LYMPHATIC THERAPY USING NEGATIVE PRESSURE A CLINICAL STUDY WITH THE LYMPHATOUCH DEVICE

Ville-Pekka Vuorinen[1], Jarkko Iivarinen[1, 2], Jukka Jurvelin[2], Olavi Airaksinen[1]
[1]*Kuopio University Hospital*
[2]*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 insufficie nc y 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 suffer ing 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 swel ing 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 LymphaTo uch 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 swel ing more effectively tha n 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 ± 17 kg (mean ± variatio n) and their height was 163 ± 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 sprea d 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 peri-

Figure 1. *The negative pressure device used in the study (LymphaTouch, HLD Healthy Life*

ods, 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.

Grip strength of the hand

Grip strength measurements were used to investigate the effect of the treatments on the functio n of the upper extremities (Jamar^{R} dynamometer, Figure 2). The measurements were taken before and after the treatment periods, and at the follow-up visit after one month.

Figure 2. *JamarRhand ^{R} dynamometer*

Volumetric limb measureme nt

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 measureme nts were performed on both arms before and after the treatment period, and at the follow-up visit after one month.

Limb circumfere nce

Figure 3. *Volumetric limb measurement*

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 measureme nt 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 measureme nt

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).

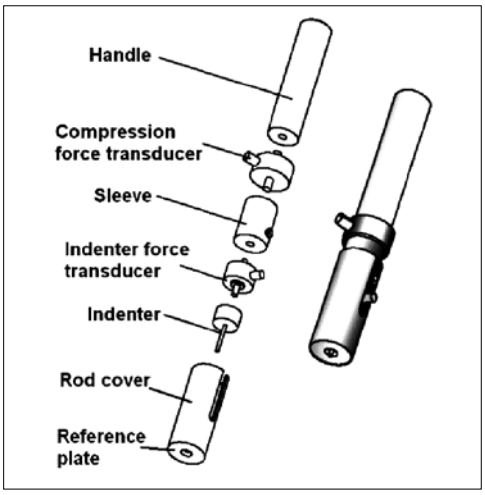

Figure 4. *Tissue stiffness meter*

Body compositio n 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 wa s 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 functio n. Subjects completed the questionnaire prior to study visits in order to track the impac t 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 mobilit y 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).

Grip strength

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

Volumetric limb measureme nt

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

The baseline was 17.7–38.0 cm for the healthy (control) arm, depending on the measureme nt site. The cir-

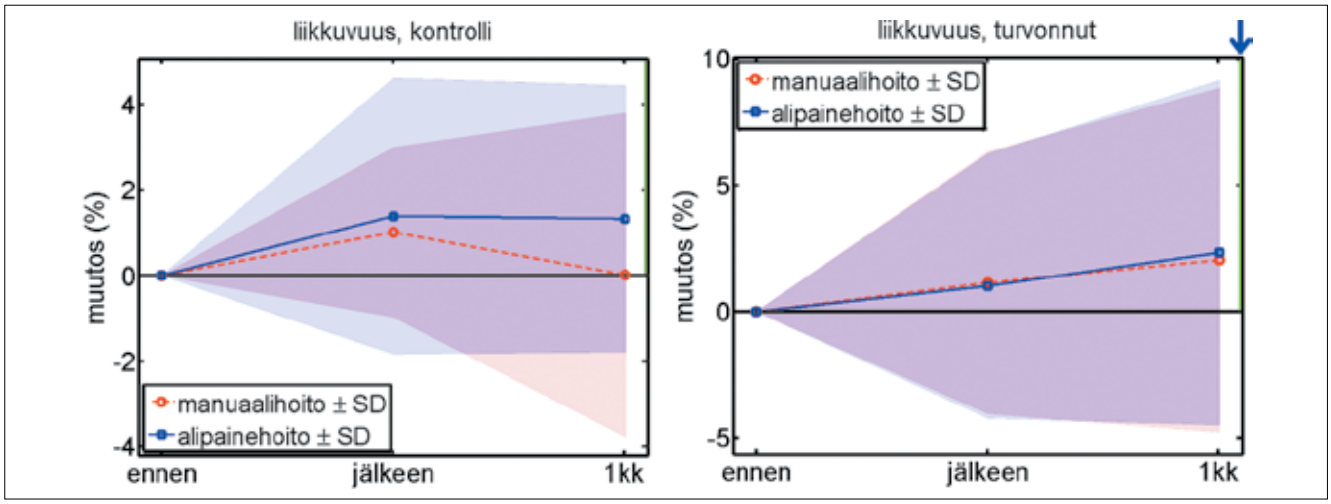

Figure 6. *Change in average mobility of arm joints in the healthy (control) arm and the swollen arm during the study. The vertical green line (arrow) indicates positive treatment*

