

SCIENTIFIC PRESENTATION AWARD

Clinical Accuracy of Continuous Hemoglobin Oxygen Saturation Monitoring Devices

Gregory Z. Bolen, BS, Gary E. Anderson, James R. Huddleson, RRT, Jeffrey B. Riley, BA, CCT, Robin G. Sutton, BS, CCP, David G. Bishop, BA, RN, CCP

Department of Extracorporeal Circulation Technology
Medical University of South Carolina
Charleston, SC

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Abstract

Three devices used to measure hemoglobin oxygen saturation in the extracorporeal circuit were studied and compared to a control. The Baxter Bentley OxySat, Oximetrix Accusat, and the Radiometer ABL4 blood gas monitor were compared to a control, the IL 282 CoOximeter. Fifty one sample points were obtained during all phases of cardiopulmonary bypass with results as follows:

TABLE 1. Comparison of Oxygen Saturation Devices

	r	DIFF	SD	P
ACCUSAT	0.94 p<.0001	-0.6	3.2	0.1834 NS
ABL4	0.93 p<.0001	-1.7	3.3	0.0008 S
OXYSAT	0.87 p<.0001	-6.8	4.4	0.0001 S

r = correlation coefficient with corresponding p value, DIFF = difference from control, SD=Standard deviation of difference, P = p value for testing the hypothesis of no difference between test device and control, NS = No significant difference, S = Significant difference

The Accusat was found to be a statistically more accurate means of monitoring hemoglobin oxygen saturations during cardiopulmonary bypass than the ABL4 and the OxySat. All devices had significant correlation with the control and with each other.

Introduction

A fundamental goal during extracorporeal circulation (ECC) is to increase organ survival by supplying an adequate amount of oxygen to meet tissue demands. The use of continuously measured mixed venous oxygen saturation (SvO₂) is one way to monitor the extent to which oxygen supply meets the oxygen demand during cardiopulmonary bypass (CPB)(1). SvO₂

Address correspondence to: Gregory Z. Bolen, Medical University of South Carolina, Dept. of Extracorporeal Technology, 171 Ashley Ave., Charleston, SC 29425-2701.

recordings may be used with arterial/venous blood gas analyses and hemodynamic indices to estimate the patient's oxygen supply/demand status. With continuous SvO₂ as a monitor of overall tissue oxygenation of the patient, recognition and management of episodes of oxygen deficiency may be accomplished earlier in the course of the patient's care (1).

In most cases, the estimates of cell demand for oxygen can be made by calculating the amount of oxygen consumed by the tissue. If the amount of oxygen supply is known and if the amount of oxygen that is returned unused in the venous blood is also known, the difference represents tissue oxygen consumption (VO₂) (2,3,6,7,12).

Equation 1

O₂ supply - O₂ return = O₂ consumption

CO (1.34 x Hgb x SaO₂) 10 - CO (1.34 x Hgb x SvO₂) = VO₂

SvO₂ = SaO₂ - VO₂

Equation 1- VO₂ equation rearranged to reflect the determinants of SvO₂. CO= Pump Output, Hgb = Hemoglobin, SaO₂ = Arterial Oxygen Saturation, SvO₂ = Venous Oxygen Saturation

When oxygen demands by the cells increase, cellular consumption of oxygen must increase accordingly. A fall in the partial pressure of oxygen, (PO₂), within the cell widens the oxygen diffusion gradient which hastens the movement of dissolved oxygen out of solution within the capillary. If the diffusion gradient is not sufficiently maintained, reduced capillary PO₂ prompts oxyhemoglobin desaturation as reflected by a falling SvO₂.

If the supply fails to meet the need for dissolved oxygen and if the use of the second defense, the venous oxygen reserve, (12,18) fails to preserve a capillary PO₂ of 20 mmHg (with a corresponding SvO₂ of 30%, at 37°C.), the reduced diffusion gradient cannot move oxygen in sufficient quantity to meet cell demands (19, 20). The inability of cells to receive an adequate amount of oxygen defines the point at which anaerobic metabolism will occur (3, 7, 18). Anaerobic metabolism results

in lactic acid production, a progressively more acidic cellular environment, and ultimately in cell injury or death.

