Clinical Evaluation of the Oxysat 2 Monitoring System

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Abstract

A clinical study was undertaken to determine the accuracy of the Oxysat 2 Monitoring System. A series of 17 patients undergoing cardiopulmonary bypass were studied to compare venous saturation and hematocrit results with standard laboratory values. Samples were analyzed using the Auto Crit Centrifuge and the Corning 2500 Co-Oximeter. Upon analysis of the data, graphs plotting correlation of hematocrit values demonstrated an r^2 value of 0.67595 between Oxysat 2 and the Corning 2500. Graphs plotting correlation of percent hematocrit using the Auto Centrifuge and Corning 2500 show an r^2 value of 0.94119. Further analysis of graphs plotting correlation of venous saturation using the Oxysat 2 and the Corning 2500 indicated an r^2 value of 0.86597.

This study indicated a statistically good correlation of saturation values using the Oxysat 2, while only a statistically moderate correlation was achieved using hematocrit results.

Introduction

The Oxysat 2[a] is a second-generation, battery-operated, microprocessor-based system providing continuous monitoring of extra-corporeal arterial and venous saturation and hematocrit values (Figure 1). This study was undertaken to evaluate the accuracy and consistency of the device.

Currently, the trend in cardiopulmonary bypass is for continuous on-line monitoring of blood gas and electrolyte values. The importance of continuous monitoring of extra-corporeal saturations has been well documented in the literature.[1,2,3,6]

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a Baxter Healthcare Corporation, Irvine, CA 92714

The Bentley "Oxysat" SM 0100 oxygen saturation meter[a] has been proven to be a reliable, accurate saturation device that has been in clinical use since 1981.[1,2] The meter has been expanded to include arterial and venous hematocrit values for continuous monitoring during cardiopulmonary bypass.

The basic principle supporting the operation of the Oxysat 2 is light directed at the blood is absorbed, reflected, and scattered in amounts equal to the degree of blood oxygenation and to the density of red blood cells. As oxygen saturation varies, blood color changes. Light directed into the blood is absorbed by it, and reflected in response to the degree of color change, and hence, to the degree of change in oxygen saturation. In the measurement of the hematocrit, light directed at the blood is scattered in response to the density of the red cells in the blood. The primary differences between the sensing of oxygen saturation and the sensing of the density of red cells are in the light wavelengths used and in the geometric relationships between the light emitter and the light detector.[5]

The HSM-400 monitor is capable of measuring saturation values within a range of 40–100 percent. The hematocrit ranges between 15–45 percent. The unit features continuous on-line, non-invasive monitoring

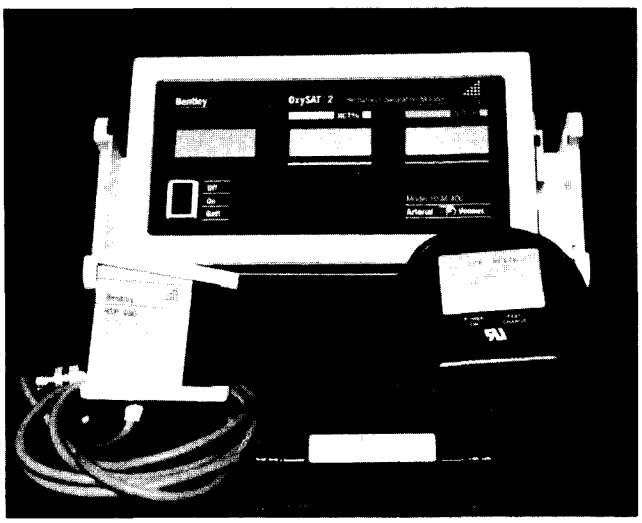
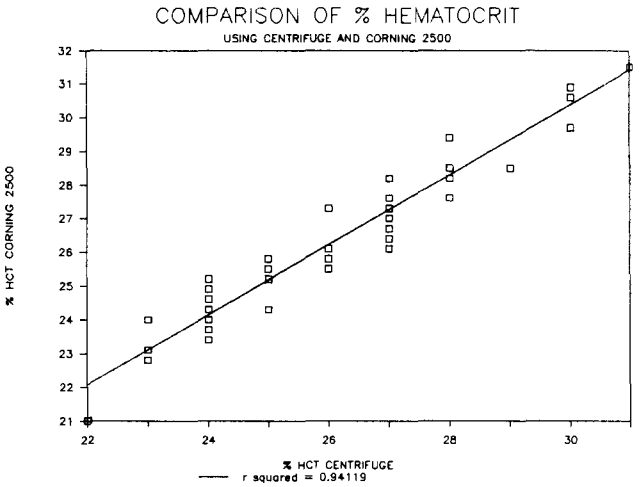


