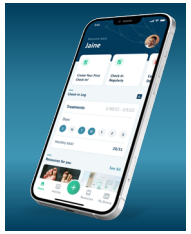
Tactile Medical At a Glance

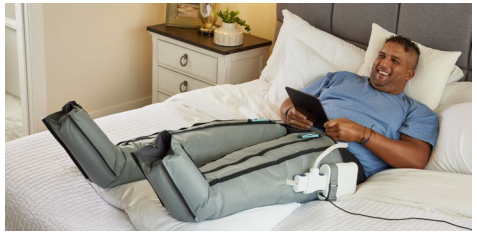
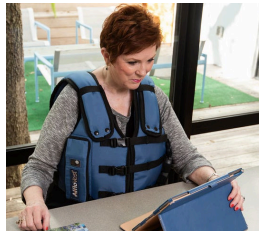
Our Mission:

To reveal and treat patients with underserved chronic conditions and help them care for themselves at home

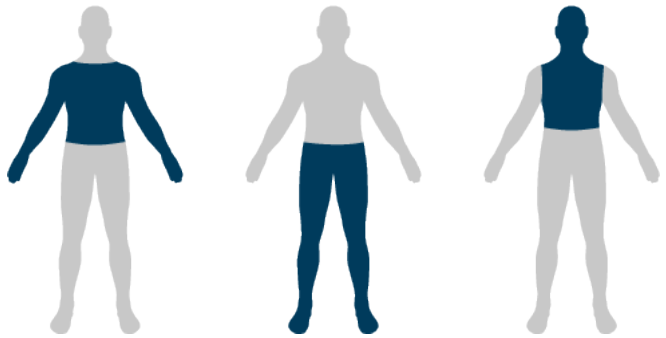
FOUNDED	1995
HEADQUARTERS	Minneapolis
TOTAL EMPLOYEES	~1,000
PATIENTS SERVED IN 2023	>77,000
PRODUCTS	Flexitouch® Plus, Nimbl™, Kylee™, AffloVest®



Supportive Care and Rehabilitation for Head and Neck Cancer Survivors



Tactile MEDICAL®

HEALING RIGHT AT HOME

Financial Disclosure Statement

The content of this program was created by the following individuals who are employed by or otherwise receive compensation from Tactile Medical

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Agenda

- Head and neck cancer overview
- Head and neck anatomy and physiology
- Treatment and rehabilitation of head and neck cancer
- Effects and sequela of head and neck cancer treatment/intervention
- Signs, symptoms and treatment of head and neck cancer-related lymphedema

Head and Neck Cancer (HNC) in the United States

The NCI estimated prevalence in 2024

4%
of all cancers

New cases:
71,110

Deaths:
16,110

Males affected more than females 2.7:1

Common Risk Factors for Head and Neck Cancers

Human papillomavirus (HPV)

- Steady increase in oropharyngeal cancer associated with HPV
  - 16.3% of oropharyngeal cancer cases before 1999
  - 71% of oropharyngeal cancer cases presently
- Younger age at diagnosis
- More responsive to treatment

Tobacco and alcohol use

- Risk is 30 times higher in those that smoke and drink heavily
- Patients tend to be older males with more comorbidities

cdc.gov/cancer/headneck/
Lechner M, Liu J, Masterson L, Fenton TR. HPV-associated oropharyngeal cancer: epidemiology, molecular biology and clinical management. Nat Rev Clin Oncol. 2022 May;19(5):306-327

Swallow Anatomy: Sagittal View

Nasal cavity: above the hard palate

Oral cavity: lips, tongue, teeth

Pharynx: nasal cavity to larynx

- Nasopharynx: nasal cavity to soft palate
- Oropharynx: soft palate to hyoid bone
- Laryngopharynx: hyoid to cricoid

Larynx: cartilaginous structure at top of trachea

- Contains vocal cords

Palate: roof of mouth, separates oral and nasal cavity

Uvula: fleshy extension hanging from back of palate

Trachea: "windpipe"

Esophagus: connects throat to stomach

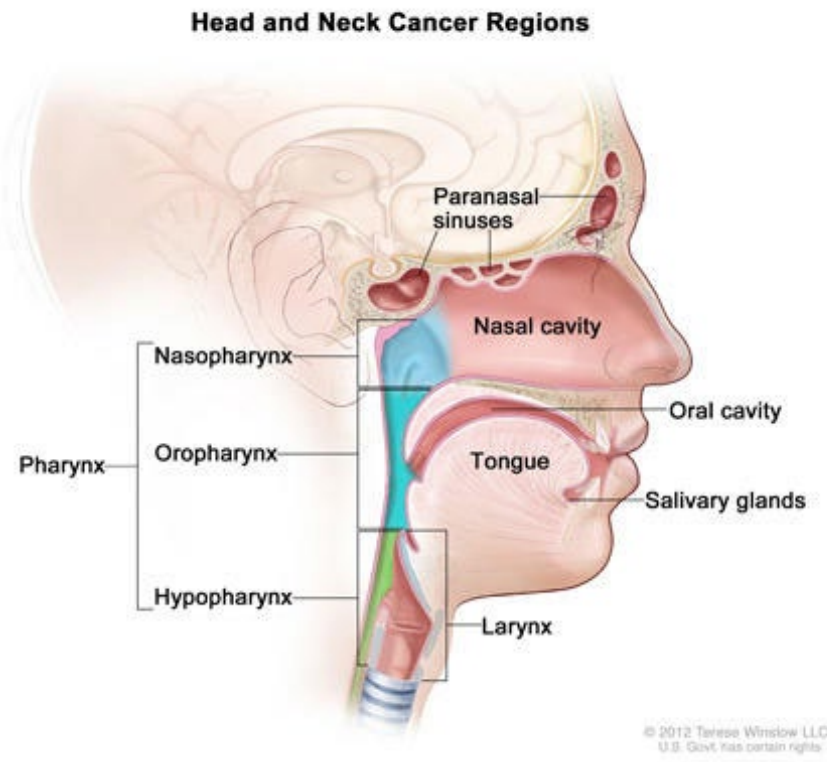


Photo Credit: Terese Winslow via cancer.giov

Swallow Anatomy: Superior View (Endoscopic/FEES)

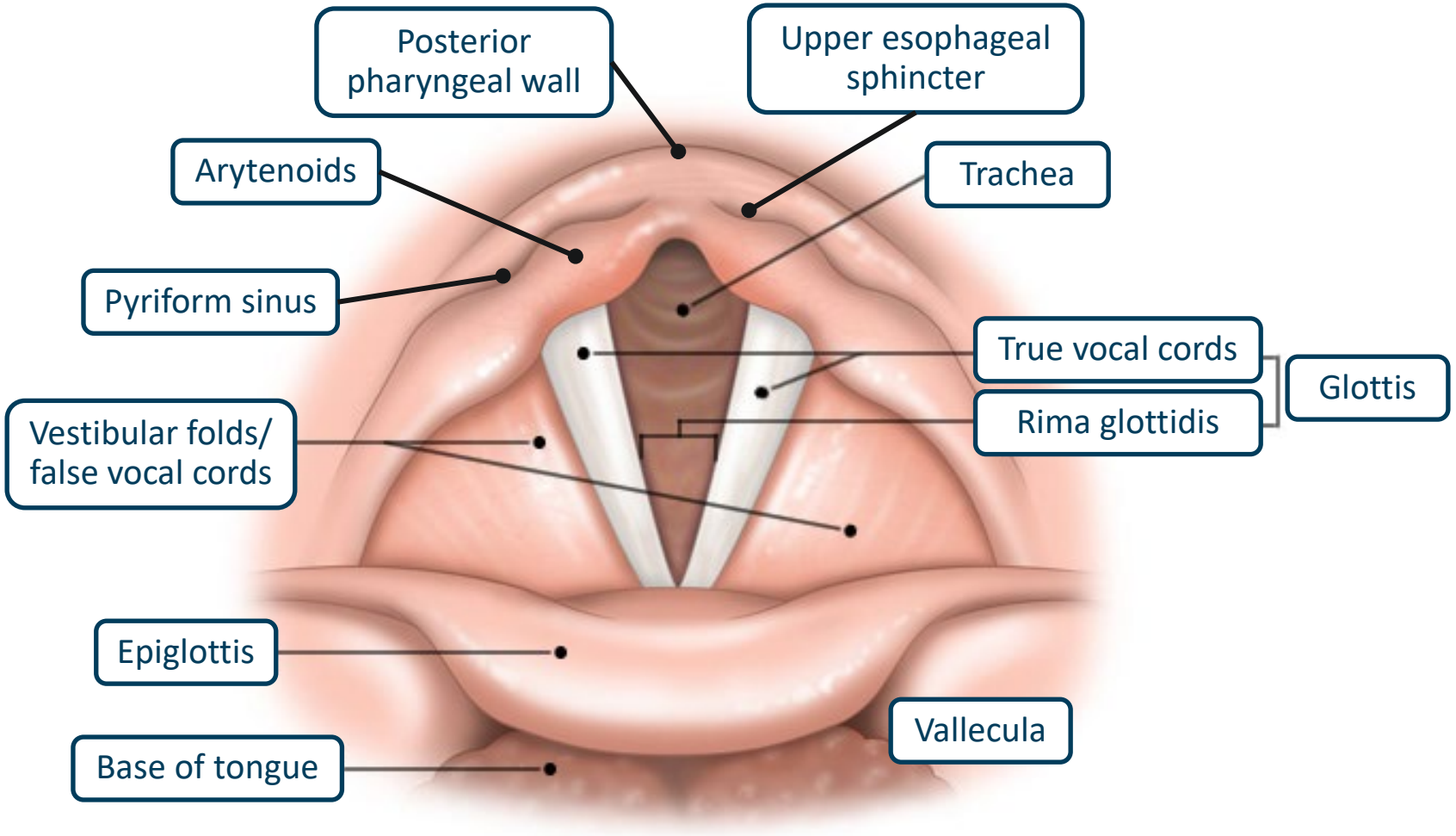


Photo credit: https://tophat.com/marketplace/science-&-math/biology/full-course/anatomy-and-physiology-in-context-john-redden-joe-crivello/797/73306/

SWALLOWING

Head and Neck Cancer Locations

Most common locations

- Oropharynx
- Oral cavity
- Larynx

Less common locations

- Nasopharynx
- Nasal cavity and paranasal sinuses
- Hypopharynx
- Salivary glands

