EXPERIMENTAL AND CLINICAL EVALUATION OF A NONINVASIVE REFLECTANCE PULSE OXIMETER SENSOR

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ABSTRACT. The objective of this study was to evaluate a new reflectance pulse oximeter sensor. The prototype sensor consists of 8 light-emitting diode (LED) chips (4 at 665 nm and 4 at 820 nm) and a photodiode chip mounted on a single substrate. The 4 LED chips for each wavelength are spaced at 90-degree intervals around the substrate and at an equal radial distance from the photodiode chip. An optical barrier between the photodiode and LED chips prevents a direct coupling effect between them. Near-infrared LEDs (940 nm) in the sensor warm the tissue. The microthermocouple mounted on the sensor surface measures the temperature of the skin-sensor interface and maintains it at a preset level by servoregulating the current in the 940-nm LEDs. An animal study and a clinical study were performed. In the animal study, 5 mongrel dogs (weight, 10–20 kg) were anesthetized, mechanically ventilated, and cannulated. In each animal, arterial oxygen saturation (SaO_2) was measured continuously by a standard transmission oximeter probe placed on the dog's earlobe and a reflectance oximeter sensor placed on the dog's tongue. In the first phase of the experiment, signals from the reflectance sensor were recorded while the dog was immersed in ice water until its body temperature decreased to 30°C. In the second phase, the animal's body temperature was normal, and the oxygen content of the ventilator was varied to alter the SaO_2. In the clinical study, 18 critically ill patients were monitored perioperatively with the prototype reflectance sensor. The first phase of the study investigated the relationship between local skin temperature and the accuracy of oximeter readings with the reflectance sensor. Each measurement was taken at a high saturation level as a function of local skin temperature. The second phase of the study compared measurements of oxygen saturation by a reflectance oximeter (SpO_2[r]) with those made by a co-oximeter (SaO_2[IL]) and a standard transmission oximeter (SpO_2[t]). Linear regression analysis was used to determine the degree of correlation between (1) the pulse amplitude and skin temperature; (2) SpO_2(r) and SaO_2(IL); and (3) SpO_2(t) and SaO_2(IL). Student's t test was used to determine the significance of each correlation. The mean and standard deviation of the differences were also computed. In the animal study, pulse amplitude levels increased concomitantly with skin temperature (at 665 nm, $r = 0.9424$; at 820 nm, $r = 0.9834$; $p < 0.001$) and SpO_2(r) correlated well with SaO_2(IL) ($r = 0.982$; SEE = 2.54%; $p < 0.001$). The results of the clinical study are consistent with these findings. The prototype reflectance pulse oximeter sensor can yield accurate measurements of oxygen saturation when applied to the forehead or cheek. It is, therefore, an effective alternative to transmission oximeters for perioperative monitoring of critically ill patients.

KEY WORDS. Monitoring: pulse oximetry. Measurement techniques: pulse oximetry.

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Optical pulse oximetry uses the absorption difference between oxyhemoglobin and deoxyhemoglobin (Fig 1) [1] in combination with the plethysmographic principle. During each heartbeat, a small amount of blood is

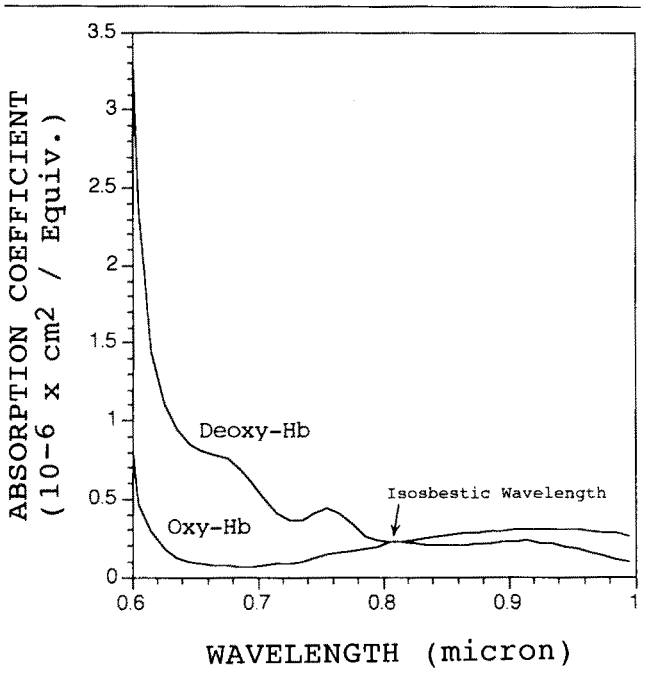


Fig 1. Absorption coefficients of oxyhemoglobin and deoxyhemoglobin molecules in the red and near-infrared regions.

pumped into tissue, which results in changes in tissue blood volume. When the forward or backward scattered light from the tissue is measured, the light signal cycles up and down with each heartbeat. This phenomenon, called photoplethysmography, has been used to noninvasively measure such variables as tissue blood flow [2], arterial blood pressure [3], and viscoelastic properties of the vessels [4]. Recent innovations by Aoyagi et al [5] indicate that arterial saturation (SaO_2) can be estimated by assuming that the pulsatile change in the forward scattered optical signal is due to changes in arterial blood volume. The pulse amplitude level thus varies depending on either the blood volume or the hemoglobin content and oxygen saturation.

In transmission oximetry, where forward scattered light is measured, the basis for tissue modeling and signal processing is the Beer-Lambert law, through which arterial saturation is measured. Two wavelengths, usually 665 and 940 nm, are used and the ratio or the square of the ratio of the pulse amplitude at each wavelength is correlated with the SaO_2. The method is limited, however, because the Beer-Lambert law does not account for the scattering of light in tissue. In addition, transmission oximeter probes can only be applied to the fingertip or earlobe, whereas reflectance probes can be applied to any portion of the body [6–8].

