Bio-Medical Research Institute

The Effects of CSI Electrical Muscle Stimulation

A Controlled Study

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The Effects of CSI Electrical Muscle Stimulation - A Controlled Study
Bio-Medical Research Institute

Research Team

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Abstract

A single blind, randomised, controlled, prospective study was undertaken to assess the effects of an abdominal electrical stimulation device using a novel technique which we refer to as C.S.I. (patent applied for). 72 menstruating women, 18 years or older, of steady weight, exercise patterns and predictable menstrual cycles were recruited. The subjects were randomised into either the treatment or the control group. The groups were balanced according to body mass index, exercise patterns and age. Informed consent was given. Those in the treatment group received a minimum of 40 x 40 minute sessions of electrical stimulation over a two month period. Psychometric, strength and anthropometric measurements were taken eight weeks apart, before and after treatment, between days 5 and 22 of each subjects menstrual cycle.

***Results**: Psychometric measurements show improved body image and well-being among the treatment group, ($p<0.05$), improvements in perceived firmness, ($p<0.01$), flatness, ($p<0.01$), and strength ($p<0.01$). Objective improvements in abdominal strength , ($p<0.05$), and flatness, ($p<0.05$) were also seen. In each case the improvements were greater than those previously observed using a similar methodology with standard abdominal electrical stimulation.*

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Introduction

Electrical muscle stimulation (EMS) is a well accepted treatment modality in medicine and in physiotherapy. In addition to the medical and physiotherapy literature, sports physiologists have done considerable work on the subject. Literature highlights include strength increases, muscle bulking and prevention of muscle wastage [1- 12]

A strong association between the use of abdominal stimulation and changes in user girth and strength has been previously identified .[13,14] However, some did not have a control group and others did not eliminate confounding factors, such as changes in diet and exercise. This study was structured to assess some of the effects of abdominal stimulation independent of weight and changes in voluntary exercises.

The variables measured were in three main categories.

- ***Strength***
- ***Anthropometric***
- ***Psychometric***

Methodology Overview

A single blind, randomised, controlled, prospective study was undertaken to assess the effects of an abdominal electrical stimulation device. 72 menstruating women, 18 years or older, of steady weight, exercise patterns and predictable menstrual cycles were recruited. The subjects were randomised into either the treatment or the control group. The groups were balanced according to body mass index, exercise patterns and age. Informed consent was given. Those in the treatment group received a minimum of 40 x 40 minute sessions of electrical stimulation over a two month period. Psychometric, strength, and anthropometric measurements were taken eight weeks apart. Statistical comparisons were then made between the two groups.

Subject Recruitment

An advertisement looking for female volunteers to take part in an 8-week research study was placed in a local newspaper (Galway City, Ireland). The advertisement stated that subjects would be compensated for their participation in the study. (This compensation amounted to one free Slendertone Body product on completion and travel expenses to the test centre.) The advertisement yielded 591 responses.

Screening Criteria

Respondents were given a brief description of the experimental protocol and the interviewer took details of their suitability to take part based on the following screening criteria:

- *Subjects must not have used EMS within the previous six months.*
- *Subjects must have maintained a stable exercise and nutrition pattern for the previous 8 weeks.*
- *Subjects must be of steady weight.*
- *Subjects' menstrual cycles must have been at least 21 days and less than 33 days long.*
- *Subjects must not be perimenopausal, post menopausal or post hysterectomy.*
- *They must not have had an IUD recently inserted.*
- *Subjects must not have given birth in the past 10 months.*
- *Subjects must not have suffered from back problems or any medical condition contraindicated with use of the product. It was decided that the significance of any other medical*

conditions present would be assessed on an individual basis.

- *Subjects must not have a Body Mass Index of less than 20.*
- *Subjects must not be more than 10 kg overweight using a Body Mass Index of 20 to 23 as a guide for normal weights.*
- *Subjects' menstrual cycles must fall between first two weeks of trial commencement*
- *Subjects must not have recently used any abdominal toning device such as an ab-roller.*

Volunteer Briefing Session

159 respondents satisfied the screening criteria and were asked to attend a presentation explaining the study. The presentation included a video demonstration of the product. The test design was described and candidates were told that they had an equal chance of being selected at random for the treatment or the control group. A detailed description of the measurement procedure was given and the commitments required of those taking part were outlined. The need for members of both the treatment and control group to maintain their regular diet and exercise routines was emphasised. The list of contraindications for involvement was also explained.

Allocation of Subjects to Treatment and Control Groups

The selection process yielded 87 suitable volunteers. Subjects were listed in ascending order of Body Mass Index. Every second subject was then assigned to the treatment group. The groups had similar recent exercise history levels.

Subject Notification

Subjects were sent appointment cards and informed of their allocation to either the treatment or the control group. They were asked not to tell the physiotherapist of their allocation in order to prevent measurement bias.

Informed Consent

In compliance with Good Clinical Practice (91/507/EC) and the NSAI standard for "Clinical Investigation of Medical Devices For Human Subjects" (I.S./EN540:1995, §5.6.11), each of the subjects was asked to sign an informed consent form prior to the start of the study. They were made aware that they were free to withdraw from the study at any time.

Premeasurement Sessions

Each subject was asked to attend a premeasurement session where the different measurements were demonstrated and explained in more detail.

Elimination Criteria

The following elimination criteria applied to the subjects:

- *If the subject is unable to perform any aspect of the study.*
- *If the subject's weight fluctuates by more than 2 kg they were eliminated from the girth measurements.*
- *If the subject admits to exceptional bingeing, dieting or exercise.*
- *If either of the subject's measurement sessions is within 4 days prior to the commencement of their period or three days afterwards.*
- *If the subject drops out.*
- *If the subject is a member of the treatment group and undergoes less than 40 sessions, including home sessions, over the eight week period.*
- *If the subject is not getting clearly visible contractions after 10 sessions.*

Subject Numbers

80 subjects presented for the premeasurement and first measurement session. Eight subjects dropped out during the course of the study for personal reasons, therefore the results are based on 37 treatment group and 35 control group subjects.

Treatment Procedure

Members of the Treatment Group were asked to attend the Slendertone Consumer Test Centre for a 40 minute supervised treatment five days each week for eight weeks. Prior to the first session, they were given a demonstration of the unit and the stimulation electrode (pad) positions. During each session, the independent research supervisor checked the pad positioning on each subject and ensured that visible contractions were obtained. The supervisor encouraged subjects to increase the unit intensity and the level achieved was recorded after each session. Subjects signed a treatment attendance sheet after each session. Members of the treatment group were also given the unit to use at home at least once during the weekend. Subjects that were unable to attend the test centre on any given day were asked to use the unit at home.

Electrode Positions

The CSI electrode position is shown in Fig 1, with the central umbilical electrode acting as a common between the two lateral electrodes which are placed between the rib cage and the pelvis.

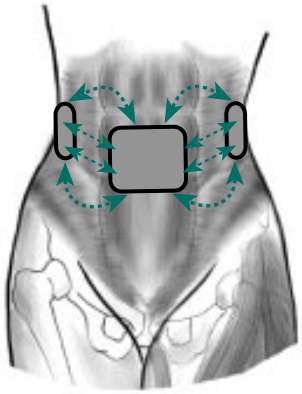


Fig 1. CSI electrode configuration

Measurement Procedure

On the appointed morning the subject presented herself to the test centre.

It was confirmed that she:

- *Had a light breakfast only, (a cup of tea / coffee and toast). At the second session it was confirmed that fluid and solid intake was similar to the first session in quantity and in digestion time.*
- *Had not consumed excessive alcohol the previous night.*
- *Was between day 5 and day 22 of her menstrual cycle.*

A separate data collection sheet was used for each measurement of each subject. On the sheet and in the computer records the subjects were identified only by their code. Data from the first measurement session was unavailable during the second. The second measurement session was usually 56 days later, unless:

- *There was a logistical difficulty or*
- *The subject was not in the required phase of her menstrual cycle.*

The following measurements were then made in sequence:

1. *Weight and girth*
2. *Anterior abdominal shape*
3. *Abdominal muscle strength*
4. *Questionnaires*

The subjects removed their shoes and any clothing that would obstruct abdominal views. Their weight and girth were then recorded. Abdominal girth was measured using an anthropometric measuring tape with consistent tension. The girth was recorded at three positions, namely, the anterior superior illiac spine (ASIS), the umbilicus and the minimum of the waist. A horizontal tape position was ensured in each case by illuminating the subject with a set of horizontal lines. In this way a consistent and repeatable tape position was guaranteed and a reliable measurement of girth was achieved. Using this technique no significant difference in mean girth was observed in either the treatment or control group. This result is at variance with earlier studies, (13,14) but they did not have such a controlled measurement technique, nor were they single blind as in this study.

Measurement of Anterior Abdominal Shape

The measurement of girth using a measuring tape, even in the controlled conditions noted above is not an indication of flatness or firmness, and is subject to various measurement errors. A three dimensional assessment is required for measurement of flatness. The method used here was Fourier transform profilometry which is a non contact, optical technique for mapping surface topography. A horizontal pattern of light and dark bands is projected at an angle onto the subject from a light projector placed below the optical axis. The distortion of the horizontal grating pattern is an indication of the surface shape.

