# BREAST CANCER RELATED LYMPHEDEMA
# THE FLEXITOUCH® SYSTEM AS AN ADJUVANT TO MAINTENANCE THERAPY

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## REASON FOR PRESENTING THE CASE STUDIES

More than 200,000 new cases of breast cancer are diagnosed annually in the U.S.[1] With early intervention and effective therapies, the majority of women can anticipate normal life-expectancies.[2] Unfortunately, side-effects of surgery and radiation may damage regions of the lymphatic system, resulting in upper extremity lymphedema.[3] An estimated 15-20% of breast cancer survivors develop the condition, characterized by increased arm volume, sensations of tightness and heaviness, and varying degrees of pain, functional impairment and quality of life deficits.[4,5] With progression, chronic inflammatory changes promote fibrosis; skin over affected areas becomes thicker, and more turgid; lymph fluid may leak through breaks in the skin leading to serious infection.[6,7]

Growing awareness of breast cancer related lymphedema has intensified the search for effective treatment. Consensus opinion supports use of a combination of techniques called complete decongestive therapy (CDT), a useful but demanding regimen whose initial benefits are difficult to sustain.[8,10] A recent pilot study utilizing the Flexitouch® Lymphedema System (Tactile Systems Technology Inc., Minneapolis, MN) as a replacement for self manual lymphatic drainage in the home demonstrated significant benefit.[9] These case reports describe the use of the Flexitouch system (FT) by two breast cancer patients after discharge from an in-clinic physical therapy program.

## CONCLUSION

Results of this eight-week evaluation of the FT suggest that it may be a superior alternative to self-MLD for long-term home management of breast cancer related lymphedema. With daily use, these patients' lymphedema was controlled, their symptoms alleviated and their quality of life improved. These outcomes along with a recent pilot study suggest that the FT should be considered as a part of out-patient lymphedema management programs.[9,15] Clinical studies to evaluate the long-term benefits of the device are warranted.

## CASE STUDY: JB STAGE II UNILATERAL LYMPHEDEMA

### Lymphedema Diagnosis

The subject is a 51 year-old woman diagnosed in November 2004 with lymph node-positive non-metastatic carcinomof the left breast [T2, N2, M0]. She underwent a left modified radical mastectomy with axillary dissection of 27 lymph nodes, nine of which were positive for cancer. Surgery was followed by courses of chemotherapy and radiation [January–June; July–September, 2005 respectively]. At the end of her final chemotherapy cycle, the patient developed unilateral stage 2 lymphedema (Figures 1-2.*)

*Figure 1*

*Figure 2*

### Medical History

The patient's medical history was non-significant for serious co-morbidities. Her records included documentation of hypertension, hypercholesterolemia, hypoglycemia, gastritis and seasonal allergies.

### Diagnostic Studies

The patient's initial tumor mass, visualized via mammography, measured 3 cm. Histological studies revealed a poorly differentiated (grade 3/3) infiltrative ductal carcinoma with the presence of vascular lymphatic invasion and tumor necrosis, calcification and multicentricity. Because the pathology findings indicated a high probability of local and/or systemic relapse, a complete metastatic workup was done. CT-scan of the chest, abdomen, and pelvis and a bone scan showed no evidence of metastatic disease.

### Physical Therapy

The patient was referred for lymphedema therapy by both her oncologist and radiation oncologist one week prior to starting radiotherapy. Professional physical therapy services were provided twice weekly for three months during and for one month following completion of radiation therapy for a total of 32 visits. Her physical therapy included a regimen of CDT, consisting of a multimodal course of 1) manual lymph drainage (MLD), 2) compression bandaging (CB) and 3) exercises and skin care.[10] The patient was fitted with a custom low stretch class II sleeve and glove for daytime and a compression device (Opera ReidSleeve®) for night time use during the physical therapy program. Additionally, the patient was instructed to perform self MLD and a variety of therapeutic exercises independently. Limb circumference measurements were taken weekly to monitor progress.

*Figure 3*

As occurs frequently even with lymphedema treatment, her degree of edema, skin turgor and associated fibrosis increased markedly during the three month period of radiation therapy.[11] At completion of the four-month physical therapy program, the patient was discharged to home therapy and provided with FT to provide the self MLD component of her home care. The remainder of her home care regimen included: compression garments and a glove; Opera compression sleeve, exercises and skin/nail care.

