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The Effect of Sensor Malpositioning on Pulse Oximeter Accuracy during Hypoxemia

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Background: **Previous studies have shown that pulse oximeters whose sensors are positioned improperly may yield erroneously low saturation (Sp_{O_2}) values on normoxemic subjects. The behavior of oximeters with malpositioned sensors during hypoxemia has not been studied. The current study is aimed at determining the behavior of several different pulse oximeters over a wide range of arterial oxygen saturation (Sa_{O_2}).**

Methods: **In each of 12 healthy volunteers, a radial artery cannula was inserted, and eight different pulse oximeters, five of which had malpositioned sensors, were applied. Subjects breathed controlled mixtures of nitrogen and oxygen to slowly vary their Sa_{O_2} from 100% to 70%. Arterial blood samples were analyzed and pulse oximeter data were recorded at five stable Sa_{O_2} values for each subject.**

Results: **The oximeters with malpositioned sensors vary greatly in their behavior, depending on both the actual Sa_{O_2} and the manufacturer and model. One oximeter underestimated saturation at all Sa_{O_2} values, while three others underestimated at high Sa_{O_2} and overestimated at low Sa_{O_2}. Linear regression analysis shows a decrease in the slope of Sp_{O_2} *versus* Sa_{O_2} in most cases, indicating a loss of sensitivity to Sa_{O_2} changes. Between-subject variation in response curves was significant.**

Conclusions: **The calibration curves of the pulse oximeters studied were changed greatly by sensor malpositioning. At low Sa_{O_2} values, these changes could cause the oximeter to indicate that a patient was only mildly hypoxemic when, in fact, hypoxemia was profound. It is recommended that sensor position be checked frequently and that inaccessible sensor locations be avoided whenever possible. (Key words: Measurement techniques, pulse oximetry: accuracy. Monitoring: hemoglobin oxygen saturation.)**

SEVERAL sources of pulse oximeter error have been identified in the recent literature. Pulse oximeter saturation (Sp_{O_2}) values that do not accurately reflect arterial oxygen saturation (Sa_{O_2}) can result from motion artifact,[1] ambient light interference,[2] dyshemoglobinemias,[3,4] intravenous dyes,[5,6] venous blood pulsations,[7] and nail polish.[8] In a recent volunteer study, Kelleher and Ruff[9] found that one pulse oximeter (Nellcor N-100, Hayward, CA) yielded erroneously low Sp_{O_2} values in normoxemic subjects when the clip-on finger sensor was intentionally malpositioned. As the sensor was gradually withdrawn from the end of the digit, the displayed Sp_{O_2} decreased to values between 86% and 95% before the pulse oximeter entered its loss-of-signal alarm mode. The range of sensor positions producing this "penumbra effect" was found to be 1–5 mm in length in most subjects. The authors concluded that this sensor malpositioning effect should be suspected whenever a pulse oximeter displays a "mild degree of desaturation."

Although this study demonstrated the existence of the penumbra effect, it leaves two important questions unanswered. (1) How does a pulse oximeter with malpositioned sensor behave when the patient is actually hypoxemic? (2) How does the penumbra effect vary among the numerous pulse oximeters in clinical use? The first question is clinically relevant, because a proposed explanation of the penumbra effect implies that Sp_{O_2} would be forced toward 85% for any Sa_{O_2} value. That is, for actual saturation greater than 85%, the pulse oximeter would underestimate saturation, but for Sa_{O_2} less than 85%, it would overestimate it. The latter situation is particularly dangerous; the Sp_{O_2} value would imply that a patient was only mildly hypoxemic when, in fact, profound hypoxemia was present. This "optical shunt" hypothesis[9] implies a behavior similar to that observed in methemoglobinemia,[4] in which the pulse oximeter loses much of its sensitivity to changes in saturation.

