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ENDERMOLOGIE® (WITH AND WITHOUT COMPRESSION BANDAGING) – A NEW TREATMENT OPTION FOR SECONDARY ARM LYMPHEDEMA

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ABSTRACT

Two treatment protocols are presented using the LPG® Endermologie® system in combination with compression bandaging as a new treatment option for secondary arm lymphedema. Both protocols were applied 4 days a week for 4 weeks but differed in Trial II in time spent clearing the regions of the trunk adjacent to the swollen limb and the addition of a larger treatment head so that a greater area could be covered more quickly. The first protocol involved 24 women and the second involved 10 women. At the end of the treatment period, both protocols demonstrated overall reductions in limb volume (134mls; 18.3% p = 0.000 and 185mls; 28%, p = 0.002), limb fluid (182mls; 28%, p = 0.000 and 216mls; 33%. p = 0.014), truncal fluid (342mls; p = 0.002 and 290mls; p = 0.066), improvements in fibrotic induration in some lymphatic territories, and significant improvements in subject reporting of heaviness, tightness, tissue hardness and limb size. Trial II demonstrated additional benefits in terms of reduction in whole arm volume at 24 hours, improved fluid and arm volume reductions, and a significant improvement in subject reported arm range of movement. The additional time spent clearing the regions adjacent to the swollen limb in the second protocol appears to produce an increase in limb volume and limb fluid loss compared to the original treatment protocol.

Keywords: Lymphedema, mechanical massage, objective outcomes

Secondary arm lymphedema still remains a problem for those who have undergone surgery and/or radiotherapy for breast cancer, with a recent review stating that in excess of 30% (1) of women who have undergone such treatment will go on to develop lymphedema. It is known that secondary lymphedema is chronic in nature (2) and therefore there is a continual focus on establishing therapies which will not only reduce the limb swelling but also the detrimental tissue changes and the accompanying subjective symptoms. One therapy is practitioner applied massage (manual lymphatic drainage, MLD), which has been shown to vary total tissue pressure, increase lymphatic transport and soften fibrotic induration (3,4). Given that MLD practitioners are not always available, the focus of this trial was to test the effect of mechanical massage delivered to the limb via the LPG® Endermologie® system. This system involves two motorized, cylindrically shaped skin rollers which are applied to the limb by an appropriately trained therapist and which picks up and massages the skin inside the

TABLE 1
Treatment Time and Protocol

	Trial I	Trial II
Treatment Time	25 minutes	30 minutes
Treatment	Ipsilateral posterior thorax and lateral side, upper arm, forearm, hand (if involved) and then reversed.	Ipsilateral to contralateral axilla, posterior thorax and lateral side, upper arm, forearm, hand (if involved) and then reversed. Extra time spent clearing posterior thorax at end of treatment. Slightly bigger treatment head used on thorax and upper arm resulting in a greater surface area being massaged.

treatment head. Pilot studies of this equipment have shown that it improves superficial lymphatic drainage and lymphatic transport capacity (5), decreases fibrotic induration (6) and functional discomfort (7). Therefore it was postulated that this type of massage would result in arm fluid and volume reductions and improvements in fibrotic induration and reported subjective symptoms.

METHODS

Before trial commencement the study was given ethics approval by the Flinders Medical Centre Clinical Research Ethics Committee, Adelaide, Australia and informed consent was obtained from each participant.

Two trials were undertaken using the same LPG® Endermologie® system applied over the same duration (4 weeks) and using the same measurement schedule. Participants in both groups were recruited through the Flinders Medical Centre Lymphedema Assessment Clinic (Adelaide, Australia). Inclusion criteria included the presence of established fibrotic induration (>1 yr) of the major arm lymphatic territories (detected by tonometry), unilateral secondary arm lymphedema related to previous breast cancer treatment (surgery + radiotherapy + chemotherapy) and a volume difference of >200mls (determined by perometry). Those who had underlying primary lymphedema, recurrent cancer, cellulitis or had received treatment in the last month were excluded from the trial.

