Remote Monitoring and Early Detection of Chronic Ulcers

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Abstract

Chronic wounds or ulcers are wounds that do not cure in the usual manner. This type of wound is most common in the old age group and in paralysis patients with an estimated 1% of the population suffering from leg ulcers. There is need to develop a device capable of remote wound monitoring that enables patients to take charge of their wound management under clinical guidance. A new wound mapping device has been developed, which is based on electrical impedance spectroscopy and involves the multi frequency characterization of the electrical properties of wound tissue under an electrode array. The main feature of the prototype device is the expected facility of the measuring array into standard commercial closed dressings and thereby protecting the wound from interference and contamination. Hence promoting wound healing, while monitoring the protected wound. Foot ulcers account for increasing risk associated with diabetes. No device continuously monitors the status of foot ulcers when patients are not hospitalized. A temperature sensor and a pH sensor are capable of monitoring diabetic foot. With the variations in the electrical resistance of a nanocomposite consisting of multiwalled carbon nanotubes and poly (styrene-b- (ethylene-co-butylene) -b- styrene) temperature is measured. The pH sensor used here is a graphene oxide (GO) layer that changes its electrical potential when the pH changes. The temperature sensor has a sensitivity of ~85 Ω/°C in the range 25°C–50°C and a high repeatability. Thus with the utility of these sensors it is highly possible for early detection of chronic ulcers.

Keywords - *Chronic ulcers, impedance spectroscopy, remote wound monitoring, Pressure Ulcers, wound temperature, wound pH.*

I. INTRODUCTION

Diabetes is one of the most common diseases and its occurrence rate is rapidly increasing. There are few million people worldwide with diabetes and this number is expected to grow up in 2040, with an estimated 55% increase in 25 years. The spreading of diabetes is unfixed in population. In the various countries, it mostly affects people in the age group of 50 years. It is also widespread among young people in middle-income countries. In 2018, Nearly 5 million people have diabetes, mostly related to the comorbidities of the disease and its complications. Among the chronic complications of diabetes, the diabetic foot (DF), a chronic ulcer condition is the most widely spread and severe because it affects 25% of patients at least once in their life with a survival expectation less than cancer. DF ulcers are correlated to several risk factors such as foot deformity, neuropathy (86% of cases), peripheral arterial disease (49% of cases) and minor foot trauma. DF is the major cause of lower extreme cutting of affected body part with a risk 20-fold higher than that of the general population and a limb amputated every 30 seconds. The healing rate of DF ulcers is defined as the rate of ulcers completely re-epithelized, stable for at least 2 weeks varies according to their pathogenesis, whereas the incidence is, depending on the reference population, 3%–5% for major amputations and 5%–40% for minor amputations. Infection in DF ulcers is a major risk factor leading to amputation, and for this reason, the monitoring of the foot ulcers status may be of a great importance to ensure the effectiveness of therapies and the safety of patients. Smart wearable autonomous negative pressure device for wound monitoring and therapy is a large-scale integrating European project seventh framework program that tackles the challenge of developing wearable devices and sensors to monitor and manage foot and venous ulcers. The objective is to deliver a personalized therapy to patients whose ulcer status is remotely monitored so that a prompt action can be put in place in case of infection. The patient need not be hospitalized and can continue their normal life while a set of wearable sensors transmits the ulcer condition to a database accessible by clinicians. There are various sensors for monitoring parameters such as water loss through the epidermis of the perilesional skin, glucose, body temperature, skin and ulcer temperature, SpO_2, levels of matrix metallo proteinases and bacteria, and the pH of the ulcer. There is a general consensus that there is a strong relationship between the ulcer temperature and the degradation of the ulcer status. In fact, an increase in the basal temperature can be a warning of the ulcer onset even 1 week before it starts. Besides temperature, an increase of pH at the wound can also be a sign of infection as it is related to the presence of bacteria that proliferate in the ulcer.

The pressure causes a loss of blood flow to the tissue resulting in necrosis, and subsequent infection is a major concern. The combination of pressure, time and is chaemia reperfusion cycles that results in a pressure ulcer varies widely between patients1–4, making them difficult to predict. Damage can occur from an ischaemic event as short as 2 h2–4, and the initial stages of damage are not easily detectable with the naked eye. By the time a surface wound is visible, the underlying tissue damage is often severe. Prevention of pressure ulcers currently relies on labor intensive vigilance in nursing care. Patients are manually turned nearly every hour to relieve pressure, and high-risk areas are visually inspected for pressure ulcers. Pressure-sensitive devices can alert nursing staff when a threshold of pressure is exceeded. Using impedance spectroscopy across flexible electrode arrays in vivo on a rat model, we find that the frequency spectra of impedance measurements are correlated in a robust way with the state of the underlying tissue across multiple animals and wound types. Flexible and stretchable electronics for bio-monitoring applications is currently an area of intense research focus. The results demonstrate the feasibility of an automated, non-invasive 'smart bandage' for early diagnosis of pressure ulcers, improving patient care and outcomes.

