A1: Is the CO-oximeter a Gold Standard?
T Aoyagi. R&D Center, Nihon Kohden Corp., Tokyo Japan

Introduction: CO-oximeters have been used for the calibration and testing of pulse oximeters with the expectation that SpO₂ should be referenced to the oxygen saturation (SO₂) of arterial blood. A study was conducted comparing the CO-oximeters available in 1996. This study varied the functional SO₂ (fSO₂) and total hemoglobin (fHb) of blood samples over a wide range. The methodology was simple so as to be repeatable by others.

Methods: Tests were performed on four models of CO-oximeters: the AVL 912 (AVL Medical Instruments, Graz, Austria); the Corning 270 (Bayer Diagnostics, Leverkusen, Germany, owner of Ciba-Comin); the IL 642 (Instrumentation Laboratory, Lexington, MA, USA); and the Radiometer OSM3 (Radiometer Medical A/S, Bromhøj, Denmark). The instruments had received regular preventive maintenance by their manufacturers and were found to be operating within the manufacturer's specifications. All blood samples were collected from a non-smoking healthy adult, i.e., the COHb level should be consistently small. Each blood sample was collected in a single syringe and, in a random order, injected into the multiple CO-oximeters in a nearly simultaneous manner. Between serial analyses, the blood was stored at 4°C.

- Test 1: Changes in fSO₂ levels were achieved by gaseous tonometry using O₂ gas containing 5% CO₂.
- Test 2: Specimens were centrifuged, serum discarded, and the packed RBC mixed with saline to make different fHb levels. The blood samples were saturated with O₂ gas containing 5% CO₂.

Results: The grouped distribution of measured values was:

<table>
<thead>
<tr>
<th>fSO₂ %</th>
<th>60</th>
<th>80</th>
<th>95</th>
<th>fHb [g/dL]</th>
<th>10</th>
<th>15</th>
<th>20</th>
</tr>
</thead>
<tbody>
<tr>
<td>AfSO₂ %</td>
<td>2.0</td>
<td>1.5</td>
<td>1.2</td>
<td>fSO₂ %</td>
<td>&gt;97.8</td>
<td>&gt;97.8</td>
<td>&gt;97.9</td>
</tr>
<tr>
<td>COHb %</td>
<td>&lt;1.7</td>
<td>&lt;2.1</td>
<td>&lt;2.2</td>
<td>COHb %</td>
<td>&lt;2.2</td>
<td>&lt;2.0</td>
<td>&lt;2.2</td>
</tr>
<tr>
<td>MetHb %</td>
<td>&lt;0.3</td>
<td>&lt;0.3</td>
<td>&lt;0.3</td>
<td>MetHb %</td>
<td>&lt;0.3</td>
<td>&lt;0.3</td>
<td>&lt;0.3</td>
</tr>
</tbody>
</table>

For Test 1, there was a bias for fSO₂ between the CO-oximeters. Therefore, the range of variability of fSO₂ (AfSO₂ = max fSO₂ - min fSO₂) was calculated. For Test 2, the true value of fSO₂ was expected at 100 % [ ]. The Radiometer OSM3 was excellent for fSO₂ over the range of fHb 5 to 25 [g/dL]. COHb was high in most instruments.

Conclusions: The Radiometer OSM3 CO-oximeter seemed to be acceptable for the measurement of fSO₂. It is impossible for the user to calibrate a CO-oximeter and the manufacturers' test reagents may not reveal degradation in the instrument's performance.

A3: Site-Dependent Lag Times in Saturation During Low Perfusion
D Behour, P Mannheimer, M Joping
1. Nellcor Oxymetry - Tyco Healthcare, Pleasanton, CA USA
2. Dept. of Anesthes., Mt. Carmel St Ann's Hosp, OSU, Columbus, OH USA

Introduction: Previous laboratory studies of pulse oximetry accuracy during rapidly induced hypoxemia revealed some delay in the time to detect changes in saturation with finger sensors compared to those placed on the ear (Ann Emerg Med 1996;38:309-14; J Clin Anesth 1999;11:313-8). In these healthy adult subjects, the mean lag times for finger sensors compared to ear sensors were between 6 to 18 sec with the largest single observation - 40 sec. We conducted a study designed to investigate the effects of cold-induced peripheral vasoconstriction (i.e., low perfusion) on the times to detect changes in saturation at various sensor placement sites (i.e., forehead, ear, and fingers). Our results revealed that in subjects exposed to a room temperature of 58 to 62 °F for about 45 minutes, substantial delays between head versus finger sensors were evident (J Clin Anesth Med 2001;163:A142). Mean lag time of finger sensors compared to head sensors was 89 sec for the first induced hypoxemia and 103 sec for the second, with some individual observations >3 min. These results were striking even when compared to results from the same subjects studied under normal conditions (room temperature 72-76 °F) during which little difference was observed in detection times between head and hand sensors. In the present study, we measured lag times between finger sensors compared to a forehead reflectance sensor (Nellcor RS-10) at the end of the study during non-motion conditions during cold induced, low perfusion.

Methods: With IRB approval and informed consent, 12 healthy adults (4 men; 8 women) age 21-45 yr were studied. Subjects were acclimated to a cold room (62°F) for 45 min prior to study to induce peripheral vasoconstriction and low digit perfusion. A Nellcor N-395 and RS-10 reflectance sensor was placed on the forehead for comparison to devices placed on the fingers of both the dorsum and motion and motion hands. Instruments were placed on the fingers: Nellcor N-395, Masimo Radical, NovaTech MARSpo₂, and Nellcor N-200. Finger placements were rotated between subjects in a balanced design. Following the last motion period, subjects were stabilized between 70 to 75% SpO₂. Inspired oxygen was then increased to near 100% and the time for each instrument to cross 95% SpO₂ was measured. Probability values were obtained using Generalized Model analysis from hypoxia test based on empirical standard error estimates. SAS statistical software was used to perform the calculations.

Results: Percent infrared modulations (%IRmod) averaged 0.45 ± 0.22 during non-motion indicating significant vasoconstriction and low digit perfusion. Table 1 lists the lag times of finger sensors compared to the RS-10 sensor, which were substantial and statistically significant (P < 0.001) with a mean lag time for the non-motion hand >1 min compared to the RS-10. There were no differences between digits, however, lag times of the motion hand were significantly less than the non-motion hand (P = 0.001).

Table 1. Lag time (seconds) of finger sensors compared to forehead sensor, where LTR = right hand vs. RS-10 and LTL = left hand vs. RS-10

<table>
<thead>
<tr>
<th>Finger</th>
<th>LTR</th>
<th>LTL</th>
<th>D (LTR-LTL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Index</td>
<td>39.5 ± 32.7</td>
<td>68.5 ± 19.8</td>
<td>-29.9 ± 46.1</td>
</tr>
<tr>
<td>Middle</td>
<td>41.4 ± 39.1</td>
<td>75.7 ± 18.8</td>
<td>-34.3 ± 45.0</td>
</tr>
<tr>
<td>Ring</td>
<td>60.1 ± 21.1</td>
<td>79.4 ± 22.8</td>
<td>-19.3 ± 17.4</td>
</tr>
<tr>
<td>Pinky</td>
<td>47.3 ± 34.2</td>
<td>68.3 ± 25.3</td>
<td>-21.2 ± 21.1</td>
</tr>
<tr>
<td>Combined</td>
<td>47.3 ± 32.1</td>
<td>73.0 ± 21.5</td>
<td>-25.7 ± 33.8</td>
</tr>
</tbody>
</table>

Conclusions: The cold room environment provided an excellent model to simulate and induce low peripheral perfusion with the %IRmod averaging approximately one order of magnitude less than that seen in normal temperatures. We conclude that the forehead sensor detected changes in saturation substantially and significantly sooner when compared to finger sensors in subjects with cold-induced peripheral vasoconstriction. We suggest that more centrally placed head sensors may offer significant advantage over finger sensors when monitoring patients with peripheral vasoconstriction or low perfusion, or in situations where rapid detection of hypoxemia is critical.
A4: Characterization of Neonatal Motion Relative to Pulse Oximetry Monitoring
MR Goldstein, ML Pernia, PL Alejo, LL Yang, BD Sindel, CG Ochikubo, GI Furman, GI Martin.
Cirrus Valley Medical Center, Queen of the Valley Campus, West Covina, CA. USA; Pediatrics Medical Group.

