Investigation of photoplethysmographs from the anterior fontanelle of neonates

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Abstract. Photoplethysmography (PPG) signals have been investigated at a new anatomical site, the anterior fontanelle (ANTF), on the hypothesis that blood supply at this location is preferentially preserved during cases of poor peripheral circulation which might cause the commercial pulse oximeters to fail to estimate accurately arterial blood oxygen saturation (SpO_2). Two custom built reflectance PPG sensors have been developed, one for placement on the fontanelle and one on the periphery (foot). A PPG processing system and software were also developed to process the raw PPG signals and to estimate SpO_2. A pilot study on sixteen babies, (9 male, 7 female) with a median age of 15.5 days (interquartile range = 46.8 days) and a median weight of 3.15 kg (SD = 0.93kg), on a neonatal intensive care unit (NICU) has been carried out. PPG signals from the ANTF were of good quality and high signal-to-noise ratio. The amplitudes of the ANTF PPGs were found to be sensitive to changes in amplitude when amplitudes were observed at the reference PPG site. Bland-Altman analysis of the gold standard blood gas analysis reveals that all three sensors are inaccurate at SaO2 < 85-90 %, but the ANTF sensor shows better mean difference than the commercial device.

1. Introduction

Neonatal intensive care relies on constant monitoring of the vital signs of the baby. Pulse oximeters are responsible for estimating arterial oxygen saturation (SpO_2). In the neonate and infant it has been shown that at times of compromised peripheral perfusion, caused by the onset of hypovolaemia, hypothermia or septicaemia, the pulse oximeter can become unreliable or fail [1-5].

The pulse oximeter relies on the presence of pulsatile blood in the area where SpO_2 sensors are attached, typically the hand or foot for neonates. Conventionally in pulse oximetry a dual-LED, red and infrared light source, illuminates the tissue, and the returning light transmitted or reflected is modulated by the pulsatile arterial blood caused by the cardiac contractions of the heart that represents blood volume changes in the vascular tissue immediately in contact with the sensor. This method of measurement is known as photoplethysmography (PPG) and is the underlying technique upon which the pulse oximeter works. The received amount of light differs for the red and infrared sources and can be attributed to either oxygenated or deoxygenated haemoglobin and can therefore be used to estimate SpO_2. Conditions such as hypovolaemia and hypothermia can cause vasoconstriction at the extremities, which reduces blood flow to the periphery, and thus the PPG signal needed for SpO_2 calculation diminishes and the pulse oximeter may fail. It is at these times that a reliable SpO_2 reading would be most beneficial, as an estimation of oxygenated blood would be useful in the treatment and diagnosis without having to perform a blood-gas analysis test as this takes time and is invasive, needing an arterial blood sample.

It has been proposed that the anterior fontanelle (ANTF), the soft area of unformed skull on a new-born, be used as an alternative site for saturation monitoring. The hypothesis underlying this is that the blood supply is preferentially preserved to the head at times of peripheral supply compromise as the body tries

to protect the most vital organs. With no obstruction offered by any bony material it is hypothesised that the ANTF can be used as an optical window where both red and infrared light can be used to make PPG measurements at a point below the scalp to directly monitor oxygen saturation. Attempts in the past have been made to record PPGs from other central sites in the neonate, such as the forehead, cheek, occiput (back of head), back [6] and the oesophagus [7]. A location such as the fontanelle may be advantageous as it is essentially totally non-invasive. Faisst *et al*. [6] have shown that a reflectance based sensor placed on the forehead and back of the head is a feasible and reliable method for monitoring neonates, but missed the opportunity f monitoring from the fontanelle. With the oesophageal studies the size and placement of the probe in the oesophagus was found to be challenging plus the oesophageal probe could not be tolerated in awake patients.

There have been some studies in the past where PPG measurements have been made from the head in both adults and neonates [8-9], but were limited to either the forehead or the earlobe. Fontanelle measurements have also been explored [10], however this work was solely focused on ascertaining at what locations of the neonatal scalp would be best suited for intrapartum monitoring, that is monitoring the unborn foetus during labour, using the neonate as a direct analogue model. Dassel et al [10] commented that although ANTF signals were present they suffered from an artefact that they attributed to the pulsations visibly present on the ANTF, and were therefore unsuitable for SpO_2 monitoring. However, with this understanding it is our belief that with careful sensor and instrumentation design and appropriate signal processing this artefact can be overcome or suppressed.

2. Methods

In order to investigate the anterior fontanelle as a measurement site for PPGs and SpO_2 it was necessary to design and build custom made sensors, instrumentation and software so as to facilitate the acquisition of the raw PPGs needed for the arterial blood oxygen saturation calculations. All instrumental parts are described below.

