



## Clinical Research

# Superior Clinical, Quality of Life, Functional, and Health Economic Outcomes with Pneumatic Compression Therapy for Lymphedema

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**Background:** Pneumatic compression therapy is one of several options for the management of lymphedema. The lack of clarity around clinical outcomes, quality of life, cost of care, and its proper application, as a function of lymphedema complexity, limit its use in clinical practice. This is compounded by difficulties associated with insurance approval and uncertainty about the role of this modality in the treatment algorithm. The purpose of this study is to elucidate the healthcare economics and value of pneumatic compression therapy for lymphedema.

**Methods:** All patients who underwent treatment for lymphedema at a single institution were followed prospectively over a 2-year period. Patient demographics, comorbidities, treatment modality, and treatment efficacy were determined. Direct costs over the 2-year period, inclusive of hospitalization and device costs, SF-36 quality of life, and leg lymphedema complexity score (LLCS), were measured.

**Results:** A total of 128 patients were enrolled over a period of 3 years for a total of 232 extremities treated for secondary lymphedema. Pneumatic compression therapy was utilized for all patients and led to a 28% decrease in absolute limb volume ( $P < 0.001$ ), decrease in body mass index (BMI) ( $P < 0.001$ ), significant improvement in SF-36 quality of life in 7 out of 8 domains ( $P < 0.001$ ), and a significant improvement in LLCS ( $P < 0.001$ ) at 1 year. A subsequent decrease in hospitalization for lymphedema-associated complications saved over \$3,200 per patient per year.

**Conclusions:** Pneumatic compression therapy leads to improved clinical outcomes, quality of life, and functional status for clinically significant lymphedema. Significant per capita direct cost savings, a beneficial impact on pay for performance measures, and a reduction in lymphedema-related complications suggest that earlier adoption of this treatment modality may offer a superior value proposition to patients, physicians, hospitals, and the healthcare system.

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## INTRODUCTION

Lymphedema is a vexing problem both in terms of clinical diagnosis and treatment. Treatment modalities include manual lymphatic drainage (MLD), medically prescribed compression garments, and pneumatic compression therapy. Although a number of surgical procedures have also been described for the management of recalcitrant lymphedema, these procedures are uncommon due to their significant morbidity.<sup>1</sup>

The effectiveness of MLD alone as a singular treatment modality is controversial. Prospectively completed studies and meta-analyses of randomized controlled trials (RCT) have found that MLD is safe, but not effective for the management of lymphedema.<sup>2-4</sup> In an analysis of 10 RCTs with 566 patients, variable results were found regarding the effectiveness of MLD.<sup>4</sup> MLD also requires treatment by a dedicated physical therapist, which, quite often, is logistically impossible, and also leads to high resource utilization and overall cost of care.

Due to these limitations, there has been an increased emphasis on the use of medically prescribed compression garments. A recent consensus statement in Phlebology recommends their use in both acute and chronic venous disorders; however, their effectiveness in the management of chronic, long-term lymphedema remains debatable.<sup>5</sup> The primary drawbacks to medically prescribed compression garments include their difficulty of wearing (particularly in older patients and those with back and mobility issues), concerns about their appearance and comfort (particularly in warmer climates), and relatively poor durability.<sup>5</sup>

Pneumatic compression devices offer alternative management for lymphedema. As in-home therapy, they offer increased convenience and availability with minimal long-term resource utilization.<sup>6</sup> Their accompanying garments are also easier to wear and remove, thereby facilitating their use in the elderly and patients with significant comorbidities. Further, their effectiveness in the management of lymphedema is well described in terms of their superior clinical outcomes, beneficial impact on the quality of life, and in limited studies, their economic value.<sup>6-15</sup>

Despite the excellent outcomes associated with pneumatic compression devices, there remain significant hurdles associated with timely insurance approval, local coverage determinations (LCDs) that limit the use of more advanced devices that may be more effective, and significant out-of-pocket expenses that limit the use of these devices in lower median income patients.<sup>16</sup> Delays in their use associated with insurance approval, financing, and in the case of one insurer, the use of pneumatic compression devices "as a treatment of last resort" may lead to additional costs and an adverse impact on quality of life.<sup>17</sup>

