Hemodynamic Monitor for Rapid, Cost-Effective Assessment of Peripheral Vascular Function

Paul P. Breen, *IEEE Member* and Gaetano D. Gargiulo, *IEEE Member*

Abstract— **Peripheral vascular diseases affect hundreds of millions of people worldwide and are often symptomless and undiagnosed. Early diagnosis is crucial for effective treatment and reducing personal and economic costs, particularly where early treatment is geared towards preventing lower extremity amputation. New diagnostic tools are needed to enable this earlier intervention. We have developed a new low-cost, easy to use, non-invasive hemodynamic monitor, *HeMo*, to address this large and growing problem. Using a novel combination of impedance tomography and electrical volumetric measurements we can calculate real-time changes in peripheral blood volume. We believe that this work will lead to the availability of a fast, easy to use and cost-effective vascular assessment tool, dramatically shortening the time to diagnosis and subsequently intervention, dramatically improving the prognosis of affected patients.**

I. Introduction

The lower limbs are susceptible to a variety of peripheral vascular diseases (PVD) including peripheral arterial disease, chronic venous insufficiency, intermittent claudication and deep vein thrombosis. These conditions have a considerable socioeconomic impact due to their high prevalence, cost of investigation, treatment and their impact on quality of life. Complicating matters, PVDs are often undiagnosed with over 60% of patients with peripheral arterial disease and diabetes remaining asymptomatic [1].

Several diagnostic tools currently exist to aid in the diagnosis of PVD. The *Ankle-Brachial Index* (ABI) is a commonly used tool in this regard. Calculated by dividing systolic blood pressure at the ankle by the higher of the two systolic brachial pressures, the ABI is relatively cheap and simple to administer. An ABI greater that 0.9 is considered normal, between 0.4 and 0.9 mild to moderate PAD and lower than 0.4 severe PAD [2], [3]. However, the ABI has poor sensitivity in patients with 'thickened arteries' such as those with diabetes, renal disease and the elderly where the ABI may appear normal [2].

Another noninvasive method, *Plethysmography*, measures changes in blood flow/volume. Several alternative methods have been used to assess peripheral vascular function including impedance, photo, strain-gauge and air plethysmography. However, these methods require a careful setup by a trained practitioner and considerable time to perform the assessment. These requirements have meant that they have been largely replaced by Duplex Ultrasound [4].

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P. P. Breen is with The MARCS Institute, University of Western Sydney, Penrith NSW, 2751 (phone: +61-2-4736-0507; fax: +61-2-9772-6326; e-mail: p.breen@uws.edu.au).

G. D. Gargiuo is with The MARCS Institute, University of Western Sydney (e-mail: g.gargiulo@ uws.edu.au).

Duplex Ultrasonography is a commonly used non-invasive methods to define anatomy, hemodynamics and lesion morphology and highly sensitive in detecting occlusions and stenosis. It is considered a gold standard in the diagnosis of CVI and revealing sites of reflux and/or obstruction in veins [5]. However, it is time-consuming and requires expensive equipment and a highly trained vascular technician, thus limiting its use.

Venography involves the injection of contrast solution into the vein of the foot using a 21-gauge butterfly needle. It has several drawbacks and attendant risks that have reduced its once widespread use. Venography can cause a chemical cellulitis with the potential for the development of tissue necrosis, ulceration, or gangrene. Other complications include postphlebographic thrombosis and syndrome, characterized by pain, tenderness, and erythema around the ankle joint not associated with thrombosis [6].

A variety of *Angiography* methods exist for the assessment of PAD [7]. Contrast angiography entails the intravascular injection of contrast agent during planar X-ray imaging. Magnetic resonance angiography is a less invasive alternative where intravascular blood is detected by virtue of its movement compared with static surrounding tissues. Contrast-enhanced magnetic resonance angiography relies on the T1 shortening effect of intravenously administered contrast media circulating in the blood. Helical computed tomography angiography requires exposure to ionising radiation and the injection of relatively large volumes of contrast material. Clearly, the cost and invasiveness of these methods means that none are suitable for routine screening.

