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Graduate Studies

EFFECTS OF ELECTRICAL MUSCLE STIMULATION ON PERCEIVED BODY
SATISFACTION AND TONE OF THE GLUTEAL MUSCLES

A Manuscript Style Thesis Submitted in Partial Fulfillment of the Requirements for the
Degree of Master of Science

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College of Science and Health
Clinical Exercise Physiology

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EFFECTS OF ELECTRICAL STIMULATION ON PERCEIVED BODY
SATISFACTION AND TONE OF THE GLUTEAL MUSCLES

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We recommend acceptance of this thesis in partial fulfillment of the candidates' requirements for the degree of Master of Science in Clinical Exercise Physiology

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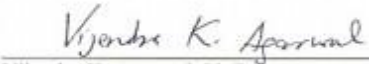
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ABSTRACT

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This study compared the effects of electrical muscle stimulation (EMS) to volitional exercise on the tone of the buttocks muscles, hip circumference, and perceived satisfaction with the buttocks region. Seventy-two females, ages 20 and 60 years, were randomly placed into one of three groups: control, exercise, or stimulation. The exercise group performed 3 sets of 10 quadruped hip extensions with each leg, 5 days per week, for 6 weeks. The stimulation group underwent stimulation for 30 minutes, 5 days per week, for 6 weeks using the Slendertone® Bottom Toner. Subjects were tested at baseline, 4 weeks, and 6 weeks. Muscle tone of the buttocks was measured using a Myotonometer®. Hip girth was measured using a spring-loaded tape measure and body satisfaction was determined using a series of questionnaires. Results were compared to a control group. There were no improvements in hip circumference or muscular tone. The exercise and stimulation group had significant improvements in score on both the Shape Evaluation and Body Satisfaction Questionnaires. When Overall Results questionnaires were summarized, 92% of subjects in the exercise group and 88% of subjects in the stimulation group felt that they had positive results following the 6-week study.

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Electrical muscle stimulation devices (EMS) are not new to the health and fitness world. Originally EMS was used in physical therapy settings to aid in strengthening immobilized muscles or to minimize atrophy following surgery (9). In the early 1960's, Kots studied EMS, which was referred to as "Russian Stimulation," on elite athletes. He found strength gains of 30 %-40% (10). After the study, Kots claimed that EMS may be more effective than exercise alone in producing strength gains (10).

A number of studies on EMS have been conducted in non-athletes. In 1992, Alon et al. examined the effects of EMS on abdominal strength and found strength improvements of 14%-22% (2). Subsequent investigations by Alon et al. found that training with EMS 5 days per week was more effective than 3 days per week (1,2,3). The abdominal region is not the only area of the body shown to respond positively to EMS training. Testing done on knee extensor and plantar flexor muscles have shown increases in strength of 17%-31% (4,8,11,15,16). A key finding in those studies which have shown strength improvements is that subjects were able to obtain muscular voluntary contractions (MVC) in excess of 60% (4,8,11).

As commercial EMS products became readily available to the general public, a study was conducted in 2002 at the University of Wisconsin-La Crosse (UW-L) to test the validity of one of the over-the-counter EMS product (Body Shapers). Results showed no changes in muscular strength, body composition, or physical appearance (12). The lack of positive results in that study was attributed to the poor quality of the product used. The stimulation was uncomfortable to use and prevented a sufficient amount of stimulation to elicit significant results (12).

In 2002, Bio-Medical Research, Ltd., a company based in Galway, Ireland,

developed the Slendertone® FLEX, an EMS product designed to increase abdominal strength and tone. The company conducted two internal studies and found increased tone and firmness of the abdominal region (6,7). In 2005, researchers at the University of Wisconsin- La Crosse conducted a study on the effectiveness of the Slendertone® FLEX abdominal belt. The study found that abdominal strength increased 49% and abdominal endurance increased 72% following 8 weeks of stimulation. Waist circumference decreased by 3.5 cm and all members of the stimulation group felt that their midsections had more tone and firmness after completing the NMES training (13).

Bio-Medical Research, Ltd. has developed a similar product designed to strengthen and tone the gluteal muscles. The purpose of this study was to test the ability of the Slendertone® Bottom Toner to reduce hip girth, increase gluteal tone, and increase perceived body satisfaction of the buttocks region. This study was part of a larger study which also examined the ability of the Slendertone® Bottom Toner's to increase muscular strength and endurance of the gluteal muscles.

METHODS AND PROCEDURES

Subjects

Seventy-two female volunteers were recruited from the La Crosse, WI area through an advertisement in a local newspaper. Subjects had to be between 20-60 years old, have a Body Mass Index (BMI) between 18-32, and could not have engaged in any lower body strength training in the previous 6 months. In addition, individuals who were pregnant, had been pregnant within the last 3 months, had a cardiac pacemaker, had any sort of abdominal implant (e.g., IUD), had any visible skin injury or disease on their buttocks, had a history of heart disease or stroke, had epilepsy, had diabetes, or had any

other medical condition involving the abdomen (e.g., hernia, abdominal ulcer) were excluded from the study.

