Non-Invasive Radial Artery Blood Pressure Monitoring Using Error Compensated Tactile Sensors and Patient Specific Oscillometry

Rory Hampson, Robert G. Anderson, and Gordon Dobie

Abstract— This paper presents a new method of measuring non-invasive blood pressure at the radial artery based on oscillometry and tonometry. A localized capacitive tactile sensor array is used with a novel algorithm based on waveform features for optimizing oscillometry ratios. A novel tonometer is presented with typically 1% measurement accuracy, with sensor errors compensated using a custom error model, and applied to blood pressure measurement at the radial artery. The tonometer gives a direct arterial waveform, and uses a manual pressure sweep to determine blood pressure. Key points on the oscillogram are correlated with optimal ratios for minimizing mean errors and standard deviation for an individual. This paper details an initial assessment into the dominant sources of error, for the purpose of determining feasibility and directing future research.

Over a limited clinical trial of $N_p = 20$, $N_o = 180$, the reported BP accuracy is MAE = 0.61/0.38mmHg and 1SD = 7.14/5.91mmHg for systolic and diastolic measurements respectively. The average load on the patient is in the order of 5N, compared with around 1000N for a brachial cuff, which represents a clear improvement in patient comfort.

This is a positive result, indicating larger scale performance within AAMI and BHS standards, and stands as a useful benchmark for further development of the system into a clinical product for rapid and comfortable BP measurement.

Clinical Relevance— This paper demonstrated that direct tonometry can measure blood pressure if sensor error is compensated by the designer. This method uses 200x less load than conventional cuffs, suitable for long term and supine use.

I. INTRODUCTION

A. Clinical Blood Pressure Measurement

Blood pressure (BP) measurement is a commonplace medical procedure for monitoring patient health. Although arterial catheterization is the 'gold standard', brachial artery pressure is considered to be clinically significant [1]. This is the method the public is likely most familiar with, where a cuff is used on the upper arm. Auscultatory methods [2], manually operated, are only used in clinical environments and are not suitable for public home use despite their accepted accuracy. Oscillometric devices, automatic cuffs, are commonplace and suitable for home use due to their ease of use. These devices are fine for BP measurement when used carefully [3] but can be inaccurate when used incorrectly, particularly by the public at home in cases of hypertension management [4]. Brachial cuffs can be uncomfortable to patients, and are not suitable for continuous use due to the risk of tissue damage.

B. Tactile Blood Pressure Measurement

Capacitive tactile (pressure) sensors have recently been applied to blood pressure monitoring in the literature [5] [6] [7] having been shown to be successful in other medical diagnosis and monitoring applications [8] [9] [10]. Tactile BP monitoring has been introduced to combat the stress and discomfort faced by patients using traditional brachial cuffs, where the high user burden of such devices limits their appeal in home care and ambulatory monitoring of health conditions. Existing methods have focused on two main strategies: Using complementary sensors and techniques such as photoplethysmography [11] and pulse transit time (requiring distributed sensors) [6], or using machine learning or transfer functions to relate distal measurements to brachial references [7] [12]. Each has their own advantages, contrasting accuracy for low user burden.

Form factor of the BP measurement solution is important when considering patient burden. Devices based on smartphones [5] [11] have great public appeal but may have difficult gaining clinical adoption due to the required certifications. Standalone devices such as wrist or finger mounted systems [7] are likely to be easier to adopt, and will still be acceptable providing they are low profile.

Each existing method achieves their goal using far less force than a traditional brachial cuff, hence their appeal in improving patient comfort.

For devices that measure distal BP, a transfer function is required to obtain brachial BP as it is well understood that distal (Radial artery or other distal arteries) BP is not the same as brachial BP [13] [14]. It is known that this can be done with empirical functions or with machine learning. Any new device operating distally would need to output brachial BP as this is considered clinically significant.

II. SCOPE OF THIS WORK

This paper shall introduce a fingertip mounted tonometer for BP measurement at the radial artery, outputting brachial BP using conventional oscillometry adjusted to have patient specific ratios using a linear regression model. The method of BP extraction will be explained in some detail. A preliminary assessment of clinical feasibility will be performed and results analyzed for accuracy and stability. Feasibility conclusions can then be drawn, directing the strategy for future research.

