OMNIA case results: Lumee Oxygen measurements representative for CLI wound healing prognosis

M Werner
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Disclosure

Speaker name:

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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** is designed to provide immediate feedback on the quality of revascularization along the entire course of the patient’s recovery.

**OMNIA is a study** designed to understand the relationship between revascularization success, traditional measures of gross hemodynamic characterization and Lumee measurement of tissue perfusion.
How does LUMEE work?

1. Excitation light from surface reader reaches hydrogel in tissue.
2. Fluorescence chemistry on hydrogel responds based on oxygen concentration.
3. The fluorescent signal from hydrogel is captured by the reader. Data sent to cloud.
A prospective, single-arm, open-label, multicenter study

- Four Lumee sensors injected with 3 in the foot, and 1 reference sensor in the arm

- Lumee measurements performed continuously during endovascular *revascularization* procedures

- Lumee measurements also performed during *functional assessment* tests performed before and after revascularization, and at follow ups

- Traditional clinical metrics sampled throughout visit schedule include: arterial duplex, toe and ankle brachial index, WIFI scores, wound characterization and photographs
OMNIA: enrollment and safety

A total of 3 study sites are actively enrolling:
• Prof. M. Brodmann, Med University of Graz / Austria
• Drs. T. Bisdas, A. Schwindt, St. Franziskus Hospital Münster / Germany
• Dr. M. Werner, Hanusch Hospital Vienna, Austria

21 subjects have been enrolled through end of 2017
• 21/21 were Rutherford Class 5 upon enrollment
• 19/21 received endovascular treatment
• 2/21 had bypass surgery after endo attempt

50 adverse events have been reported
• 27 are SAEs, all unrelated to study device
• 23 are AEs, 1 possibly related to study device (swelling described as mild and resolved at follow-up)
What information do we extract from Lumee Intra-Surgically? Reperfusion Modulation

- Defined as difference in LOI between baseline and maximum after intervention
- Larger values are associated with greater increases in tissue oxygen during the procedure
- Data can be averaged across all Lumees, or selected from a Lumee of interest
What information do we extract from Lumee Post-Surgically?

Recovery Modulation

- Defined as maximal change in LOI over a 5 minute window after the end of leg lift. It is expressed as a percentage of the baseline LOI before provocation.

- Designed to capture the ability of vasculature to autoregulate following a leg lift (e.g. hyperemia).

- Larger values (above 100%) may represent extended hyperemia associated with poor vascular function.

\[
\text{Recovery Modulation} = \left( \frac{1.7}{2.2} \right) = 77\%
\]
Provocation-response data at 1 month may provide metric of microvascular function

Response from subject that **healed**

Response from subject that **failed**

**Hypothesis:** ability of vessels to regulate blood flow after ischemic challenge may be an indicator of vascular health.
**Case report OMNIA trial**

<table>
<thead>
<tr>
<th>Sex</th>
<th>M</th>
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<tbody>
<tr>
<td>Age (yrs)</td>
<td>65</td>
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<tr>
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<td>Type 2</td>
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<tr>
<td>Foot Side</td>
<td>Right</td>
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<tr>
<td>Rutherford Class</td>
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**Wound**
Right second toe

**Therapy**
1. Treated **popliteal** during this time via 1 set of balloon inflate/deflate
2. Treated **anterior tibial** during this time via 5 sets of balloon inflate/deflate
3. Use **DCB** (Lutonix 2.0/80mm) at **anterior tibial and DP**, 1 set of balloon inflate/deflate
Lumee is responsive to the interventions delivered during revascularization.

- **Treated popliteal** during this time via 1 set of balloon inflate/deflate.
- **Treated anterior tibial** during this time via 5 sets of balloon inflate/deflate.
- Use **DCB (Lutonix 2.0/80mm)** at **anterior tibial and DP**, 1 set of balloon inflate/deflate.

Catheter exchange during this time.
Case report OMNIA trial

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Before PTA

3 Months

Provocation response

1 month
Fallbeispiel OMNIA Studie

Sex: M
Age (yrs): 65
Diabetes: Type 2
Foot Side: Right
Rutherford Class: 5

Provocation response:
- Before PTA
- 3 Months: 3%
- 6 Months: 6 months

Graph showing percentage response over time.
Subject: 03-001

Demographics

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**Wound**
Right second toe

**Therapy**

1. **Treated popliteal** during this time via 1 set of balloon inflate/deflate
2. **Treated anterior tibial** during this time via 5 sets of balloon inflate/deflate
3. Use **DCB** (Lutonix 2.0/80mm) at anterior tibial and DP, 1 set of balloon inflate/deflate

