Mini-Symposia Title:

Recent Advances on Cuff-Less Blood Pressure Measurement II

Mini-Symposia Organizer Name & Affiliation:

Jin-Oh Hahn, University of Maryland, College Park

Mini-Symposia Speaker Name & Affiliation 1:

Kang Lee, University of Toronto

Mini-Symposia Speaker Name & Affiliation 2:

Oliver Shay, Blumio

Mini-Symposia Speaker Name & Affiliation 3:

Sung-Min Park, Pohang University of Science and Technology

Mini-Symposia Speaker Name & Affiliation 4:

Marjorie Skubic, University of Missouri

S Mini-Symposia Speaker Name & Affiliation 5:

Mohan Thanikachalam, Tufts University and Dynocardia

Mini-Symposia Speaker Name & Affiliation 6:

Theme:

- ( ) 01. Biomedical Signal Processing
- ( ) 02. Biomedical Imaging and Image Processing
- ( ) 03. Micro/Nano-bioengineering; Cellular/Tissue Engineering & B...
- ( ) 04. Computational Systems & Synthetic Biology; Multiscale modeling
- (•) 05. Cardiovascular and Respiratory Systems Engineering
- ( ) 06. Neural and Rehabilitation Engineering
- ( ) 07. Biomedical Sensors and Wearable Systems
- ( ) 08. Biorobotics and Biomechanics
- ( ) 09. Therapeutic & Diagnostic Systems and Technologies
- ( ) 10. Biomedical & Health Informatics
- ( ) 11. Biomedical Engineering Education and Society
- ( ) 12. Translational Engineering for Healthcare Innovation and Commercialization

Mini-Symposia Synopsis— Max 2000 Characters

Cuff-less blood pressure (BP) monitoring is expected to improve hypertension awareness and control rates and may now be feasible due to recent technological advances in, e.g., wearable sensing. As a result, cuff-less BP monitoring devices are being widely pursued around the world. This two-part mini-symposia is about recent advances in cuff-less blood pressure measurement technology. The speakers are leaders in the field from academia and industry. This particular mini-symposium represents part two and covers innovative sensors.

Contactless Blood Pressure Measurement Using Transdermal Optical Imaging Technology

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Abstract— **This work investigates whether blood pressure can be accurately measured without contact using a smartphone camera.**

I. INTRODUCTION

Cuff-based blood pressure measurement lacks comfort and convenience. Here, we examined whether blood pressure can be determined in a contactless manner using a novel smartphone-based technology called transdermal optical imaging. This technology processes imperceptible facial blood flow changes from videos captured with a smartphone camera and uses advanced machine learning to determine blood pressure from the captured signal.

II. METHODS

We enrolled 1328 normotensive adults in our study. We used an advanced machine learning algorithm to create computational models that predict reference systolic, diastolic, and pulse pressure from facial blood flow data. We used 70% of our data set to train these models and 15% of our data set to test them. The remaining 15% of the sample was used to validate model performance.

III. RESULTS

We found that our models predicted blood pressure with a measurement bias ± standard deviation of 0.39±7.30 mmHg for systolic pressure, −0.20±6.00 mmHg for diastolic pressure, and 0.52±6.42 mmHg for pulse pressure, respectively.

IV. DISCUSSION & CONCLUSION

Our results in normotensive adults fall within 5±8 mmHg of reference measurements. Future work will determine whether these models meet the clinically accepted accuracy threshold of 5±8 mmHg when tested on a full range of blood pressures according to international accuracy standards.

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Arterial Pulse Measurement with a Contactless Radar Sensor

Oliver Shay, Chief Technology Officer, Blumio

Abstract— **Blumio presents a millimeter-wave, radar-based system for performing accurate measurements of arterial pulse waveforms and estimate blood pressure. Measured radial arterial waveforms exhibit signal comparable a reference tonometer, in both waveform shape as well as similar spectral signatures. The results observed suggest a millimeter-wave based approach for arterial pulse detection is very promising for future applications in pulse wave analysis and pulse transit time measurement for blood pressure tracking.**

I. Introduction

The use of radar for measuring basic vital signs such as heart rate and respiratory rate has been under investigation for many years [1]. More recently, research into radar-based approaches for characterizing more complex cardiovascular metrics such as PTT, pulse wave velocity (PWV), pulse arrival time (PAT) and arterial blood volume have been under investigation. In this study we present a new approach to arterial pulse sensing in which we combined the high sensitivity of a millimeter-wave signal with a wearable radar concept to create a new system for measuring arterial pulses at the wrist [2].

