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When it comes to
brain protection
and
patient safety,
hindsight is never
good enough.

FORE-SIGHT®
empowers clinicians
to protect the brain

Unparalleled
non-invasive accuracy

Detect otherwise
unnoticed cerebral
desaturation events

Individualize
management of
each patient's
needs

Cerebral Oximetry Monitoring During Transcatheter Aortic Valve Implantation (TAVI)

By Mike Hartley MB ChB, FRCA, Consultant Cardiothoracic Anaesthetist, Blackpool Victoria Hospital, Lancashire Cardiac Centre, United Kingdom

Doctors at the Lancashire Cardiac Centre in Blackpool, UK have been using the FORE-SIGHT® Absolute Tissue Oximeter as one of the measures to minimize the occurrence of adverse neurological outcomes associated with Transcatheter Aortic Valve Implantation (TAVI).

In the UK, TAVI is recommended as a treatment for patients with symptoms from severe aortic stenosis, where conventional surgical aortic valve replacement is not technically possible or carries excessive risk. Such patients are typically elderly, with multiple co-morbidities and at a high risk for procedure-related adverse neurological outcomes, including stroke.

valve implants and with a variety of access routes, including the femoral artery, subclavian artery, ascending aorta and left ventricular apex. Clinicians tailor the choice of both device and access route to the individual patient to minimize the risk of arterial access and valve delivery/deployment complications. Further consideration is given to the fact that trans-femoral and trans-subclavian procedures can be performed using local anaesthesia, if co-morbidities preclude the safe administration of general anaesthesia.

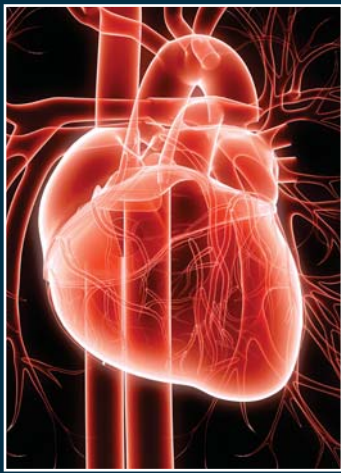


Figure 1. The screen capture was of a transapical TAVI case and demonstrates the fall in cerebral saturations with balloon dilatation and valve deployment

Eligible patients are reviewed by a multi-disciplinary team (cardiologists, cardiothoracic surgeons and anaesthetists), for acceptance for treatment and then undergo CT angiography to image the vascular tree and to determine the most appropriate TAVI treatment approach. The TAVI team at Blackpool has gained experience with both of the commercially available

The majority of TAVI procedures are performed using general anaesthesia with invasive arterial and central venous pressure monitoring and transoesophageal echocardiography. The FORE-SIGHT Absolute Tissue Oximeter is utilized throughout the peri-procedural period to guide manipulation of ventilatory and cardiovascular parameters to help ensure that cerebral tissue oxygen saturation is maintained at an appropriate level. A temporary pacing wire is inserted to facilitate rapid ventricular pacing which allows balloon dilatation of the native aortic valve and deployment of the aortic valve implant in the correct position, and, if necessary, to manage complete heart block, which is a common complication of valve implantation. Cerebral oximetry is used to ensure adequacy of cerebral perfusion and oxygenation during periods of circulatory arrest due to rapid ventricular pacing (see Figure 1) and in the period between valve dilatation and implantation, when there may be significant iatrogenic aortic regurgitation.

To date, 82 TAVI procedures have been performed at the Lancashire Cardiac Centre without adverse neurological outcome – a testimony to the approach that is being taken.



FORE-SIGHT® in Cardiovascular surgery

A Surgeon's perspective

By John Alexander, MD

Retired Chief of Cardiac and Thoracic Surgery, NorthShore University HealthSystem, Evanston Hospital, Evanston, Illinois
Clinical Professor of Surgery, University of Chicago Pritzker School of Medicine, Chicago, Illinois



John Alexander, MD

Near infrared spectroscopy (NIRS) is a real-time method used to detect tissue oxygen content. Surgical procedures, in general, and particularly cardiac surgery are abnormal physiologic states which can alter tissue oxygen levels. During cardiac surgery, non-pulsatile flow, mean perfusion pressure, cerebral vasoconstriction and overall blood flow at the tissue level can be altered by cardiopulmonary bypass. Hematocrits are usually decreased on bypass as well. Cardiac surgery patients have a high probability for subclinical occlusive arterial disease of cerebral vessels. These factors threaten adequate cerebral perfusion during surgery and place the brain of cardiac surgery patients in jeopardy for ischemic insult. The FORE-SIGHT® monitor enables a real time assessment of "net" cerebral oxygenation. Recent studies have shown significant periods of inadequate cerebral oxygenation during cardiac surgery in some patients which are associated with both clinical and subclinical neurologic injury. Inadequate cerebral oxygenation can be treated but it must be recognized before

it can be treated. FORE-SIGHT monitoring has improved our ability to detect reduced cerebral oxygenation during surgery which has enabled us to prevent the devastating impact of neurologic injury.

