Bifurcation dedicated stents.

Yes or no!!

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Interventional cardiologist
EUROMEDICA-KYANOUS STAVROS, THESSALONIKI

ICE 2013 IOANNINA
Bifurcation Lesions are Still a Challenge

- Require more time, anxiety, skill, and equipment (cost)
- Increased complications
  - peri-procedural MIs,
  - stent thrombosis, and
  - restenosis
- Suboptimal angiographic outcomes (esp. side branch ostium)
bifurcation ≠ bifurcation

DIFERENT ANATOMY – DIFFERENT APPROACH
Today’s Treatment Options with Regular Stents

... but routine two stents approach is associated with higher rate of periprocedural MI and trend towards higher rate of stent thrombosis...

there is a common acceptance that provisional SB stenting technique should be the gold standard approach in majority of bifurcations lesions...
What should be the “ideal” dedicated device for Provisional SB stenting?

Easy to implant
- Reach the carena and fit the coronary anatomy
- Simplify and shorten the procedure

Safe
- Allow permanent side branch access
- High rate of device success

Effective
- Predictable successful ostium SB stenting
  - Optimal scaffolding of the carena & side branch ostium
- Optimal long-term outcome with:
  - Low rate of restenosis (DES)
  - Low rate of stent thrombosis
Optimal stent expansion and vessel coverage could be provided by Bifurcation Dedicated Stents.
Change in cell opening diameter with overexpansion

- Large cell opening diameter may impair drug concentration in the wall
- Potential risk of plaque prolapse

Fain N., EuroPCR
Dedicated bifurcation stents

Side branch access devices

= devices that treat the MB but with some scaffolding of the SB. (Xience SBA, Nile PAX, Antares, Stentys, TwinRail, Multi-link Frontier, Pathfinder, Petal, SideKick, Bioss)

Side branch stents (Sideguard, Tryton)

Proximal bifurcation stents (Access)

Bifurcated stents (Medtronic Y stent)
MULTI-LINK FRONTIER Coronary Bifurcation
Stent System (Abbott)

two-wire & two-balloon design

- Stent portal provides ostial scaffolding and maintains access to both branches
- Side branch portal allows provisional T-stenting and subsequent procedures
The **FRONTIER** Stent Registry

Safety and Feasibility of a Novel Dedicated Stent for the Treatment of Bifurcation Coronary Artery Lesions

**Table 5.** Major Adverse Cardiac Events (MACE) Hierarchical Analysis (Intent-to-Treat Population)

<table>
<thead>
<tr>
<th>Event</th>
<th>In-Hospital (n = 105)</th>
<th>30 ± 5 Days (n = 105)</th>
<th>180 ± 10 Days (n = 105)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Q-Wave MI</td>
<td>1 (1.0)</td>
<td>1 (1.0)</td>
<td>2 (1.9)</td>
</tr>
<tr>
<td>Non-Q-wave MI</td>
<td>1 (1.0)</td>
<td>1 (1.0)</td>
<td>2 (1.9)</td>
</tr>
<tr>
<td>TLR by CABG or PCI</td>
<td>1 (1.0)</td>
<td>1 (1.0)</td>
<td>14 (13.3)</td>
</tr>
<tr>
<td>MACE</td>
<td>3 (2.9)</td>
<td>3 (2.9)</td>
<td>18 (17.1)</td>
</tr>
<tr>
<td>TVF</td>
<td>3 (2.9)</td>
<td>3 (2.9)</td>
<td>24 (22.9)</td>
</tr>
<tr>
<td>TVR excluding TLR</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>6 (5.7)</td>
</tr>
</tbody>
</table>
Trireme Antares SX

- Side Branch wire lumen: Allows placement of wire to maintain SB access at all times. Peel away prevents wire wrap.
- Torquable shaft: Allows proper alignment of OPS to SB.
- Single balloon: Allows low crossing profile.
- Ostial Preservation Structure:
  - Provides excellent ostial coverage.
  - Asymmetric “wings” allow treatment of all SB angles.
  - Radiopaque markers facilitate precise SB stent placement when needed.
Twin Rail

