SKIN REFLECTANCE PULSE OXIMETRY: IN VIVO MEASUREMENTS FROM THE FOREARM AND CALF

Y. Mendelson, PhD, and M. J. McGinn, MSc

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ABSTRACT. This study describes the results from a series of human experiments demonstrating the ability to measure arterial hemoglobin oxygen saturation (SaO_2) from the forearm and calf using a reflectance pulse oximeter sensor. A special optical reflectance sensor that includes a heating element was interfaced to a temperature controller and a commercial Datascope ACCUSAT pulse oximeter that was adapted for this study to perform as a reflectance pulse oximeter. The reflectance pulse oximeter sensor was evaluated in a group of 10 healthy adult volunteers during steady-state hypoxia. Hypoxia was induced by gradually lowering the inspired fraction of oxygen in the breathing gas mixture from 100 to 12%. Simultaneous SaO_2 measurements obtained from the forearm and calf with two identical reflectance pulse oximeters were compared with SaO_2 values measured by a finger sensor that was interfaced to a standard Datascope ACCUSAT transmittance pulse oximeter. The equations for the best-fitted linear regression lines between the percent reflectance, $SpO_2(r)$, and transmittance, $SpO_2(t)$, values in the range between 73 and 100% were $SpO_2(r) = -7.06 + 1.09\ SpO_2(t)$ for the forearm ($n = 91$, $r = 0.95$) and $SpO_2(r) = 7.78 + 0.93\ SpO_2(t)$ for the calf ($n = 93$, $r = 0.88$). The regression analysis of the forearm data revealed a mean ± SD error of 2.47 ± 1.66% (SaO_2 = 90–100%), 2.35 ± 2.45% (SaO_2 = 80–89%), and 2.42 ± 1.20% (SaO_2 = 70–79%). The corresponding regression analysis of the calf data revealed a mean ± SD error of 3.36 ± 3.06% (SaO_2 = 90–100%), 3.45 ± 4.12% (SaO_2 = 80–89%), and 2.97 ± 2.75% (SaO_2 = 70–79%). This preliminary study demonstrated the feasibility of measuring SaO_2 from the forearm and calf in healthy subjects with a heated skin reflectance sensor and a pulse oximeter.

KEY WORDS. Blood gas analyses. Monitoring: oxygen. Measurement techniques: pulse oximetry; optical plethysmography; reflectance oximetry. Equipment: pulse oximeters.

Transmittance pulse oximetry has become a widely used technique for noninvasively monitoring changes in arterial hemoglobin oxygen saturation (SaO_2). The technique is based on the spectrophotometric analysis of the optical absorption properties of blood combined with the principle of photoplethysmography.

In transmittance pulse oximetry, which is based on tissue transillumination, sensor application in adults is limited to several specific locations on the body, such as the finger tips, ear lobes, and toes. In infants, additional monitoring sites such as the palms and the feet have been used.

Recently, a new reflectance pulse oximeter has been introduced into the market. The oximeter, which is manufactured by Ciba-Corning (Ciba Corning Diagnostics, Medfield, MA), uses a special optical reflectance sensor for specific application to the forehead. Among the advantages of this technique, as advertised by the

From the Department of Biomedical Engineering, Worcester Polytechnic Institute, 100 Institute Rd, Worcester, MA 01609.

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Address correspondence to Dr Mendelson.

company, are better reliability in critical care situations such as peripheral circulatory shutdown, less interference from ambient light, and better accuracy because measurement from the forehead is relatively unsusceptible to motion artifacts.

Currently, there are no commercially available reflectance pulse oximeters for monitoring SaO_2 from locations other than the forehead. Therefore, the objective of this work was to investigate the feasibility of monitoring SaO_2 with a skin reflectance pulse oximeter from two alternative and convenient locations on the body: the ventral side of the forearm and the dorsal side of the calf. Besides extending the clinical application of pulse oximetry, it appears also that reflectance pulse oximetry from peripheral tissues may have potential advantage in the assessment of local blood oxygenation after skin transplantation and regeneration following microvascular surgery.

In this article, we describe preliminary in vivo evaluation of a new optical reflectance sensor for noninvasive monitoring of SaO_2 with a modified commercial transmittance pulse oximeter. We present the experimental evaluation of this sensor in a group of 10 healthy adult volunteers and compare SaO_2 measured with the reflectance pulse oximeter sensor, $SpO_2(r)$, with SaO_2 measured noninvasively from the finger by a standard transmittance pulse oximeter sensor, $SpO_2(t)$.

