# Pilot study of a handheld massage unit

Amanda Moseley, Neil Piller, Beverley Heidenreich, Jan Douglass


## Abstract

*Background:* Secondary arm lymphoedema is a chronic condition which affects a significant number of women and requires ongoing management. *Aims:* To pilot a new handheld massage unit which delivered vibration to the arm tissues and can be used in the home environment. *Methods:* Women with established arm lymphoedema secondary to breast cancer treatment used the handheld massage unit for 25 minutes each evening for one month. Measurements including bioimpedance (arm and truncal fluid volume), perometry (total arm volume), tonometry (tissue compliance) and subjective arm symptoms were taken at baseline, at the end of week 1, 2, 3 and 4 and at one-month follow-up. *Results:* After four weeks, there was a reduction in arm fluid of 51mls. Subanalysis demonstrated that participants who were overweight, had had multiple sights irradiated or who were moderately compliant with the regime experienced significant reductions in arm fluid volume (90mls; p=0.015, 74mls; p=0.018 and 69mls; p=0.019, respectively). Participants also reported significant improvements in limb size (p=0.007) and range of movement (p=0.000). *Conclusions:* The application of vibrational massage via a handheld unit may help women to maintain their arm lymphoedema in the home environment. *Declaration of interest:* This study was funded by Cyprossage Pty Ltd (Queensland, Australia) with the financial aspects of the study managed by Flinders Consulting Pty Ltd (South Australia, Australia).



*Key words*

Breast cancer
Arm lymphoedema
Self-massage
Home environment


Secondary arm lymphoedema is known to be a significant and lifelong problem for a proportion of women who undergo breast cancer treatment, leading to both physical and psychological morbidity. Based upon the acknowledged need for some form of therapy to keep this condition under control (Casley-Smith and Casley-Smith, 1994), a number of intensive therapies have evolved over time (i.e. complex physical therapy) to help manage both the swelling component and the subjective symptoms, such as heaviness, tightness and aching and associated quality of life issues (Moseley et al, 2007).

However, access to these therapies is not universal, instead being heavily dependent on the types of therapies available in each country and even regions, and the patient's ability to access (both geographically and economically) them. This leaves the question of how patients manage their condition in between healthcare professional consultations or when intensive therapies cannot be accessed. To help address this question, this study piloted a new handheld massage unit which delivered mild vibration (32–45Hz) to the tissues and which could be applied by the patient in their own home environment to help manage their arm lymphoedema. Based upon the premise that the application of vibration and self-massage has individually been shown to improve symptoms, wellbeing (Barclay et al, 2006) and limb volume (Barclay et al, 2006; Ohkuma, 2002; Williams et al, 2002) in lymphoedema patients, it was hypothesised that the combination of both vibration and massage would result in a limb volume reduction and improvement in limb symptoms.

## Methods

The study was given ethics approval by the Flinders Medical Centre Clinical Research Ethics Committee, Adelaide, Australia. Informed consent was obtained from each participant.

Women with established (≥1 year duration) arm lymphoedema secondary to breast cancer treatment (surgery ± radiotherapy ± chemotherapy) and a volume difference of ≥200mls between the arms were recruited to the study. Those with underlying lipoedema, primary lymphoedema, myxoedema, uncontrolled hypertension, recurrent cancer, cellulitis or who had recently (≤1 month) undergone surgery or treatment for their lymphoedema were excluded from the study.

Once recruited, each participant was given a handheld massage unit (described in the following section) to use for 25 minutes each evening in their own home, and verbal and written instructions on how to use the unit (based upon the

Amanda Moseley is Reseach Fellow, School of Medicine, Flinders University; Neil Piller is Team Leader (Lymphoedema Assessment Clinic); Beverley Heidenreich is Clinical Research Officer; Jan Douglass is Vodder® Therapist in the Department of Surgery and Lymphoedema Assessment Clinic, Flinders University and Medical Centre, South Australia, Australia

principles of manual lymphatic drainage [MLD]), as indicated in *Table 1*. Before taking the unit home, each participant was asked to go through the instructions with the researcher, so that the self-massage technique could be checked. Each participant was then asked to use the unit for one month and was given a log book to record the frequency of use of the handheld unit, so compliance could be monitored.

