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A Novel Measurement Device for Volume Management in Lower Limb Amputees: A Technical Note

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Abstract

Many amputees suffer from irritation and wounds as a result of poor residual limb volume management. Reasons contributing to failure to maintain volume properly include peripheral neuropathy, cognitive impairment, and social/cultural issues. Amputees commonly use socks of various thicknesses to account for diurnal limb volume loss. However, data relating to sock compliance is lacking due to an absence of a reliable way to collect usage data. A device was fabricated utilizing wireless RFID and socket-limb interface force detection technology to track sock usage and activity of an amputee. Pilot data was collected through both in-lab and out-of-lab protocols. The collected data showed encouraging results tracking interface force data, however accurate sock data collection was difficult. Suggested solutions include designing a more effective antenna and using the interface force data to detect limb presence to start a tag accumulator algorithm. Clinical applications for the Sock Monitor include intervention through alerting the amputee of a need for a sock change before tissue damage occurs and evidence for prosthetists to justify insurance reimbursement for components and socket replacements. The next step is to use a new prototype with better hardware and firmware to collect real-world usage data from a large group of amputees. A predictive model will be made and implemented to determine if intervention in sock usage improves comfort and limb tissue health.

Keywords

prosthetics; monitoring; RFID

I. Scope

The paper describes a novel measurement device for monitoring lower limb amputee sock usage, prosthesis accelerations, and interface forces. A background containing justification and previous related research is included. Pilot data collected from a prototype device is discussed. In addition, clinical applications for a commercialized version are discussed.

II. Background and purpose

An amputee uses a prosthesis to restore his or her ability to ambulate. The interface between the prosthesis and limb is the socket. This interface must provide a secure and reliable mechanical connection. Failure to maintain this connection can lead to irritation or tissue damage and potential subsequent mental, social and economic hardships resulting from loss of mobility. Whereas the socket is a fixed volume, the amputee residual limb fluctuates in shape and volume throughout the day, changing the quality of fit [1]. To compensate for this change, amputees currently have a limited set of technologies to choose from - stump socks, elevated vacuum systems, and variable socket geometry technology. The most affordable technology is stump socks at around \$10 - \$20 per sock compared to \$1000+ for the other systems. These socks are made of various materials, in several thicknesses. As the limb shrinks, the amputee applies progressively thicker socks to fill the void that is created. This requires the amputee to not only change the socks when necessary, but to perceive the need as well. An amputee may not notice the socket is no longer fitting properly due to peripheral neuropathy or cognitive impairment. Another issue with socks is unknown patient compliance with their use. If an amputee develops an injury on their residual limb, the prosthetist or physician relies exclusively upon the amputee to self-report sock and prosthesis usage. This method has been shown by Stepien et al. to be unreliable [2]. To investigate these problems, a low cost monitoring system is proposed.

Data on amputee sock usage is lacking. Previous research suggests if amputees were to correctly manage their stump socks, socket comfort would improve [3]. It is also thought that the incidence of limb soft tissue injury would be reduced. Dillingham et al. further highlight the need for a means to better manage diurnal volume fluctuations considering 57% of respondents to a survey indicated dissatisfaction with the comfort of their prosthesis and 24% reported either irritation or wounds due to their socket [4]. To address these issues, a prototype device was fabricated and evaluated, the results are detailed in [5]. Briefly, the device consisted of a microcontroller that followed a simple call and response protocol with a High Frequency (HF) Radio Frequency Identification (RFID) module. Utilization of RFID technology has the benefit of wirelessly tracking a tag without the need to power the tag being tracked. This feature allows for an unobtrusive and very small piece of hardware to be attached to a sensitive area of the limbsocket interface. The microcontroller housing, with an HF RFID antenna built inside the enclosure, was mounted to the exterior of a subjects socket, and RFID tags were placed on the subjects socks. The results showed that such a system was feasible. However, the HF system was prone to collision issues - where signals from multiple tags interfere - and issues related to the orientation of the RFID tags relative to the transmitting antenna. To address the deficiencies of the HF system, a new prototype was fabricated using an Ultra High Frequency (UHF) RFID system. In addition, a Force Sensing Resistor (FSR) was used to monitor the residual limb interface pressure near the proximal gastrocnemius.

The proposed system would first be used as a research tool to observe and quantify sock usage patterns for lower limb amputees who effectively manage their limb volume using socks. After collecting a sufficient amount of data, a predictive algorithm based on amputee activity would be generated, associating activity with sock changes. The algorithm would

then be implemented on the monitoring system and alert the amputee by some visual, tactile or auditory means when a sock change is needed. The expected outcome of this system would be improved amputee socket comfort and reduced incidence of residual limb tissue injury through regulated sock management.

