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Combination non-invasive radiofrequency and electrical muscle stimulation: A synergistic combination for body contouring

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Abstract

Introduction: Patients desiring noninvasive body contouring increasing require a more comprehensive approach to soft tissue laxity, muscle, and adipose hypertrophy. Previous devices have typically focused on only adipose reduction, without impact on muscle or skin laxity. This study describes the first use of noninvasive bipolar radiofrequency in combination with electromagnetic muscle stimulation.

Methods: This study was an IRB-approved study conducted at four sites (TN, TX, PA, NC). In all, 38 patients completed the three-treatment regimen of combined non-invasive bipolar RF and EMS. Efficacy of the Transform (InMode, Lake Forest, CA) treatment was assessed by numerous outcomes including sequential caliper measurements, circumference measurements, comfort during treatment, subject satisfaction, ultrasound measurements, blinded pictures evaluation, and histology.

Results: The combination of non-invasive bipolar RF with EMS was found to be safe and efficacious. The three-treatment regimen was statistically efficacious as it related to (1) subject satisfaction, (2) 1 mm ultrasound, (3) 2 mm ultrasound, (4) average of 1 and 2 mm ultrasound, (5) caliper 1 measurements, (6) caliper 2 measurements, (7) average of caliper 1 and 2 measurements, (8) subject comfort, (9) widest circumference measure, (10) 2-inches above circumference measure, (11) 2-inches below circumference measure, (12) average circumference measure, and finally, (13) blinded evaluator photograph agreement.

Conclusion: The combination of noninvasive bipolar radiofrequency and electrical muscle stimulation is a safe and effective method for treatment of skin laxity, adipose hypertrophy, and muscle.

KEYWORDS
bipolar radiofrequency, electric muscle stimulation, noninvasive bodycontouring, radiofrequency

1 | INTRODUCTION

The ideal aesthetic components of the abdomen and flank soft tissue envelope include taught or contoured skin, minimal adiposity, and well-defined underlaying muscle.[1] Non-invasive body contouring has traditionally focused on adipose reduction with modest results and little to no secondary impact on skin laxity or muscle hypertrophy. Numerous noninvasive technologies have been used to improve lipodystrophy, with the most well-known example including cryolipolysis (CoolSculpting, Allergan, Dublin, IE).[1–4] While studies showed modest improvements in adiposity, there have been issues with secondary skin laxity and the poorly understood phenomenon of paradoxical adipose hyperplasia.[5]

In the mid-2000s, electrical muscle stimulation (EMS) gained popularity within aesthetics for muscle hypertrophy, despite its use in rehabilitation many years prior.[6–8] Imaging studies demonstrated improvement in muscle hypertrophy.[9,10] However, the aesthetic utility of EMS devices fell short due to unaddressed lipodystrophy of many patients.[6,11] The rising demand for more comprehensive non-invasive body contouring solutions, has recently been met with synergistic combinations of technology that address skin laxity, adipose hypertrophy, and muscle tone. Radiofrequency (RF) technology in combination with EMS is of particular interest. RF is a familiar technology in most fields of medicine. The use of electrical current to preferentially generate heat through Ohm's law (V = IR) in target tissues such as the dermis and subcutaneous adipose tissue has been successfully used for aesthetic purposes such as fat removal, skin tightening, or cellulite reduction.[12–16] Delivering RF energy in a bipolar mechanism with precise real-time thermal control significantly advances the use of radiofrequency over the past years. The ability to volumetrically heat tissues using radiofrequency is a natural combination with EMS for two reasons; (1) heat acclimation (i.e., pre-heating muscle) allows for a more efficient contraction and faster recovery and (2) simultaneous intensive muscle workload increases lipolysis.[17,18]

The purpose of this study was to prospectively evaluate the first non-invasive body contouring platform (Transform, InMode Lake Forest, CA) to use alternating and independently adjustable bipolar RF with EMS.

2 | METHODS

This study was an IRB-approved study conducted at four sites (TN, TX, PA, NC). In all, 38 patients completed the three-treatment regimen of combined non-invasive bipolar RF and EMS. All patients independently desired non-invasive body contouring.

