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Pulse Oximetry: Evaluation of Accuracy during Outpatient General Anesthesia for Oral Surgery

A Comparison of Four Monitors

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Pulse oximetry has been shown to be accurate under steady state conditions. In this study, the accuracy of four pulse oximeters are evaluated and compared during outpatient general anesthesia for third molar extractions. The oximeters evaluated are the Nellcor N-100, the Ohmeda 3700, the Novametrix model 500, and the Bird 4400 portable pulse oximeter.

Ultralight general anesthesia for oral surgery presents a unique challenge for respiratory monitoring in that patients are often not intubated and commonly experience periods of hyper- and hypoventilation. Airway obstruction, apnea, and laryngospasm may occur easily and patients often vocalize and move during surgery. Because hypoxemia is the primary cause of morbidity and mortality during anesthesia, an accurate, continuous, and noninvasive monitor of oxygenation is critical to risk management.

Twenty ASA class I and II patients underwent outpatient general anesthesia for third molar removal using nitrous oxide-oxygen, midazolam, fentanyl, and methohexital. Arterial blood samples were obtained at five-minute intervals during anesthesia, as well as any time a desaturation of >5% occurred, for measurement of arterial SaO_2 with an IL282 CO-Oximeter. These values were compared with simultaneously recorded saturations observed for each pulse oximeter. A total of 122 arterial samples were obtained over a range of PaO_2 from 52–323 mm Hg and observed saturations of 70–100%.

The Bird 4400 portable pulse oximeter proved to be the most accurate and reliably predicted arterial saturation under these conditions ($y = 1.03x - 2.8$, $r = 0.85$). The Novametrix model 500 pulse oximeter also demonstrated a high degree of accuracy by linear regression analysis, but displayed the lowest correlation coefficient (spread of data points) overall ($y = 0.97x + 2.8$, $r = 0.80$.) The Nellcor N-100 pulse oximeter also proved to be highly accurate. ($y = 1.05x - 4.1$, $r = 0.84$.) In contrast, regression analysis of the observed saturations obtained with the Ohmeda 3700 pulse oximeter revealed that this unit significantly underestimated arterial saturation ($y = 1.20x - 19.6$, $r = 0.83$.)

This study demonstrates that despite the rigorous conditions imposed by outpatient general anesthesia for oral surgery, three of the pulse oximeters tested were linearly accurate in predicting arterial oxyhemoglobin saturation over the range of 70–100%. The Ohmeda 3700 was found to significantly underestimate arterial saturation.

Risk management, striving for maximum patient safety, is a primary concern for all practitioners of anesthesia. A major component of risk management is the development of accurate, continuous, convenient, and noninvasive physiologic monitoring. It has been stated that hypoxemia is a leading cause of morbidity and mortality during anesthesia.[1] Two surveys of mortality and morbid-

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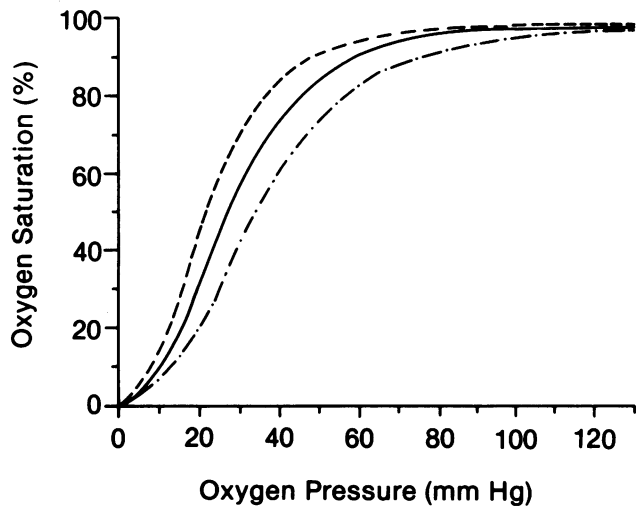
ity during dental anesthesia have found that hypoxemia is the leading single cause of death.[2,3] Hypoxia occurs readily during anesthesia. One clinical trial has documented mild to moderate arterial oxygen desaturation (>5%) in 45% of patients during general anesthesia when the anesthetics were performed by residents in a teaching hospital, and in 19% of patients when anesthetics were administered by an experienced anesthesiologist in private practice.[4] The occurrence of hypoxemia has also been demonstrated during sedation techniques and ultralight general anesthesia for dentistry.[5–7] Unfortunately, the signs and symptoms of hypoxemia may not become evident clinically until very low and dangerous levels of oxygen tension have developed.[8] Comroe and Bethelo[9] showed that skilled observers were unable to consistently recognize hypoxemia in anesthetized patients until the arterial oxygen tension dropped to a PaO_2 of less than 40 torr (saturation of <70%) (Figure 1). These data point to the critical need for the development and application of technology for more precise monitoring of the respiratory system. Ideal respiratory monitoring should continuously assess the major functions that cause hypoxemia; hypoventilation, airway obstruction, apnea, alveolar oxygen dilution, failure of oxygen supply, V/Q mismatch (physiologic shunting), and accidental esophageal or endobronchial intubation.[4,10]

