Identification and Impact of Standard Treatment Protocols on the Impairments and Activity Limitations Related to Lower Extremity Lymphedema

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IDENTIFICATION AND IMPACT OF STANDARD TREATMENT PROTOCOLS ON THE IMPAIRMENTS AND ACTIVITY LIMITATIONS RELATED TO LOWER EXTREMITY LYMPHEDEMA

By

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A DISSERTATION

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IDENTIFICATION AND IMPACT OF STANDARD TREATMENT PROTOCOLS ON THE IMPAIRMENTS AND ACTIVITY LIMITATIONS RELATED TO LOWER EXTREMITY LYMPHEDEMA

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Lower Extremity Lymphedema is a chronic condition characterized by swelling of a body part. It is typically treated with Complex Decongestive Therapy (CDT) to reduce volume. While volume reduction is the primary goal of the treatment, third party payers often require the presence of activity limitations in order to qualify for coverage. The purpose of this dissertation was to identify the types of impairments and functional limitations that occur in this population. A second goal was to determine if volume reduction from CDT is sufficient to resolve the impairments and activity limitations associated with lymphedema, or if traditional physical therapy is necessary to resolve them.

In Chapter 2, we performed a study to validate several tools to measure the change in volume that occurred with CDT. Also, a reliability study was performed on the Perometer. The results of this study found that the Perometer had excellent test-retest reliability (ICC = .99) and that the change measured by the Perometer agreed better with the change measured by the “gold standard” water displacement method, (ICC = .99) than did the change measured by the circumferential tape method (ICC = .92).
In Chapter 3, we conducted a cross sectional analysis to determine the baseline impairments and activity limitations associated with lower limb lymphedema. Subjects scored below normal values in all measures of impairments and activity limitations including active range of motion to ankle dorsiflexion and knee flexion, Heel Rise, 30 Second Chair test, Berg Balance Score (BBS), Limits of Stability (LOS), Extended Timed Get Up and Go (ETGUG), Limitation in Mobility Activities Test (LIMAT) and SF-36 Medical Outcomes Study (SF-36). Subjects with severe vs. moderate lymphedema demonstrated scored significantly worse on all tests except ETGUG. Limb Volume was correlated at a fair level with all impairment and activity limitation measures except SF36 which produced a strong correlation. Impairment measures correlated strongly with activity limitations.

In Chapter 4, we performed a longitudinal study to address several questions. Were reductions in limb volume related to improvements in impairments and activity limitations? What proportion of subjects completing 2-weeks of CDT continued to have balance impairments or activity limitations severe enough to increase the risk of falling? In subjects at increased risk of falling, does a 4-week standard physical therapy intervention produce improvements in both impairments and the activity limitations? The change in limb volume was significant after the 2 week CDT intervention. However, the loss of volume was not strongly associated with an improvement in impairments or an increase in function over the two week or additional 4 week treatment intervention. Traditional physical therapy intervention produced significant improvements in activity limitations and body function impairments.
In Chapter 5, we discussed the clinical and health care policy implications of this research. It was determined that the standard CDT treatment protocol was not sufficient to address impairments and activity limitations other than edema in subjects with lower limb lymphedema. A comprehensive evaluation of these patients requires a traditional physical therapy examination in addition to the volume evaluation to assess the associated impairments and activity limitations. Third party payer coverage guidelines require that the patient be educated to maintain the reduction in limb volume achieved by CDT. This study found a worsening of the edema occurred 4 weeks after termination of the CDT. Policy guidelines were originally developed for individuals with upper extremity lymphedema and may need to be modified for subjects with lower limb edema because of substantial differences in the types of impairments and limitations in mobility and function that occur when the lower limb is involved.
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CHAPTER 1: INTRODUCTION

Lymphedema is a condition caused by damage to or insufficiency of the lymphatic system.[1-3] Lymphedema is the accumulation of interstitial fluid in the body as a result of any reduction in the capacity of the lymphatic system to drain fluid from the interstitium and return it to the blood circulation.[4] The lymphatic system provides a one-way path for the movement of lymph back into the blood vessel system.[5] Lymphedema signs include an enlargement of limbs and/or facial and truncal areas.[6-9] Symptoms of lymphedema include heaviness, pain or numbness of the affected area as well as restricted movement.[10-12] Lymphedema can be treated with a standard course of complex decongestive therapy (CDT) by a certified physical therapist.[13]

Conceptually, CDT is based on the anatomy and physiology of the circulatory system. Starling[14] first described fluid exchange at the capillaries and venules based on the Starling equation, 10% of fluid within our blood circulatory system leaks out into the interstitial space. This excess fluid is transported back into the blood circulatory system via the lymphatic system.

Lymphatic transport begins at the initial lymphatic vessels which are located throughout the entire body and make up a network of superficial vessels that collect the excess interstitial fluid. Once in the lymphatic system, the fluid becomes lymph.[15] The initial lymph vessels then drain to lymph collectors that contain lymphangions which are pumping stations for the lymphatic system. Manual lymphatic drainage (MLD) stimulates the lymphangions to pump at a faster rate. The collectors drain to the lymph
nodes which ultimately deliver the lymph back into the blood circulation and eventually to the heart.\textsuperscript{[10]}

Manual lymphatic drainage (MLD) is a manual technique which moves the lymph from edematous areas to non-edematous regions of the body. Healthy lymphatic vessels can then remove the lymph.\textsuperscript{[16]} The body is divided into superficial lymphatic “watershed” territories so that the right and left head and neck regions drain to the right and left cervical lymph nodes. Right and left upper limbs and upper trunk drain into the right and left axillary nodes while right and left lower trunk and lower limbs drain into the right and left inguinal nodes.\textsuperscript{[17, 18]} (Figure 1.1)

Fig. 1.1 Watersheds and Lymphotomes

In addition to the MLD, three other components comprise the treatment for lymphedema; compression therapy, skin care, and exercise usually follow MLD. Compression bandages applied to the limbs often contain padding and foam adjacent to the skin. These bandages maintain pressure on the skin increasing the interstitial pressure, thus decreasing “leakage” from the capillary vessels. Also, as the lymphatic
system draws fluid away from the edematous limb area, the bandages continue to compress further. Skin care is imperative to maintain skin integrity and avoid infection. Dry skin is vulnerable to breakdown especially during compression therapy. Once compressed, an exercise program to stimulate the lymphatics is performed with the bandages applied to the affected area.\textsuperscript{[10, 15, 19]}

Many studies of the treatment of lymphedema have focused on breast cancer related lymphedema (BCRL).\textsuperscript{[1, 6, 12, 20-23]} As awareness of the effectiveness of treatment for the upper limb lymphedema has been disseminated to the medical community, other diagnoses involving other parts of the body including face, chest wall, genitalia and lower limbs have been receiving similar treatment.\textsuperscript{[12, 24-26]} Studies investigating the positive effects of CDT on the quality of life have been studied for the upper limb.\textsuperscript{[8, 27]}

Fewer studies have demonstrated the effectiveness of volume reduction using CDT in lower limb lymphedema than in upper limb lymphedema.\textsuperscript{[28-30]} However, baseline impairments, other than edema, have not been examined in the literature.\textsuperscript{[29]} The effectiveness of CDT treatment for neither the changes in function of the lower limb nor the quality of life of the individual with the condition have not been studied.\textsuperscript{[31, 32]}

The importance of the identification of impairments and activity limitations in the population of patients with lower limb lymphedema is essential for treatment justification for third party payers. The insurance companies, particularly Medicare, have limitations on the coverage of care for lymphedema patients\textsuperscript{[33-36]} which include a maximum of 10 visits or two weeks whichever comes first, and require activity limitations as a prerequisite to receive the care.\textsuperscript{[33, 36]}
This study is intended to: a) identify the baseline impairments and activity limitations of subjects with lower limb lymphedema b) determine the effectiveness of the treatment delivery, under Medicare Guidelines, for reduction of activity limitations and c) compare Medicare’s standard criteria of 2 week or 10 visits lymphedema treatment versus Medicare’s standard criteria of 2 week or 10 visits lymphedema treatment and traditional physical therapy intervention, using strengthening, range of motion and balance, to address activity limitations.

This manuscript will provide a thorough description of the anatomy and physiology of the lymphatic system. Specifically, the anatomy section will describe the peripheral and central regions of the lymphatic system. Within the peripheral system, the divisions of structure between the superficial and deep collectors, capillaries, precollectors, and ultimate collectors will be described. The analysis of the central system will describe the structural pathway to final deposition into the blood circulation system including trunks, cisterna chyli, thoracic duct and lymphotomes. The physiology of the lymphatic system will describe the motoricity of the system through the lymphangions and their contractility and conclude with the immune function, fluid homeostasis and nutritional function of the lymphatic system. The anatomy and physiology is followed by identification of the clinical conditions causing lymphedema in order to understand the pathology involved in development of lymphedema. Since activity limitations are the focus of this dissertation, an examination of the International Classification Model with respect to impairments and activity limitations associated with lymphedema follows. The factors associated with gait and balance in patients with lower limb lymphedema are discussed to direct the assessment of balance and activity
measures. An overview of the conservative treatment of lymphedema established the
treatment methodology for the study. A review of the health care delivery issues
associated with the treatment of lymphedema describes the problem and creates the main
impetus of this study.

**Anatomy and Physiology of the Lymphatic System**

The lymphatic system, an important component of the body’s circulation, was
originally discovered as “milky veins” by Gaparo Aselli in the 16th century.[37] Although
three centuries have passed, it was not until recently that interest in this “second
circulation” by the medical community has gained prominence. The greatest interest has
always focused on the primary circulation of the body, the blood circulatory system.
Consequently, our understanding of lymphatic biology lags far behind that of the blood
vasculature, even though the lymphatics are the primary route of metastasis for many
common cancers, including breast, colon, and skin cancer.[38][39]

**Major Theories**

Two major theories exist about the embryologic origin of the lymphatic system:
the *centrifugal* or venous budding theory and the *centripetal* theory. The centrifugal
theory states that the lymphatic endothelium develops from the venous endothelium. The
centripetal theory states that both systems, venous and lymphatic, develop from
undifferentiated mesenchymal cells.[40] Proponents of both theories strongly support their
views, and advances in lymphangiogenesis research may clarify which theory is correct.
“Knowledge of normal lymphatic physiology is clearly important for understanding its failure in lymphedema.”

**Anatomy**

The lymphatic system consists of lymph vessels and lymphatic organs.\[39\] It is found throughout the body with the exception of the central nervous system, where cerebrospinal fluid fulfills the normal role of lymph.\[42\] The lymph vessels are fragile, collapse easily, are difficult to visualize and have been described as being barely able to withstand 20 mmHg of pressure.\[38\] The lymph vessels conduct excess interstitial fluid back to the venous system as a drainage system that essentially parallels the venous system.\[39\] Like the venous system, lymphatic vessels become progressively larger as they progress from peripheral regions toward more central regions. Lymph nodes are intercalated into the system in order to cleanse lymph of waste products, cellular debris and various antigens as it moves more centrally to drain into the heart.\[40\] Lymph vessels distal to the nodes are called afferent vessels while those leaving the nodes for more central (proximal) regions are called efferent vessels. Lymph is ultimately returned to the venous system by trunks or ducts at the right and left venous angles-the point of junction of internal jugular and subclavian veins to form the brachiocephalic veins.\[39\] The lymphatic system differs from the circulatory system by being only a semicircular system and not having a central pump to move the fluid.\[39\]

Areas of the body that drain to a specific group of lymph nodes frequently do not have anastomotic channels to the areas that drain to another group of lymph nodes. Such circumscribed areas, in some circles, are referred to as “watershed” areas or
lymphotomes. As an example, the right thorax drains to right axillary nodes while the left thorax drains to the left axillary lymph nodes with few, if any, anastomotic channels crossing the midline. A brief consideration of Starling’s theory of fluid dynamics is helpful in understanding the complementary functioning of the circulatory and the lymphatic systems. In 1897, Starling proposed the mechanism governing fluid flow out of blood capillaries into tissues and back into venules. The theory accounted for 90% of the fluid flow between capillary and interstitial space, meaning that 10% of the ultrafiltrate must return to the circulation via the lymphatic system.

Discussions of the anatomy of the lymphatic system can involve a number of classifications of the various components. These classifications or categorizations might rely on the caliber of the vessels, the area draining into a given group of lymph nodes, or whether the vessels are draining peripheral (limbs and body wall) or central (internal organs) regions. In addition, lymph vessels draining the limbs may be divided into superficial and deep. The current description of the elements germane to this treatise will be based primarily on the size of vessels with other classification systems woven into the discussion.

Overview

Interstitial fluid, extracellular fluid not resorbed by the venous system, is taken up by the initial lymphatic vessels (capillaries) which drain into vessels known as precollectors whose convergences form vessels known as collectors. The collectors in turn converge into lymphatic trunks. Lymphatic trunks converge to form ducts that empty into the venous system at the venous angle of the heart.
**Capillaries**

The smallest of lymphatic vessels (20–40 um diameter) begin as blind–ended digitiform endothelial tubes in close proximity to the arterial and venous capillaries.\[^{40}\] The lymphatic capillary lies in a meshwork of fibrocytes, collagen fibers, elastic fibers and anchor fibers.\[^{39}\] The anchor fibers/filaments are attached to the outer surface of the capillary endothelial cells to maintain vessel patency when intercellular pressure increases as a result of edema formation.\[^{39}\] The endothelial cells have gaps between them and they rest on a discontinuous basement membrane which facilitates the passage of macromolecules into the vessel.\[^{43}\] These initial lymphatics function as force pumps that are powered by variations in total tissue pressure. These pressure variations are caused by movement, muscular contraction, respiration, and variations in external pressure as a result of massage, gravity, change in position and other similar factors.\[^{40}\]

**Precollectors**

The initial lymphatics are connected to precollectors (150um diameter) and the precollectors drain lymph from circumscribed areas toward the collectors.\[^{39}\] The precollector endothelium is surrounded by a layer of smooth muscle and connective tissue, and internally precollectors exhibit rudimentary valves that are spaced 2 to 3 mm apart.\[^{39}\] Even with the presence of smooth muscle the precollectors display no detectable vasomotor activity.\[^{42}\]
Collectors

Lymphatic vessels that are classified as collectors have a diameter of 100-600 um.\[^{39}\] Histologically, the wall of the collectors consist of three layers similar to the layers of a venous wall.\[^{39}\] From inside to outside, the tunica intima consists of an endothelium and basement membrane and some larger collectors will have an incomplete internal elastic membrane. The tunica media consists of 2-3 layers of smooth muscle while the tunica externa (adventitia) consists of loose collagenous connective tissue.\[^{39}\]

Within the collectors, endothelia folds strengthened by reticular and collagenous fibers form single or double valves that are located 6 to 20 mm apart. These are usually paired semilunar valves.\[^{39}\] The period between these valves are known as lymphangions because contraction of smooth muscle in the wall propels lymph from distal to proximal (peripheral to central).\[^{39}\] The valves passively prevent retroflow of lymph. When the smooth muscle of a lymphangion contracts the valve sinus at the proximal end of the lymphangion closes and the distal valves will open thus propelling lymph proximally.\[^{39}\]

In the limbs, the lymphatic system can be divided into a superficial (epifascial) system that collects lymph from skin and subcutaneous tissue and a deep system that drains subfascial structures such as muscle, bone and blood vessels.\[^{42}\] The two drainage systems function in an interdependent fashion through anastomotic channels such that deep lymphatics may transport lymph from the superficial or vice versa during lymphatic obstruction.\[^{42}\] The superficial and deep systems may drain at markedly different rates. In the lower limb, the subfascial system is slower than the epifascial system and it transports less lymph.\[^{42}\] Interestingly, normal flows through these anastomoses between superficial and deep channels goes from deep to superficial which is the opposite of what
usually occurs in the venous system. The superficial and deep systems of the lower limb merge within the pelvis whereas those of the upper limb merge in the axilla.

The superficial collectors generally accompany the larger cutaneous veins and drain approximately the same regions as the veins that they accompany. Typically the superficial collectors will have a better developed muscular layer and a smaller diameter than the deep collectors and the peripheral (distal) segments of the collectors will have better developed musculature than more central (proximal) segments. The deep collectors of the limbs as well as those draining viscera accompany arteries and veins such that arterial pulsations assist the pumping of lymphangions in the transport of lymph.

Superficial collector lymph vessels can be further classified as long, short, collateral, or anastomotic. Long collectors begin at the most distal part of a limb, foot or hand, and extend the length of the limb to drain into inguinal or axillary nodes. Those collectors that arise at more proximal points may be designated as short collectors while collaterals arise from a distal portion of a collector and reattach/empty at a more proximal point. Anastomotic collectors connect adjacent collectors such that lymph can be transported from one drainage area into a neighboring drainage territory.

**Trunks and Ducts**

After collectors, the next larger classification of lymph vessels is the trunks. Trunks are formed by the union of efferent lymph vessels from individual lymph node groups. Lymph trunks have thicker walls than collectors though that transition from collector to trunk may not be readily apparent. Trunks may be the final compartment
of the lymphatic drainage system prior to the dumping of lymph into the great veins or there can be a variable pattern of merging of trunks to form ducts.[44] Lymph from the right upper limb, right thorax, and right side of the head and neck will dump into the right venous angle while lymph from the remainder of the body empties into the left venous angle. Right subclavian, right jugular and right bronchomediastinal trunks may empty separately into the right venous angle or two or more of them may join to form a right lymphatic duct before emptying.[44] The left venous angle receives like named trunks as well as the thoracic duct (to be described).[44]

The majority of the lymph from the lower limb and external genitals, after passing through the inguinal nodes, enters external iliac vessels that parallel the external iliac artery and vein. Lymphatic vessels from the pelvic organs, the internal iliac(hypogastric) lymphatics, join the external iliac lymphatics to form common iliac vessels.[39]

The common iliac vessels join large lymph vessels, closely associated with the abdominal aorta, known as right and left lumbar trunks.[45] As the lumbar trunks ascend the posterior abdominal wall they receive lymphatics draining the gastrointestinal tract as well as the other abdominal viscera.[39] The lymphatics draining the abdominal organs, like the deep lymphatics of the periphery parallel the blood vessels that service the organs in question.[39] The pattern of convergence of the lymphatics from the abdominal organs with the lumbar trunks is quite variable but they all ultimately coalesce posterior to the right crus of the diaphragm and anterior to the first two lumbar vertebrae.[42] This ultimate convergence is frequently seen as a saccular structure known as the cisterna chyli while in other instances the confluence simply forms a plexus of vessels.[42]
The thoracic duct, the largest lymph vessel in the body, arises from the cisterna chyli (or the plexus formed by the confluence of abdominal trunks) and ascends the mediastinum posterior to the esophagus and anterior to the thoracic vertebrae. At the base of the neck it veers left to join the left venous angle in close proximity to the termination of the left subclavian, jugular and bronchomediastinal trunks.\[44\]

While all the lymph of the upper limb, in most individuals, drains through the axillary nodes into the subclavian trunk, some individuals possess an axillary drainage trunk that bypasses the auxiliary nodes and drains into the subclavian nodes.\[40\] If this so called deltoid-pectoral or cephalic chain of nodes is present, an individual may be less likely to develop upper limb lymphedema secondary to disruption of axillary nodes.\[40\]

**Physiology**

*Overview*

The lymph system, which develops embryologically from the venous system, is a one-cycle system, “a drainage route designed to rid the tissues of unwanted material and excess fluid.”\[6, 41\] Knowledge surrounding this extremely important mechanism of tissue fluid and lymph flow away from tissues, securing the intercellular physico-chemical environment, is rudimentary among clinicians and even physiologists studying the peripheral circulation.\[46\] The primary function of the lymphatic system, in contrast to the blood circulation, is to maintain interstitial fluid balance and provide lymphatic clearance of interstitial fluid and macromolecules. The lymphatic system, thereby, sustains osmotic and hydrostatic gradients from blood capillaries through the interstitium and stimulates convection for interstitial protein transport.\[6\]
The lymph is filtered through the lymph nodes, which trap various antigens by attracting antigen presenting or accessory cells, such as dendritic cells in various epithelia or Langerhans cells in the epidermis.\textsuperscript{[43]} These cells capture and internalize antigen through phagocytosis or endocytosis. This mechanism becomes especially important for lymph transport during night rest or anesthesia and for confined or immobilized patients in bed. All of the auxiliary forces traditionally listed in textbooks, such as limb muscle contractions, respiratory movements, and pulsation of neighboring arteries, remain secondary to intrinsic contractions of lymphatics.\textsuperscript{[46]} The forces listed assist lymph flow by enhancing the contractility of the lymphangions.

Nevertheless, as analyses during the last century became more comprehensive of both the blood circulatory and lymphatic systems, a symbiosis between the two was discovered. The lymphatic system is an integral part of the major functioning of the body, with a basis in the immune system, homeostasis, and nutrition. “The lymphatic vascular system plays important roles in the maintenance of tissue fluid homeostasis, in the mediation of the afferent immune response, and in the metastatic spread of malignant tumors to regional lymph nodes.”\textsuperscript{[37]}

**Lymphangions**

As the initial capillaries collect the interstitial fluid that becomes lymph once in the capillary, the movement proximal is maintained by the valvular compartments called lymphangions. The lymphangion has its own motoricity. Independent of external influences, it generates 5–7 action potentials per minute. The overall pulsation frequency of the lymphatic system varies between 1 and 30 per minute.\textsuperscript{[13]} General anesthesia,
muscle relaxants (such as Flaxedil), arterial pulse, spontaneous and artificial respiration, and apnea have no influence on the rhythm of spontaneous contractions.\(^{46}\)

**Contractility**

The lymphatic system has a basic organization and intrinsic and extrinsic propulsion system. Lymph flow and lymphatic contractility increase in response to tissue edema (edema safety factor), exercise, hydrostatic pressure (standing position), mechanical stimulation (massage, pneumatic compression), and warm baths. Interestingly, it has been demonstrated that exposure to cold (ice packs, near 0 degrees Celsius) also stimulates lymphatic flow.\(^{42}\)

The main propelling force for lymph flow is rhythmic contractions of lymphangions (segments of lymphatics between two unidirectional valves) that generate lymph pressure high enough to move the intralymphatic fluid centripetally.\(^{46}\) All other factors, such as muscular contractions, respiratory movements, and arterial pulsations, are secondary to spontaneous contractions of lymphatics.\(^{46}\) Lower limb lymphatics contract spontaneously and rhythmically transport daily, according to estimates, between 20 to 250 ml of lymph in a 70-kg man.\(^{46}\)

Spontaneous contractility of human prenodal lymph vessels has also been observed during x-ray lymphangiography.\(^{39}\) The smooth muscle cells of the lymph collectors are supplied with autonomic nerves.\(^{39}\) The innervation of the wall of the lymphangion is concentrated in the middle portion of the segment. Medulated and non-medulated autonomic nerve fibers form a terminal plexus in the adventitia, and they have
no direct synaptic contact with the smooth muscle cells. As in the case of blood vessels and hollow organs, adrenergic innervation through diffusion is therefore assumed here.\[39\]

The valve segments are the smallest motor units that propel lymph; transport occurs in contraction waves (10-20/min), similar to peristalsis in the small intestine. An increase in temperature results in an increase in frequency (maximum frequency at 37-41 Celsius).\[39\] The direction of lymph flow is determined by the closing of the distal valves and the opening of the proximal valves.\[39\]

In skeletal muscle, lymphatics are usually paired with arterioles, so that arterial pulsation and muscle contraction contribute to the periodic expansion and compression of initial lymphatics to enhance fluid uptake.\[42\] Intrinsic generation of action potentials within the smooth muscle induces the spontaneous contraction of one or more chambers, with the resultant active propulsion of lymph.\[42\] Intrinsic pumping of collecting vessels is the essential motor for lymph propulsion, but the flow is regulated by the supply of lymph to these collectors.\[41\]

The collectors are innervated by the autonomic nervous system and contract an average of 5-10 times per minute. This lymphangiomotoricity combines with the contraction itself, which is triggered by distention of the vessel wall. The greater the stretch, the greater the force of the contraction.\[40\] If many lymphangions contract at once and outflow is obstructed (e.g., by scarring of radiated lymph nodal areas), pressure inside the vessel can reach as high as 100 mm Hg.\[40\]
**Immune Function**

Lymphatic vasculature and lymphoid tissues are prevalent in organs that come into direct contact with the external environment, such as the skin, gastrointestinal tract, and lungs. This distribution is most likely a reflection of the protective role of the lymphatics against infectious agents and alien particles.\(^{[42]}\)

Lymph nodes also produce lymphocytes and macrophages, which are critical for immune function. They destroy bacteria, harmful viruses, and cancer cells and filter waste products.\(^{[40]}\) On the way back to the blood circulation, lymph passes through at least one lymph node, where immunological presentation of antigens and filtering can occur.\(^{[38]}\)

**Homeostasis**

As a support mechanism for body homeostasis, the lymphatic system provides ancillary support for the digestive, circulatory, and immune systems. The lymphatic system is a component of both the circulatory and the immune systems.\(^{[8, 11]}\) As such, the lymphatic system is designed to help maintain fluid balance in the tissues, fight infection, and assist in the removal of cellular debris and waste products from the extracellular spaces.\(^{[40]}\) Failures in either the digestive, circulatory, or immune systems may indicate a potential lymphatic dysfunction or a state of failure of intrinsic components in any of the individual systems.

For the purposes of this paper, a healthy lymphatic system is one described by the theory of the architecture of the lymphatic system. Individual modifications of the lymphatics system occur in different people, but the basic premise of the architecture has
been extensively studied, presented in many forums, and is widely accepted by the medical community.

A healthy lymphatic system may be a difficult system to analyze. Because of the functions of the lymphatic system, structure alone may not determine “health.” For example, as a supportive mechanism for the immune system, illness may not indicate failure to a healthy lymphatic system. As a transport system for excess interstitial fluid, swelling of the limbs after a long air flight would not necessarily indicate a failure of the lymphatic system. As a means for lipid transport, obesity or cachexia would not necessarily indicate a failure of the lymphatic system.

**Nutrition**

The lymphatic system also performs a supplementary role in the transport of digestive byproducts. Absorption of fat from the intestine occurs through the lymphatic system, which transports the lipids (chyle) to the liver.[42] Protein-rich fluid is gathered by open lymphatic capillaries that drain into progressively larger lymphatic vessels.

The main function of the ductal structure known as the cisterna chyli is the transport of ingested fat; approximately 100 ml of lymph per hour is transported through the channel.[47] Cholesterol and long-chain triglycerides in the form of chylomicrons are absorbed solely by the lymphatics system.[46]

**Summary**

The anatomy of the lymphatic system is designed as a system of mass collection catchment areas. The design ultimately transports the lymphatic fluid back into the blood
circulatory system. This system from one of disorder accessing most all areas of the body to consolidation and a final end point requires energy, as we have seen, with the need for muscular contraction, arteriole pulsation, and intrinsic auto-contractility. Movement from a dense array of pervasive one-cell thick capillaries to visible trunks and final deposition into the heart requires an intense coordination by multiple body structures and functions.

The healthy lymphatic system functions, as any drainage system would function, removing small amounts of refuse or debris from many areas to finally deliver large amounts to one location. Pathology occurs when the routes are damaged. Damage takes place often through treatment for cancer, trauma, or surgery, or may be congenital in nature. However, through a thorough understanding of the anatomy and physiology of the lymphatic system, researchers and clinicians can develop the appropriate models and most efficient means of treatment for different populations of patients who may develop lymphedema.

Clinical Conditions Causing Lymphedema

Pathology

Lymphedema results from impaired lymphatic transport caused by injury to the structure of function of lymphatic system. Lymphedema is defined as congenital (primary) or acquired (secondary) chronic tissue swelling resulting from failure of adequate lymph drainage. The condition of lymphedema results from impaired lymphatic transport caused by injury to the lymphatics, infection, or congenital abnormality. Clinical disorders of the lymphatic system occur commonly, with
edema representing an increase in interstitial fluid volume sufficient to manifest with
swelling. Any edema, from various causes, is due to an imbalance between capillary
filtration and lymph drainage.[41]

**Incidence**

Lymphedema is a prevalent disease. Approximately 10 million people have
lymphedema secondary to breast cancer and pelvic cancer therapy, recurrent infection,
injuries, or vascular disease.[42] When chronic venous insufficiency is added as a cause
there may be as many as 300 million cases of lymphedema.[42] Upper limb lymphedema is
a frequent complication of breast cancer therapy and axillary lymph node dissection, with
an estimated frequency of 5%-30% in people undergoing this procedure.[42] Worldwide,
about 90 million people have lymphedema, primarily because of parasitic infection.[42]
Upper limb volume differences of 100–200 or a circumference difference of more than 2
cm are used as a criterion for the diagnosis of lymphedema.

From studies that examined lymphedema associated with axillary versus
inguinofemoral nodal dissections, the reported incidence of resultant upper limb axillary
lymphedema was 5%-8% compared to 14%-29% for lower limb lymphedema.[49, 50] It
appears from these reports that the incidence of lower limb lymphedema may be twice as
high as that for upper limb lymphedema. But the true prevalence is difficult to estimate
due to the paucity of literature.
Causation

Although primary lymphedema is defined as congenital in nature, secondary lymphedema is edema due to a reduction in lymph flow by an acquired cause. The causes of secondary lymphedema include trauma\cite{51-53}, recurrent infection\cite{51-53} and malignancy, together with metastatic disease \cite{52, 54, 55}.

