Noninvasive continuous blood pressure monitoring via superficial temporal artery tonometry

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Abstract— Objective: **Arterial blood pressure (BP) is one of the most important physiological indexes monitored in the perioperative period, yet all existing noninvasive monitoring methods are limited in either sampling rate, measuring site or accuracy. In this work, a systematic evaluation was conducted on a novel BP monitoring approach through the use of the superficial temporal artery tonometry (STAT) method and the corresponding developed BP monitoring system.**

Methods: **Twenty-nine sessions of 30-minutes continuous BP monitoring during resting and during handgrips induced BP fluctuation were conducted in human subjects (n=10) simultaneously with the STAT method, Finapres Finometer and Pulse Transit Time (PTT) method.**

Results: **Using Finapres Finometer as the gold standard for continuous BP, our proposed device resulted in 4.8 ± 2.2 mean absolute difference (MAD) during resting and 6.5 ± 3.4 MAD during handgrips, which significantly outperformed PTT, especially in handgrips. Correlation plots and Bland-Altman plots also suggest the same conclusion.**

Conclusion: **BP monitoring via STAT was systematically evaluated and showed better performance than PTT.**

Significance: **Noninvasive and continuous perioperative BP monitoring via STAT may be feasible and appropriate.**

***Index Terms*—Continuous, Intraoperative Blood Pressure Monitoring, Noninvasive, Superficial Temporal Artery, Tonometry**

I. Introduction

ARTERIAL blood pressure (BP) is one of the most important physiological indexes that require serial monitoring in the perioperative period. BP provides valuable information about cardiac output, cardiac pressures and hemodynamic stability [1, 2]. More specifically, it has been used to evaluate the effects of anesthetic drugs on the cardiovascular system, the adequacy of noxious reflex suppression, fluid overload or deficit, need for blood replacement, and vasopressor or vasodilator therapy [3]. Studies also suggest that intraoperative hypotension is strongly associated with postoperative mortality and various organ dysfunctions [4-6]. According to a recent trial, proper control of intraoperative systolic blood pressure (SBP) lead to reduced postoperative organ dysfunction [7]. Central to the maintenance of intraoperative normotension is accurate monitoring of intraoperative BP.

Intraoperative BP is measured with either intermittent or continuous BP measuring devices. However, monitoring BP intermittently could potentially lead to missing hemodynamic events. A recent randomized trial reported that continuous noninvasive BP monitoring nearly halved the amount of intraoperative hypotension, compared to BP monitoring using a standard oscillometric cuff [8]. As for continuous intraoperative BP monitoring, an arterial line is widely used. Nevertheless, percutaneous arterial cannulation requires skill and time. It is invasive and is associated with several rare, but serious complications [2].

In order to overcome the known disadvantages of traditional cuff-based measurement methods, previous studies have suggested various non-invasive and continuous methods, such as pulse transit time (PTT) [9-14], volume clamp [15, 16] and tonometry-based method [17-21]. Though they have demonstrated advantages over the oscillometric cuff-based methods, each of them still has its own shortcoming. For instance, it has been discussed in our previous study [22] that many factors adversely affect PTT calibration. Tradition tonometry-based method like T-Line® Tensymeter uses large arteries, which requires larger pressure to flatten the arteries and hence larger device. Besides, many methods assume stable relation between BP in arm/finger and Central BP, which is not always the case, especially in operative setting.

Although it is well established and standard practice to measure BP from the arm, there are times when it is either not ideal or not possible to use the upper limb for blood pressure measurement. This is particularly relevant in surgery where only one upper limb is accessible. In these circumstances, particularly when Total intravenous anesthesia (TIVA) is being administered in the same arm, having the cuff inflating regularly may impede the smooth delivery of anesthetic. There are also occasions, particularly in orthopedic or plastic surgery, where neither arm is available, and in these circumstances, an alternative site has to be used for BP measurement [23].

