Placebo controlled trial of mild electrical stimulation

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Abstract

Background: To find ways to improve lymph flow especially when it is hot and or dry/humid when lymph loads are higher than normal. *Aims:* To determine if mild electrical stimulation of the epifascial compartment of lymphoedema limbs can improve lymphatic drainage when used in conjunction with garments. *Methods:* Patients were entered into a self-maintenance group and then allocated to an active or placebo group. The active group received 13 treatments of mild external electrical stimulation, while the placebo group had no detectable electrical stimulation. *Results:* The self-maintenance group showed increases in leg and truncal fluids (300mls), while both the active and (surprisingly) the passive treatment group showed statistically significant reductions in leg fluids of 200mls (<0.001) and 50mls (<0.001) respectively, compared to the self-maintenance group over the four weeks. Total limb volumes showed similar trends. Pain, heaviness, tightness and perceived leg size statistically significantly improved over the four-week active and placebo treatment periods. *Conclusions:* Mild external electrical stimulation of lymphatics has a positive effect on lymphoedema compared to current best practice self-management. *Declaration of interest:* This study was supported by Bodyflow International through Flinders Partners.

Key words

Secondary lymphoedema
Electrical stimulation
Garments
Limb volumes
Subjective indicators

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Secondary lymphoedema of the leg(s) is a chronic and progressive condition which is estimated to affect approximately 20–55% of patients post infection, trauma or cancer (Williams et al, 2005). Secondary lymphoedema results in excess fluid accumulation in the interstitial space, detrimental tissue changes and limb swelling, all of which can lead to both physical and psychosocial morbidity. Due to its negative impact upon the individual and the fact that it will worsen over time if left untreated (Casley-Smith and Casley-Smith, 1994), it is important

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to explore treatments which have the ability to influence lymphatic drainage, reduce swelling and improve the way in which the limb feels.

One treatment which may have the ability to help secondary lymphoedema is the Bodyflow® system (Bodyflow Pty International Ltd), which uses electrical current to stimulate the smooth muscles of lymphangion units, and to a lesser extent, the skeletal muscles of the lower limb. Such muscle stimulation has been shown to change interstitial tissue pressure which helps in lymph absorption (Mortimer, 1995; Weissleder and Schuchhardt, 2008), and increase lymph flow (Mazzoni et al, 1990; Havas et al, 2000) and the transport of inflammatory proteins (Olszewski and Engerset, 1998). While these studies were conducted on subjects without lymphoedema, they do provide an indication of the likely effect of electrical stimulation in lymphoedema. This current study is the first investigating the effect of electrical stimulation in patients with leg lymphoedema.

Given the studies on normal limbs (Mazzoni et al, 1990; Mortimer 1995; Olszewski and Engerset, 1998; Havas et al, 2000; Weissleder and Schuchhardt, 2008), the research team postulated that the bimodal muscle stimulation delivered by the Bodyflow system in combination with traditionally used compression garments would result in a

reduction in limb fluid and limb volume, reduce subjective symptoms, including heaviness, tension and pain in the limb, and improve quality of life (QoL), as well as the patient's ability to undertake activities of daily living.

The relative and comparative partitioning of the effect of the Bodyflow treatment on the smooth and skeletal musculature was not explored. However, the current selected and its amplitude were such that there was no overt (movement detected) effect on the skeletal musculature, and while the authors cannot be sure, it is likely that the prime effect may be on the musculature of the lymphatics. This affects the contraction of the lymphangions, causing it to be more powerful than the normal tonic contractions of lymphangions. The exact nature of the change in the intensity of contraction is uncertain, but a study with other stimuli to slow or poorly functioning lymphatic lymphangions showed an increase in the strength of contraction and the flow of lymph through them (McMahon et al 1994). However, the probable effect on other musculature cannot be discounted.

