Title: Signal Extraction Technology in Aviation Medicine: Perfusion-Independent Determination of Peripheral Oxygen Saturation

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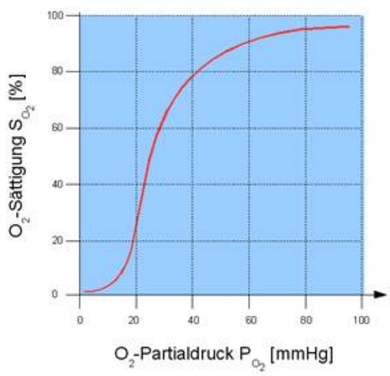
Abstract: During air rescue, the technical limitations of conventional pulse oximetry for cases of centralised circulation and shock are amplified due to additional vibration and hypobaric conditions. The current study of 50 patients evaluated different methods of peripheral oxygen saturation (SpO_2) measurement at an average altitude of 2200 feet. Signal extraction technology (SET) measured markedly higher SpO_2 -values compared to conventional methods (97% vs. 76%). The SET measurements also took considerably less time (30 vs. 90 seconds), regardless of perfusion status. In 20% of the patients, conventional pulse oximetry yielded no usable measurement. SET oximetry also allows calculation of the perfusion index (PI). In our data, PI values correlated with blood pressure (r=-0.4) and the shock index (r=0.82). In conclusion, the SET Rad5 Oxymeter gives a more reliable measurement than conventional pulse oximetry in cases of patient movement, vibration, decreased perfusion, and shock.

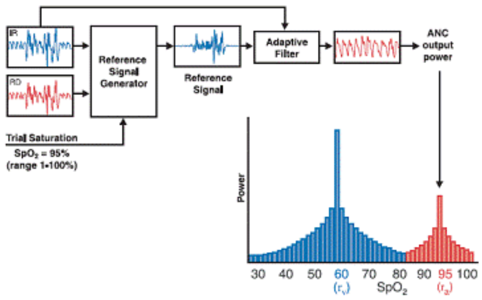
Introduction: Pulse oximetry transmits information regarding oxygen absorption and transport to the peripheral circulation. On the basis of the haemoglobin-oxygen binding curve, the relationship between peripheral oxygen saturation and the arterial partial pressure of oxygen can be derived. This derivation allows comparability between the pulse oximetry-derived peripheral saturation (SpO_2) and the calculated or measured arterial saturation (SaO_2) from arterial blood gas analysis [2,6]
The pulse rate is also indicated by pulse oscillometry. Conventional plethysmometric oximetry calculates oxygen saturation by evaluating the absorption of oxygenated haemoglobin in the near infrared spectrum (940 nm) and that of deoxygenated haemoglobin in the red spectrum (660 nm). The peripheral oxygen saturation (as a percent) is derived from this densitometry ratio, and gives the empiric percentage of oxygenated haemoglobin. Patient movement, artefact, and decreased blood flow to the area of measurement can all distort the conventional measurement of oxygen saturation. An investigation of the sensitivity and specificity of pulse oximeters showed that with patient movement and and/or hypoperfusion states, saturation extraction technology (SET) was markedly superior to conventional pulse oximetry (Nellcor). [1]

Figure 1: Oxygen-Binding Curve



Fourier Artefact Suppression Technology (FASTSat) enables signal processing irrespective of movement. This suppressed-suppressed signal is then processed with SET using a specially developed adaptive filter (adaptive noise canceller). The calculation of functional arterial saturation is performed with Fourier analysis. Specific physiologic noise frequencies for venous and arterial signals are calculated with the SET analysis. Using optical densitometry with a Discrete Saturation Transform Algorithm (DST TM), the specific non-arterial oxygen saturation is extracted from the red and infrared spectrums. The venous and arterial saturation spectrums are then separately analysed. Therefore, this technology makes possible a direct calculation (in real time) of the peripheral SaO_2.

Figure 2: Discrete Saturation Transform and FAST-SET



The pulse oximeters (Rad5) with SET also furnish a perfusion index (PI). This PI is an estimate of the pulse and perfusion intensity in the measured area, and gives a numeric value for the quality of infrared reflection. The proportion of pulsatile and non-pulsatile components of the infrared radiation correlates with blood flow in the measured area. The absolute PI value varies between individual measurements and depends on the physiologic conditions of the vessel musculature?! [4] The measured PI value correlates with immediate perfusion status, as has been clinically validated. [3]
Using the Rad5 pulse oximeter from Masimo® with SET, DSM, and FAST technology, the immediate arterial oxygen saturation is calculated and the peripheral circulation is characterized using the PI. Thus, not only oxygenation but also oxygen utilization in the peripheral circulation can be estimated. No correlation between pulse oximetry-determined perfusion index and the cardiac output has been established.

