

**THE SUN ANCON® CHI MACHINE® AEROBIC EXERCISER:
A NEW PATIENT FOCUSED, HOME BASED THERAPY
FOR PEOPLE WITH CHRONIC SECONDARY LEG LYMPHEDEMA**

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ABSTRACT

A significant proportion of those who survive lower torso cancer treatments will go on to develop clinically discernible bilateral or unilateral leg lymphedema. Although beneficial treatments exist for this condition, many are expensive and involve visits to outpatient clinics or allied health professionals—making the patient dependent upon others for treatment and maintenance. This clinical trial tested the efficacy of the Sun Ancon® Chi Machine® Aerobic Exerciser, a home based therapy that delivered both elevation and passive exercise to the legs. This machine was used in the participant's home according to a set regime with measurements being taken immediately before trial commencement, at weekly intervals and then 1 month after treatment cessation. After a three week treatment period there were statistically significant reductions in total leg volume and fluids, whole body extracellular fluid, weight and subjective leg symptoms. Lymphoscintigraphy in a sub-group of patients suggested an increase in lymphatic transport in some individuals. Although some of the fluid and symptoms had returned at the 1 month follow up, none of the parameters had returned to pre-treatment levels. This finding indicates that this equipment may have ongoing beneficial effects. This clinical trial demon-

strates that the Sun Ancon® Chi Machine® Aerobic Exerciser is an effective adjunct therapy that can be used in the patient's own home.

Secondary leg lymphedema develops from damage to the lymphatic vessels and/or lymph nodes in the leg, groin or abdominal areas. Surgery and radiotherapy related to reproductive, gastrointestinal, urinary or melanoma cancer can disrupt lymph drainage from the limb, resulting in diminished lymph transport (1). Excess lymph load on this compromised system leads to interstitial accumulation and stasis of protein-rich fluid, which provides an ideal environment for bacterial growth and increased susceptibility to infection. The presence of the protein-rich fluid and subsequent inflammatory processes also encourage the deposition of collagen and eventual tissue fibrosis (2), further hindering lymph drainage and flow. Symptoms of secondary leg lymphedema can include altered skin integrity, reduced range of movement, pain, heaviness, tightness, pins and needles, burning sensations and elevated skin temperatures. The combination of swelling and symptoms often has a significant effect on the person's quality of life and ability to perform activities of daily living.

Various treatments currently exist for secondary leg lymphedema, ranging from low

level laser, manual lymphatic drainage, elevation, exercise, compression garments, drugs such as benzopyrones (bioflavoids) and intensive complex decongestive therapy. Although these therapies have been shown to be effective (3-9), their success is reliant on patient compliance and most also require interactions with healthcare professionals. In this era of limited healthcare dollars, promotion of patient independence is encouraged (or needed). However, in concert with evidence-based practice, it is of utmost importance to establish lymphedema therapies that are demonstrated to be beneficial and which can be administered by the patient to help maintain the limb(s) between health professional visits.

This clinical trial tested the effectiveness of a home-based, lymphedema therapy by the Sun Ancon® Chi Machine® Aerobic Exerciser which delivered both elevation and passive exercise to the legs. It is well established that lymph propulsion and clearance is influenced by varying total tissue pressure (10) and that one of the most effective ways of varying tissue pressure is through leg movement. Exercise also stimulates the leg muscles, aiding drainage of both lymph and blood from the limb and the reabsorption of inflammation-causing proteins (11). Elevation can also help in clearing early stage lymphedema. Therefore it was hypothesized that the Aerobic Exerciser would aid fluid drainage from the legs resulting in volume reduction and an improvement in subjective leg symptoms and quality of life.

METHODS

The clinical trial was given ethics approval by the Flinders Medical Centre Clinical Research Ethics Committee, Adelaide, South Australia.

Participants were recruited through the Flinders Medical Centre (FMC) lymphedema, vascular and wound management clinics, local general practitioners and advertising.

Those who participated had a formal objective diagnosis of secondary lymphedema from a general practitioner, a lymphologist, a vascular specialist and/or a wound management clinical nurse consultant. Participants were required to have established (duration greater than 1 year) secondary lymphedema related to previous surgery without other conditions that could cause swelling (i.e., varicose veins). Of those who did participate in the trial, the condition was predominantly associated with cancer surgery related to bowel, cervical, reproductive, prostate or melanoma cancer.

