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ORIGINAL RESEARCH

Laryngoscope Investigative Otolaryngology

Feasibility of machine-delivered sequential massage for the management of lymphedema in the head and neck cancer survivor

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Abstract

Background: Lymphedema after treatment for head and neck cancer negatively impacts the quality of life and can produce neck tissue stiffness, dysphagia, pain, and swelling. One form of treatment for lymphedema is machine-delivered sequential lymphedema massage, which is home based and self administered. This study was undertaken to determine economic and system access to home-based lymphedema therapy and to measure patient-reported outcomes among those able to access therapy.

Methods: This study is a retrospective cohort study of 84 head and neck cancer patients who met the criteria for referral for home-based lymphedema treatment. Patients who were able to access lymphedema therapy were surveyed prior to initiation of therapy and again after therapy.

Results: Thirty-five out of 84 patients were approved for home-based therapy and received the equipment. Medicare denial of coverage (21/84) was the most common cause of the inability to access therapy. Of the 35 patients who accessed therapy, presenting complaints included: stiffness (31), pain (29), dysphagia (20), and swelling (19). The average time from completion of cancer treatment to initiation of lymphedema therapy was 9 months. Thirty-four (97%) reported compliance with prescribed therapy, 33 (94%) reported reduced fibrosis, and 30 (89%) reported improvement in activities of daily living. All reported symptoms improved with therapy in 30 (86%) patients. Thirty-two (91%) reported overall satisfaction with home-based lymphedema treatment.

Conclusions: Stiffness and pain were the most common complaints of our patients with head and neck lymphedema. Forty-two percent of patients who were recommended home lymphedema machine use were able to obtain this with cost coverage by their insurance company or by donation from the company. We found a high compliance rate and a highly reported improvement in symptoms with the machine. The only identifiable factor for the patients with less improvement in symptoms was

a greater time gap between treatment and initiation of use of home lymphedema machine.

Level of evidence: 2 Retrospective cohort analysis.

KEYWORDS
cancer, head and neck, home device, lymphedema, quality of life

1 | INTRODUCTION

Nearly 50,000 patients are diagnosed annually in the United States with cancers of the oral cavity and oropharynx.[1] Previously, head and neck cancer (HNC) was found in patients over 60 years old with extended tobacco use and alcohol consumption, but more recently, human papillomavirus (HPV) has been linked with oropharyngeal cancer and presents in patients younger than 60 years of age.[2] The rise in HPV-associated cancers concurrent with improved treatment and survival has contributed to an escalation in the number of HNC survivors in the United States. Thus, individuals who develop head and neck lymphedema may experience a greater impact from the morbidity of the condition and may be more active in seeking treatment.[3]

Head and neck lymphedema (HNL) may be categorized as involving external structures (skin and soft tissue of the face and neck), internal structures such as mucosa and underlying soft tissue of the upper aerodigestive tract (pharynx and larynx), or a combination of both. Most patients with HNL will have involvement of both internal and external structures.[4]

Currently, there is no cure for lymphedema. The most common and most widely accepted treatment method used for lymphedema is complete decongestive therapy or CDT.[5] CDT is a series of techniques including (1) a form of massage known as manual lymphatic drainage (MLD), (2) compression bandages/clothing with special padding, (3) exercises to improve the flow of lymph, and (4) skin care of the affected areas. CDT has been shown to have lasting effects on the severity of lymphedema at all stages and to improve the overall quality of life among lymphedema sufferers.[6] Much of CDT may be performed at home by the patient under the guidance of a certified lymphedema therapist. Sixty percent of patients with head and neck lymphedema can expect to have significant improvement after CDT. The highest rates of success are seen among patients who consistently and properly use CDT at least five times per week over a 3-month period.[7]

Other treatments have been reported in the literature but are not commonly observed in clinical practice. These include cooling therapy, low-level light therapy, oral medications, vacuum therapy using suction cups, and surgery with lymphaticovenous anastomosis.[6,8]

In 2016, the advanced pneumatic compression device (Flexitouch System; Tactile Medical) obtained FDA 510(k) clearance for the treatment of head and neck lymphedema (Figure 1). This system is designed to treat head and neck lymphedema by stimulating the adjacent axillary lymphatic tributary regions before directing fluid from the affected area to functioning regions. A feasibility study showed that 44 patients with head and neck lymphedema were able to successfully use the device for one 32-min treatment session. One treatment produced overall small but highly statistically significant reductions in composite metrics of the face (82.5 ± 4.3 cm vs. 80.9 ± 64.1 cm; $p < .001$) and neck (120.4 ± 12.2 cm vs. 119.2 ± 12.1 cm, $p < .001$) with no adverse events.[9]

2 | MATERIALS & METHODS

2.1 | Study design

The purpose of the current study is to retrospectively assess the patient-reported satisfaction and results of prolonged home use of this advanced pneumatic compression device for the treatment of head and neck lymphedema. Approval for the study was obtained from the Institutional Review Board of the University of Tennessee. Patients gave written consent prior to participation in this study.

