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A Novel Hybrid Reflectance Pulse Oximeter Sensor with Improved Linearity and General Applicability to Various Portions of the Body

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Abstract

The objective of this study was the development of a reflectance pulse oximeter sensor for broader clinical applications, specifically for broader arterial oxygen saturation (SaO_2) measurement from various body portions. To enhance the reflectance pulse amplitude from any body surfaces and eliminate the effect of tissue inhomogeneity, the new sensor incorporated ten LED chips for each wavelength mounted symmetrically at the radial separation distance of 7 mm around a photodiode chip. Based on the photon diffusion theory, the wavelength combination, 730/880 nm, was determined to obtain a linear relationship between the reflectance ratio and broader SaO_2 range from 100% to 30%. The improved linearity of the new sensor was evaluated in dogs (n=5) in comparison to the 665/910 nm conventional wavelength sensor. Additionally, this new reflectance sensor was applied to various body surfaces in healthy human adults (n=30). The relative reflectance pulse amplitudes from the fingertip, forehead, and chest were 1.0, 0.3, and 0.1 as normalized to the fingertip at each wavelength. These results will broaden the application sites of the reflectance pulse oximeter sensor in the hospital and home healthcare.

Introduction

Because of the high cost effectiveness nature and high precision SaO_2 measurement, the transmittance pulse oximeters have been used as the standard in the clinical situations [1-3]. The application site of the transmission pulse oximeters, however, is limited mainly to the peripheral tissue, such as fingertip, toe, from which the transmitted light can be detected. Alternately, reflectance oximeter could measure SaO_2 from various parts of body, especially from more centrally located parts such as the forehead, cheek [4-6].

Although the conventional pulse oximeter can offer a great accuracy for the SaO_2 level above 80%, its performance becomes severely affected at lower SaO_2 by the nonlinear characteristics of optical absorption and scattering by the red blood cells and other optically bulk tissues. To circumvent this inherent disadvantage, recently reflectance pulse oximeters for lower SaO_2 measurement have been developed [7,8]. Since the SaO_2 of the fetuses will become lower than 70-80% during delivery, the reflectance pulse oximeters that can measure lower SaO_2 with a greater accuracy is needed [9].

In this study, we studied further investigations concerning:

1) The relationship between the wavelength selection and the sensitivity of SaO_2 measurement within 660-800 nm range using the photon diffusion theory.
2) The applicability of the new reflectance pulse oximeter sensor for various body portions such as chest wall, to extend the sensor applications.

The theoretical and experimental studies can provide that a proper selection of the wavelength will help significantly improve the accuracy of the lower SaO_2 measurement.

Additionally, to provide insights into the sensor applicability not only to the forehead or cheek but also to the other body portions such as chest will broaden the application sites of the reflectance pulse oximetry.

Materials and Methods

The New Hybrid Reflectance Pulse Oximeter Sensor

The new hybrid reflectance pulse oximeter sensor incorporates a photodiode (PD) chip located at the center and surrounded by an optical barrier that blocks direct coupling between the light emitting diode (LED) and PD. To enhance pulsatile signal level and minimize the tissue inhomogeneity as well as the variability among the subjects, ten LED chips for each wavelength, total twenty chips, were placed symmetrically at an equal radial distance of 7 mm around the PD (Fig.1). The separation distance of 7 mm was determined through theoretical and experimental analysis to yield a maximum AC/DC ratio at each wavelength.

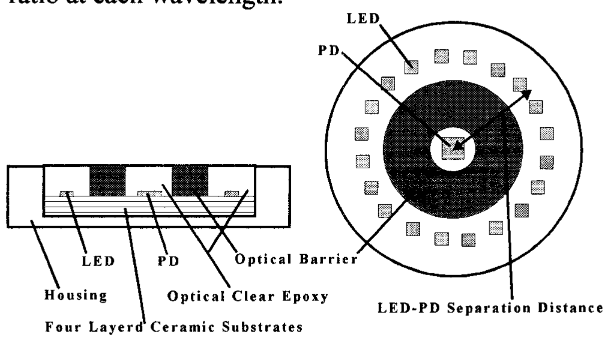

Fig.1. A schematic drawing of the newly developed reflectance pulse oximeter sensor. The diameter of the sensor is 23.0 mm with the thickness being 6.7 mm.

Theoretical Basis for the Reflectance Pulse Oximetry

Theoretical background of the reflectance pulse oximeter was based on a reflectance equation derived from the photon diffusion equation [10]. The reflectance pulse oximetry parameters such as SaO_2, venous saturation (SvO_2), hematocrit (Hct), arteriovenous blood volume (Va, Vv), and blood-free tissue optical properties were modeled into the theory to simulate the optical reflectance values; particular attention was paid to improve the over all linearity for the broader SaO_2 ranges from 100% down to 30% to be satisfied by Eq. (1).

$$SaO_2 = A \times R + B \qquad (1)$$

where A and B are the constants that are related to physiological and sensor parameters, and R is the ratio between the pulsatile (AC) and average (DC) signal at the two wavelength reflectance:

$$R = (AC/DC)_{\lambda 1} / (AC/DC)_{\lambda 2} \qquad (2)$$

In Eq.(2), the AC components of the diffuse reflectance were modeled as a fractional arterial blood volume changes ($Va + \Delta Va$) due to each heartbeat.