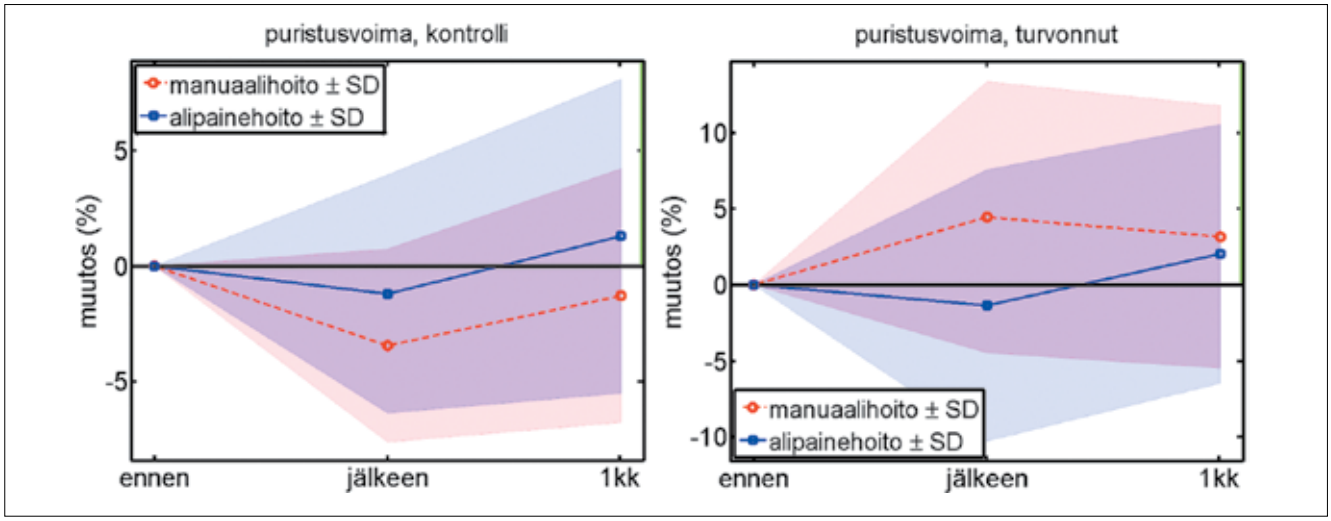

Figure 7. *Grip strength measurement results*

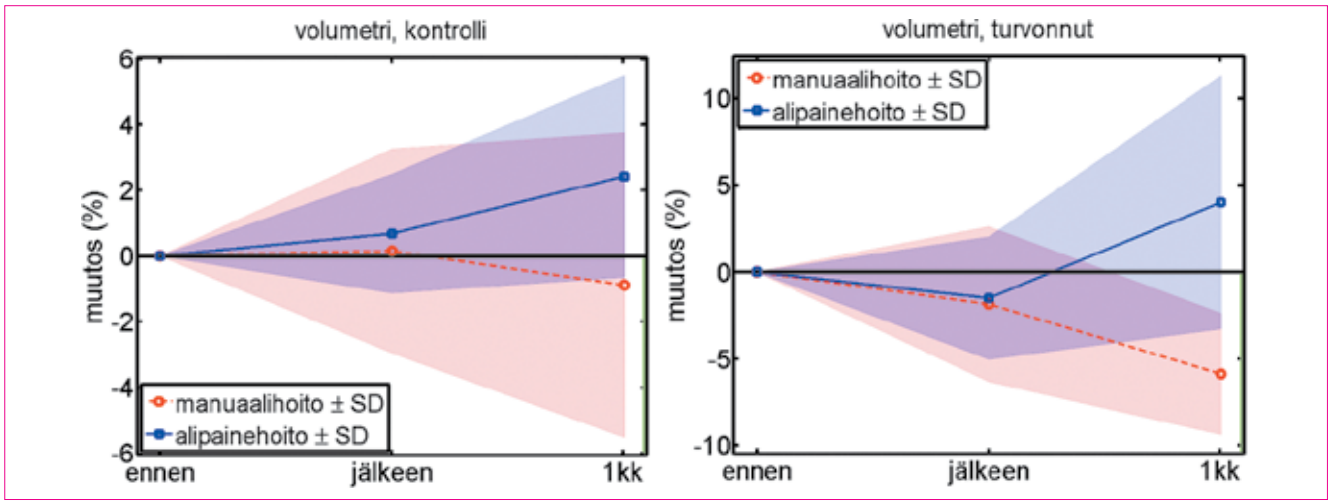

Figure 8. *Volumetric limb measurement results*

cumference of the swollen arm was 0.2–3.2 cm greater. Limb circumfere nce decreased after treatments, and the results of negative pressure therapy and manual lymph drainage therapy were about the same (Figure 9).