The reflectance pulse oximeter, as reported by Mendelson et al [9], was the first monitor to measure SaO_2 from the fingertip; the sensor was evaluated in healthy volunteers in comparison with the Hewlett-Packard ear oximeter (Hewlett-Packard, Andover, MA). Although several reflectance pulse oximeters have been described since then [10,11], no clinical application has of yet been reported. The effectiveness of reflectance pulse oximeters has been hindered by a poor signal to noise ratio and small pulsatile signals, particularly at the red wavelength. These weak signals preclude continuous measurement at the forehead or cheek. Mendelson et al [10] used multiple photodiodes around the light-emitting diode (LED) to increase the signal level, but these extra diodes increased the size of the sensor substantially and made it cumbersome for use in pediatric patients. Cui et al [12] suggested the use of a shorter wave length, around 550 nm, to enhance the pulsatile signal level. However, because of higher absorption of light by hemoglobin and lower efficiency of the LED and solid-state photodetectors at this wavelength, the use of shorter wavelengths creates difficult instrumentation problems. The Hewlett-Packard earlobe oximeter incorporates a heater to warm the tissue to approximately 40°C, thus causing vasodilation [13]. In a recent report, Mendelson and McGinn [14] incorporated the heater in their reflectance sensor. However, after 3 to 4 hours of continuous use, reflectance sensors may cause skin burns, as occurs with transcutaneous Po_2 sensors. Another drawback to the reflectance sensor is that the proper signal processing method for deriving SaO_2 does not exist. Most reflectance oximeters use the same signal processing method as transmission oximeters. Also, the accuracy of the reading given by a reflectance oximeter may be affected by the presence of venous blood, particularly when the patient is in the supine position.

In this study, a new reflectance pulse oximeter sensor, designed to circumvent the problems encountered by previous investigators, was developed. The 3-dimensional photon diffusion theory was used to model the tissue and to design an optical sensor and signal processing method. Evaluations of the sensor in animals and critically ill patients are presented.

MATERIALS AND METHODS

Theoretical Basis for the Design of the Reflectance Sensor

The 3-dimensional photon diffusion theory was used to design a reflectance sensor and signal processing method [15–17]. Parameters such as wavelength, light source, and detector separation distance were modeled into the theory to optimize the ratio of the pulsatile (AC) to the

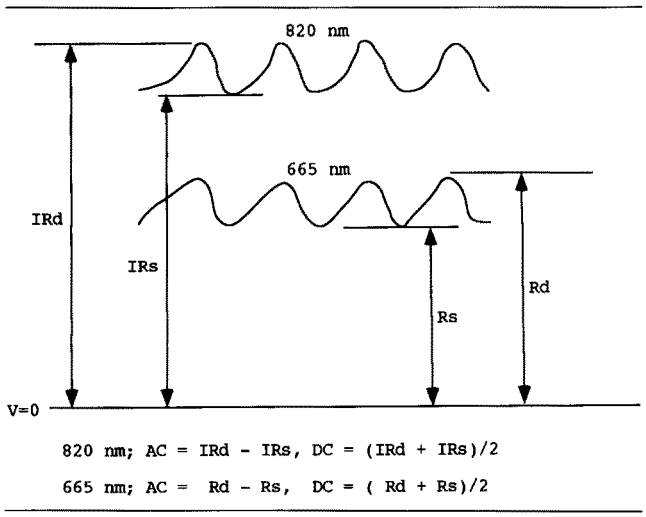


Fig 2. Graphic representation of the AC and DC components of the pulse waves used in this study. In the figure, "IR_d" and "IR_s" represent diastolic and systolic levels for 820 nm wavelength and "R_d" and "R_s" represent those for 665 nm wavelength.

average (DC) signal level (Fig 2). The linearity of the SaO_2 computation algorithms, which included (1) AC_{L1}/AC_{L2}, (2) $\log(AC)_{L1}/\log(AC)_{L2}$, and (3) a comparison between $(AC/DC)_{L1}/(AC/DC)_{L2}$ and SaO_2, was investigated for various combinations of wavelengths and sensor geometry. Here, L1 corresponds to a wavelength in the red region and L2 corresponds to a wavelength in the infrared region. The largest amplitude changes with respect to SaO_2 occur at 665 nm (Fig 3A). The AC/DC ratio increased for all wavelengths as the separation distance increased (Fig 3B). However, the absolute signal level decreased as the separation distance increased. Thus, the optimal distance had to be selected according to the limitations of the measurement system. A separation distance of 5 to 7 mm was found to be optimal; however, a distance of 3 mm was selected to best focus the light on the subcutaneous capillary beds. For the combination of the wavelengths 665 and 820 nm, the $(AC/DC)_{L1}/(AC/DC)_{L2}$ algorithm yielded the best linearity over a wide range of values for SaO_2 (Fig 3C). In addition, with this method the effect of changes in the arterial to venous blood volume distribution in tissue, venous saturation, and skin pigmentation on the computation of SaO_2 was minimized.

The Optical Sensor

The optical sensor (Fig 4) is mounted in a circular cup. This design keeps the sensor stable when it is fixed to the skin surface and minimizes heat loss to surrounding air. Inside the optical sensor, the photodiode chip is located at the center and is surrounded by an optical barrier that blocks direct coupling between the LEDs and the photodiode. The LED chips are placed symmetrically and at an equal distance around the detector to enhance pulsatile signal level and average out perturbations due to tissue heterogeneity. The wavelengths of the LEDs are 665 and 820 nm, the latter being the reference wavelength and also being close to the isosbestic wavelength of 805 nm (Fig 1). These two wavelengths, 665 nm and 820 nm, give the best linearity when used with the linear regression analysis, the computation algorithm described earlier. In addition, infrared LEDs (wavelength, 940 nm) were incorporated in the sensor to heat the tissue, if necessary. A microthermocouple mounted on the sensor surface measures the temperature between the sensor and the skin, controls the current level of the infrared LEDs, and, thus, regulates skin temperature to the preset range of 30 to 40°C.