We use the FORE-SIGHT device in much the same way we use pulse rate, blood pressure, electrocardiogram, blood gases and complete blood count. It has become another vital sign for us, in combination with the other vital signs to get a more complete picture of the patient's clinical status. None of the vital signs alone gives the full picture of the patient's status. When FORE-SIGHT is added as a vital sign, we have a more complete assessment of the overall clinical status of the patient and it provides confidence that we are protecting the brain and ensuring patient safety.

Since we began using FORE-SIGHT, we have seen fewer neurologic complications. FORE-SIGHT helps us manage pump flows and pressures better and we have been able to target blood usage more precisely. In addition, FORE-SIGHT has helped us to better understand and correct a low pCO₂ caused by hyperventilation because of hypocapnia's potential to cause cerebral vasoconstriction and its deleterious effect on cerebral oxygenation.

Excerpts from:

Reduced Cerebral Oxygen Saturation during Thoracic Surgery Predicts Early Postoperative Cognitive Dysfunction.

Tang L, Kazan R, Taddei R, Zaouter C, Cyr S, Hemmerling TM, *Br J Anaesth* 2012 Apr;108(4):623-9.

"We conclude that 50% of patients undergoing thoracic surgery show cerebral oxygen desaturation during SLV of SctO₂ of <65%. These desaturations are positively correlated with early POCD. The risk of POCD after intraoperative cerebral oxygen desaturations ranges from two-fold to 10-fold, depending on the time and degree of the decline."

FORE-SIGHT® Clinical Summary

Initial Description of Cerebral Oximetry Measurement in Heart Failure Patients.

Rifai L, Winters J, Friedman E, Silver MA. *Congest Heart Fail* 2012 Mar; 18(2):85-90.

Summary by CASMED

Heart failure (HF) is one of the most common chronic illnesses leading to major morbidity. Monitoring patient symptoms, urine output, daily weight, and a physical examination are currently used for tracking HF severity and progression. These parameters have limited accuracy. HF patients often have reduced blood flow to their entire body, including target organs like the brain, making this vital organ vulnerable to the effects of reduced oxygenation. The goal of this study was to observe cerebral oxygen saturation (SctO₂) in stable HF patients and to determine if any patient variables correlated with SctO₂. Doctors from Advocate Christ Medical Center in Chicago, IL studied 30 HF patients. Twenty-eight patients were enrolled during an outpatient cardiology clinic visit and two while hospitalized for HF. During routine physical examination, CASMED's FORE-SIGHT® sensors were placed bilaterally for 1 minute to obtain absolute SctO₂ along with a portable pulse oximeter to measure peripheral oxygen saturation (SpO₂). Patient variables were also recorded includ-

ing age, weight, height, mean arterial pressure, heart rate, and other risk factors and comorbidities associated with HF. SctO₂ and SpO₂ were easily recorded on all patients (see the Table below). There was a wide variety in SpO₂-SctO₂ difference, ranging between 19.2% and 51.4%, despite near-normal SpO₂ (92-100%) on all patients. Some patients had high SpO₂ and SctO₂, while others had high SpO₂ with low SctO₂ readings. Patients with high systolic, diastolic, and mean arterial blood pressure also had significantly higher SctO₂. (P<.01). Inversely, the presence of diabetes (P=.026) and abnormal blood cholesterol levels (P=.007) in patients correlated with lower levels of SctO₂. **Measuring peripheral SpO₂ alone inadequately represents brain oxygenation in HF patients. Absolute cerebral oximetry holds the potential to accurately reflect brain perfusion for tracking and preventing complications, earlier and better than currently used methods. In addition, cerebral oximetry may be able to guide responses to therapy, determining treatments to improve HF patients.**

	SctO ₂ (average of left and right, %)	SpO ₂ (%)	SpO ₂ -SctO ₂ (%)
Mean	67.4	97	29.2
Standard Deviation (±)	6.0	2.2	6.6
Range	47.6-76.3	92-100	19.2-51.4

Table: Mean SctO₂, SpO₂, and SpO₂- SctO₂ Difference in Heart Failure Patients (n=30)



CASMED's FORE-SIGHT® Absolute Tissue Oximeter Gains FDA Clearance for Use on Neonatal Abdomen

First tissue oximeter with a specific neonatal abdominal claim

CAS Medical Systems, Inc. a leader in medical devices for non-invasive patient monitoring, announced receipt of clearance from the U.S.

