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Comparison of nasal and forehead oximetry accuracy and pressure injury in critically ill patients

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ABSTRACT

Background: In critically ill patients, clinicians can have difficulty obtaining accurate oximetry measurements. **Objective:** To compare the accuracy of nasal alar and forehead sensor measurements and incidence of pressure injury.

Methods: 43 patients had forehead and nasal alar sensors applied. Arterial samples were obtained at 0, 24, and 120 hours. Oxygen saturations measured by co-oximetry were compared to sensor values. Skin was assessed every 8 hours.

Results: Oxygen saturations ranged from 69.8%–97.8%, with 18% of measures < 90%. Measurements were within 3% of co-oximetry values for 54% of nasal alar compared to 35% of forehead measurements. Measurement failures occurred in 6% for nasal alar and 22% for forehead. Three patients developed a pressure injury with the nasal alar sensor and 13 patients developed a pressure injury with the forehead sensor ($\chi^2 = 7.68$; $p = .006$).

Conclusions: In this group of patients with decreased perfusion, nasal alar sensors provided a potential alternative for continuous monitoring of oxygen saturation.

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Introduction

Continuous pulse oximetry monitoring is a standard of care for critically ill patients in the intensive care unit (ICU). However, clinicians frequently have difficulty obtaining an accurate oximetry measurement in patients with decreased perfusion due to peripheral vascular disease, low body temperature, or shock with vasopressor use. Several studies have demonstrated the utility of forehead sensor measurements under these clinical conditions.^{1–7} Forehead sensors use reflectance technology and measure oxygen saturation of blood from a branch of the supraorbital artery that arises from the carotid artery. Therefore, measurement of oxygen saturation at the forehead is considered to be a more central measurement than digit or ear sensor measurements. However use of this sensor requires a headband to prevent venous pulsation and

obtain accurate measurements. The headband applies up to 20 mm Hg pressure over the forehead sensor to improve accuracy.⁸ Forehead sensors with headbands have led to pressure injury at our institution despite following vendor recommendations for alternating placement from one side of the forehead to the other every 8 hours.

Two studies of newer technology oximetry sensors placed on the nasal ala, which are fed by branches of both the external and internal carotid arteries, have demonstrated rapid detection of induced desaturations and correlation with arterial oxygen saturation.^{9,10} These two studies were conducted in healthy subjects or during routine anesthesia care over several hours. Several reasons have been cited for inaccuracy of non-invasive measurements of oxygen saturation in critically ill patients. Decreased perfusion and use of vasopressors are known to impair the accuracy of oximetry sensor measurements.^{4,7} Additionally, sepsis can lead to overestimates of oxygen saturation by oximetry.¹¹ Forehead sensor measurements have also previously been reported to be higher than arterial samples in patients with chronic obstructive pulmonary disease.¹² Dark skin pigmentation was found by Feiner and colleagues to increase the bias of pulse oximetry saturation (SpO₂), as measured by digit sensors, compared to arterial oxyhemoglobin saturation (SaO₂) when SaO₂ measurements were

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less than 80%.¹³ Positioning patients in head down positions, including prone and Trendelenburg positions, has been reported to impact the accuracy of forehead sensors^{8,14}; however, impact of positioning on the nasal alar sensor is not known.

Research is needed to examine the accuracy of the alar sensor in the ICU patient population. During periods of low perfusion, patients are at risk for device related pressure injury.¹⁵⁻¹⁷ The aims of this study were to compare the accuracy of nasal alar and forehead sensor measurements with SaO₂ measurements in patients at risk for decreased perfusion and to compare pressure injury incidence with each device.

Methods

Study design

This prospective observational study was conducted in a large university-affiliated medical center between October 2014 and April 2016. The study was approved by the Human Studies Committee. Written informed consent was obtained from the patient's legally authorized representative. No patients were able to provide their own consent.