Oximeter System

The oximeter operates as follows (Fig 5). The LEDs are sequentially excited by a narrow-width pulse (10 μsec) at a frequency of 1 KHz. The light signal reflected from the tissue is amplified and differentiated from 665 to 820 nm. The systolic and diastolic levels of the pulsatile signal are then sampled and held for computation of the AC and DC values for each wavelength. A personal computer Maxy (Mitsubishi) computes SaO_2 and $SpO_2(r)$ on-line by using the following linear regression equation:

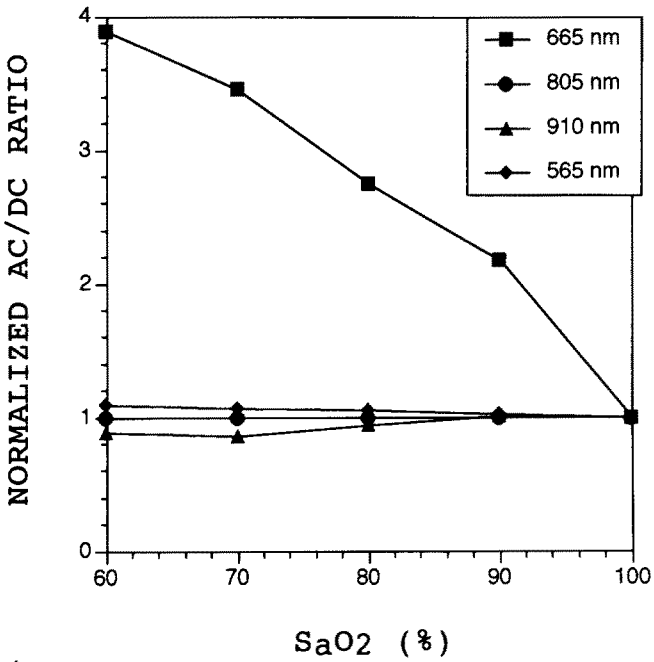
$$SpO_2(r) = A + B \times R \quad (1)$$

where A and B are constants that depend on physiologic characteristics and the sensor's geometry, and R is $(AC/DC)_{665}/(AC/DC)_{820}$ (see Fig 2).

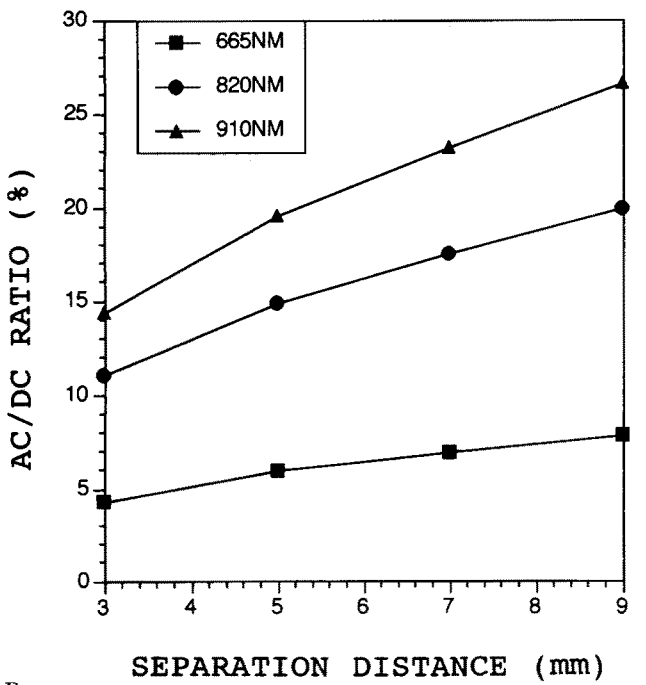
Animal Study

The experimental protocol was reviewed and approved by the Institutional Animal Review Committee. Five mongrel dogs (weight, 10–20 kg) were anesthetized with halothane in oxygen, intubated, and mechanically ventilated in the lateral position. In each dog, the femoral artery was cannulated so that arterial blood pressure could be measured and blood samples could be obtained as needed. A standard transmission pulse oximeter probe was placed on the earlobe to continuously monitor SpO_2. A reflectance pulse oximeter sensor was placed on the tongue and affixed with double-sided electrode adhesive.

The first phase of the experiment was designed to ascertain the effect of body temperature on the pulse



A



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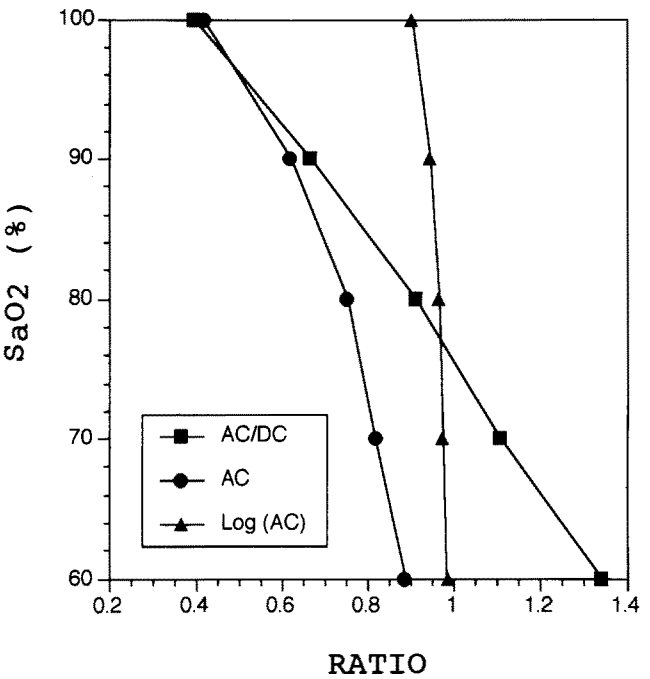


