Design and Development of Continuous Cuff-less Blood Pressure Monitoring Devices

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***Abstract*—Due to the global hypertension epidemic, a convenient, miniaturized, and cuff-less blood pressure (BP) monitoring device is desirable. During the past several years, we have attested various studies to acquire BP indirectly via pulse transit time (PTT) obtained from electrocardiogram (ECG) and photoplethysmogram (PPG). Towards this end, some progress has been achieved but the prospect of designing a device that requires neither a pressure cuff nor cross-body contact of ECG electrodes has been uncharted. In this paper, we present two approaches to determine PTT which open the door to convenient, non-invasive, and cuff-less wearables for continuous BP monitoring at home settings. The first device was designed with contact-electrode ECG and PPG sensors, located on the bicep and the ear; while the second one, which is a wrist-worn device, consisted of a non-contact ECG circuit and a piezoelectric pulse sensor. Results indicated that our novel designs enable next-generation devices, providing essential continuous BP monitoring off-the-clinic for hypertension patients as well as healthy people.**

Keywords—cuff-less; continuous BP; ECG; PPG; PTT.

I. INTRODUCTION

Uncontrolled high blood pressure (BP) or hypertension (HTN) is a common condition leading to serious cardiovascular complications. About 67 million American adults (31%) are affected by hypertension, and of those only 47% have controlled hypertension [1]. Instead of relying on periodic doctor's visits to measure BP, home-setting BP monitoring is of interest to save time and to reduce cost and labor. However, the conventional cuff-based devices are cumbersome and lack integration capability with electronics of modern smart devices. While cuff-based devices are improving, there is yet-undisclosed potential in cuff-less BP monitoring technology [2]. The recent advances in electronics and wireless technology pave the way to develop cuff-less, non-invasive BP monitoring wearable devices that can monitor patients continuously, without interrupting daily activities. The underlying principle of these devices is based on algorithms to process the time delay between the coupling cardiac electrical and mechanical signals obtained at a peripheral organ, namely pulse transit time (PTT). To date, PTT has been usually determined using simultaneous recording of electrocardiogram (ECG) and photoplethysmogram (PPG), as can be seen in **Fig. 1b** [3]. Alternatively, PTT can also be evaluated using ECG and radial pulse at peripheral arteries (**Fig. 1c**). Most of the ECG approaches require a cross-body configuration where a device worn on one arm must make contact with the other arm, thus limiting continuous measurement [3, 4]. This calls for the development of a continuous BP monitoring device which is reliable, unobtrusive, and comfortable.

In this paper, we propose two devices which can provide continuous BP monitoring. The development of these devices includes innovative designs and a new approach to acquire PTT. The first one, which shall be henceforth referred to as the bicep-worn device, presents a novel configuration for BP monitoring which is akin to a common way people wear a music player and earbuds while exercising. The second, which would be seen as a wrist-worn device, is worn entirely on the wrist. In the first approach, PTT is extracted via the time delay between ECG and PPG; whilst the wrist-worn device exploits data from non-contact ECG and radial pulse. For comparison purposes, various mathematical models were deployed to obtain BP data from PTT measurements. A wireless module was used to send the data to a remote computer. The conceptual design of both devices is illustrated in **Fig. 1a.**

II. DESIGN AND IMPLEMENTATION

We implemented two proof-of-concept wireless continuous BP monitoring devices, namely the bicep-worn device and the wrist-worn device. For both cases, the commercial-off-the-shelf (COTS) module EZ430-RF2500 (*Texas Instruments-TI*) was utilized for wireless communication demonstration.

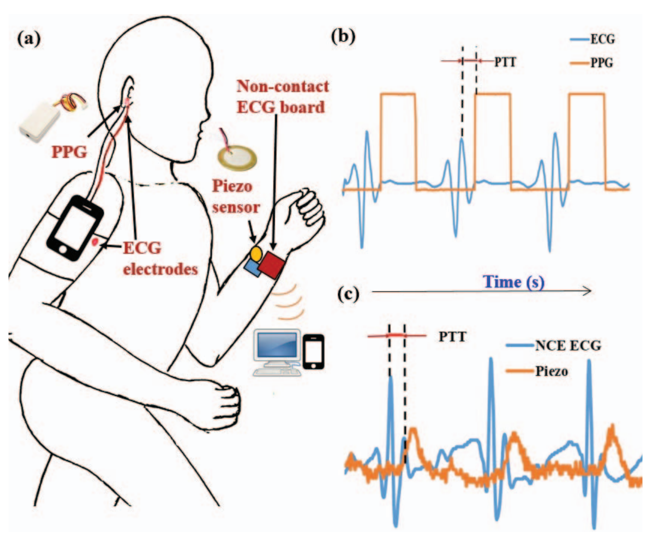

Fig. 1. **(a)** Conceptual designs of the two devices. **(b)** PTT from ECG and PPG. **(c)** PTT from NCE ECG and piezoelectric pressure sensor.