Food and Drug Administration (FDA) to market the Company's FORE-SIGHT® Oximeter to determine oxygen saturation of the abdomen of certain newborn babies. Low levels of oxygen saturation in newborns are associated with serious injury to multiple organs and can have significant long-term impact. CASMED's Small Sensor is now indicated for monitoring the absolute regional hemoglobin oxygen saturation of the abdomen of infants weighing less than four kilograms. CASMED expects that FORE-SIGHT Absolute Tissue Oximeters with this new neonatal abdomen capability will be available to the market in June 2012.

"We are proud to have the first tissue oximeter with a specific abdominal claim to be cleared by the FDA. After many years of clinical study, we were able to develop a specific FORE-SIGHT algorithm for the monitoring of the newborn abdomen with a high degree of accuracy. This clearance is further evidence of CASMED's continued commitment to provide science-based solutions to our clinician customers."

Thomas M. Patton,
President and CEO, CASMED, Branford, CT

"Clinicians now have a non-invasive and reliable monitoring solution that provides absolute oximetry values to guide clinical intervention for these vulnerable pre-term infants. Our data confirmed the accuracy of the FORE-SIGHT values compared to the invasive reference and showed a standard deviation of just +/- 5%. The ability of a non-invasive monitor to provide this level of quantitative accuracy is a meaningful milestone in the advancement of tissue oximetry as a critical tool in the care of newborns."

Khodayar Rais-Bahrami, M.D.,
Director of the Neonatal Perinatal Fellowship Program
Children's National Medical Center, Washington, D.C.

Recent Published Abstracts

Debuted at the 2012 Pediatric Academic Societies Annual meeting (PAS)

Abstract 1: Comparison of NIRS traditional vs stool compensating somatic algorithms when measuring abdominal tissue oxygen saturation on neonates.

Abstract 2: NIRS abdominal somatic tissue oxygen saturation validation model for neonates ≤ 4 kg.



Summary by CASMED

In two abstracts presented at the 2012 PAS meeting^{1,2}, a novel FORE-SIGHT® somatic algorithm to measure abdominal StO₂ in neonates ≤ 4 kg was tested and validated. Invasive blood samples using weighted umbilical venous (SuvO₂) and arterial oxygen saturation (SaO₂) were used as a reference (StO₂) in 40 patients.

$$\text{Reference StO}_2 = (0.7 \cdot \text{SuvO}_2 + 0.3 \cdot \text{SaO}_2)$$

In the first abstract¹, the novel stool-compensating NIRS algorithm was tested against a traditional NIRS algorithm to measure abdominal StO₂ in neonates. The traditional algorithm showed a high bias in 11 of the 40 patients, suggesting that stool in the babies' intestines was interfering with the accuracy of some of the measurements. The meconium in a newborn baby's stool has similar optical properties to hemoglobin, causing errors in the NIRS measurement¹. The new algorithm was able to compensate for this stool interference and showed values more closely correlated with the reference. In the second abstract², 14 subjects were used for

calibration of this novel abdominal algorithm and the remaining 26 subjects were used for testing. **The test data showed an overall bias ± precision (1SD) of -0.77 ± 5.06% with a concordance correlation coefficient (CCC) of 0.789, demonstrating strong correlation.** These study results were vital in enabling CASMED to obtain FDA clearance for monitoring the absolute abdominal saturation of infants weighing less than four kilograms.

References:

1. Said MM, Niforatos N, Rais-Bahrami K. Comparison of NIRS Traditional vs Stool Compensating Somatic Algorithms when Measuring Abdominal Tissue Oxygen Saturation on Neonates ≤ 4kg. E-PAS2012:1534.581.
2. Said MM, Niforatos N, Rais-Bahrami K. NIRS Abdominal Somatic Tissue Oxygen Saturation Validation Model for Neonates ≤ 4kg. E-PAS2012:1534.582.
3. Thompson AM, Ehrenkranz RA, Benni P. Meconium Interferes with NIRS Measurements of the GI Tract in Premature Neonates. E-PAS2010:3738.394.