Methodology

The hypothesis that the Bodyflow electrical stimulation technique could achieve a reduction in total limb fluids and improve subjective symptoms was tested in a prospective randomised controlled trial where participants received either active treatment plus a class II compression garment, or placebo treatment plus a class II compression garment. Garment-wearing was chosen as it was not expected that the additional facilitation of lymph load clearance by the external electrical stimulation would be enough to overcome high outflow rates (and poor return rates) from the dilated venous system and the lower uptake via the engorged lymphatic collector system, whose lymphangion valves may no longer be patent.

Recruitment

Ethics approval was obtained from Flinders Clinical Research Ethics Committee (#2004-5.141). Trial

participants were recruited via the lymphoedema assessment clinic at Flinders surgical oncology department. Recruitment was undertaken by a research nurse and research officer experienced with lymphoedemas. Once recruited, a diagnosis of secondary lymphoedema was confirmed by a healthcare professional based on the participant's medical history and physical examination. Patients who had associated leg swelling unrelated to secondary lymphoedema (i.e. venous oedema), who had recently had treatment or an episode of cellulitis, or who had active cancer or deep vein thrombosis, were excluded from the study.

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A total of 29 patients met the criteria for entry into the trial. Most of those who declined participating did so because of the duration of the trial (three months), the need to attend the clinic to take measurements, or because they did not like the idea of electrical currents being applied to their body.

For recruitment into the trial, the participant was required to have a minimum total fluid leg volume difference of >200mls and a diagnosis of secondary lymphoedema. Fluid distribution in the legs was obtained by 'body composition analysis' (InBody 3.0). Extremely large limbs were not used in this trial due to issues of lymphangion patency — if their valve flaps did not appose, no amount of stimulation would improve flow. This also explains the additional use of garments, so that lymphatic patency could be certain.

Randomisation was decided by the flip of a coin. The randomisation

to either placebo or active treatment had to be carefully described to the participants since those who previously received regular treatment from a therapist and who were allocated to the placebo would initially be without active treatment (with the exception of a garment) for up to three months. All participants had to be willing to wear Sigvaris compression garments and sign a written consent form. The trial was supported by Bodyflow® International (Melbourne, Victoria) and was administered and managed through Flinders Partners to maintain independence.

Trial protocol

The Bodyflow trial for each individual spanned three months, with the first month given to a self-maintenance phase (current non-interventional best practice) where a healthcare professional would educate each participant on skin care, advise on exercise and techniques for cooling down afterwards, and demonstrate how to perform self-massage on a daily basis for approximately 15–20 minutes. Education by the healthcare professional was conducted in the first days of the initial week and reviewed at the end of each week during the self-maintenance phase. This is current best practice in the authors' clinic. While all patients (29) who finally completed the trial underwent the initial self-maintenance phase, only every second patient received the full measurement protocol during the maintenance phase. Every second patient was measured fully (the first being randomly determined) to provide balance to the sample calculations. Three of these datasets were incomplete and four patients did not complete all measures, making a total of 12 patients in the self-maintenance programme. This four-week self-maintenance phase was followed by a four-week washout period and then a four-week machine phase, for which the participant was randomised to either a placebo or active treatment machine.

During the placebo or active treatment machine phase, all participants were attached to a body flow machine with the abdominal

reference plate electrodes positioned horizontally over the abdomen and below the line of the umbilicus. In addition, four electrodes were attached to the affected leg, on the medial and lateral mid-calf, and on the medial and lateral mid-thigh (each pair consisting of a cathode and anode — driving and receiving electrode — with the driver being placed most distal). For the active treatment group, the milli amperage applied to the leg electrodes was set according to the individual participant's comfort and tolerance. Therefore, there was a variation in these settings, going as low as 8mA and as high as 32mA, with an average of 23.3mA over the active treatment group. There was no observable physical difference between the active and placebo machines. For the placebo group the amplitude

dial (although not relevant), was set between 26 and 32mA, an arbitrary setting to give an indication (although false) of a current being applied to the limb. Throughout treatment the participants in each group were positioned in a supine or semi-recumbent position. Active or placebo treatment lasted for 30 minutes. The treating clinician was also blinded to the treatment programme.