These insurance constraints are due to several limitations within the scientific literature. First, the direct cost of care associated with lymphedema patients remains poorly understood. Actual costs of lymphedema-related sequelae, such as cellulitis, surgical wound management, sepsis, and pain control, have not previously been analyzed. Second,

the impact on patient quality of life that leads to functional outcomes has also never been evaluated. Documenting these functional outcomes using a recently developed survey and grading instrument known as the Leg Lymphedema Complexity Score (LLCS) is a method to ascertain the functional outcomes.<sup>18</sup>

The purpose of this paper is to present clinical outcomes, quality of life metrics, functional status, and health economic cost of care analysis for patients who undergo pneumatic compression therapy for lymphedema. A secondary aim of this paper is to quantify the impact of more advanced multichamber pneumatic compression devices that permit individualized management of complex lymphedema.

## METHODS

All patients who underwent pneumatic compression therapy of the lower extremities for secondary lymphedema were evaluated between July 2016 and June 2019 at a single center. Deidentified patient data was maintained as part of a prospectively maintained quality improvement registry (Quartz-Clinical, Surgisphere Corporation, Chicago, IL). Independent variables included patient demographics, comorbidities, lymphedema-specific disease characteristics, hospital covariates, complications, secondary interventions, and detailed cost information. Patients under the age of 18, and those with congestive heart failure, deep vein thrombosis, pulmonary embolism, untreated active infection, or active cancer, were excluded from this study. An exception to IRB approval was granted due to the quality improvement nature of this study.

Patient demographics included age, gender, and ethnicity. Comorbidities included hypertension, diabetes, peripheral artery disease, coronary artery disease, chronic obstructive pulmonary disease, the presence of a thrombophilia/pro-thrombotic state, congestive heart failure, body mass index (BMI), and extent of venous disease (CEAP score). Hospital covariates included inpatient diagnosis and procedure codes, discharge disposition, length of stay (LOS), cost of care, and inpatient mortality for all lymphedema-related admissions. Lymphedema-related complications leading to admission included lower extremity cellulitis, systemic infections emanating from a lower extremity, lymphedema wound-related issues, and debilitating lower extremity swelling. Inpatient admissions not directly related to lymphedema, such as myocardial

infarction, pneumonia, stroke, and others, were excluded.

Any secondary interventions related to lymphedema treatment were identified, and the relevant procedure, hospital admission, and cost of care were determined. The purpose of this extensive surveillance was to compose the total direct cost of care related to lymphedema 1 year prior to and at least 1 year after the initiation of pneumatic compression therapy. Dependent variables included LOS, inpatient mortality, 30-day readmission, discharge disposition, and cost of care. Direct costs were defined as those that could be completely attributed to the procedure performed or the specific admission and included the cost of any implants, supplies, medications, labs, labor, and other direct costs. Indirect costs, such as overhead, enterprise costs, malpractice insurance, and any costs not immediately attributable to the hospital stay, were excluded. Costs are adjusted using the consumer price index (CPI) and presented in 2019 USD. Examples of valid episodes of care include admission to the hospital for lymphedema-related complications, such as ulcers, infection, or pain. The cost of treatment, such as wound care procedures, antibiotics, analgesics, and related direct costs, are included. Admissions unrelated to lymphedema, such as heart failure, renal failure, unrelated infections, peripheral artery disease, etc., are excluded. We have recently described our cost accounting methods in more detail.<sup>19</sup>

Quality of life was measured using an SF-36 survey at each visit. Anatomic measurements of the bilateral lower extremities were completed by measuring the circumference at the arch, ankle, calf, low thigh, and high thigh. The length between each of those measurements and the total limb length from heel to the midpoint of the inguinal ligament were also measured. A mathematical model of the limb was created using these measurements to estimate limb volume. Lymphedema severity was measured using the LLCS, and a multiconsortium tool developed to quantify the extent of lymphedema disease.<sup>18</sup>

All variables were measured at the time of initiation of lymphedema pneumatic compression therapy, 3 months, and 1 year. Hospital admissions data was also collected for the 1-year interval prior to the index treatment. Statistical analysis was done using the built-in analytical functions of the registry and validated with SPSS 26 (IBM, Armonk, New York). Statistical significance was set at  $P < 0.05$ . Statistical testing included descriptive statistics, Student's *t*-tests, and Kaplan-Meier estimation.