C

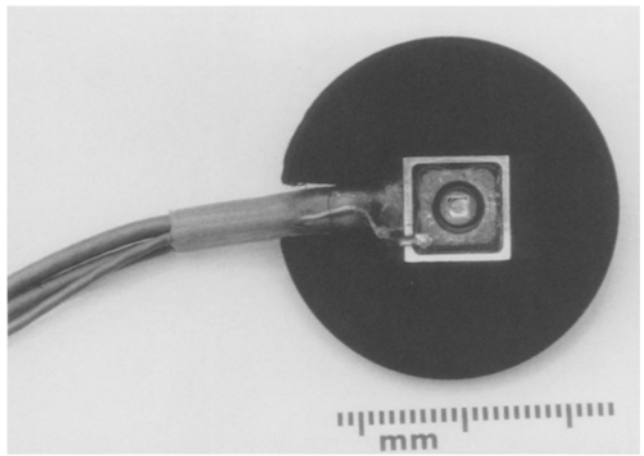
Fig 3. Theoretical results based on the 3-dimensional photon diffusion theory. (A) *Normalized AC/DC ratio plotted against* SaO_2 *for the wavelengths of 565, 660, 805, and 910 nm. The data were normalized to the AC/DC ratio at the 100%* SaO_2 *values.* (B) *AC/DC ratio versus separation distance between the LED and photodiode.* (C) SaO_2 *versus pulse amplitude ratio of two wavelengths (665 and 820 nm) for AC/DC, AC, and log(AC) algorithms.*

amplitude level reported by the reflectance sensor. Skin temperature and signals from the reflectance sensor were recorded while each dog was immersed in ice water until its body temperature decreased to 30°C. The SaO_2 of the dogs was maintained at 100% since the 665-nm signal is weakest at high saturation.

In the second phase of the experiment, the dogs' body temperatures were normal. The oxygen content of the ventilator (FIO_2) was varied to alter the SaO_2 level. When the transmission oximeter reading reached the steady-state level, blood samples were taken and analyzed for hemoglobin content and saturation by an IL-282 Co-Oximeter (Instrumentation Laboratories, Lexington, MA) SaO_2(IL). The SaO_2 was reduced stepwise to approximately 40 to 50%. This procedure was repeated several times.

Clinical Study

After informed consent approved by the Institutional Review Board was obtained (in the case of pediatric patients, informed consent was given by the parents or guardians), a sensor was attached with double-sided electrode adhesive to the patient's forehead or cheek, whichever location did not interfere with the surgical procedure. If adequate pulse levels were not obtained within 5 to 10 minutes of sensor application, the sensor



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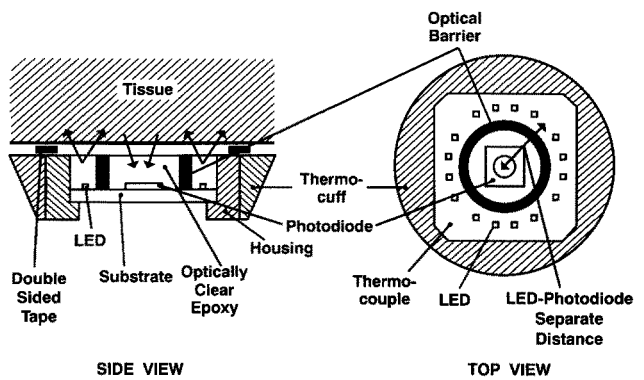

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Fig 4. (A) *Prototype hybrid optical sensor and* (B) *schematic drawing of the sensor. A double-sided adhesive is attached to the top side of the sensor* (A) *and to the skin.*

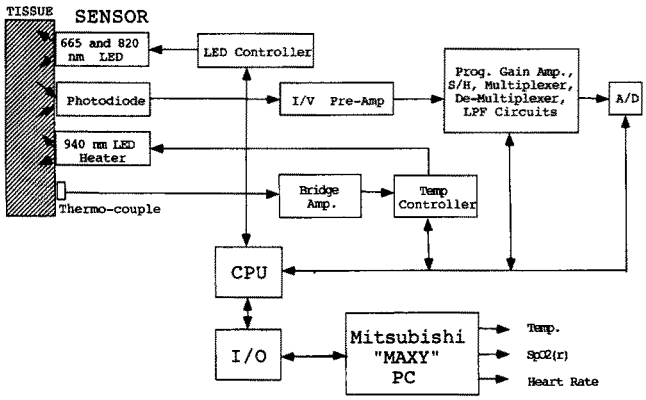

Fig 5. Block diagram of the reflectance pulse oximeter controller and data acquisition system. An LED controller controls the current through 665 and 820 nm LEDs and an I/V Pre-Amp converts the current through the photodiode that is proportional to the irradiated light level into voltage. Prog Gain Amp (programmable gain amplifier) adjusts the output voltage level, S/H (sample and hold circuit) samples and holds 665 and 820 nm diastolic and systolic reflectance values, and LPF (low pass filter) filters high-frequency noise. The bridge amplifier and temperature controller are used to monitor skin temperature and control the 940 nm LED current level. The CPU (central processing unit) controls the entire operation. A/D, analog to digital converter; I/O, input/output interface.

was moved to a new location. Or, if skin temperature was lower than 35°C, the heater was turned on.

The objective of the first phase of the clinical study was to determine the effect of local skin temperature on the accuracy of oximeter readings. The measurement of the reflectance signals was carried out at high saturation levels as a function of the local skin temperature.

The second phase of the study compared $SpO_2(r)$ measurements with $SaO_2(IL)$ and readings from a standard transmission oximeter ($SpO_2[t]$), usually from Nellcor (Haywood, CA). Critically ill patients who might have a lower SaO_2 were selected, including patients who were undergoing lobectomy of the lungs, cardiac patients with an atrial septal defect or ventricular septal defect, and pediatric patients with congenital heart disease. Some of these patients showed low SaO_2 even with oxygen therapy. Most of them required extensive routine monitoring during their operation. Monitoring included arterial cannulation, central venous pressure, pulmonary artery pressure, left arterial pressure, and cardiac output measurements. Oxygen saturation was monitored routinely by the Nellcor transmission oximeter applied to the fingertip or earlobe. As necessary, blood samples were drawn for analysis of blood gases, pH, hemoglobin content, and SaO_2.

