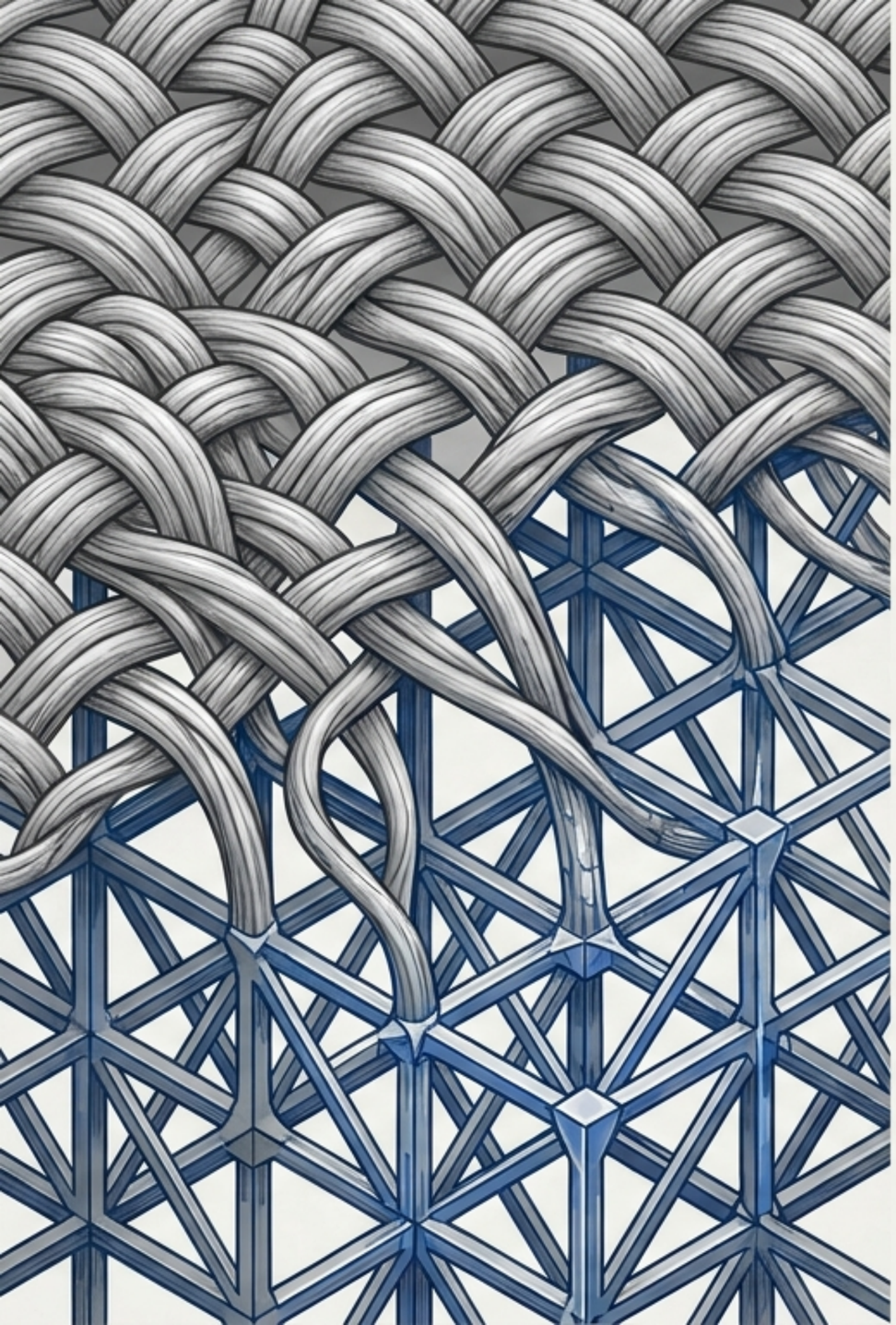


The Evolution of Lymphedema Management

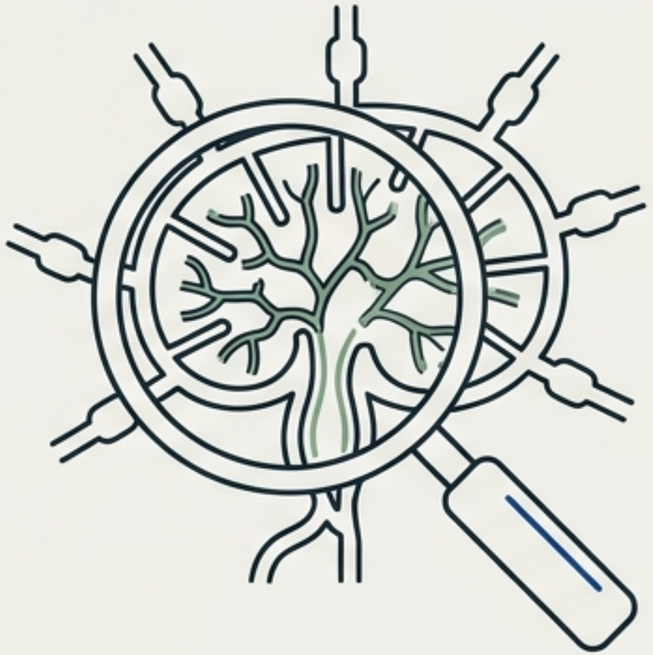
Clinical evidence and physiological mechanisms of Non-Pneumatic Compression Devices (NPCD)

