CASMED
FOR WHAT'S VITAL

ABSOLUTE NEWS

ISSUE 2 FALL, 2011

This issue

Welcome

With this second issue of "Absolute News," CASMED would like to introduce you to our US and International sales directors. Frank Gregorio and Ignacio Silva both started with CASMED in July, bringing vast experience as we build our global sales team.

Frank is our Director of North American Sales and is based in the Chicago area. Ignacio, our new Director of International Business Development, is based in Pennsylvania and has considerable experience in Europe, Asia and the Middle East. Both of these key executives have been very busy the past few months meeting with key physicians and clinicians around the globe who have an interest in learning about CASMED's FORE-SIGHT Tissue Oximetry Technology. They are dedicated to educating clinicians about tissue oximetry monitoring and how it may improve the precision of patient care.

Please contact Customer Service (800) 227-4414 or visit our website if you would like to contact either Frank or Ignacio or learn more about FORE-SIGHT Tissue Oximetry.

From left to right, Ignacio Silva and Frank Gregorio

Tissue Oximetry for Skeletal Muscles - Barth Syndrome Focus

Washington University's School of Medicine - St. Louis, MO

W. Todd Cade, PT, PhD of Washington University's School of Medicine in St. Louis, MO is working on improving the lives of individuals affected with Barth Syndrome: a rare, genetic disorder of metabolism primarily affecting males. Some characteristics of the condition are growth delay, severe mitochondrial dysfunction, and impaired ability to extract and use oxygen needed by both skeletal and cardiac muscle, causing severe exercise intolerance. Based on preliminary data collected in 2008, Dr. Cade developed a theory that supervised aerobic exercise training might improve muscle function and quality of life. He is currently enrolling patients in a study to investigate this idea, thanks to a $40,000 grant from the Barth Syndrome Foundation.

Initial biologic measurements were taken on affected adolescents and young men during cycling, including FORE-SIGHT Tissue Oximeter measurements on both the brain and quadricep skeletal muscle. These values were compared with values from their brothers, who were used as healthy controls (Figure 1). Although the Barth-affected individuals were not able to exercise as long due to fatigue, the brain saturations were similar in both groups, showing a slight decrease at peak exercise followed by a slight increase during rest. The skeletal muscle saturation showed a marked difference. The healthy subjects showed a decrease in saturation as demand for oxygen increased. However the Barth patients displayed an increase in StO_2 during exercise. This response is possibly due to an increase in blood flow to the area due to arteriolar vasodilation, combined with the inability to efficiently extract and utilize oxygen. These NIRS muscle measurements confirmed Barth Syndrome's characteristic exercise intolerance.

After preliminary data were collected, adolescents and young men enrolled in the study trained for 20-45 minutes, 3 times a week, for 12 continuous weeks at a physical therapy facility near the patients' homes. So far, three patients have been enrolled in the study with promising results. Post-training testing shows an improvement in patients' FORE-SIGHT derived skeletal muscle oxygen extraction as well as an increase in exercise tolerance. The information learned from this study may benefit others by helping to understand other mitochondrial muscle diseases and adult heart failure. Dr. Cade plans to enroll one more subject in this pilot study and use this encouraging data to apply for a larger grant.

Citation:

Data used to compile figure from: Spencer, C.T. et al. Impaired cardiac reserve and severely diminished skeletal muscle oxygen utilization mediate exercise intolerance in Barth Syndrome. *Am J Physiol Heart Circ Physiol.* 2011 Aug 26. [Epub ahead of print]

