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Usability of advanced pneumatic compression to treat cancer-related head and neck lymphedema: A feasibility study

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Abstract

Background: This functional usability study assessed ease of use, fit, comfort, and potential clinical benefits of advanced pneumatic compression treatment of cancer-related head and neck lymphedema.

Methods: Patient-reported comfort and other treatment aspects were evaluated and multiple face and neck measurements were obtained on 44 patients with head and neck lymphedema before and after 1 treatment session to assess usability and treatment-related lymphedema changes.

Results: A majority of the patients (82%) reported the treatment was comfortable; most patients (61%) reported feeling better after treatment, and 93% reported that they would be likely to use this therapy at home. One treatment produced overall small but highly statistically significant reductions in composite metrics (mean ± SD) of the face (82.5 ± 4.3 cm vs 80.9 ± 4.1 cm; $P < .001$) and neck (120.4 ± 12.2 cm vs 119.2 ± 12.1 cm; $P < .001$) with no adverse events.

Conclusion: Results found the treatment to be safe, easy to use, and well tolerated while demonstrating edema reduction after a single initial treatment.

KEYWORDS
head and neck cancer, head and neck lymphedema, manual lymph drainage, pneumatic compression

1 | INTRODUCTION

Head and neck lymphedema is a frequent complication of treatment for cancers of the head and neck. Head and neck cancer and its treatment by surgical interventions and/or radiotherapy may obstruct or disrupt lymphatic vessels and damage surrounding soft tissue.[1,2] The lymphatic disruption and tissue damage leads to an accumulation of fluid in the affected areas. This protein-rich fluid activates chronic inflammatory responses resulting in progressive skin and subcutaneous tissue fibrosis further impairing lymphatic function.[3] Although head and neck lymphedema is associated with substantial symptom burden, functional deterioration, and poor quality of life,[4] it remains underrecognized and undertreated.[1,2,5]

Reported head and neck lymphedema rates associated with head and neck cancer treatment range from 48%[6] to 90%.[7] Combined cancer treatment methods involving tumor resection, lymph node dissection, and radiotherapy result in the most severe cases of lymphedema.[8,9] Head and neck lymphedema may involve external structures (skin and soft tissues) or internal structures (mucosa, larynx, and pharynx) and both external and internal tissues are often affected and cumulatively contribute to functional impairments.[2,7] The functional impact is dependent on the anatomy involved and extent of concomitant lymphatic disruption. The most common areas of external swelling are the submental region and the neck.[10,11] Head and neck lymphedema of internal tissues can impact critical physical functions (eg, respiration, mastication, swallowing, and speaking). Similar to lymphedema

affecting the extremities, head and neck lymphedema is often associated with psychological distress and worsened quality of life.[11,12] A recent study that evaluated 733 patients with head and neck cancer treated for head and neck lymphedema, reported that the majority of patients experienced significant discomfort as well as cosmetic concerns.[10] Almost 40% of these patients incurred functional impairments associated with their lymphedema, including difficulty swallowing and difficulty breathing. The most common functional complaint of patients who had undergone total laryngectomy was difficulty breathing, which was related to submental edema causing tracheostomal obstruction.[10] Damage to the muscles of the neck and shoulders may also occur in response to regional radiotherapy and lead to decreased sensation, weakness, tightness, reduced range of motion, and other functional limitations.[12]

Management of lymphedema in the extremities is most frequently achieved with complete decongestive therapy. This multimodal treatment approach includes manual lymphatic drainage, compression bandaging/garments, therapeutic exercise, and skin care. Complete decongestive therapy is initiated in a clinic setting with treatment performed by specially trained clinicians and is transitioned to ongoing self-management at home. Treatment of head and neck lymphedema utilizes modified complete decongestive therapy techniques with a manual lymphatic drainage technique and application sequence that has been well described in the literature.[13] To achieve optimal effects, the head and neck treatment sequence includes: (1) pretreatment of the edema-free areas on the chest, including clearance of the central lymph nodes (supraclavicular and axillary); followed by (2) drainage of the peripheral edematous areas (posterior, anterior neck, and the face/head) along anatomic pathways of lymph vessels toward the central, previously cleared lymph nodes.[13,14] Complete decongestive therapy is generally initiated 4 to 6 weeks postsurgery or at the completion of radiotherapy to allow adequate tissue healing. Although current clinical data support the use of simplified versions of these complete decongestive therapy techniques at home,[10] many patients with head and neck lymphedema experience difficulty performing this treatment and/or find the treatment insufficient in effectively managing their symptoms for the long term.

