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Never Miss a Beat, Even Under Challenging Signal Conditions

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Abstract

Pulse oximetry is regularly used to guide critical clinical decisions across the care continuum. The purpose of this work was to evaluate the performance of two pulse oximetry sensors under dark pigmentation, low perfusion signal, and controlled hypoxia conditions. Two studies were completed, one utilizing bench testing methodologies and the other utilizing human participants in a laboratory setting. For both bench and human participant testing, the Nellcor™ OxySoft™ SpO_2 sensor connected to a N-600x pulse oximeter (Medtronic, Minneapolis, MN, USA) and LNCS® Neo-3 sensor connected to a RAD-97™ pulse oximeter (Masimo®, Irvine, CA, USA) were used during study procedures. Using bench testing methodology, simulating dark pigmentation and low perfusion, pulse oximetry performance was evaluated by comparing time-to-first post. In the clinical laboratory setting, pulse oximetry performance was evaluated by assessing accuracy of measured SpO_2 in healthy adult volunteers undergoing a controlled hypoxia protocol. In both bench testing and clinical laboratory settings, the Nellcor™ OxySoft™ SpO_2 sensor demonstrated better performance, as assessed by faster time-to-first post and greater accuracy compared to the LNCS® Neo-3 sensor under the combined challenging conditions of dark skin pigmentation and low oxygen saturation or perfusion.

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Introduction

Pulse oximetry is used in various settings across the care continuum to measure peripheral blood oxygen saturation (SpO_2), a non-invasive, surrogate measure of arterial blood oxygen saturation (SaO_2). Pulse oximeters continuously monitor SpO_2 by using optical transmission measurements from two light-emitting diodes, one red (660 nm) and one infrared (940 nm), and a photo detector to evaluate light absorption (Al-Halawani et al., 2023). The amount of light absorption differs between oxygenated and deoxygenated hemoglobin, which can be used to determine SpO_2 by calculating the ratio of light absorption between the two wavelengths. Melanin is known to have light absorption qualities at red and infrared wavelengths, which can can contribute to attenuation of the pulse oximetry signal and inaccurate readings (Al-Halawani et al., 2023; Chesley et al., 2022). Previous work has suggested that SpO_2 can be overestimated in individuals with greater quantities of melanin (darker skin pigmentation), with the magnitude of this overestimation appearing to increase with decreasing SpO_2 (Aoki et al., 2023). As sick patients and urgent clinical decisions impacting medical interventions are made at lower SpO_2 ranges, inaccurate readings can have cascading effects on patient care and outcomes.

Responsive, accurate pulse oximetry readings are a vital and expected component in the effective monitoring of patients. Errors in pulse oximetry readings related to skin pigmentation have been shown to impact patient outcomes, with greater skin pigmentation associated with missed (occult) hypoxemia (Burnett et al., 2022; Gudelunas et al., 2024). Occult hypoxemia is defined as when SpO_2 is measured between 92 – 96% when SaO_2 is less than 88% (Burnett et al., 2022). Occult hypoxemia has been shown to contribute to delayed care, leading to poorer patient outcomes in a variety of care settings (Fawzy et al., 2022; Gottlieb et al., 2022; Henry et al., 2023).

In the United States, medical grade pulse oximetry device

performance guidance and standards have been set by the Food and Drug Administration (FDA). Calculation of accuracy root mean square (A_{RMS}) has been used to define expected device performance, with a cut-off of ≤3% for transmittance wrap sensors, with data collected on healthy volunteers. Current final guidance from the FDA recommends at least two participants, or 15% of total sample size (whichever is larger) be darkly pigmented. Manufacturers have a responsibility beyond meeting minimum requirements, to both patients and clinicians. Further refinement of pulse oximetry to ensure health disparities due to skin pigmentation are rectified is paramount to promoting equity in monitoring for all patients. This may be achieved through appropriate adjustment for increased absorption of red light by melanin and ensuring that individuals across the pigmentation spectrum are included during development, testing, and validation of pulse oximetry devices (Jamali et al., 2022; Okunlola et al., 2022).

