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Double blind, randomised, controlled trial comparing the effectiveness of two intensities of electrical muscle stimulation training on abdominal muscle strength and self-perception measures.

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Abstract
A double-blind, prospective, randomised, controlled trial was conducted in fifty three healthy adult (27 male and 26 female) volunteers to measure the efficacy of the Slendertone System-Abs abdominal muscle trainer. Subjects were randomly assigned to a standard treatment group (T), or a low intensity treatment group (LT). Subjects trained fives times a week for six weeks (30 minutes per session). LT group subjects trained using a modified Slendertone System-Abs product that had reduced muscle stimulation intensity. Subjects in this group could elicit sensory nerve activation with minimal apparent motor nerve activation, thus approximating a placebo treatment. Physiological and psychological measures were recorded for all subjects at baseline and after 2, 4 and 6 weeks of abdominal muscle training. Physiological measures recorded included height, weight, abdominal strength, abdominal endurance and core strength. Psychometric data was recorded using a Body Satisfaction Questionnaire, a Shape Evaluation Questionnaire and an Overall Results Questionnaire. Statistical analyses of the results indicated that changes in abdominal strength were significantly greater in the T group than in the LT group at the four week (19% vs 2% resp.) and six week (29% vs 4% resp.) points. Both groups showed an improvement in ACSM paced curl test compared to baseline, with a significant ($p=0.04$) group effect in favour of the T group. Significant differences were also recorded for changes in measures of self-perception using psychometric questionnaires, though the differences were not as clear in this study as previous studies using totally passive controls. This could indicate a partial placebo effect in relation to these particular measures and/or the possibility that the low dose stimulation used in the control device had some therapeutic benefit. Neither group showed changes in body mass index over the course of the study. Abdominal muscle training using the Slendertone System-Abs product resulted in a strength and endurance training effect and is consistent with previous research in this area.

Introduction

Neuromuscular Electrical Stimulation (NMES) or Electrical Muscle Stimulation (EMS) is a well accepted treatment modality that is used in both medical and fitness applications to train human skeletal muscle. Literature highlights include strength increases and prevention of muscle wastage (Hainaut and Duchateau, 1992). In the fitness sector, the main indications include strengthening and toning of skeletal muscle.

To date a number of studies have reported changes in abdominal muscle strength, endurance and associated measures of self-perception using abdominal EMS belts. Specifically, a number of studies have focused on the Slendertone (Bio-Medical Research Ltd., Galway, Ireland) brand of muscle stimulators (Cullinane et al. 2002; Porcari et al. 2005; Anderson et al. 2006). These devices use three large stimulation electrodes, one central electrode (100mm x 100mm), located adjacent the umbilicus, and one electrode (100mm x 70mm) on each side, between the rib cage and ileac crest.

A new model Slendertone abdominal toning product with this same electrode layout has recently been introduced and has been cleared to market by the Food and Drug Administration (FDA) to strengthen, tone and firm the abdominal muscles. The purpose of this study was to investigate the changes in abdominal muscle strength, endurance and self-perception that arise from a six-week programme of abdominal muscle training with this device. Previous studies used a no-exercise control group leaving open the possibility of bias since subjects would be immediately aware which group they belonged to. The current study sought to achieve a double blind design by comparing a normal treatment group with a low-dose control group. This latter group used a modified version of the Slendertone product that had a limited maximum muscle stimulation intensity. This reduced limit was selected to provide sensory nerve activation with minimal apparent motor nerve recruitment. In this way it was intended that the LT group would "feel" a training effect without any actual muscular overload. In every other respect, the products provided to the test subjects were identical.

The null hypothesis was that there would be no difference between the groups as regards strength improvement of the abdominal muscles and furthermore that there would no difference between the groups as regards psychometric measures.

Method

Subjects

Fifty six healthy adult volunteers were recruited from the area surrounding the University of Wisconsin, La Crosse, Wisconsin, USA. Inclusion criteria required the subjects to be between 25 and 55 years old, to have a body mass index (BMI) between 18 and 30, and not have been involved in any type of formal abdominal training programme within the previous 6 months. In addition, subjects with a cardiac pacemaker, any abdominal implants, or who were currently pregnant or had given birth in the previous three months were not eligible to participate in the study. Subjects were randomly assigned into one of two groups, a treatment group (T) or a low intensity treatment group (LT). Groups were balanced according to gender, age and body mass index (BMI). Both groups were instructed not to alter their diet or

engage in any additional exercise over the course of the 6-week study period and all subjects gave written informed consent prior to participating in the trial. Three subjects were eliminated from the study based on pre-defined exclusion criteria and thus the results are based on fifty-three subjects (27 male and 26 female).

This study received ethical approval from the Institutional Review Board of the University of Wisconsin-La Crosse , USA. Subjects in both groups received $200 to participate in the study in order to assure compliance with the study protocol. On conclusion of the study, all participants received a Slendertone System-Abs abdominal training belt.

Testing

Both groups underwent an identical battery of tests. Measures were taken at week 0 (i.e. baseline measures before abdominal muscle training) and after 2, 4 and 6 weeks abdominal muscle training. Efforts were made to ensure that the time and day for each testing session was the same for each individual subject. Subjects completed a series of physiological tests and psychometric questionnaires.

The physiological tests included height, weight, abdominal circumference, waist circumference, abdominal strength, abdominal endurance and a core stability test.

