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Development of a Reflectance Photoplethysmographic Sensor used for the Assessment of Free Flap Perfusion

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Abstract— **Monitoring of free flap perfusion and early identification of flap failure is an indispensable prerequisite for flap salvage. Although many methods of free flap monitoring are available, there is still no single reliable continuous non-invasive perfusion monitoring technique which will also assist in the early recognition of flap failure. In order to overcome the current technological limitations, we have developed a multi-wavelength photoplethysmographic (PPG) sensor and processing system to systematically investigate the perfusion mechanism in flaps used in reconstructive plastic microsurgery. The new prototype reflectance photoplethysmographic sensor was evaluated on three anaesthetized patients undergoing elective breast reconstructive (Deep Inferior Epigastric Perforator Flap) surgery. PPG signals were successfully obtained pre-operatively, intra-operatively and post-operatively. These preliminary results suggest that a PPG sensor may be a suitable method for evaluating the perfusion of free flap.**

I. Introduction

Following mastectomy for breast cancer a wide variety of techniques are currently available for post mastectomy breast reconstruction. One of the most common techniques used is Deep Inferior Epigastric Perforator (DIEP) free flap, which has proven to be a major advancement in transferring lower abdominal tissue for autologous breast reconstruction. The DIEP flap has the least donor-site morbidity and will cause less postoperative pain than some of the other breast reconstructive methods [1-2]. However, it has fewer perforating vessels, thus resulting in reduced blood supply to and from the DIEP flap, so fat necrosis and partial flap loss are more common [3]. Postoperative ischemia due to arterial occlusion, or more commonly, venous occlusion, is the most common cause of failure in microvascular free flaps.

The deep inferior epigastric perforator (DIEP) flap is based on the deep inferior epigastric vessels, an artery and vein at the bottom of the rectus abdominis muscle. These vessels provide the primary blood supply to the skin and fat of the lower abdomen.

The successes of such procedures depend strongly on the maintenance of adequate perfusion in the flap. Early diagnosis of ischemia and surgical exploration to restore blood flow can often salvage the flap and may prevent graft failure. Therefore a continuous method for monitoring perfusion of the flap would assist in early detection of inadequate blood supply. Several techniques and monitoring devices have been used for assessing tissue perfusion postoperatively in an attempt to find one that is non-invasive, accurate, continuous, easy to use, reproducible and inexpensive.

Examples of monitoring devices and techniques used for assessing flap perfusion include Doppler ultrasonography, plethysmography, temperature monitoring, tissue pH monitor, transcutaneous oxygen monitoring, laser Doppler flow meter, near infrared spectroscopy (NIRS) and many more. All of these techniques share advantages and disadvantages, as well as have limitations that prevent their routine application for monitoring perfusion in free flaps such as being heavily operator dependent, time consuming and expensive. Therefore, to date there is no widely accepted and readily available intra-operative or postoperative technique to reliably assess the viability of free flaps.

Due to these limitations most clinical centers rely on intermittent clinical observations which are not standardized, can be unreliable and are also dependent on many factors including ambient lighting and individual bias.

One of the techniques used for monitoring free flap perfusion is photoplethysmography (PPG). Photoplethysmography is an optical measurement technique that can be used to detect blood volume changes in the microvascular bed of tissue [4].

There have been some studies of free flap perfusion (animals or humans) using photoplethysmographic systems [5-7]. The majority of these studies have not been performed in a systematic way to complete evaluation of DIEP flap perfusion from the intra-operative to the post- operative stages. The main effort of most of these studies was to detect arterial or venous occlusion by deliberately clamping the vessels intra operatively. Also, the majority of the previous attempts used PPG sensors that were not custom made for such applications and prolonged continuous post operative monitoring.

In an attempt to overcome the limitations of the current techniques for measuring flap perfusion, this paper describes the design, development and preliminary *in vivo* assessment of the sensor and the processing system using the principle of reflectance photoplethysmography.