There was approval by the IRB committee. All subjects attended an informational meeting and signed an informed consent form prior to beginning the study. (Appendix A) Subjects were randomly placed into a control, exercise, and stimulation group. All three groups were told not to make any alterations in their diet or current exercise regimen (except that prescribed as part of the study) in any way over the course of the study. All subjects received \$200 and a Slendertone® Bottom Toner at the conclusion of the study.

Testing

All three groups underwent an identical series of tests at the beginning of the study. The same tests were repeated at weeks 4 and 6. The tests were administered in the same order for all subjects and the measurements at each testing station were made by the same research assistant for all testing sessions. Subjects initially completed a series of questionnaires and then had buttocks circumference, muscle tone, strength, and endurance assessed. Height and weight were also assessed using a standard laboratory scale.

Questionnaires

At all testing session subjects were asked to fill out a Shape Evaluation Questionnaire and a Body Satisfaction Questionnaire. The Shape Evaluation Questionnaire (Appendix B) consists of a series of 10 statements concerning the shape and appearance of the buttocks region. Items are scored using a five point Likert scale, ranging from “strongly disagree” to “strongly agree.” The Body Satisfaction Questionnaire assessed satisfaction with buttocks shape and appearance. The items are

rated on a five point semantic differential scale. At the conclusion of the study, subjects were also asked to complete and Overall Results Questionnaire. (Appendix C) Subjects responded either “yes” or “no” to seven questions regarding results seen over the course of the study.

Hip Circumference

Hip circumference was measured at the maximal protrusion of the buttocks using a spring-loaded tape measure. Two measurements were taken and if the two measurements differed by more than one centimeter, a third measurement was taken. The average of the two closest measurements was used in the analysis.

Muscle Tone

Muscle tone of the buttocks was measured using a Myotonometer® (Neurogenic Technologies, Inc., Missoula, MT). The subjects were asked to lay face down on an examination table. The researched assistant palpated a landmark that was in the mid-portion of the right buttock. The distance from this point to the iliac crest was measured and recorded so that future measurements would be taken at the same point. The hand-held wand of the Myotonometer was then pressed into the right buttocks on the specific landmark. As the wand is pressed into the buttock, the amount of tissue deformation (in mm) is recorded by the Myotonometer software at .25 kg increments of pressure from .25 kg-2.0 kg. The software then calculates the area under the deformation curve. The measurement was repeated three times with the average of the three measurements being used in the analysis. Two sets of measurements were taken. The first set was taken with the buttocks in a relaxed state. The subject was then asked to maximally contract the buttocks and another set of measurements were taken. All

subjects wore identical exercise shorts that were provided for testing.

Training

Subjects in the stimulation group underwent stimulation 5 times per week for 6 weeks. Each session was 30 minutes long. The EMS device used in the study was the Slendertone® Bottom Toner. Subjects used Program 4, which uses a cycle of an 8 second contraction followed by a 12 second rest phase. Each subject was given an individual orientation session. During the orientation session subjects completed their first stimulation session. All of the following stimulation sessions were completed on their own. Subjects were encouraged to use the highest tolerable levels on their stimulation belt in order to achieve the strongest possible contractions. Subjects recorded the maximum intensity reach during each stimulation session in a training log.

(Appendix D)

Subjects in the exercise group completed 3 sets of 10 quadruped hip extensions on each leg, 5 times per week, for 6 weeks. Subjects were given individual instruction on how to perform the exercise properly and completed their first exercise session under the supervision of the principal investigator. The number of repetitions completed during each session was recorded in a training log. (Appendix E)

Statistical Analysis

All of the data are presented as means and standard deviations. One-way ANOVA was used to test for difference between groups for all pre-testing variables. Difference within each group, across the study period were assessed using a 2-way ANOVA with repeated measures (Group X Time). If there was a significant F ratio, Tukey's post-hoc tests were used to isolate pair wise difference. To determine difference between groups

across the study period, change scored (Pre-test to 4 week and Pre-test to 6 week) were calculated and compared using 1-way ANOVA. If there was a significant difference between groups, Tukey's post-hoc tests were used to make pairwise comparisons. Reliability of all test measurements was determined using intraclass correlations. Alpha was set at .05 to achieve statistical significance for all analyses.

RESULTS

All 72 subjects originally enrolled successfully completed the study. Descriptive characteristics of the subjects are presented in Table 1. There were no significant differences between the three groups for demographic characteristics or any of the other pre-test measures.

Table 1. Descriptive characteristics of the subjects at the beginning of the study.

Group (n)	Age (yr)	Height (cm)	Weight (kg)	BMI
Control (24)	39.5 $\pm$ 9.85	163.8 $\pm$ 8.30	66.3 $\pm$ 9.25	24.7 $\pm$ 3.14
Exercise (24)	38.1 $\pm$ 12.81	164.6 $\pm$ 7.63	67.1 $\pm$ 9.40	24.8 $\pm$ 2.93
Stimulation (24)	40.6 $\pm$ 11.53	162.9 $\pm$ 6.55	66.6 $\pm$ 9.17	25.1 $\pm$ 3.74

The stimulation group was urged to use as high as intensity as possible in order to achieve the strongest possible contractions. The peak intensity for each workout was recorded in a daily log. A weekly summary of the data is presented in Table 2. All subjects completed 30 stimulation sessions, as required. The exercise group was instructed to complete 3 sets of 10 quadruped hip extensions on each leg, 5 times per week, performing 60 contractions per session. All subjects in the exercise group completed 30 sessions.

