

# **Lymphatic therapy using negative pressure**

## **A clinical study with the LymphaTouch device**

Ville-Pekka Vuorinen<sup>(1)</sup>, Jarkko Iivarinen<sup>(1, 2)</sup>, Jukka Jurvelin<sup>(2)</sup>, Olavi Airaksinen<sup>(1)</sup>

<sup>(1)</sup> Kuopio University Hospital

<sup>(2)</sup> University of Eastern Finland

### **Introduction**

Lymphedema refers to a condition in which a part of the body becomes swollen due to the impaired flow of lymph. Lymphedema is a manifestation of lymphatic system insufficiency and disrupted lymph circulation. Edema as a consequence of tissue damage or surgery is a common problem worldwide (Bazigou et al. 2013, Hodge et al. 2011, Rockson et al. 2012). Edema resulting from a burn injury can cause tissue fluid content to increase by 5% in the skin and by 80% in subcutaneous tissue (Papp et al. 2005). Arm volume can increase by 44% due to lymphedema, with excess fluid located mainly in the subcutaneous tissue (Brorson et al. 2006). Women who have had cancer mastectomy constitute a large group of patients suffering from lymphedema. The swelling in these patients is usually located in the upper extremity and breast on the operated side (Anttila et al. 2007, Kärki et al. 2009). Unfortunately, current treatment practices for lymphedema are not effective. The swelling interferes with patients' work and everyday functioning, and lowers their quality of life.

Until now, lymphedema has been treated using various combinations of compression therapy (e.g. with pressure bags, compression bandages or compression sleeves), physical therapy, guidance and counseling, and manual lymph drainage therapy. There is little evidence of the efficacy of these treatment practices, however.

The goal of this study was to improve the diagnostics and treatment of edema patients. The study attempted to demonstrate the benefit and significance of a lymphatic therapy device (Iivarinen et al., 2013) in the treatment of patients. In particular, the aim was to verify the physiological effects of LymphaTouch negative pressure therapy in swollen tissue. The study compared lymphatic therapy administered with a negative pressure device to manual lymph drainage therapy. The study also sought to establish the safety of lymphatic therapy administered with the LymphaTouch device.

## Study hypotheses

The study hypotheses were as follows:

- The negative pressure technique of lymphatic therapy is safe for patients
- The negative pressure technique of lymphatic therapy treats swelling more effectively than traditional manual lymph drainage therapy
- The following diagnostic measurements indicate superior treatment outcomes:
  - Joint mobility measurements (range of motion)
  - Grip strength (Jamar)
  - Volumetric limb measurement
  - Measurement of limb circumference
  - MRI measurement of limb volume (Siemens 1.5 tesla)
  - Tissue stiffness measurement
  - Body composition analysis (InBody)
  - Assessment of degree of disability (FACT-B)
  - Quality of Life, QoL (DASH)

## Materials and methods

### Patients

The study included 13 women who had undergone a mastectomy involving removal of the axillary lymph nodes, and had lymphedema of an upper extremity as a result. The patients were randomized into two groups: a negative pressure therapy group (n=7, LymphaTouch device) and a manual lymph drainage therapy group (n=6). The patients had lymphedema in only one upper extremity (left arm n=8, right arm n=5). Their weight was  $86 \pm 17$  kg (mean  $\pm$  variation) and their height was  $163 \pm 6$  cm. Their average age was 62 years (range 46–77 years).

Strict inclusion criteria were applied:

- Female sex
- Lymphedema of an upper extremity following mastectomy
- Minimum of 3 months elapsed since the operation
- Maximum duration of swelling 12 months
- No neoplastic disease diagnosed previously, and the breast cancer must not have spread to other tissues

- Minimum of 1 month since the patient underwent any previous lymphatic therapy
- No other diseases that cause significant swelling

## **Materials and methods**

### Course of the study

Patient recruitment was conducted by the physician in charge of the study, physical medicine specialist Ville-Pekka Vuorinen, together with plastic surgery specialist Paula Mustonen. Patients who met the criteria were interviewed and had a preliminary clinical examination (to confirm eligibility). The course of the study was explained to the subjects orally and in writing, and they were asked for written consent to participate in the study. The ethics committee of Kuopio University Hospital granted a research permit for the study.

