Case reviews of tissue oxygen monitoring during endovascular revascularization:

Experience at Dendermonde

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I have the following potential conflicts of interest to report:

- Consulting: Abbott, BD, Biotronik, Boston Scientific, Cook, CTI vascular, iVascular, Medtronic, Philips, Terumo, Profusa
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

I do not have any potential conflict of interest
### Classification of the problem(s)

#### Tissue Loss Dominant
- Wound
  1. No ulcer and no gangrene
  2. Small ulcer or gangrene limited to toes
  3. Extensive ulcer or extensive gangrene

#### Ischemia Dominant
- **Toe Pressure (TP)**
- Transcutaneous oximetry (TcPO2)
  - 0: $\geq 60$ mmHg
  - 1: 40-59 mmHg
  - 2: 30-39 mmHg
  - 3: < 30 mmHg

#### Infection Dominant
- **Foot Infection**
  - 0: No symptoms or signs of infection
  - 1: Mild (<2 cm cellulitis/empyema)
  - 2: Moderate (>2 cm cellulitis/empyema)
  - 3: Severe (systemic response/sepsis)

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**Table 1:**

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<thead>
<tr>
<th>Ischemia – 0</th>
<th>Ischemia – 1</th>
<th>Ischemia – 2</th>
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**Table 2:**

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<th>Ischemia – 3</th>
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**Foot Infection:** I. Ischemia; W. Wound.
Assessment of ischemia

Evaluation of toe pressure and transcutaneous oxygen measurements in management of chronic critical leg ischemia: A diagnostic randomized clinical trial

Jurgen C. de Graaff, MD, PhD, a, c Dirk Th. Ubbink, MD, PhD, a Dink A. Legemate, MD, PhD, a Jan G. P. Tijssen, MD, PhD, b and Michael J. H. M. Jacobs, MD, PhD, d Amsterdam, Nieuwegein, and Maastricht, The Netherlands

Objective: The definition of critical limb ischemia (CLI) requiring vascular intervention is still under debate. The clinical eye of the physician and ankle blood pressure measurements used so far may fall short in appreciation of the severity of disease, which makes decision-making for a vascular intervention subjective. In previous studies two simple functional tests, ie, transcutaneous oxygen pressure (tcPO₂) and toe blood pressure (TP) measurements, provided reliable information about the need for vascular intervention. Therefore we evaluated the diagnostic value of tcPO₂ and TP in management of clinically suspected critical leg ischemia.

Study design: This was a diagnostic randomized controlled clinical trial. Subjects were ambulatory and hospitalized patients in a referral university hospital.

Methods: Ninety-six patients (128 legs) with clinically suspected critical limb ischemia were referred to the vascular laboratory for routine investigation. Two diagnostic management strategies were compared: conventional strategy, ie, clinical judgment and ankle pressure determined the diagnostic and therapeutic approach, and a new strategy in which tcPO₂ and TP determined the diagnostic and therapeutic approach. Main outcome measures included clinical outcome, defined as pain relief, wound healing, and limb survival.

Results: At 18-month follow-up, 26 of 62 legs treated with the conventional approach and 28 of 66 legs treated with the new approach were treated conservatively. The new method did not score significantly different from the conventional method insofar as clinical outcome: pain score, 50 versus 48; number of amputations, 8 versus 10; and number of deaths, 11 versus 8 deaths, respectively.

Conclusion: Two simple objective diagnostic tests, TP and tcPO₂, did not improve clinical outcome when incorporated into routine management of suspected critical limb ischemia.
How does the Lumee® Oxygen Platform 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.
Subcutaneous sensors directly measure tissue oxygen
Tissue oxygen dynamics quantified during revascularization

Oxygen increase during EVT

Therapeutic interventions
Rolling Baseline

\[ \text{LOI} \]
OMNIA- Oxygen Monitoring Near Ischemic Areas

- Multi-center study that enrolled 35 CLI subjects (Rutherford 4 or 5) scheduled to undergo endovascular revascularization

- Injected 3 Lumee® Oxygen sensors in the foot and 1 reference sensor in the upper arm

- Monitored oxygen during endovascular revascularizations (EVT) and at follow-up visits.

