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RESEARCH ARTICLE

Non-invasive calibration method for pulse oximeters

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Abstract

In case of a healthy subject the normal SpO_2 value is 97±2% on see level. Modern, finger probe based pulse oximeters are measuring the SpO_2 level with 1-2% error. The dispersion between subjects can reach 4%, thus such accuracy is not really demanded by the majority of clinicians. Moreover, in case of fetal pulse oximetry 5% measuring error is accepted. Considering these factors we investigated the feasibility of a non-invasive calibration method with a self-developed pulse oximeter. This method is carried out without blood sampling. Pulse oximeters are measuring the R rate, which is proportional to the SpO_2 value. Calibrating an oximeter means finding the function between the R and SpO_2. A calibrated pulse oximeter was used as reference. In the case of every subject 15 minutes long measurements were performed. The reference device and our oximeter were attached to the subject at the same time, while artificial air with 14% oxygen content was inhaled by the subject for ten minutes. The SpO_2 was measured by the reference oximeter and the R rate by our oximeter. Based on 511 measured data pairs the relationship was determined between 86-100%. The relationship was estimated by linear regression. Although the original relation is non-linear, linear estimation can be used in this small range of SpO_2 with good accuracy. The average error of the calibrated device is 2.76%, which is appropriate in medical practice. This method is easier and cheaper as the invasive calibration, but the calibrated device will have slightly bigger measuring error.

Keywords

pulse oximetry · calibration · non-invasive

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1 Introduction

The oxygen saturation is nearly constant in time, but some diseases (smoking, lung diseases etc.) can cause significant oxygen saturation downfall. In case of a heavy smoker, 94% can be a “normal” level. Below 85% hypoxia occurs. Some birth complication can cause hypoxia in the body of the fetus too. With a fetal pulse oximeter doctors and nurses can better determine if a fetus is truly hypoxic or acidotic, thus reducing or even eliminating the number of unnecessary C-sections.

Saturation of arterial blood covers information about the available oxygen content for the tissues. The oxygen saturation of the arterial blood, tissues, and venous blood can be measured with different methods. Vibratory oximetry is a novel method to measure the oxygen saturation of venous blood [1]. Relative changes of tissue (e.g. muscle) oxygen saturation can be measured by time-resolved spectroscopy [2], spatially resolved spectroscopy [3], intensity modulation spectroscopy [4], or CW NIR[1] spectroscopy [5, 6]. The arterial oxygen saturation can be measured by pulse oximeters. Based on spectroscopic principles, pulse oximeters are measuring the so called *R* rate (or ratio of the ratios), which is proportional to the arterial oxygen saturation level, called SaO_2. The arterial oxygen saturation level which is measured and displayed by a pulse oximeter is called SpO_2 level. In optimal case $SaO_2 = SpO_2$, but every pulse oximeter has some measuring error. To obtain the relation between the *R* rate and SpO_2 the pulse oximeter must be calibrated. Usually the calibration is based on real blood samples of healthy volunteers [7]. Invasive calibration method is circumstantial and expensive. Hornberg and others wanted to replace the invasive calibration method with an artificial finger with a variable spectral-resolved light attenuator in conjunction with an extensive clinical database [8]. In the present study, we investigated the opportunity of another non-invasive calibration method, in which case a calibrated pulse oximeter was used as reference, and our self-developed, wireless, compact, reflectance pulse oximeter was the device under calibration (called in this paper: DUC). The calibration was carried out by recording the SpO_2 level from the reference device and the *R* val-

[1] CW NIR: Continuous Wave Near Infra Red

ues from the DUC by different oxygen levels between 86-100% SpO_2.

Measurement error considerations

Principles of pulse oximetry were discovered in the early 80's, since then many kinds of pulse oximeters were developed with different accuracy [9]. A modern finger probe pulse oximeter measures the SpO_2 level with less than 2% error. Because the normal blood oxygen saturation level can have a dispersion of 4% between healthy human subjects, and the critical oxygen level limit is a subject dependent factor, worse accuracy could be accepted by the clinical staff also. Low perfusion, blood volume fraction differences, haematocrit level, and other factors are making the fetal pulse oximetry even more difficult [10, 11], thus 5% error is still acceptable in case of a through-cervix measurement. Usual error range of the fetal pulse oximeters is 2.5-12.9% of SpO_2 [10]. In case of our method the measuring error of the reference device is an additive error factor, but the total error could be still acceptable in conventional and in fetal pulse oximetry also.

