Use of a Portable, Nonpneumatic Active Compression Device in Treatment of Phlebolymphedema: A TEAYS Subanalysis

Todd Berland,[1] Michael Barfield,[2] Ron Winokur,[3] Sandi Davis,[4] Vicky Ralph,[5] Nancy Chatham,[6] Stanley Rockson,[7] and Thomas S. Maldonado,[1] NY, New York, Nashville, Tennessee, Denver, Colorado, Springfield, Illinois, and Stanford, California

Background: Nonpneumatic compression devices (NPCDs) have demonstrated their clinical efficacy and safety in treating lymphedema (LED) in multiple studies, including 2 recent multicentered, randomized head-to-head comparative studies with advanced pneumatic compression devices (APCDs). In the most recent study, TEAYS (ClinicalTrials.gov Identifier: NCT05507346), NPCDs demonstrated better clinical utility as well as greater efficacy and adherence than APCDs in the treatment of lower extremity swelling. This current subanalysis of TEAYS focuses on the outcomes for patients whose secondary lymphedema is associated with underlying venous etiology or phlebolymphedema (PLED).

Methods: This trial was a randomized, crossover head-to-head study performed across 9 sites in the United States in 2023. Patients were subjected to an initial 4-week washout period and then randomized to either the NPCD or a commercially available APCD. Patients used the randomly assigned initial device for 90 days followed by a second 4-week washout period before a 90-day use of the second device. The current study focuses specifically on the subanalysis of the cohort of PLED patients. Primary efficacy outcomes assessed in this study included change in affected limb volume between baseline (day 0) and end of treatment (day 90), change in Lymphedema Quality of Life Questionnaire, and treatment adherence.

Results: Analysis included a total of 71 patients with lower extremity lymphedema; 35 of whom were diagnosed with PLED and this subset comprises the study cohort for the current study. In the PLED cohort, 13 (37%) were males, average body mass index was 36.2 ± 1.68, and 19 had bilateral limbs affected (54%). Most patients had clinical stage II lymphedema: I ($n = 6$), II ($n = 20$), and III ($n = 9$). These PLED patients achieved a statistically greater mean limb volume reduction (424.49 ± 100.9 mL) while on NPCD versus (50.8 ± 112.1 mL) for APCD ($P = 0.0085$). NPCD also showed significantly better improvement in overall quality of life (1.39 ± 0.39) versus APCD (0.18 ± 0.29); ($P = 0.01$). Statistically significant improvement in adherence was also observed while on NPCD 81% versus APCD 49% ($P \leq 0.001$). No device-related adverse events were reported.

Conclusion: The NPCD is a clinically effective treatment for decreasing limb volume in patients with lower extremity LED. The NPCD was more effective than an APCD and resulted in superior

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[1]*Vascular Surgery, New York University, NY, USA.*

[2]*University Surgical Associates, University of Tennessee Health, Science Center, Nashville, TN, USA.*

[3]*Vascular and Interventional Radiology, Weill Cornell Medical Center, NY, NY, USA.*

[4]*Davis Care Physical Therapy, NY, NY, USA.*

[5]*Physical Medicine and Rehabilitation, University of Colorado, Denver, CO, USA.*

[6]*St. Johns Regional Wound Clinic, Hospital Sisters Health Center, Springfield, IL, USA.*

[7]*Cardiovascular Medicine, Stanford University, Stanford, CA, USA.*

Correspondence to: Thomas S. Maldonado, MD, Division of Vascular Surgery, New York University Langone Health, New York, NY 10016; E-mail: Thomas.maldonado@nyulangone.org

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limb volume decrease, greater improved quality of life, adherence, mobility, and patient satisfaction. The outcomes for the subset of patients diagnosed with PLED corroborates the improvements seen in the overall LED study patient population previously reported. In addition, results suggest that PLED patients may potentially benefit even more from NPCD than non-PLED patients.

INTRODUCTION

Secondary lymphedema (LED) can result as a sequela from a variety of insults to the lymphatic system, including trauma, surgery, cancer, and cancer-related treatments, most notably radiation or oncologic surgeries. When secondary LED is the associated with chronic venous hypertension, the condition is called phlebolymphedema (PLED). A large retrospective study found this type of disease as a leading cause of LED in the United States.[1–7]

The chronic and progressive nature of PLED requires a commitment to lifelong management, which includes the use of compression garments as well as compression devices in the home setting. Most recently, a mobile nonpneumatic compression device (NPCD) has demonstrated its clinical efficacy and safety in treating LED. The NPCD technology uses shape memory alloy (nickel/titanium) actuators in its garment, which contract and relax to achieve sequential gradient compression in a distal to proximal manner when specified and energized by the controller. In use, the NPCD controller is battery powered, and is designed to allow the patient to retain mobility while performing their activities for daily living versus immobilizing the patient in a supine position during a pneumatic compression treatment. In 2 separate multicentered, randomized head-to-head comparative studies with advanced pneumatic compression devices (APCDs), which is considered the current standard of care, NPCD showed superior outcomes. In the most recent study (Treatment Effectiveness of a Non-Pneumatic Compression Device versus an Advanced Pneumatic Compression Device for Lower Extremity Lymphedema Swelling: TEAYS study), NPCDs demonstrated better clinical utility as well as greater efficacy and adherence compared to APCDs.[8–11] The current study presented here evaluates key outcomes for the subset of patients from the TEAYS study who are diagnosed with PLED.

