Axxess for left main stenting

Eulogio García
Axxent LMCA Trial

- **Design:** Multi center pilot study to evaluate the AXXENT stent (LM Bifurcated Coronary Stent System)

- **Objective:** To evaluate the feasibility and safety of LMCA stenting with AXXENT stent

- **Principal investigator:** Eberhard Grube, MD Helios Heart Center, Siegburg, Germany

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Clinical FU at 6 months in 100% (N=33)

Angiographic FU at 6 months in 93.9% (N=31)

IVUS FU at 6 months in 84.8% (N=28)

Clinical FU at 12 months in 93.9% (N=31)

33 patients enrolled in 4 clinical sites in Europe
### Axxent LMCA Trial: Procedure Outcomes

<table>
<thead>
<tr>
<th>N procedures</th>
<th>33</th>
</tr>
</thead>
<tbody>
<tr>
<td>AXXENT stent device success</td>
<td>30 (90%)*</td>
</tr>
<tr>
<td>Lesion Success</td>
<td>32 (97%)</td>
</tr>
<tr>
<td>Procedure Success</td>
<td>31(94%)</td>
</tr>
<tr>
<td><strong>Stent Distribution Pattern (N, %)</strong></td>
<td></td>
</tr>
<tr>
<td>AXXENT stent only</td>
<td>2 (6.1%)</td>
</tr>
<tr>
<td>AXXENT stent in LM+ Cypher in Cx</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>AXXENT stent in LM+ Cypher in LAD</td>
<td>3 (9.1%)</td>
</tr>
<tr>
<td>AXXENT stent in LM+ Cypher in both Cx &amp; LAD</td>
<td>27 (82%)</td>
</tr>
</tbody>
</table>

*All three deployment failures occurred in 12 mm model- stent too long for vessel*
Axxent LMCA Trial: Stent Distribution Patterns

LM only 6.1% (2/33)

LM + LCX: 0%

LM + LAD: 9.1% (3/33)

LM + LCX + LAD: 82% (27/33)
### 6 Months Angiographic Outcomes

<table>
<thead>
<tr>
<th>N=31 Patients</th>
<th>Left Main</th>
<th>LAD</th>
<th>LCX</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post Procedure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MLD (mm)</td>
<td>3.63 ± 0.37</td>
<td>2.65 ± 0.41</td>
<td>2.47 ± 0.41</td>
</tr>
<tr>
<td>%DS</td>
<td>9.6 ± 5.3</td>
<td>± 6.7</td>
<td>14.6 ± 6.6</td>
</tr>
<tr>
<td>Acute Gain (mm)</td>
<td>1.80 ± 0.84</td>
<td>0.82 ± 0.71</td>
<td>0.96 ± 0.58</td>
</tr>
</tbody>
</table>

### 1 Year Clinical Outcomes

- **AXXENT LMCA trial**
  - No restenosis in the AXXENT stent.

The AXXENT stent is not CE approved and not available in any country.
Lessons from the Axxent LMCA trial

- No restenosis and or late loss in AXXENT stent.

- Restenosis and late loss in LCX elevated compared to LAD, possibly related to underdeployed stents and vessel angulation.

- No late stent thrombosis observed through 12 months FU
CASE 1

- 60-year-old-man, DM 2, HTA, smoker.
- NSTE-ACS with PCI to middle LAD in 2012 (Promus 2.25x16 mm).
- Residual LVSF 35%
- Admitted for surgical intervention of diabetic foot isquemia.
• EBU 3,5 7 French guiding catheter
• 2 BMW® guidewires (*Abbott Vascular Devices, Redwood, CA, USA*) LAD and Cx.
• Circumflex PCI: - Predilatation 2.5x11 mm Mercury balloon
  - 2.5x18 mm Biomatrix stent implantation.
- LM predilatation with 3x12 mm NC Quantum Apex (16 atm).
- 3.5x14 mm Axxess stent positioning.
Final Kissing (LAD: 4x8 mm NC Trek at 14 atm. CX:3.5x12 mm NC Trek at 14 atm).
CASE 2

- 73-year-old-man, smoker. Anterior MI in 2012 with primary angioplasty to proximal LAD.
- Residual LVSF 30%.
- Admitted with congestive heart failure (first episode).
• EBU 4 7 French guiding catheter (femoral access)
• 2 BMW® guidewires (*Abbott Vascular Devices, Redwood, CA, USA*) LAD and Cx
• Predilatation with 3x12 mm Emerge balloon at 6 atm.
• 3.5x14 mm Axxess
• Final Kissing balloon (4x9 mm NC Sprinter at 16 atm. 4.5x8 mm NC Quantum Apex at 14 atm)
73 year-old man, with hypertension, hypercholesterolemia and tabaquism.

- Chest pain with positive stress test and inferior ischemia.
- TTE: normal systolic function.
- EBU 3,5 7 French guiding catheter (radial access)
- 2 BMW® guidewires (*Abbott Vascular Devices, Redwood, CA, USA*) LAD and Cx
- Predilatation 3.5x10 NC Hiryu® (*Terumo, Tokyo, Japan*) at 12 atm
- 3.5x11 mm Axxess stent advanced to LM.
• Final Kissing balloon (3.5x10 mm Hiryu at 10 atmospheres at the LM-LAD and semicompliant Sprinter 3x15 mm balloon at 10 atmospheres at the ramus)
Placement of a single Axxess stent as new treatment strategy for Medina 1,0,0 left main stem bifurcation lesion.

2013, IC-13-00488. Journal of Invasive Cardiology
CASE 4: CAUTION (Kissing stent)

- 48-year-old. HT, Hypercholesterolemic. Previous smoker.
- Admitted due to NSTE-ACS. TTE with inferior and lateral hipocinesia and mild systolic dysfunction.
- EBU 3.5 7 French guiding catheter
- 2 BMW® guidewires (*Abbott Vascular Devices, Redwood, CA, USA*) LAD and Cx
- Predilatation with non compliant balloon Empira ® 3x12 mm at 8 atm.
- 3.5x11 mm Axxess stent.
• Kissing balloon: 3x12 mm Empira at 10 atm LAD. 2.5x12 mm Empira at 8 atm Cx.
Kissing stent: 3x14 mm Biomatrix LAD. 2.75x14 mm Biomatrix Cx.
CASE 5 (PSEUDOANEURISMA)
CONCLUSIONS

• The Axxess stent is a safe and effective device suitable for complex as well as simple bifurcation treatment strategies.

• The use of Axxess stent in LM bifurcation lesions may be considered in selected cases, achieving good lesion coverage with minimal metal amount at the bifurcation.

• The Axxess stent is especially useful in bifurcations with major affectation of the main vessel (Medina 1,0,0) where the lesion can be attempted with the implantation of this unique stent, eventually avoiding the use of additional stents.