Hypoventilation, airway obstruction, apnea, and esophageal intubation are ideally detected before the development of hypoxemia using capnography.[10,11] Failure of oxygen supply should be rapidly detected by the routine use of oxygen analyzers on all anesthesia machines. Because the final common denominator of all respiratory failure (from any cause) that leads to cell death is hypoxemia, it is desirable to also have a continuous, accurate, noninvasive monitor of arterial oxygenation. Monitors have been introduced and evaluated for this purpose, including the ear oximeter[5] and the transcutaneous oxygen monitor.[12] These monitors have several major disadvantages, however, including the need for "arterialization" of the tissue (that can produce burns), artifacts, need for extensive calibration and warm up, a significant lag time during periods when Pa_{O_2} is rapidly changing, cumbersome equipment, and expense,[10,13,14] and therefore have not been widely used.

Figure 1. The oxyhemoglobin dissociation curve: discontinuous lines represent shifts of the standard curve to the right and left.



The most recent development in this area is the pulse oximeter that was introduced in the United States in 1981 with an ear sensor probe (Biox, Boulder, Colorado), and more recently in 1983 with the finger probe (Nellcor, Hayward, California). The pulse oximeter functions by placing a pulsating vascular bed between a two wavelength (red and infrared) light source and a photodiode detector. By spectrophotometric analysis of the absorption of light at the two wavelengths as it passes through the blood, the pulse oximeter determines the ratio of red (oxygenated) to blue (deoxygenated) hemoglobin present. Pulse oximetry takes advantage of the fact that arterial pulsations cause dynamic changes in light absorption, which is maximal during systole. A ratio of the measured absorption at the two wavelengths of light during the pulsatile phase is calculated by the microprocessor and used to derive oxyhemoglobin saturation (Sa_{O_2}). This technique, thus, eliminates artifacts that would otherwise be introduced by factors such as tissue thickness and venous blood. Pulse oximetry has been shown to be quite accurate during steady state conditions in young healthy volunteers,[15] intensive care patients,[16] and during general anesthesia.[17] Reports have appeared concerning the usefulness of pulse oximetry during dental extractions under general anesthesia[18] and pediatric dentistry with conscious sedation.[19] These papers only report that the pulse oximeter is a useful monitor and that it is a more sensitive monitor for hypoxemia than visual assessment and vital sign monitoring. Accuracy, however, was not assessed, and was therefore assumed.

The purpose of this clinical trial was to obtain substantive evidence to support the accuracy of pulse oximetry during outpatient general anesthesia for oral surgery. Patients undergoing "ultralight" general anesthesia for third molar extractions are often not intubated and present a unique monitoring challenge in that periods of hyper- and hypoventilation commonly occur as boluses of intravenous anesthetic agents are given. Airway obstruction, apnea, and laryngospasm may easily occur (and must be detected and treated promptly), and patients often move and vocalize during anesthesia. In

addition, the standard methods used for monitoring of ventilation during anesthesia (auscultation and observation) are hindered significantly by drapes, clothing, the position of the surgeons, and noisy drills and equipment. Demonstration of the accuracy of pulse oximetry under these challenging circumstances, that differ significantly from "steady state" conditions, would reinforce the value of this new technology in reliably predicting arterial oxygen saturation during oral surgery. With this goal in mind it was decided to accept all patients who had a need for third molar extractions and were acceptable candidates for outpatient general anesthesia, including smokers, ASA class II patients, etc. It was felt that this approach would provide evidence of what can be expected under ordinary clinical settings. It was also decided to evaluate concurrently four of the pulse oximeters available at the time that the study was undertaken, to determine if any significant differences existed. These consisted of the Nellcor N-100 (Nellcor Inc., Hayward, California), the Ohmeda Biox 3700 (Ohmeda, Boulder, Colorado), the Novametrix model 500 (Novametrix Medical Systems Inc., Wallingford, Connecticut), and the Bird 4400 portable pulse oximeter (Bird Products Corp., Palm Springs, California) (Figure 2).

