Pediatric StO_2 Accuracy Verification of ForeSight Jr NIRS Tissue Oximetry System

Scope

This review describes the accuracy verification method and resultant performance for monitoring near-infrared spectroscopy (NIRS) tissue oxygen saturation (StO_2) of the ForeSight Jr sensor on cerebral and somatic body sites

Background

Two separate internal review board (IRB) approved protocols were undertaken in multiple institutions to gather StO_2 data from pediatric patients with a range of age, weight, ethnicity, and varied skin tones. The study enrolled children undergoing cath lab procedures or babies in the NICU, rather than healthy volunteers (as used in the StO_2 accuracy verification of adults per the ISO-2021 StO_2 device standard[1]), as it would pose safety and ethical concerns to healthy neonatal patients.

ForeSight Jr sensors emit 5 wavelengths of near-infrared light (685, 730, 770, 810, and 870 nm) and each contain two detectors purposefully placed at 12 mm and 40 mm from the light source for medium sensors and 9 mm and 25 mm for small sensors, which results in a deep detector penetration of 2.0 and 1.25 cm, respectively. The component spacing is used to separate superficial tissue from the StO_2 for the tissue of interest. The ForeSight algorithm evaluates the detected light to compensate for background tissue light absorption and scattering, as well as skin pigmentation, to derive an accurate StO_2.[2]

Medium and Small Sensors

Medium sensor – Cath-Lab protocol to verify StO_2 accuracy in subjects ≥ 2.5 kg

The medium sensor research protocol was for pediatric patients undergoing cardiac catheterization at three university teaching hospitals in the United States.

These patients had two sensors on their forehead to measure cerebral StO_2 and sensors over their lower abdomen and posterior flank. The subject's weight determined the size of the sensors used as per the device intended use. As in prior verification studies,[3,4] these StO_2 values were compared with an arteriovenous blood reference derived from arterial (SaO_2) and venous samples from multiple locations. All blood specimens were sampled at the same time as the StO_2 measurement and analyzed with a CO-oximeter for functional oxygen saturation.

For both the cerebral and somatic StO_2 data, the arterial blood specimens were from the aorta or femoral artery. The venous blood sample locations matched the tissue of interest, for cerebral and somatic measurements. For the cerebral StO_2, the catheter was placed in the jugular vein ($SjvO_2$ blood specimen) for the cerebral StO_2 and in a central venous location for the somatic measurement. Because of the varied types of congenital heart disease in the subject pool, the selected somatic sampling site for each subject was based upon a location unaffected by their particular disease. Thus, the sampling sites included the inferior vena cava (IVC), superior vena cava, right atrium, right ventricle, left pulmonary artery and/or the right pulmonary artery.

The weighted arteriovenous blood reference for StO_2 was based on the assumption that 70% of blood in both cerebral and somatic tissues is venous, while 30% is arterial.[5,6] The $SjvO_2$ blood represents venous blood in the brain, whereas the selected venous location was representative of the somatic tissues of interest.

Small Sensor – NICU protocol to verify StO_2 accuracy in subjects ≤ 5 kg

This research protocol enrolled ≤ 5 kg patients in the NICUs of 6 prestigious hospitals in the United States. An inclusion criterion was an umbilical venous catheter for routine care, which was the source for the protocol's SvO_2 blood samples for the somatic StO_2 accuracy verification.

To verify accuracy of cerebral StO_2 with a small sensor, the ForeSight Jr system was directly compared with the predicate FDA-cleared ForeSight system.[7] Unlike the other ForeSight system accuracy verification studies, this cerebral study did not include $SjvO_2$ blood specimens, because insertion of an internal jugular venous catheter is not routine in neonates. A small ForeSight Jr sensor was placed on the subject's forehead for 2 minutes, followed by a predicate small ForeSight sensor (reference) for 2 minutes. This sequence was repeated once for each subject (with all sensors applied in the same position on round-two).

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To verify accuracy of somatic StO_2, a small sensor was placed for 2 minutes on the posterior-flank and then, for 2 minutes on each of 6 anterior abdomen locations (left & right flank, liver, and over the right-lower, left-lower, and mid-lower quadrants). The venous blood reference was from the umbilical vein catheter and SpO_2 was used for the arterial blood arteriovenous reference, to avoid unnecessary arterial cannulation or blood samples outside of routine care. Blood from the IVC positioned catheter, represents venous blood to the somatic sites in these small patients.

