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Invited Paper

Tissue Viability Monitoring - A Multi-Sensor Wearable Platform Approach

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ABSTRACT

Health services worldwide are seeking ways to improve patient care for amputees suffering from diabetes, and at the same time reduce costs. The monitoring of residual limb temperature, interface pressure and gait can be a useful indicator of tissue viability in lower limb amputees especially to predict the occurrence of pressure ulcers. This is further exacerbated by elevated temperatures and humid micro environment within the prosthesis which encourages the growth of bacteria and skin breakdown. Wearable systems for prosthetic users have to be designed such that the sensors are minimally obtrusive and reliable enough to faithfully record movement and physiological signals. A mobile sensor platform has been developed for use with the lower limb prosthetic users. This system uses an Arduino board that includes sensors for temperature, gait, orientation and pressure measurements. The platform transmits sensor data to a central health authority database server infrastructure through the Bluetooth protocol at a suitable sampling rate. The data-sets recorded using these systems are then processed using machine learning algorithms to extract clinically relevant information from the data. Where a sensor threshold is reached a warning signal can be sent wirelessly together with the relevant data to the patient and appropriate medical personnel. This knowledge is also useful in establishing biomarkers related to a possible deterioration in a patient's health or for assessing the impact of clinical interventions.

Keywords: e-health, elastomer, lower limb prosthetics, rehabilitation, sensors, tissue health, wearable sensor platform

1. INTRODUCTION

The use of a well-fitting prosthesis by a health impaired or even an otherwise healthy person with a lower limb amputation can cause the development of serious tissue injuries such as pressure ulcers (decubitus ulcers, also called pressure sores) if not regularly monitored by the amputee and relevant health authority. Injuries can start deep inside the residual limb near the bone (deep tissue injury) and/or at the surface of the skin and can affect all types of tissue including the bone[1]. Of particular concern is deep tissue injury (DTI) where the ulcer becomes apparent only when it reaches the surface of the skin and severe injury has therefore already occurred. DTI is caused when the volume of tissue in the residual limb reduces resulting in downward bone movement i.e. pistoning. The downward movement of the residual limb bone may lead to boundary shear at the bone/tissue interface which may result in deep tissue injury (DTI) and the formation of ulcers that progress from the bone to the skin. Specifically, this type of injury may be caused by restricted perfusion (pressure induced ischaemia) and physical trauma caused by mechanical overload of the deep tissues[2]. In addition, shear and normal forces on the skin can result in surface pressure ulcers caused by constriction of blood flow resulting in reduced perfusion and ultimately tissue necrosis. Pressure ulcers at the skin surface can progress from the skin surface down to the bone and are apparent by the breakdown of the skin[3]. This is further exacerbated by elevated temperatures and humid micro environment within the prosthesis which encourages the growth of bacteria and skin breakdown.

Infection will accelerate the progression of ulcers and in extreme cases ulcers can be life threatening. Long term hospital admission is often necessary which is both disruptive for the patient and costly to the health authority. In addition, diabetics are at increased risk due to the additional medical complications of compromised circulation, a deficit in feeling sensation at the extremities and increased risk of infection and morbidity due to infection[4]. Diabetic patients may therefore develop a pressure ulcer sooner, suffer faster progression of the ulcer and be less likely to feel the characteristic symptoms of tissue injury, such as inflammation, than a patient considered to be healthy. It would therefore be of great

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benefit to prosthetic users and diabetics in general, and in particular lower limb diabetics, to be able to detect either the early signs of actual tissue injury before the development of serious complications; and/or monitor the conditions at the prosthetic socket/residual limb interface to give a warning of a significant increase in the risk of injury before it develops. A reliable continuous monitoring and early warning system that can alert both the user and health authority would reduce admissions to hospital; reduce the associated costs; improve patient quality of life and perhaps allow a significant reduction in the frequency of outpatient check-up appointments. In addition, the information provided by a monitoring system on areas prone to damage could contribute toward improving prosthesis design.

