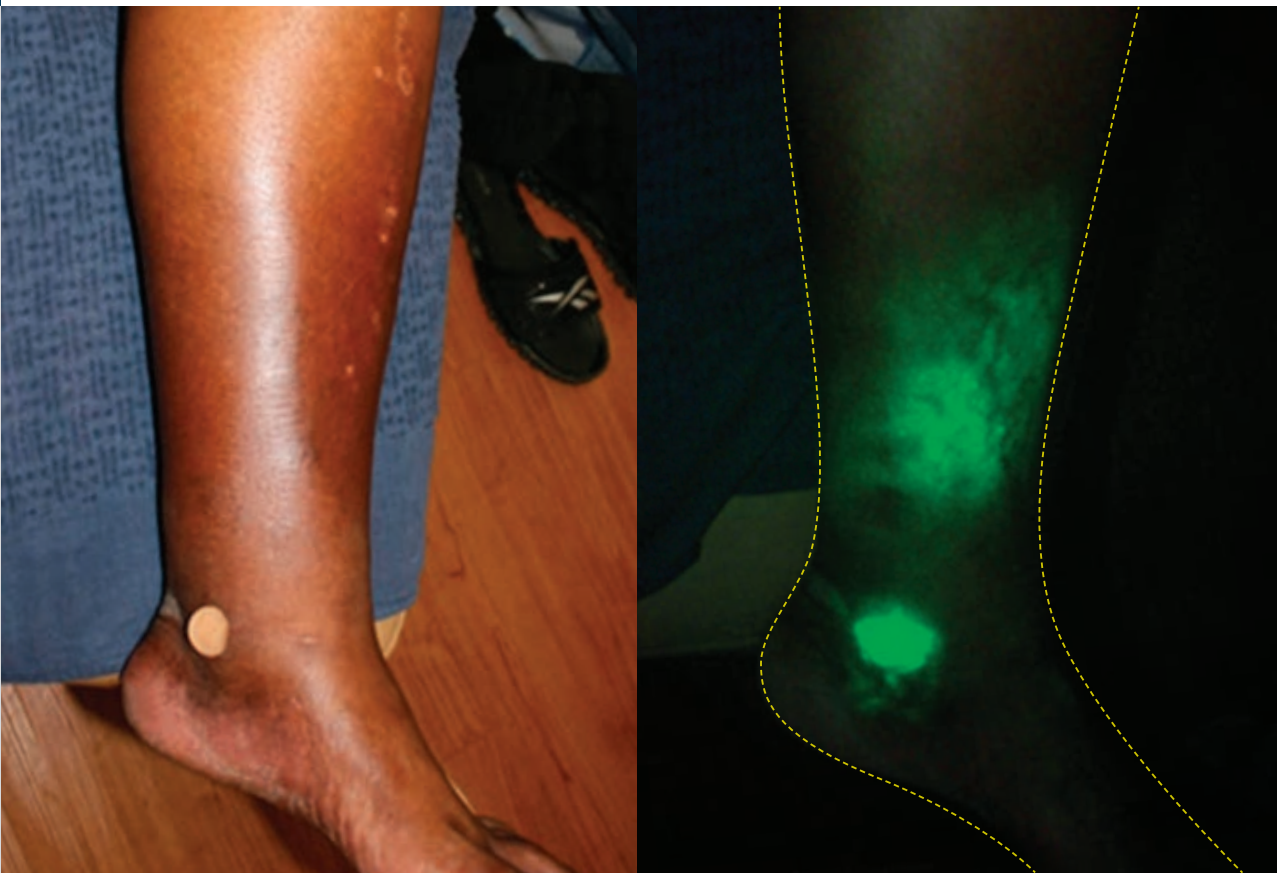


Venous Insufficiency and Chronic Edema

AUGMENT CLINICAL CARE WITH EFFECTIVE AT-HOME
TREATMENT TO IMPROVE OUTCOMES AND REDUCE COST



Fluorescence imaging illustrates lymphatic dysfunction associated with chronic venous insufficiency¹

Tactile
MEDICAL[®]

CHRONIC EDEMA INDICATES AN INADEQUACY OR FAILURE OF LYMPHATIC DRAINAGE

The veins and lymphatics form one interdependent fluid-balance system. For CVI patients with chronic edema (phlebolymphe²dema), this venolymp²hatic connection means that a singular focus on repairing veins will not resolve swelling—the lymphatics must also be addressed.