The Sun Ancon® Chi machine® Aerobic Exerciser used in the trial comprised an electric motor coupled to a gear mechanism attached to two molded ankle rests. The patient lies in the supine position (on the floor or firm bed) with the legs slightly elevated and ankles positioned in the molded rests. When the exerciser is switched on, the ankles are moved from side to side (140 times per minute \pm 10%, at a swing angle of 12 degrees) delivering elevation and a low impact, passive exercise to the legs.

Participants used the Sun Ancon® Chi machine® Aerobic Exerciser in their own home, morning and evening for three weeks adhering to the following regime: days 1-2: 5 minutes per session, days 3-7: 8 minutes per session, days 8-21: 12 minutes per session. Each participant was required to fill in a logbook so compliance to the outlined regime could be monitored. All measurements were taken at the Lymphedema Assessment Clinic (FMC) with baseline measurements taken immediately before study commencement, at weekly intervals and at 1 month post-treatment to assess for any long term treatment effects. Where possible, measurements were taken on the same day of the week and at the same time of day.

Objective Measurements

Perometry

The perometer (Pero-systems®, Germany) is a previously validated (12-14) volume measuring system which is based upon a square measuring frame that contains rows of infra-red light emitting diodes on two sides and rows of corresponding sensors on the opposite two sides. The patient sits at one end with the foot resting centrally on an adjustable support. The frame is then moved along the length of the leg from the foot to the upper thigh. The limb casts shadows in two planes and using the cross-sectional information obtained, a computer software program builds up a whole leg volume and circumferential picture (at 4mm intervals) of the entire leg.

Bioimpedance

Body bioimpedance was measured in this clinical trial with an InBody 3.0® system manufactured in Korea by Biospace Ltd®. The Inbody 3.0® is a multi-frequency body and segmental analyzer (5kHz - 500kHz) where the patient stands erect on electrode footplates and holds electrodes in the hands, resulting in eight electrode contact sites. The fixed eight point contact overcomes the problems with variable electrode placement and surface area contact. The multi-frequency technique employed accurately quantifies both total body fluid and extracellular fluid in extremities, having the ability to distinguish the gain or loss of fluid from fat and muscle (15). Previous studies have proven the validity of bioimpedance in measuring body fluids in both healthy adults and lymphedema patients (16-18).

Tonometry

Tonometry measures tissue resistance to pressure, giving an indication of the compliance of the dermis and extent of fibrotic induration in the thigh and calf lymphatic territories (19-20). The tonometer (BME, Flinders Medical Center) consists of a central plunger (1 cm diameter) weighted to a

mechanical load of 275.28 gms/cm², operating through a footplate which rests on the surrounding skin and applies a load of 12.2 gms/cm². Thus, the plunger applies a differential pressure of 263 gms/cm², and the degree of penetration of the plunger (arbitrary units) is measured by a micrometer.

Lymphoscintigraphy

Eight participants from the trial volunteered to undergo lymphoscintigraphy immediately before and after treatment to assess lymphatic transport capacity. Radioactive trisulphide colloid preparation was injected subdermally into the first interdigital space and laterodorsal areas of each foot. Afterwards, the participant was instructed to exercise the legs in a cycling motion in the supine position for 5 minutes. The patient was then scanned with a gamma camera over a 5 hour period to quantify the rate and spread of the radioactivity from the injection site to the inguinal nodes. The participant was also required to fill in an activity sheet at the first visit so that the same activities could be replicated at the second visit (as heavy exercise or long duration walking can influence lymphatic function).

Subjective Measurements

A questionnaire that assessed the participants' subjective leg symptoms, including pain, heaviness, tightness, pins and needles, cramping, burning sensations and perceived leg size was administered prior to trial commencement and then at weekly intervals. Participants were asked to rate their symptoms on a 0-10 scale as used in the McGill Quality of Life Questionnaire, where zero equated to no problem and 10 was rated as the worst imaginable. This scaling system has been previously validated (21-22).

