Breast Cancer Res Treat (2012) 131:147–158
DOI 10.1007/s10549-011-1795-5

CLINICAL TRIAL

A randomized clinical trial comparing advanced pneumatic truncal, chest, and arm treatment to arm treatment only in self-care of arm lymphedema

Sheila H. Ridner · Barbara Murphy · Jie Deng · Nancy Kidd · Emily Galford · Candace Bonner · Stewart M. Bond · Mary S. Dietrich

Received: 26 July 2011 / Accepted: 16 September 2011 / Published online: 30 September 2011

Abstract Treatment of the truncal lymphatics prior to treatment of the lymphedematous arm is an accepted, although not empirically tested, therapeutic intervention delivered during decongestive lymphatic therapy (DLT). Breast cancer survivors with arm lymphedema are encouraged to use these techniques when performing simple lymphatic drainage as part of their life-long lymphedema self-care. Self-massage is at times difficult and pneumatic compression devices are used by many patients to assist with self-care. One such device, the Flexitouch® System, replicates the techniques used during DLT; however, the need for application of pneumatic compression in unaffected truncal areas to improve self-care outcomes in arm only lymphedema is not established. The objective of this study was to compare the therapeutic benefit of truncal/chest/arm advanced pneumatic compression therapy (experimental group) verses arm only pneumatic compression (control group) in self-care for arm lymphedema without truncal involvement using the Flexitouch® System. Outcomes of interest were self-reported symptoms, function, arm impedance ratios, circumference, volume, and trunk circumference. Forty-two breast cancer survivors, (21 per group), with Stage II lymphedema completed 30 days of home self-care using the Flexitouch® System. Findings revealed a statistically significant reduction in both the number of symptoms and overall symptom burden within each group; however, there were no statistically significant differences in these outcomes between the groups. There was no statistically significant overall change or differential pattern of change between the groups in function. A statistically significant reduction in bioelectrical impedance and arm circumference within both of the groups was achieved; however, there was no statistically significant difference in reduction between groups. These findings indicate that both configurations are effective, but that there may be no added benefit to advanced pneumatic treatment of the truncal lymphatics prior to arm massage when the trunk is not also affected. Further research is indicated in a larger sample.

Keywords Lymphedema · Flexitouch® System · Pneumatic compression devices · Manual lymphatic drainage · Breast cancer

S. H. Ridner (✉) · J. Deng · N. Kidd · E. Galford · C. Bonner · S. M. Bond · M. S. Dietrich
Vanderbilt University School of Nursing, 461 21st Avenue South, Godchaux Hall, Nashville, TN 37240, USA
e-mail: sheila.ridner@vanderbilt.edu

B. Murphy
Division of Medical Oncology, Vanderbilt University School of Medicine, 777, Preston Research Building, Nashville, TN 37232-6307, USA

B. Murphy · M. S. Dietrich
Vanderbilt-Ingram Cancer Center, 2220 Pierce Avenue, Nashville, TN 37232, USA

Introduction

Lymphedema can either be primary (idiopathic) or secondary (acquired) in nature. The leading cause of secondary lymphedema in the United States is cancer treatment [1]. Breast cancer is the most frequently diagnosed cancer in women other than skin cancer [2], and despite advances in cancer treatments designed to decrease the incidence of secondary lymphedema, new lymphedema cases continue to occur in this population. Lymphedema does not necessarily occur immediately after treatment; therefore, the risk of developing lymphedema can last a lifetime. Arm

lymphedema creates both physical and psychosocial sequelae [3–12] and reduced Quality of life (QOL) [12–14]. These problems can be unrelated to the measured volume of the affected limb [5, 15].

To achieve any reasonable control over their limb volume and mitigate complications, breast cancer survivors with lymphedema must perform life-long self-care. The current standard of treatment for all types and stages (initial onset and chronic) of lymphedema is decongestive lymphatic therapy (DLT), which includes manual lymphatic drainage (MLD), bandaging, and wearing compression garments, in conjunction with isometric exercises and meticulous skin care [16]. During MLD performed for acute treatment of lymphedema, a therapist first opens lymph channels in the trunk and chest distal to the swelling, and then massages the swollen area using light hand techniques to move fluid from the affected extravascular spaces to non-affected lymph channels. Although, never empirically tested, the truncal/chest massage is used internationally by lymphedema therapists and is believed to enhance the effectiveness of treatment by opening lymph channels to receive the lymph from the affected limbs [17–20].

As patients are transitioned to self-care, they are instructed to perform a simpler, self-administered version of MLD to manage the condition. Various compression pumps have been developed during the last 25 years in attempts to offer alternative treatment modalities to self-MLD in management of both acute onset and chronic arm lymphedema. Newer devices, when used with appropriate training and education, are believed to be safer than their older counterparts because they use lower pressures to move the lymph fluid [21–23]. In some cases, older pumps moved fluid from affected limbs to genital areas causing swelling and damage to fragile lymphatics [21, 23, 24]. Truncal areas were not cleared by these pumps. One newer device, cleared by the FDA for home use, is the Flexitouch® System. This system uses lower pressures than the older pumps and applies light, dynamic, variable pressure using multi-chambered, inflatable, and stretchable fabric garments. The device's unique mechanism of action replicates the techniques used during MLD: opening lymph channels in the trunk and chest distal to the swelling prior to massaging the affected limb. The device includes three distinct treatment garments: (1) trunk; (2) chest/upper arm; and (3) lower arm. Software programming allows for variation of compression patterns to individualize treatment, as needed.

Our previous pilot study, ($N = 12$), supported treatment of the trunk in breast cancer survivors with known arm and truncal swelling [25]. Using all three treatment garments, statistically significant improvement in truncal symptoms was found after ten treatments, with, though not statistically significant, accompanying reduction in truncal girth. The therapeutic benefit of applying truncal/chest pneumatic compression therapy to open the lymph channels in individuals who do not demonstrate evident truncal edema, however, has not been investigated [20]. Therefore, the need for application of pneumatic compression in unaffected truncal areas to improve self-care outcomes in arm only lymphedema is not established.