Psychometric data was gathered using three questionnaires, the Slendertone Shape Evaluation Questionnaire, the Slendertone Body Satisfaction Questionnaire (Caulfield et al., 2002; Cullinane et al., 2002) and an Overall Psychometric Questionnaire. The Shape Evaluation Questionnaire assesses perceived abdominal shape using a set of 10 dichotomous items taken to describe various aspects relating to the shape and appearance of the abdominal region. The items are rated on a five point semantic differential scale. The Body Satisfaction Scale consists of 12 items that measure feeling about body shape on a four point Likert scale ranging from “strongly agree” to “strongly disagree”. The Overall Psychometric Questionnaire was only administered at week 6 and asked general questions relating to perceived results from abdominal muscle training.

Anthropometric Measures

Body weight was measured to the nearest 0.1 kilogram using a Toledo electronic digital scale (Mettler-Toledo Inc., Worthington, OH). Height was measured to the nearest 0.1 centimetre while the subject stood against a stadiometer. Body mass index was calculated using the formula Body Mass / Height^2. Waist circumference was measured at minimal respiration and reported to the nearest 0.1 centimetre by positioning a flexible anthropometric tape parallel to the floor and immediately above the iliac crest. Abdominal circumference was measured as the smallest horizontal circumference in the area between the ribs and the iliac crest, the level of the natural waist. Two measurements were taken at each site and the average of the two measurements was used in the analysis.

Abdominal Strength

Abdominal Strength was assessed using an isokinetic dynamometer (Biodex, USA). The subject lay supine on a movable bench in a bent knee position. The lever arm of the isokinetic dynamometer was set at 180 degrees (horizontal with the ground) and

the padded extension was placed on the lower third of the sternum. The height of the bench was adjusted for each subject so that the extension arm remained at 180 degrees. Each subject was given several practice trials to make sure the position of the lever arm was comfortable on their chest. Subjects then performed five maximal isometric contractions, with approximately 30 seconds between each repetition. The average torque for the highest two repetitions was used in the analysis.

Abdominal Endurance

Abdominal endurance was assessed using the American College of Sports Medicine (ACSM) paced curl up test. The test was conducted using a pre-recorded audiotape. The subject laid supine on a padded exercise mat, with knees bent at 90 degrees (as verified via a goniometer) and both arms extended to the sides with fingers touching a piece of masking tape. A second piece of tape was placed 12cm beyond the first. At the start of the tape (cadence of 40 curl-ups per minute), the subjects lifted their shoulder blades off the mat and slid their fingers forward until their fingertips touched the second strip of tape. Subjects performed as many curl-ups as possible without stopping. The test was terminated when subjects could no longer keep up with the cadence or could not reach the second strip of tape. The pre-recorded audiotape included 6 warm-up repetitions before the actual test began.

The term "core" is associated with the lumbo-pelvic-hip complex, trunk stability and optimal movement efficiency. A prone "plank" test, Figure 1, was used to measure core strength. Subjects lay prone with their arms beneath their chest. They elevated their body up so that their body weight rested on their forearms with elbow and shoulder angles of ninety degrees. This position was held for a period of sixty seconds prior to a number of defined movements that ends with a return to the starting position. The total hold time for this position was measured for each subject.

The study staff carrying out the measurements were blinded as to the group membership of each subject being tested. The study was therefore double blind.

Figure 1. Prone Plank starting position

Training

Subjects in both the treatment and low intensity treatment groups completed stimulation sessions 5 times per week for 6 weeks (30 minutes per session). The abdominal stimulation system consisted of a contoured belt with detachable, pre-gelled electrodes that are connected to the stimulator without externally visible leads. The electrodes were replaced at the end of the 3rd and 6th weeks of the study. Each subject was given their own belt and attended an initial training session that was supervised. At this session subjects were given instruction on how to use the device.

The remaining muscle stimulation sessions were unsupervised and were completed away from the testing centre. Subjects were encouraged to increase the amplitude on the stimulator to the highest tolerable level in order to achieve the strongest possible contractions. Subjects were instructed not to perform volitional contractions in conjunction with the stimulator and were allowed to conduct the stimulation sessions in any positions they preferred. After every session, the subject recorded the peak stimulation intensity achieved during that session.

The maximum intensity output for the treatment group unit was higher than that for the low intensity treatment group unit. The treatment group unit had a maximum pulse current output of 70mA and a pulse width of 250 microseconds (μS), thus the maximum pulse charge possible was 17.5 micro-coulombs(μC). The low intensity treatment group unit had a maximum current output of 25mA and a pulse width of 100μS, thus the total pulse power possible was 2.5μC. It was apparent from testing that the treatment group unit was capable of eliciting high force muscle contractions. The LT group unit elicited sensory nerve activation with minimal apparent motor nerve activation, thus low muscle forces resulted. Details for both units are shown in Table 1.

Unit Name	Maximum Current Output (mA)	Pulse Width (μsec)	InterPhase Interval (μsec)	Pulse Power (μC)
System Abs (Treatment)	70mA	250	100	17.5
System Abs (LT Treatment)	25mA	100	100	2.5

Table 1. Stimulation Output for Slendertone Units.

Treatment group subjects used programme 3 on the Slendertone System-Abs for the duration of the study. This is a mid-range program and reflects a moderate training dose using the unit. Subjects in the LT group had customised units with 1 program that they used for the duration of the study. All units were verified for the correct treatment parameters prior to the beginning of the study. Average training intensities for both groups are given in table 2. The unit display gives arbitrary numbers from 1-99, thus for each unit 99 corresponded to the maximum stimulation output.

	Treatment Group	LT Treatment Group
Week 1	78.7	99
Week 2	86.6	99
Week 3	87.7	99
Week 4	88.4	99
Week 5	91	99
Week 6	91.9	99

Table 2. Average stimulation intensity for each group over 6 weeks training.