- Dedicated Bifurcation Stent for Provisional T Stenting

  - DESIRE Trial
    - N=15 pts
    - Device success - 75%
    - TLR at 7-month – 14.3%
      - Adequate scaffolding of Main Vessel and Side Branch ostium

- Stent Delivery System
  - Double balloon design SDS
    - Main Vessel balloon Ø 3.0 and 3.5 mm
    - Side Branch balloon Ø 1.5 mm
  - Double RX design
  - 6 F Guiding Catheter compatible
Minvasys Nile

Nile Concept
3 generations of Nile stents:
I – First generation
II – Nile CoCr
III – Nile Pax (polymer free paclitaxel stent)

One system with two independent catheters
- Main branch balloon with stent
- Side branch balloon
Nile CroCo (Minvasys) SB access stent, 2 wires, passive rotation

- Balloon expandable cobalt chromium
- Kissing with deploying balloon and tapered balloon to limit proximal overexpansion and ensure circular in Xsection
- Polymer free Paclitaxel coating
- BIPAX clinical trial 102 patients, 99% successful placement

Paclitaxel spray coat
# Bi-Pax Registry

The Minivasys Polymer-Free Paclitaxel-Eluting Stent

## Preliminary Clinical Results

<table>
<thead>
<tr>
<th>OUTCOME, N=102</th>
<th>IN-HOSPITAL</th>
<th>OUT-OF-HOSPITAL UP TO 30 DAYS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiac</td>
<td>0% (0)</td>
<td>0% (0)</td>
</tr>
<tr>
<td>Non-cardiac</td>
<td>1% (1)</td>
<td>0% (0)</td>
</tr>
<tr>
<td>MI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q wave</td>
<td>0% (0)</td>
<td>0% (0)</td>
</tr>
<tr>
<td>Non-Q wave</td>
<td>1% (1)</td>
<td>0% (0)</td>
</tr>
<tr>
<td>TLR / TVR</td>
<td>0% (0)</td>
<td>0% (0)</td>
</tr>
<tr>
<td>MACE</td>
<td>1% (1)</td>
<td>0% (0)</td>
</tr>
<tr>
<td>Stent thrombosis</td>
<td>0% (0)</td>
<td>0% (0)</td>
</tr>
</tbody>
</table>
**BiPax trial**

**Purpose**
- Assess the safety and efficacy of the Nile® Pax Drug
- Eluting Coronary Bifurcation Stent System for the treatment of single de novo bifurcation in natives
- coronary arteries
- Prospective, non-randomized, multicenter trial
- Restenosis of the main branch and side branch by an Angiographic binary restenosis (ABR) at 9 months.
- In-stent late lumen loss at 9 months
- Clinically driven MACE (TVF) at 9 months

<table>
<thead>
<tr>
<th>6 M FU</th>
<th>85</th>
</tr>
</thead>
<tbody>
<tr>
<td>MI</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Re-PTCA</td>
<td>6 (7%)</td>
</tr>
<tr>
<td>CABG</td>
<td>2 (2%)</td>
</tr>
<tr>
<td>Death</td>
<td>2 (2%)</td>
</tr>
<tr>
<td>MACE</td>
<td>10 (12%)</td>
</tr>
<tr>
<td>TLR</td>
<td>8 (9.4%)</td>
</tr>
</tbody>
</table>

- Clinical FU 1 month
- Clinical FU 6 month
- QCA 9 month
- Clinical FU 12 month
- Clinical FU 24 month
- Clinical FU 36 month
- Clinical FU 48 month
- Clinical FU 60 month
The Petal dedicated bifurcation stent

TAXUS Petal is paclitaxel eluting, side-branch access stent delivered over two coronary guidelines
# The Petal dedicated bifurcation stent

