Persistence of Lymphedema Reduction After Noninvasive Complex Lymphedema Therapy

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We treated 119 consecutive patients with lymphedema with complex lymphedema therapy (CLT). Lymphedema reductions after CLT averaged 62.6% in the 56 patients with one affected arm and 68.6% in the 38 patients with one affected leg. In the 23 patients with bilateral affected lower limbs, lymphedema volume decreased by 3,681 cm^3 in the right leg and by 3,433 cm^3 in the left leg. Due to its small number, the group with bilateral affected arms was not analyzed. After 36 months' follow-up, the average reduction increased to 63.8% in individuals with one affected arm and remained at 62.7% in those with one affected leg. For statistical analysis, the amount of reduction after CLT in the group with bilateral affected legs was considered to be 100%. During follow-up, the right leg was maintained at 99.59% of the initial reduction and the left leg improved to 120%. Patients who were compliant showed significant increases in lymphedema reduction, whereas noncompliant patients lost part of their initial reduction.

Untreated lymphedema is most often a progressive, chronic, incurable disease.[1] Macrophages become dysfunctional in the low oxygen tension of the lymphedema fluid. This results in progressive fibrosis and secondary infections. Ultimately, lymphedema produces not only physical sequelae, such as swelling, pain, decreased motor function, paresthesias, and loss of mobility, but also psychological problems, such as depressive disorder due to the unsightliness of the lymphedema and the associated medical problems. The physical stigma causes many individuals to withdraw from family and social functions, as well as the work environment.

A consensus document on the diagnosis and treatment of peripheral lymphedema, published in 1995 by the International Society of Lymphology Executive Committee,[2] recommended comprehensive lymphedema therapy (CLT) as the initial treatment for lymphedema. This conservative, noninvasive, safe, nonoperative treatment has two phases. The first phase consists of skin care, manual lymphedema treatment, exercises, and compression with multilayered bandages. Phase 2 focuses on conserving and optimizing the reductions obtained in phase 1; this is done by means of compression with low-stretch elastic stockings or sleeves, skin care, special remedial exercises, and repeated manual lymphedema treatment as necessary.

Complex lymphedema therapy, as it is practiced today, was principally introduced, applied, and refined in Germany by the Foldis in the 1980s.[3,4] The technique, also known as combined physiotherapy,[5] was modified and supplemented with specialized physical therapy exercises by the Casley-Smiths in Australia; they called this modified techique complex physical therapy (CPT).[6]

The Foldis have treated 2,500 patients annually with CLT.[5] Reductions averaged 50% after the completion of the course of therapy, and over 50% of patients maintained their reductions during phase 2.[3,7] The Casley-Smiths have reported reductions of over 60% in 618 lymphedematous limbs.[8]

Table 1

Demographic and Disease Characteristics of Study Subjects[a]

Patients With One Affected Arm (N = 56)	
Age (years)	
Median	50 years
Interquartile range	46-70 years
Gender	
Female	54
Male	2
Type of lymphedema	
Primary	3
Secondary	53
Lymphedema grade[b]	
Grade 1	12
Grade 2	44
Arm affected	
Right	34
Left	22
Mean (± SD) duration of lymphedema (years)	3.4 ± 1.1 years
Patients With One Affected Leg (N = 38)	
Age (years)	
Median	44 years
Interquartile range	23-57 years
Gender	
Female	24
Male	14
Type of lymphedema	
Primary	21
Secondary	16
Lymphedema grade[b]	
Grade 1	2
Grade 2	30
Grade 3	6
Leg affected	
Right	18
Left	20
Mean (± SD) duration of lymphedema (years)	9.7 ± 2.2 years
Patients With Two Affected Legs (N = 23)	
Age (years)	
Median	49 years
Interquartile range	29-66 years
Gender	
Female	16
Male	7
Type of lymphedema	
Primary	18
Secondary	6
Lymphedema grade[b]	
Grade 1	3
Grade 2	17
Grade 3	4
Mean (± SD) duration of lymphedema (years)	10.4 ± 2.3 years

SD = Standard deviation

[a]The two patients with bilateral arm involvement are not included in the analysis due to the small size of this group.

[b]Grade 1 = pitting edema and reversibility upon elevation; grade 2 = nonpitting edema, fibrosis, and irreversibility; grade 3 = elephantiasis (according to criteria of International Society of Lymphology[11])

Our group described the initial use of CLT in 38 consecutive patients in the United States with follow-up of 1 year.[9,10] The initial 80% reduction in lymphedema observed following the course of CLT increased to 86% at the end of 1 year.

