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Abstract. The aim of this study is to compare a two-wavelength light emitting diode–based tissue oximeter (INVOS), which is designed to show trends in tissue oxygenation, with a four-wavelength laser–based oximeter (FORE-SIGHT), designed to deliver absolute values of tissue oxygenation. Simultaneous values of cerebral tissue oxygenation (StO_2) are measured using both devices in 15 term and 15 preterm clinically stable newborns on the first and third day of life. Values are recorded simultaneously in two periods between which oximeter sensor positions are switched to the contralateral side. Agreement between StO_2 values before and after the change of sensor position is analyzed. We find that mean cerebral StO_2 values are similar between devices for term and preterm babies, but INVOS shows StO_2 values spread over a wider range, with wider standard deviations than shown by the FORE-SIGHT. There is relatively good agreement with a bias up to 3.5% and limits of agreement up to 11.8%. Measurements from each side of the forehead show better repeatability for the FORE-SIGHT monitor. We conclude that performance of the two devices is probably acceptable for clinical purposes. Both performed sufficiently well, but the use of FORE-SIGHT may be associated with tighter range and better repeatability of data. [DOI: 10.1117/1.JBO.18.8.087006]

Keywords: infrared spectroscopy; biomedical optics; tissues; medicine; neonate; oximetry.

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1 Introduction

Near-infrared spectroscopy (NIRS) is a noninvasive method for monitoring regional tissue oxygenation (StO_2) from a reflectance-type sensor attached to the skin. NIR light penetrates the tissue and is absorbed by hemoglobin and other chromophores.[1] NIRS has been used to provide information about blood flow matching to oxygen requirements and possible ischemia or hyperemia.[2] Despite numerous publications regarding the use of this technology in various settings, such as intensive care or cardiac surgery, and awareness of its potential benefits, NIRS has not yet become a widespread standard monitoring device in clinical practice.[1,2] This is perhaps because the imprecision of the early devices was such that clinicians questioned the readiness of these devices for routine care.[3–5]

Various NIRS devices are available, but they use different techniques of measurement. Some of these devices have claims for use in neonates as trend monitors, e.g., the INVOS 5100C (Covidien, Colorado), and others claim to measure absolute tissue oxygen saturation (StO_2) e.g., FORE-SIGHT (CAS Medical Systems, Connecticut). This study focused on these two commercially available tissue oximeters: FORE-SIGHT and INVOS 5100C.

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The INVOS monitor is intended to generate changes in oximetry values and enables the recording of trends; it utilizes a light emitting diode (LED)–based sensor which uses two wavelengths (730 and 810 nm) to measure changes in StO_2. The FORE-SIGHT monitor is intended to generate absolute oximetry values; it utilizes four wavelengths of laser light (690, 780, 805, and 850 nm) to determine StO_2.

The aim of this observational study was to compare the simultaneous values of cerebral StO_2 measured with the INVOS 5100C and FORE-SIGHT oximeters in term and preterm newborns. The repeatability of the measurement was also assessed for both devices. These data were used to compare the performance of the two devices.

2 Methods

Patients were enrolled from newborns treated at the Department of Neonatology, Poznan University of Medical Sciences. The study protocol was approved by the Bioethical Committee and informed parental consent was obtained for each patient.

Thirty newborn babies were enrolled in the study: 15 term (median 38 weeks of gestation, ranges 37 to 40 weeks) and 15 preterm (median 35 weeks of gestation, ranges 32 to 36 weeks). In the term group, the median birth weight was 3380 g (ranges 2920 to 4120 g). In the preterm group, the

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median birth weight was 2375 g (ranges 1200 to 3130 g). During data acquisition, all enrolled patients were in a stable clinical condition as evidenced by pulse oximetry values within normal ranges, i.e., pulse rate and oxygen saturation measured by pulse oximetry (SpO_2).

All babies studied were breathing spontaneously without the need for supplemental oxygen and none suffered from anemia. Each newborn underwent an echocardiographic study and a head ultrasound study. Congenital heart defects, hemodynamically significant patent ductus arteriosus, anomalies of central nervous system, severe intraventricular hemorrhage (grades III and IV), and respiratory distress, were exclusion criteria.