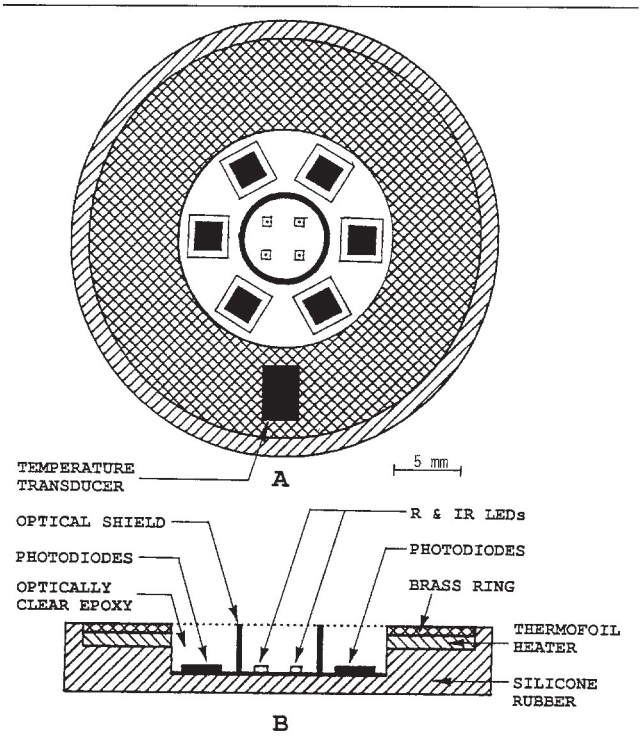

Fig 1. (A) Frontal and (B) side views of the heated skin reflectance pulse oximeter sensor. See text for explanation. R & IR LEDs = *red and infrared light-emitting diodes.*

REFLECTANCE PULSE OXIMETRY

The principle of reflectance, or backscatter, pulse oximetry is generally similar to that of transmittance pulse oximetry. Both techniques are based on the change in light absorption of tissue caused by the pulsating arterial blood during the cardiac cycle. The pulsating arterioles in the vascular bed, by expanding and relaxing, modulate the amount of light absorbed by the tissue. This rhythmic change produces characteristic photoplethysmographic waveforms, two of which are used to measure SaO_2 noninvasively.

Recently, we showed that accurate noninvasive measurements of SaO_2 from the forehead can be made with an unheated reflectance pulse oximeter sensor [1]. The major practical limitation of reflectance pulse oximetry is the comparatively low-level photoplethysmograms recorded from low-density vascular areas of the skin. Therefore, the feasibility of reflectance pulse oximetry depends on the ability to design an optical reflectance sensor that can reliably detect sufficiently strong reflectance photoplethysmograms from various locations on the skin.

In order to partially overcome this limitation, we have developed an optical reflectance sensor that includes an array of six identical photodetectors arranged symmetrically in a hexagonal configuration surrounding two pairs of red (peak emission wavelength, 660 nm) and infrared (peak emission wavelength, 930 nm) light-emitting diodes (LEDs) [1]. In another related study, we showed that by locally heating the skin under the sensor to a temperature above 40°C, it is possible to achieve a four- to fivefold increase in the magnitude of the pulsatile component detected from the forearm, and thus significantly improve the detection reliability of the reflectance photoplethysmograms [2]. The new optical reflectance sensor designed for this study combines the two features described above.

SENSOR DESIGN

The temperature-controlled optical reflectance sensor used in this study is shown in Figure 1. The major feature of the optical layout design is the multiple photodiode array, which is arranged concentric with the LEDs. This arrangement maximizes the amount of backscattered light that is detected by the sensor. The technical details related to the design and geometric

configuration of the optical components were described recently by Mendelson et al [1].

The heater consists of a ring-shaped (dimensions: 30-mm outside diameter; 15-mm inside diameter) thermofoil resistive heating element (Ocean State Thermotics, Smithfield, RI). The thermofoil heater was mounted between the surface of the optically clear epoxy, which was used to seal the optical components of the reflectance sensor, and a thin (0.005 mm) matching brass ring, which facilitates better thermal conduction to the skin. A miniature (dimensions: 2 × 5 × 1 mm) solid-state temperature transducer (AD 590, Analog Devices, Wilmington, MA) was mounted on the outer surface of the brass ring with the thermally sensitive surface facing the skin. The entire sensor assembly was potted in room-temperature vulcanizing silicone rubber to minimize heat losses to the surrounding environment. The assembled sensor weighs approximately 65 g. The sensor measures approximately 38 mm in diameter and is 15 mm thick. The heater assembly was separately interfaced to a temperature controller that was used to vary the temperature of the skin between 35 and 45°C in 1 ± 0.1°C steps.

