The Human Ear Canal: Investigation of its suitability for monitoring photoplethysmographs and arterial oxygen saturation

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Abstract

For the last two decades, pulse oximetry has been used as a standard procedure for monitoring arterial oxygen saturation (SpO_2). However, SpO_2 measurements made from extremities such as the finger, ear lobe and toes become susceptible to inaccuracies when peripheral perfusion is compromised. To overcome these limitations, the external auditory canal has been proposed as an alternative monitoring site for estimating SpO_2, on the hypothesis that this central site will be better perfused. Therefore, a dual wavelength optoelectronic probe along with a processing system was developed to investigate the suitability of measuring photoplethysmographic (PPG) signals and SpO_2 in the human auditory canal. A pilot study was carried out in 15 healthy volunteers to validate the feasibility of measuring PPGs and SpO_2 from the ear canal (EC), and comparative studies were performed by acquiring the same signals from the left index finger (LIF) and the right index finger (RIF) in conditions of induced peripheral vasoconstriction (right hand immersion in ice water). Good quality baseline PPG signals with high signal-to-noise ratio were obtained from the EC, the LIF and the RIF sensors. During the ice water immersion, significant differences in the amplitude of the red and infrared PPG signals were observed from the RIF and the LIF sensors. The average drop in amplitude of red and infrared PPG signals from the RIF was 52.7 % and 58.3%. Similarly, the LIF PPG signal amplitudes have reduced by 47.52% and 46.8% respectively. In contrast, no significant changes were seen in the red and infrared ear canal PPG amplitude measurements, which changed by +2.5% and -1.2% respectively. The right and left index finger pulse oximeters have failed to estimate accurate SpO_2 in 7 and 4 volunteers respectively, while the ear canal pulse oximeter has only failed in one volunteer. These results suggest that the ear canal may be a suitable site for reliable monitoring of PPGs and SpO_2s even in the presence of peripheral vasoconstriction.

1.   Introduction

Adequate oxygen supply to the body's tissues is required for normal body function. Knowledge of oxygen level in the blood could help assess a person's health and overall wellbeing. By monitoring the blood oxygen level, management of many life-threatening illnesses such as hypoxaemia, ischaemia, sepsis, and shock could be possible. Blood oxygen level in the human body can be measured by using a CO-oximeter, pulse oximeter, near infrared spectroscopy, etc. Pulse oximetry is currently one of the most popular and widely used techniques for measuring arterial oxygen saturation (SpO_2) [1].

Since its invention in the 1980's, pulse oximetry has revolutionised anaesthesia and critical care [2]. Pulse oximeters are now one of the most commonly used medical devices in health care; in fact they are now a standard of practice for the administration of general anaesthetic. Pulse oximeters provide an estimate of arterial oxygen saturation by shining light into the vascular tissue at two different wavelengths, and measuring the changes in light absorbances produced during arterial pulsations. The two wavelengths typically used are 660 nm in the red region and 880 nm in the infrared region of the optical absorption spectra [2]. The changes in light absorbance, detected during these arterial pulsations are electronically amplified and recorded as a voltage signal called the photoplethysmograph (PPG). The amplitude of the PPGs obtained from these two wavelengths vary with change in arterial oxygen saturation, as the absorbance of oxyhaemoglobin and deoxyhaemoglobin at these wavelengths is different [3]. The ratio of the amplitudes of these AC PPG signals and their corresponding DC values are then used to estimate SpO_2. Therefore, accurate estimation of SpO_2 using pulse oximeters depends on the quality of the PPG signals detected.

Although pulse oximeters are universally used as a reliable tool for measuring SpO_2, the device is also known to possess a few limitations. These limitations include mainly motion artifacts and poor peripheral perfusion [4]. Recent advancements in the technique have made it possible to accurately estimate SpO_2 even in the presence of some of these limitations, but the one major clinical setting in which pulse oximeters are still reported to fail is during surgical monitoring [4]. The failure of pulse oximeters during surgery is believed to be mostly due to inadequate peripheral perfusion triggered by clinical conditions such as hypovolaemia, hypothermia, and vasoconstriction [5]. These conditions are usually a result of anaesthetic agents and muscle relaxants induced into the patient's body [6].

The problem arises as all clinically used pulse oximeter systems are attached to the extremities such as the finger, toe, or earlobe. As a result, the pulse oximetry sensor is subjected to low perfusion states, leading to inaccuracies in the estimation of SpO_2. To overcome this limitation, the external auditory canal is proposed as a potential measurement site for monitoring SpO_2. Being closer to the trunk, the auditory canal is expected to have a much reduced influence from low perfusion states and, as a result, a better quality PPG signal during critical conditions which might compromise peripheral
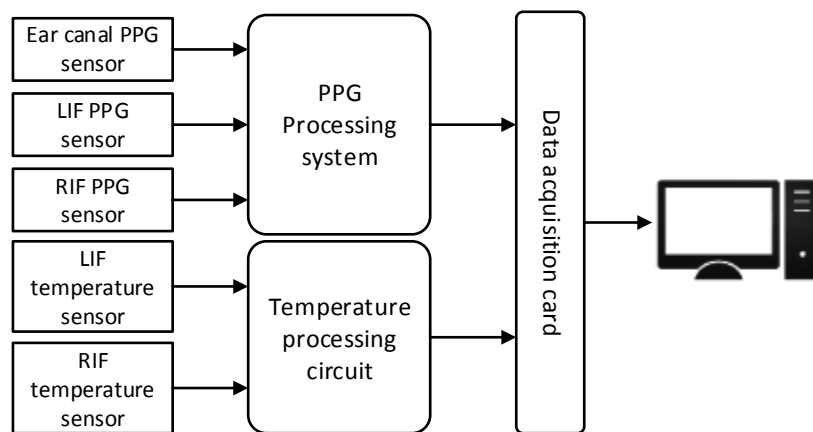
perfusion. Coupling to its physiological advantages, is the factor of comfort and ease of placement of the device, as the electronic housing can be discreetly worn behind the ear [7]. Moreover, the proposed site also has the advantage of being non-invasive, when compared with previous attempts made to measure SpO_2 in more central sites such as the oesophagus [5].

A wearable in-ear measuring system (IN-MONIT) for 24/7 monitoring of vital parameters in cardiovascular patients was previously designed by Vogel *et al* [8]. Vogel has shown that accurate estimation of heart rate was possible from the ear canal using the infrared PPG signals, but the quality of red PPG signals was reported to be of poor quality, hence estimation of SpO_2 was not possible. More recently, Venema *et al.* have conducted a hypoxic study on 10 healthy volunteers using a revised version of the IN-MONIT sensor. The results presented showed that the determination of oxygen saturation in the ear canal is feasible. However, when creating a global calibration curve from all the measurements, the accuracy level was reported to be unacceptable for use in SpO_2 measurements [9]. Moreover, the quality of the PPG signals and accuracy of SpO_2s, acquired from the auditory canal during conditions of compromised peripheral perfusion has not yet been investigated or published.

Hence in an attempt to overcome these limitations, a new reflectance ear canal PPG/pulse oximetry probe along with a PPG processing system was developed. The developed technology was then used to investigate PPGs from the ear canal and the fingers simultaneously under simulated conditions of compromised peripheral perfusion by means of a cold pressor test as previously performed by Awad *et al* [15].