MRI measureme nt of limb volume

The baseline was 10,109±2470 mm² for the swollen arm and 3002±406 mm² 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).

Tissue stiffness measureme nt

The baseline tissue stiffness was 0.27±0.05 N for the healthy (control) arm and 0.29±0.04 N

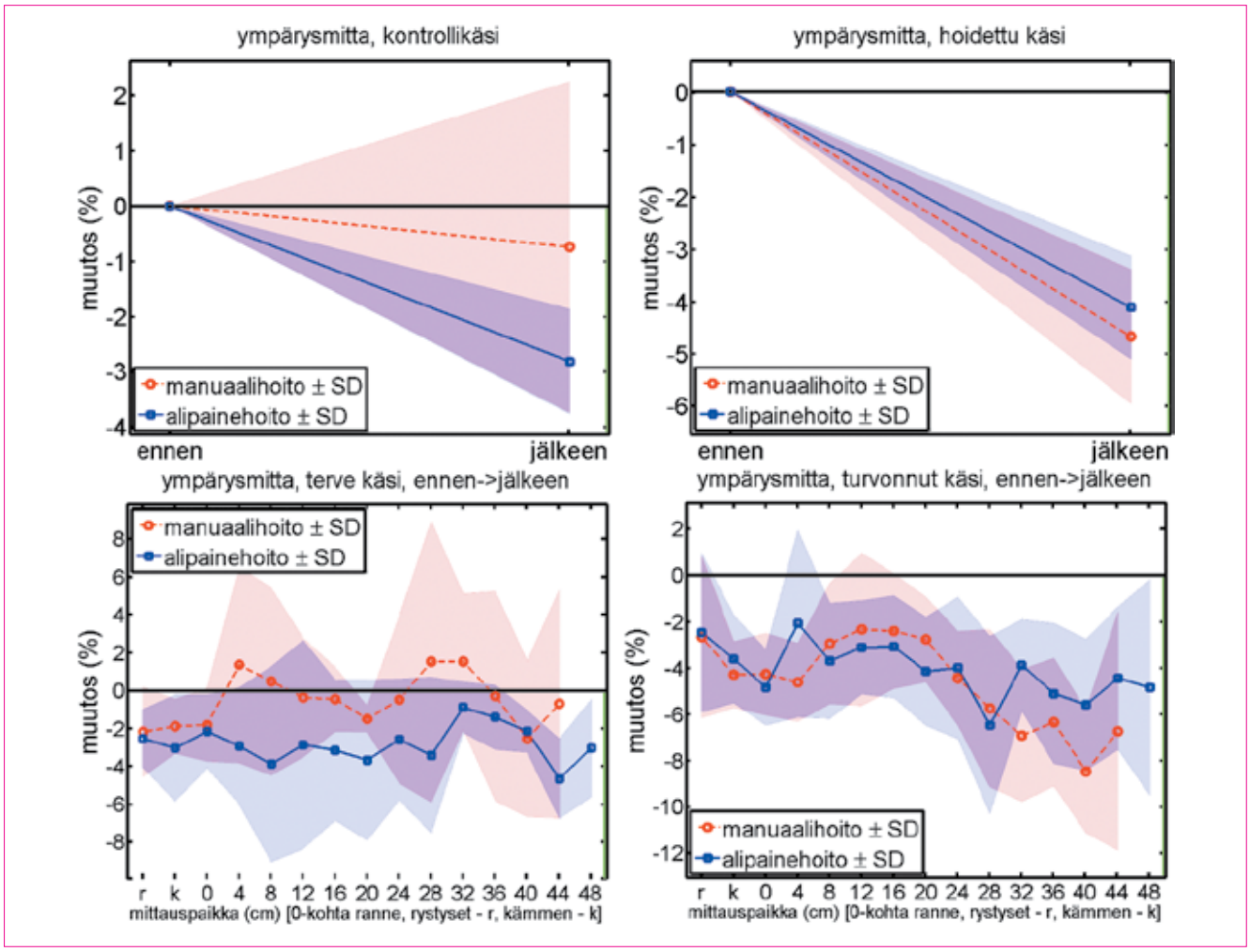

Figure 9. *Limb circumference*

