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Introduction

Compression is the standard of care for Chronic Venous Insufficiency (CVI; Rf1) and it is an important component for treating patients with lymphedema (Rf2). Both conditions are progressive if not addressed. Patients graduate to a self-management phase requiring garments with prescribed dosage to stop progression of their symptoms. Compression levels may fluctuate with garment fatigue, improper product application, and possibly leading to costly and painful exacerbations. Our long-term goal is empowering consumers to self-manage compression with "smart garments": Convenient wearable pressure sensors (WPS) are embedded in off-the-shelf hook and loop closures. Our short-term goal is demonstrating feasibility of "smart garments".

Method

We tested 3 hook-and-loop garments: Leg garment 1; leg garment 2; and an arm garment 1. There were 4 trials, each with 6 continuous hours normal activity. The first author self-applied closures to achieve therapeutic pressures monitored hourly. Leg and arm pressures were measured in anatomic position.

Wearable Pressure Sensor

The WPS-Bluetooth-iPhone interface boasts an intuitive display. The WPS contains a resilient polyurethane foam under vacuum. The WPS is 6x2x0.05 cm., with a Sensor that is thin and flexible, connecting to a system on a chip (SOC) that is 3x2x0.6 cm. The (gold) sensor is flexible and thin: 0.5 mm. We protect the skin from the thicker SOC by placement outside/between garment layers in novel pockets/pouches. This proprietary sensor is low power, allowing excellent stability and battery life (>2 months). (Rf 3).



Comparison to "Gold Standard"



We used a validated pneumatic sensor as the Gold Standard: The Picopress sensor, referred herein as PICO (Rf 4). The PICO has a 5 cm diameter thin inflatable balloon that measures pressure.

Leg garment 1



Leg garment 2

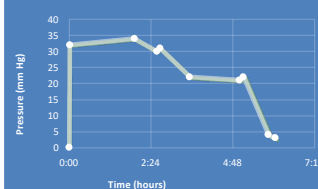


Arm garment 1

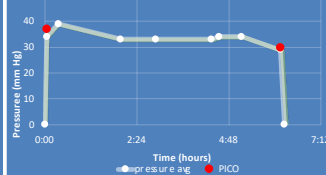


Results

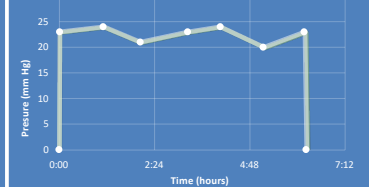
LEG GARMENT 1: PRESSURE DECREASES 30% OVER 6 HOURS WEAR TIME FOR WELL-USED LEG GARMENT



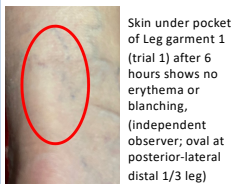
LEG GARMENT 2: PRESSURE AT ANKLE SHOWS 18% DROP IN PRESSURE OVER 6 HOURS WEAR TIME FOR UNUSED GARMENT



ARM GARMENT 1: PRESSURE UNDER WRIST NEAR-CONSTANT OVER 6 HOURS WEAR TIME FOR UNUSED GARMENT



Well-used leg garment (Leg garment 1), loses 30% of compression over 6 hours wear, whereas unused leg garment 1 and arm garment maintain compression by inspection. Overall, error was $\leq \pm 17\%$ (consistent with Rf 3). There are similar number of steps for all leg garments.



Trial	Garment	Previous garment use (approx. # uses)	Location of WPS	P start	P end	P avg +/- SD	T (hours)	Steps	%Error (Rf 3)
1	Leg garment 1	>50	Posterior-distal leg	32	22	27 +/- 6	6.0	3200	Not tested
2	Leg garment 1	>50	Posterior-distal leg	29	19	20 +/- 4	6.4	5500	<±16%
3	Leg garment 2	<10	Posterior-distal-lateral leg	34	29	34 +/- 3	6.2	4400	<±10%
4	Arm garment 1	<10	Volar proximal wrist	23	23	23 +/- 2	6.1	N/A	<±17%

Discussion

● The WPS yields reproducible, accurate, stable readings for an extended period. ● Well used garments fatigue more with use than unused ones. ● There are no obvious sign of pressure injury or discomfort. ● Results are preliminary based on small sample size and one observer. ● A "Smart Compression Garment" may apply consistent, sustainable, individualized, adequate compression for CVI and lymphedema.

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Disclosures

Robert Goldman, MD, MS, is a co-founder and part owner of WearSense LLC.
Frank Aviles PT, CLT-LANA is a consultant for WearSense, LLC

References

1. O'Meara, S., et al., Compression for Venous Leg Ulcers. Cochrane Database of Systematic Reviews, 2012(11).
2. Goldman RJ. Implementing a Wearable Sensor for Lymphedema Garments: A Prospective Study. Wound Management Prev. 2020;66(1):39-48.
3. Goldman, RJ, Bucas, G, Møller, J, Boyer J: Calibration and Accuracy of a Wearable Pressure Sensor. Poster for SLMC, Fall, 2024.
4. Chassagne F, Molimard J, Convert R, Graux P, Badel P. Numerical Approach for the Assessment of Pressure Generated by Elastic Compression Bandage. Ann Biomed Eng.

Product Trade Names

1. WPS: LS3 Wearable pressure sensor by WearSense LLC, Aston PA (wear-sense.com)
2. Leg garment 1: "ReadyWrap", medium average beige, 5 strap, L&R USA, Milwaukee, WI.
3. Leg garment 2: Classic Farrow Garment small regular leg, FarrowMed LLC (rev 3/2014)
4. Arm garment 1: "ReadyWrap", arm, medium beige, 5 strap, L&R USA, Milwaukee, WI.
5. "Gold standard": Picopress, Microlab Elettronica, Point St Nicola, Italy.

*Footnote

% ERROR = $100 \times \left| \frac{\text{WPS PRESSURE} - \text{GOLDSTANDARD}}{\text{GOLDSTANDARD}} \right|$ where || is absolute value.