Programmable Intermittent Pneumatic Compression as a Component of Therapy for Breast Cancer Treatment-Related Truncal and Arm Lymphedema

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Programmable Intermittent Pneumatic Compression as a Component of Therapy for Breast Cancer Treatment–Related Truncal and Arm Lymphedema

Tina M. Hammond[1] and Harvey N. Mayrovitz[2]

Abstract

Lymphedema is a chronic condition often requiring lifelong treatment to avoid worsening of extremity and trunk swelling with concomitant complications. The physiological basis for truncal treatment, although clinically recognized, until recently, was not well documented. Herein, we expand on earlier work by reporting on clinical outcomes, therapist observations, and subjective impressions of five patients with truncal lymphedema whose in-home self-treatment includes the Flexitouch® system (FT) pneumatic device. Patients received in-clinic complete decongestive therapy and in-home self-care including FT. Results, determined after 2 months of treatment, showed reductions in trunk and arm swelling, fibrotic tissue softening, pain reduction, and improved range of motion and flexibility. Patients reported that FT was easy and comfortable to use and enhanced in-home compliance. Results suggest that limb and trunk lymphedema can be effectively treated in the home with an advanced programmable pneumatic device with truncal coverage, such as the FT system.

Keywords

lymphedema, intermittent pneumatic compression, truncal edema, self–home care

Introduction

Lymphedema, defined as an abnormal accumulation of high-protein fluid in the tissues, is a chronic condition requiring long-term, often lifelong, treatment (Kornblith et al., 2003). Although lymphatic swelling typically presents in an affected limb, it is not always confined to the limb. Oftentimes, edema appears in the chest or breast, back, abdomen, hips, and/or buttocks. This truncal edema may be restricted to the trunk or extend to extremities as a result of lymphatic overload. As with lymphedema of the extremities, truncal lymphedema can result from lymph node dissection, radiation treatment, surgical procedures (Szuba & Rockson, 1998) or blockage of the lymphatics because of scarring, fibrosis, or adhesions (Warren & Slavin, 2007). Truncal edema is difficult to quantify, as there are no validated methods for measuring truncal edema although a new tissue water measurement method may improve this situation (Mayrovitz, 2007; Mayrovitz, Davey, & Shapiro, 2008).

The standard of care for lymphedema with or without truncal involvement is complete decongestive therapy (CDT) performed by a skilled therapist as often as twice daily for 1 to 6 or more weeks (Cohen, Payne, & Tunkel, 2001; Szuba & Rockson, 1998). CDT includes a combination of manual lymphatic drainage (MLD), multilayered low-stretch bandaging, skin care, and exercise (Korosec, 2004; Lawenda, Mondry, & Johnstone, 2009; Rockson et al., 1998). The goals of CDT are to improve lymphatic drainage and reduce swelling. Because of the chronic nature of lymphedema, another important goal of in-clinic treatment is training the patient in preparation for in-home self-care (National Lymphedema Network, 2006).

Continuity in treatment from acute care to home management is critical to avoid worsening of the swelling and associated complications (Ridner, McMahon, Dietrich, & Hoy, 2008; Szuba & Rockson, 1998), including progression or worsening of the edema (Morgan, Frandks, & Moffatt, 2005), skin changes such as fibrosis and infections (Morgan et al., 2005; Szuba & Rockson, 1998), pain that may be debilitating (Morgan et al., 2005), impaired range of motion and mobility and decrease in physical activity (Ridner, 2005), poor body image (Ridner, 2005; Rose, Taylor, & Twycross, 1991), and other psychosocial effects (Cohen et al., 2001). The goals of

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self-care are to maintain or improve reductions in the edema achieved during CDT and to reduce the risk of complications. Conservative self-care in the home includes the following elements: self-MLD, skin care, self-examination to detect diagnostic hallmarks of cellulitis, compression bandaging and/or wear and care of garments, weight control, and exercise (National Lymphedema Network, 2006). As defined by the Centers for Medicare & Medicaid Services (CMS), conservative in-home self-care must include either a compression bandage or garment system. After a 4-week trial of conservative in-home care with significant symptoms remaining, pneumatic compression devices can be used as it is a benefit covered by Medicare (Department of Health & Human Services, Centers for Medicare & Medicaid Services, 2001). Advanced pneumatic devices may be covered when a lesser pneumatic device has been used without treatment success or in cases where the patient has unique characteristics that preclude effective treatment with a nonsegmented device (E0650) or a noncalibrated device (E0651). Note, criteria may differ based on the specific third-party payer; however, these factors are generally included in most commercial payer criteria as well as Medicare.