III. Design

The initial UHF prototype used to collect data was a composite of various commercially available parts. A data logger (Sparkfun #WIG-10216, Logomatic v2) was connected to a UHF RFID system (CAEN, R1230CB-Quark Ultra Compact Embedded UHF RFID reader), a FSR (Sparkfun #SEN-09375), and powered by a 2Ah lithium polymer battery (Sparkfun #PRT-08483). Data was written to a 2GB micro SD card. The whole assembly was then secured to an ABS project box. Since the firmware initially installed on the Sparkfun data logger did not provide sufficient control of the various functions, an open source alternative was used named Logomatic Kwan Firmware v1.1 written by Chris Jeppesen. This firmware was further altered to allow sampling of the RFID system at 5 second intervals and FSR at 25Hz. Figure 1 shows the components of the monitor taken out of their case and posed without the FSR or antenna wires shown. Figure 2 shows a simplified block diagram for the sock monitor.

The whole system was attached to the pylon of a prosthesis by tying strings attached to the box around the subject's pylon. Wires for the FSR and antenna were routed to the interior of the socket as seen in Figure 3, and the box wrapped with an ace bandage. An exterior wrapping of self-adhesive sports tape provided additional security. Each socket required the fabrication of a custom antenna, the design of which varied according to the socket material. Plastic and fiber glass composite sockets had a simple dipole antenna, while carbon fiber sockets had a more complicated dipole antenna due to increased attenuation. In either design, 19.05mm Kapton tape was placed on the socket surface directly under where 12.7mm copper tape was to be placed. The copper tape was soldered together at joints and conductivity tests performed to ensure there were no shorts between poles. Coaxial cable was wired to the copper tape and connected to a network analyzer to ensure the antenna was properly tuned. 25mm × 25mm square RFID tags (Alien Technology ALN-9629) for socks were either taped onto subjects socks or placed inside of pouches made of nylon stockings. These pouches were then sewn onto the socks of subjects testing the device.

IV. Methods and results

Data was collected on 16 subjects using two separate protocols. Due to time constraints on installation set by the subjects schedules, either FSR data was collected or FSR and sock data was collected. Subjects were included in the study if they had a transtibial amputation more than 18 months prior, they were K-2 (Medicare Functional Classification Level) or higher ambulators, and their socket fit deemed acceptable for regular use by the research prosthetist. Subjects were excluded if they had current skin breakdown.

A. In-lab Protocol

The in-lab protocol was a series of activities performed under supervised conditions to both aid in identification of patterns for various modes of ambulation, as well as verify the functionality of the sock monitor device. The activities performed included timed donning/doffing, squatting, elevation of the prosthesis, walking, ascending and descending stairs, stuffing socks into a doffed prosthesis, and jumping. These activities were chosen because they represent common activities performed by amputees. The activity of particular interest from this list, was the sock stuffing test. Anecdotal evidence from amputees suggests that amputees will commonly doff their prosthesis while sitting and remove their socks for reasons of comfort. They will then stuff their socks into the empty socket. During this protocol, the subject wore socks mounted with at least one RFID tag. A summary list of the first protocol is shown below.

- Don/Doff Socket
Subject dons and doffs socket with 10 second rests in between each donning and doffing. This is repeated 3 times.
- Squatting
Subject performs 3 squats with a 10 second stand before and after squatting.
- Elevated leg raise
Subject sits in chair and places affected limb with prosthesis donned on chair in front of where they are sitting for 20 seconds. The subject then adjusts their posture continuously for an additional 20 seconds. The subject then rests in standard sitting position for 10 seconds.
- Treadmill walk
Subject walks for 60 seconds at a self-set pace.
- Stair descent and climb
Subject descends staircase in building to first landing and returns to top of stairs with 10 second rest at top and bottom.
- Socket Stuffing
Subject doffs their prosthesis, removes their socks, and places them into empty socket. A 30 second rest period is observed before the subject removes the socks and an additional 30 second rest is observed.
- Optional jumping
Subject stands still for 10 seconds before jumping at a comfortable height and pace for 10 hops. Subject then stands still for 10 seconds.

B. Out-of-lab Protocol

The second test protocol used was to mount the device onto the prosthesis and let the amputee leave and perform their typical daily activities and return 24–48 hours later for removal of the device. The purpose of this protocol was to collect real world data under

unsupervised conditions. This would then be compared with the in-lab protocol to aid in the classification of activity. While wearing the Sock Monitor under the second protocol, amputees were told to perform all their routine activities as if the sensor was not there.

C. Results

In-lab protocol: Fig. 4 and 5 shows the resulting FSR data and sock data respectively from an in-lab test. During this test, the subjects sock was fitted with 3 RFID tags held on by strips of paper tape. The tags were arranged axially on the posterior gastrocnemius from approximately 70mm from the most distal tip of the limb and separated by approximately 30mm. The RFID system was only able to successfully detect the most distal tag and momentarily detect the middle tag twice during the test. There were two instances of tags failing to be detected and one instance of tags being detected when it was not desired. However it is important to note that extraneous counts were expected during the sock stuffing procedure. The FSR data showed clear qualitative patterns in walking, sitting, standing, and walking up versus down stairs. Other activities such as jumping and squats were not as clear to discern. These results from the FSR were common among the other subjects.

