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Development and Testing of an Artificial Arterial and Venous Pulse Oximeter

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***Abstract*— The monitoring of patients healthcare is of a prime importance to ensure their efficient and effective treatment. Monitoring blood oxygen saturation is a field which has grown significantly in recent times and more specifically in tissues affected by diseases or conditions that may negatively affect the function of the tissue.**

This study involved the development and testing of a highly sensitive non-invasive blood oxygen saturation monitoring device. A device that can be used to continuously monitor the condition of tissue affected by diseases which affect the blood flow through the tissue, and the oxygen usage in tissue. The device's system was designed to specifically monitor occluded tissue which has low oxygen saturations and low perfusion.

Although with limitted validation the system was unable to accurately measure the venous oxygenation specifically, but it was able to measure the mixed oxygen saturation. With further research it would be possible to validate the system for measuring both the arterial and venous oxygen saturations.

I. Introduction

The monitoring of patients in the healthcare system has become a top priority to ensure efficient and competent treatment. There are numerous devices which are used in a clinical setting to monitor the health of patients, such as electro-cardiograms, endoscopes, ultrasound scans and blood pressure monitors to name but a few of the most common devices. These devices are used to monitor patient health as well as to aid in the patient diagnostics.

An important clinical technique is the monitoring of oxygen saturation in living tissue, which can be performed through non-invasive, in-vivo examination of the tissue, and is of interest in many areas of medicine and physiology [1]. The Pulse Oximeter (PO) is an example of the aforementioned monitoring technique and is commonly used to measure the oxygen saturation in blood and the changes of blood volume flowing through the tissue. One of its chief uses is in determining the effectiveness of and the need for supplemental oxygen.

The objective of this study was to research and investigate the possible methods to accurately determine blood oxygen saturation (SO_2). And determine a method to monitor the saturation of occluded tissue.

When monitoring occluded tissue using conventional Near Infrared Spectroscopy (NIRS) methods, a major limitation is that the tissue under question generally lacks a clearly identifiable AC component created by the pulsating arterial blood. This causes some difficulties when trying to determine SO_2 by using Aoyaki's ratio of ratios [2,3], which requires both AC and DC signal components to be prevalent in photoplethysmograph (PPG) signals. A method to overcome these shortcomings is required. Equation 1 shows how Aoyaki's ratio is calculated [3,4].

$$R = \frac{AC_r/DC_r}{AC_{ir}/DC_{ir}}$$

To effectively monitor the saturation the developed sensor is required to be highly sensitive over a wide range of saturation levels, as a possible application of the device would be for the use in monitoring tissue infected with diseases such as Meningococcemia [5,6], where tissue saturation is generally low.

The development of the system underwent the following processes to develop, evaluate and determine the viability of the system:

1. Concept generation and development for an efficient design.
2. Design and manufacture of a highly sensitive blood oxygen saturation sensor that is capable of non-invasively measuring saturation values in occluded peripheral tissues.
3. *In vitro* data collection using the designed system in a laboratory setup in conjunction with a customly developed tissue simulator.
4. *Porcine* calibration of the device and data collection during the initial testing stage (8 porcine specimens).
5. Human *in vivo* data collection with the prototype in a clinical setup. 15 volunteers were selected from patients receiving elective surgery at Tygerberg Hospital.
6. The interpretation of the *in vitro* and *in vivo* data collected, using a haematology system.
7. The calibration of the prototype using the interpreted data and reference saturation values provided by the haematology system.
8. *Statistical analysis* of the calibrated prototype to determine viability of the concept in a clinical setting.

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Through concept generation and preliminary studies it was decided that the focus of the study would be on further developing the current pulse oximetry system to suit the requirements set forth by the objectives of the study.

However, there are numerous shortcomings and limitations faced by conventional pulse oximetry [7,8,9], these include physiological-, signal processing-, substance interference- limitations and limited medical staff understanding and knowledge; all of which can cause inaccurate or incorrect readings. These limitations needed to be carefully considered and mitigated to ensure an effective device.

II. Device Development

As mentioned earlier in this document, all existing systems that are currently being used to non-invasively measure blood oxygen saturation are either dependant on a clearly detectable AC component in the photoplethysmograph, or provide inaccurate measurements due to factors such as oedema or thicker skin in older patients. The system proposed and developed aims to overcome these problems by integrating selected characteristics of the existing systems with a novel system that is able to overcome the fundamental problems associated with the absence of an AC component.

