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Treatment of Head and Neck Cancer-related Lymphedema using Advanced Pneumatic Compression: A Case Study

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Abstract

We present the case of a 70-year-old male who developed lymphedema after chemotherapy and radiation to treat squamous cell carcinoma in the right vocal cord. Soon after the cancer treatment, the patient presented with prominent laryngeal lymphedema, vocal cord paralysis, edematous false and true vocal cords, worsened vocal quality, and prominent stridor at rest. Head and neck lymphedema treatment with the Flexitouch Plus system, an advanced pneumatic compression device (APCD), was prescribed. The Flexitouch Plus prescription was for a once daily H1 treatment, at normal pressure, for 32 minutes. Lymphedema treatment using the APCD was initiated by the patient approximately 2 months after the end of his cancer treatment and lymphedema diagnosis. Three months after the final cancer treatment, and one month following the start of APCD treatment, the patient had a tracheostomy placed due to exhibiting <10-20% typical glottic aperture and recurring shortness of breath. The patient expressed discomfort with the tracheostomy. During the 9-month period after the initiation of APCD treatment, the patient exhibited improvements in several areas, including an increased glottic aperture that was stable at approximately 50-60% of typical, complete management of his lymphedema, as well as increased vocal cord mobility, and a patent airway. These improvements led to the removal of his tracheostomy 8 months after the initiation of APCD treatment. This case highlights the importance of treatment and management of head and neck cancer-induced lymphedema and fibrosis with an APCD

Keywords: Head and Neck Cancer; Lymphedema; Advanced Pneumatic Compression Device; APCD; Complete Decongestive Therapy

Introduction

Lymphedema is one of the most common complications of head and neck cancer (HNC) and its treatment interventions. The American Society of Clinical Oncology estimated that, in 2023, 66,920 people would be diagnosed with head and neck cancer, and of those, an estimated 15,400 would die. [1] As a result of the HNC, surgery, chemotherapy, or radiation, the lymphatic system is damaged and soft tissue swelling and fibrosis occurs. In many cases this leads to secondary lymphedema and fibrosis (LEF). A 2016 study, monitoring patients for 18 months after HNC treatment, described the incidence, biological mechanisms, and impact of LEF in HNC patients. All participants who were followed in this study experienced LEF at some point along the course of their cancer diagnosis, before and after treatment, as well as during recovery. [2] HNC-related LEF involves swelling in the face, neck, and shoulders, as well as internal structures, such as the larynx and pharynx. [3,4] External presentations of the disease may result in patients reporting pain and discomfort, body image issues, skin color, and texture changes, as well as decreased range of motion. [5,6] Internally, the pharynx and larynx may exhibit swelling and obstruction resulting in difficulties breathing, speaking, or swallowing. [6,7] If the edema associated with this disease is not reduced in a timely manner, chronic inflammation

leads to scarring of the fibro-fatty tissues. [8] If no action is taken, LEF patients may have long-term dependence on breathing and feeding tubes, as well as increased risk of aspiration. The treatment interventions for LEF patients typically include using manual lymphatic drainage (MLD), use of an advanced pneumatic compression device (APCD), or both.

MLD is the conventional treatment for lymphedema management using complete decongestive therapy (CDT), which occurs in 2 phases. Phase 1 is commonly performed by either a physical therapist, an occupational therapist, or a speech-language pathologist with specialized training and certification in lymphedema management. Phase 2 is a long-term self-care management protocol. [9] Phase 1 care includes consultation with a lymphedema therapist, patient education, therapist-administered manual lymphatic drainage (MLD), compression garments or bandages where indicated, skin care techniques, and a program of exercises and postural recommendations. The goal for Phase 1 care is to reduce visible or palpable LEF and manage the associated symptoms. The duration of Phase 1 care varies depending on LEF severity and therapeutic response, though 5 therapy sessions per week is recommended. [10] In this case study, length of Phase 1 care at the clinic is often dictated by insurance and the number of approved visits will vary by carrier. Many patients are approved for 4 weeks, with some receiving extensions to 6 to 8 weeks total. During Phase 2 self-care, patients must conduct a lifelong program of disease management that simulates the program from Phase 1 with compression and lymphatic massage as integral components. Unlike other chronic diseases, there are no routine or annual follow-ups to monitor the patient after Phase 1 care. Patients are expected to contact their primary care provider if LEF exacerbations or infections arise during Phase 2 care and they would then be referred to repeat Phase 1 CDT.

