FIBER-OPTIC 0.014” PRESSURE-WIRE: THE OPTOWIRE® AND OPTOMONITOR®

Olivier F. Bertrand, MD, PhD

Associate-Professor of Medicine, Laval University
Adjunct-Professor, Department of Mechanical Engineering, McGill University
Quebec Heart-Lung Institute

Coronary Physiology in the Catheterization Laboratory (9th Edition)- April 23-25, 2015
DISCLOSURES

• Consultant, Opsens

• Scientific Director of International Chair in Interventional Cardiology and Transradial Approach
  
  • operates www.theradialist.org &
  
  • organizes AIM-RADIAL congress (www.aimradial.org)

• Chair receives funding from multiple industry and other sources

• O₂ FIM study management and data analysis
CASE STORY

FFR 1

FFR 2
CASE STORY

BMW + direct stenting!
Could we have a floppy-like pressure-wire to reliably and repeatedly assess FFR in any type of lesion and any location?
UNMET NEEDS

- FFR wire which performs as a floppy-wire and allows the operator to reach and cross any lesion

- FFR wire must have enough support to work as PCI wire

- FFR wire can be directly hooked up into the cath lab monitoring system (integrated FFR measurements)

- Monitor must be easy to use and allows to print/record results

- Stable and reliable signal upon initial and repeat connexions (multiple lesions assessment /post-PCI measures)
OPTOWIRE DESIGN

- Unique features - White-light interferometry – Fiber Optic Coherence method (US patent 7,259,862)
- Unique features - Optical MEMS based pressure sensor (US patent 7,689,071 and 8,752,435)
WIRES STRUCTURE

Pressure Guidewire
- Electric wires
- Core Wire (SS)
  - Thin – low torque
  - Eccentric - whipping
  - 0.0035”-0.0055”

OptoWire
- Optical fiber
- Hollow Wire (NiTi)
  - Large – High torque
  - Concentric – No whipping
  - 0.009”-0.0075”

BMW
- Core Wire (NiTi)
  - Large – High torque
  - Concentric – No whipping
FLEXIBILITY TESTING
TORQUABILITY TESTING

![Graph showing output rotation vs. input rotation for different models, including the ideal case.](image-url)
TORQUABILITY TESTING

![Graph showing rotational delay (degrees) for BMW (n=5) and OW (n=20) compared to REF 1 (n=5) and REF 1 (n=5). The chart includes bars for Quality Factor, Hysteresis, clock lag, counterclock lag, and Whip.](image-url)
ANIMAL (PIG) TESTING

GLP Testing completed in November 2013 at Accelab (Montreal)
ANIMAL (PIG) TESTING

Prolonged parallel pressure monitoring in pig coronary model-Accelab (Montreal)
OPTOMONITOR®

Up to 1h data recording

Front

Back
O₂- OBJECTIVES

• To assess the performance of Opto-wire to cross any type of coronary lesion, except CTOs and thrombotic lesions

• To assess the ease and reliability (drift ?) to obtain Pre- and/or Post-PCI FFR values

• To evaluate the performance of Optowire as PCI wire

Presented at TCT 2014: Late-breaking New Technologies
STUDY POPULATION (N = 27)

<table>
<thead>
<tr>
<th>Condition</th>
<th>Count (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>65 +/- 10</td>
</tr>
<tr>
<td>Male</td>
<td>17 (63%)</td>
</tr>
<tr>
<td>Hx MI</td>
<td>10 (37%)</td>
</tr>
<tr>
<td>Hx PCI</td>
<td>10 (37%)</td>
</tr>
<tr>
<td>Stable angina</td>
<td>10 (37%)</td>
</tr>
<tr>
<td>Unstable angina</td>
<td>12 (44%)</td>
</tr>
<tr>
<td>NSTEMI</td>
<td>5 (19%)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>9 (33%)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>24 (89%)</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>24 (89%)</td>
</tr>
<tr>
<td>Smoker (current)</td>
<td>6 (35%)</td>
</tr>
<tr>
<td>Study Population (N = 27)</td>
<td></td>
</tr>
<tr>
<td>---------------------------</td>
<td></td>
</tr>
<tr>
<td><strong>Access (radial/ulnar)</strong></td>
<td>25/2 (100%)</td>
</tr>
<tr>
<td><strong>Diagnostic catheter</strong></td>
<td>6 (14%)</td>
</tr>
<tr>
<td><strong>Guiding catheter</strong></td>
<td>37 (86%)</td>
</tr>
<tr>
<td><strong>5Fr</strong></td>
<td>41 (95%)</td>
</tr>
<tr>
<td><strong>6Fr</strong></td>
<td>2 (4.7%)</td>
</tr>
<tr>
<td><strong>Vx diseased (1/2/3)</strong></td>
<td>17 (62%)/5 (19%)/5 (19%)</td>
</tr>
<tr>
<td><strong>Lesions</strong></td>
<td><strong>LM: 3 (7%)</strong></td>
</tr>
<tr>
<td></td>
<td><strong>LAD-Diag: 20 (47%)</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Cx-Mg: 12 (28%)</strong></td>
</tr>
<tr>
<td></td>
<td><strong>RCA: 8 (19%)</strong></td>
</tr>
<tr>
<td><strong>Ejection Fraction</strong></td>
<td>57 +/- 8%</td>
</tr>
<tr>
<td><strong>Procedure duration (min)</strong></td>
<td>45 [33-71]</td>
</tr>
<tr>
<td><strong>Contrast volume</strong></td>
<td>138 +/- 62 ml</td>
</tr>
<tr>
<td>Measurements</td>
<td>50 FFR/36 sites</td>
</tr>
<tr>
<td>-----------------------</td>
<td>----------------</td>
</tr>
<tr>
<td>N</td>
<td>60 [40-80]</td>
</tr>
<tr>
<td>% diameter stenosis</td>
<td>Type A: 4 (9%)</td>
</tr>
<tr>
<td></td>
<td>Type B1: 23 (53%)</td>
</tr>
<tr>
<td></td>
<td>Type B2/C: 16 (37%)</td>
</tr>
<tr>
<td>Reference Diameter (mm)</td>
<td>2.73 +/- 0.37</td>
</tr>
<tr>
<td>Baseline Pd/Pa</td>
<td>0.87 +/- 0.13</td>
</tr>
<tr>
<td>(300 µg IC adenosine)</td>
<td>0.78 +/- 0.14</td>
</tr>
<tr>
<td>Pressure at proximal pull-back</td>
<td>0.99 +/- 0.03</td>
</tr>
<tr>
<td>Pressure after reconnection</td>
<td>0.99 +/- 0.03</td>
</tr>
</tbody>
</table>
# FFR POST-PCI