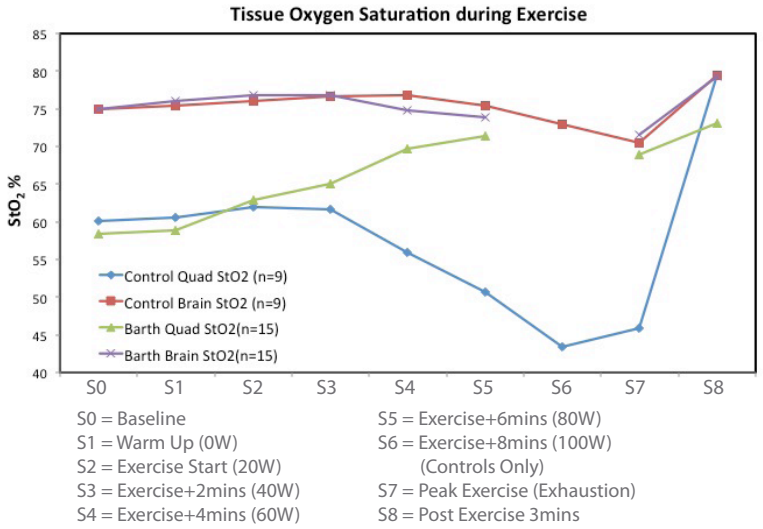

Figure 1: Subjects (both Barth Syndrome and controls) exercised on a cycle ergometer with increasing work rate until deliberate exhaustion. Barth Syndrome subjects were not able to exercise as long as the controls did as shown with the gap in data at 100W.

Doctor's Corner

Dr. Steven Greenberg, Director of Critical Care Services at NorthShore University HealthSystem University of Chicago Pritzker School of Medicine in Evanston, IL, will be giving a presentation entitled, "The Perioperative Use of Cerebral Oximetry," during a breakfast symposium at 65th PostGraduate Assembly in Anesthesiology, in New York, NY on December 12th 2011.

Dr. Mike Hartley, Consultant Cardiothoracic Anaesthetist at Blackpool Victoria Hospital Lancashire Cardiac Centre in United Kingdom will be giving a presentation entitled, "NIRS in Surgical Patients," at Update on Neuromonitoring in Rome, Italy, on December 12th 2011.

FORE-SIGHT in the EP Lab

"By using the brain as an index organ, interventions to improve cerebral oxygenation had systemic benefits. Similarly, we propose that during VT ablation, $SctO_2$ may serve as a better marker of hemodynamic stability than blood pressure".

Citation:

Miller MA et al. Activation and entrainment mapping of hemodynamically unstable ventricular tachycardia using a percutaneous left ventricular assist device. *J Am Coll Cardiol* 2011;58(13):1363-71.

Q & A

FORE-SIGHT at Memorial Regional Hospital

Dr. Robert Brooker is Chief of Cardiac Anesthesia at Memorial Regional Hospital in Hollywood, FL.

Robert F. Brooker, MD

Q: How was FORE-SIGHT (FS) Absolute Tissue Oximetry implemented in your facility?

A: The cerebral oximetry monitoring system we were using was not working well and our group was looking for a more accurate monitor for assessing cerebral perfusion. I had read about the development of the technology employed in the CASMED system. It is a significant improvement over our old monitor.

Q: What does FS Absolute Accuracy mean to you?

A: It represents a more accurate measure of the cerebral oxygen supply and demand relationship.

Q: Is FS a "standard of care" in your institution? What type of patients and cases do you monitor with FS?

A: It is standard for all patients undergoing cardiac surgery procedures including coronary bypass, valve replacements, and surgery of the aorta. We are also using the monitor in select cases where cerebral blood flow may be compromised. This includes carotid endarterectomy and orthopedic procedures using the sitting position.

Q: Is FS an essential part of your intervention protocols?

A: Yes. Cerebral oximetry is an important component of our monitoring system to ensure adequate cerebral blood flow. As such, it is used to aid in decisions regarding perfusion pressure, perfusion flows, and when transfusion of blood maybe appropriate. During carotid endarterectomy it is used selectively by some surgeons to stratify the need for carotid shunting.

Q: Would you recommend the FS Technology to your peers? What would you say to them?

A: I certainly would recommend this technology to my peers. The cerebral oximeter has played an important role in our cardiac surgical team's efforts to reduce neurologic injury and unnecessary transfusion of blood during cardiac surgery. We have come to rely on the monitor for any procedure in which the adequacy of cerebral blood flow is uncertain. The key is that the FORE-SIGHT Tissue Oximeter provides reliable data.