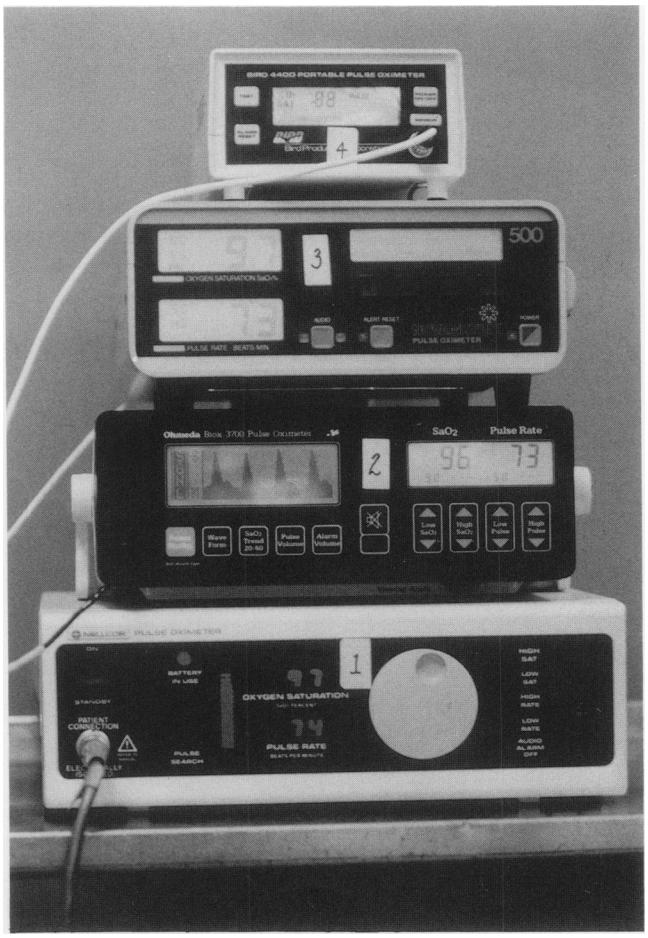


Figure 2. The four pulse oximeters as tested.

METHODS

Twenty (20) American Society of Anesthesiology class I and II patients requiring removal of third molars and who desired outpatient general anesthesia were selected. The 8 males and 12 females included 16 whites and 4 blacks. Four of the patients were smokers. The patients had a minimum of one mandibular third molar for extraction and the estimated time required for the surgery was less than one hour. The patients ranged in age from 18–49 years ($\bar{X}$ = 25.4, SD ± 8.7 years), and in weight from 50–95 kg ($\bar{X}$ = 67.9, SD ± 11.7 kg). Preoperative evaluation included a history, physical examination, hematocrit, and a urinalysis. An Allen's test was performed allowing five seconds for palmar flush as evidence of adequate collateral circulation.[20] The study was reviewed by the University of North Carolina School of Dentistry Committee on Human Subjects and informed consent was obtained from all patients.

Before surgery the following intraoperative monitors were applied: an electrocardioscope, a precordial stethoscope, an axillary temperature probe, an automated blood pressure cuff, and a pulse oximeter. An intravenous catheter was placed and a continuous infusion of 5% dextrose in water or 0.9% NaCl was begun. The patients then received sedation consisting of midazolam (2.5–10 mg) and fentanyl (0.05–0.1 mg) by intravenous titration, as well as an anticholinergic agent (atropine or glycopyrrolate.) When sedation was deemed adequate, the radial artery was cannulated with a 22-gauge catheter and was maintained with a continuous heparin flush. At this point the sensor probes from the four pulse oximeters were placed in a random fashion on the fingers of the hand with the arterial line in place (Figure 3). Placement of the probes was documented to assure that the probe from any given machine was not placed on the same finger consistently in an attempt to prevent any error that might have been introduced by this practice. The oximeter probes were then shielded from each other by placing 4 × 4 gauze pads between the fingers (Figure 4). The patient was then left unstimulated for one minute and a blood sample was obtained for "baseline" (sedated) blood gas analysis. A nasal oxygen hood was then applied and 100% oxygen administered. Another arterial sample was drawn for analysis after 1–2 minutes. General anesthesia was then induced with methohexital 1–1.5 mg/kg IV and maintained with increments of 10–20 mg as needed. Nitrous oxide at an inspired concentration of 30–50% was used initially to supple-

