

A Basic Study on the Development of Ear-type Smart Monitor for Healthcare

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Dissertation abstract

A Basic Study on the Development of Ear-type Smart Monitor for Healthcare

体調管理のためのイヤータイプ・スマート
生体情報モニター開発を目指した基礎研究

Graduate School of Natural Science & Technology
Kanazawa University

Major subject: Innovative Technology and Science
Course: Intelligent System Creation

Jihyoung Lee

Abstract

I have proposed the development of “*ear-type smart monitor*” for healthcare in daily life. This system was designed for the simultaneous and continuous monitoring of the body core temperature, heart rate (HR) and normalized pulse volume (NPV; index of α -adrenalin-mediated sympathetic control at the peripheral arteriolar vessels) using the tailored ear-piece and smartphone. However, before the full-fledged development of prototype, there have been several questions about methods of physiological index measurement. I have therefore performed four experiments. As the result;

- 1) Newly developed tympanic thermometry using the tailored ear-piece could be used to the reliable body core temperature monitor in heat and during exercise.
- 2) The green light photoplethysmography (PPG) was more suitable measurement for monitoring of HR during motion than near-infrared, red and blue light PPG.
- 3) Theoretically, the final result in modified NPV equation (include light-scattering) was the same as original NPV (assumed non-scattering). The reflection mode PPG and transmission mode PPG were indeed the comparable method to derive NPV values.
- 4) The NPV derived from the bottom of the ear-canal with reflection mode PPG was found to be a valid measure when compared with reference measurements.

This paper discussed the issues related to three physiological index measurements.

Key-words: *ear-monitor, tympanic temperature, photoplethysmography, heart rate, normalized pulse volume.*

1. Introduction

Recently, diseases and deaths related to the heat and cold waves (e.g. heat stroke) have become the serious social problem around the world [1]. Moreover, the incidence of the deaths may increase with global warming and the predicted worldwide increase in the frequency and intensity of extreme weather events [2]. Early planning can help reduce future mortality, for example the emergency management and public health prevention as healthcare, can improve health by addressing climate change [1].

Academic researchers and healthcare industrial are actively developing wearable and compact measurements, low-cost technologies for convenient and effective health screening, monitoring and personalized healthcare [3-5]. Particularly, mobile health (mHealth) is regarded as a central element for the healthcare in normal daily life. The mHealth is a part of electronic health (eHealth) and is the provision of health service and information by using mobile communication devices such as smartphone and personal digital assistant (PDA) [6].

In the present study, I have proposed the development of novel ear-type physiological variables monitoring system for healthcare in the daily life, which I call “*ear-type smart monitor*”. Fig. 1 shows the schematic of this system. This system includes the two main devices: 1) the *tailored ear-piece* to measure of various physiological variables; and 2) the *smartphone* to monitor and data analysis. This system was designed for the simultaneous and continuous monitoring of the body core temperature (T_c), heart rate (HR) and normalized pulse volume (NPV; index of α -adrenalin-mediated sympathetic control at the peripheral arteriolar vessels) [7].

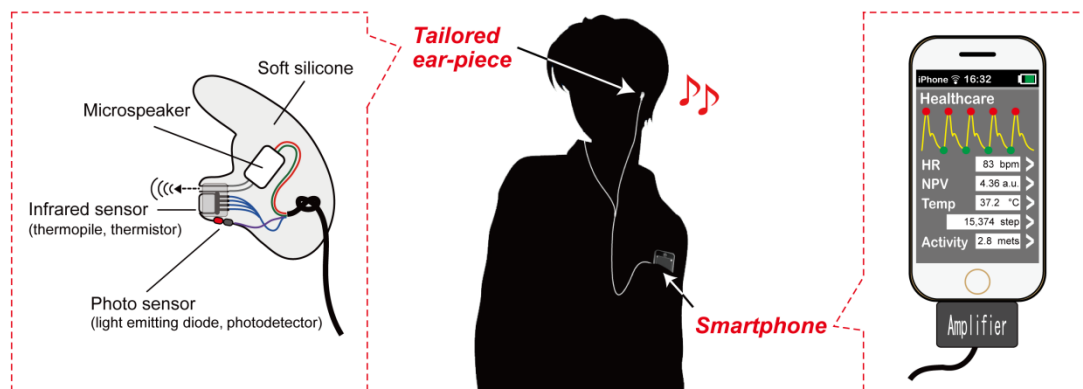


Fig. 1 The schematic of ear-type smart monitor.

However, before the full-fledged development of prototype system, there have been several questions about methods of the physiological index measurement. Therefore, in the present study, I have performed four experiments, respectively.

2. Experiments

All experimental designs were approved by the ethics committee of the Faculty of Medicine of Kanazawa University (May, 2011, No.9). All participants agreed to take part in this study voluntarily and signed an informed consent statement.

