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Ambulatory sensor for the monitoring of the edema circumference in lower limbs

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ABSTRACT

The monitoring of geometrical variations in segments of the human body is currently not widely used due to the lack of suitable devices. For lower limbs, for example, a simple measuring tape is generally used to periodically measure key dimensions. This measurement approach, and the associated lack of reproducibility, is not compatible with ambulatory monitoring and it is further recognized that precise, standardized reference points are required for the more meaningful monitoring of the lower leg. The paper presents the design and realization of a new sensor system dedicated to the measurement of geometrical variations in the lower limbs, enabling the ambulatory monitoring of leg edemic swelling during daily activity. The sensor is based on an inductive loop directly integrated into a textile band and connected to a miniaturized electronic system which sends, via wireless transmission, the perimeter value of the leg (assuming that its shape is circular) to a laptop and in the near future, to a mobile phone. The inductive loop has been modeled using Matlab to predict the inductance value and determine the necessary parameters of the electronic circuit. The portable, ambulatory device enables the measurement of perimeters ranging from 25 cm to 33 cm, with an accuracy of 0.3 cm. Stability of the sensor over the time is very good (3.4% of the full scale). Hysteresis occurs when the textile is stretched between two extreme values which can be minimized by regular calibration of the system. The presented results are significantly better than those currently obtained using the traditional measuring tape.

1. Introduction

The monitoring of geometrical variations in the lower limbs of the human body, although of clinical interest, is not widely used due to the current lack of suitable tools. There is, however, an established need to monitor limb swelling due to edema caused mainly by Chronic Venous Insufficiency (CVI) or by lymphedema. Causes and therefore treatments differ, but it remains important to monitor the evolution of the edema to ensure appropriate management. CVI is a major health issue, the prevalence in lower limbs in western countries ranging between 25–40% in women and 10–20% in men [2]. In the early stages of CVI, the swelling first occurs in the ankles and lower legs. The size of the edema generally increases during the day and reduces at night during sleep, which is not the case for the more advanced stages of the disease. Medical compression stockings (MCS), recognized as an essential component in the treatment of chronic venous insufficiency, are often used to limit this diurnal swelling [12].

Several methods for assessing the swelling in the lower limbs exist based on leg circumference or volume measurements. The most popular device used to assess the extent of edema is the simple measuring tape. This method is prone to error and the value depends on the height at which the circumference is measured [15]. The variability in lower leg tape measurements among professionals has been recently studied by Rastel et al. [13]. Measurements were performed on a model of the leg and on basic cylinders. The authors reported that for the leg model, mean and standard deviation were 22 ± 0.60 cm for the ankle, 34.2 ± 0.78 cm for the calf and 40.9 ± 2.14 cm for the leg length measurements. They concluded that precise reference points for the lower leg length measurements are clearly required. An improved measuring tape device, termed the Leg-O-Meter, has been designed to measure ankle and/or calf

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perimeters [4]. The device comprises a measuring tape fixed to a base on which the subject stands. As the system is fixed, the tape is maintained at the same height and the subject in the same position, enabling standardized measurement. Berard et al. estimated the reliability coefficient for the technique at 97.09% for the right leg and 97.08% for the left leg. The Leg-O-Meter has been compared, for long term edema monitoring, with the clinical assessment of physicians and an accuracy of 84% was found when physician diagnosis was used as the "gold standard" [3]. For leg volume measurement, the water displacement volumetry is generally considered as the "gold standard". The method is simple and has been validated in terms of reproducibility but it is not convenient in clinical practice. Moreover, it is prone to certain errors (due to water surface tension or water temperature, for example). A more convenient method based on an optoelectric volumeter has been developed, termed the Perometer® [8]. This device, enabling rapid measurement, assesses limb volume using infrared light. It has been claimed that it provides more accurate results than traditional indirect measurement of limb volume [16]. Volume can also be indirectly estimated using limb circumferential measurement based on the "frustum sign" or "disk" model methods. These methods consist in considering the leg as a truncated cone or by modeling it as a series of disks, each of constant thickness. Kaulesar Sukul et al. reported that both water displacement volumetry and the disk model method were equivalent (r = +0.99, mean $\pm$ 2s = -45 ± 78 ml) which was not the case of the frustum sign model method [9]. The swelling of the limb has also been investigated with the capacitance plethysmography in which two electrodes are placed on either side of a limb segment. When swelling occurs, the measured capacitance between the two electrodes changes. Generally, capacitance plethysmography is used in conjunction with venous occlusion to measure the blood flow. For example, Norton et al. demonstrated that the measurement of flow using this method was linearly related to total limb blood flow [11]. Wood et al. designed a capacitance system for blood flow measurement based on venous occlusion plethysmography [17]. They found a linear relationship between capacitance change and volume increase over a specific range of volumes. However, venous occlusion plethysmography is not adapted for wearable monitoring as wearable technologies are generally based on comfortable and non-intrusive sensors, if they are to be accepted by the user for daily monitoring. Other techniques exist such as imaging techniques (e.g. magnetic resonance imaging, computed tomography) but these are expensive and obviously not suited for continuous and/or ambulatory monitoring.