Three of the study visits per protocol were scheduled with patients at the first study visit: before the treatment period, after the treatment period, and one month after the end of the treatment period. Measurements for the study were performed at the physical medicine outpatient clinic of Kuopio University Hospital, and all of the study-related measurements at all study visits were performed by Ville-Pekka Vuorinen, the physician in charge of the study. The only exception to this was magnetic resonance imaging (MRI), which was performed at the Kuopio University Hospital radiology department by Petri Jokiranta, radiologist.

There were ten treatment visits, which took place on every business day of two consecutive weeks. All patient treatments were administered by the same lymphatic therapist, Tuija Nikula (Axis Fysio, Turku), who is trained in the Vodder method. Each treatment visit lasted approximately 90 minutes, during which subjects received the following treatment per protocol: 60 minutes of lymphatic therapy, arm measurements, and compression bandaging. The only difference in the treatment of the patient groups was the type of lymphatic therapy administered: either manual lymph drainage therapy or LymphaTouch negative pressure therapy (Figure 1).

### Mobility of arm joints

Joint mobility of the upper extremities was tested using a goniometer to measure seven movements of the arm. The tests were performed before and after the treatment periods, and at

the follow-up visit after one month. This was to investigate the effect of the treatments on the function of the upper extremities.



**Figure 1.** The negative pressure device used in the study (LymphaTouch, HLD Healthy Life Devices Ltd, Espoo, Finland).

#### Grip strength of the hand

Grip strength measurements were used to investigate the effect of the treatments on the function of the upper extremities (Jamar<sup>R</sup> dynamometer, Figure 2). The measurements were taken before and after the treatment periods, and at the follow-up visit after one month.



**Figure 2.** Jamar<sup>R</sup>hand dynamometer

#### Volumetric limb measurement

We took volumetric measurements to investigate the effect of the treatments on total volume of the upper extremity. Figure 3 illustrates the technique used. The volumetric measurements were performed on both arms before and after the treatment period, and at the follow-up visit after one month.



**Figure 3.** Volumetric limb measurement

### Limb circumference

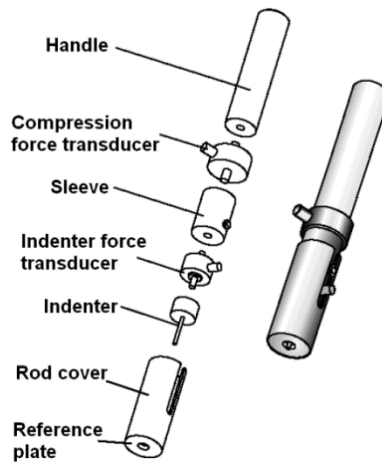
Limb circumferences were measured before and after treatments. The measurement sites were the knuckles, palm, wrist (0 cm), and at 4-cm intervals along the arm (52 cm maximum). These measurements were taken in order to investigate the effect of the treatments on arm size.

### MRI measurement of limb volume

A 1.5-tesla MRI scanner at the radiology department of Kuopio University Hospital was used for imaging of the study patients' swollen upper extremities. The MRI scans of the affected extremities were performed before the treatment period and after the treatment period. The scans were evaluated by radiologist Petri Jokiranta, who measured the total arm area and the area of muscle compartments in cross-sections of the upper extremities. This provided an estimate of the treatment effect on subcutaneous tissue area, and thus on any changes in edema.

