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A 12-Week, Prospective, Non-Comparative, Non-Randomized Study of Magnetic Muscle Stimulation for Improvement of Body Satisfaction With the Abdomen and Buttocks

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Background and Objective: Magnetic muscle stimulation (MMS) is a relatively new energy-based technology that provides a non-invasive option for body contouring through stimulation and toning of underlying skeletal muscles. This study was conducted to examine the safety, efficacy, and body satisfaction scores of MMS using a CoolToneTM prototype for the aesthetic improvement of abdominal and buttock contour.

Study Design/Materials and Methods: This was a prospective, non-comparative, non-randomized, 12-week, multicenter study. Male and female participants aged 22-65 years received 4 MMS treatment sessions to the abdomen and/or buttocks. Body Satisfaction Questionnaire (BSQ) scores for abdomen and/or buttocks were assessed at baseline, immediately post final treatment, at 4 weeks (primary endpoint), and 12 weeks post final treatment. Subject-rated Global Aesthetic Improvement Scale (SGAIS) was assessed at 4 weeks post final treatment (secondary endpoint), and 12 weeks post final treatment. Additional efficacy assessment included abdominal circumference obtained by 3D imaging at baseline, immediately post final treatment, and at 4 and 12 weeks post final treatment. A Subject Experience Questionnaire (SEQ) was used to assess treatment satisfaction and perspectives at 4 weeks and 12 weeks post final treatment. Adverse events (AEs) were monitored throughout the study.

Results: A total of 110 participants were recruited, who were 75% female, 80% Caucasian (mostly non-Hispanic), average age of 39.5 years (range 22–59) with an average body mass index (BMI) of 23.3 kg/m2 (range 18–29.9). At the 4-week post final treatment visit, the average BSQ score for participants receiving abdominal treatment ($n = 93$) was significantly improved with a 5.1 average increase in total score from baseline (possible score range 10–50) and by a 5.5 average increase from baseline for participants receiving buttocks treatment ($n = 32$) ($p < 0.05$). At 4 weeks post final treatment, the proportion of participants with SGAIS scores >"Improved" was 68.1% for participants receiving treatment of the abdomen ($n = 94$), and 81.8% for those receiving buttocks treatment ($n = 33$). The mean total decrease from baseline in waist circumference was significant at all time points. At the 12-week post final treatment visit, SEQ data revealed that a majority of participants were "Satisfied" or "Very Satisfied" with overall treatment results and "Agreed" or "Strongly Agreed" that they were motivated to maintain results either by working out or by additional treatment. A total of 6 AEs related to the device and/or treatment were reported, which resolved spontaneously during the study.

Conclusion: Treatment of the abdomen and/or buttocks with MMS was well-tolerated and demonstrated significant improvement in aesthetic appearance through the 12-week post final treatment study duration. As a stand-alone treatment, MMS expands the range of options for individualized treatment planning for patients seeking abdominal and/or

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gluteal muscle toning.

Key words: Non-invasive body contouring; Magnetic muscle stimulation; MMS, Abdominal muscle toning; Gluteal muscle toning

INTRODUCTION

Non-invasive techniques for improvement of body contour have become increasingly popular in aesthetic medicine, as they can be customized to individual patient treatment goals and involve minimal-to-no downtime. While many non-invasive procedures target fat reduction such as cryolipolysis, radiofrequency, thermal laser therapy, and high-intensity focused ultrasound, they do not address the underlying skeletal muscle definition [1,2]. Interestingly, this gap in treatment offerings has seemingly prompted advancements in liposuction, a gold standard in body contouring procedures, to include selective fat removal and grafting to create the abdominal muscle definition that patients are increasingly seeking [3]. Likewise, a desire for a sculpted and lifted buttock contour is also reflected by a rising trend in buttock augmentation procedures (fat grafting, implants, and lifts) which has increased by 77% in the United States between 2014 and 2018 [4].

Electromagnetic muscle stimulation is an energy-based treatment modality that has been used for some time as a safe and effective treatment for musculoskeletal and urogynecological disorders as well as to augment resistance training [5–7]. More recently, magnetic muscle stimulation (MMS) has also been introduced as a treatment to improve body aesthetics by improving abdominal and gluteal skeletal muscle definition [8–14]. The CoolTone™ device (Allergan Aesthetics, an AbbVie Company) was Food and Drug Administration cleared in 2019 for (i) improvement of abdominal tone, strengthening of abdominal muscles, and development of a firmer abdomen and (ii) strengthening, toning and firming of buttocks and thighs [15]. In contrast to electrical muscle stimulation, MMS creates pulsating magnetic fields that penetrate skin and fat and induce an electrical current at the skeletal muscle level. This leads to depolarization and initiation of action potential for muscle contraction, delivering a rapid and sustained rate of muscular contraction that is not attainable with manual exercise [16,17].

The momentum behind the use of electromagnetic muscle stimulation in aesthetic medicine is driven not only by the fact that it is a non-invasive, relatively painless application but by treatment outcomes that correspond with a high level of patient satisfaction [8,9,13,14]. An attribute that makes MMS an ideal tool for body contouring is its utility as a stand-alone treatment for muscle toning or in a multi-modal approach depending on the patients' other body contouring goals [14]. This study examined the safety and efficacy of MMS for improving aesthetic appearance of the abdomen and buttocks. The primary and secondary outcomes assessed change from baseline in body satisfaction outcomes and subject global aesthetic improvement of treatment areas at 4 weeks post final treatment, respectively.

