StO_2 Sensor

A forum for trends and tissue oxygen monitoring in trauma and critical care

Issue 4 – March 2007

New InSpectra™ StO_2 Tissue Oxygenation Monitor brings new insight to trauma teams

In this issue

Dr. Gene Moore, Chief of Surgery and Trauma Services at Denver Health Medical Center, comments on the case.

Physicians caring for trauma patients will now have an additional tool to assess the condition of those patients with a monitor from Hutchinson Technology that continuously and noninvasively measures local tissue oxygen saturation (StO_2).

The **InSpectra™ StO_2** Tissue Oxygenation Monitor, which recently received both FDA market clearance and the European CE mark, uses near infrared spectroscopy and a patented algorithm to noninvasively and continuously provide a direct measurement of StO_2. It is indicated for use in monitoring patients during circulatory or perfusion examinations of skeletal muscle, or when there is a suspicion of compromised circulation. The device was designed for use in trauma environments where there is a need to directly monitor compromised tissue oxygenation associated with hemorrhagic shock.

"Other means of assessing tissue oxygenation in patients with hemorrhagic shock are snapshots of the past, and are indirect or invasive, or both," said Christina Temperante, president of Hutchinson Technology's BioMeasurement Division. "In contrast, our device is noninvasive and provides an immediate, direct and continuous measurement, filling a critical and widely recognized information gap in the monitoring of trauma patients."

The **InSpectra StO_2** System consists of a monitor, an optical cable and a single-use sensor that is applied to the thenar eminence at the base of the thumb. The sensor emits near infrared light to illuminate muscle tissue below the surface of the skin. Returned light is then analyzed to produce a direct measurement of oxygen saturation in the microcirculation of the muscle tissue.

Shipments of the **InSpectra StO_2** System for clinical use began in December.

In 2002, Hutchinson Technology introduced the **InSpectra StO_2** System's predecessor, the **InSpectra** Tissue Spectrometer. The device was designed primarily for research and has been used in numerous studies exploring the potential of StO_2 in trauma, sepsis, vascular disease, and other medical applications. The new **InSpectra StO_2** System is the first tissue oxygenation monitor specifically designed for clinical use in trauma.

Study finds StO_2 functions as well as base deficit in indicating hypoperfusion.

Study results were presented by Stephen M. Cohn, MD, lead investigator, at the American Association for the Surgery of Trauma Annual Meeting, September 2006. The final paper, entitled "Tissue Oxygen Saturation Predicts the Development of Organ Dysfunction During Traumatic Shock Resuscitation," was published in Journal of Trauma, January 2007. The quotes included in this article are taken from Dr. Cohn's presentation at AAST.

In 2004, Hutchinson Technology initiated a prospective observational clinical study with the cooperation of seven Level I trauma centers to identify the role that tissue oxygen saturation (StO_2) monitoring with the **InSpectra™ StO_2** System could play in hemorrhagic shock and resuscitation.

The study was designed to determine if StO_2 measurements on the thenar eminence are an indicator of hypoperfusion. Multiple organ dysfunction syndrome (MODS) was chosen as the indicator of hypoperfusion because it is generally accepted that early hypoperfusion is associated with later development of organ dysfunction. The study also assessed StO_2's ability to monitor tissue oxygenation changes during resuscitation. More than 380 patients were enrolled. Hutchinson Technology believes it is one of the largest prospective clinical studies ever conducted in the field of trauma care.

"The principle findings of the study, therefore, were that tissue oxygen saturation provided information within the first hour of ED arrival to aid in the discrimination of patients who later go on to develop multi-organ dysfunction and death."

Study objectives

In order to determine if StO_2 measurements on the thenar eminence indicate hypoperfusion in trauma patients, the study objectives included:

1. Determine the ability of StO_2 to predict the development of MODS.
2. Determine the ability of StO_2 to predict mortality, red blood cell transfusion, and coagulopathy.
3. Determine if a predictive relationship exists between StO_2 or base deficit, and ventilator-free days, ICU-free days, and/or LOS.
4. Compare the area under the ROC curve of base deficit and StO_2 to predict MODS and mortality.