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Systematic validation of measuring BP from the superficial temporal artery (STA) was first introduced with a volume clamp based device [24]. Because of its underlying method, real-time control and relatively higher hold down pressure were required. Besides, only limited samples of a short period of cardiac pulses were analyzed. To overcome those shortages, we proposed a novel BP monitoring method based on superficial temporal artery tonometry (STAT) in our prior studies [22, 25]. Different from most methods that measure BP from the arm, STAT directly measures BP in brain level, which is kept normotension in most scenarios and thus a stable indicator of central BP.

Although some preliminary results have been shown in previous studies, no systematic quantitative analysis of STAT has been conducted. In order to fully investigate the potential of STA as a measuring site and STAT as a method for BP monitoring, we conducted 29 sessions of 30-minutes continuous BP monitoring during resting and during handgrips induced BP fluctuation in ten human subjects. Then the measurements from STAT and the measurements from a PTT based method were compared to the measurements from a Finapres® Finometer.

II. Method

The development of the BP monitoring system in this study is based on the ambulatory multi-modality cerebral monitoring system (MCMS-1), introduced in our previous study [22]. The human studies were approved by the Massachusetts General Hospital institutional review board.

A. Sensors in the BP monitoring system

Similar to the previous MCMS-1 system, the following sensors were included in the proposed BP monitoring system: (1) near-infrared spectroscopy (NIRS) based cerebral hemodynamic sensors, (2) ECG electrodes, (3) accelerometry sensors. A tonometry sensor was added in this study. The structure of our NIRS hemodynamic sensor was previously reported in [26]. Briefly, a dual wavelength (785nm and 830nm) laser led was used as the light source (Axcel Photonics, Inc.), and two OPT101 photodiodes (Texas Instruments, Inc.) were used as detectors. Laser power at each wavelength was about 3.5mW (constant during the monitoring period), under the maximum permissible exposure standards for skin illumination. ECG was acquired through standard chest leads and Ag-AgCl electrodes. Synchronized photoplethysmography (PPG) at forehead from NIRS based sensor and ECG were used to calculate PTT, tonometer placed at STA was used for STAT BP calculation, whereas accelerometry was recorded to monitor the orientation and motion of the head of subjects.

A lightweight wearable BP sensing module was developed, which can be easily attached to a regular pair of eyeglasses, a headband, or to headphones. The structure of the BP sensing module on glasses can be seen in Fig. 2. This BP sensor module was developed using 3D printing. Two important features were incorporated in the design of the BP sensor module to achieve successful STA tonometry: (1) Optimized positioning of the blood pressure sensor. This was achieved by fine-tuning of the STA localization in both x and y directions. (2) Adjustable external pressure for tonometry, achieved by screw-controlled adjustable hold-down pressure. The piezoresistive blood pressure sensor has a sensing area of 14.5mm in diameter, sensing a range of 0~300mmHg, 5KOhm overall resistance (of the resistor sensor bridge), with a sensitivity of 250 uV/mmHg. Preliminary tests revealed that most glasses have enough elastic force to provide the hold-down pressure needed, and the hold-down pressure can remain relatively stable for hours.

The detailed description of the recording system can be found in our previous study [22].

B. Superficial Temporal Arterial Tonometry

STA is a major artery which locates on both sides of the head. Advantages of using STA as the measurement site were discussed in our previous study [22]. Compared to other tonometry based method, STA (1) is easy to identify and localize; (2) does not require a cuff or much pressure to compress or occlude (we have demonstrated quality STA tonometry data with less than 50 gram-force of pressure, similar to the pressure from regular eyeglasses, which does not cause much discomfort during long term monitoring); (3) moves much less than a wrist, and hence is less susceptible to motion artifacts during ambulatory monitoring; (4) provides a BP measurement at the brain level, which is critical for monitoring of cerebrovascular status and stroke prevention.