The pneumatic compression devices used in this study were the E0651-SC-2004-OC, a basic 4-

chamber pneumatic compression device, and the E0652-SC-3008-DL advanced 8-chamber pneumatic compression device (Bio Compression Systems, Inc., Moonachie, New Jersey). The E0651-SC-2004-OC basic compression device creates a sequential gradient across the extremity and has a cycle time of 18 sec per chamber. The next-generation advanced E0652-SC-3008-DL is a user-programmable and calibrated device that delivers individualized pressure to each of the 8 chambers, permitting customized therapy to patients with lymphedema. This device has a cycle time of just 6.5 sec per chamber, permitting more fine-tuned control of pressure gradient modulation and the opportunity to complete nearly twice the amount of compressions in a typical session.

A subgroup analysis was completed comparing the performance of the basic and advanced pneumatic compression devices. A propensity-score matched analysis was done using patient comorbidities and demographics as the predictors and a match tolerance of 0.5. Statistical testing between the 2 groups was then completed, as discussed above. Due to different starting points in leg circumference and volume between the 2 devices, change in these 2 variables is presented as a percentage of change compared to the index.

Patients were treated with pneumatic compression therapy for two 30-minute intervals per day at a pressure of either 40 mm Hg or 50 mm Hg. Patients were encouraged to do their therapy daily and to take their device with them if they traveled. This was facilitated by the relative ease of putting on and taking off the compression garment, modulating the pressure to achieve both clinical efficacy and comfort, and having the device available at all times. Overall compliance was assessed by way of surveys and monthly follow up by a physician assistant.

## RESULTS

A total of 128 patients were enrolled over the 3 years of this prospectively completed study. Two patients were excluded due to insurance reasons, and 9 patients were lost to follow up. There was a total of 232 extremities treated in the remaining 117 patients; only 2 patients had a single extremity treated for lymphedema. Patients were compliant with the duration and quantity of therapy sessions ( $64 \pm 12$  min for 1.94 sessions per day at 1 month), but gradually decreased the quantity of sessions to one per day while keeping the duration of this session at approximately 30 min over a period of time ( $37 \pm 18$  min for 1.3 sessions per day at 12 months).

**Table I.** Demographics for patients in this study

Variable	Value
Age (years)	55.2 ± 12.0
Female	60.7%
White	70.1%
Black	12.8%
Hispanic	6.0%
Asian	11.1%
DM	22.2%
Smoking	19.7%
HL	30.8%
HTN	25.6%
CABG	4.3%
MI	2.6%
IHD	5.1%
CVA/TIA	0.9%
CKD	2.6%
ESRD	0.9%
COPD	8.5%
Neuropathy	11.1%
PAD	10.3%

A significant number of patients with clinically significant comorbidities underwent pneumatic compression therapy for lymphedema.

DM, diabetes mellitus; HL, hyperlipidemia; HTN, hypertension; CABG, coronary artery bypass graft; MI, myocardial infarction; IHD, ischemic heart disease; CVA/TIA, cerebrovascular accident/transient ischemic attack; CKD, chronic kidney disease; ESRD, end-stage renal disease; COPD, chronic obstructive pulmonary disease; PAD, peripheral artery disease.

The average age was 55.2 ± 12.0 years, and 60.7% of the patients were women. Peripheral artery disease (PAD), as diagnosed by an ABI < 0.9, was present in 10.3% of patients. The remaining demographic and comorbidity data can be found in Table I. Venous insufficiency was present in 23 patients (19.7%), primarily in the form of limited great saphenous vein reflux greater than 500 ms. These patients were not candidates for endovenous ablation due to the inability to obtain insurance authorization (11 patients), severe morbid obesity with BMI > 45 (4 patients), and patient preference (8 patients). Ten patients (8.5%) had postthrombotic syndrome secondary to prior severe deep vein thrombosis. All patients had a primary diagnosis of secondary lymphedema.

A statistically significant reduction in limb circumference and volume was seen at 3 months and 1 year for the arch, ankle, calf, low thigh, and high thigh measurements ( $P < 0.001$  for index vs. 3 months and index vs. 1 year for each measurement category). Absolute limb volume decreased by 16.5% at the calf and 17.5% at the thigh at 3 months, and by 27.4% at the calf and 28.7% at the thigh at 1 year compared to index

measurements ( $P < 0.001$  for each interval and group) (Table II).