Recently Published Abstract - Debut at ASA 2011

Performance of 5 Cerebral Oximeters During Hypoxia in Healthy Volunteers

Summary by CASMED

	FORE-SIGHT	INVOS	NIRO-200NX	EQUANOX Classic	EQUANOX Advance
Prec (±1SD)	3.90	9.72	9.64	8.12	6.27
Bias	-1.73	-0.05	1.23	-2.48	-2.84
A_{rms}	4.26	9.69	9.68	8.47	6.86

Table 1: Precision, Bias, and A_{rms} of FORE-SIGHT compared to competitive technologies. Bias is presented as [Reference CX - Measured Value].

In the first independent study of its kind, the authors looked at simultaneous measurements from five near-infrared spectroscopy (NIRS) cerebral oximeters: FORE-SIGHT® (CAS Medical Systems, Branford, CT, USA), INVOS® 5100C (Covidien, Boulder, CO, USA), EQUANOX™ Model 7600 (Nonin Medical, Plymouth, MN, USA) with both EQUANOX Advance™ and EQUANOX Classic™ sensors, and NIRO-200NX (Hamamatsu Photonics, Hamamatsu City, Japan) on adult volunteers. The device readings were directly compared against the commonly used invasive standard of weighted CO-oximetry jugular bulb and arterial oxygen saturation values during episodes of deliberate oxygen desaturation. All of these monitors have FDA clearance with the exception of the NIRO-200NX which has CE Marking. The results demonstrate that the FORE-SIGHT monitor has the greatest precision (3.90) for measuring absolute changes in cerebral tissue oxygen saturation. This result is consistent with two previously published validation studies which showed precisions of 3.70[1] and 3.12[2].

Citation:

1. MacLeod DB, Ikeda K, Keifer JC, Moretti J, and Ames W. Validation of the CAS adult cerebral oximeter during hypoxia in healthy volunteers. *Anesth Analg* 2006; 102:S162.
2. MacLeod DB, Ikeda K, Vacchiano C. Absolute and trending accuracy of FORE-SIGHT and INVOS cerebral oximeters in healthy volunteers. *American Society of Anesthesiologists* 2009;A298.

Abstract Reference:

Philip E. Bickler, M.D.,Ph.D., John R. Feiner, M.D., Helge Eilers, M.D., Mark Rollins, M.D.,Ph.D. University of California at San Francisco, San Francisco, California, United States. Presented at the American Society of Anesthesiologists 2011;LBT07.

FORE-SIGHT - A Global Perspective

Portugal

Accuracy & Reproducibility

by Francisco A. Lobo, MD
Anesthesiology Department, Division of Neuroanesthesia
Pharmaeria - Research Center, Hospital Geral de Santo António, Porto – Portugal

I was in Amsterdam a few months ago for the ESA and EuroSIVA annual meetings when, during a dinner, I tried to guess how much oxygen was circulating in the brain of the other guests after a delicious sauvignon blanc with a grilled hake fillet. Hard task if we had to use a non-absolute brain oximeter (i.e., not a FORE-SIGHT)! During prior years, those who wanted to non-invasively monitor brain oxygenation had to establish a baseline and manage therapy accordingly. That extra analysis was clearly a limitation for ICU patients and during surgery, especially when sudden events occur.

Recently, we compared readings from two different FORE-SIGHT monitors on the same patient undergoing spine surgery. With the first FORE-SIGHT, we started to monitor before induction of intravenous anesthesia (propofol and remifentanil) while the patient breathed room air. The second FORE-SIGHT was started after stable anesthesia with controlled ventilation and breathing 100% oxygen. The readings were similar and are proof of the consistent accuracy and reproducibility of FORE-SIGHT values.

In my mainly neuroanesthesia clinical practice, FORE-SIGHT has been essential for detecting and responding to cerebral ischemic events. Brain trauma and Neuro ICU care, temporary clipping of cerebral arterial circulation, "controlled" hyperventilation, carotid surgery and spine surgery during positioning in prone or "Jack-Knife" positions, are examples of procedures or events with high risk of brain ischemia. These procedures can be associated with poor outcomes if early detection and prompt interventions are not taken. I highly recommend the use of FORE-SIGHT to provide a window over the at-risk brain.