Bench testing can provide insights into sensor performance in a controlled environment, that allows for repeated testing without risk to participants, including those at the limits of device abilities. Clinical testing allows for evaluation of device performance during intended use in a controlled environment. In this report we present data collected from both bench and clinical laboratory settings to evaluate the performance of two pulse oximetry sensors under dark pigmentation, low perfusion signal, and controlled hypoxia conditions.

Methods

Two studies were completed, one utilizing bench testing methodologies and one utilizing clinical laboratory testing methods.

Test Devices

For both bench and human participant testing, the Nellcor™ OxySoft™ SpO_2 sensor connected to a N-600x pulse oximeter (Medtronic, Minneapolis, MN, USA) and LNCS® Neo-3 sensor connected to a RAD-97™ pulse oximeter (Masimo®, Irvine, CA, USA) were used during study procedures.

Bench Testing

This test was designed to evaluate sensor performance by measuring time-to-first post under the simulated conditions of low perfusion and dark skin pigmentation. A Fluke Prosim8 (Fluke®, Everett, WA) was used as a patient simulator for pulse rate and SpO_2. The dark, thick finger setting was employed, with heart rate at 150 beats per minute and SpO_2 at 95% across all tests. To simulate low perfusion, pulse amplitude was set to 0.5% and a black opaque drape was placed over the sensor to reduce noise from ambient light. A SPOT Light SpO_2 Functional Tester (Fluke®, Everett, WA), consisting of an artificial finger, on which the tested finger sensors were applied, was connected to the Simulator. Both Nellcor™ and Masimo® finger sensors had their calibration information encoded into the Simulator. A single round of testing was completed on 20 sensors for each device. Using an automated data acquisition system, time-to-first post was collected, with start time defined as when the sensor was plugged into the monitor and end time was when both SpO_2 and pulse rate were posted on the monitor.

Clinical Laboratory Testing

This prospective, non-randomized study was conducted in accordance with the Declaration of Helsinki and all local regulatory requirements. The protocol was approved by the institutional review board and all participants provided written informed consent prior to commencement of study procedures.

Apparently healthy adults were recruited from the community through referrals, word of mouth, and advertisements. Potential participants completed a pre-screening questionnaire prior to reporting to the laboratory to complete a health screening and undergoing study procedures. Individuals were eligible for enrollment into the study if they 1) were male or female aged 18 to 50 years, 2) weight greater than 40kg, 3) non-smoker or had not smoked within 48 hours prior to study procedures, and 4) cleared health assessment and screening on day of study procedures. Participants were excluded if any of following were present: 1) body mass index greater than 39.5, 2) compromised circulation, injury, or physical malformation of fingers, hands, ears or forehead/skull or other sensor sites which would limit the ability to test sites needed for the study, 3) pregnant, trying to get pregnant, or who have a urine test positive for pregnancy on the day of the study. 4) known respiratory condition, 5) known heart or cardiovascular conditions, 6) self-reported health conditions identified on the health assessment form.

Participants were monitored for heart rate, blood pressure, and SpO_2 throughout study procedures. Baseline vital signs and skin pigmentation using the Monk Skin Tone scale and colorimeter (Konika Minolta CM-700d, Tokyo, Japan), were collected. Both pulse oximeter sensors were placed on the participant and covered with black photo tape to prevent optical interference between sensors. A controlled hypoxia protocol was followed, where participants were connected to a breathing circuit and gas mixture was adjusted according to the following target SpO_2 plateaus: 95-100%, 89-94%, 85-88%, 80-84%, 75-79%, and 70-74%. Data was collected at each plateau once stable readings, as defined by International Organization for Standardization (ISO 80601-2-61:201:2017E) (ISO, 2017), were achieved. Participant well-being was monitored throughout study procedures and procedures were stopped at any indication of decompensation or participant refusal to continue with the protocol. After finishing study procedures, participants were monitored to ensure stable vital signs.

All SpO_2 measurements from both pulse oximetry devices were compared against an indirect measure of SaO_2. A transfer standard system is a specific oximeter and sensor (in this case: Nellcor™ N-600x pulse oximeter paired with a FLEXMAX reusable sensor; Medtronic, Minneapolis, MN) identified by serial numbers that have previously been compared to blood co-oximetry. Indirect SaO_2 was calculated using a transfer standard equation that converts SpO_2 as measured by the transfer standard system to the indirect SaO_2.

