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In vitro evaluation of the CeVOX continuous central venous oxygenation monitoring system*

W. Baulig,[1] A. Dullenkopf,[1] P. Hasenclever,[2] E. R. Schmid,[1] and M. Weiss,[3]

[1]Division of Cardiac Anaesthesia, University Hospital Zurich, Rämistrasse 100, 8091 Zurich, Switzerland

[2]Clinic of Cardiac Surgery, University Hospital Zurich, Rämistrasse 100, 8091 Zurich, Switzerland

[3] Department of Anaesthesia, University Children's Hospital Zurich, Steinwiesstrasse 75, 8032 Zurich, Switzerland.

Correspondence to:

Werner Baulig, MD
Division of Cardiac Anaesthesia
Institute of Anaesthesiology
University Hospital Zurich
Rämistrasse 100
8090 Zurich
Switzerland

Tel +41 44 255 49 17
Fax +41 44 255 45 61
E-mail werner.baulig@usz.ch

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Summary

We investigated the in vitro performance of the CeVOX system for continuous monitoring of central venous oxygen saturation by spectrophotometry. Oxygen inflow into the system was varied, and oxygen saturation values measured by CeVOX ($S_{cevox}O_2$) were documented. Blood samples were simultaneously taken to assess oxygen saturation by co-oximetry (SO_2), and values were compared by Bland-Altman analysis. Sixty-six data pairs were obtained at $S_{cevox}O_2$ and SO_2 values ranging between 16–99% and 5.5–100%, respectively. Overall, $S_{cevox}O_2$ only slightly overestimated SO_2 (mean bias +2.4%), but limits of agreement (± 2 SD of bias) were high (–11.8 / +16.6%). $S_{cevox}O_2$ underestimated SO_2 at higher oxygen concentrations and overestimated it at lower oxygen concentrations. There was a nearly linear correlation of the mean bias of $S_{cevox}O_2$ and SO_2, suggesting a systematic error. We conclude that the current version of the CeVOX system does not reliably reflect SO_2 values.

Keywords: Monitoring, central venous oxygenation, central venous catheter, spectrophotometry

Abstract: 146 words

Text: 2069 words

Monitoring of central venous oxygen saturation ($S_{cv}O_2$) is important for guiding haemodynamic management in children and adults during major elective surgery [1-4]. It is also one of the core targets for early goal-directed therapy in the treatment of septic shock in adults [5-8]. Standard means to monitor $S_{cv}O_2$ consist of repeated blood drawing from a central venous catheter placed in the superior vena cava and analysis of the blood using co-oximetry [9].

However, this approach is intermittent, increases workload and costs, and results in contamination of stopcocks and iatrogenic blood loss. Therefore, reliable techniques for continuous monitoring of $S_{cv}O_2$ would be desirable.

One such technique is spectrophotometry using near-infrared light [9]. The recently introduced CeVOX system (Pulsion Medical Systems, Munich, Germany) consists of a disposable spectrophotometric probe that can be inserted into the distal lumen of a central venous catheter placed with its tip in the superior vena cava. Tissue chromophores, such as haemoglobin, absorb near-infrared light depending on their oxygenation state. Changes in chromophore concentrations and oxygenation states, revealed by comparing emitted and detected near-infrared light, can therefore be quantified using the modified Lambert-Beer law [10-12]. Data are available about the reliability of the CeVOX system [10, 11], but the aim of this study was to validate performance of the CeVOX system in an in vitro model.

Methods

For the purpose of monitoring $S_{cevox}O_2$, light of three wavelengths (660, 805 and 880 nm) is transmitted through a fiberoptic probe inserted into the distal lumen of a central venous catheter placed in the superior vena cava. The tip of the fiberoptic probe must protrude past the distal end of the catheter by 2-3 cm. It is connected to the optical module of the CeVOX system, and light reflected from the haemoglobin in the red blood cells is transmitted back by a second fiberoptic line. The sensor in the optical module analyses the reflected light and determines light extinction. This information is transferred to the CeVOX system, and $S_{cevox}O_2$ is calculated and displayed on the screen (Fig 1). Before starting continuous measurements, a calibrating maneouver using a blood sample analysed by co-oximetry is required.