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III. SYSTEM DESIGN

The proposed tonometer, shown in Figure 1, consists of a Pressure Profile Systems 2x5 element custom capacitive tactile array (PPS UK Limited., UK), noted as TactileBP. This has a nominal 1% accuracy over the range 0-250mmHg at calibration conditions. This sensor was curved and calibrated in an optimized shape to fit between the radial styloid process and the adjacent flexor tendon and maximize contact with the radial artery. This is the point where pulse is typically taken. A calibrated K-type thermocouple (Electrocomponents plc, UK) is affixed to the array to compensated for thermal error.

The device is designed to fit on the index or middle finger, with a small screen to assist the operator in palpating the artery at the proper rate similar to [5]. The system features a rechargeable battery and integrated processor.
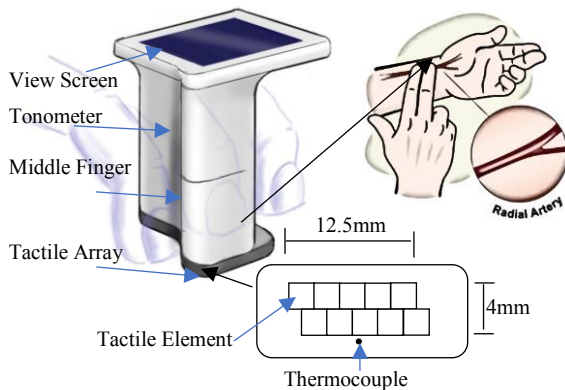

Figure 1 - Proposed Tonometer Design. A small tactile array is joined with a thermocouple on a fingertip actuator. A screen guides the user in proper positioning and arterial compression.

IV. SIGNAL PROCESSING PATHWAY AND OPERATION

The device is pressed gently into the radial artery, with increasing pressure, following a guide on the screen similar to [5] [11]. The measurement takes approximately 30s for best results, but can be done in as low as 10s. The long axis of the sensor array is perpendicular to the radial artery. The pressure rises until enough data is collected, or the reading reaches 200mmHg for comfort. The sensor output is processed as shown in Figure 2.

The capacitance of the sensor elements is translated to pressure by a calibrated lookup table. Adjustments are then made in real time in the error compensation stages for temperature, hysteresis, creep, and inter element cross coupling depending on the measured surface temperature, number of pulses/loading cycles, and elapsed time respectively. These terms correct for any error and drift in the sensor reading, maintaining the accuracy during trials.

The data is lowpass filtered in real time to provide an estimate of the current applied pressure to the user. Once the measurement is complete, the recorded data is analyzed in more detail as shown in 'load/pulse pressure extraction' in Figure 2. The data is truncated to the duration of the experiment, and lowpass filtered to extract the applied load. The raw data is high pass filtered to give the oscillometry pressures. Signal artefacts caused by patient breathing are removed by fitting a sinusoidal signal with constrained frequency ranges to the data and subtracting the result. This results in a signal of variable pulse pressures beat by beat. The upper and lower bounds of the pulse signals are then enveloped, and the difference between the envelopes is plotted against applied load to form the oscillogram.

Key points about the shape of the oscillogram are used to adjust the oscillometry ratios from their population defaults [15] to achieve better individual accuracy.

The load (artery) pressure applied at the calculated ratios of the peak pulse pressure are read from the oscillogram to get systolic and diastolic pressures respectively [16].
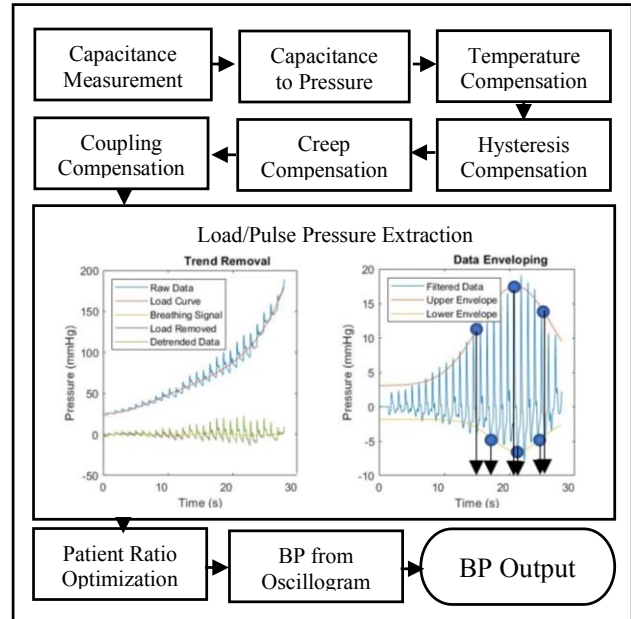

Figure 2 - Signal Processing Steps. Measurements that produce unusual values or have poor quality data are flagged and redone..

