Use of Neuromuscular Electrical Stimulation for Abdominal and Quadriceps Muscle Strengthening: A Randomized Controlled Trial

Leah K. Spring, DO,*† Kathleen Petrell, BA,* Joaninha Depina, BA,* and Jeffrey S. Dover, MD*‡

BACKGROUND Radiographic imaging has demonstrated muscle hypertrophy after treatment with noninvasive body contouring devices that target skeletal muscles.

OBJECTIVE This pilot study sought to evaluate whether increased muscle mass translated to improved functional strength and endurance.

METHODS A prospective, single-center, randomized open-label controlled study included 26 subjects randomized into 3 groups: 2 treatment groups and 1 control group. Both treatment groups received 4 neuromuscular electrical stimulation (NMES) treatments over a 2-week period. Muscle performance testing was conducted at baseline and 2-week and 4-week posttreatment. Anthropometric measurements were assessed at baseline and at 4-week posttreatment. Study participants completed subject satisfaction surveys and a personal experience assessment.

RESULTS Treatment with NMES resulted in statistically significant improvements in abdominal and quadriceps strength and endurance from baseline through 4-week posttreatment. Mean waist circumference decreased and quadriceps circumference increased, both nonsignificantly. Subject satisfaction regarding abdominal and quadriceps strength was reported as "satisfied or very satisfied" in 89% and 92% at 4-week and 8-week posttreatment, respectively.

CONCLUSION Treatment of the abdomen and quadriceps with NMES leads to significant improvements in muscular strength and endurance.

Muscular strength and endurance enhance athletic performance across a wide range of activities while simultaneously reducing risk of injury.[1,2] Although functional gains in muscular strength and endurance have traditionally been the hard-won outcome from a dedicated strength training regimen, it may be possible to augment that regimen through the use of noninvasive body contouring devices, specifically those that target muscular development.[3]

Neuromuscular electrical stimulation (NMES) devices use applied electrical current to stimulate motor neurons to activate muscle fibers of skeletal muscle and have been used historically by both rehabilitation therapists to increase muscle mass, strength, and function[4–8] and athletes to induce muscle hypertrophy and strengthening.[9] Although many studies over the past 4 decades have demonstrated that NMES promotes muscular growth and strength,[6–8,10–12] other studies have shown no improvements.[13–15] These variations in clinical outcomes are likely secondary to markedly different treatment parameters and frequency capabilities (the number of electrical pulses delivered per second) of the NMES device.[16,17]

The truSculpt flex (Cutera, Brisbane, CA) is a NMES device cleared by the FDA to "strengthen, firm, and tone the abdomen, buttocks, and thigh." Compared with traditional electrical muscle stimulation devices, which deliver 10 mA or less of energy, the truSculpt flex delivers 10 to 30 mA of energy with 3 treatment mode options ("Prep Mode," "Tone Mode," and "Sculpt Mode") to create multiple types of muscle contractions. Preliminary data using ultrasound imaging after 4 to 6 treatment sessions with truSculpt flex showed an average 30% increase in muscle mass and a modest reduction in overlying adipose thickness.[18]

This pilot study was designed to evaluate whether the increase in muscle mass after truSculpt flex treatment translated to increased strength and endurance. This study also sought to determine which treatment protocol elicited a greater functional gain, and when peak response was reached.

*From the *SkinCare Physicians, Chestnut Hill, Massachusetts; †Commander, Medical Corps, United States Navy, Naval Medical Center Portsmouth, Portsmouth, Virginia; ‡Department of Dermatology, Yale University School of Medicine, New Haven, Connecticut*

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Address correspondence and reprint requests to: Leah K. Spring DO, Department of Dermatology, Naval Medical Center Portsmouth, 620 John Paul Jones Cir, Portsmouth, VA 23708 or e-mail: Leah.k.spring@gmail.com

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Materials and Methods

This was a prospective, single-center, randomized open-label controlled trial. Study approval was granted by the New England Institutional Review Board in compliance with all applicable Federal regulations governing the protection of human subjects. Eligible subjects were physically active men or women between the ages of 21 and 65 years with a stable body weight and body mass index (BMI) equal to or less than 27.

