2021 43rd Annual International Conference of the
IEEE Engineering in Medicine & Biology Society (EMBC)
Oct 31 - Nov 4, 2021. Virtual Conference

A Soft Robotic Sleeve for Compression Therapy of the Lower Limb

Luca Rosalia, Kimberly K. Lamberti, Madison K. Landry, Cécile M. Leclerc, Franklin D. Shuler*, Nevan C. Hanumara*, *Member IEEE*, Ellen T. Roche*, *Member IEEE*

***Abstract*—'We present the development of a soft robotic-inspired device for lower limb compression therapy with application in the treatment of lymphedema. This device integrates the control capabilities of pneumatic devices with the wearability and low cost of compression garments. The design consists of a three-layered soft robotic sleeve that ensures safe skin contact, controls compression, and secures the device to the patient limb. The expandable component is made of interconnected pockets of various heights, which passively create a graduated compression profile along the lower limb. The system is inflated by a pump and a microcontroller-actuated valve, with force sensors embedded in the sleeve that monitor the pressure applied to the limb. Testing on healthy individualsq demonstrated the ability to reach clinically relevant target pressures (30, 40, 50 mmHg) and establish a distal-to-proximal descending pressure gradient of approximately 40 mmHg. Device function was shown to be robust against variations in subject anatomy.**

***Clinical Relevance*— This system provides controllable, graduated, compression therapy to lymphedema patients in an economical, portable, and customizable package.**

***Index Terms*—Soft robotics, lymphedema, compression therapy, medical devices.**

I. Introduction

LYMPHEDEMA affects as many as 10 million people in the United States alone and 250 million people worldwide [1], [2]. This condition involves swelling of the extremities, due to the accumulation of excessive lymph in soft tissues and affected individuals suffer from a number of physical challenges, including restricted range of motion, pain, altered sensation, and skin discoloration in the affected limb[3], [4]. In addition, their quality of life is often aggravated by significant emotional and psychosocial sequelae [3].

L. Rosalia and K. Lamberti are with the Harvard-MIT Program in Health Sciences and Technology, at the Massachusetts Institute of Technology, Cambridge, MA 02139, USA

M.K. Landry is with the Dept. of Electrical Engineering and Computer Science at Massachusetts Institute of Technology, Cambridge, MA 02139, USA

C. Leclerc is with the Dept. of Mechanical Engineering at the Massachusetts Institute of Technology, Cambridge, MA 02139, USA

F. Shuler was with the Dept. of Orthopaedic Surgery at the Marshall University School of Medicine, Huntington, WV 25701, USA

E.T. Roche is with the Institute for Medicine and Engineering Science and the Dept. of Mechanical Engineering at the Massachusetts Institute of Technology, Cambridge, MA 02139, USA (etr@mit.edu).

N.C. Hanumara is with the Dept. of Mechanical Engineering at the Massachusetts Institute of Technology, Cambridge, MA 02139, USA (hanumara@mit.edu).

*These authors are senior co-authors and contributed equally.

Compression therapy, the primary treatment for lymphedema, aims to enhance drainage of the lymph from the extremities. This can be administered manually in the form of massages, through the use of compression garments or with pneumatic devices [5]. Compression garments are available in a variety of sizes, styles, and degrees of elasticity, can be worn for a prolonged time and keep the patient fully mobile. However, their efficacy depends largely on their fit to the individual patient's anatomy and their application is especially challenging in patients with a reduced range of motion and at risk of skin damage [6], [7].

Pneumatic devices are recommended for patients who are unable to apply compression garments and, especially, those at risk of wounds. [8], [9]. While broadly varying in complexity, these devices generally consist of an inflatable sleeve that provides compression and a pneumatic pump [10], [11]. Some devices deliver uniform pressure to the limb, by means of a single inflatable compartment, whereas others are capable of producing a spatiotemporal pressure gradient that progressively decreases from the distal to the proximal segment of the limb in an intermittent or peristaltic manner [12], [13]. However, the use of pneumatic devices remains limited due to their elevated cost and poor portability [10].

This work presents the development, prototyping and testing of a soft robotic device for lower limb compression therapy. The system is designed to meet therapeutic needs, while combining the wearability of compression garments with the control capabilities of existing pneumatic devices.

II. Methods

A. System overview

An overview of the system is shown in Figure 1. This device consists of an inflatable compression sleeve, engineered to apply graduated pressure along the limb, sandwiched between a breathable, washable, skin protective inner layer and a durable outer layer. The entire sleeve wraps around the limb and can be gently secured with Velcro straps. The applied pressure is generated by the microcontroller-regulated pneumatics with pressure feedback. Once the target pressure is reached, the pump and valve system can be disconnected from the sleeve, leaving the user mobile. In the event of overinflation, a relief valve is provided for manual decompression.