5–10 Million+

Affected individuals in the United States.

>$1 Billion

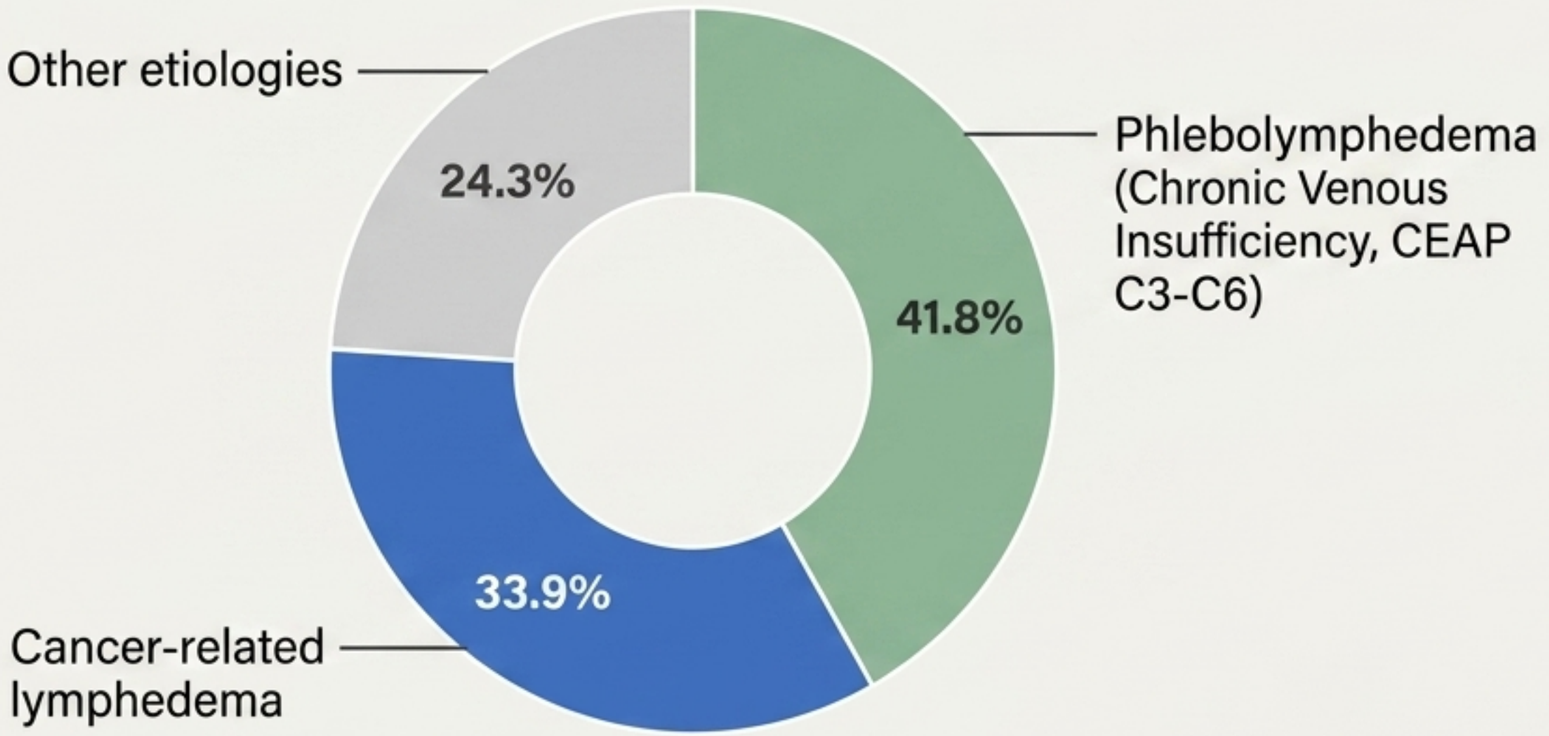
Estimated lymphedema-related healthcare costs over a 5-year period.



