Melanin Matters: Skin Tone and Accuracy in Tissue Oximetry

Evidence to support the use of FORE-SIGHT® tissue oximetry for improved performance in dark-skinned patients.

- The amount of melanin in a patient’s skin generally correlates with skin tone (the darker the skin, the more melanin present), but patients may also have sub-epidermal “birthmarks” or other non-visible melanin deposits.
- The absorption of NIR light by melanin can cause tissue oximeters to interpret higher amounts of deoxygenated hemoglobin than are actually present, resulting in a lower StO₂ (rSO₂) reading.
- Falsely low readings can lead to unnecessary interventions, creating the potential for increased risks for the patient, and increased cost of care.
- To address the issue of melanin interference in tissue oximetry readings, FORE-SIGHT tissue oximetry compensates for chromophores with similar absorption profiles to melanin.
- Evidence suggests that the INVOS™ monitor could be subject to significant differences (~12 percentage points on average) in rSO₂ readings with regard to dark-skinned versus light-skinned patients.
- Internal FORE-SIGHT data shows a much smaller difference (~1 percentage point on average), suggesting the FORE-SIGHT technology may generate more consistent results across patients with both light and dark skin.
- One study utilizing the INVOS monitor showed that a material subset of African American patients had pre-induction rSO₂ readings of less than 50%, below an intervention threshold according to historical clinical guidelines for using the INVOS monitor.
- Other biological chromophores such as those present in patients with high bilirubin or in newborns with meconium in their stools can present similarly to melanin, and evidence suggests that FORE-SIGHT algorithms can compensate for those substances as well.
Near Infrared Spectroscopy 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 of the technology have been largely overcome. However, not all tissue oximeters have sufficiently addressed the issue of melanin interference.

Melanin’s purpose in the body is to absorb light (namely, from the sun) to protect internal organs from damage. When exposed to too much sunlight, skin may tan or burn: this is the result of the body releasing more melanin to protect itself. This light absorption ability also applies to near infrared (NIR) light, which is why large amounts of melanin can confound oximetry readings. The absorption curve for melanin is similar to deoxygenated hemoglobin at certain wavelengths, which is likely a reason that darker-skinned patients (who have higher amounts of melanin in their skin) could generate lower StO₂ readings with certain monitors. The tissue oximeter might mistake the light being absorbed by the melanin for light absorbed by deoxygenated hemoglobin.

One way to ensure a tissue oximeter can generate accurate readings on patients of all skin types is to estimate and compensate for the melanin present in the skin. The FORE-SIGHT ELITE tissue oximeter does just that by interrogating the tissue with five different wavelengths of NIR light and utilizing the absorption curves of not only oxy- and deoxy-hemoglobin, but also of chromophores such as melanin. By solving for chromophores like melanin, FORE-SIGHT can provide reliable and clinically consistent readings regardless of the color of the patient’s skin.

This concept may explain the phenomenon demonstrated in a published case report out of Thomas Jefferson University, where they utilized the INVOS device on a 71-year-old African American patient undergoing coronary artery bypass. The patient’s baseline rSO₂ was between 40-45% immediately after induction, and dropped consistently during the procedure to levels of 20-30%. The team performed a number of interventions attempting to improve oxygenation, including volume expansion, increased flow, and vasopressors. In the ICU, simultaneous tracings from INVOS and FORE-SIGHT monitors were obtained (Figure 1), the latter of which showed cerebral saturations to be adequate – greater than 60% bilaterally, while INVOS readings remained below 30%. Based upon the FORE-SIGHT reading, vasopressor support was weaned quickly with no change in cerebral saturations. The patient had no neurologic deficits or mental status changes postoperatively, further suggesting that the INVOS readings between 20-30% for an extended period may not have been reflective of patient status.

The authors concluded:

“The case presented demonstrates the importance of reliable cerebral oximetry measurement, as unnecessary interventions were done to improve an inaccurate reading. We have encountered this situation repetitively in patients with dark skin in our practice with those on various support devices, including extracorporeal membrane oxygenation, total artificial heart, and biventricular assist device. In these patients, falsely low readings were found on relative oximetry (INVOS system), but were normal when measured by absolute cerebral oximetry (FORESIGHT system).”

