Home-Based Lymphedema Treatment in Patients With Cancer-Related Lymphedema or Noncancer-Related Lymphedema

Sheila H. Ridner, PhD, RN, Elizabeth McMahon, PhD, Mary S. Dietrich, PhD, and Sunday Hoy, Esq.

Purpose/Objectives: To compare treatment protocol adherence, satisfaction, and perceived changes in emotional and functional status between patients with lymphedema with and without cancer using the home-based Flexitouch® (Tactile Systems Technology, Inc.) system for lymphedema self-care.

Design: Quasi-experimental, pre- and post-test design.

Setting: Private homes in the continental United States and Alaska.

Sample: 155 community-dwelling individuals with lymphedema: 93 with cancer-related lymphedema and 62 with noncancer-related lymphedema.

Methods: A survey was completed before use of the Flexitouch system. Participants received in-home education about device use, safety precautions, and the two-phase therapy protocol. A post-therapy survey was completed during the maintenance phase of the protocol.

Main Research Variables: Use of the Flexitouch system, treatment protocol adherence, participant satisfaction, and emotional and functional status.

Findings: Participants without cancer were more adherent to the prescribed protocol. Both groups were satisfied with the system, perceived it to be effective, and reported improvement in physical and emotional status. Participants' use of professional manual lymphatic drainage (MLD) therapy, self-MLD, and bandaging declined after they initiated use of the Flexitouch system.

Conclusions: Patients using the Flexitouch system were satisfied with the device and perceived it to be beneficial in management of their lymphedema.

Implications for Nursing: Patients using the Flexitouch system should be assessed for adherence to the prescribed treatment protocol and use of other self-care treatments. Healthcare professionals should facilitate communication among members of the lymphedema treatment team and the patient when problems are noted.

Key Points . . .

- Despite advances in laboratory science to identify and understand the origins of primary lymphedema and modifications of cancer treatment to decrease secondary lymphedema, new lymphedema cases continue to be identified.
- Lymphedema requires burdensome, lifelong self-care to stimulate lymphatic drainage.
- Improved at-home treatment methods are needed.
- Participants reported satisfaction and perceived benefit from using a new home-based lymphedema treatment system that promotes lymphatic drainage.

Lymphedema is a condition in which excessive fluid and protein accumulate in the interstitial spaces (Rockson, 2001). It occurs when the lymphatic system cannot accept fluid from the interstitium, cannot transport lymph into the circulatory system, or both (Browse, Burnand, & Mortimer, 2003). Lymphedema can arise from primary (idiopathic) or secondary (acquired) conditions. Primary lymphedema occurs in about 1 of every 10,000 individuals (Townsend, Beauchamp, Evers, & Mattox, 2001). Secondary lymphedema occurs as a result of trauma to the lymphatic system. The leading cause of secondary lymphedema in the United States is cancer treatment. Lymphedema rates in patients treated for cancer vary based on cancer type, site, severity, and treatment, as well as length of time post-treatment and criteria used for lymphedema diagnosis (Cormier, Davidson, Xing, Evans, & Armer, 2006; Starritt et al., 2004). Incidence of

Sheila H. Ridner, PhD, RN, is an assistant professor in the School of Nursing at Vanderbilt University in Nashville, TN; Elizabeth McMahon, PhD, is a clinical psychologist in the Psychiatry Department at Kaiser Permanente in Fremont, CA; Mary S. Dietrich, PhD, is a research associate professor, statistician, and assistant professor of medicine in the School of Nursing at Vanderbilt University; and Sunday Hoy, Esq., is the director of clinical research at Tactile Systems Technology, Inc., in Minneapolis, MN. *The surveys were mailed by the manufacturer of the device discussed in this article because the company had access to the potential participants' addresses. Data analysis and interpretation were conducted without input from the manufacturer. Ridner, McMahon, and Dietrich have not received any financial support or compensation from the manufacturer. Hoy is employed by the manufacturer. Participants purchased the devices with personal funds or through insurance coverage. Mention of specific products and opinions related to those products do not indicate or imply endorsement by the* Oncology Nursing Forum *or the Oncology Nursing Society. (Submitted June 2007. Accepted for publication November 21, 2007.)*

Digital Object Identifier: 10.1188/08.ONF.671-680

upper-extremity lymphedema in women after breast cancer treatment is estimated to be 20%–36% at 2 years post-treatment, increasing to 30%–45% at 15 or more years post-treatment (Erickson, Pearson, Ganz, Adams, & Kahn, 2001). Even by the lowest estimates, lymphedema affects hundreds of thousands of people in the United States (American Cancer Society, 2006).

Early diagnosis and treatment of lymphedema improve patient outcomes (Ramos, O'Donnell, & Knight, 1999). Untreated lymphedema or lymphedema unresponsive to treatment progresses through three stages of increasing severity (Pain & Purushotham, 2000). In stage I, limb elevation temporarily relieves swelling but does not change the underlying lymphatic dysfunction. In stage II, elevation does not relieve swelling, the limb can become firmer and not pit with pressure, and skin changes may be noted. In stage III, enlargement of tissues causes severe swelling, thick skin, and large skin folds. Fibrosis occurs in stages II and III.

Despite advances in identifying and understanding the origins of primary lymphedema and improved cancer treatments designed to decrease the incidence of secondary lymphedema, new lymphedema cases continue to occur and be identified for many reasons. First, lymphatic research is a young investigative field; it will be many years before preventive or curative interventions are available. Second, improvements in cancer detection and treatment have increased the absolute numbers of cancer survivors, leaving more at risk for developing lymphedema. Third, because cancer survivors are living longer, they also are aging, and because lymphedema occurs more frequently in older cancer survivors, more people will be at risk for developing lymphedema (Armer & Fu, 2005). Fourth, changes in cancer treatment have reduced but not eliminated lymphedema as a treatment side effect (Fleissig et al., 2006; Morrell et al., 2005). Fifth, the activities of organizations such as the Lymphatic Research Foundation and the National Lymphedema Network have increased lymphedema awareness and accentuated the importance of diagnosis and treatment. Finally, certain populations that are increasing in number in the United States may be at greater risk of developing lymphedema. A study of low-income survivors of breast cancer found an overall lymphedema rate of 63% in a study population of breast cancer survivors, with rates of 75% among Latinos and 77% among African American women (Eversley et al., 2005).

