Treatment effectiveness of a non-pneumatic compression device versus an advanced pneumatic compression devce for lower extremity lymphedema

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Disclosures

- Koya Advisory Board/CMO

Lymphedema Background

Definitions and Overview

- Abnormal accumulation of protein-rich lymph fluid and fibroadipose tissues resulting from injury, infection, or congenital abnormalities of the lymphatic system[1]
- Primary-develops due to lymphatic system malformation and is rare (1/100,000) or Secondary- develops as result from damage or dysfunction of the lymphatic system and is more common (1/1000)[2]

Signs and Symptoms

- Edema in the extremities
- Hyperkeratosis
- Lymphorrhea

Lymphedema in the Lower Extremities

- Secondary lymphedema due to chronic venous insufficiency (CVI) is the most common form[3]
- CEAP C3-C6 patients represent lymphatic failure and should be considered for treatment similar to lymphedema[4]

Current Treatment Options

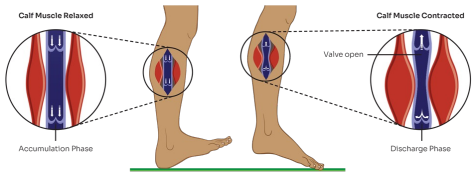
Conservative therapy including
- **Elevation of limb,**
- **Prescribed exercise, and**
- **Use of compression garments**

When conservative therapy is no longer adequate, pneumatic compression devices (PCD) are added

Prescribed Exercise is Mostly Overlooked

- **Performed with donning compression bandage/garments**
- **Active range of motion (ROM), strength, stretching**
- **Begin slow and build tolerance**
- **Include diaphragmatic breathing**
- **Increase muscle and joint pump efficiency**
- **Increase venous and lymphatic return**

Engaging the Veno-muscular Calf-pump (aka the "second heart") is Key to Maintaining Lymphatic and Venous Health



Current Treatment Gaps

- Renders the patient immobile during treatment
- Requires treatment to be plugged into an outlet
- Prevents movement including in the muscles and joints
- Difficult to self—administer
- Disruptive to ability to perform ADLs

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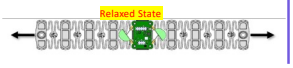
Source: istock-1279015504

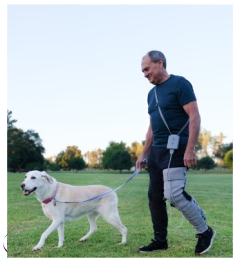
Non-pneumatic compression
Mobile active dynamic compression

Unique properties of SMA

Patented Flexframe® platform



Potential to Close Treatment Gaps With NPCD
... a paradigm shift from pneumatic compression



- Allows for patient mobility and ambulation during treatment
- Allows for engagement of muscle and joint movements, which can enhance lymph transport
- Provides both static compression and active sequential gradient compression
- Minimizes interference with performing daily ADLs

From the American Venous Forum

Results from a comparative study to evaluate the treatment effectiveness of a nonpneumatic compression device vs an advanced pneumatic compression device for lower extremity lymphedema swelling (TEAYS study)

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ABSTRACT

Objective: Advanced pneumatic compression devices (APCDs) have been shown to be effective in treatment of lower extremity lymphedema in the home setting. However, adherence to self-care has been poor, and APCDs require patients to remain immobile during treatment. We evaluated the safety and efficacy of a novel nonpneumatic compression device (NPCD) for treating lower extremity lymphedema vs an APCD.

Methods: A randomized, crossover head-to-head study was performed at nine sites in 2023. Patients were randomized to either the NPCD or a commercially available APCD. Patients used the randomly assigned initial device for 90 days with a 4-week washout period before a comparable 90-day use of the second device.

Results: A total of 71 patients (108 affected limbs) with lower extremity lymphedema were analyzed. Compared with the APCD, the NPCD was associated with a greater mean decrease in limb edema volume (a mean limb volume decrease of 369.9 ± 68.19 mL [$P < .05$] vs 83.1 ± 67.99 mL [$P < .05$]). Significant improvement in Quality of Life was achieved for NPCD and but not for APCD treatment (score improvement of 1.01 ± 0.23 [$P < .05$] for NPCD vs 0.17 ± 0.18 [$P > .05$] for APCD). Patients reported greater adherence (81% vs 56%; $P < .001$) and satisfaction with the NPCD (78% vs 22%) compared with APCD. No device-related adverse events were reported.

