Towards using tissue oxygen measurements across the continuum of care for CLI management: *lessons learned from the OMNIA study*

*Miguel Montero-Baker, MD*
Division of Vascular Surgery and Endovascular Therapy
Baylor College of Medicine
Houston, TX, USA
Disclosure

Speaker name: Miguel Montero-Baker

I have the following potential conflicts of interest to report:
☐ Consulting
☐ Employment in industry
☒ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☐ I do not have any potential conflict of interest
Lumee® Oxygen Platform

- **Lumee® Oxygen Platform** is designed to continuously monitor tissue oxygen.

- **OMNIA is a study** designed to characterize the relationships between revascularization success, traditional hemodynamics, and tissue oxygen.

- **Interim OMNIA analysis** reveals a potential association between tissue oxygen data and wound improvement.
How Does Lumee® Oxygen Work

- Soft biocompatible hydrogel sensor injected into subcutaneous space
- Excitation light from surface reader reaches hydrogel in tissue.
- Fluorescence chemistry on hydrogel responds based on analyte concentration. Reader collects emissions and data sent to cloud.
OMNIA- Oxygen Monitoring Near Ischemic Areas

**Study Design**
- Enrolled CLI subjects (Rutherford 4 or 5) scheduled to undergo endovascular revascularization
- Prospective, single-arm, open-label, multicenter study. 35 subjects enrolled.
- Injected 3 Lumee® Oxygen sensors in the foot and 1 reference sensor in the upper arm

**Protocol**
- Lumee® measurements performed during endovascular revascularization (EVT) procedures
- Lumee® measurements also performed during functional assessment tests conducted before and after revascularization, and at follow-up visits over 12 months.
- Also sampled: arterial duplex, toe and ankle brachial index, WiFi scores, wound characterization and photographs.

**Analysis**
- Features of oxygen increase extracted from continuous Lumee data
- Wound healing assessed during follow-ups based on objective criteria
- Sensor locations considered in data interpretation
- Retrospective classification analysis determines potential diagnostic power of Lumee® Oxygen to predict success of EVT
Clinical need in CLI for tool to provide objective assessment of perfusion
Pre-op analysis captures microvascular response to positional maneuver

**Healthy volunteer**

**Subject improved**

**Subject deteriorated**

**Metric:** dynamic response of oxygen to leg lift

**Physiological basis:** assess microvascular capacity
Responsivity to leg lift at pre-op / follow up visits may predict likelihood of successful EVT.

Response across visits

Legend:
- *p=0.04

Diagram:
- LOI Ratio to Arm
- Responsivity
- Improvement
- No change/Deteriorated
- Time
- Leg-lift provocation
- PreOp, Discharge, 3 month, 6 month
Pre-op leg lift data may characterize microvascular health

**Fisher’s Exact test**: 75% probability data are associated with wound healing
Clinical need in CLI for tool to provide objective assessment of perfusion
Intra-op analysis captures oxygen increases during revascularization

**Metric**: magnitude of oxygen increase during EVT

**Physiological basis**: assess oxygen increases offered by restored arterial blood flow
Intra-op LOI analysis associated with wound healing at 3 months post-EVT

Fisher’s Exact test: 96% probability data are associated with wound healing

*Exploratory Retrospective Analysis
Clinical need in CLI for tool to provide objective assessment of perfusion

Pre-operative triage

Intra-operative monitoring of revascularization

Post-operative monitoring
Baseline oxygen in targeted angiosomes show increases following EVT

Subjects that improved by 3 months

*p=0.03

Subjects that did not improve by 3 months

*p=0.4
Post-op oxygen increases may characterize gains achieved by EVT

**Fisher’s Exact test:** 79% probability data are associated with wound healing
Clinical need in CLI for tool to provide objective assessment of perfusion

Pre-operative triage
Intra-operative monitoring of revascularization
Post-operative monitoring
Improved risk prediction possible by combining independent assessments made at each phase in care.

