ACIST RxI: A Monorail pressure microcatheter

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Issues regarding the work flow of FFR

1. Set up/zero/drift
2. IV hyperemia
3. Pressure wire handling
4. Multiple pressure wire manipulations

Opportunities for Improvement
1. Increase stability
2. Improvement wire handling
3. Facilitate rapid pressure sensor placement
Available FFR Technologies

**Pressure Wire Technology**

- Specially constructed 0.014” wire
- Sensor incorporated into distal end at junction of radiopaque and radiolucent segments
- Piezo-electric technology
- Performance not as robust as dedicated coronary wire

**Micro-Catheter Technology**

- Does not require a specialized guidewire but can be delivered over standard coronary wire (Rapid Exchange)
- Low-profile catheter with pressure sensor incorporated into distal end
- Fiber-optic technology
Microcatheter Rxi Pressure System
The RXi system combines fiber-optic technology with the ultra-thin ACIST Navvus™ Rapid Exchange FFR MicroCatheter delivered over any standard 0.014” guidewire. Minimizes wire exchanges.

**Ultrathin Profile**

- **1.9F × 1.5F**
- **0.025” × 0.020”**

**26 cm distal shaft**
Micro-Catheter FFR Technology
Fiber Optic Pressure Sensor Technology

• Pressure is measured by detecting the cavity width using a Fabry–Pérot white-light interferometer

• Blood pressure causes the sensor's distal face to flex inward, reducing the width of the cavity.

• Sensor not vulnerable to electrical interference.
Bench Data: 80% AS

3 mm Vessel

Pressure drop v/s Flow rate
80% Area Stenosis

\[ y = 0.0013x^2 + 0.0577x \]
\[ R^2 = 0.9999 \]

2.5 mm Vessel

Pressure drop v/s flow rate
80% Area Stenosis

\[ y = 0.0022x^2 + 0.1265x \]
\[ R^2 = 0.9973 \]
ACCESS-NZ Study
Micro-Catheter FFR vs. Pressure Wire Measurements

Clinical indication for coronary angiography
Native target vessel diameter > 2.5 mm with TIMI 3 flow
Investigator-determined indication for FFR

Micro-Catheter FFR System
ACIST Navvus RXI™ Rapid Exchange

Pressure Wire FFR System
St. Jude Medical Certus

Determine Agreement between FFR obtained with each system during maximum hyperemia

Patient Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
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<tbody>
<tr>
<td>N</td>
<td>50</td>
</tr>
<tr>
<td>Age</td>
<td>42 – 86 (average 65.6 years)</td>
</tr>
<tr>
<td>Male</td>
<td>80%</td>
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<tr>
<td>NYHA Class I or II</td>
<td>54%</td>
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RXi Compared to PW Alone
Bland-Altman Plot of RXi and PW FFR’s

- Bias (-0.01)
- 95% Limits of Agreement (-0.13 to 0.10)
Agreement Between Systems – Navis+guide wire vs guidewire alone

Effect of the Navvus MicroCatheter’s size on FFR measurements

FFR measured by pressure wire with Navvus MicroCatheter present vs FFR measured by pressure wire only.
ACCESS-NZ Study
Pressure Drift: Pressure Wire vs. Micro-Catheter

**Mean Drift**
- Pressure Wire: 0.06
- Micro-Catheter: 0.02
- P = 0.014

**Clinically Significant Drift**
- Pressure Wire: 33%
- Micro-Catheter: 13%
- P = 0.022

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Case Example

68-year-old man with chest pain to his left shoulder and arm walking on his treadmill. HBP, CHOL, GERD

ETT in hospital positive with ST changes and CP.

Symptoms have been ongoing for 2 months. Denies diaphoresis, nausea, or other associated symptoms.
LCA, RAO cr

LAO, caud
FFR Assessment of Long LAD w pullback and of D1 ostial lesion
FFR of LAD with microcatheter
### FFR of Diagonal branch

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<tr>
<th>Pa</th>
<th>Pd</th>
<th>Pv</th>
<th>FFR</th>
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<tbody>
<tr>
<td>95</td>
<td>61</td>
<td>0</td>
<td>0.65</td>
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Graph showing the pressure data over time.
### Resting Ratio after POBA of LAD

<table>
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<tr>
<th>Pa</th>
<th>Pd</th>
<th>Pv</th>
<th>FFR</th>
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<tbody>
<tr>
<td>89</td>
<td>73</td>
<td>0</td>
<td>0.82</td>
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![Graph showing blood pressure and FFR values](image-url)
Despite multiple Sequential Balloon inflations, kissing balloon inflation needed
Final. The enemy of good is better
FFR in complex lesions

- Microcatheter Rxi facilitates multiple pressure/FFR measurements over your chosen best guidewire(s)
- Eliminates need to recross lesions with guidewire
- Promotes rapid pressure without loosing wire position
- Facilitates rapid FFR at any time during procedure