

A Novel Wearable System for Lymphedema Therapy

THE PROBLEM

Lymphedema is a debilitating, progressive disease caused by the lymphatic system's inability to properly move fluid through the body. Fluid buildup causes painful swelling and recurrent infections, restricts mobility, and hardens the skin. More than 10 million Americans are estimated to live with lymphedema—more than the populations affected by ALS, MS, Parkinson's, and muscular dystrophy combined.¹

fluid. They are hot, difficult to wear and remove, and adherence is highly variable.

Exercise: Helps stimulate lymphatic flow but is insufficient as a standalone therapy and presents adherence challenges for patients with pain, fatigue, or advanced swelling.

Patients typically rely on Certified Lymphedema Therapists (CLTs) to manage care and understand their treatment options. However, there is a profound national shortage, with as few as one CLT available for every 2,500 to 3,000 patients.² Therefore, there is a need for increased access to trained caregivers, especially in rural areas.

Lymphedema patients need additional treatment options. An ideal solution must be easy to use to encourage adherence, readily available, and highly effective in everyday surroundings. Additionally, the solution must be portable and allow daily activities during treatment. Ideally, it will also reduce the burden of CLT shortages by allowing therapists to treat more patients.

THE SOLUTION

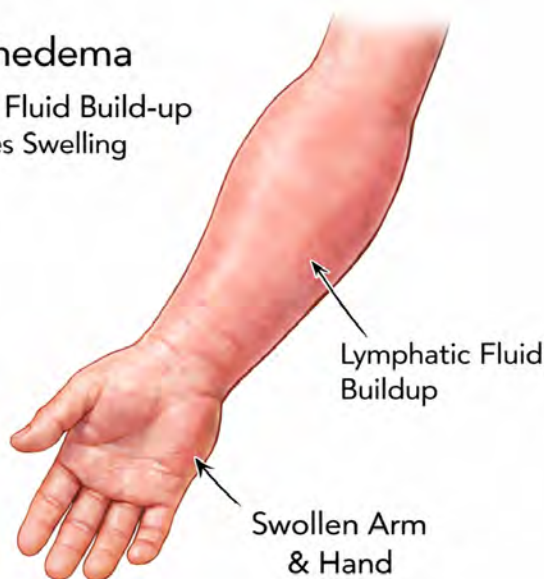
Carilion Clinic Innovation, in collaboration with the Virginia Tech Biomedical Engineering and Mechanics (BEAM) Department, developed a novel device that meets all these unmet needs. The device is a sleeve with embedded vibration motors, offering greater effectiveness than traditional compression garments or exercise and a much smaller profile than traditional pumps. Patients can easily carry the sleeve home, providing greater access than massages.

The device combines several concepts to create a novel treatment method for lymphedema:

- » Targeted vibration motors that activate in a rhythmic pattern simulating Manual Lymphatic Drainage therapy performed by therapists.
- » Distributed compression to assist fluid movement without restricting mobility.
- » Silicone layers engineered to efficiently and safely transmit vibratory energy through soft tissue.
- » Sequenced treatment patterns designed to break down, mobilize, and reabsorb lymphatic fluid.

Lymphedema

Lymphatic Fluid Build-up
Causes Swelling



Patients can manage lymphedema symptoms using several treatment methods, but each presents limitations:

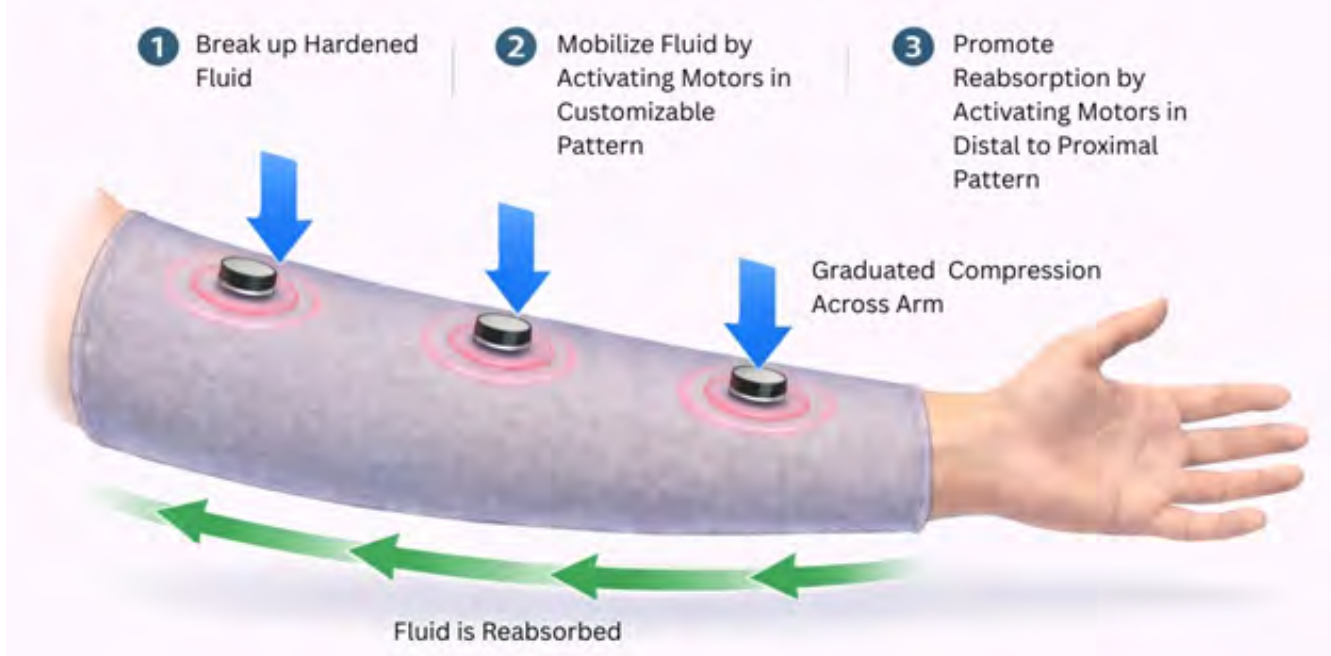
Manual Lymphatic Drainage (MLD): Effective but requires frequent in-person visits, which can be difficult due to therapist shortages, travel barriers, and insurance limits on visit frequency.

Pneumatic Compression Pumps: Commonly used but bulky, restrictive, and require patients to remain stationary, with the pump plugged into an electrical outlet for around 60 minutes a day. The limb being treated must be immobile, limiting function and independence. Pumps also pose transportation challenges, take up space at home, and do not support mobility or day-to-day activities.

Compression Garments: Useful for containing swelling but cannot mobilize or clear lymphatic



Lymphedema Device White Paper



In addition to the novel treatment method, the device recognizes patients' real-world needs. The following features were included to maximize adherence:

- » Battery powered, with one charge providing hours of treatment
- » USB-C recharging
- » Lightweight and compact for travel
- » Ability to operate as a stand-alone device or integrate with a smartphone app
- » Quiet, discreet profile suitable for use at home, work, or on the go
- » Flexible and comfortable enough to encourage consistent daily use

Lymphedema robs patients of substantial freedom and comfort. This device restores them.

PROGRESS TO DATE

Currently, various prototypes have been developed. The most recent version includes all features intended for use in the final product. Pilot testing on healthy subjects has demonstrated that the device is safe. Additionally, testing

performed on lymphedema patients revealed reduced swelling and increased mobility.

FUTURE WORK

Carilion Clinic Innovation is currently partnering with LymphaVibe LLC, a startup founded by oncology rehabilitation specialist Tara Newberry, who invented the device. The next steps for development are:

- » Gather funding, including SBIR and commercialization-focused grants
- » Establish ISO13485 compliant design controls
- » Conduct usability analysis and testing
- » Refine the design and reach design lock
- » Conduct complete clinical trials

The device currently is designed for upper extremities only, to focus on mastectomy patients. After launching LymphaVibe for the upper extremities, the company plans to develop future versions for other body parts, including the lower extremities and trunk, creating a full body system.

REFERENCES

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2. **Allied Services.** Finding a Lymphedema Expert: LANA Certified Therapist. 2024. <https://www.allied-services.org/news/2024/january/finding-a-lymphedema-expert-lana-certified-thera/>