Statistics

Repeated Measures ANOVA was conducted on changes from baseline for both groups. A new response variable was created by subtracting the baseline from the

strength measurements at Weeks 2, 4 and 6, where *higher* values of the new response represent an *improvement* in strength, negative values represent a dis-improvement. This analysis permitted an investigation of (i) longitudinal change in strength improvement at the three time points, (ii) difference in mean strength improvement in Treatment and LT Treatment groups and (iii) difference in mean strength improvement for gender. All analyses were performed using Minitab 15 and SPSS14.

Results

Fifty three subjects successfully completed the study. Data from three subjects was excluded from the final analysis. One LT group member withdrew from the study due to dissatisfaction with the training intensity elicited by the attenuated device. One subject was disqualified for doing additional sit-up exercises while a third subject stopped EMS training after a mild, anticipated adverse event that involved heavier than usual blood flow during menses. For the final analysis there were 27 subjects in the treatment group (14 male and 13 female) with 26 subjects in the LT treatment group (12 male and 14 female). For the purposes of this analysis, data is presented as mean ± SD unless otherwise stated.

Descriptive characteristics of the subjects who were used in the analysis are presented in Table 3.

Group	Mean Age	BMI	Age Range
Treatment	40 ± 8.7	24 ± 2.2	26 – 53
LT Treatment	38.8 ± 8.5	25.7 ± 2.4	25 – 53

Table 3. Age and BMI profiles of the study subjects.

There were no significant differences between groups at the start of the study and there were no significant changes in body weight for either group over the course of the study.

Variable	Group	Pre-Test	2 Week	4 Week	6 Week
Body Weight (kg)	Treatment	71.4 ± 11.4	71.5±11.4	71.5+11.4	71.7±11.4
	Low Dose Treatment	77.2 ± 9.4	77.3 + 9.5	77.0±9.7	77.2 ± 9.74
Body Mass Index ($kg.m^{-2}$)	Treatment	24.4 ± 2.2	24.4 ± 2.3	24.4 ± 2.3	24.5 ± 2.4
	Low Dose Treatment	25.7 ± 2.5	25.8 ± 2.4	25.7 ± 2.5	25.7 ± 2.5
Waist Circumference (cm)	Treatment	82.3 ± 9.2	81.9 ± 9.6	80.4 ± 13.7	82.0 ± 9.5
	Low Dose Treatment	85.0 ± 8.6	84.6 ± 8.7	83.0 ± 8.8	84.3 ± 8.9
Abdominal Circumference (cm)	Treatment	90.0 ± 7.9	88.4 ± 8.3	88.0 ± 8.6	87.6 ± 8.3
	LowDose Treatment	94.0 ± 7.5	92.4 ± 7.3	90.5 ± 7.4	90.5 ± 7.4

Table 4. Results for body weight, body mass index, waist circumference and abdominal circumference.

There was no difference in the mean anthropometric measurements for body weight, body mass index or waist circumference in either group.

Abdominal Muscle Strength.

The mean isometric strength for each group at each time point are summarised in Figure 2. and change from baseline is tabulated in Table 5

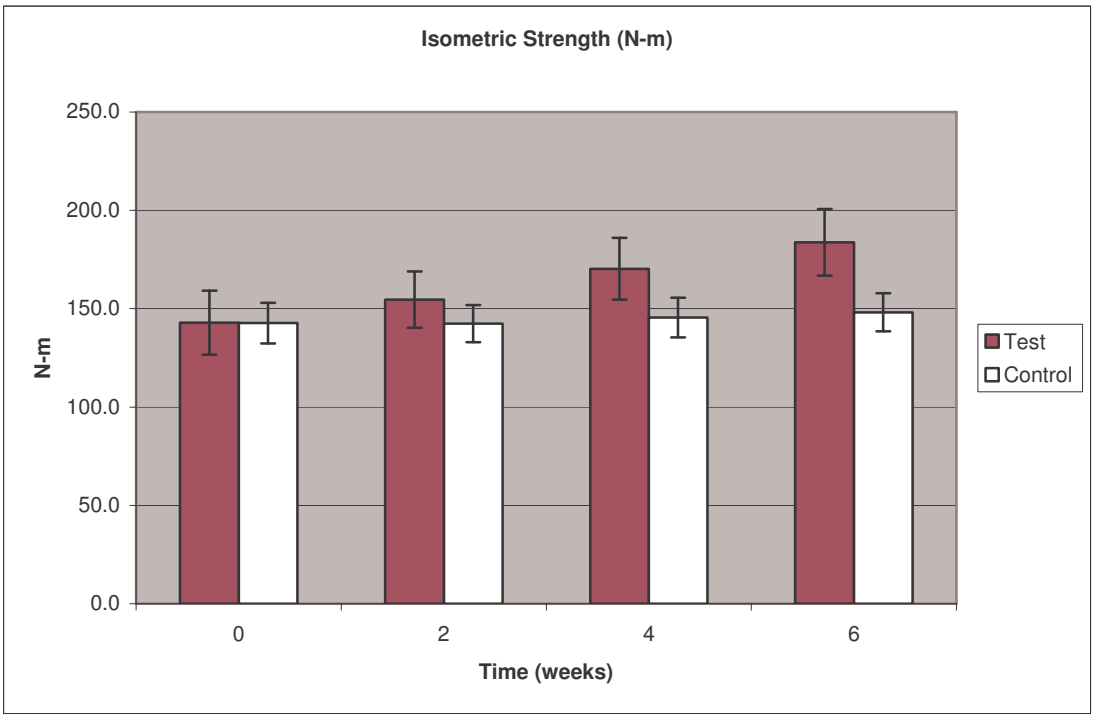

Fig 2. Mean Isometric Strength over time. Error bars are +/- 95% CI

	Group	2 Week	4 Week	6 Week
Abdominal Strength (Nm)	Treatment	11.7 ±21.3	27.4* ± 22.9	40.9* ± 24.2
	LT Treatment	-0.2 ± 14.0	2.8 ± 7.5	5.5 ± 7.2

*Table 5. Mean difference in abdominal muscle strength improvements for each measurement point. * denotes that differences are significant.*

There was a significant difference in the mean improvement in strength across the 3 weeks ($p<0.001$) and across the two groups ($p<0.001$). There was no evidence of a significant gender effect ($p=0.661$).

