

Advances in Noninvasive, Portable Medical Monitoring for Early Identification of Hemodynamic Instability

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Presenter Disclosures

Babs Soller, PhD

Personal financial relationships with commercial interests relevant to this presentation during the past 12 months:

- Stock ownership: *Reflectance Medical Inc.*
- Advisory Board: *Reflectance Medical Inc.*
- Patents received and pending: *University of Massachusetts, assigned to Reflectance Medical Inc*

Personal financial relationships with non-commercial interests (e.g., government or other nonprofit funding) relevant to this presentation, within past 12 months:

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 - Combat Casualty Care Research Program
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 - Center for Commercialization of Advanced Technology (SoCal)

tissue perfusion

- Blood flow is not uniformly distributed to tissue.
 - During hypovolemia, blood flow to the heart and brain are protected at the expense of the splanchnic circulation and the muscle.
- Insufficient oxygen leads to tissue acidosis, cellular dysfunction, organ injury and death if hypoperfusion and oxygen debt continue for a long time.

tissue perfusion

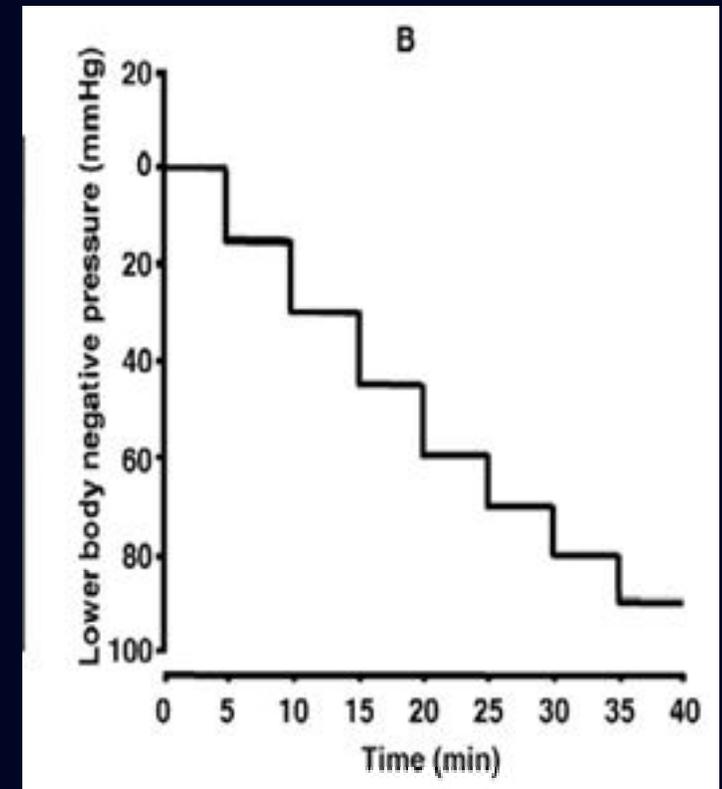
- Rapid & early recognition of increased oxygen extraction and therapy to improve tissue perfusion has been shown to improve patient outcomes.
 - Rivers et al, N Engl J Med 2001; 345: 1368-1377.
 - McKendry et al, BMJ 2004; 329:438-444.
 - Pearse et al, Crit Care 2005; 9:R687-R693.
- Standard hemodynamic monitoring only assesses global circulatory status, not organ function or the microcirculation – new technologies are needed.

military motivation



- **Triage** – identification of casualties who appear “OK” but are actually in compensated shock.
- **Transport** – real-time, continuous, early warning of hemodynamic instability during evacuation from the middle east to Europe or US.

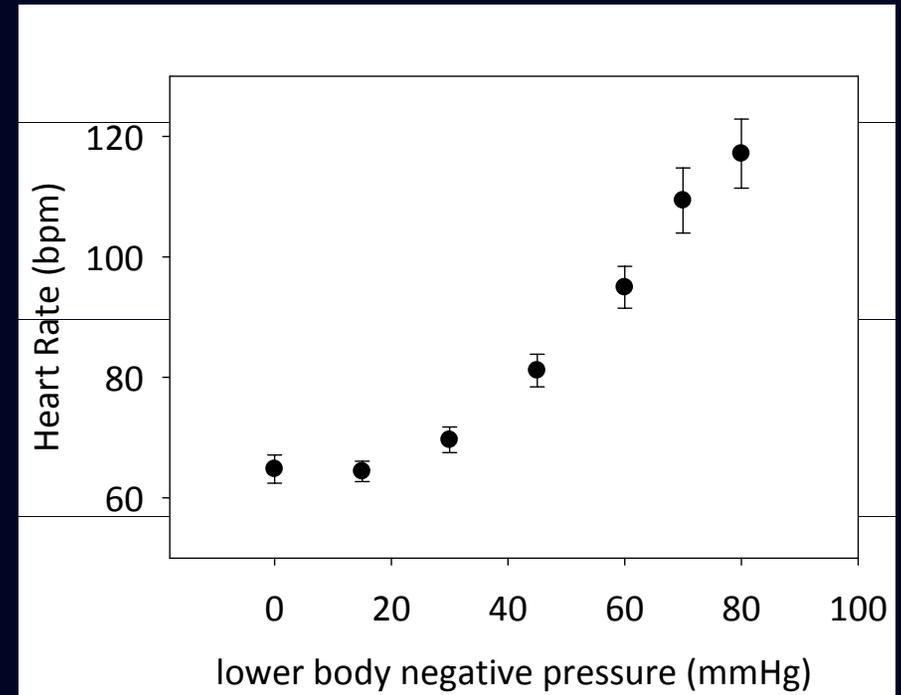
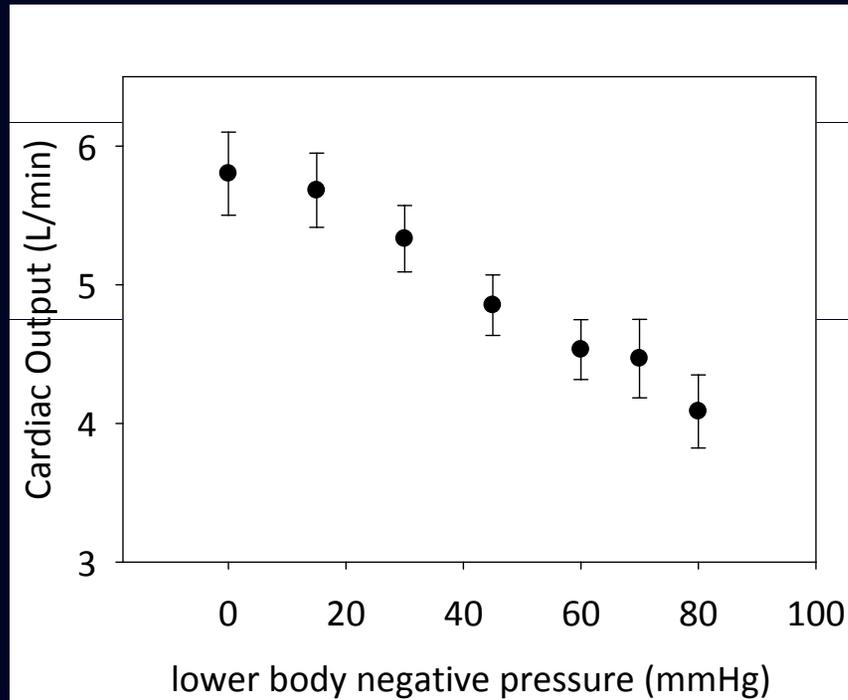
LBNP model of human response to central hypovolemia in a controlled setting