978-1-7281-1178-0/21/$31.00 ©2021 IEEE

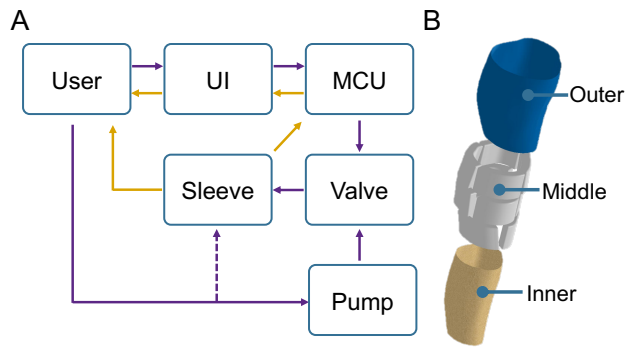

Fig. 1. System and workflow overview. A) Flow diagram showing the relationship between the user and the components of the system. B) Exploded representation of the three layers of the compression sleeve. UI: user interface. MCU: microcontroller unit.

B. Mechanical design

Figure 1B depicts the three layers of the compression sleeve, which was fabricated using techniques developed for the soft robotics field [14]. The inflatable bladder consists of three rows of air-filled pockets that expand under pneumatic pressure to provide compression to the limb (Figure 2). The pockets' heights increase from the proximal to the distal end of the bladder (h = 0.5, 0.75, 1.25 cm), delivering maximal pressure at the ankle and minimal pressure at the knee.

The pockets were manufactured by vacuum forming and heat sealing. The positive mold (Figure 2A) was 3D-printed (Objet 30, Stratasys) and used with a Dental Vacuum Former (Yescom) to shape two thermoplastic polyurethane (TPU) sheets (HTM 8001-M polyether film, American Polyfilm, Inc) into the pocket geometry. The negative mold (Figure 2B) was laser cut from acrylic to define the pockets' outline. A heat press (QXAi, Powerpress) sealed the two layers together, creating an enclosed compartment (Figure 2C).

An inextensible fabric (Oxford fabric, Seattle fabrics Inc.) was then heat-sealed to one side of the bladder. Once secured to the limb, the discrete pockets abut and form a contiguous surface. The outer layer ensures inward expansion of the pockets to guarantee maximal compression for optimal therapy outcomes. The inner layer consists of soft fabric.

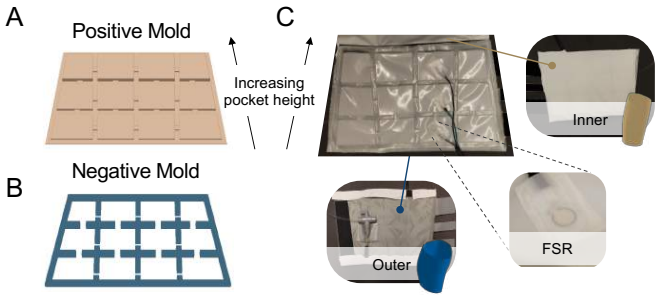

Fig. 2. A) Positive and B) negative molds utilized in the manufacturing of the compression sleeve. C) Illustration of the prototype, with details of the inner layer, the FSRs, and of the outer layer.

C. Control

The control module is composed of a user interface (UI), an electrical pump, a solenoid valve (2 way, 2 position, McMaster-Carr), a battery, force sensitive resistors (FSRs) (Flexiforce A301, Tekscan), and a microcontroller unit (Teensy 3.2, PJRC). The UI includes an OLED screen, which displays the user-defined target pressure and the real-time average of the three FSRs, and buttons to define the target pressure. One calibrated FSR is placed on the central pocket of each row, providing readings for the proximal, middle, and distal positions along the compression sleeve.

During application, the user connects the pump and valve assembly, sets the desired target pressure on the UI and manually activates the pump. The system switches to an active state, opens the solenoid valve, and allows air to flow from the pump into the bladder. Once the FSRs indicate that the target average pressure is reached ($\pm 5\,\mathrm{mmHg}$), the valve is closed, and the system moves to the neutral state. The bladder stops inflating and the pump can be manually turned off and disconnected from the sleeve together with the solenoid valve and microcontroller unit.

D. Assessment

The function of the prototype was tested by members of the team (age = 26 $\pm$ 2.6 yr, 2 males, 1 female) with variable leg sizes and anatomies to determine whether each target pressure value could be reached accurately and maintained over short period of time. As an indicator of variability, the subjects' body surface areas were calculated with the Du Bois method [15]. In addition, we sought to determine the scale and consistency of the pressure gradient generated along the limb of choice and across subjects. A single device must accommodate this variation, since the degree of swelling may vary significantly with disease progression.