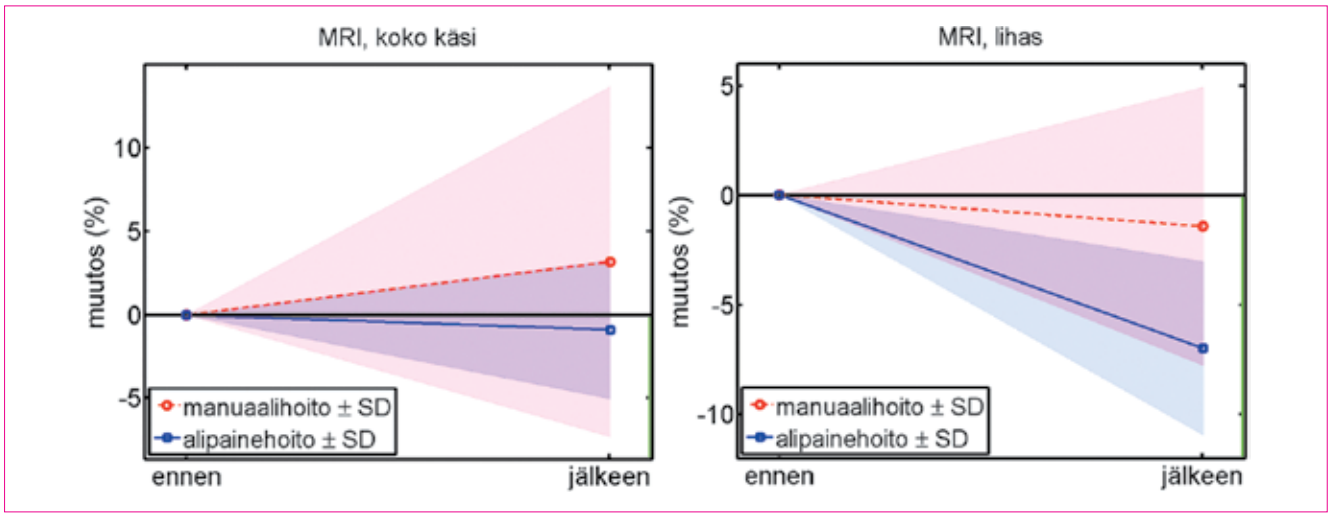

Figure 10. *MRI measurement of limb volume*

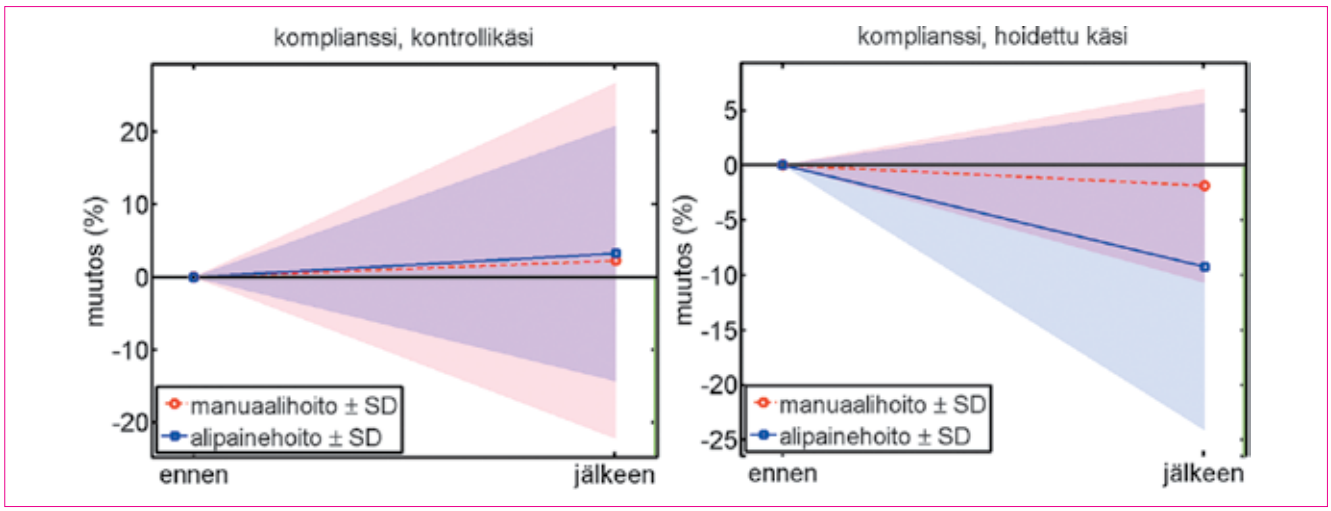

Figure 11. *Tissue stiffness measurement*

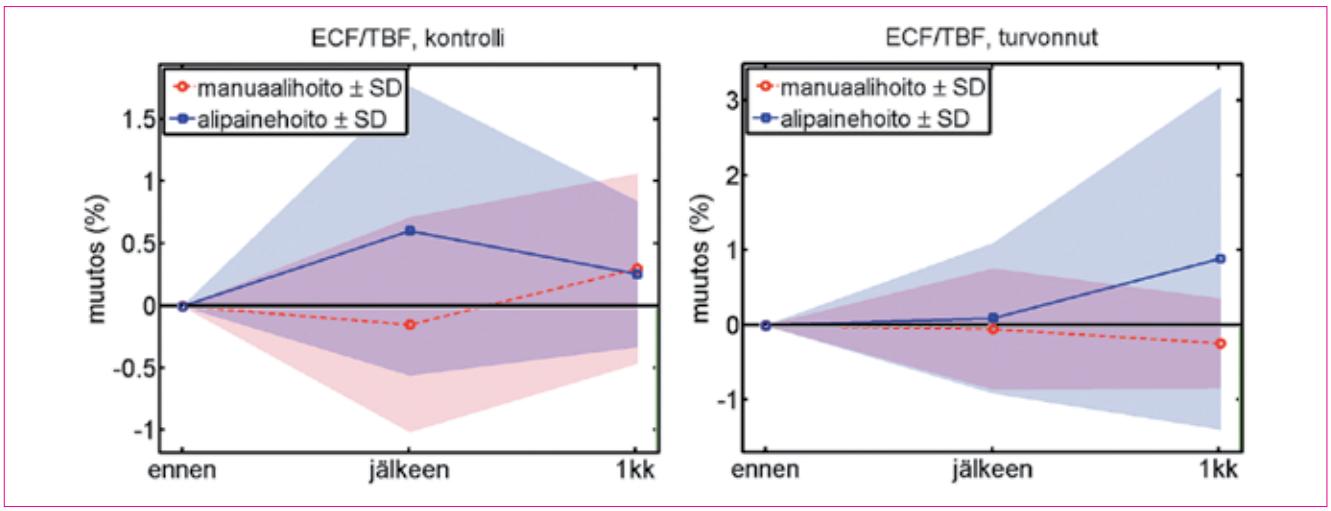

Figure 12. *Body composition analysis*

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).

Body compositio n fluid indices

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

Assessment of degree of disability

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

Quality of Life

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

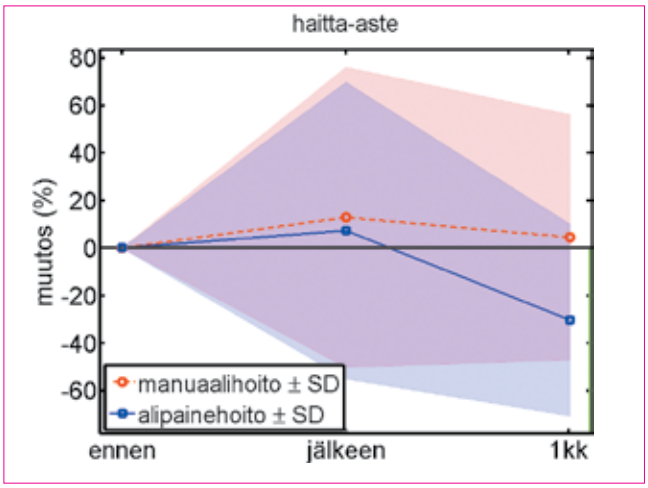

Figure 13. *Degree of disability experienced by the patient before and after the treatment period*

