Initial Trial of a Telemetric Monitoring System for Prosthesis Use following Lower Limb Amputation

Initial Trial of a Telemetric Monitoring System for Prosthesis Use following Lower Limb Amputation.

Schofield T [1], Harting M [2,6], Britton D [2,6], Graham L [3], Campbell G [3,4], Lee B [1,5], Cundell J [3,5], Vincent J[5], Cleland I [5], O'Connor G [1]

Introduction

For lower limb amputees, prosthesis use is critical for achieving independent mobility and enhancing quality of life. However, use of a weight-bearing prosthesis is commonly associated with shear stress trauma, inflammation, infection, and residual limb ulceration. Each year, up to 75% of amputees experience skin complications leading to cessation of use, often requiring clinical intervention. At 5 years, there is a 17% re-amputation rate. Diabetes affects up to 75% of amputees, with resultant sensory and immunological impairment, and is associated with late presentation with advanced skin complications. Identification of skin complications is currently based on subjective self-inspection, or routinely-scheduled clinical visits.

In the residual limb, local temperature and moisture changes are associated with the development of skin trauma and infection. In diabetic foot studies, temperature changes have been shown to precede skin breakdown. Potentially, changes in local temperature and moisture within the socket of a prosthesis can identify early skin inflammation, before the onset of ulceration. This may create the opportunity for an 'early warning' indicator, to limit the progression of skin damage and to inform limb management and rehabilitation planning. Direct skin monitoring of the limb within the prosthesis during use has proven problematic, and potentially unsafe.

This study was developed to assess the feasibility of a **prosthesis-based sensor** using standard communication protocols in transmitting real-time analysis of the socket environment.

Objectives

- To assess the **functionality** of the multimodal sensor system embedded in a polyethylene closed-cell foam **(Pelite)** liner in a lower limb prosthesis, during routine use.
- To assess the **transmission** and communication of sensor data in routine prosthesis use.
- To assess the correlation of the monitored sensor parameters with the **socket environment** changes within the prosthesis.

Methods

20 established amputees recruited to a one-month trial. The wearable electronics sensor was built into the pelite liner, and had no direct skin contact. Participants were requested to provide daily socket comfort scores and report on difficulties concerning system or prosthesis.

- **20 established transtibial amputees**, living independently, requiring renewal of a patella-tendon bearing pelite socket liner. Enrolment for **4-week** study period.
- **Multimodal sensor** was embedded in the liner base, with a perforated pelite separator.
- **No** direct skin contact.
- **Sensor data** recorded at 10 minute intervals:
  - read-on-demand system, interrogated by the mobile phone, equipped with a multimodal sensing capability
  - large area temperature sensor, directly measuring the socket temperature,
  - environment reference temperature sensor
  - humidity sensor,
  - three-axis accelerometer
  - raw data in native format transmitted in the Bluetooth.
  - mobile phone provides a time-stamp and GPS information.
- Bluetooth data communication to mobile phone app and cloud.
- Daily **Socket Comfort Score** and 'problem' record.
- Offline Post-study exploratory **data analysis**.

This study is supported by Innovate UK project "*Non-Invasive Telemetric Sensing for Lower Leg Amputee Surface Skin Management*" (project number 103947)

Results

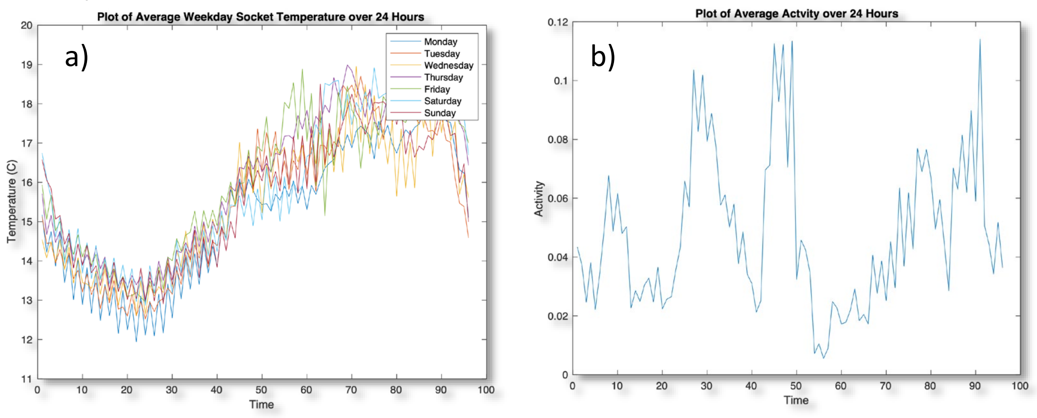
20 participants recruited:
- 3 participants withdrew – (study coincided with Covid pandemic).
- 1 participant deceased prior to commencement.
- 1 sensor system malfunction – use of concurrent silastic liner.

15 participants studied:
- 4 experienced data loss due to mobile phone signal interruption
- During study, 2 had prosthesis discomfort + 2 had skin inflammation leading to cessation of use.
- In total, **66 weeks** of data were obtained for analysis.