Testing involved assessment of the steady state response at three different target pressures within the range of clinical use, namely 30, 40, and 50 mmHg. Steady state values were computed by averaging each sensor reading for a total of 10 sec, 5 sec after valve closure. For each test, the portable pump was activated with an input set pressure of p_{in} = 3 psi (155 mmHg), higher than the target pressures. This test was conducted five times (n = 5) for each target pressure. (MIT Committee on the Use of Humans as Experimental Subjects Protocol 2107000447.)

III. Results and Discussion

A. Device control and pressure gradient

Figure 3A illustrates the sleeve prototype wrapped around the lower limb, with details of the Velcro straps and relief valve. Representative inflation curves are shown in Figure 3B, while the corresponding steady state mean and standard deviation are summarized in Figure 3C. This shows moderately better control at intermediate and higher target pressures, as indicated by comparison of the corresponding

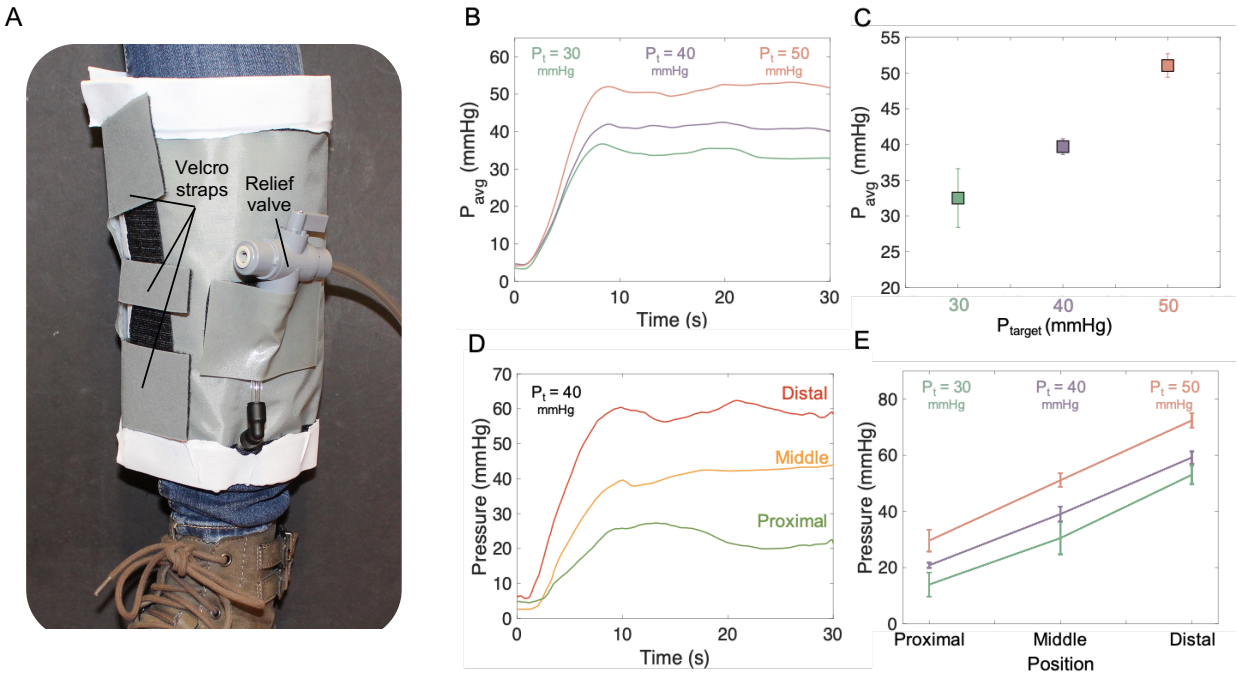

Fig. 3. A) Illustration of the sleeve around the calf. Average pressure readings at different target values (30, 40, 50 mmHg), B) throughout inflation, and C) at steady state. D) Representative pressure readings of the proximal, middle, and distal sensors over time for one target pressure (40 mmHg). E) Steady state proximal, middle, and distal pressures at different targets (30, 40 and 50 mmHg), showing an approximately linear pressure gradient along the limb.

error bars. These plots also highlight that the pressure exerted by wearing of the device alone remains negligible prior to inflation ($p_i = 4.2 \pm 0.5$ mmHg), indicating that the fastening mechanism does not apply significant pressure to the limb. This minimizes the risk of skin damage in proximity of the attachment points.