ANALYSIS

Data were analyzed in conjunction with a

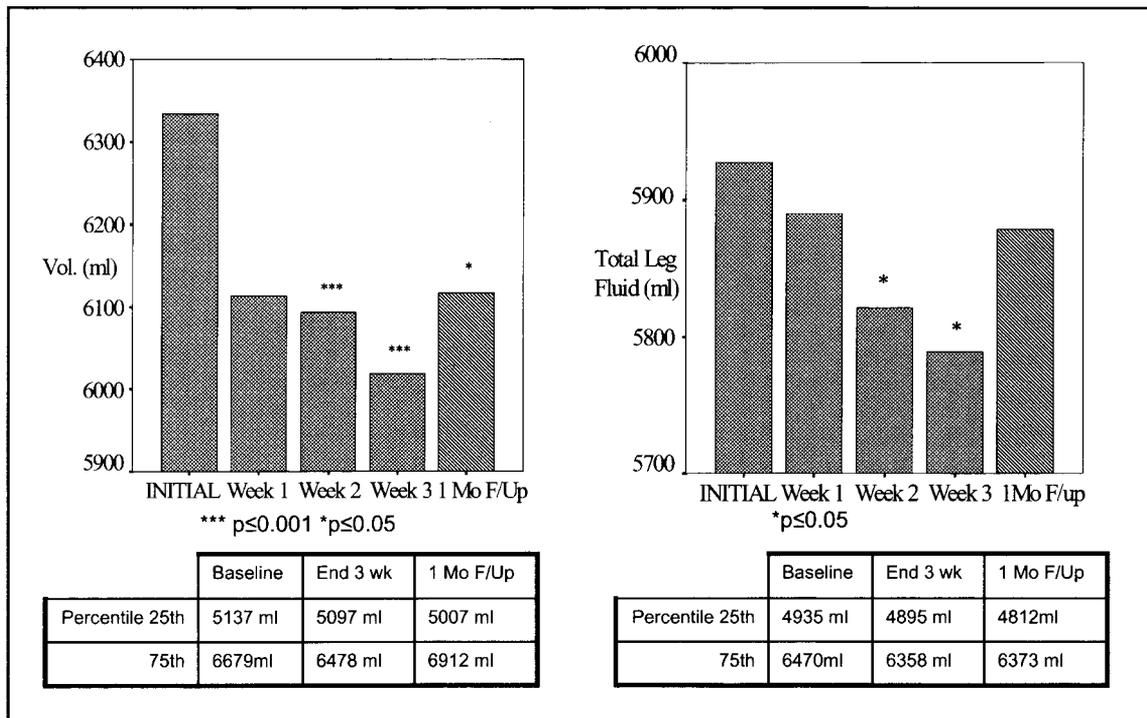


Fig. 1. a-left) Change in total leg volume (ml) over three weeks of treatment and then at 1 month follow up as measured by perometry; b-right) Change in total leg fluid (ml) over three weeks of treatment and at 1 month follow up (1 Mo F/Up) as measured by bioimpedance.

Clinical Epidemiologist using SPSS (version 10.5.5) to determine differences between onset of treatment, the last day of treatment and one month after treatment cessation. As the sample group data were not normally distributed, a two related samples non-parametric Wilcoxon test (Monte Carlo 99%) was used. This test compares the magnitude of differences between pairs, where $p < 0.05$ is statistically significant. Data are presented as median values and quartiles.

RESULTS

Thirty three people with chronic secondary lymphedema participated in the trial, 28 females and 5 males aged 39 - 88 years (mean 59 years \pm 13 yrs), 55% exhibited unilateral swelling and 45% exhibited bilateral swelling. Although a few partici-

pants missed some days in the treatment regime due to sickness, there was an overall 95% compliance rate with the regime.

Leg Changes

There was a statistically significant total leg volume reduction in the affected leg(s) as measured by perometry over 3 weeks (median 330 ml; $p = 0.001$; Fig. 1a). There was some fluid return (median 100 ml) at the 1 month follow up compared to the week 3 time point ($p = 0.12$, n.s.), but this did not return to pre-treatment levels, and volume at the 1 month follow up remained statistically lower than pre-treatment level ($p = 0.032$). In concert with the total leg volume reduction, bioimpedance demonstrated a fluid reduction in the affected leg(s) after three weeks of treatment (median 120 ml; $p = 0.021$; Fig. 1b).