2.   Materials and Methods

The experimental set-up used in this study is shown in 'figure 1'. In this experiment, the ear canal sensor was placed in the right ear canal of the volunteer. Two custom made finger PPG sensors along with temperature sensors were attached to the index finger of the right and left hands. The PPG and temperature data was simultaneously acquired by a data acquisition card.
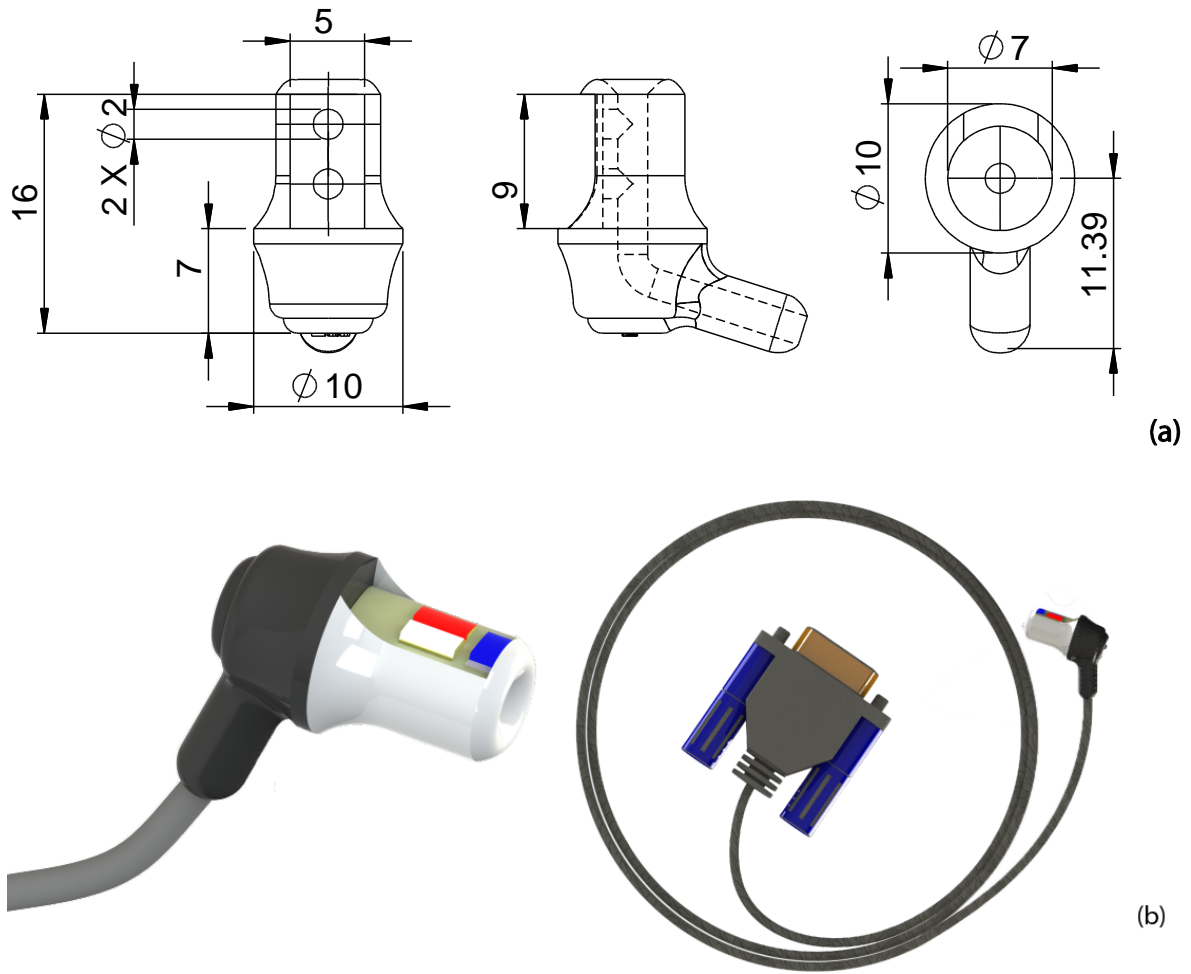

Figure 1 . Block diagram of the set-up used for the experiment on volunteers during a cold pressor test.

2.1   Ear canal pulse oximeter probe

A reflectance ear canal pulse oximeter probe was constructed. The probe consists of two main modules; a specially designed headphone shaped sensor casing and an optoelectronic reflectance sensor sealed inside the casing [10]. The physical dimensions and the shape of the ear canal probe were determined by the anatomical characteristics and geometry of the auditory canal. In adults, the external auditory canal is approximately 25 mm in length and 8 mm in diameter. The opening of the ear canal is oval, averaging 9 mm in height and 7 mm in width [11]. The outer external auditory canal is skin lined soft cartilage connected to a hard bony inner external auditory canal. There is a slight angulation between the outer and inner parts. Therefore, the physical dimensions of the probe should be small enough to fit inside the external auditory canal comfortably, while being big enough to firmly hold itself against the walls of the ear canal. The length of the probe should also be slightly smaller than the outer external auditory canal, so that the angulation between the cartilaginous outer canal and bony inner canal can be avoided.

2.1.1.   Ear canal probe casing.

Taking these anatomical features into consideration, a headphone shaped sensor casing was designed. The casing was designed in a computer aided design program known as Solid Works 2012 (Dassault Systemes SolidWorks Corp.) and was manufactured using Object24 Desktop 3D printer (Stratasys Ltd). The mechanical drawings and 3D models of the ear canal sensor are shown in 'figure 2'. The casing consists of a small rectangular extruded cut in which the micro-optic sensor is sealed. The dimensions of the rectangular slot are the same as the optoelectronic sensor. The external diameter of the part of the casing which is inserted into the auditory canal is 7 mm. The casing also contains an inverted 'L' shaped hollow cavity extending from one side of the probe to another and two small holes perpendicular to the cavity with a diameter of 2 mm. These apertures are used to run a 4 core ultra-flexible cable, which provide electrical contact between the optical components and the PPG processing system. The diameter of the sensor is 3 mm higher at the distal end; this is to prevent the probe from accidently being inserted too deep into the ear canal. The front end of the probe was designed to be dome shaped, in order to provide a smooth and comfortable feeling while placing the probe in the ear canal.
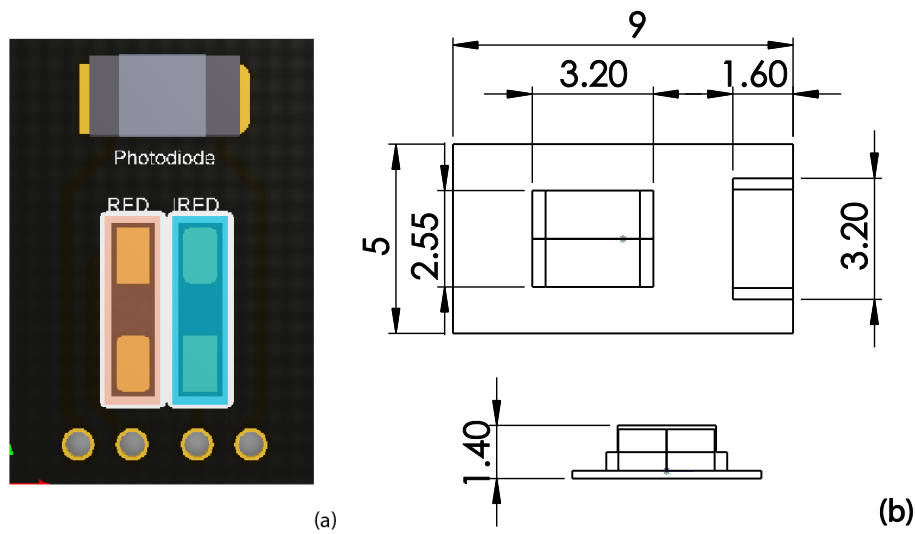
Figure 2: (a) The mechanical drawings and (b) 3D sketch of the ear canal sensor.