The current study presents 3-year follow-up data on 119 consecutive patients treated with one course of CLT at the Lymphedema Therapy facility in Woodbury, New York. The relationship of compliance to maintenance and optimization of lymphedema reduction is also analyzed.

PATIENTS AND METHODS

Study Population

This study includes all 119 consecutive patients with lymphedema treated with CLT at the Lymphedema Therapy facility in Woodbury, New York from 1992 to 1995. Of the 119 patients, 56 had a single affected arm, 2 patients had both arms affected, 38 patients had one affected leg, and 23 patients had both legs affected.

The demographic and disease characteristics of the patients with one afflicted arm, one involved leg, and two affected legs are summarized in Table 1. Because of the small number of patients with bilateral arm involvement, this group was not included in the analysis.

Lymphedema was graded according to the criteria of the International Society of Lymphology.[11] Grade 1 denotes pitting edema and reversibility upon elevation; grade 2, nonpitting edema, fibrosis, and irreversibility; and grade 3, elephantiasis.

Clinical Analysis

To determine the volume of lymphedema in each limb, circumferences were measured at 10-cm intervals with a flexible tape. The same physical therapist measured the patient's limb at each visit. Volume was calculated for each 10-cm segment by utilizing the formula for a truncated cone:

$$\text{Volume} = H\,(Ct^2 + Ct \times Cb + Cb^2)\,/12$$

Where H = height, Ct = circumference of the top of the cone, and Cb = circumference of the base of the cone. The total volume of lymphedema was calculated by adding the

volume for each 10-cm increment.

The percentage change in edema was calculated according to the following formula:

$$\text{Percentage change in edema} = (Vf - Vi)/(Vi - Vn) \times 100$$

Where Vi = the initial volume of the lymphedematous limb, Vf = the final volume of the lymphedematous limb, and Vn = normal limb volume.

Treatment

Patients received CLT, which consists of the following four steps:

1. The skin is meticulously cleaned, lubricated, and debrided. Also, antimicrobial therapy is administered as needed, using standard techniques.

2. Gentle manual pressure is applied to each of the dermal lymphotomes to direct lymph flow to the nonobstructed lymph nodal areas.[6] A firm, sustained manual pressure is applied to the watershed areas of adjacent lymphotomes, with particular emphasis on the lymphedematous region. A watershed is the area drained by a single lymphotome. This is carried out in a predetermined manner aimed at redirecting lymph flow by opening and dilating the collateral vessels across watersheds from the edematous to the normal lymphotomes. The pattern of manual pressure is individualized for each patient. Detailed descriptions of the manual pressure techniques, lymphotome clearances, and pathways of lymph drainage can be found in reference 6.

3. Using proper techniques, bandages are applied to the affected extremity to increase tissue pressure. First, the afflicted limb is covered with stockinette topped with cotton batting. Chips of latex in gauze bags are applied over fibrotic areas. Then, a low-stretch compressive bandage (Comprilan; Biersdorf AG, Hamburg, Germany) is wrapped in multiple layers over the affected extremity. All bandages are worn 24 hours daily throughout the course of therapy.

4. After the compressive bandages have been applied, individualized exercises are performed to enhance lymphatic flow from peripheral to central drainage compartments. These exercises are aimed at augmenting muscular contraction, enhancing joint mobility,

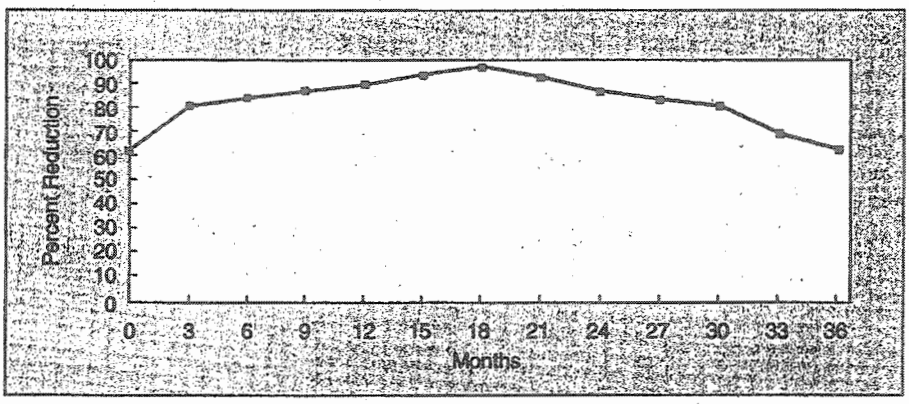


Figure 1: Persistence of lymphedema reduction in patients with one lymphedematous arm

