Direct Accuracy Performance Comparison of Cerebral Oximeter Devices
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**Background**
Reported accuracy values of various cerebral oximeters are difficult to compare without identical patient cohorts and testing methodology.

**Objective**
The purpose of this study is to measure the accuracy of commercially available cerebral oximeter monitors tested on identical subjects to eliminate selection bias and ensure uniform data analysis.

**Methods**
Controlled oxygen desaturation sequences were performed on 23 healthy volunteer subjects of mixed gender and ethnicity. Values reported by four cerebral oxygenation monitors were compared against simultaneous invasive weighted CO-oximetry jugular bulb and arterial oxygen saturation reference measurements.

**Results**
Precision for the cerebral oximeters tested ranged from 3.90% to 9.72% (1SD) and $A_{\text{ms}}$ accuracy from 4.26% to 9.69%.

**Conclusions**
Performance among the tested monitors varied considerably. The FORE-SIGHT Oximeter demonstrated the greatest precision and accuracy.

**Introduction**
An imbalance between cerebral oxygen supply and demand can lead to cerebral hypoxic/ischemic injury and has been reported across a wide spectrum of disorders. Lower levels of cerebral oxygenation have been associated with increased cognitive dysfunction, a higher incidence of major organ morbidity, worse outcomes, and extended hospital length of stay. Difficulties in detecting cerebral ischemia as it occurs may cause missed opportunities to prevent or minimize permanent ischemic brain and other organ injury.

Measurements of cerebral oxygenation are useful in assessing the balance between cerebral metabolic supply and demand. Direct invasive methods of measurement such as jugular venous oximetry and brain tissue oxygen tension are expensive and less than ideal. In contrast, cerebral oximetry with near infrared spectroscopy (NIRS) offers a noninvasive, continuous and easy to use measurement of cerebral tissue oxygen saturation and continues to gain acceptance as a crucial monitoring tool in critical care environments.

Cerebral oximetry has been available as a monitoring device for over a decade. Recent refinements to NIRS technology have resulted in more reliable oximeters with increased accuracy performance. Currently, at least three manufacturers have FDA clearance to market NIRS based cerebral oximeters in the United States, but direct comparisons of accuracy among these monitors has been difficult. Some studies have been published where a single monitor brand has been compared to an invasive standard to determine accuracy. Individual studies, however, provide limited guidance for clinicians to compare the accuracy of devices due to the possibility of patient selection bias or variability in methodologies. Until now, only one published study compared two branded monitors against a mixed venous and arterial reference standard within the same patient cohort.

While head-to-head comparisons in clinical settings have been reported, objective evaluation of the accuracy of the devices without an invasive standard is difficult.

To provide a direct comparison of accuracy performance among commercially available cerebral oximeter monitors without selection bias, this comparative study evaluated the precision of four commercially available cerebral oximeters on the same subjects. Results are also compared with previously published studies conducted with similar reference methods to determine consistency.

**Devices**
Simultaneous measurements from four commercially available near-infrared spectroscopy (NIRS) cerebral oximeters: FORE-SIGHT® (CAS Medical Systems, Branford, CT, USA), INVOS® 5100C (Covidien, Boulder, CO, USA), EQUANOX™ Model 7600 (Nonin Medical, Plymouth, MN, USA) with both EQUANOX Advance™ and EQUANOX Classic™ sensors, and NIRO®-200NX (Hamamatsu Photonics, Hamamatsu City, Japan) on adult volunteers. The reported cerebral oxygenation values (variously identified as $\text{SctO}_2$, $\text{rSO}_2$, and TOI) were compared against the commonly recognized invasive standard of weighted CO-oximetry jugular bulb and arterial oxygen saturation values during episodes of deliberate oxygen desaturation. All of these monitors have FDA clearance with the exception of the NIRO-200NX which has only CE Mark.

**Methods**
Healthy adult volunteers were enrolled in this IRB-approved volunteer study after obtaining written informed consent at the Hypoxia Research Laboratory at the University of California, San Francisco. Sensors from different manufacturers were randomly placed on alternating right or left sides of each subject’s forehead for each hypoxia run. An internal jugular vein catheter was placed at the position of the subject’s superior jugular bulb and an arterial catheter was placed in the subject’s radial artery. During the study period, all

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*This Configuration minimized systematic inter-device interference across the study.*
Discussion

This study represents the first detailed comparative performance analysis of cerebral oximeters using an invasive reference standard and a common cohort, testing methodology, and data analysis. Large differences were observed in the precision of commercially available monitors in healthy adult volunteers undergoing induced hypoxia events with precisions ranging from ±3.90% to ±9.72% (1SD). The FORE-SIGHT Oximeter measured cerebral oxygenation with the greatest precision (3.90%) and $A_{rms}$ accuracy (4.26%). Data from this study is consistent with several earlier validation studies. Two reports of the FORE-SIGHT Oximeter demonstrated similar precisions of 3.70%\(^6\) and 3.12%\(^6\), respectively. Furthermore, one of those studies also included a comparison to an INVOS monitor and measured an INVSX precision of 9.62%\(^6\), consistent with the precision of 9.69% reported in this study. The current results, however, do not agree with another INVSX reported volunteer hypoxia study showing a precision of 5.0%\(^9\).

The EQUANOX Classic sensor has FDA clearance as a trending sensor, but absolute accuracy data published earlier indicated a $A_{rms}$ of 8.3%\(^{10}\), similar to the $A_{rms}$ of 8.47% determined in this study. In contrast with a previous study where EQUANOX Advance sensors reported an $A_{rms}$ value of 4.10%\(^6\), this investigation measured an $A_{rms}$ accuracy for those sensors of 6.86%. No standard deviation was available in the previous study.

The variations in measured accuracy across investigations highlight the difficulty of comparing performance across studies employing different subjects and methodology. This study controlled experimental and analysis conditions to ensure traceability of truly comparative data.

Room air measurement values are important because they often are used as a baseline for determining treatment interventions based upon decrements or trends in that value.\(^{11}\) The FORE-SIGHT Oximeter reported all room air values (Figure 6) in the expected range for healthy adults of 60% to 80%, with a distribution mirroring the reference values. Other manufacturer’s oximeters reported a wide variety of subject room air saturation values ranging from less than 40% to greater than 80%. Large variability in baseline room air values may undermine treatment confidence when intervention at fixed oxygenation levels (e.g., 60%) are prescribed or when the values are used to stratify risk for cardiac patients prior to on-pump surgery.\(^{11}\)

Clinical Implications

Clinicians should be aware of the limitations of certain cerebral oximeters as accuracy varies considerably among brands. Advancements in NIRS technology as found in the FORE-SIGHT Oximeter provide improved accuracy affording clinicians increased confidence to intervene appropriately in the care of their patients.
Fig 1: Scatter Plot Graph Comparing FORE-SIGHT with Reference CX

Fig 2: Scatter Plot Graph Comparing INVOS with Reference CX

Fig 3: Scatter Plot Graph Comparing NIRO-200NX with Reference CX

Fig 4: Scatter Plot Graph Comparing EQUANOX Classic with Reference CX

Fig 5: Scatter Plot Graph Comparing EQUANOX Advance with Reference CX
References

9. KOS1274. Somanetics INVOS 5100B FDA 510(K) premarket notification.