MATERIALS AND METHODS

Study Design and Participants

This was a 12-week, non-comparative, non-randomized study conducted in 8 study sites in the United States. MMS treatments were administered using a prototype of the CoolTone™ device. Patients could receive treatment to the abdomen or buttocks, or both, and treatment was administered two times a week, spaced at a minimum of 1 day apart, for 2 consecutive weeks; a total of four treatment sessions for each body area. Study assessments were to occur at baseline, immediately post final treatment, and at 4 and 12 weeks post final treatment. Safety was surveyed throughout the study. The protocol conformed to the ethical guidelines of the 1975 Declaration of Helsinki, was approved by an institutional review board (NCT 03983304) and obtained informed consent prior to treatment.

Eligible participants were male or female aged 22–65 with a body mass index (BMI) $\leq$30 kg/m^2. Eligibility also required that participants had no weight change exceeding 5% of body weight in the month prior to study start and agree to maintain weight within 5% during the study and refrain from any new muscle training exercises of the treatment areas during the study period. Exclusion criteria omitted candidates who had received any invasive fat reduction procedures (e.g., liposuction and mesotherapy) in the treatment areas, anyone who had taken weight loss supplements in the month prior to study start, or anyone with a metal implant or active implanted electrical device such as a cardiac pacemaker, cochlear implant, intrathecal pump, hearing aids, defibrillator, or drug delivery system.

Study Assessments

Primary outcome measure was the change from baseline in the participants' feelings about body shape assessed using a Body Satisfaction Questionnaire (BSQ) specific to abdomen and buttocks at baseline, immediately post final treatment, 4 weeks post final treatment (primary endpoint), and 12 weeks post final treatment. The BSQ, an assessment tool previously used in neuromuscular electrical stimulation body contouring studies, consists of 10 dichotomous word pairs presented with an option to assess body shape and appearance (e.g., flat vs. rounded, weak vs. strong, and attractive vs. unattractive) using a 5-point semantic differential scale 1 (most negative) to 5 (most positive) [14,18,19]. The cumulative score ranges between 10 and 50 based on the numerical response to each item. Secondary efficacy was assessed by participant rating of improvement in the appearance of the treated area using the Subject-graded Global Aesthetic Improvement Scale (SGAIS). The SGAIS asks participants to rate their change using a 7-point Likert scale consisting of the following options: Very Much

Improved (3), Much Improved (2), Improved (1), No Change (0) Worse (−1), Much Worse (−2), and Very Much Worse (−3). The scores and percentage of participants who reported a score ≥1 (Improved, Much Improved, or Very Much Improved) was evaluated 4 weeks post final treatment (secondary endpoint) and 12 weeks post final treatment.

Additional efficacy assessments included circumference measurement of the abdominal area. Waist circumference was obtained by 3D imaging (QuantifiCare LifeViz® Body, Cumming GA, USA) as an average of three measurement planes (top of the umbilicus and 5 cm above/below the umbilicus) and captured along with standardized photographs, at baseline, immediately post final treatment, and at 4 and 12 weeks post final treatment. Participants were also asked to rate their experience using a Subject Experience Questionnaire (SEQ) for the respective body area treated. The SEQ-assessed motivations to try MMS treatment, agreement with treatment outcome statements (Strongly Agree, Agree, Not Sure, Disagree, or Strongly Disagree), and overall satisfaction with treatment results (Very Satisfied, Satisfied, Not Sure, Dissatisfied, or Very Dissatisfied) were assessed at 4 and 12 weeks post final treatment.

Safety

The frequency of device-related adverse events (AEs), including device-related serious AEs (SAEs), was monitored at each visit. Pain assessments were conducted immediately following each treatment session using an 11-point semantic differential scale 0 (no pain) to 10 (worst possible pain).

Analysis

A two-sided test with $\alpha = 0.05$ cut-off was used to determine the level of significant difference for the primary endpoint. The Per-Protocol (PP) population was defined as all treated participants followed for 4 weeks who maintained weight within 5% range of weight at first treatment.

RESULTS

Participant Characteristics

A total of 110 participants (83 females and 27 males) with an average age of 39.5 years (range: 22–59) were enrolled (Table 1). Mean baseline body weight and BMI were 145.9 lbs (range: 99–215) and 23.3 kg/m^2 (range: 18.0–29.9), respectively.

Treatment Populations

A total of 110 participants were enrolled and treated in the study. Data were excluded from the primary efficacy analysis for three participants for >5% weight change allowed by the protocol. Further reduction in the PP analysis population was due to treatment discontinuation ($n = 2$), non-compliance ($n = 2$), consent withdrawal ($n = 1$), pregnancy ($n = 1$), and lost to follow-up ($n = 1$). Thus, 100 participants were evaluated; 76 participants received treatment to the abdomen, 6 received treatment to the buttocks, and 28 received treatment to both the abdomen and buttocks (Table 2). Ultimately, evaluable data for primary endpoint analysis was available for 92 abdomen treatments and 32 buttocks treatments.

TABLE 1. Participant Demographics

Characteristic, statistic	Proportion of participants ($N = 110$)
Gender, *n* (%)	
Female	83 (75.5)
Male	27 (24.5)
Mean age, years (range)	39.5 years (22–59)
Mean weight, lbs (range)	145.9 (99.0–215.0)
Mean BMI, kg/mg^2 (range)	23.3 (18.0–29.9)
BMI by category, *n* (%)	
≤18.5 kg/mg^2	2 (1.82)
18.5–24.9 kg/mg^2	82 (65.5)
25.0–30.0 kg/mg^2	26 (21.8)
Race, *n*[a] (%)	
Caucasian	88 (80.0)
Asian	9 (8.2)
Other	8 (7.3)
Black/African American	4 (3.6)
Ethnicity, *n* (%)	
Non-Hispanic	80 (72.7)
Hispanic	30 (27.3)
Fitzpatrick skin phototype	
I–III	80 (72.7)
IV–VI	30 (27.3)

BMI, body mass index.
[a]Missing entry ($n = 1$).