Chronically underdiagnosed and undertreated, necessitating early intervention to prevent irreversible progression.

Source: Greene AK (2015), Roberson ML et al. (2021).

Phlebolymphedema is the primary etiology of lower extremity cases

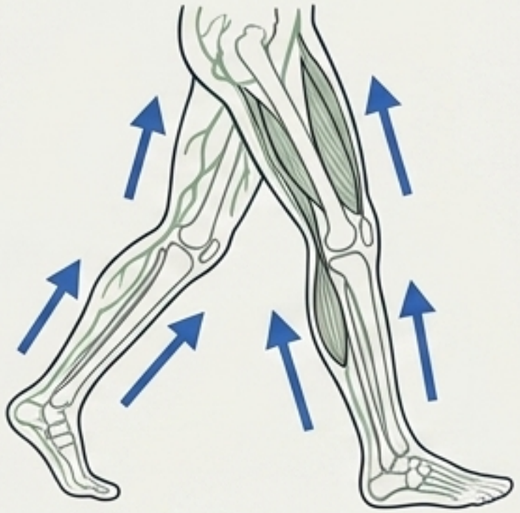


Elevated venous pressure disrupts lymphatic function. The American Venous Forum (2022) mandates treating CVI as lymphedema to optimize management.

Data from 440 lower extremity lymphedema cases.
Source: Dean et al. (2020).

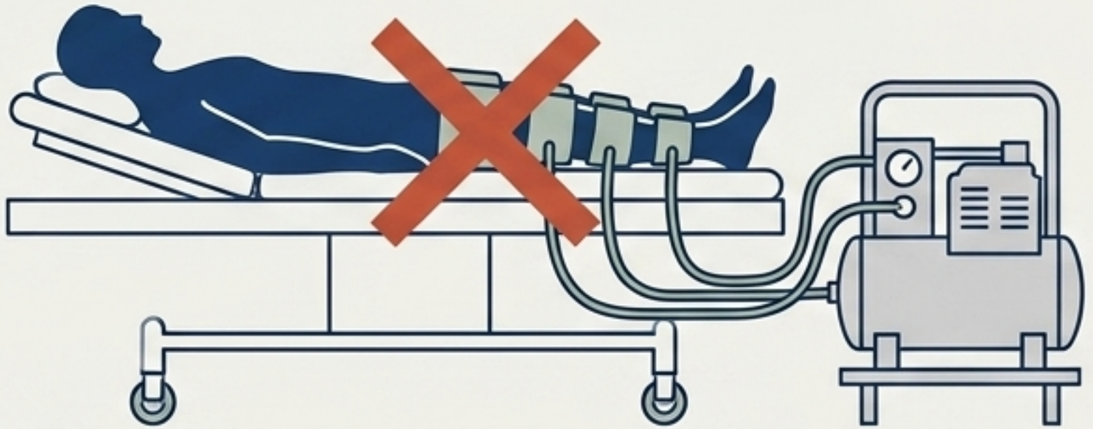
The immobilization paradox of traditional pneumatic compression

The Goal



Optimal lymphatic drainage and deep **lymphangion** contractions require **active muscle movement.**

The Status Quo



Current guidelines utilize pneumatic compression devices (PCDs) as adjuncts. However, requiring user **immobilization in a supine position directly impairs the muscle pump activation essential for venous and lymphatic return.**

PCDs also suffer from complex application and poor patient adherence, driving disease progression

Redefining compression mechanics: Pneumatic vs. Non-Pneumatic

	APCD (Standard)	NPCD (Evolution)
Actuation Source	Stationary air compressors & air-inflated sleeves.	Electromechanical actuators utilizing Nitinol (shape memory alloy).
Patient Posture	Immobilized / Supine.	Active / Mobile (facilitates activities of daily living).
Physiological Mechanism	Passive sequential compression.	Multi-modal (Static containment + Sequential compression + Muscle pump activation).
Profile	Bulky, noisy, complex application.	Compact, mobile-powered, noiseless, wearable.