Data Analysis

In processing $SpO_2(r)$ on line, usually 4 heartbeats were averaged to yield 1 data point. Linear regression analysis was performed to determine the degree of correlation between (1) the pulse amplitudes and the skin temperature, (2) $SpO_2(r)$ and $SaO_2(IL)$, and (3) $SpO_2(t)$ and $SaO_2(IL)$. Student's *t*-test was used to determine the significance of each correlation; $p < 0.001$ was considered significant. Since the correlation analysis does not yield the accuracy of measurement, mean and standard deviation of the differences between (1) $SpO_2(r)$ and $SaO_2(IL)$ and (2) $SpO_2(t)$ and $SaO_2(IL)$ were also computed [18]. The mean is the bias of the measurement. It indicates whether one method systematically overestimated or underestimated values reported by another method. The standard deviation of the bias, which is often referred to as the precision, represents the variability of random error and indicates the 95% confidence limit.

Finally, the mean errors and standard deviations of each measurement were computed. The mean error was defined as the absolute bias divided by the corresponding SaO_2(IL).

RESULTS

Animal Study

The results of the laboratory study indicate that pulse amplitude levels increase as skin temperature increases (Fig 6) (665 nm, $r = 0.9424$; 820 nm, $r = 0.9834$; $p < 0.001$). When the temperature was maintained above 34 to 35°C, there were sufficient pulsatile signal levels at 665 nm (pulse amplitude of approximately 20 yielded sufficient signal to noise ratio) for computation of SpO_2(r). Over the saturation range of 40 to 100%, the measurements of SpO_2(r) showed an excellent correlation with SaO_2(IL) ($r = 0.982$; SEE = 2.54%; $p < 0.001$) (Fig 7A). Figure 7B shows the scatter plot between the differences; that is, SpO_2(r) − SaO_2(IL) compared with SaO_2(IL). Corresponding mean and standard deviation of differences were −0.1205 and 2.84, respectively. The means and standard deviations and errors for various ranges of SaO_2 are summarized in

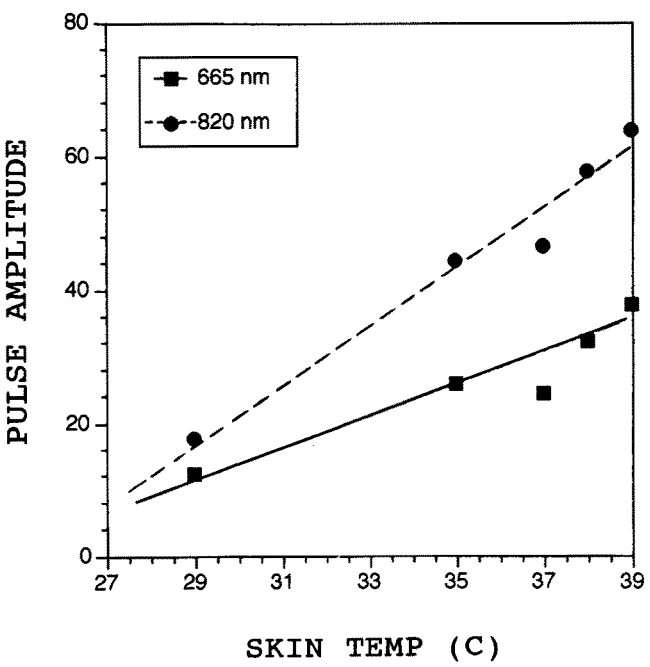

Fig 6. Pulse amplitudes at 665 and 820 nm versus skin temperature obtained in a dog. The best fitted linear regression equations were as follows: 665 nm; Y = 2.28 × − 54.7, r = 0.942, and 820 nm; Y = 4.38 × −110, r = 0.9834.

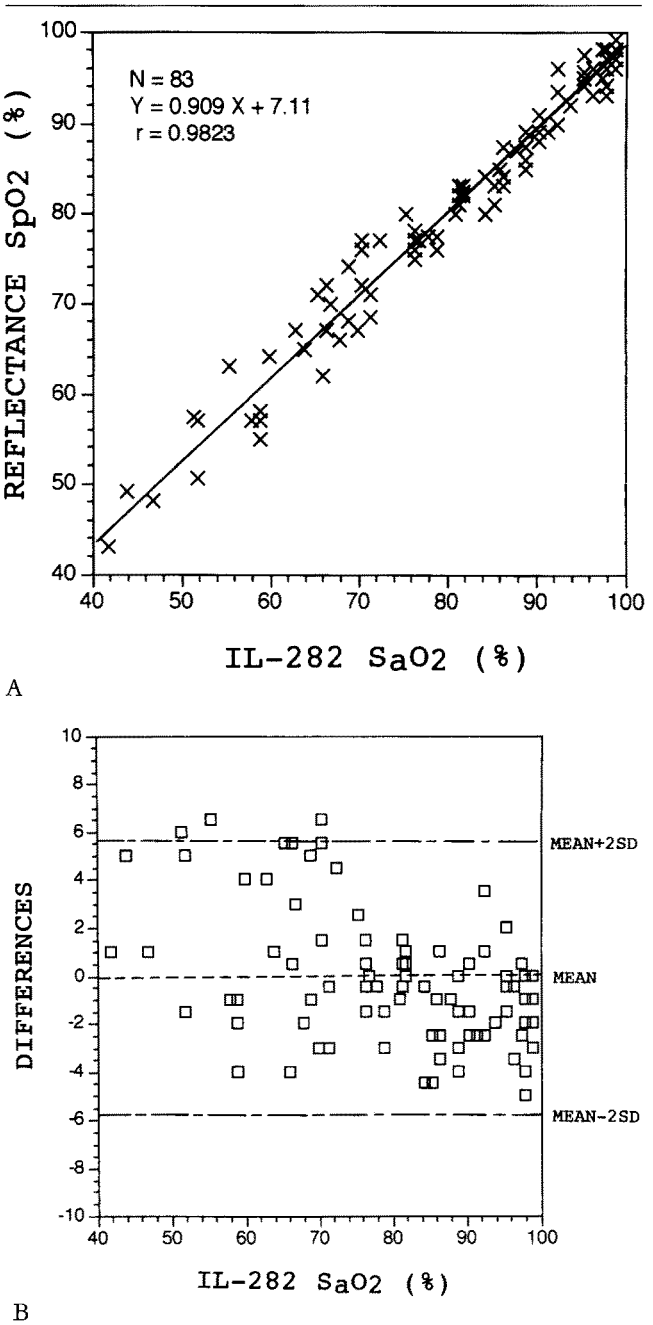

Fig 7. Correlation plots between (A) *SpO_2*(r) and *SaO_2(IL) and* (B) *differences, SpO_2(r) − SaO_2(IL), and SaO_2(IL) in dogs.*