Iatrogenic lymphedema is not an uncommon condition. A wide range of therapeutic surgical procedures during which the lymphatics may cause inadvertent damage to the lymphatics.\cite{46} Radical mastectomy and ilioinguinal dissection are two of the operations in which removal of lymph vessels and nodes is an integral part of the procedure. In other surgical interventions as, for example, cardiac operations, the thoracic duct may be injured.\cite{46} In a recent study, groin dissection for malignant melanoma was followed by measurable lymphedema in approximately 66% of the patients.\cite{46} In other studies, the incidence rate of postmastectomy lymphedema varies from 3% to 14% and even more in some series, depending on the extent of the axillary dissection.\cite{46}

These studies and others show that development of edema depends on several factors. These are as follows: (a) number of injured lymphatics, (b) the speed of development of new lymphatic connections, (c) coexistence of deep thrombophlebitis with venous blood stasis and subsequent lymph overproduction, (d) preexistence of idiopathic lymph stasis (post inflammatory, praecox, tarda), and (e) postischemic capillary permeability with high filtration rate and augmented lymph production.\cite{46}

Other less common diagnoses may stem from local or systemic causes. Systemic causes include congestive heart failure, renal failure, hypoalbuminemia, and protein-losing nephropathy.\cite{56} Local causes include primary and secondary lymphedema.
Thus, identification of a specific ratio of upper limb to lower limb would be speculative.

Summary

Consideration of the specific anatomical topography of the lymphatic system, can create the basis of future treatment for pathologies of the lymphatic system. Because of the worldwide prevalence of lymphedema, the more thoroughly the lymphatic system is understood, the more researchers and clinicians will pursue greater accuracy in diagnoses, development of appropriate models of treatment, and advances in innovative treatments. Despite recent progress in research and consequent understanding, much more remains to be discovered about the lymphatic system and its functioning. With greater attention to this system in both homeostatic and pathologic states, researchers and clinicians will be able to perform preventative interventions, render more accurate diagnoses, and administer more immediate and effective treatment to patients with lymphedema.

Disablement and Lymphedema

In 2001, the World Health Organization (WHO) produced a major revision to a previous classification system, the Nagi Model. The original classification system was originated in 1980 and was contemporary with but independent of Nagi’s work. This
system was entitled the *International Classification of Impairments, Disabilities, and Handicaps* (ICIDH)[72] The revision is entitled the *International Classification of Functioning, Disability and Health* which like the disablement model attempted to provide a coherent biopsychosocial view of health states from a biological, personal, and a social perspective.[73-75] The ICF identifies 4 levels within its contextual framework: Health Conditions, Function, Activity and Participation.[72]

The term *Health Conditions* is used to represent disease, disorders, injury, or trauma, aging and congenital anomaly. The ICF identifies 3 levels within the *Function* category; functioning at the level of body or body parts, the whole person and the whole person in their complete environment. These levels, in turn, contain 3 domains of human function: body functions and structures, activities and participation.[72, 76] The term disability is used to denote a decrement at each level (i.e. impairment, activity limitation, and participation restriction).[72]

The first domain is *body functions and structures*. *Body Functions* are the physiologic functions of the body systems (including psychological functions). *Body Structures* are anatomical parts such as organs, limbs, and their components. *Impairments* are problems in body function or structure as a significant deviation or loss.[72] The second domain, *activity*, is defined as the execution of a task or action by an individual. Problems performing activities are referred to as activity limitations. The third domain, *participation*, is involvement in a life situation.[72, 76] Problems participating in life situations are described as participation restrictions. The ICF model will be utilized to describe relationships among disease, impairment, activity limitations and participation restrictions in people with lymphedema.
**Health Conditions**

Lymphedema is a disease of the lymphatic vascular system. This study utilized the International Society of Lymphology classification system to identify subjects as having Primary or Secondary Lymphedema.[77]

Lymphedema produces impairments in body structure in the form of increased limb volume due to edema. Subjects with lymphedema may also have impaired body structure due to morbid obesity. Increased limb volume may also produce impaired joint range of motion and impaired strength relative to the individual’s body mass.

Medicare guidelines require that patients demonstrate activity limitations in order to be eligible for reimbursement. Theoretically, impaired strength and ROM would limit the patient’s ability to perform daily activities. However, the activity limitations associated with lymphedema have not been extensively studied. One study pointed to the possibility that physical function could be a more appropriate measure than volume excess in the assessment of breast cancer-related lymphedema (BCRL).[78] This study demonstrated that manual dexterity was significantly impaired in the affected arm but was not associated with arm volume excess. Interestingly, the authors concluded that present-day assessment, treatment, and monitoring of BCRL concentrates on the excess volume of the arm, which does not appear to correlate with the level of physical dysfunction.[78]

Another study, however, found that following breast cancer surgery in subjects who reported swelling about 72% said they had no problem and full use of their affected arm in their daily lives. Only 3% reported that they rarely used their arm on a daily basis.[79] Although current treatment methods have been shown to significantly improve
patients’ perceptions of their own physical functions,\textsuperscript{[27, 78]} objective testing of arm function before and after treatment has rarely been performed.\textsuperscript{[78]} The information available for the upper limb on the relationship between limb volumes and activity limitation suggests that subjective reports by patients show activity improvement with volume reduction. However, little information is available for the lower limb, since treatment for lymphedema has primarily focused on the upper limb due to the prevalence of the treatment of breast cancer.\textsuperscript{[29]}

There have been studies conducted which examined conditions that involve diagnoses often associated with lower limb lymphedema. However, these studies did not identify the causation to be associated with lymphedema. Among the few studies conducted, one was developed to gain insight into gait, activity limitation, and endurance, impairment, in patients with severe chronic venous insufficiency, which may be associated with edema to the legs. Study results indicated a disturbed gait and decreased calf muscle endurance in patients with severe chronic venous insufficiency. These results point to a possible role for gait and strength training in the rehabilitation process of patients with severe chronic venous insufficiency.\textsuperscript{[80]} Considering the relationship of lower limb lymphedema to chronic venous insufficiency, the potential exists for activity deficits.

Ability to participate in life is closely associated with the concept of Quality of Life (QOL) and improved QOL is increasingly recognized as an important measure of success in rehabilitating a patient with chronic limb edema. Chronic limb edema is a chronic disorder which can adversely affect quality of life.\textsuperscript{[81]} As with outcome measures of function, quality of life (QOL) measures are equally important in assessing the success
of rehabilitation of a patient with chronic limb edema. In one study, patients with peripheral lymphedema had significantly greater mean improvement in QOL scores compared with patients with upper limb lymphedema. \( p = 0.02 \) The results of this study showed that significant improvements were made in the QOL of patients exhibiting peripheral lymphedema following complete decongestive therapy (CDT), which is not necessarily correlated with limb volume reduction.\(^{[81]} \) Activity measures were not tested in this study.

Another study was carried out to describe the physical disability and psychosocial impact of chronic lymphedema in patients attending filariasis clinics in the Colombo district, Sri Lanka. The majority of patients had lower limbs affected, with a significant association with the limb swelling and difficulty in walking. The swollen limb affected the work of employed patients, and persons reported loss of job. Approximately 25% reported having problems interacting with the community, 6% interacting with family, and 8.7% felt that they were rejected by society.\(^{[82]} \) This study compared subjective reports of limb volume only to the reported participation restriction that resulted from the condition.

In the present study, patients with either unilateral or bilateral lymphedema of the lower limbs are at risk for impairments and activity limitations. It is postulated that factors that may produce effects of activity loss include the following: (a) increased weight and girth of one or both of the lower limbs affecting the gait cycle and dynamic balance, (b) loss of strength and range of motion (c) decreased activity due to increased energy requirements, and (d) psychosocial issues of body image and hesitancy to participate in community activities.
One study performed a review of literature and found very few articles that utilized outcome measures for chronic limb edema. The study pointed out that outcome measures in chronic limb edema have been adopted in clinical practice in a haphazard manner. The authors further state that little discussion has taken place regarding the purpose of outcome assessment/measurement techniques, and little agreement is in evidence on the most appropriate outcome assessment/measurement techniques.\textsuperscript{[83]}

**Impairments Associated with Gait and Balance in Patients with Lower Limb Lymphedema**

*Center Of Gravity*

The ability to control intentional movements of the center of gravity (COG) when leaning or performing weight shifting activities is critical to the successful performance of various tasks associated with activities of daily living (ADLs).\textsuperscript{[84]} Dynamic postural control, which is necessary for activities of daily living, may be compromised as a result of underlying pathology and/or physical deconditioning.\textsuperscript{[85]}

A previous study has identified impairments included severe pain to the leg, range of motion loss to the lower limbs, increased girth to the lower limb (ies) in a subject with bilateral lower limb lymphedema.\textsuperscript{[29]} Impairments which may cause problems controlling the center of gravity over the base of support may include: Pain, Increased limb size, girth and weight, Decreased Scar Mobility, Altered Sensation, Loss of Range of Motion, Impaired Strength, Impaired Skin Integrity, Impaired Muscular Endurance, Impaired Cardiovascular Endurance, Impaired Coordination, and Impaired Balance.
Secondary Consequences of Lymphedema  
Deconditioning

Considerable data are available on the detrimental physiological effects of restricted physical activity on health and physical functioning. Most individuals with a chronic disease or disability become less physically active.[86] The decrease in physical activity leads to a cycle of deconditioning that results in impairments of multiple physiologic systems.[86] Impairments associated with inactivity include: loss of range of motion, impaired strength, impaired muscular endurance, impaired cardiovascular endurance, impaired coordination, and impaired balance.

Subjects with lymphedema, while demonstrating many of the impairments associated with inactivity in the general population present with unique impairments. The alterations in daily activities can be the exacerbated by of a psychosocial impairment. The impairment can result from a fear of injury, negative self/body image, and embarrassment of condition.[87] These impairments can lead to a decrease in physical mobility and an increase in activity limitations. Thus the inactivity associated with lymphedema can result from the physical enlargement of the leg leading to impairments in range of motion, strength, pain, and balance and can be worsened by the psychosocial aspects of the condition.

Conservative Treatment of Lymphedema

Goals

The goals of lymphedema management are to prevent the progression of the condition, to reduce and maintain limb size, to alleviate symptoms, to prevent infection,
to improve mobility and ability to perform ADLs, and to improve overall psychological well-being.\[^{10}\]

**International Society of Lymphology Recommendations**

Treatment for lymphedema can be divided into conservative, pharmacologic, and surgical approaches.\[^{56}\] For the purposes of this study, the conservative approach is the identified treatment of interest. Conservative treatment was identified and defined by the International Society of Lymphology\[^{88}\], as discussed below.

In 1995, and recently amended in 2003, the ISL published its recommendations for lymphedema therapy, which are accepted in many countries around the world.\[^{77, 89}\] The ISL recommends physiotherapy (Complete Decongestive Physiotherapy [CDP]) that consists of manual lymphatic drainage, compressive bandaging, decongestive exercises, and meticulous skin care.\[^{77, 89}\] The ISL emphasizes that the aim of lymphedema management must be the permanent restoration of the disturbed equilibrium between lymphatic protein load and lymph vascular transport capacity (i.e., protein content of interstitial fluid to normal).\[^{90}\] In conjunction with the above measurements, each subject was assessed for stage of lymphedema. These were calculated based on the ISL’s definitions of the four stages of lymphedema. (Table 1.1)

**Factors Influencing Delivery of Care**

Treatment of patients with lymphedema has been well documented.\[^{10, 12, 91-93}\] However, important factors are involved in the delivery of care for these patients that influence their ability to receive the treatment. The first factor for the patient is locating a
health care professional who has received the certification to treat lymphedema. The second factor is whether the patient’s insurance company covers the services required. It is necessary to understand the treatment philosophy and each of these factors when delivery of care is attempted. The treatment of established lymphedema varies from the decision to administer no treatment at all to pursuing a host of aggressive surgical procedures, as was particularly the case in the past. Current best practice, theoretically, is to undergo a course of CDT by a certified healthcare practitioner; however, due to one or more of the above factors, this may not be the case.

**Terminology and Theoretical Description of Care**

CDT has been a common phrase for the treatment for lymphedema and compromises the four parts of treatment; MLD, Skin Care, Compression and remedial exercises. Additional terms are used to describe the treatment technique, including combined physical therapy (CPT), also known as complete or Complex Decongestive Physiotherapy (CDP), and complex lymphedema therapy (CLT) which was principally introduced, applied, and refined in Germany by the Foldi’s in the 1980s. This technique, also known as Combined Physiotherapy, was modified and supplemented with specialized exercises by Casley Smith in Australia and the technique is called the modified technique Complex Physical Therapy (CPT). Finally, a consensus was agreed upon in New York in February, 1998, in which the Foldi’s, Leduc, the Vodder School, and Casley-Smith agreed to the term Decongestive Lymphatic Therapy (DLT) as a suitable name for this treatment. Despite this consensus, multiple terms are still used to define the treatment technique.
Manual Lymphatic Drainage (MLD) is a gentle manual technique (very different from classic massage) in which, by means of delicate skin touching and finger movements, lymphatic drainage is stimulated.\textsuperscript{[89]} The technique stimulates the lymphangiomotoric activity. This stimulation directs the lymphatic flow away from the edematous part of the body, thereby decreasing the edema and fibrous changes.\textsuperscript{[97]} Gentle manual pressure is applied to each of the dermal lymphotomes to direct lymph flow to nonobstructed lymph nodal areas. This pressure is carried out in a predetermined manner aimed at redirecting lymph flow by opening and dilating the collateral vessels across watersheds. A single watershed is drained by a single lymphotome.\textsuperscript{[95]} The method is designed to mobilize edema fluid from distal to proximal areas and from areas of stasis to healthy lymphatics.\textsuperscript{[98]}

Vodder's MLD technique is composed of four basic hand movements that lightly massage the skin: stationary circles, pump, scoop, and rotary. In stationary circles, hand movement consists of placing the fingers flat on the skin and moving them about in stationary circles or continuous spirals. Each circle consists of a smooth increase of pressure and a smooth decrease of pressure into the tissues. The stationary circles are primarily used to treat the neck, face, and lymph nodes. Pump movement is created by placing the palms face down with the thumb and fingers in the same direction to move the skin in oval circles. The wrist rather than the fingertips is used in this movement.\textsuperscript{[99]}

In the scoop movement, the palm is facing upward with a rotating wrist, which creates a corkscrew-type movement. Pressure is exerted on the inward stroke with no pressure on the outward stroke. The rotary technique consists of individual movements, in which the palm faces down on the skin and turns in an inward spiral movement. At the
same time, the thumb moves in a circular manner during the pressure phase. The rotary technique is used on flat areas of the body. Following whatever massage technique is used in the manual lymphatic drainage; compressive bandages are applied to the edematous limb(s).

A theoretical treatment plan for a patient with unilateral or bilateral lower limb lymphedema would utilize the stimulation of the specific areas. Initial contact with the patient occurs at the cervical region. This is the location which ultimately drains the lymphatic fluid into the blood circulatory system. A thorough stimulation of the cervical region begins the process of decongestion. To create another catchment area for the excessive lymphatic fluid, stimulation takes place to bilateral axillary regions. Subsequent lateral truncal stimulation from axillary region to pelvic region opens collateral vessels. The larger lymphatics and nodes of the trunk form a “reservoir” into which the lymphatics of the limb drain. Once this area is cleared, it creates an empty space into which the lymph from the affected limbs can be emptied easily.[96] To bypass the overwhelmed or insufficient inguinal nodal system, the stimulation is directed proximal to distal and medial to lateral for one or both of the lower limbs.[96]

The strokes involved with the stimulation of the lymphatic system are extremely light in pressure, and the massage should exert no more pressure than 30 to 40 mm Hg. As a rule, there should be no reddening of the skin or pain during the massage.[99] The massage is accomplished with the palm of the hand and the fingers, which are either flat or curved to fit the area being treated. Sometimes the area is so small that only the distal parts of the fingers can be used.[96] One hand follows the other to keep the lymph always moving in the desired direction to prevent possible backflow. MLD uses butterfly-light
touch with gentle pumping movements while the hands are rotated spirally into and out of the tissue. A combination of round or oval, small or large, or deep or shallow movements are used to move the skin rather than stroking the skin. These movements comprise the Vodder technique of MLD. Following the MLD, skin care is performed. Skin care is essential to prevent skin problems for a “limb at risk”. The skin must be kept supple, moist, and in good general condition. Trauma to the limb (e.g., knocks, abrasions or cuts; burns, including sunburns; and insect bites) must be avoided carefully and, if they occur, treated. The limb also must be kept spotlessly clean and dried gently and very carefully.

Compressive bandages are the next essential part of the physical therapy intervention for the lymphedema to maintain the reductions achieved by MLD. Low elastic (low-stretch) bandages are used to provide compression during the treatment. Compression bandages cause a mild increase in total tissue pressure, and, with exercise, they provide a variation in total tissue pressure that will increase lymphatic drainage by (a) increasing uptake by initial lymphatics, and (b) increasing pumping by the lymphangions.

The bandages are particularly necessary for lymphedema because a feature of the disease is the loss of elastic fibers from the tissues. Graded compression, with the greater compression distally and lesser proximally, is necessary to promote drainage proximally.

Another important result of the compressive bandages is the relationships associated with Starling’s Equation. This equation states: The amount of fluid formed depends upon the permeability of the capillary wall (filtration coefficient) and the
gradient of hydrostatic and oncotic pressure between blood and tissue. \cite{100} (Oncotic pressure is the osmotic pressure created by protein colloids in plasma.) The hydrostatic pressure difference causes filtration, while the oncotic pressure difference causes resorption.\cite{100} If an oncotic pressure gradient exists across a semipermeable membrane such as a capillary wall, water is drawn across the barrier until the concentrations on both sides are equal.

The dramatic reduction of edema by compression therapy can be explained by the reduction of lymphatic fluid in the tissue (interstitial fluid), rather than by an improvement of lymphatic transport. The combination of manual lymphatic drainage, which mobilizes the lymphatic system, and compression therapy, which inhibits additional interstitial fluid, results in a reduction of overall volume in the tissue. The daily repetition of treatment consequently produces significant results in loss of volume. With bandages applied, remedial range of motion exercises are performed to stimulate the lymphatic system through muscle pump and skin stretching.

**Treatment Application**

The International Society of Lymphology (ISL) published its recommendations for lymphedema therapy, which are accepted in many countries around the world.\cite{89} There are two phases, each with four steps.

Phase 1 consists of the following:

1. Meticulous skin and nail care, including treatment of any infection.

2. Manual lymphatic drainage, a massage technique designed to stimulate lymph vessels to contract more frequently and to channel lymphatic fluid toward adjacent,
functioning lymph systems. The drainage begins with stimulation of the lymphatic-adjacent basins, and then, for lymphedema of the lower limbs, proceeds to progressive manual decongestion of the trunk, hip, groin, leg, and more distal regions.

3. Compression bandaging performed immediately after massage. Bandages are applied sequentially from the distal limb to the groin, with progressive reduction in compression pressure. Multiple layers of minimally elastic cotton bandages are applied with overlying foam inserts that increase pressure in areas that are particularly fibrotic and to ensure uniform pressure distribution.

4. With bandages in place, the therapist guides the patient through a series of exercises intended to increase lymph flow in all available lymph channels and in collateral pathways. The exercises involve range of motion activities to the lower limbs.

Phase 2 (initiated promptly after Phase 1) aims to conserve and optimize the results obtained in Phase 1. Phase 2 consists of compression by a low stretch elastic stocking or sleeve, skin care, continued “remedial” exercise, and repeated light massage as needed.\textsuperscript{[101]}

1. Meticulous skin and nail care.
2. Surgical support garments (stocking or hosieries) worn during the day.
3. Low stretch bandages worn overnight.
4. Ten minutes of specific lymphedema exercises performed twice a day with the compressive bandages in place. These exercises include active range of motion to the involved limb.\textsuperscript{[77, 102]}
**Frequency and Duration**

Theoretically, the frequency and duration of treatment for patients with lymphedema varies based on the phase of therapy and stage of the disease. Different authors have suggested protocols based on phase and/or stage. One study suggested for a stage I lymphedema patient in phase 1 that treatment be performed daily for duration of 14-21 days. A stage II lymphedema patient in phase 1 should receive treatment twice daily with duration of 24-28 days. And a stage III patient should receive treatment 2-3 times daily with duration of 28-35 days.\(^{[89]}\) Another study recommended standard treatment regime requiring 2-4 hours each day, administered over a 30-day period.\(^{[95]}\) Another study utilized a plateau in reduction in the involved limbs to guide the termination of therapy.

There is no consensus as to the duration and intensity of treatment. Results ranged from 4-25 days of treatment, with one or two 90-minute treatments on each day. The average patient required 15.7 days.\(^{[103]}\) In a further study, patients underwent a treatment frequency of 3-5 visits a week for 3-5 weeks, and this duration was considered the standard of care for patients being treated for lymphedema.\(^{[104]}\)

Although treatment parameters are not standardized, the patient who has lymphedema often must rely on insurance for coverage. Coverage was passed into law with the Women's Health and Cancer Rights Act (WHCRA) of 1998. If WHCRA applies to a patient who is receiving benefits in connection with a mastectomy and the patient elects breast reconstruction, coverage must be provided for in the following ways:

1. All stages of reconstruction of the breast on which he mastectomy has been performed.
2. Surgery and reconstruction of the other breast to produce a symmetrical appearance.

3. Prostheses and physical complications of all stages of mastectomy, including lymphedema.\[105\]

The law was created specific to patients who have undergone mastectomy (ies). It does not guarantee coverage for other forms of lymphedema. However, the treatment duration and frequency has been used in the policies for third party payers.

The standard of care for the treatment of lymphedema does not address a potential treatment plan for impairments and/or activity limitations that may be associated with the condition. As described in the policies and procedures of the various insurance plans and in the recommendations of the ISL, lymphedema is treated as the diagnosis rather than one of many impairments due to an underlying diagnosis. Conceptually, impairments and activity limitations related to this population of patients should follow a physical therapy treatment plan based on the evaluation of all deficits not just edema, but application of treatment is often limited by restrictions or criteria imposed by third party payers. Original criteria for treatment was based on breast cancer related lymphedema.

**Health Care Delivery issues associated with the treatment of Lymphedema**

*Centers for Medicare and Medicaid*

For lymphedema patients, the Centers for Medicare and Medicaid Services established a 2-week episode with a maximum of 10 visits for the treatment of lymphedema. This policy was established based on the ability of the patients to care for themselves or on the ability of a caregiver to assume care.
Medicare’s coverage determination uses the term complex decongestive physiotherapy (CDP) which consists of skin care, manual lymph drainage, compression wrapping, and exercises. Although there is no means for Medicare to allow payment of the total treatment via one treatment code, payment will be allowed for the therapy services associated with the treatment (i.e., 97001 (physical therapy evaluation), 97002 (physical therapy re-evaluation), 97003 (Occupational Therapy Evaluation), 97004 (occupational therapy re-evaluation), 97110 (Therapeutic Exercise), 97140 (Manual Therapy) and 97535 (Self Care). Other services such as skin care and the supplies associated with the compression wrapping are included in the therapy services performed during each session.

The goal of this therapy is not the achieve maximum volume reduction, but to ultimately transfer the responsibility of the care from the clinic, hospital, or doctor, to home care by the patient, patient’s family or patient’s caregiver. Unless the patient is able to continue therapy at home, there is only temporary benefit from the treatment. The endpoint of treatment is not when the edema resolves or stabilizes, but when the patient and/or their cohort are able to continue the treatments at home. Patients who do not have the capacity or support system to accomplish these skills in a reasonable time are not good candidates for CDP coverage by Medicare. The patients may not be covered by Medicare for treatment.

It is expected that therapy education sessions would usually last for 1 to 2 weeks, with the patient attending 3-5 times per week, depending on the progress of the therapy. After that time, there should have been enough teaching and instruction that the care could be continued by the patient or patient caregiver in the home setting. The maximum
benefits of treatment are not expected unless the patient continues treatment at home. The coverage of the CDP therapy by Medicare would only be allowed if all of their conditions have been met. (Table 1.2)

Other Insurance

Other insurance companies, such as Aetna Insurance, consider the treatment of lymphedema with different coverage limitations, as follows:

Aetna considers a course of complex decongestive physiotherapy (CDP), also called manual lymphatic drainage, medically necessary when both of the following criteria are met:

The member has any of the following conditions:

Intractable lymphedema of the limbs, unrelieved by elevation; or

One or more previous admissions to treat complications of intractable lymphedema (i.e. cellulitis, ulceration); or

Evidence of ulceration due to lymphedema; and

The member has shown a past record of compliance and the member or his/her caregiver is capable of following the instructions associated with CDP.

An initial course of CDP may require 30 days, or in the case of lower limb care, 45 days. Medical review occurs after 25 visits and are limited to 4 units per day[106]

Cigna Insurance offers benefits similar to those offered by the Centers for Medicare and Medicaid services, as follows:

Cigna Healthcare covers complex lymphedema therapy (CDT) as medically necessary for the treatment of intractable lymphedema when ALL of the following are met:

Documented failure of a reasonable course of conservative medical management that includes home exercises, limb elevation, and compression garments.
The lymphedema is directly responsible for impaired functioning in the affected limb.

The complex lymphedema therapy is prescribed by a physician or performed under the supervision of a physician.

Humana Health Insurance states that the coverage determination as follows:
Humana members may be eligible under the Plan for manual lymphatic drainage when performed by a certified manual lymph drainage (CMLD) therapist. Note: The treatment may be applied towards the number of allowable visits of the physical therapy benefit.[34]
A plan with a limit of 10 visits would thus place the allowable number of visits the same as that of the Centers for Medicare and Medicaid Services.

A program of complex lymphedema therapy provided 2-5 times per week for two weeks is generally considered medically necessary for the treatment of primary or secondary lymphedema, in the absence of any contraindications. Programs that go beyond a four-week period are generally considered not medically necessary. Most patients are able to progress to an exclusively home-based, self managed program after an initial in-office program of 1-2 weeks.[107]

The variability of coverage occurs between insurances, however, The Centers for Medicare and Medicaid Services policy on lymphedema persists as the standard of care delivery for private insurances. However, a patient has the option of continuation of therapy services beyond the limitations put forth by the insurance company, if they are able to pay for the services privately.
Problem Statement

Lymphedema is a chronic condition. It can be managed but not corrected due to the absence of damaged lymphatic pathway. Lower limb lymphedema is a chronic disorder in which the major component of management is diagnosis and symptom control.\textsuperscript{[108]} Effective treatments for lymphedema and chronic edema have been widely documented to decrease the volume of the limb.\textsuperscript{[5-10]} The most often utilized treatment involves the four-part intervention of manual lymphatic drainage, skin care, compression bandaging, and remedial exercise.\textsuperscript{[91, 92, 108, 109]} Although the techniques for treatment have been in use since the early 1900s, it was not until October 20, 1997, that coverage for the treatment was allowed by the Medicare system.\textsuperscript{[5, 6]}

Of the four components involved with CDP, only one specifically addresses exercise. The exercises instructed are remedial, to be practiced when the patient is wearing the compression bandages. They force the muscles and joints to further propel any stagnant lymph and interstitial fluid proximally, increasing volume and force of flow. Exercise sessions consist of approximately 15-minute routines to be self-performed by the patient while bandaged.\textsuperscript{[103]} This exercise regime is designed to promote lymph drainage and not to strengthen or increase range of motion. Typically, patients do not receive any treatments designed to improve their activity ability beyond those directed at decreasing limb volume. Lymphedema is defined by one impairment; excessive volume. The treatment is designed to address the one impairment. The presence of other impairments and subsequent activity limitations is part of the criteria for treatment but is not directly addressed by CDT.
For subjects with lower limb lymphedema, the performance of an exercise protocol that stimulates the lymphatic system may not be sufficient to address the impairments associated with the condition or modify their activity abilities, because the impairments require a different intervention by the physical therapists. Remedial exercises may be insufficient to address the associated impairments and activity limitations.

Without baseline data, the effectiveness of the treatment for lymphedema to change the patient’s activity ability as well as the edema is inconclusive. Four related questions must be raised;

First, what are the baseline impairment and activity deficits of subjects with unilateral or bilateral lower limb lymphedema?

Second, if baseline data identified the activity deficits, does the treatment for edema change the activity deficits within the 2-week episode of care?

Third, if baseline data identified the impairments, does the treatment for edema change the impairments within the 2-week episode of care?

Fourth, if, after the 2-week episode of care, reevaluation indicates continued activity deficits, is a 4-week intervention of standard and usual physical therapy intervention effective in modifying these activity deficits?

The future of treatment for lower limb lymphedema requires baseline data of activity mobility and quality of life. Subsequently, the effects of the present standard of care for the treatment of lymphedema must be evaluated on the merits of the changes in volume as well as benefit to function and quality of life.
Purpose of the Study

The purpose of this study of lower limb lymphedema was multifaceted. First, this study investigated the criterion validity of the optoelectronic method (Perometer) as a measure of change in limb volume against the “gold standard” water displacement method of measurement in lymphedema patients. The study also assessed the reliability of the Perometer.

Second, the study was designed to identify the types and severity of impairments and activity limitations and determine if these are associated with the severity and/or duration of the lymphedema. The study then examined if the change in limb volume modified the impairments and/or activity deficits. Finally, the study examined of the subjects completing the intervention for treatment for lymphedema, how many scored under 45 on the berg scale and/or above 20 on the Expanded Timed Up and Go test requiring an additional 4 weeks physical therapy intervention. Additionally, did the additional four weeks of physical therapy intervention modify the impairments and activity limitations compared to the 2 week lymphedema intervention?

Research Questions and Hypotheses

This study addressed eight research questions and corresponding hypotheses:

Research Question 1: What are the type and severity of impairments seen in patients with lower limb lymphedema?

Hypothesis 1.1: The Limits of Stability, Berg Balance, 30 Second Chair Test, Heel Rise Test and range of motion of subjects with LE lymphedema will differ from the normative values for these tests.
Research Question 2: What are the type and severity of activity limitations seen in patients with lower limb lymphedema?