To estimate the individual difference and feasibility of BP measurements using BP-glass at STA, we performed tests on additional 40 subjects, aged 41 ± 21 (range: 8 to 90) years old, with body mass index (BMI) from 23.3 ± 3 (range: 16 to 29) and none of whom had previous medical training. After less than two minutes of training on STA localization, we recorded the time required for the subject to localize their own STA in each hemisphere, and the STA of another person (validated by expert judgment). 100% of the subjects were able to localize their STA, taking 9.3 ± 6.8 sec to localize their own STA, and 11.4 ± 10 sec to localize the STA of another person. With additional practice, localization time decreased.

Following the solid mechanical structure model and the simplifications adopted from [1], we have that the tonometry signal is a function of the contact length, artery deformation stress and the vessel's internal pressure. When the sensor is pressed at a stable hold-down distance (i.e. resulting a stable deflection of the vessel), the tonometry signal is only a function of the internal pressure plus a constant. Hence, we hypothesized that the STAT and the internal pressure have a stable linear relation within the range of the blood pressure fluctuation, when above situation is satisfied.

C. Data analysis algorithms

Data analysis for BP from STAT, PTT and other parameters were performed in the Matlab environment using algorithms we developed.

To calculate BP from STAT, the parameters (slope and intercept) of the linear relation between them were calibrated with three seconds of continuous BP measurements from Finometer and the corresponding STAT measurements. The

calibration point was defined as the earliest point where all recorded signals (STAT, ECG, acceleration, NIRS, and BP from Finometer) were in a relative stable state. i.e., they varied little in frequency and amplitude. Parameters calculated from this calibration are then used throughout the experiment to map the STAT to continuous BP value. Systolic BP (SBP) and diastolic BP (DBP) used in the analysis were obtained with an envelope detection and then filtered with a 0.1Hz to 1Hz bandpass Butterworth filter. Mean BP was then calculated from SBP and DBP with the definition:

$$MBP = \frac{SBP + 2DBP}{3} \tag{1}$$

The BP recordings from Finometer was processed with the same filter to obtain the SBP, DBP, and MBP from Finometer.

To calculate BP from PTT, we adopted the algorithm introduced in the original PTT-BP study [11], which modeled the relation between PTT and SBP/DBP as:

$$DBP = \frac{SBP_0}{3} + \frac{2DBP_0}{3} + Aln\left(\frac{PTT_{w_0}}{PTT_W}\right) - \frac{\frac{(SBP_0 - DBP_0)}{3} PTT_{w_0}^2}{PTT_w^2},$$
$$SBP = DBP + \frac{(SBP_0 - DBP_0)PTT_{w_0}^2}{PTT_w^2} \tag{2}$$

In (2), PTT_W is a weighed PTT, A is a subject-dependent coefficient but can be approximated for a population. The parameters with the subscript "o" are those obtained from the calibration, which is exactly the same period used in STAT calibration. PTT model integrated with Photoplethysmogram Intensity Ratio [27] was also tested in a few experiments, but no substantial improvement is obtained. Therefore, we still adopted the former model to calculate BP from STAT. The resulting SBP and DBP were then interpolated into 250Hz signals for later comparison.

D. Experiment protocol

To systematically evaluate the accuracy of BP measurements using STAT in both static and dynamic settings, we conducted experiments with two different stages: stable BP monitoring and induced BP fluctuation monitoring. 10 subjects (age, 29.5 years; systolic BP, 113.2 ± 14.2 mmHg; diastolic BP, 70.5 ± 11.3 mmHg; 7 males;) participated the test

Every subject was asked to wear a pair of regular glasses with the STA tonometry module attached. The tonometry sensor was positioned above the left-side STA. The optical hemodynamics probe was secured on the right side of the forehead, over the right prefrontal cortex (midway between 10/20 position F3 and Fp1), via its adhesive surface and a headband. An accelerometer was attached to the headband to record head movement. Three channel ECG signals were simultaneously recorded. All channels were sampled at 250Hz. At the beginning of the test, cuff from ABPM was fastened on the right arm of the subject to provide calibration. The finger cuff from Finometer was on the middle finger of the left hand. The left middle finger of the subject was positioned at the heart level.