Experimental set-up

An 8.5F four-lumen central venous catheter with a length of 20 cm and a distal lumen of ≥0.038 in (Pulsion Medical Systems) was inserted into a black test chamber with a volume of 100 cm^3. A CeVOX 2F fiberoptic probe (PV2022-35, Pulsion Medical Systems) was introduced into the distal lumen of the central venous catheter, secured by the integrated luer lock system, and connected to the optical module of the CeVOX device (PC3000, Pulsion Medical Systems). The test chamber was connected to a paediatric cardiopulmonary bypass circuit consisting of a roller pump and a thermoregulating device (Paediatric Pump S3, Stöckert Instruments, Munich, Germany), a Safe Mini oxygenator (Polystan/Maquet-CP, Hirlingen, Germany), a Safe Micro Reservoir (Polystan/Maquet-CP) and a real-time blood gas analyser unit (CDI 500, Terumo, Eschborn, Germany) to monitor PCO_2. Pressurized O_2, N_2 and CO_2 were connected to a fresh gas mixer (full automatic gas blender, Stöckert Instruments) (Fig 1) to provide air mixtures with various concentrations of oxygen at

physiological PCO_2. The whole system was filled with 300 ml of human blood provided by one of the investigators. Anticoagulation was performed by adding 10,000 IE heparin sodium (Hoffman la Roche AG, Grenzach-Wyhlen, Germany). The flow rate provided by the pump was kept constant at 1000 $ml.min^{-1}$ throughout the experiments, and blood pressure in the test chamber was held at 15 cm H_2O. Blood was warmed to 37°C, and alpha-stat blood PCO_2 was held within physiological range (5-7 kPa), as continuously monitored by the real-time blood gas analyser unit of the extracorporeal circuit and confirmed by blood gas analysis. Blood samples were analysed using multi-wavelength haemoximetry (ABL 626/620, Radiometer Medical A/S, Akandevey 21, DK-2700 Bronshoj, Denmark).

After steady-state values for $S_{cevox}O_2$ at 70% were reached, the CeVOX system was calibrated according to the reference manual of the manufacturer. The circulating blood was then gradually desaturated by changing the fresh gas mixture of the membrane oxygenator from oxygen to nitrogen and vice versa. With each change of the oxygen saturation level and after a steady-state condition of $S_{cevox}O_2$ was obtained, $S_{cevox}O_2$ values were recorded and blood samples were taken simultaneously from the distal lumen of the central venous catheter for analysis of pH, partial oxygen tension, PCO_2, sodium bicarbonate ($NaHCO_3$), base excess, SO_2, and haemoglobin concentration (Hb).

Statistics

Data are expressed as mean (±SD) and range as appropriate. Agreement between $S_{cevox}O_2$ and SO_2 measured by co-oximetry was assessed by Bland-Altman analysis [13]. Linear regression analysis was performed to compare $S_{cevox}O_2$ and SO_2 and the difference values of $S_{cevox}O_2$ and SO_2 with SO_2. To test the influence of pH, PCO_2, $NaHCO_3$, base excess, Hb, and temperature on the mean bias of $S_{cevox}O_2$ and SO_2, a multiregression analysis was performed. StatView 5.02 and SPSS 13 software were used for statistical analysis.

Results

Three series of measurements were undertaken on three occasions, using identical experimental set-ups and, for each set-up, a new fiberoptic probe. A total of 66 $S_{cevox}O_2$ readings and simultaneous measurements of SO_2 were obtained and analysed. Metabolic parameters are listed in Table 1. $S_{cevox}O_2$ and SO_2 ranged between 16–99% and 5.5–100%, respectively (Fig 2). Simple regression analysis demonstrated a high linear correlation between $S_{cevox}O_2$ and SO_2 (r^2=0.97, p<0.0001) (Fig 2). However, the Bland-Altman analysis revealed poor agreement between $S_{cevox}O_2$ and SO_2. Although the mean bias was low (+2.4%), the limits of agreement (± 2 SD of bias) amounted to –11.8 / +16.6% (Fig 3). $S_{cevox}O_2$ underestimated SO_2 at higher values and overestimated it at lower values. A nearly linear correlation between the mean bias of $S_{cevox}O_2$–SO_2 and SO_2 was found, which is expressed by the equation ($S_{cevox}O_2$–SO_2) = 14 – 0.2*SO_2(%) (R^2 = 0.65, p>0.0001) (Fig 3b)**.** Mean bias and limits of agreement of $S_{cevox}O_2$ and SO_2 were similar when data pairs were compared between the three fiberoptic probes (data not shown). Mean bias of $S_{cevox}O_2$ and SO_2 was influenced by Hb (p = 0.0143) but not by pH, PCO_2, $NaHCO_3$ base excess or temperature. The subgroup analysis of data pairs in the range 10–49% SO_2 and 50–100% SO_2 resulted in a mean bias (limits of agreement) of +9.4% (+1.2 / +17.6%) and –2.1% (–10.9 / +6.1%), respectively.

