

Interim results from the OMNIA study – utilization of micro oxygen sensors during CLI therapy

M Montero-Baker

30 Jan 2018

Disclosure

Speaker name:

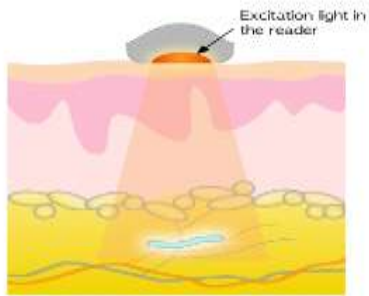
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I have the following potential conflicts of interest to report:

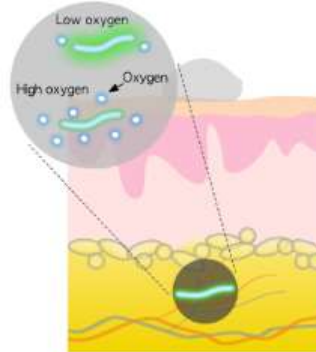
- Consulting
 - Employment in industry
 - Stockholder of a healthcare company
 - Owner of a healthcare company
 - Other(s)
-
- I do not have any potential conflict of interest



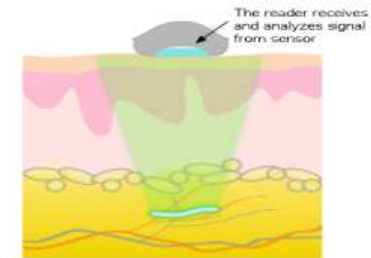
How does LUMEE work?



Excitation light from surface reader reaches hydrogel in tissue.



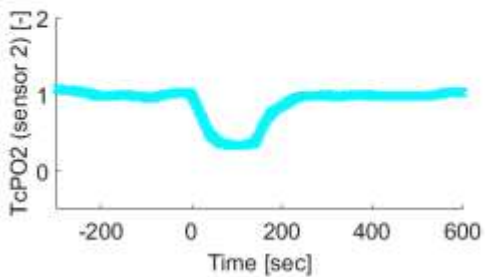
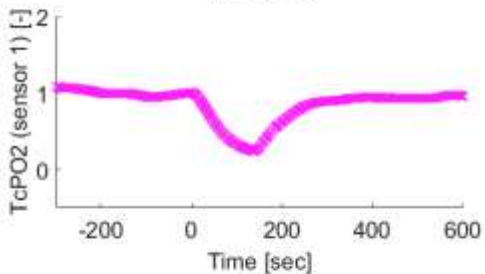
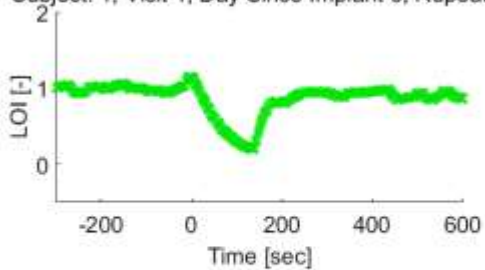
Fluorescence chemistry on hydrogel responds based on oxygen concentration



The fluorescent signal from hydrogel is captured by the reader. Data sent to cloud.

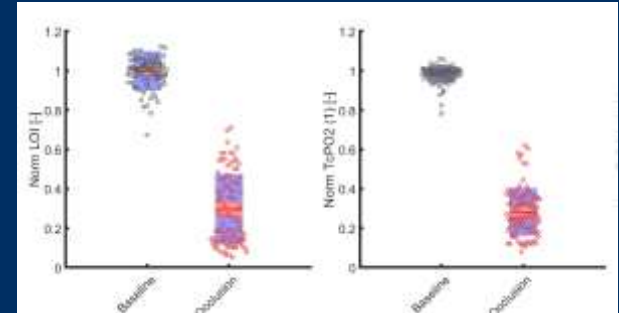
Pressure-cuff occlusion test provides first *in vivo* validation that Lumeo effectively measures tissue oxygen