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>All patients (N=28)</th>
<th>Procedural characteristics (N=28)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medina classification</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.1.0</td>
<td>17.9% (5)</td>
<td>100.0% (28)</td>
</tr>
<tr>
<td>0.1.1</td>
<td>7.1% (2)</td>
<td>53.6% (15)</td>
</tr>
<tr>
<td>1.0.0</td>
<td>14.3% (4)</td>
<td>SB only</td>
</tr>
<tr>
<td>1.0.1</td>
<td>7.1% (2)</td>
<td>MB and SB</td>
</tr>
<tr>
<td>1.1.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.1.1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Target lesion vessel</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left anterior descending artery</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Circumflex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right coronary artery</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reference vessel diameter (mm)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Minimum lumen diameter (mm)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Percent diameter stenosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lesion length (mm)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Technical performance (N=28)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Technical success&lt;sup&gt;a&lt;/sup&gt;</td>
<td>96.4% (27)</td>
<td>100.0% (28)</td>
</tr>
<tr>
<td>Post procedure % diameter stenosis ≥30% in MB</td>
<td>3.6% (1)</td>
<td>70.6±20.1 (28)</td>
</tr>
<tr>
<td>Post procedure % diameter stenosis ≥50% in SB</td>
<td>3.6% (1)</td>
<td>19.3±9.5 (28)</td>
</tr>
<tr>
<td>Post procedure TIMI &lt;3 in MB</td>
<td>0.0% (0)</td>
<td></td>
</tr>
<tr>
<td>Post procedure TIMI &lt;3 in SB</td>
<td>0.0% (0)</td>
<td></td>
</tr>
<tr>
<td><strong>Procedural performance (N=28)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical procedural success&lt;sup&gt;b&lt;/sup&gt;</td>
<td>92.8% (26)</td>
<td>28.0% (7)&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>In-hospital death</td>
<td>0.0% (0)</td>
<td>25.0% (7)</td>
</tr>
<tr>
<td>In-hospital myocardial infarction (MI)</td>
<td>3.6% (1)</td>
<td></td>
</tr>
<tr>
<td>In-hospital target vessel revascularisation (TVR)</td>
<td>0.0% (0)</td>
<td></td>
</tr>
<tr>
<td>Technical failure</td>
<td>3.6% (1)</td>
<td></td>
</tr>
<tr>
<td><strong>Device performance (N=28)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TAXUS Petal stent implanted&lt;sup&gt;c&lt;/sup&gt;</td>
<td>89.3% (25)</td>
<td></td>
</tr>
</tbody>
</table>

<sup>a</sup> Technical success defined as the achievement of the primary end point of target vessel revascularisation freedom at 12 months in both branches of the target bifurcation.

<sup>b</sup> Clinical procedural success defined as the achievement of the primary end point of target vessel revascularisation freedom at 12 months in both branches of the target bifurcation.

<sup>c</sup> Device performance defined as the percentage of patients in whom the TAXUS Petal stent was implanted.
BIOSS Stent system

Mid-marker of the delivery system

One special balloon with two diameters corresponding to main vessel and main branch diameters

DISTAL DIAMETER  PROXIMAL DIAMETER

DISTAL SEGMENT  PROXIMAL SEGMENT

LARGE STENT CELL

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Cumulative clinical results
(12 months)

- TVR – 5/60 (8%)
- TVF – 16%
- PCI in another vessel – 15/60 (25%)
12 months angiographic results (%DS)

BiOSS stent reduces side branch compromise in comparison with historical control
STENTYS Self-apposing Coronary Stent is to treat lesions that are close to proximity to a bifurcation with SB angulation 30°-70°
# Stentys Clinical Program

## BIFURCATIONS

**OPEN I**
- Single Arm
- 6 Month QCA and IVUS FU
- Device: 7F BMS
- Status: FU complete (n=40)
- Validation of disconnecting technology

**OPEN II**
- Randomized
- Device: 6F DES

## AMI

**APPPOSITION I**
- Single Arm
- 3 Day and 6 month QCA and IVUS FU
- Device: 6F BMS
- Status: Enrolment completed (n=25)

**APPPOSITION II**
- Randomized
- 3 Day QCA and OCT FU
- Device: 6F BMS
- Status: Start Q4 2009
OPEN I Study - Results

95% success rate

6 months QCA: Main Branch (Stentys DES, n=25)