Inclusion and exclusion criteria

A convenience sample of 43 patients were recruited from a 36-bed surgical/burn/trauma intensive care unit (ICU) and a 34-bed medical ICU. Included patients were 18 years of age or older, had an existing arterial catheter, and had evidence of hypoperfusion due to at least one of the following: 1) Difficulty obtaining a consistent signal from a digit or ear sensor; 2) Receiving ≥ 0.10 mcg/kg/min of norepinephrine, or 3) Core temperature $\leq 35^{\circ}\text{C}$. Inclusion criteria for norepinephrine dosage and hypothermia were selected based on known circumstances for decreased peripheral perfusion. Patients were excluded if there were any anatomic impediments (burns, wounds, dressings, etc.) to placement of the sensor on the nasal ala, a hemoglobin value < 5 g/dL, a history of known dyshemoglobinemias evidenced by carboxyhemoglobin levels $> 10\%$ or methemoglobin level $> 2\%$, inability to obtain consent from a surrogate, or a consideration for comfort care in discussions of the ICU team and the family. No patients with a craniotomy or frontal lobe injuries were included due to concerns with the forehead sensor headband application.

Procedures

Current practice at our institution is to place a forehead sensor when no signal can be obtained from digit sensors or if the digit sensor is inaccurate compared to SaO₂ measurements. Forehead reflectance oximetry sensors (Nellcor, Max-Fast) were in place in 40 of the patients at the time of enrollment; one patient had the forehead sensor placed at the time of enrollment, and forehead sensors could not be applied to two patients (one patient was prone and one with a helmet). Estimated placement time of the forehead sensor was determined based on patient ICU admission time, documentation in chart by RN regarding placement, or time of hypotension and change in oxygen saturation noted in the chart. A Velcro headband was used with all forehead sensors. Nasal alar oximetry sensors (Xhale Assurance) were placed upon patient enrollment. After a 10-15 minute stabilization period and validation that pulse rate signals from the sensors matched electrocardiographic heart rate, an arterial blood sample for hemoglobin saturation battery with SaO₂ measurement was obtained. An advanced practice registered nurse (APRN) member of the research team collected all of the data from sensor measurements and arterial blood samples. Nasal and fore-

head sensor measurements were recorded simultaneously. Poor plethysmograph was noted. Data collectors also noted if a question mark was displayed despite adjustment attempts of a sensor. When a question mark is displayed, no sensor pulse oximetry number is displayed and was considered a sensor measurement failure. The three measurements were again obtained 24 hours after initial sensor placement and 4-5 days (96-120 hours) after placement. The first two measurements were obtained in the first 24 hours during the period of highest acuity of critical illness and patients' highest risk for decreased perfusion. The third measurement was obtained 96-120 hours later to measure accuracy of the sensor when patients were expected to be less acutely ill and to assess for pressure injury risk with extended wear.

Forehead and nasal ala skin was assessed at time of enrollment. To reduce the risk of pressure injury and following our current hospital practice based on vendor recommendations, we moved location of the sensor from one side of the forehead to the other side and nasal ala to opposite ala every 8 hours. At that time, the skin underlying the sensor was inspected for pressure injury. A bedside data collection sheet for documentation of skin assessment was utilized. Education was provided to all nurses prior to start of the study and in real time upon patient enrollment. An APRN member of the research team performed the assessment on day shift and the bedside registered nurse (RN) performed the assessment between 1500-0700. Pressure injury staging guidelines from the National Pressure Ulcer Advisory Panel (NPUAP) were utilized.¹³ All nurses in the institution assess skin regularly and document using descriptive wording based on the NPUAP pressure injury staging criteria. A second APRN member of the research team assessed the skin if any pressure injury was suspected; all determinations of pressure injury were validated. Prior to this study, forehead sensors were continued if patients developed a pressure injury and peripheral site measurements were inaccurate. Due to the high incidence of pressure injury associated with forehead sensors in our institution, the research protocol included removal of the forehead sensor if the first 2 nasal alar measurements were within 3% of the SaO₂ (clinical definition of accuracy) or when a pressure injury related to the forehead sensor occurred. If a pressure injury was identified related to the nasal alar sensor, the sensor was removed. If pressure injury developed at both sensor sites, the patient was removed from the study.

Measures

At each measurement (initial, at 24 hours and at 4-5 days), mean arterial pressure from the arterial catheter and temperature (obtained from bedside monitor), fraction of inspired oxygen (FiO₂, obtained from ventilator), and vasopressor medication and dose infusing (obtained from infusion pumps) were recorded. SaO₂ was measured with a calibrated Radiometer ABL800 Flex Series blood gas instrument in the clinical laboratory. Demographic and clinical data retrieved from the electronic medical record included age, gender, race, admitting diagnosis, hemoglobin level on enrollment and at 96-120 hours, and body mass index (BMI). APACHE II score was calculated by one member of the research team from data extracted from the electronic medical record at time of ICU admission.