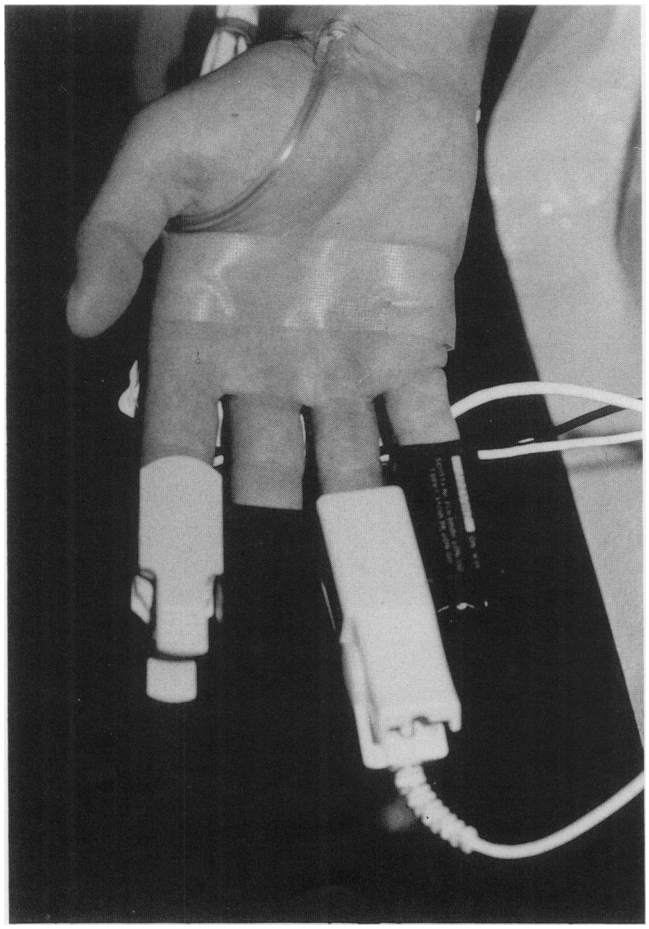


Figure 3. The four finger probes and arterial cathether in place.

ment anesthesia. Arterial blood samples for analysis of measured hemoglobin saturation by an IL282 CO-Oximeter (Instrumentation Laboratory Inc, Lexington, Massachusetts) were obtained every five minutes during the procedure and any time a desaturation of >5% occurred. Blood samples were placed immediately in ice and delivered to the North Carolina Memorial Hospital Blood Gas Laboratory in a timely fashion for analysis. Saturation values displayed by each of the four oximeters were recorded at the precise moment blood sampling was done for comparison and analysis. An attempt was made not to draw blood samples using excessive negative pressure so that arterial blood would not be "stolen" from the radial side of the arch. In an attempt to avoid obtaining samples that were all in the hyperoxic range the nasal oxygen hood was removed at a point estimated to be the halfway point in the surgical procedure, and the patient subsequently allowed to breath room air. A fully equipped anesthesia machine for administration of positive pressure ventilation, should it have been necessary, was immediately available. Any time arterial desaturation occurred and persisted for longer than several seconds oxygen was administered. A standard anesthesia record was kept intraoperatively for all patients.

RESULTS

The mean duration of anesthesia was 22.8 minutes (SD ± 10). Four to seven blood samples were analyzed for each patient. A total of 122 arterial samples were obtained over a range of Pa_{O_2} of 52–323 torr and observed saturations of 70–100%. Samples were analyzed for measured hemoglobin saturation, total hemoglobin, carboxyhemoglobin, methemoglobin, and oxygen content by the IL282 CO-Oximeter. Methemoglobin levels ranged from 0–0.7% for all patients. Carboxyhemoglobin levels ranged from 0.1–2.0% in the nonsmokers and 2.7–6.2% in the smokers. Standard statistical methods were used that included calculation of means, standard deviation of the mean, least squared

Figure 4. The finger probes were shielded from each other to prevent "cross-talk".