Herein we describe a mobile sensor platform that has been developed for use with lower limb prosthetic users. This system uses an Arduino board that encompasses sensors for temperature, gait, orientation and pressure measurements. This monitoring system is designed such that it unobtrusively gathers data from multiple wearable sensors and transfers this information periodically to a central health authority database server via a wireless transfer protocol. The wearable multi-sensor platform is coupled with an Android smartphone for the user to check his monitored levels and also receive warning signals from medical personnel if a critical threshold level is reached. Additional features like battery monitoring unit have also been inbuilt into the platform for reducing power failures and thus losing patient data. Hence, this platform is portable, wearable, comfortable, secure, robust and, most critically, reliable in the measurement, logging and communication of data. This continuous monitoring system presents a novel approach to injury prevention as it would be useful to provide early warning of tissue injury

2. ARCHITECTURAL OVERVIEW OF THE WEARABLE PLATFORM

The design of the wearable sensor platform has to be such that it can unobtrusively gather data from multiple wearable sensors and transfers this information periodically to a central health authority database server via a wireless transfer protocol. It would therefore be of great benefit to prosthetic users and diabetics in general, and in particular lower limb diabetics, to be able to detect either the early signs of actual tissue injury before the development of serious complications; and/or monitor the conditions at the prosthetic socket/residual limb interface to give a warning of a significant increase in the risk of injury before it develops. A reliable continuous monitoring and early warning system that can alert both the user and health authority would reduce admissions to hospital; reduce the associated costs; improve patient quality of life and perhaps allow a significant reduction in the frequency of outpatient check-up appointments[5]. In addition, the information provided by a monitoring system on areas prone to damage could contribute toward improving prosthesis design.

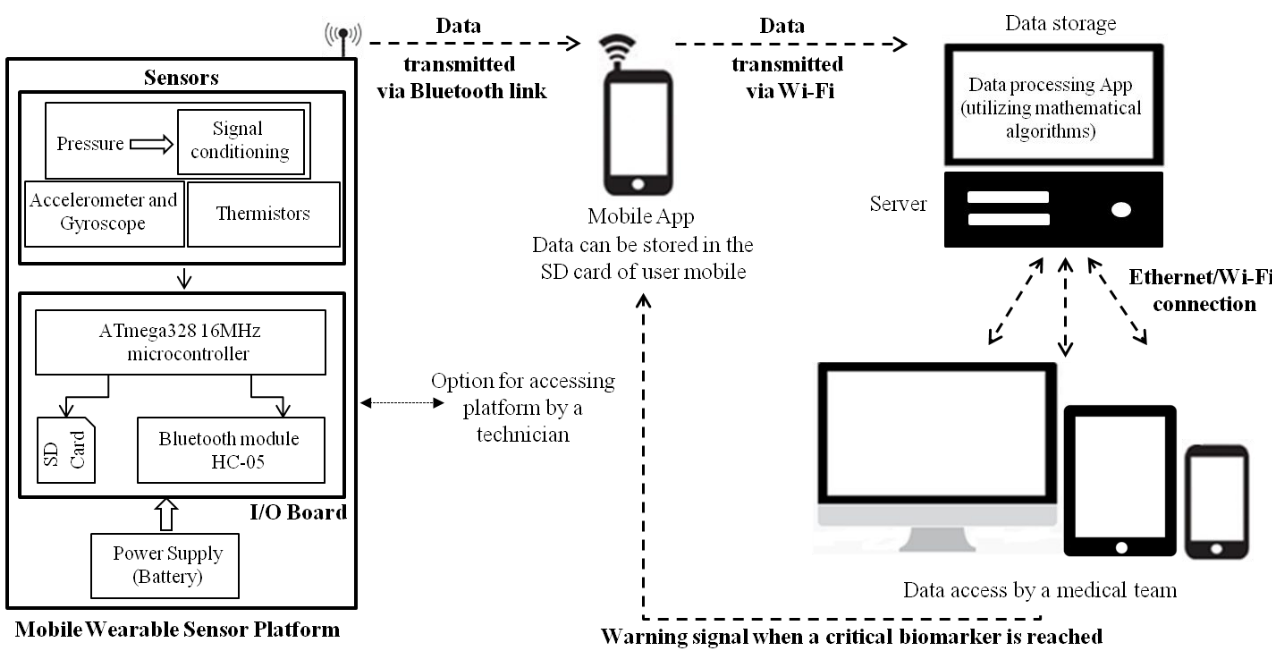


Figure 1. Architecture of the data flow in the multi-sensor wearable platform.