The traditional Starling Principle (*next page, top*) held that capillary oncotic pressure drove reabsorption of interstitial fluid into the venules, leaving approximately 10 percent to be removed by the lymphatic system. However, subsequent research has revealed the role of the endothelial glycocalyx layer in the capillary bed: there is no net venous reabsorption and interstitial fluid returns to the circulation only via the lymphatics (*next page, bottom*).^{3,4}

CVI-RELATED CHRONIC EDEMA IS A TWO-SYSTEM FAILURE THAT REQUIRES EARLY DETECTION AND COMPREHENSIVE TREATMENT

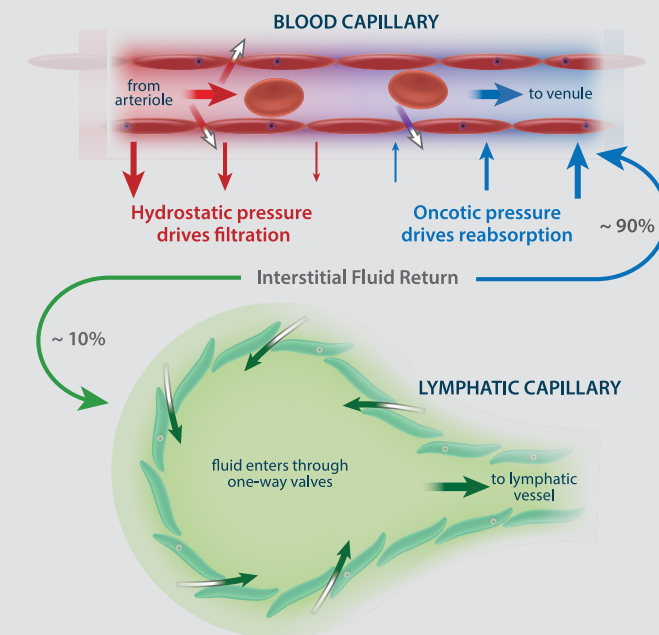
Phlebolymphe⁵dema occurs when an excessive burden of capillary filtrate overwhelms the lymphatics, most often due to venous hypertension. Just as CVI causes microangiopathic changes in the venous system, prolonged chronic edema can permanently damage the lymphatics,⁵ paving the way for progressive infection and complications,⁶ increased office visits, and costly treatments and hospitalizations.

Compression garments and appropriate endovenous or surgical interventions can reduce venous hypertension. However, phlebolymphe⁷dema requires early detection and comprehensive lymphatic therapy to reduce buildup of protein-rich edema and thereby lower risk of infection and inflammation.⁷ Pneumatic compression devices (PCDs) can complement acute lymphatic therapy and improve patient self-care. Only the Flexitouch[®] Plus system has been proven to stimulate the lymphatics,⁸ improve outcomes,^{9,10} lower costs^{9,10} and improve quality of life¹¹ for phlebolymphe¹¹dema patients.

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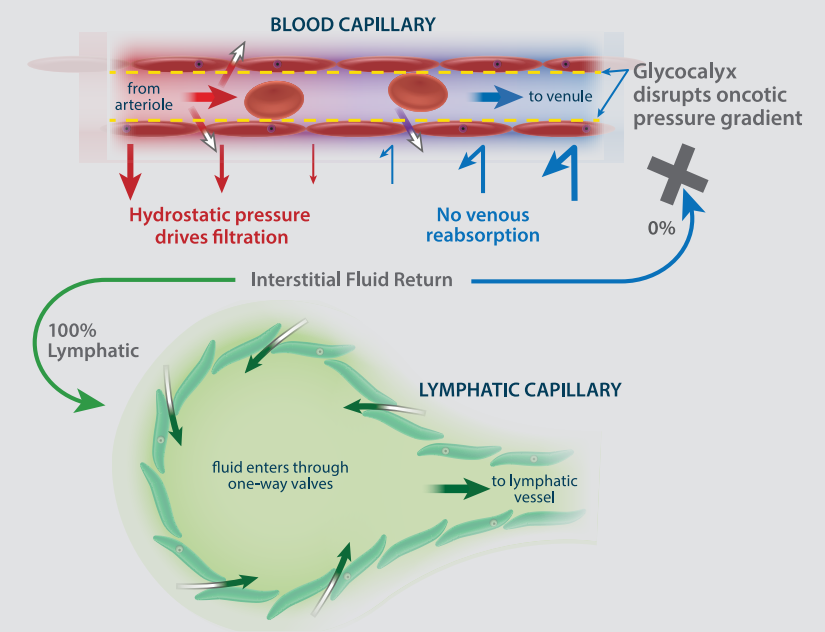
THE IDEAL MEDICAL TREATMENT FOR CVI WOULD ACHIEVE BOTH A DECREASE IN CAPILLARY FILTRATION AND AN IMPROVEMENT IN LYMPHATIC FUNCTION.”