Exclusion criteria included inability to perform the required physical testing, use of medications or supplements for weight loss or metabolism enhancement within 3 months of study participation, pregnancy, breastfeeding, cardiovascular disease, neurologic disorders, gastrointestinal disease, abdominal or inguinal hernias, malignant tumors, autoimmune or connective tissue disease, and any electronically, magnetically, or mechanically activated implants (pacemaker, internal defibrillator, or cochlear implant) or metal implants. Subjects were also excluded if they had a history of cosmetic procedures (cryolipolysis, radiofrequency, or electromagnetic) to the target area within 3 months of study participation, surgical procedures in the target area within the past 6 months, or any prior invasive fat reduction procedures (liposuction) in the area of intended treatment. All participants agreed to maintain their current diet and exercise routines throughout the study period.

Subjects were enrolled and randomly assigned into 3 groups: 1 control group and 2 treatment groups. Treatment consisted of four 45-minute NMES (truSculpt flex, Cutera, Brisbane, CA) treatment sessions over a 2-week period. This device features 16 surface electrodes (6 × 6 cm), which were placed simultaneously on adhesive gel pads applied to bare skin overlying the rectus abdominis (4 electrodes), external abdominal obliques bilaterally (4 electrodes), and rectus femoris bilaterally (8 electrodes). The participants were treated at intensity settings that elicited maximum muscle contraction without unacceptable discomfort. Subjects in the "2TM + 2SM" cohort received 2 treatments on "Tone Mode," followed by 2 treatments on "Sculpt Mode". Subjects in the "4TM" cohort received 4 treatments on "Tone Mode."

The primary study efficacy end point was abdominal and quadriceps strength and endurance, as assessed with both isometric and isokinetic physical tests at baseline and 2-week and 4-week posttreatment.

Single-Leg Wall Sit

Subjects were instructed to stand with feet approximately shoulder width apart, against a smooth vertical wall before slowly sliding his/her back down the wall to assume a position with both knees and hips at a 90° angle. Timing started when the right foot was raised off the ground and was stopped when the subject could not maintain the position, and the foot was returned to the ground. After a timed 2-minute period of rest, the other leg was tested.

Static Abdominal Muscle Endurance

Subjects were instructed to lie supine with their knees bent at 90° on a padded exercise mat with hands palms down at their sides. Two strips of tape were placed parallel to each other and perpendicular to the length of the subject's body: the first positioned at the subjects' fingertips and the second placed 3.5 inches caudally. Subjects were instructed to perform an abdominal curl-up by sliding their fingers along the mat until they reached the second line of tape. This position was held and timed until the subject could no longer maintain position on the tape.

Dynamic Abdominal Muscle Endurance

Following a timed 2-minute rest after performing the same test, the subjects returned to the same position on the mat and were instructed to perform repeated curl-ups to the beat of a metronome set to 40 beats per minute, which translated to a steady, controlled cadence of 40 curl-ups per minute. Curl-ups were counted until the subject could no longer maintain proper form or maintain cadence.

The primary safety end point was subject discomfort during and after treatment, as well as incidence and severity of adverse events (AEs) during the study period. A visual analog pain scale (VAS) was used to assess pain intensity during and immediately after treatment. Skin responses after treatment were evaluated by the study physician and documented. The severity of the responses was rated as mild, moderate, or severe. Adverse events were monitored throughout the study.

Secondary study end points were anthropometric measurements (BMI, waist, and thigh circumference) assessed at baseline and 4-week posttreatment, and assessment of subject satisfaction through a 5-point Likert satisfaction scale and personal experience assessment. Body weight and height were measured using a Health o meter professional scale. BMI was calculated using the National Institute of Health's online BMI calculator. Waist and thigh circumference (centimeters) were assessed at baseline and 4-week posttreatment. Subjects were instructed to stand with their feet flat on a standardized fixed footprint mat, hands on contralateral shoulders, arms raised to a 90-degree position from their body, and the head facing straight ahead. Waist circumference was measured at the superior aspect of the umbilicus. Thigh circumference was measured bilaterally at the midpoint between the inguinal crease and proximal border of the patella. Subjects were instructed to maintain a relaxed position, with weight equally distributed on both feet, and to breathe normally. Measurements were taken 3 times and recorded to the nearest 0.1 cm.

At 4-week and 8-week posttreatment, study participants completed a 5-point Likert satisfaction scale to assess their perception of their abdominal and quadriceps strength. A personal experience assessment (PEA) consisting of 9 questions assessing the participant's feelings about their body shape, appearance, and the overall result was completed at 8-week posttreatment. The PEA is an assessment tool used in previous neuromuscular electrical stimulation device studies.[19]

Statistical analysis was performed using the nonparametric Kruskal–Wallis test to determine whether there were differences between the groups. Two group comparisons were made using the nonparametric Mann–Whitney *U* test. A *p*-value of 0.05 or less was considered statistically significant.