2.1.2. *Optoelectronic reflectance sensor.*

The optoelectronic sensor itself is a small Printed Circuit Board (PCB) consisting of a red and an infrared surface mount Light Emitting Diode (LED) and a surface mount photodetector. Both the LEDs emit light into the tissue lining of the ear canal, while the photodetector detectes the back scattered radiation from the tissue and produces an output proportional to the detected radiation level. The red and infrared emitters used in the design of the sensor are ceramic chip type LEDs, with peak emission wavelengths at 658 nm and 870 nm respectively (CR 50 1M and CR 50 IRH, Excelitas technologies, U.S.A). The reason for the choice of these wavelengths is that the absorption spectra of oxyhaemoglobin and deoxyhaemoglobin at these wavelengths is relatively flat and there is a large difference in the absorption characteristics [1]. The photodetector used is a flattop photodiode with an active area of 0.65 mm^2 and peak sensitivity at 900nm (SR 10 BP-B–H, Excelitas technologies, U.S.A). The separation distance from the centre of the photodiode to the centre of each LED was set to be 5 mm, as experimental studies have shown that a separation of 4 to 5 mm between the emitter and the photodetector provides good signal-to-noise ratio PPG signals [2]. The sensor has dimensions of 9 mm x 5 mm x 1.5 mm.

The emitters are connected antiparallel to each other and are switched alternately to allow individual sampling of light at each wavelength. The sensor was designed using an electronic design automation software package known as Altium Designer (Altium Limited, Sydney, Australia) and manufactured by the process of photolithography. The optical components were soldered on the respective copper pads of the PCB, using a reflow soldering oven, maintained at low temperatures (200°C to 250°C). four core ultra-flexible cable was drawn through the mechanical casing of the ear canal sensor and then soldered on to the PCB using the vertical interconnecting access (via's) holes. Once the wires were soldered, the PCB was fixed firmly into the specially designed PCB slot in the probe casing.

Figure 3: (a) Optoelectronic reflectance sensor used in the ear canal PPG/pulse oximeter probe showing the emitters and photodetector, (b) mechanical drawing of the sensor.

The other end of the multicore cable was soldered to a male DE9 connector, which provides communication between the probe and the PPG processing system. To avoid direct contact between the optical components and the skin lining of the ear canal, the whole aperture holding the micro-optic sensor was sealed using clear epoxy resin (DYMAX 141-M, Dymax Corporation, Torrington, CT). Two reflectance finger PPG probes, optically identical to the ear canal sensor were also developed to facilitate comparisons between PPG signals and SpO_2s obtained from the ear canal and the periphery. The finger probes were made using the commercial pulse oximeter finger clips. The finger sensors were sealed completely in clear epoxy to prevent any contact with water during the volunteer study.

2.2   *PPG processing system*

Two identical dual channels, dual wavelength PPG processing systems were developed to detect, sample, record and display red and infrared raw PPG signals from the ear canal, right index finger and left index finger simultaneously [12]. The electronic circuitry of the PPG processing system was split in separate individual modules which were then interconnected by a double sided system bus. The individual modules include a power supply module, a current source module, a transimpedance

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amplifier module, a probe connector module and a core module. A simplified block diagram of the processing system is shown in 'figure 4'.
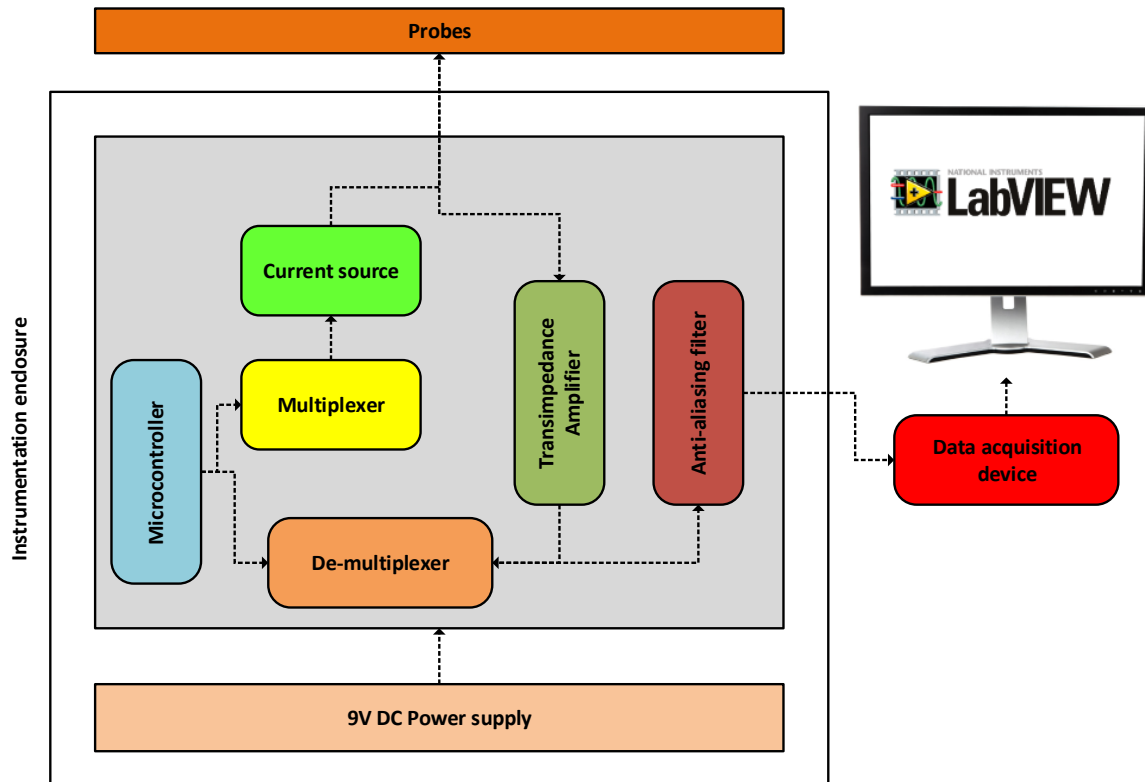

Figure 4: Basic block diagram of the PPG processing and data acquisition system.

2.2.1   Instrumentation of processing system.

The red and infrared emitters on each channel are driven by two independent current driver circuits consisting of three main parts: a reference control voltage circuit, a voltage multiplexing circuit and a modified Howland current source.

The reference control voltage circuit provides independent control over the LED currents on both channels. Each LED on both channels is controlled by an individual control voltage circuit. The design of all the four circuits is similar, except the reference voltage on one of the channels is generated by a National Instruments data acquisition card (NI DAQ) and the other by a constant on-board 1V regulator. Therefore, allowing digital control of LEDs on one channel and analogue control of LEDs using trimmers on the other. Due to the limited number of analogue output channels on the DAQ card, digital control of LEDs on both channels was not possible.