CLASSICAL MODEL: NOW KNOWN TO BE INCORRECT



Traditionally it was taught that 90% of interstitial fluid was reabsorbed by the venous system. This is now known to be incorrect.

MODERN VIEW: GLYCOCALYX MODEL


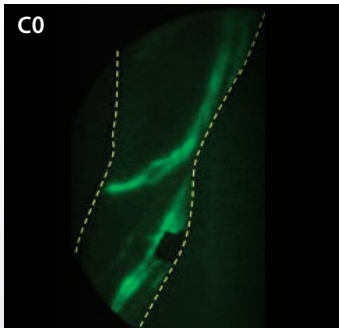

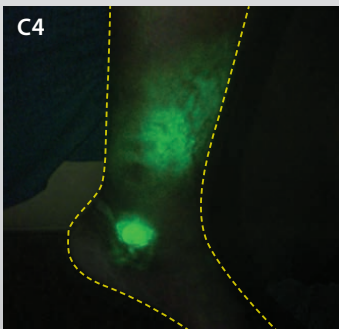
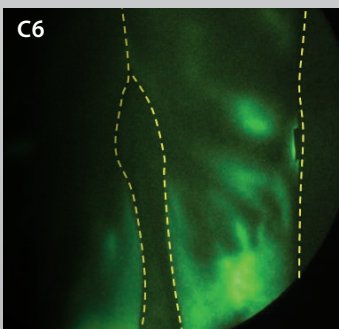


Modern evidence shows the endothelial glycocalyx prevents venous reabsorption. Therefore, all chronic edema indicates an inadequacy or failure of lymphatic function.^{3,4}

CVI-RELATED CHRONIC EDEMA
(PHLEBOLYPHEDEMA)

LYMPHATIC CHANGES ARE PRESENT IN EARLY CLINICAL STAGES
OF CHRONIC VENOUS DISEASE

In biopsies, patients with CVI show structural lymphatic changes, including collapsed lumens and disturbance of lumen-opening filaments, resulting in reduced function.⁵ This chart illustrates how lymphatics can be impacted at each clinical stage of the Comprehensive Classification System for Chronic Venous Disorders (CEAP).^{1,2}

CHRONIC VENOUS DISEASE (CVD) CLINICAL STAGE			LYMPHATIC INVOLVEMENT SHOWN VIA NEAR INFRARED FLUORESCENCE LYMPHATIC IMAGING ¹		LYMPHEDEMA (LE) CLINICAL STAGE	
C0	No Clinical Signs		<p>A healthy lymphatic system (right) allows lymph to enter and flow through lymphatic capillaries. In early stage venous disease, lymphatics are able to manage the venous filtrate overload.</p>		<p>Stage 0: Latent No clinical signs.</p>	
C1	Telangiectasias or Reticular Veins					
C2	Varicose Veins					
C3	Edema (Pitting)		<p>Lymphatics are unable to accommodate excess venous filtrate, so swelling occurs.³</p> <p>Prolonged excess venous filtrate overburdens lymphatics, resulting in protein buildup and permanent damage and/or obstruction.³</p>		<p>Stage 1: Pitting Edema Soft swelling, resolves with elevation or overnight.</p>	
	Edema (Non-pitting)				<p>Stage 2: Non-pitting Edema Swelling with deepened skin folds and notable tissue changes such as fibrosis, scaly skin, and possible hyperkeratosis; does not resolve with elevation.</p>	
C4	C4a: Pigmentation or Eczema		<p>Exaggerated immune reactions such as stasis eczema and allergic contact dermatitis are indicative of compromised lymphatic immune function.⁶ Dermal backflow follows hemosiderin staining.¹</p> <p>Chronic inflammation and fibrosis are indicative of a buildup of fluid and proteins that the lymphatics are unable to clear due to insufficiency or failure. Fibrosis indicates protein-rich buildup from lymphatic insufficiency, regardless of swelling. Corona phlebectatica is recognized as a leading predictor of venous ulcer with risk profile similar to other C4 skin changes.</p>		<p><i>Left unmanaged, lymphedema can progress to:</i></p> <p>Stage 3: Lymphostatic Elephantiasis Extensive and/or disfiguring fibrotic swelling, blistering and ulcerations, lymphorrhea, hyperkeratosis, papillomas, and recurrent infections.</p>	
	C4b: Lipodermatosclerosis or Atrophie Blanche					
	C4c: Corona Phlebectatica					
C5	Healed Venous Ulcer		<p>Scar tissue disrupts lymphatic drainage.</p> <p>Open wound disrupts superficial lymphatics and lymph fluid leaks from the ulcers.</p>			
C6	Active Venous Ulcer					