Hypothesis 2.1: Timed Get Up and Go, LIMAT Functional, SF-36 Physical Activity Scale scores of subjects with LE lymphedema will differ from the normative values for these tests.

Research Question 3: In subjects with lower limb lymphedema, is the severity of the impairments (balance, lower limb strength, range of motion, and pain) related to the severity of the lymphedema (based on International Society of Lymphology classification standards)

Hypothesis 3.1: At baseline, Limits of Stability, Berg Balance, 30 Second Chair Test, Heel Rise Test, and range of motion scores of subjects with LE lymphedema scores will differ by International Society of Lymphedema class.

Research Question 4: Is the severity of the activity limitations in subjects with lower limb lymphedema related to the severity (based on International Society of Lymphology classification standards) of the lymphedema, or to co-impairments of balance, lower limb strength and range of motion, or some combination of all of these?

Hypothesis 4.1: At baseline, Timed Get Up and Go, Function, SF-36 Physical Activity Scale, and LIMAT scores of subjects with LE lymphedema scores will differ by International Society of Lymphedema class.

Hypothesis 4.2: At baseline, severity of lower limb impairment as measured by Limits of Stability, Berg Balance, 30 Second Chair Test, Heel Rise Test, and range of motion scores will be related to severity of activity limitations, as measured by Timed
Get Up and Go, SF-36 Physical Activity Scale, and LIMAT Function scores in subjects with LE lymphedema.

Research Question 5: Is a change in limb volume related to an improvement in activity limitation?

Hypothesis 5.1. At the end of a 2-week period, the change in Perometer measurements will relate to an improvement in scores of Timed Get Up and Go, SF-36 Physical Activity Scale, and LIMAT Function scores of subjects with LE lymphedema.

Research Question 6: Is decrease in limb volume related to improvement in impairments of balance, strength, and range of motion?

Hypothesis 6.1: At the end of a 2-week period, changes in Perometer measurements will relate to improvement in Limits of Stability, Berg Balance scores, strength, and range of motion scores of subjects with LE lymphedema.

Research Question 7: What is the proportion of subjects who have completed the 2-week intervention and continue to have a balance impairments or activity limitations severe enough to increase the risk of falling, and how does this proportion compare with the baseline characteristics of subjects who do and do not have problems, indicating the need for additional rehabilitation?

Hypothesis 7.1: Subjects who score < 45 on the Berg Balance Scale after 2 weeks of treatment will differ from subjects who score 45 > on baseline measures of disease severity, impairments, and activity limitations.

Research Question 8: Does a 4-week standard physical therapy intervention to address impairments in strength, ROM, and balance produce improvements in impairments and the activity limitations?
Hypothesis 8.1: There will be a significant change in Limits of Stability, Berg Balance scores, 30 Second Chair Test, Heel Rise Test, and range of motion scores of subjects with LE lymphedema following a 4-week standard physical therapy intervention.

Hypothesis 8.2: There will be a significant change in Timed Get Up and Go, SF 36 Physical Activity Scale, and LIMAT Function scores of subjects with LE lymphedema following a 4-week standard physical therapy intervention.

Hypothesis 8.3: There will be a relationship between changes in impairments and changes in activity limitations.

Detailed Specification of Sample

Sampling Method

Subjects

Sample and Sample Size

This study was conducted at The Flagler Institute for Rehabilitation, an outpatient facility that specializes in the treatment of lymphedema. The Flagler Institute for Rehabilitation Building encompasses 4400 sq ft of clinical space and all equipment was located at the Institute. Funding for study related costs was provided by the researcher.

Patients who had been referred to The Flagler Institute for Rehabilitation for treatment of lower limb lymphedema comprised the study population. A convenience sample of adults who were patients of The Flagler Institute for Rehabilitation was selected.

The sample size required a minimum of 28 subjects, as identified by GPower analysis. The criterion for this sample estimation was based on testing for a
significant Spearman’s $r$. The $N$ (subjects) established was for a large effect size at power $= .80$ for $\alpha$ (two-tailed) = .05.

**Inclusion and Exclusion Criteria**

The following inclusion criteria were used to determine eligibility to participate in the study:

1. males and females, with a diagnosis of either unilateral or bilateral lower limb edema or lymphedema, ages 18-75.
2. ability to ambulate independently either with or without an assistive device.
3. accepted as patients of The Flagler Institute for Rehabilitation.
4. met the criteria of the Medicare plan for treatment of lymphedema.
5. able to tolerate a moderate exercise program.

Subjects with any of the following conditions were excluded from participation in this study:

1. acute congestive heart failure.
2. acute lower limb deep vein thrombosis.
3. lower limb arterial disease.
4. lower limb joint replacements.
5. acute or chronic hip fractures.
6. severe lower limb arthritis.
7. acute low back pain.
8. neurologic conditions such as Parkinson disease or Cerebral Vascular Accident.
Recruitment and Informed Consent

Upon initial evaluation with a treating therapist, the patients were given a form to sign consenting to and approval to discuss the research with the investigator. After written approval to discuss the research was obtained, patients met with the researcher who explained the protocol. During this meeting, the researcher obtained informed consent from the subjects if they chose to participate. They were also informed that if they chose to participate they could withdraw from the study at any time and that withdrawal would not affect the delivery of care to them under their insurance guidelines. Once approval was attained and consent signed, the researcher initiated the evaluation and measurement process.

Measures

Measures of subject demographic and clinical characteristics

Basic demographic information was gleaned, including age, height, weight, gender, education, marital or assistant status, and length of time since onset of edema or lymphedema

Health Condition Outcome Measures

Intervention Questionnaire

A three-part questionnaire (Appendix B) identifying pertinent questions for the subjects was administered at three separate times. Part 1 was administered prior to the onset of the research intervention. Part 2 was administered on the final day of the first 2
weeks of lymphedema treatment. Part 3 was administered on the final day of the 6-week research protocol.

The first part of the questionnaire requested information from the subjects regarding the type and location of the lymphedema, prior treatments, ability to self regulate condition, and assistance at home. The second part requested information regarding the first 2 week episode of treatment, whether garment fitting had been performed and subject’s plans for future treatment. The third and final part requested information regarding whether the subject participated in the 4 week interventional component of the study and a subjective report of their activity status over the past 4 weeks.(Appendix B). Time for administration of each part is approximately 5 minutes.

**ISL Staging of Lymphedema**

In conjunction with the above measurements, each subject was assessed for stage of lymphedema. These were calculated based on the ISL’s definitions of the four stages of lymphedema as discussed prior. (Table 1.2)

**Body Structure Impairments Outcome Measures**

**Volumetric Measurement with the Perometer**

The subjects were measured for edema or lymphedema in bilateral lower limbs by means of the Perometer. (Fig 1.2) The Perometer calculated the volume measure of the limbs at baseline, at the 2-week interval, and at the 6-week interval. The measurements were recorded electronically and comparisons made among the three measures.
The data incorporated the maximal excursion of the frame. The vertical distance was established as the baseline for further measurements. This establishment allowed for the change in edema to be compared accurately and reliably between the initial, 2-week, and 6-week measurements.

![Fig 1.2 Perometer](image)

**Active and Passive Range of Motion**

Active range of motion (AROM) of the lower limbs was measured following standard protocol at baseline, at the 2-week interval, and at the 6-week interval. Range of motion measures were determined by use of goniometric measurement for the ankle and knee.\textsuperscript{[111]} Interrater reliability of goniometric measurement has been well documented of ankle plantar and dorsi flexion and knee flexion and extension.\textsuperscript{[112, 113]}

Goniometric measurement followed standard protocol.\textsuperscript{[114]} Knee flexion and extension goniometric measurement utilized the alternative positioning secondary to the potential positioning limitations of the subject population. The subject was positioned
supine rather than in the primary measurement position, which is prone. Initially, the hip was in 0 degrees of flexion, extension, abduction, and adduction, but as the knee began to flex, the hip was also flexed. The alignment of the goniometer adhered to the following protocol:

1. Center the fulcrum of the goniometer over the lateral epicondyle of the femur.
2. Align the proximal arm with the lateral midline of the femur, using the greater trochanter as reference.
3. Align the distal arm with the lateral midline of the fibula, using the lateral malleolus as reference.\textsuperscript{[114]}

Ankle dorsi flexion and plantar flexion goniometric measurement utilized the recommended testing positioning. The subject was positioned supine with the knee flexed at least 30 degrees. The foot was positioned in 0 degrees of inversion and eversion. The alignment of the goniometer followed the following protocol:

1. Center the fulcrum of the goniometer over the lateral aspect of the lateral malleolus.
2. Align the proximal arm with the lateral midline of the fibula, using the head of the fibula as reference.
3. Align the distal arm parallel to the lateral aspect of the fifth metatarsal.\textsuperscript{[114]}

\textit{Strength}

Subjects were tested for strength to the quadriceps and triceps surae at baseline, at the 2-week interval, and at the 6-week interval. Quadriceps testing was performed
utilizing the 30-second chair test,[115] and triceps surae were tested utilizing the heel rise test.[116]

The 30-second chair-stand test was administered using a chair without arms placed against a wall. The test began with the subject seated in the middle of the chair, back straight, feet approximately shoulder-width apart and placed on the floor at an angle slightly back from the knees, with one foot slightly in front of the other to help maintain balance when standing. At the tester’s signal “Go,” the subject rose to a full stand (body erect and straight) and then returned back to the original seated position. The subject was instructed to be fully seated between each stand. The score calculated was the total number of stands executed correctly within 30 seconds (more than halfway up at the end of the 30 seconds counted as a full stand). A total of 10 repetitions is the minimal level of expected performance.[115]

The heel rise test procedure required the subject to stand straight and then begin to rise and lower on the balls of the feet in rhythm with a metronome, which was set at a rate of one heel rise every 2 seconds. Each subject was allowed to touch the examiner with a single finger for balance. The test was terminated if the subject leaned or pushed down on the examiner, the subject’s knees were flexed, the plantar flexion range of motion was decreased by more than 50% of the starting range of motion, the subject stopped or asked to stop, or the subject was asked to stop by the examiner.[116,117]

**Berg Balance Test**

The Berg Balance Test (BBS) consists of 14 items of activities measured on a 5-point ordinal scale. Each activity is scored based on the level of ability for each item. The
scores are then added for a cumulative score (a score of 45 or below of a possible total of 56 indicates risk for falls). Higher scores indicate better balance. The activities vary from simple tasks, such as maintaining one’s stability in standing, to dynamic tasks, such as changing the base of support when lifting a lower limb or performing the same movements with increased speed. A study comparing four activity tests, including the BBS, in discriminating fallers from non-fallers in older people, showed that the BBS was the most powerful performance based test of the four in discriminating fallers from non-fallers.

The Berg Balance measure was calculated at baseline, at the 2-week interval, and at the 6-week interval. Subjects who scored at or below 45 after the 2-week interval were identified to continue with an additional 4 weeks of physical therapy.

**Limits of Stability**

The Smart Balance Master system was utilized to conduct the limits of stability testing. The Limits of Stability (LOS) measures volitional control of the center of gravity. The LOS test is a series of sway angles defining, for each direction from center, the center of gravity sway angle that places the center of gravity at the outer boundaries of the base of support. Moderate to high reliability of the LOS test has been found in a study of healthy adults when tested on two occasions 1 week apart. The LOS is a quantifiable, objective representation of balance.

The Smart Balance Master system is a mobile piece of equipment consisting of dual static force plates and a computer monitor. Each footplate rests on two force transducers with the sensitive axes oriented vertically. The transducers in turn provide
input to the computer. The software program filters the center-of-pressure data and then calculates, tracks, and displays the centre of gravity (COG) on the monitor. Data from the assessments are recorded in the form of COG sway or moving velocity. The resultant variables are normalized to account for differences in body weight and height and can be used to compare balance in individuals differing in height and weight.

The Limits of Stability testing procedure was adapted from prior literature. During the LOS test, participants were instructed to move to two predetermined square targets, with the center target representing the starting position. The targets were located on a video screen at eye level. Targets were spaced at 180-degree intervals around an oval, representing 100% of the distance from the center position to the subjects’ theoretical LOS. Subjects were asked to move the cursor from the center target to the designated target so that the cursor coincided with the target displayed. Subjects were then asked to hold the position for 8 seconds and then return to the center target. The path of each subject’s targets was sequentially highlighted in a clockwise direction during testing. Subjects’ feet were repositioned if necessary following a loss of balance or foot shift during testing. One practice trial in the cardinal planes was allowed to familiarize subjects with the test.

The measures recorded from this test were the Endpoint Excursion (EPE) and Maximum Excursion (MXE). Endpoint excursion is the distance of the first movement toward the designed target, expressed as a percentage of the maximum limits of stability distance. The endpoint is considered to be the point at which the initial movement toward the target ceases. Maximum excursion is the maximum distance achieved during the
The data were raw and not normalized. The Limits of Stability measure was calculated at baseline, at the 2-week interval, and at the 6-week interval.

**Activity and Participation Level Outcome Measures**

**Expanded Timed Get Up and Go (ETGUG)**

Originally, the Expanded Timed Up and Go (ETUG) test was used to measure basic activity mobility. The ETUG was developed to answer the shortcomings of prior iterations of a fall risk screening tool namely the ‘Get up and Go’ and the ‘Timed up and Go’ (TUG). The GUG aimed to screen fall risk in elders through the performance of a combined task: rise from an armed chair, walk 3 meters, turn, walk back and sit down again. The test was modified and described as the ‘Timed up and Go’ by timing the combined tasks. The ‘Expanded Timed Get Up and Go’ (ETGUG) was further developed which used an armless chair increased the distance and timed the combined tasks as one task. The ETGUG administration involves recording in seconds the time taken to complete rising from a chair, walking 30 feet, turning, walking back to the chair, and sitting. A sample of adults without balance problems were able to complete this test in under 20 seconds, whereas a sample of those dependent in most activities of daily living and mobility skills completed the test in more than 30 seconds.
The ETGUG measure was calculated at baseline, at the 2-week interval, and at the 6-week interval. Subjects who scored at or above 30 after the 2-week interval were identified to continue with an additional 4 weeks of physical therapy. The interpretation of the scoring identified that the 30 second result was the demarcation measure to identify at risk elders who required additional therapy intervention.\[88\]

**Limitation in Mobility Activities Test (LIMAT)**

Subjects completed the LIMAT, a 38-item health survey. In this test, four concepts are assessed: (a) transfers—activity, (b) transfers—impairments, (c) mobility—activity, and (d) mobility—impairments. The LIMAT was calculated at baseline, at the 2-week interval, and at the 6-week interval. Appendix A summarizes all data acquisition measurements. Table 2 summarizes the 10 standard measures to be employed by name and normal standards for each measure.
SF-36 Medical Outcomes Study

Subjects completed the Medical Outcomes Study, a 36-item short form health survey (SF-36). The SF-36 was constructed to survey the patient’s point of view in monitoring medical care outcomes. The scoring of standardized responses to standardized questions is an efficient way to measure health status. The SF-36 is a well-established self-administered questionnaire, shown to be robust across a range of populations. The SF-36 questionnaire includes one multi-item scale measuring each of eight health concepts: (a) physical functioning, (b) social functioning, (c) limitations in usual role activities because of physical or emotional role, (d) bodily pain, (e) general mental health, (f) vitality, and (g) general health perceptions.

The SF-36 permits scoring of the set of eight scales displayed as a profile of health status concepts. The scores are easy to compute, and considerable information regarding their interpretation is established. The SF-36 measures was administered and calculated at baseline, at the 2-week interval, and at the 6-week interval. The scoring is explained in Table 1.3

Subject Treatment Intervention

Intervention

Each Subject received the standard lymphedema evaluation which includes the following:

1. Patient history and subjective reports of activity limitations
2. Demographics information
3. Volumetric measurement with the Perometer
4. Integumentary assessment

5. Impairment and performance testing

The standard intervention for the treatment of lymphedema proceeded for the initial 2 weeks. The standard intervention involved the use of manual therapy by a trained therapist, followed by skin care, compressive wrappings of the limb, and remedial exercises. The duration of each episode was approximately 1 hour, performed 5 times per week for 2 weeks. After the initial 2-week interval of standard intervention, each group was retested. Those subjects who demonstrated activity deficits based on testing criteria continued for a 4-week intervention to address the activity deficits. Again at the 6-week interval, each group was tested a final time.

The physical therapy intervention for the treatment of lymphedema was performed by therapists certified in the treatment of lymphedema. All subjects received this component of the research protocol. Each daily treatment consisted of the following four steps:

1. Meticulous skin and nail care, including treatment of any infection.

2. Manual lymphatic drainage (MLD) with education on same to subject. MLD, as previously discussed is a massage technique designed to stimulate lymph vessels to contract more frequently and to channel lymphatic fluid toward adjacent, functioning lymph systems. The drainage began with stimulation of the lymphatics’ adjacent basins, and then, for lymphedema of the lower limbs, progressive manual decongestion of the trunk, hip, groin, leg, and more distal regions. MLD was followed by education to patient and/or assistant.
3. Compression bandaging performed immediately after massage. Bandages were applied sequentially from the distal limb toward the groin, with progressive reduction in compression pressure. Multiple layers of minimally elastic cotton bandages were applied with overlying foam inserts that increase pressure in areas that are particularly fibrotic and to ensure uniform pressure distribution.

4. With bandages in place, the therapist guided the patient through a series of exercises intended to increase lymph flow in all available lymph channels and in collateral pathways. The exercises included heel slides, knee extensions and ankle pumps. These exercises were concluded with 15 minutes on a piece of recumbent exercise equipment.

After the initial 2-week episode of care during which the subjects only received the treatment for lymphedema, all subjects were re-tested based on the established protocol. Subjects who tested below 45 on the Berg Balance Scale and/or above 20 seconds on the ETGUG test continued with an intervention to address the impairment and activity limitations. [135] The standard and usual care with physical therapy to address the activity deficits is based on the principles of balance. The three postural movement strategies that are typically used by healthy adults for controlling balance: (1) the ankle strategy, in which balance adjustments are made at the ankle joint and the individual sways as an inverted pendulum; (2) the hip strategy, in which adjustments are made predominantly at the hip; and (3) the suspensory strategy, in which the subject flexes at the ankle, knee, and hip to lower the center of gravity toward the base of support. [136] Normally, three classes of sensory inputs are available for balance control: (1) somatosensory inputs, (2) visual inputs, and (3) vestibular inputs. It has previously been shown that healthy adults
rely primarily on somatosensory inputs under normal sensory conditions in which all sensory inputs are available.\cite{136}

Each subject received the same protocol or treatment to address the physiologic component necessary to achieve the balance and activity mobility. These treatment components included:

a) Passive Range of Motion to bilateral lower limbs

b) Manual Progressive Resistive Strengthening to bilateral lower limbs

c) Transfer Training – Sit to Stand

d) Postural Training – with Cueing for proper alignment

e) Postural Training – on incline with and without compliant surface

f) Balance Training – on level surface with and without compliant surface and with and without visual feedback

g) Erect Stretching and balance on ramp with asymmetry

h) Gait training with or without device with cueing

i) Erect strengthening ankle

j) Recumbent Nustep 15 minutes

The group requiring the 4 week interventional component performed these activities on a 3 times a week basis. Once completed, subjects were retested as per research protocol.

**Data Management and Analysis**

Data analysis was performed using the SAS statistical software PC SAS version 9.1.3. Specific data analyses were performed base on the hypotheses developed.

Descriptive statistics were calculated to characterize the demographic and clinical characteristics of subjects at baseline. Inferential statistics were used to test each
hypothesis and analyze the data. Each research question is stated, followed by the corresponding hypotheses and data analysis methods.

**Research Question 1.** What is the type and severity of impairments seen in patients with lower limb lymphedema?

**Hypothesis 1.1:** The Limits of Stability, Berg Balance, 30 Second Chair Test, Heel Rise, and range of motion of subjects with LE lymphedema will differ from the age-matched normative values for these tests.

**Analysis:** A paired t test was used to determine whether the Limits of Stability, SF-36 Pain Scale, Berg Balance Score, 30 Second Chair Stand, Heel Rise and ROM scores of subjects with lymphedema differed from the age group normal values for these measures.

**Research Question 2:** What is the type and severity of activity limitations seen in patients with lower limb lymphedema?

**Hypothesis 2.1:** Timed Get Up and Go and SF-36 Physical Activity Scale scores of subjects with LE lymphedema will differ from the normative values for these tests.

**Analysis:** A paired t test was used to determine whether the Timed Get Up and Go and SF-36 Physical Activity Scale scores of subjects with lymphedema differed from the normal values for these measures.

**Research Question 3:** In subjects with lower limb lymphedema, is the severity of the impairments (balance, lower limb strength, range of motion, and pain) related to the severity of the lymphedema (based on International Society of Lymphology classification standards).
Hypothesis 3.1: At baseline, Limits of Stability, Berg Balance, SF-36 Pain Scale, strength, and range of motion scores of subjects with LE lymphedema scores will differ by International Society of Lymphedema class.

Analysis: A one-way ANOVA was used to compare the baseline Limits of Stability, Berg Balance, SF-36 Pain Scale, strength, and range of motion scores of subjects with LE lymphedema assigned to the four International Society of Lymphedema classification groups.

Research Question 4: Is the severity of the activity limitations in subjects with lower limb lymphedema related to the severity (based on International Society of Lymphology classification standards) of the lymphedema or to co-impairments of balance, lower limb strength and range of motion, or some combination of all of these?

Hypothesis 4.1: At baseline, Timed Get Up and Go, SF-36 Physical Activity Scale, and LIMAT scores of subjects with LE lymphedema scores will differ by International Society of Lymphedema class.

Analysis: A one-way ANOVA was used to compare the baseline Timed Get Up and Go, SF-36 Physical Activity Scale, and LIMAT scores of subjects with LE lymphedema assigned to the four International Society of Lymphedema classification groups.

Hypothesis 4.2: At baseline, severity of lower limb impairment as measured by Limits of Stability, Berg Balance, SF-36 Pain Scale, strength, and range of motion scores will be related to severity of activity limitations, as measured by
Timed Get Up and Go, SF-36 Physical Activity Scale, and LIMAT scores in subjects with LE lymphedema.

**Analysis:** A Spearman correlation coefficient was calculated to examine the relationship between the severity of lower limb impairment as measured by Limits of Stability, Berg Balance, SF-36 Pain Scale, strength, and range of motion scores and the severity of activity limitations as measured by Timed Get Up and Go, SF-36 Physical Activity Scale, and LIMAT.

**Research Question 5:** Is a change in limb volume related to an improvement in activity limitation?

**Hypothesis 5.1.** At the end of a 2-week period, the change in Perometer measurements will relate to an improvement in scores of Timed Get Up and Go, SF-36 Physical Activity Scale, and LIMAT scores of subjects with LE lymphedema.

**Analysis:** A Spearman correlation coefficient was calculated to examine the relationship between the change in Perometer measurements and the change in severity of activity limitations, as measured by Timed Get Up and Go, SF-36 Physical Activity Scale, and LIMAT. The Spearman was used due to the small sample size and potential non normal variable distribution.

**Research Question 6:** Is decrease in limb volume related to improvement in impairments of balance, pain, strength, and range of motion?
**Hypothesis 6.1**: At the end of a 2-week period, changes in Perometer measurements will relate to improvement in Limits of Stability, Berg Balance scores, SF-36 Pain Scale, strength, and range of motion scores of subjects with LE lymphedema.

**Analysis**: A Spearman correlation coefficient was calculated to examine the relationship between the change in Perometer measurements and the change in lower limb impairment, as measured by Limits of Stability, Berg Balance, SF-36 Pain Scale, strength and range of motion scores.

**Research Question 7**: What is the proportion of subjects who have completed the 2-week intervention and continue to have a balance impairments or activity limitations severe enough to increase the risk of falling, and how does this proportion compare with the baseline characteristics of subjects who do and do not have problems, indicating the need for additional rehabilitation?

**Hypothesis 7.1**: Subjects who score < 45 on the Berg Balance Scale after 2 weeks of treatment will differ from subjects who score 45 > on baseline measures of disease severity and duration, impairments, and activity limitations.

**Analysis**: Subjects were classified as at risk of falls or not at risk of falls based on whether or not their Berg Balance Scale score was below 45. A student’s t test was used to compare the subjects at risk of falls to subjects not at risk of falls on baseline measures of lymphedema duration, Limits of Stability, Berg Balance, strength and range of motion scores, Timed Get Up and Go, SF-36 Physical Activity Scale, and LIMAT.

**Analysis**: A Mann-Whitney U was calculated to compare the subjects at risk of
falls to subjects not at risk of falls on baseline SF-36 Physical Activity Scale and International Society of Lymphedema classification.

**Research Question 8**: Does a 4-week standard physical therapy intervention to address impairments in strength, ROM, and balance produce improvements in both the impairments and the activity limitations?

**Hypothesis 8.1**: There will be a significant change in Limits of Stability, Berg Balance scores, SF-36 Pain Scale, strength, and range of motion scores of subjects with LE lymphedema following a 4-week standard physical therapy intervention.

**Analysis**: A paired $t$ test was calculated to determine whether there was a significant change in Limits of Stability, Berg Balance scores, SF-36 Pain Scale, strength, and range of motion.

**Hypothesis 8.2**: There will be a significant change in Timed Get Up and Go, SF 36 Physical Activity Scale, and LIMAT scores of subjects with LE lymphedema following a 4-week standard physical therapy intervention.

**Analysis**: A paired $t$ test was calculated to determine whether there was a significant change in Timed Get Up and Go, SF-36 Physical Activity Scale, and LIMAT.

**Hypothesis 8.3**: There will be a relationship between changes in impairments and changes in activity limitations.

**Analysis**: A Spearman correlation coefficient was calculated to examine the relationship between the change in lower limb impairment, as measured by Limits of Stability, Berg Balance, SF-36 Pain Scale, strength and range of motion.
scores, and the change in activity limitations, as measured by Timed Get Up and Go, SF-36 Physical Activity Scale, and LIMAT.

_Potential risks to subjects_

The usual care for lymphedema involves skin care, massage (manual therapy), compressive wraps, and exercise. The usual care for balance problems includes activities involving exercise, walking, and balance activities. There are minimal risks associated with the research related activities. The limits of stability test involves a minimal risk of falls. To prevent falls, the testing equipment uses a safety harness. The harness is attached to a frame above the platform securing the subject while he/she is tested.