**Lumee: Intra-operative reperfusion**
Average LOI increase was 20.5 [-] was very high (in 93rd percentile out of 19 sampled subjects)

**Lumee: Functional Assessment**
Recovery modulation at 1-3 months of >100% of baseline is a feature consistent with non-responding patients
Provocation response data

Pre-procedure (day 1)  | Discharge (day 2)  | 1- Month (day 23)  | 3-Month (day 96)

Extended hyperemia observed at 1- and 3- month follow ups
**Subject:** 03-002

**Demographics**

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**Wound**

Left first toe

**Diabetes**

Type 2

**Gangrene**

1

**Ischemia**

3

**Infection**

N/A

**WIFI Risk**

3

**Tissue oxygen index**

(1) (2) (3)

**Lumee: Intra-operative reperfusion**

Average LOI increase of 15.6 [-] was high (in 73rd percentile out of 19 sampled subjects)

**Lumee: Functional Assessment**

Maximal recovery modulation at 1 - 3 months of <100% is a feature consistent with healing patients

**Therapy**

1. Treated SFA and popliteal a. via 4 sets of balloon inflate/deflate
2. Treated fibularis a. via 3 sets of balloon inflate/deflate and stent
3. Balloon 1X

**Toe Pressure [mmHG]**

Pre-Op 1 Discharge 1 Month 3 Month 6 Month

32 135 88 62 62

**ABI**

0 0.39 0.91 0.611 0.71

**TBI**

0.177 0.758 0.489 0.344 0.41

**Wound Area cm²**

Pre-Op Discharge 1 Month 3 Month 6 Month

1 1 0 0 0

**Gangrene**

1 0 0 0 0

**Ischemia**

3 1 0 0 0

**Infection**

N/A N/A N/A N/A 0

**WIFI Risk**

3 1 1 1 1

**Provocation response**

0% 50% 100%

Pre Dis 1mo 3mo 6mo
Lumee sensors show slow response until last balloon treatment and catheter removal

Treated SFA and popliteal a. via 4 sets of balloon inflate/deflate

Treated fibularis a. via 3 sets of balloon inflate/deflate and stent

Unable to locate sensor
Provocation response data

No hyperemia observed at 1- and 3-month follow ups
OMNIA compares measures of reperfusion with wound healing

### Clinical observations
- Wound healing transitions between follow-up visits assessed from clinical observations
- Evaluated by Profusa using photos and wound size

### Lumee Results
- Intra-op, reperfusion modulation
- Post-op, recovery modulation

<table>
<thead>
<tr>
<th>Site</th>
<th>Subject</th>
<th>Diabetes</th>
<th>WIFI Risk</th>
<th>@ 1 month</th>
<th>@ 3 month</th>
<th>@ 6 month</th>
<th>Wound Area</th>
<th>Toe Pressure</th>
<th>Angiosome</th>
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<td>002</td>
<td>Type II</td>
<td>4</td>
<td>Improved</td>
<td>Improved</td>
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<td>5.9</td>
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<td>5.2</td>
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### WIFI Risk
- Risk of amputation assessed by WIFI at enrollment
- Characterizes initial wound burden

### Key
- **Lumee Response**
  - Positive Reperfusion
  - Elevated Hyperemia

### Key Wound status
- Healing
- No Change
- Worsening

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Clinical observations

Lumee Intrasurgical [LOI]

Lumee 1-mo Functional Assessment [%]
Intra-operative LOI change is correlated with TBI

- Analysis performed on subjects completing 3-month follow up with TBI reported (n=9)

- For each subject, change in TBI after revascularization is plotted on x-axis, and intra-op change in LOI is plotted on y-axis

- Marker size indicates risk of amputation assessed by WIFI scores at enrollment

- Marker color represents wound healing (green), no change (yellow), or worsening (red) through 3 month follow up

Results show highly positive correlation between LOI and TBI

\[ r = 0.53 \]
\[ p < 0.03 \]
Summary and Future Plans

**Initial phase of study:** (first 21 subjects enrolled)

**Goal:** establish feasibility and generate hypotheses

**Preliminary findings:**
- Intra-op LOI measurements of reperfusion reveal functional benefit of intervention
- Post-op LOI evaluation of microvascular function may be indicator of long term healing

**Next phase of study:** (next 30 subjects enrolled)

**Goal:** refine methods and test hypotheses

**Ongoing questions:**
- Refine classification algorithms using both intra-op and post-op measurements to predict wound healing
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