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Design and Evaluation of a New Reflectance Pulse Oximeter Sensor

Y. MENDELSON, PHD, J. C. KENT, MS, B. L. YOCUM, BS, AND M. J. BIRLE, BS

The design and construction of a new optical reflectance sensor suitable for noninvasive monitoring of arterial hemoglobin oxygen saturation with a pulse oximeter is described. The reflectance sensor was interfaced to a Datascope ACCUSAT pulse oximeter that was specially adapted for this study to perform as a reflectance oximeter. We evaluated the reflectance sensor in a group of 10 healthy adult volunteers. SpO_2 obtained from the forehead with the reflectance pulse oximeter and SpO_2 obtained from a finger sensor that was connected to a standard ACCUSAT transmittance pulse oximeter were compared simultaneously to arterial blood samples analyzed by an IL 282 CO-Oximeter. The equation for the best fitted linear regression line between the reflectance SpO_2 and HbO_2 values obtained from the reference IL 282 CO-Oximeter in the range between 62 and 100% was: SpO_2 (%) = 4.78 + 0.96 (IL); n = 110. The regression analysis revealed a high degree of correlation (r = 0.98) and a relatively small standard error of the estimate (SEE = 1.82%). The mean and standard deviations for the difference between the reflectance SpO_2 and IL 282 measurements was 1.38 and 1.85%, respectively. This study demonstrates the ability to acquire accurate SpO_2 from the forehead using a reflectance sensor and a pulse oximeter.

The recent development of transmittance pulse oximeters by combining optical plethysmography with the spectrophotometric determination of hemoglobin oxygen saturation in arterial blood (SpO_2) has provided a widely used technique for monitoring hypoxemia.

With transmittance pulse oximeters, sensor application is limited to several peripheral locations where light can be readily transmitted and detected, such as the finger tips, ear lobes, and toes on adults, and the foot or palms on infants. Alternatively, skin reflectance oximetry could enable SpO_2 measurement from more centrally located parts of the body such as the forearms, chest, and forehead, which cannot be monitored using conventional transillumination techniques.

It appears that reflectance pulse oximetry may be particularly suitable for direct assessment of fetal distress resulting from hypoxia during delivery, if used in addition to monitoring fetal heart rate by a scalp ECG electrode. Another suggested application of noninvasive reflectance pulse oximetry is for monitoring SpO_2 in the external carotid artery through a sensor applied to the skin near the superficial temporal artery.[1]

In this article we describe the design and construction of an optical reflectance sensor suitable for noninvasive monitoring of SpO_2 with a pulse oximeter. The experimental evaluation of the new sensor and verification that SpO_2 obtained with the reflectance sensor compare favorably with: (a) SpO_2 measured simultaneously by a finger sensor connected to a standard transmittance pulse oximeter, and (b) HbO_2 measured by the IL 282 CO-Oximeter from samples of arterial blood in a group of 10 healthy adult volunteers is presented.

PULSE OXIMETRY

The principle of pulse oximetry was proposed by Aoyagi *et al*[2] and further developed by Yoshiya *et al*.[3] This unique approach is based on the change in light absorption by tissue. The change is caused primarily by arterial blood pulsation. The pulsating arterioles in a vascular bed, by expanding and relaxing, modulate the amount of light absorbed by the tissue and thus produce a characteristic photoplethysmographic waveform. The changes in light absorption are used to measure SpO_2 noninvasively.

Initial attempts to develop a noninvasive oximeter that can measure oxygen saturation by analyzing the absolute light intensity that is diffusely reflected from the skin were only partially successful, mainly because of limited accuracy associated with variations in tissue attenuation and differences in skin pigmentation. Recently, we showed that accurate SpO_2 measurements can be made utilizing a reflectance sensor and the concept of pulse oximetry.[4,5] We found that SpO_2 can be calculated from the ratio of the reflected red and infrared photoplethysmograms based on a normalization in which the pulsatile (ac) component of the red and infrared photoplethysmograms is divided by the respective nonpulsatile (dc) component. The conversion of the red/infrared ratios to SpO_2 is performed by an empirical calibration of the oximeter. This process is performed by comparing the red/infrared ratios measured by the pulse oximeter with blood HbO_2 values obtained from an *in vitro* oximeter.

The excursions of photoplethysmographic signals detected by reflectance and transmittance sensors when placed on the forehead and finger, respectively, are inversely related to changes in arterial blood pulsations. Although the amplitude of the pulsatile component of the two waveforms is different, the shapes of the pho-

From the Worcester Polytechnic Institute, Biomedical Engineering Program, Worcester, MA 01609.
Address correspondence and requests for reprints to Yitzhak Mendelson, PhD, Biomedical Engineering Program, Worcester Polytechnic Institute, 100 Institute Rd., Worcester, MA 01609.

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toplethysmograms are virtually identical, as illustrated in Figure 1.