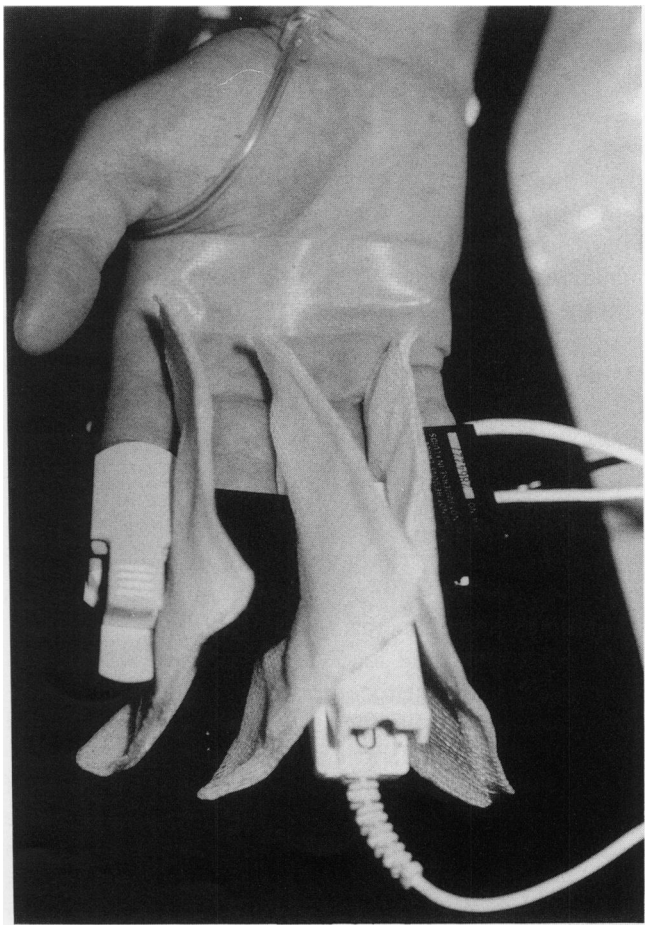


Table 1. Data Analysis: Observed Saturation versus Measured Saturation

	Correlation Coefficient (r)	*y-Intercept (b)*	*Slope (m)*	*Standard Error*
Nellcor N-100	0.84	−4.1	1.05	2.98
Ohmeda 3700	0.83	−19.6	1.20	3.58
Novametrix 500	0.80	2.8	0.97	3.30
Bird 4400 (port)	0.85	−2.8	1.03	2.84

linear regression analysis, and calculation of residuals. To determine accuracy for each pulse oximeter, the observed oximeter saturation values were used as the dependent variable (y), and compared with the in vitro measured arterial saturation values (IL282 CO-Oximeter) as the independent variable (x), and expressed as the least squared linear regression. Each regression equation is expressed as the slope, intercept, standard error of the estimate, and the correlation coefficient (*r*). Table 1 summarizes these statistics for the observed versus measured saturations. Figures 5–8 illustrate the scatter plots of the data for each machine, as well as the line of regression obtained by least squared linear regression analysis.

As can be observed from the regression analysis, the Nellcor N-100 pulse oximeter proved to be highly accurate, with the regression of observed saturations versus measured arterial saturations of $y = 1.05x - 4.1$ ($r = 0.84$) (Figure 5). The Novametrix model 500 pulse oximeter also reliably predicted measured arterial saturation with a regression of $y = 0.97x + 2.8$ ($r = 0.80$) (Figure 6). The Bird 4400 portable pulse oximeter displayed the highest accuracy with a regression equation of $y = 1.03x - 2.8$ ($r = 0.85$) (Figure 7). In contrast, regression analysis of the observed saturations obtained with the Ohmeda 3700 pulse oximeter versus the measured arterial saturations revealed a regression equation

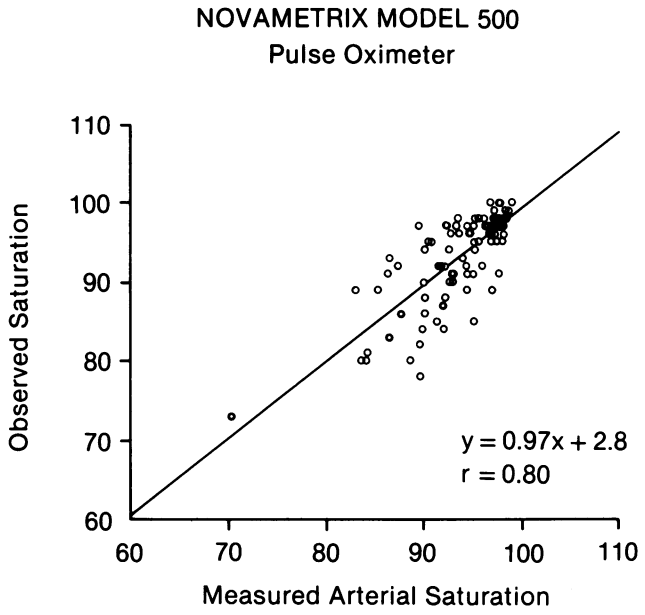


Figure 6. Regression line for the Novametrix model 500 pulse oximeter.

Figure 5. Regression line for the Nellcor N-100 pulse oximeter.