Once cell death occurs (or any other cellular event that prohibits cell use of available oxygen, such as cyanide toxicity (21), increased capillary density, increased arteriovenous shunting, or hemoglobinopathies (23)) a less than normal fall in oxygen tension in the accompanying capillary bed results. Consequently, higher capillary PO₂ requires less dissociation of oxygen from hemoglobin. Elevated SvO₂ may then signify that even though oxygen may be adequately supplied, cell dysfunction is so severe that the available oxygen is not being used.

Cardiac disease patients in various stages of anemia, low cardiac output syndrome, ischemia, and acid-base imbalance have compensated for their inadequate tissue perfusion by decreasing hemoglobin affinity for oxygen (22). This decreasing hemoglobin affinity results in an increased P₅₀ value, (normal P₅₀ = 27 mmHg), which results in a rightward shift in the oxygen dissociation curve (ODC). A rightward shift in the ODC makes it possible to meet a greater oxygen demand with same tissue PO₂.

The early innovation by Brinkman et al in 1944 (24) yielded an instrument called "Cyclops" by which reflection from the forehead was analyzed to obtain SaO₂ noninvasively. Following this innovation, various instruments have been devised to noninvasively obtain arterial or tissue SO₂. It was 1962 when the basis of modern reflection oximetry was established by Polanyi and Hehir (13) who used fiber optics to guide the light at specific wavelength into the blood stream and to measure SO₂ in vivo. In 1972, Johnston, et al. (4) devised a solid state fiber-optic oximeter, and catheter tip hybrid type systems which were further developed by Yee, et al. (5) and Schmitt, et al. (14). For application to CPB, Vurek, et al. (15) constructed a dual wavelength oximeter whose sensor was mounted in-line to continuously monitor the adequacy of oxygenation by the artificial lung.

In deriving SO₂ from the optical reflection measurement in whole blood, Polanyi and Hehir computed the ratio of the reflectance at two specific wavelengths, one in the red and the other in near infrared regions, to approximate SO₂ using the following relationship:

Equation 2

$$SO_2 = A + B \times R_{805}/R_{665}$$

where R₈₀₅ and R₆₆₅ are the reflectance at the wavelength of 805 and 665 nm, A and B are the constants that depend on the characteristic of the blood and sensor. However, due to the nonlinear effect of light scattering occurring at the interface of plasma and red blood cells, this method may yield errors unless the correction is made as the hematocrit variation occurs (9).

a. Baxter Bentley Laboratories Inc., Irvine, CA 92704

b. Oximetrix Inc., Mountainview, CA 94013

c. Radiometer America Inc., Westlake, OH 44145

d. Instrumentation Laboratories Inc., Lexington, MA 02173

Also, the nonlinear relationship between reflectance ratio and SO₂ at the lower SO₂ values may add errors in this method. In order to minimize errors due to hematocrit variation, Pittman and Duling (8) employed a third wavelength at the isosbestic region in transmission measurement.

The purpose of this study is to analyze three devices used to measure or estimate SvO₂ during CPB and to compare these results to a control. The Baxter Bentley OxySat(a), Oximetrix Accusat(b), and the Radiometer ABL4 blood gas monitor (c) were compared to the Instrumentation Laboratory (IL) 282 CoOximeter (d) as the control.

The Bentley OxySat oxygen saturation monitor is a small, noninvasive, electronic, digital, battery operated, dual wavelength optical device (7). An infrared (905 nm) light emitting diode (LED) and a red (655 nm) LED that alternately illuminates blood as it flows through a plastic cuvette. The ratio of the infrared to the red signal received by the photo transistor is computed by a single electro-optical feedback circuit. The ratio is linearly related to the blood oxygen saturation over the range of 40% to 100%. Oxygen saturation can be monitored by attaching probes to cuvettes mounted in the CPB line. The cuvette is a plastic, straight through connector with a window in it through which the optical coupling is made. The OxySat allows for high speed, on-line, full flow SO₂ measurement with a 30 second response time (17).