Discussion

We investigated the performance of the CeVOX system for continuous monitoring of central venous oxygen saturation in an in vitro setting. The main findings were that (1) the agreement between $S_{cevox}O_2$ and SO_2, measured by co-oximetry, was poor, especially at low and high SO_2 values; (2) the CeVOX system considerably overestimated low SO_2 values and underestimated high SO_2 values; and (3) no better agreement was found in the clinically relevant range of oxygen saturation.

The technical prerequisites for continuous measurements of oxygen saturation in the blood using spectrophotometry have been available for more than 40 years [14]. Multiple clinical and experimental investigations have compared oxygen saturation values derived from fiberoptic catheters with those obtained by co-oximetry, but the results are inconsistent (Table 2). Some authors suggested that fiberoptic devices based on three (instead of two) reference light wavelengths might increase accuracy [15-18], but this conclusion was based on linear correlation coefficients. A high linear regression coefficient, however, is meaningless and can be misleading in the context of methods comparison, because correlation does not necessarily mean agreement. Other investigators, using Bland-Altman analyses for methods comparison, found no difference whether two or three reference light wavelengths were used [19-23].

The CeVOX system, investigated here, is based on three reference light wavelengths and characterised by one transmitting and one detecting fiberoptic filament. Advantages of the CeVOX system are that it is easy to handle and does not necessitate additional invasive venous access because the disposable 2F fiberoptic catheter can be inserted into a standard central venous line. Various lengths (30–48 cm) of the fiberoptic catheter facilitate its use in connection with a variety of central venous catheters in adults. In infants, however, as

recently reported by Müller and colleagues [24], insertion of a separate 16-gauge single-lumen catheter into a femoral vein is required to enable the use of the 2F fiberoptic probe.

The high linear correlation coefficient between $S_{cevox}O_2$ and SO_2, as measured by co-oximetry in the current study, confirms the findings of previous investigators who compared fiberoptic measurements of SO_2 with SO_2 assessed by co-oximetry [15, 23, 25]. Using Bland-Altman analysis as the appropriate statistical approach [13], the agreement between $S_{cevox}O_2$ and SO_2, measured by co-oximetry in our study, was poor.

Most recently, Huber and colleagues [11] compared SO_2 values obtained with a 2F CeVOX fiberoptic probe and a 4F Edward oximetry catheter against values measured by co-oximetry in an in vitro setting similar to that used in the present study. They reported an excellent correlation between fiberoptic measurements and SO_2 values determined by co-oximetry for both the CeVOX and Edward oximetry fiberoptic probes ($r^2 = 0.98$ and 0.99, respectively). However, the Bland-Altman plots for both probes revealed high limits of agreement (–11.2 / +10.85 and –7.7 / +9.6, respectively) and demonstrated overestimation at low SO_2 and underestimation at high SO_2. Fiberoptic SO_2 values were most accurate near the calibration point of 70%. These authors concluded that fiberoptic oximetry and co-oximetry gave nearly identical results over a wide range of oxygen saturations, but they recommended repeated recalibration to reduce the occasionally observed drift of fiberoptic oximetry values. In the current investigation similar results were found, with limits of agreement even higher than those reported by Huber and colleagues [11]. Contrary to that study, poor agreement between $S_{cevox}O_2$ and SO_2 determined by co-oximetry was also found near the calibration point.

