Smart-Cuff: A Wearable Bio-Sensing Platform with Activity-Sensitive Information Quality Assessment for Monitoring Ankle Edema

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***Abstract*—Leg swelling produced by retention of fluid in leg tissues is known as peripheral edema, which is regarded as a symptom for various systematic diseases such as heart or kidney failure. In current clinical practice, edema is manually assessed by clinical experts. Such an assessment can often be inaccurate and unreliable especially if it is made by different operators at different times. Despite the importance of monitoring edema for the purpose of evaluating the course of disease or the effect of treatment, quantifying peripheral edema in a continuous and accurate fashion has remained a challenge. In this paper, we propose a wearable real-time platform (namely, Smart-Cuff), which integrates advanced technologies in sensing, computation, and signal processing and machine learning for continuous and real-time edema monitoring in remote and in-home settings. Given that peripheral edema is highly dependent on various contextual attributes such as body posture, we present an activity-sensitive approach to discard erroneous or contextually invalid sensor data in order to meet the requirements of both energy efficiency and quality of information. Examination of our hardware prototype demonstrates the effectiveness of the proposed force-sensitive resistor-based edema sensor (with an R^2 of 0.97 for our regression model) as well as the activity monitoring mechanism (over 99% accuracy) that provide the means to perform reliable data sanity check on ankle circumference measurements in a continuous manner.**

I. Introduction

Peripheral edema is one of the primary symptoms of volume overload in the body due to onset or exacerbation of a variety of systemic diseases that could disturb cardiovascular, renal, or hepatic system [1]–[3]. It could also emerge as a side effect of many medications or as a symptom in venous, metabolic, and inflammatory diseases, chronic lymphedema, post-surgery, and pregnancy [1], [2], [4]. Edema secondary to lymphatic or venous diseases of lower limb usually presents as a chronic asymmetric swelling, whereas edema due to systemic diseases such as heart, liver, and renal failure develops symmetrically in both lower limbs [4]. Edema occurs when lymph formation exceeds lymphatic drainage in extra-cellular space [3], [5]. Hypoal-buminemia and increased intra-capillary hydrostatic pressure are considered as the main causes of increased lymph formation [6].

When conducting research in the area of peripheral edema monitoring, the main questions that arises is "where on the body can peripheral edema be monitored most effectively?" While it is feasible to measure peripheral edema from various lower-body locations, it appears that the medical community has reached a unanimity that ankle edema is the best representative of the peripheral edema. The practicability and dependability of eight different methods of peripheral edema measurement as well as their association with the classic clinical assessment of edema were investigated in [2]. It is concluded that ankle circumference measurement is an almost perfect inter-examiner and intra-examiner agreement in assessment of peripheral edema [2], [7]. Moreover, numerous past studies have confirmed the validity of lower limb edema estimation by means of circumference measurement [8]–[12]. In addition to easiness, circumference-based measurement of lower limb volume is a rapid way for edema changes assessment that could be used in substitute of water displacement method [13], [14] which is considered as the gold standard method for this purpose [15]. Therefore, in this paper our goal is to monitor ankle circumference as the most promising assessment in edema monitoring.

Monitoring lower limb edema in the clinic is usually straightforward and often subjective. In most cases, after the subject is stabilized in desired position for the preferred amount of time, a human operator uses simple tools and methods such as tape measure to carry out the task. Another method is to apply pressure on the skin with the tip of thumb.

Clinicians estimate the amount of ankle edema based on the amount of time it takes for the pitting to come back to its original level after finger is removed.

In spite of the importance of monitoring edema in many patients for evaluating the course of disease or the effect of treatment over time, quantifying peripheral edema accurately and continuously is still a challenge [2], [16]. To the best of our knowledge, the community is currently lacking a smart real-time edema monitoring system, able to fully meet the challenge of remote edema monitoring. In continuous monitoring, several contextual factors besides the actual disease of an individual becomes important. For example, distribution of peripheral edema is different in ambulatory versus sedentary patients. Lower limb edema formation is sensitive to change in type of activity as well as body posture of the person [17].