A. First Prototype

The first prototype of the proposed system was focused around the initial development of a system [10], which could be used to monitor patients suffering from ischemic conditions causing low perfusion such as meningococcemia, which often spreads rapidly where due to low arterial oxygen saturations (S_aO_2) readings pulse oximetry has had limited success as a monitoring tool. The study attempted to address these limitations by developing an Artificial Pulse Oximeter (APO) capable of accurately measuring both S_aO_2 and the venous oxygen saturation (S_vO_2) in low saturation and perfusion scenarios.

An 'Artificial Pulse Generator' (APG) was integrated into the design to overcome the absence of the AC component in the PPG signal by generating an artificial pulse in the tissue. S_aO_2 and S_vO_2 were calculated according to an arterio-venous hypothesis dependent on the arterial-to-venous compliance. Schoevers calibrated the APO by performing an empirical in-vitro calibration approach, and validated the results by performing an in-vivo clinical study [10].

Figure 1. First system prototype of the APO

Schoevers' results were neither comprehensive nor entirely conclusive, but it was hypothesized that with further development of the APO system, an accurate determination of S_aO_2 and S_vO_2 would be possible.

B. Second Prototype

Besides the further development of a multi-wavelength pulse oximeter and a more accurate APG, a small synchronized ECG and respiratory sensors were developed to run in conjunction with the rest of the system to be able to monitor and validate the other physiological parameters. The respiratory sensor was used to calibrate and test the measurement of respiratory rate determined by the pulse oximeter. An accelerometer was also added to the finger probe to monitor motion in the area of the probe.

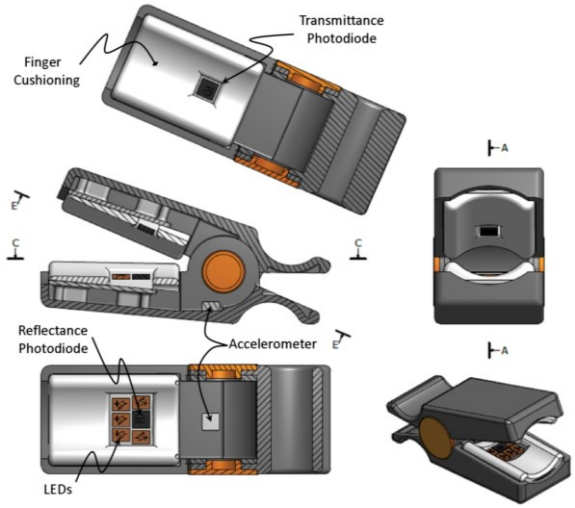

Figure 2. Finger probe layout

The prototype system using the selected concept was then developed and manufactured to overcome abovementioned problems in currently available pulse oximeters and to achieve the goals as set forth by the studies objectives. The developed system included a five-wavelength pulse oximeter including both reflective and transmittance photodiodes. The finger sensor layout can be seen in Figure 2.

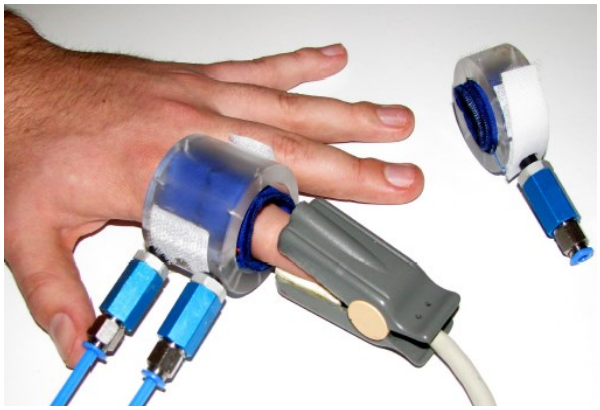

Figure 3. Artificial Pulse Generator and finger probe on a subject

However, the artificially generated pulse in the blood and tissue of the finger is the basis upon which Artificial Pulse Oximetry (APO) is based. In a scenario where there is low perfusion or the tissue is occluded, an artificial pulse generates an AC component in the PPG signal, which can thus be used to determine the mixed blood oxygen saturation. Furthermore, in a scenario were there isn't low perfusion and there is thus a pulsatile component generated by the cardiac

output in the tissue, it would be possible to get a comparison between the PPG generated by the arterial component of the blood to that of the PPG signal generated the APO i.e. the mixed movement of both the arterial and venous components.