Literature Review

Lymphedema is a chronic condition for which treatment is available, but no cure exists. It is associated with impairment of function, significant psychosocial morbidity, and decreased quality of life (QOL). Physical sequelae can include impaired mobility, decreased range of motion and physical function, pain, compromised immune function, and increased incidence of acute inflammatory episodes and infection (including life-threatening systemic infections such as erysipelas or cellulitis, sometimes requiring hospitalization) (American Cancer Society, 2006; Ehrlich, Vinje-Harrewijn, & McMahon, 2005; Morgan, Franks, & Moffatt, 2005). Psychological sequelae include increased anxiety (especially social anxiety), depression, phobias, social withdrawal, sexual dysfunction, negative body image, loss of confidence in the body, lowered self-esteem, anger, and frustration (Augustin, Bross, Foldi, Vanscheidt, & Zschocke, 2005; Johansson et al., 2003; McMahon, 2005; McWayne & Heiney, 2005; Ridner, 2005; Rowland & Yancik, 2006; Williams, Moffatt, & Franks, 2004). Lymphedema is associated with decreased QOL (Armer & Heckathorn, 2005; Kornblith et al., 2003; Ridner). The decreased QOL can be unrelated to the objectively measured volume of the lymphedematous limb (Morgan et al.; Starritt et al., 2004).

Current lymphedema treatments are less than optimal, and improved home-based treatments are needed. Notably, many patients who comply with all prescribed treatment recommendations experience acute exacerbations of swelling and infections. Lymphedema treatment requires the intervention of specially trained healthcare professionals. The current gold standard of treatment is complete decongestive therapy (CDT), which includes manual lymphatic drainage (MLD), compression garments and bandaging, and meticulous skin care (Petrek, Pressman, & Smith, 2000). However, other treatments are used at times, such as pneumatic compression devices, ultrasound, and lasers (Balzarini et al., 1993; Piller & Thelander, 1998; Richmand, O'Donnell, & Zelikovski, 1985). Liposuction and macrosurgical or microsurgical techniques occasionally are undertaken when noninvasive treatment fails (Johansson, Albertsson, Ingvar, & Ekdahl, 1999; Johansson, Lie, Ekdahl, & Lindfelt, 1998). The long-term benefits of invasive procedures are unknown, and any improvements in limb size are maintained only with compression garments.

Regardless of the type of volume-reduction treatment, burdensome lifelong self-care that includes compression, self-administered MLD, and skin care is required to maintain volume reduction after CDT or to achieve additional volume reduction. The physical demands of self-MLD and application of compression garments may be difficult for patients with limited arm mobility because of the effects of cancer treatment or lymphedema itself and for those with comorbid conditions such as obesity or arthritis. Self-care is emotionally distressing because the activities require more than an hour every day. Also, many third-party payers do not cover repeated CDT and MLD sessions, compression garments, or other supplies; therefore, financial problems often arise. In addition, the social and psychological impact of wearing visible compression garments or the visual effects of lymphedema may be traumatic.

Study Rationale

Reducing treatment burden may improve self-care and produce better patient outcomes (Boris, Weindorf, & Lasinkski, 1997). Various types of garments and compression pumps have been developed in attempts to reduce patient burden and improve outcomes. Older-generation compression pumps can present an unacceptable risk of potential damage to the lymphatic system and, in some cases, when used to treat lower-limb lymphedema, can contribute to the development of genital edema (Boris et al., 1998; Cheville et al., 2003). Newer devices, when used with appropriate training and education, are believed to be safer than their older counterparts because they are designed to follow the physiologic principles of MLD. The segmented, programmable Flexitouch® (Tactile Systems Technology, Inc.) system (see Figure 1) is one example of a new-generation device. Unlike limb-isolating compression devices that compress only the limb itself, the Flexitouch system applies light, dynamic, variable pressure to the affected limb and beyond the limb junction to the trunk

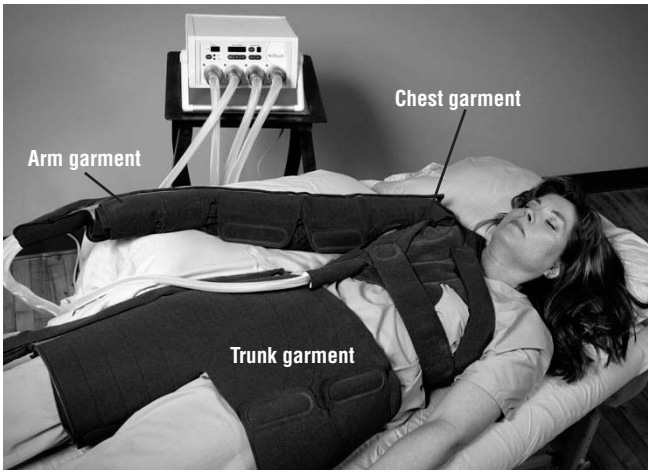

Figure 1. Flexitouch® System

using multichambered, inflatable, and stretchable fabric garments. The garments have narrow chambers, ranging from 3.8–4.4 cm wide, which simulate the work-and-release action of a therapist's hand. The average applied pressure is mild, in contrast to the static higher pressures associated with traditional compression pumps (Mayrovitz, 2007). Results from a small, prospective, randomized, crossover pilot study (N = 10) comparing the Flexitouch system to self-administered MLD revealed a statistically significant difference ($p = 0.002$) in arm volume reduction with the Flexitouch system (Wilburn, Wilburn, & Rockson, 2006). However, adherence to treatment protocols, satisfaction with the device, and response to at-home treatment have yet to be studied. Thus, the purpose of this quasi-experimental pre-/post-test study was to evaluate treatment protocol adherence, satisfaction, perceived effectiveness (maintaining limb size or achieving further reduction), and perceived physical and emotional responses to treatment of home-based individuals using the Flexitouch system. Specifically, comparison of responses was made between two patient groups most likely to use the device: individuals with primary, noncancer-related lymphedema and those with cancer-related secondary lymphedema. Findings from such comparisons can be useful in determining whether the previously tested protocol (Wilburn et al.) is acceptable and perceived as beneficial to patients regardless of lymphedema cause or duration. Specific research questions included the following.

