SCIENTIFIC PRESENTATION AWARD

# Clinical Accuracy of Continuous Hemoglobin Oxygen Saturation Monitoring Devices

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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 Co-Oximeter. 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 |
| ABL-4 | 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 IL282, SD = Standard deviation of difference, p = p value for testing the hypothesis of no difference between test device and IL282, 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 saturatrion ($SvO_2$) is one way to monitor the extent to which oxygen supply meets the oxygen demand during cardiopulmonary bypass (CPB)(1). $SvO_2$ recordings may be used with arterial/venous blood gas analyses and hemodynamic indices to estimate the patient's oxygen supply/demand status. With continuous $SvO_2$ 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 ($VO_2$) (2,3,6,7,12).

Equation 1

$$O_2 \text{ supply} - O_2 \text{ return} = O_2 \text{ consumption}$$
$$CO\ (1.34 \times Hgb \times SaO_2)\ 10 - CO\ (1.34 \times SvO_2) = VO_2$$
$$CO \times Hgb \times 13.4 \times (SaO_2 - SvO_2) = VO_2$$

$$SvO_2 = SaO_2 - \frac{VO_2}{CO \times Hgb \times 13.4}$$

Equation 1- $VO_2$ equation rearranged to reflect the determinants of $SvO_2$. CO=Pump Output, Hgb = Hemoglobin, $SaO_2$ = Arterial Oxygen Saturation, $SvO_2$ = 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, ($PO_2$), within the cell widens the oxygen diffusion gradient to hasten the movement of dissolved oxygen out of solution within the capillary. If the diffusion gradient is not sufficiently maintained, reduced capillary $PO_2$ prompts oxyhemoglobin desaturation as reflected by a falling $SvO_2$.

If the supply fails to meet the need for dissolved oxygen and if

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the use of the second defense, the venous oxygen reserve, (12,18) fails to preserve a capillary $PO_2$ of 20 mmHg (with a corresponding $SvO_2$ 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 recieve 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 hemogobinopathies (23)) a less than normal fall in oxygen tension in the accompanying capillary bed results. Consequently, higher capillary $PO_2$ requires less dissociation of oxygen from hemoglobin. Elevated $SvO_2$ 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 a increased $P_{50}$ value, (normal $P_{50}$ = 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 $PO_2$.

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 $SaO_2$ noninvasively. Following this innovation, various instruments have been devised to noninvasively obtain arterial or tissue $SO_2$. 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 $SO_2$ 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 $SO_2$ 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 $SO_2$ using the following relationship:

Equation 2
$SO_2 = A + B \times R805/R665$

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). Also, the nonlinear relationship between reflectance ratio and $SO_2$ at the lower $SO_2$ 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 $SvO_2$ during CPB and to compare these results to a control. The Baxter Bentley OxySata, Oximetrix Accusatb, and the Radiometer ABL4 blood gas monitor (c) were compared to the Instrumentation Laboratory (IL) 282 Co-Oximeter (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 $SO_2$ 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 $SO_2$ 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 $SO_2$ 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 Lite 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 $SO_2$ digitally (11).

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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