NIRS measurements were performed on the first and third day of life. Values of StO_2 were recorded simultaneously, using the FORE-SIGHT (CAS Medical Systems, Connecticut) and INVOS 5100C (Covidien, Colorado) devices. Both devices are cleared for use in neonates by the United States Food and Drug Administration.

One sensor of each oximeter was placed on the right and the other on the left side of the baby's forehead. The smallest available sensors were used: for the FORE-SIGHT monitor, it was the sensor identified by the manufacturer as the "small size sensor"; for the INVOS monitor, it was the "neonatal cerebral sensor." The distance between sensors was about 3 to 4 cm.

Before the start of data acquisition, sensors were checked for possible light interference. This was done by recording signals when only the FORE-SIGHT sensor was active, then when only the INVOS sensor was active, and finally when both sensors were active. StO_2 numerical values and their plots on monitors were observed for rapid changes associated with simultaneous operation. If there had been evidence of optical crosstalk, the distance between sensors would have been increased; however, this was not necessary in any of the studied patients.

The recording was divided into two parts. First, 5 min for stabilization of the StO_2 signal and then 3 h of recording. Subsequently, the FORE-SIGHT and INVOS sensor positions were switched to the contralateral side and a further 3 h of recording was performed. Preductal saturation (SpO_2) was concurrently measured by pulse oximetry (Nellcor N-600x, Covidien Nellcor Puritan Bennett, Colorado). Thirty minutes of stable signal recording (e.g., calm baby, with no procedures performed, without changes of position the head and supine position of the body, without SpO_2 desaturations <85%, or without symptoms of respiratory distress) was chosen for analysis. The maximum sampling rate for each device was used for acquisition of StO_2 values (approximately 6 s for the INVOS device and 2 s for the FORE-SIGHT device, which are the device settings fixed by the manufacturers).

Statistical analysis was performed using the Bland–Altman method (MedCalc software ver. 12.3.0.0, Mariakerke, Belgium).[6] Mean StO_2 values during recorded periods were analyzed as single points of measurement. The analysis consisted of two parts: (1) the assessment of agreement between mean StO_2 values that were measured simultaneously by the INVOS and FORE-SIGHT oximeters and (2) the assessment of repeatability of StO_2 measurements before and after the change of sensor positions for each device. Both monitors were also observed for possible adverse effects associated with their use.

3 Results

In both the term and preterm groups, the mean values of cerebral StO_2 recorded by the INVOS and FORE-SIGHT devices were similar, with differences not exceeding 3.5%. However, higher StO_2 standard deviations were found for the INVOS in both patient groups (Table 1).

Table 1 Cerebral tissue oxygen saturation values recorded in full term and premature newborns.

	Full term		Premature	
	Mean	SD	Mean	SD
StO_2 INV 1 1	78.6	6.1	81.9	5.2
StO_2 INV 1 2	81.0	7.6	82.7	6.6
StO_2 INV 3 1	83.3	5.6	78.5	5.2
StO_2 INV 3 2	82.6	7.2	77.1	6.4
StO_2 FS 1 1	78.1	4.2	80.2	4.2
StO_2 FS 1 2	80.4	3.9	80.0	4.2
StO_2 FS 3 1	79.8	4.0	77.9	4.3
StO_2 FS 3 2	80.1	3.9	78.5	3.5

Note: StO_2 INV 1 1: values recorded with the INVOS device on the first day of life before sensor positions were changed; StO_2 INV 1 2: values recorded with the INVOS device on the first day of life after sensor positions were changed; StO_2 INV 3 1: values recorded with the INVOS device on the third day of life before sensor positions were changed; StO_2 INV 3 2: values recorded with the INVOS device on the third day of life after sensor positions were changed; StO_2 FS 1 1: values recorded with the FORE-SIGHT device on the first day of life before sensor positions were changed; StO_2 FS 1 2: values recorded with the FORE-SIGHT device on the first day of life after sensor positions were changed; StO_2 FS 3 1: values recorded with the FORE-SIGHT device on the third day of life before sensor positions were changed; StO_2 FS 3 2: values recorded with the FORE-SIGHT device on the third day of life after sensor positions were changed. SD, standard deviation.