METHODS

The study design for the TEAYS study, a prospective, multicenter, randomized, single, crossover clinical trial conducted across 9 study sites in the United States, has been previously described.[11] Eligible patients with a confirmed diagnosis of primary or secondary unilateral or bilateral lower extremity LED were included. The current study focuses specifically on the subanalysis of the cohort of PLED patients.

Primary efficacy outcomes assessed in this study included change in affected limb volume between baseline (day 0) and end of treatment (day 90), change in Lymphedema Quality of Life Questionnaire (LYMQOL), and treatment adherence. Calculation of limb volume by circumference measure was performed by a trained therapist using a calibrated tape measure. Measurements were taken every 4 cm, and the volume of a truncated cone is calculated according to the Kuhnke formula, summing the 8 neighboring circumference measures. Measurements were performed for all affected limbs, regardless of whether LED was unilateral or bilateral.

For the quality of life (QoL) assessment, limb-specific LYMQOL survey was used (Appendix). The LYMQOL is a 20-item clinically validated disease-specific survey tool that was administered at days 0 and 90 for each device treatment period. The survey assesses the effects of LED on QoL through both an overall score (scored 1-10) and 4 sub scores: symptoms (pain, swelling, and numbness), body image and appearance, function (activities of daily living; e.g., eating, writing, and dressing), and mood (e.g., sleep disruption, depression, and irritability). The subdomains are scored from 1 (not at all) to 4 (a lot). The total score is calculated by summing all scores and dividing by the total number of items. The domain-specific subscores reflect improvement as a lower score, and the overall QoL score reflects improvement by a higher score. Changes from days 0 to day 90 for the total score and each sub score were calculated.

Treatment adherence was reported through patient diaries over the 90-day course of treatment for each device. Adherence was calculated as the percentage of reported daily use (minimum of 1 hour) over the treatment period (i.e., patients who used device for the entire 90 days achieved 100% adherence, whereas those who

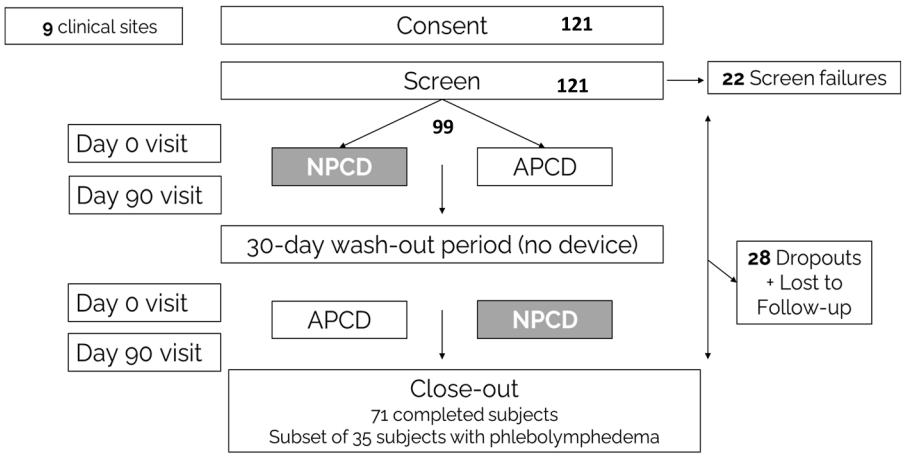

Fig. 1. Study design.

used device every other day reported 50% adherence).

Secondary outcomes included safety as measured by device-related adverse events (AEs) (e.g., pressure-induced wounds, allergic reactions to garments, pain from use of device, or thermal burns) throughout the course of study, and a patient survey administered at the end of the study. The survey evaluated the patient's preference for treatment modality as well as their perceived mobility and device portability during treatment and whether they experienced decreased the use of their compression garments during each treatment period. Reports on truncal swelling before and after device use were also collected.

Additional disease-related health episodes and resource utilization were collected, including episodes of cellulitis, ulceration, hospitalization, LED-related physical therapy visits, and compression stocking use over the past 12 months before device use and during the study duration with each device treatment.

Randomization and Treatment

The study design is depicted in Figure 1. An initial 30-day washout period was established in which no compression devices were used. During this period, patients were allowed to continue their conservative care, which included the use of compression garments, without any physical therapy visits. After this initial 30-day period, each patient was randomized to receive either the NPCD or the APCD treatment for 90 continuous days. At the end of the treatment duration (day 90), another 30-day washout period was established in which no compression device was used, and patients were subsequently crossed over to the alternate device treatment. For each device treatment arm, measurements were collected at day 0 and day 90, except for the patient study survey, which was performed at the end of the study. All patients were trained on how to use the devices and don/doff the respective device accessory garments. Study devices included either the NPCD Dayspring device (Koya Medical, Dallas, TX) or a commercially available APCD (of the 71 patients who completed the study, 2 used an Airos E0652 device (AIROS Medical, Audubon, PA), 1 used a Lympha Press E0652 device (Lympha Press, Chadds Ford, PA), and the remaining 68 patients used the E0652 Flexitouch plus [PG32-G3] device (Tactile Medical, Minneapolis, MN). Patients were instructed to use the assigned device once daily on the study limb for a minimum of 60 minutes. Patients were permitted to continue the use of compression garments and the general duration of use was captured using the patient survey at the end of the study.

