THE UNIVERSITY OF ARIZONA
MEDICAL CENTER

Implatable microsensors:

A potential approach to optimize results

Miguel F. Montero-Baker[1], MD; Kit Yee Au-Yeung, PhD[2]; Nataile A. Wisniewski, PhD[2]; Soya Gamsey, PhD[2]; Luis Morelli-Alvarez[3], MD; Joseph L. Mills Sr.[1], MD; Kristen L Helton[2], PhD

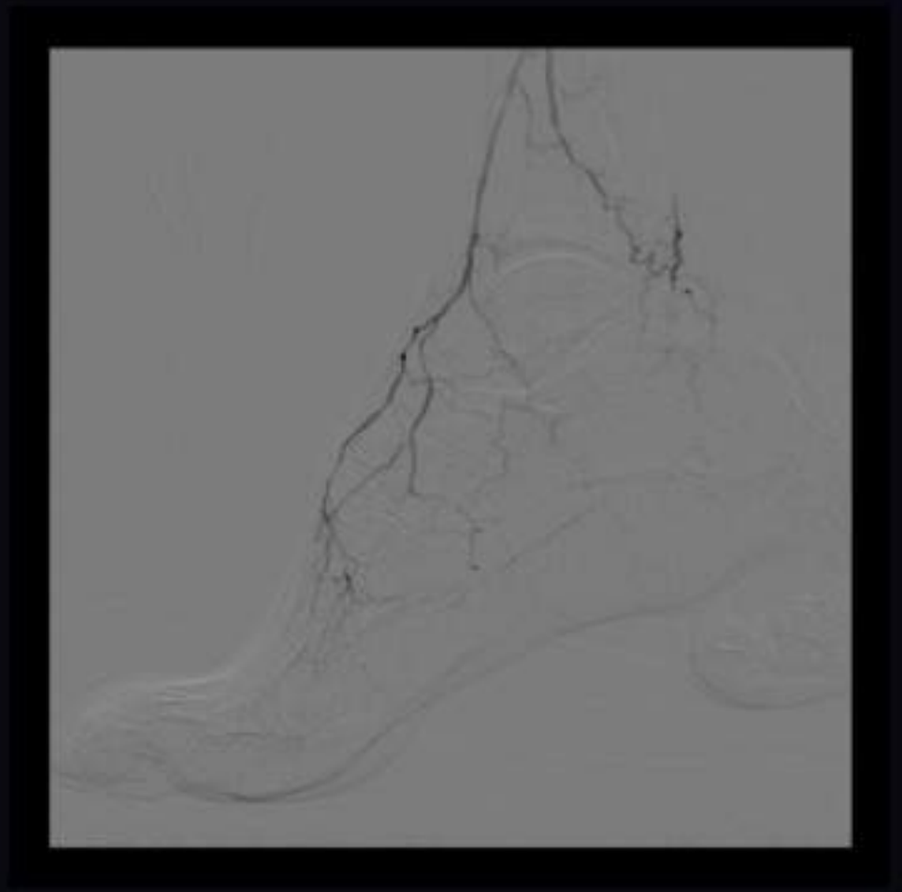
Proctor/trainer
- Abbott Vascular
- COOK
- Medtronic
- GORE
- Phillips (Volcano)
- Spectranetics

Advisory board
- Abbott Vascular

Stock holder
- Therompeutics
- Profusa

Research
- Phillips (Volcano)
- Mercator
- Verinyan

Suboptimal non-invasive methods to determine global foot perfusion...



Suboptimal on-table performance goals...