Using the Bland–Altman method, the limits of agreement (LOA) for StO_2 values recorded simultaneously by the INVOS and FORE-SIGHT devices were 8.3% to 11.8% for full term babies and 7% to 11.8% for preterm babies. Values of bias ranged from 0.5% to 3.5% for full term newborns and from −1.4% to 2.7% for preterm newborns (Fig. 1).

The LOA for StO_2 values recorded before and after the change of NIRS sensor position for the INVOS device was 9.1% to 11.2% for full term babies and between 9.6% and 11% for preterm babies. Values of bias for the INVOS device ranged from −2.4% to 0.7% in the full term babies and from −0.8% to 1.4% for the preterm group (Fig. 2).

The LOA for StO_2 values before and after the change of NIRS sensor position for the FORE-SIGHT device were 5.5% to 7.3% in the full term group and 8.4% to 9% in the preterm group. Values of bias for the FORE-SIGHT device ranged from −2.3% to −0.3% for the full term group and from −0.7% to 0.2% for the preterm group (Fig. 3).

There were no adverse effects associated with the use of either device during the study.

4 Discussion

Comparison of StO_2 values recorded simultaneously by the INVOS and FORE-SIGHT devices in this neonatal population, revealed reasonable agreement with a bias up to 3.5%, showing

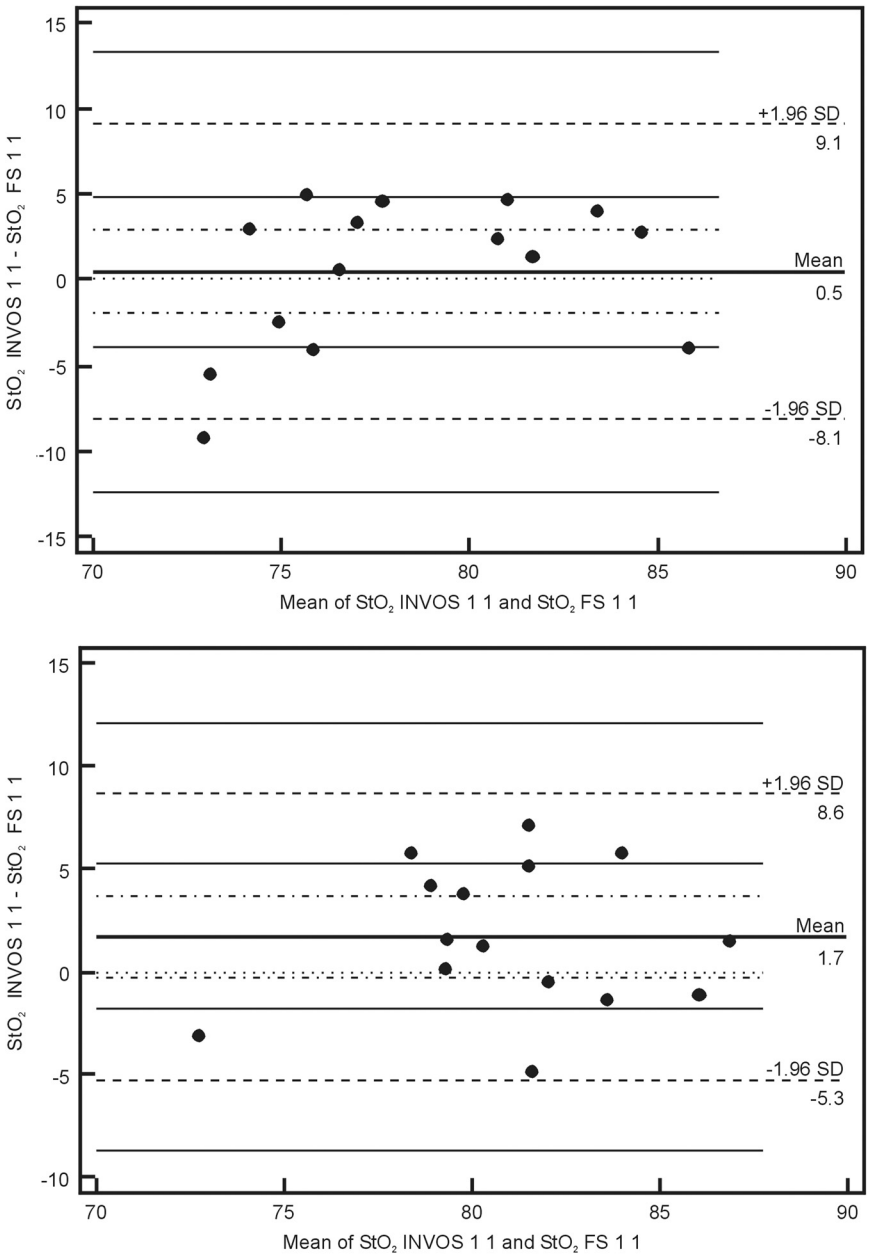

Fig. 1 Bland–Altman plots showing the agreement between regional cerebral tissue oxygenation (StO_2) values of full term (upper plot) and preterm (lower plot) newborns recorded simultaneously using INVOS and FORE-SIGHT devices on the first day of life before the change in position of oximeter sensors. StO_2 INVOS 1 1: values recorded for INVOS on the first day of life before the change in position of oximeter sensors; StO_2 FS 1 1: values recorded using FORE-SIGHT on the first day of life before the change in position of oximeter sensors.