Figure 3 shows the manufactured finger cuff system and probe.

The developed system met the requirements set forth by the functional analysis by being able to generate an artificial pulse, drive two photodiodes and five LEDs as well as monitor heart and respiratory rates.

III. System Testing

To test, calibrate and validate the system three different testing models where evaluated and developed namely:

A. *In-vivo Porcine model*

To perform a validation and calibration of the designed system, it was decided to perform an in-vivo animal test setup to compare the testing technique to that of other studies, including that of Aoyaki's in-vitro test setup (Edrich *et al*., 2000). However many physiological limitations were faced during animal experimentation, the results of which provided a testing base line but where ultimately inconclusive. The results were compared and analyzed against the in-vitro test setup.

B. *In-vitro laboratory testing model*

The in-vitro technique employed in this study was an expanded and modified version of that used in the studies performed and discussed by Edrich et al. in 2000 [11]. The modified in-vitro setup consisted of two identical sub-circuits, namely the arterial and venous simulating loops. The arterial circuit was used to calibrate the sensors for conventional pulse oximetry i.e. localised analysis of only the arterial saturation. The combined circuits of both the arterial and venous loops was used to verify and calibrate the overall absorption and reflection of two blood volumes which differ in oxygen saturation levels i.e. both arterial and venous volumes. The calibration procedure was divided into two phases, namely conventional arterial calibration and arterio-venous validation.

C. *Human clinical testing model*

The final stage of the study was to perform a descriptive and comparative case control study that could be used to verify and validate the prototype system. The clinical trial was performed on each volunteer during elective surgery where the limb was to receive a tourniquet for the purposes of the surgery.

The pulse oximeter was placed on the patient's finger and the inflatable cuff was wrapped around the same finger (in most cases the index finger). The subject was asked to keep their body movement to a minimum during the test procedure. The APO was then used to take baseline measurements of the patient's oxygen saturation and a blood sample was taken, to be used in a blood gas analyzer to obtain a valid reference value for the oxygen saturation. The test setup is shown in Figure 4.

The tourniquet was then inflated to a pressure sufficient to cut off all normal blood circulation to the subject's hand. This is to simulate the occluded nature of affected tissue. A short period of time was allowed for the saturation value in the tip of the finger of interest to decrease to a suitable value.

IV. Results

Through testing it was found that the transmittance photodiode had a larger level of ambient noise, caused by increased scattering through the tissue as well as an increased susceptibility to ambient light. The signals where filtered and optimized for the necessary usage in the system.

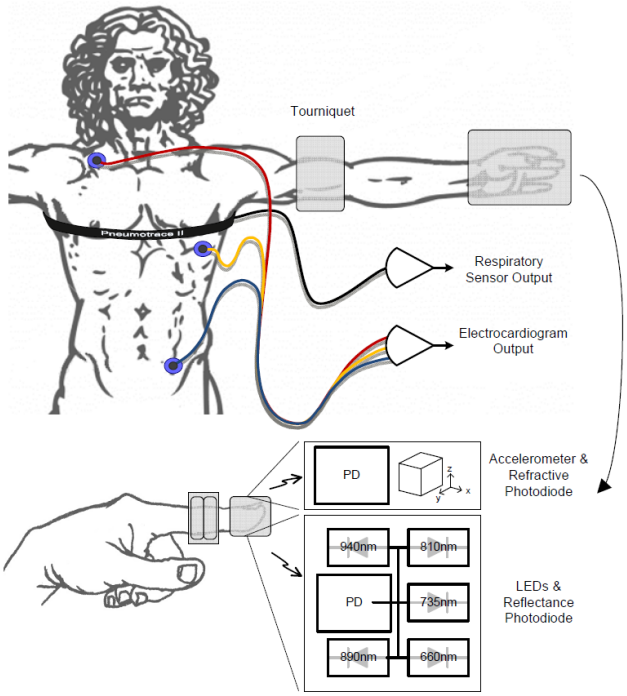

Figure 4. Clinical study – test settup

The signal quality from the ECG and respiratory sensors was good with minimal noise. However placement of the respiratory probe proved to be a critical factor, as the inductive strap was susceptible to over stretching that induces error signals.

