Analysis of changes in decision-making process during optical coherence tomography-guided percutaneous coronary interventions: New Insights from the LightLab Initiative

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on behalf of the LightLab Initiative Investigators.
Optical coherence tomography imaging during percutaneous coronary intervention impacts physician decision-making: ILUMIEN I study

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Conclusion

Physician decision-making was affected by OCT imaging prior to PCI in 57% and post-PCI in 27% of all cases.

• Use of intracoronary imaging during PCI affects physician decision-making and is associated with reduced mortality
• Barriers to uptake include perceived lack of benefit and adverse impacts on workflow
• The LightLab Initiative was set up to assess the utility of implementing OCT into PCI workflow
• The study was designed and sponsored by Abbott

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The LightLab Initiative:

- 12 US centers with ongoing prospective PCI procedural data collection by trained & embedded Field Clinical Engineer
- Multiphase program to examine role & impact of OCT use

**Baseline Phase:** Assessment of current practice and collection of data for comparison to future phases

**Phase 1 Decision Making:** Adoption of LightLab OCT-focused workflow (LL WF) and the effect on accuracy/precision

**Phase 1 Efficiency:** Standardization of LightLab OCT-focused workflow (LL WF) and the effect on efficiency

**Phase 2:** Optimization of workflow to reduce angiographic pre-diagnosis steps and improve efficiency

**Phase 3:** Expansion of workflow to increased procedural complexity and case presentations
How was the study executed?

The LightLab Workflow

Prescriptive utilization of the full range of information from OCT pre PCI and post PCI to guide treatment decisions

1. Physiologic Assessment
2. Plaque Morphology
3. Lesion Length
4. Vessel Diameter
5. Angiographic Co-Registration
6. Medial Dissection/Stent Edge Assessment
7. Stent Apposition
8. Stent Expansion

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How was the study executed?

**Who?** Study population
- All PCIs by participating physicians potentially eligible
- Decision on the part of physician whether each PCI was clinically appropriate for OCT and for LightLab inclusion

**What?** Treatment decision-making
- Lesion morphology, number
- Vessel preparation strategy
- Stent diameter & length
- Vessel optimization/post-dilation strategy

**How?** Prospective data collection
- Recorded on study proforma
A total of 2203 procedures were assessed in this phase of the LL program (March 6, 2019 – March 12, 2020)

2203 procedures

710 OCT guided PCI procedures

604 LL WF guided PCI procedures

864 Lesions

652 Lesions with LightLab Workflow

1493 procedures excluded:
• 997 diagnostic
• 165 surgical referral
• 25 aborted PCI
• 71 IVUS guided PCI
• 235 Angiography guided PCI

106 OCT procedures excluded:
• 61 only pre-PCI OCT performed
• 45 only post-PCI OCT performed

212 lesions excluded:
• 193 angiography guided
• 7 only pre-PCI OCT performed
• 6 only post-PCI OCT performed
• 6 poor OCT pullback quality

Study Population

LightLab Workflow Procedures (n=604)

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Planned/staged procedures</td>
<td>181/604</td>
<td>30%</td>
</tr>
<tr>
<td>Access Site</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radial</td>
<td>357/573</td>
<td>62%</td>
</tr>
<tr>
<td>Femoral</td>
<td>210/573</td>
<td>37%</td>
</tr>
<tr>
<td>Radial &amp; Femoral</td>
<td>6/573</td>
<td>1%</td>
</tr>
<tr>
<td>Mechanical Support</td>
<td>9/604</td>
<td>2%</td>
</tr>
<tr>
<td>Multivessel</td>
<td>63/604</td>
<td>10%</td>
</tr>
<tr>
<td>STEMI</td>
<td>33/604</td>
<td>6%</td>
</tr>
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</table>

LightLab Workflow Lesions (n=652)

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Left Main</td>
<td>20/642</td>
<td>3%</td>
</tr>
<tr>
<td>RCA</td>
<td>188/642</td>
<td>29%</td>
</tr>
<tr>
<td>LAD</td>
<td>310/642</td>
<td>48%</td>
</tr>
<tr>
<td>CX</td>
<td>100/642</td>
<td>16%</td>
</tr>
<tr>
<td>Ramus</td>
<td>14/642</td>
<td>2%</td>
</tr>
<tr>
<td>Vein Graft</td>
<td>10/642</td>
<td>2%</td>
</tr>
<tr>
<td>Lesion Type</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>34/650</td>
<td>5%</td>
</tr>
<tr>
<td>B</td>
<td>258/650</td>
<td>40%</td>
</tr>
<tr>
<td>C</td>
<td>358/650</td>
<td>55%</td>
</tr>
<tr>
<td>In-stent Restenosis</td>
<td>115/651</td>
<td>18%</td>
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<tr>
<td>Long Lesions (OCT Lesion length ≥ 28 mm)</td>
<td>286/652</td>
<td>44%</td>
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<tr>
<td>Chronic Total Occlusions</td>
<td>21/652</td>
<td>3%</td>
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<tr>
<td>Bifurcations</td>
<td>66/648</td>
<td>10%</td>
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<tr>
<td>Ostial Lesions</td>
<td>30/652</td>
<td>5%</td>
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OCT changes angiographic-based decisions in 88% of lesions