2.1 Sensor Design

A reflectance custom made PPG/SpO_2 sensor has been developed. The mean size of the ANTF is approximately 220 mm^2 [11], having the shape of an irregular quadrilateral (figure 1), where the area ABCD = (AC x BX)/2.

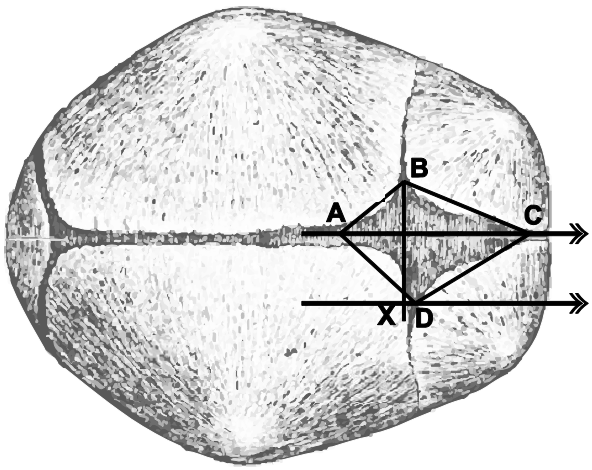

Figure 1: Top-oblique view of neonatal skull with superimposed irregular quadrilateral, mean size = 220 mm^2

A design for the ANTF SpO_2/PPG sensor was then finalised (figure 2), and components selected. The red light source chosen was a 660 nm LED, with dimensions (L × W × H) of 2 mm × 1.25 mm × 1.1 mm (KP-2012SRC, Kingbright, Taiwan). The infrared light source was a 940 nm LED with identical dimensions (KP-2012F3C, Kingbright, Taiwan). The photodetector was a photodiode with dimensions (L × W × H) of 5 mm × 4.25 mm × 1.12 mm and an active area of 7.5 mm^2 (TEMD5010X01, Vishay,

USA). This is a broad-spectrum (410 nm – 1100 nm) photodetector with a peak sensitivity at 940 nm, and a reverse light current (IR) of 45 – 55 µA. The LEDs were placed at a distance of 5 mm from the photodetector, on both sides, see figure 2, to keep the same volume of tissue illuminated for each light source. A third light source (λ3 - a green 525 nm LED) was built into the sensor for further studies, but was left deactivated for these trials.

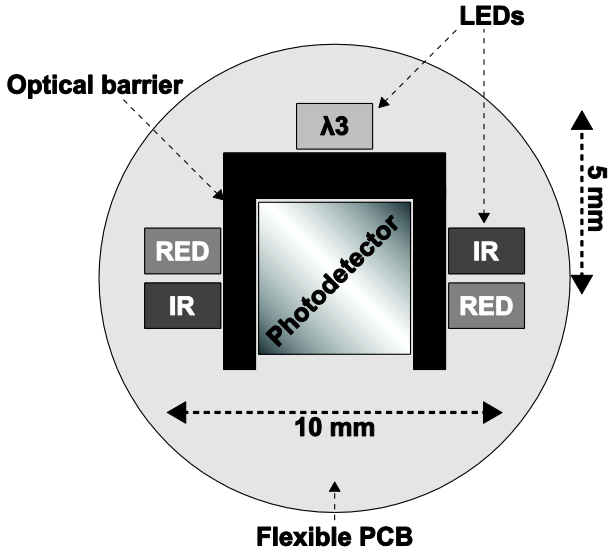

Figure 2: Component layout (LEDs, photodiode and optical barrier) of the ANTF SpO_2/PPG sensor.

A printed circuit board (PCB) was constructed from a flexible copper substrate (Pyralux, DuPont, USA) and components arranged and soldered into place before being sealed with a medical grade epoxy resin (Dymax Corporation, USA). The finished sensor head was then encased into a reconstructed ECG electrode (Ambu Blue, Ambu A/S, Denmark), and terminated with a ribbon cable and 9-pin connector (figure 3). A sensor for the peripheral location to aid the planned simultaneous acquisition of PPGs from either the hand or the foot was also constructed and was optically and electrically identical to the ANTF sensor. Both sensors were checked for electrical and thermal safety [12].

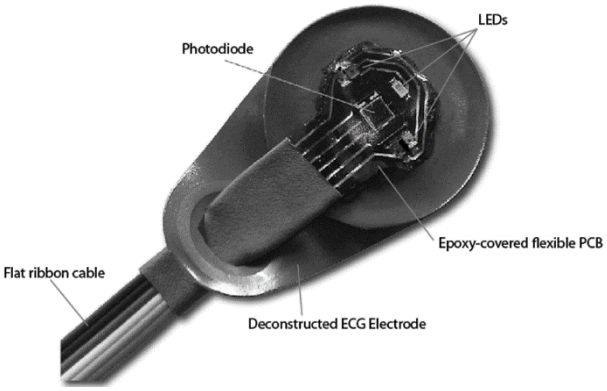

Figure 3: Finished ANTF SpO_2/PPG sensor.