An SF-36 quality of life survey was completed at the index visit, 3 months, and 1 year for 111 patients (94.9%). Eight domains of health were measured at each visit, including physical functioning, role limitations due to physical health, role limitations due to emotional problems, energy/fatigue, emotional well-being, social functioning, pain, and general health. A composite score was also calculated. Over the 1-year follow-up period, we noted that patients had a statistically significant improvement in each quality of life subgroup ( $P < 0.001$ ) except role limitations due to emotional problems ( $P = 0.096$ ) (Table III and Fig. 1).

An improvement in the LLCS total score and grade was seen at 3 months ( $P = 0.004$  for the total score and  $P = 0.027$ ) and at 1 year ( $P < 0.001$  for both) (Table IV). The primary drivers for this change were the improvements in limb edema, tissue texture, skin integrity, skin changes, and pain. A disproportionate improvement in BMI, mobility, and activities of daily life (ADLs) was seen at 1 year. Overall improvement in the LLCS was seen in the composite Lymphedema Life Impact Scale (LLIS) that is a subpart of the LLCS. As the LLCS was released in late 2017, this survey instrument was completed for 79/117 patients (67.5%).

An additional variable of both clinical and statistical significance was BMI (Table V). The BMI at index was 36.4, with improvement seen at 3 months (BMI = 35.1,  $P = 0.116$  versus index) and at 1 year (BMI = 34.0,  $P = 0.004$ ). The number of patients in the overweight ( $25.0 \leq \text{BMI} \leq 29.9$ ), class 1 obesity ( $30.0 \leq \text{BMI} \leq 34.9$ ), class 2 obesity ( $35.0 \leq \text{BMI} \leq 39.9$ ), and class 3 obesity ( $\text{BMI} \geq 40$ ) changed over time due to progressive weight loss with only 14.5% of patients still in the class 3 range at 1 year (vs. 32.5% at index). This decrease in BMI was reflected in the increased mobility and ADLs seen in the LLCS score and the improvement in physical functioning, role limitations due to physical health, and general health scores in the SF-36.

The total number of inpatient admissions, the geometric mean length of stay (GMLOS), rate of inpatient mortality, and the direct cost of care were calculated for each patient for a 1-year interval prior to the initiation of pneumatic compression therapy and for the year following the initiation of treatment (Table VI). Lymphedema-related admissions, length of stay, and costs decreased significantly ( $P < 0.001$  for all groups) after the initiation of pneumatic compression therapy. Admission prior to treatment was driven primarily by cellulitis (43

**Table II.** Average lower extremity circumference at index, 3 months, and 1 year with *P*-values

Location	Index	3 Month	1 Year	Index versus 3 months ( <i>P</i> value)	Index versus 1 year ( <i>P</i> value)
Arch measurement (cm)	25.0	23.1	22.4	<0.0001	<0.0001
Ankle measurement (cm)	26.7	24.8	24.0	0.0008	<0.0001
Calf measurement (cm)	42.4	38.8	36.2	<0.0001	<0.0001
Low thigh measurement (cm)	47.8	43.6	40.8	<0.0001	<0.0001
High thigh measurement (cm)	53.6	48.7	45.3	<0.0001	<0.0001

**Table III.** SF-36 quality of life survey results averaged by category and time period

Change over time	Index	3 Month	1 Year	Index versus 3 months ( <i>P</i> value)	Index versus 1 year ( <i>P</i> value)
Physical functioning	20.8	26.5	30.5	0.0002	<0.0001
Role limitations due to physical health	36.3	47.4	55.5	0.0005	<0.0001
Role limitations due to emotional problems	81.5	77.8	77.5	0.1215	0.0959
Energy/fatigue	37.5	44.5	50.7	0.0001	<0.0001
Emotional well-being	33.4	43.7	49.9	<0.0001	<0.0001
Social functioning	47.5	55.9	66.6	0.0002	<0.0001
Pain	64.0	75.2	90.1	<0.0001	<0.0001
General health	30.5	36.3	42.3	0.0024	<0.0001
SF-36 Average	43.9	50.9	57.9	0.0001	<0.0001

*P*-values are presented for index versus 3 months and index versus 1 year.

patients), skin ulceration requiring surgical wound care (23 patients), and sepsis (9 patients). All lymphedema-related admissions after the initiation of treatment occurred within the first 3 months and were secondary to cellulitis (6 patients) and surgical wound care (6 patients).