Electromechanical compression driven by phase transformation

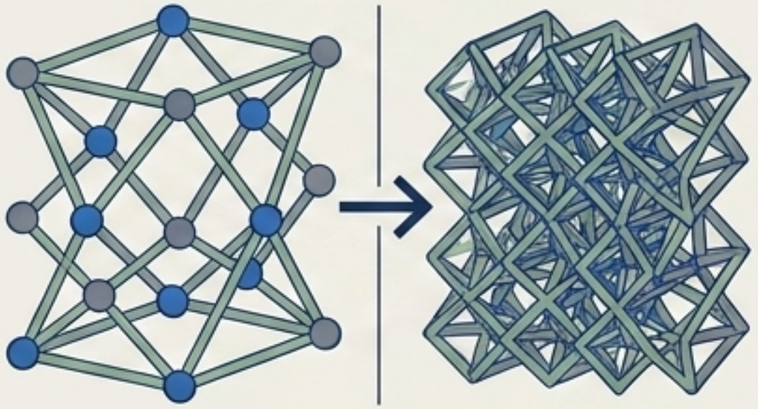
Phase Transformation Sequence Chart

1 → 2 → 3

1 The Trigger

Low-voltage electrical current.

2 The Shift



Relaxed State **Contracted State**

Nitinol shape-memory alloy contraction.

3 The Application

$$P = F/A$$

P:	**F:**	**A:**
Therapeutic Pressure (0-100 mmHg gradient)	**Force** generated by Nitinol contraction	**Contact area** of the inelastic garment

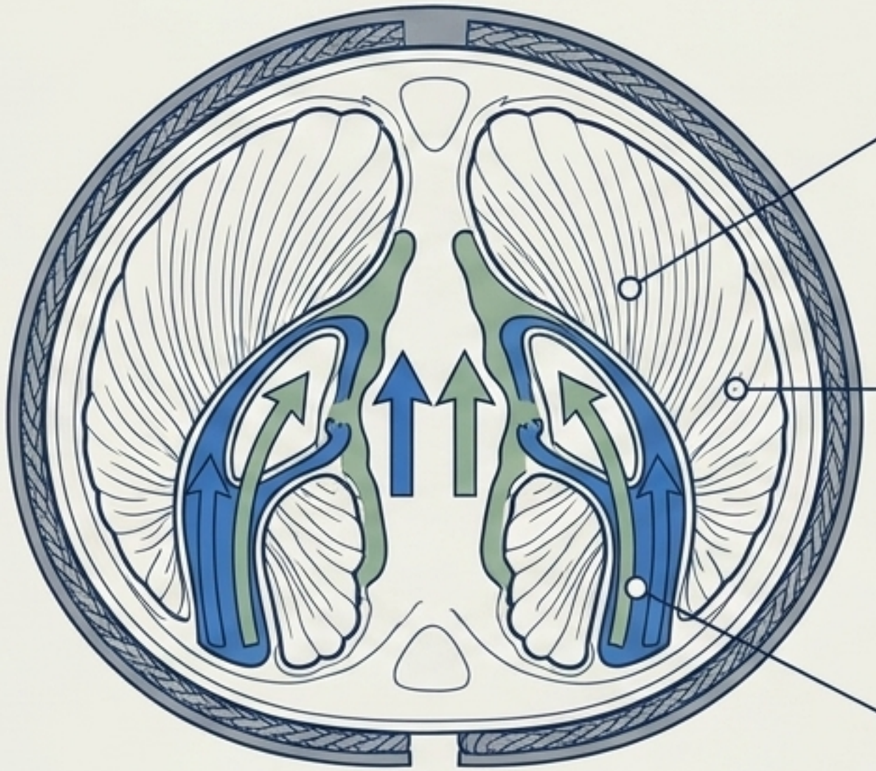
This allows for noiseless, highly responsive, distal-to-proximal fluid drainage without stationary air pumps or fluid backflow.

Mobility unlocks the synergistic microcirculatory relationship

Passive Compression

Supine APCD therapy relies solely on extrinsic, passive fluid movement.