Dr. Convertino's lab, US Army Institute of Surgical Research

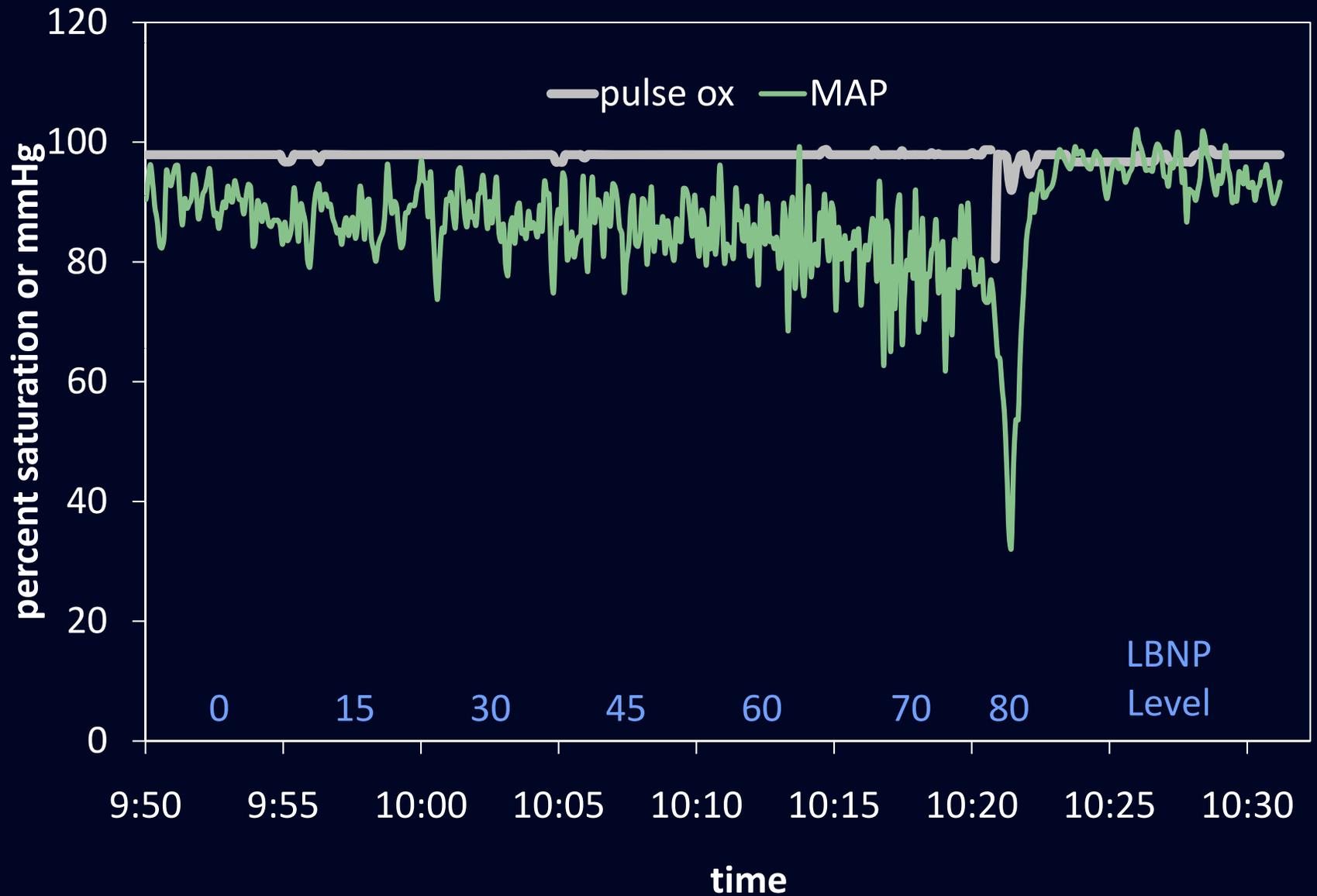
LBNP=lower body negative pressure

LBNP mimics reduction in cardiac output and increase in heart rate seen in hemorrhage

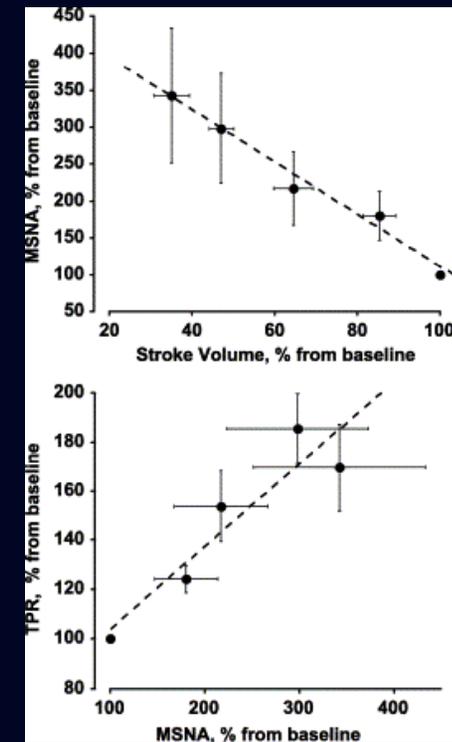
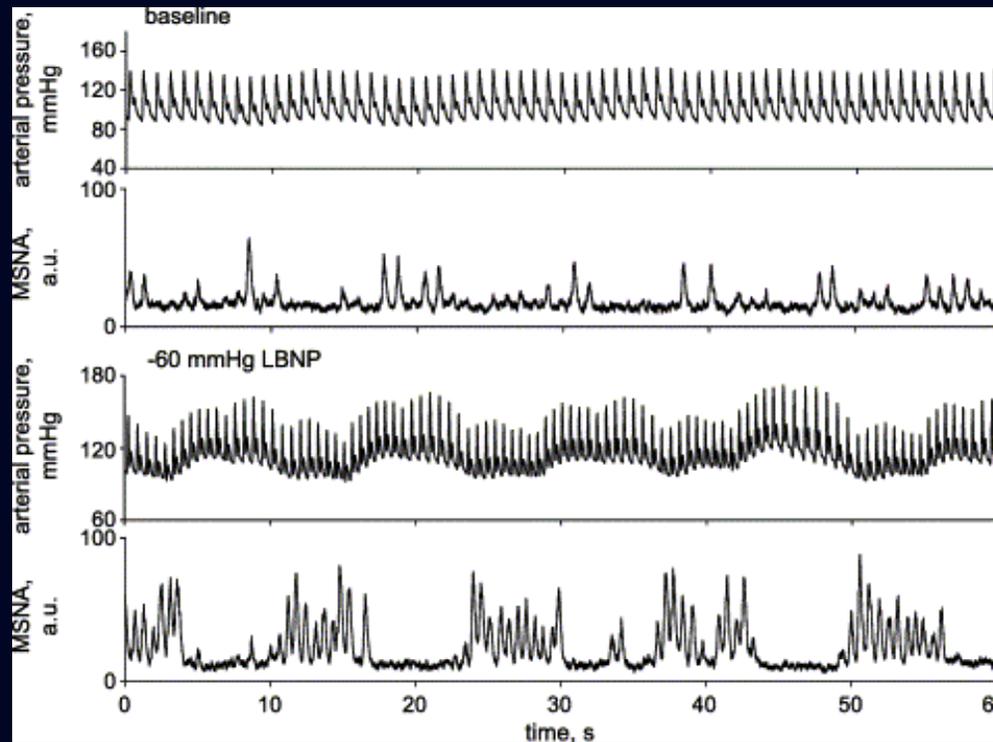