2.2 Instrumentation and Software

Circuitry was designed, prototyped, tested and debugged to produce a dual-sensor PPG processing PCB. This was enclosed into instrumentation housing with a dedicated battery power supply and data acquisition card (USB-6212, National Instruments, USA). External controls for LED intensities and photodiode gain were included on the casing, as wells as the termination connectors for the two sensors.

The gain on each photodiode (one for each sensor) was preset before the beginning of trials and kept constant across all studies. It was necessary to have a slightly higher gain on the ANTF sensor, but this discrepancy is compensated for by the process of normalisation, during post-processing. This is where the AC PPG amplitude is divided by the DC PPG amplitude to give a relative intensity of pulse amplitude vs. the light absorbed by all other tissues. The bandwidth of the raw signals acquired by the PPG system were filtered using active low-pass 2nd order Sallen-Key Butterworth filters (cut-off frequency of 20 Hz).

Custom software written in LabVIEW (National Instruments, USA) to record, process and display the raw PPG signals and give an online estimation of heart rate and SpO_2 was developed simultaneously with the instrumentation and loaded onto a laptop computer. The computer and instrumentation were connected by a standard USB-B cable. This virtual instrument (VI) can be seen in figure 4, which illustrates the final PPG/SpO_2 system. Built into the VI was a function to timestamp events during the real time monitoring such as blood gas tests, start or end of a measurement period, reading of vital signs from the bedside monitors or any other hospital procedure that might have a bearing on the signals/results. The system was then safety-checked by the biomedical engineering department of the hospital where the planned trials were held.

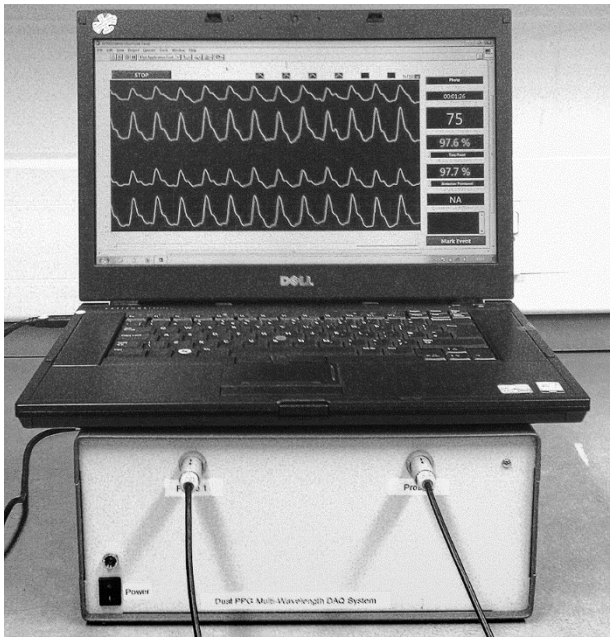

Figure 4: Complete system showing the PPG processing system with the two sensors connected and the Virtual Instrument on the laptop computer.

2.3 Clinical Protocol

Following research ethics approval and parental consent, measurements were carried out on 16 neonates (9 male, 7 female) with a median gestational age of 15.5 days (inter-quartile range = 46.8 days) and a median weight of 3.15 kg (SD = 0.93kg). Candidates for ANTF PPG monitoring were selected on ward rounds by the lead clinician against the list of inclusion/exclusion criteria specified in the approved protocol. All patients were categorized as either ASA 1, 2 or 3 (American Society of Anaesthesiologists physical status classification system) where 1 is the least critical and the neonate did not require respiratory support. ASA 2 patients were on conventional ventilator support. ASA 3 patients were more severely ill and needed mechanical ventilation with high frequency oscillation, which utilises small tidal volumes to effectively ventilate a patient with reduced risk of ventilator-associated lung injury. All patients were sedated and receiving varying concentrations of inspired oxygen. In this study there were

five ASA 1 patients (not on mechanical respiratory support), eight ASA 2 patients (on conventional ventilator respiratory support) and three ASA 3 patients (on oscillatory support). One ASA 1 patient failed to yield adequate PPGs from the ANTF and the patient was excluded from the study. The possible reason for the failure was perhaps due a smaller sized fontanelle and hence the optical probe was not fully trans-illuminating through the ANTF.