There were 40 females and 5 males enrolled. Average age was 48 (STD) and average weight 150lbs (STD 21.1), respectively, with average BMI of 24.4. For all outcomes, only subjects that completed all visits at all time points were utilized for analysis (n = 38). The effectiveness endpoints were calculated based on those patients whose weight remained stable during the study period. A subject was defined as having maintained her/his weight during the treatment period if it remained within ±3% (inclusive) of baseline for the respective period. For all outcomes, only subjects that completed all visits at all time points were utilized for analysis (n = 38). Efficacy of the Transform (InMode, Lake Forest, CA) treatment was assessed across 13 outcomes: (1) caliper measurement 1, (2) caliper measurement 2, (3) average caliper measurement (caliper 1 and 2), (4) widest circumference measurement, (5) 2 inches above circumference measurement, (6) 2 inches below circumference measurement, (7) average circumference measurement, (8) subject comfort during the treatment, (9) subject satisfaction, (10) ultrasound #1/mm measurement, (11) ultrasound #2/mm measurement, and (12) average ultrasound (#1/mm and #2 mm) measurement, (13) photographs blinded evaluation. Data were collected on the outcomes either once, twice, or three times. Thus, depending on the outcome, either a one-sample t-test, paired samples t-test, or within-subjects repeated measures ANOVA was conducted.

3 | RESULTS

3.1 | Subject satisfaction (3 months post-treatment)

Subject satisfaction at 3 months post-treatment was measured on a scale which ranged from −2 (very disappointed) to 2 (very satisfied). Therefore, a score of 0, indicating neutral, was utilized as the comparison point for the sample. The sample mean was 0.45 (STD 1.06), and the one sample t-test against a hypothesized mean (0) was statistically significant, $t(37) = 2.61$, $p = 0.01$. Thus, the study's patients were significantly more satisfied 3 months after the treatment compared with a hypothesized neutral satisfaction level.

3.2 | Ultrasound measurement

Three outcome variables were measured at two time points (first treatment and 3 months post-treatment)—the 2 ultrasound measurements, along with the averaged value of those two measurements. All three paired samples t-tests were statistically

TABLE 1 Ultrasound measurements at 1 and 3 months post-treatment

Outcome	Treatment mean (SD)	3M mean (SD)	Mean diff (SD)	t-value	p-value
1 mm ultrasound	28.05 (28.59)	24.98 (28.88)	3.07 (3.05)	6.19	<0.001
2 mm ultrasound	28.14 (28.39)	24.75 (28.38)	3.39 (4.15)	5.04	<0.001
Avg ultrasound	28.00 (28.46)	24.87 (28.52)	3.13 (2.55)	7.56	<0.001

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significant, indicating a statistical improvement (lowering of the ultrasound measurements) for all three variables. The following table and graph display the relevant statistical information (Table 1, Graph 1).

3.3 | Caliper measurements

A decrease in all caliper measurements would indicate an improvement across time at all 3 measurements. The first outcome variable measured three times was caliper 1. The omnibus test was statistically significant, $F_{(2, 70)} = 9.70$, $p < 0.001$; the effect was linear, with each measurement mean decreasing from baseline (m = 22.43) to 1-month follow-up (m = 20.23) to 3-month follow-up (m = 19.5). Consulting the pairwise comparisons demonstrates that baseline differs from 1-month and 3-month measurements; however, 1-month and 3-month do not differ statistically from one another, indicating that the caliper 1 measurement improves by 1-month and stays improved at 3-months, though the 3-month measure is qualitatively lower than the 1-month measure.

The second outcome variable measured three times was caliper 2. The omnibus test was statistically significant, $F_{(2, 70)} = 7.91$, $p < 0.003$; the effect was linear, with each measurement mean decreasing from baseline (m = 22.42) to 1-month follow-up (m = 20.74) to 3-month follow-up (m = 19.58). Consulting the pairwise comparisons demonstrates that baseline differs from 1-month and 3-month measurements; however, 1-month and 3-month do not differ statistically from one another, indicating that the caliper 1 measurement improves by 1-month and stays improved at 3-months, though the 3-month measure is qualitatively lower than the 1-month measure.