TREAT EARLY

TREAT EARLY

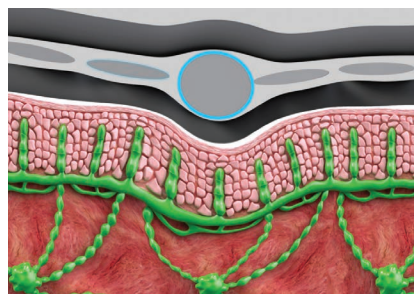
CHOOSE CLINICALLY PROVEN AT-HOME TREATMENT WITH HIGH PATIENT SATISFACTION AND COMPLIANCE¹³



FLEXITOUCH® PLUS SYSTEM

The Flexitouch Plus system is the only pneumatic compression device clinically proven to stimulate the lymphatic system⁸ and is backed by the most extensive body of clinical evidence of any pump on the market.

FLEXITOUCH MECHANISM OF ACTION



The unique mechanism of action of the Flexitouch system stimulates the lymphatic system to remove excess fluid and reduce edema. The pneumatic chambers sequentially inflate and deflate for just a few seconds each, creating a gentle wave-like application of pressure to stimulate the movement of lymphatic fluid and direct it toward properly functioning areas of the body.

OUR COMMITMENT TO RESEARCH

Our commitment to research has resulted in dozens of peer-reviewed clinical studies and scholarly articles—more than any other pneumatic compression manufacturer. The results of two studies are highlighted here:

EVIDENCE SUPPORTING OPTIMAL TREATMENT OF PHLEBOLYMPHEDEMA¹⁰

A study of 1,065 patients with CVI and lymphedema (phlebolymphectoma) published in the *Journal of Vascular Surgery* found Flexitouch use significantly reduced per-patient phlebolymphectoma-related costs when compared with alternative treatment modalities (all pumps used in conjunction with conservative therapy):

↓69%

Reduction vs.
conservative therapy alone

↓85%

Reduction vs.
simple lymphedema pumps

↓53%

Reduction vs.
other advanced
lymphedema pumps

AT-HOME FLEXITOUCH TREATMENT IMPROVES HEALTH OUTCOMES AND REDUCES COSTS⁹

A study of 344 non-cancer-related lymphedema patients published in the *Journal of the American Medical Association Dermatology* found that lymphedema treatment utilizing the Flexitouch system resulted in long-term reductions in healthcare utilization and costs:^{9b}



↓75%

Reduction in rate
of cellulitis episodes

+



↓40%

Reduction in rate of
outpatient hospital visits

=



↓36%

Reduction in rate of
lymphedema-related
costs per patient

SEE HOW WE'RE BRINGING THE FUTURE OF HEALING HOME AT TACTILEMEDICAL.COM

Tactile Medical is a leader in developing and marketing at-home therapy devices that treat chronic swelling conditions such as lymphedema and chronic venous insufficiency. Our Mission is to help people suffering from chronic diseases live better and care for themselves at home. Our unique offering includes advanced, clinically proven pneumatic compression devices, as well as continuity of care services provided by a national network of product specialists and trainers, reimbursement experts, patient advocates and clinicians. This combination of products and services ensures that tens of thousands of patients annually receive the at-home treatment necessary to better manage their chronic conditions. Tactile Medical takes pride in the fact that our solutions help increase clinical efficacy, reduce overall healthcare costs and improve the quality of life for patients with chronic conditions.