In summary, either for research or patient management, my practice definitely improved after use of FORE-SIGHT, with clearly improved outcomes for my patients.

The Netherlands

The Need for and Routine Use of Absolute Tissue Oximetry

by Ervin E. Ševerdija, PhDc, Senior Clinical Perfusionist
Departments of Extracorporeal Circulation and Cardiothoracic Surgery
Maastricht University Medical Centre, Maastricht, The Netherlands

Although Jöbsis[1] introduced the first transcranial near infrared spectroscopy (NIRS) nearly 35 years ago, it was only recently that NIRS became a standard for monitoring brain metabolism. In 1999, we brought NIRS into clinical practice at the Maastricht University Medical Centre. During the ensuing years, the acceptance of NIRS has evolved from complete scepticism of the first-generation devices to full enthusiasm with the FORE-SIGHT Absolute Tissue Oximeter.

Murkin et al.[2] performed an elegant randomized, prospective study in coronary artery bypass surgery. They showed that by using cerebral rSO_2 to avoid profound cerebral desaturations, there were significantly fewer incidences of major organ dysfunction. Yao et al.[3] performed a prospective observational study in a similar patient population and concluded that cerebral oxygen desaturation is associated with early postoperative neuropsychological dysfunction. Next, Heringlake et al.,[4] in a prospective study of 1,178 patients, found that a preoperative cerebral $SctO_2 \leq 50\%$ is an independent predictor of short- and long-term mortality in patients undergoing on-pump cardiac surgery. Finally, and owing to the improved NIRS accuracy of the FORE-SIGHT Absolute Tissue Oximeter, Fischer et al.[5] demonstrated specific lower threshold values in combination with exposure time that were associated with severe outcomes. Commenting on the advancements found in FORE-SIGHT, Dr. Fischer concluded, "A potential advantage of absolute brain tissue oxygenation is that threshold values may be more strongly associated with adverse outcomes than trends."

Maastricht University Medical Centre Maastricht, the Netherlands

Maastricht University Medical Centre was the first hospital in the Netherlands to use FORE-SIGHT Absolute Cerebral Oximetry for routine monitoring of all cardiac surgical patients (>1000/year). Today, thanks to recent developments and studies of NIRS, perfusionists finally have a powerful monitor to optimize intraoperative cerebral protection.

Citations:

1. Jöbsis FF. Noninvasive infrared monitoring of cerebral and myocardial oxygen sufficiency and circulatory parameters. *Science* 1977;198(4323):1264-7.
2. Murkin JM, Adams SJ, Novick RJ, Quantz M, Bainbridge D, Iglesias I, Cleland A, Schaefer B, Irwin B, Fox S. Monitoring brain oxygen saturation during coronary bypass surgery: A randomized, prospective study. *Anesth Analg* 2007;104(1):51-8.
3. Yao FS, Tseng CC, Ho CY, Levin SK, Illner P. Cerebral oxygen desaturation is associated with early postoperative neuropsychological dysfunction in patients undergoing cardiac surgery. *J Cardiothorac Vasc Anesth* 2004;18(5):552-8.
4. Heringlake M, Garbers C, Käbler JH, Anderson I, Heinze H, Schön J, Berger KU, Dibbelt L, Sievers HH, Hanke T. Preoperative cerebral oxygen saturation and clinical outcomes in cardiac surgery. *Anesthesiology* 2011;114(1):58-69.
5. Fischer GW, Lin HM, Krol M, Galati MF, Di Luozzo G, Griepp RB, Reich DL. Noninvasive cerebral oxygenation may predict outcome in patients undergoing aortic arch surgery. *J Thorac Cardiovasc Surg* 2011;141(3):815-21.

Standard of Care at NorthShore University HealthSystem

In my clinical practice, the number of patients at high-risk for postoperative neurologic injuries has increased dramatically over the past 10 years.

The FORE-SIGHT cerebral oximeter provides the clinician with immediate access to absolute measurements of cerebral oxygenation. Early detection of cerebral desaturation events allows for prompt interventions, which may enhance recovery and reduce adverse postoperative events.