Mean bias of $S_{cevox}O_2$ and SO_2 assessed by co-oximetry in our in vitro study showed a slope, suggesting linear dependency on SO_2 measured by co-oximetry. Analyzing the two subgroups

of data pairs with co-oximetric SO_2 ranging from 50–100% and 0–49%, respectively, the slope of the mean bias of $S_{cevox}O_2$ and co-oximetric SO_2 was highest in the range 0–49%. The subgroup analyses confirmed the overestimation of SO_2 in the low range of co-oximetric SO_2 values by $S_{cevox}O_2$ and the underestimation of SO_2 in the high range of $S_{cevox}O_2$ and co-oximetric SO_2. In both subgroups, however, no difference was found with regard to the limits of agreement between $S_{cevox}O_2$ and SO_2 assessed by co-oximetry. The nearly linear dependency of the mean bias of $S_{cevox}O_2$ and SO_2 values obtained by co-oximetry on co-oximetric SO_2 values was confirmed when the data obtained by the three different fiberoptic probes were analysed separately, possibly suggesting a systematic error in the CeVOX algorithm.

One possible reason for the suggested systematic error may be the calibration factor (CAL-Value) of the CeVOX system, recommended by the manufacturer. Postprocessing the measured data by stepwise reduction of the recommended CAL-Value by 7, 16 and 23% led to a disappearance of the slope of the mean bias. However, mean bias changed from nearly 0 to –5.8% without any impact on the limits of agreement.

Another cause and possible limitation of this study may be the impact of metabolic changes oxygen saturation measured by spectrophotometry. In particular, increasing values of carbon dioxide tension cannot be manipulated in our experimental setting. Haney and colleagues [28] reported in dogs a significant overestimation of spectrophotometrically measured mixed venous oxygen saturation as carboxyhaemoglobin increases. Because the CeVOX system does not detect the presence of carboxyhaemoglobin we cannot exclude its increase. Carbon dioxide tensions in our experimental setting were found to lie between the upper physiologic and the hypercapnic range, which may explain in part the overestimation of low oxygen saturation values, but not the observed underestimation in the high range of oxygen

saturations. Contrary to this in vitro study, the influence of metabolic parameters are preventable in an in vivo setting by preserving normocapnia and a balanced metabolic state.

Reliability of continuous central venous oxygen saturation readings is of particular importance in the lower range (<60% $S_{cv}O_2$), where therapeutic interventions become necessary. During and after palliative congenital cardiac surgery in neonates and small infants with cyanotic heart diseases, $S_{cv}O_2$ may range from 35 to 55%. In this setting the CeVOX device has serious limitations.

In conclusion, our in vitro evaluation of the CeVOX system revealed poor agreement between fiberoptic measurements and saturation values determined by co-oximetry. Whether technical advancements and adaptations of the algorithm might improve performance of the CeVOX system remains to be seen.

Declaration of Interests:

There were no financial or non-financial competing interests in the accomplishment of this study.

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Table 1. Metabolic parameters. Values are expressed as mean (SD [range]).

Parameter	
Temp. (°C)	36.8 (0.27 [36.4 - 37.2])
Hb ($g.dl^{-1}$)	12.3 (0.1 [11.0 - 13.5])
Hct (%)	38.0 (2.5 [34.1 - 41.3])
PCO_2 (kPa)	5.54 (0.56 [4.87 - 6.7])
pH	7.33 (0.03 [7.22 - 7.40])
$NaHCO_3$ (kPa)	21.3 (2.49 [17.80 - 26.7])
BE (kPa)	–3.94 (0.31 [8.5 - 1.0])

Abbreviations: Temp., temperature; Hb, haemoglobin; Hct, haematocrit; PCO_2, partial carbon dioxide tension; $NaHCO_3$; BE, base excess.

Table 2. Studies investigating the reliability of spectrophotometry-based continuous assessment of oxygen saturation

• **Author;year** •	• **Wave length**	• **No. of subjects**	• **Pearson** •	• **Bias (%)**	• **Limits of Agreement (%)**
• Fahey; 1984[14]	• 3	• 84 patients	• 0.95	•	•
• Gettinger; 1987[15]	• 3 • 2	• 10 animals	• 0.99 • 0.81	•	•
• Zaune; 1990[26]	• 2 • 2	• 15 patients • 15 patients	• 0.87 • 0.86	• -1.3 • -0.1	• ± 2.8 • ± 3.2
• Pond; 1992[25]	• 2	• 52 patients	• 0.92	• -1.7	• ± 7.0
• Scuderi; 1994[21]	• 3 • 2 • 2	• in vitro • in vitro • in vitro	•	• +3.2 • -1.3 • -10.0	• ± 4.8 • ± 6.6 • ± 13.8
• Armaganidis; 1994[22]	• 3 • 2 • 1	• 14 patients • 15	•	• +1.0 • -0.2	• ± 7.8 • ± 8.1 • ± 24.6