In this paper, we propose a multi-faceted platform which can effectually relate technological and clinical challenges of utilizing wearable bio-sensing technologies along with body posture/activity identification, validation algorithms and machine learning techniques for the purpose of continuous ankle edema monitoring. A self-calibrated, activity-aware edema measurement which can be used to provide patients or care givers with accurate feedback for timely intervention. With advancements in the field of bio-sensing and remote patient monitoring, it is important to take the benefit of potential technologies that provide continuous and remote edema monitoring.

II. Preliminaries

A. Motivation

Monitoring the extent of edema (ankle circumference) is essential as to evaluate the development of disease, effectiveness of therapy, and the degree of response to treatment. Quantification of the edema level could motivate patients to keep up following their treatment plan and working with their therapist to achieve the desired goals especially in situations where the treatment is burdensome for the patient or it happens quite gradually over a long period of time. Additionally, the ability to accurately and continuously measure and monitor the amount of peripheral edema in patients would help researchers to better understand the efficacy of therapeutic procedures or medications without interfering with patient's daily routines. Finally, quantification of the swelling relief could work as a ground truth for treatment plans that need to be financially supported by insurance companies.

As an example, heart failure is one of the causes of peripheral edema. Approximately, two-thirds of patients admitted to hospitals due to heart failure exacerbation show significant signs of volume overload such as lower limb edema [6]. Heart failure is the major cause of hospitalization and readmission in patients of +65 years of age in the United States [18] with approximately 25% rate of readmission in 30 days following discharge of which many may be preventable [19]. Each year, over 2.8 million physician office, hospital outpatient, and emergency department visits in addition to 1 million hospitalizations occur due to heart failure [18].

TABLE I
Lower Limb Edema Formation in Different Conditions [23], [24]

Body Condition	**Edema level**
After 30 minutes of standing	Increase
Spine to sitting	None
After 20 minutes of sitting	Increase
After 20 minutes of lying	Decrease
After 40 minutes of standing	Increase
After 30 seconds of lowering leg in a sitting position	Increase

Continuous monitoring can effectively reduce the number of unnecessary visits and potentially prevent readmissions by assisting physicians for timely intervention which saves both the families and the healthcare system a huge amount of cost.

B. Related Work

In this section, we briefly review some of the previous studies that have been carried out on development of quantification technologies for peripheral edema. These technologies can be generally classified based on their built-in sensor or variable they attempt to measure. We will also discuss the dynamic nature of lower limb edema based on the existing literature. We note that the dynamic nature of changes in ankle edema makes continuous monitoring of lower limb edema challenging and warrants for development of technological approaches for information aquality assessment and assurance.

Kawano et al. developed a volume measurement device called sensoring wire for edema of lower leg (SWELL) for workers during the standing work tasks. In this device, a flexible wire, flat spring, coil spring and a strain gauge are deployed. The wire is wound around the lower leg to measure the extent of swelling [20]. Gause et al. worked on an extensometer for measuring surface area changes of the human body. This structure includes a wide and thin responsive conductive elastomeric band which can be adapted to different parts of the body [21]. Anderson has developed a cable extension transducer device for measurement of body parts circumference. The transducer includes a cable extension that is attached to a rotary shaft and a precision potentiometer. The amount of cable extension is transduced to a resistance value that is used to calculate the length value [22]. These devices, however, do not provide any remote connectivity. It is also not built for continuous monitoring purposes. Furthermore, the main application area is for use in workplaces rather than medial purposes. These systems also do not involve any intelligent data analysis and algorithmic data processing capabilities.