The use of APCDs to treat head and neck LEF began in 2017. [11] A 2020 pilot randomized control trial was conducted and APCD use was associated with significant improvement in perceived ability to control lymphedema and a reduction in visible external swelling as evidenced by scored digital photography. [12] APCD use was also associated with reduced soft tissue symptoms (eg, heaviness and tightness), neurological symptoms (eg, tingling, pins and needles), and improved ability to swallow solids. Study participants reported that APCD use was more effective than Phase 1 CDT. [12] APCD care utilizes wearable garments that emulate MLD care to help direct and move excess fluid from an impaired lymphatic region to healthy regions, where fluid can be absorbed and processed naturally by the body. Using an APCD, the patient can administer self-care treatment from the convenience of their own home without requiring that they complete difficult to perform MLD on themselves. The Flexitouch Plus system (Tactile Medical, Minneapolis, MN, USA), used by this case study patient, is a clinically proven ACPD used to stimulate the lymphatic system (Figure 1). The Flexitouch Plus is cleared by the FDA for market use in the USA (K170216, HCPCS code E0652). The Flexitouch Plus system consists of 2 primary components: the controller and garments. The controller is a programmable pneumatic compressor with 4 connector outlets. Each connector has 8 outflow ports, where the hose of each garment attaches. Air passes through the hoses creating inflation and deflation in the garment chambers. The garments cover the areas of the body where treatment may be necessary, such as the head, neck, chest, and extremities. The Flexitouch Plus garment chambers inflate sequentially, each chamber inflating before the adjoining distal chamber deflates. This creates a dynamic wave to direct interstitial fluid back into the cardiovascular system through the lymphatic capillaries. The head and neck garments are designed to cover the face, neck, and chest, and are made of soft, pliable fabric, designed to fit the contours of the body and secured by hook-and-loop fasteners.

Figure 1: Flexitouch Plus System Being Used with Head and Neck Garments (courtesy of Tactile Medical marketing material)

While LEF has no known cure, evidence shows that early and decisive therapy may improve patient outcomes in the lymphedema patient population. [2,13] This paper presents a case report of a patient with HNC-related LEF and the benefits of APCD care, using the head and neck Flexitouch Plus system.

Case Presentation

Disease Development

A 70-year-old male with a 30-year smoking history, who reported quitting around 2021, had an onset of dysphonia in 2021 with an exacerbation in March 2022. Neck computed tomography (CT) on April 19, 2022, revealed an asymmetry of the right vocal cord, concerning for paralysis. The patient then underwent a pan endoscopy with biopsy of the right vocal cord on May 23. Pathology indicated invasive, moderately differentiated keratinizing squamous cell carcinoma. He was treated with 1 course of chemotherapy (cetuximab - Erbitux®), performed from June 27 to August 1. Concurrent radiation 72 Gy with 30 total fractions was performed, with the final treatment on August 3. He

maintained a regular oral diet without any associated coughing or choking and did not require use of his gastrostomy tube. The gastrostomy tube was removed on August 31. The case timeline is presented in Figure 2.

The patient was diagnosed with lymphedema on August 4, 2022. On August 24, the patient reported increased dysphonia symptoms and an MRI revealed uptake in the right thyroid. Laryngoscopy with stroboscopy found radiation changes to the larynx, including absent waveform propagation of the right vocal cord with minimal propagation of the left. The patient was found to be using ventricular compression during phonation, as a method of compensation that further contributed to his dysphonia. Despite these findings, an endoscopic swallow examination showed the patient continued to demonstrate normal deglutitive function.

On August 30, an MRI of the patient's neck was negative for any mass lesion but had uptake and enhancement in the right thyroid cartilage from some mild edema. The patient's voice was noticeably worse at this visit. A nasopharyngoscopy was performed to assess his laryngo-pharyngeal condition and his airway had nonobstructive edema. There was no stridor or distress noted. The evaluation found no evidence of polyposis, purulence, mass lesions, or pooling of secretions. The patient was instructed by his care team to sleep with the head of his bed elevated.

