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New Pulse Rate Monitoring in Ear-using a Piezoelectric Sensor

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Abstract— **This study has developed "EarPulse system" that is an IN-EAR monitoring device that addresses the issues of the currently available devices in reliability and convenience. One of the vital signs that show the status of human's health is "Heart rate". There have been a number of researches in attempts to develop wearable devices with the function of measuring heart rate. Since measuring heart rate in ear can provide stable data regardless of a user's movement and also be non-intrusive and non-obtrusive, the EarPulse system was designed and produced as an in-ear-monitoring device. This study has conducted a comparative experiment in sixty volunteers to evaluate the reliability of the EarPulse system. The results from the test were analyzed by correlation analysis, agreement analysis, and statistical analysis with SSPS (p<0.001). The analyses showed there were no differences between the EarPulse system and the other commercially available reference devices in measurement. In conclusion, the EarPulse system introduced in this study offers not only the new body part for measuring pulse rate but also a practical solution with full guarantee of reliability and convenience.**

I. Introduction

Wearable sensors and systems have evolved to the point that they can be considered ready for clinical application. The interest for wearable systems originates from the need for monitoring patients over an extended period of time. In earlier studies, the most of the researches for health monitoring in out-of-hospital conditions focused on home monitoring system.[1] Home monitoring devices had most functions of medical equipment in hospitals; measuring heart rate, respiration rate, SpO2, body temperature, blood glucose and blood pressure. Although the performances of home devices were not as good as what the hospitals can offer, the interfaces of home monitoring devices has been far superior to the ones used by hospitals because it was designed to be used with ease. Another upside to the home monitoring devices is that the data collected is automatically transmitted for analysis to medical staffs in hospitals or care-givers through network without having the patients leave their residences. These researches of home monitoring devices implemented embedded sensors in different places or structures at home, constructions, or electrical appliances). For instance, a fully automated system to monitor physiological data at home was developed by Ogawa[2] and coworkers. An electrocardiographic (ECG) monitor in the bathtub measures heart function during bathing, a temperature monitor in the bed measures body temperature, and a weight monitor built into the toilet serves as a scale to record weight. Unfortunately, these home monitoring devices as well as hospital equipment offered limited mobility, if any, and were unable to monitor vital signs continuously in daily activities.

In recent years, wearable sensors have been developed and produced along with advanced electronic and communication technology in order to measure physiological signals. These devices are aimed for low power consumption and minimal form. This trend can make the power consumption of the wearable sensing devices more efficient and small size encourages people to wear the device for a long duration. As a result, wearable sensing devices such as clothing, wristwatches[3], rings[4], or accessories equipped with various embedded sensors have been widely developed. There are various types of wearable devices produced to the date. One of them is an accessory type (e.g., necklace). This type offers and encourages the patients to use on daily basis but it cannot gather reliable data. Another type is to embed sensors as a part of clothing, such as a belt or band but is uncomfortable to wear. In order to overcome their shortcomings, there have been a number of studies to resolve some of these issues. The many devices as mentioned before, can measure variable vital signals. One of the most useful signals for the determination of an emergency condition is "heart rate". Heart rate could be measured by various types of sensor in wearable devices but the quality of measurement is often unreliable due to a user's movement.

II. Background and approach

The sensors in this research are aiming for unconscious and also non-intrusive. The prerequisite in body parts suitable for wearable sensor are: 1) parts easy to wear the sensing device. 2) parts do not disturb a user's routine life. 3) parts that could not be affected by strenuous exercise or movement. After a through consideration of each body part of human body, human head seems to be the best suited to fulfill the prerequisites above. There are some regions on the head that can measure pulse wave including parts passing through carotid arteries on the head and neck. Among the regions, the ear was selected and it is the most sensible body part because the population is already used to the idea of electronic devices in ears. The hearing aid for hearing impaired and ear-buds for iPods are the prime examples. In-ear devices are easy to wear and also tend to stay in place during active and strenuous movements (e.g. joggers using ear-buds). The requirements for the in-ear sensor in order to measure the pulse rate are as follow: 1) as small as possible (because it could be worn into the inside of ear) 2) a very soft material because sense of the ear is sensitive to contact