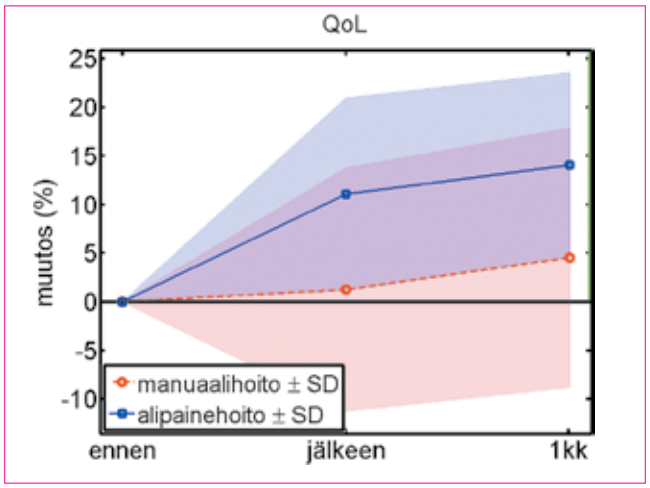

Figure 14. *Quality of Life before and after the treatment period*

Conclusions

The study indicates that LymphaTouch therapy is a safe form of treatment for lymphede ma 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%).

Treatment protocol of breast cancer patient lymphedema

One complication of breast cancer treatment is secondary upper limb lymphedema in the hand and arm on the operated side of the patient. Lymphedema can also occur in part or the whole of the upper body quadrant on the operated side. It is caused by the surgical removal of axillary lymph nodes (Inn. axillares) and radiation therapy. Modern surgical techniques and improved means of limiting and dosing radiation therapy leave 64 to 89 per cent of operated patients with sufficient lymphatic capacity to completely avoid lymphedema. Today the risk of developing secondary upper limb lymphedema is around 36 per cent, depending on the surgical technique, administered radiation therapy, individual lymphatic capacity and structure, further postoperative treatment and the patient's adherence to instructions.

Less than twelve months after surgery

The body tries to compensate for the lost lymphatic capacity by growing new lympholymphatic anastomoses. Excessive scar formation complicates and blocks the formation of anastomoses. Therefore, movements of the shoulder joint should be minimized for 10 to 14 days after the operation, ensuring uninterrupted scar development. At the same time however, metabolic activity without any compressive obstructions in the arm must be ensured.

The LymphaTouch therapy aims to activate and create new lymphatic connections for healthy, functioning lymph node groups by using negative pressure to generate space for the flow of fluid in the tissue. Fluid loads are carried across watersheds to functioning lymph nodes, using the lymphatic network of the unaffected side of the patient.

The effects of radiation treatment on lymphatic therapy

If the irradiated area is very irritated, it should not be treated with lymphatic therapy for next two to six weeks after the last radiation treatment. The surrounding, non-irradiated areas may be treated earlier as needed. Acute effects of radiation therapy are mostly transient, but external mechanical irritation may intensify them, which can lead to irreversible, chronic damage. A chronic consequence can be radiogenic fibrosis in the skin (where the elasticity of the skin deteriorates). Irradiated lymph node groups can no longer be used in therapy, that is, you may not work in their direction. If there is radiogenic fibrosis in the skin, you should activate metabolism of this are by gentle way. Instead, you start the treatment at the edge of the fibrosis and continue in the direction of non-irradiated area.

Treatment protocol:

Post-mastectomy upper limb lymphedema (if skin changes – need to report and follow reactions)

Pressure adjustments should always be based on tissue properties and patient comfort. The physical features of the patient should be considered when changing the mouthpiece. The treatment times in parenthesis are advisory, and can vary depending on the patient's condition. Monitor the patient's reactions and response to the treatment. Review contraindications. After the treatment, the patient should drink two liters of water within five hours.

- The patient's sensations are used as a guide throughout the treatment. Use less pressure or slower pulsation if the patient experiences pain or for some other reason finds the sensation to be too intense (write down any unusual sensations). Note! Open wound skin or leaking blisters should not be treated.
- The movement of fluid often causes various sensations in patients. These should be noted and recorded. In very rare cases the sensations indicate that the treatment is unsuitable for the patient.
- Patients' sensations can vary widely and be rather intense. However, you should not discontinue the treatment. Instead, the intensity of the sensation can be reduced by using less pressure or a slower pulsation.
- In the first treatment session, remember that this is a new experience for the patient with LymphaTouch. The sensations caused by this kind of negative pressure treatment are new for most people and they need to become used to it. Explain what you are going to do.