Methods

Over a 15-month period, seven Level I trauma centers in the US enrolled 383 patients, 50 of whom developed MODS. Patients who had sustained major blunt and/or penetrating trauma and required blood transfusion within six hours of admission were enrolled. StO_2 monitoring was started on the thenar eminence within 30 minutes of ED arrival and recorded continuously for 24 hours. Clinicians were blinded to StO_2 results. Additionally, standard hemodynamic parameters recorded as part of patient care were collected for the first 24 hours. These included base deficit and clinical outcomes.

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Conclusions

Among the study's conclusions:

1. StO_2 below 75% may indicate serious hypoperfusion in trauma patients. In the trial, 78% of patients who developed MODS, and 91% of patients who died, had StO_2 below 75% in the first hour of arrival in the emergency department (ED).
2. StO_2 above 75% indicates adequate perfusion. Trauma patients who maintained StO_2 above 75% within the first hour of ED arrival had an 88% chance of MODS-free survival. StO_2 was significantly different during the course of resuscitation for patients who developed MODS compared to those who did not.
3. StO_2 functions as well as base deficit in indicating hypoperfusion in trauma patients, with the added benefits of being continuous, direct and noninvasive. The results for minimum StO_2 within the first hour after ED arrival compared favorably for both the MODS and mortality outcomes when compared to maximum base deficit collected within the first hour.
4. No device-related adverse events were observed during the study.

"In addition, the StO_2 provided the same discriminatory powers as base deficit or systolic blood pressure with respect to the ability to predict both MODS and mortality."

Principal Investigators

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  Denver Health Medical Center
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  San Antonio

For a complete review of this and other studies on the use of StO_2 in hemorrhagic shock, visit www.htibiomeasurement.com.

Study Conclusions: StO_2 functions as well as Base Deficit in indicating hypoperfusion

Outcome	Min StO_2* < 75%	Max BD* > 6 mEq/L
MODS (Table 6) Sensitivity (95% CI)	78%	78%
Mortality (Table 7) Sensitivity (95% CI)	91%	75%
Outcome (Bad/Good)** (Table 8) Negative Predictive Value (NPV) (95% CI)	88%	78%

*In the first hour of ED arrival

**(MODS and Mortality combined)

Cohn et al. Tissue Oxygen Saturation Predicts the Development of Organ Dysfunction During Traumatic Shock Resuscitation. *J Trauma.* 2007:62(1):44–55.

Case Study: Tissue oxygenation (StO_2) monitoring in uncontrolled bleeding

*This case study is one of several hundred cases taken from the multi-site, prospective, observational clinical StO_2 Trauma Study sponsored by Hutchinson Technology Inc., in which clinicians were blinded to StO_2 measurements. This case study represents an example of a compromised circulation situation where the **InSpectra™** System's general indications apply. This case is not intended to represent the general findings of the overall study. Study results have been published and may have limitations.*

The Case:

58-year-old obese (BMI 32) woman, injured in a low mechanism moped vs. car crash at 11:45. History of hypertension, adrenal mass, hyperthyroidism, COPD. Tissue oxygenation (StO_2) levels on the thenar eminence, measured with an **InSpectra™** Tissue Spectrometer, were blinded to the clinician.

The Clinical Course:

12:05 ED arrival, SBP 80
12:10 FAST exam negative x 2, nurse's note: IV fluids, labs drawn, patient responds to questions appropriately, speaking complete sentences, respirations unlabored, refuses pain medication
12:00–13:00 2 liters crystalloid infused
12:24 hemoglobin 15.3, thenar StO_2 93, slowly decreases to 65 over 30 minutes (clinicians blinded to StO_2 per study protocol)
12:55 transported to CT where, per verbal report, patient became profoundly hypotensive and unresponsive, rushed back to ED
13:10 emergently intubated; FiO_2 100%; repeat FAST exam positive
13:15 2 units PRBC in ED
13:20 to OR for splenectomy
13:20–14:45 OR time
13:35 3 units PRBC
Patient discharged nine days post admission

The Commentary:

By Dr. Gene Moore
Chief of Surgery and Trauma Services, Denver Health Medical Center

"First, I would say that most of us, as Trauma Directors, would be embarrassed to see a case like this in our trauma center. The fact is I was the attending on this patient. The fact is I did see this patient in the Emergency Department. More important, the fact is that I, as well as my entire team, missed the fact that this lady was in a life-threatening situation from a ruptured spleen. And, frankly, I think that any honest Trauma Director would tell you that they've seen the exact same pattern take place in their facility.