Both trial groups had the LPG® Endermologie® system applied to the affected arm and adjacent areas by a trained Occupational Therapist four days a week for four weeks (resulting in 16 treatment sessions in total). Immediately after each treatment session, compression bandaging consisting of a gauze sleeve, high density foam rubber and 2-3 layers of short stretch bandaging was applied to the arm. Participants were asked to wear the compression bandaging over night (if tolerated) and to fill in a log book so compliance could be monitored. Compression bandaging was considered to be important in order to gain the greatest reduction and importantly to maintain LPG treatment associated reduction. However, compression bandaging was not worn over the 3 days of non-treatment, which generally encompassed the weekend. This gave participants time to undertake activities which were restricted while wearing the bandaging and gave the skin the opportunity to be uncovered. At the end of 4 weeks of treatment each woman was

TABLE 2
Participant Characteristics

	Trial I	Trial II	p
Number	24	10	0.005
Age (yrs)	63.3 ± 10.7 (38 - 84yrs)	60.3 ± 7.6 (45 - 72yrs)	0.818
Surgery (%)			
Partial Mastectomy + Axillary Clearance	37.5	20.0	0.027
Total Mastectomy + Axillary Clearance	62.5	80.0	
Received Radiotherapy (%)	83.3	90.0	0.313
Time since onset of LO (mos)	30.6 ± 43.2 (2-192 mos)	24.2 ± 24.1 (2-60 mos)	0.523
Arm Fluid volume at baseline (Mean) (± S.D.)	2,207 ml (± 434)	2,438 ml (± 399)	0.982

encouraged to purchase a new compression garment for the affected arm and to continue self- maintenance techniques (predominantly skin care and self massage) over the next 1 month period. Measurements were taken at baseline, directly after the first treatment session, 24 hours after the first treatment session, at the beginning and end of each treatment week and at 1 month post treatment.

The two trials differed slightly in the duration of the treatment given at each session and the treatment technique (summarized in *Table 1*). At the end of the first trial (n=24) it was found that although the treatment technique did result in significant overall volume reductions, there was a transient increase (not significant) in the upper arm volume after the first massage and at 24 hours follow up (as measured by perometry, see results section). This indicated that perhaps fluid was not adequately draining through this area and based upon this, a second pilot study (n=10) was undertaken with a slightly different treatment technique emphasizing clearance of the root of the limb and its adjacent trunk, to try and negate these increases.

Measurement

Measurements were made using validated techniques and equipment including multi-frequency (5-500Hz) bio-impedance (8,9) to measure arm and truncal fluid, Opto-electronic Perometry (10,11) to measure arm volume, and Tonometry (12) to measure fibrotic induration in the lymphatic territories of the forearm, upper arm, posterior and anterior thorax. The contralateral arm was measured as a control comparison with these three methods of measurement. A 10 point Likert scale (13) was used to rate participants' subjective complaints such as: pain, heaviness, tightness, tissue hardness, range of movement and limb size.

Analysis

TABLE 3
Forearm, Upper Arm and Whole Arm Volume (mls) Serially over Trial Duration (Measured by Perometry)