Fig 2 depicts the optical set-up, showing the relationship between the camera and the projector, whose optical axes intersect at a point on a reference screen.

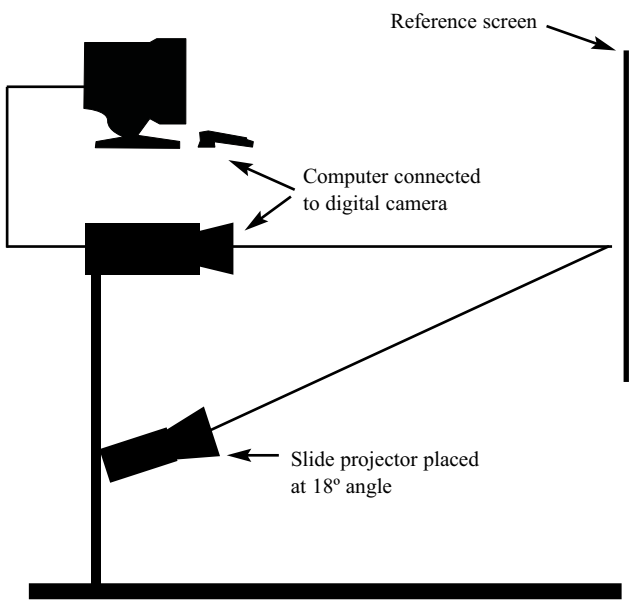


Fig 2. Optical set-up

Fig 3 shows the image, as seen by the camera, of the light pattern projected onto the reference screen.

Fig 3. The projection of grating pattern onto the reference screen.

Fig 4 shows the distortion pattern of the horizontal line pattern when the reference screen is replaced by a sector of a spherical test object.

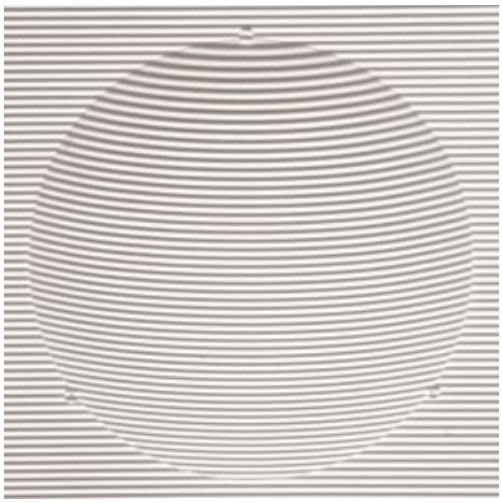


Fig 4. The distortion of this grating pattern (shown Fig 3.) by a spherical phantom test object. Daily calibration measurements were taken with this object.

In effect, the computer measures the displacement of each point of each distorted horizontal line from the corresponding point of the undistorted image pattern, and thereby calculates the distance of each point from the reference plane.

Fig 5 shows a contour map of the spherical object, where the contours are similar to contours on a map. The superimposed triangle is used for aligning body markers.

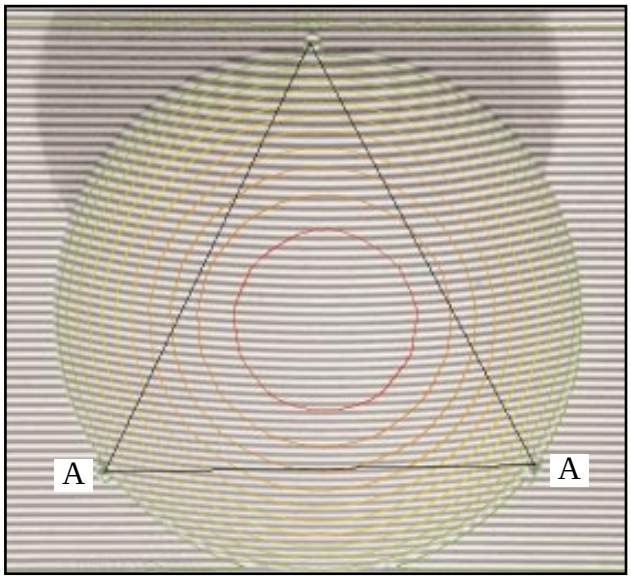


Fig 5. The contour map of the test object image.

Fig 6 shows a cross section, in millimeters, of the base of the triangle A-A shown in Fig 4

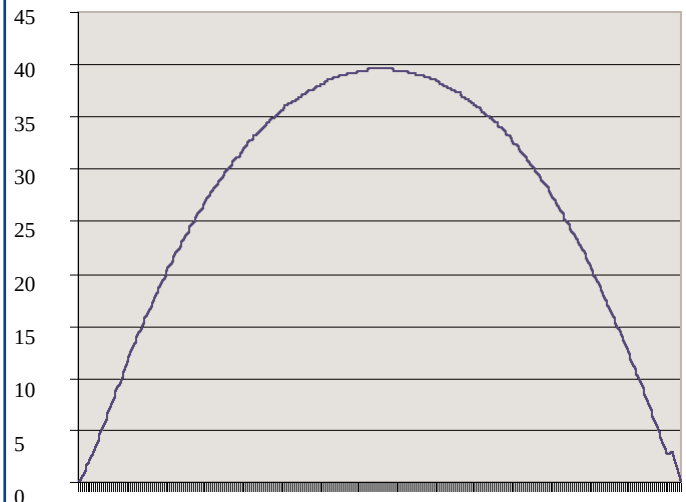


Fig 6: Cross section AA

Subject Marking

Before any images were captured the skin over the anterior superior iliac spines (ASIS) and the xiphy-sternum were marked. These boney points were used as reference points for the Fourier transform profilometry.

These anatomical landmarks form a triangle and the measuring system evaluates abdominal flatness within the region.

Subject Positioning

The subject was invited to stand on a platform, positioned in front of the camera. The reference plane coincides with the front of the platform. One or more plinths could be added or removed from the platform, according to subject height. (The umbilicus height was brought approximately level to the optical axis of the camera). The number of plinths was recorded to ensure similar positioning for the second measurement session. At the front of the platform there was a thigh-high horizontal bar, normal to the camera.

Subject Images

Three views of each subject were acquired, two forms of frontal view and one side view.

Frontal Views:
For the “free stance” Fig 7, the subject stood comfortably with one foot on either side of a black line, facing the camera and along its optical axis approximately one inch from a thigh high horizontal bar.

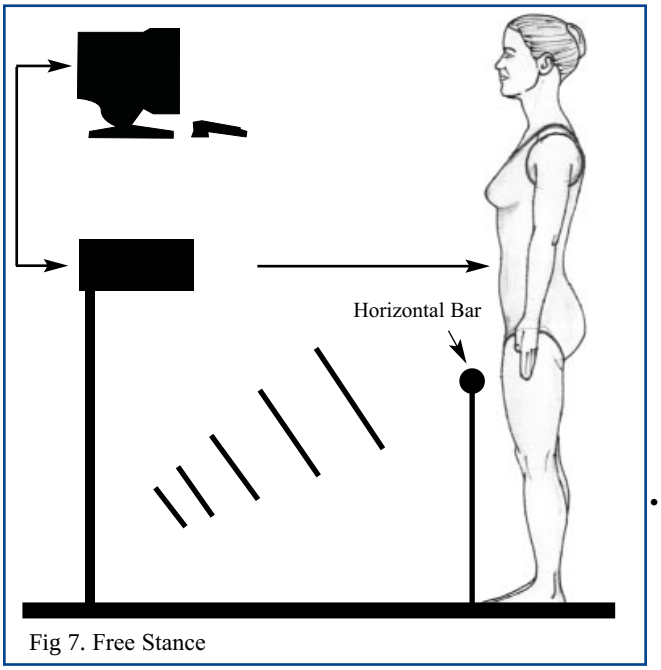


Fig 7. Free Stance

For the "fixed stance" Fig 8, the subject was asked to move forward until they were standing comfortably against the horizontal bar. They were not allowed to lean against the bar in order to reduce sway. Coloured parallel lines were marked on the plinths, 1cm apart. These were at right angles to the optical axis. The line at the tip of the hallus magnus was noted so that the subject's feet and thighs could be exactly repositioned for the second measurement session. If the physiotherapist noted marked upper body sway the subject's stance was further stabilised by a xiphy-sternal probe and this was noted for the second session.