### Tissue stiffness measurement

We measured tissue stiffness in order to investigate whether the treatment caused changes in skin elasticity. Skin elasticity (tissue stiffness) was measured using an indentation device developed for this purpose (Figure 4) (Arokoski et al. 2005, Iivarinen et al. 2011). The tissue stiffness measurements were performed on both upper extremities before and after the treatment period. The measurement sites were the back of the hand, the midpoint of the forearm (lateral and medial) and the midpoint of the upper arm (lateral).



**Figure 4.** Tissue stiffness meter

### Body composition analysis

We used body composition analysis to measure limb changes caused by the treatment. This was done using the InBody 720 device (Figure 5), which measures the proportion of extracellular fluid (ECF) to total body fluid (TBF). The device indicates how much of the extracellular fluid is in the trunk and in each of the extremities. Body composition analysis was performed for each study subject before the treatment period, after the treatment period, and at the follow-up visit after one month.



**Figure 5.** InBody 720 body composition analysis device

### Assessment of degree of disability

The DASH questionnaire was used to assess the degree of disability caused by impaired arm function. Subjects completed the questionnaire prior to study visits in order to track the impact of the swelling of the arm.

## Quality of Life

The FACT-B questionnaire is used to monitor the quality of life of breast-cancer patients. Subjects completed the questionnaire prior to study visits.

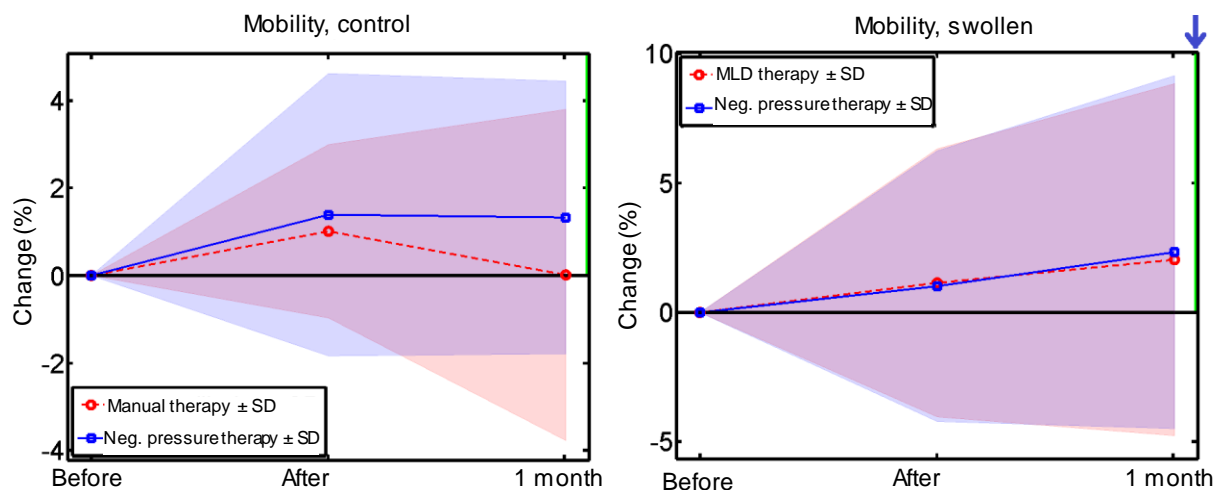
## **Results**

### Patient safety

A total of 9 patients were treated with LymphaTouch negative pressure therapy during the study and in pilot treatments conducted earlier, for a total of 90 treatments. The study patients reported no adverse effects at all from the LymphaTouch treatments administered. Very mild discomfort, associated mainly with skin symptoms caused by compression bandages, was reported by 3 patients. None of the study patients discontinued the study prematurely.