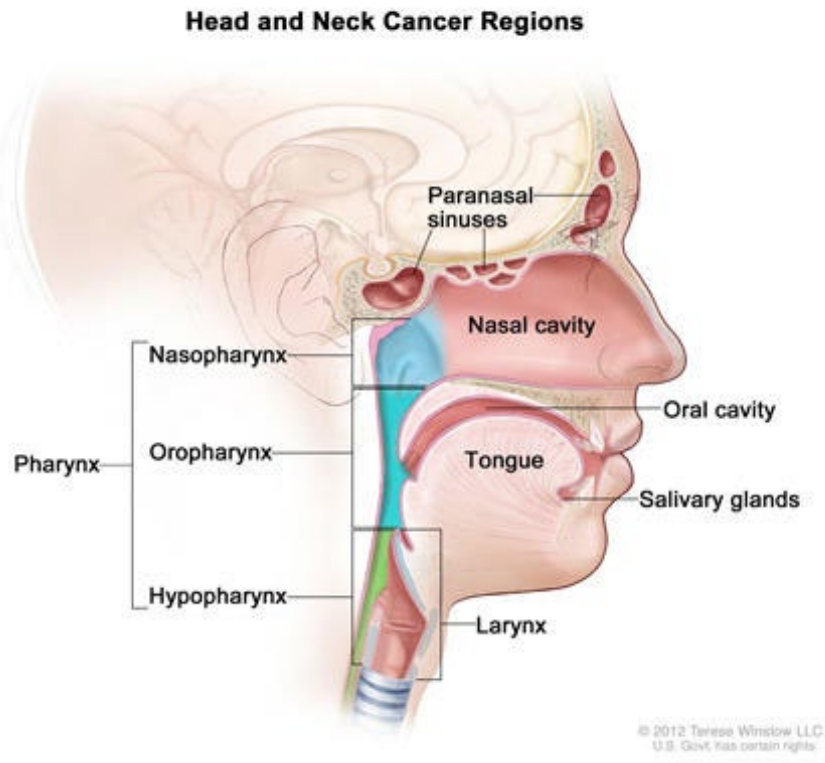


Photo Credit: Terese Winslow via cancer.giov

95% of cancers are squamous cell carcinoma, impacting mucosal lining and surfaces

Head and Neck Cancer Signs and Symptoms

- Hoarseness/voice changes
- Chronic sore throat
- Chronic cough and/or globus sensation
- Difficulty with/painful swallowing
- Surface lesions/bleeding
- Referred ear pain
- Bad breath
- Swollen neck lymph nodes

Photo credit: Oregon Ear, Note and Throat Center

Dahiya K, Dhankhar R. Updated overview of current biomarkers in head and neck carcinoma. *World J Methodol*. 2016;6(1):77-86. Published 2016 Mar 26. doi:10.5662/wjm.v6.i1.77

Diagnostics

Biopsy	Imaging	Blood tests: biomarkers
▪ Laryngoscopy ▪ Endoscopy ▪ Fine needle aspiration ▪ Core needle ▪ Surgical biopsy	▪ MRI ▪ CT ▪ US ▪ PET scan ▪ Modified/barium swallow study ▪ Bone scan	▪ **Oropharyngeal cancer** • Human papilloma virus (HPV) • p16INK4A (p16) ▪ **Nasopharyngeal cancer** • Epstein-Barr virus (EBV)

Economopoulou P, de Bree R, Kotsantis I, Psyrri A. Diagnostic Tumor Markers in Head and Neck Squamous Cell Carcinoma (HNSCC) in the Clinical Setting. *Front Oncol*. 2019;9:827. Published 2019 Aug 29. doi:10.3389/fonc.2019.00827

Lymphatic Anatomy of the Head and Neck

Lymphatics Nodes and Vessels of the Head and Neck

Lymphatic nodes and vessels

Divided into two major groups

- **Superficial vessels and nodes**
  - Drain lymph from scalp, face and neck into superficial ring of lymph nodes at junction of the neck and head
- **Deep vessels and nodes**
  - Arise from deep cervical lymph nodes
  - Converge to form l and r jugular lymphatic trunks

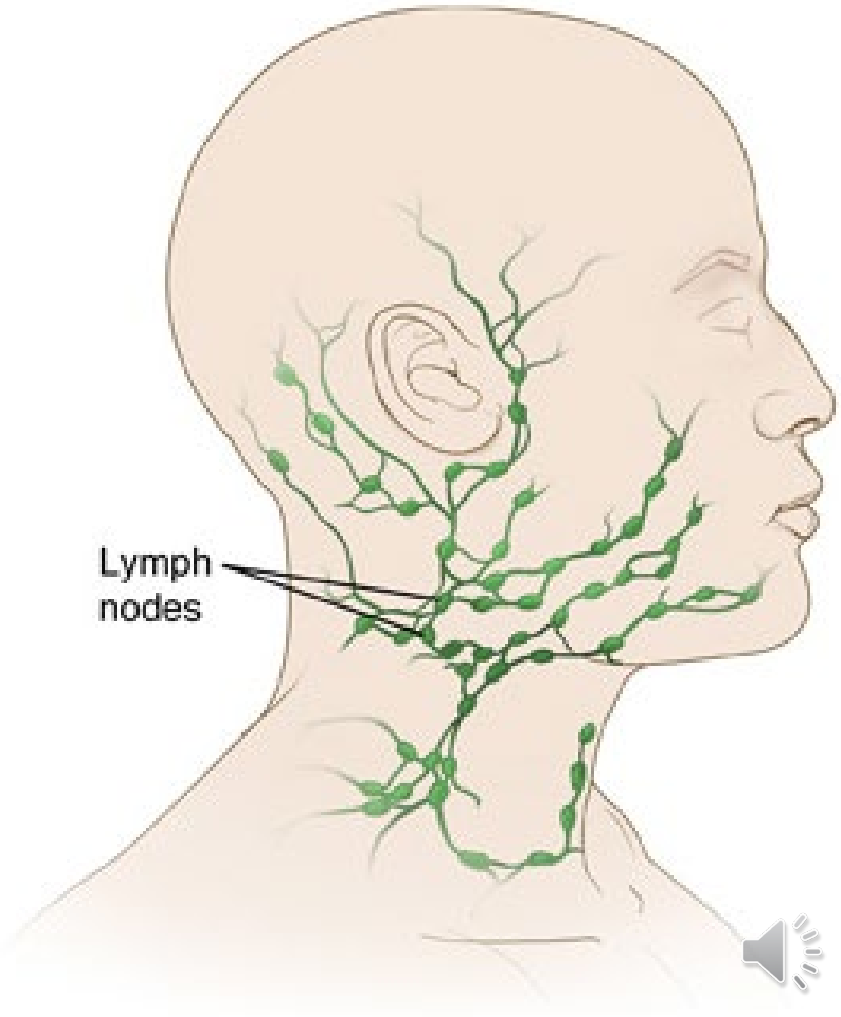
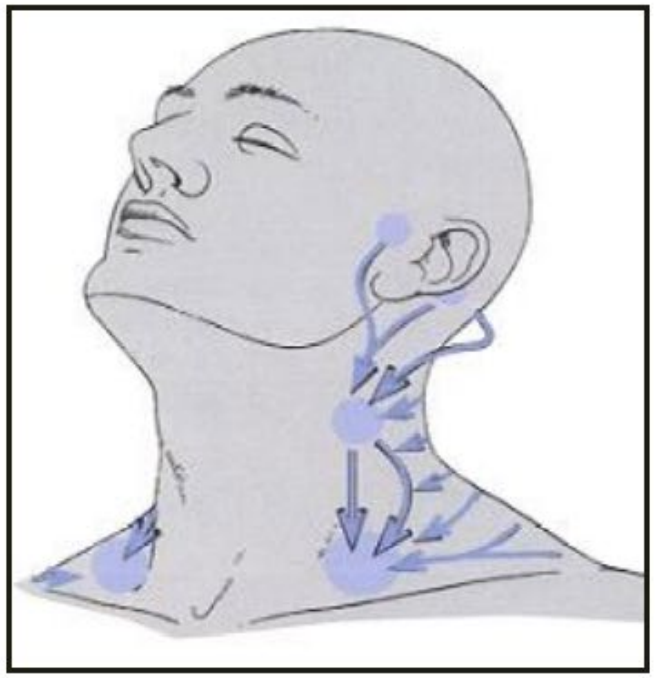
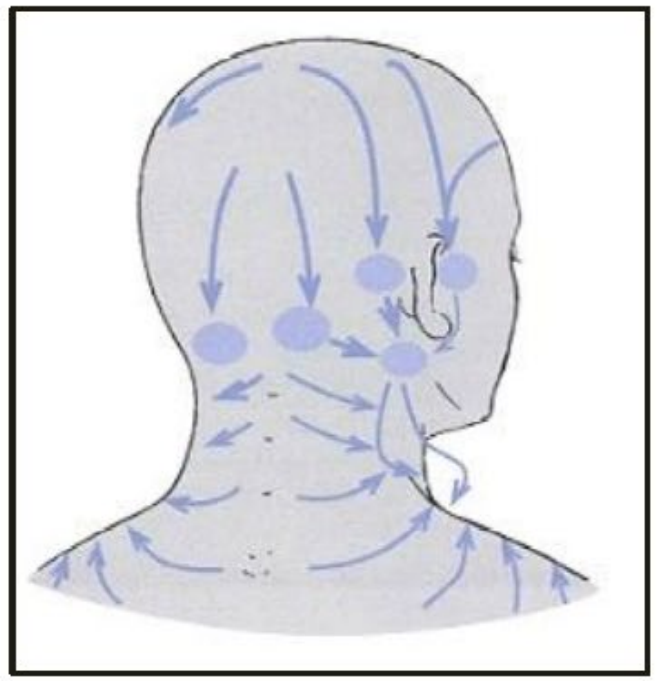


Photo credit: Spectrum Health Lakeland Ear, Nose and Throat

Head and Neck Lymph Drainage Patterns





Lymph Node Regions

American Academy of Otolaryngology classification of cervical lymph nodes

- Corresponds to drainage of the tumors
- Lymph nodes removed during tumor removal are based on patterns of metastases that are predictable relative to primary site of disease
  - **Level I: Ia:** submental, **Ib:** submandibular
  - **Level II:** upper internal jugular (deep cervical) chain
  - **Level III:** middle internal jugular (deep cervical) chain
  - **Level IV:** lower internal jugular (deep cervical) chain
  - **Level V: Va:** supraclavicular/**Vb:** spinal accessory
  - **Level VI:** central (anterior) compartment
  - **Level VII:** anterior superior mediastinum and tracheoesophageal grooves