The test procedure was as follows. Before the BP monitoring test, the resting BP of the subject was measured by an electrical cuff sphygmomanometer, and the subject was asked to do a maximum handgrip strength test using an electronic hand dynamometer. Then, the recording system described above was worn by the subject under the assistance from the researchers. After that, the recording both from our system and from Finometer were started. Then, the BP of the subject was measured by an electrical cuff sphygmomanometer again. Then, 20 minutes of BP was recorded, while the subject was asked to sit quietly and try to reduce any movement in the head. Following that, the induced BP fluctuation monitoring stage started. Sustained handgrip exercise [28] was used to induce BP fluctuation. This excercise was first used to compare BP measurement of Finometer and inter-arterial BP monitoring in a previous study [29]. Four separate sessions of handgrip exercise were performed by the subject, separated by three 30-seconds intervals where the subject stopped the exercise and rest. Every handgrip exercise was performed by gripping the hand dynamometer using the right hand. The hand dynamometer was held at 30% of the subject's maximal strength for as long as the subject could hold on, i.e., till fatigue. Each handgrip exercise typically raised blood pressure 20-40 mmHg higher. After the handgrip exercises, another 10 minutes of resting BP was recorded.

III. RESULT

In total, 29 experiments were recorded. Recordings from 8 experiments were discarded due to the use of a broken pressure sensor. Another recording was discarded because of too much movement during test compared to the rest of the tests, based on the readings from the accelerometer. Therefore, 20 recordings were included in the analysis.

We adopted the IEEE 1708 standard [30] (IEEE Standard for Wearable, Cuffless Blood Pressure Measuring Device) to evaluate the accuracy of measurement in both resting BP monitoring and induced BP fluctuation monitoring, where measurements from Finometer were treated as the gold standard.

The Main Absolute Difference (MAD) defined in IEEE 1708 was calculated by (3):

$$MAD = \frac{\sum_{i=1}^{n} |p_i - y_i|}{n} \tag{3}$$

Where p_i is the proposed device measurement and y_i is the measurement from reference measurement, which is that from Finometer in our case. The MAD accuracy level classification with comparison to the ANSI/AAMI SP10 [31] and BHS evaluation systems [32] can be found in Table. I.

We evaluated SBP, DBP and MBP measurements from the resting BP monitoring and induced BP fluctuation monitoring respectively using MAD. Note that we evaluated resting and induced status separately, and measurements in comparison are continuous instead of discrete, thus the grading cannot be directly interpreted as the grading of the device. Therefore, MAD is directly used as a metric. Because of the irregular two-second self-calibration process in the Finometer approximately every 60 seconds, the SBP, and DBP output from Finometer were affected by irregular 2s peak noise. Nevertheless, MBP is much less affected by this due to the peaks in SBP and DBP cancels each other in addition. To provide a better continuous gold standard, we adopted MAD of MBP as the main metric.

TABLE I
MAD ACCURACY LEVEL WITH COMPARISON TO THE ANSI/AAMI SP10 AND BHS EVALUATION SYSTEMS

MAD (mmHg)	ANSI/AAMI SP10	BHS	IEEE 1708
≤ 4	pass	Grade A	A
4-5	pass	Mostly in A, less in B	A
5-6	pass or fail	mostly in B, less in A, extremely less in C and D	B
6-7	mostly fail, less pass	mostly in C, less in B and D	C
≥ 7	fail	Worse than C	D

A. *Accuracy of measurement in resting*

The accuracy of measurement in the resting phase was evaluated on the starting 20 minutes of every valid recording. The MAD of SBP, DBP, MBP from our proposed system and PTT method can be found in Table. II. In resting status, when comparing MAD in SBP, DBP, and MBP, STAT method demonstrated similar performance as PTT.