Out-of-lab protocol: Out of the 16 subjects that participated in either pilot data collection protocol, 12 recorded both sock and FSR data either in or out of the lab. Three of the 12 participated in multiple sessions. To quantify the success of the sock monitor collection, the FSR value was compared to the number of tags detected at a shared time stamp. If the FSR value was non-zero and the tag count was zero, or if the FSR value was zero but the tag count was non-zero, then the detection was considered an error. In other words, if no tags were detected during an inventory and the FSR indicates the presence of a limb, or if there is a non-zero tag count but the FSR indicates the absence of a limb, then there was an erroneous detection or lack of detection during that inventory cycle. In order for a tag to be counted, a limb must be in the socket. Likewise, there should not be any tags counted while the limb is not in the socket. The number of errors would be summed and divided by the total number of inventories to get an error percentage. This value was then subtracted by 1 to get the percentage of the reads where there was at least 1 tag successfully detected. Out of all the tests, 54.25% ($\pm 34.31\%$) of the time at least 1 tag was detected. However, in the calculation of this value, when the FSR value is zero and the sock count is zero, detection is considered successful. To get a more appropriate representation of the successful inventory cycles, a second value was computed that considered this comparison as an error. Given this correction, out of all 17 tests, 31.39% ($\pm 26.00\%$) of the time at least 1 tag was detected successfully. One subject that participated in three separate collections successfully detected at least 1 tag 74.65% ($\pm 5.14\%$) of the time. When adjusting for the zero error, the successful detection percentage falls to 55.15% ($\pm 20.82\%$).

V. Discussion

Results from the amputee subject tests showed promising results that overcame the limitations of a previous prototype device. However, the inconsistent detection of RFID tags is concerning. Potential causes and solutions are currently being explored such as a modified

antenna design and coupling FSR data with tag count data to create a filtering algorithm. Previous experiments in antenna design have shown that there is a small detection window where the tags must reside to be detected [5]. This window refers to a region relative to the antenna where tags are able to be detected. It is thought that during the tests the tags are not in this detection window, or may move in and out of the detection window during ambulation, causing the sporadic detection. Additional research in antenna design that would extend the detection area to the whole socket would be beneficial to the project. An alternative solution is to couple FSR data with the tag counts to determine how many socks are worn. For example, while the FSR detects the presence of a limb, software will be accumulating a list of all tags seen until the limb is removed. This accumulated counter value will then represent the number of socks worn by the amputee during a given period of time.

A. Current Device

As a result of the collected pilot data, a second device was fabricated for collection in a second study with a larger population. The device uses a Texas Instruments MSP430F5638 microprocessor to control the operation of the various components. Sensors include an Analog Devices ADXL345 3-axis accelerometer, CAEN R1230CB-Quark Ultra Compact Embedded UHF RFID reader and an Interlink Electronics 12.7mm FSR. The device is powered by a 2Ah lithium polymer battery. Data is recorded onto onboard flash memory. This device has the ability to connect to multiple analog sensors through multiplexed pins and communicate to a computer for purposes of uploading and downloading data via Bluetooth.

B. Clinical Application

A large percentage of the lower limb amputee population experiences skin irritation and wounds as a result of their prosthetic socket not fitting correctly [4]. These wounds can include ulcers, inclusion cysts, calluses, and verrucous hyperplasia [6]. It is thought that with proper volume management using stump socks, both amputee comfort and the incidence of limb injury can be improved. If amputees were to wear this device, the amputee could be alerted when a sock change is needed based off of their activity. As electronics miniaturization and active RFID tag technology improves, this device could allow for wireless communication and powering of embedded sensors. Predictive algorithms could be devised based on other factors such as socket humidity, temperature or strain, rather than activity alone. In addition to improving the comfort for the amputee, prosthetists would not only have the data necessary to know if a socket change is needed but would also have the data to submit to insurance companies for reimbursement. This is currently a significant problem for prosthetists.

VI. Conclusion

The results discussed are largely qualitative in nature and are meant to inform the reader of the potential for this device. The described device overcomes the problem of lack of data regarding amputee sock usage. Currently, there is no reliable way to record usage other than self-reporting. The proposed device gives researchers a valuable tool to accurately and

reliably record the activity and sock usage of an amputee. This device also has the potential to be used as a commercial device to improve socket comfort by actively reminding amputees to change their socks based on a time schedule, activity or some other algorithm.

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Fig. 1. Disassembled view of components posed for documentation, FSR and antenna wires not shown. Quarter is shown for size comparison.

Fig. 2.
Block diagram of Sock Monitor system.

Fig. 3. Sock Monitor mounted to transtibial prosthesis before wrapping applied to pylon and sensor box.

Fig. 4.
Subject 1 FSR data from in-lab testing.

Fig. 5.
Subject 1 Sock usage from in-lab testing.

TABLE I

Summary of successful tag count results.

	Mean	Standard Deviation
%Correct	54.25%	34.31%
Zero-Adjusted %Correct	31.39%	26.00%
Subject 2	74.65%	5.14%
Subject 2 - Zero-Adjusted	55.15%	20.82%