2.1 Reliability of Non-contact Tympanic Temperature Measurement

The tympanic temperature measurement has been widely used to monitor of T_c [8]. The measurement of tympanic temperature would appear to be the most appropriate technique for continuous monitoring of T_c . However, the reliable use of tympanic temperature as an index of T_c during heat stress and exercising has been seriously questioned [8]. For example, some studies reported that the tympanic temperature was lower than T_c (e.g. esophageal and rectal temperature) during exercise due to the influence of ambient temperature [9, 10]. To the best of my knowledge, there is no convenient device for the continuous monitoring of tympanic temperature. Therefore, although the non-contact tympanic temperature measurement is an established method [11], I have developed a variant of this having certain novel features that make it particularly suitable for reliable and continuous monitoring [12]. The device allows tympanic temperature monitoring based on an infrared-radiation-type method, which I call “*tailored ear-piece tympanic thermometry*”. The purpose of this experiment was to examine the reliability of the developed system for continuous tympanic temperature monitoring in heat stress and during exercise [13].

2.1.1 Participants: Ten male participants, with a mean age of 22.9 ± 1.9 S.D. years.

2.1.2 Measurements: Left-side ear; the non-contact thermo-pile (5φ; 10TP583T, Ishizuka Elec. Corp.) for tympanic temperature. Right-side ear; the contact thermistor (3φ; SZL-64, TECHNOL SEVEN Co., Ltd.) for tympanic temperature as a reference (DS103, TECHNOL SEVEN Co., Ltd.: accuracy ± 0.02 °C, resolution 0.001 °C). Stomach; the telemetry pill (12φ*20 mm; CorTemp, HQ Inc., USA: accuracy ± 0.1 °C, resolution 0.01 °C) for gastrointestinal temperature as a reference of T_c [8, 9].

2.1.3 Experimental Design: I carefully placed the thermo-pile and thermistor at the ear, and then fixed it by infusing an impression material (detax addition, DETAX GmbH & Co. KG, Germany). The six stages of the experiment were carried out: (a) each volunteer wore a bathing suit and had the temperature sensors attached in the appropriate positions; (b) rest for 10 min; (c) 42 °C water bathing for 30 min; (d) the natural cooling for 40 min; (e) the cycle ergometer exercise for 40 min; (f) the natural cooling for 20 min.

2.1.4 Data analyses: I used Pearson’s correlation analysis and *Bland-Altman* analysis for assessing the differences between the two measuring methods [14].

2.2 Most Suitable PPG Light Color for HR Monitor During Motion

The reliability of HR derived from the photoplethysmography (PPG) signals measured during motion [15]. One approach for the robust measurement of PPG signals during motion, based on the optical characteristics of tissue, can be the choice of light wavelength [16, 17]. The light sources used with PPG have been chosen at various wavelengths including the near-infrared (NIR), red, green, and blue [16]. Particularly, green light PPG has been shown to have the least influence from motion artifacts when compared with the NIR light PPG [16, 17]. Despite the possible advantages of green light PPG, in terms of susceptibility to artifact little is known about the accuracy of HR measured by green light PPG during motion. Therefore, the purpose of this experiment was to discover the most suitable light color of PPG for measuring HR during normal daily life, where motion is likely to be a significant issue [18].

2.2.1 Participants: Twelve male participants, with a mean age of 22.8 ± 1.8 S.D. years.

2.2.2 Measurements: The NIR (810nm), red (645nm), green (530nm) and blue (470nm) light emitting diode (LED) and its accompanying photodiode (PD) were placed side by side; reflection mode PPG (PPGr_NIR, PPGr_red, PPGr_green and PPGr_blue). Additionally, a NIR LED and its PD were placed on opposite sides; transmission mode PPG (PPGt_NIR). The photo-sensors were allocated sequentially in rotation between participants to the index, middle and ring finger. The ECG was derived from limb leads (CM5) as a HR reference. The motion was measured by a 3-axis accelerometer at the distal part of the finger.

2.2.3 Experimental Design: The experiment was started with a 3 min rest period. Next, the participant underwent three conditions, each for 16sec: horizontal motion (HM), vertical motion (VM), and baseline (BL). Each condition was separated by an 8 sec rest period, and the order of each condition was counter-balanced across participants. The set of three conditions was repeated three times. In the HM and VM, the participants waved their right hand connected to the sensor at a rate of 8 Hz paced by a computer metronome. The PPG signals were controlled by adjusting the intensity of the LED to achieve the same pulse amplitude. The whole experiment was repeated two times. Firstly, PPGt_NIR, PPGr_NIR and PPG_green were used. Secondly, PPGr_red, PPGr_green and PPGr_blue were used.

2.2.4 Data analyses: Firstly, beat-by-beat HR measured by each PPG was averaged for each 16 sec condition. Next, Pearson's correlation analysis and *Bland-Altman* analysis were performed [14]. Secondly, frequency spectral analysis for determined the signal-to-noise ratio (SNR) was performed using the pulse and acceleration wave by fast Fourier transform (FFT). SNR values were compared statistically by means of the two-way analysis of variance (ANOVA), and then post-hoc comparison was performed by the Tukey's Honestly Significant Difference (Tukey HSD) test.

