Applications of Tactile Imaging in Calibration-less and Cuff-less Blood Pressure Monitoring for Home Care

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***Abstract*— This paper presents a concise review of current Tactile Imaging research, and industrial innovations, applied to blood pressure (BP) measurements in home and ambulatory care. This paper also presents a review of current accepted methods in measuring blood pressure, with appropriate standards required for new and innovative measurement technologies.**

The application of Tactile Imaging in BP monitoring has led to several advances in industry and in literature, culminating in solutions implemented on widely available smartphones. Naturally such solutions have great appeal in home care markets, especially amongst the 'worried well' and fitness communities. However such systems do not see widespread uptake in clinical practice, with clinicians favoring more traditional measurement technologies despite continuous pressure from the public and clinicians for more accurate and comfortable systems. Though the reasoning for this is largely down to the strict standards for medical devices, and not a small amount of clinical inertia, it must be acknowledged that the mechanics and theory of operation of many incumbent non-invasive BP measurement systems are not well understood.

This paper highlights the important findings and recent developments in calibration-less and cuff-less BP monitoring, based on Tactile Imaging, to aid others in advancing this rapidly developing field.

***Clinical Relevance*— This work establishes an understanding of current developments in Tactile Imaging applied to continuous blood pressure monitoring in both clinical and home environments, a new area of study for a technology seeing clinical traction and commercial success in other medical diagnostic applications including Breast and Prostate cancer diagnostics.**

I. Introduction

Blood Pressure (BP) monitoring is a well-known tool in clinical diagnosis. Although many devices and techniques exist to measure BP, the biomechanical factors that govern BP changes throughout the body are not well understood or characterized. There are multiple complex factors that influence it; but broadly speaking these can be broken down into cardiac output and systemic vascular resistance [1]. The ideal blood pressure will deliver a column of blood to the end organ that is under sufficient pressure to meet its metabolic demand but not damage it or the arterial endothelium.

The two problematic states in BP characterization are: Hypertension, and Hypotension. The diagnosis of either condition is usually a protracted affair, uncomfortable to the patient, and often unclear in its absolute meaning. The introduction of Tactile Imaging, a blanket term for any high spatial resolution stress measurement system, to this field has led to significant reductions in measurement time and discomfort in patients. Despite this, the technology faces an uphill battle against existing techniques for BP measurement, and clinical standards that are often considered antiquated and slow the advance of incumbent technologies.

These issues shall be discussed in detail in the subsequent sections of this paper, along with: the reasoning for adopting Tactile Imaging in the clinical environment, and the reasoning for the slow uptake of such devices in clinical care despite the emergence of the large international 'worried well' home care market, and a review of Tactile Imaging technologies applied to BP estimation in the clinical environment and at home.

A. Hypertension in the United Kingdom

The Global Burden of Disease Study recognizes that hypertension is the second biggest known global risk factor for morbidity and mortality. Within the UK, it is the third after tobacco consumption and poor diet [2]. Left untreated, hypertension causes endothelial damage and dysfunction, resulting in high resistance vasculature. This affects both large and small arteries and can manifest as cerebrovascular, peripheral arterial, carotid and coronary artery disease [3]. It also leads to a structural change of the myocardium resulting in left ventricular hypertrophy that can progress to left ventricular dysfunction and heart failure. Certain organs with a "delicate" microvascular structure such as the retina or kidney are susceptible to specific complications, namely hypertensive retinopathy and nephropathy [1] [3].

In over 90% of cases, the exact cause of hypertension is not identified (primary or essential hypertension), as such the mainstay of treatment is preventing the end-organ damage associated with this condition using antihypertensive medication. There are specific cases where an underlying cause of hypertension can be identified, broadly categorized as secondary hypertension. In this setting, while the underlying condition can occasionally be managed, the first-line treatment is often antihypertensive medication [1] [4].

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BP is normally distributed, as such there is not a specific BP above which hypertension exists. However, the National Institute for Health and Care Excellence (NICE) recommends commencing treatment for those with a sustained BP above 140/90mmHg [4]. Meanwhile, trial data such as the Systolic Blood Pressure Intervention Trial (SPRINT) have suggested there is a maximal benefit when the target systolic BP is 120mmHg. A debate that particularly low BP targets will result in a paradoxical rise in morbidity and mortality due to a lack of sufficient end-organ perfusion prevails, but this has not been born out in the literature to date. Ettehad and colleagues performed a meta-analysis of all large scale blood pressure lowering trials from 1966 to 2015; this included over 600,000 participants and had no exclusion criteria due to co-morbidities. One of their conclusions was that a sustained gradual reduction in systolic BP of 10mmHg was associated with a 13% reduction in all-cause mortality [5].