Prior to the study the ANTF and foot sensors were cleaned with alcohol wipes and placed into clear adhesive sterile pockets (Tegadern™, 3M, MN, USA). The foot PPG sensor was secured on the sole of the foot with standard medical tape. The lead clinician then manoeuvred the ANTF sensor over the fontanelle until PPGs with good amplitude and signal-to-noise ratio were observed. The ANTF sensor was then secured into position with a bandage that was wrapped around the back of the head. Figure 5 shows the ANTF sensor in situ on a male patient. When the next routine blood sample was taken for blood gas analysis the study was commenced and time stamped in the data file with the time-stamp function of the VI. The results from this blood gas analysis were used as the gold-standard reading to compare readings from the custom made sensors and that of a commercial SpO_2 device placed as part of the routine procedure.

When PPG signals with good quality amplitudes from both sensors and both wavelengths were visible, a baseline reading for a period of up to 30 minutes began. The oxygen concentration was then increased by 50% from the baseline value and monitoring was continued for up to one hour. After one hour the FiO_2 was reduced back to the baseline. Monitoring continued for a further 30 minutes. The total maximum study length for one patient was two hours.

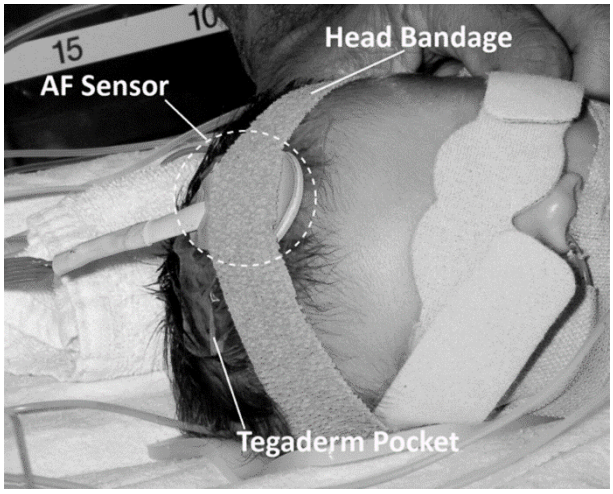

Figure 5: The ANTF SpO_2/PPG sensor in situ on a male patient.

3. Results

3.1 Photoplethysmographic Signals – Amplitude Analysis

Good quality PPG signals were obtained successfully from the ANTF and foot for 15 neonates. Figure 6 shows a twenty-second trace of the signals recorded simultaneously from both locations.

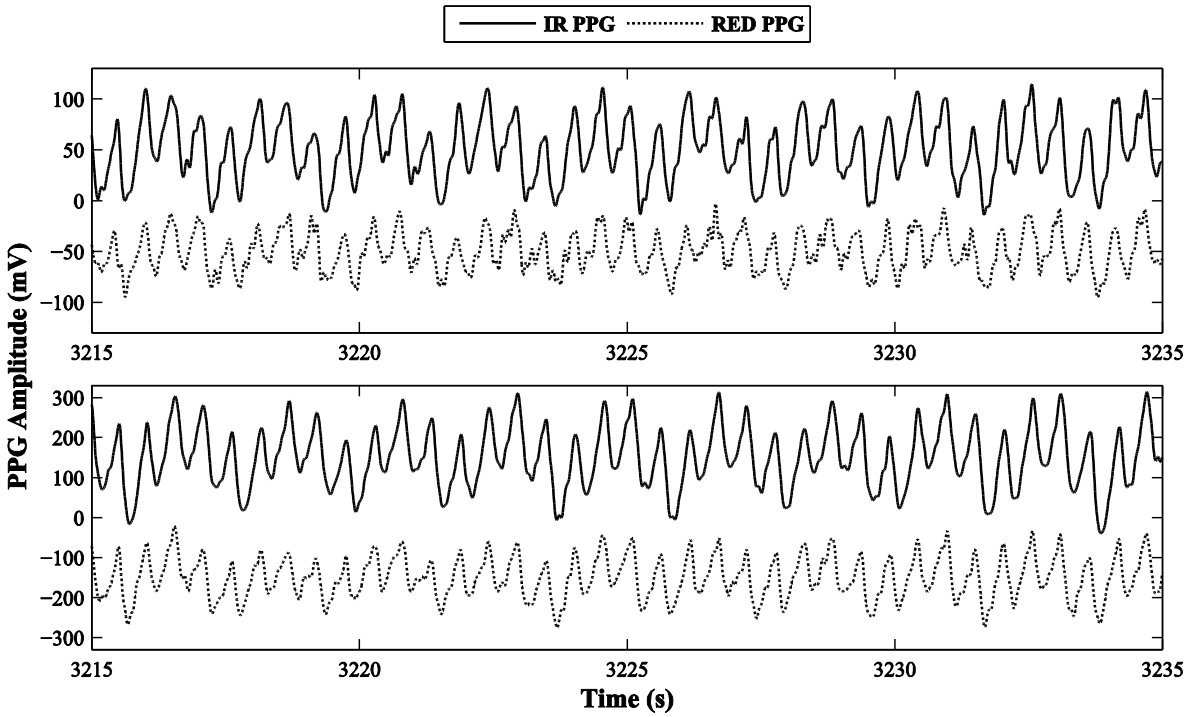

Figure 6: Raw Photoplethysmographic Signals from the anterior fontanelle (top axes) and the foot (bottom axes), mean HR = 110 bpm. The modulation seen is due to respiratory artefact.