Conclusions: The novel NPCD is an effective treatment for decreasing limb volume in patients with lower extremity lymphedema. The NPCD was more effective than an APCD and resulted in superior limb volume decrease, greater improved quality of life, adherence, mobility, and patient satisfaction. (J Vasc Surg Venous Lymphat Disord 2024;■:101965.)

Keywords: NPCD; Nonpneumatic compression; Pneumatic compression; Dayspring; Lymphedema treatment; Lower extremity lymphedema; Phlebolymphedema

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Objectives and Endpoints

Objective

- Compare treatment effectiveness between Dayspring®, a novel non-pneumatic, smart battery powered compression device (NPCD), and advanced pneumatic compression device (APCD) in lower extremity lymphedema patients

Primary Endpoints

- Change in limb volume from baseline
- Change in Quality of Life (LYMQOL) from baseline
- Treatment adherence during study period

Secondary Endpoints

- Safety: adverse events during study period
- Study subject preference questionnaire

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Inclusion / Exclusion Criteria

Inclusion	Exclusion
≥ 18 yrs	History or presence of a systemic disorder that could place the subject at increased risk from sequential compression
Capable of signing and following study protocol	Inability or unwillingness to consent, follow protocol or was involved in clinical trial in past 30 days
Diagnosis of • Primary or secondary unilateral or bilateral lower extremity lymphedema or • Lower extremity phlebolymphedema from chronic venous insufficiency	Conditions that would prevent safe and effective use of the study devices (cellulitis, open-wounds, healing-wounds, etc.) Subjects with poorly controlled asthma Women who are pregnant, planning a pregnancy or nursing at study entry Diagnosis of • Lipedema • Active or recurrent cancer (< 3 months since completion of chemotherapy, radiation therapy or primary surgery for the cancer), • Acute infection (in the last four weeks) • Acute thrombophlebitis (in last 6 months), • Pulmonary embolism or deep vein thrombosis within the previous 6 months, • Pulmonary edema, • Congestive heart failure (uncontrolled/uncompensated) • Chronic kidney disease with acute renal failure • Epilepsy

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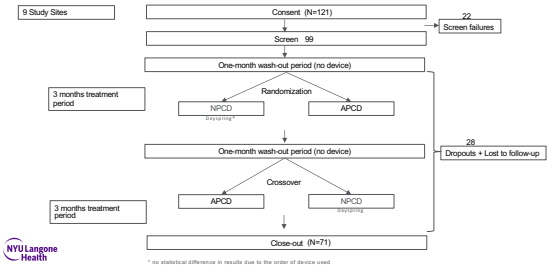
Prospective Multicenter, Randomized with A Single Crossover



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Endpoint Measurements

- Volume in the lower extremities was measured using tape measure and calculated using truncated cone model across the length of limb (every 4cm from the ankle)
- Perimetric change in the foot region was measured using tape measure
- Impact on Quality of life (QOL) was measured using Lymphedema Quality of Life Questionnaire (LYMQOL), a validated clinical survey
- Treatment adherence was recorded by the subject diaries during the study period
- Subjects completed a treatment preference questionnaire at the end of the study

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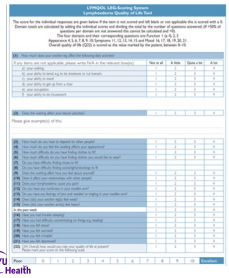
Validated QoL Instrument—LYMQOL LEG-Scoring System



- Overall QoL score range (0-10). Higher is better
- Subscore range for Function, Appearance, Symptoms, and Mood (1-4). Lower is better

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Table I. Patient demographics

Patients	71
Age, years	58.7 ± 1.8
Gender: Female (male)	52 (19)
Race/ethnicity	
Asian	2
Caucasian	58
African American	8
Hispanic	3
Average body mass index	32.6 ± 1.1
Primary/secondary lymphedema	11/60
Affected limbs: unilateral (left/right)/ bilateral	34 (18/16)/37
Lymphedema history (years since diagnosis)	8.1 ± 0.9
Lymphedema clinical stage I, II, III	13, 44, 14
Patients with sleep apnea	34%

Values are mean ± standard error or number.