Treatment sessions were divided over the month into four treatments on the first week, and three treatments per week over the following three weeks, a total of 13 treatment sessions. With the exception of the first week, participants were instructed to apply their compression garment directly after each treatment session. It was

impossible to apply any blinding to the treatment programme as far as the patient was concerned, but to aid in the perception patients were told that the application of the electrical treatment may only be felt as a slight tingle or not at all.

Each participant was measured for Sigvaris, class II compression garments at the start of the machine phase in order for the garments to be available for fitting at the end of the first week of treatment. Those participants who required custom-made Sigvaris compression garments were measured before the machine phase trial started to ensure that all patients, no matter what type of garment was used, had them available and fitted at the end of the first week. Although a potential confounder, a comparison between the made-to-measure garment subgroup and the off-the-shelf garment subgroup showed no significant differences in the main measurement parameters. The trends, however, indicated that a larger subgroup size may show that the made-to-measure garments had a greater supportive impact on the Bodyflow treatment than the off-the-shelf ones.

The start of the trial was arranged to coincide with the arrival of the custom-made garments (while the off-the-shelf garments were available immediately, it often took a week to obtain the made-to-measure ones. Thus, no garments were worn by either group in the first week). Participants were also instructed on the application of garments, their care and washing instructions in accordance with the manufacturer's directions. To monitor compliance, each participant was given a log book to record the frequency and duration of time each day that they wore their garments.

At the completion of the four-week treatment (machine) phase, participants were encouraged to continue wearing their compression garments and to postpone any changes in physical activities or start any other treatment for a month, at which time their final measures would

Table 1

Patient details: self-maintenance, active and placebo groups

	Self-maintenance	Active group	Placebo group
Background details:			
Number	12	16	13
Gender			
▸▸ Female	10 (83.3%)	13 (81.3%)	11 (75.9%)
▸▸ Male	2 (16.7%)	3 (18.8%)	3 (23.1%)
Age	57.8 years (±14.2) (25–78 years)	57.3 years (±11.6) (40–79 years)	60.3 years (±15.1) (25–76 years)
Medical history:			
Hypertension			
▸▸ Medicated	5 (41.7%)	5 (31.3%)	4 (28.6%)
▸▸ Unmedicated	2 (16.7%)	1 (6.3%)	3 (21.4%)
Lymphoedema details:			
Affected leg			
▸▸ Right	3 (25.0%)	6 (37.5%)	1 (7.7%)8 (61.5)
▸▸ Left	5 (41.7%)	5 (31.3%)	4 (30.8%)
▸▸ Bilateral	4 (33.3%)	5 (31.3%)	
Lymphoedema duration	146.4 months (+117.3) (2–384 months)	105 months (+79.1) (2–257 months)	186.7 months (6+155.3) (6–528 months)
Lymphoedema status			
▸▸ Mild	4 (33.3%0	5 (31.3%)	2 (14.3%)
▸▸ Moderate	6 (50.0%)	3 (18.8%)	10 (71.4%)
▸▸ Severe	2 (16.7%)	8 (50.0%)	1 (7.7%)

be taken to evaluate the longer-term benefit of the treatment. Participants who had received the placebo were offered the opportunity to receive the active treatment at a time mutually convenient to the patient and the clinic schedule, but they are not included in this study report.

Complete patient details are provided in *Table 1*.

Measurements

Objective measurements were made with previously validated equipment and techniques and consisted of:

▸ Bioimpedance (Inbody®, Korea) to measure whole body composition and limb fluid volume (Mikes et al, 1999; Cornish et al, 2001; Moseley et al, 2002)

▸ Perometry (Perosystems®, Germany) to measure whole limb volume (Leduc et al, 1992; Stanton et al, 1997; Labs et al, 2000)

▸ Tonometry (Biomedical Engineering, Flinders Medical Centre) to measure fibrotic induration of the tissues (Clodius et al, 1976; Stanton et al, 2000).

Each measurement of bioimpedance (fluids), perometry (leg volumes) and tissue tonometry (fibrosis) was taken twice and averaged (sometimes three times if the first two were greatly different) at each assessment.

