovascular treatment of femoropopliteal lesions. We employed intravascular ultrasound (IVUS) to investigate the predictors of restenosis after DCB treatment.

Methods: This prospective and single-center study was performed to examine 1-year primary patency and to identify the risk factors for restenosis by analyzing clinical characteristics, angiographic measurements, and lesion models. We included 107 consecutive patients undergoing DCB treatment for femoropopliteal lesions from July 2009 to March 2012.

Results: The primary patency rate was 92% at 1 year. The annual restenosis rate was 36.7%. The Cox proportional hazards model revealed that restenosis was independently associated with chronic total occlusion (CTO) (p<0.001), lesion length (p<0.001), and lesion area (p<0.001). The optimal cutoff values of postprocedural MLA for preventing 1-year restenosis were 12.7 mm² (sensitivity: 0.87, specificity: 0.89) for CTO, 10.0 mm² (sensitivity: 0.87, specificity: 0.96) for lesion length, and 4.5 mm² (sensitivity: 0.87, specificity: 0.99) for lesion area.

Conclusions: Restenosis after DCB treatment was shown to correlate with CTO, circumference, and postprocedural MLA as evaluated by IVUS. Moreover, smaller vessel sizes might represent a particular DCB strategy due to the difficulty of restoring a sufficient postprocedural lumen area by balloon dilatation.

Keywords
femoropopliteal segment, drug-coated balloon, intravascular ultrasound, endovascular treatment

Introduction

Horie K, J Endovasc Ther. 2022;29(1):66-75
MLA: 14.7 mm²
IN.PACT DCB
Medtronic

PTX 3.5 μg/mm²

IN.PACT RING

POST PTA

POST DCB
LUTONIX DCB
BARD

POST PTA

PTX 2.0 μg/mm²

POST DCB
Masahiko Fujihara MD, Kishiwada Tokushukai Hospital, Osaka, Japan

Ranger DCB
Boston Scientific

POST PTA

PTX 2.0 μg/mm²

POST DCB
78 years Female
R3 Severe Claudication
Dyslipidemia, Past Smoker

CASE 01

JET2022
LIVE case
POST DCB

What is the minimum lumen area?
え？マジで？
Huh? Something's wrong.

MLA 1.5x3.1 (3.3mm²)

MLA 1.37x4.93 (5.7mm²)
With DES strategy, with or without IVUS, no effect on patency rate.
Aneurysmal degeneration was significantly higher in the IVUS group.

Optical Frequency Domain Imaging (OFDI)

Since 2013 OFDI (Terumo) a second-generation OCT technology, has been used in coronary interventions. OFDI can complement the problems of OCT and, in combination with fast spiral pullback (40 mm/s), can image lesions of approximately 15 cm in length at high frame rates, and evaluation of large vessels (up to 9 mm of scan diameter).

The features of OFDI were thought to be useful for peripheral interventions, and a regulatory approval trial was conducted in a small number of patients. Based on the results, **OFDI became commercially available for clinical use in 2021**

Kawamori H.
Lesion Morphology - Fibrous plaques and Soft plaques -

Atherosclerotic plaques present between the IEL and lumen as mass lesions (focal thickening) or loss of the layered vessel wall structure.

Fibrous plaques comprise collagen or smooth muscle cells and present with high backscattering and a relatively homogeneous OCT light signal.

Soft plaques, synonymous with lipid-rich plaques, appear as low-signal-intensity regions with diffuse borders due to considerable light scattering from lipid components.
Lesion Morphology - Calcification Type
as a signal-poor or heterogeneous region with a sharply delineated border (i, ii, and iii may appear mixed)

i) Intimal calcification
ii) Medial calcification
iii) Nodular Calcification

Nodular calcification refers to a high backscattering mass that protrudes into the lumen with strong signal attenuation and an irregular surface.
Lesion Morphology – Thrombus –

A thrombus appears as an intramural mobile mass that either attaches to the luminal surface or floats within the lumen. OFDI can categorize a thrombus as red or white.

**Red thrombus**, rich in red blood cells, appears as an intramural mobile mass protruding into the lumen with high backscattering and attenuation.