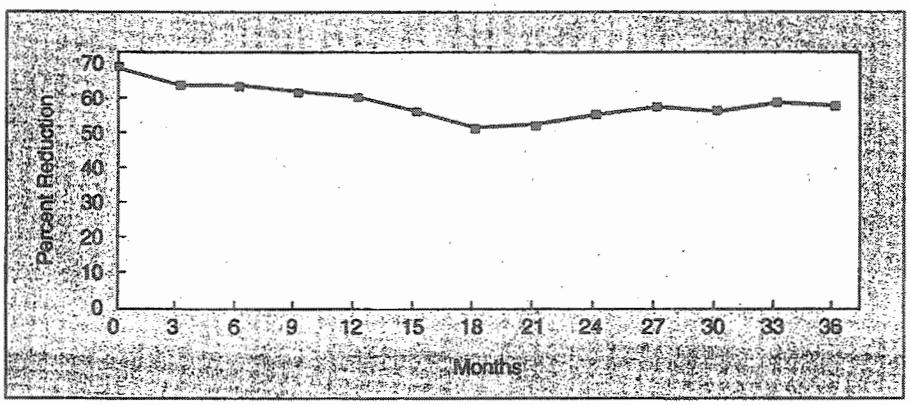


Figure 2: Persistence of lymphedema reduction in patients with one lymphedematous leg

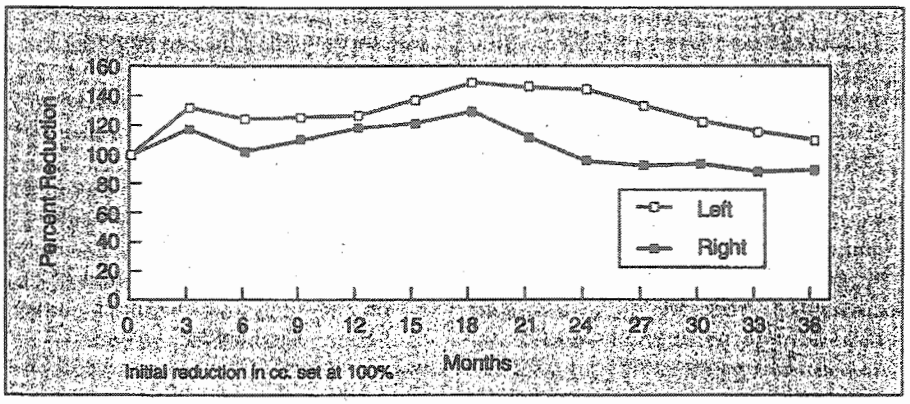


Figure 3: Persistence of lymphedema reduction in patients with two lymphedematous legs

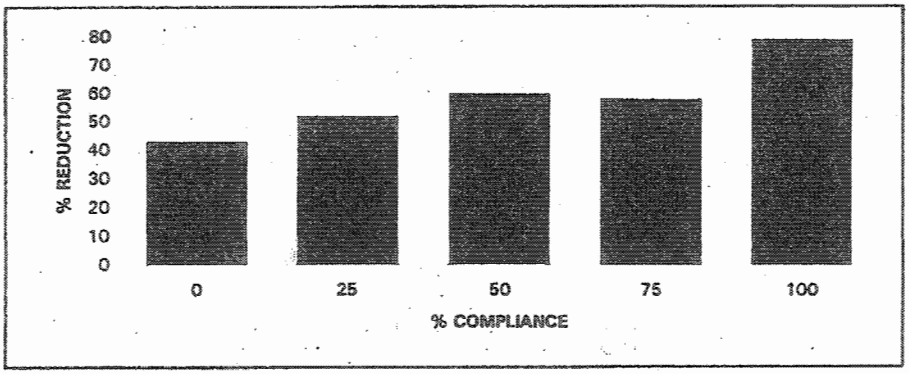
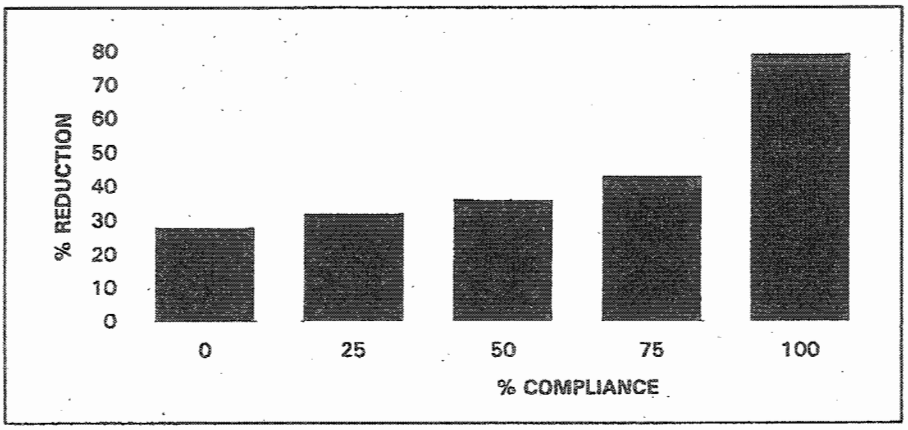