2.3 Modified Normalized Pulse Volume

NPV derived from the photoplethysmogram, which is based on the Beer-Lambert-Bouguer law that describes the relationship between the intensity of incident light (I_o) and transmitted light (I), when the light passes through a non-scattering medium. NPV could be derived simply by normalizing the magnitude of the ac component (ΔI_{ac}) to the mean dc component (I_{dc}), giving the following relationship [7]:

$$NPV = \Delta I_{ac} / I_{dc} (\propto \Delta V_a)$$

However, the validity of original NPV [7] must be questioned since it is based on the assumption that the light passes through a non-scattering medium. In fact, when light passes through biological tissues it is extensively scattered as well as absorbed. So, the modified Beer-Lambert-Bouguer law, which includes the influence of light-scattering, should be considered [19]. The purpose of this experiment was 1) to derive the modified NPV (mNPV) theory to validate mathematical relationship in real biological tissues. 2) to validate the mNPV, I compared the mNPV derived from transmission mode PPG as a reference with the mNPV derived from reflection mode PPG [20].

2.3.1 Theory of mNPV: mNPV derived from the photoplethysmogram, which is based on the modified Beer-Lambert-Bouguer law that describes the relationship between the I_o and I , when the light passes through absorptive and scattering media. The relationship between the ΔV_a , the pulsatile change in the arterial blood volume, and PPG signal components can be expressed by the following equation:

$$\Delta V_a = -(k\varepsilon C)^{-1} \Delta I_{ac} / I_{dc}$$

there may be considered to be direct proportionality on the assumption that the mean absorptivity (ε), the hematocrit (C) and the volume correction factor (k) of the total blood are constant. I may state the mNPV:

$$mNPV = \Delta I_{ac} / I_{dc} (\propto \Delta V_a)$$

This theoretical derivation, serves to validate the use of the mNPV mathematical relationship in real tissues where there are both absorptive and scattering processes. This provides more confidence in the use of the NPV index when the method is applied to reflection PPG, where multiple scattering events are key aspects of photon propagation [20].

2.3.2 Participants: Two groups of participants, ten young males (young group; age: 21.8 ± 1.0 years), and six middle-aged males (middle-aged group; age: 48.8 ± 10.9 years).

2.3.3 Measurements: ANIR LED (940nm) and a PD were placed on the index finger, in the transmission mode PPG. The other NIR LED and photodiode of each pair being placed side by side of the distal part of the middle finger, in the reflection mode PPG.

2.3.4 Experimental Design: Participants were subjected to challenge: cold pressor test (CPT; 4°C) of the right hand up to the wrist to induce peripheral vasoconstriction [21]. The stages of the experiment were carried out in the following order: (a) adaptation for 10 min; (b) BL for 5 min; (c) the CPT for 90 s; (d) rest for 5 min.

2.3.5 Data analyses: logarithmic transformation was applied to NPV to normalize the distribution (\ln NPV). \ln NPV values were averaged to produce BL, CPT1, CPT2 and CPT3 values, respectively. These values were compared statistically by means of the one-way ANOVA, and then post-hoc comparison was performed by the Ryan's method. Furthermore, \ln NPV reactivities ($\Delta \ln$ NPV) were calculated by subtracting the BL values from the CPT1, CPT2 and CPT3 values, respectively. Then, Pearson's correlation analysis was performed.

2.4 Ear Normalized Pulse Volume

Traditionally, the photoplethysmogram has been obtained from the fingertip with the light source and detector in the transmission configuration [22]. Other anatomical sites have also been used, in some cases, such as the toe and ear lobe, with transmission optodes and in other cases, including the forehead and esophagus, using the reflectance configuration. Of all of these possible sites, the different locations on and in the ear can have several advantages. The vessels of the deep auricular artery, which originates from either the maxillary or the superficial temporal artery, ascend through the bony wall of the ear-canal from the parotid gland under the ear-canal, with its branches providing a supply to the lining and periphery of the ear-canal [23]. Furthermore there is relative freedom from motion artifacts produced, for example, during walking [24]. Despite these potential advantages, the NPV derived from the ear has not yet been validated. Furthermore, the most suitable site around the ear-canal for the robust measurement of PPG signals using tailored ear-piece has not yet been examined. Therefore, the purpose of this experiment was 1) to validate the ear NPV; 2) to investigate the collection of PPG-derived measurements from different regions of the ear to discover where these is the most suitable for measuring PPG using tailored ear-piece [20].

2.4.1 Participants: Same with the modified normalized pulse volume experiment.

2.4.2 Measurements: ANIR LED (940nm) and a PD were placed on opposite sides of the distal part of the index finger, in the transmission mode PPG. For all other measurement sites the reflection mode PPG was used, with the LED and PD of each pair being placed side-by-side; at the top and bottom of the ear-canal (ECT and ECB, respectively); the upper and lower part of the ear-auricle on the left ear (EAU and EAL, respectively).

