StO_2 Sensor

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

Issue 3 – May 2006

Welcome to the third 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.

In this issue

StO_2 Clinical Usage in Iraq
An Interview with Dr. Greg Beilman

Dr. Greg Beilman, Director of Surgical Critical Care at the University of Minnesota and a trauma surgeon at North Memorial Hospital in Minneapolis, has long been interested in the potential utility of the tissue hemoglobin oxygen saturation (StO_2) measurement in trauma care. He first conducted research involving StO_2 measurements, derived from a Hutchinson Technology near infrared spectroscopy (NIRS) device, in 1994. In that study[1], a splenectomized porcine model of hemorrhagic shock, hind limb measurements of StO_2, and oxygen delivery measurements taken from pulmonary arterial catheterization showed a linear relationship with a high degree of correlation. Subsequent animal studies[2] further heightened his interest in clinical applications for tissue spectroscopy. In 2003, Dr. Beilman accepted an invitation from Hutchinson Technology to join our Trauma Advisory Board, a group of highly recognized trauma and critical care physicians who help guide our efforts in developing technology for clinical applications.

Dr. Greg Beilman in Iraq

Dr. Beilman is also a Colonel in the U.S. Army Reserve, and served in Kosovo in 2000. In June, 2005, he was called to duty in Iraq to serve as the sole general surgeon in a combat support hospital near Tikrit. Before he left, he asked Hutchinson Technology to lend him an **InSpectra™** Tissue Spectrometer, Model 325 to bring along, and we eagerly complied. Though it has FDA and CE clearance, the 325 was designed primarily for research use and has a limited clinical track record. We anticipated learning much from Dr. Beilman's experiences and were not disappointed.

During his 93 days close to front-line combat in Iraq, Dr. Beilman treated nearly 300 patients of many nationalities and widely diverse levels of injury or illness. He used the **InSpectra™** Tissue Spectrometer, Model 325 during treatment of about 10 percent of these patients. We asked him about his experiences.

continued >

Why did you bring an InSpectra™ Tissue Spectrometer to Iraq?

With the animal work I have done with the device in a hemorrhagic shock model, I felt pretty strongly that we were going to see the same type of changes in a patient that we saw in these studies. As a trauma surgeon who has had the opportunity to serve overseas, I felt this situation could provide the opportunity to assess quickly if the device is going to provide useful information in this setting.

Did the device fulfill your expectations?

When I evaluate a device, I am exploring whether it gives me information that correlates with a clinical condition of the patient and if I can use that information to make treatment decisions. Also, does it track with the appropriate treatment? I would say in my small experience — and I have to stress small experience — this device tracked the physiologic status of the patient very well during resuscitation. StO_2 dropped when they were sick and returned towards normal with interventions.

"One potential use would be as a screening tool to help sort out people who are in shock in the field or in smaller hospitals, or for people who present initially in the emergency room."

How many patients did you monitor with the device?

About a dozen. There were about 30 more with a normal StO_2. We did not feel we needed to use it to further evaluate these patients.

How did you decide which patients to monitor with the device?

Typically, in that setting patients did not come in one by one but three or four at a time. We had the device positioned in the bay that was going to receive the patients we felt would be the sickest. Once the nurses and I worked together to train everybody on it, we just put it on the patients that showed up in that trauma bay. The patients I was most interested in monitoring were the ones that came in with an obvious physiologic abnormality, so I could correlate the abnormality with the StO_2 measurement.

What were your working conditions, and did they affect the performance of the device?

It was a modified field setting. We worked in climate-controlled buildings, air conditioned and some plumbing, that the army had taken over. They tried to seal the buildings from the dusty environment; however, I say tried, because nothing really seals out the dust. The device functioned pretty well for the three months. I simply had to clean the air filters on the back of the monitor every couple of weeks to remove the dust.

Did you measure StO_2 on the thenar?

Yes, when it was not covered in blood or the patient had not lost his arms. If we could not measure thenar StO_2, we measured on the deltoid or anterior thigh. My impression is that the deltoid or anterior thigh probably runs a little lower in terms of average StO_2, and I think this has been shown in internal studies. I was also fortunate that most patients were skinny and physiologically healthy before their injury.

Could you provide us an example of the device in use?

