Randomized Control Trial Demonstrates Flexitouch® Provides Significant Symptom Improvement for Head and Neck Cancer-Related Lymphedema

Original Article:	Advanced Pneumatic Compression for Treatment of Lymphedema of the Head and Neck: A Randomized Wait-List Controlled Trial
Journal:	*Supportive Care in Cancer*
Publication Date:	June 2, 2020
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INTRODUCTION

More than 90% of patients treated for head and neck cancer (HNC) develop lymphedema.[1] Head and neck lymphedema (HNL), which manifests as external and/or internal swelling, is linked to functional deficits, psychological distress and decreased quality of life.[2] Early, aggressive treatment and ongoing self-care are critical to countering lymphedema progression; however, many HNL patients lack access to certified therapists, face cost or insurance barriers to treatment, or have cognitive or physical limitations that impede self-care. Cost-effective, home-based HNL treatment options are needed.

OBJECTIVE

The purpose of this randomized, wait-list controlled trial was to evaluate the Flexitouch Head and Neck advanced pneumatic compression device (APCD; HCPCS code E0652) in HNC survivors with lymphedema. Primary endpoints were safety and feasibility; secondary endpoints were efficacy, adherence barriers, and user satisfaction.

METHODS

HNC survivors diagnosed with lymphedema who had undergone professional lymphedema therapy, or had been unable to access therapy, were randomized to either standard at-home self-management or at-home Flexitouch use. Follow-up visits to evaluate safety, feasibility, objective assessments and patient-reported outcomes occurred at 1, 4 and 8 weeks. The final sample size included 43 patients: 24 in the control group and 19 in the intervention group.

RESULTS

Safety and Feasibility

This trial supports the safety and feasibility of the Flexitouch APCD for HNL treatment in cancer patients. While four serious adverse events occurred during the trial, none were related to device use. Compliance data supported the feasibility of once-daily use; prescribed twice-daily use yielded low compliance, most often due to patient-reported time constraints. Flexitouch treatment was well tolerated. Study participants were able to master use of the device without difficulty, with low user error.

Patient Reported Outcomes

Relative to patients in the control group, Flexitouch patients reported:

- Statistically significant improvement in swallowing solids (p=0.016) and mucous-related symptoms (p=0.050) on the Vanderbilt Head and Neck Symptom Survey with General Symptom Subscale (VHNSS-GSS); improvement trend was demonstrated for swallowing liquids (p=0.099)
- Statistically significant reductions in severity of soft tissue (p=0.008) and neurological (p=0.047) symptom clusters on the Lymphedema Symptom Intensity and Distress Survey—Head and Neck; improvement trends were noted in clusters related to oral symptoms (p=0.099) and impact of symptoms on activity (p=0.080)
- Stable levels of pain as reported on the VHNSS-GSS; notably, control group patients experienced increasing pain, resulting in a statistically significant difference between study groups (p=0.008)

- Improved ability to control lymphedema at home (p=0.003)

Objective and Functional Assessments

- Evaluation with digital photography demonstrated a greater decrease in the number of external sites with observable swelling for the Flexitouch group, reaching statistical significance for every view: front (p<0.001), right (p=0.004), and left (p=0.005)
- Clinical evaluation of external swelling found a change in the number and severity of swollen sites in favor of the Flexitouch group, but differences did not reach statistical significance
- Cervical and jaw range of motion were both evaluated; the largest effects showed change in favor of the Flexitouch group, though no single measure reached statistical significance

DISCUSSION

Lymphedema is a chronic condition that requires ongoing self-management. In this randomized control trial, Flexitouch use was associated with improved patient-perceived ability to manage lymphedema, a critical component of successful therapy. Though conducted with a small sample, the trial found that Flexitouch use was associated with statistically significant improvements in reported symptoms and visible swelling. Notably, Flexitouch treatment resulted in a significant improvement in patient-reported swallow function; as stated by the authors, Flexitouch use may become an integral component of therapy for HNL-related dysphagia should these results be confirmed. Contradicting widespread belief, this study demonstrated that lymphedema patients may experience significant pain; Flexitouch use was associated with less pain than standard care. Sample size was insufficient to power statistical significance in functional measures in a population with such a heterogeneous presentation of signs and symptoms. Further investigation in larger studies is needed.

KEY POINTS

- HNL patients experience significant symptom burden and require better tools for daily home management
- Once-daily Flexitouch use was safe, well tolerated and easily mastered
- Flexitouch treatment demonstrated statistically significant improvements in:
  - patient-perceived ability to control lymphedema at home
  - patient-reported symptoms: swallow function; severity of mucous-related, soft tissue and neurological symptoms
  - visible external swelling

References

1. Control group patients experienced a statistically significant increase in pain while Flexitouch group remained stable
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;14(4):198–205.
2. 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. *Lymphat Res Biol.* 2019;17(6):661–670.

This study was funded in part or in total by Tactile Medical.

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