First treatment session, pre-treatment = central treatment, takes more than half of the time:

- Central pre-treatment
- Arm treatment, moistening, skin care
- Water drinking guideline
- A bandage on the upper limb
- Instructions for exercise at home
- How to take bandage off and when and why
- Shower and arm cleaning during the treatment season (no sauna)

- Three pumps at one place, three to five changes of place, distance between lanes in relation to the size of the patient.
- "When the hand responds" (becomes thinner/looser = the lymphatic connections are working better way) → The time used for central pre-treatment is gradually shortened. At first it is important to use the LT device carefully, applying the lowest treatment protocols pressures and current pulsation.
- Central pre-treatment, the patient is lying on the back (prone position). However, large size patients can start in a seated position and lie down on the back later (position should be as comfortable as possible for the patient).

Treatment 1 (2 and 3 if needed) Central pre-treatment

1. Mouthpiece (50) or 60, pressure 50–80 mmHg, pulsation 2.0–(2.5)s (in a seated or lying on the back) Treatment of the supraclavicular fossa (terminus),
2. Mouthpiece (60) or 80, pressure 60–100 mmHg, pulsation 2.0–(2.5) s (in a seated position) Treatment of the shoulder line (the edge of trapezius)
3. Mouthpiece 80, pressure 80mmHg, pulsation 2 s

Move on the spine all the way from up to down.

4. Mouthpiece 80, pressure 100–180 mmHg, pulsation 2.0–2.5 s

The fascia treatment method is used over the spine by lifting and turning during suction. Down and up, slalom and up and down again.

Healthy side

5. Mouthpiece 60, pressure 50–80 mmHg, pulsation 2.0–2.5 s

Lnn. axillares – treatment of the arm pit (unaffected side)

6. Mouthpiece 60, pressure 50–80 mmHg, pulsation 2.0–2.5 s
   Treatment of musculus deltoideus
7. Mouthpiece 60 or 80, pressure 80–110 mmHg, pulsation 2.0–2.5 s
   Chest and intercostal spaces from the unaffected side
8. Mouthpiece 80, pressure 80–100 mmHg, pulsation 2.0–2.5 s Treatment of the abdominal area, with the xiphoid process at the top of triangle, from which two or three points are taken on each side of the triangle – towards the top of the ilium
9. Mouthpiece 60 or 80, pressure 50–100 mmHg, pulsation 2.0–2.5 s Anastomosis (on top of the sternum, towards the unaffected arm pit (axilla))
10. Mouthpiece 60 or 80, pressure 50–100 mmHg, pulsation 2.0–2.5 s
    The "affected side" → gradually proceeding, until you are on top of musculus deltoideus
11. Mouthpiece 60-80, pressure 80 mmHg, pulsation 2.0 s Lnn. inguinalis the operated side – treatment of the groin
12. Mouthpiece 60, pressure 50–100 mmHg, pulsation 2.0–2.5 s Intercostal spaces
13. Mouthpiece 60 or 80, pressure 50–100 mmHg, pulsation 2.0 s Transport from the watershed at the waist to the inguinal lymph nodes
14. Mouthpiece 60 or 80, pressure 50–100 mmHg, pulsation 2.0–2.5 s The side up to the arm pit (scar)
15. Mouthpiece 60 or 80, pressure 50–100 mmHg, pulsation 2.0–2.5 s
    Parasternal on the "affected" side (if not irradiated)
16. Intercostal, Mouthpiece 60, pressure 50–100 mmHg, pulsation 2.0–2.5 s
    Lying on the stomach:
    Mouthpiece 60 or 80, pressure 50–120 mmHg, pulsation 2.0–2.5 s
17. Mouthpiece 60 or 80, pressure 80–120 mmHg, pulsation 2.0–2.5 s

Trapezius, supraclaviculares

18. Mouthpiece 60 or 80, pressure 80–120 mmHg, pulsation 2.0–2.5 s
    Back (the unaffected quadrant of the upper body) intercostal
19. Mouthpiece 60 or 80, pressure 50–100 mmHg, pulsation 2.0–2.5 s
    Anastomosis
20. Mouthpiece 60 or 80, pressure 80–120 mmHg, pulsation 2.0–2.5 s
    The "affected side" cf. the front side and hand to the top of musculus deltoideus
21. Mouthpiece 60 or 80, pressure 50–80 mmHg, pulsation 2.0–2.5 s
    Transfer to the unaffected side from the "affected side"
22. Mouthpiece 60 or 80, pressure 50–100 mmHg, pulsation 2.0–2.5 s
    Anastomosis from the waist
23. Mouthpiece 60 or 80, pressure 50–100 mmHg, pulsation 2.0–2.5 s
    The side, ad musculus deltoideus on the back side

If there is no swelling on the body, paravertebral and intercostal areas can be treated briefly. If it is difficult for the patient to lie on the stomach, the patient may lie on the side with the "affected" hand on a Psoas pillow.