Table 1. Statistical Analysis of Arterial Saturation Levels Measured by the Reflectance Pulse Oximeter in Dogs

		Mean (SD)	
% SaO_2	Data Points	Difference	% Error
80–100	45	−1.23 (1.89)	1.92 (1.51)
60–79	27	1.13 (3.10)	3.84 (2.87)
40–59	11	1.36 (3.66)	5.94 (4.34)

Table 2. Profile of the Patients Involved in the Heated Sensor Oximetry Study

Patient No.	Race	Age	Sex	Procedure
1	White	58 yr	Male	CAB
2	White	6 yr	Male	Fontan procedure
3	White	2 yr	Male	Resection of sequestered right lung
4	White	45 yr	Male	Wolf-Parkinson-White syndrome
5	White	4 mo	Male	Tetralogy of Fallot
6	White	5 yr	Male	Coarctation of aorta
7	White	60 yr	Female	ASD repair
8	White	2 yr	Male	Pectus excavatum
9	White	50 yr	Male	Mitral valve replacement
10	White	50 yr	Male	CAB
11	White	4 yr	Male	Tetralogy of Fallot

Abbreviations: CAB, coronary artery bypass; ASD, atrial septal defect.

Table 1. The accuracy of measurements was high in the SaO_2 range between 80 and 100% (1.92 ± 1.51%).

Clinical Study

Table 2 profiles the patients involved in the study that compared the signal amplitude with skin temperature. In these patients, signal amplitudes were recorded at random and, in some cases, the infrared heater was used to regulate the skin temperature. Even when the heater was used, however, none of the patients suffered burns from the sensor. In the clinical study, as in the animal study, the pulse amplitude level tended to increase as skin temperature increased (Fig 8) (665 nm, $r = 0.9904$; 820 nm, $r = 0.9822$; $p < 0.001$). The data suggest that a skin temperature of 35°C or above yields a detectable pulsatile signal (digital number of 20 or greater) at 665 nm. This finding is consistent with the results of the dog study.

Table 3 profiles the patients involved in the study comparing $SpO_2(r)$ with $SaO_2(IL)$ and $SpO_2(t)$. Figure 9 shows the correlation plot between the $SpO_2(r)$ and $SaO_2(IL)$, and the relationship between the differences; i.e., $SpO_2(r) - SaO_2(IL)$ and $SaO_2(IL)$). Figure 10 shows the same comparison for the Nellcor oximeter. The statistics found in Figs 9 and 10 are summarized in Table 4. The percent error of the reflectance oximeter was 1.86 ± 1.49% in the SaO_2 range between 80 and 100%, while that of the Nellcor was 2.57 ± 2.13%.

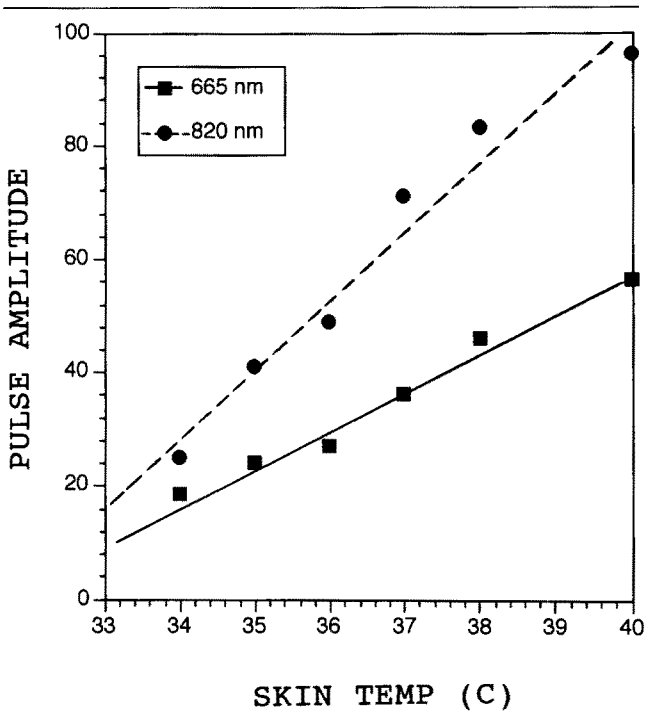

Fig 8. Pulse amplitudes of 665 and 820 nm versus skin temperature obtained in human patients (average, 7 patients). The best fitted linear regression equations were as follows: 665 nm; Y = 6.61 × − 207.7, r = 0.9904, and 820 nm; Y = 12.35 x −391.9, r = 0.9822.

DISCUSSION

As demonstrated in this study, the prototype reflectance pulse oximeter sensor functioned satisfactorily both in dogs and in critically ill patients in the operating room. The sensor was affixed to the forehead or cheek for 4 to 5 hours continuously without causing any skin burns. The performance of the sensor was consistent throughout the duration of each application. The errors in $SpO_2(r)$ measurements were similar to those seen with transmission oximeters.

Equation 1 can predict the $SpO_2(r)$ quite accurately. The errors seen in the clinical measurements mainly come from difficulty in maintaining a stable level SaO_2 during data sampling. Since the measurements were

Table 3. Profile of the Patients Involved in the Comparative Study Between the Reflectance Pulse Oximeter, Transmission Oximeter, and IL-282 Co-Oximeter.