Subjective symptoms including pain, heaviness, tightness, pins and needles, burning sensations, cramping, perceived limb size and range of movement and ability to undertake activities of daily living were rated on a 10-point Likert scale, which had been used and validated for similar sample groups by the authors. Quality of life assessment was based upon the McGill Quality of Life questionnaire (Cohen et al, 1997).

In the self-maintenance phase, all objective measurements were made at the beginning (baseline) of the trial and at the end of weeks 1, 2, 3 and 4. In the active/placebo phase, all objective measurements were taken immediately before treatment (baseline) and following the first treatment, before the
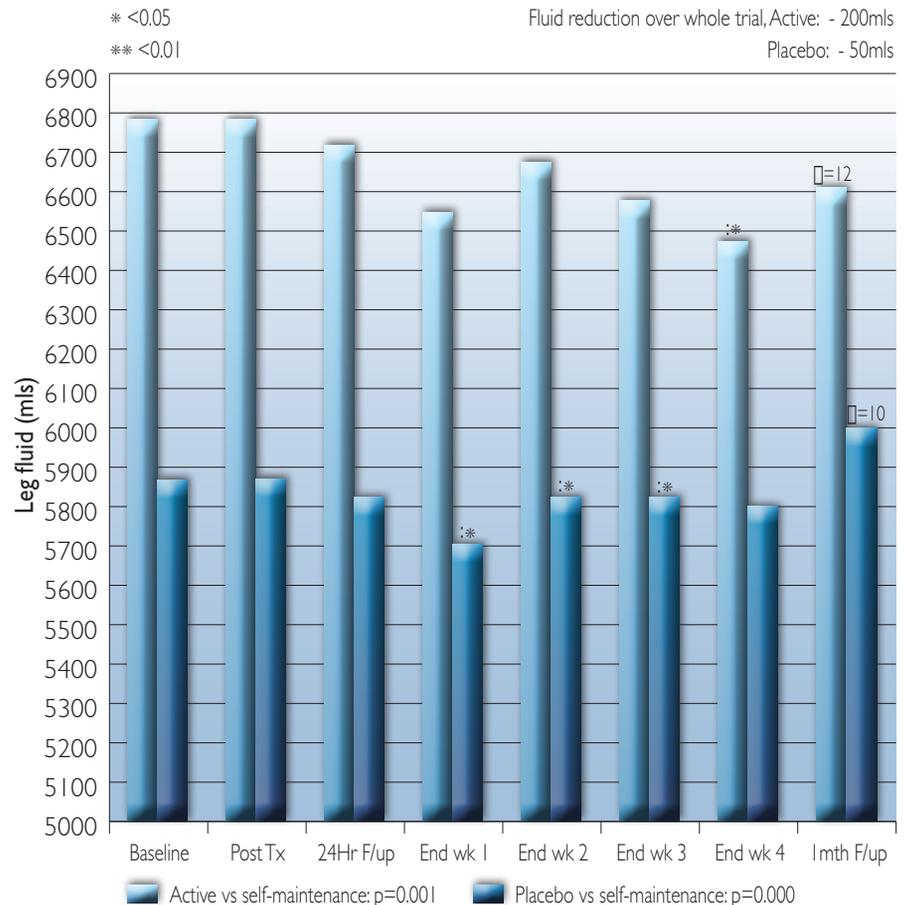

Figure 1. Change in leg fluid volume (measured via bioimpedance) over time — active treatment and placebo treatment.

second treatment (at 24 hours follow-up), and at the end of the first week. After this objective measurements were taken at the beginning and end of each treatment week and then at one-month follow-up to determine whether there had been any long-term benefits. A number of patients (seven) did not attend one-month follow-up despite repeated calls, thus weakening this aspect of the study.

Subjective measurements (symptoms and quality of life) were made at entry into the trial (baseline) and at the end of the trial (completion of active or placebo treatment).

SPSS version 14 was used to record and analyse all data.

