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Combination of monopolar 2 MHz radiofrequency and electrical multidirectional stimulation for reducing abdominal circumference and enhancing the muscle definition in subjects with overweight range body mass index

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Abstract

Background: The popularity of noninvasive body contouring procedures has been steadily increasing in recent years, however, studies evaluating its effectiveness in individuals with overweight range body mass index (BMI) are limited.

Objective: To evaluate the efficacy and safety of combined 2 MHz radiofrequency (RF) and electrical multidirectional stimulation (EMDS) for the improvement of the abdominal contour in subjects with overweight range BMI.

Methods: Twelve participants with overweight range BMI (23.6–24.9 kg/m²) underwent a single RF treatment, followed by a series of six EMDS treatments. Follow-up assessments (abdominal circumference [AC] and skinfold thickness measurements) were scheduled 1, 2, and 3 months after the final session.

Results: At 1 month after the final treatment, a 3.1% (2.6 ± 0.47 cm, mean ± SD) significant reduction in mean AC was observed ($p < 0.001$) and a maximal skinfold thickness reduction of 14% (4.6 ± 1.1 mm) was also noted ($p = 0.032$). Transient dysesthesia lasting 2–3 hours after EMDS treatment was the most common adverse effect reported by 5 of 12 subjects (41.7%), with no other serious side effects.

Conclusions: Combined RF and EMDS treatments are safe and effective, yielding significant reductions in both AC and skinfold thickness in patients with overweight range BMI, causing only minimal and transient adverse effects.

KEYWORDS

abdominal contouring, adipocyte, electrical multidirectional stimulation, fat cell, monopolar radiofrequency, muscle stimulation, noninvasive

INTRODUCTION

Body contouring is the alteration of the body's appearance through changes in size or shape. While diet and exercise can improve the body's contour, certain areas like the abdomen are more prone to persistent fat deposits. Previously, surgical intervention through liposuction or abdominoplasties were the mainstay

interventions for this problem. However, because of associated surgical risks and significant downtime, the demand has shifted toward effective, noninvasive body contouring options.^{1–3}

Various noninvasive contouring modalities have emerged as a result, which enhances the body's appearance through the removal of excess fat or by improving skin laxity.⁴ Among the leading noninvasive technologies

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for body contouring are radiofrequency (RF) devices. These devices emit RF energy waves that provide selective volumetric heating of the mid-dermis up to the subcutaneous tissue layer. This results in both collagen stimulation in the dermis for skin tightening and adipocyte damage in the subcutaneous layer for fat reduction.³

Other more recent approaches to body contouring targets the skeletal muscle beneath the skin and subcutaneous tissue via electrical or magnetic stimulation.² Electrical multidirectional stimulation (EMDS) generates electrical impulses leading to depolarization and initiation of the action potential at the skeletal muscle level. The device triggers rapid and sustained supramaximal contractions not attainable through manual exercise, resulting in muscular hypertrophy and reduced fat.⁴⁻⁷

Because the skin, adipose tissue, and muscle all contribute to the body's overall contour, the approach to body sculpting must be tailored to a patient's body type.⁸ For decades, body mass index (BMI) has been used as a gauge of body size, correlating with relative body fat percentage and associated risk for diseases.⁸⁻¹⁴ With noninvasive procedures, the lipolytic responsiveness of adipose tissue has been shown to be inversely proportional to a patient's BMI.² Thus, individuals with overweight range BMI and greater adiposity would require a more aggressive treatment plan to be able to achieve significant improvements in their body contour. This study then aimed to investigate the efficacy and safety of a combined monopolar 2 MHz RF device and EMDS for improving abdominal contour in Asian subjects with overweight-range BMI (23.0–24.9 kg/m²).¹¹

MATERIALS AND METHODS

This was a prospective nonrandomized, self-controlled study to evaluate the efficacy and safety of a combined monopolar 2 MHz RF device and EMDS for Asian subjects with overweight-range BMI. This study was approved by the Siriraj Institutional Review Board (SIRB), Faculty of Medicine, Siriraj Hospital, Mahidol University, Bangkok Thailand (Si 252/2020). Written informed consent was obtained from all study subjects and was conducted from April 16 to October 19, 2020.