Introduction: We observed that neonates exhibited frequent motions that caused interference with a pulse oximeter’s (PO) ability to reacquire the signal between motion epochs [1]. This study was designed to characterize and categorize neonatal motion patterns potentially affecting PO performance in hospitalized infants.

Methods: A random sample of 6 infants requiring PO monitoring were instrumented with a Nellcor-395 (Pleasanton, CA) and observed continuously. The N-395 was selected because the Motion Indicator (MI) data can be used as a marker of motion (“illuminates when the monitor detects motion sufficient to affect the readings”) [2]. A computer collected SpO2, pulse rate, and MI data. The number and duration of motion events were tabulated from the MI and matched to the type of motion observed. The duration of motion epochs was grouped into five categories: < 10 s, 10 - 30 s, Continuous (> 30 s), Contiguous (a cluster of motion epochs ≤ 5 s apart), and Persistent (Contiguous epochs ≥ 30 s).

Results: Infant demographics were: 2 girls/4 boys, weight of 1,784 ± 672 gms. and gestational age of 33 ± 5 wks. 3 were on supplemental oxygen. There were 8 studies (duration 3 ± 1.3 hours) in 6 subjects for a total duration of 23.7 hours. The observed motions included: clenched, jerking, kicking, squirming and stretching. Most motion events were short in duration, however many short motion epochs occurred continuously. The longest period of persistent motion was nearly 5 minutes.

<table>
<thead>
<tr>
<th>Motion Epochs</th>
<th>Events</th>
<th>Time (h) and (mean ± range)</th>
<th>(%) of total</th>
<th>Mean ± range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>3,537</td>
<td>3.93 ± 16.9%</td>
<td>4.0 ± 5.8</td>
<td>1 - 58</td>
</tr>
<tr>
<td>&lt; 10 s duration</td>
<td>3191</td>
<td>2.22 ± 9.4%</td>
<td>2.5 ± 2.2</td>
<td>1 - 9</td>
</tr>
<tr>
<td>≥ 10 s duration</td>
<td>346</td>
<td>1.71 ± 7.2%</td>
<td>17.8 ± 9.2</td>
<td>10 - 58</td>
</tr>
<tr>
<td>Continuous</td>
<td>32</td>
<td>0.37 ± 1.6%</td>
<td>41.5 ± 7.6</td>
<td>30 - 58</td>
</tr>
<tr>
<td>Contiguous</td>
<td>1,944</td>
<td>5.52 ± 23.3%</td>
<td>10.2 ± 20.1</td>
<td>5 - 290</td>
</tr>
<tr>
<td>Persistent</td>
<td>153</td>
<td>2.76 ± 11.6%</td>
<td>64.0 ± 38.4</td>
<td>30 - 290</td>
</tr>
</tbody>
</table>

Conclusions: This objective categorization of neonatal motions is consistent with our prior observations that pulse oximeters can be routinely affected by motion [1]. This pattern of motion epochs explains why pulse oximeters have lengthy and bothersome false alarms in the NICU [3,4].

References:

A5: Performance of Motion-Resistant Pulse Oximeters in Tracking Neonatal Heart Rate Variability
MR Goldstein, GI Furman, ML Pernia, PL Alejo, LL Yang, BD Sindel, CG Ochikubo, GI Martin.
Cirrus Valley Medical Center, Queen of the Valley Campus, West Covina, CA. USA; Pediatrics Medical Group.

Introduction: Motion resistant pulse oximeters (MRPO) have fewer false alarms than conventional pulse oximeters during neonatal motion [1]. The monitoring and analysis of heart rate variability is important to the physiologic assessment of the acutely ill neonate [2]. We observed that some MRPOs “froze” the displayed pulse rate (PR) during rapid changes in an infant’s heart rate (HR). Masimo SET (a MRPO) has been found to track bradycardia [3], but does it or other MRPOs accurately follow acute changes in heart rate?

Methods: Seven neonates with a history of decisive HR changes where monitored concurrently with four MRPOs: the Agilent Viridia 24C rev B, Radical with Masimo SET V3, Nellcor N-395 V1620, and Novametrix MARS v. eng-2001-13. MRPO sensors were placed in a randomized fashion on each limb. The PR of the MRPOs was compared to the HR from the ECG channel of the Agilent Viridia 24C. The PR and HR were collected via a computer at 1 Hz. MRPO PR data was categorized as “frozen” (i.e., missed PR Δ) if the displayed PR was constant (defined as Δ ≤ 1 BPM for ≥ 10 s), while a good quality ECG tracing measured an acute change ≥ 25 BPM (i.e., a change of meaningful physiologic consequence).

Results: 74 epochs of acute HR deceleration or acceleration were found in 23.7 hours of data collection. The range of missed PR Δ (1-31) reveals large and significant differences in the four MRPOs tested. The Novametrix MARS unit had the highest rate of missed PR Δ followed by the Agilent Viridia, and the Nellcor N-395. The Masimo SET tracked the ECG HR variability most closely with one missed episode.

<table>
<thead>
<tr>
<th>Missed Change in PR</th>
<th>Masimo SET</th>
<th>Nellcor N-395</th>
<th>Agilent Viridia</th>
<th>Nova. MARS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>13</td>
<td>22</td>
<td>31</td>
</tr>
</tbody>
</table>

Conclusions: Of the four motion-resistant pulse oximeters tested, the Radical with Masimo SET was the only one that reliably tracked acute heart rate changes in the neonates tested. The other pulse oximeters froze extensively and missed events of diagnostic importance.

References:
A6: World's First Combined Digital Pulse Oximetry Pulse Oximetry and Carbon Dioxide Tension Ear Sensor
J Hayoz, R. Rohling, A. Tschupp.
1. Sentec AG, Thun, Switzerland
2. Privat Klinik Bethanien, Zürich, Switzerland

Introduction: The idea of combining pulse oximetry with the measure of cutaneous N2 pressure within a single sensor was suggested in the mid-1980s [1,2]. However, the absence of a reliable measurement site limited the practicability of such a sensor. In 1999, Rohling et al. [3] and Tschupp et al. [4] demonstrated the ear lobe to be a reliable measurement site to assess patient's oxygenation and ventilation non-invasively and continuously with a SpO2-PCO2 single-sensor. In the present paper we report first results obtained with V-Sign™, the world's first digital SpO2-PCO2 ear sensor.