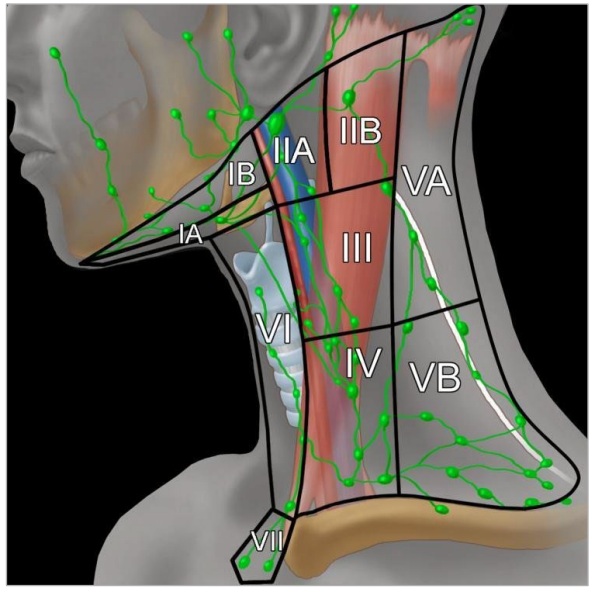
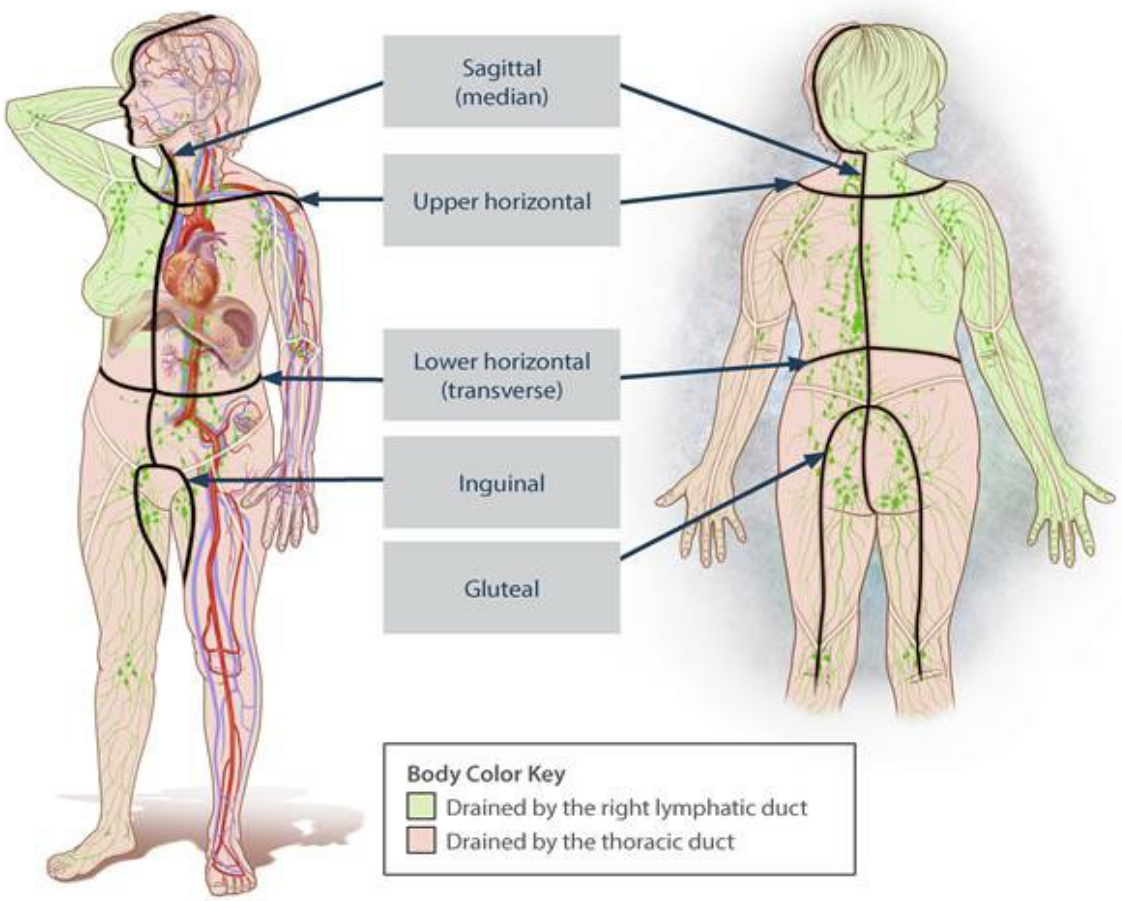
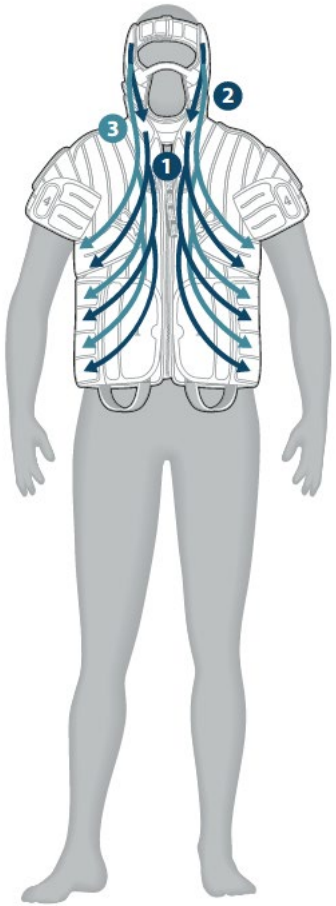


Photo credit: ResearchGate

Lymphatic Watersheds

Linear areas on the skin that separate territories





Head and Neck Cancer: Treatment

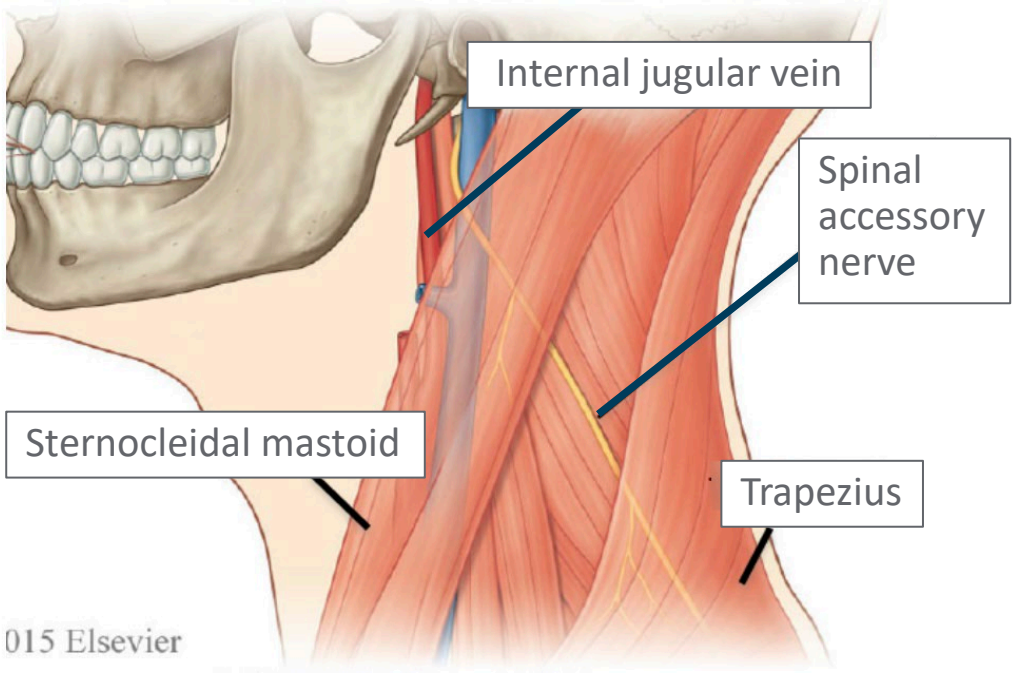
Head and Neck Surgery

Selective neck dissection

- Removes only lymph nodes where cancer is likely to spread
- Muscle and nerve tissue are spared
- Incidence of lymphedema is low

Modified radical neck dissection

- Removes lymph nodes from level I-V
- Type 1 – spares the spinal accessory nerve
- Type 2 – preserves the internal jugular vein as well
- Type 3 – additionally spares the SCM



Radical neck dissection

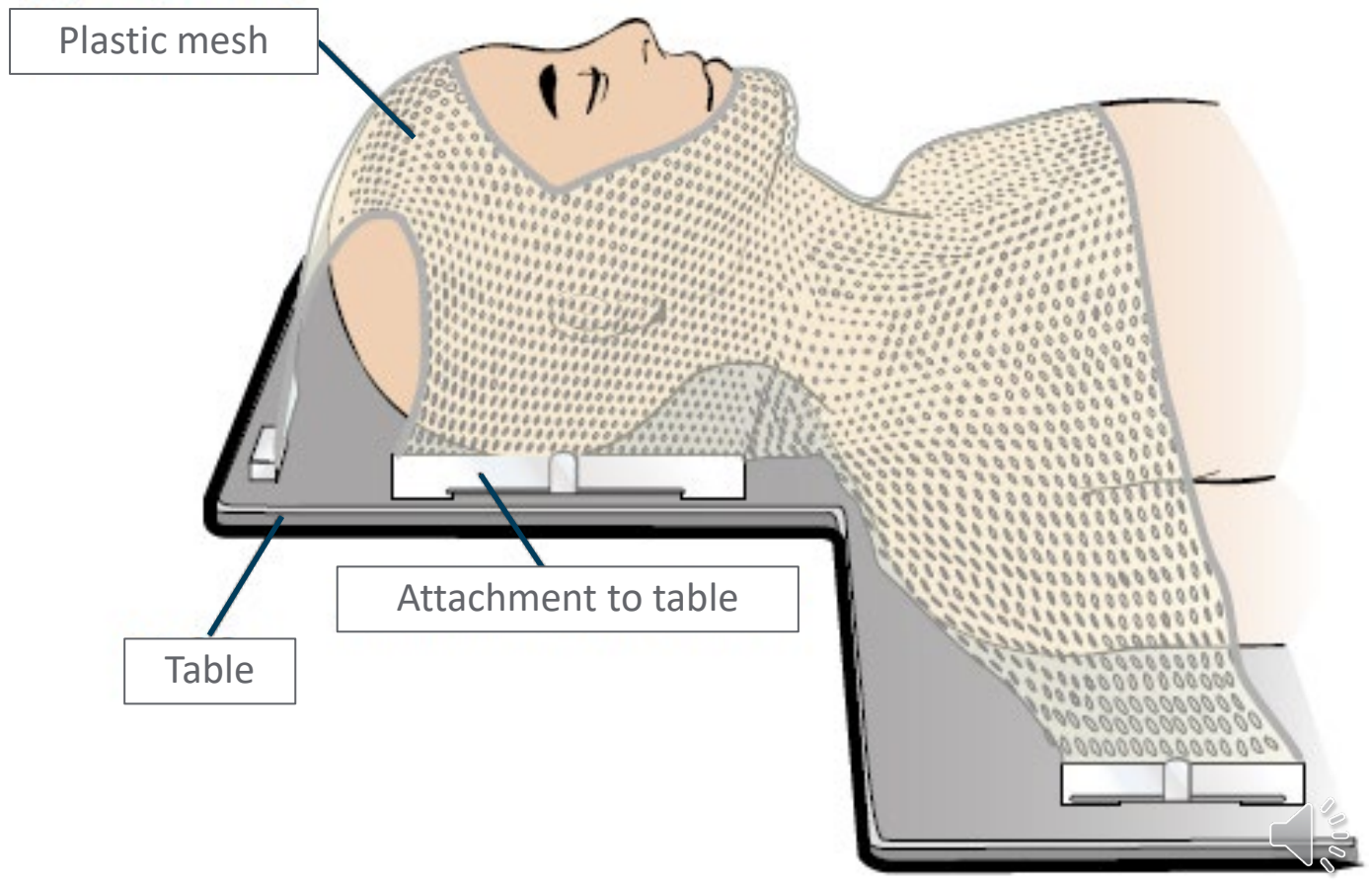
- Removes nearly all the lymph nodes on affected side
- Removes the spinal accessory nerve, internal jugular vein, and SCM

