A Wearable Pendant Sensor to Monitor Compliance with Range of Motion Lymphatic Health Exercise*

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Abstract-Lymphedema is a chronic and debilitating condition affecting 1 in 1000 Americans and there is no known cure for it. The optimal lymph flow (TOLF) is an effective preventive exercise program designed to reduce the risks of lymphedema. This paper proposes a portable and wearable medical device to monitor compliance with the TOLF therapy. Specifically, the wearable pendant sensor (WPS), a low-fidelity prototype of the proposed design, is developed and tested in comparison with a markerless optical motion capture system (Kinect) for measurement accuracy during shoulder abductionadduction and flexion-extension exercises. It is shown that the Kendall's Tau between the measurements obtained from the WPS and Kinect devices yields a correlation coefficient $\rho =$ 0.807 for abduction-adduction exercise and $\rho = 0.783$ for flexion-extension exercise with a significance level of p < 0.001, indicating a strong correlation and high statistical significance. Following careful clinical assessment and validation, preliminary engineering design of this paper can be transformed into an Internet of Things (IoT)-based medical device to facilitate telemonitoring of TOLF therapy. Deployment of such an IoT-based device in patient homes can permit remote assessment of motor function to enhance treatment adherence.

Clinical Relevance—This paper documents a WPS with potential to render an IoT-based medical device for monitoring adherence to TOLF exercise program to prevent the risk of postoperative lymphedema.

I. INTRODUCTION

The lymphatic system is responsible for transporting protein molecules throughout the body and any obstruction in the lymphatic vessel leads to fluid build-up that is termed as lymphedema [1]. It is a chronic and debilitating condition that does not have a known cure. Although, the primary cause of lymphedema is genetic, injuries to the lymphatic system and radiation exposure can cause lymphedema. Approximately 40% of breast cancer survivors suffer from lymphedema affecting their quality of life [2], [3]. These patients are additionally affected by physical deformities that lower their self-esteem and degrade their emotional well-being [1], [3]. Patients undergoing any surgery with lymph node dissection face a lifetime risk of developing lymphedema. Programs for educating patients and increasing their awareness about postoperative lymphedema have shown optimistic results in reducing the risks of developing lymphedema [4].

The optimal lymph flow (TOLF) is an effective therapeutic exercise program designed to reduce the risks of lymphedema in post-operative breast cancer patients [5]. TOLF program is a self-care strategy prescribed to patients to promote lymph

flow and optimize body mass index. TOLF program includes easy-to-learn and use exercises such as: (*i*) muscle-tightening deep breathing, (*ii*) muscle-tightening pumping, (*iii*) largemuscle exercises such as walking, and (*iv*) shoulder exercises [5]. Monitoring the patient progress and compliance during TOLF is crucial, as non- or under-performance of exercise, as well as exercising incorrectly, may be detrimental to patient wellbeing. The use of a sensor-based system to track patient motion during exercise can provide feedback to them about the amount and accuracy of their performance and promote homebased telemonitoring, which can potentially reduce the cost of treatment. In [6], a markerless motion capture (MOCAP) device, *viz.*, the Kinect, was used as an exercise guidance system to promote patient adherence for the TOLF program.

MOCAP technologies show promise in detecting limb movements. MOCAP systems are broadly classified as: (*i*) optical marker-based systems (gold standard) [7], (*ii*) electromagnetic position tracking systems [8], (*iii*) markerless optical systems [9], and (*iv*) inertial sensing systems [10], [11]. However, these motion capture systems require trained personnel, which reduces their potential for use in home-based environments. Although [6] uses the Kinect for the shoulder range of motion (ROM) and breathing measurements, the markerless MOCAP devices are sensitive to changes in lighting; have measurement inaccuracies due to occlusion; and can potentially jeopardize patient privacy [11], [12].

Recent advancements in sensing and connectivity have been utilized for wellness, remote monitoring, and patient care. These sensors and connected systems for healthcare applications are broadly classified under the umbrella term "Health-IoT". Furthermore, these systems have enabled patient-centric and individualized treatment. The Health-IoT devices can integrate multiple sensors and promote long-term monitoring from patient homes, reducing the burden of travel, and improving the ability to provide healthcare services to remote locations. In this paper, we propose a low-cost mechatronic device capable of measuring TOLF exercises with potential to render an Internet of Things (IoT)-based medical device. Section II provides insights on the design motivation and methodology for the development of IoTbased wearable sensor for TOLF. Section III describes the design and development of a low-fidelity prototype and preliminary experimental testing for validation of the device. Section IV concludes the paper by suggesting future directions on clinical and home-based evaluation of the proposed device.

