Impact of overexpansion strategies: Insights from bench Testing

Robert-Jan van Geuns, MD, PhD
Professor of Interventional Cardiology,
Thoraxcenter, Erasmus Medical Center,
Rotterdam, the Netherlands
Overexpansion frequently utilized!

LM (bifurcation) PCI

- Large diameter:

**Original Studies**

A Prospective Intravascular Ultrasound Investigation of the Necessity for and Efficacy of Postdilation Beyond Nominal Diameter of 3 Current Generation DES Platforms for the Percutaneous Treatment of the Left Main Coronary Artery

James A. Shand, MD, MRCR, Divyesh Sharma, MBBS, MRCR, Colm Hanratty, MD, FRCR, Anthony McClelland, MD, FRCR, Ian B. A. Menown, MD, FRCR, Mark S. Spence, MD, FRCR, Geoffrey Richardson, MD, FRCR, Niall A. Herity, MD, FRCR, and Simon J. Walsh, MD, FRCR

### TABLE III. MSA and Mean MaxSD of Investigational DES Following 5.5 and 6.0 mm Semicompliant Balloon Dilation Within the LMS

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<tr>
<th>Stent platform</th>
<th>Nominal diameter (mm; Model description)</th>
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<th>Proximal MSA (mm²), mean (SD)</th>
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MaxSD: maximal stent diameter; mm: millimeter; MSA: maximal stent area; n: number.
IVUS LM in male pts (Rotterdam)

- IVUS data on 865 LAD->LM pullbacks, male patients
- ‘non-diseased’ LM (i.e. minimal plaque burden, <50% of LM circumference with intimal thickening) in only 17.6% of pts (N=152)
- Average vessel diameter, vessel area
- Correlation with body surface area (BSA)
IVUS LM vessel diameter (VD)

- Average VD: 5.60 cm
- Mean VD: 5.47 cm
- Only in 13% <5 cm
Overexpansion is frequently utilized.

Impact on radial strength and recoil unclear.

- Ostial stenting: High Radial strength*

Nicolas Foin, EuroIntervention 2013; 8: 1315-.

“Average measured crown angle at nominal pressure after deployment ranged from 45º to 79º, compared to a range of 130º to 158º after maximal dilatation.”

Recoil and radial strength not measured.

Overexpansion Bench testing:

**Tubular model**
Nicolas Foin, EuroIntervention 2013; 8: 1315-1325.

- Stent: 2.75, 3.00, 3.50, 4.00
- POT: 4.0, 5.0 NC or 6.0 Semi-compliant at **14 atm**

Effect of pressure not studied

**Bifurcation model**

- Proximal MV = **3.5** mm, distal MV = **2.75** mm, SB = 2.75 mm, MV/SB angle = 45°
- Stent: 3.0 mm
- FKBD: 2 x 3.0 NC balloon; POT: 3.75 NC
- **10 atm**

Single pressure, single balloon combination only
FKBD and POT in LM PCI

- Different sizes of Balloons for FKBD
- Different pressures
- Recoil and radial strength for Platinum Chromium Stent of 4.0 mm, target to reach 6 mm

<table>
<thead>
<tr>
<th>PostDilation Method</th>
<th>Group Number</th>
<th>Sample Size</th>
<th>Post-Deployment Catheter</th>
<th>Size (mm)</th>
<th>Pressure (atm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>POT-SC/LP</td>
<td>1</td>
<td>3</td>
<td>Maverick XL</td>
<td>6.0 x15</td>
<td>6</td>
</tr>
<tr>
<td>POT-SC/SP</td>
<td>2</td>
<td>10</td>
<td>Maverick XL</td>
<td>6.0 x15</td>
<td>14</td>
</tr>
<tr>
<td>POT-NC/HP</td>
<td>3</td>
<td>3</td>
<td>NC Emerge</td>
<td>6.0 x15</td>
<td>24</td>
</tr>
<tr>
<td>FKBD-US/SP</td>
<td>4</td>
<td>3</td>
<td>Apex</td>
<td>4.0 x15 + 3.5 x15</td>
<td>12</td>
</tr>
<tr>
<td>FKBD-OS/LP</td>
<td>5</td>
<td>3</td>
<td>Apex</td>
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<td>3</td>
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Methods

Stents deployed in an aqueous bath at standard temperature of 37 +/- 1 degree Celsius.