- Oxygen increases ($\Delta$ LOI) calculated during EVT evaluated for 98 sensors in total.

- Data used as benchmark for cases sampled by new generation Lumee® Oxygen Platform (percentile of $\Delta$ LOI as compared to data from OMNIA)
Dendermonde Case Reviews
CASE 1, male, 76yr

• Risk factors
  ✓ IDDM type 2
  ✓ AHT
  ✓ Hypercholesterolemia

• Comorbidities
  ✓ CABG, several PCI
  ✓ PTAS left SFA

• Present state
  ✓ Necrotic lesion right lateral foot;
  ✓ OPTIMALIZED WOUND CARE & OFF-LOADING SINCE 8 WEEKS...
  ✓ DUS: triphasic signal CFA, SFA, PA, ATA; no signal ATP
CASE 1
CASE 1
Tissue oxygen: Substantial increases observed during revascularization at 3 locations on the foot (increases ranked in 50th-70th percentile per OMNIA).
CASE 1

PRE PROCEDURE

3 WEEKS POST PROCEDURE

7 WEEKS POST PROCEDURE

Take away: Revascularization achieved both angiographic success & increases in tissue oxygen that translated to wound healing
CASE 2, MALE, 82 yr

- **Risk factors**
  - IDDM type 2
  - Smoking ++
  - Hypercholesterolemia

- **Comorbidities**
  - several PCI
  - Bilateral CAS, pEVAR, bilateral BTK treatment, D2 amputation left

- **Present state**
  - Deep diabetic malum perforans left foot
  - DUS: triphasic signal CFA, SFA, PA, weak monophasic distal signals
CASE 2
CASE 2
Tissue Oxygen: Substantial variability among sensor location
Laterally placed sensor detected relatively high increase (76th percentile per OMNIA)
Medially placed sensor detected relatively low increase (38th percentile per OMNIA)
CASE 2

PRE PROCEDURE

2 WEEKS POST PROCEDURE

4 WEEKS POST PROCEDURE
Take away:
Tissue oxygen increases observed at some (but not all) locations translated to wound healing. Ongoing work focuses on guiding interpretation of sensors from multiple locations.
CASE 3, MALE, 89yr

- **Risk factors**
  - IDDM type 2
  - Smoking ++
  - Severe arterial hypertension

- **Comorbidities**
  - several PCI
  - Repeated BTK treatments bilateral

- **Present state**
  - Since several months deteriorating ulcers right leg and foot, several debridements, infection control
  - DUS: triphasic signal CFA, SFA, PA, bad distal signals
CASE 3
CASE 3
Lumee LOI readings vs. time:

Sheath insertion

Remove sheath

Sheath insertion

First inflation balloon

Second inflation balloon

Third inflation balloon

Fourth inflation balloon

Oxygen 3l

Loss of dorsal/medial signal

Tissue Oxygen:
Oxygen traces show relatively low dynamics during EVT
Trends show decreases throughout the procedure

<table>
<thead>
<tr>
<th>Sensor ID</th>
<th>ΔLOI [-]</th>
<th>Percentile [%]</th>
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<tbody>
<tr>
<td>Medial</td>
<td>5.6</td>
<td>56</td>
</tr>
<tr>
<td>Lateral</td>
<td>0.9</td>
<td>9</td>
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<tr>
<td>Dorsal</td>
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CASE 3

PRE PROCEDURE

2 WEEKS POST PROCEDURE

4 WEEKS POST PROCEDURE
CASE 3

6 WEEKS POST PROCEDURE  12 WEEKS POST PROCEDURE  16 WEEKS POST PROCEDURE

Take away: Procedure did not result in oxygen increases in a procedure that led to wound deterioration and finally BTK amputation
Executive summary

- Lumee Oxygen measurement used to monitor endovascular revascularization (EVT) procedures in BTK cases: experience with 8 cases in 2 hospitals

- Lumee Oxygen sensors injected, located, and monitored successfully. Data analyzed to calculate oxygen dynamics during EVT.

- Case data used to highlight relationships between oxygen dynamics measured at point locations, anatomical target of delivered interventions, and treatment outcome.