The question of variability among oximeters is also important because each manufacturer uses a different algorithm for noise rejection. The penumbra effect occurs at a low signal-to-noise ratio; thus, the Sp_{O_2} error could be a function of the low signal-to-noise performance of the instrument.

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The current study aimed at determining the behavior of several pulse oximeters whose sensors were intentionally malpositioned on healthy volunteers in whom a wide range of Sa_{O_2} values were generated.‖ Both earlobe and digit sensors were employed, since both locations are subject to the penumbra effect. For the purpose of this study, a malpositioned sensor is one in which the light source and detector remain properly aligned with one another, but the light pathways between the two do not all fall within tissue.

Materials and Methods

This volunteer study was approved by the University Human Subjects Review Committee, and informed consent was obtained from each subject. The 12 subjects ranged in age from 25 to 41 yr. All were in good health; nine were white; three were black; and one was a cigarette smoker (also black). A 20-G cannula was inserted in the radial artery of the nondominant hand of each subject, for obtaining arterial blood specimens. All specimens were analyzed for arterial *p*H, arterial carbon dioxide tension, and arterial oxygen tension by a Nova model Stat-3 blood gas analyzer (Waltham, MA). Hemoglobin concentrations, including total hemoglobin (Hb), oxyhemoglobin ($O_2Hb\%$), carboxyhemoglobin (COHb%), and methemoglobin (MetHb%), were determined in each sample by a Radiometer model OSM-3 co-oximeter (Copenhagen, Denmark). Both instruments were calibrated daily as recommended by the manufacturers.

All subjects were monitored by continuous electrocardiogram, automated noninvasive blood pressure, mass spectrometer respired gas analyzer (Ohmeda model 6000, Boulder, CO), and a processed electroencephalogram (Lifescan, Diatek, San Diego, CA). In addition, each subject was monitored by eight different pulse oximeters, whose manufacturers, model numbers, and sensor locations are given in table 1. Three of the eight pulse oximeter sensors were positioned normally and used as controls; the remaining five were malpositioned. The Nellcor N-200 was selected as a control because it exhibits a very short penumbra, which makes it difficult to malposition in a repeatable fashion. The other two controls were both reflectance pulse oximeters, which are not subject to the penumbra effect.

Table 1. Pulse Oximeter Manufacturer, Model Number, Software Version, Sensor Type, and Sensor Site for Each Instrument Used in the Study

Manufacturer	Model	Software Version	Sensor Model	Site	Attachment
CIBA	310	1.0	473803	Forehead	Strap
CIBA	310	1.0	473802	Digit	Tape
Criticare	504	3.1	518	Ear	Clip
Novametrix	500	1.4	8619	Ear	Clip
Nellcor	100	5.4	D25	Digit	Tape
Nellcor	200	2.7	Durasensor	Digit	Tape
Ohmeda	3700	Rev M	8122003	Ear	Clip
Ohmeda	3740	7.0	8124002	Digit	Clip

The malpositioned sensors were placed as follows. While the subject breathed room air, the sensor was withdrawn from the finger or earlobe in 1-mm steps until no Sp_{O_2} value was displayed. The most distal sensor position at which the correct heart rate (±5%) was determined reliably by the oximeter with no error messages displayed was used as the study location. Each sensor was carefully taped in place to minimize the risk of additional movement. Subjects were instructed to remain as motionless as possible once the sensor locations were fixed.

After all sensors were positioned, room air data were recorded for 10 min to ensure that the Sp_{O_2} and heart rate values measured by all pulse oximeters were repeatable. Arterial blood samples were obtained and analyzed near the beginning and end of this baseline period to ensure stable physiologic conditions. Subjects were then instructed to breathe normally through an anesthesia circle system while the FI_{O_2} value was adjusted downward stepwise. The FI_{O_2} was controlled by a variable mixture of nitrogen and oxygen, with a total fresh gas flow rate of 6 l/min. Each FI_{O_2} value was maintained for 4 min after obtaining a stable inspired gas mixture, as indicated by the mass spectrometer. Two arterial blood specimens were obtained during the final 2 min at each FI_{O_2} and analyzed by co-oximeter and blood-gas analyzer. Pulse oximeter data (Sp_{O_2} and heart rate) were recorded every minute during the entire experiment.