- Does a difference exist in the level of self-reported adherence with the recommended treatment protocol between participants with cancer-related lymphedema and those with lymphedema from noncancer causes?
- Is adherence to the recommended treatment protocol associated with sociodemographic variables, lymphedema duration, lymphedema severity, or infection frequency?
- Does a difference exist in stated satisfaction with the device between participants with cancer-related lymphedema and those with lymphedema from noncancer causes?
- Does a difference exist in perceived effectiveness of the device (limb volume reduction) between participants with cancer-related lymphedema and those with lymphedema from noncancer causes?
- Does a difference exist in perceived impact of the device on physical and emotional well-being between participants with cancer-related lymphedema and those with lymphedema from noncancer causes?
- What impact does use of the Flexitouch system have on at-home lymphedema self-care routines?

Methods

Setting and Sample

All individuals in the United States whose independent, private healthcare providers prescribed the Flexitouch system and whose treatment was initiated from March 1, 2004, to May 10, 2006, were invited to participate in the study. Prescribing physicians were not interviewed about their reasons for prescribing the system, nor had the manufacturer asked them to prescribe the system. Participants purchased the system from the manufacturer either with insurance coverage or personal funds. For insurance to cover the Flexitouch system, patients typically must fail other methods of lymphedema treatment, such as compression garments, bandaging, exercise, and elevation, and be unable to use nonsegmented or nonprogrammable pumps. The sample consisted of community-dwelling individuals living in the continental United States or Alaska with lymphedema in one or more limbs.

Procedures

Participants gave consent for use of data collected during the study. Institutional review board approval was obtained from Vanderbilt University for analysis of a de-identified data set. Participants completed a pretherapy survey before initiating use of the Flexitouch system. Trained Flexitouch instructors provided approximately one hour of in-home education before system use. Participants were instructed in proper device usage, methods for donning and doffing the garments, and the therapy protocol. Specifically, participants were instructed to remove all restrictive clothing and jewelry before use, not eat immediately before therapy, lie flat with the limb slightly elevated, wrap garments snugly to ensure good skin contact, not interrupt therapy sessions, complete the entire one-hour treatment, and follow additional therapist- and physician-prescribed care including but not limited to nocturnal bandaging, compression garments, exercises, and skin care. The therapeutic protocol directed the participants to use the device for one hour twice per day for each affected area for the first month, then for one hour once per day thereafter as maintenance for each affected area. Participants completed a post-therapy survey after the first month of use.

A pretherapy questionnaire was sent to 286 individuals when or before they received the device; 241 returned the pretherapy survey and were sent a post-therapy questionnaire. To encourage participants to return the post-therapy survey, a research assistant called users who had not returned the questionnaire within two months of receiving the device. During the phone call, participants were encouraged to return the survey and offered the option of completing the survey over the phone. To eliminate data collection bias, the research assistant was not employed by the Flexitouch system manufacturer, had no previous contact with participants, and directly read from the survey when asking questions. Participants who received phone calls were asked, "Is there anything else you would like to add?" after the survey was completed.

Table 1. Characteristics of Respondents Who Completed the Post-Therapy Survey and Those Who Did Not

	Post-Treatment		Missing		Total	
Variable	**n**	**%**	**n**	**%**	**N**	**%**
Lymphedema cause						
Secondary (cancer related)	93	60	47	63	140	61
Secondary (noncancer related)	42	27	20	27	62	27
Primary	20	13	8	11	28	12
Gender (p = 0.499)						
Female	134	87	64	83	198	85
Age (years) (p = 0.012)						
≤ 40	15	10	5	7	20	9
41–50	49	32	17	22	66	29
51–60	61	40	29	38	90	39
≥ 61	29	19	26	34	55	24
Lymphedema severity						
Mild	4	3	2	3	6	3
Moderate	69	49	41	56	110	52
Severe	67	48	30	41	97	46
Time since diagnosis						
< 6 months	58	40	23	34	81	40
0.5–1 year	31	21	14	21	45	21
1–2 years	25	17	11	16	36	17
2–3 years	8	6	5	7	13	6
> 3 years	24	16	15	22	39	18
Lymphedema infection interferes with ADL						
None	80	56	33	47	113	53
Little	28	20	12	17	40	19
Moderately	19	13	10	14	29	14
Quite a bit	12	9	7	10	19	9
Extremely	3	2	8	11	11	5
Lymphedema infection frequency in swollen limb[a]						
Once per year	21	45	15	46	36	45
Twice per year	16	34	11	33	27	34
3–4 per year	5	11	5	15	10	13
> 4 per year	5	11	2	6	7	9
Lymphedema infection duration[a] (p = 0.027)						
1 week	13	50	11	85	24	62
1–2 weeks	4	15	1	8	5	13
2–3 weeks	2	8	1	8	3	8
> 3 weeks	7	27	–	–	7	18

[a] Of the respondents who reported infections

ADL—activities of daily living

Note. Not all respondents answered all questions. Because of rounding, percentages may not total 100.