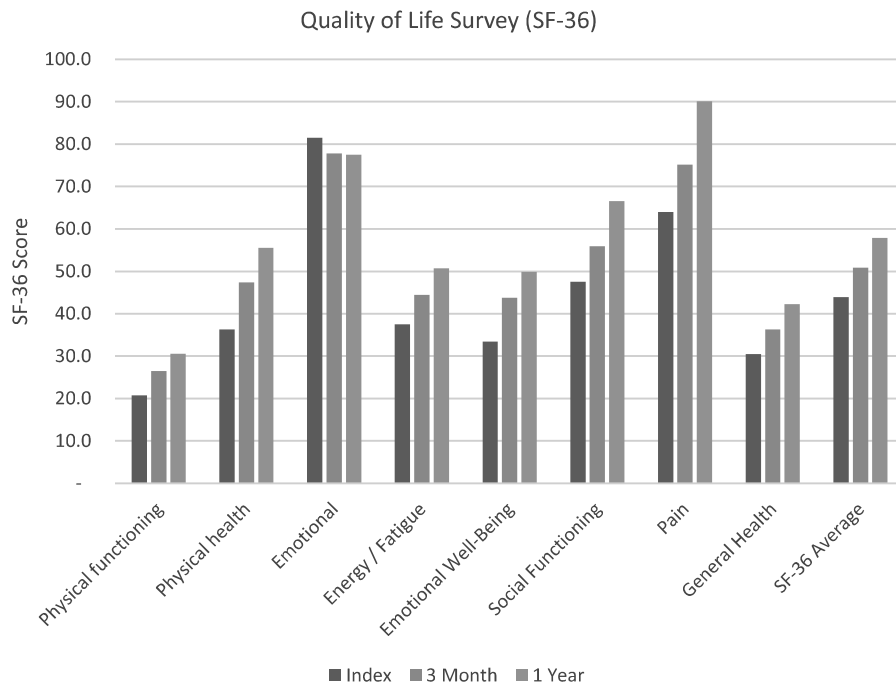
Due to the differences between the 2 devices used in this study, a subgroup analysis was completed to determine whether the technology and advanced features of the E0652-SC-3008-DL led to a measurable clinical difference. A propensity-score matched analysis was completed with patients matched on their demographics and comorbidities. A total of 64 patients were matched in a 1:1 ratio with no post-matching statistical difference in their demographics, comorbidities, BMI, or pathology. Postmatched statistical analysis revealed a significantly greater SF-36 quality of life score within the physical functioning ( $P < 0.01$ ) and pain ( $P < 0.01$ ) categories at 3 months, a more rapid decrease in limb circumference and volume at 3 months ( $P < 0.01$ ) and at 1 year ( $P < 0.001$ ), and fewer inpatient admissions ( $P < 0.05$ ) favoring the advanced device. The percent

change in limb volume for the basic device was a 21.8% reduction in the limb volume at 1 year compared to a 31.2% reduction for the advanced device ( $P < 0.001$ , Fig. 2).

The more rapid improvement seen with the advanced device translated into a 5 fold lower rate of admission for lymphedema-related complications (relative risk reduction from 0.84 to 0.16 admissions per patient), leading to a decrease in the cost of care. While the cost savings with the basic device was \$3,097 per patient, the savings were even greater with the advanced device at \$5,080 per patient ( $P < 0.001$ ). The number of admissions per patient and GMLOS was lower, as well (Table VII).

## DISCUSSION

The improvement in leg circumference and volume, decrease in lymphedema-associated complications, and improvement in patient quality of life is similar to that reported in prior studies.<sup>6,7,10,12-15</sup> Pneumatic compression therapy leads to a 28.1%



**Fig. 1.** SF-36 quality of life survey scores by subgroup and average. *P*-values are given in Table II and are significant for all subgroups except for the emotional category.

**Table IV.** Leg lymphedema complexity score (LLCS) at index visit, 3 months, and 1 year with *P* values

Change over time	Index	3 Month	1 Year	Index versus 3 months ( <i>P</i> value)	Index versus 1 year ( <i>P</i> value)
LLCS total	27.4	25.3	22.2	0.0044	<0.0001
LLCS grade	2.7	2.5	2.4	0.0265	<0.0001

Both the average total score and average grade are given.

