Interface Monitoring System to Promote Residual Limb Health

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Background

The interface between a prosthesis user's socket and residual limb is often problematic, with socket fit and suspension issues leading to residual limb problems (Fig. 1). This proposal builds on development of thin, flexible, and stretchable epidermal sensor technology capable of transforming healthcare from reactive and hospital-centered to preventive, proactive, evidence-based, and person-centered. This new sensor technology offers 'skin-like' properties to enable intimate, complete non-invasive integration with the patient. The epidermal sensor shown in Fig. 2 [1] may allow clinicians to monitor their patients, and the general public to assess, continuously, their health and well-being. These epidermal sensors allow us to develop the proposed interface monitoring system, designed to promote residual limb health in persons who wear prostheses.

*Fig. 1 Residual limb problems **(a)** & **(b)** ulcers **(c)** invaginations*

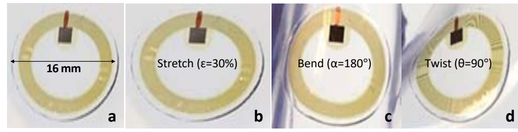

*Fig. 2 Epidermal sensors **(a)** undeformed **(b)** stretched **(c)** bent **(d)** twisted*

Aims

Work on this project involves collaboration across institutions to:

1. Develop 'skin-like' temperature, pressure, and shear sensors, with wireless operation that operate inside a prosthetic socket.
2. Develop computational modeling and algorithms for statistical signal processing of the sensor data and pattern recognition to create a user-friendly interface for clinicians and patients.
3. Apply the proposed sensor technologies and data processing and pattern recognition techniques to prosthetic clinical practice. The continuous capture, storage and transmission of sensor data are critical to the design of lower limb prosthetics for improved health and healthcare.

Sensor Development

We developed a wireless sensor-reader system (Fig. 3) that can collect temperature data beneath a prosthetic socket. We are also developing piezoelectric pressure sensors to examine socket-limb interface pressure when the prosthesis is worn.

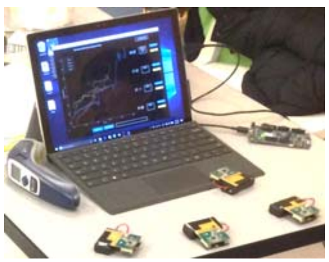

Fig. 3 The reader system includes a reader card, readers, and the logging software.

Wireless Sensor-Reader System Capabilities

- Data from multiple sensors can be collected simultaneously for an estimated 5 hours.
- Reader cards can transmit sensor data wirelessly to a computer up to 10 meters away.
- Data can be viewed on a real-time data plot on the computer.
- Sensors adopt an ultrathin (<1 mm), soft design to minimize irritation at the skin interface, with sufficient durability for reliable use when worn beneath the socket (Fig. 4).

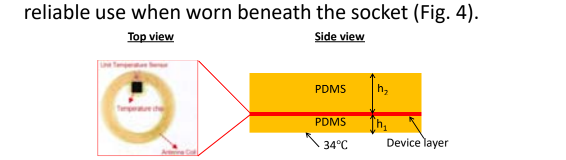

Fig. 4 The sensor components and the magnetic loop antenna for wireless power and data transmission are located between two soft layers of the elastomer poly(dimethylsiloxane) (PDMS) to ensure durability and to provide soft interfaces with excellent thermal coupling to the skin.

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Clinical Application

Focus Groups Used to Gather Stakeholder Input

Information gathered from prosthesis users and certified prosthetists indicate that efforts to develop a residual limb monitoring system should focus on temperature and pressure as priorities, preferably for short-term troubleshooting of socket issues that cause residual limb problems.

Temperature Data Validation

To confirm that the sensors provide valid temperature data from within the prosthesis, we assessed the temperature readings by comparing them to commercial thermocouples. We collected data on an able-bodied subject wearing a below-knee prosthesis simulator. Temperature readings from our sensors were within ±1.1°C of the thermocouple temperature readings.

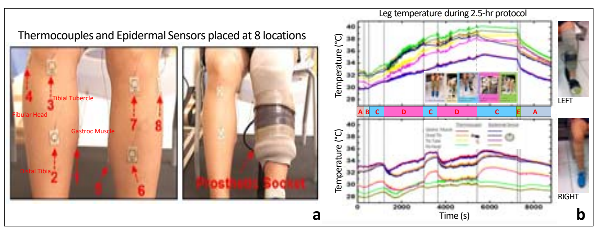

*Fig. 5 **(a)** Able-bodied subject wearing prosthesis simulator and **(b)** leg temperature during set activities*

Testing on a Below-Knee Amputee Subject

The epidermal sensors were tested for 5 consecutive days by a below-knee amputee, confirming that they did not cause any skin irritation or discomfort and that sensors survived at least a day of socket wear. Collection of temperature data highlighted issues of connectivity between the sensor and reader to be addressed.

Fig. 6 Epidermal sensors on residual limb

Fig. 7 Readers attached to exterior of prosthesis

Signal Processing

We reviewed existing literature regarding temperature measurements inside prosthetic sockets and developed initial measurement models of the fluctuations in skin temperature as it relates to residual limb health. To develop an initial understanding of leg temperature, we collected data using commercial thermocouples. One able-bodied subject performed a set of activities (Fig. 5) while wearing a below-knee prosthesis simulator for two socket conditions representing a good and poor fit. Different methods of data analysis were then developed to quantify the spatial and temporal dynamics of thermal recordings.

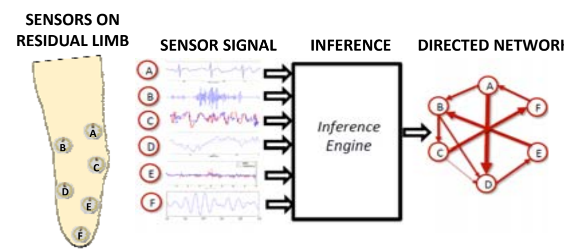

Fig. 8 Conceptual model of the sensor signals of various modalities being inferenced

We utilized Directed Information Graphs estimated from the 8 simultaneous time series pertaining to temperature recordings. The directed information, a measure shown to be consistent with Granger's notion of causality, is able to capture nonlinear relationships [2]. Fig 9. shows initial estimates of directed information capture thermal dynamics for left and right legs. Our next step is to utilize graph-based statistics and machine learning methods to provide decision support tools for optimal socket usage.

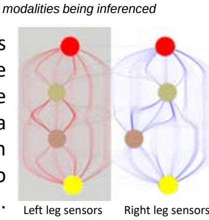

Fig. 9 Directed Information Estimation of Temperature Sensors. *Colored nodes represent thermocouples located in the same location as Fig. 5(b). Each node has outgoing edges and ingoing edges indicative of the directed information flow, giving us an understanding of the dynamics of temperature profiles.*

References

[1] Kim et al. (2011). "Epidermal electronics." Science 333(6044):838-843.
[2] Quinn et al. (2015). "Directed Information Graphs." IEEE Transactions on Information Theory, 61(12):6887-6909.