The Oximetrix Accusat monitoring system facilitates the use of the Oximetrix Shaw Catheter system. The system is a special purpose reflection spectrophotometer which provides continuous noninvasive monitoring of the SO₂ without blood sampling or electrical connection to the patient. The Accusat contains fiber optics for light transmission through the Accusat Light Pipe, which is connected to the OS/1271, Optical Module. The Optical Module contains three solid-state LED in the red and infrared light spectrum, and a solid state light detector. Light from the LED is transmitted through the light pipe fiber optics and through a window in the optical "T" connector to illuminate blood flowing past. The optical "T" connector is placed in the CPB line. The reflected light signals are then converted into electrical signals and then amplified for transmission to the OS/1270A Processor. The Oximetrix OS/1270A Processor computes SO₂ values based on the electrical signals transmitted from the Optical Module. These values are continuously displayed in numerical form. The processor also displays a reflected light intensity signal which provides an indication of whether or not the Light Pipe is properly positioned and the system is functioning properly. The three wavelength technology results in more sensitivity to changes in the hematocrit, blood pH, blood flow, and temperature (25). The microprocessor interprets the signal and then averages the computed mean SO₂ digitally (11).

The IL 282 and the ABL4 have shown accuracy and repeatability of SO₂ values during CPB and are used as the standard for comparison (10, 11, 13). The IL 282 CoOximeter utilizes a thallium/neon hollow cathode lamp, which emits light at the desired four wavelength (353, 585, 594, 626 nm)(10). The ABL4 blood gas monitor analyzes a single anaerobic sample to

determine the pH and PO₂ which are used to estimate the SO₂ from the results obtained.

Materials and Methods

Fifty one sample points were observed during all phases of CPB on a total of eight male and female adult patients having coronary artery bypass grafts or valve surgery. The IL 282 CoOximeter was used as the control for all SO₂ readings. The IL 282 was calibrated and the full range of quality control samples were tested daily.

During the circuit set-up, before each clinical case, an Oximetrix Accusat 1/2" Optical "T" tubing connector and a Bentley OxySat 1/2" optical transmission cell (OTC) were placed in the venous tubing of the circuit. The OxySat probes and meter were tested for proper calibration ($\pm 2\%$) using colored calibration cuvettes supplied by the manufacturer. The probes were then attached securely to the OTC. The Accusat Light Pipe (fiber optics) and the OS/1271 Optical Module were attached to the Oximetrix Opticath OS/1270A Processor and the system was standardized per operating manual. The Accusat system was calibrated after the initiation of CPB by running an anaerobic venous sample in the IL 282 CoOximeter and using that SvO₂ reading to calibrate the Accusat SvO₂ reading per operators instructions. The ABL4 Blood Gas Analyzer (c) used for the study had the full range of quality control samples run before each study case and also automatically performed one and two point calibration throughout the study.

Anaerobic venous sampling was performed every twenty minutes during the CPB period. The following parameters were measured from or simultaneous to the sampling: venous blood temperature, percent hematocrit (determined by centrifuged method), OxySat SvO₂, ABL4 SvO₂, Accusat SvO₂, IL 282 CoOximeter SvO₂, partial pressure of venous oxygen (PvO₂) at 37°C and PvO₂ corrected to actual blood temperature.

The results were entered in a computer software file (e) so that graphic and statistical analysis(f) could be performed. The following statistical data were calculated: correlation coefficient (r), standard error (SE), mean difference from control (Diff), and p value. All P values are significant at p<.001.

Results

The data which was obtained was entered into the Lotus 123 program and statistical analysis (f) was performed utilizing the BMDP statistical software program. A scatter diagram of the raw data is shown in Figure 1. Measurement accuracy of the ABL4 is depicted in Figure 2. It shows that the ABL4 correlated with the IL 282 was significant ($r = 0.93$, $SD = 3.3$). Figure 3 depicted the measurement accuracy of the OxySat to the IL 282 and again the correlation was significant ($r = 0.87$, $SD = 4.4$). The accuracy of the Accusat, shown in Figure 4, correlated the best with the IL 282 ($r = 0.94$, $SD = 3.3$). The instruments were tested for the affect of hematocrit on the measurement accuracy and as seen in Figure 5, there was no significant affect. The affects that temperature had on the devices are shown in Figure

6, there was no significant affect. The affect of changing PvO₂ is displayed on Figure 7, which shows relatively no change with changing PvO₂. Statistical comparison of the oxygen saturation devices to the IL 282 is depicted in Table 1.

