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The Sensing Endotracheal Tube

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Abstract— Current pulse oximetry sensors are not very well suited to use in anaesthetised patients as it has been shown that during episodes of reduced peripheral circulation they do not function correctly or fail all together [1], [2]. To address this problem a new design for a photoplethysmography (PPG) endotracheal (ET) sensor to monitor pulse rate and oxygen saturation (SpO_2) internally is presented. Flexible printed circuit board (PCB) technology and miniature optoelectronic components have been implemented and integrated with a custom instrumentation system [3]. The sensor adheres and conforms to the curvature of standard french-gauge 7 and 8 ET tubes at the point just above the inflatable cuff within the laryngeal positioning markings. A 3D-modelled, optically clear, soft silicon encapsulation electronically and thermally isolates the electronic components whilst providing a smooth surface to aid the insertion on the ET tube during standard intubation procedures. A pilot study with 5 patients (3 Female, 2 Male), undergoing abdominal and limb laproscopic procedures has demonstrated the operation of the sensing ET tube, showing good quality red and infra-red PPG signals. Preliminary signal analysis reveals heart rate can be measured via PPG successfully, with saturation (SpO_2) readings in close agreement with the commercial monitors of 97.9 % (STD 0.2 %) and 98.6 % (STD 0.8 %) respectively.

I. Introduction

Pulse oximeter probes, placed on the finger or earlobe are used in all cases requiring general anaesthesia for measurement of arterial oxygen saturation (SpO_2). They are not however ideally suited for use in anaesthetised patients, as they have been shown to function incorrectly during episodes of reduced peripheral circulation [1], [2]. Peripheral blood flow is commonly disrupted during surgery, especially during cardiac or other major procedures, by hypotension, vasoconstriction, surgical blood loss or during weaning from cardiopulmonary bypass. Furthermore the probe is susceptible to malpositioning during surgery, for example when the patient is moved (or simply by being bumped or leant on by members of the surgical team).

All of these events can produce incorrect SpO_2 readings [4], [5], [6], [7]. In severe cases, the pulse oximeter may fail altogether, often at times when the patient is in a highly critical condition, i.e. when monitoring is most needed. Lack of continual reliable SpO_2 readings compromises patient safety while efforts to restore monitoring places an unwelcome operational burden on the anaesthetist. Uninterrupted electronic records on patient information systems are increasingly important for effective postoperative care and follow up of adverse events. There is therefore urgent need for improved performance of pulse oximetry in these most vulnerable patient groups.

Current intra-operative monitoring systems require a large number of sensors placed on the body surface including ECG electrodes, blood pressure cuffs, skin temperature sensors as well as SpO_2 probes. These sensors must operate through a layer of skin, fat and muscle and as a result may suffer from compromised accuracy and reliability. Sensors can also be detached accidentally and require multiple connections to the patient monitor using a large number of electrical cables with the potential to be snagged or tripped over, leading to monitoring failures. The connecting cables also complicate and hinder the transfer of patients to theatre, positioning of the patient, placement of surgical drapes as well as the actual surgery.

Pulse oximetry is perhaps the most important development in patient monitoring in the last forty years, however its limitations are well known and well documented. Dark skin pigmentation is known to affect light penetration causing signal detection failures and in some cases, overestimation of oxygen saturation [8]. Pulse oximeters are sensitive to rapid limb movement (e.g. when shivering) [9]. If peripheral perfusion is compromised, as can occur in vascular disease, low cardiac output or simply because the patient is cold, the pulse oximeter may fail [5]. Cardiopulmonary bypass is especially challenging as a viable pulse signal is sometimes absent for long periods as the patient re-warms [10].

Despite improvements in the accuracy of pulse oximetry brought about by advances in signal processing over the last decade or so [11], reliable and dependable SpO_2 readings still depend on adequate peripheral perfusion.

To overcome this limitation, Kyriacou et al. described an internally placed reflectance pulse oximetry system in 2001 that allowed detailed investigation of SpO_2 measurements and the PPG signals, from which the SpO_2 signals are derived [12] from the oesophageal wall. The oesophagus was chosen as a potentially suitable central monitoring site as it is readily accessible in most anaesthetised patients and is perfused directly by main arteries.