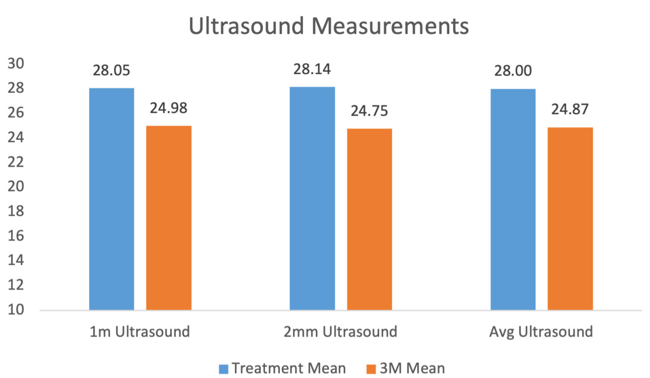
The third outcome variable measured three times was the average of the 2 caliper measurements. The omnibus test was statistically significant, $F_{(2, 70)} = 9.22$, $p < 0.001$; the effect was linear, with each measurement mean decreasing from baseline (m = 22.42) to 1-month follow-up (m = 20.49) to 3-month follow-up (m = 19.54). Consulting the pairwise comparisons demonstrates that baseline differs from 1-month and 3-month measurements; however, 1-month and 3-month do not differ statistically from one another, indicating that the caliper measurement improves by 1-month and stays improved at 3-months, though the 3-month measure is qualitatively lower than the 1-month measure. The following graph displays the mean values across the 3 time points for the 3 caliper outcome variables (Graph 2).

A decrease in all circumference measurements would indicate an improvement across time. All of the within-subjects omnibus ANOVA tests were statistically significant, indicating improvement; (1) Widest $F_{(2, 72)} = 8.30$, $p = 0.001$, (2) 2-inches above $F_{(2, 72)} = 8.65$, $p = 0.001$, (3) 2-inches below $F_{(2, 72)} = 6.56$, $p = 0.01$, (4) average $F_{(2, 72)} = 12.32$, $p < 0.001$. That is, all of the circumference measurements (widest, 2-inch above, 2-inch below, and average) differed from treatment 1, 1-month post-treatment, or 3-month post-treatment. Consulting the pairwise comparisons demonstrates that baseline differs from 1-month and 3-month measurements; however, 1-month and 3-month do not differ statistically from one another, indicating that the average circumference measurement improves by 1-month and stays improved at 3-months, though the 3-month measure is qualitatively lower than the 1-month The following graph displays the mean values of the circumference measurements at treatment 1, 1-month post-treatment, and 3-months post-treatment (Graph 3).

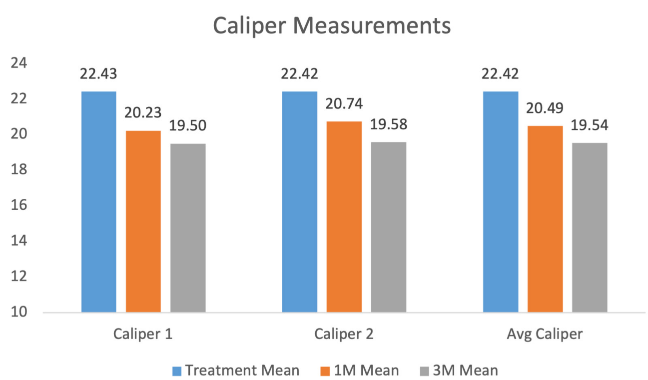
3.4 | Subject comfort

Subject comfort (−2 = painful, 2 = very comfortable) was evaluated in two ways—comparing each of the 3 measurements to a hypothesized value of 0 (indifferent) and comparing the three time point measurements to one another. The three one sample *t*-tests were statistically significant. Meaning, the patients perceived each of the 3 treatments as generally more comfortable than neutral. The following table displays the mean values and the relevant statistical information (Table 2).