Ambulatory Venous Pressure is measured by introducing into a dorsal foot vein a 21-gauge needle, which is then connected to a pressure transducer. The rise/fall of venous pressure is indicative of the health of the vascular bed. Like venography, ambulatory venous pressure measurement is invasive and not suitable for screening, or for repeated examinations to monitor the results of therapy [6], [8].

Each vascular assessment method has advantages and limitations. ABI is fast and cheap but may misdiagnose those with diabetes and the elderly, both growing high-risk populations. Plethysmography has failed to gain traction over ultrasound imaging methods as they incur similar time and personnel commitment. Duplex ultrasound is the mainstay assessment procedure but due to its time-consuming nature and cost is often reserved for use where the patient is already symptomatic. Angiography, Venography and Ambulatory Venous Pressure measures are excellent but are highly invasive and carry attendant risks.

The main motivation behind developing a new peripheral vascular assessment device is the fact that many individuals

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with PVD are asymptomatic and go undiagnosed or are diagnosed late in the development of the disease. Indeed the difficulties with peripheral vascular assessment go beyond the diagnosis and include the assessment of treatment outcomes and progression of the disease. Early diagnosis is essential for effective treatment and reducing socioeconomic costs, particularly in patients with diabetes where early endovascular treatment is geared towards preventing lower extremity amputation. There is an urgent need for new tools to quantify alterations in limb hemodynamics and their contribution to impaired functional capacity [9]. For this reason we have developed a novel hemodynamic monitor, *HeMo*, specifically for the purpose of assessing peripheral vascular function. This platform technology can provide low-cost, rapid, dynamic measurement of blood volume in a defined region of the extremities. We believe this is an ideal combination for the diagnosis of a range of peripheral vascular diseases.

II. Methods

A. Specification of a New PVD Assessment Device

In the development of this device we considered the following factors to be essential.

Ease of use: One of the hurdles preventing current technologies gaining more widespread use is the training requirement for their implementation. For this reason any potential device needs to be intuitive and have minimal training requirements.

Speed of use: Should the diagnostic test take an extended period of time to complete then the use of the device will be limited. Thus, the device needs to implement fast, reliable diagnostic routines.

Low cost: There are a wide variety of healthcare professionals who could take advantage of a peripheral vascular assessment tool including general practitioners, vascular assessment labs and high-risk foot clinics. Cost, as always, is an impediment to the availability of any technology and therefore we aim at creating a device which may eventually be sold for ~$5k, a fraction of the cost of a duplex ultrasound machine (> $30K) or plethysmograph (APG Air Plethysmograph $21k).

Ability to detect both venous and arterial conditions: Both venous and arterial conditions may be asymptomatic or may have inconclusive symptoms. Indeed many patients do not fully inform their clinician of their symptoms. Ideally any screening tool would be capable of providing a holistic overview of function such that, at the very least, a comparison may be made to a healthy data.

Real value measure: Comparison of limb hemodynamics is highly informative as it may highlight limb specific abnormalities (e.g. presence of DVT). For such a comparison real value measurements (e.g. ml) are more useful than an arbitrary unit. Tracking of a condition and treatment outcome is also made easier and intuitive with a real value measure.

Wearable Solution: It has been highlighted by others the there is a need for new tools to quantify the impact of impaired hemodynamics on functional capacity [9]. Gait is intrinsic to the function of the lower limbs and for this reason the ability to measure hemodynamic changes during movement and gait would be a major improvement in clinical assessment. For this reason a wearable device that does not impact the kinematics and hemodynamics of gait is highly desirable.

B. Hemodynamic Monitor Concept

To enable the clinical and technical needs as specified we developed a novel hemodynamic monitor concept. At its core this hemodynamic monitor, *HeMo*, incorporates an impedance measurement system consisting of a ring of electrodes surrounding the limb. This provides measures of impedance change related to blood volume in the enclosed limb segment (Fig. 1). While this system cannot provide a true blood volume measurement (i.e. mL of blood), it does provide quality information relating to the relative change in blood volume. It is also highly responsive to dynamic changes in blood volume. The impedance measurement system requires ultra-high input impedance amplifiers to capture data from the recording electrodes such that electrode impedance changes over time have minimal effect.