Significant barriers exist to the successful treatment of truncal and limb lymphedema, particularly in the home setting. The affected areas may be difficult to reach because of impaired mobility (Ridner et al., 2008) or because of their location, such as the back. The location of the affected area also complicates application of compression bandaging, which proves much more difficult to apply to the trunk than to the extremities. Self-care is emotionally challenging because of the daily time required (Ridner et al., 2008; Rose et al., 1991). Self-MLD is physically demanding and requires the patient's complete attention (Cheville, 2007). These demands inhibit the patient's ability to maintain compliance, particularly as the patients are often coping with cancer or its aftermath. This self-care regimen may also lead to repetitive stress injuries of the already compromised limb or unaffected limb.

Effective home treatment, especially of the truncal region, is difficult. However, failure to treat the truncal lymphatics presents significant additional risks including development of a fibrous band at the limb junction and development of new areas of edema in the truncal quadrant adjacent to the affected limb. Ineffective treatment may result in pain in the back, chest, shoulder, worsening neuropathic pain in the fingers, and infection.

Despite diligent efforts to adhere to the in-home treatment regimen many patients experience exacerbations of lymphedema or infections and require further rounds of in-clinic treatment including CDT or antibiotic treatment (Ridner et al., 2008). Although the specialized attention provided by therapists is often psychologically supportive to patients (Rose et al., 1991), the costs associated with cycling through multiple sessions of CDT escalate. Some third-party payers do not cover repeated CDT sessions, creating financial burdens for patients (Ridner et al., 2008). Treatment improvements that can ease the physical and emotional burdens of in-home self-care while maintaining or improving outcomes are needed.

Figure 1. Flexitouch® fitted for treating upper extremity. Upper extremity system includes arm, chest, and trunk garments
Source: Reprinted with permission from Tactile Systems Technology, Inc.

The Flexitouch® system (FT; Tactile Systems Technology, Inc., Minneapolis, MN) is an advanced, programmable pneumatic device with a therapeutic approach based on the anatomy and physiology of the lymphatic system (Tactile Systems Inc., 2008). Therapy consists of the dynamic application of mild pressure directed over specific lymphatic pathways. FT has features that can address certain treatment barriers associated with truncal lymphedema. The FT trunk garments provide treatment to the shoulder, breast, back, abdomen, buttock, and suprapubic area (see Figure 1). The programmable features of FT are designed to simulate MLD, including initial proximal truncal treatment (preparation) followed by drainage. FT delivers a therapeutic pressure that is relaxing and mild, applied in a dynamic pressure and release rhythm, as opposed to the squeeze-and-hold action of other pumps. FT device programming allows therapy to be tailored to meet the specific needs of patients such as those with wound sites, ulcers, or painful areas. This article expands on an earlier work that provided the physiological basis for truncal treatment for individuals with lymphedema (Mayrovitz, Brown-Cross, Mayrovitz, & Golla, in press). Although the clinical need for truncal treatment has been well recognized (Foeldi, 1994), clinical outcomes in this area have not been evaluated. This article reports on the clinical outcomes, therapist observations, and subjective impressions of patients

Table 1. Patient Clinical Features

Patient	Surgical Procedure	Nodes Removed	Radiation Treatment	Chemo Treatment	Lymphedema Locations	In-Clinic FT Use (% of Visits)
1	Mastectomy	12	Yes	Yes	Arm and trunk	0
2	Mastectomy	14	Yes	Yes	Arm and trunk	64
3	Mastectomy	20	Yes	Yes	Arm and trunk	58
4	Lumpectomy	23	Yes	Yes	Arm and trunk	40
5	Lumpectomy	6	Yes	No	Arm and trunk	67

Note: Some patients received in-clinic FT treatment and all used FT as a component of at-home self-care.

with truncal and limb lymphedema following in-clinic and home treatment including FT.