Also, the theory was used to study the effect of sensor geometry, particularly the separation distance between the light source and detector, on the pulsatile signal level.

Animal Study (Broader range of SaO_2 measurement)

The new reflectance pulse oximeter sensor was evaluated in the anesthetized dogs with body weight of 15-20 Kg (n=5). The reflectance pulse oximeter sensor was attached to the inner lining of the mouth. The oxygen content of the gases inside the respiration bag was reduced by stepwise changes in SaO_2 of about 10%. The arterial blood samples were analyzed using the Ciba Corning blood gas analyzer model 188. The study was carried out initially with the new 730/880 nm sensor, followed with the conventional 665/910 nm sensor. The recorded data were sampled at 500 Hz and analyzed using an IBM PC/AT machine. The R values were derived using the FFT (fast Fourier transform) method to determine AC and DC components of these stored data, allowing to eliminate the effect of signal drifts such as due to respiration. The performance of two sensors was comparatively analyzed [7].

Human Study (Applicability to various body portions)

The applicability of new reflectance pulse oximeter to the various body portions was evaluated in healthy human adults (n=30) breathing an ambient air. The new and conventional reflectance pulse oximeter sensors have been attached to the various parts of the human body, e.g. fingertip, forehead, and center of the chest (on the sternum). These reflectance AC (pulsatile) amplitudes were normalized at the fingertip reflectance AC amplitude at each wavelength.

Results

The theoretical analysis of the reflectance pulse oximetry is shown in Fig. 2. Conventionally, the red wavelength of 660 nm was used in combination with the near infrared wavelengths such as 910 nm. Its combination led to a nonlinear relation between the R values and SaO_2. The linear regression line estimate can give an accurate SaO_2 for the range of 100-70%, but below 70% discrepancies from the line increases. With 730-770/880-910 nm pair, improved linear relationships exist between the R values and SaO_2 for the range of 100-30%.

Fig. 3a and 3b show the R values vs. SaO_2 of the 665/910 nm and 730/880 nm sensor as obtained in the dog study (n=5). As predicted by the theoretical analysis (Fig. 2), the relationship between the R values and SaO_2 of the 665/910 nm sensor was quite non-linear; a linear regression line can be applied to the SaO_2 values above 70%. On the other hand, the 730/880 nm sensor revealed a linear relationship between the R values and SaO_2 over 100-30% range. When we examine the accuracy of the two sensors for the high SaO_2 region, $70<SaO_2<100\%$, the 730/880 nm sensor showed a slight improvement of the standard error from 3.50 to 2.11%. In the lower saturation region, $30<SaO_2<70\%$, the improvement was significant with the standard error of the 730/880 sensor being 2.69% as compared with that of the 665/910 sensor being 9.49% [7].

Fig. 4 compares the relative pulse amplitudes from forehead, chest (upper), and chest (lower) for wavelengths of 665, 730, 810, and 880 nm. These data were obtained in healthy adult humans (n=30) without any difficulties. The relative amplitude of the head was about 30% and that of the chest about 10%.

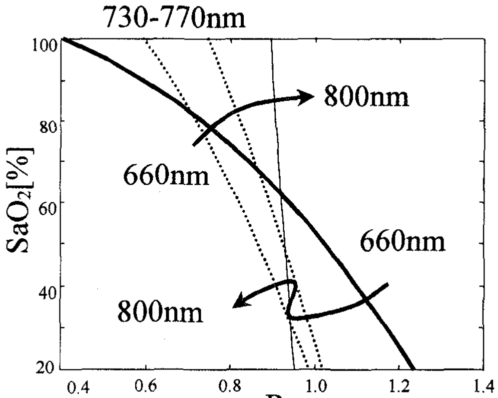

Fig.2. The results of the theoretical analysis of the reflectance pulse oximetry. Through the sensor wavelength: λ_1 changed within 660-800 nm, the improved linearity relations between R values and broader SaO_2 range were observed within 730-770 nm range. The other wavelength: λ_2 was fixed at 880 nm.

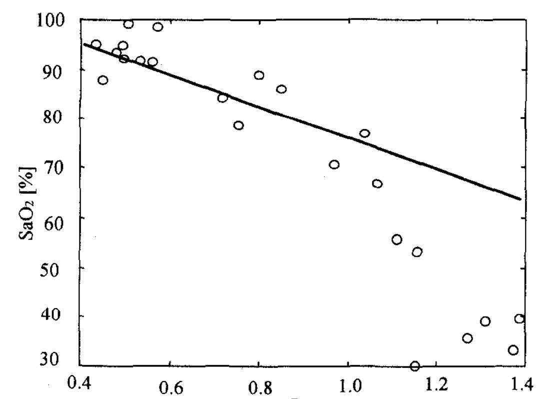

Fig.3-a. Experiment result of the conventional wavelength combination, 665/910 nm, reflectance pulse oximeter sensor. The discrepancies of the experimental results from the solid line were increased as lower SaO_2 below 70%.