Reconstructive surgery

- Free and autogenous flaps
- Bone grafts

Head and Neck Radiation Therapy

- Definitive
- Fractionated
- Hypofractionated
- Pre- or post-operative
- Concurrent
- Palliative



https://www.mskcc.org/cancer-care/patient-education/radiation-therapy-head-and-neck

Chemotherapy

Features	Systemic chemotherapy	Targeted chemotherapy	Immunotherapy
Target	Rapidly dividing cells	Specific molecular target	Immune system
Specificity	Low	High	High
Side effects	Severe and widespread	Milder, target-dependent	Immune-related
Scope	Broad (many cancers)	Restricted to targetable cancers	Limited to immune-responsive cancers
Durability	Short-term (repeated cycles)	Resistance can occur	Long-lasting (immune memory)

Head and Neck Cancer Treatment Side Effects

Surgery	Radiation	Chemotherapy
▪ Scar adhesions and fibrosis ▪ Speech and swallow disorders ▪ Nerve damage (spinal accessory) ▪ Loss of sternocleidomastoid ▪ Loss of function such as trismus	▪ Dental complications ▪ Mucositis ▪ Xerostomia ▪ Alterations in taste ▪ Trismus/TMJ ▪ Skin changes ▪ Infection ▪ Osteonecrosis ▪ Fibrosis ▪ Lymphedema	▪ Myelosuppression ▪ Cardiotoxicity ▪ Cancer-related fatigue ▪ GI upset ▪ Cognitive dysfunction ▪ Joint pain ▪ Soft tissue inflammation ▪ Epidermal and dermal changes

How Does Cancer Affect the Lymphatic System?

Baseline

- Presence of tumor affects lymphatic fluid movement

Surgery

- Removal of lymph nodes, muscle and nerve tissue increases risk for lymphedema

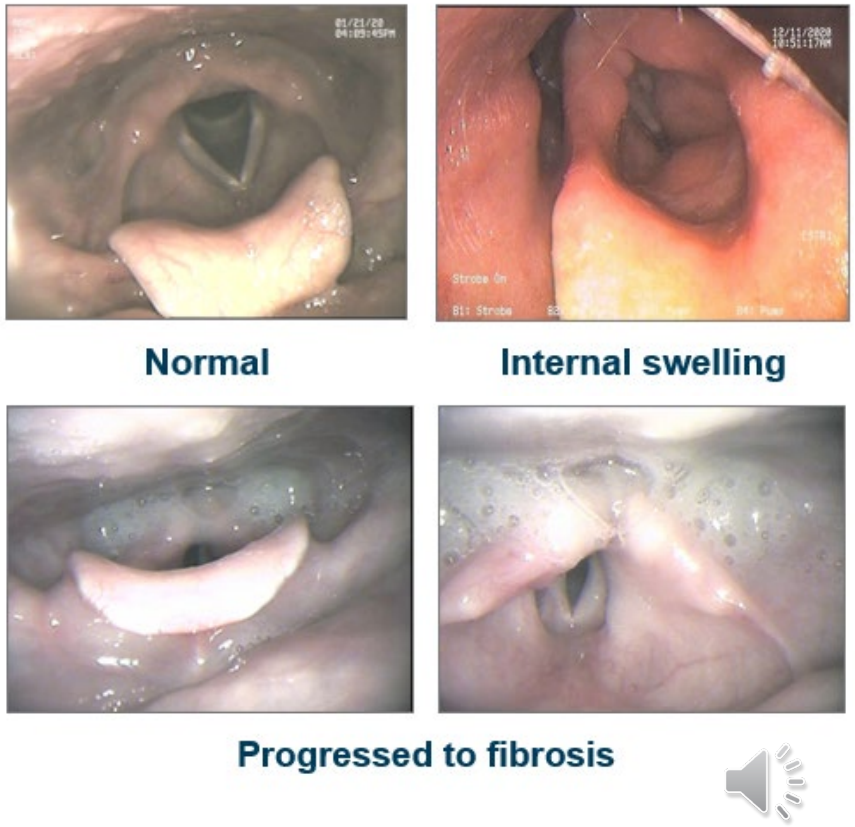
Radiation

- Radiation increases risk of lymphedema through decreased lymphatic proliferation potential, interstitial fibrosis compressing lymphatic vessels and mechanical insufficiency of lymphatic system

Chemotherapy

- Fluid retention and decreased lymphatic propulsion rate

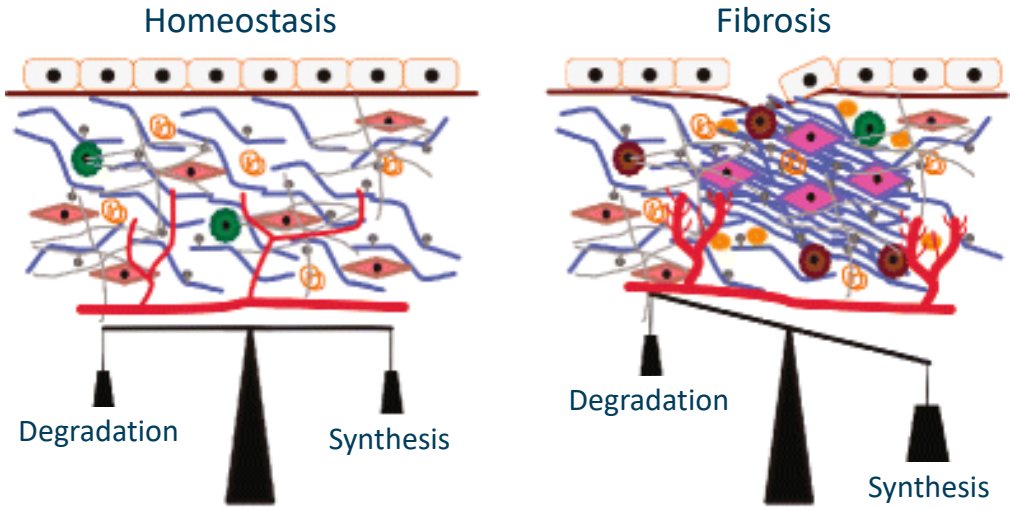
Radiation results in acute, chronic and late affect toxicities



1. Ridner SH, Dietrich MS, Niermann K, Cmelak A, Mannion K, Murphy B. A Prospective Study of the Lymphedema and Fibrosis Continuum in Patients with Head and Neck Cancer. Lymphat Res Biol. 2016 Dec;14(4):198-205.
2. Chaput G, Ibrahim M, Towers A. Cancer-related lymphedema: clinical pearls for providers. *Curr Oncol*. 2020;27(6):336-340.
3. Allam,O. et al. The impact of radiation on lymphedema: a review of the literature. Division of Plastic and Reconstructive Surgery, Yale University, New Haven, CT, USA . Dec 24, 2019
4. Johnson AR, Granoff MD, Lee BT, Padera TP, Bouta EM, Singhal D. The Impact of Taxane-based Chemotherapy on the Lymphatic System. *Ann Plast Surg*. 2019;82(4S Suppl 3):S173-S178. doi:10.1097/SAP.0000000000001884

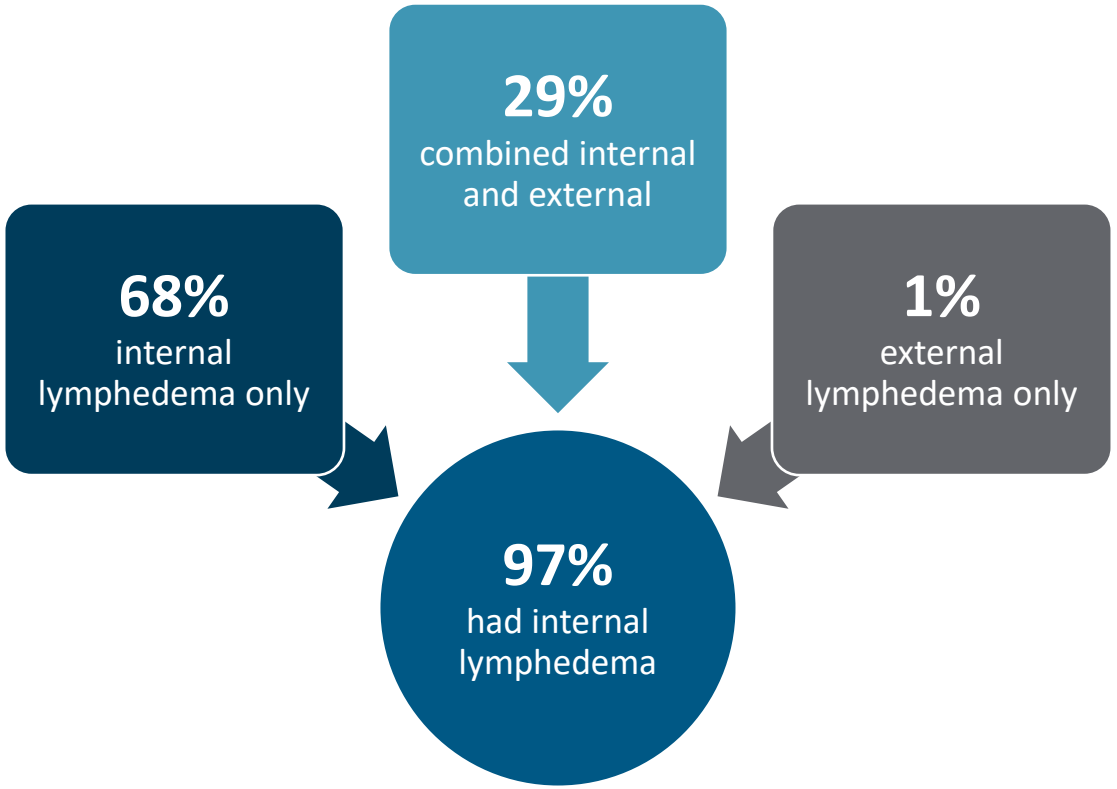
Radiation Fibrosis

- Repetitive, chronic tissue injury
- Excessive ECM buildup
- Pathological tissue changes occur
- Functional impairment results



Coelho, N.M., McCulloch, C.A. Contribution of collagen adhesion receptors to tissue fibrosis. Cell Tissue Res 365, 521–538 (2016). https://doi.org/10.1007/s00441-016-2440-8