Subject: 1; Visit 1; Day Since Implant 6; Repeat 1



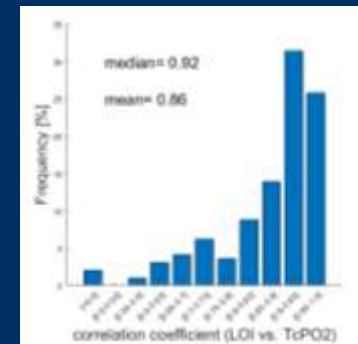
Sensitivity

Lumeo and TcPO2 both detect **statistically significant deviation from baseline** during pressure cuff occlusion



Proportionality

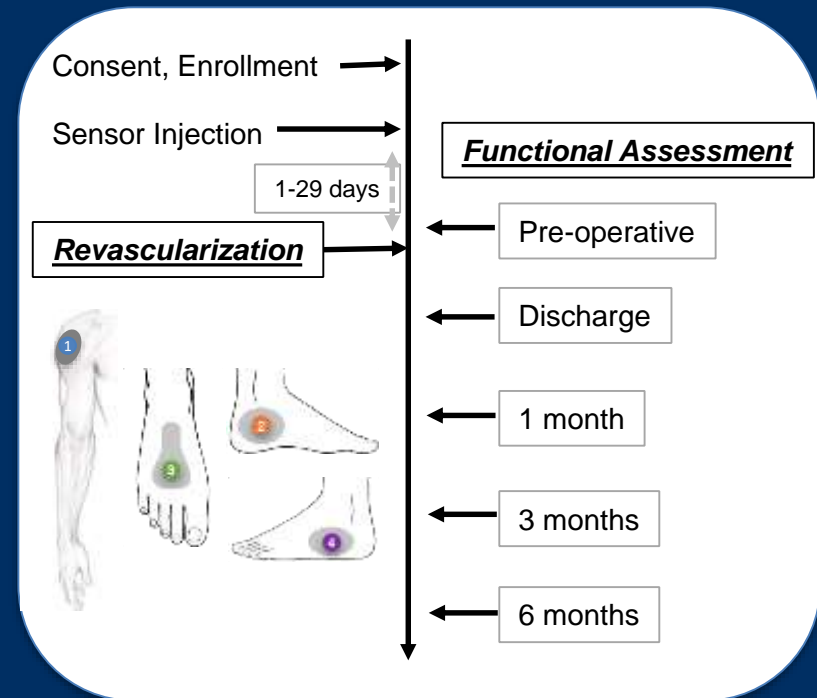
Lumeo time traces are highly correlated with TcPO2



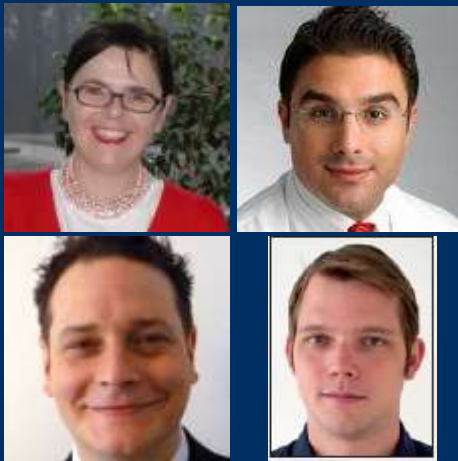
Results indicate **Lumeo Oxygen sensors accurately and reliably sense changes in tissue oxygen *in vivo***

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: 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