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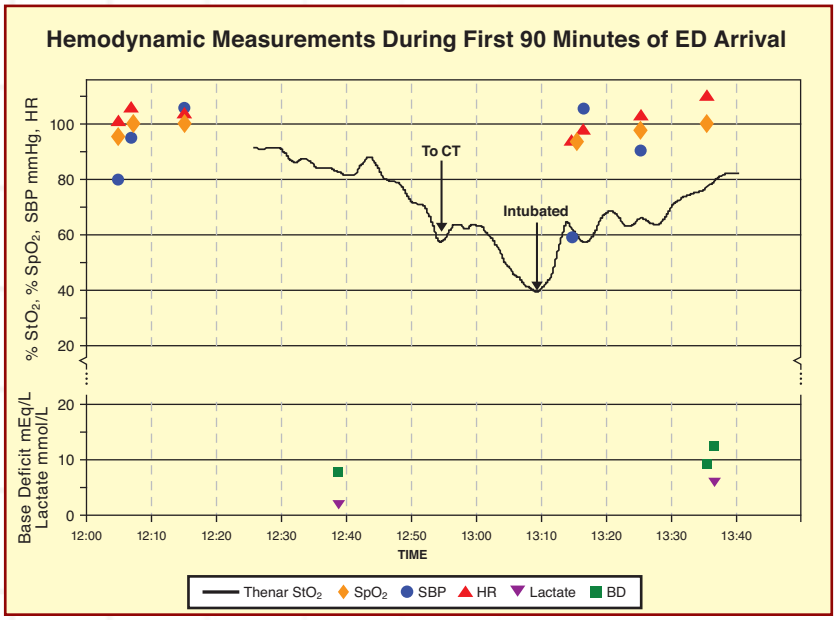

"This is a classic situation. These patients come to a very busy trauma center by ambulance. Everyone rushes into the room, often 25 or 30 of us. As soon as the first blood pressure is revealed and it looks normal, everybody vanishes and the patient says, 'What's all the commotion about?' She refuses pain medication, goes to the CT scanner, and 20 minutes later, your staff pages you because the patient is now hypotensive.

Dr. Gene Moore, when he's not on the job at Denver Health Medical Center

"So, it couldn't be a more classic potential use for the **InSpectra StO_2** monitoring device. I think what is clearly reflected in the numbers is that, although the blood pressure/heart rate aren't recorded in the chart, clearly the Emergency Department nurses who were transporting this patient to the CT scanner were observing her vital signs, and therefore, we have to assume that her vital signs remained normal. In fact, by the time she reached that scanner, she must have been in the throes of shock, and StO_2 clearly preceded the drop in blood pressure as a signal to impending disaster.

"In most hospitals, when you're transporting patients from the Emergency Department to the CT suite, there is some obligatory travel time and distance between the two. In some hospitals, the scanner is getting closer to the ED, but in fact, transport time is still an issue. And so, we currently use portable vital signs monitors that aren't quite as accurate and are not quite as easy to see. I also think that ED nurses become pretty comfortable with conversing with the patient, and as long as the patient is alert and not complaining, and the monitor doesn't look alarmingly different, they get rather passive and lax about attending to the trends and recording it. You can imagine transporting a patient on a gurney with a clipboard. You don't have time to be rolling the patient to the scanner and writing out a bunch of numbers, particularly when the numbers look like they haven't changed.

"If I had been looking at the StO_2 numbers on the **InSpectra StO_2** monitor, there's no question that I would have paused before sending this woman to CT. As soon as that trend went down, I would have said 'Wait a second. Let's look at the base deficit, let's get a central line in this lady, and let's figure out what her volume is doing here before we move her because she may need to go to the operating room.'

"I would have initiated all of those things. Now, I could have made the same mistake we already made here, but I suspect that we would have found her CVP was low; we would have documented her systolic blood pressure and mean arterial pressure were falling; and we would have seen the base deficit, which isn't terrible, but seven is getting to a level where we're worried. I suspect we probably would have re-ultrasounded her, and we likely would have ended up in the Operating Room."