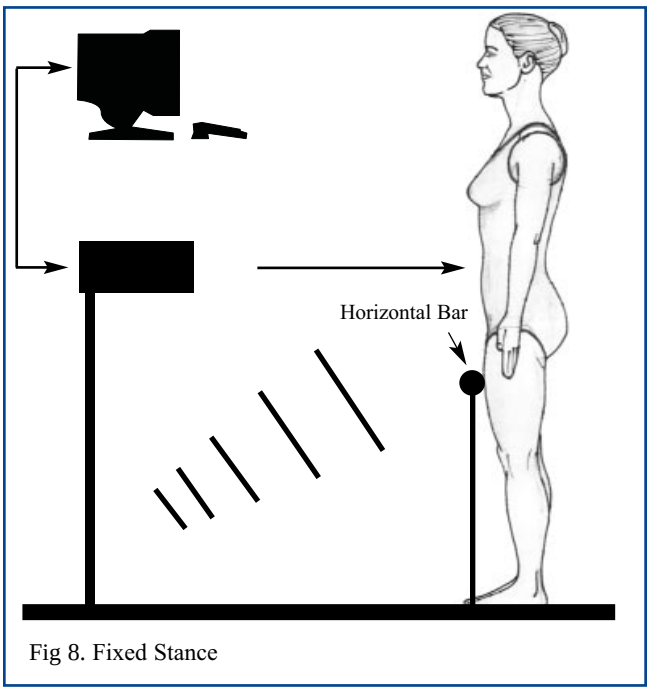


Fig 8. Fixed Stance

Side View:
Full side profile view was also taken Fig 9. The subject stood at right angles to the camera in a known position with the Malleoli over the long bar of a cross marked on plinth. The subject looked at a fixed eye-level mark on the facing wall.

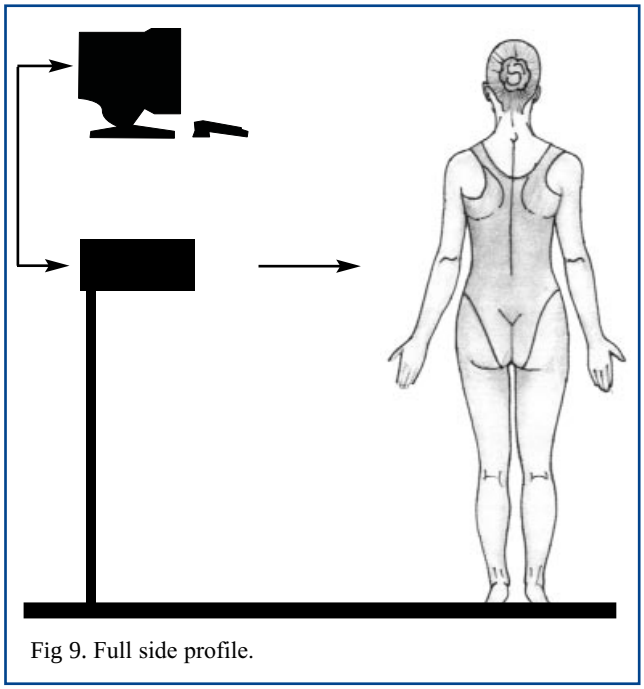


Fig 9. Full side profile.

In each of the stances the physiotherapist waited for the subject to be relaxed and breathing comfortably before recording a 12.5 second sequence of 50 images. This report considers only the images from the fixed stance.

Analysis of Video for Fourier Transform Profilometry

Fig 10 shows a typical abdominal image before processing. Fig 11 shows the same image with the computed 3D contours superimposed. The images may be understood as a simple topographical map, with 10 mm contours drawn in intervals from the highest point downwards.

The innermost band encloses those areas of the abdomen that are less than 10mm back from the most protuberant part of the abdomen. Subsequent bands enclose areas that are 20mm, 30mm, 40mm, and 50mm back from this point.

Because the shape of the abdomen changes during the breathing cycle, images for analysis were selected from the dwell point of expiration only. This was done using a specially designed video image sequencing system which allowed the investigator to step the video frame by frame and so select the dwell images. Furthermore, the video image sequence was assessed by the physiotherapist investigator to determine if the breathing pattern was normal and regular.

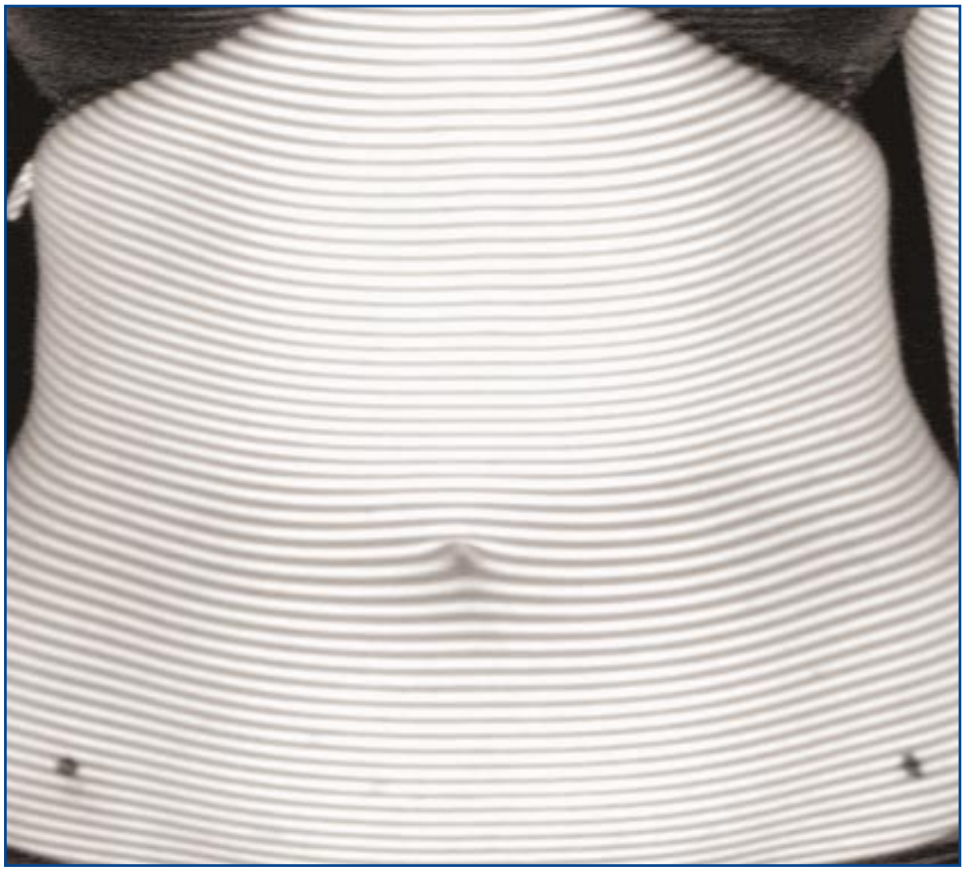


Fig 10. Raw Abdominal image

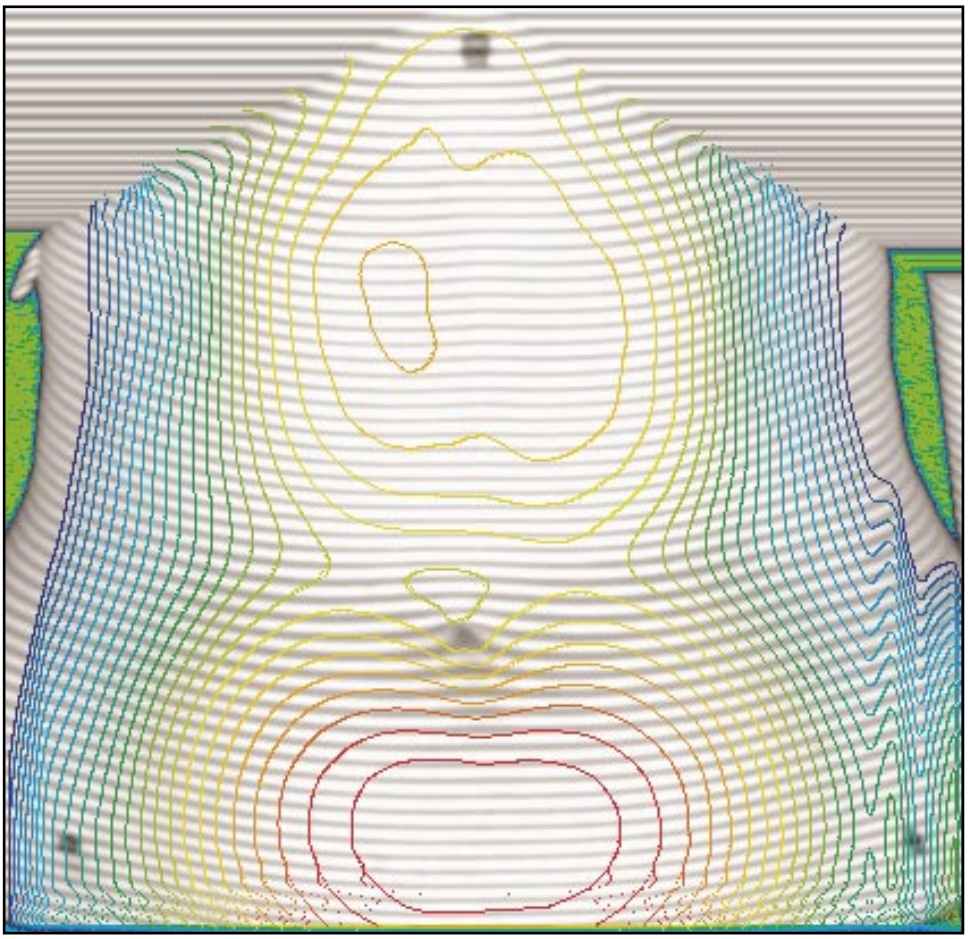


Fig 11. With contours superimposed

There are no generally accepted criteria for the comparative analysis of abdominal contour maps. In order to quantify the apparent changes in abdominal flatness the abdominal surface cross section in the horizontal plane from the subject's left anterior superior illiac spine (ASIS) was computed. This had been marked by the physiotherapist prior to image acquisition. Fig 12 illustrates typical cross section curves obtained from a subject, showing an ensemble of dwell images from before and after the trial period. In this example, the subjects post trial cross section shows an improvement in flatness compared to the pre-trial measurement.

