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Measurement of Cuffless Blood Pressure by Using a Magnetoplethysmogram Pulsimeter

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Abstract

A wearable wrist magnetoplethysmogram (MPG) pulsimeter was developed for blood pressure (BP) monitoring using a magnetic field-sensing semiconductor Hall device. The pulsimeter contains a permanent magnet attached to silicon housing at the centre of a radial artery. BP and pulse rate were measured without using a cuff, utilizing an MPG pulsimeter consisting of a small and portable apparatus containing the measurement system with hardware and software for transforming the measured radial artery pulse waves into voltage signals. To acquire precise BP, the signals generated by the MPG pulsimeter were simultaneously compared with systole and diastole areas in the radial artery pulse wave. The pulse wave data for three clinical participants (normal BP, hypotension, and hypertension) were analysed. Analysis of pulse waves measured during testing of the arterial pulsimeter was conducted using two BP equations. The BP values calculated from these equations for the radial artery pulse wave data acquired during a 5-s-long window by using the MPG pulsimeter were compared to the BP values measured using electronic or liquid mercury BP meters. Our results are likely to be useful for developing a biomedical signal storage device for mobile U-healthcare applications.

Keywords: Central artery pressure; Blood pressure; Radial artery pulse wave; Magnetoplethysmogram

Introduction

The brain's vasculature relies on the central aorta, and there is a direct correlation between atherosclerosis of the central aorta and that of the neurovascular system [1,2]. This relation between the brain's vascular system and the central aorta has been evaluated recently in terms of the central arterial pressure (CAP) and the compliance of aorta. In the United States, there are 50 million hypertension patients, and 3 million patients exhibit normal self-adjustment, making them similar to patients with normal blood pressure (BP). The remaining patients exhibit malfunctioning self-adjustment [3,4].

Clinical trials suggest that patients with high-resistance hypertension are more likely to develop cerebral thrombosis compared to patients with normal-resistance hypertension, when both groups are treated to the same extent by using anti-hypertension medication [5,6].

As a rule, BP is measured during the systolic and diastolic cycles. BP can be measured at several points during the systolic and diastolic cycles [7]. The systolic pressure can be measured after the Korotkoff sound is first detected, while the diastolic pressure can be measured after the sound is no longer detected. The systolic pressure occurs when a ventricle is contracted, and it is pumping blood out of the heart. The diastolic pressure occurs when a ventricle is relaxed, and is being refilled with blood. The blood flow ceases when a blood vessel is pressurized [8].

As the pressure decreases, blood will start to flow again and sound can be detected. The pressure at which this occurs is called the systolic pressure. At some point, the sound is no longer detected as the pressure decreases further. The pressure at this point is called the diastolic pressure. The blood pressure is reported in the units of millimeters mercury (mmHg).

The CAP is calculated as a peak height of a pressure waveform that is formed when the forward and reflected waves in the central aorta combine [1-3]. For the central aorta, the CAP during the systolic stage cannot be measured using a general-type BP device monitoring the upper brachial artery. The pulse wave travels along the wall of the artery, and the amplitude of the wave is partially reduced as it passes a branching point. A fraction of the pulse wave, called the forward wave, is transmitted and continues to propagate along the wall. A complementary fraction, called the reflected wave, is reflected and propagates backward [4-6].

Thus, on top of the baseline pressure, the central aorta experiences additional pressure when the forward and reflected waves superpose. The pressure owing to the central arterial pulse wave depends on the heart contractibility, the extent of a blood vessel's stiffness, peripheral revascularization, and the stiffness and function of peripheral blood vessels [9].

The central aorta is frequently subject not only to arteriosclerosis but also to atherosclerosis; thus an increase in the CAP can aggravate atherosclerosis. The causes underlying a gradually increasing CAP include abnormal acceleration of aging, hypertension, hyperlipidemia, and diabetes [3-5]. These are classified as diseases that are very likely to induce arterial stiffness and yield malfunctioning blood vessels.