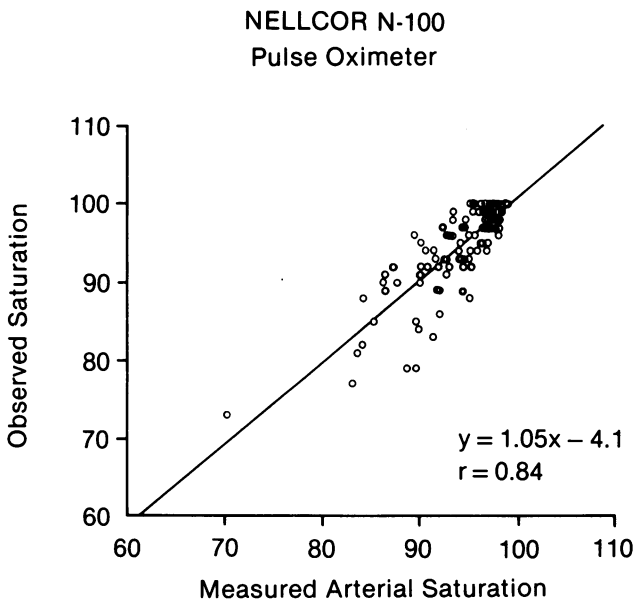
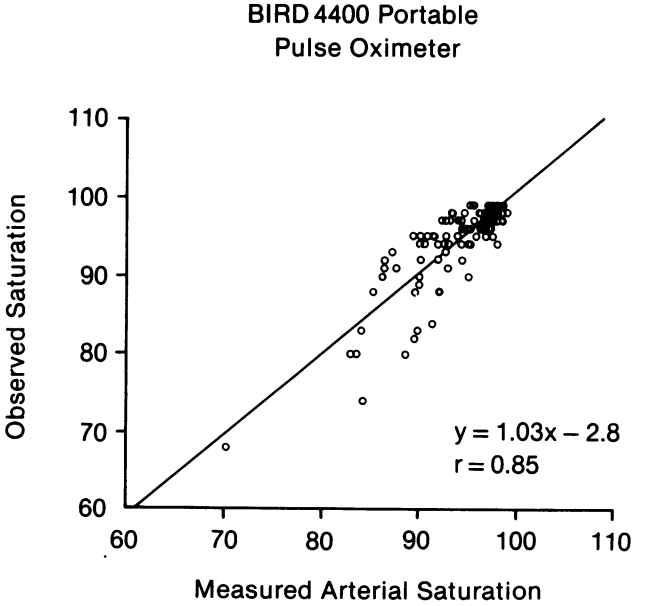


Figure 7. Regression line for the Bird 4400 portable pulse oximeter.



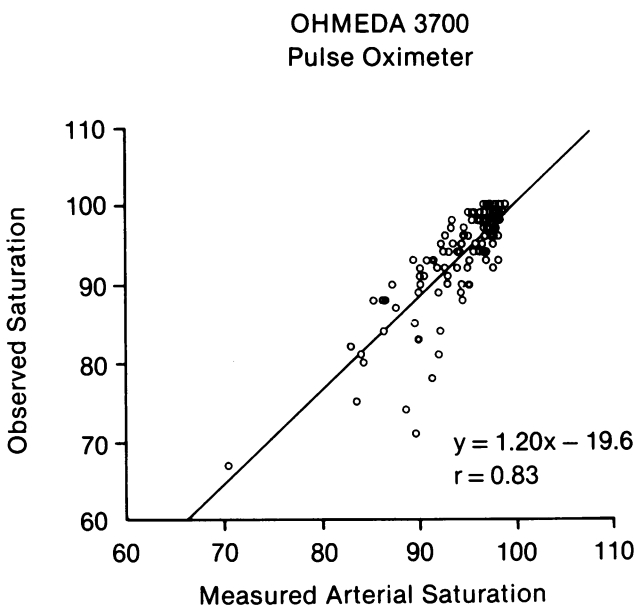


Figure 8. Regression line for the Ohmeda 3700 pulse oximeter.

of y = 1.20x − 19.6 (r = 0.83) (Figure 8), indicating that this oximeter tended to significantly underestimate arterial saturation.