TABLE 1
Subjective Leg Symptoms - Before and After Treatment and at 1 Month Follow up*

Symptom	Initial	Range	Final	Range	p =	1 month	Range	p =
Pain	3.7	1-5.5	2.0	1-2.8	0.04	3.5	1-5.8	0.12
Tightness	6.0	3-7.5	2.0	1-3.0	0.00	5.0	3-7.0	0.00
Heaviness	5.0	2.5-8	2.0	1-4.8	0.00	5.0	3-7.0	0.00
Cramping	2.5	1-2.5	1.8	1-2.0	0.48	2.2	1-2.8	0.50
Pins & Needles	2.7	1-2.5	1.4	1-2.0	0.08	1.7	1-1.8	0.25
Burning feeling	2.5	1-3.0	1.4	1-2.0	0.07	1.6	1-1.8	0.41
Skin dryness	4.0	1-6.0	2.0	1-4.0	0.01	1.0	1-4.5	0.01
Limb size	7.0	5-8.0	5.0	3-6.8	0.00	5.0	3-7.0	0.23

*based upon a 0 - 10 scale where 0 = no problem and 10 = worst imaginable problem

Again, some fluid returned at the 1 month follow up (median 90 ml; $p = 0.137$, n.s.) and this lower level was not significantly different from pre-treatment levels.

There were also statistically significant improvements in subjective leg symptoms, including pain, tightness, heaviness, skin dryness and perceived leg size at week 3 (Table 1). At the 1 month follow up the majority of these symptoms had increased, but not back to original pre-treatment values. Only tightness, heaviness, and skin dryness remained statistically significant at this time point. No significant differences were detected in the leg tissues as measured by tonometry during the trial period.

Whole Body Composition Changes

There was a steady decline in whole body extracellular fluid volume over the three weeks of treatment (median 300 ml; $p = 0.019$; Fig. 2a). Some of the body extracellular fluid volume returned after treatment cessation ($p = 0.89$, n.s.), but not back to original pre-treatment levels, with the difference between pre-treatment and 1 month follow up remaining statistically

significant ($p = 0.039$). Participants also experienced a reduction in body weight (median 0.5kgs; $p = 0.015$; Fig. 2b). Notably, this weight loss also remained stable at the 1 month follow up when compared to end of treatment ($p = 0.98$; significant to initial), even though some fluid had returned to the affected leg(s). Although some of the weight loss could be attributed to the fluid loss from both the legs and whole body, this could also be due to a reduction trend in percentage body fat and body mass index. Decreases in percentage body fat [0.71% ($p = 0.745$, n.s.)] after three weeks of treatment and at the 1 month follow up [0.79% ($p = 0.499$, n.s.)] were not significant. The total group's body mass index showed a downward trend by 0.15 Kg/m² after three weeks of treatment ($p = 0.058$, n.s.). At 1 month follow up, it had not returned to the original pre-treatment levels (data not shown). Changes in both the affected leg(s) and whole body composition were significantly correlated (data not shown).

Lymphoscintigraphy

Of the eight participants who underwent lymphoscintigraphy immediately prior to and