V. PATIENT SPECIFIC RATIO ADJUSTMENT

Using training data collected during the clinical trial, optimal ratios were calculated for systolic and diastolic respectively, for each individual in order to minimize their mean error and standard deviation as individuals.

24 key points on the envelopes shown in Figure 2, corresponding to the amplitudes and gradients at the points of maximum/minimum amplitude, and maximum/minimum gradient on both envelopes, and the coincident points on the opposing envelope are identified and respective values stored.

Linear regression was then used to produce 2x 24 variable functions that generate the optimal (or near optimal) ratios for systolic and diastolic respectively for use in oscillometry.

This approach contrasts existing methods [15] by calculating ratios and using conventional oscillometry, rather than fitting a physical model to live data and using that parameter fit to estimate BP. The approach is similar in concept to [7] in that waveform features are used with linear regression to transfer distal measurements to brachial measurements, however this approach differs in the features used: Individual pulse waveforms are used in previous works, oscillogram envelope shape used in this work.

VI. CLINICAL TRIAL AND METHODOLOGY

The experimental process used in this work was approved by the University of Strathclyde Research Ethics Committee, and all participants provided informed consent. An initial limited trial was performed in response to the ongoing international pandemic in order to guide further research strategy. 20 volunteers were used in the initial test study, aged 20-35, heights 155-185cm, 15% female. 9 measurements were made on each individual with the proposed tonometer and flanked with measurements from an Omron Evolv brachial cuff (Omron Corp., JP) known to be suitable when used carefully [3]. Measurements were redone at a different time if total variation in reference BP exceeded 15mmHg across the 9 measurements.

The tonometer and cuff were applied to the left arm by an experienced operator, when the patients were suitably relaxed. Data was recorded as detailed in Section IV. Patient data was randomly split into training (N=12) and test (N=8) sets. K-Fold cross validation was performed to determine the stability of the system to population variance, where the test and training data were reshuffled to produce new training and test sets. All analytical steps used the same testing data.

Analysis of the raw data was performed to allow assessment of the effect of error compensation and relative performance of each processing step. BP estimates not noted as 'Ratio Adjustment' use population default ratios [17]. Systolic and diastolic estimates are analyzed separately in accordance with relevant BHS and AAMI standards.

VII. CLINICAL RESULTS

The mean result of K-Fold validation is shown in Figure 3. The results show that the standard deviation improves with each additional compensation step, and mean error generally improves with increasing error compensation. The BP estimates at the radial artery draw close to AAMI requirements when the sensor is fully compensated using standard ratios, however the results meet the standard when ratio adjustment is applied.
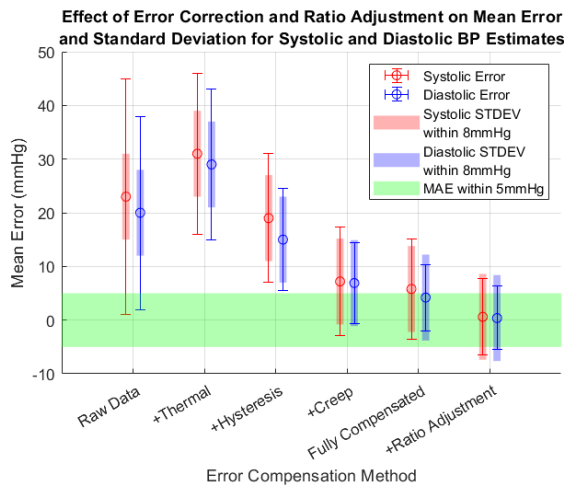

Figure 3 –Systolic and Diastolic errors at each signal processing stage. Fixed ratios at the radial artery do not meet AAMI standards, but ratio adjustment does. Error bars show 1SD.