SENSOR DESIGN

The basic optical sensor of a pulse oximeter consists of a red and an infrared light emitting diode (LED) and a suitable photodetector. In a transmittance pulse oximeter sensor, the LEDs and the photodetector are mounted in opposition, whereas in a reflectance sensor, the LEDS and the photodetector are mounted side by side. The wavelength of the red LED is typically chosen from regions of the spectra where the absorption coefficient of Hb and HbO_2 are markedly different (*e.g.*, 660 nm). The infrared wavelength, on the other hand, is typically chosen from the spectral region where the difference in absorption coefficients of Hb and HbO_2 is relatively small (*e.g.*, 930 nm). The spectral response of the photodetector must overlap the emission spectra of the red and infrared LEDs.

Practically, the major limitation in reflection pulse oximetry is the comparatively low-level photoplethysmograms typically recorded from low-density, vascular areas of the skin. The feasibility of reflection pulse oximetry, therefore, is essentially dependent on the ability to design a sensor that can detect sufficiently strong reflection photoplethysmographic signals from various locations on the body.

The light from the LEDs in the reflectance sensor is diffused by the skin in all directions. This suggests that to detect most of the backscattered radiation from the skin, the photodetector must be able to detect light from an area concentric with the LEDs. The intensity of the backscattered light decreases in direct proportion to the square of the distance between the photodetector and the LEDs; thus the photodetector should be mounted close to the LEDs. We found experimentally that a separation of 4–5 mm between the LEDs and photodetector provides the best sensitivity in terms of detecting adequately large pulsatile components. We also found that when multiple photodetectors are arranged at equal distances around the LEDs, the total amount of backscattered light that can be detected by the reflectance sensor is directly proportional to the number of photodetectors.

The optical reflectance sensor used in this study consists of two red (peak emission wavelength: 660 nm) and two infrared (peak emission wavelength: 930 nm) LED chips (dimensions: 0.3 × 0.3 mm), and six silicon photodiodes (active area: 2.74 × 2.74 mm) arranged symmetrically in a hexagonal configuration as shown in Figure 2. To maximize the fraction of backscattered light collected by the sensor, the currents from all six photodiodes were summed. The LEDs and photodiode chips were mounted with conductive epoxy (Epo-tek H31, Epoxy Technology, Inc. Billerica, Massachusetts) on a ceramic substrate (dimensions: 13.2 × 13.2 × 0.25 mm) that was housed in a standard 24-pin (dimensions: 19 × 19 mm) microelectronic package (AIRPAX, Cambridge, Maryland), which is commonly used for packaging electronic circuits. The optical components were interconnected and wired to the package pins with 1-mil (0.0254-mm diameter) aluminum wires, by a conventional ultrasonic bonding technique. To minimize the amount of light transmission and reflection between the LEDs and the photodiodes within the sensor, a ring-shaped, optically opaque shield of black Delrin (Dupont, Wilmington, Delaware) was placed between the LEDs and the photodiode chips. The optical components were encapsulated inside the package using optically clear adhesive (NOA-63, Norland Products, Inc., New Brunswick, New Jersey). The microelectronic package was mounted inside a black Delrin housing (dimensions: 3.2-cm diameter × 1.5-cm high). The sensor can be attached to the skin by means of double-sided adhesive tape. The weight of the entire sensor assembly is approximately 11 g.

SIGNAL PROCESSING

The optical reflectance sensor was interfaced to a com-

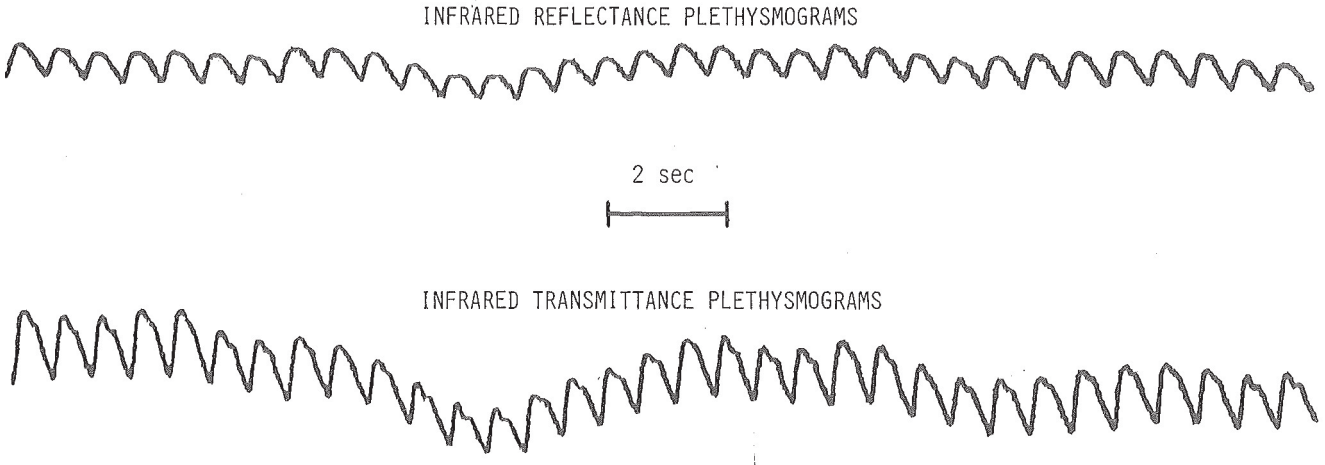

Figure 1. Relative infrared reflectance and transmittance photoplethysmograms recorded from the forehead and finger, respectively.

