New Bifurcation Stent – Long Term Outcomes

Alan Yeung, M.D.
Angioplasty Summit 2003
Atherosclerosis at Coronary Bifurcations

Plaques tend to be concentrated at bifurcations or bends, where local alterations in shear stress, flow separation, turbulence, and stasis are known to occur."

Location of Restenosis

- 0% in-stent restenosis in the main
- 15.9% in-stent restenosis in the side branch
- 12 of 13 restenoses occurred in ostium of side branch
SLK-View™ System

- Size 3.0/3.5mm
- Side aperture: 2.5 /3.0mm
- Stent length-17 mm
- 316 L Stainless steel
- Balloon expandable
- 4 marker system

Flexible marker

Radiopaque Markers
Proximal stent profile – 0.074”.
Distal stent profile – 0.055”.
Closed cell design.
Laser-cut 316L stainless steel.
Balloon expandable.

### Catalog Number | Stent Length | Stent Diameter | Side Hole Opening
--- | --- | --- | ---
3025 OTW | 17 mm | 3.0 mm | 2.5 mm
3530 OTW | 17 mm | 3.5 mm | 3.0 mm

CE marked approved.
SLK-View™ Stent and Delivery system

Over The Wire (OTW) delivery system

Advantages:
1. Automatically aligns to vessels of various sizes and take-off angles
2. Accurate side branch with the dual-lumen catheter and delivery system
3. Prevents wire crossing
4. Ease of use
5. Proper stent placement validated by four markers
SLK-View™ Stent and Delivery system

- Dual Side Rapid Exchange (DSX™) Delivery System

Dual Side Rapid Exchange 3-wire Technique

Patient and lesion characteristics:

- 52-year old male
- LAD/D2
- Reference: 3.0 mm
- Side branch: 2.0 mm

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Miguel Perez Carreno Hospital, Caracas, Venezuela.
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Dual Side Rapid Exchange (DSX™) Delivery System

Dual Side Rapid Exchange 3-wire Technique

- Place the main vessel wire in the main vessel and the safety wire (optional) in the side branch.
- Pre-dilate the side branch vessel (optional).
- Pre-dilate the main vessel.
- Place the side branch wire in the main vessel.
- Advance the SDS to the proximal position of the bifurcation.
- Pull the side branch vessel wire and negotiate to the side branch vessel.
- Insert the side branch wire into the side branch vessel.
- Withdraw the safety wire.
- Advance the SDS to the bifurcation until the side sheath marker separates from the center marker and deploy stent.

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Study objectives:
To determine the safety and performance of the SLK-View™ System for treatment of patients presenting bifurcation lesion of a main coronary artery and collateral side-branch vessel.

Study design:
Prospective, non-randomized, multicenter trial at 4 sites (Germany, Italy, South Korea & Venezuela).

Study duration:
6 months clinical & angiographic follow-up.
Primary endpoints:

**Determination of device success -**
- Attaining < 50% residual diameter stenosis of target vessel.
- Successful stent deployment and delivery system removal.

**Determination of procedural success -**
- Attaining < 50% residual diameter stenosis of target vessel, [Angiographic success].
- In-Hospital MACE rate.

Secondary endpoints:
- Out-of-hospital (30 days & 6 months) MACE rate.
- Re-stenosis at 6 months.
Data collection:
• At baseline (clinical)
• At 1 month (clinical follow-up)
• At 6 months (clinical and angiographic follow-up).

Inclusion criteria (angiographic):
• Primary reference vessel 3.0 to 3.5 mm (visual estimation).
• Target lesion located within parent native coronary artery.
• Target lesion length 10 mm - <17 mm (visual estimation).
• Side branch >2 mm diameter located within the lesion.
• Target lesion stenosis of ≥ 50% and ≤ 100%

Exclusion criteria (angiographic):
• Significant unprotected left main disease. Target lesion is in left main coronary artery or within 2 mm of the origin of the LAD, LCX or RCA.
• Excessive vessel tortuosity or calcification.
• Intraluminal thrombus within target vessel.
• Side branch requires treatment.
<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patients</strong></td>
<td>81 patients</td>
</tr>
<tr>
<td><strong>Lesions</strong></td>
<td>84 lesions</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td>Male - 76.2% : Female - 23.8%</td>
</tr>
<tr>
<td><strong>Mean Age</strong></td>
<td>58.2 ± 9.7</td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td>Asian: 61.7%, Caucasian: 27.2%, Hispanic:11.1%</td>
</tr>
<tr>
<td><strong>CAD Risk Factors</strong></td>
<td>Previous MI: 25%, Hypertension: 38%, Diabetes: 17.5%, Hyperlipidemia: 30%, Smoking: 31.2%</td>
</tr>
</tbody>
</table>
SLK View™ OUS Trial

Patients characteristics & demographics:

Enrollment by CCS Classification

<table>
<thead>
<tr>
<th>Class</th>
<th>% of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>49</td>
</tr>
<tr>
<td>II</td>
<td>32</td>
</tr>
<tr>
<td>III</td>
<td>17</td>
</tr>
<tr>
<td>IV</td>
<td>2</td>
</tr>
</tbody>
</table>
Lesion characteristics:

Target Lesion Distribution

- **LAD**: 64%
- **LM**: 14%
- **RCA**: 11%
- **CX**: 11%
Lesion characteristics:

Target lesion characteristics by QCA – Quantitative Coronary Angiography (LM cases excluded).

<table>
<thead>
<tr>
<th></th>
<th>Target vessel</th>
<th>Side branch</th>
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<tbody>
<tr>
<td>Length (mm)</td>
<td>10.84 ± 4.56</td>
<td>-</td>
</tr>
<tr>
<td>Diameter (mm)</td>
<td>3.11 ± 0.47</td>
<td>2.21 ± 0.38</td>
</tr>
<tr>
<td>MLD (mm) Minimum Luminal Diameter</td>
<td>1.07 ± 0.47</td>
<td>1.24 ± 0.61</td>
</tr>
<tr>
<td>Diameter Stenosis (%)</td>
<td>64.2 ± 14.54</td>
<td>39.43 ± 24.85</td>
</tr>
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Results: Side branch treatment

| Stent in side-branch         | 22%                |
| No stent in side-branch      | 78%                |
SLK View™ OUS Trial

Results: Acute outcome and in-hospital MACE

- 97.5% Device Success
- 98.8% Angiographic Success
- 98.8% Procedural Success
- 100.0% Side branch accessibility post deployment
- 1.2% in Hospital MACE
Results: In-hospital MACE in various trials

- 1.2% AST 2002
- 5.0% Lefevre et al. 2001 *
- 7.2% Suwaidi et al. 2001 **


Results: 6 months re-stenosis rate (%)

- 32.6% Side branch
- 27.9% Parent vessel
Results: Restenosis rates for bifurcation lesions in various trials

- 63% Sheiban et al. ***
- 45% Brener et al. **
- 56% Yamashita et al. *
- 27.9% AST 2002


Results: 6 months MACE rate (%)
Proximal Ostial Coverage Stent
Slit Concept

- A side aperture stent designed to expand radially and outwardly into the side branch.
- Provides stenting of the proximal ostial lesion.
- Same delivery systems as SLK-View stent.
- Easy to align.
- Comply with side branch take off angle up to about 45°
- Kissing balloons is required.
True Bifurcation Stent
Tulip Concept

- Treats all the bifurcation ostium and allows for drug delivery to this area.

- A crown structure that is lifted into the side branch and expanded.

- The crown is expanded with unique spear head balloon.
END