

Addressing Skin Pigmentation Bias in NIRS Tissue Oximetry

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Abstract: Current functional near infrared spectroscopy devices may show measurements bias and reduced accuracy related to diverse skin pigmentations hindering measurement reliability. In this work, the possibility to overcome this issue with time-domain near-infrared spectroscopy technique is assessed, first on phantom and then in-vivo, on a large cohort of pediatric subjects covering a wide range of skin pigmentations.

1. Introduction

The widespread adoption of functional near-infrared spectroscopy (fNIRS) devices exploiting light diffusion in biological tissues has brought attention to critical challenges associated with their accuracy and reliability across the spectrum of skin pigmentations [1]. Indeed, melanosomes situated at the basal layer of the epidermis in human skin, distribute melanin throughout the epidermal thickness, varying between 100 and 300 μm thicknesses across different anatomical regions. The presence of melanin significantly influences the optical properties in the first layer of probed tissues, particularly affecting light absorption. Intrinsic features of Time-domain near-infrared spectroscopy (TD-NIRS) can potentially rectify issues related to superficial layer optical properties, enhancing the accuracy of oximetry readings across diverse skin pigmentation ranges. In this study, we conducted TD-NIRS measurements on tissue mimicking skin phantoms to assess the possibility of overcoming skin pigmentation bias retrieving promising results; we then performed measurements on a cohort of 350 healthy pediatric subjects, encompassing the full spectrum of skin pigmentation to evaluate the issue in-vivo.

2. Methods

A set of 6 skin phantoms was developed, encompassing the full range of equivalent melanosome volume fraction that can be found in the epidermis across human population. Phantoms have been manufactured with a scattering coefficient of 20 cm^{-1} and a average thickness of $200\text{ }\mu\text{m}$. Nigrosine chromophore was included with different concentrations in the phantoms to mimic melanin's absorption for different pigmentation levels. Then, another set of tissue mimicking phantoms [2] has been used to vary equivalent StO₂ and tHb values in the bottom layer, in order to test the effect of the overlapped pigmented superficial layer. After the phantom test, we conducted non-invasive in-vivo measurements at the Buzzi Children's Hospital, Milano (Italy), utilizing a compact commercially available TD-NIRS tissue oximeter [3] and the "Goccia, G5" optical probe (PIONIRS s.r.l., Italy) with a source-detector distance of 2.5 cm. Enrolled subjects were clinically stable subjects aged between 0 and 18 years. The Fitzpatrick scale was employed [4] to assess skin pigmentation.

3. Results

Phantom measurements showed maximum deviations from bulk phantom nominal values of $< 1\%$ for StO₂ and tHb values across all combinations of overlying pigmentation-mimicking phantoms. From the in-vivo campaign, the statistical analysis one way ANOVA did not reveal significant differences within different clusters for both tHb and StO₂ values.

4. References

- [1] Kwasa J, et al. Demographic reporting and phenotypic exclusion in fNIRS. *Front Neurosci.* 2023;17:1086208. 2023 doi:10.3389/fnins.2023.1086208.
- [2] Pifferi et al., "Performance assessment of photon migration instruments: the MEDPHOT protocol," *Appl. Opt.* 44, (2005)
- [3] Lacerenza, M., "Performance and reproducibility assessment across multiple time-domain near-infrared spectroscopy device replicas", in *Design and Quality for Biomedical Technologies XV*, 2022, vol. 11951. doi:10.1117/12.2609404.
- [4] Fitzpatrick TB. The Validity and Practicality of Sun-Reactive Skin Types I Through VI. *Arch Dermatol.* 1988;124(6):869–871. doi:10.1001/archderm.1988.01670060015008

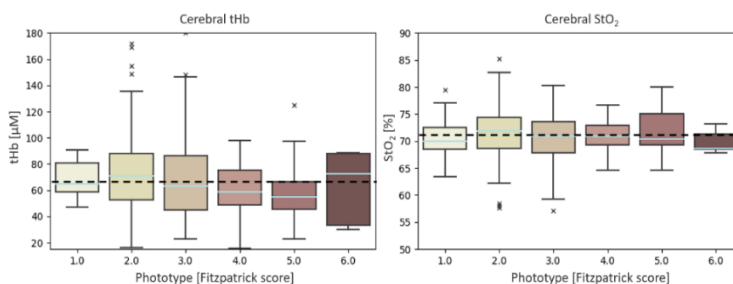


Figure 1: Distribution of the frontotemporal tHb (left) and StO₂ (right) across 350 pediatric patients clustered by Fitzpatrick score.