Continuous Non-Invasive Blood Pressure Monitoring System

- ## Introduction

Blood Pressure is a key health parameter, monitoring of which is crucial in identification of multiple conditions. Major conditions like stroke, heart disease is largely attributed to elevated blood pressure.

With 8 million deaths in a year, health systems have long acknowledged just how potent this hidden slow poison is. Blood flow also needs to be monitored during medical procedures being performed on the patient, be it drug administration or surgery.

A parameter of such significance cannot be neglected in any situation and a solution that is compatible with the user must be reached. Occasional visits to the doctor or periodic use of the massive blood pressure cuff is both uncomfortable and insufficient. Given that masked hypertension is a bigger killer than sustained hypertension, continuous monitoring of blood pressure is necessary. It will also help understand the influencing factors based on variations caused by the patient's lifestyle. Successful integration of such a device into the user's life requires that the usage of the product be comfortable and discreet.

Current devices/methods for blood pressure monitoring include sphygmomanometers which are bulky and can be erranous because of factors like cuff size. Such a device is suitable for occasional usage.

PPG sensor based predictions for blood pressure can also be made but such a system has numerous limitations , dissolving patient uniqueness by a constant prediction algorithm which is based on bulk data. There is no equation which can determine blood pressure based on just the blood volume , which invalidates such methods for diagnosis or even trustable readings.

Pulse transit time is also used for BP estimation but region of measurement possesses high sensitivity to many factors rendering such readings unsatisfactory.

Tonometry is another method where the radial artery is occluded with contact surface taking the shape of a flat plane. This method is prone to error since the device has to apply all its pressure onto a very small region which can lead to slight shape variations of the artery wall. Such a method is also not feasible for continuous evaluation.

Volume clamping relies on the principle of maximum volume variation for a pressure pulse about a certain volume. This is understood by treating the lumen variation as an oscillating system. Maximum oscillation is observed about the point with minimum potential energy. This method requires high precision actuators and cannot be used by a regular person, it requires a stationary patient and cannot instantly detect any vascular tone changes.

The goal of this project is to develop a wearable blood pressure monitoring device the size of a smart band with accuracy matching clinical standards and active control to adapt to variable change. The method used aims to minimize user discomfort ensuring its wearability for long periods without any compromise on the accuracy. The project aims to make the wearable a one for all device, ranging from diagnosis, continuous usage to a tracker during medical procedures.

- Brief description

The device is situated at the distal end of the radial and ulnar artery and is in the shape of a regular watch. The device houses arrays of PPG and Pressure sensors, it also contains a mechanical unit which can generate pressure on the skin contact area.

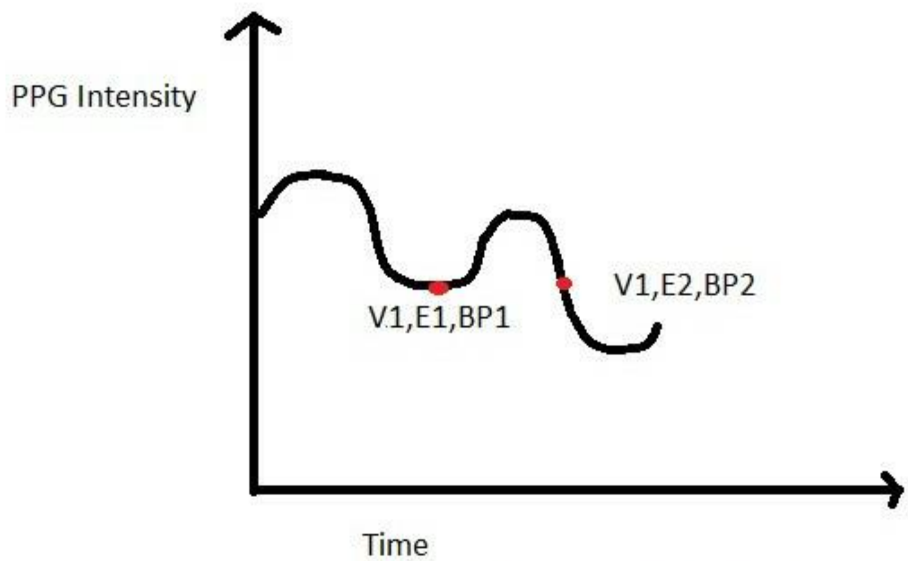
The volume of the arterial lumen is affected by factors like instantaneous blood pressure, vascular tone, arterial wall stiffness, static and dynamic pressure. Transmural pressure is the pressure difference across the wall of a blood vessel and is indicative of the properties of the different layers of the artery walls.

The mechanical unit exerts a small continuously varying force on the arteries and corresponding PPG and pressure readings are noted. After a few pulses, the force is increased drastically and quickly reduced.The device keeps repeating these steps based on feedback obtained from the sensors.

Phase 1

The small varying force that the unit exerts causes slight occlusion of the artery and this change is reflected in the obtained PPG waveform.

It will be observed that points at certain phases in the obtained PPG waveform lie at the same level . But points at these phases were not on the same level when the mechanical unit wasn't applying any force. This waveform shift and subsequent attainment of such points is a result of constant transmural pressure for any given lumen volume. Since transmural pressure indicates only properties of the arterial walls, such points can be explained by the fact a variation of blood pressure between two points was matched by an equal variation of external pressure. Since external pressure is known, we now also know the variation of the blood pressure waveform(dP/dt). Note that absolute value of blood pressure is still not known.