B. *Accuracy of measurement in handgrips*

Out of 20 recordings, 14 contains significant BP fluctuation (>= 20 mmHg). The MAD of SBP, DBP, MBP from STAT and PTT method can be found in table 2. Compared to PTT method, results indicated that STAT had tracked the BP fluctuations significantly better (*Mann–Whitney U test*, p<0.01).

Fig 1a shows typical measurements in handgrips using STAT, PTT, and Finometer. During the BP fluctuation induced by four hand grips, BP from STAT shows reasonably accurate monitoring of BP in amplitude and delay, when compared with BP from Finometer. While BP from PTT method failed to track the BP fluctuations.

TABLE II
MAD OF SBP, DBP, MBP IN STAT AND PTT DURING RESTING AND INDUCED BP MONITORING.

		SBP (skewness)	DBP (skewness)	MBP (skewness)
Resting	STAT	**6.8 ± 2.3 (0.6)**	5.0 ± 2.7 (2.0)	**4.8 ± 2.2 (1.6)**
	PTT	8.6 ± 3.8 (1.1)	**4.3 ± 1.9 (1.7)**	5.3 ± 2.6 (1.6)
Induced	STAT	**9.6 ± 4.0 (0.3)**	**6.9 ± 4.0 (1.0)**	**6.5 ± 3.4 (1.8)**
	PTT	18.3 ± 6.4 (0.3)	8.9 ± 2.6 (-0.6)	11.7 ± 3.6 (-0.4)

Skewness was used to better demonstrate the skewed distribution of the MAD, which cannot be fully characterized with only standard deviation.

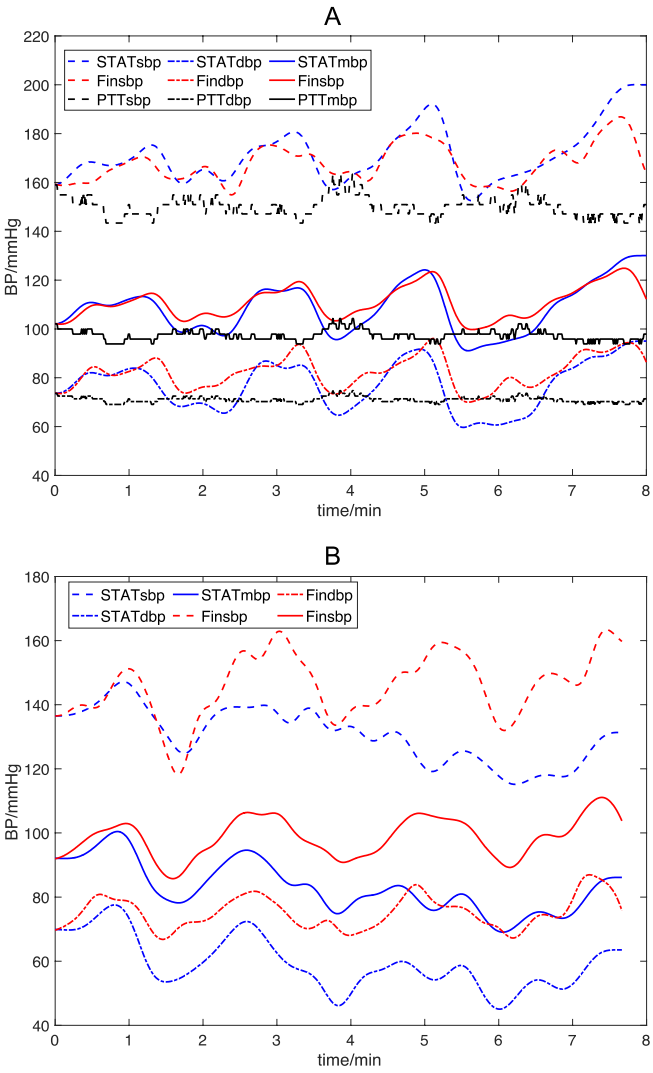

Fig. 1. (A) BP monitoring in induced fluctuation (B) STAT baseline drift in induced fluctuation. SBP, MBP and DBP are plotted in dashed lines, solid lines and dash-dotted lines, separately. BP from STAT, Finapres and PTT are plotted separately in blue, red and black lines.