**Table V.** Body mass index and morbid obesity stage at index, 3 months, and 1 year

Effect on obesity	Index	3 Month	1 Year
BMI	36.4	35.1	34.0
Normal BMI (N)	- (0%)	3 (2.6%)	5 (4.3%)
Overweight (N)	27 (23.1%)	28 (23.9%)	33 (28.2%)
Class 1 (N)	24 (20.5%)	28 (23.9%)	33 (28.2%)
Class 2 (N)	28 (23.9%)	33 (28.2%)	29 (24.8%)
Class 3 (N)	38 (32.5%)	25 (21.4%)	17 (14.5%)

BMI changes are not significant from index to 3 months ( $P = 0.1162$ ) but become significant at 1 year ( $P = 0.0037$ ).

Overweight:  $25.0 \leq \text{BMI} \leq 29.9$ .

Class 1 obesity:  $30.0 \leq \text{BMI} \leq 34.9$ .

Class 2 obesity:  $35.0 \leq \text{BMI} \leq 39.9$ .

Class 3 obesity:  $\text{BMI} \geq 40$ .

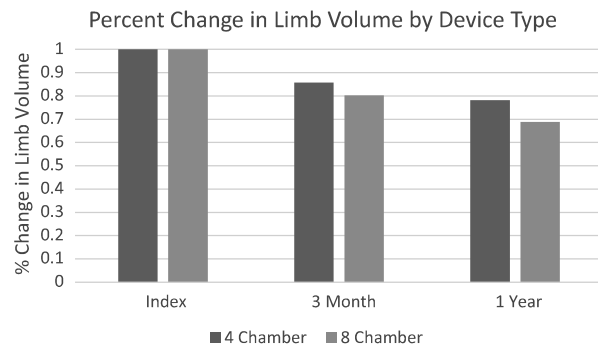
reduction in limb volume at 1 year ( $P < 0.001$ ), and this is strongly correlated with a 31.8% improved quality of life scores at 1 year ( $P < 0.001$ ;  $R^2 = 0.82$ ).

Functional outcomes, as further assessed by the LLCS, indicate significant improvements in mobility and ADLs. While not previously measured by other studies, we have found that pneumatic compression

**Table VI.** Pay for performance and clinical outcomes metrics for lymphedema patients who underwent pneumatic compression therapy

Admission	1 Year preindex	1 Year postindex
# Admissions/patient	0.84	0.16
GMLOS	4.18	2.95
Inpatient mortality	-	-
Direct cost/patient	\$4,239	\$600

The number of admissions per patient, geometric mean length of stay (GMLOS), rate of inpatient mortality, and direct cost per patient are given over the course of a year prior to initiation of therapy (1 year preindex) and for a year after initiation (1 year postindex).



**Fig. 2.** Percent change in limb volume by type of device at the time of initiation of treatment, 3-month follow up ( $P < 0.01$ ), and 1-year follow up ( $P < 0.001$ ).

therapy for lymphedema is associated with a statistically significant decrease in BMI at 1 year ( $P = 0.004$ ). While limited as a strong correlation due to the design of this study ( $R^2 = 0.77$  versus limb volume change), one hypothesis for the significant improvement seen is that pneumatic compression therapy reduces the disability associated with severe lymphedema, thereby leading to increased mobility and activity, which in turn, drives a decrease in weight. The absolute improvement seen in limb volume and function, the dramatic improvement in the LLCS, and the quality of life scores, are most likely due to improved stimulation and function of the lymphatic system and subsequent clearance of lymph volume from the extremity.

There is support for this hypothesis within this data set. The correlation between treatment efficacy and improved function is strong and directly associated with increased weight loss. Decreased limb volumes, as time of therapy increased, were directly related to improved quality of life measures and functional outcomes at 3 months and 1 year. Further, the association between morbid obesity and the onset of lymphedema is well described.<sup>20</sup> If proven through more rigorous studies, the association between pneumatic

compression therapy and improvement of morbid obesity has a number of major secondary public health implications.

Both the quality of life survey and LLCS demonstrated an improvement in physical function and mobility. This was best illustrated in the current cohort by 2 previously wheelchair-bound patients, who ambulated to their 1-year follow-up appointment using only a cane. Both of these patients had significant weight loss, migrating from class 3 morbid obesity to class 1 morbid obesity over the 1-year follow-up period.

