Peripheral CTO treatment – clinical experiences with rapid-exchange devices

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Disclosures

Speaker name:

**Michael Lichtenberg**

I have the following potential conflicts of interest to report:

- [x] Consulting (CR Bard, Biotronik, COOK, Optimed, Straub Medical, Terumo, Volcano, Boston)
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)

- [x] I do not have any potential conflict of interest
Background

- There is growing evidence that long SFA and BTK lesions revascularisations can be performed safely with good primary and secondary patency rates
- Challenging situations in
  - Chronic limb ischemia
  - CTO with severe calcification
Rapid exchange / Monorail technique

Established in endovascular procedures

– Interventional cardiology for decades

– Endovascular therapy for carotid interventions

– Endovascular treatment of renal artery stenosis and visceral artery interventions
PRO and CON of RX technique

**PRO**

- Low crossing profile
- Short guide wires needed
- Fast exchange of devices
  - Maybe reduced radiation dose
  - Maybe saver for patients

**CON**

- Modern OTW devices also have low crossing profile
- Low pushability for calcified lesions, kinking of iliac arteries and CTO (long SFA land BTK lesion)
MISAGO Stent System

- Low stress concentration
- Resistance against bending, compression and torsion
- Low fracture rate in MISAGO Trials
- One hand accurate positioning
- Less resistance at stenting
More than 5000 pts worldwide undergoing or planned in studies with Misago in SFA and popliteal arteries

Misago 1 EU
- 55 pts
- Single arm
- Primary Endpoint: TLR@6M
- Published 2012

Misago 2 EU
- 744 pts
- Single arm
- Primary Endpoint: TLR@6M
- Published 2013

Osprey JP
- 100pts
- Randomized 1:1 vs POBA
- TCT 2014

E-MISAGO EU
- 3331pts
- Single arm all comers registry
- Primary Endpoint: Patency@12M
- Ongoing

BATTLE EU
- 186 pts
- Randomized 1:1 vs Zilver PTX
- Primary Endpoint: Freedom for in-stent restenosis@12M
- Ongoing

RX registry EU
- 525 pts
- Single arm
- Ongoing

OSPREY USA
- 200 pts
- Single arm
- Primary Endpoint: TLR@12M
- Ongoing

More than 5000 pts worldwide undergoing or planned in studies with Misago in SFA and popliteal arteries
The MISAGO Registries in EU

TLR 10.1% at 1 year
Mean LL 63.9 mm

744 patients

-55 patients
## Stent fracture rate

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Misago 1</td>
<td>1.7 %</td>
</tr>
<tr>
<td>Misago 2</td>
<td>3.1 %</td>
</tr>
<tr>
<td></td>
<td>Numbers Tested: (Bending/Compression/Torsion)</td>
</tr>
<tr>
<td>------------------</td>
<td>---------------------------------------------</td>
</tr>
<tr>
<td>Misago</td>
<td>5/5/5</td>
</tr>
<tr>
<td>Absolute</td>
<td>3/3/1</td>
</tr>
<tr>
<td>Smart</td>
<td>3/3/1</td>
</tr>
<tr>
<td>Luminexx</td>
<td>3/3/1</td>
</tr>
<tr>
<td>Sentinol</td>
<td>3/3/1</td>
</tr>
<tr>
<td>LifeStent</td>
<td>1/1/1</td>
</tr>
<tr>
<td>Sinus-SuperFlex</td>
<td>1/1/1</td>
</tr>
</tbody>
</table>
MISAGO RCT - Japan OSPREY

Occlusive/Stenotic Peripheral artery REvascularization study

- Multi-center/multi-national, prospective study for SFA disease
- JP arm: randomized trial comparing PTA
- 100% data independent monitoring
- Independent Core Lab in USA
- PTA as a control arm – standard of care (regulatory study)
## MISAGO RCT - Japan

### Baseline lesion characteristics

<table>
<thead>
<tr>
<th>Items</th>
<th>Control-arm</th>
<th>Stent-arm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesion length</td>
<td>79.2+-46.0</td>
<td>79.2+-38.3</td>
</tr>
<tr>
<td>&lt;80mm</td>
<td>51%</td>
<td>49%</td>
</tr>
<tr>
<td>&gt;80mm</td>
<td>49%</td>
<td>51%</td>
</tr>
<tr>
<td>RVD (mm)</td>
<td>5.1+-0.9</td>
<td>5.0+-0.8</td>
</tr>
</tbody>
</table>

