Development of an optical probe to investigate the suitability of measuring photoplethysmographs and blood oxygen saturation from the human auditory canal

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Abstract— **Pulse oximetry has become a standard for patient monitoring in the operating room, and the finger is the most common site used for monitoring blood oxygen saturation (SpO$_2$). However, SpO$_2$ measurements made from extremities such as the finger, ear lobe and toes become susceptible to inaccuracies, when patients become hypothermic, hypovolemic and vasoconstrictive. This is due to the week arterial pulsations detected in these conditions. To overcome this limitation, 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. A dual wavelength optoelectronic sensor along with a processing system was developed to investigate the suitability of measuring photoplethysmographic (PPG) signals and SpO$_2$ values in the human auditory canal. A pilot study was conducted on 12 healthy volunteers to validate the developed sensor. The red and infrared PPG signals obtained from all the volunteers were of very good quality. The SpO$_2$ values recorded from the ear canal were compared with simultaneously acquired data from a commercial finger pulse oximeter. The results show good correlation between the commercial pulse oximeter and the custom made ear canal sensor (r^2 = 0.825).**

I. INTRODUCTION

Pulse oximetry has, since its invention in the 1980's, revolutionised anaesthesia and critical care [1]. 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. The technique provides an accurate and robust measure of arterial oxygen saturation (SpO$_2$) by shining light into the vascular tissue, and measuring the changes in light absorbance produced during arterial pulsations [2]. These changes in light absorbance, sensed during arterial pulsations, are recorded as a voltage signal known as photoplethysmograph (PPG). Pulse oximeters depend on the quality of the PPGs acquired at the measurement site to accurately estimate SpO$_2$.

Although pulse oximeters are universally used as a reliable tool for measuring SpO$_2$, the device is also known to possess significant limitations. These limitations include motion artifacts, electromagnetic interferences, intravenous dyes, venous pulsations, poor peripheral perfusion etc.[2–4]. Recent advancements in the technique have made it possible

to accurately estimate SpO$_2$ even in the presence of these limitations [5], but the one major clinical area 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. The problem arises as all clinically used pulse oximeter systems are attached to the extremities or at least peripheral tissue (i.e., finger, toe, or earlobe). As a result, the sensor is subjected to low perfusion states, leading to inaccuracies in 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 signal in critical conditions of hypothermia, shock or sepsis. Coupling to its physiological advantages to other more common sites, is the factor of comfort and invisibility of the device, as even its electronic housing can be discreetly worn behind the ear. This has brought interest in applying it to portable monitoring, to be used in early diagnosis of cardiovascular diseases [6–8].

Vogel *et al.* has developed a wearable in-ear measuring system (IN-MONIT) for 24/7 monitoring of vital parameters in cardiovascular patients. The results obtained by using the sensor have shown that the red PPG signals obtained from the auditory canal were of poor quality. It was concluded that enhancement in red PPG signals is required in order to calculate SpO$_2$ from the auditory canal [6]. 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 demonstrate 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 became unacceptable for use in SpO$_2$ measurements [8]. Also, the peak wavelength of the red emitter used in the IN-MONIT sensor is at 760 nm. The difference in the absorption between the haemoglobin (Hb) and oxyhaemoglobin (HbO$_2$) is much lower at this wavelength as it is near the isobestic point, and may lead to inaccuracies when calculating SpO$_2$. Moreover, the quality of the PPG signals and accuracy of SpO$_2$s, 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 was developed along with a PPG processing system to investigate PPGs and estimate SpO$_2$ from the external auditory canal. This paper presents the design and development of the

proposed technology and provides a preliminary *in vivo* assessment of its performance.

II. MATERIALS AND METHODS

A. Construction of ear canal probe

A reflectance ear canal pulse oximeter probe was constructed. The probe consists of two main modules; a micro-optic reflectance sensor and a specially designed sensor casing.

The micro-optic reflectance sensor 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. 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. The photodetector used is a flattop photodiode with an active area of 0.65 mm^2 and peak sensitivity at 900nm. 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 food signal-to-noise ratio PPG signals [9]. The sensor has dimensions of 9 mm x 5 mm x 1.4 mm. A diagram of the sensor is shown in Figure 1. 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).
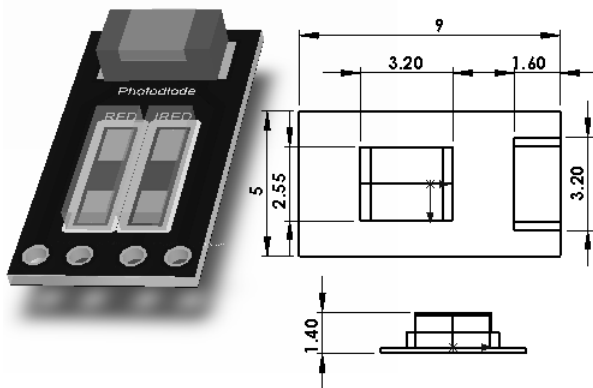

Fig. 1. Optoelectronic reflectance sensor used in the ear canal PPG/pulse oximeter probe showing the emitters and photodetector.