Post-op monitoring of StO₂ at Evanston Hospital

*"As an Anesthesiologist and Intensivist, I have the unique opportunity to provide complete perioperative care for our cardiac surgical patients. While cardiac surgical mortality has declined over the past several decades, neurologic complications continue to be a major contributor to patient morbidity. **The FORE-SIGHT® Cerebral Oximeter is routinely utilized in our cardiac surgical operating rooms to provide absolute measurements of regional cerebral oxygenation.** Previous studies suggest that intraoperative cerebral desaturations are associated with poor postoperative outcomes. However, these studies have not determined the incidence of postoperative cerebral desaturations and their possible effect on overall outcomes. **We recently identified a high incidence (53%) of cerebral desaturation events in the immediate postoperative cardiac surgical period. A majority of these desaturations lasted for greater than 1 hour, which has been associated with worse outcomes in previous studies that focus on intraoperative cerebral oxygen desaturations.** We hope that we will eventually be able to institute appropriate earlier interventions that will improve patient outcomes, by utilizing the FORE-SIGHT Cerebral Oximeter in the intensive care unit to detect and act upon cerebral oxygen desaturations."*

Steven Greenberg, MD

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Evanston Hospital NorthShore
University HealthSystem
Clinical Assistant Professor,
Department of Anesthesiology/
Critical Care,
University of Chicago,
Pritzker School of Medicine



FORE-SIGHT - A Global Perspective

EARLY CLINICAL RESEARCH IN VASCULAR SURGERY USING ABSOLUTE TISSUE OXIMETRY

By *Vincenzo Schiavone, MD*

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Pineta Grande Hospital, Castel Volturno (CE), Italy

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Pineta Grande Hospital, Castel Volturno (CE), Italy

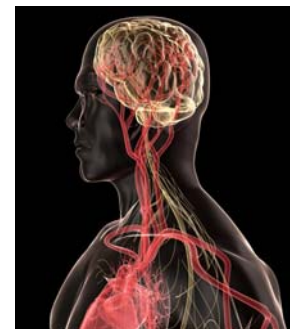


Pineta Grande Hospital,
Castel Volturno (CE), Italy

Oxygen metabolism monitoring by near-infrared spectroscopy (NIRS) is a widespread accepted method to evaluate tissue perfusion and avoid ischemic damage. In the vascular surgery field, NIRS can be used to detect cerebral ischemia during carotid endarterectomy (CEA). A novel NIRS technology is now available with the FORE-SIGHT® Absolute Tissue Oximeter, capable of measuring tissue oxygen saturation more precisely than other devices. This advance in technology is the basis for enabling the device to reliably measure absolute values of tissue oxygen saturation (StO₂). This, in turn, eliminates the need to establish

pre-induction baseline measurements and enables the use of threshold values to guide clinical interventions. Currently, we are conducting a clinical study on 60 patients in need of CEA, randomly allocated into 2 groups: the group A of 30 patients will undergo surgery according to our standard protocol; the group B (30 patients) will undergo surgery according to the standard protocol together with the support of the FORE-SIGHT monitoring. All patients will undergo surgery with the same anaesthesia protocol and with the same surgical technique. From January to March 2012, 18 patients undergoing vascular surgery for critical carotid disease were enrolled in the study. **The preliminary results demonstrate that the routine use of FORE-SIGHT oximetry as guidance for optimal tissue perfusion could reduce the incidence of adverse events, showing promptly cases of sub-optimal tissue perfu-**

sion, alerting the clinician to an otherwise unrecognized adverse event and allowing the surgeon to make the right procedure, as appropriate, without delay. In conclusion, absolute tissue oximetry is a non-invasive technology that has the potential to provide accurate and straightforward information to tailor management during the peri-operative period and to link optimal tissue perfusion with a shortened hospital stay, reduction in cost, and improved in-hospital and short-term outcomes.



*FORE-SIGHT Absolute Tissue Oximeter is indicated for use on skeletal muscle of patients 4-50kgs.

Upcoming Conferences in 2012

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

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|--------------|---|
| June 9 - 12 | Euroanaesthesia (ESA), Paris, France |
| June 11 - 15 | Duke University 5 th Annual Emerging Technologies in the OR, Orlando FL, USA |
| Sept 13 - 16 | New England Society of Anesthesiologists, Newport RI, USA |
| Sept 16 - 19 | German Society of Anesthesiology and Intensive Care Medicine, Berlin, Germany |
| Sept 20 - 23 | Florida Perfusion Society: Case Reports in the Sun, Tampa FL, USA |
| Oct 13 - 15 | American Society of Anesthesiologists (ASA), Washington DC, USA |
| Oct 27 - 31 | European Academy of Cardiothoracic Surgery (EACTS), Barcelona, Spain |
| Nov 15 - 17 | MEDICA, Dusseldorf, Germany |
| Dec 8 - 10 | PostGraduate Assembly in Anesthesiology (PGA), New York NY, USA |

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If you have a suggestions or if you would like to be considered for an article submission in CASMED's Absolute News, please call 203.315.6341 or email us at fore-sight@casmed.com