Figure 1. The Oxysat 2 Monitoring System.



Graph 1. Shows the correlation of hematocrit using centrifuge and Corning 2500. r^2 value is 0.94119.

of blood through sterile optical transmission cells of various sizes placed in either the venous or arterial lines. A probe attached to the optical cell relays optical impulses to the monitor, which processes and displays the data on the screen. The probe is designed with three slots on one side and two on the other to prevent incorrect seating of the optical cell.

Since each monitor is factory calibrated, test cells are provided as a means of checking calibration of the probes prior to attachment to the optical cell. These standardized readings should be within one percent for hematocrit values and two percent for saturation levels.

The rear panel has an output for analog signal and a digital Rs232c port providing output for printing data.

In the event the unit is not operating properly, a series of error messages indicate the specific malfunction. An attached quick-check instruction card assists in troubleshooting potential problems.

Materials and Methods

The accuracy and consistency of the Oxysat 2 monitoring system was tested by correlating the data from the Oxysat 2 database with the Auto Crit centrifuge[b] for hematocrit readings, and the Corning 2500 co-oximeter[c] for hemoglobin and saturation values. These laboratory instruments were calibrated each day prior to use according to the methods described in the operator's manual. Quality control calibration checks to three levels were also performed within ±2 standard deviations to assure accuracy of the instruments.

The Oxysat 2 meter SM-0100 was also used to compare venous saturation values. This unit was checked prior to each study using its precalibrated test cell to assure accurate performance. The Oxysat 2 unit was checked in the same manner. Both units were found to be within the specific calibration values each time they were used.

Venous blood samples were drawn from the extracorporeal circuit every 20–30 minutes during stable perfusion periods of at least 5 minutes duration prior to sampling. Samples were selected primarily during periods of stable hypothermia and normathermic cardiopulmonary bypass. A ten ml syringe was used to clear the line prior to obtaining test samples. Five mls of venous blood were withdrawn from the venous line via a sampling manifold located on the pump console. Samples were immediately sent to the stat lab for analysis. Data from the test unit was also recorded at this time. A series of 17 patients with 59 samples was obtained for the database.

Standardized operating perfusion protocol was utilized on all cases.

b Clay Adams, Parsippany, NJ 07054
c Ciba-Corning Diagnostics Corporation, Medfield, MA 02052

Results

Six graphs were plotted to evaluate the saturation and hematocrit values obtained from the database.

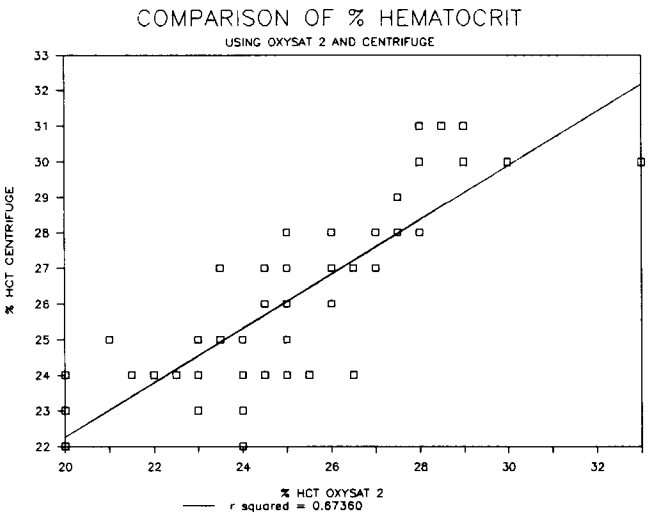
Graph 1 represents the comparison of two laboratory hematocrit standards. Plotting the Corning 2500 against the centrifuge resulted in an R^2 value of 0.94119. This reveals a very good correlation between these two standards.

