ASSESSING FOOT PERFUSION AFTER BTK REVASCULARIZATION

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TRANSPORT

BTK disease

DISTRIBUTION

BTA disease / microcirculation / end-wound-perfusion
Ischemic > Magic Threshold > Non-ischemic

Pattern of arterial disease

Wound & Wound Care

Co-morbidities & Nutritional Status
ing. In our study, whether or not direct flow based on the angiosome concept was achieved and how many crural vessels and below-the-ankle vessels were successfully treated did not predict wound healing. In-

Utsunomiya et al – JEVT 2014
The First-in-Man “Si Se Puede” Study for the use of micro-oxygen sensors to determine dynamic relative oxygen indices in the feet of patients with limb-threatening ischemia during endovascular therapy

Miguel F. Montero-Baker, MD, Kit Yee Au-Yeung, PhD, Natalie A. Wisniewski, PhD, Soya Gamsey, PhD, Luis Morelli-Alvare, MD, Joseph L. Mills Sr, MD, Marianella Campos, MD, and Kristen L. Helton, PhD, Tucson, Ariz; South San Francisco, Calif; and San José, Costa Rica
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.
Direct measurements of tissue oxygen would better inform decisions during CLI management.

Intra-operative monitoring of revascularization surgery:
- Assess technical success

Post-operative monitoring:
- Assess arterial patency and microvascular function

Guide selection of therapies and wound care strategies:
OMNIA - Oxygen Monitoring Near Ischemic Areas

- Study enrolled CLI subjects scheduled to undergo endovascular revascularization
- A prospective, single-arm, open-label, multicenter study with 30 subjects enrolled.
- Injected 3 Lumee™ Oxygen sensors in the foot and 1 reference sensor in the upper arm

- Traditional clinical metrics sampled:
  - WIfI
  - ABI and TBI
  - wound characterization
  - photographs

- Lumee™ Oxygen measurements performed during endovascular revascularization (EVT) procedures
- Lumee™ Oxygen measurements also performed during functional assessment tests performed before and after revascularization, and at follow-up visits

Consent, Enrollment
Sensor Injection
1-29 days
Revascularization
Intra-procedure monitoring

Pre-operative
Discharge
1 month
3 months
6 months
12 months

Long term monitoring
What do microsensors show during EVT procedures?
**Subject: 01-015**

**Demographics**

- **Sex**: M
- **Age (yrs)**: 84
- **Diabetes**: Type 2
- **Foot Side**: Right
- **Rutherford Class**: 5

**Tissue oxygen index**

**Therapy**

- Balloons inflations 6x (total) in areas of Tibialis Ant, Truncus Arteriosus, A Tibialis posterior. Balloon to ankle 2x

**Assessment**

- Improved at 3 month (wound score and wound size)

**Wound Assessment**

<table>
<thead>
<tr>
<th></th>
<th>Pre-op</th>
<th>Discharge</th>
<th>1 month</th>
<th>3 month</th>
<th>6 month</th>
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<tbody>
<tr>
<td><strong>Wound</strong></td>
<td>1</td>
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<td><strong>Ischemia</strong></td>
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<tr>
<td><strong>Infection</strong></td>
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<td>None</td>
<td>0</td>
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</table>
1x balloon in PTA armada - tibia anterior

Insert sheath

1x balloon in PTA armada truncus arteriosus

2x balloon in distal ankle

End procedure

Same: 1x balloon in PTA tibia anterior

1x balloon in tibia posterior PTA
Oxygen increase during EVT is associated with wound healing (Exploratory Analysis)

- Substantial intra-subject variability
- Increases in oxygen during EVT greater in subjects that improved

Angiosome based sensor analysis

Graphs showing increase in oxygen during EVT with different subject outcomes.
What do microsensors show during follow-up visits?
What information do we extract from Lumee™ Oxygen 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.

Reactive hyperemia = Max during recovery / baseline
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
Hyperoxia on 1 month follow up vs. clinical improvement

- Analysis performed on subjects completing Lumee™ Oxygen sampling at 1 month follow up AND completed 3-month follow up (n_subjects = 20)

- Each marker shows the average reactive hyperemia assessed at 1 month visit
Combination of peri-operative data with 1 month follow up

- Analysis combines increases observed during EVT (x-axis) with oxygen overshoot observed at 1 month follow up (y-axis)

- Data show that low reperfusion and high oxygen overshoot following leg lift may be an indicator of non-improvement
Combination of peri-operative data with 1 month follow up

<table>
<thead>
<tr>
<th>n</th>
<th>Measure</th>
<th>Value (%)</th>
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<tbody>
<tr>
<td>20</td>
<td>Sensitivity</td>
<td>100</td>
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<tr>
<td></td>
<td>Specificity</td>
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<td></td>
<td>PPV</td>
<td>78</td>
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<tr>
<td></td>
<td>NPV</td>
<td>100</td>
</tr>
<tr>
<td></td>
<td>Fisher’s exact</td>
<td>P&lt;0.001</td>
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</table>

Oxygen overshoot after leg lift at 1 month

Increase in oxygen over baseline during EVT
OMNIA Exploratory Analysis: Summary

• Lumee™ data analyzed for 28 subjects completing EVT with follow up through: 3 months

• **Lumee™ Oxygen increases observed during EVT** were significantly larger in subjects that showed improvement compared with subjects that did not

• **Lumee™ Oxygen assessments of microvascular function** at follow-up visits may provide enhanced classification of healing. Combined peri-op and follow-up classification yielded sensitivity (100%), specificity (75%) and a significant association with wound healing (p<0.001)

• Results indicate that **Lumee™ Oxygen measurements during EVT may provide predictive value to assess wound healing**
THANK YOU
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