2.4.3 Experimental Design: Same with the modified normalized pulse volume experiment.

2.4.4 Data analyses: Same with the modified normalized pulse volume experiment.

3. Results & Discussions

3.1 Reliability of Non-contact Tympanic Temperature Measurement

The present experiment method employs a tailor-made ear-piece which effectively achieves a hermetically sealed condition. The results clearly showed (Fig. 2), by linear regression analysis, a strong correlation between the infrared tympanic temperature (T_{ty}) and both the direct tympanic temperature ($T_{ty\text{-contact}}$) and the gastrointestinal temperature (T_{gi}). Further, the *Bland-Altman* analysis demonstrated strong agreement between the pairs of measurements. Although, the T_{gi} was found to be 0.27 °C and 0.37 °C higher than T_{ty} in both experiment, it has been reported that the rectal temperature is affected by the physical activity of legs and arms [25]. This tendency, which also exists for the rectal temperature, is consistent with the findings of previous studies [26]. Thus, these findings suggest that the tympanic temperature measure by the tailored ear-piece might be the reliable method to monitor of T_c in heat condition and during exercise [12, 13].

3.2 Most Suitable PPG Light Color for HR Monitor During Motion

The present experiment results clearly showed that, in terms of susceptibility to motion artifact, the green light PPG is better for the monitoring of HR during motion than the NIR, red and blue light PPG, and these results appear to be comparable to other studies for green light PPG [16, 17]. The limit of agreement (for the *Bland-Altman* plots) of HR measured by green light PPG was smallest among that of HR measured by NIR, red and blue light PPG when compared with reference measurements (Fig. 3). Moreover, the SNR value of the green and blue light PPG were higher than the SNR value of the NIR and red light PPG (Fig. 4). The potential explanation for the poor results of NIR and red light PPG: The NIR and red light PPG reflects the volume change in the blood vessel in the dermis and subcutis [27] due to the deeper penetration depth in the tissue [28]. The subcutis consists of loose connective tissue (include blood vessels) and fat [29]. So, the NIR and red light PPG signal was quite sensitive to motion artifacts. On the other hand, the SNR of blue light PPG were comparable to the SNR of green light PPG (Fig. 4), while the poor results (larger limit of agreement than HR measured by green light PPG; see Fig. 3 panel A.6 and A.5) of HR measured by blue light PPG: The blue light PPG reflects the volume change in small blood vessel in the skin surface due to the relatively shallow penetration depth [28]. The shape of the pulse wave depends upon the properties of the blood vessels [15]. So, the poor results of HR measured by blue light PPG could be caused by the different shape of the pulse wave. Thus, these findings suggest that the green light PPG appears to be the most suitable method for the monitoring of HR during normal daily life [18].