Pre-PCI OCT Impact: 83% of Lesions

Post-PCI OCT Impact: 31% of Lesions

Cumulative OCT Impact: 88%
Lesion assessment and treatment decisions that impact final stent expansion

Pre-PCI OCT Impact: 83% of Lesions  
Post-PCI OCT Impact: 31% of Lesions

Cumulative OCT Impact: 88%

Blue bars indicate decisions that impact stent expansion.

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Inaccurate diagnosis of Calcium severity drives changes in vessel preparation strategy

Predicted Lesion Morphology on Pre-PCI OCT Pullback

<table>
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<tr>
<th>Calcium</th>
<th>Fibrous Plaque</th>
<th>Other</th>
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<tr>
<td>4%</td>
<td>47%</td>
<td></td>
</tr>
<tr>
<td>27%</td>
<td>22%</td>
<td></td>
</tr>
<tr>
<td>11%</td>
<td>30%</td>
<td>4%</td>
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- 47% Change
- 41% Change
- 20% Change

Calcified Lesions

Vessel preparation methods performed in 47% with device change:
- 49% Pre-dilatation with compliant or non-compliant balloons
- 26% Pre-dilatation with cutting or scoring balloons
- 25% Atherectomy or laser

Vessel preparation methods performed in 27% without device change:
- 88% Pre-dilatation with compliant or non-compliant balloons
- 2% Pre-dilatation with cutting or scoring balloons
- 10% Atherectomy or laser

Note: Excludes n=257 lesions where vessel prep was performed before pre-PCI OCT

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Angiographic guidance lead to inaccurate stent diameter in 38% of stented lesions.
Ability to detect stent underexpansion enables targeted optimization

Minimum Expansion by Group*:

- **Overall**: 80 ± 14.5%  n=652
- **Additional Optimization**: 73 ± 14.6%  n=248
- **No Additional Optimization**: 84 ± 12.7%  n=404

- **Population of lesions that followed the LightLab guided workflow achieved 80% minimum stent expansion on average**
- **Physicians performed targeted optimization in subset of lesions (38%) based on post-PCI OCT assessment**

*Note: 80% is the mean expansion for the entire population. 84% is for the sub-group where no additional optimization was performed and represents the final expansion for the procedure. 73% is the sub-group where additional optimization was performed without a final OCT.

Post dilatation performed in 85% of lesions before post-PCI OCT
How was the study executed?

The LightLab Workflow

Prescriptive utilization of the full range of information from OCT pre PCI and post PCI to guide treatment decisions

PRE-PCI PULLBACK → TREATMENT → POST-PCI PULLBACK

1. Physiologic Assessment
2. Plaque Morphology
3. Lesion Length
4. Vessel Diameter
5. Angiographic Co-Registration
6. Medial Dissection/Stent Edge Assessment
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The essentials to remember

• OCT guidance impacted decision-making in 88% PCI cases in this prospective dataset

• The majority of changes occurred during diagnosis/planning & on treatment strategy derived from pre-PCI OCT pullback (83%):
  • Accurate classification of angiographically-underestimated lesions (eg Ca²⁺)
  • Additional/altered vessel preparation strategy
  • Correct vessel sizing leading to changes in planned stent diameter & length

• The population of lesions treated that followed LightLab-guided workflow achieved 80% stent expansion on average

• The unprecedented granularity of the volume of collected procedural data in this real-world cohort demonstrates a clear and important impact of OCT on lesion assessment, procedural planning and stent optimization
## Acknowledgements

### LightLab Initiative Investigators & Affiliated Hospitals

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Investigators</th>
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<tbody>
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<td>Eric Osborn, Eric Secemsky, Marie-France Poulin, Hector Tamez</td>
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<td><strong>Via Christi St. Francis &amp; Kansas Heart Hospital</strong></td>
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<td>Jossel Disengi</td>
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