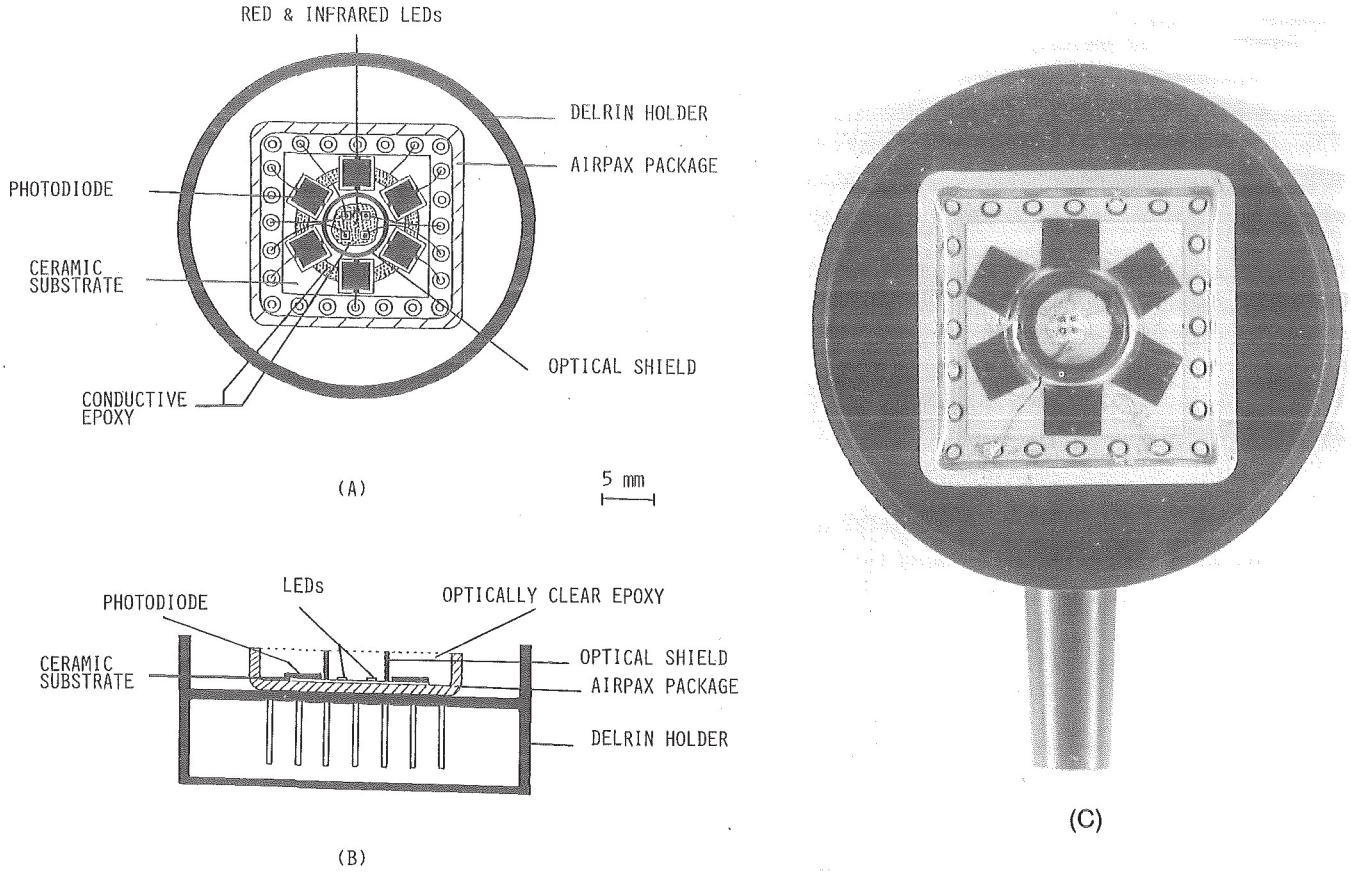

Figure 2. Diagram (A and B) and photograph (C) of the reflectance pulse oximeter sensor.

mercially available ACCUSAT (Datascope, Paramus, New Jersey) pulse oximeter.[6] The oximeter circuitry generates separate digital pulses to energize alternately the red and infrared LEDs in the sensor. The time-multiplexed current pulses from the photodiodes, which correspond to the red and infrared light intensities reflected from the skin, are first converted by the oximeter to proportional voltage pulses. The pulses are subsequently demultiplexed into two separate channels. The red and infrared photoplethysmographic signals are then amplified and high-pass filtered to separate the ac and dc components of each photoplethysmographic waveform.