A 19-year-old young man, caught in the middle of an altercation between coalition forces and Iraqi insurgents, was shot in the left hip. He came in severely hypotensive, and with a distended abdomen. Initial evaluation showed his systolic blood pressure was in the 60s, his heart rate was 150. The **InSpectra** device read 52 [87 ± 6% is considered normal[3]]. Resuscitation

continued >

with lactated ringers brought his heart rate down and blood pressure up. The StO_2 tracked that as well and went up. We took him to the operating room to remove an injured segment of small bowel and debrided some tissue, and closed his abdomen.

In the ICU, his physiological parameters were normal at that point, and his StO_2 was in the low 80s. Over the next two hours, he became hypotensive. His StO_2 dropped into the low 60s, his heart rate went up to about 120 or 130, and his systolic blood pressure was in the high 80s or low 90s. I aggressively resuscitated him. He was mildly coagulopathic and anemic. So we administered two units of FFP, a unit of packed cells, and two liters of lactated ringers. This produced a good result, both in terms of his blood pressure and heart rate. His StO_2 went back up into the low 80s.

Over the next six hours, he developed progressive signs of an abdominal compartment syndrome with mildly lower blood pressure, mildly increased heart rate but increased peak airway pressures and oliguria. With that, his StO_2 dropped into the low 60s again. We took him back to the operating room, opened up his abdomen, packed him open and after that physiologic change, his pressures normalized, his physiologic parameters normalized, as did his StO_2, which came up into the low 90s.

This is a good example of how the device works. One issue, however, is whether this device can serve as a "canary" for somebody in shock that is subtle enough physiologically that we are not seeing it on our clinical exam. I cannot answer that question at this point with my small experience. But it certainly seems to be another parameter that could be used to look at patients who have acute hemorrhagic shock and track response to interventions during resuscitation.

Do you believe the device could prove useful in other clinical settings?

I believe it has potential uses, and I stress potential, because we really do not have any strong clinical evidence in people yet. One potential use would be as a screening tool to help sort out people who are in shock in the field or in smaller hospitals, or for people who present initially in the emergency room. For example, someone who comes in with an injury or who potentially has a bad infection. If StO_2 is normal, you would at least know that the oxygen delivered to the tissues is in a reasonable range which allows you some time to sort out what is going on and take care of some things. If it is abnormal, it may be prudent to consider an aggressive resuscitation protocol.

Do you plan to incorporate tissue spectroscopy into your clinical practice?

I hope to integrate it into our ER practice at North Memorial in the initial evaluation of trauma patients. I would also like to further study how it might be integrated into a hospital practice.

What modifications would you recommend for the InSpectra™ 325 device to make it more clinically useful?

I suggest an internal battery so we can unplug the device and make it portable without having to go through a new warm-up period. Also, make it small enough to flop on the bottom of the bed as you move the patient around, and finally, develop a patient interface that adheres to the skin more effectively.

Putting StO_2 aside for the moment, what were some of the other lessons learned from your experiences in Iraq?

One clear lesson was that armor saves lives. I want to say that over and over again. Body armor and the armoring of trucks saved significant numbers of lives in this conflict compared to what we have seen in other conflicts.

Tourniquets for battle field injuries save lives as well. That was something I was told in residency that we should never use. In my humble experience, however, tourniquets kept people alive long enough to make it to definitive care. Properly applied tourniquets with a reasonable transport time, less than a couple of hours, result in soldiers who make it to the hospital alive rather than dead.

1 Beilman GJ, Groehler KE, Lazaron V, Ortner JP. Near infrared spectroscopy measurement of regional tissue oxyhemoglobin saturation during hemorrhagic shock. *Shock*. 1999;12:196-200.

2 Beilman GJ, Myers D, Cerra FB, et al. Near-infrared and nuclear magnetic resonance spectroscopic assessment of tissue energetics in an isolated, perfused canine hind limb model of dysoxia. *Shock*. 2001;15:392-397.

3 Crookes BA, et al. Can Near-Infrared Spectroscopy Identify the Severity of Shock in Trauma Patients? *Journal of Trauma*, 2005. 58(4):806-816.