The objective of this study was to examine the therapeutic benefit of advanced pneumatic compression treatment to the truncal/chest/arm (experimental condition) versus pneumatic compression treatment to the arm only (control condition) in self-care of arm lymphedema. The outcomes of interest were: (1) physical and psychological symptoms; (2) function, and; (3) arm and truncal volume/girth.

We hypothesized that: (1) the number, severity, and intensity of physical and psychological symptoms would be significantly reduced after 1 month of home use with the Flexitouch® System truncal/chest/arm pneumatic compression treatment when compared to using the Flexitouch® System arm only pneumatic compression treatment; (2) functional assessment scores would be significantly higher after 1 month of home use with the Flexitouch® System truncal/chest/arm compression when compared to using the Flexitouch® System arm compression only; (3) arm volume would be significantly reduced after 1 month of home use in participants using the Flexitouch® System truncal/chest/arm compression when compared to using the Flexitouch® System arm compression only, and; (4) truncal girth would be less after 1 month of home use with the Flexitouch® System truncal/chest/arm treatment when compared to the Flexitouch® System arm only treatment.

Materials and methods

This randomized clinical trial was approved by the Vanderbilt University Institutional Review Board and the Vanderbilt-Ingram Cancer Center Scientific Review Committee. Participants were consented and randomized, 1:1, into one of two groups (truncal/chest/arm compression [experimental] or arm compression only [control]) via computer-generated randomization using a permuted block scheme. Participants in the study were at least 6 months post-surgery and/or post-radiation treatment for breast cancer and 21 years of age or older. They were required to have documented arm lymphedema as evidenced by: (1) a 2 cm difference in girth at any anatomical location on the affected arm compared to the unaffected arm determined by the average of two circumferential measurements, or a Lymphedema index ratio (LIR), representing the impedance difference between affected and unaffected arms of 1.163 when the dominant arm was the affected arm, or 1.109 when the non-dominant arm was the affected arm. These values were based on data previously collected by

the team that were indicative of symptomatic lymphedema. Additional criteria included being willing and able to drive to the study site as needed, not currently using a compression pump, and not undergoing DLT by a therapist. None had diagnosed or clinically evident truncal swelling.

Participants were recruited through a registry of breast cancer survivors known to have lymphedema and from the community at-large. Individuals were screened using a three-phase screening process—Phase 1: screening by study staff via the telephone; Phase 2: after reviewing initial screening data for those with no obvious exclusionary criteria, further medical information was obtained and reviewed by the PI and the study physician; Phase 3: an on-site physical screening for Stage II arm lymphedema (i.e., limb elevation alone rarely reduces tissue swelling and pitting may or may not present) [26].

Forty-seven participants enrolled. Three participants were withdrawn from the experimental group by the PI (one had recurrent cellulitis after not wearing a compression sleeve, one reported a "tired arm" with no specific complaints of pain or discomfort, and one due to family pressure to not be in a research study). Two participants were withdrawn from the control group. One was withdrawn by the PI for non-compliance with treatment and one "changed" her mind about being in the study. No adverse events directly related to the use of the device were reported or observed.

Data collection instruments

Demographic and medical data

Demographic information, age, and gender were gathered, along with self-reported breast cancer and lymphedema disease and treatment information via nurse interview.

Symptoms

The Lymphedema symptom intensity and distress survey-Arm (LSIDS-A) (Table 1) was used to evaluate physical, psychological, or situational symptoms. The LSIDS-A is a 36 item symptom survey previously tested in this population with a known Cronbach's alpha of .95 [27]. The instrument first requires participants to indicate the presence of a symptom ("yes" or "no"). If a symptom was experienced in the past week, participants then rate its intensity (degree of severity) and associated distress (degree of bother) on two separate ten point numeric scales, with one representing "slight" and ten representing "severe" intensity or distress. The resulting symptom burden score is derived by multiplying the intensity and distress values for each symptom to arrive at a weighted value, that may range from '0' (no symptoms reported) to '100' (maximum intensity and distress). These individual weighted values are subsequently averaged to arrive at an overall index of symptom burden. The internal consistency of these scores (using Cronbach's Alpha) ranged from 0.93 to 0.94 for the three times of assessment in this study. This indicates that the items of the LSIDS-A correlate well with each other and tend to measure a single phenomenon (i.e., symptoms related to arm lymphedema).

Function

The 15-item Functional assessment screening questionnaire (FASQ; Activity Level/Function) was used to assess function [28, 29]. This instrument contains a five point response format with anchors of (0) "someone else does this" to (4) "no difficulty performing task." The internal consistencies of the FASQ scores (using Cronbach's Alpha) in this study ranged from 0.82 to 0.87 for the three times of assessment.

Physical measurements

Four study staff who had conducted physical measurements of both arms and trunks in a previous study completed 99% of the measurements. One measurement was conducted by someone with no previous experience. However, this person was also trained by the first author (PI) to insure consistency of measurements across all the raters. The first author and an administrative assistant served as measurement controls for initial staff retraining or initial training prior to participant enrollment and for monthly re-evaluations throughout the duration of the study. During these sessions, study staff measured both controls and were critiqued regarding placement of tape and tension applied to the limb. Controls were measured twice by each staff member, findings averaged, and then measurements among staff were compared for agreement by the first author. Agreement within 0.20 cm among study staff on the controls when conducting these measurements was required and retraining took place if such agreement was not initially apparent. One staff member completed 40% of the measurements made during the study; 62% of the patients were measured by two different staff; and 10% by one staff member.