We use the FORE-SIGHT device in patients undergoing beach chair position surgery. Many patients have cerebral desaturation events that occur in the absence of other hemodynamic changes; such events would otherwise be undetected without FORE-SIGHT monitoring. We believe that early detection and treatment of cerebral desaturations may reduce the risk of neurocognitive dysfunction after surgery, and may also decrease the occurrence of rarer catastrophic neurologic injuries like stroke.

Glenn S. Murphy, MD
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FORE-SIGHT Clinical Corner

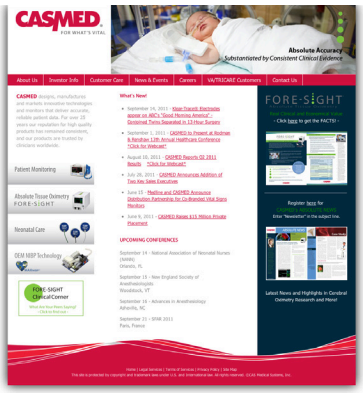
What are your peers saying?

Visit us at www.casmed.com. Click on the "FORE-SIGHT Clinical Corner" on our website for notes on recently published papers.

We had a great response to our first "Absolute News" earlier this year, and hope that you found the articles here in our second issue helpful to your practice.

If you have a suggestion or idea or if you would like to be considered for an article submission in CASMED's Absolute News, please call 203.315.6953 or email us at fore-sight@casmed.com

Latest News



Visit Our New website!

Please visit us at www.casmed.com.

You can find helpful, up-to-date information on the clinical and economic value of FORE-SIGHT, along with a number of recently published clinical papers.

You can also register to receive future issues of "Absolute News" by email.

Upcoming Conferences in 2011 - 2012

For a full list of our upcoming conferences, please visit our website www.casmed.com

Oct 14 - 16	Pennsylvania State Perfusion Society, King of Prussia, PA, USA
Oct 14 - 19	**American Society of Anesthesiologists (ASA), Chicago, IL, USA**
Dec 10 - 12	**65th PostGraduate Assembly in Anesthesiology (PGA), New York, NY, USA** • Dr. Steven Greenberg will be presenting "The Perioperative Use of Cerebral Oximetry"
Dec 11 - 14	**Update on Neuromonitoring, Rome, Italy** • Dr. Mike Hartley will be presenting "NIRS in Surgical Patients"
Jan 15 - 20	30th Annual Symposium: Clinical Update in Anesthesiology, Surgery and Perioperative Medicine, Rio Grande, Puerto Rico
Jan 18 - 20	**Society for Technology in Anesthesia (STA), Palm Beach, FL, USA**
Jan 24 - 28	7th International Conference on Brain Monitoring and Neuroprotection in the Newborn , Clearwater Beach, FL, USA
Jan 29 - 31	The Society for Thoracic Surgeons, Fort Lauderdale, FL, USA
Feb 12 - 15	**41st Annual Meeting of the German Society for Thoracic and Cardiovascular Surgery (GSTCVS), Freiburg, Germany**
Feb 16 - 18	Sanibel Symposium, Fort Myers, FL, USA
Feb 16 - 18	7th International Update on Interdisciplinary Neuroscience - EURO-NEURO Meeting, Vienna, Austria
Feb 17 - 19	The 7th Annual Canadian Winter Cardiac Team Meeting, Quebec, Canada
Feb 18 - 21	12th Annual International Symposium on Congenital Heart Disease, St. Petersburg, FL, USA
Feb 23 - 26	Society for Pediatric Anesthesia Winter Meeting, Tampa, FL, USA
Feb 29 - Mar 4	32nd Annual Cardiothoracic Surgery Symposium (CREF), San Diego, CA, USA
Mar 11 - 16	SCA 17th Annual Update on Cardiopulmonary Bypass, Aspen/Snowmass Village, CO, USA
Mar 25 - 30	**15th World Federation of Societies of Anesthesiologists (WFSA)/World Congress of Anesthesiologists, Buenos Aires, Argentina**
Mar 28 - 31	AmSECT International Conference, Orlando, FL, USA

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