N=30 human subjects

LBNP ended as blood pressure starts to drop,
no change in pulse oximeter



during LBNP, like hemorrhage, homeostasis maintained through vasoconstriction

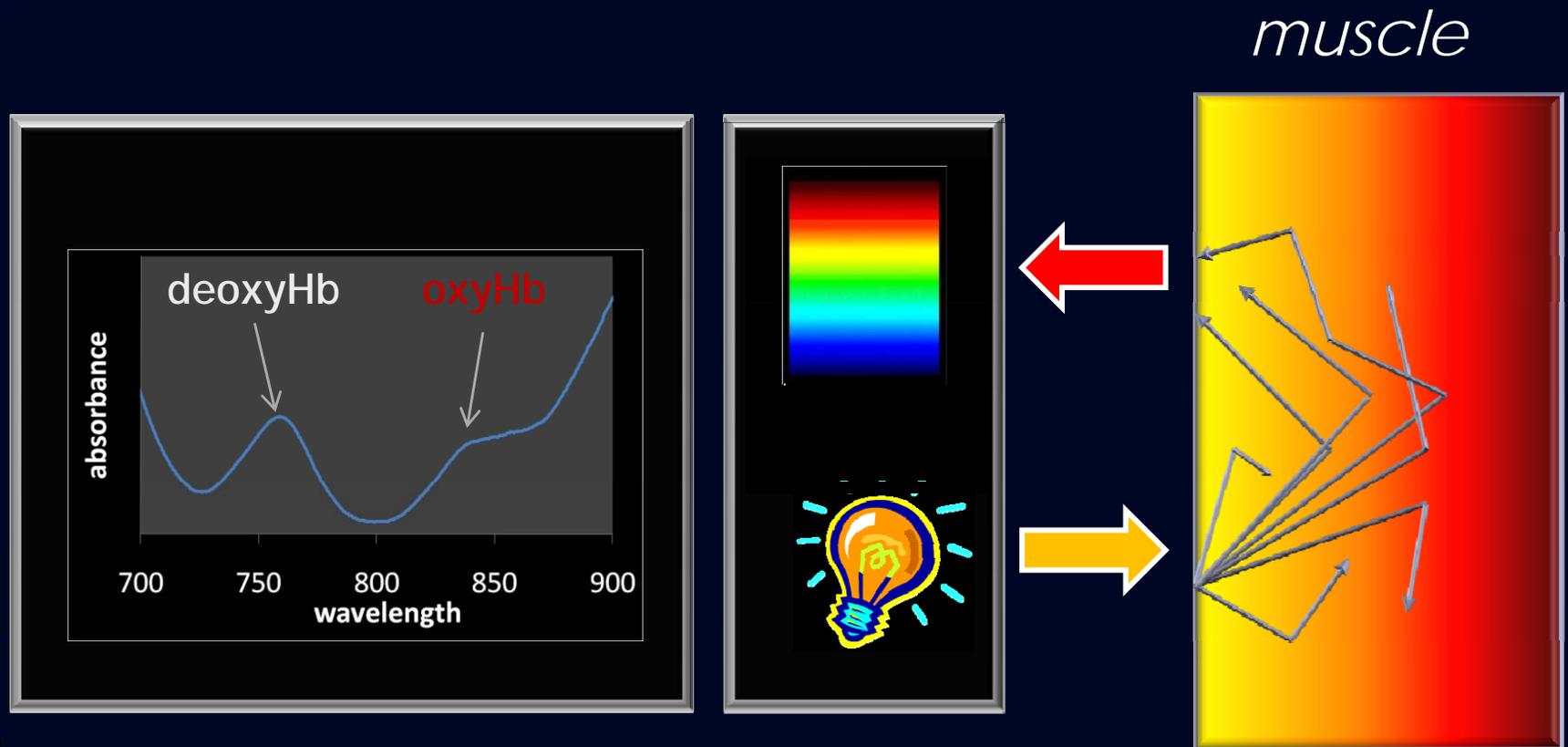


Convertino et al, Auton Neurosci 2004; 111: 127-134.

LBNP simulates early, compensated hemorrhage and is being used by the Army to evaluate new technologies for future use by medics.

near infrared spectroscopy (NIRS)

noninvasive technology to assess tissue perfusion

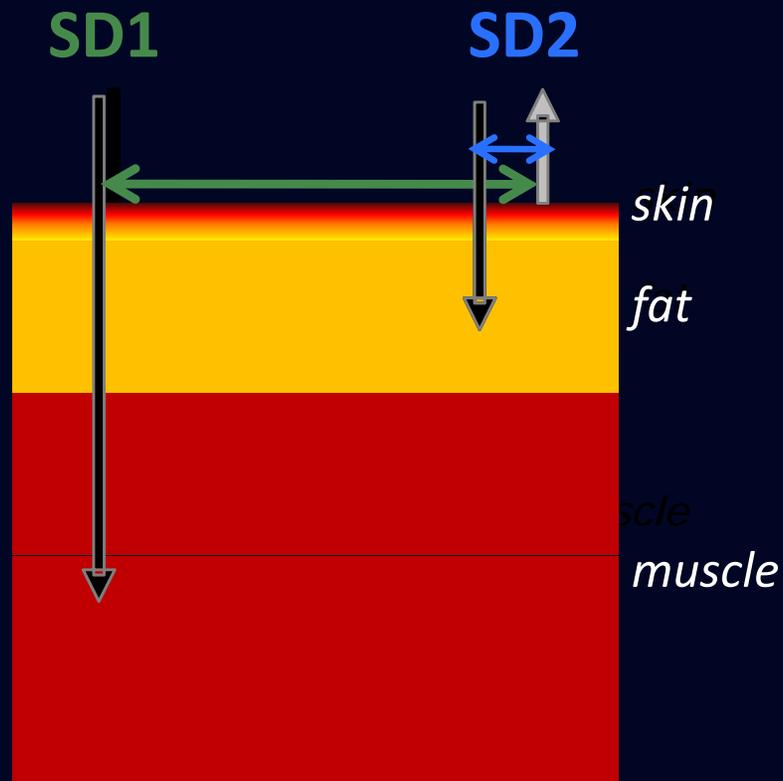


in NIRS, measured light absorbance results primarily from the blood in the venules

1. Both large and small blood vessels absorb light.
2. For small blood vessels, some light passes through and is reflected back by muscle fibers.
3. For large blood vessels, all light is absorbed and none is reflected back so is not detected.
4. In tissue, 70-80% of blood is contained in the venules, the remaining in arterioles and capillaries.