Methods: The digital V-Sign probe - operated at 42°C - combines the elements of an optical pulse oximeter and a Severynhaus-type PCO2 sensor. Its built-in mixed signal microprocessor amplifies, digitizes and pre-analyses the measured signals at the point of patient care. Twelve adult volunteers were studied following a standardized protocol. After sensor placement brief stable oxygen desaturation was induced by inhalation of an O2-N2 mixture (10/90 by vol.) during 4 minutes. After a rest the subjects voluntarily hold their breath (apnea), hyperventilated in ambient air, and finally inhaled a CO2-N2 mixture (10/20/70 by vol.) during 3 minutes. Starting from a stable PCO2 level the PCO2 response times for apnea/hyperventilation/CO2-breathing situations are defined as the times after which the PCO2 value increased/decreased/increased by more than 1.0mmHg per 12s. Similarly, SpO2 response times for apnea situations are defined as the time after which the previously stable SpO2 value increased by more than 2% per 12s. V-Sign-PCO2 values were compared to state of the art pulse oximeter readings (Nellcor N395, Durasensor Fingercap).

Results:

![Graph](image)

Fig. 1: Response time during apnea for PCO2 (----), SpO2 (---), and SpO2-N395 (--.--). Fig. 2: BA analysis of data obtained during brief stable oxygen desaturation.

Conclusions: The results demonstrate that V-Sign measures relevant ventilation parameters reliably and fast.

References:

A7: Low Power Motion Tolerant Pulse Oximetry
J Huang, M Bernstein.
Siemens Medical Systems, Electro-Medical Group, Danvers MA USA

Introduction: Since its introduction as an operating room parameter, pulse oximetry has been adopted over an ever-broadening range of clinical settings. From the original application in anesthesia, the parameter has spread to the ICU than to the general care floor. The progression has exposed pulse oximetry to greater motion artifact, which leads to an increase in false alarms and reduced monitoring accuracy. Over the last few years, a new generation of motion tolerant pulse oximeters has become available from several manufacturers. These devices have significantly improved the usefulness of oximetry as a safety monitor outside the operating room. To date, these motion tolerant devices are relatively large and power hungry, making ambulatory & telemetry monitoring cumbersome and relatively impractical. Siemens Oxisure Plus takes a new approach to motion tolerant pulse oximetry. Utilizing an innovative algorithmic structure which is inherently less computationally intensive than the more traditional DSP techniques used by other systems, significantly lower power consumption has been achieved. The purpose of this study was to measure the motion performance of the new algorithm using established standards.

Methods: Sixteen healthy adult volunteers were used in laboratory motion tests to measure the impact of motion on the accuracy of monitoring. Three Oxisure Plus monitors were connected to each hand of each volunteer subject. One hand remained stationary, while motions were performed with the other hand. The motions were based on the description of motions in a recent 510K for a commercial motion tolerant pulse oximeter [1]. During the motions, the saturation of the volunteer was gradually reduced to approximately 70% by administering a breathing mixture with less oxygen than room air. Field tests were performed on adult, pediatric and neonatal subjects. Subjects were selected based on the presence of sufficient motion to make monitoring with conventional (non-motion tolerant) pulse oximeters impractical.

Results: The data from laboratory testing were reduced by calculating the standard deviation of the differences between the moving and non-moving hand [2]. The result was less than 1% degradation in SpO2 accuracy during motion. In the field, Oxisure Plus monitoring effectiveness on difficult motion cases was demonstrated to be similar to that of other modern motion tolerant oximeters.

Conclusions: The lab testing has demonstrated that the accuracy of Oxisure Plus during motion meets the same qualitative standard used to test the current generation of motion tolerant oximeters. More importantly, the field testing results demonstrate that this unit represents a truly portable alternative for motion tolerant SpO2 monitoring.

References:
1. FDA 510K # 510419, Masimo SET Radial Pulse Oximeter with umbilical A
ABSTRACTS

A8: An Evaluation of Pulse Oximetry Performance During Motion Artifact in a Cold Room Environment in Three Pulse Oximeters Designed for Use in Motion.

M. Jopling, P. Mannheimer, D. Bebou.

1. Dept. of Anesth., Mt Carmel St. Anns Hosp. OSU, Columbus, OH USA
2. Nellcor Oximetry - Tyco Healthcare, Pleasanton, CA USA

Introduction: Several pulse oximetry signal processing methodologies have been introduced for the continuous and accurate reading of saturation (SpO2) during patient motion. We evaluated three of these technologies: (Nellcor/Oximart: XL® in N-395, Masimo SET® in Masimo Radical, Novametrix MARSPO2®) and a conventional generation oximeter (Nellcor N-200). This study investigated the effects of challenging motion artifact during cold induced low peripheral perfusion on the performance characteristics of these four pulse oximetry technologies.

Methods: With IRB approval and informed consent, 12 healthy volunteers (4 men, 8 women) age 21-45 yr were studied. Subjects were acclimatized to the cold room (62°F) for 45 min prior to study to induce peripheral vasconstriction and low digit perfusion. The motion protocol consisted of rubbing or scratching motion periods (2-3 min each) during 1) stable normoxia (SpO2 = 93-97%), 2) two rapid desaturations-resaturation epochs from 100 to 70 then back to 100% and 3) stable hypoxia (SpO2 = 73-77%). Instruments were allowed at least 30 seconds recovery between motions. Motions were voluntary in response to an audible sound repeated at random intervals between 0.75 to 3.75 Hz. Motion amplitudes were between 0.5 to 2.0 cm. Each instrument on the motion hand was compared to a like instrument on the same digit of the non-motion hand, and sensor sites were rotated between subjects in a balanced design. The following performance measures were calculated: E7% (time test and control SpO2 values differed by > 7%); Drop-out (% time instrument failed to display a non-zero value); RMSD (root mean square of the differences) and Pt (performance index = 100 - E7 - Drop-out). For the N-395 and N-200, percent IR modulation (%IRmod) was measured during all non-motion and motion periods for both the non-motion and motion hands. Receiver Operator Characteristic (ROC) parameters were calculated on a per-subject and per-device basis for SpO2. Sensitivity and specificity were calculated for each motion device at 17 cut-points ranging from 100 to 70%. For all cut-points, hypoxia was defined as SpO2 < 85% for the corresponding device on the control hand. An ROC curve was constructed for each device and area under the curve (AUC) was calculated using the trapezoidal rule. ROC parameters were then compared among device models using generalized linear model analysis.

Results: Percent IRmod averages 0.45 ± 0.22 during non-motion indicating significant vasconstriction and low digit perfusion. Rubbing motions increased the apparent IRmod by 69% to an average of 0.77 ± 0.31. Scratchings increased the apparent IRmod by 423% to an average of 2.4 ± 1.1. The performance measures for all motion periods combined are summarized in the following table.