Measurements were taken at baseline (prior to the first use of the handheld unit), at the end of week 1, 2, 3 and 4 and at one month follow-up. Measurements with validated equipment included:

- Inbody® Bioimpedance (Korea), which measures limb fluid volume (Moseley and Piller 2007; Cornish et al, 2001)
- Tonometry, which measures the compliance of the tissues and fibrotic induration in the lymphatic territories (Stanton et al, 2000; Clodius et al, 1976)
- Perometry® (Germany), which measures total limb volume (Stanton et al, 1997; Leduc et al, 1992).

Computer software (PeroPlus®) linked to the perometer was used to analyse both whole limb volume in addition to forearm and upper arm volume (separately). Subjective problems such as pain, heaviness, tightness, tissue hardness, limb temperature, perceived limb size and range of movement were rated on a 10-point Likert scale (Lee et al, 2002).

## Handheld unit

Before applying vibrational massage to human populations, the optimal form of cycloid vibration for promoting lymphatic drainage was first tested in a pig model (full trial results to be reported elsewhere). These animal studies determined that vibration applied via a handheld unit at low–moderate frequency with low–moderate force was the most optimal form of therapy. Based on this, a handheld unit was designed that was able to be easily gripped and applied to the arm (*Figure 1*).

## Analysis

All data were analysed using SPPS® (version 14.0). As the study group was normally distributed in terms of arm volume at baseline, the paired sample student T-test was used to analyse changes over time, where $p < 0.05$ is significant. Data is presented as means (± standard error of the mean).

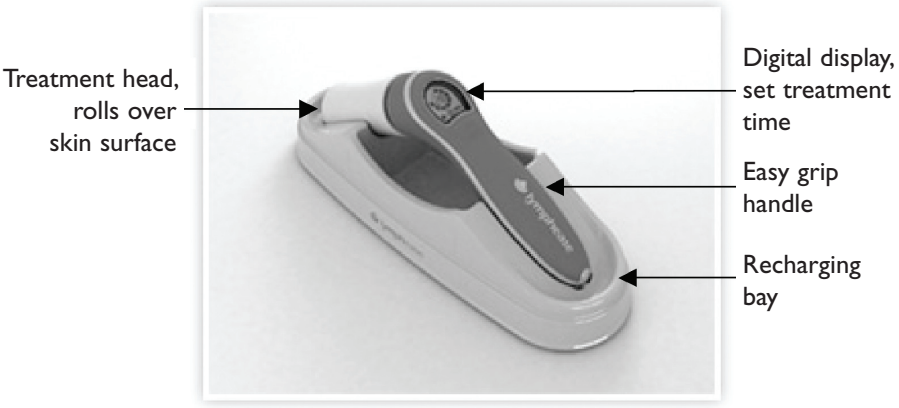
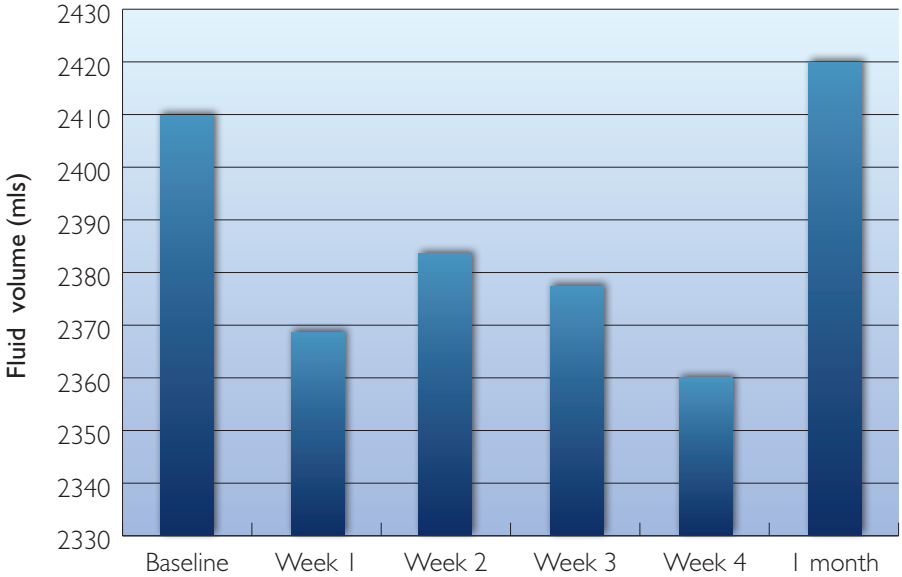



**Figure 1. Handheld (Lymphease®) massage unit.**

## Results

Thirty women with secondary arm lymphoedema were recruited to the study, with twenty-six completing the study (*Table 2*). Four women withdrew due to sickness or an inability to meet the measurement schedule, while an additional four women were unable to attend the one-month follow-up measurement.