Internal and External Lymphedema Following Head and Neck Cancer Treatment



Most common internal locations

- Epiglottis
- Arytenoids
- Pharyngoepiglottic folds
- Aryepiglottic folds

Most common external locations

- Submental region
- Neck

Higher severity of internal and external LE

- More severe dysphagia
- Poorer-patient reported outcomes
- Need for more diet modifications

Jeans, C, Ward, EC, Brown, B, et al. Association between external and internal lymphedema and chronic dysphagia following head and neck cancer treatment. *Head & Neck*. 2021; 43: 255– 267. https://doi.org/10.1002/hed.26484

Internal and External Lymphedema Following Head and Neck Cancer Treatment

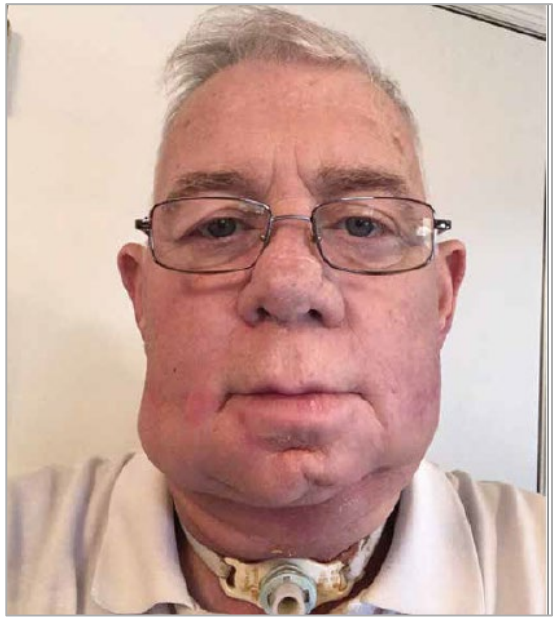
A 2024 systematic review of 12 studies reported	A 2024 cross-sectional study of 59 patients treated for HN cancer 6 months to 3 years prior found
▪ Internal lymphedema prevalence is consistently higher than external lymphedema. ▪ HNL significantly impacts QOL and physical function, including discomfort, tightness, swallowing diffulties, and psychological distress.	▪ Lymphedema prevalence is 94% with a median severity score of 9/24. ▪ Patients with higher lymphedema scores experienced poorer speech, indicating a moderate correlation between lymphedema severity and speech

Gaitatzis et al. Patient-reported outcome measures and physical function following head and neck lymphedema—a systematic review. Journal of Cancer Survivorship. September 2024.

Arends et al. Lymphedema and trismus after head and neck cancer, and the impact on body image and quality of life. Cancers 2024. 16(3), 653.

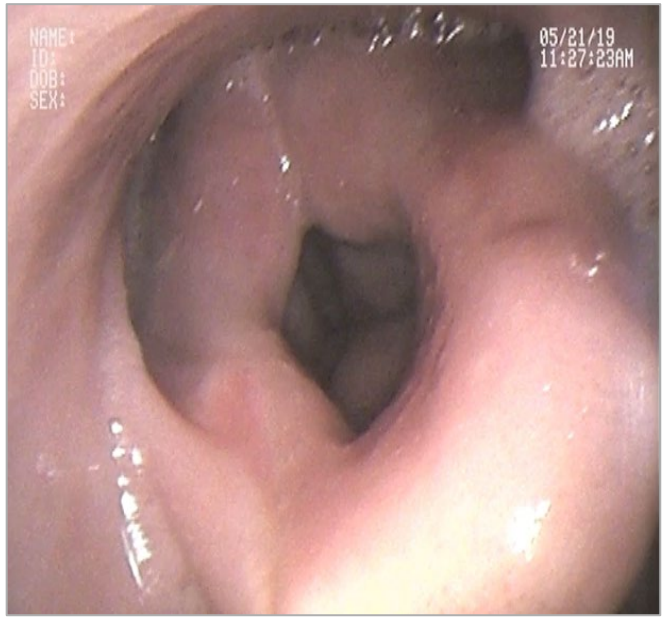
Assessment of
Head and Neck Lymphedema

How Can We Identify External and Internal Head and Neck Lymphedema in Our Own Patients?

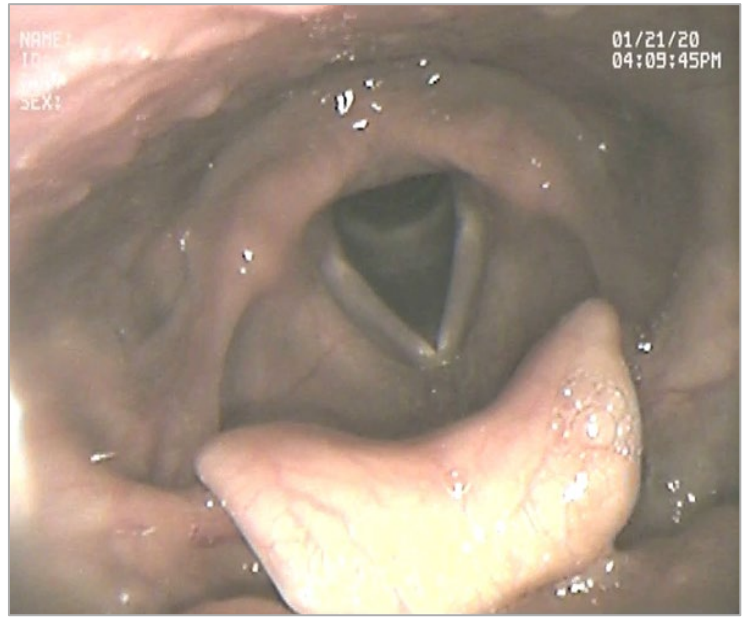


*Patient consent on file at Tactile Medical

External swelling



Internal swelling: epiglottis, arytenoids



Normal structure reference

- We need to be recognizing, diagnosing and treating both external and internal lymphedema
- Assess internal structures for swelling
- A patient may have only internal swelling

Clinical Head and Neck Assessment

Examine

- Oral cavity/oropharynx
  - Lips, gums, teeth, tongue, floor of mouth, hard palate, soft palate, uvula, tonsils
- Edema
- Drainage/abscess/infection
- Cervical and shoulder ROM
- Strength
- Balance

Ask about

- Changes in sensation
- Pain
- Globus
- Difficulty swallowing
- Change in voice quality/pitch/volume
- Mastication/chewing
- Other symptoms

Other assessment tools

- Photographs
- Fibrosis scale
- External measurements
  - Facial/neck composite
  - MD Anderson Cancer Center head and neck lymphedema protocol
- Patient reported outcome measures (PROM)
- Patterson scale for internal lymphedema

Preliminary Experience with Head and Neck Lymphedema and Swallowing Function in Patients Treated for Head and Neck Cancer, Jan S. Lewin, Katherine A. Hutcheson, Denise A Barringe,r Brad G Smith, Perspectives on Swallowing and Swallowing Disorders (*Dysphagia*) June 2010

Staging HNC Lymphedema: External

MD Anderson Cancer Center facial and neck composites

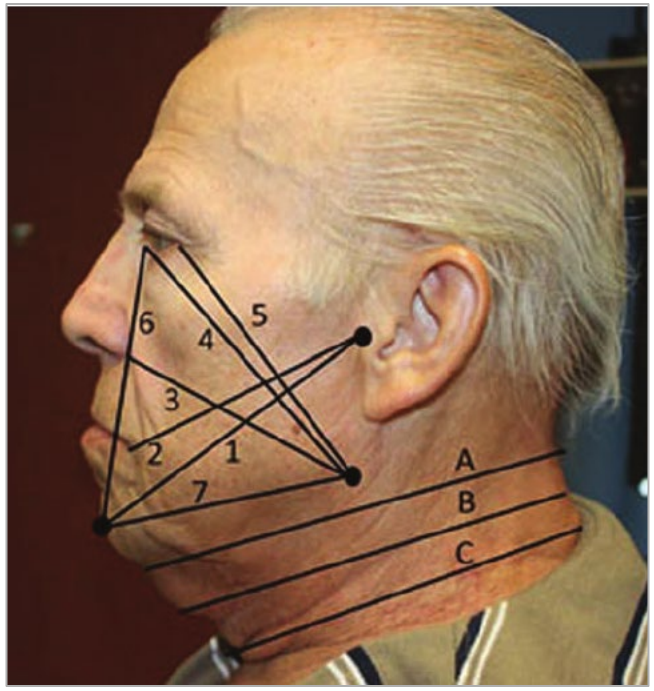


Photo Credit: MD Anderson

MD Anderson Cancer Center head and neck lymphedema staging

Stage	Exam findings
0	No swelling, but a sense of heaviness in the neck
1a	Visible mild swelling without pitting. Reversible
1b	Visible mild swelling with pitting. Reversible
2	Firm pitting swelling that is irreversible. No visible tissue changes
3	Irreversible tissue changes with scarring and fibrosis

NCI-CTCAE v4.03 Grading for Radiation Induced Fibrosis

Fibrosis grade	Induration	Appearance
0	None	Normal skin
1	Mild induration	Able to move skin parallel to plane (sliding) and perpendicular to skin (pinching up)
2	Moderate induration	Able to slide skin, unable to pinch skin; limiting instrumental ADL
3	Severe induration	Unable to slide or pinch skin; limiting joint movement or orifice (e.g., mouth, anus); limiting self care ADL
4	Generalized	Associated with signs or symptoms of impaired breathing or feeding

Head and Neck Cancer Treatment-Related Lymphedema Patient Symptom Screener

CHECK ALL THAT APPLY[1–4]

- ☐ Swelling in any part of the face/head, neck
- ☐ Changes in voice
- ☐ Difficulty swallowing, chewing, speaking or breathing
- ☐ Globus sensation (feeling of something stuck in the throat)
- ☐ Changes in vision or hearing
- ☐ Heaviness or tightness in the affected area
- ☐ Difficulty moving or decreased range of motion of the head/neck
- ☐ Pain, tingling, numbness in the affected area
- ☐ Changes in taste
- ☐ Congestion

1. ahns.info/survivorship_intro/topical_review-lymphedema/
2. headandneck.org/lymphedema/
3. cancer.gov/about-cancer/treatment/side-effects/lymphedema
4. Doersam JK, Dietrich, MS, Adair MA, Rhoten B, Deng J, Ridner SH. A Comparison of Symptoms Among Patients with Head and Neck or Truncal Lymphedema and Normal Controls. *Lymphatic research and biology*. 2019;17(6):661– 670. doi.org/10.1089/lrb.2019.0034

