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A Practical Design and Implementation of a Low Cost Platform for Remote Monitoring of Lower Limb Health of Amputees in the Developing World

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ABSTRACT In many areas of the world accessing professional physicians ''when needed/as needed'' might not be always possible for a variety of reasons. Therefore, in such cases, a targeted e-Health solution to safeguard patient long-term health could be a meaningful approach. Today's modern healthcare technologies, often built around electronic and computer-based equipment, require an access to a reliable electricity supply. Many healthcare technologies and products also presume access to the high speed internet is available, making them unsuitable for use in areas where there is no fixed-line internet connectivity, access is slow, unreliable, and expensive, yet where the most benefit to patients may be gained. In this paper, a full mobile sensor platform is presented, based around readily-purchased consumer components, to facilitate a low cost and efficient means of monitoring the health of patients with prosthetic lower limbs. This platform is designed such that it can also be operated in a standalone mode, i.e., in the absence of internet connectivity, thereby making it suitable to the developing world. Also, to counter the challenge of power supply issues in e-Health monitoring, a self-contained rechargeable solution to the platform is proposed and demonstrated. The platform works with an Android mobile device, in order to allow for the capture of data from a wireless sensor unit, and to give the clinician access to results from the sensors. The results from the analysis, carried out within the platform's Raspberry Pi Zero, are demonstrated to be of use for remote monitoring. This is specifically targeted for monitoring the tissue health of lower limb amputees. The monitoring of residual limb temperature and gait can be a useful indicator of tissue viability in lower limb amputees especially those suffering from diabetes. We describe a route wherein non-invasive monitoring of tissue health is achievable using the Gaussian process technique. This knowledge will be useful in establishing biomarkers related to a possible deterioration in a patient's health or for assessing the impact of clinical interventions.

INDEX TERMS Accelerometer, e-health, elastomer, extrapolation, gait, Gaussian processes for machine learning (GPML), gyroscope, interpolation, lower limb prosthetics, rehabilitation, sensors, tissue health, wearable sensor platform.

I. INTRODUCTION

With the recent advances in internet and mobile communications devices, along with ubiquitous computing, there has been a tremendous growth in the field of wearable technologies. This has enabled countless possibilities of monitoring patients in the field over extended periods of time [1]. Amputees, especially those suffering from diabetes, are at a great risk of losing the remaining 'good' leg because of the compromised blood flow to the limbs and predisposition to skin breakdown. This coupled with volume fluctuation of the limb within the socket can result in pistionings, skin breakdown as well as a poor gait pattern. 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 and the need to travel to see with the physician. In addition, the information provided by a monitoring system on areas prone to damage could contribute toward improving prosthesis design. While the technologies and principles considered as candidates may already exist, to date, no such early warning system has been implemented and, as such a continuous monitoring system to provide an early warning of tissue damage presents a novel approach to injury prevention. This approach can especially be useful for rural and impoverished countries, wherein the doctors' work with limited resources and challenging conditions and often may not be available at short notice. Thus, the continuous monitoring of residual limb tissue health of amputee patients would not only be useful as a part of diagnostic procedure, routine maintenance or during supervised recovery from a surgical procedure but also reduce the burden of the overworked doctors.

However, the financial costs associated with it are substantially high as around 75% of those affected by diabetes live in middle or low income countries [2]. Many healthcare technologies and products presume that access to internet and reliable electricity is a given, making them unsuitable for the developing world. Hence, it is imperative to design a wearable system which is dependable, low-priced, does not rely on mains power supply and that can operate in the absence of internet connectivity. Also, if the sensors are placed directly in contact with the skin then continuous monitoring could lead to issues like skin irritation and chaffing. Therefore, we have developed and tested a non-invasive measurement approach in which the sensor is placed on the elastomer and the skin temperature is predicted using our custom developed mathematical algorithm – Gaussian processes for machine learning (GPML). Along with the residual limb temperature, the gait of the user is also analyzed to provide valuable information regarding the health as well as the shape and volume changes of the limb tissue. In our work, we describe the development of such a wearable platform for lower limb amputees which that is capable of gathering data from the sensors (placed on the elastomer) and transmitting this data to an Android mobile device, which relays it to a Raspberry Pi Zero acting as a server, for the purpose of viewing and analyzing the data by healthcare professionals in low income countries.

A. CONTRIBUTIONS

This paper makes the following four contributions. Firstly, a low-power, low-cost wearable sensor platform is presented, based upon standard consumer-purchasable components, for self-contained use where there is no reliable electricity supply or internet connectivity available. Secondly, we have successfully implemented, tested and validated GPML to accurately predict the in-socket residual limb temperature by monitoring the temperature between socket and liner without a need for any skin contact by a sensor. The challenge of calibrating the mathematical model for various ambient temperatures has also been addressed in this study by using interpolation/extrapolation techniques. Thirdly, analysis of walking pattern of the amputee subject by determining the joint angles (in our case, the shank angle) of the residual limb will be useful in differentiating between the normal and abnormal gait profile of an individual, thereby helping to predict the occurrence of pressure ulcers. Finally, a machine-learning based approach to determining bio-markers for use in monitoring tissue viability in amputees has been demonstrated. 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 local server for post processing, allowing medical authorities to access and review user data to identify any possible deterioration in tissue health which could be indicators of residual limb volume fluctuation.

II. BACKGROUND

Recent advances in internet and mobile communications along with a public desire for monitoring gadgets, the development of wearable user self-monitoring devices for measuring and logging a wide range of parameters such as calories burnt, steps taken, body mass index, SpO2 and heart rate have become extremely popular. In addition, the popularity of smartphone apps for health monitoring is now commonplace. "In fact, it is estimated that at least 70% of Americans monitor at least one health indicator with 60% tracking weight, exercise and diet; while 33% track quantities such as blood pressure (BP), glucose and sleep patterns" [3]. Although these devices and apps are designed for the consumer market, this technology has opened up the possibility of the application of e-health towards routine remote patient monitoring by health authorities [4]. As developing technology allows e-health devices increasingly to become smaller, lighter and smarter, they become more attractive for use in the permanent and continuous monitoring of patients.