Figure 4: Effect of Compliance—Reduction in lymphedema in patients with one lymphedematous arm (A—above) and patients with one lymphedematous leg (B—below), according to the degree of compliance



strengthening the limb, and reducing the muscle atrophy that frequently occurs secondary to lymphedema.

The treatment regimen requires approximately 2 to 4 hours each day, and is administered over a 30-day period. All of the procedures are performed by a licensed physical therapist who has undergone specific training at our center.

Upon completion of CLT, patients are fitted with compression garments, ranging in pressure from 30 to 60 mm Hg. The maintenance program following CLT consists of 24-hour compression garment wear and a patient-specific physical therapy exercise program to be performed twice daily at home for 15 to 20 minutes.

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Statistical Methods

All available patients were included in the study. Separate analyses were performed for patients with one affected arm, those with one affected leg, and those with bilateral leg involvement. As mentioned above, since usable data were available for only two patients with two affected arms, this group was not analyzed.

A mixed models repeated measures analysis of covariance (RMANCOVA) was used to analyze the data for each group separately. The within-groups factor was the time since the initial course of therapy. The between-groups factor was the degree of compliance (compliance with exercises and use of compression garments averaged together).

For the purpose of this analysis, compliance at the initial visit was set at 100%. All assumptions were examined for each model and appeared to have been met. None of the demographic and disease characteristics (age, gender, type of lymphedema, lymphedema grade, and duration of lymphedema) differed significantly between the compliant and noncompliant patients.

In our study, compliance was evaluated by the percentage of time the patients wore a compression garment and their adherence to special physical therapy exercises. Compliance was analyzed at each follow-up visit. No additional courses of CLT were administered to the study group.

In the 22 patients with bilateral leg disease, the initial reduction in lymphedema was calculated as the total volume lost during CLT. The patients with bilateral lower limb disease did not have a normal leg to use for comparison in the calculation of percentage change in edema. Therefore, for the purpose of statistical analysis of this group, the total amount of volume lost (in cubic centimeters) at the initial visit was set at 100%. The subsequent percentage reductions were based on this initial setting.

After the initial course of CLT and lymphedema reduction, 9 of the 56 patients with unilateral arm lymphedema were lost to follow-up, 2 patients expired from their primary disease, 3 did not return for follow-up, and 4 patients moved out of the area. Among the 39 patients with unilateral lower limb lymphedema, 2 died, 1 was lost to follow-up, and 5 moved. Of the 22 with bilateral lower limb lymphedema, 2 expired, 2 were lost to follow-up, and 1 left the area.

RESULTS

All 117 patients who received a complete course of CLT for their disease in one arm, one lower limb, or both lower limbs were analyzed separately. Among the 56 patients with lymphedema of one upper extremity, lymphedema decreased by an average of 62.6% following CLT. Lymphedema continued to decline during follow-up, and the reduction reached a maximum of 97.3% at 18 months following treatment. At 36 months, the reduction averaged 63.8%, which was more than the initial reduction with CLT (Figure 1).