_Summary_

The preliminary information in combination with a preliminary study established the basis for the dissertation research. The preliminary study examined the measurement devices over an initial treatment episode to determine the effectiveness of the measurement tool (Perometer). The dissertation research examined a group of subjects with lower limb lymphedema over a two week course with pre and post testing. Following, the two week episode, subjects identified with activity deficits continued over a 4 week physical therapy regime. Testing then occurred after the final 4 weeks to compare baseline to post-intervention after 4 weeks for the fall risk group. The dissertation research examined the information gleaned to assess the specific questions related to subjects.
### Table 1.1
International Society of Lymphology Staging for Lymphedema

<table>
<thead>
<tr>
<th>Stage</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>This is a latent, subclinical condition in which no overt swelling is apparent but lymphatic vessels have been injured and lymphatic pathways disrupted. Stage 0 can exist for several years.</td>
</tr>
<tr>
<td>1</td>
<td>This stage is described as early stage lymphedema, in which there is fluid accumulation which resolves with elevation of the limb. Pitting may be present.</td>
</tr>
<tr>
<td>2</td>
<td>This stage is characterized by pitting when the skin is pressed, and elevation alone no longer resolves the swelling. Late Stage II involves the formation of fibrosis and less evidence of pitting when the skin is pressed.</td>
</tr>
<tr>
<td>3</td>
<td>This is a late stage of lymphedema, also called lymphostatic elephantiasis. At this stage, no pitting is evident, but one or more skin changes may appear, such as fat deposits, warty overgrowths, and acanthosis (a benign thickening of the skin).</td>
</tr>
</tbody>
</table>

### Table 1.2 Medicare reasons for coverage of lymphedema treatment

<table>
<thead>
<tr>
<th>Condition Number</th>
<th>Condition Reasons for Coverage by Medicare</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>There is a physician documented diagnosis of lymphedema; and the physician specifically orders CDP.</td>
</tr>
<tr>
<td>2</td>
<td>The patient is symptomatic for lymphedema, with limitation of function related to self-care, mobility, and/or safety</td>
</tr>
<tr>
<td>3</td>
<td>The patient or patient caregiver has the ability to understand and comply with home care continuation of treatment regimen</td>
</tr>
<tr>
<td>4</td>
<td>The services are being performed by a health care professional who has received specialized training in this form of treatment</td>
</tr>
<tr>
<td>5</td>
<td>The therapy services for CDP must be provided either by or under the direct personal supervision of the physician or independently practicing therapist.(^{(105)})</td>
</tr>
<tr>
<td>Clinical Measure</td>
<td>Test Measure Normal Standards</td>
</tr>
<tr>
<td>--------------------------------------</td>
<td>------------------------------</td>
</tr>
<tr>
<td>Volumetric Measurement</td>
<td>Variable</td>
</tr>
<tr>
<td>ISL Staging of Lymphedema</td>
<td>0 - 3</td>
</tr>
<tr>
<td>Active Range of Motion</td>
<td></td>
</tr>
<tr>
<td>Ankle Dorsiflexion</td>
<td>Normal</td>
</tr>
<tr>
<td>Ankle Plantarflexion</td>
<td>20 degrees</td>
</tr>
<tr>
<td>Knee Flexion</td>
<td>135 degrees</td>
</tr>
<tr>
<td>Knee Extension</td>
<td>0 degrees$^{[137]}$</td>
</tr>
<tr>
<td>Passive Range of Motion</td>
<td></td>
</tr>
<tr>
<td>Ankle Dorsiflexion</td>
<td>Normal</td>
</tr>
<tr>
<td>Ankle Plantarflexion</td>
<td>20 degrees</td>
</tr>
<tr>
<td>Knee Flexion</td>
<td>135 degrees</td>
</tr>
<tr>
<td>Knee Extension</td>
<td>0 degrees$^{[137]}$</td>
</tr>
<tr>
<td>Strength</td>
<td></td>
</tr>
<tr>
<td>Ankle Plantarflexion</td>
<td></td>
</tr>
<tr>
<td>Heel Rise Test</td>
<td>25 Repetitions$^{[116, 117]}$</td>
</tr>
<tr>
<td>Knee Extension</td>
<td>10 repetitions$^{[115]}$</td>
</tr>
<tr>
<td>30-Second Stand Test</td>
<td></td>
</tr>
<tr>
<td>Limits of Stability</td>
<td>100</td>
</tr>
<tr>
<td>Berg Balance Test</td>
<td>45/56$^{[118]}$</td>
</tr>
<tr>
<td>Timed Up and Go</td>
<td>30 seconds$^{[88]}$</td>
</tr>
<tr>
<td>LIMAT</td>
<td>100 - 0$^{[138]}$</td>
</tr>
<tr>
<td>No of items</td>
<td>SF-36 Interpretation of low and high scores&lt;sup&gt;134&lt;/sup&gt;</td>
</tr>
<tr>
<td>-------------</td>
<td>--------------------------------------------------------</td>
</tr>
<tr>
<td>Physical Functioning</td>
<td>10</td>
</tr>
<tr>
<td>Role Limitations due to Physical problems</td>
<td>4</td>
</tr>
<tr>
<td>Social Functioning</td>
<td>2</td>
</tr>
<tr>
<td>Bodily Pain</td>
<td>2</td>
</tr>
<tr>
<td>General Mental Health</td>
<td>5</td>
</tr>
<tr>
<td>Role Limitations due To emotional problems</td>
<td>3</td>
</tr>
<tr>
<td>Vitality</td>
<td>4</td>
</tr>
<tr>
<td>General Health Perceptions</td>
<td>5</td>
</tr>
</tbody>
</table>
CHAPTER 2: LIMB VOLUME MEASUREMENT IN LYMPHEDEMA PATIENTS: COMPARISON OF THE WATER DISPLACEMENT, CIRCUMFERENTIAL, AND PEROMETER METHODS

BACKGROUND

It has been estimated that 150 million people worldwide suffer from some form of lymphedema.\textsuperscript{[139]} Lymphedema represents an imbalance between lymphatic load and lymphatic transport capability,\textsuperscript{[140]} resulting in limb swelling. Identification of lymphedema involves measurement of affected limbs in comparison with unaffected ones, as well as monitoring treatment through measurement of volume reduction. Assessment of the efficacy of volume reduction therapy requires adequate estimation of progressive limb-segment volume changes in milliliters (ml).\textsuperscript{[139]}

The water displacement method for measuring the volume of objects has been used for thousands of years.\textsuperscript{[141]} This method, has been used to measure limb volume by immersing the limb in a tank of water, collecting the overflow, and measuring the volume of the displaced water.\textsuperscript{[139, 142]} The water displacement method is recognized as the “gold standard” for measuring limb volume (ml).\textsuperscript{[141 Grace 1996],[142]}

The circumferential tape measure method was developed as a more feasible alternative to the water displacement method. This method is routinely used by clinicians treating lymphedema. The circumferential method uses a tape measure to assess limb size and shape.\textsuperscript{[143]} Circumferential measurements of a limb are taken at preselected distances along the length of the limb.\textsuperscript{[139, 141]} These measurements are used to calculate an estimate of the limb volume (ml).
The optoelectronic method using a Perometer represents a third method for measuring limb volume. This method was developed within the last two decades in Germany. The Perometer uses infrared sensors to detect limb circumference to determine limb volume. The Perometer is commonly used in Europe but has only recently been introduced into the United States. The Perometer has been shown to be both reliable and a valid instrument for measuring limb volume.

This study had two purposes. First, the study assessed the test-retest reliability of the Perometer method for measuring limb volume. Second, it compared the criterion validity of the Perometer to the circumferential tape measure method as a measure of change in limb volume against the “gold standard” water displacement method.

**MATERIALS AND METHODS**

*Design of Trial*

This was a measurement study in which subjects who received a course of complex decongestive therapy over a two week period were measured at baseline once using the water displacement and circumferential tape measure methods twice and using the Perometer method. All three measurements were repeated after completing two weeks of treatment.

*Sample Subjects*

A convenience sample of 18 subjects was recruited over a one year period from patients receiving complex decongestive therapy at a clinic that specializes in the
treatment of edema and lymphedema. Approval for the study was obtained from the Institutional Review Board of The University of Miami and written consent was obtained from all subjects.

**Inclusion and Exclusion Criteria**

Inclusion criteria were that the subjects were either males or females, at least 18 year of age, and referred by a physician to the Flagler Institute of Rehabilitation for treatment of edema of the upper or lower extremity or both.

Potential subjects with open wounds were excluded from participating because water immersion for the water displacement method could compromise wound healing.

**Procedure**

Each subject was measured immediately prior to treatment and after 2-weeks of treatment. In some subjects, more than one extremity was measured. Measurements were made during the patients' normal treatment sessions for lymphedema. Treatment was performed by the therapists at The Flagler Institute for Rehabilitation. Treatment to reduce limb volume took place 3 to 7 times a week for 45-60 minutes and consisted of skin care, manual lymphatic drainage, compression therapy and remedial exercises.

The measurements for the water displacement and circumferential tape methods were performed twice, immediately prior to treatment and after 2-weeks of treatment. The measurements for the Perometer measures were repeated 3 times, twice consecutively immediately prior to treatment and once after 2-weeks of treatment.
Measurements for all subjects by all three methods were made in exactly the same manner. (Table 2.1)

**Perometer Method**

The Perometer measurement was performed for two purposes. The first purpose was for comparison to the water displacement and circumferential tape measurement methods. The second purpose was to assess the reliability of the unit by performing two consecutive measurements on the same subject at the same episode.

The unit is an upright optoelectronic measurement device that accommodates a subject standing on its base. A square frame arises from the base, surrounding the extremity and elevates up to the limits of the body structure. Within the frame are several hundred infrared light transmitters on two sides of the frame. Each light corresponds to a light receiver facing it on the opposite two sides. When the frame is elevated, light is blocked by the limb from being received by the opposite receptor on two sides of the frame. Two diameters of the limb being perpendicular to each other are calculated and correspond to a specific position of the frame. The measurements are recorded every half centimeter and electronically calculated by the equation of a frustum. A frustum is a truncate cone and is a close approximation to the shape of a limb. The formula used to calculate the frustum volume was:

\[
V = \frac{1}{12\pi} \sum_{i=1}^{n} L ( \cdot -1 + \cdot )
\]

Where \( n \) = the number of segments, \( L \) = length of each segment, and \( \cdot \) = circumference at each end of the segment.\(^{148}\)
In the measurement of subjects' upper limb by the Perometer measurement method, the subject sat in a chair alongside the Perometer, with the upper limb placed in a dependent position. For the upper limb, a fist was made and the hand was placed on the base of the unit. For the lower limb, the subject stood on a platform. A frame was lifted up around the limbs until it was unable to raise higher due to anatomical limitations and the measurement was made electronically.

The Perometer measurement of the limbs corresponded with the same section limb used in the water displacement method and circumferential tape methods. The distances were chosen as the exact levels of water drainage escaping from the volumeters used in the water displacement method. For the arm, the measurement started 18.5 cm proximal to the metacarpophalangeal joint, with a closed fist, and terminated 46.5 cm proximal. For the leg, the measurement started 18.5 cm proximal to the heel pad and terminated 52.5 cm proximal. The software allowed the limb measures to correspond to the above lengths. This process took approximately 4 seconds and required no contact with the subject's limbs.

*Water Displacement Method*

The measurement of the limbs by the water displacement method required three separate volumeters. One volumeter, 30 inches by 8 inches by 7.5 inches, was used for the gross measurement of the upper limb. A second volumeter, 24 inches by 13.74 inches by 6.5 inches, was used for gross measurement of the lower limb. The final volumeter, 9 inches by 13.75 inches by 6.25 inches, was used for the distal segments, hands and feet.
Final segment calculations for comparison required subtraction of the distal volume from the total limb volume.

The volume of water was collected in containers. Each container was weighed with the displacement on a JScale platform scale. This scale has an auto-zero tracking to reset the scale between measures. After which the weight of the container was removed from the total leaving the weight of the volume alone. The weights were documented and then calculated into milliliters for comparison. Calculations for volume were determined by using the formula: \[ x(\text{ml}) = \frac{3785 \text{ ml} \times y \text{ lbs}}{8.33 \text{ lbs}} \], with \( x \) = volume of segment expressed in ml, 3785 ml = ml in a gallon of water, \( y \) = weight of water of measured segment in lbs, and 8.33 lbs = weight of a gallon of water.

To initiate the process, the volumeters were placed in a shower. Each volumeter was filled to the level of the runoff spout with tepid water. The subjects were instructed in performance of the immersion to simulate the positioning of the measures for the Perometer by leaning over and placing the arm into the volumeter. The volumeter for the upper limb had a centrally placed rod to the unit that demarcated the depth of the immersion of the limb. The hand was placed in a fist position, with the metacarpal directly contacting the rod. While the patient stood and flexed the trunk, the upper limb was immersed to the point at which the contact with the rod simulated the measures with the circumferential method and the Perometer. In order to immerse the distal segment into the second volumeter, the subject sat in a chair and maintained a perpendicular position to the base while immersing the segment. Final volume of the segment was determined by subtracting the distal segment of the limb from the entire limb. The method was adapted from standard volumeter measurement protocol.\(^{[149]}\)
For the lower limb, a subject stepped up onto a stepstool and then lowered the affected limb into the lower limb volumeter, displacing the water into the associated container. After removing the extremity from the container and drying of the limb, the subject placed the limb into the volumeter for the foot segment, displacing the water into a container. Two measurements were taken similar to the upper extremity. The volume for the foot was subtracted from the entire lower limb measurement. This process took approximately 20 minutes.

*Circumferential Tape Measurement Method*

The circumferential method involved the use of two identical measurement devices constructed of a length of board marked with a centimeter ruler and an end plate affixed at a right angle at the base. One unit was demarcated to measure the arm and the other for the leg using identical distances as in the Perometer and volumetric methods.

The circumferential measures were taken utilizing a Gulick spring-loaded tape-measure[^150]. An identifiable marking on the piston was used to maintain equal pressures throughout the study to provide precise circumferential measurements. The subject was seated in front of an adjustable table that supported either the upper limb or the lower limb, with the shoulder at 90 degrees or knee joint at neutral with subject supine. As the limb lay on the measurement device, a circumferential measure was taken perpendicular to the ruler. The circumference was recorded at 4 cm intervals for each limb based on the Perometer and water displacement settings. The measurements were computed utilizing a software program created by the Bioscience Research Institute.[^151] All measurements
were recorded and input into a software formula for a frustum to determine approximate volume. \cite{148}

Statistical Analysis

An Intra-class correlation coefficient was calculated to examine the test-retest reliability of the two pre-treatment Perometer measures. Difference scores for all three methods were calculated by subtracting the post treatment limb volume from the pre-treatment limb volume. ICCs were calculated to determine the level of agreement between the difference scores calculated for the water displacement method and the difference scores for the other two methods.

RESULTS

Subjects Characteristics The subjects (N=18) included 50% male (N=9) and 50% female with 31 total limbs measured. Twenty two percent of the subjects (N=4) had one upper limb tested and 0% (N=0) had both upper limbs tested. Twenty two percent of the subjects (N=4) had one lower limb tested while 39% (N=7) had two limbs tested. Subjects tested with multiple upper and lower extremities included 6% (N=1) with one upper and two lower extremities and 6% (N=1) with two upper and one lower extremity. The related primary diagnoses resulting in the lymphedema included 22% orthopedic (N=4), 50% cancer (N=4), 17% (N=3) venous insufficiency and 11% (N=2) obesity. (Table 2.2)
Pre-test measures Inter-class Correlation

The ICC agreement between the water displacement method and the circumferential tape method for the pre-test measures was .98. The ICC agreement between the water displacement method and the Perometer for the pre-test measures was .99. The ICC agreement between the Circumferential method and the Perometer for the pre-test measures was .98. (Table 2.3)

Test-Retest Reliability

The ICC for agreement between the two baseline Perometer measures was 1.00.

Limb Volume

The differences between the pre-post treatment limb volume measures were calculated for each method. The mean difference was 2.86 ml (sd 215.32 ml) for the water displacement method, 2.77 ml(sd 209.91 ml) for the circumferential tape method and 4.45 ml (sd 205.03 ml) for the optoelectronic method. (Table 2.4) The ICC for agreement between the change measured by the water displacement method and change measured by the Perometer was .99. However, The ICC for agreement between the change measured by the water displacement method and change measured by the tape measure method was only .92. (Table 2.5)

DISCUSSION

The results of this study found that the Perometer had excellent test-retest reliability (ICC = 1.0) and that the change measured by the Perometer agreed better with
the change measured by the “gold standard” water displacement method, (ICC = .99) than did the change measured by the circumferential tape method (ICC = .92).

Prior studies had examined relationships among the three limb volume measurement methods at one point in time. The results of this study are supported by the following studies for the reliability of the Perometer. Tierney et al. who found that the Perometer method agreed almost exactly with water displacement \( (r = .97) \). However, these authors contended that due to the variation of the tape measurement calculations, the circumferential method overestimated the volume and correlated at \( r = .72 \) for the frustum calculations. Stanton et al. established that the volume calculations using the Perometer method and circumferential methods correlated very stronger for measurements on three types of limbs \( (r = 0.999 \) for the mannequin limbs, \( r = 0.985 \) for normal human upper limb, and \( r = 0.988 \) for lymphedema arms). Megan et al. also found strong correlations between the circumferential and water displacement methods \( (r = .93) \). While accuracy of one time measurements of a limb volume are critical, the ability of a measurement tool to detect change over time is essential.

The purpose of this study was to identify the best method for measuring pre-post treatment change in limb volume. The fact that limb volume change measured by the “gold standard” water displacement method agreed more strongly with that of the Perometer method than the tape measure method suggests that the Perometer is more effective than tape measure for documenting change in volume of limbs of lymphedema patients.
CONCLUSION

The results of this study suggest that the Perometer is a reliable measurement of the change in volume of a limb with accuracy equivalent to the water displacement method. Although both the circumferential and optoelectronic measures of limb volume are strongly correlated with the water displacement measures at pretest, the Perometer method appears to be better able to detect volume change due to treatment than the circumferential tape method based on correlation analysis.

The water displacement method provides direct measurement of the volume of the limb, which neither of the other methods provides. The size of the volumetric apparatus is modest and can be stored when not utilized. The cost is modest and feasible for most clinics and research organizations. Many clinicians believe that this method provides the truest measure of limb volume, and as a result it is considered the “gold standard for lymphedema measurement”\(^{[141, 142]}\). However, the apparatus is cumbersome and requires extensive cleaning, the technique cannot be used with subjects with physical disabilities, wounds or skin deficits, and the procedure is time-consuming.\(^{[139-141]}\)

The tape measure or circumferential method provides a simple, easy method that requires minimal and inexpensive apparatus. The size of the apparatus is minimal, and the process requires no cleaning after use. The low cost is a benefit to both clinic and research facility. However, although the method is reliable, it is an indirect method and thus does not provide an exact measure of the limb. The procedure is time-consuming, and errors can be made in positioning of measurements to be taken as well as the perpendicular measurement of circumference. In addition final volume measurements require data input and formula calculations.\(^{[139-141]}\)
The optoelectronic method with the Perometer is speedy in procedure time and patient positioning. Data collection, storage, and retrieval are automatic. However, the size of the apparatus requires dedicated space, which can be prohibitive for some clinics and research facilities. In addition, the cost of the Perometer is significant relative to the other methods.\textsuperscript{[139, 141, 143]} The decision to use one or another of these methods would be likely based on a combination of the advantages and disadvantages. Whichever method of measurement clinicians choose, the findings of this study outcomes suggest that while the water displacement is the ideal measurement tool, comparable volume measurements of limbs in lymphedema patients can be made with the other two methods as well. Therapists or facilities with lesser patient caseloads may choose one of the less expensive devices, realizing that for their situations the cost/benefit ratio of the Perometer may not be feasible.

Therapists or facilities involved with research or with high caseloads of lymphedema patients may choose the Perometer. The cost/benefit would be realized over time, with decreased non-productive time and improved ease of data management and retrieval. The Perometer has high accuracy in the ability to detect limb volume change with excellent demonstrated reliability. Thus, clinical investments in the optoelectronic equipment would be appropriate and would substantially aid the treatment monitoring of patients with lymphedema.
Table 2.1
*Study Design*

<table>
<thead>
<tr>
<th>Measurement Method</th>
<th>Pretreatment</th>
<th>2-Week Posttreatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water Displacement Method</td>
<td>Volume Measurement 1</td>
<td>Volume measurement 2</td>
</tr>
<tr>
<td>Circumferential Method</td>
<td>Volume Measurement 1</td>
<td>Volume Measurement 2</td>
</tr>
<tr>
<td>Optoelectronic Method</td>
<td>Volume Measurement 1a</td>
<td>Volume Measurement 2</td>
</tr>
<tr>
<td></td>
<td>Volume Measurement 1b</td>
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Table 2.2: Patient Characteristics (N=18)

<table>
<thead>
<tr>
<th>Variable</th>
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<tbody>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>9</td>
<td>50%</td>
</tr>
<tr>
<td>Female</td>
<td>9</td>
<td>50%</td>
</tr>
<tr>
<td>Diagnosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Orthopedic</td>
<td>4</td>
<td>22%</td>
</tr>
<tr>
<td>Cancer</td>
<td>9</td>
<td>50%</td>
</tr>
<tr>
<td>Venous insufficiency</td>
<td>3</td>
<td>17%</td>
</tr>
<tr>
<td>Obesity</td>
<td>2</td>
<td>11%</td>
</tr>
<tr>
<td>Limbs tested</td>
<td></td>
<td></td>
</tr>
<tr>
<td>One upper only</td>
<td>4</td>
<td>22%</td>
</tr>
<tr>
<td>Two upper only</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>One lower only</td>
<td>4</td>
<td>22%</td>
</tr>
<tr>
<td>Two lower only</td>
<td>7</td>
<td>39%</td>
</tr>
<tr>
<td>One Upper/Two Lower</td>
<td>1</td>
<td>6%</td>
</tr>
<tr>
<td>Two Upper/Two Lower</td>
<td>1</td>
<td>6%</td>
</tr>
</tbody>
</table>

Table 2.3: Agreement among the Three Measures of Limb Volume at Baseline

<table>
<thead>
<tr>
<th>Method</th>
<th>ICC</th>
<th>% p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water x Circumferential</td>
<td>.98</td>
<td>.96-.99</td>
</tr>
<tr>
<td>Water x Optoelectronic</td>
<td>.99</td>
<td>.98-.99</td>
</tr>
<tr>
<td>Circumferential x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Optoelectronic</td>
<td>.99</td>
<td>.98-.99</td>
</tr>
</tbody>
</table>

*p < .05.
Table 2.4  
*Descriptive Statistics for Volume Changes by Measurement*

<table>
<thead>
<tr>
<th>Volume:</th>
<th>Pretreatment to Posttreatment</th>
<th>N</th>
<th>Minimum</th>
<th>Maximum</th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water Displacement:</td>
<td>Pretreatment</td>
<td>31</td>
<td>818</td>
<td>5180</td>
<td>3253</td>
<td>1414</td>
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<tr>
<td></td>
<td>Posttreatment</td>
<td>31</td>
<td>772</td>
<td>5271</td>
<td>3248</td>
<td>1394</td>
</tr>
<tr>
<td></td>
<td>Posttreatment – Pretreatment</td>
<td>31</td>
<td>-358</td>
<td>673</td>
<td>2.86</td>
<td>215.32</td>
</tr>
<tr>
<td>Circumferential:</td>
<td>Pretreatment</td>
<td>31</td>
<td>1072</td>
<td>5413</td>
<td>3381</td>
<td>1443</td>
</tr>
<tr>
<td></td>
<td>Posttreatment</td>
<td>31</td>
<td>1058</td>
<td>5353</td>
<td>3352</td>
<td>1412</td>
</tr>
<tr>
<td></td>
<td>Posttreatment – Pretreatment</td>
<td>31</td>
<td>-370</td>
<td>466</td>
<td>2.77</td>
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<td>Optoelectronic:</td>
<td>Pretreatment</td>
<td>31</td>
<td>870</td>
<td>5581</td>
<td>3357</td>
<td>1452</td>
</tr>
<tr>
<td></td>
<td>Posttreatment</td>
<td>31</td>
<td>824</td>
<td>5496</td>
<td>3357</td>
<td>1424</td>
</tr>
<tr>
<td></td>
<td>Posttreatment – Pretreatment</td>
<td>31</td>
<td>-364</td>
<td>409</td>
<td>4.45</td>
<td>205.03</td>
</tr>
</tbody>
</table>

*In ml.*
Table 2.5  
Agreement among the Three Measures in Detecting Limb Volume Change Pre-post Intervention

<table>
<thead>
<tr>
<th>Method</th>
<th>ICC</th>
<th>% p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water x Circumferential</td>
<td>.92</td>
<td>.84-.95</td>
</tr>
<tr>
<td>Water x Optoelectronic</td>
<td>.99</td>
<td>.98-.99</td>
</tr>
<tr>
<td>Circumferential x Optoelectronic</td>
<td>.92</td>
<td>.84-.96*</td>
</tr>
</tbody>
</table>

*p < .05.
CHAPTER 3: IMPAIRMENTS AND ACTIVITY LIMITATIONS ASSOCIATED WITH LOWER EXTREMITY LYMPHEDEMA

OVERVIEW

It has been estimated that 150 million people worldwide suffer from some form of lymphedema.\[139\] Lymphedema represents an imbalance between lymphatic load and lymphatic transport capability,\[140\] resulting in limb swelling. The lymphatic system is a vascular retrieval system that in part returns leaked fluid from the vascular system and is a complementary system to the blood circulatory system that maintains equilibrium of fluid content within the body. With normal functioning, excessive extravascular fluid is automatically absorbed and returned to the heart by the lymphatic system. On average, approximately 2 liters of lymph return to the circulatory system via the large veins entering the heart every day. Absence of or damage to the lymphatic system may produce lymphedema.\[5, 18\]

Primary lymphedema is caused by a congenital defect in lymph vessel or lymph node development. Secondary lymphedema results from damage to the lymphatic structures\[153\][154] and can result from surgical resection or radiation for the treatment of cancer located in the abdominal region, including ovarian, uterine, vulvar, prostate, and malignant melanoma. Other causes of secondary lymphedema include trauma, venous insufficiency, clot formation, or surgical procedures. \[18\]

Four criteria are used to diagnose lymphedema: 200 ml increase in limb volume changes (LVC); a 10% increase in limb volume LVC; 2 cm increase in limb circumference; and report of heaviness or swelling, either "now" or "in the past year."\[155\] An imaging technique, radionuclide lymphoscintigraphy, is occasionally used to identify
the exact location of blockage or damage to the lymphatic system.\textsuperscript{[156]} This technique involves injecting a radioactive dye with radiolabeled tracers into the interstitial space of the involved extremity and monitored with a gamma camera.\textsuperscript{[157]} The technique has been used for decades and is reliable and reproducible. \textsuperscript{[157]} Although excellent for diagnosis, this technique for testing is not available too many individuals with lymphedema because of limited facilities and/or practitioners unfamiliarity. Thus, volume changes have been the major criteria for diagnosing lymphedema\textsuperscript{[14, 158, 159]}

The treatment for lymphedema involves a four-part method called complex decongestive therapy (CDT). The method consists of manual lymph drainage, compression therapy, skin care and remedial exercises\textsuperscript{[13]} CDT is performed by a physical therapist or other health care practitioner who has completed the postgraduate certification course required by Medicare.\textsuperscript{[33]}

In the manual lymphatic drainage (MLD) technique, the therapist uses the hands to lightly stretch the superficial layers of the patient’s skin. The stretching of the skin stimulates the lymphatic vessels’ propulsion mechanism to move the lymph from the involved extremity to areas in the body which are able to drain the lymph using intact vessels. Each quadrant of the body drains to a corresponding field: left leg to the left inguinal nodes, right leg to the right inguinal nodes, left upper quadrant to the left axillary nodes, and right upper quadrant to the right axillary nodes. When one field has damage to or insufficient lymphatic vessels, MLD can redirect the flow to the other fields.\textsuperscript{[12, 29]}

Following the MLD, compressive wraps are applied to the extremity to enforce the reduction of the lymph and prevent further interstitial fluid from filling the extremity.\textsuperscript{[10, 18]} In combination with the wraps, pressure pads and/or foam are often used
to increase pressure to specific areas. CDT is an effective intervention for the treatment of lymphedema.\cite{2, 29, 108, 160}

**Health Care Delivery Issues Associated with the Treatment of Lymphedema**

**Centers for Medicare and Medicaid**

For lymphedema patients, the Centers for Medicare and Medicaid Services (CSM) established standard criteria of a 2-week episode with a maximum of 10 visits. This policy was established based on the assumption that either the patient or a caregiver would assume responsibility for performing the wrapping necessary to manage the limb volume long term.\cite{33} To qualify for reimbursement for CDT, CMS requires that the patient is symptomatic for lymphedema, with limitation of function related to self-care, mobility, and/or safety.\cite{33} The standards and protocols for treatment established by CMS often are the basis for which other third party payers establish benefits.\cite{35, 36}

**International Classification of Function, Disability and Health**\cite{161}

The ICF model\cite{161} provides a useful framework for understanding the relationships among the impairments and activity limitations associated with lower extremity lymphedema.\cite{161} Damage to the lymphatic vessels (body structure) can result in body function impairment including decreased removal of interstitial fluid and increased edema to extremities. The increased edema can result in increased protein content of interstitial fluid resulting in fibrosis; decreased skin moisture and nutrition resulting in cellulitis, infection, and wound development. Eventually the edema can result in decreased range of motion, strength, and balance ability; and increased pain.
These impairments may lead to activity limitations. These may include difficulty arising from a chair, inability to climb stairs, difficulty in meal preparation and household duties, inability to perform personal hygiene, and inability to engage in community ambulation. These structural deficits and impairments may also result in participation restrictions, in the areas of employment, independent living, and socialization.

Theoretically, the guidelines established by CMS assume that the treatment for lymphedema will change activity limitations. Optimum lower extremity function is necessary for basic mobility activities, including transfers, ambulation, and balance. Increased edema (body impairment) has negative effects on muscle function. For example, one study found that the effects of increased fluid in the knee joint resulted in a 30% reduction in quadriceps muscle torque. The negative effect on muscle function directly affects the ability to perform sit to stand tasks (activity limitations) from a chair. After a 2 week episode of care, along with limb volume reduction, an improvement in physical performance measures is expected.

**Study Purpose**

The purpose of this study was to determine the type and severity of impairments and activity limitations seen in patients with lower extremity lymphedema. We also examined the impact of disease severity by comparing the impairments and activity limitations of subjects with moderate and severe lymphedema. In addition, we examined the relationship among impairments and activity limitations in this population.
Methods

Design of Study and Subjects

The findings presented in this paper represent a cross-sectional analysis of the baseline data from a prospective cohort study of patients in treatment for lower extremity lymphedema. Standard measures were used to collect information on lymphedema severity, impairments, and activity limitations prior to initiating CDT to treat lower limb lymphedema.

A convenience sample of 21 subjects was selected from patients referred to an outpatient physical therapy clinic that specializing in the treatment of lymphedema. The subjects all had a diagnosis of primary or secondary lymphedema. Recruitment continued for a 2-year period from a consecutive series of patients who presented for lymphedema treatment at The Flagler Institute for Rehabilitation, West Palm Beach, Florida. Approval for the study was obtained from the Institutional Review Board of the University of Miami, and written consent was obtained from all subjects.

Inclusion and Exclusion Criteria

Subjects were males or females, ages 18-75, with a diagnosis of either unilateral or bilateral lower extremity edema or lymphedema, and met the criteria of the Medicare plan for treatment of lymphedema. Subjects also had to have the ability to ambulate independently either with or without an assistive device and tolerate a moderate exercise program.

Subjects were excluded if they had any of the following conditions: (a) acute congestive heart failure, (b) acute lower extremity deep vein thrombosis, (c) lower
extremity arterial disease, (d) lower extremity joint replacements, (e) acute or chronic hip fractures, (f) severe lower extremity arthritis, (g) acute low back pain, and (h) neurologic conditions such as Parkinson’s disease or cerebral vascular accident.

**Procedures**

Baseline information was collected on all subjects prior to initiating treatment. For each subject, pretreatment measurements were taken of the affected limbs. Depending on the subject, more than one extremity was measured. The measurements took place during the patients' normal treatment sessions for lymphedema, at which time they completed questionnaires, underwent limb volume measures and data measurement, and completed physical testing of balance and strength.

**Measures**

*Demographic and Clinical Characteristics*

Demographic information was collected from the subjects, including age, height, weight, gender, and length of time since onset of edema or lymphedema type and location of the lymphedema, prior treatments, ability to self-regulate the condition, and assistance at home.