2.1 Hardware Overview

Our sensing platform is composed of a number of discrete components as seen in Figure 1. The center of the platform is an Arduino (ATmega328 16 MHz) microcontroller. The wearable platform can be interfaced with a number of sensors but in our design for the prosthetic users, temperature, gait and pressure measurement sensors are introduced. The temperature, gait and interface pressure data of the residual limb of an amputee subject can be monitored by a medical team at pre-defined sampling rate. The Arduino platform is capable of communicating via Bluetooth, Wi-Fi or cellular networks. Since the Bluetooth module is as small as 12.7 mm x 27 mm with an operating voltage of 1.8 V, it was selected for data communication in our wearable platform design. The microcontroller was connected to an HC-05 Bluetooth module, which communicated over Serial Port Profile (SPP). An Android smartphone was paired with this module and connected over Bluetooth such that the data collected by the Arduino board is transferred onto the software (customized mobile app) running on the smartphone. The data is simultaneously backed up on the SD card in the wearable sensor platform and also on the smartphone.

After the data is received by the smartphone, it is then transmitted over Wi-Fi to a central monitoring server where it is stored in a Postgres database. This allows for the retrieval and processing of the sensor data using mathematical learning algorithms like Gaussian Processes modelling technique on a data processing app[6]. This clinically relevant information can be then accessed by authorized medical personnel over a secure password protected generated report. If the measured parameter on the residual limb of the amputee subject reaches a critical level, then a warning message is sent on to the smartphone of the amputee by the concerned medical personnel for a check-up appointment.

2.2 Software Overview

The comma- separated data from the sensors interfaced on the Arduino platform are transmitted via the Bluetooth link between the HC-05 module and Android smartphone. Each of these samples was transmitted over a single line of text data. Within the mobile app in the Android smartphone, the incoming data over Bluetooth is stored after each sample is tagged as a part of the 'stream'. The concept of streams is introduced in order to differentiate between samples of different experiments, such that it can be analyzed later.

The platform is equipped to handle temporary connection failure scenarios like loss of Bluetooth link between HC-05 module and Android smartphone; and no Wi-Fi/cellular network for the Android smartphone to connect to the server. If the Bluetooth connection is lost, then the HC-05 module buffers the unsent data (if sufficient memory is available) and then tries to retransmit them upon re-establishing of the connection. In the event of no Wi-Fi/cellular network for the Android smartphone to connect to the server, the Android creates a local database and stores all the samples. When the connectivity is available it carries out a synchronization routine with the server. The synchronization process involves identification of the last received sample ID for a given stream and then recognizing if any further samples with a larger sample ID exist for that stream. It should be noted that for this synchronization logic to be work the sample ID should always monotonically increment over time and the same has been implemented in the application[7].

2.3 Battery Monitoring

The wearable platform is entirely dependent on battery power for the realization of monitoring the tissue viability in lower limb amputees. Continuous monitoring along with transmission of sensor data will deplete the battery powering the Arduino microcontroller over a period time, thereby leading to failures. In order to alleviate this situation, a battery monitoring unit is included in our design of the multi-sensor wearable platform. The design of the battery monitoring unit simply consists of a two resistor voltage divider circuit which converts the terminal voltage of the battery powering the board (typically 9-12 V) to a lower voltage in order to be read by the Arduino microcontroller as seen in Figure 2. Utilizing Ohm's law, the voltage drop V_{out} across resistor R_2 as seen in equation 1, is fed to the analog input pin $V_{in}$of the microcontroller.

$$V_{out} = \frac{R_2}{R_1 + R_2} V_{Battery} \tag{1}$$

The reduced lower voltage seen by the microcontroller analog input pin is then converted to the actual battery voltage $V_{Battery}$by multiplying it with the voltage conversion ratio. The system is designed such that when the battery monitoring circuit detects that $V_{Battery} \leq 5$ V, which is the minimum for arduino board to operate ,a message saying 'Battery Level Low' is sent to the user's smartphone. This would enable the user to detect low battery levels of the platform and replace it in order to minimize the risk of data loss due to power failures[8].