Sensor devices

The Nellcor™ OxiMax™ Forehead SpO₂ sensor has reported accuracy in the range of 70% to 100% during low perfusion and a heart rate range of 25 to 250 beats/minute.¹⁸ Xhale Assurance® nasal alar sensor also has reported accuracy with a SpO₂ range of 70-100% and a heart rate range of 30-240 beats/minute.¹⁹

Table 1
Patient Demographic and Clinical Characteristics

| Characteristic | |
|--|----------------------|
| Age (years) ^a | 60.1 ± 16.1 |
| Gender | |
| Female – no. (%) | 26 (60%) |
| Race – no. (%) | |
| Caucasian | 30 (70%) |
| African American/Black | 13 (30%) |
| Inclusion Criteria – no. (%) | |
| Inconsistent digit oximetry signal | 42 (98%) |
| Vasopressors | 39 (91%) |
| Core temperature ≤ 35° C | 8 (19%) |
| Admitting Diagnosis – no. (%) | |
| Sepsis | 11 (26%) |
| Cardiac Arrest | 6 (14%) |
| Respiratory Failure | 6 (14%) |
| Metastatic Cancer Medical | 4 (9%) |
| Abdominal Surgery | 4 (9%) |
| Gastrointestinal Bleed | 3 (7%) |
| Liver Failure | 2 (5%) |
| Trauma | 1 (2%) |
| Orthopedic Surgery | 1 (2%) |
| Pancreatitis | 1 (2%) |
| Total Laryngectomy | 1 (2%) |
| Overdose | 1 (2%) |
| Heart Failure | 1 (2%) |
| Myocardial Infarction | 1 (2%) |
| APACHE II ^a | 35.5 ± 8.5 |
| Body Mass Index ^a | 29.2 ± 9.5 |
| Hemoglobin Day of Enrollment (g/dL) ^a | 10.1 ± 2.3 |
| Hemoglobin Day 5 (g/dL) ^a | 8.2 ± 1.1 |
| Norepinephrine Dose at enrollment ^a | .18 ± .15 mcg/kg/min |
| Epinephrine Dose at enrollment ^a | .06 ± .06 mcg/kg/min |
| Vasopressin Dose at enrollment ^a | .04 units/min ± .02 |

^a Mean ± SD.

APACHE II, Acute Physiology and Chronic Health Evaluation.

Data analysis

All data were entered into SPSS 22 (IBM Corporation). Approximately, 100 measurements are generally recommended for Bland-Altman analysis; therefore a sample size of 40–50 subjects was targeted. Descriptive analysis included frequency, median or mean and standard deviation calculations. Clinical accuracy for forehead and nasal sensor measurements were binary indicator variables. A value of 1 was given if the sensor value was within the range of the respective SaO₂ value ± 3%. A value of 0 was given if the value was outside of the range. The frequency and percentages for clin-

ical accuracy between forehead and nasal measurements with SaO₂ measurements were calculated. Bland-Altman analysis for repeated measures of sensor and SaO₂ values were conducted to evaluate the level of agreement between forehead and nasal measurements with SaO₂. Upper and lower Bland-Altman limits of agreement were calculated and scatter plots of the difference between forehead and SaO₂ values and nasal and SaO₂ values against the average of the sensor and SaO₂ measurements were generated.^{20,21} The odds ratios for association between race and clinical accuracy of forehead and nasal sensors were estimated and tested using Chi square analysis. Chi square analysis was also used to analyze difference in pressure injury incidence between the two sensors. Statistical significance was set at alpha = 0.05.

Results

The final study population included 43 critically ill patients. All but one patient demonstrated an inconsistent digit oximetry signal and 39 (91%) patients were on vasopressors. Sepsis was the most frequent admitting diagnosis with 11 (26%) participants followed by cardiac arrest 6 (14%) and respiratory failure 6 (14%). Of note, the mean APACHE II score was quite high at, 35.5 ± 8.5. Demographic and clinical characteristics are summarized in Table 1. Measurements at each data collection point are found in Table 2. At the time of enrollment, most patients were receiving two or more vasopressors with a mean arterial pressure of 68.9 ± 12, and a mean Fraction of inspired oxygen of 71.6 ± 25.3.