Active NPCD Compression



Calf muscle pump yields a **65% ejection fraction**.

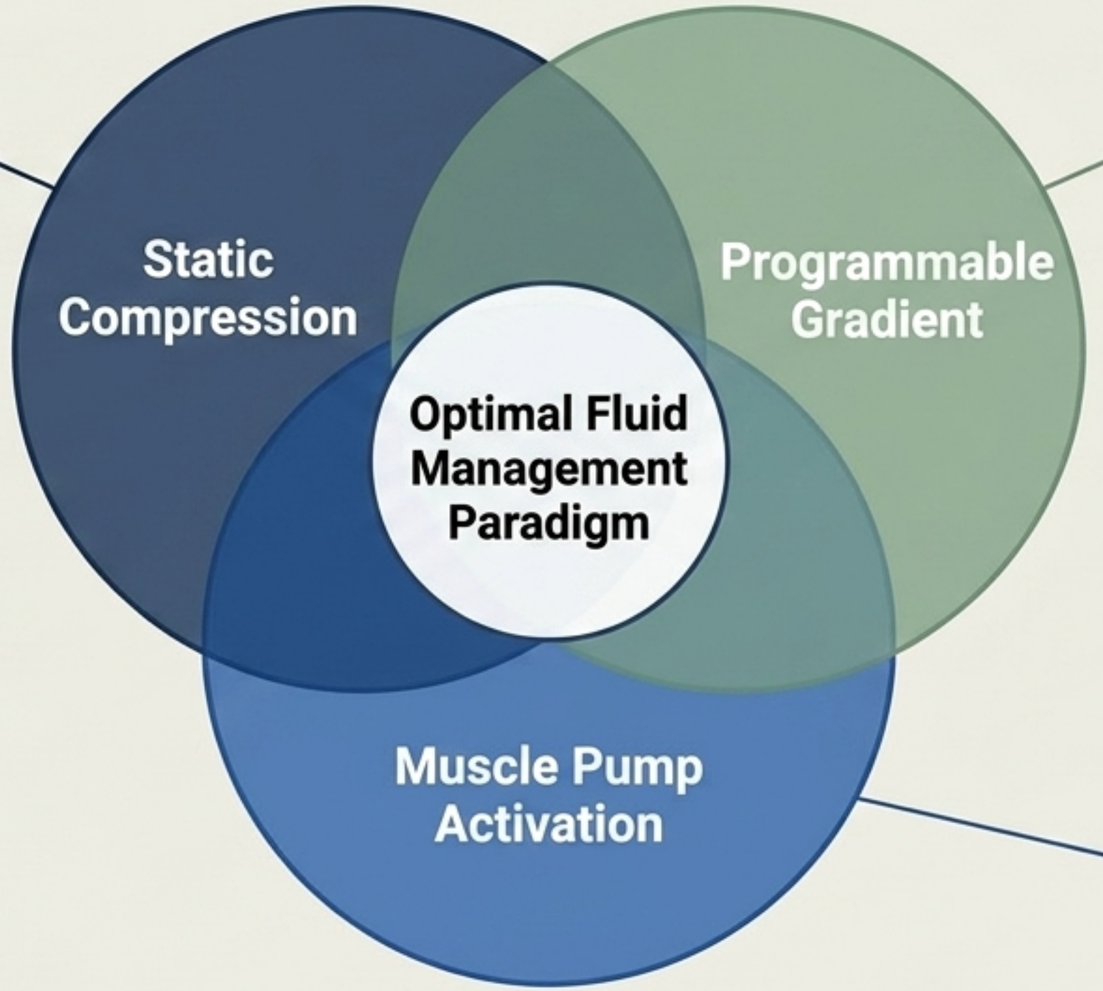
Responsible for the majority of lower extremity **venous return**.

Exercise directly improves ejection fraction, overriding the 5x venous volume increase caused by venous reflux.

Active calf muscle pump enhances internal venous and lymphatic return through contraction.

The Triad of Efficacy: Optimal fluid management

Lightweight, inelastic garment conforming to the limb for continuous edema containment.



Adjustable, sequential distal-to-proximal active pressure (0-100 mmHg).

Untethered design enables ambulation, engaging natural lymphangion contractions and venous ejection.