Graph 2 represents the comparison of hematocrit values using the Oxysat 2 and centrifuge. The database resulted in an R^2 value of 0.67360. When the hematocrit values using the Oxysat 2 and Corning 2500 were analyzed, the resulting R^2 value was 0.67595 (Graph 3).

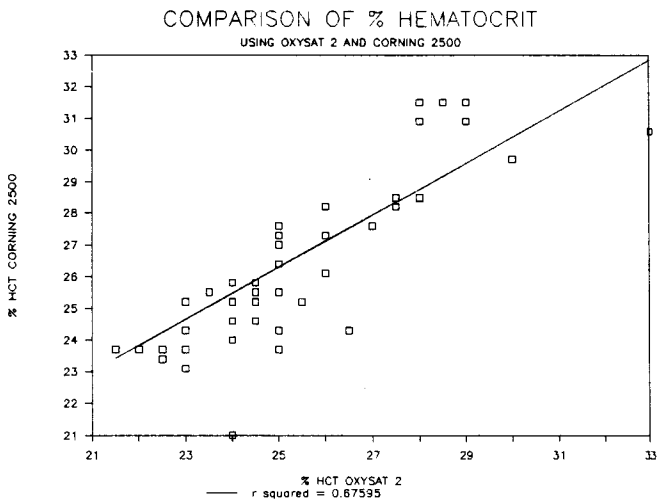
Graph 4 represents a comparison of venous saturation values. This graph shows an excellent correlation between the Oxysat SM 0100 and the Oxysat 2. The R^2 value is 0.97976. Because of the strong correlation between these two units, we also saw similar values when compared to the Corning 2500 co-oximeter.

Graph 5, using the Oxysat 2 and Corning 2500, represents an R^2 value of 0.86941.

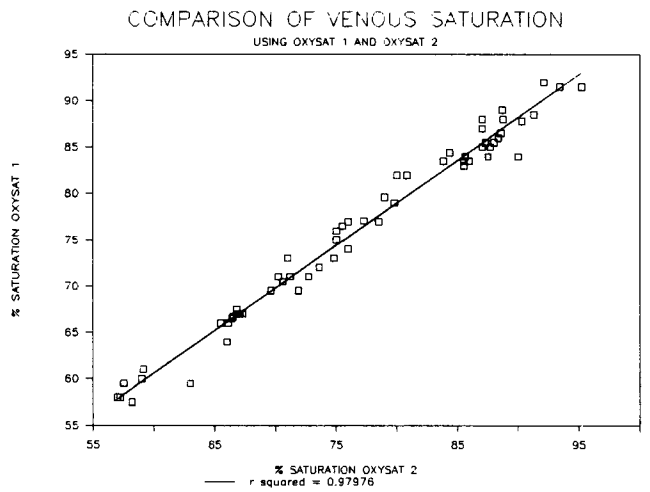
Similar results using the Oxysat SM 0100 in Graph 6 show an R^2 value of 0.86597.