InSpectra™ StO_2 System testing today: From surgical suites to mountain peaks

The **InSpectra™ StO_2** Tissue Oxygenation Monitoring System has not only been tested in health care facilities around the world, it has also found its way up the French Alps — and soon will reach the summit of Mount Everest. The latter two locations are the work of Dr. Michael (Monty) Mython and his colleagues at University College London, where Dr. Mython is Professor of Anaesthesia and Critical Care.

Dr. Mython has been interested in the subject of tissue oxygenation for almost 15 years, originally looking at its impact in the gastro-intestinal tract. His interest was piqued at a meeting of the European Shock Society where he saw the **InSpectra StO_2** System and heard Dr. Didier Payen present data which suggested hemoglobin oxygen saturation in tissue (StO_2) would add value to the management of hemodynamics. "Based on what I heard and saw at that meeting, I sought out the company and said I'd like to learn more about the technology," said Dr. Mython.

One of Dr. Mython's prime areas of interest was the high-risk surgical patient. Both his work and the work of others over the years on patients undergoing major surgery demonstrated that a deficit of tissue oxygenation in the perioperative period resulted in significantly increased morbidity and mortality.

Dr. Mython and his team had been seeking a monitor that would identify deficits of tissue oxygenation — information that would direct them to modify their therapy to improve overall outcomes. They had monitors that took them part way to achieving these goals, but as Dr. Mython points out, "In general, they are very invasive. One of the appealing things about using near infrared spectroscopy technology is that it not only takes us closer to our goal of having a measure of tissue oxygenation, it is also noninvasive."

Some of the research being conducted by Dr. Mython and his colleagues is taking place in typical health care environs. Case in point: an associate, Dr. Mark Hamilton, is testing the effect of pre-surgical exercise on major surgery patients. He has patients exercise on a special floor exerciser prior to surgery to see if the measurement of tissue oxygenation on a limb makes it possible to identify patients who are at greater risk when they undergo surgery. His hypothesis is that patients who experience an acute reduction in tissue oxygenation levels are more likely to have poor outcomes following major surgery. He has demonstrated that the model works, but is still in the process of determining the impact on outcomes.

Dr. Hamilton is also using the tissue oxygenation monitor to describe the pattern of changes during cardiac surgery, and to relate the levels in the postoperative period to subsequent outcomes. Preliminary results, according to Dr. Mython, suggest that oxygen levels detected in the peripheral tissues may predict poor outcomes.

Other studies are taking place in more rarified atmosphere. Just outside the French village of Chamonix, Dr. Mython and his team took an **InSpectra StO_2** System into the Alps and recorded tissue oxygenation