2 Principles

With the arterial blood the oxyhemoglobin carries the oxygen from the lungs to the tissues. One hemoglobin molecule can transfer four O_2 molecules in optimal case. In a theoretical estimation, the oxygen saturation of the arterial blood can be expressed as the rate of the oxygenated hemoglobin and the full hemoglobin quantity [12]:

$$SpO_2 = \frac{HbO_2}{HbO_2 + Hb} \tag{1}$$

SpO_2: Oxygen saturation of arterial blood
HbO_2: Concentration of oxygenated hemoglobin
Hb: Concentration of reduced hemoglobin.

The light absorption ability of the hemoglobin depends on the oxygen content of the molecule. This phenomenon can be observed not only in the NIR[2] spectrum, but in the visible light region also: the arterial blood has scarlet color, but the blood in the veins has bluish red color. Based on this phenomenon the arterial oxygen saturation can be determined with the help of the Lambert-Beer law [13].

The expression 'pulse oximeter' comes from the pulsating waveform of the useful part of the measured light signal. In the tissues only the arterial blood throbs, thus a light beam which is passing through the tissues will be modulated by the arterial pulsation. This means it will have a small AC level on a high DC level. With appropriate filtering the significant part (the AC part) can be filtered and amplified, and the effect of the other tissue types can be eliminated. At least two light sources (LEDs) with different wavelengths are used to produce the measuring light, which is passing through the tissues and sensed by the photodetector. Because of some limitations the wavelength of the light sources should be between 650 nm and 1000 nm. In Fig. 1 a sample waveform from a pulse oximeter measuring head can be seen. The measured and digitalized signal is evaluated by a

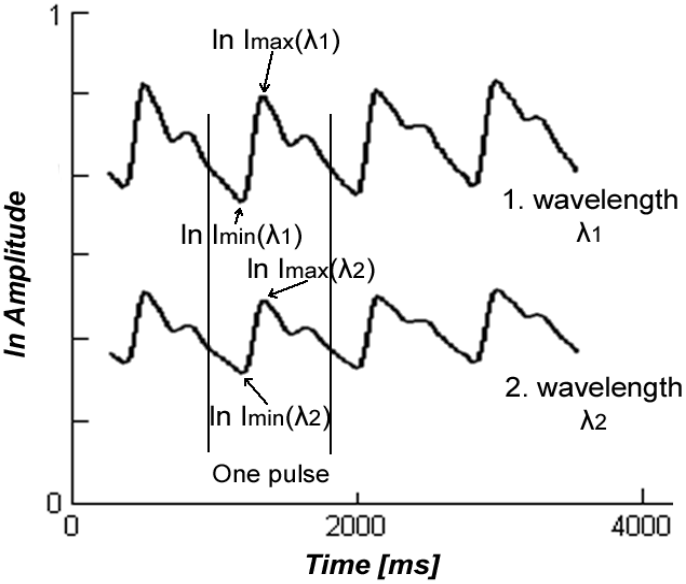

Fig. 1. Sensed signal of an oximeter measuring head with two light sources

microcontroller or a DSP[3] and displayed to the user. The evaluation software determines the *R* rate from the amplitudes of the pulse waves. Every pulse has a maximum and a minimum amplitude value (see Fig. 1). Usually the next formula is used to calculate the *R* rate:

$$R = \frac{\ln \frac{I_{\max}(\lambda_1)}{I_{\min}(\lambda_1)}}{\ln \frac{I_{\max}(\lambda_2)}{I_{\min}(\lambda_2)}} \tag{2}$$

$I_{max}(\lambda_1)$: Maximum amplitude of the pulse at the first wavelength
$I_{min}(\lambda_1)$: Minimum amplitude of the pulse at the first wavelength
$I_{max}(\lambda_2)$: Maximum amplitude of the pulse at the second wavelength
$I_{min}(\lambda_2)$: Minimum amplitude of the pulse at the second wavelength

Eq. (2) is deduced from the Lambert-Beer law [13]. *R* is calculated on every pulse, then 8-64 subsequent values are averaged. The SpO_2 value which belongs to the measured *R* value is read out from the calibration table, which is in the memory of the DSP.

