Luminor DCB makes it different and favourable in CLI (LUMINOR registry, 12-month data)

V. Riambau, MD. PhD,

on behalf of the LUMINOR collaborators
Prof. and Chief of Vascular Surgery Division,
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University of Barcelona
Consultant/Advisor/Research

- Aptus Endosystems
- Bolton Medical
- Cordis
- Medtronic
- iVascular
- Bayer
- MSD
- Ferrer
- GE
- ASTA ZENEKA
- W.L. Gore
- Jotec

Proctor

- Bolton Medical
- Cook
- Medtronic
- W.L. Gore
- Aptus
- Cordis
- Jotec
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• Material and Methods
• Results
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Oceanus 14 and 35 platforms

1. Long tip with high crossing capability
2. Good shape
   - Short Shoulders
3. Quick deflation time
PTX microcrystalline structure
- Dosage: 3 μg/mm²

Excipient: Water Reduced Ester
- Drug/excipient ratio: 80/20

Transfertech® Coating technology. Multilayer, Uniform nanodrops by ultrasonic spray
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Material and Methods

Luminor Registry is an observational, prospective, multicenter study with single-arm treatment for stenotic or occlusive lesions or in-stent stenosis of the femoro-popliteal (FP) and below the knee (BTK) vessels. Clinical trials.gov identifier: NCT02458911

**PRIMARY ENDPOINTS**
To analyse the performance of Luminor 14 and 35 in terms of primary patency, defined as freedom from >50% restenosis as indicated by duplex ultrasound peak systolic velocity ratio (PSVR) <3 in the target vessel with no re-intervention, and freedom of serious adverse events defined as death, amputation and TLR during a minimum of 12-month follow-up period.

**SECONDARY ENDPOINTS**
Include quality of life assessment and other clinical or hemodynamic complications.
Material and Methods

- A total of **207 validated Rutherford 2-5 cases** have been recruited during a 15-month period following an intention to treat basis.
- All the procedures have followed the **instructions for use**.
- Primary stenting or atherectomy were **excluded**.
- **Adjuvant drug treatment** was applied for all patients [Clopidogrel 75 mgr/day + ASA 100 mgr/day (one month) and ASA 100 mgr/day (indefinite)].
## Material and Methods (CLI)

### Demographics

<table>
<thead>
<tr>
<th>Demographics</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with CLI</td>
<td>148</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>101</td>
<td>68.2</td>
</tr>
<tr>
<td>Age (years)</td>
<td></td>
<td>73.2±11.4</td>
</tr>
<tr>
<td>Diabetes</td>
<td>106</td>
<td>71.6</td>
</tr>
<tr>
<td>Smoking and ex-smoking</td>
<td>80</td>
<td>54.0</td>
</tr>
<tr>
<td>Arterial Hypertension</td>
<td>129</td>
<td>87.2</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>85</td>
<td>57.4</td>
</tr>
<tr>
<td>Chronic Renal Failure (stage ≥3)</td>
<td>44</td>
<td>29.7</td>
</tr>
<tr>
<td>Rutherford Class</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>24</td>
<td>16.2</td>
</tr>
<tr>
<td>5</td>
<td>124</td>
<td>83.8</td>
</tr>
</tbody>
</table>
### Lesion characteristics

<table>
<thead>
<tr>
<th>Description</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesions (n)</td>
<td>180</td>
</tr>
<tr>
<td>Lesion length (mm)</td>
<td>77.4±50.3</td>
</tr>
<tr>
<td>Chronic Total Occlusions–CTO (%)</td>
<td>53.9</td>
</tr>
<tr>
<td>Stenosis (%)</td>
<td>46.1</td>
</tr>
<tr>
<td>BTK (%)</td>
<td>48.9</td>
</tr>
<tr>
<td>Severe calcification (%)</td>
<td>56.7</td>
</tr>
</tbody>
</table>
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## Early Results (CLI)

<table>
<thead>
<tr>
<th>30-Days follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>All-cause mortality</td>
</tr>
<tr>
<td>Major amputations</td>
</tr>
<tr>
<td>TLR</td>
</tr>
</tbody>
</table>
Results @ 1 year follow-up
Primary Patency

87.7%
Results @ 1 year follow-up
Survival

LUMINOR registry: CLI subgroup

85.1%
Results @ 1 year follow-up
Freedom from Amputation

LUMINOR registry: CLI subgroup

84.7%
Results @ 1 year follow-up
Freedom from TLR

LUMINOR registry: CLI subgroup

92.1%
Results @ 1 year follow-up
Primary Patency

LUMINOR registry: BTK subgroup

85.9%
Results @ 1 year follow-up
Survival

88.2%
Results @ 1 year follow-up
Freedom from Major amputation

LUMINOR registry: BTK subgroup

79.0%
Results @ 1 year follow-up
Freedom from TLR

89.6%
• Background
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Summary

• REAL WORLD experience with LUMIMOR DCB is highly positive in terms of safety and effectiveness even in patients with a very poor clinical and anatomical conditions.
<table>
<thead>
<tr>
<th>Hospital</th>
<th>PI</th>
<th>Collaborator 1</th>
<th>Collaborator 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>1- H. Getafe</td>
<td>Dr. Francisco Acín</td>
<td>Dra. Cristina Cañibano Domínguez</td>
<td>Dr. Ignacio Michel Guisasola</td>
</tr>
<tr>
<td>2- H. La Paz</td>
<td>Dr. Luis Riera del Moral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3- H. Clínica</td>
<td>Dr. Vicente Riambau</td>
<td>Dr. Xavier Yugueros</td>
<td>Dr. Gaspar Mestres</td>
</tr>
<tr>
<td>4- H. Parc Taulí</td>
<td>Dr. Antonio Giménez Gaibar</td>
<td>Dra. Sara Rioja Artal</td>
<td></td>
</tr>
<tr>
<td>5- H. Ourense</td>
<td>Dr. Nilo Mosquera Arochena</td>
<td>Dr. Ignacio García Fernández</td>
<td>Dra Rebeca Vazquez Dopazo</td>
</tr>
<tr>
<td>6- H. Asturias</td>
<td>Dr. Manuel Alonso</td>
<td>Dra. Carol Padron Encalada</td>
<td></td>
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<tr>
<td>7- H. Burgos</td>
<td>Dr. Francisco Medina</td>
<td>Dr. Ignacio Agúndez Gómez</td>
<td>Dra. Monica Herrero Bernabé</td>
</tr>
<tr>
<td>8- H. Basurto</td>
<td>Dra Reyes Vega</td>
<td>Dr. Ricardo Asensio García</td>
<td>Dra. Esther Bravo Ruiz</td>
</tr>
<tr>
<td>9- H. Donostia</td>
<td>Dr. Mariano Juan de Blas Bravo</td>
<td>Dra. Ainhoa Garcia</td>
<td>Dr. Jose María Egaña</td>
</tr>
<tr>
<td>10- H. Cruces</td>
<td>Dr. Juan Luis Fonseca Legrand</td>
<td>Dra. Ana Apodaka</td>
<td>Dra. Ederi Mikelarena Monteiro</td>
</tr>
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