Such systems, if implemented for lower limb prosthetic users, will allow remote monitoring of amputee's residual limb tissue health by measuring temperature, gait and pressure levels. This would be useful in studying and perhaps predicting in advance the volume fluctuation, pistioning, skin health and poor gait of the amputee patient. The architecture of such medical monitoring systems may consist of on-body (non-invasive) or in-body sensors along with a microcontroller unit (MCU) for control and pre-processing. The communication module may consist of a smart-phone for user interface and a transmitter for data transfer via the internet to a central server.

The data collected can be used to provide an early warning of, serious health threats along with the geographical location and movement patterns as well. If there is a deviation in the normal behavioural pattern, it might be an indicator that medical intervention is required which might then be used to trigger an emergency response. This early warning can have multiple benefits like reduction in hospital admission in already overstretched health authorities as well potentially saving lives. Also, the need for scheduled appointments at outpatient clinics and doctor's surgeries can be reduced. Furthermore, this continuous monitoring can be useful in providing a more accurate evidence of patient health status that would be otherwise remain unrecorded [1]. Nonetheless, one major challenge in bringing e-health technologies to the developing world is the common dependence upon both a reliable internet connection, and a reliable electricity supply, along with keeping the cost to a minimum. This is considered in our solution, since the platform is designed to operate as a low-power, standalone solution, without requiring external connectivity, able to be recharged using a solar panel. As the sensor platform developed creates its own WiFi network, there is no need for any external infrastructure to be present for the platform to be used.

III. TECHNICAL ARCHITECTURE

The design of the wearable sensor platform has to be such that it can unobtrusively gather data from a wearable sensor and transfer this information periodically to a database server, running on the Raspberry Pi, 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 early warning system that can alert a health professional of warning signs may 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, if platforms like this were to be deployed to communities for use on an ongoing basis. In addition, the information gathered by a monitoring system on areas prone to damage could contribute toward improving prosthesis design. In scenarios where permanent reliable connectivity is not available, the platform can also be used in a standalone mode, where a WiFi network is created by the equipment, and the remainder of the platform connects to this system. There is therefore no requirement for internet connectivity to use the platform.

Our design is architected in order to make as low-power a solution as possible, using as much off-the-shelf equipment as practical, such that kits maybe assembled out of commonly available items. Minimal equipment is used, in order to reduce the complexity of the system, and to reduce the cost of each unit as possible. For example, the data storage and processing is carried out on a Raspberry Pi Zero embedded computer. It also acts as a WiFi access point, through a USB-connected wireless adapter, eliminating the need for a dedicated wireless access point. The Raspberry Pi Zero hosts an HTTP-based API, and acts as a DHCP server on the WiFi network, allowing for the rest of the platform to be connected.

The data logger device is comprised of two components – the prosthesis-mounted monitor with sensors, and an Android smartphone. The Android platform was selected on account of its widespread penetration within emerging markets, and the relatively low cost of entry-level handsets, reducing the overall cost of the proposed solution. By connecting an Android device to the WiFi hotspot created by the Raspberry Pi, the application software may be downloaded directly from the Raspberry Pi, where no internet access is available.

The prosthesis-mounted equipment requires an Arduino microcontroller, an HC-05 serial Bluetooth module, two temperature sensors, and a MPU6050 6-axis accelerometer and gyroscope module. The accelerometer and gyroscope data is transmitted from the Arduino microcontroller, over the Bluetooth link, to the Android smartphone running the data gathering software. The smartphone application maintains a local copy of the data on its SD card as backup, and transmits batched data over WiFi to the Raspberry Pi Zero. The Android smart phone provides an interface to control the data logging, adjusting parameters as required to ensure that the patient information is kept separately, and ensuring that it is correctly associated with the patient the data was gathered from [4].

A. 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 16MHz) microcontroller. The wearable platform can be interfaced with a number of sensors but in our design for the prosthetic users, temperature and gait measurement sensors are introduced. The temperature and gait 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 12.7mm × 27mm, with low power consumption due to reduced range and bandwidth, it was selected for data communication between the sensor and mobile phone. The microcontroller was connected to an HC-05 Bluetooth

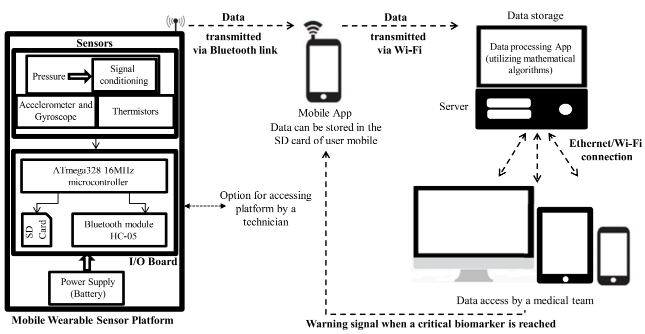


FIGURE 1. Architecture of the data flow in the multi-sensor wearable platform.

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 [5].

After the data is received by the smartphone, it is then transmitted over Wi-Fi to the Raspberry Pi Zero, acting as the data collection server, where it is stored in a Postgres database after being received by the web API. 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. This clinically relevant information can be then accessed by medical personnel, using the secure WiFi link from their own device, or from the smartphone used for data collection. Where the system is deployed offline there may be scenarios where there is only one mobile device available, both for data gathering and retrieval – the reporting interface is designed for access from both desktop and mobile browsers to facilitate this.

The clinician has access to data from each of their patients from within their interface. After selecting a patient identifier, all previous sessions recorded with the monitoring platform are visible, and can be accessed. It is possible therefore to compare the gait profile and predicted residual limb skin temperature between patients, or to monitor deterioration or variations over time for one patient. The clinician interface provides access to the features discussed in Sections VII and VIII, allowing for feedback to be given to the patient in real-time (residual limb skin temperature and the shank angle).