The voltage multiplexing circuit generates a timed switching signal used to turn on the red and infrared LEDs alternatively. The LEDs are switched on alternatively in order to allow independent sampling of red and infrared light by the photodetector. Switching is attained by connecting the outputs of the control voltage circuits to a dual 4-channel analogue multiplexer (MC14052). The

inputs of the data select lines are timed clocks generated by an 8-bit Atmel micro-controller (ATtiny 2313-20SU). The microcontroller is programmed to produce two clocks with a frequency of 1 KHz.
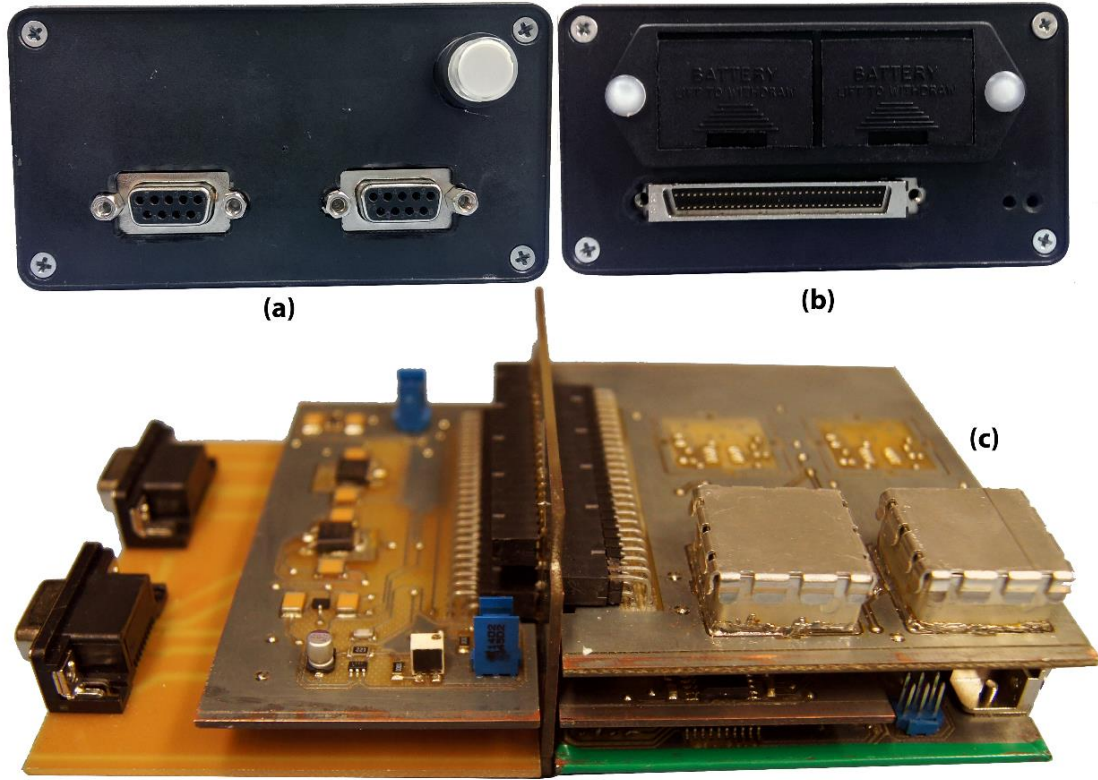
The modified Howland current source converts the switching voltage signal into current that can be used to turn on the LEDs. The input of the current source is the switching signal generated by the multiplexing circuit. The driving LED current used for these experiments was 20 mA. The primary advantages of the Howland current source, over other current sources are its simplicity and ability to produce high output impedance.

The transimpedance amplifier converts and amplifies the photocurrents generated by the photodetector into a mixed voltage signal. The strength of the signal from the amplifier depends on the intensity of light detected by the photodiode and the gain resistor. The gain of the amplifier was 150000.

As the photodetector cannot distinguish between light photons detected from the red and infrared emitters, an 8-channel analogue demultiplexer (MC14051D) is used to separate the signals. Two demultiplexers were used to separate red and infrared PPG signals on each channel. The inputs for the data select lines are timed clocks generated by an 8-bit Atmel micro-controller (ATtiny 2313-20SU). Each output from the demultiplexer is then fed through individual low pass filters with a cut-off frequency of 40Hz. This is to remove the high frequency switching noise associate with the demultiplexed raw PPG signals.

2.2.2 Mechanical construction of the processing system.

Printed circuit boards (PCB) of all the modules, used in the processing system were designed using an electronic design automation software package known as Altium Designer and were manufactured using a Bungard Computer Controlled Drilling machine (CCD2). Double sided copper clad boards of 1.6 mm thickness were used to manufacture all the PCBs. All the surface mount components were then soldered on the respective pads, using a reflow soldering oven, maintained at low temperatures (200ºC to 250ºC). Through hole components were hand soldered.   All the PCBs, along with a dual 9V PP3 battery case were housed in a rectangular portable unit measuring 16.0 x 10.3 x 5.4 cm. As shown in 'figure 5', the front panel of the unit incorporates two standard female DE9 connectors for connecting two probes, and an on/off switch to control the system. The rear panel consists of a 68-pin serial bus connector for interfacing to a National Instruments data acquisition card and access to two trimmers which can be used to control the LED currents.

Figure 5: Photographs of the PPG Processing system; (a) front panel, (b) back panel, and (c) mechanical assembly.

2.3   Temperature sensors

Two thermistor based fast response temperature probes were constructed to assess the temperature difference between left and right hands, during the volunteer study. The thermistor used was TP-TSD202A - fast response thermistors from BIOPAC systems, Inc. The thermistor was 5 mm long, with a diameter of 1.7 mm. The response time of the thermistor was 0.6 sec. As no calibration data was provided by the thermistor manufacturer, both the thermistors were calibrated in a controlled environmental chamber (BINDER KMF 115, BINDER GmnH, Germany). The temperature of the chamber was increased from 5 to 40ºC, with 1ºC increment every 10 minutes. During this time, the computer recorded the change in voltage as a waveform, and saved the data into a file. Once the calibration procedure was complete, linear fit polynomial equations were derived for both the thermistors. These equations were then used to calculate skin temperature.

$$T = -52.23(x) + 50.01 \qquad \text{Equation 1}$$
$$T = -49.06(x) + 47.36 \qquad \text{Equation 2}$$

2.4   Data acquisition and hardware control

Two 16-bit data acquisition cards (DAQpad-6015, National instruments corporation, Austin, Texas) were used to digitise the red and infrared PPG signals acquired from the processing systems. A 14-bit DAQ card (USB 6009, National instruments corporation, Austin, Texas) was also used to digitise the

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Temperature signals. The DAQ cards were also used to control the LED currents on channel 1 of both the PPG processing systems. A LabVIEW (National Instruments Corporation, Austin, TX) virtual instrument (VI) was also implemented;

- To accurately digitise and acquire the red and infrared PPG signals from both the channels of the two PPG processing systems.
- To digitise and acquire temperature signals.
- To filter the raw PPG signals and extract the AC and DC components and calculate SpO_2 for all the channels.
- To display and save all the acquired signals and computed values.

The PPG and temperature signals were sampled at a rate of 1 KHz. Four digital filters in varying configuration were used to filter the PPG and temperature signals, and are listed below:

- Red and infrared raw PPG signals from both the processing system were filtered using a band-pass filter to extract the AC component of the signal. The filter was configured to be a 4th order Butterworth filter with upper and lower cut-off frequencies at 5 Hz and 0.5 Hz.
- The DC component of red and infrared signals was extracted using a 2nd order Butterworth low-pass filter with a cut-off frequency of 5 Hz.
- The temperature signals were filtered using a 2rd order Butterworth low-pass filter with a cut-off frequency of 2 Hz.