Sensor Data Reliability:
- Sensor 'drop-out' rates and **missing data values averaged 5-6%** overall.
- The battery level of all sensors was stable over the course of the study.

DATA ANALYSIS

ACTIVITY & TEMPERATURE data reflected the different patterns of prosthetic use, and the pattern of diurnal variation. Examples:



The temperature profiles were determined by both the large area sensor close to the skin (external sensor) and a sensor on the circuit board inside the pod (internal sensor). The time scale is expressed as the percentage (0 – 100) of the day from midnight-to-midnight UTC.

Figure 1. a) temperature averaged for individual days in the week over the entire monitoring time, b) activity throughout the day, averaged over all days.

INDIVIDUAL DATA

Patterns of temperature, humidity, mobility and activity were obtained for each participant. Below is a sample analysis from one participant chosen at random

Enhanced activity in the afternoon, until 18:00, is correlated with the change in temperature. The mobility, defined as the total distance travelled in the last hour determined from cell phone GPS, shows a similar behaviour indicating walking activity. Exercise is accompanied by a steady increase in humidity. As expected, activity leads to an increase in limb temperature, and hence increased socket temperature. Ten participants showed a temperature rise, lagging behind activity, which continued at least 30 minutes after activity ceased. In contrast *eight* participants exhibited a considerable **temperature increase, independent of activity**. Of these, *five* had discontinued prosthesis wear within two days after that event, citing **SKIN PROBLEMS.**
These observations have allowed the development of other performance metrics, including the lag between activity and socket temperature and the lag between the reference and socket temperatures, both derived from normalised differences. The latter also proved to be an excellent indicator of whether the prosthesis is being worn or not.

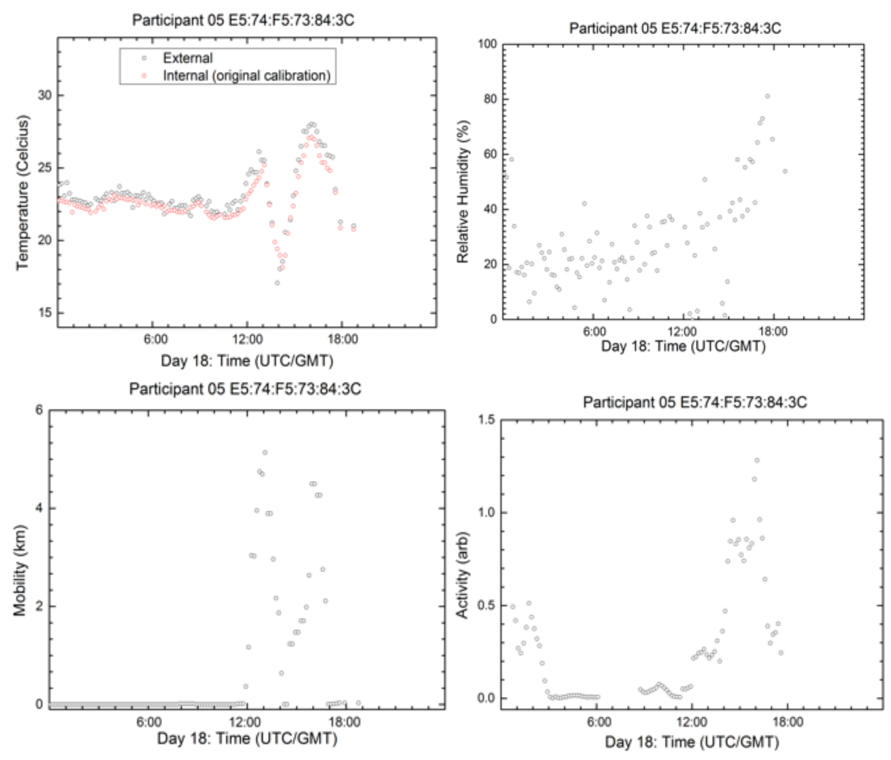


Figure 2: Participant P05 (chosen at random as an example): **Temperature, humidity, activity**, and **mobility** for a 24-hour period.

Conclusions

- Results of this Phase I study have indicated that the **sensing platform** is robust, and the data collected is reliable. Using the system, it is possible to obtain unbiased information concerning prosthesis wear.
- Data from the study confirmed that, although a **rule-based alerting strategy** can be the same for all participants, each has their own baseline behaviour and characteristics. Hence the algorithms need to be personalised by implementing adaptive adjustment of the thresholds.
- Predictive analysis techniques can highlight trends that may enable timely intervention.
- Further developments will focus on applying machine learning to data collected in a **Phase II trial** to test a new provision of care for amputees.

Affiliations

[1] Bioflex Yarns Ltd, Belfast N Ireland, United Kingdom
[2] Dept of Physics, University of Cape Town, Rondebosch 7701 Cape Town, South Africa
[3] Belfast Heath & Social Care Trust, Musgrave Park Hospital, Belfast N Ireland, United Kingdom
[4] Opcare Ltd, Belfast N Ireland, United Kingdom
[5] Ulster University, Belfast N Ireland, United Kingdom
[6] PST Sensors Europe Ltd, Sedgefield England, United Kingdom