3 Methods

The reference oximeter and the DUC are based on the described principles. The difference is that the DUC does not have a calibration table yet, so it can measure the *R* rate, but cannot display the related SpO_2 level. In Fig. 2 the calibration table

[2] NIR: Near Infra Red

[3] DSP: Digital Signal Processor

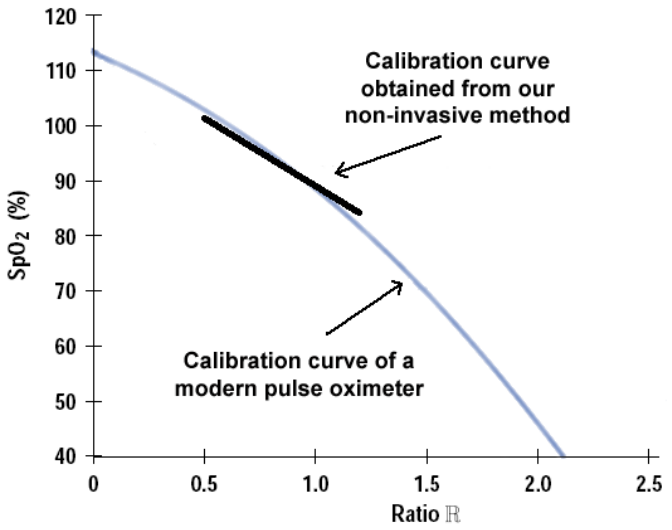

Fig. 2. Graphically demonstrated calibration table

of a modern oximeter is displayed graphically. In the case of our non-invasive calibration method the calibration table is approximated by a regression curve. The algorithm was the least squares method. The data were obtained by non-invasive measurements of four female and five male healthy subjects. The DUC and the calibrated reference oximeter (Koike Medical Ltd.: Finger BePUL2) were attached to the subject's fingers, so the SpO_2 value measured by the reference oximeter and the R rate measured by DUC could be observed at the same time. A respiration mask was fixed to the face of the subject. The mask was connected to a high pressure artificial air tank through a valve, a humidity increaser, and a pressure compensatory bag. The valve was intended to switch between normal air and artificial air with low oxygen content. Each measuring cycles were 15 minutes long. In Fig. 3 the averaged SpO_2 level of the subjects can be seen during the 15 minutes long measurements. In the first two minutes normal air was breathed by the subject, the oxygen saturation is in the normal region, which is 97±2%. Then, during ten minutes artificial air with 14% oxygen content was breathed. In the low oxygen condition period the SpO_2 level of the subjects decreased significantly. The lowest measured value was 86%, which is still over the dangerous level. From the tenth minute the oxygen level became into a steady state. In steady state the partial oxygen pressure of the breathed air and the arterial oxygen level are balanced. In the last three minutes normal air was supplied again. The oxygen saturation started to increase fast, and in 1.5 minutes it reached the normal level. During every 15 minutes long measurements the R rate and the SpO_2 values were recorded in every 15 seconds. In case of the nine subjects 8240 heart beats were recorded and evaluated. The R rate was calculated by every beat, than every 15 seconds of data were averaged. The SpO_2 was measured also in every 15 seconds by the reference oximeter. From the 8240 heart beats 511 R rate - SpO_2 value pair were obtained.

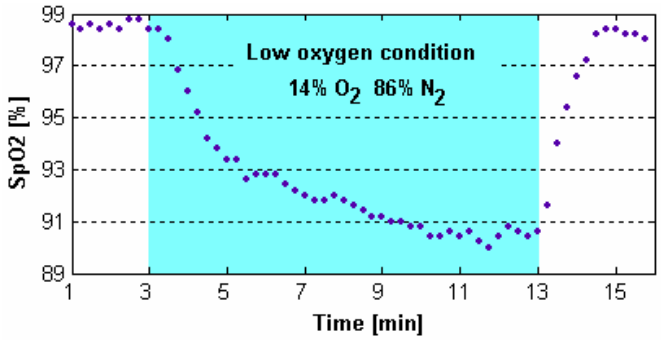

Fig. 3. SpO_2 level of the subjects during the experiment

Error calculation

In case of our non-invasive calibration method the error of the reference device will be added to the error of the calibration. Thus, the error of the calibrated device (DUC) can be expressed as:

$$E_{\text{calibrated oximeter}} = E_{\text{reference oximeter}} + E_{\text{calibration}}[\%] \quad (3)$$