Statistical Analysis

The software packages used for data analysis for this prospective study were Microsoft Excel (Office Professional Plus 2021, Version 2508; Microsoft Corp, Redmond, WA) and STATA (StataCorp, College Station, TX). Changes in measured outcomes from days 0 to day 90 for both groups and categorical variables were presented as proportions, normally distributed continuous variables presented as mean ± standard error, and skewed continuous variables presented as median (interquartile range). Assumptions were checked; nonparametric alternatives were

Table I. Study demographics-phlebolymphedema (PLED) versus nonphlebolymphedema (non-PLED) subsets

Number of patients by subtype	$N = 35$ PLED	$N = 36$ Non-PLED
Mean age	58.5 ± 2.63 yrs[a]	59 ± 2.37 yrs[a]
Gender: M (F)	13 (22)	6 (30)
Race/ethnicity		
Asian	0	2
Caucasian	31	28
African American	4	4
Hispanic	0	2
Average BMI	36.2 ± 1.68[a]	29.0 ± 1.24[a]
CEAP score (C1, C2, C3, C4, C5)	0, 10, 13, 5, 7	-
Affected limbs: unilateral (L/R)/ bilateral	16 (9/7)/19	18 (9/9)/18
Lymphedema history (years since diagnosis)	7.9 ± 1.2[a]	8.4 ± 1.42
Lymphedema clinical stage I, II, III	6, 20, 9	7, 24, 5
Percentage of subjects with sleep apnea	43%	25%

BMI, body mass index; CEAP, clinical signs, etiology, anatomy, and pathophysiology).
[a]Reported as mean ± standard error.

considered as needed for skewed distributions. Univariate and multivariable analyses were performed with candidate variables and outcome measures. Statistical significance was tested using a 2-sided alpha level of 0.05 and with appropriate multiple testing correction (Bonferroni or Benjamini–Hochberg) approach when needed, with each limb considered a unique observation. A priori sample size calculation was performed based on the primary end point of percentage reduction in limb volume (converted from circumference). Assuming an effect size of 10% reduction in volume (standard deviation of 12%), with a 2-sided $\alpha = 0.05$ and power = 80%, we estimated that 40 participants per arm would be required. We enrolled significantly higher than this threshold (plus the cross over effect per arm), exceeding the requirement and thereby ensuring sufficient power to detect the hypothesized difference.

STUDY RESULTS

Patient Demographics

A total of 121 patients were screened and 22 failed at screening; 99 patients entered the study. Over the entire study, 24 patients withdrew consent and 4 were lost to follow-up or were missing data. Of the 24 patients who withdrew consent, 3 dropped out of the study before assignment of a treatment device, 6 during the APCD group, and 15 during the NPCD group. All patients had a confirmed diagnosis of LED. Diagnosis of LED was clinical (lymphoscintigraphy was not required; diagnosis of chronic venous disease was based on h/o deep venous thrombosis or documented venous reflux on duplex ultrasound). All patients were on conservative therapy (including, but not limited to exercise, manual lymphatic drainage, compression garments, and elevation of limb) before day 0. There were 35 patients (49%) who were diagnosed with PLED and 36 patients (51%) who were diagnosed with non-PLED. For this subset analysis, the demographics of the PLED subjects compared to the non-PLED subjects are summarized in Table I.

Primary End Points and Efficacy

Edema reduction and limb volume. In the PLED group, for the NPCD treatment arm, the mean limb volume decreases with standard error of 424.4 ± 100.9 mL ($P = 0.0011$) and a median of 349 mL was achieved versus that of 50.8 ± 112.06 mL ($P = 0.65$) and a median of 7.5 mL for the APCD treatment arm (Fig. 2). Statistical significance for comparing mean limb volume decreases between the treatment arms was achieved, favoring NPCD ($P = 0.0085$).

In the non-PLED group, for the NPCD treatment arm, the mean limb volume decreases with standard error of 317.3 ± 92.42 mL ($P = 0.0049$) and a median of 210 mL was achieved versus that of 114.9 ± 78.7 mL ($P = 0.42$) and a median of 73 mL for the APCD treatment arm (Fig. 2). Statistical significance for comparing mean limb volume decreases between the treatment arms was achieved, favoring NPCD ($P = 0.034$).

Changes in the foot were monitored by measurements at the metatarsal heads and midfoot for both treatment groups between day 0 and day 90, and no significant difference was detected between either group for the PLED or the non-PLED subsets (Fig. 3).