Exploring StO_2 in Hemorrhagic Shock
An Interview with Dr. Jacques Duranteau

*Jacques Duranteau, MD, PhD, is professor in anesthesiology and intensive care at the Bicêtre Hospital at the University of Paris. Since graduating from medical school in 1986, he has published dozens of peer-reviewed articles on assessment of volume status, ischemia reperfusion, oxidative stress in critically ill patients, assessment of tissue oxygenation in critically ill patients, and microcirculation in shock. Given these interests, it makes sense that he would want to explore the utility of the StO_2 measurement in trauma care. Last October, he began research using Hutchinson Technology's **InSpectra**™ Tissue Spectrometer, Model 325. We asked him to update us on his research.*

What is the purpose of your research involving the InSpectra™ Tissue Spectrometer, Model 325?

We want to test whether the device could be useful for patients in hemorrhagic shock as it is not easy during the initial phase of hemorrhagic shock to monitor these patients. Usually, we have mean arterial pressure (MAP) and heart rate to conduct our resuscitation. I think that StO_2, which is an oxygenation parameter, could be useful for adjusting resuscitation, adjusting fluid expansion, hemoglobin concentration, or in the use of catecholamine.

It is very important to have simple monitoring because hemorrhagic shock is a very unstable situation. The monitoring has to be accurate and continuous, since it is important to get a very quick idea of the evolution of hemorrhagic shock. The monitor has to be easy to use and easy to interpret. I think this device could be great for tissue oxygen saturation because it does indeed seem very easy to use and reliable. Again, I want to test this. It also makes sense to me to monitor on the thenar because this area should be one of the first areas in the body to sacrifice circulation during hemorrhagic shock. If you can correct this value, maybe you correct all the other oxygenation values in the body as well.

Are you using other oxygenation parameters now?

Yes, we use venous saturation from a central or femoral catheter. These are continuous readings now, with a monitor, but the problem of course is access. Or you can also test discontinuously with a blood gas analyzer. What is great with StO_2 is that you can quickly get a value noninvasively. In our research, we are comparing venous saturation values by femoral catheter with tissue oxygen saturation. We are looking at any possible correlation of venous saturation with the StO_2.

Can you describe the trial?

We want to capture patients in hemorrhagic shock. We perform the monitoring as quickly as possible when the patients arrive in the hospital. It is very important to get the StO_2 value quickly, during the hemorrhagic shock, when the patient has a very low arterial pressure. This is the time when it would be important to have tissue saturation as an index of oxygenation. The idea is also to see the evolution of this parameter during

continued >

resuscitation and if there is parallel recovery of mean arterial pressure.

It is too early to tell if the correlation is good or not. The research will be concluded in about six months.

How might the device be used in the hospital?

If it proves useful, it could be used in the hospital phase, not only in hemorrhagic shock but also possibly during septic shock as an additional monitor for the physician. I think that during hemorrhagic shock it is a plus because it is very difficult to quickly get sophisticated monitoring. It might also prove useful in the pre-hospital phase.

> "It is very important to get the StO2 value quickly, during the hemorrhagic shock, when the patient has a very low arterial pressure. This is the time when it would be important to have tissue saturation as an index of oxygenation."

Having worked in both the U.S. and France, could you describe the differences between their emergency medical systems?

The main difference is that in the U.S. you have only paramedics at the accident scene, while in France each unit has a physician and nurse as well as a driver. This unit makes the triage after the examination of the patient. We call it the S.A.M.U (Services D'aide Medicale Urgente). In France, the dispatching physicians of the S.A.M.U. direct patients to the appropriate facility according to the results of the on-scene assessment. Thus, many patients bypass emergency departments. The S.A.M.U. handles all pre-hospital triage of patients. Anyone can reach it through a dedicated phone number. There are 95 S.A.M.U. regions in France, each with one or two main hospitals able to take in trauma patients. There are five in Paris.

Please contrast the role of the anesthesiologist in France with the trauma surgeon in the U.S.

In France, the anesthesiologists are present in the operating room, as they are in the U.S. They are also in charge of surgical intensive care. Some are also in charge of the S.A.M.U. system. Therefore, they are deeply involved in intensive care as well as pre-hospital care. It is a big difference in comparison to the U.S. In France, there is an orthopedic surgeon, general surgeon, and specialty surgeon, but no trauma surgeon as you have in the U.S. The anesthesiologist assesses the patient, and takes charge of the patient during resuscitation, scanning, and hospitalization—everything up to the operating room, where the surgeon takes charge.

What changes are taking place in the way France conducts emergency medicine?

Over the last few years, we have seen the development of dedicated trauma centers. This is a clear trend.

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

StO_2 Science
Why Thenar for StO_2 Measurement?