The physical volume of the analyzed limb is simultaneously calculated in mL. This is done by measuring the circumference of the limb at multiple points using pre-calibrated integrated electroresistive bands and calculating the volume as a series of truncated cones. It should be noted that this volume measurement is accurate for static measures but does not provide quality information on dynamic changes. However, by combining the dynamic accuracy of impedance measurement with the static accuracy of volume calculations, the device can auto-calibrate allowing us to generate accurate dynamic measurements of blood volume (in ml) in the extremities.

The preferred placement of the vsystem elements is shown in Fig. 1. Electrodes and electroresistive bands are located on the lower limb. Accelerometers incorporated at the shank and thigh enable the detection of posture and movement/gait. They also provide a means for detecting appropriate data epochs to perform calibration.

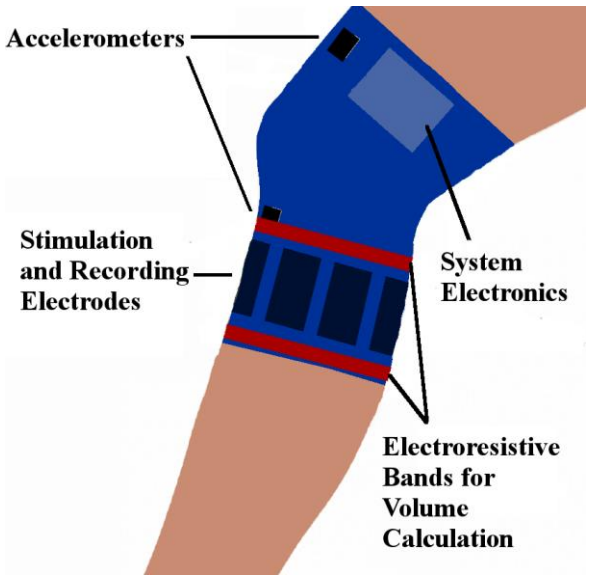

Figure 1. Diagram of HeMo Device.

III. Results

A prototype version of *HeMo* and a block diagram of its circuitry may be seen in Figs. 2 and 3. This prototype incorporated two electroresistive (ER) bands sewn into the top and bottom of an elasticated fabric cuff. The ER bands were made of carbon-black impregnated rubber with a resistance of ~150Ω/cm at rest. Four electrodes were stitched in place between the ER bands at 90 degrees to each other.

A. Static Volume Calculation

Pre-calibrated ER bands were used to calculate limb volume when the user was in a static position. The ER bands were calibrated by placing the cuff on several cylinders of known circumference. With a constant current applied, voltages was recorded and equated to the known circumferences. These equations were then used for radaii calculation when a subject subsequently wore the cuff. Limb volume was calculated using these radaii (r_1 and r_2) and a known distance between them, h (1). The cuff was quite rigid longitudinally; as a result we found that this distance (h) did not vary substantially when worn by a subject in various positions.

$$Volume = \frac{\pi}{3}h(r_1^2 + r_1 r_2 + r_2^2) \quad (1)$$

B. Dynamic Impedance Measurement

To avoid capacitive effects of the skin, impedance measurements were calculated based on the peak voltage in response to a constant current pulsatile stimulus. The constant current, pulsed stimulus was biphasic with a pulse width of 300µs and frequency of 30Hz. The maximum stimulus current is sufficiently low such that it is not perceivable by the subject.

C. Calculating Dynamic Changes in Limb Blood Volume

Recordings of accelerometer signals, limb volume, impedance and blood volume are shown in Fig. 4 where an individual subject moves from the standing position to lying before elevating their leg and finally standing.