Patient No.	Race	Age	Sex	Procedure
1	White	50 yr	Male	Right upper lobectomy
2	White	50 yr	Female	Left upper lobectomy
3	White	50 yr	Male	Right upper lobectomy
4	White	50 yr	Female	Right upper lobectomy
5	White	4 d	Male	Repair coarctation PA banding
6	White	50 yr	Female	Upper lobectomy
7	Black	40 yr	Female	Right upper lobectomy
8	White	68 yr	Male	CAB
9	White	75 yr	Male	CAB
10	White	68 yr	Female	Right upper lobectomy
11	Black	35 yr	Female	Thrombectomy of access
12	White	71 yr	Male	Thrombectomy of access
13	White	66 yr	Male	CAB
14	White	66 yr	Male	AVR
15	White	54 yr	Female	CAB
16	White	70 yr	Male	CAB, MVR
17	White	70 yr	Male	CAB
18	White	50 yr	Male	Thyroidectomy

Abbreviations: PA, pulmonary artery; CAB, coronary artery bypass; AVR, aortic valve replacement; MVR, mitral valve replacement.

made at random in critically ill patients, the actual SaO_2 level may not be accurate. During weaning from extracorporeal cardiopulmonary bypass, there was only one instance in which the $SpO_2(r)$ level decreased to the high 80s, although the Nellcor oximeter indicated an $SpO_2(t)$ in the high 90s. This error may have been caused by pooling of the venous blood in the vascular bed when the patient was in the supine position. Since the clinical study involved only 2 black patients, no conclusions can be drawn yet regarding the effect of skin pigmentation on the accuracy of measurements. This relationship requires further investigation through clinical studies that include more black patients and patients with different skin pigmentation.

The reflectance pulse oximeter's pulse amplitude level, which was defined AC in this study, is of major concern, particularly when the measurement is made from the forehead or cheek. In this study, multiple light sources were used to enhance the signal level and average out the effect of tissue heterogeneity. The effect is similar to what Mendelson et al [10] achieved by using multiple photodiodes. However, since we used LEDs, which are smaller than photodiodes (0.5 mm^2 as opposed to 2 to 3 mm^2), we did not have to increase the

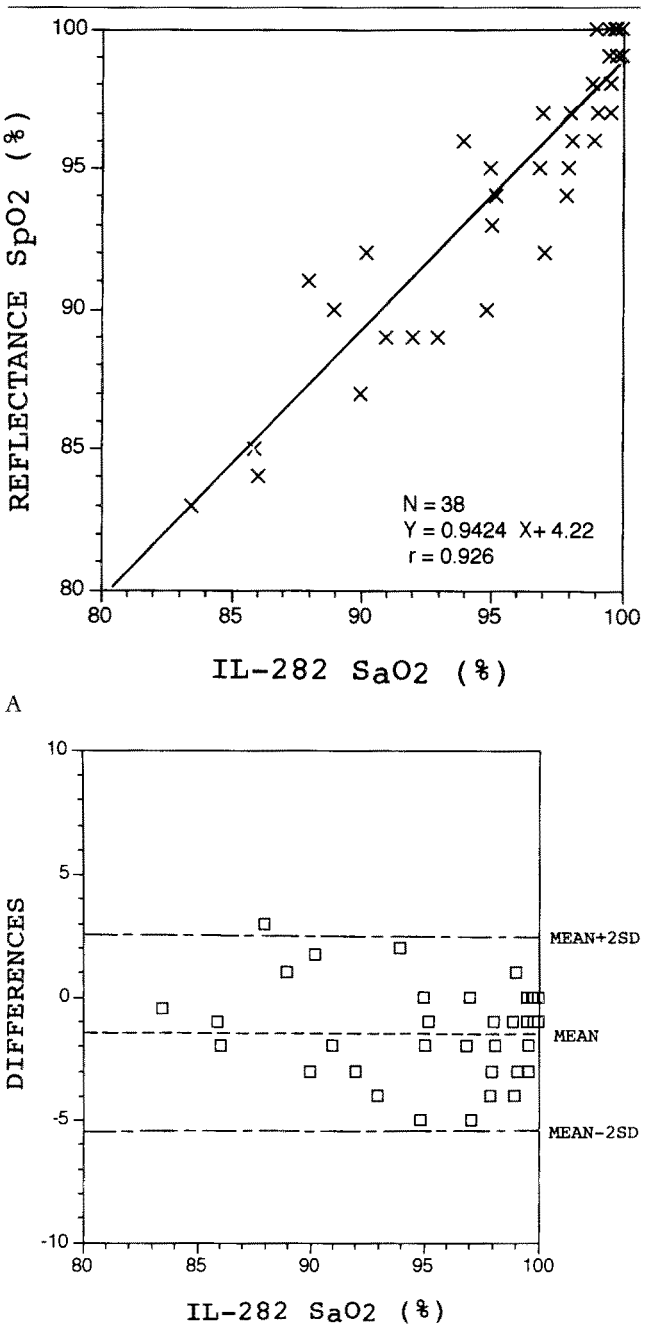

Fig 9. Correlation plots of the reflectance oximeter (A) $SpO_2(r)$ versus $SaO_2(IL)$ and (B) differences, $SpO_2(r) - SaO_2(IL)$, versus $SaO_2(IL)$ in critically ill patients.

