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 insufficiency.¹
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 (phlebolymphedema), this venolymphatic connection means that a singular focus on repairing veins will not resolve swelling—the lymphatics must also be addressed.\(^\text{2}\)

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).\(^\text{3,4}\)

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

Phlebolymphedema 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,\(^\text{5}\) paving the way for progressive infection and complications,\(^\text{6}\) increased office visits, and costly treatments and hospitalizations.

Compression garments and appropriate endovenous or surgical interventions can reduce venous hypertension. However, phlebolymphedema requires early detection and comprehensive lymphatic therapy to reduce buildup of protein-rich edema and thereby lower risk of infection and inflammation.\(^\text{7}\) 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,\(^\text{8}\) improve outcomes,\(^\text{9,10}\) lower costs\(^\text{9,10}\) and improve quality of life\(^\text{11}\) for phlebolymphedema patients.

THE REVISED STARLING PRINCIPLE

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.\(^\text{3,4}\)
# CVI-Related Chronic EDEMA (Phlebolymphedema)

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

<table>
<thead>
<tr>
<th>CHRONIC VENOUS DISEASE (CVD)</th>
<th>LYMPHATIC INVOLVEMENT SHOWN VIA NEAR INFRARED FLUORESCENCE LYMPHATIC IMAGING(^1)</th>
<th>LYMPHEDEMA (LE)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CLINICAL STAGE</strong></td>
<td><strong>CLINICAL STAGE</strong></td>
<td></td>
</tr>
<tr>
<td><strong>C0</strong></td>
<td>C0</td>
<td>Stage 0: Latent</td>
</tr>
<tr>
<td>No Clinical Signs</td>
<td>No Clinical Signs</td>
<td>No clinical signs.</td>
</tr>
<tr>
<td><strong>C1</strong></td>
<td>Telangiectasias or Reticular Veins</td>
<td>Stage 1: Pitting Edema</td>
</tr>
<tr>
<td></td>
<td>Telangiectasias or Reticular Veins</td>
<td>Soft swelling, resolves with elevation or overnight.</td>
</tr>
<tr>
<td><strong>C2</strong></td>
<td>Varicose Veins</td>
<td>Stage 2: Non-pitting Edema</td>
</tr>
<tr>
<td></td>
<td>Varicose Veins</td>
<td>Swelling with deepened skin folds and notable tissue changes such as fibrosis, scaly skin, and possible hyperkeratosis; does not resolve with elevation.</td>
</tr>
<tr>
<td><strong>C3</strong></td>
<td>Edema (Pitting)</td>
<td>Stage 3: Lymphostatic Elephantias</td>
</tr>
<tr>
<td></td>
<td>Edema (Pitting)</td>
<td>Extensive and/or disfiguring fibrotic swelling, blistering and ulcerations, lymphorrhrea, hyperkeratosis, papillomas, and recurrent infections.</td>
</tr>
<tr>
<td></td>
<td>Edema (Non-pitting)</td>
<td>Left unmanaged, lymphedema can progress to:</td>
</tr>
<tr>
<td><strong>C4</strong></td>
<td>C4a: Pigmentation or Eczema</td>
<td>Stage 3: Lymphostatic Elephantias</td>
</tr>
<tr>
<td></td>
<td>C4b: Lipodermatosclerosis or Atrophie Blanche</td>
<td>Extensive and/or disfiguring fibrotic swelling, blistering and ulcerations, lymphorrhrea, hyperkeratosis, papillomas, and recurrent infections.</td>
</tr>
<tr>
<td><strong>C5</strong></td>
<td>Healed Venous Ulcer</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Healed Venous Ulcer</td>
<td></td>
</tr>
<tr>
<td><strong>C6</strong></td>
<td>Active Venous Ulcer</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Active Venous Ulcer</td>
<td></td>
</tr>
</tbody>
</table>

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

---

1. In biopsies, patients with CVI show structural lymphatic changes, including collapsed lumens and disturbance of lumen-opening filaments, resulting in reduced function. This chart illustrates how lymphatics can be impacted at each clinical stage of the Comprehensive Classification System for Chronic Venous Disorders (CEAP).
CHOOSE CLINICALLY PROVEN AT-HOME TREATMENT WITH HIGH PATIENT SATISFACTION AND COMPLIANCE

FLEXITOUCH® PLUS SYSTEM
The Flexitouch Plus system is the only pneumatic compression device clinically proven to stimulate the lymphatic system 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 PHLEBOLYMPHEDEMA
A study of 1,065 patients with CVI and lymphedema (phlebolymphedema) published in the Journal of Vascular Surgery found Flexitouch use significantly reduced per-patient phlebolymphedema-related costs when compared with alternative treatment modalities (all pumps used in conjunction with conservative therapy):

- **169%** Reduction vs. conservative therapy alone
- **185%** Reduction vs. simple lymphedema pumps
- **153%** Reduction vs. other advanced lymphedema pumps

AT-HOME FLEXITOUCH TREATMENT IMPROVES HEALTH OUTCOMES AND REDUCES COSTS
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:

- **175%** Reduction in rate of cellulitis episodes
- **140%** Reduction in rate of outpatient hospital visits
- **136%** Reduction in rate of lymphedema-related costs per patient
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 offerings include advanced, clinically proven pneumatic compression devices and 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 is proud that our solutions help increase clinical efficacy, reduce healthcare costs and improve 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:

Flexitouch is a registered trademark and Healing Right at Home is a trademark of Tactile Medical.
©2019 Tactile Medical. All rights reserved. D/N: 500325-000-00 Rev. B 05/2019