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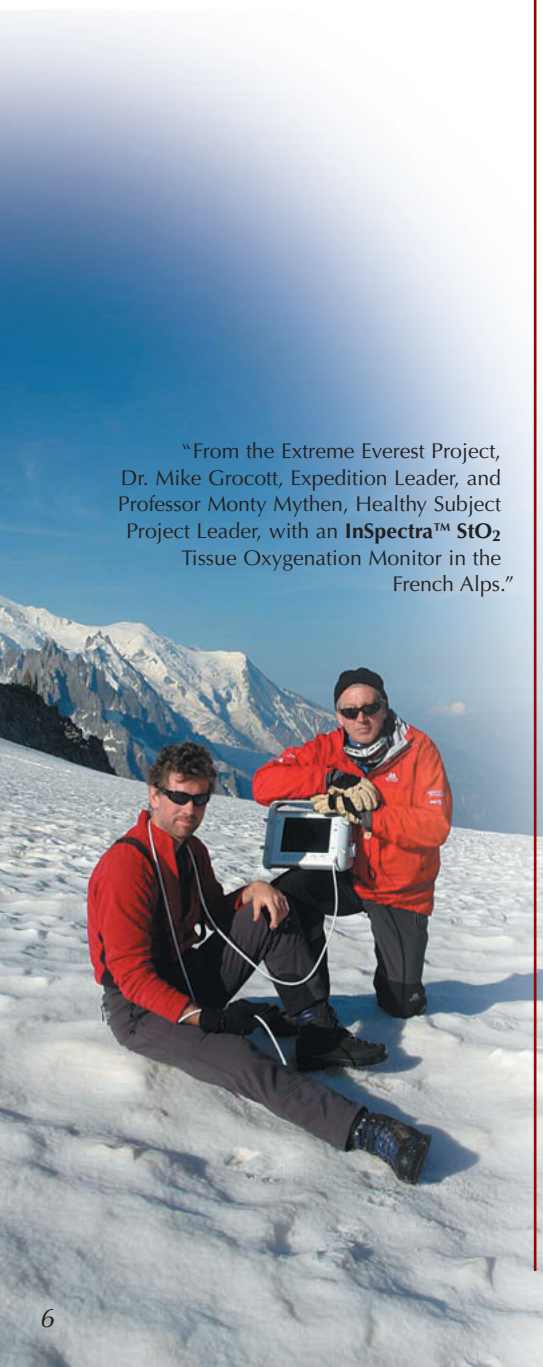
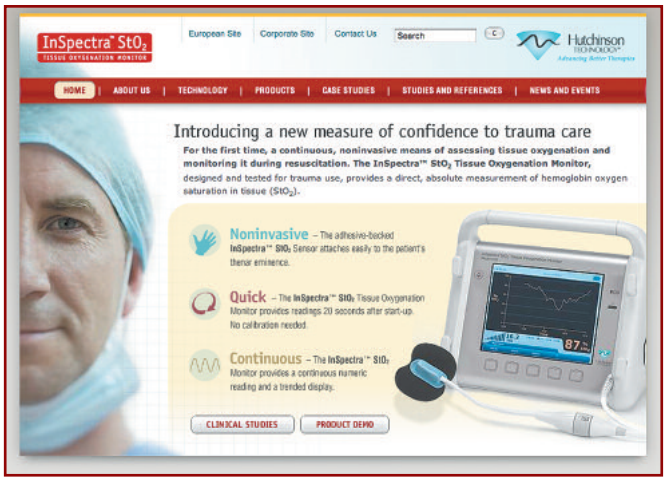


"From the Extreme Everest Project, Dr. Mike Grocott, Expedition Leader, and Professor Monty Mython, Healthy Subject Project Leader, with an **InSpectra™ StO_2** Tissue Oxygenation Monitor in the French Alps."

measurements on a group of volunteers at approximately 1,000 meters and again at 3,300 meters. According to Dr. Mythen, the system provided reproducible and reliable measures of tissue oxygenation in this anecdotal test. "Using the monitoring probe on the thenar eminence produced the changes one would anticipate," he says. "When people exert themselves, a resting limb demonstrates the slight initial rise in tissue oxygenation consistent with them exerting themselves and increasing overall oxygen delivery. We saw a very immediate response. We were also able to confirm how user-friendly and robust the technology is."

Next year, in another high-level test of the technology, Dr. Mythen and his colleagues will convene the Extreme Everest Project. The group will attempt to climb to the summit of Mount Everest and mount a human physiology experiment along the way. They will set up mobile laboratories at several altitudes and do detailed physiological measurements on hundreds of healthy volunteers, including experiments involving near infrared spectroscopy tissue oxygenation monitoring.

To contact Dr. Mythen, e-mail him at m.mythen@ich.ucl.ac.uk.



New information, video demonstration available on website

Now available on Hutchinson Technology's expanded website, www.htibiomeasurement.com:

- A thorough review of the science behind StO_2
- A look at the technology that drives the new **InSpectra™ StO_2** Tissue Oxygenation Monitor
- An updated compendium of research papers, clinical presentations and published articles on StO_2
- Product specifications
- A video demonstrating how to use the new **InSpectra StO_2** Tissue Oxygenation Monitor

StO_2 Research Presentations

Tissue oxygen saturation predicts the development of organ dysfunction during traumatic shock resuscitation

Cohn SM, Nathens AB, Moore FA, Rhee P, Puyana JC, Moore EE, Beilman GJ.
Presented at the American Association for the Surgery of Trauma Annual Meeting, September 2006.