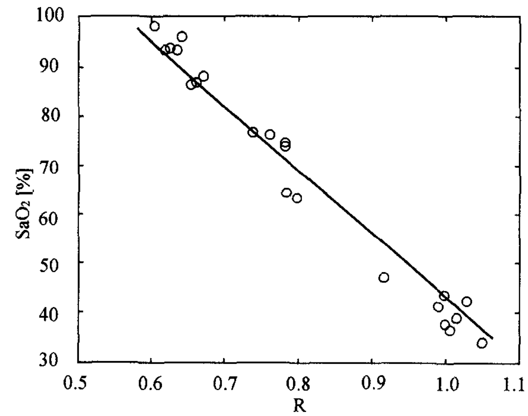

Fig.3-b. Experimental results of the new wavelength combination, 730/880 nm, reflectance pulse oximeter sensor. The excellent linearity was observed between R values and broader SaO_2 range.

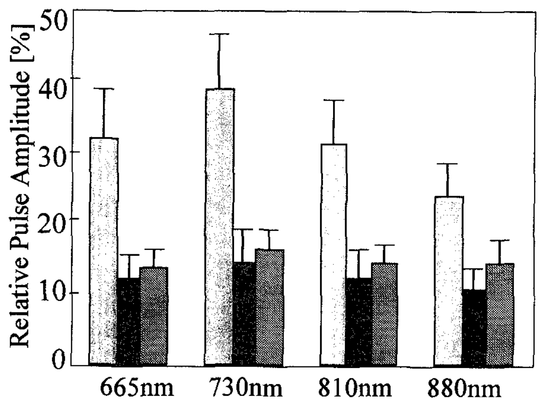

Fig.4. The relative pulse amplitude of the reflectance signals from the forehead, chest (on the upper and lower parts of the sternum) at each wavelength were obtained from healthy adult subjects (n=30). These amplitude signals were normalized at the reflectance pulse amplitude of the fingertip at each wavelength.

:forehead, :chest (upper), :chest (lower)

Discussion and Conclusion

In this study, the new hybrid reflectance pulse oximeter sensor for a broader SaO_2 range measurement and applicable to various body parts has been evaluated in animals and healthy human subjects.

As for the SaO_2 measurement, predicted by the theoretical analysis (Fig.2), the new reflectance pulse oximeter sensor has improved linearity over the broader SaO_2 range from 100% to 30% (Fig.3-b). Additionally, the theoretical analysis suggested that the significant linearity can be observed with the 730-

770/880-910 nm combination in comparison to 660/880-910 nm pair. The improved linearity was also predicted with 770-800/880-910 nm combinations. These wavelength pairs, however, have lower sensitivity to SaO_2 in practical use.

As reported earlier [7,8], the closer are the two wavelengths, the better is the result. Because of choosing two wavelengths closer to each other, we can equalize the penetration depth into the tissue and thus the sampling area. However, if the two wavelengths are too close to each other such as 780/880 nm, sensitivity to SaO_2 change is lost (Fig.2). Thus, from the penetration depth equalization as well as sensitivity points of view, 730/880 nm pair would be most suitable when it is compared with the 660/910 nm pair.

Concerning the applicability to any body portions, the new reflectance pulse oximeter sensor could yield good reflectance signals. According to the principle of the pulse oximetry, the applicable area of the reflectance pulse oximeter is limited to the sites from which the reflectance pulse signals can be detected. The relative reflectance pulsatile signal amplitude of the chest was about 10% in comparison to that of the fingertip (Fig.4). Although the reflectance signals from the abdomen (data not shown) could be detected, these reflectance signals were too small with the relative pulse amplitude being only a few %. Therefore, we need further investigations to study the relation between the reflectance pulse amplitude and the tissue structure differences such as fat, bone, and arteriovenous blood distributions and to clarify the limitation of the sensor application sites, particularly with patients in operating room and in ICU.

Additionally, the mean values of the R, Eq (2), have no significant differences ($p<0.05$) at each wavelength pair among various body portions in spite of the pulsatile (AC) amplitude signals being deferent at each location. This result suggests that a single calibration curve may be applicable to various portions of the body.

In the future, the theoretical analysis of the pulse oximetry will help account for the sensor errors depending on arteriovenous distributions, other hemochromes and dyes. Furthermore, the reflectance pulse oximeter sensor will be applied to various location of the body in the hospital and home healthcare to aid in early diagnostics of cardiopulmonary as well as peripheral circulatory disorders.

Acknowledgement

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