For treatment to the abdomen, each treatment session consisted of one or two cycles (30 minutes each) based on the treatment area's size and the investigator's discretion. Each session for the buttocks consisted of two cycles, one per side (30 minutes each). For participants receiving treatment of both abdomen and buttocks, the treatment visit consisted of one or two cycles delivered to the abdomen and two cycles delivered to the buttocks separately. Treatment was administered by a single applicator secured directly over the umbilicus to target the abdominal muscles or a single applicator secured directly over each buttock to target the gluteal muscles. The device's output intensity was escalated to a tolerable level depending on patient feedback, with average maximum intensities ranging from 98% to 100% across treatment sessions in both body areas.

Study Outcomes

For the primary endpoint at the 4-week post final treatment visit, the mean change in BSQ score from baseline was significant for participants ($n = 92$) receiving treatment of the abdomen (+5.1 points) and also for participants ($n = 32$) receiving treatment of the buttocks (+5.5 points) ($P < 0.05$) (Fig. 1). Significant BSQ score improvements were still observed at the 12-week visit for

TABLE 2. Treatment Groups

	Week 1				Week 2			
Abdomen (n=76)								
Session (# cycles*)	1st (1-2)		2nd (1-2)		3rd (1-2)		4th (1-2)	
Buttocks (n=6)								
Session (# cycles)	1st (2)		2nd (2)		3rd (2)		4th (2)	
Abdomen + Buttocks (n=28)								
Session (# cycles)	Ab 1^{st} (1-2)	Bt 1^{st} (2)	Ab 2^{nd} (1-2)	Bt 2^{nd} (2)	Ab 3^{rd} (1-2)	Bt 3^{rd} (2)	Ab 4^{th} (1-2)	Bt 4^{th} (2)

Ab, abdomen; Bt, buttocks.
*Up to 2 cycles per session could be used to treat the abdomen based on the size of the area and investigator's discretion.

abdomen (+4.8) and buttocks (+4.9) ($P < 0.05$). For the secondary endpoint at the 4-week visit, an SGAIS score of ≥1 (inclusive of Improved, Much Improved, and Very Much Improved) was reported by 68.1% of participants ($n = 94$) who received treatment of the abdomen, and 81.8% of participants ($n = 33$) who received treatment of the buttocks (Fig. 2). The proportion of participants reporting SGAIS improvement decreased to 65.6% (abdomen) and 71.9% (buttocks) at the 12-week visit. However, the proportions of participants reporting SGAIS score of ≥2 (Much Improved or Very Much Improved) from week 4 to week 12 post-treatment increased for those receiving treatment of the abdomen (14.9%–21.5%) and was maintained for those who received treatment of the buttocks (18.2%–18.8%).

Abdominal Circumference

The mean (standard deviation) decrease from baseline in waist circumference was significant at all time points; immediately (−11 mm [16]), 4 weeks (−6 mm [12]), and 12 weeks (−5 mm [15]) ($P < 0.05$) post final treatment (Fig. 3).

Participant Experience and Satisfaction—Abdomen

The majority of participants at the 4-week (61.7%) and 12-week (54.8%) post final treatment visits reported they were "Satisfied" or "Very Satisfied" with their overall treatment results on the SEQ (Fig. 4). A majority of participants (≥50%) "Agreed" or "Strongly Agreed" with most of the SEQ items regarding treatment results of their abdomen at the 4-week visit (Fig. 5). Most "Agreed" or "Strongly Agreed" that they were happier with their overall appearance at the 4-week (62.4%) and 12-week visit (60.2%). At the 4-week visit, a high proportion also "Agreed" or "Strongly Agreed" with feeling motivated to maintain their results by working out (78.7%) or with additional follow-up treatments (60.6%) with trends persisting through the 12-week visit (69.9% and 62.4%, respectively). Most also "Agreed" or "Strongly Agreed" that they felt more confident (56.4%), stronger (50.0%) and

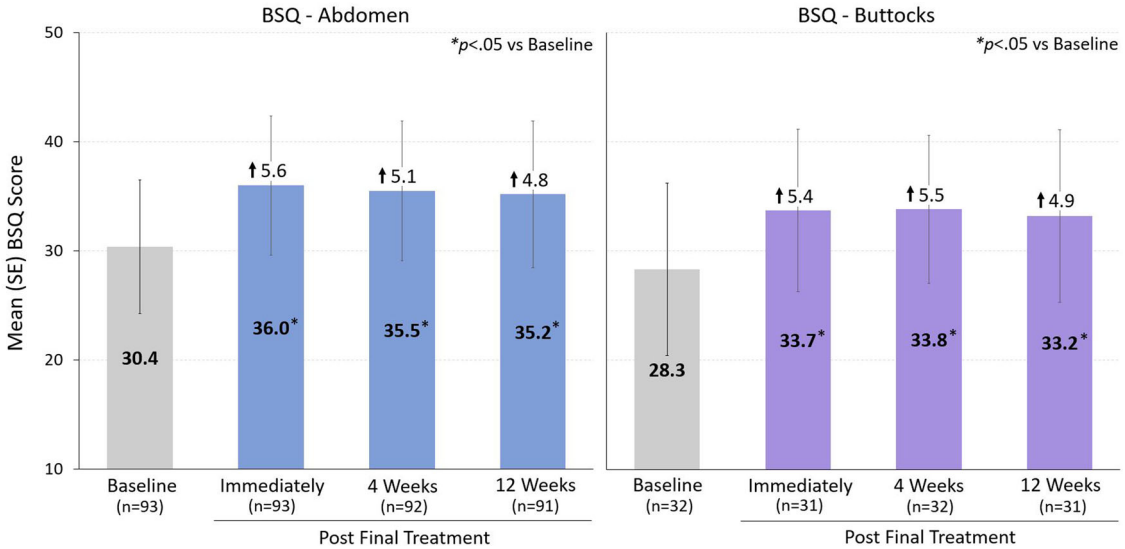

Fig. 1. Improvement in Body Satisfaction Questionnaire (BSQ) scores up to 12 weeks post final treatment.