that average measurements were close. LOA were up to 11.8%, which is probably acceptable for clinical use. To our knowledge, this is the first time that a direct comparison between these two technologies has been made in newborn babies. However, precision of the StO_2 measurement needed for clinical purposes remains controversial. It is not strictly defined and the results of available studies are not easily comparable. Different authors have studied this issue with various study protocols: e.g., variable recording periods, different approach to sensor placement, and different patients. Various statistical methods were used in different papers.[6–8] Comparisons were also made between different types and models of devices. In some studies comparing INVOS and NIRO oximeters their performance was found to be similar (with LOA of 14.7%).[8,9] Other reports described significant disparities between cerebral StO_2 values (with mean differences of 10%) and unacceptable LOA (15.6%).[7,10,11] In a study assessing the influence of INVOS 4100 sensor location on the StO_2 measurements it was found that LOA between StO_2 at the two different sensor locations on the forehead ranged from 10.7% to 12.1% with bias of 2.3% to 2.7%, which was considered to be unacceptable disagreement.[4] Interestingly, using an INVOS monitor, Wijbenga et al.[12] reported up to 18% difference in StO_2 between different brain regions in the same patient. In neonates, precision of StO_2 measurement has been reported to increase with increasing tissue homogeneity.[13] Based on the previous studies, it seems that the issue of acceptable agreement between various NIRS devices has not been clearly defined and different authors accept different ranges of LOA. Perhaps

