ARC Journal of Dermatology
Volume 8, Issue 3, 2025, PP 44-52
ISSN No. (Online) 2456-0022
DOI: https://doi.org/10.20431/2456-0022.0803005
www.arcjournals.org

Racial Bias in Pulse Oximetry: Implications for Dermatologic Surgery and Cutaneous Vascular Assessment

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Received: 25 March 2025 Accepted: 08 April 2025 Published: 24 April 2025

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Abstract

Pulse oximetry is a cornerstone of perioperative and critical care, yet mounting evidence reveals systematic racial biases in oxygen saturation (SpO_2) measurements, disproportionately affecting individuals with darker skin tones. While existing research primarily attributes these disparities to melanin absorption, other biological factors—such as hemoglobin variants and vascular physiology—remain insufficiently explored. This review synthesizes current findings and highlights gaps in understanding the full biological underpinnings of these inaccuracies. Additionally, device-specific variability among pulse oximeter models remains poorly characterized. While some studies, such as those by Leeb et al., have identified significant performance differences, a comprehensive evaluation across all available devices is lacking. Addressing this gap is critical for developing standardized regulatory measures that account for racial disparities in device accuracy. Despite increasing recognition of these biases, most studies rely on retrospective or controlled experimental designs, limiting real-world applicability. This review emphasizes the need for longitudinal, prospective studies to assess the clinical impact of SpO_2 inaccuracies over time. Moreover, existing research largely overlooks pediatric populations, where undetected hypoxemia can have severe consequences, particularly in neonates and infants with darker skin tones. By addressing these gaps, this review aims to inform clinical guidelines, technological advancements, and regulatory policies to improve the accuracy of pulse oximetry for all racial and age groups. Through a multidisciplinary approach integrating biomedical research, engineering, and healthcare policy, we propose strategies to enhance equity in perioperative monitoring, dermatologic surgery, and pediatric care.

1. Introduction

The capacity of pulse oximetry to provide continuous, non-invasive monitoring of arterial oxygen saturation (SpO_2) makes it an essential tool in perioperative, critical, and dermatological care.[1] This technology is crucial in various clinical settings—including emergency rooms, intensive care units, and operating theaters—where it guides oxygen therapy and facilitates early detection of hypoxemia.[2]

The operation of pulse oximeters is grounded in the principles of light absorption and the Beer-Lambert law. They utilize two wavelengths of light, typically red (660 nm) and infrared (940 nm), emitted by light-emitting diodes (LEDs) and passed through a pulsatile vascular bed such as an earlobe or fingertip. Oxygenated hemoglobin (HbO_2) absorbs more infrared light, while deoxygenated hemoglobin (Hb) absorbs more red light.[3] A photodetector on the opposite side of the sensor measures the intensity of transmitted light at each wavelength. The device calculates the ratio of absorbed red to infrared light, which fluctuates in response to pulsatile changes in arterial blood volume. Using this ratio, the proportion of HbO_2 is estimated to produce a continuous SpO_2 readout. Calibration

algorithms then convert the raw signal into clinically meaningful oxygen saturation values. [4] Despite its widespread clinical value, mounting evidence has exposed a critical flaw in pulse oximetry: racial bias. Studies show that pulse oximeters frequently overestimate oxygen saturation in individuals with darker skin pigmentation, resulting in unrecognized hypoxemia. [5] This inaccuracy carries significant clinical implications, particularly in pediatric and dermatological populations, where precise readings are essential for timely management, as well as in perioperative settings where accurate oxygen monitoring is vital. Although the influence of melanin on light absorption is acknowledged, other contributing factors—such as tissue thickness, perfusion variability, and device-specific calibration algorithms—are gaining recognition as additional sources of error. [6]

A comprehensive understanding of this issue demands a multidisciplinary approach that incorporates clinical outcomes, underlying biological mechanisms, and regulatory oversight. It is essential to investigate the limitations of current technologies across different devices and diverse patient populations to identify points of failure. Pediatric patients present unique challenges, as inaccuracies in oxygen measurement during key developmental periods may result in long-term adverse effects. Persistent disparities in pulse oximetry performance highlight the urgent need to reevaluate calibration standards, advance inclusive sensor technologies, and implement regulatory frameworks that promote diagnostic equity. [7]

This review explores the intersection of race, technology, and clinical care to understand how pulse oximetry can evolve to serve all patients—regardless of skin tone—within perioperative care, dermatologic surgery, and pediatric medicine. Addressing these disparities is not only a technological imperative but a public health priority rooted in the principles of equitable, evidence-based care.