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II. METHODS

A. Photoplethysmographic Sensor

A new reflectance, multi-wavelength photoplethysmographic sensor was developed (Figure 1) which consisted of two infrared (IR) and two red (R) ceramic chip surface mount LEDs (peak emission wavelengths at 940 nm and 660 nm respectively) and a photodiode (single photodiode with an active area of 7.5 mm^2 with spectral range sensitivity between 400-1100 nm). A diagram of the developed sensor is shown in Figure 1. The distance between the LEDs and the photodiode was 5 mm as such distance has been proven to provide good quality PPGs in reflectance pulse oximetry [8]. The shape of the sensor was circular and designed to be small enough in order to be accommodated on the exposed part of the DIEP flap during and after the operation. The sensor was coated and UV cured using medically graded clear epoxy in order to provide adequate shielding and to minimize excess electrical impedance caused by direct skin contact and also to avoid any damage to the optical components of the sensor.

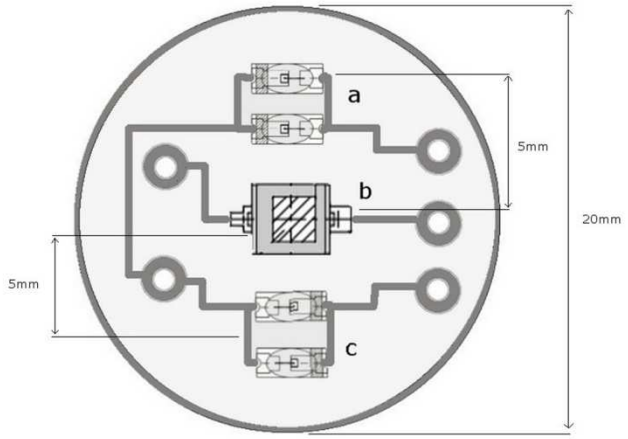

Fig. 1. Reflectance photoplethysmographic flap sensor; a: IR surface mount LED; b: PIN photodiode in miniature flat plastic package; c: Red surface mount LED.

Undesired scattered light reflections from the surface of the flap, as well as direct light paths between the LEDs and the photodiode, were minimized by optically shielding the LEDs and photodiode inside the sensor assembly. The flap sensor was designed using printed circuit board (PCB) technology utilizing the commercial software package Altium Designer (Altium Limited, Sydney, Australia) [9].

B. Processing System

A battery powered processing system has been designed and developed to drive the optical components of the photoplethysmographic sensor and also to detect and pre-process the red and infrared ac and dc PPG signals. Digitization of the acquired signals was then achieved using a 12-bit data acquisition card (DAQCardTM-6024E) by National Instruments. A Virtual Instrument (VI) implemented in LabView was also developed. The VI is used for the acquisition, displaying, analysis and storing of all acquired PPG signals. A block diagram of the processing system is shown in Figure 2.

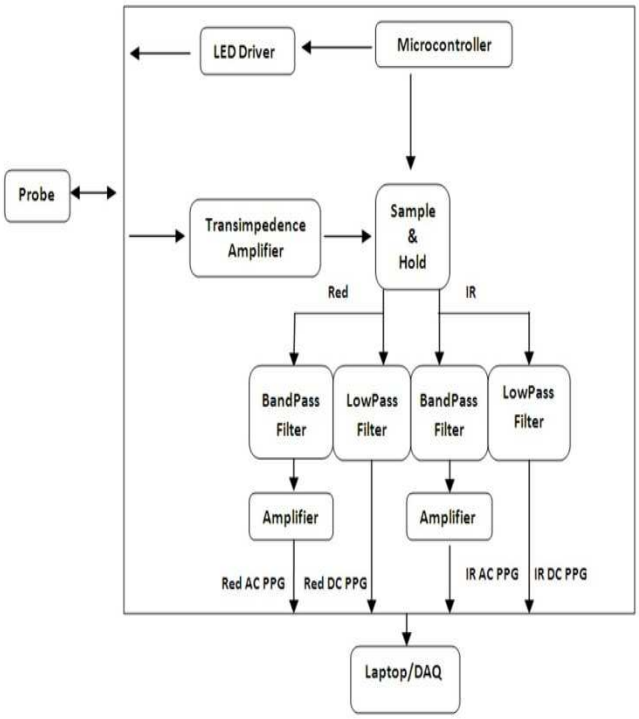

Fig. 2. Block Diagram of the processing system.