Among the 39 patients with unilateral lower extremity lymphedema, CLT reduced lymphedema by an average of 68.6%. Over the 36-month follow-up period, the average reduction decreased to 62.7%, which did not represent a

Figure 6: Right Arm, Same Patient—The lymphedematous right arm of patient #1 before (Figure 6A—left) and after (Figure 6B—middle) CLT and also during follow-up (Figure 6C—right)

Figure 6A

Figure 6B

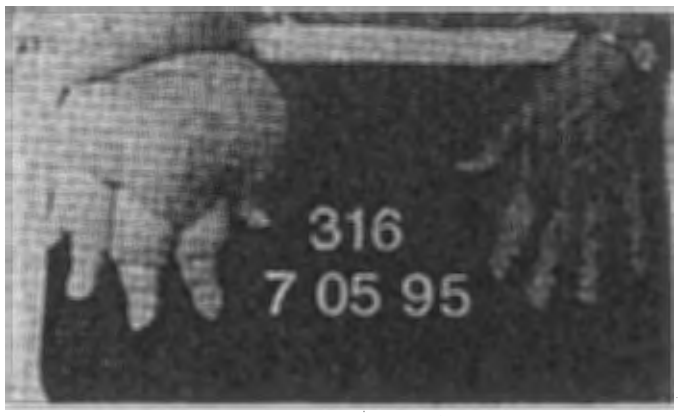

Figure 5A

Figure 5: Secondary Upper Extremity Lymphedema—The lymphedematous right hand of patient #1 before (Figure 5A—top) and after (Figure 5B—bottom left) CLT and during follow-up (Figure 5C—bottom right).

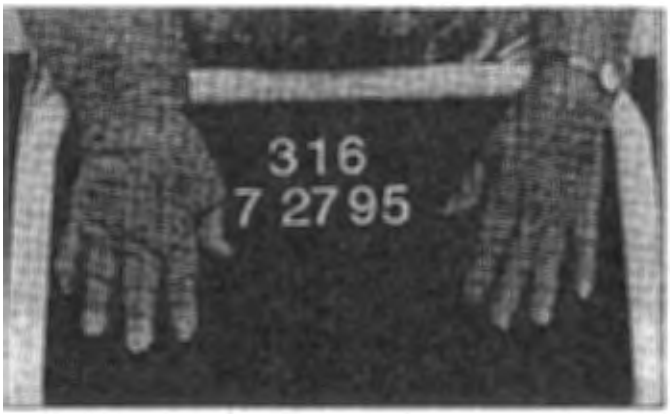

Figure 5B

Figure 5C

significant change from the initial reduction (Figure 2).

In the 22 patients with bilateral lower limb lymphedema, the average reduction in leg volume was 3,681 cm^3 in the right leg and 3,432 cm^3 in the left leg. As mentioned above, in order to calculate each individual's maintenance of reduction over the follow-up period, the initial reduction value was set at 100%. During follow-up, the reductions reached a high of 134% in the right leg and 154% in the left leg at 18 months. At the end of 36 months, the reduction was maintained at 100% in the right leg and increased to 120% in the left leg. These calculations included all patients regardless of compliance (Figure 3).

Compliance

Compliance was analyzed in patients with one affected leg and those with one affected arm. As mentioned, the group with one affected arm had an average lymphedema reduction of 63% following CLT. Individuals who were noncompliant maintained a 43% subsequent reduction, those with 25% compliance had a 53% reduction, those with 50% compliance had a 60% reduction, and those with 75% compliance had a 58% reduction. However, in patients who were 100% compliant, lymphedema reduction increased to 79% during follow-up (Figure 4A). The difference between the 100% compliant group and the other groups was statistically significant ($P < .001$).

In the individuals who had one lymphedematous leg, the average decrease in lymphedema after CLT was 69%. In patients who were 0%, 25%, 50%, 75%, and 100% compliant, lymphedema reductions during follow-up were 28%, 32%, 36%, 42%, and 79%, respectively (Figure 4B). The difference between the 100% compliant group and the other groups was statistically significant ($P < .001$).

CASE REPORTS

To demonstrate the benefits of CLT, three patients' courses will be illustrated.

