Value Of Lumee Implantable Micro Oxygen Sensors In The Treatment Of CLTI Patients

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Disclosures
• Education/Trainig: Abbott, BARD, Boston Scientific, COOK, Phillips
• Advisory Board: Abbott, Medtronic, BARD
• Research: BARD, Shockwave Medical, Mercator, Boston Scientific
• Ownership: Thermopeutics, Profusa

TRANSPORT
DISTRIBUTION
BTK disease
BTA disease / microcirculation / end-wound-perfusion

Ischemic > Magic Threshold > Non-ischemic
Pattern of arterial disease
Wound & Wound Care
Co-morbidities & Nutritional Status
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-

WOUND BLUSH

OMNIA study – O2 monitoring w/Lumee

- "OMNIA" study
  - Validation of the technology as a tool during CLI therapy
  - N=100 individuals
  - 4 sites in USA, 4 sites in EU

- Primary Investigators
  - Brodmann, M
  - Shishebor, M*
  - Montero-Baker, M **

*Awaiting FDA clearance to enroll
**Will not directly enroll; oversight

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 around 30, 90, 180, and 365 days after revascularization

Arterial duplex, toe and ankle brachial index, WiFI scores, wound characterization and photographs.

OMNIA - Oxygen Monitoring Near Ischemic Areas

- A prospective, single-arm, open-label, multicenter study. Currently 30 subjects enrolled.
- Enrolled subjects diagnosed with CLI (i.e. Rutherford 5)

What information do we extract from Lumee Intra-Surgically?

Dynamically assessed increases in oxygen

- Oxygen increased calculated as maximum increase of each measured sensor between baseline and maximum value experienced during EVT
- Larger values of reperfusion are associated with larger increases in oxygen
- Response from multiple sensors interpreted by averaging sensors within angiosome of the wound

Direct oxygen increases observed during EVT vs. treatment outcome

- Analysis of 21 subjects completing follow-up through 3-month (25), 6-month (17), and 12-month (3)
- Each marker shows the average oxygen increase over baseline during revascularization procedure for sensors located in same angiosome as wound
- Marker size shows severity of disease at enrollment (larger is more severe)
- Colors shows status at each follow-up evaluation
Comparison of direct oxygen increases during EVT with TBI assessed before/after

- X-axis represents the change in TBI between pre and post EVT
- Y-axis represents the increase in direct oxygen over baseline during EVT
- Data show moderate positive correlation (r=0.74, p<0.01)

Conclusions

- The variability across management (and technique) of patients with CLTI is broad
- A bar other than angiography should help determine success
- Current non-invasive methods are cumbersome to apply intrasoperatively (and not transformable into a user-driven interface)
- Micro-oxygen sensors are at an early stage, but may become disruptive in time
- Longitudinal follow up with sensors can empower wound care specialists