Eighty-eight separate SaO₂ measurements were obtained for comparisons to the nasal alar sensors; there were 69 comparisons with forehead sensors at those same times. Ten patients (23%) completed the 120 hours of the study, with three separate measurements being obtained. Four patients also had three measurements obtained, but the final measurement was obtained early because the patient was withdrawn from the study before 120 hours. Fig. 1 displays the number of measurements obtained at each time period and the reasons for withdrawal from the study, as well as the reasons that forehead sensor measurements were not obtained.

The 88 SaO₂ measurements obtained at the three time points ranged from 69.8–97.9%; 18% were less than 90%. The nasal sensor measurements were within 3% of the SaO₂ measurement for 47 of 88 measurements (54%), whereas the forehead sensor measurements were within 3% of the SaO₂ measurement for 24 of 69 measurements (35%). Of note, the initial nasal sensor readings overestimated SaO₂ in 60% of the measurements in sepsis patients and

Table 2
Measurements at each data collection point

| | Time of Enrollment | 24 Hours after Enrollment | 96–120 Hours after Enrollment |
|---|---------------------|---------------------------|-------------------------------|
| Forehead SpO ₂ ^a | 89.5 ± 12.4(n = 41) | 95.9 ± 4.8(n = 26) | 98 ± 2.8(n = 2) |
| Nasal SpO ₂ ^a | 87.1 ± 14.1(n = 43) | 91.9 ± 7.2(n = 31) | 92 ± 10.5(n = 14) |
| Lab SaO ₂ ^a | 92.7 ± 6(n = 43) | 93 ± 3.6(n = 31) | 94.4 ± 2.5(n = 14) |
| Within 3% of SaO ₂ + | | | |
| Forehead | 11 (27%) | 12 (46%) | 1 (50%) |
| Nasal | 21 (49%) | 17 (55%) | 11 (79%) |
| Unable to Obtain Signal+ | | | |
| Forehead | 13 (32%) | 2 (8%) | 0 |
| Nasal | 3 (7%) | 2 (6%) | 0 |
| Mean Arterial Pressure mm Hg ^a | 68.9 ± 12 | 69.3 ± 9.5 | 67 ± 12.6 |
| FiO ₂ ^a | 71.6 ± 25.3 | 54.6 ± 18.6 | 46.4 ± 16.5 |
| Temperature °C ^a | 36.6 ± .9 | 36.7 ± .64 | 36.7 ± .99 |
| Vasopressors+ | | | |
| None | 4 (9%) | 3 (7%) | 5 (12%) |
| One | 14 (33%) | 15 (35%) | 4 (9%) |
| Two | 18 (42%) | 10 (23%) | 4 (9%) |
| Three | 7 (16%) | 4 (9%) | 1 (2%) |

^a Mean ± SD; + no. (%).FiO₂, fraction of inspired oxygen.