For this work, an FMCW radar architecture was chosen to transmit a millimeter-wave signal towards the skin surface and track this reflected signal. FMCW is an advantageous approach because it allows for range resolution (unlike single-frequency systems) and better signal to noise ratio compared to other broad-band radar approaches such as ultrawideband [1].

II. Methods

A wearable enclosure was constructed to house a developmental stage FMCW on a chip system and allow the radar antennas to be positioned above the skin surface. Simultaneous recordings of electrocardiogram and radial arterial pressure waveforms using a tonometer on the wrist were made along with radar measurements on the opposing wrist on 12 subjects (age range 33 to 68 years).

III. Results

Fig. 1 shows a comparison of the radar and tonometer signals over a 10 second window, and demonstrates signals that have a varying amount of correlation (as determined by the beat by beat R^2 values shown in Table I).

This work was supported by Infineon Technologies, CardieX, the Thiel Foundation and the National Science Foundation under grant number 1746660.

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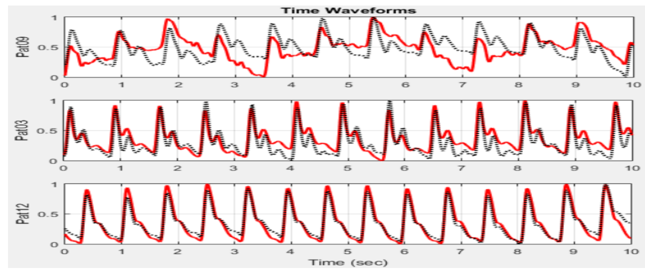

Fig. 10. Example waveforms (left side) for subjects with varying signal qualities: low quality (top – Pat09), typical (middle - Pat03) and high quality (bottom – Pat12). Note that each plot shows a comparison of radar (red, solid) tonometer (black, dotted) based signals.

TABLE I
Summary of Human Measurements

Subject #	Phase Deviation (radians RMS)	Radar vs. Tonometer R^2
Pat01	0.1047	0.90
Pat02	0.0049	0.80
Pat03	0.0315	0.86
Pat04	0.0052	0.90
Pat05	0.0055	0.93
Pat06	0.0192	0.94
Pat07	0.0053	0.77
Pat08	0.0189	0.94
Pat09	0.0287	0.72
Pat10	0.0103	0.91
Pat11	0.0099	0.82
Pat12	0.0253	0.99

IV. Discussion & Conclusion

In this study, we present a millimeter-wave approach to arterial pulse measurement. Measurements from the subjects showed pulse waveforms with distinct peaks, shapes that are characteristic of arterial pulses. The waveform quality observed in this work strongly suggests that this approach will enable the future development in pulse wave analysis and pulse transit time measurement for blood pressure monitoring.

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Flexible strain sensor toward truly continuous pulse wave monitoring

Sung-Min Park*, Sehong Kang, Vega Pradana Rachim, Pohang University of Science and Technology

***Abstract*—A pulse wave monitoring system provides multiple information related to an individual's cardiovascular health. While there are multiple commercially available pulse wave devices, most of the them have rigid and bulky structure causing discomfort to users. In this work, a flexible, thin patch type strain sensor is described for continuously monitoring of pulse waves. The proposed sensor exploits the piezoresistivity of conductive polymer, polyaniline (PANI) to detect pulse wave. The sensor can collect pulse wave signal from carotid, radial and tibial artery by attaching it on the skin. Especially, pulse wave signal from radial artery showed high agreement with commercial sensors (LOA<2%). Moreover, the proposed PANI sensor demonstrates capability for various signal acquisition, other than pulse wave, such as motion and respiration detection. We believe that this sensor can be used as a wearable, continuous physiological signal monitoring device that gives clinically meaningful insights into a patient's condition in real-time.**

I. INTRODUCTION

The affordable and reliable mobile healthcare services are needed globally as the increasing prevalence of chronic patients and aging population. Mobile healthcare is focused to be an enabler that intermediates the patients and their doctors or medical experts for the more personalized, pervasive, and preventive healthcare system[1]. One of the key requirements for successful implementation of reliable mobile healthcare is related to unobtrusive sensing[2]. A flexible electronic technology has a large potential to revolutionize the mobile healthcare with the capability of a truly non-obstructive and continuous bio-signal assessment.

