StO_2 Sensor

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

Issue 1– March 2005

Welcome to the first issue of *StO_2 Sensor*, a newsletter for the Trauma and Critical Care communities in the United States and Europe. Hutchinson Technology's BioMeasurement Division is very pleased to bring you this newsletter and the forum it provides.

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In this issue

Trends in the Practice of Trauma Surgery: An Interview with Dr. Anthony Meyer

Dr. Anthony Meyer, MD PhD, shares his insights about the ways in which trauma surgery may evolve over the next ten years. Dr. Meyer is Professor and Chairman of the Department of Surgery at the University of North Carolina, Chapel Hill, and a member of the BioMeasurement Division's Trauma and Critical Care Advisory Board.

Dr. Meyer, how has trauma surgery evolved over the last twenty years and what changes are taking place now?

Trauma care has become less operative because of advances in diagnostic procedures and non-operative management of specific injuries. Now, for every dozen trauma patients I see, only one may need surgery. There has also been a significant decrease in violent crime in the U.S., so that has further reduced the need for trauma surgery.

Currently, there is a transition from trauma surgery to a combination of trauma surgery, critical care, and emergent general surgery. Eventually, trauma surgery might include some procedures that are now performed by neurosurgeons or orthopedic surgeons, such as ICP catheter placement, and irrigation and closure of open fractures.

Dr. Anthony Meyer

In the future, where will trauma surgery be provided?

I believe it will be performed in two different environments. Large Level I trauma centers would continue to be important. They would do high volumes of trauma surgery and be the places most innovations are developed. They will handle many of the most complex cases sent from smaller hospitals.

The majority of all surgical care, including trauma surgery, would be done in hospitals that might serve communities of 10,000 people. In those settings, you would not need six surgeons with the different subspecialties. A small hospital might have two surgeons who could handle common cases and do trauma surgery and emergency surgery.

How might medical education change to meet these needs?

A variety of changes in education and certification are being considered right now. For instance, a new curriculum may use a total of six years, rather than five years, post-medical school. The first three years might involve training residents in core surgery. The next three years might involve less general abdominal or cancer surgery but include three years of trauma and acute care surgery, as well as orthopedic or neurosurgery. You might

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Dr. Anthony Meyer Interview cont.

also pick up a certificate in surgical critical care. Five years from now, the situation may not be terribly dissimilar from today. However, in ten to fifteen years, when all the faculty are trained in the basics of emergent, orthopedic, and neurosurgery, some of those topics may be taught in larger trauma centers.

"The patient needs a special kind of trust in the surgeon. . ."

The situation is challenging. Information is evolving so quickly, it is hard to be totally skilled in everything. In many areas, there will be subspecialties. Nevertheless, there will still be a large role for comprehensive general surgeons. Overall, changes of this type would provide earlier specialization. It would take less time to develop a high level of expertise, but it would be in a narrower area.

What about staffing needs, Dr. Meyer?

Because of sub-specialization, only trauma and acute care surgeons (or maybe comprehensive general surgeons) may be qualified to do trauma surgery. In a large Level I trauma center, where you must have a surgeon on call seven nights a week, you may need a minimum of five to ten trauma surgeons in the department to handle night call and daily patient follow up. This creates a need for more surgeons at a time when the number of medical students choosing to specialize in trauma is declining. In past years, there have been up to 40 percent more applicants than surgical residency positions. Now, about 7 percent of positions in the U.S. are unfilled. There are several reasons for this including reduced reimbursement and the increased risk of malpractice lawsuits. However, the principal reason is the desire among medical students for a more balanced lifestyle with fewer on-call hours and irregular schedules. Imagine you are a surgeon with a family at home and, when you are on call, you have to be within 20 minutes of the hospital at all times. Or maybe you have to spend a full weekend at the hospital. Once your night call has ended, you still have to work the next day. The thrill wears off quickly. But unless more surgeons are trained, less trauma care may be available in the future and there could be fewer Level I trauma centers.

Would using a work shift system be better?

No, I believe the quality of care would suffer significantly. Here are a few negative scenarios that shift work might cause: Imagine you are a patient and Dr. X is supposed to take out your colon cancer. When the day of your surgery comes, you are told that Dr. X was on call during the previous shift and cannot do your surgery. Or, what if Dr. X does your surgery, then you do not see him or her until six days have gone by. What if you get sick, have complications, or want explanations? What if someone you have never talked with before comes to tell you about the extent of your cancer? Imagine a patient saying, "Well, it is 8 am on Wednesday so my doctor must be so and so." I do not think patients or family members are going to like any of those situations.