Arm

To obtain the circumferential measurements, a non-stretch, retractable, Gulick II Tape that applies four ounces of tension when used. Arms were measured at the metacarpal shaft of the hand and then, starting at the ulnar styloid, in 10 cm intervals to the shoulder [30–32]. Each

Table 1 LSIDS-A instructions and sample items for each symptom below circle yes or no to indicate whether you have had this symptom during the past week

Symptom	Yes/No		Intensity (Slight→Severe)										Distress (Slight→Severe)									
Heaviness in your arm	Yes	No	1	2	3	4	5	6	7	8	9	10	1	2	3	4	5	6	7	8	9	10
Difficulty in raising arm above head	Yes	No	1	2	3	4	5	6	7	8	9	10	1	2	3	4	5	6	7	8	9	10
Flaky skin on your arm	Yes	No	1	2	3	4	5	6	7	8	9	10	1	2	3	4	5	6	7	8	9	10

If you circle yes, please rate how intense this symptom was using the 1–10 point scale. Also rate how distressed you were by this symptom using the 1–10 point scale

measurement was made twice and the average was used in the analysis. Arm volume was subsequently calculated using only the measurements between the first (10 cm) and last (40 cm) consistent placements, thus avoiding the variable measurements due to individual differences between the ulnar styloid and the first 10 cm, as well as between the last 10 cm measurement (40 cm above the initial measurement) and the shoulder. The volume of each cylinder formed between each 10 cm assessment point on the arm was calculated using the formula:

$$\pi \times (C/2\pi)^2 \times \text{height}$$

where '*C*' was equal to the circumference at each point of measurement and height was 10 cm. Each of the three cylinder volumes for each arm (between 10–20 cm, 20–30 cm, and 30–40 cm) were summed to arrive at the total arm volume.

A bioelectric impedance device, with a single-frequency of <30 kHz, manufactured by ImpediMed (Mansfield, Australia), was used to measure extracellular fluid volume. This device was chosen because the measurement of extracellular fluid, a primary variable of interest, does not require use of more expensive, multi-frequency devices. Participants were measured in a supine position with their

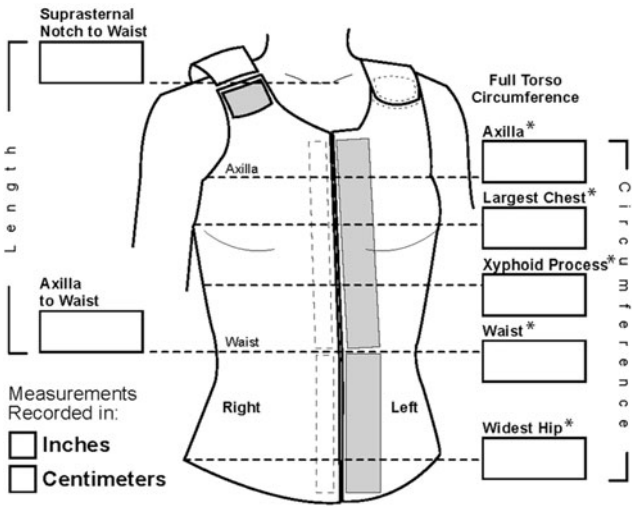

Fig. 1 Reprinted with permission from JoViPak Corporation

legs not touching and their arms to the side not touching the trunk.

Trunk Though not a primary study outcome, the trunk was measured in five locations as indicated on Fig. 1 to determine if lack of truncal treatment had a negative effect on the torso. Each measurement was made twice and the average was used in the analyses. Measurements were completed while participants stood with arms extended to sides.

Body mass index (*BMI*) The Harpenden pocket stadiometer was used to measure height (Seritex, Inc.) and the portable UC-321S body weight scale was used to measure weight. BMI was subsequently calculated using the formula [33]:

$$(\text{weight}_{\text{lbs}} \times 703)/(\text{height}^2_{\text{in}})$$

Intervention

Study staff first interviewed the participants concerning demographics and medical history. All participants were then seen in a laboratory setting for baseline assessments; study staff administered training on use of the device, and an initial supervised self-treatment took place. During pre-treatment baseline assessments height, weight, and circumferential measurements of the arms and trunk were taken. The bioelectric impedance device was then used to obtain the LIR. The arms and trunk were examined by study staff; findings were documented using a standardized skin checklist. The participants then completed the self-report surveys and were randomly assigned to either the experimental or the control group.

To insure proper technique was followed and to observe for any participant problems, the first treatment was conducted under staff supervision in the laboratory. Before the treatment, participants viewed a training video demonstrating the Flexitouch® System garments and controller operation. Immediately following the training video, participants were asked to void, to remove any constrictive clothing and jewelry, and to change into scrub suits. An arm stockinette was placed over the affected limb. Participants were then fitted for the compression garments. They

were shown how to correctly don the garments and instructed on the use (settings) of the Flexitouch® System controller. They were then required to remove the Flexitouch® System garments and reapply them unassisted. Re-education took place if needed.

The manufacturer's recommended standard pressures were used for both the experimental and control groups. A published technical report indicates the mean overall pressure applied is approximately 9.0 ± 4.2–13.7 ± 4.9 mmHg [20]. The gentle, wavelike pressure peaks for a split second with an immediate release. It is this dynamic, mild pressure and release rhythm that is thought to stimulate lymphatic activity.

The experimental group's program was set for the upper extremity, chest, and truncal treatment (U1) (Fig. 2) and they received a total dose of 30 one hour per day treatments during the study. The control group's program was set for arm only (U4) (Fig. 3), with no treatment being administered in the chest or truncal areas. They received a total dose of 30, 36 min per day treatments while on study. During the laboratory observed treatment, participants rested supine on a massage table with their head and affected arm supported on pillows. Study staff remained present during the treatment to observe the participant for tolerance and comfort. No participants voiced discomfort or asked to stop the treatment.

After completion of the first treatment in the laboratory, the arm, and trunk were examined and measurements were repeated as a safety check to insure no one experienced undue skin irritation or swelling. No participants experienced any identified problems, thus all undergoing the initial treatment were given dates for subsequent visits and instructions for completion of a home diary, in which they documented their home-based treatment times and comments.