To help patients meet the substantial challenge of managing head and neck lymphedema, an advanced pneumatic compression device for at-home use has been developed. The advanced pneumatic compression device (Flexitouch System; Tactile Medical, Minneapolis, MN) achieved Food and Drug Administration 510(k) clearance in September of 2016 to include the treatment of head and neck lymphedema. The purpose of the current study was to assess the functional usability of this advanced pneumatic compression device for the treatment of cancer-related head and neck lymphedema as well as potential clinical benefits.

2 | MATERIALS AND METHODS

2.1 | Study design and subjects

The primary purposes of this prospective, functional usability study were to assess the ease of application, garment fit and comfort, and treatment comfort of an advanced pneumatic compression system specifically designed to treat patients with head and neck lymphedema. Secondary purposes were to assess safety and acute edema changes after a single treatment. Approval for the study was obtained from the Institutional Review Board and the Office of Research Administration at Mercy Hospital (St. Louis, MO) and was conducted in full accordance with ethical principles of the Helsinki Declaration. The goals and requirements of the study were explained to all prospective participants and each provided written informed consent before participation.

A convenience sample of subjects with head and neck lymphedema who had previously been treated for head and neck cancer by physicians affiliated with Mercy Hospital St. Louis or Washington University Physicians Group, and were currently receiving or had completed in-clinic complete decongestive therapy were considered for the study. Subjects had to be 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), acute internal jugular venous thrombosis, increased intracranial pressure, acute radiation dermatitis, acute facial infection, and/or any condition in which increased venous and lymphatic return is undesirable.

The medical history of head and neck cancer treatment was obtained and all subjects were assessed by a qualified and experienced physical therapist certified in lymphedema treatment by the Lymphology Association of North America, for the stage of lymphedema based on tissue characteristics using the MD Anderson Cancer Center Head and Neck Lymphedema rating scale.[10]

2.2 | Treatment device and procedure

The Flexitouch System 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.[15–19] Garments were specifically designed to permit treatment of head and neck lymphedema. The head and neck garments are constructed of nylon with a total of 14 pneumatic chambers

FIGURE 1 The Flexitouch System for the head and neck. A, Controller; B, front view; and C, side view [Color figure can be viewed at wileyonlinelibrary.com]

covering part of the head, neck, and chest, as illustrated in Figure 1. The device applies brief applications of dynamic pressure in a wave-like manner to the treatment area. The 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.

Each subject was trained by a lymphedema therapist in the proper method to apply the head and neck garments. They were then asked to demonstrate their ability to don the garments, which was assessed by the clinician. After donning, the device was powered on and treatment was initiated for a 32-minute session. Upon completion, the subject was asked to remove the garment and the subject's ability to doff the garments was assessed. Subject-reported outcomes were obtained via a series of questions to assess garment comfort and treatment. The following major categories were queried: (1) garment comfort; (2) treatment comfort; (3) feeling posttreatment; and (4) likeliness to use at home. The rating and corresponding responses to these 4 queries are summarized in Table 1. Safety outcomes were captured on adverse event forms.

To assess for possible acute changes in edema, metric measurements of the neck and face were performed pre-device and post-device use, as illustrated in Figure 2. At each of 3 neck sites and 14 face sites, the metric measurements are made once before and after treatment. Use of this method has been reported in previous research conducted by MD Anderson Cancer Center.[10] Three circumferential neck measurements are taken with a calibrated tape measure designated as A, B, and C, as illustrated in Figure 2. These measurements are summed to provide a single total neck composite score. In addition, 7 facial surface length

TABLE 1 Queried categories and patient responses (N = 44)

Rating	Garment comfort		Treatment comfort		Feeling post treatment		Likeliness of home use	
1	Very comfortable	9	Very comfortable	21	Much better	7	Very likely	36
2	Somewhat comfortable	16	Somewhat comfortable	15	Somewhat better	20	Somewhat likely	5
3	Neutral	15	Neutral	8	About the same	12	Unsure	2
4	Somewhat uncomfortable	4	Somewhat uncomfortable	0	Somewhat worse	0	Somewhat unlikely	0
5	Very uncomfortable	0	Very uncomfortable	0	Much worse	0	Very unlikely	1
6	N/A		N/A		Too brief to tell a difference	1	N/A	

Abbreviation: N/A, not applicable.