B. OVERALL SOLUTION DESIGN

The two design goals of the overall solution were to minimize the cost, while also keeping power consumption low. By using readily available, off-the-shelf components where possible, the cost of the solution was kept to a minimum, while also facilitating the sourcing of replacement parts for field repairs. Where possible, components are designed to be modular, using standard USB cables for interconnection and power.

Minimization of power consumption was also a consideration, in order to allow for use of the system in areas with unreliable power supplies. In particular, the overall solution was designed to operate from a rechargeable USB power pack, therefore permitting use at night. Combining this with a USB solar panel would allow the power pack to be re-charged during daylight hours. Section VI considers the power consumption of the overall solution in more detail.

The main components used by the presented solution, along with their approximate retail costs for individual quantities, are as follows. A Raspberry Pi Zero (£4), micro SD card (£3) and USB WiFi adapter (£6) are used as a server. The sensor utilizes an Arduino Uno (£6) and an HC-05 Bluetooth module (£4), with an MPU-6150 movement sensor (£5) and two thermistors (£1). A 20,000 mAh power bank (£20) is used as the main power supply for use off-grid, along with a USB output solar panel (£36). Finally, a LiPo charge controller (£1) is used to control the charging of the wireless sensor module's Lithium Polymer battery (£2), and various USB and micro USB cables are used to supply power to the various components. The only additional requirement is an Android smartphone, to be connected to the sensor platform.

C. 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 scenarios, such that it can be analyzed later. This allows for comparisons to be carried out, either between patients or for one patient over time, making it possible to compare previous experiments, identifying trends or deterioration.

The platform is equipped to handle connection failure scenarios like loss of Bluetooth link between HC-05 module and Android smartphone; and a lack of Wi-Fi 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 the un-sent samples upon re-establishing the connection. In the event of no Wi-Fi/cellular network being available on the Android smartphone to connect to the server, Android application creates a local database and stores all samples and timestamps. When 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, as implemented in the application. Considering the need for the system to be both usable when given to a patient for use away from the clinician, as well as used with a clinician monitoring the readings being reported to the Raspberry Pi server for analysis, the application permits either use-case, transparently and without configuration, by carrying out the synchronization process whenever connectivity to the server is possible.

The data retrieval interface was implemented as a Flask-based web application, written in Python. A responsive Bootstrap interface was created, to allow the same management and data retrieval interface to be used from both fixed and mobile devices. The Flask application also presents an API for the synchronization of data to the server from the mobile application. The underlying data gathered from sensors is stored in a local Postgres database, held on the Raspberry Pi Zero. In order to ensure that no personal or identifying information (even a patient identifier) is held on the smartphone (which may be shared between users, or also used by the clinician), a stream-based model for the upload of data is implemented. Within the stream-based model, the Android application requires only a single setting to be adjusted prior to issuing the device to a new patient for use. This is designed to facilitate use of the one platform, where all equipment must be self-contained and brought by the clinician, who may not be an expert in configuring the platform. Rather than configuring accounts within the application, the clinician simply creates a new stream from the server configuration interface. This displays a numerical stream ID, which is entered into the Android application. Having set the stream ID, the server is able to map this stream to a patient, but no information pertaining to the patient is exposed to the smartphone [5].

D. 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 9-12Volts) to a lower voltage in order to be read by the Arduino microcontroller. 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 $V_{Battery} \leq 5V$, which is the minimum for arduino board to operate, a battery level warning message is sent to the user's smartphone. This alerts the user with both a visual and audible indication, using the platform's notifications API. This enables the user to detect low battery levels of the platform and charge it, in order to minimize the risk of failing to capture data due to power failures [1], [6].

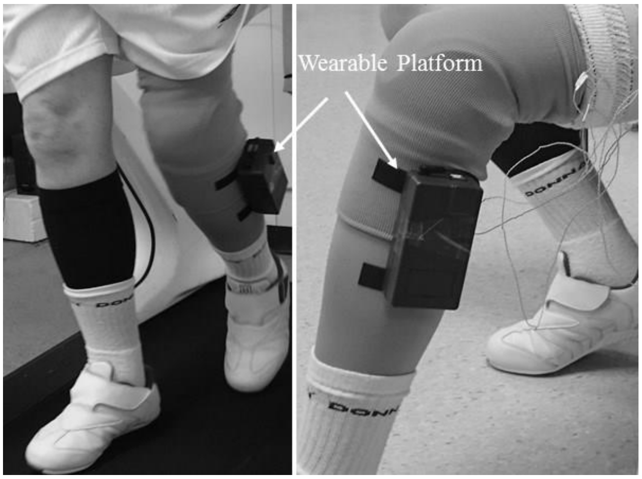
IV. CONNECTIVITY SELECTION

Our initial design of the platform incorporated WiFi connectivity directly within the Arduino module, but we revised this design decision on account of considerably higher power consumption experienced. When considering the goals of minimizing cost and inconvenience of our solution, a standard Android smartphone was used for the network-based connectivity for two reasons. Firstly, the clinician is able to use the smartphone as a web browser to access the results from the platform, removing the need for a second device to access the interface. Secondly, it is likely that Android-based smartphones may already be available to clinicians in developing countries, further reducing the cost of each system.

In order to ensure that the platform is as usable as possible within developing countries, the full solution is designed to be self-contained, and able to be charged from a single small solar cell. To also permit use at night, indoors, or during inclement weather, an off-the-shelf 5V 20Ah battery power supply is contained within the platform. This battery pack is charged by the solar panel. By using a USB-based equipment for all charging and power components of the system, it is possible to easily replace the battery pack, or use an alternative USB-based power supply where needed.