Treatments two through 30 were completed unobserved in the participants' homes. For treatment two, there was a start/stop call, in which the study staff called participants prior to the treatment and immediately after, according to the length of their treatment time. This allowed for the participants to ask any questions and inform staff of difficulties or complications they might have experienced while donning the garment or during treatment. Primarily, the participants' remarks pertained to adjustment of the garments or comments that the treatment went well with no problems.

The mid-point and end-of-study measurements, which were identical to the baseline assessments, were conducted at either the participants' homes or at the study lab depending on the participants' preferences.

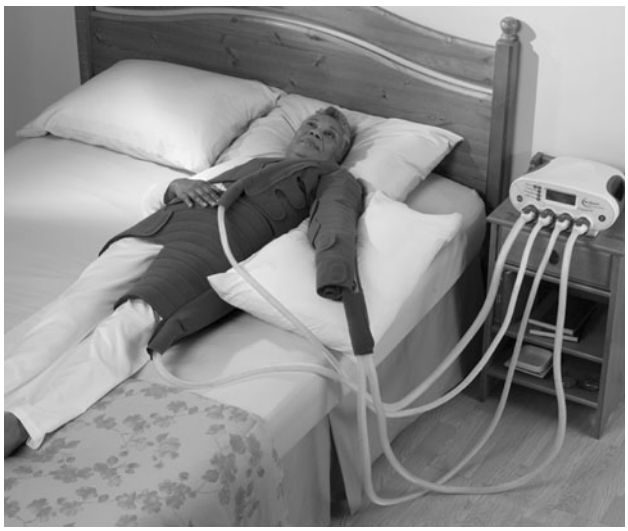

Fig. 2 Truncal/chest/arm configurations

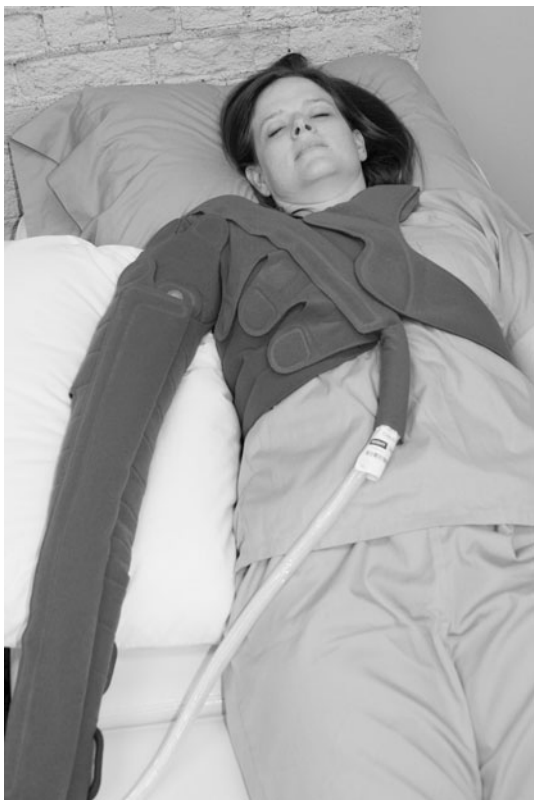

Fig. 3 Arm only configuration

Statistical procedures

All statistical summaries and analyses were conducted using SPSS version 18. Frequency distributions resulting in counts and percentages were used to summarize the nominal and ordinal participant characteristics. Chi-square tests of independence were used to test for differences in those characteristics between the two study groups. Because most of the continuous patient characteristics and study measures had slightly to severely skewed distributions, for

consistency, all such data (with the exception of age and function which were normally distributed) were summarized using medians and the 25th–75th interquartile range (which represents the middle 50% of cases regardless of the shape of that distribution). Between group comparisons of demographic and clinical characteristics were conducted using Mann–Whitney tests. To control for some clinically (although not statistically) significant differences in the baseline values of many of the study measures, the baseline value of each outcome measure was included as a covariate in analysis of covariance used to test for differences between the groups at the end of the study. All data were rank transformed to meet the parametric assumptions of analysis of covariance. To aid in further illuminating the effects of the arm versus the truncal/chest/arm device, standardized effect sizes for the changes from baseline to end-of-study were calculated and reported. These effect sizes are based on the standard Cohen effect size measure and allow for the direct comparison of effects standardized for the scale and variability of the values. For example, a

Table 2 Demographic characteristics ($N = 42$)

Characteristic	Study group	
	Arm only ($N = 21$)	Truncal/chest/arm ($N = 21$)
Marital status ($P = .719$)		
Married	13 (61.9%)	12 (57.1%)
Single/Widowed	6 (28.6%)	8 (38.1%)
Other	2 (9.5%)	1 (4.8%)
Work status ($P = .855$)		
Employed Full time	12 (57.1%)	10 (47.6%)
Employed Part time	1 (4.8%)	2 (9.5%)
Homemaker	2 (9.5%)	2 (9.5%)
Retired	5 (23.8%)	4 (19.0%)
Unemployed	1 (4.8%)	2 (9.5%)
Other	0 (0.0%)	1 (4.8%)
Insurance status ($P = .516$)		
Private insurance	13 (61.9%)	14 (66.7%)
Other	8 (38.1%)	6 (28.6%)
None	0 (0.0%)	1 (4.8%)
Residence ($P = 1.000$)		
Urban/Metropolitan	16 (76.2%)	16 (76.2%)
Rural/Other	5 (23.8%)	5 (23.8%)
Income ($p = .526$)		
<$10,000	0 (0.0%)	2 (9.5%)
$10,000–$30,000	4 (19.0%)	3 (14.3%)
$30,001–$60,000	4 (19.0%)	4 (19.0%)
>$60,000	10 (47.6%)	11 (52.4%)
Do not care to respond	3 (14.3%)	1 (4.8%)
Race ($P = .326$)		
Caucasian	20 (95.2%)	17 (81.0%)
African American	1 (4.8%)	3 (14.3%)
Other	0 (0.0%)	1 (4.8%)
Education ($P = 1.000$)		
≤12th grade	4 (19.0%)	4 (19.0%)
College/graduate	17 (81.0%)	17 (81.0%)
	Mean ± SD (Min, Max)	Mean ± SD (Min, Max)
Age (years) ($P = .019$)	56.9 ± 8.1 (38, 71)	50.8 ± 8.1 (37, 65)
	Median [25th, 75th IQR] (Min, Max)	Median [25th, 75th IQR] (Min, Max)
BMI ($P = .571$)	30.1 [26.1, 32.6] (21, 51)	30.8 [26.1, 35.5] (21, 48)