An initial clinical study, performed in patients undergoing general anaesthesia showed that reliable signals could be obtained in all subjects, and that the optical pulse signals were significantly larger in amplitude than those obtained from a probe of similar geometry clipped onto the finger. A follow-on clinical study [13], [14] investigated and compared oesophageal and finger PPG signals and SpO_2 measurements in 49 patients undergoing hypothermic cardiothoracic by-

pass surgery. Measurable PPG traces at red and infrared wavelengths were obtained in the oesophagus in all 49 patients. Of the 49 patients included in the study, it was found that five patients had one or more periods of at least ten consecutive minutes during which the commercial finger pulse oximeter failed to display SpO_2 values, despite being correctly positioned on the finger. Conversely, the oesophageal pulse oximeter operated successfully throughout these periods.

Internal sensors offer significant improvements in accuracy and reliability over surface sensors. The wall of the trachea is so-far an unexplored but readily accessible and highly vascularised tissue bed and offers a single central site from which a wide range of clinical variables may be measured. It has been proposed that a new, novel flexible PPG sensor, able to detect the required signals needed for SpO_2 and pulse rate measurements, be utilised to investigate whether the PPG signals from the tracheal wall are suited to this monitoring modality.

II. METHODS

A. Endotracheal Sensor

A custom, flexible, printed circuit board (PCB) and silicone rubber covering were modelled in SolidWorks (Dassault Systèmes, France). The requirement of the sensor to be flexible so that it could be attached to the curved surface of a standard endo-tracheal tube (adult sizes 7 and 8) meant that compromises had to be made on component placement and geometry, most notably the components had to be arranged linearly, with the red LED closer to the photo diode. The centre-to-centre distances of the red and infra-red LED to the photodiode were 7 mm and 13 mm respectively. This may affect the accuracy of SpO_2 measurements as the light is not passisng through the exact same tissue bed. A 3D projection of the sensor head is shown in figure 1. Overall dimensions of the the sensor, including the silicone covering are 435 x 29 x 1.3 mm (L x W x H).

The PCB was manufactured on a polyester film with a thickness of 75 μm (Melinex, DuPont, USA) with a sensor interface at the distal end incorporating one 660 nm (red) and one 940 nm (infra-red) LED (KP-3216 series LEDs, Kingbright, Taiwan) and a broad spectrum (400 - 1100 nm) high sensitivity PIN photo diode (VEMD6010X01,Vishay Semiconductors, USA). The components were bonded to the PCB with a flexible epoxy resin (Light Weld 488-Series, DYMAX, USA) and electrically and thermally insulated with the custom 3D-modelled, clear, silicone rubber covering (Silpuran 6000, Wacker Chemie, Germany). The circuit board was insulated with a UV-cured flexible ink (Electrodag 452SS, Henkel, Germany) and terminated at the proximal end by a 5-pin connector (Crimpfelx, Nicomatic, France).

The completed sensors were designed to be single use devices to ensure maximum patient safety and prior to trials were cleaned, sealed in blister packs and chemically sterilised (ETO procedure) by a specialised sterilisation company. The sensors were also put under a bio-burden test to check for any harmful pathogens or contaminants.
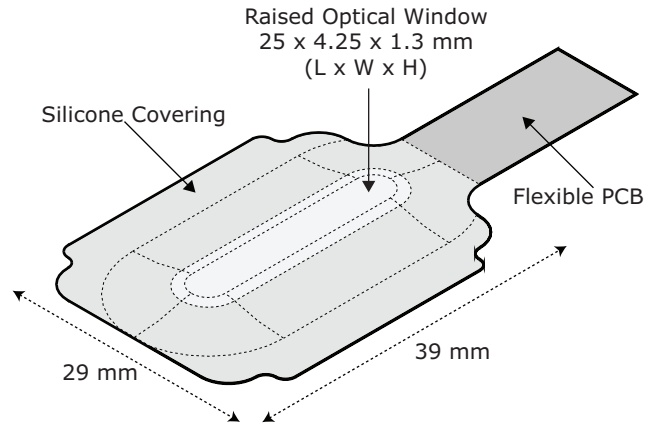

Fig. 1. A 3D model of the distal (sensing) end the ETT sensor, depicting the silicone covering and optical window/cavity for the LEDs and photo-diode.

