SUPERA STENT VS NITINOL STENTS FOR CHRONIC TOTAL OCCLUSIONS OF THE FEMOROPOPILITEAL ARTERY: THE SUPERFAST STUDY

Dr. Konstantinos Katsanos, MSc, MD, PhD, EBIR
Asst. Prof. Interventional Radiology
School of Medicine, Patras University Hospital, GR
Honorary Consultant Interventional Radiologist
Guy’s and St. Thomas’ Hospitals, London, UK

Conflicts of interest
- Research support from ABBOTT

Chronic total occlusions
- Approx. 1/3 of infrainguinal lesions
- More frequent in advanced CLI patients
- Complex recanalization – often subintimal
- Lower crossing and success rates
- More prone to recoil and stenting
- Higher plaque volume – frequently calcified
- Higher rate of restenosis and stent failure

Hong SJ, et al. Outcomes of stenting long chronic total occlusions of the femoropopliteal artery. JACC CI. 2015

HYPOTHESIS: The SUPERA biomimetic stent may conform and perform better than old nitinol stents in femoropopliteal CTO lesions

INCLUSION CRITERIA
- Femoropopliteal segment (P2 and P3 allowed)
- Chronic total occlusions ONLY (any length)
- Subintimal or intraluminal (+/- re-entry)
- At least single vessel run-off
- Matching to historical control (n=175)
- Restenosis (by Duplex PSVR 2.4) @1 year
- Major adverse limb events (MALE) @1 year

Stent design evolution

SUPERFAST design

PS matching
- Propensity scores
- 1:1 matching
- Nearest neighbour
- Caliper 0.2
- IBM SPSS v.23 (R)
- Kaplan Meier (390d)
- Hazard Ratio (95% CI)
### Standardized differences

#### Unmatched
- 107 Control
- 68 SUPERA

#### Matched
- 53 Control
- 53 SUPERA

### Baseline variables (matched)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Control (n=53)</th>
<th>SUPERA (n=53)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>73.2±12.1 (50-94)</td>
<td>75.8±10.0 (55-94)</td>
<td>0.363</td>
</tr>
<tr>
<td>Gender (male)</td>
<td>32/53 (60.4%)</td>
<td>34/53 (64.2%)</td>
<td>0.690</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>30/53 (56.6%)</td>
<td>30/53 (56.6%)</td>
<td>1.000</td>
</tr>
<tr>
<td>Hypertension</td>
<td>44/53 (83.0%)</td>
<td>43/53 (81.1%)</td>
<td>0.801</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>33/53 (62.3%)</td>
<td>33/53 (62.3%)</td>
<td>1.000</td>
</tr>
<tr>
<td>Smoking habit</td>
<td>59/53 (55.1%)</td>
<td>35/53 (51.5%)</td>
<td>0.121</td>
</tr>
<tr>
<td>Chronic kidney disease</td>
<td>24/53 (45.3%)</td>
<td>21/53 (39.6%)</td>
<td>0.557</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>31/53 (58.5%)</td>
<td>29/53 (54.7%)</td>
<td>0.696</td>
</tr>
<tr>
<td>Rutherford stage</td>
<td>4.3±1.1 (3-6)</td>
<td>4.3±1.0 (3-6)</td>
<td>0.658</td>
</tr>
<tr>
<td>Popliteal artery lesion</td>
<td>19/53 (35.8%)</td>
<td>18/53 (34.0%)</td>
<td>0.839</td>
</tr>
<tr>
<td>Subintimal recanalization</td>
<td>37/53 (69.8%)</td>
<td>30/53 (56.6%)</td>
<td>0.161</td>
</tr>
<tr>
<td>Total occlusion length (cm)</td>
<td>15.0±10.0 (2-40)</td>
<td>14.3±10.4 (2-40)</td>
<td>0.610</td>
</tr>
<tr>
<td>Baseline run-off score</td>
<td>1.6±0.9 (0-3)</td>
<td>1.6±0.9 (0-3)</td>
<td>0.939</td>
</tr>
<tr>
<td>Completion run-off score</td>
<td>1.7±0.8 (0-3)</td>
<td>1.8±0.7 (0-3)</td>
<td>0.827</td>
</tr>
<tr>
<td>Number of stents</td>
<td>1.6±0.7 (1-4)</td>
<td>1.7±0.8 (1-4)</td>
<td>0.444</td>
</tr>
<tr>
<td>Overlapping stents</td>
<td>21/53 (39.6%)</td>
<td>27/53 (50.9%)</td>
<td>0.244</td>
</tr>
<tr>
<td>Stent diameter (mm)</td>
<td>6.1±0.4 (4-7)</td>
<td>5.3±0.6 (5-7)</td>
<td>0.000</td>
</tr>
<tr>
<td>Total stent length (cm)</td>
<td>18.5±11.2 (4-40)</td>
<td>22.5±10.8 (6-46)</td>
<td>0.033</td>
</tr>
<tr>
<td>Dual antiplatelet therapy</td>
<td>30/53 (56.6%)</td>
<td>35/53 (66.0%)</td>
<td>0.321</td>
</tr>
<tr>
<td>Anticoagulation therapy</td>
<td>7/53 (13.2%)</td>
<td>10/53 (18.9%)</td>
<td>0.429</td>
</tr>
</tbody>
</table>

### Restenosis (>50%)

- Log rank = 0.008
- Baseline = 0.000
- HR (95%CI) = 0.40 (0.20-0.79)

60% reduction of risk of restenosis

### Restenosis subgroups

- SFA/P1(excl.P2+P3) intraluminal

<table>
<thead>
<tr>
<th>Time (days)</th>
<th>Control</th>
<th>SUPERA</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>88%</td>
<td>56%</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>88%</td>
<td>57%</td>
<td></td>
</tr>
</tbody>
</table>

60% reduction of risk of restenosis

### Baseline imaging

- long SFA occlusion

- RIGHT crossing balloon SUPERA
FUP @15 months

Recurrent limb ischemia

Log rank = 0.020
Breslow = 0.010
HR (95%CI) = 0.40 (0.18-0.85)
60% reduction of recurrent ischemia

Log rank = 0.125
Breslow = 0.147
HR (95%CI) = 0.23 (0.05 – 1.36)

Log rank = 0.048
Breslow = 0.028
HR (95%CI) = 0.47 (0.23-0.98)
53% reduction of MALE events

Major amputations

Patient survival

Amputation-free survival

MALE events
(freedom from TLR, major amputation, or recurrent limb ischemia)
**Conclusions**

- SUPERA reduced the hazard of vessel restenosis and recurrent ischemia by ≈ 60%.
- SUPERA showed numerically less major amputations at 1 year.
- SUPERA significantly reduced the hazard of MALE events by ≈ 55%.
- SUPERA is the stent of choice for CTO lesions.

**The SUPERFAST team**