Comparative Usability Evaluation of a Novel Gradient Compression System Versus Standard Compression Garments

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Introduction

- Under normal conditions, valves within the venous system direct blood from the superficial into the deep system, which return the blood back towards the heart.
- A host of illnesses and disease states can affect these anatomic functions contributing to the development of venous insufficiency.
- Chronic venous insufficiency leads to pooling of the blood and fluid in the legs.
- Patients may first experience edema in the lower extremities.
- Over time, trophic changes in the tissues appear and eventually skin necrosis and ulcerations occur.
- Daily use of compression garments is recommended to treat lower extremity edema and reduce the risk of ulcer formation, but the use of traditional compression garments in this patient population can be a challenge.

Methods

- The purpose of this study was to assess the usability of an innovative compression garment (AWCS) indicated for use in patients with venous insufficiency, lower extremity edema or a history of venous leg ulcers.
- This pilot study was conducted with 7 consented subjects over the age of 18.
- The evaluation included points of interaction between the user and the device, including all elements of the device with which the user interacts.
- All users were asked to populate a 3 Part questionnaire to assess the subject's feedback of their current compression garment, feedback after utilizing the AWCS garment and feedback comparing their current compression garment to the AWCS garment.

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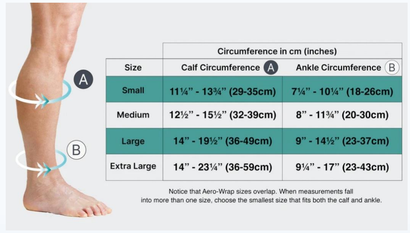
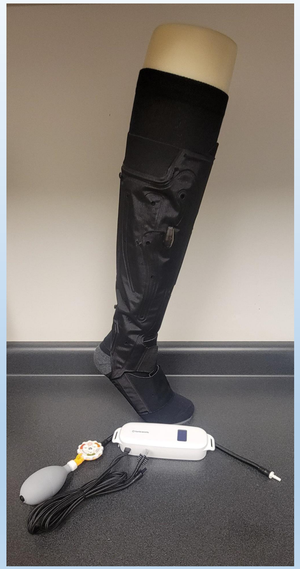
Product Components



Size	Circumference in cm (inches)	
	Calf Circumference (A)	Ankle Circumference (B)
Small	11¼" - 13¾" (29-35cm)	7¼" - 10¼" (18-26cm)
Medium	12½" - 15½" (32-39cm)	8" - 11¾" (20-30cm)
Large	14" - 19½" (36-49cm)	9" - 14½" (23-37cm)
Extra Large	14" - 23¼" (36-59cm)	9¼" - 17" (23-43cm)

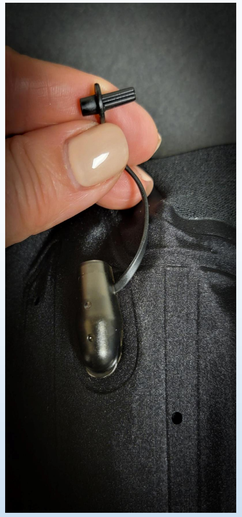
Notice that Aero-Wrap sizes overlap. When measurements fall into more than one size, choose the smallest size that fits both the calf and ankle.

Sizing Guide

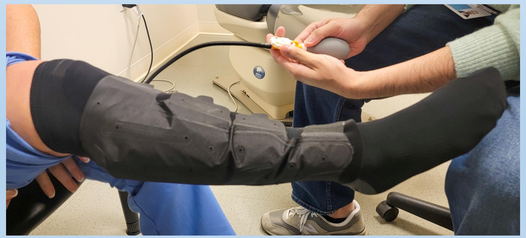


Aero-Wrap Compression System

Adjustable Compression Dial



Valve Stem Cover and Deflation Key



10-15 pumps to inflate garment. Internal valves do no allow over inflation.

Survey Questions

Aero-Wrap Gradient Compression System Questions:

1. I would wear the Aero-wrap garment frequently (5-7 days per week).
2. I find the Aero-wrap garment difficult to use.
3. I find the Aero-warp garment is easy to use.
4. I would need the help of someone (family, caregiver) to be able to use the Aero-wrap garment.
5. I found the functions of the Aero-wrap compression system meet my needs.
6. I found the Aero-wrap compression garment fit to be comfortable without slippage or binding.
7. I would imagine that most people could use the Aero-wrap compression garment with ease.
8. I found the Aero-wrap compression garment very cumbersome to remove.
9. I would feel confident going out in public wearing the Aero-wrap compression garment.
10. I would be open to switching to the Aero-wrap compression garment.

Comparison Questions:

1. I prefer the Aero-wrap compression garment over my current compression garment.
2. I found the Aero-wrap compression garment easier to apply than my current compression garment.
3. I found the comfort of the Aero-wrap compression garment to be better than my current compression garment.
4. I found the Aero-wrap compression garment easier to remove than my current garment.
5. I would wear the Aero-wrap compression garment more often than my current compression garment.

*AWCS: Aero-Wrap Gradient Compression System

Results

- Subjects rated the usability of the AWCS garment higher than traditional compression wear. (6:1)
- Subjects found the AWCS garment was to be easier to apply compared to SOC compression garments. (7:0)
- Subjects found the comfort of the Aero-wrap compression garment to be better than the current compression garment. (6:1)
- Subjects found the Aero-wrap compression garment easier to remove than the current garment. (7:0)
- Subjects would wear the Aero-wrap compression garment more often than the current compression garment. (6:1)
- Furthermore, the increased ease of self-application of the AWCS reduced patient exertion and decreased time spent on edema management supporting an increased patient QOL.

Discussion

- Adherence to traditional compression garments can be limited due to difficulty with donning the devices. Increased age, limited range of motion, decreased dexterity, poor eyesight, decreased strength and agility are common reasons patients have difficulty adhering to compression garment use.
- The AWCS was found to be very user friendly thus it has the potential to improve patient outcomes in this at-risk patient population.

References

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