The pressure gradient generated along the lower limb is shown in Figure 3(D-E). Figure 3D shows a representative inflation curve at one target pressure (40 mmHg) for the three FSRs. The corresponding steady state average and standard deviation values for each individual FSR at three target pressures (30, 40, 50 mmHg) are shown in Figure 3E. These results highlight that an approximately linear distal-to-proximal descending pressing gradient of 38.4 ± 1.9 mmHg is achieved, enhancing lymph drainage.

B. Inter-subject device performance

Results from the three subjects are summarized in Figure 4. Measurements of the steady-state average pressures at the target value of 40 mmHg are shown in Figure 4A, and the distal, middle, and proximal pressure readings for each subject are illustrated in Figure 4B. These results demonstrate that this device is robust against anatomical variations, since it continues to achieve user-defined target pressures, within a small tolerance, and consistently generate a distal-to-proximal gradient across the subjects. It should be noted that the pressure gradient for subject 3 (BSA = 2.24 m^2) is lower (23.2 ± 4.0 mmHg) than in subject 1 (BSA = 1.67 m^2) (38.4 ± 1.9 mmHg), and 2 (BSA = 1.78 m^2) (34.7 ± 9.3 mmHg), indicating a moderate negative correlation between BSA and pressure gradient.

C. Limitations and Future Work

This work highlighted that further design developments and testing may be required to more comprehensively characterize device function and clinical impact, especially in the context of the target patient population.

Firstly, the use of a limited number of embedded sensors limits the amount of real-time information on the pressure distribution to a relatively small portion of the limb. Studies of the spatial pressure distribution should be conducted through a combination of computational and experimental methods. Finite element analysis could be used to optimize the bladder geometry to ensure that pressure is applied uniformly around the limb and that pressurization does not result in contact stress points, which would increase the risk of wound formation. Use of an increased number of sensors or of force sensing technologies with a larger area could improve feedback on the spatial pressure distribution.

Secondly, since skin and wound care may require lymphedema patients to remove and re-apply compression garments several times every day, leading to possible variations in the orientation of the sleeve around the lower limb, the effect of variations in sleeve positioning and orientation should be investigated with appropriate modeling or testing.

Finally, our analysis demonstrated that this device is robust against anatomical variations, although a small effect on the pressure gradient generated by the device was seen. This may

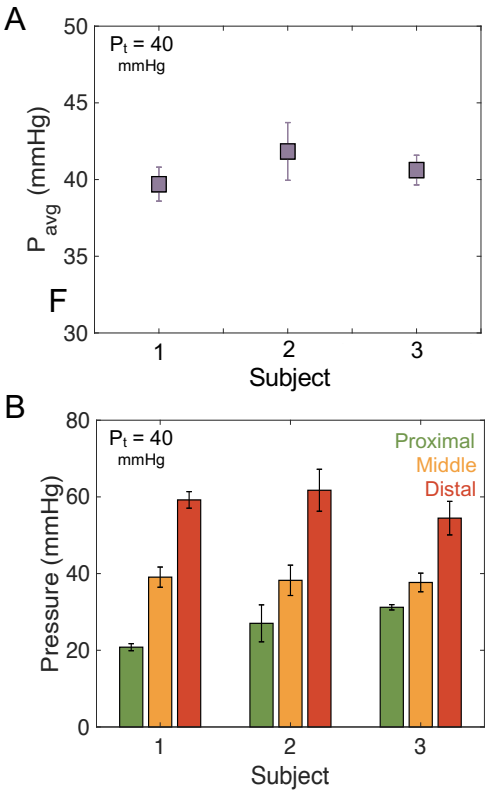

Fig. 4. Subject variability results. A) Average pressure readings and B) distal, middle, and proximal readings for three subjects at a targets of 40 mmHg. BSA_1 = 1.67 m^2; BSA_2 = 1.78 m^2; BSA_3 = 2.24 m^2.

be circumvented via a computationally driven patient-specific design optimized to a given anatomy and therapeutic goal.

IV. Conclusion

We propose a soft robotics architecture which is capable of generating controlled, graduated compression in the lower limb, with application in the treatment of lymphedema. In addition, this device could provide support in post-exercise recovery or be used for other medical conditions, such as chronic venous insufficiency or peripheral vascular disease, where compression therapy is recommended [16]. The device consists of a specialized three-layered robotic sleeve which allows for comfort, ease of use and application, and mobility, as well as a control system which enables the system to reliably reach and maintain user-defined target pressures. Through testing on healthy volunteers, the device shows promise as a way to precisely and reliably deliver pressure profiles. Combined with a computationally driven patient-specific design workflow, this device could have improved robustness and enhanced therapeutic outcomes.