In case of calculating the calibration error ($E_{calibration}$) we substituted the calibration curve obtained from present study Eq. (5) to the data evaluation software of the DUC making able the DUC to display not only the measured R values but the corresponding SpO_2 values also. The error is the difference between the SpO_2 values measured by the DUC and the reference oximeter. The average error can be expressed as:

$$E_{\text{calibration}}[\%] = \frac{1}{n} \cdot \sum_{i=1}^{n} \left| \hat{y}_i - y_i \right| \quad (4)$$

where n is the number of the measured data pairs, y_i is the i-th SpO_2 value measured by the reference oximeter, and $\hat{y}_i$ is the i-th SpO_2 value measured by the DUC. The reference oximeter data are supposed to be the true values. However, they are not the true SaO_2 values, because every oximeter has measuring error, the reference oximeter also. The average error of the reference oximeter is written in its manual, and it is considered by calculating the total error ($E_{\text{reference oximeter}}$) as it is shown in Eq. (3).

4 Results

The 511 data pairs obtained from the measurements on nine subjects can be seen in Fig. 4. In full range the $SpO_2 - R$ rate relation is non-linear. In Fig. 2 it seems to have a parabolic shape. However, in a small region linear approximation can be accurate. To prove this we fitted linear and quadratic polynomial regression curves also to the data. The difference between the two determination coefficients[4] is 0.0001, so linear regression can be used with good accuracy in the region of 86-100% SpO_2. As outcome result of our experiments, the equations of the linear regression curve:

$$SpO_2 = -24.87R + 113.8 \quad (5)$$

[4] Determination Coefficient or R-square, R^2. This statistic measures how successful the fit is in explaining the variation of the data.

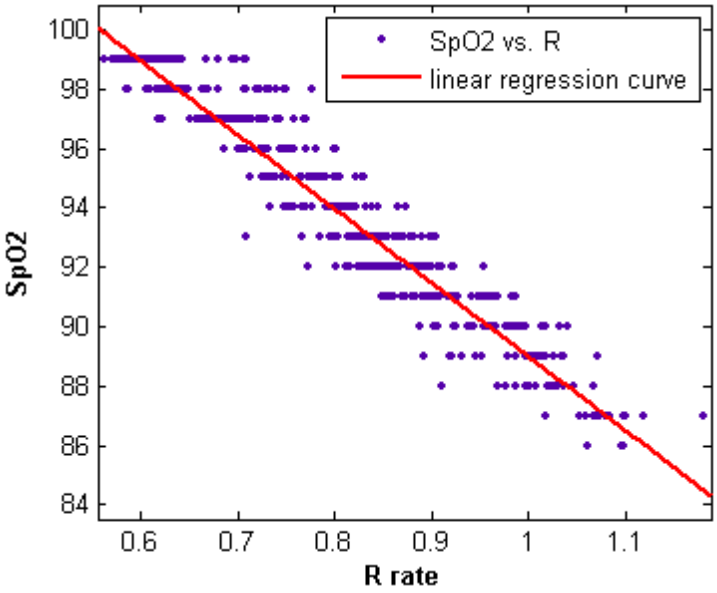

Fig. 4. 511 pieces of measured data pair, and a linear curve fitted to the data

The determination coefficient of the curve is 0.92. The mean determination coefficient calculated by each of the 9 subjects is: 0.93±0.08 (mean ±SD). This means that the regressions have good correlation. Eq. (5) should be used in the range of SpO_2=86-100%.

Error calculation

Based on Eq. (3) the measuring error of the DUC was calculated. According to the user's manual, the Finger BePUL2 reference oximeter has 2% measuring error in the range of 70-100% SpO_2. Based on Eq. (4) the average error of the calibration is 0.76%. So the total average error of the calibrated device is 2.76%.

5 Discussion

Eq. (5), as the result of our experiment can be used to calculate the SpO_2 value from the measured R value in the range of 86-100% SpO_2. The determination coefficient of the regression curve which describes the relation is 0.92, which means linear approximation can be used with good accuracy in this small region of SpO_2. Our wireless pulse oximeter (DUC) can measure the R rate, and with the result of present study it is able to calculate the SpO_2 level also.

The measuring error of a modern pulse oximeter is ±1-2% in the range of SpO_2=70-100%. The DUC has 2.76% error, so slightly more as an invasive-calibrated oximeter. However in medical practice this difference is negligible in most of the cases.

6 Conclusion

Considering the advantages of the method and the described error factors, our non-invasive calibration method can be useful in case of conventional pulse oximetry and with the extension of the calibration range to lower saturations in case of fetal pulse oximetry also. To decrease the error of the method, more reference oximeters from different manufacturers with higher accuracy should be used for the measurements.

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