SUBJECTS AND METHODS

Data Acquisition

Each of the two heated optical reflectance sensors were separately interfaced to a temperature controller and a commercially available ACCUSAT (Datascope Corp, Paramus, NJ) pulse oximeter [3].

Two of the three ACCUSAT pulse oximeters were modified to function as reflectance pulse oximeters. The modification, which was described in a separate study [1], included the adjustment of the red and infrared LED intensities in the reflectance sensors so that the reflectance photoplethysmograms were approximately equal to transmittance photoplethysmograms measured by a standard transmittance sensor from an average size adult finger tip.

The third ACCUSAT transmittance pulse oximeter was used as a reference to measure $SpO_2(t)$ from the finger tip. The specified accuracy of this transmittance pulse oximeter is ±2.0% and ±4.0% for SaO_2 values ranging between 70 and 100% and 60 and 70%, respectively [3]. The three pulse oximeters were adapted to provide continuous digital readouts of the AC and DC components of the red and infrared photoplethysmograms.

Readings from each of the three pulse oximeters were acquired every 2 seconds through a standard RS-232C serial port interface using an AT&T 6300 personal computer. The conversions of the reflectance red/infrared (R/IR) ratios measured by the two reflectance pulse oximeters to $SpO_2(r)$ were performed by using the calibration algorithm obtained in a previous calibration study in which measurements were made with a similar nonheated sensor from the forehead [1].

In Vivo Study

The ability to measure $SpO_2(r)$ from the forearm and calf was investigated in vivo during progressive steady-state hypoxia in humans.

Measurements were acquired from 10 healthy nonsmoking male adult volunteers of different ages and skin pigmentations. The study was performed in compliance with the University of Massachusetts Medical Center's review guidelines on human experimentation. Each volunteer was informed of the complete procedure as well as the possible risks associated with breathing hypoxic gas levels. Each volunteer received monetary compensation for participation in this study. The subject distribution included 1 East Indian, 3 Asians, and 2 darkly tanned and 4 lightly tanned Caucasians. Their ages ranged from 22 to 37 years old (mean ± SD, 27.5 ± 4.9 years). Measured blood hematocrits were in the range of 40 to 50.5% (mean ± SD, 45.7 ± 3.2%).

All instruments were allowed to warm up for at least 30 minutes before the study. The transmittance sensor of the pulse oximeter was attached to the index finger. The reflectance sensors were attached to the ventral side of the forearm and the dorsal side of the calf by using a double-sided transparent adhesive ring. In cases where an abundance of hair prevented intimate contact between the sensors and the skin, the contact was improved by loosely wrapping the sensor and the limb with an elastic strap. The temperature of each reflectance sensor was set to 40°C and remained unchanged throughout the entire study.

A standard lead-I electrocardiogram and end-tidal carbon dioxide levels were continuously monitored by a Hewlett-Packard 78345A patient monitor (Hewlett-Packard, Andover, MA). Each subject was placed in a supine position. A face mask was tightly fitted over the subject's nose and mouth, and the subject was instructed to breathe spontaneously while we administered different gas mixtures of nitrogen and oxygen. The inspired gas mixture was supplied by a modified Heidbrink anesthesia machine (Ohio Medical Products, Madison, WI). The breathing circuit of the anesthesia machine was equipped with a carbon dioxide scrubber (soda lime). The inspired oxygen concentration was adjusted between 12 and 100% and was monitored continuously

throughout the study with an IL 408 (Instrumentation Laboratories, Lexington, MA) oxygen monitor, which was inserted in the inspiratory limb of the breathing circuit.

Steady-state hypoxia was gradually induced by lowering the inspired fraction of oxygen in the breathing gas mixture. Initially, the inspired oxygen concentration was changed in step decrements, each step producing approximately a 5% decrease in $SpO_2(t)$ as determined from the display of the ACCUSAT transmittance pulse oximeter. The inspired oxygen was maintained at each level for at least 3 minutes until the pulse oximeter readings reached a steady level (i.e., SaO_2 fluctuations of less than $\pm 3\%$). When the inspired oxygen level reached 12%, the process was reversed. Thereafter, the inspired oxygen level was increased in a similar stepwise manner to 100%. Data were recorded during both desaturation and reoxygenation.