**Sequenced classification algorithm**
- Classify based on Pre-op
- Classify based on Intra-op
- Classify based on Post-op

Build decision-tree based on individual classifications

Predict risk for healing

**Model prediction per-patient**

<table>
<thead>
<tr>
<th>Intra-op</th>
<th>Pre/Post</th>
</tr>
</thead>
<tbody>
<tr>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>+</td>
<td>+</td>
</tr>
</tbody>
</table>

*Exploratory Retrospective Analysis*
**Exploratory Retrospective Analysis**

Tissue oxygen data sampled across the continuum of care provides stronger predictions of wound healing

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>62</td>
<td>76</td>
<td>71</td>
<td>94</td>
</tr>
<tr>
<td>Specificity</td>
<td>57</td>
<td>71</td>
<td>57</td>
<td>57</td>
</tr>
<tr>
<td>Probability of association</td>
<td>75%</td>
<td>96%</td>
<td>79%</td>
<td>99%</td>
</tr>
<tr>
<td>Diagnostic Odds Ratio</td>
<td>3</td>
<td>8.1</td>
<td>3.3</td>
<td>21.0</td>
</tr>
</tbody>
</table>

*Exploratory Retrospective Analysis*
Envisioned post-EVT care algorithm

<table>
<thead>
<tr>
<th>Angiographic assessment</th>
<th>Follow up plan</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Technical success</strong></td>
<td>Re-examine in 1 month</td>
</tr>
<tr>
<td><strong>Partial success</strong></td>
<td>Re-examine in 2 weeks</td>
</tr>
<tr>
<td><strong>Technical failure</strong></td>
<td>Reconsider Revasc Strategy</td>
</tr>
<tr>
<td><strong>Likely to heal</strong></td>
<td>Overhaul vascular care / palliative care</td>
</tr>
<tr>
<td>Arterial resupply</td>
<td>Lumee® suggests</td>
</tr>
<tr>
<td>translates to microvascular perfusion</td>
<td>collateralization</td>
</tr>
<tr>
<td>Arterial supply</td>
<td></td>
</tr>
<tr>
<td>adequate /</td>
<td></td>
</tr>
<tr>
<td>collateralization</td>
<td></td>
</tr>
<tr>
<td>sufficient</td>
<td></td>
</tr>
<tr>
<td>Lumee® suggests</td>
<td></td>
</tr>
<tr>
<td>collateralization</td>
<td></td>
</tr>
<tr>
<td><strong>Uncertain</strong></td>
<td></td>
</tr>
<tr>
<td>Micro-vessels</td>
<td></td>
</tr>
<tr>
<td>functional but not</td>
<td></td>
</tr>
<tr>
<td>efficient</td>
<td></td>
</tr>
<tr>
<td>Indicates potential</td>
<td></td>
</tr>
<tr>
<td>collateralization</td>
<td></td>
</tr>
<tr>
<td>Indicates potential</td>
<td></td>
</tr>
<tr>
<td>collateralization</td>
<td></td>
</tr>
<tr>
<td><strong>Unlikely to heal</strong></td>
<td></td>
</tr>
<tr>
<td>Arterial supply is</td>
<td></td>
</tr>
<tr>
<td>futile</td>
<td></td>
</tr>
<tr>
<td>Indicates no</td>
<td></td>
</tr>
<tr>
<td>collateralization</td>
<td></td>
</tr>
<tr>
<td>No flow and no</td>
<td></td>
</tr>
<tr>
<td>collateralization</td>
<td></td>
</tr>
</tbody>
</table>

Lumee® assessment

Envisioned post-EVT care algorithm

Follow up plan

- Re-examine in 1 month
- Re-examine in 2 weeks
- Reconsider Revasc Strategy
- Overhaul vascular care / palliative care
Summary

- **OMNIA has integrated Lumee® Oxygen into EVT** to continuously monitor tissue oxygen in 33 subjects.

- Tissue oxygen data sampled during pre-EVT office visit, monitored during revascularization, and increases assessed post-EVT.

- **Results show that ‘continuum of care’ algorithms may increase the predictive utility of Lumee® Oxygen data.** Diagnostic odds ratio improved from 11.7 (best during EVT) to 21.0 (for pre-, intra-, post-EVT).

- **Findings indicate that Lumee® Oxygen may provide functional assessment of EVT technical success** and may serve as adjunct to angiography to guide choices during procedures.
Towards using tissue oxygen measurements across the continuum of care for CLI management: *lessons learned from the OMNIA study*

Miguel Montero-Baker, MD
Division of Vascular Surgery and Endovascular Therapy
Baylor College of Medicine
Houston, TX, USA