In 2014, clinicians from Medstar Washington Hospital published a review of 3,282 consecutive patients undergoing cardiac surgery between 2010 and 2012. The study examined cerebral rSO₂ readings provided by INVOS technology, broken down between the patients self-identified as African American or Caucasian. The study found that on average, the pre-induction and skin closure rSO₂ readings in the African American group were 12 and 13 points lower than the Caucasian group, respectively (Figure 2).
The authors then plotted the distributions of the pre-induction rSO₂ values (Figure 3). The misalignment of the distributions is notable. We have taken the liberty of shading the pre-induction values lower than 50% rSO₂, as that is one of the INVOS monitor's published intervention thresholds according to historical clinical guidelines. This analysis appears to indicate that roughly 40% of the African American patients in this study might have required immediate pre-induction intervention according to historical guidance published by INVOS.

In response to these publications, we conducted a retrospective review of FORE-SIGHT validation data that resulted in cerebral oximetry readings from 101 subjects with either light or dark skin (moderate skin tone subjects were excluded, consistent with the Medstar publication) breathing room air. The results of this analysis can be seen in Figure 4. While INVOS monitoring demonstrated a 12-point difference in mean pre-induction oximetry values, FORE-SIGHT monitoring demonstrated only a 1-point difference between the two groups. The distributions of data for the two groups are aligned, and no subjects generated readings below 60.

The limitations of this comparison should be noted. The Medstar patient group was very large, the dark-skinned patients generally had more risk factors, and the FORE-SIGHT data set small by comparison. The FORE-SIGHT data was also generated using presumed-healthy volunteers, not sick patients undergoing cardiac surgery as in the publication. That said, multivariate analysis of the Medstar data permitted the investigators to conclude that the difference in reported oxygenation values was consistent with the assumption that “skin pigment attenuates the transmission of NIR light and thus, potentially disturbs the estimation of cerebral oxygen saturation.”

Additionally, there are other biologic substances that mirror the absorption characteristics of melanin. Chromophores present in some patients with high bilirubin or newborn patients who still have meconium in their stools are two examples. Because FORE-SIGHT technology detects and compensates for the effects of substances like melanin, it may perform better than other tissue oximeters in these patients.

We believe this information as a whole demonstrates that melanin matters in tissue oximetry. Melanin can make oxygenation readings seem lower than they are, which could lead to unnecessary interventions, as appeared to be the case at Thomas Jefferson Hospital, and potentially increased risk for the patient and/or increased cost of care. Low baseline readings – especially those below 50% or even 40% – make intervention protocols using a “percent change from baseline” methodology challenging. We also believe this information demonstrates that not all tissue oximeters perform identically when it comes to compensating for melanin – and that the oximeter of choice for consistent performance across all skin tones should be FORE-SIGHT tissue oximetry.

Figure 2. Cerebral Oxygen Saturation (rSO₂)

<table>
<thead>
<tr>
<th></th>
<th>AA patients (n=1186)</th>
<th>Cauc Patients (n=2096)</th>
<th>P-value</th>
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<tbody>
<tr>
<td><strong>Pre-induction</strong>, left [mean (SD), %]</td>
<td>53 (13.3)</td>
<td>66 (12.2)</td>
<td>&lt; 0.01</td>
</tr>
<tr>
<td><strong>Pre-induction</strong>, right [mean (SD), %]</td>
<td>53 (13.3)</td>
<td>65 (12.3)</td>
<td>&lt; 0.01</td>
</tr>
<tr>
<td><strong>Pre-induction</strong> [mean (SD), %]</td>
<td>53 (12.6)</td>
<td>65 (11.6)</td>
<td>&lt; 0.01</td>
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<tr>
<td>Skin closure, left [mean (SD), %]</td>
<td>49 (11.4)</td>
<td>62 (11.3)</td>
<td>&lt; 0.01</td>
</tr>
<tr>
<td>Skin closure, right [mean (SD), %]</td>
<td>49 (11.4)</td>
<td>62 (11.5)</td>
<td>&lt; 0.01</td>
</tr>
<tr>
<td>Skin closure [mean (SD), %]</td>
<td>49 (10.9)</td>
<td>62 (11.0)</td>
<td>&lt; 0.01</td>
</tr>
</tbody>
</table>

*Preoperative rSO₂ by ethnic group. The number of patients associated with each level of rSO₂ is depicted. Notice the normal distribution of the data in each ethnic group with that in AAs being systematically lower. Appeared as Figure 1 in Sun, et al. Shading added by CASMED.

Note: FORE-SIGHT chart data uses the room air readings from a mix of FORE-SIGHT G1 and FORE-SIGHT ELITE monitors across a broad range of presumed-healthy volunteers in multiple studies.
References