Table 2. Average stimulator intensity levels used during the study.

	Average	Range
Week 1	76±12.1	55-99
Week 2	83±11.3	64-99
Week 3	87±11.5	64-99
Week 4	87±11.7	64-99
Week 5	90±11.0	64-99
Week 6	91±10.5	69-99

A summary of the Overall Results Questionnaire are presented in Table 3.

Subjects in the control group did not feel as though they had any positive changes over the course of the study. Ninety-two percent of the subjects in the exercise group and 88% of subjects in the stimulation group felt that they had positive results over the course of the study. The results in Table 3 shows nearly identical numbers of subjects in the exercise and stimulation groups felt that their bottoms were firmer, stronger, more toned, shapelier, and more uplifted, as well as feeling that their jeans fit better after the 6-week study.

Table 3. Positive responses to individual questions on the Overall Results Questionnaire.

	Control	Exercise	Stimulation
Q1: Had positive results		22 (92%)	21 (88%)
Q2: Bottom muscles firmer		20 (83%)	21 (88%)
Q3: Bottom muscles stronger		22 (92%)	20 (83%)
Q4: Bottom muscles more toned		19 (79%)	20 (83%)
Q5: Bottom more shapely		14 (58%)	14 (58%)
Q6: Bottom more uplifted		17 (71%)	16 (67%)
Q7: Jeans fit better		17 (71%)	16 (67%)

There were no significant changes in body weight, BMI, or hip circumference over the course of the study for any of the groups (Table. 4). Reliability of hip circumference over the measurements was $R=.98$. There was a significant improvement in Myotonometer readings (ex., a lower score represents less tissue deformation when a similar amount of force is applied) from pre-test to 6 weeks in all three groups, but there were no between group difference. Reliability of Myotonometer measurements were $R=.69$ in the relaxed state and $R=.73$ in the contracted state.

Table 4. Changes in body composition and muscle tone over the course of the study.

	Pre-test	4 Week	6 Week
Body Weight (kg)			
Control	66.3 $\pm$ 9.25	66.5 $\pm$ 8.96	66.7 $\pm$ 9.07
Exercise	67.1 $\pm$ 9.40	67.1 $\pm$ 9.59	67.3 $\pm$ 9.36
Stimulation	66.6 $\pm$ 9.17	66.8 $\pm$ 9.43	66.9 $\pm$ 9.42
Body Mass Index			
Control	24.7 $\pm$ 3.14	24.8 $\pm$ 3.13	24.9 $\pm$ 3.07
Exercise	24.8 $\pm$ 2.93	24.8 $\pm$ 3.07	24.8 $\pm$ 3.03
Stimulation	25.1 $\pm$ 3.74	25.2 $\pm$ 3.81	25.3 $\pm$ 3.85
Hip Circumference (cm)			
Control	101.6 $\pm$ 7.11	102.3 $\pm$ 6.93	102.5 $\pm$ 6.82
Exercise	100.8 $\pm$ 6.20	101.1 $\pm$ 6.13	101.7 $\pm$ 6.07
Stimulation	102.6 $\pm$ 7.83	103.4 $\pm$ 7.80	103.9 $\pm$ 7.80
Muscle Tone (relaxed)			
Control	26.0 $\pm$ 2.10	23.9 $\pm$ 2.33	23.4 $\pm$ 1.85*
Exercise	25.3 $\pm$ 2.18	24.0 $\pm$ 2.24	23.0 $\pm$ 2.46*
Stimulation	24.2 $\pm$ 2.99	23.1 $\pm$ 2.05	22.7 $\pm$ 2.23*
Muscle Tone (contracted)			
Control	22.2 $\pm$ 3.05	21.0 $\pm$ 3.14	20.0 $\pm$ 2.49*
Exercise	22.2 $\pm$ 3.28	21.2 $\pm$ 3.60	20.0 $\pm$ 3.66*
Stimulation	20.0 $\pm$ 3.32	19.6 $\pm$ 2.46	19.1 $\pm$ 2.82*

* Significantly different than pre-test ($p<.05$)

Total scores for the Shape Evaluation and Body Satisfaction questionnaires are presented in Table 5. Both the exercise and stimulation groups had a significant improvement in total score on both questionnaires from pre-test to 4 weeks and pre-test to 6 weeks. These improvements were significantly different from the control group, but not from each other.

Table 5. Changes in total score on the Shape Evaluation and Body Satisfaction Questionnaires over the course of the study.

