

Wearable Electrical Stimulation to Improve Lymphatic Function

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Abstract – The lymphatic system is a network of vessels and glands spread throughout the body. It plays a vital role in transport mechanisms and overall functioning of tissues. Lymphoedema is a long-term condition caused by impaired lymphatic drainage. It can lead to skin damage, recurring infections and reduced body functions. This work has developed and tested a fabric based wearable electrical stimulation device for lymphoedema management. The electrodes and conductive interconnections were directly printed onto an everyday clothing fabric using screen-printing technique. The wearable device is lightweight, highly flexible, breathable, conformable, and can be cleaned to enable reuse. Lymphatic imaging was used to identify changes in lymph behaviour resulting from use of the e-textile device. Preliminary results confirm increase in lymphatic function through use of the wearable device.

Index Terms—Wearable technologies, e-textiles, electrical stimulation, lymphoedema, healthcare

I. INTRODUCTION

The lymphatic system regulates tissue fluid homeostasis, immune cell trafficking, and the absorption of dietary fats [1]. Measurement and stimulation of the lymphatic system is a growing field of biomedical research, fuelled by an increasing awareness of its role in cancer growth and metastasis [2]. Failure of the lymphatic system results in much slower, mainly diffusive, movement of nutrients, and the accumulation of waste products. The associated increase in interstitial pressures can lead to tissue swelling or, in extreme cases, lymphoedema. Lymphoedema is generally managed with pressure garments and manual therapies, using constant and/or intermittent loading cycles whose operating profiles are predominantly based on anecdotal evidence. The short-term benefits of these interventions have been demonstrated by improved quality of life measures [3] and changes to limb volume [4]. However, the relative efficacy of these treatments is still uncertain, and minimal differences have been observed between pneumatic compression devices and more traditional therapies (manual drainage and compression garments) [5].

Functional electrical stimulation (FES) has been advocated as a means to stimulate venous flow. It has been demonstrated as an effective intervention for managing the risk of venous thromboembolism (VTE) [6-8], aiding the healing of venous leg ulcers (VLUs) [9] and it is a feasible option for managing post-operative oedema [10]. Despite the evidence of FES as an effective method of promoting fluid transport, there has been limited research on the use of stimulation on individuals with lymphoedema. Small

observational studies indicate that the treatment is effective compared to no intervention [11] and its relative efficacy is comparable to standard treatment options [12]. However, to date, ergonomic electrical stimulation textiles that can be incorporated into garments have not been developed.

Advances in materials technology and fabrication methods now enable electronic devices to be fabricated on everyday clothing fabrics for wearable healthcare applications, such as health monitoring (e.g. ECG, EEG, EMG) [13-15] and treatment (e.g. stroke rehabilitation) [16]. Screen-printing is a straightforward and cost effective fabrication technique widely used in both the textile and printed electronics industries. It can facilitate significant freedom in terms of pattern designs and geometries. The materials are only printed on the area where it is necessary, allowing the device to retain good flexibility and breathability. In the present work, a screen-printed electrode device is developed with the aim of improving the lymphatic functions via electrical stimulation. The device was evaluated in a small healthy cohort to evaluate changes in lymphatic behaviour.

II. WEARABLE DEVICE FABRICATION AND TEST

A. Fabric electrode fabrication

The wearable device was made by printing four functional layers on a polyester/cotton fabric. The top views of the resulting patterns after printing each layer are shown in Fig 1-Fig 4:

- i) An interface layer (Fabink UV-IF1004) to provide a smooth

surface on the fabric;

- ii) A conductive silver layer (Fabink TC-C4007) to form the conductive pads and the interconnections;
- iii) An encapsulation layer (Fabink UV-IF1004) over the interconnections to provide protection for the conductive tracks and electrical insulation;
- iv) A carbon loaded rubber dry electrode layer (Fabink TC-E0002) to form a good connection between the conductive pads and the skin.