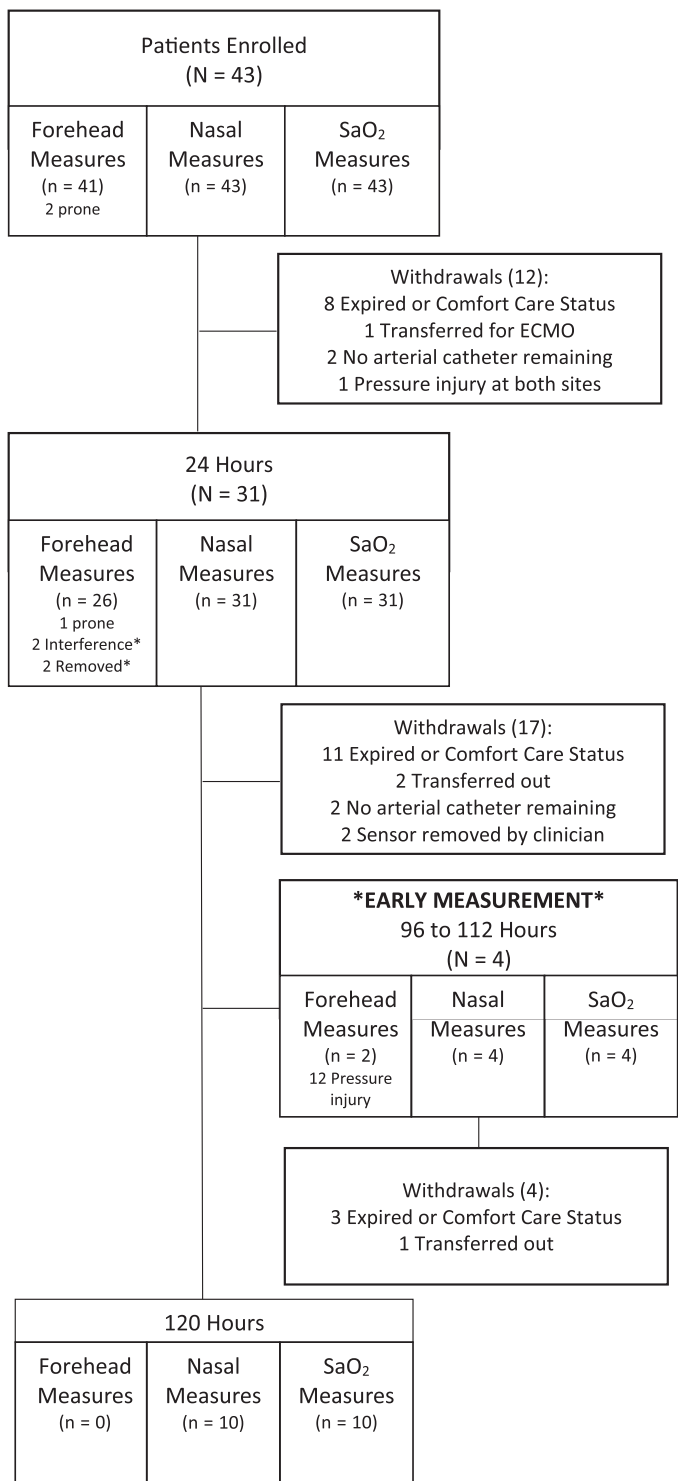


Fig. 1. Patient Enrollment and Study Progress *mechanical interference from EEG leads or helmet with Blakemore tube.

forehead readings overestimated SaO₂ in 63% of the measurements in sepsis patients. An inability to obtain a signal (measurement failure), displayed on the monitor with a question mark, was noted for five measurements (6%) with the nasal sensor and for 15 measurements (22%) with the forehead sensor. Poor plethysmograph waveform was noted for 6 nasal measurements and 1 forehead measurement. Each of these measurements were > 3% different than the SaO₂.

Bland-Altman analysis shows the difference between the forehead sensor and SaO₂ methods against the average of the two measures (Fig. 2). Points are labeled by the subject number. The mean difference between the forehead sensor and SaO₂ methods (-0.8%) and Bland-Altman limits of agreement are shown on the scatter plot as well. The limits appear to fit the data well. Fig. 3 shows the difference between the nasal sensor and SaO₂ methods against the average of the two measures. On average, the nasal sensor method resulted in a measurement approximately 3.4% lower than the SaO₂ method. The limits of agreement here appear to fit the data well. However, participant 37 appears to be an extreme outlier with respect to the difference in the measures.

While there were many diagnoses at admissions, sepsis, cardiac arrest and respiratory failure were the most common. Eleven patients had a diagnosis of sepsis at admission, 6 had cardiac arrest and 6 had respiratory failure. For nasal alar measurements, 46.2% of measurements for sepsis patients were within clinical accuracy, 69.2% of the measurements for cardiac arrest patients, and 54.5% of the measurements for respiratory failure patients. Among the forehead measurements, 28.6% with a sepsis diagnosis were clinically accurate, 54.5% for cardiac arrest patients, and 62.5% among respiratory failure patients. There were no statistically significant results.

Thirty patients were Caucasian and 13 were African American/Black. The top three admitting diagnoses were the same for each race category. Among Caucasians, there were 56 pairs of nasal and SaO₂ values and 26 pairs among African Americans. Caucasians were 2.65 times more likely to have a clinically accurate nasal measurement than African Americans. This association was statistically significant (p = 0.04). There were 37 pairs of forehead and SaO₂ values for Caucasians and 17 pairs among African Americans. Caucasians were 1.2 times more likely to have a clinically accurate forehead measurement than African Americans. However, this association was not statistically significant (p = 0.74).