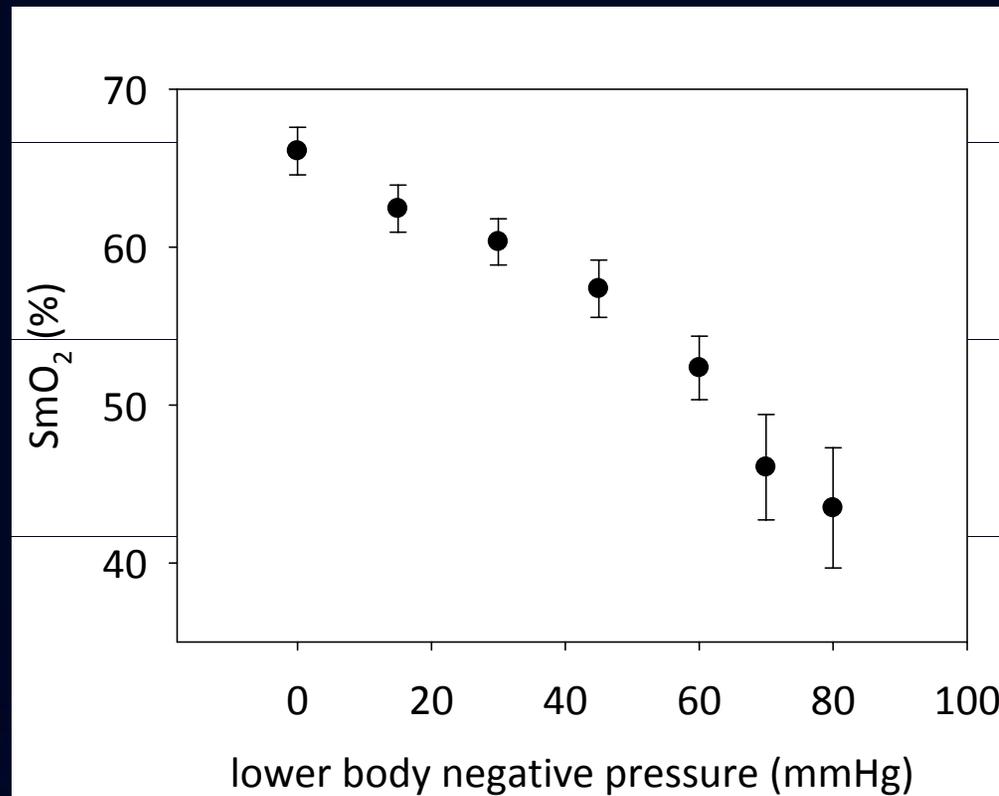
NIRS-determined SO_2 reflects microvascular hemoglobin oxygen saturation after oxygen has been released to cells.

skin pigment & fat correction required for determination of absolute concentrations



- first sensor detects light from skin, fat, & muscle
- second sensor detects light from just skin & fat
- we mathematically eliminate the skin and fat information to leave just spectra from the muscle microcirculation

evaluation of CareGuide muscle oxygenation in LBNP model of central hypovolemia



after

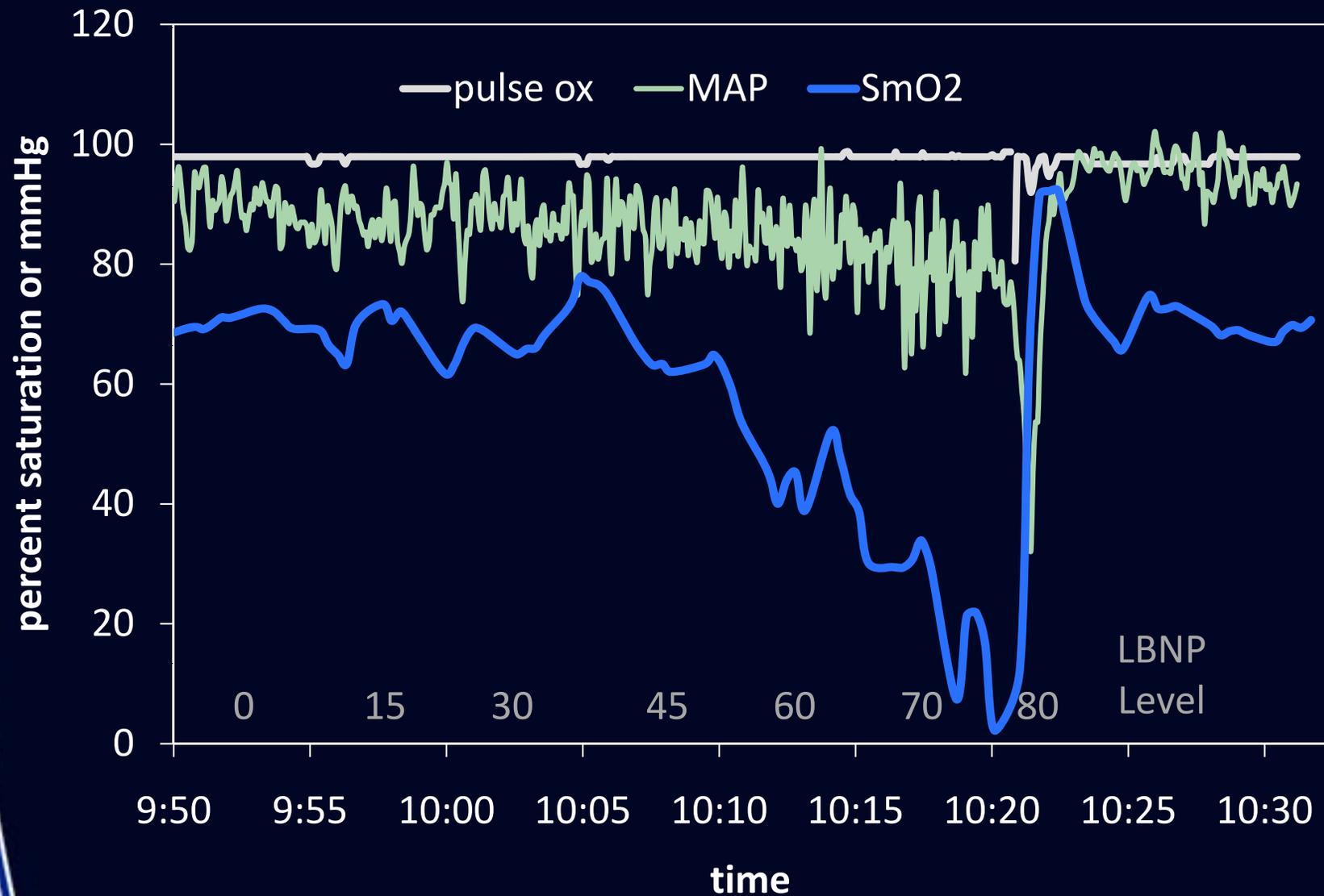
Soller et al, J Appl Physiol 2008; 104: 475-481

Unique implementation of NIRS to determine oxygen saturation from muscle alone (SmO₂), without interference of blood flow from skin or fat through use of dual-light source sensor.