After careful considerations to meet the requirements above, a piezoelectric is selected to measure pulse wave because it is customizable for the tiny space with excellent

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sensitivity to low frequency movements. The ear is an organ with fine senses that not only detects sound but aids in balance. The ear consists of outer, middle and inner ear. Among 3 parts of the ear, the outer ear is only one available to wear. We checked where the most nearest blood vessels to outer ear-veins or arteries-are located to measure pulse rate. The blood vessels that we were looking for were 1) internal jugular veins and 2) internal carotid arteries in the middle of outer and middle ear anatomically. The internal jugular vein begins in the posterior compartment of the jugular foramen, at the base of the skull, passing through the middle ear for external ear canal as seen Figure 1. The internal carotid artery arises from the common carotid arteries where these bifurcate into the internal and external carotid artery. It passes by the bottom of the middle ear and curves to the medial. We concluded that as a source of pulse wave, the internal jugular vein was the most appropriate to measure pulse rate because it was near enough to measure pulse wave.

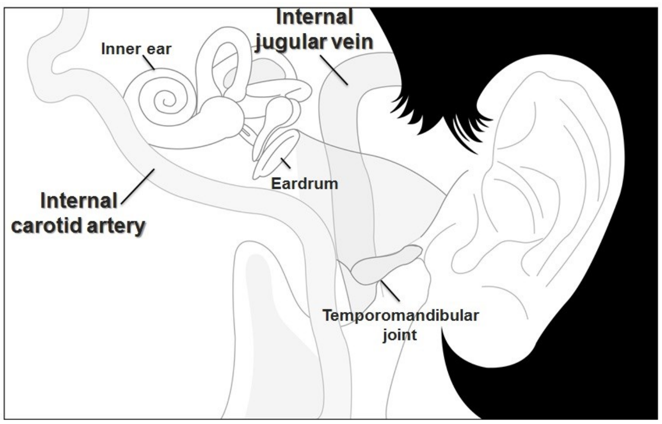

Figure 1. Internal carotid artery and jugular vein on the head

The focus of the study is to develop a sensor to detect and measure the change in pulse pressure from jugular vein for the reasons explained above. EarPulse system developed by this study is the non-intrusive and wearable type in order to gain pulse wave from jugular vein. Now the design and implementation of EarPulse system are described in the following section.

III. MATERIAL

A. System Overview

The overall architecture of the proposed EarPulse system (Figure 2) is composed of two parts: one is EarPulse device to acquire and transmit pulse wave signal and the other is a mobile device with EarPulse analysis program to extract its feature and pulse wave peak as shown in Figure 3. The analog part of the EarPulse system is non-intrusive and contains a piezoelectric sensor to detect the pulse wave generated by the jugular vein. This circuit conceives an instrumentation amplifier with a total gain and bandwidth of 27dB and 10Hz respectively. The pulse wave is converted to a digital signal with sampling rate (f_s) of 200Hz for pulse rate extraction. The 12-bit digitized data at the micro-controller unit (MCU) is transmitted via radio frequency (RF-2.4GHz frequency range) communication to the personal computer. The computer serves as an RF receiver and a host for EarPulse analysis program. EarPulse device transmits digitalized pulse wave using wireless communication described above. EarPulse analysis program low-pass filters the received signal for noise reduction and then runs rule-based signal process to extract the feature of pulse wave in order to detect the peak of pulse wave at its final stage of processing. The system based on android OS showed the value of pulse rate obtained from the period of detected peak waves.