The patient needs a special kind of trust in the surgeon, especially if that patient is going to trust that surgeon

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Dr. Anthony Meyer Interview cont.

to do an invasive procedure on them. That type of trust is vastly different from the trust that the patient develops with an internist the patient might see once or twice a year. It is also a totally different level of trust than the one a patient needs to take pills or follow dietary advice. I believe patients want to hold onto those special relationships and surgeons do too.

Dr. Meyer, as the medical community develops new solutions for training surgeons and providing trauma care, what advice would you have?

I think we need to develop solutions that focus on our principal goal, which must be the best possible patient care, both in the quality of care and patient satisfaction. I think you will find physicians and people who want to be physicians are attracted to that philosophy.

In our next issue, we will explore the trauma surgery model in Finland.

Welcome to *StO_2 Sensor*

Welcome to the first issue of *StO_2 Sensor*, a newsletter for the Trauma and Critical Care communities in the United States and Europe. Hutchinson Technology's BioMeasurement Division is very pleased to bring you this newsletter and the forum it provides.

Our corporate headquarters are in Hutchinson, Minnesota.

As a global leader in the development and manufacture of suspension assemblies for hard disk drives, Hutchinson Technology Inc. (HTI) has significant engineering expertise in electronics, optical metrology (including near infrared spectroscopy), and precision manufacturing. The mission of HTI's BioMeasurement Division, founded in 1996, is to fully understand our customer's requirements, and combine this understanding with our technologies to provide products and services that improve the quality of healthcare. In addition to our team of internal experts, we are fortunate to have valuable guidance from the highly respected physicians on our Trauma and Critical Care Advisory Board. We are dedicated to building long term relationships and creating new solutions in trauma and critical care. Currently, our focus is on noninvasively monitoring tissue oxygen saturation (StO_2) using near infrared technology. The **InSpectra™** Tissue Spectrometer will provide this new metric. Long term, our plans include exploring the use of other technologies to complement our near infrared platform.

In future issues, *StO_2 Sensor* will address contemporary topics and keep you informed of our research and development. We welcome your comments and look forward to working with you.

Chris Temperante
President, BioMeasurement Division

StO_2 Science

Near Infrared Spectroscopy (NIRS)
The diagnostic potential of optical methods has been widely known since Jöbsis first demonstrated that transmittance measurements of near infrared (NIR) radiation could be used to monitor the degree of oxygenation of certain metabolites.[1] This led to the development and increasingly widespread use of clinical near infrared spectroscopy for a safe, noninvasive means of monitoring tissue oxygen saturation.

[1]Jöbsis FF. *Science*. 1977;198: 1264-1267.

How the InSpectra™ Tissue Spectrometer Functions
The **InSpectra™** Tissue Spectrometer functions as a tissue oxygen saturation monitor by sending near infrared light into tissues such as skin, bone, and muscle where it is absorbed by chromophores (hemoglobin and myoglobin) that have absorption wavelengths in the near infrared region (approx. 700–1000 nm). These chromophores vary in their absorbance of NIR light, depending on changes in oxygenation.

The measurement of hemoglobin oxidation values in tissue is based on spectrophotometric principles that relate light absorption to chemical concentration.

When light enters tissues (reference intensity), it can either be scattered or absorbed. A portion of the light that is not absorbed is returned (sample intensity) as an optical signal and analyzed. The sample intensity is approximately 100 million times less than the reference intensity. A large difference between sample and reference intensity signifies a higher absorbance of light, while a small difference signifies a lesser absorbance. Large absorbance values are associated with high tissue hemoglobin concentration and low hemoglobin oxygen saturation. The absorption spectra of oxygenated and deoxygenated hemoglobin are well characterized and provide a means to calculate the ratio of oxygenated hemoglobin to total hemoglobin expressed as percent hemoglobin saturation, StO_2.

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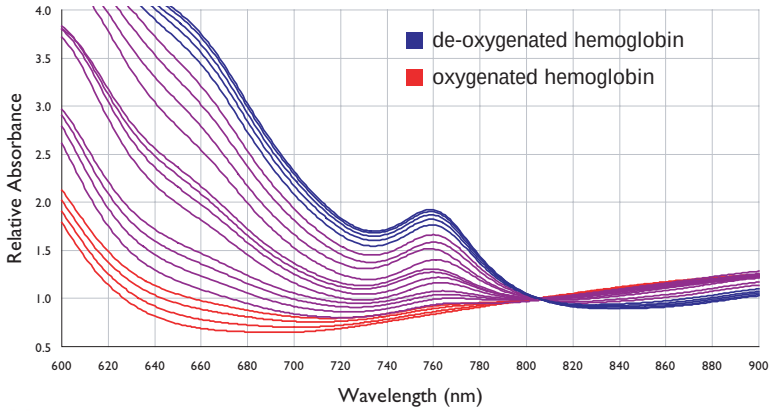
What is StO_2?

StO_2 is the ratio of oxygenated hemoglobin to total hemoglobin in the microcirculation of peripheral skeletal muscle.