The results from the arteriovenous reference were compared with ForeSight sensor StO_2 values to derive the bias and precision. The medium sensor analysis used data only from the Cath-Lab protocol, while the small sensor analysis combined values from both the Cath-Lab and NICU protocols.

Results

The medium sensor was applied to subjects of balanced gender and various ethnicity (African American, American Indian, Asian, Caucasian, and Hispanic). The patient age and weight ranges were 0.1 to 16.7 years and 3.3 to 73.3 kg, respectively. The medium sensor had an StO_2 bias and precision (at 1 standard deviation) of 0.97 ± 5.43% (n=72) for the cerebral site, and -0.14 ± 5.75% (n=67) for somatic sites (see Figures 1 & 2). The range of StO_2 values for cerebral and somatic sites were across a wide range of saturations (Table 1).

The small sensor was applied to subjects of balanced gender and various ethnicity (African American, American Indian, Asian, Caucasian, and Hispanic). The patient age and weight ranges were 1 to 317 days and 0.5 to 7.7 kg, respectively. The small sensor had an StO_2 bias and precision (at 1 standard deviation) of -0.74 ± 5.98% (n=73) and 2.35 ± 5.25% (n=54) for the somatic sites (Figures 3 & 4). The range of StO_2 values for cerebral and somatic were across a wide range of saturations (Table 1).

Discussion

There are multiple facets in accuracy performance testing that likely improved performance (and what was the rationale of each).

1 Use of the ISO 80601-2-85:2021 standard for performance of cerebral tissue oximeter equipment[1] (i.e., the reference for StO_2 is defined in the standard and used as part of regulatory submissions)

2 The sensor emitter and detectors are spaced specifically for each size sensor to match the target tissue depth by patient size (i.e., the target tissue of interest is interrogated to derive StO_2, while correcting for superficial tissues)[8]

3 Accuracy performance data were from pediatric patients, representing the population of intended use (i.e., assuring the verified performance was demonstrated over a range of patient age, weight, and ethnicity with varied skin tones)[2]

At the time of this publication, we are unaware of another NIRS manufacturer with compliance to the 2021 ISO standard, the volume and breath of tested pediatric patients, or the tight precision of accuracy performance.

Conclusions

The ForeSight Jr system with medium and small sensors demonstrated high accuracy in a broad sampling of pediatric age, weight, and ethnicity with varied skin tones. Per the FDA cleared indications for use, the ForeSight system can accurately determine cerebral and somatic StO_2 values on any age child via a range of sensor sizes.[8] As of this writing, no other NIRS manufacturer has claimed conformance to the ISO standard for accuracy performance in children.

Sensor Size	Body Site	Wt. Range (IFU)	Accuracy (bias ± precision @ 1sd)	StO_2 Test Range
Medium	Cerebral	≥ 3 kg	0.97 ± 5.43	44 to 91%
Medium	Somatic	≥ 3 kg	-0.14 ± 5.75	52 to 88%
Small	Cerebral	< 8 kg	-0.74 ± 5.98	44 to 90%
Small	Somatic	< 5 kg	2.35 ± 5.25	66 to 96%

Table 1: Summary of ForeSight Jr system accuracy validation findings with indications for use of sensors

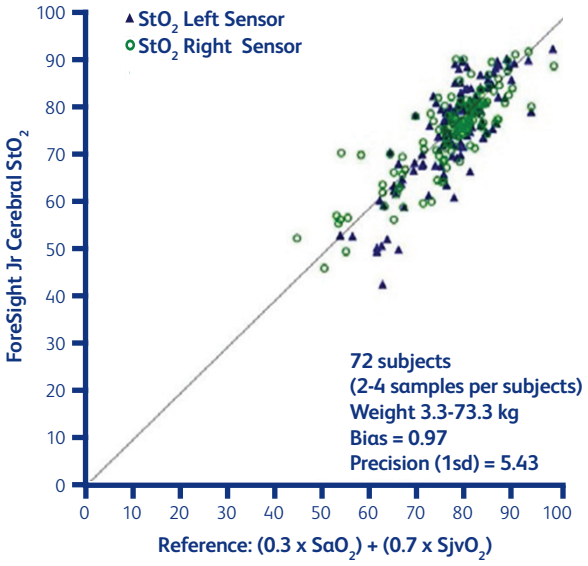

Figure 1: StO_2 vs Reference with medium ForeSight Jr sensor on cerebral sites
Each blue triangle is the left-forehead StO_2 value linked to the simultaneous set of SaO_2 and $SjvO_2$ blood samples. Each green circle is the right-forehead StO_2 value linked to a simultaneous set of SaO_2 and $SjvO_2$ blood samples.