2. Clinical Implications and Outcomes

Certain genetic variants of hemoglobin display distinct ancestral origins. For example, the rs334 allele, a variant in beta-globin gene associated with sickle cell disease, is derived from Africa while the rs9399137 allele, associated with HbF regulation, is derived from Europe.[8,9] Meanwhile, α-Thalassemia deletions are most prominent in Southeast Asians and Thai individuals.[10] Similarly, distinctions in physiology exist in Black and White individuals, with studies finding differences in left ventricular-vascular coupling and coronary vasomotor reactivity.[11,12] Differences also exist in microcirculation, with distinctive responses of resistance arterioles to elevated intraluminal pressure in Black and White individuals.[13]

Such biological variation impacts the accuracy of pulse oximeters. As pulse oximetry determines hemoglobin oxygen saturation levels based on light absorption by oxy- and deoxyhemoglobin at only two wavelengths, variant hemoglobin that has alternative absorption spectra impedes pulse oximeter accuracy.[14] Furthermore, differences in vascular physiology and microcirculation can lead to differences in perfusion pressures, leading to variability in SpO2 reading.

Although all pulse oximeters yield some level of racial bias, some models are more capable of handling such differences. Feiner et al. 2007 found that the Nonin clip was the least biased device, with a mean bias (Spo2 − Sao2) of 0.60%. Other models included the Masimo Radical, with a mean bias (Spo2 − Sao2) of −1.58% with the disposable sensor and 2.61% for the clip-on sensor.[15] A mean bias of 2.59% was found for the Nellcor clip, of 3.6% for the Nellcor disposable, and of 2.43% for the Nonin disposable. At low Sao2, dark skin experienced greater bias; adhesive/disposable sensors showed more bias than clip-on ones. Dark-skinned participants at low Sao2 showed up to 10% variation in saturation estimations between sensors.[15] These differences may occur due to the presence of melanin, which absorbs light to interfere with the pulse oximeter, but may also exist due to the physiological differences between individuals.

Specifically, perfusion pressure, which may vary due to differences in vascular physiology, has also shown an effect on pulse oximeter performance between different racial groups. Nellcor N-600 with a mean bias of -0.35 was shown to outperform Masimo Radical-7 with a bias of 1.62. [16] Other studies support this finding and evaluate additional pulse oximeters such as the Nihon Kohden OxyPal Neo which outperformed both the Nellcor N -600 and Masimo Radical-7, and the Philips Intellivue MPS which performed slightly better than the Maximo Radical, but worse than the Nellcor N-600 [17], indicating that certain models are able to overcome bias more effectively.

Overestimation of oxygen levels in individuals with darker skin tones can lead to risks in surgery, ICU care, and chronic disease management. In perioperative settings, accurate oxygen monitoring is crucial to ensure adequate oxygenation during and after surgery, reducing the risk of surgical-site infections and supporting proper recovery. [18] In regards to dermatological surgery, incorrect overestimation of oxygen levels can result in poor wound healing, skin-graft failure, and increased risk of infection. Meanwhile, in the ICU, proper oxygenation is considered an essential therapy for critically ill patients and can be a life saving therapy for those with respiratory failure. Improper oxygenation due to occult hypoxemia can lead to potential cellular hypoxia and organ failure, indicating the severity of pulse oximeter inaccuracies. [19]