In-segment Restenosis 1 (4%)

In-stent Late Loss (mm)

<table>
<thead>
<tr>
<th>Location</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proximal MB</td>
<td>0.39±0.62</td>
</tr>
<tr>
<td>Distal MB</td>
<td>0.40±0.50</td>
</tr>
</tbody>
</table>

6 month QCA: Side Branch

In-segment Restenosis (n=56) 9 (16%)

<table>
<thead>
<tr>
<th>Condition</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>with SB balloon expandable stent (n=17)</td>
<td>1 (6%)</td>
</tr>
<tr>
<td>w/o SB balloon expandable stent (n=39)</td>
<td>8 (21%)</td>
</tr>
</tbody>
</table>

Excellent result when "cross-over" to 2 stents

TCT 2010

Hellenic Institute of Cardiovascular Diseases
OPEN II Study

- **DESIGN**
  Prospective, non-randomized, single-arm, multicenter study

- **OBJECTIVE**
  To evaluate the long-term safety and efficacy of the STENTYS PES stent in bifurcation lesions in routine clinical practice.

- **PRIMARY ENDPOINT**
  Major Adverse Cardiac Events (MACE) at 6 months post-procedure, defined as
  - Cardiac death
  - Target vessel related MI
  - CABG
  - Clinically driven TLR
Study population

217 patients enrolled

Not fulfilling inclusion criteria (n=4)
- Left main (n=3) (1 death, unknown cause)
- Medina Class = 0,0,1 (n=1)

Stent placement unsuccessful (n=5)
- Stent did not pass the lesion (n=5)

Study population (n=208)
### Clinical outcomes at 6 months

<table>
<thead>
<tr>
<th>Event</th>
<th>Patients</th>
<th>Event rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>MACE</td>
<td>21</td>
<td>10.1 %</td>
</tr>
<tr>
<td>Cardiac death</td>
<td>1</td>
<td>0.5 %</td>
</tr>
<tr>
<td>Emergent CABG</td>
<td>0</td>
<td>0 %</td>
</tr>
<tr>
<td>Target vessel MI</td>
<td>9</td>
<td>4.3 %</td>
</tr>
<tr>
<td>Clinically driven TLR</td>
<td>11</td>
<td>5.3 %</td>
</tr>
<tr>
<td>Death from any cause</td>
<td>1</td>
<td>0.5 %</td>
</tr>
<tr>
<td>Definite Stent thrombosis</td>
<td>2</td>
<td>1.0 %</td>
</tr>
</tbody>
</table>
| Acute / Sub-Acute / Late     | 2 / 0 / 0| 1.0 / 0 / 0%
| Probable Stent thrombosis    | 0        | 0%         |
MACE according to KB

No Final Kissing Balloon
Final Kissing Balloon

P=0.81
• Coronary aneurysm
• Ectasic segment
• Tapering
• Bifurcated lesion
• Saphenous Vein Graft
• Absolute vessel diameters (4.5-5.0mm)
• High thrombus load
In animal models, Abbott Bifurcation DES demonstrated equivalent safety results to XIENCE V:

- Drug released and tissue concentration equivalent to XIENCE V (70 - 80% of everolimus released at 28 days)
- Neointimal composition comparable to XIENCE V
- Near complete to complete luminal endothelialization
- Equivalent vascular response and pharmacokinetics
Dedicated bifurcation stents

Side branch access devices

= devices that treat the MB but with some scaffolding of the SB. (Xience SBA, Nile P4x, Antares, Stentys, TwinRail, Multi-link Frontier, Pathfinder, Petal, SideKick, Bioss)

Side branch stents (Sideguard, Tryton)

Proximal bifurcation stents (Access)

Bifurcated stents (Medtronic Y stent)
Tryton Side Branch Stent™
Product Picture – Zone Technology

Zone 1: Side Branch
Superior scaffolding secures the side branch and delivers the performance you expect from your workhorse stent