**White thrombus**, rich in platelets, appears as an intramural mass with homogeneous backscattering and low attenuation.
Baseline Angiography

Post DCB
Pre | Sc | Xc | Xc braze up | Post DCB
---|---|---|---|---
0.85x2.64mm (1.6mm²) | 0.98x3.25mm (2.9mm²) | 1.88x2.41mm (3.9mm²) | 3.26x4.32mm (11.9mm²) | 4.81x5.23mm (20.0mm²)

MLA analysis
Which areas need Imaging?
NO impact for aort-iliac disease?
In the 12-month restenosis rate was not significantly different between IVUS and Angio groups. IVUS use in aortoiliac lesions may be unnecessary.
Masahiko Fujihara MD, Kishiwada Tokushukai Hospital, Osaka, Japan

81 years old
Female
Severe Claudication
Hypertension
Dyslipidemia
ABI 0/0
P/O breast cancer
Post EVT

ABI 0/0 → 0.82/0.66

Admission 2N3D
Which areas need Imaging?
Now under investigation
How to vessel dilate BTK lesion optimally?

Accurately Identify Vascular Morphology Using IVUS

Optimal balloon size selection Improve the clinical outcomes


23 patients; endovascular procedure for tibial artery due to CLTI (R5).

Both IVUS and OFDI were used for vascular evaluation.

33 BTK Vessels

33 Limbs

27 ATA and 6 PTA

Comparisons
- AltaView (Terumo)
- VisiCube (Terumo)
- Fastview (Terumo)
- Lunawave (Terumo)

Lesion morphology: fibrous plaques, calcification (intimal, medial, nodular), thrombus

Vessel size, lumen size

Endovascular Therapy
Bare Balloon Angioplasty

4 months Clinical Outcomes
primary patency by DUS, TLR, wound healing rates, and all-cause mortality rate.
### OFDI-evaluated infrapopliteal lesion morphology

<table>
<thead>
<tr>
<th>Morphology</th>
<th>% (95% CI)</th>
<th>[n/total]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fibrous Plaque</td>
<td><strong>93.9</strong>% (79.8 - 99.3%)</td>
<td>[31/33]</td>
</tr>
<tr>
<td>Nodule</td>
<td><strong>9.1</strong>% (1.9 - 24.3%)</td>
<td>[3/33]</td>
</tr>
<tr>
<td>Intimal Calcification</td>
<td>42.4% (25.5 - 60.8%)</td>
<td>[14/33]</td>
</tr>
<tr>
<td>Medial Calcification</td>
<td><strong>72.7</strong>% (54.5 - 86.7%)</td>
<td>[24/33]</td>
</tr>
<tr>
<td>Thrombus</td>
<td><strong>48.5</strong>% (30.8 - 66.5%)</td>
<td>[16/33]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Visualize</th>
<th>% (95% CI)</th>
<th>[n/total]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prox.EEM.</td>
<td><strong>29.6</strong>% (13.8 - 50.2%)</td>
<td>[8/27]</td>
</tr>
<tr>
<td>Prox.Lumen.</td>
<td>96.3% (81.0 - 99.9%)</td>
<td>[26/27]</td>
</tr>
<tr>
<td>Mid.EEM.</td>
<td><strong>40.0</strong>% (22.7 - 59.4%)</td>
<td>[12/30]</td>
</tr>
<tr>
<td>Mid.Lumen.</td>
<td>96.7% (82.8 - 99.9%)</td>
<td>[29/30]</td>
</tr>
<tr>
<td>Distal.EEM.</td>
<td><strong>50.0</strong>% (29.1 - 70.9%)</td>
<td>[12/24]</td>
</tr>
<tr>
<td>Distal.Lumen.</td>
<td>96.0% (79.6 - 99.9%)</td>
<td>[24/25]</td>
</tr>
</tbody>
</table>
My algorithm for using IVUS in EVT

**Stenosis**
- **AIA**
  - Measurement of vessel diameter
  - Observation of special conditions
- **FPA**
- **BTK**

**Occlusion**
- **AIA**
  - Use to Cross CTO
- **FPA**
  - Measurement of vessel diameter
  - Observation of special conditions
- **BTK**
  - Not very effective for clinical?

Not required except in special situations
Clinical expert consensus document on standards for lower extremity artery disease of imaging modality from the Japan Endovascular treatment conference

**Short title:** Imaging modality expert consensus document for peripheral intervention


**From the JET Imaging consensus (JEIC) development Task Force**

Masahiko Fujihara Cardiovasc Interv Ther. 2022 Jul 19.
Thank you for your attention

Masahiko Fujihara MD
Kishiwada Tokushukai Hospital
Osaka Japan

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