In the present work, we developed a magnetoplethysmogram (MPG) pulsimeter that utilizes a magnetic field-sensing semiconductor Hall device for acquiring precise BP [10-12]. We sought to develop a wrist-wearable MPG pulsimeter for accurately measuring both the BP and pulse rate of a moving subject [13,14]. In addition, such a cuffless MPG pulsimeter can be incorporated into a wrist-wearable device for accurate measurements of BP and radial artery pulse [15].

Materials and Methods

Participants

The participants were recruited using the following typical three criteria: average people having normal BP; and average people having low BP, which was defined as below 110 mmHg and 70 mmHg of systolic and diastolic pressure, respectively; average people having hypertension; The participants chosen for our research had to meet certain selection criteria. Applicants who were not excluded based on the exclusion criteria listed below, or who did not have a communication impediment, such as a reading or writing impediment, and who satisfied the following five criteria were chosen for inclusion in this study:

- The candidate must be an adult volunteer aged between 20 years and 30 years who is not rejected based on the exclusion criteria.
- The candidate must have a BP value measured by using electronic or mercury liquid BP meters.
- The candidate had to be a volunteer who agreed to our clinical studies agreement.
- The candidate had to be an individual whose condition could be determined by a clinical trial coordinator.

In this study, we excluded applicants who were not psychologically stable or who had an acute serious illness. We also excluded any person who had a chronic disease of the heart or any other diseases that might interfere with the interpretation of the results and the therapeutic effect.

Applicants who had experienced clinical studies related to a pulsimeter within 1 month of our study were excluded, as were those who had diseases such as seizures or perception disorders, who wore cardiac pacemakers or who had implants with metal joints, prosthodontics, etc. All of these could affect the diagnosis made using the pulsimeter and make the clinical study difficult.

Experimental design

Periodic motion of an arterial vessel (such as the radial artery) induces variations in the vessel thickness and vessel distance from the skin surface. The pulse vessel periodicity is related to the electrocardiogram (ECG), and the blood flow velocity changes periodically [16].

The wearable medical device developed in this study consisted of a permanent magnet, Hall's device, the measuring module, a light emitting diode (LED), a display panel, a USB port, and a switch. The permanent magnet had a diameter of 2 mm and its height was 1 mm, and the surface magnetic field generated by it was ~300 Oe [17-20].

The permanent magnet was installed at the center of a silicon rubber piece and glued using epoxy. The silicon rubber piece made a good contact with skin and applied uniform pressure on the radial artery.

The permanent magnet glued using epoxy at the center of the silicon rubber was positioned on the so-called "Chwan" point of the radial artery and the device enclosed the wrist by making contact with the skin surface, as shown in Figure 1(a).

A cylindrical permanent magnet in contact with the skin above the radial artery moved easily in response to the shock made by a pulse. For measuring the pulse wave in this experiment, the distance between the Hall device and the permanent magnet was in the 2.0-3.0 mm range. One permanent magnet in the measuring module moved by 1 mm up and down owing to the periodic motion of the radial artery vessel. The actual wrist-wearable device, featuring the measured radial artery waveforms, is shown in Figure 1(b).

The electrical output signal of the pulse wave was acquired in self-examination measurements performed by the MPG pulsimeter equipped with the Hall device that automatically established a base point based on variations in the magnetic field intensity. Depending on the fluctuation of the permanent magnet, the acquired signals were filtered for eliminating noise. Pulse waveforms could be collected, analyzed, and transferred to a personal computer at a rate of 1000 points/s. After selecting one section, five repeating pulse waveforms were calculated by the MPG pulsimeter by using a custom algorithm [17].

The permanent magnet and the Hall device were placed inside an air bladder and made good contact with the biggest pulse spot in the radial artery. The weight of the MPG pulsimeter was ~80 g, including the battery.

The electrical power consumed by this device during its operation was provided by a lithium battery and was under 1.7 W (500 mA, 3.4 V). With a fully charged battery, the device can keep the high/low blood pressure data for one day. Persons with normal BP were distinguished from those with high BP based on the pulse relation between systolic BP and regular arteriotony, which is able to divide by the shape of pulse wave [21-23].