FIGURE 1

OXYGEN SATURATION MEASUREMENT ACCURACY RAW DATA TRENDS

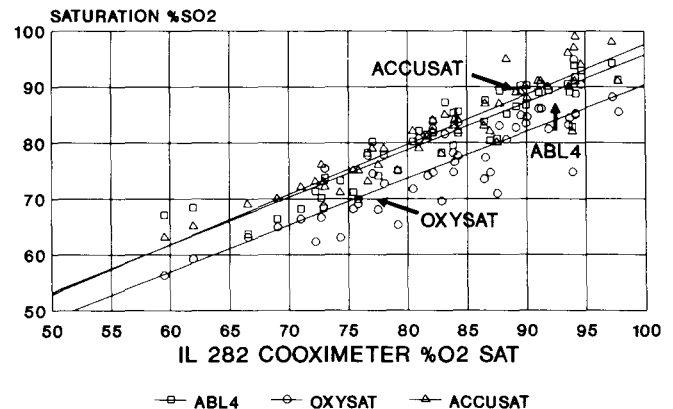


FIGURE 2

OXYGEN SATURATION MEASUREMENT ACCURACY ABL4 VERSUS IL282

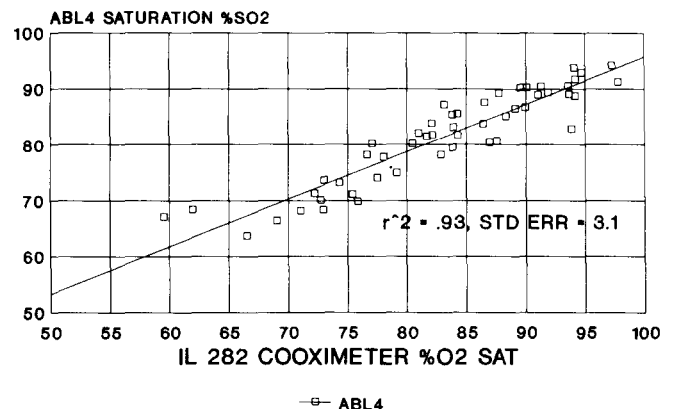
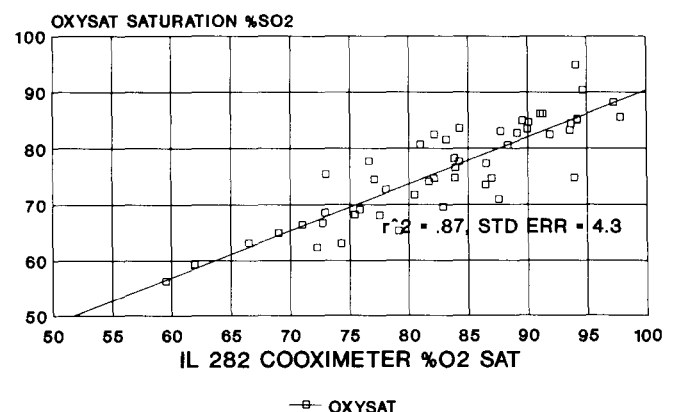


FIGURE 3

OXYGEN SATURATION MEASUREMENT ACCURACY OXYSAT VERSUS IL282



e. Lotus 1-2-3, Lotus Development Corp., Boulder, CO
f. BMDP statistical software program