<table>
<thead>
<tr>
<th>Motion Device</th>
<th>N-395</th>
<th>Radical</th>
<th>MARSPO2</th>
<th>N-200</th>
</tr>
</thead>
<tbody>
<tr>
<td>E7 (%)</td>
<td>29 ± 11</td>
<td>30 ± 12</td>
<td>25 ± 10</td>
<td>47 ± 18</td>
</tr>
<tr>
<td>Drop-out (%)</td>
<td>2 ± 4</td>
<td>5 ± 7</td>
<td>22 ± 16</td>
<td>5 ± 11</td>
</tr>
<tr>
<td>RMSD</td>
<td>87 ± 26</td>
<td>12 ± 60</td>
<td>94 ± 20</td>
<td>18 ± 80</td>
</tr>
<tr>
<td>Pt</td>
<td>70 ± 12</td>
<td>65 ± 16</td>
<td>53 ± 10</td>
<td>48 ± 16</td>
</tr>
<tr>
<td>AUC of ROC</td>
<td>0.93 ± 0.07</td>
<td>0.86 ± 0.06</td>
<td>0.73 ± 0.11</td>
<td>0.63 ± 0.10</td>
</tr>
<tr>
<td>Sensitivity</td>
<td>0.91 ± 0.10</td>
<td>0.88 ± 0.16</td>
<td>0.77 ± 0.16</td>
<td>0.69 ± 0.21</td>
</tr>
<tr>
<td>Specificity</td>
<td>0.26 ± 0.15</td>
<td>0.30 ± 0.16</td>
<td>0.45 ± 0.19</td>
<td>0.17 ± 0.13</td>
</tr>
</tbody>
</table>

Conclusions: The cold room environment provided an excellent model to simulate and induce low peripheral perfusion with the %IRmod averaging approximately one order of magnitude less than that seen in normal temperatures. The addition of the rubbing and scratching motions provided two very different levels of challenge to the instruments significantly decreasing the signal to noise ratio. During the challenging condition of motion and low perfusion, the Nellcor N-395 exhibited the best accuracy and lowest drop-out rate compared to the other technologies tested.


R. Kepetic and MT Peterson.

Clinical Research Group, Masimo Corporation, Irvine, CA USA.

Introduction: Most pulse oximetry (PO) devices incorporate user selectable averaging times (AT) (typically from 2 to 20 seconds). Some clinicians use AT to reduce the false alarm rate of conventional PO. However, researchers have cautioned that extending the AT can lead to an underestimation of meaningful desaturation (DS) events by up to 60% [1]. Others found that patient generated motion corrupted 50% of the old PO recordings during studies of neonatal sleep [2]. However, the American Academy of Sleep Medicine expressed a need for high fidelity SpO2 with the argument that DSs of as little as 4% and lasting as briefly as 10 seconds can be indicative of obstructive sleep apnea [3]. This diagnostic need and desire for rapid response to SpO2 Δ is highlighted in neonatal care (where motion artifact is commonplace) [4]. Motion resistant pulse oximeters (new PO) have been introduced which reduce the frequency of false alarms. We compared the performance of the old and new PO technologies with data files containing neonatal DS and resaturation (RS) events.

Methods: Neonates with a history of acute DS were studied. Source (raw RIR data) was collected and replayed through a PC-based pleth wave generator to recreate the original time-saturation profile for input to the PO under test. The output of each test PO was compared to the Source (the reference for DS, RS and timing of epochs). The setup provided reproducible input signal allowing the PO technologies and AT to be independent test variables. Test devices included two new PO's: the Masimo SET Radical in 2-second FastSat mode and the Nellcor N-395 (no user selectable AT), and an old PO (the Nellcor N-200 set in mode 2, the fastest AT). Non-motion periods were chosen so as to not unduly affect the N-200 performance. Differences for the test PO values from each Source SpO2 (Δs, in %) and time in seconds to report that SpO2 (phase lag, PL) for every peak and trough were tabulated. These values were totaled for each subject and then compiled as a whole. SpO2 Δs of < 4% were not counted.

Results: 45 minutes of Source data from 4 neonates contained 80 pairs of DS (trough) and RS (peak) epochs. The findings were consistent between subjects, the degree of DS and RS Δ was large and differences in POs were significant (other devices vs. Masimo). The mean Source peak SpO2 was 90.4 ± 10.5 (range from 45.6 to 99) and the mean Source trough 68.6 ± 15.4 (range from 9.4 to 92.2). Masimo in 2-second FastSat mode (FastSat) caught all SpO2 epochs, whereas, 2 were missed by the N-200 and 8 by the N-395. The Radical PO in 2-second FastSat mode most closely replicated the magnitude of Source ΔSpO2 and shared the same PL with the N-200.

<table>
<thead>
<tr>
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<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Peak</td>
<td>0.0 ± 0.9</td>
<td>0.0 ± 2.7</td>
<td>0.4 ± 3.4</td>
<td>0.4 ± 2.4</td>
<td>9.4 ± 1.8</td>
<td>7.8 ± 1.6</td>
</tr>
<tr>
<td>Trough</td>
<td>-1.0 ± 5.5</td>
<td>-3.7 ± 6.1</td>
<td>-9.4 ± 5.3</td>
<td>-4.8 ± 1.8</td>
<td>-5.1 ± 2.7</td>
<td>-6.3 ± 0.9</td>
</tr>
</tbody>
</table>

*p < 0.01  **p < 0.05  ***difference not significant

Conclusions: Pulse oximeter averaging time can affect tracking of SpO2 Δ. The Masimo Radical, in 2-second FastSat mode, had the greatest fidelity for tracking Δs during 80 pairs of neonatal desaturation and resaturation epochs. Even without motion, use of the Nellcor N-200 (in the shortest averaging time) and the N-395 (no user selectable averaging time) resulted in missed SpO2 Δs and blunting of the degree of SpO2 Δ. The N-395 had the longest delay to report an SpO2 Δ.

References:
A10: Signal Identification and Quality Indicator™ for Motion Resistant Pulse Oximetry
P. Lang, M. Peterson.
Masimo Corporation, Irvine, CA USA

Introduction: Motion artifact is a common cause of conventional pulse oximeter failure and reduced accuracy [1]. Manufacturers have addressed this limitation by educating users to examine the plethysmographic waveform for acceptable morphology [2]. In contrast, motion-resistant pulse oximeters have been shown to be accurate even when displaying an apparently “noisy” plethysmographic waveform [1].

It is important that new display methods are provided to indicate that the Spo2 and pulse rate measurements are based on data of adequate integrity. One approach is to display a visual signal quality indicator. Masimo's Radical Signal Extraction pulse oximeter displays a Signal Identification and Quality indicator (Signal IQ™), which is implemented as a scrolling horizontal line with superimposed vertical bars (Fig. 1). The height of each bar is proportional to the signal quality. With extremely poor signal quality a “Low Signal IQ” test message is displayed (Fig. 2).

No Motion

Phleg

Moderate Motion

Intense Motion

Methods: To verify that the “Low Signal IQ” message reliably indicates compromised data integrity, we analyzed 10 neonatal pulse oximetry files that contained motion epochs of sufficient intensity to cause failure of one or more motion resistant pulse oximeters. A trained clinical observer annotated the motion events. The motion indicator from the Nellcor N-395 was collected to further document the presence and duration of motion. A Spo2 value was considered erroneous if it deviated > 10% from the other motion resistant pulse oximeters without clinical justification.

Results: 36.2 hours of data were collected. Motion – as indicated by the N-395 motion indicator – was present 14.8% of the time (320.7 min.). There were 13 episodes where the Radical Spo2 was considered erroneous resulting in a significant false alarm (displayed Spo2 < 85% for > 10 seconds). During these episodes, the Low Signal IQ message displayed continuously. In total, the Low Signal IQ message displayed 1.4% of the time. The N-395 had 26 significant false alarms (displayed Spo2 < 85%) and the Motion Indicator was activated during each of these episodes. The Motion Indicator and the “Low Signal IQ” message both yielded high sensitivity in detecting erroneous data. However, the specificity of the “Low Signal IQ” message for detecting compromised signal integrity was much greater than that of the Motion Indicator.