Instruments

Demographic information, age, and gender questions were included in the pretherapy survey. Participants self-reported disease and treatment information. The **Short-Form Health Survey (SF-12)** (Gandhi et al., 2001; Ware, Kosinski, & Keller, 1996) was used to measure physical and mental aspects of QOL. The survey consists of 12 items measured on five-point scales and has eight subscales: general health, physical functioning, role physical, bodily pain, mental health, vitality, social functioning, and role emotional. Global physical and mental health scores can be calculated using the subscale scores. Test-retest intraclass correlations of 0.75 for the physical scale and 0.71 for the mental scale have been documented (Hurst, Ruta, & Kind, 1998). The SF-12 has demonstrated discriminate validity when used with individuals with and without arm lymphedema ($p < 0.01$) (Paskett, Naughton, McCoy, Case, & Abbott, 2007). A typical item is, "During the past four weeks, how much did pain interfere with your normal work including both work outside the home and housework?" (Ware, Kosinski, Turner-Bowker, & Gandek, 2005, p. 249). Items from the SF-12 were modified on the post-therapy survey (e.g., "Since using the Flexitouch system, how much did pain interfere with your normal work including both work outside the home and housework?") to reinforce consideration of use of the Flexitouch system during responses.

Analysis

Statistical data analysis was conducted with SAS® (version 9.1.3), SPSS® (version 15.0.1), and Stata® (Release 9). Patient characteristics, adherence patterns, and other responses to the pre- and post-therapy surveys initially were summarized with descriptive statistics. For categorical responses (nominal

as well as ordered), frequency distributions were used. For continuous responses (SF-12 global and subscale scores), measures of central tendency (mean and median) and variability (standard deviations and interquartile ranges) were used to describe the distributions. Because some of the distributions of values for the SF-12 scores were not distributed normally (skewed), nonparametric statistical methods (e.g., Spearman rank correlations, Wilcoxon signed-ranks tests for paired data) were used in conjunction with the parametric statistical methods (e.g., Pearson correlations, repeated-measures analysis of variance with difference contrasts) to assess the reliability of statistical conclusions. In all cases, conclusions based on nonparametric and parametric tests were in agreement. However, because of the skewed nature of the distributions of the SF-12 scores, bias-corrected bootstrapped 95% confidence intervals were calculated. Study group comparisons of nominal categories were conducted using chi-square tests of independence; comparisons of ordered categories (e.g., adherence, satisfaction) used Mann-Whitney tests. Spearman rank correlations were used to measure the degree of association between ordinal variables. An alpha level of 0.05 was used for establishing statistical significance, and all tests were two tailed.

Results

Sample Characteristics

Of the 241 participants who returned the pretherapy survey and received devices, 155 (64%) completed information required for the analyses reported here. For inclusion, participants were required to indicate the cause of their lymphedema and return a follow-up, post-therapy survey during the maintenance phase of the protocol. The time between the pretherapy and post-therapy surveys averaged approximately seven months (range = 1–22 months). Sixty percent of the participants completed the study in six months or less and 85% completed it within a year. Pretherapy characteristics of the participants who completed the study and those who did not are summarized in Tables 1 and 2. Those returning the post-therapy survey tended to be younger, had longer durations of infections, and reported higher baseline physical and mental health characteristics ($p < 0.05$).

Characteristics of the study participants with lymphedema secondary to cancer and those with lymphedema originating from some other source are summarized in Table 3. Relative to the participants with lymphedema from other sources, a higher percentage of participants in the cancer group were female (97% versus 71%, $p < 0.001$), were older ($p = 0.007$), reported less severe lymphedema ($p = 0.001$), and reported less time between lymphedema cause and lymphedema diagnosis ($p = 0.040$).

Adherence by Group

The prescribed usage protocol of the Flexitouch system at the time the participants completed the post-therapy survey was once per day. Statistically significant differences were found in the patterns of adherence to the prescribed protocol between the types of lymphedema groups ($p = 0.022$). Among participants with noncancer-related lymphedema, approximately 56% reported following the prescribed maintenance protocol of one time per day, with 7% reporting use more than once per day. Comparable percentages among the participants with cancer-related lymphedema were 32% following the prescribed protocol, 21% more than once per day. A total of 47% of the participants from the cancer group reported use below prescribed protocol or not at all. Of those, 39% reported use of more than once per week and 4% reported no use. On the other hand, a total of 37% of the participants with lymphedema not secondary to cancer reported lower than prescribed use; 27% of them were using the device more than once per week and 7% were not using it at all.

Table 2. Physical and Emotional Health Scores of Respondents Who Subsequently Completed the Post-Therapy Survey and Those Who Did Not

SF-12 Characteristic	$\bar{X}$	SD	Median	p
Global physical health				0.043
Completed post	60.59	16.14	60.0	
Missing post	55.77	16.33	52.5	
General health				0.547
Completed post	62.00	18.47	60.0	
Missing post	63.66	19.80	60.0	
Physical functioning				0.065
Completed post	44.64	13.70	50.0	
Missing post	40.85	14.71	40.0	
Role physical				0.007
Completed post	64.71	25.26	60.0	
Missing post	54.93	23.54	50.0	
Bodily pain				0.042
Completed post	71.00	24.62	80.0	
Missing post	63.66	24.68	60.0	
Global mental health				0.021
Completed post	69.52	17.72	72.5	
Missing post	63.63	16.85	62.5	
Mental health				0.009
Completed post	70.57	18.92	70.0	
Missing post	63.52	16.83	60.0	
Vitality				0.336
Completed post	58.57	21.28	60.0	
Missing post	55.77	16.87	60.0	
Social functioning				0.192
Completed post	72.29	22.58	80.0	
Missing post	67.89	24.02	60.0	
Role emotional				0.008
Completed post	76.64	23.98	80.0	
Missing post	67.32	23.66	60.0	

SF-12—Short-Form Health Survey

Variables Influencing Adherence

No statistically significant association was found between reported use patterns and age group, gender, lymphedema severity, or time since diagnosis. In addition, no statistically significant association was found between reported use patterns and limb volume change. No statistically significant correlations were found between device use and infection frequency in the affected limb or interference with daily activities as a result of infections, perhaps related to the low incidence of infections in the study sample.