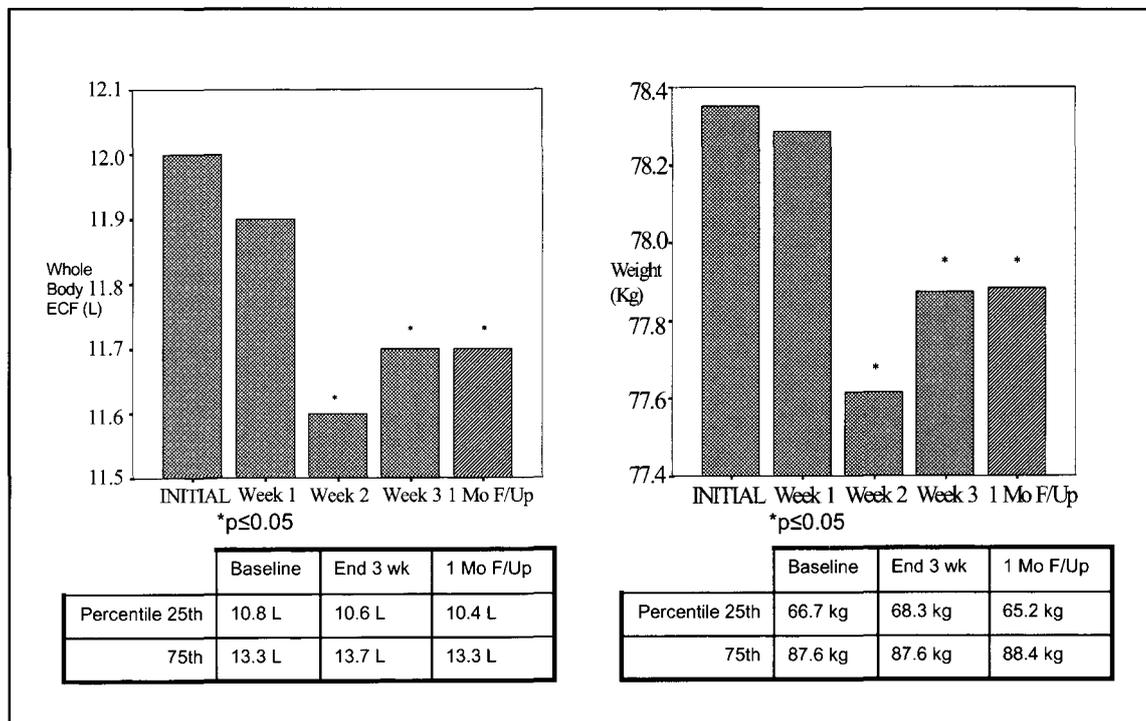


Fig. 2. a-left) Changes in whole body extracellular fluid volume (L) over three weeks of treatment and at 1 month follow up as measured by bioimpedance; b-right) Changes in weight (Kg) over three weeks of treatment and at 1 month follow up as measured by bioimpedance.

after treatment, three participants showed increased lymphatic transport function in the post-treatment scan and MBq count.

Fig. 3 shows an example of a patient who demonstrated improvement in both clinical measurements and lymphoscintigraphy. The post-treatment graph of this patient shows how lymphatic transport was increased (as measured by MBq counts) after 3 weeks of treatment. The participants (n=5) who did not demonstrate an improvement in the clinical trial had notable dermal back flow in both the pre and post scans.

Side Effects

The most commonly reported side effects were knee pain (17%), dizziness immediately after treatment session (8%) and neck pain (10%). A small percentage (8%) of the participants found the ankle moldings to be

uncomfortable on their legs. The neck and knee pain generally occurred in those who had pre-existing conditions such as arthritis. The knee and neck discomfort was eliminated by putting a pillow under these areas to give them support while using the Aerobic Exerciser. Giving participants sheep skin ankle protectors that padded the lower legs alleviated leg discomfort caused by the moldings.

DISCUSSION

Overall the group experienced a statistically significant fluid loss and volume reduction in their affected leg(s). There was also a decrease in whole body extracellular fluid volume. The reduction in fluid volume and body extracellular fluid were strongly correlated. By bioimpedance, there was also a statistically significant weight loss over three