<table>
<thead>
<tr>
<th>Pulse Oximeter</th>
<th>Indicator</th>
<th># False Alarms</th>
<th>% Indicator Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nellcor N-395</td>
<td>Motion</td>
<td>26</td>
<td>14.8</td>
</tr>
<tr>
<td>Masimo Radical</td>
<td>Low SIQ</td>
<td>13</td>
<td>1.4</td>
</tr>
</tbody>
</table>

Conclusions: We confirmed the Signal IQ and the Low Signal IQ message could help verify the accuracy of the displayed Spo2 from the Masimo SET Radical. The Low Signal IQ message demonstrated high sensitivity to detecting poor signal quality without being displayed an excessive amount of the monitoring time.

References:

A11: Fourier Artifact Suppression Technology provides reliable Spo2 in rapid and accurate interpretation of pulse oximetry
R. Neumann, S. Kastle.
Agilent Technologies, Boeblingen Germany

Introduction: Philips’ FAST-Spo2 algorithm (Fourier Artifact Suppression Technology) uses patented digital techniques in the frequency domain and a proprietary analysis of the resulting Fourier spectrum to remove noise from the signal. An FFT generates Fourier spectral peaks representing the pulse, the pulse harmonics, noise and artifact, and any noise and artifact harmonics. Scoring techniques and a broad knowledge based rule-set are used to analyze the peaks. The analysis uses numerous technical and physiological criteria as well as quality indicators. Peaks from noise and artifact are eliminated by failure to pass this analysis leaving only the actual pulse and its harmonics. Bench testing was done to compare the artifact suppression performance of this new FAST-Spo2 technology (Philips CMS Rel. C.0) with a conventional pulse oximeter (CMS Rel. A.0) and two other new generation pulse oximeters, Nellcor N395 (Rev. 1.7) and Masimo Radical (V3).

Methods: To get a clinical relevant result, a performance testing method was searched, which addresses the clinical application in two ways. First the used test signals should reflect the clinical environment and second the performance measures should be based on clinical factors. Therefore a test method as described by Kastle et al [1]. In contrast to other laboratory testing with healthy adult volunteers and simulated, artificial motion patterns ECG, this bench test method is based on a clinical database, which contains data from critical ill neonatal, pediatric and adult patients and a wide range of real artifacts such as motion, respiratory overlay and shivering, which were performed in a clinical environment under true care conditions. The performance ranking is done by an error-weighting scheme, which was obtained by an international survey among clinicians. The performance was evaluated separately for the Spo2 error, the Pulse Rate error and the time a device was not providing any value (INOP time).

The overall rank is defined by the sum of these three performance factors.

Results: Out of 15 different patient signals and 11 different artifact types 24 test combinations were defined. Each of these combinations was generated with 4 different signal-to-noise ratios (0.25, 0.5, 1.0, 2.0) leading to 96 test episodes of 150 seconds each, representing a total test time of 240 minutes. The overall performance rank of Philips’ FAST-Spo2 was slightly better than the two other new generation pulse oximeters, the Nellcor N395 and Masimo Radical. All new generation pulse oximeters show significant improvements (N395: 27%, Masimo: 28%, CMS C.O. 35%) over conventional pulse oximeter technology.

Conclusions: Although there are only small differences between the two systems, there are significant differences in the three components of the performance: The N395 had the smallest Spo2 error portion when it provided a value, but this performance was due to the largest portion of not giving a value. On the other hand the Masimo Radical had only a small time of giving no value, but only at the expense of having the largest Spo2 error portion. Philips’ FAST-Spo2 showed a behavior that is leveled in-between. These test results provide a good insight on the different strategies of the devices and how the manufactures have defined the threshold between showing ambiguous values and alerting the user that no reliable value can be obtained.

References:
A12: A Silver Standard for Corroboration of SpO2 during Motion
MT Peterson, JJ Novak, RJ Kopotic, JM Goldman.
Masimo Corporation, Irvine, CA USA

Introduction: CO-oximetry of arterial blood is the “gold standard” for calibrating and validating SpO2 values of pulse oximeters (POs). However, when evaluating PO performance during motion or rapid SpO2 changes, blood sampling is difficult or impossible. We have developed a computational technique for deriving accurate SpO2 during short epochs of red (R) and infrared (IR) photoplethysmography (pleth), “Silver Standard” (Ag-R/IR).

Methods: We collected PO data on 6 healthy adults during normoxemia and hypoxemia while they performed intermittent random motions of one hand. External temperature was used to change peripheral perfusion. Volunteers were instrumented with right and left index finger thermocouples, a reference PO (control hand) and two test POs (test hand): a Masimo Radical (Masimo Corp., Irvine, CA); and a Nellcor N-200 (Nellcor, Pleasanton, CA). A computer collected all data. Subjects entered a cool room (18-20°C) and their hands were immediately warmed (heating pad ~ 40°C), until the PO IR modulation (i.e., Perfusion Index, PI) was ~ 5%. The heating pad was removed and the subject acclimated to the cool room over 20 to 30 minutes. At 5-10 min intervals during the cooling phase, subjects breathed room air, followed by inhalation of a hypoxic gas mixture to a target plateau of 80% SpO2 and performed intermittent random hand motions. This normoxemia to hypoxemia protocol was performed 3 times per subject as their PI decreased. From the test R Radical PO, epochs of motion-free R and IR pleth data (in the midst of random motion) were analyzed. Periods of motion-free R and IR plethysmographic data consisting of at least 3 pleths (cardiac cycles) were identified. The 3 pleths qualified for Ag-R/IR analysis if the waveform morphology was similar in appearance to that occurred during non-motion periods of ~10 seconds in length. From these qualified pleths, the SpO2 value via conventional analysis was ratio of the filtered, normalized R and IR data (SpO2calc) was computed. SpO2calc and the displayed SpO2 values from the test and control hands were compared (SpO2ref = the SpO2 value from a non-motion control). Descriptive statistics were performed.

Results: 80 sets of data were analyzed. Finger temperature decreased on average from 34.4 ± 2.6 to 19.5 ± 3.6°C, while the PI dropped from 4.7 ± 1.5% to 0.48 ± 0.04%. SpO2calc to SpO2ref bias was 0.6 ± 1.4%. To test if gross changes in PI adversely affected accuracy of SpO2calc, we evaluated the data from the first and last room air trials for each subject (i.e., warmest vs. coldest periods). In this subset, “warm” SpO2calc to SpO2ref bias was 0.1 ± 0.8% and the “cold” SpO2calc to SpO2ref bias was 0.3 ± 1.0% (not significant by chi squared test).

<table>
<thead>
<tr>
<th></th>
<th>N = 80</th>
<th>Mean (%)</th>
<th>Range (%)</th>
<th>Δ from SpO2ref</th>
<th>Range (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SpO2ref</td>
<td>92.6 ± 7.4</td>
<td>75 to 100</td>
<td>Mean (%)</td>
<td>Range (%)</td>
<td></td>
</tr>
<tr>
<td>SpO2calc</td>
<td>92.0 ± 7.6</td>
<td>74.5 to 100</td>
<td>-0.6 ± 1.4</td>
<td>-6.5 to 2.4</td>
<td></td>
</tr>
<tr>
<td>Radical</td>
<td>92.0 ± 7.5</td>
<td>75 to 100</td>
<td>-0.6 ± 1.6</td>
<td>-6.0 to 3.5</td>
<td></td>
</tr>
<tr>
<td>N-200</td>
<td>82.6 ± 8.2</td>
<td>64 to 100</td>
<td>-10.0 ± 9.4</td>
<td>-36.0 to 4.0</td>
<td></td>
</tr>
</tbody>
</table>

Conclusions: In healthy adults, the silver standard technique could reproducibly find and calculate an accurate SpO2 in the midst of motion epochs and over a wide range of local perfusion. Although tedious, this technique can verify SpO2 accuracy of a pulse oximeter without use of either blood CO-oximetry or a reference PO on a motion-free, well-perfused site.