		• patients • 8 patients		• +1.3	
• Janvier; 1994[20]	• 3 • 2 • 2	• in vitro • in vitro • in vitro	•	•	• ± 9.0 • ± 8.6 • ± 14.2
• Rouby; 1990[18]	• 3 • 2 • 2	• 11 patients • 8 patients • 12 patients	• 0.97 • 0.86 • 0.83	•	•
• Bongard; 1995[23]	• 3 • 2	• 7 animals • 7 animals	• 0.99 • 0.99	• +3.7 • +0.2	• ± 2.3 • ± 2.5
• Kirkeby-Garstad; 2000[27]	• 2	• 61 patients	•	• -1.6	• ± 11.4

Figure legends

Fig 1 Experimental setting: position of the CeVOX fiberoptic probe in a light protection black box integrated into an exctracorporeal circuit.

Fig 2 Linear regression plot for comparison of $S_{cevox}O_2$ values and SO_2 measured by co-oximetry (n = 66; $r^2 = 0.97$) (dotted line: line of identity).

Fig 3 Bland-Altman plot for comparison of $S_{cevox}O_2$ and SO_2 measured by co-oximetry (n = 66; mean bias +2.4%; limits of agreement [± 2 SD] –11.8 / +16.6%). Mean bias shows a nearly linear correlation with ($S_{cevox}O_2 + SO_2$)/2 expressed in the equation ($S_{cevox}O_2 – SO_2$) = $15 – 0.19*SO_2(\%)$; $R^2 = 0.58$ (dotted line)

Figures

Figure 1.