Before the study began, an ACCUSAT pulse oximeter was modified by adjusting the intensities of the red and infrared LEDs so that the dc component of each photoplethysmogram was approximately equal to the corresponding dc level obtained from transmittance photoplethysmograms as measured by a standard ACCUSAT sensor designed for a finger. The adjustment was performed while the reflectance and transmittance sensors were applied to the forehead and right index finger of a white subject breathing ambient air. No further adjustments were made throughout the study. The reflectance oximeter was adapted to provide a continuous readout of the ac and dc components of the red and infrared photoplethysmograms.

In addition to the modified ACCUSAT pulse oximeter, a second standard ACCUSAT transmittance pulse oximeter was used to measure SpO_2 with a finger sensor. SpO_2 from each of the two pulse oximeters was acquired every 2 s (0.5 Hz) using an AT&T 6300 personal computer. The conversion of the transmitted and reflected red/infrared ratios measured by each ACCUSAT pulse oximeter to SpO_2 was performed using the same internal calibration algorithms. The exact algorithm for calculating SpO_2 was unavailable.

IN VIVO EVALUATION

The purpose of this study was to evaluate the performance of the reflectance pulse oximeter sensor during progressive steady-state hypoxia in humans and to compare the values obtained with the reflectance sensor to those from an ACCUSAT transmittance pulse oximeter and from the IL CO-Oximeter detecting the HbO_2 of simultaneously drawn arterial blood samples.

Tests were performed on 10 healthy, nonsmoking, adult volunteers of different ages and skin pigmentations in compliance with the University of Massachusetts Medical Center review guidelines for humans experiments. The subject distribution was: one deeply pigmented black, two subjects of lightly pigmented Oriental descent, and

two darkly tanned and five lightly tanned whites. Subject age ranged from 22–39 years (mean ± SD: 29.2 ± 5.6 years). Measured hematocrit was in the range of 35–44% (mean ± SD: 40 ± 2.65%). Each volunteer was informed of the complete procedure and possible risks associated with arterial cannulation and hypoxic gas breathing. Each volunteer received monetary compensation for participation in the study.

A modified Allen's test for assessing the radial and ulnar arterial blood circulation to the hand was performed on each subject prior to arterial cannulation. A Teflon cannula (22-gauge, 3.2-cm long) was inserted into the radial or ulnar artery of each subject after the subcutaneous tissue around the puncture site was anesthetized locally with a 1-ml injection of 1% lidocaine hydrochloride (Xylocaine).

All instruments warmed up for at least 30 min before the study. The transmittance sensor of the ACCUSAT pulse oximeter was attached to the index finger on the hand opposite that of the arm with the arterial cannula. The sensor of the reflectance pulse oximeter was attached to the middle of the forehead. Samples of arterial blood (approximately 1 ml/sample) were drawn into 3-ml heparinized syringes and analyzed immediately by the Instrumentation Laboratories IL 282 CO-Oximeter (Instrumentation Laboratories, Lexington, Massachusetts). Simultaneous measurements of total hemoglobin (Hb), oxyhemoglobin (HbO_2), carboxyhemoglobin (HbCO), and methemoglobin (Hi) were obtained from each blood sample. The arterial cannula was flushed with 0.9% normal heparinized saline solution (1000 units/250 ml) between blood samplings. Care was taken to ensure that the arterial line and the blood-sampling syringes were free of air bubbles.

A standard lead I ECG and the end-tidal CO_2 were continuously monitored by a Hewlett-Packard 78345A patient monitor (Hewlett-Packard, Andover, Massachusetts). Each subject was placed in the supine position. A face mask was tightly fitted over the subject's mouth and nose, and the subject was asked to breathe spontaneously different O_2 and N_2 gas mixtures. The inspired O_2/N_2 gas was supplied by a modified Heidbrink anesthesia machine (Ohio Medical Products, Madison, Wisconsin). The breathing circuit was equipped with a CO_2 scrubber (soda lime). Inspired O_2 concentration was adjusted between 10 and 100% and was monitored continuously with an IL 408 oxygen monitor that was inserted in the inspiratory part of the breathing circuit.

