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A Novel Stretch Sensor to Measure Venous Hemodynamics

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Abstract

Chronic venous insufficiency is a debilitating condition causing varicose veins and venous ulcers. The pathophysiology includes reflux and venous obstruction. The diagnosis is often made by clinical examination and confirmed by Venous Doppler studies. Plethysmography helps to quantitatively examine the reflux and diagnose the burden of deep venous pathology to better understand venous hemodynamics, which is not elicited by venous duplex examination alone. However, most of these tests are qualitative, expensive, and not easily available. In this paper, we demonstrate the potential use of a novel stretch sensor in the assessment of venous hemodynamics during different maneuvers by measuring the change in calf circumference. We designed the stretch sensor by using semiconductor strain gauges pasted onto a small metal bar to form a load cell. The elastic and Velcro material attached to the load cell form a belt. It converts the change in limb circumference to a proportional tension (force of distension) when placed around the calf muscle. We recorded the change in limb circumference from arrays of stretch sensors by using an in-house data acquisition system. We calculated the venous volume (VV), venous filling index (VFI), ejection fraction (EF) and residual venous volume (RVV) on two normal subjects and on two patients to assess venous hemodynamics. The values (VV > 60 ml, VFI < 2ml/s, EF > 60%, RVV < 35%) in normal subjects and (VV < 60 ml, VFI > 2ml/s, EF < 60%, RVV > 35%) in patients were comparable to those reported in the literature.

Keywords: stretch sensor, venous hemodynamic, plethysmography, venous duplex

1. Introduction

The pathophysiology of reflux and venous obstruction due to chronic venous insufficiency is a debilitating condition causing varicose veins and venous ulcers. The diagnosis is often made by clinical examination and confirmed by Venous Doppler studies [1-2]. There are three systems in the venous circulation of the lower extremity namely superficial, deep veins, and perforators. Normal physiology allows blood to flow from superficial to deep veins via perforators and then returns the blood to the heart in unidirectional flow. When there is damage to the valves, blood can flow bidirectionally, causing the volume overload in the lower extremities leading to the pathological changes. The goal of further evaluation is to characterize the misdirection of venous blood volume [2-3]. It is, therefore, crucial to study the venous hemodynamic, which is not elicited by venous duplex examination alone. Plethysmography helps us to quantitatively examine the reflux and diagnose the burden of deep venous pathology (degree of venous obstruction, ejection capacity of calf muscle pump).

Different plethysmographic measurement of venous reflux includes Strain-Gauge Plethysmography (SGP) using silastic conductor tube which is stretched by a change in calf circumference. This, in turn, increases the resistance resulting in a voltage

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change which is acquired for further analysis. The disadvantage of this technique is that it is susceptible to degrade over time resulting in the change in conductivity of the silastic conductor. Impedance Plethysmography (IPG), on the other hand, results in a change in resistance due to change in limb circumference which is directly proportional to relative volume change [4]. The disadvantage of this method is that it is cumbersome as it is sensitive to sensor placement. Photoplethysmography (PPG) is another method which uses a light source in the infrared wavelength to emit light into the tissue. The light is absorbed by the blood and whatever is reflected or transmitted is measured by a reflective/transmissive based photo detector, and net absorption is displayed as a line tracing [4]. The disadvantage of this method is that it is also sensitive to sensor placement. Dielectric elastomer described in [5], uses a flexible capacitor with stretchable dielectric attached to 2 parallel plate electrodes. When the electrodes are pulled uniaxially or biaxially, it changes the area and thickness of the sensor (stretch mode) resulting in the change in capacitance. One of the major drawbacks of this sensor is that the accuracy is affected by speed and, therefore, the capacitive based stretch sensor requires good circuit design to achieve better accuracy [5]. The 'StretchSense', based on this principle is commercially available. However, it is expensive. Air Plethysmography (APG) is considered as the gold standard. It uses a 30-40 cm length air cuff that is attached to the lower leg from knee to ankle. The low-pressure cuff provides a precise quantitative evaluation of volume changes of the entire lower leg [4]. Although APG is considered the gold standard, it is not readily available because it is expensive. As discussed, there are different techniques available such as PPG, IPG, APG etc. However, most of these tests are qualitative, expensive, and not easily available [4-9]. In this paper, we demonstrate the measurement of venous volume using arrays of the novel stretch sensor and thereby enable us in developing a novel prototype instrument for measuring venous hemodynamic.