Measurement of pulse wave

The diastole was defined as the starting point of a representative pulse wave and the systole was defined as the first zero point of the first differential wave. Here, the starting point is the notch point. The systolic peak (or augmentation point) was defined as the second or third zero point in the sixth differential of a pulse wave for normal blood pressure. The notch point was defined as the zero point of the third or fourth of the sixth differential of a pulse wave for high blood pressure [24-26].

Figure 1(a) shows a photograph of a mockup radial artery used for clinical testing and a wrist-wearable MPG pulsimeter that utilizes a Hall device element and a permanent magnet. The distance between the surface of a silicon rubber piece and the measuring part of the Hall device was 3 mm.

Figure 1(b) shows a photograph of the real wrist-wearable MPG pulsimeter measuring a pulse wave, and schematic shows the cross-section with a detailed description of the device's components. The pressure chamber between the part contacting the skin and the pulse-sensing parts was filled with air. An operating MPG pulsimeter continuously displayed processed pulse waves on a liquid crystal display (LCD) monitor.

After appropriate research volunteers for this study had been identified the inclusion and exclusion criteria, we established the process and method of pulse measurement. After the participants were selected for the normal BP group, the low BP group, and the hypertension group had been given a 5-minute break, the pulse waves were measured using the pulsimeter (3 minutes interval), which was followed by a 1-minute rest period and then another 3-minute pulse-wave acquisition.

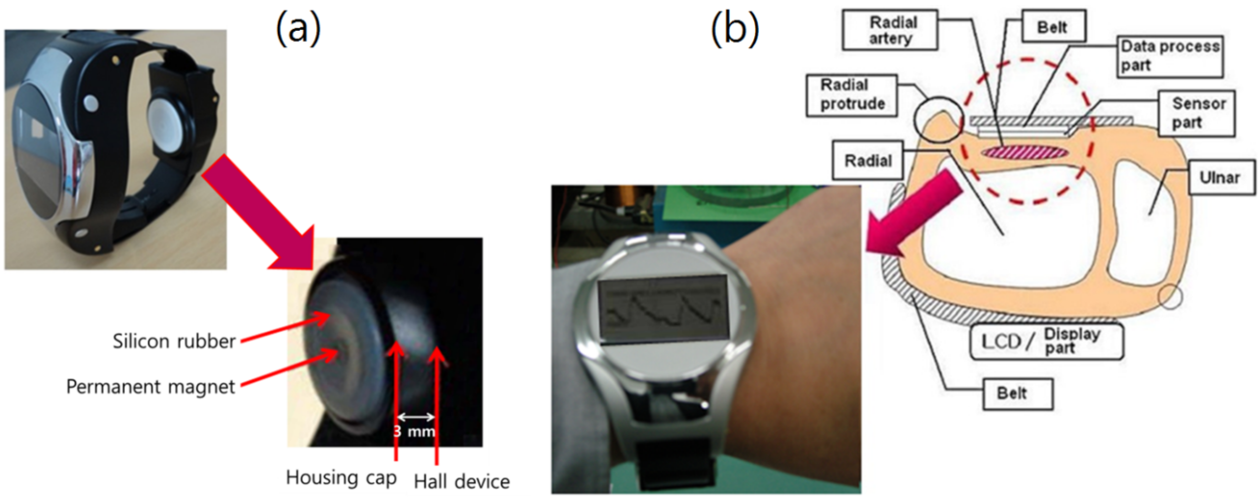


Figure 1: Photographs of (a) a mockup radial artery used for clinical testing and (b) a fully functioning wrist-wearable MPG pulsimeter. Schematic shows the cross-section with a detailed description of the device's components.

Statistical analysis of clinical data

The number of participants for the clinical trial was not calculated because this research was an exploratory preliminary research to understand the algorithm for using the pulsimeter to measure the diastolic blood pressure (P_d) and the systolic blood pressure (P_s).

For a normal distribution based on 5 people in each group, the parametric statistical method can be used. Thus, such a distribution could be used in our study with 15 participants (7 males and 8 females) in the group.