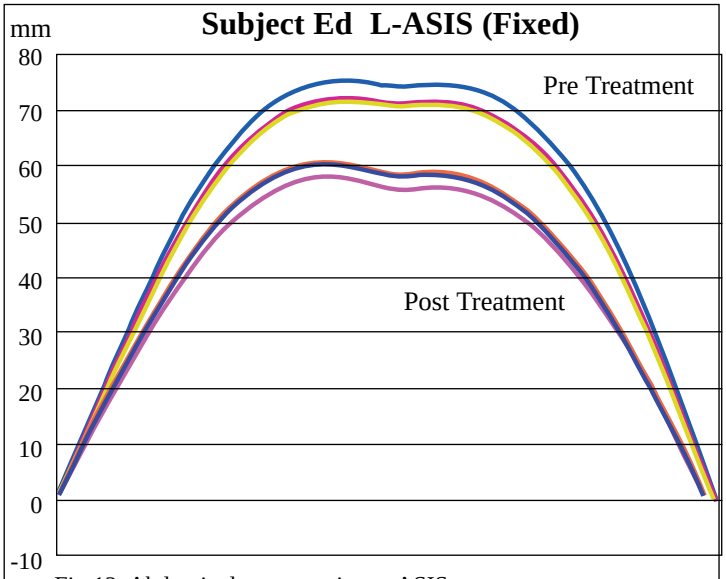


Fig 12. Abdominal cross section at ASIS

Graphs corresponding to four dwells in the breathing cycle of both before and after sessions were computed. For the purposes of analysis the median graph from each session was used. The vertical height of the graph represents the skin surface at the level of the ASIS. The maximal height represents the most protruberant part of the abdomen at this level. A decrease in this height represents an improvement in abdominal flatness.

Result of Flatness Measure:

There was an average 5.1% improvement in the treatment group compared to 1.1% for the control group. Analysis with Student's t–test rated this finding as significant to the 0.05 level, $p<0.05$.

Strength Measurement

The Abdominal Muscle Dynamometer.

The subject lay on a specially constructed test table as illustrated in Fig 13, with the knees bent to approximately 90 degrees. A padded shoulder harness was fitted to the subject and attached through a hole in the table to a force sensing device directly below. The harness and linkage to the force gauge was tightened to a comfortable level which nonetheless prevented movement of the subject from the table. The gauge was a Cooper Instruments Imada digital force gauge DPS 220R, which was connected to a PC allowing realtime measurement and plotting of the force against time.

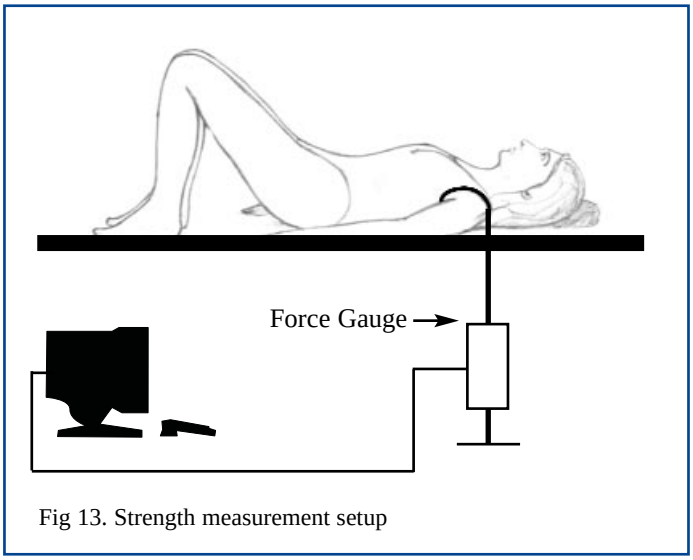


Fig 13. Strength measurement setup

The subject started from a position with the head raised from the table and the chin tucked in, arms folded across the chest. Since there was little or no movement of the subject the force in the gauge is an indication of the abdominal muscle strength. Sit-up movements tend to involve hip flexors and momentum effects which can mask the contribution of the abdominal muscles.
The subject was exhorted to build up to maximal effort over two seconds and to sustain the effort for a further 3 seconds. The subject could not see the screen plotting their efforts and the investigator was blind as to the group membership of the subject. Three to four efforts were made unless the subject was clearly not making maximal effort. A 30 second rest was allowed between efforts. A typical plot is shown in Fig 14, with tensile force shown as negative. The baseline is the starting tension in the harness and linkage. The peak value is the maximum force sustained by the abdominal muslces.

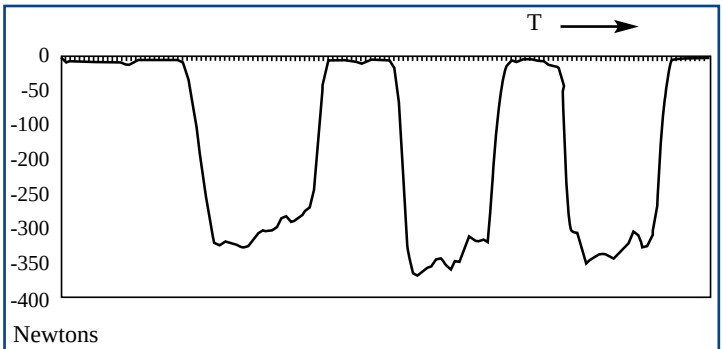


Fig 14. Typical Force curves showing 3 distinct efforts

Fig 15 and table 1 shows the average result for the two groups, for the three efforts, expressed as a percentage of the pre-trial measurement. Over the period of the trial, the control group showed little change (-0.4%) in mean strength as measured by the first effort, whereas the treatment group showed an increase of 11.5%. For the second effort, the control group showed a larger decline with respect to their pre-trial measurement, while the treated group maintained the improvement at 12.7%. In the third effort, the treated group did not maintain the same level of improvement, but on the other hand the control group declined even more.

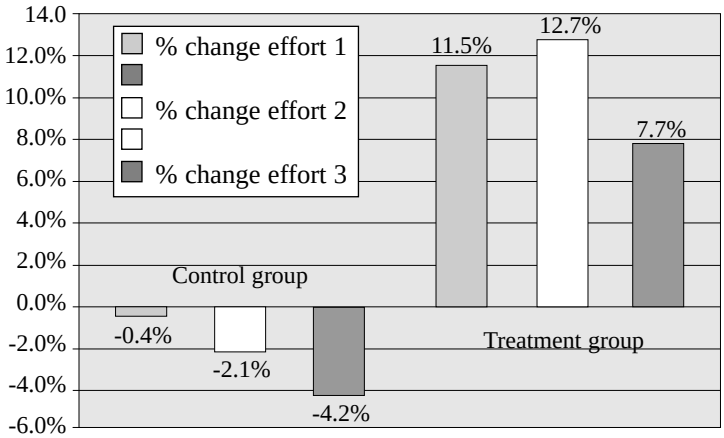


Fig 15 Force Gauge Test

	Control Group n=32	Treatment Group n=34	
% change in effort 1	-0.4%	11.5%	P<.0.5
% change in effort 2	-2.1%	12.7%	P<.025
% change in effort 3	-4.2%	7.7%	P<.025

Table 1.

Psychometric Data Analysis

Introduction

Subjects were asked to complete a standardised questionnaire on the days of their first and second measurements. The questionnaire measured attitudes towards body shape using semantic differential and Likert rating scales. The research supervisor explained the questionnaire format to each subject and observed completion.

Analysis of Question 1 - Semantic Differential Scales

Subjects were asked to describe the appearance of their stomachs using 10 semantic differential rating scales. Subjects had to choose between 5 points on each scale, for example if a subject thought that her stomach muscles were quite strong she might mark the relevant scale as follows:

When the results were analysed, each point was allocated a score starting with 1 for the point nearest to the negative adjective and ending with 5 for the point nearest the positive adjective. The average scores for each parameter were calculated by group. The difference in the average scores before and after the study are presented in Table 2.

A positive change in each score indicates a move towards the positive adjective and a subsequent improvement in the perception of the group over the eight week period. As can be seen from the table, the treatment group displayed positive changes in their scores across all parameters while, in the majority of cases, the control group scores remained constant or declined slightly. The greatest changes in score were seen along the firmness, flatness, hardness and shape parameters for the treatment group.

