

Lymphedema Related to Head and Neck Cancer Treatment

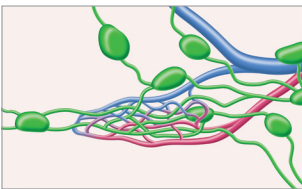
Understanding, recognizing and treating this pervasive condition.



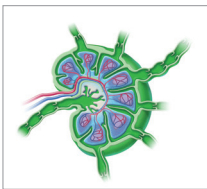
What is Lymphedema? Why is it So Common?

Lymphedema is a build-up of extracellular fluid comprised primarily of protein, cellular debris and other molecules in the interstitium. This build-up can cause swelling and discomfort. Lymphedema is often a chronic condition and can progressively become more severe. Therefore, early and careful management is needed to help reduce lymphedema symptoms and keep them from getting worse.

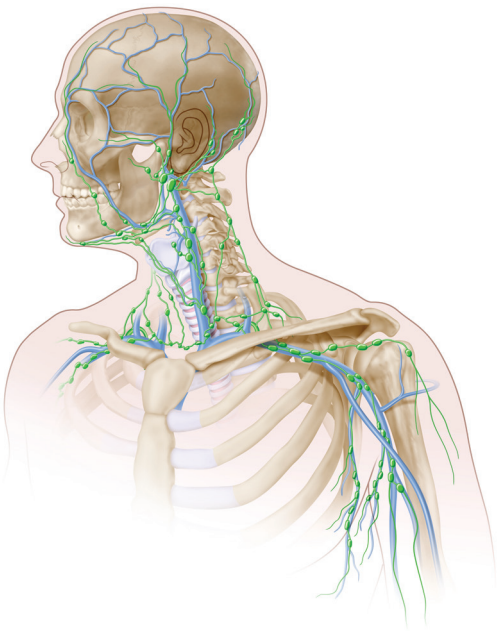
- Over one-third of the body's lymph nodes are in the head and neck
- Tumors, surgery and radiation cause lymphatic damage to nodes, vessels and capillaries
- Damage to the lymphatics leads to swelling, inflammation and fibrosis – both internally and externally



Lymphatics in Capillary Beds



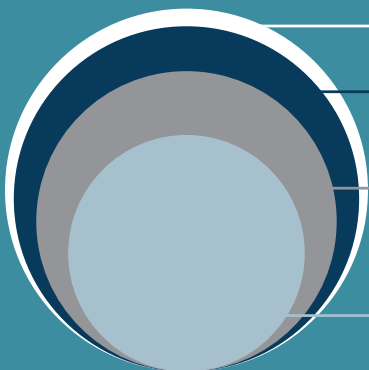
Lymph Node with One Way Valves



An Increasingly Prevalent Condition

Increasingly, human papillomavirus (HPV) patients make up the head and neck cancer population.¹ These patients are younger and incidence rates are increasing. Survival rates are also increasing, leaving patients to cope for decades with the burdensome effects of their cancer treatment.

12 MONTHS POST-TREATMENT



All HNC patients

90%
have lymphedema

75%
of lymphedema cases are moderate/severe

47%
have moderate/severe fibrosis

90%
of patients
have lymphedema
symptoms after
head/neck
cancer treatment²

Head and Neck Lymphedema Presents Internally and Externally



Lymphedema Significantly Impacts Quality of Life

Across the patient population, symptom presentation varies widely based on cancer site, stage, and treatment strategy. The location of symptoms makes lymphedema related to head and neck cancer particularly problematic for patients.