II PROBLEM DESCRIPTION

In order to characterize the success of a given wound treatment,the most commonly measured wound-related parameters are wound volume, wound area, maximal wound depth, width of the wound margin (the layer between the wound and healthy tissue), and type of tissue affected. It is critically important to accurately and precisely determine and document the size of a wound and the progress (or otherwise) of its healing in order to chose/develop the most effective treatment. Wound surface area is commonly determined using a range of differing techniques, which involve removing the dressing and either:

a) fine-tipped pen is used for tracing the wound on transparency film and is analyzed by counting traced squares manually or by digital means using planimeter or digitizer

b) Using a scaled photograph of the wound.

Both these categories of techniques are found to be relatively reliable as long as they are performed and analyzed by the same investigator, the trend is more important than the exact wound area. The techniques fail, however, if a multicenter trial is performed as it is not always possible to use the same investigator, and hence, ensure the same systematic errors. Unfortunately, given the general awkwardness of the position of chronic wounds, it is generally not possible for the patient to perform the measurement him/herself, though it could be performed in some cases by a family member.

In wound management there is no technique available readily that could be handled by the patient or his family. The professional clinician is required to identify the progress of wound healing and to decide on any further treatment based on the wound characterization. No technique is available that could perform/enable this characterization without the removal of the wound dressing, which can lead to disturbance of the wound healing processes and to increased risk of contamination.

III. METHODOLOGY

In order to measure ulcers and other wounds conveniently and effectively, a non disruptive 3-D technique is required, preferably operated by means of a small handheld device, which can be used with little training, or more optimally, remotely/automatically operated, and viewed by a clinician. One technique which could potentially provide non disruptive 3-D measurements is electrical impedance spectroscopy (EIS). It is based on the measurement of the tissue impedance and could enable the investigator to not only measure wound area and depth but also to precisely assess the wound brink, and after some calibration measurements, establish the type of tissue present, all without removing the dressing, and thus, avoiding interfering with wound healing.

Electrical (bio-) impedance spectroscopy involves the characterization and analysis of electrical properties of tissue over a range of frequencies and has been used by the authors to characterize and map wounds.

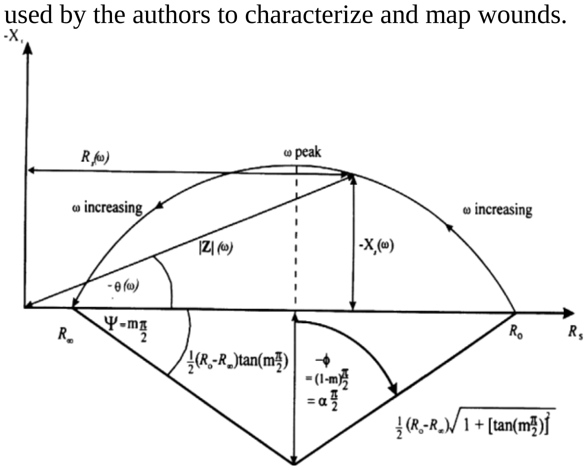

Fig 1. Typical impedance locus

Infection in DF ulcers is a major risk factor leading to amputation, and for this reason, the monitoring of the foot ulcers' status may be of a great importance to ensure the effectiveness of therapies and the safety of patients.

The objective is to provide a personalized therapy to patients whose ulcer status has been remotely monitored so that a appropriate action can be taken in case if infection was identified. For continuous monitoring of status of ulcers the patient need not be hospitalized and can continue their normal life by implanting a set of wearable sensors for transmitting the ulcer condition to a database which can be accessible by clinicians. Transepidermal water loss of the perilesional skin, glucose, body temperature, skin/ulcer temperature, SpO_2, levels of matrix metalloproteinases and the pH of the ulcer are monitored by usage of sensors placed in patient. In general agreement there is a strong relationship between the ulcer temperature and the degradation of the ulcer status.