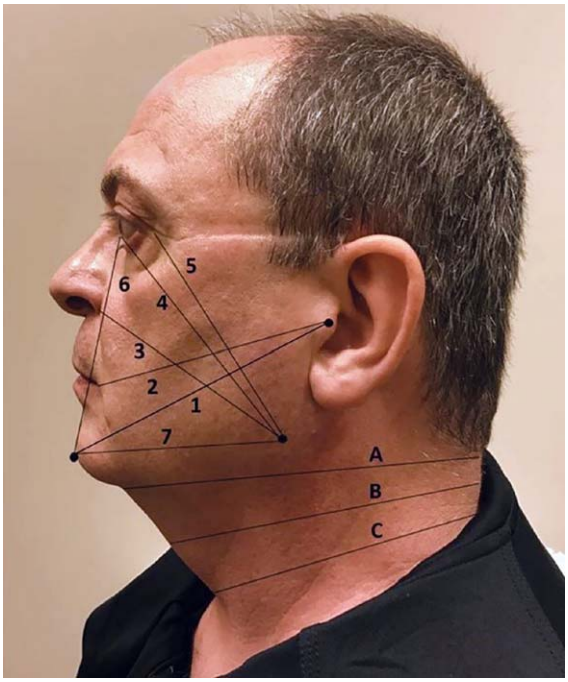

FIGURE 2 Face and neck measurements to determine face and neck composite metrics. Measurement start and endpoints for facial metrics as follows: line 1 = tragus to the chin; line 2 = tragus to the mouth corner; line 3 = mandible to the nasal wing; line 4 = mandible to the medial canthus; line 5 = mandible to the exocanthus; line 6 = chin to the medial canthus; and line 7 = mandible to the chin. Measurement for the neck perimeter as follow: A = superior neck; B = middle neck; and C = inferior neck. Facial metrics on both face sides are summed to yield a single total face composite value. Neck A, B, and C perimeters are summed to yield a single total neck composite value [Color figure can be viewed at wileyonlinelibrary.com]

measurements (numbered 1 through 7 in Figure 2), are performed on both sides of the face. For each side of the face, the metrics were summed to produce a hemifacial composite. The sum of the hemifacial composite scores is termed the total facial composite and was the parameter used to assess facial edema change. Neck and face total composite values were determined for each patient pre-device and post-device treatment.

2.3 | Analysis

Subject responses to the questionnaire were categorized as positive or nonpositive. A response rating of 1 or 2 was considered a positive response and a response rating of 3, 4, 5, or 6 was considered a nonpositive response. To determine if the number of positive responses differed significantly from the nonpositive responses, a 1×2 contingency table was used for a chi-square analysis with an exact Fisher test for significance. Pretreatment and posttreatment face and neck composite values were compared using paired t tests with a P value $< .05$ considered a statistically significant change.

3 | RESULTS

A total of 44 subjects participated in this research study. The study group consisted of 34 men with ages of 61.0 ± 9.7 years (mean $\pm$ SD; range 42-81 years) and 10 women with ages of 60.0 ± 5.4 years (range 51-67 years). Subject demographics and head and neck cancer treatment characteristics are provided in Table 2. Table 3 summarizes lymphedema stage by number and percentage of subjects who presented within each stage. In this study population, the largest proportion of patients (54.5%) presented with stage 2 head and neck lymphedema with firm, pitting irreversible edema.

3.1 | Clinician-assessed subject donning/doffing garments

After a brief training, subjects attempted to don the garments appropriately. Within 2 attempts, 31 subjects (70%) demonstrated independent ability to don the garments properly; the remaining 13 (30%) required minimal assistance. Nearly all 42 of the subjects (95%) demonstrated an independent ability to doff the garments with only 2 (5%) needing minimal assistance.