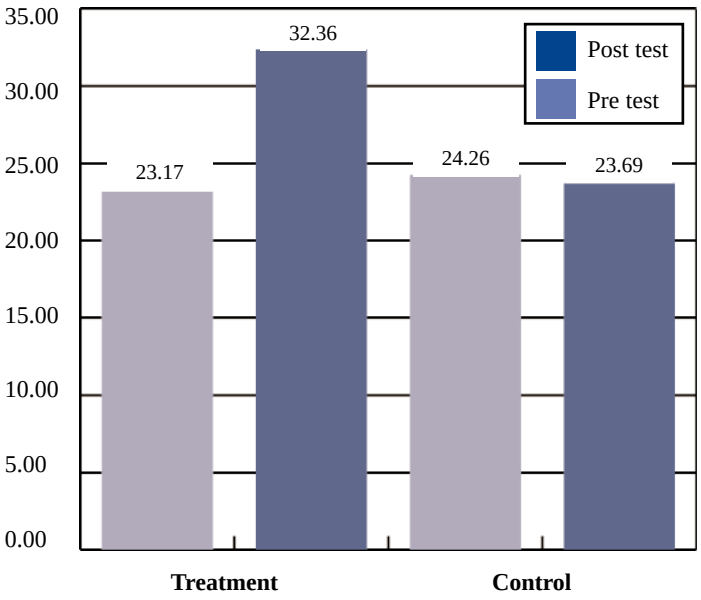
PARAMETERS			TREATMENT GROUP* Average Change	CONTROL GROUP* Average Change
Wobbly	>>	Firm	1.31	-0.06
Rounded	>>	Flat	1.28	-0.06
Soft	>>	Hard	1.22	0.06
In poor shape	>>	In good shape	1.19	-0.35
Large	>>	Small	0.83	-0.03
Clothes are too tight	>>	Clothes fit	0.78	-0.44
Unattractive	>>	Attractive	0.69	0.00
Fat	>>	Thin	0.67	-0.06
Weak	>>	Strong	0.64	-0.06
Stretch marked	>>	Smooth	0.50	0.41
Total average change along scores**			9.08	**-0.57**

Table 2 Average Change, Semantic Differential Scales

***Maximum average change in score along each scale is 4**
**** Maximum total average change is 40**

The following graphs illustrate the average changes in the score for each parameter.

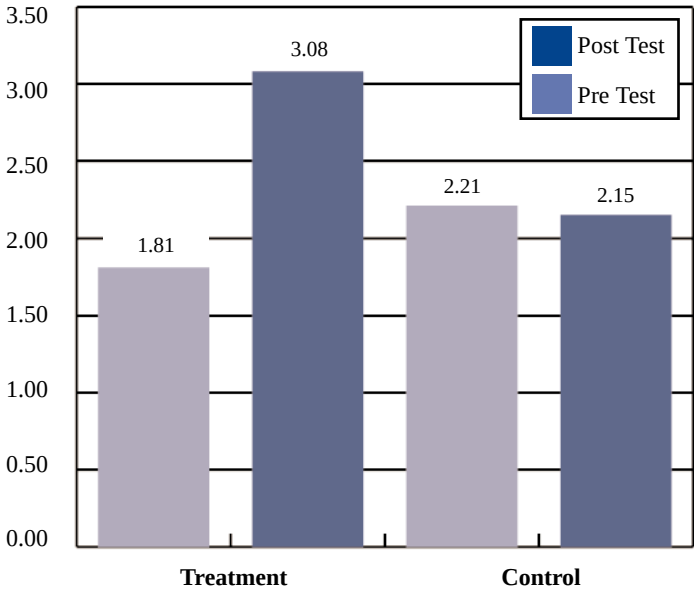
Average Score Across All Body Image Scales Pre And Post Test
p<0.001



Average Total Change In Rating Scales			
	Pre test	**Post test**	**Average change**
Treatment	23.17	32.36	9.08
Control	24.26	23.69	-0.57

Table 3

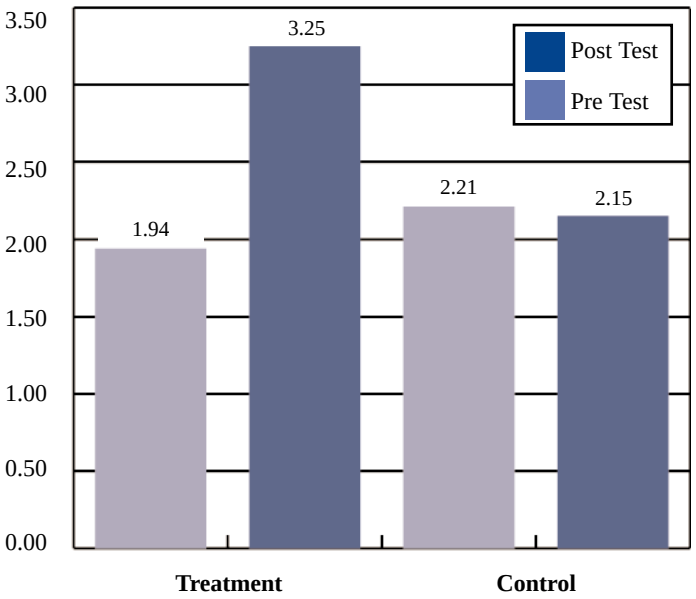
Flatness - Average Subject Rating Pre And Post Test
p<0.001



Flatness - Average Change In Score			
	Pre Test	**Post Test**	**Average Change**
Treatment	1.81	3.08	1.28
Control	2.21	2.15	-0.06

Table 5

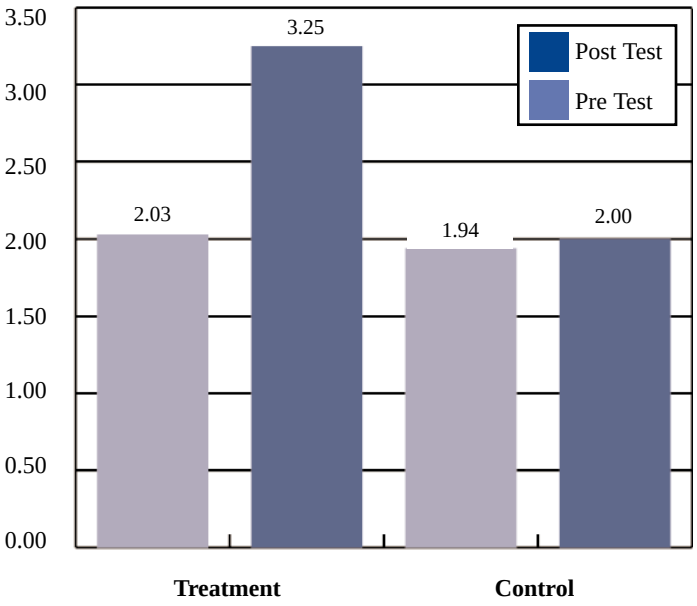
Firmness - Average Subject Rating Pre And Post Test
p<0.001



Firmness - Average Change In Score			
	Pre test	**Post test**	**Average change**
Treatment	1.94	3.25	1.31
Control	2.21	2.15	-0.06

Table 4

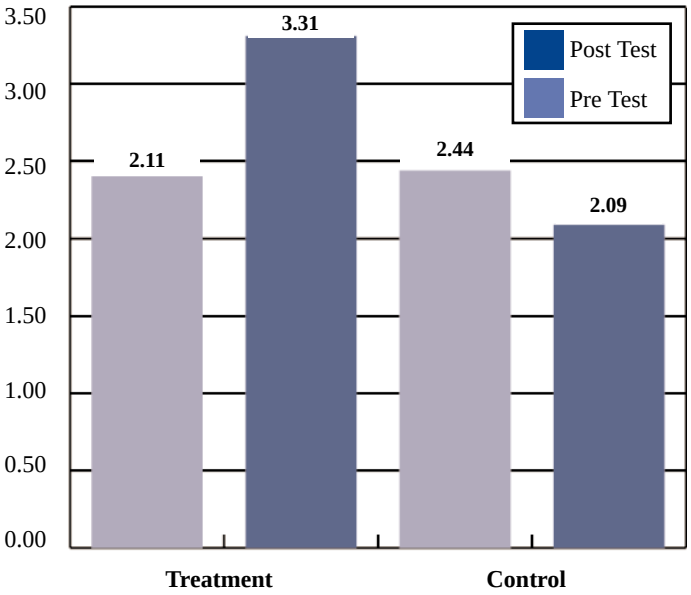
Hardness - Average Subject Rating Pre And Post Test
p<0.001



Hardness - Average Change In Score			
	Pre test	**Post test**	**Average change**
Treatment	2.03	3.25	1.22
Control	1.94	2.00	0.06

Table 6

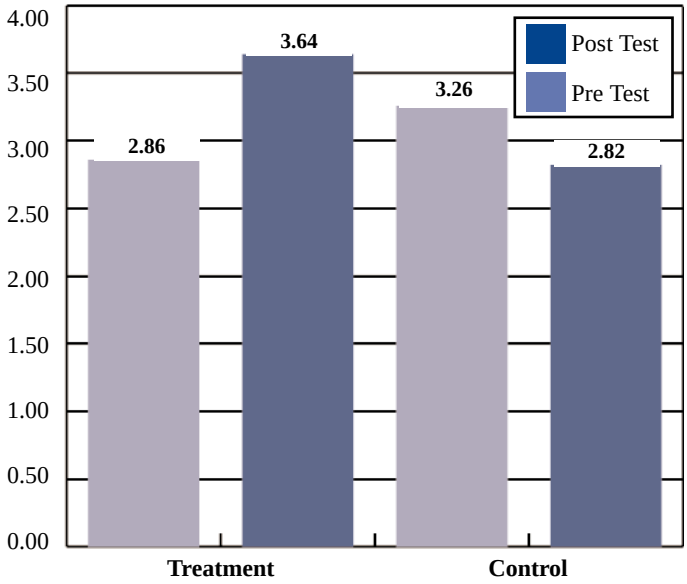
Good Shape - Average Subject Rating Pre And Post Test
p<0.001