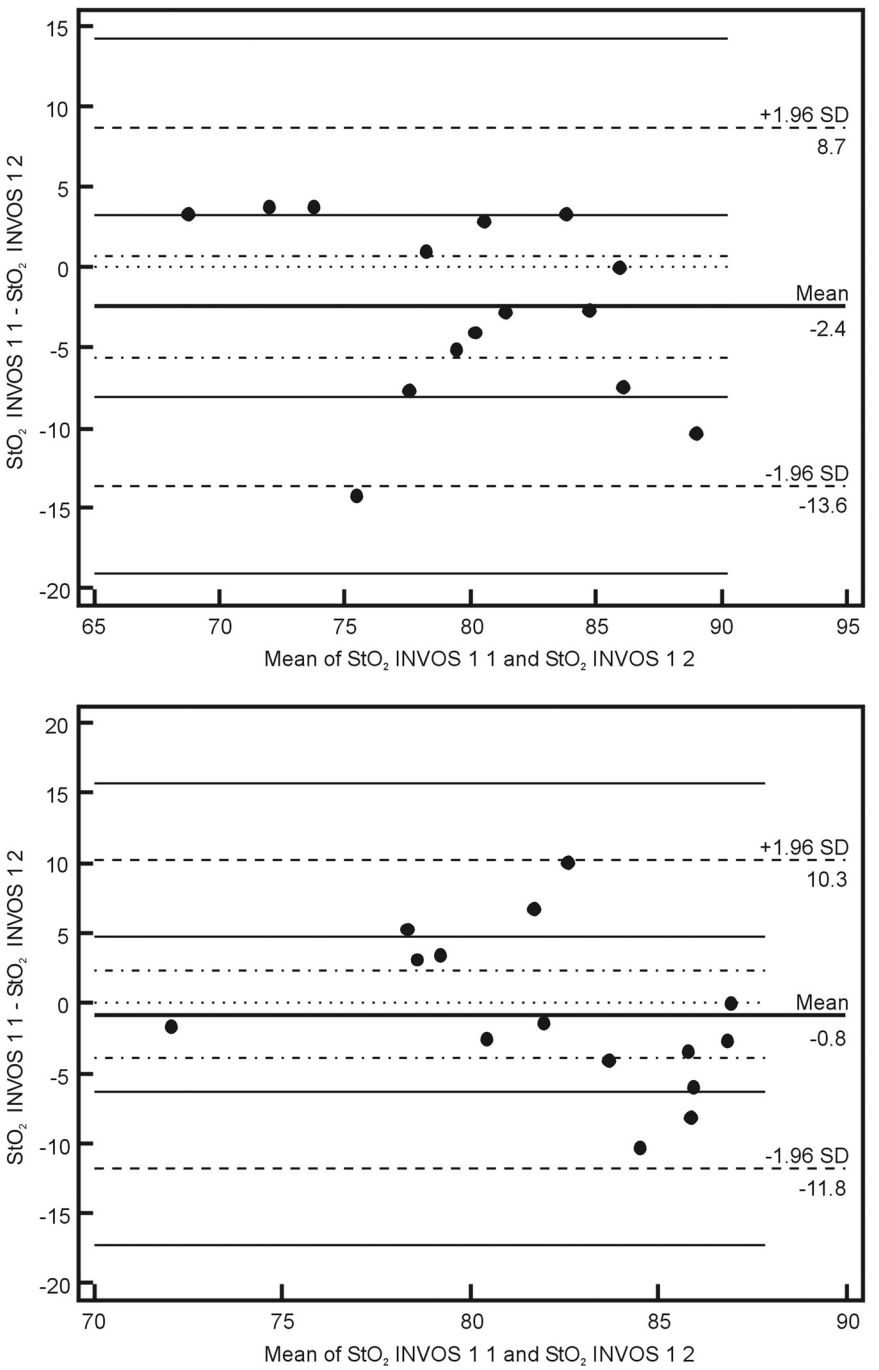

Fig. 2 Bland–Altman plots showing the agreement between regional cerebral tissue oxygenation (StO_2) values of full term (upper plot) and preterm (lower plot) newborns recorded before and after the change in position of oximeter sensors using INVOS device on the first day of life. StO_2 INVOS 1 1: values recorded for INVOS on the first day of life before the change in position of oximeter sensors; StO_2 INVOS 1 2: values recorded using INVOS on the first day of life after the change in position of oximeter sensors.

acceptable precision for tissue oximetry should be similar to that required for pulse oximetry so interventions could be finely managed.

The approach to the sensor placement and data acquisition varied between studies.[8,14] In our study, lack of interference was verified before each set of data acquisition so simultaneously recorded StO_2 values were reliable (with emitters and detectors orientation similar to previous studies).[12] In a study by Moerman et al., INVOS oximeter was found to interfere with FORE-SIGHT, increasing the variability of the signal. However, induced variability was small and the interference did not influence mean StO_2 values.[15]

Analysis of our data revealed a larger standard deviation for values obtained using the INVOS StO_2 oximeter than the FORE-SIGHT device, suggesting greater StO_2 variability for the INVOS device. Similar observations were reported in the studies comparing the accuracy of the FORE-SIGHT and INVOS devices in adults.[15,16]

In a study comparing NIRO 300 and INVOS 5100, the reproducibility of cerebral StO_2 measurements was found to be