With more than 1 in 4 adults affected by hypertension in the UK, the treatment, management and healthcare burden is understandably significant; Public Health England estimates that the resultant cost of managing diseases associated with hypertension to be in the region of £2.1billion per annum [6]. In short, hypertension is costly to society and its treatment saves lives and reduces morbidity.

B. Hypotension in the United Kingdom

The physiological state of hypotension is caused by either insufficient cardiac output, insufficient systemic vascular resistance or a combination of both. If blood pressure falls significantly, it will lead to a state of "shock" where there is insufficient end-organ perfusion.

It is generally accepted that a patient with a systolic BP of less than 90mmHg and associated sympathetic autonomic symptoms can be considered hypotensive. They will if left in this state go on to develop irreversible end-organ damage within a very short period of time. A sudden reduction in blood pressure of >30% baseline can have this effect despite the systolic blood pressure remaining within "normal" limits.

In the postoperative period, the Royal College of Anesthetists consensus statement would advocate treatment within ten minutes of an episode of hypotension [7]. Despite this recognition of the need for time-critical intervention, most patients on a general hospital ward will have observations taken intermittently every 4-6 hours [8] [9].

A comparison of antecedents before cardiac arrest, death and intensive care admission for 638 patients in the United Kingdom and New Zealand found that the most common antecedent was a systolic BP of <90mmHg [10].

There is now a recognition in the literature that there is a role for continuous non-invasive arterial pressure monitoring [7] [11] and it is the change in BP that is most important rather than a singular measurement.

II. Currently accepted Blood Pressure Monitoring Methods in Clinical and Home Care

There are numerous accepted clinical techniques for the measurement of BP, some methods are capable of high accuracy, and others are capable of continuous operation. The appropriate choice of technique is often driven by resourcing, or patient urgency, rather than simply selecting the most accurate or powerful measurement system. The consideration of patient comfort leads research trajectories in this field.

A. Discrete Time and Discontinuous Measurement Methods

The Auscultatory technique remains the standard to which all other non-invasive techniques are held. It is accurate in healthy individuals, but it does have some recognized limitations in clinical practice [12], [13]. A key component of its accuracy stems from the fact that the bell of a stethoscope is overlying the brachial artery in effect placing the measuring sensor directly over the artery [14]. Korotkoff's technique [15] is accurate provided that the arterial walls are compliant and not calcified. Thus far, it has proven difficult to automate this process, as the significant variation in frequencies of the Korotkoff's sounds and varying arterial location between patients did not initially lend itself to machine learning [11]. This may be something that would be technologically possible now; however, the prevalence and acceptance of other techniques mean further development is unlikely.

Oscillometry and, its sister technique of, Vascular Unloading has seen recent development into automated commercially available systems. Although these systems have seen widespread adoption in primary clinics and the home care markets, their accuracy is often questioned in the literature as they use calculation factors that do not change to match the population variance [16].

B. Continuous Time Measurement Methods

Arterial catheterization is regarded as the 'gold standard' for measuring BP, as it makes a measurement of intra-arterial pressure directly. If connected to a digitizer or a graphical output, such a system can output a beat-by-beat BP estimate at the point of catheter insertion. Such systems are typically used as reference standards and intermediary steps for research on pulse waveform morphology [17]. Despite being the 'gold standard', catheterization is rarely used outside of secondary care facilities due to the large healthcare infrastructure required and the significant list of complications that can arise, including: pseudoaneurysm formation, nerve damage, distal ischemia and infection.

Applanation Tonometry, like arterial catheterization, can provide a continuous output of the pulsatile waveform. However, tonometry devices must be calibrated using another method such as auscultation.. As they require support from another BP measurement technique, they are rarely used outside of clinical trials and academia [18], although there are always exceptions [19]. Tonometry devices do not exhibit the clinical complications and patient discomfort prevalent with other techniques, however their accuracy is limited to that of the calibration media, typically only 15% [20].