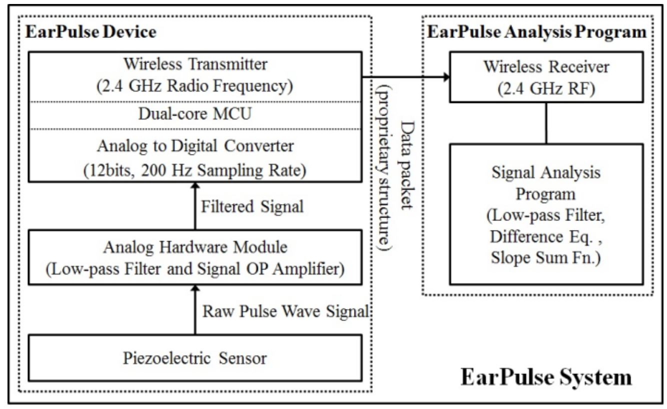

Figure 2. EarPulse System Diagram

B. Sensor

In order to pick up and analyze the pulse wave which is detectable near jugular veins on the skin of the posterior ear canal, a piezoelectric sensor was selected since not only it is customizable for the tiny space, but it is very sensitive and responsive to low frequency movements in the 0.7 to 12 Hz, the range of interest. The piezoelectric sensor is capable to convert physical force to electric current. It can therefore detect the pulse wave signal from the detectable area as shown in

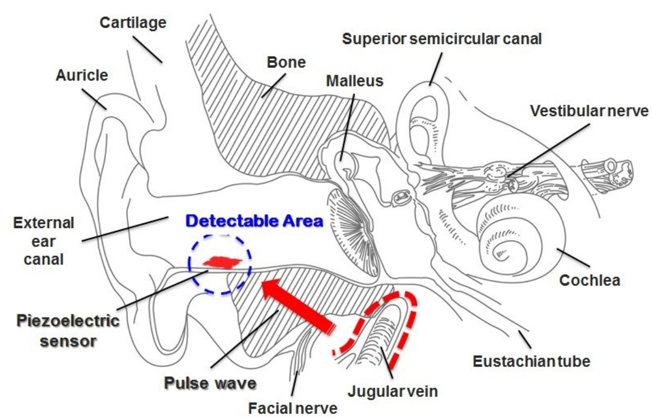

Figure 3. The sensor dimensions are 8mm x 8mm x 56um considering sensor sensitivity and the physical space limitation of human ear canal

D. Equipment

A newly invented apparatus is one of the significant parts to measure pulse wave accurately in this work. Since the proposed system is featured with vibration detection in the inside of the ear canal, there are several careful considerations for various sensing environments as follows:

- In terms of noise: vibration from talking and chewing activities, vibration from scrubbing on face, vibrations from a gap between skin and the apparatus, vibrations of the apparatus when users are moving their body
- In terms of pulse wave measurement: enough ability of adhere to the skin
- In terms of wearability: wearable with convenience

To meet all of the considerations above, an innovative apparatus was designed and developed. The apparatus is in the shape of scissors, as shown in Figure 4, to resolve concerns by utilizing extension spring for noise cancelation, semi-custom ear-mold for better wearability and pulse wave measurement. The apparatus is a state-of-the-art form factor that includes all essential components such as analog filter, digital and RF logic, sensor and tiny-size battery.

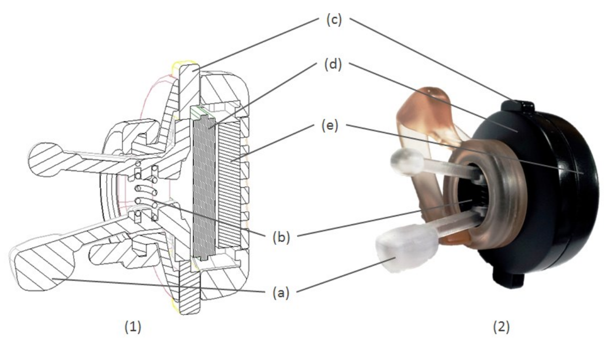

Figure 4. (1) Cross sectional view of the proposed apparatus, (2) Actual view of the proposed apparatus