Results

Fluid volume changes (*Figure 1*)

Self-maintenance phase

Over the four weeks of self-maintenance for the 11 valid subjects

(one had an incomplete dataset and this was excluded) in this group, there was an increase in average limb fluid volume of 300ml (measured by bio-impedance), but this did not represent a significant change (p=0.158) in the fluid volume of the affected limb, although there was what the authors felt to be a biologically important gradual increase in limb volumes of 4.7% over the four-week maintenance period, compared to the baseline measurement. Of course these volume changes must be tempered by the fact that there may have been changes to musculature over this time associated with increased activity or exercise.

Active treatment group

At the end of the fourth week of active treatment there was a statistically significant (p< 0.01) reduction in fluids (measured by bioimpedance) of 200ml compared to the baseline in the active group, and a 500ml (<0.001) reduction

compared to the self-management group at the same time. The majority of patients in the randomly allocated active group were previously part of the self-management group but not all of them were measured fully, as part of the self-management programme. However, a significant proportion (120mls) of this loss was regained at the one-month follow-up — such that the difference was no longer statistically significant. Maintaining an achieved outcome in the post-treatment phase is an obvious difficulty.

Placebo treatment group
At the end of the fourth week of passive treatment there was a statistically significant (p< 0.05) reduction in fluids (measured by bio-impedance) of 50ml compared to the baseline in the active group and a 350ml (<0.001) reduction compared to the self-management group at the same time. The majority of patients in the randomly allocated passive treatment group were previously part of the self-management group but, as before, not all of them were measured fully as part of this self-management programme. However, all of this loss and a biologically important but non-statistically significant gain (200ml) was observed at the one-month follow-up compared to the end of the trial.

Total limb volume changes
Total limb volume changes were measured using perometry, which encompasses all changes within the limb including changes in muscularity, fat mass and fluids (*Figure 2*).

Self-maintenance group
Perometry measurements (which show total limb volume changes) at the same time and similar time intervals showed an 8ml increase (p=0.324). However, it must be remembered that perometry cannot measure limb volume changes in the most proximal part of the thigh. It is thus likely that this is the reason why perometry did not mirror the 300ml increase in fluid shown by bio-impedance.

Active treatment group
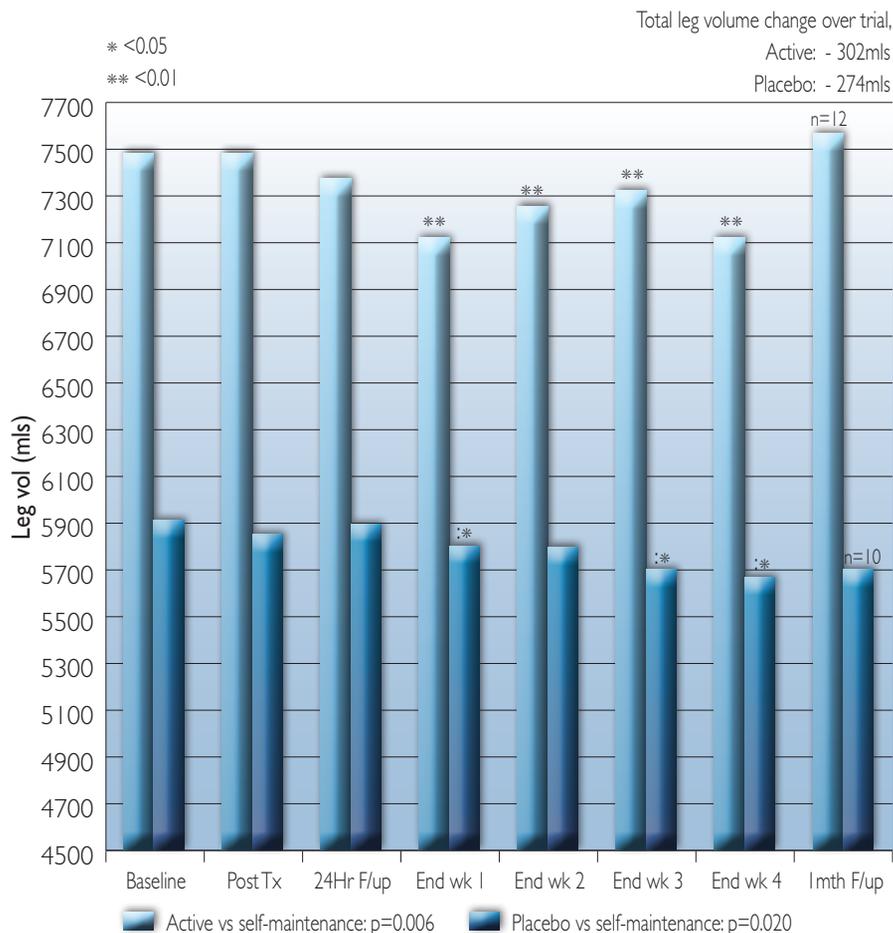Over the four weeks of the active

