

Part Results of a Large Scale Clinical Trial of the

HSIN TEN Aerobic Exerciser (Chi Machine)

as the mainstay of management for secondary lymphoedema and venous oedema of the legs of men and women

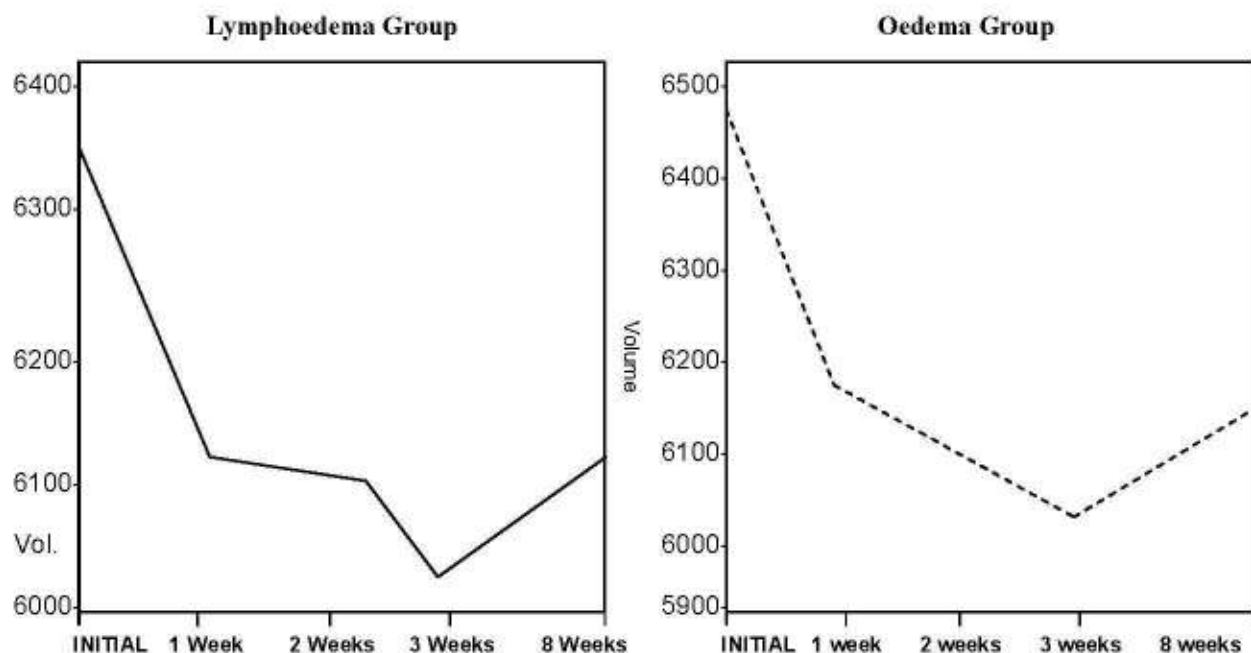
Conducted at Flinders University Medical Centre, Adelaide, Australia in the Lymphoedema Assessment Clinic under the Supervision of Professor Neil Piller and the conduct of the Chief Research Officer, Ms Amanda Moseley.

Lymphoedema (swelling) of the legs occurs in men following surgery and/or radiotherapy for the treatment of bowel and prostate cancer and in women following cervical, bowel or other reproductive system cancers. About 30% of all men and women who have these treatments develop some form of limb swelling. It is believed another 30% of patients have subjective problems such as aches/pain, heaviness, and problems with quality of life and activities of daily living. **Oedema** occurs when the venous blood system is not draining and/or circulating well. It is estimated about 5-6% of the adult population suffer venous oedema. A further number suffer from some discomfort of the limbs or problems with quality of life and activities of daily living.

In this trial, two groups of patients with leg swelling were involved, one with lymphoedema due to problems with the functioning of the lymphatic system and another with swelling due to problems with the blood vascular system. Each patient was measured fully prior to the start of the trial, at weekly intervals and one month after the trial completion. Some 2000 data bits were collected from each patient at each visit. These included: volume and circumference of the limbs using perometry, fluid content, and composition using bio-impedance and tissue fibre using tonometry. Questionnaires were administered to determine the impact of the swelling on the person's quality of life and ability to undertake activities of daily living.