3.2 | Subjective patient assessments

Table 1 shows the responses for each of the analyzed patient-reported parameters. For purposes of the present analysis, response ratings of 1 or 2 were considered as positive responses and response ratings of 3, 4, 5, or 6 were considered nonpositive responses. This placed rating 3, the neutral response, in the nonpositive category as a conservative estimate. To determine if the number of positive responses differed significantly from the nonpositive responses, a 1×2 contingency table was used for a chi-square analysis with an exact Fisher test for significance. Results of these analyses are shown in Table 4. These results indicate no statistically significant difference between positive and nonpositive responses with respect to the question of garment comfort mainly because of the placement of the neutral response as a nonpositive category. However, results show statistically significant differences between positive and nonpositive responses with respect to the questions of treatment comfort, how the subject feels posttreatment, and the likeliness of the patient using the treatment device at home. For all 3 of these response parameters, positive responses were statistically greater than nonpositive responses.

3.3 | Changes in facial and neck measurements

A single treatment session was associated with an overall small but highly statistically significant reduction (P

TABLE 2 Subject demographics and cancer treatment history (N = 44)

Demographic/characteristic	No. of subjects (%)
Age, years	
Mean (SD)	61 (8.9)
Sex	
Male	34 (77)
Female	10 (23)
Ethnicity	
Not Hispanic or Latino	42 (95)
Hispanic or Latino	2 (5)
Race	
White	41 (94)
Black or African American	1 (2)
American Indian or Alaska Native	1 (2)
Asian	1 (2)
Head and neck cancer treatment	
Surgery and radiation and chemotherapy	17 (39)
Surgery and radiation	11 (25)
Radiation and chemotherapy	15 (34)
Radiation	1 (2)
Surgery type	
Combined (resection of primary tumor and lymph nodes)	26 (59)
No surgery	16 (37)
Resection of primary tumor	1 (2)
Resection of regional lymph nodes	1 (2)
Surgical procedure (not mutually exclusive)	
Glossectomy	10
Neck dissection[a]	7
Pharyngectomy	2
Tonsillectomy	2
Submandibular gland resection	2
Mandibulectomy	1
Laryngectomy	1
Other[b]	2
Feeding tube	
Yes	8 (18)
Tracheal stoma	
Yes	2 (5)

[a]1 = radical; 3 = modified; 1 = selective; and 2 = unspecified.
[b]1 = lip reconstruction; and 1 = thyroidectomy.

value $< .001$) in both the neck and the face composite metrics, as summarized in Table 5. Further analysis of individual changes showed that 20% of patients demonstrated a neck composite reduction of at least 2%, and 43% of patients demonstrated a face composite reduction of at least 2%. A 2% change in face or neck composite value is relevant as it has been defined in previous literature as the threshold for clinically important reduction in head and neck lymphedema.[10] No adverse events in this study were reported.

4 | DISCUSSION

Functional deficits related to head and neck cancer are particularly distressing for patients, especially when compounded by head and neck lymphedema. The most basic functions, such as ease of respiration, mastication, swallowing, and speaking are core to subsistence from both a physical and psychological perspective. To date, sustaining self-management of head and neck lymphedema has been challenging. Frequent complaints of the head and neck lymphedema population are the time-consuming and physical nature of the at-home treatment regimen. These patients often have numerous daily healthcare tasks to complete, including managing a tracheostomy and/or gastrostomy tube, and completing advanced oral hygiene. Patients with functional deficits are often assigned an exhaustive exercise routine, including facial, oral motor, neck, and postural exercises, aside from completing self-administered manual lymphatic drainage, which can be awkward or arduous for a patient to perform independently. The difficulties for the patient to carry out self-manual lymphatic drainage increase in the presence of functional impairments in range of motion caused by surgical or radiation-associated scapular dysfunction or chemotherapy-induced neuropathy. In addition, radiation-associated fibrosis can result in reduced skin sensation in the affected area, reducing the sensory feedback needed to optimally perform these treatment techniques. The difficulty in performing self-treatment and/or the diminishing treatment effects often result in poor treatment adherence, which further limits effective self-management. A

TABLE 3 Stage of lymphedema using the MD Anderson Cancer Center head and neck lymphedema Rating Scale.[10]

Stage	Description	No. of subjects (%)
0	No visible edema but patient reports heaviness	0 (0)
1a	Soft visible edema; no pitting, reversible	1 (2.3)
1b	Soft pitting edema; reversible	15 (34)
2	Firm pitting edema; not reversible; no tissue changes	24 (54.5)
3	Irreversible; tissue changes	4 (9.1)

TABLE 4 Patient subjective positive versus nonpositive responses

Statistical parameter	Garment comfort	Treatment comfort	Feeling posttreatment	Likeliness to use at home
Chi-square	0.818	17.818	7.364	32.818
df	1	1	1	1
Exact significance	0.451	0.000	0.01	0.000

major goal of this pilot study was to determine the feasibility of helping patients with head and neck lymphedema in this process via the use of advanced pneumatic compression.