Good Shape - Average Change In Score			
	Pre Test	**Post Test**	**Average Change**
Treatment	2.11	3.31	1.19
Control	2.44	2.09	-0.35

Table 7

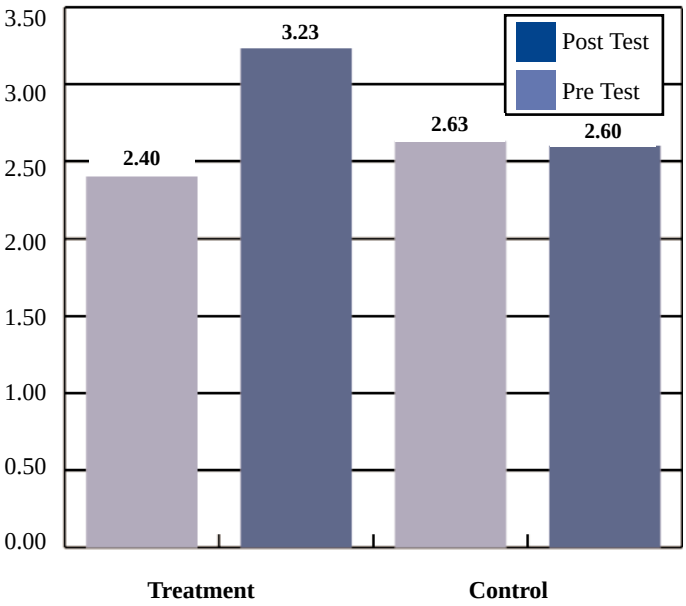
Clothes Fit - Average Subject Rating Pre And Post Test
p<0.001



Clothes Fit - Average Change In Score			
	Pre Test	**Post Test**	**Average Change**
Treatment	2.86	3.64	0.78
Control	3.26	2.82	-0.44

Table 9

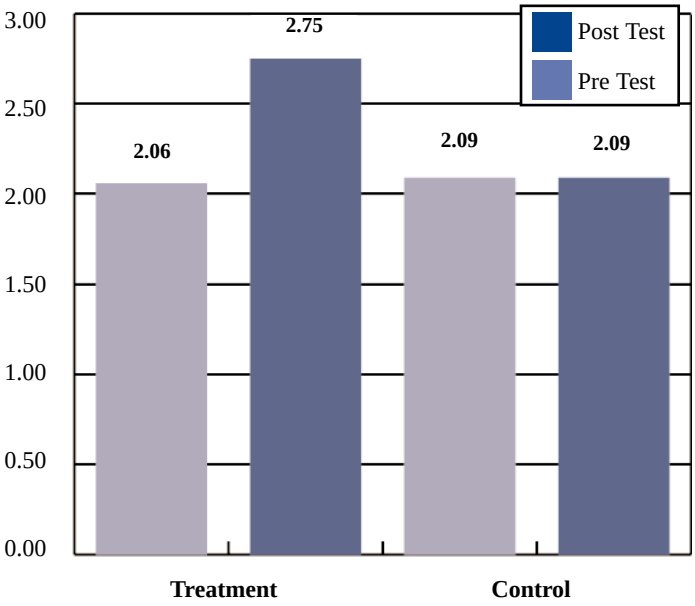
Size - Average Subject Rating Pre And Post Test
p<0.001



Size - Average Change In Score			
	Pre Test	**Post Test**	**Average Change**
Treatment	2.40	3.25	0.83
Control	2.63	2.60	-0.03

Table 8

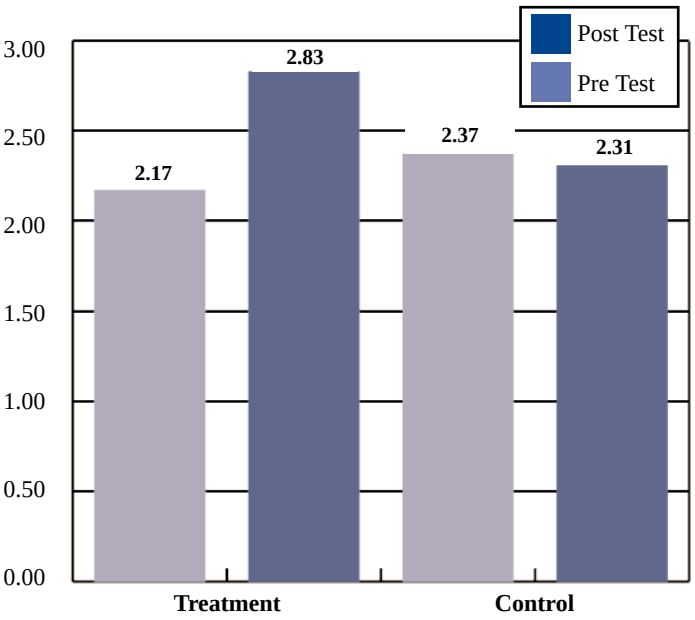
Attractiveness - Average Subject Rating Pre And Post Test
p<0.001



Attractiveness - Average Change In Score			
	Pre Test	**Post Test**	**Average Change**
Treatment	2.06	2.75	0.69
Control	2.09	2.09	0.00

Table 10

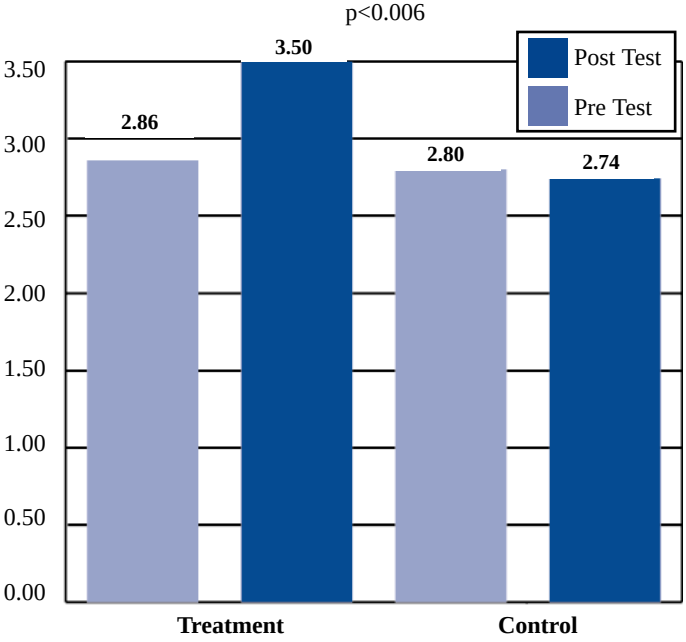
Thinness - Average Subject Rating Pre And Post Test
p<0.001



Thinness - Average Total Change In Rating Scales			
	Pre Test	**Post Test**	**Average Change**
Treatment	2.17	2.83	0.67
Control	2.37	2.31	-0.06

Table 11

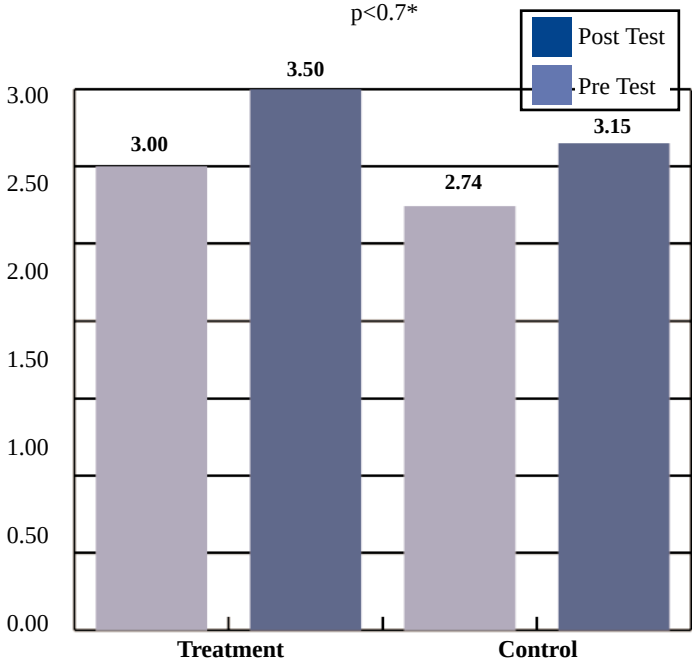
Strength - Average Subject Rating Pre And Post Test
p<0.006



Strength - Average Change In Score			
	Pre Test	**Post Test**	**Average Change**
Treatment	2.86	3.50	0.64
Control	2.80	2.74	-0.06

Table 12

Smoothness - Average Subject Rating Pre And Post Test
p<0.7*



Smoothness - Average Total Change In Rating Score			
	Pre Test	**Post Test**	**Average Change**
Treatment	3.00	3.50	0.50
Control	2.74	3.15	0.41

Table 13

* Note: The results along the smoothness parameter are not significant (p<0.7).