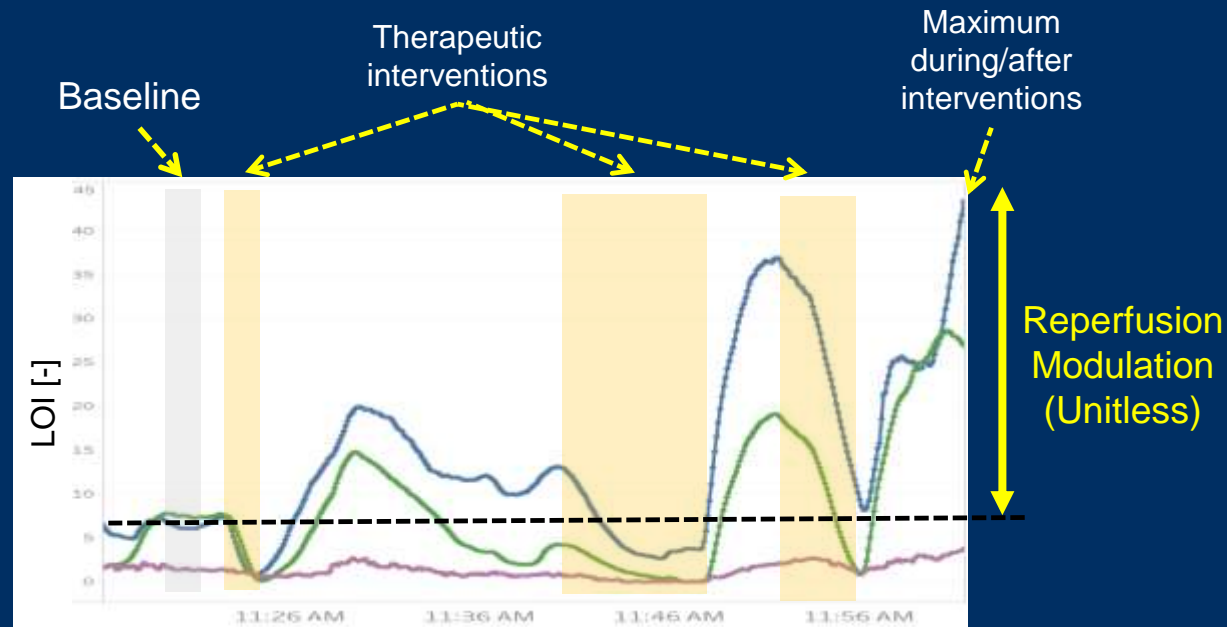
50 adverse events have been reported

- 27 are SAEs, all unrelated to study device
- 23 are AEs, 22 unrelated to study device
 - 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

