



LYMPHA PRESS®
CLINICAL STUDIES



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WHAT CLINICIANS ARE SAYING ABOUT LYMPHA PRESS®

“We have actually seen in real time the way the Lympa Press device can activate the lymphatics to enhance lymphatic flow—using near-infrared imaging technology. This validates what we understand clinically, that patients improve when they use the Lympa Press PCD.”

CAROLINE E. FIFE, MD, Chief Medical Officer, Intellicure, Inc.

REAL-TIME IMAGING SHOWS LYMPHA PRESS® INCREASES LYMPH VESSEL FUNCTION IN LYMPHEDEMA PATIENTS

Movement of lymph during pneumatic compression treatment in lymphedema subjects visualized by near-infrared fluorescence lymphatic imaging.

PUBLICATION: M.B. Aldrich, J.C. Rasmussen, A. Ben Noon, J.R. Morrow, K. Ashforth, B. Crews, C.E. Fife. World Congress of Lymphology, San Francisco CA, September 2015. Abstract.

STUDY SIZE: 4 patients

The effect of Lympa Press® in the affected legs of patients with lymphedema was visualized using near infrared fluorescence imaging, clear Lympa Press leg sleeves, and Lympa Pants® with clear windows. Lympa Press treatment increased lymphatic function during and after single PCT sessions in all the lymphedema affected limbs, as well as in the unaffected limbs. The pulsation of lymphatic vessels was increased significantly during and after treatment from baseline. In all patients, distal to proximal transport was observed. In one patient, pulsation of the vessels was observed in synchronization with the Lympa Press inflation/deflation cycle, demonstrating the direct effect of Lympa Press treatment on the transport activity of the lymphatic vessels. Measurements taken before and after a single one-hour treatment session showed significant reduction in swelling of the affected extremity in all patients, further demonstrating that treatment increased lymph flow and decongested the affected areas.

CONCLUSION: Near-infrared fluorescence lymphatic imaging, together with clear Lympa Press garments, proved that Lympa Press® significantly increased lymphatic function and transport in the affected extremities of lymphedema patients, both during and immediately after treatment.

This groundbreaking study is the first to demonstrate the direct effect of pneumatic compression on lymphatic function in lymphedema-affected extremities, and showed how Lympa Press® stimulated lymph vessel uptake and transport in “real time” during a treatment session.

LYMPHA PRESS® COMPARED WITH IN-CLINIC MANUAL LYMPH DRAINAGE

A randomized study comparing manual lymph drainage with sequential pneumatic compression for treatment of postoperative arm lymphedema.

PUBLICATION: K. Johansson, E. Lie, C. Ekdahl, J. Lindfelt. Department of Physical Therapy and Department of Surgery, University Hospital, Lund, Sweden., (1998) *Lymphology*, 31, 56-64.

STUDY SIZE: 28 patients

Manual lymph drainage (MLD) was compared with Lympha Press® for treatment of unilateral arm lymphedema in 28 women previously treated for breast cancer. Following two weeks of therapy with a standard compression sleeve with maintenance of steady arm volume, patients were randomly assigned to either of two treatment regimens (MLD performed according to Vodder technique for 45 min./day, and Lympha Press® with a pressure of 40-60 mmHg for two hours/day). Both treatments were carried out for two weeks.

RESULTS: MLD and Lympha Press® each significantly decreased arm volume but no significant difference was detected between the two treatment methods.

This randomized trial compared Lympha Press® to MLD performed in-clinic. Lympha Press® and MLD were equally effective at reducing swelling. (Study funded by research grants from the Cancer Foundation of Sweden).

LYMPHA PRESS® COMBINED WITH IN-CLINIC MANUAL LYMPH DRAINAGE

Severe lymphedema of the arm as a potential cause of shoulder trauma.

PUBLICATION: R. Avrahami, E. Gabbay, B. Bsharah, M. Haddad, A. Koren, J. Dahn, A. Zelikovski. (2004) *Lymphology*, 37, 202-205.

STUDY SIZE: 10 patients

This study assessed the role of lymphatic physical therapy in reducing disabling shoulder pain in patients with lymphedema of the shoulder. Ten women with arm lymphedema after surgery for breast cancer were examined. All had shoulder pain. Five patients had a tear in the supraspinatus muscle and five had chronic bursitis. Treatment consisted of manual lymph drainage and pneumatic compression with Lympha Press®.

RESULTS: The combined treatment reduced arm volume by an average of 170 ml, with improvement of arm mobility and a drastic reduction in shoulder pain. Lymphedema of the arm can cause severe shoulder trauma, pain and disability. Proper treatment can reduce these effects. Patients should be referred for early treatment and follow-up to avoid permanent damage to the shoulder muscles.

Patients with severe lymphedema and shoulder pain were treated with Lympha Press® and in-clinic MLD. Treatment decreased arm volume by an average of 170 ml, improved arm mobility and dramatically reduced pain.