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A. *Bicep-Worn Device*

The bicep-worn device consists of a unit for signal filtering and amplification and a unit for wireless data transmission worn on the bicep with wired, contact ECG electrodes attached to the bicep and to the back of the ear, and with a COTS PPG sensor (*Seeed Studio*) clipped to the earlobe as shown in **Fig. 1a.** An instrumentation amplifier (INA331, *TI*) was chosen as the pre-amplifier because of its low-power, low-cost, and low-noise amplification of differential signals. It has a high common mode rejection ratio (CMRR) of 94 dB, high input impedance of approximately 1013 Ω and a low input bias current of less than 10 pA. After the pre-amplifier stage, the signal was filtered by a passive high-pass filter followed by two cascaded low-pass filters (OPA333, *TI*) in order to obtain the ECG frequency range of 0.5-150 Hz. The OPA333 offers excellent CMRR without the crossover associated with traditional complementary input stages, which makes it ideal for driving analog-to-digital converters (ADCs) without degradation of differential linearity. **Fig. 1b** shows a simultaneous recording of ECG and PPG.

B. *Wrist-Worn Device*

The wrist-worn device consists of a pulse pressure sensor, and a non-contact electrode board (NCE) for ECG acquisition (**Fig. 1a**). Different from the contact ECG approaches, NCE ECG could be obtained without any effects from the skin (sweat, hair, etc.), thus becoming of interest for off-the-clinic measurements. The piezoelectric sensor (*Audiowell,* **Fig. 1a**) was tailored to fit on the wrist above the radial artery. The NCE records ECG data by capacitively coupling with the body. The electrode plate was electrically insulated, therefore acting as a dielectric between the electrode and the subject's skin. Owing to its extremely low-input bias current (3 pA), INA116 (*TI*) was chosen to amplify the coupling signal. The output was then offset by 1.5 V and passed through a twin-T notch 60 Hz filter with a buffered output. A simultaneous acquisition of NCE ECG and radial pulse can be seen in **Fig. 1c.**

C. *Wireless Communication*

The communication between the wearables and the base station (a personal computer in this work) is based on two eZ430-RF2500 modules [5]. The module has a CC2500 transceiver chip and a small chip antenna which supports multiple channel and low-power radio frequency communication in the 2.4 GHz Industrial, Scientific and Medical (ISM) band. A low-power MSP430 embedded microcontroller helps in capturing and processing the signal. The wireless communication range is up to 35 m in normal situations. The receiver module uses Universal Asynchronous Receiver/Transmitters (UART) to communicate with a computer at 9600 baud rate. The microcontroller-unit (MCU) with 16 MHz performance can be used to process data in real time and communicate with a smartphone.

D. *Mathematical Models*

Relationship between Systolic BP (SBP) and PTT was modeled based on physical behavior and regression. These mathematical models have subject-specific constants, A and B, that account for other physical parameters that influence BP, like arterial wall elasticity, age and blood density [6]. The equation for each subject using different models was found by linearly curve fitting the measured BPs and the experimentally obtained PTTs. These equations are subject to change with modifications of the parameters affecting A and B, thus requiring recalibration. We investigated several models that have been reported in literature. The first model (1) is based on the inverse relationship between PTT and BP [7]. This model assumes that, at a fixed distance from the heart with other parameters constant, BP depends only on the time that the pulse takes to travel along the distance.

$$SBP = A/PTT + B \tag{1}$$

The second model (2) is derived similarly to (1) and relates Systolic BP (SBP) inversely to the square of PTT [8].