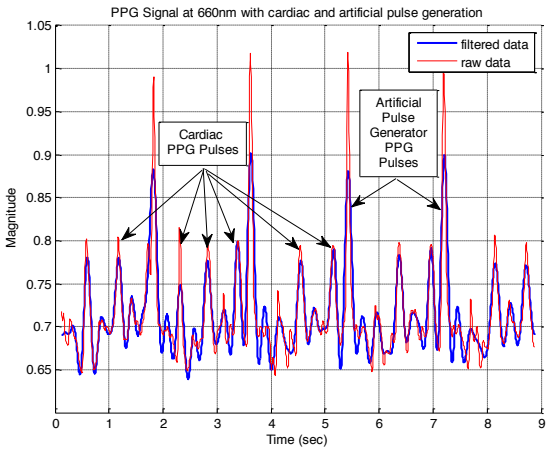

Figure 5. Generated PPG signals showing cardiac and artificially generated pulses

With the APG engaged, in non-occluded tissue, both the cardiac output pulses (heart beat) and artificial pulses are clearly discernable (Figure 5), the cardiac pulses are verified by the ECG signal and likewise the artificial pulses are generated by the microcontroller, thus their positions can be controlled and extrapolated. Figure 5 illustrates the difference in magnitude of the cardiac and artificial pulses.

With all of the data collected from the different calibration techniques, a comparison of the data and calibration curves was required. The data analysis performed on the in-vitro and clinical testing was of mixed oxygen saturations with tissue effects; whereas the data obtained in the porcine study was for a purely arterial signal. Figure 6 (top) shows the calibration curves developed by the different test setups. Through categorization, the arterio-venous absorption compliance was determined to be in an order of 1.5, and applied to the calibration curve it is modified to the form plotted in Figure 6 (bottom), which shows the average curve fits for all the data. The bias differences of the curves can be attributed to the differences in tissue and simulated tissue absorption. By normalizing the calibration curves to the levels of the clinical testing, the slope correlation between the curves can be compared to determine the effectiveness of the different calibration procedures.

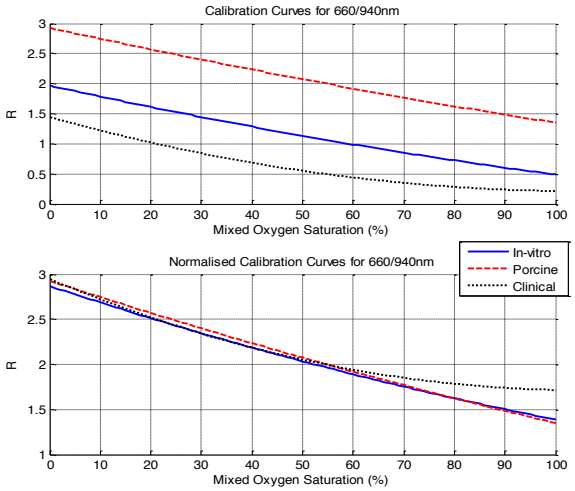

Figure 6. Calibration curves generated by different testing techniques, where R is a normalised calculation of Aoyakis Ratio.

Through experimentation and testing of the different testing models a correlation between the calibration curves was developed, however within the data collected there was a large degree of scatter in each of the different is testing models. This low confidence interval needs to be improved by performing further studies and improving the signal extraction algorithms. But this type of inaccuracy has been observed in numerous types of commonly used pulse oximeters even in the optimal range of SO_2>85% [12].

However, even with the large possible error in the results the study has shown it is possible to artificially generate a regular pulse in occluded tissue, and thus make it possible to measure the oxygen saturation non-invasively through pulse oximetry, which was previously not possible.

V. Conclusion

Testing of the APO proved that it was possible to artificially generate a repeatable pulse in fully occluded tissue and can be used to calculate the oxygen saturation in low saturation scenarios. The initial results showed the system to have a relatively high error, but with further testing and the improvement of calibration techniques the accuracy of the device can be improved.

Through testing of the developed device it was found that making use of the multiple wavelengths may provide valuable data about the tissue being monitored but further research and system development would be required to fully utilize the extra data.

In conclusion, though the results of the study do not prove to be the most accurate with the limited testing performed, it was shown that it is possible to non-invasively measure the oxygen saturation in occluded tissue and improve the performance of oximeters during low saturation scenarios. With alternative clinical validation techniques it would be possible to calibrate the system for both S_aO_2 and S_vO_2, though in this study the accuracy of such results are still inconclusive. Further testing and data collection will be required to optimize S_vO_2 calculation techniques.

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