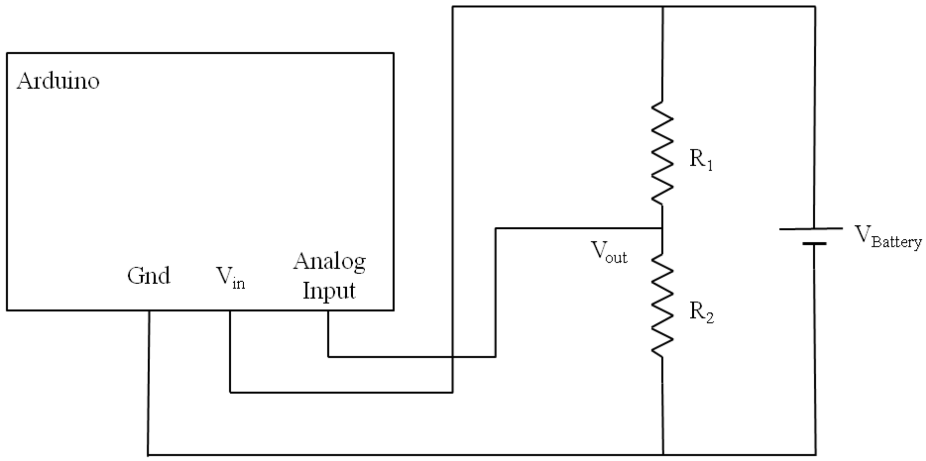


Figure 2. Battery monitoring circuit of the wearable sensor platform.

3. SENSOR TECHNOLOGIES

Pressure ulcers are especially prevalent in areas over bony prominences[9, 10]. Knowledge of the real time pressure distribution over such sensitive areas is therefore desirable, allowing clinical intervention to take place before serious injury occurs. To that end, a wearable piezoelectric pressure monitoring sensor has been developed. This sensor together with the necessary signal conditioning electronics has been integrated with the multi sensor e-Health platform consisting of temperature and gait sensors to realize a reliable, non-invasive and inexpensive method of remote tissue viability monitoring.

It is a critical that the multi-sensor wearable monitoring system is affordable if large scale rollout is to succeed in the developing world. Careful choice of sensor types and signal conditioning can provide the necessary precision and reliability necessary while at the same time minimizing costs. An MPU-6050 accelerometer and gyroscope module along with thermistors was used to monitor the gait and temperature of the residual limb. For tissue/liner interface pressure monitoring, the use of piezoelectric elements is an attractive option – piezoelectric devices are inexpensive with the unit price of PZT types costing less than one US dollar. With proper signal conditioning, these devices are ideal for pressure sensing, being robust and durable. In addition, PZT devices exhibit good linearity in the force range of interest, have high sensitivity, good stability and are highly responsive to impact pressures[11]. Although piezoelectric devices cannot be used to measure truly static pressures, the use of high charge sensitivity materials such as PZT and careful signal conditioning design allow the measurement of very low frequency pressure signals below 100 mHz, while at the same time allowing high frequency impact pressure signals to be detected. In addition, piezoelectric devices require no power source at the sensor site, and wiring is required only for the sensor signal. A 20 mm diameter PZT disc with a capacitance of 20 nF (silver/brass electrodes) was investigated for use as a pressure sensor, and a charge mode amplifier was designed for the signal conditioning.

The electrical admittance of the sensor is the sum of the sensor geometric capacitive susceptance and the non-zero conductance that results from the dielectric loss in the sensor bulk material. The use of charge amplification provides a virtual ground for the sensor allowing operation of the sensor in short-circuit mode. Short-circuit mode effectively bypasses the sensor's internal admittance and the response is therefore dependent only on the amplifier electronics and the mechanical properties of the sensor and elastomer liner interface material. The signal measured by the sensor is now insensitive to changes in the sensor capacitance caused by fluctuations in the dielectric constant of the sensor with temperature. Where the alternative option of voltage mode signal conditioning is used, the effect of capacitance changes with temperature will result in fluctuations at the low end -3 dB cut-off frequency and the gain, both of which are dependent on the sensor capacitance. The effect of sensor cable capacitance is also bypassed in short circuit mode. The electric field across the sensor is therefore effectively zero and the charge produced flows directly into the virtual ground at the charge amplifier input. The charge generated is directly proportional to the force applied to the sensor in the 3-direction (normal) to the sensor surface. In short-circuit mode, the relationship between charge generated and force is simply $q = d_{33}F$ where q is the instantaneous charge (C) produced in response to an applied force, F is the applied force

(N) and d_{33} is the piezoelectric coefficient (C/N). The d_{33} subscripts refer to the charge produced on the electrode surface perpendicular to the 3-direction in response to a force applied in the 3-direction. It is necessary that the signal conditioning electronics can operate using the regulated 5 V single DC supply provided by the Arduino platform. In addition, since the platform uses a single alkaline type 9 V battery power supply, it is critical that power consumption be kept as low as possible to maximize battery life and preserve the reliability of data collection for as long a duration as possible. Furthermore, it is desirable that the sensor signal be insensitive to changes in temperature at the sensor site.