Results

Of the 26 subjects enrolled, 24 completed all 4 NMES treatments and 15 completed both the 2-week and the 4-week posttreatment strength and endurance testing. Of those who did not complete the study protocol, 1 subject withdrew after the first treatment because of scheduling issues, 1 subject only completed 2 treatments due to the COVID-19 state-mandated lockdown, and 9 subjects completed all 4 treatments but could not participate in in-person muscle testing because of the COVID-19 state-mandated lockdown. The mean age of the participants was 39 (23–57) years, and mean BMI before treatment was 24.0. Most of the enrolled subjects were active at baseline, with 84%, 81%, and 84% self-reporting their current exercise programs were of at least moderately heavy intensity, lasting more than 30 minutes in duration, and occurring more than 3 times per week, respectively.

Anthropometric Assessments

There were no significant changes in BMI from the baseline to 4-week follow-up. Both the treatment groups appreciated a reduction in waist circumference that did not reach statistical significance. Group 2TM + 2SM achieved a mean waist circumference reduction of 1.8 cm, whereas Group 4TM achieved a mean reduction of 0.8 cm. The control group's mean waist circumference increased 0.3 cm from baseline to 4-week posttreatment. Mean thigh circumferences of all NMES-treated subjects increased 1 (left) and 1.5 (right) cm, but this also did not reach statistical significance.

Functional Testing

Single-Leg Wall Sit

Subjects in Group 2TM + 2SM demonstrated a 43.9% and 82.1% increase in duration (seconds) one could maintain a single-leg wall sit at 2-week and 4-week posttreatment, respectively, for the right leg and 24.5% (2 weeks) and 119.3% (4 weeks) for the left leg. Compared with control ($n = 3$), individuals in Group 2TM+ 2SM achieved a statistically significant change from baseline for both the right leg ($p < .05$) and the left leg ($p < .03$) (Figure 1).

Subjects in Group 4TM ($n = 6$) demonstrated a 36.6% and 55.7% increase in duration (seconds) at 2 weeks and 4 weeks, respectively, for the right leg and 49.4% (2 weeks) and 76.1% (4 weeks) for the left leg. Compared with control, individuals in Group 4TM achieved a statistically significant change from baseline for the left leg ($p < .03$), but not the right ($p = .9$). There was no statistically significant difference between the 2 treatment protocols.

Static Abdominal Muscle Endurance

Group 2TM + 2SM demonstrated a 14.3% and 42.6% increase in duration (seconds) a treated individual could maintain a static abdominal contraction at 2-week and 4-week posttreatment, respectively. Group 4TM demonstrated a 102% increase in duration at 2-week posttreatment, which fell to a 57% improvement from baseline at 4 weeks. Although both treated groups demonstrated improvement, only Group 2TM + 2SM achieved a statistically significant change from baseline compared with control ($p < .03$) (Figure 2).

Dynamic Abdominal Muscle Endurance

There was an overall improvement in how many abdominal curl-ups a treated individual could perform at the 2-week and 4-week posttreatment visits compared with (Figure 3) baseline. This improvement remained relatively stable at both posttreatment visits. Group 2TM + 2SM appreciated a 49.8% and 45.9% improvement from baseline at 2 weeks and 4 weeks, respectively. Group 4TM appreciated a 73.2% and 72.5% improvement from baseline at 2 weeks and 4 weeks, respectively. Neither group's improvements achieved statistical significance compared with control.