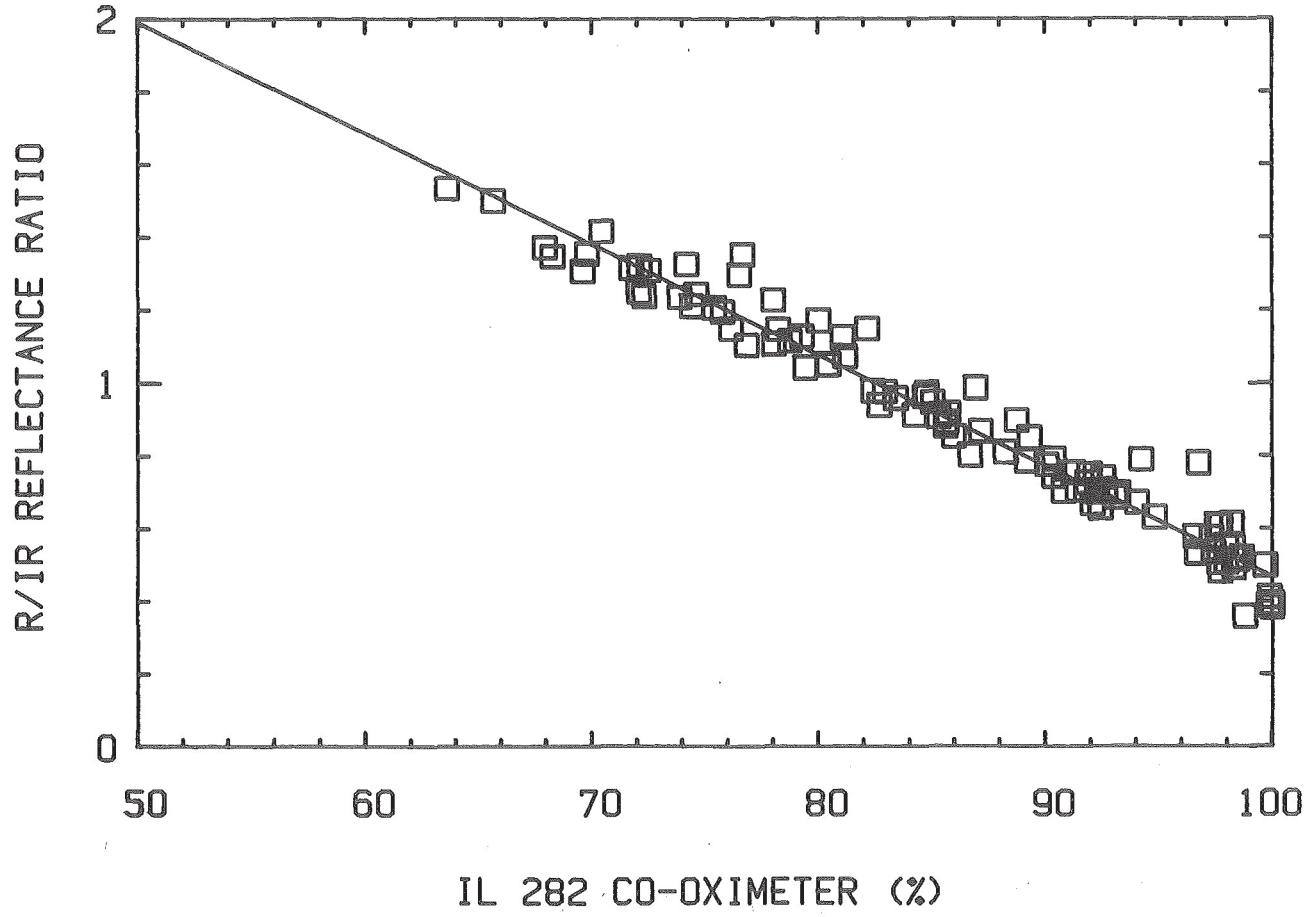

Figure 3. Comparison of the IL 282 CO-Oximeter (x-axis) and the red/infrared ratios measured by the reflectance pulse oximeter (y-axis) during progressive steady-state hypoxia in 10 subjects. $y = 3.51 - 0.030x$; $r = -0.98$; SEE = 0.060; $n = 110$; $p < 0.001$. The solid line represents the best fitted linear regression line.