Treatment session after "response" (the second or third session):

Central pre-treatment -> see the description above 1–23.

In all the stages of treatment, the size of the treatment head is chosen in accordance with the patient's body (size and structure). Based on the patient's sensation, it is used with a pressure of 50 to 150 mmHg and pulsation of 2.0 to 2.5.

24. Mouthpiece 60 or 80, pressure 50–100 mmHg, pulsation 2.0–2.5 s

Musculus deltoideus on the back side → move across the watershed, one hand's breadth to the unaffected side

25. Mouthpiece 60 or 80, pressure 50–100 mmHg, pulsation 2.0–2.5 s
    Upper arm, lateral side:
26. Mouthpiece 60 or 80, pressure 50–80 mmHg, pulsation 2.0–2.5 s
    Proceeding gradually, transport out
27. Mouthpiece 60 or 80, pressure 50–80 mmHg, pulsation 2.0–2.5 s

Inn. axillares and inguinales

28. Mouthpiece 60 or 80, pressure 50–100 mmHg, pulsation 2.0–2.5 s
    Upper arm dorsal side (→ lat.) transport,
29. Mouthpiece 60 or 80, pressure 50–80 mmHg, pulsation 2.0–2.5 s
    axillares, inguinales

Lying on the back:

30. Mouthpiece 60 or 80, pressure 50–120 mmHg, pulsation 2.0–2.5 s
    Reopen connection to the healthy side
31. Mouthpiece 60 or 80, pressure 50–100 mmHg, pulsation 2.0–2.5 s
    Musculus deltoideus, across, back
32. Mouthpiece 60 or 80, pressure 50–100 mmHg, pulsation 2.0–2.5 s
    Upper arm, lateral side (to the elbow)
33. Mouthpiece 60 or 80, pressure 50–10 mmHg, pulsation 2.0–2.5 s
    Upper arm, medial → lat. → transport across the watershed
34. Mouthpiece 60 or 80, pressure 80–100 mmHg, pulsation 2 s.

The shoulder and the deltoid region are treated thoroughly. Lymph nodes at the elbow are activated.

35. Mouthpiece 35, 50 or 60, pressure 100–150 mmHg, pulsation 2.0–2.5 s. Treat the palm, the back of the hand and the fingers
36. Mouthpiece 50 for the wrist and 60 for the forearm, pressure 80–150 mmHg, pulsation 2 s The wrist is treated with slow, upward, "lifting" movements toward the elbow, all the way up to the elbow crease. The pressure is kept low at first, after that increased to a maximum of 150 mmHg as patient comfort permits.
38. Mouthpiece 50, pressure 160 mmHg, 2 s.

The wrist is manipulated with a "handshake grip" while the wrist interspaces are treated

39. Mouthpiece 60, pressure 160–250 mmHg, pulsation 2 s.
    The base of the palm is treated.
40. (* High-frequency vibration
    Mouthpiece 60, pressure 80–130 mmHg, work/rest ratio 80%, 80–60 Hz

The entire arm is treated with long, tenacious strokes up to the supraclavicular fossa

41. Mouthpiece 60, pressure 60–80 mmHg, pulsation 2 s

The entire arm is treated with long, tenacious strokes up to the supraclavicular fossa.

42. Then place a bandage on the swollen upper limb of the affected side.

- In further sessions, proceed further down in the hand, otherwise normal treatment from the elbow downward, but apply pressure laterally on the medial side of the elbow.
- Ten treatment sessions altogether, 60 minutes per session.

(* High-frequency vibration can be used to enhance treatment initiated at the basic settings.

The unique combination of high-frequency vibration and negative pressure therapy can be an effective way to reach different layers of tissue.

The pressure level should be higher than at the basic settings when high-frequency vibration is used, 100–200 mmHg. Work/rest ratio 80%, pulsation 2 s.

90–70 Hz: Superficial tissue layers, drawing out fluid and swelling.

60–50Hz: Deeper tissues, fascia, acute muscle injuries.

40–20 Hz: Deep tissue layers, joints, tendon injuries. Fibrous and sclerotic tissue.

Treatment begins with superficial layers and proceeds to deeper layers as the condition requires.

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Контакты:
Tiina Puustinen. Email: tiina.puustinen@hldmail.com