2. Design Methodology

End-supported-centre loaded load cell was constructed using semiconductor strain gauges (BCM strain gauges B2-120-P-3) and an aluminum bar (31 mm x 5 mm x 3 mm) as described by Wankhar et al. [9]. A pair of strain gauges pasted on the top face and bottom face of the beam will experience tension and compression respectively. These strain gauges along with fixed resistors form a Wheatstone bridge to give an output voltage proportional to the bending of the beam. The output of the strain gauge bridge connects to a DC Bridge amplifier for further processing. Eq. (1) is the standard form of the strain on the surface of the beam as measured by the strain gauges for centre-loaded end supported beam:

$$\frac{\Delta l}{l} = \frac{4\,Fl}{E\,bh^2} \tag{1}$$

3.1. Static calibration of the stretch sensor

Static calibration of the overall stretch sensor consisting of the load cell attached to the Velcro (rigid) and elastic (spring) material was done. Offset correction was done before measurements were taken. The change in length due to stretching of the elastic band was recorded by using an in-house data acquisition system 'CMCdaq'.

The setup for measuring venous volume by measuring the change in calf circumference using arrays of 3 stretch sensors is shown in Fig. 1. This is a novel prototype instrument for quantifying venous function.

The total volume measured by the stretch sensor is calculated using Eq. (2):

$$\Delta V = \frac{h}{4\pi}(2C_1\Delta C_1 + \Delta C_1^2 + 2C_2\Delta C_2 + \Delta C_2^2 + 2C_3\Delta C_3 + \Delta C_3^2) \tag{2}$$

where, h = Height of the stretch sensor belt, ΔC = Change in circumference measured by the stretch sensor

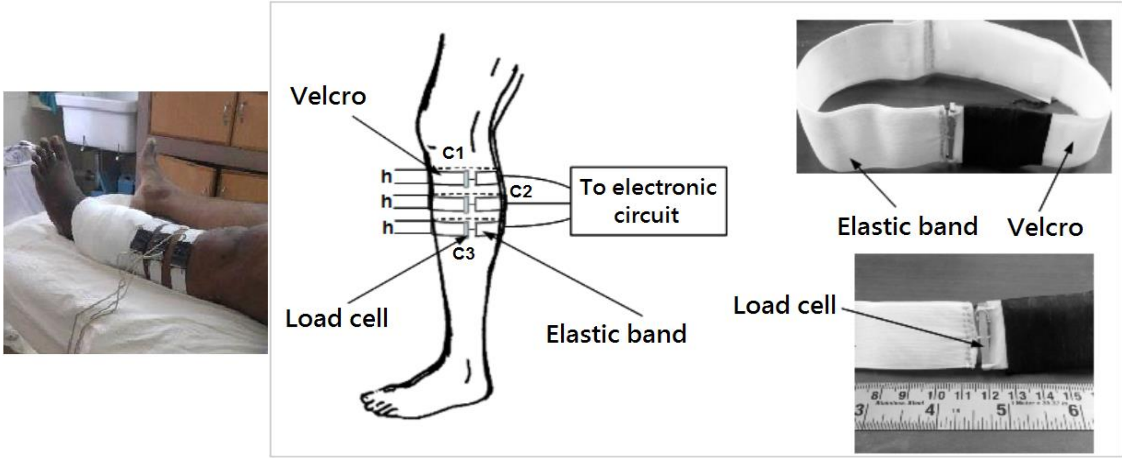


Fig. 1 Setup for measuring venous volume by measuring change in calf circumference using arrays of stretch sensors