### Mobility of arm joints

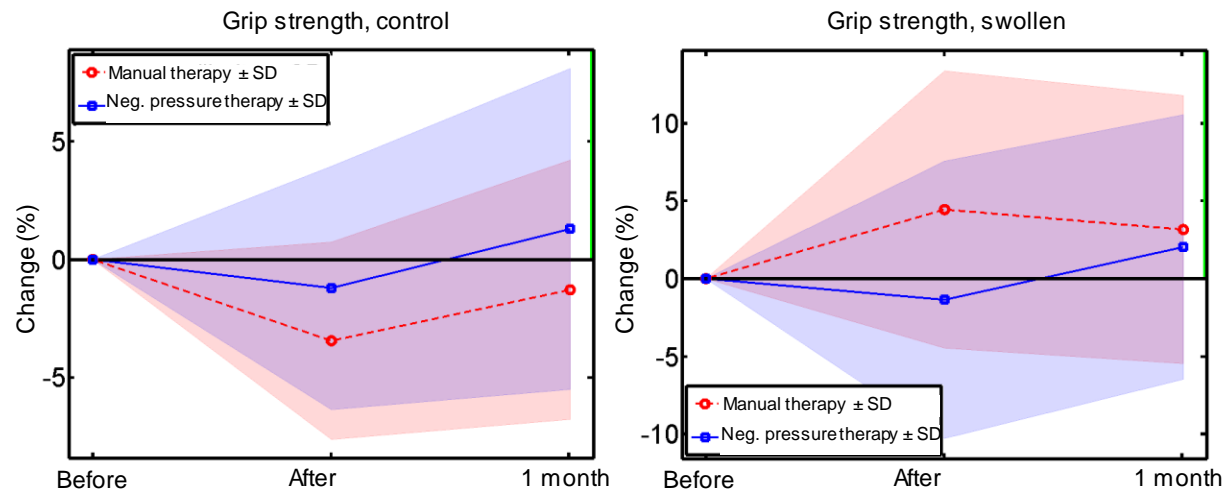
The baseline for an individual test ranged from 0 to 155 degrees. The joint mobility measurements and grip strength measurements revealed no significant changes after the treatments. The results were similar for negative pressure therapy and manual lymph drainage therapy (Figure 6).



**Figure 6.** Change in average mobility of arm joints in the healthy (control) arm and the swollen arm during the study. The vertical green line (arrow) indicates positive treatment outcomes.

### Grip strength

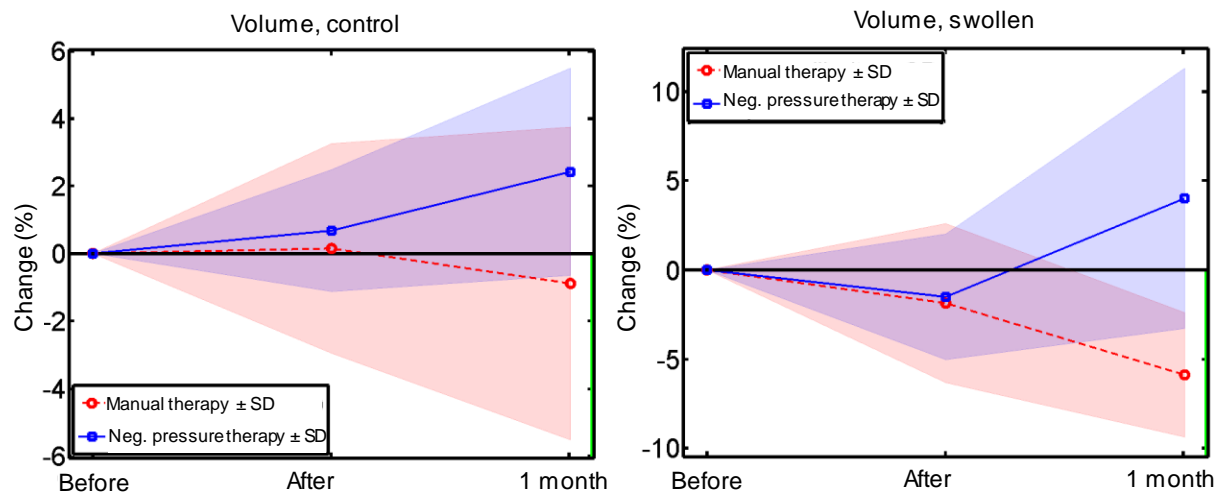
No significant changes in grip strength of the hands were found. The baseline was  $26 \pm 5$  kg for the healthy arm and  $25 \pm 5$  kg for the swollen arm (Figure 7).