For a 1-year period, the Flexitouch System was recommended to any patient that had been treated in the head and neck clinic and reported symptoms of stiffness, pain, dysphagia, or swelling. All patients included in the study had been documented to have lymphedema by our physical therapist. Most of the patients had received or were receiving physical therapy for CDT, and several were treated by speech therapy as well. All of the cancer patients had completed their treatment. Subjects were at least 18 years old, cancer-free at study entry, and at least 4 weeks post-cancer treatment to qualify for participation. Patients were excluded if they had uncontrolled hyperthyroidism, carotid sinus hypersensitivity, carotid artery disease, bradycardia (in the absence of a pacemaker), increased intracranial pressure, acute radiation dermatitis, or acute facial infection. The patients were seen regularly in the office during their lymphedema treatment.

2.2 | Treatment device

The Flexitouch System (Figure 1) consists of a controller that provides segmental, calibrated gradient pneumatic compression (US HCPCS code E0652) paired with inflatable garments. This device has been used to effectively treat limb lymphedema, and now, a garment has been created for head and neck use. The nylon garment has 14 pneumatic chambers covering the head, neck, and chest. The device applies brief applications of dynamic pressure in a wave-like manner to the treatment area.

FIGURE 1 The Flexitouch system for the head and neck. (A) Controller; (B) front view; and (C) side view.

Each patient was visited by a company representative who demonstrated device use and then observed the patient effectively using the device. Each patient used the system for a 32-min session. Afterward, the garment was removed and stored until the next treatment.

2.3 | Analysis

A record was kept pertaining to the subjects' approval or denial of the device. If the patient was denied for insurance reasons of if the patient declined to use the product, the reason for denial was documented. Other information obtained from the medical record included initial diagnosis, treatment modalities, presenting symptoms, age, sex, BMI, treatment by ancillary services such as physical and speech therapy, time from treatment to time of obtaining the Flexitouch System, and compliance with device use (number of times per day and average time of use).

Subject-reported outcomes were obtained via a series of questions to assess satisfaction. Subject-reported outcomes were obtained via a series of questions to assess satisfaction. We asked the patients in the office a list of five yes or no questions. This took less than 5 min. We asked if they were compliant (used the device daily for 32 min), if they felt an overall symptom improvement, if they have improvement in their stiffness/fibrosis, if they were able to become more active, and if they were glad they obtained the device. We kept the questionnaire simple and direct, as this was a pilot study.

TABLE 1 Diagnoses of patients receiving the Flexitouch system.

Diagnosis in patients receiving Flexitouch system	
Initial Diagnosis	**# of Patients**
Oral cavity cancer	10
Oropharynx cancer	9
Larynx cancer	9
Temporal bone cancer	1
Maxillary sinus cancer	1
Nasopharynx cancer	1
Hypopharynx cancer	1
Occult primary	1
Osteoradionecrosis of the mandible/maxilla	1
Breast cancer	1

3 | RESULTS

The Flexitouch System was prescribed for 84 patients. Thirty-five patients were able to acquire the device. The cases of 16 patients were pending review by insurance companies at the time of submission. Twenty-nine patients were denied the device by private insurance ($n = 3$), Medicaid ($n = 5$), and Medicare ($n = 21$). Two patients declined the product.

Of the 35 patients who were able to acquire the Flexitouch System, diagnoses included oral cavity cancer (10), oropharynx cancer (9), larynx cancer (9), temporal bone cancer (1), maxillary sinus cancer (1),

TABLE 2 Primary cancer treatment modality used in patients receiving the Flexitouch system.

Treatment in patients receiving Flexitouch system	
Treatment modality	**# of patients (%)**
Surgery, chemotherapy, and radiation	19 (50%)
Chemotherapy and radiation	10 (27%)
Surgery	4 (11%)
Surgery and radiation	3 (8%)
Radiation	1 (3%)

TABLE 3 Questionnaire completed by patients who used the Flexitouch system.