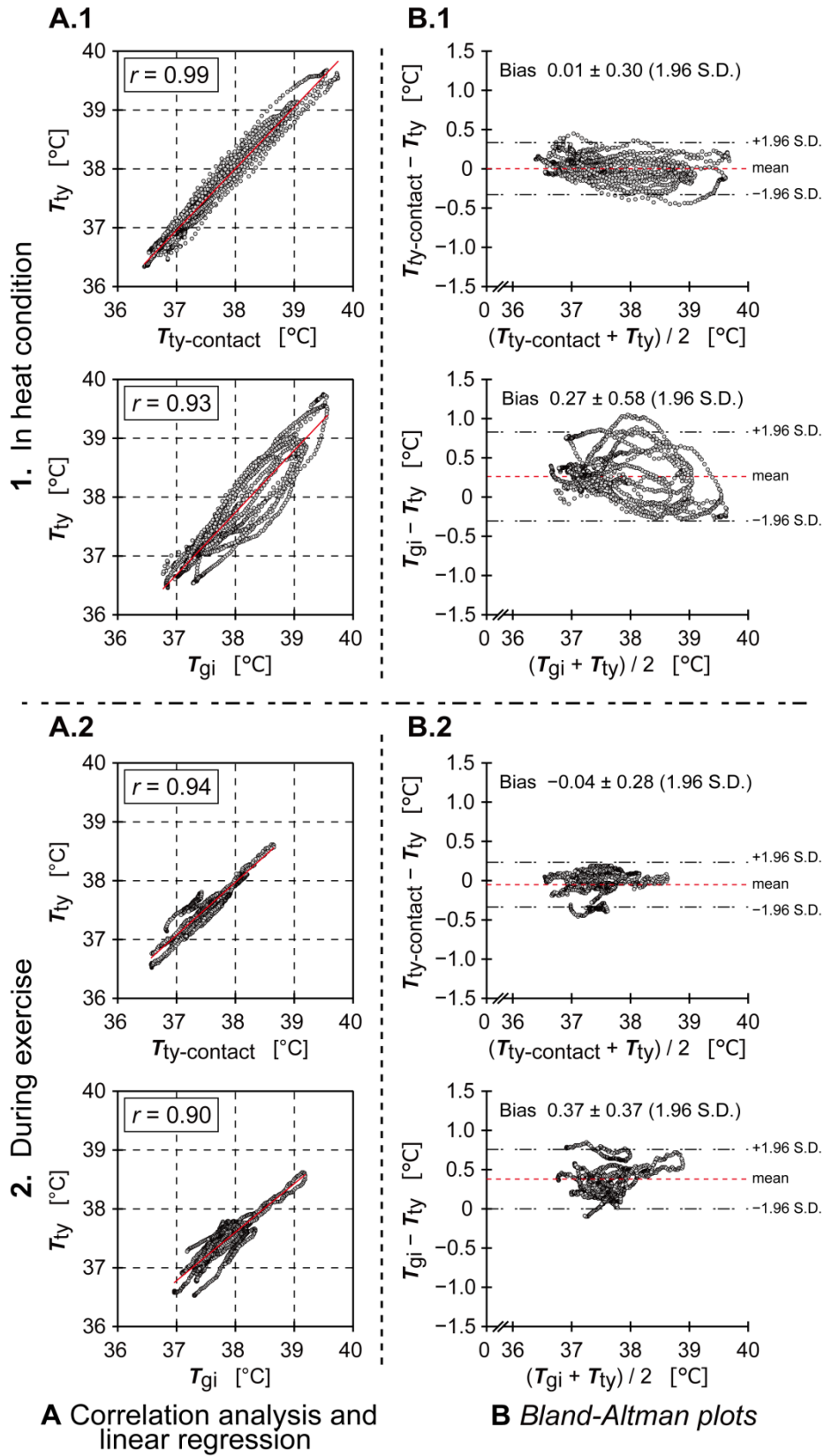


Fig. 2 Statistical analysis results of comparative evaluation tests [13]. (A) The scatter plot for correlation analysis; (B) *Bland-Altman* plots. (1) In heat condition; (2) During exercise.