Standardized Assessments: Function, Psychosocial

- National Comprehensive Cancer Network: Functional Assessment of Cancer Therapy HNC Symptom Index (FACT NCCN HNSI-22)
- Vanderbilt Head and Neck Symptom Survey version 2.0 (VHNSS)
- Lymphedema Symptom Intensity and Distress Survey-Head and Neck (LSIDSH&N)
- MD Anderson Symptom Inventory: Head and Neck
- Hospital Anxiety and Depression Scale (HADS)
- Body Image Scale (BIS)
- EAT: 10 (focuses on swallow)
- Functional scales: Oswestry Neck Disability Index and Quick Dash Shoulder Disability Index
- **Communicate with disciplines about which outcome measures in order to be comprehensive and avoid duplication**
- **Patient's symptoms can be latent: assess over time**

If patient's edema is improving, function and perception should be improving as well

Deng j, Murpghy BA, Dietrich MS, et al. Impact of secondary lymphedema after head and neck cancer treatment on symptoms, functional status and quality of life. *Head Neck*. 2013;35 (7):1026-1035: doi;10.1002/hed.23084

Imaging Assessment of Head and Neck Lymphedema

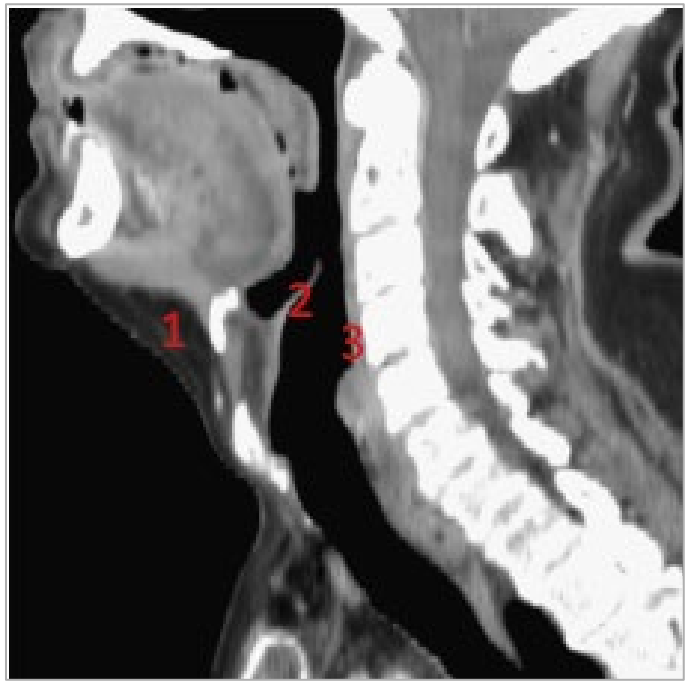


Fig. 1. Baseline CT scans

1. No submental fat
2. Epiglottis not thick
3. No prevertebral soft tissue swelling at C3 (posterior pharyngeal wall)

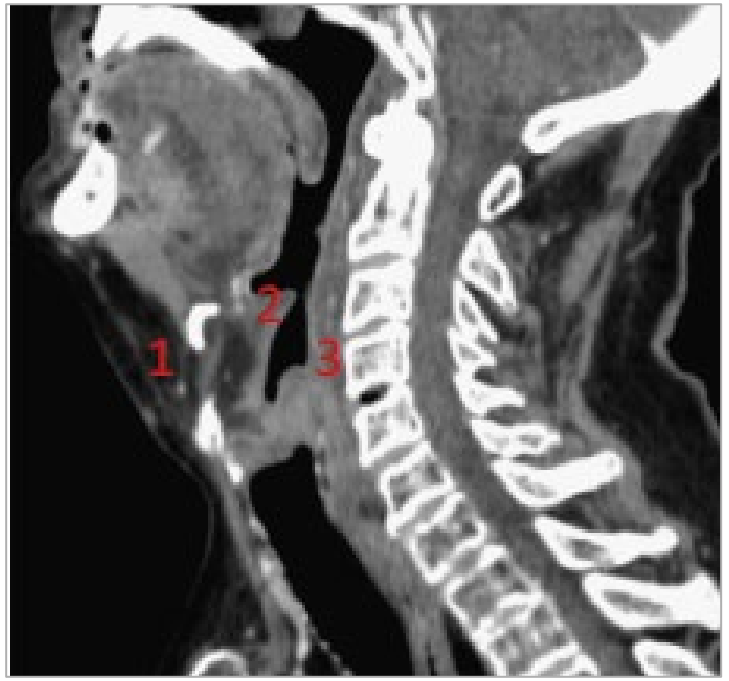


Fig. 2. Seven-month post treatment scans

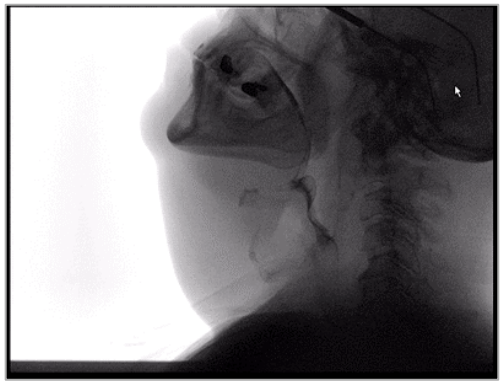
1. Submental tissue changes
2. Epiglottis thickened
3. Prevertebral soft tissue swelling at C3 (posterior pharyngeal wall)

Deng J, et al. Assessment and measurement of head and neck lymphedema: State-of-the-science and future directions. *Oral Oncology.* 2018 51 (431-437)

Imaging Assessment of Suspected Dysphagia

Modified barium swallow study (MBS)

- SLP and radiologist, radiology tech
- Performed in hospital radiology dept or radiology clinic
- Uses barium mixed with food/liquid
- Assesses oral, pharyngeal and cervical esophageal stages of swallow
- Lateral view



Fiberoptic endoscopic evaluation of swallowing (FEES)

- SLP
- Performed anywhere
- Uses food color mixed with food/liquid
- Assesses pharyngeal stage before during and after the swallow, has “white out” period at moment of swallow
- Superior view

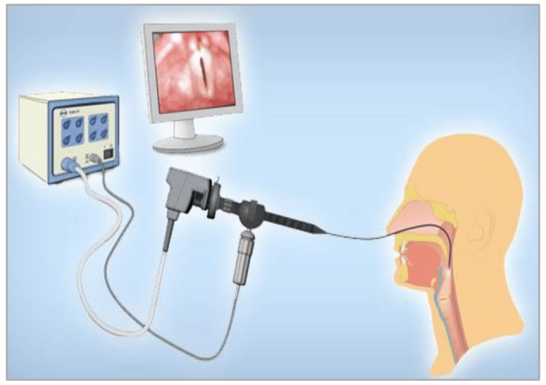


Photo credit: https://www.researchgate.net/figure/Fiber-optic-endoscopic-evaluation-of-swallowing-FEES-reproduced-from-ATMOS-2010_fig9_325813440

Deng J, et al. Assessment and measurement of head and neck lymphedema: State-of-the-science and future directions. *Oral Oncology*. 2018 51 (431-437)

Imaging Assessment: Revised Patterson Scale: Internal Lymphedema

Severe lymphedema on any single item on the Patterson Scale correlates with swallowing dysfunction[2]

	Normal	Mild	Moderate	Severe	Not evaluable
Epiglottis				✖	
Vallecula					
Pharyngoepiglottic folds					
Aryepiglottic folds					
Arytenoids					
False vocal folds					
True vocal folds					
Pyriform sinuses					

Scoring options: maximum severity score, number of internal sites affected by HNL, sum severity score[3]

1. Starmer, H. M., Drinnan, M., Bhabra, M., Watson, L., & Patterson, J. (2021). *Development and reliability of the revised Patterson Edema Scale. Clinical Otolaryngology, 46(4), 752–757.* doi:10.1111/coa.13727
2. Jackson LK, Ridner SH, Deng J, Bartow C, Mannion K, Niermann K, Gilbert J, Dietrich MS, Cmelak AJ, Murphy BA. Internal Lymphedema Correlates with Subjective and Objective Measures of Dysphagia in Head and Neck Cancer Patients. *J Palliat Med*. 2016 Sep;19(9):949-56
3. Jeans C, Brown B, Ward EC, Vertigan AE, Pigott AE, Nixon JL, Wratten C, Boggess M. A Prospective, Longitudinal and Exploratory Study of Head and Neck Lymphoedema and Dysphagia Following Chemoradiotherapy for Head and Neck Cancer. *Dysphagia*. 2022 Oct 29

Lymphedema Treatment

Complete Decongestive Therapy (CDT)

Phase I: In-clinic 2-4 week duration	Phase II: Self-care lifetime duration
Goal: Decongest/reduce volume	**Goal: Maintain reduction/minimize progression**

Daily treatments
▪ Manual lymph drainage (MLD)
▪ Compression
▪ Exercise
▪ Education
  • Precautions/risk reduction
  • Sleeping positions
  • Skin care
  • Oral hygiene
	Ongoing therapy
	▪ Manual lymph drainage (self massage or advanced pneumatic compression)
	▪ Compression garments
	▪ Exercise
	▪ Skin care/oral hygiene

What is Conservative Care for Head and Neck Lymphedema?

Compression

- Head and neck surgeons often dispense or recommend to patients following surgery or when post op healing has occurred
- Encourage ENTs to do the same

Elevation while sleeping

- Patients often sleep propped up on pillows to a 45-degree angle to aid fluid drainage to prevent overnight buildup
- 5-7 inch bed wedge is typically sufficient

Exercise

- General exercise, walking, range of motion exercises are all good. Patients are often in PT/OT for strength, balance, posture, ROM

Other therapy

- SLP and/or swallow exercises should be utilized for patients with dysphagia
- CLT to address edema, fibrosis, ROM, provide education on skin care, self MLD

Compression Options

Jobst® Epstein facioplasty support

Pad with channels (SIGVARIS®)

Chin strap (JoViPak®)

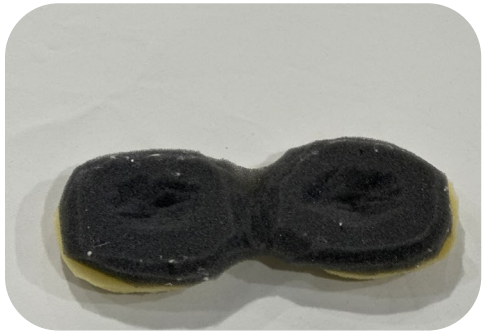
Peri-auricular neck pad (JoViPak®)

Custom face mask

Full face mask (JoViPak®)

Short stretch bandaging with foam inserts

Sember et al 2017



Eye compression using gray foam

Additional Intervention for the Head and Neck

Kinesio tape applications

- Lymph fluid drainage
- Reduce fibrosis
- Improve posture
- Restore muscle imbalance