Stent expansion and malapposition were evaluated by implanting the stents in silicon tube phantom models of 6 mm.

Precalibrated Measurement Scope

Stent and Tube Dimensions

Ellipticity Index (EI)

Malapposition

\[
EI = \frac{\text{Max Inner SD}}{\text{Min Inner SD}}
\]

Malapposition Area (MA/mm²) = Tube ID Area – Stent OD Area

SD: Stent Diameter
FKBD in large vessels: Results

**Outer Diameter**
- FKBD-US: 12 atm
- FKBD-LP: 4 atm
- FKBD-RPB: 12 atm

**Ellipticity**
- FKBD-US: 3.5 + 4.0
- FKBD-LP: 4.0 + 5.0

**Area**
- FKBD-US
- FKBD-LP
- FKBD-RPB
- Target
FKBD in large vessels: Results

- **Size**
  - Adequate size necessary
- **Pressure**
  - High pressure indicated
- **Serious ellipticity**

**Outer Diameter**

- FKBD-US
- FKBD-LP
- FKBD-RPB

**Area**

- FKBD-US
- FKBD-LP
- FKBD-RPB
- Target
**Optimalization of the POT**

- Semi- Compliant vs Non-compliant balloons?
- Pressure
  - 6 vs 14 or 24 atm.

<table>
<thead>
<tr>
<th>Stent/Balloon Size</th>
<th>Pressure</th>
<th>Stent/Balloon Dimensions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Synergy II™ 4.0mm</td>
<td>Nominal</td>
<td>11.0 OD 4.24</td>
</tr>
<tr>
<td></td>
<td>RBP</td>
<td>16.0 OD 4.48</td>
</tr>
<tr>
<td>NC Quantum Apex™ 5.0mm</td>
<td>Nominal</td>
<td>12.0 4.95</td>
</tr>
<tr>
<td></td>
<td>RBP</td>
<td>18.0 5.15</td>
</tr>
<tr>
<td>Apex™ 5.0mm</td>
<td>Low</td>
<td>4.0 4.79</td>
</tr>
<tr>
<td></td>
<td>Nominal</td>
<td>6.0 4.99</td>
</tr>
<tr>
<td></td>
<td>RBP</td>
<td>12.0 5.30</td>
</tr>
<tr>
<td>Maverick 6.0mm</td>
<td>Nominal</td>
<td>6.0 6.00</td>
</tr>
<tr>
<td></td>
<td>RBP</td>
<td>14.0 6.46</td>
</tr>
<tr>
<td>Emerge NC 6.0mm</td>
<td>Nominal</td>
<td>6.0 6.09</td>
</tr>
<tr>
<td></td>
<td>RBP</td>
<td>14.0 6.28</td>
</tr>
</tbody>
</table>
Optimization of the POT

Maverick 6 mm balloon

![Diagram showing Maverick 6 mm balloon at 6 atm and 14 atm pressures.]

Outer Diameter

<table>
<thead>
<tr>
<th>POT-LP</th>
<th>POT-RPB</th>
<th>POT-NC</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 atm</td>
<td>12 atm</td>
<td>24 atm</td>
</tr>
</tbody>
</table>

Ellipticity

<table>
<thead>
<tr>
<th>POT-LP</th>
<th>POT-RPB</th>
<th>POT-NC</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

Area

<table>
<thead>
<tr>
<th>POT-LP</th>
<th>POT-RPB</th>
<th>POT-NC</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>30</td>
<td>40</td>
<td>50</td>
</tr>
</tbody>
</table>
Optimalization of the POT

