

Flexitouch System is Well Tolerated and Shows Significant Edema Reduction in Head and Neck Cancer Patients

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

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INTRODUCTION

Head and neck lymphedema is a frequent complication of treatment for cancers of the head and neck due to disruption of lymphatic vessels and damage surrounding soft tissue which results in accumulation of protein-rich fluid in the affected areas and chronic inflammatory responses and tissue fibrosis.^{1,2,3} Reported head and neck lymphedema rates associated with head and neck cancer treatment range from 48%⁵ to 90%,⁶ yet it remains an under recognized and undertreated condition.^{1,2,4} Head and neck lymphedema may involve external structures (skin and soft tissues) or internal structures (mucosa, larynx, and pharynx) or both, and cumulatively contribute impairments of basic functions such as respiration, mastication, swallowing, and speaking.^{2,6} A 2% change in edema, as measured by composite value, has been defined in previous literature as the threshold for clinically important reduction in head and neck lymphedema.¹

OBJECTIVE

The primary purposes of this prospective, functional usability study were to assess the ease of application, garment fit and comfort, and treatment comfort of a novel 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.

METHODS

44 patients with cancer related head and neck lymphedema who underwent or were undergoing complete decongestive therapy were evaluated in this study. Donning and doffing of garments was assessed by clinicians after providing a brief training prior to device usage. Patient-reported usability outcomes were evaluated through a series of questions, and multiple face and neck measurements were obtained before and after one 32 minute treatment session to assess usability and treatment-related lymphedema changes.

Face and neck edema measurements: pre-treatment and post-treatment summary

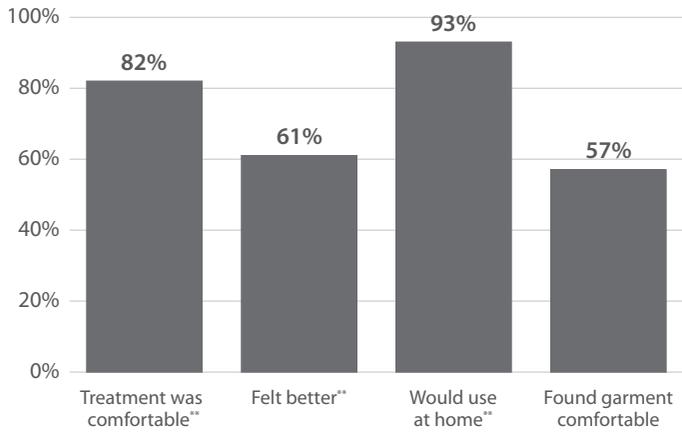
Neck Composite Pre-treatment	Post-treatment	P value	Face Composite Pre-treatment	Post-treatment	P value
120.4 ± 12.2	119.2 ± 12.1	< .001**	82.5 ± 4.3	80.9 ± 4.1	< .001**
Overall % reduction	1.00 ± 1.18		Overall % reduction	1.18 ± 1.23	
Patients with ≥ 2% [†] reduction	9 (20%)		Patients with ≥ 2% reduction	19 (43%)	

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

**statistically significant.

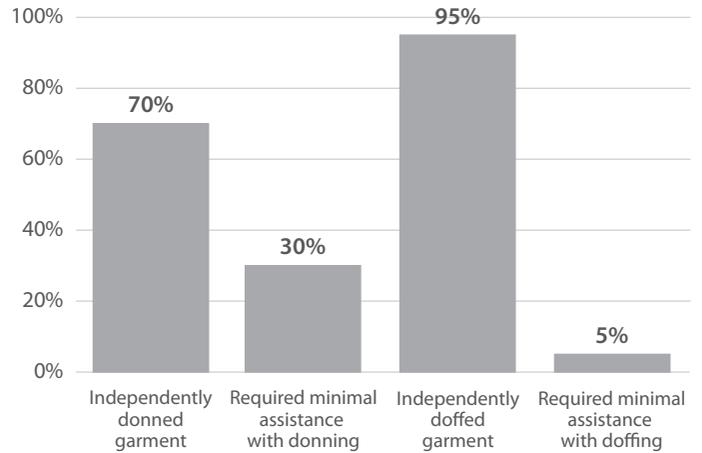
† A ≥2% reduction was deemed clinically important in previous literature (or research).¹

Patient Reported Outcomes



** Indicates statistical significant difference between positive and non-positive response

Clinician-Assessed Subject Garment Usability



RESULTS

One 32 minute treatment session produced overall significant reductions in facial composite measurement ($p < .001$) and neck composite measurements ($p < .001$) with no adverse events. A 2% composite reduction was achieved in 43% of patients for face measurements, and 20% for neck measurements after a single treatment session. A majority of the patients (82%) reported the treatment was comfortable; most patients (61%) reported feeling better after treatment, and nearly all (93%) reported that they would be likely to use this therapy at home. Most of the patients (70%) demonstrated independent ability to don the garments properly; with the remaining 13 (30%) required minimal assistance. Nearly all (95%) of the subjects demonstrated an independent ability to doff the garments with only 2 (5%) needing minimal assistance.

DISCUSSION

Existing methods for self-management of head and neck lymphedema have been physically challenging and time-consuming, which often results in poor treatment adherence and worsening outcomes. These findings provide

encouragement for this new treatment related to ease of use, likelihood of continued use, and significant edema reduction after a single treatment session.

CONCLUSION

Results demonstrate the treatment to be safe, easy to use, and well tolerated, while showing statistically significant and clinically important edema reduction after a single initial treatment.

KEY POINTS

- Statistically significant reductions in composite edema measurement was achieved in 63% of patients (face or neck) after a single 32 minute treatment session, with no adverse events
- Patients found the Flexitouch treatment comfortable (82%), they felt better (61%), and nearly all said they would use the treatment at home (93%)
- The Flexitouch treatment for head and neck lymphedema was found to be safe, easy to use and well tolerated with promising clinical benefits long term

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