<table>
<thead>
<tr>
<th>N Lesions</th>
<th>24 FFR/19 sites</th>
</tr>
</thead>
<tbody>
<tr>
<td>LAD-Diag: 14 (60%)</td>
<td>Cx: 7 (30%)</td>
</tr>
<tr>
<td>Cx: 7 (30%)</td>
<td>RCA: 2 (10%)</td>
</tr>
<tr>
<td>Number of stents (DES/BVS)</td>
<td>1.2 +/- 0.6</td>
</tr>
<tr>
<td>Stent diameter (mm)</td>
<td>2.68 +/- 0.38</td>
</tr>
<tr>
<td>Stent length (mm)</td>
<td>19.8 +/- 7.2</td>
</tr>
<tr>
<td>Largest balloon (mm)</td>
<td>2.8 +/- 0.4</td>
</tr>
<tr>
<td>Max pressure (ATM)</td>
<td>20.5 +/- 5.2</td>
</tr>
<tr>
<td>Angiographic Success</td>
<td>23 (100%)</td>
</tr>
<tr>
<td>Pd/Pa baseline</td>
<td>0.90 +/- 0.07</td>
</tr>
<tr>
<td>FFR (300 µg IC adenosine)</td>
<td>0.83 +/- 0.08</td>
</tr>
<tr>
<td>Pressure at proximal pull-back</td>
<td>0.97 +/- 0.02</td>
</tr>
<tr>
<td>Pressure after reconnection</td>
<td>0.97 +/- 0.02</td>
</tr>
</tbody>
</table>
OPTOWIRE 001 VS 002

0.3 mm
0.4 mm

Dimensions:
- 3.5 cm
- 28 cm
- 175 cm

Components:
- Pressure Window
- Optical Pressure Sensor
- Nafion
- Spiral Hypotube
- Optical Fiber
- PTFE Coated Shaft
- Optical Connector
LAD ASSESSMENT
Risk factors:

- Dyslipidemia
- Family history of CAD
- Hypertension
- Diabetes mellitus type 2?
  - Obesity

Clinical presentation (April 2015):

- NSTEMI
TIME FRAMES

2010 2011 2012 2013 2014 2015

R&D

Optowire & Optomonitor

O₂ FIM Study (Canada)

Animal Testing Q4: Japan approval

Q2: CE- Mark
FDA (510k) pending
Canada pending
STRUCTURE
FFR WIRE INTRA-LV
SEVERE AORTIC STENOSIS
Rapport Echo Adulte

Identification: [redacted]
Né(e) le: 1950-03-13 (yyyy-MM-dd)
Âge: 65 an(s)
Raison de l'examen: Évaluer valve aortique

Date de l'examen: 2015-04-08 14:06
Taille: 166 cm
N° dossier: 720060
Localisation patient: 2e ND HEMO
Poids: 106 kg
PA: 117/70 mmHg
SC: 2,1 m²
FC: 84

Synthèse
Sténose valvulaire aortique : sévère.
Gradient transaortique maximal: 101 mm Hg.
Gradient transaortique moyen: 60 mm Hg.
L'appareil valvulaire aortique est tricuside et non bicuside.
Aorte ascendante de calibre normal.
Remodelage concentrique du VG.
Le septum interventriculaire est sigmoïde.
Un gradient de pression intraventriculaire gauche de 80 mm Hg a été mesuré.

Ventricule gauche
Le ventricule gauche est d'une taille globalement normale. Remodelage concentrique du VG. La masse du VG a été mesurée à 103.4 g/m². (N hommes:<116 ; HVG légère 116-131, modérée 132-148, sévère >148). Un gradient de pression intraventriculaire gauche de 80 mm Hg a été mesuré. Le septum interventriculaire est