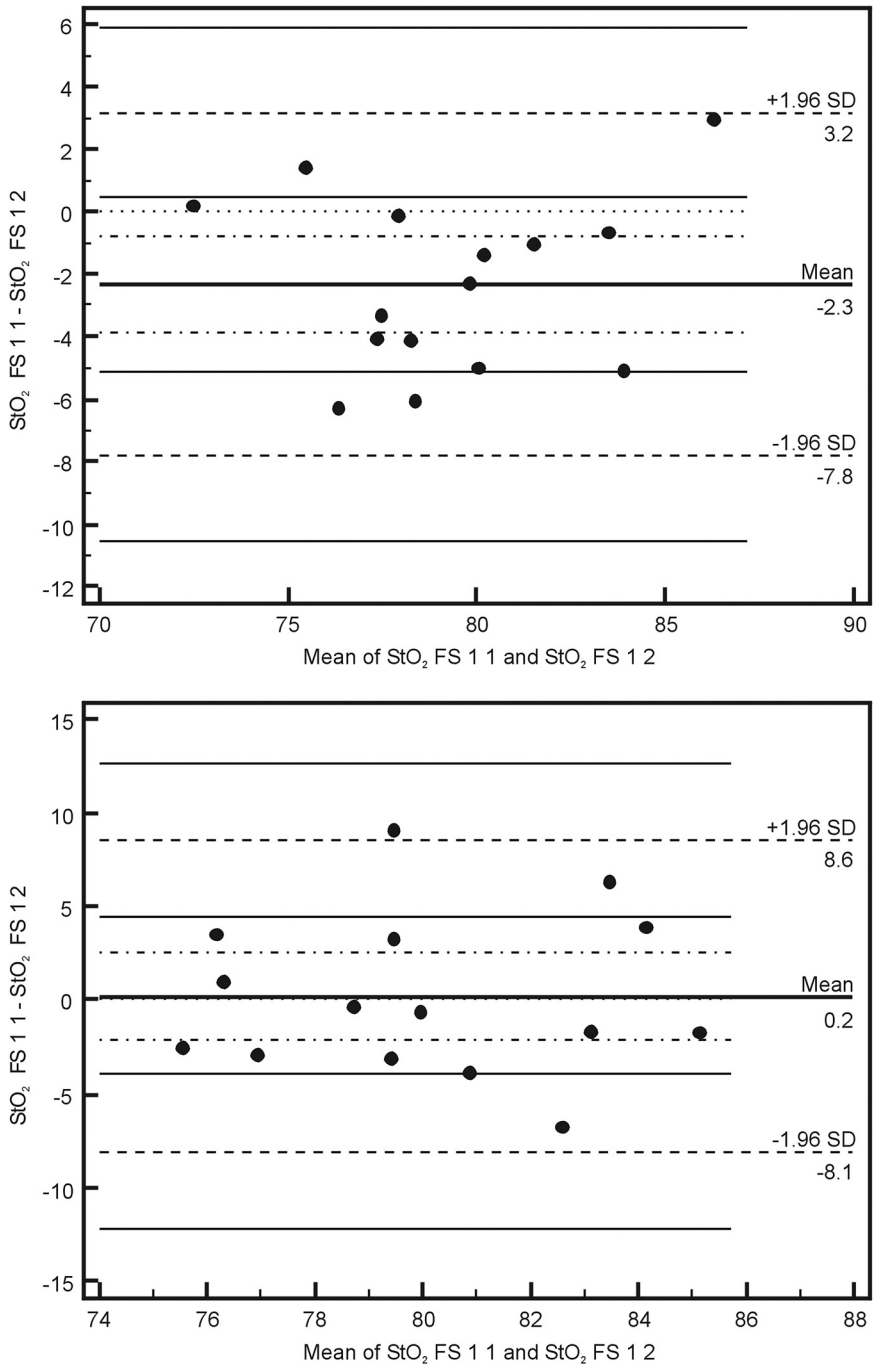

Fig. 3 Bland–Altman plots showing the agreement between regional cerebral tissue oxygenation (StO_2) values of full term (upper plot) and preterm (lower plot) newborns recorded before and after the change in position of oximeter sensors using FORE-SIGHT device on the first day of life. StO_2 FS 1 1: values recorded using FORE-SIGHT on the first day of life before the change in position of oximeter sensors; StO_2 FS 1 2: values recorded using FORE-SIGHT on the first day of life after the change in position of oximeter sensors.