Within the limitations of the present single-arm, single-treatment study design, the present findings indicate the potential utility of this technology. In addition, these findings provide a basis and foundation for subsequent evaluations of a more extensive nature with studies that have longer device usage and patient follow-up and a suitable control group.

The major new findings that provide such encouragement relate to several specific areas. First, within 1 treatment session, most subjects (70%) were able to don the garments independently and almost all were able to doff the garments without assistance supporting ease of use. Second, a high majority of subjects (93%) reported the likelihood of at-home use of this device and almost 70% of the patients reported feeling better after the initial treatment session. Third, a surprising finding in our sample was that 63% of patients experienced a clinically significant reduction in either neck or facial composite measurements after just 1 pneumatic compression device treatment.

As noted though, the general implications of these findings are limited by the current experimental design. For those patients who were receiving outpatient complete decongestive therapy at the time of the study, this could be a confounding factor on the results. To minimize this, however, subjects did not receive any other treatment on the day of the study. Because all patients received the intervention, the assessing clinician was not blind to the intervention, therefore, it is possible that assessor measurement bias could have existed. Nonetheless, for patients in the general head and neck lymphedema population who find the self-manual lymphatic drainage particularly challenging, the pneumatic compression device could be a suitable adjunctive option for treatment. Whether such patients will actually use the device cannot be known from the current study, but the high in-clinic patient acceptance of this pneumatic compression device treatment with no adverse events suggests that it might help manage symptoms, mediating symptom burden if adopted for consistent long-term use with the potential for improving health.

Improved health and reduction in health events impact health economics and utilization of services. For patients with lymphedema in the limbs, cost effectiveness of the pneumatic compression device use has been demonstrated when preventable adverse outcomes (eg, cellulitis, clinic visits, and hospitalization) are avoided.[15] The question as to whether similar health economic benefits might be achieved with pneumatic compression device use for head and neck lymphedema is a question worth addressing in future randomized controlled trials. Indeed, future research is needed to assess the long-term effectiveness of device treatment on edema reduction, symptom burden, and quality of life in patients with head and neck lymphedema with differing stages of lymphedema as well as compliance and effectiveness with comparator treatments. Further investigations should consider use of instrumentation, such as endoscopic evaluation and internal photographs, to visualize and measure the internal lymphedema-affected areas to assess whether treatment benefits can be documented at these critical sites.

Greater access to effective options for the self-management of head and neck lymphedema also reduces the burden on the limited pool of experienced head and neck lymphedema specialists. These specialists work in a demanding reimbursement environment that requires improved access,

TABLE 5 Change in face and neck composite values pretreatment to posttreatment

Neck composite Pretreatment	Posttreatment	*P* value	Face composite Pretreatment	Posttreatment	*P* value
120.4 ± 12.2	119.2 ± 12.1	< .001	82.5 ± 4.3	80.9 ± 4.1	< .001
Overall % reduction	1.00 ± 1.18		Overall % reduction	1.18 ± 1.23	
Patients with reduction ≥ 2%	9 (20%)		Patients with reduction ≥ 2%	19 (43%)	

Data entries are overall mean ± SD in units of cm for absolute values. Overall percent reduction (% reduction) is calculated as 100* (posttreatment-pretreatment)/pretreatment for each patient and then averaged overall.

increasing clinical volume, fewer in-clinic visits, less counseling time, and achievement of quality outcomes. Access to an effective head and neck lymphedema device for home use might very well improve achievement of this quality outcome mandate with fewer clinic resources, but remains to be determined.

How we appear visually to others, or, more importantly, how we think we appear to others, can have a profound impact on our self-esteem affecting socialization, employment, and quality of relationships. Any treatment tool that provides consistent and effective assistance in self-management of head and neck lymphedema should be considered an investment in this population's overall quality of life.

CONFLICT OF INTEREST

Dr. Mayrovitz is a scientific advisor to Tactile.

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