Pulse oximetry data were recorded by a validated, computerized data acquisition system. Device values were sampled once per second and averaged, taking into account circulation time delays and differences in device response times.

Statistics

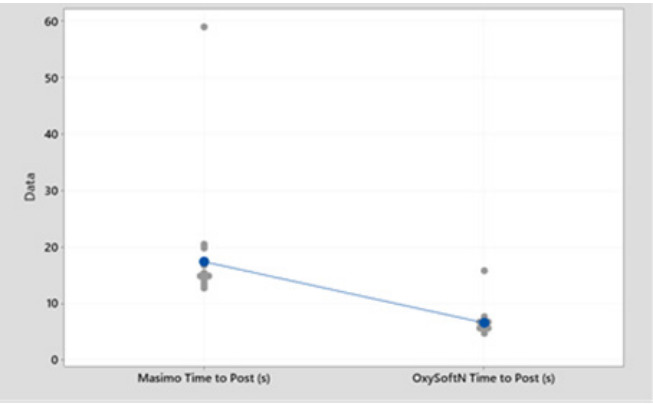
For bench testing, a sample size of 20 sensors was determined to be necessary to achieve a confidence level of at least 90% for all relevant tests. A formal sample size calculation was not completed for the clinical laboratory testing. Analyses were performed using Minitab (version 20.1.3). Statistical tests were 2-sided; statistical significance was accepted at $p < 0.05$.

Results

Bench Testing

The Nellcor™ OxySoft™ SpO_2 sensor reported a significantly faster time-to-first post compared to LNCS® Neo-3 sensor (6.58 ± 2.29 seconds, 17.40 ± 9.97 seconds, respectively; $p < 0.001$), with the calculated difference in means greater than 6.05 seconds (95% confidence). Additionally, as shown in **Figure 1**, the Nellcor™ OxySoft™ SpO_2 sensor showed less variability in recorded values compared to LNCS® Neo-3 sensor.

Figure 1: *Time-to-First Post, Individual Value Plots for LNCS® Neo-3 and Nellcor™ OxySoft™ SpO2 sensor*



Clinical Laboratory Testing

Table 1 presents baseline characteristics of the 13 participants included in the data analysis. All participants identified as Black or African American and recorded a G (7) or H (8) on the Monk Skin Tone scale. Individual Typology Angle (ITA) was calculated from colorimeter measures. ITA is a continuous variable, considered an objective measure of melanin content in skin, where more negative values correspond to more melanin (Verkruysse & Jaffe, 2024). Mean ITA was -45.7 ± 15.3 (range: (-62.23) – (-14.7)). **Figure 2** depicts distribution of participant ITA values.

The Nellcor™ OxySoft™ SpO_2 sensor reported lower average mean bias error (0.72) than the LNCS® Neo-3 sensor (1.93), when compared to the reference value of indirect SaO_2 (**Figure 3**). The bias towards higher-than-expected SpO_2 readings, notably at lower blood oxygenation levels, of the LNCS® Neo-3 sensor can be visualized in **Figure 4.** These findings suggest that the LNCS® Neo-3 sensor reported a higher SpO_2 value, on average, compared to the reference indirect SaO_2. This same elevation in SpO_2 was not noted for Nellcor™ OxySoft™ SpO_2 sensor.

Figure 2: *Histogram of distribution of skin pigmentation of participants, as measured by Individual Typology Angle (ITA), where more negative ITA corresponds to darker skin pigmentation.*