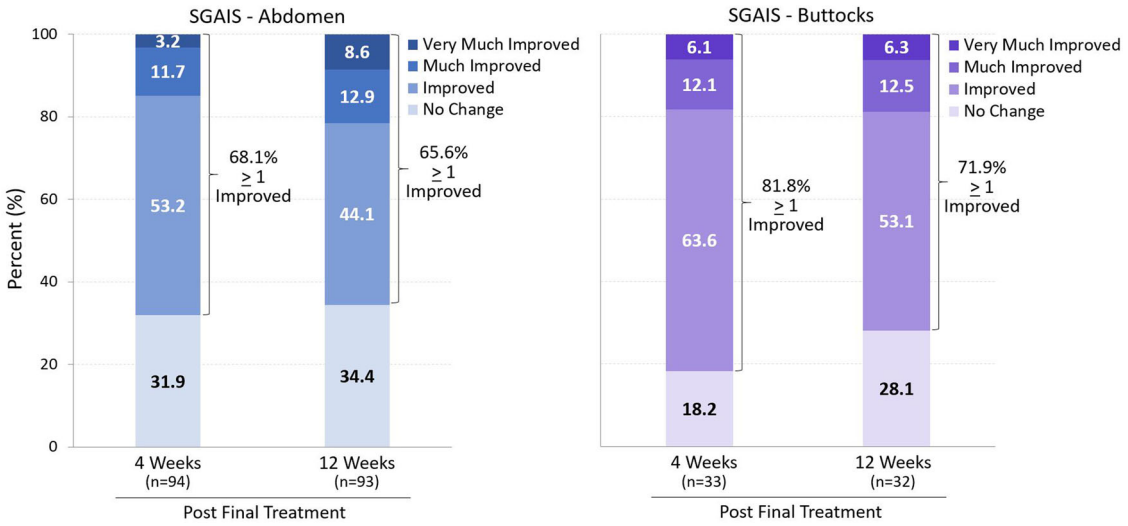

Fig. 2. Improvement in Subject-Rated Global Aesthetic Improvement (SGAIS) score up to 12 weeks post final treatment.

their clothes felt and looked better (55.3%) at the 4-week visit, which decreased only slightly when asked again at the 12-week visit (53.8%, 48.4%, and 52.7%, respectively) (Fig. 5).

Participant Experience and Satisfaction—Buttocks

The majority of participants reported they were "Satisfied" or "Very Satisfied" with their treatment results at the 4-week (75.8%) and 12-week (62.5%) post final treatment visits (Fig. 4). Most participants (>51.5%) "Agreed" or "Strongly Agreed" with all the SEQ items regarding treatment results of their buttocks at the 4-week visit (Fig. 6). Most "Agreed" or "Strongly Agreed" that they were happier with their overall appearance at the 4-week (72.7%) and 12-week (68.8%) visits. At the 4-week visit, a high proportion also "Agreed" or "Strongly Agreed" with feeling motivated to maintain their results by working out (87.9%) or with additional follow-up treatments (78.8%), with a similar trend reported at the 12-week visit (71.9% and 75.0%, respectively). Most also "Agreed" or "Strongly Agreed" that their buttocks felt lifted and toned (78.8%), they felt more confident (63.6%), and their clothes felt and looked better (51.5%) at the 4-week visit, which decreased somewhat when asked again at the 12-week visit (51.6%, 59.4%, and 40.6%, respectively) (Fig. 6).

Motives for Seeking Treatment

At the 12-week post final treatment visit, the top three motives selected on the SEQ for wanting to try MMS treatment for either abdomen or buttocks were "I want to appear more toned" (up to 90.3%), "I want to look better in my clothes" (up to 62.5%), and "I want to feel more confident" (up to 54.8%) (Fig. 7).

Safety

A total of six AEs (four mild menstrual cycle irregularities; one moderate menstrual cycle irregularity; and one mild soreness/discomfort in chest) related to the device and/or treatment were reported by six participants, of which, the latter two resulted in study discontinuation (Table 3).

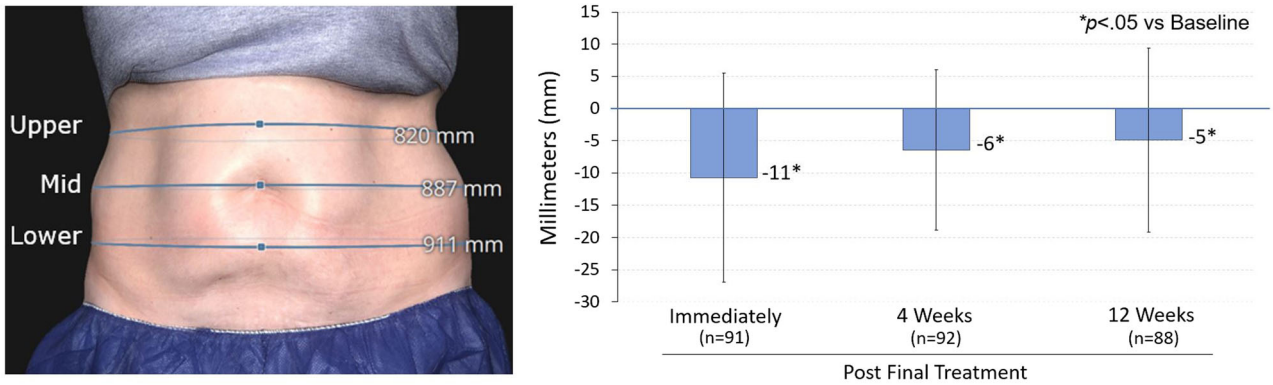

Fig. 3. Mean (standard deviation) Total Decrease in Waist Circumference up to 12 Weeks Post Final Treatment Determined by Three-Dimensional Imaging.