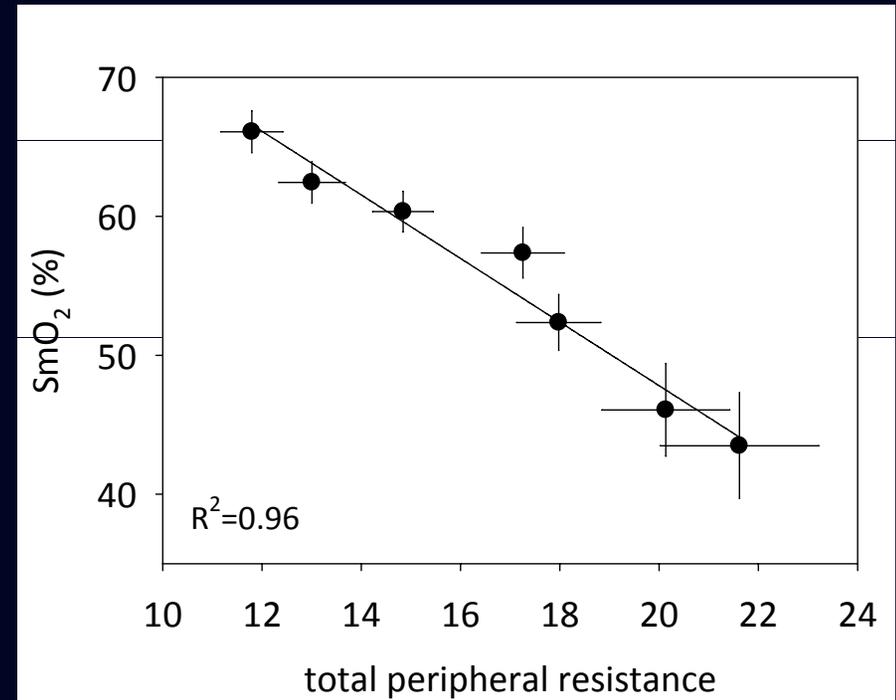
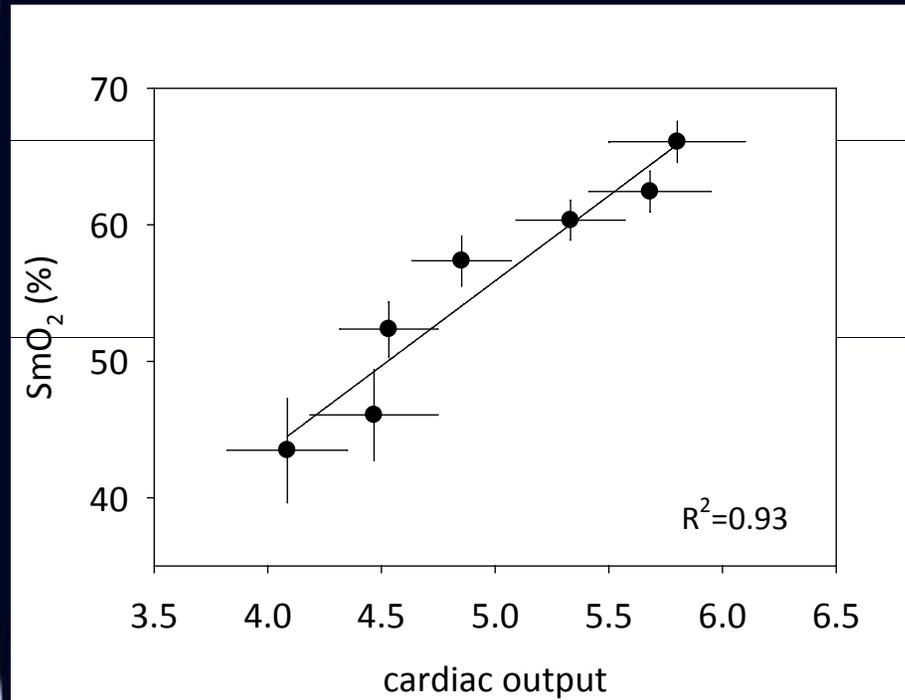
Yang et al, Opt Express 2007; 15: 13715-13730

N=30 human subjects

SmO₂ indicates hypovolemia before decrease in blood pressure or pulse ox



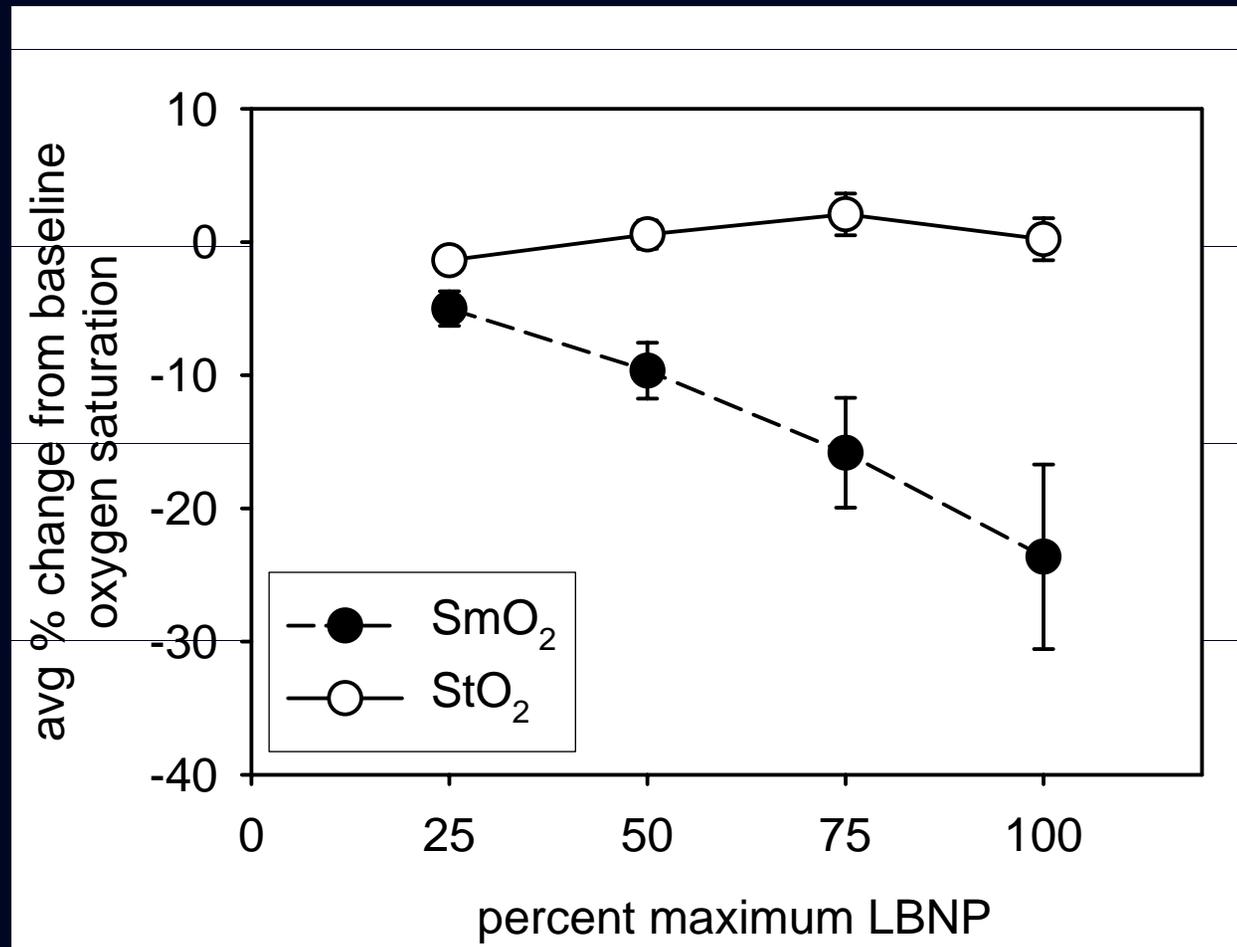
SmO₂ tracks cardiac output and total peripheral resistance during LBNP to presyncope



after
Soller et al, J Appl Physiol 2008; 104: 475-481

N=30 human subjects

muscle SO_2 (SmO_2) is an early indicator of hypovolemia, but tissue SO_2 (StO_2) is not



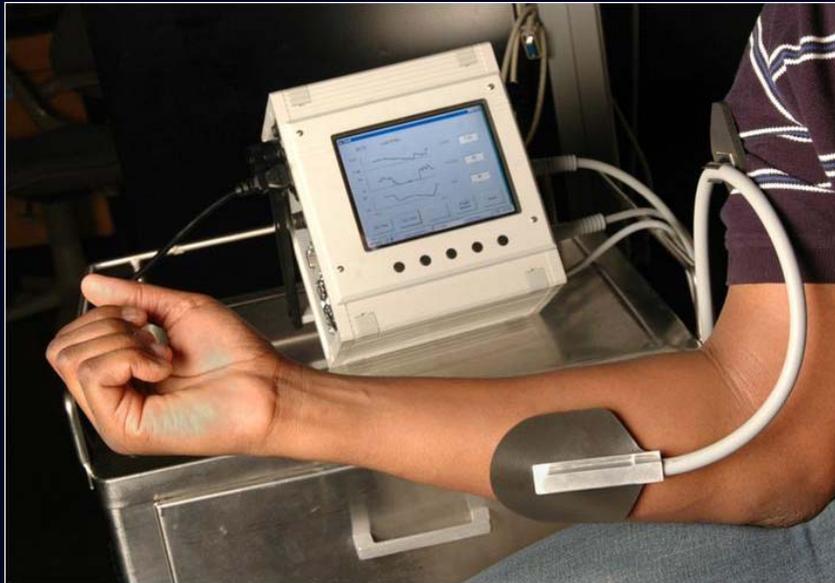
Soller et al, Crit Care Med 2008; 36: 176-182.