Figure 1

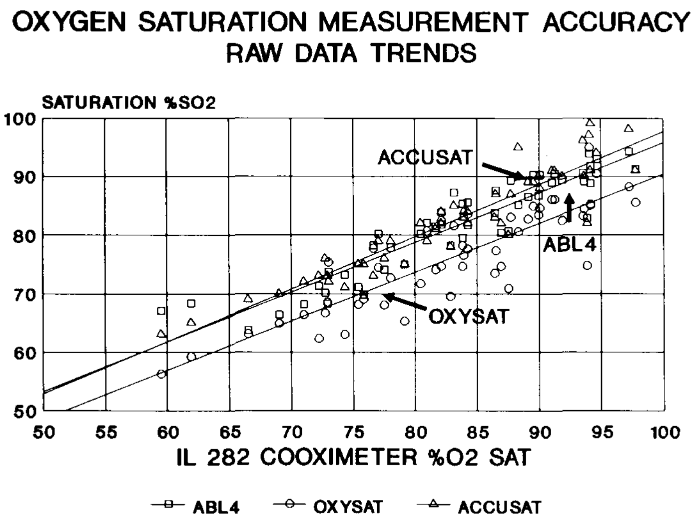



Figure 2

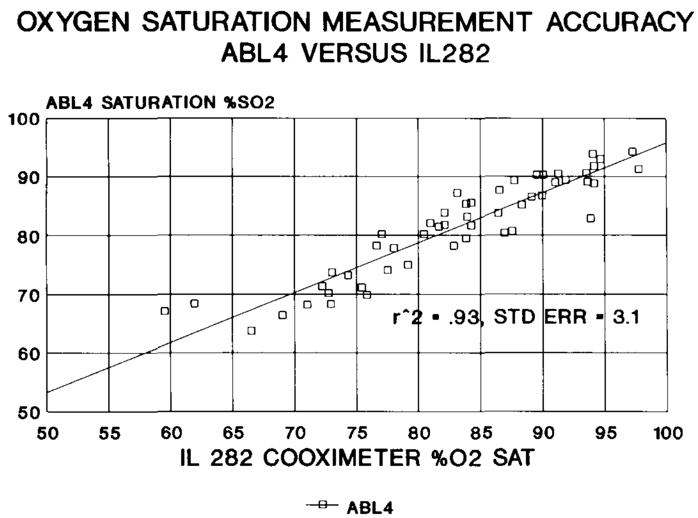



Figure 3

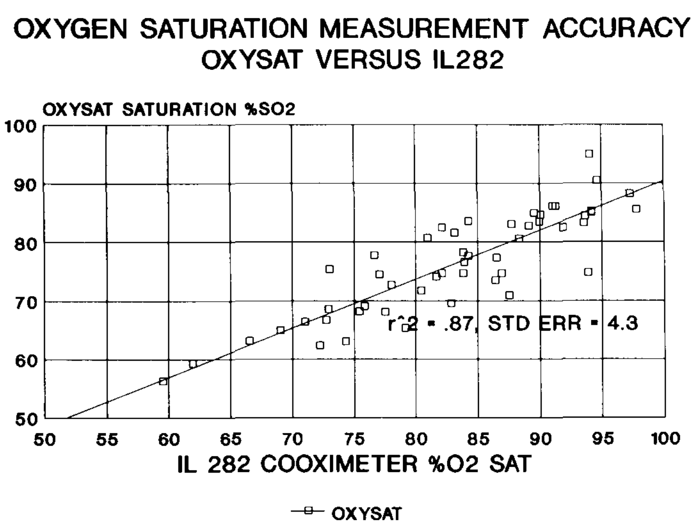



Figure 4

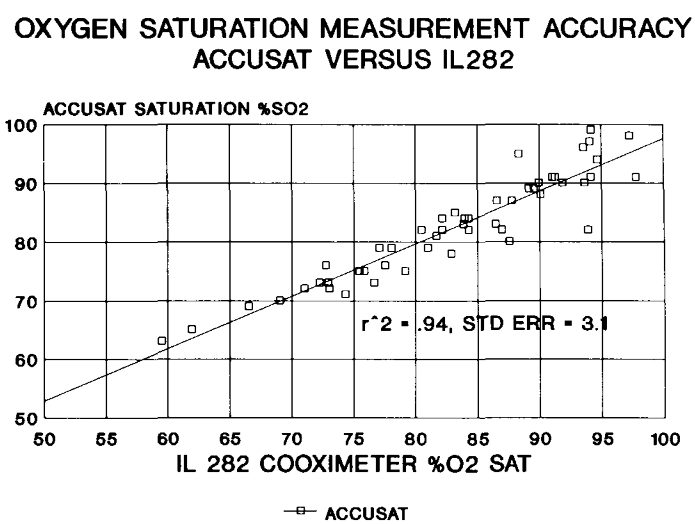


Figure 5

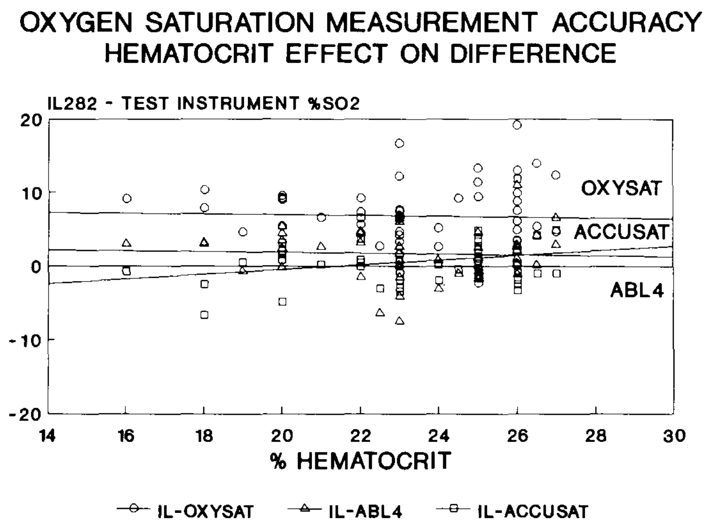



Figure 6

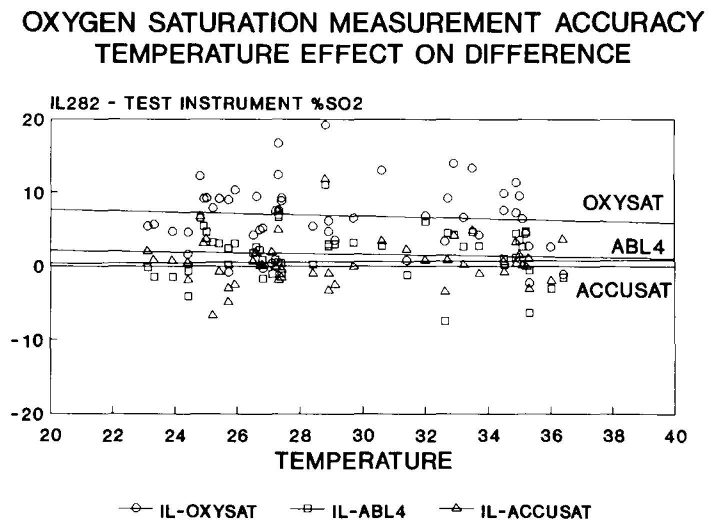
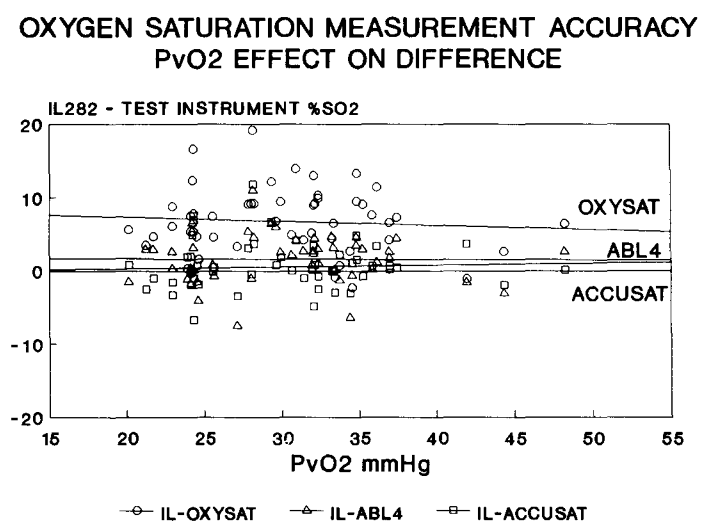



Figure 7



The IL 282 and the ABL4 have shown accuracy and repeatability of $SO_2$ 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 $PO_2$ which are used to estimate the $SO_2$ 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 $SO_2$ 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 Lite 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 $SvO_2$ reading to calibrate the Accusat $SvO_2$ 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 20 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 $SvO_2$, ABL-4 $SvO_2$, Accusat $SvO_2$, IL 282 Cooximeter $SvO_2$, partial pressure of venous oxygen ($PvO_2$) at 37°C and $PvO_2$ 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 (S.E.), 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 $PvO_2$ is displayed on Figure 7, which shows relatively no change with changing $PvO_2$. Statistical comparison of the oxygen saturation devices to the IL 282 is depicted in Table 1.

## Discussion

The continual monitoring of venous oxygen saturation is a practice that is now being embraced by many perfusionists 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 $SvO_2$ approximates measured saturation under adverse physiological condition. The Fick equation (equation 1) describes the relationship between $VO_2$, arterial and venous oxygen content difference ($AVO_2$) 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 $AVO_2$ 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 $VO_2$ is directly proportional and the pump output is inversely proportional to the $AVO_2$ difference.

Equation 3

$$\frac{VO_2}{\text{pump output}} = AVO_2$$

During CPB if the pump output is decreased and the $VO_2$ still remain 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. 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 increase risk of contamination and distraction while drawing samples. Both the Accusat and OxySat provide indication that proper position is established with the connectors. The advantages of the Accusat 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

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

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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