**THIS PATIENT POPULATION EXHIBITS SIGNIFICANTLY INCREASED RISK
OF DEPRESSION AND SUICIDE – EVEN WHEN CANCER FREE³**

LYMPHEDEMA SYMPTOMS INCLUDE:⁴

- **Dysphagia**
- **Reduced range of motion**
- **Swelling** – internal and external
- **Vocal changes or difficulty speaking**
- **Pain, tightness and discomfort**
- **Scarring or fibrosis**
- **Tingling and numbness**
- **Difficulty breathing**

1. Gillison et al *J Clin Oncol* 2015. doi: 10.1200/JCO.2015.61.6995 2. Ridner, S.H., et al, *Lymphat Res Biol*, 2016. 14(4): p. 198-205.
3. Osazuwa-Peters et al *Cancer* 2018. doi: 10.1002/cncr.31675 4. Doersam et al. *Lymphat Res Biol* 2019. doi: 10.1089/lrb.2019.0034.

Barriers to Professional Lymphedema Care

Research shows that only 15% of head and neck cancer survivors utilize professional therapy from an Speech Language Pathologist (SLP) or Certified Lymphedema Therapist (CLT) for their symptoms¹. When patients do receive treatment, the typical therapy can be difficult for patients to continue on their own for the long term.

CONSERVATIVE LYMPHEDEMA TREATMENT AND ITS SUBSTANTIAL BARRIERS

Conservative Treatment	Barrier for Long Term Utilization ²
In-clinic therapy with professional manual lymphatic drainage (MLD)	▪ Distance from specialists ▪ Access to specialists ▪ Time or financial barriers ▪ Lack of insurance coverage
Self MLD	▪ Difficulty given impacted anatomy ▪ Difficult learning curve
Compression masks	▪ Impractical for daily living ▪ Uncomfortable

only a **58%** positive patient response rate to professionally-directed home management strategies and limited access to professional therapy³

UNTREATED LYMPHEDEMA MAY PROGRESS TO FIBROSIS

1. Wang et al *Head Neck* 2019. doi: 10.1002/hed.25844. 2. Deng and Murphy *Support Care Cancer* 2016. doi:10.1007/s00520-016-3356-2. 3. Smith BG et al *Otolaryng Head Neck* 2015. doi: 10.1177/0194599814558402. 4. Karaca-Mandic et al *JAMA Dermatol* 2015. doi: 10.1001/jamadermatol.2015.1895. 5. Ridner et al *Oncol Nurs Forum* 2008. doi: 10.1188/08.ONF.671-680. 6. Ridner et al *Lymphat Res Biol* 2016. doi: 10.1089/lrb.2016.0001.

Advanced Pneumatic Compression Device for Lymphedema Treatment

Given the difficulties survivors of head and neck cancer face with ongoing self treatment of their lymphedema symptoms, an advanced pneumatic compression device (APCD) offers an easy to use, effective option. APCDs are clinically proven and widely used for the management of cancer related lymphedema.^{4,5}

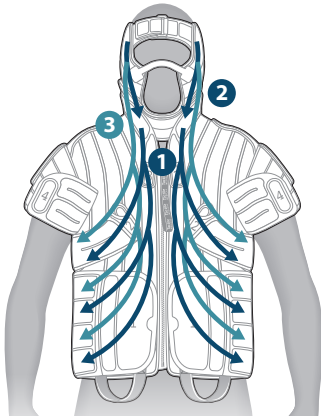
**Flexitouch® Plus is the only pneumatic compression device
510(k) cleared for use in the head and neck.**

Mechanism of Action of the Flexitouch Plus System

The Flexitouch Plus APCD provides dynamic pressure to stimulate 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 wavelike application of pressure to stimulate the movement of lymphatic fluid and direct it toward properly functioning areas of the body.