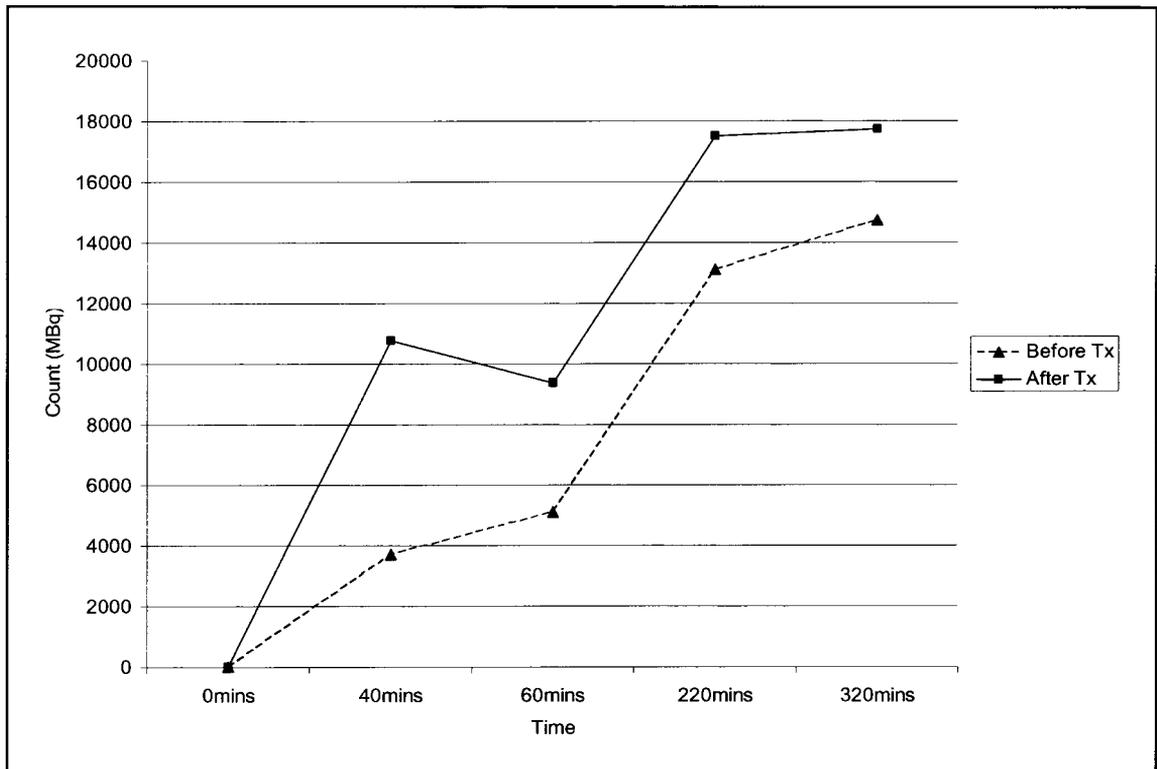


Fig. 3. Lymphoscintigraphy: MBq counts indicating radioactivity transit through the affected leg before and after treatment.

weeks of treatment along with reduction trends in percentage body fat and body mass index. This may be of importance as some people who have lymphedema find it difficult to exercise and therefore control their weight (which puts an extra load on the already compromised lymphatic system). The Aerobic Exerciser provides one way to mimic exercise and lose some weight without the need to undertake strenuous exercise.

With the loss of fluid there were also improvements in perceived leg symptoms. In particular after 3 weeks of treatment there were statistically significant improvements in leg pain, tightness, heaviness, skin dryness and how the participants perceived the size of their leg(s). Symptoms such as cramping, burning feelings and pins and needles did not improve significantly with treatment. Participants indicated on a quality of life

questionnaire that it was easier to undertake physical activities such as climbing stairs and exercising. This resulted in a more positive body image with participants viewing themselves as less impaired and reporting a reduction in depression associated with their condition (data in preparation).

Lymphoscintigraphy performed in 8 participants before and after treatment showed improvement in lymphatic transport to the inguinal nodes in 3; however, the remaining 5 who initially demonstrated significant dermal back flow did not demonstrate an improvement in lymphatic transport. No measurements of the ultimate transport to the central circulation were obtained. This small sample may provide a clue to a possible mode of action for the Aerobic Exerciser in stimulating the lymphatics in those who do not have a major

obstruction but not being able to stimulate the lymphatics in those where there is a significant blockage (as indicated by dermal back flow). In those individuals, the blockage itself may need to be addressed first (maybe by laser or massage) and the Aerobic Exerciser then used as an adjunct therapy. Future studies are needed to examine this possible mechanism and treatment utilization.

Although leg volume, total leg fluid, and whole body extracellular fluid increased after 1 month of treatment cessation, no parameters returned to original pre-treatment levels. This observation and the fact that some parameters such as total leg volume and whole body extracellular fluid volume remained statistically lower than pre-treatment levels at the 1 month follow up may suggest that the Aerobic Exerciser has beneficial effects that last at least one month. However, it is felt that for optimal results the machine should be used on a continual basis for leg maintenance. Although there were some side effects from using the machine, these only occurred in a relatively small proportion of participants and generally occurred in those with pre-existing joint/bone problems. Overall this form of therapy was well received and tolerated.

In conclusion, the Sun Ancon® Chi Machine® Aerobic Exerciser was shown to be effective in reducing total leg volume, leg fluids, whole body extracellular fluid, and weight as well as improving subjective symptoms of the participants. These results are encouraging as lymphedema is a chronic condition that worsens over time (23) and needs constant maintenance. Lymphoscintigraphy suggests a possible clue as to a mode of action in stimulating non-obstructed lymphatics. This effect warrants further investigation in groups with and without significant dermal back flow problems.

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