change of ten points from a baseline value of 50 with an observed standard deviation of 20 points results in an effect size for the change of 0.5 (a half standard deviation). The same amount of change within a sample with an observed standard deviation of ten (less variable responses) results in a standardized effect size of 1.00 (a full standard deviation). The effect sizes reported therefore standardize the changes within groups and are independent of baseline values that may differ between groups. All tests of statistical significance maintained a maximum alpha value of .05 ($P < .05$).

Results

Characteristics of sample

The sample ($N = 42$) consisted primarily of Caucasian females and had an average age of 53.8 years (SD = 8.6). All participants had Stage II lymphedema and had received a surgical intervention for breast cancer. Thirty-three met both LIR and 2 cm inclusion criteria (15 in the experimental group, 18 in the control group), while nine met only 2 cm criteria (seven in the experimental group, two in the control group). The demographic and medical characteristics of the participants randomly assigned to either the arm only or truncal/chest/arm study conditions are summarized in Tables 2 and 3. BMI did not differ between groups and other than age and duration of lymphedema, the participants were very similar. As shown, the women in the truncal/chest/arm group tended to be younger (51 vs. 57 mean years, $P = .019$) and correspondingly had been diagnosed with lymphedema at an earlier age (46 vs. 52 median years, $P = .044$). These women also had experienced a shorter period of time between their surgery for breast cancer and the onset or diagnosis of lymphedema (7 vs. 15 median months, $P = .038$). There was a 99% protocol adherence rate for both groups.

Table 3 Medical characteristics ($N = 42$)

Characteristic	Study group	
	Arm only ($N = 21$)	Truncal/chest/arm ($N = 21$)
Location of breast cancer ($P = .879$)		
Left	10 (47.6%)	10 (47.6%)
Right	9 (42.9%)	8 (38.1%)
Bilateral	2 (9.5%)	3 (14.3%)
Stage of breast cancer ($P = .743$)		
0/I	5 (23.8%)	4 (19.0%)
II	9 (42.9%)	10 (47.6%)
III	7 (33.3%)	6 (28.6%)
IV	0 (0.0%)	1 (4.8%)
Type of cancer treatment ($P = .637$)		
Surgery	1 (4.8%)	0 (0.0%)
Surgery & radiation	3 (14.3%)	3 (14.3%)
Surgery & chemotherapy	2 (9.5%)	4 (19.0%)
Surgery, radiation & chemotherapy	15 (71.4%)	14 (66.7%)
Type of surgery ($P = .390$)		
Lumpectomy	10 (47.6%)	10 (47.6%)
Mastectomy	9 (42.9%)	6 (28.6%)
Other	2 (9.5%)	5 (23.8%)
	Median [25th, 75th IQR] (Min, Max)	Median [25th, 75th IQR] (Min, Max)
Time since breast cancer diagnosis (years) ($P = .389$)	5.0 [1.5, 11.5] (1, 15)	4.0 [2.0, 6.0] (1, 15)
Time from surgery to lymphedema onset (months) ($P = .038$)	15.0 [8.5, 29.0] (1, 109)	7.0 [3.5, 15.5] (1, 72)
Lymphedema duration (months) ($P = .715$)	44.0 [13.0, 109.5] (1, 171)	42.0 [16.5, 69.0] (0, 148)
Age at lymphedema onset (years) ($P = .044$)	52.0 [45.5, 58.0] (37, 70)	46.0 [41.5, 51.5] (33, 59)

Symptoms

The number of symptoms reported at each time of assessment, as well as the self-reported burden from those symptoms, are summarized in Table 4. At the end of the study, there was a statistically significant reduction in both the number of symptoms and overall burden from those symptoms within each of the study groups ($P < .01$). However, after controlling for baseline values, there were no statistically significant differences in the number of symptoms between the groups ($P = .145$). There was a stronger differential effect on the self-reported burden scores with the arm only group demonstrating a greater (although not statistically significant, $P = .051$) relative reduction in burden from baseline (effect size $= -0.89$) than that seen in the truncal/chest/arm group (effect size $= -0.44$). These findings for symptom number and burden did not change meaningfully after controlling for the observed associations of BMI, age, time since breast cancer diagnosis, and duration of lymphedema.

Effect sizes also were generated within each of the groups for the individual symptoms reported by at least 50% of the participants at baseline (see Table 4). Substantial reductions in burden were seen in one or both of the groups for arm swelling, heaviness, tightness, and aching.

Function

All participants were high functioning upon enrollment into the study ($M = 21.1$, SD $= 5.8$) and this level of functioning was maintained throughout study participation (M $= 20.6$, SD $= 6.2$). Thus, there was no statistically significant overall change ($P = .897$), or differential pattern of change between the groups in function ($P = .408$).