Forehead sensors were in place for 37.4 hours during data collection plus a mean of 14.1 hours prior to study enrollment for a total of 51.5 hours. Nasal sensors were in place for 66.2 hours during data collection. Three patients developed a pressure injury related to the nasal sensor; two were Stage 1 and one was Stage 2. Thirteen patients developed a pressure injury related to the forehead sensor; nine were Stage 1, three were Stage 2 and one was a deep tissue injury. Two patients developed pressure injury at both sensor sites. There were a significantly higher number of patients with a pressure injury related to the forehead sensor compared to the nasal alar sensor ($\chi^2 = 7.68$; p = .006).

Discussion

In this comparative observational study of patients with severe impairments of systemic perfusion, we found that nasal alar oximetry sensor measurements were more frequently within 3% of measured SaO₂ values than forehead sensor measurements. The Bland-Altman analysis demonstrated a lower mean difference (-0.8%) between the forehead and SaO₂ than the mean difference between the nasal and SaO₂ measurements (-3.4%). However, neither the forehead nor the nasal sensors provided accurate measurements in some critically ill patients, and both the forehead and the nasal sensor had outliers below the lower level of agreement. Failure of the sensors to measure, observed with display of a question mark, and poor plethysmograph waveform observations occurred frequently. With the small number of clinicians collecting the data, user placement and troubleshooting to maximize signal was consistent and likely did not contribute to measurement failure or poor plethysmograph. In clinical practice, these are times that SaO₂ measurements should be obtained.

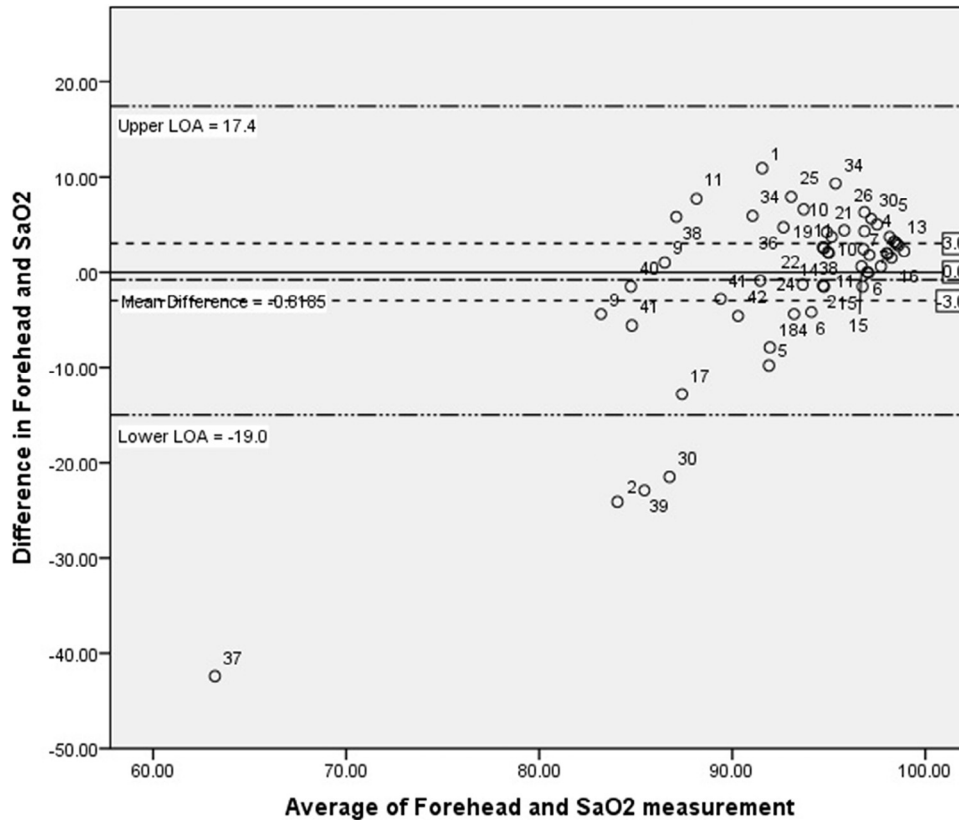


Fig. 2. Bland-Altman Plot: Agreement Between Forehead Sensor Measurements and Co-oximetry Arterial Saturation Measurements. LOA = Limits of Agreement.