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II. DESIGN METHODOLOGY AND MOTIVATION

A. Design motivation

Based on the American Cancer Society's recommendations, the TOLF exercise program was designed for post-operative breast cancer patients to improve the lymph flow in their upper limbs. It was designed for in-person administered therapy with assistance from trained nurses. However, the requirement to perform these exercises at least twice a day (morning and night) [5] with continued support by a skilled nurse is not feasible and cost prohibitive. A homebased TOLF exercise adherence device can enable patients to perform exercises accurately for prescribed repetitions. Moreover, internet connectivity and data-driven analytics can allow patients to perform TOLF at their homes while nurses or therapists can access the data remotely to monitor the patient compliance and performance with the exercise routine. The TOLF consists of seven exercises [6], which require simultaneous monitoring of shoulder ROM and breathing. In our prior research, we have demonstrated that smartphones are effective tools for data-driven assessment [13]. Specifically, smartphones are endowed with powerful on-board processors, sophisticated internet connectivity, and sensors, which can be leveraged for data-driven telemonitoring. Based on the TOLF requirement and ubiquity of smartphones, we were motivated to design a low-cost, portable, and wearable mechatronic device capable of measuring the shoulder ROM and breathing. Furthermore, utilization of smartphone's internet connectivity can enable telemonitoring and treatment compliance.

B. Design methodology

We propose to design a sleeve-based wearable pendant sensor (WPS), to be worn by a user on both the left and right upper arms, for measuring each shoulder's ROM. The wearable sensors are to be embedded with Bluetooth low energy endowed microcontrollers (μ C) for wireless data transfer to the smartphone. A smartphone application will acquire the data from both the left and right WPS devices and the smartphone's microphone will be used to capture the breathing pattern of user. In a prior research, smartphone's microphone has been used to measure the breathing rate for sleep pattern analysis [14]. Additionally, the smartphone application will utilize the internet connectivity to transfer data to skilled nurses through cloud platforms for a seamless databased patient remote monitoring. An illustration of the proposed cloud based TOLF exercise monitoring system is presented in Figure 1.

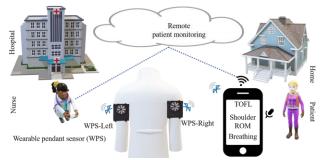


Figure 1. Illustration of proposed IoT and smartphone based TOLF exercise monitoring system

III. PROTOTYPE DESIGN AND EXPERIMENTAL VALIDATION

A. Prototype design and development

The feasibility of the envisioned prototype is realized by developing a low-fidelity proof-of-concept WPS device without Bluetooth connectivity to measure the shoulder ROM during exercises such as abduction-adduction and extensionflexion by the user. In contrast to other angular measurement approaches such as the Kinect, inertial sensors, magnetic sensors, etc., the novel WPS device design utilizes a simple gravity-based contact closure approach for measuring shoulder ROM. Inspired from the conductive tilt sensor of [15], the WPS device consists of eight conductive fabric-based petals encapsulated in a 3D printed enclosure with a pendulum at its center that rotates about a fixed central pivot. With a WPS device mounted on a user arm, the arm movements in 3D space cause the movement of the pendulum due to gravity. Throughout the rotation, the pendulum remains in contact with at least one of the conductive petals, completing an electrical circuit. The petals are connected with eight digital input-output pins of the μC , yielding a measurement resolution of $\frac{360}{8}$ = 22.5°. Additionally, the μ C is connected to: (*i*) a buzzer that provides feedback of the device status to the user and (ii) an SD card for long-term data storage and further processing. Figure 2a shows the schematic representation of the signal flow diagram and electronic components mounted in the WPS device. Figure 2b shows the WPS device designed for the measurement of shoulder ROM during TOLF. Figure 2c shows the schematic of the electrical connectivity of the pendulum and petals sewed to a wearable sleeve.

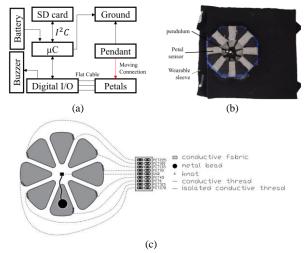


Figure 2. (a) Schematic representation of the signal flow diagram and electronic components mounted in WPS; (b) WPS prototype designed for measurement of shoulder ROM during TOLF; and (c) pendulum and petals sewed to the wearable sleeve

B. Prototype testing

To validate the measurement accuracy of the developed WPS device prototype, we conducted a preliminary study to compare the measurements obtained from the WPS *versus* the Kinect, a commercially available markerless motion capture device. Although, Kinect is inaccurate in measuring ROM, prior literature has reported acceptable shoulder measurement accuracy during: abduction-adduction movements with the Kinect facing the front of the user and flexion-extension movements with the Kinect facing the side of the user under movement [11], [12]. A MATLAB program was created to simultaneously acquire data from the WPS device and Kinect for data storage and further processing. Three users were asked to perform shoulder abduction-adduction movements for five trials each and the measurements from both the WPS device and Kinect were saved for comparison. Next, the three users performed shoulder flexion-extension movements for five trials each and the resulting measurements were saved for Additionally, comparison. as а proof-of-concept demonstration, during one of the exercises, a user was asked to wear a smartphone headset and perform breathing corresponding to a TOLF exercise routine [6]. Figure 3a shows a user wearing the WPS device for performing the abductionadduction exercise and Figure 3b shows the screen capture of the Kinect video feed with a user performing the abductionadduction exercise. Figure 4a shows the time series plot of angular measurements acquired from the WPS and Kinect during the abduction-adduction experiment. Figure 4b shows the time series plot of angular measurements acquired from the WPS and Kinect during the flexion-extension experiment.