LYMPHA PRESS® COMBINED WITH IN-CLINIC MANUAL LYMPH DRAINAGE, BANDAGING, AND EXERCISE

Treatment of monstrous elephantiasis.

PUBLICATION: F-J Schingale, (1999) *Lymphlogie in Forschung und Praxis*, Special edition.

STUDY SIZE: Case report

Inpatient treatment of a young primary lymphedema patient is described. Patient was bedridden for years due to massive swelling of her legs. Therapy was performed with manual lymph drainage, bandaging, Lympha Press®, and guided exercise in the Lympho-Opt Klinik in Germany.

Patient was discharged after six months with a reduction of 81.2 kg (179 lbs).

RESULTS: Combination therapy with MLD and Lympha Press® is effective in treating an extreme case of lymphedema.

This case report describes in-clinic reduction of massive lower extremity lymphedema resulting in a total weight loss of 179 lbs.

INPATIENT REDUCTION WITH LYMPHA PRESS®

Sequential pneumatic compression for lymphedema: a controlled trial.

PUBLICATION: Richmand DM, O'Donnell TF Jr, Zelikovski A. (1985) *Arch Surg*, Oct, 120(10), 1116-1119.

STUDY SIZE: 25 patients

A prospective study of seven patients with upper extremity and 18 patients with lower extremity lymphedema was performed. Treatment was applied for 24 hours in an inpatient setting. All extremities showed a decrease in circumferential measurements. Lower extremity leg volume was reduced by 45%. No elevation in serum muscle enzyme levels was noted. The Lympha Press® reduced lymphedema rapidly and safely. Follow up at three to six months after treatment showed that patients who were compliant with use of static compression garments maintained retention of 50% or more of their reduction.

In this study, patients obtained safe and rapid reduction averaging 45% loss in circumference. Follow up at three and six months showed that patients who were compliant with compression garments maintained 50% or more of their reduction.

Long-term results of compression treatment for lymphedema.

PUBLICATION: C.J. Pappas, MD, and T.F. O'Donnell Jr, MD, FACS. (1992) *Journal of Vascular Surgery*, 16, 555-564.

STUDY SIZE: 49 patients

The long-term courses of 49 patients managed by one surgeon were reviewed to assess the long-term effects of a program entailing (1) sequential external pneumatic compression (SEP), (2) elastic compression stockings to maintain the post-SEP girth, and (3) daily skin care. Limb girths measured at nine levels on the limb were obtained serially in follow-up visits (mean: 25 months) by an independent observer to provide an objective response to therapy. The relative reduction was determined by the difference between the pretreatment, postacute treatment, and long-term treatment girths. In long-term follow-up, 26 of the patients maintained a full response (reduction at >3 levels), whereas 10 maintained a partial response (reduction at ≤3 levels). At late follow-up, calf and ankle girths were reduced by an absolute value of 5.37 ± 1.01, and 4.63 ± 0.88 cm in the full-response group and 5.43 ± 1.58 and 3.98 ± 1.18 cm in the partial response group over pretreatment measurements. The degree of subcutaneous fibrosis in relationship to the duration of the edema appeared to influence results greatly. The treatment of lymphedema with SEP and compression stockings is associated with long-term maintenance of reduced limb girth in 90% of patients.

This study in a group of 49 patients showed that treatment of lymphedema with Lympha Press® and compression stockings was associated with long-term maintenance of reduced limb girth in 90% of patients.

PNEUMATIC COMPRESSION FOR SELF-MANAGEMENT AT HOME

Practical lymphedema self-management: An assessment of patient satisfaction and perceived effectiveness of treatment modalities.**PUBLICATION:** K. Ashforth, J. Cosentino. (2012) *Lymphology*, 45 (Suppl), 367-370.**STUDY SIZE:** 30 patients

The purpose of this study was to examine preference for, and compliance with home treatment modalities for individuals living with lymphedema. Thirty people with lymphedema resulting from cancer with surgery and lymph node excision were surveyed for satisfaction and compliance with their home care regimen. All had received treatment with compression, skin care, elevation, exercise and training in self-performance of manual lymphatic drainage (MLD). Those surveyed carried out individualized home programs which included self-MLD, bandaging, elastic, quilted and rigid compression garments, and use of an intermittent pneumatic compression pump (IPC). Those who had access to all modalities (based on insurance coverage) rated pneumatic compression most effective (100%) followed by quilted compression (72.7%) and MLD and elastic compression (each 63.6%).

This survey found that 100% of patients using pneumatic compression in the home rated pneumatic compression more effective than self-applied MLD, bandaging, elastic/rigid and quilted compression.

Proper Pressure: Transitioning lymphedema patients to home care with pneumatic compression.**PUBLICATION:** K. Ashforth, (2012) *Advance for Physical Therapy and Rehab Medicine*, 23(15), 19-21.