Pay for performance and clinical outcomes also significantly improved through the use of pneumatic compression therapy. By capturing lymphedema-related inpatient admissions, GMLOS, mortality, and direct cost of care over a 2-year period, we were able to reduce the impact of outliers and ascertain a more reliable estimate of health economic impact using pneumatic compression in this patient population. There was a significant improvement in all of these variables at the conclusion of the study ( $P < 0.001$ ).

Collectively, the 117 patients in our study led to a \$425,799 reduction in the direct cost of care by avoiding secondary complications associated with lymphedema, or \$3,639 per patient. Patients who were most likely to be readmitted after prescription of therapy were those who had a delay in acquiring the device due to insurance reasons ( $n = 9$ ), difficulty with financing due to limitations in insurance coverage ( $n = 8$ ), and other factors ( $n = 2$ ). All readmissions that occurred were in this group and occurred within the first 3 months after the prescription of therapy.

Currently, there is a 4-week approval period with Medicare that seeks the use of more conservative medical measures prior to the prescription of a pneumatic compression device. This trial requires patients to use a medical compression garment, participate in regular exercise, and elevate the leg. MLD is also recommended in this population. Failure to significantly improve over this 4-week period

**Table VII.** Number of admissions per patient, geometric mean length of stay (GMLOS), inpatient mortality, and direct cost per patient for 1 year prior to initiation of therapy (Pre) and for 1 year after initiation of therapy (Post) for the basic (E0651-SC-2004-OC) and advanced (E0652-SC-3008-DL) pneumatic compression devices

Admission	Basic device		Advanced device	
	Pre	Post	Pre	Post
# Admissions/Pt	0.75	0.18	1.06	0.13
Avg LOS	4.19	3.07	4.18	2.50
Inpatient mortality	-	-	-	-
Direct cost/Pt	\$3,775	\$679	\$5,470	\$390

The advanced device led to an additional \$1,983 in cost savings per patient compared to the basic device ( $P < 0.001$ ).

makes patients eligible for pneumatic compression therapy.

While a dedicated analysis is needed to further ascertain the impact of this 4-week period, this study demonstrates that there is utility in the earlier adoption of pneumatic compression therapy for patients with complex lymphedema. Elimination of this waiting period may advance the provision of safe, timely, efficient, cost-effective, equitable, and patient-centered care to patients with lifestyle-limiting and clinically significant lymphedema. Earlier adoption may help improve pay for performance outcomes and direct costs of care by avoiding lymphedema-related complications due to delays in care.

Further, there is an argument to be made from a health economic perspective to improve coverage of pneumatic compression therapy by private insurers. A cost/benefit analysis indicates that earlier provision of care to patients with clinically significant lymphedema leads to a lower overall cost of care by way of a reduction in the Medicare Spend Per Beneficiary (MSPB) or its equivalent for private insurers, insurance spend per capita.

Guard rails to maximize appropriate and more timely utilization of pneumatic compression therapy may be considered, such as clear documentation of clinically significant lymphedema in conjunction with the LLCs. Patients with significant disability due to their lymphedema may receive a disproportionately positive impact with earlier therapy, along with patients who have had prior inpatient admissions for lymphedema-related complications. Successful application of these criteria could have led to an additional \$70,144 in direct cost reduction in our study.

Finally, there is a significantly greater utility in the advanced pneumatic compression device. By doubling the number of chambers and permitting a more finely graded pressure gradient, this device accelerated the limb volume reduction and led to better clinical outcomes at 1 year compared to the

basic device. Our propensity-score matched analysis revealed superior pay for performance and clinical outcomes as early as 3 months, with enduring benefits seen at 1 year that were superior to the basic device. A financial analysis demonstrated that universal use of the advanced multichamber pneumatic compression device could have led to additional direct cost savings of \$1,983 per patient, or an overall \$232,065 health economic impact.

## CONCLUSION

Pneumatic compression therapy leads to improved clinical outcomes, quality of life, and functional status for patients with clinically significant lymphedema. Significant per capita direct cost savings, a beneficial impact on pay for performance measures, and reduction in lymphedema-related complications suggest that earlier adoption of this therapy for appropriate patients may lead to better health-care outcomes for a lower overall cost. Pneumatic compression therapy achieves safe, timely, cost-effective, efficient, and patient-centered care in the management of lymphedema with no significant complications or adverse outcomes.