C. Issues with Current Methods in Home Care

The tried and tested methods of BP measurement, although fit for purpose, are not without their problems that restrict the breadth of their use at home and in the clinic. Issues affecting and limiting the home use market typically stem from ease of use, or lack thereof, and the clinical infrastructure required to run high accuracy systems. The limiting factor in the clinical environment for continuous BP monitoring is balancing accuracy with the risk of patient complications.

The disadvantages associated with auscultation include "white coat effect", the need for a qualified technician and the time it takes to carry out the procedure. These inhibit the use of such systems at home. Perhaps most importantly, is that this is a singular snapshot measurement and does not demonstrate the trends in physiology that are vital to managing chronic and acute health [16].

The issue of a singular snapshot is similarly true for automated oscillometry devices and, with the need for repeated measurements to determine trends, compounds with the issue of discomfort during use to limit its recurrent use both at home and in the clinic [14]. It is well understood that repeated and continuous use of brachial oscillometry and auscultatory devices can cause tissue necrosis and nerve damage in the upper arm. Despite the risk from excessive use, oscillometry is still the most popular technique in the home care market [6]. The constant whine of the inflating bladder, and the near randomly occurring inconvenient discomfort home care oscillometry devices create make such devices almost a necessary evil.

Naturally, catheterization is not suitable for use at home due to the high level of clinical infrastructure required to operate. Similarly tonometry is not suitable for home use due to the relatively complex calibration process.

III. Cuff-less Blood Pressure Monitoring Methods using Tactile Imaging

Research in recent years has focused on developing BP monitoring technologies for the home care market, specifically: wearables for continuous monitoring [21] and smartphone based systems [22] for the fitness app craze of today. A range of solutions have been investigated, including: improving tonometry, making oscillometry wearables, and developing smartphone based vascular unloading systems.

A. Analytical Solutions and Waveform Morphology

Tonometry has always been limited by its need for calibration against a more stable reference, and this is largely necessitated by the variability in patient tissue properties and a poor understanding of mechanics governing the propagation of intra-arterial pressure to the surface of the skin [18]. To that end, there has been advances in how the simple spring-dashpot model of the wrist (for radial BP) has been solved.

In order to evaluate radial BP using uncalibrated tonometry, the tissue properties must be known in order to determine the pressure loss transfer function through the wrist tissue. The robotic feedback control method [23] uses a large robot to estimate the properties of the tissues, by tracking the motion of the skin above the radial artery. Though the accuracy of this method is very good, 4% compared with 15% for tonometry, it lacks the practicality of a clinically viable system due to the massive infrastructure cost.

Despite the impracticality of the robotic control system, the method develops a validated model for estimating intra-arterial BP should the tissue properties be known. Various methods have been proposed to do this, with one of the most promising being waveform morphology. In this technique, a modified wind-kessel model is used to estimate radial artery elasticity from the waveform, particularly the wave shape, obtained from a tonometer [24]. Although this waveform morphology technique does not provide BP directly, it can be used as a stepping stone towards BP through tissue modelling [23], with tissue elasticity measured via a dermal elastometer, or combined with other significant waveform features [25].

B. Empirical Solutions and Machine Learning

The field of tactile BP monitoring has seen greater strides when machine learning is applied. Many of the wearables and innovative public technology hitting the headlines incorporate either basic machine learning in the form of linear regression [21] or an empirically derived transfer function similar to traditional oscillometry [22]. The accuracy of machine learning based systems are usually better than that of the empirical transfer function based systems, whose accuracy is comparable with traditional brachial oscillometry systems.

The finger wearable technology cannot really be described as cuff-less as it does use a small inflating bladder on the fore finger, however it does apply tactile imaging in its traditional sense – an array of force sensing elements designed to support each other and improve overall system accuracy. The use of multiple sensing elements, as opposed to a single bladder pressure gauge from traditional oscillometry allows for greater noise rejection and for spatial filtering to be applied.

Tactile imaging can be reduced from an array to a single sensing element, when combined with other sensing technologies. For BP monitoring this is typically a photoplethysmography (PPG) sensor [22]. Simplification like this can significantly reduce the cost of producing public home use BP monitoring solutions, as tactile arrays can often be prohibitively expensive.

C. Adoption in Clinical Practice and Home Care

The recent advances in wearable and cuff-less BP monitoring have seen success and widespread public approval, however they are too new to receive any adoption in clinical practice, and are likely not to be adopted into clinical practice in the near future (>10 years). This is partly due to accuracy concerns with peripherally wearable devices, that may work well on healthy patients but will fall short of the required standards when there is any less in limb perfusion, something that commonly happens when injured or severely ill [1].