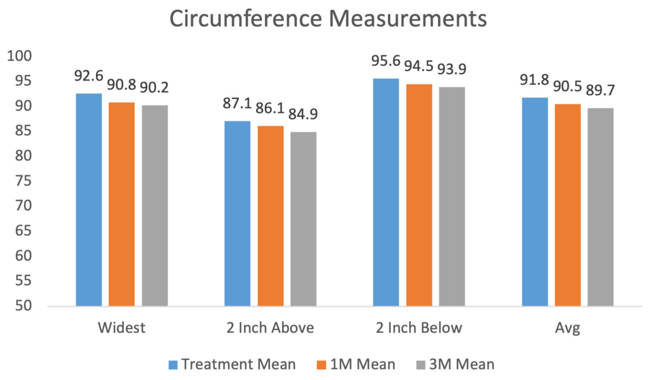
Additionally, the 3 subject comfort values were compared to one another to determine there was no change in comfort



GRAPH 1 Ultrasound measurements at 1 and 3 months post-treatment



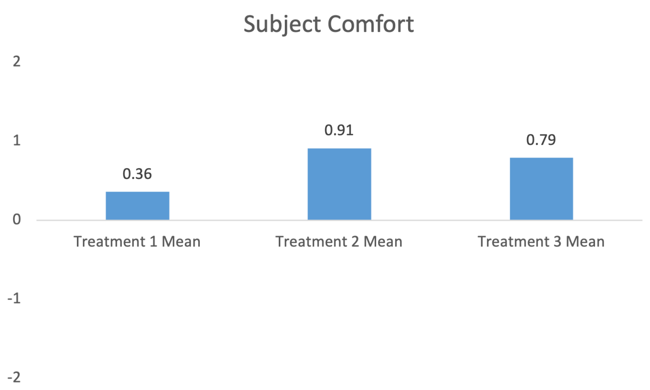
GRAPH 2 Caliper measurements at 1 and 3 months post-treatment



GRAPH 3 Circumference measurements

TABLE 2 Subject comfort

Outcome	Treatment mean (SD)	*t*-value	*p*-value
Subject comfort treatment 1	0.38 (1.05)	2.13	0.04
Subject comfort treatment 2	0.89 (0.84)	6.44	<0.001
Subject comfort treatment 3	0.78 (0.96)	4.86	<0.001



GRAPH 4 Subject comfort

across time. The scores improved at each measurement, and the difference was statistically significant and linear, ($F_{(2, 64)} = 5.79$, $p = 0.02$). This indicates that patients did not change their evaluations that each treatment was generally comfortable; however, when considering the pairwise comparisons, each treatment was significantly less painful than the first treatment. In other words, each treatment was comfortable, and treatments 2 and 3 were statistically more comfortable than treatment 1. The following graph displays the mean values of the subject comfort scores at each treatment (Graph 4).

3.5 | Photographs blinded evaluations

This was assessed using blinded evaluators, which included medical professionals not familiar with the device or study. Three blinded evaluators received training and were evaluated to be competent before being able to perform assessment of images for the study. They received instructions to evaluate overall changes/improvement and carried out their assessments separately. Each evaluator received 2 files: PowerPoint presentation with before (B) and after (A) images (marked with either letter A or B) randomized in a different order and an excel file with subjects' codes to document their assessment. The aim was to identify the before image (A or B). It was hypothesized that 2 of the 3 blind evaluators would agree on overall improvement in body appearance by picking the correct before images based on photographs for at least 70% of patients.

In the study, the percent agreement was 91%. Moreover, the 91% was statistically significantly higher than the hypothesized value of 70% ($z = 2.63$, $p < 0.01$), indicating that for this outcome variable, efficacy significantly exceeded the baseline standard of success.

3.6 | Histology

Four consented subjects underwent biopsies of the treated areas at baseline and at the 3 month follow-up visit. Histological sections were stained using, H&E, elastin, and Masson's trichrome, and all samples demonstrated an increase in dermal thickness, and some demonstrated increase in collagen fiber thickness. No dermal scar formation was noted.

