Differences in clinical outcomes of low COF stent vs high COF stent proven in clinical practice

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Disclosure

Speaker name:

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I have the following potential conflicts of interest to report:

☑ Speaker fees, travel support, research grant: Biotronik
Low vs High COF Stents
Animal Study

COF Correlation to Neointimal Area, Results After 28 and 90 Days

Low-COF vs High COF stent in porcine iliac arteries

28d Cohort: Hybrid Landrace-Yorkshire
90d Cohort: Yucatan Mini Swine

Neointimal area measured at histologic cross-sections

Funovics et al: publication in progress
Low vs High COF Stents - clinical Study

30 Patients, retrospective analysis after de-novo SFA stenting with low-COF Stent

1yr – 2yr post implantation with CT or Angio available

Martin Funovics, unpublished data

Pearson correlation: 0.465, p<0.01
Study Hypothesis:

Oversizing/stiffer stents $\rightarrow$ high COF $\rightarrow$
neointimal hyperplasia $\rightarrow$
early restenosis
BIOFLEX-COF
(chronic outward force)

investigator initiated
blinded
prospective randomised (2 groups)
de-novo SFA lesions
primary nitinol stenting
high vs. low COF
2 groups:

- Low-COF stent: Biotronic Pulsar
  - minimal oversizing, „soft“ expansion curve

- High-COF Stent: (Bard Life Stent)
  - 1-2mm oversizing, „stiff“ expansion curve
Diameter vs. COF

The graph illustrates the relationship between stent diameter and COF (Coefficient of Friction) for different stent types. The x-axis represents the stent diameter in millimeters, and the y-axis represents the COF in N/mm. The graph shows curves for various stent types, including Biotronik Pulsar-18 (6 x 100), BARD LifeStent XL (6 x 100), Boston Scientific Innova (6 x 100), Cook Zilver Flex (6 x 100), and Medtronic EverFlex Entrust (6 x 100). Two circles indicate specific points on the graph for 2mm oversize and 1mm oversize conditions.
Outcome Variable

- % of restenosis measured at CT-Angiography
- NOT: binary restenosis (too insensitive)
- NOT: doppler US (operator-dependent)
- NOT: TLR (patient-dependent & insensitive)

Discrete variable, 15-100 values per patient
Measurement of stent diameter
Measurement of lumen diameter
Results at 1 yr:
Chronic outward force
Restenosis
Restenosis in %
Log (restenosis) in mm²

Intima hyperplasia logarithmized

Frequencies

LifeStent

Pulsar

-2.00

0.0

2.00

4.00

0.0

100.0

200.0

300.0

400.0

0.0

100.0

200.0

300.0

400.0
## Mean & absolute Restenosis in %

<table>
<thead>
<tr>
<th></th>
<th>High COF</th>
<th>Low COF</th>
<th>P-Value</th>
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</thead>
<tbody>
<tr>
<td><strong>Mean Restenosis (%)</strong></td>
<td>35.43±30.91</td>
<td>26.21±24.71</td>
<td>&lt;0.001 t-test &amp; Mann–Whitney U test</td>
</tr>
<tr>
<td><strong>Absolute Restenosis (mm²)</strong></td>
<td>2.73±2.70</td>
<td>1.75±1.90</td>
<td>&lt;0.001 t-test &amp; Mann–Whitney U test</td>
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</tbody>
</table>
Subgroups & correlations
Conclusion

• BIOFLEX-COF:
  – 1st RCT to assess COF
  – Generous inclusion criteria, “real-world data”
  – 4x difference in COF between groups
  – Sig. lower restenosis in low COF group
  – Clinically relevant amount (26% vs 35%) at 1 year
Differences in clinical outcomes of low COF stent vs high COF stent proven in clinical practice

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