Bioimpedance measurements demonstrated that there was an initial arm fluid loss of 43mls (±110mls; p=0.244) at the end of the first week of treatment, with steady losses over weeks 2 and 3, and overall fluid loss of 51mls (±121mls; p=0.086) at four weeks (*Figure 2*). Measurement at one-month follow-up demonstrated that the fluid had returned to the arm, with an increase of 60mls (±150mls; p=0.068). Bioimpedance measurements also demonstrated a 96mls reduction in truncal fluid at the end of four weeks (±138mls; p=0.493), with an increase in truncal fluid of 68mls (±118mls; p=0.570) at one-month follow-up. A subgroup analysis was also undertaken investigating the effects of body weight, the area of the body that underwent radiotherapy, and treatment compliance on arm fluid volume change.




| | Baseline | Week 1 | Week 2 | Week 3 | Week 4 | 1 mth f/up |
|---|---|---|---|---|---|---|
| SEM | 133 | 110 | 118 | 121 | 121 | 150 |
| p value | - | 0.244 | 0.278 | 0.210 | 0.086 | 0.068 |

**Figure 2. Change in arm fluid volume (mls) as measure by bioimpedance over trial duration.**

**Table 1**

**Instructions on how to use the handheld massage unit**

| Phase | Time |
|---|---|
| **Clearing the adjacent areas** | |
| 1. Roll the unit along both sides of the neck from the shoulder to the base of the skull and back | 2 minutes each side |
| 2. Use the head of the massage unit to massage gently into the non-affected arm pit | 1 minute |
| 3. Using the side of the massage unit, sweep across the top of the breast from the midline to the non-affected armpit | 1 minute |
| 4. Using the side of the massage unit, sweep above the breast or scar from the affected armpit to the midline | 1 minute |
| 5. Rest the side of the massage unit in the groin crease on the same side as the affected arm | 1 minute |
| 6. Using the side of the massage unit sweep from underneath the breast or scar to the groin crease on the same side as the affected arm | 1 minute |
| **Massage the affected arm** | |
| 1. Using the side of the massage unit, sweep from the back of the elbow and up over the shoulder | 2 minutes |
| 2. Lift arm up, then using the side of the massage unit, sweep the inner side of the upper arm from the elbow down the side of your body. Make sure you pass the massage unit behind the armpit and not directly into it | 2 minutes<br>2 minutes |
| 3. Using the side of the massage unit, sweep the outer side of the forearm from the hand to the elbow | 2 minutes |
| 4. Using the side of the massage unit, sweep the inner side of the forearm from the hand to the elbow | 5 minutes |
| 5. Massage nominated area — each participant chose an area of the arm that they wished to specifically massage with the handheld unit | |
| **To finish** | |
| 1. Using the side of the massage unit, use long strokes from the affected outer fingers, over the outer arm to over the shoulder | 1 minute |
| 2. Using the side of the massage unit, use long strokes from the inner fingers, over the inner arm and down the side of the body | 1 minute |
| 3. Using the side of the massage unit, use long strokes from the affected armpit to the non-affected armpit | 1 minute |
| **Total time** | **25 minutes** |

This demonstrated that being overweight (BMI ≥30) and having multiple irradiated sites did not affect the outcome. In fact, both subgroups experienced significant reductions in fluid volume; 90mls (±31.8mls; p=0.015) and 74mls (±28.3mls; p=0.018) respectively (*Table 3*), while those who were moderately to completely compliant with the use of the unit had a significant arm fluid reduction of 69mls (±26.5mls; p=0.019).