Kinesio tape application example

Photo Credit: The Movement Clinic

Myofascial release

- Gentle, sustained pressure to connective tissue restrictions
- Scar releases

Elastomere

- Putty mold placed under compression

Silicone scar pads

- Softens scars
- Better for more superficial scars

Modalities

- Hivamat
- Low level laser

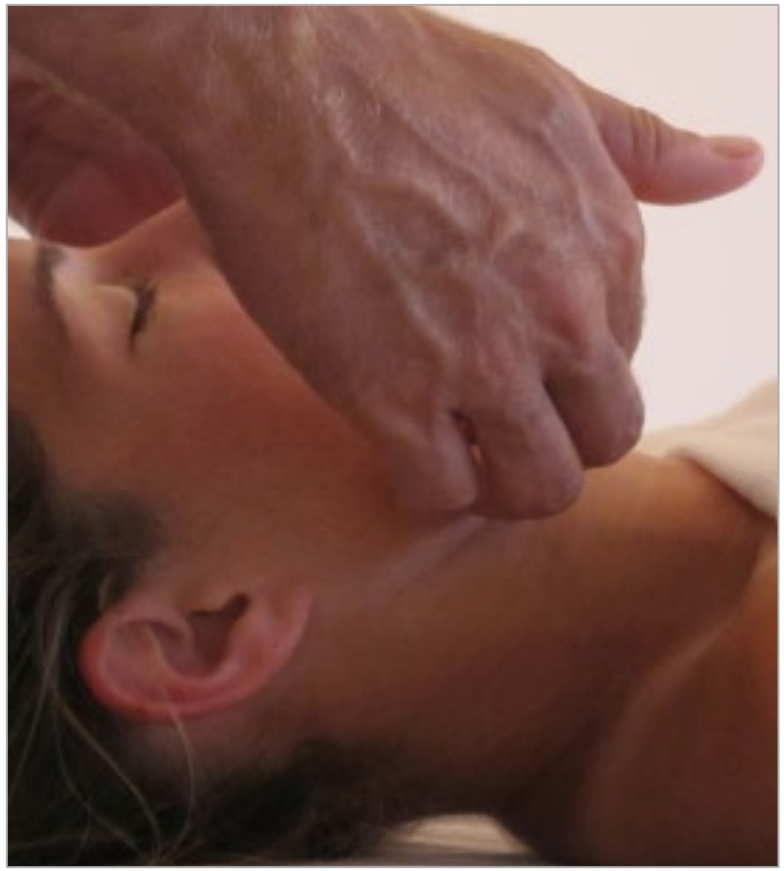
Manual Lymph Drainage (MLD) Benefits

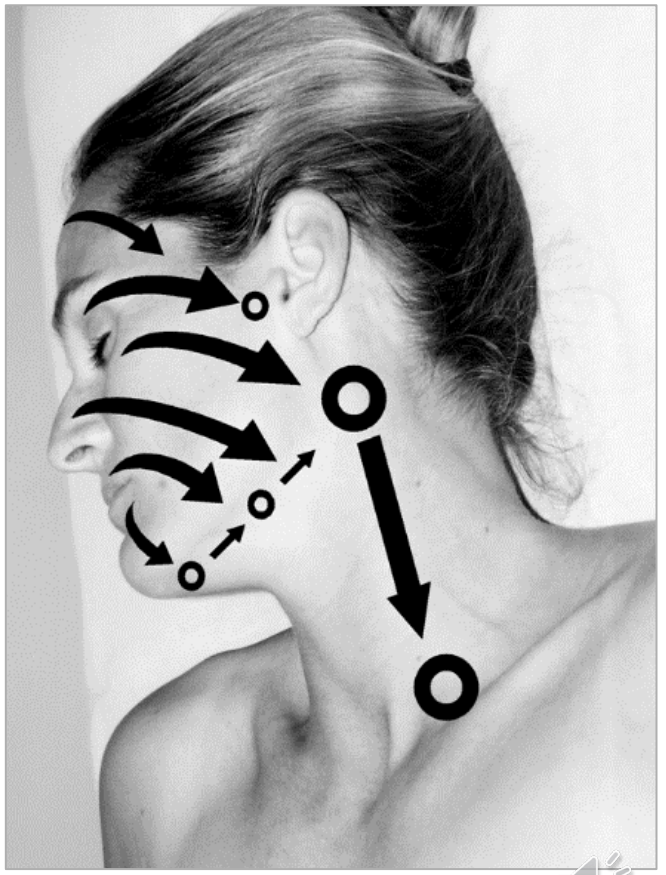
Decrease

- Risk of infection
- Fibrosis
- Pain

Improve

- Tissue health
- Speech
- Swallowing
- Saliva production
- ROM
- Appearance
- QOL





Drainage pattern of superficial lymphatics

Photo credits: https://www.realbodywork.com/articles/lymphatic-drainage-techniques/ , Zuther, J. Secondary Lymphedema of the Head and Neck. Lymphedemablog.com May 11th, 2012

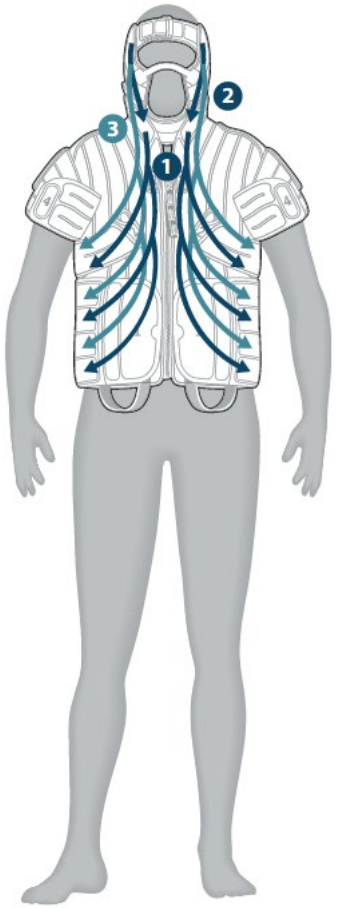
FLEXITOUCH PLUS ComfortEase Head and Neck Treatment

The only pneumatic compression device indicated for the treatment of head and neck lymphedema

- Proven technology for management of lymphedema
- Dynamic pressure to stimulate lymphatic function
- Accommodates patients with tracheostomies or laryngectomies, including external tubing

Treatment time: 32 minutes

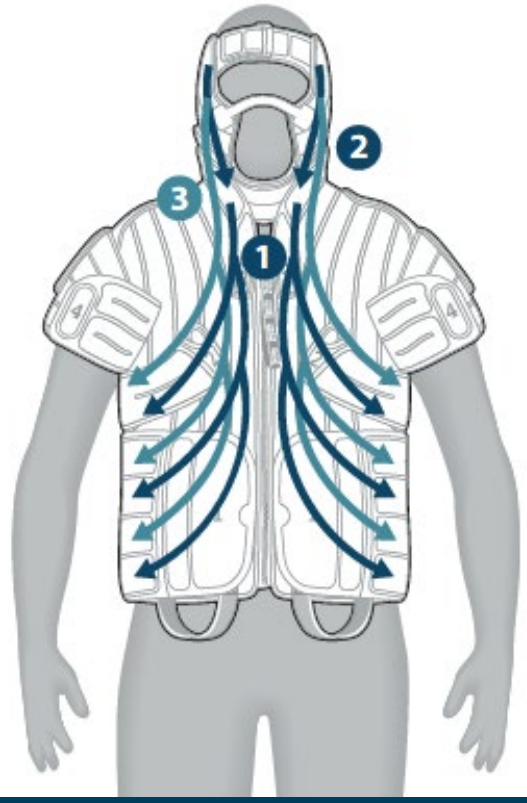
- Decongestion of chest, neck and head
- Lymphatic fluid from head also directed towards lateral and posterior lymphatic pathways of neck
- Trunk/chest treatment directs fluid towards healthy axillary lymph nodes



When to Refer Patients for Lymphedema Treatment/Pneumatic Compression

Clinical presentation

- Intraoral/external edema
- Fibrosis/adhesions
- Pain (internal/external)
- Impaired swallow (dysphasia)
- Impaired communication
- Decreased head/neck, UE, shoulder ROM
- Trismus (mouth opening 35 mm or less)[1]
- Xerostomia/dry mouth



Clinical signs of lymphedema: refer to CLT/SLP/Flexitouch

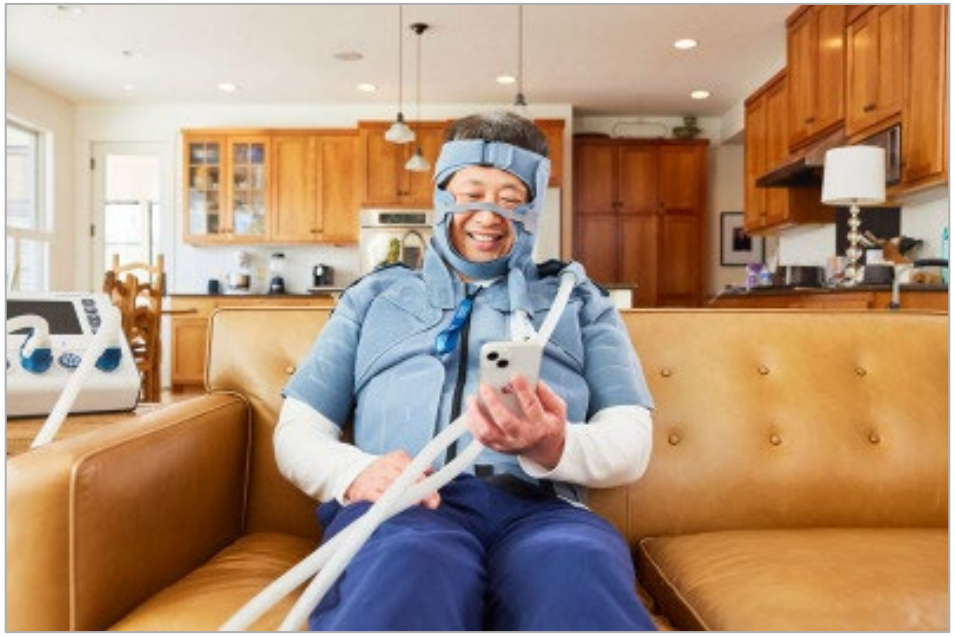
1. van der Geer SJ, van Rijn PV, Kamstra JI, Roodenburg JLN, Dijkstra PU. Criterion for trismus in head and neck cancer patients: a verification study. Support Care Cancer. 2019 Mar;27(3):1129-1137. doi: 10.1007/s00520-018-4402-z.