B. Photoplethysmographic Instrumentation

Custom back-end PPG instrumentation has been developed [3] to drive the active elements of the sensor and process the raw signals ready for data storage on a laptop computer. The PPG device, named ZenPPG by its' creators, has the ability to drive multiple physiological sensors and can be customised for nearly any clinical trial or *in vivo* study. The current configuration, chosen for these clinical trials of the ETT sensor, incorporates two single PPG ports, each with the capability of driving two LEDs and sensing from one photo diode. One port will be used for driving the custom ETT sensor, whilst the other is designed to drive a commercial probe (Masimo, USA) for the purpose of comparison of PPGs from a traditional peripheral location. This is connected to an isolation data-acquisition (DAQ) card (National Instruments, USA) which is in turn connected to a laptop computer running the DAQ software and data-logging software (LabVIEW, National Instruments, USA).

The LabVIEW virtual instrument (VI) developed to run ZenPPG acquires data at a rate of 1 kHz, and can control the individual brightness of individual LEDs on the attached sensors. Data is saved in the form of a text file, and includes the capability to manually stamp the data file with time-markers to aid in the synchronisation of data with events in the clinical trial, i.e. patient movement or the noting down of specific vital readings from the commercial monitors.

C. Pilot Investigation

The planned initial clinical trial has been set up to establish whether or not PPG signals can be obtained from the tracheal wall, and to assess their suitability in pulse rate measurement and SpO_2 estimation. This will be compared with the same readings as taken by the commercial monitors, as well as with a commercial sensor (Masimo, USA) attached to the ZenPPG system.

Five patients (3 Female, 2 Male), mean age 46.6 years (std 16.7 years), mean weight 75.7 kg (std 20.6 kg), were recruited from surgical lists at Bart's NHS Trust, London UK. Each patient was recruited into the study by a GCP (Good

Clinical Practice) trained clinical member of the investigation team. Each recruit was given an information sheet explaining the nature of the study and adequate time to decide (48 hours) if they wanted to participate. A consent form was acquired from willing recruits and after the anaesthetisation procedure an endo-tracheal tube with a pre-attached ETT sensor was placed into the trachea as per normal intubation procedure.

Prior to intubation the sensor was checked for operability (sensor attached to ZenPPG and LEDs operated by software), then adhered to the tube just above the inflatable cuff just past the laryngeal guidance markers. The sensor was situated on the inside curve of the tube so that the sensor would face anteriorly. The sensor was switched on once the patient was situated on the operating table and in a secure position.

Recordings commenced from a time when adjustments to LED intensities were made so that PPG signals from the ETT sensor could be observed on the laptop display from both the infra-red and red channels. Recordings were complimented with manually-entered time markers that were taken approximately every minute. Each marker was accompanied by an SpO$_2$ and pulse rate reading from the clinical monitors for comparison during data analysis.

Recordings were ceased after 1 hour. The ETT sensor was detached from ZenPPG but left *in-situ* for the remainder of the surgical procedure. The sensor was only removed once the Anaesthetist removed the endo-tracheal tube when waking the patient as is normal procedure.

III. RESULTS

Recorded signals were down-sampled and filtered using a 3325th order band-pass FIR filter (0.3 - 5 Hz) in Matlab (MathWorks Inc, USA). Signals were visually inspected and a 5 minute window of good quality signals was selected for preliminary analysis from each patient. Figure 2 shows a typical 20 second trace of the filtered PPG signals observed from the ETT sensor. Notice that the red and infra-red signals display similar amplitude. Signals were then passed through a custom algorithm to normalise and measure the amplitude of the signals.