	1st tx	24hrs	Wk 1	Wk 2	Wk 3	Wk 4	1 mo f/up
Trial I							
Forearm							
Change (mls)	-7	-34	-61	-78	-82	-102	+22
SD	(±39.5)	(±56.7)	(±60.4)	(±60.3)	(±67.9)	(±66.8)	(±54.1)
p=	0.410	0.011	0.000	0.000	0.000	0.000	0.122
Upper arm							
Change (mls)	+7	+10	-5	-27	-26	-32	+7
SD	(±18.8)	(±37.2)	(±33.8)	(±32.5)	(±42.3)	(±30.1)	(±40.4)
p =	0.089	0.240	0.417	0.000	0.004	0.000	0.134
Whole arm							
Change (mls)	0	-24	-66	-105	-108	-134	+29
SD	(±43.3)	(±84.9)	(±77.2)	(±81.5)	(±96.5)	(±87.6)	(±102.0)
p =	0.811	0.184	0.000	0.000	0.000	0.000	0.066
Trial II							
Forearm							
Change (mls)	-13	-64	-107	-128	-135	-138	+30
SD	(±28.9)	(±54.0)	(±66.2)	(±93.4)	(±97.5)	(±110.0)	(±105.5)
p=	0.185	0.005	0.001	0.002	0.001	0.003	0.349
Upper arm							
Change (mls)	-6	+3	-16	-21	-37	-47	+3
SD	(±10.2)	(±28.9)	(±36.8)	(±35.9)	(±31.3)	(±34.7)	(±37.5)
p =	0.106	0.580	0.184	0.015	0.003	0.002	0.857
Whole arm							
Change (mls)	-19	-61	-123	-149	-172	-185	+33
SD	(±26.4)	(±64.9)	(±95.0)	(±118.2)	(±118.6)	(±139.8)	(±147.8)
p =	0.063	0.018	0.003	0.003	0.001	0.002	0.370

All data were analyzed using SPSS (version 12.0). Both groups were evenly distributed in terms of arm volume at baseline, therefore paired sample student T-test analysis was used and $p < 0.05$ was considered significant. The percentage change in actual edema was calculated according to Swedborg (14).

RESULTS

Twenty four women aged 63.3 ± 10.7 (mean ± SD) yrs participated in the first trial, and 10 women aged 60.3 ± 7.6 yrs participated in the second trial *(Table 2)*. In the first trial it was observed that there were reductions in the forearm volume but a transient increase (not significant) in the upper arm volume (as measured via perometry) directly after the first massage (+ 7mls; 3.1% actual edema) and 24 hours post massage (+ 10mls; 4.3% actual edema; *Table 3*). After this time, there were steady reductions in whole arm volume (forearm + upper arm) culminating in a loss of 134mls (18.3% actual edema; p = 0.000). The major loss occurred in the forearm region

TABLE 4
Arm and Truncal Fluid (mls) over Trial Duration (Measured by Bioimpedance)

	1st tx	24hrs	Wk 1	Wk 2	Wk 3	Wk 4	1 mo f/up
Trial I							
Trunk Fluid							
Change (mls)	-24	-96	- 150	- 187	- 248	- 342	+100
SD	(±218.0)	(±432.9)	(±404.0)	(±489.1)	(±421)	(±487.1)	(±459.7)
p =	0.586	0.289	0.082	0.073	0.008	0.002	0.298
Arm Fluid							
Change (mls)	-17	-62	-96	- 137	- 133	- 182	+51
SD	(±46.9)	(±138.7)	(±136.7)	(±148.7)	(±157.4)	(±169.6)	(±125.4)
p =	0.088	0.038	0.002	0.000	0.000	0.000	0.060
Trial II							
Trunk Fluid							
Change (mls)	0	-20	-40	- 270	- 270	- 290	+78
SD	(±141.1)	(±225.1)	(±306.2)	(±405.6)	(±392.3)	(±438.3)	(±345.6)
p =	1.000	0.785	0.689	0.065	0.075	0.066	0.519
Arm Fluid							
Change (mls)	-13	-60	-116	-194	-211	-216	+97
SD	(±80.6)	(±92.5)	(±139.5)	(±194.1)	(±203.1)	(±223.1)	(±190.9)
p =	0.622	0.070	0.027	0.012	0.009	0.014	0.163

(102mls; 17.9% actual edema; p = 0.000) with a smaller reduction in the upper arm region (32mls; 5.8% actual edema; p = 0.00). Arm fluid (as measured by bioimpedance) was reduced at the end of 4 weeks of treatment (182mls, 28% actual edema; p = 0.000), as was truncal fluid (342mls, p = 0.002: *Table 4*). Tonometry demonstrated trends towards improvement in the forearm and posterior thorax lymphatic territories, with a significant softening in the anterior thorax region (p = 0.006). Measurements taken on the contralateral arm were not significantly changed (data not shown). Reported subjective parameters such as pain, heaviness, tightness, tissue hardness and arm size were all significantly reduced at trial end *(Table 5)*. All subjective measurements non-significantly increased at 1 month follow up, but did not return to pre-treatment levels (although not significantly different).

