Continuous monitoring of tissue oxygen dynamics during endovascular revascularization provides functional assessment that could be missed by discrete measurements at start and end.

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Disclosure

Speaker name: Martin Werner

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 CONTINUOUS MEASUREMENTS OF TISSUE OXYGEN DURING REVASCULARIZATION?

- **Lumee® Oxygen** provides continuous real-time tissue oxygen at point location(s)
  - Measurements integrated into EVT

- **Segmental blood pressures** (ABI/TBI) sample hemodynamics at discrete times before and after revascularization.
  - Measurements not used to monitor EVT during procedures

- This talk considers what features of *continuously monitored oxygen* dynamics may be best associated with treatment outcome
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

Protocol

Analysis

- 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
OMNIA- OXYGEN MONITORING NEAR ISCHEMIC AREAS

Study Design

- Features of oxygen increase extracted from continuous Lumee® data

Protocol

- Wound healing assessed during follow-ups based on objective criteria

- Sensor locations considered in data interpretation

Analysis

- Retrospective classification analysis determines potential diagnostic power of Lumee Oxygen to predict success of EVT
**DISCRETE** EVALUATION OF OXYGEN CHANGES RESULTING FROM EVT

- **Sheath inserted**
- **Therapeutic interventions**
- **Sheath removed**

**Time**

- Oxygen at start of EVT
- Oxygen changes between start and end of EVT
- Oxygen at end of EVT
CONTINUOUS OXYGEN MONITORING DETECTS DYNAMICS DURING EVT

Sheath inserted  →  Therapeutic interventions  →  Sheath removed

Intra-EVT Oxygen Increase

Time

LOI [-]
REAL EXAMPLE OF DYNAMICS CAPTURED BY DYNAMIC MONITORING

Sheath inserted

Therapeutic interventions

Sheath removed

Start/End oxygen increase is near zero

Dynamic oxygen increase >30 LOI units
CONTINUOUS OXYGEN DYNAMICS MAY BE A STRONGER PREDICTOR OF OUTCOME THAN DISCRETE ASSESSMENT OF OXYGEN OR TBI

<table>
<thead>
<tr>
<th>Metrics</th>
<th>Lumee® start to end</th>
<th>Lumee® dynamic</th>
<th>TBI start to end</th>
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</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>65</td>
<td>76</td>
<td>47</td>
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<tr>
<td>Specificity</td>
<td>71</td>
<td>71</td>
<td>86</td>
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<tr>
<td>Diagnostic Odds Ratio</td>
<td>4.6</td>
<td>8.1</td>
<td>5.4</td>
</tr>
</tbody>
</table>

*Exploratory Retrospective Analysis*
CONTINUOUS OXYGEN MONITORING PROVIDES SENSITIVITY TO DIFFERENT KINDS OF INFORMATION THAN DISCRETE INCREASES

Sheath inserted
Therapeutic interventions
Sheath removed

Maximum rate of oxygen increase during EVT

Time

LOI [-]
MULTIPLE OXYGEN FEATURES IMPROVES CHARACTERIZATION OF TREATMENT OUTCOME

Magnitude Oxygen Increase

Rate of Oxygen Increase

*Exploratory Analysis
MULTIPLE OXYGEN FEATURES ASSESSED DURING EVT MAY PROVIDE IMPROVED PREDICTION OF TREATMENT OUTCOME

<table>
<thead>
<tr>
<th>Metrics</th>
<th>TBI (start to end)</th>
<th>Lumee® (start to end)</th>
<th>Lumee® During EVT (increase)</th>
<th>Lumee® During EVT (increase and rate)</th>
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<tbody>
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<td>N</td>
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</tbody>
</table>

*Exploratory Retrospective Analysis*
OMNIA proved feasibility to monitor tissue oxygen during EVT using Lumee® Oxygen

Continuous oxygen dynamics are a stronger predictor of EVT outcome than discrete assessment of oxygen or TBI; diagnostic odds ratio for continuous Lumee® (8.1), discrete Lumee® (4.6), TBI (5.4).

Algorithms developed to estimate both magnitude of oxygen increases and the rates of change in oxygen traces sampled during EVT. Combined features may be an improved predictor of treatment outcome; diagnostic odds ratio of 10.

Analysis shows potential diagnostic value of continuous oxygen data measured by Lumee® Oxygen during EVT.
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