There was evidence of an interaction between weeks and groups ($p<0.001$) suggesting that the difference in the mean improvement in strength between the groups is not of the same magnitude at the different measurement points. This interaction is displayed graphically in Figure 3 where the mean percentage improvement in abdominal

isometric muscle strength is greater at all time points for the treatment group, and the difference between the groups increases across time.

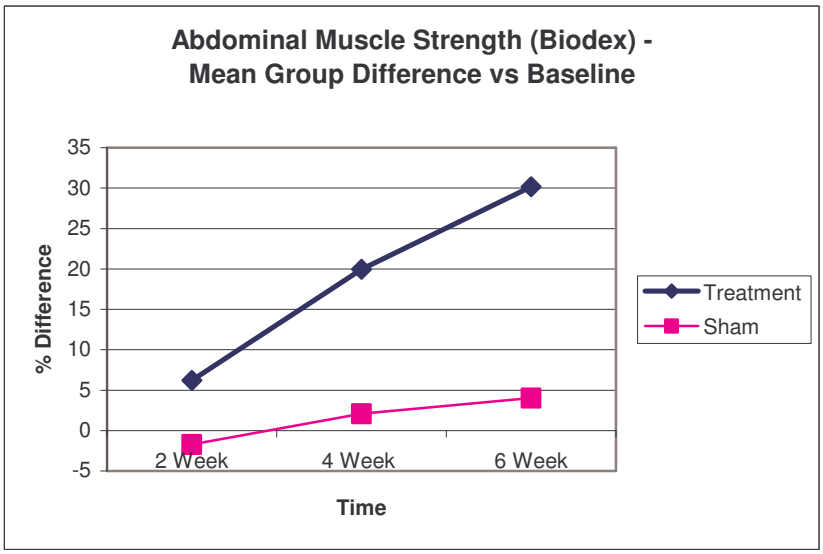

Figure 3. Mean changes in abdominal muscle isometric strength from baseline for both groups.

Sample estimates of the difference in mean abdominal strength improvement at each of the three time points are given in table 6. In addition, an interval estimate of the likely difference in the population mean improvement between the groups is provided for each week.

	Week 2	Week 4	Week 6
Treatment – LT Treatment (Nm)	11.9 [-0.35, 24.1]	24.6 [12.9, 36.3]	35.4 [17, 35.2]

Table 6. Difference in mean abdominal strength improvement and corresponding Bonferroni adjusted 95% simultaneous confidence intervals.

There was no significant difference in the mean improvement at week 2, however differences were significant at weeks 4 and weeks 6 as identified through the significant interaction.

Abdominal Muscle Endurance

The performance of the two groups is summarised in Fig 4.

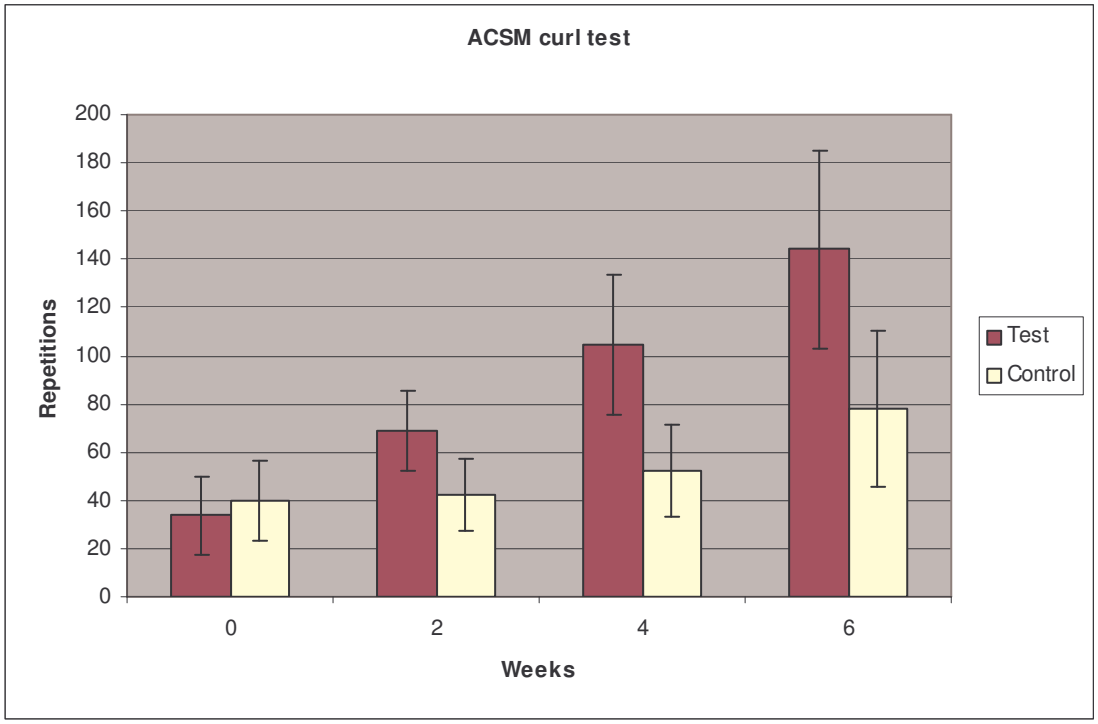

Fig 4. Mean of curl completions over time. Error bars are 95% CI

The changes from baseline are reported for both groups in table 7.