**Figure 7.** Grip strength measurement results

### Volumetric limb measurement

The volumetric limb measurements revealed no significant changes after the treatments (Figure 8). The baseline was  $2075 \pm 536$  mL for the healthy arm and  $2303 \pm 475$  mL for the swollen arm.

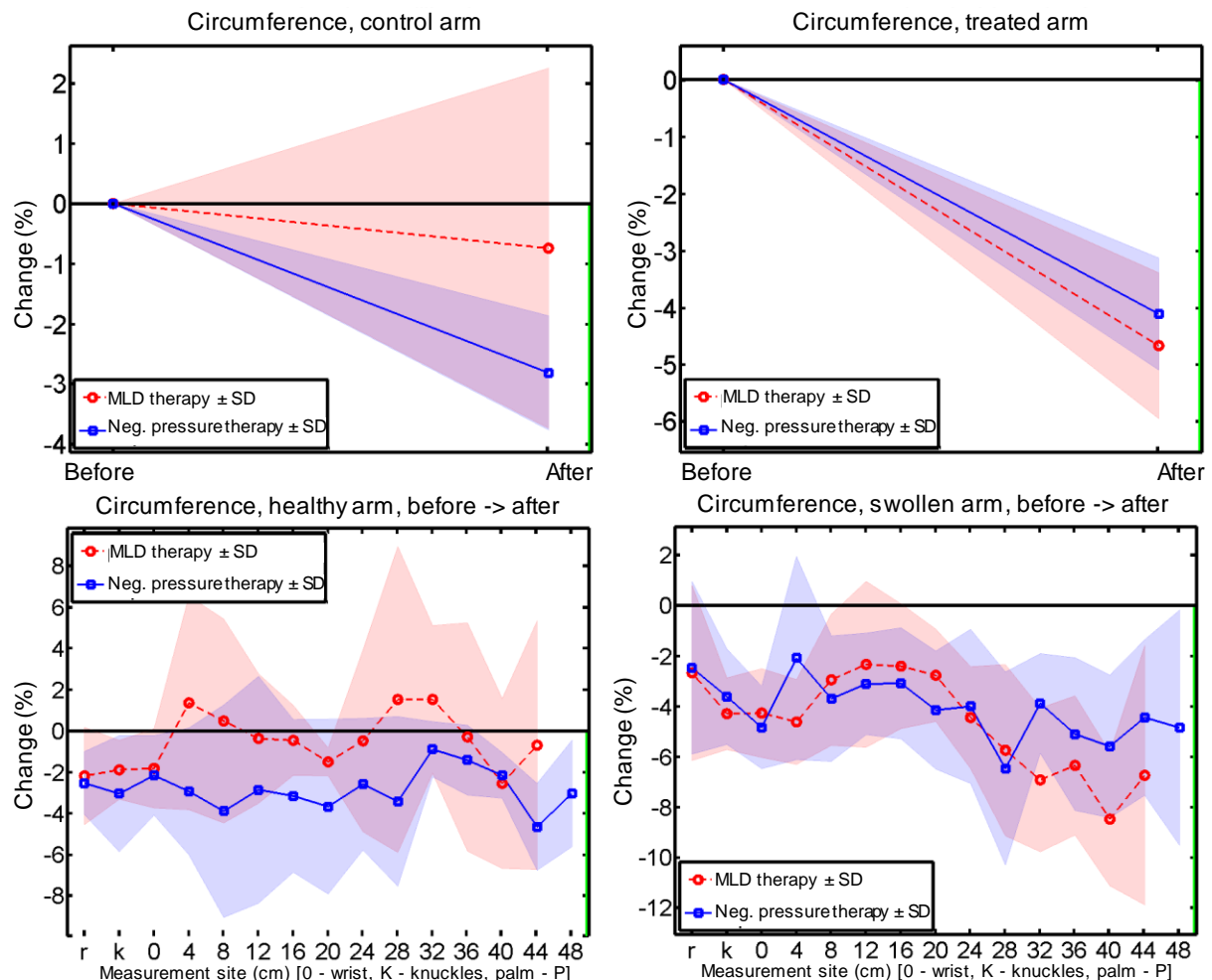