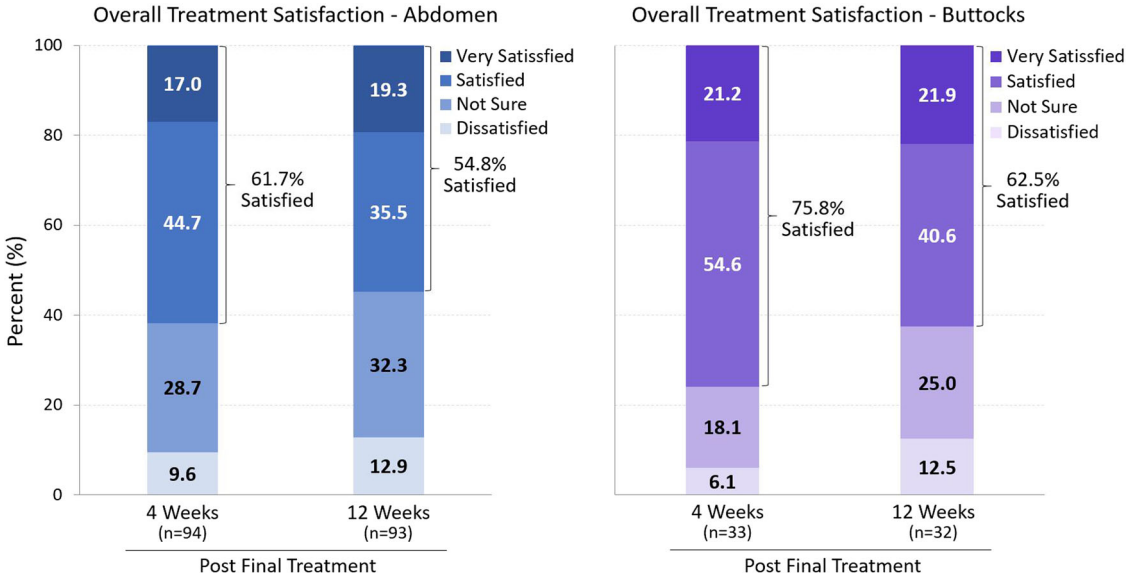

Fig. 4. Overall Satisfaction with Treatment Results up to 12 Weeks Post Final Treatment Determined by Subject Experience Questionnaire (SEQ).

All AEs were mild to moderate in intensity, all resolved spontaneously during the study period, and no device-related SAEs were reported. The average pain scores reported immediately after each treatment session were <1 at any treatment session. Across all four treatment sessions, a score of "0" was reported by 74.0%–88.0% of participants receiving abdominal treatment and 85.3%–91.2% of participants receiving buttocks treatment.

DISCUSSION

MMS is unique among non-invasive body contouring treatments because it improves contour by toning and firming underlying skeletal muscles. The results of this study show that a series of four MMS treatment sessions significantly improved the aesthetic appearance of the abdomen and/or buttocks throughout the 12-week post final treatment study duration. At the 4-week post final treatment visit, average body satisfaction scores for treatment of the abdomen and buttocks improved by +5.1 and +5.5 points, respectively (Fig. 1). SGAIS scores also indicated perceived improvement, with a majority of participants rating themselves at least "Improved" for treatment of the abdomen (68.1%) and buttocks (81.8%) by the 4-week visit, which persisted through the 12-week visit (Fig. 2) In addition, overall treatment satisfaction at

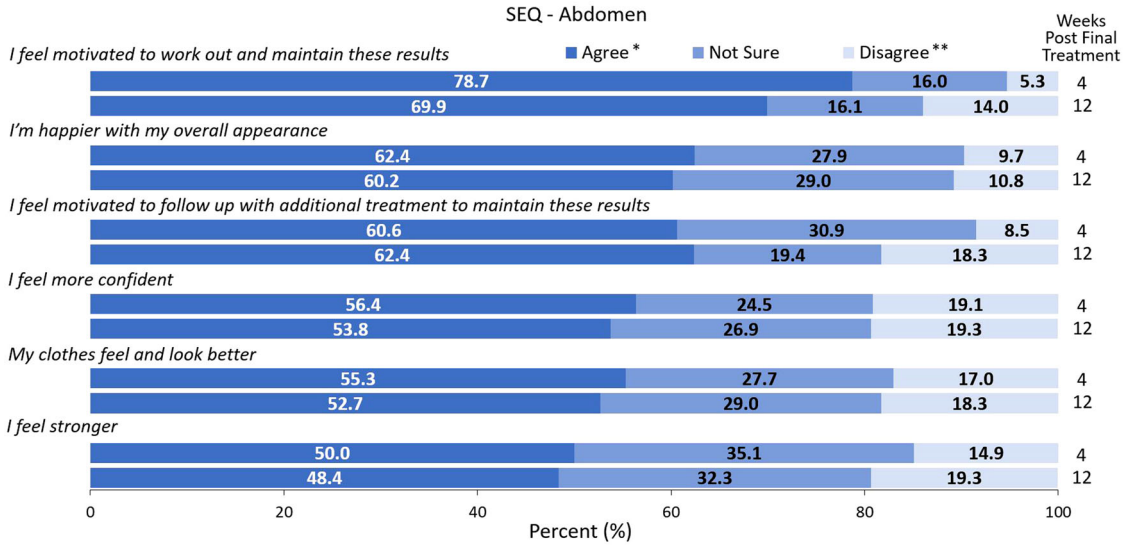

Fig. 5. Subject Experience Questionnaire (SEQ) Results up to 12 Weeks Post Final Treatment of the Abdomen.