In chronic disease management, especially of chronic lung disease, oxygen therapy can be essential, indicating the detriment of occult hypoxemia in numerous medical settings. [20]

Inaccuracy in pulse oximetry has also been observed in neonates, infants, and children. In a study conducted with 294 preterm infants, SpO2 overestimation was 1.5x greater for Black infants as opposed to White infants. This can be especially concerning in preterm infants, where precise oxygen monitoring is critical for preventing complications such as bronchopulmonary dysplasia and retinopathy of prematurity. This is further complicated by the disproportionate effects of phototherapy, jaundice, and fetal hemoglobin on darker skin tone infants, which can exacerbate the inaccuracies of pulse oximeters. [21]

Furthermore, delayed hypoxia detection can lead to severe consequences, including congenital heart disease in juvenile cardiac patients, and intraventricular hemorrhage and death in preterm newborns. Occult hypoxia in pediatric intensive care units can exacerbate multi-organ dysfunction and lengthen hospital stays, hence exacerbating healthcare inequalities. [22] Improved pulse oximeter calibration, technological advancements, and clinician awareness is vital to improve pulse oximetry accuracy across individuals of all skin tones.

3. Current Barriers and Limitations

3.1. Pulse Oximetry and Biological Underpinnings

For about 5 decades, pulse oximetry has been known as a non-invasive yet widely used tool that measures hemoglobin oxygen levels in arterial blood, known as arterial oxygen saturation (SpO2). Through the pulse oximetry device, two different light wavelengths, red (600 nm) and infrared (950 nm) light, are absorbed by oxyhemoglobin and deoxyhemoglobin. Oxyhemoglobin absorbs more infrared light, whereas deoxyhemoglobin absorbs more red light. The ratio of absorbance at these wavelengths are then calculated through spectrophotometry, which is then interpreted into its respective SpO2 percentages.[23] This SpO2 percentage is an estimate of the true arterial oxygen saturation (SaO2). However, the question regarding various skin tones challenges SpO2 accuracy and healthcare outcomes.

Melanin is the primary pigment to skin tone variations, which can be further categorized into Eumelanin and Pheomelanin. Eumelanin is responsible for darker (brown-black) skin tones, whereas pheomelanin is responsible for lighter (yellow-red) skin tones. [24] Natural melanin levels are determined genetically, but can undergo changes due to hormones, aging, and skin pigment disorders. Depending on the melanin amount, this can interfere with light absorption. Individuals with higher concentration of melanin are characterized with darker skin, which has a higher absorption for red light. Therefore, through the pulse oximetry device, less red light would be transmitted, skewing the SpO2 ratio calculation. Likewise, light scattering is also larger in darker skin. [25] When light enters the skin, light scatters either randomly (Rayleigh scattering) or forward (Mie scattering). With more melanin, this translates to increasing density and optical properties, which will cause a more forward directed light scattering pattern. [26] However, pulse oximetry devices usually rely on the randomized diffuse scattering pattern. Ultimately, the device will then misinterpret the forward light scattering pattern, overestimating the amount of oxygen in hemoglobin.

In 2024, a systematic review led by Martin et al. evaluated pulse oximetry device accuracy based on different skin tones. The review included 44 reports, which involved 222,644 participants. Only 31% of these participants were reported as non-White ethnicity or had non-light skin tones. 68% of the 44 reports found that pulse oximetry overestimated SpO2 in participants with darker skin tones. This can lead to delayed treatment, harm to the patient, or both. [19] Additionally, in 2020, Sjoding et al. showed that SpO2 in Black individuals were 3 times more likely to have occult hypoxemia than White individuals. Their