Because measurements using a MPG may give rise to differences depending on sex, we divided the candidates by sex and then classified them into three groups: the normal BP group, the low BP group, and the hypertension group.

Comparisons of the mean values of the variables age, height, weight, BMI(weight/(height)2; kg/m2), P_s, P_d, body temperature, and pulse wave were done for the normal BP group, the low BP group, and the hypertension group.

Results

A wrist-wearable cuffless MPG pulsimeter for clinical use is shown in Figure 2 and Figure 3; this pulsimeter utilizes a Hall device for acquiring data.

For solving the positioning problem according to the pressing intensity and the moving artifacts, and for acquiring precise pulse wave signals, which may depend on individual patient wrist characteristics, we developed a new cuffless wrist-wearable pulsimeter that features the comparison of seven Hall devices to one as shown in Figure 1.

Each module with its Hall device and permanent magnet senses one position on the radial artery. For measuring BP by using the pulse wave obtained from the radial artery based on the analysis of the non-pressurized pulse wave, which detects minute changes in the magnetic field of a permanent magnet, we used two phenomenological equations that are often used in Oriental diagnostic medical practice for estimating the BP.

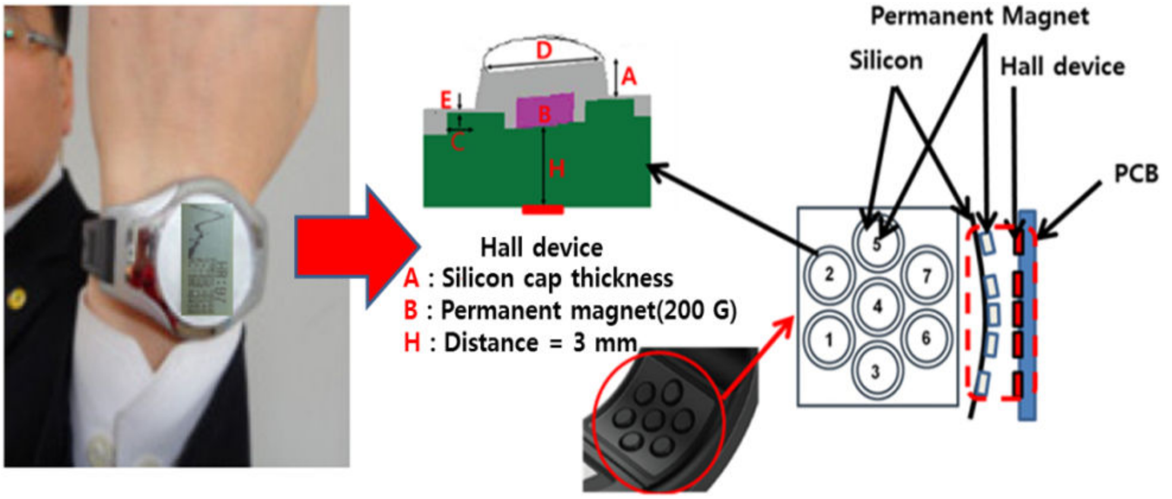


Figure 2: A photograph of the cuffless wrist-wearable MPG pulsimeter showing the results of BP measurements and major parameters after processing the pulse wave. Schematic of a combination of seven modules, each with its Hall device and permanent magnet sensing one position on the radial artery.

Figure 3 shows the cuffless wrist-wearable MPG pulsimeter equipped with seven Hall sensors contacting on the radial artery. Any patient's condition (for example obesity, atrial fibrillation, circumference of thick and thin wrist) can be affected the reliability of the measurements. To maintain the reliability of the measurements according to the various circumferences of wrist, MPG pulsimeter was composed of the major parts such as soft rubber band, clip rail, and band clip for the length adjustment.

By a preliminary and detailed investigation about wrist circumferences depending on males and females, we design to specify it and give insights about the necessity of a randomized trial, considering all the possible interferences for the various wrist features. The lengths of band of male and female are 150~220 mm and 150~290 mm with a width of above 26 mm. The length adjustment unit with a maximum of 70 mm is positioned at the end of band rail.