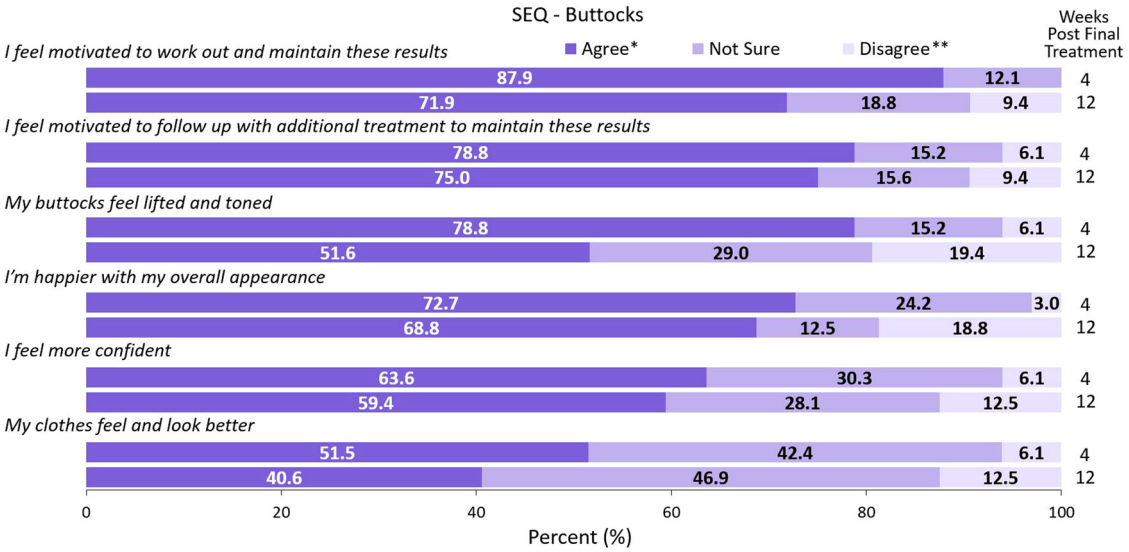

Fig. 6. Subject Experience Questionnaire (SEQ) Results up to 12 Weeks Post Final Treatment of the Buttocks.

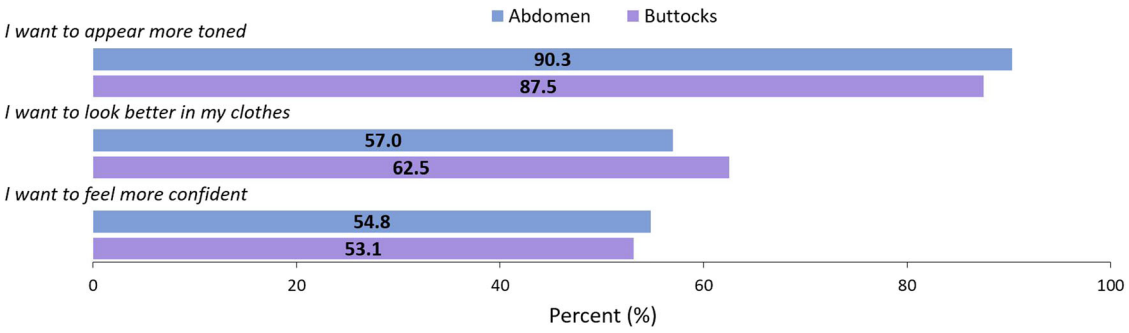

Fig. 7. Top Three Motives for Trying Magnetic Muscle Stimulation Treatment Assessed at 12 Weeks Post Final Treatment Determined by Subject Experience Questionnaire (SEQ).

the 12-week visit was reported by the majority of participants for both treatment areas (54.8% for abdomen and 62.5% for buttocks) (Fig. 4). Treatment outcome data collected from the patient's perspective provides insight into the real value of treatment. In this case, regardless of treatment area, the impact on quality of life was positive and multidimensional, as many felt not only more confident (up to 63.6%) and happier with their overall appearance (up to 72.7%), but they also felt motivated to work out and maintain results (up to 87.9%) (Figs. 5 and 6).

MMS is not expected to impact subcutaneous fat, and as participants maintained baseline weight by ±5%, the changes observed in waist circumference detected by three-dimensional measurement may be attributable to dimensional changes occurring in the abdominal muscles as a result of treatment (Fig. 3) [17]. Though not measured in this study, the literature describing the results following treatment with a high-intensity focused electromagnetic device has reported a decrease in the abdominal rectus muscle separation (~10%) and an increase in abdominal muscle thickness (~14%) for up to 1 year following a series of four to eight treatments in some participants [10–12]. Allthough muscle hypertrophy could detract from the circumferential reduction measurements, the strengthening of select muscle groups may support a reduction. For instance, strengthening and

TABLE 3. Safety Data (Safety Population)

Adverse events (AEs)	Intensity	Number of occurrences
Menstrual cycle irregularity	Mild	4
Menstrual cycle irregularity[a]	Moderate	1
Soreness/discomfort[b]	Mild	1

[a]Discontinued due to AE.
[b]Discontinued treatment due to discomfort in left chest area.