Four FI_{O_2} values less than 21% were used for each subject. The lowest FI_{O_2} of approximately 10% was chosen to yield an Sa_{O_2} value of 70–74%. The subject was instructed to remove the breathing circuit mouthpiece if he experienced any unpleasant symptoms during the hypoxemic protocol, and verbal contact was

‖ The term Sa_{O_2} is used here, as by convention, to denote "functional" arterial hemoglobin saturation, *i.e.*, 100 × O_2Hb/(reduced hemoglobin + O_2Hb). The "fractional" saturation, $O_2Hb\%$, is defined as 100 × O_2Hb/total hemoglobin.

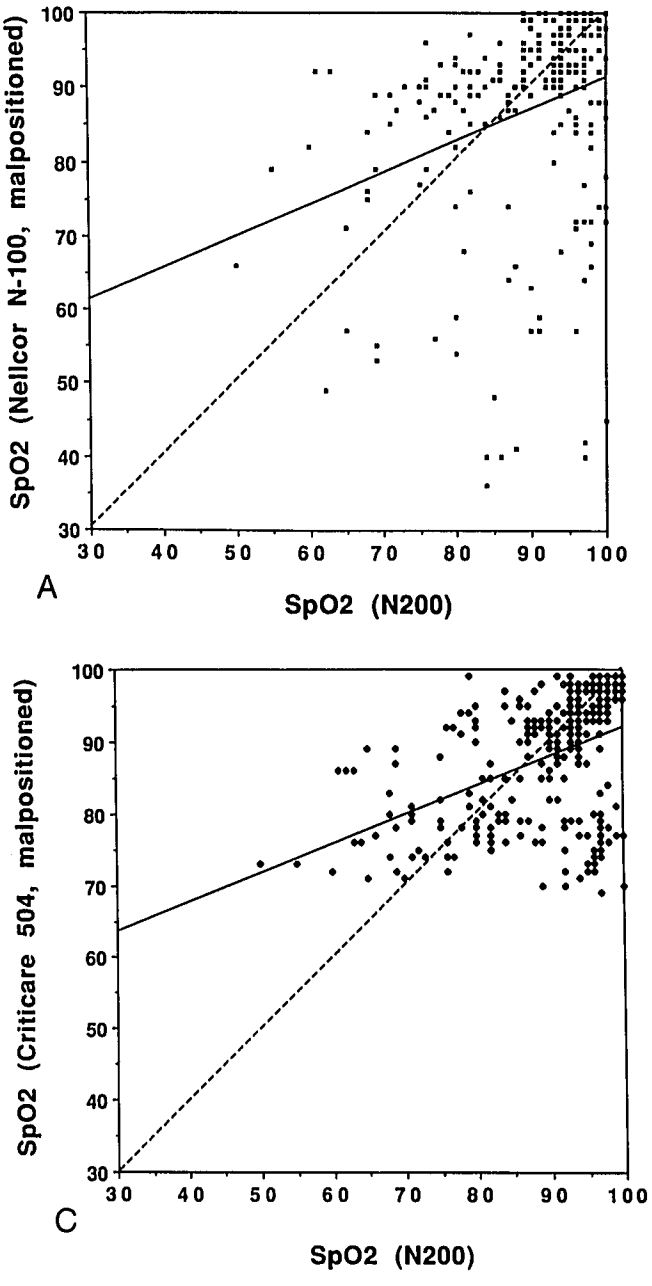

Fig. 1. Sp_{O_2} values from three pulse oximeters with malpositioned sensors *versus* simultaneous Sp_{O_2} values of properly positioned control oximeter (Nellcor N-200, finger). Pooled data for 12 subjects are shown for: (*A*) Nellcor N-100, finger sensor; (*B*) Ohmeda 3700, earlobe sensor; and (*C*) Criticare 504, earlobe sensor. Linear regression best-fit (solid line) and line of identity (dashed line) are shown. See table 2 for corresponding statistics.

maintained at all times. The protocol was abandoned immediately if the subject did not respond appropriately to questions. After the lowest FI_{O_2} value, the subject breathed 100% O_2 for 10 min while a final set of data and blood gases were recorded.