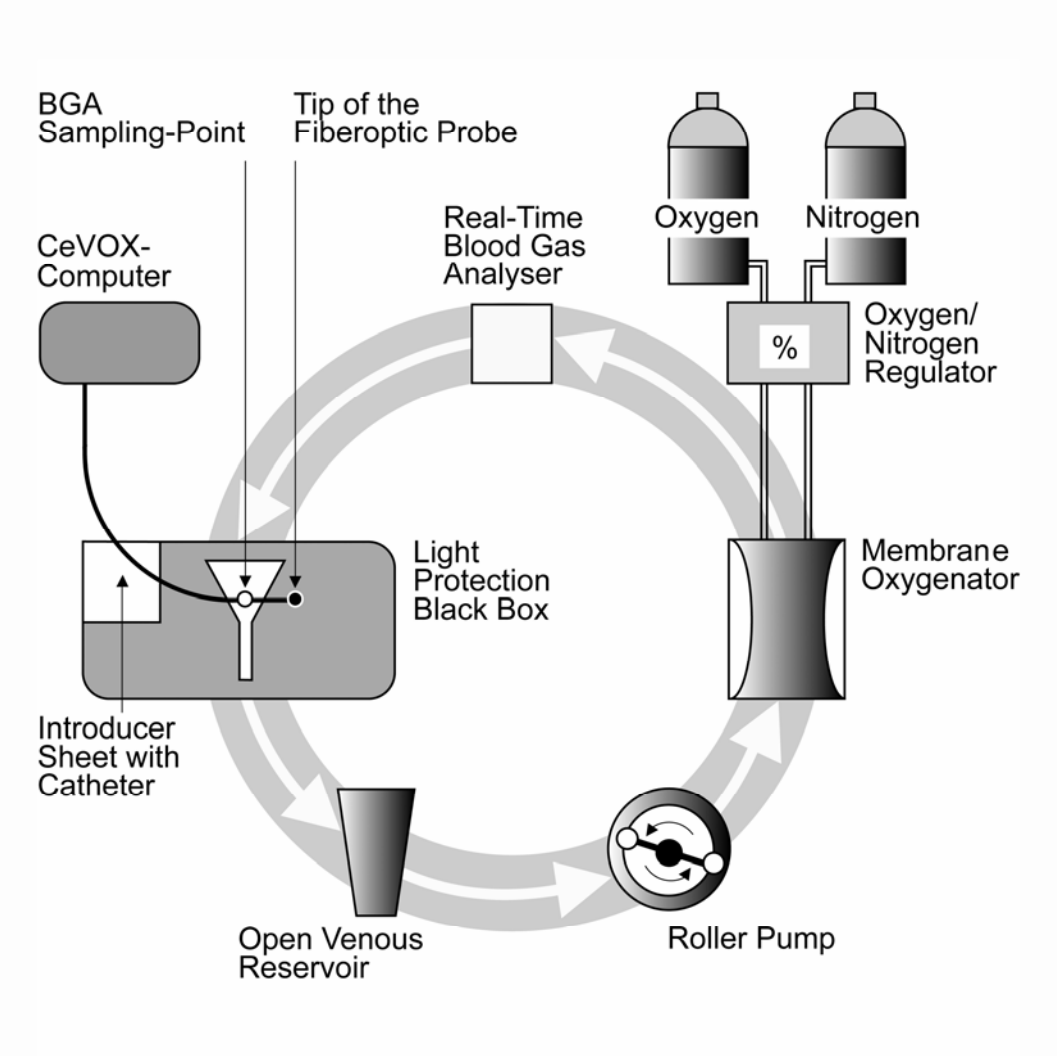


Figure 2.