The extracted AC and DC components of the red and infrared PPG signals were then used to calculate the 'R' value using equation 3.

$$Ratio \ (R) = \frac{AC_{658}}{DC_{658}} \Big/ \frac{AC_{870}}{DC_{870}} \qquad \text{Equation 3}$$

The R value was then used to compute arterial oxygen saturation using an empirically derived calibration equation (equation 4) [1].

$$SpO_2 = 110 - 25(R) \qquad \text{Equation 4}$$

2.5   Volunteer Study

2.5.1   Subjects

With the approval of City University London Senate Research Ethics Committee, a cold pressor study was carried on 15 healthy volunteers, 7 male, 8 female, aged between 18-36 (mean age $\pm$ SD : 26.2 $\pm$ 4.8 years) and with no history of cardiovascular disease. The experimental protocol was clearly explained to all the participants and a written consent was obtained from all the participants prior to

the experiment. The subjects were asked not to smoke and exercise for at least two hours before the experiment.

2.5.2   Experimental protocol

The experiments were carried out at the Biomedical Engineering Research Group (BERG) laboratory, School of Engineering and Mathematical Sciences, City University London under room temperatures between 22 ± 2°C. During the experiments, all the subjects were made to sit in a comfortable chair, with both hands resting on soft cushions, arranged to a height equivalent to their heart position. Once the volunteer was comfortable in the position;

- The ear canal PPG sensor was placed 9 mm deep into the right ear canal
- Two in-house designed finger PPG probes were connected to the index fingers of the right and left hands
- Two skin temperature sensors were connected on the right and left hand of the volunteer.

Baseline readings were obtained from all the volunteers for 2 minutes, before they were notified with a countdown (3 -> 1) to slowly start immersing their right hand into the ice bath maintained at approximately 1°C. After 30 seconds into the ice bath, they were again notified to slowly start removing there right hand from the ice bath and place it back on the surface. The monitoring was continued until the volunteer's hand rewarmed to a temperature above 22°C.

Figure 6: Photograph of the ear canal PPG/SpO2 probe placed inside the right ear of a volunteer.

2.5.3   Data Analysis

The recorded PPG and temperature signals were extracted separately for analysis. The extracted data was analysed as follows:
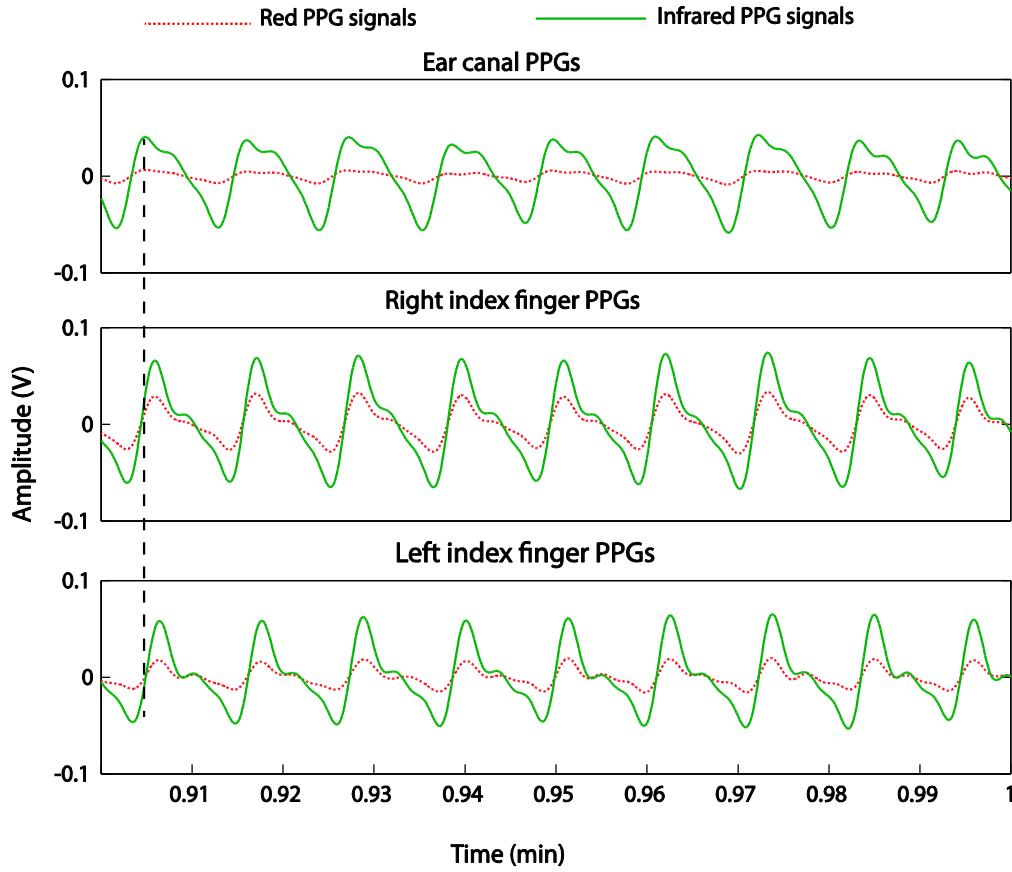
- The mean amplitude of red and infrared AC PPG signals acquired from the ear canal, the left index finger and the right index finger were calculated during all three stages of the

experiment (before ice water immersion, during ice water immersion and after ice water immersion) for each volunteer

- The mean of the means ($\pm$SD) for red and infrared AC PPG signals obtained from all the volunteers were calculated and compared during all three stages

- Pared t-tests were then performed on the data to see the effect of peripheral vasoconstriction on the PPGs acquired from the ear canal, left and right index finger. A P-value <0.05 was considered to be statistically significant.

- In order to demonstrate the effect of compromised peripheral perfusion on the estimation of arterial oxygen saturation, SpO_2 values were calculated from the PPG signals acquired from the volunteers, during all three phases of the experiment, and the % drop of SpO_2 during ice water immersion was calculated.