Table 1a and 1b shows the mean AC PPG amplitudes from the ANTF and the foot at both wavelengths from all FiO_2 monitoring periods.

Table 1a: Mean normalised red (660 nm) AC PPG amplitudes over a period of at least 10 minutes continuous PPG recording for each patient. Missing values marked with "-".

	RED Normalised Amplitudes (mV)					
Patient #	**Pre FiO_2 increase**		**During FiO_2 increase**		**Recovery from FiO_2 application**	
	Foot	**ANTF**	**Foot**	**ANTF**	**Foot**	**ANTF**
1	123	67	116	74	111	87
2	49	34	35	30	39	22
4	26	31	-	-	-	-
5	143	36	123	36	125	30
6	144	30	90	37	92	32
7	39	34	26	34	24	26
8	18	27	17	37	27	34
9	54	29	23	29	40	23
10	137	34	120	29	84	31
11	157	50	131	53	122	52
12	17	20	18	28	-	-
13	15	25	17	17	14	17
14	157	41	197	28	259	38
15	217	18	-	-	-	-
16	66	10	-	-	-	-
Mean	**91**	**32**	**76**	**36**	**85**	**36**
SD	**66**	**14**	**61**	**15**	**71**	**19**
Measurements (n)	**15**	**15**	**12**	**12**	**11**	**11**

Table 1b: Mean normalised infrared (940 nm) AC PPG amplitudes over a period of at least 10 minutes continuous PPG recording for each patient. Missing values marked with "-".

Patient #	IR Normalised Amplitudes (mV)					
	Pre FiO_2 increase		During FiO_2 increase		Recovery from FiO2 application	
	Foot	ANTF	Foot	ANTF	Foot	ANTF
1	50	96	48	140	46	167
2	88	100	82	77	73	77
4	25	43	-	-	-	-
5	272	152	252	136	241	117
6	225	24	181	25	149	22
7	37	26	29	29	26	23
8	21	37	25	50	32	52
9	59	56	56	35	60	34
10	316	92	325	58	188	65
11	175	100	176	122	155	101
12	24	40	27	38	-	-
13	35	51	38	43	32	39
14	211	46	257	50	305	77
15	190	37	-	-	-	-
16	128	17	-	-	-	-
Mean	**124**	**61**	**125**	**67**	**119**	**70**
SD	**100**	**38**	**108**	**42**	**96**	**45**
Measurements (n)	**15**	**15**	**12**	**12**	**11**	**11**

The PPG amplitudes, calculated as the distance between the highest peak and lowest trough over a 2 second period, across the entire monitoring time for each patient at each wavelength at both monitoring sites, were correlated against each one another. This was done to highlight the observation made during clinical trials that when one set of PPG amplitudes changed there was a corresponding change at the other site, thus demonstrating the sensitivity of the ANTF sensor to any changes that were global between the foot and the ANTF, i.e. SpO_2. These correlation results were also tested for significance using a one tailed test at the $p < 0.05$ confidence level. Overall 30 tests were performed (15 red PPG correlations and 15 IR PPG correlations), and only one test from the IR group failed at the 0.05 significance level. All significant results were plotted into the histogram in figure 7, easily observable for both wavelengths is that more than two thirds of the significant results for both wavelengths had a moderate to very strong ($R = 0.4 – 1$) correlation score.