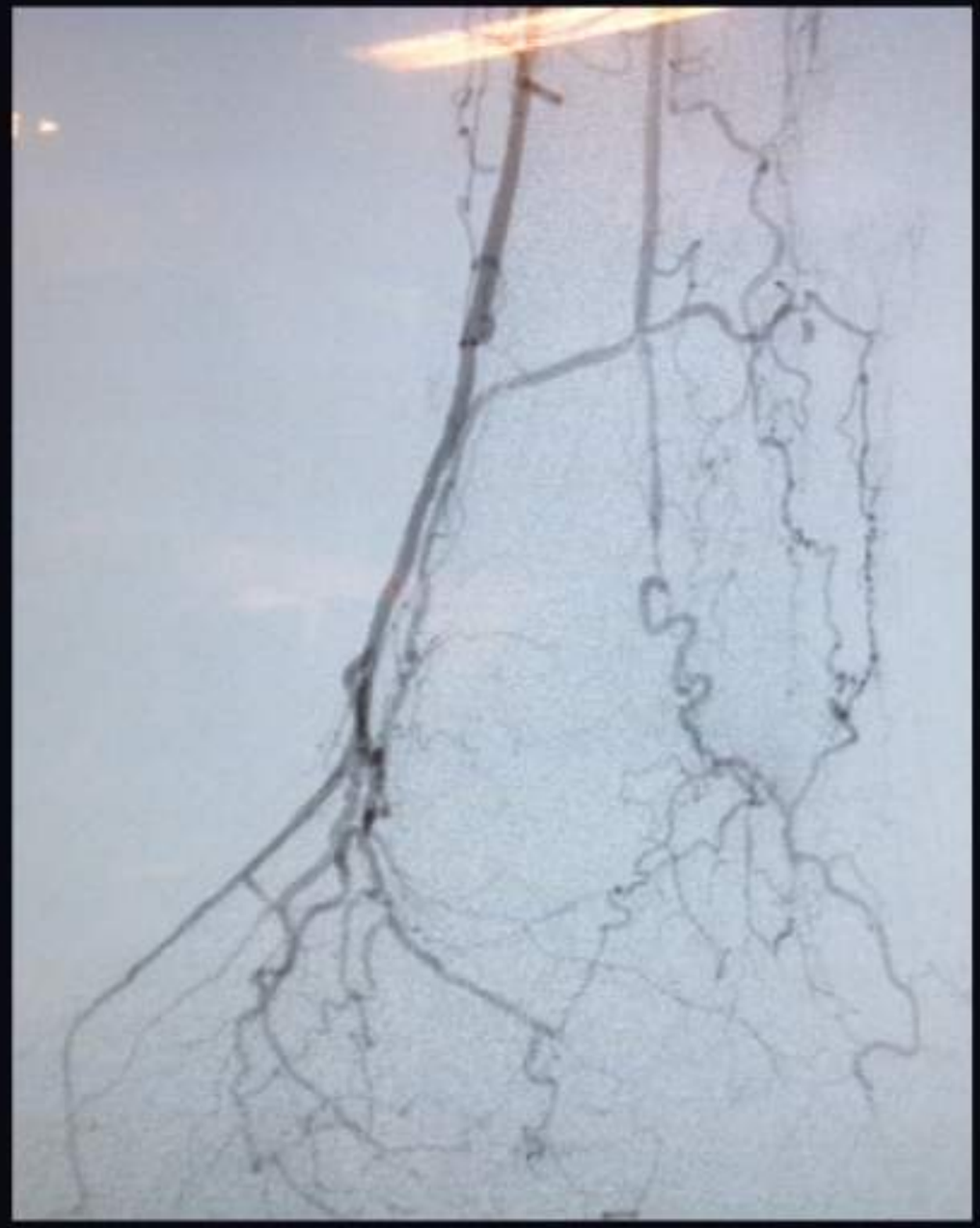
F3.2 Endovascular treatment of infrapopliteal occlusive disease

Endovascular procedures below the popliteal artery are usually indicated for limb salvage and there are no data comparing endovascular procedures to bypass surgery for intermittent claudication in this region.

Angioplasty of a short anterior or posterior tibial artery stenosis may be performed in conjunction with popliteal or femoral angioplasty. Use of this technique is usually not indicated in patients with intermittent claudication.