	Pre-test	4 Week	6 Week
Shape Evaluation Score			
Control	25.6 $\pm$ 7.43	25.8 $\pm$ 7.61	26.7 $\pm$ 8.13
Exercise	24.5 $\pm$ 7.66	29.2 $\pm$ 7.00*#	31.0 $\pm$ 6.91*#
Stimulation	21.9 $\pm$ 4.80	30.3 $\pm$ 7.73*#	32.2 $\pm$ 8.32*#
Body Satisfaction Score			
Control	25.2 $\pm$ 7.04	26.5 $\pm$ 7.04	26.9 $\pm$ 6.68
Exercise	25.3 $\pm$ 6.88	29.0 $\pm$ 6.34*#	30.8 $\pm$ 6.21*#
Stimulation	23.5 $\pm$ 5.26	28.9 $\pm$ 7.03*#	32.1 $\pm$ 8.52*#

* Significantly different than pre-test ($p < .05$)

Change from pre-test is significantly different than the change for the control group at the same time point ($p < .05$)

DISCUSSION

A major finding of this study was that the results of both the Shape Evaluation and Body Satisfaction Questionnaire indicated positive improvements by subjects in the stimulation and exercise groups, as did the Overall Results Questionnaire. Ninety-two percent of subjects in the exercise group and 88% of subjects in the stimulation group felt as though they had positive benefits as a result of training. Similar percentages of subjects in both groups felt better about the tone, strength, firmness, and shape of their bottom.

Even though results from the Overall Results Questionnaire and individual items on the Shape Evaluation and Body Satisfaction questionnaires reflected that subjects felt their muscles were more toned after the study, these results were not supported by the Myotonometer measurements. When looking at the Myotonometer results, all three groups had similar, significant reductions in Myotonometer readings in the relaxed and contracted states. After discussions with the manufacturer, it was felt that these lower readings were a calibration issue. The Myotonometer wand was recalibrated before each testing period (pre-test, 4-week, 6-week). Calibration is done with a gel pad provided by the manufacturer. It is most likely that differences in room temperature or just aging of the gel pad resulted in a different calibration values, thus altering results over the course of the study.

Another factor that probably came into play was the reliability of the Myotonometer readings. The intraclass correlations for repeated measurements were $R=.69$ and $R=.73$ for the relaxed and contracted states, respectively. It is likely that the Myotonometer might not be sensitive enough to detect changes in muscle tone in the

buttock region, where there is generally a relatively thick layer of subcutaneous fat compared to other body parts. Previous reliability tests of the Myotonometer have shown excellent test-retest results, with R-values of 0.80-0.93 (5). However, those values were obtained on the rectus femoris, vastus lateralis, biceps femoris, and gastrocnemius muscles, all of which are regions of the body with generally less subcutaneous fat than that gluteal region (5).

There was no change in hip circumference after 6 weeks of training in the stimulation or exercise group. These results of previous studies regarding reductions in girth measurements are inconclusive. One study found a significant reduction in waist circumference following abdominal stimulation, (13), while two studies did not (12,14). The reduction in waist circumference in the 2005 study was attributed to a “pulling-in” or girdle effect of stronger abdominal muscles or an improvement in posture. Strengthening the gluteal muscles would not have this same effect, as the two body parts are anatomically different and serve different roles in the body.

Results showed that 6 weeks of exercise training improved body satisfaction just as well as 6 weeks of stimulation training. Gains with exercise training were achieved by performing 60 quadruped hip extensions per day, 5 days per week. Performing the hip extensions took 5 to 7 minutes to complete per session. Improvements with stimulation training were achieved by performing stimulation 30 minutes per day, 5 days per week. For those who either can not or do not want to perform volitional exercise the Slendertone® Bottom Toner is a suitable alternative for increasing one’s body satisfaction. Though the results of the stimulation and exercise groups were nearly identical, the exercise group was able to achieve the improvements with only 5 to 7

minutes of daily exercise compared to the stimulation group which trained 30 minutes each day to achieve similar results.

CONCLUSION

Use of the Slendertone® Bottom Toner resulted in similar improvements in subjects' self-perceived shape and tone of the buttocks compared to performing 60 quadruped hip extension movements. However, neither intervention positively affected hip circumference or objective measurements of muscle tone of the bottom muscles.

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APPENDIX A

INFORMED CONSENT

INFORMED CONSENT

Slendertone Bottom Toner Stimulation Study

I, _____ (print name) give my informed consent to participate in a research project designed to investigate the potential benefits of using the Slendertone Bottom Toner training device.