Physical measurements

Arm volume was assessed using bioelectrical impedance and circumferential measurement. Descriptive statistics and respective between group differences and within group effect sizes for these measures are summarized in Table 5. Similar to results seen for the symptom reports, there were statistically significant reductions in bioelectrical impedance within both of the groups from their respective baseline values (arm: effect size $= -0.31$, $P = .004$;

Table 4 Summaries of changes in symptoms and symptom burden from baseline to end of study ($N = 42$)

	Study group	
	Arm only ($N = 21$) Median [25th, 75th IQR] (Min, Max)	Truncal/chest/arm ($N = 21$) Median [25th, 75th IQR] (Min, Max)
Number of symptoms ($P = .145$)*		
Baseline	12.0 [7.5, 16.0] (1, 20)	15.0 [9.5, 20.0] (3, 27)
End of study	6.0 [4.0, 11.5] (0, 21)	10.0 [6.0, 17.5] (3, 28)
Effect size	−0.72**	−0.43**
Overall symptom burden ($P = .051$)*		
Baseline	2.6 [1.4, 7.2] (0.2, 20.7)	9.7 [1.4, 22.8] (0.2, 47.4)
End of study	1.1 [0.5, 2.0] (0, 19.5)	4.0 [0.8, 9.2] (0.1, 26.3)
Effect size	−0.89**	−0.44**
Specific symptoms***		
Heavy arm	−0.28	−0.84
Tight arm	−0.44	−0.76
Pain arm	−0.40	−0.27
Ache arm	−0.66	−0.67
Swelling arm	−1.14	−0.59
Hard arm	−0.33	−0.53
Appearance concerns	−0.25	−0.34
Less sexually attractive	−0.21	−0.19
Loss body confidence	−0.35	−0.14
Fatigue	−0.29	−0.23
Loss sleep	0.03	−0.15
Decrease physical activity	−0.34	−0.32

The effect sizes are Cohen's *d* statistics for the change from baseline to end-of-study using transformed values to meet assumption

*Tests of differences in the changes between groups

**Statistically significant changes within groups

***All values in these cells are effect sizes for the changes in symptoms reported by at least 50% of the participants at baseline

Table 5 Summaries of changes in impedance, arm volume, and circumferential measurements from baseline to end of study ($N = 42$)

Location	Study group			
	Arm only ($N = 21$)		Truncal/chest/arm ($N = 21$)	
	Median [IQR]		Median [IQR]	
Impedance ($P = .481$)*				
Baseline	1.31 [1.21, 1.48]		1.25 [1.09, 1.77]	
End of study	1.26 [1.12, 1.41]		1.20 [1.05, 1.62]	
Effect size	−0.31**		−0.15**	
Affected arm volume ($P = .609$)*				
Baseline (ml)	2346.55 [1952.38, 2661.56]		2526.83 [2198.08, 3346.96]	
End of study (ml)	2376.53 [1934.68, 2622.99]		2539.93 [2168.28, 3295.97]	
% Change from Baseline	−0.38 [−2.56, +1.34]		−2.66 [−4.20, −0.55]	
Effect size	−0.04		−0.07	
Unaffected Arm Volume ($P = .471$)*				
Baseline (ml)	2104.12 [1738.20, 2305.31]		2159.26 [1811.79, 2635.06]	
End of study (ml)	2114.57 [1722.92, 2289.93]		2114.33 [1810.88, 2639.21]	
% Change from Baseline	−0.81 [−1.69, +1.69]		−0.56 [−1.90, +0.71]	
Effect size	+0.02		−0.04	
Circumferential measure	Affected	Unaffected	Affected	Unaffected
Hand	−0.20 [−0.52, +0.17]	−0.18 [−0.49, +0.16]	−0.05 [−0.41, +0.49]	−0.07 [−0.30, +0.08]
Effect size	−0.16	−0.10	+0.04	−0.11
Wrist	−0.20 [−0.38, +0.07]	−0.05 [−0.15, +0.20]	−0.13 [−0.61, +0.04]	−0.05 [−0.30, +0.10]
Effect size	−0.12	−0.01	−0.07	−0.09
CM10	−0.65 [−1.11, +0.03]	+0.17 [−0.17, + 0.45]	−0.78[−1.55, −0.11]	−0.10 [−0.70, +0.46]
Effect size	−0.15	+0.08	−0.22	−0.05
CM20	−0.25 [−0.51, +0.18]	−0.10 [−0.25, +0.21]	−0.23[−0.44, +0.20]	−0.10 [−0.33, +0.19]
Effect size	−0.07	−0.06	−0.05	0.00
CM30	0.00 [−0.46, +0.46]	−0.05 [−0.22, +0.15]	−0.53[−0.99, −0.02]	−0.18 [−0.45, +0.20]
Effect size	−0.03	+0.03	−0.11	−0.06
CM40	0.00 [−0.46, +0.28]	−0.02 [−0.54, +0.30]	−0.30[−0.71, +0.04]	+0.05 [−0.40, +0.32]
Effect size	−0.02	+0.01	−0.09	−0.01
Last	−0.10 [−0.80, +0.85]	−0.45[−0.73, +0.16]	−0.15[−0.81, +0.97]	+0.05 [−0.25, +1.35]
Effect size	+0.07	−0.03	−0.05	+0.11

The effect sizes are Cohen's d statistics for the change from baseline to end-of-study using transformed values to meet assumption

*Tests of differences in the changes between groups

**Statistically significant changes within groups

truncal/chest/arm: effect size = −0.15, $P = .023$). The difference in reduction between the two study groups was not statistically significant ($P = .481$).

As with the previously reported bioelectrical impedance measures, there was no statistically significant difference in the patterns of changes in circumferential measurement and resulting arm volume calculations between the study groups in either the affected or unaffected arms. However, a statistically significant reduction in affected arm volume was seen overall with both groups combined ($P = .018$). Descriptive summaries and respective within group effect sizes for each of the arm circumferential measures are also displayed in Table 5. Finally, as shown in Table 6, truncal size remained largely unchanged from baseline to end-of-study across study groups.