The second trial demonstrated that the transient increase in the upper arm volume could be modulated with a decrease of 6mls (6.8% actual edema; p = n.s.) after the first massage and a very small increase of 3mls (2.9% actual edema; p = n.s; *Table 3*) at 24 hours. Similar losses to the first trial were seen after this time, with a decrease of 138mls in the forearm (24% actual edema; p = 0.003), 47mls in the upper arm (8.6% actual edema; p = 0.002) and 185mls in the whole arm (23% actual edema; p = 0.002; *Table 3*) after 4 weeks of treatment. Arm and truncal fluid also decreased (216mls; p = 0.014 and 290mls; p = 0.066, respectively; *Table 4*). Measurements taken on the contralateral arm and tonometry assessments were not significantly changed. The same subjective parameters were also significantly reduced, with the addition of range of movement (p = 0.013; *Table 5*), which was not observed in the first

TABLE 5
Subjective Parameters at Baseline, End of 4 Weeks of Treatment, and at 1 Month Follow Up

	Trial I	Trial II
Pain		
Baseline	1.8 (±1.5)	2.7 (±2.7)
Week 4	1.0 (±0.1)*	1.0 (±0.0)
1 month f/up	1.0 (±0.0)	2.0 (±1.5)
Heaviness		
Baseline	3.3 (±2.5)	4.7 (±3.1)
Week 4	1.2 (+0.5)**	1.5 (±1.3)**
1 month f/up	1.9 (±1.5)	2.6 (±1.9)
Tightness		
Baseline	2.8 (±2.3)	4.8 (±2.6)
Week 4	1.1 (±0.3)**	1.8 (±1.3)**
1 month f/up	1.9 (±1.9)	2.6 (±2.2)
Tissue Hardness		
Baseline	3.3 (±2.5)	4.4 (±2.9)
Week 4	1.2 (+0.5)**	2.0 (±1.6)*
1 month f/up	1.9 (±1.5)	2.7 (±2.3)
Arm Size		
Baseline	5.7 (±2.1)	6.3 (±2.3)
Week 4	3.2 (+2.1)**	3.9 (±2.2)**
1 month f/up	3.9 (±2.1)	4.2 (±2.0)
Range of Movement		
Baseline	1.8 (±1.9)	3.6 (±2.5)
Week 4	1.2 (±0.6)	1.4 (±0.9)*
1 month f/up	1.6 (±1.2)	2.3 (±1.8)

*p<0.05; **p<0.01

trial. At 1 month follow up the subjective measurements increased, but again these had not returned to pre-treatment levels (although not significantly different).

Compliance and Adverse Effects

In the first trial, 87.5% of participants were compliant with the compression bandaging, 4.2% could not tolerate the bandaging and wore a compression garment as an alternative and 8.3% could not tolerate any form of compression. In the second trial 90% of participants were compliant with the bandaging and 10% wore a compression garment. It was deemed clinically appropriate to offer participants the alternative of wearing a compression garment when the bandaging could not be tolerated, as this ensured that the participant still received the benefits of some form of compression and helped to maintain compliance. In trial I, the subjects reported compliance with compression as: not at all (16.7%), slightly (12.5%), moderately (33.3%), and completely (37.5%). In trial II, 10% were slightly

TABLE 6
Comparison of Changes in Arm Volume and Subjective Symptoms as a Result of LPG® Plus Compression and MLD plus Compression