Even if accuracy was not in question the fact of the matter is that the advances we are seeing in BP monitoring, where a measurement can even be made on an iPhone with no external components [26], simply is outpacing the regulatory bodies. Specifically ISO/CD81060/3 is still at committee level which will have specific regulations for continuous non-invasive arterial pressure measurement (CNAP) devices. Fortunately IEEE1708/a exists to allow such radical devices to be approved and validated. However this will only apply to dedicated hardware, like wearables [21] and not to grafted systems like iPhones where the iPhone itself would need to be validated and approved as a medical device for clinical use.

IV. Conclusion

It is clear that the measurement of blood pressure has a vital role both in the acute care of individual patients and also with regards to the global burden of disease. There are established techniques for singular measurements of blood pressure, and these have their limitations.

Underlying all emerging or less popular techniques are the fundamental principles of fluid dynamics and the pioneering work done at the beginning of the 19th century by a number of dedicated physiologists. In the 21st century, we are seeing these principles being applied with novel sensors and significant amounts of computer processing power.

The domain of blood pressure monitoring is no longer in the general practitioner's surgery or as singular measurements conducted at the patient's bedside. There are benefits to be had to patients, clinicians and potentially consumers, in having non-invasive continuous monitoring of blood pressure. The potential for tailored and personalized blood pressure measurements has not been fully explored. It remains to be seen if some of the measurements taken in order to derive systolic and diastolic blood pressure may have more clinical significance than the derived parameter.

The validation and regulatory protocols for the newer blood pressure measuring devices that shun the standard pneumatic cuff will have to be very broad and diverse; it is likely that in order to validate some of these devices at the extremes of physiology there will need to be an incorporation of specific clinical cases. There will be a significant burden of work conducting these newer protocols, and this will have a direct impact upon the notifiable bodies used for validation.

References

[1] J. G. Murphy and M. A. Lloyd, "Mayo Clinic Cardiology: Concise Textbook," Rochester, MN, Mayo Scientific Press, 2007, pp. 599-611.

[2] M. H. Forouzanfar, L. Alexander, H. R. Anderson, V. F. Bachman, S. Biryukov and M. Brauer, "Global, regional, and national comparative risk assessment of 79 behavioural, environmental and occupational, and metabolic risks or clusters in 188 countries, 1990-2013: a systemic analysis for the Global Burden of Disease Study 2013.," *The Lancet,* vol. 386, no. 10010, pp. 2287-2323, 2015.

[3] R. E. Schmeider, "End organ damage in hypertension," *Dtsch. Arztebl Int.,* vol. 107, no. 49, pp. 866-873, 2010.

[4] National Institute for Health and Clinical Excellence, "Hypertansion: clinical management of primary hypertension in adults (Clinical guidline 127)," 2011.

[5] D. Ettehad, C. A. Emdin, A. Kiran, S. G. Anderson, T. Callender and J. Emberson, "Blood pressure lowering for the prevention of cardiovascular disease and death: a systematic review and meta-analysis.," *The Lancet,* vol. 387, no. 10022, pp. 957-967, 2016.

[6] NHS, "Health Matters: combating high blood pressure," UK Gov., [Online]. Available: https://www.gov.uk/government/publications/health-matters-combating-high-blood-pressure/health-matters-combating-high-blood-pressure.. [Accessed 19 01 2020].

[7] M. D. McEvoy, R. Gupta, E. J. Koepke, A. Feldheiser, F. Michard and D. Levett, "Perioperative Quality Initiative consensus statement on postoperative blood pressure, risk and outcomes for elective surgery.," *British Journal of Anaesthesia,* 2019.

[8] J. Kellet and F. Sebat, "Make vital signs great again - A call for action.," *Eur. J. Intern. Med.,* vol. 45, pp. 13-19, 2017.

[9] S. Mohammed Iddrisu, J. Considine and A. Hutchinson, "Frequency, nature and timing of clinical deterioration in the early postoperative period.," *J. Clin. Nurs.,* vol. 27, no. 19-20, pp. 3544-3553, 2018.

[10] J. Kause, G. Smith, D. Prytherch, M. Parr, A. Flabouris and K. Hillman, "A comparison of antecedents to cardiac arrests, deaths and emergency intensive care admissions in Australia and New Zealand, and the United Kingdom - the ACADEMIA study.," *Resuscitation,* vol. 62, no. 3, pp. 275-282, 2004.