This article describes the application and use of Lympha Press® pneumatic compression for home care, including types of systems, criteria for selection, insurance coverage issues, contraindications and choice of pressure. If edema is limited to the extremities, an extremity-only appliance is usually sufficient and has the advantage of being lower profile and easier to comply with. However, if the lymphatic system in the trunk is damaged, it needs treatment as well. Appliances have been developed to treat the trunk and torso. Pneumatic compression can be particularly effective for patients who have widespread edema or have limited range of motion, strength and endurance. Patients using pneumatic compression at home have high compliance and satisfaction levels.

This review article summarizes the uses, recommendations and benefits of pneumatic compression therapy at home.

RESULTS: As an adjunctive treatment for appropriate patients, pneumatic compression is an effective tool for achieving decongestion in both the acute and maintenance phases of treatment. Its high degree of patient acceptance, as well as availability, make it a valuable treatment option.

Home therapy for lymphedema**PUBLICATION:** A. McLeod, (1989) *Home Health Care*, Summer, 18-19.

A description of a home lymphedema treatment program for children, as applied by the Hospital for Sick Children in Canada. Lympha Press® pneumatic compression treatment was applied at home after an in-patient assessment. Lympha Press® treatment was provided according to an individualized routine, with the limb in elevation, use of a recommended compression garment, specific exercise, education, skin hygiene and infection prevention. All components of the home program must be followed if the benefit is to be maximized. Six of nine patients were followed for two years and showed a positive response to the full regime, with a mean decrease in involved limb circumference of 23%. Pneumatic compression treatment as an adjunct to a conservative home program offers a much needed advancement to the medical management of lymphedema.

This clinical report describes successful home therapy with Lympha Press® pneumatic compression, exercise, compression and education, maintaining a 2-year circumferential reduction of 23%.

LYMPHA PRESS® AND LYMPHA PANTS™ USED WITH COMPLETE DECONGESTIVE THERAPY FOR LIPEDEMA

Lymphedema treatment decreases pain intensity in lipedema.

PUBLICATION: G. Szolnok, E. Varga, M. Varga, M. Tuczai, E. Dósa-Rácz, L. Kemény. (2011) *Lymphology*, Dec;44(4), 178-82.

STUDY SIZE: 38 patients

Lipedema is a disproportional obesity featuring light pressure-induced or spontaneous pain. On the basis of our clinical observations, lymphedema therapy, as practiced in our clinic, reduces the perception of pain beyond leg volume reduction. We therefore aimed to measure pain intensity prior and subsequent to treatment. Thirty-eight women with lipedema were enrolled in the study with 19 patients undergoing treatment and 19 serving as the control group using exclusively moisturizers. Treatment consisted of once daily manual lymph drainage (MLD), intermittent pneumatic compression (IPC), and multilayered short-stretch bandaging performed throughout a 5-day course. Pain was evaluated with a 10-item questionnaire, a pain rating scale (PRS), and the Wong-Baker Faces scale. Treatment resulted in a significant reduction of pain with a decrease in mean scores of all three measures. In the control group, only PRS showed significant decrease.

RESULTS: This treatment regimen not only reduces leg volume and capillary fragility, but also reduces pain intensity in patients with lipedema.

In this study, treatment with MLD, compression therapy and Lympha Press® with Lympha Pants™ reduced leg volume, capillary fragility and pain associated with lipedema.

LYMPHA PANTS COMPRESSION AND PAIN RELIEF (Experimental Pain Study)

Large body area compression exerts analgesic modulation on experimental pain.

PUBLICATION: L. Honigman, O. Bar-Bachar, D. Yarnitsky, Y. Granovsky. 9th Congress of the European Pain Federation, Vienna, Austria, 2015. Abstract.

STUDY SIZE: 30 volunteers

Healthy volunteers received a pain stimulus in the form of heat applied to the hands, before treatment and during compression of the lower body at 60 mm Hg with Lympha Press Optimal® and Lympha Pants®. The compression was applied randomly to three areas of the body: to feet only, to feet and legs, and to the entire lower body. The pain level from the pain stimulus felt by each subject was assessed continuously throughout treatment. Compression applied to the larger areas (feet and legs, entire lower body) reduced the sensation of experimental pain applied to the arms, showing significant analgesic effect of the Lympha Pants® action. Subjects reported no discomfort from the compression itself.

CONCLUSION: The Szolnok study from 2011 showed Lympha Pants therapy reduced pain in patients with lipedema. This neurological study shows that pneumatic compression with the Lympha Pants® may have an application as a pain reducing modality, in addition to, or separate from, lymph drainage.

In this neurological study, compression with Lympha Pants® and Lympha Press Optimal® reduced the perception of experimental pain stimulus applied to the hands, showing that large-area lower-body compression may have an analgesic effect.

Learn more about Lympha Press® systems.

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