Treatment Protocols	Arm Vol. Change	Subjective Change		Reference
Trial I: 25mins of LPG® + compression bandaging over 16 sessions (n = 24)	Trial I: ↓134mls (18.3%) p=0.000	Trial I & II: ↓ heaviness ↓ tightness ↓ tissue hardness ↓ arm size	p < 0.01 p < 0.01 p < 0.05 p < 0.01	present study
Trial II: 30mins of LPG® + compression bandaging over 16 sessions (n = 10)	Trial II: ↓185mls (23%) p = 0.002	Trial I only: ↓ pain	p < 0.05	
		Trial II: ↓ range of movement	p < 0.05	
MLD + Compression (n = 17)	↓156mls (23%) p < 0.01	↓ heaviness ↓ tension ↓ pain	p = 0.03 p = 0.01 p = 0.00	Korpon et al (2003) (17)
Compression bandaging for 3 wks followed by 45mins of MLD for 5 days (n = 18)	↓47mls (11%) p < 0.001	↓ tension ↓ heaviness ↓ pain	p < 0.001 p < 0.001 p < 0.03	Johansson et al (1999) (16)
2 weeks of wearing a compression sleeve (30-40 mmHg) followed by 45mins of MLD + sleeve over 10 sessions (n = 12)	↓75mls (15%) p < 0.001	↓ tension ↓ heaviness	p = 0.01 p = 0.008	Johansson et al (1998) (15)

compliant, 20% moderately compliant and 70% were completely compliant all by self-report. The main complaint after the first week of treatment in both trials was increased urination and thirst (10% in the first trial, 35 % in the second trial), this was possibly related to the fluid mobilization. Apart from this, the massage delivered by the LPG® Endermologie® system was very well tolerated. Some participants, however, found that the bandaging disrupted their sleep as it was itchy and uncomfortable.

DISCUSSION

While the two treatment protocols produced similar results, the second protocol conferred additional benefits in terms of reducing arm volume at 24 hours, an improved trend in arm fluid and volume reductions, and a significant improvement in reported arm range of movement. These improvements may be related to clearing the pathway to the contralateral axilla, the extra time spent clearing the posterior thorax region and the use of the larger, mechanized treatment head which more efficiently mobilized the tissues over a larger area.

As new techniques of treating secondary lymphedema emerge on to the market, clinicians need to know the benefits of such techniques so that patients can be adequately informed. The LPG system reduces arm fluid and volume, with the reductions being comparable to similarly designed studies using massage plus compression (15-17,

Table 6). Additional benefits of this treatment regime include reductions in truncal fluid, softening of fibrotic induration and improvements in subjective parameters. It is noted that the sample sizes are small for these two trials, which was largely due to the commitment required for the treatment regime and the fact that some participants did not wish to undergo compression bandaging. The latter fact made adding a compression only comparison group unattainable, however, Trial 1 does show (with Trial II close to significance) a reduction in truncal fluid which may be difficult to explain with only compression of the arm. Despite the small trial sizes and large standard deviations, significance was reached in many of the measured parameters. Future studies with more subjects and a longer follow-up period for confirmation are warranted.

It should be emphasized that the LPG system and compression bandaging should be administered by a trained health professional who understands the underlying pathophysiology of lymphedema and who can continually assess the patient's response to treatment. The fact that subjective measurements increased at 1 month follow up (not returning to baseline) emphasizes the importance of continuing self-maintenance regimes such as performing self-massage and wearing a compression garment. It is of significance that the parameters had not returned to baseline, as long term data collected by Casley-Smith and Casley-Smith (18) and studies involving placebo groups (19-21) demonstrates that the lymphedematous arm will progressively worsen without some form of therapy. This shows that the self massage and compression instigated by the participants in this study did help to arrest some of this worsening and that all patients should be encouraged to undertake self-maintenance activities in between health professional visits to maintain the benefits gained from intensive treatment.