Noninvasive near infrared spectroscopy-derived StO_2 predicts mortality in severe traumatic injury

Beilman GJ, University of Minnesota
Presented at the American College of Emergency Physicians Annual Meeting, October 2006.

Tissue O_2 saturation is an early indicator of mortality and blood transfusion needs in severe trauma

Puyana JC, Polanco P, Peitzman AB, Nathens AB, Moore FA, Rhee P, Beilman GJ, Moore EE, Cohn SM.
Presented at the Annual Congress of the European Society of Intensive Care Medicine, September 2006, Barcelona, Spain

Thresholded area over the curve (TAOC) of spectrometric tissue oxygen saturation (StO_2) as an indicator of volume resuscitatability in an acute porcine model of hemorrhagic shock

Zenker S, Polanco PM, Kim H, Torres A, Vodovotz Y, Clermont G, Pinsky MR, Puyana JC.
Presented at the 20th Annual Scientific Meeting of the Eastern Association for the Surgery of Trauma, January 2007.

Other research studies presented at the 2006 ESICM Meeting, Barcelona, Spain

Post-occlusive reactive hyperemia in weaning failure monitored by near-infrared spectroscopy.

Poriaz IM, Kontogiorgi M, Angelopoulos E, Kritikos K, Basios N, Nanas S, Roussos C, Routsie C.

Muscle oxygen consumption is decreased in septic patients

Creteur J, Buchele GT, Sales Jr J, Ospina G, Vincent J.

Muscle tissue oxygenation in septic patients treated with activated protein C

Rinaldi L, Busani S, Girardis M.

Microcirculatory effects using high molecular hydroxyethyl starch solutions in a porcine faecal peritonitis

Marx G, Simon TP, Schuerholz T, Petzel P, Haugvik SP, Forberger C, Reinhart K.

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StO_2 Research Presentations cont.

Determinants of post arterial occlusion reoxygenation measured by NIRS

Amathieu R, Heyer L, Bonnin P, Payen D.

Oxygen tissular saturation (StO_2) measured by NIRS in patients admitted to the intensive care unit

Mesquida J, Maluenda M, Masip J, Baigorri F, Artigas A.

Microcirculatory changes in patients with sepsis or septic shock under vasopressin substitution

Klinzing S, Reinhard C, Simon T, Reinhart K, Marx G.

Microcirculatory dysfunction in ICU patients with sepsis

Renieris P, Gerovasili V, Poriazi M, Loukas T, Markaki V, Routsi C, Roussos C, Nanas S.

Muscle oxygenation in low flow state and sepsis: Correlation to hemodynamics and outcome

Mozina H, Strahovnik I, Podbregar M.

Diffuse micro-oxygenation impairment in acute haemorragic shock

Heyer L, Rezlan E, Madadaki C, Rabuel C, Schourando P, Payen D.

Differential micro-oxygenation dysfunction in haemorrhagic and septic shock patients

Heyer L, Madadaki C, Rezlan E, Welschbillig S, Matco J, Payen D.

Effects of activated protein C on the microvascular response to reactive hyperemia in patients with septic shock

Sales, Jr JA, Büchele GL, Ospina GA, Creteur J, Vincent JL.

NIRS Assessment of microcirculation in septic and polytraumatized patients

Borrat X, Sanchez-Etayo G, Mercadal J, Tercero F, De la Riba N, Israel T, Adalia R, Zabala E.

Non-invasive assessment of the microcirculation in ICU patients

Nanas S, Renieris P, Gerovasili V, Poriazi M, Kritikos K, Aggelopoulos E, Kolias S, Zervakis D, Routsi C, Roussos C.

Changes in the microcirculation during human endotoxemia measured with Near Infra Red Spectroscopy

Pickkers P, Gotink K, Draisma A, van der Hoeven H.

StO_2 Research Publications

Tissue Oxygen Saturation Predicts the Development of Organ Dysfunction During Traumatic Shock Resuscitation

Cohn SM, Nathens AB, Moore FA, Rhee P, Puyana JC, Moore EE, Beilman GJ.
J Trauma. Jan 2007 Vol 62(1), pp44–53.