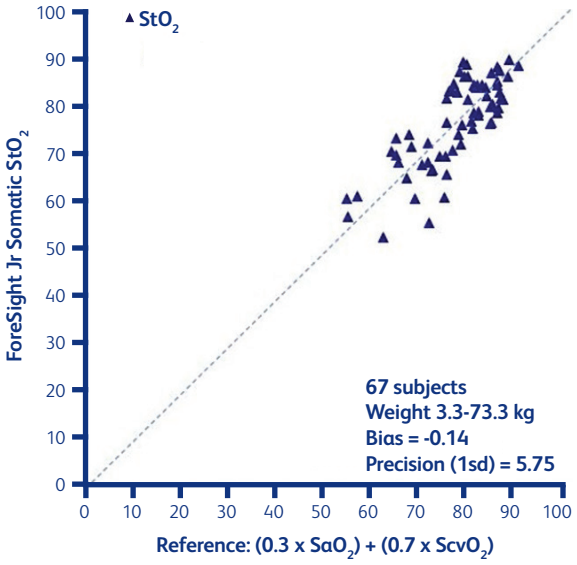

Figure 2: StO_2 vs Reference with medium ForeSight Jr somatic sensor
Each blue triangle is the StO_2 value linked to a simultaneous set of SaO_2 and venous $ScvO_2$ blood samples.

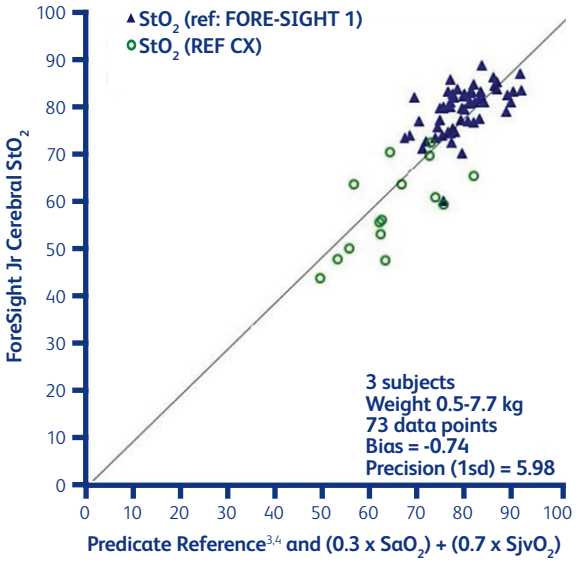

Figure 3: StO_2 vs Reference with small ForeSight Jr sensor on cerebral sites
Each blue triangle is the StO_2 value linked the predicate reference, and the green circles are each simultaneous set of predicate SaO_2 and $SjvO_2$ blood samples.

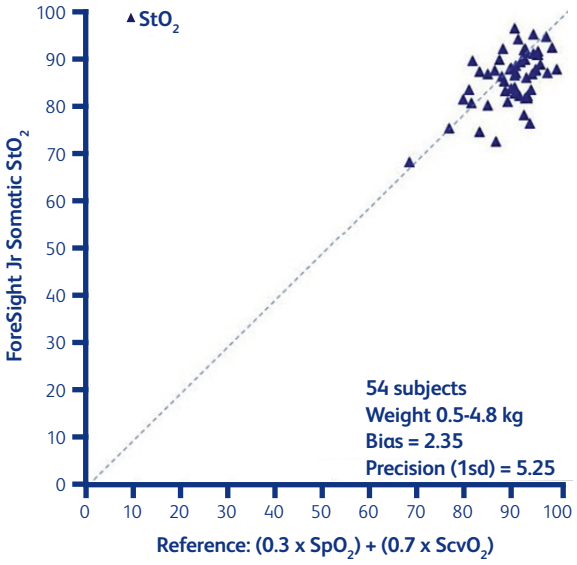

Figure 4: StO_2 vs Reference with small ForeSight Jr sensor on somatic sites
Each blue triangle is the StO_2 value linked to a simultaneous set of SpO_2 and venous $ScvO_2$ blood sample values.

References

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