Near-infrared spectroscopy (NIRS) offers an accurate and noninvasive monitoring method for quantifying the percent of oxygen saturation (%StO_2), in localized tissue.[1-2]

This is a fluctuating measurement that changes as the conditions of supply and demand change in the muscle tissue being measured.

Hutchinson Technology's monograph on "Why Thenar" provides rationale and validation of the thenar eminence for StO_2 measurement. The following is a synopsis of the monograph.

Measurement of tissue saturated oxygen is different from other kinds of oxygenation measurements.

Tissue oxygen saturation (StO_2) is the quantification of the ratio of oxygenated hemoglobin to total hemoglobin (oxy and deoxy-hemoglobin) in the microcirculation of skeletal muscle, and as such represents the available oxygen in the capillaries of the muscle tissue being measured, i.e., a tissue-specific measurement of oxygenation.[3] Other methods such as pulmonary artery catheterization focus on the systemic oxygen saturation of arterial blood supply.

The advantages of choosing the thenar eminence site for the measurement of StO_2 are several.

The muscle of the thenar is readily identifiable, accessible and the thickness of the underlying tissue is relatively consistent from person to person regardless of the size of the individuals.[4]

Thorén[5] has suggested that the forearm during shock, when there are significant reductions in blood flow, serves as an indicator of circulatory conditions of the whole skeletal muscle vascular bed. Therefore, the thenar may serve as an ideal site for measurement of tissue oxygen saturation.

A normal range for StO_2 has been reported to be 87% in two independent clinical studies.

Crookes et al[4] reported the value for StO_2 in the thenar muscle of normal healthy individuals to be 87 ± 6%. This range of StO_2 was determined while studying the relationship between shock state and StO_2 in trauma patients. By comparison, the mean StO_2 thenar value for trauma patients was 83 ± 10% (no shock) and 45 ± 26% (severe shock).

Likewise, Skarda et al[6-7] reported the mean thenar value to be 87.4% for healthy volunteers, while studying the correlation of thenar systemic oxygen delivery and oxygen consumption in patients with severe sepsis. Thenar values were measured by NIRS (combined with arterial and venous occlusion cuffing) and invasive hemodynamic techniques.

No significant differences have been reported for thenar blood flow index between males and females.

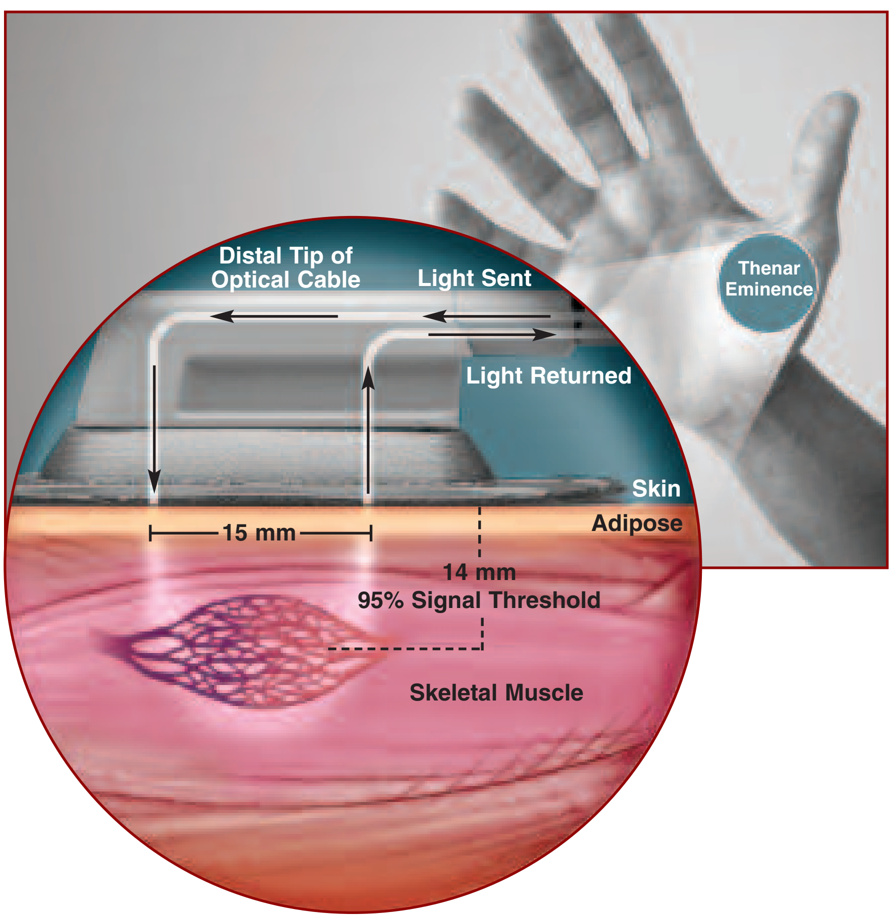
An HTI Internal Study (2003)[8] quantified a thenar blood flow index (BFI) for males and females of the dominant hand in supine and elevated positions (n = 23, 13m/13f). No significant differences were found.