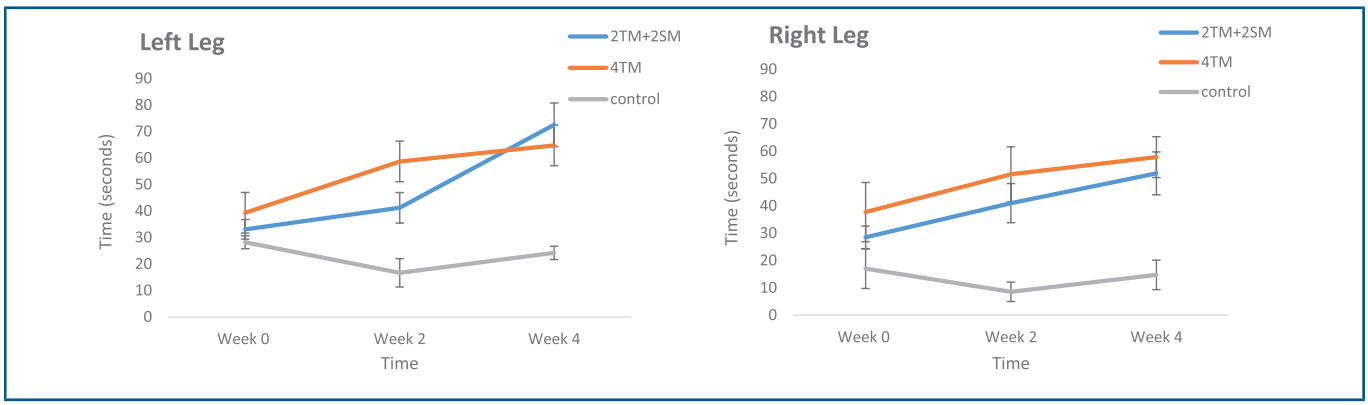

Figure 1. Single-leg wall sit functional testing at baseline, 2-week posttreatment, and 4-week posttreatment for both the left leg and the right leg.

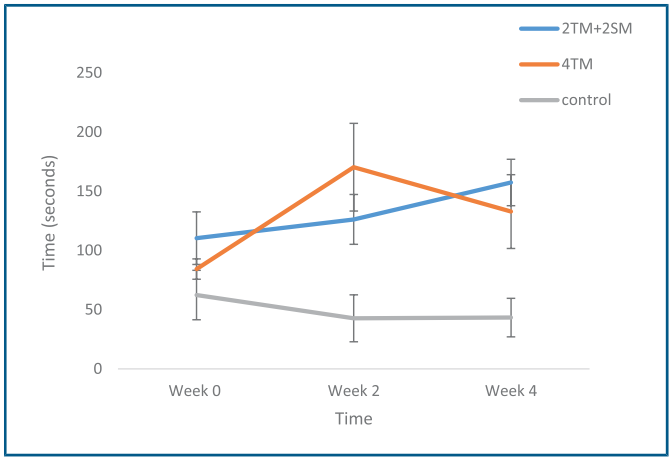

Figure 2. Static abdominal muscle endurance functional testing at baseline, 2-week posttreatment, and 4-week posttreatment.

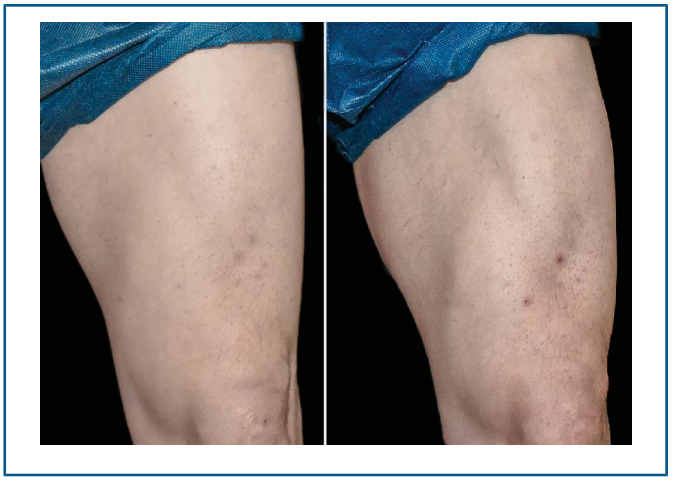

Figure 4. Baseline (left) and 4-week posttreatment (right).

Safety and Tolerability

Discomfort was minimal (mean = 0 on a 0–10 VAS scale). No treatment sessions were terminated prematurely because of discomfort. All AEs were anticipated (listed in the operator manual/treatment guidelines) and resolved within 24 hours. The most commonly reported treatment-associated effects were mild-to-moderate tingling/numbness (73% of participants), mild-to-moderate erythema (36%), mild muscle soreness (3%), and mild-to-moderate random muscle contractions (3%). Rarely reported AEs were a mildly increased heart rate, mild skin hypersensitivity, mild "warm" sensation, frequent urination, and mildly increased hunger. There were no unanticipated AEs.