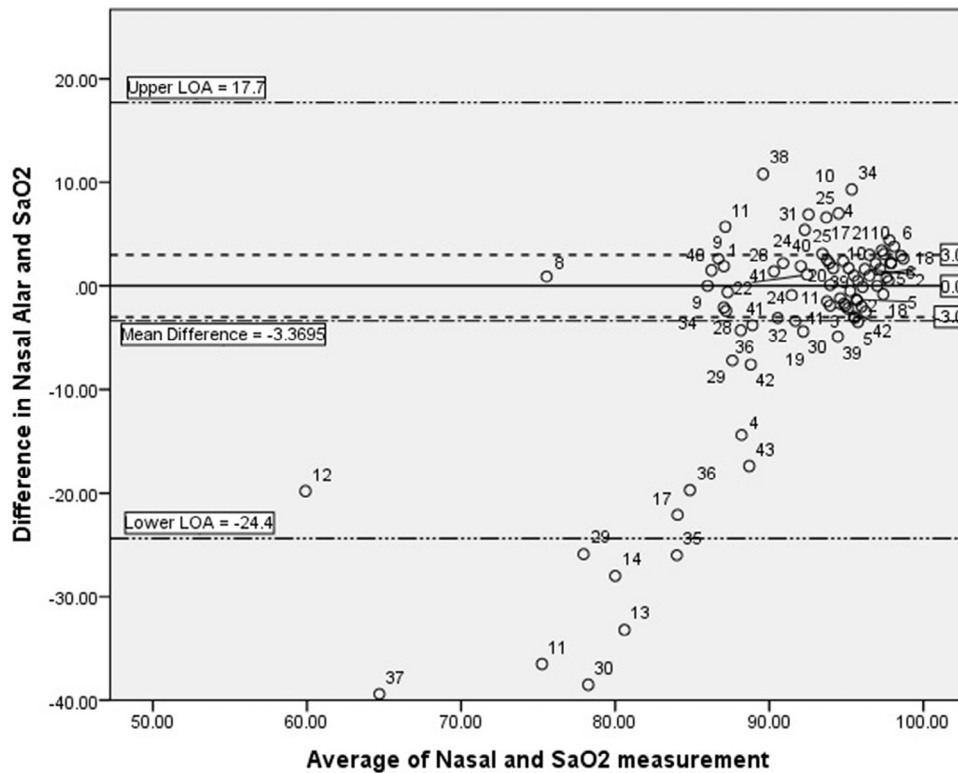


Fig. 3. Bland-Altman Plot: Agreement Between Nasal Sensor Measurements and Co-oximetry Arterial Saturation Measurements. LOA = Limits of Agreement.

Oximetry sensor technology data from more than two decades ago showed that nasal and forehead sensors were less accurate than digit oximetry sensors.²² However, with the development of reflectance sensor technology, forehead sensors have demonstrated accuracy superior to that of digit oximetry sensors.^{1,3,4,7} Recently, nasal alar sensors have demonstrated good accuracy in healthy volunteers with induced hypoperfusion and in patients undergoing operative procedures.^{9,10} Both nasal and forehead sensors measure oxygen saturation in the central circulation, and thus should provide a more clinically accurate measurement of oxygen saturations than digit sensors during states of decreased peripheral perfusion. A recent study compared SaO₂ with neonatal sensors applied on the nasal ala in patients with burns to all 4 limbs and ears and found weak correlation with the nasal alar placed sensor overestimating SaO₂.²³ While this is an excellent population to examine the nasal alar sensor, a sensor specifically designed to measure saturation at the nasal ala is preferred thus making comparisons with this study difficult.

In our study, the nasal alar and forehead sensors were tested in patients with severely impaired perfusion, nearly all of whom had failure of digit pulse oximetry measurements. The high acuity of these patients was demonstrated by the elevated APACHE II score, the use of multiple vasopressors in most patients, and the high mortality rate, with half of the patients expiring or being switched to comfort care during the study period. It should be noted that for patients who survived to day 4 or 5, the nasal alar sensor provided clinically accurate measurements 79% of the time, in conjunction with use of lower amounts of vasopressors and improving systemic perfusion.