Figure 2. Change in total leg volume (measured via perometry) over time — active treatment and placebo treatment.

treatment group there was a total limb fluid volume reduction of just over 300mls. This was statistically significantly better than the self-maintenance phase from the end of the first week of the active treatment of the study (p=0.006), and was statistically significantly better than the pre-treatment baseline for the active group (p<0.01) for all four treatment weeks. While it is a weakness of the study that not all of the participants were measured fully as part of the self-management programme, this does not invalidate the findings due to the nature of the selection process, i.e. random). Total limb volumes (measured by perometry) also showed a 300ml average reduction over this time, but also returned to be non-significantly different from pre-treatment values at the one-month follow-up. These changes mirrored the fluid volume change patterns as measured using bioimpedance.

Placebo treatment group
Over four weeks of placebo treatment there was a 50ml reduction in limb fluid volume (measured by bio-impedance) and a surprising 274ml average reduction in total limb volume (measured by perometry). Like the active group, this was statistically better from the end of week 1 (p<0.01) until the end of the trial, and it was statistically significantly better than the self-management phase (p=0.02). However, in the active treatment group, the good outcome was lost at follow-up.

Truncal fluid changes
These values were recorded as part of the body composition picture and measured by bioimpedance. While there was a tendency to increase (300mls) over the self-maintenance period, this represented only a 2% change in the total truncal volume. Interestingly, there were similar (non-

significant) although lesser increases in the active treatment group (100mls) and placebo treatment group (200mls), the latter of which was only significant at the end of week 4 (p<0.01).

Tonometry
Tonometry is used as a surrogate measure of the extent of induration (fibrosis) in the major lymphatic territories.

There were no significant differences in induration of any of the lymphatic territories over the self-maintenance, active or placebo treatment phases, with the exception of the calf territory of the affected limbs at the end of the four-week active treatment, where there was a softening from 4.3 (+1.2) units to 5.1 (+1.3) (p<.05).

Subjective symptoms
Self-maintenance group
There were no significant changes with the exception of a perceived general hardening of the tissues of the affected limb with a change from 4.6 (+2.8) to 2.8 (+3.1) units on the 10-point Likert scale (p<0.049).

Active treatment group
There were no significant changes with the exception of:
- Pain which reduced from 2.1 (+3.1) to 0.3 (+0.8) (p<0.04) over the four weeks of treatment
- Heaviness which significantly reduced after the first treatment

from 3.6 (+2.5) to 2.3 (+/- 2.4) (p=0.05), and which remained improved but was only again significant at the end of the trial (1.0 +/- 1.1) (p<0.003), indicating an almost complete absence of pain in many patients
- Tightness which reduced from 2.8 (+1.8) to 1.0 (+/- 1.1) (p<.05) over the four-week period
- Perceived leg size which reduced from 6.0 +/- 2.8 to 3.8 +/- 3.1 (p<.05) over the four weeks, and perceived range of movement which improved within 24 hours of the first treatment and held that improvement over the four weeks of the trial (p<.01).

Placebo treatment group
Interestingly, there was a range of unexpected improvements in various subjective parameters in this group, including pain, heaviness and tightness and perceived leg size at the end of the four weeks of placebo, all of which were significant (p<0.05).