DISCUSSION

Oxygen transport depends on the ability of hemoglobin to reversibly load and unload large quantities of oxygen at physiologic oxygen tensions. The relationship between oxygen tension and oxyhemoglobin saturation is described by the oxyhemoglobin dissociation curve (Figure 1). The "S" shape of the curve is important for physiologic uptake and delivery of oxygen in the body. In the lungs the hemoglobin is almost totally saturated over a wide range of Pa_{O_2} (flat portion of curve), whereas at the tissues a large amount of oxygen is unloaded as desaturation occurs over a relatively small drop in Pa_{O_2} (steep portion of curve).[21] Oxyhemoglobin saturation that is measured by the pulse oximeter is termed "functional" or "reversible" saturation (reported as "observed" saturation in our results.) It is defined as the ratio of the oxyhemoglobin to the sum of oxyhemoglobin plus reduced hemoglobin. Functional saturation excludes the dyshemoglobin species as if they were not present. It, therefore, deals only with hemoglobin that is actually available for oxygen transport. The observed (functional) saturations obtained from the pulse oximeter are compared with "measured" oxygen saturations obtained by CO-Oximetry. The CO-Oximeter actually measures "total" or "fractional" saturation that is defined as the ratio of oxyhemoglobin to the sum of all hemoglobin species present (whether or not the hemoglobin are available for oxygen transport). For example, if a patient has a total hemoglobin of 16 g, 12 of which are oxygenated, 3 reduced, and 1 carboxyhemoglobin, the functional saturation (from the pulse oximeter) would equal 12/15 = 80%, whereas the actual "total" hemoglobin saturation (from the CO-Oximeter) would be 12/16 = 75%. As a result of this discrepancy in the definitions of oxygen saturation, a direct correlation of observed (functional) saturation and total, fractional (CO-Ox) saturation will only correlate exactly if no dyshemoglobins are present. Yelderman reported a correlation between Nellcor N-100 plus oximeter readings and measured CO-Oximeter saturations with a regression equation of y = 1.03x − 2.33 (r = 0.98). This high correlation probably reflects his patient population, which consisted of five young, healthy, nonsmokers and the steady state sampling conditions. These patients should have been relatively free of carboxyhemoglobin and methemoglobin, and therefore the functional and total hemoglobins would be expected to correlate well if the instrument was accurate. It is felt that the "functional" saturation actually provides the most physiologic indication of oxygen content versus oxygen saturation, rather than representing an erroneous value.[15] It reflects the ratio of the oxygen content actually present to the maximum amount capable of being present, because dyshemoglobins are incapable of carrying oxygen. Ideally it would be clinically desirable to know if some hemoglobin is bound to carbon monoxide or in the methemoglobin form, however this is not the primary function of the pulse oximeter. The purpose of the monitor is to reflect how well the anesthetist is doing in actually oxygenating the patient's blood as compared with the best that could possibly be attained with the hemoglobin that is available, and this is reflected best by the functional saturation. Pulse oximeters are therefore designed to measure functional saturation in that they use two wavelengths of light. A specific wavelength is needed to measure each hemoglobin species. The two wavelengths used in pulse oximetry measure oxy- and deoxyhemoglobin. If total hemoglobin saturation were desired, an additional two wavelengths would be required to measure carboxy and methemoglobins. Although such a pulse oximeter would report true total hemoglobin saturation, it would be much more complex, large, and expensive than the current units. Fortunately the functional saturation (requiring only two wavelengths) is probably the more clinically relevant value for assessing adequacy of ventilation.

In evaluating accuracy it is most important to examine the regression line equation; y = mx + b, where m is the slope and b is the y-intercept. This equation indicates

Table 2. Predicted Arterial Saturation (y) at x = 50% Sa_{O_2} From Regression Equations

Pulse Oximeter	*y*
Nellcor N-100	48.4
Ohmeda 3700	40.4*
Novametrix 500	51.3
Bird 4400	48.7

* = significant error

closeness to the "line of identity" where the slope is 1 and the y-intercept is 0, that would indicate perfect accuracy. Therefore, in evaluating the regression equation for any given device, the closeness of the slope (m) to 1 and the y-intercept (b) to 0 indicates the degree of accuracy of the device. Examination of our data reveal that the highest degree of accuracy was demonstrated by both the Bird 4400 portable plus oximeter (m = 1.03, b = −2.8) and the Novametrix model 500 (m = 0.97, b = 2.8). The Nellcor N-100 pulse oximeter also proved to be highly accurate (m = 1.05, b = −4.1). These values are very similar to those obtained by Yelderman for the Nellcor N-100 (y = 1.03x − 2.33).[15] In contrast, the Ohmeda 3700 did not demonstrate such accuracy under these conditions with the oximeter tending to significantly underestimate actual saturation (m = 1.20, b = −19.6).