## REFERENCES

1. Lee JH, Chang DW. Surgical treatment of primary lymphedema. *Lymphat Res Biol* 2017;15:220–6.
2. Freire de Oliveira MM, Costa Gurgel MS, Pace do Amaral MT, et al. Manual lymphatic drainage and active exercise effects on lymphatic function do not translate into morbidities in women who underwent breast cancer surgery. *Arch Phys Med Rehabil* 2017;98:256–63.
3. Schonvvetter B, Soares JL, Bagatin E. Longitudinal evaluation of manual lymphatic drainage for the treatment of gynoid lipodystrophy. *An Bras Dermatol* 2014;89:712–8.
4. Huang TW, Tseng SH, Lin CC, et al. Effects of manual lymphatic drainage on breast cancer-related lymphedema: a systematic review and meta-analysis of randomized controlled trials. *World J Surg Oncol* 2013;11:15.



5. Rabe E, Partsch H, Hafner J, et al. Indications for medical compression stockings in venous and lymphatic disorders: an evidence-based consensus statement. *Phlebology* 2018;33:163–84.
6. Pappas CJ, O'Donnel TF. Long-term results of compression treatment for lymphedema. *J Vasc Surg* 1992;16:555–64.
7. Blumberg SN, Berland T, Rockman C, et al. Pneumatic compression improves quality of life in patients with lower-extremity lymphedema. *Ann Vasc Surg* 2016;30:40–4.
8. Tran K, Argáez C. Intermittent Pneumatic Compression Devices for the Management of Lymphedema: A Review of Clinical Effectiveness and Guidelines. Ottawa, Ontario: Canadian Agency for Drugs and Technologies in Health, 2017.
9. Uzkeser H, Karatay S, Erdemci B, et al. Efficacy of manual lymphatic drainage and intermittent pneumatic compression pump use in the treatment of lymphedema after mastectomy: a randomized controlled trial. *Breast Cancer* 2015;22:300–7.
10. Franks PJ, Moffatt CJ. Intermittent pneumatic compression devices in the management of lymphedema. *JAMA Dermatol* 2015;151:1181–2.
11. Yüksel A, Gürbüz O, Velioglu Y, et al. Management of lymphoedema. *Vasa* 2016;45:283–91.
12. Karaca-Mandic P, Hirsch AT, Rockson SG, et al. The cutaneous, net clinical, and health economic benefits of advanced Pneumatic compression devices in patients with lymphedema. *JAMA Dermatol* 2015;151:1187–93.
13. Zaleska MT, Olszewski WL. The effectiveness of intermittent pneumatic compression in therapy of lymphedema of lower limbs: methods of evaluation and results. *Lymphat Res Biol* 2019;17:60–9.
14. Lerman M, Gaebler JA, Hoy S, et al. Health and economic benefits of advanced pneumatic compression devices in patients with phlebolympheidema. *J Vasc Surg* 2019;69:571–80.
15. Muluk SC, Hirsch AT, Taffe EC. Pneumatic compression device treatment of lower extremity lymphedema elicits improved limb volume and patient-reported outcomes. *Eur J Vasc Endovasc Surg* 2013;46:480–7.
16. Medicare licensed coverage determination for pneumatic compression devices. Available at, <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33829&ver=38&Date=&DocID=L33829&bc=iAAAABAAA&AAAA&>. Accessed June 23, 2019.
17. Blue cross blue shield corporate medical policy for pneumatic compression pumps. Available at, [https://www.bluecrossnc.com/sites/default/files/document/attachment/services/public/pdfs/medicalpolicy/pneumatic\\_compression\\_pumps\\_for\\_lymphedema\\_and\\_venous\\_ulcers.pdf](https://www.bluecrossnc.com/sites/default/files/document/attachment/services/public/pdfs/medicalpolicy/pneumatic_compression_pumps_for_lymphedema_and_venous_ulcers.pdf). Accessed June 23, 2019.
18. Leg lymphedema complexity score. Available at, <https://www.ilwti.com/pages/lymphedema-severity-score>. Accessed June 23, 2019.
19. Desai SS. Impact of early cannulation grafts on quality and cost of care for patients with end-stage renal disease. *Ann Vasc Surg* 2019;60:203–10.
20. Chopra K, Tadisina KK, Brewer M, et al. Massive localized lymphedema revisited: a quickly rising complication of the obesity epidemic. *Ann Plast Surg* 2015;74:126–32.