The design of the sensor casing is 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 [10]. 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. Thus, 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.

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). Figure 2 shows the mechanical drawings and 3D models of the ear canal sensor. The casing consists of a small rectangular extruded cut in which the micro-optic sensor is sealed. The diameter of the part of the casing which is inserted into the auditory canal is 7 mm. The casing consists of an inverted 'L' shaped cavity that is used to run a 4 core ultra-flexible cable, which provides electrical contact between the optical components and the PPG processing system.
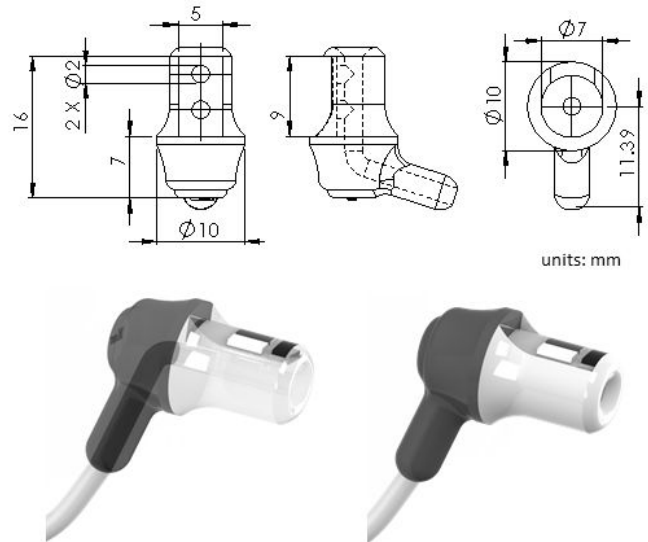

Fig. 2. 3D sketch and the mechanical drawings of the ear canal sensor.

To stop the probe from accidently being inserted too deep into the ear canal, the diameter of the probe is 3 mm bigger at the distal end of the probe. 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. To avoid direct contact between the optical components and the skin lining the ear canal, the whole aperture holding the micro-optic sensor was sealed using clear epoxy resin. A reflectance finger PPG probe, optically identical to the ear canal sensor was also developed to facilitate comparisons between PPG signals and SpO_2s obtained from the ear canal and the finger.

B. PPG processing system and data acquisition system

A dual channel, dual wavelength PPG processing system was developed to detect, sample, record and display raw PPG signals from the ear canal and the finger simultaneously. A simplified block diagram of the processing system is shown in Figure 3. 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 purpose of the reference control voltage circuit is to provide independent control over the LED currents on both channels. The voltage multiplexing circuit is used to generate a timed switching signal to turn on the red and infrared LEDs alternatively. Hence, allowing 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 output of the multiplexer is dependent on the data select lines. The inputs of the data select lines are timed clocks generated by

an 8-bit Atmel micro-controller (ATtiny 2313-20SU). The output of the multiplexing circuit is then passed through a modified Howland current source, to convert the switching voltage signal into currents, used to turn on the LEDs. The current across the LEDs is continuously monitored by a dual, low power instrumentation amplifier (INA2128U). This is attained by inputting the voltage across the load resistor and the current after the load resistor as differential inputs to the instrumentation amplifier.
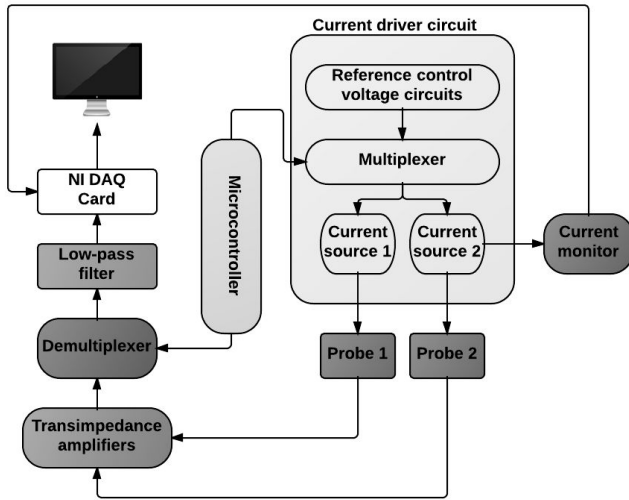

Fig. 3. Basic block diagram of the PPG processing and data acquisition system.