Not all near infrared spectroscopic systems are equal

- Our unique implementation, which eliminates blood contribution from skin, allows:
 - sensitive determination of muscle oxygen
 - simultaneous determination of tissue acidosis (pH)
 - measurements which track well understood physiology
- Robust clinical studies of new monitoring technologies are required prior to routine patient use, however technologies which are unsuccessful in the laboratory, are likely to perform poorly in a clinical or field setting.

portable noninvasive SmO_2 /pH/Hct monitor developed UMass Medical School team

Limitations of the portable fiber optic monitor:



- Fiber optic cables are fragile and cumbersome
- Very high power requirements limit battery life.
- Costly and difficult to manufacture

Reflectance Medical solid state spectroscopic sensor developed for military & space use

portable, fiber optic system

filament lamp

grating spectrometer

fiber optic cables



handheld, solid state system

LED array

chip-scale spectrometer

direct contact

CareGuide noninvasive trauma monitor

CareGuide

a) **measures impaired tissue perfusion and acidosis;**

- Quantitative, continuous, determination of microcirculatory muscle oxygen & pH
- used with existing treatment protocols to rapidly reverse poor tissue perfusion

b) **completely noninvasive, portable & highly automated;**

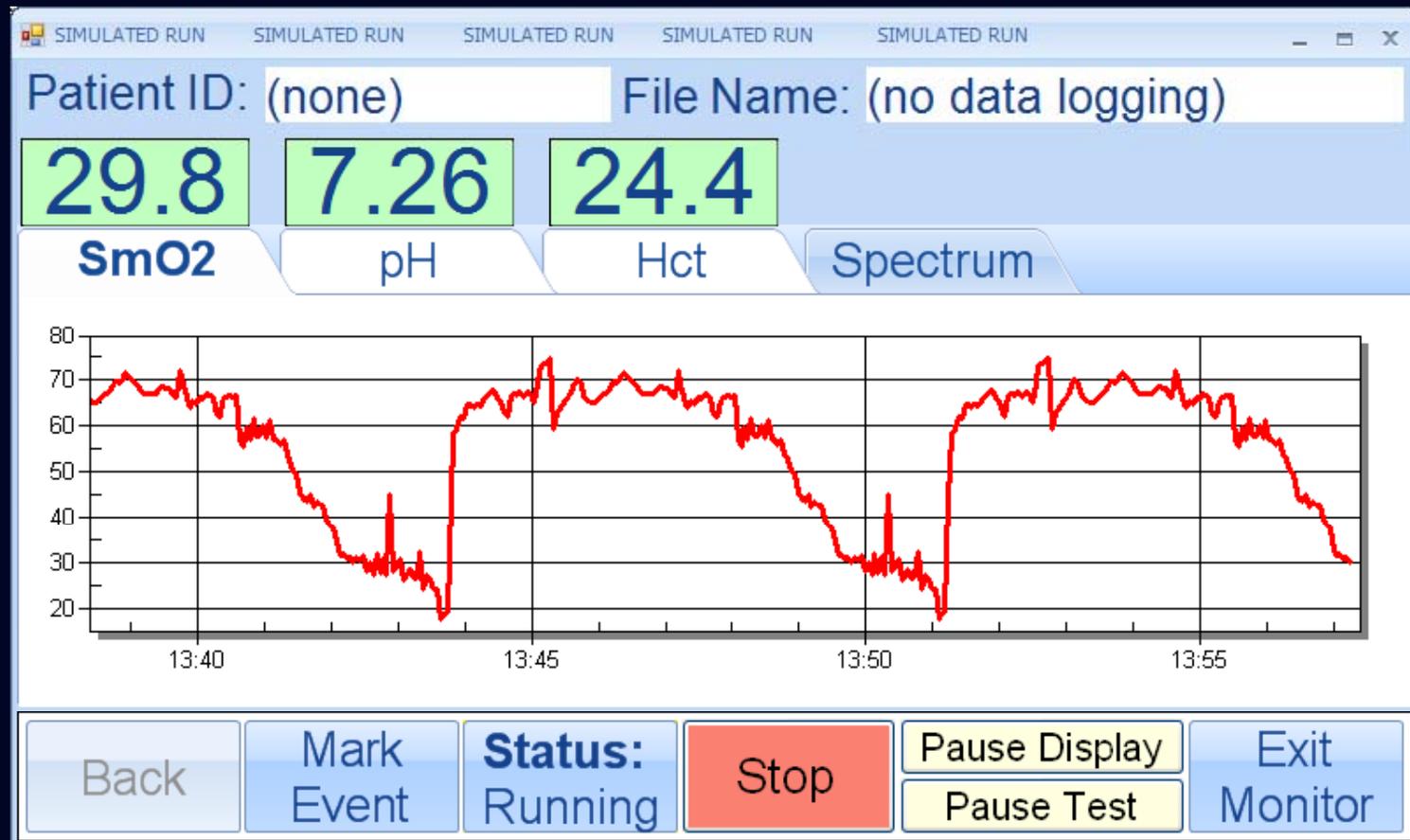
- easy for nursing staff & medics



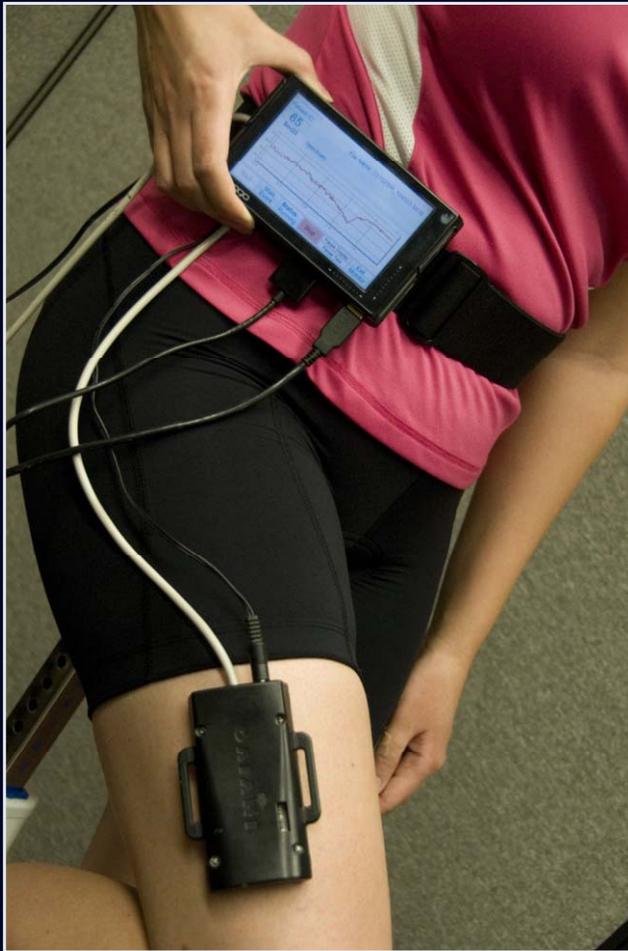
CareGuide prototype

- Noninvasive
- Continuous
- Can be used over any major muscle

CareGuide displays current value of 3 parameters, along with trends for each

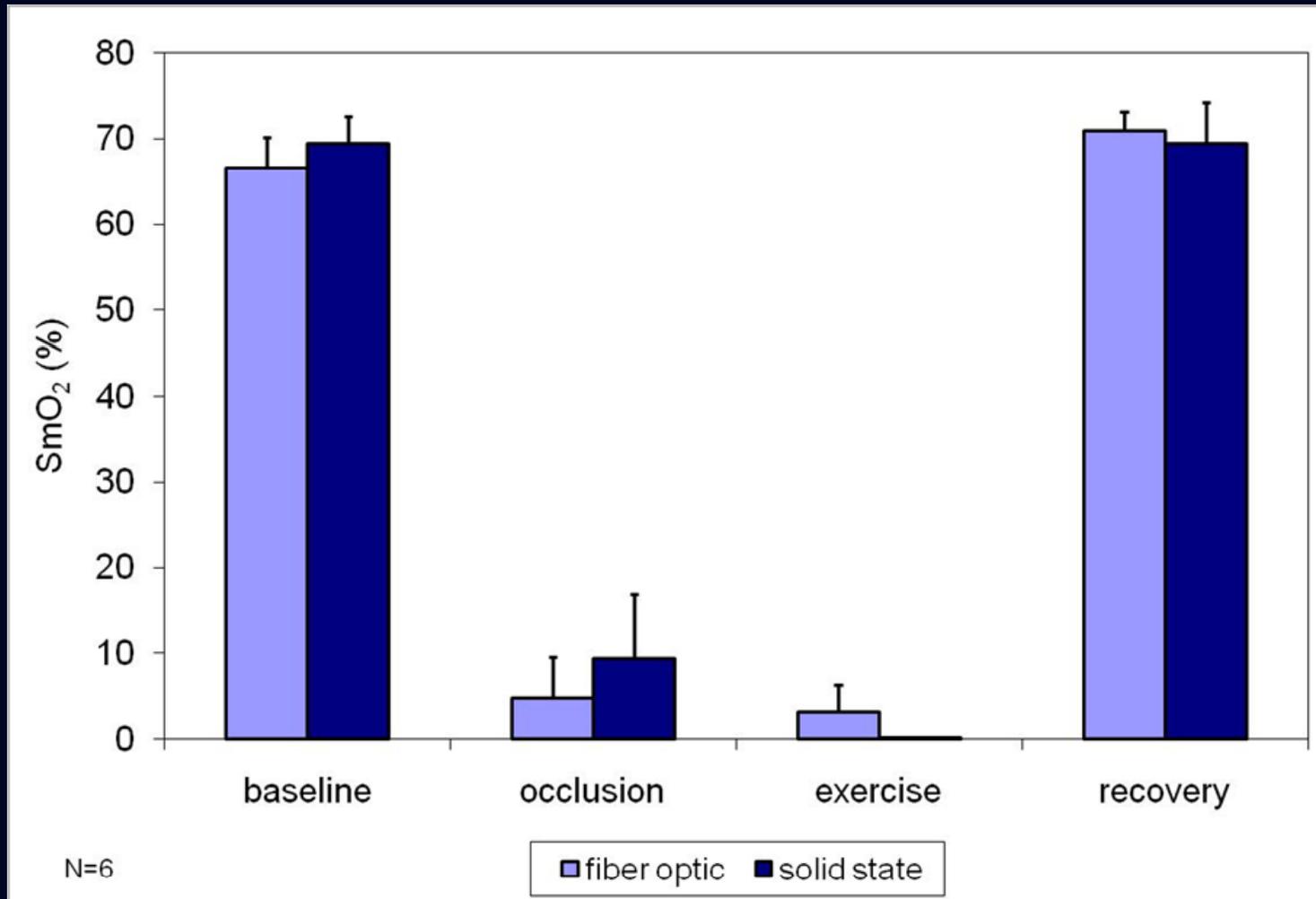


CareGuide is highly automated

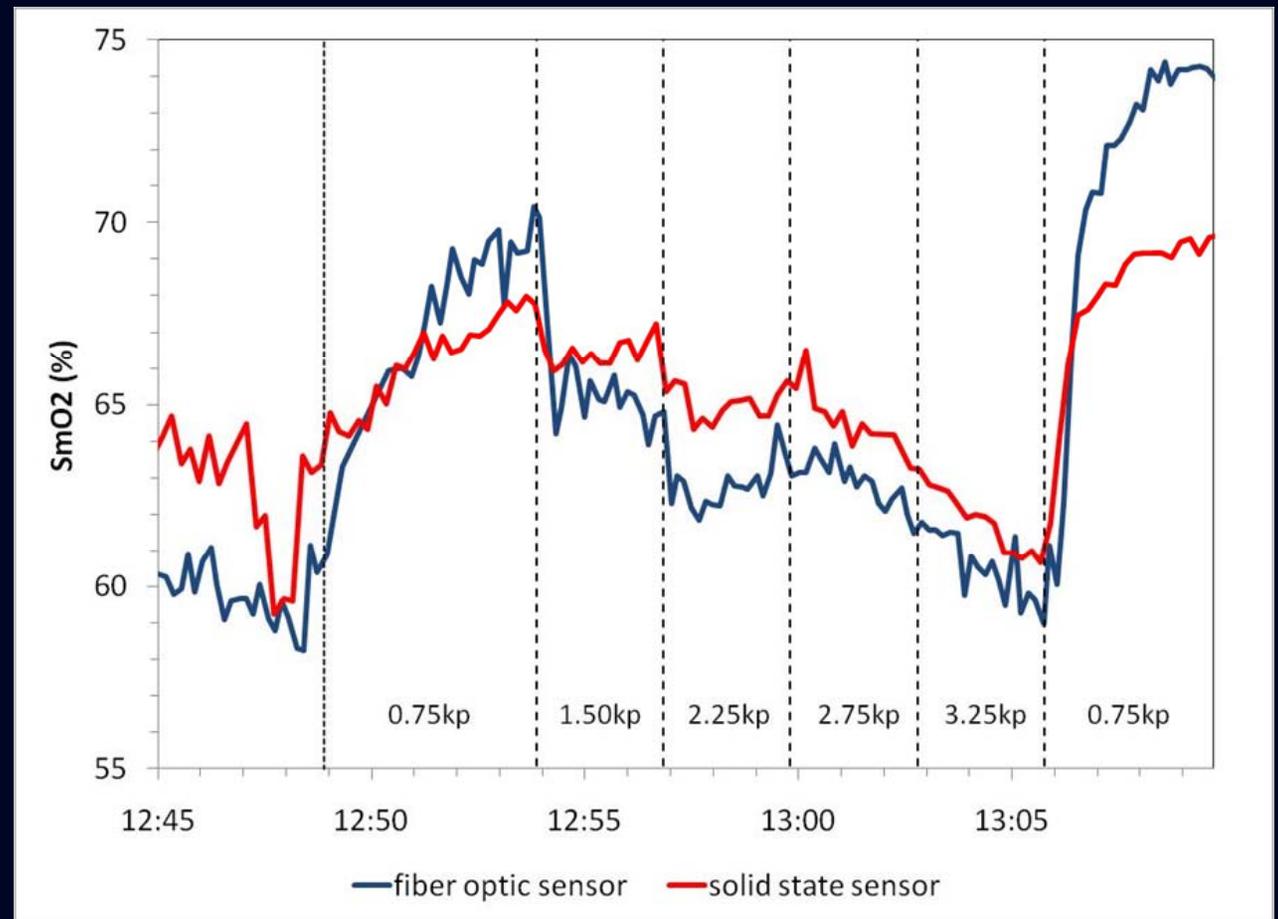
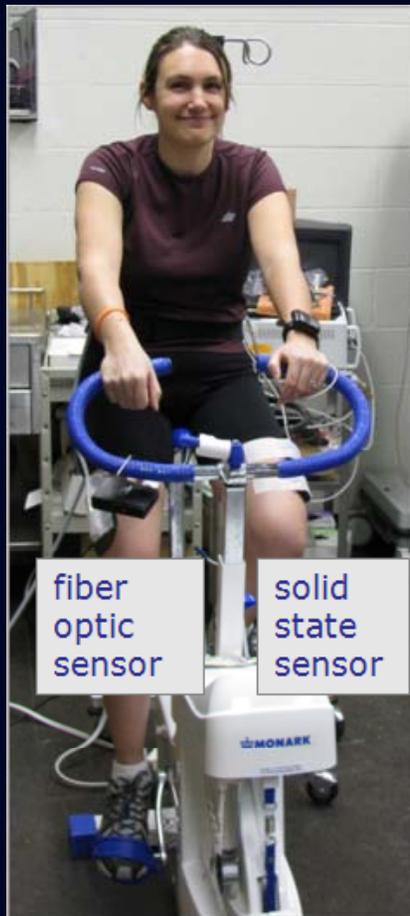