C. Context-Sensitive Edema Monitoring

Evening edema of the lower limbs occurs physiologically after sitting and standing. In healthy individuals this edema is commonly asymptomatic and disappears during night sleep [25]. In one study, the volume of the dominant leg of 60 normal subjects was taken before and after 30 minutes of standing, sitting or supine lying motionless for 30 minutes. The results

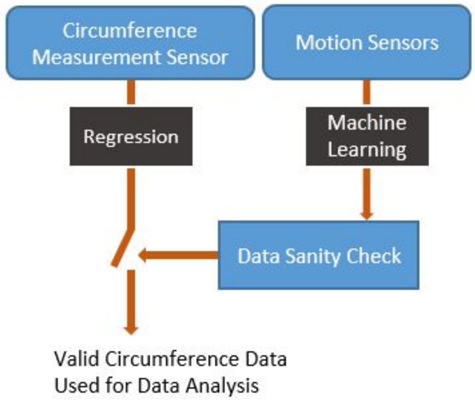


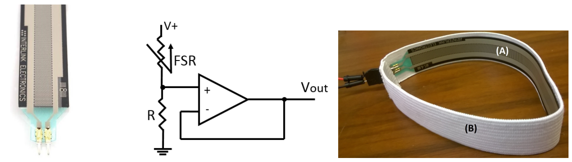
Fig. 1. High level description of Smart-Cuff

showed that a considerable increase in lower limb volume was found in subjects after 30 minutes of still standing. Standing posture led to the maximum increase in foot and ankle volume followed by sitting and then supine lying [24]. Table I shows the lower limb edema formation in different conditions. Based on clinical literature, the lower limb volume change is strongly associated with body posture. For example, in a case study on twenty one healthy subjects over 18 years of age the lower limb volume significantly increased during a period of 30 minutes of standing motionless. Therefore, measurement should be interpreted based on the body posture of patient during the day. This requires a reliable body posture/activity detection system along with the edema measurement device.

III. System Overview

We propose an activity-aware edema monitoring platform composed of two wearable sensors and related software algorithms. Such a platform, is responsible for providing valid data regarding ankle circumference (or peripheral edema in general). While one sensor is in charge of providing measurements on ankle circumference, the system is accompanied by wearable motion sensors for activity/body posture monitoring in order to gather data regarding context in which the ankle circumference data is being collected.

Unlike most of available technologies and devices that measure the ankle edema without considering the validity of this measurement, Smart-Cuff is complemented with a data sanity check algorithm to overcome this shortcoming. Fig. 1 illustrates the high level description of the proposed platform. Smart-Cuff is equipped with two types of sensors: circumference measurement sensor and motion sensors. Circumference measurement sensor readings are fed to a regression model to provide the correlated ankle circumference data. Readings from motion sensors are fed to a machine learning algorithm that outputs the subject's activity/body posture. Data sanity check utilizes these outputs to validate the readings of circumference measurement sensor. Such validation is accomplished based on medical literature (i.e., Table I) and possible noise in ankle circumference measurements.



(a) FSR (b) Conversion Circuit (c) Circumference Cuff

Fig. 2. Circumferential sensor cuff including Long force sensitive resistor (FSR), elastic cuff, and coversion circuit

IV. System Components and Data Processing

A. Sensing Hardware

Our wearable device consists of two sensor types, a processing unit, and a transmission module. The ankle circumference sensor along with the other parts need to be wearable, low-cost, energy efficient, and robust enough to allow for continuous monitoring and large scale deployment. A prototype of our proposed hardware is built for the test and proof of functionality. The hardware consists of three components: 1) Circumferential Sensor Cuff; 2) Inertial Sensor; and 3) Data Collection/Transmission as described in the following.