Standard statistical methods for analyzing "methods comparison" data were used. The Sp_{O_2} values from each malpositioned pulse oximeter were plotted against simultaneous values from either of two "gold standards," namely, Sa_{O_2} from the *in vitro* co-oximeter or Sp_{O_2} from a control pulse oximeter with properly positioned sensor. For each such comparison, we calculate the mean and standard deviation of the differences between the two methods, as recommended by Altman and Bland.[10] The mean difference, or "bias," represents systematic error or tendency of the pulse oximeter to consistently

overestimate or underestimate saturation. The standard deviation of the difference, or "imprecision," represents random error or lack of repeatability of the measurement. In addition, we calculate a linear regression for each comparison (slope, intercept, and SE of the estimate) and a correlation coefficient. Both pooled data and single-subject data were analyzed in this way to determine the degree of intersubject variability.

Results

One subject, the only smoker in the study, became lethargic at an Sa_{O_2} of 95% (O_2Hb% = 91%, COHb% = 4.2%, MetHb% = 1.0%) and did not complete the protocol. The remaining 11 subjects completed the protocol without unpleasant symptoms; all reached minimum Sa_{O_2} values of 70–74%. The three control pulse oximeters (Nellcor N-200 finger, Ciba-100 finger, Ciba-100 forehead, Medfield, MA) each yielded Sp_{O_2} values that agreed with co-oximeter Sa_{O_2} values to within manufacturers' specifications. The Nellcor N-200 was the most accurate of the controls, yielding values for bias ± imprecision of −0.65 ± 1.84, R = 0.98, from the 12 subjects' pooled data (n = 93). Nellcor specifies an uncertainty (SD) of ±2% for Sp_{O_2} values greater than 80%, which corresponds to an imprecision of 2%.

Figure 1A shows multiple subject Sp_{O_2} values for the malpositioned Nellcor N-100 (finger) plotted *versus* simultaneous Sp_{O_2} values of a control pulse oximeter (N-200). Figure 1B is a corresponding plot for the malpositioned Ohmeda 3700 (earlobe), and figure 1C shows data using the Criticare 504 (earlobe; Milwaukee, WI). Each plot shows a line of identity (dashed) and a linear regression best-fit line (solid). Though all three pulse oximeters with malpositioned sensors show large random error, they exhibit strikingly different behavior otherwise. The Ohmeda 3700 consistently underestimates Sa_{O_2}, whereas the Nellcor N-100 and Criticare 504 tend to underestimate Sa_{O_2} at high saturation values and overestimate it at low values. Plots of malpositioned Sp_{O_2} values *versus* co-oximeter Sa_{O_2} values show the same trends but with fewer data points. For example, figure 1A contains 244 data points; the corresponding plot using Sa_{O_2} as the abscissa contains 73 data points.

Table 2 shows methods comparison statistics for Sp_{O_2} from the five oximeters with malpositioned sensors *versus* both control Sp_{O_2} and co-oximeter Sa_{O_2}. The ta-

Table 2. Method Comparison Statistics for Malpositioned Sensor Pulse Oximeter Sp_{O_2} Values Compared with (1) *In Vitro* Co-Oximeter Sa_{O_2} Values and (2) Control Pulse Oximeter (N-200, Finger) Sp_{O_2} Values, Pooled Data for 12 Subjects