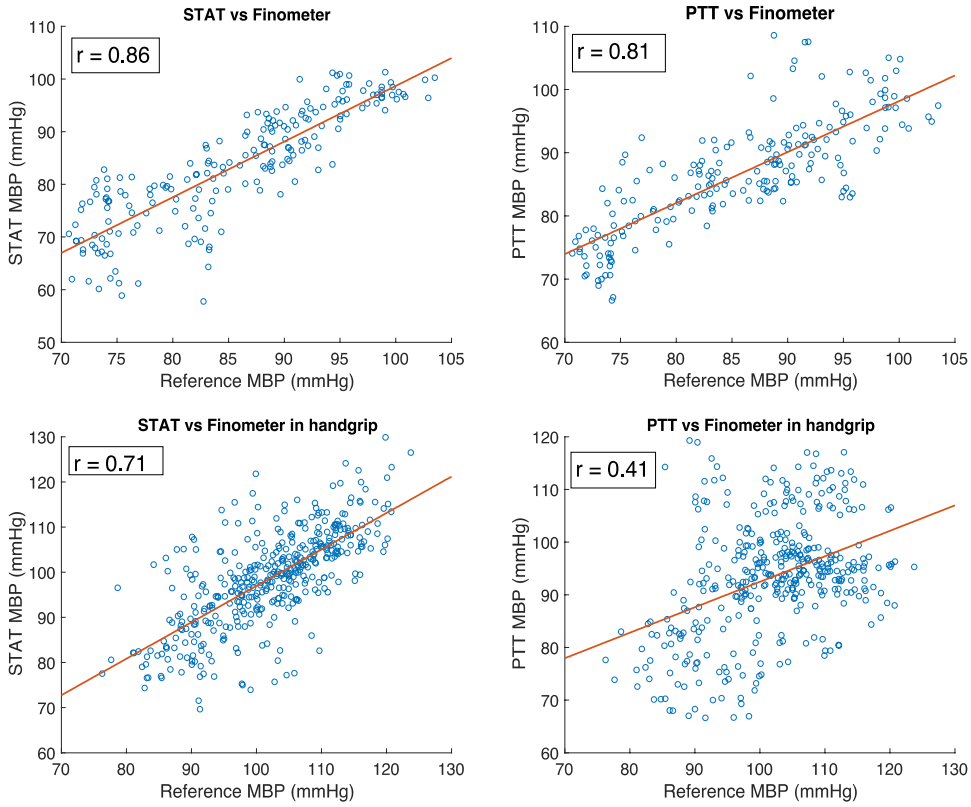

Fig. 2. Correlation plots between PTT, STAT and Finometer during resting and handgrip. The upper row shows the Pearson's correlation coefficients between MBP measured from STAT and Finometer and MBP measured from between PTT and Finometer, in resting state, respectively. The lower row shows the correlations in same settings, but in handgrip state.

Fig. 1b demonstrates the drift of STAT baseline in induced BP fluctuation monitoring, which was the main cause of the MAD performance drop during induced BP fluctuations. However, the shape of the fluctuation was largely captured by STAT measurement. Thus, it is possible to recover the true fluctuation if the baseline could be calibrated when combining methods using other modalities, such as PTT.

C. Accuracy of measurement in handgrips

Because of the high sampling rates of the BP signals, in order to perform and visualize the agreement test, the BP time series were separated into segments in time for agreement analysis. The average of a segment was then treated as one BP measurement with relatively lower sampling rate. For the resting phase, every recording was separated into 10 segments, resulting in an average measurement about every 2 minutes. For induced fluctuation phase, however, the recording was separated into 30 segments to assess the ability in tracking fluctuation, which results in measurements about every 15 seconds.