These results demonstrate that the combination of non-invasive bipolar RF with EMS was efficacious as it related to a bevy of outcome variables. That is, either across time or compared to a hypothesized value, the three-treatment regimen was statistically efficacious as it related to (1) subject satisfaction, (2) 1 mm ultrasound, (3) 2 mm ultrasound, (4) average of 1 and 2 mm ultrasound, (5) caliper 1 measurements, (6) caliper two measurements, (7) average of caliper 1 and 2 measurements, (8) widest circumference measure, (9) 2-inches above circumference measure, (10) 2-inches below circumference measure, (11) average circumference measure, (12) subject comfort and finally, (13) blinded evaluator photograph agreement.

4 | DISCUSSION

This study demonstrates that the combination of EMS and bipolar radiofrequency is a synergistic and effective non-invasive body contouring treatment. To the best of our knowledge, this is the first prospective study to evaluate combined bipolar RF and EMS for non-invasive body contouring. While this study did demonstrate the safety and efficacy of the Transform (InMode Lake Forest, CA) device across the parameters measured, there were a number of limitations. Despite the adequate sample size ($n = 38$) for statistical analysis, a larger sample size would have allowed for a higher power study. The use of control groups (only RF or EMS) would have also elucidated the contribution of each individual technology independently and

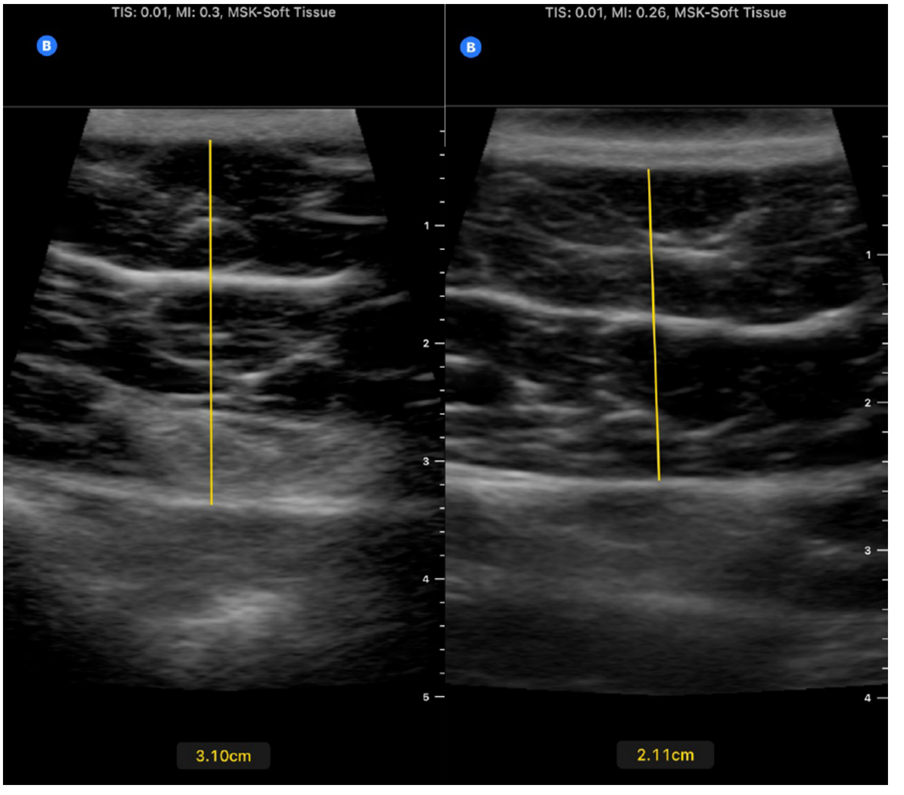


FIGURE 1 Ultrasound images before and after Transform (InMode, Lake Forest, CA) treatment Before and after ultrasound measurements

