Interim Report of the BIOFLEX-COF RCT - comparing high vs low chronic outward force of nitinol stents in the SFA

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Disclosure

Speaker name:

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I have the following potential conflicts of interest to report:

Travel support, Speakers Bureau, Consulting:

Cook, Biotronik, Bolton Medical
Background – what is COF?

COF is:

Force exerted by a nitinol stent on the vessel wall

Chronic: after pre- and postdilatation
Background – how big is COF?

COF depends on:

- Oversizing (stent size vs. vessel size)
  - (operator dependent, every mm)
- Stent Material
  - „stiffness“ of the stent (a.k.a. „spring constant“)
- Irregularities in the lesion
  - After pre and postdilatation
COF differs in lesions

Nominal Stent Diameter

Stent placement

After balloon post-dilatation
Study Hypothesis:

Oversizing/stiffer stents → high COF → neointimal hyperplasia → early restenosis
Swine data

28 days FUP

Astron Pulsar – 8.78
Lifestent – 17.02

Soft (Pulsar-18)

Stiff (LifeStent)

90 days FUP

Astron Pulsar – 6.9
Lifestent – 19.32
VIPER – lessons learned
Patients & Lesions

<table>
<thead>
<tr>
<th>High COF</th>
<th>Low COF</th>
</tr>
</thead>
<tbody>
<tr>
<td>40 Patients</td>
<td>40 Patients</td>
</tr>
<tr>
<td>63% male</td>
<td>68% male</td>
</tr>
<tr>
<td>68yrs</td>
<td>69yrs</td>
</tr>
<tr>
<td>55% smokers</td>
<td>43% smokers</td>
</tr>
<tr>
<td>108mm lesion</td>
<td>148mm lesion</td>
</tr>
<tr>
<td>30% occl</td>
<td>43% occl</td>
</tr>
<tr>
<td>AFS 5,08mm</td>
<td>5,16mm</td>
</tr>
<tr>
<td>BTK 10/40</td>
<td>BTK 9/40</td>
</tr>
<tr>
<td>ABI 0,63</td>
<td>ABI 0,64</td>
</tr>
</tbody>
</table>
COF Measurement

Diameter (mm)

COF (N/mm²)

- BIOTRONIK Pulsar 7/150
- BARD Lifestent FlexStar (XL) 7/150

Diameter (mm)
COF (partial sample)

- LifeStent
- Pulsar-18
Outcome parameter

Lumen diameter at CT-Angio measured at every mm
Conclusion

• 1st RCT to assess COF in nitinol stents
• Implantation successful
• COF difference between groups approx 3x
• Recruitment completed

• 1yr data hopefully available @ LINC 2019.