Explanation of the Study

I have been informed that this study is open to individuals between the ages of 20-60 years of age who have not engaged in a regular lower body resistance training program in the past 6 months, do not have a history of heart disease or stroke, do not have a cardiac pacemaker, do not have an abdominal implant of any type (e.g., IUD), do not have any visible skin injury or disease on their buttocks, do not have any medical condition involving the abdomen (e.g., hernia), are not pregnant, or who have been pregnant in the past 3 months, are not epileptic, and are not diabetic. As a subject in this study, I realize that I may be placed in one of three groups: either a control group, an exercise group, or a stimulation group. Regardless of which group I am placed in, I have been informed that I must maintain my current exercise and lifestyle habits (e.g., diet) over the course of the study. I have been informed that if I am placed in the control group, I will only undergo the testing portion of the study. If I am placed in the exercise group, I will be required to perform 3 sets of 10 hip extensions exercises with each leg while I am on my hands and knees, 5 days per week for 6 weeks. I have been informed that if I am placed in the stimulation group, I must participate in 30 minute stimulation sessions 5 days per week for 6 weeks. These sessions will involve a commercially available belt that provides an electrical current to the muscles of my buttocks, resulting in muscular contractions. The first of these sessions must be completed at the University of Wisconsin-La Crosse under the supervision of a trained research assistant. All other stimulation sessions will be conducted on my own. I have also been informed that I must report to the testing laboratory three times during the 6-week study: at the beginning, 4-week point, and 6-week point (end) of the study.

Testing

I have been informed that the testing will involve measurement of height and body weight, hip circumference, buttocks strength and endurance, and evaluation of how I perceive the appearance, firmness, and tone of my bottom. Height and body weight will be measured with a standard laboratory scale. Circumference measurements of my hips will be made with a tape measure. For the buttocks strength measurement I will be lying face down on a padded table. I will be asked to exert as much force as possible while trying to lift my dominant leg off of the table. To determine the endurance of my buttocks muscles, I will be asked to perform as many hip extensions as possible while on my hands and knees. To determine muscle tone, I will lay face-down on an examination table. A hand-held device designed to measure muscle tone (a myotonometer) will be pressed onto my buttocks, while force measurements are taken. These measurements will be taken while my buttocks are relaxed, and when they are maximally contracted. Because of the potentially embarrassing nature of this measurement, this test will be conducted by a female research assistant and all subjects will wear identical nylon shorts that will be provided. I will also be asked to evaluate the appearance and tone of my bottom by filling out a series of questionnaires.

Risks and Discomforts

I have been informed that I can stop the testing or training at any time I wish. If I am in the stimulation group, the type of electrical stimulation used in this study will result in strong muscular contractions of the buttocks. Additionally, I may experience a prickling sensation under the electrodes during stimulation and skin redness at the electrode sites following periods of stimulation. To minimize any risks, an explanation and demonstration regarding the proper use of the stimulator will be given to me. Additionally, the first stimulations session will be under the supervision of the study staff. I have been informed that like any unaccustomed muscular activity (exercise), this may result in muscle soreness. If I am in the exercise

group, I have been informed that performing hip extension exercises may also result in muscle soreness.

Benefits to be Expected

I have been informed that participation in this study may include increases in strength, tone, and firmness of the buttocks musculature and an enhanced feeling about the appearance of my bottom. For the general public, information relative to the effectiveness of buttocks stimulation will be obtained. I have also been informed that if I successfully complete the study I will receive \$200, plus a Slendertone Bottom Toner (retail value of \$150). If I drop out of the study for any reason, the \$200 will be prorated based upon my time of involvement and distributed accordingly.

Confidentiality of Data Collected

I consent to the publication of the results of this study so long as the information is disguised so that no identification of individual subjects can be made and only summary data is used. I further have been informed that although a record will be kept of my participation in the experiment, all subjects will be identified by number only.

Responsibilities of the Participant

I have been informed that if any symptoms or complications occur before, during, or after the research project, I will inform the staff. I consider myself to be in good health and to my knowledge I do not have any limiting physical condition or disability, especially related to my heart, which would preclude my participation in the tests described above. If I become pregnant during the course of the study, I will immediately inform the staff and withdraw from the study. I have also been informed that regardless of which group I am in, I am to maintain my current exercise and lifestyle habits over the course of the study. If my body weight goes up or down by more than 5 pounds from the beginning to the end of the 6-week study period, I will be removed from the study at that time.

I have been informed that in the unlikely event of any injury or illness occurring as a result of this research, the Board of Regents of the University of Wisconsin System, and the University of Wisconsin-La Crosse, their officers, agents and employees, do not automatically provide reimbursement for medical care of other compensation. You or your third party payor, such as your health insurer or Medicare, must provide payment for treatment of any injury or illness. If any injury or illness occurs in the course of the research, or for more information, please notify the investigator in charge. I have been informed that I am not waiving any rights that I may have for injury resulting from negligence of any person or the institution.

Contact Person

If I have any other questions that arise I may feel free to contact the principal investigator John Porcari at (608) 785-8684. Questions in regards to the protection of human subjects may be addressed to the University of Wisconsin-La Crosse Institutional Review Board for the Protection of Human Subjects at (608) 785-8124.

Participant's Signature: _____ Date: _____

Investigator's Signature: _____ Date: _____

APPENDIX B

THE SHAPE EVALUATION QUESTIONNAIRE

1. Please indicate whether you agree or disagree with the following

statements by marking an “X” in the corresponding box.

	Strongl y Agree	Agre e	Neither Agree Nor Disagree	Disagr ee	Strongl y Disagre e
My bottom looks uplifted					
My bottom feels firm.					
My bottom muscles seem tight.					
My bottom feels toned.					
My bottom is shapely.					
My bottom looks smooth.					
My bottom looks toned.					
I feel positive about my shape.					
My clothes fit well.					
I feel confident about the shape of my bottom.					

