How to assess procedural success in complex CLI-settings? Initial OMNIA results: unique tool in the assessment and clinical management of CLI

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Disclosure

Speaker name:

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.
OMNIA - Oxygen Monitoring Near Ischemic Areas

- 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 Summary through end of 2017

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

Diabetes status
- Type II (15)
- Type I (1)
- None (3)
- Unconfirmed (2)

50 adverse events have been reported
- 27 are SAEs, all unrelated to study device
- 23 are AEs, 22 unrelated to the study
  - 1 possibly related to study device (mild swelling 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
Subject: 02-001

Demographics

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<td>Diabetes</td>
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<tr>
<td>Rutherford Class</td>
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Wound
Left first toe (lateral)

Therapy
1. Treated popliteal a. artherectomy and 4 sets of balloon inflate/deflate
2. Repeat Hawk Balloon
3. Treated anterior tibialis a. balloon inflate/deflate + Provastin

Angiography
Flow to foot re-established

Lumee: Intra-operative reperfusion
Average LOI change was 6.3 [-] was very high (in 53rd percentile out of 19 sampled subjects)

Lumee: Functional Assessment
Recovery modulation at 1-3 months of <100% of baseline is a feature consistent with healing patients
Subject: 01-007

Demographics

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Wound
Left first toe (with necrosis)

Therapy
1. Treated tibial-peroneal trunk via 1 set of balloon inflate/deflate
2. Treated ant. Tibialis via 1 set of balloon inflate/deflate

Angiography
Flow to foot not re-established

Stop

Lumee: Intra-operative reperfusion
Average LOI change was -1 [-] was very low (in 13th percentile out of 19 sampled subjects)

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

Wound Images

Pre-Tx

No Photo

1 month

3 month

6 month

Wound Area cm²

Pre-Op Discharge 1 Month 3 Month 6 Month

Wound

Gangrene

Ischemia

Infection

WIFI Risk

Pre-Op Discharge 1 Month 3 Month 6 Month

ABI

TBI

Toe Pressure [mmHg]

Pre-Op Discharge 1 Month 3 Month 6 Month

ABI

TBI

Pre-Op Discharge 1 Month 3 Month 6 Month

Wound Area cm²

Pre-Op Discharge 1 Month 3 Month 6 Month

Tissue oxygen index

Provocation response

Pre-Op Discharge 1 Month 3 Month 6 Month

0% 50% 100% 150% 200%
Intra-op Lumee shows predictive value for wound healing
(Stratification by Wound Status at 3 months)

- Analysis performed on subjects completing Lumee sampling through 3-month follow up
- For each subject, *average intra-op LOI change across sensors* located within same angiosome as the wound (n=11)
- Subjects were stratified by wound healing status as improve, no change, or worsen
- Size of markers indicates risk of amputation assessed by WIFI scores at enrollment

Results show that *larger increases in LOI were associated with wound healing* outcomes
High / low intra-op Lumee predicts healing through 6 months

LOI Change > 10 predicted wound healing in 5/6 subjects
LOI Change < 0 predicted non-response in 2/2 subjects
Summary and Future Plans

**Initial phase of study:**
(First 25 subjects enrolled)

**Goal:** establish feasibility and generate hypotheses

**Preliminary findings:**
Changes in LOI measured during endothelial revascularization were predictive of wound healing

**Next phase of study:**
(Next 25 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
Acknowledgements

OMNIA PIs

Medical University
Graz, Austria
• Marianne Brodmann M.D.

St Franziskus-Hospital
Munster, Germany
• Theo Bisdas, M.D.
• Arne Schwindt M.D.

Hanusch Hospital
Vienna, Austria
• Martin Werner M.D.

Clinical Research Team

Profusa
San Francisco, USA
• Kerstin Rebrin, M.D., Ph.D.
• Kit Yee Au-Yeung, Ph.D.
• Wayne Menzie, Ph.D.
• Stephen Kanick, Ph.D.

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• Michael Conte, M.D.