A temperature-sensitive nanocomposite material was prepared for monitoring the temperature. It consists of multiwalled carbon nanotubes and is dispersed in toluene within an insulating phase of a thermoplastic elastomer. Here due to the temperature variations there is a change in electrical resistance. A digital multimeter was used for log resistance values and a thermostatic bath as a reference temperature. A volume equal to 10 μL of the dispersion was drop casted onto a pair of gold electrodes (length of 7 mm) and let dry at room temperature to obtain a film. The electrodes were fabricated onto a Kapton substrate (thickness of 50 μm; CAD Line, Pisa, Italy). Copper tracks were obtained by photolithography and electroplated with nickel and gold to fabricate the electrodes (thickness of copper 35 μm, nickel 3.0 μm, and gold 1.2 μm). The nanocomposite film was used and is annealed at a temperature of 145°C for the duration of 4 hours. This kind of treatment may decrease the sensitivity but will improve the stability.

Graphene oxide was used to measure pH because of the property of the material which changes its potential when the pH changes while placed in water solution. Figure 2 shows the temperature sensor.

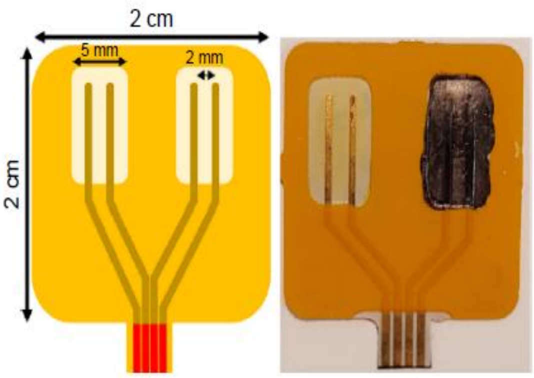

Fig2.Temperature Sensor

A GO layer coated the working electrode (WE) of a screen printed-board. The board has gold counter electrode (CE) and Working Electrode (diameter 4 mm) and the reference electrode (RE) which consists of Ag/AgCl. The electrical contacts are in silver. The pH was measured by the change of the open circuit potential between the working electrode and the reference electrode .Five microliters of a Graphene oxide is dispersed in water and was deposited onto the Working Electrode and let dry at room temperature. The pH sensor was compared with a commercial pH meter and different pH values were obtained by adding NaOH and HCl solutions.

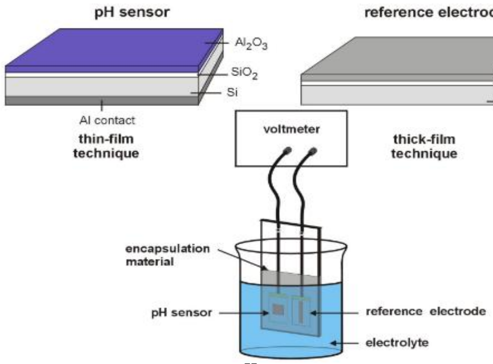

Fig3.P^H measurement

Fig 3 represents P^H measurement .When pressure is applied to a localized area of the body for an extended time, the resulting loss of blood flow and subsequent reperfusion to the tissue causes cell death and a pressure ulcer develops. Preventing pressure ulcers is challenging because the combination of pressure and time that results in tissue damage varies widely between patients and the underlying damage is often severe by the time a surface wound becomes visible. Presently, there is no method to detect early tissue damage and enable intervention. A flexible, electronic device that non-invasively maps pressure-induced tissue damage, even when such damage cannot be visually observed. Using impedance spectroscopy across flexible electrode arrays in vivo on a rat model, the impedance is robustly correlated with tissue health across multiple animals and wound types. The results demonstrate the feasibility of an automated, non-invasive smart bandage for early detection of pressure ulcers.

IV. SYSTEM DESIGN

The device hardware is illustrated with a DSP controlling the measurement application and multiplexers switching the measurement signal across the electrode array. Fig 4.shows the overview of ulcer mapping system. The device is battery powered to ensure patient safety. During initial trial the discrete frequencies between 11 and 935 Hz were chosen. The choice of frequencies involves a tradeoff between measurement time and amount of information. For the multi electrode array, the more values of lower frequencies are used in the measurement for the longer total measurement time. The current setup of ten different frequencies allows for measurements in less than 30 s at 25 distinct positions over the wound, providing enough information to apply data interpretation modeling as described earlier. The measurement current is achieved by a voltage-controlled current source and is chosen to restrict the output current to a safe limit, i.e., 10 μA (rms). The output signal from the voltage controlled current source is then switched to the electrode array through a bank of multiplexers. An instrumentation amplifier is used to measure individually the voltage between each electrode under test (*V*TEST) and the reference electrode (*V*REF). The output signal from the instrumentation amplifier is sent into an amplifier/filter stage for further conditioning. The gain of the instrumentation amplifier needs to be variable, since the skin impedance measurements are frequency dependent, however, good signal strength is required for the A/D conversion. A current-to-voltage converter is used to convert the applied current through the electrode-skin impedance into a voltage to be measured. Again, this voltage is later amplified by a second stage to ensure that good use is made of the A/D's range (±5 V). The amplifier/filter circuitry is used to condition the signals (voltage and current), to amplify the input signals so as to make good use of the A/D's range (±5 V) and also to reduce aliasing errors from out-of-band noise and interference, i.e., anti aliasing filter. Custom-designed software has been programmed to facilitate communication between the device and the computer. It enables the clinician to add patient data, take an impedance reading, and display the information about wound size and wound healing statistics. In these trials, the device is only being used in the three electrode setup with a fixed reference electrode. This supplies "instant" information on wound size and severity. In order to gain information about the wound volume a four electrode technique will be utilized, where, after a quick scan against a defined reference electrode, the device can determine, which electrodes are on healthy and which on wounded tissue. The appropriate electrode combinations can then be chosen automatically, providing information on the depth of the wound as well as the type of tissue present.Clinicians involved in the treatment of chronic as well as acute wounds have shown an interest in this tool, not only for wound monitoring but also as an objective outcome measure in clinical trials investigating wound healing products and techniques. It could be used in the objective assessment of new dressing types or alternative techniques, such as electrical stimulation, laser, or vacuum therapy, which claim to enhance the healing process.