				Linear Regression			
Oximeter	Bias (mean error)	Inprecision (SD of error)	R	Slope ± SE	Intercept ± SE	SE of Estimate	No. of Pooled Data Points
Criticare 504 (earlobe)							
(1)	−0.90	10.95	0.328	0.315 ± 0.030	59.8 ± 23.8	8.75	96
(2)	−2.14	9.85	0.450	0.44 ± 0.028	48.3 ± 24.0	8.26	301
Nellcor N-100 (digit)							
(1)	−2.14	13.7	0.326	0.489 ± 0.044	43.3 ± 35.3	12.9	73
(2)	−1.28	15.7	0.171	0.27 ± 0.048	64.5 ± 35.5	14.2	244
Novametrix 500 (earlobe)							
(1)	4.93	6.06	0.781	0.582 ± 0.016	41.9 ± 12.4	4.56	78
(2)	4.24	4.17	0.924	0.68 ± 0.009	33.0 ± 12.5	2.74	211
Ohmeda 3700 (earlobe)							
(1)	−10.2	12.1	0.730	0.850 ± 0.042	3.05 ± 33.6	12.3	91
(2)	−11.5	8.53	0.781	1.12 ± 0.028	−22.0 ± 33.9	8.46	304
Ohmeda 3740 (digit)							
(1)	0.49	6.10	0.783	0.605 ± 0.016	35.4 ± 13.0	4.78	81
(2)	0.17	4.05	0.892	0.73 ± 0.011	24.1 ± 13.1	3.28	226
Nellcor N-200 (1) (digit) control	−0.65	1.84	0.980	1.050 ± .002	−5.42 ± 0.12	1.84	93

ble includes values of bias, imprecision, correlation, linear regression slope and intercept (with uncertainties), and standard error of the estimate (SEE). With the exception of the Ohmeda 3700 (earlobe), all malpositioned sensors exhibit a regression slope much less than unity and a large positive y-intercept. This indicates decreased sensitivity to changes in Sa_{O_2}, also shown in figures 1–3. On the other hand, the Ohmeda 3700 (fig. 1B) has a linear regression slope greater than unity and a negative y-intercept. This oximeter shows increased sensitivity to Sa_{O_2} changes, but consistently underestimates Sa_{O_2} as shown by the large negative bias.

The effects of sensor malpositioning are clarified further by single-subject data. Figure 2 shows a portion of the data from the Ohmeda 3700 (earlobe), distinguishing the data for two of the 12 subjects. Two separate linear regressions are shown, along with corresponding statistics. The single-subject data fall much closer to their linear regression lines than do the pooled data, as evidenced by the smaller SEE values (table 2). Figure 3 shows data from three different pulse oximeters with malpositioned sensors on one subject, illustrating the wide range of Sp_{O_2} values that can be displayed simultaneously, particularly at low saturations.

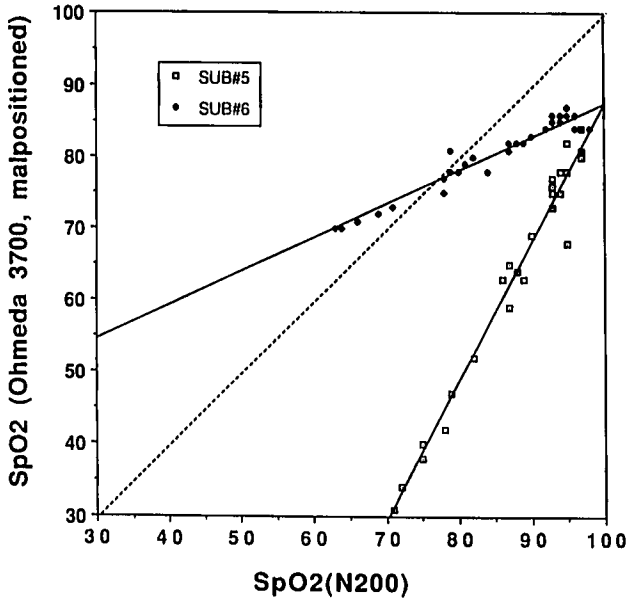

Fig. 2. Sp_{O_2} values for malpositioned Ohmeda 3700 (earlobe) *versus* control Sp_{O_2} values: single-subject data showing two individuals and their separate linear regressions. Single-subject data fall much closer to regression lines than pooled data (fig. 1), but the regressions for different individuals vary widely. Linear regression, subject 5: Y = 0.471 X + 40.3, SEE = 1.59, R = 0.952; subject 6: Y = 1.94 X − 106, SEE = 2.78, R = 0.986.