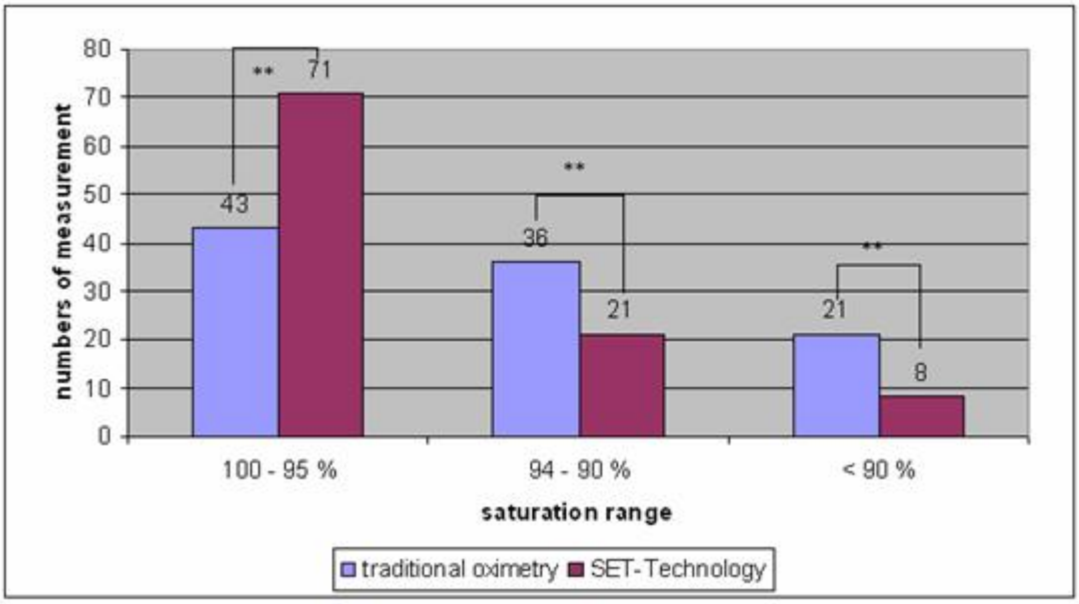
The determination of peripheral oxygen saturation (SpO_2) is widely used in prehospital medicine. [5, 7, 8] SpO2 measurements are consistently performed during the supervision of air-transported patients. [5] In clinical practice, it is accepted that saturation determination is not possible in cases of decreased peripheral circulation, violent movement of patients or helicopter vibrations, or hypothermia.
The goal of the current study, then, is to compare the use of SET with conventional pulse oximetry during air rescue/transport. The improved signal quality with SET should allow more stable determinations than conventional oximetry, even in cases of patient movement, vehicle vibration, and conditions of decreased perfusion.

Materials and Methods: SpO_2 determinations were carried out during air rescue/transport of patients over a period of three months. Both index fingers were used to perform simultaneous readings with reusable probes. The Rad5 (Masimo®) instrument was used for SET-measurements, and conventional plethysmometric oximetry was measured with the Oxysensor II with integrated Propag Encore© (Nellcor®).Examinations were performed at a cruising altitude of 2000 to 3000 feet. Initial measurements were performed with the Rad5 probe on the patients left index finger, and the Nellcor® Oxysensor II on the right. The oximeters were then reversed for a second measurement. Both measurements were admitted into calculations to avoid bias based on side differentiation. A total of 200 oxygen saturation readings were recorded for 50 patients. Non-invasive blood pressure determination was not performed during the saturation readings. However, vital signs (pulse and blood pressure) were recorded. Temperature measurement was not performed but variability between the extremities was ruled out tactilely.The time-to-signal (TTS) as well as the calculated PI were measured with the SET oximetry on maximally sensitive mode. Indications for bilateral oxygen saturation measurements were patients with reduced perfusion, shock (cardiogenic, hypovolemic, or hypoglycaemic), or peripheral hypothermia. In patients with arterial access (n=8) for continuous blood pressure measurement, the results of peripheral saturation were compared with the values of arterial oxygen saturation calculated with an Istat® blood gas analyser.Statistical analysis was performed using SPSS version 11.5. Level of significance was defined as $p<0.05$. The Chi-Square test as well as the Student t-test was performed.

Results: SET oximetry was performed with the Rad5 oximeter from Masimo© on 50 patients during air transport.
Fifty-two percent of patients (n=26) had conditions affecting the heart and/or vascular system. Ten patients (20%) were transported because of intracerebral haemorrhage, and 18% (n=9) were victims of polytrauma with multiple injuries. Five patients (10%) had otherwise acute illnesses with shock-like symptoms. Twenty-two percent of patients (n=11) were mechanically ventilated. The descriptive statistics showed no significant differences between the illness-groupings or between spontaneously breathing and artificially ventilated patients. On average, the systolic blood pressure was 120.7±23.6

mmHg and the heart rate 93.4±20.5 beats per minute. The mean arterial pressure (MAP) averaged 75.5±12.8 mmHg.
In 27% of patients (n=14), the shock index (SI) was =1 while the average SI was 1.2±0.4. SI was calculated as the ratio of heart rate to MAP.
Using conventional oximetry, the average SpO_2 values were 76.3±39.5%. In contrast, the average value with SET oximetry was 97±4.1%. Figure 1 shows all oxygen saturation measurements for one measurement side. This measured value is significantly higher using the Student t-Test ($p<0.001$).
PIs calculated with SET oximetry averaged 3.3±1.3. All patients with SI =1 had PIs >2.5, while those with SI <1 had PIs <2.5. The Person Correlation Coefficient between PI and SI was 0.81, and the difference between the two was significant ($p<0.001$). The comparison of PI and heart rate as well as PI and SpO_2 was also statistically significant ($p<0.001$), without a correlation ($r=0.12$). In contrast, MAP and PI showed a negative correlation ($r=-0.4$). No analysis for correlation with temperature was carried out.