Hemoglobin Absorbance Spectra



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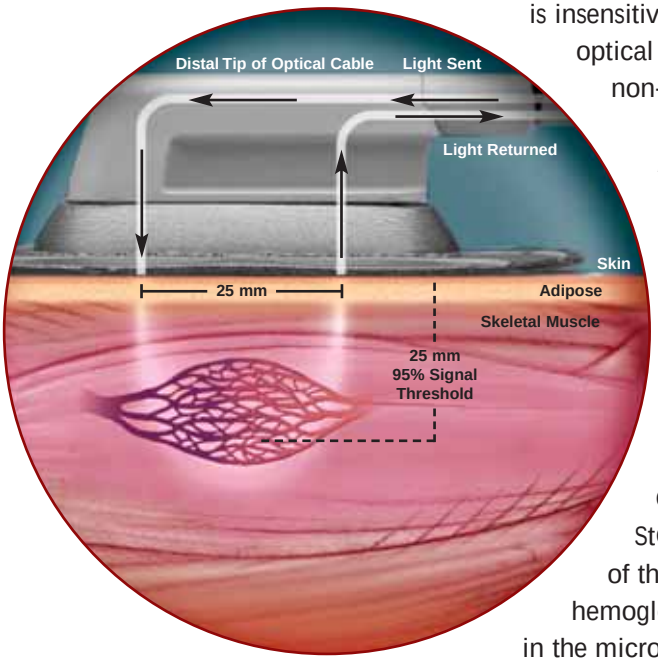

The **InSpectra™** Tissue Spectrometer measures tissue absorbance values at 680, 720, 760 and 800 nm, and transforms these values using a scaled second derivative algorithm to provide a tissue spectral measurement that is insensitive to total hemoglobin, optical path length changes, and non-homogeneous tissue.

In our next issue, we will continue discussing the scaled second derivative algorithm and its advantages for measuring tissue oxygen saturation.

StO_2: Tissue Oxygen Saturation

StO_2 is the quantification of the ratio of oxygenated hemoglobin to total hemoglobin in the microcirculation of skeletal muscle, and is an absolute number. Near infrared spectroscopy uses specific, calibrated wavelengths of near infrared light to noninvasively illuminate the tissue below the skin. These wavelengths of light scatter in the tissue and are absorbed differently dependent on the amount of oxygen attached to hemoglobin in the arterioles, venules, and capillaries. The depth of tissue measured is directly related to the distance between the illumination fibers and detection fibers: studies have shown that with 25mm optical probe spacing, approximately 95% of the detected optical signal is from a depth of 0–23mm.

StO_2 and Other Measures of Oxygenation

Previously, there were two basic kinds of oxygenation measurements—hemoglobin oxygen saturation in the blood (SO_2, SaO_2, SpO_2) and partial pressure of oxygen in the skin ($TcPO_2$).

How StO_2 Differs from SpO_2

StO_2 measures the oxygen saturation of local muscle tissue and does not require a pulsatile flow. StO_2 will change as the conditions of supply and consumption change in the muscle tissue being measured. SpO_2 provided by pulse oximetry measures the systemic oxygen saturation of arterial blood prior to delivery to the microcirculation where oxygen is exchanged with the cells, and requires a pulsatile flow. This is a systemic measure and is fairly constant regardless of whether the measurement site is the earlobe, finger, or big toe.

How StO_2 Differs from $TcPO_2$

NIRS can be used to measure StO_2 at various depths of tissue—skin, subcutaneous tissue, and muscle. Transcutaneous PO_2 measures the partial pressure of oxygen in the skin only.

For more information on StO_2, visit our website at www.htibiomeasurement.com

StO_2 Research Presentations

Use of Near-Infrared Spectroscopy in Early Determination of Irreversible Hemorrhagic Shock

Taylor J, MD (presenter), Beilman G, MD. University of Minnesota.

Animal study; pig model; *n*=12; StO_2 monitoring of the leg and stomach identified unresuscitatable animals after the initial resuscitative bolus; *p* value: leg–0.002; stomach–0.019; r^2 combined model–0.875.

Presented at American Association for the Surgery of Trauma 2004

Studies Describing and Validating the Reliability, Sensitivity, and Robustness of Hutchinson Technology Inc. Spectrometry for Tissue Oxygen Assessment

Myers D (presenter), Hutchinson Technology Inc. Cooper C, PhD, University of Essex, UK. Beilman G, MD, et al. University of Minnesota.

The proprietary, ratioed 2nd derivative technology for tissue oxygen assessment is a simple solution to the problems encountered when using formulas based on homogeneous tissue assumptions or complicated measurement techniques to assess light scattering and absorption. The technology allows accurate measurement using varying probe spacing and depth of measurement.