Each subject was assessed for stage of lymphedema. These stages were assigned based on the ISL’s definitions. Stage 0 is a latent, subclinical condition in which no overt swelling is apparent but lymphatic vessels have been injured and lymphatic pathways disrupted. Stage 0 can exist for several years. Stage I is early lymphedema, characterized by fluid accumulation which resolves with elevation of the limb. Pitting may be present.
Stage II is characterized by pitting when the skin is pressed, and elevation alone no longer resolves the swelling. In late Stage II, fibrosis may form, resulting in less evidence of pitting when the skin is pressed. Stage III is also called lymphostatic elephantiasis. At this stage, no pitting is evident, but one or more skin changes may appear, such as fat deposits, warty overgrowths, and acanthosis (a benign thickening of the skin).

**Body Function Outcome Measures**

**Volumetric Measurement with the Perometer**

The limb volume of the involved extremities were measured using a Perometer, an optoelectronic device that measures the volume of an extremity.\[^{164}\] The Perometer is an extremity scanner using infrared lamps and photo sensors. While the patient is standing, a frame housing the sensors is lifted around the limb to the desired height. Circumferential measurements are taken every half centimeter. With an equation for a frustum, the volume is determined for the extremity.\[^{141, 143, 147}\] The Perometer was shown to be highly reliable with an ICC = .99\[^{141}\] and was shown to be a valid test for the measurement of volume.\[^{143}\]

**Active and Passive Range of Motion Measures**

Active range of motion measures of the ankle and knee were obtained using a goniometer following a standard protocol.\[^{111}\] Ankle dorsi flexion goniometric measurement utilized the recommended testing positioning. The subject was positioned supine with the knee flexed at least 30 degrees. The foot was positioned in 0 degrees of inversion and eversion. Knee flexion and extension were measured using a goniometer
with the subject positioned supine rather prone. High Interrater reliability has been documented with an ICC = .97 using this method. The goniometer has been shown to be a valid instrument for joint measurement.\cite{165}

**Strength Measures**

**Calf Strength**

Triceps surae strength was tested utilizing the heel rise test.\cite{116} The test measures the number of times a subject can rise onto the toes based on the following criteria. The subject stands erect, lifting bilateral heels rising onto toes and then returning onto heels in rhythm with a metronome set at a rate of one heel rise every 2 seconds. Each subject was allowed to touch the examiner with a single finger for balance. The test was terminated if the subject leaned or pushed down on the examiner, the subject’s knees were flexed, the plantar flexion range of motion was decreased by more than 50% of the starting range of motion, the subject stopped or asked to stop, or the subject was asked to stop by the examiner. Twenty-five repetitions are considered normal.\cite{116} The heel rise was shown to be highly reliable with ICC = .89.\cite{116,166,117}

**Quadriceps Strength**

Quadriceps strength was determined utilizing the 30-second chair test.\cite{115} The 30-second chair test counts the number of times the subject rises to the standing position from a straight-backed chair without the use of the hands and returns to a seated position over a 30-second interval. There is a 1-second pause between each sequence, and 10 repetitions are considered normal.\cite{115} The Chair Stand Test provides a reliable indicator
(ICC = .84 for men, .92 for women) of lower body strength and has also been shown to be safe and sensitive method in detecting age-related declines in strength and the effects of physical training in older adults.\textsuperscript{[115]}

**Limits of Stability**

The Smart Balance Master system was utilized to conduct Limits of Stability (LOS) testing, which measures volitional control of the center of gravity.\textsuperscript{[120-122, 167]} The subject stands upright on a force plate. The instructions direct the subject in keeping the body rigid and leaning forward and backward as far as possible while maintaining the full plantar surface of the feet in contact with the force plate. The extreme or each position is held approximately 2 seconds.\textsuperscript{[168]}

The LOS testing produces a percentage of age adjusted norms for sway.\textsuperscript{[123]} Since the percentage is relative to age, 100\% is considered normal. Moderate to high reliability of the LOS test has been found (ICC = .88 - .93).\textsuperscript{[124, 169]}

**Berg Balance Test Measurement**

The Berg Balance Test (BBS) consists of 14 items measured on a 5-point ordinal scale. Each activity is scored based on the level of ability needed for each item. The scores for each item are then added for a cumulative score to measure the balance of subject. Higher scores indicate subjects’ better balance.\textsuperscript{[118]} A score of 45 or below of a possible total of 56 indicates risk for falls.\textsuperscript{[118]} High reliability of the Berg Balance Score has been identified. (ICC = .97)\textsuperscript{[170]} Previous research has shown that showed that the BBS was the most powerful functional test of four in discriminating fallers from non-fallers.\textsuperscript{[119]}
Activity and Participation Level Outcome Measures

Expanded Timed Get Up and Go Measurement

The Expanded Timed Get Up and Go (ETGUG) test was used to measure basic functional mobility. The time taken to complete rising from a chair, walking 30 feet, turning, walking back to the chair, and sitting is recorded in seconds (Figure 1). A score greater than 20 seconds is considered to indicate a risk for falls. The ETGUG has been show to have good reliability (ICC = .85).

SF-36 Medical Outcomes Study (SF-36)

Subjects completed the Medical Outcomes Study, a 36-item short-form health survey. This is a well-established self-administered questionnaire, shown to be robust across a range of populations. The physical function subscale of the SF-36 was used to assess physical limitations. A low score indicates significant limitations in all activities, including bathing and dressing. A high score indicates the ability to perform all types of physical activities, including the most vigorous without limitations of health. Reliability has been demonstrated extensively with ICC = .90 and above.

Limitation in Mobility Activities Test (LIMAT)

The Limitations in Mobility Activities Test is a measure of mobility and the impairments affecting mobility. The LIMAT has a 26-item Transfer and Mobility scale and a 9-item impairment scale. The LIMAT was based on ICF concepts and uses ICF language. Items on the Transfer and Mobility scale range in difficulty from “Sit up on the
side of the bed” to “Run a short distance.” Items on the Impairment scale include “Pain,” “Stiffness,” and “Weakness.” Scale scores are calculated by adding the item level scores and dividing by the total possible score. Scores theoretically range from 0 to 100, with higher scores indicating greater limitation or impairment. The ICC for the inter-rater reliability of the rater administered Transfer and Mobility scale score was .96, and the Impairment Scale score was .90. (unpublished data) In the inpatient setting, the LIMAT Transfer and Mobility scale score is strongly correlated with the LIMAT Impairment Scale score (r=.75, p<.0001). In addition, the LIMAT Transfer and Mobility scale score is strongly correlated with FIM combined mobility and transfer items (r = .87, p < 0001).

Table 3.1 summarizes the 10 standard measures used and normal standards for each measure.

**Statistical Analysis**

The data were analyzed using the PC SAS version 9.1.3 for Windows. Descriptive statistics were calculated to describe the demographic and clinical characteristics of the subjects. Independent *t*-tests and chi-square statistics were used to compare subjects classified as having moderate vs. severe lymphedema. Spearman correlation coefficients were used to examine the relationships among disease, impairment, and activity limitation variables.

**Results**

**Descriptive Statistics of Sample**

Potential participants were recruited from January 2008 to December 2009. Twenty-one subjects completed all testing. One subject withdrew because of complaints
of anxiety when attempting to perform the limits of stability (LOS) test. Venous insufficiency was the most common primary diagnosis, resulting in lower extremity lymphedema. Cancer was the second most common, including anal, bladder, cecum, non-Hodgkin’s, and stomach. (Figure 3.2).

The subjects had a mean age of 58.34 years, with a mean height of 66.38 inches. Males represented 47.6% of the cohort. Subjects presented with a mean limb volume of 17325 (range 1577-36388 ml). Fifty-seven percent of the subjects had lymphedema in both lower extremities (n = 12). Severity of lymphedema was classified as moderate (n = 14) for 66.7% of the subjects and severe (n = 7) for 33.3% (Table 3.2).

Comparison to Normal Values

Descriptive statistics of the impairments and activity limitations are included in Table 3. Deviations from normal scores are displayed in Table 3.3.

Range of Motion

All range of motion values were significantly below normative values. The subjects had a mean ankle dorsiflexion of 1.4 degrees, which was significantly below the normative value of 20 degrees (p < .0001). Comparing subjects with moderate versus severe lymphedema the mean ankle dorsiflexion for the moderate group was greater than that of the severe group (2.4 vs. -.5 degrees, p = .01).

Mean score for active knee flexion was 110 degrees for the group, which was significantly below the normal values of 135 degrees by a mean of 24.98 degrees (p <
The moderate group had a mean of 116.64 degrees, and the severe group had considerably less, 96.8 degrees ($p = .007$).

**Strength**

All strength measures were significantly below normal values for the group. The subjects had a mean heel rise score of 11.5 repetitions, which was significantly below the normative value of 25 repetitions ($p < .0001$). The mean heel rise repetitions for the moderate was greater than that of the severe group (13.2 vs. 8 repetitions = .04).

The subjects had a mean 30-second sit-to-stand score of 6.8 repetitions, which was significantly below the normative value of 10 repetitions by a mean of 3.24 repetitions ($p = .014$). The mean heel rise repetition was 8 repetitions for the moderate group, and 4.3 repetitions for the severe group ($p = .04$).

**Balance**

For the Berg Balance scores, the mean scores of the group were below normal with a mean Berg Balance score of 38.8, which was significantly below the normative value of 56 ($p = .014$). The mean score was 46.5 for the moderate group, and 23.6 for the severe group ($p = .0017$).

For the limits of stability, the mean percentage scores of the group were below normal. Subjects had average LOS percentage score of 68.5, which was significantly below the normative value of 100 ($p < .0001$). The mean percentage score for the moderate group was 73.9 compared to 57.6 for the severe group ($p = .03$).
Activity Limitations

For the Expanded Timed Get Up and Go, the subjects had a score of 33.3 seconds, which was significantly greater than the 20-second standard for fall risk ($p = .05$). When subdivided by severity, the mean score was 20.3 for the moderate group, and 59.3 for the severe group ($p = .12$).

Participation Limitations

The LIMAT scores differed significantly from the normal values of a score of 0. Subjects had an average score of .30, which was significantly above the 0 score expected for normal ($p < .0001$). The mean score for the moderate group was .19, with .52 for the severe group ($p = .0004$). SF-36 scores were also significantly different from normal values of a score of 100. The subjects scored 32.6, which was significantly below the normal values of 100 ($p = .0004$). The mean score was 46.1 for the moderate group, and 5.7 for the severe group ($p = .0004$).

Relationships among Limb Volume and Impairments and Activity Limitation at Baseline

Limb Volume

Limb volume was not correlated with either ROM or strength as measured by the Heel Rise and 30 sec Chair stand test. (Table 4) Limb volume was moderately correlated to balance as measured by the BBS ($r = -.47$, $p = .03$) and to activity limitation as measured by the LIMAT ($r = .48$, $p = .03$) and SF-36 Physical Function ($r = -.52$, $p = .02$) (Table 4)
**Range of Motion**

There was no relationship between dorsiflexion ROM and any of the impairments or activity limitations. Knee flexion ROM was moderately correlated with quad strength as measured by the 30 sec chair stand and with activity limitations as measured by the ETUG, LIMAT and SF-36 (Table 3.4).

**Strength**

Neither plantar flexor strength (Heel rise) nor quad strength (30 sec. chair stand) were related to balance as measured by LOS. Quad strength was moderately correlated with balance as measured by the BBS, but plantar flexor strength produced a fair correlation ($r=-.37$, $p=.10$). Both strength measures were related to all three activity limitation measures, with the relationships stronger for quad strength than for plantar flexor strength (Table 3.4).

**Balance**

Balance as measured by the Berg was strongly correlated with all three activity limitation measures. The strongest relationship was with the LIMAT ($r=-.82$, $p < .0001$). However, balance as measured by the LOS test was not related to the BBS, ETGUG or LIMAT but was fairly correlated with SF-36 (Table 3.4).

**Correlations of Volume and Activity Limitations**

Volume showed a strong positive correlation with LIMAT ($r = .48$) and a strong negative correlation with SF-36 ($r = -52$).
Correlations of Impairments and Activity Limitations.

The correlations of range of motion, strength, and balance with activity and participation limitations produced many strong correlations. Ankle dorsiflexion showed only a weak correlation with all activity limitations. Knee flexion showed with a moderate correlation with SF-36 ($r = .41$), ETGUG ($r = -.40$) and LIMAT ($r = -.46$).

The heel rise showed a moderate correlation with SF-36 ($r = .47$) and a moderate negative correlations with ETGUG ($r = -.42$) and LIMAT ($r = -.48$). The 30-second chair rise produced a moderate positive correlation with ETGUG ($r = .67$) and strong negative correlations with LIMAT ($r = -.70$) and SF-36 ($r = .71$). Berg Balance scores showed strong negative correlations with ETGUG ($r = -.82$) and LIMAT ($r = -.70$) and a strong positive correlation with SF-36 ($r = .76$) (Table 3.4).

Correlations of Activity Limitations

The three measures of activity limitation were all strongly correlated. ETGUG showed a strong positive correlation with LIMAT ($r = .84$) and a strong negative correlation with SF-36 ($r = -.78$). LIMAT and SF-36 produced the strongest negative correlation ($r = -.88$) (Table 6).

Discussion

The results of this study identified the type and severity of impairments and activity limitations found in patients with lower extremity lymphedema. The cohort of subjects scored below test normal values on all impairment and activity measures. Although there are very few studies describing the impairments and activity limitations
associated with lower extremity lymphedema, some information is available describing the activity limitations resulting from the weight and size of the involved extremity in BCRL.\textsuperscript{[173]}

There may be similarities between the impairments and activity limitations in Breast Cancer Related Lymphedema (BCRL)\textsuperscript{[79, 174]} and those associated with lower extremity lymphedema.\textsuperscript{[175, 176]} The range of motion and strength deficits found in BCRL, though, may differ for lower extremity lymphedema for several reasons. Treatment for breast cancer often involves surgery directly to the axilla and/or radiation to the same area. Loss of range of motion and strength to the shoulder could be a direct result of the complications of the treatment. An additional potential cause of upper extremity impairments and activity limitations may be the fact that breast cancer patients are instructed to avoid activities using the involved arm to decrease the risk of developing lymphedema.\textsuperscript{[177]} Patients with lower extremity lymphedema cannot entirely avoid using their lower extremities because of the need to ambulate.

The severe lymphedema group scored statistically significant below the moderate group in all impairment and activity measures except for the ETGUG. While the mean ETGUG scores for the moderate and severe groups differed by 29 seconds, statistical significance was not achieved (p=.12). The impact of the disease severity on not only the impairment but also the activity limitations suggests that addressing lymphedema before it reaches the severe stage would be optimal. This idea is supported by a recent study that examined the predictive factors for response to CDT in patients with BCRL. One of the conclusions from this study was that treatment for lymphedema should occur in the early stages.\textsuperscript{[79]}
The impairments related to lower extremity lymphedema correlated strongly with the activity and participation limitations. When volume of the extremity and its effect on activity limitations were considered in the present cohort, subjects with lower extremity lymphedema who had larger volumes of their limb(s) and severe lymphedema were more likely to have activity limitations. These results are consistent with Ryan et al., who found that a majority of women (51%) altered their everyday activities because of swollen legs.\[^{87}\]

In the present study, range of motion limitations of the knee produced were strongly correlated with activity limitations and participation restrictions. This finding is supported by previous studies that have shown that 90 degrees of motion are needed to go up and down stairs. Getting up from a chair requires just slightly more motion (93 degrees). And lifting an object requires at least 117 degrees of flexion.\[^{178}\] Interestingly, dorsiflexion range of motion did not correlate with either of the other impairments, activity limitation or participation restrictions. There was a fair correlation with ankle dorsiflexion and berg balance scores. This finding is contrary to one study in which it was shown that subjects with decreased dorsiflexion were more prone to falling.\[^{179}\] However, the present finding is supported by a lack of correlation of ankle range of motion and decreased activity.\[^{180}\]

The strength limitations measured by the 30-second chair and heel rise and the balance measure with the Berg Balance test were found to have strong correlations with all activity and participations limitations. As expected, these findings support other studies which found ankle and knee strength deficits to affect activity limitations.\[^{181}\] Berg Balance scores also strongly correlated with activity limitations.\[^{133}\]
All activity and participation measures correlated strongly with each other. These findings support prior studies that have shown strong negative correlations between the SF-36 physical function scale and the Timed Up and Go Test, an earlier variation of the ETGUG.\(^{[182]}\)

This study determined that lymphedema severity is a predictor of activity limitations in subjects with lymphedema. The study also revealed those with more severe impairments had more severe activity limitations. The study highlights the need to address components of physical functioning at the early stages of lymphedema. Also, that reduction in limb volume is not the only important outcome and practitioners should be measuring other physical and quality of life outcomes. Early diagnosis and appropriate evaluation by a physical therapist are imperative not only for the lymphedema treatment program but also to address the potential impairment and activity limitations associated with lymphedema.
Figures and Tables

Figure 3.1 Expanded Timed Get Up and Go (Wall, Bell et al. 2000)
Figure 3.2 Diagnoses

Diagnoses

- Venous Insufficiency (43%)
- Other Cancers (23%)
- Ovarian Cancer (14%)
- Primary Lymphedema (10%)
- Trauma (5%)
- Amyloidosis (5%)
Table 3.1

*Standard Measures*

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<th>Test Measure Normal Standards</th>
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<td>Underweight</td>
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<td>18.5 – 24.9</td>
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<tr>
<td>25 – 29.9</td>
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<td>30 &amp; Above</td>
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<td>Knee Flexion</td>
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<td>Passive Range of Motion</td>
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<td>Knee Flexion</td>
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<td>Timed Up and Go</td>
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<td>100 -0 scale[^138^]</td>
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Table 3.2

Demographic and Anthropometric Characteristics of Subjects as a Group and With Moderate vs. Severe Lymphedema

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<th>Moderate (n=14)</th>
<th>Severe (n=7)</th>
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</thead>
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<td>60.4 (11.8)</td>
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<td>(n)</td>
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<td>7189.6 (3744.1)</td>
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determined with the *t* test for independent variables and chi-square analysis.
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<th>Moderate (n=14)</th>
<th>Severe (n=7)</th>
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<td>8 (3.8)</td>
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Table 3.3
Clinical Characteristics of Subjects with Moderate vs. Severe Lymphedema
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<tr>
<th>Characteristics</th>
<th>Norm value</th>
<th>All Subjects (n=21)</th>
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<td>&lt;.0001</td>
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<td>.52 (.17)</td>
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<td>$\bar{x}$ (SD)</td>
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<td>5.7 (6.7)</td>
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<td>Duration: (=&lt; 1 yr/&gt;1 yr)</td>
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<td>9/12</td>
<td>NA</td>
<td>8/6</td>
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<td>9/12</td>
<td>NA</td>
<td>3/11</td>
<td>6/1</td>
</tr>
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<td>11/10</td>
<td>NA</td>
<td>4/10</td>
<td>7/0</td>
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</table>

$^a$ Paired t-test testing whether the difference from normal is different from zero

$^b$ Student’s t-test or chi-square analysis.
Table 3.4  
*Relationships among Disease, Impairments and Activity Limitations*

<table>
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<th>Dorsi Flex ROM</th>
<th>Knee Flex ROM</th>
<th>Heel rise</th>
<th>30 sec. chair</th>
<th>Berg</th>
<th>LOS</th>
<th>Extended timed get up and go</th>
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CHAPTER 4: THE EFFECT OF COMPLEX DECONGESTIVE THERAPY AND THERAPEUTIC EXERCISE ON THE IMPAIRMENTS AND ACTIVITY LIMITATIONS ASSOCIATED WITH LOWER EXTREMITY LYMPHEDEMA

GENERAL DESCRIPTION

Lymphedema is a widespread disease, with an estimated 150 million people worldwide suffering from some form of lymphedema.\textsuperscript{[139]} Lymphedema represents an imbalance between lymphatic load and lymphatic transport capability, resulting in limb swelling.\textsuperscript{[140]} The causes of lymphedema are varied and can affect every part of the body. Approximately 10 million people have lymphedema secondary to cancer therapy, recurrent infection, injuries, or vascular disease.\textsuperscript{[42]} Worldwide, about 90 million people have lymphedema, primarily because of filariasis, a parasitic infection.\textsuperscript{[42]} When chronic venous insufficiency is added as a cause, there may be as many as 300 million cases of lymphedema.\textsuperscript{[42]}

Based on studies that examined lymphedema associated with axillary versus inguinofemoral nodal dissections, the reported range of upper extremity lymphedema from breast cancer related lymphedema (BCRL) was 5\%–8\% compared to 14\%–29\% for lower extremity lymphedema.\textsuperscript{[49, 50]} It appears from these reports that the incidence of lower extremity lymphedema may be twice as high as that for upper extremity lymphedema. Because of increased awareness of the condition, lower extremity lymphedema is becoming a more common treatment diagnosis in rehabilitation settings.\textsuperscript{[2, 3, 184]} Currently, treatment has been primarily focused on limb volume reduction.\textsuperscript{[8, 12]} However, the impairments and activity limitations may be a more important outcome than volume reduction alone.
Worldwide, filarial lymphedema accounts for the majority of cases of lower extremity lymphedema. The perceived physical disability and psychosocial impact can be devastating to an individual with this condition.\cite{82,185} Treatment is based on reduction of the volume. Whether the reduction in volume changes the physical disability is unknown.\cite{186-190} Impairments including severe leg pain and range of motion loss in the lower extremities are often associated with the condition.\cite{29} However, it is not clear whether treatments reducing limb volume reduce the associated impairments or activity limitations.

A thorough examination of the activity limitations associated with lymphedema is needed for several reasons. First, the treatment of lymphedema of the lower extremity involves a reduction of volume through stimulation of the lymphatic system by complex decongestive therapy (CDT). CDT consists of four components. The first is manual lymphatic drainage (MLD), a skin stretching manual technique that stimulates lymphatic activity and drain fluid. Second, skin care is performed to avoid dryness and breakdown. Third, compression therapy is applied to the edematous area including short stretch bandages and specific padding. Forth, remedial exercises are performed while bandages are donned to promote venous and lymphatic flow.\cite{12}

The treatment model does not incorporate interventions to address the impairments and activity limitations associated with lower extremity lymphedema. Third party payers require that lymphedema be associated with activity limitations to qualify for reimbursement for physical therapy. In addition, insurance companies have restricted the amount of treatment that will be reimbursed.\cite{33-36,105} Medicare, for example, allows 2 weeks or 10 days of lymphedema treatment, whichever takes place first.\cite{33}
Health Care Delivery issues associated with the treatment of Lymphedema
Centers for Medicare and Medicaid

The Centers for Medicare and Medicaid Services have established a 2-week timeframe with a maximum of 10 visits for the treatment of lymphedema. This policy was established based on the assumption that either the patient or a caregiver would assume responsibility for performing the wrapping necessary to manage the limb volume after completion of CDT.[33] To qualify for reimbursement for CDT, CMS requires that the patient is symptomatic for lymphedema, with limitation of function related to self-care, mobility, and/or safety.[33] The standards and protocols for treatment established by CMS often are the basis for which other third party payers establish benefits.[35, 36]

International Classification of Function, Disability and Health[161][161]

The ICF model[161] provides a useful framework for understanding the relationships among the impairments and activity limitations associated with lower extremity lymphedema. Damage to the lymphatic vessels (Body structure) can result in body function impairment including; decreased removal of interstitial fluid; increased edema to extremities, increased protein content of interstitial fluid resulting in fibrosis; decreased skin moisture and nutrition resulting in cellulitis, infection and wound development; decreased range of motion, strength and balance ability; and increased pain.

These impairments may lead to activity limitations. The activity limitations may include difficulty arising from a chair, inability to climb stairs, difficulty in meal preparation and household duties, inability to perform personal hygiene and community ambulation. These structural deficits and impairment may result in participation restrictions including employment, independent living and socialization.
Theoretically, the guidelines established by CMS assume that reducing the limb volume of patients with lymphedema will change the associated activity limitations. Optimum lower extremity function is necessary for basic mobility requirements including transfers, ambulation and balance. Increased limb volume due to edema (Body Impairment) may have negative effects on muscle function. One study found that increased fluid in the knee joint resulted in a 30% reduction in quadriceps muscle torque. Impaired muscle function directly affects the ability to perform sit to stand tasks (Activity Limitations) from a chair. Currently CMS and other third party payers assume that the prescribed two week limb volume reduction intervention criteria will improve the associated activity limitations.

The purpose of this study was to determine whether a change in limb volume produced by Complex Decongestive Therapy over a 2-week episode related to an improvement in activity limitations, and determine the proportion of subjects who are still at increased risk for falls. Of those subjects at risk for falls, does a 4-week standard physical therapy intervention to address impairments in strength, ROM, and balance produced improvements in the activity limitations. The objective was to evaluate these interventions toward enhanced protocols for treatment of patients with lymphedema.

Methods

Design

This study was a prospective cohort study, conducted at The Flagler Institute for Rehabilitation, an outpatient facility that specializes in the treatment of lymphedema. All
equipment was located at the Institute. Funding for study-related costs was provided by the researcher.

Participants and Recruitment

The study population was comprised of patients who had been referred to The Flagler Institute for Rehabilitation for treatment of lower extremity lymphedema. Prior to initiation of data collection, the study was approved through the University of Miami Institutional Review Board. The consent process began after referral to the facility by a physician; the patients were given a form to sign signifying approval to discuss the research with the investigator. Once approval was attained and consent signed, the researcher initiated the evaluation and intervention. A convenience sample of 22 subjects who met inclusion criteria was recruited for participation.

Inclusion and Exclusion Criteria

To participate in the study, subjects were males or females, ages 18-75, with a diagnosis of either unilateral or bilateral lower extremity edema or lymphedema and met the criteria of the Medicare plan for treatment of lymphedema. Subjects had to be able to ambulate independently either with or without an assistive device, and tolerate a moderate exercise program.

Subjects were excluded if they had any of the following conditions: (a) acute congestive heart failure, (b) acute lower extremity deep vein thrombosis, (c) lower extremity arterial disease, (d) lower extremity joint replacements, (e) acute or chronic hip
fractures, (f) severe lower extremity arthritis, (g) acute low back pain, and (h) neurologic conditions such as Parkinson’s disease or cerebral vascular accident.

**Intervention**

**Phase I: 2 Weeks of CDT**

All subjects were measured at baseline and then received a standard lymphedema evaluation followed by 2 weeks of CDT as described previously. Each session lasted approximately 1 hour. Subjects were seen 5 times per week for 2 weeks. Following the initial 2-weeks of CDT for lymphedema, subjects were retested on all outcome measures. Subjects who were classified at increased fall risk based by scoring at or below 45 on the Berg Balance Test and above 20 seconds on the expanded Timed Get Up and Go test were provided with an additional 4 weeks of physical therapy.

**Physical Therapy Intervention Protocol**

For this study, subjects who were at risk for falls after the 2 week lymphedema intervention underwent an additional 4 week physical therapy intervention to address the impairments and activity limitations. The physical therapy intervention for balance and mobility was designed based on the principles of balance. The three postural movement strategies that are typically used by healthy adults for controlling balance are as follows: (a) the ankle strategy, in which balance adjustments are made at the ankle joint and the individual sways as an inverted pendulum; (b) the hip strategy, in which adjustments are made predominantly at the hip; and (c) the suspensory strategy, in which the subject flexes at the ankle, knee, and hip to lower the center of gravity toward the base of
support.\textsuperscript{[136]} Normally, three classes of sensory inputs are available for balance control: (a) somatosensory inputs, (b) visual inputs, and (c) vestibular inputs. It has previously been shown that healthy adults rely primarily on somatosensory inputs under normal sensory conditions in which all sensory inputs are available.\textsuperscript{[136]} (Appendix I) The impairments of volume, range of motion, strength and balance have been identified in the literature to directly affect a subject’s activity and participation restrictions. Volume reduction in subjects with BCRL is associated with an increase in grip strength.\textsuperscript{[104]} Volume reduction is also related to an increased knee range of motion following edema reduction by CDT.\textsuperscript{[29]} Ankle dorsi flexion range of motion loss is related to increased incidence of falls.\textsuperscript{[180]} Strength of the ankle plantar flexors is associated with the ability of subjects to control their anterior and posterior limit of stability.\textsuperscript{[191]} Knee extension strength is closely related to walking ability in adults\textsuperscript{[163]} Balance testing using the berg balance score and limits of stability are associated with decreased activity.\textsuperscript{[133, 191, 192]}

\textit{Phase II: 4 Weeks of Physical Therapy for Balance and Mobility}

The physical therapy intervention provided to subjects with balance and mobility deficits after CDT consisted of passive and active stretching to increase lower extremity ROM, progressive resistive exercise to increase lower extremity strength, balance training on level, inclined and compliant surfaces, posture training, gait training and endurance activities. During this period, subjects followed instruction on self CDT while undergoing this intervention. Subjects were seen 3 times per week for 4-weeks.
At the 6-weeks post enrollment both subjects who did and did not receive the additional 4 weeks of physical therapy were tested a final time.

**Outcome Measures**

All outcome measures were performed at three separate points in time: pre-treatment, 2-week post-treatment and 6-week follow-up.

**Demographic and Clinical Characteristics Measure**

Demographic information was collected from the subjects, including age, height, weight, gender, and length of time since onset of edema or lymphedema.

**Intervention Questionnaire**

Subjects completed a questionnaire requesting information on the type and locations of the lymphedema, prior treatments, ability to self-regulate the condition, and assistance at home.

**ISL Stage of Lymphedema**

In conjunction with the above measurements, each subject was assessed for stage of lymphedema. These stages were assigned based on the ISL’s definitions. Stage 0 is a latent, subclinical condition in which no overt swelling is apparent but lymphatic vessels have been injured and lymphatic pathways disrupted. Stage 0 can exist for several years. Stage I is early lymphedema, characterized by fluid accumulation which resolves with elevation of the limb. Pitting may be present. Stage II is characterized by pitting when the
skin is pressed, and elevation alone no longer resolves the swelling. In late Stage II, fibrosis may form, resulting in less evidence of pitting when the skin is pressed. Stage III is also called lymphostatic elephantiasis. At this stage, no pitting is evident, but one or more skin changes may appear, such as fat deposits, warty overgrowths, and acanthosis (a benign thickening of the skin).