Zone 2: Transition
Provides radial strength and coverage to the side branch and ostium regardless of bifurcation angle and geometry

Zone 3: Main Branch
Minimal metal to artery ratio (M:A) allows seamless integration with your DES

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Tryton Deployment Procedure

- Position Side Branch Stent
- Deploy Side Branch Stent
- Advance Wire into Main Branch
- Position Main Vessel Stent
- Kissing Post-Dilatation of Bifurcation
- Procedure Complete
E-Tryton Study (n=304)

**MACE: Discharge to 6 month follow-up**

<table>
<thead>
<tr>
<th>Hierarchical MACE</th>
<th>Cardiac death</th>
<th>NSTEMI</th>
<th>TLR</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0 (0.0%)</td>
<td>2* (0.8%)</td>
<td>7 (2.8%)</td>
</tr>
</tbody>
</table>

**Total TLR = 9 (3.6%)**
- MB Stenosis >50% = 6 (2.4%)
- SB Stenosis >50% = 3 (1.2%)

*Pt. #1: CPK elevation (no q wave) associated with target lesion without evidence of stent thrombosis*
*Pt. #2: CPK elevation (no q wave) not associated with target lesion without evidence of stent thrombosis*
## Tryton Data: 600+ patients (registry data)

<table>
<thead>
<tr>
<th>Study/Registry</th>
<th>Published or Presented</th>
<th>Patients (FU)</th>
<th>FU (M)</th>
<th>TLR</th>
<th>Thrombosis</th>
<th>MI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tryton Side-Branch Stent: First In Man</td>
<td>EuroIntervention 2009, ESPC 2011</td>
<td>30</td>
<td>6</td>
<td>3.3%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>IUVANT (Prof. Bartorelli)</td>
<td>Presented TCT 2010</td>
<td>31</td>
<td>9</td>
<td>3.2%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Rotterdam-Poznan Real World Registry</td>
<td>CG 77:998-806 (2011)</td>
<td>96</td>
<td>6</td>
<td>4.0%</td>
<td>0%</td>
<td>3.1%</td>
</tr>
<tr>
<td>E-Tryton Registry 150-Benelux</td>
<td>Presented EuroPCR 2011 (submitted for publication)</td>
<td>296</td>
<td>6</td>
<td>3.0%</td>
<td>0%</td>
<td>0.7%</td>
</tr>
<tr>
<td>Wolverhampton Experience</td>
<td>Presented BIT 2011</td>
<td>66</td>
<td>8</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Beaumont Experience</td>
<td>Presented EuroPCR 2011</td>
<td>169</td>
<td>17.8</td>
<td>2.3%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td><strong>&gt;600</strong></td>
<td></td>
<td><strong>≤4%</strong></td>
<td></td>
<td><strong>0%</strong></td>
</tr>
</tbody>
</table>

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The Cappella Sideguard™ Stent

The Cappella Sideguard coronary SB stent is a self expanding trumped shaped nitinol stent with a 3-segment design (cup, transition zone and anchor)

3 sizes: 2.5 for SB 2.25-2.5mm
         2.75 for SB 2.5-2.75mm
         3.25 for SB 2.75-3.25mm
The Cappella Sideguard™ Stent

1. Wire both branches and pre-dilate
2. Inflate Sideguard® balloons catheter to split sheath and deploy stent
3. Advance and deploy main vessel stent
4. Once deployed, the main vessel stent secures Sideguard® into place
# The Cappella Sideguard™ Stent

## Table 1. Clinical outcomes at 12-months of the Sideguard-1 and Sideguard-2 studies.

<table>
<thead>
<tr>
<th>Major adverse cardiac event (MACE)</th>
<th>Sideguard™ implants (N=83)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Up to 30 days</td>
<td>4.8% (4/83)</td>
</tr>
<tr>
<td>Up to 6-months</td>
<td>10.8% (9/83)</td>
</tr>
<tr>
<td>Up to 12-months</td>
<td>12% (10/83)</td>
</tr>
</tbody>
</table>