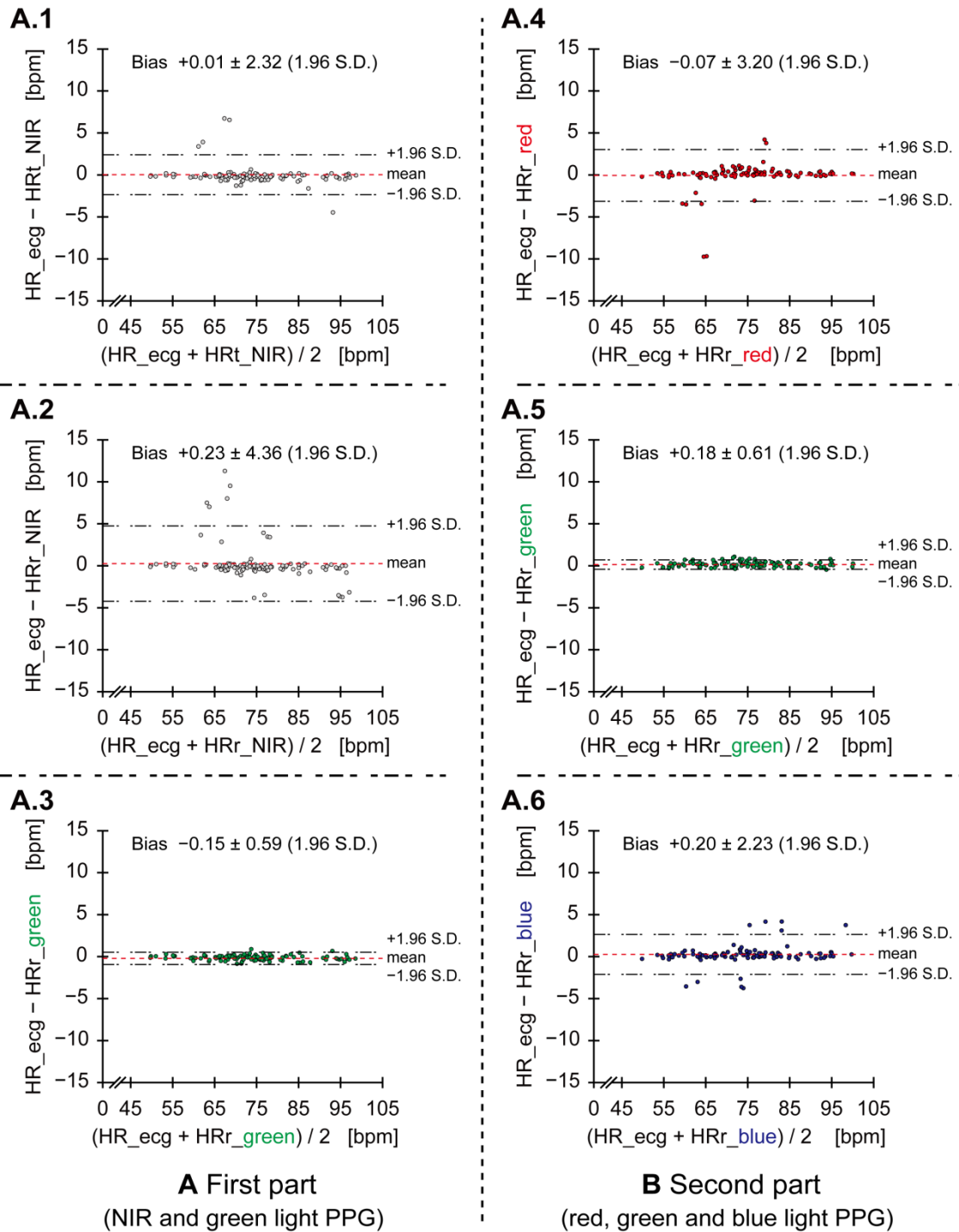


Fig. 3 Six Bland-Altman plots for different HR measurements [18]. (A) First part experiment for HR measure by ECG (HR_{ecg}), NIR and green light PPG; (B) Second part experiment for HR measured by ECG, red, green and blue light PPG. (1) HR measured by NIR light transmission mode PPG (HR_{t_NIR}); (2) HR measured by NIR light reflection mode PPG (HR_{r_NIR}); (3 and 5) HR measured by green light reflection mode PPG (HR_{r_green}); (4) HR measured by red light reflection mode PPG (HR_{r_red}); (6) HR measured by blue light reflection mode PPG (HR_{r_blue}).

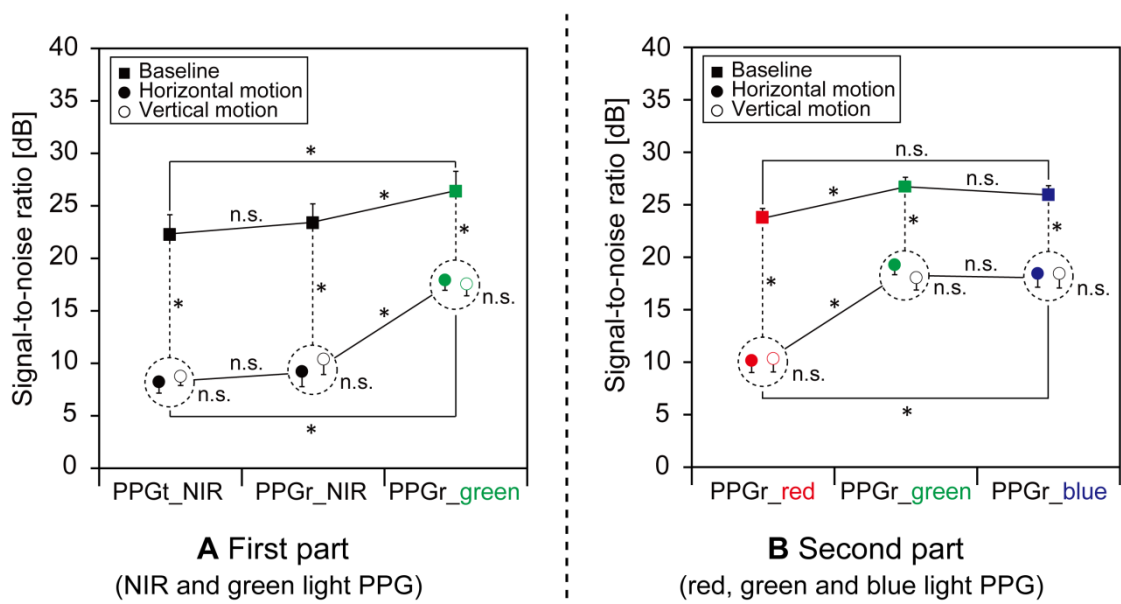


Fig. 4 Mean of the SNR for five different PPG waveforms [18]. (A) First part experiment with NIR light transmission mode PPG (PPGt_NIR), NIR light reflection mode PPG (PPGr_NIR) and green light reflection mode PPG (PPGr_green); (B) Second part experiment with red light reflection mode PPG (PPGr_red), PPGr_green and blue light reflection mode PPG (PPGr_blue). Among the all condition (baseline, horizontal and vertical motion). Error bar is standard error of the mean (S.E.M.). * $p < 0.05$.

3.3 Modified Normalized Pulse Volume

It is noteworthy, theoretically, the final result in mNPV equation (include light-scattering and absorption) was the same as original NPV equation (assumed non-scattering in the tissue). Therefore, I have justified in using the term “NPV” instead of “mNPV” in this experiment. In the experiment, I have used the transmission mode PPG as well as the reflection mode PPG when measuring NPV (NPVt and NPVr, respectively). The transmission and reflection modes of PPG have been studied by others [30], who reported that the pulsatile and non-pulsatile changes in intensity of light were found to be very similar whether measured by transmitted or reflected light. In the present experiment although the each absolute value of \ln NPV is different due to the volume correction factor (k), CPT produced strong statistical relationships between transmission PPG measurements in the index finger, $\Delta \ln$ NPVt as a reference, and reflection measurements in the middle finger, $\Delta \ln$ NPVr (Fig. 5). Thus, these results support the view that the transmission mode PPG and the reflection mode PPG are indeed the comparable method to derive changes in NPV values [20].