V. IMPLEMENTATION OF THE WEARABLE SENSOR PLATFORM

The capability of the designed mobile wearable sensor platform was tested on a trans-tibial traumatic amputee subject in a climate controlled chamber. This investigation was carried out under ethical approval granted by the University of Strathclyde Ethics Committee (Ref UEC13/04). The subject was asked to perform a 35 minute protocol which consisted of resting (sitting) for 10 minutes, walk at a self-selected speed of 0.54 meters/second on a treadmill for 10 minutes, and finally rest for 15 minutes. The subject wore a 6mm Pelite liner with a resin laminate socket with the wearable sensor platform attached on to the shank segment (near to the knee joint) of the prosthetic limb. Figure 2 indicates the positioning of the wearable sensor platform in relation to the prosthesis of the subject during different activity levels. Four thermistors and an MPU-6050 module interfaced with the wearable platform, providing the residual limb and liner interface temperature profile at the lateral and medial sides and the



(a) (b)

FIGURE 2. The wearable sensor platform positioned on the prosthesis of the amputee subject during various activity levels as (a) walking on treadmill at a self-selected speed (b) sitting/resting.

orientation of the limb respectively. Data from the sensors was sampled at 25Hz for the entire 35 minute protocol. This study was conducted in Scotland for the Spring/Summer profile where the ambient temperature ranges from approximately 10°C-25°C. Hence, the temperatures from this range were picked. We conducted the experiment at 10°C and then repeated for 15°C, 20°C, and 25°C. The temperature profile of the residual limb and the liner were analyzed for different ambient temperatures and it was noted that in all the cases the trace of the liner temperature was very closely correlated with that of the residual limb temperature. This enabled us to implement the Gaussian processes modelling technique to predict the residual limb temperature by monitoring the liner interface temperature with an accuracy of 95% [7], thereby providing a non-invasive measurement practice. The accelerometer and gyroscope data from the inertial measurement unit MPU-6050 is fused together to provide an indication of the shank angle during different activity levels. This would help to understand and analyze the gait, its different phases and thus would provide significant information about the amputee's normal and abnormal limb profile at different ambient temperatures.

As per the overall design, the residual limb skin temperature and gait profile data was reliably collected, transmitted and stored in a secure local server for post processing by the wearable platform. These trials verified the design and implementation strategy of the wearable platform in a clinical environment. This work will enable us to determine the envelope in estimating the statistical power i.e. how many subjects are needed to make the trials clinically significant and thus will be useful in extending it on a greater amputee population for further testing before its deployment.

VI. OVERALL POWER CONSUMPTION

As discussed previously in Section III.B, the overall power consumption of the platform was designed to be minimized, in order to facilitate use in areas without reliable grid-based electricity. The monitoring platform's power consumption can be split into two main components – the usage of the Raspberry Pi-based server, and the wireless sensor unit (including mobile phone, if necessary). Note that the power consumption of the Android mobile phone is not considered within these measurements, since different devices have significantly different power profiles, and it is likely that an existing Android device would be used in order to reduce the overall cost of this system. The peak current consumption of the Raspberry Pi (including all connected peripherals including WiFi interface) was measured during initial power-up to be 357 mA. This settled in under a minute to a steady-state idle consumption of 190 mA. During active data logging, the current consumption rose to 218 mA. These current draws were measured at 5V DC, using a PortaPow Premium USB power monitor, and are accurate to ±0.2%. Therefore, with a 20 Ah 5V USB power bank used as the power supply, a runtime of in excess of 3 days was achievable from a full charge of the power bank. The wireless sensor unit draws 80.7mA during the data acquisition and transfer of the sensor data via Bluetooth to the Android device.

Using a 20W USB output solar charger, capable of supplying 2.4A to a single USB output, the 20 Ah power pack could be recharged in around 12 hours, assuming sufficient sunlight was available for the solar panel to operate without available light being a constraint.

VII. TEMPERATURE MONITORING

A mathematical model utilizing the Gaussian processes for machine learning (GPML) to predict the residual limb skin temperature of the amputee has been developed [6]. The challenge of non-invasively monitoring the residual limb skin temperature has been addressed in the modeling technique. That study was conducted on a subject performing various tasks in an environmental chamber at different ambient temperatures, and clearly indicated that the residual limb skin temperature and the liner temperature are majorly affected by both the ambient temperature and the activity level of the subject.

The GPML approach is non-parametric in nature i.e. it utilizes the training data provided to determine the underlying function. It enables the implementation of Bayesian framework in a simple way [8], [9] by inferring the joint probability distribution over all possible outputs for all inputs. Bayes' theorem states that the posterior probability of a condition is given by the product of the prior probability and the likelihood in the light of the evidence.

The model designed takes the liner temperature as the input x and the predicted output is the residual limb skin temperature y. Processing was performed with custom developed software (using MATLAB, Mathworks). Since the temperature profile of the residual limb and the ambient temperature are closely correlated, individual Gaussian process models were defined using the obtained data from experimentation (as discussed in Section V) for temperatures of 15°C, 20°C and 25°C. The Gaussian model was individually trained for each of the ambient temperatures on which the tests were done.

The predictive model developed led to results which are in 95% confidence interval and translate to an accuracy of ± 0.5°C. However, with the residual limb temperature profile varying with changes in environmental temperatures, the Gaussian model has to be trained with individual datasets which correspond to changes in ambient temperature. The clinical trials required to calibrate the model are quite intensive as well as expensive. Hence, the introduction of estimation techniques, namely interpolation and extrapolation, can be utilized for prediction of residual limb temperature (at a given environmental temperature) from the GPML model calibrated for a different ambient temperature.

Consider that there are a set of N data points $x_1, x_2, \ldots x_N$ with function value $f(x)$. The determination of $f(x)$ for any arbitrary x in between the smallest and largest x_i's is known as interpolation; if x lies outside the given range then it is known as extrapolation. For these estimation process, there are two stages involved – fit an underlying function for the given data points and then evaluate that function for the target point x. However, this two stage method is computationally less efficient and more prone to round off errors. Interpolation done locally using the nearest neighbor approach is better than the previous but the interpolated values $f(x)$ might not have a continuous first order or higher derivative. This is because the interpolated function might become discontinuous because of the switching of the local points [10].