study reported SaO2 of <88% found in 11.7% of measurements in Black patients versus 3.6% in White patients.[27] This data is especially concerning as clinicians rely on SpO2 values to guide clinical decisions. These inaccuracies can lead to serious consequences that may impact patient health and outcomes. Calibration methods are limited in literature. However, the discrepancies in SpO2 values in various skin tones brought attention to the need of improving calibration algorithms. In 2022, a multi-wavelength approach was tested by Ochoa-Gutierrez et al. to detect and potentially correct any skin tone discrepancies.[28] Another study done in 2024 by Bierman et al. tackled another piece of the same issue. To eliminate melanin bias, pulse oximeters should be calibrated to a narrower spectral bandwidth to avoid melanin distortion.[26] This would reduce interference from melanin by focusing on wavelengths that are less absorbed by melanin. These recent studies suggest that in order to address racial bias, calibration algorithms will need to include both greater spectral precision and broader spectral data. With these technological advancements, pulse oximeters can be a safer and more reliable measurement in diverse populations.

3.2. Regulatory Standards, Implementation Barriers, and Ethical Considerations

The U.S. Food and Drug Administration (FDA) plays a role in medical devices by regulating its safety, security, and effectiveness. Based on the product's level of risk, it is categorized into one of three classes: I, II, or III. According to Sjoding et al., two metrics are used for pulse oximeters: (1) bias and (2) accuracy root mean square (ARMS). Bias measures the average direction and size of a pulse oximeter "error" or the difference between the SpO2 reading and SaO2 measurement. ARMS combines both bias and "random error" (variability in "bias" difference) to evaluate an overall accuracy. It is considered as a statistical measure of error. For instance, if a device overestimates SpO2 by 2.5% and the precision is only 2%, the ARMS value comes out to be 3.2%. The higher the ARMS value, the worse the accuracy. FDA requires ARMS to be ≤ 3% for transmittance pulse oximeters and ≤ 3.5% for reflectance devices, or else it is inaccurate by their standard. However, with any bias, ARMS is not reliable. [27, 29]

A pulse oximetry guidance document under the FDA was drafted in 2007 and officially issued by March 4, 2013. [30] For pulse oximetry device manufacturers, the FDA required a clinical study of 10+ subjects of various ages and genders, in which at least 15% includes darker skin tones. However, Sjoding et al. pointed out that the FDA does not require manufacturers to report performance by subgroup, like skin tone or race. This would invite a false sense of device accuracy with ARMS hiding subgroup bias and approving subpar performing devices in certain populations. Another issue was how subjects used are normally healthy in controlled environments. This questioned the clinical use of the device since real world clinical thresholds are for instance between SpO2 88-92%. Also, small differences in pulse oximeter readings can have detrimental risks like hypoxemia, especially in the Black population. Sjoding et al. suggested that potentially having larger studies can assure general safety in all racial groups. The post-marketing surveillance also seems limited, but ICU databases show monitoring pulse oximeters can prove better accuracy and safety as well. [27]

With the concerns of pulse oximetry accuracy on various skin tones and the emphasis on health equity, algorithm transparency, and safety concerns, the FDA created an updated pulse oximetry guidance draft in January 2025. The draft addresses Sjoding et al.'s concerns. Clinical studies are required to be done on a diverse participant population, increasing participants with darker skin tones to at least 25%. Devices are now tested on a range of clinically relevant O2 saturation levels between 70-100%. Manufacturers will be required to state the device's accuracy limitations, especially across various skin tones. Premarket submissions will also be open to all types of submissions, not just limited to the 510(k)s.[30] Therefore, regardless of the regulation, all pulse oximeter manufacturers are expected to follow a certain standard for evaluating and demonstrating device performances. This will enforce manufacturers under FDA approval to have more accountability when used for the medical community. With these new guidelines, some controversial barriers are now being addressed.