$$SBP = A/PTT^2 + B \tag{2}$$

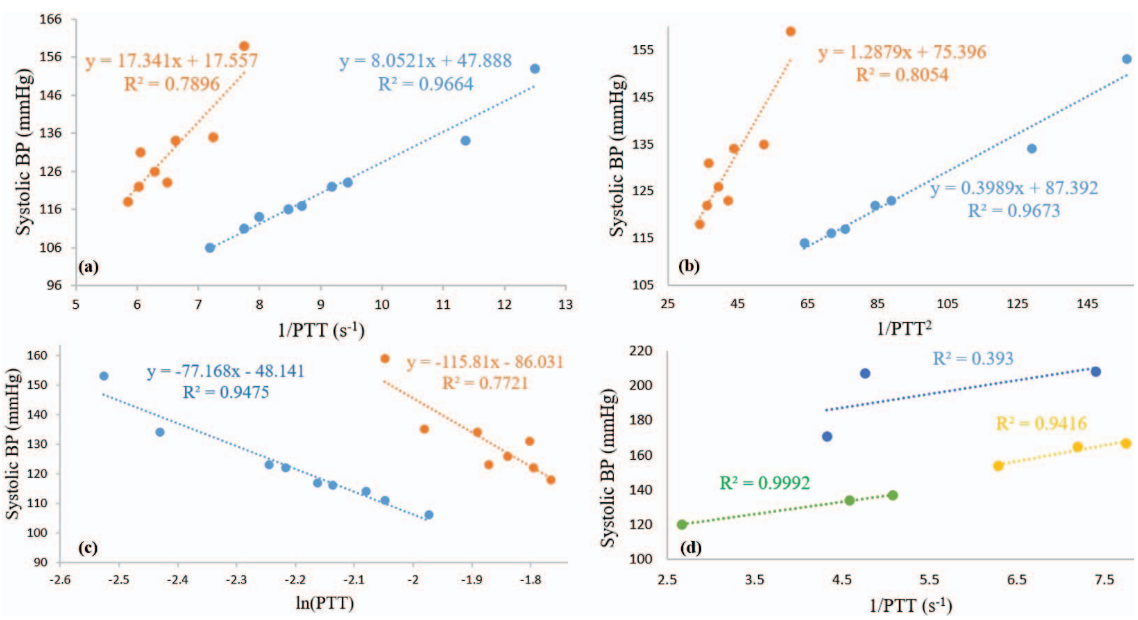

Fig. 2. Relationship between BP and **(a)** Inverse PTT; **(b)** Inverse square PTT; and **(c)** Log PTT. **(d)** BP of multiple subjects verses inverse PTT.

The third model (3) explores the relationship between arterial elasticity and pulse wave velocity (PWV) [4]. PWV of the pressure wave is inversely proportional to PTT and depends on the distance between heart and point of measurement. Arterial elasticity is exponentially related to PWV. On basis of this equation, SBP can be related to PWV.

$$SBP = A \times \ln(PTT) + B \quad (3)$$

III. Experiments and Results

Various PTTs were obtained using our devices at different exercise levels simultaneously with base-line BP acquisition using a COTS pressure cuff (5 series, *Omron*). The subject's BP decreased and his PTT increased over time as expected and, as can be seen in **Fig. 2a**, the relationship between the BP and the inverse of the PTT was approximately linear. The healthy subject underwent this trial again on a different day and produced results with some similarities and some differences. While both sets of data were roughly linear, the data produced trend-lines of different slopes between sets. Also, where one set of data showed the inverse of PTT to decrease between every sample, the other set of data demonstrates a less predictable pattern. Other models capturing the relationship between BP and the inverse of the square of the PTT, as well as the natural log of PTT can be seen in **Figs. 2b** and **2c**, respectively. The results were comparable to that of the relationship using the inverse PTT. Next, three healthy subjects were tested while resting after three scenarios: sitting at rest (no exercise – $\mathbf{S_1}$), a light exercise of 20 jumping jacks ($\mathbf{S_2}$) and a heavier exercise of 60 jumping jacks ($\mathbf{S_3}$). Data were taken and analyzed using model (1) following each scenario via the previously described method and then plotted in **Fig. 2d**.

IV. Discussions and Conclusion

We have demonstrated two continuous BP monitoring systems based on ECG and either PPG or pulse pressure data. Our results suggested that PTT and BP may be modeled with a linear relationship between BP and either the inverse of PTT or the inverse of PTT^2. However, these models appear to differ from person to person and trial to trial (**Fig. 2d**). We hypothesized the differences, such as the linearity, may provide insights into the present health status of the individual. It is also apparent that, with the present technology, the wearers would need to frequently calibrate using a gold standard BP device in order to obtain acceptable accuracy. Experimental errors may have contributed to the unpredictability of the data in part, but it is suspected that the behavior of human body may simply have more complicated behavior than a simple linear relationship can provide in some cases. Parametric equations of PTT as a function of time may be required for future optimization of BP calculations.

Our wrist-worn device with NCE suggested that continuous PTT acquired by a conventional ECG device contacting multiple areas of the body may be reduced to a single, NCE ECG device integrated in regular accessories, such as watches or clothes. Therefore, our future work includes miniaturization and integration of our devices into existing systems, with communication with smartphones and cloud computing, enabling real-time and distanced diagnoses and monitoring. We will also carry out real-case investigations and optimization of the BP calculation algorithm with a bigger sample size and machine learning-based programs, using additional parameters such as motion, pose and body temperature. Both systolic and diastolic BP will be thoroughly studied.

In conclusion, the bicep-worn device is novel because, up to date, there is no device that prepares the way for continuous, cuff-less BP monitoring worn solely on one side of the body and not requiring cross-body contact, supporting practical scenarios, such as training. Furthermore, the wrist-worn device propagates this development by showing in principle that such a device may be unnoticeably integrated into a watch. Our approaches hold promise to integrate the valuable feature of continuous BP monitoring into wearables in the coming era of the mobile health (m-Health) and internet of things (IoTs).

Acknowledgments

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