Near-infrared spectroscopy (NIRS) can continuously and noninvasively monitor tissue oxygen saturation (StO_2) in muscle and was used on high risk torso trauma patients to predict outcome. Conclusions included StO_2 performed similarly to base deficit in identifying poor perfusion and predicting the development of MODS or death after severe torso trauma.

Continuous Muscle Tissue Oxygenation in Critically Injured Patients: A Prospective Observational Study

Ikossi DG, Knudson MM, Morabito DJ, Cohen MJ, Wan JJ, Khaw L, Steward CJ, Hemphill C, Manley GT.
J Trauma. Oct 2006 Vol 61(4), pp780–790.

Critically injured patients may remain in a state of occult under-resuscitation that sets the stage for sepsis and organ failure, and an accurate measure of resuscitation after injury remains elusive despite normalization of vital signs. Two continuous measures of peripheral tissue oxygenation were evaluated to detect hypoperfusion: 1) the Licox polarographic tissue oxygen monitor (PmO_2 and the **InSpectra** near-infrared spectrometer (StO_2). Initial low values for either PmO_2 or StO_2 were associated with post-injury complications.

Tissue oxygen saturation, measured by near-infrared spectroscopy, and its relationship to surgical-site infections

Ives CL, Harrison DK, Stansby GS.
Br J Surg. Oct 20 2006; Vol 94(1), pp87-91.

Tissue oxygen tension has been shown to predict surgical-site infections (SSIs), common after major abdominal and groin bypass surgery. This study assessed if the noninvasive measurement of tissue oxygen saturation was as accurate. Findings included there is a difference in postoperative surgical-site oxygen saturation between patients who subsequently develop SSIs and those who do not, and prediction of SSIs provides opportunities for intervention and prevention.

Tissue-oxygenation assessment using near-infrared spectroscopy during severe sepsis: confounding effects of tissue edema on StO_2 values

Poeze M.
Intensive Care Med. 2006 May Vol 32(5) pp788–789.

Occult hemodynamic abnormalities, in critically ill septic patients, that cannot be detected using standard monitoring techniques may be detected by the measurement of tissue oxygen saturation (StO_2). This study evaluated if the

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degree of edema in these patients was a confounding factor to this measurement. While it was found that the degree of edema and tissue thickness in patients with septic shock are confounding factors during the measurement of muscle in StO_2 using NIRS, the thenar muscle showed the lowest variance. Whether the high variability in StO_2 is more related to the level of edema than to the intrinsic heterogeneity of tissue oxygenation during sepsis remains to be determined.

A single bolus of 3% hypertonic saline with 6% dextran provides optimal initial resuscitation after uncontrolled hemorrhagic shock

Watters JM, Tieu BH, Differding JA, Muller PJ, and Schreiber MA.
J Trauma. Jul 2006 Vol 61(1), pp75–81.

This study examined effects of a single bolus of hypertonic saline (HTS) with or without (+/–) dextran (D) after uncontrolled hemorrhage (UH) to determine optimal fluid composition for early resuscitation of hemorrhagic shock to restore perfusion without increasing blood loss, hypothermia, acidosis, or coagulopathy. Conclusions included a single bolus of 3% D after uncontrolled hemorrhagic shock produces an adequate and sustained rise in MAP and StO_2 and attenuates hypercoagulability. Resuscitation with 7.5% +/– D produces significantly increased urine output accompanied by a decline in MAP and StO_2 over time. A single bolus of 7.5% D results in significant dilutional anemia and relative hypofibrinogenemia.

Look for us at these US and International Meetings

7th World Congress on Trauma, Shock, Inflammation and Sepsis
March 13–17, 2007
Munich, Germany

Society of Trauma Nurses 2007 Annual Meeting
March 24–25, 2007
Caesar's Palace
Las Vegas, NV

Trauma, Critical Care & Acute Care Surgery 2007
March 26–28, 2007
Caesar's Palace
Las Vegas, NV

ISICEM International Symposium on Intensive Care and Emergency Medicine
March 27–30, 2007
Brussels, Belgium

European Association for Trauma and Emergency Surgery EATES and European Trauma Society ETS
May 23–26, 2007
Graz, Austria

Urgences 2007
May 30 – June 1, 2007
Paris, France

Euroanaesthesia
June 9–11, 2007
Munich, Germany

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