Fig. 2 and Fig. 3 demonstrate the correlation and Bland-Altman plots between BP from STAT, BP from PTT, BP measurements from Finometer, both in resting BP and induced fluctuating BP monitoring. During the resting phase, STAT showed similar or slightly better performance as PTT in both correlation and Bland-Altman plots. Both methods had reasonably good precision in BP measurements in terms of agreement with the reference. However, during induced fluctuation phase, compared to PTT, measurements from STAT exhibited much stronger correlation and much less deviation to the reference.

IV. Discussion

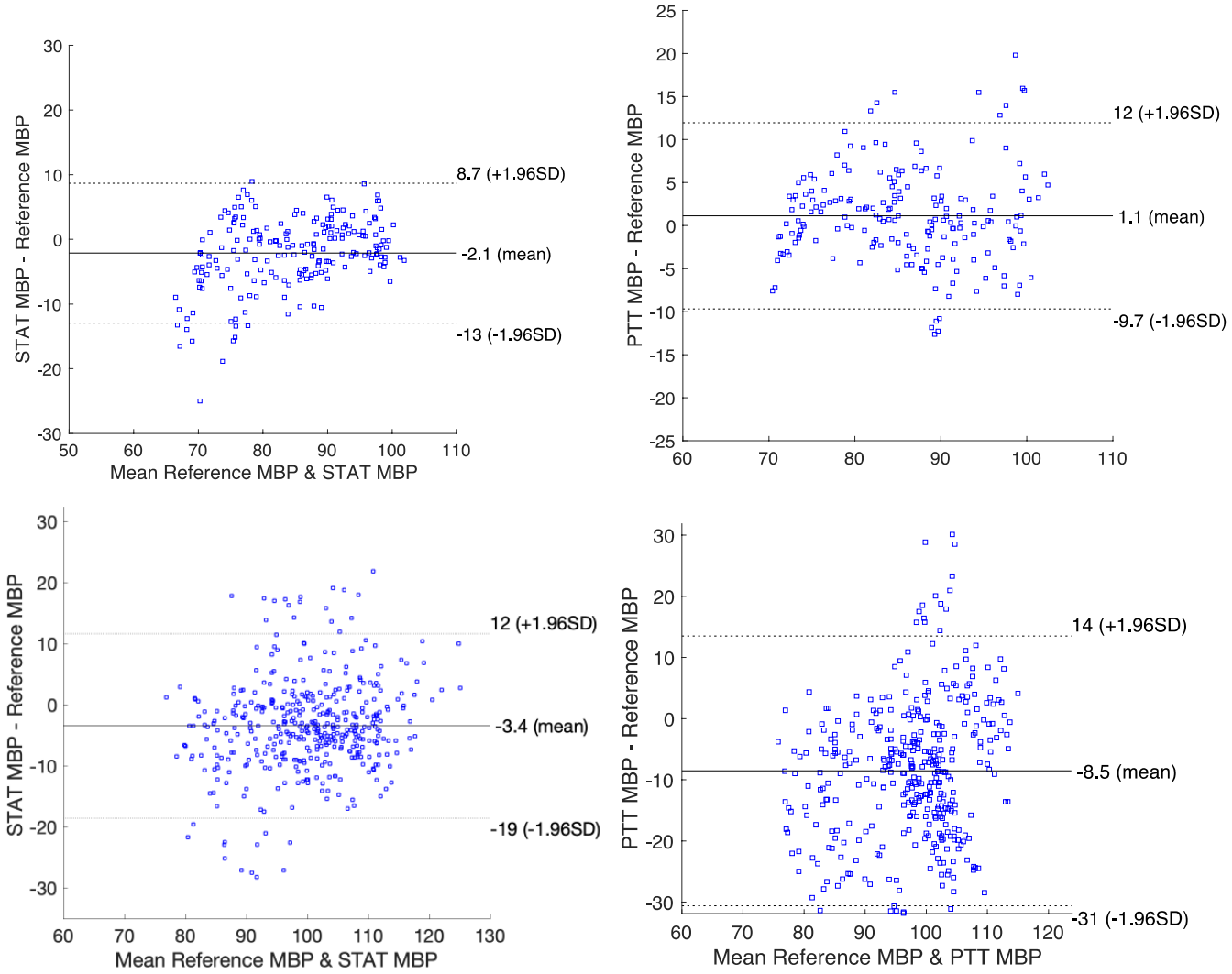

Fig. 3. Bland-Altman plot between PTT, STAT and Finometer during resting and handgrip. The upper row shows the Bland-Altman plot between MBP measured from STAT and Finometer and MBP measured from between PTT and Finometer, in resting state, respectively. The lower row shows Bland-Altman plots in same setting, but in handgrip state.

We systematically evaluated our BP monitoring device based on single point STAT and compared its performance with PTT and Finometer in both resting and induced BP fluctuation period. To the best of our knowledge, this is the first systematic analysis of BP monitoring of single point STAT method. Although the results indicate that STAT is a promising continuous, non-invasive BP monitoring method, especially during BP fluctuation, there are still several limitations in this work.

Currently, external BP calibration at the beginning of monitoring is still required, which is a known limitation in single point STAT with stable pressed depth. We are now developing stepped compression and multi-sensor STAT to achieve the ultimate goal of removing this need. Our experiments showed that although not desired, a short initial calibration in BP monitoring experiment can be tolerated. In fact, almost all cuff-less BP monitoring methods, such as PTT, require initial calibration or calibration during and after the BP monitoring. In certain clinical applications, like intraoperative BP monitoring, initial calibration is normally allowed, thus the feasibility of using single point STAT can be assured.

Another limitation of single point STAT is its susceptibility to motion artifact and followed unstable hold-down pressure. Subject behaviors including head/jaw movement, speaking, gritting teeth and body movement in height level may tamper the accuracy of BP monitoring. In spite of that, the motion artifacts might not be a problem in scenarios where the subject does not demonstrate significant movements, such as under operational BP monitoring under anesthesia.