2. How do you feel about the appearance of your bottom?
Please circle the corresponding number.

Very Dissatisfied	1	2	3	4	5	Very Satisfied
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Satisfied

3. How do you feel about the tone of your bottom (or gluteal) muscles?
Please circle the corresponding number.

Very Dissatisfied	1	2	3	4	5	Very Satisfied
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Satisfied

4. How do you feel about the shape of your bottom?
Please circle the corresponding number.

Very Dissatisfied	1	2	3	4	5	Very Satisfied
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Satisfied

APPENDIX C

OVERALL RESULTS QUESTIONNAIRE

Slendertone® Bottom Toner
BMR-09-2012

FORM: Overall Questionnaire – Results

This form is to be completed at the end of the study

Participant ID: 07-2001- Date: _____

**For the following questions, please answer *Yes or No*.
ALSO rate your acceptability by using the scale indicated
and circling the your response**

1. Did you notice any positive changes in your bottom over the 6-week study period.

Yes No

Please rate your acceptability of the results.

0 _____ 1 _____ 2 _____ 3 _____ 4
Scale: 0-1=Unacceptable; 2-3=Acceptable; 4=Highly Acceptable

2. My bottom muscles are firmer.

Yes No

Please rate your acceptability of how firm your bottom muscles are.

0 _____ 1 _____ 2 _____ 3 _____ 4
Scale: 0-1=Unacceptable; 2-3=Acceptable; 4=Highly Acceptable

3. My bottom muscles are stronger.

Yes No

Please rate your acceptability of how strong your bottom muscles are.

0 _____ 1 _____ 2 _____ 3 _____ 4
Scale: 0-1=Unacceptable; 2-3=Acceptable; 4=Highly Acceptable

4. My bottom muscles are more toned. <i>Please rate your acceptability of how toned your bottom muscles are.</i> 0 _____ 1 _____ 2 _____ 3 _____ 4 Scale: 0-1=Unacceptable; 2-3=Acceptable; 4=Highly Acceptable	Yes No
5. My bottom is more shapely. <i>Please rate your acceptability of how shapely your bottom is.</i> 0 _____ 1 _____ 2 _____ 3 _____ 4 Scale: 0-1=Unacceptable; 2-3=Acceptable; 4=Highly Acceptable	Yes No
6. My bottom is more uplifted. <i>Please rate your acceptability of how uplifted your bottom is.</i> 0 _____ 1 _____ 2 _____ 3 _____ 4 Scale: 0-1=Unacceptable; 2-3=Acceptable; 4=Highly Acceptable	Yes No
7. My jeans fit better around my bottom. <i>Please rate your acceptability of how your jeans fit.</i> 0 _____ 1 _____ 2 _____ 3 _____ 4 Scale: 0-1=Worse than before; 2-3=Better than before; 4=Much better than before	Yes No
Please provide any additional comments:	

Initials of Participant

Date:_____

APPENDIX D

SUBJECT'S TRAINING SCHEDULE

Slendertone® Bottom Toner Training Schedule

Participant Study Number: BMR-09-2012 -

Instructions for Participant:

Please fill in the date, as well as the peak intensity of muscle stimulation for each of your 30-minute muscle stimulation sessions.

Please bring this schedule and your muscle stimulation belt to the study clinic for each of your scheduled visits.

Week 1

Date	Session	Program #	# of Minutes	Peak Intensity Reached
	1	4	30 minutes	
	2	4	30 minutes	
	3	4	30 minutes	
	4	4	30 minutes	
	5	4	30 minutes	

Week 2

Date	Session	Program #	# of Minutes	Peak Intensity Reached
	1	4	30 minutes	
	2	4	30 minutes	
	3	4	30 minutes	
	4	4	30 minutes	
	5	4	30 minutes	

Week 3

Date	Session	Program #	# of Minutes	Peak Intensity Reached
	1	4	30 minutes	
	2	4	30 minutes	
	3	4	30 minutes	
	4	4	30 minutes	
	5	4	30 minutes	

Participant Initials

Date*Page 2 of 2***Slendertone® System Abs Training Schedule****Participant Study Number: BMR-09-2012 -****Week 4**

Date	Session	Program #	# of Minutes	Peak Intensity Reached
	1	4	30 minutes	
	2	4	30 minutes	
	3	4	30 minutes	
	4	4	30 minutes	
	5	4	30 minutes	

Week 5

Date	Session	Program #	# of Minutes	Peak Intensity Reached
	1	4	30 minutes	
	2	4	30 minutes	
	3	4	30 minutes	
	4	4	30 minutes	
	5	4	30 minutes	

Week 6

Date	Sessi on	Program #	# of Minutes	Peak Intensity Reached
	1	4	30 minutes	
	2	4	30 minutes	
	3	4	30 minutes	
	4	4	30 minutes	
	5	4	30 minutes	

Participant Initials

Date

APPENDIX E

QUADRUPED HIP EXTENSION TRAINING SCHEDULE

Hip extension Training Schedule

Participant Study Number: BMR-09-2012 -

Instructions for Participant:

Please fill in the date, as well as the repetitions

Please bring this schedule and to the study clinic for each of your scheduled visits.