Static volume and impedance measurements are taken while the subject is lying down with their leg elevated and when the subject standing is up. From these measurements, a minimum measure of limb section volume (V_{min}) and a maximum measure of electrical impedance (Z_{max}) are obtained. From the standing measurements, a maximum measure of limb section volume (V_{max}) and a minimum measure of electrical impedance (Z_{min}) is obtained. In its simplest form this provides a simple linear equation of the form y =mx + c to convert impedance to blood volume for with two calibration points (2) at any time point, i, where c is an offset calculated by (3).

$$Blood\ Volume\ (i) = \frac{V_{max} - V_{min}}{Z_{max} - Z_{min}} Z(i) + c \quad (2)$$

$$c = V_{min} - \frac{V_{max} - V_{min}}{Z_{max} - Z_{min}} Z_{max} \quad (3)$$

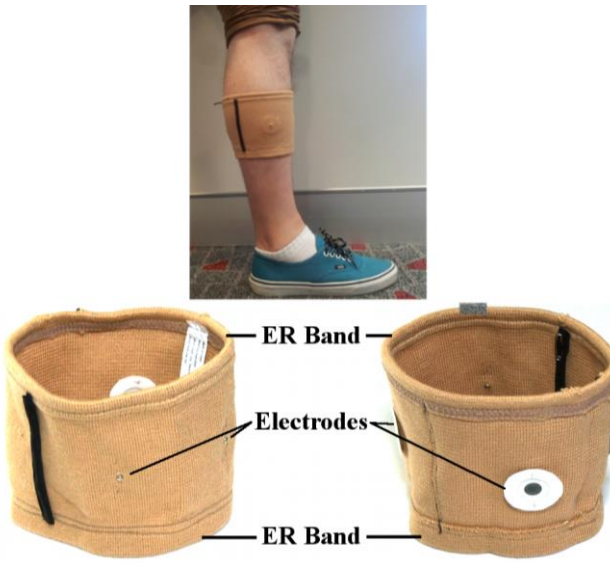

Figure 2. *HeMo* prototype shown as worn by subject (top and bottom left) and turned inside out (bottom right). Thigh/shank accelerometers and electrode/electroresistive (ER) band connection cables are not shown.

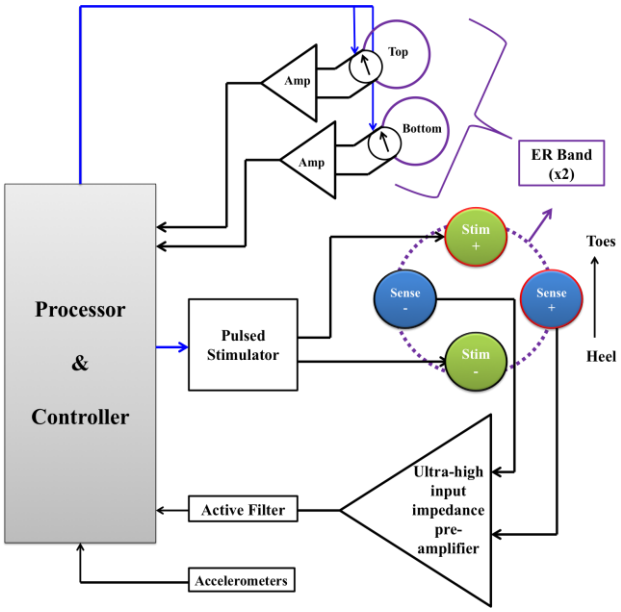

Figure 3. Block diagram of *HeMo* prototype circuitry. A constant current stimulus is applied to the electroresistive (ER) bands with the resulting voltage amplified and recorded. A pulsed stimulus is applied to two of the four electrodes. Recorded voltage from the orthogonal electrode pair is amplified, filtered and recorded. Accelerometer signals are also recorded before the entire data set is processed.