**Body Function Outcome Measures**

*Volumetric Measurement with the Perometer*

The limb volume of the involved extremities was measured using a Perometer. This is an optoelectronic device that measures the volume of an extremity by using infrared lamps and photo sensors.[164] While standing, the frame housing the sensors is lifted around the limb to the desired height. Circumferential measurements are taken every half centimeter. Using an equation for a frustum, the volume is determined for the extremity.[141, 143, 147]. The Perometer was shown to be highly reliable with and ICC = .99. The Perometer was shown to be a valid test for the measurement of volume.[143]

*Active and Passive Range of Motion Measures*

Active range of motion measures of the ankle and knee were obtained using a goniometer following standard protocol.[111] Ankle dorsiflexion goniometric measurement utilized the recommended testing positioning. With the subject positioned supine with the knee flexed at least 30 degrees. The foot was positioned in 0 degrees of inversion and eversion. Knee flexion and extension were measured with the subject positioned supine rather than prone. High interrater reliability has been documented for
goniometry with an ICC = .97. The goniometer has been shown valid instrument for joint measurement.\[165\]

\textit{Strength Measures}

\textit{Calf Strength}

Triceps surae strength was tested utilizing the heel rise test.\[116\] The test measures the number of times a subject can rise onto his toes based on the following criteria. The subject stands erect rising onto tiptoes and then lowering onto the balls of the feet in rhythm with a metronome set at a rate of one heel rise every 2 seconds. Each subject was allowed to touch the examiner with a single finger for balance. The test was terminated if the subject leaned or pushed down on the examiner, the subject’s knees were flexed, the plantar flexion range of motion was decreased by more than 50% of the starting range of motion, the subject stopped or asked to stop, or the subject was asked to stop by the examiner. Twenty five repetitions is considered the number of repetitions to complete for a healthy adult.\[116\] The heel rise was show to be highly reliable with ICC=.89.\[116, 117, 166\]

\textit{Quadriceps Strength}

Quadriceps strength was determined utilizing the 30-second chair test.\[115\] The 30-second chair test counts the number of times the subjects arising to the standing position from a straight backed chair without the use of their hands and returning to a seated position over a 30 second interval. There is a one second pause between each sequence. 10 repetitions is considered normal.\[115\] The Chair Stand Test provides a reliable (ICC=.84 for men and .92 for women) indicator of lower body strength and has also been
shown to be safe and sensitive method for detecting age-related declines in strength and
the effects of physical training in older adults.\textsuperscript{115}

\textit{Limits of Stability}

The Smart Balance Master system was utilized to conduct Limits of Stability
(LOS) testing, which measures volitional control of movement.\textsuperscript{120-122, 167} Subjects stood
upright on a force plate. The instructions were to keep body rigid and lean forward and
backward only as far as possible while maintaining the full plantar surface of the feet in
contact with the force plate and to hold in each extreme position for approximately 2
seconds.\textsuperscript{168}

The LOS testing produces a percentage of age adjusted norms for sway.\textsuperscript{123} Since
the percentage is relative to their age, 100\% is considered normal. Moderate to high
reliability of the LOS test has been found.\textsuperscript{\textit{ICC} = .88 - .93}\textsuperscript{124, 169}

\textit{Berg Balance Test Measurement}

The Berg Balance Test (BBS) consists of 14 items measured on a 5-point ordinal
scale. The scores for each item are then added for a cumulative score provides a
comprehensive objective measure of balance. A score of 45 or below of a possible total
of 56 indicates risk for falls.\textsuperscript{118} Higher scores indicate better balance.\textsuperscript{118} The BBS
powerfully discriminates fallers from non-fallers.\textsuperscript{119} High reliability of the Berg
Balance Score has been identified.\textsuperscript{\textit{ICC} = .97} \textsuperscript{170}
Expanded Timed Get Up and Go Measurement

The Expanded Timed Get Up and Go (ETGUG) test was used to measure basic functional mobility. The time taken to complete rising from a chair, walking 30 feet, turning, walking back to the chair, and sitting was recorded in seconds. (Figure 1) A score greater than 20 seconds indicates a risk for falls. [88] The ETGUG has been show to have good reliability. (ICC = .85) [128]

Activity and Participation Level Outcome Measures

SF36 Medical Outcomes Study

Subjects completed the Medical Outcomes Study, a 36-item short-form health survey (SF-36). This is a well-established self-administered questionnaire, shown to be robust across a range of populations [78, 134] One of the eight health concepts within the SF36 was used to assess physical limitations [78]. A low score indicate significant limitations in all activities including bathing and dressing. A high score indicates the ability to perform all types of physical activities including the most vigorous without limitations of health. [171] Reliability has been demonstrated extensively with ICC = .90 and above. [172]

Limitation in Mobility Activities Test (LIMAT)

The Limitations in Mobility Activities Test is a measure of mobility and the impairments affecting mobility. The LIMAT consists of a 26 item Transfer & Mobility scale and a 9 item impairment scale. The LIMAT was based on ICF concepts and uses ICF language. Items on the transfer & mobility scale range in difficulty from “Sit up on
the side of the bed” to “Run a short distance”. Items on the Impairment scale included “Pain”, “Stiffness” and “Weakness”. Scale scores were calculated by adding the item level scores and dividing by the total possible score. Scores theoretically range from 0 to 100 with higher scores indicating greater limitation or impairment. The in-patient version of the LIMAT is rater administered and the outpatient version is administered by self-report. The ICC for the inter-rater reliability of the rater-administered was .96 for the transfer & mobility scale score and .90 for the impairment scale score. In the in-patient setting, the LIMAT Transfer and Mobility scale score is strongly correlated with the LIMAT impairment Scale score ($r=0.75, p<0.0001$). In addition, the LIMAT Transfer and Mobility scale score is strongly correlated with FIM combined mobility and transfer items ($r=0.87, p<0.0001$).

Table 4.2 summarizes the 10 standard measures used by name and standards for each measure.

**Data Management and Analysis**

Data analysis was performed using the SAS statistical software PC, SAS version 9.1.3. Descriptive statistics were calculated to characterize the demographic and clinical characteristics of subjects at baseline. Student’s $t$-tests and chi-square statistics were used to compare subjects receiving additional rehabilitation to those who did not. Repeated measures ANOVA was used to compare the change in the fall-risk and non fall-risk groups in the change in impairments over the two intervention periods. Spearman correlation coefficients were used to examine the relationships among the changes in disease, impairment, and activity limitation variables and limb volumes.
To determine whether a change in limb volume produced by Complex Decongestive Therapy over a 2-week episode related to an improvement in activity limitations, a Spearman correlation coefficient was calculated to examine the relationship between the change in Perometer measurements and the change in severity of functional limitations, as measured by ETGUG, SF36 Physical Activity Scale, and LIMAT.

To determine whether a 4-week standard physical therapy intervention to address impairments in strength, ROM, and balance produced improvements in the activity limitations in subjects with lower extremity lymphedema, paired $t$-tests were calculated to determine the change in ETGUG, SF36 Physical Activity Scale, and LIMAT.

**Results**

**Descriptive Statistics of Sample**

Potential participants were recruited from January 2008 to December 2009. Twenty-one subjects of the 22 enlisted completed the two week CDT intervention. Ten subjects completed the 4 additional weeks of rehabilitation (4 week post CDT) and 5 of the subjects who did not receive rehabilitation returned for follow up testing. One subject withdrew because of complaints of anxiety when attempting to perform the limits of stability (LOS) test. Venous insufficiency was the most common primary diagnosis. The grouping “other cancer-related diagnoses” included anal, bladder, cecum, non-Hodgkin’s, and stomach was the next most common. (Figure 2) The subjects had a mean age of 58.34 years, with a mean height of 66.38 inches. Subjects presented with a mean limb volume of 17325ml. (range 1577-36388ml) Fifty-seven percent of the subjects had lymphedema in both lower extremities. ($n = 12$) (Table 4.3)
Comparison of Subjects at Fall-Risk and Non Fall-Risk

After completing the 2-week CDT intervention for lymphedema, subjects were retested. Eleven subjects received scores at or below 45 on the BBS, and more than 20 seconds on the ETGUG continued in the fall-risk group. This group received an additional 4 weeks of physical therapy intervention. Males and females were equally represented. However, a greater percentage of males required the additional intervention (71.4%) than females (35.7%). The subjects who had severe lymphedema (Stage III) required rehabilitation more frequently (85.71%) than subjects with moderate edema (Stage II) (28.57%). All subjects who entered the physical therapy intervention component had duration of lower extremity lymphedema greater than 1 year. Significantly fewer subjects with duration greater than 1 year required no additional physical therapy. (Table 4.4)

Relationship Between Change in Limb Volume and Changes in Impairments and Activity Limitations

All subjects showed a significant change in limb volume after the 2 week CDT intervention; however the reduction was not related to a change in impairments or a change in activity limitations. (Ankle Dorsiflexion \(r=-.20\), Knee Flexion \(r=.13\), Calf Strength \(r=-.05\), Quad Strength \(r=-.15\), BBS \(r=-.12\), LOS \(r=-.25\), ETGUG \(r=.18\) LIMAT \(r=.30\) and SF36 \(r=-.13\)) (Table 4.5)
Change in Impairments and Activity Limitations following CDT and Physical Therapy Intervention

The combined groups experienced a significant decline in limb volume and a significant time effect (p=.0087). A moderate decline of 6.24% in volume occurred pre-post CDT (sd 7.54, p=.0063), however a small non significant worsening in volume of -2.6% occurred from post test to follow-up (sd 5.3, p=.08) The change was similar for both groups (p=.93). However, changes in volume percentage post CDT was significant for both groups, the fall-risk group decreased 5.8% (sd 8.5, p=.058) and the non fall-risk group decreased 7.1% (sd 6.0, p=.057). Although not statistically significant, negative percentage changes occurred for both groups with the fall-risk group increasing in volume 2.9% (sd 5.1, p=.10) and the non fall-risk group increasing in volume 2.0% (sd 6.4, p=.54). Changes in impairments and activity limitations are summarized in Table 7.

There was a significant overall time (p<.0001) and time*group effect (p<.0001) for ankle dorsiflexion. A small non significant improvement of 1 degree occurred pre-post CDT (sd1.2, p = .75), however a significantly large improvement of 7.1 degrees occurred from post CDT to follow-up (sd 4.1, p<.0001). Neither the fall-risk group nor the non fall-risk group produced a significant change in active dorsiflexion over the 2 week CDT intervention. Over the post CDT to follow up timeframe, the fall-risk group improved 9.4 degrees (sd 2.4, p=<.0001) while the non fall-risk group only improved by 2.5 degrees (sd 2.5, p=.09)

The changes in knee flexion overall produced a significant time effect (p<.0001) but no time*group effect (p=.94) indicating that there was no difference between the groups in the amount of change. Negligible change occurred pre-post CDT, however, a change of 9.5 degrees (sd = 8.01, p=.0004) improvement occurred over the post CDT to
follow up timeframe for the whole group. Although the time*group effect did not meet statistical significance, the fall-risk group improved by 9.9 degrees (sd 5, p=.0002) from post CDT to follow up. The non fall-risk group did improve by 8.9 degrees (sd 13.22, p=.21) but did not reach significance possibly due to the larger variance.

Strength testing for quadriceps produced both significant time and time*group effects (p<.0001,p=.0003) A small (<1) repetition change in quadriceps strength occurred pre-post CDT , however, a larger 3.7 repetition change (sd 2.8, p=.0001) occurred from post CDT to follow up for the whole group. While the time*group effect achieve significance, the fall-risk group quadriceps strength worsened pre post CDT .9 repetitions (sd 1.1, p=.03) while the non fall-risk remained relatively the same. The fall-risk group improved 5.1 repetitions (sd 1.7, p<.0001) from post CDT to follow up while the non fall-risk group only increased by 1 repetition (sd 2.6, p=.43)

Plantarflexor strength followed a similar pattern as quadriceps strength. Analysis showed significance for both time and time*group effects (p<.0001, p=.0028). As with quadriceps strength, the plantar flexor strength declined pre post CDT by .66 repetitions (sd = 4.9, p = .6) but improved by 8.3 repetitions (sd 7.1, p=.0005) over the post CDT to follow up timeframe. The overall time*group interaction was significant and in both timeframes. For the pre post CDT timeframe, the fall-risk group worsened the number of repetitions by 2 (sd 3.5, p=.11) while the non fall-risk group improved the number of repetitions by 2 (sd 6.5, p = .53). Over the post CDT to follow-up timeframe, a large improvement of 12 repetitions (sd 5.3, p <.0001) occurred for the fall-risk group while the non fall-risk group only improved by 1 repetitions (sd 3.6, p=.57).
The mean score for the fall-risk at the start of the post CDT was 25.5 while the non fall-risk was 54.2 out of a 56 maximum score. (Table 4.7) There was an overall time and time*group effect for the BBS.\(p<.0001, P<.0001\) A 2.1 (sd 3.7, \(p = .04\)) increase in scores occurred pre post CDT and a 13.9 (sd 12.3, \(p = .0006\)) increase in scores occurred over post CDT to follow-up. The time*group significant interaction occurred over the post CDT to follow up timeframe. A large 20.3 (sd 9.9, \(p=.0001\)) occurred for the fall-risk group while a small 1.2 (sd 2.2, \(p = .28\)) improvement for the non fall-risk group.

The LOS had an overall time and time*group effect.\(p<.0001, p=.038\). However a worsening occurred of the LOS by 17.9% (sd 12.9, \(p<.0001\)) pre post CDT but then dramatically improved by 24.1% (sd 15.5, \(p<.0001\)) from post CDT to follow-up. A worsening of the LOS occurred by 21.8% (sd 10.8, \(p=.0001\)) with the fall-risk group and 10.2% (sd 14.5, \(p=.19\)) with the non fall-risk group. A reversal of this trend occurred from post CDT to follow-up. A 30% (sd 12.4, \(p<.0001\)) improvement in LOS with the fall-risk group and an 11.6% (sd 14.1, \(p = .14\)) occurred with the non fall-risk group.

There was an overall time effect for the ETGUG. (\(p=.0065\)) Very little change occurred pre-post CDT, however, there was an overall improvement of 19.9 seconds (SD 33.6, \(p=.04\)) from post test to follow-up for the whole group. Although the overall time*group effect failed to achieve statistical significance (\(p=.13\)), the fall-risk group improved 28.4 sec from post test to follow-up (sd 38.9, \(p=.05\)) while the non fall-risk group only improved by 3 seconds (sd 3.5, \(p=.12\)).

The LIMAT Function and SF 36 Function scales both produced overall time and time group effects.\(p<.0001, p=.008; p<.0001, p=.0034\) Negligible change for the LIMAT occurred pre-post CDT, however, an improvement of .15 (sd .18, \(p = .006\))
occurred over post CDT to follow-up. The time*group interaction was significant for post CDT to follow-up. The fall-risk group improved by .22 (sd .13, p = .0005) while the non fall-risk group remained relatively the same. The SF 36 function subscale followed a similar pattern. A small change occurred pre post CDT, however, a large 27.3 (sd 27.7, p=.002) improvement occurred post CDT to follow-up. The overall time*group effect was significant for the post CDT to follow-up timeframe. The fall-risk group improved by 39.5 (sd 24.2, p =.0006) while the non fall-risk group actually minimally declined by 3 (sd 16.1, p=.70)

**Relationships Among Changes in Impairments and Changes in Activity Limitations**

The changes in dorsiflexion were strongly correlated with changes in plantar flexor strength (r=.53) while the changes in knee flexion ROM produced a fair correlation (r=.46). Knee flexion range of motion produced fair correlations plantar flexor strength (r=.46) and with knee extension strength (r=.34). However, changes in dorsiflexion ROM (r=.68) and plantar flexor strength(r=.69) were, in general, more strongly correlated with changes in balance as measured by BBS than were changes in knee flexion (r=.08) or quad strength (r=.59). (Table 4.6)

The changes in dorsiflexion range of motion but not the changes in knee flexion range of motion strongly correlated with changes in activity and participation restrictions. However, both the changes in plantar flexor and knee extension strength produced strong correlations with the changes in activity limitations as measured by the ETGUG, LIMAT and SF-36 Physical Function sub-scale.
Changes in balance, as measured by the Berg, were strongly associated with changes in activity limitations. However, only the changes in LIMAT were strongly correlated with the changes in LOS.

Discussion

In this study, patients with lower extremity lymphedema were treated with the initial goal of decreasing limb volume. Insurance policies indicate that activity limitations are a requirement to obtain treatment. However, the loss of volume was not associated with an improvement in impairments or a decrease in activity limitations over the two week or additional 4 week treatment episode. On the other hand, for those subjects with the most activity limitations, an episode of traditional physical therapy interventions produced significant improvements in activity limitations and body function impairments. Of those subjects who continued with the physical therapy intervention, all had lymphedema of the lower extremities for more than 1 year. No subject with lymphedema for less than 1 year required an additional physical therapy intervention.

Presently, in most cases when a patient is referred for lymphedema treatment it is usually under the coverage of a third party payer. As with Medicare, the coverage of services is to not achieve maximum reduction in the volume but to teach the patient how to continue to reduce and maintain the volume on their own. However, the study showed that after a four week timeframe following the completion of the two week intervention, subjects were not able to maintain nor did they reduce their volume further.

The BBS change over the pre post CDT timeframe showed a small improvement, however the change in LOS was markedly worsened. The contradictory results may be
due to the fact that the BBS and LOS test different constructs (static vs. dynamic balance) and another possible explanation is that the patients wore compression bandages the entire time between appointments for the 2 weeks of CDT. The effects of immobilization on decreased sensorimotor input has been shown to affect motor behavior.\[193\] An additional consideration for potential effects of the compressive bandages was that accurate sensory information is critical to effective motor control. The bandages compressing the feet potentially limit information concerning the external conditions of the body, especially in a weight-bearing condition.\[194\]

Other considerations with regard to this patient population involved the potential inactivity which may have occurred prior to treatment and the potential for continued inactivity that could occur during CDT. The consequences of inactivity are substantial. The specific consequences of inactivity, especially for a person with a chronic disease such as lymphedema, are numerous. Primarily, inactivity can lead to reduced cardiovascular fitness, impaired circulation to the lower extremities, and decreased strength.\[86\] Secondarily, an inactive lifestyle can produce diminished self-concept, greater dependence on others for daily living, and reduced ability for normal societal interactions.\[86\]

The results of this study identify a key missing component of the lymphedema treatment paradigm. Currently, the treatment is designed to address only limb volume. However, edema is but one of the many impairments associated with this condition. These impairments and resulting activity limitations are not addressed in the lymphedema treatment protocols either as requirements from the insurance companies or in the specialty education physical therapists and other health care professionals must complete.
to treat these patients. Based on the other impairments and activity limitations of patients with lower extremity lymphedema, a professional must possess the education and training to evaluate and treat not only the edema but the other deficits as well.
Table 4.1  
International Society of Lymphology Staging for Lymphedema

<table>
<thead>
<tr>
<th>Stage</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>This is a latent, subclinical condition in which no overt swelling is apparent but lymphatic vessels have been injured and lymphatic pathways disrupted. Stage 0 can exist for several years.</td>
</tr>
<tr>
<td>1</td>
<td>This stage is described as early stage lymphedema, in which there is fluid accumulation which resolves with elevation of the limb. Pitting may be present.</td>
</tr>
<tr>
<td>2</td>
<td>This stage is characterized by pitting when the skin is pressed, and elevation alone no longer resolves the swelling. Late Stage II involves the formation of fibrosis and less evidence of pitting when the skin is pressed.</td>
</tr>
<tr>
<td>3</td>
<td>This is a late stage of lymphedema, also called <em>lymphostatic elephantiasis</em>. At this stage, no pitting is evident, but one or more skin changes may appear, such as fat deposits, warty overgrowths, and acanthosis (a benign thickening of the skin).</td>
</tr>
</tbody>
</table>
Table 4.2
*Standard Measures*

<table>
<thead>
<tr>
<th>Clinical Measure</th>
<th>Test Measure Normal Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volumetric Measurement</td>
<td>Variable</td>
</tr>
<tr>
<td><strong>Body Mass Index</strong></td>
<td></td>
</tr>
<tr>
<td>Below 18.5</td>
<td>Underweight</td>
</tr>
<tr>
<td>18.5 – 24.9</td>
<td>Normal</td>
</tr>
<tr>
<td>25 – 29.9</td>
<td>Overweight</td>
</tr>
<tr>
<td>30 &amp; Above</td>
<td>Obese[183]]</td>
</tr>
<tr>
<td><strong>ISL Staging of Lymphedema</strong></td>
<td>0 - 3</td>
</tr>
<tr>
<td><strong>Active Range of Motion</strong></td>
<td>Normal</td>
</tr>
<tr>
<td>Ankle Dorsiflexion</td>
<td>20 degrees</td>
</tr>
<tr>
<td>Ankle Plantarflexion</td>
<td>50 degrees</td>
</tr>
<tr>
<td>Knee Flexion</td>
<td>135 degrees[137]</td>
</tr>
<tr>
<td>Knee Extension</td>
<td>0 degrees[137]</td>
</tr>
<tr>
<td><strong>Passive Range of Motion</strong></td>
<td>Normal</td>
</tr>
<tr>
<td>Ankle Dorsiflexion</td>
<td>20 degrees</td>
</tr>
<tr>
<td>Ankle Plantarflexion</td>
<td>50 degrees</td>
</tr>
<tr>
<td>Knee Flexion</td>
<td>135 degrees[137]</td>
</tr>
<tr>
<td>Knee Extension</td>
<td>0 degrees[137]</td>
</tr>
<tr>
<td><strong>Strength</strong></td>
<td></td>
</tr>
<tr>
<td>Ankle Plantarflexion</td>
<td></td>
</tr>
<tr>
<td>Heel Rise Test</td>
<td>25 Repetitions[116, 117]</td>
</tr>
<tr>
<td>Knee Extension</td>
<td>10 repetitions[115]</td>
</tr>
<tr>
<td>30-Second Stand Test</td>
<td></td>
</tr>
<tr>
<td><strong>Limits of Stability</strong></td>
<td>100</td>
</tr>
<tr>
<td><strong>Berg Balance Test</strong></td>
<td>56[118]</td>
</tr>
<tr>
<td><strong>Timed Up and Go</strong></td>
<td>20 seconds[88]</td>
</tr>
<tr>
<td>SF36</td>
<td>0-100 scale</td>
</tr>
<tr>
<td><strong>LIMAT</strong></td>
<td>100 -0 scale</td>
</tr>
</tbody>
</table>
Table 4.3  
Demographic and Anthropometric Characteristics of Lymphedema Subjects Who Did and Did Not Receive Rehabilitation.

<table>
<thead>
<tr>
<th></th>
<th>All Subjects (n=21)</th>
<th>Rehab (n=10)</th>
<th>No Rehab (n=11)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (y) ( \bar{X} ) (SD)</td>
<td>58.3 (11.8)</td>
<td>58.4 (11.6)</td>
<td>58.3 (12.51)</td>
<td>.98</td>
</tr>
<tr>
<td>Range</td>
<td>35-74</td>
<td>37 - 73</td>
<td>35 - 74</td>
<td></td>
</tr>
<tr>
<td>Sex: men/women (n)</td>
<td>7/14</td>
<td>5/5</td>
<td>2/9</td>
<td>.12</td>
</tr>
<tr>
<td>Weight (lb) ( \bar{X} ) (SD)</td>
<td>239.8 (101.6)</td>
<td>291.6 (124.7)</td>
<td>192.82 (39)</td>
<td>.036</td>
</tr>
<tr>
<td>Range</td>
<td>136-540</td>
<td>185 - 540</td>
<td>136 - 280</td>
<td></td>
</tr>
<tr>
<td>Volume (ml) ( \bar{X} ) (SD)</td>
<td>9299 (5303.2)</td>
<td>10486 (6389.4)</td>
<td>8219.7 (4100.6)</td>
<td>.34</td>
</tr>
<tr>
<td>Range</td>
<td>1797.5-22841</td>
<td>1797.5 - 22841</td>
<td>2124.5 – 14506.5</td>
<td></td>
</tr>
</tbody>
</table>

determined with the \( t \) test for independent variables and chi–square analysis
Table 4.4
Clinical Characteristics of Lymphedema Subjects at Fall-Risk and Non Fall Risk

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>All Subjects (n=21)</th>
<th>Fall-Risk (n=10)</th>
<th>Non Fall-Risk (n=11)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dorsiflexion - Active</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>$\bar{x}$ (SD)</td>
<td>1.4 (4.2)</td>
<td>2.5 (4.2)</td>
<td>2.5 (4.2)</td>
<td>.021</td>
</tr>
<tr>
<td>Range</td>
<td>-7 - 7</td>
<td>-7 - 7</td>
<td>-7 - 7</td>
<td></td>
</tr>
<tr>
<td>Knee flexion- Active</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>$\bar{x}$ (SD)</td>
<td>110.0 (16.9)</td>
<td>106 (15.7)</td>
<td>113.6 (17.9)</td>
<td>.036</td>
</tr>
<tr>
<td>Range</td>
<td>75 - 130</td>
<td>80 - 127</td>
<td>75 - 130</td>
<td></td>
</tr>
<tr>
<td>Heel Rise</td>
<td></td>
<td></td>
<td></td>
<td>.13</td>
</tr>
<tr>
<td>$\bar{x}$ (SD)</td>
<td>11.5 (5.7)</td>
<td>9.5 (4.67)</td>
<td>13.27 (6.08)</td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>4 - 27</td>
<td>4 - 17</td>
<td>6 - 27</td>
<td></td>
</tr>
<tr>
<td>30 Sec. Sit to Stand</td>
<td></td>
<td></td>
<td></td>
<td>.0041</td>
</tr>
<tr>
<td>$\bar{x}$ (SD)</td>
<td>6.8 (4.0)</td>
<td>4.3 (3.5)</td>
<td>9 (3.1)</td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>0 - 16</td>
<td>0 - 9</td>
<td>4 - 16</td>
<td></td>
</tr>
<tr>
<td>Berg Total</td>
<td></td>
<td></td>
<td></td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>$\bar{x}$ (SD)</td>
<td>38.8 (17.3)</td>
<td>23.1 (11.09)</td>
<td>53.18 (3.57)</td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>9 - 56</td>
<td>9 - 49</td>
<td>44 - 56</td>
<td></td>
</tr>
<tr>
<td>Limits of Stability (%)</td>
<td></td>
<td></td>
<td></td>
<td>.56</td>
</tr>
<tr>
<td>$\bar{x}$ (SD)</td>
<td>68.5 (16.6)</td>
<td>66.2 (17.24)</td>
<td>70.55 (16.6)</td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>32 - 99</td>
<td>32 - 99</td>
<td>39 - 98</td>
<td></td>
</tr>
<tr>
<td>Timed Get up and Go (sec)</td>
<td></td>
<td></td>
<td></td>
<td>.049</td>
</tr>
<tr>
<td>$\bar{x}$ (SD)</td>
<td>33.3 (36.8)</td>
<td>51.4 (47.92)</td>
<td>16.82 (3.79)</td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>12 - 185</td>
<td>24 - 185</td>
<td>12 - 25</td>
<td></td>
</tr>
<tr>
<td>LIMAT Function</td>
<td></td>
<td></td>
<td></td>
<td>.0005</td>
</tr>
<tr>
<td>$\bar{x}$ (SD)</td>
<td>.30 (.22)</td>
<td>.46 (.20)</td>
<td>.16 (.12)</td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>0 - .82</td>
<td>.17 - .82</td>
<td>0 - 35</td>
<td></td>
</tr>
<tr>
<td>SF36 Physical Funct</td>
<td></td>
<td></td>
<td></td>
<td>.0017</td>
</tr>
<tr>
<td>$\bar{x}$ (SD)</td>
<td>32.6 (32.3)</td>
<td>11 (13.08)</td>
<td>52.27 (32.2)</td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>0 - 100</td>
<td>0 - 40</td>
<td>5 - 100</td>
<td></td>
</tr>
<tr>
<td>Duration: (=&lt; 1 yr/&gt;1 yr)</td>
<td>9/12</td>
<td>0/10</td>
<td>9/2</td>
<td>.0002</td>
</tr>
<tr>
<td>Severity (mod/Severe)</td>
<td>14/7</td>
<td>4/6</td>
<td>10/1</td>
<td>.0134</td>
</tr>
<tr>
<td>Fall risk (risk/no risk) Berg</td>
<td>9/12</td>
<td>9/1</td>
<td>0/11</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Fall risk (risk/no risk) ETGUG</td>
<td>11/10</td>
<td>10/1</td>
<td>1/10</td>
<td>&lt;.0001</td>
</tr>
</tbody>
</table>

determined with the t test for independent variables and chi-square analysis.
Table 4.5
Pre-Post treatment correlations with changes in volume and changes in impairments and activity limitations

<table>
<thead>
<tr>
<th></th>
<th>Dorsi Flex ROM diff Pre-Post</th>
<th>Knee Flex ROM diff Pre-Post</th>
<th>Heel rise diff Pre-Post</th>
<th>30 sec chair Quad Diff Pre-Post</th>
<th>Berg diff Pre-Post</th>
<th>LOS diff Pre-Post</th>
<th>ETGUG diff Pre-Post</th>
<th>LIMAT Function diff Pre-Post</th>
<th>SF36 Phys. diff Pre-Post</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume difference Pre-Post</td>
<td>r=-.20 p=.93</td>
<td>r=.13 p=.55</td>
<td>r=-.05 p=.82</td>
<td>r=-.15 p=.52</td>
<td>r=-.12 p=.60</td>
<td>r=-.25 p=.28</td>
<td>r=-.18 p=.44</td>
<td>r=.30 p=.18</td>
<td>r=-.13 p=.58</td>
</tr>
</tbody>
</table>
Table 4.6
Baseline to follow-up correlations with changes in impairments and activity limitations