Quality of Life (LYMQOL). In the PLED group, significant improvement in QoL was achieved for NPCD and but not for APCD treatment. Overall LYMQOL score improvements of 1.39 ± 0.39 ($P = 0.015$) and a median of 1.0 for NPCD versus that of 0.18 ± 0.29 ($P = 0.53$) and a median of 0.0 for APCD were achieved. Statistical significance for comparing overall LYMQOL improvement between the 2 treatment arms was achieved, favoring NPCD

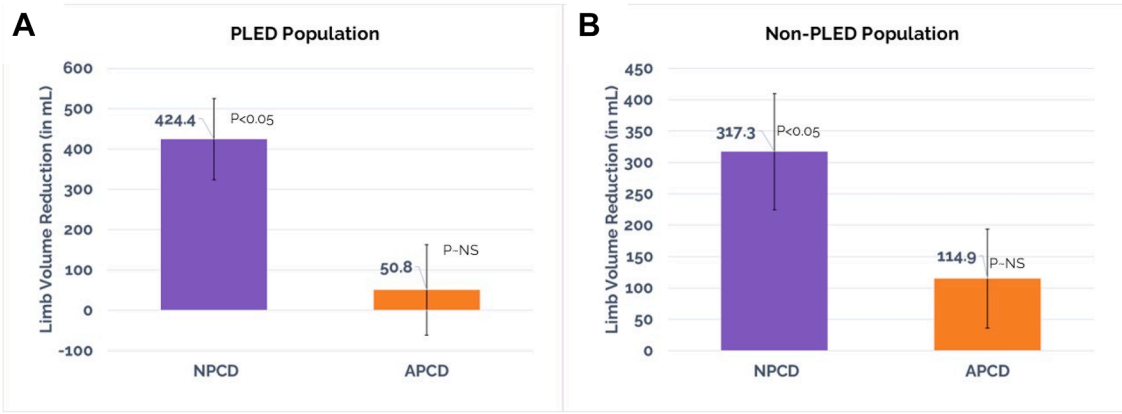

Fig. 2. Change in mean limb volume compared to baseline, **(A)** PLED versus **(B)** non-PLED subsets.

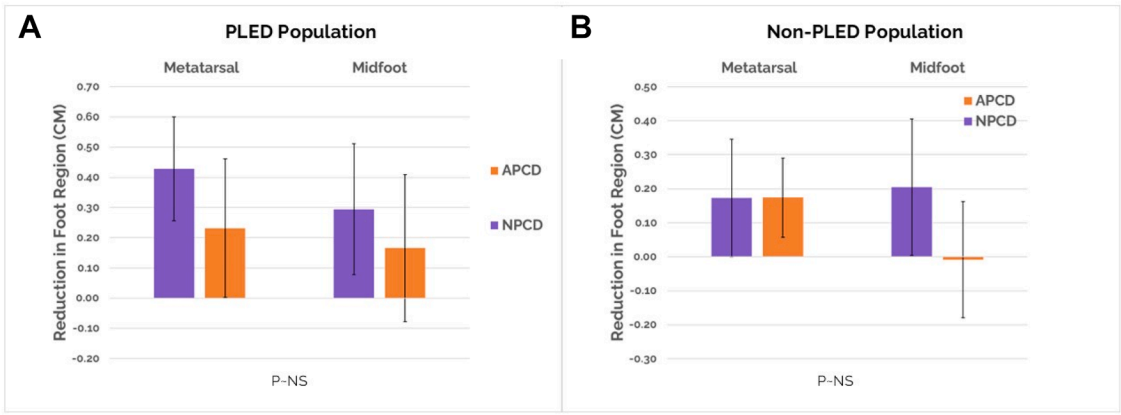

Fig. 3. Mean change in the foot region, **(A)** PLED versus **(B)** non-PLED subsets.

($P = 0.01$). Significant improvement in LYMQOL functional subscores were mixed for both treatment arms. The NPCD treatment arm achieved statistically significant improvement across all but 1 subscore (mood, −0.16; $P = 0.11$), whereas the APCD treatment arm achieved no statistical significance in any of the subscores. Statistical significance for comparing the LYMQOL functional subscore improvements between the 2 treatment arms was achieved in function, appearance, and symptoms, favoring NPCD, but not in mood.

In the non-PLED group, although there were improvements in QoL, they were not significant for either NPCD or APCD. Overall LYMQOL score improvements of 0.64 ± 0.24 ($P = 0.103$) and a median of 0 for NPCD versus that of 0.16 ± 0.23 ($P = 0.51$) and a median of 0.0 for APCD were achieved. Refer to Table II and Figures 4 and 5 for a summary of the primary outcomes, including LYMQOL. LYMQOL is a validated clinical tool and 1.0 point (the lowest count) in the overall score is considered clinically meaningful.

Treatment adherence. In the PLED group, treatment adherence was reported as 81% ± 4% (with a median of 92% for NPCD and 49% ± 6.5% with a median of 46% for APCD. Statistical significance was achieved comparing adherence for the 2 treatment arms, favoring NPCD ($P \leq 0.001$).