There is increasing evidence to support a recommendation for angioplasty in patients with CLI and infrapopliteal artery occlusion where in-line flow to the foot can be re-established and where there is medical co-morbidity. In the case of infrapopliteal angioplasty, technical success may approach 90% with resultant clinical success of approximately 70% in some series of patients with CLI. Salvage rates are reported as being slightly higher.

TASC 2 consensus




4
7
3
2
6

Lumee (micro oxygen sensing platform)

Measure Tissue Oxygen Concentration Continuously

- Injectable oxygen-sensitive hydrogel, placed in the subcutaneous tissue
- A signal detection instrument that is placed on skin surface
- Data viewing on a computer, showing a continuous time series of oxygen level measured

The First-in-Man "Si Se Puede" Study for the use of micro-oxygen sensors (MOXYs) to determine dynamic relative oxygen indices in the feet of patients with limb-threatening ischemia during endovascular therapy

Miguel F. Montero-Baker, MD,[a,b] Kit Yee Au-Yeung, PhD,[c] Natalie A. Wisniewski, PhD,[d] Soya Gamsey, PhD,[d] Luis Morelli-Alvarez, MD,[e] Joseph L. Mills Sr, MD,[a] Marianella Campos, MD,[e] and Kristen L. Helton, PhD,[c] *Tucson, Ariz; South San Francisco, Calif; and San José, Costa Rica*

Objective: Patients with limb-threatening ischemia exhibit uneven patterns of perfusion in the foot, which makes it challenging to determine adequate topographic perfusion by angiography alone. This study assessed the feasibility of reporting dynamic relative oxygen indices and tissue oxygen concentration from multiple locations on the foot during endovascular therapy using a novel micro-oxygen sensor (MOXY; PROFUSA, Inc, South San Francisco, Calif) approach.

Methods: A prospective, 28-day, single-arm, observational study was performed in 10 patients who underwent endovascular therapy for limb-threatening ischemia. At least 24 hours before therapy, four microsensors were injected in each patient (one in the arm, three in the treated foot). The optical signal from the microsensors corresponded to tissue oxygen concentration. A custom detector on the surface of the skin was used to continuously and noninvasively measure the signals from the microsensors. The ability to locate and read the signal from each injected microsensor was characterized. Oxygen data from the microsensors were collected throughout the revascularization procedure. The timing of therapy deployment was recorded during the procedure to assess its relationship with the microsensor oxygen data. Oxygen data collection and clinical evaluation were performed immediately postoperatively as well as postoperatively on days 7, 14, 21, and 28.