In this study, we propose a patch type pulse wave sensor using conductive polymer, Polyaniline(PANI), that can be truly flexible, easily fabricated, highly repeatable, low cost, and usable for the long term in a daily life condition. The proposed sensor showed high linearity and high sensitivity for pulse wave monitoring. With its excellent electromechanical property, the same sensor could robustly record pulse waves or mechanical parameters from different parts of the body.

II. RESULTS

To evaluate the capability in collecting multiple vital signals, the proposed PANI sensor was attached to various parts of the body and evaluated its performance. The proposed sensor successfully detected pulse waves from different parts of the body by simply attaching it without any extra force (Fig. 1) and the test results showed that the proposed sensor performance agreed well with commercially available photoplethysmogram (PPG) device (Fig. 2).

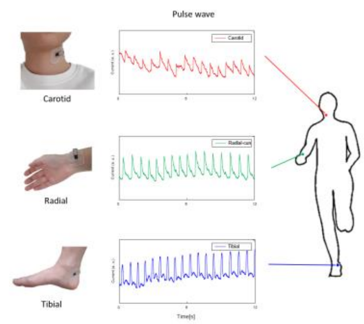

Figure 1. Proposed PANI sensor measuring pulse wave signal in multiple measurement site.

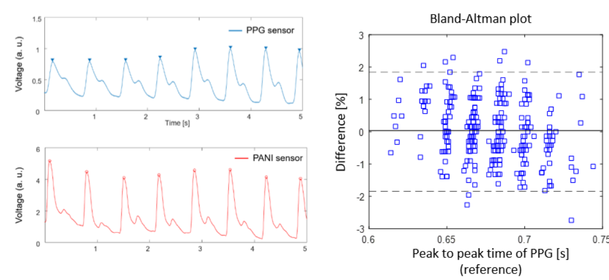

Figure 2. Validation experiment result on acquired pulse wave signal with PPG sensor. (a) signal from the two sensors, (b) Bland-Altsman plot of the signals

III. DISCUSSION & CONCLUSION

The proposed PANI sensor is considered as a flexible, wearable patch sensor that is suitable for long term, continuous, monitoring of pulse wave signal. The PANI sensor can be optimized for certain body structure and monitor different vital signal signals including pulse wave of carotid, radial and tibial artery; respiratory; and swallowing saliva. Moreover, the PANI sensor is compatible with low-cost materials and simple manufacturing processes, so it can be offered as a disposable, inexpensive sensor in a future.

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Speaker 1 Synopsis: Combining a Physiological Model with Ballistocardiogram Measurements for Cuff-less Blood Pressure

Marjorie Skubic, Electrical Engineering & Computer Science
Giovanna Guidoboni, Electrical Engineering & Computer Science; Mathematics
Mihail Popescu, Health Management & Informatics
University of Missouri, Columbia, MO

Ongoing collaborative work at the University of Missouri has been investigating passive sensing for health monitoring in the home, with the goal of recognizing early health problems and, thus, facilitating proactive treatment [1]. Versions of this in-home sensor system with automated health alerts has been tested longitudinally in the homes of older adults, beginning in 2005. As part of this work, the team has developed a hydraulic bed sensor (flexible tubes filled with water) that captures the ballistocardiogram and respiration signals, while positioned under the bed mattress [2]. The ballistocardiogram (BCG) is a signal generated by the repetitive motion of the human body due to sudden ejection of blood into the great vessels with each heartbeat. Main heart malfunctions, such as congestive heart failure and valvular disease, have been shown to alter the BCG signal, which then yields a great potential for passive, noncontact monitoring of the cardiovascular status. We have recently shown that by tracking the morphology of the BCG signals over time, i.e., extracting features of the waveform, changes in systolic blood pressure can be monitored through passive sensing with a bed sensor [3].