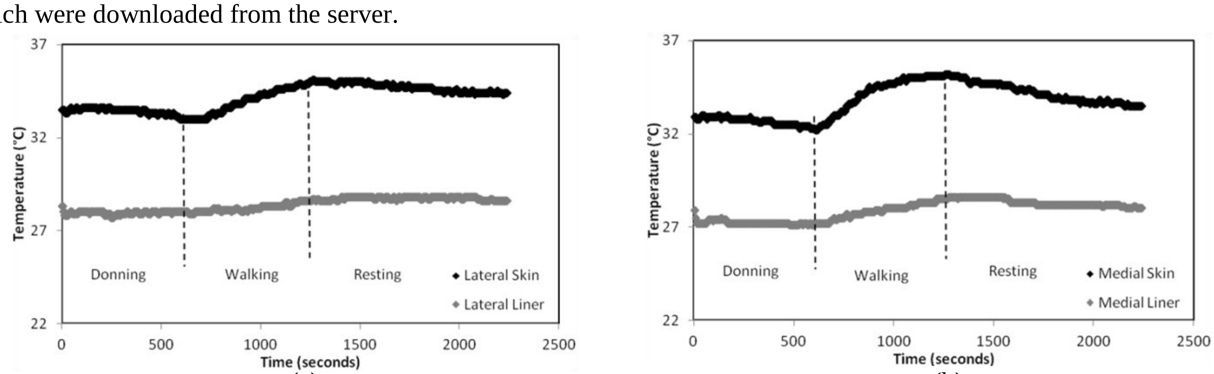
The force applied to the sensor is equal to the area integral of the pressure distribution over the surface of the sensor. The pressure distribution across the sensor can therefore be obtained given the shape of the pressure distribution. In the general case where it can be assumed the force is applied uniformly over the sensor surface, the pressure distribution is simply F/A across the sensor surface where A is the area of the sensor surface electrode. The charge amplifier was designed to operate from the 5 V unipolar supply provided by the Arduino platform, incorporate a differential charge input, be DC biased at the mid-supply voltage (2.5 V) and have a single-ended voltage output with a range of 0 to 5 V for interfacing with the Arduino platform. The circuit design consists of a dual charge amplifier differential stage followed by a variable gain differential to single ended output amplifier. The DC biased single-ended voltage output provides a signal suitable for direct interface with the Arduino platform. Since the use of shielded cable is precluded due to its relatively large diameter, the differential input was incorporated to suppress common-mode electromagnetic interference (EMI) signals that the sensor cable may be exposed to during everyday use. To minimize the common-mode offset voltage at the amplifier output, low tolerance components were used throughout. In addition, metal film resistors and polystyrene/polypropylene capacitors were used to minimize temperature fluctuations and noise. At low frequencies the effect of the sensor and elastomer liner mechanical damping and inertial masses can be safely neglected since the influence of these becomes significant only at high frequencies. The amplifier output response to an applied force is therefore reduced to that of the amplifier alone which behaves as a first order high pass filter with a frequency response function given by equation 2:

$$\frac{V_o(j\omega)}{F(j\omega)} = -\frac{2d_{33}\, j\omega}{C_f(j\omega + \frac{1}{C_f R_f})} \tag{2}$$

where $V_o(j\omega)$ and $F(j\omega)$ are the frequency domain output voltage of the amplifier and force applied to the sensor respectively, C_f and R_f are the amplifier feedback capacitances and resistances, d_{33} is as before, and ω is the frequency (rad/s).To be useful as a pressure sensor, the device must be sensitive enough to measure the minimum pressure at which capillaries close. In addition, the device must be able to respond to the low frequencies that the residual limb is exposed to within the prosthetic socket in everyday life. This means that the sensor must have a cut-off frequency substantially below1Hz. In addition, the sensor must be sensitive to low pressures applied over small areas of the sensor surface. Such conditions occur where, for example a bony prominence applies a non-uniform pressure distribution across the sensor surface.

