Point of care device for diagnosing and treatment of diabetes related peripheral arterial disease

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Abstract. Diabetes is a leading cause of micro vascular complications such as neuropathy and peripheral vascular disease. It is also associated with an accelerating atherosclerosis. Peripheral arterial disease (PAD) is manifestation of atherosclerosis which can pre date the diagnosis of diabetes. PAD is prevalent in diabetes and has a silent nature of progression. ABI is used as a reproducible and accurate non-invasive method for measurement and detection of PAD and the determination of disease complexity. Toe pressure and Toe brachial index (TBI) is useful in the evaluation of people with medial arterial calcification, where the ABI is considered as less accurate. Hence the aim is to develop a device which can assist humans to predict diabetic vascular disorder and treat them. The proposed system uses the toe brachial index (TBI) for detection of PAD. The normal range of TBI is from 0.5-0.95, below this value the person is diagnosed for PAD and above this value would be considered as unclassified due to calcification of blood vessel. The proposed device is a microcontroller based system that can monitor TBI and accordingly treat the vascular issue by providing compression.

1. Introduction
Diabetes affects 387 million of the world population. About 15% of patients with Diabetes have micro vascular complications during the time of diagnosis suggesting that they have the disease for a long time at the time of diagnosis. Peripheral arterial disease (PAD) is prevalent in diabetes and has a silent nature of progression. The presence of PAD increases the risk of losing the affected region in patients with diabetic foot ulceration. It is also accompanied by a high likelihood for cardiovascular and cerebrovascular disease [1-2]. The major symptoms are pain when walking, foot wounds those are slow to heal, one foot being colder than the other. The other symptoms include pale or shiny foot, numbness in feet, brittle toe nails etc. Care of patients with both diabetes and PAD becomes crucial. Ankle Brachial Index (ABI) & Toe Brachial Index (TBI) are the commonly reproducible and accurate non-invasive measurement for the detection of PAD and the determination of disease complexity. Toe pressure is used in addition when screening for peripheral arterial disease (PAD) of the lower limb due to arterial calcification. It may be used as a valuation method for lower limb vascular utility [2-5]. In many vascular units, ankle brachial pressure, and toe brachial index is used as measurement for clinical assessment and is analysed in daily practice. Based on the observations it is suggested that non-invasive measurement of toe pressure and toe brachial index are associated with cardiovascular disease, diabetes and overall impermanence. It is also used for amputation free survival of patients with peripheral artery disease [6-10]. The normal range for the ankle brachial index (ABI) is between...
0.9 and 1.3. An index value under 0.9 means that blood is struggling to get to the legs and feet, while index of 0.4 to 0.9 indicate mild to moderate PAD and index of 0.4 and lower indicates severe Peripheral arterial disease ‘[13]’. The cut-off value of toe pressure is random and keeps varying for each condition. Generally toe pressure of 70 to 110 mmHg or TBI > 0.5 to 0.75 is considered normal and anything below is considered as diagnosis of Peripheral arterial disease ‘[14]’. In comparison to the standard values, the TBI in young and healthy individuals is higher than the normal range. This makes a difference that when the toe pressure measured in young adults the standard range condition is not satisfied. They have an elevated toe pressure up to 0.95. Hence the standard range determination has to be altered on considering young adults ‘[15]’. The blood pressure is obtained using optical method by placing an IR light and photodetector. The sensed signal produces pulse rate from which blood pressure is obtained using several methods which helps in acquiring exact blood pressure similar to that obtained using a manual or automated blood pressure monitor ‘[21-23]’. The various methods of treatment for this is designed earlier like Ultrasonic Debridement, Vacuum assisted closure (VAC) therapy, Hyperbaric Oxygen Therapy (HBOT), negative pressure wound healing, vascular compression-suction treatment (VCT), whole body vibration, and sequential compression method ‘[11, 12, 16-20]’ help in treating the patient and also a therapy which reduces the risk of amputation. Hence these systems have thus helped us in designing an efficient system that incorporates an optical blood pressure measuring system from toe and a normal blood pressure monitor from the arm by which TBI is calculated. When the value falls below the threshold the system automatically activates the compression unit which provide the therapy.