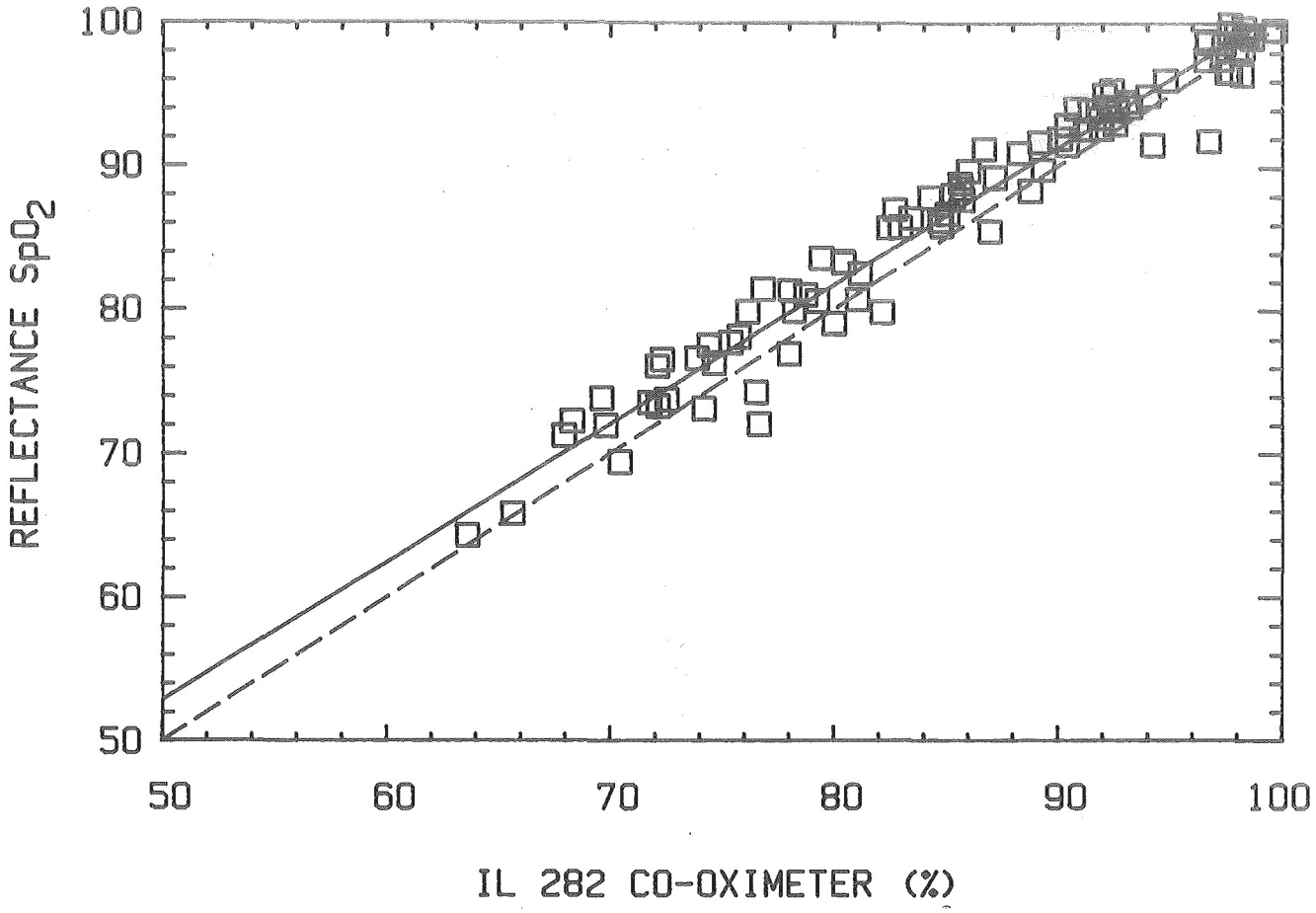

Figure 4. Comparison of SpO_2 measurements obtained from the reflectance pulse oximeter (y-axis) and the IL 282 CO-Oximeter (x-axis) during progressive steady-state hypoxia in 10 subjects. $y = 4.78 + 0.96x$; $r = 0.98$; SEE = 1.82; $n = 110$; $p < 0.001$. The solid line represents the best fitted linear regression line. The dashed line represents identity.

Progressive hypoxemia was gradually induced by changing the inspired fractions of O_2 and N_2. To provide a relatively uniform distribution of SpO_2 data points, samples were recorded during both desaturation and reoxygenation. Initially, the inspired O_2 concentration was changed in step decrements, each producing approximately a 5% decrease in SpO_2 as determined from the ACCUSAT transmittance pulse oximeter display. The inspired O_2 was maintained at each level until the pulse oximeter readings were stable. When the inspired O_2 reached 10%, corresponding to a saturation of approximately 65%, the process was reversed, and the inspired O_2 was increased in a similar stepwise manner to 100%. SpO_2 from the ACCUSAT and the reflectance pulse oximeters during blood sampling was acquired every 2 s (0.5Hz), using an AT&T 6300 personal computer.

None of the subjects showed ECG abnormalities before or during the study. All subjects tolerated the procedure well, without adverse reactions.

DATA ANALYSIS

For each step change in inspired O_2, readings from the ACCUSAT transmittance and reflectance pulse oximeters were averaged for 10 s before and after blood sampling and compared with the corresponding HbO_2 values measured by the IL 282 CO-Oximeter. To avoid operator biases, the data from each pulse oximeter were acquired automatically by the computer and later subjected to the same statistical tests. Averaged readings for the 10 subjects were pooled and a least-squares linear regression analysis was performed. Student's t test determined the significance of each correlation; $p < 0.001$ was considered significant.