In the non-PLED group, treatment adherence was reported as 80% ± 4.2% with a median of 89% for NPCD and 62% ± 5.3% with a median of 69% for APCD. Statistical significance was achieved comparing adherence for the 2 treatment arms, favoring NPCD ($P = 0.0024$).

Figure 6 contains a graphical representation of these results.

Table II. Summary of data for PLED and non-PLED subset for the NPCD and APCD groups

	Device	PLED	Non-PLED
Mean limb volume change (in mL)	NPCD	Mean with SE: 424.4 ± 100.9 Median: 349 *P = 0.0011*	Mean with SE: 317.3 ± 92.42 Median: 210 *P = 0.0049*
	APCD	Mean with SE: 50.8 ± 112.06Median: 7.5 *P = 0.65*	Mean with SE: 114.9 ± 78.70 Median: 73 *P = 0.42*
	NPCD versus APCD	*P = 0.0085*	*P = 0.034*
Change in foot region (mid foot) in CM	NPCD	Mean with SE: 0.29 ± 0.22 Median: 0.2 *P = 0.18*	Mean with SE: 0.20 ± 0.20 Median: 0.20 *P = 0.32*
	APCD	Mean with SE: 0.17 ± 0.24 Median: −0.1 *P = 0.53*	Mean with SE: −0.01 ± 0.17 Median: 0.1 *P = 0.96*
	NPCD versus APCD	*P = 0.40*	*P = 0.14*
Change in foot region (meta-tarsal) in CM	NPCD	Mean with SE: 0.43 ± 0.17 Median: 0.6 *P = 0.036*	Mean with SE: 0.17 ± 0.17 Median: 0.20 *P = 0.34*
	APCD	Mean with SE: 0.23 ± 0.23 Median: 0.3 *P = 0.34*	Mean with SE: −0.17 ± 0.12 Median: 0.2 *P = 0.13*
	NPCD versus APCD	*P = 0.36*	*P = 0.39*
Overall LYMQOL	NPCD	Mean with SE: 1.39 ± 0.39 Median: 1.00 *P = 0.015*	Mean with SE: 0.64 ± 0.24 Median: 0 *P = 0.103*
	APCD	Mean with SE: 0.18 ± 0.29 Median: 0 *P = 0.53*	Mean with SE: 0.16 ± 0.23 Median: 0 *P = 0.51*
	NPCD versus APCD	*P = 0.01*	*P = 0.10*
LYMQOL − function	NPCD	Mean with SE: 0.37 ± 0.12	Mean with SE: 0.11 ± 0.08
	APCD	Mean with SE: −0.02 ± 0.11	Mean with SE: 0.16 ± 0.08
	NPCD versus APCD	*P = 0.008*	*P = 0.36*
LYMQOL − appearance	NPCD	Mean with SE: 0.34 ± 0.10	Mean with SE: 0.22 ± 0.08
	APCD	Mean with SE: 0.09 ± 0.08	Mean with SE: 0.12 ± 0.06
	NPCD versus APCD	*P = 0.021*	*P = 0.15*
LYMQOL − symptom	NPCD	Mean with SE: 0.19 ± 0.09	Mean with SE: 0.12 ± 0.08
	APCD	Mean with SE: 0.02 ± 0.09	Mean with SE: 0.05 ± 0.06
	NPCD versus APCD	*P = 0.05*	*P = 0.25*
LYMQOL − mood	NPCD	Mean with SE: 0.16 ± 0.13	Mean with SE: 0.10 ± 0.08
	APCD	Mean with SE: 0.01 ± 0.07	Mean with SE: 0.06 ± 0.05
	NPCD versus APCD	*P = 0.11*	*P = 0.36*
Adherence (in %)	NPCD	Mean with SE: 81 ± 4 Median: 92	Mean with SE: 80 ± 4.2 Median: 89
	APCD	Mean with SE: 49 ± 6.5 Median: 46	Mean with SE: 62 ± 5.3 Median: 69
	NPCD versus APCD	*P ≤ 0.001*	*P = 0.0024*

CM, centimeters; SE, standard error.

Secondary End Points and Safety

No device-related AEs or device-related severe AEs were reported in either the NPCD or the APCD treatment arms. Unrelated to either devices, the following AEs were reported during the course of the study: 2 mild AEs (with a fall on ice and rolled ankle, both resolved); 12 moderate AEs (Mohs surgery, torn calf muscle, allergy to medication, COVID, sciatic leg pain, ankle sprain, implantation of a heart loop recorder, knee injections for pain, cellulitis, allergy to Bactrim; all resolved with medical or surgical intervention; and cancer recurrence managed with ongoing medical intervention); 15 moderate severe AEs (cardiac arrhythmia,