<table>
<thead>
<tr>
<th></th>
<th>Dorsi Flex ROM Diff</th>
<th>Knee Flex ROM Diff</th>
<th>Heel rise Diff</th>
<th>30 sec chair – Quad Diff</th>
<th>Berg Diff</th>
<th>LOS Diff</th>
<th>ETGUG Diff</th>
<th>LIMAT Funct. Diff</th>
<th>SF36 Phys. Diff</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume Diff</td>
<td>r= -.04 p=.90</td>
<td>r=.29 p=.28</td>
<td>r=.06 p=.82</td>
<td>r=.19 p=.51</td>
<td>r=.20 p=.48</td>
<td>r=.50 p=.06</td>
<td>r= 0.00 p=1.0</td>
<td>r= 0.00 p=1.0</td>
<td>r=.17 p=.55</td>
</tr>
<tr>
<td>Dorsi Flex ROM Diff</td>
<td>r=.14 p=.61</td>
<td>r=.53 p=.05</td>
<td>r=.29 p=.30</td>
<td>r=.68 p=.005</td>
<td>r=.48 p=.07</td>
<td>r=.77 p=.0007</td>
<td>r=.50 p=.05</td>
<td>r=.62 p=.01</td>
<td></td>
</tr>
<tr>
<td>Knee Flex ROM Diff</td>
<td>r=.46 p=.08</td>
<td>r=.34 p=.21</td>
<td>r=.08 p=.77</td>
<td>r=.27 p=.92</td>
<td>r=.35 p=.21</td>
<td>r=.05 p=.85</td>
<td>r=.06 p=.84</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heel rise Diff</td>
<td>r=.44 p=.10</td>
<td>r=.69 p=.004</td>
<td>r=.07 p=.79</td>
<td>r=.65 p=.009</td>
<td>r=.52 p=.05</td>
<td>r=.45 p=.10</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30 sec chair Diff</td>
<td>r=.59 p=.02</td>
<td>r=.21 p=.46</td>
<td>r=.58 p=.02</td>
<td>r=.58 p=.02</td>
<td>r=.46 p=.09</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Berg Diff</td>
<td>r=.25 p=.37</td>
<td>r=.75 p=.0012</td>
<td>r=.77 p=.0009</td>
<td>r=.62 p=.01</td>
<td>r=.17 p=.55</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LOS Diff</td>
<td>r=.22 p=.44</td>
<td>r=.49 p=.06</td>
<td>r=.57 p=.03</td>
<td>r=.36 p=.19</td>
<td>r=.38 p=.16</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 4.7
Changes in impairments and activity limitations by group and by timeframe

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Pre Treatment N=21</th>
<th>2 week Post Treatment</th>
<th>6 week Follow - Up</th>
<th>p - value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No Rehab (NR)</td>
<td>Rehab (R)</td>
<td>No Rehab (NR)</td>
<td>Rehab (R)</td>
</tr>
<tr>
<td>VOL 1-2-3 NR = 5 R = 10</td>
<td>8911.7 4716.2</td>
<td>10486.3 6389.4</td>
<td>8232.2 4460.4</td>
<td>9797.8 5609.1</td>
</tr>
<tr>
<td>Dorsi Flexion ROM 1-2-3</td>
<td>3.4 2.2</td>
<td>.25 4.1</td>
<td>3.8 2.5</td>
<td>.2 3.9</td>
</tr>
<tr>
<td>Knee Flexion ROM 1-2-3</td>
<td>106.8 22.4</td>
<td>106.2 15.7</td>
<td>106.4 22.1</td>
<td>106.2 15.1</td>
</tr>
<tr>
<td>Quad Strength 1-2-3</td>
<td>9 4.4</td>
<td>4.3 3.5</td>
<td>9 3.8</td>
<td>3.4 2.6</td>
</tr>
<tr>
<td>Calf Strength 1-2-3</td>
<td>12.4 6</td>
<td>9.5 4.7</td>
<td>14.4 8.14</td>
<td>7.5 3</td>
</tr>
<tr>
<td>Limits of Stability 1-2-3</td>
<td>71 14.5</td>
<td>66.2 17.2</td>
<td>61.4 13.1</td>
<td>44.4 15.2</td>
</tr>
<tr>
<td>Berg Total 1-2-3 NR = 5 R = 10</td>
<td>52.6 5.1</td>
<td>23.1 11.1</td>
<td>54.2 2.5</td>
<td>25.5 10.7</td>
</tr>
<tr>
<td>ETGUG 1-2-3 NR = 5 R = 10</td>
<td>18.2 4.1</td>
<td>51.4 47.9</td>
<td>18.6 5.7</td>
<td>55.1 57.8</td>
</tr>
<tr>
<td>LIMAT Funct 1-2-3 NR = 5 R = 10</td>
<td>.17 .12</td>
<td>.46 .20</td>
<td>.13 .16</td>
<td>.47 .18</td>
</tr>
<tr>
<td>SF 36 Physical Scale 1-2-3 NR = 5 R = 10</td>
<td>52 30.5</td>
<td>11 13.1</td>
<td>56 35.4</td>
<td>13 13.8</td>
</tr>
</tbody>
</table>
Figure 4.1 Expanded Timed Get Up and Go

Figure 4.2 Diagnoses related to lymphedema

Diagnoses

- Venous Insufficiency (43%)
- Other Cancers (23%)
- Ovarian Cancer (14%)
- Primary Lymphedema (10%)
- Trauma (5%)
- Amyloidosis (5%)
CHAPTER 5: SUMMARY AND CONCLUSION

The primary question addressed in this dissertation was whether the standard and customary intervention for the treatment of lower extremity lymphedema was effective in resolving the activity limitations required for treatment coverage by third party payers. Worldwide, the incidence of lower extremity lymphedema is dominated by filariasis, mostly in tropical countries. Millions of people suffer with the condition. Many of the research studies for this condition have identified the clinical manifestations, disability and psychosocial impact of the disease.\[82,187,195\] Treatment in these tropical regions is limited by lack of resources and knowledge of and treatment for the condition.\[188\] Much of the clinical research on lower extremity lymphedema has been performed on this patient population. However, the research has not focused on the specific impairments, activity limitations or participation restrictions.

From 1987 to 2006, the once virtually neglected field of lymphatic research has exploded with a 112% growth in publications using the word “lymphatic” in them when searched in the United States National Library of Medicine National Institute of Health database. When the word “lymphangiogenesis” is identified, a 15,800% growth just over the past 8 years has occurred. These research studies have focused on the biomedical aspect of lymphedema.\[196\] When the words “lymphedema” and “manual lymphatic drainage” are used to search a meager 103 results have occurred since 1975. When adding the words “lower extremity” the database reveals just 16 articles.

The clinical research for lymphedema in the United States has primarily focused on Breast Cancer Related Lymphedema in the past.\[197-200\] However, with the increased incidence of lower extremity lymphedema secondary to cancer treatment, venous
insufficiency and obesity, focus has begun to be directed to lower extremity lymphedema. However, as in the tropical regions of the world, the treatment for lymphedema in the United States is limited by lack of resources and knowledge of and treatment for the condition. Medical schools dedicate minimal time to the education of the lymphatics system and to the treatment of lymphedema. Physical therapists and other health care professionals must complete post graduate certification courses in order to be able to treat the condition.

It has been well documented that the treatment for lymphedema (CDT) reduces limb volume. The next logical progression in clinical research is to define the impairments and functional limitations associated with the condition and then determine if the treatment for the condition improves them. In order to identify if complex decongestive therapy effectively addresses activity limitation or if this patient population requires a tradition physical therapy program, eight questions had to be addressed.

**Research Question 1. What is the type and severity of impairments seen in patients with lower extremity lymphedema?**

The group of lower extremity lymphedema subjects presented with significantly lower scores than standards in all impairments. Range of motion testing at baseline produced significantly lower scores than normal. When divided into groups based on severity, the severe group presented with scores significantly worse than the moderate group. Hoppenfeld reported norms for ankle dorsiflexion (20 degrees) and knee flexion (135 degrees). The subjects in this trial had active range of motion of ankles and knees far less than the norms reported by Hoppenfeld. Subjects in the severe group
performed active range of motion far less than the moderate group. The results found in this study support the assumption that lymphedema will lead to range of motion loss and that more severe edema leads to more severe impairments.\cite{201, 202}

Strength testing produced significantly lower scores than normal. Lundsford et al. report norms for the Heel Rise test (25 repetitions).\cite{116} The subjects in the trial performed the Heel Rise test with fewer repetitions and the severe group performed far fewer than the moderate group than the norm reported by Lundsford et al. Jones et al. reported norms for the 30 second Chair Stand test (10 repetitions).\cite{203} The group performed significantly less repetitions and the severe group performed less than the moderate group than the norms reported by Jones et al. Strength training has recently been closely examined because of the usual restrictions on exercise place on lymphedema patients. Studies have shown strength deficits of the upper extremity in subjects who are at risk for upper limb lymphedema but do not have the condition\cite{204} Other studies looked at strength of subjects who do have upper extremity lymphedema to determine if the exercise exacerbated the condition.\cite{205, 206} However, the studies were not designed to establish the cross sectional baseline deficits of the lymphedema subjects prior to treatment.

Balance testing produced significantly lower scores than normal. Bogle et al. reported the norm for the Berg Balance Score (56) and the level at which scored below would indicate fall risk (\(<45\)).\cite{118} The group scored significantly below the norm; and the severe group scored even farther below the fall risk level while the moderate groups mean remained above the fall risk level as report by Bogle et. Limit of Stability testing produced significantly lower scores than normal. Melzer et al. described the norm for the
LOS as the age-matched maximum a person can lean in any direction (100%).\textsuperscript{[191]} The group scored significantly lower and the severe group even lower than the moderate group below the norm reported by Melzer.

Strength, range of motion and balance associated with the lower extremity lymphedema have not been studied prior to this investigation.

**Research Question 2: What is the type and severity of activity limitations seen in patients with lower extremity lymphedema?**

The cohort group of lower extremity lymphedema subjects presented with significantly greater activity limitations and participation restrictions than normal healthy individuals. Activity limitations were tested using the ETGUG. Wall et al reported norms for the ETGUG (20 seconds) which established a cut point above which fall risk is increased. Although the ETGUG score for subjects with lymphedema was an average of 13 seconds greater than the normal score this difference failed to achieve statistical significance because of extreme variability in the data due to one subject.

Subjects with lymphedema also scored significantly worse than norms on the other activity limitation measures, LIMAT Function and SF36 Function. The LIMAT uses a scale of 100 – 0 where 0 is normal. The group scored significantly worse and the severe group far worse than the moderate group than the normal established by the authors. Anderson et al reported the norm for SF36 to be 100. The group scored significantly worse and the severe group scored worse than the moderate group below the norm reported by Anderson et al.\textsuperscript{[207]}
**Research Question 3:** In subjects with lower extremity lymphedema, is the severity of the impairments (balance, lower extremity strength, range of motion, and pain) related to the severity of the lymphedema (based on International Society of Lymphology classification standards)?

Subjects with moderate and severe lymphedema differed significantly in the type and severity of impairments. The severe group was more impaired in calf and quadriceps strength, range of motion to the knees and ankles relative to the moderate group. Balance measures were also significantly worse in the severe group relative to the moderate group including BBS and Limits of Stability.

Subjects with severe lymphedema were significantly larger, and presented with significantly more limb volumes than the moderate group.

**Research Question 4:** Is the severity of the activity limitations in subjects with lower extremity lymphedema related to the severity (based on International Society of Lymphology classification standards) of the lymphedema, or to impairments of lower extremity strength, range of motion, balance or some combination of all of these?

At baseline, total volume measures of the lymphedema related strongly to LIMAT function score and the SF36 physical score in that larger volume was associated with greater activity limitation. The only activity limitation measure that did not strongly correlate to volume was the ETGUG score which demonstrated a weak correlation.
The activity limitations as measured by the ETGUG, LIMAT, and SF36 strongly correlated with Knee flexion active range of motion but only weakly with ankle dorsiflexion such that more impaired ROM was associated with greater activity limitation. Strength associated strongly with activity limitations. The heel rise test, measuring calf strength, and 30 second chair test, measuring quadriceps strength, had a strong correlation with ETGUG, LIMAT and SF36 in that more impaired strength was associated with greater activity limitations. Balance as measured by the Berg Balance Score produced similar results producing a strong correlation with ETGUG, LIMAT and SF36. More impaired balance was associated with greater activity limitation. The limits of stability balance test did not correlate with any of the activity limitation tests.

**Research Question 5: Is decrease in limb volume related to improvement in impairments of balance, pain, strength, and range of motion?**

While Complex Decongestive Therapy reduced the limb volume of the involved extremity, there was no evidence that reduced limb volume resolved the impairments.

The change in limb volume over the 2 week intervention did not correlate with change in impairments as tested by ankle dorsiflexion, knee flexion, Heel rise (calf strength), 30 second chair test (quadriceps), Berg Balance Score and Limits of Stability. Although there was a significant reduction in limb volume pre to post treatment (p=.0097) there were no correlations between change in limb volume and changes in any of the impairments.
Research Question 6: Is a change in limb volume related to an improvement in activity limitation?

The change in limb volume over the 2 week intervention did not correlate with change in activity limitations as tested by ETGUG, LIMAT function or SF36 Functional scale. While Complex Decongestive Therapy reduced the limb volume of the involved extremity, there was no evidence that reduced limb volume reduced activity limitations.

Although there was a significant reduction in limb volume from pre-test to 6 week follow-up the changes in volume did not correlate in any of the activity limitations.

Research Question 7: What is the proportion of subjects who have completed the 2-week intervention and continue to have a balance impairments or functional limitations severe enough to increase the risk of falling, and how does this compare with their baseline, indicating the need for additional rehabilitation?

Twenty-one subjects initiated the intervention of CDT and were tested at baseline. After completing the two week intervention and retested, ten subjects (47.6%) demonstrated balance impairments and functional limitations severe enough to increase the risk of falling.

The ten subjects who continued with rehabilitation had scores after CDT on the Berg balance score and/or ETGUG indicating they were at risk for falls. These same subjects upon initial evaluation for lymphedema presented with scores on the Berg Balance Score and/or ETGUG which placed them at risk for falls.
**Research Question 8: Does a 4-week standard physical therapy intervention to address impairments in strength, ROM, and balance produce improvements in both the impairments and the activity limitations?**

Ten subjects completed the 4 week physical therapy intervention. The 4 week physical therapy program produced significant improvement in impairments and activity limitations. Strength increased in both the plantar flexors and quadriceps muscles. Balance improved as measured by both the Berg Balance and Limits of Stability tests. However it is important to note that the limits of stability declined after the CDT intervention and then significantly improved over the physical therapy intervention phase. Changes from pre treatment to follow up were not statistically significant for LOS. Activity limitations as measured by the LIMAT and SF-36 also improved from the post treatment to follow up and from pre to follow up.

**Limitations**

**Blinding**

The individual who was responsible for administering all measures was aware of the subjects’ characteristics and the interventions they received. Ideally, the tester would be blinded to intervention status to eliminate a potential source of bias. Another potential bias occurred because the subjects were aware of the study procedures. The knowledge that one group was to continue with a physical therapy intervention program based on impairment and activity limitations could have resulted in poorer performance by subjects during the testing. Blinding of the subjects was not possible.
Attrition

Attrition occurred during the follow up of the group that did not receive physical therapy intervention. Only five subjects of the 11 returned for follow up testing. Although the change over the 4 week period in impairments and activity limitations of the 5 subjects who did not receive rehab differed significantly from the change occurring in the physical therapy group, a stronger comparison could have been made if all 11 subjects had been included in the analysis.

Attrition within the No Rehab group represented a potential threat of bias if those who did not follow up were systematically different from the original No Rehab group who remained in the study. If attrition bias occurred it could directly affect the external validity of this study in which the longitudinal sample no longer represented the original sample. As a result the remaining sample could not be generalizable to the original population that we sampled. Also, systematic as opposed to random attrition could negatively affect the internal validity of this study by altering the correlations among the variable we tested in this study. This problem could have occurred in the study if the group that did not return had unique characteristics and became underrepresented in the original group.

Sample Size

The sample size need to attain power at .80 for a large effect size was 26, as identified by GPower analysis. The sample estimation was based on testing for a significant Spearman’s r. The N (subjects) established was for a large effect size at power = .80 for α (two-tailed) = .05. This study had two components. The first part analyzed 21 subjects over a two week period. The second part continued with 10 subjects in the
Rehab group. The other 11 subjects in the No Rehab were to return for follow up testing 4 weeks after their completion of the initial 2 weeks. However, 5 subjects actually returned for the follow up. The power of our study indicated an 80% probability of achieving a significant result if an effect exists. With 21 subjects participating in the first segment of the research, the Gpower analysis decreased to .70. The additional 5 subjects would have elevated the power to .80. The second segment of the study analyzed 15 total subjects (10 Rehab, 5 No Rehab). A Gpower analysis for a two tailed t tests revealed a power of .52 when using 15 subjects in order to achieve a large effect size (r=.50). The .52 power makes it less likely that the study would achieve significant results. However despite the .52 power, large effect sizes were calculated with the difference in ankle dorsiflexion and its correlation with the differences in Heel Rise Test, BBS, LOS, ETGUG, LIMAT and SF36. Similar results occurred with the differences in 30 Second Chair Test and Heel Rise Test and BBS, ETGUG, and LIMAT.

A large number of subjects were excluded from participating in the research study. The exclusion criteria eliminated subjects with diagnoses which were contraindications to the lymphedema treatment or factors that would influence mobility activities. Unfortunately, due to the limited understanding of the health care community on diagnosis and treatment for lymphedema, subjects are usually referred when the symptoms become severe. Often times co-morbidities are already present that could influence research such as this.
Directions for Future Research

This study investigated the baseline characteristics of subjects with lymphedema. The directions for future research can build on to this study. Future research should initially begin with a continuation of this study to gather more subjects. Since lymphedema can result from many etiologies, a larger sample would allow for separation by underlying diagnosis to determine impairments and activity limitations unique to each group.

Another avenue of future research is to compare obese subjects and obese lymphedema subjects. The future study would examine both groups with the same criteria as this present study. This could eliminate the potential effect that the outcomes were obesity related and not lymphedema related. The obese group also could undergo the physical therapy intervention for the four week period to identify if changes would occur in this group relative to the lymphedema group. It would be an interesting comparison to see if the changes in strength, range of motion and activity limitations were limited to the lymphedema group or could be generalized to a group with morbid obesity.

Further studies of interest would involve medical community surveys to determine the knowledge and experience base of the practitioners with regard to lymphedema and the community resources available to treat the condition. Another study could involve examining the subjects who have been referred for therapy with lower extremity lymphedema to determine the information regarding their referral, length of time with the condition, and other questions intended to determine the patient and medical community knowledge of this condition. Within this study, a periodic follow up
examination could occur over years to determine the progression of lymphedema and the impairment and functional limitations acquired over time.

Determining the most effective exercise strategies would also be a component of future research. It is essential to determine the effectiveness of exercise to treat the impairment and functional limitations, both as a treatment option in clinics as well as a home based module.

**Health Care Policy Implications**

The treatment of Lymphedema has been identified by the insurance companies and certification programs as a volume deficit reduction issue. It is the only physical impairment which has a specific limitation on the number of visits or duration to treat it. Based on the findings of this research, the patient who presents with lymphedema should undergo a thorough physical therapy evaluation. Treatment should follow the criteria for all rehabilitation which is by definition a return to pre-morbid function. Physical therapy should continue based on the need for the skill of the therapist to continue intervention not an arbitrary visit count or duration limit.

Patients who present with lymphedema but do not have activity limitations should not be prevented from receiving insurance coverage for their condition. This study showed a dramatic worsening of impairments and activity limitations in subjects with severe versus moderate edema. Lymphedema left untreated can escalate into a more severe stage of the condition. By reducing, controlling and maintaining lymphedema it may be possible to limit co-morbidities and potential loss in quality of life for patients.
A bill, H.R. 4662, recently submitted to congress, outlines the potential changes to coverage and treatment of lymphedema by all insurances. The “Lymphedema Diagnosis and Treatment Savings Act of 2010, proposes allowing of Lymphedema certified health care practitioners, such as a licensed massage therapists and licensed practical nurses, be able to treat patients with Lymphedema as long as they are directly supervised by a Certified Physical or Occupational Therapist. Presently, most state laws and practice acts allow only a Physical Therapist or Occupational Therapists Assistant to treat under a Physical or Occupational Therapists. The state practice acts and laws would have to be amended to allow the other practitioners to treat lymphedema while being supervised. If allowed to treat, a greater concern regarding the implications of the detection of potential co-morbidities and activity limitations arises. This bill is focused, as are the insurers and certification programs, on the edema only without considering of impairments and activity limitations and quality of life.

**Conclusions**

Recognizing and treating lymphedema in the early stages may minimize co-morbidities, impairments and activity limitations. Upon admission for care, patients with lower extremity lymphedema should be evaluated for impairments and activity limitations, as well as edema. The lymphedema treatment should also be combined with a traditional physical therapy intervention when indicated.

The cost of health care needs to be controlled. For practitioners and insurers to move from a reactive approach, in which significant deficits must occur before treatment is delivered to a more proactive approach can greatly decrease potential health costs. By
initiating care early in the onset of swelling, physical therapists can help prevent potential medical conditions, such as cellulitis, infections, and wounds, and as this study has shown, physical impairments and activity limitations.
REFERENCES


105. Services, C.F.M.a.M.


150. Company, L.I., *Gulick II Tape Measure:* Lafayette, IN.


APPENDIX I

Physical Therapy Intervention

1. Passive Range of Motion to bilateral lower extremities


3. Transfer Training – Sit to Stand

4. Postural Training – with cueing for proper alignment

5. Postural Training – on incline with and without compliant surface

6. Balance Training – on level surface with and without compliant surface and with and without visual feedback

7. Erect Stretching and balance on ramp with asymmetry

8. Gait training with or without device with cueing

9. Erect strengthening ankle

10. Recumbent Nustep 15 minutes
APPENDIX II

The Cohort Flowchart

Assessed for eligibility
N=40

Screening

Excluded (n = 18)
Not meeting inclusion criteria (n=17)
Declined Participation (n=1)

Consented Baseline Testing (n=22)

Withdrawn (n=1)
Anxiety during LOS

Completed 2 week CDT Intervention
Retested (n=21)

Additional PT (n=10)
Retested after 4 weeks (n=10)

No Additional PT (n=11)
Retested after 4 weeks (n=5)
APPENDIX III

Research Questionnaire  Subject ID#: 

Please fill out the questionnaire by circling the number that corresponds with the correct answer or filling in the answer in the designated space.
PART 1  Pre-research Questionnaire
PART 2  Post 2-week Research Questionnaire
PART 3  Post 6-week Research Questionnaire

PART 1

Date Completed: ______________________

1. What type of lymphedema do you have?
   1. Primary (born with lymphedema OR onset during childhood/puberty/adult without and apparent reason)
   2. Secondary (due to cancer surgery or radiation treatment OR resulting from trauma, infection, other surgeries, accident, venous insufficiency)

2. What are the affected areas?
   1. Left leg
   2. Right leg
   3. Both legs

3. Have you been treated previously for the lymphedema?
   1. Yes
   2. No

4. When did you complete your most recent previous treatment for lymphedema?
   Date: ______________________

5. When you completed your most recent treatment for lymphedema, were you fitted for a stocking?
   1. Yes
   2. No

6. If yes, did you receive your stocking?
   1. Yes
   2. No
PART 1 Research Questionnaire

7. If yes, were you able to apply your stocking?
   1. By yourself
   2. With someone’s help
   3. Unable to wear stocking

8. If yes, why have you returned for therapy to treat the lymphedema?
   1. Unable to perform by myself or caregiver
   2. Unable to put on or take off the stocking
   3. There is a recent swelling in my legs
   4. I tried to treat myself but was not successful

9. Are you aware of the limitations of coverage for the treatment of lymphedema by Medicare?
   1. Yes
   2. No

10. Do you feel that the lymphedema has affected your day-to-day activities?
    1. Yes
    2. No

11. What types of problems do you experience related to your lymphedema (circle all that apply)?
    1. Pain
    2. Swelling
    3. Numbness
    4. Skin integrity (open skin areas, wounds, leakage of fluid)
    5. Redness or skin discoloration
    6. Other (Please specify)

12. Do you exercise and/or take walks regularly?
    1. Yes
    2. No

13. Do you have someone who can assist you with treatment or putting on and taking off (a) stocking(s)?
    1. Yes
    2. No
PART 2 Research Questionnaire  Subject ID#: 
(Complete Following the Post 2-week Research Protocol)

Date Completed: ____________________

1. Identify the number of days you were able to attend treatment within the 2-week period.

   Number of days: ______________

2. Which of the following best describes how much time you were able to keep the compression wraps on your legs during the time you were not in therapy?

   1. None of the time
   2. Some of the time
   3. Most of the time
   4. Almost all of the time

3. Which of the following best describes how your ability to perform your day-to-day activities has changed following the 2 weeks of treatment?

   1. It has gotten a lot worse
   2. It has gotten a little bit worse
   3. It has not changed
   4. It has gotten a little better
   5. It has gotten a lot better

4. Have you been measured for a compression garment?

   1. Yes
   2. No

5. If no, why?

   1. Unable to travel to facility to be measured
   2. Unable to afford the cost for the garments
   3. Unable to set up an appointment to be measured
   4. Decided not to acquire a compression garment
   5. Other (Please specify)

6. If yes, were you given a garment at the time of the measurement?

   1. Yes
   2. No
PART 2  
Research Questionnaire  
Subject ID#:  

7. If yes, and you were not given a garment at the time of measurement, when were you told that you will receive the garment?  
Days: ________________

8. If you did not meet the criteria to continue in the interventional research, do you or your assistant feel capable of managing the lymphedema independently?  
1. Yes  
2. No

9. If “No,” how do you plan on continuing the treatment for your lymphedema?  
1. I will do the best I can  
2. I will pay privately to have a therapist treat me  
3. I will try alternative treatments to decrease the volume such as medication, external pump mechanism.  
4. I will not try to treat the lymphedema  
5. Other (Please specify)
PART 3 Research Questionnaire Subject ID#: (Complete Following the Post 6-week Research Protocol)

Date Completed: ____________________

1. Did you continue with the interventional component of the research protocol? That is, did you successfully maintain the treatment of the lymphedema? (Success is defined as consistent wearing of a compression garment and/or application of compression wraps, additionally performing manual lymphatic drainage.)

   1. Yes
   2. No

2. Which of the following best describes how your ability to perform your day-to-day activities has changed following the 4 additional weeks of treatment?

   1. It has gotten a lot worse
   2. It has gotten a little bit worse
   3. It has not changed
   4. It has gotten a little better
   5. It has gotten a lot better

3. If you were measured for a compression garment at the end of the 2-week treatment for the lymphedema and DID NOT receive your compression garment at the time of measurement, when did you receive the garment?

   Number of days later: ____________________

4. If you received your garment after the lymphedema treatment ended, were you able to maintain the lymphedema treatment yourself or with an assistant performing the manual lymphatic drainage and compression wrapping and/or garment?