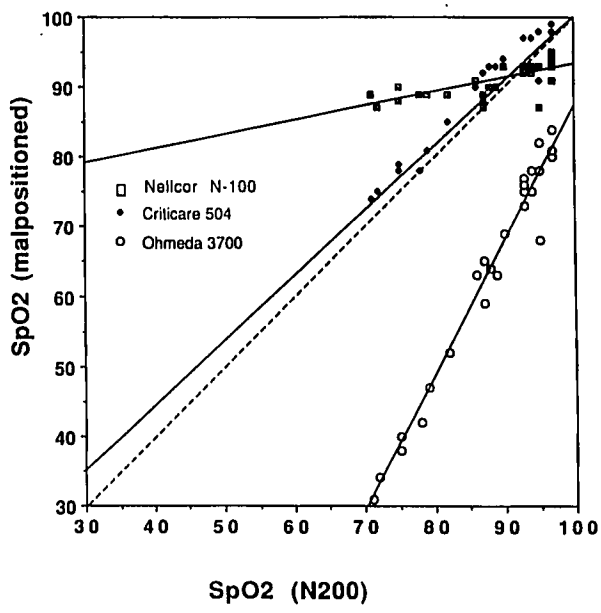

Fig. 3. Sp_{O_2} values for one subject *versus* control Sp_{O_2} values: three malpositioned oximeters. For a given individual during hypoxemia, a pulse oximeter with malpositioned sensor may underestimate saturation (Ohmeda 3700), overestimate saturation (Nellcor N-100), or be acceptably accurate (Criticare 504). The single-subject regression lines seen in this figure will differ for other individuals. Linear regression, Ohmeda 3700: Y = 1.94X −106, SEE = 2.78, R = 0.986; Nellcor N-100: Y = 0.202X + 73.1, SEE = 1.77, R = 0.702; and Criticare 501: Y = 0.960X + 6.21, SEE = 1.90, R = 0.975.

Discussion

In the original paper describing the penumbra effect, a pulse oximeter with malpositioned sensor was shown to yield falsely low Sp_{O_2} values in normoxemic subjects.[9] In the current study, we found that sensor malpositioning actually changes the entire calibration curve of the pulse oximeter. Different pulse oximeters are affected in markedly different ways, as seen in figure 1. Four of the five malpositioned oximeters yielded significant decreases in linear regression slope accompanied by large y-intercepts (table 2). This implies that, though these instruments may underestimate saturation at high Sa_{O_2} values, they will overestimate it at lower values. For example, the Nellcor N-100 yielded Sp_{O_2} values as high as 92% when the actual Sa_{O_2} was less than 70%.

The pooled data of figure 1 exhibit much random variability, as shown by the large values of imprecision and SEE (table 2). However, the single subject data of figure 2 provide a much "tighter" fit to the corresponding linear regressions, shown by smaller SEE values and larger R values. Much of the random variability of figure 1 is thus between-subject rather than within-subject variability. As shown in figure 3, for a given subject we may find pulse oximeters with malpositioned sensors whose Sp_{O_2} values are either too high or too low during hypoxemia. Linear regression lines such as that of the Nellcor N-100 in figure 3 are most concerning. The small slope of this regression (0.34) indicates a significant loss of sensitivity to Sa_{O_2} changes. That is, the oximeter not only yields large errors but may fail to follow trends in saturation.