Individual results may vary.

Indications/contraindications: Indications, contraindications, warnings, and instructions for use can be found in the product labeling supplied with each device.

Caution: Federal (U.S.) law restricts this device to sale by or on the order of a licensed healthcare practitioner.

References:

1. Rasmussen JC, Aldrich MB, Tan IC, et al. Lymphatic transport in patients with chronic venous insufficiency and venous leg ulcers following sequential pneumatic compression. *J Vasc Surg Venous and Lymphat Disord.* 2016;4(1):9–17.
2. Partsch H, Lee BB. Phlebology and lymphology—A family affair. *Phlebology.* 2014; 29(10): 645–647.
3. Mortimer PS, Rockson SG. New developments in clinical aspects of lymphatic disease. *J Clin Invest.* 2014;124(3):915–21.doi:10.1172/JCI71608.
4. Levick JR, Michel CC. Microvascular fluid exchange and the revised Starling principle. *Cardiovasc Res.* 2010;87(2):198–210.
5. Scelsi R, Scelsi L, Cortinovis R, Poggi P. Morphological changes of dermal blood and lymphatic vessels in chronic venous insufficiency of the leg. *Int Angiol.* 1994;13(4):308–11.
6. Ruocco E, Brunetti G, Brancaccio G, Schiavo AL. Phlebolympheidema: Disregarded cause of immunocompromised district. *Clin Dermatol.* 2012;30(5):541–3.
7. Farrow W. Phlebolympheidema—a common underdiagnosed and undertreated problem in the wound care clinic. *J Am Col Certif Wound Spec.* 2010;2(1):14–23.
8. Adams KE, Rasmussen JC, Darne C, et al. Direct evidence of lymphatic function improvement after advanced pneumatic compression device treatment of lymphedema. *Biomed Opt Express.* 2010;1(1):114–125.
9. Karaca-Mandic P, Hirsch AT, Rockson SG, Ridner SH. The cutaneous, net clinical, and health economic benefits of advanced pneumatic compression devices in patients with lymphedema. *JAMA Dermatol.* 2015;151(11):1187–1193. The study analyzed upper and lower extremity lymphedema patients with cancer related (9a) and non-cancer related lymphedema (9b) treated with the Flexitouch System. The study evaluated use of the Flexitouch System as a tool for the treatment of lymphedema. The study documented a reduction in the rate of cellulitis episodes following use of the Flexitouch System for the treatment of lymphedema. The Flexitouch System is not used for nor intended for use to treat cellulitis.
10. Lerman M, Gaebler JA, Hoy S, et al. Health and economic benefits of advanced pneumatic compression devices in patients with phlebolympheidema. *J Vasc Surg.* 2019;69(2):571–80.
11. Blumberg SN, Berland T, Rockman C, et al. Pneumatic compression improves quality of life in patients with lower-extremity lymphedema. *Ann Vasc Surg.* 2016;30:40–4.
12. Lurie F, Passman M, Meisner M, et al. The 2020 update of the CEAP classification system and reporting standards. *J Vasc Surg Venous Lymphat Disord.* 2020;8(3):342–352. doi:10.1016/j.jvsv.2019.12.075
13. Ridner SH, McMahon E, Dietrich MS, Hoy S. Home-based lymphedema treatment in patients with cancer-related lymphedema or noncancer-related lymphedema. *Oncol Nurs Forum.* 2008;35(4):671.

Patient photos courtesy of Dr. Tony Gasparis or patient photo consent on file at Tactile Medical.

Tactile Medical

3701 Wayzata Blvd, Suite 300
Minneapolis, MN 55416 USA
T: 612.355.5100
F: 612.355.5101

Customer Service

Toll Free Tel: 833.382.2845 (833.3TACTILE)
Toll Free Fax: 866.435.3949
Hours: 7 a.m. to 7 p.m. CT, Monday–Friday
tactilemedical.com

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