Microvascular fluid exchange favors steady-state filtration in the venous system; integrating these three modalities aligns with contemporary pathophysiological understanding (Levick & Michel, 20

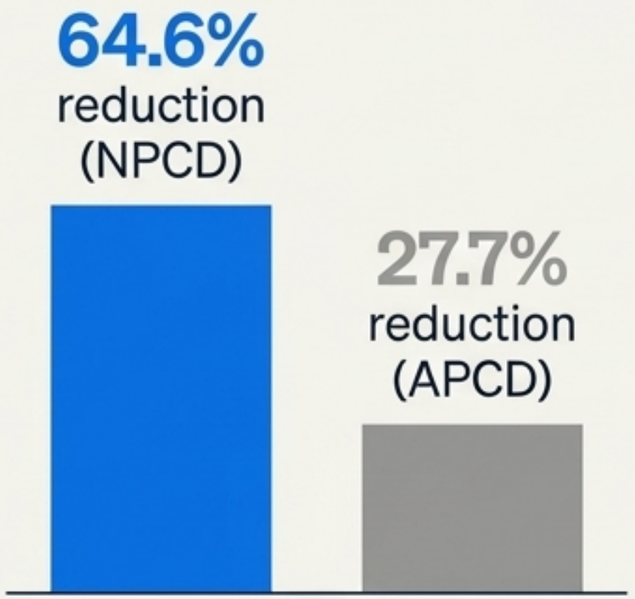
Head-to-head RCT clinical validation

Trial Identity	Trial Design	Intervention	Duration	Endpoints
NILE (Upper Extremity). Published in Journal of Vascular Surgery.	Prospective, Multi-center, Randomized, Head-to-Head Single Crossover.	NPCD vs. APCD	28 days per arm (with 4-week washouts).	Mean reduction in limb edema volume, LYMQOL, adherence, safety.
TEAYS (Lower Extremity). Published in Journal of Vascular Surgery.	Prospective, Multi-center, Randomized, Head-to-Head Single Crossover.	NPCD vs. APCD	90 days per arm (with 4-week washouts).	Mean reduction in limb edema volume, LYMQOL, adherence, safety.

Evaluated across 14 U.S. clinical sites. Patients with active cellulitis or skin ulcerations were excluded.

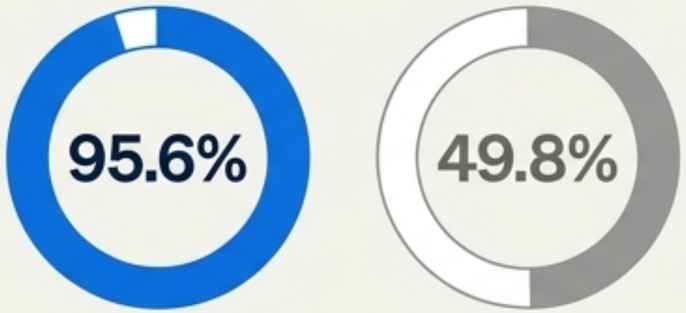
NILE Trial Data: Upper extremity lymphedema

Volume Reduction



($P < 0.05$)

Adherence



95.6% adherence (NPCD)

49.8% adherence (APCD)

($P < 0.01$)

Quality of Life & Satisfaction

LYMQOL improvement score:

2.44 (NPCD) vs **0.00** (APCD). ($P < 0.01$).

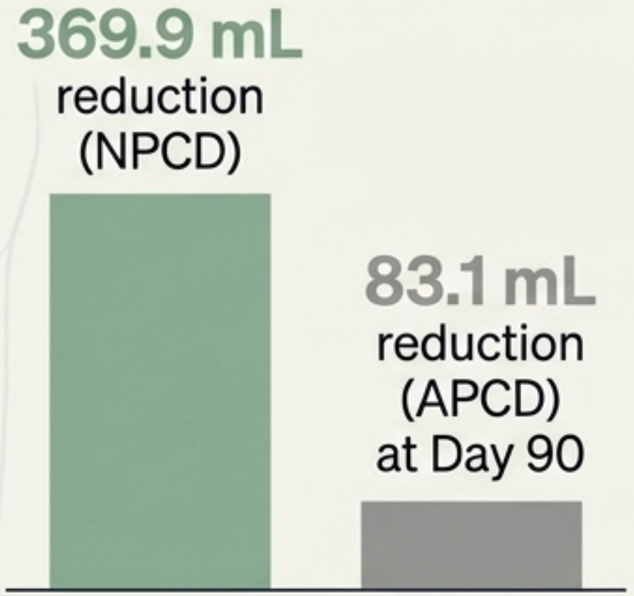
Patient Satisfaction:

90% (NPCD) vs **14%** (APCD).