In our predictive modeling using GPML, continuity of the derivatives is a concern and hence cubic spline interpolation/extrapolation technique is used. The basic principle of cubic spline is that on each interval between the data points the interpolation formula is represented by a cubic function. For N data points, the spline function $S(x)$ can be represented as

$$S(x) = \begin{cases} C_1(x), & x_1 \le x \le x_2 \\ C_i(x), & x_{i-1} \le x \le x_i \\ C_N(x), & x_{N-1} \le x \le x_N \end{cases} \tag{2}$$

where each C_i is a cubic function. A general cubic function has the form

$$C_i(x) = a_i + b_i x + c_i x^2 + d_i x^3 \tag{3}$$

To define the spline function, the coefficients a_i, b_i, c_i and d_i are to be determined for each i by utilizing the boundary conditions. Since there are $4N$ coefficients to be determined by $4N$ conditions, the known values can be plugged into the $4N$ conditions to solve the system of equations. Because the coefficients of the function are determined non-locally, the cubic spline function is continuous through the second derivative. They also tend to be more stable than polynomial function thereby reducing wild oscillations between the data points [11]. It should be noted that the extrapolation also follows the same estimation routine as interpolation.

The cubic spline interpolation/extrapolation technique is studied for various scenarios and compared with the actual predicted in-socket temperature. It can be seen from Figure 3 that the actual GPML model prediction at ambient temperature of 15°C is compared with its counterpart extrapolated value obtained from the models at 20°C and 25°C. Other scenarios are also illustrated in Figure 4 and Figure 5.

A. RESULT ANALYSIS

In this study the performance of the estimation techniques are compared with the prediction of the Gaussian model. The degree of closeness of interpolated and extrapolated values with the actual predicted values are compared using the Root Mean Squared Error (RMSE). Calculation of RMSE involves squaring the difference between the predicted and corresponding observed values, averaging it over the sample and then finally taking its square root. This can be written as

$$RMSE = \sqrt{\frac{1}{n} \sum_{i=1}^{n} e_i^2} \tag{4}$$

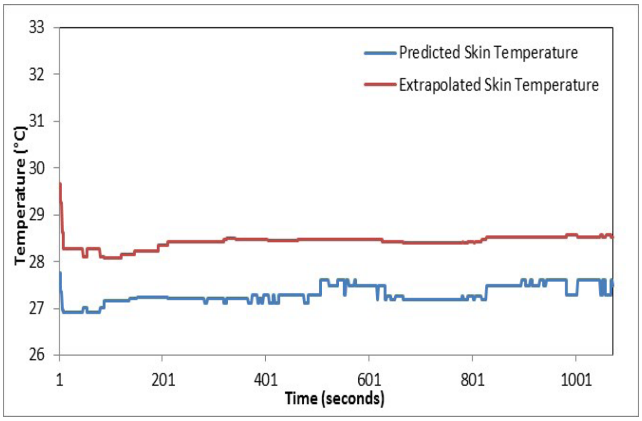


FIGURE 3. Illustration of prediction with Gaussian Process regression for ambient temperature of 15°C along with the extrapolated output of residual limb temperature for the same temperature from the models at 20°C and 25°C.

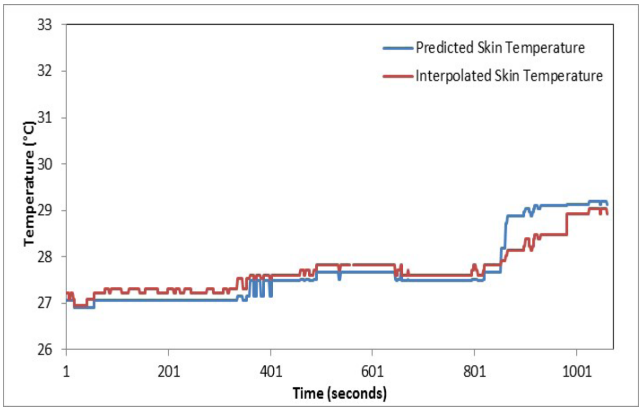


FIGURE 4. Illustration of prediction with Gaussian Process regression for ambient temperature of 20°C along with the interpolated output of residual limb temperature for the same temperature from the models at 15°C and 25°C.

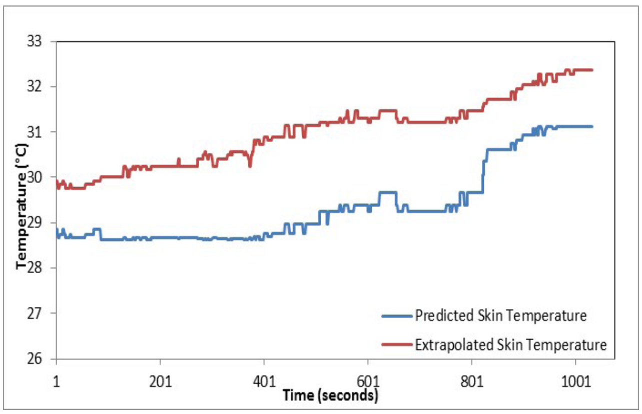


FIGURE 5. Illustration of prediction with Gaussian Process regression for ambient temperature of 25°C along with the extrapolated output of residual limb temperature for the same temperature from the models at 15°C and 20°C.

where the error is given by $|e_i| = |f_i - y_i|$; f_i is the interpolated/extrapolated value and y_i the predicted value from the Gaussian model. RMSE has a quadratic error rule, where the errors are squared before being averaged. This could be useful when large errors are undesirable in a statistical model [12]. The RMSE of different interpolation/extrapolation scenarios is compared in Table 1.

TABLE 1. RMSE for different scenarios of estimation.