3.2. Measurement of venous volume using the novel stretch sensor

For measuring venous volume, the subject performed different maneuvers as described in [1, 10]. At the beginning of the experiment, the subject was asked to lie down in a supine position. The subject's leg to be assessed was lifted to 45° angle for about a minute so that the veins are emptied and then the leg was placed back in the initial position. This was done to lower the venous pressure in the legs to a zero line (pressure) of the right atrium (≈ 0 mmHg) which was recorded as baseline volume us ing an in-house data acquisition system [10]. Then the subject was asked to stand slowly and load on the non-assessed leg. The assessed leg was in non-weight bearing position so that the leg venous pressure increases due to the hydrostatic column of blood extending from the right atrium to the assessed leg [10]. The blood volume increases as the veins are elastic and this change in volume was recorded. Fig. 2 illustrates the different parameters as measured by the novel stretch sensor during different maneuvers. The measurement between baseline volume in the supine position ('1') and the erect volume plateau is known as venous volume (VV). We also determined the venous refilling time (VFT90), which is the time from which the volume increases from baseline ('2') to 90% VV and venous filling index (VFI) was calculated using Eq. 3(a). The volume then increases till it plateaus ('3'). During this time, the subject was in a standing position and supported only on the non-assessed leg. Then, the subject was asked to weight bear both legs and performed a single plantar flexion ('4'). The subject then unloads the assessed leg (non-weight bearing stance, '5') again. This produced a change in the volume called the ejection volume (EV). Ejection fraction (EF) was then calculated using Eq. 3(b). Now the subject was asked to perform the same maneuver (plantar flexion) 10 times ('6'), which caused a larger volume reduction. The residual volume (RV) was measured as the difference between the volume after 10 plantar flexions and the baseline volume. The residual volume fraction (RVF) was calculated by dividing RV by VV as given by Eq. 3(c).

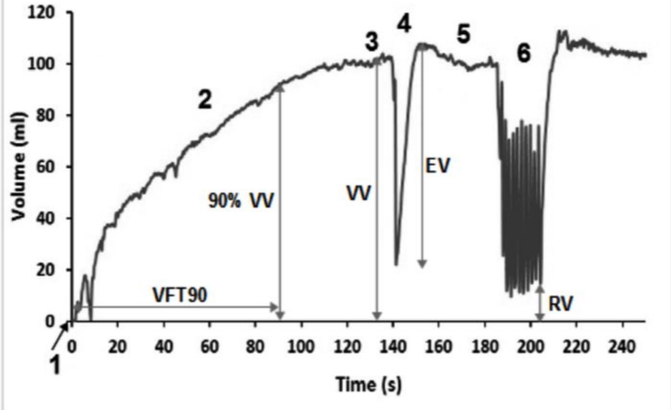


Fig. 2 Change in venous volume during different maneuvers measured by the stretch sensors

The equations for calculating VFI, EF, and RVF are as follows:

$$VFI = \frac{90\%\ VV}{VFT_{90}} \tag{3a}$$

$$EF = \frac{EV}{VV}100 \tag{3b}$$

$$RVF = \frac{RV}{VV}100 \tag{3c}$$

3. Results

3.1. Static calibration of the stretch sensor

The overall stretch sensor is non-linear in its characteristics because of the properties of elastic band attached to the belt as shown by the static calibration curve in Fig. 3. Fitting a linear equation to the data by linear regression from a single sensor is shown in Fig. 3 (a). Eqs. (4) and (5) provide the relationship between force and change in length of the stretch sensor belt.

$$y = 0.915x - 0.1065 \tag{4}$$

with R^2= 0.9652

$$y = 3.1445x - 7.0357 \tag{5}$$

with R^2 = 0.9972, where y is force and x is change in length.