100% of NPCD patients indicated the device **facilitated exercise,** compared to **0%** of APCD patients. Subanalysis validated efficacy in older adults (>65).

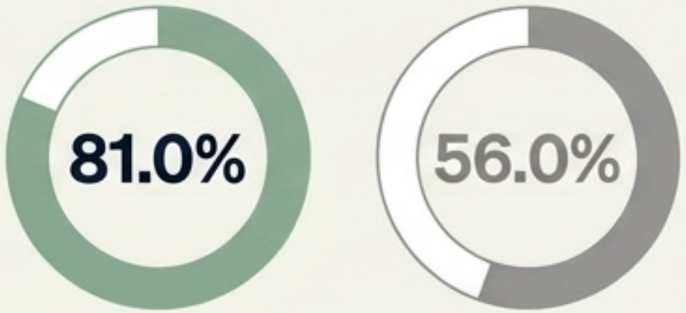
TEAYS Trial Data: Lower extremity lymphedema

Absolute Volume Reduction



($P < 0.05$)

Adherence



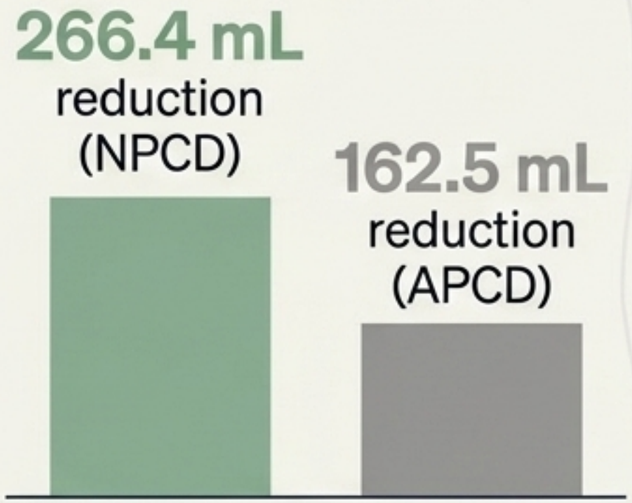
81.0% adherence (NPCD)

56.0% adherence (APCD)

($P < 0.001$)

Device-Naïve Subgroup

Device-Naïve Patients (n=31)



($P < 0.05$)

Mean LYMQOL improvement was significantly greater for NPCD (1.01) vs APCD (0.17) ($P < 0.05$). Outcomes remained meaningfully better for NPCD even when adjusting for treatment sequence bias.

Driving down adverse events and hospital utilization

0% incidence of disease-related cellulitis.

0% incidence of ulcerations.

0 hospital days required.

4% incidence of cellulitis.

1% incidence of ulcerations.

8 average hospital days per patient.

Safety Profile Note: Zero device-related adverse events reported in either the NILE or TEAYS trials for NPCD. Potential minor drawbacks limited to localized skin irritation.

Real-world integration and established access

Clinical Footprint

Over 10,000 patients treated to date, supported by 11 research studies including qualitative imaging and open-label research.

Active HCPCS Codes

E0680: NPCD Controller

E0678, E0679, E0682: Limb-specific accessories

Payer Acceptance

Centers for Medicare and Medicaid Services (CMS) recognize NPCD as therapeutically distinct from pneumatic compression.

Established fee schedule is comparable to advanced APCDs (E0652).

Accessible via regional/national commercial payers, Medicare, Medicaid, and Veterans Affairs. FDA-cleared for lymphedema, phlebolymphedema, venous insufficiency, and lipedema.

Synthesizing the evidence for modern clinical guidelines

Convergence Flowchart

Prescribed Exercise (Evidence Level: 1C)

Compression Garments (Evidence Level: 1A)

Intermittent Pneumatic Compression (Evidence Level: 2B)

NPCD seamlessly integrates all three modalities into a single, patient-centric therapy. It is the only modality that allows for Level 1C active exercise simultaneously with Level 2B active compression.

NPCD represents a safe, clinically superior hybrid approach. It should be considered after conservative treatment failure and formally integrated into future lymphedema management guidelines to reduce adherence barriers and optimize fluid management.