**MACE at 12 months**
- Cardiac death: 1.2% (1/83)
- Myocardial infarction: 3.6% (3/83)
- Target lesion revascularisation: 9.6% (8/83) *

**Other revascularisations at 12 months**
- Ischaemia-driven target vessel revascularisation: 3.6% (3/83)

<table>
<thead>
<tr>
<th>Angiographic follow-up</th>
<th>Main vessel (N=73)</th>
<th>Side branch (N=73)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Late loss</td>
<td>0.21</td>
<td>0.58</td>
</tr>
<tr>
<td>% Diameter stenosis</td>
<td>12%</td>
<td>25%</td>
</tr>
</tbody>
</table>

*Note: Unpublished data provided by Cappella Inc; *Includes two in hospital thrombosis events*
Dedicated bifurcation stents

- Side branch access devices
  - devices that treat the MB but with some scaffolding of the SB. (Xience SBA, Nile PAx, Antares, Stentys, TwinRail, Multi-link Frontier, Pathfinder, Petal, SideKick, Bioss)

- Side branch stents (Sideguard, Tryton)

- Proximal bifurcation stents (Axcess)

- Bifurcated stents (Medtronic Y stent)
Axxess (Devax)

Biolimus A9 coated AXXESS stent

- self-expanding
- nickel-titanium
- conically shaped
- is placed at the level of the carina
- needs to be precisely nested at the carina to be
- effective and in majority cases will need another stent to fully treat the bifurcation

Conventional DESs
Advantages and limitations

- Stent does not cover whole bifurcation region, but only proximal region
- Does not require rotation for alignment
- Requires second stent implantation (85% in DIVERGE trial) – cost!!!
- Difficult to be exactly positioned
- 8 Fr guide cath required
<table>
<thead>
<tr>
<th>Study</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>AXXESS</td>
<td>- Bare metal version of AXXESS Stent</td>
</tr>
<tr>
<td>N=43</td>
<td>- Safety and effectiveness study</td>
</tr>
<tr>
<td></td>
<td>- 6 month follow-up completed</td>
</tr>
<tr>
<td>AXXESS PLUS</td>
<td>- Evaluated drug-eluting AXXESS stent to BMS</td>
</tr>
<tr>
<td>PLUS N=139</td>
<td>- Safety and effectiveness study</td>
</tr>
<tr>
<td></td>
<td>- 3 yr FU completed, 5 yr FU will be presented at TCT 2011</td>
</tr>
<tr>
<td>DIVERGE</td>
<td>- International safety and effectiveness study</td>
</tr>
<tr>
<td>N=302</td>
<td>- Evaluated best practices from AXXESS Plus</td>
</tr>
<tr>
<td></td>
<td>- 3 year follow-up available</td>
</tr>
<tr>
<td>AXXENT</td>
<td>- Multi-center pilot study for AXXESS Left Main stent</td>
</tr>
<tr>
<td>N=33</td>
<td>- Study showed potential for effective LMCA intervention</td>
</tr>
<tr>
<td></td>
<td>- 12 month follow-up completed</td>
</tr>
</tbody>
</table>
### 6 Month Follow UP QCA

<table>
<thead>
<tr>
<th></th>
<th>Parent Vessel</th>
<th>Side Branch</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Late Loss</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>In Axess stent</td>
<td>0.09 ± 0.56</td>
<td>-</td>
</tr>
<tr>
<td>In stent – all stents</td>
<td>0.21 ± 0.48</td>
<td>0.21 ± 0.45</td>
</tr>
<tr>
<td>In segment (stents + 5mm)</td>
<td>0.23 ± 0.49</td>
<td>0.22 ± 0.46</td>
</tr>
<tr>
<td><strong>Percent Diameter Stenosis</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>In stent</td>
<td>4.3 ± 18.56%</td>
<td>16.3 ± 19.4%</td>
</tr>
<tr>
<td>In segment (stents + 5mm)</td>
<td>29.3 ± 16.69%</td>
<td>28.5 ± 18.2%</td>
</tr>
<tr>
<td><strong>Restenosis</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Axess stent only</td>
<td>4.0%</td>
<td>-</td>
</tr>
<tr>
<td>In stent only</td>
<td>5.6%</td>
<td>7.9%</td>
</tr>
<tr>
<td>All- Stent, PTCA, + 5mm edges</td>
<td>10.5%</td>
<td>13.7%</td>
</tr>
</tbody>
</table>