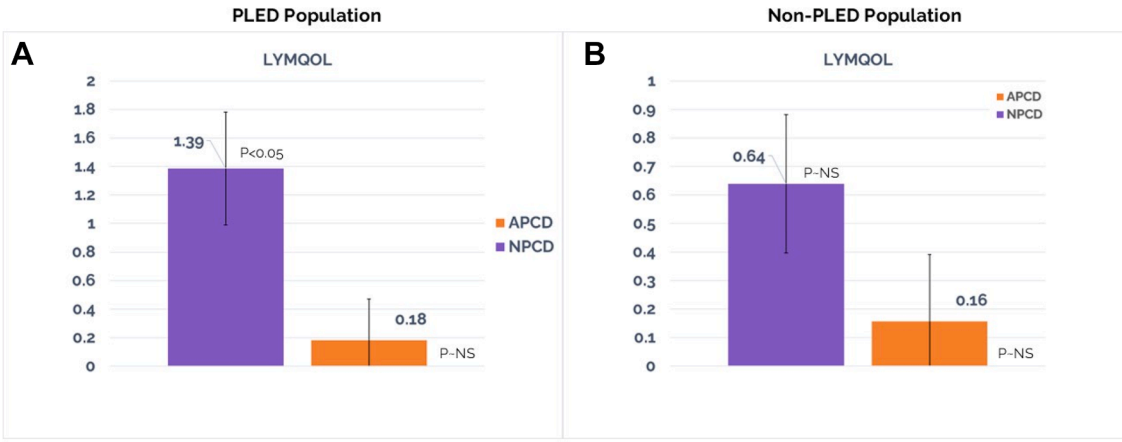

Fig. 4. Overall LYMQOL, **(A)** PLED versus **(B)** non-PLED subsets.

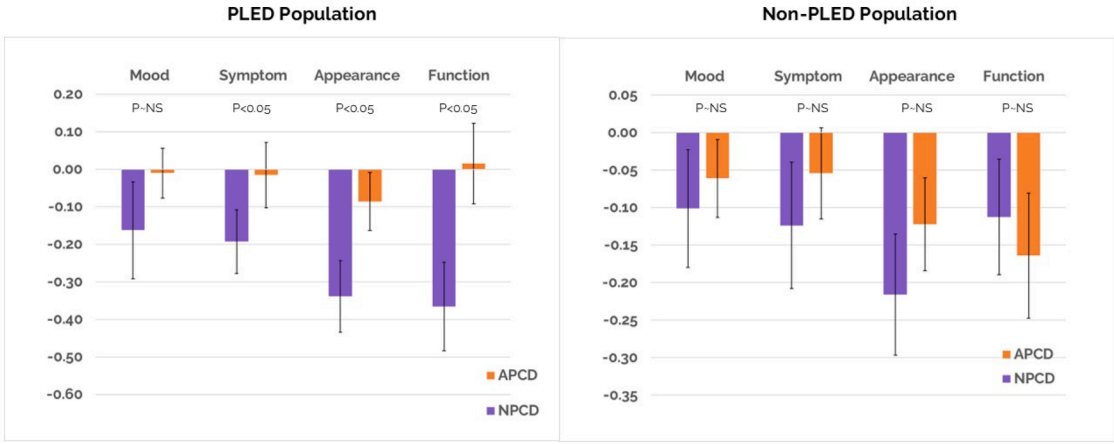

Fig. 5. LYMQOL improvement, PLED versus non-PLED subsets.

hospitalization, pacemaker implantation, neck pain/fusion with rod placement, fall with metatarsal break and numbness, torn meniscus, urinary tract infection requiring hospitalization, urinary retention, retinal surgery, cataract surgery, wound vac treatment, and stent placement; all resolved with medical or surgical intervention).

No truncal swelling or worsening was reported (compared with baseline) for any patients for either group and for either of the subsets (PLED or non-PLED).

For the patient survey, which was administered at the end of the study, a majority of the patients (85% in the PLED group and 97% in the non-PLED group) reported being active during NPCD treatment (0% for APCD treatment for PLED and non-PLED group). Patients also responded on their overall preference, with a majority preferring NPCD treatment as their treatment choice (85% in the PLED group and 71% in the non-PLED group) compared to (15% in the PLED group and 29% in the non-PLED group) for the APCD treatment.

In addition, patients also reported a decreased use of compression stockings in both groups. For the PLED subset, 68% of patients on NPCD treatment reported a decreased use of compression stockings compared with 12% of patients on APCD treatment reporting decreased use of compression stockings. Similarly, for the non-PLED subset, 64% of patients on NPCD

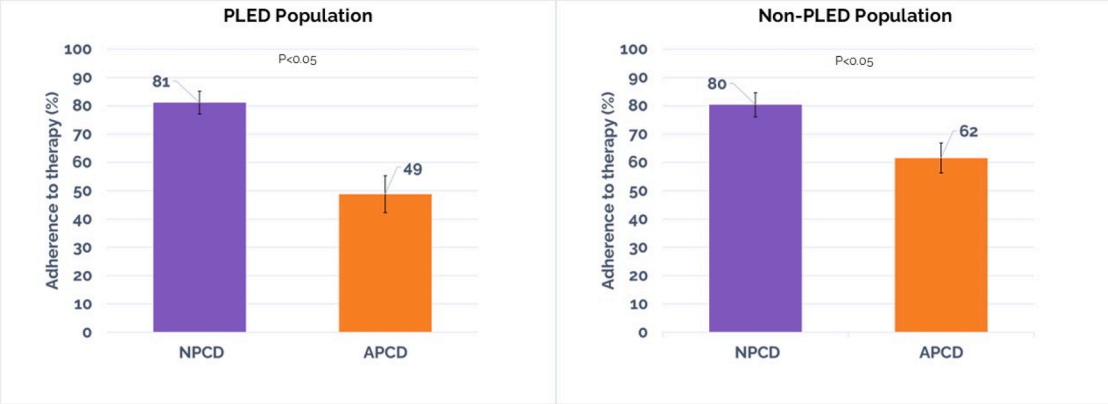

Fig. 6. Adherence to treatment, PLED versus non-PLED subsets.