Patient #1: A Woman With Secondary Upper Extremity Elephantiasis

This 84-year old woman developed severe grade 3 elephantiac lymphedema of the right upper extremity and hand in 1969 secondary to mastectomy plus axillary node dissection and radiation therapy. The patient had a history of multiple episodes of cellulitis. Prior to treatment, the patient's right upper extremity and hand were completely

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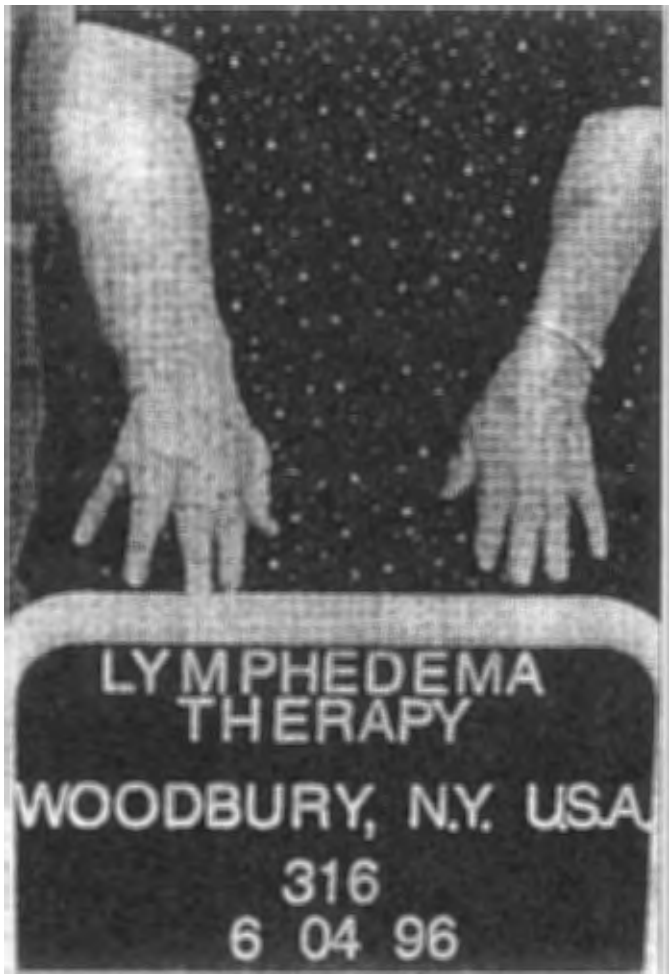

Figure 6C

nonfunctional, and she required assistance with all activities of daily living.

The patient received four weeks of CLT and achieved a 77% reduction in the edema of her right upper extremity. On her most recent follow-up visit, the lymphedema had improved to a 92% reduction. Her right hand is now functional, and she is much more independent in dressing and other activities of daily living. Figures 5 and 6 show this patient's hand and arm, respectively, before and after CLT and during follow-up.

Patient #2: A Man With Primary Lower Extremity Lymphedema

This 20-year-old male has had primary lymphedema of the left lower extremity since age 7. At age 12, he developed scrotal and penile edema that rapidly progressed with chylous reflux and leakage from the scrotum, buttocks, and left thigh. The patient had elephantiac skin, several open areas on the left thigh and buttocks, and numerous papillomas. Over the ensuing 8 years, he required hospitalization monthly in the ICU for cellulitis-septic shock. The patient has had several debulking surgeries on the lower extremity, scrotum, and penis, and sclerosing treatment of the abdominal lymphatics to reduce chylous reflux.

In November 1993, when the patient developed septic shock again, he received 14 CLT treatments. After a 2-week hospitalization, he received 13 additional days of CLT. After the 27 treatments, all open areas healed and papillomas, skin flaps, and bulges were greatly reduced in size and depth.

The patient was infection-free for 1 year, at which time he had an episode of cellulitis. The patient was treated in the hospital for 8 days with skin debridement, trunk massage, and compressive bandaging. With CLT, he lost 82 of the 89.1 cm^3 of leg volume that developed during the episode of acute cellulitis. After this course of therapy, he bandaged himself at night and wore a Custom Jobst one-legged panty (60-mm Hg pressure) during the day.

The patient was well for 18 months until April 1996, when he was hospitalized for 7 days for cellulitis of the left hip. He was able to wear his compression garments after a few days in the hospital, and as a result, the left lower extremity remained stable. No residual increase in lymphedema oc-

Figure 7: Primary Lower Extremity Lymphedema—The lymphedematous left leg of patient #2 before (Figure 7A—left) and after (Figure 7B—middle) CLT and during follow-up (Figure 7C—right)

Figure 7A

Figure 7B

Figure 7C

curred after the hospitalization.

The patient continues with his lymphedema exercises twice daily, and is once again doing very well, attending college and working. The two episodes of cellulitis in the 3 years since his CLT treatments were infrequent compared to his monthly hospitalizations for cellulitis prior to this form of therapy. Figure 7 shows the patient's leg before and after CLT and during follow-up.