similar.[7] Good reproducibility was described for NIRO 300 in neonates;[17] however, in other studies that utilized the same device, the reproducibility was found to be poor.[18,19] After switching the sensor position to the opposite side of the forehead, we found better repeatability for the FORE-SIGHT monitor. This might be explained by the different software algorithms but since complete algorithms have not been published, this issue remains unclear. Differences in wavelengths utilized by INVOS and FORE-SIGHT monitors might also influence measurements and were proposed as a possible reason of larger StO_2 range of INVOS by Moerman et al.[15] Other possible reasons of differences between StO_2 measured by the compared NIRS oximeters include an unequal penetration depth due to different light intensity, sensitivity of light detector, different spacing between emitter and detectors, and variable sensitivity to extracranial tissue contamination.[15,20]

Closer agreement of measurements using the FORE-SIGHT oximeter as compared with the INVOS oximeter was also described in a study on healthy adults when StO_2 values from five different oximeters were compared with the simultaneous

weighted invasive jugular bulb CO-oximetry and arterial oxygen saturation measurements.[21] In a study by MacLeod et al., differences between StO_2 and CO-oximetry values in some subjects exposed to hypoxia were quite high for the INVOS "giving the appearance that cerebral oxygenation was falling more rapidly than it really was".[16] In theory, this might be important in the intensive care of preterm infants, who might be unintentionally exposed to hyperoxia in response to apparently low values of StO_2.[22]

The NIRS devices tested in the study use continuous wave (CW) method, which measures changes in light absorption by recording the changes in the intensity of light both transilluminated through or reflected by photon scattering in tissue. A spatially resolved (SR) NIRS device measures intensity changes at multiple light sources and detector spacings. The SR device uses the gradients of the optical signal from this multidistance measurement to quantify the NIRS parameters. The INVOS device uses two detectors placed 30 and 40 mm from the LEDs to measure the relative regional value of StO_2.[9,23,24]

The FORE-SIGHT small sensor has a light source composed of a fiber optic light guided from the monitor with a prism and a light detector at a fixed distance of 25 mm from the light source. Unlike the pediatric and adult size FORE-SIGHT sensors, there is no scalp detector for sampling extracranial tissue, so the SR method is not applied. The laser intensity for each wavelength is monitored and the detector samples the strength (i.e., attenuation) of each wavelength upon exiting the skin–sensor interface at the assumed path length ($1/2 \times 25$ mm or ℓ). The characteristic absorbance (ε) for each wavelength in relation to oxy- and deoxy-hemoglobin is known and differs widely over the range of infrared and red light used by FORE-SIGHT. These data are entered into wavelength iterations of a modified Beer–Lambert equation ($\varepsilon_\lambda \times \ell \times c$), where c is the hemoglobin concentration. Thus, a wavelength resolved CW methodology is used to derive the oxygen saturation of hemoglobin in the tissue under the sensor. A proprietary algorithm in combination with a large database of direct blood oximetry from neonatal systemic arterial and brain venous specimens is used to calculate the absolute value of cerebral StO_2.[25]

The FORE-SIGHT algorithm is supposed to provide improved StO_2 measurement accuracy thanks to "compensation for wavelength dependent absolute quantification, scattering losses, and by accounting for interference from other background light absorbers."[26] An advantage of tissue oximeters that give absolute values rather than monitoring relative change is that there is no need for baseline calibration.[27]

NIRS manufacturers apply empirical calibration coefficients based upon clinical and optical phantom data. NIRS tissue oxygen saturation values are then related to the calibration reference as determined from the weighted venous and arterial oxygen saturations (75/25 for INVOS and 70/30 for FORE-SIGHT).

There are some limitations to the present study. All enrolled newborns were in a stable clinical condition with their SpO_2 within normal limits and, unlike studies performed on healthy adults, our patients were not exposed to hypoxic or hyperoxic episodes. Monitoring babies with cardiopulmonary instability and with a known history of desaturations might have been a useful addition to our study, possibly providing more information about the oximeters' performance. Our findings may also contribute to the development of a definition of the range of normal StO_2 values for stable term and preterm newborns, given the context of our stated exclusion criteria.

In summary, absolute oximeter StO_2 values using the FORE-SIGHT device and relative oximeter StO_2 values using the INVOS device seem to be comparable in stable newborn babies, suggesting that these devices can be used interchangeably and data can be compared. However, the FORE-SIGHT monitor showed less variability of recorded StO_2 values and closer agreement of StO_2 measurements between values recorded before and after changing the NIRS sensor position. More studies are needed to understand the clinical significance of these findings.

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