Questionnaire for patients receiving Flexitouch system	
Question	**% of patients that answered yes**
Were you complaint with the device?	95
Did your symptoms improve with the device?	81
Did your fibrosis improve?	92
Did your participation in activities of daily living improve?	84
Were you satisfied with the device?	89

nasopharynx cancer (1), hypopharynx cancer (1), occult primary (1), osteoradionecrosis of the mandible and maxilla (1), and breast cancer (1) (Table 1). Treatment included radiation, chemotherapy, and surgery, or some combination of these modalities (Table 2). The subjects presented with a variety of post-treatment complaints, including stiffness ($n = 24$), pain ($n = 22$), dysphagia ($n = 16$), and swelling ($n = 15$). With the exclusion of a patient who received the device 8 years after his cancer treatment, the average time from completion of treatment to device acquisition was 0.74 years. Thirty patients received physical therapy with a certified lymphedema therapist in addition to use of the Flexitouch device, and 14 patients were treated by a speech-language pathologist for dysphagia. Thirty-three patients used the device once daily, one used the device twice daily, and one patient was non-compliant with the daily regimen. The average time of device use was 4.4 months. The patients' responses to the questions regarding compliance and satisfaction with the Flexitouch System are recorded in Table 3. Ninety-seven percent of patients reported daily compliance with the prescribed treatment regimen. Eighty-six percent of patients reported improvement in symptoms with the use of the device. Ninety-four percent reported reduction in fibrosis, 89% reported improvement in activities of daily living, and 91% reported overall satisfaction with the device.

4 | DISCUSSION

Head and neck lymphedema is a particularly challenging disease, beginning with diagnosis. As lymphedema is a progressive edematous disease due to abnormal lymph circulation, lymph flow evaluation is critical for evaluation and diagnosis. The head and neck region is significantly smaller than the extremities, making it difficult to apply lymphoscintigraphy, the gold standard of lymphedema evaluation, in head/neck lymphedema evaluation. Alternatively, near-infrared fluorescent lymphography (NIFL) has been applied with precise visualization of the head and neck lymphatics.[10]

As conservative treatments including CDT are anti-symptomatic and do not address the pathophysiology of obstructive lymphedema, life-long treatment is usually required. To address this challenge, various physiologic or reconstructive surgeries have been applied to treat refractory head and neck lymphedema. Lymphatic bypass surgeries involve transferring functional lymph nodes, with microanastamosis with vasculature in the recipient bed to maintain their blood supply, to restore physiological lymphatic flow to the area in which the native lymph nodes have been removed.[8]

As our center does not currently have access to NIFL or innovative lymphatic bypass surgeries, we were interested in whether or not tools such as the Flexitouch system were more accessible and feasible for our patients.

The Mayrovitz group assessed the ease of use, fit, comfort, and potential clinical benefits of one treatment session of the Flexitouch system in 44 patients with head and neck lymphedema.[9] We expanded on their findings and observed the effects of using the device once daily for a prolonged period (average time of device use was 4.4 months) in 35 patients.

The patients in our series presented with head and neck lymphedema symptoms—predominantly including stiffness, pain, dysphagia, and swelling—which impact the quality of life as well as participation in activities of daily living. The great majority of our patients reported improvement in these symptoms with the use of the Flexitouch System and also reported high levels of compliance with the device.

There are barriers to insurance coverage that, perhaps, could be improved with further data on the high rates of compliance, patient satisfaction, and symptom improvement with the use of the Flexitouch system. Only 44% of the patients who were prescribed the device were able to acquire it with cost coverage by insurance or donation from Tactile Medical. A particularly disturbing finding is that a higher percentage of African American subjects were denied the device than the Caucasian subjects. Fifty-two percent of the Caucasian subjects were able to acquire the device, compared with only 20% of African American subjects.

A great limitation of this project is that it is a retrospective review. This study did not control for patients who received physical therapy versus those who did not. In fact, a large portion of our patients received both physical therapy and the Flexitouch device (81%). In future studies, we would like to compare the results of patients who received traditional lymphedema therapy with physical therapy, Flexitouch therapy alone, or both.

Our center is interested in becoming more proactive in the intervention for lymphedema now that the effects have been shown to be so long lasting and prevalent. This study aimed to evaluate the impact of adding the Flexitouch to the treatment strategy. Moving forward,

this utility will be evaluated in a prospective manner. Its efficacy in improving dysphagia secondary to lymphedema in head and neck cancer survivors is currently being assessed in a randomized and prospective manner.

5 | CONCLUSION

Stiffness and pain were the most common complaints of our patients with head and neck lymphedema. Thirty-two percent of patients who were recommended home lymphedema machine use were able to obtain this with cost coverage by their insurance company or by donation by the company. Half of the patients who received the machine had previous surgery, radiation, and chemotherapy. In this study, there was a high compliance rate and a highly reported improvement in symptoms with the machine. The only identifiable factor for the patients with less improvement in symptoms was a greater time gap between treatment and initiation of use of home lymphedema machine. Prospective data include the results when combining Flexitouch with other therapies is needed.

FUNDING INFORMATION

This research received no external funding.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

Data supporting reported results are available and can be provided on request.

INFORMED CONSENT STATEMENT

Informed consent was obtained from all subjects involved in the study.

INSTITUTIONAL REVIEW BOARD STATEMENT

The study was approved by the Institutional Review Board of the University of Tennessee.

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