Materials and Methods

Patients

Persons included in this case study series consisted of five female patients (46-66 years of age) who had previously been diagnosed with breast cancer treatment– related lymphedema in the upper extremity and trunk that had been referred for in-clinic lymphedema therapy. Four out of five of these individuals had been unsuccessful in controlling lymphedema symptoms at home as demonstrated by increased swelling in the limb and trunk when they presented at the clinic. One individual was newly diagnosed. On examination in the clinic, all patients demonstrated signs of truncal edema based on palpation and on the asymmetrical appearance of the chest, back, and/or trunk areas. The clinical features of these patients prior to treatment are summarized in Table 1. Clinic treatment consisted of a combination of MLD and FT as follows. For Patients 2 through 5, the affected arm was treated with FT and while it was operating MLD was performed on the neck, sternum, contralateral torso, and inguinal area. This procedure was, on average, used on more than half of the clinic visits, but on some visits only MLD was used. Table 1 indicates the frequency of FT in-clinic use for each patient. Patient 1 received MLD treatment in clinic and also used the FT at home. In addition, all patients received in-clinic exercise and short-stretch compression bandaging and/or compression garments for the affected arm. The in-home self-care regimen, which was introduced during the course of the clinic visits, included exercise, skin care, dietary and nutritional recommendations, short-stretch bandaging, and compression garments (including in some cases compression bra, tank, or pantyhose) and instruction in use of the FT system. All patients used the FT as part of their daily home care program initiated toward the end of their in-clinic treatment.

Measurements and Assessment Parameters

Truncal changes were estimated by determining the change in average truncal circumferences based on measurements

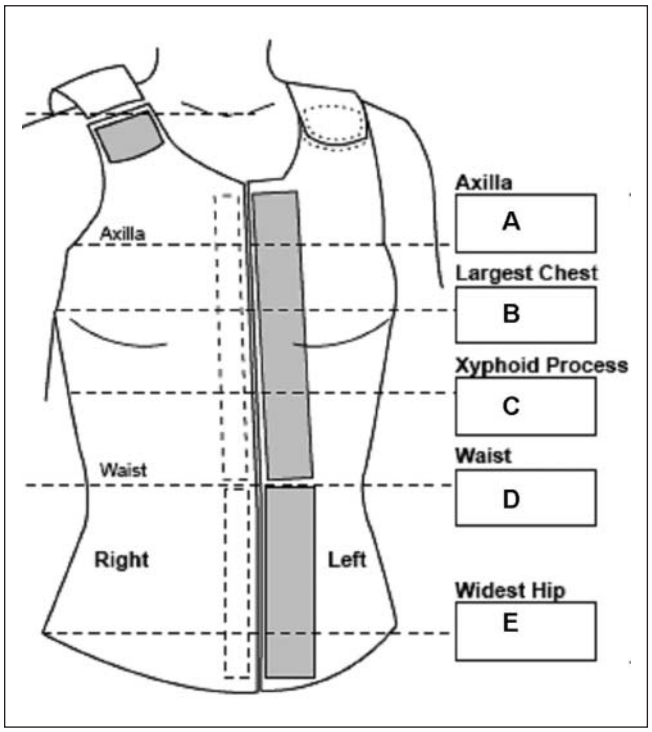

Figure 2. Trunk circumference measurement sites.
All circumferences are measured with a calibrated fixed tension tape measure
Source: Reprinted with permission from JoV.Pak Corporation.

before starting treatment and after 2 months of therapy sessions with FT. The circumferential measurements were made using a calibrated controlled tension tape measure (Gulick type; www.jansenmedical.net). The truncal circumference change for each patient was determined as the average of the changes at each of the five measured sites A through E as referenced in Figure 2.

Arm circumferences were measured either automatically using a Juzo® Perometer (Model 2000; Juzo, Cuyahoga Falls, OH) or manually using the tape measure at 4-cm intervals along the arm starting at the wrist. Both methods were used at different times because at the time of a given evaluation, the Perometer was not always available for use. The Perometer is an optoelectronic measuring device in which

the arm is scanned to determine the arm circumference at standardized sites (Stanton, Northfield, Holroyd, Mortimer, & Levick, 1997; Tierney, Aslam, Rennie, & Grace, 1996). With both the automated and the manual method, the measured circumferences were used to calculate arm volume based on a truncated cone model (Karges, Mark, Stikeleather, & Worrell, 2003; Mayrovitz, 2003). For the Perometer, the algorithm is automated. In the case of manual measurements, volume is determined by a validated software algorithm (Limb Volumes Professional 5.0; www.limbvolumes.org). Volumes obtained based on perometer and manual methods have been shown to agree closely (Mayrovitz, Sims, & Macdonald, 2000).

In addition to the quantitative measures, patients provided subjective impressions of their experience, and the therapist made clinical observations regarding changes in fibrosis, range of motion and mobility, compliance with at-home treatment, and other parameters. Written informed consent was obtained from the patients to review their records, obtain measurements, and report subjective information.