During a scheduled office visit on September 14, the patient presented with prominent laryngeal lymphedema and absent waveform propagation of the right vocal cord with a planar defect. The patient was instructed to go to the ER if he exhibited severe shortness of breath. At his next office visit on September 28, the patient presented with significant laryngeal lymphedema without improvement. A laryngeal stroboscopy showed that the patient had approximately 50% typical glottic aperture from a well-compensated right vocal cord paralysis, with fixation in a median position. At this visit, the patient was instructed by his care team to go to the ER if he experienced severe dyspnea.

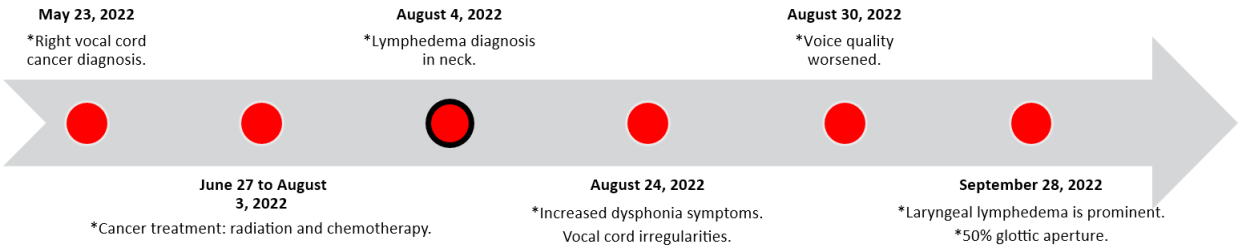

Figure 2: Timeline of Case Presentation.

Lymphedema Treatment Begins

During his visit on September 14, the patient agreed with his healthcare team to begin management of his significant lymphedema. To address his condition, he was prescribed the head and neck Flexitouch Plus system for daily use. The Flexitouch Plus prescription was for a once daily H1 treatment, at normal pressure, for 32 minutes; the patient initiated Flexitouch Plus treatment on September 30. Laryngeal stroboscopy was performed September 28 and November 8. Both assessments showed prominent laryngeal lymphedema, a planar defect, and absent waveform propagation. The patient timeline from the early stages of lymphedema treatment are presented in Figure 3.

During an office visit on November 21, the health care team found the patient had severe lymphedema and hoarse vocal quality and stridor both at rest and during conversation. The laryngoscopy with stroboscopy performed that day showed well-compensated right vocal cord paralysis with fixation in a median position, as well as lymphedema changes medializing the left vocal cord, resulting in <10-20% typical glottic aperture. There was a planar defect of the vocal cords, left superior to right, and significant compression with ventricular phonation. The patient was instructed to go to the ER that day for placement of a tracheostomy. The patient was taken directly to the OR as his care team alerted the ENT surgeons of the worsening symptoms the patient was exhibiting. A cuffed 6-0 Shiley tracheostomy tube was inserted between the 2nd and 3rd tracheal rings with no complications recorded from the procedure. During the placement, the right true and false vocal cords were noted to be edematous.

On December 1, the patient stated he was having a hard time breathing through the tracheostomy with no relief from suctioning. A bronchoscopy was performed through the tracheostomy stoma and there was granulation tissue formation at the distal end of the tube that blocked approximately 90% of his trachea. There were no mass lesions, excess secretions, or bleeding found. To mitigate the blockage, the patient was scheduled for laser bronchoscopy and a change to a Shiley XLT (extended-length tracheostomy) cuffless tube. During his visit on December 7, he reported not liking the

tracheostomy and that it was uncomfortable. Despite the tracheostomy discomfort, a bronchoscopy was performed with no mass lesions, secretions, or bleeding found. A PET scan on December 2, revealed that the uptake in the vocal cords had nearly completely resolved and he was negative for evidence of cancer elsewhere.