Satisfaction

Ninety percent of the study participants reported that they were satisfied with the Flexitouch system. Of them, more

Table 3. Sample Characteristics by Cause of Lymphedema

Characteristic	Noncancer Related		Cancer Related		Total	
	n	%	n	%	N	%
Gender (p < 0.001)						
Female	44	71	90	97	134	87
Age group (years) (p = 0.007)						
≤ 40	10	16	5	5	15	10
41–50	22	36	27	29	49	32
51–60	22	36	39	42	61	40
≥ 61	7	12	22	24	29	19
Lymphedema severity (p = 0.001)						
Mild	1	2	3	4	4	3
Moderate	18	33	51	60	69	49
Severe	36	66	31	37	67	48
Time since diagnosis (p = 0.040)						
< 6 months	18	33	40	44	58	40
0.5–1 year	9	17	22	24	31	21
1–2 years	10	19	15	16	25	17
2–3 years	3	6	5	5	8	6
> 3 years	14	26	10	11	24	16
Lymphedema infection interferes with ADL						
None	26	48	54	61	80	56
Little	13	24	15	17	28	20
Moderately	9	17	10	11	19	13
Quite a bit	6	11	6	7	12	9
Extremely	–	–	3	3	3	2
Lymphedema infection frequency in swollen limb[a]						
Once per year	8	38	13	50	21	45
Twice per year	11	52	5	19	16	34
3–4 per year	2	10	3	12	5	11
> 4 per year	–	–	5	19	5	11
Lymphedema infection duration[a]						
1 week	5	36	8	67	13	50
1–2 weeks	4	29	–	–	4	15
2–3 weeks	2	14	–	–	2	8
> 3 weeks	3	21	4	33	7	27

[a] Of the respondents who reported infections

ADL—activities of daily living

Note. Not all respondents answered all questions. Because of rounding, percentages may not total 100.

than 65% reported that they were extremely satisfied. No statistically significant differences were found in reported satisfaction with the device between the groups with lymphedema related to cancer or from some other cause, among the age groups, or by gender. However, those who reported that they used the devise as prescribed reported statistically significant higher levels of satisfaction (p = 0.008), a pattern repeated in both lymphedema groups. All of the 7% of study participants who said they were dissatisfied with the device were using it less than the prescribed protocol or not at all.

Perceived Effectiveness

No statistically significant difference between the lymphedema groups was found in perceived effectiveness as measured by self-reported limb volume change. Positive limb volume outcome was defined as a participant perceiving that limb volume had been maintained or reduced with device use. Ninety-five percent of participants reported a self-perceived positive limb volume outcome. Of them, 42% reported self-perceived limb volume decreases as much as 20%, and an additional 20% reported decreases of less than 20%.

Physical and Emotional Health

Tables 4 and 5 provide summaries of the physical and emotional health assessments prior to and after use of the Flexitouch system. Clinically and statistically significant improvements occurred in all areas of perceived physical and emotional health ($p \leq 0.006$). Improvements were observed over time regardless of whether lymphedema was related to cancer.

Self-Care Impact

Figure 2 summarizes use patterns of various treatment protocols other than the Flexitouch system (e.g., bandaging, garments, self- and clinician-administered MLD) and changes in patterns. Garments were the most frequently used additional treatment before use of the Flexitouch system (76%) and at follow-up (69%). A statistically significant drop occurred in the use of clinician-administered MLD from 60% before using the device to 13% at follow-up (p < 0.001). Statistically

significant decreases in the use of bandaging ($p < 0.001$) and self-MLD ($p = 0.003$) also were noted. Participants with cancer-related lymphedema used garments more than those with lymphedema from other causes before receiving the system (82% versus 68%, $p = 0.046$); however, that difference disappeared at follow-up (71% versus 66%). No other statistically significant differences were found between self-reports of the use of bandaging, garments, or self- or clinician-administered MLD by the lymphedema groups at pre- or post-therapy, nor were any statistically significant differences found in changes in use patterns between the groups. In general, use of those other types of treatments decreased. No statistically significant associations between the reported uses of other treatments and the extent of use of the Flexitouch system were detected at follow-up.

Discussion

This study compared questionnaire data from individuals with cancer-related lymphedema and those with noncancer-related lymphedema before and after adding the Flexitouch system to their regimens of lymphedema self-care. Adherence to prescribed, at-home self-care has been identified as the most important factor in treating lymphedema; thus, nonadherence to prescribed treatment represents a barrier to improving outcomes (Boris et al., 1997). Almost half of patients with chronic disease have problems following their treatment regimens (Dunbar-Jacob et al., 2000), and based upon the current findings, those with lymphedema have similar difficulties. In this study, participants with noncancer-related lymphedema demonstrated greater treatment adherence than their cancer-related lymphedema counterparts. A possible explanation for the difference is that because individuals with noncancer-related lymphedema had lymphedema that was more severe and longer in duration, they were more motivated to adhere to the recommended protocol in hopes of achieving a good outcome (Bodenheimer, Lorig, Holman, & Grumbach, 2002; Kralik, Koch, Price, & Howard, 2004). The lack of a statistically significant difference in perceived limb volume change among the groups of participants using the device with similar frequencies suggests that primary and secondary lymphedema may respond similarly to the Flexitouch system.

Both participant groups were satisfied with the device and perceived it as beneficial. The high level of satisfaction across groups (90%) may reflect the participants' acceptance of the device and a willingness to integrate it into their treatment regimens.

The frequency of use was not significantly correlated with perceived limb volume change. This may reflect participants' understanding that maintaining limb size and achieving volume reduction are acceptable outcomes of Flexitouch system use. Also, perhaps certain participants perceived similar results using the system less frequently than others. A previous pilot study of the treatment device (Wilburn et al., 2006), using a validated measure of limb volume carried out by trained medical personnel, reported findings of improvement similar to those reported by study participants. Therefore, further study evaluating whether a correlation exists between objective and perceived limb volume change may be of value.

