Diagnostic performance potential of periprocedural tissue oxygen monitoring to assess functional success of endovascular revascularization

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Disclosure

Speaker name: Marianne Brodmann

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.
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.
HOW DO WE EXTRACT CLINICAL VALUE FROM MULTIPLE POINT MEASUREMENTS OF TISSUE OXYGEN DURING REVASCULARIZATION?

• *Lumee® Oxygen* provides continuous real-time tissue oxygen at point location(s)

• Sensor placement can be uniformly specified or customized to suit wound location or target of intervention

• Pilot analyses developing association between oxygen dynamics and treatment outcome

• This talk develops strategies to interpret data from multiple locations to provide guidance for optimal sensor placement locations
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
OMNIA- OXYGEN MONITORING NEAR ISCHEMIC AREAS

Study Design

• 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.

Protocol

Analysis

Consent, Enrollment

Sensor Injection

1-3 days

Intra-procedure monitoring

Revascularization

Long term monitoring

Pre-operative

Discharge

1 month

3 months

6 months

12 months

1-3 days
OMNIA- OXYGEN MONITORING NEAR ISCHEMIC AREAS

- **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
## ENROLLMENT SUMMARY

### Demographics

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Mean</th>
<th>+/- SD</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>73.7</td>
<td>12</td>
<td>43 - 90</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
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<tr>
<td>Male</td>
<td>27</td>
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<tr>
<td>Female</td>
<td>8</td>
</tr>
<tr>
<td>Diabetes</td>
<td></td>
</tr>
<tr>
<td>Type 1</td>
<td>1</td>
</tr>
<tr>
<td>Type 2</td>
<td>27</td>
</tr>
<tr>
<td>None</td>
<td>7</td>
</tr>
<tr>
<td>Revascularization</td>
<td></td>
</tr>
<tr>
<td>EVT</td>
<td>33</td>
</tr>
<tr>
<td>Bypass</td>
<td>2</td>
</tr>
<tr>
<td>Affected Limb</td>
<td></td>
</tr>
<tr>
<td>Right</td>
<td>17</td>
</tr>
<tr>
<td>Left</td>
<td>18</td>
</tr>
</tbody>
</table>

### Wound/Hemodynamics at enrollment

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Mean</th>
<th>+/- SD</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wound size [cm²]</td>
<td>1.9</td>
<td>2.7</td>
<td>0 – 13.7</td>
</tr>
<tr>
<td>ABI [-]</td>
<td>0.8</td>
<td>0.5</td>
<td>0 – 1.9</td>
</tr>
<tr>
<td>TBI [-]</td>
<td>0.3</td>
<td>0.2</td>
<td>0 - 1.4</td>
</tr>
</tbody>
</table>

### Enrollment / Analysis

- 35 subjects enrolled
- 2 subjects did not undergo endovascular revascularization
- 3 subjects lost to follow up
- 2 subjects withdrew consent
- 3 subjects excluded based on sensor location
- 1 subject excluded based on angiography

### Adverse Event Reporting

- 83 adverse events were reported
- 1 AE was described as “possibly related to study device” (swelling forefoot, most likely related to underlying disease); described as mild and resolved at follow-up.
QUANTIFICATION OF OXYGEN INCREASES DURING EVT

Sheath insertion
- Popliteal treated with PTA inflation (1x)
- Anterior tibial treated with PTA inflation (5x)
- Anterior tibial treated with PTA balloon (1x)

End procedure

Graph showing time vs. lumee oxygen index from 11:20 to 12:05 on April 20, 2017, with different oxygen increases at each marked event.
**LUMEE® MEASUREMENTS AT MEDIAL LOCATION ON THE FOOT PROVIDES STRONGEST PREDICTIVE POWER**

*Exploratory retrospective classification analysis, including cross-validation*
ANALYZING OXYGEN DATA ACROSS MULTIPLE SENSOR LOCATIONS PROVIDES STRONGER PREDICTIVE POWER THAN SELECTING LOCATION CLOSEST TO WOUND

*Exploratory retrospective classification analysis, including cross-validation*
**ASSAYING TISSUE OXYGEN FROM LOCATIONS OF INTEREST PROVIDES SUPERIOR PREDICTIVE POWER COMPARED TO TBI**

<table>
<thead>
<tr>
<th>Metrics</th>
<th>TBI</th>
<th>Lumee Closest to Wound</th>
<th>Lumee Medial Location</th>
<th>Lumee Average or Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>N</strong></td>
<td>26</td>
<td>22</td>
<td>24</td>
<td>24</td>
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<tr>
<td><strong>Sensitivity</strong></td>
<td>47</td>
<td>67</td>
<td>76</td>
<td>76</td>
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<tr>
<td><strong>Specificity</strong></td>
<td>86</td>
<td>71</td>
<td>71</td>
<td>71</td>
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<tr>
<td><strong>Fisher’s Exact</strong></td>
<td>0.14</td>
<td>0.11</td>
<td>0.04</td>
<td>0.04</td>
</tr>
<tr>
<td><strong>Diagnostic Odds Ratio</strong></td>
<td>5.4</td>
<td>5.0</td>
<td>8.1</td>
<td>8.1</td>
</tr>
</tbody>
</table>

*Exploratory retrospective classification analysis, including cross-validation*
OMNIA has integrated Lumee® Oxygen into EVT to continuously monitor tissue oxygen in 33 subjects.

Tissue oxygen data collected from 3 Lumee® Oxygen sensors at specified locations on the foot (i.e. medial, dorsal, lateral).

Point assessments of tissue oxygen from the medial location on the foot were stronger predictors of treatment outcome than other locations.

Assessment of tissue oxygen from multiple locations, or based on angiosomal maps, may be better than selecting a location proximal to the wound.

Ongoing research considering link between measurement locations, wound location, and angiosome targeted by interventions.
ABOUT LUMEE® OXYGEN PLATFORM

• Wired platform: CE Mark in September 2016

• Wireless platform: CE Mark January 2020

• **Indications for use:**
  
  "The Lumee® Oxygen Platform is an adjunct instrument intended for continuous and long-term monitoring of the oxygen in the subcutaneous tissue in the upper extremity, shoulder, or lower extremity. It is indicated for use in patients with potential acute and/or chronic changes in tissue oxygen levels who may benefit from monitoring. It should not be used as the sole basis for diagnosis or therapy."

• More information can be found at Profusa.com
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