FIGURE 4

**OXYGEN SATURATION MEASUREMENT ACCURACY
ACCUSAT VERSUS IL282**

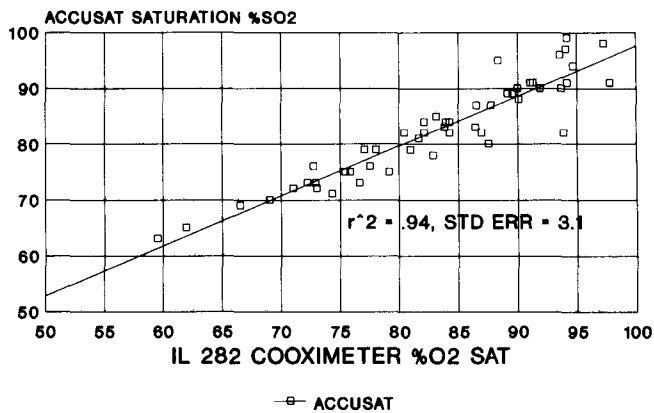


FIGURE 5

**OXYGEN SATURATION MEASUREMENT ACCURACY
HEMATOCRIT EFFECT ON DIFFERENCE**

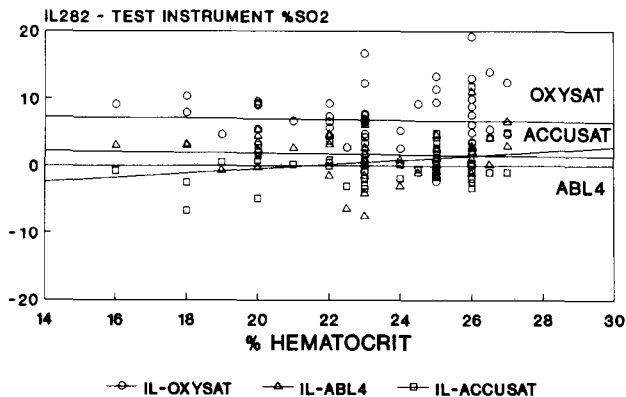


FIGURE 6

**OXYGEN SATURATION MEASUREMENT ACCURACY
TEMPERATURE EFFECT ON DIFFERENCE**

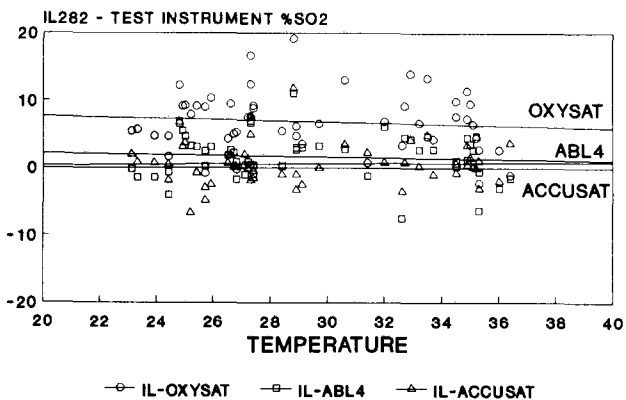
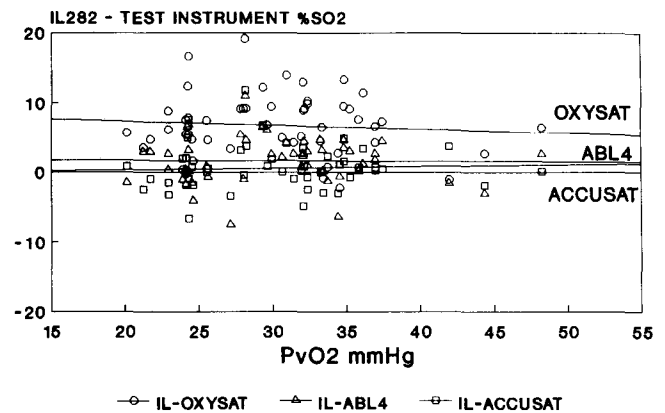


FIGURE 7

**OXYGEN SATURATION MEASUREMENT ACCURACY
PvO2 EFFECT ON DIFFERENCE**



Discussion

The continual monitoring of venous oxygen saturation is a practice that is now being embraced by many perfusionist during CPB. This information allows the perfusionist to insure that the patient is being sufficiently perfused by supplying an adequate amount of oxygen to meet tissue demands (1). The value of a continuous determination of mixed venous saturation depends on how accurately the SvO₂ approximates measured saturation under adverse physiological condition. The Fick equation (equation 1) describes the relationship between VO₂, arterial and venous oxygen content difference (AVO₂) and cardiac output (pump output). The relationships between the variables allow for the adjustment of conditions during CPB. Since the venous saturation is a component of the AVO₂ difference, the greater this difference the greater the oxygen consumption, providing the pump output remains the same. By rearrangement of this equation, it is found that the VO₂ is directly proportional and the pump output is inversely proportional to the AVO₂ difference.