Similarly, linear equation to the data by linear regression from all other sensors shown in Fig. 3 (b) is given by Eqs. (6), (7), (8), and (9) for sensors 2 and 3 respectively.

$$y = 0.9142x - 0.1155 \tag{6}$$

with R^2 = 0.9418

$$y = 3.1928x - 6.9242 \tag{7}$$

with R^2= 0.9982

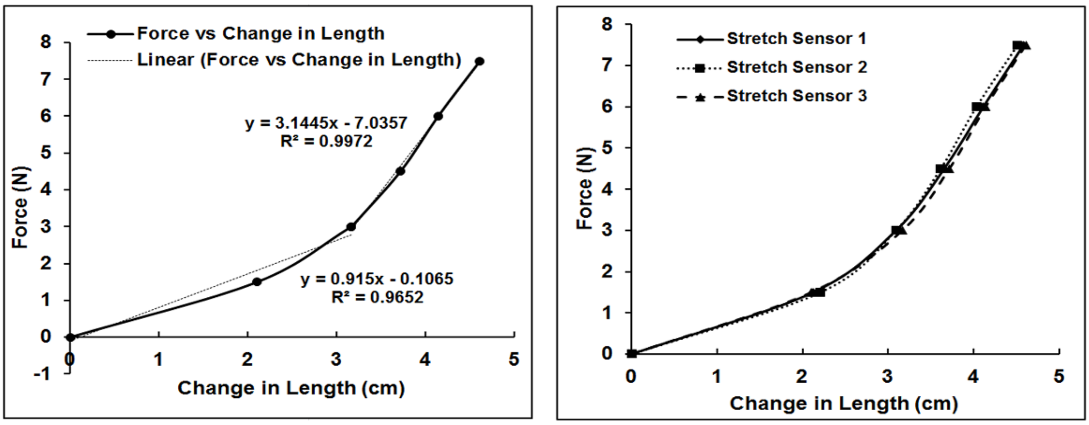
$$y = 0.9274x - 0.1118 \tag{8}$$

with R^2 = 0.9555

$$y = 3.0342x - 6.4521 \tag{9}$$

with R^2= 0.9976, where y is force and x is change in length.

For all applications, the stretch sensor is pre-loaded/stretched to a length change of 2 cm or more, indicating the region of operation is in the second part of the curve with $R^2 \geq 0.9972$ (Fig. 3(a)).



(a) Static calibration curve of one stretch sensor (b) Static calibration curve of all 3 stretch sensors

Fig. 3 Static calibration curve of one stretch sensor and all 3 stretch sensors

3.2. Measurement of venous volume using the novel stretch sensor

We calculated venous volume (VV), venous filling index (VFI), ejection fraction (EF) and residual venous volume (RVF) on two normal subjects (1male, 1female) and two patients (2 males). Fig. 4 shows the changes in venous volume during different maneuvers measured by the stretch sensors for venous hemodynamic assessment on one normal subject. The calculated parameters were VV = 100 ml, VFI = 1 ml/s, EF = 84.4%, and RVF = 14.9% in a male subject, and VV = 65 ml, VFI = 0.5 ml/s, EF = 61%, and RVF = 29.7% in a female subject. Similarly, Fig. 5 shows the changes in venous volume during different maneuvers measured by the stretch sensors on one patient. The calculated values were VV = 51 ml, VFI = 4.6 ml/s, EF = 40%, and RVF = 41%, and VV = 55 ml, VFI = 5.6 ml/s, EF = 58%, and RVF = 38% in 2 male patients respectively. The measured parameters that quantify venous function on 2 healthy subjects (VV > 60 ml, VFI < 2 ml/s, EF > 60 %, RVF< 35%) and 2 patients (VV < 60 ml, VFI > 2 ml/s, EF < 60%, RVF> 35%) were comparable to those reported in the literature [3, 7-8, 11].