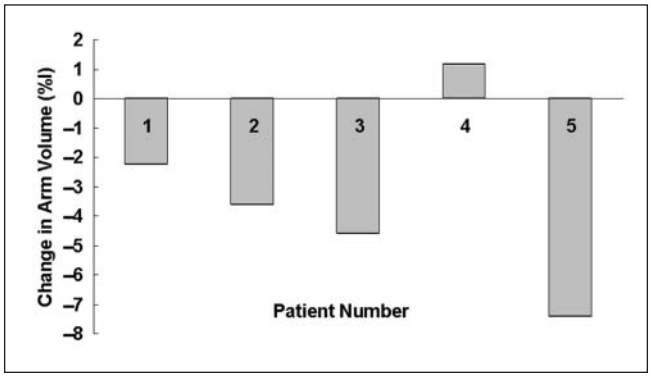

Figure 3. Change in affected arm volumes. The percentage changes in arm volume for each patient are based on the difference between the values prior to initiating treatment and the values after 2 months.

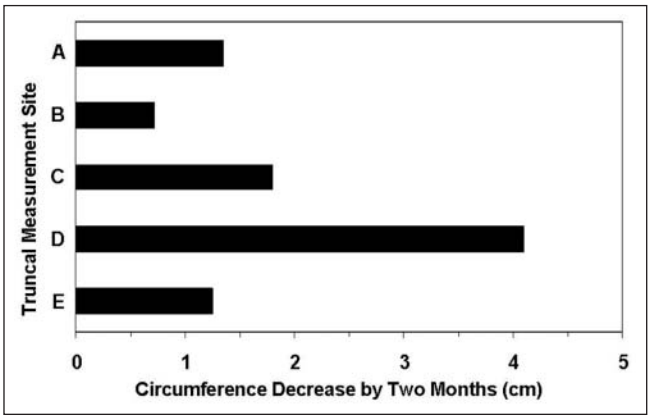

Figure 4. Decreases in truncal circumference. Values shown are the average decreases in centimeters for each measurement site defined by Figure 2.

Results

Limb Volume Changes

Affected limb volumes of four of the five patients decreased after 2 months of in-clinic therapy supplemented with FT usage as shown in Figure 3. The range of reduction was from 2.2% to 7.4%. In one patient (Patient 4), volume increased slightly (1.2%), which may have been related to the fact that during the time of her in-home treatment she was caring for a terminally ill family member so there may have been an understandable lapse in her compliance to the recommended self-therapy regimen as well as an exacerbation of edema because of stress-related issues.

Trunk Circumference Changes

The average reductions in trunk circumferences for measured sites are shown in Figure 4. It may be noted that all measured sites (defined by Figure 2) showed a reduction in circumference with the largest reduction (4 cm) at Site D (waist).

Patient Self-Reporting

Patients cited self-MLD as the component that most limited their well-intended compliance to self-administered home care. This was especially true when they had coexisting morbidity that included arthritis in two patients, carpal tunnel syndrome in one patient, or repetitive stress injuries and tendinitis that interfered with their self-MLD efforts as reported by three patients. Therapist and patient observations revealed that, in two patients who were affected by fibrosis prior to the start of treatment, the fibrotic tissue softened after incorporating FT treatment. One of these had firm radiation fibrosis of the pectoral/axillary area that softened noticeably very soon after initiation of FT. One patient, who prior to treatment had a significantly limited range of motion, reported increased flexibility after incorporating FT system usage in her clinic and home care regimen. All patients reported decreases in pain, tightness, and stiffness after FT use. Patients also reported that they were better able to comply with the various other components of self-care after incorporating FT treatment. The patients reported that self-treatment with FT was effective without undue interference in their daily lives.

All patients reported increased voiding volume and frequency after incorporating FT treatment in comparison to pre-FT use. These are encouraging by-products of effective lymphatic flow from the tissues and into the general circulation. As blood passes through the kidneys, they regulate the influx of excess fluid in the blood by eliminating these fluids

via urination. Patients reported FT to be comfortable during treatment and easier to use than self-MLD. Patients also reported improvement in activities of daily living.