**Figure 8.** Volumetric limb measurement results

### Limb circumference



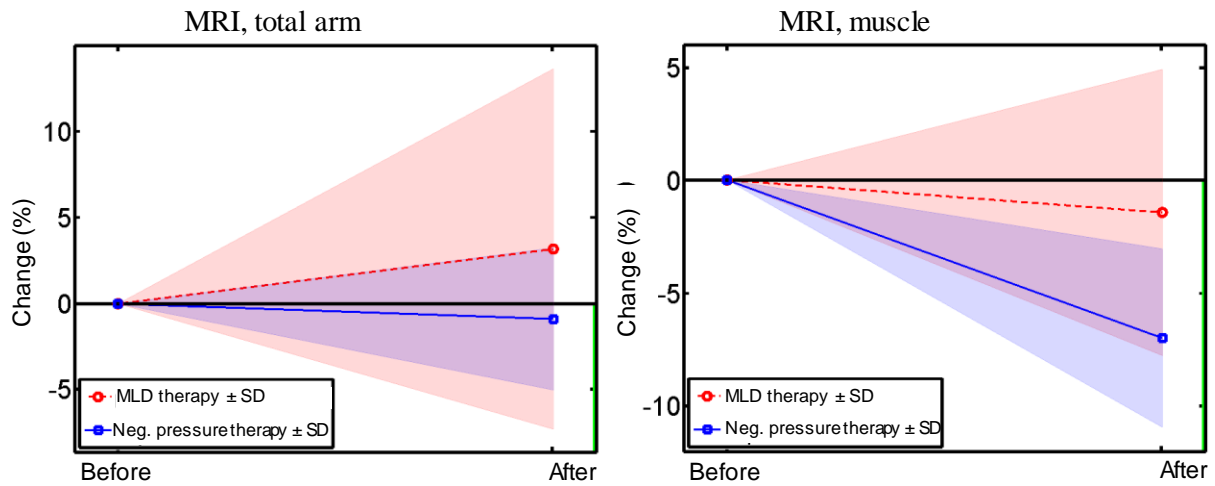
The baseline was 17.7–38.0 cm for the healthy (control) arm, depending on the measurement site. The circumference of the swollen arm was 0.2–3.2 cm greater. Limb circumference decreased after treatments, and the results of negative pressure therapy and manual lymph drainage therapy were about the same (Figure 9).