1) Circumferential Sensor: Fig. 2 shows the hardware prototype and its components for measuring ankle circumference. The circumferential sensor cuff utilizes a long force sensitive resistor (FSR), shown in Fig. 2a, which wraps inside an elastic band and covers 50% of the band. As illustrated in Fig. 2c, the wearable cuff consists of two areas as follows. Area (A) is non-elastic and covered by the force sensitive resistor. Area (B) is merely made of elastic materials that allow the cuff to be flexibile with circumference changes. FSR is attached to a Force-to-voltage conversion circuit, shown in Fig. 2b. Resistor R is selected to maximize the desired force sensitivity range and to limit the current through the force sensitive resistor. We also use an LM358 op-amp. The low bias current of LM358 reduces error due to the source appendance of the voltage divider. The output of FSR divider is given by (1):

$$V_{out} = \frac{V+}{[1 + (\frac{R_{FSR}}{R})]} \quad (1)$$

2) Inertial Sensor: To measure physical activity/posture, we use a 9DOF inertial measurement unit (IMU). The motion sensor device consists of three sensors: a triple-axis gyroscope, a triple-axis accelerometer, and a triple-axis magnetometer. These sensors are initially used for hardware prototyping to study requirements of an activity-sensitive edema monitoring device. In our experimental validation, we also investigate which subset of these sensors will be sufficient to accurately detect activities/postures that are needed for our edema monitoring application.

3) Processing/Transmission Module: Outputs of all sensors including force sensitive resistor and motion sensors are processed using an on-board ATmega328 and sent wirelessly to a smartphone using a Bluetooth mate. Force sensor output is converted to digital output using the ADC on ATmega328.

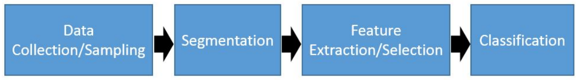


Fig. 3. An overview of activity recognition process

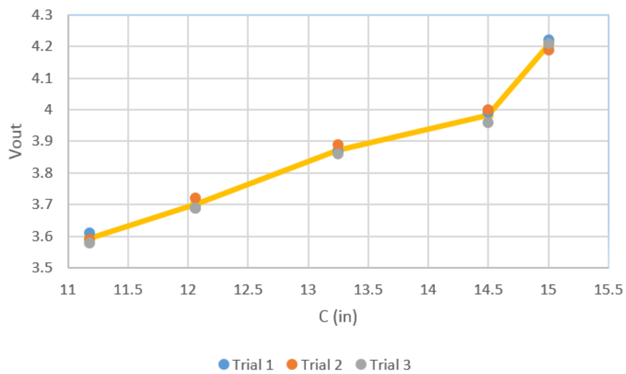


Fig. 4. Force-to-voltage circuit output of different subjects.

B. Data Processing

Our data analysis consists of a regression model that transforms sensor readings generated by circumferential sensor into ankle circumference measurements, and an activity classification algorithm that detect context of the user upon which a valid ankle circumference measurement in determined. The linear regression model is given by

$$C \; = \alpha V_{out} + \beta \tag{2}$$

where C denote the ankle circumference and α and β are coefficients of the model.

Fig. 3 illustrates a high level description of our activity recognition. Motion sensors are first sampled at 100 Hz. A set of statistical features are extracted from a sliding window and used to train an activity classifier using standard machine learning algorithms. Upon occurrence of a valid activity/posture indicating formation of lower limb edema, the data sanity check issues a 'valid' signal indicating that the current circumferential measurement is valid for transmission to a back-end server and for clinical interventions.

V. Experimental Model and Results

In this section, we first elaborate on our experimental protocol and obtained results for circumference measurement cuff and then discuss the same route for activity/body posture identification.