2. Methodology
The proposed system consists of three different units of which two units are used for data acquisition and the other one for therapy. The data acquisition system is designed for getting the pressure values from the arm and the toe. The pressure from arm is obtained using a blood pressure monitor and sent to the master controller. The pressure from toe is acquired using optical method by placing an existing sensor that is used to acquire BP from index finger ‘[21-23]’, from which systolic and diastolic pressure values can be determined. The required systolic toe pressure is alone sent to the controller. Then the toe pressure is calculated by using the formula:

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\text{Toe brachial index (TBI) = systolic pressure of toe / systolic pressure of the arm.}
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This gives a value called the TBI which is to be between particular range of 0.5-0.95 stated earlier. The third unit comes into function when the TBI is less than the defined range where a compression cuff is placed to provide compression sequentially with a defined time interval of 15 seconds and 5 seconds for relaxation of blood vessels and to improve blood flow. The compression cuff is placed in the calf region. All the 3 units are controlled by an ATmega328 microcontroller and an LCD is used for displaying the pressure values and TBI. Since the system is divided into 3 the power supply is given by three 9v battery which is highly durable. The entire work flow of the designed system is shown in (Figure 1). The systolic blood pressure is obtained by placing the BP unit on the wrist, while the toe blood pressure is obtained by placing the sensor on the large toe finger of the user and a Velcro strap is used to tighten and prevent external light falling on the light detector. The compression cuff is placed between the calf muscle and ankle region. This region was chosen in order to make sure that the setup is placed near the extremities and also a region which is not bony in nature which impacts more direct pressure to the vessels. The entire setup of the device is shown in (Figure 2).
3. Results

The designed system of three units as stated above runs properly under normal condition with the given power supply of 9V. The output of each unit and the calculated TBI value is displayed on the LCD connected to the controller. If the calculated TBI value falls lower than 0.5 the compression cuff gets started and produces compression near the calf region. The sequential compression of the compression cuff is expected to improve blood flow to the extremities. The values calculated can also make user aware of entering into the diabetic PAD condition. The output of the two units helps in concluding that the system works properly. The entire system functions normally and is expected to function similarly when tested with patients. The (Table 1) is the result of the T1 values obtained from the designed device and the existing device VERSALAB Auto. The results show that all participants fall under normal condition except for the 2 who need further diagnosis due to high TBI values. The comparison of the TBI values states the deviation of values from the standard device to the existing one.

| Table 1. Comparison of data obtained from designed and existing device. |
|---------------------------------------------------------------|
| **Brachial** | **Toe BP (mmHg)** | **Calculated TBI** | **Brachial BP (mmHg)** | **Toe BP (mmHg)** | **Calculated TBI** | **Difference in TBI** |
| **BP** | **Versalab Auto** | **Versalab Auto** | **Designed Device** | **Versalab Auto** | **Designed Device** | **Designed Device** |
| Sub 1 | 134 | 97 | 0.72 | 139 | 109 | 0.78 | + 0.06 |
| Sub 2 | 136 | 156 | 1.14 | 128 | 145 | 1.13 | - 0.01 |
| Sub 3 | 109 | 121 | 1.1 | 102 | 125 | 1.22 | + 0.12 |
| Sub 4 | 139 | 119 | 0.85 | 135 | 124 | 0.91 | + 0.06 |
| Sub 5 | 123 | 114 | 0.92 | 128 | 116 | 0.93 | + 0.01 |
| Sub 6 | 122 | 116 | 0.95 | 125 | 118 | 0.94 | - 0.01 |

**Figure 1.** Flow Diagram.  
**Figure 2.** Working Model.
4. Discussion
The design of the proposed system is very simple and user friendly when compared with other existing ABI and TBI devices. The therapy unit attached to the diagnostic unit makes more advantageous than the other existing systems where they only calculate the ABI or TBI and display it. Most of the existing systems are of laboratory based or hospital based systems which require the assistance of a trained professional to operate the device, but our system is designed in such a way that it can be used by the user itself without any assistance. The designed system works similar to that of standard device (Versalab Auto) with very minimum deviation. The system also helps the user in identifying if he is nearing or already in the state of diabetic PAD which makes the user aware of his state of diabetic health. A timely use of the device with therapy makes the user of it to recover quickly from the disease when nearing the stage of diabetic PAD. Since we use compression on the body as we generally know that flow in a tube when blocked and released increases the total flow and is given for a particular duration of time it acts as a massager and also therapy unit for the user. The compression provided by the system is not very high that might cause a clot or any other complications due to it. A device that helps in both prediction and therapy for a disease that is complicated is very less in market and also for a disease like diabetic PAD is very rare. Hence this system is designed to make the people get benefited and stay healthy at least for an extended period of time.

5. Conclusion
The main objective of the work is to assist the patients who have low blood flow to lower extremities. The device is designed in such a way that it is easy to operate and cost effective at the same time. The addition of compression cuff to the setup would be of major assistance to the user on improving the flow of blood to extremities and with a simple and compact design. The device is to be tested on diabetic patients for efficient working of the unit. The designed device would be of great use for the diabetic PAD affected people and also as a predictor for diabetic related vascular disease people. The future work completely relies on testing the device and addressing of power supply issues for more improved blood flow and to optimizing it accordingly.

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