The sample size was calculated using nQuery software 6.0 (Statistical Solutions). Unpublished data from Cutera Inc. demonstrated an average muscle thickness increment of 0.25 ± 0.09 cm after six EMDS treatment sessions. The sample size calculation was based on the likelihood of achieving at least 10% increase in muscle thickness with a type I error of 0.05 and a type II error of 0.2. The sample size was determined to be 11. Thirteen participants were enrolled to cover for a 20% drop-off. All subjects with BMI within the overweight range of 23.0–24.9 kg/m² underwent a single 15-minute treatment

with a monopolar 2 MHz RF device, followed by six 45-minute EMDS treatments.

Participants had to refrain from undergoing other procedures in the treatment area and were instructed to maintain the same weight, diet, and lifestyle throughout the study. Exclusion criteria included pregnancy, lactation, medical conditions contraindicating the application of an electromagnetic field, heart disorders, patients with cardiac pacemakers or internal defibrillators, unhealed wounds on the abdomen, the presence of metal implants, skin abnormalities on the treatment area, allergy/sensitivity to adhesive pads, noninvasive cosmetic procedures on the abdomen within 3 months of study commencement, and any prior invasive cosmetic surgery to the abdomen, such as liposuction.

Treatment

Treatment was conducted according to a standardized protocol. Two experienced operators (Y. N. and C. A.) performed all treatment sessions together. All patients received a single RF treatment (truSculpt[®] iD; Cutera Inc.), followed by an EMDS treatment (truSculpt[®] flex; Cutera Inc.) on their first visit. The subsequent EMDS treatments were scheduled twice a week, 2–3 days apart to complete six sessions. The RF device in this study utilizes a 2 MHz RF energy with real-time temperature control. Treatment is completely automated once the handpieces are in position. Four to six (depending on abdominal surface area) 40 cm² hands-free RF handpieces with 300 W output at 2 MHz were placed simultaneously over multiple localized fat pockets. All handpieces were applied using an adhesive return pad, which served as the grounding point to return the electric current to the console during the procedure. The temperature setting started at 43°C, was increased gradually to >45°C within 5 minutes and maintained for 10 minutes for deep volumetric heating of fat tissue.

EMDS treatment was performed using four pairs of handpieces applied to the abdominal region to directly target the rectus abdominis (RA), abdominal obliques, and transverse abdominis muscles. The device can be set to deliver the electrical currents according to three operational modes (*Prep*, *Tone*, or *Sculpt*), with the intensity being independently adjustable for each output channel. The *Prep* mode is used to create a twisting motion to warm up, stretch the muscles and slowly build a tolerance to muscle contractions. This mode is only necessary for nonactive patients (patients who barely exercise and whose muscles are weak). The *Tone* mode works to contract the muscle, hold it to the point of exhaustion, and then relax it to increase strength and enhance endurance. The *Sculpt* mode is applied to quickly, deeply, and sequentially contract the muscles to build muscle mass.

All patients underwent the first two EMDS treatments in *Tone* mode and the subsequent four treatments in *Sculpt* mode, with the intensity of contractions adjusted according to each participant's tolerability. None of the patients underwent the *Prep* mode because all of them were working individuals with an active lifestyle.

Study evaluation

Objective assessment

Quantitative evaluations included measurements of bodyweight, height, abdominal circumference (AC), abdominal skinfold thickness at baseline and at 1, 2, and 3 months after the final treatment. The AC was measured using a standard tape measure while standing with feet 25–30 cm apart and the weight evenly distributed. AC was taken on the horizontal plane, midway between the inferior margin of the last rib and the crest of the ilium. Abdominal skinfold thickness was measured 5 cm below the umbilicus using a 60 mm pinch caliper. To reduce variability, measurements for each participant were taken by the same investigator throughout the study.

Magnetic resonance imaging (MRI) study

To determine the effect on the abdominal muscles, MRI was done. Due to financial limitations, MRI scans were taken for only one random participant at baseline and at 1 month after the final treatment. MRI of the abdomen was performed using the 3-Tesla MRI (SIGNA Architect; GE Healthcare) with a phased array abdominal coil. Three-dimensional volume rendering of the RA muscle was also performed by using GE 3D Advantage Workstation v4.6 software (GE Healthcare) by an experienced musculoskeletal radiologist (N. L.).

Subjective assessment

Subjects evaluated the improvement of their overall abdominal contour compared to baseline photographs during all follow-up visits. Improvements were graded on a quartile scale as follows: slightly better (<25%), fair (25%–50%), good (51%–75%), and excellent (>75%).

Photographic documentation (Canon EOS REBEL T5i Digital SLR Camera; Canon Thailand) was obtained using identical camera settings and lighting at baseline and on all follow-up visits at 1, 2, and 3 months after the final treatment. All patients were photographed from five views in a standing position: front view, 45° right and left oblique views, and 90° right and left lateral views, with images taken from a 1-m distance.

Safety and tolerability assessments

Adverse effects and recovery times were recorded after each session and on all follow-up visits. Immediately after each treatment, study subjects were asked to rate the level of pain associated with the procedure using a 10-point pain scale with 0 = no pain and 10 = severe pain.

Statistical analyses

Descriptive analysis was used for the demographic data. Statistical analysis was done using repeated measure analysis of variance for parametric distribution and paired-samples *t*-test (normality) for comparing the means of two dependent groups. Calculations were performed using statistical software (IBM Corp. Released 2016. IBM SPSS Statistics for Windows, Version 24.0. Armonk: IBM Corp.), with a $p < 0.05$ indicating significance.

RESULTS

Twelve of 13 subjects received the full treatment protocol and were followed up to completion. One subject withdrew from the study due to reasons unrelated to the treatment. Table 1 demonstrates the demographic profile of the study participants.

A significant maximum reduction of mean AC (2.6 cm, 3.1% from baseline; $p < 0.001$) was observed at the 1-month follow-up (Figures 1–3). Skinfold thickness reduction of 4.6 mm (14%; $p = 0.01$) was also significant at 1 month after the final treatment. This reduction was maintained until the 2-month follow-up (Figure 4).

MRI study

One month after the final treatment session, an MRI study of a random patient (A 35-year-old female with a

TABLE 1 Demographic and baseline characteristics of the study subjects

Characteristics	RF + EMDS
Number of subjects	12
Age (years; mean ± SD)	38.4 ± 9.3
Gender	
Female	9 (75%)
Male	3 (25%)
Bodyweight (kg; mean ± SD)	66.5 ± 7.3
BMI (kg/m ² ; mean ± SD)	24.4 ± 0.5

Abbreviations: BMI, body mass index; EMDS, electrical multidirectional stimulation; RF, radiofrequency.

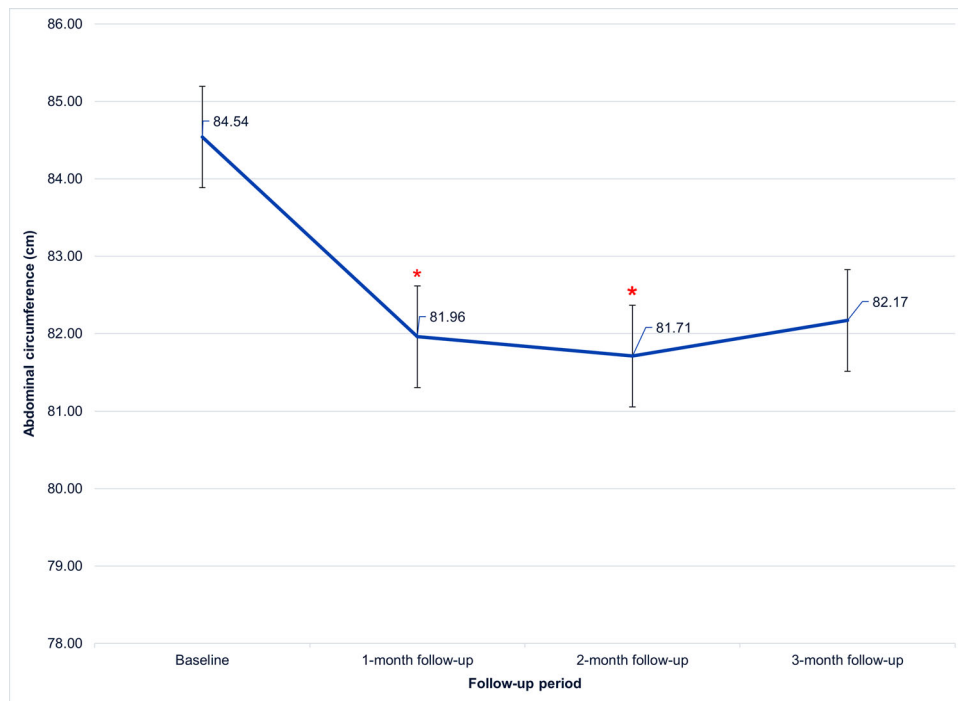


FIGURE 1 Mean abdominal circumference at baseline, and at 1, 2, and 3 months after the final treatment. * $p < 0.05$, compared to baseline.

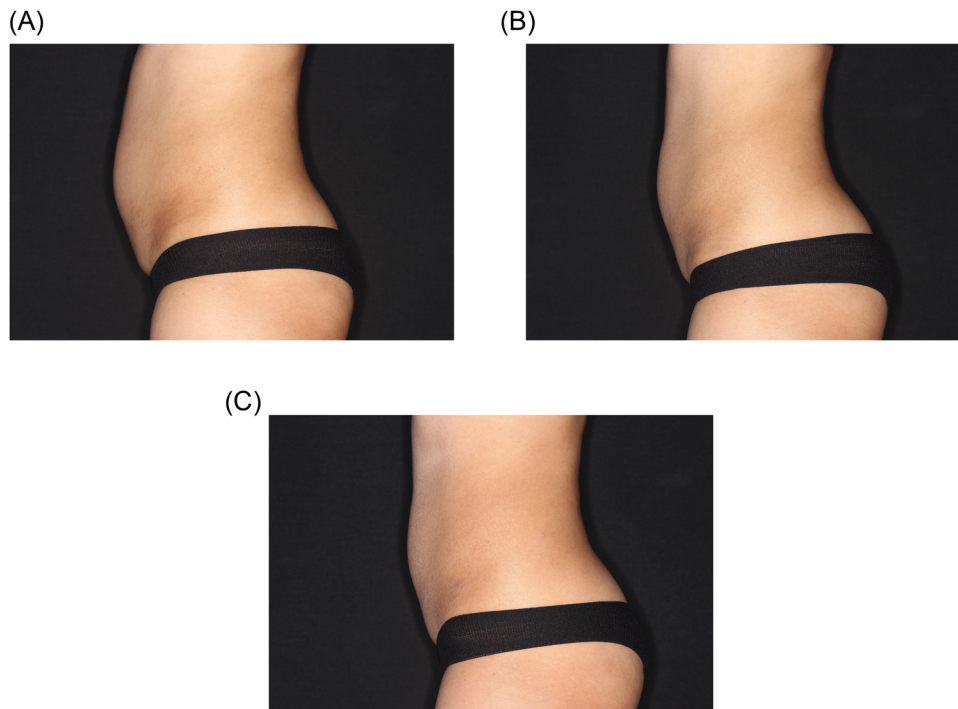


FIGURE 2 A 47-year-old female participant who received one monopolar 2 MHz RF treatment, combined with six EMDS treatment sessions for the abdomen. At baseline (A), at 1 month post final treatment (B), and at 3 months post final treatment (C). BMI: 23.6 kg/m², abdominal circumference: -3.5 cm (-4.2%), skinfold thickness: -6 mm (-27.8%), weight change: -0.6 kg (-1%). EMDS, electrical multidirectional stimulation; RF, radiofrequency.

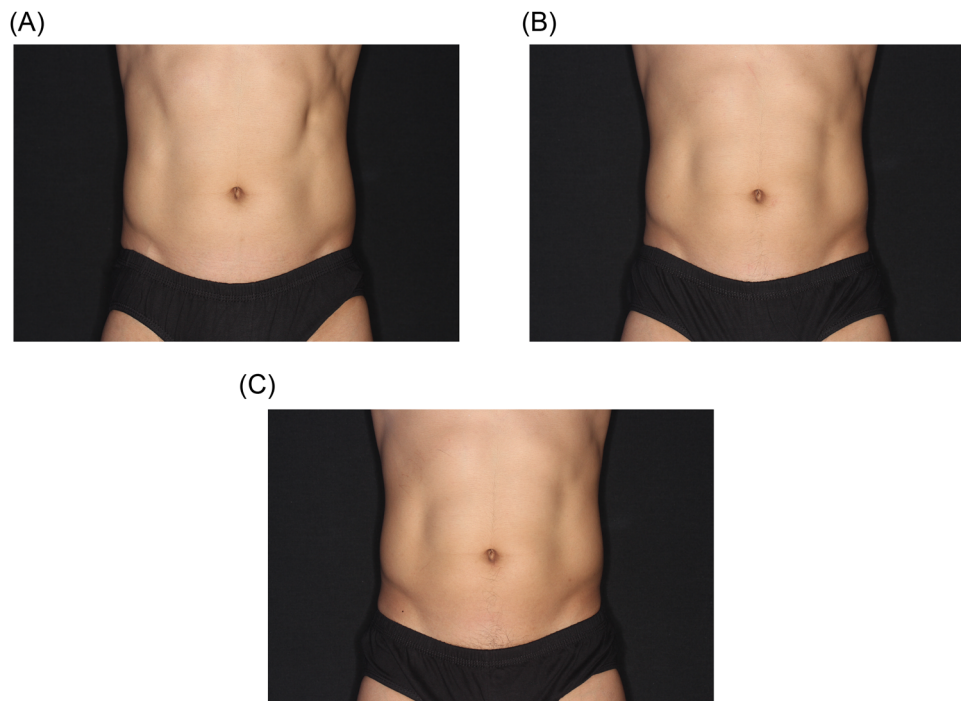


FIGURE 3 A 32-year-old male participant with persistent fat deposits on the abdomen despite regular physical exercise. At baseline (A), at 1 month after receiving one monopolar 2 MHz RF treatment, combined with six EMDS treatment sessions (B), and at 3 months post final treatment (C). BMI: 24.3 kg/m², abdominal circumference: -1.5 cm (-1.9%), skinfold thickness: -10 mm (-41.6%), weight change: +0.8 kg (+1.1%). EMDS, electrical multidirectional stimulation; RF, radiofrequency.

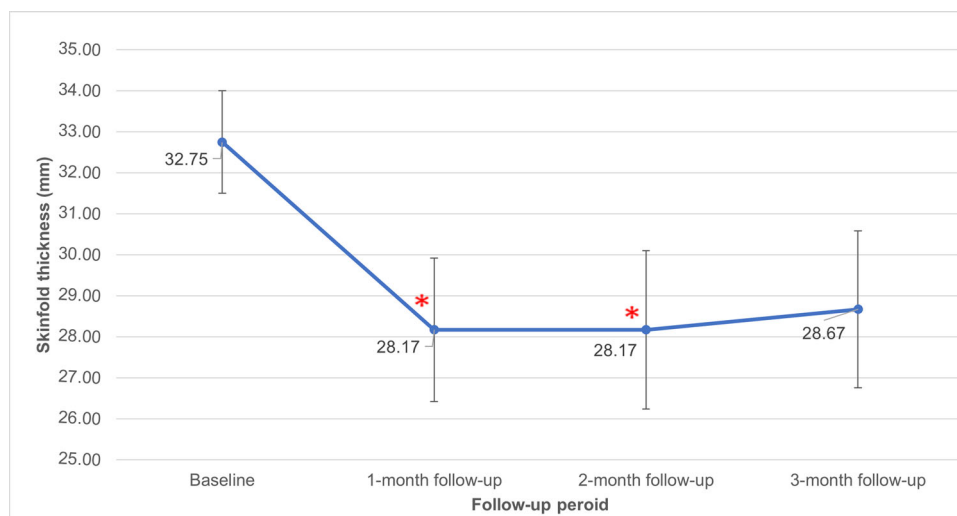


FIGURE 4 Mean fat thickness at baseline, and at 1, 2, and 3 months after the final treatment. * $p < 0.05$, compared to baseline.

BMI of 24.5 kg/m² and an AC of 86 cm) showed a 9.8% and 4.3% volume increase (an average of 7%) of the right and left RA muscles respectively, compared to baseline (Figure 5). The MRI study also demonstrated a 10% (2.8 mm) of subcutaneous fat thickness reduction (2.81 cm at baseline and 2.53 cm at 1-month follow-up), whereas the pinch caliper showed a 21% (8 mm) reduction of skinfold thickness (38 mm at baseline and 30 mm at 1-month follow-up) in this patient.

Subjective assessment

All participants assessed the improvement of their overall abdominal contour on each follow-up visit. The majority (76.9%) of participants reported fair to excellent improvement at the 1-month follow-up. At the 3-month follow-up, the proportion of participants reporting excellent (>75% quartile) improvement further increased to 30.8% from 7.7% at 1 month.

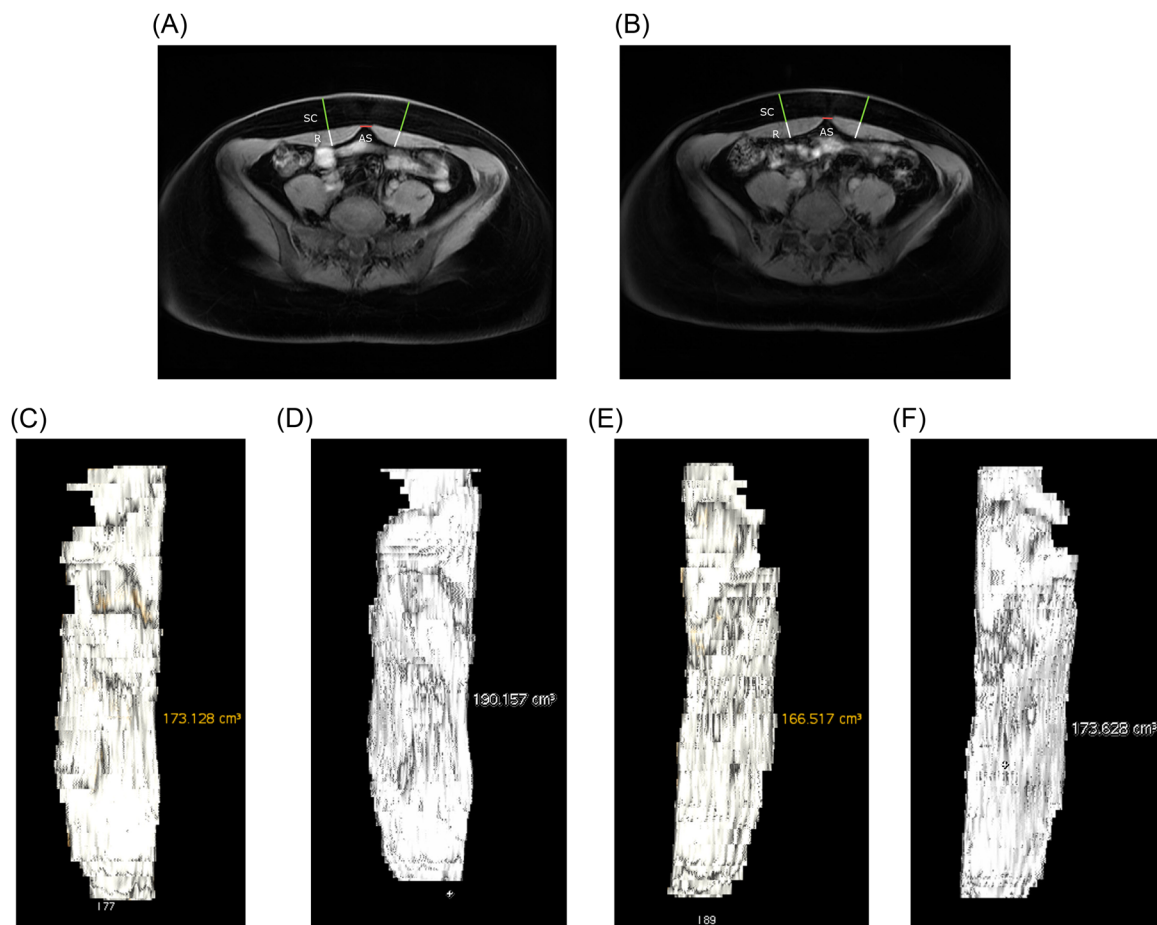


FIGURE 5 Axial MRI images of a random patient were selected at 3 cm below the umbilicus level. The thickness of rectus abdominis muscle (R), the thickness of subcutaneous fat tissue (SC), and abdominal separation width (AS) were measured. At baseline (A) and 1-month after the last (sixth) treatment session (B). Volume rendering images of the right rectus abdominis muscle, at baseline (C), and at 1 month after the last treatment (D). Volume rendering images of the left rectus abdominis muscle, at baseline (E) and at 1 month after the sixth treatment (F). Note muscle thickening, decreased subcutaneous fat thickness, decreased width of abdominal separation, and increased muscle volume of right (9.8%) and left (4.3%) rectus abdominis. MRI, magnetic resonance imaging.

All participants reported improvement in muscle definition beginning at 1-month and maintained up to the 3-month follow-up visit.

Safety and tolerability assessment

All treatments were well-tolerated. Participants reported the EMDS treatment to be painless, whereas the average pain score for the RF treatment was 0.3 (range: 0–3) on a 10-point scale. No serious immediate or delayed adverse effects were reported during the treatment and throughout the follow-up period. The most common immediate skin reaction to monopolar RF was mild to moderate erythema observed in all subjects which lasted for approximately 1 hour. Five of 13 subjects (38.5%) also experienced transient dysesthesia following the EMDS treatments which completely resolved after 2–3 hours.

DISCUSSION

The advent of noninvasive technologies has caused a paradigm shift in the field of body sculpting which was previously limited to surgical interventions. Spurred by increasing demand for simple and effective in-office procedures, the field has seen the rapid development of new energy-based contouring devices. Compared to surgical interventions, these noninvasive methods offer an improved safety profile, minimal recovery time as well as reduced cost. When used appropriately, noninvasive devices demonstrate significant clinical efficacy. However, these technologies also exhibit certain limitations and are generally reserved for patients with low BMI and limited areas of adiposity.^{2,3}

Our previous investigation using EMDS monotherapy for patients with normal range BMI (18.5–22.9 kg/m²) has evidenced the efficacy of this modality for body contouring. After a series of six EMDS sessions spaced 2–3 days

apart, participants exhibited a significant decrease in both AC and skinfold thickness at 1 month after the final treatment.¹⁵ EMDS works by generating electrical impulses that specifically target motor nerves causing depolarization and thus muscle contraction. Similar to repeated muscular contractions during high-intensity exercise, the anticipated effect from this modality is muscular hypertrophy with a concomitant reduction of fat.^{4,6,16}

For noninvasive modalities that target skeletal muscles, however, previous studies have demonstrated less significant changes in patients who are overweight with higher BMI compared to thinner patients. This may be due to the greater interspacing adipose tissue that impede the conduction of currents from the handpiece. Since these modalities act by inducing a lipolytic reaction in fat cells adjacent to contracting muscles, the decreased intensity of muscle contraction would cause a smaller reduction of fat.¹⁷⁻¹⁹ With this in mind, we added a single monopolar RF treatment before the series of six EMDS treatments for this study population with overweight-range BMI. The result is a significant 2.6 cm reduction of mean AC (3.1% from baseline; $p < 0.001$) at the 1-month follow-up and a significant skinfold thickness reduction of 4.6 mm (14%; $p = 0.032$) one month after the fifth treatment, with results maintained up to 2 months.

RF devices use RF energy waves to cause preferential volumetric heating of the mid-to-deep dermis or subcutaneous tissue. The thermal injury causes contracture and denaturation of collagen fibers in the dermis and induces adipocyte apoptosis in the subcutaneous layer.^{20,21} As such, it can decrease laxity, reduce cellulite, and improve body contour.²²⁻²⁴ In monopolar devices, RF waves are passed from a single electrode through the skin and subcutaneous tissue toward a return pad, whereas in bipolar or multipolar RF devices, the energy passes between electrodes within the same handpiece.²²⁻²⁵ Because of this configuration, energy from a monopolar device is able to penetrate deeper into tissues.^{3,26,27}

A recent trial evaluated the effect of the same monopolar 2 MHz RF device used in this study for adipose tissue reduction in the abdomen and flanks. Using a single 15-minute RF treatment to the target areas, a significant fat thickness reduction was achieved (24% in the abdomen, 22% in the flanks) at 12 weeks via ultrasound measurement.³ This is congruent with the findings of this study, wherein a reduction in both AC and skinfold thickness up to 2 months was seen after a single RF session followed by six EMDS treatments. Whether the combined effect of the two modalities is synergistic and impacts the longevity of the outcome is beyond the scope of this study and will have to be explored further.

The goal of combining RF and EMDS is to target the different layers that influence the body's contour. While our primary endpoint was to evaluate the effect of these devices on fat reduction in overweight participants,

the mechanism of action of EMDS would also cause a corresponding effect on muscle. Indeed, MRI scans of a representative participant in this study showed a 7% average volume increase of the RA muscle at the 1-month follow-up compared to baseline. Due to financial limitations, however, this effect of muscular hypertrophy is only demonstrated for a single participant in this study and should therefore be interpreted with caution.

Similar to EMDS, another device that targets skeletal muscles for noninvasive contouring utilizes high-intensity focused electromagnetic (HIFEM) technology. In contrast to the electrical stimulus that EMDS provides, HIFEM utilizes pulsating magnetic fields to induce depolarization leading to muscle contraction.^{16,28-31} Studies using HIFEM have reported significant muscular changes, causing increased thickness and decreased separation of the RA muscles.^{8,17-19,32} In addition, it has also been shown to cause a 15.7% average reduction in subcutaneous layer thickness following a series of four 30-minute treatment sessions.⁸

The recent surge of technological innovation in the field of body contouring has seen the development of various noninvasive devices that can help improve the body's appearance. In addition to RF, EMDS, and HIFEM machines, other technologies such as cryolipolysis, 1,064-nm diode lasers, and ultrasound have also been developed as an alternative to surgical body contouring.² Similar to RF, these modalities all induce adipocyte apoptosis in the subcutaneous tissue, however, the mechanism by which this is achieved all differ. Cryolipolysis employs controlled cooling to specially target areas of adipose tissue. This cold-induced damage triggers panniculitis leading to apoptosis without affecting the surrounding structures.^{2,33} In contrast, the 1,060-nm diode laser utilizes prolonged selective thermal heating of adipocytes to reach temperatures between 42°C and 47°C causing cell membrane disruption.³⁴ Ultrasound devices, whether high frequency or low frequency use acoustic energy to achieve fat reduction.² High-frequency ultrasound causes selective adipocyte destruction via two mechanisms: first is through vibratory and shear forces that mechanically disrupt the adipocyte plasma membrane, and second is via rapid increase of focal subcutaneous tissue temperature to 55°C, resulting in coagulative necrosis and adipocyte death.^{2,35} On the other hand, low-frequency ultrasound emits focal ultrasound waves to mechanically and nonthermally disrupt subcutaneous fat cells.³⁶

In terms of fat reduction, however, not a single noninvasive modality is considered the gold standard, especially in comparison to surgical interventions such as liposuction.³ Similar to this study, other investigators have delved into the use of combined treatment regimens to be able to achieve better outcomes. These combinations include cryolipolysis and shockwaves,^{37,38} low-level laser therapy and vibration therapy,²¹ as well as focused ultrasound and RF.²⁰ While combined modalities may

offer additive or even synergistic effects, individualizing treatments with combination therapies will have to be balanced with affordability, convenience, and safety for each patient as maintenance sessions are recommended to obtain longer lasting results.

The findings of our study are limited by the following factors: first, the gender distribution of the participants was not in equilibrium. As males and females exhibit differential adiposity, unequal distribution may have affected the results. Second, the proportion of effect attributable to each modality cannot be ascertained from this study's design. Thus, recommendations for future studies include a study population with equal gender distribution and comparator groups to assess the magnitude of the effect of combined RF with EMDS compared to both RF and EMDS treatments alone.

CONCLUSIONS

The combination of RF and EMDS treatments for body contouring is safe and effective, yielding significant reductions in both AC and skinfold thickness and as well as improving abdominal muscle definition in patients with overweight-range BMI, causing only minimal and transient adverse effects.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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