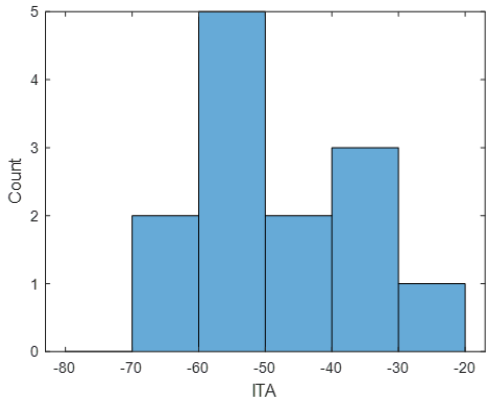
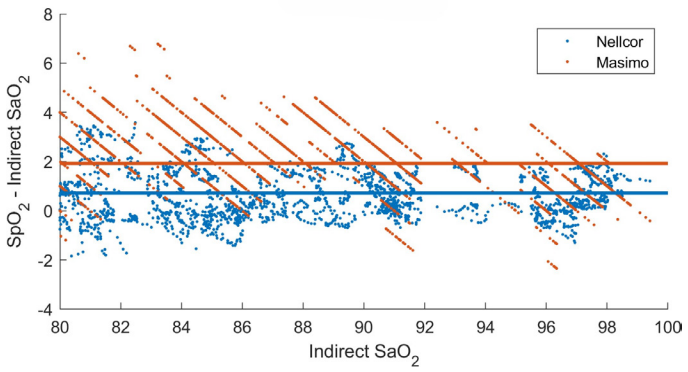


Table 1. Baseline Characteristics	
Parameter	**Mean ± standard deviation (minimum, maximum)**
Age (years)	25.5 ± 4.4 (20 – 33)
Height (inches)	67.5 ± 3.5 (62 – 72)
Weight (pounds)	162.6 ± 25.7 (135.6 – 197.4)
Body Mass Index	25.2 ± 3.6 (17.6 – 30)
Systolic Blood Pressure (mmHg)	120.9 ± 10.8 (103 – 136)
Diastolic Blood Pressure (mmHg)	71.5 ± 8.6 (60 – 87)
Heart Rate (beats per minute)	74.9 ± 12.9 (57 – 109)
SpO2 (%)	96.8 ± 1.4 (94 – 99)
Monk Skin Tone Category	**Count (%)**
G (7)	10 (77)
H (8)	3 (13)
Individual Typology Angle (ITA) Category	
> 30	0 (0)
30 – (-30)	2 (15)
< -30	11 (85)

Figure 3. *Plot of mean bias error for Nellcor™ OxySoft™ SpO_2 and LNCS® Neo-3 sensors. Indirect SaO_2 appears on the x-axis and the difference between measured SpO_2 and reference value appears on the y-axis. The blue dots represent the difference in indirect SaO_2 and measured SpO_2 from the Nellcor™ OxySoft™ sensor. The orange dots represent the difference in indirect SaO_2 and measured SpO_2 from the LNCS® Neo-3 sensor. The blue line represents the average bias error of the Nellcor™ OxySoft™ sensor. The orange line represents the average bias error of the LNCS® Neo-3 sensor. Data from the Nellcor™ OxySoft™ sensor is plotted to two decimal points, whereas data from LNCS® Neo-3 sensor is plotted to the nearest integer.*

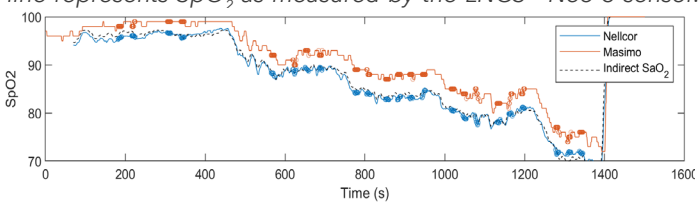


Discussion

The Nellcor™ OxySoft™ SpO_2 sensor demonstrated higher responsiveness (bench testing) and lower bias (clinical laboratory testing) compared to the LNCS® Neo-3 sensor under the combined challenging conditions of dark skin pigmentation and low oxygen saturation or perfusion. Our results are consistent with a previous study, which found a faster time-to-first post for the Nellcor™ monitoring system compared to the Masimo® monitoring system (Khoury et al., 2021). Further, previous reports have observed overestimation of SpO_2 in darkly pigmented individuals, most notably at clinically important SpO_2 values (Fawzy et al., 2024; Gudelunas et al., 2024).