treatment reported a decreased use of compression stockings compared with 6% of patients on APCD treatment reporting decreased use of compression stockings.

Figure 7 contains a graphical representation of these results.

Disease-Related Health Episodes and Resource Use

Select disease-related health episode and resource use data were also collected at the beginning of the study and captured after 90 days of treatment with each device. Baseline average number of episodes in the 12 months before study enrollment was 0.6 ± 0.1 for cellulitis and 0.3 ± 0.1 for ulceration. For resource use, the baseline average number of days in the 12 months before study enrollment for hospitalization associated with complications from LED was 1.0 ± 0.4, and for use of compression stockings, it was 304.3 ± 14.6. The average number of LED-related physical therapy visits in the 12 months before study was 19.5 ± 3.7.

During the NPCD treatment period, for both the PLED and non-PLED subsets, no episodes of cellulitis, ulceration, or hospitalization were reported. Average LED-related physical therapy visits during this 90-day study period were found to be 0 visits for the PLED subset and 0.39 visits for the non-PLED subset, all for the NPCD group.

During the APCD treatment period, there were a total of 3 cases (∼4%) of cellulitis reported and 1 case of ulceration reported (∼1%), all of which were resolved with medical intervention. The 3 cases of cellulitis were observed in the non-PLED subset, whereas the ulceration was observed in the PLED subset. A total of 8 hospitalization days were also reported during APCD treatment period. Four of these were observed in the non-PLED subset, whereas the other 4 were observed in the LED subset. Average LED-related physical therapy visits during this 90-day study period were found to be 3.35 visits for the LED subset and 1.86 visits for the non-PLED subset, all for the APCD group.

A summary of the health resource utilization data is shown in Tables III (PLED) and IV (non-PLED).

DISCUSSION

In the TEAYS study,[11] a total of 71 patients (108 affected limbs) with lower extremity LED 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 vs. 83.1 ± 67.99 mL). Significant improvement in QoL was achieved for NPCD and but not for APCD treatment (score improvement of 1.01 ± 0.23 for NPCD vs. 0.17 ± 0.18 for APCD). Patients reported greater adherence (81% vs. 56%; $P \leq 0.001$) and satisfaction with the NPCD (78% vs. 22%) compared with APCD.

In the current study, analysis of subset of 35 patients diagnosed with PLED were performed. PLED patients achieved statistically greater mean limb volume reduction (424.4 ± 100.9 mL) while on NPCD versus (50.8 ± 112.1 mL) for APCD. NPCD also achieved significantly better improvement in overall QoL (1.39 ± 0.39) versus APCD (0.18 ± 0.29). Statistically significant improvement in adherence was also observed while on NPCD 81% versus APCD 49%. No device-related AEs were reported.

Specifically looking at the mean edema reduction, PLED patients treated with NPCD demonstrated greater benefit than their non-PLED

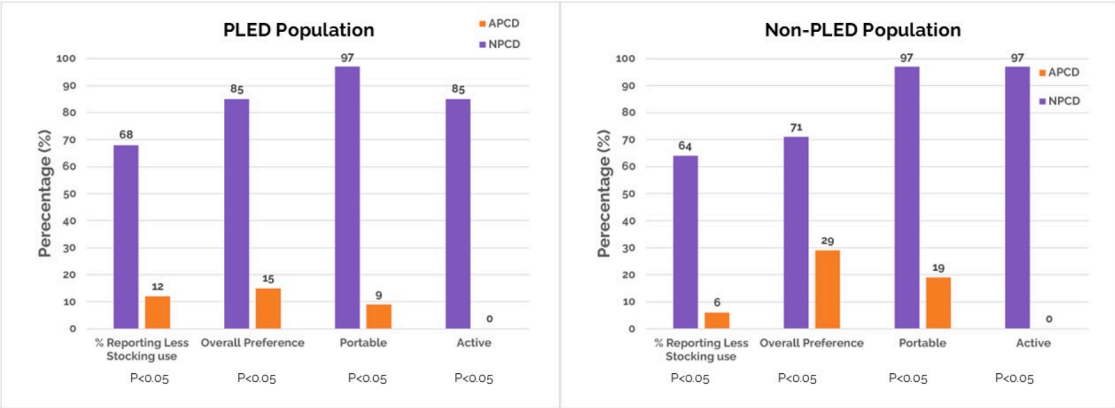

Fig. 7. Subject preference questionnaire, PLED versus non-PLED subsets.

