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Authors	Komolibus, Katarzyna;Jayet, Baptiste;Stetson, Paul;Andersson-Engels, Stefan
Publication date	2024
Original Citation	Komolibus, K., Jayet, B., Stetson, P. and Andersson-Engels, S. (2024) 'Investigation of skin pigmentation influence on the diffuse reflectance signal and oxygen saturation', Optica Biophotonics Congress: Biomedical Optics 2024 (Translational, Microscopy, OCT, OTS, BRAIN), Fort Lauderdale, Florida, United States, 7–10 April 2024. Technical Digest Series (Optica Publishing Group, 2024), paper TM1B.3 (2pp). https://doi.org/10.1364/TRANSLATIONAL.2024.TM1B.3
Type of publication	Conference item
Link to publisher's version	10.1364/TRANSLATIONAL.2024.TM1B.3
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Download date	2025-05-20 08:02:46
Item downloaded from	https://hdl.handle.net/10468/16644

Optica Biophotonics Congress: Biomedical Optics 2024 (Translational, Microscopy, OCT, OTS, BRAIN) © Optica Publishing Group 2024

Investigation of skin pigmentation influence on the diffuse reflectance signal and oxygen saturation

Katarzyna Komolibus[1], Baptiste Jayet[1], Paul Stetson[2], Stefan Andersson-Engels[1,3]
[1]*Biophotonics@Tyndall, Tyndall National Institute, Lee Maltings, Dyke Parade, Cork, Ireland*
[2]*Raydiant Oximetry Ireland Ltd.*
[3]*School of Physics, University College Cork, Western Road, Cork, Ireland*
Author e-mail address: katarzyna.komolibus@tyndall.ie

Abstract: Using Monte Carlo simulations we show the effect of different melanin concentrations in epidermal layer on the diffuse reflectance signal and the relationship of the double ratio with oxygen saturation levels.

1. Introduction

While the impact of skin pigmentation on the performance of clinical pulse oximeters has been observed for decades [1, 2], the recent COVID-19 pandemic has finally given this important issue the long overdue attention it deserves. A recent comparison of oxygen saturation levels in adults has demonstrated a notable overestimation of SpO_2 and increased incidence of occult hypoxemia in patients who self-identify as Black [3]. Similar results have been reported for measurements of SpO_2 in both infants [4] and children [5]. The U.S. Food and Drug Administration has issued a communication [6] acknowledging concerns about lower accuracy of pulse oximeters in darker pigmented patients and provided clinicians with recommendations for more cautious use. Several improvements and mitigation strategies have been proposed including, but not limited to, adequate diversity of study subjects, harmonisation of accuracy standards and quantification of pigment [7]. Despite growing attention from regulatory bodies and clinical investigators, the proposed solutions focus on collecting more meaningful data and understanding the biases observed clinically, while no technological advancements have been proposed so far to address the current limitations of pulse oximetry. To understand the fundamental origin of the bias introduced by skin pigmentation, in this work we investigate the effect of different melanin concentrations on the diffuse reflectance signal and resulting oxygen saturation in a simple two-layer model using Monte Carlo (MC) simulations.

2. Methods

This work is carried out entirely using simulation tools. The MC algorithm used for simulations is based on GPU-accelerated MCML - CUDAMCML code [8]. The simplified model used for demonstrating the concept consists of two layers: (1) a 60 µm thick layer representing properties of epidermis with varying melanin concentration and (2) a 3 cm thick layer representing muscle tissue with blood volume changes representing diastolic and systolic cardiac phases. In the superficial layer, the absorption coefficient $\mu_a(\lambda)$ is calculated using varying melanin volume fraction f_{mel} using equations from [9], while the scattering coefficient has been calculated using the scattering amplitude *a* and scattering power *b* summarized in Table 1. For simplicity, the scattering properties of epidermis did not change as a function of melanin concentration. The simulations were performed for wavelengths of 660 nm and 940 nm, typical for pulse oximetry, and f_{mel} ranging from 0 to 40%, representing a wide variety of skin pigmentation levels. The absorption coefficient of the deeper muscle layer was calculated using the following assumptions: blood to tissue ratio of 5%, arterial blood fraction of 0.25, total hemoglobin content of 1.9 $mmolL^{-1}$. The oxygen saturation levels were varied from 71% to 99% and a 5% arterial blood volume change was used to simulate the cardiac pulse.