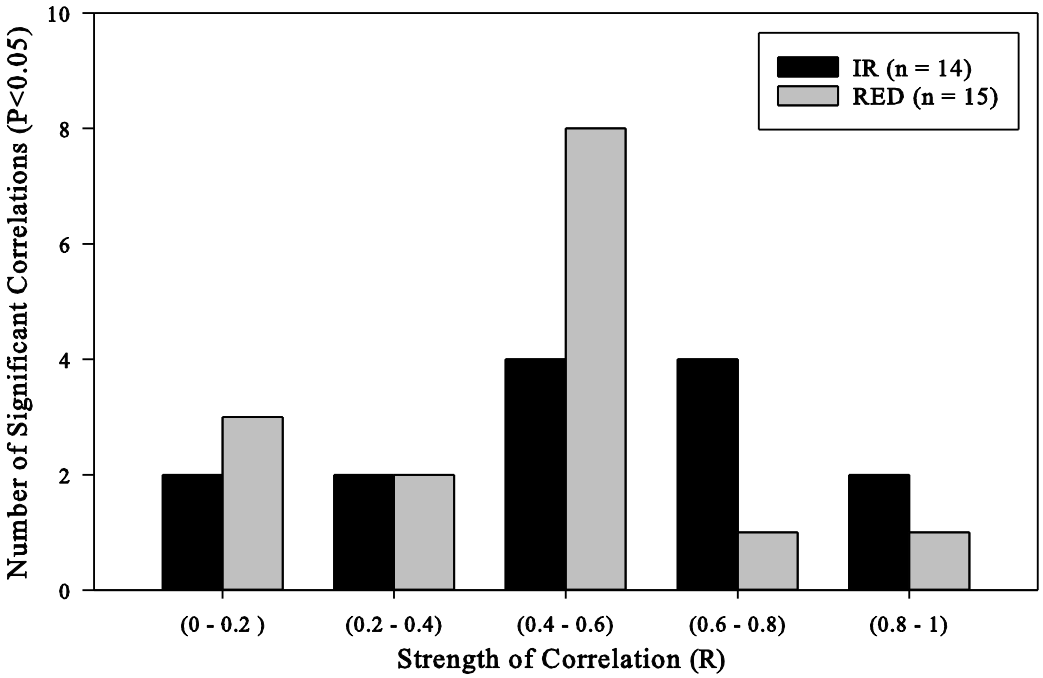

Figure 7: Histogram of significant ($p < 0.05$) correlation scores of the different PPG wavelengths between monitoring sites.

An analysis of the PPG signals was made by computing the difference between the amplitudes of the red and infrared signals between locations. These results were then placed in a boxplot in an effort to visualise any change in PPG amplitude difference between the different ASA classed patients, see Figure 8a and 8b. A correlation between these values and the ASA of the patient was also conducted in an effort to highlight possible measurable differences between difference in amplitude and the ASA of the patient (Table 2). These correlations were also test for statistical significance using a one tailed test at the $p < 0.05$ confidence level.

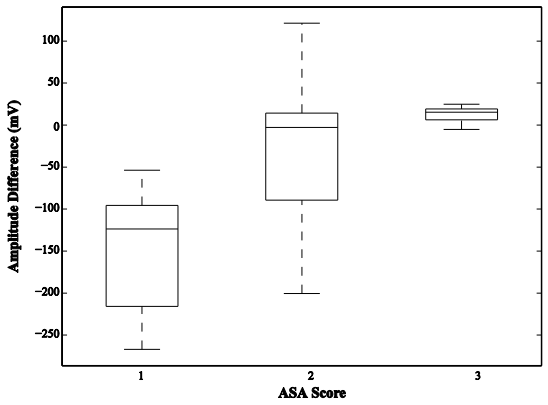

Figure 8a: Box-plot of decreasing IR PPG amplitude difference (ANTF – Foot) at the three ASA Scores studied.

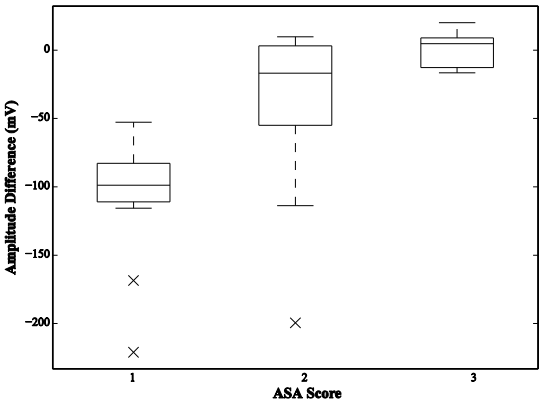

Figure 8b: Box-plot of decreasing RED PPG amplitude difference (ANTF – Foot) at the three ASA Scores studied

Table 2: Correlation (R) of amplitude differences and ASA scores, with P values ($p < 0.05$).

FiO_2 Period	Pre FiO_2 increase		During FiO_2 increase		Recovery from FiO_2 application	
LED	**RED**	**IR**	**RED**	**IR**	**RED**	**IR**
Correlation Coefficient (R)	0.599	0.627	0.792	0.653	0.668	0.635
P Value	0.018	0.012	0.002	0.021	0.025	0.036
Number of Samples	15	15	12	12	11	11

3.2 Blood oxygen saturation (SpO_2) calculations

The developed custom-made instrumentation is un-calibrated for SpO_2 measurements, however preliminary SpO_2 calculations were made in order to compare SpO_2 values between the two sites measured by the custom instrumentation and with the commercial pulse oximeter and the gold standard blood-gas analyser.