Scenario	RMSE (ºC)
Extrapolated in-socket temperature at 15ºC from the Gaussian models at 20ºC and 25ºC	1.43
Interpolated in-socket temperature at 20ºC from the Gaussian models at 15ºC and 25ºC	0.46
Extrapolated in-socket temperature at 25ºC from the Gaussian models at 15ºC and 20ºC	1.58

The results indicate that the RMSE error is substantially more in the extrapolation scenarios as compared to that with the interpolation. This can be easily explained as extrapolation is the process of estimating a variable that is outside the observation range and does is subject to greater uncertainty. In spite of this, this estimation technique is able to identify the trend of the predictive model to a great extent. It can be easily further improved by reducing the 5°C temperature interval for which the interpolation and extrapolation is been done.

VIII. GAIT ANALYSIS

In order to analyze human motion, the standard technique is by utilizing high-speed cameras to capture the human motion. Studies have been done by integrating the three-dimensional motion using multi-camera systems and reaction force measurement to track the movement of human body parts in a complex [13], [14]. However, this technique of optical motion analysis requires complex signal conditioning and is time consuming in nature. It also needs to be pre-calibrated, thereby making it expensive and limited to laboratory research. For the application in daily life with different environments, it is imperative for the gait monitoring system to be flexible, low-cost and wearable in nature. To implement this philosophy of home-based rehabilitation and tele-rehabilitation, many kinds of wearable (body-fixed) sensor system based on single or multiple accelerometer and gyroscope combinations can be utilized [15]–[18]. This would especially be useful for monitoring and detecting the early signs of tissue damage for lower limb amputees' activities outside of a laboratory [19]–[22].

Wearable sensor systems for biomedical applications in gait monitoring can be used in two different ways: one is about walking feature assessment for daily physical activities [23]–[30], wherein the data obtained from inertial sensors - accelerometer or gyroscope, are directly used as inputs of some inference techniques; and another direction is for determining the joint angle, body position and orientation accurately by fusing the data of different inertial sensors so as to decrease the errors of the quantitative human motion analysis [31]. In our research, the data from accelerometer and gyroscope is combined to estimate the shank angle of the amputee's residual limb, so our approach focuses on the second option for quantitative human motion analysis [31].

Inertial measurement units (IMUs) or inertial sensors, measure acceleration, angular rate and sometimes the magnetic field vector of a body in their own three-dimensional local

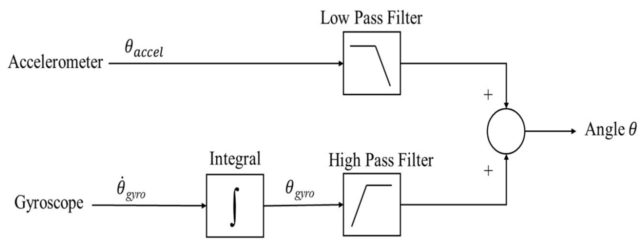


FIGURE 6. Schematic of the complementary filter.

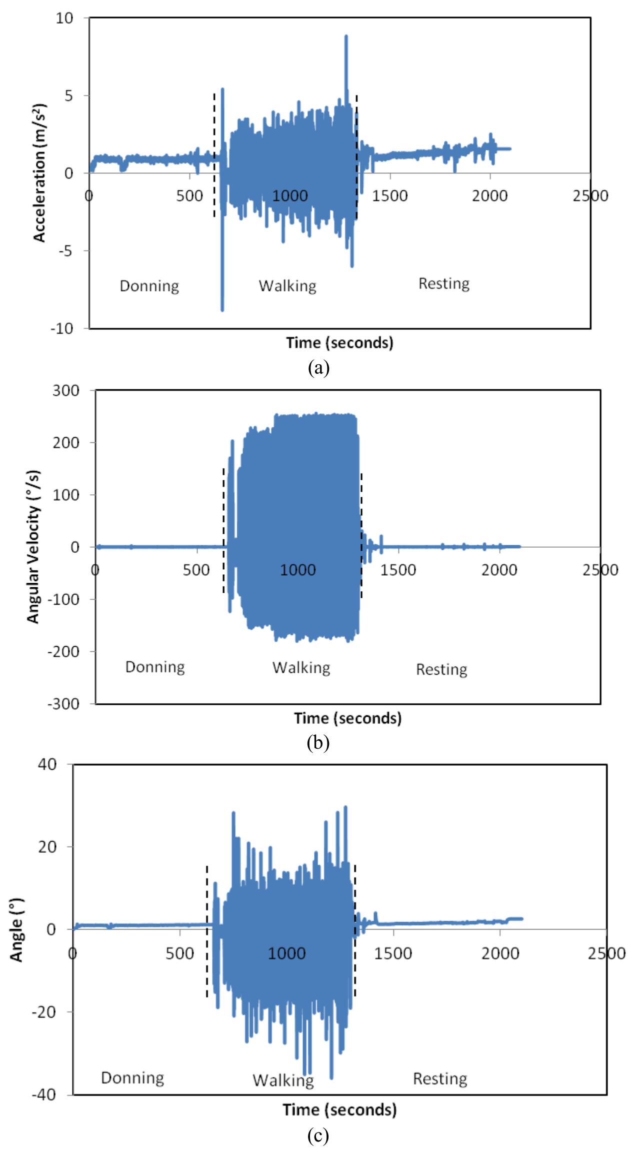


FIGURE 7. (a) Measured acceleration (b) Angular velocity (c) Shank angle obtained by the implementation of complementary filter at an ambient temperature of 10°C.