Maverick 6 mm balloon

Emerge NC 6 mm

Outer Diameter

6 atm  14 atm  24 atm

Ellipticity

0  0.5  1  1.5

POT-LP  POT-RPB  POT-NC

Area

0  10  20  30  40

POT-LP  POT-RPB  POT-NC  Target
POT: Pressure and Balloon type

Relation of Stent Outer Diameter to Inflation Pressure

- NC Emerge
- Maverick XL
## Overview for 6mm tubing

<table>
<thead>
<tr>
<th>POT 6 mm</th>
<th>SC 6 ATM</th>
<th>SC 14 ATM</th>
<th>NC: 24 ATM</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MA: 8.40mm², El 1.0</td>
<td>MA: 1.10mm², El 1.0</td>
<td>MA: 0mm², El 1.0</td>
</tr>
</tbody>
</table>
|          | Max SOA 20.80mm²  
Max SOD 5.10mm | Max SOA 28.60mm²  
Max SOD 6.00mm | Max SOA 30.30mm²  
Max SOD 6.22mm |
| FKBD     | MA: 6.20mm², El 1.5 | MA: 8.20mm², El 1.2 | MA: 1.80mm², El 1.2 |
|          | Max SOA 22.80mm²  
Max SOD 6.50mm | Max SOA 20.90mm²  
Max SOD 5.70mm | Max SOA 27.20mm²  
Max SOD 6.90mm |

- **3.5 + 4.0 12 ATM**
- **4.0 + 5.0 4 ATM**
- **4.0 + 5.0 12 ATM**
Radial strength and recoil

I) Radial Strength after Over Expansion
Synergy™ 4.0x16mm, n=10,
*6mm ANOVA p<0.001

II) % Recoil after Over Expansion
Synergy™ 4.0x24mm, n=10
*4mm ANOVA, p < 0.001

III) % Stent Surface to Artery after Over Expansion
Synergy™ 4.0x16mm, n=10

IV) Stent Length after Over Expansion
Synergy™ 4.0x16mm, n=3
*5mm & 5.75mm ANOVA, p<0.001
The 4.00mm thin strut platinum chromium stent can be expanded to a 6.22mm outer stent diameter but high pressure are necessary.

FKBD needs adequately sized ballons.

FKBD overexpansion results in excentric deformation and large malapposition areas.

Radial strength is still maintained despite stent overexpansion. Stent recoil and % surface to artery ratio decreased as stents were overexpanded.
POT solution?

- Size of non-compliant balloons?
  - 5 or 6 mm
- Pressure
  - 6 vs 14 and 24 atm.
FKBD for overexpansion: Target of 6 mm

- Size of non-compliant balloons?
  - 3.5 + 4.0 mm?
  - 4.0 + 5.0 mm?
- Pressure
  - 4 or 6 vs 12 atm.

Work of JiangMing Fam, National Heart Centre Singapore
<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>A</td>
<td>Synergy™ 4.0 x 28mm stent deployed at 16 atm</td>
</tr>
<tr>
<td>B</td>
<td>Distal Stent: 5.0 x 15mm balloon (RBP 12 atm)</td>
</tr>
<tr>
<td>C</td>
<td>Proximal Stent: 5.0 x 15mm balloon (RBP 12 atm)</td>
</tr>
<tr>
<td>D</td>
<td>POT: 6.0 x 15mm balloon (SC/SP)</td>
</tr>
<tr>
<td>E</td>
<td>FKBD: 5.0 x 15mm and 4.0 x 15mm balloons (SS/SP)</td>
</tr>
</tbody>
</table>

FKBD: Final Kissing Balloon Dilation  
POT: Proximal Optimization Technique  
RBP: Rate Burst pressure  
SC: Semicompliant  
SP: Standard pressure
Methods

Initial Deployment
Requirements of LM stents

<table>
<thead>
<tr>
<th>LM stents</th>
<th>Synergy</th>
</tr>
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<tbody>
<tr>
<td>Large Diameter</td>
<td>Labeled expansion till 5.75mm. Data till 6.0 mm</td>
</tr>
<tr>
<td>Ostial stenting</td>
<td>0.27 N/mm</td>
</tr>
<tr>
<td>Frequent overlapping stents</td>
<td>Strut thickness 74-81 µm, Biodegradable coating</td>
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<td>Frequent 2 stent bif approach</td>
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<tr>
<td>Elderly Population</td>
<td>Abluminal coating only Biodegradable coating</td>
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**Radial Strength of current DES**