**Figure 9.** Limb circumference

#### MRI measurement of limb volume

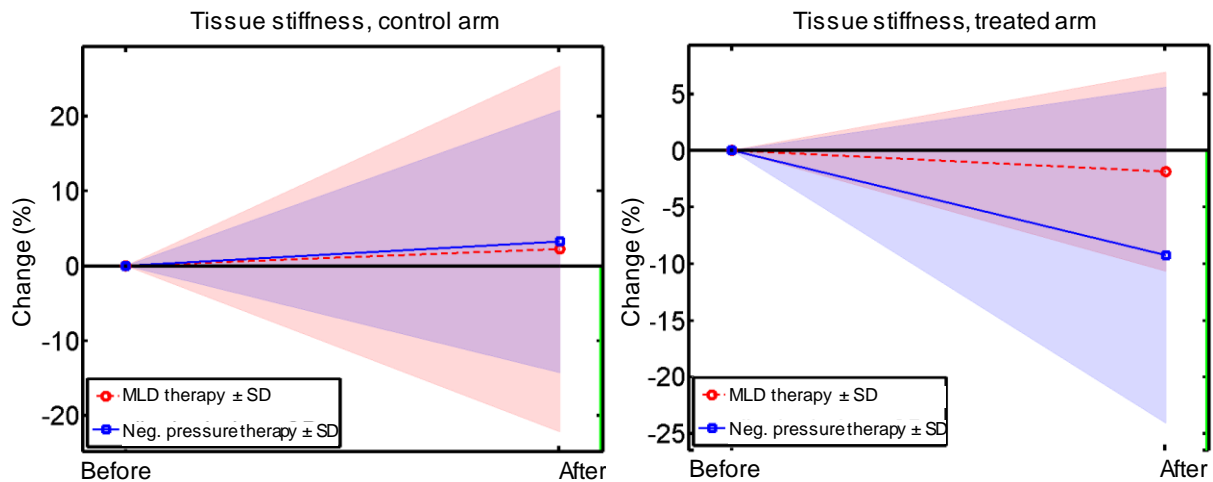
The baseline was  $10,109 \pm 2470 \text{ mm}^2$  for the swollen arm and  $3002 \pm 406 \text{ mm}^2$  for the arm muscles. The total arm volume as measured by MRI did not change, but the volume of muscle tissue decreased by an average of 7.0% following negative pressure therapy (Figure 10).



**Figure 10.** MRI measurement of limb volume

### Tissue stiffness measurement

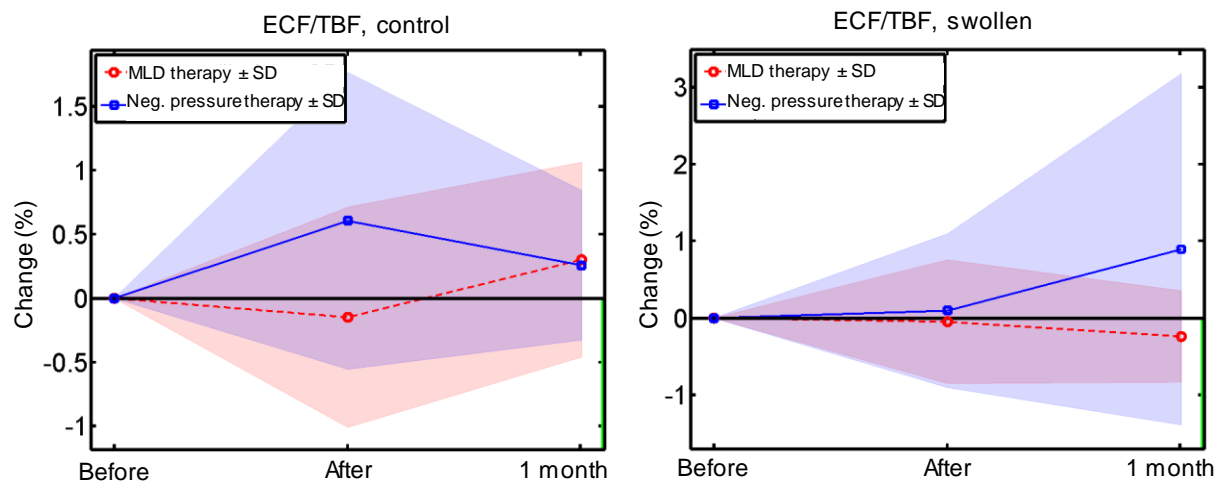
The baseline tissue stiffness was  $0.27 \pm 0.05$  N for the healthy (control) arm and  $0.29 \pm 0.04$  N for the swollen arm. Negative pressure therapy decreased tissue stiffness more effectively than manual lymph drainage therapy, by an average of 9.2% (Figure 11).