All subjects tolerated the procedure well without adverse reactions. None of the subjects showed electrocardiographic abnormalities before or after the study. Each subject was studied for approximately 1 hour.

Data Analysis

To avoid operator biases, the data from each pulse oximeter were acquired automatically by the computer and later subjected to the same statistical tests.

For each step change in inspired oxygen, readings from the three pulse oximeters were averaged consecutively over a period of 20 seconds. Averaged readings from 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.

Although the correlation coefficient of the linear regression (r) provides a measure of association between the $SpO_2(r)$ and $SpO_2(t)$ measurements, it does not provide an accurate measure of agreement between the two variables. Therefore, the measurement accuracy was estimated on the basis of the mean and standard deviations of the difference between the readings from the transmittance and reflectance pulse oximeters. The mean of the difference between the pulse oximeter measurements, which is often referred to as the bias, was used to assess whether there was a systematic over- or underestimation of one method compared with the other. The standard deviation of the bias, which is often referred to as the precision, represents the variability or random error. Finally, we computed the mean errors and standard deviations of each measurement. The mean error is defined as the absolute bias divided by the corresponding $SpO_2(t)$ values.

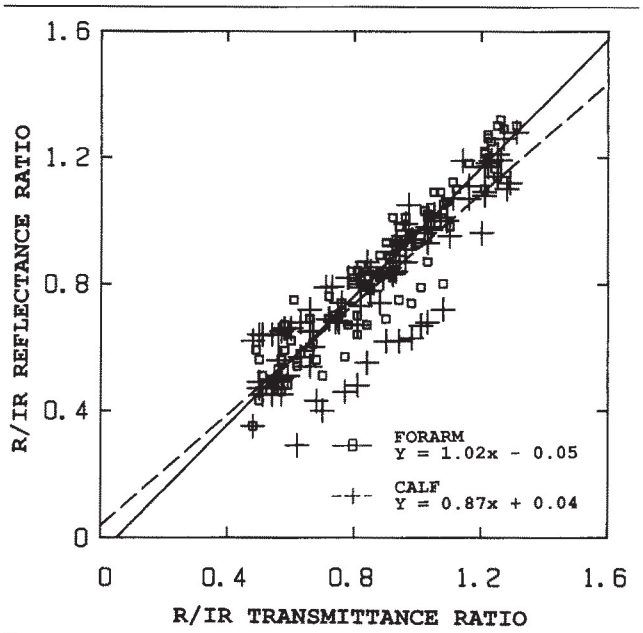

Fig 2. Comparison of red/infrared (R/IR) *ratios measured by the modified reflectance pulse oximeter (y axis) and the standard transmittance pulse oximeter (x axis) during progressive steady-state hypoxia in 10 healthy subjects. The solid line represents the best-fitted linear regression line for the forearm measurements. The broken line represents the best-fitted linear regression line for the calf measurements.*

RESULTS

Normalized R/IR ratios and $SpO_2(r)$ values measured by the reflectance pulse oximeters from the forearm and calf of the 10 subjects were compared with the normalized R/IR ratios and $SpO_2(t)$ values measured simultaneously by the transmittance pulse oximeter from the finger. A total of 91 and 93 pairs of data points measured simultaneously from the forearm and calf, respectively, were used in the regression analysis, which provided the estimated slopes and intercepts of the linear regression lines. Each pair of data points represents a different hypoxic level.

Regression analysis of the normalized R/IR ratios measured from the reflectance pulse oximeters from the forearm and calf (y axis) versus the normalized R/IR ratios measured simultaneously by the transmittance pulse oximeter from the finger tip (x axis) is shown in Figure 2. The equations for the best-fitted linear regression lines were $y = -0.05 + 1.02x$ ($r = 0.94$, SEE = 0.08, $p < 0.001$) for the forearm and $y = 0.04 + 0.87x$ ($r = 0.88$, SEE = 0.11, $p < 0.001$) for the calf.