Patient #3: A Woman With Secondary Upper Extremity Lymphedema

A 70-year-old female had a right mastectomy with axillary node dissection followed by radiation therapy in 1984. Minimal edema occurred immediately after the surgery. In 1987, a moderate increase in the lymphedema caused arm discomfort.

The patient was treated for several months with a sequential compression pump. The edema progressed during therapy, and the patient had her first attack of cellulitis in the right arm. Subsequently, episodes of cellulitis recurred approximately every 2 months.

The patient received 4 weeks of CLT in May 1993 and achieved an 82% reduction in the lymphedema of her right upper extremity. Initially, she was fitted with a compression sleeve and glove, and she progressed to an 85% reduction. The patient no longer requires the use of the compression glove and is wearing the compression sleeve from the wrist to axilla only. She has had no further episodes of cellulitis since CLT. Figure 8 shows the patient's arm before and after CLT and during follow-up.

DISCUSSION

Complex lymphedema therapy has been utilized throughout the world. The basic principle of this therapy is to increase lymphatic drainage by opening collateral circulation from the obstructed lymphotomes into normally functioning lymphotomes.

The Foldis have used CLT to treat over 2,500 patients a year in Germany, and average a 55% reduction in lymphedema in their initial phase of treatment.[5] Their treatment program also has a second phase, which consists of periodic combined physiotherapy for the patient, compressive bandaging, gar-

Figure 8: Secondary Upper Extremity Lymphedema—The lymphedematous right arm of patient #3 before (Figure 8A—left) and after (Figure 8B—middle) CLT and during follow-up (Figure 8C—right)

Figure 8A

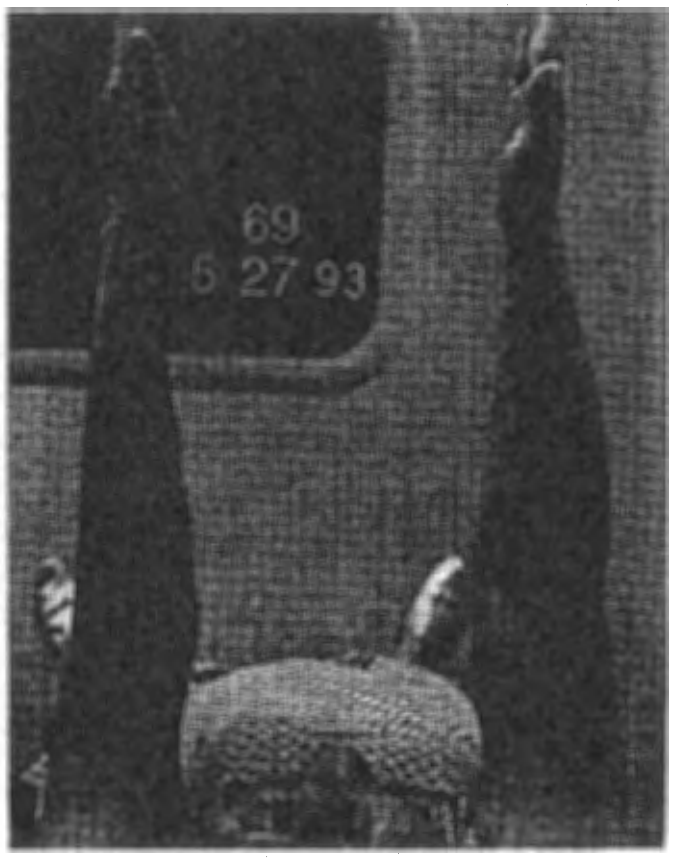

Figure 8B

ments, and physical therapy exercises.

It has been difficult for the Foldis to obtain long-term follow-up data on their patients due to the dispersal of many of the patients, as well as German medical regulations prohibiting visits for long-term follow-up. In a 3-year follow-up program, 50% of their patients maintained the initial reduction in lymphedema.[12]

The Casley-Smiths have reported on 618 lymphedematous limbs treated with CPT by multiple therapists throughout Australia. Their results are similar to those obtained by the Foldis and those achieved in our study. The Casley-Smiths found that maintenance of lymphedema reductions, reported for 219 limbs, was directly related to compliance.[8]

Our previous study showed reductions of 73% in arm lymphedema and 88% in leg lymphedema. The reductions of 63% in arm lymphedema and 69% in leg lymphedema seen in the current study, although slightly lower from these earlier results, are not significantly different.