Discussion

Lymphedema is a chronic and often debilitating condition that is increasingly being seen in patients receiving home health care and throughout the general population. Substantial risks of complications are associated with failure to recognize its presence because, without treatment, the condition grows progressively worse. Risks are also associated with inadequate or incomplete therapy. Therapeutic truncal clearance, conducted prior to or in conjunction with a program of lymphedema therapy, is universally accepted by professional therapists as being an essential part of therapy but is often rejected by third-party payers, in part because of inadequate understanding of its essential role. Although this therapeutic component is based on sound physiological principles, there has not been, nor will there likely be, peer-reviewed testing because it is deemed unethical to subject patients to therapy without truncal treatment. The anatomical and physiological basis for its use have been described in the hope that a greater understanding of its underlying principles would result in a better recognition of its need as an essential component of lymphedema therapy (Mayrovitz et al., in press). Therein, it was also emphasized that effective lymphedema therapy, including truncal treatment, could be provided using advanced programmable intermittent pneumatic compression devices such as the FT®. In the present article, a series of case studies have been presented so as to provide further discussion and concrete examples of its use and outcomes.

In this regard, it is important to realize that the physical and emotional requirements of in-home self-care for lymphedema are especially demanding (Ridner et al., 2008), and as a result, compliance is commonly poor even for committed, disciplined patients, often leading to worsening of the swelling or complications and necessitating repeat visits for intensive, expensive in-clinic CDT (Ridner et al., 2008; Szuba & Rockson, 1998). The FT®, because of its automated features, its ease of use, and its high comfort factor, can ease the physical and emotional burdens of in-home self-care while maintaining or improving beneficial effects. The cases presented herein attest to this. For example, during in-home self-care including FT, four of the five patients experienced reductions in measured limb volume, and all experienced a decrease in truncal swelling. The one patient who did not experience limb volume reduction was providing care for a dying loved one; the resulting stress and physical and emotional demands placed on her may have reduced her compliance, a possibility that emphasizes the need to make in-home care as comfortable and accessible as possible.

In addition to these positive outcomes, therapist and patient observations indicated softening of fibrotic tissue, reductions in pain, and improvements in range of motion and flexibility after implementing FT treatment. Patients reported that FT was easy to use and comfortable. Enhanced compliance with in-home treatment incorporating FT may reflect the patients' perception that their self-treatment was effective and did not interfere with their daily lives. At the time of this writing, none of the patients had returned to the clinic for follow-up treatment because of a lymphedema exacerbation and are apparently controlling their truncal and limb lymphedema successfully in the home.

Results of this case series illustrate the importance of truncal treatment and suggest that lymphedema can be effectively and safely treated in the home with a pneumatic device that provides truncal coverage, such as the FT system. While these patients presented with truncal involvement, the physiological basis and need for truncal treatment in patients with limb lymphedema, even in the absence of observed truncal swelling, is an important part of the standard of care for lymphedema (Mayrovitz, in press). Additional studies evaluating the use of this device in patients without observed truncal swelling would be warranted to further explore the significance of this treatment.

Conclusion

The incidence of breast cancer is 12.7% according to the National Cancer Institute estimates. As historically between 20% and 35% of breast cancer survivors develop lymphedema at some point, the overall burden is large. This suggests a growing need for skilled in-home lymphedema care when the challenge of adequate self-care becomes insurmountable. Comorbid diagnoses of blindness, cognitive, or physical dysfunction can be indicators of such need at home.

Often lymphedema therapists recommend and recruit in-home nursing care services to assist patients when self-care is insufficient. Without continued maintenance at home, therapists recognize that lymphedema progressively worsens. When this is the case, nursing scope of practice, capability, and training is a strong compliment to conducting lymphedema care in the home. Although nurses are generally not trained in lymphedema therapy, they can quickly learn and adapt the necessary techniques from lymphedema therapists as part of the patients' transition to home care.

Nurses are experts in assessing patients' level of assistance, physical or cognitive abilities, duration of need, and severity of the lymphedema. Other lymphedema therapy components for home care nursing can be included in training to include skin care, wound care, taking measurements, lymphatic drainage, FT assistance, compression bandaging, donning compression garments, guiding decongestive exercise, emotional care and support, documentation, managing supplies, medications, and care staff.

The growing numbers of patients with lymphedema who require skilled in-home nursing care for their lymphedema

may now or in the near future represent an increased demand for home health care nurses who are skilled in lymphedema care at home.

Declaration of Conflicting Interests

Dr. Mayrovitz indicates he is now a scientific advisor to Tactile Systems Technology Inc., but declares no conflict of interest with respect to the authorship or the publication of this article. Tina Hammond declares no conflict of interest.

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Bios

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Tina Hammond, PTA, CLT-LANA has been working with lymphedema patients as a certified lymphedema therapist since 1995. She has conducted multiple lymphedema education classes and in-services for the medical community and patients during that time, and is currently working toward her DPT.