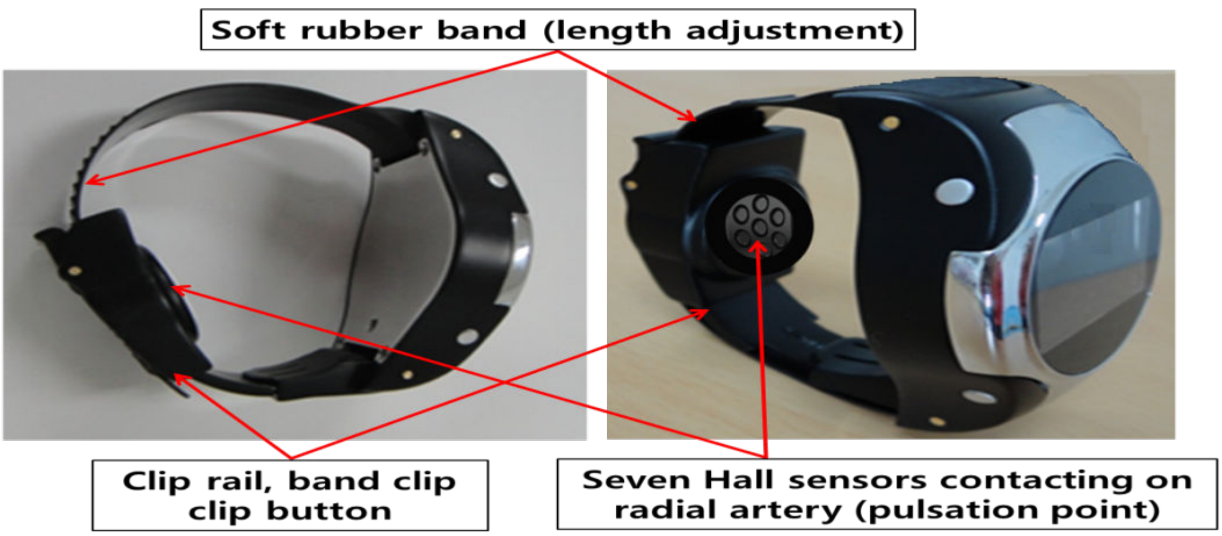


Figure 3: Photographs of the cuffless wrist-wearable MPG pulsimeter equipped with seven Hall sensors contacting on the radial artery. To maintain the reliability of the measurements according to the various circumferences of wrist, MPG pulsimeter was composed of the soft rubber band, the clip rail, and the band clip for length adjustment.

Figure 4 shows seven pulse waveforms measured for one clinical participant by using the seven measuring modules (each with its own Hall device and permanent magnet) of our wrist-wearable pulsimeter in Figure 2 and Figure 3. The seven waveforms were measured simultaneously under steady pressure. After defining the noise filtering process, setting the region, and setting the maximal value and starting point for the acquisition of radial artery pulse waves, temporal signals for all measuring modules were plotted against the measurement time (seconds). The seven pulse waveforms were very similar.

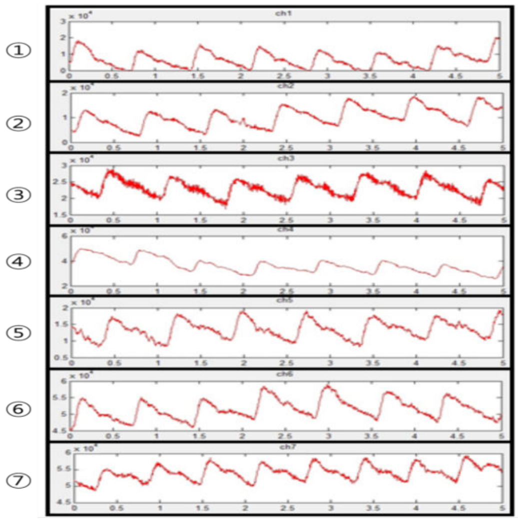
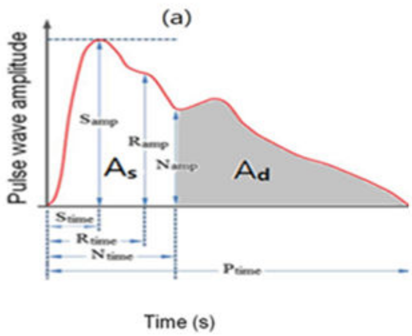


Figure 4: Seven pulse waveforms measured for one clinical participant by the seven modules, each with a Hall device and permanent magnet, obtained using the wrist-wearable MPG pulsimeter under steady pressure.