Normalizing the signals and calculating the amplitude for these 5 minute signals shows that the red and infra-red signals have a mean amplitude of 205.6 mV (STD 292.0 mV) and 437.3 mV (STD 628.3 mV) respectively from the ETT sensor. The commercial sensor attached to the ZenPPG, taking measurements from a periphery location (PER) conversely shows signals with a lesser degree of variance at 103.8 mV (STD 53.4 mV) and 214.4 mV (STD 109.3 mV) respectively for the red and infra-red signals. Figure 3 shows the bar-plot of the amplitude analysis form the individual patients. The large variance seen in the ETT signals as opposed to the PER signals is largely due to the results from the 3rd volunteer who displayed much greater AC amplitudes than the other subjects at 719.4 mV (STD 83.4 mV) and 1544.0 mV (STD 229.3 mV), red and infra-red respectively at the ETT sensor. Interestingly the same patient displayed the smallest normalised amplitude at the
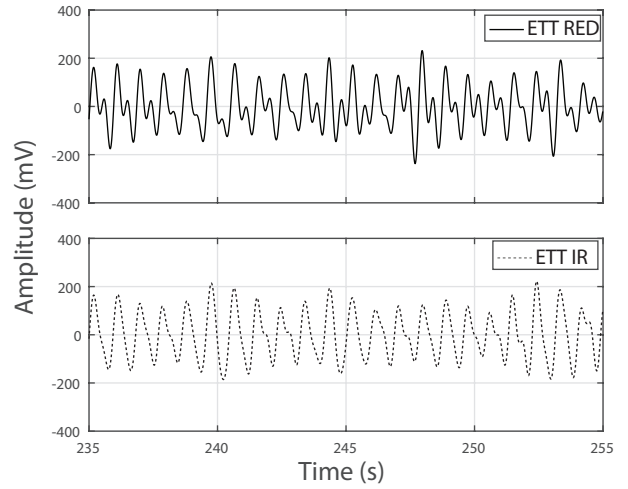

Fig. 2. Red and Infra-red PPG signals from the ETT sensor, 20 second sample, showing good definition of the main PPG peaks in both plots. Average pulse rate = 67 bpm.

periphery location at 61.5 mV (STD 31.74 mV) and 132.7 mV (STD 78.4 mV) for the red and infra-red signals.
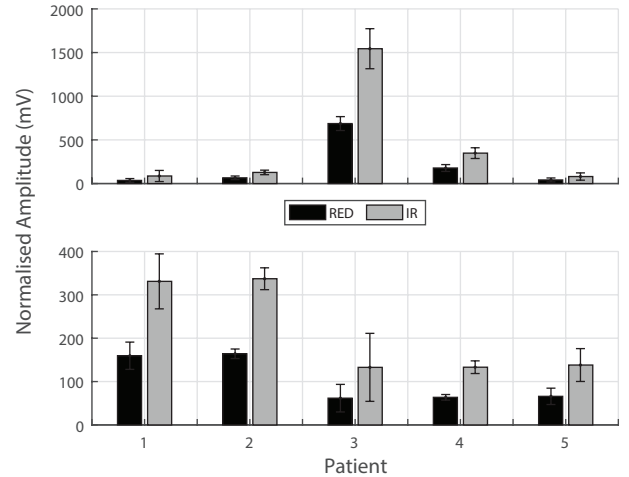

Fig. 3. Mean normalised amplitudes with standard deviation bars for the ETT sensor (top) and PER sensor (bottom), total signal length per patient = 5 minutes.

Consideration now has to be taken for what these signals can reveal about the health of the patient. All signals were analysed in 10-second segments, and either passed through a custom algorithm that calculated pulse rate via fast-Fourier-transform method and SpO$_2$ using the method set out in [15] and shown in equation 1 and 2.

$$SpO_2 = 110 - 25R \tag{1}$$

where...