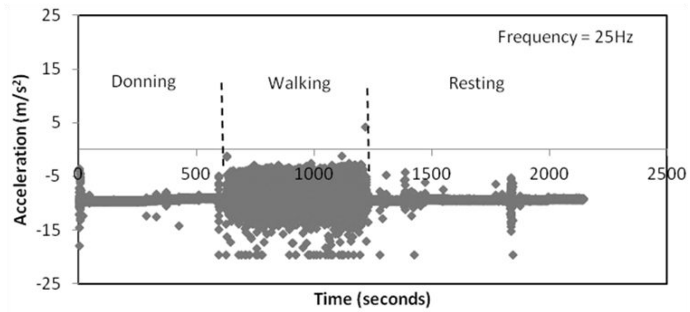
4. RESULTS

Figs. 3 and 4 indicate the temperature and acceleration profiles of the residual limb at an ambient temperature of 20℃ which were downloaded from the server.

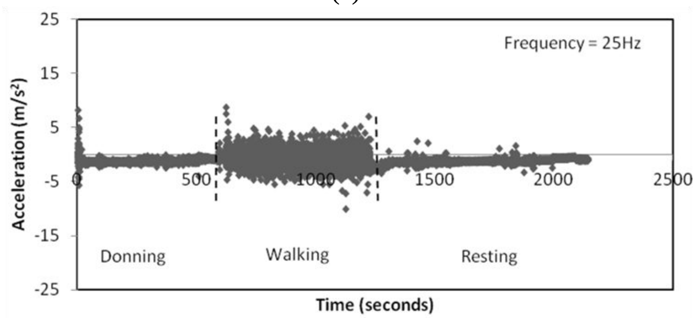


(a) (b)

Figure 3. Profiles of the residual limb and liner temperature sat (a) lateral side (b) medial side



(a)



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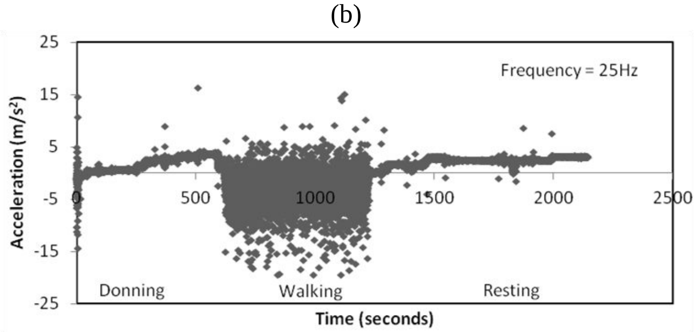

(c)

Figure 4. Acceleration measured in the (a) x-direction (b) y-direction (c) z-direction

To simulate the effect of a bony prominence, a 6 mm diameter nylon rod attached to the cone of a loudspeaker along its longitudinal axis was used to apply forces to the sensor surface at variable frequencies and magnitudes. The force was applied to the sensor through a sample of 2 mm thickness silicone elastomer material commonly used in prosthetic socket liners. A load cell was used to ensure a constant peak force was applied by the 6mm nylon rod through the liner to the piezoelectric sensor surface. A dual supply differential input to single-ended output charge amplifier was designed and built for use with the experimental set up for data collection shown in Figure 5. An Agilent function generator was used as the signal source applied to the loudspeaker and an Agilent DSO7052A Oscilloscope was used to measure the resulting output voltages from the signal conditioning amplifier.