Equation 3

$$\frac{\text{VO}_2}{\text{pump output}} = \text{AVO}_2$$

During CPB if the pump output is decreased and the VO₂ still remains unchanged this will be recognized as a decrease in the venous saturation. The perfusionist may then increase the pump output. The in-line devices allow immediate access to this information.

Chung et. al. (26) demonstrated that the cardiac output early after CPB can be reliably predicted by a plot of venous oxygen saturation at various flow rates on CPB, based on in-line monitoring of venous oxygen saturation (26).

The in-line monitors allow the perfusionist continuous monitoring abilities without increased risk of contamination and distraction while drawing samples. Both the Accusate and OxySat provide indication that proper position is established with the connectors. The advantages of the Accusate system is

the ability to adjust the calibration to a known in-vitro SO_2 . The Oximetrix monitor provide continuous visual trending during CPB. Visual and audible, upper and lower limits, SO_2 alarms can be set via the Oximetrix monitor.

Our results show that neither, the OxySat, Accusat, or ABL4 device were significantly affected by a change in the hematocrit, temperature, or PvO_2 in Figures 5, 6, 7. The OxySat, a two wavelength system, consistently showed lower SvO_2 readings in Figures 1 and 3. The protocol does not allow one to conclude whether the lower reading observed occurred due to the adverse physiologic conditions, time, or both.

The Accusat, a three-wavelength system, accurately reflects measured SvO_2 , as illustrated in Figures 1-4, during a wide variety of clinical conditions and a valuable tool for the perfusionist during CPB.

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Questions and Answers

Owen Jenkins, Sydney Australia:

Q. Why is the IL the control? Isn't it inappropriate to say that you have a more accurate determination when really; if you compared the ABL as the control then the Oxsat would be more accurate?

A. We are in the process of looking into the literature on this device, the IL282 once did a comparison against the Lexicon which I am told is like the gold standard. Lexicon is also very sensitive to performance by the technician. The literature does show the comparison with the 282 and that shows very close correlation with the ABL4. I was unable to find any literature in reference to the Lexicon or the IL282 with comparison to this device. We also had the IL282 in our stat lab which was relatively close to where we were working. We tried to obtain a Lexicon for our analysis but were unable to do so.

Jeff Riley, Charleston, SC

Q. I thought I would come back here to give you some reasons to use the computer. Good presentation Greg. One of the problems we have always had is what is the gold standard for bypass. On the saturation monitors your standard errors when compared to the IL282 were 3-4 1/2% best case which is about as close as we can expect. Continuous saturation monitors agree with benchtop standards and is ± 5 or 6% saturation. Which can leave a 25% error in calculating oxygen consumption. Should we be able to measure saturation more accurately?

A. I agree with your statement. We were quite interested to see what the results were with this device. As a student perfusionist we have a tendency to get focused in on numbers and not so much the treating of patients. And I think the more accurate the device means better perfusionists.

Q. We have had papers presented in this forum before that suggest subtle changes in oxygen content as the blood moves through our circuit even from the point of what we feel is full oxygenation to another point distal. Did you vary the position of the sensing sites at all? Do you think that may have been a factor at all?

A. No, we wanted to do our set up with Oxsat probes in line. We wanted to make a good correlation with safety in mind in case of a problem. No we didn't vary.

Steve Ecker, Irving, CA

Q. Did the temperature of the blood make any difference in comparison between the devices?

A. We varied our temperature from 23°C to 37°C venous blood temperature. You saw a slight deviation with the Accusat as opposed to the ABL4 and the Oxsat, but statistically it was not significant.