- Frequency domain analysis was performed on the infrared PPG signals acquired from the ear canal and finger, to determine the frequency of sympathetic interactions modulating cardiovascular function.
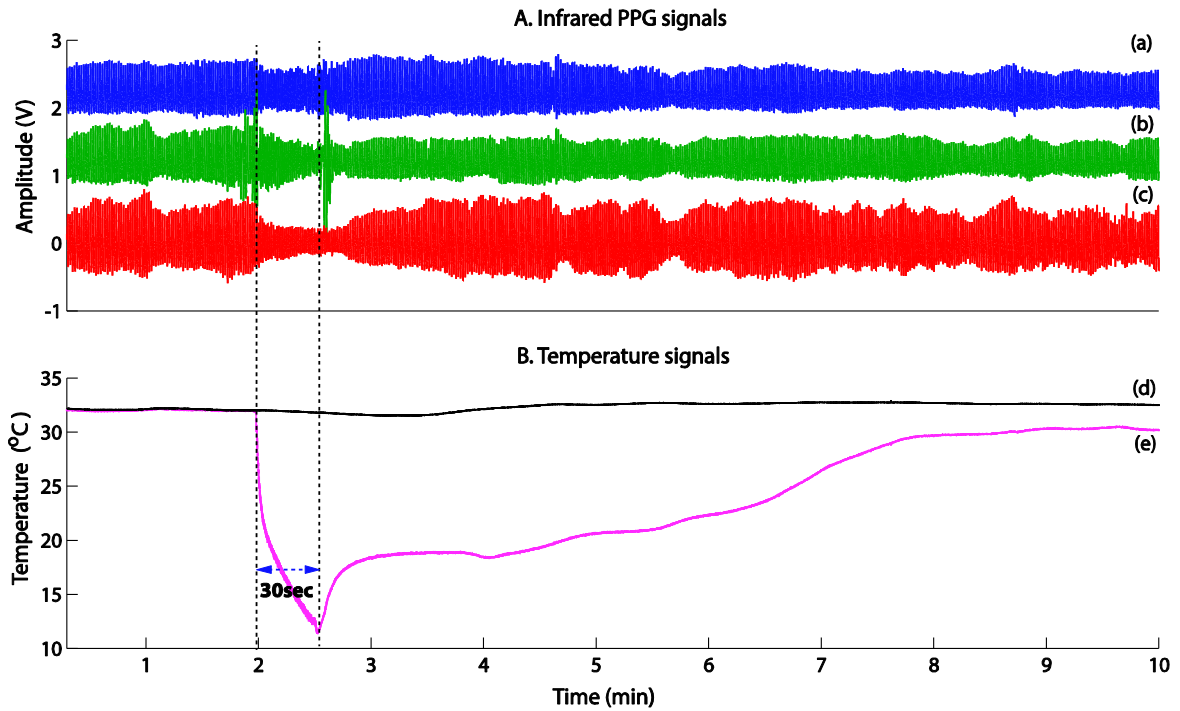
3. Results

Good quality photoplethysmographic signals with high signal-to-noise ratio were obtained from the prototype ear canal and finger probes. The morphology of the PPG signals obtained from ear canal were slightly different to the PPG signals acquired from finger sensors, in almost all the volunteers, however all the signals correspond accurately with the cardiac cycle. A sample of the PPG signals acquired from the ear canal, the left index finger and the right index finger for a period of 10 seconds from a volunteer is shown in 'figure 7'. A dicrotic notch is clearly visible in the diastolic phase of the finger PPG signals, when compared to the ear canal PPG signals. These changes in the morphology of the PPG signals are thought to be due to variations in vascular compliance and peripheral resistance of various arteries [13]. A slight shift in phase between the finger and ear canal PPG signals is also apparent in 'figure 7'. This is expected, as the ear being closer to the heart than the finger, the time taken for arterial pulsations to travel from the heart to the ear canal is less than the time taken for the pulsations to reach the finger.

Figure 7: A 10 seconds segment of red and infrared AC PPG signals of a randomly selected volunteer recorded simultaneously from ear canal, right index finger and left index finger.

Amplitude of AC PPG signals

The infrared AC PPG signals acquired from the ear canal, the right index finger (RIF) and the left index finger (LIF), and the simultaneously acquired temperature signals from both right and left index fingers of a randomly selected volunteer are shown in 'figure 8'. The y-axis on figure 8(A) represents the amplitude of the AC PPG signals, whereas the y-axis on 'figure 8(B)' represents temperature in degree centigrade (°C) for a period of 10 min.

Figure 8: A. Infrared AC PPG signals recorded from (a) the ear canal, (b) the right index finger and (c) the left index finger of a volunteer.   B. Simultaneously obtained temperature reading from (d) the left index finger and (e) the right index finger of the same volunteer for a period of 10 min.

It can be observed from 'figure 8' that the PPG signals acquired from the right index finger decrease in amplitude as soon as the right hand is immersed in the ice water. This is due to vasoconstriction resulting from the activation of the sympathetic nervous system, during the event of ice water immersion. The temperature of the right hand has doped from $31^{o}C$ to $8^{o}C$ during this period. It can also be noticed from 'figure 8', that the PPG signals acquired from the left index finger decreased in amplitude although the temperature of the left index finger remains relatively constant, while only a very little effect is seen on the amplitude of the ear canal PPG signals. Once the right hand was immersed in ice, the quality of the PPG signals has also started to degrade with time in few volunteers, as shown in 'figure 9', but the quality of the PPG signals from left index finger has not changed. This may result in inaccurate estimation of SpO_2 by the pulse oximeter. Once, the hand was out of the ice bath, the blood vessels dilate, causing an increased blood flow to the hand and an increase in temperature of the hand. Hence, an increase in amplitude of PPG signals is seen in 'figure 8' after the ice water immersion. Similar effects were seen in all the volunteers.
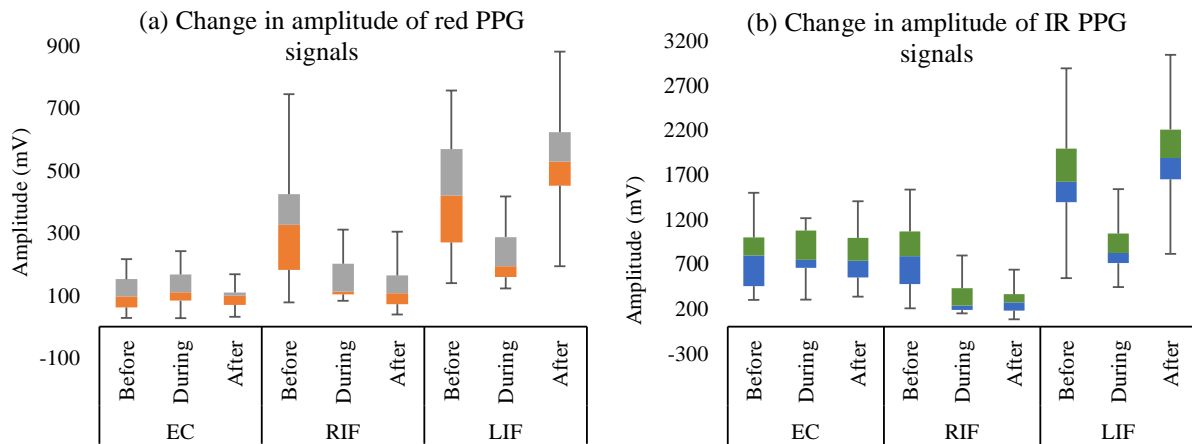
Figure 9: PPG signals from (a) right index finger change with time during ice water immersion, when compared with (b) left index finger.

The mean of the means (±SD) (mean Peak to peak amplitude) of AC red and infrared PPG signals acquired from the ear canal (EC), the right index finger (RIF) and the left index finger (LIF) during all three stages of the experiments are shown in 'table 1'. Also, the data is graphically displayed with the use of Box and Whickers plot in 'figure 10'. The amplitude of red and infrared signals acquired from the EC has remained relatively constant throughout the experiment, whereas the amplitude of PPG signals from the RIF and the LIF have dropped significantly during the ice water immersion.

Table 1: Mean of the means (±SD) of AC red and infrared PPG signals acquired from the ear canal (EC), right index finger (RIF) and left index finger (LIF), during all three stages of the experiments.

	Before immersion			During immersion			After immersion		
	EC	RIF	LIF	EC	RIF	LIF	EC	RIF	LIF
Red									
Mean (mV)	109	321	424	121	151	222	104	159	521
SD ($\pm$)	60	197	194	62	76	85	60	133	210
Infra-red									
Mean (mV)	800	776	1715	790	324	912	797	391	1960
SD ($\pm$)	384	427	835	305	208	375	321	342	830

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Figure 10: Box and whiskers plot demonstrating the change in mean PPG amplitude of (a) red and (b) infrared (IR) PPG signals obtained from all three sensors during the cold pressor test.