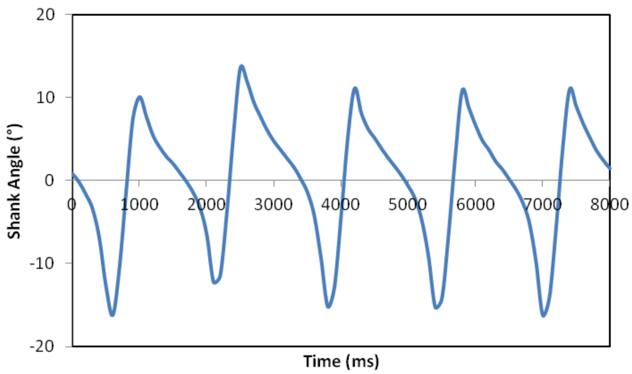


FIGURE 8. **Estimation result of the rotational angle at the shank at an ambient temperature of 10°C.**

coordinate system [32]. An IMU detects the current change in position by using the accelerometer and detects changes in rotation like yaw, pitch, and roll by using the gyroscope. Because the accelerometer measures all the forces working on the system, it is quite prone to noise. The data from the accelerometer is reliable in long term and so a low pass filter can be used. The gyroscope on the other hand, has a tendency to drift significantly over a period of time. Since the gyroscope data is reliable only on short term, a high pass filter can be utilized. Many algorithms for determining the sensor orientation estimation have been proposed [33]; however in this work, in order to estimate the absolute angle is derived by combining the accelerometer and gyroscope data using a complementary filter. The integration of the output of a gyroscope θ_{gyro} feeds into a high pass filter and the output of an accelerometer θ_{accel} feeds into a low pass filter as seen in Figure 6.

The basic concept of this filter is to enhance advantages of each sensor. For example, the angular estimation using a gyroscope has a good accuracy in the sense of angular direction at high frequencies and the angular estimation using an accelerometer has a good accuracy at low frequencies. Hence for the complementary filter, if $G(s)$ is the low pass filter for the accelerometer then the high pass filter for the gyroscope is $1 - G(s)$. These can be written as in equations (5) and (6) where τ is the time constant and determines the filter cut-off frequencies.

$$G(s) = \frac{1}{1+\tau s} \tag{5}$$

$$1 - G(s) = \frac{\tau s}{1+\tau s} \tag{6}$$

The transfer function of the angle θ of the complementary filter can be written as

$$\theta = \frac{1}{1+\tau s}\theta_{accel} + \frac{\tau s}{s(1+\tau s)}\dot{\theta}_{gyro} = \frac{\theta_{accel} + \tau\dot{\theta}_{gyro}}{1+\tau s} \tag{7}$$

Digitizing this and using backward difference yields equation (8) as

$$1 + \tau s = \left(1 + \frac{\tau}{\Delta t}\right) - \frac{\tau}{\Delta t}z^{-1} \tag{8}$$

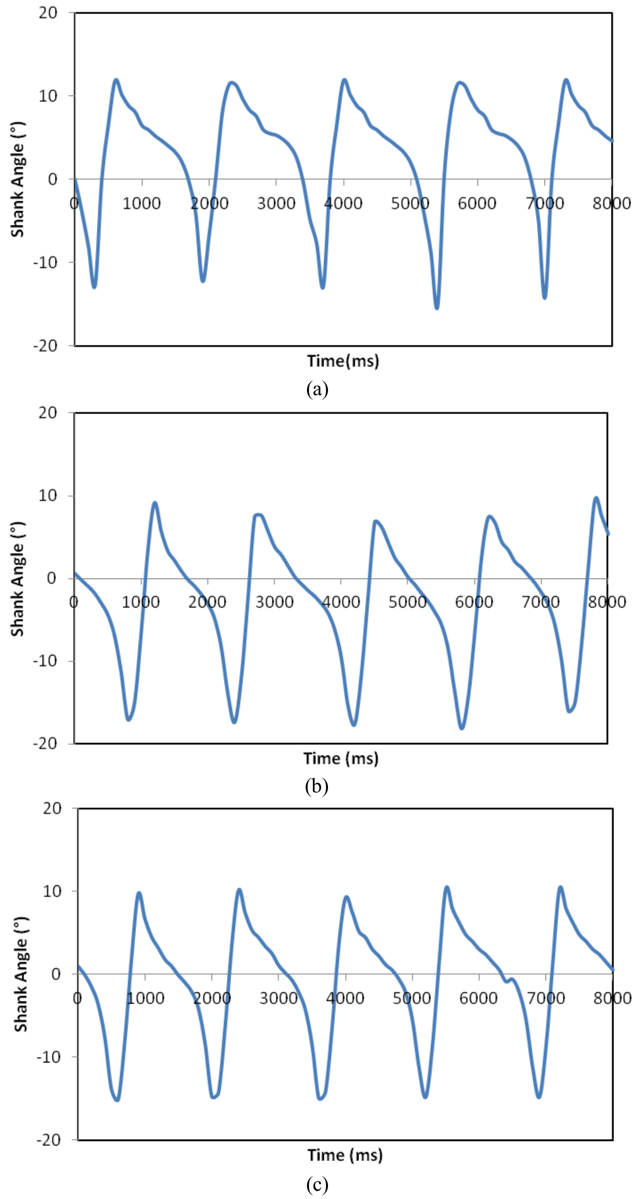


FIGURE 9. **Estimation result of the rotational angle at the shank at an ambient temperature of (a) 15°C (b) 20°C (c) 25°C.**

Substituting this in equation (7) and rearranging leads to

$$\theta_k = \alpha\left(\theta_{k-1} + \dot{\theta}_{(gyro)k}\Delta t\right) + (1-\alpha)\,\theta_{(accel)k} \tag{9}$$

where $\alpha = \tau/(\tau + \Delta t)$

In our design, the optimum filter coefficient α is 0.98 which is computed by running the filter at different time constants with a fixed sampling rate of 25 Hz. It should be noted that the lower the time constant, the more horizontal acceleration noise will be allowed to pass through. Figure 7 indicates the acceleration, angular velocity and the computed shank angle of the amputee subject at an ambient temperature of 10°C during the 35 minute experimental protocol.

The region of interest in the clinical trial is when the amputee subject is walking on the treadmill for 15 minutes.