Flexitouch Plus closely mimics manual lymphatic drainage, directing fluid from the:

- 1** Neck and chest toward the underarm
- 2** Head and face toward the neck
- 3** Head, neck and face toward the healthy regions of the chest in one continuous motion



**32-minute daily
treatment time**

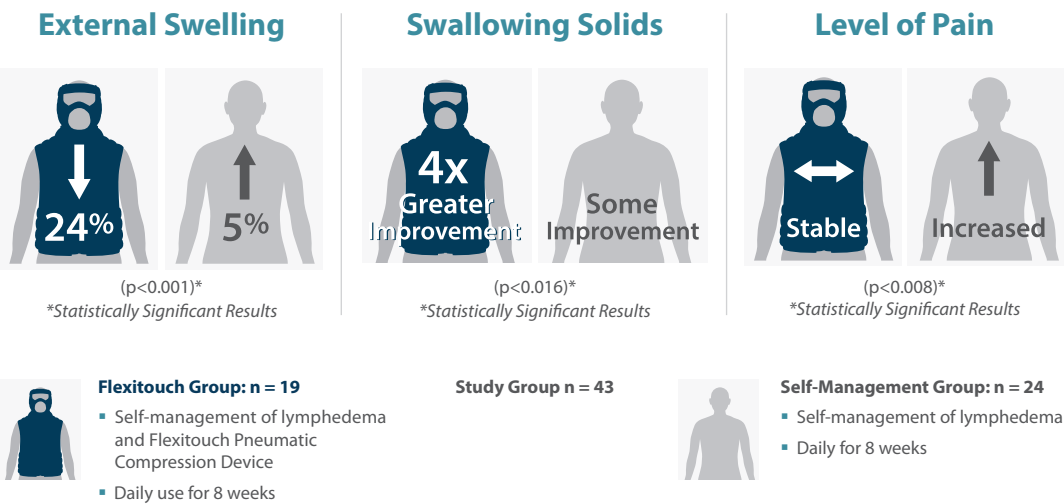


**89% of patients
report improvement in head
and neck swelling⁶**

Randomized Control Trial Demonstrates Clinical Efficacy

A range of studies support Flexitouch Plus advanced pneumatic compression for treatment of head and neck cancer-related lymphedema, including the first randomized control trial studying Flexitouch vs. Self management alone.¹

Vanderbilt researchers found **statistically significant improvements** with the use of Flexitouch compared to self management alone.



FLEXITOUCH ALSO DEMONSTRATED IMPROVEMENTS IN:

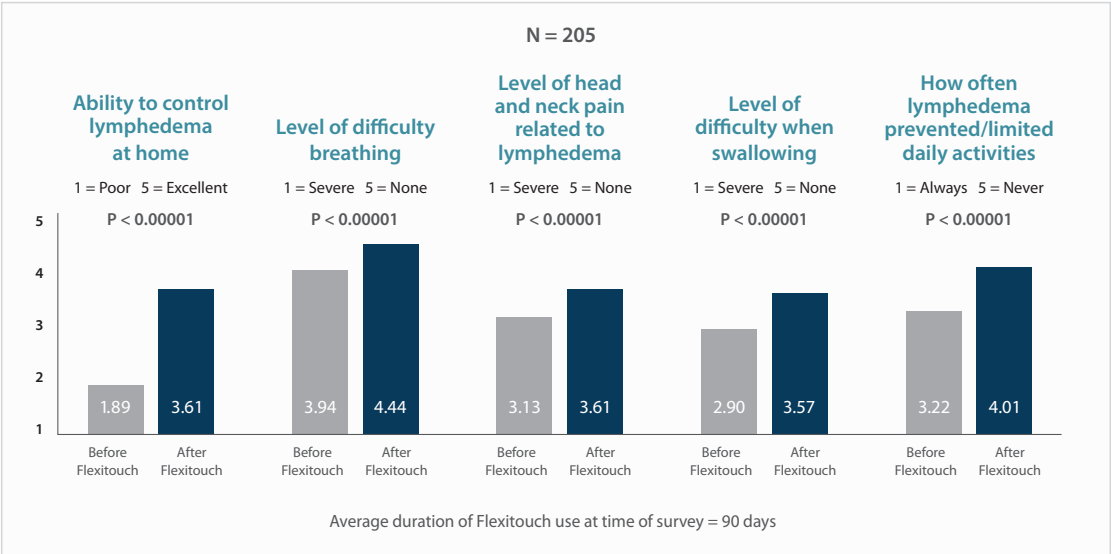
- Mucous-related symptoms (p=.050)
- Severity of soft tissue symptoms (p=.008)
- Severity of neurological symptoms (p=.047)