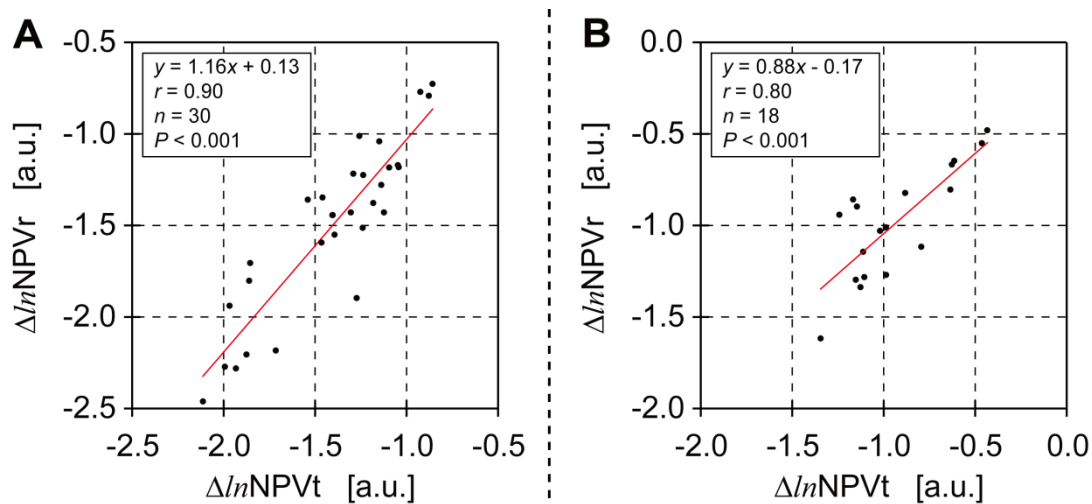


Fig. 5 Two scatter plots of \ln NPV reactivities derived from two different PPG [20]. (A) In the ‘young’ group, Pearson’s correlation analysis and the linear regression between $\Delta \ln$ NPV from an index finger using transmission mode PPG ($\Delta \ln$ NPVt) as a reference and $\Delta \ln$ NPV from a middle finger using reflection mode PPG ($\Delta \ln$ NPVr); (B) In the ‘middle-aged’ group, between $\Delta \ln$ NPVt and $\Delta \ln$ NPVr. During baseline and while performing cold pressor test, $\Delta \ln$ NPV is the reactivities (the difference between baseline and test values) of \ln NPV. $\Delta \ln$ NPV is expressed in arbitrary units (a.u.).

3.4 Ear Normalized Pulse Volume

The results show that, among the ear sites considered (the top and bottom of ear-canal, the upper and lower part of ear-auricle), the NPV ($\propto \Delta V_a$) values derived from reflection PPG measurements at the bottom of the ear-canal (NPVr_ECB) have the closest relationships with the reference (NPVt_IF; NPV derived from transmission mode PPG at the index finger) data. This is judged, firstly, by the significant decreases that are observed in \ln NPVr_ECB from the baseline values to the values obtained during the CPT. These decreases of \ln NPVr_ECB indicate vasoconstriction by sympathetic activity during the exposure to the stressful stimuli [7]. Secondly, good relationships were observed during the CPT between $\Delta \ln$ NPVt_IF as the reference with $\Delta \ln$ NPVr_ECB, (Fig. 6). These relationships could be explained by the reported location of the origin of the deep auricular artery on the lining of the ear-canal. The vessels of the deep auricular arteries ascend through the bony wall of the ear-canal from the parotid gland under the ear-canal, with branches providing a supply to the lining of the ear-canal [23]. That is, the change of the blood volume at the bottom of the ear-canal is larger than the change of the blood volume at the different placements of the ear. Thus, these findings suggest that NPVr_ECB could be used as an alternative to NPVt_IF, and the bottom of ear-canal appears to be the most suitable placement for the measuring of ear pulsation using tailored ear-piece [20].