Subject Satisfaction and Personal Experience Assessments

The 5-point Likert scale subject satisfaction questionnaire revealed 89% of subjects (n = 18) were satisfied to very satisfied with their abdominal and quadriceps strength at 4 weeks, which increased to 92% (n = 12) at 8 weeks. Subjects were satisfied to very satisfied (83%) with their overall physical appearance at 4-week and 8-week posttreatment. In addition, at 8 weeks, 75% of the subjects (n = 12) slightly to strongly agreed their results would have taken many months to achieve in the gym, and 100% reported they slightly to strongly agreed their results were very motivating, improved their self-esteem, increased their confidence, and made them more likely to feel comfortable wearing a bathing suit in public. The subjects' assigned treatment protocol did not seem to affect their satisfaction because both groups reported similar scores.

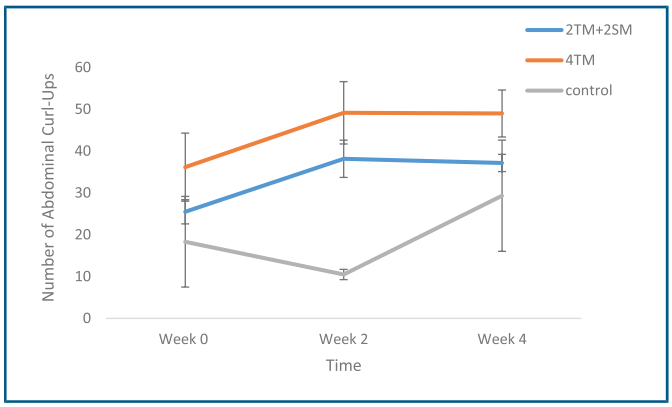

Figure 3. Dynamic abdominal muscle endurance functional testing at baseline, 2-week posttreatment, and 4-week posttreatment.

Discussion

There is a growing body of literature describing efficacy of muscle building devices in the aesthetic arena. Previous studies have assessed degree of aesthetic improvement, patient satisfaction, and radiographic imaging.[20–22] To the best of the authors' knowledge, this is the first study that has assessed physical performance using one of these aesthetic devices.

In this pilot study, a NMES device was evaluated for its ability to improve abdominal and quadriceps strength and endurance as measured by isometric and isokinetic muscle testing in healthy adults. Statistically significant improvements in the duration of time an individual was able to maintain right-leg and left-leg single-leg wall sits, improvements in the duration one could hold a static abdominal curl-up, and perform abdominal crunches to a set cadence

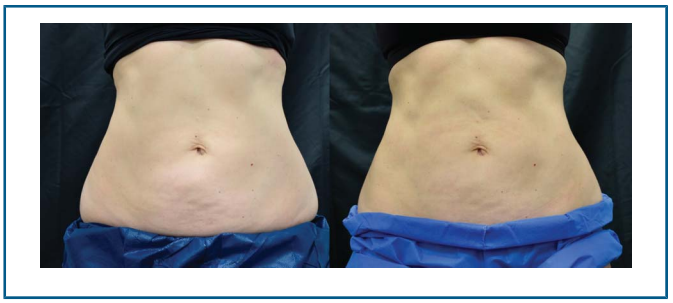

Figure 5. Baseline (left) and 4-week posttreatment (right).

Figure 6. Maximal abdominal contraction at baseline (left) and 4-week posttreatment (right).

were appreciated in both the treatment groups at 2-week and 4-week posttreatment. Subject satisfaction was equally high in both the groups, treatments were well-tolerated, and no serious adverse events were reported. Photographs of representative subjects (Figures 4–6) demonstrated a modest but appreciable improvement of aesthetic appearance.

This study's statistical significance was limited by the abrupt and unanticipated state-mandated lockdown in response to the COVID-19 pandemic, which resulted in only 15 of 26 subjects completing all treatments and all posttreatment assessments. In addition, the protocol of this study planned to assess all subjects at 8-week posttreatment to determine peak response and duration of response, but as this testing period also fell within the state-mandated lockdown, it was cancelled. Early termination of this study and small sample size limited the power of the results; however, the results the authors achieved show promise.

Future studies including more subjects, subjects of varying physical abilities, and correlation of functional strength with radiographic imaging are merited. This study has also set the stage for additional investigations to determine the ideal timing of a "booster treatment" to achieve superior and sustained functional outcomes.

Conclusion

Four 45-minute treatments with a neuromuscular electrical stimulation device led to statistically significant improvement in abdominal and quadriceps strength and endurance, as well as modest favorable changes to waist circumference and thigh circumference that was sustained through 4-week posttreatment. Subject satisfaction was high, and no serious side effects were reported.

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