A detailed description of the printer, screens, printing and curing processes used in the electrode fabrication is available in a previous publication [16].

The design shown in Fig 4 was evaluated in this work. The distance between two electrodes is 18 mm which was selected based on both the SENIAM guidance 8 “European Recommendations for Surface ElectroMyoGraphy” [17] and experiments.

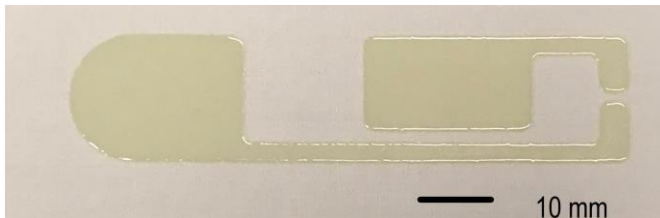


Fig 1. Printing the interface layer onto fabric.

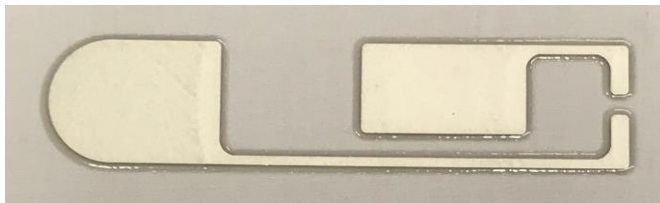


Fig 2. Printing a conductive silver layer onto the interface layer.



Fig 3. Printing an encapsulation layer onto the interconnections.

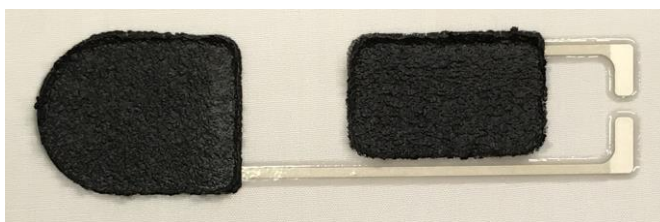


Fig 4. Printing an electrode layer onto the conductive pads.

B. Electronic control system

An electronic control circuit with a footprint of 30 mm in diameter was developed with an LED display function to indicate the level of

stimulation from 1 to 7. Two push buttons were designed into the system to adjust the stimulation level and switch the device on and off. STM8S103F2 microcontroller was used to provide basic stimulation signals, safety mechanism and control of the stimulator. A boost-up converter was used to generate a high voltage to the electrode. The voltage varies depends on the skin impedance but the maximum current applied to the electrode was always kept at 27 mA. The stimulation signal was a 1 Hz square wave but the stimulation level is controlled by varying the pulse width. The details of pulse width variation are shown in Table 1.

Table 1. Corresponding pulse widths at different stimulation levels.

Stimulation level	Pulse width
Level 1	50 μ s
Level 2	70 μ s
Level 3	100 μ s
Level 4	140 μ s
Level 5	200 μ s
Level 6	280 μ s
Level 7	400 μ s

The tolerance of pulse width varied between $\pm 0.5\%$ at 50 μ s to 2% at 400 μ s. The pulse width of lower level was always 0.707 times than that of the higher level. The pulse rise time was designed to be as fast as possible, ideally less than 5 μ s but the decay time depends on the load (i.e. skin impedance). However, the stimulation level wasn't affected by the load variation as the microcontroller automatically adjusted the output voltage. The overall power consumption was around 90 mW under load but, when the system was in sleep mode, only 0.3 mW was consumed.

In addition, a safety mechanism was implemented in both the hardware and software to ensure the maximum stimulation current was always less than 27 mA regardless of the load resistance [18]. The finished electrical circuit board and 3D printed electronic circuit cover are shown in Fig 5 and Fig 6. The electronic circuit was connected to the conductive tracks on the electrodes using two small crocodile clips.