$$R = \frac{AC_{red}/DC_{red}}{AC_{ir}/DC_{ir}} \tag{2}$$

The results were compared with the timestamps from the original data file, and each patient over the 5 minute window

had between 5 and 7 time-stamps available in that time period. The mean vital statistics for pulse rate and oxygen saturation (n = 30) show good agreement with the clinical readings at 63.2 bpm (STD 12 bpm) and 97.9 % (STD 0.6 %) vs. 63.0 bpm (STD 12.4 bpm) and 98.6 % (STD 0.8 %) for the ETT sensor and the clinical readings respectively. The reference peripheral sensor meanwhile confirms this observation at 63.2 bpm (STD 11.6 bpm) and 97.9 % (STD 0.2 %) for the same time period. The observed means for each patient can be seen in figure 4.
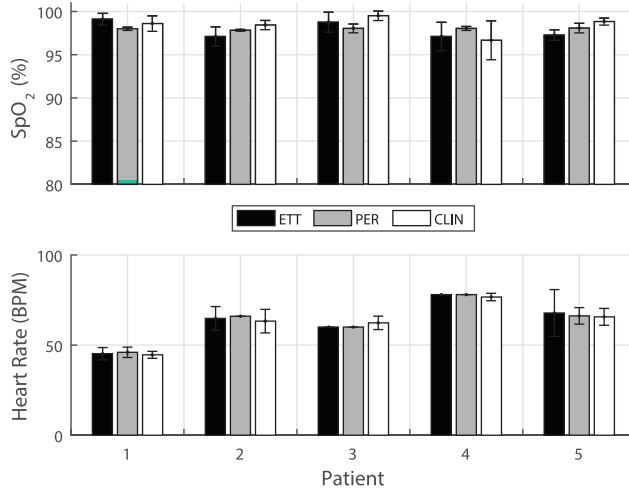

Fig. 4. Mean vital statistics for each patient with all three sensors, SpO_2 top, and heart rate (PPG-derived) bottom.

IV. DISCUSION

The filtered signals from the ETT sensor, before normalisation, regularly displayed red PPG signals of similar or sometimes greater amplitude than the infra-red signals. For sensors where the estimated light path of the illuminating light is thought to be equal for both wavelengths, the infra-red signal AC amplitude is normally observed to be 2 - 2.5 times greater. Generally it is not considered best practice to design a sensor where the light path for both signals is different as different areas of differently-oxygenated tissues may be illuminated that could affect the overall SpO_2 estimation.

As pointed out in section II-A a compromise had to be made on component selection and placement due to the materials being used and the components available. When the signal is normalised, however, the expected average red/infra-red ratio between the AC amplitudes is observed in all patients.

In this trial it has been shown that with normalisation of the AC signals the estimated SpO_2 is very close to the clinical reading, and on average 0.7 % less, with a similar variation. This is confirmed by the reference probe connected to the same measurement system, and therefore any inaccuracy in the readings may solely be down either to the sensor placement or the algorithms used for SpO_2 estimation. Since the commercial monitors all use proprietary algorithms it is

impossible to know what averaging is being done on the observed SpO_2 value, and therefore it may the case that this sensor with this component configuration needs specific calibration.

Heart rate estimates do not rely on specific areas of tissue being illuminated, except that an arterial pulsatile component is present so that a frequency analysis can be performed via FFT so that HR can be calculated. In this regard the ETT sensor has shown to be as accurate as the commercial sensor, with a slightly higher variance, but this may be due only to the specific averaging routine carried out on the HR estimate on the commercial monitors.

The third patient was observed to have much greater ETT signal amplitudes than the other 4 patients. Whilst it is desired that large amplitude signals are acquired from subjects, it is not necessarily translatable to vital sign monitoring that is either more accurate or with less variance. In-fact the individual SpO_2 estimation for this particular subject was on average -1.9 % lower, whilst the remaining subjects were -1 % or less.

V. CONCLUSION

A larger pilot study to confirm the accuracy and produce the efficacy needed to prove this technology is needed. In this pilot investigation, however, the required PPG signals have been proven to be of suitable quality to calculate heart rate and SpO_2 effectively.

Vital-signs monitoring from the trachea using specially designed sensors appears to be a viable alternative to traditional monitoring solutions, and has the potential to compliment or replace traditional sensors in clinical (surgical or ICU) use where traditional sensors may be known to present difficulties during placement or during use.

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