### Summary of Therapeutic Intervention

The patient began using the FT twice daily for 1½ hours in the morning and 1½ hours in the evening for eight weeks. (Figure 3.) The FT utilizes a two-phase preparation and drainage sequence which prepares the trunk and drains the limb much like MLD therapy. This device is designed to replace self MLD in the home as part of continued lymphedema therapy maintenance. Significant design elements include small curved garment chambers to redirect flow; inflation and deflation timing of one to three seconds in duration; and therapy application to the trunk and chest.[12] As with MLD, preparation therapy initiates at the trunk via specially designed trunk and chest garments. Therapy then progresses to a drainage

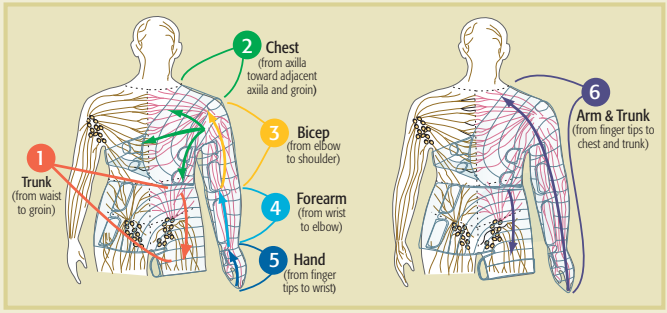


*Figure 4*

phase with an emphasis on the affected limb as well as the chest and/or trunk. (Figure 4.) The product design elements and treatment method are consistent with the principles of MLD therapy.

To monitor progress of the home care regimen, the circumference of the affected limb was measured weekly for eight weeks at the seven sites used for fitting custom compression sleeves. Results were compared to measurements taken at discharge from physical therapy. In addition, fibrosis was measured by clinical observation including evaluation of skin tightness and pitting. Functional status and dexterity were measured by evaluating fine motor movements.

### Analysis

Arm circumference measurement changes pre-and post therapy with the FT were non-significant. [dependent t-test (P = .973; alpha set at .05)] reflecting the ability of the FT to maintain improvements in limb girth that were achieved during CDT. (Figure 5.) Positive changes were also noted in skin turgor. Noted decrease in fibrosis was observed. Functional status was reported to have improved as well.

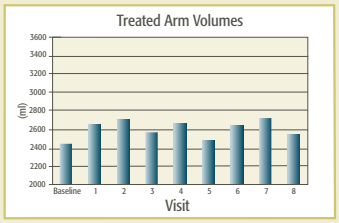


*Figure 5*

### Discussion and Treatment Outcomes

Lymphedema is not curable, but the condition can be controlled and often improved with a regimen of individually prescribed therapeutic strategies. One of the difficulties in managing lymphedema patients is the tendency for in-clinic therapeutic gains to dissipate during home maintenance.[13,14] In this patient, it is significant that after eight weeks of device usage, she was able to maintain limb girth. The patient had previously experienced continued worsening of edema symptoms. There were also clinically important changes in her skin fibrosis; tightness was reduced and softness and pliability increased, resulting in improved limb function and dexterity. Her dexterity and fine motor skill was improved such that she was again able to work with horses and even ride occasionally. This was a significant quality of life gain for this patient who had given up many of her usual activities due to limitations in her motion and dexterity. In a large proportion of patients receiving professional in-clinic lymphedema therapy, discontinuation of treatment is followed by progressive worsening of symptoms.[13,14] In this patient, incorporating the FT at home allowed her to maintain her limb volume and improve functionality.

The subject was compliant with device usage which also likely contributed to the positive outcomes in this case report. Because the device is technique independent, the subject was able to provide therapy without concern for many of the physical and psychological barriers to treatment adherence that contribute to high rates of long-term failure with MLD. It is hypothesized that these distinguishing features may contribute to a patient's improved ability to manage his/her lymphedema in the home.

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## CASE STUDY: GF STAGE II UNILATERAL LYMPHEDEMA

### Lymphedema Diagnosis

The patient is a 47 year-old woman diagnosed in December 2004 with carcinoma of the right breast with extensive axillary lymph node metastasis. A radical modified mastectomy was performed shortly after diagnosis. Four months after the surgery, the patient was diagnosed with right unilateral stage 2 lymphedema. (Figures 6-8.*)

*Figure 6*

*Figure 7*

*Figure 8*

### Medical History

The patient's medical history was non-significant for serious co-morbidities. Her records included documentation of bilateral tubal ligation and ovarian cyst removal.

### Diagnostic Studies

The surgical pathology report documented a tumor mass measuring 8.8 x 5.0 cm with well differentiated cellular architecture and focal lymphatic invasion. Histological studies revealed T3, N1b, MO carcinoma of the breast with lymphatic invasion. Five of eight excised nodes were positive including one measuring 2 cm with evidence of extracapsular extension. The tumor was ER/PR positive and HER positive. Consistent with the pathology findings, a complete metastatic workup was done. CT-scan of the chest scan showed no evidence of metastatic disease.