Both groups experienced significant improvements in all areas of perceived physical and emotional health between the pretherapy and post-therapy assessments. The findings suggest that, regardless of lymphedema cause, the Flexitouch system may have a positive effect on the QOL of those us-

Table 4. Short-Form Health Survey[a] Global and Subscale Physical Health Scores for Lymphedema Secondary to Cancer (n = 70) and Not Secondary to Cancer (n = 43)

	Presurvey			Postsurvey			
Scale	$\bar{X}$	**SEM**	**CI**	$\bar{X}$	**SEM**	**CI**	**p**
Global physical health							
Not cancer	59.24	2.72	53.66, 64.48	69.59	2.14	65.47, 73.60	
Cancer	59.61	1.91	55.86, 63.63	69.39	1.54	66.14, 72.18	
Total	59.47	1.56	56.68, 62.63	69.47	1.32	66.97, 72.10	< 0.001
General health							
Not cancer	59.07	3.10	53.95, 66.51	65.12	2.54	60.93, 70.70	
Cancer	62.29	2.13	58.57, 66.57	67.14	1.92	63.43, 71.14	
Total	61.06	1.64	58.05, 64.25	66.37	1.53	63.54, 69.56	0.006
Physical functioning							
Not cancer	41.86	2.32	37.67, 46.98	50.47	1.84	46.98, 53.95	
Cancer	45.86	1.42	43.00, 48.57	50.29	1.34	47.57, 52.86	
Total	44.34	1.30	41.86, 46.90	50.35	1.09	48.14, 52.39	< 0.001
Physical role							
Not cancer	64.88	3.90	57.44, 72.91	78.60	3.36	71.40, 84.65	
Cancer	60.29	2.97	54.57, 66.29	75.57	2.60	70.71, 81.00	
Total	62.04	2.36	57.43, 66.81	76.73	1.99	72.83, 80.88	< 0.001
Lack of pain interference[a]							
Not cancer	71.16	3.97	64.19, 79.53	84.19	3.04	78.60, 90.23	
Cancer	70.00	2.84	64.29, 75.43	84.57	2.25	79.71, 88.57	
Total	70.44	2.32	65.84, 75.04	84.42	1.77	80.71, 87.79	< 0.001

[a] "Bodily Pain" Short-Form Health Survey scale was renamed to indicate that a higher score (less interference from pain) is a more positive assessment.

CI—95% confidence interval; SEM—standard error of the mean

Table 5. Short-Form Health Survey[a] Global and Subscale Mental Health Scores for Lymphedema Secondary to Cancer (n = 70) and Not Secondary to Cancer (n = 43)

	Presurvey			Postsurvey			
Scale	$\bar{X}$	SEM	CI	$\bar{X}$	SEM	CI	p
Global mental health							
Not cancer	66.74	2.80	61.28, 72.15	80.35	1.85	76.86, 84.19	
Cancer	69.14	2.16	65.18, 73.29	78.86	1.69	75.43, 81.89	
Total	68.23	1.69	64.89, 71.48	79.42	1.27	76.66, 81.70	< 0.001
Mental health							
Not cancer	69.77	3.13	63.72, 75.81	83.02	1.67	80.00, 86.28	
Cancer	68.71	2.15	64.57, 72.86	80.14	1.50	77.29, 83.14	
Total	69.12	1.79	65.58, 72.48	81.24	1.16	79.20, 83.72	< 0.001
Vitality							
Not cancer	55.35	3.62	49.30, 63.72	66.98	2.75	61.40, 72.56	
Cancer	59.71	2.54	55.14, 65.43	66.29	2.09	62.57, 70.86	
Total	58.05	2.06	54.16, 62.30	66.55	1.65	63.72, 70.09	< 0.001
Social functioning							
Not cancer	66.05	3.25	60.47, 73.02	81.40	3.51	74.42, 88.37	
Cancer	74.00	2.71	68.86, 79.43	84.00	2.63	78.57, 89.43	
Total	70.97	2.03	67.43, 75.40	83.01	2.13	78.23, 86.73	< 0.001
Emotional role							
Not cancer	75.81	3.67	68.84, 83.26	90.00	2.42	85.12, 94.65	
Cancer	74.14	2.95	68.29, 80.00	85.00	2.22	80.57, 89.29	
Total	74.78	2.30	70.62, 79.38	86.91	1.68	83.45, 90.00	< 0.001

[a] "Bodily Pain" Short-Form Health Survey scale was renamed to indicate that a higher score (less interference from pain) is a more positive assessment.
CI—95% confidence interval; SEM—standard error of the mean

ing it. The general trend in declining use of other types of lymphedema self-care treatment was expected because the Flexitouch system promotes acute lymphatic drainage, as do self- and clinician-administered MLD and bandaging. The Flexitouch system may reduce self-care burden as well as patient and insurance expenses for clinician-administered MLD sessions. The slight decrease in wearing of garments raises a possible concern that participants may have discontinued that component of self-care despite receiving instructions to continue to use such garments as prescribed.

Limitations

Findings should be considered in relation to the study's limitations. First, post-therapy questionnaires were obtained from only 64% of participants. Data suggest that despite efforts to improve response rates from all participants, those responding were younger, had better global physical and psychological health scores, and had more problems with infections than those who did not respond. Thus, a possible response bias occurred. However, respondents' written and verbal comments included criticisms as well as praise, suggesting that respondents were willing to voice dissatisfaction. Second, use of a convenience sample of patients with lymphedema whose healthcare professionals requested the Flexitouch system limits the generalizability of findings. Third, information about volume improvement in the affected limb(s) was self-reported. Thus, only the patients' perceptions of change were provided; whether actual physical improvements of the limb(s) occurred is unknown. Fourth, the absence of a pure control group raises the possibility that the positive findings may reflect a placebo response. Despite the limitations, the study obtained valuable information.