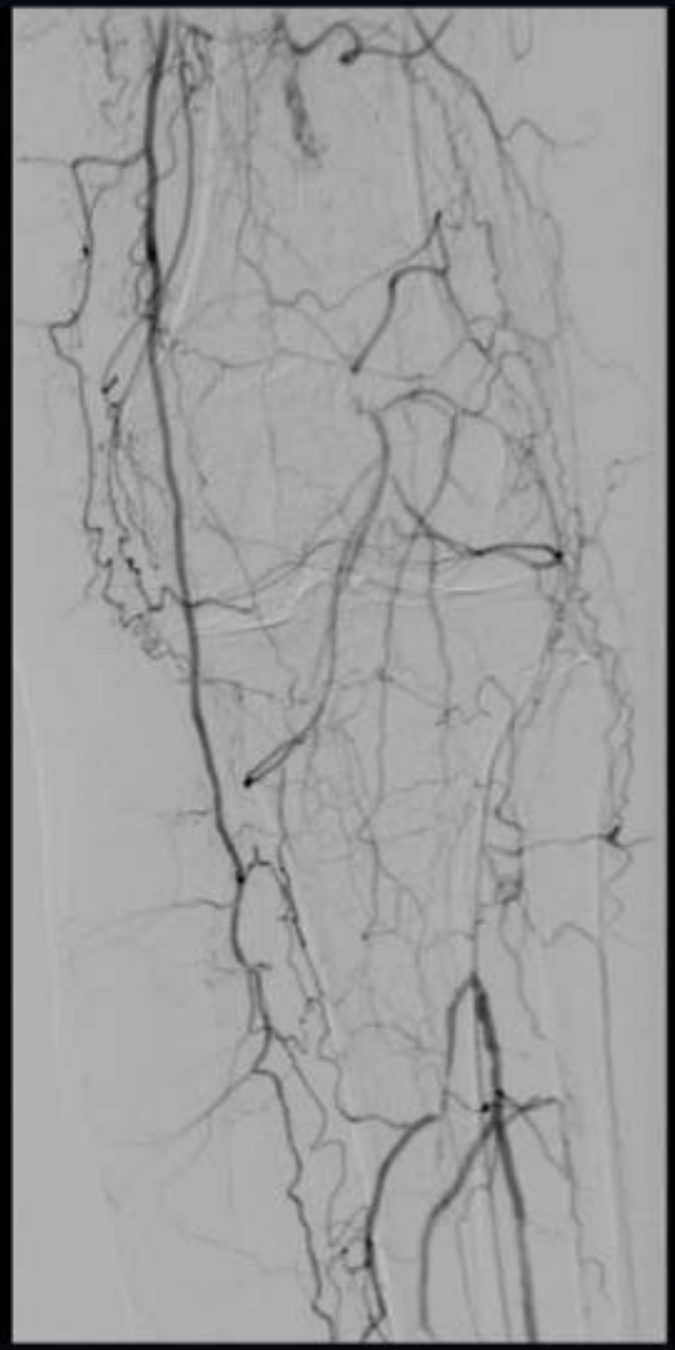
Results: The study enrolled 10 patients (50% male) with ischemia (30% Rutherford class 4, 70% Rutherford class 5). Patients were a mean age of 70.7 years (range, 46-90 years), and all were Hispanic of varying origin. Microsensors were successfully read 206 of 212 times (97.2%) in all patients during the course of the study. Microsensors were compatible with intraoperative use in the interventional suite and postoperatively in an office setting. In nine of 10 revascularization procedures, at least one of the three MOXYs showed an immediate change in the dynamic relative oxygen index, correlating to deployed therapy. Moreover, there was a statistically significant increase in the concentration of oxygen in the foot in preoperative levels compared with postoperative levels. No adverse events occurred related to the microsensor materials.

Conclusions: This MOXY approach appears to be safe when implanted in patients with limb-threatening ischemia undergoing endovascular recanalization and is effective in reporting local tissue oxygen concentrations over a course of 28 days. Further testing is needed to determine its potential effect on clinical decision making, both acutely on-table and chronically as a surveillance modality, which ultimately can lead to improved healing and limb salvage. (J Vasc Surg 2015;61:1501-10.)