The photodiode detects the reflected light energy from the tissue and generates a current proportional to the incident energy. The photocurrents generated by the photodetector are then converted into a mixed voltage signal by a transimpedance amplifier. 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. The demultiplexer transmits the input data, on to one of its 8 output lines depending on the clocks generated by the microcontroller, hence separating the red and infrared signals. 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. These raw PPG signals are then digitised by a16- bit data acquisition card (DAQpad-6015 National instruments corporation, Austin, Texas). A LabVIEW virtual instrument (VI) was implemented to display and record the raw PPG signals on a laptop computer. The AC and DC components of the raw PPG signals were extracted, and the 'R' values were calculated using equation 1.

$$Ratio\ (R) = \frac{\frac{AC_{658}}{DC_{685}}}{\frac{AC_{870}}{DC_{870}}} \qquad (1)$$

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

$$SpO_2 = 110 - 25\ R \qquad (2)$$

Mechanically, the entire circuitry is split into individual PCB modules which are interconnected by a double sided system bus. All the PCBs are designed using Altium Designer and were manufactured using a Computer Numeric Control machine (CNC). Two 9V PP3 batteries supplied power to the entire system. The PCBs of all the modules 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.

C. Preliminary investigation of the ear canal probe

In order to validate the functionality of the ear canal probe, a volunteer study was carried out on 12 healthy individuals. The study was approved by City University London Senate Research Ethics Committee and volunteer consent was acquired prior to the study. All the volunteers were made to sit on a comfortable chair and were monitored for the following signals:

- PPG signals and SpO$_2$ from the ear canal were monitored by placing the prototype ear canal sensor 9-mm deep into the right ear canal (Figure 4).

- An optically identical finger probe was connected to the index finger of the right hand, to monitor PPG signals and SpO$_2$s.

- A Masimo Radical-7 commercial pulse oximeter probe (Masimo Inc., Irvine, CA, USA) was connected to the middle finger of the right hand, to also monitor SpO$_2$s.

The LED currents on both ear canal and finger probes were kept constant throughout the study, at 20 mA. All the volunteers were requested to keep body and facial movements to a minimum throughout the study to avoid motion artefacts. Simultaneous PPGs at both wavelengths from both sites (ear and finger) were monitored for at least 10 minutes. Mean arterial oxygen saturations (ear and custom made finger and commercial finger pulse oximeters) for each volunteer were calculated from the recorded data. The mean SpO$_2$ value measured using the ear canal probe and custom made finger probe were then compared with the values obtained from the commercial pulse oximeter. The performance of the ear canal probe was assessed by calculating the Pearson's correlation coefficient (r^2). An r^2 value between 0.5 and 1.0 was considered to be statistically accurate.

Fig. 4. Photograph of the ear canal PPG/SpO$_2$ probe placed inside the right ear of a volunteer.

III. RESULTS

Good quality photoplethysmographic signals with high signal-to-noise ratio were obtained from the prototype ear canal probe. Figure 5 shows the red and infrared PPG signals obtained using the ear canal and finger PPG sensors. Although the amplitude of the red and infrared PPGs obtained from the ear canal were slightly smaller than the finger in all the volunteers, the SpO_2 calculated showed good correlation.
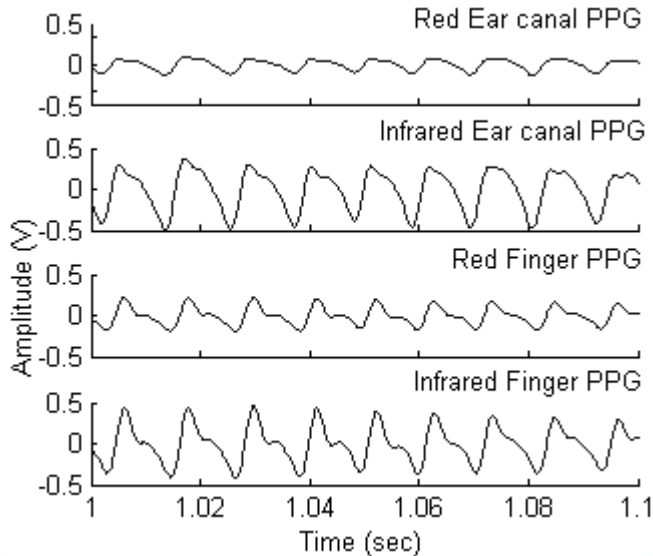

Fig. 5. Shows the red and infrared photoplethysmographs obtained from ear canal and index finger.

Mean arterial oxygen saturation values measured from each volunteer, using the ear canal sensor, finger sensor and the commercial pulse oximeter are shown in Table 1. It can be seen from the table that the SpO_2 values obtained from the commercial pulse oximeter are in good agreement with the custom designed ear canal probe and the finger probe.