The patient presented for his next appointment, on December 20, with a Shiley #6 tracheostomy tube in place and able to use finger occlusion for speech without a heat moisture exchanger (HME). At this time, he reported not having used his Flexitouch since undergoing the tracheotomy in November, because the APCD head garment configuration did not currently accommodate the presence of the tube. According to the compliance log downloaded from the Flexitouch Plus controller tracking the usage of the device for treatment, from September 30 to November 20, the patient had completed 51 days of treatment out of the 52 days during that period, a usage rate of 98.1%. At the December 20 visit, the patient reported significant coughing and discomfort from the tube. His inner cannula was removed during his scheduled tracheostomy evaluation and a large amount of very thick, glue-like secretions were found. An HME was placed and he was instructed by his care team to use it at all times, as tolerated. No significant stridor was noted after inner cannula replacement and HME placement. The laryngeal stroboscopy that was also performed during this visit demonstrated there were no changes in findings since the previous scope on November 21 and the patient's glottic aperture remained at <10-20% of typical.

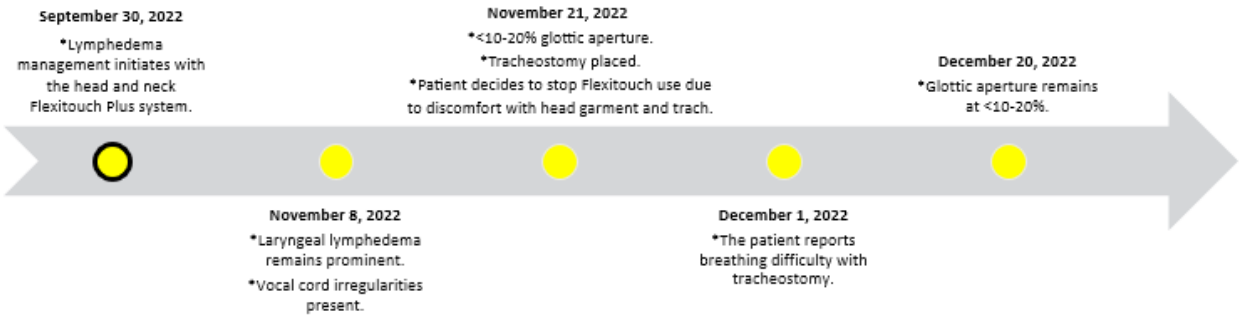

Figure 3: Timeline from the Early Stages of Lymphedema Treatment.

Patient Recovery

The patient's recovery timeline is shown in Figure 4. During an office visit on December 28, the patient's Flexitouch Plus head garment was refitted by his care team to prevent interference with his tracheostomy and he resumed consistent use of his APCD, once daily, at normal pressure, for 32 minutes. The patient was issued Passy-Muir Speaking Valve (PMV) and reported tolerating its use. At a follow-up visit on January 10, 2023, the patient reported consistent use of his APCD since the previous visit. A laryngoscopy with stroboscopy showed an improvement in the laryngeal lymphedema and revealed stable right vocal cord with fixation in a median position, resulting in <10% typical glottic aperture. He reported consistent use of the HME without issue. At his next appointment on January 19, the patient reported consistent use of the HME. A routine surveillance nasopharyngoscopy revealed the patient had a highly functional oropharyngeal swallow and was cleared to continue a regular diet as tolerated.

The patient had 3 office visits from the end of January to the end of March 2023 and each visit found he was tolerating PMV use, had a highly functional oropharyngeal swallow, and was without tracheostomy issues. During this time, the patient was again more compliant with the APCD treatment, with treatment logged on 50 out of 76 days between December 28 and March 10 (usage rate of 65.8%).

On April 6, the patient's surveillance stroboscopy found stable right vocal cord paralysis but significantly improved left vocal cord mobility with fixation in a paramedian position, resulting in approximately 50-60% typical glottic aperture, a significant improvement from his previous stroboscopy on January 10 where there was <10-20% of typical glottic aperture. The planar defect of the vocal cords, left superior to right, was still present, as well as roughness, resulting in slightly irregular waveform propagation. Laryngeal lymphedema continued to show improvement. The patient was advised by his care team to continue PMV use during all waking hours.