Variable	Group	2 Week	4 Week	6 Week
Abdominal Endurance (reps)	Treatment	33.9 ± 56.6*	68 ± 123.2	106.3 ± 182.8
	LT Treatment	2.4 ± 21.8	11.35 ± 45.71	35.4 ± 62.6

*Table 7. Mean difference in abdominal muscle endurance improvement for each measurement point. * denotes that differences are significant.*

There was evidence of a significant difference in the mean improvement across time ($p<0.001$). There was evidence of a difference in mean improvement when comparing the Groups ($p=0.034$).

The Interval estimates of the likely difference in mean ACSM improvement in the population of interest provide evidence of a significant improvement in mean ACSM after Week 2 (Table 8). Neither of the other comparisons achieved significance; however both intervals suggest a possible borderline Group difference in favour of Group 1 as the intervals all tend to the positive direction.

	Week2	Week 4	Week 6
Treatmant – LT Treatment	31.4 [2, 60.8]	66.4 [-7.1, 120.4]	82.1 [-22.9, 164.7]

Table 3. Difference in Mean ACSM Improvement and corresponding Bonferroni Adjusted 95% Simultaneous Confidence Intervals

Prone Plank Test

Group mean improvement in prone plank test performance is given in Table 9 for all measurement points.

Variable	Group	2 Week	4 Week	6 Week
Abdominal Endurance (reps)	Treatment	6.9 ± 11.3	17.8 ± 26.3	18.3 ± 23.9
	LT Treatment	5.7 ± 16.8	7.5 ± 21	12.9 ± 21.7

*Table 9. Mean difference in core strength improvement for each measurement point. * denotes that differences are significant.*

Analysis of core strength data suggested a significant change in mean improvement across the three measurement points (p=0.001). There was no evidence of a significant group (p=0.27) or gender effect (p=0.98). There was no evidence of an interaction between group and time (p=0.19) suggesting that the difference in the mean improvement in strength was comparable across time. (Table 10)

	Week 2	Week 4	Week 6
Treatment –LT Treatment	1.18 [-8.6, 11]	10.36 [-5.95, 26.7]	5.39 [-10.1, 20.8]

Table 10. Difference in mean prone plank improvement and corresponding Bonferroni adjusted 95% simultaneous confidence intervals.

Psychometric Data

Body Satisfaction Questionnaire

This was a 10 item questionnaire in which subjects rated their perception on a 5 point scale between opposite descriptors of body satisfaction, for example strong v weak, hard v soft etc. The score for each subject was the average of the ratings for the 10 items.

The body satisfaction score for both groups improved during the course of the study, as depicted in the following boxplot.

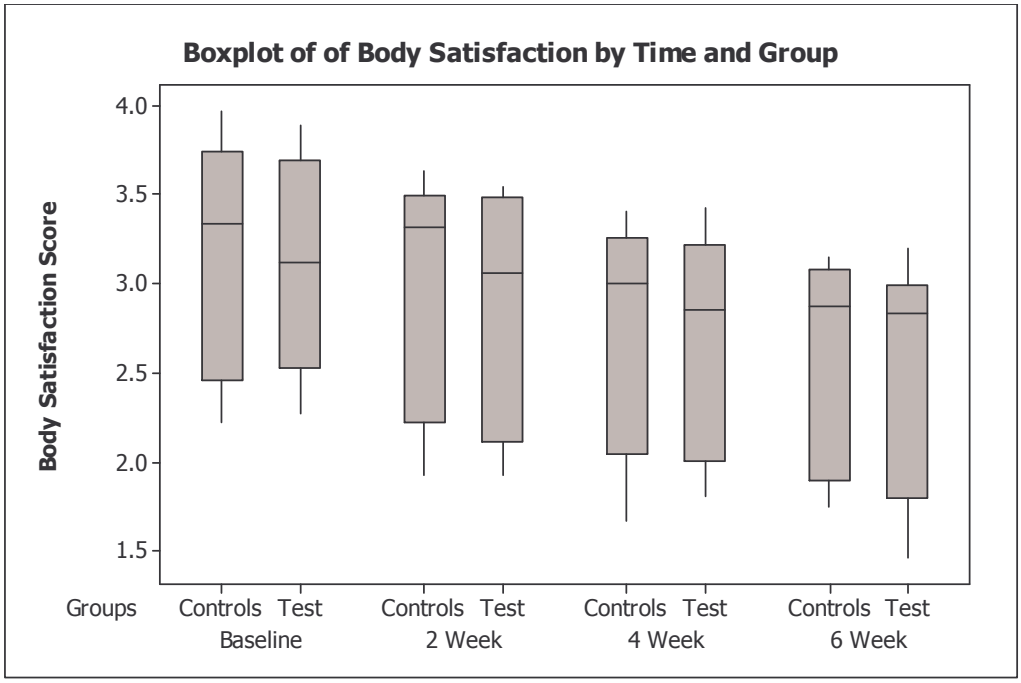

Fig 5. Summary of Body Satisfaction score movement with time.