Perometry measurements demonstrated that the greatest volume reduction occurred in the forearm region, with an overall loss at trial end of 25mls (p=0.247; ±156mls; *Figure 3*). At one-month follow up there was increase in forearm volume 15mls (±185mls; p=0.322), but the overall forearm volume had not returned to the baseline value. All subjective arm problems showed improvement, with significant improvements occurring in perceived limb size and range of movement at the end of four weeks of treatment (p=0.007 and 0.000, respectively; *Table 4*). At one-month follow-up, heaviness, tightness, limb temperature and limb size increased, with the increase in limb size being statistically significant (p=0.021). In contrast to this, the improvements in pain and range of movement were maintained over the one-month period (*Table 4*). Tonometry measurements showed no significant change over the study duration.

Analysis of compliance with the handheld unit demonstrated that 70% of participants were moderately to completely compliant with the use of the unit over the study duration (a breakdown of compliance for each week is presented in *Table 5*). Reported adverse effects related to unit use included headache after applying the unit to the neck (7.7%), the unit was heavy to use (9.6%), and discomfort after applying the massage unit too forcefully (11.5%). The headache and discomfort can be addressed by emphasising to patients that the handheld unit requires gentle application to the neck and arm and checking the patient's application technique. The heaviness of the unit has been addressed in its final design and production.

## Discussion

Although the limb volume achieved in this study was small (51mls or approximately 5%), the reduction was in line with other studies which have investigated the effects of self-massage on secondary arm lymphoedema (Barclay et al, 2006; Williams et al, 2002). In addition, the fluid reduction of 51mls achieved in this study is comparable to those achieved by hydrotherapy (32mls, Johansson et al, 2004; and 48mls, Box et al, 2004) and the application of compression bandaging (20mls, Johansson et al, 1999; and 38mls, Korpon et al, 2003). There was also a reduction in truncal fluid and significant reductions in perceived limb size and range of movement. Of interest would be research that investigated the application of handheld massage in combination with other forms of established lymphoedema therapy, such as complex physical therapy. (CPT)

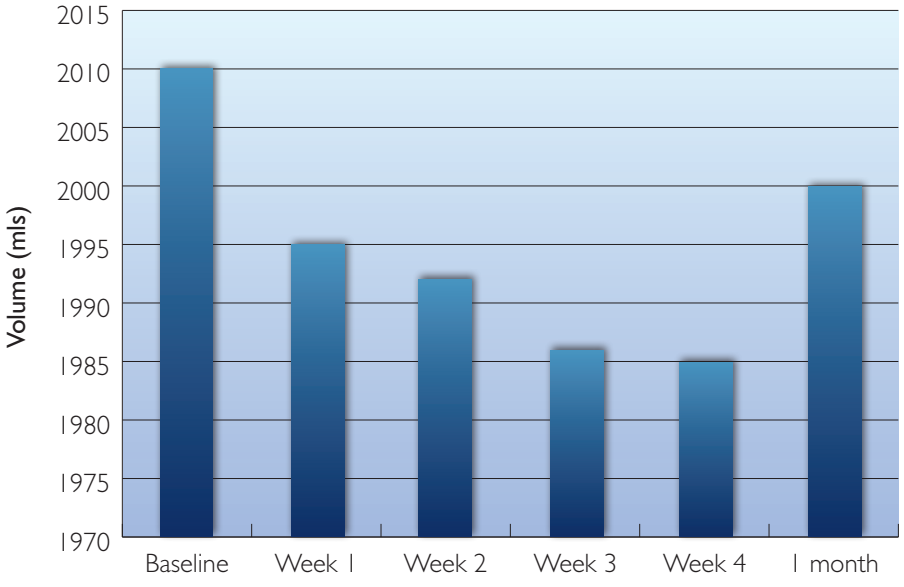
This study has also demonstrated that those who were overweight or who had had multiple sites irradiated — two things that could possibly confound lymphatic drainage (Ozaslan and Kuru, 2004; Johansson et al, 2002) still achieved a significant reduction in arm fluid volume, demonstrating that this unit may be suitable for use in a wide range of people

who have developed arm lymphoedema secondary to breast cancer treatment.

Used on a daily basis, this handheld massage unit can help women with established secondary arm lymphoedema manage their condition at home. This is important, as research has shown that the implementation of ongoing treatment is required to maintain the limb (Moseley et al, 2007).