A comparison of $SpO_2(r)$ readings from the reflectance pulse oximeter (y axis) and $SpO_2(t)$ readings mea-

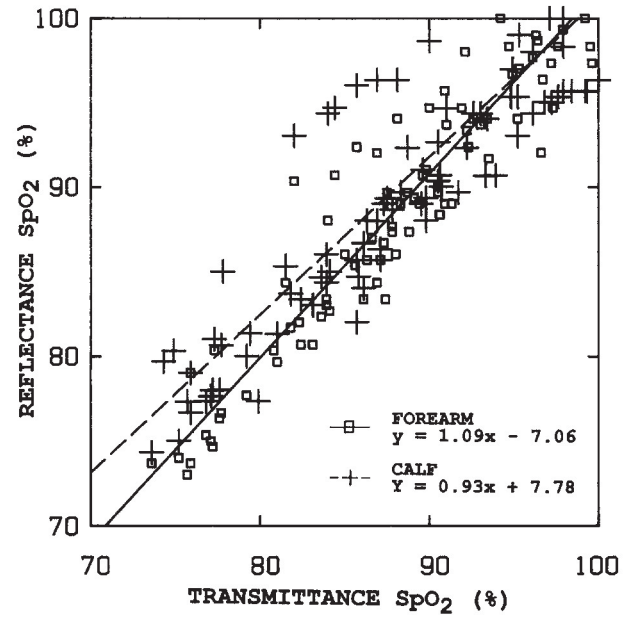

Fig 3. Comparison of percent arterial hemoglobin oxygen saturation (SpO_2) measurements obtained from the modified reflectance pulse oximeter (y axis) and SpO_2 values measured by a standard transmittance pulse oximeter (x axis) during progressive steady-state hypoxia in 10 healthy subjects. The solid line represents the best-fitted linear regression line for the forearm measurements. The broken line represents the best-fitted linear regression line for the calf measurements.

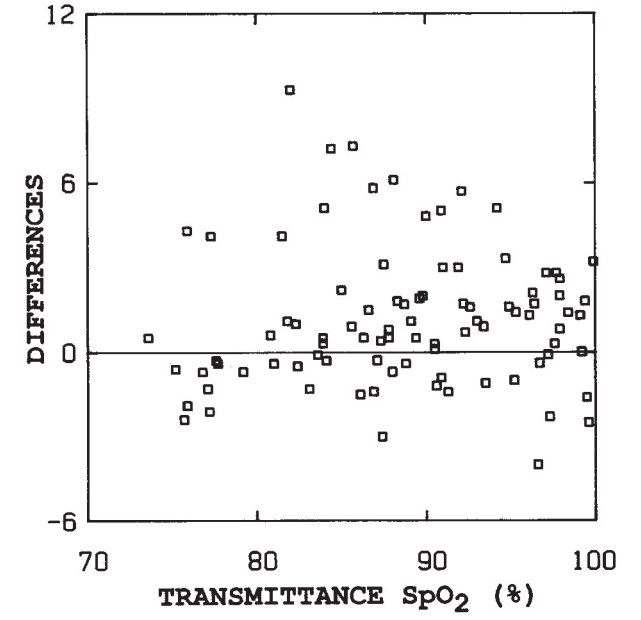

Fig 4. Mean differences between arterial hemoglobin oxygen saturation (SpO_2) measured from the forearm by the modified reflectance pulse oximeter and the standard transmittance pulse oximeter measurements from the finger tip.

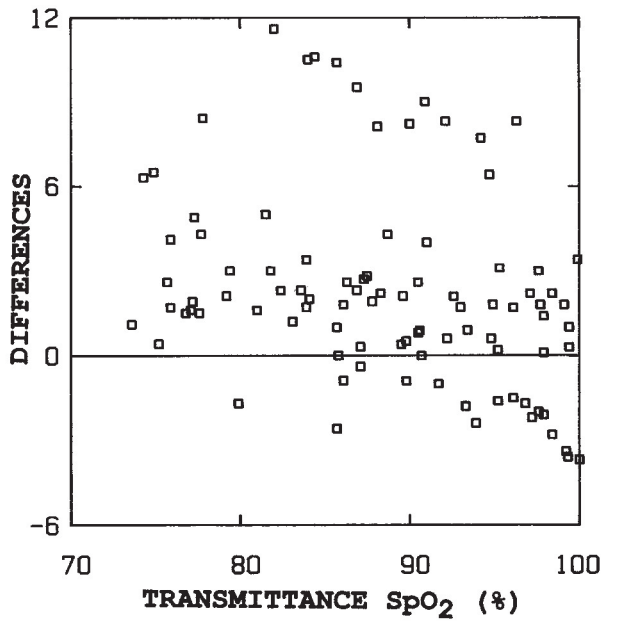

Fig 5. Mean differences between arterial hemoglobin oxygen saturation (SpO_2) measured from the calf by the modified reflectance pulse oximeter and the standard transmittance pulse oximeter measurements from the finger tip.