The variability, or stability, of the method to population variation is shown in Figure 4. The improvement in mean error and standard deviation for systolic and diastolic measurements using ratio adjustments are shown. Separate ratio adjustment has been performed for the non-error compensated data, showing that it does not have a positive effect on BP error if the sensor error is high (about half of the total pulse pressure). This shows that it is important to properly calibrate and characterize sensor response in these applications.

Uncompensated methods are typically 4x less robust to population variance than properly compensated data. This is due to interpersonal variation that is amplified by the sensor sensitivity to thermal/creep errors. The ratio adjustment method, with error compensation maintains mean errors and standard deviations generally within AAMI standards. Increased sample sizes will likely bring this value in tighter.
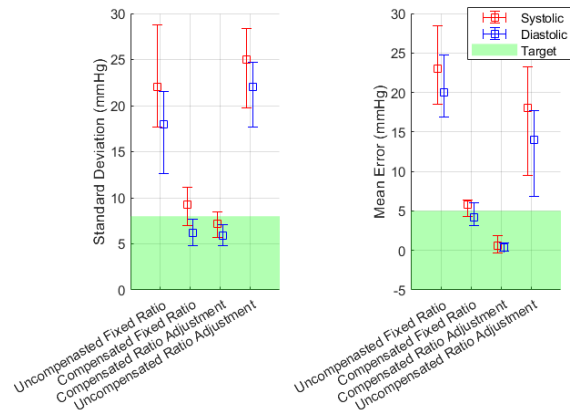

Figure 4 - Variability in mean error and standard deviation as test population varies through K-Fold validation. This shows good stability for error compensated values. This indicates that error compensation is more important than ratio adjustment. Error bars show max/min of the variation.

VIII. DISCUSSION

From the results in Figure 3 it is clear that error compensation is critically important to the proper function of tactile BP devices. It is similarly apparent that even with an ideally compensated sensor it is not feasible to obtain brachial BP from the radial artery using fixed ratio oscillometry, which is not unexpected [13] [14]. This is the point of the ratio adjustment, and the transfer functions proposed by other authors. It is clear that the ratio adjustment method is a feasible method for obtaining brachial BP, reducing both the mean error and standard deviation of the estimates from the proposed tonometer.

Like with all tonometers, it is important that the device be used correctly to maintain accuracy [18], and it is likely that observer sensitivity will be observed with this device. Future research will investigate this, following the feasibility of the method. The low load applied by this design in use (5N) is significantly lower than the 1000N applied by brachial cuffs and represents a drastic improvement in patient comfort.

A. Error sources and mitigation

It has been shown that error compensation reduces the mean error and standard deviation to near the AAMI target accuracy, limited by the deviation between radial and brachial pressures. From Figure 4, it is clear just how important error control is, with the ratio adjustment method failing when sensor error is high. The weighting of each error source (thermal, hysteresis, creep, coupling) on the BP estimate depends on the environmental conditions and the experimental process, however each is important. The coefficients for each error term are one time calibrated. These errors are mitigated using error control models for each term.

Height differences between the brachial cuff and radial measurement is a source of error that is mitigated using proper wrist placement to negate hydrostatic differences.

Operator error plays a significant role in error accumulation, however this is mitigated by binning bad data where insufficient pulses were recorded, or the data was not the correct shape, or there was excessive motion artefacts. This occurred in approximately 12% of measurement trials.

B. Study Limitations

The feasibility study had a number of limitations, particularly in the sample population size and in the reference standard used. These were caused by logistical issues over the duration of this work, and so limited the scope. This study has been sufficient to gauge the feasibility of the proposed technology and identify the dominant error sources, however additional clinical testing with larger populations and dual observer auscultation reference measurements is required.

Another limitation was the use of a single observer using both the proposed tonometer and the reference device. This invites the prospect of interobserver variability in performance that should be investigated in future works.

IX. Conclusion

The proposed method is effective at measuring clinically significant blood pressure, at the radial artery, with significantly less force than a traditional cuff. It has been shown that it is critically important to thoroughly characterize the tactile sensor response, particularly in this application where there error budget is low.

The proposed technology has been shown to be feasible, and so future work shall focus on expanded clinical trialing and robust blinded assessment of interobserver reliability.

As calibration has been shown to be critically important, it will be important in future work to assess the long term stability of this, and similar, technology to determine the life span of the calibration. This will allow for this device and technology to become a useful clinical product aimed at improving patient comfort during BP monitoring.

Acknowledgment

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