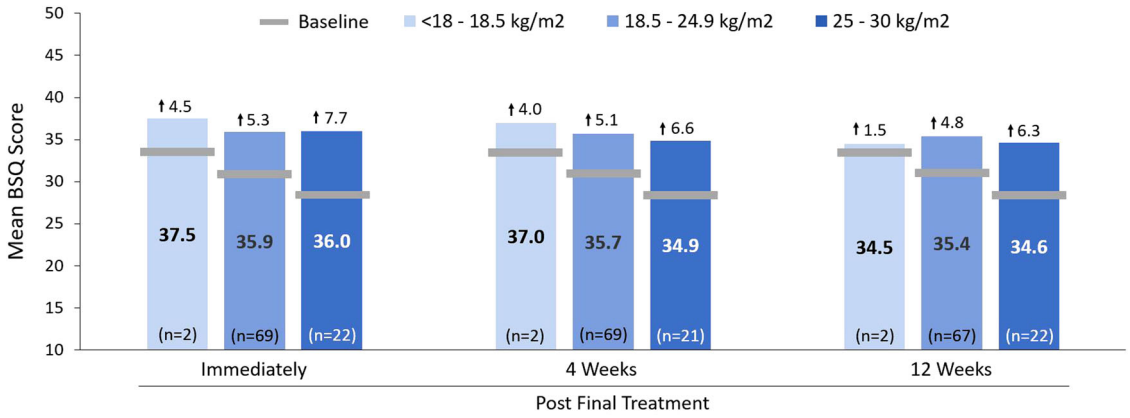

Fig. 8. Improvement in Mean Body Satisfaction Questionnaire (BSQ) Scores from Baseline Among Participants in Different Body Mass Index (BMI) Categories Who Received Treatment of the Abdomen.

toning of the abdominal muscle groups would likely also include the transverse abdominal muscles, which lie beneath the rectus abdominis and act like a natural corset providing supportive compression for the abdominal wall and internal organs. Although physiological measurements are required to confirm this, it would support observations seen in a prior study where select participants who had a weight increase from baseline still achieved visible improvement in abdominal contour [14].

There was minimal pain reported with the administration of treatment to either the abdomen or buttock area (score of <1 at any treatment session), and stimulation intensities up to 100% were sustained by a majority of participants. Although side effects following MMS treatment were mostly mild and transient, there were reports of mild/moderate menstrual cycle irregularities. This potential side effect should be discussed with patients considering treatment.

As with any aesthetic treatment, patient selection and expectation management are key considerations. Consensus regarding ideal candidates for MMS is lacking, although it has been suggested that more significant

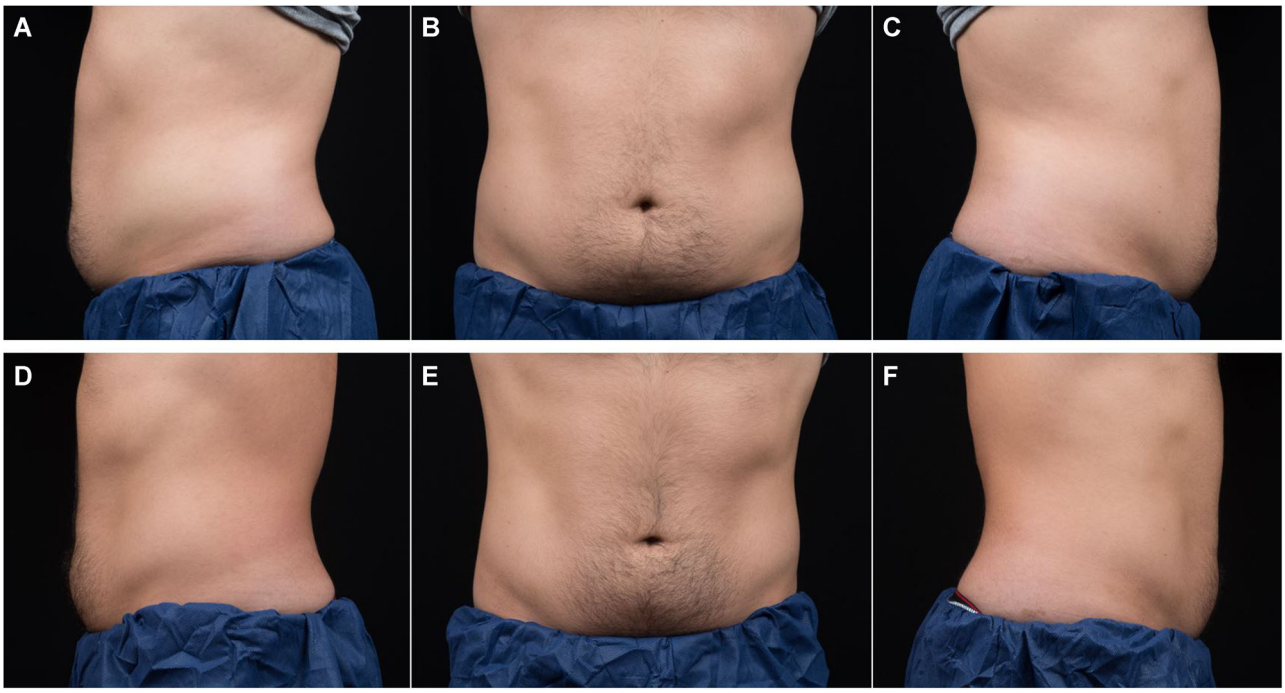

Fig. 9. A 30-year-old male participant who received four MMS treatment sessions (one cycle per session) for the abdomen. At baseline (**A**–**C**) and the 4-week post final treatment visit (**D**–**F**). BSQ score change from baseline: +15 points. Weight change from baseline: −4.0 lbs. BSQ, Body Satisfaction Questionnaire; MMS, magnetic muscle stimulation.