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Primary Endpoint: Mean Change in Limb Volume from Baseline

Fig 3. Limb volume response. *APCD*, advanced pneumatic compression device; *NPCD*, nonpneumatic compression device.

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Primary Endpoint: Mean Change in the Foot from Baseline

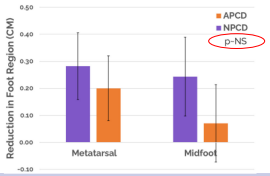

Fig 4. Mean change in the foot. *APCD*, advanced pneumatic compression device; *NPCD*, nonpneumatic compression device.

- Change or response is defined by perimetric measurement of the specific regions of the foot
- No statistically significant difference between the two device cohorts

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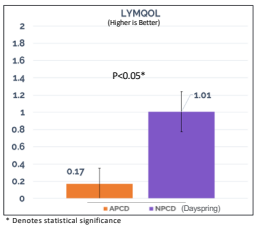
Primary Endpoint: Mean Change in LYMQOL (Overall) from Baseline



* Denotes statistical significance

- Subjects using Dayspring/NPCD achieved an improvement of 1.01 ± 0.23 (mean with standard error)
- Subjects using APCD achieved an improvement of 0.17 ± 0.18 (mean with standard error)
- Statistically significant difference between the two cohorts, favoring Dayspring/NPCD

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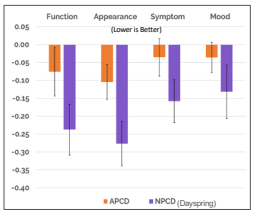
Primary Endpoint: Mean Change in LYMQOL Subscores from Baseline



* Denotes statistical significance

LYMQOL Subscores	Dayspring/ NPCD (Mean Change)	APCD (Mean Change)	P Value
Function	-0.24	-0.08	P<0.05*
Appearance	-0.28	-0.10	P<0.05*
Symptoms	-0.16	-0.04	P<0.05*
Mood	-0.13	-0.04	P~0.1

- Statistically significant differences in Function, Appearance and Symptoms subdomains favoring Dayspring/NPCD
- No statistical difference in the Mood subdomain

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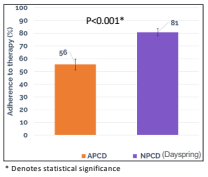
Primary Endpoint: Mean Treatment Adherence



* Denotes statistical significance

- Treatment adherence was defined as device usage once per day for approximately 1-hour in accordance with device labeling
- Dayspring/NPCD cohort reported mean adherence of 81% ± 2.9%
- APCD cohort reported mean adherence of 56% ± 4.2%
- Statistically significant difference between the two cohorts, favoring Dayspring/NPCD

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Secondary Endpoints: Safety and Subject Preference

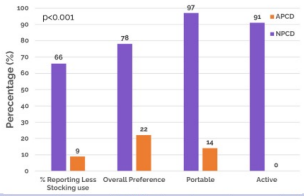

Fig 8. Patient preference questionnaire results. *APCD*, advanced pneumatic compression device; *NPCD*, non-pneumatic compression device.

Safety

- No device-related adverse events (AEs) or device-related severe adverse events (SAEs) in either Dayspring or APCD cohorts

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Conclusions

Met primary and secondary endpoints

Primary (NPCD vs. APCD)

- **Greater Reduction in limb volume**
- **Improvement in overall Quality of Life (LYMQOL)**
- **Improved Treatment adherence**

Secondary (NPCD vs. APCD)

- **Patients prefer one treatment over the other: 78% NPCD vs. 22% APCD (more active/portable)**
- **No AE/SAEs associated with either NPCD or APCD cohort were reported**

Dayspring treatment has demonstrated more favorable outcomes compared to APCD treatment

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