A PPG amplitude measurement algorithm was written in MATLAB (The MathWorks, USA) and used as an input to a second algorithm design to calculate SpO_2. The signals were split into sections of 2 seconds in length, and the peak-to-peak AC amplitude and average DC amplitude were computed. A ratio of AC to DC PPGs was calculated for the red and infrared wavelengths separately then combined to reveal a "Ratio of Ratios" or "R – value" see equation 1.

$$R = \frac{AC_{RED}/DC_{RED}}{AC_{IR}/DC_{IR}} \quad \text{(eqn. 1)}$$

A common linear equation was then used as to compute SpO_2, see equation 2 [13].

$$SpO_2 = 110 - 25R \quad \text{(eqn. 2)}$$

The mean SpO_2 values were calculated for each patient in each period and are shown in Table 3.

Table 3: Mean SpO_2 Values in each period for each patient. Missing values marked with "-".

	SpO_2 (%)								
#	**Pre FiO_2 increase**			**During FiO_2 increase**			**Recovery from FiO_2 application**		
	Foot	**ANTF**	**Com**	**Foot**	**ANTF**	**Com**	**Foot**	**ANTF**	**Com**
1	99	93	100	99	97	100	99	97	99
2	96	102	95	99	101	99	97	103	94
4	84	92	78	-	-	96	-	-	-
5	97	104	93	98	103	99	97	104	96
6	94	80	97	98	74	100	95	74	96
7	84	78	98	88	81	99	87	81	99
8	89	92	97	94	92	98	89	94	98
9	87	97	99	100	89	100	94	93	99
10	99	101	100	101	98	97	99	98	100
11	88	97	92	91	99	99	90	97	93
12	93	98	98	93	92	100	-	-	-
13	99	98	100	99	100	100	99	99	100
14	91	88	100	91	96	96	89	98	99
15	82	98	98	-	-	-	-	-	-
16	97	96	94	-	-	-	-	-	-
Mean	**92**	**94**	**96**	**96**	**93**	**99**	**94**	**94**	**97**
SD	**13**	**8**	**6**	**14**	**9**	**1**	**14**	**9**	**3**
n	**15**	**15**	**15**	**12**	**12**	**12**	**11**	**11**	**11**

The results of 26 separate blood gas analyses (gold standard blood oxygen saturation measurement), taken from across all the trials are shown in table 5 along with the corresponding SpO2 values from the three sensors. This data was then used to construct the Bland-Altman graphs in figure 9, to compare the operation of the three sensors against the gold standard.

Table 5: Blood Gas (SaO_2) analysis with corresponding SpO_2 readings from all three sensors, commercial, foot and fontanelle.

Measurement	SaO_2	Commercial SpO_2	Foot SpO_2	ANTF SpO_2
1	98	100	98	93
2	90	95	96	102
3	68	78	83	92
4	95	93	97	104
5	98	97	92	78
6	98	98	89	81
7	73	97	88	91
8	86	99	84	80
9	94	100	99	101
10	91	92	91	99
11	100	98	92	100
12	97	100	99	98
13	99	100	91	92
14	96	98	83	98
15	100	100	97	97
16	90	98	99	101
17	100	100	89	81
18	68	99	94	92
19	97	98	98	84
20	95	100	101	98
21	95	97	95	100
22	100	99	94	97
23	100	100	102	101
24	96	100	91	94
25	98	99	98	97
26	83	96	98	101
Mean	**92.5**	**97.3**	**93.7**	**94.2**
SD	**9.5**	**4.5**	**5.4**	**7.5**

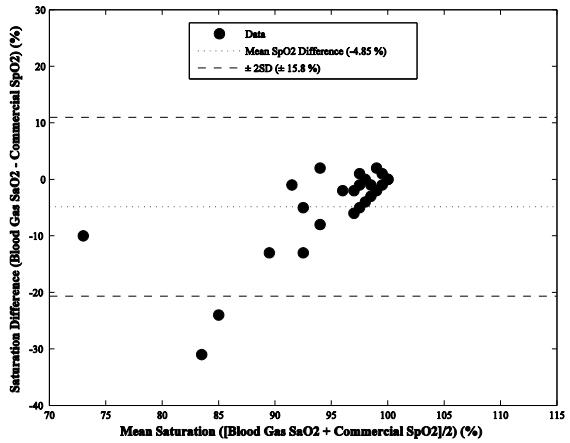

Figure 9a: Bland-Altman plots of the blood gas results taken (n = 26) during trials against the recorded SpO2 from the bedside monitor.