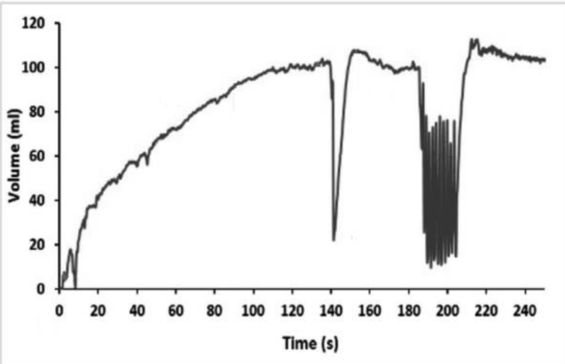


Fig. 4 Changes in venous volume during different maneuvers measured by the stretch sensors on a normal subject (VV=100 ml, VFI=1 ml/s, EF=84.4%, RVF = 14.9%)

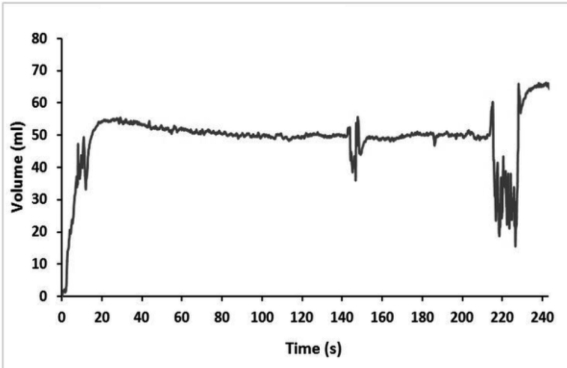


Fig. 5 Changes in venous volume during different maneuvers measured by the stretch sensor on a patient (VV=51 ml, VFI=4.6 ml/s, EF=40%, RVF=41%)

4. Discussion

Fig. 4 and Fig. 5 show noticeable differences in the waveform which is evident from the calculated values of VV, VFI, EF, and RVF. However, the very distinctive region in the waveform is also the regular peak seen with each tip toe during repeated plantar flexion in a normal subject and random peaks in a patient. The random peaks with each tip toe may be due to the inability of the calf muscle to contract normally because of the pathological changes in the venous system of the lower extremities. This also means that there is an indirect effect of the deep veins which are entirely encased within the muscle and bone. Since the calf muscle (pump) is not capable of functioning normally, this would result in the pooling of blood as evident from the data (RVF > 35%) shown in Fig. 4. In the normal situation, when the calf muscle contracts, the pressure in the deep veins increases to nearly 250 mmHg allowing the ejection of blood to the heart uni-directionally [12]. This is possible since the ejection fraction of the calf muscle pump is 65 % as compared to thigh pump which is only 15 % [12]. In our study, the venous duplex was also performed on patients and it showed (i) increased superficial reflux, (ii) no deep venous reflux, (iii) no deep venous thrombosis and (iv) increased perforator reflux. The increased perforator reflux could possibly be attributed to valvular incompetence in the perforators. This would further result in increased superficial reflux due to retrograde flow from the perforators to the superficial veins when the pressure in the deep veins increases during muscle contraction (VFI = 4.6 ml/s, minor reflux) in one of the patient [11].

In summary, we demonstrated the assessment of venous hemodynamic by using the stretch sensors, which has not been reported in the literature. The belt can be used with great ease besides; it can provide continuous information about the dynamic movement or changes in limb circumference over time. This is desirable in a clinical setting that requires simple and fast means of assessment as well as meaningful information.

5. Conclusions

Commercially available air plethysmograph (APG) which is used as a standard tool for assessment of venous hemodynamic is very expensive for a low income and developing country like India. We have shown the possibility of measuring venous volume and therefore, assessment of venous hemodynamic by using arrays of the novel stretch sensors along the calf muscle. Although the result looks promising, more data collection is required for validating the novel device for its applications in clinical settings.

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