Discussion

Within each of the study groups, both experienced a statistically significant improvement in symptoms by the end of the study. There was no difference based on treatment

Table 6 Summaries of truncal circumferences at baseline and end of study ($N = 42$)

Location	Study group	
	Arm only ($N = 21$) Median (25th, 75th IQR)	Truncal/chest/arm ($N = 21$) Median (25th, 75th IQR)
Axilla ($P = .320$)		
Baseline (cm)	95.9 (87.9, 99.8)	96.2 (90.8, 101.7)
End of study (cm)	95.2 (87.8, 99.4)	97.2 (90.6, 103.3)
Effect size	−0.07	0.00
Largest chest ($P = .464$)		
Baseline (cm)	102.6 (93.2, 108.7)	103.8 (96.8, 112.5)
End of study(cm)	103.9 (93.3, 109.7)	104.9 (95.5, 113.1)
Effect size	+0.04	0.00
Xyphoid ($P = .672$)		
Baseline (cm)	93.6 (93.3, 98.1)	92.9 (86.7, 101.5)
End of study (cm)	91.1 (82.9, 98.8)	92.4 (86.4, 102.6)
Effect size	−0.06	−0.03
Waist ($P = .907$)		
Baseline (cm)	93.5 (83.2, 99.6)	93.0 (83.5, 103.1)
End of study (cm)	91.6 (82.5, 100.2)	92.7 (83.5, 104.3)
Effect size	0.00	+0.01
Hip ($P = .618$)		
Baseline (cm)	107.9 (100.2, 118.3)	111.0 (103.7, 120.5)
End of study (cm)	108.1 (99.6, 120.7)	111.3 (102.7, 120.7)
Effect size	+0.01	−0.02

The effect sizes are Cohen's d statistics for the change from baseline to end-of-study using transformed values to meet assumption

group. It should be noted, however, that despite a well-defined randomization procedure, individuals in the experimental group (truncal/chest/arm treatment) had a higher number of symptoms at baseline than the arm only participants. Thus, while individuals with high symptom burden benefited from the truncal/chest/arm treatment configuration, it is unknown if they would have had a similar response to the arm only treatment configuration. In addition, while duration of lymphedema did not differ between groups, the experimental group had developed lymphedema more quickly after cancer treatment and at a younger age. It is unclear if these differences impacted our findings, but future studies should consider stratifying samples based upon these variables.

Participants in both groups reported a high level of function upon entry into the study; therefore it was not surprising that no improvement was noted in either group. This suggests that the FASQ may not be sensitive enough to evaluate function in this population or alternatively, overall these patients were too high functioning for this to be a reasonable self-care outcome.

Although both bioimpedance and circumferential measurements were used, we did not find the expected differences in arm size reduction based upon garment configuration. While it is thought that opening truncal lymph channels is needed to promote arm volume reduction, [17] there was no apparent advantage to truncal decongestion in this study in patients with arm swelling alone and no clinically evident truncal swelling. As both groups had statistically significant improvement in symptoms and arm volume, truncal clearance did not appear to play a major role in these positive outcomes. Because the patients did not have truncal swelling upon study enrollment, we did not expect truncal girth reduction, however, neither group demonstrated any newly acquired truncal swelling as a result of treatment or lack of treatment to the trunk. Using physical examination and truncal measurements, we were unable to palpate any fluid in the trunk, identify asymmetrical swelling suggestive of fluid, or find a significant difference in girth using circumferential measurement. Statistical comparisons of the truncal girth at baseline and end-of-study where not significant. Thus, there did not appear to be a pooling of fluid when the truncal and chest garments were not used nor were there any other adverse events.

A recently published study on this device that utilized near-infrared fluorescence imaging techniques to assess lymph vessel activity offers one possible explanation for these results [34]. Study findings demonstrated a significant increase in lymph vessel contractility not only in treated limbs but in non-treated areas, as well [34]. This suggests that the unique therapeutic action provided by the device's dynamic pressure and release rhythm may actually increase lymphangiomotion beyond the treated limb. Much like

MLD, the initial pressure thrust enhances resorption of fluid into the lymph capillaries and the subsequent release leads to refilling of the lymph vessels. The frequency of the filling and emptying cycle in the initial lymphatics is one of the most important factors that influences, systemic lymph transport [17]. The mechanism of action and the design of this pneumatic compression device with its repetitious treatment sequence may, therefore, overcome the need for truncal clearance by enhancing systemic lymphatic response. Alternatively, though not empirically tested, the pressure settings or time allotted for truncal clearance may have been insufficient to promote enough truncal clearance to impact outcomes, or truncal clearance prior to arm massage in patients without truncal swelling may not be necessary.

Reduction of limb size in both groups suggests either treatment configuration may be effective for self-care; however, these findings raise several critical questions as to the value of truncal clearance in the self-treatment of arm lymphedema that does not extend to the trunk. This is worth further exploration as arm only treatment takes less time resulting in less patient burden.

Given these preliminary findings, further research with a larger sample is needed. Such research may include studies comparing: (1) truncal clearance pressures; (2) pressure only to thrust and release techniques; or (3) lymphedema treatment of the arm with and without truncal clearance in either pneumatic devices or manual therapies. Studies of the direct impact of the truncal garments on truncal swelling may also be warranted. In any studies, careful consideration should be given to the primary outcomes. While arm volume reduction alone may be the desired primary outcome in studies of acute treatment of lymphedema, studies concerning the lymphedema self-care population, may best target outcomes such as symptom reduction, self-care adherence, and arm volume stability as these offer more clinically meaningful outcome data.

Acknowledgment The authors wish to thank the breast cancer survivors with lymphedema who participated in the study and to acknowledge Joey O'Dell for her assistance in preparation of this manuscript. This study was funded by a grant from Tactile Systems Technology, Inc.