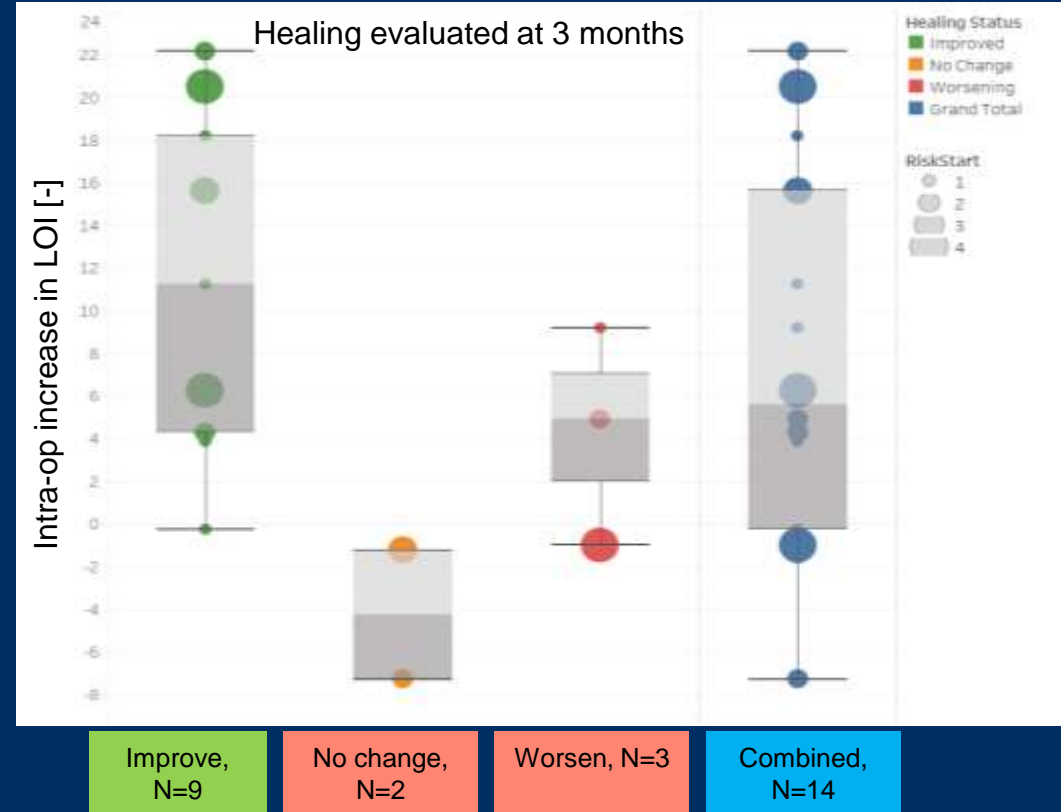


Intra-op Lumeo shows predictive value for wound healing

(Stratification by Wound Status)

- Analysis performed on subjects completing Lumeo sampling through 3-month follow up (n=14)
- For each subject, average intra-op LOI change across all sampled sensors was calculated
- 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

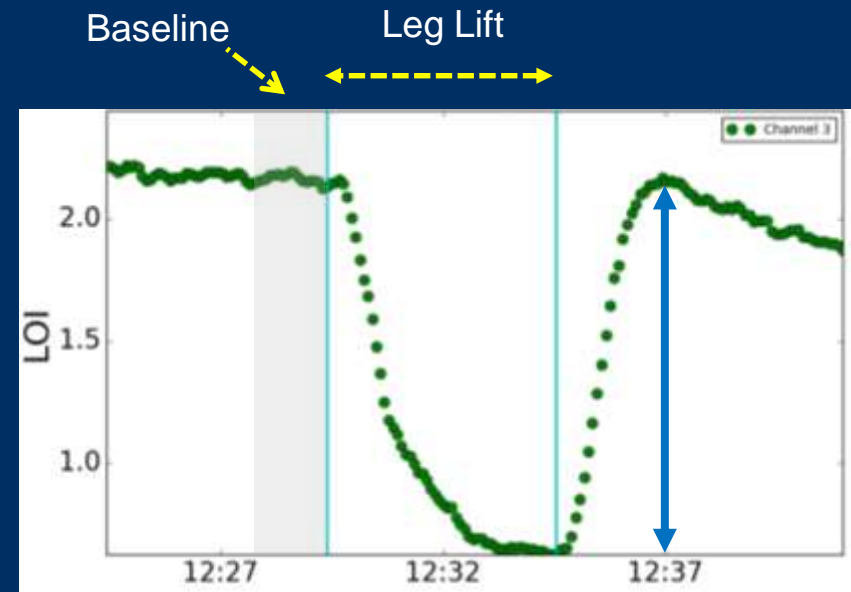
Results show that **larger increases in LOI were associated with wound healing** outcomes



What information do we extract from Lumeo 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