The LEDs, red and infrared, are driven by two independent LED drivers. The processing system allows the flexible adjustment of the driving currents on demand. A programmable microcontroller (AVR ATtiny2313) was programmed to generate two timing signals at a frequency of 100Hz in order to control the LED drivers so at no time both LEDs were on. The photodiode detects the energy backscattered by the tissue and gives an output current proportional to the intensity of the light detected. The detected current is then converted to a voltage using a transimpedance amplifier. The output of the transimpedance amplifier contains mixed PPG signals corresponding to red and infrared wavelengths. This signal is then passed through sample and hold which is synchronized to the clock signals used to switch the LEDs on/off, which separates the red and infrared signals. These signals are then filtered to extract the ac (bandpass filter) and dc (lowpass filter) PPG components for each wavelength. Both ac PPG signals are then amplified before digitization. The output PPG signals are then digitized and further analyzed by the LabView VI on a laptop and the DAQCard. PPG traces corresponding to infrared and red wavelengths are obtained simultaneously and displayed on the personal computer screen. All acquired signals are also saved in text format for further post processing and analysis.

C. Preliminary Investigation of Free Flap Sensor

Approval from the Ethics Committee was obtained to

study patients undergoing DIEP surgery. The preliminary clinical trials were carried out at St Andrews Centre for Burns and Plastic Surgery at Broomfield Hospital, which is one of the biggest regional specialist Plastic Surgery Units in the UK. Research & Development and individual surgeons' approval was also acquired from the Centre. In addition, informed consent was obtained from each patient prior to the surgery.

Pilot investigations were carried out to test the functionality of the PPG sensor. To ensure the safety of the patient the PPG sensor was placed inside a sterile transparent adhesive film dressing (3M^{TM} Tegaderm^{TM} Film) and for intra-operative readings the multicore cable, which connects the sensor to the processing system was also covered using a sterile camera sleeve (EASI-DRAPE, Leonhard Lang ^{LTD}). In all instances the sensor was taped onto the skin surrounding the flap. Intra-operative sterile tape (Op-Tape, Winner Medical Group Inc) was used and Pre and post-operative surgical tape (3M^{TM} Transpore^{TM}) was used to secure the sensor to the flap.

The first PPG measurements took place pre-operatively at the donor site (lower abdominal region) after the patient was anaesthetized. The second PPG measurement took place in the operating room as the flap was re-perfused (release of the arterial and venous clamps) in its final position (in the recipient site). During these measurements the sensor was attached to the exposed skin of the flap. The main effort of these measurements was to capture the reperfusion of the flap.

Post-operatively the flap was monitored intermittently with the custom made PPG sensor. These intermittent PPG measurements followed the routine clinical observation intervals of the flap by the surgical team and were as follows; every 15 minutes in approximately the first two hours (case dependent), every 30 minutes for the following four hours and hourly for the next 12 hours. During these measuring intervals the PPG sensor was positioned on the flap (taped) and PPG signals were acquired for approximately two minutes at each interval.

III. Results

Photoplethysmographic signals were successfully recorded at all stages of the flap operation.

A. Pre-operative Measurement

A pre-operative measurement was taken from the donor site (abdominal area). Figure 3 shows a typical IR ac PPG signal with large amplitudes and high signal to noise ratio.

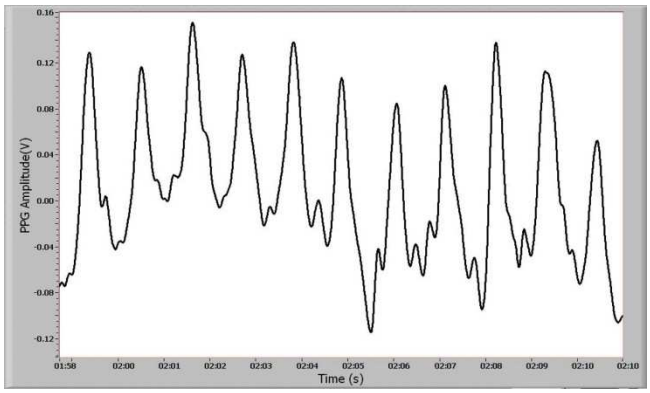

Fig. 3. Pre-operative IR ac PPG from donor site (lower abdomen).

B. Intra-operative Measurement

Following anastomosis of the vessels of the free flap to the recipient site, arterial and venous clamps were removed thus resulting in blood flow through the free flap. Figure 4 depicts the PPG signals before and after the release of the arterial clamp. In the first section of Figure 4, a low amplitude noise can be seen (no PPG was observed). As the clamps were removed at approximately 01:50 seconds (see Figure 4) a noticeable rise in the amplitude was observed and within the first minute after the clamp removal the PPG signals increased in amplitude which suggests the successful reperfusion of the flap.