A13: Clinicians Learn to Utilize the Improved Accuracy and Reliability of the Masimo SET® Oximeter in Weaning CABG Patients
SK Rentow, CG Durbin Jr.
University of Virginia Health System, Charlottesville, VA USA

Introduction: Patients should receive the lowest FiO2 necessary to maintain adequate PaO2 and pulse oximetry (PO) provides a convenient monitor. During a prospective study of the impact of improved PO on clinical practice, we found that caregivers more rapidly weaned cardiac surgery patients from a high FiO2 (as well as obtaining fewer ABGs), when they had access to data from a Masimo SET® Oximeter (MSO) as compared to a conventional pulse oximeter (CPO) (Omidha 3740). With this improved accuracy, we demonstrated that data from the MSO was more reliable than that from the CPO, with less PO failure and “down time”. Clinicians also seemed to believe the data from the MSO was more accurate than that from the CPO, using it to wean FiO2 more quickly. We evaluated this change in patient management over time during the controlled trial as clinicians learned to effectively utilize more reliable PO.

Methods: 86 adult cardiac surgery patients with good preoperative ventricular function, following CABG surgery, were enrolled in the study. On arrival in the ICU, both a CPO and a MSO were attached to the same hand of each patient. Patients were randomly assigned to have the display of only one of the devices available to the bedside caregivers with the other device “blinded”. No other clinical interventions were changed. We determined the time until weaning to FiO2 ≤ 0.4, time until extubation, and number of ABGs during weaning. We grouped patients by their enrollment order into the study. We compared the results in the first 30 patients enrolled to the results in the last 30 patients enrolled. In order to minimize the effect of changes in staffing patterns, unit census and other immeasurable factors, the weaning time using the CPO was considered the control time for each comparison. Differences were analyzed using students t for paired data and non-parametric techniques, when appropriate. Significance was determined at p<0.05.

Results: The time to wean to FiO2 ≤ 0.4 was significant (Figure). In the first 30 patients, there was a small difference; MSO patients weaned in 83% of the time of control patients (NS). In the last 30 patients the MSO patients weaned in 22% of CPO weaning time (p<0.05). There were fewer ABGs with the MSO over the entire study (2.7 ± 1.2 vs. 4.1 ± 1.6 MSO vs. CPO; p<0.001) but that difference did not change over time.

Conclusions: One use of pulse oximeters is to guide oxygen therapy. We determined that clinicians learned to change patient management based upon their independently identifying the more useful monitoring technology. This experimental design (randomized patients and blinded clinicians) is a powerful method to evaluate the impact of new technology. The demonstration of a positive change in behavior is strong support that evaluation and learning is taking place. We suggest that this is a better way to study innovation and improvements in technologies in a clinical domain.

References:
A14: Improved Accuracy of the Masimo SET® Oximeter (MSO) Increases Caregiver Confidence in Saturation Values
SK Rostow, CG Durbin Jr.
University of Virginia Health System, Charlottesville, VA USA

Introduction: During a study of the impact of improved pulse oximetry (PO) on clinical practice, we found that caregivers more rapidly weaned FiO₂ while obtaining fewer ABGs, when they had access to data from an MSO as compared to conventional PO (CPO) (Ohrmeda 3740). [1,2]. We found that MSO data was more reliable than CPO, with less PO failure and “down time”. Clinicians also seemed to believe the MSO data was more accurate than CPO and weaned FIo₂ more quickly. In order to evaluate the validity of this belief, we examined the relationship between SaO₂ from clinically indicated ABGs and the SpO₂ reported by both pulse oximeters.

Methods: 86 adult cardiac surgery patients with good preoperative ventricular function, following CABG surgery, were studied. On arrival in the ICU, both a CPO and a MSO were attached to the same patient. Patients were randomly assigned to have the display of only one of the devices available to the caregivers with the other device “blinded”. No other interventions were changed. Comparison of the SpO₂ for each oximeter and the SaO₂ calculated from the ABG was made (t-tests, p<0.05).

Results: There were a total of 283 ABGs: 134 obtained while the MSO was unblinded and 149 while the CPO was unblinded. The bias (mean ± SD) was calculated as the difference between the SpO₂ and the average of the SpO₂ and SaO₂ for each oximeter, independent of blinding condition for all ABGs obtained (Table). Because of the large range of CPO bias, the calculation was repeated using only the ABG data obtained when the oximeter was used unblinded. However, the bias was not significantly improved by this grouping. The frequency distribution of the bias was calculated and grouped (Figure). MSO produced a bias >5% significantly less frequently than CPO; 3% versus 15% of all ABGs (p<0.05).

<table>
<thead>
<tr>
<th></th>
<th>MSO</th>
<th>CPO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bias mean</td>
<td>0.53</td>
<td>-0.82</td>
</tr>
<tr>
<td>Bias SD</td>
<td>1.7</td>
<td>2.8</td>
</tr>
<tr>
<td>Maximum</td>
<td>8.4</td>
<td>8.2</td>
</tr>
<tr>
<td>Minimum</td>
<td>-6</td>
<td>-24</td>
</tr>
</tbody>
</table>

Conclusions: MSO had a smaller bias then CPO and CPO had a greater frequency of biases > 5% SpO₂. The improved MSO accuracy, as seen by the smaller average and narrower range of biases, improved clinician confidence in MSO data and resulted in fewer confirmatory ABGs.

References:

A15: An Investigational Study to Assess the Performance of Pulse Oximeters under the Presence of Motion Artifact
AB Shang, Duke University Medical Center, Durham, NC USA

Introduction: Several pulse oximetry (PO) manufacturers are now offering devices that make claims of motion resistance [1]. The standards needed to address this issue have not kept pace. The goal of this study is to create a testing method that would provide a systemic, reproducible standard for a minimum resistance to motion.

Methods: IRB approval was obtained from Duke University and the FDA. All manufacturers with representatives on the ASTM subcommittee F29.11.05 were polled for clinically relevant motion, and the results were then discussed by the ISO PC subcommittee [2]. From these forums, five motions were agreed upon [3]. Pulse oximeters were attached to the middle three fingers of both hands and the motions were studied in the right (“Test”) hand, using the other, motionless (“Reference”) hand as control. Motion was monitored by using a feedback loop consisting of an analog tracing of the raw IR plethysmographic signal. A baseline signal tracing was established (the IR signal with Test hand at rest). The first motion was then performed for 1 minute, with the subject using IR feedback 5 times the baseline amplitude. At 1 minute, the SpO₂ values of both the Test and Reference hands were recorded. Then, both hands were left motionless for 60 seconds. This sequence was repeated for the other 4 motions.

Results: The study is still ongoing. Preliminary results are encouraging for the successful development of a motion standard. Items of interest include:
1. Initial analysis shows trends towards a bimodal distribution separating motion resistant and non-motion resistant pulse oximeters. However, this separation is incomplete.
2. Incomplete separation of motion resistant versus non-motion resistant pulse oximeters is occurring mainly because of failure of devices claimed to be motion resistant. Our current failure criteria are measurements outside of claimed accuracy specifications (± 3%) for at least a 15-second period during the 60-second test period for each motion. The current score required to pass is 60 %, or passing 3 out of 5 of the described motions. Experience has shown that if a device fails a particular motion test, its value remains outside of accuracy specifications until the end of the test period.
3. Determination of the minimal amount of plethysmographic noise needed to allow the appropriately engineered motion resistant devices to pass, while failing non-motion resistant devices. Currently, the amount of noise generated is at least 5 times the amount of signal. This assumes that all the devices that currently claim motion resistance are truly motion resistant. This also assumes that devices without claims of motion resistance have no significant degree of motion resistance.