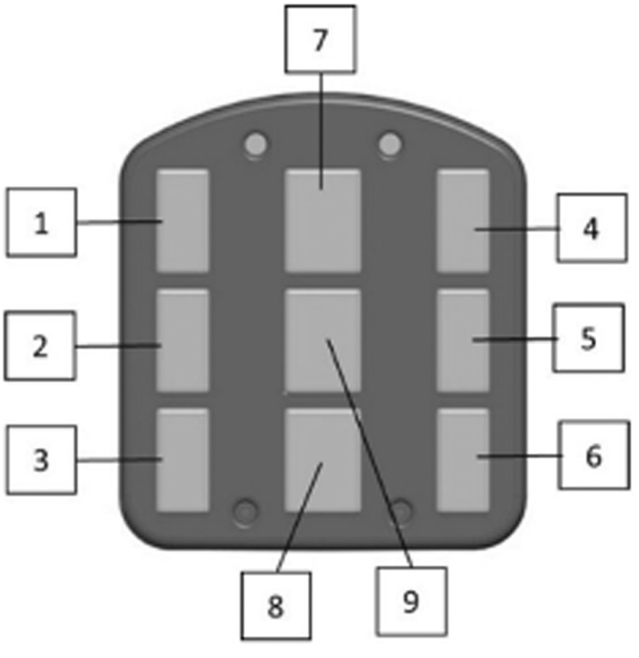


FIGURE 2 Electrode configuration (Transform, InMode, Lake Forest, CA)

quantified the synergistic effect of the combination treatment. The use of ultrasound (Figure 1), as well as caliper and circumferential measurements, inevitably leads to user variability/error. Optimally, the use of more objective imaging, such as CT/MRI, would have been preferred to objectively quantify fat vs. muscle components of the subject's treatment.

The use of radiofrequency in both minimally invasive and noninvasive aesthetic treatments has grown rapidly over the past 20 years. Initial challenges with early aesthetic radiofrequency devices included the ability to precisely control temperature while volumetrically heating target tissue. The noninvasive bipolar RF device (Transform, InMode, Lake Forest, CA) in this study successfully addresses these limitations. (Figure 2) The electrode configuration is bipolar in nature, where the depth of penetration of RF energy is half the distance between electrodes providing a deep and volumetric thermal treatment. As seen in Figure 2, RF energy is delivered between positive electrodes #1–6 and negative electrodes #7–9. Each electrode has an embedded temperature sensor providing continuous and consistent thermal energy within the preset parameters. Numerous studies have shown that heating dermal tissue to 42°C will trigger a healing cascade that leads to neocollagenesis and elastin formation.[19] In animal studies, after 10 min of exposure to temperatures of 39–43°C, the amount of collagen increased from an average of 9% before therapy to 25.9% after 3 month follow-up compared with no change in untreated areas.[20,21] Other studies have similarly shown through electron microscopy that collagen fibrils had a greater diameter post-RF treatment.[22] The balance between temperatures that trigger a nonablative wound healing response to remodel collagen as opposed to ablating collagen is relatively narrow.[12] RF has not only been proven effective for skin tightening, but it has also been studied and proven effective in diminishing adipocytes. Studies investigating the use of RF for subcutaneous fat reduction have shown reduction ranging from 4.9% to 29.0%, with a weighted average of 14.58%.[23–25] The relationship of adipocyte apoptosis follows a time–temperature Arrhenius

FIGURE 3 (A, B). Before and after results from noninvasive bipolar RF with EMS (Transform, InMode, Lake Forest, CA)