(b)

Parameters of Pulse Wave	Definitions
S_{amp}	Systolic peak amplitude
R_{amp}	Reflective peak amplitude
N_{amp}	Notch peak amplitude
S_{time}	Systolic peak time
R_{time}	Reflective peak time
N_{time}	Notch amplitude time
P_{time}	Period time

A_s : the area of systolic
A_d : the area of diastolic

Figure 5: A typical pulse waveform and the definitions of major parameters for the typical pulse wave measured by a clip-type pulsimeter equipped with a magnetic sensing Hall device. Here, A_s and A_d define the systolic and diastolic areas, respectively, separated by the notch amplitude N_{amp} at time N_{time}.

Figure 5a shows a typical pulse wave form with major parameters such as S_{amp}, R_{amp}, N_{amp}, S_{time}, R_{time}, N_{time}, P_{time}, A_s, and A_d that define the nine major parameters of the pulse wave [17,18].

The definitions of the nine parameters of the pulse wave in Figure 5(a) are given in the table in Figure 5(b). In addition, the definitions of the nine pulse wave parameters in each area are provided in Figure 5(a).

The clinical data were used for calculating the average values of the pulse wave parameters over five consecutive pulse waves [12,17].

The parameters S_{amp}, N_{amp}, A_s, and A_d are especially important because they define, respectively, the systolic peak amplitude, the notch peak amplitude, the systolic area, and the diastolic area, which is separated from the systolic area by the notch amplitude N_{amp} at time N_{time} [11,17,21].

These average values were automatically saved as clinical data to an Excel file.

Discussion

The main property of the pulse wave for calculating the estimated BP was extracted by applying the difference between the ratio of the systolic amplitude and the notch amplitude of the pulse wave. This must be performed for the systolic and diastolic areas.

Because the air inside the air bladder containing the permanent magnet can be changed by relative pressure, the pressure applied to the sensing part of the MPG pulsimeter is maintained at the same value until the pulse waveform is displayed.

For a more precise BP estimation, we divided the data from the clinical trial into five consecutive pulse waveforms.

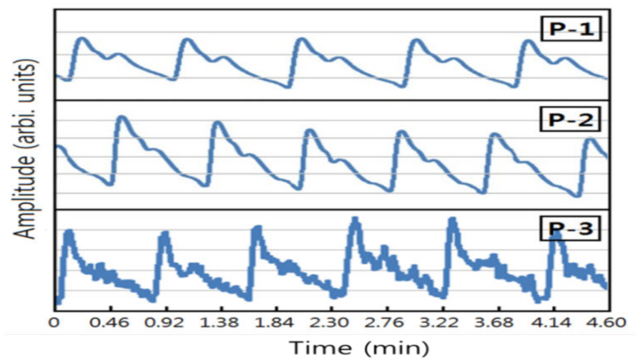


Figure 6: Three pulse waveforms obtained after applying filtering to 4.6-min-long recordings for three different clinical participants with: 1) normal BP (patient P-1); 2) low BP (patient P-2); and 3) hypertension (patient P-3).