continued >

StO_2 measurement at the thenar site has also been shown to be minimally affected by differences in local factors such as position.

In an HTI clinical study (California, 2005)[9] where the hand was placed in five different positions, three regions of the hand were evaluated: the thenar eminence, the abductor digiti minimi, and the first dorsal interosseous. The control StO_2 value was significantly different than all values after a position change of the abductor digiti minimi, but the thenar control value was not significantly different from the values at each positional change.

The StO_2 control value of the first dorsal interosseous was not significantly different in most positions, except when the arm was straight down. What this means is simply that the thenar has shown consistent values no matter the position, therefore supporting an enhanced confidence in use of the thenar site, regardless of the hand position.



StO_2 measurements show less variation when adipose, or soft, tissue depth is no greater than 6.0mm.

An HTI clinical study (Scotland, 2002)[10] reported the relationship between soft tissue oxygenation, measured by NIRS, and body mass index (BMI) as a measure of soft tissue depth. The results indicated there was almost no correlation of StO_2 to BMI ($n = 100$) ($r^2 = 0.14$). However an important secondary finding was that the analysis of covariance indicated StO_2 variation increased when the soft tissue depth was greater than 6.0mm. Thenar soft tissue is less than 6.0mm.

Edema and its influence on the measurement of StO_2 can be a confounding factor. Thenar however has shown minimal effect from the influence of edema.

Poeze[11] has reported that the edema thickness was smallest in the thenar muscle (median 0.19 SD 0.09) and largest in the femoral muscle (median 1.27 SD 0.57), of the five muscle sites studied: thenar, deltoid, brachial, vastus, and gastrocnemius.

Absolute StO_2 values were significantly correlated with the degree of edema ($r^2 = -0.44$, $p < 0.0001$) and with the total tissue thickness from skin to muscle ($r^2 = -0.64$, $p < 0.0001$).

An HTI Internal Study (Minnesota, 2004)[12] investigated the influence of edema on StO_2 measurement and found that the thenar muscle was

continued >

StO_2 Science cont.

minimally affected by edema, yet still had sufficient hemoglobin for accurate StO_2 measurements.

In this study, weight gain by water was used as an index of edema in patients with sepsis and measured 3 times daily for 3 days (n = 10). Data from weight gain was categorized into 3 groups: < 10% gain, 11–30% gain and > 30% gain. A comparison of the means of the 3 groups of weight gain showed no significant correlation to thenar StO_2 (95% CI, p = .149). Also the comparison of the means of the 3 groups of weight gain showed no significant correlation to the water spectral peak at 970nm (95% CI, p = .0001).

Hence – Why Thenar?

- An established normal range
- Similarities in males and females
- Less influence to position change than other areas on the hand
- Soft tissue depth less than 6.0mm
- Minimal adipose tissue influence
- Minimal edema influence

Each of the above factors as documented in clinical research validates your choice of the thenar eminence to measure local tissue oxygenation during shock.

For a copy of the complete monograph, please contact the BioMeasurement Division of Hutchinson Technology Inc.

1 Beilman GJ, Groehler KE, Lazaron V, Ortner JP. Near-infrared spectroscopy measurement of regional tissue oxyhemoglobin saturation during hemorrhagic shock. *Shock*. 1999;12:196-200.

2 Matchert SJ, Cooper CE. Absolute quantification of deoxyhaemoglobin concentration in tissue near infrared spectroscopy. *Phys Med Biol*. 1994;39:1295-1312.

3 Beilman GJ, Myers D, Cerra FB, et al. Nearinfrared and nuclear magnetic resonance spectroscopic assessment of tissue energetics in an isolated, perfused canine hind limb model of dysoxia. *Shock*. 2000;15(5):392-397.