Statistical Analysis of Arterial Oxygen Saturation (SaO_2) Levels Measured from the Forearm and Calf by the Modified Reflectance Pulse Oximeters

Location/ % SaO_2	No. of Data Points	Mean Value (SD)	
		Difference	% Error
Forearm			
90–100	42	1.25 (2.55)	2.47 (1.66)
80–89	37	0.52 (2.85)	2.35 (2.45)
70–79	12	−0.82 (1.96)	2.42 (1.20)
Calf			
90–100	43	1.57 (4.00)	3.36 (3.06)
80–89	33	2.22 (4.00)	3.45 (4.12)
70–79	17	1.95 (2.42)	2.97 (2.75)

sured simultaneously from the transmittance pulse oximeter (x axis) is shown in Figure 3. The equations for the best-fitted linear regression lines were $y = -7.06 + 1.09x$ ($r = 0.95$, SEE = 2.62, $p < 0.001$) for the forearm and $y = 7.78 + 0.93x$ ($r = 0.88$, SEE = 3.73, $p < 0.001$) for the calf.

Figures 4 and 5 show the percent differences between $SpO_2(r)$ and $SpO_2(t)$, that is, $SpO_2(r) - SpO_2(t)$, obtained from the forearm and calf data plotted in Figure 3, respectively. The corresponding means and standard deviations of the differences and errors for the forearm and calf measurements are summarized in the Table.

Data were summarized for three different ranges of $SpO_2(t)$ values between 70 and 100%.

DISCUSSION

Commercially available transmittance sensors can be used on only a limited number of peripheral locations of the body. Brinkman and Zijlstra [4] and Cohen and Wadsworth [5] showed that instead of tissue transillumination, noninvasive monitoring of SaO_2 can be performed based on skin reflectance spectrophotometry. More recently, we described an improved optical reflectance sensor that was used for measuring SaO_2 from the forehead with a modified commercial transmittance pulse oximeter [1].

Measuring large reflectance photoplethysmograms from sparsely vascularized areas of the skin is challenging. Differences in capillary densities between various locations on the body are known to affect the magnitude and quality of the reflected photoplethysmograms. For example, estimated average capillary density of the human forehead is approximately 127 to 149 loops/mm^2, whereas the capillary densities of the forearm and calf are approximately 35 to 51 and 41 loops/mm^2, respectively [6,7]. Furthermore, the frontal bone of the forehead provides a highly reflective surface that significantly increases the amount of light detected by the reflectance sensor. Therefore, reflected photoplethysmograms recorded from the forehead are normally larger than those recorded from the forearm and calf. Local skin heating could be used as a practical method for improving the signal-to-noise ratio of the reflected photoplethysmograms from the forearm or calf areas and thus reduce the measurement errors in reflectance pulse oximetry.

The approach presented in this article demonstrated that SaO_2 can be estimated by using a heated skin reflectance sensor from the forearm and calf over a relatively wide range of SaO_2 values. This technique may provide a clinically acceptable alternative to currently available transmittance pulse oximeters. In a previous study [2], we found that the ability to measure accurate SaO_2 values with a reflectance skin oximeter is independent of the exact skin temperature. We noticed, however, that a minimum skin temperature of approximately 40°C is generally sufficient to detect adequately stable photoplethysmograms. Furthermore, our experience in healthy adults also has shown that at this skin temperature, the heated sensor can remain in the same location without any apparent skin damage.

Note that despite the proven advantage of local skin heating to increase skin blood flow, reflected photoplethysmograms recorded from the forearm and the calf are considerably weaker than those recorded from the forehead. Therefore, the mean errors for the $SpO_2(r)$ measurements from the forearm and calf are higher than the corresponding errors for similar $SpO_2(r)$ measurements made with an unheated reflectance sensor from the forehead. For comparison, relative to SaO_2 measured with a noninvasive transmittance pulse oximeter, the SEE for $SpO_2(r)$ measurements obtained from the forehead using a similar unheated optical reflectance sensor were 1.82% [1]. The SEE obtained in this study using the heated reflectance sensor were 2.62% for the forearm and 3.73% for the calf measurements. Despite those differences, it is apparent that the degree of correlation obtained in this preliminary study is encouraging and in selected clinical applications may be acceptable. We conclude that reflectance pulse oximetry from the forearm and calf may provide a possible alternative to conventional transmittance pulse oximetry and reflectance pulse oximetry from the forehead. Further studies, however, are needed in order to compare our reflectance pulse oximeter against SaO_2 measurements obtained directly from arterial blood samples. Additional work to investigate the source of variability in reflectance pulse oximetry is in progress.

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