

Aria Free™

The smallest and lightest lower limb pneumatic compression device (PCD)*¹

Usability Evaluation of a Novel Compact Pneumatic Compression Device for the Treatment of Lymphoedema: Pilot Study¹

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Introduction

Lymphedema is a chronic condition affecting between 90 and 250 million people worldwide.^{2,3} The effects of lymphedema can be debilitating and if left untreated, lymphedema progresses over time, severely affecting a person's quality of life.⁴ Lymphedema is characterized clinically by chronic swelling, localized pain, skin atrophy and increased vulnerability to bacterial infection.² The goal of treatment is to reduce the volume of the affected limb, improve symptoms and reduce morbidity.²

Aria Free is a lightweight, compact pneumatic compression device (PCD) for the treatment of lymphedema, consisting of a compact pump and streamlined garment. It incorporates a Hi-Res™ technology and delivers comfortable pressure over 35+ channels. Aria Free has been designed to establish more points of contact, enhancing stimulation of the skin and encouraging lymphatic movement and clearance of lymph through the body's natural lymphatic system.

Study Objective

The study evaluated the subjective fit, ease of use and comfort of the Aria Free device as well as the subjective comfort of a 45-minute therapy session.

Study Design

A single-center, open-label, single-arm study, 15 patients with lower limb lymphedema were asked to evaluate the use of a novel lightweight, compact PCD, Aria Free for the treatment of lymphedema.

Study was conducted in two phases evaluating the following:

- Phase 1: Fitting of the Aria Free PCD
- Phase 2: Comfort of the Aria Free device over a 45-min usage period

All 15 patients received a 45-minute therapy session with the Aria Free PCD and evaluated the following:

- Overall fit of the garment
- Ease of use
- Comfort level

1.85% mean limb volume reduction

Highlights¹

Limb Volume Reduction

A single 45-minute treatment session with the Aria Free resulted in a statistically significant reduction in mean limb volume.

High subjective comfort ratings

Comfort During Therapy

Therapy Comfort and Comfort During Use were both highly rated, with median subjective ratings of 10 out of 10.

Smallest and lightest

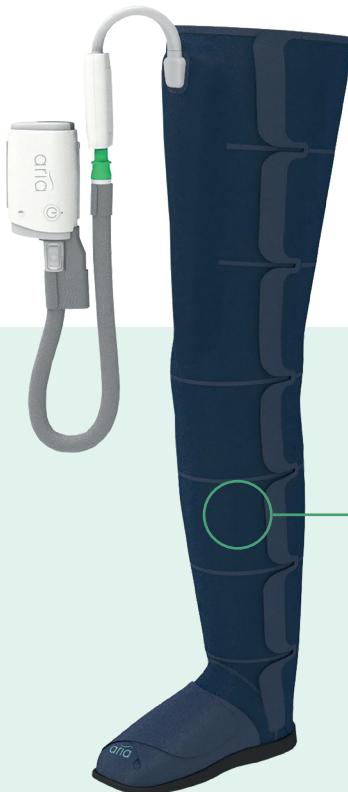
Compact System

Aria Free is the smallest and lightest lower limb PCD in the US Market.^{**}

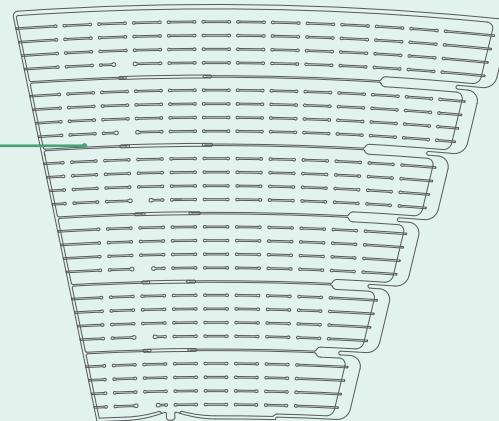
Conclusion

The clinical evaluation of this study from 15 participants, supports the use of Aria Free PCD. The device fit well, was easy to use, provided comfortable therapy and reduced leg edema.

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Aria Free is designed to be flexible and convenient. A unique garment design incorporating innovative Hi-Res technology and comfortable pressure. Together, these features have been designed to drive patient adherence and daily use of the system with a goal of improving overall quality of life.



Proprietary Hi-Res Technology

Delivers gradient sequential pressure and gentle massage over 35+ air channels to encourage lymphatic movement and clearance of lymph through the body's natural lymphatic system.

* In the US Market.

** A survey¹ of all basic and advanced lower limb pneumatic compression devices for lymphedema over the last 10 years showed Aria Free to be the smallest and lightest device at 0.7lbs and 0.6L. The closest alternative was 3.3lbs and 4.9L.

1 Devitt, M., Ramanan, D., Armitstead, J., Zhu, X., & Mackie, H. (2022). Usability evaluation of a novel compact pneumatic compression device for the treatment of lymphoedema: Pilot study. *Phlebology: The Journal of Venous Disease*, 0268355522109622. <https://doi.org/10.1177/02683555221096298>

2 Chang, D. W., Suami, H., & Skoracki, R. (2013). A prospective analysis of 100 consecutive lymphovenous bypass cases for treatment of extremity lymphedema. *Plastic and Reconstructive Surgery*, 132(5), 1305–1314. <https://doi.org/10.1097/prs.0b013e3182a4d626>

3 Garza, R., Skoracki, R., Hock, K., & Povoski, S. P. (2017). A comprehensive overview on the surgical management of secondary lymphedema of the upper and lower extremities related to prior oncologic therapies. *BMC Cancer*, 17(1). <https://doi.org/10.1186/s12885-017-3444-9>

4 Morgan, P. A., Franks, P. J., & Moffatt, C. J. (2005). Health-related quality of life with lymphoedema: A review of the literature. *International Wound Journal*, 2(1), 47–62. <https://doi.org/10.1111/j.1742-4801.2005.00066.x>

Aria Free is intended for use by medical professionals and patients at home for the treatment of lymphedema, chronic edema, venous insufficiency, and wound healing. The system is for single-patient use and is only intended for adult patients (over 18 years). A prescription is required. We currently offer a leg garment only. As we develop additional garments, we will expand our selection.