THE FUTURE IS HERE NOW, AND ITS ELECTRICAL

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FFR CLINICAL EVIDENCE DEVELOPMENT

WW FFR Procedures


Method validation
NEJM Landmark trial
FFR concept

Safety
DEFER, RCT
Safe to defer PCI
Left Main, Ostial Tandem lesions
ACS nonculprit
Bypass

Patient Subsets
MVD

Patient Outcome & Cost Efficiency
1A ESC PCI Guidelines
FAME 1, RCT
FFR-guided PCI better than angio guided
FAME 2, RCT
FFR-guided PCI better than OMT
FAME 3 Initiated
FFR-guided PCI vs CABG

ACS->
FFR USAGE IS GROWING. FAST

FFR % usage vs PCI*

<table>
<thead>
<tr>
<th></th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>US</td>
<td>19%</td>
<td>22%</td>
<td>25%</td>
<td>28%</td>
<td>30%</td>
<td>32%</td>
</tr>
<tr>
<td>Europe</td>
<td>8%</td>
<td>9%</td>
<td>10%</td>
<td>10%</td>
<td>11%</td>
<td>11%</td>
</tr>
<tr>
<td>Japan</td>
<td>8%</td>
<td>9%</td>
<td>10%</td>
<td>12%</td>
<td>12%</td>
<td>13%</td>
</tr>
<tr>
<td>WW (US,JPN,EU)</td>
<td>13%</td>
<td>14%</td>
<td>16%</td>
<td>17%</td>
<td>18%</td>
<td>19%</td>
</tr>
</tbody>
</table>

Total number of FFR Procedures divided by number of PCI
ELECTRICAL OR OPTICAL SENSORS?

- Emerging FFR Manufacturers (BSC, OPSENS, ACIST) All use similar optical pressure sensors
- Why does St Jude use Electrical (Piezo-Resistive) Sensors, and how are these being further developed?
1 ST JUDE’S ELECTRICAL SENSOR IS STABLE
REALLY?

- All FFR devices on the market have some level of measurement inaccuracy.
- Not all vendors disclose this information publicly.

<table>
<thead>
<tr>
<th>Device</th>
<th>St. Jude Medical PressureWire™ Pressure Guidewire</th>
<th>ACIST Navvus™ Pressure Catheter</th>
<th>Volcano Verrata™ Pressure Guidewire</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pressure guidewire</td>
<td>Pressure guidewire</td>
<td>Catheter</td>
<td>Pressure guidewire</td>
</tr>
<tr>
<td>Sensor technology</td>
<td>Piezo-resistive (Electrical)</td>
<td>Optical Fabry-Perot</td>
<td>Piezo-resistive (Electrical)</td>
</tr>
<tr>
<td>Pressure accuracy</td>
<td>+/-1 mmHg plus +/-3% of reading</td>
<td>+/-3% of reading or +/-3 mmHg, whichever is greatest</td>
<td>Not specified in IFU</td>
</tr>
<tr>
<td>Pressure range</td>
<td>-30 to 300 mmHg</td>
<td>-30 to 300 mmHg</td>
<td>Not specified in IFU</td>
</tr>
<tr>
<td>Frequency response</td>
<td>0-25 Hz</td>
<td>Not specified in IFU</td>
<td>Not specified in IFU</td>
</tr>
<tr>
<td>Zero thermal effect</td>
<td>&lt; 0.3 mmHg/deg C</td>
<td>&lt; 0.4 mmHg/deg C</td>
<td>Not specified in IFU</td>
</tr>
<tr>
<td>Zero drift</td>
<td>&lt; 7 mmHg/hour</td>
<td>&lt; 7 mmHg/hour</td>
<td>Not specified in IFU Per FDA approval: &lt;5 mmHg/10minutes</td>
</tr>
</tbody>
</table>
WHAT IS THE CAUSE OF DRIFT?

Drift related to AO/Procedure

- Changing height of AO transducer
- Capillary forces in catheter
- Wedging guide in Ostium
- Needle in Y-connector
- Catheter with side-holes
- Contrast power injector

Drift related to PressureWire

- Temperature shift from room to patient
- Instrumentation calibration
- Blood/saline remnants on connector
- Microscopic-air bubbles trapped inside sensor capsule
MICRO-BUBBLES?

Microscopic-volumes of encapsulated gas may cause pressure shift when dissolving from sensor housing.
WHEN DO DRIFT OCCUR?