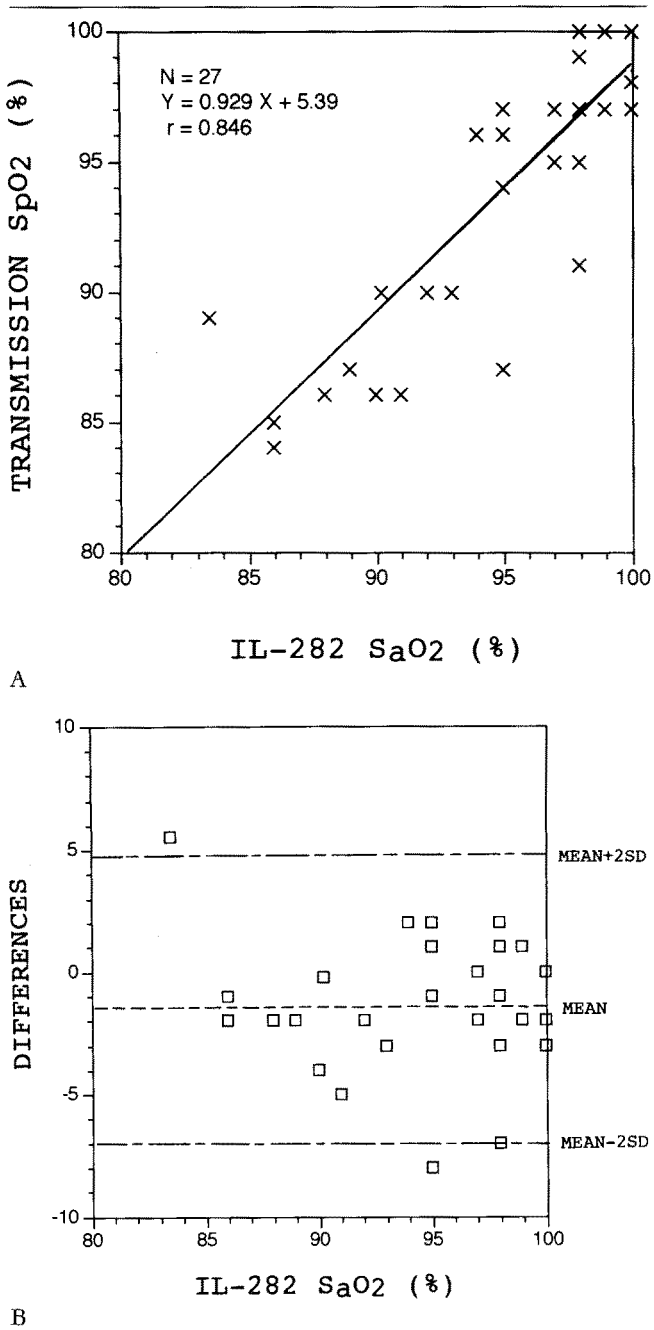

Fig 10. Correlation plots of the transmission oximeter (Nellcor): (A) $SpO_2(t)$ versus $SaO_2(IL)$ and (B) differences, $SpO_2(t) - SaO_2(IL)$, versus $SaO_2(IL)$ in critically ill patients.

Table 4. Statistical Analysis of Arterial Saturation Levels Measured by the Reflectance Pulse Oximeter and Nellcor Transmission Oximeter in Critically Ill Patients

			Mean (SD)	
	% SaO_2	Data Points	Difference	% Error
SpO2(r)	80–100	38	−1.39 (2.00)	1.86 (1.49)
SpO2(t)	80–100	27	−1.32 (2.84)	2.57 (2.13)

size of the sensor. Another important factor in optimizing the signal levels was the proper spacing of the LEDs and the photodiode. Although the theoretical study indicated the AC/DC ratio would improve as the distance between the light source and the detector increased, increasing the separation distance decreases the absolute signal level. Although we found that a separation distance of 5 to 7 mm was optimal, we used a separation distance of 3 mm to focus the light on the subcutaneous capillary bed. By thus focusing the light, we were able to obtain adequate pulsatile signals and minimize the use of the infrared heater. By minimizing use of the heater, we greatly reduced the possibility of skin burns that occur secondary to tissue heating, as with transcutaneous Po_2 sensors.

Another important consideration is the maintenance of local skin temperature, which helps maintain good peripheral circulation. A reduction in peripheral circulation due to local hypothermia results in a diminution of the pulsatile signal. This effect is predominant at the 665-nm wavelength because optical absorption at this wavelength is lower than that at the near-infrared wavelength when saturation is high. The room temperature in the operating room and the intensive care unit is usually between 15 and 18°C. This low temperature reduces circulation to the skin and subcutaneous tissues substantially, and thus weakens the pulsatile signal. To solve this problem, initially, we placed the sensor package in a circular cup to reduce heat loss to surrounding air. In addition, heat generated by the 665 and 820-nm LEDs warmed the tissue underneath the sensor. The signal level usually stabilized 5 to 10 minutes after the sensor was applied to the skin. However, if the pulsatile signal was not detectable within 5 to 10 minutes after application of the sensor, the 940-nm LEDs were turned on to warm the tissue. The animal and human studies both revealed that when the sensor-skin interface temperature was maintained at 34 to 35°C or higher, there was substantial pulsatile signal at both wavelengths.

If the skin temperature under the sensor area was maintained at an adequate level, low blood pressure (even as low as 50 mm Hg systolic) did not prevent us

from detecting a sufficient pulsatile signal. This result was confirmed in several patients who underwent open heart surgery with a normothermia procedure. Thus, the maintenance of local temperature seems to be of prime importance in the successful operation of the reflectance pulse oximeter.

Reflectance pulse oximeters continuously and noninvasively determine $SpO_2(r)$. In contrast to transmission oximeter sensors, which are applied to the fingertip or earlobe, reflectance oximeter sensors are applied to the forehead or cheek and may be used to monitor blood supply to the vital organs. Since the patient's head and face are exposed to clinicians during surgery, the application and replacement of sensors are much easier with reflectance sensors than with transmission probes. The clinical importance of the different locations for the sensors awaits further study. Also, the reflectance sensor can be used easily with pediatric patients and may even be appropriate for use in premature infants and neonates. For the purposes of research, the sensor can be applied to the surface of any organ. In conclusion, the new reflectance pulse oximeter can yield accurate $SpO_2(r)$ measurement from the forehead or cheek, and therefore provides an alternative to transmission pulse oximeters for monitoring critically ill patients in the operating room.

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