The percentage change in amplitude of red and infrared PPG signals during the ice water immersion in all the volunteers is shown in 'table 2'. It is evident from 'table 2' that the change in the ear canal PPG signal amplitude due to the ice water immersion is much less compared to the right and left index fingers. There is a significant drop in the amplitude of PPG signals acquired from the RIF and LIF. In the RIF, a substantial drop of more than 65% was observed in four healthy volunteers. In the LIF, a similar drop was seen in one volunteer.

Table 2: The percentage change in amplitude of red and infrared PPG signals during ice water immersion in all the volunteers

% Drop	No. of volunteers					
	Red EC	Infrared EC	Red RIF	Infrared RIF	Red LIF	Infrared LIF
< 5%	10	9	1	1	1	0
5% - 25%	4	5	3	2	2	3
25% - 45%	1	1	2	2	2	5
45% - 65%	0	0	5	6	9	6
65% - 85%	0	0	4	4	1	1

The average drop in the amplitude of red and infrared RIF PPG signals is 52.7 % and 58.3%, while the LIF PPG signal amplitudes have reduced by 47.52% and 46.8% respectively. In contrast, the ear canal PPG signals have changed by +2.5% and -1.2%. After the ice water immersion, the amplitude of the PPG signals acquired from the LIF have increased to a value higher than the baseline reading, while the amplitude of the PPG signal acquired from the RIF have only increased to a value equal to half its initial reading.

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To check for any statistical significance between the mean PPG amplitudes before, during and after the cold pressor test, a Kruskal-Wallis One Way Analysis of Variance on Ranks was performed on the data. A non-parametric test was used, as some of the data were not normally distributed. Normality was tested using Kolmogorov-Smirnov test. A significant difference was found between the groups. To isolate the group or groups that differ from the others all pairwise multiple comparison procedure (Student-Newman-Keuls Method) was used. All the statistical analysis was performed using statistical analysis software known as SigmaPlot. The results are shown in 'table 3' together with the corresponding P value.

Table 3: Results of One Way Analysis of Variance Test between the mean amplitudes of each sensor during all three stages of the study

Sensor	Wavelength	Comparison	Statistical significance (P<0.05)	P value
Ear Canal	Red	Before vs During	No	=0.928
		During vs After	No	
		After vs Before	No	
	Infrared	Before vs During	No	=0.997
		During vs After	No	
		After vs Before	No	
Right index finger	Red	Before vs During	Yes	=0.019
		During vs After	No	
		After vs Before	Yes	
	Infrared	Before vs During	Yes	=0.007
		During vs After	No	
		After vs Before	Yes	
Left index finger	Red	Before vs During	Yes	<0.001
		During vs After	Yes	
		After vs Before	No	
	Infrared	Before vs During	Yes	<0.001
		During vs After	Yes	
		After vs Before	No	

From 'table 3', it can easily be observed that, the effect of peripheral vasoconstriction on the amplitude of ear canal PPG signals is almost negligible. However, significant differences can be seen in the amplitude of the PPG signals acquired from RIF and LIF, during the cold pressor test. The

amplitude of the PPG signals from the LIF have increased to a value equivalent to the baseline after the ice water immersion, while the amplitude of the PPGs in the RIF show significant differences when compared before and after the ice water immersion.

3.1   Arterial oxygen saturation

Arterial oxygen saturation (SpO_2) values were calculated for each volunteer during all three stages of the experiment, in order to demonstrate the effect of compromised peripheral perfusion on the estimation of arterial oxygen saturation. 'Table 4' shows the mean SpO_2 values calculated during all three stages of the experiment. Although SpO_2 is a global variable and would not change in healthy volunteers from one site to another, a decrease in the mean SpO_2 was observed during ice water immersion in the right and left index fingers. However, the SpO_2 calculated from the ear canal remained relatively constant. During baseline readings, the correlation (r^2) between the SpO_2s calculated from the ear canal probe and the RIF probe is -0.45. The correlation between the SpO_2s calculated from the ear canal probe and the LIF probe is 0.514. The correlation between the LIF and the RIF is 0.37.

Table 4: Mean SpO_2 values calculated from custom made PPG sensors.

	Before immersion SpO_2 (%)±SD	During immersion SpO_2 (%)±SD	After immersion SpO_2 (%)±SD
Ear canal	100.2 ± 1.5	99.3 ± 2.3	100.2 ± 2.2
Right index finger	97.4 ± 1.2	94.0 ± 5.7	97.1 ± 1.8
Left index finger	97.8 ± 1.6	94.6 ± 5.1	97.5 ± 2.1

Although the mean SpO_2 values calculated from the right and left index finger have decreased during the ice water immersion, the sensors have truly only failed to estimate SpO_2 in a few healthy volunteers. Hence, a large standard deviation in SpO_2 values is evident during the ice water immersion. In the rest of the volunteers the estimated SpO_2s were accurate and close to the baseline reading. A drop in SpO_2 value above 4% during the ice water immersion was considered to be a failure. The ear canal pulse oximeter has successfully estimated SpO_2 during all three stages of the experiment. The percentage drop in SpO_2 during ice water immersion in all the volunteers is given in 'table 5'. The right index finger pulse oximeter has failed to estimate accurate SpO_2 in 7 healthy volunteers, while the left index finger pulse oximeter has failed to estimate SpO_2 in 4 healthy volunteers. Compared to the finger sensors, the ear canal pulse oximeter has only failed in one volunteer.

Table 5: summary of pulse oximeters failure in 15 healthy volunteers

SpO$_2$ % drop	No. of volunteers		
	Ear canal	Right index finger	Left index finger
< 1%	11	4	5
1% to 4%	3	4	6
> 4%	1	7	4

3.2   Frequency domain analysis

A frequency domain analysis was conducted on the infrared PPG signals from RIF and ear canal in order to demonstrate the influence of sympathetic nerve activity on the peripheral and cerebral blood flow.   During the cold pressor test, when the right hand is immersed in the ice water, the thermoregulatory mechanism of the body initiates the sympathetic nervous system, in order to maintain the normal body temperature [14]. The sympathetic nervous system changes the arterial distensibility to counter the heat loss. The degree of sympathetic control over blood circulation can be measured by a low frequency spectrum analysis of the varying PPG signals acquired from the finger. Also, by comparing the power spectrum of the finger PPG signal with the power spectrum of the ear canal PPG signals, the strength of the sympathetic and vagal nerve activity on peripheral and cerebral blood circulation can be determined. The power spectrum of the ear canal and right index finger DC PPG signals acquired from four volunteer is shown in 'figure 11'.
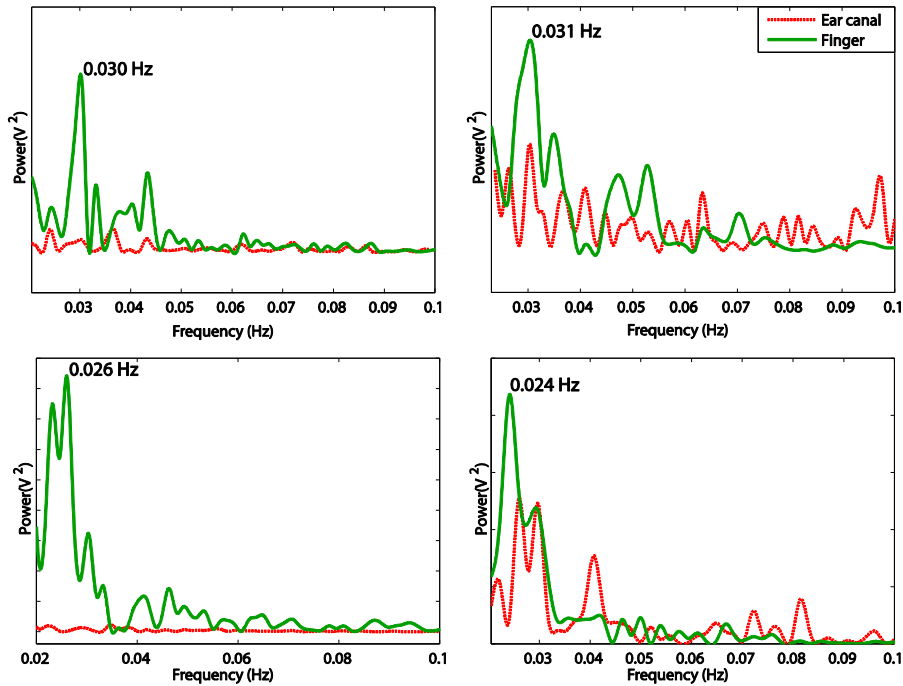