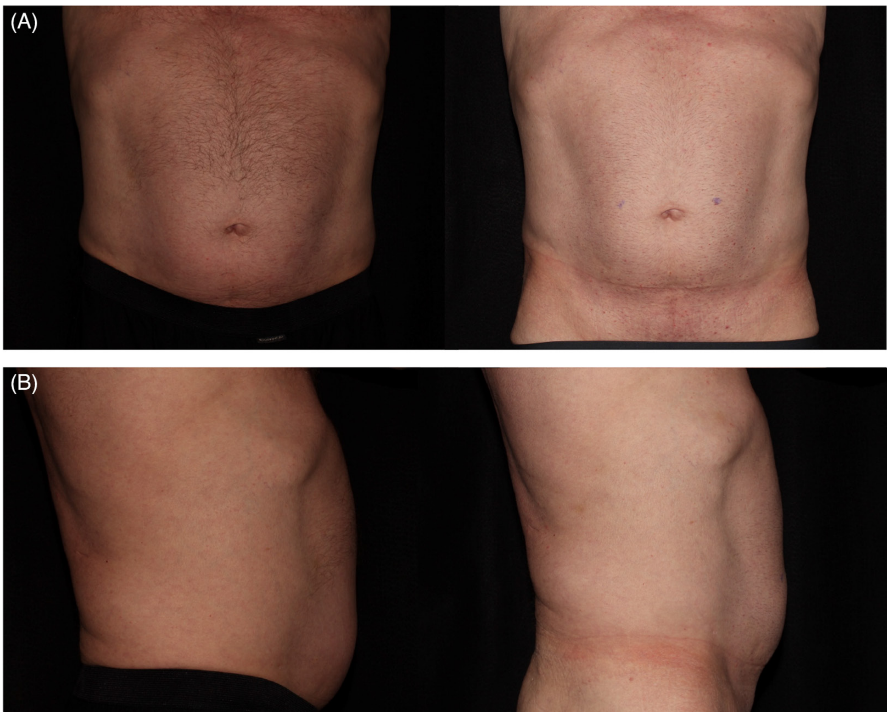


FIGURE 4 (A, B). Before and after results from noninvasive bipolar RF with EMS (Transform, InMode, Lake Forest CA)

equation where it is more effective to treat tissue at lower temperatures for longer periods of time rather than higher temperatures for shorter periods of time. It has been shown that with a minimal 15-min exposure time, apoptosis can be initiated with temperatures of 42°C and exposure time to trigger apoptosis decreases as the temperature rises.[21] Apoptosis is achieved with temperatures of up to 45°C whereas higher temperatures may result in immediate cell death or necrosis.[21]

Electrical muscle stimulation combined with RF provides multiplicative benefits compared with EMS treatment on its own. It has been well documented that natural and induced heat acclimatization improves muscle contractility as well as recovery.[26,27] EMS functions to produce supra-physiologic muscle contractions through direct stimulation of neuromuscular pathways. The electric stimulus induces electric currents through motor nerves leading to propagation of muscle contraction, leading to hypertrophy/hyperplasia. This effect not only improves the tone and volume of muscle but also impacts lipolysis due to local energy consumption leading to breakdown of triglycerides stored in fat cells to glycerol and free fatty acids.[21] As shown in prior studies, the combination of heat and mechanical stimulation of muscle induces significantly higher expression of heat shock proteins as well a myosatellite cells that ultimately lead to muscle hypertrophy and myofiber development.[28,29] On its own, EMS has been shown to produce average subcutaneous fat reduction of 19.6% (17.5–23.3%),[30,31] average muscle thickening of 15.1% (14.8–15.4%)[30,31] and average reduction in abdominal separation of 9.95%.[30,31]

In combination, EMS and RF provide a synergistic noninvasive body contouring solution that addresses muscle, adipose tissue, and soft tissue laxity (Figures 3 and 4). Prior studies demonstrate that the synergy of RF and EMS yields >50% higher improvement in subcutaneous fat reduction, muscle thickening, and abdominal muscle separation.[24] The addition of bipolar radiofrequency with tight temperature control allows for the delivery of volumetric heat while EMS provides supraphysiologic muscle contraction leading to muscle hypertrophy and augmentation of lipolysis.

5 | CONCLUSION

This preliminary study demonstrates combination of bipolar temperature regulated RF with EMS is safe and effective for muscle hypertrophy as well as fat reduction and soft tissue contraction. This study is ongoing to continue to investigate the outcomes of this combination technology.

AUTHOR CONTRIBUTIONS

ED performed manuscript preparation and data analysis. SC, LB, GB, MG, RR performed and designed research study.

ETHICAL APPROVAL

All procedures performed in this study involving human participants were IRB approved and in accordance with the Helsinki declaration for ethical standards. Enrolled patients provided written informed consent in accordance with scientific and ethical study standards and principles. All equiptment used are FDA cleared and intended for clinical use.

DATA AVAILABILITY STATEMENT

Data that supports these findings beyond what is found in this manuscript is available on request from the individual study sites upon reasonable request.

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