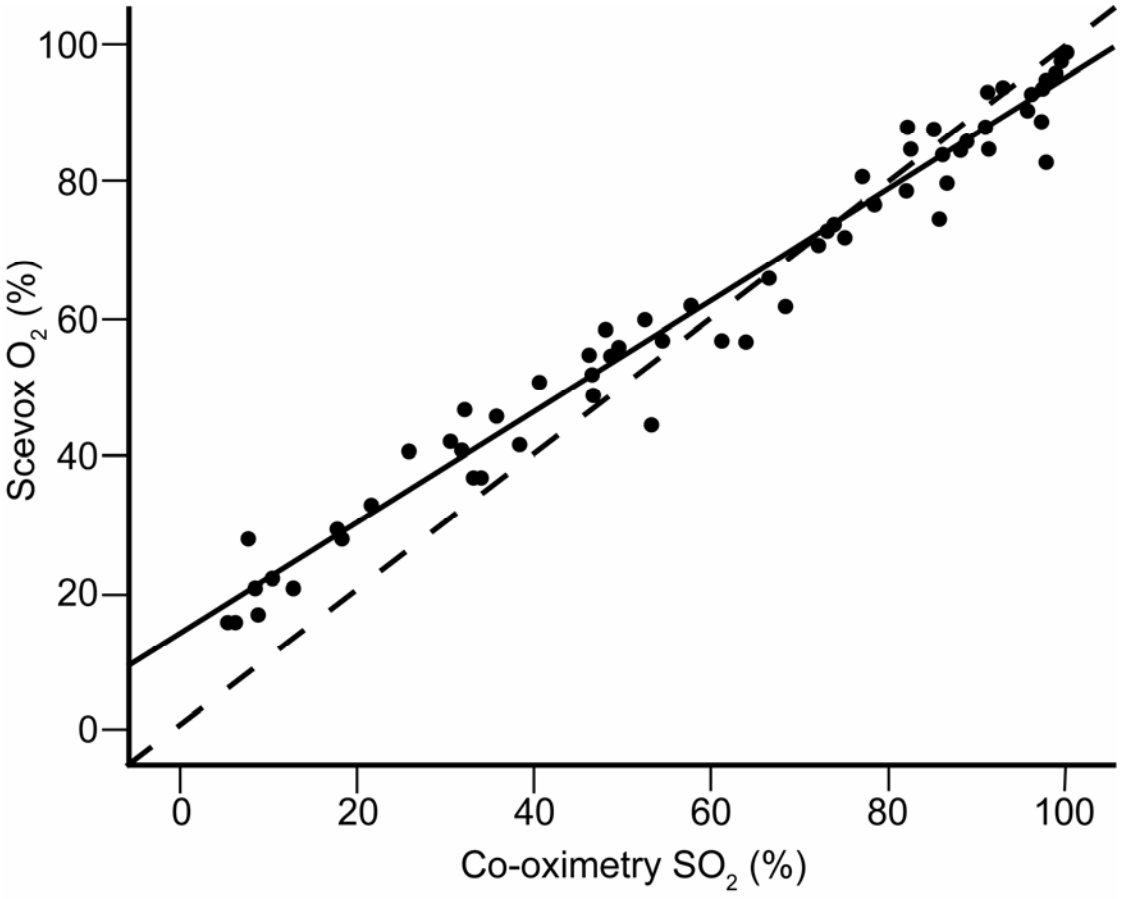
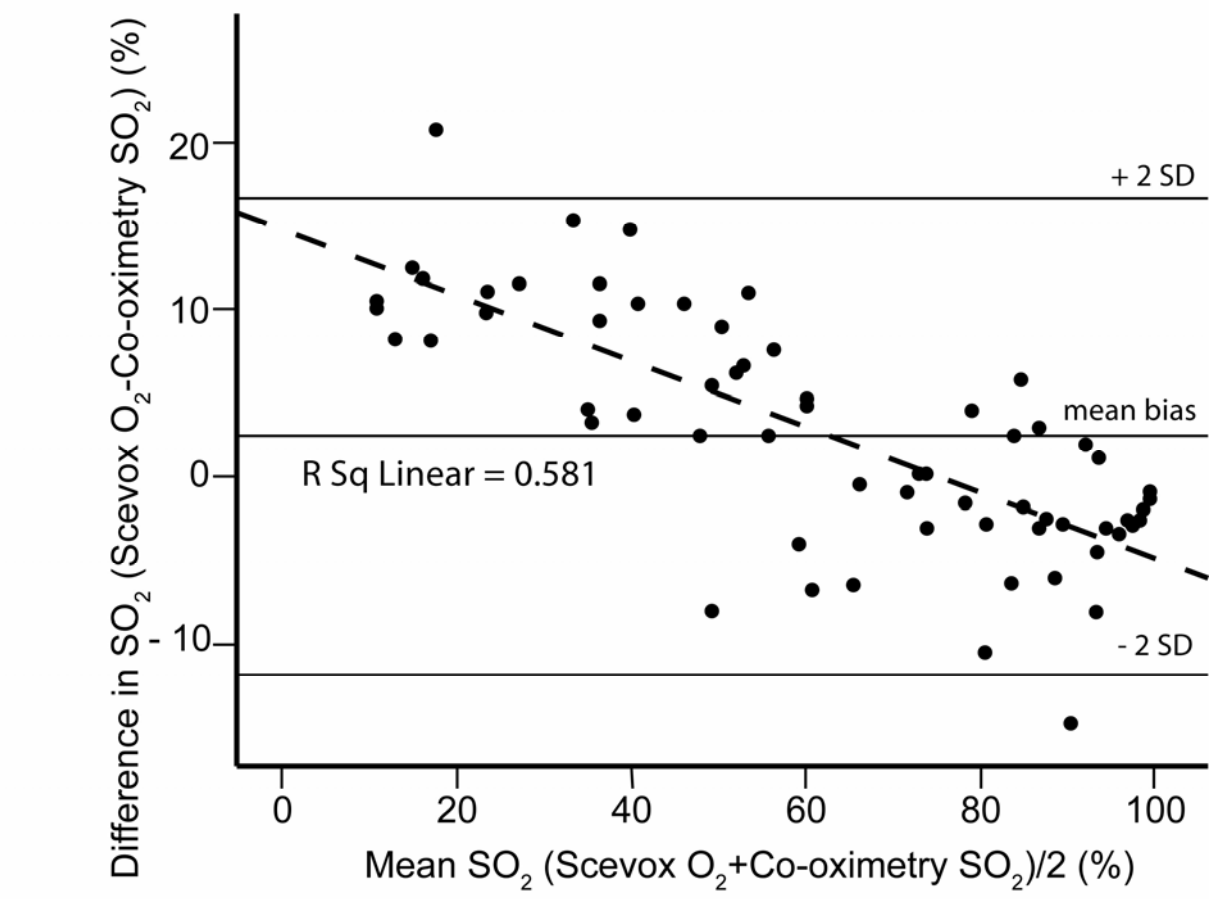


Figure 3.


Difference in SO2 (Scevox O2-Co-oximetry SO2) (%)
20
10
0
- 10
+ 2 SD
mean bias
- 2 SD
R Sq Linear = 0.581
0
20
40
60
80
100
Mean SO2 (Scevox O2+Co-oximetry SO2)/2 (%)