Discussion: As this study continues, several challenges present themselves. The first is to use the iterative process to create a test that is fair, yet rigorous enough to provide the appropriate challenge to the pulse oximeters being tested. The object is to create a minimum standard using the simplest model, healthy non-smoking adults, in order to allow reproducibility. However, the ultimate goal must be kept in sight, which is the improvement of patient care. It is important to recognize that there are other potentially important factors that could influence the performance of these devices in the clinical setting. These factors include peripheral temperature, comorbidities, medications, and any other conditions that decrease peripheral perfusion. A decrease in peripheral perfusion reduces the amount of signal that can be detected. As the amount of signal decreases, the amount of noise needed to degrade device performance decreases. However, it is beyond the scope of this initial attempt at standardization to try and control for these variables. These questions remain for further investigation.

References:
1. FDA document #K991823, #K993637, #K96260, #K973887, #K990966, and #K006794.
2. ISO TC 121/SC3 Minutes from Luncheon Meeting 1/16/01.
3. FDA Research Involved with Human Subjects Committee # 01-017R / Duke University IRB # 2773-01-3ER.
A16: Accuracy of Two Pulse Oximetry Devices with Motion Artifact Reduction Technology on Very Small Birth Weight Infants in an Intensive Care Nursery
S Slogic.
Dartmouth Hitchcock Medical Center, Lebanon, NH USA

Objective: To evaluate the accuracy of Masimo Radical and the Nellcor N-395 pulse oximeters on Very Small Birth Weight infants (VSBW). Both machines employ motion artifact technology. Motion artifact interferes with accurate SpO2 values, particularly in conditions of low peripheral blood flow when "...the motion-added signal tends to predominate over the pulse signal so that the (Red/Infrared) ratio transmitted to the photoreceptor produces a false SpO2 value" [1]. Motion and conditions of low perfusion are common in premature infants and are a continuous source of inaccurate SpO2 measurement. Motion artifact reduction technology uses filters to separate non-arterial noise from the arterial signal and thus improve the accuracy of SpO2 readings.

Methods: Blood gas values from critically ill VSBW infants were compared with simultaneous SpO2 readings. Infants were entered into the evaluation if they were critically ill with functioning arterial lines in place. Simultaneous SpO2 was measured on post-natal days to avoid potential pre-natal admixture. Arterial blood gases (ABG) were drawn as ordered by the physician for clinical reasons; no ABG's were ordered for the sole purpose of comparing machine accuracy to ABG's. ABG's were measured in a Bayer 855 Blood Gas, Electrolyte and CO-oximeter analyzer. Functional oxyhemoglobin saturation (SaO2) was computed by the following equation: SaO2 = FO2 × Hb / I - (FCO2 × Hb + FmetHb) × 100. Two hundred and thirty-eight paired test values were obtained. The difference between the SpO2 and measured SaO2 of the ABG were calculated for each pair and the mean difference (bias) and Standard Deviation (precision) was calculated. A paired t test was performed on the means to determine if there was a statistically significant difference between the two instruments.

Results: Two hundred thirty-eight values were collected on 9 patients. Results are listed below.

<table>
<thead>
<tr>
<th></th>
<th>Masimo Radical</th>
<th>Nellcor N-395</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean difference from ABG (bias)</td>
<td>-2.614**</td>
<td>-0.484**</td>
</tr>
<tr>
<td>Median difference from ABG</td>
<td>-2.554**</td>
<td>-0.444**</td>
</tr>
<tr>
<td>Standard deviation of the differences (precision)</td>
<td>2.197</td>
<td>2.101</td>
</tr>
<tr>
<td>Paired t test value</td>
<td>7.2362 (* = P&lt;0.001)</td>
<td></td>
</tr>
</tbody>
</table>

Conclusions: The Nellcor device was statistically more accurate than the Masimo device when compared to measured functional saturation on critically ill VSBW infants. The Masimo device consistently read lower SpO2 values when compared with measured functional saturation.

References:

A17: Continuous Non-invasive Monitoring of Mean Arterial Blood Pressure
I Störmer1, P Buttgereit2
1. Institute of Anesth, Heinrich-Heine-University, Düsseldorf, Germany
2. BiomechLab, Nordrhein-Westfalen, Germany

Introduction: Continuous mean arterial blood pressure (MAP) monitoring is important in clinical medicine and research. Measurement by arterial catheter is associated with considerable risks. We present an alternative method with test data (N=9).

Methods: The presented technique is based on detection of pulse waves in the thorax and calf by a biocompliance method. The pulse transit time (PTT) from thorax to calf is measured (Fig. 1). According to the Moens-Korteweg equation (1,2), changes of MAP are calculated from PTT(3). After having obtained informed consent, patients were instrumented before induction of general anesthesia. MAP was measured continuously by arterial catheter (MAPi) and the PTT based method (MAPz) during induction (Fig. 2). MAPz was calibrated to the first ten beats of MAPi. Data is presented in mmHg as MW ± SD. The results were plotted according to the method of Bland and Altman. The 95% confidence interval is given.

Figure 1: Instrumentation and Pulse Waves

Figure 2: Measurement Session

Results: The mean difference of MAPi and MAPz was 0.03 ± 8.56 mmHg. The 95% confidence interval ranged from -17.11 to 17.17. Furthermore, the PTT-based method tends to estimate higher MAPs at lower blood pressures and lower MAPs at higher blood pressures than the invasive method. This might reflect the well-known problem of resonance overshoot in commonly used arterial lines. This hypothesis is supported by the finding that comparison of invasive measurements to oscilometric measurements of MAP shows a pattern similar to the PTT-based method.

Conclusions: We hypothesize that the PTT-based method is more accurate than invasive measurements. However, further data is needed to confirm this.

References:
1. Moens AL. Die Pulskurve. JF Brill, Leiden, 1878
A18: Improved Detection of Obstructive Sleep Apneas-related Hypoxemia using Masimo SET Pulse Oximetry in Children
H Trang, V Leske, S Bourguiba, C Gaultier.
Department of Physiology, Robert Debre Hospital, Paris France

Introduction: Children with obstructive sleep apneas (OSA) generally present with short apaees-hypopneas (OAH) and periods of partial upper airway obstruction associated with hypoxemia. The number of hypoxemic episodes, and the time spent with desaturation during sleep are major indicators for severe OSA.

Objective: To evaluate the impact of Masimo SET® pulse oximetry (Irvine, CA) which uses a new technology for signal processing in low signal-to-noise conditions, as compared to one of the most commonly used pulse oximeters, the N-200 (Nellcor®, Pleasanton, CA), and Nellcor’s newest Oximax technology, the N-395.