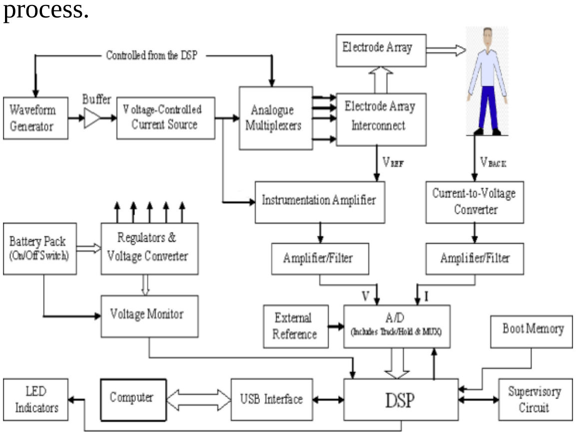

Fig 4.Overview of ulcer mapping system

V. RESULT and CONCLUSION

Multiplexed electrode array maps tissue impedance: We have designed and implemented an electronic sensing device that measures spatially correlated complex impedance in vivo using a multiplexed electrode array. The device consists of an electrode array to contact the skin and control hardware that performs impedance spectroscopy across the array. The following two versions of the electrode array were developed: (1) a commercial rigid printed circuit board with gold-plated electrodes, and (2) a flexible bandage-like array produced using inkjet printing on a plastic substrate. The rigid device was a robust calibration platform that allowed us to develop the method of detecting pressure ulcers using impedance spectroscopy while, in parallel, developing the flexible device to use that method in vivo.

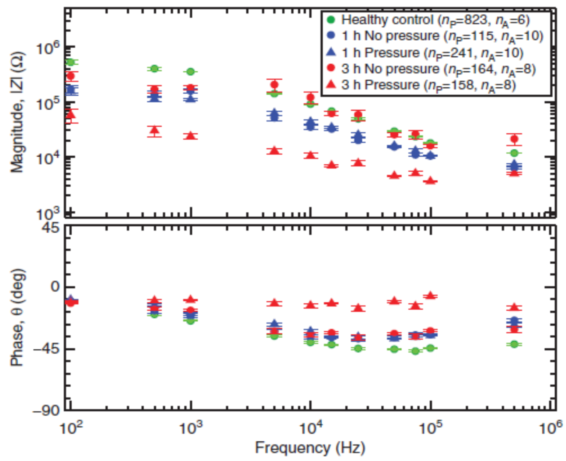

Fig 5 Average impedance using rigid array

In addition to the detection of pressure ulcers, we have also demonstrated that our device can track the state of open skin wounds (Supplementary Information and Supplementary Fig. 4). Our measurements confirm that we can identify not only the size and shape of an excision by determining the border of the wound but we can also differentiate between a moist wound (exposed wound bed, potentially pus and so on) and a healing, scab-covered wound. With a slight change in instrumentation, the same device can also be used to measure voltage at each electrode with respect to a common reference, creating a map of the voltage and endogenous electric field across the wound. It is well known that cells can be directed to migrate with an applied electric field, and there is evidence, although somewhat controversial, that applying an electric field may assist in the healing process. The device demonstrated here provides the capability to test the extension of these theories from cells to complex tissues in vivo. Thus, it could be adapted to sense the endogenous field, apply an external field and monitor the response of the tissue to the stimulus, providing much-needed evidence regarding the efficacy of electrical stimulation for healing chronic wounds.

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