Table 1. Optical properties

Layer	a	b	Thickness [cm]
Epidermis	3.015	0.964	0.006
Muscle	1.0368	0.4668	3

3. Results and discussion

Figure 1 shows the results of simulations for source detector separation of 2 cm. The SpO_2 as a function of the double ratio *R*, calculated as $(AC_{660}/DC_{660})/(AC_{940}/DC_{940})$, has been fitted with line equation (R^2>0.98) and the calibration curve has been established as 120.6-47.3R. Even for the highest melanin concentrations the SpO_2 results obtained stay within the +/-3.5% RMSE error, indicating no substantial over- or -underestimation of the SpO_2 even at lower saturation levels. This suggests that any spectral effect that melanin may have on the SpO_2 measurements, cancels out while calculating the double ratio. Indeed, since the melanin is only located in a superficial layer with very little blood, we can assume that its effect can be modelled as a simple wavelength-dependent transmission filter $T_{mel}(\lambda)$ that is the same for the AC and DC components. The double ratio considering the $T_{mel}(\lambda)$ filter can then be written as $R_{mel} = (AC_{660}\times T_{mel(660)}/DC_{660}\times T_{mel(660)})/(AC_{940}\times T_{mel(940)}/DC_{940}\times T_{mel(940)})$, where AC_{660}, DC_{660}, AC_{940} and DC_{940} are the AC and DC values for 660 nm and 940 nm without melanin, respectively. This equation simplifies to the original definition of the double ratio. The underlying assumption of the transmission due to melanin being the same for AC and DC is valid only if most of the detected photons travelled through both layers, i.e. the quantity of detected photons that travelled only through the top layer is small compared to the quantity of detected photons that reached the second layer. This is always true in transmission pulse oximetry, and generally true in reflection pulse oximetry provided that the source-detector distance is big enough compared to the thickness of the top layer. Larger confidence interval bars with increased melanin fraction in Figure 1b suggest that decreased light levels observed for highly pigmented skin contribute to lower signal-to-noise ratio (SNR) and can be the source of bias observed in clinical settings.

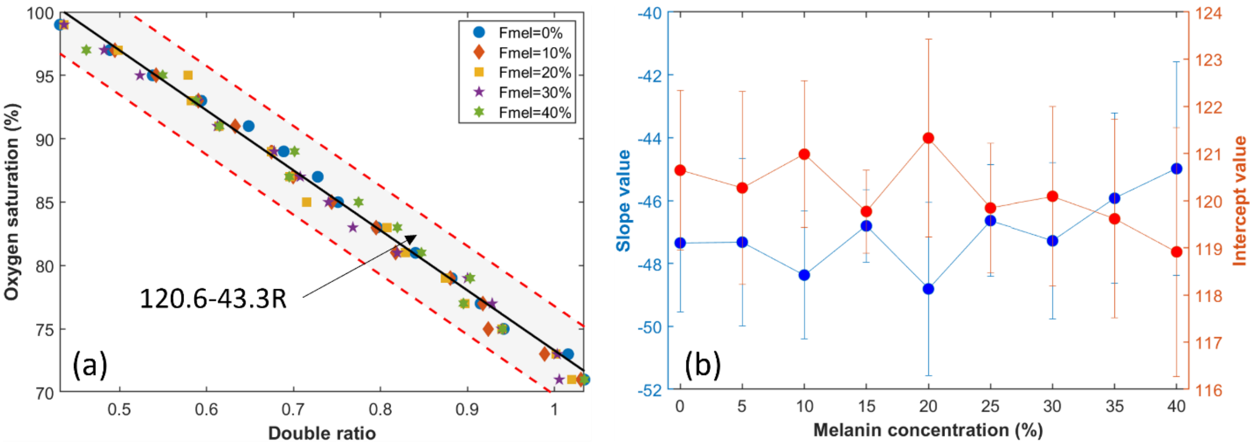

Figure 1. (a) Oxygen saturation versus double ratio for different melanin concentrations (symbols shown in the legend), shaded area highlights the RMSE error of 3.5%; (b) slope of the fitted lines with increased melanin concentration (left y-axis, in blue), and intercept of the fitted lines with increased melanin concentration (right axis, in red), bars represent 95% confidence interval.

4. Conclusions

Results indicate that even the highest simulated level of melanin concentration does not affect the calibration curve substantially. This in turn suggests that any clinically observed bias associated with highly pigmented skin is fundamentally related to deteriorating SNR due to lower light levels [10], which is especially important in the case of the AC component at 660 nm.

Acknowledgements

We would like to acknowledge Raydiant Oximetry and the Science Foundation Ireland (SFI/22/RP-2TF/10293 and SFI-12/RC/2276_P2_IPIC).

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