Frequency Distribution of Change in Semantic Differential Scores

The semantic differential rating scales allowed a maximum change of 4 to be recorded between pre and post test scores. The following table outlines the frequency with which the changes between pre and post test scores were recorded among treatment and control group members. After the trial, 91.67% of the treatment group reported an improvement in firmness and 77.78% reported an improvement in flatness. Along all parameters, at least 50% of the treatment group increased their score by one point or more along the five point scales when they filled out the questionnaire for the second time.

Table 14. Frequency Distribution of Change in Semantic Differential Scores

		Disimprovement				No Change	Improvement			
		-4	-3	-2	-1	0	1	2	3	4
Flat	%Treatment Group	0.00%	0.00%	0.00%	0.00%	22.22%	38.89%	33.33%	0.00%	5.56%
	%Control Group	0.00%	0.00%	5.88%	14.71%	58.82%	20.59%	0.00%	0.00%	0.00%
Firm	%Treatment Group	0.00%	0.00%	0.00%	0.00%	8.33%	63.89%	19.44%	5.56%	2.78%
	%Control Group	0.00%	0.00%	2.94%	8.82%	67.65%	17.65%	0.00%	0.00%	0.00%
Strength	%Treatment Group	0.00%	0.00%	2.78%	8.33%	27.78%	36.11%	16.67%	5.56%	0.00%
	%Control Group	0.00%	0.00%	2.94%	20.59%	58.82%	17.65%	0.00%	0.00%	0.00%
Thin	%Treatment Group	0.00%	0.00%	2.78%	2.78%	41.67%	30.56%	22.22%	0.00%	0.00%
	%Control Group	0.00%	0.00%	2.86%	25.71%	48.57%	20.00%	2.86%	0.00%	0.00%
Small	%Treatment Group	0.00%	0.00%	0.00%	8.57%	34.29%	31.43%	20.00%	2.86%	2.86%
	%Control Group	0.00%	2.86%	5.71%	14.29%	51.43%	20.00%	5.71%	0.00%	0.00%
Attractivness	%Treatment Group	0.00%	0.00%	2.78%	2.78%	33.33%	44.44%	16.67%	0.00%	0.00%
	%Control Group	0.00%	0.00%	2.94%	17.65%	55.88%	23.53%	0.00%	0.00%	0.00%
Hard	%Treatment Group	0.00%	0.00%	2.78%	2.78%	16.67%	44.44%	19.44%	8.33%	5.56%
	%Control Group	0.00%	0.00%	2.86%	17.14%	60.00%	14.29%	2.86%	2.86%	0.00%
Good Shape	%Treatment Group	0.00%	0.00%	0.00%	5.56%	11.11%	52.78%	22.22%	5.56%	2.78%
	%Control Group	2.94%	2.94%	11.76%	17.65%	41.18%	20.59%	2.94%	0.00%	0.00%
Smoothness	%Treatment Group	0.00%	0.00%	0.00%	5.56%	44.44%	44.44%	5.56%	0.00%	0.00%
	%Control Group	0.00%	0.00%	5.88%	17.65%	29.41%	35.29%	2.94%	5.88%	2.94%
Clothes Fit	%Treatment Group	0.00%	2.78%	0.00%	5.56%	30.56%	30.56%	30.56%	0.00%	0.00%
	%Control Group	2.94%	5.88%	2.94%	29.41%	40.18%	14.71%	2.94%	0.00%	0.00%

Likert Rating Scales

Subjects were asked to agree or disagree with a range of statements relating to their attitudes to the appearance of their stomachs and body shapes before and after use of the unit. The percentage breakdown of the responses before and after the study are recorded in the following tables. There is a strong movement towards the positive response for each statement following use of the unit by the treatment group. After the trial, 44% of the treatment group agreed that their stomachs felt flat and 66% agreed that their stomachs felt firm compared with 6% and 3% before the trial respectively. 54% of the treatment group agreed and an additional 17% strongly agreed that they had noticed an improvement in their shape. 47% of the treatment group agreed and 8% strongly agreed that they felt more confident. 14% strongly agreed and 63% agreed that they had felt more positive about their shape recently. The vast majority of treatment group respondents agreed or strongly agreed that their clothes fitted better than before (76%), that their stomachs felt firm (66%) and that their stomach muscles felt tight. (68%).

The control group, however does not appear to have experienced any significant change in attitude towards their shape in general as can be seen from the following tables.

Analysis of Response Distribution Pre and Post Test Likert Rating Scales

My stomach feels flat					
Treatment Group	Strongly Disagree	Disagree	No opinion	**Agree**	**Strongly Agree**
Pre-test	30.56%	63.89%	0.00%	**5.56%**	**0.00%**
Post-test	2.78%	41.67%	11.11%	**44.44%**	**0.00%**
Change (n = 36)	-27.78%	22.22%	11.11%	**38.88%**	**0.00%**
Control Group	Strongly Disagree	Disagree	No opinion	**Agree**	**Strongly Agree**
Pre-test	28.57%	57.14%	2.86%	**8.57%**	**2.86%**
Post-test	14.29%	80.00%	0.00%	**5.71%**	**0.00%**
Change (n = 35)	-14.28%	22.86%	-2.86%	**-2.86%**	**-2.86%**

Table 15

My clothes seem to fit better than before					
Treatment Group	Strongly Disagree	Disagree	No opinion	**Agree**	**Strongly Agree**
Pre-test	14.71%	41.18%	29.41%	**14.71%**	**0.00%**
Post-test	0.00%	2.94%	20.59%	**64.71%**	**11.76%**
Change (n=35)	-14.71%	-38.24%	-8.82%	**50.00%**	**11.76%**
Control Group	Strongly Disagree	Disagree	No opinion	**Agree**	**Strongly Agree**
Pre-test	6.06%	42.42%	39.39%	**9.09%**	**3.03%**
Post-test	3.03%	48.48%	36.36%	**12.12%**	**0.00%**
Change (n = 34)	-3.03%	6.06%	-3.03%	**3.03%**	**-3.03%**

Table 17

My stomach feels firm					
Treatment Group	Strongly Disagree	Disagree	No opinion	**Agree**	**Strongly Agree**
Pre-test	22.86%	65.71%	8.57%%	**2.86%**	**0.00%**
Post-test	0.00%	28.57%	5.71%	**62.86%**	**2.86%**
Change (n=35)	-22.86%	-37.14%	-2.86%	**60.00%**	**2.86%**
Control Group	Strongly Disagree	Disagree	No opinion	**Agree**	**Strongly Agree**
Pre-test	14.29%	74.29%	5.71%	**5.71%**	**0.00%**
Post-test	20.00%	65.71%	5.71%	**8.57%**	**0.00%**
Change (n = 35)	5.71%	-8.58%	0.00%	**2.86%**	**0.00%**

Table 16

My stomach muscles seem tight					
Treatment Group	Strongly Disagree	Disagree	No opinion	**Agree**	**Strongly Agree**
Pre-test	11.43%	68.57%	11.43%	**8.57%**	**0.00%**
Post-test	0.00%	14.29%	17.14%	**57.14%**	**11.43%**
Change (n=34)	-11.43%	-54.28%	5.71%	**48.57%**	**11.43%**
Control Group	Strongly Disagree	Disagree	No opinion	**Agree**	**Strongly Agree**
Pre-test	14.71%	58.82%	14.71%	**11.76%**	**0.00%**
Post-test	8.82%	79.41%	2.94%	**8.82%**	**0.00%**
Change (n = 33)	-5.89%	20.59%	-11.77%	**-2.94%**	**0.00%**

Table 18

I have been feeling more positive about my shape recently					
Treatment Group	Strongly Disagree	Disagree	No opinion	**Agree**	**Strongly Agree**
Pre-test	20.00%	40.00%2	20.00%	**20.00%**	**0.00%**
Post-test	2.86%	2.86%	17.14%	**62.86%**	**14.29%**
Change (n=35)	-17.14%	-37.14%	-2.86%	**42.86%**	**14.29%**

Control Group	Strongly Disagree	Disagree	No opinion	**Agree**	**Strongly Agree**
Pre-test	8.57%	42.86%	14.29%	**34.29%**	**0.00%**
Post-test	0.00%	42.86%	25.71%	**31.43%**	**0.00%**
Change (n=35)	-8.57%	0.00%	11.42%	**-2.86%**	**0.00%**

Table 19

I have been feeling fitter than usual recently					
Treatment Group	Strongly Disagree	Disagree	No opinion	**Agree**	**Strongly Agree**
Pre-test	19.44%	33.33%	27.78%	**19.44%**	**0.00%**
Post-test	2.78%	16.67%	33.33%	**33.33%**	**13.89%**
Change (n = 36)	-16.66%	-16.66%	5.55%	**13.89%**	**13.89%**

Control Group	Strongly Disagree	Disagree	No opinion	**Agree**	**Strongly Agree**
Pre-test	5.71%	45.71%	22.86%	**25.71%**	**0.00%**
Post-test	8.57%	48.57%	22.86%	**20.00%**	**0.00%**
Change (n = 35)	2.86%	2.86%	0.00%	**-5.71%**	**0.00%**