[11] F. Michard, D. I. Sessler and B. Saugel, "Non-invasive arterial pressure monitoring revisited.," *Intensive Care Med.,* vol. 44, no. 12, pp. 2213-2215, 2018.

[12] J. N. Cohn, "Blood pressure measurement inshock. Mechanism of inaccuracy in auscultatory and palpatory methods," *JAMA,* vol. 199, no. 13, pp. 118-122, 1967.

[13] G. S. Stergiou, B. Alpert, S. Mieke, R. Asmar, N. Atkins and S. Eckert, "A Universal Standard for the Validation of BLood Pressure Measuring Devices: AAMI/ESH/ISO Collaboration Statement," *Hypertension,* vol. 71, no. 3, pp. 368-374, 2018.

[14] J. Waugh, A. Halligan and A. Shennan, "Blood pressure measurement - does anyone do it right?: An assessment of reliability of equipment in use and the measurement techniques of clinicians.," *J. Fam. Plann. Reprd. Health Care,* vol. 27, no. 4, p. 241, 2001.

[15] Y. L. Shevchenko and J. E. Tsitlik, "90th Anniversary of the development by Nikolai S. Korotkoff of the auscultatory method of measuring blood pressure," *Circulation,* vol. 94, no. 2, 1996.

[16] G. Stergiou, A. Kollias, G. Parati and E. O'Brien, "Office Blood Pressure Measurement: The Weak Cornerstone of Hypertension Diagnosis," *Hypertension,* vol. 71, no. 5, pp. 813-815, 2018.

[17] A. L. Pauca, N. D. Kon and M. F. O'Rourke, "The second peak of the radial artery pressure wave represents aortic systolic pressure in hypertensive and elderly patients," *British Journal of Anaesthesia,* vol. 92, no. 5, pp. 651-657, 2004.

[18] T. Birch, "Continuous Non-Invasive Blood-Pressure Measurements," in *7th Mathematics in Medicine Study Group*, Southampton, 2007.

[19] O. Kemmotsu, M. Ueda, H. Otsuka, T. Yamamura, D. C. Winter and J. S. Eckerle, "Arterial tonometry for noninvasive, continuous blood-pressure monitoring during anesthesia," *Anesthesiology,* vol. 75, no. 2, pp. 330-340, 1991.

[20] E. O'Brien, B. Waeber, G. Parati, J. Staessen and M. G. Myers, "Blood pressure measuring devices: recommendations of the european society of hypertension," *British Medical Journal,* vol. 322, no. 7285, pp. 531-536, 2001.

[21] R. Narasimhan, T. Parlikar, G. Verghese and M. V. McConnell, "Finger-Wearable Blood Pressure Monitor," in *40th Annual International Conference of the IEEE Engineering in Medicine and Biology Society (EMBC),* Honolulu, 2018.

[22] A. Chandrasekhar, C. Kim, M. Naji, N. Keerthana, J. Hahn and R. Mukkamala, "Smartphone-based blood pressure monitoring via the oscillometric finger-pressing method," *Science Translational Medicine,* vol. 10, 2018.

[23] A. C. Lin, H. Huang, Y. Su, C. Shin, Y. Wang, H. Chiang, H. Tung and J. Lin, "On measuring the instantaneous blood pressure in an artery via the tissue control method," *Physiological Measurement,* vol. 28, pp. 937-951, 2007.

[24] C. Wei, S. Huang and C. Bau, "Using the spring constant method to analyze arterial elasticity in type 2 diabetic patients," *Cardiovascular Diabetology,* vol. 11, no. 39, 2012.

[25] J. Lee, Z. Ghasemi, C. Kim, H. Cheng, C. Chen, S. Sung, R. Mukkamala and J. Hahn, "Investigation of Viscoelasticity in the Relationship Between Carotid Artery Blood Pressure and Distal Pulse Volume Waveforms," *IEEE Journal of Biomedical and Health Informatics,* vol. 22, no. 2, pp. 460-470, 2018.

[26] A. Chandrasekhar, K. Natarajan, M. Yavarimanesh and R. Mukkamala, "An iPhone Application for Blood Pressure Monitoring via the Oscillometric Finger Pressing Method," *Nature Scientific Reports,* vol. 8, no. 13136, 2018.