4 Crookes BA, Cohn SM, Bloch S, et al. Can near infrared spectroscopy identify the severity of shock in trauma patients? *J Trauma*. 2005 April;58(4):806-816.

5 Thorén O. In: *Blood flow patterns of the forearm of critically ill post-traumatic patients. A plethysmographic study*. Göteborg, Sweden. Department of Surgery, University of Göteborg; 1974:5-6.

6 Skarda D, Taylor J, Mulier K, Myers D, Beilman G. Dynamic near-infrared spectroscopy measurements in patients with severe sepsis correlate with invasive hemodynamic measurements. Poster presented at: 25th International Symposium on Intensive Care and Emergency Medicine; March 21-25, 2005; Brussels, Belgium.

7 Skarda DE, Taylor JH, Mulier KE, Myers DE, Beilman GJ. Near-infrared spectroscopy in patients with severe sepsis correlates with invasive hemodynamic measurements. Abstract presented at: 2nd Joint Meeting of Surgical Infection Society (Europe and North America); May 5-7, 2005; Miami, Florida.

8 Myers D, McGraw M. Thenar eminence flow index measurement. HTI Internal Study, Minnesota; March 2003.

9 Pozos R, Hom C, Lopez J, Vasquez P. Comparison of at rest StO_2 measurements on different hand muscles within the hand. HTI Internal Study, San Diego State University, California; Jan-Feb 2005.

10 Hope M, Hajducka C, McQueen M. A determination of the relationship between soft tissue oxygenation, measured by near-infrared spectroscopy, and soft tissue composition. HTI Internal Study, The Royal Infirmary, Edinburgh, Scotland; Jan-Feb 2002.

11 Poeze M. Tissue-oxygenation assessment using near-infrared spectroscopy during severe sepsis: confounding effect of tissue edema on StO_2 values. *Intensive Care Med*. In press.

12 Skarda D, Taylor J, Mulier K, Myers D, Beilman G. Effect of weight gain and water accumulation on StO_2 measurements. HTI Internal Study, Fairview-University Medical Center, Minnesota; 2004.

StO_2 Research Publications

Reliability of Near-Infrared Spectroscopy for Determining Muscle Oxygen Saturation During Exercise

Austin KG, Daigle KA, Patterson P, Cowman J, Chelland S, Haymes EM.
Research Quarterly For Exercise And Sport. 2005; Vol 76; 440-449.

Near infrared spectroscopy is currently used to assess changes in oxygen saturation of the muscle during exercise. Changes to muscle oxygenation as a result of training, injury, nutritional status, or the environment can affect the performance of the cardiorespiratory system. The findings of this study, using a Lactate Threshold/VO_2max Protocol (running), indicate NIRS can be a reliable tool for measuring the changes in oxygen saturation of venous hemoglobin (StO_2) during exercise on a treadmill and cycle.

Changes in Muscle Tissue Oxygenation during Stagnant Ischemia in Septic Patients

Pareznik R, Knezevic R, Voga G, Podbregar M.
Intensive Care Medicine. 2006; Vol 32(1); 87-92.

A prospective observational study in the medical ICU of a general hospital revealed changes in the rate of thenar muscle tissue deoxygenation (StO_2), measured using near infrared tissue spectroscopy, during stagnant ischemia in severe sepsis and septic shock patients. StO_2 decreased slower in septic shock patients, after hemodynamic stabilization, than in patients with severe sepsis or localized infection and in healthy volunteers. The decrease was correlated with Sequential Organ Failure Assessment (SOFA) score ($r = 0.739$, $p < 0.001$). StO_2 increased in survivors after ICU stay and improvement of sepsis in both septic shock and severe sepsis and was correlated with SOFA score.

Evaluation of Tissue Saturation as a Noninvasive Measure of Mixed Venous Saturation in Children

Levy RJ, Stern WB, Minger KI, Montenegro LM, Ravishankar, Rome JJ, Nicolson SC, Jobes DR.
Pediatric Critical Care Medicine. 2005; Vol 6; No 6.