Subjects #	Masimo Radical-7 (SpO_2 %)	Ear canal (SpO_2 %)	Index Finger (SpO_2 %)
1	99	100.5	98.7
2	98	98.6	97.3
3	96	97.3	94.8
4	100	99.8	97.6
5	98	98.8	97.5
6	100	100.2	96.8
7	98	99.9	98.8
8	98	100.3	97.2
9	97	99.9	96.9
10	96	97.1	97.8
11	98	98.5	98.1
12	95	96.0	91.0
Mean	**98**	**98.9**	**96.8**
STD	**±2**	**±1.46**	**±2.12**

Table 1.Comparison of SpO_2 values obtained from the commercial pulse oximeter with the custom built ear canal probe and finger probe.

The correlation (r^2) between the SpO_2s calculated from the ear canal probe and the commercial pulse oximeter is 0.825. The correlation between the SpO_2s calculated from the ear canal probe and the custom built finger probe is 0.694. The correlation between the custom built finger probe and the commercial pulse oximeter is 0.632. A total of 60 pairs of SpO_2 values from the 12 volunteers were used to compare the ear and the commercial finger pulse oximeter using a Bland and Altman analysis [11]. Calculations of the bias, estimated by the mean difference (d) and the standard deviation of the differences (s) were performed to assess the degree of agreement between the two pulse oximeters. The bias (d) is the ear pulse oximeter reading minus the commercial finger pulse oximeter reading and was +1.15 % with a standard deviation (s) of 0.88 %. Hence, the limits of agreement for the SpO_2 data (ear and commercial finger) were:

$$d - 2s = +1.15 - (2*0.88) = - 0.584 \%$$
$$d + 2s = +1.15 + (2*0.88) = + 2.9 \%$$

IV. CONCLUSION

An optoelectronic ear canal sensor has been designed for measuring arterial oxygen saturation from the auditory canal. The preliminary results obtained from the volunteer study suggest that the auditory canal could be used as an alternative measurement site for measuring arterial oxygen saturation.

Following all the developmental and evaluation stages the technology will now be used for more rigorous *in vivo* studies in both volunteers and patients.

REFERENCES

[1] J. G. Webster, Ed., *Design of Pulse Oximeters*, 1st ed. Taylor & Francis, 1997.
[2] J. Moyle, *Pulse Oximetry*, 2nd Edition. Wiley-Blackwell, 2002.
[3] P. A. Kyriacou, A. R. Moye, A. Gregg, D. M. Choi, R. M. Langford, and D. P. Jones, "A system for investigating oesophageal photoplethysmographic signals in anaesthetised patients," *Med Biol Eng Comput*, vol. 37, no. 5, pp. 639–643, Sep. 1999.
[4] P. A. Kyriacou, S. Powell, R. M. Langford, and D. P. Jones, "Esophageal pulse oximetry utilizing reflectance photoplethysmography," *Biomedical Engineering, IEEE Transactions on*, vol. 49, no. 11, pp. 1360 –1368, Nov. 2002.
[5] J. Goldman, M. Petterson, R. Kopotic, and S. Barker, "Masimo Signal Extraction Pulse Oximetry," *Journal of Clinical Monitoring and Computing*, vol. 16, no. 7, pp. 475–483, 2000.
[6] S. Vogel, M. Hülsbusch, T. Hennig, V. Blazek, and S. Leonhardt, "In-ear vital signs monitoring using a novel microoptic reflective sensor," *IEEE Trans Inf Technol Biomed*, vol. 13, no. 6, pp. 882–889, 2009.
[7] M. El-Khoury, J. Sola, V. Neuman, and J. Krauss, "Portable SpO2 Monitor: A Fast Response Approach," in *IEEE International Conference on Portable Information Devices, 2007*, pp. 1 –5.
[8] B. Venema, N. Blanik, V. Blazek, A. Opp, and S. Leonhardt, "Advances in Reflective Oxygen Saturation Monitoring With a Novel In-Ear Sensor System: Results of a Human Hypoxia Study," *IEEE Transactions on Biomedical Engineering*, vol. 59, Jul. 2012.
[9] Y. Mendelson and B. D. Ochs, "Noninvasive pulse oximetry utilizing skin reflectance photoplethysmography," *IEEE Transactions on Biomedical Engineering*, vol. 35, no. 10, pp. 798 –805, Oct. 1988.
[10] Anthony F. Jahn and J. Santos-Sacchi, *Physiology of the Ear*. Cengage Learning, 2001.
[11] J. Martin Bland and D. Altman, "Statistical methods for assessing agreement between two methods of clinical measurement," *The Lancet*, vol. 327, no. 8476, pp. 307–310, Feb. 1986.