Two weeks later, on April 21, he reported tolerating the PMV during all waking hours. The laryngeal stroboscopy at this visit showed a well-compensated right vocal cord paralysis with now intact left vocal cord mobility, 50-60% typical airway capacity, and no evidence of disease. His care team determined that the patient was now a good candidate for waking hour capping of his trach, as tolerated. For his office visit on May 5, the patient reported tolerating capping during all waking hours for the last 2 weeks without issue. His stroboscopy results continue to demonstrate

vocal cords with stable right paralysis and improved left mobility as well as glottic aperture to be 50-60% of typical. With multiple visits showing consistent improvement, his care team decided the patient was now a good candidate for capping at all times, as tolerated. After over 2 weeks doing well with capping and no reported setbacks, the patient was decannulated without incident on May 23. The patient had 1 follow-up visit each month in June and July and presented both times without any respiratory distress following his decannulation and a rough but stable vocal quality. The stroboscopies continued to show stable, well-compensated right vocal cord paralysis, a patent airway, and no evidence of disease for the patient.

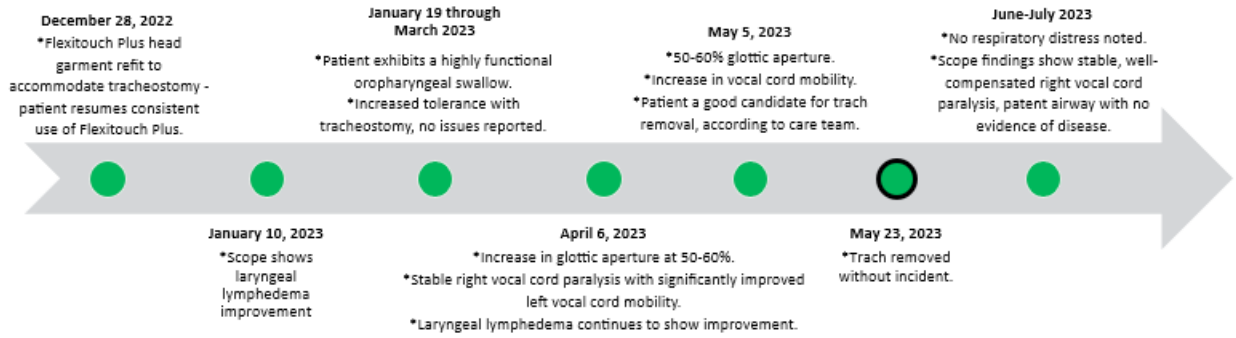

Figure 4: Timeline of Patient Recovery.

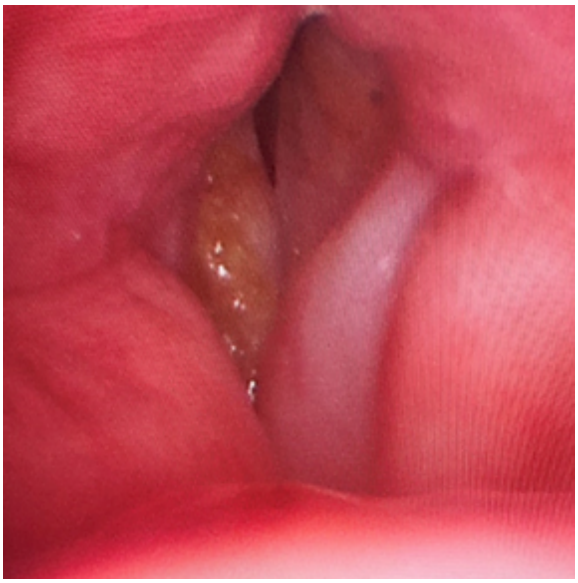

Figure 5: Laryngeal Stroboscopy from November 21, 2022. Tracheostomy placed on this date. Glottic aperture <10-20%.

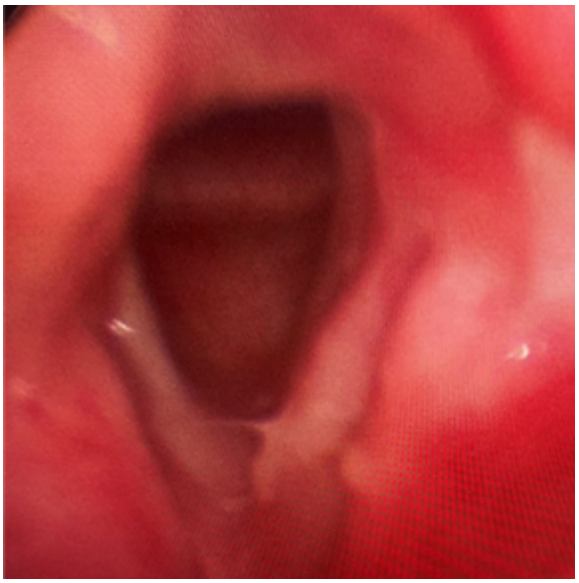

Figure 6: Laryngeal Stroboscopy from May 23, 2023. Tracheostomy removed on this date. Glottic aperture 50-60% of typical.