*Results are based on the median change in scores from baseline measurements.
More information at tactilemedical.com and full data table available on clinicaltrials.gov*

Flexitouch Plus users experienced
4 times greater
improvement in swallowing
solids than non-Flexitouch Plus users¹

Patient Reported Outcomes Study: Significant Improvement in Symptoms

In a study of 205 patients who received the Flexitouch, pre-treatment to post-treatment comparisons showed improvements in all surveyed symptoms, most notably in the level of difficulty when swallowing²

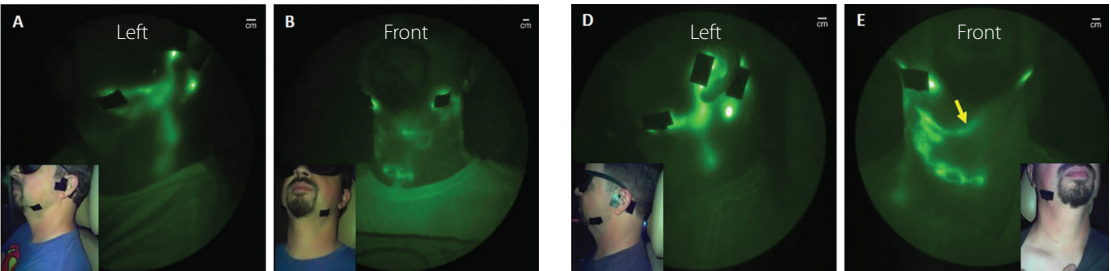


Imaging Study: Improved Lymphatic Flow with Flexitouch Plus

In a study in which 10 patients underwent imaging with indocyanine green dye, all patients showed improved lymphatic uptake after two weeks of using the Flexitouch Device.³

Flexitouch produces the same physiological impact in the breast cancer-related population; flow is directed from the damaged area toward healthier nodes.

The Flexitouch clears pathways downstream from the swollen areas so the pooled lymph can start flowing again.



1. Ridner et al *Lymphat Res Biol* 2016. doi: 10.1089/lrb.2016.0001. 2. Gutiérrez et al *Head Neck* 2020. doi: 10.1002/hed.26110. 3. Gutierrez et al *Otolaryng Head Neck* 2019. doi: 10.1177/0194599818823180.

TREATMENT RESULTS



Before



3 months



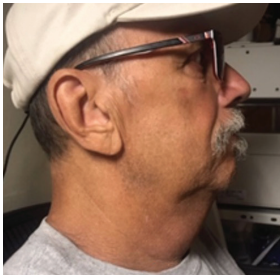
8 months



Before



After



Before: 3 months post-radiation treatment



After: One 32-minute Flexitouch Plus treatment



DOWNLOAD OUR SYMPTOM
SCREENER TO HELP IDENTIFY YOUR
PATIENTS' CHRONIC SWELLING.

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.

Individual results may vary.

Indications for Use: The Flexitouch Plus system and garments for legs, arms, trunk, and chest are intended for use by medical professionals and patients who are under medical supervision, for the treatment of many conditions such as: lymphedema; primary lymphedema; post mastectomy edema; phlebotymphedema; lipedema; edema following trauma and sports injuries; post immobilization edema; venous insufficiency; reducing wound healing time; treatment and assistance in healing stasis dermatitis, venous stasis ulcers, or arterial and diabetic leg ulcers. The Flexitouch Plus system and garments for the head and neck are intended for use by medical professionals and patients who are under medical supervision for the treatment of head and neck lymphedema.

Contraindications: 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.

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