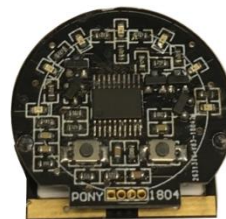


Fig 5. Electrical circuit.



Fig 6. 3D printed circuit cover.

C. Test methods

The effect of the wearable electrodes (Fig 7) on lymphatic function was assessed on a cohort of five healthy participants (3 males, 2 females; age range 21-34 years; BMI range 22.4-31.9kg/m²). These were recruited locally from the University Of Southampton under ethical approval (ERGO-29696). Participants were provided with

information sheets, and written informed consent was obtained. They were initially invited to participate in a screening evaluation.

Lymphatic activity was characterised using a standardized technique involving near-infrared fluorescence lymphatic imaging (NIRFLI). An Indocyanine Green (ICG) contrast agent was injected to help visualise dermal lymphatic vessels [19-20]. To review briefly, ICG was diluted in a saline solution to achieve the required dose for testing (50µL, 0.05% w/v). This micro dose was injected sub-dermally between a participant’s toes by a qualified professional, with a 30 minute non-intervention period for uptake into local lymphatic vessels. Excitation of ICG and video capture of fluorescence emission was achieved using an NIR imaging system (Fluobeam® 800) with associated software (Fluobeam v3.1.1, Fluopotics, France). This system incorporates an integrated laser (780 nm) and CCD sensor, with appropriate filters to isolate fluorescence of ICG (peak 830 nm).

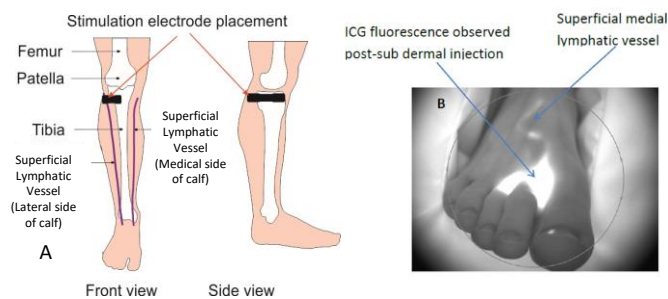


Fig 7. Test set up on the calf muscle and placement location.

Proprietary image processing code enabled the lymphatic activity to be extracted quantitatively from the NIR video data. Lymph packets were identified as bright regions on video frames, and tracked in subsequent frames to measure the number of lymph packets and their movement using a droplet morphometry and velocimetry (DMV) approach [19]. Here image subtraction, binary conversion, and centroid tracking provided the basis to identify and measure each transient lymph packet captured within the 5-minute video sequences. Each transient event was analysed to provide x and y coordinates of the packet centroids, whereby the resultant displacements could be estimated. An extended Kalman filter was applied to ensure that the centroid axes from distinct packets were isolated between the video frames. A lymph packet was defined as a transient event whereby lymph fluid was transported through a vessel >30mm. The minimum fluorescence intensity for detecting lymph events was 20.

All examinations were performed in a temperature and humidity controlled room (24° ± 1° C; relative humidity, 30%-40%). Subjects were asked to wear shorts and lay supine on a plinth with the head supported by a pillow and tilted upward to 45°. A simple A-B-A design was used to assess the effects of the device before (A), during (B) and after (A) stimulation. Stimulation was applied to the common peroneal nerve via the wearable electrode device for a 15-minute period. Lymphatic imaging was acquired for the final 5 minutes of this period. Then after a 15-minute non-intervention period another imaging sequence was carried out.

III. RESULTS AND DISCUSSION

A. Electrode devices

An interface layer of ~230µm total thickness was printed to create a smooth surface on the fabric. The interface layer was built over four printing-curing cycles. After achieving a smooth interface layer on top of the fabric, good conductivity (~0.2 Ω/cm) was obtained by printing a layer of 10 µm thick conductive silver. The interconnections were encapsulated using a ~30µm layer of Fabink UV-IF1004. The thickness of the electrode layer was 2 mm, similar to that of gel electrodes commonly used in electrical stimulation applications. The device had very good flexibility and conformability and it is possible to clean it using either wipes or by washing for reuse. The device was placed over the common peroneal nerve in order to stimulate the calf pump mechanism.