Patients with sepsis, representing 26% of the patient population in this sample, were a particularly problematic group. Both nasal and forehead sensor measurements had fewer clinically acceptable values in patients with sepsis than in patients with cardiac arrest or respiratory failure; however the differences were not statistically significant. Dark skin pigmentation was also found to impact accuracy results. Measurements from both sensors were more likely to be clinically accurate among Caucasians than in African American/Black patients. These results support previous findings that dark skin pigmentation decreases the accuracy of pulse oximetry measurements.¹³ Limited experience with two patients in the prone position suggested that positioning did not impair the clinical accuracy of nasal alar sensor oxygen saturation measurements. No observations on patients in the Trendelenburg position during the study data were recorded. Finally, while the differences in the measures were not normally distributed, the Bland-Altman for repeated measures analysis is helpful in visualizing where there might be issues with the measures being observed. When SaO₂ measures are below 85%, both sensors had decreased accuracy.

Device related pressure injury is a concern for critical care clinicians. As technology advances, critically ill patients are subjected to an increasing number of devices with a potential for pressure injury. To that end, devices that are easy to manage and have a low risk of inducing pressure injury are important. The nasal alar sensor is easier to reposition than the forehead sensor as no headband is required. In this study, regular repositioning of both devices occurred every 8 hours, yet a lower incidence of pressure injury was observed with use of the nasal alar sensor compared to the forehead sensor. Despite moving the sensors every 8 hours, device-related pressure injury occurred with both sensors. After rotation of the sensor, there was blanchable redness or skin discoloration and an indentation of the tissue at the previous sensor site, which were likely early signs of potential pressure injury that resolved with repositioning of the device. In a non-research setting, pressure injury rates with the forehead sensor may be even higher due to the more time consuming process for repositioning. Most of the patients in

this study who sustained a pressure injury with use of the nasal alar sensors were receiving two or more vasopressors, a known risk factor for developing pressure injury^{24,25} especially when vasopressin is one of the vasopressors.²⁴ Thus, the highly compromised systemic perfusion of the subjects in this trial may have likely contributed to observed high incidence of pressure injury. Nonetheless, further study is needed to determine if rotation of the device more frequently could have reduced the incidence of pressure injury from both sensors, particularly in those with severely impaired perfusion.

This study has several limitations, including the small sample size from one institution. The large number of missing data points may have impacted Bland Altman analysis; however the limits of agreement with the exception of one outlier appear to fit the data.²⁰ High levels of positive end expiratory pressure (PEEP) administered during recruitment maneuvers have been found to decrease the accuracy of forehead sensors.²⁶ We did not record PEEP levels as part of the study protocol although they should be included in future research. Forehead sensor wear time during the time period of maximal hypoperfusion may have been longer than nasal sensor wear time during similar time periods, which may have led to the observed higher pressure injury rates with use of forehead sensors. However, overall duration of nasal alar sensor use was longer than use of the forehead sensors, since many of the forehead sensors were discontinued during the course of the study. Finally, we did not examine the number of alarms generated with the different sensors. In the interest of preventing alarm fatigue, alarm type and frequency should be examined in future research of the forehead and nasal sensors.

In summary, accurate oxygen saturation measurements can be difficult to obtain in critically ill patients at risk for decreased peripheral perfusion due to vasoconstriction and vasopressor administration, hypothermia, sepsis, or peripheral vascular disease. In this group of patients, nasal alar sensors had better clinical accuracy and less measurement failures than forehead reflectance oximetry. Forehead sensors had a lower mean difference from SaO₂ measurements than nasal alar sensors. In addition, fewer pressure injuries were observed with use of the nasal alar sensors. Septic patients and patients with dark skin pigmentation in particular provide a challenge to accurate pulse oximetry measurements using either method. Clinicians should verify pulse oximetry measurements in patients with decreased peripheral perfusion with laboratory SaO₂ measurements especially with SpO₂ measurements $\leq 85\%$ in the setting of poor perfusion. Although it was still not possible to obtain accurate signals from some of these critically ill patients, use of nasal alar sensors appears to provide a promising alternative for continuous monitoring of oxygen saturation in critically ill patients with substantial impairment of systemic perfusion.

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