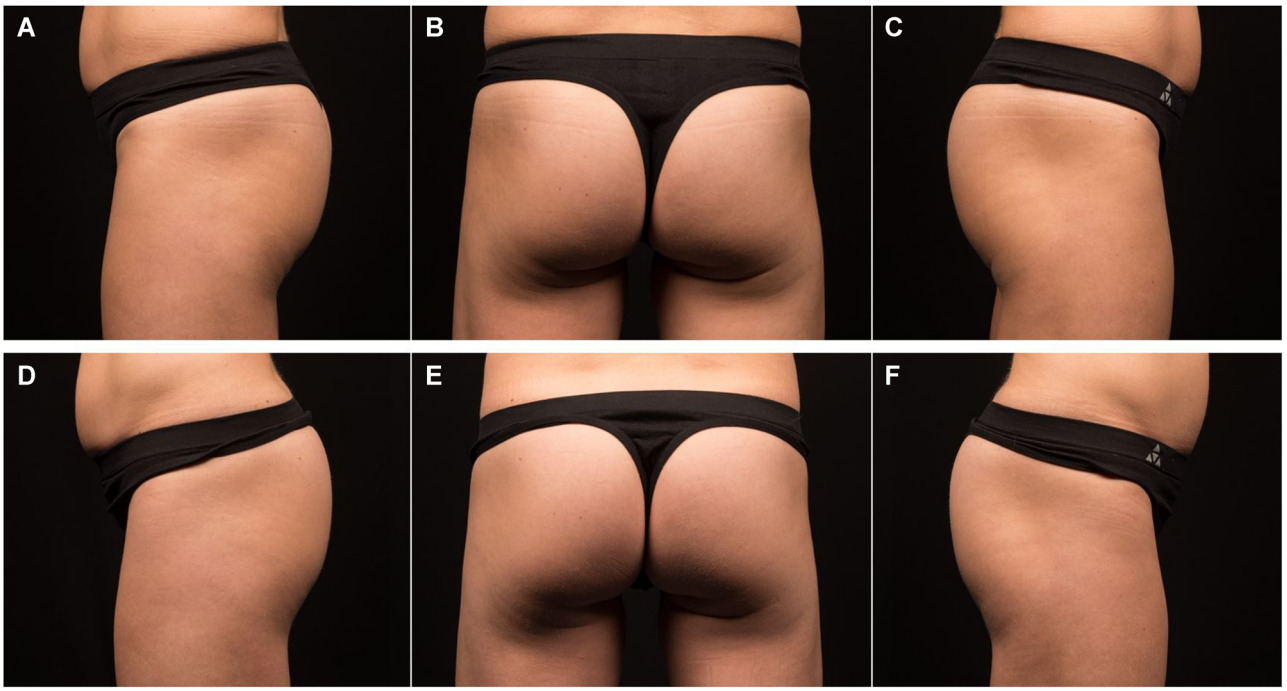

Fig. 10. A 39-year-old female participant who received four MMS treatment sessions (one cycle per side, per session) for the buttocks. At baseline (**A**–**C**) and the 4-week post final treatment visit (**D**–**F**). BSQ score change from baseline: +11. Weight change from baseline: −0.2 lbs. BSQ, Body Satisfaction Questionnaire; MMS, magnetic muscle stimulation.

visible changes are possible with thinner (lower BMI) patients due to less subcutaneous fat [8,10]. The inductive effect of the magnetic field is believed to taper with distance from the magnetic coil, which may be relevant for patients presenting with thicker subcutaneous fat tissue [8,10]. Interestingly, this study demonstrates improvement in participants representing a range of BMI with those in the higher BMI ranges (25–30 kg/m^2, $n = 22$) reporting the greatest difference from baseline in body satisfaction scores at all assessment time points among participants who received treatment of the abdomen (Fig. 8). This suggests that even though visible effects may not be as obvious (potentially with higher BMI patients), treatment satisfaction is achieved. With body contouring treatment modalities that reduce subcutaneous fat, the use of pre- and post-treatment photos can be an effective tool to demonstrate visible aesthetic improvement. However, with MMS, a multi-factorial approach to assess outcomes may be necessary to capture the unseen value of treatment. Although representative pre- and post-treatment photos show modest visual improvements in muscle definition and body contour, the corresponding BSQ scores indicated significant improvement (Figs. 9 and 10). Photographs cannot reliably portray the feeling of strengthening and toning that occurs following treatment, demonstrated by the positive participant experience data.

As MMS is a relatively new treatment modality in aesthetic medicine, this large multicenter study is an important data contribution in support of MMS as a safe and effective non-invasive treatment to improve body contour and body satisfaction. These data also demonstrate that treatment results for the abdomen and/or buttocks are durable throughout 12 weeks post-treatment, which agrees with suggested treatment intervals of every 3–6 months cited in previous studies [8,10]. Investigators in this study recommend single treatments scheduled once a month for maintenance and optimal results, rather than repeating the entire series of treatments every 3–6 months. Possible limitations with this study may include a limited number of treatment sessions (four total), the lack of a control group, and lack of objective measurement of physiological change associated with the muscles in each treatment area. Future studies that also include a control group with a sham treatment are needed to further investigate the efficacy of this treatment modality.

CONCLUSION

Treatment with MMS was well-tolerated with minimal procedural pain and mostly mild AEs and demonstrated significant improvements in BSQ scores and aesthetic appearance following abdominal and/or gluteal muscle toning. In addition, the majority of participants expressed that they were motivated to maintain their results through exercise (or retreatment) at the final follow-up visit. As a stand-alone treatment, MMS expands the range of individualized treatment planning options for patients seeking muscle strengthening, toning, and

firming of their abdomen and/or buttocks. Importantly, MMS represents a body contouring modality that can positively impact the self-perception of body aesthetics.

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