IV. Discussion & Conclusion

We have developed a novel system for the measurement of blood volume in the lower limb. Using a combination of impedance and circumference measurements we may derive a dynamic measure of blood volume in the limb. This device may have substantial benefits for clinicians, as it provides a simple means of assessing peripheral vascular function. The fact that it provides blood volume changes in non-arbitrary

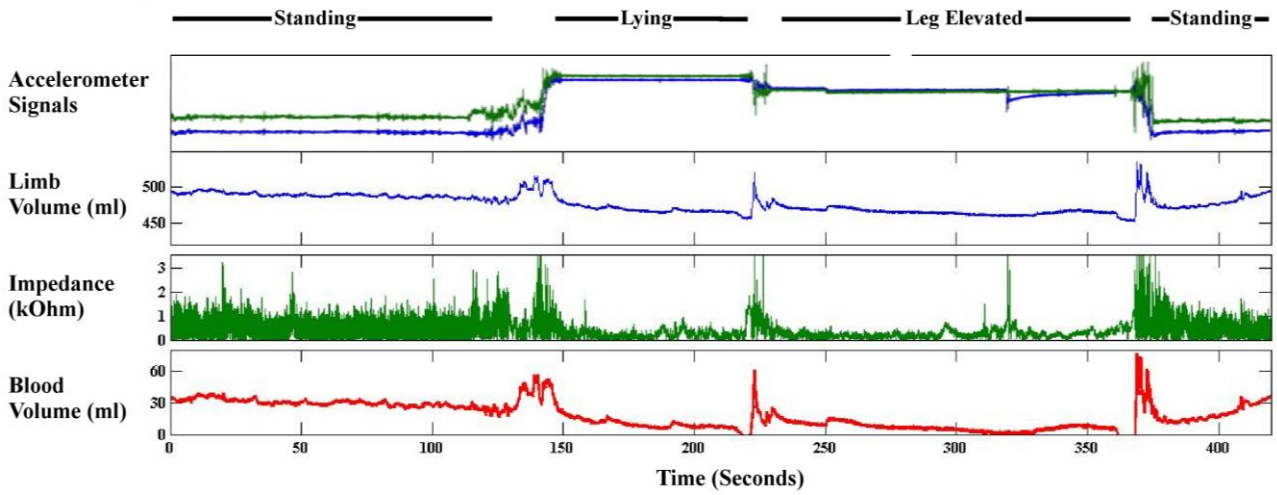

Figure 4. Recording of limb volume, electrical impedance and calculated blood volume as subject moves from standing to lying, with leg elevated and back to standing. Note: the impedance shown is raw recorded data in reponse to repetitive current pulses, so only the peak values are of importance.

units (i.e. ml) is highly beneficial as it allows the comparison of function in both limbs and at multiple time points.

Several validated plethysmography methods currently exist for the diagnosis of a variety of vascular diseases including chronic venous insufficiency, deep vein thrombosis and peripheral arterial disease [10]–[13]. We believe that the *HeMo* device is capable of implementing all of these existing methods but simply, faster and with less training. A futher benefit is that all of this may be achieved with a device that is an order of magnitude cheaper than a plethysmograph or ultrasound device.

Typically, ambulatory measurements of peripheral vascular function are only achievable through insertion of a needle into a vein or artery. As the *HeMo* device may be made fully wearable, dynamic measures of peripheral hemodynamics during movement and gait may be made routinely and non-invasively.

Future work is required to validate the ability of *HeMo* to accurately measure changes in limb blood volume. This may be achieved for limb volume changes using water displacement or optical volumeter during thigh compression or tilt if possible. The linearity of both the electroresistive bands and the impedance measures require further scrutiny as does the fact that the leg is not truly conical. Ultimately, we need to assess the utility of this device in aiding the diagnosis of peripheral vascular diseases in comparison to established gold standard methods.

This work is a first step in the development of a tool for fast and cost-effective assessment of a variety of peripheral vascular diseases. The availability of a portable, user-friendly and reliable vascular assessment device outside of the traditional specialized laboratories (e.g. use by a general practitioner or public health nurse) could dramatically shorten the time to diagnosis and subsequent intervention. This would have a tremendous effect on the socioeconomic cost of these conditions.

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