Figure 6 shows three example waveforms that were used for estimating and deriving the intuitive equations for BP that appear below. We identified the main parameters necessary for deducing the equation for the estimated BP; these parameters were the systolic peak amplitude S_{amp}, the notch peak amplitude N_{amp}, the systolic area A_s, and the diastolic area A_d. Using these parameters, the following equations were deduced by analyzing Figure 4:

$$P_s[\text{mmHg}] = \frac{1+\frac{N_{amp}}{S_{amp}}}{\frac{S_{amp}}{N_{amp}}} A_s \quad (1)$$

$$P_d[\text{mmHg}] = \frac{1+\frac{N_{amp}}{S_{amp}}}{\frac{S_{amp}}{N_{amp}}} A_d \quad (2)$$

Applying equations (1) and (2) to the measured data we estimated the systolic and diastolic blood pressure. The important quantities for this estimation were as follows: P_s, the systolic blood pressure; P_d, the diastolic blood pressure; S_{amp}, the systole amplitude; N_{amp}, the notch point amplitude; A_s, the systolic area; A_d, the diastolic area. Here, the blood pressure was measured in mmHg.

Table 1 suggests the possibility to deduce the value of the CAP by measuring the pulse waveforms in a carotid artery. In addition, these results suggest that the MPG pulsimeter is a reliable medical device based on Oriental diagnostic methods and can be used for predicting atherosclerosis in the cardiac circulatory system. The pulse waveforms for a carotid artery in the neck and a radial artery in the hand wrist were individually measured using the developed MPG pulsimeter equipped with a permanent magnet and a Hall device. The CAP was better correlated with cardiac vascular disease than with brachial arterial BP. Because the CAP is usually measured by inserting a catheter into a blood vessel, clinical data on central pulse measurement are not widely available. However, the developed device enables to measure BP and CAP without using cuffs or invasive devices such as a catheter. Controlling the CAP is widely used together with BP treatment for reducing the incidence of cardiovascular diseases.

Table 1: Pulse wave parameter values and comparison of the estimated and measured BP values, for three representative patients participating in the clinical study

Patient No.	Parameter values of pulse wave							Estimated BP value		Measured BP value	
	S_{amp}	S_{time}	N_{amp}	N_{time}	P_{time}	A_s	A_d	P_s	P_d	P_s	P_d
P-1	54.2	0.12	29.06	0.34	0.96	146	106	119	87	120	85
P-2	34.6	0.1	17.8	0.3	0.77	141	91.8	110	71	110	70
P-3	76.8	0.11	45.82	0.27	0.77	150	94	143	89	145	87

Table 2 shows the comparison between the measured value and the estimated value of BP from fifteen clinical patients. We compared the values of estimated BP from pulse wave data collected by MPG pulsimeter at the left wrist for 5 s with the measured values of BP obtained by an electron sphygmomanometer at the right upper arm. The standard deviation of the error in the values of estimated P_s and P_d obtained from equations (1) and (2) are calculated as 2.6 and 2.2. Since the value of the standard deviation was close to the limit on the International BP Standard, this device could be commercialized as a non-pressurization BP and arterial pulsimeter. If we are able to build up more data and thus develop a suitable equation that is able to decrease the error of systolic BP readings, our pulsimeter will be suitable for commercial applications.

Table 2: Comparison of the measured value and the estimated value of BP applied to the clinical data. 1* Number; 2* Estimated; 3* Measured; 4* M-Value - E-Value; 5* Standard Deviation

Classification	Systolic Blood Pressure (Ps) (mmHg)			Diastolic Blood Pressure (P_d) (mmHg)		
Clinical #1*	E2*-Value	N3*-Value	Error4*	E-Value	M-Value	Error
1	119.4	120	0.6	87	85	-2
2	124.4	127	2.6	86.5	84	-2.5
3	123.7	126	2.3	84.7	83	-1.7
4	121.6	123	1.4	81.6	84	2.4
5	122.5	121	-0.5	88.1	86	-2.1
6	109.9	110	-0.1	71.4	70	-1.4
7	107.4	110	2.6	70.7	74	3.3
8	110.3	109	-1.3	72.3	75	2.7
9	111.3	108	-3.3	73.1	75	1.9
10	112.4	107	-5.4	71.8	74	2.2

11	143.1	145	1.9	89.4	87	-2.4
12	140.2	144	3.8	88.7	89	-1.7
13	139.5	140	0.5	89.1	93	2.9
14	141	143	2	90.1	92	1.9
15	141.6	146	4.4	87.3	89	1.7
S. D.5*			2.6			2.2

Several important issues need to be considered for successfully predicting cardiac diseases. These include 1) a change in the blood flow between the systole and diastole stages, 2) the pressure that makes the blood flow, and 3) a change in the blood vessel's diameter. A catheter is usually inserted for detecting a change in the blood flow volume. This method is invasive and inaccurate, yielding especially significant errors in low-amplitude measurements (e.g., when measuring a change in the diameter of the coronary artery).