Table 20

I have been feeling more confident recently					
Treatment Group	Strongly Disagree	Disagree	No opinion	**Agree**	**Strongly Agree**
Pre-test	5.56%	41.67%	27.78%	**25.00%**	**0.00%**
Post-test	0.00%	13.89%	30.56%	**47.22%**	**8.33%**
Change (n=36)	-5.56%	-27.78%	2.78%	**22.22%**	**8.33%**

Control Group	Strongly Disagree	Disagree	No opinion	**Agree**	**Strongly Agree**
Pre-test	5.71%	37.14%	31.43%	**22.86%**	**2.86%**
Post-test	0.00%	40.00%	40.00%	**20.00%**	**0.00%**
Change (n = 35)	-5.71%	2.86%	8.57%	**-2.86%**	**-2.86%**

Table 21

Recently, I have noticed improvements in my shape					
Treatment Group	Strongly Disagree	Disagree	No opinion	**Agree**	**Strongly Agree**
Pre-test	8.57%	51.43%	22.86%	**17.14%**	**0.00%**
Post-test	0.00%	14.29%	14.29%	**54.29%**	**17.14%**
Change (n=35)	-8.57%	-37.14%	-8.57%	**37.15%**	**17.14%**

Control Group	Strongly Disagree	Disagree	No opinion	**Agree**	**Strongly Agree**
Pre-test	2.86%	62.86%	20.00%	**14.29%**	**0.00%**
Post-test	2.86%	54.29%	22.86%	**20.00%**	**0.00%**
Change (n=35)	0.00%	-8.57%	2.86%	**5.71%**	**0.00%**

Table 22

Recently, I have been feeling healthier than usual					
Treatment Group	Strongly Disagree	Disagree	No opinion	**Agree**	**Strongly Agree**
Pre-test	8.33%	36.11%	38.89%	**16.67%**	**0.00%**
Post-test	0.00%	16.67%	22.22%	**61.11%**	**0.00%**
Change (n=36)	-8.33%	-19.44%	-16.67%	**44.44%**	**0.00%**

Control Group	Strongly Disagree	Disagree	No opinion	**Agree**	**Strongly Agree**
Pre-test	2.86%	45.71%	25.71%	**22.86%**	**2.86%**
Post-test	0.00%	48.57%	25.71%	**22.86%**	**2.86%**
Change (n = 35)	-2.86%	2.86%	0.00%	**0.00%**	**0.00%**

Table 23

Recently, I have noticed improvements in my posture					
Treatment Group	Strongly Disagree	Disagree	No opinion	**Agree**	**Strongly Agree**
Pre-test	11.11%	50.00%	36.11%	**2.78%**	**0.00%**
Post-test	0.00%	19.44%	44.44%	**36.11%**	**0.00%**
Change (n=36)	-11.11%	-30.56%	8.33%	**33.33%**	**0.00%**

Control Group	Strongly Disagree	Disagree	No opinion	**Agree**	**Strongly Agree**
Pre-test	5.71%	54.29%	34.29%	**5.71%**	**0.00%**
Post-test	0.00%	62.86%	34.29%	**2.86%**	**0.00%**
Change (n=35)	-5.71%	8.57%	0.00%	**-2.85%**	**0.00%**

Table 24

Overall Satisfaction With Stomach Appearance And Body Shape

Subjects were asked to rate their satisfaction with the appearance of their stomachs and body shapes in general. Following use of the unit for 8 weeks, 47% of the treatment group said that they were either satisfied or very satisfied with the appearance of their stomach. One in 9 members of the treatment group were not satisfied as can be seen from the following table.

36% of the treatment group said that they were satisfied with body shape in general after the 8 week study compared with 11% prior to the start of the trial.

How do you feel about the appearance of your stomach

Treatment Group	Very Dissatisfied	Dissatisfied	No opinion	**Satisfied**	**Very Satisfied**
Pre-test	33.33%	33.33%	27.78%	**5.56%**	**0.00%**
Post-test	2.78%	8.33%	41.67%	**41.67%**	**5.56%**
Change (n=36)	-30.55%	-25.00%	13.89%	**36.11%**	**5.56%**

Control Group	Very Dissatisfied	Dissatisfied	No opinion	**Satisfied**	**Very Satisfied**
Pre-test	25.71%	42.86%	25.71%	**5.71%**	**0.00%**
Post-test	17.14%	42.86%	31.43%	**8.57%**	**0.00%**
Change (n=35)	-8.57%	0.00%	5.72%	**2.86%**	**0.00%**

Table 25

How do you feel about your body shape in general ?

Treatment Group	Very Dissatisfied	Dissatisfied	No opinion	**Satisfied**	**Very Satisfied**
Pre-test	16.67%	27.78%	44.44%	**11.11%**	**0.00%**
Post-test	2.78%	8.33%	52.78%	**36.11%**	**0.00%**
Change (n=36)	-13.89%	-19.45%	8.34%	**25.00%**	**0.00%**

Control Group	Very Dissatisfied	Dissatisfied	No opinion	**Satisfied**	**Very Satisfied**
Pre-test	5.71%	34.29%	48.57%	**11.43%**	**0.00%**
Post-test	2.86%	42.86%	42.86%	**8.57%**	**2.86%**
Change (n=35)	-2.85%	8.57%	-5.71%	**-2.86%**	**2.86%**

Table 26

Summary of Results

Improved body image and well-being among the treatment group, ($p<0.05$), improvements in perceived firmness, ($p<0.01$), flatness, ($p<0.01$), and strength ($p<0.01$). Improvements in abdominal strength, ($p<0.05$), and flatness, ($p<0.05$).

In each case the improvements were greater than those previously observed (using a similar methodology) with standard abdominal electrical stimulation[15].

Discussion of Results

The measurement of physical data relating to the abdomen is confounded by many factors. Principle among them is that the measurement itself changes that which is being measured. There is a tendency of people whose abdomen is being assessed to brace it or pull it in. This has a masking effect on any topographical data that is being gathered. In addition, the shape of the abdomen changes with hydration, the menstrual cycle and breathing. In this study, attempts were made to control each of these factors. Perhaps the truest topographical measure is how the subjects, themselves, reported the changes. As they noted the changes, day in, day out over the trial period rather than the snap shot which the acquisition of physical data inevitably is. As with all psychometric data, one must raise the possibility that the subjects reported greater changes than they felt. It is felt that their answers were a fairly true and accurate reflection of the attitudes at the time because:

- There was no incentive to mislead.
- They were unlikely to remember the answers they gave on semantic differential scales eight weeks previously.
- There was internal consistency between the Likert and the semantic differential scales.
- They did not report improvement across all of the questions asked as one would expect of a group eager to please. For instance, the treatment and control groups reported similar changes in the parameter of smoothness but not for firmness.

Of the objective data acquired, the strength data is the most reliable as there is a maximal voluntary contraction and predictable rate of fatigue. The (blinded) physiotherapist exhorted each subject to a maximal contraction. Sub maximal contractions tend to be evident from the graphs of force versus time and poor efforts could be repeated after a rest period.

Improvements in body shape, strength and self perception have all been previously reported using standard EMS techniques. This trial differed in two aspects. Firstly, an innovative, patent pending, abdominal stimulation technique was used. Secondly, for the first time, reliable, quantitative data measuring abdominal flatness was available.

Comparing the data to a previous study[15], with a similar methodology, the results strongly support the hypothesis that the new

CSI abdominal stimulation technique is a major advance. This study was conducted over eight weeks compared to four for the previous study. However, results tend to have plateaued by four weeks. (Ballantyne and Donne[16] at Trinity College Dublin showed that strength gains and tone changes tend to plateau at or before four weeks, respectively). The observed strength gains are less than those noted by Ballantyne and Donne using a similar EMS technique, (20-30%), and those reported by many others using EMS on the quadriceps and other accessible muscle groupings, e.g. Balogan. The difference is presumed to relate primarily to the sarcomere length at which the muscle strength was measured, (subject flat, knees at 90° angle).

The large girth reductions associated with weight loss were not seen as subjects maintained their regular diet and exercise patterns. Weight loss in excess of 2kg was an elimination criterion. The conformational changes seen with profilometry are consistent with the reports of the subjects themselves. These changes are consistent with changes in abdominal muscle strength, tone and (resting) fibre length affecting abdominal shape and contours.

From observations and reports made during the study it was evident that the subjects were getting a strong, deep and comfortable contraction with this stimulation technique. On examination they were found to brace their lower back muscles during strong abdominal contractions. Thus the lower back muscles were also exercised. In addition to paraspinal muscles, weak abdominal muscles are now thought to be a strong contributing factor in lower back pain. As many people with lower back pain are unable to do voluntary exercises this technique offers a potential new treatment for a common but serious ailment.

Conclusion

The findings support previous studies showing that abdominal EMS positively impacts on abdominal shape, tone, strength and user well-being. The new CSI technique is more effective than the standard abdominal EMS techniques previously studied by this research group.

Notes

A more complete literature review is available in Electrotherapy Explained (second edition, 1994),Lowe & Reid, published by Butterworth Heinemann.

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