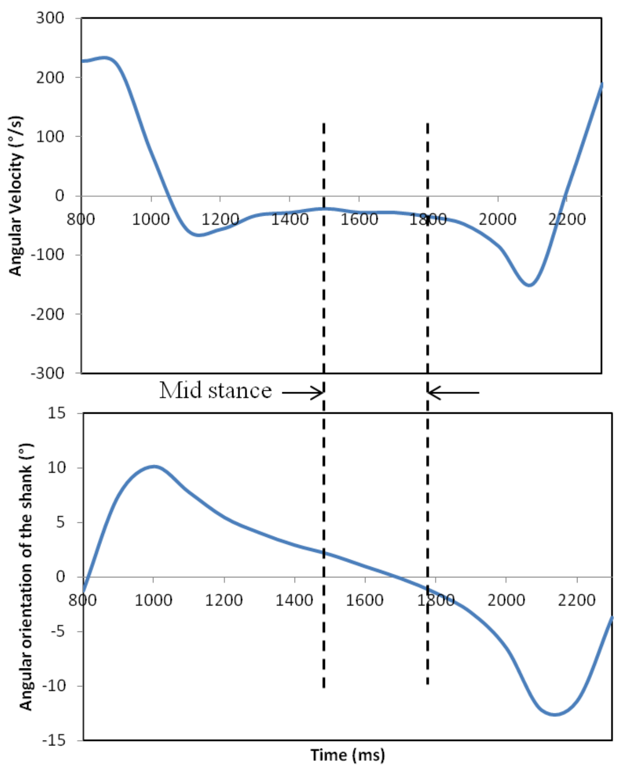


FIGURE 10. Calibration of mid stance in the gait cycle by combining signals of gyroscope and accelerometer.

Analyzing this would give insight into the movement of the residual limb with the corresponding shank angle during the gait cycle. As shown in Figure 8, an off-line analysis was made to analyze the leg motion during the walking period for an 8 seconds timeframe at an ambient temperature of 10°C. The experiments data were processed using MATLAB, Mathworks, in which a complementary filter was designed (as described earlier) to estimate orientation of the shank.

Similarly, the orientation angle of the shank is computed for ambient temperatures of 15°C, 20°C, and 25°C as seen in Figure 9. From Figures 8 and 9 it can be noted that, the shank angle profile of the amputee subject have been consistent in all ambient temperatures.

The human walking pattern can be analysed by phases more accurately as it signifies the functional effect of different motions on joints and segments. A normal walking gait cycle can be divided into eight different gait phases including initial contact, loading response, mid stance, terminal stance, pre-swing, initial swing, mid swing and terminal swing [32]. The phases of the gait pattern on the IMU sensor were calibrated with measurements of a commercial high-speed cameras. In order to determine the gait phase from the IMU sensor, the movement of the amputee's residual limb is captured using a high-speed camera. The camera is capable of shooting video at 120 frames per second in HD 720p. The climate-controlled chamber where the measurements were done was a medium lighted room to minimize noise due to high sun activity. The camera and the wearable system were synced in time, such that both the IMU data and the video from the camera could be correlated by their timestamps. The amputee subject with the positioned wearable platform while walking on the treadmill for 15 minutes was video recorded. For each measurement, a single video file was created using the camera software. Using video editing tools, videos were edited such that only one full gait cycle was left from the original file video. The shank angle so deduced by fusing the accelerometer and gyroscope data is then linked with the gait cycle video to correctly analyse and identify the gait phase. This can be seen from the shank angle profile in Figure 10 wherein the profile for the mid stance phase can be correlated with the angular velocity obtained from the gyroscope and the shank angle computed by fusing the inertial sensor data. Similarly, profiles for the other gait phases can be calibrated and studied.

IX. DISCUSSIONS AND CONCLUSION

The feasibility of a multi-sensor wearable platform has been demonstrated for use in monitoring tissue viability in trans-tibial amputees. Both temperature and gait sensors can be used to predict the health of the residual limb in lower limb amputees. In particular, in order to bring about the benefits of being able to use this technology in areas of the developing world where there is no reliable network connectivity or electricity, the sensor platform has been designed to be both low power and low cost. Therefore, the priorities of the design were to use readily available off-the-shelf hardware as possible, to facilitate ease of construction and maintenance of the sensor platform, while also ensuring it had sufficiently low power consumption to make battery-operated operation feasible, with solar energy used to recharge the battery pack. Since the residual limb skin temperature is affected by the ambient temperature to a great extent, the wearable platform will also be interfaced with a temperature sensor to provide information about the ambient temperature in real-time before its deployment. This will enable the presence of the estimation techniques as described previously in an accurate fashion for a non-clinical environment. With the inclusion of estimation techniques in the GPML algorithm we have been able to develop, demonstrate and validate a generalized model for contactless temperature prediction of the residual limb. This estimation technique is an added feature for the wearable sensor platform and is essential in reducing the cost of calibration for the model, thereby making it easier to roll out to a greater amputee population. Cubic spline interpolation or extrapolation was introduced in the model at a given ambient temperature to predict the residual limb temperature profile at another ambient temperature. We have also shown that if the RMSE are subtracted from the respective interpolated/extrapolated value then these estimates are as good as the predicted values which are in the 95% confidence interval. Also, human motion analysis i.e. identification of the various stages of the gait cycle was demonstrated and implemented using a developed wearable sensor system by calibrating the IMU. Sensor data has been reliably collected, transmitted and stored in a secure server application within a Raspberry Pi Zero, allowing for post processing in an offline environment where no internet connectivity is available. This permits a clinician to access and review user data to identify any possible deterioration in health. However, depending on the duration of the wearable platform usage, only a small time snippet of movement and skin temperature is recorded and processed, and this may not be necessarily representative. This remote monitoring platform would prove most useful aid for doctors and clinicians in the developing world, taking into account the unique challenges in such regions (lack of connectivity and reliable power supplies). But it should be noted that it does not do away with the need of having face to face appointments with them.

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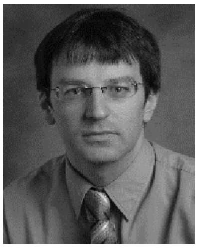

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