There was no significant difference between the groups.

Shape Evaluation Questionnaire

This was a 12-item questionnaire that asked subjects to rate their level of agreement/disagreement with a set of statements relating to body shape. The change in the number of subjects in each of 4 levels of agreement was assessed. Broadly speaking, an increased proportion of both groups expressed agreement with positive statements about body shape by week 6 of the study, as depicted in Figure 6.

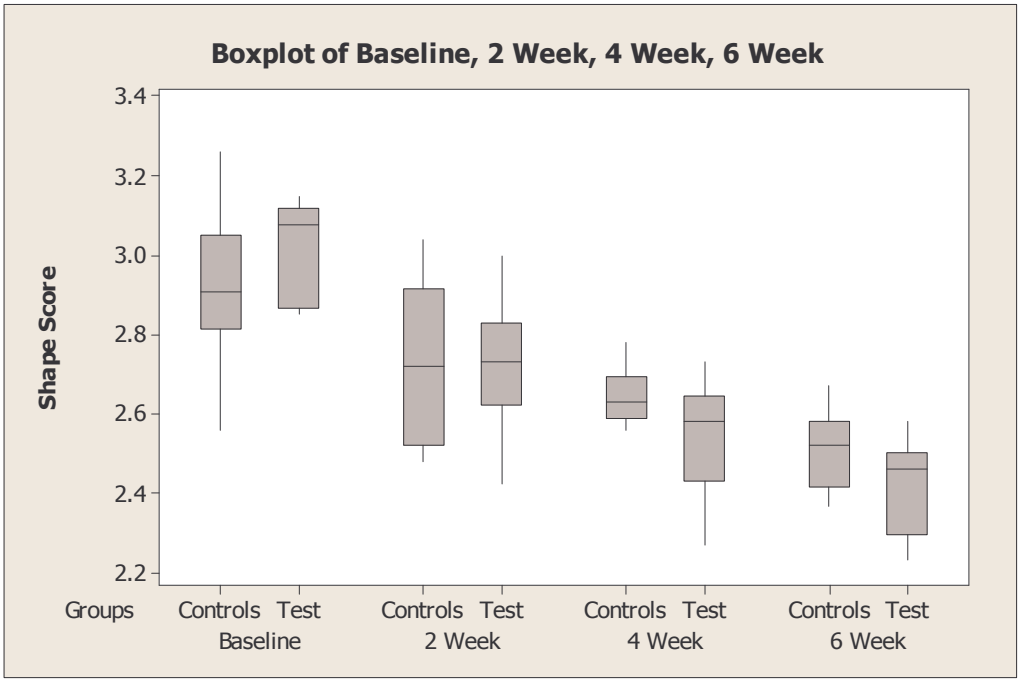

Figure 6. Shape Evaluation Scale – Treatment vs Low Intensity Treatment at each measurement point.

Non-parametric statistics were used to evaluate the Shape Evaluation Scale. A Mann Whitney-U test was used to confirm that there was no difference between baseline scores for both groups, p=0.19.

Differences between baseline and 4 weeks and the difference between baseline and 6 weeks were calculated separately for both groups. The change for both groups was compared at 4 and 6 weeks using a Mann Whitney-U test. The results showed that the difference between the groups was significant at 4 weeks, p=0.03, and was borderline but did not achieve significance at 6 weeks p=0.053.

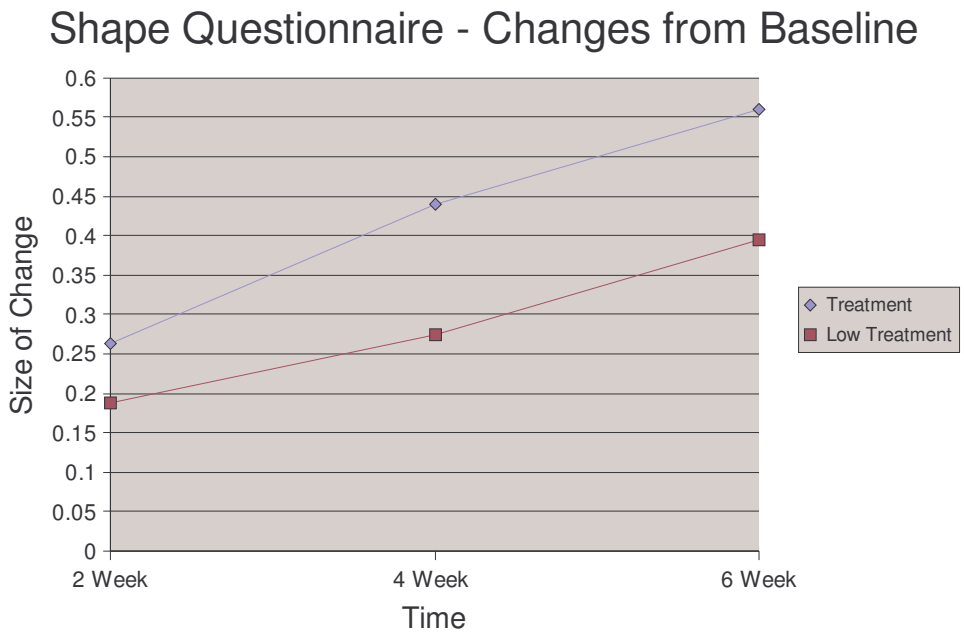

Figure 7. Baseline changes for both groups for the Shape Evaluation Scale.