A prospective observational study to evaluate tissue saturation as a noninvasive measure of mixed venous saturation in children undergoing cardiac catheterization was conducted at Children's Hospital of Pennsylvania. Invasive catheterization is often technically difficult in the pediatric population and the benefit is often outweighed by the inherent risks of the procedure. Thus, a near-continuous noninvasive method to measure SvO_2 is needed. A noninvasive tissue saturation monitor using near-infrared spectroscopy was used to measure muscle tissue hemoglobin oxygen saturation (StO_2) and compared to invasive measurements of superior vena cava (SVC) saturation. While no meaningful correlation was found, the researchers are hopeful that further evaluation of the technology will improve the use of near-infrared spectroscopy for better noninvasive assessment of hemodynamics in pediatric patients.

Note: The **InSpectra™** Tissue Spectrometer has not been cleared by the FDA for predicting, diagnosing, or assessing hemorrhagic shock or sepsis. 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™** System, Model 325, is a non-invasive monitoring system that measures an approximated value of percent hemoglobin oxygen saturation (StO_2). The **InSpectra™** System is indicated for use in monitoring patients during circulatory or perfusion examinations of skeletal muscle or when there is a suspicion of compromised circulation.

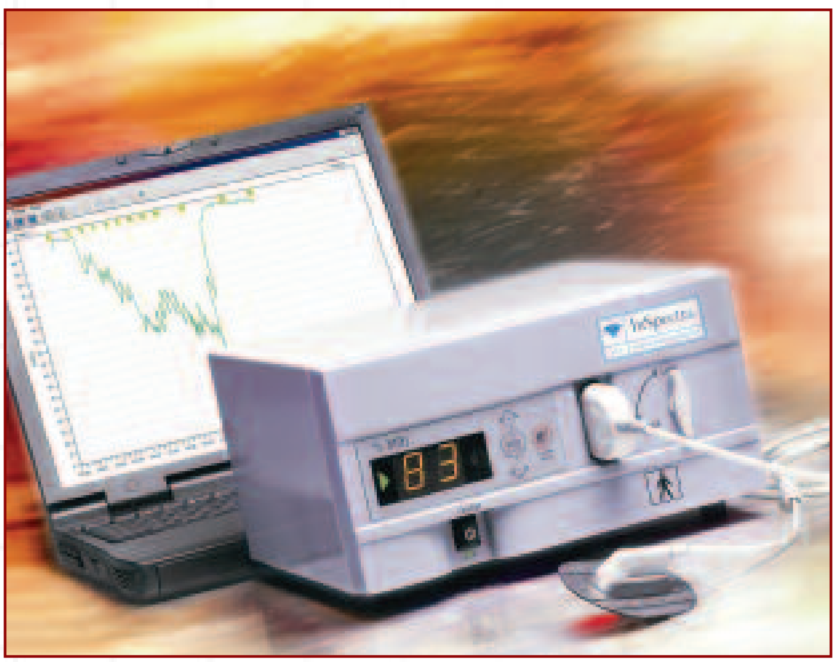
StO_2 Research Presentations

Non-Invasive Real-Time Quantification of Cardiovascular Reserve in Human Circulatory Shock

Torres A, Polanco P, Pinsky MR, Kim H, Puyana JC.
Presented as an Oral Poster at the Academic Surgical Congress First Annual Meeting in San Diego, CA

Introduction: Presently, the bedside assessment of cardiovascular adequacy in the critically ill trauma patient is not practical. Compensatory mechanisms often restore blood pressure and vital organ blood flow despite ongoing hypovolemia and hypoperfusion. We reasoned that delay in the restoration of tissue oxygenation following vascular occlusion would identify impaired cardiovascular reserve. The **InSpectra™** System near infrared sensor measures tissue O_2 saturation (StO_2) in a continuous and non-invasive fashion.

Hypothesis: Dynamic changes in StO_2 may assess cardiovascular reserve, if coupled to a defined circulatory stress.



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.

Methods: We measured the time course of thenar eminence StO_2 in 7 normal volunteers (controls) and 3 trauma patients during blood pressure cuff-induced total vascular occlusion (cuff inflation to 20mm Hg > systolic pressure until StO_2 < 35%) and release. This procedure was repeated four times in controls and twice in patients. Controls exercised their thenar muscles during the final occlusion maneuver to assess for the effect of changing metabolic rate on this response.