D. Electric Circuit

Analog circuit that processes the signal through the piezoelectric sensor generates pulse wave signal. The Raw Signal from the sensor is pre-amplified by 3dB and transferred to a buffer. After passing through the 2-pole sallen-key low pass filter, the signal is amplified again by 24dB. The amplified signal then goes into an offset control circuit and finally the desired output is produced. 2-pole sallen-key filter circuit is often used in the processing of vital signs in systems such as electrocardiogram (ECG) or electromyogram (EMG), etc. The output pulse wave from the offset control circuit has a range between 0 ~3.0 in voltage, after taking base line through the offset control's

The digital circuit in this study consists of power regulator, microcontroller and antenna. The power regulator produces +3.0 volts that powers the whole circuit to operate. The microcontroller has a radio frequency (RF) of 2.4GHz communication band and its task is to convert analog signal of pulse wave to digital. While converting analog to digital, microcontroller sampling frequency is 100Hz and support 12-bit resolution in the range of 0~+3.0 volt. The RF Power output specifications in microcontroller and antenna have 0dB and 0.5dB respectively.

IV. Method

A. Pulse Detection

An effective algorithm for detecting the onset of arterial blood pressure (ABP) pulses is applied for the pulse detection of this study. The pulse detection algorithm involves morphological conversion/transformation of raw pulse wave signal into a more robust signal that is easy to process. The signal then can be passed through a set of knowledge based rules for the extraction of pulse wave peak. The focus of algorithm is to analyze transformation feature since the original pulse wave (RawPw) signal is less impulsive and distinct. In this context, windowed and weighted slope sum function (SSF) is utilized for enhancing the upslope of pulse wave and suppressing the remainder. The end of SSF passed pulsed wave (SsfPw) and the peak of RawPw correspond to each other. The decision rules are then applied on SsfPw for the detection of RawPw peak. The pulse detection algorithm is written in Java language.

B. Experiment

Sixty volunteers with good health in young-middle age group from local community formed the clinical experiment basis. Each participant signed an informed consent form prior to the experiment and had no self-reported diseases such as hypertension, diabetes, hyperlipidemia, cardiac infarction, cardiac insufficiency, and arrhythmia etc. The demographic information of the participated subjects is summarized in

Table 1. Demographic information of participated subjects

	N	Age	Height (cm)	Weight (kg)
Male	46	33.00±4.98	172.52±5.21	72.52±10.84
Female	14	30.57±5.34	162.14±3.30	49.86±3.26
Total	60	32.43±5.19	170.10±6.57	67.23±13.68

Two commercially available monitoring devices were selected as reference devices to EarPulse device. One is fingertip pulse oximeter (model name: OnyxⅡ) (Nonin Medical Inc. 2011) of Nonin Medical Inc. OnyxⅡ is the world's first fingertip pulse oximeter with a wireless communication protocol built in. By periodically transmitting heart rate and blood oxygen level information over to a paired Bluetooth station, the device collects and analyzes the status of the patient. The other reference device is arm-band type pulse oximeter (model name: myTRECK: accuracy is +/-3 bpm) (Scosche Industries 2011: accuracy is +/-3 bpm) of Scosche Industries.

C. Procedure

Clinical experiment was performed according to the following steps. The pulse rate data from EarPulse and OnyxⅡ were automatically recorded by our developed software program and Nonin's OEM SpO_2 solution program concurrently. The pulse rate data from myTRECK was manually recorded by a tester, every five second using myTRECK iPhone application program. The pulse rate data were acquired by three different monitoring devices at the same time for the direct comparison.

- Step 1: The subject wears three different pulse rate monitoring devices (EarPulse – inside of right ear, OnyxⅡ – forefinger of right arm, and myTRECK – left arm).
- Step 2: Data recording for 15 seconds while the subject is sitting on the chair.
- Step 3: Data recording for 15 seconds while the subject is standing on the floor.
- Step 4: Data recording for 15 seconds while the subject is sitting on the chair, after the subject performs standing high jump continuously for 30 seconds.
- Step 5: 1 minute break.
- Step 6: Data recording for 15 seconds while the subject is sitting on the chair, after the subject performs standing high jump continuously for 60 seconds.