A. Circumference Measurement

In this experiment, we show the correlation between the change in ankle circumference and the output of our circumference measurement unit and extracted regression model. Five human subjects with weights between 136 and 241 pounds have been asked to wear the device. Our data collection have been reviewed and approved by Washington State University

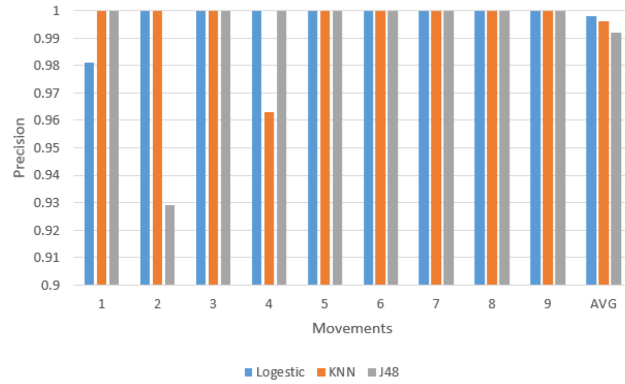


Fig. 5. Precision of activity recognition

(WSU) Institutional Review Board (IRB) before these experiments are conducted. Fig. 4 exhibits the relation between the FSR divider output (Vout) and subject's ankle circumference (C). In order to further demonstrate the reliability of our circumference measurement device, we repeated the experiment 3 times and the results remained consistent. This observation suggests that the proposed device is capable of reproducing the same voltage in different trials. The minor difference in each trial can be explained by human errors. Eq. (3) is the linear regression model extracted from the data collected in first trial. Regression model achieved and R^2 value of 0.97.

$$C \; = 6.4061 V_{out} - 11.6322 \tag{3}$$

B. Activity/Posture Identification

In this experiment, five human subjects were asked to perform different activity/postures in a natural setting for 50 seconds wearing 5 9DOF IMUs on the left ankle, right ankle, left wrist, right wrist, and waist. These activity/postures include lying against the left side (1), lying against the right side (2), prone (3), sitting on a chair (4), sitting on a chair with legs up (5), sitting on the ground (6), standing (7), supine (8) and walking (9). Readings were transmitted to a Galaxy S4 phone paired to the IMUs worn by each subject and then stored in the phone's memory using a basic Android application we built. This application is capable of pairing and collecting IMU readings simultaneously. Note that using 5 nodes for activity/posture detection is an exhaustive approach (especially when activities are not very detailed and similar to each other). However by performing feature selection on the collected data, we try to optimize the setting by reducing the number of nodes and utilized sensors to simplify the hardware aspect of our system while maintaining the high quality.

Sensor readings have been captured at 100Hz sampling frequency and segmented into windows of 300 samples with 0.8 data overlap between successive segments. In feature extraction part, we extracted a set of statistical features (amplitude of signal segment, median of signal, mean value of signal, maximum value of signal, minimum value of signal, peak to peak amplitude, standard deviation, variance, root mean

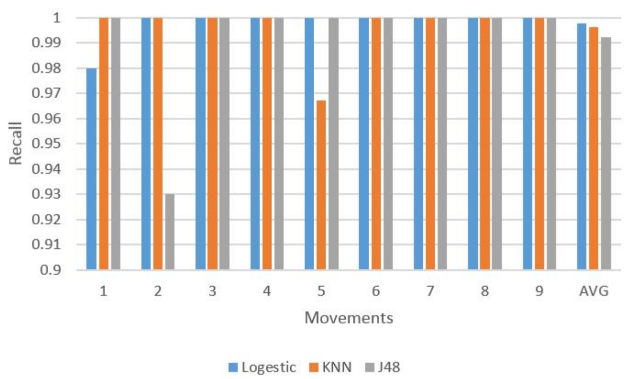


Fig. 6. Recall of activity recognition

TABLE II
AVG. PRECISION FOR 9 MOVEMENTS USING 5 NODES VS L-A VS L-A MGT

[nodes,sensors]	[all,all]	[L-A,all]	[L-A,Magnetometer]
Avg. Precision	0.998	0.996	0.992
Avg. Recall	0.997	0.994	0.990

square power, and start to end value) that has been shown to be very effective in activity recognition [26]. Extracted features were, then, fed into various classifiers where 66% of samples are training data and the remaining 34% are test data. Fig. 5 and Fig. 6, respectively, show the activity/body posture precision and recall accuracy with five nodes based on different classification algorithms. As you can see, logistic regression yields the highest outcome.