Presented at International Society of Oxygen Transport to Tissue 2004

The **InSpectra™** Tissue Spectrometer System measures tissue oxygenation (StO_2) directly in muscle tissue at various depths using a contact probe that rests on or adheres to the skin.

Prediction of Surgical Site Infections using Spectrophotometry: Preliminary Results

Ives T, MD (presenter), Harrison D, MD. University Hospital of North Durham, UK.

At 12 hrs, StO_2 in the abdominal surgery post-op group that developed surgical wound infections within 30 days (n=7) was significantly lower than the StO_2 in the group that did not develop post-surgical infections (n=10).

Presented at International Society of Oxygen Transport to Tissue 2004

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StO_2 Research Presentations cont.

Microvascular Response to Reactive Hyperemia is Altered in Septic Patients

Carollo T (presenter), Creuteur J, DeBacker D, Vincent JL. Erasme Hospital, Bruxelles, Belgium.

The upward slope of thenar eminence StO_2 recovery following arterial occlusion in septic patients (n=51) was not as steep as the slope of recovery in ICU patients without sepsis (n=10) or healthy volunteers (n=18).

Presented at European Society of Intensive Care Medicine 2004

Persistent Altered Microvascular Reactivity is Predictive of Mortality in Septic Patients

Carollo T (presenter), Creuteur J, DeBacker D, Vincent JL. Erasme Hospital, Bruxelles, Belgium.

On day 1 and day 2 after sepsis/septic shock diagnosis, the upward slope of StO_2 in the thenar eminence following arterial occlusion was significantly steeper in survivors (n=21) than in the non-survivor group (n=16). An improvement in recovery during the first few days of admission is associated with a better outcome in this study.

Presented at European Society of Intensive Care Medicine 2004

Improvement of Muscle Tissue Deoxygenation During Stagnant Ischemia in Survivors of Severe Sepsis

Pareznick R (presenter), Voga G, Knezevic R, Podbregar M. Department of Intensive Medicine, General Hospital, Celje, Slovenia.

The downward slope of thenar eminence muscle deoxygenation following arterial occlusion was statistically steeper in healthy volunteers (n=17) than it was in patients experiencing severe sepsis (n=8) or septic shock (n=6). As the septic patients improved, the slope steepened, but post-occlusion recovery was still slower than healthy controls.

Presented at European Society of Intensive Care Medicine 2004

Note: The **InSpectra™** Tissue Spectrometer has not been cleared by the FDA for diagnosing, assessing, or predicting hemorrhagic shock, sepsis, or surgical site infections. In addition, the device has not been cleared by the FDA for use on the abdomen. The study results are currently being reviewed for publication and may have limitations. Additional clinical studies are required to establish the value of these measurements in assessing patient status related to any of these conditions.

Hutchinson Technology Incorporated's **InSpectra™** Tissue Spectrometer System, Model 325, is a noninvasive monitoring system that measures an approximated value of percent hemoglobin oxygen saturation (StO_2). The **InSpectra™** Tissue Spectrometer 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 **InSpectra™** Tissue Spectrometer is intended to noninvasively and continuously measure hemoglobin oxygen saturation: in the upper extremity, shoulder, or lower extremity.

Hutchinson Technology Inc. Announces Multi-Site, Prospective Trial on Hemorrhagic Shock Monitoring

At the Directors Forum held during AAST 2004, BioMeasurement Division President Chris Temperante announced that HTI has initiated a multi-site, prospective clinical trial to determine the role that tissue oxygen saturation (StO_2) monitoring can play in trauma resuscitation.

The objectives of the study are:

1. *to determine the ability of StO_2 to predict the development of MODS, and*
2. *to determine if a predictive relationship exists between StO_2 and mortality, red blood cell transfusion, coagulopathy, BD, ventilator-free days, ICU days, and/or LOS.*

With this inaugural issue of *StO_2 Sensor*, HTI releases the names of the investigators and sites participating in the trial. They are:

- **E. Moore** — **Denver Health, Denver, Colorado**
- **G. Beilman** — **North Memorial Medical Center, Robbinsdale, Minnesota**
- **S. Cohn** — **University of Texas Health Science Center, San Antonio, Texas**
- **F. Moore** — **Memorial Hermann, Houston, Texas**
- **A. Nathens** — **Harborview Medical Center, Seattle, Washington**
- **P. Rhee** — **Los Angeles County Hospital and USC Medical Center, Los Angeles, California**
- **A. Peitzman** — **University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania**

According to Temperante, "the logistics, careful statistical design, and expense of this study demonstrate our commitment to ensure that the products we bring to the resuscitation market offer proven clinical utility." The enrollment goal of the study is a minimum of 200 patients during 2005.

Preview of next issue

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- Trauma and Critical Care Advisory Board

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