INTRA-SENSOR ANALYSIS OF SUBCUTANEOUS OXYGEN MICROSENSORS REVEAL HETEROGENEOUS REPERFUSION DURING REVASCULARIZATION PROCEDURES FOR CLI PATIENTS

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Jan 24, 2019
Disclosure

Speaker name: Miguel Montero-Baker

I have the following potential conflicts of interest to report:

- [ ] Consulting
- [ ] Employment in industry
- [X] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)

- [ ] I do not have any potential conflict of interest
Clinical need exists for oxygen monitoring approach

Clinicians need to measure what they manage

Ischemia in PAD is complex

- Arterial insufficiency
- Microvascular impairment

Advanced tools developed for revascularization

- Endovascular access (BTK)
- Plaque removal and stenting

CLI management decisions poorly informed

- EVT success based on structure (not function)
- Clinical hemodynamics indirectly sample oxygen
Lumee™ Oxygen Platform is designed to measure oxygen and may provide immediate feedback on the quality of revascularization along the entire course of the patient’s recovery.
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
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

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)
Insert sheath

1x balloon in PTA armada - tibia anterior

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

Smoothed O2

Time

Channel 1

Channel 2

Channel 3

Channel 4
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

Graph showing increase in oxygen during EVT for different subjects with data points indicating improved, deteriorated, and no change conditions.

Bar chart showing the distribution of oxygen increase at 3 months for different subject groups.
What do microsensors show during follow-up visits?
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

**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 ($n_{\text{subjects}} = 20$)

- 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

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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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