4. Technological Innovations and Industry Efforts

Traditionally, pulse oximetry has relied on photoplethysmography (PPG) which utilizes red and infrared wavelengths to measure changes in blood volume and estimate blood oxygen saturation (SpO2) levels in patients. Oxygenated hemoglobin absorbs a higher ratio of infrared to red light, while the opposite is true of deoxygenated hemoglobin. [31] Therefore, this

ratio was thought to be an accurate estimation of SpO2. However, many other factors have been identified that can influence results, one being skin pigmentation. The Monte Carlo simulation found that at both red and infrared wavelengths, darker skin had an absorption coefficient that was 11 times greater than that of lighter skin. [25] Bierman et. al 2024 found that commercial pulse oximeters estimated that patients with higher concentrations of melanin had falsely high SpO2 levels compared to patients with lower melanin concentrations.[26] This puts patients with darker skin at a higher risk of not receiving proper treatment for hypoxia. Multi-wavelength oximetry aims to expand beyond red and infrared usage to account for differences in melanin concentrations and improve SpO2 estimations for patients with darker skin tones. The AS7341 prototype currently being developed at the University of Illinois-Urbana-Champaign, measures 7 additional wavelengths to more accurately estimate SpO2 levels despite varying skin pigmentations. [32]

Artificial intelligence (AI) has also shown to be applicable to improving pulse oximetry methods and measuring SpO2 levels in patients. When AI models are given PPG signals and true oxygen saturation levels from arterial blood gas measurements as the mode of training, it is able to "discern intricate relationships and mitigate the influence of confounding factors" including melanin concentrations in the skin. [33] One remaining issue to this strategy is limited amount of research inclusive to diverse skin tones, as most pulse oximetry data has historically been calibrated using patients with low melanin concentrations. [33]

Despite substantial evidence that traditional PPG techniques can be inaccurate for patients with higher melanin concentrations, not all companies who manufacture pulse oximeters have updated their technology to address these issues. Medtronic's Nellcor pulse oximeters all continue to utilize the traditional red and infrared wavelengths.[34] Alternatively, Masimo Rainbow SpO2 technology uses 7 wavelengths of light to measure total hemoglobin and methemoglobin which cannot be measured by oximeters using only two wavelengths.[35] Masimo pulse oximeters have also been shown to maintain accuracy in both normal and low perfusion settings regardless of the patients' skin tone.[36] Advancements such as these have the potential to improve outcomes of dermatological surgeries, where maintaining adequate oxygenation in tissues is essential for healing.

5. Policy and Regulatory Landscape

5.1. Current FDA & WHO Guidelines

Currently, the US Food and Drug Administration (FDA) guidelines do not mandate racial bias testing in pulse oximeter development, despite the widespread critical use of the device. The FDA uses the root mean square difference to evaluate the accuracy of pulse oximeters and recommends that studies include subjects with a range of skin pigmentations, specifying "at least two darkly pigmented subjects or 15% of the subject pool, whichever is larger."[37] Research indicates that individuals with dark skin tones experience a higher incidence of technical difficulties, greater measurement bias, and increased rates of occult hypoxemia, which may contribute to less aggressive clinical management and a heightened risk of mortality.[6] The absence of manufacturing regulations for pulse oximeter development and the lack of inclusion of dark skin tone subjects creates inaccurate and unreliable oxygen saturation results, widening the gap of systemic racial bias in oxygen saturation measures.[24] To address the racial bias readings, the FDA needs to mandate manufacturers to regulate studies by increasing the variety of diverse populations, specifically dark skin tones, to have enough data to be reliable and accurate in the real world.[38] Additionally, medical training should highlight the limits of pulse oximetry and encourage a wider clinical evaluation.[39] By implementing these measures, reliability would improve and ensure an accurate reading for all patients regardless of skin tone. These regulations will reduce racial disparities in the healthcare setting and improve overall patient outcomes.

5.2. Advocacy for Regulatory Reform

Advocacy for regulatory reform is crucial to ensure that pulse oximeter results are accurate and reliable regardless of skin tone, thus prompting equitable healthcare outcomes. In recent years, there has been an increase in studies highlighting the inaccuracies of pulse oximetry measurements on dark skin tone.[7,40] Current regulations for the pulse oximeter are failing patients of racial and ethnic minorities, thus contributing to health disparities. Based on the need, policies must be updated to require the development and testing of pulse oximeters to undergo testing on a broader range of demographic groups, including those with darker skin tones (Lipnick). Policy changes should mandate device manufacturers to incorporate diverse and representative sampling in addition

to standardized skin tone measurements to guide the development of a more equitable pulse oximetry performance.[42] Manufacturers should be required to report the performance variations of their devices across different demographic groups, allowing healthcare providers to better assess device performance and its potential impact on patient care.[27] These policy changes are crucial for developing a more equitable healthcare environment where pulse oximeters can be relied upon to deliver accurate and consistent results for every patient, regardless of skin color.