Methods: 24 patients (mean 10.1 ± 5.3 yrs, range 1.5-17.1) had overnight sleep studies, with recordings of the classical neurophysiologic and respiratory signals. In addition, pulse oximetry (SpO₂) was recorded using Masimo SET (8's averaging mode), Nellcor N-200 (5-7's averaging mode), and N-395. OAH were identified using signals from nasobuccal thermistors, rib cage and abdominal motions. For each OAH, the baseline SpO₂, maximal desaturation, and desaturation time (time spent with desaturation >3%) were determined. Desaturation time was tabulated below as Mean ± SD (range). Hypoxemic OAH were defined as OAH associated with a desaturation >3% observed in either one of the 3 pulse oximeters.

Results: A total of 176 hypoxemic OAH were identified, among which 63 OAH were ≤20 s of duration. Hypoxemic OAH were more frequently detected by Masimo SET than by neither Nellcor oximeter; the shortest difference in the detection rate was for short OAH ≤20 s. Mean desaturation time was longer using Masimo SET; the greatest difference in mean desaturation time was for short OAH ≤20 s. The failure of Oximax to identify hypoxemia may be due to its method of freezing on the last reliable value.

<table>
<thead>
<tr>
<th>Detection rate (%)</th>
<th>Masimo SET</th>
<th>N-200</th>
<th>N-395</th>
</tr>
</thead>
<tbody>
<tr>
<td>OAH</td>
<td>176</td>
<td>81% **</td>
<td>49%</td>
</tr>
<tr>
<td>OAHs≤20s</td>
<td>63</td>
<td>65% **</td>
<td>17%</td>
</tr>
</tbody>
</table>

Conclusions: Masimo SET® allowed better detection of hypoxemic OAH during sleep as compared to the N-200 and N-395 pulse oximeters. The performance of Masimo was the highest for short OAH (≤20 s duration), a feature needed to diagnose children with obstructive sleep apneas.

A19: Blood Oxygenation of Brain Tissue by Time Resolved Diffuse Reflectance Measurements
H Wabnitz1,2, J Steinbrink1,2, H Rinneberg1, H Obrig1, A Villringer2
1. Physik & Metrologische Informationstechnik, Physikalisch-Technische Bundesanstalt, Berlin Germany
2. Neurologische Klinik, Charité, Humboldt-Universität, Berlin Germany

Introduction: Whereas pulse oximetry determines oxygen saturation of arterial blood, the other optical methods may be used to obtain blood oxygenation parameters in tissue and thus yield information on both oxygen delivery and oxygen consumption. Non-invasive determination of blood oxygen saturation by near-infrared spectroscopy (NIRS) is of particular interest in brain tissue [1]. Recording the time of flight of photons in addition to the intensity of diffusely reflected light offers the chance to eliminate the influence of overlying tissue.

Short laser pulse

Distribution of times of flight of photons

Methods: Time-resolved diffuse reflectance was measured using a portable system suited for bedside monitoring. Optodes separated by 2 cm were attached to the head, and diffuse reflectance was measured with subnanosecond time resolution. Pulses of a few 100 ps duration were provided by three diode lasers (PicQuant GmbH, Berlin) at wavelengths of 684 nm, 780 nm, and 826 nm. Photons were detected by a fast photomultiplier (R7400U-12, Hamamatsu). A time-correlated single photon counting system (SIC 300, Becker & Hickl GmbH, Berlin) was used to record distributions of times of flight of photons. Analysis of the shape of the measured distributions allows the separation between the effects of scattering and absorption. Since photons with long times of flight penetrate on average deeper into the tissue than early photons, information about the depth where absorption occurred can be obtained. Two different problems have been investigated: (i) Determination of depth-resolved changes in oxy- and deoxyhemoglobin concentration in tissue, e.g., during functional stimulation in the brain; (ii) determination of oxygen saturation in the cortex.

Results: (i) A method has been developed to achieve depth resolution of absorption changes [2]. This method relies on a layered head model and time-dependent mean partial path lengths that are obtained by Monte-Carlo simulations. It has been successfully applied to analyze several in-vivo experiments, inducing absorption changes by, e.g., motor stimulation or a bolus of contrast agent (ICG). Absorption changes in the brain and in the overlying tissue could be determined separately. (ii) Tissue oxygenation in deeper layers was investigated using a homogeneous diffusion model with special emphasis on late photons. This method was tested by Monte-Carlo simulations and applied to in-vivo experiments on volunteers.

Conclusions: The concept to infer absorption in different layers of the head by analyzing time-resolved reflectance measurements has proven to be successful. Further studies should indicate whether blood oxygenation parameters in the cortex determined in this way deliver useful diagnostic information, e.g., in stroke patients or during open heart surgery under cardiac arrest.

References:
A20: Development of a Method of Pulse Oximetry at the Nasal Septum

C Wedelt, VE Sehah, MWM Stratingh, H Wolke, A Petry.
1. Clinic for Anesthesia and Intensive Care, Kiel, Germany
2. Anesth-Therapie des Herzgemeins, Univ. of Leipzig, Germany
3. University Clinic for Anesthesia and Intensive Care, Marburg, Germany
4. Clinic for Anesthesia and Medicine, Univ. of Luebeck, Germany

Introduction: For patients in critical states such as shock, hypotension, centralization or hypothermia, sufficient oxygen-supply is crucial. Pulse oximetry - as the standard method of its non-invasive monitoring - often fails in these situations, as the signal can then no longer be detected by peripherally positioned probes (e.g., fingers, toes, ears). Probes positioned on more central sites perfused by vessels from the carotids such as the back of the nose [1] or the buccal mucosa [2] either showed no better results than peripheral probes [1] or were prone to technical shortcomings [2]. This investigation [3] aimed at evaluating the septum nasi as an alternative, technically easily accessible site for a central placed pulse-oximetry probe.

Methods: Following IRB approval and written informed consents from all subjects, 50 patients were included in this prospective trial, who underwent standardized anesthesia for cardiac surgery with extracorporeal circulation in mild hypothermia (28 - 32°C) as a model for the critical cardiovascular states mentioned above [4]. Pulse-oximetric data were gathered with two identical oximeters (N-3000, Nellcor / Idstein), with probes (Dura-Y™, Nellcor) attached to a finger (FP) and the nasal septum (NP) of the patient. Oximetric data were gathered throughout the operation-time except the phase of the clamping of the aorta and were bimunitarily documented in direct comparison. Additionally, every 10 minutes arterial blood samples were taken, analyzed (Device for arterial blood-gas analysis (BGA), Gem 6, Mallinckrodt / Hennef) and compared with the data of the two oximeters. Also the MAP, HR, Temperature (nasal and rachtal) were regularly documented.

Results: In the course of the investigation, from 50 patients altogether 7313 oximetric measurements were taken and documented in direct comparison (NP: 3668; FP: 3655). These included „drop outs“, when either one or both of the probes failed to pick up a signal. The NP showed a significantly lower „drop out“ rate than the FP (NP: 18%; FP: 25%). In many cases the NP also picked up the signal substantially earlier following aortic declamping, reperfusion and rewarming and responded far quicker and more reliable to desaturations resulting from operatively necessary phases of apnoea [3]. Adverse effects of the nasal probe of any kind did so far not occur, possibilities for technical improvements remain to be further investigated.

Conclusions: The septum nasi is a technically easily accessible, safe and clinically convincing alternative site for a pulse-oximetric probe. Particularly for patients in critical states such as shock, hypotension, centralization or hypothermia, it often facilitates a reliable non-invasive monitoring of oxygen-supply, when the present standard methods of pulse-oximetric monitoring at the patient’s fingers, toes or ears fail. This method could therefore become a sensible addition to the standard monitoring of critically ill patients e.g. in cardio-vascular surgery, emergency medicine or postoperative recovery.

References: