



Body Contouring

Preliminary Report

Evaluation of a Combination Approach to Improving Muscle Tone and Decreasing Subcutaneous Tissue Thickness Using a Sequential, Dual-Modality, Energy-Based Device

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Abstract

Background: The body shaping market has long been at the forefront of the aesthetic industry. With technological advances, patient demand for body sculpting in terms of reduction in subcutaneous tissue and enhancement of muscle has seen continual growth. Several devices have emerged in the space; however, few achieve both subcutaneous tissue reduction (SQR) and voluntary muscle increase (VMI) as measured by thickness, during the same treatment session.

Objectives: This article presents the results of a pilot study on a unique approach to subcutaneous tissue reduction and increasing muscle thickness using a dual-modality, energy-based device.

Methods: Twelve compliant patients (8 females and 4 males with an average age of 40 years) were enrolled in this single center, prospective study. All patients were treated with the dual-modality device (850 nm superluminescent diode matrix and electrical muscle stimulation), with external applicators being placed over the lower abdomen. The patients received 5 weekly treatments. Ultrasound measurements, photographs, weight, and waist measurements were taken at baseline, prior to the start of the fifth treatment, and at the 2-week and 2-month follow-up visits.

Results: At the 2-month follow-up visit, the average SQR was 34.03% and the VMI measured 22.97% in all patients who completed the study. All patient and physician evaluations rated the results as satisfactory or better. There were no complications.

Conclusions: Preliminary data show this dual-modality, electrical muscle stimulation/superluminescent diode matrix system provides both a safe and effective treatment for the reduction of subcutaneous tissue thickness and an increase in muscle definition and thickness. Objective and subjective evaluations demonstrated high levels of efficacy and satisfaction in all patients.

Level of Evidence: 2

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Therapeutic

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The body shaping market has long been at the forefront of the aesthetic industry. With technological advances, patient demand for body sculpting in terms of reduction in subcutaneous tissue and enhancement of muscle has seen continual growth.¹ Historically, patients had to make a choice between voluntary muscle increase (VMI) and subcutaneous tissue reduction (SQR), which are both essential components of body contouring treatments.^{2,3} When looking at this 2-factor approach in this highly competitive and in-demand market, there are many devices that offer each modality, independently. However, with those devices, both components are not addressed during the same treatment session. These types of energy-based systems are outlined in the following paragraphs.

Muscle stimulation offers 3 popular methods including electrical muscle stimulation (EMS), electromagnetic stimulation (EMGS/high-intensity focused electromagnetic field [HIFEM]/magnetic stimulation [MS]), and transcutaneous electrical nerve stimulation (TENS). In order to promote growth and enhance external definition, these treatments target striated musculature (somatic nervous system), which will stimulate movement in the 3 types of muscle fibers that make up skeletal muscle—slow twitch oxidative (Type I) muscle fibers, fast-twitch oxidative-glycolytic (Type IIA) muscle fibers, and fast-twitch glycolytic (Type IIX) fibers.⁴

TENS therapy involves the use of low-voltage electrical currents. A TENS device delivers the current through the skin at or near nerves to cause them to involuntarily twitch. Nerves around the muscle fiber may cause small, involuntary muscle spasms. It was traditionally used for the purpose of relieving pain, but it can stimulate muscles for the purposes of strengthening and rehabilitating them. Efficacy for treating pain and/or muscle rehabilitation is still unconfirmed.⁵⁻⁷

MS, EMGS, functional magnetic stimulation,⁸ or HIFEM delivers magnetic waves to stimulate the muscles of the body. The electromagnetic field is sent transdermally through the body, inducing a current of sufficient amplitude and duration to stimulate a multitude of highly dense and involuntary muscle contractions.⁹ It is not selective for specific muscle types. When looking at other modalities for stimulation, magnetic stimulation has become an increasingly popular method. Although this is an effective method, issues arise with specific targeting of tissue and energy confinement. Magnetic stimulation does not specifically illicit a response from only the desired target tissues and may, in fact, nonselectively treat all muscle types in the wave path, inadvertently delivering energy to surrounding anatomical structures.¹⁰⁻¹²

EMS utilizes external electrodes in order to selectively deliver electrical currents to the targeted tissue. These currents are transferred into an ion flow at the point of the electrode-tissue interaction. These ions flow to the axons of nerve fibers, in order to trigger firing, causing focused muscle contractions. These replicated stimuli over a

designated period of time will yield the desired effect of muscle growth.¹³ EMS has been studied and seems to be a promising alternative to traditional strength training and muscle conditioning.¹³⁻¹⁵

In addition to increasing muscle thickness and improving muscle definition, subcutaneous tissue heating is a necessary component of body sculpting. Three popular methods for subcutaneous tissue heating include radiofrequency (RF), infrared lasers, and diode arrays.

RF systems operate on Ohm's Law and create a thermal effect by utilizing the resistance created by an electromagnetic field.¹⁶ Although effective, this technology can have issues with selectivity and/or thermal energy adversely affecting adjacent areas, leading to over and under treatment of nontargeted tissue.¹⁷ RF works well for external treatments of the skin and superficial tissue; however, there are limits to the depth of penetration, which inhibits the ability to treat subcutaneous tissue and musculature.¹⁸

Infrared lasers can be selectively filtered to target specific tissue in a more controllable manner than RF and have been successfully utilized in this manner. The drawback of laser deep heating is the limited size of the area that can be effectively treated, increasing treatment time.¹⁹ Highly focused laser light must be precisely titrated in order to be effective while maintaining a safe application. In addition, the utilization of laser energies necessitates a higher degree of safety precautions.²⁰

Diode arrays or a superluminescent diode matrix (SDM) combine the selectivity of a laser with the ability to treat larger areas by utilizing a series of diodes filtered to a specific wavelength. This allows for the targeting of specific and deeper tissue structures with minimal thermal wake affecting the superficial tissue.²¹ Larger applicators, covering greater surface areas, are available using SDM compared with other modalities, potentially decreasing treatment time. The absorption coefficient of water at the wavelength used with SDM is ideal for transdermal penetration to the proper depth for SQR.²²

A recently introduced system incorporates both EMS for increasing muscle thickness and enhancing definition and a SDM for heating and reducing the subcutaneous tissue layer in a single, noninvasive procedure. Although employing both energies sequentially, the total treatment time is under 46 min per session. This "STEP" program, or Sequential Thermal and Electrical Pulse, is used to effectively and safely deliver the proper energy to the intended tissue, inducing muscle hypertrophy and subcutaneous tissue reduction. Thus, in this pilot study, the results of changes in voluntary muscle thickness and subcutaneous tissue reduction using both the EMS and the SDM, sequentially, in a single treatment utilizing proprietary treatment protocols will be evaluated (Video).

The goal of the study was to evaluate the safety, efficacy, and overall clinical performance of the device in sequentially



Video. Watch now at <http://academic.oup.com/asjopenforum/article-lookup/doi/10.1093/asjof/ojae024>

administering thermal and electrical pulses to warm the subcutaneous layer and induce muscle contractions.

METHODS

Patient Selection

Fourteen patients were enrolled in this study at a single site (the author's private practice, New York, NY) and went through treatment and follow-up visits from February 9 to September 9, 2022. Two patients were noncompliant and removed from the study before completion. Patients enrolled in the study underwent medical clearance and had no prior history of treatment with noninvasive body sculpting devices, abdominal liposuction, or prior surgery or scars in the treated area. Interested patients who were pregnant or planned on becoming pregnant during the treatment series did not qualify for participation. Patients carrying out any weight loss procedures, the presence of metal implants in the treatment area, a pacemaker or internal defibrillator, diabetes, cardiac issues, uncontrolled thyroid disease, uncontrolled high blood

Table 1. Device Specification and Features

Manufacturer	El.En. Group
Device type	SDM/EMS
Wavelength	850 nm diode \pm 5 nm
No. of applicators	4 with EMS
Power density	Up to 1.15 W/cm ²
Spot size	6 \times 6 cm (36 cm ²)
Attachment to the patient	Flexible band with Velcro
Skin cooling	Sapphire window with continuous flow parallel contact cooling
Safety	Patient safety/pause button

SDM, Superluminescent diode matrix; EMS, electrical muscle stimulation.

pressure, active infection in the treatment area, open wounds, photosensitivity/photosensitizing medication, auto-immune skin diseases, mental illness, tattoos in treatment area, skin irritation/skin cancer in the treatment area, or any other underlying medical conditions that could interfere with wound healing were also excluded from the study. The study was approved by Allendale IRB.

Measurements were performed at the same documented anatomic location by the 2 primary investigators at all visits. This measurement was taken at a point 1 cm below the umbilicus. Consistency at this point was individually determined for each patient. The measurements were taken with the patients standing on their stocking feet. This distance was determined for each patient by dropping a vertical and measuring the distance from the predetermined point below the umbilicus to the floor. This distance was then marked at 3 other points circumferentially around the patient. These 4 points were then used to measure the waist circumference using a self-closing tape measure. This technique was repeated multiple times per waist measurement and proved to be reliable and reproducible. This predetermined point was also used by all patients as their individual point for ultrasound measurements. The ultrasound device was positioned at this level perpendicular to the long axis of the rectus abdominis muscle and centered directly in the middle of the muscle, equidistant from the medial and lateral muscle edges. Patients were instructed not to change their usual and customary diet and exercise routines throughout the treatment series. Patients did not adjust, add to, or limit their food intake during the study. If active, patients were instructed to maintain their daily exercise routine without any adjustments in frequency, duration, or intensity. If they did not exercise prior to enrolling in the study, they were instructed not to add any exercise routines during the study. Patients were weighed at each visit, and a history was taken as far as their diet and exercise. Medical

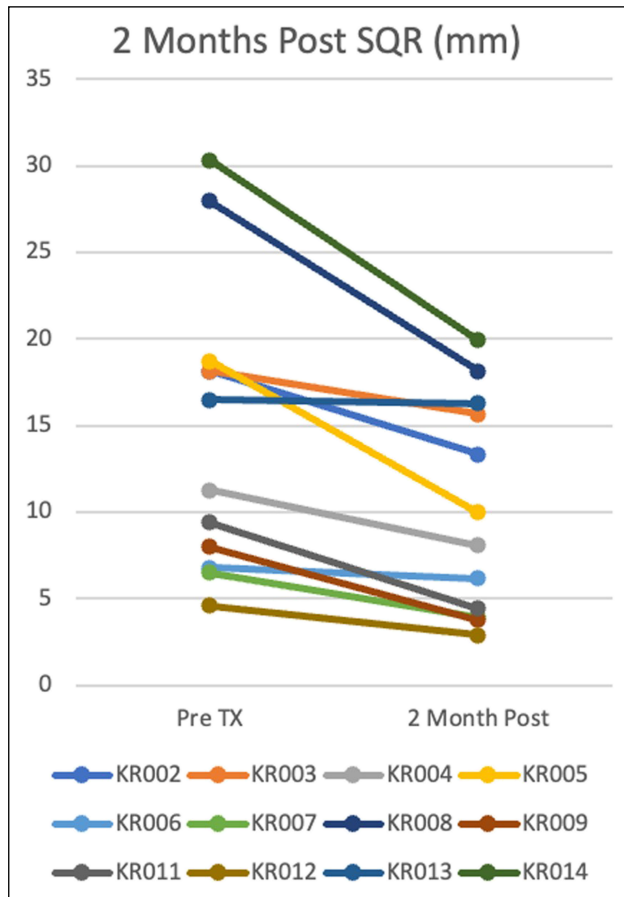


Figure 1. Two-month postsubcutaneous tissue reduction (SQR): measurement of SQR through ultrasound before treatment series and 2 months after final treatment in millimeters. Patients: KR002, 31, F; KR003, 65, F; KR004, 34, M; KR005, 30, M; KR006, 69, F; KR007, 26, F; KR009, 26, M; KR010, 27, F; KR011, 28, F; KR012, 50, F; KR013, 43, M; KR014, 45, F. X-axis: pre-TX—measurement of SQR through ultrasound before treatment series; 2 months postmeasurement of SQR through ultrasound 2 months after final treatment. Y-axis: measurement of subcutaneous tissue in millimeters from 0 to 35 mm.

events or significant changes to lifestyle would be reported to Rothaus Plastic Surgery. All patients signed treatment and photograph release consent forms and reviewed their medical history with the medical director. They acknowledged the risks and expectations of the treatment, through these consent forms, and any contraindications/exclusionary criteria for treatment were ruled out. All patients received treatment in the same area, the abdomen, and agreed to a 5 weekly (± 5 days) treatment series with sequential EMS and SDM. Follow-up visits were scheduled for 2 weeks and 2 months after the final treatment visit. Measurements (weight, waist, ultrasound, and photographs) were taken before the first and fifth treatments and during the 2 follow-up visits.

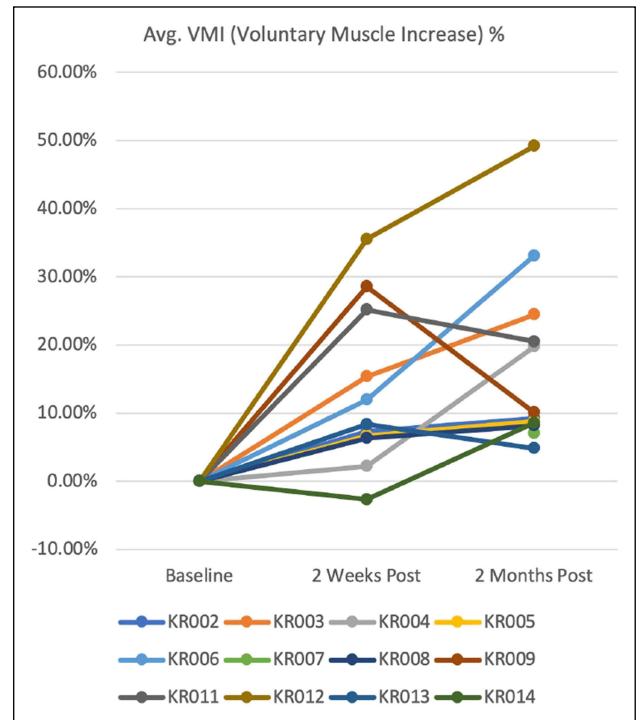


Figure 2. Average voluntary muscle increase (VMI) %: measurement of VMI as a percentage through ultrasound at 2 weeks post and 2 months after final treatment. Patients: KR002, 31, F; KR003, 65, F; KR004, 34, M; KR005, 30, M; KR006, 69, F; KR007, 26, F; KR009, 26, M; KR010, 27, F; KR011, 28, F; KR012, 50, F; KR013, 43, M; KR014, 45, F. X-axis: baseline—ultrasound measurement of muscle thickness, through ultrasound, before treatment series. Two-week postultrasound measurement of muscle thickness, through ultrasound, 2-week postfinal treatment. Two-month postultrasound measurement of muscle thickness, through ultrasound, 2-month postfinal treatment. Y-axis: percentage of increase or decrease in muscle thickness.

Protocol

Subcutaneous tissue and muscle thickness were measured using the Clarius L7 HD Linear Handheld Ultrasound Scanner (Clarius, Vancouver, British Columbia, Canada).²³ All patient ultrasound measurements were taken 1 cm below umbilical. The protocol followed to maintain consistency at this point has previously been described above. Measurements were taken by the same 2 investigators throughout the study process.

The device employed was the Physiq (El.EN./Deka Lasers Inc., Florence, Italy) which has 4 infrared applicators each with a 6 x 6 cm spot size (36 cm²) and 300 infrared diodes (SDM) internally (Table 1). Each applicator emits an 850 nm wavelength with a maximum power density of 1.15 W/cm². Each of the 4 applicators has 2 electrodes for EMS and an internal cooling system complete with a sapphire glass window and continuous flow parallel contact cooling in order to maintain safe skin surface temperatures of 25 to 30°C. Clear

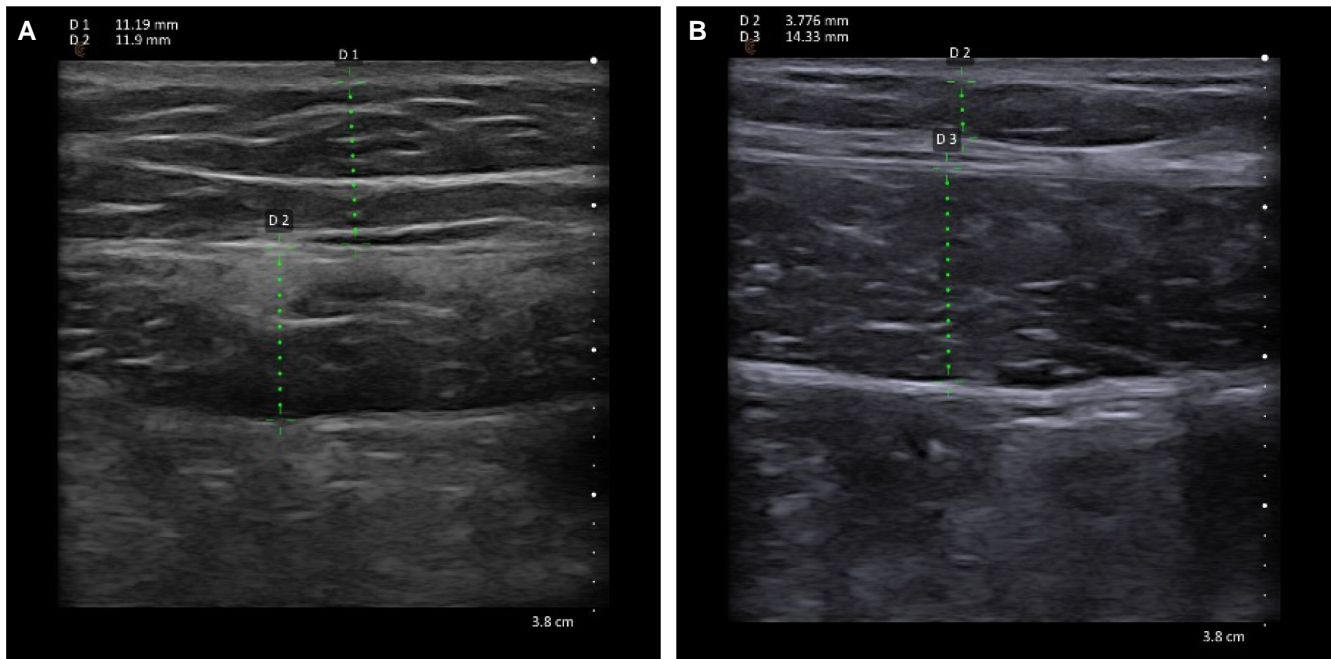


Figure 3. (A) Pretreatment image for a 28-year-old female patient, presenting a complaint for body contouring, underwent Physiq procedure. D1: Pretreatment subcutaneous tissue thickness measurement in millimeters. D2: Pretreatment muscle thickness measurement in millimeters. (B) Two-month posttreatment image for same 28-year-old female patient. D2: 2-month posttreatment subcutaneous tissue thickness measurement in millimeters. D3: 2-month posttreatment muscle thickness measurement in millimeters.

conductive gel pads are placed on each applicator before use and secured to the patient with a soft, flexible band. Proper placement is confirmed by visual muscle stimulation and inspection of each applicator being flushed on the tissue. Sequential thermal and electrical pulses (STEP) were used in all patients. This consists of a timed sequence of alternating EMS and SDM. Patients were instructed to manually massage the treated area twice a day between treatment visits using a provided lotion.

RESULTS

Of the 14 patients enrolled, 6 were males and 8 were females. The age range was 26 to 69 with an average age of 39.5. Both males and females were enrolled and had weights ranging from 123 to 203 lbs. The average waist circumference was 35.07 inches. The average BMI for all patients was 23.38. Patients experienced mild warming and visible muscle contraction throughout the STEP treatment cycles. Although little-to-no discomfort was reported during the SDM cycles, if mild discomfort (heat) was reported during the SDM cycle, parameters were slightly reduced, maintaining clinically effective levels, with zero discomfort. There was no discomfort reported during the EMS cycles. Immediately before the fifth treatment session, the observed SQR, as measured by ultrasound, was 22.75%

(2.94 mm). At the 2-week and 2-month follow-up visits, patients demonstrated an average SQR of 30.71% and 29.60%, respectively (Figure 1). Before the fifth treatment, the average increase in voluntary muscle thickness (VMI) was 18.74%. At the 2-week and 2-month follow-up visits, patients demonstrated an average VMI of 13.17% and 16.98%, respectively (Figure 2). Representative ultrasound results and accompanying data can be seen in Figure 3A, B and Table 2 as well as Figure 4A, B and Table 3. Pretreatment and 2-month follow-up treatment photographs are shown in Figures 5A-D and 6A, B. The continued decline in SQR and loss of VMI posttreatment are acknowledged in the discussion section. The average follow-up was 2 months (for all patients). Patient satisfaction averaged 4.4, on the 5-point Likert Scale.²⁴ The satisfaction surveys were conducted before subsequent treatment sessions upon arrival at the clinic. The surveys were included with the intake forms, without any bias or direction from staff. Patients did not have access to their measured results, photographs, or providers prior to completing the surveys. All of the study patients rated the treatment results and experience as “Satisfied” or “Very Satisfied” with none of the patients grading the treatment as “Very Dissatisfied,” “Dissatisfied,” or “Neutral.”

Physician grading was performed using the Global Aesthetic Improvement Scale (GAIS). The GAIS ranges from “1—Very Much Improved” down to “5—Worse.”

Table 2. Pretreatment and 2-Month Follow-up Data for KR011, a 28-Year-Old Female Patient

TX # (KR011)	Pre Tx	2-Month F/U Visit
Weight	138.8 lbs	135.8 lbs
Subcutaneous	11.19 mm	3.776 mm
Muscle	11.9 mm	14.33 mm
SQR		7.414 mm
SQR%		66.26%
VMI		2.43 mm
VMI%		20.42%

KR011, patient identification; 2-Month F/U Visit, 2 months postfinal treatment of series photograph; Pre Tx, pretreatment visit; SQR, subcutaneous tissue thickness measurement in millimeters; SQR%, subcutaneous tissue thickness percentage change; TX#, treatment visit header; VMI, voluntary muscle thickness measurement; VMI %, voluntary muscle thickness measurement percentage change.

None of the study patients experienced significant pain, burns, or other adverse events. There were no complications in this study. No patients required or requested early exit from the study. Physician satisfaction, as evaluated by the 2 investigators, averaged 2.16 on the GAIS.²⁵ All study patients had marked improvement with the majority having “2—Much Improved” and “1—Very Much Improved” scores. SQR and VMI remained stable throughout the 2-month follow-up period. At the final follow-up visit, ultrasound measurements of muscle thickness increase and subcutaneous tissue decrease had not significantly changed. Thus, results were maintained throughout the study period in spite of the absence of further treatment with this device or any other treatment.

DISCUSSION

Twelve patients completed the study. Two patients were removed for noncompliance (weight gain, failure to attend treatment sessions, and follow-up visits per the study guidelines). This dual-modality device incorporating the STEP treatment protocol enables the treatment of the 2 main tissues targeted in body sculpting, muscle, and subcutaneous tissue. In order to achieve efficacy, each tissue is simultaneously targeted during a single session with 2 sequentially delivered energy modalities. The average measured percentage of decrease in the subcutaneous tissue (SQR) and the measured percentage of VMI in the 12 compliant patients were 32.94% and 23.50%, respectively, at the 2-week follow-up and 34.03% and 22.97%, respectively, at the 2-month follow-up visit. The minimal change observed from the 2-week follow-up and 2-month follow-up visits demonstrates that positive clinical outcomes were maintained. The

Table 3. Pretreatment and 2-Month Follow-up Data for KR012, a 50-Year-Old Female Patient

TX # (KR012)	Pre Tx	2-Month F/U Visit
Weight	132 lbs	131 lbs
Subcutaneous	5.475 mm	3.545 mm
Muscle	7.245 mm	12.74 mm
SQR		1.93 mm
SQR%		35.25%
VMI		5.495
VMI%		75.85%

KR012, patient identification; 2-Month F/U Visit, 2 months postfinal treatment of series photograph; Pre Tx, pretreatment visit; SQR, subcutaneous tissue thickness measurement in millimeters; SQR%, subcutaneous tissue thickness percentage change; TX#, treatment visit header; VMI, voluntary muscle thickness measurement; VMI %, voluntary muscle thickness measurement percentage change.

decrease in VMI beginning at the 2-week follow-up visit was expected with no maintenance treatments being incorporated. This was discussed pretreatment with all patients who were subsequently offered maintenance treatments with EMS alone if desired at the study conclusion. Studies show muscle atrophy is likely to occur as soon as after 2 weeks of inactivity or disuse.^{26,27} The results were maintained as patients continued to demonstrate a decrease in the subcutaneous tissue throughout the follow-up period. Although patient tissue histologies were beyond the scope of the IRB approval for this study, the mechanism of apoptosis in adipose tissue subject to extremes in temperature is well documented and as is the increase in adipose temperature with the 850 nm diode energy employed in this device.

All patients exhibited the desired improvement: a decrease in the measured thickness of the subcutaneous tissue (SQR) and an increase in the measured voluntary muscle thickness (VMI); thus, documenting the efficacy of this simultaneous, dual-modality approach. Patient compliance dramatically enhanced the results of this device.

In comparison with other energies, such as RF, ultrasound, and laser, the relatively lower affinity of the SDM for water is better suited for this application. It penetrates the skin to the targeted tissue needed for SQR without excessive superficial cutaneous heating due to its lower water absorption than competing energies. This minimizes unnecessary overheating of the surface tissue, reducing the potential for discomfort and burns, while allowing a greater percentage of the effective energy to penetrate the skin surface layers and reach the target tissues.²⁸

The EMS portion of the STEP program induces muscle movement. Muscle movements promoted by this type of system allow for the direct replication of neuroreceptor stimulation in the brain. This differs from twitch muscle

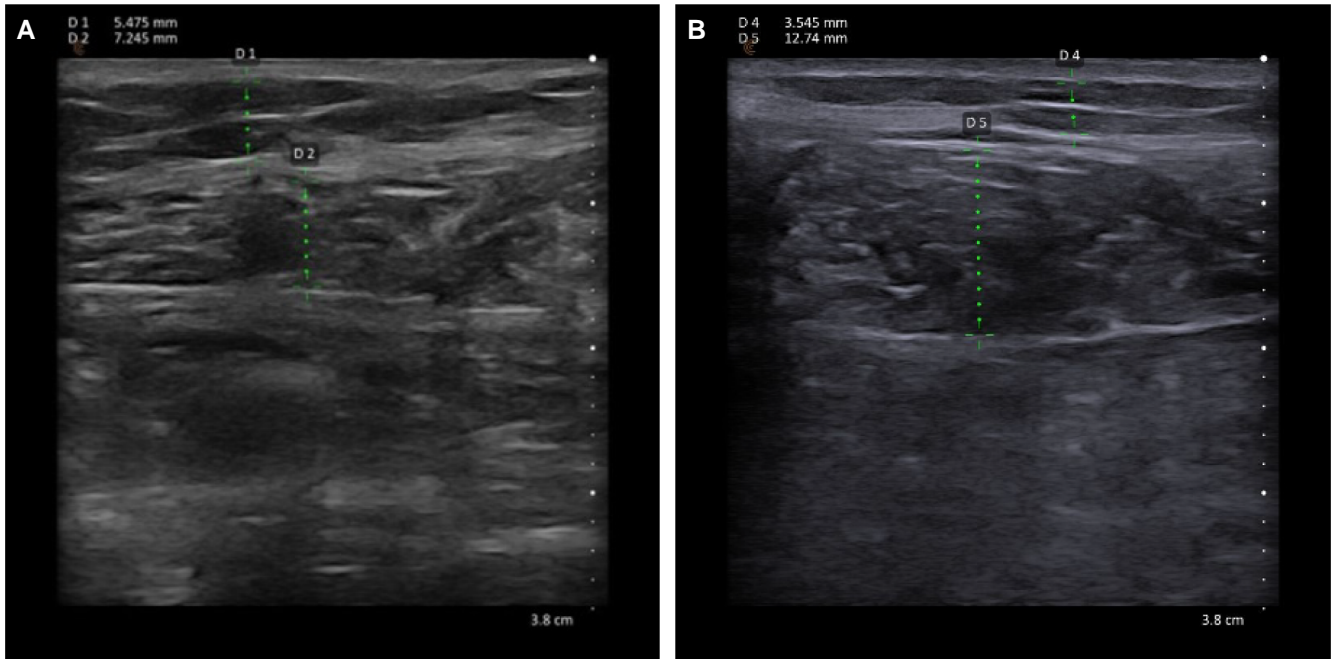


Figure 4. (A) Pretreatment image for a 50-year-old female patient, presenting a complaint for body contouring, underwent Physiq procedure. D1: pretreatment subcutaneous tissue thickness measurement in millimeters. D2: Pretreatment muscle thickness measurement in millimeters. (B) Two-month posttreatment image for same 50-year-old female patient. D4: Two-month posttreatment subcutaneous tissue thickness measurement in millimeters. D5: 2-month posttreatment muscle thickness measurement in millimeters.

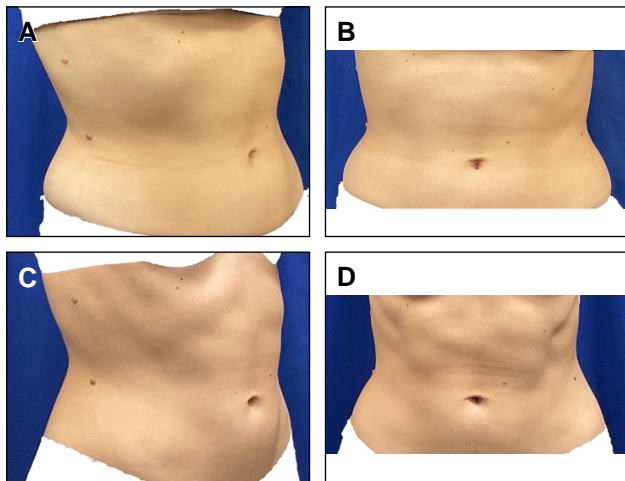


Figure 5. (A) and (B) are pretreatment images for a 26-year-old female patient, presenting a complaint for body contouring, underwent Physiq procedure. (C) and (D) are 2-month posttreatment images for same 26-year-old female patient.

stimulation, TENS, and other types of external EMS which only affect the end nervous response.

Other devices on the market require separate and independent treatments to induce muscle stimulation or adequately heat subcutaneous tissue. STEP allows for both

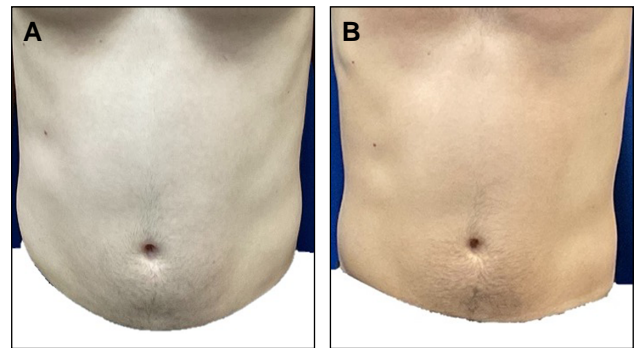


Figure 6. (A) Pretreatment and (B) 2-month posttreatment images for a 34-year-old male patient, presenting a complaint for body contouring, underwent Physiq procedure.

tissues to be addressed in a single treatment session. This involves a continuous cycle of sequential thermal pulsing and muscle stimulation, allowing effective temperatures to be reached rapidly and maintained throughout the treatment without compromising patient comfort and safety.

Although this study was a success in terms of results, we acknowledge that a larger sample size and longer follow-up would be of interest to reinforce these results and determine whether treatments would need to be repeated periodically. A 2-month, as opposed to a longer, follow-up after the last treatment was chosen as the final data point of the

study, as this represented a point that was in excess of 3 months from the initial treatment and consistent with the time frame seen in results reported with competing energy devices. In addition, no treatments were provided during the 2-month interval. Although, perhaps, one might have theoretically seen a further improvement in the SQR, the VMI could be expected to reverse without ongoing treatments.²⁸ Future studies involving larger numbers of patients followed over varying intervals might provide more information as to the ideal protocol for combining SDM and EMS for maximal patient results.

CONCLUSIONS

This preliminary report demonstrates how this dual modality, EMS/SDM system provides both a safe and effective treatment for the reduction of subcutaneous tissue using SDM and an increase in muscle thickness using EMS. High levels of satisfaction were noted in patients and physicians alike. Objective measurements (ultrasound, waist measurement, and photography) showed marked improvement.

Disclosures

Clarius L7 HD Linear Handheld Ultrasound Scanner (Clarius, Vancouver, British Columbia, Canada) was loaned for use in this study by Cartessa Aesthetics, LLC (Melville, NY). The authors declared no potential conflicts of interest with respect to the research, authorship, and publication of this article.

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