The elastic relaxation of the tonometry sensor holding material (e.g., glasses) and the elastic relaxation of skin and STA might also contribute to the baseline drift of STAT yielded BP, which results in lower accuracy. When the heart level is controlled, the accuracy of BP monitoring is mostly affected by the motion artifacts that change the hold down pressure. A potential solution to control this effect is to use multi-sensor STAT instead of single sensor STAT to dynamically monitor changes in the hold pressure. After that, software correction or

physical correction with a step motor could be implemented to improve the performance, which coincides with our developing solution for BP self-calibration.

Due to the limitation in time and current restriction on STAT method, only a limited number of subjects were recruited, and thus limited number of experiments were conducted in the first phase of the clinical test. However, because of the continuous nature of STAT method, we believe that the scale of experiments in this work is enough to prove that effectiveness of STAT method for the current stage, which is BP monitoring under a restricted setting. Also, compared to most BP monitoring experiments based on continuous non-invasive method, a relatively long period of BP was recorded in this work. That being said, effectiveness in a specialized scene, e.g., intraoperative BP monitoring, requires further experiments in corresponding settings. After resolving these restrictions discussed above, a larger scale of general experiments of STAT is also necessary for its use in wearable ambulatory BP monitoring.

V. Conclusion

In this work, continuous, noninvasive BP monitoring via single point STAT using a multi-modality BP monitoring device was systematically analyzed and validated against Finapres Finometer and PTT based method in both resting and handgrip induced BP fluctuation. Compared to PTT, both quantitative and qualitative results suggest that our proposed method has a similar performance in resting and a much better performance in induced BP fluctuation. Results including MADs, correlation and Bland-Altman plots proved that error in STAT BP measurements is comparable to the Finometer device. At this stage, this method could be used for intraoperative BP monitoring where the patient is anesthetized and as an alternative method when the upper limb is not available for BP monitoring, with further validation in a larger scale and more diverse groups of subjects.

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