Overall Psychometric Questionnaire - RESULTS:

At the conclusion of the study participants reported their perceived results overall, having taken part in the training intervention. This data was collected in a simple 10-item questionnaire that recorded their agreement or disagreement with a set of statements. The questions examined whether they perceived any results having used the device, and the number of weeks elapsed before they saw results (if any). It continued to ask about the kind of results perceived, for example firmness, flatness, improved clothes fit etc.

Eighty four (84%) of the Test group reported noticing results at 5 weeks and 100% of the Test group noticed results at 6 weeks compared with 30% (4 weeks) and 37% (6 weeks) for the Control group (p=0.002). Of the Test group, (92.3%) agreed the firmness of their abdominal muscles had increased compared with 63% for the Control group. (P=0.026). For the remaining items, both groups had appreciable proportions that reported improvement and, while the trend favoured the treated group, there was no statistically significant difference between the groups.

Discussion

Electrical muscle stimulation is a well established treatment modality and is primarily used to strengthen weak or atrophied muscle. For healthy muscle, the evidence is that short duration (6 weeks or less) EMS training induces muscle strengthening effects that are similar to, but not greater than, voluntary exercise (Hainaut and Duchateau, 1992). It has been reported that greater percentage increases in muscle strength have been observed in weaker muscles (Johnson et al., 1977) non-dominant limbs, (Romero et al., 1982) and women compared with men (Fahey et al., 1985; Selkowitz, 1985). The magnitude of the reported strength gain varies from study to study and may be attributable to differences in experimental protocol and muscle tested. Halbach and Strauss (1980) recorded a 22% increase in maximum voluntary contraction (MVC) for the quadriceps muscle group following 15 muscle stimulation sessions. Similarly after 15 muscle stimulation sessions using a smaller muscle group, namely the adductor pollicis, Canon and Cafferelli (1987) exhibited a 15% increase in MVC.

Voluntary resistance training studies report similar results to those outlined above. Grimby et al. (1973) showed a 32% increase in MVC after an intervention which consisted of 30 triceps muscle training sessions. Carolyn and Cafarelli (1992) reported a 32% increase in MVC for the quadriceps muscle for a protocol of 24 training sessions.

To date a number of studies have looked at changes in abdominal muscle strength with EMS training. These include Alon et al. (1987), Alon et al. (1992), Cullinane et al. (1999), Ballantyne and Donne (1999) and Porcari et al. 2005. A summary of mean strength changes and confidence intervals for the current study in addition to previous studies are shown in table 12 and figure 4.

	2 Week	4 Week	6 Week	8 Week
Abdominal Strength (%)	13.43 [3.97, 14.28]	26.06 [11.68, 33.12]	28.6 [16.63, 40.59]	35.35 [16.59, 53.71]

Table 11. Study Summary of Mean isometric strength changes and 95% confidence intervals arising from abdominal muscle stimulation training. Not all of the cited studies provided sufficient information to calculate confidence intervals so the values shown here are the averages of the upper and lower limits of the confidence intervals of those studies which did allow such calculation. For this reason, the aggregate confidence interval is not always symmetric about the aggregate mean.

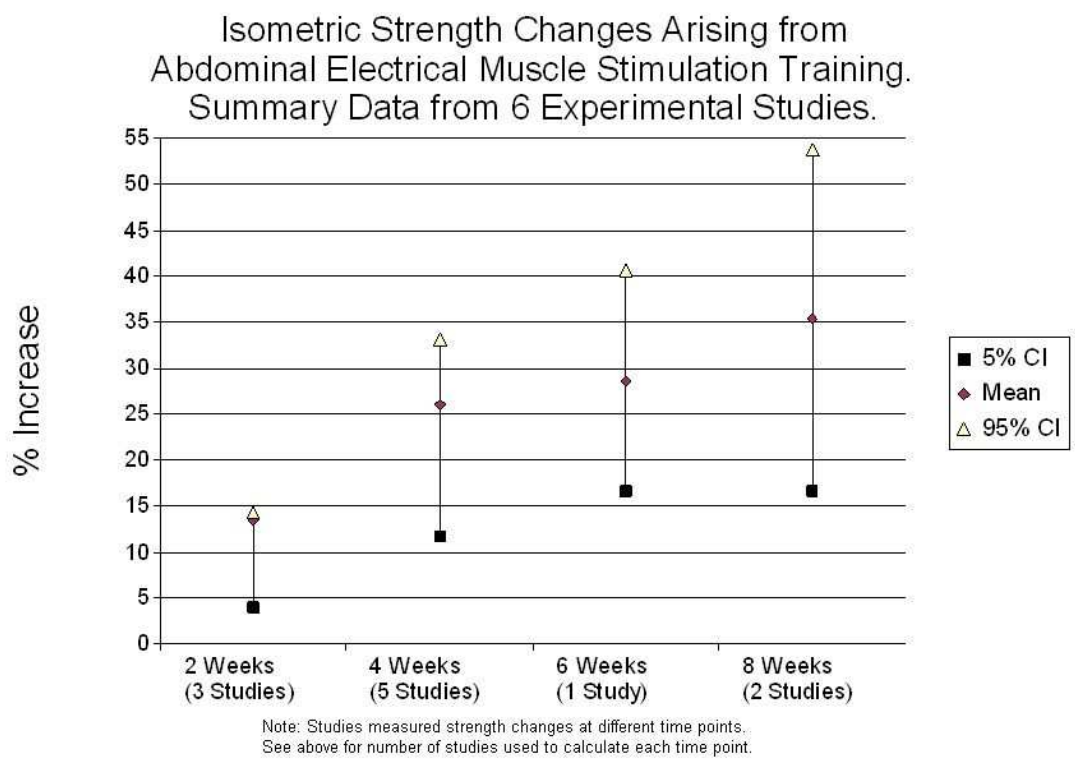

Figure 8. Graphical representation of mean isometric strength changes, and mean confidence interval limits, from 6 experimental studies using abdominal electrical muscle stimulation.