Quality of life
While there were trends in most measures of the quality of life of those in the active treatment group, there were no statistically significant improvements. Although some approached statistical significance (and would likely to be so with a larger sample size), it seemed from patient comment that the changes were practically significant for some of the individual patients. A larger sized group

would see these as being significant statistically.

There were no significant changes or trends in the quality of life for the placebo treatment group.

Weekend effect
Weekends were characterised by no active or placebo treatment, just wearing compression garments. Although patients reported a high level of compliance (approximately 75% and 80% of the total weekend time respectively for the active and placebo treatment group) of wearing garments, there were indications at the end of the trial (when some patients were followed up) that this was often not so. While a complete statistical analysis was not undertaken on this data due to its potential weakness, there seems to be a trend in the active group that leg fluid volumes (mirrored by total leg volumes) continued to improve, while in the placebo group there was an accumulation of fluids, especially in the second and third weekends. Interestingly, when leg fluid volumes are down, truncal fluids are higher, perhaps indicating a link here (*Table 2*), which may be related to the ability to clear fluids (which have left the limbs and

Table 2

Weekend effect: average change in leg fluids, total volume and trunk fluid over each weekend

	Weekend 1	Weekend 2	Weekend 3
Active			
Leg fluid	+80 (+/-15) mls	-140 (+/-34) mls	-10 (+/-15) mls
Leg volume	+102 (+/-32) mls	-176 (+/-51) mls	-70 (+/-27) mls
Trunk volume	+150 (+/-35) mls	+350 (+/-104) mls	+400 (+/-210) mls
Placebo			
Leg fluid	+105 (+/-17) mls	+60 (+/-35) mls	+20 (+/-15) mls
Leg volume	+100 (+/-21) mls	+79 (+/-24) mls	+86 (+/-56) mls
Trunk fluid	+275 (+/-45) mls	+175 (+/-62) mls	+100 (+/-102) mls

entered the deep trunkal lymphatics) from these vessels in the abdominal and thoracic areas. These major lymphatic collectors are potentially capacitance vessels, which in the shorter or longer term may hold lymphatic fluid in them as it passes from the legs to the exit point of the ductus. Of course, any additional mesenteric lymph load may slow down lymph clearance from this area, and perhaps have an impact on its clearance more distally from the limbs. It is an area which needs significant further research to better establish linkages.

Discussion

There must be a continuing search for other strategies to help improve lymphatic drainage. One possible strategy is to make the existing (or remaining) lymph collectors work harder and thus carry a greater lymph load. Since there are both myogenic and neurogenic factors affecting lymphangion (the structural and functional unit of the lymphatic system) contractility, in the authors' opinion benefit may be gained from external electrical stimulation. This study investigated this possibility.

The background details of the self-maintenance, active and placebo groups demonstrate that they were fairly comparable, that the participants had longstanding lymphoedema and that there was a mixture of mild, moderate and severe lymphoedema within the different groups. The four-week self-maintenance phase resulted in an increase in all objective parameters including leg fluid (300mls), leg volume (8mls) and truncal fluid (300mls). This is in comparison to both the active and placebo groups, who had a significant reduction in leg fluid (200mls and 50mls respectively) and leg volume (302mls and 274mls respectively). The reductions in both the leg fluid and total leg volume in both the active and placebo groups were also significant in comparison to the self-maintenance phase. This is important as it indicates that current best maintenance leads to a slight worsening of the condition, while the active treatment (Bodyflow and compression) and the placebo (compression only) both resulted in control gains.

In contrast, the active group experienced a reduction in truncal fluid (200mls), while both the placebo and self-maintenance group experienced an increase in truncal fluid (200mls and 300mls respectively).

Since there are both myogenic and neurogenic factors affecting lymphangion (the structural and functional unit of the lymphatic system) contractility, in the authors' opinion benefit may be gained from external electrical stimulation.