NCCN Clinical Practice Guidelines in Oncology

Survivorship Version 2.2024: December 9, 2024

Survivors should be educated regarding

- Signs and symptoms of lymphedema and importance of rapid reporting
- Self-care management including **pneumatic compression**



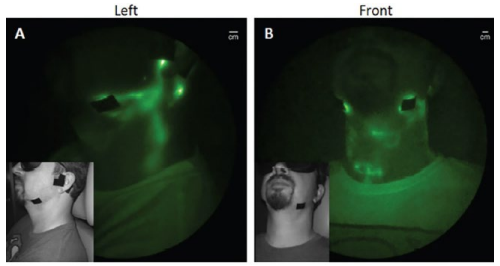
Treatment Response to Single and Multiple Sessions

10 head and neck LE pts, single treatment and after two weeks of treatment

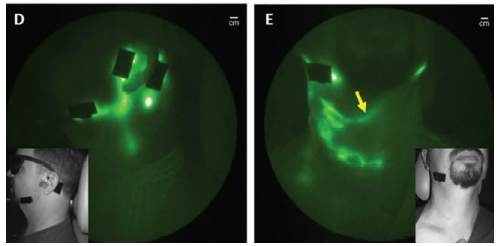
- 10/10 pts showed improved lymphatic uptake with single treatment
- 6/8 pts showed reduced dermal backflow
  - 1 case had complete resolution of backflow
- 10/10 pts reported feeling somewhat or much better
- 5/10 pts reported improved swallow and/or reduced tightness in throat
- Reductions in facial composite scores were seen along with reduced backflow and subject-reported improvements

Example: after two weeks of Flexitouch, pt shows

- Reduced dermal backflow
- Better-formed lymphatics/drainage to nodes
- Pumping lymph right to left toward heathier vessels



Visit 1: pre-therapy



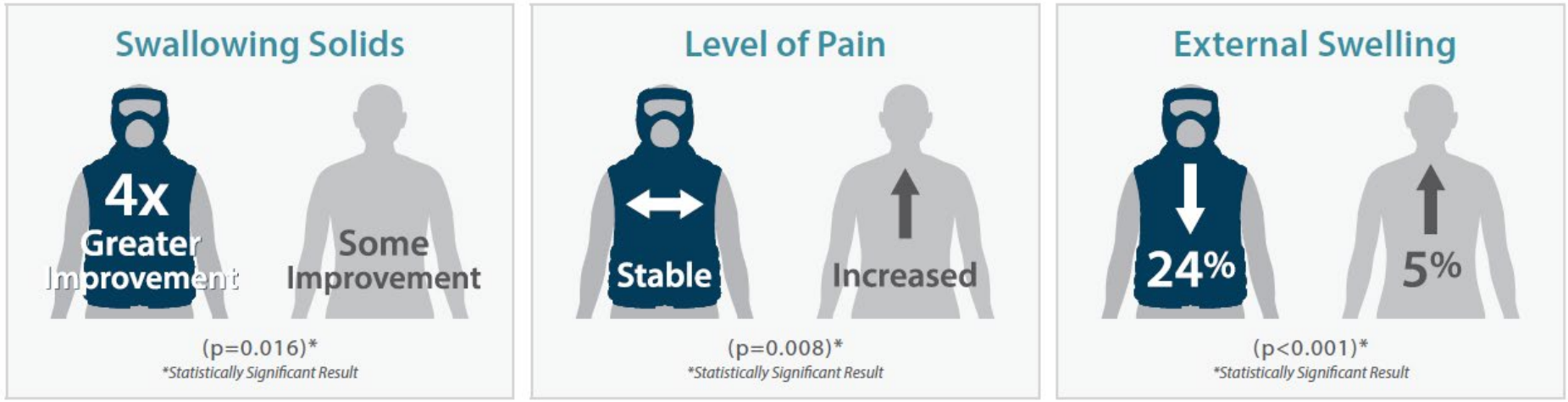
Visit 2: after 2 weeks of FT use

Gutierrez, C., et al., Head and Neck Lymphedema: Treatment Response to Single and Multiple Sessions of Advanced Pneumatic Compression Therapy. *Otolaryngology – Head and Neck Surgery*. First published 29 Jan 2019. doi.org/10.1177/0194599818823180

FLEXITOUCH Improves Head and Neck Cancer-Related Lymphedema

In the first randomized control trial of home management of head and neck lymphedema, Vanderbilt researchers found statistically significant improvements with the use of Flexitouch

Flexitouch vs. self-management alone



Study Group N = 43

Flexitouch Arm: n = 19
- Self-management of lymphedema + Flexitouch Pneumatic Compression Device
- Daily use for 8 weeks

Self-Management Arm: n = 24
- Self-management of lymphedema
- Daily for 8 weeks

Results are based on the median change in scores from baseline measurements

Ridner, S.H., Dietrich, M.S., Deng, J. et al. Advanced pneumatic compression for treatment of lymphedema of the head and neck: a randomized wait-list controlled trial. *Support Care Cancer* (2020). doi.org/10.1007/s00520-020-05540-8

Before and After 8 Weeks of FLEXITOUCH Use

Ridner, S.H., Dietrich, M.S., Deng, J. et al. Advanced pneumatic compression for treatment of lymphedema of the head and neck: a randomized wait-list controlled trial. *Support Care Cancer* (2020). doi.org/10.1007/s00520-020-05540-8

Patient Results

Before **2 months**

Before: 3 months post-radiation treatment

After: one 32-Minute Flexitouch Plus treatment

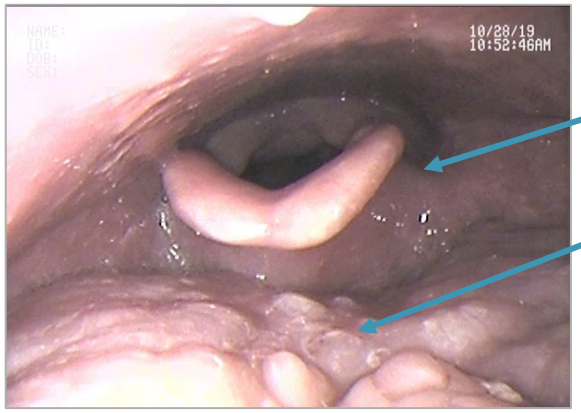
Before **1 treatment** **8 months**

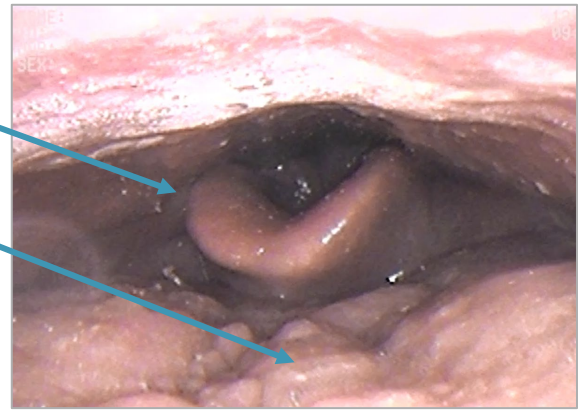
*Patient photos and consent on file at Tactile Medical.

Case Study:
Effects after FLEXITOUCH Discontinuation

Regular use of Flexitouch
2 months after radiation

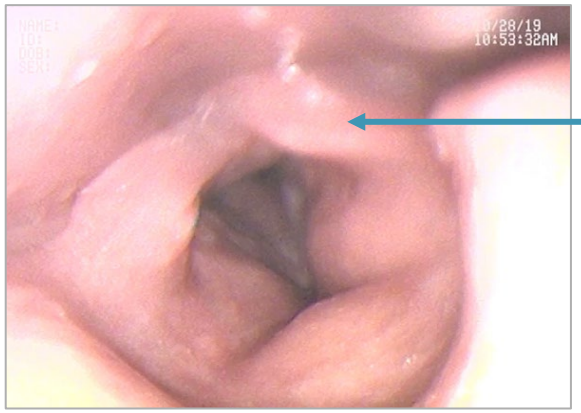
Non-compliance
for 2 weeks over holiday



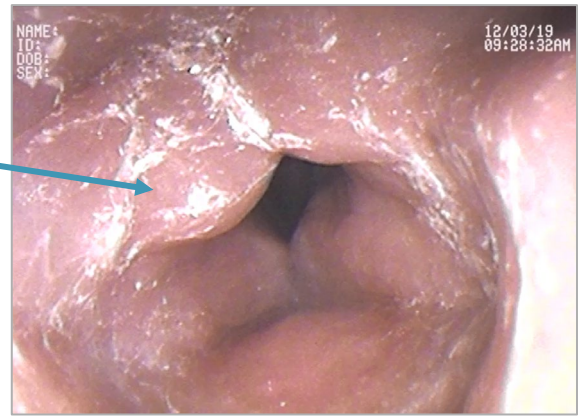


Epiglottis

Base of tongue



Arytenoids/ post cricoid swelling



Conclusions

- Successful, comprehensive care for HNC survivors includes an integrated team approach, education and awareness of the disease and providing tools and support for guidance
- Lymphedema is an underserved condition for the HNC survivor, while >90% of patients experience this condition during and after treatment

Permission for use of patient images on file at Tactile Medical.

Frequently Asked Questions

- What are the symptoms of lymphedema in the head and neck?
- Can a speech language pathologist diagnose lymphedema?
- Does lymphedema increase the risk of head and neck cancer recurrence?
- What does long term management look like?

Tactile MEDICAL®

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FLEXITOUCH PLUS System FDA Indications for Use and Contraindications

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 to increase lymphatic flow in the treatment of many conditions such as:

- Primary and secondary lymphedema
- Post mastectomy edema
- 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
- Lipedema
- Phlebolymphedema

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 include

- Heart failure (acute pulmonary edema, decompensated acute heart failure)
- Acute venous disease (acute thrombophlebitis, acute deep vein thrombosis, acute pulmonary embolism)
- Severe peripheral artery disease (critical limb ischemia including ischemic rest pain, arterial wounds or gangrene)
- Active skin infection/inflammatory disease (acute cellulitis, other uncontrolled skin or untreated inflammatory skin disease)
- Any circumstance where increased lymphatic or venous return is undesirable
- During pregnancy (applies to Flexitouch Plus trunk accessory)
- Note: Specific contraindications for head and neck garments are listed on the following slide

Complete Flexitouch Plus Instructions for Use are available in the system User Guide or at tactilemedical.com

FLEXITOUCH PLUS System FDA Indications for Use and Contraindications

Head and neck additional contraindications

The head garment and the vest for head and neck for the Flexitouch Plus system should not be used if you have one or more of the following conditions:

- Uncontrolled hyperthyroidism or parathyroidism (for which an endocrinologist recommends against neck compression)
- Carotid sinus hypersensitivity syndrome
- Symptomatic carotid artery disease, as manifested by a recent transient ischemic attack (within 30 days), ischemic stroke, or amaurosis fugax (monocular visual ischemic symptoms or blindness)
- Symptomatic bradycardia in the absence of a pacemaker
- Internal jugular venous thrombosis (within 3 months)
- Increased intracranial pressure or other contraindication to internal or external jugular venous compression
- Acute radiation dermatitis, unhealed surgical scar, unhealed or open wound(s), surgical flap less than 6–8 week post-operative
- Facial or head and neck dermal metastasis
- Acute facial infection (e.g., facial or parotid gland abscess)

Complete Flexitouch Plus Instructions for Use are available in the system User Guide or at tactilemedical.com

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