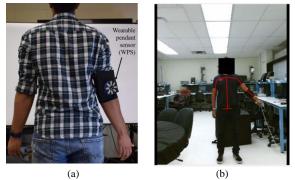


Figure 3. (a) WPS device worn by a user performing shoulder abduction-adduction exercise and (b) screen capture of MATLAB interface simultaneously acquiring data from the WPS and Kinect

C. Data analysis, experimental results, and discussion

The 15 trials $(3_{users} \times 5_{trials})$ for each of the abductionadduction exercises (similarly for flexion-extension exercises) were concatenated to create two time series signals corresponding to the WPS and Kinect. To determine the correlation between the measurements obtained from the WPS device and Kinect, the Kendall's Tau and root mean square error (RMSE) were computed between their measurements. The results of this statistical analysis are provided in Table I. The Kendall's Tau values of greater than 0.75 demonstrate a very strong correlation with a high statistical significance (p < 0.001). Despite the resolution of the WPS being 22.5°, the RMSE between the WPS device and the Kinect is less than 30° , indicating that the developed device performs ROM measurements similar to the Kinect. Figure 5a shows the unfiltered audio signal of the user's breathing and Figure 5b shows the filtered audio signal after the application of a 1000-3400Hz band-pass filter, during an abduction-adduction TOLF exercise (Figure 5c top panel). Finally, Figure 5c (bottom panel) shows the peak envelope of the filtered breathing signal, color-coded to identify epochs for inhale and exhale.

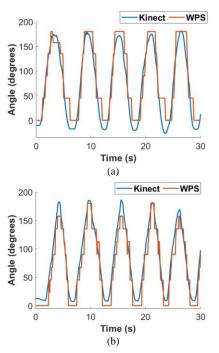


Figure 4. (a) Time series plot of angular measurements obtained from the WPS and Kinect for shoulder abduction-adduction exercise and (b) time series plot of angular measurements obtained from the WPS and Kinect for shoulder flexion-extension exercise

TABLE I.	EXPERIMENTAL RESULTS OF COMPARATIVE STUDY
	BETWEEN WPS VS. KINECT

<u>(1)</u>	Statistical analysis	
Shoulder exercise	Kendall's Tau (p)	RMSE
Abduction-adduction	0.807	21.496°
Flexion-extension	0.783	27.559°

Furthermore, Figure 5c reveals that during the first two trials the user breathing was synchronized with the exercise. However, during the last two trials the breathing did not synchronize with the exercise. The intended application of TOLF compliance monitoring and adherence requires repetition counting, maximum ROM, and synchronization of breathing and exercise, all of which are demonstrably achieved by our prototype. Hence, the proposed design methodology and prototype can be adapted to develop a more robust WPS device suitable for patient use.

IV. CONCLUSION AND FUTURE DIRECTIONS

This paper presented a wearable sensor approach for the design of a medical device to monitor compliance with and adherence to the TOLF exercise program. A low-fidelity mechatronic prototype is developed for experimental verification and the results indicate that there is a high degree of correlation between the data obtained from the developed WPS device and an existing MOCAP system. The testing of current prototype was limited to two TOLF shoulder exercises, however the results indicate that the developed device is capable of monitoring compliance parameters, such as maximum ROM and repetitions. The breathing patterns, an essential component for TOLF compliance, were obtained during one shoulder exercise using a smartphone microphone.

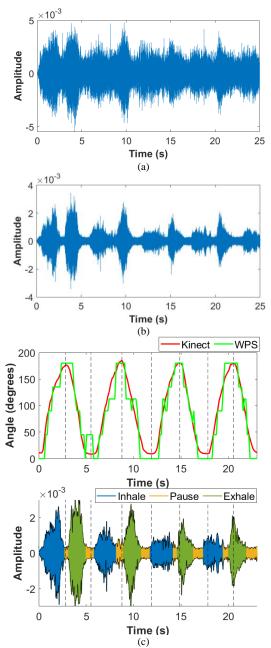


Figure 5. (a) Unfiltered audio recording of a user breathing during shoulder abduction-adduction exercise; (b) 1000-3400 Hz band-pass filtered audio signal; and (c) abduction-adduction exercise and peak envelope of the filtered signal indicating the inhale and exhale epochs

Our future work will integrate shoulder ROM and breathing for holistic compliance monitoring of additional TOLF exercises. A new prototype can be developed by using a μ C with Bluetooth connectivity to render an IoT-based medical device that additionally incorporates machine learning algorithms for automated feedback to patients and nurses. In our prior research, we developed a grasp rehabilitation device using mechatronics [16] that is being used for clinical trials with multiple sclerosis patients in telerehabilitative settings with multiple subjects in New York City [17]. After developing the IoT-based WPS design, similar clinical trials can be conducted to assess the performance and effectiveness of the WPS device with patients, which will improve its potential for commercialization and broader adoption.

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DECLARATION

This paper on the engineering design and testing of the WPS did not entail experiments with human subjects. Preliminary experiments for data collection were performed by the authors themselves. Experiments involving human subjects using WPS will be conducted following the Institutional Review Board approval and reported elsewhere.

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