Implications

Nursing Practice

Nurses who see patients with lymphedema always should ask what self-care practices patients are using to manage their lymphedema and how they perceive their self-care activities are affecting their lymphedema and their lives. As the Flexitouch system gains broader use, oncology nurses are likely

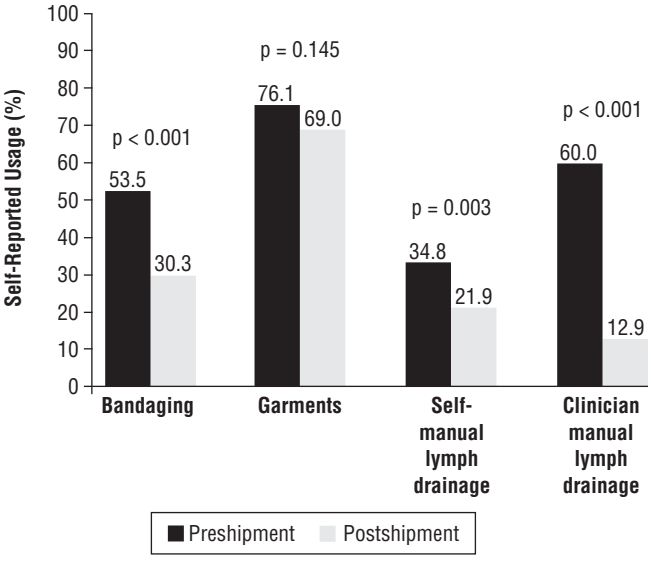

Figure 2. Use of Various Treatment Protocols Before and After Receipt of Flexitouch System

to see patients who are using the system. Because adherence with prescribed protocols may vary, nurses should ask patients using the system about the prescribed frequency and duration of treatment sessions and actual patient practice. They also should assess patients' use of other necessary self-care treatments, particularly garments and compression sleeves. Patients should be encouraged to follow all prescribed protocols. If they are confused about what self-care regimens they should follow, nurses may facilitate communication between the lymphedema treatment team and patients for clarification.

Future Research

Findings from this study suggest that, subjectively, most individuals with limb lymphedema perceive the Flexitouch system to be beneficial. Randomized clinical trials comparing limb volume change in individuals using the Flexitouch system to those using standard MLD treatment, limb-isolating pneumatic compression devices, or standard MLD used in conjunction with the Flexitouch system or limb-isolating pneumatic compression devices would provide valuable information about the objective clinical benefit of the system. Longitudinal studies comparing the cost-effectiveness of the device in patients using self-MLD to those using the device also are indicated. Such studies should include device cost; the number, duration, and severity of infections; cost of treating infections; cost for professional MLD or CDT required to maintain or regain limb volume reduction; and other expenses such as compression bandages or garments.

Conclusions

Surveys of therapy satisfaction are important outcome indicators that can be used to determine which variables are associated with treatment adherence and satisfaction and to guide further patient-specific protocol development. Results from the study suggest that patients using the Flexitouch system are satisfied with the system and perceive it as beneficial in managing their lymphedema.

Author Contact: Sheila H. Ridner, PhD, RN, can be reached at sheila.ridner@vanderbilt.edu, with copy to editor at ONFEditor@ons.org.

References

American Cancer Society. (2006). *Lymphedema: Understanding and managing lymphedema after cancer treatment.* Atlanta, GA: Author.

Armer, J.M., & Fu, M.R. (2005). Age differences in postbreast cancer lymphedema signs and symptoms. *Cancer Nursing, 28*(3), 200–209.

Armer, J.M., & Heckathorn, P.W. (2005). Postbreast cancer lymphedema in aging women: Self-management and implications for nursing. *Journal of Gerontological Nursing, 31*(5), 29–39.

Augustin, M., Bross, F., Foldi, E., Vanscheidt, W., & Zschocke, I. (2005). Development, validation, and clinical use of the FLQA-I, a disease-specific quality-of-life questionnaire for patients with lymphedema. *VASA—Journal for Vascular Disease, 34*(1), 31–35.

Balzarini, A., Pirovano, C., Diazzi, G., Olivieri, R., Ferla, F., Galperti, G., et al. (1993). Ultrasound therapy of chronic arm lymphedema after surgical treatment of breast cancer. *Lymphology, 26*(3), 128–161.

Bodenheimer, T., Lorig, K., Holman, H., & Grumbach, K. (2002). Patient self-management of chronic disease in primary care. *JAMA, 288*(19), 2469–2475.

Boris, M., Weindorf, S., & Lasinkski, S. (1997). Persistence of lymphedema reduction after noninvasive complex lymphedema therapy. *Oncology, 11*(1), 99–109.

Boris, M., Weindorf, S., & Lasinkski, S. (1998). The risk of genital edema after pump compression for lower limb lymphedema. *Lymphology, 31*(1), 15–20.

Browse, N., Burnand, K.G., & Mortimer, P.S. (2003). *Diseases of the lymphatics.* London: Hodder Arnold.

Cheville, A.L., McGarvey, C.L., Petrek, J.A., Russo, S.A., Taylor, M.E., & Thiadens, S.R. (2003). Lymphedema management. *Seminars in Radiation Oncology, 13*(3), 290–301.

Cormier, J.N., Davidson, L., Xing, Y., Evans, W.J., & Armer, J.M. (2006). Lymphedema is common among postoperative cancer survivors [Abstract 18524]. *Journal of Clinical Oncology, 24*(18, Suppl.).

Dunbar-Jacob, J., Erlen, J.A., Schlenk, E.A., Ryan, C.M., Sereika, S.M., & Doswell, W.M. (2000). Adherence in chronic disease. *Annual Review of Nursing Research, 18,* 48–90.

Ehrlich, A., Vinje-Harrewijn, A., & McMahon, E. (2005). *Living well with lymphedema.* San Francisco: Lymph Notes.

Erickson, V.S., Pearson, M.L., Ganz, P.A., Adams, J., & Kahn, K.L. (2001). Arm edema in breast cancer patients. *Journal of the National Cancer Institute, 93*(2), 96–111.

Eversley, R., Estrin, D., Dibble S., Wardlaw, L., Pedrosa, M., & Favila-Penney, W. (2005). Post-treatment symptoms among ethnic minority breast cancer survivors. *Oncology Nursing Forum, 32*(2), 250–256.

Fleissig, A., Fallowfield, L.J., Langridge, C.I., Johnson, L., Newcombe, R.G., Dixon, J.M., et al. (2006). Post-operative arm morbidity and quality of life. Results of the ALMANAC randomized trial comparing sentinel node biopsy with standard axillary treatment in the management of patients with early breast cancer. *Breast Cancer Research and Treatment, 95*(3), 279–293.