"Si se puede" Feasibility Study: Overview

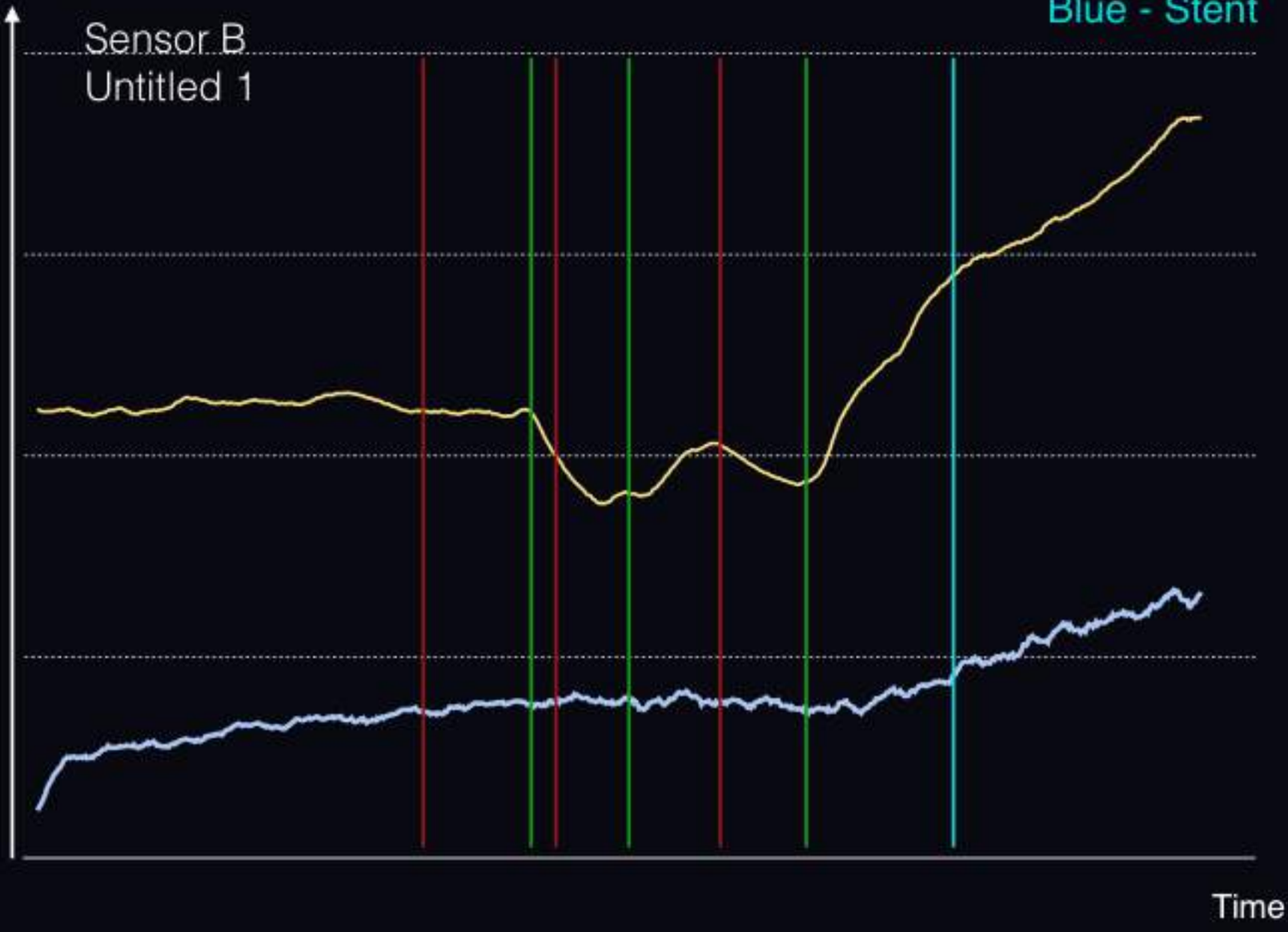
Design	A prospective, observational, single-arm study of 10 threatened limb patients with planned revascularization procedure
Primary Endpoint	Characterize the feasibility of measuring tissue oxygen concentration using sensors placed in the lower limb
Secondary Endpoint	Characterize the safety of sensor use
Procedural Overview	• *Pre-Op*: Injected sensors at 3 locations on the lower limb, and 1 location on the upper arm, to collect baseline data 1-7 days before procedure • *Intra-Op*: Oxygen data were collected continuously during the procedure; the time of therapy deployment were recorded • *Post-Op*: Oxygen data were collected before hospital discharge and up to 28 days after procedure.