### Side Branch Analysis

<table>
<thead>
<tr>
<th>6 Month Follow Up</th>
<th>Wire Only (N=26)</th>
<th>PTCA (N=40)</th>
<th>Stent (N=70)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>In-segment</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MLD, mm</td>
<td>1.59</td>
<td>1.49</td>
<td>1.82*</td>
</tr>
<tr>
<td>%DS</td>
<td>31.0</td>
<td>33.1</td>
<td>25.4†</td>
</tr>
<tr>
<td>Late lumen loss, mm</td>
<td>0.24</td>
<td>0.19</td>
<td>0.21</td>
</tr>
<tr>
<td>Restenosis, %</td>
<td>12.0</td>
<td>25.0</td>
<td>7.9</td>
</tr>
<tr>
<td>5mm osium</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MLD, mm</td>
<td>1.65</td>
<td>1.54</td>
<td>2.15‡</td>
</tr>
<tr>
<td>%DS</td>
<td>28.2</td>
<td>30.7</td>
<td>11.5§</td>
</tr>
<tr>
<td>Late lumen loss, mm</td>
<td>0.20</td>
<td>0.18</td>
<td>0.28</td>
</tr>
</tbody>
</table>
DIVERGE Follow Up

Lead in Cases ≤ 3 per site

Enrollment N=302

6 Months Check up (N=302)

Angiography N=140 (94% FU)

9 Months N=301 (99.7% clin. FU)

12 Months N=300 (99.4% FU)

2 years N=300 (99.4% FU)

3 years N=294 (97.4% FU)

IVUS Evaluation N=68 (91% FU)

5 Year Annual Follow Up
9 Month Restenosis

Any In-segment bifurcation restenosis: 6.4% (9/140 at 9 months)

Location Analysis:

- Proximal edge: 2.8%
- SB stent: 4.8% (105 SB stents)

Parent Vessel
3 pts RS

Side Branch RS
2 pts Both

4 pts

"Lowest restenosis rates ever reported in a bifurcation study of any kind"
9-month Clinical Outcomes

Primary Endpoint

<table>
<thead>
<tr>
<th>Event</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>MACE*</td>
<td>7.6</td>
</tr>
<tr>
<td>Death</td>
<td>0.7</td>
</tr>
<tr>
<td>Cardiac Death</td>
<td>0.7</td>
</tr>
<tr>
<td>MI</td>
<td>4.3</td>
</tr>
<tr>
<td>id-TLR</td>
<td>4.3</td>
</tr>
<tr>
<td>id-TVR</td>
<td>6.3</td>
</tr>
</tbody>
</table>

*MACE: a composite of Death, MI and id-TLR
3-year Clinical Outcomes
Cumulative Rates

MACE* | Death | Cardiac Death | MI | id-TLR | id-TV
--- | --- | --- | --- | --- | ---
16.3 | 3.1 | 2.0 | 7.5 | 10.2 | 12.2

*MACE: a composite of Death, MI and id-TLR
Agostoni P., oral presentation, EuroPCR 2011.
Dedicated bifurcation stents

Side branch access devices

= devices that treat the MB but with some scaffolding of the SB. (Xience SBA, Nile PAX, Antares, Stentys, TwinRail, Multi-link Frontier, Pathfinder, Petal, SideKick, Bioss)

Side branch stents (Sideguard, Tryton)

Proximal bifurcation stents (Access)