counterparts. For those PLED patients, the mean limb volume reduction achieved was 424.4 mL while treated with NPCD compared with 50.8 mL treated with APCD, that is, those PLED patients appeared to have achieved 7 times greater edema reduction while on NPCD treatment arm. In contrast, non-PLED patients also achieved a better mean limb volume reduction while on NPCD compared to APCD, the difference, although statistically significant, is not as pronounced, 317.3 mL for NPCD and 114.9 mL for APCD. Furthermore, the PLED cohort appeared to achieve more reduction in both the midfoot and metatarsal foot regions while on NPCD (0.29 and 0.43 vs. APCD 0.17 and 0.23, respectively) numerically favoring NPCD.

A 3-year retrospective analysis involving 440 eligible patients with lower extremity LED showed that chronic venous insufficiency (CVI) (PLED), not cancer, was the predominant cause of lower extremity LED.[6] These finding supports the well accepted understanding that PLED stems from CVI, where damaged venous valves or alternatively venous occlusion from prior injury/thrombosis impair venous return, and eventually contribute to lymphatic fluid overload. As highlighted in the TEAYS study, NPCD differs from pneumatic compression in both mechanism and design. Pneumatic compression provides sequential compression while requiring patient to be immobilized and remain in a supine position for the duration of the treatment. In a stark contrast, NPCD utilizes both static and sequential gradient compression as well as provide added benefits for ambulation and subsequent activation of calf and thigh pumps[12]—both of which are critical to managing PLED and venous health. This mobility-driven approach reflects the contemporary approach to managing PLED acknowledges the lymphatic—venous[13–15] connection in fluid management.

The TEAYS study and this subsequent PLED sub analysis have shown that NPCD not only enhances treatment adherence but also provide additional plausible explanations for combined effects of synergistic modalities that have been well established

Table III. Health resource utilization, during the study with each device (PLED)

Subjects	With NPCD for 3 months	With APCD for 3 months
Phlebo subset who completed the study	35	35
Average cellulitis episodes	0	0
Average ulceration episodes	0	0.03 ± 0.03*
Average hospitalization days	0	0.12 ± 0.08*
Average # of physical therapy visits	0	3.35 ± 1.14*
Percentage of subjects reporting decreased use of compression garments	68%	12%

*Reported as mean ± standard error.

Table IV. Health Resource Utilization, during the study with each device (non-PLED)

Subjects	With NPCD for 3 months	With APCD for 3 months
Non-Phlebo subset who completed the study	36	36
Average cellulitis episodes	0	0.08 ± 0.05*
Average ulceration episodes	0	0
Average hospitalization days	0	0.11 ± 0.09*
Average # of physical therapy visits	0.39 ± 0.33*	1.86 ± 0.59*
Percentage of subjects reporting decreased use of compression garments	64%	6%

*Reported as mean ± standard error.

in prior published literature and consensuses,[16] supporting a comprehensive treatment lymphatic drainage and venous return.

LIMITATIONS

Common biases in crossover studies include unintended biases such as order of which device was first used and whether there is an unforeseen carryover effect from one treatment arm to the comparator. Additional analyses were performed to examine effect with respect to order of device. In addition, despite the initial 30-day washout period, some patients who have prior experience with an APCD may retain preconceived notions about that device, which may have influenced compliance.

CONCLUSIONS

CVI associated with lymphatic damage (PLED) is a predominant cause of lower extremity LED, which arises from a compromised or poorly functioning venous system. Although traditional recommendations like compression and elevation remain foundational, a significant treatment gap exists that addresses not only objective clinical outcomes, such as limb volume reduction, but also factors like QoL and patients' adherence to daily treatment regimens. The TEAYS study demonstrated that NPCD is a clinically effective and safe treatment option for lower extremity LED while demonstrating superiority in key outcomes such as limb volume reduction, QoL, and adherence compared to the traditional use of APCDs. The PLED subgroup analysis further reinforces these conclusions, showing that both PLED and non-PLED patients gained meaningful clinical benefits from NPCD; with PLED patients potentially benefiting even more due to the comprehensive treatment approach offered by NPCD and the distinct pathophysiology involving CVI as the underlying etiology for PLED.

CREDIT AUTHORSHIP CONTRIBUTION STATEMENT

Todd Berland: Writing – review & editing, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Michael Barfield:** Writing – review & editing, Investigation, Data curation. **Ron Winokur:** Writing – review & editing, Investigation, Data curation. **Sandi Davis:** Writing – review & editing, Investigation, Data curation. **Vicky Ralph:** Writing – review & editing, Investigation. **Nancy Chatham:** Writing – review & editing, Investigation, Data curation. **Stanley Rockson:** Writing – review & editing, Supervision, Investigation, Data curation, Conceptualization. **Thomas S. Maldonado:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Formal analysis, Data curation, Conceptualization.

SUPPLEMENTARY DATA

Supplementary data related to this article can be found at https://doi.org/10.1016/j.avsg.2026.02.039.

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