Discussion

There are currently many pathways of lymphedema management, which include consultation with a lymphedema therapist, education, therapist-administered or self-care MLD, exercise, skin care, and compression garments or devices. This case reveals the difficulties associated with HNC-related LEF and the importance of early treatment with at-home APCD care. Therapy for this patient was initiated during the first months after the lymphedema diagnosis. Overall, this patient responded very well to APCD therapy and will continue at-home care with his Flexitouch Plus system to manage his HNC-related LEF. Daily APCD treatment for this patient began September 30th, 2022. During this time, the patient's significant lymphedema was reduced to negligible levels, his oropharyngeal swallow was normal, and the patient's glottic aperture increased from <10-20% (Figure 5), to a more manageable level, approximately 50-60% of typical (Figure 6). It should be noted, that in this case, the patient had no significant change of medication from August 2022 to July 2023.

After the placement of his tracheostomy, the APCD head garment did not accommodate the tracheostomy tube. A refitting was performed to accommodate the tube. Improvement can be made for future LEF treatment approaches using an APCD, with health care providers assessing APCD use and garment fit after tracheostomy placement, and patient training to properly fit their garment when a tracheostomy tube is present.

Another opportunity to improve patient care is to ensure consistent device use and adherence to the Flexitouch Plus prescription of once daily H1 treatment, for 32 minutes, at normal pressure. Although the patient was initially very compliant with the treatment plan, treatment ceased when the tracheostomy was placed. Immediate refitting of the garment is indicated under these clinical circumstances. After the head garment was refitted to accommodate his tracheostomy, the patient had consistent use of the APCD and showed improved treatment compliance. The patient's consistent APCD use coincided with the greatest improvement in lymphedema symptoms and his other post-cancer treatment complications, such as increased glottic aperture with a patent airway and increased vocal cord mobility. The decrease in Flexitouch Plus usage rates after the garment resizing, versus prior to tracheostomy placement, may be attributable to the patient's decision to administer APCD treatment less frequently due to the improvement in his symptoms. This interpretation of the patient's frequency of APCD usage is speculative and may not be the causative motivation.

Since treatment of LEF in patients with HNC with an APCD is still a developing area in medicine and may be new to members of healthcare, this case study offers evidence of its efficacy and emphasizes the need for further study. During the period prior to resizing of his Flexitouch head garment to accommodate his trach, the patient's care team member found his airway to be entirely lost and was not certain if they were dealing with a lymphedema issue or if these were radiation effects of the laryngeal cartilage structure, becoming more medial and presenting in the left vocal cord. Before Flexitouch Plus was prescribed as treatment for this patient, a member of the patient's care team was unsure if Flexitouch Plus would help him achieve tracheostomy removal. However, this healthcare provider knew that pursuing this treatment would not hurt his situation and decided to proceed, as an elimination of lymphedema would clarify the underlying etiology of the medialization and could possibly provide added benefit to this patient. This decision proved to be a critical factor in the eventual positive patient outcome. Further research will need to be conducted to add to the limited but growing pool of studies that involve HNC-related LEF treatment using APCDs.

Conclusion

This case highlights the importance of treatment and management of head and neck cancer-induced lymphedema and fibrosis with an APCD.

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Author contributions: MR was responsible for the conceptualization, methodology, data curation, and writing. KJ was responsible for conceptualization, review, and editing.

Funding: MR is an employee of Tactile Medical. KJ is a principal investigator in a study affiliated with Tactile Medical.

Institutional Review Board Statement: Informed Consent Statement: Written informed consent was obtained from the patient to publish this paper (including the photo).

Data Availability Statement: Data supporting the study results can be provided followed by request sent to the corresponding author's e-mail.

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