- SYNERGY Stents: 0.27
- Xience Xpedition Stent: 0.18
- Resolute Integrity™ Stent: 0.17
- BioMatrix Flex™ Stent: 0.13
### Overview for 6mm tubing

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<th>POT-LP</th>
<th>POT-RBP</th>
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<td>MA: 8.4 mm², El 1.0</td>
<td>MA: 1.1 mm², El 1.0</td>
<td>MA: 6.2 mm², El 1.5</td>
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- **A**: Max SOA 20.8 mm², Max SOD 5.1 mm
- **B**: Max SOA 28.6 mm², Max SOD 6.0 mm
- **C**: Max SOA 22.8 mm², Max SOD 6.5 mm

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<tr>
<td>MA: 8.2 mm², El 1.2</td>
<td>MA: 1.8 mm², El 1.4</td>
</tr>
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</table>

- **D**: Max SOA 20.9 mm², Max SOD 5.7 mm
- **E**: Max SOA 27.2 mm², Max SOD 6.9 mm

**Legend**
- A: POT-LP  
- B: POT-RBP  
- C: FKBD-US  
- E: FKBD-RBP
- LP: Low pressure
- RBP: Rated burst pressure
- US: Undersized
- FKBD: Final kissing balloon dilation
- POT: Proximal optimisation technique
- El: Elliptical index
- MA: Malaposed area
- SOA: Stent outer area
- SOD: Stent outer diameter

Fig 3C-E: FKBD always results in an elliptical shape. Pressure will increase stent area, diameter, ovalisation and strut apposition.
Methods

• In vivo bench testing

• July - September 2014

• Synergy II™ stent (Boston Scientific, MN, USA; Galway, Ireland)
  – unique large vessel design
  – thin strut platinum chromium
  – 4mm

• Stents deployed in an aqueous bath at standard temperature of 37 +/− 1 degree Celsius

• Stent expansion and malposition were evaluated by implanting the stents in silicon tube phantom models
FKBD for Overexpansion: Target of 6 mm (Outer SD)

- Size of non-compliant balloons
  - 3.5 + 4.0 mm (FKBD-US)
  - 4.0 + 5.0 mm

- Pressure
  - 4 (FKBD-LP) vs 12 atm (FKBD-RBP)

Finet’s Law\(^1\):

\[
\text{Diameter of Main Branch} = \frac{2}{3} (\text{Diameter of main distal branch} + \text{Diameter of side branch})
\]

SD: Stent Diameter

---

Proximal Optimization Technique
6.0 x 15mm balloon (RBP 14 atm)

Final Kissing balloon Dilation
5.0 x 15mm and 4.0 x 15mm balloons
(RBP 12 atm)
Methods

Initial Deployment

1A
- 6.0 x 30mm outer silicon tube
- Synergy™ 4.0 x 28mm stent deployed at 16 atm
- 5.0 x 15mm inner silicon tube

1B
- Distal Stent: 5.0 x 15mm balloon (RBP 12 atm)

1C
- Proximal Stent: 5.0 x 15mm balloon (RBP 12 atm)

Distal End
Post Dilation

Proximal End
Post Dilation
Summary

- LM PCI requires optimized stent design
- $6 \text{ mm} = 28.3 \text{ mm}^2$ is possible with Synergy
- Undersized FKBD:
  - Serious Ellipticity + Serious malapposition
- Adequate sized FKBD
  - Serious Ellipticity + Minimal malapposition if adequate pressures are used
- POT
  - Does not follow normal compliance chart.
  - At High pressures: full apposition
**IDEAL-Left Main: Improved Drug Eluting stent for ALI comers Left Main**

**Sponsor:** Glasgow Jubilee National Hospital

**Principal Investigators:**
- Professor Keith Oldroyd, MD(Hons)
- Professor Robert-Jan van Geuns, MD, PhD
- Paul Barragan, Principle Investigator France
- Maciej Lesiak, Principle Investigator Poland
- Robert Byrne, Principle Investigator, Germany
- Evgeny Merkulov, Principle Investigator, Russia
- Evelyn Regar, OCT substudy
Objective