In other work, Guidoboni et al. have developed a closed loop physiological model of the cardiovascular system, as shown in Fig. 1 [4]. The model has been shown to generate cardiovascular outputs that are consistent with physiological measurements, including the BCG signal. Recent work has also been investigating different BCG measurement systems with the aim of transforming the BCG signal of each measurement modality into a BCG signal generated by the physiological model. The overall goal of using the model is facilitate the interpretation of changes in the BCG waveform morphology on the basic principles of physiology in order to enable the identification of early changes in cardiac or cardiovascular function. Measurement modalities under investigation include a replica of Starr's suspended bed [5], load cells positioned under the bed posts, and the hydraulic bed sensor developed by our team [2].

The focus of this talk is to extend the earlier work on tracking systolic blood pressure changes [3] by combining it with the recent physiological model [4]. In our previous work, we demonstrated the capture of *relative* systolic blood pressure through the monitoring of morphological features. That is, we could detect changes in systolic blood pressure through passive monitoring. In our new work, we are combining physiological model-based methods with the BCG measurements to obtain the *actual* systolic blood pressure value. This new work offers a more personal monitoring of cardiovascular health and extends the work on passive monitoring for proactive health management.

*Research supported in part by the National Institutes of Health and the National Library of Medicine.

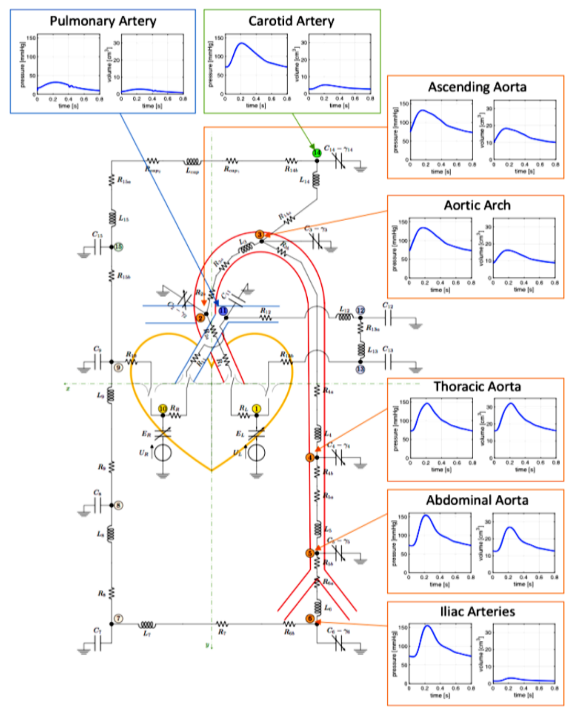

Figure 1. Physiological model of the cardiovascular system [4]

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Speaker Synopsis

Mohan Thanikachalam, M.D., CEO, Dynocardia, Inc, Boston MA

Abstract— **There is an unmet clinical need for standalone, wearable continuous non-invasive blood pressure (cNIBP) monitor for out-patient diagnosis and management of hypertension (HTN) or high BP and in-patient monitoring of BP. To address the need, the founding science at Tufts University and Massachusetts Institute of Technology led Dynocardia team to develop the ViTrack™. The ViTrack uses a proprietary new method to measure BP and is the first standalone cuff-less, wearable cNIBP technology. Work completed to date includes the development of hardware and software, bench-top studies, animal validation studies, and clinical studies. In clinical studies, ViTrack meets FDA standards. ViTrack has the potential to disrupt the way BP is measured and managed.**