Therefore, we use logistic regression for further node/feature selection analysis. Table II illustrates the average accuracy of five nodes versus left ankle node versus the magnetometer embedded in left ankle IMU. The results show that for this level of motion detection, a single magnetometer is able to satisfyingly provide our proposed edema monitoring framework with activity/posture information.

VI. Future Direction

Recent advancements in wireless technology, development of sensitive sensors, and evolution of sophisticated machine learning algorithms has made it possible to design a state-of-the-art technology that could remotely monitor peripheral edema. This in association with remote monitoring of other biometrics such as weight, heart rate, and blood pressure provides more tools to today's health care system endeavor to keep patients out of hospital. However, in terms of hardware architecture and algorithms there are still some challenges that need to be perfectly addressed. The proposed prototype is still in its early stages. Building a fully wearable Smart-Cuff using e-textile technology can be considered as a future work. We can utilize the output data for conducting post data analysis. Such analysis aims to find trends in calibrated data and provide both patients and therapists with insights such as patient's severity of condition (namely, edema index). These outputs could be remotely shared in a real-time fashion with health care providers so that they can promptly provide advice or intervene if needed to prevent consequences of disease exacerbation. Those algorithms include the front end sensing which allows for data gathering, sensor calibration and back-end data processing algorithm.

Front End Sensing Algorithms: our system requires a number of basic algorithms to efficiently handle tasks such as data collection (sampling, storing) and data transmission. The front end sensing algorithms aim to maximize data collection/transmission efficiency.

Calibration Algorithm: a calibration algorithm is needed to map the ankle circumference measures into a calibrated value based on inertial readings from other sensors and overlook the possible noise in edema measurement sensor. It should result in more consistency and accuracy in measurement.

Back End Data Analysis Algorithm: the purpose of such analysis is (a) to find correlation between ankle circumference measurement and physical attributes of the patient (contextual readings) (b) to find patterns in data that could lead to medical problems and (c) to provide the physician with an edema index (which indicates the severity of patient's condition) in a continuous fashion. We refer to this approach as back end data analysis. Back end data analysis can be potentially addressed by machine learning and artificial intelligence techniques such as pattern recognition and classification algorithms. Contextual information such as amount of physical activities could be used to infer the patient's level of fatigue over time. The ankle circumference measure and activity/body posture history could be provided for the pattern recognition algorithm. Whereas inputs of the classifier could be statistical features of data extracted from motion sensor(s) (In Section V, we demonstrated that one sensor is sufficient for the desired task). Edema index could be calibrated with level of patient's daily activity where a higher level of activity (meaning those activities which add to edema volume) would result in a higher edema index threshold.

VII. Conclusion

In this article, we proposed a real-time and context aware edema measurement platform. We built a prototype for a Smart-Cuff, able to (1)continuously monitor the ankle circumference changes in edema patients and (2)validate the output with data sanity check to remove the medically invalid or noisy output. As mentioned, peripheral edema is one of early signs for various medical diseases. Some of such diseases are in fact deadly conditions that often result in frequent hospitalizations which costs huge amounts for both patients and the healthcare-system. The proposed Smart-Cuff enables the caregivers to continuously and remotely monitor the edema level in patients without any manual intervention. The experimental results indicate that firstly, Smart-Cuff is able to sense the circumferential change in a very acceptable level (with an R^2 of 0.97 for our regression model) and secondly, the IMU employed in this prototype is able to almost fully identify the different activity/postures (even with utilizing only the magnetometer embedded in the IMU, we have achieved over 99% accuracy) which are of importance for the sanity check purposes. This is an integral step that takes the edema monitoring to a whole new level and finally fulfills the need for a cost-effective, accurate, real-time and most importantly context aware system which provides both patients and caregivers with high quality assessment.

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