The reduction in truncal fluid in the active group may be related to the pulsating suction cups applied to the lower abdomen region, which in the first author's opinion may help to clear fluid through this region. At one-month follow-up there was an increase in leg fluid and volume and truncal fluid in both the active and placebo groups, and in some patients in the trial these parameters did return to baseline, indicating that ongoing treatment is important in secondary lymphoedema. The changes in all groups of the truncal fluids (especially over weekends) are interesting, and should be explored further as they may have a strong influence on fluid clearance from the legs.

Other parameters such as weight, tonometry and blood pressure underwent little change in the self-maintenance group. In the active group there was a non-significant reduction in weight (0.6kgs) and a significant improvement in the tonometry reading in the calf region (indicating less fibrotic induration), which was maintained at the one-month follow-up measurement. The placebo group also experienced a non-significant reduction in weight (0.4kgs) and a non-significant improvement in the tonometry reading taken in the calf region. However, the improvement in fibrotic induration in the calf region was not maintained

in the placebo group at one-month follow-up.

With regards to subjective symptoms, the self-maintenance group only experienced a significant improvement in perceived tissue hardness.

Both the active and placebo groups experienced a significant improvement in pain, heaviness, tightness and perceived limb size, while only the active group had a significant improvement in limb range of movement, and the placebo group had a significant improvement in pain, heaviness and tightness and perceived leg size.

The reduction in pain in both the active and placebo groups was significant both statistically and practically and should not be ignored. Even if this were the only improved parameter, its reduction is important for the individual.

Neither group showed significant improvements in summated quality of life, but both groups did show some change in some of the parameters. Larger sample sizes would see some of these becoming statistically significant.

In the active group, improvements in how clothes fitted, self-consciousness, nervousness, depression related to the condition, control over their life and feelings of being supported were observed.

In the placebo group, improvements included ability to sleep, self-consciousness, impact upon daily life, job ability, nervousness and control over their life. Given the fact that this is only placebo these outcomes are interesting and relevant and could be further explored.

Overall, the treatment group experienced a greater reduction in excess leg fluid and total leg volume, with the achieved reductions (20–30%) being comparable to what can be achieved by pneumatic pump therapy (Bergan et al, 1998).

The active group also experienced a reduction in truncal fluid, which did not

occur in either the self-maintenance or placebo group.

Both the active and the placebo groups experienced improvements in subjective symptoms plus quality of life and activities of daily living issues. This is potentially an interesting area to debate, as it is not the first time when placebo effects have been shown to be very strong (Begley, 2008), although in this case we must indicate that the 'placebo group' were fitted with stockings, so in reality we are measuring the effect of support garments alone in this instance. The similar improvements in the placebo group is most likely to be related to lying in the supine position for 30 minutes (and hence the legs are not in a dependent position), in combination with wearing class II compression garments, with compression being shown to decrease the amount of interstitial fluid formation and to prevent blood and lymph backflow (Yasuhara et al, 1996), in addition to improving the reabsorption of colloid proteins (Leduc et al, 1990).

Conclusion

Our current best practice of self-management of a chronic lymphoedema limb results in some worsening of the condition, both objectively and subjectively. This study has demonstrated the treatment of leg lymphoedema with the Bodyflow system (which delivers a mild external stimulation to the musculature of collecting lymphatics and possibly the body's skeletal musculature), in addition to wearing class II compression garments, results in statistically significant and important practical and biological reductions in leg fluid and volume, truncal fluid and fibrotic induration (in the calf region).

Treatment also resulted in some subjective improvements, but these were not always statistically significant. It was also clear that control generally lessens over a weekend when treatments are not applied, although as the treatment programme progressed the weekend effect was not as marked. The placebo treatment also achieved good outcomes over the self-maintenance programme. Given that

the placebo group wore garments after each treatment, this group's outcomes may be an indication of the effect of garments alone. In view of the fact that some individual cases (longer term lymphoedemas) gained better objective and subjective outcomes than shorter term ones, there may be some benefit in follow-up of chronic long-term patients. Given the objective and subjective trends, longer treatment periods may achieve better outcomes. A larger scale trial is warranted. JL

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