Gandhi, S.K., Salmon, J.W., Zhao, S.Z., Lambert, B.L., Gore, P.R., & Conrad, K. (2001). Psychometric evaluation of the 12-item Short Form Health Survey (SF-12) in osteoarthritis and rheumatoid arthritis clinical trials. *Clinical Therapeutics, 23*(7), 1080–1098.

Hurst, N.P., Ruta, D.A., & Kind, P. (1998). Comparison of the MOS Short Form-12 (SF12) health status questionnaire with the SF36 in patients with rheumatoid arthritis. *British Journal of Rheumatology, 37*(8), 862–869.

Johansson, K., Albertsson, M., Ingvar, C., & Ekdahl, C. (1999). Effects of compression bandaging with or without manual lymph drainage treatment in patients with postoperative arm lymphedema. *Lymphology, 32*(3), 103–110.

Johansson, K., Holmstrom, H., Nilsson, I., Ingvar, C., Albertsson, M., & Ekdahl, C. (2003). Breast cancer patients' experiences of lymphoedema. *Scandinavian Journal of Caring Sciences, 17*(1), 35–42.

Johansson, K., Lie, E., Ekdahl, C., & Lindfelt, J. (1998). A randomized study comparing manual lymph drainage with sequential pneumatic compression for treatment of postoperative arm lymphedema. *Lymphology, 31*(2), 56–64.

Kornblith, A.B., Herndon, J.E., Weiss, R.B., Zhang, C., Zuckerman, E.L., Rosenberg, S., et al. (2003). Long-term adjustment of survivors of early-stage breast carcinoma, 20 years after adjuvant chemotherapy. *Cancer, 98*(4), 679–689.

Kralik, D., Koch, T., Price, K., & Howard, N. (2004). Chronic illness self-management: Taking action to create order. *Journal of Clinical Nursing, 13*(2), 259–267.

Mayrovitz, H.N. (2007). Interface pressures produced by two different types of lymphedema therapy devices. *Physical Therapy, 87*(10), 1379–1388.

McMahon, E. (2005). *Overcoming the emotional challenges of lymphedema.* San Francisco: Lymph Notes.

McWayne, J., & Heiney, S.P. (2005). Psychological and social sequelae of secondary lymphedema: A review. *Cancer, 104*(3), 457–466.

Morgan, P.A., Franks, P.J., & Moffatt, C.J. (2005). Health-related quality of life with lymphoedema: A review of the literature. *International Wound Journal, 2*(1), 47–62.

Morrell, R.M., Halyard, M.Y., Schild, S.E., Ali, M.S., Gunderson, L.L., & Pockaj, B.J. (2005). Breast cancer-related lymphedema. *Mayo Clinic Proceedings, 80*(11), 1480–1484.

Pain, S.J., & Purushotham, A.D. (2000). Lymphedema following surgery for breast cancer. *British Journal of Surgery, 87*(9), 1128–1141.

Paskett, E.D., Naughton, M.J., McCoy, T.P., Case, L.D., & Abbott, J.M. (2007). The epidemiology of arm and hand swelling in premenopausal breast cancer survivors. *Cancer Epidemiology, Biomarkers and Prevention, 16*(4), 775–782.

Petrek, J.A., Pressman, P.I., & Smith, R.A. (2000). Lymphedema: Current issues in research and management. *CA: A Cancer Journal for Clinicians, 50*(5), 292–307.

Piller, N.B., & Thelander, A. (1998). Treatment of chronic post mastectomy lymphedema with low laser therapy: A 2.5 year follow-up. *Lymphology, 31*(2), 74–86.

Ramos, S.M., O'Donnell, L.S., & Knight, G. (1999). Edema volume, not timing, is the key to success in lymphedema treatment-evolution of the complex decongestive techniques. *American Journal of Surgery, 178*(4), 311–315.

Richmand, D.M., O'Donnell, T.F., Jr., & Zelikovski, A. (1985). Sequential pneumatic compression for lymphedema. A controlled trial. *Archives of Surgery, 120*(10), 1116–1119.

Ridner, S.H. (2005). Quality of life and a symptom cluster associated with breast cancer treatment-related lymphedema. *Supportive Care in Cancer, 13*(11), 904–911.

Rockson, S.G. (2001). Lymphedema. *American Journal of Medicine, 110*(4), 288–295.

Rowland, J.H., & Yancik, R. (2006). Cancer survivorship: The interface of aging, comorbidity, and quality of care. *Journal of the National Cancer Institute, 98*(8), 504–505.

Starritt, E.C., Joseph, D., McKinnon, J.G., Lo, S.K., de Wilt, J.H.W., & Thompson, J.F. (2004). Lymphedema after complete axillary node dissection for melanoma: Assessment using a new, objective definition. *Annals of Surgery, 240*(5), 866–874.

Townsend, C.M., Jr., Beauchamp, R.D., Evers, B.M., & Mattox, K.L. (2001). *Sabiston textbook of surgery: The biological basis of modern surgical practice* (16th ed.). Philadelphia: Saunders.

Ware, J.E., Kosinski, M., & Keller, S.D. (1996). A 12-item short-form health survey: Construction of scales and preliminary tests of reliability and validity. *Medical Care, 34*(3), 220–233.

Ware, J.E., Kosinski, M., Turner-Bowker, D.M., & Gandek, B. (2005). *How to score version 2 of the SF-12 Health Survey.* Lincoln, RI, and Boston: QualityMetric Incorporated and Health Assessment Lab.

Wilburn, O., Wilburn, P., & Rockson, S.G. (2006). A pilot, prospective evaluation of a novel alternative for maintenance therapy of breast cancer-associated lymphedema. *BioMed Central Cancer, 6*(1), 84–94.

Williams, A.F., Moffatt, C.J., & Franks, P.J. (2004). A phenomenological study of the lived experiences of people with lymphedema. *International Journal of Palliative Nursing, 10*(6), 279–286.