- Automated system check prior to each use.
- Automatic system set-up optimizes data collection for each individual patient.
- On-the-fly error checking detects and corrects for conditions which could degrade data quality.
- Designed to work on active muscles.
- Battery or AC operation.

equivalence with fiber optic sensor arterial occlusion + exercise study



equivalence with fiber optic sensor cycling demonstration



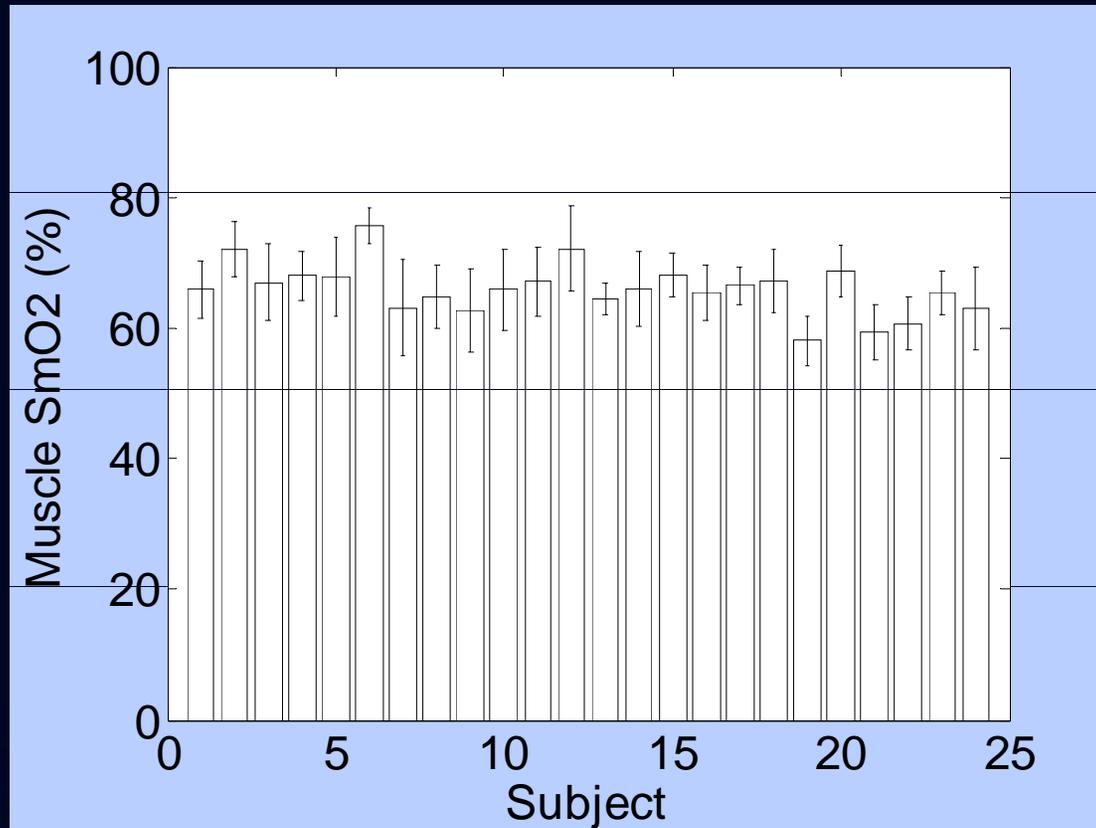
conclusions

- NIRS assesses oxygenation in the micro-circulation.
- During early hypovolemia, microvascular oxygen is reduced by peripheral vasoconstriction, as a response to maintain blood pressure.
- Muscle oxygen saturation (SmO_2) measurements track the compensatory response to hypovolemia, providing an early warning.
- Not all NIRS monitors are equal. Results depend on sensor design and algorithms to calculate SO_2 .

conclusions

- Muscle pH can also be calculated from near infrared spectra and provides an earlier indication of tissue acidosis than venous pH, lactate or base excess.
- A portable, robust, lightweight noninvasive system has been demonstrated to be equivalent to the fiber optic trauma monitor.
- One sensor is flexible enough for accurate measurement of tissue oxygen and pH on all skin colors and through fat as thick as 20mm.

repeatability of SmO_2 measurement on forearm of normal subjects (N=24)



5 replicate measurements, separated by at least 48 hrs
average variation in $\text{SmO}_2 = 4.7\%$

relationship between LBNP and hemorrhage

Classification	Stage I		Stage II		Early Stage III		Late Stage III	
Hemorrhage	Mild		Moderate		Severe		Shock	
LBNP	10 to 20 mmHg		20 to 40 mmHg		> 40 mmHg		Collapse	
	LBNP	Hem	LBNP	Hem	LBNP	Hem	LBNP	Hem
HR	↑	↔	↑	↑	↑	↑	↑ or ↓	↓
MAP	↔	↔	↑	↔	↑	↑	↓	↓
SV	↓	↓	↓	↓	↓	↓	↓	↓
Qc	↓	↓	↓	↓	↓	↓	↓	↓
CVP	↓	↓	↓	↓	↓	↓	↓ or ↔	↓ or ↔
SNA	↑	↑	↑	↑	↑	↑	↓	↓
NE	↑	↑	↑	↑	↑	↑	↓	↓
PVR	↑	↑	↑	↑	↑	↑	↓	↓
AVP	↔	↔	↔	↔	↑	↓ or ↔	↑	↑
PR	↔	↔	↔	↔	↑	↓ or ↔	↑	↑
Ang II	NA	↔	NA	↔	NA	↔	NA	↑
PPH	↔	↔	↔	↔	↑	↑	↑	↑

Convertino et al, Crit Care Med 2007; 35: 1145-1152.