I. INTRODUCTION

The current cNIBP technologies use indirect model-based methods, such as volume clamp, pulse transit time, and photoplethysmography [1]. These methods do not directly measure pressure, but use proxy measures to indirectly infer BP. While some of the devices based on these technologies have received FDA approval, they require external calibration with single-time point measurements with arm cuff BP devices. Since current cNIBP devices do not independently measure BP, are cumbersome to use and are unreliable [1], these devices have failed to penetrate the market. The ViTrack utilizes a new methodology we have created called the Tactile Kymograph. In this method, the forces exerted by the underlying arterial pressure wave and the skin surface motions are measured spatiotemporally within the contact region on the skin over the superficial arteries, such as the radial artery at the wrist, to provide measure of systolic (SBP) and diastolic (DBP) BP over the beat-to-beat timeline. The ViTrack consists of unique optomechanical tactile sensor array (100x spatial resolution when compared to human touch at fingertips), which we have developed together with signal processing software. ViTrack's optomechanical sensor captures the spatiotemporal forces and the skin motions at micron scale. Because ViTrack provides a calibrated pressure wave form from a large vessel, other physiological parameters such as heart rhythm and respiratory parameters can measured continuously.

II. METHODS

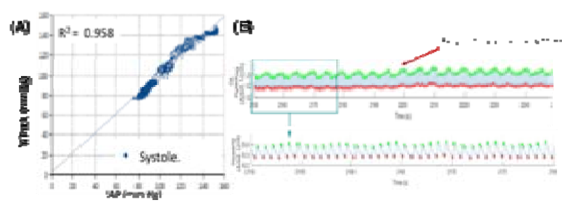
Bench top studies: In a mock circulatory loop multiple versions of the ViTrack hardware and software were built and optimized to accurately track intra-luminal beat-to-beat pressure in 3D-printed artificial arterial phantoms (across a range of stiffness) encased in silicon rubber of variable thickness (simulating skin and subcutaneous soft tissue), under various hemodynamic simulations Animal Studies: Experiments with both pigs and rabbits were performed. During the studies, data was simultaneously recorded from the ViTrack by imaging the femoral artery and from the intra-arterial fibreoptic pressure transducer in the same femoral artery and compared. Clinical studies: In clinical studies, the ViTrack was compared to auscultatory method. At all times, auscultatory measurements were made by two well-trained observers and a minimum of 3 readings were made per observer. A minimum of 3 ViTrack readings per subject was collected and an average of the readings were compared to average auscultatory readings.

*Research supported by NIH. M. Thanikachalam is the CEO of Dynocardia, Inc 110 Canal Street, 4th Floor, Lowell, MA 01852., phone: 617-775-9402; e-mail: mohant@ Dynocardia.care).

III. RESULTS

In benchtop studies, the fully developed, perfected and calibrated ViTrack device was able accurately track (correlation coefficient = 0.99) beat to beat BP over a wide range of pressure and various hemodynamic simulations. Animal studies showed that ViTrack correlates well (R2 value = 0.958) with intra-arterially measured pressure [Fig 1(a)], tracks beat-to-beat BP, and captures respiratory variance through BP measurements [Fig 1(b) and data not shown].

Figure 1. *Pig Experiment: Comparing ViTrack to intra-arterial pressure (IAP). (A) correlation with IAP; (B) beat-to-beat BP tracing with ViTrack.*



Clinical data from 80 subjects, both male and female, with a wide range of BP (Range: 86-180 SBP; 60-110 DBP), demonstrated that the ViTrack technology estimates BP in accordance with FDA standards (Association for the Advancement of Medical Instrumentation [AAMI] standard: mean offset < 5mmHg; standard deviation <8 mmHg). The clinical studies also demonstrated that ViTrack continuously tracks beat-to-beat BP and BP variability with repeatability and minimal drift.

IV. DISCUSSION & CONCLUSION

The results from the benchtop, animal and clinical studies establish the feasibility of ViTrack as a standalone cNIBP device. Currently, we are initiating multi-center trial to validate ViTrack against intra-arterial pressure over wide range of patients and hemodynamic conditions. ViTrack, once fully developed, will provide real-world continuous BP for improved diagnosis and management HTN and benefit 1.4 billion people globally. In hospitals, ViTrack will be a noninvasive alternative to the decidedly invasive arterial pressure monitor and will directly address monitoring gaps that result from the cuff-based BP monitors so that if patients deteriorate, early detection occurs and adverse events are avoided.

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