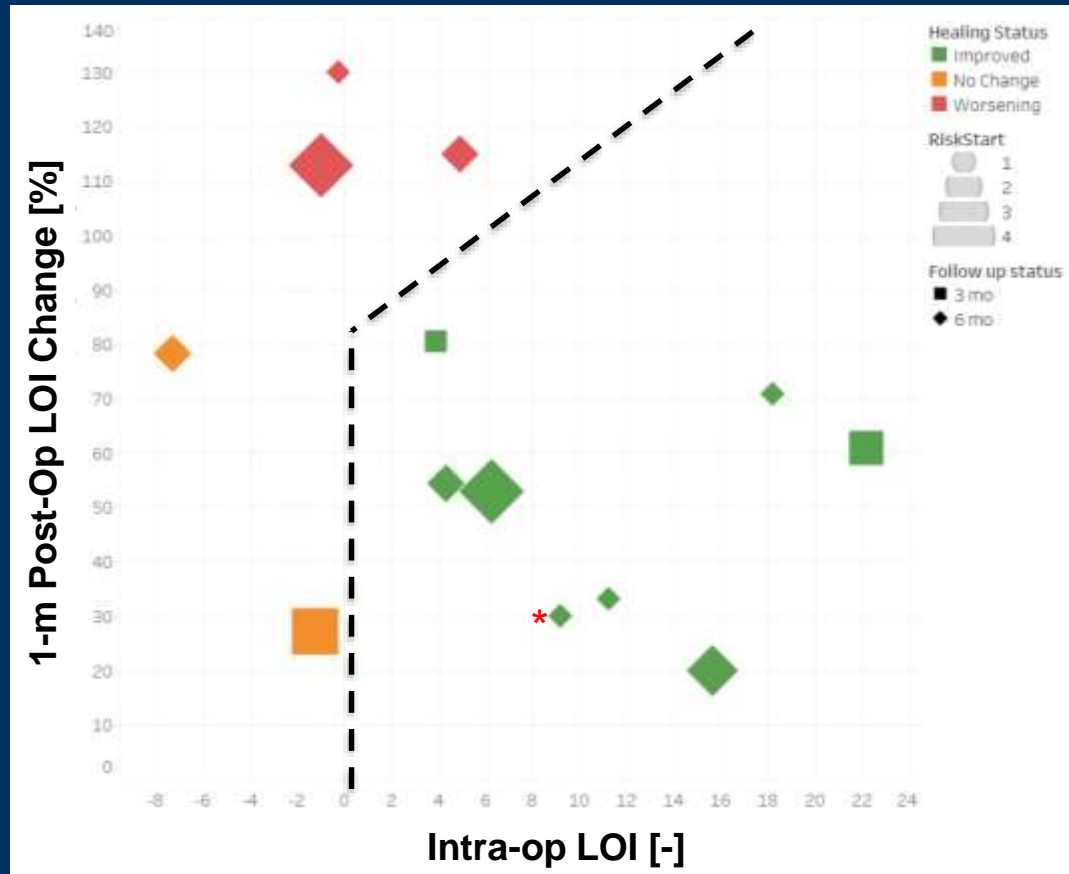


$$\begin{aligned} \text{Recovery Modulation} &= (1.7/2.2) \\ &= 77\% \end{aligned}$$

Intra-op + Post-op Lumea improves predictive value

- Analysis performed on subjects completing both intra-op and post-op Lumea sampling through 3-month follow up (n=13)
- For each subject, average intra-op LOI is plotted on x-axis, average 1-m post-op LOI change is 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)

Combination of intra-op and post-op data **reveals potential clustering and predicts wound healing in 12/13 subjects**



Asterisk (*) identifies patient underwent re-intervention in weeks after revascularization

Summary and Future Plans

Initial phase of study:

(first 25 subjects enrolled)

Goal: establish feasibility and generate hypotheses

Preliminary findings:

- Intra-op LOI measurements of reperfusion reveal functional benefit of intervention
- Combination of intra-op and post-op LOI measurements 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

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Graz, Austria

- Marianne Brodmann M.D.



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Munster, Germany

- Theo Bisdas, M.D.
- Arne Schwindt M.D.



Hanusch Hospital

Vienna, Austria

- Martin Werner M.D.



Clinical Research Team

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San Francisco, USA



- Kerstin Rebrin, M.D., Ph.D.
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- Wayne Menzie, Ph.D.
- Stephen Kanick, Ph.D.



Medical Advisory Committee

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- Michael Conte, M.D.





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Thank you!

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