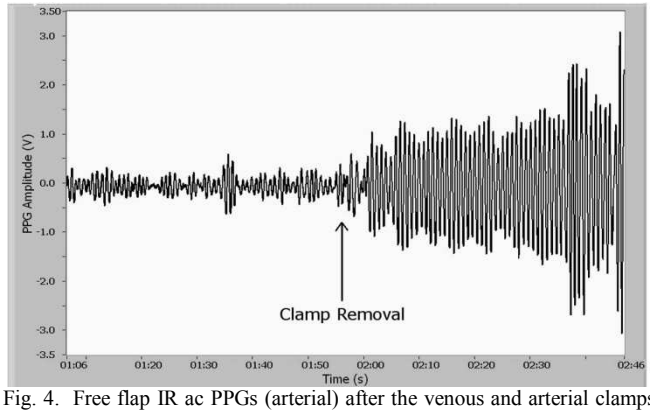

Fig. 4. Free flap IR ac PPGs (arterial) after the venous and arterial clamps were removed.

Figure 5 shows a 10 second period of IR ac PPGs following clamp removal.

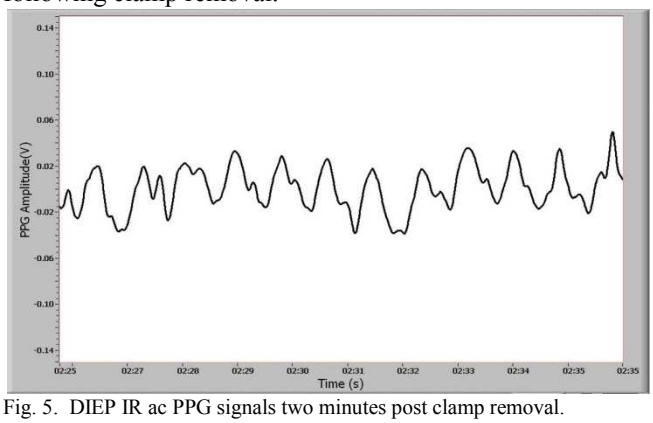

Fig. 5. DIEP IR ac PPG signals two minutes post clamp removal.

C. Post-operative Measurement

Good quality post-operative PPG measurements were also obtained. Figure 6 shows typical ac PPGs at both wavelengths (red and infrared). It can be observed that the PPG signals are slightly modulated by a spontaneous breathing artifact.

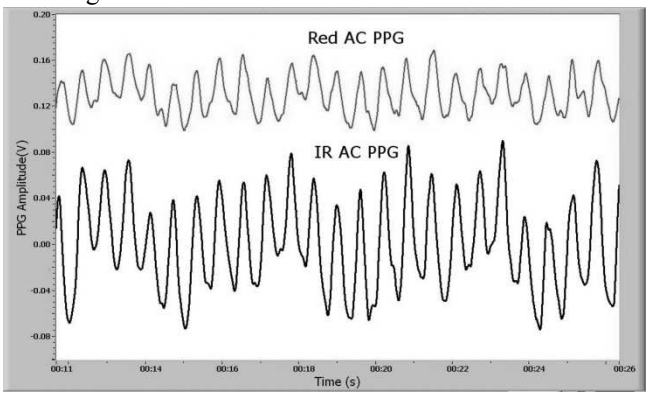

Fig. 6. Post-operative Red and IR ac PPG signals from the DIEP flap.

IV. Conclusion

A multi-wavelength photoplethysmographic flap perfusion sensor and processing system has been successfully designed and developed. The system was used in preliminary clinical trials for pre-operative, intra-operative and post-operative measurements. Good quality photoplethysmographic signals, which act as a good indicator of good perfusion, from the free flaps were acquired during the operation and in the postoperative period. This seems to be the first time that a multi-wavelength (red and infrared) PPG system has been used for monitoring PPG in flaps simultaneously. The acquired red and infrared PPGs provide the advantage of estimating blood oxygen saturation continuously in these flaps.

In conclusion, this work details the design and development of a new free flap photoplethysmographic sensor, and presents preliminary clinical measurements. The results of this pilot study suggest that such technology has the potential to be used for the assessment of flap perfusion (pre-operatively, intra-operatively, and post-operatively). Clinical trials are currently underway in order to evaluate the technology further and investigate flap perfusion more rigorously.

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