During clinical laboratory testing to assess accuracy of the pulse oximetry devices, the Nellcor™ OxySoft™ SpO_2 sensor reported lower mean error bias than the LNCS® Neo-3 sensor, when compared to the reference indirect SaO_2. Across all target SpO_2 values (70% - 100%), the LNCS® Neo-3 sensor recorded higher than expected SpO_2, most notably at SpO_2 values of less than approximately 90%. Though not an enpoint in this study, occult hypoxemia is associated with delayed care and poorer outcomes (Fawzy et al., 2022; Gottlieb et al., 2022; Henry et al., 2023). One notable observation is that Nellcor™ OxySoft™ SpO_2 sensor did not overestimate SpO_2 at any tested SpO_2 level. Overestimation of SpO_2 was noted for the LNCS® Neo-3 sensor, in agreement with previous publications demonstrating overestimation of SpO_2 by pulse oximetry devices manufactured by Masimo® in darkly pigmented participants, particularly at lower SpO_2 values. (Fawzy et al., 2024; Gudelunas et al., 2024). The current results support the assertion that the Nellcor™ OxySoft™ SpO_2 sensor performs better compared to LNCS® Neo-3 in individuals with darker skin pigmentation. One distinguishing feature of the Nellcor™ OxySoft™ SpO_2 sensor is the inclusion of brighter LEDs, with a red photocurrent approximately eight times, and infrared photocurrent approximately 1.6 times, that of the predicate pulse oximetry sensor (Nellcor™ MaxN). Given the light absorbing quality of melanin as a recognized factor that can attenuate the pulse oximetry signal and contribute to inaccuracy in SpO_2 measurements (Al-Halawani et al., 2023; Chesley et al., 2022), it may be that these brighter sensor lights influenced study results.

Figure 4. *Example of indirect SaO_2 and SpO_2 data from one participant (ITA of -59). Time is represented on the x-axis and SpO_2 is represented on the y-axis. The dashed line represents the reference value of indirect SaO_2. The blue line represents SpO_2 as measured by the Nellcor™ OxySoft™ sensor. The orange line represents SpO_2 as measured by the LNCS® Neo-3 sensor.*



Unrecognized hypoxemia can lead to delayed treatment, which can ultimately contribute to disparities in health (Jamali et al., 2022). Previous work has demonstrated that bias in SpO_2 accuracy appears to be amplified with the combination of higher melanin concentration and clinically challenging conditions such as low perfusion and low oxygenation (Fawzy et al., 2024; Gudelunas et al., 2024; Starnes et al., 2025). This observation was reflected in the results presented in this report, supporting the notion that inaccuracies in SpO_2 are more pronounced at lower perfusion and/or oxygenation levels for those with greater skin pigmentation.

Including individuals across the pigmentation spectrum during development and validation of pulse oximetry devices can help promote equity in monitoring for all patients. For clinical trials evaluating our pulse oximetry technology, we are committed to enrollment goals of at least 25% of participants in the Monk Skin Tone category H-J (8-10), with 50% of those participants having an ITA of ≤ –50. With the patient at the center of our work and purpose, a key factor in our approach to device design continues to be establishing trust with the communities in which we engage, the individual participants involved in our studies, and the patients and healthcare providers that rely on our technology, from the beginning of development, through clinical testing, to use.

One inherent limitation of bench testing, is that data is collected under simulation conditions and may not be truly representative of use in the clinical setting. The bench testing methodology allows for a very controlled environment and test conditions, ensuring that each test device received the same input, making objective comparison of device performance possible. One notable limitation of the clinical laboratory analysis was the use of an indirect measure of SaO_2 to serve as the reference value for SpO_2. Blood gas analysis is considered the gold standard for measuring blood oxygenation and is the measurement used for verification studies in ISO and FDA guidance on pulse oximetry (Al-Halawani et al., 2023). As this was not a verification study, we did not collect blood samples, prompting the use of the indirect SaO_2 measurement as the reference value. This indirect method compares the SpO_2 data from a sensor that had previously been verified for accuracy using blood reference data to the sensor under study. This methodology is supported for non-verification studies evaluating pulse oximetry (ISO, 2017).

Using a mixed methods approach, this report evaluated performance of pulse oximetry sensors under the combined challenging conditions of dark skin pigmentation and low perfusion or oxygen saturation. The Nellcor™ OxySoft™ SpO_2 sensor showed better responsiveness and lower SpO_2 bias compared to the LNCS® Neo-3 sensor.

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