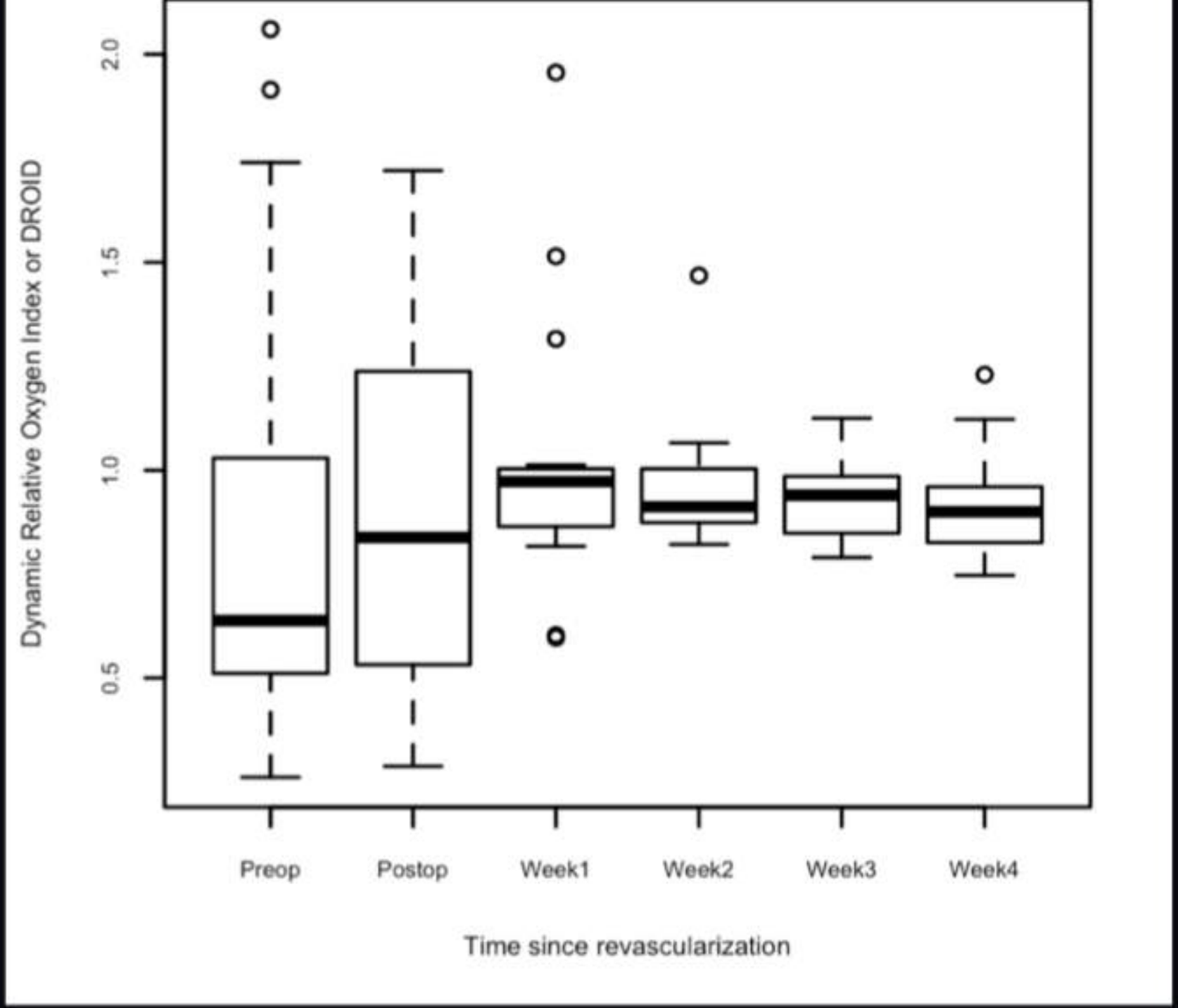
Case Study

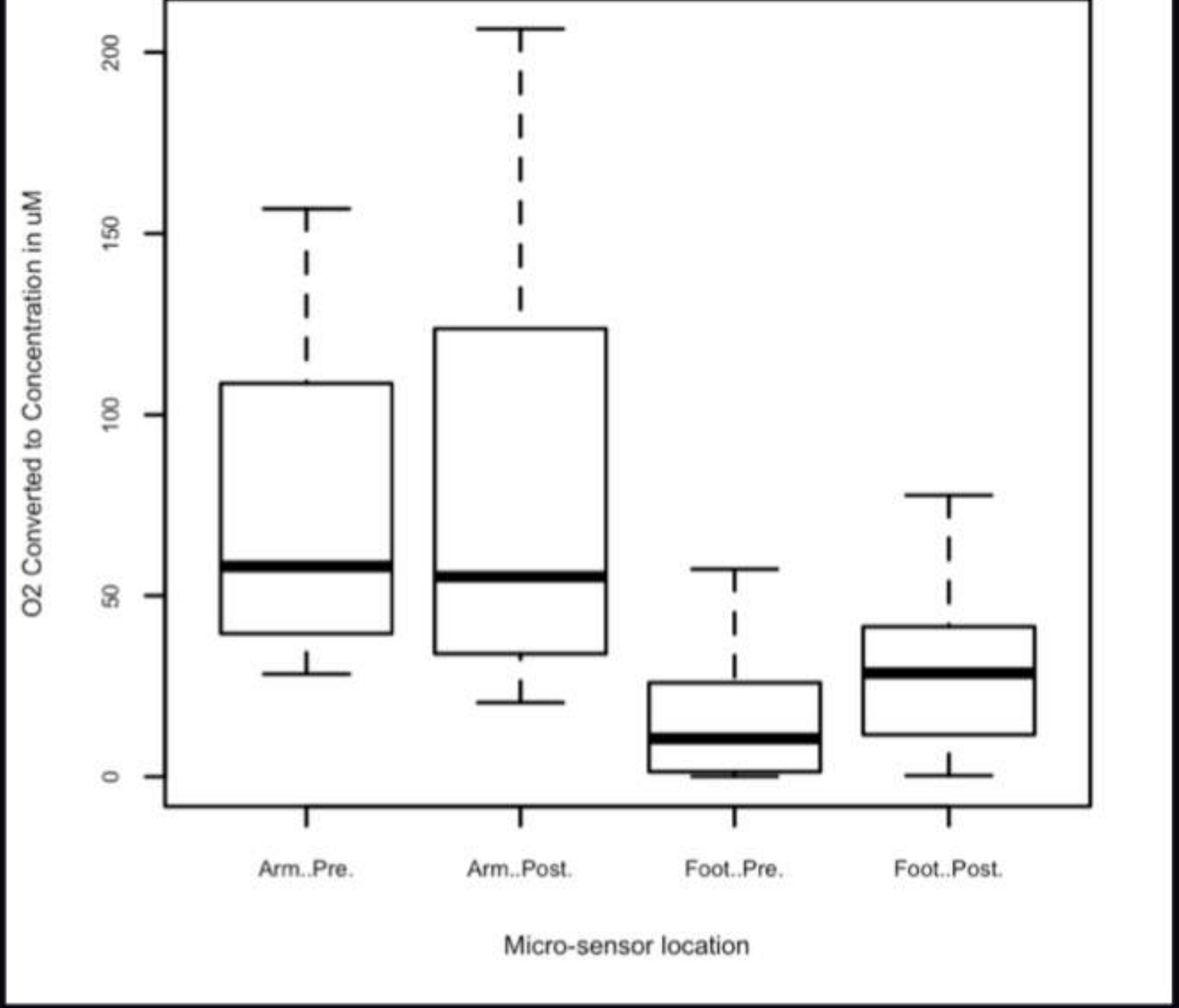


Intra-Operative Data

Red - Balloon Inflation
Green - Balloon Deflation
Blue - Stent




Dynamic Relative Oxygen Index or DROID
0.5
1.0
1.5
2.0
Preop
Postop
Week1
Week2
Week3
Week4
Time since revascularization



- Sensors are safe in patients with

- Sensors are safe in patients with threatened limb

- Sensors demonstrate differences in oxygen concentration pre and post endovascular therapy

- The time-response relationship demonstrates a trend toward quicker changes when dealing with distal disease (direct flow patterns)

- There's an urgent need to validate these procedures and set performance goals in a

- Apart from posing itself as a future GPS for acute on-table decision making, the very stable nature of its oxygen sensing capabilities opens a door to a new era of follow-up.