Example: Both red points are at the same volume during external pressure variation. E,BP are external pressure and blood pressure respectively. Since transmural pressure is the same for a given volume , (E1-E2)=(BP1-BP2).

Phase 2

The rapid increase and decrease of external pressure is performed to obtain absolute values of blood pressure. The increase of external pressure leads to significant decrease of lumen size. As stated earlier, there is a certain volume about which amplitude of oscillations is the maximum. Since returning force in our situation is caused by the transmural pressure , dV/dT is maximum at this volume where T=Transmural Pressure and V= Lumen size. Transmural pressure at this point is 0 , which means the external pressure is equal to the instantaneous blood pressure. Further decrease of the lumen size will again increase the transmural pressure. In the term dV/dT=(dV/dt)/(dT/dt), dT can be written as d(Blood Pressure-External Pressure)=d(Blood Pressure)-d(External Pressure). External pressure at any instant is known to us, d(Blood Pressure)/dt was already calculated during Phase 1 and hence we can instantly determine point of 0 transmural pressure and thus the absolute blood pressure waveform. External pressure is reduced to 0.

- This method minimizes occlusion(compressed state) time and can calculate blood pressure within a few pulses.
- Mechanical unit doesn't require precision control since variation of external pressure is the core of this method. This also makes the method less susceptible to error due to movement or hand placement.(eg. A person sleeping on the bed with his hand under his wife's pillow)

Phase 3

The blood pressure waveform is now known, but our calculations were performed considering a certain vascular tone. Vascular tone is controlled by a number of mechanisms , change in vascular tone will cause change in transmural pressure at any given volume. It is implied that the point of 0 transmural pressure also changes. Finapres is based on the volume clamp method where pressure of an external cuff is continuously varied to maintain the point of maximum variation. At fixed time intervals(around 30 seconds) the cuff pressure is independently varied based on an algorithm to find out if point of maximum variation has shifted, ie if there is change in vascular tone.

Without identification of this point, it is not possible to conclude whether PPG waveform variation is due to change in blood pressure or due to an added contribution of vascular tone change.

We continuously monitor PPG waveform from both the ulnar and radial artery. When change is noted in the PPG waveform, the waveforms of the radial and ulnar artery are compared. Starting under the assumption that variation is solely due to blood pressure change, points with same time phase are assigned blood pressure values based on the previously obtained transmural pressure. If these two points indicate different blood pressures then it is confirmed that vascular tone change is a contributing factor for waveform variation. Since the two arteries are not identical , vascular tone change will have different volume change for a given transmural pressure.

Phase 1,2 will be repeated when tone change is identified .

- Instant identification of vascular tone change helps avoid unnecessary periodic occlusion.
- Immediate notification of such changes will help medical staff react on time.

Finer corrections

Static pressure variation is due to the differing elevation of the wrist relative to the heart. Since blood pressure at heart elevation is the true value, correction must be performed based on wrist elevation. Viscosity contributes minimal blood pressure loss and will not be considered.

An initial calibration can be performed by making the device user lie down with arms lying along their body. They will lift the forearm about the elbow joint and maintain them at an angle of 45 and 90 degrees. Measurement at 2 different angles will help calculate blood density and refine the PPG signal. The signal is influenced by factors like epithelial fat and also does not provide us with the exact cross section of the artery lumen. Measuring at different elevations will help compare almost uniform artery contraction/expansion with shape deformation which is more influenced by the structure surrounding the artery like epithelial fat, bone bed, device placement, external pressure. We can also correct for external pressure deformation volume vs Blood Pressure change deformation volume and construct approximate mathematical models which can remove first order errors. Pressure degradation due to surrounding tissues can also be corrected using multiple points obtained during calibration. Thus we can improve the accuracy of the PPG signal and thus our blood pressure reading.

Note- Measurement at elevation will not be able to correct for height variation in situations where blood density is frequently changed.

Representation Only: In both cases , PPG sensor displays reading V1 for a certain pulse phase. But transmural pressure is dissimilar in the same artery even when there is no change in vascular tone. PPG volume can now be corrected to a more accurate value.

Force can be applied using air pumps but they are a bulky actuation unit. A mechanical instability based actuator is being developed which could potentially improve force amplification multifold.

Advantages

The method significantly improves patient comfort, uses a number of checks to attain clinical accuracy while also not being bulky. It combines the best qualities from all blood pressure monitoring device classes to become a truly one for all device .

Development

Development of Proof of Concept is essential for such a device.

It will comprise 2 PPG sensors and a pressure sensor, PoC will not contain a mechanical unit or any other actuator for force application. Since the mechanism just requires some kind of varying external pressure, we will manually apply force on the device. Mild force will be applied for a few seconds followed by a quick compression and release of the artery. We will repeat when the device notifies change in vascular tone. This process will be carried out for a duration of 5 mins in a group of patients. Same patient group will be tested every week for a month and necessary improvements in the method and algorithm will be made to make accuracy meet clinical standards. Constant consultation with field experts will be performed during development of PoC to better understand their requirements.

Appropriate funding may be seeked even during development of PoC if need be. We seek to eventually develop the device as a full-fledged health tracker with complete interactive guidance software.

The goal is to develop a device matching clinical gold standards for BP measurements which will enable its usage in hospitals , clinics and as a health tracker by the general population.