The other important thing to acknowledge is the fact that the majority of participants in this study commented that having the ability to apply the handheld massage unit in the home environment gave them a sense of control over their condition, acknowledged in the literature as one of the important facets of empowerment (Aujoulat et al, 2008). In terms of cost, the unit is currently marketed in Australia for $995 (AUD) and in the United Kingdom and other European countries for €800. Although this is a significant cost, the potential for this type of product to help maintain and control arm lymphoedema in the home environment makes it an attractive option for some patients.

Regular healthcare professional consultation is likewise important, both in terms of checking the technique and application of the handheld massage unit and the response to the treatment regime. For those who find it difficult (due to mobility, location or finances) to regularly visit a healthcare professional, this consultation may be achieved via telephone check-ups (Galan et al, 2004; Partridge, 2004), or internet technology (Vallejo et al, 2007; Brophy et al, 2004); both of which have been shown to be effective in the assessment and management of chronic conditions. JL




| | Baseline | Week 1 | Week 2 | Week 3 | Week 4 | 1 mth f/up |
|---|---|---|---|---|---|---|
| SEM | 170 | 166 | 163 | 158 | 156 | 185 |
| p value | - | 0.104 | 0.216 | 0.188 | 0.247 | 0.322 |

**Figure 3. Change in forearm volume (mls) as measured by perometry over trial duration.**

**Table 2**

**Background details of the study group**

| | |
|---|---|
| Age | 42–81 years<br>Mean: 60.1 years (±9.9 years) |
| Surgery:<br>▸▸ partial mastectomy + axillary clearance<br>▸▸ potal mastectomy + axillary clearance | <br>13 (50%)<br>13 (50%) |
| Radiotherapy | 24 (92.3%) |
| Lymphoedema duration | 12–180 months<br>mean 79.8 months (±50 months) |
| Lymphoedema status:<br>▸▸ mild<br>▸▸ moderate<br>▸▸ severe | <br>9 (34.6%)<br>12 (46.2%)<br>5 (19.2%) |
| Arm fluid volume difference at baseline | 651.5mls (±394.4mls) |

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**Table 3**

**Subgroup analysis: fluid volume change at end of trial in participants who were overweight, had had multiple sites irradiated and who were moderately to completely compliant with the handheld unit**

| Subgroup | n | Fluid change | SEM | p value |
|---|---|---|---|---|
| Overweight, high % fat mass | 13 | -90mls | 31.8 | 0.015 |
| Radiotherapy to axilla, chest wall, supraclavicular areas | 18 | -74mls | 28.3 | 0.018 |
| Moderately to completely compliant | 18 | -69mls | 26.5 | 0.019 |

**Table 4**

**Subjective arm problems at baseline, end of week 4 and one-month follow-up**

| Problem | Baseline | Week 4 | p | One-month follow-up (n=22) | p |
|---|---|---|---|---|---|
| Pain | 2.0 | 1.5 | 0.249 | 1.5 | 0.486 |
| Heaviness | 4.0 | 3.3 | 0.169 | 3.9 | 0.028 |
| Tightness | 3.5 | 3.3 | 0.774 | 3.5 | 0.135 |
| Limb temperature | 2.4 | 1.8 | 0.067 | 2.2 | 0.061 |
| Perceived arm size | 6.8 | 5.2 | 0.000 | 5.8 | 0.021 |
| Range of movement | 3.6 | 2.04 | 0.007 | 2.4 | 1.000 |

**Table 5**

**Compliance with massage unit use over trial duration**

| Compliance | Week 1 | Week 2 | Week 3 | Week 4 |
|---|---|---|---|---|
| Completely | 57.7% | 53.8% | 57.7% | 53.8% |
| Moderately | 19.2% | 19.2% | 3.8% | 15.4% |
| Somewhat | 11.5% | 7.2% | 19.2% | 11.5% |
| N/K | 11.5% | 19.2% | 19.2% | 19.2% |


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## Key points

- Self-massage and vibration have separately been shown to improve limb volume, symptoms and wellbeing in lymphoedema populations.
- The application of self-massage and vibration (in the form of a handheld unit) resulted in a reduction in arm fluid and volume, and statistical improvements in perceived arm size and range of movement.
- Once treatment had ceased, arm fluid and volume increased and some symptoms returned, demonstrating the importance of ongoing treatment and management of secondary arm lymphoedema.