Another method of evaluating this data is to use the regression equation produced for each pulse oximeter to test its accuracy in predicting arterial saturation (y) at a given Sa_{O_2} (x). Table 2 shows these values as calculated for an Sa_{O_2} of 50% for each oximeter. This analysis reveals that the Bird 4400 might be expected to underestimate the Sa_{O_2} by 1.3%, the Nellcor N-100 would underestimate by 1.6%, the Novametrix model 500 would overestimate Sa_{O_2} by 1.3%, and the Ohmeda 3700 might underestimate the Sa_{O_2} by 9.6%. Flick and Block suggest that a 4% difference in measurement of saturation is a significant error.[22] If this criterion is accepted, the Ohmeda 3700 is the only pulse oximeter of the four tested that produces significant error. Kagle et al[23] recently evaluated the Ohmeda 3700 pulse oximeter. They initially evaluated the Ohmeda 3700 with "version J" software as we did. Using the finger probe they found that the oximeter tended to significantly underestimate arterial saturation under steady state conditions. Regression analysis yielded an equation of y = 1.21x − 19.1 (r = 0.98). These values agree very closely with our results. The correlation coefficient is higher probably due to the steady state conditions. When these investigators reported these findings to the manufacturer, the oximeter's software was modified (version "XJ1"), that resulted in improved accuracy with a regression equation of y = 0.96x + 4.59 (r = 0.99) under steady state conditions, which is more comparable to the other three oximeters we evaluated.

Examinations of the correlation coefficients (r values) obtained reveals the highest r for the Bird 4400 portable pulse oximeter (0.85), followed by the Nellcor N-100 (0.84), the Ohmeda 3700 (0.83), and the Novametrix model 500 (0.80). The value of the correlation coefficient is that it indicates how closely the data obtained fall around the regression line (ie, indicates data spread). It is not surprising that the spread obtained with data obtained during outpatient general anesthesia for oral surgery with its dynamic nature would be larger than under steady state conditions. In evaluating the Ohmeda 3700 pulse oximeter for accuracy, Kagle et al[23] tested the unit under both steady state conditions as well as during rapid desaturation. They reported a correlation coefficient during steady state testing of r = 0.98, but found a correlation coefficient of only r = 0.78 during rapid desaturations. Our data was obtained partially under steady state conditions and during periods of rapid desaturations. Our correlation coefficients are, therefore, between those obtained at each condition exclusively. Our correlation coefficients are not nearly as high as those obtained in the laboratory setting[15] or the ICU setting,[16] where the conditions were steady state. No attempt was made in our study to eliminate any results that occurred during periods when the numbers were rapidly changing (conditions were not "steady state") nor were particularly difficult patients excluded. It is known from the other studies cited that the pulse oximeter is very accurate in the ideal setting. Our purpose was to evaluate accuracy in "true to life" clinical circumstances imposed by outpatient general anesthesia rather than the ideal. Because conditions for sampling at each data point were identical for each pulse oximeter during our study, comparison of the correlation coefficients obtained for the individual oximeters serves as a valid indication of the deviations of the data points around the regression line (spread).

Combining the correlation coefficient (spread) results and the accuracy results (regression lines), the pulse oximeters tested would be ranked comparatively on a scale of 1–4 from best to worst as shown in Table 3.

Despite the fact that the slope and the y-intercept values of the Novametrix 500 deviate from ideal equally to the Bird pulse oximeter's, the Novametrix is ranked second in accuracy due to the fact that it tended to overestimate the arterial saturation, which is potentially a more dangerous error than the underestimation by the other oximeters.

Pulse oximetry is a clinically useful monitor for continuously determining arterial oxygen saturation during

Table 3. Comparative Ranking* of Four Pulse Oximeters, by Correlation Coefficient (*r* Value) and Accuracy

	r Values	*Accuracy*
Nellcor N-100	2	3
Ohmeda 3700	3	4
Novametrix 500	4	2
Bird 4400 (port)	1	1

* On a scale of 1–4; 1 is best and 4 is worst.

ultralight general anesthesia for oral surgery. Our data indicate that despite the rigorous conditions imposed by this technique three of the pulse oximeters evaluated were linearly accurate in predicting arterial oxyhemoglobin saturation over the range evaluated (70–100%). The Ohmeda 3700 pulse oximeter (with version J software) tended to significantly underestimate Sao_2. The pulse oximeter requires no calibration or warm up period, is noninvasive, is rapidly responsive, tissue and venous artifacts are eliminated, requires no tissue "arterialization" or preparation, and tissue pigmentation does not affect readings. These advantages combined with the accuracy demonstrated make the pulse oximeter the most ideal monitor available for continuous assessment of oxygenation during outpatient general anesthesia. The pulse oximeter combined with the use of capnography[10] provides a system for respiratory monitoring that is continuous and noninvasive and reflects the state of adequacy of ventilation (alveolar gas exchange) and oxygenation concurrently.

ACKNOWLEDGMENTS

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