The present study indicated a 19% and 29% strength gain at 4 and 6 weeks. This appears to be in line with results from other EMS studies as depicted in Fig 8 and indeed with results reported for conventional strength training studies.

The magnitude of the strength changes evident in this study are less than those reported by Porcari (2005). In the current study a 20% change was apparent after 4 weeks whereas a 34% strength increase was recorded by Porcari (2005). In the current study, the mean age of treatment group subjects was on average, 4 years less than those in the previous study. This may have contributed to the slightly higher results observed in the previous study as the training status and thus baseline measure of the subjects was likely to be lower than subjects in the current study. Perhaps more important, a greater number of the treatment sessions were supervised in the earlier study leading to improved compliance with the treatment protocol. Insofar as the present study better represents the real home use situation, it perhaps offers a more reliable estimate of actual outcomes in the general population.

Significant differences between the groups at 2 and 4 weeks were observed for improvements in abdominal endurance as measured by the ACSM paced curl test. The data at week 6 suggest a strong but non-significant trend in favour of the test group. The performance improvement of the test group in this study was considerably better that the equivalent test in the Porcari 2005 study which showed a 100% improvement in abdominal endurance for treatment group subjects with a 28% improvement for a passive control group subjects over an 8 week period. It may be the case that a learning effect is an inherent part of this muscular endurance test, or indeed that a certain strength gain is acquired through EMS without the requirement

to develop significant training forces. Alon et al. (1992) reported strength improvements even with very low levels of abdominal electrical stimulation.

Similarly data gathered for the core strength test showed that non-significant differences were recorded for changes at each measurement point. The treatment group was seen to improve in core strength to a greater degree at each measurement point with a mean change of 18.3% after 6 weeks. The control group showed a 12.9% change over the same period. It is likely that slight improvements in abdominal muscle endurance alongside a possible learning effect may have resulted in improved scores as evident in the low intensity treatment group. This is a novel test and may also exhibit some reproducibility issues that contributed to large variance in scores recorded. Performance in the test was seen to depend a great deal on technique. It is plausible that the overall improvement reflected an improved technique which may have masked any therapeutic difference that may have existed between the groups

Previous studies have shown that abdominal EMS, or a combination of EMS plus exercise, have a positive effect on body image measures (Cullinane et al. 2002, Anderson et al. 2006, Porcari et al. 2005). The differences between the groups in this study with regard to psychometric measures were less pronounced than in these studies, which used passive controls. There are several possible explanations for this effect. There may have been a placebo effect whereby subjects receiving the low dose treatment benefited psychologically from using the device. Alternatively, or in addition, there may have been a therapeutic benefit even in the low dose for these measures. The low dose stimulation was calculated to minimise force development within the muscle and thereby to minimize a training effect that was believed to be dependent upon muscular overload. The low level stimulation may nonetheless have had a training effect, for example, at a neurological level by improving motor unit recruitment.

This study was designed to overcome practical difficulties in the implementation of a placebo controlled double blind trial in an electrical stimulation intervention. The double blind, placebo controlled study design is widely accepted among scientists as the best means to reduce important sources of subject and assessor bias. However, it is an ideal that is not always achievable when assessing the effectiveness of some medical devices, as well as in exercise and physical therapy interventions. To achieve subject blindedness in such trials, both the real and sham treatments must be indistinguishable from each other. If the treatments look or feel different then there is a risk that the subject will discover which arm of the study they are in. This is especially true when, inevitably, subjects compare experiences amongst themselves.

There are thousands of research papers in the scientific literature dealing with the training and rehabilitation effects of electrical stimulation of muscle. A recent review is that by Bax et al. 2005. They carried out a systematic review of randomized controlled trials to assess whether EMS strengthened the quadriceps femoris muscle in normal and impaired populations. Out of over 2000 citations produced by the search procedure on the major databases, they accepted only 35 papers for detailed review. Of these 35 papers, it appears that only one was a double blind study, underlining the practical difficulty of achieving this optimal design in an EMS study on strengthening effects.

The design of the present study sought to achieve an optimal compromise by providing the control group with an identical device to the treatment group, but which operated at a lower intensity. That lower intensity was selected such that it would give a strong sensory sensation but minimal apparent motor nerve activation. Research experience with EMS indicates that to gain muscle strength, the stimulation should typically induce 15-25% or more of the maximal volitional contraction (MVC). Hence the treatment dose was selected to be well below this threshold. The compromise in design with respect to a true sham treatment is that there may have been some residual therapeutic benefit which did not depend on the generation of large forces in the muscle. Alon et al. (1992) studied the effects of very low intensity, long duration (3h) electrical stimulation on the strength and endurance of the abdominal muscles in a randomized controlled study of 38 subjects. They found a statistically significant mean strength increase of 14% after 4 weeks in the treatment group, whereas the control group did not change. While the low intensity group in the present study only used the device for 30 minutes per day, there may have been some neurological training effect leading to their improved ACSM curl performance and improvement in psychometric measures.

Conclusions

Abdominal muscle stimulation using the Slendertone System-Abs products results in abdominal strength changes and associated changes in measures of self-perception. Strength changes are significant after 4 weeks training using the Slendertone System-Abs product. Differences in abdominal muscle endurance between the groups, although not statistically significant, indicated a positive trend in favour of the treated group.

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