This study will investigate the short term angiographic and long term clinical outcome of after implantation of an improved drug eluting coronary artery stent (Everolimus-eluting Platinum Chromium Stent with Abluminal Bioabsorbable Polymer) with shorter post interventional dual antiplatelet therapy (DAPT) in comparison to a conventional drug eluting stent with a permanent Polymer followed by 12 months DAPT for treatment of unprotected left main coronary artery disease.
Study design:

A multicenter, prospective, randomized study (Synergy vs Xience) with a clinical follow-up of 5 years

Study population:

Subjects with an indication for coronary artery revascularisation by ESC guidelines and accepted for PCI of the left main coronary artery will be included in the study
The primary endpoint

The primary endpoint is MACCE, including death from any cause, MI, stroke, or ischemia-driven target vessel revascularization (TVR) at 2 years after the procedure. (Non-inferiority) \((N=818)\)

Primary invasive endpoint

Superiority Healing Score by OCT at 3 months follow-up \((N=100)\)

First patient in 31 Dec 2014: Target last patient Nov 2015
Thank You
Larger Diameter

Original Studies

A Prospective Intravascular Ultrasound Investigation of the Necessity for and Efficacy of Postdilation Beyond Nominal Diameter of 3 Current Generation DES Platforms for the Percutaneous Treatment of the Left Main Coronary Artery

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Circle of 4.0 = 12.6 mm²
Circle of 5.0 = 19.6 mm²

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<td>Resolute Integrity</td>
<td>3.5 (Large vessel)</td>
<td>1</td>
<td>14.1 (±1.1)</td>
<td>10.5 (±1.5)</td>
<td>10.8</td>
<td>4.7</td>
</tr>
</tbody>
</table>

MaxSD: maximal stent diameter; mm: millimeter; MSA: maximal stent area; n: number.
FKBD for overexpansion: Target of 6 mm

- Size of non-compliant balloons?
  - 3.5 + 4.0 mm?
  - 4.0 + 5.0 mm?
- Pressure
  - 4 or 6 vs 12 atm.
Risk of undersized FKBD
IVUS LM in male pts (Rotterdam)

- IVUS data on 865 LAD->LM pullbacks, male patients
- ‘non-diseased’ LM (i.e. minimal plaque burden, <50% of LM circumference with intimal thickening) in only 17.6% of pts (N=152)
- Average vessel diameter, vessel area
- Correlation with body surface area (BSA)
IVUS LM vessel diameter (VD)

- Average VD: 5.60 cm
- Mean VD: 5.47 cm
- Only in 13% <5 cm
Relation with BSA

• No clear correlation of VD or VA with BSA

\[ y = 5.095x + 15.117 \]
\[ R^2 = 0.03485 \]

\[ y = 0.605x + 4.3401 \]
\[ R^2 = 0.03571 \]
Large diameter:
No all stents are the same

<table>
<thead>
<tr>
<th>Stent System</th>
<th>Labeled Nominal</th>
<th>Labeled Post-Dilatation Limits*</th>
</tr>
</thead>
<tbody>
<tr>
<td>SYNERGY Stent System</td>
<td>2.25 to 2.75</td>
<td>3.00 to 4.00</td>
</tr>
<tr>
<td>Promus PREMIER™ Stent System</td>
<td>2.25 to 2.50</td>
<td>2.50 to 3.50</td>
</tr>
<tr>
<td>Xience Xpedition™ Stent System</td>
<td>2.25 to 2.50</td>
<td>2.75 to 4.00</td>
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<td>Resolute Integrity™ Stent System</td>
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</tr>
</tbody>
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*SYNERGY Stent, Promus PREMIER Stent, Xience Xpedition Stent and Resolute Integrity Stent DFU.
Importance of knowing stent design threshold diameters and post-dilatation capacities to optimise stent selection and prevent stent overexpansion/incomplete apposition during PCI

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Overexpansion has limitations, especially when sizing to the distal main branch of a bifurcation. Potential resulting in serious malapposition