The SpO_2 displayed by two-wavelength pulse oximeters account only for the presence of HbO_2 and Hb in the blood. The presence of HbCO, Hi, or any other interfering substance in the blood is not accounted for. Therefore, the term often used to represent SpO_2 measured by pulse oximeters is functional saturation, *i.e.*, $HbO_2/(Hb + HbO_2)$. The IL 282 CO-Oximeter, on the other hand, displays the percentage of oxygenated hemoglobin expressed as a fraction of the total hemoglobin present in the blood, *i.e.*, $HbO_2/(Hb + HbO_2 + HbCO + Hi)$. To compare SpO_2 measured by the pulse oximeters with corresponding readings from the IL 282

CO-Oximeter, both HbCO and Hi values from each blood sample were used to convert the IL 282 readings to functional SpO_2, according to the following relationship[7]:

$$\%SpO_2 \text{ (functional)} = (HbO_2 \times 100)/(100 - HbCO - Hi).$$

RESULTS

A total of 110 pairs of data points were used in the regression analysis, which gave the estimated slopes and intercepts of the regression lines. An average of 11 blood samples was collected from each subject. Each pair of data points represents a different hypoxic level. Regression analysis of the HbO_2 values obtained from the IL 282 CO-Oximeter (x-axis) vs the normalized red/infrared ratios (y-axis) as measured by the reflectance pulse oximeter is shown in Figure 3. The equation for the best fitted linear regression line was: $y = 3.51 - 0.030x$; $r = -0.98$; SEE = 0.060; $p < 0.001$. A comparison of SpO_2 readings from the reflectance pulse oximeter (y-axis) and the IL 282 CO-Oximeter (x-axis) is shown in Figure 4. The equation for the best fitted linear regression line was: $y = 4.78 + 0.96x$; $r = 0.98$; SEE = 1.82; $p < 0.001$. Figure 5 shows the comparison of SpO_2 values measured by the ACCUSAT reflectance pulse oximeter (y-axis) and the ACCUSAT transmittance pulse oximeter (x-axis). The linear regression equation for this comparison is: $y = 5.85 + 0.95x$; $r = 0.98$; SEE = 2.23; $p < 0.001$. The standard deviations of the mean differences between the reflectance oximeter SpO_2 and IL 282 HbO_2 values for four different saturation ranges are summarized in Figure 6.

DISCUSSION

Pulse oximetry has become a widely utilized medical technology, particularly in anesthesia and intensive care. Pulse oximeters offer significant monitoring advantages because of their reliability, simple operation, and the benefit of providing continuous SpO_2 monitoring.

Noninvasive monitoring of oxygen saturation based upon skin-reflectance spectrophotometry was first described by Brinkman and Zijlstra.[8] They showed that changes in oxygen saturation can be recorded noninvasively from an optical sensor attached to the forehead. The use of light reflection instead of tissue transillumi-