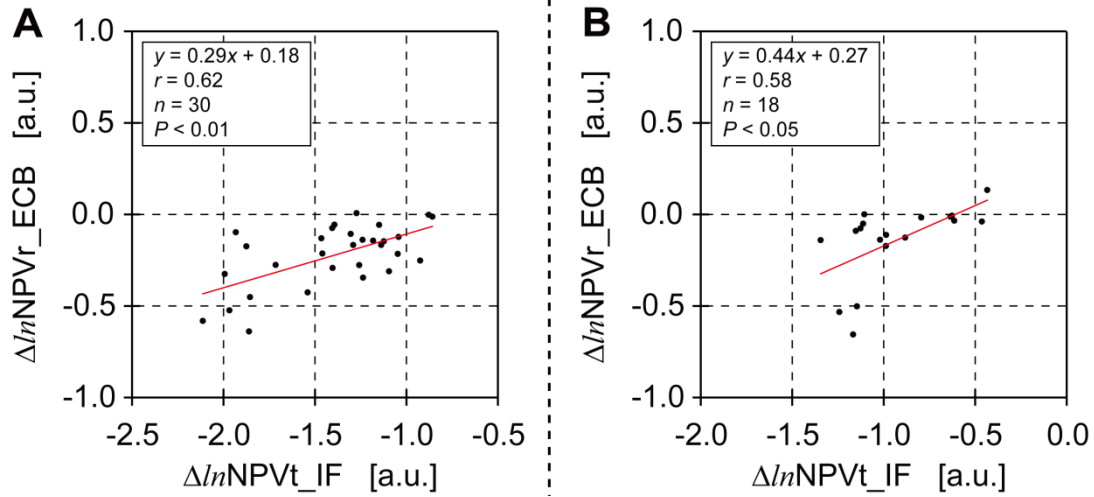


Fig. 6 Two scatter plots of \ln NPV reactivities derived from the index finger and the bottom of ear-canal [20]. (A) In the ‘young’ group, Pearson’s correlation analysis and the linear regression between $\Delta \ln$ NPV from an index finger using transmission mode PPG ($\Delta \ln$ NPVt_IF) as a reference and $\Delta \ln$ NPV from the bottom of the ear-canal using reflection mode PPG ($\Delta \ln$ NPVr_ECB); (B) In the ‘middle-aged’ group, between $\Delta \ln$ NPVt_IF and $\Delta \ln$ NPVr_ECB. During baseline and while performing cold pressor test, $\Delta \ln$ NPV is the reactivities (the difference between baseline and test values) of \ln NPV. $\Delta \ln$ NPV is expressed in arbitrary units (a.u.).

4. Conclusion & Limitations

In conclusion, these results suggest that the proposed “*ear-type smart monitor*” could allow the continuous monitoring of the T_c and NPV. Furthermore, if the green light PPG is used in the tailored ear-piece to measure of pulsation, the HR measured by this system during motion might be more reliable.

However, despite these experiments, there still remain several possible questions for physiological variables measurement. That is the validity of NPV derived from the bottom of ear-canal using green light reflection mode PPG. The collection (ac and dc components as well as NPV) of green light PPG-derived measurements from ear has not yet been examined. Moreover, the reliability of HR derived from ear-canal using green light PPG in normal daily life, where motion is likely to be a significant issue, has not yet been examined. Therefore, further studies are needed to examine the HR and NPV derived from green light ear PPG under various situations [31, 32]. Also, further studies are needed to develop of prototype system for the monitoring of T_c , HR and NPV with the smartphone application as *iPhysioMeter* [33].

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学位論文審査報告書（甲）

1. 学位論文題目（外国語の場合は和訳を付けること。）

A Basic Study on the Development of Ear-type Smart Monitor for Healthcare

体調管理のためのイヤータイプ・スマート生体情報モニター開発を目指した基礎研究

2. 論文提出者 (1) 所属 システム創成科学 専攻 知的システム創成 講座

(2) 氏名 李 知炯

3. 審査結果の要旨（600～650字）

平成26年1月28日に第1回学位論文審査委員会を開催し、提出された学位論文及び関係資料について詳細に検討した。更に平成26年1月29日に行われた口頭発表後、第2回学位論文審査委員会を開催し、慎重に協議した結果、以下の通り判定した。

本論文は、日常生活での健康管理等に焦点を当て、生理指標（深部体温 - 鼓膜温、心拍数 - 外耳道光電容積脈波のピーク間隔、交感神経活動 - 基準化脈波容積；NPV）を「個人適合型の外耳道密閉型耳栓」から取得し、スマートフォンなどの携帯型記録機器を通してチェックする「自己健康管理」として利用できるような「イヤータイプ・スマート生体情報モニター」の開発を提案し、そのシステムを具現化するために基礎研究を行ったものである。すなわち、目標とするシステム開発に向け ①深部体温指標としての“鼓膜温”が連続計測可能な本耳栓方法に基づく装置を試作し、本法の計測精度について実験的に検証すると共に、②日常活動中でより正確な心拍数を計測するため、光の波長に着目し、緑色光を用いた反射式光電容積脈波における心拍数の正確さを実験的に検証した。また、本耳栓を用いてNPVを計測するため、③反射式NPVの妥当性を理論的・実験的に検証、さらに、④耳部におけるNPVの妥当性と最適な計測位置について実験的に検証した。

以上のように本研究は、日常生活で健康管理可能な当該システムを具現化するための学術的・技術的課題を解決しており、今後の携帯医療研究分野に多大な寄与が期待できると考える。よって、本論文は博士（工学）に値するものと判定する。

4. 審査結果 (1) 判定（いずれかに○印） 合格 ・ 不合格

(2) 授与学位 博士（工学）