References

1. Browse N, Bernand KG, Mortimer PS (2003) Diseases of the lymphatics. Oxford University Press Inc., New York
2. American Cancer Society (2009) Facts and figures, 2009. American Cancer Society, Atlanta
3. American Cancer Society (2006) Lymphedema: understanding and managing lymphedema after cancer treatment. American Cancer Society, Atlanta
4. Ehrlich A, Vinje-Harrewijn A, McMahon E (2005) Living well with lymphedema. LymphNotes, Lymph Links, San Francisco
5. Morgan PA, Franks PJ, Moffatt CJ (2005) Health-related quality of life with lymphoedema: a review of the literature. Int Wound J 2:47–62. doi:10.1111/j.1742-4801.2005.00066.x
6. Ridner S (2005) Quality of life and a symptom cluster associated with breast cancer treatment-related lymphedema. Support Care Cancer 13:904–911
7. Augustin M, Bross F, Földi E, Vanscheidt W (2005) Development, validation and clinical use of the FLQA-I, a disease-specific quality of life questionnaire for patients with lymphedema. Vasa 34:31–35
8. Johansson K, Holmström H, Nilsson I, Ingvar C, Albertsson M, Ekdahl C (2003) Breast cancer patients' experiences of lymphoedema. Scand J Caring Sci 17:35–42
9. McMahon E (2005) Overcoming the emotional challenges of lymphedema. LymphNotes, San Francisco
10. McWayne J, Heiney SP (2005) Psychologic and social sequelae of secondary lymphedema: a review. Cancer 104:457–466. doi:10.1002/cncr.21195
11. Rowland JH, Yancik R (2006) Cancer survivorship: the interface of aging, comorbidity, and quality care. J Natl Cancer Inst 98:504–505. doi:10.1093/jnci/djj154
12. Williams A, Moffatt C, Franks P (2004) A phenomenological study of the lived experiences of people with lymphoedema. Int J Palliat Nurs 10:279–286
13. Armer JM, Heckathorn PW (2005) Post-breast cancer lymphedema in aging women: self-management and implications for nursing. J Gerontol Nurs 31:29–39
14. Kornblith AB, Ligibel J (2003) Psychosocial and sexual functioning of survivors of breast cancer. Semin Oncol 30:799–813. doi:10.1053/j.seminoncol.2003.08.025
15. Starritt EC, Joseph D, Mckinnon JG, Lo SK, De Wilt JHW, Thompson JF (2004) Lymphedema after complete axillary node dissection for melanoma: assessment using a new, objective definition. Ann Surg 240:866–874
16. Petrek JA, Pressman PI, Smith RA (2000) Lymphedema: current issues in research and management. CA Cancer J Clin 50:292–307
17. Földi M, Földi E, Kubik S, Asmussen P (2006) Textbook of lymphology: for physicians and lymphedema therapists, 2nd edn. Urban & Fischer, Munich
18. Twycross RG, Jenns K, Todd J (2000) Lymphoedema. Radcliffe Medical Press Ltd., Abingdon
19. Casley-Smith JR, Boris M, Weindorf S, Lasinski B (1998) Treatment for lymphedema of the arm—the Casley-Smith method: a noninvasive method produces continued reduction. Cancer 83:2843–2860. doi:10.1002/(SICI)1097-0142(19981215)83:12B+<2843:AID-CNCR38>3.0.CO
20. Mayrovitz HN, Brown-Cross D, Mayrovitz BL, Golla AH (2009) Lymphedema: role of truncal clearance as a therapy component. Home Health Care Manag Pract 21:325–337. doi:10.1177/1084822309331484
21. Boris M, Weindorf S, Lasinski B (1998) The risk of genital edema after external pump compression for lower limb lymphedema. Lymphology 31:15–20
22. Cheville AL, McGarvey CL, Petrek JA, Russo SA, Taylor ME, Thiadens SRJ (2003) Lymphedema management. Semin Radiat Oncol 13:290–301. doi:10.1016/s1053-4296(03)00035-3
23. Segers P, Belgrado JP, Leduc A, Leduc O, Verdonck P (2002) Excessive pressure in multichambered cuffs used for sequential compression therapy. Phys Ther 82:1000–1008
24. Eliska O, Eliskova M (1995) Are peripheral lymphatics damaged by high pressure manual massage? Lymphology 28:21–30
25. Ridner SH, Murphy B, Deng J, Kidd N, Galford E, Dietrich MS (2010) Advanced pneumatic therapy in self-care of chronic lymphedema of the trunk. Lymphat Res Biol 8:209–215. doi:10.1089/lrb.2010.0010

26. International Society of Lymphology (2009) Consensus document of the international society of lymphology: the diagnosis and treatment of peripheral lymphedema. Lymphology 42:51–60
27. Ridner SH, Dietrich M (2010) Development of the lymphedema symptoms intensity and distress survey arm. J Clin Oncol ASCO Suppl 28
28. Millard R (1989) The functional assessment screening questionnaire: application for evaluating pain-related disability. Arch Phys Med Rehabil 70:303–307
29. Millard R (1991) A critical review of questionnaires for assessing pain-related disability. J Occup Rehabil 1:289–302
30. Latchford S, Casley-Smith JR (1997) Estimating limb volumes and alterations in peripheral edema from circumferences measured at different intervals. Lymphology 30:161–164
31. Deltombe T, Jamart J, Recloux S, Legrand C, Vandenbroeck N, Theys S, Hanson P (2007) Reliability and limits of agreement of circumferential, water displacement, and optoelectronic volumetry in the measurement of upper limb lymphedema. Lymphology 40:26–34
32. Kosir MA, Rymal C, Koppolu P, Hryniuk L, Darga L, Du W, Rice V, Mood D, Shakoor S, Wang W (2001) Surgical outcomes after breast cancer surgery: measuring acute lymphedema. J Surg Res 95:147–151
33. Centers for disease control (2011) Body mass index. http://www.cdc.gov/healthyweight/assessing/bmi/. Accessed 13 Aug 2011
34. Adams KE, Rasmussen JC, Darne C, Tan I (2010) Direct evidence of lymphatic function improvement after advanced pneumatic compression device treatment of lymphedema. Biomed Opt Express 1:114–125. doi:10.1364/BOE.1.000114