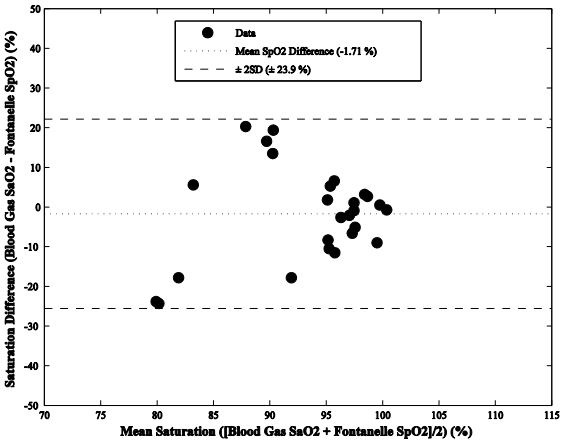

Figure 9b: Bland-Altman plots of the blood gas results taken (n = 26) during trials against the recorded SpO2 from the computed SpO2 from the ANTF sensor.

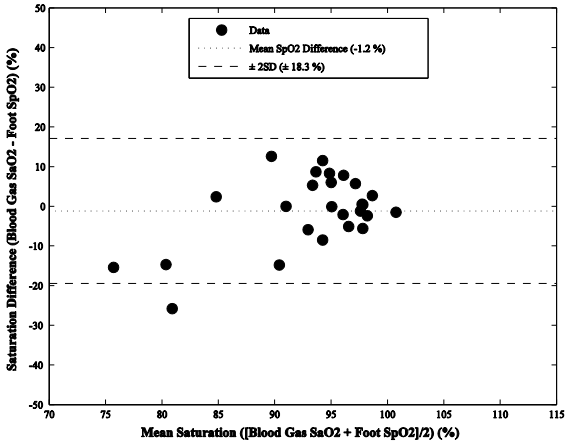

Figure 9c: Bland-Altman plots of the blood gas results taken (n = 26) during trials against the recorded SpO2 from the computed SpO2 from the foot sensor.

4. Discussion and Conclusion

This study has shown successfully the real time acquisition of PPGs at two wavelengths from the anterior fontanelle. Initial results indicate good correlations with statistical significance ($p < 0.05$) between PPG amplitudes of the same wavelength at the two investigated sensor locations. This suggests that the fontanelle may be sensitive to variations in oxygen that may indicate global oxygen saturation change.

There were no cases within the trial period where peripheral compromise occurred. The results from the amplitude difference analysis are interesting, however, as the correlation between the calculated difference in PPG amplitude between the two sites and the ASA score for the patient was strongly positive in all cases, thus supporting the assumption that the more sick a patient becomes the patient is more at risk of peripheral supply shutdown, i.e. the PPG amplitude difference between the ANTF and the foot reduced caused by the reduction of amplitude at the peripheral site. As these are only preliminary results further more rigorous studies are needed to support more robustly this finding.

Comparisons of SpO_2s from both custom PPG sensors have been made and compared with the bedside commercial SpO_2 monitor.

Comparing the blood gas results with the corresponding SpO_2 values on a Bland-Altman graph shows that the ANTF and reference foot sensor both have better mean differences in SpO_2 estimation (-1.71 % and -1.2 % respectively) than the commercial device (-4.8 %), but slightly larger variance (2SD = ± 23.9

% and ± 18.3 %), again the most accurate estimations (figure 9b and 9c) are when SaO_2 > 95 %. This result suggests that the ANTF foot sensor is measuring closer to the true SaO_2 than the pulse oximeter in the hospital, with the large standard deviation also being of a similar magnitude; however for SaO_2 < 95% the accuracy declines also. From table 5 it is clear that when SaO_2 drops below about 90 % all the oximeters struggle to report accurate saturations, including the commercial device. It seems unusual that a calibrated device (commercial SpO_2) has less accuracy than the un-calibrated one, and an argument can be made that the smaller standard deviation observed from the commercial device compensates by reducing overall erroneous readings (falsely high and low SpO_2s).

In summary, the ANTF was deemed to be a viable alternative site for monitoring PPGs and SpO_2 in neonates, providing of course that the patient is not experiencing complications that may cause their blood oxygen saturation to full to critical levels, however seeing as the commercial device struggled to give accurate readings at these times also it could be that traditional SpO_2 methods are not yet sophisticated enough to be relied upon during these critical moments, and should be used instead as an indicator of real-time oxygenation change that then needs confirmation by the traditional blood gas analysis tests. More rigorous studies are needed to look at the effect of the anatomical differences at the fontanelle that may affect the way PPG signals are acquired, as this may have had a bearing on SpO_2 calculations that could not be foreseen. Further studies are needed in order to test the hypothesis that the ANTF will be a more reliable site (compared with the periphery such as the foot) for monitoring SpO_2 at times of compromised peripheral circulation.

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