Results: We found that 1) the decrease in thenar StO_2 within subjects during baseline occlusion and recovery were highly reproducible across repeated occlusions; 2) at rest, the decrease in StO_2 started 20–30 seconds post-occlusion and reached < 35% by 2.2 to 4 min; 3) post-deflation recovery occurred rapidly in all controls (< 8 sec); 4) exercise markedly increased the rate of StO_2 decrease during occlusion (< 30 sec) but did not alter the rate of recovery. In one trauma patient following resuscitation, recovery was also < 10 sec. However, in the remaining 2 patients with circulatory shock without hypotension (lactate > 3mmol/l, MAP > 70mm Hg), the slope of recovery post-occlusion was markedly decreased requiring > 2 min to return to baseline.

Conclusions: These preliminary data suggest that the real-time StO_2 response to transient vascular occlusion may identify subjects with compensated circulatory shock.

Upcoming Events Sponsored by Hutchinson Technology

2006 4th Annual Directors' Forum
Thursday, September 28, 2006
In conjunction with AAST 2006 at the Hilton New Orleans Riverside
New Orleans, LA

Look for us at these US and International Meetings

European Trauma Congress
May 14–17, 2006
Ljubljana, Slovenia

ESA Euroanesthesia 2006
June 3–6, 2006
Madrid, Spain

Point/Counterpoint XXV Trauma and Critical Care 2006
June 5–7, 2006
Crowne Plaza Williamsburg at Fort Magruder
Williamsburg, VA

Urgences 2006
June 6–8, 2006
Paris, France

12th Annual San Antonio Trauma Symposium 2006
September 19–21, 2006
Henry B. Gonzalez Convention Center
San Antonio, TX

7th European Congress of Trauma and Emergency Surgery (EATES)
September 6–9, 2006
Malmo, Sweden

European Shock Society 12th Biennial Congress
September 14–16, 2006
Ulm, Germany

Annual Congress of the European Society of Intensive Care Medicine
September 24–27, 2006
Barcelona, Spain

65th Annual American Association for the Surgery of Trauma (AAST) 2006
September 28–30, 2006
Hilton New Orleans Riverside
New Orleans, LA

Enrollment Complete in Multi-Site, Prospective Trial on Hemorrhagic Shock Monitoring

Hutchinson Technology is pleased to announce that enrollment has been completed in its largest prospective clinical trial. Seven sites participated, enrolling a total of 385 patients.

The trial was initiated in October 2004 to determine the role tissue oxygen saturation (StO_2) monitoring with the **InSpectra™** Tissue Spectrometer can play in hemorrhagic shock and resuscitation. The primary objectives of the trial are:

1. to determine the ability of StO_2 to predict the development of MODS
2. to determine if a predictive relationship exists between StO_2 and mortality, red blood cell transfusion, coagulopathy, base deficit, ventilator-free days, ICU-free days, and/or LOS. Patients were included who had major trauma and needed blood within six hours of admission.

"The size and scope of this study underscores our commitment to demonstrate the clinical utility and economic value of the product we're bringing to the market," said BioMeasurement Division President Chris Temperante.

The investigators and participating sites were:

E. Moore	Denver Health Medical Center, Denver, CO
G. Beilman	North Memorial Medical Center, Robbinsdale, MN
S. Cohn	University of Texas Health Science Center, San Antonio, TX
F. Moore	Memorial Hermann, Houston, TX
A. Nathens	Harborview Medical Center, Seattle, WA
P. Rhee	Los Angeles County Hospital and USC Medical Center
J. Puyana	University of Pittsburgh Medical Center

"I would like to salute the professionalism and hard work of the principal investigators, study coordinators, and data collection staff at our participating sites," said Temperante. "They did an outstanding job dealing with the challenges of screening 1,200 patients within 30 minutes of admission, 24 hours a day."

The company expects the results of this study to be available later this year. Questions can be directed to Brian Kane: brian.kane@hti.htch.com or 800-419-1007 x1295.

Hutchinson TECHNOLOGY®
Advancing Better Therapies

Hutchinson Technology Incorporated
BioMeasurement Division

40 West Highland Park Drive NE
Hutchinson, MN 55350-9784
USA
tel: 800.419.1007
tel: 320.587.1926
fax: 320.587.1555
biom.usa@hti.htch.com
www.htibiomeasurement.com

European Business Office
IJsselburcht 3
6825 BS Arnhem
The Netherlands
tel: +31 26 365 3371
fax: +31 26 365 3372
biom.eu@hti.htch.com
www.inspectra.info

 5008828