Week 1

Date	Session	Program #	# of Minutes	Peak Intensity Reached
	1	4	30 minutes	
	2	4	30 minutes	
	3	4	30 minutes	
	4	4	30 minutes	
	5	4	30 minutes	

Week 2

Date	Session	Program #	# of Minutes	Peak Intensity Reached
	1	4	30 minutes	
	2	4	30 minutes	

	3	4	30 minutes	
	4	4	30 minutes	
	5	4	30 minutes	

Week 3

Date	Session	Program #	# of Minutes	Peak Intensity Reached
	1	4	30 minutes	
	2	4	30 minutes	
	3	4	30 minutes	
	4	4	30 minutes	
	5	4	30 minutes	

Participant Initials

Date

Page 2 of 2

Hip Extension Training Schedule

Participant Study Number: BMR-09-2012 -

Week 4

Date	Session	Program #	# of Minutes	Peak Intensity Reached
	1	4	30 minutes	
	2	4	30 minutes	
	3	4	30 minutes	
	4	4	30 minutes	
	5	4	30 minutes	

Week 5

Date	Session	Program #	# of Minutes	Peak Intensity Reached
	1	4	30 minutes	
	2	4	30 minutes	
	3	4	30 minutes	

	4	4	30 minutes	
	5	4	30 minutes	

Week 6

Date	Sessi on	Program #	# of Minutes	Peak Intensity Reached
	1	4	30 minutes	
	2	4	30 minutes	
	3	4	30 minutes	
	4	4	30 minutes	
	5	4	30 minutes	

Participant Initials

Date

APPENDIX F

REVIEW OF LITERATURE

REVIEW OF RELATED LITERATURE

This review will examine the effect of electrical muscle stimulation (EMS) training on muscular tone, hip circumference, and self-perceived body satisfaction. This review also presents data on the reliability of the Myotonometer, the device used to test muscle tone in the present study.

Clinical Application of Neuromuscular Electrical Stimulation Device

Electrical muscle stimulation (EMS) devices have been a mainstay in physical therapy settings for years. Case reports in recent years have examined the use of EMS devices post-surgery. Petterson et al. conducted a 6-week study on a 62 year-old male who had strength deficits in the quadriceps following a total knee arthroplasty. By using volitional exercise paired with stimulation, the client was able to demonstrate a 25% strength increase of the effected quadriceps muscles (13). Similar to the study by

Petterson et al., Mintken et al. used EMS in a patient following a lower limb surgical procedure. A 65 year-old female was given EMS treatments beginning 48 hours following total knee arthroplasty. She was treated with stimulation twice daily for 3 weeks and then once daily for 3 additional weeks. The 6 weeks of stimulation were coupled with traditional physical therapy. Measurements were taken at week 3 and week 6. Post-rehabilitation measurements were taken at week 12. Peak quadriceps torque was 16%, 29%, and 56% greater, respectively, than preoperative levels at weeks 3, 6, and 12. The authors stated that the quadriceps muscles weaken following surgery and early EMS may improve functional outcomes. This is important because weakened quadriceps muscles have been associated with numerous functional limitations, including an increased risk of falling (12).

The notion of treating stroke victims with EMS is growing in the therapeutic community. Studies have shown EMS treatment improves functional skills and the ability to complete activities of daily living. Evidence also shows that EMS, particularly ones that incorporate task-specific strategies, is effective in limb motor relearning responses (7).

Effects of Electrical Muscle Stimulation on Healthy Individuals

Studies on EMS have also been conducted on healthy individuals. In the early 1960's, Kots studied EMS, which he referred to as "Russian Stimulation," on elite athletes. He found strength gains of 30-40% (10). After the study, Kots claimed that EMS training may be more effective than exercise alone in producing strength gains (10). Currier and Mann compared the effects of EMS with various resistance training models. Four groups were used: a stimulation group, an exercise group, a combination group

(which incorporated exercise and stimulation), and a control group. Training was done three times per week for 5 weeks. Results showed significant improvements in isometric strength in the stimulation group, exercise group, and combination group over the control group. However, no significant changes were found in isokinetic strength or girth among the four groups (8).

A number of studies on EMS have been conducted on non-athletes. Alon and colleagues conducted a series of studies that investigated the effect of EMS on abdominal strength and endurance (1,2,3). In 1992, Alon et al. found strength improvements of 14%-22% with the use of EMS (2). A subsequent study by Alon et al. found that training with EMS 5 days per week was more effective than 3 days per week (2).

The abdominal region is not the only area of the body shown to respond positively to EMS training. Testing done on knee extensor and plantar flexor muscles has shown increases in strength of 17%-31% (4, 12,17,18). A key finding in those studies was that subjects were able to obtain muscular voluntary contractions (MVC) in excess of 60% (4,8,11).