This loss of sensitivity to Sa_{O_2} changes is similar to that encountered in a previous laboratory study of the effects of methemoglobinemia on pulse oximetry.[4] A possible explanation proposed in that paper regards the effect of signal-to-noise ratio on the pulse oximeter's calculation of Sp_{O_2}. The pulse oximeter computes the ratio of the fluctuating (AC) absorbance to the mean (DC) absorbance at each of the two light wavelengths, 660 and 940 nm. It then calculates the ratio R of these two intensity ratios: $R = (AC_{660}/DC_{660})/(AC_{940}/DC_{940})$. The value of Sp_{O_2} for a given value of R is found in a "look up" table stored in the pulse oximeter software. The addition of large amounts of "noise" to both the numerator and denominator of R will tend to drive this ratio toward unity. An R value of 1.0 corresponds to an Sp_{O_2} value near 85%. Thus, a poor signal-to-noise ratio could force Sp_{O_2} toward 85% and blunt the response to Sa_{O_2} changes. This type of behavior is seen in figures 1A and 1C, and in one of the curves in each of figures 2 and 3. This possible mechanism does not explain the Ohmeda 3700 behavior seen in figure 1B and in the single-subject curves of figures 2 and 3. The O-3700 may handle low signal-to-noise conditions differently than the other models tested.

We have used both tape-on (disposable) and clip-on (nondisposable) pulse oximeter sensors in this study. Tape-on sensors are subject to two different types of malpositioning: (1) sensor positioning such that light pathways do not all pass through tissue, and (2) misalignment of the light source and detector. The first type was the subject of the present study and of the previous study of Kelleher and Ruff.[9] The second type of malpositioning was avoided by maintaining good visual alignment of the source and detector in the tape-on sensors. Sensor misalignment can cause loss of signal (no displayed Sp_{O_2} value), but erroneous Sp_{O_2} values caused by misalignment have not been reported.

Pulse oximetry may be the most important advance in intraoperative monitoring of the past 30 yr. However, like any device, it has limitations and sources of error. It is well known that dyshemoglobins, intravenous dyes, venous pulsations, and nail polish can produce large Sp_{O_2} errors even when the displayed pulse rate is accurate.[3–8] We now must add sensor malpositioning to the list of sources of Sp_{O_2} error in the presence of an accurate pulse rate. This error is particularly important in that it can occur in any patient during any procedure, and if the sensor is not visible to the user, there may be no other evidence of malpositioning. Furthermore, a malpositioned sensor may produce Sp_{O_2} values that are falsely low, falsely high, or correct, depending on the instrument, the patient, and the actual hemoglobin saturation. The tendency of some oximeters to produce falsely high Sp_{O_2} values at low saturations (fig. 1) is especially disturbing. This could lead the clinician to believe that a patient was only mildly hypoxemic when, in fact, he was severely hypoxemic. It is not our purpose here to show that some pulse oximeters are "better" than others in their penumbra response. We have tested only a few models and only one sensor and software version for each model. We have demonstrated that different instruments show a wide variety of responses, so that the behavior of one model cannot be expected to apply to another, even from the same manufacturer.

The clinical consequences of this study are straightforward. The most effective way to guard against penumbra effect errors is to keep the oximeter sensor visible at all times. During procedures in which both arms must be tucked in at the patient's side, one should consider using an earlobe sensor or other facial sensor. Nasal bridge and forehead sensors are available, and other sites such as the buccal region, nasal septum or alae, and even the tongue are under investigation. If a digit on an inaccessible hand or foot must be used, tape-on sensors may provide more security than clip-on sensors. Finally, the clinician should maintain a high index of suspicion. If the Sp_{O_2} value is displayed intermittently or if the displayed pulse rate is not always correct, the sensor position should be checked immediately. We also recommend rechecking sensor position after any movement or repositioning of the pa-

tient, movement of the anesthesia machine, or placement of surgical drapes.

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