Although double-blind studies are one of the mainstays of scientific investigation, Rothman and Michels have asserted that unless there is persuasive ethical justification, any study proposing the use of placebo in place of effective treatment should be disapproved and ignored.[13] Both the Casley-Smiths and Foldis have stated that a meaningful blinded study on massage, exercises, and compression not only is difficult to perform with a control group but also is unethical since it is well recognized that CPT is highly effective and devoid of side effects.[5,8] Therefore, in this study, we report on all the consecutive patients who received CLT at our facility. The significant reductions in all types and grades of lymphedema achieved with CLT were well maintained.

Phase 2 is considered an essential part of lymphedema therapy. This phase involves the utilization of compressive bandages or garments, special physical therapy exercises, and/or maintenance retreatment. Following CLT, the maintenance program for our patients has consisted of the use of compressive garments and performance of special physical therapy exercises, without subsequent courses of CLT.

Impact of Compliance

Our analysis of compliance showed that the more compliant patients had a significantly increased rate of mainte-

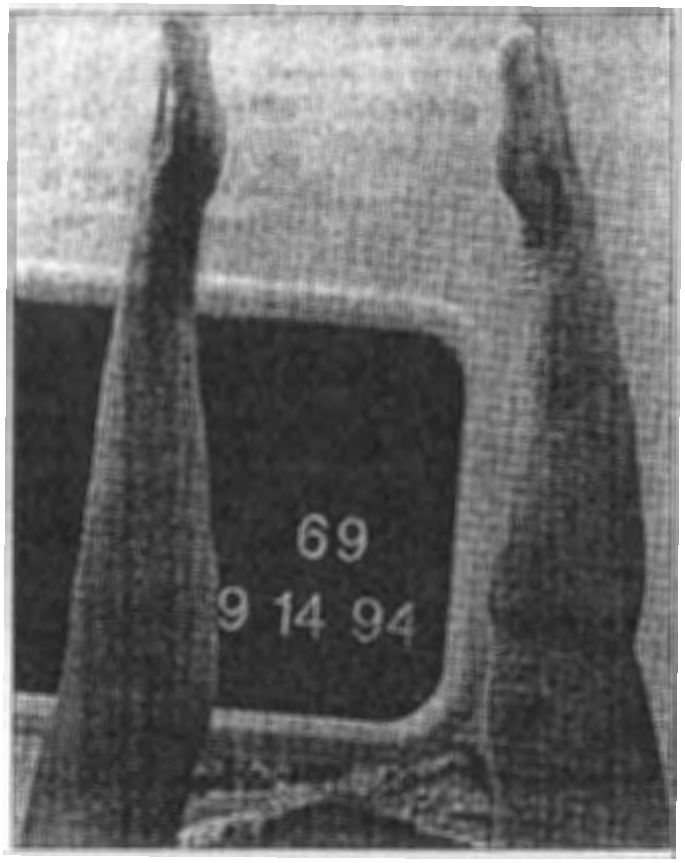

Figure 8C

nance of and further decreases in lymphedema reduction. This was particularly evident in the patients with one affected lower limb; in this group, patients who were totally noncompliant had a lymphedema reduction of only 28% after 3 years. In those who were fully compliant, lymphedema reduction increased from an average of 68% to 79% after 3 years.

Evaluation of patients with 25%, 50%, and 75% compliance showed increased reductions with increasing compliance. When compliance was analyzed in patients with one affected arm, similar benefits of greater compliance were seen in all categories.

Drawbacks of CLT

There are several drawbacks of CLT. First, the treatment is labor intensive.[14] Also, CLT requires specially trained physicians and therapists.[5] As Foldi has stated, "It would be easier and cheaper to prescribe drugs than to use this labor intensive manual lymph treatment and bandaging. Unfortunately, no substitute has been found for combined physiotherapy."[5]

There are few well-trained lymphedema physical therapists in the US. Unfortunately, without any certification for properly trained physical therapists in lymphedema, many poorly trained therapists perform treatments with poor results.

SUMMARY

Complex lymphedema therapy produces an initial rapid decrease in all stages of lymphedema. The lymphedema reductions achieved with this safe, noninvasive treatment can be maintained and may even improve over time.

Patient compliance with the use of compressive garments and performance special exercises has a direct bearing on the maintenance of and increase in initial reductions. Not only does the long-term reduction in lymphedema improve patients' medical, physical, and economic quality of life, but also the increased comfort, appearance, and function are potent psychological stabilizers.

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