Each patient was allocated an Hsin Ten Aerobic Exerciser (Chi Machine) which they used for 21 days in their home adhering to the following regime: Days 1-2: 5 minutes both morning and evening, Days 3-7: 8 minutes both morning and evening, Days 8-21: 12 minutes both morning and evening. Patients returned to Flinders University Medical Centre at the end of each week for a further full assessment. In addition there was a one month follow up measurement to assess the longer term impact of the treatment. Included in the results presented below are the findings from 33 chronic lymphoedema sufferers and 25 with venous oedema. A group of normal patients was tested but these results are not presented here.

Results (Major findings) Full statistical analysis was performed by Dr. Adrian Esterman, Deputy Director Clinical Epidemiology and health Outcomes Unit. Some statistical outcomes will be presented in the talk.



These results are for research and development explanation only and have not been approved by FDA.

The important points of the above graphs are an average volume loss of over 320mls in the lymphoedema group and an average volume loss of 430mls in the oedema group. In concert with this was a reduction in circumference of the affected limb and body weight. Volume changes were confirmed by perometry and by bio-impedance.

Subjective Measurements - How the legs felt (smaller numbers indicate better)

Condition	Lymphoedema			Oedema		
	Initial	Final	1 Month	Initial	Final	1 Month
Pain	3.7	2.0	3.5	4.0	1.0	2.5
Tightness	6.0	2.0	5.0	5.0	2.0	3.5
Heaviness	5.0	2.0	5.0	5.0	2.0	2.5
Skin dry	4.0	2.0	1.0	4.2	2.7	2.6
Limb size	7.0	5.0	5.0	6.0	4.5	4.0
Cramps	n/a	n/a	n/a	5.0	1.0	3.0

(These values are the means of the respective group)

Changes in Quality of Life and Activities of Daily Living (% showing improvement)

	Lymphoedema	Oedema
Range of movement	55%	68%
Increase in ability to exercise	36%	56%
Walking up/down stairs	27%	40%
Improvement in sleeping	21%	25%
Easier to get dressed	15%	20%
Positive impact on daily life	45%	56%
Decrease in depression assoc. with condition	21%	16%
Satisfaction with treatment regime	85%	88%
Feeling of control over condition	67%	52%

Other improvements reported by the overall group

Shoes felt looser (34%), higher energy levels (10%), greater flexibility (12%), more relaxed (24%), feeling of well-being (16%), reduced abdominal congestion (7%), and improved shape of limb (26%).

Summary

The intent of this summary sheet is not to present a detailed statistical analysis of the outcomes of the trial but to give you a feeling of the very positive effects of the Aerobic Exerciser. Over the 3-week treatment period there was a significant loss of fluid from the affected leg with an associated improvement in how the legs felt. Once patients ceased treatment there was some return of fluid and symptoms but not to the level prior to treatment indicating a longer-term treatment effect. With the loss of fluid there were improvements in patients' Quality of Life and ability to undertake activities of living. This included an improvement in their leg range of movement that made exercise, walking up and down stairs, and getting dressed in the morning a lot easier.

There were also other benefits associated with the use of the machine, some patients reported that they found it relaxing and felt it improved their energy levels and well-being. The majority of patients were extremely happy - with using it in their own home, at their convenience, and felt that this gave them control over their condition. Results show the impact of the aerobic exerciser is rapid even for these chronic conditions which generally had not responded well to previous treatments. They also show a post treatment effect. The exerciser however, needs to be used daily to gain the best results. Many other parameters were measured including blood flow, lymphatic transport capacity and immune system function. These and other relevant outcomes will be presented in the discussion of the research and linked to the optimal use of the exerciser. Full details of these findings will be submitted for publication in a learned International journal and will be presented in full at the forthcoming International Congress of Lymphology in Genoa Italy and at the World Phebiology Congress in Rome.

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