### Physical Therapy

The patient was scheduled to begin lymphedema therapy one week before initiation of a course of radiotherapy. She received a total of 32 professional lymphedema treatments provided at intervals of twice weekly for three months during and for one month following completion of radiation therapy. Her CDT regimen consisted of a multimodal course of 1) manual lymph drainage, 2) compression bandaging, 3) exercises and 4) skin care.[10] During the physical therapy program, the patient was fitted with a custom class II sleeve and glove for daytime wear and an Opera ReidSleeve for nighttime use. As part of the program, the patient was taught and asked to perform self manual lymph drainage and a variety of therapeutic exercises independently. Progress was monitored with weekly limb circumference measurements. Unfortunately, despite her participation in this aggressive CDT program, the patient's degree of edema, skin turgor and associated fibrosis increased markedly during a three month period of radiation therapy.[11] At completion of the four-month physical therapy program, the patient was discharged to home therapy and provided with FT to provide the self MLD component of her home care. The remainder of her home care regimen included: compression garments and a glove; Opera compression sleeve, exercises and skin/nail care.

### Summary of Therapeutic Intervention

The patient began using FT twice daily for 1½ hours in the morning and 1½ hours in the evening for eight weeks. The patient was instructed to utilize the FT daily in place of self MLD. Progress was monitored with eight weekly measurements of the affected limb at each of the seven sites used for fitting custom compression sleeves and then compared to the measurements taken at discharge from physical therapy. Additional outcomes measured include fibrosis, pain, and functional status. FT therapy was discontinued at the end of week six when the patient developed active cellulitis and required antimicrobial therapy. The infection was not attributed to the subject's use of the FT. After four days, treatment was resumed to complete the eight week trial.

### Analysis

Changes in arm circumference post FT therapy were significant [dependent t-test ($P = .022$; alpha set at .05)] at six weeks and non-significant at eight weeks ($P = .975$). Figure 9 illustrates the comparison between the treated arm (Tx Arm) and the non-affected arm (Norm Arm). Figure 10 documents the changes in edema volume from baseline to conclusion of treatment with FT after week eight. (Visit 8) Edema volume decreased from an initial value of 733 ml (29.2% edema) to 315 ml at week six (12.9% edema).

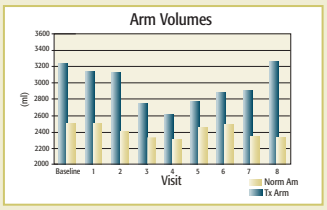


*Figure 9*

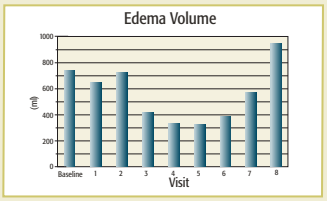


*Figure 10*

Unfortunately, the cellulitis episode that occurred at the end of week six resulted in a loss of these therapeutic gains in volume reduction. Gains achieved in fibrosis, skin texture, limb function and dexterity although impacted by the infection, were regained quickly once the infection subsided.

### Discussion and Treatment Outcomes

Although chronic and incurable, lymphedema can often be controlled with a regimen of individually prescribed therapeutic strategies. In this breast cancer patient, despite early participation in an aggressive CDT program before, during and after radiotherapy, radiation-induced injury to the lymphatic system resulted in rapidly worsening lymphedema.[13,14] Because the patient's condition could not be controlled with traditional CDT alone she was enrolled in an eight week trial of adjuvant therapy with the FT.

The patient was compliant with her daily therapy and the intervention proved successful; at the end of week six, her limb circumference was reduced significantly. She experienced favorable changes in her other symptoms; fibrosis-related skin tightness was reduced and softness and pliability increased. Limb function and dexterity improved markedly. As edema decreased in her hand, fine motor movement became smoother and improved. The patient was able to quantify the improvement in her fine motor skills by being faster at her cashier job. Unfortunately, at the end of week six, the patient experienced an episode of acute cellulitis that caused interruption of therapy for four days. The occurrence of this infection likely affected her continued progress. At the end of week eight, her limb measurements had returned to baseline. Because the patient was unavailable for continued therapy beyond the eight week period, we are unable to report on the long term ability to regain the volume reductions that were initially realized. Other gains in skin texture, limb function and dexterity were quickly regained after the infection.

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* The patients agreed to participate in this study and signed an informal consent document (Figures 1, 2, 6, 7 and 8.)


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