**Figure 11.** Tissue stiffness measurement

### Body composition fluid indices

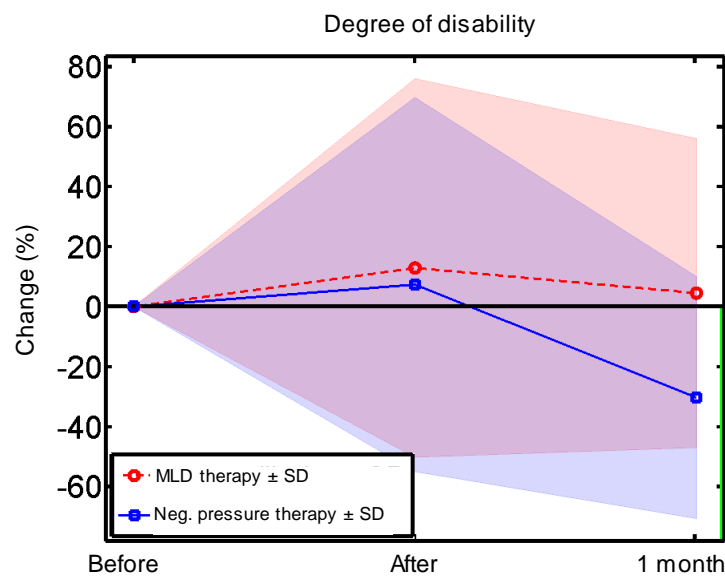
The baseline was  $0.335 \pm 0.004$  for the control arm and  $0.343 \pm 0.004$  for the swollen arm. Body composition changes were negligible after the treatments (Figure 12).



**Figure 12.** Body composition analysis

### Assessment of degree of disability

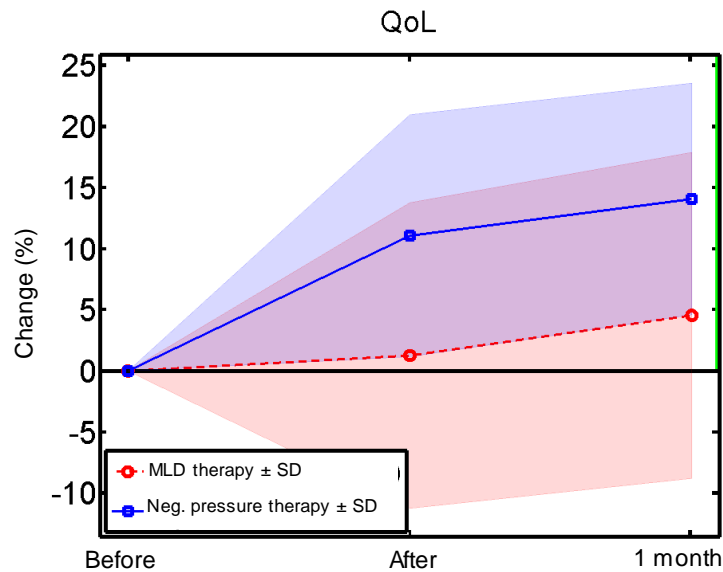
The baseline was  $21 \pm 12\%$ . The degree of disability decreased by an average of 30.2% after negative pressure therapy (Figure 13).



**Figure 13.** Degree of disability experienced by the patient before and after the treatment period

### Quality of Life

Quality of Life was  $102 \pm 14$  at baseline and improved by an average of 14.0% after negative pressure therapy (Figure 14).



**Figure 14.** Quality of Life before and after the treatment period

## Conclusions

The study indicates that LymphaTouch therapy is a safe form of treatment for lymphedema patients. The study demonstrated that the negative pressure method resulted in changes in the volume, MRI and tissue stiffness parameters. Most of the changes observed can be considered positive. The study results indicate that the LymphaTouch negative pressure technique treats edema more effectively than traditional manual lymph drainage therapy. It caused larger decreases in the edematous volume of muscle tissue (7%) and in tissue stiffness (9.2%). In addition, it caused greater improvement in the patients' Quality of Life variable (14%).

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