### TASC classification

<table>
<thead>
<tr>
<th></th>
<th>TASC A</th>
<th>TASC B</th>
<th>TASC C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control (%)</td>
<td>49.0</td>
<td>43.1</td>
<td>7.8</td>
</tr>
<tr>
<td>Stent (%)</td>
<td>55.1</td>
<td>42.9</td>
<td>2.4</td>
</tr>
</tbody>
</table>
### MISAGO RCT - Japan

#### Results: Freedom from TLR

<table>
<thead>
<tr>
<th></th>
<th>30Days</th>
<th>12Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stent (%)</td>
<td>100.0 (48/48)</td>
<td>83.3 (8/48)</td>
</tr>
<tr>
<td>Bailout (%)</td>
<td>100.0 (23/23)</td>
<td>82.6 (4/23)</td>
</tr>
<tr>
<td>PTA (%)</td>
<td>54.9 (28/51)</td>
<td>47.1 (27/51)</td>
</tr>
</tbody>
</table>

#### Results: Safety at 1 yr

<table>
<thead>
<tr>
<th></th>
<th>Death</th>
<th>Amputaions</th>
<th>Stent thrombosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stent (%)</td>
<td>2 (1/50) *</td>
<td>0 (0/50)</td>
<td>0 (0/50)</td>
</tr>
<tr>
<td>Bailout (%)</td>
<td>0 (0/23)</td>
<td>0 (0/23)</td>
<td>0 (0/23)</td>
</tr>
<tr>
<td>PTA (%)</td>
<td>0 (0/28)</td>
<td>0 (0/28)</td>
<td>-</td>
</tr>
</tbody>
</table>

*AMI
MISAGO RCT - Japan
Fracture rate of Misago

As evaluated by independent core lab outside Japan

No Fracture was observed
Prospective, real-life, non-randomized multicenter registry using the Misago RX nitinol stent

434 pts. out of 3,331 enrolled in 85 hospitals in 20 EU countries had calcified lesions in SFA longer than 80mm

**Primary endpoints:**

- Freedom from all causes of death, index limb amputation and target lesion revascularization within 30 days
- Target Vessel Patency at 1 year
# SFA (Long; Ca$^{+2}$)-lesion types

<table>
<thead>
<tr>
<th></th>
<th>SFA (Ca$^{+2}$,&gt;80mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lesion Length (mm)</strong> *</td>
<td>120 [88;200] N=437</td>
</tr>
<tr>
<td><strong>RVD (mm)</strong></td>
<td>5.7±0.7 N=437</td>
</tr>
<tr>
<td><strong>DS (%)</strong></td>
<td>93.5±9.8 N=437</td>
</tr>
</tbody>
</table>

*Median with 25 and 75 percentiles
SFA (Long; Ca$^{+2}$)-results

Safety and Effectiveness up to 1 year *

<table>
<thead>
<tr>
<th>Event</th>
<th>12 M FUP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>2.8</td>
</tr>
<tr>
<td>Cardiac</td>
<td>1.2</td>
</tr>
<tr>
<td>Vascular</td>
<td>0.2</td>
</tr>
<tr>
<td>TLR</td>
<td>7.6</td>
</tr>
<tr>
<td>TVR / non-TLR</td>
<td>1.2</td>
</tr>
<tr>
<td>Amputation</td>
<td>1.6</td>
</tr>
<tr>
<td><strong>Primary Patency (%)</strong></td>
<td><strong>90.3</strong></td>
</tr>
</tbody>
</table>

* Per patient analysis: for multiple events only the first event per patient is counted

**Primary Patency – defined as stenosis < 50 %* on DUS (PSVR <2.4) or absence of TLR
Consistent growing clinical evidence coming from randomised clinical studies and registries from different geographies confirms the value of Misago stent in treating long and calcified lesions in SFA and popliteal arteries.

The results of observed patency, symptom improvement and stent fractures are highly comparable to published data.
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- Vascular Center, Arnsberg Clinic, Arnsberg, Germany

Faculty:
Prof. Marianne Brodmann, Prof. Thomas Zeller
Dr. Michael Lichtenberg, Dr. Wilhelm Stahlhoff
PD Dr. Andrej Schmidt, Prof. Giovanni Torsello
Prof. Karl-Ludwig Schulte

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Peripheral CTO treatment –
clinical experiences with rapid-exchange devices

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