V. RESULT

Descriptive pulse rate data with mean, standard deviation (SD), and standard error (SE) of three monitoring device are summarized in Figure 5. The myTRECK, OnyxⅡ, and EarPulse showed 73.27±11.0, 73.62±10.79, and 74.43±11.07 respectively in 'sitting' protocol, 78.47±10.52, 79.10±10.30, and 79.45±10.34 respectively in 'standing' protocol, 84.22±10.25, 85.65±10.50, and 85.98±9.65 respectively in 'sitting, after 30s running' protocol, and 94.02±13.36, 95.30±13.77, and 95.63±13.58 respectively in 'sitting, after 60s running' protocol.

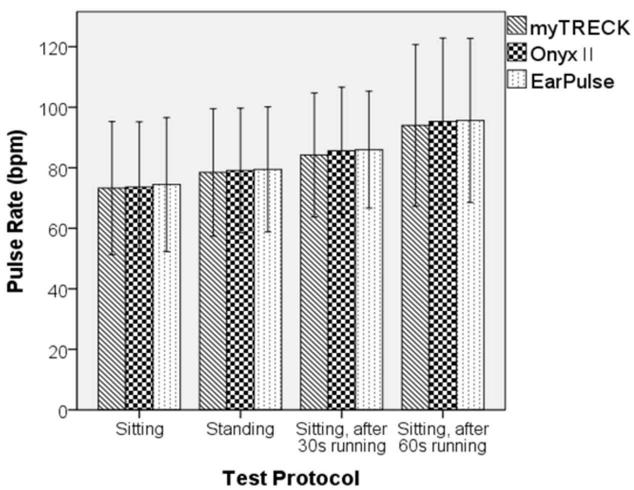

Figure 5. Description of pulse rate data measured by three different monitoring devices

As they shows, mean data of pulse rate tends to increase, as test protocol is changed. The differences in pulse rate data among OnyxⅡ, myTRECK, and EarPulse were analyzed, and the results are described in Figure 6.

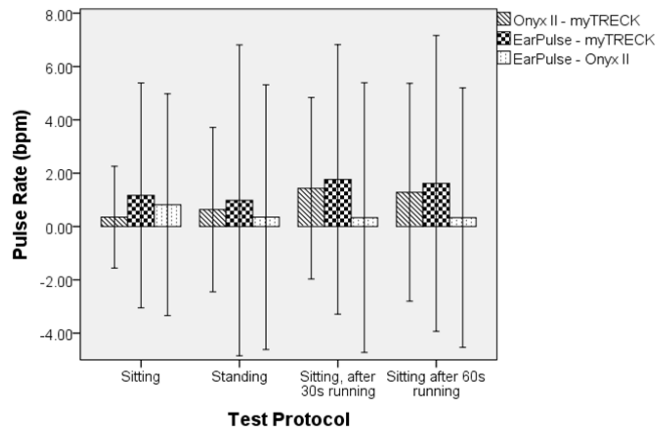

Figure 6. Description of difference pulse rate data measured by three different monitoring devices

VI. CONCLUSION

In this study, a wearable system was researched and EarPulse system was developed. The newly developed system can be used to measure vital sign non-intrusively during any daily activities. This system has several strengths 1) It allows a user to use this system to detect vital signs non-intrusively 2) Even in sudden acute conditions, it can check and record a user's health status 3) Due to simple interface of the system compared to hospital equipments, the use of this system may be easy and convenient. As a result, the EarPulse system has its own advantages following the trend that wearable systems will be a part of routine clinical evaluations.

The agreement analysis result for evaluating the performance of the proposed system showed that EarPuse is as accurate as the other reference devices currently commercially available. Even with an apparatus that sticks well to skin in ear canal, there arose noise problems caused by several vigorous movements and activities including running, shouting or opening the mouth. However, the proposed device could gain appropriate pulse rate during any other daily activities. (e.g. reading a book and sitting at work)

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