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REFERENCES

1. Williams, AF, PJ Franks, CJ Moffatt: Lymphoedema: Estimating the size of the problem. Pall. Med. 19 (2005), 300-313.
2. Casley-Smith, JR, Judith R Casley-Smith: Volume alterations in lymphoedema; untreated, and after complex therapy (C.P.T), benzo-pyrones, or both. Lymphology 27(suppl) (1994), 627-631.
3. Mortimer, PS: Managing lymphoedema. Clin. & Experiment. Der. 20 (1995), 98-106.
4. Földi, M, E Földi, H Weissleder: Conservative treatment of lymphoedema of the limbs. Angiology 36 (1985), 171-180.
5. Campisi, C, F Boccardo, WF Azevedo (Jr), et al: LPG Systems in the Treatment of Peripheral Lymphedema. Lymphology 35(suppl.) (2002), 364-367.
6. Campisi, C, F Boccardo, WF Azevedo, et al: LPG system in the treatment of peripheral lymphoedema: Clinical preliminary results and perspectives. Euro. J. Lymphology 10 (35-36), 14-17.
7. Guillot, B: Prospective study of the use of LPG technique in the treatment of cutaneous fibrosis induced by radiotherapy. XXII Congress National de Medecine Esthetique (2001).
8. Moseley, A, N Piller: Relationships between limb size and composition using objective measures. Their role in providing better treatment outcomes. Lymphology 40(suppl.) (2008), 170-175.
9. Ward, L, N Byrne, K Rutter, et al: Reliability of multiple frequency bioelectrical impedance analysis: An inter-machine comparison. Am. J. Human. Biol. 9 (1997), 63-72.
10. Stanton, A, J Northfield, B Holroyd, et al: Validation of an optoelectronic limb volumeter (perometer). Lymphology 30 (1997), 77-97.
11. Leduc, O, P Klien, C Rasquin, et al: Reliability of a volume measuring device (Volumeter®) for human limbs. Eur. J. Lymphology 3 (1992), 53-56.
12. Clodius, L, I Deak, N Piller: A new instrument for the evaluation of tissue tonometry

in lymphoedema. Lymphology 9 (1976), 1-5.
13. Lee, JW, PS Jones, Y Mineyama, et al: Cultural differences in responses to a Likert scale. Res. Nurs. & Health. 25 (2002), 295-306.
14. Swedborg, I: Effects of treatment with an elastic sleeve and intermittent pneumatic compression in post-mastectomy patients with lymphoedema of the arm. Scand. J. Rehab. Med. 16 (1984), 35-41.
15. Johansson, K, E Lie, C Ekdahl, et al: A randomized study comparing manual lymph drainage with sequential pneumatic compression for treatment of postoperative arm lymphedema. Lymphology 31 (1998), 56-64.
16. Johansson, K, M Albertsson, C Ingvar, et al: Effects of compression bandaging with or without manual lymph drainage treatment in patients with postoperative arm lymphedema. Lymphology 32 (1999), 103-110.
17. Korpon, MI, G Vacariu, B Schneider, et al: Effects of compression therapy in patients with lymphedema after breast cancer surgery. Annual Congresses of the American College of Phlebology, San Diego, California (2003), online www.phlebology.org Annual Meeting Abstracts.
18. Casley-Smith, JR, Judith R Casley-Smith: Volume alterations in lymphoedema; Untreated, and after complex therapy (C.P.T), benzo-pyrones, or both. Lymphology 27(suppl.) (1994), 627–631.
19. Casley-Smith, JR, RG Morgan, NB Piller: Treatment of lymphedema of the arms and legs with 5,6-BENZO-[á]-PYRONE. New Eng J Med 329 (1993), 1158-1163.
20. Pecking, AP, B Fevrier, C Wargon, et al: Efficacy of Daflon 500mg in the treatment of lymphedema (Secondary to conventional therapy of breast cancer. Angiology 48 (1997), 93-98.
21. Box, R, T Marnes, V Robertson: Aquatic physiotherapy and breast cancer related lymphoedema. 5th Australasain Lymphology Association Conference Proceedings (2004), 47-49.

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