Evaluation of the Physiologic Characteristics of Drug-Eluting Stents at Implantation and During Follow-up

Marcel van ’t Veer1,2, Nico Pijls1,2, Wilbert Aarnoudse1,2, Jacques Koolen2, Frans van de Vosse1
Department of Biomedical Engineering, Medical engineering
1Eindhoven University of Technology, Eindhoven, The Netherlands, 2Catharina Hospital, Eindhoven, The Netherlands

Introduction
Drug-eluting stents have been introduced with the prospect of a considerable reduction of the restenosis rate after percutaneous coronary intervention (PCI). The restenosis rate after stent placement can be reduced from approximately 20% with bare metal stents (Bx VelocityTM) to approximately 10% when using drug-eluting stents (CypherTM).

The aim of this study was to investigate physiologic parameters like fractional flow reserve (FFR), hyperemic stent gradient (HSG), and shear stress at implantation and during six-month follow-up.

Methods
Twenty patients accepted for PCI of at least two coronary arteries with comparable vessel- and stenosis characteristics received one drug-eluting (Cypher) and one bare metal stent (Bx Velocity) of comparable length and diameter. Coronary pressure, FFR, and trans-stent gradients were measured just after stent implantation and at 6-month follow-up. Coronary wall shear stress was calculated from QCA, coronary flow velocity, and blood viscosity just after stent implantation and at 6-month follow-up.

Results
Just after stent implantation no differences were seen between the two stents. In contrast, after six months the FFR (table 1) as well as the HSG (table 2) were significant higher in the Cypher stent with respect to the Bx Velocity stent. Moreover, the diameter within the stent remained larger in the Cypher stent. Consequently the shear stress was more homogeneously distributed throughout the Cypher stent (fig.2).

Conclusions
The drug-eluting Cypher stent shows significant better physiologic characteristics at six months in comparison to the bare metal Bx Velocity stent, respectively a higher FFR, higher HSG and a more homogeneous shear stress were found.

Table 1: FFR just after stent implantation and at six-month follow-up.

<table>
<thead>
<tr>
<th>FFR</th>
<th>Cypher</th>
<th>Bx Velocity</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Just after implantation</td>
<td>0.90±0.06</td>
<td>0.88±0.67</td>
<td>P=0.525</td>
</tr>
<tr>
<td>6-month follow-up</td>
<td>0.91±0.05</td>
<td>0.83±0.10</td>
<td>P=0.014</td>
</tr>
</tbody>
</table>

Table 2: HSG just after stent implantation and at six-month follow-up.

<table>
<thead>
<tr>
<th>HSG</th>
<th>Cypher</th>
<th>Bx Velocity</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Just after implantation</td>
<td>0.97±0.02</td>
<td>0.96±0.04</td>
<td>P=0.152</td>
</tr>
<tr>
<td>6-month follow-up</td>
<td>0.99±0.01</td>
<td>0.91±0.09</td>
<td>P=0.01</td>
</tr>
</tbody>
</table>

Figure 1: Representation of a drug-eluting stent. The cross-section schematically shows the stent-structure with the coating containing the drug.

Figure 2: Shear stress calculated at three positions for both stents after six months. The averaged values for the shear stress differ significantly (P=0.034).

Average shear stress 1.7±0.7 Pa

Average shear stress 2.6±1.5 Pa