All the above methods are not suitable for ambulatory applications and only a few ambulatory devices dedicated to the edema monitoring have been developed. For example, Zhang et al. presented an instrumented sock based on two magnetic sensors and an electromagnet [19]. Tests performed in-vitro demonstrated an accuracy of about 0.3 mm in perimeter measurements over the range 22 cm to 23.2 cm. Another wearable system has been developed by Yu et al. which comprises stretch sensors, based on dielectric electro-active polymer (DEAP), acting as variable capacitors [18]. When the sensors are stretched, their capacitance value changes due to the geometrical modifications. The authors demonstrated the validity of the measurement system and its ability to detect tiny changes in edema.

Most of the ambulatory devices dedicated to the measurement of volume variations in the human body are used on the trunk to monitor respiration rate. One such technique, proposed by Cohen [5] is termed Respiratory Inductive Plethysmography (RIP) as it is based on the inductance plethysmography principle in which the resonant frequency of an oscillator changes with respiratory volume. Two coils can be used, one placed around the rib cage and the other around the abdomen to assess the thoracic and abdominal volumes [20]. Reilly et al. have applied this method to realize a continuous ambulatory measurement of lower abdominal girth [14]. Data was stored over the day and was downloaded via a serial link to a PC. The frequency measurement was performed using to a microcontroller whose crystal clock operated at 4 MHz. As the inductance was placed around the rib cage, its length was sufficiently long (approx. 100 cm) to operate at relatively low frequencies which can be easily measured using the microcontroller. For the lower limbs, as perimeters are smaller, self-inductance values will be lower and consequently the resonant frequencies will be higher. In this latter case, inductance plethysmography requires specific electronics enabling accurate measurement of frequencies around 1 MHz.

Fig. 1. The conductive loop formed from the commercially-available elastic ribbon Condustretch closed at both extremities by sewing, before being shewn onto the stretchable textile band.

In this paper, an ambulatory device for the monitoring of the edema size variation based on the inductance plethysmography principle is presented. The inductive loop is directly integrated into a textile band and connected to a miniaturized electronic system which sends, via wireless transmission, the perimeter value of the edemic limb to a laptop. The variation in perimeter, which is an important consideration in edema monitoring, can be calculated in terms of the difference from the first measurement in the day performed after a simple calibration procedure. The design of the sensor will be presented below, the self-inductance of the inductive loop is calculated according to a recent computational method. The associated electronics, based on a programmable component, will be described. Tests have been performed on physical models of two different shapes (circular and elliptic) to evaluate the influence of shape on the response of the sensor and to determine the coefficients to be implemented in the programmable component for the direct calculation of the test perimeter.

2. Materials and methods

2.1. Instrumentation

The ambulatory device consists of two parts: (i) the sensor, an inductive coil attached to a textile support and (ii) the electronic part. The self-inductance variations are transformed into frequency differences using an oscillator. The programmable component then calculates the frequency and the corresponding perimeter and finally sends this value, via a Bluetooth Low Energy transmission, to a laptop. In a future embodiment, data will be sent to a mobile device.

2.1.1. The sensor

The sensor is formed from an insulated metallic wire (0.35 mm diameter) embedded in a narrow, commercially-available elastic ribbon (Condustretch 1CI-0.35, Tibtech, Roncq, FR). The wire is formed into a sinusoidal shape with a 7 mm spatial period and a 5 mm height, with an elasticity of 170% and an electrical resistivity 0.93 Ω/m. A complete, limb-encompassing loop is formed by sewing the two extremities of the ribbon together, the ribbon itself being shewn onto a stretchable textile band (Fig. 1). The perimeter of the resulting ribbon can vary from 16 cm to 36 cm, which is in agreement with reported physiological variations. A shielded cable, comprising two wires, ensures the connection between the loop and the electronic circuit.

Self-inductance calculation. The first step is to determine the self-inductance of the sinusoidal-shaped loop and to predict its