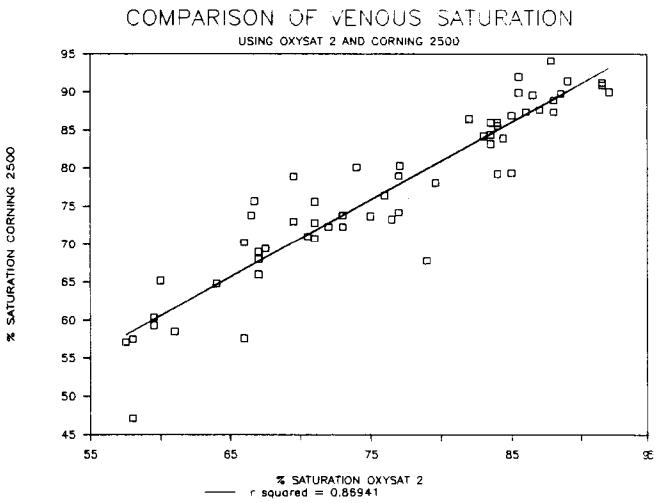
Graph 2. Shows the correlation of hematocrit using Oxysat 2 and centrifuge. r^2 value is 0.67360.



Graph 3. Shows the correlation of hematocrit using Oxysat 2 and Corning 2500. r^2 value is 0.67595.



Graph 4. Shows the correlation of venous saturation using Oxysat 1 and Oxysat 2. r^2 value is 0.97976.



Graph 5. Shows the correlation of venous saturation using Oxysat 2 and Corning 2500. r^2 value is 0.86941.

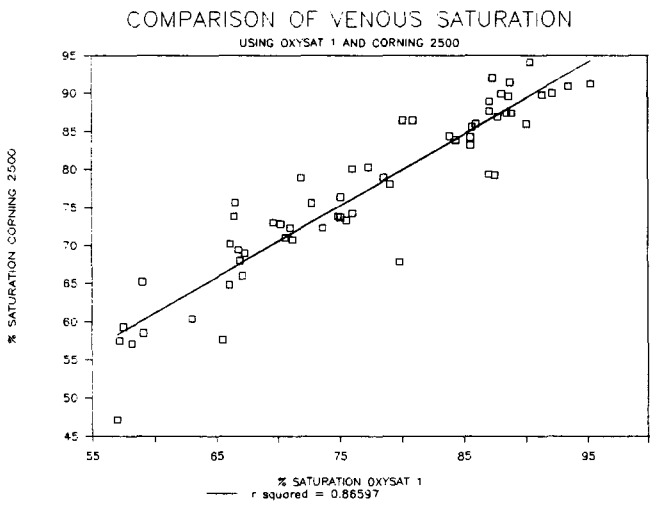
Discussion

Based upon the data, the saturation data reveals very good correlation between both saturation units (Graph 4). This is to be anticipated since the saturation technology has not changed between these two units. The correlation between the Corning 2500 saturation and Oxysat 2 was statistically good (Graph 5).

The importance of hematocrit during cardiopulmonary bypass is well established in the literature.[4,7] Having continuous readings may help with fluid management and gas transfer data.

In the evaluation of the data, we chose to compare our two laboratory standards to see how they correlate. Based upon this data, we saw very good correlation (Graph 1). There is always some standard deviation with all laboratory values, so we were not surprised to see R^2 values of 0.94119.

Analyzing the comparison between both the centrifuge and Corning 2500, the R^2 value was 0.67595



Graph 6. Shows the correlation of venous saturation using Oxysat 1 and Corning 2500. r^2 value is 0.86597.

(Graph 3). These results resulted in a statistically moderate correlation.

Based upon these findings, the Oxysat 2 may be useful for trending hematocrit and blood saturation during the course of cardiopulmonary bypass.

Acknowledgment

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References

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Questions from the Audience

Question: What is the advantage of continuous monitoring for saturation?
Answer: It is what you can find in this particular device if you have a fluid shift. It will show up before you get back to your bench mark or somewhere along the line you have a major dose of cardioplegia that happens to get in because you can't arrest the heart. The surgeon gives a liter more than you expected, you can see the results of this right away, and you can take appropriate action ahead of time.