- If PW drift occurs it is most commonly early on in the procedure.
- After initial pressure drift pressure measurement is normally stable.
CAN WE REACH A DRIFT-FREE FFR PROCEDURE?

Improving procedure/accuracy of AO-pressure reading

- Repeated training of the cathlab staff
  - Adherence to protocol – need for standardization
- FFR Instrumentation
  - On-screen step-by-step procedure guide
  - Software automatic detecting and avoiding common artifacts/user mistakes
ST JUDE'S ELECTRICAL SENSOR CAN BE MADE WIRELESS
Ease of use

- Quick, wireless setup
- Cable free patient environment
- No cables crossing sterile barrier
- No cables to limit wire movement
WHY WIRELESS?

Accuracy

- New, calibrated, measurement electronics for every case – Accurate, no need for annual checkup or calibration
- Analog-Digital conversion at the wire – no transmission loss
WHY WIRELESS?

Flexibility

- All St Jude FFR systems share the same wireless AO source: Wi-box
- Allows a mix of Mobile or Integrated FFR/OCT systems, covering all cathlab rooms
- Minimal installation/cabling requirements
HOW DOES IT WORK?

1. Transmitters and Receivers lock to each other using unique identification codes
2. “Frequency-Hopping” technology change transmitting frequency 400 times/second
3. Stable and reliable communication also in instrumentation-packed cathlabs
ST JUDE’S ELECTRICAL SENSOR CAN MEASURE FLOW
PRESSUREWIRE: PRESSURE & FLOW

Pressure sensor

Temperature sensor
HOW DO WE GET FLOW FROM TEMPERATURE?

1. THERMO-DILUTION - BOLUS

IMR - Index for microcirculatory Resistance

\[ \text{IMR} = \frac{\Delta \text{Pressure}}{\text{Flow}} = \frac{P_d}{T_{mn}} \]

CFR – Coronary Flow Reserve

\[ \text{CFR} = \frac{\text{Hyp flow}}{\text{Resting flow}} = \frac{1/T_{mn_{\text{Hyp}}}}{1/T_{mn_{\text{Rest}}}} \]

Transit mean time (Tmn)

Distal Pressure (Pd)


HOW DO WE GET FLOW FROM TEMPERATURE?

2. THERMO-DILUTION - INFUSION

\[ Q_b = \text{Infusion rate} \times \left( \frac{T_{\text{infusion}}}{T_{\text{mix}}} \right) \times k \]

\[ k = 1.08 \]

Volumetric blood flow (ml/min)

Direct Volumetric Blood Flow Measurement in Coronary Arteries by Thermodilution
HOW DO WE GET FLOW FROM TEMPERATURE?

SENSOR AND CABLE TEMPERATURE FROM PW AERIS 2.0 ON QUANTIEN -WORK IN PROGRESS
HOW DO WE GET FLOW FROM TEMPERATURE?

3. THERMO-CONVECTION FLOW VELOCITY

Elevated sensor temperature +5°C
Sensor housing +1-2°C

Blood flow cools sensor temperature proportionally to blood flow rate

Red: Reference flow probe
Blue: PressureWire Thermo Convection flow

Internal St Jude Animal data
Arjen van der Horst, Medical Engineering and Physics, July 2011 Volume 33, Issue 6, Pages 684–691
HOW DO WE GET FLOW FROM TEMPERATURE?

3. THERMO-CONVECTION FLOW VELOCITY

Internal St Jude in-vitro data
HOW DO WE GET FLOW FROM TEMPERATURE?

PRESSURE AND THERMOCONVECTION FLOW FROM PW AERIS 2.0 ON QUANTIEN – WORK IN PROGRESS
Combined assessment of Epicardial and Microvascular disease may lead to improved diagnosis and outcomes

Enabling FFR and IMR/CFR on a FFR-guidewire designed for every day PCI usage may move combined assessment into every day clinical practice
CONCLUSION

THE ELECTRICAL SENSOR TECHNOLOGY USED IN ST JUDE’S PRESSUREWIRE ENABLES:

1. HIGH MEASUREMENT RELIABILITY
2. WIRELESS CONNECTIVITY
3. COMBINED ASSESSMENT OF FFR & IMR/CFR
THE FUTURE IS HERE NOW (ALMOST) AND ITS ELECTRICAL
THANK YOU FOR YOUR ATTENTION