Acknowledgments

This paper is dedicated to Dr. Frank Shuler, our friend and mentor, who inspired this project and passed away in January 2021. This project was conducted under the auspices of the MIT Medical Device Design Course - https://meddevdesign.mit.edu.

References

[1] S. G. Rockson and K. K. Rivera, "Estimating the population burden of lymphedema," *Annals of the New York Academy of Sciences*, vol. 1131, no. 1, pp. 147–154, 2008.

[2] H. Schulze, M. Nacke, C. Gutenbrunner, and C. Hadamitzky, "Worldwide assessment of healthcare personnel dealing with lymphoedema," *Health economics review*, vol. 8, no. 1, p. 10, 2018.

[3] J. Douglass, P. Graves, and S. Gordon, "Self-care for management of secondary lymphedema: a systematic review," *PLoS neglected tropical diseases*, vol. 10, no. 6, p. e0004740, 2016.

[4] J. N. Cormier, R. L. Askew, K. S. Mungovan, Y. Xing, M. I. Ross, and J. M. Armer, "Lymphedema beyond breast cancer: A systematic review and meta-analysis of cancer-related secondary lymphedema," *Cancer*, vol. 116, no. 22, pp. 5138–5149, 2010.

[5] I. Tzani, M. Tsichlaki, E. Zerva, G. Papathanasiou, and E. Dimakakos, "Physiotherapeutic rehabilitation of lymphedema: State-of-the-art," *Lymphology*, vol. 51, no. 1, pp. 1–12, 2018.

[6] M. Karafa, A. Karafova, and A. Szuba, "The effect of different compression pressure in therapy of secondary upper extremity lymphedema in women after breast cancer surgery," *Lymphology*, vol. 51, no. 1, pp. 28–37, 2018.

[7] A. Finnane, M. Janda, and S. C. Hayes, "Review of the evidence of lymphedema treatment effect," *American Journal of Physical Medicine & Rehabilitation*, vol. 94, no. 6, pp. 483–498, 2015.

[8] N. Dunn, E. M. Williams, M. Fishbourne, G. Dolan, and J. H. Davies, "Home management of lower limb lymphoedema with an intermittent pneumatic compression device: a feasibility study," *Pilot and feasibility studies*, vol. 5, no. 1, p. 113, 2019.

[9] M. B. Aldrich, D. Gross, J. R. Morrow, C. E. Fife, and J. C. Rasmussen, "Effect of pneumatic compression therapy on lymph movement in lymphedema-affected extremities, as assessed by near-infrared fluorescence lymphatic imaging," *Journal of innovative optical health sciences*, vol. 10, no. 02, p. 1650049, 2017.

[10] K. Tran and C. Argáez, "Intermittent pneumatic compression devices for the management of lymphedema: a review of clinical effectiveness and guidelines," 2017.

[11] M. Zaleska, W. L. Olszewski, P. Jain, S. Gogia, A. Rekha, S. Mishra, and M. Durlik, "Pressures and timing of intermittent pneumatic compression devices for efficient tissue fluid and lymph flow in limbs with lymphedema," *Lymphatic research and biology*, vol. 11, no. 4, pp. 227–232, 2013.

[12] J. J. Phillips and S. J. Gordon, "Intermittent pneumatic compression dosage for adults and children with lymphedema: A systematic review," *Lymphatic research and biology*, vol. 17, no. 1, pp. 2–18, 2019.

[13] D. M. Richmand, T. F. O'Donnell, and A. Zelikovski, "Sequential pneumatic compression for lymphedema: a controlled trial," *Archives of Surgery*, vol. 120, no. 10, pp. 1116–1119, 1985.

[14] E. T. Roche, M. A. Horvath, A. Alazmani, K. C. Galloway, N. V. Vasilyev, D. J. Mooney, F. A. Pigula, and C. J. Walsh, "Design and fabrication of a soft robotic direct cardiac compression device," Aug 2015, volume 5A: 39th Mechanisms and Robotics Conference.

[15] B. Shuter and A. Aslani, "Body surface area: Du bois and du bois revisited," *European Journal of Applied Physiology*, vol. 82, no. 3, pp. 250–254, Jun 2000.

[16] M. Stücker, O. Danneil, M. Dörler, M. Hoffmann, E. Kröger, and S. Reich-Schupke, "Safety of a compression stocking for patients with chronic venous insufficiency (cvi) and peripheral artery disease (pad)," *JDDG: Journal der Deutschen Dermatologischen Gesellschaft*, vol. 18, no. 3, pp. 207–213, 2020.