Figure 1: Saturation Range (n=200)



** $p < 0.001$

Table 1 shows the frequency distribution of the measured parameters across from the calculated PI. PI and SI values are the average values.

Table 1: Perfusion Index (calculated with SET)

Systolic BP (mmHg)	Perfusion Index	Shock Index	SpO_2 in %	SET SpO_2 in %
<60	4.1	1.8	63.6	99.0
60 - 70	3.7	1.7	65.4	98.7
70 - 80	3.2	1.5	73.5	98.7
80 - 90	3.4	1.3	88.1	98.6
90 - 100	2.5	1.0	90.6	99.2
100 -120	1.4	0.8	96.4	98.5
120-140	1.4	0.7	97.8	95.6
>140	2.9	0.6	97.6	98.7

The time to signal (TTS) was determined from the time of probe placement to the time of signal reading in segments of 15 seconds. The average TTS for traditional plethysmometric oximetry was 90±60 seconds. For SET oximetry, it was 30±15 seconds ($p<0.05$). Blood gas analysis with the Istat® analyser was performed to validate the measured saturation values. There was no significant difference between the values generated by blood gas analysis (average SaO_2 97.0 %) and those from the SET oximeter (average SpO_2 97.1 %) ($p > 0.05$). In comparison, the average measured SpO_2 from the conventional oximeter from Nellcor® (76.3%) was significantly less than the calculated SaO_2 of 97.0% from blood gas analysis ($p < 0.05$).

Discussion: Measurement of SpO_2 using conventional plethysmometric methods is limited for patients in shock or with other causes of peripheral vasoconstriction and decreased perfusion. Hyperoxia, dysfunctional haemoglobin, glaring ambient light, and electromagnetic disturbances also bring about measurement errors. During air transport, other factors such as vibration and turbulence, temperature changes due to environmental pressure changes, and oxygen tension can also interfere with conventional pulse oximetry, [8] leading to measurement errors and loss of signal. In the patients investigated here, 20% of conventional oximetry measurements were insufficient due to patient movement, vibration, decreased perfusion, and/or hypothermia.

These problems severely restrict prehospital emergency medicine, and exclude a very useful diagnostic and therapeutic tool. Repercussions of these limitations were reported in a study investigating prehospital oxygenation of traumatised patients in shock. In that study, 10.5% of patients were insufficiently oxygenated (paO_2–<–80 mmHg). [5] It can be assumed with a PaO_2 of 60-80 mmHg that a measurable decrease in oxygen saturation should be present (see Figure 1).

In the current study, the perfusion index correlated with the shock index. There was a negative correlation between blood pressure and PI. In cases of decreased circulation, stable oxygen saturation values could still be obtained using the SET oximetry. In contrast, conventionally measured SpO_2 values decreased with lower blood pressure and with increased shock index values (see Table 1The SpO2 values measured with SET oximetry did not decrease under the same conditions. Blood gas analysis validated the readings from the SET oximeter (97.0% versus 97.1%). Although the SaO_2 values from the blood gas analyses were calculated and not directly measured, the difference with the conventional pulse oximetry values was substantial.

Conclusion: During air transport, limitations of conventional pulse oximetry are increased. Besides pathologic alterations in perfusion, during air flight there are altitude-dependent temperature and barometric pressure drops as well as flight-dependent vibration and turbulence. Although there is minimal physiologic limitation at 2000-3000 feet, the pathophysiologic changes are substantial when compared to ground transport [8] In aviation medicine, oxygen saturation is an indispensable diagnostic and therapeutic tool. The observed error of conventional SpO_2 measurements of 20% (n=10), in addition to the already decreased specificity and sensitivity of measured oxygen saturation, is unacceptable. Repercussions on the quality of prehospital care are evident [5]

There was a significant difference between the values of oxygen saturation measured with conventional oximetry and with SET (SpO_2 76% vs. 97%). Unlike with plethysmometric oximetry, with SET, the SpO_2 could be measured regardless of perfusion. There was an identifiable correlation between the mean arterial pressure and the perfusion index. SET oximetry is markedly superior to conventional oximetry in situations of hypotonic circulation with decreased peripheral circulation, particularly for patients in shock (SI>1). As well, the time to signal (TTS) of the SET oximetry is significantly shorter than that of conventional oximetry (30 vs. 90 seconds). In aviation medicine, therefore, SET oximetry has enormous advantages. Implementation of the SET Masimo measurement technology into monitor systems (i.e. Medtronic, Corpuls, etc.), would have a similar cost to that of the Nellcor sensors. From the price of the individual Rad5 device, it can be assumed that the price of the two technologies are comparable.

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