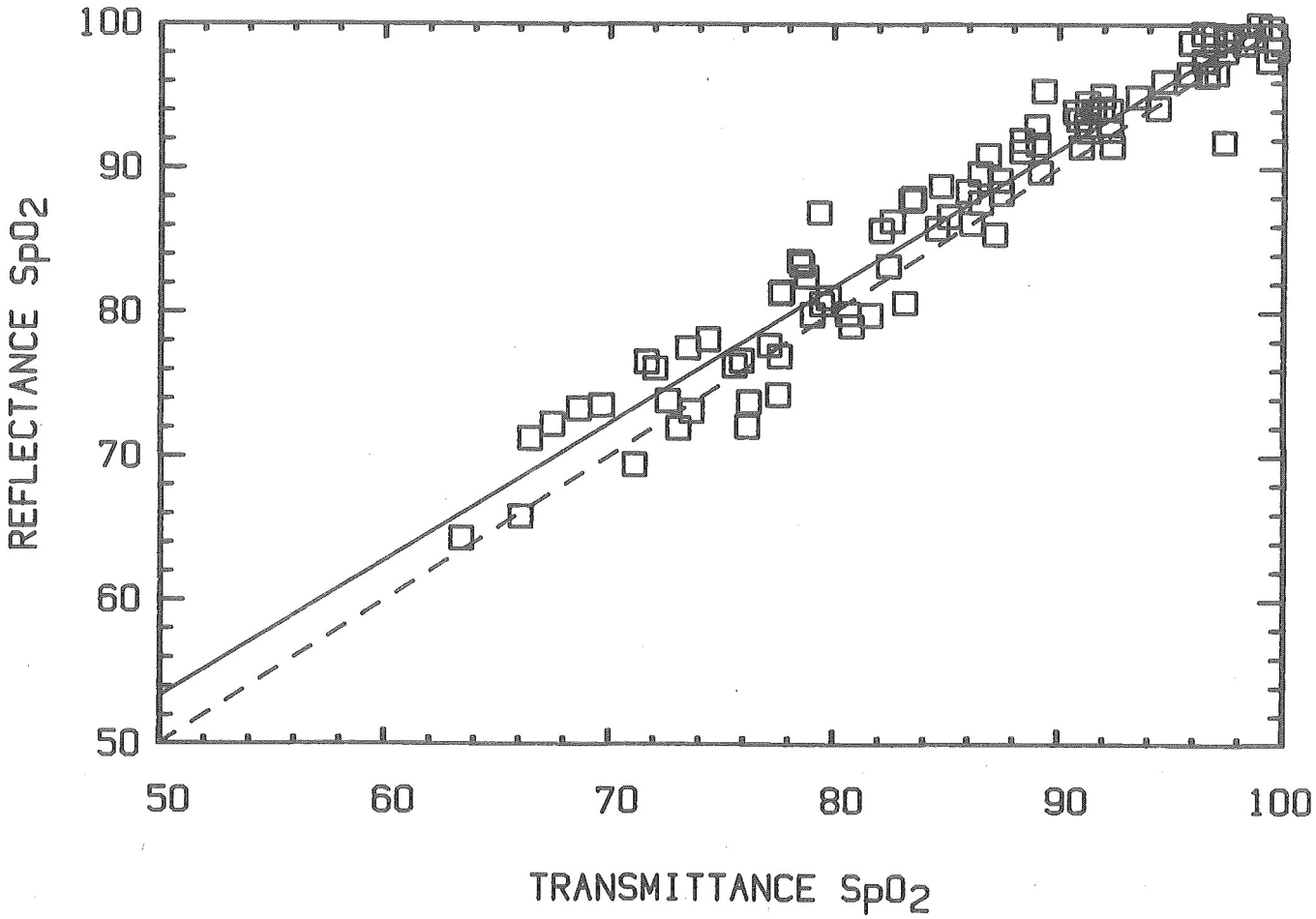

Figure 5. Comparison of SpO_2 measured by the reflectance pulse oximeter (y-axis) and the finger transmittance pulse oximeter (x-axis) during progressive steady-state hypoxia in 10 subjects. $y = 5.85 + 0.95x$; $r = 0.98$; SEE = 2.23; $n = 110$; $p < 0.001$. The solid line represents the best fitted linear regression line. The dashed line represents identity.

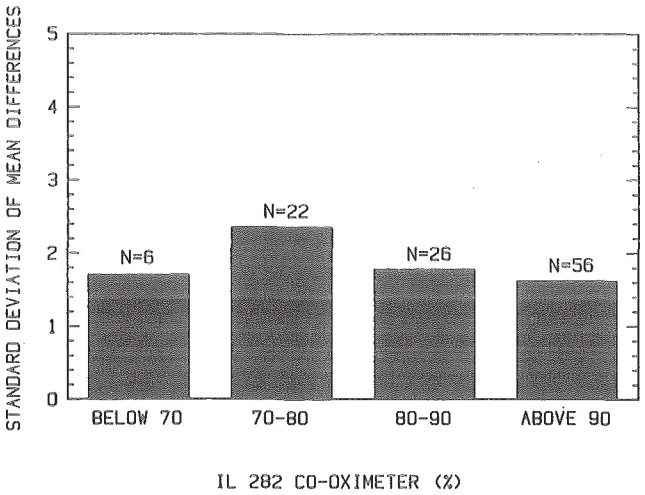

Figure 6. Standard deviations of the mean differences between the reflectance pulse oximeter and the IL 282 CO-Oximeter. N is the number of paired data points included in the statistical analysis.

nation was suggested to enable noninvasive monitoring from virtually any skin surface. More recently, Cohen and Wadsworth[9] and Takatani[10] attempted to develop a skin reflectance oximeter utilizing a similar spectrophotometric approach. In those three reflectance oximeters, oxygen saturation was calculated from the absolute light intensity diffusely reflected (backscattered) from the skin. Although these developments represent significant advancements in noninvasive oximetry, the major problems were limited accuracy, poor reproducibility, and difficulties in absolute calibration.

Available transmittance pulse oximeters can be used only on a few specific peripheral locations. The approach presented in this article demonstrates that SpO_2 can be measured from an alternate site, specifically the forehead. This technique provides a clinically acceptable alternative to presently available transmittance pulse oximeters. Although we found that reflectance photoplethysmograms can be detected from several locations on the body (*e.g.*, forearm, chest, and back), the relatively small, photoplethysmographic signals lead to practical problems when processed by the pulse oximeter. Therefore, the choice of the forehead as a site for our study was based on the fact that at this location, relatively large reflectance photoplethysmographic signals can be detected.

The relationship between the red/infrared ratios measured by the reflectance pulse oximeter and HbO_2 measured by the IL 282 CO-Oximeter produced a regression relationship similar in slope and intercept to that observed from transmittance pulse oximeters.[11] This suggests that SpO_2 monitoring from the forehead can be performed successfully using a reflectance sensor connected to a standard transmittance pulse oximeter without significant modifications of hardware and software.

SUMMARY

We compared simultaneous SpO_2 from a reflectance pulse oximeter sensor attached to the forehead and from a transmittance pulse oximeter with a sensor attached to a finger with HbO_2 from arterial blood samples in a group of 10 healthy adult volunteers. A high degree of correlation was found for SpO_2 between 62 and 100%. Relative to arterial blood samples, the SEE for the reflectance pulse oximeter was 1.82%. We conclude that in situations in which a transmittance pulse oximeter cannot be used reliably, the forehead may be considered as a suitable alternative site for monitoring SpO_2 with a reflectance pulse oximeter sensor.

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