Figure 11: Power spectrums of ear canal and finger PPG signals.

The sympathetic nerve activity can be seen easily at 0.03 Hz in both the PPG signals. However, the power of the finger PPG signal is much greater than that of the ear canal PPG. This shows that the degree of sympathetic control on peripheral blood vessels is much higher than the blood vessels supplying blood to the ear canal (cerebral blood vessels). A similar affect was observed in all the volunteers.

4.   Discussion

The aim of this study was to investigate the suitability of the human auditory canal as a central site for reliable monitoring of PPGs and the estimation of SpO_2. Also, this study compared a traditional PPG/SpO_2 monitoring site such as the finger with the proposed site (ear canal), during induced vasoconstriction (cold pressor test). The hypothesis underlying this study was that, blood to the ear canal is usually supplied by the branches of the common carotid artery, which contributes directly to the perfusion of the brain. This circulation will be preferentially preserved as long as possible and scarcely will experience any modulations by the sympathetic perivascular nerves during shock, hypothermia, hypovolaemia and vasoconstriction as the peripheral perfusion will. Hence, SpO_2 estimation from the ear canal should be possible even in cases where the peripheral perfusion is compromised.

A miniaturised optoelectronic reflectance ear canal pulse oximeter probe was developed along with two optically identical finger pulse oximeter probes. Two identical dual channel, dual wavelength processing system were also designed to pre-process, display and store ear canal and finger PPG signals. The developed technology was used to demonstrate the effect of poor peripheral perfusion on conventional finger pulse oximeter as opposed to the proposed ear canal pulse oximeter. A cold pressor test was used to stimulate the vasoconstrictive responses commonly seen in clinical setting.

The results show that measurable, good quality red and infrared PPG signals can be obtained from the human auditory canal and the periphery using the custom built sensors. The finding of our results were different from the results presented by Vogel and Venema [8, 9], as the sensor design, placement in the ear canal and the choice of the LED wavelengths were different that those described by the above mention authors.

The ear canal PPG signals were found to be morphological different to the finger PPG signals. PPG pulse features such as the dicrotic notch in the diastolic phase, arrives earlier in ear canal signals when compared to the finger PPG signals. The ear canal PPG signals bear high resemblance to the arterial pressure pulse recorded from the aortic arch. These physiological features were supressed in the finger PPG signals due to the increase in vascular compliance and peripheral resistance of blood vessels. Hence, by further decomposing the ear canal PPG signal, valuable clinical information regarding cardiovascular function might be extracted.

In this study, 15 volunteers underwent a 30 sec period of profound vasoconstrictive stimulation by immersing their right hand into an ice bath. Once the hand is immersed into ice water, the sudden change in temperature forces the thermoregulatory centre to stimulate the sympathetic nervous system, in order to maintain homeostasis. This leads to an increase in volumetric elasticity and vessel wall stiffness of peripheral blood vessels. This in turn causes the blood pressure and heart rate to increase. Hence, during ice water immersion most of the peripheral body parts are affected, as it is in the case of an anesthetised critically ill patient. In these cases, the amplitude and the quality of the PPG signals detected decreases, which leads to inaccurate estimation of SpO_2. Similar effects were observed in all the volunteers who participated in this study.

As soon as the right hand was immersed in the ice water, the amplitude of the PPG signals acquired from the right index finger (cold finger) and the left index finger (warm finger) reduced significantly, while the amplitude of the ear canal PPGs stayed relatively constant, as seen in 'figure 8'. In the RIF, an average percentage drop of 45% or more was found in approximately 63% of volunteers, while 56% of the volunteers had a similar drop in the LIF. However, the ear canal PPG signal amplitudes have never dropped more than 26% in any volunteer. These findings show that with induction of vasoconstrictive stimulus in the right hand, other peripheral parts such as the left hand are prominently affected. Nevertheless, the ear canal is found to be reasonably immune to these effects. Once the hand was out of the ice water, the amplitude of the PPG signals increased with temperature. From 'table 3', it is observed that the amplitude of the LIF has shown no significant difference when compared before and after the ice water immersion. However, significant differences were found in the RIF before and after the ice water immersion. This indicates that the amplitude of the PPG signals after the ice water immersion have not increased by a greater extent, although the temperature of the right hand has increased to a minimum temperature of 24°C in all the volunteers.

The baseline SpO_2 results from the ear canal pulse oximeter are in good agreement with both the finger pulse oximeters. During the cold pressor test, the SpO_2s from both the finger pulse oximeters dropped considerably. This was expected since the drop in amplitude of the red and infrared AC PPG signals was not proportional during the ice water immersion, leading to an increase in the 'R' value and conversely a drop in the SpO_2. Mean drops of 0.9%, 3.4% and 3.2% were observed in the ear canal, RIF and LIF pulse oximeters respectively in all the volunteers. However, SpO_2 is a global variable, and would not change from site to site in healthy volunteers. Therefore, the drop or failure of pulse oximeters is purely due to reduction in amplitude and quality of PPG signals, resulting from vasoconstriction of peripheral blood vessels. As mean drop is not an appropriate indicator of pulse oximeter failure, a minimum drop in SpO_2 value of 4% in any given volunteer was considered to be clinically significant or as a failure. A drop in SpO_2 higher than 4% was found in 47% of the volunteers in the RIF pulse oximeter, while 27% of the volunteers experienced similar drop in the LIF

pulse oximeter. Compared to the finger pulse oximeters, the ear canal pulse oximeter has only failed in one volunteer.

The degree of sympathetic control over peripheral blood circulation as opposed to cerebral blood supply during ice water immersion was measured by low frequency spectrum analysis of DC PPG signals in 4 volunteers. The sympathetic activity was observed between 0.02-0.03 Hz in both the PPG signals in all volunteers. However, the power of the finger PPG signal was much greater than that of the ear canal PPG. This shows that the degree of sympathetic control on peripheral blood vessels is much higher than the blood vessels supplying blood to the ear canal.

In conclusion, a new and potentially clinically useful non-invasive ear canal pulse oximeter system has been successfully developed and tested. The system promises reliable monitoring of SpO_2 in conditions of compromised peripheral perfusion. Further evaluation of the developed technology in critically ill patients is underway.

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