Bifurcated stents (Medtronic Y stent)
Medronic Dedicated Bifurcation Stent

* Trouser shaped
* Delivers over two wires
* Passive rotation to align
* Branch Trial FIM_BMS enrolment 60pts in NZ and Australia
* Device success 83% of 53 patients with simple lesions
* FIM Delivery issues were important
Devax AXXESS (broken black line) dedicated bifurcation stent pushes atheroma away from flow divider and leaves no drug-eluting struts near the flow divider

Flow divider does not need struts and drug

Uncovered struts at carina predispose to ST (Nakazawa)

(Ormiston modified from Virmani)
“A” Family Techniques. There are challenges with Dedicated Stents that deliver over 2 wires - Wire bias can prevent delivery

Wire bias directs stent away from SB preventing alignment

Predicted self rotation does not occur

“Bifurcation Stenting” Wiley
eds Waksman and Orniston

Hellenic Institute of Cardiovascular Diseases
Wire wrap ("twisting") can prevent device advancement and alignment with the SB.
Evolution of Bifurcation Therapy

- **BMS**
- **DES**
- **DES Gen 2**
- **Kissing balloons**
- **Provisional SB stenting**
- **Jailed wires**
- **POT**
- **Final kiss w NC balloons**

- **Angio success**
- **In-hospital MACE**
- **12 month TVR**

Hellenic Institute of Cardiovascular Diseases

www.e-Cardio.gr
We need dedicated bifurcation stent because-

While outcomes with a single stent in a bifurcation are good, outcomes when two stents are used is suboptimal

- Stent distortion
- Multiple layers of struts
- High drug dose
- Flow disturbance
- Uncovered struts
- Malaposed struts esp at carina
- Lack of scaffolding
- Polymer damage
We need dedicated bifurcation stent because-

While outcomes with a single stent in a bifurcation are good, outcomes with two stents are suboptimal

- Stent distortion
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- Lack of scaffolding
- Polymer damage

Dedicated bifurcation stents are an interventionalist’s dream as may
- Simplify procedure
- Improve procedural success
- Decrease stent thrombosis
- Decrease restenosis

(Lefevre, EuroIntervention suppl 2012)
• **Dedicated bifurcation stents are a historical concept and are no longer needed!**

Bernard Chevalier, MD, FESC, FACC, FSCAI

ICPS Massy

France 2013
Structure-function scaling laws of vascular trees

\[ D_{\text{mother}}^3 = D_{\text{daughter}_1}^3 + D_{\text{daughter}_2}^3 + \ldots \]

Murray's law

\[ D_{\text{mother}} = 0.67 \times (D_{\text{daughter}_1} + D_{\text{daughter}_2} + \ldots) \]

G. Finet

Finet et al. Eurointervention 2007: 490-8
Patient customized dedicated stent:
Do it yourself!
Sizing MB stent: Proximal optimisation technique (POT)

\[ D_1 = \frac{2}{3} (D_2 + D_3) \]

Optimal Provisional SB Stenting
POT + KBT(+-POT)
culotte
Conclusions

• Theoretically, dedicated stents were the best answer for treating complex bifurcation lesion.
  – Permanent SB access
• But:
  – Huge variations in anatomy & pathology makes device choice complex
  – Inventory should be large
  – Not all of them are DES
  – Their use is frequently more complex than bifurcation techniques
  – Treatment with regular DES using provisional stenting provide excellent results
  – Cost-effectiveness is questionable

• Bioabsorbable scaffold: an additional reason to forget these complicated devices?
CONSIDERATIONS

- Dedicated bifurcation systems vary on design, material and profile; therefore, it is reasonable to believe that they will have different indications mainly due to anatomical and morphological factors.

- Overall, all systems have shown positive clinical outcomes in selected cases; however, there is lack of comparative studies between each other and most importantly, against current standard technique ("provisional").

- Still, they will probably be the ultimate solution for bifurcation PCI.
Bifurcation Lesions are a “Pain in the Butt”

**conclusion**

- more time, anxiety, skill and equipment required
- increased complication
- easy to monitor
- less complications
- subjective to any group's outcomes
- no dedicated devices with validated benefit

ΕΥΧΑΡΙΣΤΩ !!!