5.3. Ethical and Legal Considerations

As the increase in studies raises the issue of ethical and legal concerns regarding the accuracy of pulse oximetry, it is clear that pulse oximetry bias is a public health concern. The inaccurate measures in individuals with dark skin tones can lead to undiagnosed hypoxemia, resulting in delayed intervention, poorer health outcomes, and increased mortality.[43,44] Given that the inaccurate readings are disproportionately affecting individuals with dark skin, it is clear that the pulse oximeter bias is a public health concern that warrants regulatory reforms. Addressing pulse oximeters as a public health concern is essential for ensuring accurate and reliable measurements for all patients regardless of skin tone.

6. Future Directions

Innovations in multi-wavelength oximetry are crucial for improving pulse oximetry accuracy across diverse skin tones. Multi-wavelength approaches, such as those using time domain diffuse reflectance spectroscopy, have shown promise in accounting for the impact of skin pigmentation on SpO_2 measurements.[1] Designs that test for skin melanin levels directly on the pulse oximeter or through a smartphone are also being developed.[2] These methods can help mitigate the bias introduced by melanin absorption,which affects the accuracy of traditional two-wavelength pulse oximeters.

Artificial intelligence (AI) and machine learning can also refine SpO_2 readings by correlating real-time arterial blood gas measurements with pulse oximeter data. AI-enhanced pulse oximetry can improve accuracy and equity by using diverse datasets and addressing algorithmic biases.[3] This is reliant on global and racially diverse datasets with large-scale, multicenter studies, which can be used to train AI models and validate pulse oximeter accuracy. These technologies can also expand the measurement range to include hypoxemic levels and enhance model interpretability.[4] Prospective cohort studies integrating real-world clinical outcomes are necessary to understand the clinical implications of pulse oximeter inaccuracies. These studies should include objective pigmentation quantification methods, such as the individual typology angle, to replace subjective skin tone classifications which are currently frequently used.[5]

Encouraging industry-wide collaboration amongst clinicians, engineers, and policymakers can help address disparities and improve device accuracy. Engineers provide a unique perspective on device development and AI integration, while policy-makers and clinicians play a larger role in ensuring representative clinical trials. Together, professionals can revise regulatory standards, foster interdisciplinary research, and promote transparency in device performance data.[6]

7. Conclusion

Pulse oximetry is crucial throughout perioperative care, however, it has been shown that they can contribute to significant racial biases in medical settings. Inaccuracies with pulse oximeter measurements are not solely due to differences in melanin concentrations, and can also be attributed to skin temperature, excessive movement, poor perfusion, and abnormal hemoglobin. [33] Advancements in pulse oximeter technology such as multi-wavelength sensors [32, 35] and incorporation of AI processing models [45] have shown to improve accuracy for estimating SpO2 across patients of varying skin tones. Historically, only patients with low melanin concentrations were used to calibrate these models. Therefore, future research must make a point to include patients of all skin tones so that AI-models can use data from a diverse population set. Additionally, more device manufacturers need to update their products from two-wavelength to multi-wavelength pulse oximeters to ensure equitable patient care. Advancement on these fronts will lead to improved patient outcomes following dermatologic surgery where pulse oximetry is integral in ensuring proper tissue perfusion.

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Citation: *Ochuwa Precious Imokhai et al. Racial Bias in Pulse Oximetry: Implications for Dermatologic Surgery and Cutaneous Vascular Assessment. ARC Journal of Dermatology. 2025; 8(3):44-52. DOI:https://doi.org/10.20431/2456-0022.0803005*