   1. Yes
   2. No
### APPENDIX IV

#### BERG BALANCE SCALE


**Patient Identifier:**

**Grading:** Record the lowest category which applies

<table>
<thead>
<tr>
<th>Item</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Sitting to Standing:</td>
<td></td>
</tr>
<tr>
<td>- 4-Able to stand with no hands and stabilize independently</td>
<td></td>
</tr>
<tr>
<td>- 3-Able to stand independently w/ding hands</td>
<td></td>
</tr>
<tr>
<td>- 2-Able to stand using hands after several tries</td>
<td></td>
</tr>
<tr>
<td>- 1-Needs Min. assist. to stand or to stabilize</td>
<td></td>
</tr>
<tr>
<td>- 0-Needs Mod. or Max. assist. to stand</td>
<td></td>
</tr>
<tr>
<td>2. Standing Unsupported</td>
<td></td>
</tr>
<tr>
<td>- 4-Able to stand safely 2 min.</td>
<td></td>
</tr>
<tr>
<td>- 3-Able to stand 2 min. with supervision</td>
<td></td>
</tr>
<tr>
<td>- 2-Able to stand 30 sec. unsupported</td>
<td></td>
</tr>
<tr>
<td>- 1-Needs several tries to stand 30 sec. unsupported</td>
<td></td>
</tr>
<tr>
<td>- 0-Unable to stand 30 sec. unassisted</td>
<td></td>
</tr>
<tr>
<td>3. Sitting unsupported, feet on floor</td>
<td></td>
</tr>
<tr>
<td>- 4-Able to sit safely and securely 2 min.</td>
<td></td>
</tr>
<tr>
<td>- 3-Able to sit 2 min. under supervision</td>
<td></td>
</tr>
<tr>
<td>- 2-Able to sit 30 sec.</td>
<td></td>
</tr>
<tr>
<td>- 1-Unable to sit 10 sec.</td>
<td></td>
</tr>
<tr>
<td>- 0-Unable to sit without support 10 sec.</td>
<td></td>
</tr>
<tr>
<td>4. Sitting to Standing</td>
<td></td>
</tr>
<tr>
<td>- 4-Sits safely from standing, minimal use of hands</td>
<td></td>
</tr>
<tr>
<td>- 3-Controls descent by using hands</td>
<td></td>
</tr>
<tr>
<td>- 2-Uses backs of legs against chair to control descent</td>
<td></td>
</tr>
<tr>
<td>- 1-Sits independently with uncontrolled descent</td>
<td></td>
</tr>
<tr>
<td>- 0-Needs assistance to sit</td>
<td></td>
</tr>
<tr>
<td>5. Transfers (one way toward seat with armrest, and one way toward a seat without armrest)</td>
<td></td>
</tr>
<tr>
<td>- 4-Able to transfer safely with minimal use of hands</td>
<td></td>
</tr>
<tr>
<td>- 3-Able to transfer safely with definite use of hands</td>
<td></td>
</tr>
<tr>
<td>- 2-Able to transfer with verbal cueing or supervision</td>
<td></td>
</tr>
<tr>
<td>- 1-Needs one person to assist transfer</td>
<td></td>
</tr>
<tr>
<td>- 0-Needs two people to assist or supervise to be safe</td>
<td></td>
</tr>
<tr>
<td>6. Standing Unsupported, Eyes closed</td>
<td></td>
</tr>
<tr>
<td>- 4-Able to stand 10 sec. safely</td>
<td></td>
</tr>
<tr>
<td>- 3-Able to stand 20 sec. with supervision</td>
<td></td>
</tr>
<tr>
<td>- 2-Able to stand 3 sec.</td>
<td></td>
</tr>
<tr>
<td>- 1-Unable to keep eyes closed 3 sec. but is steady</td>
<td></td>
</tr>
<tr>
<td>- 0-Needs help to keep from falling, eyes open</td>
<td></td>
</tr>
<tr>
<td>7. Standing Unsupported, Feet together</td>
<td></td>
</tr>
<tr>
<td>- 4-Able to place feet together and stand 1 min. safely</td>
<td></td>
</tr>
<tr>
<td>- 3-Able to place feet together and stand 1 min. with supervision</td>
<td></td>
</tr>
<tr>
<td>- 2-Able to place feet together independently, unable to hold 30 sec.</td>
<td></td>
</tr>
<tr>
<td>- 1-Needs help to get feet together, able to maintain 15 sec.</td>
<td></td>
</tr>
<tr>
<td>- 0-Needs help to attain position, unable to hold 15 sec.</td>
<td></td>
</tr>
<tr>
<td>8. Reaching Forward, Arm at 90 deg., fingers straight</td>
<td></td>
</tr>
<tr>
<td>- 4-Can reach forward comfortably 10 in. or more</td>
<td></td>
</tr>
<tr>
<td>- 3-Can reach forward 5-10 in. safely</td>
<td></td>
</tr>
<tr>
<td>- 2-Can reach forward 2-5 in. safely</td>
<td></td>
</tr>
<tr>
<td>- 1-Reaches forward but needs supervision for safely</td>
<td></td>
</tr>
<tr>
<td>- 0-Needs help to keep from falling</td>
<td></td>
</tr>
<tr>
<td>9. Standing, Pick up object from floor in front of feet</td>
<td></td>
</tr>
<tr>
<td>- 4-Able to pick up slipper (shoe) safely and easily</td>
<td></td>
</tr>
<tr>
<td>- 3-Able to pick up slipper, needs supervision</td>
<td></td>
</tr>
<tr>
<td>- 2-Unable to pick up but reaches to within 2 in., keeping balance</td>
<td></td>
</tr>
<tr>
<td>- 1-Unable to pick up and needs supervision while trying</td>
<td></td>
</tr>
<tr>
<td>- 0-Unable to try, need assistance to keep from falling</td>
<td></td>
</tr>
<tr>
<td>10. Standing, turning to look over one shoulder, then other</td>
<td></td>
</tr>
<tr>
<td>- 4-Looks behind to both sides, weight shifts well</td>
<td></td>
</tr>
<tr>
<td>- 3-Looks behind one side only, other side shows less weight shift</td>
<td></td>
</tr>
<tr>
<td>- 2-Turns sideways only but maintains balance</td>
<td></td>
</tr>
<tr>
<td>- 1-Needs supervision when turning</td>
<td></td>
</tr>
<tr>
<td>- 0-Needs assistance to keep from falling</td>
<td></td>
</tr>
</tbody>
</table>

*Continued On Next Page*
**BERG BALANCE SCALE CONTINUED FROM PREVIOUS PAGE**

<table>
<thead>
<tr>
<th>Item</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>11. Turn 360 degrees&lt;br&gt;4-Able to turn 360 safely, less than 4 sec. each direction&lt;br&gt;3-Able to turn safely to one side only, less than 4 sec.&lt;br&gt;2-Able to turn 360 deg. safely but slowly&lt;br&gt;1-Needs close supervision or verbal cueing&lt;br&gt;0-Needs assistance when turning</td>
<td></td>
</tr>
<tr>
<td>12. Dynamic Weight Shifting. Standing, touch each foot to stool alternately. Continue until 4 touches with each foot.&lt;br&gt;4-Safe, independent, completes 8 steps in 20 sec.&lt;br&gt;3-Safe, independent, takes more than 20 sec.&lt;br&gt;2-Able to complete 8 steps without aid, with supervision&lt;br&gt;1-Able to complete 2-4 steps with Minimal assistance&lt;br&gt;0-Unable to try or needs assistance to prevent falling</td>
<td></td>
</tr>
<tr>
<td>13. Standing Unsupported. One Foot in Front. Heel close but does not need to touch toes of rearmost foot (Tandem Standing)&lt;br&gt;4-Able to place foot tandem and hold 30 sec.&lt;br&gt;3-Able to place foot independently and hold 30 sec.&lt;br&gt;2-Able to take small step independently and hold 30 sec.&lt;br&gt;1-Needs help to step but can hold 15 sec.&lt;br&gt;0-Loses balance while stepping or standing</td>
<td></td>
</tr>
<tr>
<td>14. Standing On One Leg&lt;br&gt;4-Able to lift leg independently and hold more than 10 sec.&lt;br&gt;3-Able to lift leg independently and hold 5-10 sec.&lt;br&gt;2-Able to lift leg independently and hold up to 3 sec.&lt;br&gt;1-Tries to lift leg, unable to hold, remains standing independently&lt;br&gt;0-Unable to try or need assistance to prevent fall</td>
<td></td>
</tr>
</tbody>
</table>

**TOTAL SCORE /55**

**ADMINISTERING THERAPIST’S INITIALS**

Therapist signatures:

__________________________

__________________________

__________________________
APPENDIX V

<table>
<thead>
<tr>
<th>Activity</th>
<th>No Difficulty</th>
<th>Some Difficulty</th>
<th>Much Difficulty</th>
<th>Some Assistance</th>
<th>Much Assistance</th>
<th>Unable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sit up on the side of the bed</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Stand up from the bed</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Get on and off the toilet</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Get in and out of bath</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>tub/shower</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Get up and down from sofa</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Get up and down from chair</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>with arms</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Getting in and out of car</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Stoop to pick up an object</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>from the floor</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

To what extent is the pt's ability to perform the activities above impaired by the following problems?

<table>
<thead>
<tr>
<th>Impairment</th>
<th>No Problem</th>
<th>Mild Problem</th>
<th>Moderate Problem</th>
<th>Severe Problem</th>
<th>Complete Problem</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fear of movement (b152)</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Loss of vision (b210)</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Loss of sensation (b260-b279)</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Pain (b280)</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Fatigue (b459)</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Stiffness (b710)</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Weakness (b730)</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Loss Balance (b755)</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Muscle Tone (b735)</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>
Limitation in Mobility Activities Test

Mobility (Walking and moving d450-d469)

For each of the activities below, please indicate if the pt. needs help or has difficulty performing the activity.

<table>
<thead>
<tr>
<th>Activity</th>
<th>No Difficulty</th>
<th>Some Difficulty</th>
<th>Much Difficulty</th>
<th>Assistance</th>
<th>Much Assistance</th>
<th>Unable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Walk 10 feet indoors</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Turn around in a complete circle</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Walk 50 feet indoors</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Walk 150 feet indoors</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Walk carrying a light object</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Climb and descend a curb</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Walk a block</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Walk up and down a gentle slope</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Step over a low obstacle</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Climb a flight of stairs</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Walk on grass or gravel</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Walk several blocks</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Walk up and down a steep slope</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Walk carrying a heavy object</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Climb several flights of stairs</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Walk a mile or more</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Run a short distance</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

To what extent is the pt's ability to perform the activities above impaired by the following problems?

<table>
<thead>
<tr>
<th>Impairment</th>
<th>No Problem</th>
<th>Mild Problem</th>
<th>Moderate Problem</th>
<th>Severe Problem</th>
<th>Complete Problem</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fear of movement (b152)</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Loss of vision (b210)</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Loss of sensation (b250-b279)</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Pain (b280)</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Fatigue (b455)</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Stiffness (b710)</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Weakness (b730)</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Loss Balance (b755)</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Muscle Tone (b735)</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>
**LIMAT KEY**

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Difficulty</td>
<td>Able to perform activity without assistance, without extra time or extra effort</td>
</tr>
<tr>
<td>Some Difficulty</td>
<td>Able to perform activity without assistance, but requires some extra time or extra effort</td>
</tr>
<tr>
<td>Much Difficulty</td>
<td>Able to perform activity without assistance, but requires a lot of extra time or extra effort or both</td>
</tr>
<tr>
<td>Some Assistance</td>
<td>Able to perform activity with one handed assistance from one person, or requires verbal cueing for safety</td>
</tr>
<tr>
<td>Much Assistance</td>
<td>Able to perform activity with two handed assistance from one person</td>
</tr>
<tr>
<td>Unable</td>
<td>Unable to perform the activity with the assistance of only one person</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Problem</td>
<td>None, absent, negligible (0-4%)</td>
</tr>
<tr>
<td>Mild Problem</td>
<td>Slight, low (5-24%)</td>
</tr>
<tr>
<td>Moderate Problem</td>
<td>Medium, fair (25-49%)</td>
</tr>
<tr>
<td>Severe Problem</td>
<td>High, extreme (50-95%)</td>
</tr>
<tr>
<td>Complete Problem</td>
<td>Total (96-100%)</td>
</tr>
</tbody>
</table>

**Operational Definitions for the LIMAT**

<table>
<thead>
<tr>
<th>Activity</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Walk room to room indoors</td>
<td>25 ft</td>
</tr>
<tr>
<td>Walk carrying a light object</td>
<td>Book</td>
</tr>
<tr>
<td>Climb and descend a curb</td>
<td>4” – 6”</td>
</tr>
<tr>
<td>Walk a block</td>
<td>Standard US city block ~300 ft</td>
</tr>
<tr>
<td>Walk carrying a heavy object</td>
<td>≥ 10 lbs</td>
</tr>
<tr>
<td>Walk up and down a gentle slope</td>
<td>&lt;10%, slope of 2 ft or greater</td>
</tr>
<tr>
<td>Step over a low obstacle</td>
<td>Small bolster</td>
</tr>
<tr>
<td>Climb a flight of stairs</td>
<td>12-14 stairs</td>
</tr>
<tr>
<td>Walk several blocks</td>
<td>2 or more, &gt;600 ft</td>
</tr>
<tr>
<td>Walk on grass or gravel</td>
<td>25 ft</td>
</tr>
<tr>
<td>Climb several flights of stairs</td>
<td>Maximum of 4 Flights</td>
</tr>
<tr>
<td>Walk up and down a steep slope</td>
<td>&gt;10%, slope of 5 ft or greater</td>
</tr>
<tr>
<td>Walk a mile or more</td>
<td>-------</td>
</tr>
<tr>
<td>Run a short distance</td>
<td>50 ft</td>
</tr>
</tbody>
</table>
APPENDIX VI

SF36 Health Survey

**INSTRUCTIONS:** This set of questions asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. Answer every question by marking the answer as indicated. If you are unsure about how to answer a question please give the best answer you can.

1. **In general, would you say your health is:** (Please tick one box.)
   - Excellent
   - Very Good
   - Good
   - Fair
   - Poor

2. **Compared to one year ago, how would you rate your health in general now?** (Please tick one box.)
   - Much better than one year ago
   - Somewhat better now than one year ago
   - About the same as one year ago
   - Somewhat worse now than one year ago
   - Much worse now than one year ago

3. **The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?** (Please circle one number on each line.)

<table>
<thead>
<tr>
<th>Activities</th>
<th>Yes, Limited A Lot</th>
<th>Yes, Limited A Little</th>
<th>Not Limited At All</th>
</tr>
</thead>
<tbody>
<tr>
<td>3(a) Vigorous activities, such as running, lifting heavy objects,</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>participating in strenuous sports</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3(b) Moderate activities, such as moving a table, pushing a vacuum cleaner,</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>bowing, or playing golf</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3(c) Lifting or carrying groceries</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>3(d) Climbing several flights of stairs</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>3(e) Climbing one flight of stairs</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>3(f) Bending, kneeling, or stooping</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>3(g) Walking more than a mile</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>3(h) Walking several blocks</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>3(i) Walking one block</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>3(j) Bathing or dressing yourself</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

4. **During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?** (Please circle one number on each line.)
   - Yes
   - No

<table>
<thead>
<tr>
<th>Problems</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>4(a) Cut down on the amount of time you spent on work or other activities</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>4(b) Accomplished less than you would like</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>4(c) Were limited in the kind of work or other activities</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>4(d) Had difficulty performing the work or other activities (for example,</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>it took extra effort)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5. **During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (e.g. feeling depressed or anxious)?** (Please circle one number on each line.)
   - Yes
   - No

<table>
<thead>
<tr>
<th>Problems</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>5(a) Cut down on the amount of time you spent on work or other activities</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>5(b) Accomplished less than you would like</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>5(c) Didn't do work or other activities carefully as usual</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>
6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours, or groups? (Please tick one box.)
   - Not at all
   - Slightly
   - Moderately
   - Quite a bit
   - Extremely

7. How much physical pain have you had during the past 4 weeks? (Please tick one box.)
   - None
   - Very mild
   - Mild
   - Moderate
   - Severe
   - Very severe

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)? (Please tick one box.)
   - Not at all
   - A little bit
   - Moderately
   - Quite a bit
   - Extremely

9. These questions are about how you feel and how things have been with you during the past 4 weeks. Please give the one answer that is closest to the way you have been feeling for each item.
   - (Please circle one number on each line.)
<table>
<thead>
<tr>
<th></th>
<th>All of the Time</th>
<th>Most of the Time</th>
<th>A Good Bit of the Time</th>
<th>Some of the Time</th>
<th>A Little of the Time</th>
<th>None of the Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>9(a) Did you feel full of life?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>9(b) Have you been a very nervous person?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>9(c) Have you felt so down in the dumps that nothing could cheer you up?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>9(d) Have you felt calm and peaceful?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>9(e) Did you have a lot of energy?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>9(f) Have you felt downhearted and blue?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>9(g) Did you feel worn out?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>9(h) Have you been a happy person?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>9(i) Did you feel tired?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
</tbody>
</table>

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)? (Please tick one box.)
   - All of the time
   - Most of the time
   - Some of the time
   - A little of the time
   - None of the time

11. How TRUE or FALSE is each of the following statements for you?
   - (Please circle one number on each line.)
<table>
<thead>
<tr>
<th></th>
<th>Definitely True</th>
<th>Mostly True</th>
<th>Don't Know</th>
<th>Mostly False</th>
<th>Definitely False</th>
</tr>
</thead>
<tbody>
<tr>
<td>11(a) I seem to get sick a little easier than other people</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>11(b) I am as healthy as anybody I know</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>11(c) I expect my health to get worse</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>11(d) My health is excellent</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

Thank You!
**APPENDIX VII**

Data Collection Form

<table>
<thead>
<tr>
<th>Number</th>
<th>Data Questions</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Body Weight</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Height</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>BMI = (Weight in pounds / Height in inches$^2$) x 703</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>ISI staging of lymphedema</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Perimeter Measure – Left Lower Extremity</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Perimeter Measure – Right Lower extremity</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Active Range Of Motion – Ankle Dorsiflexion</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Active Range Of Motion – Ankle Plantar Flexion</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Active Range Of Motion – Knee Flexion</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Active Range Of Motion – Knee Extension</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>Passive Range Of Motion – Ankle Dorsiflexion</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>Passive Range Of Motion – Ankle Plantar Flexion</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>Passive Range Of Motion – Knee Flexion</td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>Passive Range Of Motion – Knee Extension</td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>Strength – Quadriceps – 30-second chair rise</td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>Strength – Triceps Surae – Heel Rise Test</td>
<td></td>
</tr>
<tr>
<td>17</td>
<td>Limits of Stability – Endpoint Excursion</td>
<td></td>
</tr>
<tr>
<td>18</td>
<td>Limits of Stability – Maximum Excursion</td>
<td></td>
</tr>
<tr>
<td>19</td>
<td>Berg Balance Test</td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>Timed Get up and Go</td>
<td></td>
</tr>
<tr>
<td>21</td>
<td>SF-36</td>
<td></td>
</tr>
<tr>
<td>22</td>
<td>SF-36 Pain Scale</td>
<td></td>
</tr>
<tr>
<td>23</td>
<td>SF-36 Physical Activity Scale</td>
<td></td>
</tr>
<tr>
<td>24</td>
<td>LIMAT</td>
<td></td>
</tr>
</tbody>
</table>

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Research Enrollment Request

This document is designed to discuss with you a research study that the physical therapist, Kevin Kunkel, is doing at this facility. The purpose of the study is to evaluate the effectiveness of the treatment for lymphedema on daily functional activities. Your participation in this study would last about 2 - 6 weeks and would require up to 22 visits to our office. These visits are the approximate number of visits you would normally receive for your condition. The information that will be gathered as part of your treatment will be analyzed as part of the research. All of the tests or measures except two are part of your normal treatment. Two additional measures, one a balance test and two questionnaires will also be administered. The standing balance test will be safely administered as you will wear a harness attached to a sturdy frame above you to prevent a fall.

If you wish to hear more about the study, please sign below and the information will be forwarded to Kevin Kunkel who will discuss the consent process with you. If you chose to not participate, you will continue with your treatment and Kevin Kunkel will not discuss the research with you. Your treatment will not be affected if you chose to not participate in the study.

If you wish to hear more about the research Please check the “yes” statement and sign below. If you do not wish to hear more about the research do not check the “yes” statement but still sign below.

___ Yes, I wish to hear more about the research study

Subjects Name (Printed) Subjects Name (Signature)

Date
APPENDIX IX

Consent (Permission) to Participate in a Clinical Research Study

Title of Study: IDENTIFICATION AND IMPACT OF STANDARD TREATMENT PROTOCOLS ON THE IMPAIRMENTS AND FUNCTIONAL DEFICITS RELATED TO LOWER EXTREMITY LYMPHEDEMA
Eprost #: 20060955
Principal Investigator: Kathryn E. Roach, PhD, PT
Department: Physical Therapy
Phone Number: (305) 284-4535
Email Address: keroach@miami.edu
Study Contact Name: Kevin Kunkel MSPT, MLD-CDT
Study Contact Telephone Number: (561) 436 - 3273
Study Contact Email: k.kunkel@umiami.edu

READ THE FOLLOWING CAREFULLY

This consent form contains important information, so that you can decide if you wish to take part in this study. If you have any questions that remain unanswered, please ask the study investigator or one of his/her research study personnel before signing this form.

You are being asked to give permission for you to volunteer to participate in a research study. Before you give your consent (permission) for you to be part of this study, please read the following and ask as many questions as necessary to be sure that you understand what your participation will involve.

PURPOSE

You have been referred to The Flagler Institute for Rehabilitation for physical therapy for the treatment of swelling in your legs. The purpose of this research study is to identify physical problems such as loss of joint motion and strength and problems performing day to day activities associated with your condition which is known as lymphedema. Also, the study is designed to identify changes that may occur in your ability to perform day-to-day activities as a result of the treatment for the lymphedema.

NUMBER OF STUDY PARTICIPANTS

If you decide to be in this study, you will be one of approximately 60 people enrolled in this research study.

UNIVERSITY OF MIAMI HEALTH SYSTEM
Miami, FL 33136
(305) 243-4000

CLINICAL RESEARCH CONSENT FORM

NAME:

MRR:

AGE: DOB: / / 

PAGE 1 OF 7
DURATION OF STUDY

You will receive usual care for the treatment of lymphedema which typically requires 6 to 10 sessions over a two week period. You will then be tested to measure your balance abilities. The test involves simple tasks, such as keeping stable while standing to lifting a leg and performing movements with increased speed. This is called the Berg Balance Test and is part of standard treatment.

If the Berg Balance test indicates that you continue to have a balance problem, placing you at risk of falling, we will consult your doctor to recommend additional physical therapy to correct this balance problem. The additional physical therapy is part of usual care for patients with lymphedema who have persistent balance problems. If you receive additional physical therapy, the treatment is typically 2-3 times a week for four additional weeks. You will continue to be enrolled in the research protocol as long as you continue to receive physical therapy.

PROCEDURES

As part of the normal care for lymphedema, we will examine the severity of the swelling in your legs, the strength and flexibility of your legs, your ability to get up and down and walk and your ability to keep you balance while performing different activities. Also, as part of the normal care for lymphedema, you will be asked to complete a paper and pencil questionnaire that asks how the swelling in your legs affects your mobility and your quality of life. This initial examination will be performed by a lymphedema certified physical therapist.

If you agree to participate in this study we will use the information we collect about your clinical problem to conduct research about the effect leg swelling has on your ability to perform your activities of daily life. We will also have you complete one additional questionnaire and perform an additional balance test that are not part of usual care for lymphedema. The questionnaire consists of 46 items dealing with difficulty moving around and walking. It takes about 15 minutes to complete. The balance test will involve standing on a platform that detects how you are able to shift your weight forward and backward. The platform does not move but can detect your weight shifting and record it. The movement tested is like reaching over a counter or leaning back to reach up to a shelf. You will wear a harness that is attached to a frame directly above where you will be standing. This harness is designed to prevent a fall during the test. This test takes about 10 minutes to complete.

The testing procedures will take place at three separate times. The first testing time will be upon the first day of treatment. The second testing time will be 2 weeks after the first day of treatment. The third time will be six weeks after the first day of treatment.
Some participants who, based on the results of our testing, require additional physical therapy for problems associated with the lymphedema will continue for a minimum of 4 additional weeks of therapy. This therapy will involve activities to improve their balance and walking.

The time involved, other than your regular treatment, will be approximately 60 minutes for each testing session. All tests will take place prior to the time of your regularly scheduled treatment sessions. The only time that may require you to return for testing outside of your regular care would be if you do not receive additional physical therapy beyond the initial 2 week period. In such case; you will be asked to come into the office 4 weeks after your last treatment session for lymphedema to undergo the standard clinical tests plus the two additional research tests.

Your usual care involving complex decongestive physiotherapy (CDT) will be performed by a Flagler Institute for Rehabilitation staff physical therapist certified in the treatment of lymphedema. If you require additional usual care treatment for a balance problem, this treatment will be performed by a Flagler Institute for Rehabilitation licensed physical therapist.

Overall Design

All testing will be performed on the premises of The Flagler Institute for Rehabilitation. Procedures will be approved by the University of Miami Research Ethics Board or similar entity contracted by the University. You will be under the care of your referring physician during the treatment and research protocol. All testing procedures will be discussed with the subjects and their written approval and informed consent obtained. In addition, you will be asked to complete a questionnaire regarding your condition. If you feel uncomfortable answering some of the questions in the questionnaire, do not answer them.

STANDARD OF CARE VERSUS RESEARCH

If you chose to be part of this research protocol, the treatment you receive for the lymphedema will not be changed from standard treatment of lymphedema. The results of the tests taken as part of the standard treatment will be analyzed as part of the research. The results will be gathered prospectively from the medical record. The additional test, Limits of Stability, is not a standard test for lymphedema but is often used in conditions in which a person's balance is a problem. The questionnaire, Limitation in Mobility Activities Test (LIMAT), is not part of standard care but is used to identify functional problems.

RISKS AND DISCOMFORTS
The usual care for lymphedema involves skin care, massage, compressive wraps, and exercise. The usual care for balance problems includes activities involving exercise, walking, and balance activities. There are minimal risks associated with the research related activities.
The stability test involves a minimal risk of falls. To prevent falls, the testing equipment uses a safety harness. The harness is attached to a frame above the platform securing you while you are tested.

If you choose to withdraw from the study at any time, you will continue to receive your prescribed treatment at the Institute.

If you have any concerns or questions about your participation, you can discuss them with the co-investigator, Kevin Kunkel, either in person or at the numbers listed above. If you have any discomfort or injury from participation, please also contact him immediately.

In addition, there may be uncommon or previously unknown risks that might occur. You should report any problems to the research staff.

You have the right to ask any questions about the potential and/or known hazards of this study at any time. You will be asked to tell the study investigator or your doctor about any possible side effects you might have at any time during the study.

**BENEFITS**

Research is designed to benefit society by gaining new knowledge. You will not benefit personally from being in this research study.

**ALTERNATIVES**

You have the alternative not to participate in this study. If you do not participate in the study, you will receive the standard physical therapy interventions previously described without the balance test on the standing platform and without having to answer the 46-items questionnaire about difficulty walking and moving around.

**COSTS**

You or your insurance company will be responsible for medical costs of treatment for your condition. The time needed for testing for this study is not billed to your insurance company or to you. If you have insurance, your insurance company may or may not pay for the costs of normal treatment. If you do not have insurance, or if your insurance company refuses to pay for your normal treatment for the lymphedema, you will be expected to pay.
INCENTIVES/PAYMENTS TO PARTICIPANTS

You will not be paid for taking part in this study.

COMPENSATION FOR STUDY-RELATED INJURY

Although risks are unlikely, if injury should occur, treatment will in most cases be available. If you have insurance, your insurance company may or may not pay for these costs. If you do not have insurance, or if your insurance company refuses to pay, you will be expected to pay. Funds to compensate for pain, expenses, lost wages and other damages caused by injury are not routinely available.

VOLUNTARY PARTICIPATION / WITHDRAWAL FROM STUDY

Your participation in this study is voluntary. You may refuse to participate, or withdraw from the study at any time, without penalty or loss of benefits to which you are otherwise entitled. This will not affect the medical care you receive from the study investigator. You must tell the study investigator if you wish to stop taking part in the study. Your participation in this study may be discontinued, without your consent, at any time by the study investigator, if he/she believes that participation in the study is no longer in your best interest. The Institutional Review Board (IRB), regulatory authorities, or the sponsor may also discontinue your participation in the study.

Principal Investigator
Kathryn E. Roach, PhD, PT
Associate Professor, Associate Director of Research
University of Miami
Miller School of Medicine
Department of Physical Therapy
Day Telephone: (305) 284-4535

Co-Investigator
Kevin Kunkel, MSPT
Doctoral Student
University of Miami
Miller School of Medicine
Department of Physical Therapy
Day Telephone: (561) 436-3273

If you cancel your permission after you have started in the study, the study staff and the study investigator will stop collecting your health information. Although they will stop collecting new information about you, they may need to use the information they have already collected to evaluate the study results. If you start the study and then you cancel your permission, you will not be able to continue to participate in the study. This is because the study staff and/or the Study investigator would not be able to collect the information needed to evaluate the study intervention.

UNIVERSITY OF MIAMI HEALTH SYSTEM
Miami, FL 33136
(305) 243-4000

CLINICAL RESEARCH CONSENT FORM

NAME:

MRN:

AGE:________ DOB:____/____/____

PAGE 5 OF 7
CONFIDENTIALITY

By signing this consent, you authorize the Investigator(s) and his/her/their staff to access your medical records and associated information as may be necessary for purposes of this study. Your records and results will not be identified as pertaining to you in any publication without your expressed permission. The Investigator and his/her collaborators, staff will consider your records confidential to the extent permitted by law. The Food and Drug Administration (FDA) and Department of Health and Human Services (DHHS) may review these research records. Your records may also be reviewed for audit purposes by authorized University of Miami employees or other agents who will be bound by the same provisions of confidentiality.

Your privacy and confidentiality will be protected under the Health Insurance Portability and Accountability Act (HIPAA). Information regarding your status as a patient is stored in a password protected database exclusively available to your treating facility. Information regarding your participation in the research study will be linked by an ID number which is electronically stored in a password protected database and exclusively available to the investigators only. Any written documentation will be electronically scanned into the database for the research and subsequently be destroyed (shredded) once data backup is verified.

The study site personnel may use your information to notify you of appointments, send you appointment reminders, or schedule additional appointments.

WHOM TO CONTACT

If at any time you have any questions about the study, you may contact Kevin Kunkel or Kathryn E. Roach, PhD, PT at (305) 284-4535. In case of study-related injury, please contact Kevin Kunkel at (561) 436 – 3273

If you have any questions relating to your rights as a research subject, please contact the University of Miami's HUMAN SUBJECTS RESEARCH OFFICE (HSRO), at 305-243-3195.
AGREEMENT OF DECISION TO PARTICIPATE
You will receive a copy of this signed informed consent form.

I have read this consent, which is printed in English (a language which you read and understand). This study has been explained to my satisfaction and all of my questions relating to the study procedures, risks and discomforts, and side effects have been answered. If I have any further questions regarding this study, or in the event of a study-related injury, I should contact the appropriate person named above. Based on this information, I voluntarily agree to give permission (consent) for me to take part in this study.

_________________________________________  ___________________________
Signature of Participant                      Date

_________________________________________  ___________________________
Printed Name of Participant                   Date

_________________________________________  ___________________________
Signature of Person Obtaining Consent         Date

_________________________________________  ___________________________
Printed Name of Person Obtaining Consent      Date

UNIVERSITY OF MIAMI HEALTH SYSTEM
Miami, FL 33136
(305) 243-4000

CLINICAL RESEARCH CONSENT FORM

NAME: ________________________________

MRN: ________________________________

AGE: ______ DOB: ______/____/____