B. Effects on Lymphatic functions

Fig 8 shows the lymphatic behaviour varied at baseline, with normative values similar to that in the published literature [19-20].

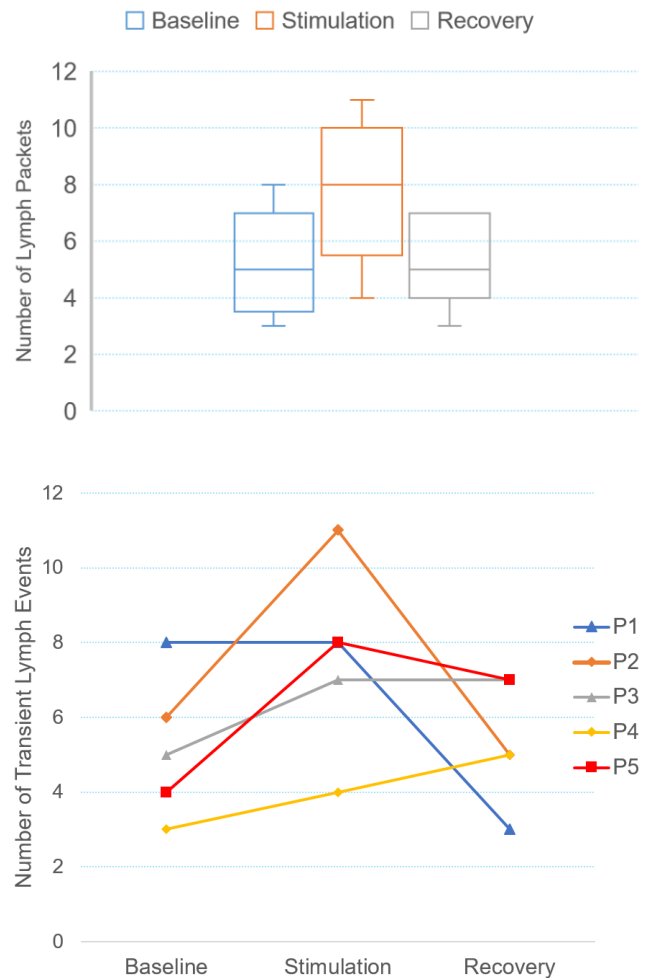


Fig 8. Box and Whisker plots of lymphatic activity pre- and post-electrical stimulation via the e-textile, (top) overall results; (bottom) 5 individual lymph events.

The number of transient lymph events increased during the period of stimulation from a median of 5 (range 3-8) at baseline to 8 (range 4-11) during stimulation over the 5 minute imaging periods. This increase in activity then returned to basal levels (median = 5) during the recovery phase. Four out of the five participants revealed an increase in lymphatic behaviour during stimulation.

IV. CONCLUSION AND FUTURE WORK

This letter has demonstrated the design and fabrication of an electrode based wearable device for improving lymphatic function. The printed device exhibits good flexibility and breathability. The Tests on five healthy individuals revealed an increase in lymphatic behaviour for the majority (4/5) of the participants. This is in agreement with previous studies that have assessed the effects of stimulation on lymphatic behaviour [11-12]. The limited improvements in lymphatic activity observed in one participant (P1), could have been a result of device application, whereby the common peroneal nerve was not stimulated to the same extent on the first participant (learned effect).

Future work will further improve the integration between the fabric electrode and electronic control to remove the wires between the two components. The electrode size will be improved to optimise lymphatic function while minimising the effects on the flexibility and breathability. The device will then be incorporated within a compression garment to assess the effects of dual therapy on cohorts of individuals with lymphoedema.

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