Commercial Neuromuscular Electrical Stimulation Devices

As more studies found that EMS could be effective at eliciting muscular gains in healthy adults, companies began to market over-the-counter products promising get-fit-quick results. In 2002, a study conducted at the University of Wisconsin-La Crosse examined the efficacy of the Bodyshapers (model BM1012BT) to increase muscular strength, decrease body weight, and improve muscular tone and firmness. Twenty-seven volunteers were randomly assigned to either a stimulation or control group. Both groups participated in stimulation training three times per week for 8 weeks. Subjects in the

control group were given a Bodysapers unit, however, the electrodes were adjusted so they did not transmit enough electrical current to cause significant muscular contraction. Muscles stimulated included the biceps femoris, quadriceps, biceps, triceps, rectus abdominals, and the obliques. An identical battery of laboratory tests (body weight, body fat, isometric and isokinetic strength) was conducted pre and post-testing. Questionnaires were given to all subjects as a means to quantify perceived body shape results. Photographs were also taken pre and post-testing and independently reviewed to grade muscular firmness and tone.

Results of the study contradicted claims made by the manufactures. There were no significant changes found in body weight, body fat, or muscular strength. The photographs and the questionnaires also found no positive changes. The authors stated that a critical threshold of contractibility was not achieved with the commercial device; muscles values contracting of less than 20% of maximal strength values. Additionally, the quality of the electrodes was of very poor quality and the stimulation was uncomfortable for the subjects to use (14).

In 2002, Bio-Medical Research, Ltd. a company based in Galway, Ireland, developed the Slendertone® FLEX, an EMS product designed to increase abdominal strength and tone. The company conducted two internal studies and found increased tone and firmness of the abdominal region (6,8). There were also increases in isometric strength and isometric endurance, as well as positive perceived outcomes by the subjects (6,8). As the device's popularity grew in Europe, Bio-Medical Research, Ltd. petitioned the Food and Drug Administration (FDA) to sell the product in America. To be cleared by the FDA, impartial testing needed to be conducted on the product. In 2005,

researchers at the University of Wisconsin- La Crosse conducted a study on the effectiveness of the

Slendertone® FLEX abdominal belt. The study found that abdominal strength increased 49% and abdominal endurance increased 72% following 8 weeks of stimulation. Waist circumference decreased by 3.5 cm and all members of the stimulation group felt that their midsections had more tone and firmness after completing the EMS training. (15).

In 2008, Porcari et al. tested the Slendertone® System Abs Device (Unpublished results). This product was also produced by Bio-Medical Research, Ltd. and was similar to the Slendertone® FLEX, except that it was approximately 30% stronger. The purpose of the study was to test the effectiveness of the device on anthropometric measures, body satisfaction, and muscular strength and endurance of the abdominal muscles. The test protocol was similar to the previous study conducted at UW-L. Fifty-six adults participated in the study and were randomly assigned to a high or a low intensity group. Subjects used the belt five times per week, 30 minutes per session, for 6 weeks. In this study, belts for the low intensity stimulation group (control group) were altered to prevent them from causing muscular contractions. The impulse was strong enough, however, to cause some tactile sensation.

Similar to the 2002 study conducted by Porcari et al., there were no significant changes in body weight, BMI, abdominal circumference, or waist circumference in either group. Overall, 96% of participants in the high intensity group reported positive results, compared to only 56% of the low intensity group. The high intensity group had 92% improvement in firmness and an 81% improvement in muscular tone. The low intensity group had a 63% improvement in firmness and a 56% improvement in muscular

tone.

The high intensity group had significant improvements in isometric strength and curl-ups compared to the low intensity group.

Although results were not as significant as the high intensity group, the low intensity group did show improvement in all areas being examined. The authors concluded that these positive results could be attributed to subjects learning how to perform the tests or the placebo effect, since the low intensity units did not result in any significant muscular contractions (16).

Myotonometer

In order to objectively measure muscular tone in the current study, a Myotonometer® (Neurogenic Technologies, Inc., Missoula, MT) was used. A Myotonometer is an electronic hand-held device that quantifies muscle stiffness, tone, compliance, and strength. The device is placed on the subject's skin overlaying the muscle to be tested. Deformation is measured in response to force applied to the muscle via the Myotonometer wand. The Myotonometer was originally called the Myoton-2 myometer.

Test and re-test reliability of the Myoton-2 myometer on muscle stiffness was examined by Bizzini and Mannion in 2003. Over a 2 day period, 10 volunteers were tested for muscular stiffness of the rectus femoris, vastus lateralis, biceps femoris, and

gastronomies muscles. Good test-retest results were shown, resulting in R values of 0.80-0.93. With the consistent results it was concluded that the Myoton-2- myometer was in fact a reliable device for muscle stiffness measurements (5).

Summary

In conclusion, there have been a number of studies showing positive improvements in muscular strength and endurance with the use of EMS, both in a clinical population as well as in healthy adults. However, the impact that EMS has on body appearance and measures of girth are not as clear. More researching is needed to better understand their effects and to gauge their impact on muscular tone and body satisfaction.

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