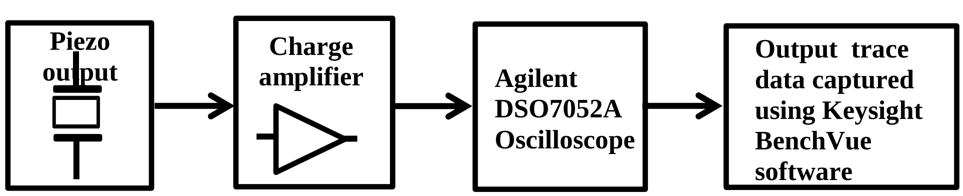

Figure 5. Measurement setup block diagram

The combined sensor/amplifier was investigated for low-end frequency response and force magnitude response to determine the low frequency behavior, response linearity and sensitivity to applied pressures around the capillary closure pressure. For the frequency response measurements, a peak force of $0.12\ \mathrm{N}$ magnitude was applied at all frequencies to achieve a peak sensor pressure of $4300\ \mathrm{N/m^2}$ applied uniformly over the nylon rod area. This is the minimum pressure required to close capillaries. The frequency response results are shown in Figure 6.

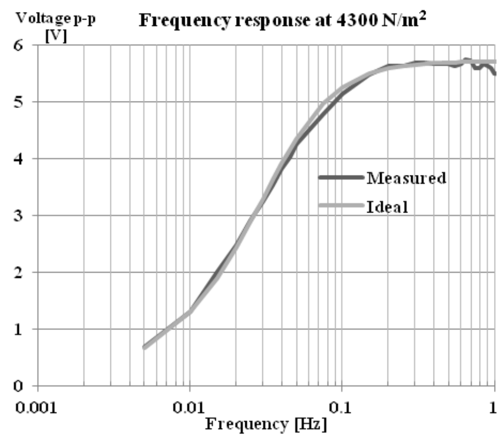

Figure 6. Low frequency response of amplifier conditioned signal

The grey curve describes the theoretical 'ideal' frequency dependent magnitude of the voltage given by equation 1 for amplifier feedback capacitances and resistances of $10\ \mathrm{nF}$ and $300\ \mathrm{M\Omega}$ respectively. It is clear that the measured response very closely matches the theoretical 'ideal' response described by the grey curve. The -3 dB cut-off frequency achieved is $50\ \mathrm{mHz}$. This figure can be further reduced significantly by increasing the feedback resistance and/or the feedback capacitance. Very large time constants are achievable allowing static forces to be measured beyond 30 minutes. However, increasing the feedback resistance increases both noise and output DC offset voltages due to the Opamp bias currents and input offset voltages. The alternative of increasing the feedback capacitance also has the effect of reducing the gain, however this attenuation can be compensated for by introducing gain at the output stage differential to single end amplifier.

The amplifier output for forces applied via the nylon rod at $100\ \mathrm{mHz}$ and $1\ \mathrm{Hz}$ with no preload are shown Figure 7. It can be seen that there is good linearity in the range around $0.12\ \mathrm{N}$ at which capillaries close. A similar linear response has been observed for a similar range of forces at higher preload forces up to $5\ \mathrm{N}$. This is equivalent to $200\ \mathrm{kN/m^2}$, typical of the level of pressures developed in the everyday use of prosthetic devices. When coupled with suitable signal conditioning, the PZT device investigated can be used to measure pressure signals down to very low frequencies with high sensitivity and good linearity. Both low and high pressures can be measured by suitable choice of feedback components. High pressures typical of those developed within prosthetic devices can be measured down to very low frequencies with quasi-static pressure measurement possible at time constants of over 30 minutes.

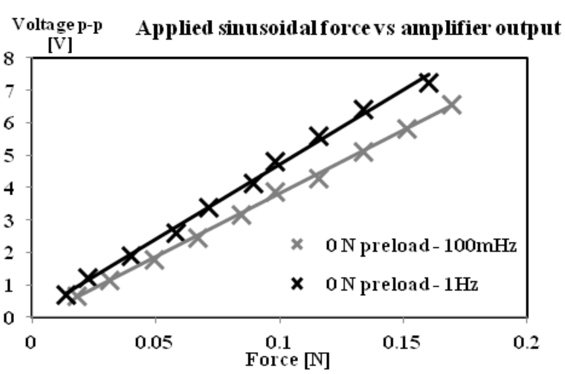

Figure 7. Amplifier output vs sinusoidal force at 100mHz and 1Hz

5. CONCLUSION

The feasibility of a multi-sensor wearable platform has been demonstrated for use in monitoring tissue viability in trans-tibial amputees. The versatility of the platform makes it applicable for use in other regions where tissue health monitoring is a concern. Sensor data has been reliably collected, transmitted and stored in a secure server for post processing allowing medical authorities to access and review user data to identify any possible deterioration in health.

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