On the other hand, measuring BP is easier compared with measuring a change in the blood flow. However, successfully predicting cardiac disease and measuring microcirculatory pressure requires estimating the CAP. The microcirculatory pressure correlates with, and directly affects the cardiovascular circulation. In addition, the CAP is directly related to the damage to the cardiovascular system. The microcirculatory pressure and the CAP cannot be measured using the current technology. Rather than using the CAP, cardiac disease can be predicted based on the brachial blood pressure.

Rapid advances in medical technology prompted developing methods for non-invasive estimation of the CAP, and clinical trial for testing this state-of-the-art technology have been performed since 2010. Furthermore, the CAP has been adopted by the Western medical practitioners as a method of choice for blood pressure treatment since 2010 [3]. Yet a method for accurate measurement of the CAP is still lacking. Notwithstanding, both the International Hypertension Meeting and the International Academy of Cardiology have officially agreed to adopt the brachial blood pressure and the CAP in the treatment of cardiac disease. Furthermore, both the United States and Europe have agreed to adopt the brachial blood pressure and the CAP for the treatment of BP [2,27,28]. In 2010, Japan's Hypertension Academy proposed using the brachial blood pressure and the CAP for managing BP, as described in the revised "Measuring blood pressure and clinical evaluation" guide book on treating hypertension [28].

To maintain the health of a human, reference values for cardiac output and total resistance of blood flow corresponding to this cardiac output were tabulated. Real cardiac output/ reference values for cardiac output and real total resistance/ criteria values of blood flow were set up to obtain a heart index and a total resistance index of the blood flow. Secondly, the BP was classified from the self-adjustment perspective by using a heart index and total resistance index of blood flow.

Conclusions

A wrist-wearable MPG pulsimeter equipped with a magnetic field-sensing semiconductor Hall device and a permanent magnet attached to silicon housing at the centre of the radial artery was developed for BP monitoring. This pulsimeter can acquire precise BP and pulse rate values by using a cuffless device containing a hardware and software system for measuring radial artery pulse waves transformed into voltage signals. The systolic and diastolic areas and the systolic and notch amplitudes of the radial artery pulse wave were used simultaneously for obtaining systolic and diastolic BP. The clinical tests for three human subjects (normal BP, hypotension, and hypertension) yielded precise BP similar to the BP values measured using conventional devices. Two estimated BP equations obtained using the cuffless arterial pulsimeter during 5 s show the analysis of the pulse wave measured during the testing of the arterial pulsimeter.

Based on the theoretical background, we developed a MPG pulsimeter for BP measurements, which enables measuring the brachial pressure and the CAP. Classifying BP in terms of hypertension, normal blood pressure, and hypotension is not efficient for preventing a cerebral vascular disease or a cardiovascular disease. Therefore, accurate self-adjustment is recognized as an essential and fundamental factor of any successful BP therapy. One of the goals of a successful BP therapy is to be able to simultaneously manage the brachial pressure and the CAP. Central aorta frequently develops not only arteriosclerosis but also atherosclerosis; thus, the CAP increases, worsening the outcome of artherosclerosis. Thus, the CAP is more closely related to the etiology of cardiac vascular diseases than the brachial arterial BP.

One important advantage of the proposed MPG pulsimeter is its portability, which allows using it as a wrist-wearable device for accurate BP measurement. This medical device can also yield data that are usually obtained by performing complicated procedures, such as for measuring the brachial pressure and the CAP, allowing to efficiently obtain precise BP. The developed MPG pulsimeter may be useful for developing a biomedical signal storage device for mobile U-health applications.

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