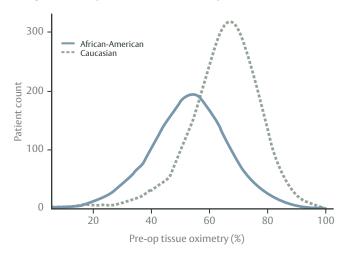


Tissue oximetry uses light waves to penetrate the skin and evaluate oxygen saturation. Higher levels of melanin can make oxygenation readings seem lower than they are, which could lead to unnecessary interventions and increased risk for the patient and/or increased cost of care (Figure 1).^{1,2,3} ForeSight tissue oximetry system has been designed to account for the skin pigmentation variance in individuals by interrogating the tissue with five different wavelengths of near-infrared spectroscopy (NIRS) utilizing a proprietary algorithm to estimate and compensate for the effect of melanin in the measurement.⁴

Figure 1. Preoperative tissue oximetry, Sun et. al.



Melanin and its complexity in oximetry

Near infrared spectroscopy (NIRS) has been utilized in medicine for decades, always with the goal of providing clinicians with more information about their patients while remaining noninvasive. Many early limitations (light absorption or scattering) of the technology have been largely overcome. However, one limitation that has not been widely addressed is the issue of melanin interference. The absorption curve of NIR light for melanin is similar to deoxygenated hemoglobin at certain wavelengths,

providing potential for melanin to confound tissue oximetry readings if the system does not account for it. This potentially erroneous reading could lead to unnecessary interventions in procedures, which can increase the risk for the patient.

Five different wavelengths of NIRS with ForeSight tissue oximetry system

To ensure accurate readings on patients of different skin types, ForeSight system was designed with a unique 5th wavelength to accommodate for the melanin present in the skin. Incorporating five different wavelengths of NIR light analyzes the tissue at the points where oxygenated and deoxygenated hemoglobin are more greatly distinguished.⁵ Utilizing the absorption curves of oxygenated and deoxygenated-hemoglobin and other chromophores such as melanin enables ForeSight system to provide reliable and consistent readings regardless of the color of the patient's skin.⁵

There are other biologic substances that mirror the absorption characteristics of oxy- and deoxyhemoglobin. Chromophores present in some patients with high bilirubin or newborn patients who still have meconium in their stools are two examples.^{6,7} Because the ForeSight system and its algorithm are designed to compensate for the effects of these substances, it can perform in such patients or conditions.^{7,8}

ForeSight system test for the melanin effect

oximetry measurements during

Stannard et. al, noted in a previous study that darker skin pigmentation appears to cause underestimation of regional oxygen saturation for certain cerebral oximetry devices. This underestimation of regional oxygen saturation presents a risk of triggering unindicated interventions and may limit its utility for predicting adverse outcomes. The authors retrospectively evaluated ForeSight cerebral

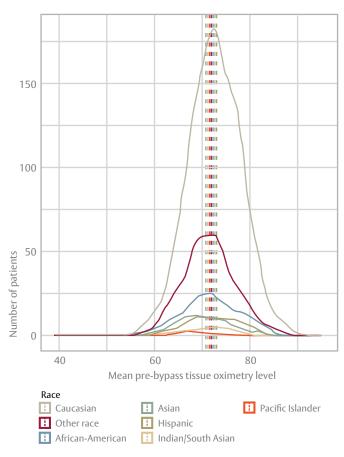
Edwards

cardiac surgery with self-reported race and quantified the impact of race on the reading. There were 4267 patients studied and included a self-reported race cohort of Caucasian, African American, Asian, Hispanic, Indian/South Asian, and Pacific Islander patients. After adjusting for perioperative variables, differences in readings less than 2% were observed between racial groups (Figure 2).4

Conclusion

Melanin can make oxygenation readings seem lower than they are, which could lead to unnecessary interventions, and potentially increased risk for the patient and/or increased cost of care.¹ It is for these reasons that melanin is an important consideration in tissue oximetry technologies.

Figure 2. ForeSight sensor readings by race, Stannard et. al.



References

- 1. Sun X, Ellis J, Corso P, Hill P, Chen F, Lindsay J. Skin pigmentation interferes with the clinical measurement of regional cerebral oxygen saturation. *British Journal of Anaesthesia*. 2014;114(2):276-280. doi:10.1093/bja/aeu335.
- 2. Murkin, JM, Adams, SJ, Novick, RJ, Quantz, M, Bainbridge, D, Iglesias, I, Cleland, A, Schaefer, B, Irwin, B, Fox, S. Monitoring Brain Oxygen Saturation During Coronary Bypass Surgery: A Randomized, Prospective Study. *Anesth Analg* 2007; 104:51-8.
- 3. Feldmeier C, Pitcher H, Hirose H, Cavarocchi N. Relative vs. Absolute Cerebral Oximetry: does a Skin Pigmentation Effect Normal values on cardiopulmonary Support? Austin Journal of Surgery. 2014;1(1): 1003.
- 4. Stannard B, Levin MA, Lin HM, Weiner MM. Regional cerebral oximetry is consistent across self-reported racial groups and predicts 30-day mortality in cardiac surgery: a retrospective analysis. J Clin Monit Comput. 2020 Feb 2.
- 5. Benni PB, MacLeod, D, Ikeda, K, Lin, HM. A validation method for near-infrared spectroscopy based tissue oximeters for cerebral and somatic tissue oxygen saturation measurements. *Journal of Clinical Monitoring Computing* 2017; DOI 10.1007/s10877-017-0015.
- 6. Thompson A, Benni P, Seyhan S, Ehrenkranz R. Meconium and Transitional Stools May Cause Interference with Near-Infrared Spectroscopy Measurements of Intestinal Oxygen Saturation in Preterm Infants. Advances in Experimental Medicine and Biology. 2012:287-292. doi:10.1007/978-1-4614-4989-8_40.
- 7. Said, MM, Niforates, N, Rais-Bahrami, K. Validation of near infrared spectroscopy to measure abdominal somatic tissue oxygen saturation in neonates. *Journal of Neonatal-Perinatal Medicine* 6 (2013) 23–30 DOI 10.3233/NPM-1365112.
- 8. Hoffman GM, et al. Effect of Bilirubin on Regional Oxygen Saturation Measures by Two NIRS Devices. ASA 2017; Abstract A1201.

For professional use. For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use (consult eifu.edwards.com where applicable).

Edwards devices placed on the European market meeting the essential requirements referred to in Article 3 of the Medical Device Directive 93/42/EEC bear the CE marking of conformity.

Edwards, Edwards Lifesciences, the stylized E logo, and ForeSight are trademarks of Edwards Lifesciences Corporation or its affiliates. All other trademarks are the property of their respective owners.



Edwards Lifesciences • Route de L'Etraz 70, 1260 Nyon, Switzerland • edwards.com

